



# Pharmacovigilance in the Community: A Special-Interest Group of the International Society of Pharmacovigilance

Mohamed A. Elhawary<sup>1,2</sup> · Rebecca Noss<sup>3,4</sup> · Loubna Alj<sup>5,6</sup> · Manal Younus<sup>7,8,9</sup> · Mayada Alkhakany<sup>8,10</sup> · Hadir Rostom<sup>11,12</sup> · Angela Caro-Rojas<sup>13,14</sup> · Thamir M. Alshammari<sup>9,15,16</sup>

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## 1 Introduction

Pharmacovigilance (PV) continues to evolve globally and has changed in the last few decades from depending on a reactive approach based on spontaneous reporting of adverse drug reactions (ADRs) to a more proactive and patient-centred approach [1]. To keep pace with these developments, PV stakeholders should adopt a multidisciplinary framework to release the untapped potential of their PV allies in the community [2].

Community pharmacists are often regarded as "the first point of contact" among healthcare professionals (HCPs) due to their high accessibility to the public [3]. However, on a daily basis, patients collect their medications from the pharmacy without seeking any clarification. Pharmacy staff often inquire, "Do you have any questions for the pharmacist?" to which the response is frequently "no" [4]. This recurring dialogue in general does not allow the pharmacists to

inform the patients of any essential information with regard to their medication. This lack of communication is a barrier to adverse event reporting, if it occurs, and undermines trust in healthcare systems. In turn, this can negatively impact on compliance with medications and increase the susceptibility to accepting misleading information.

Therefore, community pharmacists and other HCPs, should be familiar with ways to communicate risk. It is important for HCPs to be aware of the integrated PV landscape, which addresses all circumstances where safety issues may occur (e.g., medication error, abuse, poor quality, misuse, and drug addiction and falsified products) and to include not only conventional medicines but also biological products and herbal medicines.

This calls for boosting the partnership between national PV centres and community-based pharmacies. This will be of interest to the International Society of Pharmacovigilance (ISoP), as a scientific non-profit organisation through

✉ Mohamed A. Elhawary  
mohamed.ahmed.elhawary19@gmail.com;  
mohamedmetwally.alhawary@pharma.asu.edu.eg

<sup>1</sup> Egyptian Ministry of Health and Population, Expanded Programme on Immunization (General Secretary of ISoP Egypt Chapter), Cairo, Egypt

<sup>2</sup> Faculty of Pharmacy, Ain Shams University, Cairo, Egypt

<sup>3</sup> Noss Research Consulting LLC (Chair of the ISoP PV in the Community SIG), Columbus, OH, USA

<sup>4</sup> ISoP Pharmacovigilance in the Community SIG, Columbus, OH, USA

<sup>5</sup> Centre Anti Poison et de Pharmacovigilance du Maroc, Ministry of Health and Social Protection, Rabat, Morocco

<sup>6</sup> Field Epidemiology Training Program, Ecole Nationale de Santé Publique, Ministry of Health and Social Protection, Rabat, Morocco

<sup>7</sup> Iraqi Pharmacovigilance Centre, Ministry of Health (Vice President of ISoP Middle East Chapter), Baghdad, Iraq

<sup>8</sup> ISoP Patient Engagement SIG, London, UK

<sup>9</sup> International Society of Pharmacovigilance, Middle East Chapter, Dubai, UAE

<sup>10</sup> Regional Patient Engagement, Boehringer Ingelheim (Chair of ISoP PatEG-SIG), Dubai, UAE

<sup>11</sup> International Society of Pharmacovigilance (ISoP), Egypt Chapter, Cairo, Egypt

<sup>12</sup> Faculty of Pharmacy, MSA University (President of ISoP Egypt Chapter), 6th of October City, Giza, Egypt

<sup>13</sup> Pontificia Universidad Javeriana (President of ISoP), Bogotá, Colombia

<sup>14</sup> International Society of Pharmacovigilance, ISoP Secretariat Ltd, London, UK

<sup>15</sup> Department of Clinical Practice, Faculty of Pharmacy, Jazan University (President of ISoP Middle East Chapter), Jazan, Saudi Arabia

<sup>16</sup> Pharmacy Practice Research Unit, Faculty of Pharmacy, Jazan University, Jazan, Saudi Arabia

its special-interest group on pharmacovigilance in the community.

## 2 ISoP Special-Interest Group on Pharmacovigilance in the Community

In 2024, the ISoP Executive Committee supported the establishment of a new special-interest group (SIG) on PV in the community to be a focal point for ISoP members who are interested in engaging community pharmacists among other HCPs to minimise the risk of ADRs and improve other PV processes [5].

Community pharmacists are HCPs who have most regular contact with the general public. The ISoP PV Community SIG believes that it is important to keep pharmacists at the forefront of medication safety practices and to provide them with the required tools to consolidate a medication safety culture within the community.

