



# Ethical Challenges and Dilemmas in Pharmacovigilance: A Commentary on Principles and Practices

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## ABOUT THE STUDY

Pharmacovigilance plays a vital role in ensuring the safety and efficacy of medications. As the field continues to evolve, it faces various ethical challenges and dilemmas. This commentary aims to shed light on the ethical principles and practices that guide pharmacovigilance and explore the complexities inherent in this critical discipline.

### Ethical principles in pharmacovigilance

Pharmacovigilance is built on a foundation of ethical principles, primarily aimed at safeguarding the well-being of patients and promoting public health. The first and foremost principle is patient autonomy, which upholds the right of individuals to make informed decisions about their healthcare. In pharmacovigilance, this translates to ensuring that patients have access to accurate and comprehensible information regarding the potential risks and benefits of medications.

Another crucial ethical principle is beneficence, which emphasizes the duty of healthcare professionals to act in the best interests of their patients. In pharmacovigilance, this involves proactively monitoring and assessing the safety profile of drugs, promptly reporting adverse events, and taking appropriate actions to minimize harm. The principle of non-maleficence, closely related to beneficence, underscores the obligation to do no harm, both at the individual and population level.

### Ethical challenges and dilemmas

Despite the clear ethical principles guiding pharmacovigilance, several challenges and dilemmas arise due to a variety of factors. One major challenge is the balance between ensuring patient safety and maintaining public trust in the pharmaceutical industry. Transparency in reporting adverse events and potential risks is essential, but there may be conflicts of interest when drug manufacturers are involved in data collection and analysis. Striking the right balance between transparency and maintaining

public trust requires careful navigation of these complex relationships.

Another ethical challenge is the need for comprehensive and timely reporting. Pharmacovigilance heavily relies on healthcare professionals, patients, and regulatory bodies to report adverse events. However, underreporting is a prevalent issue, often due to lack of awareness, fear of litigation, or insufficient systems for reporting. The underreporting of adverse events hampers the ability to identify and mitigate potential risks, compromising patient safety.

Furthermore, the ethical implications of post-marketing surveillance should be acknowledged. Clinical trials, while crucial for initial drug approval, may not fully capture all possible adverse effects. Hence, pharmacovigilance after a drug's release is essential to detect and address previously unrecognized risks. Balancing the need for rigorous pre-marketing testing with post-marketing surveillance presents an ongoing ethical dilemma.

The advent of big data and real-world evidence poses both opportunities and challenges in pharmacovigilance. On one hand, access to vast amounts of data can enhance the identification of safety signals and provide a more comprehensive understanding of drug risks. However, ensuring the privacy and confidentiality of patient data, while still utilizing its potential, requires robust ethical frameworks and appropriate safeguards.

### Ethical practices in pharmacovigilance

To address these challenges and dilemmas, several ethical practices should be implemented in pharmacovigilance. First, raising awareness among healthcare professionals and the general public about the importance of reporting adverse events is significant. Improved education and training programs can empower healthcare providers to recognize and report adverse events promptly.

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Additionally a culture of transparency and accountability is preeminent. Collaboration between regulators, pharmaceutical companies, healthcare professionals, and patients should be based on shared goals and values. Open communication channels, including whistleblower protections, can encourage the reporting of potential risks without fear of reprisal.

Moreover, the integration of pharmacovigilance into the drug development process is vital. Implementing a robust risk management plan from the earliest stages of drug development can facilitate the proactive identification and mitigation of potential risks. This includes conducting thorough pre-market clinical trials, implementing comprehensive post-marketing surveillance strategies, and actively monitoring the safety profile of drugs throughout their lifecycle.

Furthermore, ethical considerations should extend beyond the realm of pharmacovigilance itself. Regulatory bodies play a

critical role in overseeing drug safety, and they must ensure that ethical standards are upheld in the approval and monitoring processes. Policies and guidelines should be regularly reviewed and updated to reflect emerging ethical challenges and to align with evolving societal expectations.

Pharmacovigilance faces various ethical challenges and dilemmas that require careful consideration and proactive solutions. Upholding the principles of patient autonomy, beneficence, and non-maleficence is essential in ensuring the safety and well-being of patients. By addressing the ethical challenges through comprehensive reporting, transparent practices, proactive risk management, and collaboration among stakeholders, pharmacovigilance can continue to evolve as a critical pillar of patient safety and public health. Only through a commitment to ethical principles and practices can we navigate the complexities of pharmacovigilance and ensure the continued trust and confidence of patients and society as a whole.