



Review paper

Role Of Pharmacovigilance in Oncology: Ensuring the Safety of Chemotherapy and Targeted Drugs.

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ABSTRACT

Pharmacovigilance is a critical component of modern healthcare, playing a pivotal role in detecting, assessing, understanding, and preventing adverse drug reactions (ADRs). In oncology, its importance is heightened due to the complex and often toxic nature of anticancer therapies. Conventional chemotherapeutic agents, while effective, are non-selective and can damage healthy cells, causing systemic toxicities such as myelosuppression, cardiotoxicity, nephrotoxicity, and gastrointestinal disturbances. Targeted therapies, designed to act on specific molecular pathways, offer improved efficacy and reduced off-target effects but present unique safety challenges, including dermatologic, hepatic, cardiovascular, and hematologic toxicities. Effective pharmacovigilance systems facilitate early detection of ADRs, support regulatory decision-making, guide clinical practice, and enhance patient safety. This review provides an overview of pharmacovigilance in oncology, focusing on the safety monitoring of chemotherapy and targeted drugs, regulatory frameworks, reporting mechanisms, challenges in ADR detection, and future directions, including integration of digital tools, pharmacogenomics, and real-world data to optimize drug safety. Proactive pharmacovigilance is essential to ensure safe and effective cancer therapy, improving clinical outcomes and patient quality of life.

INTRODUCTION

Cancer remains a leading cause of morbidity and mortality worldwide, accounting for millions of deaths annually (Bray et al., 2018). Advances in oncology have led to the development of highly effective anticancer therapies, including

conventional chemotherapeutic agents and novel targeted drugs. While these therapies have significantly improved survival rates and quality of life, they are associated with a wide spectrum of adverse drug reactions (ADRs), ranging from mild, transient effects to severe, life-threatening complications (DeVita et al., 2021). The narrow

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therapeutic index, polypharmacy in cancer patients, comorbidities, and interindividual variability in drug response further complicate the safety profile of anticancer treatments. Pharmacovigilance, defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or other drug-related problems, has emerged as a critical discipline in oncology (WHO, 2023). Its primary goal is to safeguard patients by identifying, analysing, and mitigating risks associated with drug therapy. In oncology, pharmacovigilance assumes heightened importance due to the inherent toxicity of anticancer drugs and the increasing complexity of treatment regimens, including combination therapies and long-term maintenance treatments (Bate & Lindquist, 2017). Chemotherapy, the mainstay of cancer treatment for decades, is characterized by non-selective cytotoxicity, targeting rapidly dividing cells. While effective against malignant cells, it also affects normal proliferating cells, such as those in the bone marrow, gastrointestinal tract, and hair follicles, leading to a spectrum of toxicities. Common ADRs include myelosuppression, nausea, vomiting, mucositis, cardiotoxicity, nephrotoxicity, and hepatotoxicity (Rang et al., 2020). The severity and occurrence of these ADRs depend on the type of chemotherapeutic agent, dosage, administration schedule, patient age, comorbidities, and genetic predispositions. Monitoring and managing these toxicities require meticulous observation, timely reporting, and proactive intervention, all of which are facilitated by robust pharmacovigilance systems. The advent of targeted therapies has revolutionized oncology by specifically inhibiting molecular pathways implicated in tumour growth and progression. Agents such as tyrosine kinase inhibitors (TKIs) and monoclonal antibodies aim to maximize

