

Pareto Analysis-Based Risk Stratification and Prevention Strategies for Adverse Drug Reactions in our Hospital (2022-2025)

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ABSTRACT

Background: Adverse Drug Reactions (ADRs) severely affect clinical medication safety, and the Pareto principle is widely applied to identify key risk factors in pharmacovigilance. Systematic retrospective analysis of hospital ADR data helps clarify ADR distribution characteristics. **Objectives:** To analyze the epidemiological characteristics of ADRs in a single hospital and screen high-risk factors, so as to provide evidence for rational clinical medication and targeted ADR prevention. **Materials and Methods:** A retrospective study was conducted on ADR data reported to the National Adverse Drug Reaction Monitoring System from 2022 to 2025. Basic information of ADRs was statistically organized, and the Pareto principle was utilized to classify key risk indicators. **Results:** A total of 567 ADR reports were collected, including 188 severe, 376 common, and 3 newly reported non-serious cases. Hematological disorders, elderly patients (≥ 60 years), intravenous administration, and combined use of anticancer drugs and traditional Chinese patent medicines were categorized as Category A high-risk factors with prominent cumulative proportions. **Conclusion:** Hospital ADRs show obvious clustering characteristics. Targeted intervention and precise management for the confirmed high-risk links can effectively reduce ADR risks and improve clinical medication safety.

Keywords: Adverse drug reactions, Drug safety, Pareto method, Prevention strategies, Rational drug use.

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INTRODUCTION

Adverse Drug Reactions (ADRs) are broadly defined as adverse outcomes that arise from the standard use of approved medications, that are unrelated to the intended therapeutic purpose and pose potential risks to the body (Zhang *et al.*, 2025). Severe ADRs not only substantially prolong hospital stays and increase treatment costs, but also elevate the risk of death, representing a major issue in global clinical pharmacovigilance and public health (Gosselt *et al.*, 2022; Miguel *et al.*, 2014). With the continuous expansion of the range of clinical medications and the growing prevalence of polypharmacy, the incidence and complexity of ADRs continue to escalate (Oliveira *et al.*, 2013; Yan *et al.*, 2025). This trend

can not only result in premature treatment discontinuation, regimen modification and diminished therapeutic efficacy, but also substantially strains the healthcare system and imposes considerable financial burdens on patients (Jalloh *et al.*, 2026; Parracha *et al.*, 2023). Consequently, systematically elucidating the epidemiological features, distribution patterns and risk factors of ADRs is of paramount importance for enhancing medication safety and mitigating drug-related morbidity (Carandang *et al.*, 2024; Wang *et al.*, 2022).

Current ADR monitoring systems primarily rely on general descriptive statistics, which often hinders the accurate differentiation of key risk factors from minor, confounding variables (Hammad *et al.*, 2025). This ambiguity may result in the misallocation of prevention and control resources and lead to inefficient intervention strategies (Padmawar *et al.*, 2026). The Pareto Principle, referred to as the 80/20 rule, is grounded in the core concept of "the vital few and the trivial many." By employing data ranking and cumulative percentage analysis, this principle facilitates the quantitative identification of the dominant factors driving overall outcomes (Alkiyat, 2021; Chen *et al.*, 2021). It



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has shown robust efficacy in healthcare quality assurance, risk forecasting, and pharmacovigilance management (Tian *et al.*, 2026; Müller *et al.*, 2014). Notably, this approach effectively addresses the limitations inherent in traditional descriptive analyses, allowing for the precise delineation of ADR high-risk targets and providing a scientific basis for the development of stratified, targeted, and focused prevention and control strategies (Mondal *et al.*, 2026; Tao *et al.*, 2026).

Based on the aforementioned clinical demands and methodological advantages, this study performed a retrospective analysis of 567 ADR reports submitted by our hospital to the National Adverse Drug Reaction Monitoring System during 2022-2025. We systematically evaluated the distribution characteristics of ADRs in terms of affected systems, patient demographics, administration route and suspected drugs, and further applied the Pareto analysis to identify core high-risk factors. The objective of this study was to identify the clustering patterns of ADRs at our hospital and key prevention and control targets, thereby providing objective evidence and actionable guidance for optimizing clinical medication management, implementing targeted prevention and intervention and sustainably improving medication safety.

MATERIALS AND METHODS

Data Sources

This retrospective study was conducted at a secondary general hospital in Shanghai, China. We retrieved all ADR reports submitted by our hospital to the National Adverse Drug Reaction Monitoring System between January 1, 2022 and December 31, 2025. All reports were independently assessed and verified by clinical pharmacists to guarantee data completeness, accuracy, and adherence to national monitoring guidelines. In total, 567 valid ADR reports were finally enrolled for further analysis.

Inclusion and Exclusion Criteria

Inclusion Criteria: (1) ADRs occurring after drug administration with complete documentation, consistent with the official definition of ADRs issued by the National Medical Products Administration of China: undesirable responses unrelated to therapeutic indications observed when an authorized drug is used at standard dosages and in accordance with approved clinical practice. (2) Comprehensively documented reports including patient demographics (age, sex), detailed medication information (drug name, administration route, dosage, treatment duration), ADR clinical manifestations, onset time, interventions, and prognosis, without missing critical data. (3) Reports independently assessed and verified by ≥ 2 clinical pharmacists, free of logical inconsistencies, falsified data, or missing key details. (4) ADRs occurring within the study interval (January 1, 2022-December 31, 2025) and promptly reported to the National Adverse Drug Reaction Monitoring System in strict compliance

with hospital protocols and national regulatory requirements. (5) Patients without severe comorbidities (e.g., severe hepatic/renal dysfunction, malignant tumors) that may confound ADR evaluation. If comorbidities are present, a lack of direct causal association with the ADR must be clearly confirmed.

