Preventability of Adverse Drug Reactions to Anticancer Drugs: Insights from the Database of the Regional Drug Information and Pharmacovigilance Center

Thi Thu Thuy Nguyen

thuyntt1@hiu.vn

Hong Bang International University

Quoc Binh Nguyen

Cho Ray Hospital

Thi Kim Uyen Nguyen

Hong Bang International University

Huynh Quoc Thang Do

Health Technology Assessment & Application Research Institute

Research Article

Keywords: adverse drug reaction, anticancer drugs, pharmacovigilance

Posted Date: January 22nd, 2026

DOI: https://doi.org/10.21203/rs.3.rs-8443768/v1

Additional Declarations: No competing interests reported.

Abstract

Background

Adverse drug reactions (ADRs) are common events in cancer therapy and may result in prolonged hospitalization or death. In Vietnam, there is a paucity of studies assessing the severity and preventability of ADRs using data from the regional pharmacovigilance system. This study was therefore carried out to characterize these ADRs, determine their severity, and assess their preventability.

Methods

A retrospective, cross-sectional study of ADR reports related to anticancer drugs submitted to the Ho Chi Minh City Regional Drug Information and Pharmacovigilance Center was conducted between January 1 and December 31, 2023. Causality between suspected drugs and ADRs was assessed using the WHO-UMC causality assessment system; eligible reports were further evaluated for preventability using the WHO P-method.

Results

A total of 291 reports were included in the analysis after excluding reports related to drug quality and those not associated with anticancer drugs. The results showed that female patients (72.9%) experienced ADRs more frequently than male patients (26.1%), with the 18–64 age group accounting for 66.7% of cases. Causality assessment using the WHO scale identified 253 reports (86.9%), corresponding to 433 drug–ADR pairs, as having a causal relationship between the suspected drug and the ADR. These reports were subsequently evaluated for preventability, and 2 reports (0.8%) were determined to be preventable. The most common anticancer drugs causing ADRs were carboplatin (21.2%) and paclitaxel (20.1%). Non-serious ADRs accounted for 70.8%, whereas 18.2% required hospitalization or prolonged hospital stay and 6.3% resulted in death. Two cases (0.8%) were deemed preventable, attributed to a history of drug hypersensitivity (cisplatin) and therapeutic duplication (epirubicin).

Conclusion

Most anticancer drug–related ADRs in this study were non-serious, although a considerable proportion still resulted in hospitalization or death. The identification of preventable ADRs highlights the need for ongoing monitoring and evaluation to inform appropriate preventive strategies and enhance patient safety in cancer treatment.

1. Introduction

Cancer remains one of the leading causes of death worldwide, with incidence and mortality rates rising rapidly, particularly in low- and middle-income countries [1]. Advances in cancer management, including chemotherapy, targeted therapy, and immunotherapy, have substantially improved patient survival. However, these treatment modalities are often associated with a significant risk of adverse drug reactions (ADRs), which may adversely impact therapeutic outcomes. According to the World Health Organization (WHO), an ADR is defined as “any noxious and unintended response to a drug that occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease” [2]. ADRs are common among oncology patients and may lead to hospitalization or prolonged hospital stay [3]. Miranda et al. (2011) reported that approximately one in ten cancer patients presenting to the emergency department experienced an ADR-related event [4]. Similarly, Levan et al. (2018) found that 21% of oncology inpatients experienced ADRs, over 60% of which were considered preventable [5]. These findings underscore the importance of establishing a comprehensive pharmacovigilance system and active surveillance mechanisms to monitor ADRs in cancer treatment. Systematic monitoring of ADR characteristics, frequency, and underlying causes enable healthcare professionals to identify risk factors early, develop preventive strategies, and ultimately improve the safety of cancer therapies.

Vietnam has implemented a national pharmacovigilance system since 2009, comprising Drug Information and Adverse Drug Reaction (DI & ADR) Centers at local and national levels that collect, process, and analyze ADR reports from healthcare facilities nationwide. Nevertheless, no studies have yet assessed the preventability of ADRs associated with cancer treatment using data from regional DI & ADR Centers. Existing studies are largely single-centered and mainly focus on general ADR characterization [6], [7]. This evidence gap hinders the development of effective interventions to reduce preventable ADRs, optimize medication safety, and improve cancer treatment outcomes.

The Ho Chi Minh City Regional DI & ADR Center serves as the primary hub for ADR reporting from tertiary and provincial hospitals across southern Vietnam. Its database therefore reflects real-world patterns of anticancer drug use across multiple levels of care, allowing for a comprehensive assessment of ADR profiles in the region. To date, no studies have evaluated the severity and preventability of ADRs using this database. This study was thus conducted to describe the characteristics, classify the severity, and assess the preventability of ADRs related to anticancer drugs using data from the Ho Chi Minh City Regional DI & ADR Center.

2. Methods

2.1. Design and setting of the study

A cross-sectional descriptive study was conducted from January 1 to December 31, 2023, at the Ho Chi Minh City Regional DI & ADR Center. Data were retrospectively collected from the ADR reports, including all reports related to anticancer drugs submitted to the center's database during this period.

2.2. Study sample

2.2.1. Inclusion criteria and exclusion criteria

The inclusion and exclusion criteria are presented in Table 1.

Table 1. Inclusion criteria and exclusion criteria

Inclusion criteria	Exclusion criteria
- ADR reports from the DI & ADR Center with at least one anticancer drug identified as the suspected drug.	- Reports in which the suspected drug was not an anticancer drug. - Reports related to drug quality issues. - Reports describing reactions following drug provocation or hypersensitivity testing.

2.2.2. Sampling Method

All reports that met the inclusion criteria and did not meet any exclusion criteria were included in the analysis.

