

Pharmacovigilance and Adverse Drug Reactions Reporting Process in West-Bank, Palestine

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ABSTRACT

Active national pharmacovigilance programmes are needed to monitor adverse drug reaction (ADR) data in local populations. The objective of this study was to describe the knowledge, experiences, attitudes and perceived barriers to reporting of suspected ADRs by community and hospital pharmacists in West Bank, Palestine. Between December 2014 and March 2015 we conducted a survey about the knowledge and attitude of pharmacists (n = 270) using a face-to-face questionnaire. The questionnaire consisted of questions about the sociodemographic characteristics of the pharmacists, their knowledge of pharmacovigilance and their attitudes towards ADR reporting. Main outcomes measured: The majority of the pharmacists (62.6%) worked in the community pharmacies and more females responded to the questionnaire than males (59% vs 41%). only 11.9% could conceptually or actually define 'pharmacovigilance' correctly while one quarter of the respondent pharmacist (24.9%) could define ADR correctly. The hospital clinical pharmacists defined 'pharmacovigilance' correctly with higher significance (P<0.001) when compared with community pharmacists. Only 12.2% had ever reported an ADR. The majority of these reports (85%) done by the hospital pharmacists (p<0.0001). The main reasons that discourage the pharmacists from reporting ADRs were 'no enough information available from the patient (76.7%)', and 'they did not know how to report (66.7%)'. The majority of the respondents (92.0%) felt that reporting ADR was their duty and (82%) participants were interested in participating in the National Pharmacovigilance Programme in Palestine. The results show that Palestinian pharmacists have poor knowledge about pharmacovigilance. There is an urgent need for educational programs to train them about pharmacovigilance and ADR reporting scheme.

Keywords: Pharmacovigilance, Adverse Drug Reaction, Reporting, Palestine.

INTRODUCTION

Adverse drug reactions (ADRs) are encountered commonly in daily practice, many of which are preventable (1, 2, 3). A study by Arulmani et al. indicates that 3.4% of the hospital admissions may be attributed to ADRs. In addition, 3.7% of hospital patients developed ADRs during their hospital stay (4). It is obvious that ADRs constitutes an economic burden on the health care system not to mention the obvious morbidity and mortality associated with ADRs (5, 6). Thus, early detection and prevention of ADR may be necessary.

Traditionally, the role of the pharmacist was limited to the preparation and dispensing of drugs prescribed by the physician. Recently, the role of the pharmacist has expanded to other aspects of patient care (7, 8). These roles include reporting ADRs, improving patients' health, and economic outcomes. Pharmacists can play an important role in ADR reporting and pharmacovigilance by increasing the number as well as the quality of submitted reports (9, 10). However, in many countries the knowledge of pharmacists about pharmacovigilance and ADR reporting is poor and the rate of reporting is low (11, 12, 13).

Till this published paper, there is no pharmacovigilance center in Palestine; however efforts from the Palestinian Ministry of Health and Pharmacist association are commence to establish a Palestinian pharmacovigilance center. In order to enhance the role of health professionals in spontaneous reporting in the near future, it might be necessary to conduct an analysis of practice; attitude and knowledge of health care professional in order to design strategies that modify and enhance reporting.

Evaluating the knowledge, behaviors and experiences of pharmacists relating to spontaneous reporting of ADRs is very important and lacking in Palestine. When pharmacists have sufficient knowledge of the ADR reporting process, they can improve other healthcare professionals' knowledge about ADR reporting (14). To the best of our knowledge no studies have evaluated pharmacists' knowledge and attitudes toward ADRs reporting in the hospital and community settings in Palestine. Our study was in the unique position to assess their understanding and knowledge about the Pharmacovigilance and spontaneous ADRs reporting scheme. Therefore the objective of this study was to describe the knowledge, experiences, attitudes and perceived barriers to reporting of suspected ADRs by community and hospital pharmacists in West Bank, Palestine.

MATERIALS AND METHODS

Study design, settings and study subjects

This is a cross-sectional study that was conducted in four of the largest cities in West Bank Palestine; Ramallah, Hebron, Bethlehem and Nablus. The study commenced in December 2014 and continued for 3 months. Two hundred and seventy (270) pharmacists were included in the study with a response rate of 77.1%. Pharmacists from all specialties working in hospitals, independent and chain pharmacies were enrolled in the study after obtaining an informed consent. Those who were not willing to participate or did not return the questionnaire within the stipulated time were excluded.

