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FROM THE ISoP

The Role of ISoP in the Advancement of Pharmacovigilance in Low-and Middle-Income Countries (LMICs)

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1 Introduction

The slow development of pharmacovigilance (PV) in low- and middle-income countries (LMICs) calls for an analysis of the challenges and opportunities for enhancing its growth in these countries. In the aftermath of the thalidomide tragedy in the early 1960s, and pockets of medicine-related harm still occurring to this day, it is evident that many countries in LMIC continue to give little priority to the field [1, 2]. Although many of the national pharmacovigilance centers in these countries joined the World Health Organization (WHO) Program for International Drug Monitoring (PIDM) in the 1990s and early 2000, the practice of PV remains at a rudimentary phase compared to the more mature systems in many developed countries [3, 4].

The global PV landscape and societal context have shifted swiftly in the last few decades and are still changing. PV has expanded in scope and increased its focus to all health products, and to all circumstances where adverse events may occur such as medication error, abuse, misuse, and drug addiction. PV has shifted from using a reactive approach that relies on spontaneous reporting to a more proactive approach with the introduction of active surveillance, benefit-risk assessment, risk-management planning, risk communication, and minimization strategies.

In many LMICs, the rapid growth in the population as well as the increased purchasing power of the middle class have resulted in a higher demand for high-quality, safe, and efficacious medicines and healthcare products. Supply inequities may increase the risk for adverse outcomes as they increase the chances for the circulation of substandard and falsified medicinal products assumed to be pharmacologically equivalent and off-label use of approved products [5]. The safety monitoring of medicines must meet up with this changing demand for safer medicines, both in speed and in rigor.

The International Society of Pharmacovigilance (ISoP) is a professional, independent, non-profit organization that is open to anyone with an interest in the safe and effective use of medicinal products. It aims to foster PV scientifically and

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educationally and enhance all aspects of the safe and proper use of medicines and medical devices, in all countries [6].

ISoP provides a forum for advancing the science of PV through open sharing of experiences and knowledge exchange. It strives to achieve this through its regional chapters in different continents and countries, the Special Interest Groups (SIGs), and biannual international conferences held in different countries around the world.

The activities of ISoP provide its members in LMICs the opportunity to network, generate, and share innovative ideas for strengthening their capacity in safety monitoring. ISoP believes that it is essential to increase and enhance the professional capacity of its members to address the ever-growing and complex challenges related to medicine and patient safety. This is of particular relevance to members in LMICs, who generally have access to fewer resources than their counterparts in other parts of the world.

A look at some of the challenges facing PV in LMICs will provide a clear picture of the opportunities therein and the role society can play in advancing the practice in those geographies.

2 Pharmacovigilance (PV) Challenges and Opportunities for Low- and Middle-Income Countries (LMICs) within the International Society of Pharmacovigilance (ISoP)

In general, poor communication between patients and HCPs is another reason for under-reporting. In addition, poor or ineffective communication between adverse drug report (ADR) reporters and PV centers also undermines the willingness to report. Risk and safety communication can be challenging for PV specialists who collect and assess information about adverse reactions, especially in LMIC, when they are not properly equipped to undertake such communication. It is therefore necessary to detect the enablers along with their corresponding barriers for building their abilities in PV including risk and safety communication to ensure that the PV cycle (safety monitoring loop) is always completed through timely and appropriate communication of identified safety issues and to show authorities have understood what is being reported to them [7].

Another critical drawback is the limited use of electronic reporting systems and over-dependence on paper-based record-keeping systems in healthcare settings in these countries. This undermines timely identification, characterization, and assessment of risks, and prompt communication of potential safety signals to different medical products [8]. However, countries also need to be mindful of some of the challenges inherent in implementing electronic reporting systems, including having adequate infrastructure, the need for continuous updates to the hardware and software, strict data protection requirements, and ongoing user training.

In addition, in some countries, there is limited drug regulatory capacity and inadequately trained staff. According to Olsson et al. in their review of PV systems in 55 emerging countries, the absence of trained staff and local specialists in the national pharmacovigilance centers and pharmaceutical companies is one of the primary limitations to advancing PV in these countries [9–11].