2.3. Instruments

2.3.1. Causality Assessment

The WHO-UMC causality assessment system was applied, which is widely used in pharmacovigilance practice for the evaluation of individual case safety reports. This method considers clinical–pharmacological aspects of the case and the quality of the information provided. Based on defined criteria, causality is categorized into six levels: certain, probable/likely, possible, unlikely, unclassified, and unclassifiable [8]. Reports categorized as certain, probable/likely, or possible were considered to have a causal relationship between the suspected drug and ADR. For reports containing multiple drug–ADR pairs with different causality categories, the highest category was assigned.

2.3.2. Severity Assessment

ADR severity was classified according to clinical outcomes. An ADR was considered serious (serious adverse event – SAE) if it resulted in one of the following: death, life-threatening event, persistent or significant disability/incapacity, hospitalization or prolongation of hospitalization, or congenital anomaly/birth defect. All other ADRs were classified as non-serious [9].

2.3.3. Preventability Assessment

Reports with an established causal relationship were further evaluated for preventability using the WHO P-method [10]. Preventability assessment was conducted independently by two trained reviewers using the standardized WHO P-method checklist. Any discrepancies between the two assessments were resolved through discussion to reach consensus; when consensus could not be achieved, a third

reviewer adjudicated the final decision. Results were classified into three categories: preventable, non-preventable, and not assessable. An ADR was deemed preventable when at least one critical criterion was identified. ADRs with no identified criteria were considered non-preventable. Cases with insufficient or missing data were classified as not assessable. Each report could contain more than one ADR [11]. Drug references for assessment were prioritized as follows: Vietnam National Drug Formulary, official package inserts (US/UK/France), Micromedex, and relevant clinical treatment guidelines.

2.4. Study variables

General characteristics of ADR reports included the level of the reporting healthcare facility and the reporter category. Patient-related characteristics included age group, sex, and history of allergy. Drug-related characteristics included the causality assessment between the suspected anticancer drug and ADR, indication for drug use, reported pharmacological class, suspected drug names, severity classification and outcome of the ADR, ADR classification by System Organ Class (SOC) [12], [13], clinical manifestations of ADRs related to anti-cancer drugs.

For preventable ADRs (pADRs), data were collected on the affected organ systems, clinical manifestations, and classification of pADRs according to the underlying cause.

2.5. Statistical Analysis

Data were processed using Microsoft Excel 2010. Continuous variables with normal distribution were presented as mean ± standard deviation; those with non-normal distribution were presented as median (interquartile range). Categorical variables were presented as frequencies and percentages.

2.6. Ethical Approval

All data were used exclusively for research purposes and were anonymized and kept confidential at the DI & ADR Center. The study protocol was approved by the Institutional Review Board of Hong Bang International University (Approval No. 160/PCT-HĐĐĐ-SĐH).

3. Results

A total of 3,307 ADR reports from healthcare facilities were submitted to the Ho Chi Minh City DI & ADR Center between January 1 and December 31, 2023. After excluding reports related to drug quality issues and those in which the suspected drug was not an anticancer drug, 291 reports remained (accounting for 8.8% of all ADR reports in 2023).

The general characteristics of ADR reports

The general characteristics of ADR reports are presented in Table 2.

Table 2. General Characteristics of ADR Reports (n = 291)

Characteristics		Frequency (Percentage) n = 291
Level of Healthcare Facility	Provincial/City Hospitals	180 (61.9)
	Districts Hospitals	0 (0.0)
	Central Hospitals	93 (32.0)
	University Hospitals	18 (6.2)
	Private Hospitals	0 (0.0)
Type of reporter	Doctors	224 (77.0)
	Pharmacists	35 (12.0)
	Other healthcare staff	25 (8.6)
	Unknown	7 (2.4)
Gender	Male	76 (26.1)
	Female	212 (72.9)
	Not reported	3 (1.0)
Age group	< 18 years	14 (4.8)
	18 – 64 years	194 (66.7)
	≥ 65 years	83 (28.5)
History of allergy	Antibiotics	2 (0.7)
	Anticancer drugs	0 (0.0)
	Other drugs	6 (2.1)
	Non-drug allergies	0 (0.0)
	Not reported	283 (97.3)

As shown in Table 2, most ADR reports related to anticancer drugs were submitted from provincial or city hospitals (61.9%), followed by central hospitals (32.0%) and university hospitals (6.2%). Regarding reporter category, the majority of ADR reports were submitted by doctors (77.0%) and pharmacists (12.0%). Female patients accounted for a higher proportion of ADR cases than males, with a male-to-female ratio of 1:2.79. Most ADR reports involved patients aged 18–64 years (66.7%). Information on allergy history was available for only a small proportion of patients, with 2.1% reporting drug allergy (mostly to non-anticancer drugs).

Drug-Related Information causing ADRs

Causality between anticancer drugs and ADRs was evaluated using the WHO-UMC causality assessment system. As each report could involve one or multiple drugs, and each drug could be associated with one or more ADRs, the total number of drug–ADR pairs was determined. Accordingly, the 291 included reports generated a total of 487 drug–ADR pairs. The results are presented in Table 3.

