



International Society
of Pharmacovigilance

Drug Safety: putting patients first in pharmacovigilance

Ms Angela Caro Co-Chair of Medication Errors SIG and President International Society of Pharmacovigilance (ISOP) Dr Brian Edwards, Co-Chair of Medication Errors SIG and Vice President International Society of Pharmacovigilance (ISOP)

IMSN meeting Day 1 **Monday 23 October 2023**

Patient Engagement Group



Empower Patients to Enhance Safety



Patient Engagement Special Interest Group (PatEG-SIG)

ISoP established the Patient Engagement Special Interest Group (PatEG-SIG) to describe, develop, and promote patient engagement in pharmacovigilance

The Central Role of Patient Engagement

- Patient engagement is widely recognized as crucial for high-quality healthcare and as a critical component of pharmacovigilance, both at the level of healthcare delivery, medicine regulation, and risk minimization activities.
 - 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.
 - Patient panels and organizations are the most valuable contributors for developing and disseminating information, decision aids, and educational materials for safe and effective use of medicines.
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Vision

Enhance the core role of patients in medication safety.



Mission

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





Founding Members

Chair

Dr. Mayada Alkhakany

Co chair

Dr. Manal Younus

Advisory Committee members

Priya Bahri

Angela Caro Rojas

Linda Harmark

Helen Haskell

Helen Ndagije

Regions Represented

Europe

USA

Canada

Latin America

Asia

Africa



Patient Engagement SIG Activities

- Research & publications
- Awareness campaigns
- Training activities
- General advocacy for the role of the patient in pharmacovigilance
- Broad collaboration with patients, patient organizations, regulatory authorities, academia, others



Patient Engagement Group
A Special Interest Group

PRESENTS

PATIENT ENGAGEMENT **FROM DIFFERENT** **perspectives**



ONLINE: ZOOM



Friday, May 20th 2022



6 PM CET



meet the
Advisory
Committee
of the group!



International Society
of Pharmacovigilance



J.Christophe Delumeau



Ban Al-Shimran



Mayada Alkhakany



Helen Haskell



Priya Bahri



Manal Younus



LindaHarmark



Angela Caro



Manoj Swaminathan



Katila George



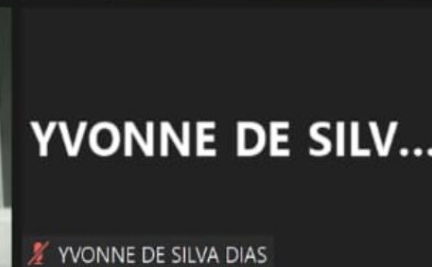
Mohamed A. Elhawary



Walaa's iPhone



Mariana Vieira



YVONNE DE SILV...

YVONNE DE SILVA DIAS



Constanza Moreno



Morouje Alkhate...

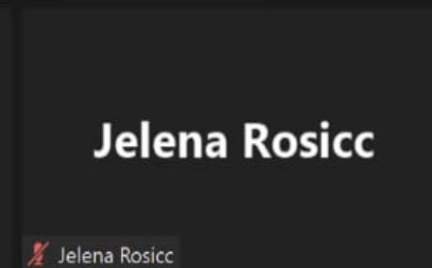
Morouje Alkhateeb



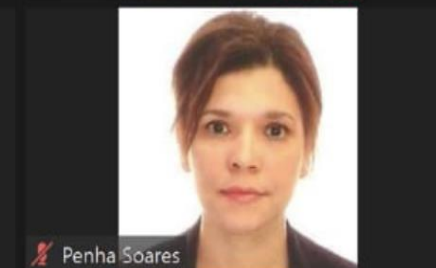
Salma Eltahir



ZOOM Leaders



Jelena Rosicc



Penha Soares

Drug Safety

<https://doi.org/10.1007/s40264-023-01313-4>

FROM THE ISoP

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

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“Issues”agenda



DEFINE ISSUES



DETERMINE WHAT STEPS ARE REQUIRED



WORK COLLABORATIVELY AND CREATIVELY BOTH
WITHIN AND OUTSIDE ISOP TO DEVELOP,
IMPLEMENT, AND CIRCULATE INNOVATIVE
SOLUTIONS



PatEG-SIG Strategies

1. Wider Networking of the PatEG-SIG
2. Developing Patient Engagement Frameworks for Pharmacovigilance in Healthcare
3. Monitoring Developments in Patient Engagement in Pharmacovigilance
4. Exploring Opportunities and Challenges of Digitalization of Healthcare for Pharmacovigilance Engagement of Patients
5. Fostering Patient Engagement in Regulatory Pharmacovigilance

1. Wider Networking of the PatEG-SIG



Establish efficient liaisons within ISoP and with relevant external stakeholders.