Exclusion Criteria: (1) Suspected ADR reports with an ambiguous causal association between drug exposure and adverse events, in which adverse events cannot be definitively excluded as being attributable to underlying diseases, concomitant medications, dietary factors, or other non-drug-related factors. (2) Incomplete reports missing critical data (e.g., patient age, sex, drug name, ADR manifestations, dosage) that could not be restored or supplemented following verification by clinical pharmacists. (3) Duplicate reports, defined as repeated submissions of the same ADR event by different staff, departments, or time points, where only the earliest valid report was retained. (4) Reports verified as false or fictitious by ≥ 2 clinical pharmacists through comprehensive assessment of medical records, medication charts, laboratory data, and other supporting evidence. (5) Reports of ADRs occurring outside the study interval (before January 1, 2022, or after December 31, 2025) or those not formally submitted to the National Adverse Drug Reaction Monitoring System. (6) Reports of adverse events related to drug overdose, misuse, abuse, or off-label administration inconsistent with the approved dosage and instructions. (7) Reports involving patients with multiple severe comorbidities that preclude reliable differentiation between ADRs and complications of underlying diseases.

Research Methods

Descriptive statistics were utilized to characterize the epidemiological features of ADRs using percentages and proportions. Annual and quarterly incidence, counts of severe ADRs, and new suspected ADRs were systematically collated and analyzed to explore the distribution patterns of ADRs according to administration route, patient demographics (age, sex), pharmacological classes of suspected causative agents, and affected organ systems. The analytical framework adhered to the methodological standards for pharmacoepidemiological research specified in the Chinese Guidelines on Methodology for Pharmacoepidemiological Research (T/CPHARMA 002-2019). To determine high-priority ADR categories for targeted intervention, the Pareto principle (80/20 rule) was adopted for classification and ranking. Briefly, all ADR types were sorted in descending order of frequency, and the corresponding cumulative percentage was computed for each category. According to cumulative percentages, ADRs were stratified into three levels for hierarchical prevention and management: (1) Category A (Primary Prevention): Cumulative percentage $< 80\%$; (2) Category B (Secondary Prevention): Cumulative percentage $80\%-90\%$; (3) Category C (Routine Surveillance): Cumulative percentage $> 90\%$.

Observation Indicators

Consistent with the core analytical objectives of descriptive statistics and the Pareto approach, the primary observation indicators of this study included: annual and quarterly distribution of ADRs (for temporal trend analysis), reporter profile, administration route distribution, patient demographic characteristics (age stratification, sex distribution), classification of suspected causative drugs, affected organ systems and ADR severity grading based on criteria issued by the National Medical Products Administration, and occurrence of new ADRs. These indicators comprehensively encompass key determinants of ADR development, ensuring systematic and thorough descriptive analysis while providing adequate quantitative data for risk stratification using the Pareto analysis, thereby supporting the scientific rigor, reliability, and clinical applicability of the study findings.

Statistical Analysis

Descriptive statistics were utilized to characterize the epidemiological features of ADRs using percentages and proportions. The Pareto principle (80/20 rule) was adopted to stratify ADRs into three priority levels (Category A, B, and C) based on their cumulative percentages.

Ethical Statement

This retrospective study was approved by the Ethics Committee of Shanghai Second People's Hospital (Approval No. 2026-KY-05). Patient consent was waived due to the retrospective and anonymized nature of the data analysis.

RESULTS

Annual and Quarterly Distribution of ADRs

As shown in Figure 1a, from 2022 to 2025, the number of reported ADRs in our hospital remained generally stable: 137 cases in 2022, 146 in 2023 (a year-on-year increase of 6.57%), 146

in 2024 (stable relative to 2023), and 138 in 2025 (a year-on-year decrease of 5.48%). The number of serious ADRs peaked in 2023 and declined annually thereafter: 43 cases (31.38%) in 2022, 57 (39.04%) in 2023, 49 (33.56%) in 2024, and 39 (28.26%) in 2025. Three new general ADRs were identified: 2 in 2024 attributed to Compound Glycyrrhizin Tablets and Vitality Su Oral Solution, and 1 in 2025 presenting as leukopenia induced by Kangai Injection.

As shown in Figure 1b, regarding quarterly distribution across the four-year study period, there were 143 cases in the first quarter, 106 in the second quarter, 159 in the third quarter, and 159 in the fourth quarter. Overall, ADR incidence was highest in the third and fourth quarters and lowest in the second quarter, a pattern potentially associated with quarterly variations in outpatient volume, medication diversity, and the intensity of clinical pharmacist medication reviews.