Table 3. Causality Assessment Results for Anticancer Drug–ADR Pairs

Causality category	Drug-ADR pairs (n, %) n = 487	Reports (n, %) n = 291
Certain	14 (2.8)	9 (3.1)
Probable/Likely	199 (40.9)	108 (37.1)
Possible	220 (45.2)	136 (46.7)
Unlikely	48 (9.9)	33 (11.3)
Unclassified	4 (0.8)	4 (1.4)
Unclassifiable	2 (0.4)	1 (0.3)

As shown in Table 3, A total of 487 drug-ADR pairs were evaluated, of which 433 pairs (88.9%) were classified as “Certain”, “Probable/Likely”, or “Possible”, indicating a causal relationship between the suspected drug and the ADR. These pairs were recorded in 253 reports, accounting for 86.9% of the total reports in the study. In contrast, the remaining 54 pairs (11.1%) were classified as “Unlikely”, “Unclassified”, or “Unclassifiable”, meaning the causal relationship between the drug and ADR could not be clearly determined

Following causality assessment using the World Health Organization – Uppsala Monitoring Centre (WHO-UMC) system, 253 reports (86.9%)—comprising 433 drug–ADR pairs—were confirmed to have a causal relationship between the suspected anticancer drug and the ADR. These reports were subsequently evaluated for preventability using the WHO P-method, resulting in the identification of 2 preventable ADR cases (0.8%). The data used to analyze the criteria related to the drug and ADR included all drug–ADR pairs and all ADR reports classified as “Certain,” “Probable/Likely” or “Possible.”

Reports classification by drug indication

The classification of reports by drug indication are presented in Figure 1.

As shown in Figure 1, among 253 ADR reports related to anticancer drugs, the largest proportion belonged to the category “Factors influencing health status and contact with health services” (Z00–Z99) with 49.0%, followed by “Neoplasms” (C00–D48) with 48.6%. Other categories accounted for lower proportions, including “Infectious and parasitic diseases” (A00–B99) (1.2%), “Diseases of the blood and immune system” (D50–D89) (0.8%), and “Diseases of the digestive system” (K00–K93) (0.4%).

Most reported cancer drug classes causing ADRs

The most reported cancer drug classes causing ADRs are presented in Figure 2.

Note: *L01X includes targeted therapies and newer antineoplastic agents not classified under conventional chemotherapy groups.

Figure 2. Most reported cancer drug classes causing ADRs (n=433)

As shown in Figure 2, among 433 anticancer drug-ADR pairs, the largest proportion belonged to the “Other Antineoplastic Agents” class (L01X) (52.2%), followed by “Plant Alkaloids and Other Natural Products” (L01C) (30.3%) and “Cytotoxic Antibiotics” (L01D) (9.0%). The remaining drug classes accounted for ≤ 6.0% each.

Most reported cancer drugs causing ADRs

The most reported cancer drugs causing ADRs are presented in Figure 2.

As shown in Figure 3, carboplatin was the most frequently reported drug (21.2%), followed by paclitaxel (20.1%) and pembrolizumab (9.5%). All other drugs accounted for less than 7.0% each.

Severity and outcomes of anticancer drug–related ADRs

The severity and outcomes of ADRs related to anticancer drugs are presented in Table 4.

Table 4. Severity and outcomes of ADRs related to anticancer drugs

	All ADR reports related to anticancer drugs (n = 253)
	Frequency (Percentage)
Severity of ADR	
Death	16 (6.3)
Life-threatening	8 (3.2)
Hospitalization/Prolonged Hospital Stay	46 (18.2)
Persistent/Significant Disability	0 (0.0)
Congenital Anomaly/Birth Defect	1 (0.4)
Non-serious	179 (70.8)
Insufficient Information	3 (1.2)
ADR Outcome	
Death related to ADR	0 (0.0)
Death unrelated to drug	10 (4.0)
Not recover	8 (3.2)
Recovering	84 (33.2)
Recovered with sequelae	0 (0.0)
Recovered without sequelae	59 (23.3)
Missing information	92 (36.4)

As shown in Table 4, most ADRs related to anticancer drugs were classified as non-serious (70.8%), while the majority of serious ADRs resulted in hospitalization or prolonged hospital stay (18.2%) and 16 cases resulted in death (6.3%). Regarding outcomes, 33.2% were still recovering at the time of reporting, 23.3% had fully recovered without sequelae, and only 3.2% had not recovered. In 36.4% of cases, the recovery status was unknown.

System Organ Class (SOC) classification of anticancer drug–related ADRs

The SOC classification of anticancer drug–related ADRs are presented in Figure 4.

As shown in Figure 4, red blood cell disorders were the most frequently reported SOC category (36.0%), followed by general disorders (25.7%), white blood cell and RES disorders (23.3%), platelet/bleeding/clotting disorders (19.4%), and skin/subcutaneous tissue disorders (19.4%). ADRs affecting other organ systems accounted for less than 12.0% each.

Clinical manifestations of anticancer drug–related ADRs

The clinical manifestations of anticancer drug–related ADRs are presented in Figure 5.

As shown in Figure 5, anemia was the most frequently reported manifestation (34.8%), followed by leukopenia (20.9%), pruritus (19.8%), and thrombocytopenia (16.6%). All other manifestations were reported in less than 11.0% of cases.

Preventability evaluation of ADRs related to cancer drugs

The preventability evaluation of ADRs related to cancer drugs are presented in Table 6.

Table 6. Preventability evaluation of ADRs related to cancer drugs

Cause of Preventable ADR (n = 253)	**Frequency (Percentage)**
Preventable	**2 (0.8)**
History of hypersensitivity to the drug or other drugs in the same class (Cisplatin)	1 (50.0)
Therapeutic duplication (Epirubicin)	1 (50.0)
Non-preventable	**249 (98.4)**
Not assessable	**2 (0.8)**

As shown in Table 6, of the 253 ADR reports related to anticancer drugs included in the preventability assessment, 2 reports (0.8%) were assessed as 'preventable', while the cases deemed 'non-preventable' accounted for the highest proportion, with 249 reports, corresponding to 98.4%. Among the two pADR reports, one was attributed to a known history of drug hypersensitivity to cisplatin or another drug in the same class, and the other was due to therapeutic duplication with epirubicin (50.0% each).