Finally, medical and pharmacy students in LMICs may recognize the importance of ADR reporting and have the intention to report ADRs after graduation but may lack the requisite PV competencies and infrastructure to do so during their professional practice. This may result from the lack of standards for PV education in their countries or because PV education is not embedded in the pre-service training curriculum. A pivotal point for the future of PV is to build the competencies of HCPs during their undergraduate studies to recognize that ADR detection, reporting, and management is a critical component of clinical practice and patient care [12].

2.1 Opportunities and Strategies for ISoP to Advance PV in LMICs

2.1.1 Promoting Pharmacovigilance Awareness and Education

Almost 20 years ago, ISoP experts have developed a pharmacovigilance curriculum in collaboration with WHO. The WHO-ISoP pharmacovigilance curriculum, which is available in *Drug Safety*, the official journal of ISoP, is a comprehensive modular resource material that includes a theoretical part, practical tasks, and key literature references [13].

It covers the main aspects of PV, including biochemical, clinical, regulatory, and methodological aspects. Furthermore, it addresses issues pertinent to highly industrialized and less industrialized countries, including their different healthcare structures and issues. It achieves diversity in the topics covered. For instance, genetic testing, risks related to monoclonal antibodies, adverse events following immunization, counterfeiting, record linkage, periodic safety update reports, and communication to HCPs are all topics covered in the curriculum. The curriculum is therefore able to integrate key practical and emerging aspects of PV into existing educational programs and bridge the chasm between PV theory and practice. Countries in LMIC can thus enhance the PV capacity by adapting the ISoP PV curriculum in the teaching of relevant courses for undergraduate and postgraduate students in medicine, pharmacy, nursing, and related professions.

In September 2022, ISoP signed a memorandum of understanding with the Institute of Pharmacovigilance (IPV)

to formalize the ongoing collaboration to establish a Global Pharmacovigilance Professional Certification (GPPC) project. The project aims to establish global standards for career development in PV [14].

When fully implemented, the certification process will provide another opportunity for PV practitioners in LMICs to acquire the requisite competencies for optimal performance of their roles and responsibilities in ensuring the safety of medicines and better outcomes for the patients who use them.

During the COVID 19 pandemic, the Middle East chapter organized a series of webinars to share countries' experiences on PV and vaccine vigilance strategies. This helped countries to learn from each other. These strategies were developed following a PV assessment that highlighted the need to strengthen PV systems in Middle East countries.

2.1.2 Networking within ISoP and with Other International Organizations

SIGs, which are an important part of the ISoP operational strategy, operate as global networks without regional limitations [15]. They cover several areas of interest on PV. Currently, there are established SIGs on women's medicines, risk communication, risk minimization for Asian countries, Herbal and Traditional Medicines, PV Professional Qualification Framework, Medication Errors, Vaccine surveillance, Pharmacogenomic, Medical Device Safety, Patient Engagement, Drug Safety in Older Patients, and Ecopharmacovigilance [8, 16–21].

These SIGs play an important role in addressing pertinent issues because they enable members to interact on issues of current interest in their area of practice and to network with other experts within ISoP.

SIGs include professionals from various disciplines working in many different reputable entities with a long history in the field of PV such as the WHO, Council for International Organizations of Medical Sciences (CIOMS), Drug Safety Research Unit (DSRU), Institute for Safe Medication Practices (ISMP), Uppsala Monitoring Center (UMC), European Medicines Agency (EMA), Netherlands Pharmacovigilance Center "Lareb," Medicines and Healthcare Products Regulatory Agency (MHRA), Food and Drug Administration (FDA), European Training Programme In Pharmacovigilance and Pharmacoepidemiology (Eu2P), the Rabat Collaborating Center (RCC), and the Africa Collaborating Center (ACC).

