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

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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-administered 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.

1. Introduction

In 1971, the Committee on Safety of Drugs in the UK reported that “No drug which is pharmacologically effective is entirely with-
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 pharmacoconomics. 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 (Овчинникова Е. А. [Ovchinikova 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 (Bahloli and Dewey 2021). The sample size was calculated using the formula \( X = Z_{0.025} \times \sqrt{p(1-p)/MOE^2} \), 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 pharmacists 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.

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

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

ADR = adverse drug reaction.

a Mean.
b Range.

Table 1: Demographics of community pharmacists and the ADRs reported by their customers.
(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 (%)       | Sex (%)       | University of graduation (%) | Position in pharmacy (%) | Region (%) |
|------------------------------------------------------------------------|-------------|---------------|-----------------------------|--------------------------|------------|
|                                                                        | Male (32.1) | Female (34.6) | Government (31.2)           | Junior (65.2)            | South (%)  |
| There is no time for reporting                                         | 293         | 31.6          | 31.7                        | 32.7                      | 28.8       |
| The community pharmacy is not the right place for reporting            | 690         | 74.5          | 74.6                        | 73.0                      | 97.9       |
| There are not many ADRs that are worth reporting                       | 583 (63.7)  | 61.9          | 61.6                        | 64.6                      | 45.8       |
| Unavailability of an internet connection                               | 258 (28.1)  | 27.6          | 26.5                        | 34.4                      | 35.6       |
| A. The work environment                                               |             |               |                             |                          |            |
| There is no time for reporting                                         | 293         | 32.2          | 31.5                        | 32.7                      | 28.8       |
| The community pharmacy is not the right place for reporting            | 690         | 74.9          | 75.9                        | 73.0                      | 97.9       |
| There are not many ADRs that are worth reporting                       | 583 (63.7)  | 61.8          | 61.6                        | 64.6                      | 45.8       |
| B. Communication with patients and ADR identification                  |             |               |                             |                          |            |
| Uncertainty about whether the drug is the cause                        | 742 (80.9)  | 81.1          | 79.8                        | 81.7                      | 74.6       |
| Concerns about patient confidentiality                                 | 541 (59.0)  | 59.0          | 58.3                        | 64.7                      | 59.3       |
| Concerns about affecting the patient's trust in the pharmacist         | 562 (62.1)  | 62.5          | 61.5                        | 65.0                      | 60.3       |
| Mistrust in what the patient says                                      | 670 (73.2)  | 72.9          | 74.2                        | 71.6                      | 71.0       |
|                |             |               |                             |                          |            |
| C. The reporting process                                              |             |               |                             |                          |            |
| Not knowing where the paper report form should be submitted           | 594         | 64.4          | 65.1                        | 61.1                      | 67.8       |
| The paper report form is too complicated                               | 385         | 42.3          | 41.2                        | 45.7                      | 39.7       |
| Not accessing the paper report form                                    | 736         | 80.2          | 82.6                        | 83.5                      | 81.0       |
| Not enough information about ADRs                                      | 322 (35.3)  | 33.6          | 39.1                        | 46.0                      | 45.6       |
| Not knowing/remembering what the paper form looks like                 | 518 (56.5)  | 59.8          | 58.8                        | 65.1                      | 62.7       |
| Not having the information needed for reporting                        | 640 (70.0)  | 68.9          | 72.1                        | 71.0                      | 72.9       |
| It is difficult to get copies of the paper report form                  | 714 (77.8)  | 78.0          | 78.6                        | 78.5                      | 86.4       |
| Electronic reporting is difficult                                      | 547 (60.0)  | 59.9          | 58.8                        | 56.3                      | 67.2       |
| Unclear what ADRs are                                                  | 489 (53.4)  | 51.7          | 57.5                        | 55.0                      | 47.5       |
| Not enough information about the reporting process                      | 691 (75.4)  | 74.9          | 75.9                        | 76.6                      | 67.8       |
| D. Responsibility                                                       |             |               |                             |                          |            |
| I want to publish the case in my name and not just report it          | 209 (22.8)  | 23.5          | 20.6                        | 24.4                      | 22.0       |
| Concerns about legal issues that may arise from reporting              | 352 (38.5)  | 38.8          | 37.5                        | 41.6                      | 39.7       |
| Reporting is the responsibility of the physician, not the pharmacist   | 196 (21.5)  | 23.8          | 16.5                        | 23.9                      | 22.8       |
| Reporting is the responsibility of the hospital pharmacist, not the   | 213 (23.3)  | 24.8          | 18.9                        | 25.0                      | 28.8       |
| Reporting is the responsibility of the clinical pharmacist, not the   | 268 (29.3)  | 30.7          | 25.0                        | 28.1                      | 30.5       |
| Reporting is not important                                             | 106 (11.6)  | 12.2          | 10.0                        | 11.2                      | 10.2       |
| Reporting may negatively affect the pharmacist's job                   | 135 (14.7)  | 15.4          | 12.9                        | 18.0                      | 13.8       |
| Reporting an ADR for a single case makes no difference                 | 404 (44.3)  | 45.7          | 39.8                        | 47.1                      | 33.9       |
| Licensed medicines are safe                                            | 443 (48.5)  | 47.2          | 52.8                        | 52.3                      | 42.1       |
| Nothing obliges pharmacists to report or prevents them from reporting  | 625 (98.1)  | 69.3          | 65.1                        | 66.0                      | 49.2       |
| Assume the doctor will report                                          | 447 (90.0)  | 49.6          | 47.2                        | 50.0                      | 50.5       |
| Assume the nurse will report                                           | 235 (25.7)  | 24.0          | 29.4                        | 25.6                      | 19.0       |
| Assume the patient will report                                         | 388 (42.4)  | 41.0          | 45.4                        | 41.4                      | 42.4       |
| Assume someone from the patient's family will report                  | 363 (39.5)  | 38.5          | 41.8                        | 42.6                      | 37.3       |
| Difficulty communicating with the treating medical team                | 603 (63.5)  | 66.5          | 62.5                        | 63.2                      | 71.2       |
| Concerns about having to follow up with the patient after reporting    | 401 (42.8)  | 42.4          | 46.8                        | 46.8                      | 48.2       |
| Reporting ADRs is not a priority                                       | 182 (19.8)  | 22.5          | 12.9                        | 20.9                      | 22.0       |
| If the ADR is severe, the patient must be referred to the physician,  | 591 (64.7)  | 66.4          | 59.8                        | 65.3                      | 65.5       |
| Worried that I am incorrect to report                                  | 518 (56.5)  | 53.2          | 64.9                        | 56.3                      | 49.2       |

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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-
ADRs reporting rates. Egyptian community pharmacists from improving spontaneous (Kopciuch et al., 2019). As such, once other barriers have been conducted in the UK and Poland that identified lack of time to be a community pharmacists. This contradicts the findings of some studies cited as a barrier to ADR reporting by only 32.1% of Egyptian 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 point in time. 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.

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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 Bahlotl: 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.

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Appendix A. Supplementary material

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

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