efficacy while minimizing systemic toxicity. However, they are not devoid of adverse effects; off-target toxicities, delayed adverse events, and rare but severe reactions may not be apparent during pre-marketing clinical trials. Common ADRs include skin rash, hypertension, hepatotoxicity, cardiotoxicity, and hematologic abnormalities (Dienstmann et al., 2020). Pharmacovigilance is vital for detecting these events, understanding their mechanisms, and implementing strategies to mitigate risk. Regulatory authorities worldwide have established frameworks to ensure ongoing safety monitoring of anticancer drugs. Key examples include the International Council for Harmonisation (ICH) E2E guidelines, the WHO Programme for International Drug Monitoring, and national programs such as India's Pharmacovigilance Programme (PvPI) (FDA, 2022; EMA, 2022). These systems rely on both spontaneous reporting and active surveillance to collect safety data, identify signals of new ADRs, and support regulatory actions, including label changes, warnings, or drug withdrawal. Despite these frameworks, under-reporting, variability in data quality, and delayed detection remain significant challenges in oncology pharmacovigilance. Integration of new technologies, such as electronic health records, mobile reporting applications, artificial intelligence (AI)-based signal detection, and pharmacogenomic profiling, is poised to enhance pharmacovigilance in oncology. Real-world data and post-marketing surveillance studies provide insights into long-term safety profiles and population-specific risks that may not be captured in clinical trials. Such proactive approaches are essential to ensure that the benefits of chemotherapy and targeted therapies outweigh their risks (Pirmohamed, 2018). In conclusion, pharmacovigilance in oncology is indispensable for optimizing the safety and efficacy of cancer treatment. By systematically monitoring ADRs,



implementing regulatory measures, and adopting innovative surveillance strategies, healthcare professionals can improve patient outcomes, reduce morbidity, and enhance quality of life. This review focuses on the role of pharmacovigilance in monitoring the safety of chemotherapy and targeted drugs, highlighting current practices, challenges, and future directions in this rapidly evolving field.

2. Principles and Objectives of Pharmacovigilance in Oncology

Pharmacovigilance involves systematic processes designed to detect, assess, understand, and prevent adverse effects associated with drug therapy. In oncology, where anticancer drugs often carry high toxicity risks, these processes are especially critical (WHO, 2023). The overarching goals of pharmacovigilance in this context are to ensure patient safety, optimize therapeutic efficacy, support regulatory compliance, and guide evidence-based clinical decision-making (Bate & Lindquist, 2017).

2.1 Core Principles

The core principles of pharmacovigilance in oncology include:

- **Early Detection of Adverse Drug Reactions (ADRs):** Prompt identification of both common and rare toxicities is crucial to minimizing patient harm (Rang et al., 2020).
- **Assessment and Analysis:** ADRs are evaluated for severity, causality, and preventability using standardized tools such as the WHO-UMC causality assessment or Naranjo algorithm (Naranjo et al., 1981; WHO, 2000).
- **Risk Management:** Strategies such as dose modification, premedication, supportive therapies, and treatment schedule adjustments

are implemented to reduce ADR risk (Pirmohamed, 2018).

- **Communication:** Timely dissemination of safety information to healthcare professionals, regulatory authorities, and patients ensures informed treatment decisions (FDA, 2022).
- **Continuous Monitoring:** Pharmacovigilance extends beyond clinical trials into post-marketing surveillance, as real-world usage often uncovers previously unrecognized ADRs (Dienstmann et al., 2020).

2.2 Objectives in Oncology

The objectives of pharmacovigilance in oncology are multifaceted:

Patient Safety: Preventing morbidity and mortality associated with ADRs from chemotherapy and targeted therapies.

Optimized Therapy: Balancing therapeutic efficacy with potential toxicities to maximize patient benefit while minimizing harm (DeVita et al., 2021).

Regulatory Compliance: Adhering to international and national guidelines, including ICH E2E guidelines, WHO recommendations, and country-specific programs such as India's Pharmacovigilance Programme (PvPI) (EMA, 2022; PvPI, 2023).

Knowledge Generation: Enhancing scientific understanding of drug safety, including identification of novel ADRs, risk factors, and long-term effects (Pirmohamed, 2018).

Improvement of Clinical Practice: Informing oncologists, nurses, and pharmacists to refine monitoring protocols, supportive care strategies, and patient counselling (Bate & Lindquist, 2017).

