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FROM THE ISoP

The ISoP PatEG-SIG for Promoting Patient Engagement in Pharmacovigilance: A Change of Paradigm is Needed

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1 Introduction

Effective healthcare systems must build patient-centered ecosystems. Patients can share decision-making in such systems. Patients' and caregivers' voices can be heard more loudly if healthcare professionals (HCPs) and policymakers use innovative, collaborative, and interdisciplinary methods. These methods can empower patients and help create a patient engagement framework role [1]. In this context, effective communication approaches that aim to understand patients' perspectives, experiences, and needs should be applied in creating any executable frameworks for collaboration between patients and different stakeholders [2]. As using shared decisions on the appropriate treatment options, including use of medicines and devices require optimal dialogue to communicate efficacy and safety.

1.1 Patient Engagement in Pharmacovigilance: A Change of Paradigm is Needed

The fact that patients are more willing than ever to be involved in their therapeutic decisions is still not sufficiently recognized, especially in developing countries [3]. In addition, patients' panels and organizations are the most valuable contributors for developing and disseminating information, decision aids, and educational materials for an effective and safe use of medicines [4]. For the most part, patients are in favor of the transparency of healthcare systems, and expect HCPs to engage them throughout the whole healthcare process [5, 6]. This expectation is increasingly recognized in many countries around the globe. More patients expect their engagement in making their own treatment decisions, participating in the development and evaluation of services, and taking part in policy development. The still current paradigm model for marginalized patient participation in many places is due to three main reasons [7]:

- Patients are overwhelmingly hesitant to participate because they feel unauthorized to do so.
- HCPs predominantly deny handing over power to patients. This denial is multifactorial: they were not taught to involve patients, and they are hesitant to renounce the current model of healthcare [8].
- In a considerable number of countries, only a few of patients have easy access to their medical records, and mostly these records are incomplete or inaccurate, especially when they are paper based rather than held in an electronic system [9, 10].

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Therefore, there is a need for change in the paradigm of the relationship of patients and the wider system that is meant to care for their health when it comes to optimizing use of medicines and devices. Furthermore, with specialized educational programs, patients can be involved in research as a source of data on adverse drug reactions (ADRs). As such, getting them engaged can potentially lead to improvement in the quality and credibility of ADRs reports and thus identify signals more efficiently via the reporting of suspected cases or precisely describe the outcome of the ADR and its clinical management. In addition, they could have an incentive to coauthor study protocols and reports, to set the design or execution of research on risks and risk acceptance, and at a later step, be involved in the developing of risk minimization measures and their evaluation [11, 12].

Furthermore, patient engagement is already widely recognized as a crucial of high-quality healthcare in general and as a critical component of pharmacovigilance, both at the level of healthcare and medicine regulation and risk minimization activities [13].

From our specific view as those concerned with pharmacovigilance as the science and practice to reduce problems and harm with medicines and promote patient safety, we call for scientific and legal underpinning of frameworks of collaboration specifically for patient safety among patients, HCPs, and policymakers. We do so on behalf of the International Society of Pharmacovigilance (ISoP) as founding members of its Special Interest Group (SIG) on patient engagement. In this article we present the new ISoP-SIG and the role it can play in furthering patient engagement in pharmacovigilance.

2 Setting Up the ISoP Special Interest Group on Patient Engagement (PatEG-SIG)

ISoP established the Patient Engagement Special Interest Group (PatEG-SIG) to describe, develop, and promote patient engagement in pharmacovigilance [14]. ISoP special interest groups are open to all ISoP members and can invite experts, such as the PatEG-SIG did by inviting a patient advocate as one of its founding members.

The vision of this SIG is to enhance the core role of patients in medication safety, and its specific mission covers the following:

- Help shape the future of patient involvement in therapeutic decision-making, safety surveillance, and safe use of medicines.
- Foster appreciation of the patient contribution to medication safety, and share examples across stakeholders.
- Support knowledge, networks, and independent patient representation in medication safety systems.
- Advance independent patient involvement in development of policies and guidelines around medication safety.