As shown in Figure 2a, from 2022 to 2025, pharmacists represented the primary reporters of ADRs at our hospital, accounting for 85.01% of all submissions. This proportion showed an overall upward trend with a transient decline in 2024 (78.10% in 2022, 84.25% in 2023, 81.51% in 2024, and 96.37% in 2025), as shown in Figure 2b. By contrast, the proportion of reports from physicians was relatively low at 12.87%, while nurses contributed 2.12%. Notably, clinical healthcare professionals exhibited insufficient spontaneous reporting awareness, with the majority of ADRs detected by clinical pharmacists during medication order review.

Distribution by Route of Administration

As shown in Figure 2c and 2d, from 2022 to 2025, ADR reports at our hospital involved three distinct routes of administration. Among these, intravenous administration accounted for 465 cases (82.01%) (78.83% in 2022, 84.93% in 2023, 82.19% in 2024, 82.88% in 2025), and remained the predominant target for ADR prevention and control. Oral administration accounted for 97 cases (17.11%), with notable quarterly fluctuations.

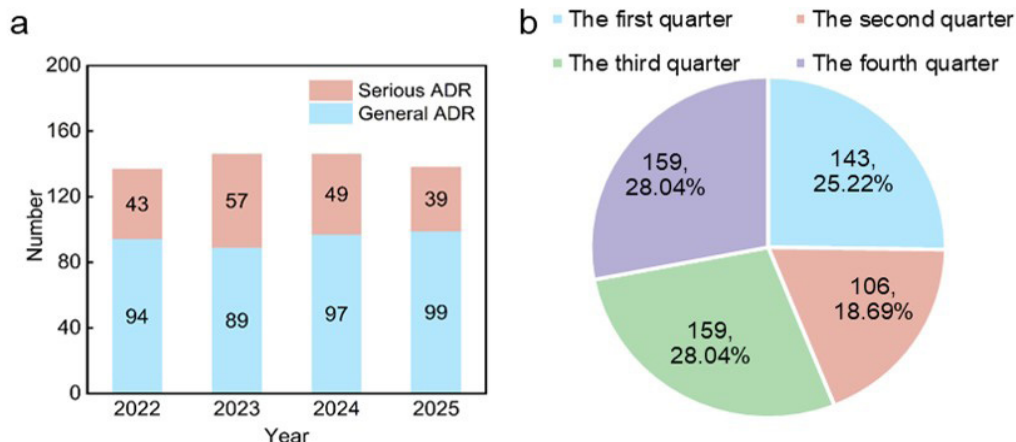


Figure 1: (a) Quarterly distribution of ADR cases in our hospital from 2022 to 2025; (b) The number of ADR cases in our hospital from 2022 to 2025. Composition of Reporters.

Topical administration accounted for 5 cases (0.88%), occurring only sporadically in certain quarters with no related reports documented in 2024.

Characteristics of the Patient Population

As shown in Figures 3a and 3b, in terms of age distribution, elderly patients (aged ≥ 60 years) represented the population predominantly affected by ADRs, accounting for 65.26% of total cases over the four-year study period and showing an overall upward trend with a slight decline in 2025 (57.66% in 2022, 64.75% in 2023, 69.86% in 2024, and 67.39% in 2025). The 40-59 and 20-39 age groups accounted for 24.51% and 8.47% of cases, respectively. Only sporadic cases were observed annually in patients aged <20 years, representing an aggregate proportion of merely 1.76%.

As shown in Figures 3c and 3d, in terms of gender distribution, 354 female patients (62.43%) were documented, outnumbering 213 male patients (37.57%) (Table 1). The overall male-to-female

ratio across the four-year study period was approximately 1:1.66, with the proportion of female patients exceeding 50% each year and peaking at 67.12% in 2024.

Distribution of Drug Classes Causing ADRs

As shown in Figures 4a and 4b, from 2022 to 2025, anticancer agents were the primary cause of ADRs at our hospital, accounting for a total of 320 cases (56.44%). This proportion peaked at 62.33% in 2023, decreased moderately to 54.79% in 2024, and remained relatively stable at 54.35% in 2025. Next, traditional Chinese patent medicines (89 cases, 15.70%) and antimicrobial agents (70 cases, 12.35%) were the next most frequent categories. Other drug classes (cardiovascular, gastrointestinal, sedative-hypnotics, etc.) accounted for a smaller proportion (15.51%), and were mainly observed in 2024 and 2025, indicating a gradual diversification of drug-related ADR distribution. Notably, restricted anticancer drugs induced 68 ADR cases over the four-year study period, most of which were associated with severe hematological injury, thus representing a key priority for monitoring and intervention.