Invite experts from outside pharmacovigilance to address the scientific–medical, cultural, linguistic, social, political, and media–technological complexity of patient engagement in pharmacovigilance.



Wider presence through journal articles, webinars, conference presentations, virtual symposiums, and interactive training.

2. Developing Patient Engagement Frameworks for Pharmacovigilance in Healthcare

- 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.
 - We aim to provide information on the risks and risk minimization measures in a way that supports the dialogue between HCPs and patients.
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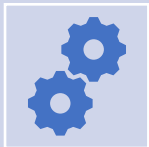
3. Monitoring Developments in Patient Engagement in Pharmacovigilance

- 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 will be evaluated, as patients can involve themselves in reshaping public policy, for example, through public deliberation and regulatory comment processes.
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4. Exploring Opportunities and Challenges of Digitalization of Healthcare for Pharmacovigilance Engagement of Patients



Telehealth can 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.



The PatEG-SIG intends to be strategic in its outlook and have the resilience to respond to emerging situations or needs.

5. Fostering Patient Engagement in Regulatory Pharmacovigilance

- PatEG-SIG is targeting the development of high-quality concepts for patient engagement and best practices that can be merged into operational everyday pharmacovigilance.
- PatEG-SIG members are employed in a range of pharmacovigilance settings, including national pharmacovigilance centers, regulatory agencies, academic institutions, patient organizations, and the pharmaceutical industry, and are well placed to advance the topic at a global level.
- The most pressing needs for pharmacovigilance engagement are in the planning and evaluation of risk minimization measures.
- PatEG-SIG members have been involved in developing models for understanding engagement events in pharmacovigilance and adapting discourse to respondent objectives, including an interactive LMIC reporting system that provides information on medicines as well as reporting.

PatEG- SIG Member Activities

- To date, PatEG-SIG members have worked collaboratively on original research articles, systematic reviews, and a descriptive analysis relating to patient engagement.
- These and similar activities may present opportunities for other SIG members to join PatEG-SIG as collaborators.



Proposed PatEG-SIG Activities

Collaboration

- Develop a training program with universities to educate HCPs about the importance of active listening to the patients.
- Work with non-profit organizations to support the early involvement of patients in clinical trial objectives and design.
- Work with health authorities to raise awareness of the importance of involving the patients in drug decision-making.

Awareness activities

- Awareness/training campaign for physicians on the importance of engaging patients in understanding their disease conditions and treatment choices, including management of potential medication side effects.
- Awareness/training campaign for pharmacists on the importance of spending time to instruct patients in proper use and correct storage of their medications.
- Awareness/training campaign for nurses on the importance of educating patients on how to manage their disease, dietary regimen, and medication side effects.
- Teach-back technique is a powerful technique to ensure the engagement of the patient in dialogue.

Join ISoP PatEG-SIG!



ISOP MEMBER MORE THAN THREE
YEARS



PASSIONATE ABOUT SUPPORTING
THE PATIENT UTILIZING DIFFERENT
TOOLS AND CHANNELS



HAVE A CONNECTION WITH THE PATIENT
ORGANIZATIONS/SOCIETIES IN YOUR COUNTRY
OR REGION

If you would like to join the group, please submit an application form at
<https://my.forms.app/form/6197c0af7d2e520c5414b674>
or email isoppatienteg@gmail.com

PatEG-SIG Social Media



<https://twitter.com/PatientegIsoP>



<https://www.facebook.com/ISO-Patient-Engagement-Group-103127862204528/>



<https://www.linkedin.com/company/isop-patient-engagement-group>

Thank you!



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