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REVIEW ARTICLE

Global pharmacovigilance systems: Evolution, challenges, and future prospects

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ABSTRACT

Pharmacovigilance (PV) plays a critical role in ensuring drug safety and protecting public health worldwide. Over the decades, global PV systems have evolved significantly—from early-stage spontaneous reporting mechanisms to increasingly sophisticated frameworks that integrate electronic health records, real-world data, and advanced analytics. This review provides a comprehensive overview of the historical development of pharmacovigilance systems across key regions, including the European Union, the United States, and low- and middle-income countries, highlighting the diversity in regulatory approaches and infrastructural capacities. Despite notable progress, the field continues to face persistent challenges such as underreporting, data silos, regulatory fragmentation, and the need for harmonized global practices. The emergence of digital health technologies, artificial intelligence, and global data-sharing initiatives offers promising avenues to strengthen pharmacovigilance systems, improve signal detection, and enhance proactive risk management. This review also explores the future landscape of pharmacovigilance, emphasizing the importance of patient engagement, international collaboration, and adaptive regulatory strategies to meet the complex demands of modern drug safety surveillance.

INTRODUCTION

Global pharmacovigilance refers to the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems throughout the lifecycle of medications. It is a critical aspect of drug safety, particularly in the context of an increasingly complex pharmaceutical landscape characterized by rapid advancements in technology, evolving regulatory frameworks, and the need for international cooperation. The evolution of pharmacovigilance systems has been shaped by historical milestones, including the establishment of collaborative regulatory frameworks and the incorporation of modern technologies such as artificial intelligence (AI) and real-world evidence (RWE) in monitoring drug safety[1-4]. Despite its significant advancements, global pharmacovigilance faces numerous challenges, including underreporting of adverse drug reactions (ADRs), data quality issues, and compliance complexities across different jurisdictions[5-7]. These challenges hinder the effectiveness of monitoring systems and raise concerns about patient safety and public health. Notably, the integration of AI has the potential to revolutionize pharmacovigilance by enabling quicker identification of safety signals, although it also introduces new challenges related to data quality and algorithmic biases[8-10]. Looking ahead, the future of pharmacovigilance is likely to involve a shift from reactive to proactive models, emphasizing comprehensive risk management, enhanced international collaboration, and innovative data-driven approaches. Initiatives such as the International Coalition of Medicines Regulatory Authorities (ICMRA) aim to harmonize global efforts and improve the efficiency of drug safety assessments across borders[11,12]. The incorporation of advanced analytics and patient engagement in reporting systems is expected to further enrich pharmacovigilance practices, ensuring that they adapt to the evolving healthcare landscape and maintain public trust in pharmaceutical products[13,14]. In summary, global pharmacovigilance is a dynamic field marked by historical evolution, technological advancements, and ongoing challenges that underscore its importance in safeguarding patient health. As stakeholders work towards more robust and integrated systems, the ability to effectively monitor and respond to drug safety issues will be crucial in fostering a safer pharmaceutical environment worldwide[15-17].

HISTORICAL EVOLUTION OF PHARMACOVIGILANCE

The history of pharmacovigilance is a rich and complex narrative that traces its roots back to ancient civilizations. The earliest known records of pharmacovigilance can be found in societies such as Egypt, Greece, and Rome, where practitioners documented the effects of various medicinal substances on patients[1]. Over the centuries, the practice evolved, reflecting advancements in medical knowledge and a growing awareness of the importance of drug safety monitoring.

Significant Milestones

The evolution of pharmacovigilance is marked by several key milestones that have shaped its development. In the early 1990s, European Union member states began collaborating more closely to create a unified regulatory framework for drug safety, which led to the establishment of more integrated systems for monitoring and assessing drug safety across member countries[2]. This initiative laid the groundwork for modern pharmacovigilance practices and highlighted the necessity of international cooperation in ensuring drug safety. As the field continued to advance, pharmacovigilance expanded beyond post-marketing surveillance to include proactive measures such as parallel scientific advice to pharmaceutical companies during the development phase. This allowed for the exchange of information regarding ongoing assessments and mitigation strategies for product shortages[3,4]. Such developments emphasize the dynamic nature of pharmacovigilance, adapting to emerging challenges in the pharmaceutical landscape.