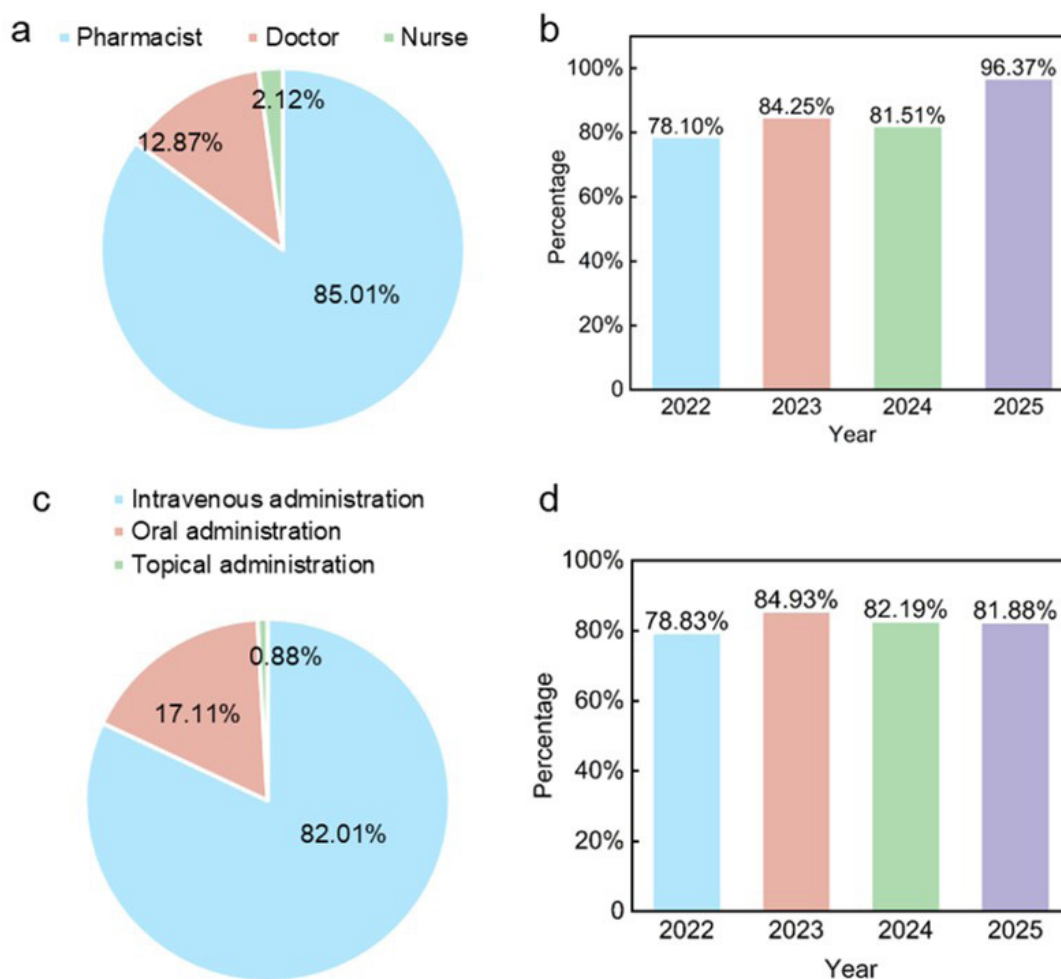


Figure 2: (a) Composition of pharmacist for ADRs reporting in our hospital from 2022 to 2025; (b) The proportion of pharmacists reporting ADRs cases in our hospital from 2022 to 2025; (c) The administration routes of ADRs cases in our hospital from 2022 to 2025; (d) The proportion of intravenous administration in ADRs cases in our hospital from 2022 to 2025.

