



ASSESSMENT OF THE INCIDENCE, PATTERN, AND SEVERITY OF CHEMOTHERAPY-INDUCED ADVERSE DRUG REACTIONS IN CANCER PATIENTS

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DOI: <https://doi.org/10.5281/zenodo.23278850>



How to cite this Article: Kshitij Kapoor, Umesh Chandra Gupta, Abhi Prajapati, Ajeet Singh*, Dr. Manju Pandey. (2026). Assessment of the Incidence, Pattern, and Severity of Chemotherapy-Induced Adverse Drug Reactions in Cancer Patients. European Journal of Biomedical and Pharmaceutical Sciences, 13(10), 422–426.
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Article Received on 15/09/2026

Article Revised on 05/10/2026

Article Published on 10/10/2026

ABSTRACT

Chemotherapy is a major component of cancer treatment but is frequently associated with adverse drug reactions (ADRs) that negatively affect patient well-being, treatment adherence, and clinical outcomes. Nausea and vomiting are among the most common chemotherapy-induced adverse effects, particularly with highly emetogenic chemotherapy. Evidence summarized in this review indicates that ADRs commonly involve the hematological, gastrointestinal and nervous systems, with neutropenia, anemia, mucositis, nausea/vomiting and peripheral neuropathy among the major toxicities. A comparative study involving 162 women with ovarian cancer receiving cisplatin-based chemotherapy demonstrated that the duration of nausea was an important determinant of well-being, independent of nausea intensity. Chemotherapy ADRs may be predictable and dose-dependent or idiosyncratic and immune-mediated. Important risk factors include patient characteristics, comorbidities, treatment intensity, combination therapy and pharmacogenetic variation, including DPYD and UGT1A1 variants. Assessment incorporates clinical and laboratory monitoring, causality tools such as Naranjo and WHO-UMC, and severity grading using CTCAE. Management includes antiemetic prophylaxis, growth-factor support, hydration, dose modification and pharmacogenomic-guided interventions. Systematic pharmacovigilance and proactive toxicity monitoring are essential for reducing chemotherapy-related morbidity and improving patient safety.

KEYWORDS: chemotherapy; adverse drug reactions; pharmacovigilance; chemotherapy-induced nausea and vomiting; neutropenia; toxicity; CTCAE; pharmacogenomics.

1. INTRODUCTION

Chemotherapy aims to cure or control cancer, but cytotoxic and many targeted agents can produce unintended harmful effects at therapeutic doses. ADRs are important causes of morbidity and may require dose reduction, treatment delay or discontinuation. Reported burdens vary according to cancer type, treatment regimen, patient population and healthcare setting. The source material reports ADR frequencies of approximately 40% in some pediatric cohorts and more than 60% in adult cohorts. The most frequently affected systems are hematological, gastrointestinal and neurological. These toxicities can impair quality of life and increase healthcare utilization. This review synthesizes evidence on the epidemiology, classification, mechanisms, risk factors, detection, severity assessment, prevention, management and pharmacovigilance of chemotherapy-induced ADRs.^[4,21,24]

2. METHODOLOGY

A broad literature search was described using PubMed, Scopus and other relevant databases. Search concepts included chemotherapy, adverse drug reaction, toxicity, incidence and related terms. Priority was given to systematic reviews, meta-analyses, clinical trials, observational studies and clinical practice guidelines. Evidence available up to mid-2025 was considered in the source material. Extracted variables included study design, population, chemotherapy agents, reported ADRs, incidence, assessment methods and evidence level. Pharmacovigilance and pharmacogenomic evidence were also considered. ADR classification systems, CTCAE severity grading, Naranjo and WHO-UMC causality assessment, and preventive and management strategies were synthesized thematically. Because the supplied material describes a broad literature review rather than a formally registered systematic

review, no pooled meta-analysis was independently performed for this manuscript.^[1,2,3,4,5,8,9,10]

3. RESULTS AND DISCUSSION

3.1 EPIDEMIOLOGY

Chemotherapy-related ADRs are frequent, although incidence varies substantially by population and regimen. The supplied evidence reports 41.5% ADR occurrence in a pediatric Ethiopian cohort and 63.6% in an adult Ethiopian cohort, while an African pediatric systematic review reported a pooled prevalence of approximately 62.0%. Intensive multi-agent regimens may increase toxicity, particularly hematological and gastrointestinal toxicity.^[1,2,3,5,8,10]

