



A REVIEW ON PHARMACOVIGILANCE

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Abstract

Pharmacovigilance is an essential component of healthcare systems, focusing on the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. This review explores the evolution, current practices, challenges, and future directions of pharmacovigilance. The study highlights the integration of advanced technologies, such as artificial intelligence and real-world data analytics, to enhance drug safety monitoring. Furthermore, the paper underscores the importance of global collaboration in improving pharmacovigilance systems.

KEY WORDS: Pharmacovigilance.

Introduction

Pharmacovigilance (PV) has become a cornerstone of public health initiatives to ensure medication safety. Defined by the World Health Organization (WHO), pharmacovigilance aims to minimize risks associated with pharmaceutical products while maximizing their benefits. As the global pharmaceutical market expands, the need for robust PV systems has intensified. This review provides a comprehensive overview of pharmacovigilance practices and emerging trends, emphasizing their significance in safeguarding patient health.

Historical Perspective

Pharmacovigilance traces its roots to the thalidomide tragedy of the 1960s, which revealed the devastating consequences of inadequate drug safety monitoring. This incident catalyzed the establishment of regulatory frameworks and organizations, such as the WHO Programme for International Drug Monitoring. Since then, PV has evolved significantly, adopting more sophisticated methodologies to address the complexities of modern pharmacology.

Current Practices

Pharmacovigilance encompasses several key activities:

1. **Adverse Drug Reaction (ADR) Reporting:** Spontaneous reporting systems (SRS) remain the backbone of PV activities worldwide.
2. **Signal Detection:** Utilizing statistical methods and data mining techniques to identify new safety signals.
3. **Risk Management Plans (RMPs):** Regulatory authorities require pharmaceutical companies to implement RMPs as part of the drug approval process.



4. **Post-Marketing Surveillance (PMS):** Monitoring drugs in real-world settings to detect rare or long-term ADRs.

Challenges in Pharmacovigilance

Despite advancements, PV faces numerous challenges:

- **Underreporting:** ADRs are often underreported due to lack of awareness or fear of legal repercussions.
- **Data Overload:** The vast amount of data from electronic health records, social media, and other sources can overwhelm PV systems.
- **Global Disparities:** Resource limitations in low- and middle-income countries hinder the implementation of effective PV systems.
- **Regulatory Harmonization:** Divergent regulations across countries complicate global pharmacovigilance efforts.

Emerging Trends

The integration of technology is revolutionizing pharmacovigilance:

1. **Artificial Intelligence (AI):** AI algorithms are being used for signal detection and predictive analytics.
2. **Real-World Evidence (RWE):** Harnessing data from electronic health records, registries, and wearable devices to enhance drug safety monitoring.
3. **Patient-Centered Approaches:** Engaging patients in reporting ADRs through mobile apps and online platforms.
4. **Global Collaboration:** Initiatives like the WHO Global Individual Case Safety Reports (ICSRs) database promote information sharing among member countries.

Future Directions

The future of pharmacovigilance lies in:

- Developing standardized global PV guidelines.
- Expanding training programs for healthcare professionals to improve ADR reporting.
- Leveraging blockchain technology for secure and transparent data sharing.
- Enhancing patient engagement through education and accessible reporting tools.

Conclusion

Pharmacovigilance is indispensable for ensuring drug safety and protecting public health. While significant progress has been made, addressing existing challenges requires a multi-faceted approach involving technology, policy, and education. As pharmacovigilance continues to evolve, its integration with innovative tools and global partnerships will play a crucial role in shaping safer healthcare systems.

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