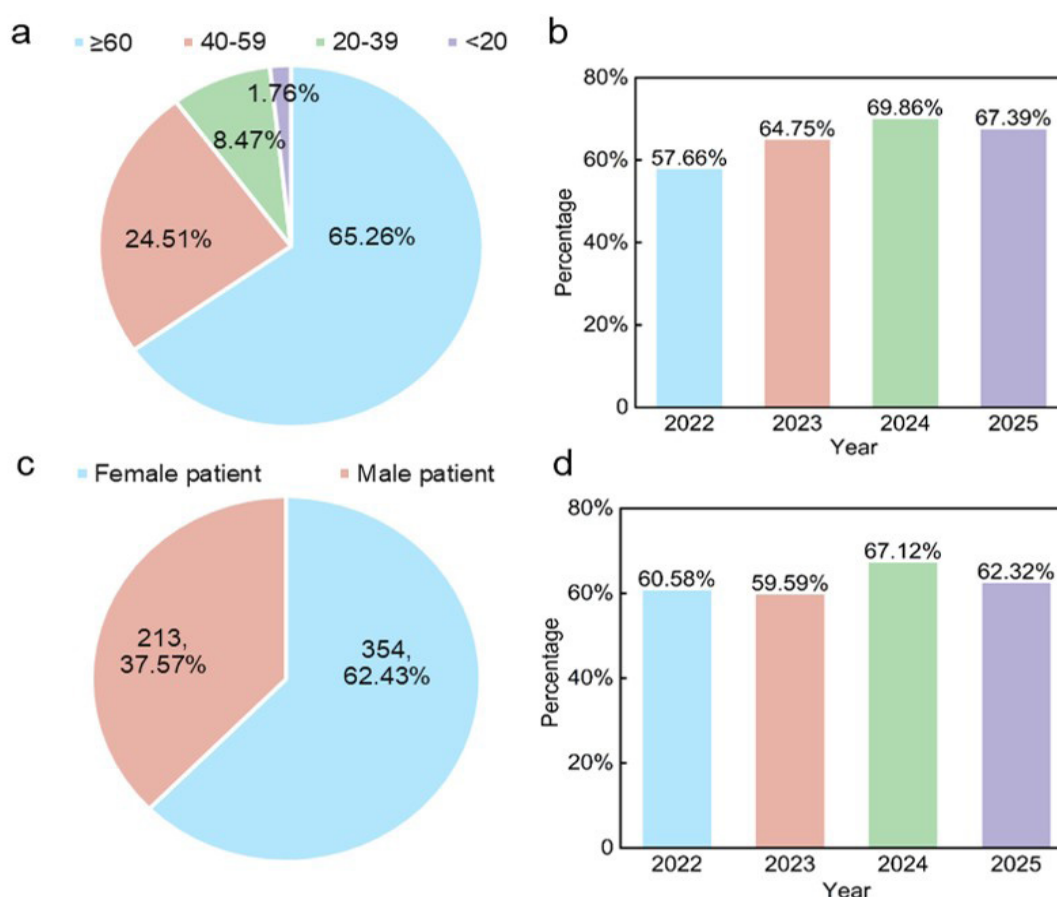


Figure 3: (a) Age composition of reported patients from 2022 to 2025; (b) The proportion of ADR patients aged 60 and above in our hospital from 2022 to 2025; (c) Gender distribution of ADR patients in our hospital from 2022 to 2025; (d) The proportion of female patients with ADR cases in our hospital from 2022 to 2025.

Table 1: Age distribution in our hospital's ADRs reports from 2022 to 2025.

Age	Male	Female	Number of Cases	Cumulative Percentage	Category (A/B/C)
≥60	138	232	370	65.26%	Category A (Priority)
40-59	44	95	139	89.77%	Category B (Secondary)
20-39	24	24	48	98.24%	Category C (Common)
0-19	7	3	10	100.00%	Category C (Common)
Total	213	354	567	-	-

As shown in Table 2, an analysis of the distribution of drug categories associated with ADR over the past four years revealed that anticancer drugs ranked first, accounting for 320 cases (56.44%), and were classified as Category A agents requiring priority monitoring. Collectively, they constitute the primary source of ADRs in our hospital. This finding is closely consistent with clinical practice. On the one hand, the standard of cancer diagnosis and treatment in our hospital has been continuously improved in recent years, which has expanded the clinical application scope of anticancer drugs and increased the number of patients receiving these agents. Consequently, the number of ADR reports related to anticancer drugs has also increased. On the other hand, anticancer drugs inherently exhibit strong cytotoxicity, and their mechanisms of action primarily involve

the inhibition of cell proliferation. While effectively eliminating tumor cells, these agents are prone to inducing damage to normal tissue cells. Common ADRs associated with anticancer drugs include myelosuppression, gastrointestinal reactions, and liver and kidney dysfunction. Furthermore, some anticancer drugs are associated with delayed adverse reactions, which increases the difficulty of ADR monitoring. In addition, some cancer patients have underlying multi-organ diseases, impaired immune function, or combination chemotherapy regimens, all of which further increase the risk of ADRs. Therefore, anticancer drugs must be designated as a top priority for ADR monitoring in our hospital, with a particular focus on strengthening real-time monitoring during treatment and improving early warning systems for adverse reactions.

ADRs associated with traditional Chinese patent medicines constituted 15.70% of all reported cases, ranking second. These medicines were also categorized as Category A agents requiring priority surveillance, a phenomenon that merits heightened clinical attention. Traditional Chinese patent medicines are characterized by complex chemical compositions, diverse pharmacological targets, and substantial interindividual variability. The occurrence of ADRs is frequently associated with ingredient complexity, insufficient processing standardization, inappropriate syndrome differentiation and treatment, and concurrent polypharmacy. In clinical practice, some clinicians lack comprehensive knowledge regarding the pharmacological properties and contraindications of traditional Chinese medicine formulations, resulting in inaccurate syndrome differentiation, excessive dosage, or unnecessarily prolonged treatment courses.

Furthermore, irrational concomitant use of traditional Chinese medicine and Western medicines may induce potential drug-drug interactions and precipitate ADRs. Additionally, self-medication with traditional Chinese medicine formulations without professional supervision further increases the risk of adverse events. Notably, traditional Chinese medicine-related ADRs predominantly present as allergic reactions or gastrointestinal discomfort; many such reactions are mild, insidious, and easily overlooked in routine clinical practice. Accordingly, targeted training regarding the rational use of traditional Chinese medicine formulations should be strengthened, the practice of syndrome differentiation-based prescribing should be standardized, and a dedicated ADR surveillance system for traditional Chinese medicine should be established to minimize medication-related harm.