3.2 Classification

ADRs can be classified mechanistically as Type A (augmented), which are generally predictable and dose-dependent, and Type B (bizarre), which are less predictable and may be immune-mediated. Organ-system classification provides additional clinical utility and includes hematological, gastrointestinal, neurological, cardiovascular, renal, hepatic, dermatological and immunological toxicities.^[1,2,3,5,8,10]

3.3 Major Toxicities

Neutropenia is a major dose-limiting toxicity and can predispose patients to infection and febrile neutropenia. Chemotherapy-induced nausea and vomiting are particularly important with highly emetogenic regimens such as cisplatin. Mucositis and diarrhea may become dose-limiting with selected antimetabolites. Peripheral neuropathy is associated with platinum agents, taxanes and vinca alkaloids. Anthracyclines and trastuzumab may produce cardiotoxicity, while cisplatin is associated with nephrotoxicity. Hypersensitivity and infusion reactions occur with selected taxanes, platinum compounds and monoclonal antibodies. Alopecia and fatigue also contribute substantially to treatment burden.^[5,20,22,23]

3.4 Risk Factors and Mechanisms

Risk is influenced by age, sex, nutritional status, performance status, comorbidities, renal and hepatic function, previous treatment, dose intensity and combination therapy. Pharmacogenetic variation is clinically relevant for selected agents. DPYD variation can increase fluoropyrimidine toxicity, whereas UGT1A1 variation is associated with irinotecan toxicity. Mechanistically, chemotherapy may damage rapidly dividing normal tissues, suppress bone marrow, injure gastrointestinal mucosa, induce neuronal injury, generate oxidative and inflammatory damage, or trigger immune-mediated reactions.^[9]

3.5 Assessment and Pharmacovigilance

Detection requires clinical assessment and laboratory monitoring, including CBC, liver function and renal function testing where appropriate. Patient-reported symptoms are important for nausea, mucositis, neuropathy and other toxicities. Suspected ADRs can be evaluated using Naranjo or WHO-UMC causality criteria. Severity is commonly graded using CTCAE. Documentation and reporting to pharmacovigilance systems support signal detection and improve medication safety. Proactive monitoring, including structured telephone follow-up and electronic reporting, may improve detection of clinically important toxicity.^[8,12,13,14]

3.6 Prevention and Management

Prevention is based on chemotherapy-specific risk assessment and supportive-care protocols. Antiemetic prophylaxis is selected according to emetogenic risk. G-CSF is used for appropriate patients at elevated febrile-neutropenia risk. Hydration and electrolyte monitoring are important with cisplatin. Dose modification or treatment delay may be necessary for clinically significant toxicity. Pharmacogenomic testing, particularly DPYD-guided fluoropyrimidine therapy where recommended, represents a preventive approach to selected severe ADRs.^[5,20,22,23]

Table 1: Classification of Chemotherapy-Induced ADRs.

ADR type	Major examples	Common agents	Principal mechanism	Clinical consequence ^[1,2,3,5,8,10]
Hematological	Neutropenia, anemia, thrombocytopenia	Anthracyclines, platinum agents, taxanes	Bone-marrow suppression	Infection, bleeding, fatigue ^[5,20,22,23]
Gastrointestinal	Nausea, vomiting, diarrhea, mucositis	Cisplatin, 5-FU, irinotecan, methotrexate	Mucosal injury and emetic pathway activation	Dehydration, malnutrition ^[8,12,13,14]
Neurological	Peripheral neuropathy	Oxaliplatin, paclitaxel, vincristine	Neuronal/axonal injury	Pain and sensory impairment ^[19]
Cardiovascular	Cardiomyopathy, heart failure	Doxorubicin, trastuzumab	Myocardial injury	Reduced cardiac function ^[6]
Renal	AKI, electrolyte imbalance	Cisplatin, methotrexate	Tubular injury	Renal dysfunction ^[7]
Hepatic	Transaminase elevation, hepatotoxicity	Methotrexate, L-asparaginase	Hepatocellular injury	Impaired liver function ^[1,5,10]

Dermatological	Alopecia, rash	Taxanes, anthracyclines	Effects on rapidly dividing cells	Cosmetic/psychological burden ^[1,5,10]
Immunological	Hypersensitivity, infusion reactions	Taxanes, platinum agents, monoclonal antibodies	Immune-mediated response	Rash, bronchospasm, anaphylaxis ^[1,5,10]

Table 2: Chemotherapy ADRs According to Onset.