Such networking and interactions are promoted in ISoP as it keeps members engaged in medication safety practices through the exchange of new ideas and provides updates on the latest innovative approaches and practices. Furthermore, the SIGs give members a chance for personal and professional advancement in their area of interest through collaboration on research, paper publications, panel discussions, and meeting presentations with the ultimate goal of strengthening medication safety. This networking provides members from LMICs with the opportunity to share their ideas, learn from their peers, and be mentored by more experienced colleagues in the field.

The networking is ensured as well within the chapters. The initiative of the ISoP Middle East chapter of setting up the country representative project allowed the establishment of networks of exchange between pharmacovigilance centers in Middle East countries to discuss safety signal management and common safety issues within the region.

Recognizing the disparity in earnings between PV practitioners in high-income and LMICs, ISoP instituted a special reduced membership fee designed to encourage participation by PV practitioners in LMICs. This has provided an opportunity for everyone interested in PV to aspire to enhance their capacities regardless of their income level. This has enhanced the participation of people from LMICs in ISoP activities that are designed to build the capacities necessary for robust and effective safety monitoring.

2.1.3 Organization and Participation in Domestic and International Events

Within our international professional society, there are ISoP national and regional chapters that are locally established groups of ISoP members who actively address the needs arising from PV activities in their respective countries (e.g., Egypt, China, Indonesia, etc.) or regions (e.g., Africa, Middle East, Latin America, North America, Europe, etc.). They work to promote PV in their territory of influence and support those in need of assistance. The ISoP chapters not only work in their geographical region, but they also work jointly to contribute to various activities within the Society including the annual *World Patient Safety Day* marked in the month of September every year, regional training courses, and the hosting of annual global conferences. The chapters' contributions include providing high-quality trainings, organizing seminars, webinars, and media chats that highlight the pre-selected topical patient safety issues for the year. Providing such an open platform for discussion with international experts in the field of PV contributes to building the capacities of different stakeholders and making them aware of the latest and best medication safety practices [22].

The Latin-American Chapter of ISoP has supported initiatives like the "*Bogota Declaration for Latin-American Pharmacovigilance advances*," produced in 2016 and included in the 74th Uppsala Reports, which included strategic axes that have been working up to now, including the training and support of PV professionals in the region. Proof of that was the Annual Meeting of ISoP held in Bogotá, Colombia in 2019, which mobilized PV dialogue in the Latin-American region,

and increased interest in working in medication safety. As an example, a specific topic for this meeting was the inclusion of Medication Errors prevention, supported by the Medication Errors Special Interest Group of ISoP launched in 2017.

ISoP also organized three PV training courses in collaboration with the Uppsala Monitoring Center in Latin America. In 2016, Lima-Peru was the first location, then Panama City in 2017, and Guayaquil-Ecuador in 2018 was the last location. The activities offered training opportunities for Latin American members and other members interested in PV in the region.

Another remarkable insight was that ISoP through its Egypt chapter in 2020 collaborated with the Uppsala Monitoring Center in setting a bold agenda for the MedSafetyWeek. This became an amulet for the years that followed by transforming the MedSafetyWeek from being an annual virtual campaign on social media for HCPs and the public, to being a hybrid event that takes the campaign further by directly engaging institutional stakeholders, such as hospitals, academia, NPOs, community pharmacies, and pharmaceutical companies. Individual stakeholders such as pharmacists, pharmacy students, and PV staff of pharmaceutical companies also participated in different field activities parallel to the social media campaign to cultivate the culture of ADR reporting and boost PV awareness [23, 24]. Students were the most active and vital participants in the campaign's field activities. This encouraged the Egypt chapter to create a proposal with the Egyptian Pharmaceutical Students Federation (EPSF), which is part of the International Pharmaceutical Students' Federation (IPSF) in the Netherlands, to engage students in technical workshops with various stakeholders in PV to accumulate experiences and build capabilities based on real PV operations and medication safety practices. This simulation helps the students to deeply understand the multidisciplinary nature of this science. Subsequently, such a partnership was an incremental approach towards an expanded framework with the IPSF Secretariat and later on in establishing the ISoP Student Group in 2023 [25]. In this context, the new SIG, which includes student members from the LIMCs, provides chances to network with other PV students on an international scale and with senior colleagues in PV for future opportunities, for example, research collaborations, including the ISoP Fellows community.