3. Safety Concerns Related to Chemotherapy

Chemotherapy remains a cornerstone of cancer treatment, targeting rapidly dividing malignant



cells. However, its non-selective mechanism also affects normal proliferative cells, leading to a wide spectrum of adverse drug reactions (DeVita et al., 2021). These ADRs can be classified based on organ systems, severity, and type of chemotherapeutic agent. Common toxicities include hematologic effects such as myelosuppression, gastrointestinal effects like nausea, vomiting, and mucositis, cardiotoxicity, nephrotoxicity, hepatotoxicity, and alopecia (Rang et al., 2020). The severity and incidence of these ADRs are influenced by drug type, dose, administration schedule, patient age, comorbidities, and genetic predispositions, underscoring the need for vigilant pharmacovigilance in clinical practice.

3.1 Common Chemotherapeutic Agents and Associated ADRs

Chemotherapeutic agents are associated with diverse toxicities depending on their class and mechanism of action (DeVita et al., 2021; Rang et al., 2020).

- Anthracyclines (e.g., Doxorubicin, Epirubicin):
- Cardiotoxicity: Dose-dependent cardiomyopathy and heart failure.
- Myelosuppression: Neutropenia, thrombocytopenia, anaemia.
- Gastrointestinal toxicity: Nausea, vomiting, mucositis.
- Alkylating Agents (e.g., Cyclophosphamide, Cisplatin):
- Nephrotoxicity: Cisplatin-induced renal impairment.
- Haemorrhagic cystitis: Cyclophosphamide-mediated bladder toxicity.
- Neurotoxicity: Peripheral neuropathy (cisplatin).
- Antimetabolites (e.g., Methotrexate, 5-Fluorouracil):

- Myelosuppression: Bone marrow suppression leading to infection risk.
- Mucositis: Oral and gastrointestinal inflammation.
- Hepatotoxicity: Elevation of liver enzymes with chronic therapy.
- Plant Alkaloids (e.g., Paclitaxel, Vincristine):
- Peripheral neuropathy: Dose-limiting neurotoxicity.
- Myelosuppression: Neutropenia and thrombocytopenia.
- Hypersensitivity reactions: Particularly with paclitaxel formulations containing Cremophor EL.

3.2 Mechanisms of Chemotherapy Toxicity

Chemotherapy-related toxicities arise through multiple mechanisms (Pirmohamed, 2018; Rang et al., 2020):

DNA Damage: Direct cytotoxic effects on DNA induce apoptosis in both malignant and normal cells.

Oxidative Stress: Generation of reactive oxygen species contributes to organ damage, including cardiotoxicity.

Disruption of Cell Signalling: Non-specific interference with cellular pathways affects multiple organ systems, leading to systemic toxicities.

3.3 Role of Pharmacovigilance in Chemotherapy Safety

Pharmacovigilance is critical in monitoring and mitigating chemotherapy-induced ADRs (Bate & Lindquist, 2017):

Monitoring ADRs: Recording incidences of myelosuppression, mucositis, organ toxicity, and hypersensitivity reactions.

Dose Adjustments: Using real-time safety data to modify dosing schedules to reduce toxicity.



Supportive Care: Implementing interventions such as antiemetics, growth factors, or hydration to prevent or manage ADRs.

Regulatory Reporting: Submitting ADR reports to national and international databases to detect safety signals and trends.

3.4 Case Examples

Doxorubicin-induced cardiotoxicity: Long-term monitoring with echo cardiography and biomarkers prevents irreversible heart damage.

Cisplatin nephrotoxicity: Hydration protocols and renal function monitoring mitigate risk.

Cyclophosphamide-induced haemorrhagic cystitis: Prophylactic use reduces bladder toxicity.

4. Pharmacovigilance for Targeted Drugs

Targeted therapies have transformed oncology by selectively interfering with molecular pathways implicated in cancer growth and progression (Dienstmann et al., 2020). Unlike conventional chemotherapy, which affects all rapidly dividing cells, targeted drugs aim at specific oncogenic drivers, offering improved efficacy and often reduced systemic toxicity. However, these agents present unique safety challenges, including delayed adverse effects, off-target toxicities, and rare but severe reactions that may not appear during pre-marketing trials. Pharmacovigilance for targeted therapies involves proactive monitoring to detect these ADRs, understand their mechanisms, and implement strategies to mitigate risk. This includes post-marketing surveillance, real-world evidence collection, and integration of digital reporting systems to rapidly identify safety signals (Pirmohamed, 2018; FDA, 2022). Common ADRs associated with targeted therapies include dermatologic reactions, hepatotoxicity, cardiovascular events, and hematologic abnormalities, all of which necessitate dedicated vigilance and risk management strategies.