Questionnaire

The final form of the questionnaire consisted of 25 questions was designed using the precedence set by similar studies, (15-18) to obtain information regarding the demographics of the respondents, knowledge regarding the ADR reporting system, attitude and practice of ADR reporting, and the factors that encouraged and discouraged reporting. Content validity was assessed by distributing the questionnaire to small randomly selected group of Palestinian pharmacists recruited to complete the validation process. The initial draft of questionnaire was hand delivered to those pharmacists to help review the structured questionnaire and perform any amendments needed.

Data collection and ethical consideration

Well trained team consists of four pharmacist researchers visited each pharmacy and invited community and hospital pharmacists to participate in the study after explaining the aims of the study. A written consent form was obtained from each participant who wished to participate in the study. Participants were told that all information provided was completely confidential and the results would be presented anonymously.

Statistical Analysis

Student's t-test was used to compare continuous data. The χ^2 test was used to compare categorical data. All p-values presented are two-tailed. P-Values<0.05 were considered statistically significant. The analyses were performed using SPSS version 19.0.

RESULTS

Demographics

A total of 350 registered pharmacy practitioners were approached. Only 270 responded to the survey with 270 pharmacists having all questions completely answered. The average response rate was 77.1%. The demographics of the respondents are presented in Table 1. The mean age of the pharmacists was 32.9 (SD=6.5) years, with varying degree of education, 77% with Bachelor degree in Pharmacy, 11% with Master Degree; 4% with Pharm. D. and only 2% with Ph.D. More females responded to the question-

naire than males (59% vs 41%). The majority of the pharmacists (62.6%) worked in the community pharmacies and their experience in practice ranged from 1 to 26 years, the median years of experience were 6.8 years.

Table (1): Demographic information for participated Pharmacists (n=270).

| Variables | Frequency (%) |
|------------------------------|---------------|
| Age (in years) | |
| 20-29 | 143 (53.0) |
| 30-39 | 99 (36.7) |
| >40 | 28 (10.4) |
| Mean (SD) | 33.1 (5.8) |
| Gender | |
| Female | 159 (58.9) |
| Male | 111 (41.1) |
| Experience (in years) | |
| <5 | 61 (22.6) |
| 5-10 | 136 (50.4) |
| >10 | 73 (27.0) |
| Degree of education | |
| Diploma | 8 (2.9) |
| Bachelor degree | 213 (78.9) |
| Master degree | 27 (10.0) |
| Pharm D degree | 16 (6.0) |
| PhD degree | 6 (2.2) |
| Employment status | |
| Community Pharmacy | 169 (62.6) |
| Hospital Pharmacy | 79 (29.3) |
| pharmaceutical industry | 10 (3.7) |
| sales and marketing | 8 (2.9) |
| Academic | 4 (1.5) |

SD: Standard Deviation, Pharm D: Doctor of Pharmacy. PhD: Doctor of Philosophy.

Table (2): Patient counseling about ADR, n(%) for 270 respondents.

| Questions | Never | Rarely | Sometimes | Frequently | Always |
|--|-----------|-----------|-----------|------------|------------|
| How often do you ask your patient if he/she is allergic to medications? | 0 | 24 (8.8) | 81 (30.0) | 65 (24.1) | 100 (37.0) |
| How often do you ask a female if she is pregnant when dispensing teratogenic/ abortive medication? | 0 | 11 (4.1) | 43 (15.9) | 81 (30.0) | 135(50.0) |
| How often do you counsel your patients about ADRs that they may experience from their medication? | 3 (1.1) | 24 (8.8) | 52 (19.3) | 78 (28.9) | 113 (41.9) |
| How often do you discuss an ADR with your pharmacist colleague? | 13(4.8) | 24 (8.8) | 54 (20.0) | 75 (27.8) | 104 (38.5) |
| How often do you discuss an ADR with the prescriber? | 27 (10.0) | 83 (30.7) | 68 (25.2) | 41 (15.2) | 51 (18.9) |

ADR: Adverse Drug Reaction

Pharmacist counseling, knowledge regarding pharmacovigilance and ADR reporting

Pharmacists were asked to define the terms 'pharmacovigilance' and 'adverse drug reaction'. The open-ended questions were evaluated according to the WHO's definition.

Of the responding pharmacists, only 11.9% could conceptually or actually define 'pharmacovigilance' correctly while one quarter of the respondent pharmacist (24.9%) could define ADR correctly. The hospital clinical pharmacists defined 'pharmacovigilance' correctly with higher significance ($P<0.001$) when compared with community pharmacists. Significant difference was also found between the Pharm D Pharmacists and Bachelor degree pharmacist ($P<0.001$) for the definition of ADR. Only 23 (22%) of the participants said that they were familiar with the ADR reporting process. The responses to knowledge items are illustrated in Table 2; about half of the pharmacists only ever discuss ADR with the patients, prescribers or colleagues. Very few (11.2%) of the participants said they reported ADRs when they occurred and most of those from hospital pharmacists ($p<0.0001$). The main reasons for not reporting ADRs; (71.5%) said that they were not aware of the method of reporting, (11.6%) said that ADR reporting was the duty of physicians and hospital pharmacists, and 4 (8.3%) said that all ADRs are familiar and already reported in the medication leaflet.

