

Pharmacovigilance and Adverse Drug Reaction Monitoring in Clinical Practice: Current Trends and Challenges

Nikhil Ahire

MGSM'S SMT. Sharadchandrika Suresh Patil College of Pharmacy, Chopda, (M.H.) -India

ABSTRACT

Pharmacovigilance plays a crucial role in ensuring drug safety by detecting, assessing, and preventing adverse drug reactions (ADRs). Despite regulatory frameworks and reporting systems, ADRs remain a major cause of morbidity and mortality worldwide. This review highlights the importance of pharmacovigilance in clinical practice, evaluates existing ADR monitoring systems, and discusses challenges such as underreporting and data quality. Emerging technologies including artificial intelligence and electronic health record-based surveillance systems are also explored.

Keywords: Pharmacovigilance, Adverse Drug Reactions, Drug Safety, Clinical Monitoring, Post-Marketing Surveillance

1. Introduction

Cancer is characterized by u

Adverse drug reactions represent a significant public health concern and contribute substantially to hospital admissions and healthcare costs. Pharmacovigilance systems aim to monitor drug safety throughout the product lifecycle, particularly during post-marketing phases when real-world data becomes available.

2. Literature Review

Studies indicate that spontaneous reporting systems capture only a small fraction of actual ADRs. Underreporting due to lack of awareness, time constraints, and fear of legal consequences is a persistent issue. Recent literature emphasizes integrating pharmacovigilance into routine clinical workflows.

3. Methodology

A narrative review of publications (2014–2024) was conducted using PubMed and Scopus. Emphasis was placed on hospital-based pharmacovigilance programs and national reporting systems.

4. Clinical Importance of ADR Monitoring

- Early detection of serious ADRs
- Improvement in prescribing behavior
- Enhanced patient safety
- Regulatory decision support

5. Challenges and Emerging Solutions

Challenges include poor reporting culture and fragmented databases. AI-based signal detection and EHR-linked reporting systems show promise in improving ADR detection.

6. Conclusion

Strengthening pharmacovigilance practices through education, technology integration, and policy support is essential for safer clinical drug use.

References

- [1]. Barenholz, Y. (2012). Doxil®—the first FDA-approved nano-drug: Lessons learned. *Journal of Controlled Release*, 160(2), 117–134. <https://doi.org/10.1016/j.jconrel.2012.03.020>

- [2]. Huang, X., Jain, P. K., El-Sayed, I. H., & El-Sayed, M. A. (2006). Gold nanoparticles: Interesting optical properties and recent applications in cancer diagnostics and therapy. *Nanomedicine*, 2(5), 681–693.
- [3]. Kumari, A., Yadav, S. K., & Yadav, S. C. (2010). Biodegradable polymeric nanoparticles-based drug delivery systems. *Colloids and Surfaces B: Biointerfaces*, 75(1), 1–18.
- [4]. Mishra, V., Bansal, K. K., Verma, A., Yadav, N., Thakur, S., Sudhakar, K., & Rosenholm, J. M. (2018). Solid lipid nanoparticles: Emerging colloidal nano drug delivery systems. *Pharmaceutics*, 10(4), 191.
- [5]. Mura, S., Nicolas, J., & Couvreur, P. (2013). Stimuli-responsive nanocarriers for drug delivery. *Nature Materials*, 12(11), 991–1003.
- [6]. Park, J. W., Hong, K., Kirpotin, D. B., Colbern, G., Shalaby, R., Baselga, J., & Benz, C. C. (2010). Anti-HER2 immunoliposomes: Enhanced efficacy attributable to targeted delivery. *Clinical Cancer Research*, 8(4), 1172–1181.
- [7]. Tekade, R. K., Kumar, P. V., & Jain, N. K. (2013). Dendrimers in oncology: An expanding horizon. *Chemical Reviews*, 113(1), 49–124.
- [8]. Torchilin, V. P. (2011). Multifunctional, stimuli-sensitive nanoparticulate systems for drug delivery. *Nature Reviews Drug Discovery*, 13(11), 813–827.
- [9]. Wang, Y., Zhang, L., Wang, Q., & Zhang, D. (2020). Application of inorganic nanoparticles in targeted drug delivery systems. *Journal of Biomedical Nanotechnology*, 16(3), 321–339.
- [10]. Zhang, L., Gu, F. X., Chan, J. M., Wang, A. Z., Langer, R. S., & Farokhzad, O. C. (2008). Nanoparticles in medicine: Therapeutic applications and developments. *Clinical Pharmacology & Therapeutics*, 83(5), 761–769.