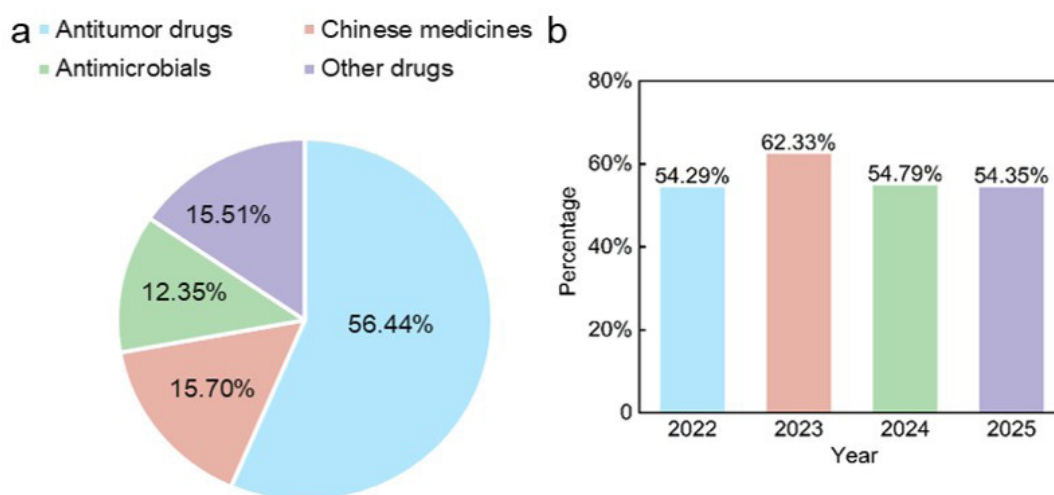


Figure 4: (a) Distribution of ADR drug categories in our hospital from 2022 to 2025; (b) The proportion of ADRs caused by anti-tumor drugs in our hospital from 2022 to 2025.

Table 2: Distribution of drug categories in ADR reports from our hospital (2022-2025).

Drug category	Number of cases (%)	Cumulative proportion	Category (A/B/C)
Anticancer Drugs	320 (56.44%)	56.44%	Category A (Priority)
Traditional Chinese medicines	89 (15.7%)	72.14%	Category A
Antimicrobials Drugs	70 (12.35%)	84.49%	Category B (Secondary)
Central Nervous System	16 (2.82%)	87.31%	Category B
Cardiovascular System	15 (2.65%)	89.96%	Category B
Nutritional Support	13 (2.29%)	92.25%	Category C (Routine)
Diagnostic Drugs	12 (2.12%)	94.37%	Category C
Digestive System	9 (1.59%)	95.96%	Category C
Hematological System	7 (1.23%)	97.19%	Category C
Endocrine and Hormonal Agents	7 (1.23%)	98.42%	Category C
Respiratory System	5 (0.88%)	99.30%	Category C
Urinary System	3 (0.53%)	99.82%	Category C
Immunomodulators	1 (0.18%)	100%	Category C
Total	567	100%	

Antimicrobials represented 12.35% of total ADR reports and were classified as Category B agents for secondary monitoring, ranking as the third leading cause of ADRs in our hospital. As one of the most frequently prescribed drug classes in clinical practice, ADRs associated with antimicrobials are primarily attributed to antimicrobial resistance, dosage regimens, administration routes, and interpatient variability. With the implementation of standardized campaigns for the rational use of antimicrobials, the appropriateness of antimicrobial use in our hospital has improved substantially. Nevertheless, some clinicians still fail to rigorously adhere to the principle of “prior antimicrobial susceptibility testing”, resulting in inappropriate use of broad-spectrum agents, excessively prolonged treatment courses, or irrational combination therapy, all of which predispose to ADRs. Furthermore, certain antimicrobial agents (e.g., cephalosporins and quinolones) are commonly associated with adverse events including hypersensitivity reactions and intestinal microbiota dysbiosis. Prolonged exposure may also promote antimicrobial resistance, thereby exacerbating associated safety risks. Accordingly, continuous optimization of antimicrobial stewardship is warranted to enforce susceptibility testing, enable targeted drug selection based on infection type and microbiological culture results, and standardize dosage and treatment duration, ultimately mitigating the incidence of ADRs.

ADRs associated with Central Nervous System (CNS) and cardiovascular agents accounted for 2.82% and 2.65% of total reports, respectively. Both drug classes were categorized as Category B for secondary monitoring, and the incidence of ADRs was frequently associated with the intrinsic pharmacological profiles of the agents and patients' underlying comorbidities. CNS agents (e.g., sedatives, hypnotics, and antiepileptics) readily disrupt central nervous system function, with typical ADRs including dizziness, somnolence, and confusion. This pattern is particularly pronounced in elderly patients, in whom age-related declines in hepatic and renal function and impaired metabolic capacity may precipitate drug accumulation, consequently elevating the risk of adverse events. Cardiovascular agents (e.g., antihypertensives and antiarrhythmics) possess a narrow therapeutic index, and inappropriate dose titration may readily elicit ADRs including blood pressure instability and recurrent arrhythmias. Moreover, given that many patients present with multiple cardiovascular disorders, complex polypharmacy further amplifies the risk of ADRs. Accordingly, when prescribing these agents in clinical practice, clinicians should rigorously individualize dosage regimens based on disease status, hepatic and renal function, and interpatient variability, and strengthen vital sign monitoring throughout treatment to ensure timely detection and intervention of adverse reactions.

The remaining nine drug categories, including nutritional support agents and diagnostic agents, each accounted for fewer than 3% of total ADR reports, with a combined proportion of

only 15.51%. These were classified as Category C, corresponding to drugs requiring routine monitoring. The incidence of ADRs associated with these agents is relatively low and is frequently related to irrational medication use or individual patient tolerance. Examples include metabolic disturbances induced by overuse of nutritional support agents, as well as local irritation or hypersensitivity reactions elicited by diagnostic agents. Although the ADR risk associated with these drug categories is low, routine monitoring should still be strengthened and medication administration procedures standardized to prevent adverse events stemming from inadequate attention to clinical details.