4. Discussion

This study recorded 291 ADR reports related to anticancer drugs after excluding reports related to drug quality and reports where the suspected drug causing ADR was not an anticancer drug. Most ADR reports related to anticancer drugs came from provincial (61.9%) and central hospitals (32.0%). Female patients had a higher ADR rate than males (1:2.79), with most cases in the 18–64 age group (66.7%). Only 2.1% of patients reported drug allergies, mostly to non-anticancer drugs. Causality assessment using the WHO scale identified 433 pairs (88.9%), the pairs were classified as “Certain”, “Probable/Likely”, or “Possible”, indicating a causal relationship between the suspected drug and the ADR. These pairs were recorded in 253 reports, accounting for 86.9% of the total reports in the study. Regarding the classification of anticancer drug–related ADR reports by ICD-10 indication, the category “Factors influencing health status and contact with health services” (Z00–Z99) accounted for the highest proportion (49.0%). The most frequently reported drug classes causing ADRs were “Other antineoplastic agents” (L01X) (52.2%) and “Plant alkaloids and other natural products” (L01C) (30.3%),

with carboplatin (21.2%) and paclitaxel (20.1%) being the two most commonly implicated drugs. Most ADRs were classified as non-serious (70.8%), with 16 fatal cases (6.3%). Blood disorders, particularly anemia and leukopenia, were the most common clinical manifestations. In terms of preventability, only 2 ADR reports (0.8%) were assessed as preventable, while 98.4% were classified as non-preventable. Among the two preventable reports, one was attributed to a known history of hypersensitivity to cisplatin, and the other was due to therapeutic duplication involving epirubicin.

The results showed that female patients (72.9%) experienced ADRs more frequently than male patients (26.1%), with the 18–64 age group accounting for the majority of cases (66.7%), consistent with the study by Fatmi et al. (2022), which found a higher rate of adverse drug reactions (ADR) in female patients (59.9%), and the study by Deepti Chopra et al. (2016), where the majority of patients with ADRs were in the 21-60 age group (79.5%) [14], [15]. The assessment results showed that 88.9% of the drug-ADR pairs were classified as certain, probable/possible, or possible, while 11.1% were classified as unlikely, unclassified, or unclassifiable. These findings are consistent with those reported by Ismail et al. (2024) [16]. Establishing a "certain" causal relationship remains challenging, especially due to the use of multiple drugs in cancer and the presence of multiple comorbidities, which complicates identifying the cause. Additional limitations include the lack of drug concentration measurements in plasma, as even therapeutic doses can produce different concentrations due to variations in product quality, genetic polymorphisms, hypersensitivity to target tissues, drug interactions, and liver or kidney dysfunction.

After assessing the causal relationship between the drug and ADR according to the WHO scale, 253 ADR reports were identified as having a causal relationship with anticancer drugs, corresponding to a total of 433 drug–ADR pairs with established causality. Regarding the indication for medication, the highest proportion was related to health status factors and healthcare service contact (49.0%) and neoplasm (48.6%). The most common anticancer drug causing ADR was carboplatin (21.2%), followed by paclitaxel (20.1%), which corresponds with another study [3], [17], [18]. In terms of severity, non-serious ADRs were the most common (70.8%), followed by ADRs leading to hospitalization (18.2%) and 16 fatal cases (6.3%), with no reports of permanent disability. After treatment, 33.2% of patients were still recovering, and 23.3% had fully recovered without sequelae. These results are consistent with Ingrand et al. (2019), who reported that approximately 44.5% of cancer patients experienced at least one severe ADR during chemotherapy [19]. However, our findings differ from Chopra et al. (2016), who reported only 12.9% severe ADRs [14]. This difference may be due to variations in sample size and research methods. Anemia was the most common clinical manifestation (34.8%), followed by leukopenia (20.9%), pruritus (19.8%), and thrombocytopenia (16.6%), which is consistent with the findings of Fatmi et al. (2022) [15].

Preventable ADRs accounted for only 0.8% of cases (2/253), whereas 99.2% were classified as non-preventable. The main preventable causes were drug administration despite a known history of hypersensitivity (50%) and therapeutic duplication (50%). These results are in line with a meta-analysis by Hakkarainen et al. (2012), which found pADRs accounted for 1.6–2.0% of hospital admissions or emergency visits [20], though the proportion observed in this study is markedly lower than in previous studies. For instance, Mukerem Sultan et al. (2025) in Ethiopia reported 43.9% preventable ADRs,

whereas Patel et al. (2018) found that 17.0% were preventable or definitely preventable [18], [21]. This difference may be explained by sample size and setting, as most prior studies were conducted in single institutions, whereas our study utilized a large dataset representing the entire southern region of Vietnam. The very low rate of pADRs observed here may reflect the intrinsic nature of anticancer drugs, which often have a narrow therapeutic index and cytotoxic effects on both malignant and healthy cells, resulting in ADRs even under appropriate dosing [22], [23]. Many such events (e.g., nausea, alopecia, myelosuppression) are therefore considered “unavoidable” unless a treatment error occurs. Another contributing factor may be the quality of ADR report data; insufficient details on prescribing, dispensing, or patient history limit the ability to fully assess preventability. Moreover, Vietnam’s spontaneous reporting system is still evolving and relies heavily on doctors (77.0% of reports in this study), which may result in under-reporting of errors occurring during drug preparation or dispensing.

