

Enhancing pharmacovigilance through patient engagement: perspectives and strategies

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ABSTRACT

Pharmacovigilance, as defined by the World Health Organization, is the science and activities related to the detection, assessment, understanding, and prevention of adverse events or any other possible drug-related problem. The Council for International Organizations of Medical Sciences Working Group XI has provided a comprehensive definition of patient engagement, highlighting mechanisms related to patient engagement such as direct patient reporting of adverse events, patient advisory roles, and established feedback channels. In recent years, patient roles in different aspects of healthcare, including medicine development, regulations, and the safe use of medicines are witnessing increased attention and expansion. This presentation sheds light on the importance of engaging patients in different pharmacovigilance activities, discusses patient engagement mechanisms contributing to drug safety, and addresses the strategies and the challenges associated with enhancing patient engagement.

Patient engagement is currently a cornerstone for monitoring and evaluating the safety of medicinal products, particularly since its emergence as a key element of pharmacovigilance¹. Patient participation in different activities brings valuable perspectives and unique insights, thereby enhancing pharmacovigilance efforts and supporting the real-world experiences². However, addressing accessibility, awareness, and trust barriers dictates a need for

meaningful patient participation. The objectives of my presentation are to highlight the importance of patient engagement in pharmacovigilance, to discuss the patient engagement mechanisms contributing to drug safety, and to outline the strategies and challenges in supporting patient engagement.

My presentation highlights the definition of patient engagement based on the work of the Council for International Organizations of Medical Sciences Working

Group XI and its relationship with the World Health Organization's definition of pharmacovigilance. Examples describing the evolving practices in the global pharmacovigilance systems that demonstrate the value of patient participation are presented, and so are the importance and the methods of this engagement. I also discuss the challenges facing patient engagement in pharmacovigilance and the strategies allowing us to address these challenges.

Patient engagement in pharmacovigilance through the incorporation of real-world evidence and patient perspectives has been shown to enhance the quality and the relevance of safety data. A more robust pharmacovigilance system could be established through direct patient reporting, participation in advisory roles, and the application of feedback mechanisms. However, widespread engagement is still a challenge due to issues related to accessibility, trust, and patient awareness. Strategies that could be implemented in an effort to address these challenges include improving patient education, leveraging digital tools, and fostering collaborative environments in which patients feel valued as partners.

Patient engagement is a very crucial step forward

in a new era in the field of pharmacovigilance. The direct and active patient involvement in different aspects related to drug safety monitoring and assessment paves the way to improved and comprehensive pharmacovigilance data quality and, consequently, to improved patient health outcomes. Finally, the evolving innovative approaches employing digital health technologies will support and strengthen the role of patients in pharmacovigilance. Ensuring patients' voices are reached out loud and their experiences are shared is a crucial step in shaping the regulatory decision-making for the new future of safety monitoring.

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Conflicts of interest

None exist.

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