In 2021, the Africa chapter of ISoP in collaboration with other ISoP chapters, National Medicines Regulatory Affairs (NMRAs), and some multinational pharmaceutical companies undertook a series of training aimed at building the capacity of its members to respond to the increasing demand for more involvement of marketing authorization holders (MAHs), particularly indigenous ones, in the safety monitoring of their approved products. The chapter has also created three technical working groups (public relations and communication, research and academia, and regulatory practices) through which it hopes to get its members directly involved in the society's activities and agenda setting [26].

2.1.4 Participation in Research, Project Implementation, and Article Publication

A key aim of the establishment of ISoP is to foster PV. This is typically achieved through the conduct of research by its members. ISoP members have undertaken countless research tasks about various topics of interest in PV spanning multiple geographies. This is evidenced by the high number of abstracts submitted each year for the annual meetings and published in *Drug Safety* [27, 28]. In addition, ISoP members implement numerous PV projects to strengthen pharmacovigilance in LMICs [29]. It is worth mentioning that during the annual meeting of 2022 in Verona, ISoP announced the creation of the "Sten Olsson Poster Prize" in recognition of Sten Olsson's contribution to PV. The plan each year is to award this prize to a poster submission to the annual meeting that best demonstrates the advancement of pharmacovigilance in a low- and middle-income setting [30].

This focus on research and project implementation creates another avenue within the society to strengthen international research collaborations that build the capacity of budding researchers in LMICs. The publication of such research work increases visibility for PV activities in LMICs in addition to creating capacity.

2.1.5 New Paradigms and Visions in Pharmacovigilance

The traditional way whereby PV was seen as a reactive science waiting to analyze an event that has occurred is constantly being challenged and re-evaluated. This is why ISoP's new vision is to position PV not only as a proactive science that focuses on the safety of medicines but as one that promotes a holistic culture of patient safety. It seeks to achieve this through various means, including sustained messaging about the prevention of medication error, use of design processes based on human factors (ergonomics), and massive promotional and educational campaigns that promote the safe use of medications. PV centers in LMICs are key in the new vision and the changing paradigm for safety monitoring.

ISoP also promotes the inclusion and open discussion about new technologies and innovative thinking on emerging issues. Ecopharmacovigilance, materiovigilance, and the role of artificial intelligence/machine learning in PV are some of the lively discussions and conversations that are generating interest in PV. ISoP members from less resourced countries participating in these discussions within the various Special Interest groups or during ISoP organized

webinars can benefit from the cumulative advanced knowledge in these fields that is often found in the SIGs.

2.1.6 Participation in Strategic Leadership in Pharmacovigilance

ISoP promotes inclusive leadership by having leaders in every region. Currently, ISoP has a presence in more than 100 countries, organized in chapters by regions with a good representation of leaders promoting activities in LMIC. ISoP's top leadership including the president are elected from among its members. This provides an opportunity for members from LMIC to be part of the highest decision-making body of the society—the Advisory Board that determines the strategic objectives and directions for global PV. Members from a LMIC have served meritoriously as Presidents of the Society including the incumbent president. These leaders serve as role models for younger colleagues to emulate in embracing PV as a path to personal professional development and public service.

3 Conclusion

Pharmacovigilance is a multi-sectoral discipline essential for achieving optimal outcomes for patients in the process of healthcare delivery. Individual and institutional stakeholders in the public and private sectors play a crucial role in improving PV practices in both high- and low-income countries. Nonprofit organizations such as ISoP can actively enhance PV practices in all countries to attain the public health goal for safer use of medicines. By developing standards, guidelines, curricula, tools, technologies, strategies, and policies, and by enhancing international collaboration amongst its members, ISoP offers numerous opportunities for enhancing the practice of PV in LMICs for all those with an interest in the clinical, scientific, and regulatory aspects of patient safety.

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