In terms of cumulative proportion, the top three drug categories (anticancer agents, traditional Chinese patent medicines, and antimicrobial agents) accounted for 84.49% of all ADR reports. Among these, anticancer agents and traditional Chinese patent medicines represent the primary targets for ADR prevention and control, indicating a high degree of concentration in ADR occurrence at our hospital. Prioritizing surveillance of these three drug categories can effectively mitigate the overall ADR risk across the hospital. In line with the requirements for stratified management (Categories A, B, and C), clinical departments should establish a tiered surveillance mechanism. For Category A agents (priority surveillance), assign dedicated personnel to oversee full-course surveillance, regularly analyse ADR occurrence patterns, and refine treatment regimens. For Category B agents (secondary surveillance), enhance medication guidance and conduct regular audits to promptly rectify irrational prescribing practices. For Category C agents (routine surveillance), ensure standardized routine documentation and follow-up to facilitate the timely detection and management of adverse events. Furthermore, it is crucial to strengthen training on rational medication use, provide guidance on optimal pharmacotherapy, standardize medication administration processes, and reduce irrational prescribing practices.

ADR-Affected Systems/Organs and Clinical Manifestations

Given that individual patients may experience multiple concurrent ADRs, for analytical consistency, the case numbers presented in Table 3 reflect only the frequency of involvement for each affected organ or system. The organ or system most commonly implicated in ADRs induced by anticancer agents was the blood and hematopoietic system (54.67%, 310/567), followed by the skin and subcutaneous tissue (32.10%, 182/567).

Distinct clinical patterns were observed across different ADR types: hematologic disorders were predominantly attributed to anticancer agents, manifesting mainly as leukopenia and thrombocytopenia; skin and subcutaneous tissue disorders were mostly associated with antimicrobial agents and traditional Chinese patent medicines, presenting primarily as rash and pruritus; gastrointestinal disturbances were mainly induced by

Table 3: Affected systems or organs and clinical manifestations in ADRs reports from Our Hospital (2022-2025).

ADR Type	Clinical Manifestations	Number of Cases (%)	Cumulative Percentage	Classification (A/B/C)
Hematological disorders	Leukopenia, coagulation disorders	310 (54.67%)	54.67%	Category A (Major)
Skin and appendage disorders	Rash, pruritus	182 (32.10%)	86.77%	Category B (Minor)
Gastrointestinal system damage	Nausea, vomiting, diarrhea, abdominal pain, upper gastrointestinal bleeding	48 (8.47%)	95.24%	Category C (Common)
Cardiovascular system disorders	Elevated blood pressure, facial flushing	21 (3.70%)	98.94%	Category C
Central and peripheral nervous system disorders	Dizziness, palpitations, chest tightness	4 (0.71%)	99.65%	Category C
Other types of harm (endocrine, urinary, etc.)	Gynecomastia, elevated kidney function	2 (0.35%)	100.00%	Category C
Total		567	100.00%	

traditional Chinese patent medicines and select oral formulations, with the main symptoms including abdominal discomfort and vomiting.

DISCUSSION

Analysis of ADR Characteristics

Over the four-year study period, the overall number of ADR reports at our hospital remained relatively stable. The proportion of serious ADRs peaked at 39.04% in 2023 and exhibited a gradual declining trend year by year (Masiliūnienė *et al.*, 2025). The identification of newly reported ADRs reflects continuous improvements in the depth and accuracy of ADR surveillance at our hospital (Chung & Lin, 2025). Nevertheless, there is still opportunity for optimization in the overall number of reports. The slight decrease in the number of reports observed in 2025 was attributed to variations in clinical workflow and adjustments to the medication profile during that year. In terms of quarterly distribution, ADRs were most frequent in the third and fourth quarters, mainly due to increased patient volume, wider medication diversity, and more rigorous medication order review by clinical pharmacists, which facilitated the identification of additional previously unreported cases. The fewest ADRs occurred in the second quarter, which was associated with seasonal fluctuations in clinical activity and variations in patient medication adherence.

In terms of reporter composition, pharmacists have consistently constituted the primary contributors to ADR reporting (Aizpurua-Arruti *et al.*, 2025), with their relative proportion increasing annually, reflecting the important role of clinical pharmacists in ADR monitoring. However, insufficient awareness among clinical healthcare professionals regarding independent

reporting remains a persistent challenge (García-Abeijon *et al.*, 2023). The majority of ADRs were identified by pharmacists during medication order review, which was related to heavy workload, insufficient emphasis on ADR reporting, and unfamiliarity with reporting protocols among clinical healthcare professionals. Efforts to enhance awareness and training should be continuously strengthened to resolve these issues.

In terms of administration routes, intravenous administration has consistently been associated with a high incidence of ADRs (Almalag *et al.*, 2022; Bhojan *et al.*, 2025). This observation can be explained by the fact that drugs enter directly into the bloodstream, resulting in rapid elevations in plasma drug concentrations and generating strong physiological stimulation. Furthermore, some patients received infusions at an excessively rapid rate or with incompatible drug combinations during intravenous therapy. These findings highlight the necessity to enhance standardized management of intravenous administration, strictly regulate infusion rates, and ensure appropriate drug compatibility to minimize ADR risk.

