Evaluation of the pharmacists knowledge, awareness and practices towards pharmacovigilance in Syria

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Abstract

Background: The system of pharmacovigilance in Syria is administered by the Syrian Ministry Of Health (MOH), it is responsible for receiving reports from the patient all over the country for possible Adverse Drug Reactions (ADRs).
Pharmacists are members of this system and play a very important role in its implementation. Until now, Few pharmacists know about this system in Syria, how to deal with it, or even how important it is.

Aims: To discover Syrian pharmacists' knowledge, awareness, proceedings, and possible obstacles encountered while reporting the (ADRs). and to estimate the sociodemographic data from Damascus and rural Damascus.

Methods: We used a self-administered, cross-sectional, questionnaire-based survey conducted on a random sample of 235 registered pharmacists in 2 Syrian governorates.

Results: 84% was the rate of response, 45% had a familiarity with the PV system in Syria but the rest didn't. Some of them have received complaints from patients about unknown side effects, and their percentage was 60%, only 22% reported it. The most significant percentage of notifications was through the company's representative (10%), and 6% used the Ministry of Health (MOH) form.

Conclusions: Pharmacists who participated in the survey showed limited knowledge about pharmacovigilance (PV), also about its importance and extent of application in Syria. They had overlapping attitudes toward the reports, although they emphasized the importance of it. However, the current level of participation is rather low.

Introduction

Pharmacovigilance is defined by the WHO as science and activities related to the detection, assessment, understanding and prevention of side effects or other drug-related problems. while medicinal products are authorized after an assessment of their quality, safety and efficacy and a positive benefit-risk balance (1), the information that can be obtained before placing a medicinal product on the market is limited and a thorough understanding of the benefit-risk balance is required The benefit of a drug can only be defined more precisely after it has been approved, taking into account the findings from "real" use (1). Their main goal is to minimize the risks associated with the drugs used and maximize their benefits and improve patient safety and quality of life. According to guidelines from global health authorities, pharmacovigilance units around the world record adverse events caused or likely to be caused by the use of a specific drug (1). PV activities include: Collection and management of security data drugs, reviewing case reports for new "signals", proactive risk management to minimize potential drug risks, communicating and educating stakeholders and patients. This hassle-free post-marketing surveillance whose primary objective is to protect the public from new medicines when they first come to market (2).

The Syrian PV system was established in 2011 managed by the Syrian Ministry of Health. It provides all health services to citizens including; infectious and non-communicable disease surveillance and a local pharmacovigilance department. The local PV office is linked to general hospitals, health programs, pharmaceutical companies and the World health organization- Uppsala monitoring center; WHO-UMC at international level.

Pharmacovigilance officers are available in hospitals to assist with education and training (3,4). Before the war crisis (2011), Syria sought to keep pace with its pharmacovigilance activities, which led to Syria becoming an associate member of WHO-UMC in 2012 and a full member of WHO-UMC in 2018 (5,6).

However, during the recent war crisis, many health facilities were attacked and destroyed, forcing millions of Syrians to seek help from the WHO. In addition, a group of organizations and health professionals have taken initiatives to improve health care and healthcare delivery in Syria, forming the Syrian International Health Coalition (SICH) that was formed in 2012. All of these measures were aimed at compensating for the weakening in the health system (2).

There is a need for complete assessment in the health the post-crisis period, there will be an urgent need for a development process designed for screening and evaluating the health situation in the country using a comprehensive approach, including the health sector and the social economy (3).

During the post-crisis period, a thorough health assessment in the country is necessary. There is an urgent requirement for developing processes aimed at screening and evaluating the country's health situation using a comprehensive approach that encompasses both the health sector and the social economy.