This study has several strengths, including the use of a large-scale database from the Ho Chi Minh City DI & ADR Center, encompassing tertiary and provincial hospitals across southern Vietnam, thus providing a comprehensive overview of ADRs in cancer treatment in this region. The retrospective cross-sectional design included all 3,307 ADR reports received in 2023, enhancing representativeness and minimizing selection bias. Furthermore, the use of WHO-UMC causality assessment and WHO P-method for preventability evaluation standardized the assessment process and improved comparability with international studies. Nevertheless, the study has some limitations. The retrospective design relied on existing reports, many of which lacked detailed information on prescribing, dispensing, and patient history, limiting the ability to fully evaluate preventability. In addition, reliance on voluntary reporting, primarily from physicians, may lead to the under-reporting of errors at other stages of the medication-use process. Overall, this study provides real-world evidence on the characteristics, severity, and preventability of ADRs in cancer treatment and highlights the need for targeted interventions to reduce preventable ADRs and improve patient safety. The findings can support healthcare authorities in designing training programs, improving ADR reporting quality, and optimizing cancer care. Overall, this study provides real-world evidence on the characteristics, severity, and preventability of ADRs in cancer treatment and highlights the need for targeted interventions to reduce preventable ADRs and improve patient safety. The findings can support healthcare authorities in designing training programs, improving ADR reporting quality, and optimizing cancer care

5. Conclusion

Most anticancer drug–related ADRs in this study were non-serious, although a considerable proportion still resulted in hospitalization or death. The identification of preventable ADRs highlights the need for ongoing monitoring and evaluation to inform appropriate preventive strategies and enhance patient safety in cancer treatment.

Abbreviations

ADR

Adverse drug reaction
pADR
Preventable adverse drug reaction
DI
Drug information
WHO
World Health Organization
UMC
Uppsala Monitoring Centre
SOC
System Organ Class

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Institutional Review Board of Hong Bang International University (Approval No. 160/PCT-HĐĐĐ-SĐH). All data were used exclusively for research purposes and were anonymized and kept confidential at the DI & ADR Center. Given the retrospective nature and the anonymity of the data, the need for individual informed consent was waived.

Consent for publication

Not applicable

Availability of data

The datasets generated by or analyzed during the current study are available from the author, Thi Thu Thuy Nguyen (thuyntt1@hiu.vn), upon reasonable request.

Competing interests

The authors declare that they have no competing interests

Funding

This research did not receive any grant from funding agencies in the public, commercial, or non-profit sectors.

Authors' contribution

TTTN and QBN conceptualized the manuscript. TTTN wrote the original draft. TTTN, QBN, TKUN, and HQTD supervised the process. TTTN and reviewed and edited the manuscript. All authors read and approved the final manuscript.

Acknowledgements

We would like to extend our sincere gratitude to the Ho Chi Minh City DI & ADR Center. Their invaluable support in granting access to key data and information significantly facilitated the research process and contributed greatly to its successful completion.

References

1. Stewart BW, Kleihues P. World Cancer Report. IARC press Lyon; 2003.
2. Organization S, WHO Meeting on the Role of the Hospital in International Drug Monitoring. WH; (1968: Geneva, International drug monitoring: the role of the hospital, report of a WHO meeting [held in Geneva from 18 to 23 November 1968], Geneva, Internet 1969, Available: https://apps.who.int/iris/handle/10665/40747, Accessed on: 17 Sep, 2025.
3. Ramasubbu SK, Pasricha RK, Nath UK, Das B. Frequency, nature, severity and preventability of adverse drug reactions arising from cancer chemotherapy in a teaching hospital. J Family Med Prim Care. 2020;9(7):3349–55.
4. Miranda V et al. Adverse drug reactions and drug interactions as causes of hospital admission in oncology, (in eng), *J Pain Symptom Manage*, vol. 42, no. 3, pp. 342 – 53, Sep 2011.
5. Lavan AH, O'Mahony D, Buckley M, O'Mahony D, Gallagher P. Adverse Drug Reactions in an Oncological Population: Prevalence, Predictability, and Preventability, (in eng), *Oncologist*, vol. 24, no. 9, pp. e968-e977, Sep 2019.
6. Tăng XH, Trần ML, Nguyễn TPT, Nguyễn vàVT. Phân tích thực trạng báo cáo phản ứng có hại của thuốc tại Bệnh viện sản nhi Nghệ An giai đoạn 2020–2021, *Tạp chí Y học Việt Nam*, 513, 1, 2022.
7. Tú NNT, Hiền TT, Thủy VTB, Nga vàPTH. Khảo sát thực trạng báo cáo phản ứng có hại của thuốc tại Bệnh viện Thành phố Thủ Đức, *Tạp chí Y học Cộng đồng*, 2, 6, p. 121, 2018.
8. World Health Organization. (2013). *The use of the WHO-UMC system for standardised case causality assessment*. Available: https://www.who.int/publications/m/item/WHO-causality-assessment. Accessed on: 22 Sep, 2025.
9. U.S. Food and Drug Administration. (2023). *What is a Serious Adverse Event?* Available: https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event. Accessed on: 22 Sep, 2025.
10. World Health Organization. Reporting and learning systems for medication errors: the role of pharmacovigilance centres, 2014.
11. Benkirane R, et al. Assessment of a new instrument for detecting preventable adverse drug reactions, (in eng). Drug Saf. Volume 38. pp. 383 – 93; Apr 2015. 4.
12. (2005). *The WHO Adverse Reaction Terminology – WHO-ART*.
13. U.S. Department Of Health And Human Services. Common Terminology Criteria for Adverse Events (CTCAE), version 5.0, 2017.