4.1 Overview of Targeted Therapies

Targeted therapies have transformed oncology by selectively acting on molecular pathways involved in tumor proliferation, angiogenesis, and metastasis (Dienstmann et al., 2020). These therapies include:

Tyrosine kinase inhibitors (TKIs): Imatinib, Erlotinib, Gefitinib

Monoclonal antibodies: Trastuzumab, Bevacizumab, Rituximab

Proteasome inhibitors: Bortezomib

Signal transduction inhibitors: mTOR inhibitors (Everolimus, Temsirolimus)

These drugs target pathways such as EGFR, VEGF, HER2, BCR-ABL, and PI3K/Akt/mTOR, which are critical in tumour progression and survival (Pirmohamed, 2018).

4.2 Common Adverse Drug Reactions

Although targeted therapies are more selective than conventional chemotherapy, they can cause organ-specific or off-target ADRs, sometimes emerging after prolonged use (Rang et al., 2020).

- Dermatologic Toxicities: Rash, hand-foot syndrome, alopecia (common with EGFR inhibitors like Erlotinib and Gefitinib).
- Cardiotoxicity: Trastuzumab-induced heart failure and left ventricular dysfunction; QT prolongation with some TKIs.
- Hepatotoxicity: Elevation of liver enzymes and hepatitis (observed with Lapatinib and Imatinib).
- Hematologic Abnormalities: Anaemia, neutropenia, thrombocytopenia (seen with proteasome inhibitors and TKIs).
- Hypertension and Thromboembolic Events: Particularly with anti-angiogenic agents like Bevacizumab.



- **Gastrointestinal Toxicities:** Diarrhoea, nausea, mucositis, which can lead to dehydration and electrolyte imbalance.

4.3 Role of Pharmacovigilance in Targeted Therapy

Pharmacovigilance ensures early detection, assessment, and mitigation of ADRs from targeted therapies (Bate & Lindquist, 2017):

Signal Detection: Monitoring post-marketing reports for rare or delayed toxicities.

Risk Assessment: Understanding dose-response relationships and patient-specific risk factors.

Regulatory Action: Updating drug labels, issuing warnings, or recommending dosage modifications.

Clinical Guidance: Informing oncologists on monitoring schedules, supportive care, and preventive strategies.

4.4 Examples of Safety Monitoring

Imatinib: Post-marketing surveillance revealed hepatotoxicity and edema, prompting specific monitoring recommendations.

Trastuzumab: Detection of cardiotoxicity led to guidelines for baseline and periodic echocardiography.

Bevacizumab: Gastrointestinal perforation risk prompted label warnings and patient selection criteria.

5. Comparative Analysis: Chemotherapy vs. Targeted Drugs

While both chemotherapy and targeted drugs are integral to cancer treatment, their safety profiles, monitoring requirements, and ADR patterns differ significantly (DeVita et al., 2021; Dienstmann et al., 2020).

Feature Chemotherapy Targeted Drugs

Mechanism: - Non-specific cytotoxicity, Specific molecular targeting

Common ADRs: - Myelosuppression, mucositis, nephrotoxicity, cardiotoxicity, Skin rash, hepatotoxicity, cardiotoxicity, hypertension

Onset of ADRs: - Often acute and dose-dependent
Can be delayed; may appear weeks/months later

Monitoring: - Frequent CBC, liver/kidney function, cardiac monitoring, Organ-specific monitoring: ECG, echocardiography, liver enzymes

Personalization Limited High; guided by biomarkers and genetic profiling

Post-marketing Surveillance: - Essential for rare toxicities, Crucial for delayed or off-target ADRs

5.1 Implications for Pharmacovigilance

Chemotherapy: ADRs are often predictable, dose-related, and require immediate interventions such as antiemetics or growth factors.