Methods

Study design

The study was conducted from March 2023 to July 2023. The study was a self-contained, questionnaire-based survey conducted among a random sample of registered pharmacists in two Syrian provinces, the Syrian capital Damascus and surrounding villages Damascus (Rif Damascus). Interpretative Phenomenological Analysis (IPA) was used in this study which is a qualitative research approach that focuses on understanding how individuals interpret and make sense of their experiences. It aims to explore the subjective meanings and emotions that participants attach to their lived experiences. In IPA, researchers typically conduct in-depth interviews or analyze texts, such as written narratives or diaries, to gain rich insights into the participants' perspectives. The process of IPA involves identifying and analyzing themes that emerge from the participants' accounts, with an emphasis on capturing the nuances and complexities of their experiences. We have aimed to maintain a close connection to the participants' viewpoints, allowing the themes to be grounded in the individuals' own words and perspectives.

Survey tool

A comprehensive search for relevant articles/studies was conducted in PubMed, WHO and the Syrian Ministry of Health. The search approach included MeSH keywords or the terms' pharmacovigilance, adverse drug reactions, pharmacist, and "Syria".

The self-administered questionnaire was developed after reviewing relevant literature and surveys previously used in similar studies, including demographic information, respondents' understanding of the concept of pharmacovigilance, SPS, reporting of adverse reactions, their reporting practices, and perceived factors. Importance of PV, as motivations or barriers to reporting. The semi-structured questionnaire contained 11 items divided into 4 main sections. The first section contained three entries: Demographics, Professionals, Pharmacists, and the second part consisted of two questions that assessed respondents' knowledge of some basic Primary terms. These questions focused on general definitions and specific differences between different PV concepts. The third had four questions about ADR, how it is reported and why. The last part was a general open-ended question for respondents to make suggestions for increased involvement of pharmacists in reporting alternative drug interactions and ways to improve awareness of PV in Syria.
Sociodemographic Characteristics: This section aims to gather basic information about the respondents, such as age, gender, educational level, place of practice, and experience. The data collected in this section provide an overview of the sample demographics and allow the researchers to understand the characteristics of the pharmacists who participated in the survey.
Pharmacists' Knowledge of Pharmacovigilance Concepts: The second part of the survey contains multiple-choice questions to assess the pharmacists' knowledge of basic pharmacovigilance (PV) concepts. The responses to these questions indicate the level of understanding and awareness of PV among the pharmacists.

Data acquisition

Researchers visited pharmacists in their offices to invite them to participate in an anonymous study. The survey was conducted manually or online, with Google Forms being used for the online survey. A web link to the online survey was provided to the pharmacists via SMS or WhatsApp. Throughout the survey, the team did not offer any further help or clarification. However, the participant that did report their ADR were asked to provide a copy of their reports.

Data analysis

The results were analyzed statistically using the SPSS program. The Pearson Chi-squared test was utilized to calculate the P-values for categorical variables, with a

significance level of <0.05. Descriptive analysis was employed to describe the collected data, while qualitative analysis was used to categorize the pharmacists' comments.

Results

Demographics

360 pharmacists returned 235 valid surveys (65.2%) in the two cities together, the remaining pharmacists refused to participate, kept the questionnaire promising to fill it out later, but lost it or failed to return it the next day, or returned incomplete surveys. First section of the survey in (Table 1) showed that there are statistically significant differences in (age - educational level - place of practicing the profession) where the P-value was less than 0.05. Results are statistically significant for "gender and years of experience" where the P-value was greater than 0.05. Most answers were from the age group (20-29) with a percentage of 60%, and the majority of the respondents were females with a percentage (70%). The largest percentage of the respondents was from workers in private pharmacies with a rate of (42%), and finally most of the answers were from those with experience of (2-5) years with a rate of (33%).