Experience of ADR reporting

The experience and practice of ADRs reporting by pharmacists is shown in Table 3. It is obvious that about (245, 90.7%) of the pharmacists had noticed at least one ADR in a patient per a year, while only (33, 12.2%) had ever re-

ported an ADR. The majority of these reports (85%) done by the hospital pharmacists ($p < 0.0001$). Reporters mostly submitted their documentation to their hospitals, but also some submitted directly to the drug manufacturer.

Table (3): Pharmacists Practice toward ADRs reporting procedure.

| Questions | Number | % |
|--|--------|------|
| How often do the patients report you ADRs of medications? | | |
| More than once a week | 62 | 23.0 |
| Once a month | 83 | 30.7 |
| A few times a year | 100 | 37.0 |
| Never | 25 | 09.3 |
| Have you ever reported any ADR?? | | |
| Yes | 33 | 12.2 |
| No | 237 | 87.8 |
| Do you know what is the period within which you should report a serious ADR experienced by a patient? | | |
| Yes | 14 | 5.2 |
| No | 256 | 94.8 |
| Do you know to whom you should report the ADRs? | | |
| The Ministry of health (MOH) | 87 | 32.2 |
| The pharmaceutical association | 25 | 9.3 |
| Drug Company | 127 | 47.0 |
| Prescriber | 27 | 10.0 |
| Others | 4 | 1.50 |
| How do you prefer to report the ADRs? | | |
| A phone call to drug company | 70 | 25.9 |
| The representative of the drug company | 57 | 21.1 |
| Using adverse drug reaction reporting form | 102 | 37.8 |
| Mail via internet | 35 | 13.0 |
| Others | 6 | 2.2 |

ADRs: Adverse Drug Reactions.

Pharmacists were also asked about their preferred method of reporting ADR, 37.8% of them believed that using a specific form was their preferred method of reporting, while 25.9%, 21.1%, and 13.0% preferred to report via phone calls to the drug company, informing the representative of the drug company verbally or by using internet, respectively

Pharmacists Attitudes toward Pharmacovigilance and ADR reporting process

There were 7 questions related to the perceptions of the pharmacists towards ADR reporting and pharmacovigilance. In general, the respondents had a positive attitude towards ADR reporting and pharmacovigilance. The majority of the respondents (92.0%) believed that we need a pharmacovigilance centre in this country and (87%) felt that reporting ADR was their duty. n (82%) participants were interested in par-

participating in the National Pharmacovigilance Programme in Palestine. However, the majority felt that they weren't adequately trained in ADR reporting process. The details regarding the re-

sponses of pharmacists about their attitudes towards ADR reporting and pharmacovigilance are listed in Table 4.

Table (4): Pharmacists' attitudes towards the reporting of suspected ADR's (n=270).

| Questions | Yes | No | Not Sure |
|--|------------|------------|-----------|
| Do you believe that we need a pharmacovigilance centre in this country | 248 (91.9) | 13 (4.8) | 9 (3.3) |
| Do you think reporting ADR is a pharmacist's duty? | 221 (81.9) | 24 (8.9) | 25 (9.3) |
| Do you believe reporting ADRs will improve patient safety? | 256 (94.8) | 11 (4.1) | 3 (1.1) |
| Are you interested in participating in the ADRs reporting system? | 221 (81.9) | 32 (11.9) | 17 (6.3) |
| Reporting ADRs causes inconvenience in the working place | 24 (8.9) | 218 (80.7) | 28 (10.4) |
| Do you feel that you are adequately trained in ADR reporting? | 32 (11.9) | 229 (84.8) | 9 (3.3) |
| Does your workplace encourage you to report an ADR? | 221 (81.9) | 32 (11.9) | 17 (6.3) |

ADRs: Adverse Drug Reactions

Factors influencing the pharmacists to report ADRs were evaluated in this study. Most of pharmacist indicated that they report reactions of serious nature, unusual reactions, and reactions that have been not reported before. Factors that may discourage the pharmacists to report

ADRs were also illustrated in table 5. The main reasons that discourage the pharmacists from reporting ADRs were "no enough information available from the patient (76.7%)", "they did not know how to report (66.7%)" and "The ADR is too trivial to report (67.1%).