The SIG activities will include, but are not limited to, research activities, publications, initiating awareness, and provide training activities, as well as more general advocacy for the role of the patient in pharmacovigilance. This will be achieved through a collaboration with patients and patient organizations, regulatory authorities, academia, and all other stakeholders interested in patient engagement.

Overall, the PatEG-SIG's work will be to set an "issues" agenda, define what steps are required, and work collaboratively and creatively both within and outside ISoP to develop, implement, and circulate innovative solutions. A participatory approach involving patients for planning and evaluating communication interventions on risks and safe use of medicines has been outlined for application by the pharmacovigilance and research communities.

The following describes the strategies, which the PatEG-SIG founding members have proposed and agreed upon with all SIG members.

3 Strategies of the PatEG-SIG to Support a Paradigm Shift

3.1 Wider Networking of the PatEG-SIG

Like the other ISoP SIGs and chapters, the PatEG-SIG is committed to establishing efficient liaisons within ISoP, such as with the ISoP SIG on Medicinal Product Risk Communication [2], as well as relevant stakeholders outside of the ISoP.

Furthermore, the ISoP PatEG-SIG will actively connect with pertinent experts outside traditional pharmacovigilance circles and invite them to participate in developing further strategies that could address the scientific–medical, cultural, linguistic, social, political, and media–technological complexity of patient engagement in pharmacovigilance. The SIG will invite such experts to the ISoP's annual meetings each year to review possible recommendations for another challenge in patient engagement so it can gradually progress.

It is crucial that HCPs develop social and communication skills and particularly increase empathy with patients. This means understanding the patient's feelings and acting coherently with that information. Against this background, and in line with the PatEG-SIG's goals, the main aim is to achieve impactful outputs of this wider networking, in the form of, for example, journal articles, webinars, conference presentations, virtual symposiums, and interactive training. Already, a subgroup of the PatEG-SIG has worked collaboratively on original research articles, systematic reviews, and a descriptive analysis relating to patient engagement, and this may

present opportunities for other SIG members to join these projects as collaborators.

3.2 Developing Patient Engagement Frameworks for Pharmacovigilance in Healthcare

Many studies have proven that those who are actively engaged in the treatment journey often have a better health outcome and mitigate the risk of further complications. The best way to involve patients is by informing them about their disease and involving them in the clinical decision-making process about their treatment options [15].

However, depending on the form and channel of involvement, the patient's role in the treatment journey is still negotiable. The pharmacovigilance community has the responsibility to provide information on the risks and risk minimization measures in a way that supports the dialogue between HCPs and patients about the effects, positive and negative, of the medicines, invite the patients to be the most important part of the healthcare team, and empower the patient to consider the different treatment options advised by the HCP. For this dialogue, HCPs should be conscious that the treatment effects impact directly on the patients and their lives.

Although patient education does not translate automatically to patient engagement, it could be considered an incremental step that can provide a potential strategy to engaging patients and HCPs in an open dialogue. Accordingly, it would allow for key stakeholders to distinguish which framework is the most effective and to identify a series of enablers, along with their corresponding barriers, for the sake of patient involvement throughout the decision-making process [16]. It is worth mentioning that family members and (other) informal caregivers play an essential role as advocates, and supporting and educating them can help to improve patient safety as well.

The PatEG-SIG aims to provide a focal point for ISoP members interested in patient engagement on pharmacovigilance. The SIG aims to share news items, research findings, regulatory actions, and other information on patient engagement issues that have been identified worldwide. This might encompass potential barriers and opportunities where SIG members may have data or experiences to share.

3.3 Monitoring Developments in Patient Engagement in Pharmacovigilance

The PatEG-SIG sees monitoring the developments of engaging patients in pharmacovigilance as requiring multiple ways of measurements that take into account the different aspects of stakeholders to assess the patient's capacity for engagement. In addition, the flexibility of the policies of the stakeholder organizations that seek to apply the best standards of patient engagement is evaluated, as patients can involve themselves in reshaping public policy, for example, through public deliberation and regulatory comment processes.