Table 1 Sociodemographic characteristic of the responding Syrian pharmacists (*n* = 235), 2023

Parameter	Sample		P-value
	Count	%	
Age (years)			**0.020***
23-29	141	%60	
30-39	47	%20	
40-49	23	%10	
50-59	17	%7	
>60	3	%3	
Gender			
Male	70	%30	**0.98**
Female	165	%70	
Highest pharmacy degree			
Bachelor	185	%79	
Masters	40	%17	**0.003***
PhD/Pharm D	10	%4	
Professional Practice setting			
In-house hospital pharmacy	17	%7	
Private retail pharmacy	99	%42	
Pharmaceutical lab	16	%7	
Pharmaceutical representative	44	%19	**0.001***

Drugs lab	2	%1	
University lecturer	19	%8	
non	38	%16	
Experience (years)			
<2	38	%28	
2-5	45	%33	**0.12**
6-10	23	%17	
11-15	5	%4	
>15	24	%18	

*statistically significant at level 0.05

Some basic concepts of pharmacovigilance:

The second part of the survey contained a series of multiple choice questions to assess pharmacists' knowledge of some basic PV concepts (Table 2). There is a decrease in knowledge about the pharmacovigilance system in Syria, where the response rate to the first question was (45% yes? 55% no) and there are many answers one could ask for.

When asked whether you had a patient complaint about unknown or unrecorded side effects of the medicine, the number of responses was 81. They answered only "yes" (60%). Only 30 responses (22%) reported this complaint; in contrast to the remaining 51 cases (38%).

They report that the highest percentage (10%) of reports went through a company representative, with nearly 6% reported by the State Department. Most of these concerned patient safety (11%), reflecting the very low level of pharmacovigilance among pharmacists in Syria.

Studies in neighboring countries indicate a low local awareness of PV among pharmacists, but there is rapid and well-documented development on the subject.

Our results on the Syrian pharmacist's knowledge on this topic compared to neighboring countries showed that the pharmacist is still clueless about side effects and the science of pharmacovigilance because of the inability to define the concept or to distinguish related terms.

Also in relation to Dr. Anas Bahnasi, published in 2018, shows that 76% are unaware of the SPS supported by the Syrian Ministry of Health. If we assume that this percentage is very close to our results, it indicates several things, the most important of which is that the SPS system is still at the lowest level in the country and the pharmacist is aware of its importance and unaware of its continuing magnitude and constant advancement around the world

Table 2: Perception of Syrian pharmacists of pharmacovigilance, 2023

	Question	Yes		No	
		count	%	count	%
1	Have you heard of the pharmacovigilance system in Syria of the Ministry of Health?	106	45%	129	**55%**
2	How did you learn about the SPS pharmacovigilance system?	106	45%	129	**55%**
	• Circular of the Ministry of Health	23	10%	-	-
	• A seminar	16	7%	-	-
	• conference	5	2%	-	-
	• Workshop	5	2%	-	-
	• Other pharmacists	23	9%	-	-
	• other	33	14%	-	-
3	Have you encountered a complaint by a patient about side effects of a drug that are unknown or not written down?	141	60%	94	**40%**
4	Has this complaint been reported?	52	22%	89	**38%**
5	If the answer is yes, what was the means of notification used?	52	22%	-	-
	• Ministry of Health	14	6%	-	-
	• Pharmaceutical company over the phone	4	2%	-	-
	• company representative	25	10%	-	-
	• online	5	2%	-	-
	• other	4	2%	-	-
6	What is the main purpose of reporting a complaint?	52	22%		
	• Patient safety	27	11%		
	• Clinical case exchange	7	3%		
	• Knowledge of recent side effects	16	7%		
	• Other	2	1%		

Knowledge of the Syrian pharmacovigilance system, attitude and practice.

A total of 235 pharmacists, 106 of them did not know about the SPS provided by the Ministry of Health. Those who were aware of the system said they had acquired this knowledge from other pharmacists (9%) or through formal publications by the Ministry of Health (10%), about (11%) by seminars, conferences and workshops.

Pharmacist's comments, participation in the Syrian pharmacovigilance System.

The survey included one open-ended question, and in it pharmacists were asked to provide suggestions how to improve the SPS in the country, Around 61 pharmacists answered it and were categorized under 3 major themes , they are:

- Emphasis on the Ministry to follow the following procedures:

  " Preventing non-pharmacists from attending pharmacies. "

  " Entering basic medical information about public health and medicine for the stage of preparatory and secondary education."

  " Definition of the PV within the study plan for medical colleges in universities."