Current Trends and Future Directions

Today, pharmacovigilance systems are increasingly integrated with technology, utilizing drug safety software solutions to enhance patient safety by monitoring drug interactions and adverse events in real time[5]. These technological advancements facilitate the early detection of safety signals, enabling timely interventions that mitigate potential risks to patients' health. Looking forward, the vision for international engagement in pharmacovigilance focuses on expanding collaboration, communication, and coordination among regulatory agencies globally. By working together, agencies can optimize their collective resources to address the growing complexities of drug safety, ensuring rigorous safety standards and maintaining public trust in pharmaceutical products[6,7]. The ongoing evolution of pharmacovigilance reflects an enduring commitment to enhancing patient safety and adapting to the ever-changing landscape of healthcare.

CURRENT GLOBAL PHARMACOVIGILANCE SYSTEMS

Pharmacovigilance (PV) is a critical component of drug safety, focusing on monitoring the safety of medications throughout their lifecycle. Given the limitations of clinical trials in identifying rare adverse drug reactions (ADRs), ongoing efforts to enhance reporting systems and maintain vigilance in drug safety are essential[8,9]. Various countries have developed integrated systems to collect and evaluate individual ADR cases, creating an international database that facilitates the sharing of ADR reports[10]. This collaborative approach helps ensure that drugs are marketed only after proving sufficient safety and efficacy, thereby protecting public health[11].

Role of Artificial Intelligence in Pharmacovigilance

Today, artificial intelligence (AI) has become a necessity in pharmacovigilance, enabling more efficient and effective monitoring of drug safety. Machine learning models are now capable of analyzing vast amounts of data, helping to identify potential safety signals more quickly than traditional methods[12]. However, the integration of AI into PV also presents challenges, including the need for robust data quality and the potential for algorithmic biases[12].

Innovations and Future Directions

The future of pharmacovigilance is poised to shift beyond mere compliance to a more proactive model, utilizing AI-powered automation alongside real-world evidence (RWE) and advanced analytics[12,13]. Companies like

ArisGlobal are leading this transformation through innovative solutions like the #NAVAx LifeSphere, which integrates AI and automation to streamline pharmacovigilance processes[12,13]. As the field evolves, it is crucial for professionals in life sciences to ask whether they are leveraging AI to its full potential or merely fulfilling compliance requirements[12]. The ongoing development of integrated systems that connect patient devices, healthcare provider systems, and pharmaceutical databases in real-time will further enhance the efficiency and effectiveness of global pharmacovigilance efforts[13].

International Cooperation

Efforts to strengthen global pharmacovigilance systems also involve international collaboration, as exemplified by the International Coalition of Medicines Regulatory Authorities (ICMRA). This coalition aims to create a strategic approach to pharmacovigilance, addressing postapproval changes and safety-related issues in a coordinated manner across countries[13,14]. Such collaboration can significantly improve the speed and effectiveness of drug safety assessments, ultimately benefiting public health[13,14].

CHALLENGES IN PHARMACOVIGILANCE

Pharmacovigilance faces several challenges that hinder its effectiveness in monitoring drug safety and ensuring patient welfare. These challenges include limitations in reporting systems, data quality issues, compliance concerns, and the evolving landscape of drug regulation.

Limitations of Reporting Systems

One of the primary challenges in pharmacovigilance is the underreporting of adverse drug reactions (ADRs). Healthcare professionals may lack awareness or training to recognize and report these reactions, which leads to an incomplete understanding of a drug's safety profile[1,15]. Moreover, many existing reporting systems are not user-friendly, deterring healthcare providers from submitting necessary reports[16].