Temporal category	Typical onset	Representative ADRs	Clinical significance ^[1,2,3,5,8,10]
Immediate	Minutes–hours	Hypersensitivity, infusion reactions, vomiting	Potential emergency ^[8,12,13,14]
Acute	Within 24–48 h	Nausea, vomiting	Affects hydration and treatment tolerance ^[8,12,13,14]
Early delayed	2–7 days	Neutropenia, diarrhea, mucositis	Requires active monitoring ^[5,20,22,23]
Delayed	1–3 weeks	Myelosuppression, alopecia, neuropathy	May affect subsequent cycles ^[19]
Cumulative/late	Months–years	Cardiotoxicity, persistent neuropathy	Long-term morbidity ^[19]

Table 3: Selected Key Studies of Chemotherapy-Induced ADRs.

Study	Design/setting	Population	Main finding	Evidence/quality ^[1,5,10]
Workalemahu et al. (2020)	Cross-sectional; Ethiopia	Pediatric cancer patients (n=311)	41.5% overall ADRs; treatment-related factors identified	Moderate; observational ^[1,2,3,5,8,10]
Shrmeka et al. (2025)	Prospective observational; Ethiopia	Adults (n=154)	63.6% overall ADRs; nausea/vomiting and alopecia common	Moderate–high; prospective ^[8,12,13,14]
Kassa et al. (2025)	Systematic review/meta-analysis; Africa	Children; ~1175 across 5 studies	Pooled ADR prevalence 62.0% (95% CI 36.9–87.1)	High; systematic review ^[1,2,3,5,8,10]
Krzyzanowska et al. (2019)	Pilot toxicity-monitoring study; Canada	Breast cancer; n=77	Telephone monitoring associated with reduced ED visits (IRR 0.54)	Pilot evidence ^[1,5,10]
Crawford et al. (2004)	Literature review	Cancer chemotherapy	Highlighted neutropenia as a major cause of morbidity	Review evidence ^[5,20,22,23]

Table 4: Risk Factors and Associated ADRs.

Risk domain	Examples	Potential consequence ^[1,5,10]
Patient-related	Age, nutritional status, comorbidities, performance status	Greater systemic toxicity ^[1,5,10]
Organ function	Renal/hepatic impairment	Drug accumulation and toxicity ^[1,5,10]
Genetic	DPYD, UGT1A1 and other variants	Drug-specific severe toxicity ^[9]
Treatment-related	High dose, intensive or combination therapy	Myelosuppression and GI toxicity ^[1,5,10]
Drug-related	High emetogenicity/nephrotoxicity	Vomiting or renal injury ^[8,12,13,14]
Previous therapy	Prior chemotherapy/radiotherapy	Cumulative toxicity ^[1,2,3,5,8,10]
Supportive care	Inadequate prophylaxis/monitoring	Preventable complications ^[1,5,10]
Drug interactions	Concomitant medicines affecting metabolism	Altered drug exposure ^[1,5,10]

Table 5: ADR Assessment and Pharmacovigilance.

Stage	Method/tool	Purpose	Outcome ^[1,5,10]
Detection	Clinical assessment, laboratory monitoring	Identify suspected ADR	Early recognition ^[1,2,3,5,8,10]
Causality	Naranjo / WHO-UMC	Assess drug–ADR relationship	Causality category ^[16]
Severity	CTCAE	Grade toxicity	Grade 1–5 ^[15]
Preventability	Schumock–Thornton	Identify preventable ADRs	Preventability classification ^[1,2,3,5,8,10]
Documentation	ADR reporting forms	Capture clinical details	Pharmacovigilance record ^[1,2,3,5,8,10]

Intervention	Dose modification/supportive care	Reduce toxicity	Improved tolerance ^[1,5,10]
Follow-up	Clinical reassessment	Determine outcome	Recovery/persistence/progression ^[1,5,10]

Table 6: Prevention and Management of Common Chemotherapy ADRs.