14. Chopra D, Rehan HS, Sharma V, Mishra R. Chemotherapy-induced adverse drug reactions in oncology patients: A prospective observational survey, (in eng), *Indian J Med Paediatr Oncol*, vol. 37, no. 1, pp. 42 – 6, Jan-Mar 2016.
15. Fatmi SM, Bagati KD, Dutta S, Sharma J. Characterisation of seriousness and outcome of adverse drug reactions in patients received cancer chemotherapy drugs–A prospective observational study. Curr Med Res Pract. 2022;12(1):20–5.
16. Ismail SH, Jabeen A, Nabi M, Chashoo N, Magray S. Assessment of pattern of adverse drug reactions with chemo-therapeutic drugs in a tertiary care hospital of Government Medical College Anantnag: a prospective observational study. Int J Basic Clin Pharmacol. 2024;13(5):1.
17. Prasad A, Datta PP, Bhattacharya J, Pattanayak C, Chauhan AS, Panda P. Pattern of adverse drug reactions due to cancer chemotherapy in a tertiary care teaching hospital in Eastern India. J Pharmacovigil. 2013;1(2):107.
18. Shrmeka MS, Semman MF, Moges BT, Dereja FN, Garedo AW. Chemotherapy-related adverse drug reaction and associated factors among adult cancer patient attending Jimma medical center oncology unit. Southwest Ethiopia PLoS One. 2025;20(5):e0321785.
19. Ingrand I, et al. Serious adverse effects occurring after chemotherapy: A general cancer registry-based incidence survey. Br J Clin Pharmacol. 2020;86(4):711–22.
20. Hakkarainen KM, Hedna K, Petzold M, Hägg S. Percentage of patients with preventable adverse drug reactions and preventability of adverse drug reactions–a meta-analysis. PLoS ONE. 2012;7(3):e33236.
21. Patel SR, Gupta SD, Patel KP, Malhotra SD, Patel PRIJoB, Pharmacology C. Analysis of adverse drug reactions in a tertiary care emergency medicine department: prevalence, preventability and reporting. Int J Basic Clin Pharmacol. 2018;7(9):1787.
22. Basak D, Arrighi S, Darwiche Y, Deb S. Comparison of anticancer drug toxicities: paradigm shift in adverse effect profile, *Life*, vol. 12, no. 1, p. 48, 2021.
23. Yan H, et al. Anticancer therapy-induced adverse drug reactions in children and preventive and control measures. Front Pharmacol. 2024;15:1329220.

Figures

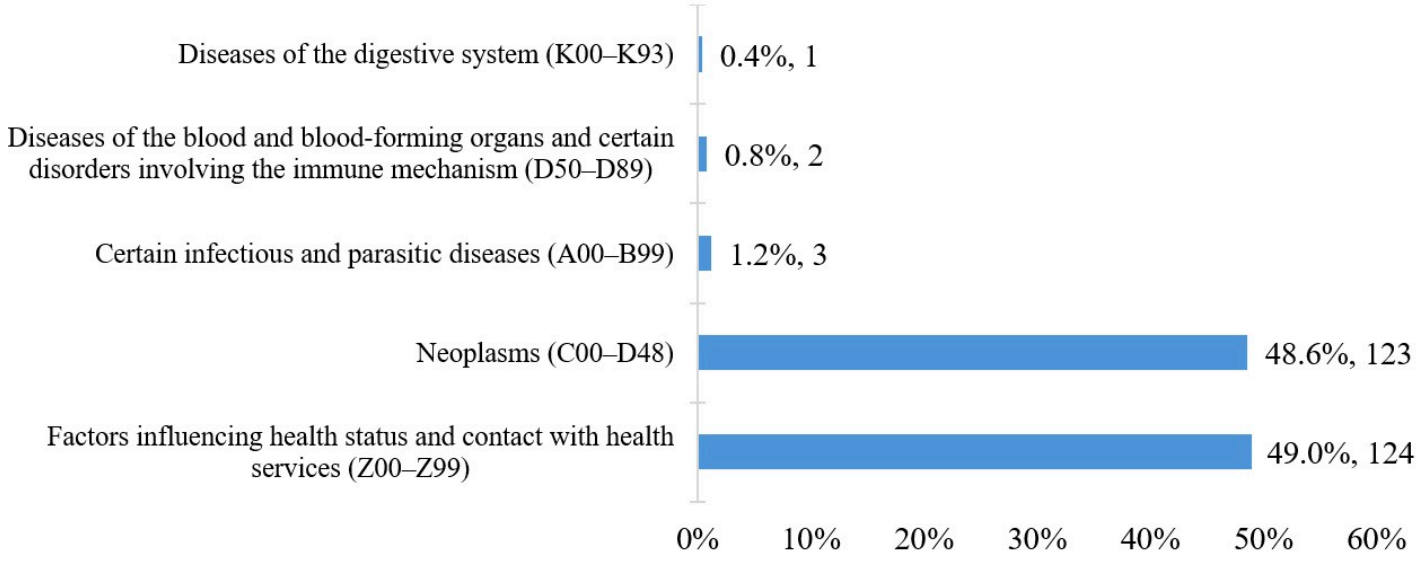

Figure 1

Classification of Anticancer Drug–Related ADR Reports by Indication ICD-10 (n=253)