Data Quality and Consistency

Ensuring the quality and consistency of safety data is crucial for effective pharmacovigilance. However, variations in data collection practices across different regions can result in discrepancies and inconsistencies, making it difficult to analyze and interpret data reliably[17,18]. Robust data management processes, including validation and standardization, are essential yet often lacking in practice, contributing to challenges in maintaining accurate safety data across various sources and databases[19,20].

Compliance and Regulatory Requirements

Pharmaceutical companies and medical device manufacturers face rigorous regulatory requirements for safety reporting. Non-compliance can lead to penalties and reputational damage, yet understanding and adhering to diverse regulations can be complex, particularly for global organizations[17]. Continuous education and training are necessary to ensure that stakeholders are familiar with the applicable regulations and guidelines for their products and regions[18].

Evolving Landscape and Technological Advances

The rapid advancement of technology presents both opportunities and challenges for pharmacovigilance. While data analytics and digitalization can enhance monitoring processes, they also require significant adaptation and integration efforts within existing systems[14, 21]. The COVID-19 pandemic has highlighted the need for agile regulatory approaches, but it has also exposed existing vulnerabilities in pharmacovigilance frameworks that must be addressed for future resilience[14,22].

FUTURE PROSPECTS FOR PHARMACOVIGILANCE

Pharmacovigilance is poised to undergo significant transformations in response to advancements in technology and the evolving landscape of healthcare data management. The integration of artificial intelligence (AI) and machine learning (ML) is expected to enhance data collection and analysis, enabling more effective monitoring of drug safety and adverse events[6][23]. These technologies can facilitate the rapid processing of large datasets, allowing for real-time surveillance and timely interventions to protect patient safety[24].

Regulatory Compliance and Data-Driven Approaches

The future of pharmacovigilance is increasingly aligned with data-driven regulatory frameworks. In Europe, initiatives like the Data Analysis and Real World Interrogation Network (DARWIN EU) emphasize the use of real-world evidence to address gaps in regulatory knowledge, thus enhancing decision-making processes regarding drug safety and efficacy[19,25]. Such approaches will likely lead to more comprehensive risk management strategies, ensuring that pharmacovigilance systems adapt to the growing complexity of healthcare data.

Ethical Data Management and Patient Engagement

Continuous investment in ethical data management practices is crucial for maintaining patient confidentiality and regulatory compliance. The adoption of secure technologies, such as blockchain and cloud infrastructures, promotes sustainability in pharmacovigilance operations while ensuring that patient data is handled responsibly[26]. Furthermore, fostering patient engagement through innovative platforms can improve reporting systems, encouraging more individuals to share their experiences with medications, which is vital for identifying adverse drug reactions[27].

Comprehensive Risk Management

A key component of future pharmacovigilance efforts will involve the development of robust Risk Management Plans (RMPs) and Post-Authorization Safety Study (PASS) reports. RMPs will continue to play an essential role in outlining risk management systems throughout a drug's lifecycle, while PASS reports will provide ongoing assessments of drug safety and the effectiveness of risk minimization strategies[26]. As new safety information emerges, these documents will be regularly updated to reflect the most current understanding of a product's risk profile.

Challenges and Opportunities

Despite the promising advancements, pharmacovigilance will face challenges, particularly in harmonizing international regulatory standards and ensuring compliance across diverse markets. However, the continuous evolution of monitoring systems and the integration of advanced analytics present substantial opportunities to enhance patient safety and public health outcomes[22,28]. By leveraging innovative technologies and fostering collaboration among global stakeholders, pharmacovigilance can effectively adapt to emerging challenges and improve the overall safety of medications.

CONCLUSION

Global pharmacovigilance systems have advanced significantly, evolving from basic reporting models to more integrated, technology-driven frameworks. While progress is evident, challenges such as underreporting, regulatory disparities, and limited data sharing remain. To ensure safer and more effective drug surveillance, future efforts must prioritize international collaboration, patient involvement, and the adoption of digital tools. A unified, proactive, and adaptive approach will be essential to meet the demands of modern healthcare and protect public health globally.

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