Table (5): Factors that may discourage pharmacists to report ADRs.

| Item | Agree | Disagree | Not Sure |
|---|------------|------------|-----------|
| Uncertain association between the drug and the adverse reaction | 153 (56.7) | 86 (31.9) | 31 (11.5) |
| The ADR is too trivial to report | 183 (67.8) | 68 (25.2) | 19 (7.0) |
| Concern that a report will generate extra work | 89 (33.0) | 148 (54.8) | 33 (12.2) |
| Lack of confidence in discussing the ADRs with the prescriber | 137 (50.7) | 113 (41.9) | 20 (7.4) |
| No enough information available from the patient | 197 (73.0) | 59 (21.9) | 14 (5.2) |
| Lack of time to fill in a report | 116 (43.0) | 132 (48.9) | 22 (8.1) |
| Fear of legal liability / Fear of facing legal problems | 121 (44.8) | 118 (43.7) | 31 (11.5) |
| Consider it the doctors' responsibility | 35 (13.0) | 213 (78.9) | 22 (8.1) |
| Did not know how to report | 191 (70.7) | 54 (20.0) | 25 (9.3) |

ADRs: Adverse Drug Reactions.

DISCUSSION

According to our knowledge, this is the first study from West Bank, Palestine which evaluates the Knowledge, practice and attitudes of the pharmacists towards pharmacovigilance. The present study firstly demonstrates that the majority of the pharmacists in West Bank have insufficient knowledge about pharmacovigilance and ADRs reporting process. There are several reports from other countries which commonly emphasize the problem of the ADR under-reporting among pharmacists (19-22).

Despite the lack of knowledge in the majority of pharmacists, the present study revealed that hospital pharmacists was better knowledgeable compared to community pharmacists in ADR reporting procedures. This may be attributed to the fact that hospital pharmacists are in direct contact with other health care professionals such as physicians and nurses who are more often involved in the identification of potential ADRs, thus they are more exposed to situations where there is a need to manage or to report such adverse effects.

Previous study showed that hospital pharmacists report 20 times more frequently than community pharmacists, this was due to the fact that the hospital pharmacist was better educated and informed about pharmacovigilance practice (19).

About half of the pharmacists 47% in this study believed that if they want to report ADRs they will send their report to drug Company or their representatives; this revealed the need for authorized organization for reporting ADR in Palestine.

Spontaneous reporting programs are the most widely reporting programs operate on the basis that all ADRs should be reported despite uncertainty about a causal relationship. Even in the developed countries where the pharmacovigilance programs are well-established, a high level of under-reporting is documented (23-25). The majority of study participants believed of the importance of the presence of pharmacovigilance center in this country and considered ADRs reporting to be a natural

task for pharmacists, as well as main responsibility of all healthcare providers, however ADRs reporting is extremely low regardless these positive attitudes, similar to other studies (20, 26). However Pharmacist can play a major role in preventing ADRs reporting. In the developing countries, patients prefer to contact pharmacists first for any consultation regarding their medications because they easily accessed healthcare providers. Therefore, pharmacists need to take a more active role in the assessment and decision making concerning the safety of patient medications.

In the present study it was noted that also hospital pharmacists have insufficient knowledge of pharmacovigilance practices and reporting process. The main reasons for underreporting of ADRs are no enough information available from the patient, they did not know how to report and the ADR is too trivial to report. These findings were similar to results of a study performed on pharmacists in other countries (27-29). Pharmacists and other healthcare providers should consider ADRs reporting as an obligation at their working places and ADRs reporting systems in hospitals should be a priority basis for the success of the pharmacovigilance programs and the better clinical management of the patients.

Previous studies have demonstrated that knowledge and attitudes play an important role on ADR reporting (19). Furthermore, attitudes may be modifiable variables. Granas et al. (20) have shown that pharmacists' reporting-related attitudes can be significantly modified in a positive manner following educational programs that influence the ADR reporting. Developing a written hospital policy, better cooperation with clinicians, training, simplifying the system, allocation of time for ADR reporting, publicity and Promotion will improve the ADR reporting among Pharmacists and other healthcare professionals. In this country further studies needed to evaluate the influence of the education and training programs on the ADR reporting behaviors.

The main limitations of this study that the study findings could not be generalized to all community and hospital pharmacists as more

national studies needed. Also we are aware of some methodological weaknesses of our study; as the questionnaire relied on pharmacists' self-rated assessment of their own practice and attitudes, pharmacists might have been unwilling to reveal their practice deficiencies.

CONCLUSIONS

The results show that Palestinian pharmacists have poor knowledge about pharmacovigilance. There is an urgent need for educational programs to train them about pharmacovigilance and ADR reporting scheme.

CONFLICT OF INTERESTS

The authors report no conflicts of interest in this manuscript.

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