Targeted Therapy: ADRs may be idiosyncratic, organ-specific, and necessitate long-term surveillance.

Pharmacovigilance systems must be flexible, integrating both acute and delayed safety data to inform clinical practice.

5.2 Patient-Centric Monitoring

- Active patient reporting enhances ADR detection.
- Electronic health records and mobile applications enable real-time monitoring.
- Pharmacogenomic profiling identifies patients at higher risk for specific ADRs, supporting safer therapy selection (Pirmohamed, 2018).

6. Role of Pharmacovigilance Centres and Reporting Systems

Pharmacovigilance in oncology relies on structured reporting systems and dedicated centres to monitor, analyse, and respond to ADRs (WHO,

2023). These systems form the backbone for early detection of safety signals, risk management, and regulatory decision-making. Key functions include:

- Collection of spontaneous and active ADR reports.
- Signal detection and causality assessment.
- Risk communication to healthcare providers and patients.
- Recommendations for label updates, treatment modifications, or drug withdrawal when necessary.

International, regional, and national pharmacovigilance programs, including the WHO Programme for International Drug Monitoring, FDA's FAERS, EMA's EudraVigilance, and India's PvPI, play crucial roles in ensuring oncology drug safety (FDA, 2022; EMA, 2022; PvPI, 2023).

6.1 National and International Pharmacovigilance Programs

Pharmacovigilance in oncology relies on national and international frameworks to ensure systematic monitoring of ADRs:

WHO Programme for International Drug Monitoring (PIDM): Coordinates global ADR reporting via the Uppsala Monitoring Centre (UMC) and provides tools for causality assessment, signal detection, and data sharing among member countries (WHO, 2023).

Pharmacovigilance Programme of India (PvPI): Collects ADR reports from healthcare professionals across India, maintains the Indian Pharmacopoeia Commission database, and integrates with global safety monitoring systems (PvPI, 2023).

FDA (USA) and EMA (Europe): Mandate post-marketing surveillance for all anticancer drugs, maintaining databases such as FAERS (FDA Adverse Event Reporting System) and EudraVigilance for signal detection (FDA, 2022; EMA, 2022).

6.2 Reporting Mechanisms

- Spontaneous Reporting: Voluntary submission of ADRs by physicians, nurses, and pharmacists; useful for rare or delayed reactions but prone to under-reporting due to awareness or time constraints.
- Active Surveillance: Includes cohort event monitoring, registry studies, and post-marketing clinical trials, enabling systematic safety data collection.
- Electronic Reporting Systems: Web-based platforms, mobile applications, and integrated hospital systems facilitate real-time ADR submission, trend analysis, and rapid signal detection (Bate & Lindquist, 2017).

6.3 Strategies to Improve Safety Reporting

Healthcare Professional Training: Workshops and educational programs raise awareness about ADR reporting.

Integration in Clinical Workflow: Embedding ADR reporting in electronic medical records streamlines documentation.

Patient Engagement: Encouraging patient self-reporting enhances detection of subjective ADRs such as fatigue, rash, or neuropathy.

Regulatory Collaboration: Coordination between pharmaceutical companies, hospitals, and regulatory authorities ensures timely action.

Feedback Mechanisms: Providing feedback to reporters improves participation and data quality.

6.4 Challenges in Oncology Pharmacovigilance

Complexity of chemotherapy and targeted therapy regimens.



Concomitant medications and comorbid conditions complicating ADR attribution.

Late-onset or cumulative toxicities appearing after long-term therapy.

Limited awareness and engagement among oncology professionals (Pirmohamed, 2018).

7. Case Studies and Success Stories

Pharmacovigilance has significantly enhanced the safety of anticancer drugs through real-world ADR detection and risk mitigation.

7.1 Trastuzumab (Herceptin)

Issue: Post-marketing cardiotoxicity.

Action: Baseline and periodic echocardiography, dose adjustments, and monitoring protocols were implemented.