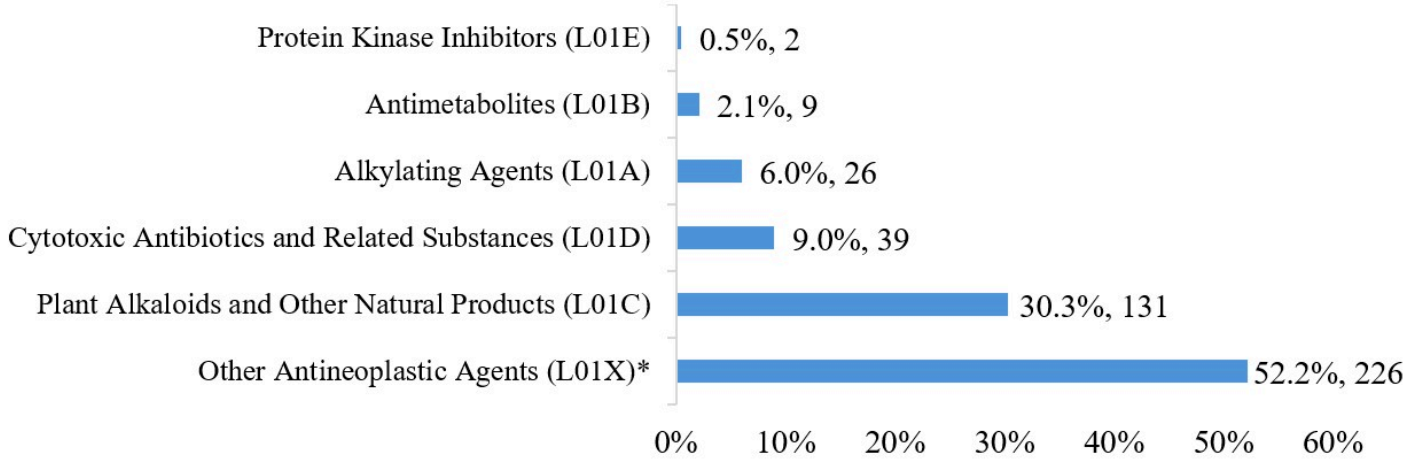

Figure 2

Most reported cancer drug classes causing ADRs (n=433)

Note: *L01X includes targeted therapies and newer antineoplastic agents not classified under conventional chemotherapy groups.

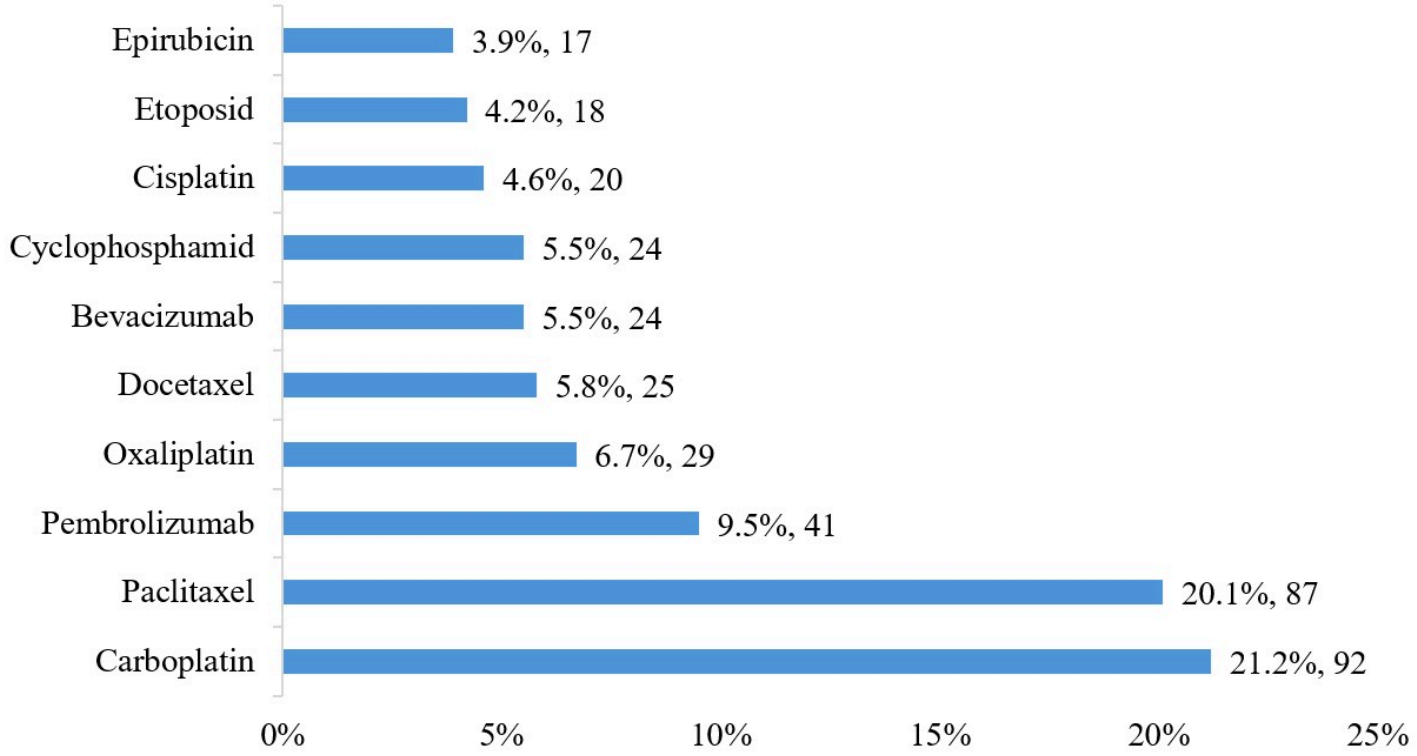

Figure 3

Most reported cancer drugs causing ADRs (n=433)