Regarding patient demographics, elderly patients represented a high-risk population for ADRs (Jennings *et al.*, 2019; Van Staa *et al.*, 2024), accounting for a cumulative 65.26% of total cases over the four-year study period (Pareto Category A, indicating priority for prevention and control). This finding was mainly attributable to multiple comorbidities, impaired hepatic and renal function, and extensive polypharmacy in this population, which collectively compromise drug metabolic capacity and elevate ADR risk. The incidence of ADRs was significantly higher in females than in males, which may be associated with greater drug sensitivity, disparities in medication adherence, and a higher proportion of female patients with cancer (Aljohmani & Yildiz, 2025). These results highlight the importance of establishing personalized

therapeutic regimens and strengthening medication monitoring for elderly and female patients.

In terms of drug categories associated with ADRs, anticancer agents consistently represented the predominant drug class (Tewari *et al.*, 2019; Yan *et al.*, 2024), accounting for more than 50% of total cases (Pareto Category A). This finding was mainly attributed to the intrinsic high cytotoxicity and narrow therapeutic window of anticancer drugs, as well as their extensive clinical utilization. In particular, restricted anticancer drugs exhibited a high incidence of severe ADRs, warranting intensified pharmacovigilance for this category. Owing to the wide indications and low irritability of traditional Chinese patent medicines, their relative proportion increased annually, peaking at 21.01% in 2025 and ranking second (also classified as Pareto Category A). However, traditional Chinese patent medicines exhibit relatively limited therapeutic efficacy, and the adverse reactions listed in their package inserts remain unclear (Huang *et al.*, 2021). These observations suggest that the prevention and control of ADRs associated with proprietary Chinese patent medicines must be given serious attention to avoid adverse reactions caused by improper diagnosis or excessive dosing. It is recommended that targeted prevention, standardized administration, and enhanced monitoring be implemented for these two major drug categories.

Pareto analysis revealed that hematological ADRs were categorized as Category A and were strongly associated with the extensive use of anticancer and antimicrobial agents (JS *et al.*, 2026; Wu *et al.*, 2025), representing a top priority for ADR prevention and control. Adverse reactions involving the skin and subcutaneous tissue were classified as general prevention and control types, whereas other ADR types occurred at relatively low rates and could be managed via routine monitoring. This classification approach facilitates the identification of priority targets for ADR intervention and enhances the efficiency of risk management strategies (Li *et al.*, 2025).

Existing Issues

Clinical healthcare professionals showed inadequate awareness of spontaneous ADR reporting and low enthusiasm for proactive submission. Most ADR cases were only detected by pharmacists during medication order review, resulting in underreporting of some mild ADRs. Meanwhile, continuous efforts for monitoring novel ADRs remain to be strengthened. Only three new non-serious ADRs were identified over the four-year study period, indicating a need to improve the ability to identify rare and novel ADRs. Furthermore, the standardization of medication use remains suboptimal for certain drug categories, especially for restricted anticancer agents and traditional Chinese patent medicines, with issues including inappropriate drug combinations and improper administration routes, which increase the risk of

ADRs. Additionally, capabilities for identifying and analyzing rare ADR types (such as endocrine and urinary system injury) are insufficient, and experience in the clinical management of such cases remains limited.

Prevention and Control Recommendations

(1) Tiered and Targeted Prevention and Control. Category A (hematological toxicity), anticancer agents, elderly patients, and intravenous administration should be designated as the highest priorities for targeted intervention.

(2) Strengthened Reporting Management. First, clearly define the responsibilities of physicians, pharmacists and nurses. Second, optimize reporting procedures. Third, link training to performance assessments, and improve the spontaneous reporting rate.

(3) Comprehensive Medication Management. First, implement specialized review and therapeutic drug monitoring for anticancer agents. Second, standardize intravenous drug combinations, infusion rates and diluents. Third, strictly adhere to syndrome differentiation principles and dosage guidelines for traditional Chinese patent medicines.

(4) Management of High-Risk Populations. Individualize dosage adjustments and simplify medication regimens for elderly patients, and enhance monitoring of hepatic and renal function as well as therapeutic drug concentrations.

CONCLUSION

From 2022 to 2025, ADRs at our hospital exhibited distinct characteristics, including well-defined high-risk populations, concentrated administration routes, high-incidence drug classes, and focused affected organ systems.

A tiered prevention and control strategy based on Pareto analysis could precisely identify key priorities for ADR prevention and control. Combined with a stratified management approach, targeted interventions could be implemented for core prevention and control targets, including elderly patients, intravenous administration, anticancer drugs, and key affected organ systems.

Finally, by optimizing the ADR reporting mechanism, enhancing comprehensive whole-process medication management, and clarifying prevention and control priorities at each stage, we can effectively improve clinical medication safety. This approach provides scientific support for rational drug use and risk prevention and control in our hospital, thereby safeguarding patient medication safety.

ACKNOWLEDGEMENT

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ABBREVIATIONS

ADR: Adverse drug reaction; **ADRs:** Adverse drug reactions; **CNS:** Central nervous system.

CONFLICT OF INTEREST

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

AUTHORS CONTRIBUTION

Yuanchao Kang: Research concept and design, Collection and/or assembly of data, Data analysis and interpretation, Writing the article, Critical revision of the article, Final approval of the article. Shizhe Chen: Data analysis and interpretation, Writing the article, Critical revision of the article. Yanwen Hao: Research concept and design, Collection and/or assembly of data, Data analysis and interpretation, Critical revision of the article, Final approval of the article. Yan Lin: Research concept and design, Collection and/or assembly of data, Critical revision of the article, Final approval of the article.

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