  " Increase communication between healthcare providers. "

- Activation of health services through:

  " Creating an integrated and effective electronic medical network for all workers in the medical sector through regular accounts that allow the exchange of observations and observations, leading to the issuance of forecasts and early warnings."

  " Conducting a follow-up for patients who take new medications to identify the effectiveness of the drugs and the possible effects they may have."

  " Publication of recent side effects in scientific journals."

- Some other suggestions:

  "Activating free workshops through dispensaries and cultural centers on the importance of the PV."

  " Holding workshops within government hospitals about this."

  " Clarify how to properly and correctly report recent side effects. "

  " Following up the global scientific and pharmaceutical progress."

In the context of pharmacovigilance, monitoring and understanding drug interactions are crucial components of ensuring medication safety and optimizing patient outcomes. Reporting drug interactions to PV programs helps in continuously evaluating the safety of medications and promoting the responsible use of pharmaceutical products. Pharmacovigilance can be directly related to the role of pharmacist by detection of Adverse Drug Reactions (ADRs), assessing the impact of drug interactions, identifying High-risk drug combinations and communicating Safety information.

Discussion

Syrian pharmacovigilance perceptions and baseline assessment

This study is one of the few studies on this topic conducted in Syria. Knowledge of the SPS by healthcare professionals, particularly pharmacists, is very important. This ADR expertise contributes significantly to the development of pharmaceutical practice and is directly related to patient health and safety. Therefore, efforts by various parties should be intensified and necessary steps taken to identify side effects and reports received to ensure the success of the national solar PV program. Studies in neighboring countries indicate a low local awareness of PV among pharmacists, but there is rapid and well-documented development on the subject (7).

Our results on the Syrian pharmacist's knowledge on this topic compared to neighboring countries showed that the pharmacist is still clueless about side effects and the science of pharmacovigilance because of the inability to define the concept or to distinguish related terms. Even compared to a study published in 2018 by Dr. Anas Bahnasi showing that 76% are unaware of SPS supported by the Syrian Ministry of Health (6). This percentage is believed to be very close to our results, indicating several things. The most important of these is that the SPS system is still at the lowest level in the country and the pharmacist is unaware of its importance, scope and constant evolution worldwide. This is a serious indicator of the inefficiency of the Ministry of Health's publicizing activities Despite the age difference between the survey participants, young people aged between 20 and 29 are characterized by the greatest knowledge despite several years of experience (7,8).

Pharmacy bachelor's graduates were the most familiar with the PV concept, followed by master's graduates and least so by doctoral students, which also contradicts the study above where master's graduates achieved the highest

percentage. There was no significant difference between the three groups at the level of using the reporting system.

Perceived obstacles and incentives

We have identified several factors that discourage pharmacists from reporting adverse reactions. The first disadvantage was the time constraints. First and foremost was a lack of knowledge of the reporting process and concern that these side effects might be misreported. Some of these factors have been found in other studies in the region (8, 9, 10, 11).

Around 70% of our pharmacists indicated the limited availability of prescriptions as the main obstacle. Other obstacles cited are a lack of knowledge about how to report, time constraints, and the fear of incorrectly reporting side effects (11, 12). Our pharmacists did not see lack of clinical training, complacency or legal responsibility as barriers to using the reporting system.

We hypothesize that the low reporting rate in our sample may be related to the retail environment in Syrian pharmacies, with minimal pharmacist-patient interaction, ignorance of terms, confusion in the reporting process and requirements, and limited access to declaration forms.

Observations on the degree of participation in the pharmacovigilance system

The analysis of the pharmacists' observations revealed uncertainty about the whereabouts and handling of the reports sent, in particular they had doubts about the transparency with which their reports were handled. It is clear that the Ministry of Health needs to provide clear explanations on how to properly handle these reports.

While these points are listed on the program's website the Ministry of Health should establish awareness programs for PV and feedback channels and promote them more generally to practicing pharmacists in all sectors. The submission process involved submitting the form by fax or email (8). An adequate solution to this problem would be a direct online application with a confirmation of receipt (13, 14). The feedback also indicated that pharmacists were disappointed with the complexity of the form itself and the submission process.