The mission of this SIG is to foster the centric role of HCPs, community, and hospital pharmacists in PV. The specific aims of this SIG are outlined as follows:

- Update community pharmacists with latest PV communication approaches, focused on ADRs.
- Disseminate quarterly news and updates by email to the SIG members.
- Establish a forum to discuss any concerns regarding ADRs and refute infodemic misinformation.
- Where possible, organise regular sessions at the ISoP mid-year or annual meeting on the topic of PV in the community.
- Strengthen collaboration between pharmacovigilance centres and community-based pharmacies.
- Issue and update guidelines for community pharmacists to describe their roles and missions in medication safety.
- Organise annual training courses on PV and medication safety in the context of the SIG.

The core of ISoP's operational strategy lies in the collaboration between its Chapters and SIGs, who join forces to address worldwide medicine safety issues.

## 3 Addressing Safety Issues of Medicines in the Community

To address the safety issues of medicines within the community and with national and regional chapters (e.g., Egypt, Middle East, LATAM), Community SIGs will establish liaison within ISoP on Patient Engagement, Risk Communication, Drug Safety in Older Patients and Medication Errors.

## 3.1 Risk Communication for Safer Use of Medicines

As Community pharmacists act as an interface between patients (or their caregivers) and the medical system, they receive a wide range of medication-related complaints. There are barriers to reporting potential ADRs of a pharmaceutical product (e.g., time constraints for both pharmacist, patient or consumers. Also, the infrastructure of some pharmacies does not allow for privacy, etc.). However, the main reason could be their unwillingness to alarm patients [6]. This poor understanding of how to communicate risk could lead to worsening of ADRs especially if they are serious and unexpected.

Online pharmacies are becoming more widespread, especially since the Covid-19 pandemic. They reduce the level of communication between patients and pharmacists by removing "face-to-face" contact [7]. This will impact on the way in which pharmacists connect with patients – reducing direct "human" interaction and as a consequence the patient-pharmacists relationship becomes a mere commercial transaction.

One of the SIG strategies is to update members with the latest approaches to communication on ADRs without affecting patient adherence.

## 3.2 Self-Diagnosis and its Consequences Risks

Diagnosis must be made by qualified HCPs (e.g., physicians), using all available information to ensure accuracy and the correct management plan for the patient. Certain mild conditions can be managed with over-the-counter (OTC) medicines without the need to visit a healthcare facility. In these instances, self-diagnosis is often used, where patients assess their health using resources like symptom checklists and medical history to determine the treatment. This concept is becoming more common with the availability and ease of access to artificial intelligence (AI) tools. These tools can enable access to summarised medical content but there is no mechanism to differentiate between accurate and inaccurate content. This lack of medical expertise using AI gadgets can pose significant risks to patients who self-prescribe. Professional guidance is important, particularly in the case of severe forms of a condition [8].

Since various diseases exhibit similar symptoms, this could expose users of these AI tools to risk, as they cannot provide an accurate assessment when symptoms overlap. This is especially so in countries where there are limited restrictions on dispensing medications and individuals are more likely to self-diagnose and take inappropriate medicines, worsening their condition. This is particularly

common in low- and middle-income countries with high healthcare costs and limited health insurance coverage. In response, the ISoP PV in the Community SIG, together with the ISoP Middle East Chapter and ISoP PatEG SIG, hosted several webinars to discuss the risk of self-diagnosis and its effect on routine medication safety. These webinars addressed this issue with more focus to the misuse of antibiotics and their dispensation without prescriptions, highlighting its significant societal consequences in terms of the antibiotic resistance.

### 3.3 Paradigm Shift is Needed for Patient Safety

The shift of community pharmacists has moved from product-oriented to patient-centred practices where the main focus is on care services like medication therapy management, adherence support, and preventive health interventions. Patient engagement is central to the success of this model. Active patient/pharmacist engagement can facilitate improved healthcare delivery and patient outcomes [7].

Most literature considers active patient participation through community pharmacy services as a major motivating factor in improving consultancy effectiveness. Therefore, the ISoP PV in the Community SIG will collaborate with the ISoP Patient Engagement SIG to create channels for sharing the knowledge about medication safety.

### 3.4 Polypharmacy as a Challenge

Another challenge faced daily by community pharmacists is polypharmacy and its risks (e.g., increasing the incidence of drug-drug interactions). In the context of safety monitoring, polypharmacy hinders the PV process making it difficult to distinguish the cause of the suspected ADRs. Causality assessments became more complex because the ADRs may have been misinterpreted as symptoms of their comorbid conditions [9]. This complicates design of optimal risk minimisation measures. The ISoP PV in the Community SIG is developing a blueprint on this topic, through which community pharmacists can be trained in this domain.

### 3.5 Medication Errors to be Prevented

Medication errors (ME) are considered a daily challenge for community pharmacists [10]. There are potentially two main scenarios that enhance the occurrence of MEs [11]:

- Unsuitable environment to dispense medication that promotes the risk of dispensing errors.
- Poor communication between HCPs and patients leading to misunderstanding during the counselling, or misinterpretation of the prescription.