ADR	Monitoring/prevention	Management ^[1,2,3,5,8,10]
Neutropenia/FN	CBC; risk-based G-CSF prophylaxis	Antimicrobials and G-CSF when indicated ^[5,20,22,23]
Nausea/vomiting	Emetogenicity-based antiemetic prophylaxis	5-HT ₃ /NK1 antagonists, dexamethasone ± olanzapine ^[8,12,13,14]
Anemia	Hemoglobin monitoring	Transfusion or selected ESA therapy ^[1,5,10]
Thrombocytopenia	Platelet monitoring	Platelet transfusion when indicated ^[1,5,10]
Diarrhea	Early symptom reporting; hydration assessment	Loperamide, fluids; escalation when severe ^[1,5,10]
Mucositis	Oral assessment and hygiene; selected cryotherapy	Analgesia, oral care, hydration ^[18]
Neuropathy	Baseline and periodic neurological assessment	Dose modification; duloxetine for painful neuropathy ^[19]
Nephrotoxicity	Creatinine/electrolytes; hydration	Hydration, electrolyte correction, dose adjustment ^[1,5,10]
Cardiotoxicity	Baseline/periodic cardiac monitoring	Cardiac evaluation and appropriate cardioprotective therapy ^[6]
Hypersensitivity	Risk assessment and premedication when indicated	Stop/slow infusion and emergency management; desensitization in selected cases ^[1,5,10]

4. Figure 1. Workflow for Assessment of Chemotherapy-Induced ADRs

CHEMOTHERAPY ADMINISTRATION

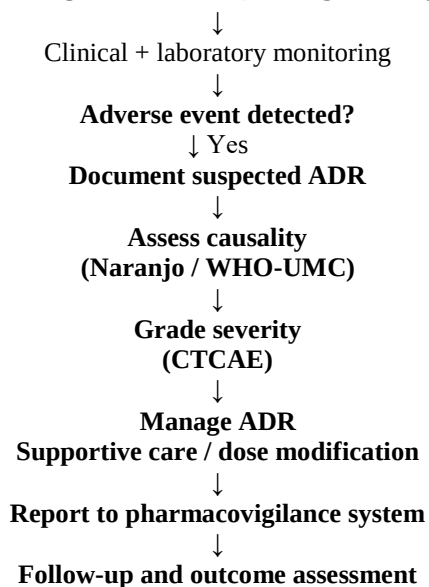


Figure 1: The workflow integrates detection, documentation, causality assessment, CTCAE severity grading, management, pharmacovigilance reporting and follow-up. The supplied source describes decision points such as whether an adverse event is detected.

5. Quality of Life and Clinical Impact

ADRs can compromise daily functioning, treatment adherence and quality of life and may increase hospital utilization and healthcare costs. The comparative

cisplatin study described in the source material found that nausea duration was an important determinant of well-being even after accounting for nausea intensity. This finding emphasizes that symptom duration, not only severity, should be considered when assessing chemotherapy-related burden. Hematological toxicity may lead to infection and hospitalization, while persistent neuropathy, fatigue, alopecia and gastrointestinal symptoms can produce longer-term functional and psychosocial consequences.^[4,21,24]

6. Knowledge Gaps and Future Directions

Important gaps remain in standardized reporting of low-grade toxicities, patient-reported outcomes and long-term effects of newer anticancer therapies. Harmonization of CTCAE, PRO-CTCAE and pharmacovigilance reporting could improve comparability. Further real-world research is needed in resource-limited settings. Pharmacogenomic implementation beyond established gene-drug associations and development of predictive toxicity models may support individualized prevention.^[9]

7. LIMITATIONS

This review is based on the supplied literature synthesis and its cited evidence. The underlying studies differ in population, cancer type, regimen, methodology and reporting standards; therefore, incidence estimates should not be interpreted as directly comparable across all settings. Several sources are observational or single-center studies, limiting generalizability. The review should be updated with verified bibliographic details before journal submission.

8. CONCLUSION

Chemotherapy-induced ADRs remain a major challenge in oncology and encompass hematological, gastrointestinal, neurological, cardiovascular, renal, hepatic, dermatological and immunological toxicities. Effective management requires risk stratification, appropriate prophylaxis, standardized causality and severity assessment, active monitoring and timely intervention. Integration of pharmacovigilance, patient-reported outcomes and evidence-based pharmacogenomic testing can support a more preventive approach to chemotherapy safety and improve patient well-being.^[4,21,24]

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