We found that the available form did not contain any indication or explanation of the action taken by the Ministry of Health as a result of the reporting process.

Although these steps are explained in the Department of Health's education programs, these programs are limited and cannot reach the right number of pharmacists.

Finally, pharmacists find their involvement in a patient's treatment plan to be minimal. This has proven to be a major obstacle for pharmacists in delivering clinical services, even in Western countries (9, 14, 15, 16). It has been difficult for pharmacists to identify and manage various drug-related issues, including side effects or side effects, since they did not have complete access to the patient's past and present medical situation.

Our study had some limitations. Most respondents did not have reliable internet access at their office, which limited access to the online reporting system. This obstacle was not considered in our study. Most of the pharmacists interviewed (9) practiced in the community, which may have contributed to the low awareness and usage. Many pharmacists left some questions unanswered or gave the same score for answers to many questions, which may have introduced some bias in the answers to those questions. The study was limited in number of participants who were ready to take part in this study. In addition, the number of pharmacists who left comments was very small. Additionally, since the system is still in the early stages of implementing adverse reaction reporting, many pharmacists may encounter several obstacles when attempting to use the system for the first time in the future.

Conclusion

The pharmacists who participated in the survey showed limited knowledge of PV and the Syrian PV system and had relatively diversed attitudes towards reporting. While recognizing the importance of reporting ADRs, participation is currently low. The reason for the lack of reporting was the uncertainty about the fate of the reports, how to deal with them, the complexity of the models and the bad publicity of the pharmacovigilance program. A prospective study covering all Syrian provinces would provide more valuable data to support the results of our study.

تقييم اليقظة الدوائية لدى الصيدلي في سورية

الخلفية: نظام التيقظ الدوائي في سوريا تديره وزارة الصحة السورية , وهي مسؤولة عن تلقي التقارير من المريض في جميع أنحاء البلاد عن التفاعلات الدوائية الضارة المحتملة. الصيادلة أعضاء في هذا النظام ويلعبون دورًا مهمًا جدًا في تنفيذه. حتى الآن ، قلة من الصيادلة يعرفون عن هذا النظام في سوريا ، وكيفية التعامل معه ، أو حتى مدى أهميته.

الأهداف: اكتشاف معرفة الصيادلة السوريين حول التيقظ الدوائي ، ووعيهم ، وإجراءاتهم ، والعقبات المحتملة التي واجهوها أثناء الإبلاغ عن الآثار الجانبية الحديثة , ولتقدير البيانات الاجتماعية الديموغرافية من دمشق وريف دمشق.

الطريقة: استخدمنا مسحًا مقطعيًا ذاتيًا قائم على الاستبيان تم إجراؤه على عينة عشوائية من 235 صيدليًا مسجلاً في محافظتين سوريتين .

النتائج: 84٪ كان معدل الاستجابة ، 45٪ لديهم معرفة بنظام اليقظة الدوائية في سوريا لكن البقية لم تكن كذلك. وقد تلقى بعضهم شكاوى من مرضى حول آثار جانبية غير معروفة ، وكانت نسبتهم 60٪ ، و 22٪ فقط أبلغوا عنها ، وكانت النسبة الأكبر من الإخطارات عبر مندوب الشركة (10٪) ، و 6٪ استخدموا استمارة وزارة الصحة.

الاستنتاجات: الصيادلة الذين شاركوا في المسح أظهروا معرفة محدودة عن اليقظة الدوائية ، وكذلك حول أهميتها ومدى تطبيقها في سوريا ..كانت لديهم مواقف متداخلة تجاه التقارير ، رغم أنهم أكدوا على أهميتها
ومع ذلك ، فإن المستوى الحالي للمشاركة منخفض نوعًا ما. كانت أسباب قلة الإدراك ، عدم فهم مصير التقارير بعد الإخطار ، وكيفية التعامل معها ، وندرة التعميم الكافي على مستوى الدولة حول هذا النظام.

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