These possible circumstances feature in other different types of MEs (e.g., prescribing inappropriate OTC medicines) [12]. Of course, there are other contributory factors to unsafe medication safety practices (e.g., illegible handwriting and incomplete prescription). With regard to issues of the look-alike sound-alike medications (LASA), there are many guidelines that have been developed by the Institute for Safe Medication Practices (ISMP) and the American Society of Health-System Pharmacists (ASHP) to address such matters and community pharmacists should be aware of these standards to ensure the quality of the services they provide [13]. To maintain the reporting of these safety events, it is important to establish strong ties between PV centres and community pharmacies. Thus, the ISoP PV in the Community SIG seek to bridge the divide between the two stakeholders by setting up communication pathways that support the safety surveillance of medicines.

## 4 Community Empowerment in Advancing Safety Monitoring

### 4.1 Barriers to Consolidate the Culture of Medication Safety among the Community

There are several reasons why community pharmacists and other HCPs refrain from reporting ADRs [14]. One primary reason is the absence of a strong reporting culture within some countries, where PV systems are underdeveloped or not well-integrated into clinical practice. This lack of an established reporting framework can lead to uncertainty about the importance of ADR reporting, as it is not consistently reinforced in their professional environment [15]. Additionally, some HCPs are unsure whether ADRs stem from a medication safety issue or are a consequence of clinical error, which creates reluctance to report due to concerns about professional liability.

Time constraints are another critical factor. The limited duration allocated for patient consultations often does not allow enough time to thoroughly discuss ADRs. Furthermore, resource limitations, such as the absence of user-friendly reporting tools or insufficient training on PV, also contribute to underreporting. Addressing these challenges through improved systems, clearer guidelines, and better training can enhance ADR reporting and patient safety.

### 4.2 ISoP Supports National Pharmacovigilance Systems Around the Globe

In countries where reporting ADRs and MEs is voluntary, the community pharmacists can have a negative perception about the ADR reporting process and see it as an additional burden [16]. Therefore, many PV centres are prioritising the

establishment of different initiatives to highlight the importance of HCP reporting of ADRs [17].

In 2021, the Egyptian Pharmaceutical Vigilance Centre (EPVC) launched the “Community Club EPVC” [18]. This aims to activate the role of the community-based pharmacies on PV and to encourage the use of the e-portal of EPVC. The e-portal will enable the submission of individual case safety reports (ICSRs) by the community-based pharmacies, which will enable the Egyptian pharmaceutical market to monitor any safety issues (e.g., counterfeit medicines). Since its creation, the ISoP Egypt chapter (whose mission is to enrich PV practices in Egypt, in full support for the national Egyptian PV system), executed several awareness campaigns and educational programmes [19]. The Egyptian chapter conducted a technical workshop tailored to community pharmacists at the WHO World Health Day on the 7th April, 2024 to shed light on EPVC’s initiative among pharmacists and to stress the importance of being part of such network. An awareness session was also arranged for the patients and their caregivers.

The training included items related to the pharmacists’ daily work routine. Medication safety should start with appropriate prescribing based on a risk/benefit analysis, followed by a comprehensive medication review before dispensing, preparation, and administration.

In addition, decision making should be made after accurate communication and engagement of patients. In line with this, the WHO guidance on Medication Safety in Polypharmacy has been adopted to develop the training for this SIG [20].

The agenda of the technical workshop covers the following topics:

- Introduction to Pharmacovigilance.
- Sources, types, classification, and risk factors of ADRs.
- Terminologies of MedDRA for coding medication errors by the VigiFlow.
- Methods of designing ways to collect high quality ICSRs and build a positive ADR reporting culture.
- Collecting high quality of ICSRs.
- Validity of the ICSRs.
- ICSR management and signal detection and assessment.
- Root cause analysis of MEs.
- Pharmacovigilance in specific populations.
- Risk minimisation measures and risk communication.

Patients with chronic diseases and associated disorders need to use multiple medications because they suffer from multiple long-term illnesses. Consequently, polypharmacy in these cases is necessary and legitimate despite its risks.

The intent of the awareness lecture, dedicated to patients, was to empower them to play an active role in the PV cycle by educating them about PV activities. Patient awareness

of the importance of their ADR reporting can only lead to better understanding of their medication and, thus, avoid unnecessary risks. Nowadays patients are more willing to be engaged in their own therapeutic decisions and in the PV process. With appropriate education, patients can be engaged in the development of risk minimisation measures.

## 5 Conclusion

The ISoP PV in the Community SIG aims to make a significant positive impact on patient safety by recruiting new PV allies within the community and involving them in the PV cycle. International Society of Pharmacovigilance, as a leading organisation in the field of PV, will continue to collaborate with all PV stakeholders to consolidate PV in all aspects of the community to ensure the safer use of medicines worldwide. Current ISoP members with an interest in integrating the PV within the community are invited to join the SIG, which is keen to attract members from different backgrounds (e.g., regulatory authorities, pharmaceutical companies, health institutions, patient organisations, etc.). If you would like to join the ISoP PV in the community SIG, or have questions, please contact the SIG Coordinator, Rebecca Noss by e-mail to ISoP administration (administration@isoponline.org).

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