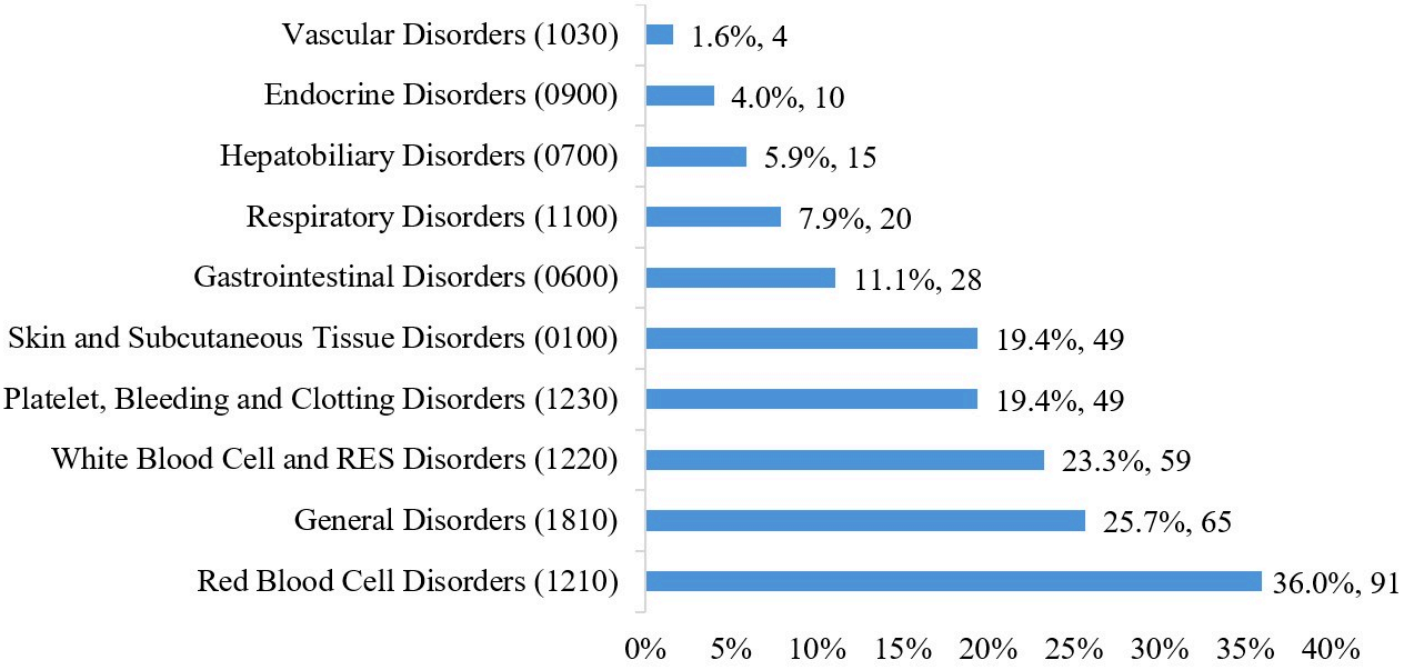

Figure 4

SOC classification of ADRs related to anticancer drugs (n=253)

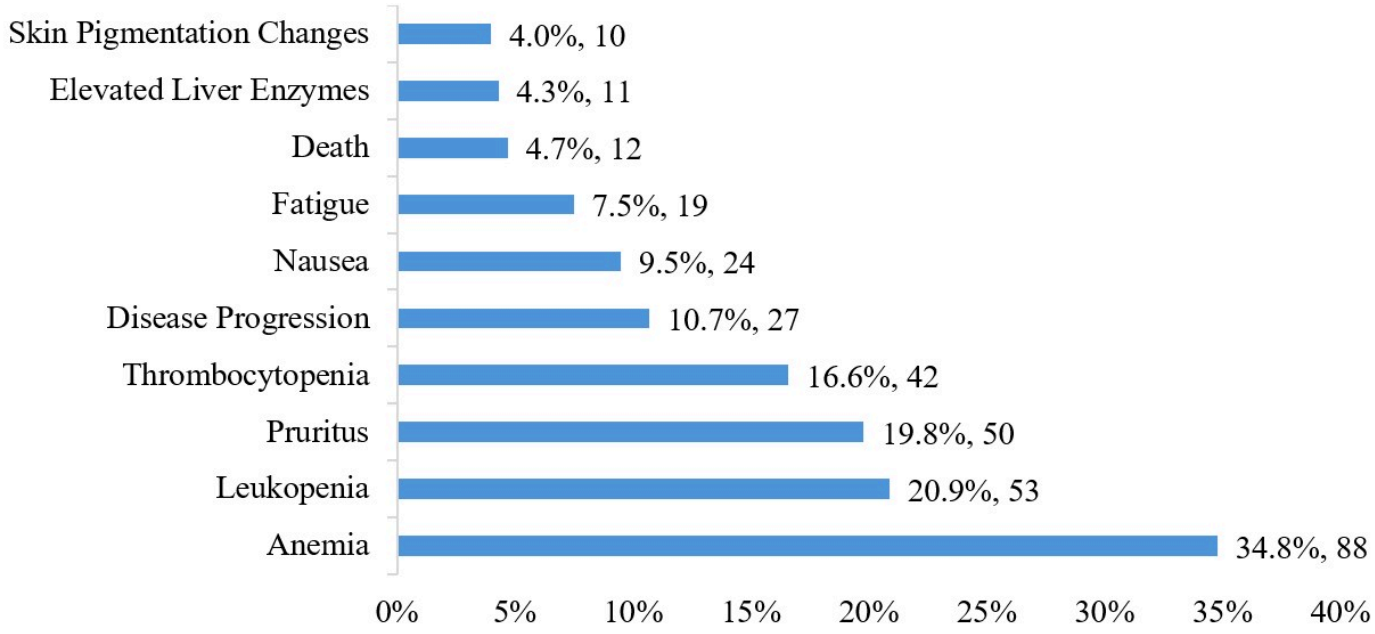

Figure 5

Clinical manifestations of ADRs related to anticancer drugs (n=253)