Impact: Reduced incidence of severe cardiac events while maintaining therapeutic efficacy (Dienstmann et al., 2020).

7.2 Bevacizumab (Avastin)

Issue: Gastrointestinal perforation and severe hypertension.

Action: Label updates and patient selection guidelines were introduced.

Impact: Improved patient safety and risk awareness.

7.3 Imatinib (Gleevec)

Issue: Hepatotoxicity and edema during long-term use.

Action: Liver function monitoring and dosing recommendations were established.

Impact: Early detection of ADRs and prevention of severe complications.

These examples demonstrate the practical value of pharmacovigilance in mitigating risks associated with chemotherapy and targeted therapy.

8. Future Aspects of Pharmacovigilance in Oncology

The landscape of oncology pharmacovigilance is rapidly evolving, driven by technological advancements, precision medicine, and real-world data collection. Future strategies aim to enhance early ADR detection, improve patient safety, and optimize therapeutic outcomes (Pirmohamed, 2018; WHO, 2023).

8.1 Big Data and Artificial Intelligence (AI)

Big Data Analytics: Aggregates patient data from electronic health records, registries, and insurance claims to identify ADR patterns.

AI and Machine Learning: Predicts potential toxicities, identifies at-risk populations, and prioritizes safety signals.

Benefit: Enables rapid signal detection and timely regulatory interventions (Rang et al., 2020).

8.2 Pharmacogenomics and Personalized Medicine

Genetic variations influence drug metabolism, efficacy, and toxicity.

Incorporating pharmacogenomic data allows personalized dosing and risk stratification for chemotherapy and targeted drugs.

Example: TPMT genotyping before thiopurine therapy reduces myelosuppression risk (Pirmohamed, 2018).

8.3 Real-World Evidence (RWE) and Registries

Observational studies, patient registries, and post-marketing surveillance provide insights into long-term safety.

RWE captures diverse populations often excluded from clinical trials, identifying rare, delayed, or cumulative toxicities.

8.4 Patient-Centric Pharmacovigilance

Empowering patients to report ADRs via apps, portals, or structured questionnaires improves data quality.

Patient-reported outcomes (PROs) provide real-time insights into symptomatic toxicities, quality-of-life impacts, and adherence issues.

8.5 Collaborative and Global Approaches

International collaboration among regulatory authorities, hospitals, and pharmaceutical companies strengthens pharmacovigilance networks.

Harmonization of reporting standards and real-time data sharing accelerates identification of safety signals.

Emerging initiatives focus on predictive pharmacovigilance, integrating clinical, genomic, and epidemiologic data (Bate & Lindquist, 2017).

CONCLUSION

Pharmacovigilance in oncology is a vital discipline that ensures the safe and effective administration of both chemotherapy and targeted therapies (Bate & Lindquist, 2017; Pirmohamed, 2018). While these agents are indispensable in cancer treatment, they present distinct safety challenges. Chemotherapy is frequently associated with predictable, dose-dependent toxicities affecting multiple organ systems, whereas targeted therapies can produce unique, sometimes delayed, and organ-specific adverse drug reactions (ADRs) that require ongoing vigilance (DeVita et al., 2021; Dienstmann et al., 2020). The effectiveness of pharmacovigilance depends on robust reporting systems, active surveillance, well-established regulatory frameworks, and collaboration among healthcare professionals, patients, and regulatory authorities (WHO, 2023; FDA, 2022). The integration of emerging technologies—including artificial intelligence, big data analytics, and pharmacogenomics—enables proactive,

personalized, and real-time monitoring of ADRs, enhancing the detection and management of both common and rare toxicities (Rang et al., 2020; Pirmohamed, 2018). Ultimately, pharmacovigilance improves patient outcomes, reduces treatment-related morbidity, and contributes to the advancement of oncology practice. By systematically detecting, evaluating, and mitigating ADRs, healthcare providers can maintain the delicate balance between maximizing therapeutic efficacy and ensuring patient safety, reinforcing the overarching goal of delivering effective, safe, and patient-centred cancer care.

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