3.4 Exploring Opportunities and Challenges of Digitalization of Healthcare for Pharmacovigilance Engagement of Patients

It seems clear now, especially after the coronavirus disease 2019 (COVID-19) pandemic, that health digitalization is permeating all aspects of the community. In fact, digital technology helps with the collection, exchange, and analysis of real-world data.

Telehealth is relatively new and is getting a lot of attention and publicity. It gives patients greater access to digital resources than ever before, which is considered one part of patient empowerment. In addition, telehealth can enable HCPs to monitor patient health remotely. Moreover, digital technologies (e.g., telemedicine, drone shipment of medicinal products to patients, sensors, or wearable devices to measure vital signs or functional abilities, etc.) can support some clinical trial visits [17, 18]. It can also increase the opportunity for patients to play an active role, but it is important to remain vigilant of potential risks and challenges. The PatEG-SIG is developing a blueprint on this topic, through which it aims to advance practice in this domain.

While videoconferencing seems to be convenient, it may have negative consequences, such as increasing the risk of fragmenting healthcare [19]. Furthermore, the decision-making based on virtual visits may not be optimal if the patient has a complex medical history, because virtual visits lack an in-person evaluation, which may hinder precise diagnosis. The PatEG-SIG intends to be strategic in its outlook and have the resilience to respond to emerging situations or needs.

3.5 Fostering Patient Engagement in Regulatory Pharmacovigilance

It is crucial not only to engage patients in their therapeutic decision-making, but also to have them participate in other aspects of their medicine, including development, regulations, and safety [20].

Unfortunately, not all countries' regulatory authorities are currently entailing patient participation in their provisions, policies, and plans.

Therefore, the PatEG-SIG is targeting the development of concepts for patient engagement at high-quality level along with best practices that can be merged into operational everyday pharmacovigilance. The members of the PatEG-SIG are employed in a range of pharmacovigilance settings, including national pharmacovigilance centers, medicines' regulatory agencies, academic institutions, patient

organizations, and the pharmaceutical industries. Collectively, these members bring a range of skills, expertise, and experience across patient engagement and pharmacovigilance; thus, the PatEG-SIG is well placed to advance the topic at a global level and in ways that are impactful.

However, several good examples of World Health Organization (WHO)-listed authorities have shown how the government can play an active role in involving patients in different aspects. This is an area of much study and work using both qualitative and quantitative approaches, specifically in low- and middle-income countries (LMICs) [7, 21].

During the pandemic and despite the challenging healthcare infrastructure in the LMICs, many success stories were shared regarding counteracting misinformation, rapid identification of the risks of vaccines, and putting the patient at the core of the service [22]. Finally, how the information about the medicine is presented to the patient will make a huge difference in the regulatory and health framework as well. Hence, the patient's journey from the pre- to post-authorization phases, in addition to their role in decision-making related to their medicine choices and safety, should be monitored to ensure patient safety and optimal use of medicines.

Many regulators seek to increase the involvement of patients in their activities [23–25]. Specifically for pharmacovigilance, a model has been suggested that delineates engagement along three dimensions: breadth about the quantity and diversity of those involved; depth about how far they are involved in informing or participating in regulatory decisions; and texture related to the ways and meanings of the interactions [26]. This model has demonstrated analytical value for understanding engagement events, and the importance of a discourse adapted to the respective objectives of such events has been highlighted for regulators [27]. The most pressing needs for pharmacovigilance engagement exist in the planning and evaluation of risk minimization measures [11, 20].

4 Conclusion

Overall, the ISoP PatEG-SIG aims to activate and support developing patient engagement in pharmacovigilance at an expert-quality level, resulting in best practices that can be integrated into operational everyday pharmacovigilance both in healthcare and at the health policy level, and hence contribute to enabling informed therapeutic choices and keeping patients safe.

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Declarations

Disclaimer On behalf of the ISoP PatEG-SIG, the views expressed in this article are personal to the authors, and are not knowingly the position of any other body unless explicitly stated. As regards Priya Bahri, the views expressed in this article are her personal views and may not be understood or quoted as being made on behalf of or reflecting the position of her employing organization, that is, the European Medicines Agency (EMA), or one of its committees or working parties.

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