E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.31838/ijprt/16.01.673

Research Article

Fatal Adverse Drug Reactions: A Retrospective Forensic and Pharmacovigilance Study in DHQ Hospital Charsadda

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Received: 14.03.2026, Revised: 04.06.2026, Accepted: 13.06.2026

ABSTRACT
Background: Adverse drug reactions (ADRs) are an uncommon but important cause of death that can be prevented. More effective integration of clinical and pharmacovigilance and forensic evidence will enhance the identification of the medicine related deaths.
Objective: To determine the clinical patterns, suspected medicines, causality, preventability and forensic characteristics of fatal ADRs at DHQ Hospital Charsadda.
Methods: The study is a retrospective observational study consisting of 86 suspected fatal ADR cases between January and June 2025. The clinical files, medication charts, death records, pharmacovigilance forms, available post mortem and toxicological report were studied. The WHO-UMC system was used to assess causality, and the modified Schumock and Thornton criteria were used to assess preventability. Crude binary logistic regression was used to assess factors related to potentially preventable reactions.
Results: The mean age was 58.6 ± 16.4 years, 55.8% of patients were male and 59.3% had polypharmacy. Anticoagulants and antiplatelet medicines were the leading suspected drug class (23.3%), followed by antimicrobial agents (20.9%) and glucose-lowering medicines (14.0%). Major haemorrhage was the most frequent fatal manifestation (23.3%), followed by anaphylaxis (17.4%) and severe hypoglycaemia (12.8%). Overall, 59.3% of reactions were considered potentially preventable. Medication error (AOR = 8.14; p = 0.010), inadequate monitoring (AOR = 4.72; p = 0.018) and polypharmacy (AOR = 3.21; p = 0.026) were independently associated with preventability. Only 20.9% of cases had been formally reported to a pharmacovigilance centre.
Conclusion: A considerable proportion of suspected fatal ADRs appeared preventable. Stronger medication review, laboratory monitoring, dose adjustment and pharmacovigilance reporting may reduce medicine-related mortality.

Keywords: Adverse Drug Reaction, Fatal Outcome, Pharmacovigilance, Forensic Medicine, Medication Error, Polypharmacy, Preventability.

INTRODUCTION

Adverse drug reactions are harmful and unintentional effects from the use of medicinal products and continue to be a significant concern for patients' safety. Many reactions are not serious and go away, but others can be serious and may lead to long-term hospitalization, disability or death. The clinical effects are especially alarming in the elderly and in persons with multiple diseases who often take multiple drugs at the same time. In a prospective study of medical admissions in England, ADRs accounted for a significant proportion of hospitalisation, and were more prevalent among persons with more multimorbidity and polypharmacy [1-3]. A similar study of spontaneous reports from Germany showed that the vulnerability of older people to adverse medication effects was an important factor in the development of serious harm related to medication use [4].

Although fatal ADRs are a relatively small percentage of all ADRs reported, the public-health significance of fatal ADRs is high because of the number of commonly prescribed medicines involved. There were variations in the pattern of fatal ADRs found in a global analysis of the WHO pharmacovigilance database by age, sex and geographical region [5, 6]. In Korea, the number of fatal events accounted for 0.2% of the national ADR reports with the main suspect drug classes including antibacterial agents, antimycobacterial medicines and analgesics[7]. An analysis of VigiBase by the Iraqi data collection centre, however, revealed that antineoplastic medicines were the most common category [8]. The differences indicate that the profile of fatal reactions is affected by the structure of the reporting system, disease pattern, and population characteristics, as well as by local prescribing practices [9-11].

The combination of patient vulnerability, medication risks, and medication use process weaknesses are often responsible for medication-related deaths. Inappropriate dosage, drug interactions and inadequate laboratory monitoring, polypharmacy, and advanced age can increase the risk of experiencing severe harm. The potential for catastrophic bleeding, prolonged hypoglycaemia with glucose-lowering drugs, and anaphylaxis, organ toxicity or serious skin reactions with antimicrobial drugs. The French IATROSTAT study showed that a significant number of hospital admissions for ADR were preventable [12]. So, prevention involves structured medication reconciliation, medication dose adjustment, and screening and monitoring for medication interactions in a timely fashion [13-15].

The identification of fatal ADRs is difficult because of competing causes of death in the seriously ill patient. Although the presence of a suspected medicine in toxicological analysis of a blood sample does not in itself establish the cause of the illness, especially if the concentration is within the therapeutic range. The temporal relationship, the clinical course, biological plausibility, alternative diagnoses, and postmortem findings and toxicology have to be integrated to provide reliable assessment. Because hospital deaths may not be clearly documented on death certificates or routine administrative records, they may reveal medicine-related deaths that go unreported [16]. In addition, spontaneous pharmacovigilance systems suffer from incompleteness of documentation and under-reporting, which might result in delayed identification of relevant local safety signals [17].

Evidence concerning fatal ADRs in district-level hospitals of Pakistan remains limited, particularly where clinical pharmacovigilance findings are examined together with forensic and toxicological information. Local investigation is necessary because patterns derived from international databases may not reflect medicine availability, prescribing behaviour, monitoring capacity and patient characteristics in Charsadda. Therefore, this study was conducted to describe the demographic and clinical characteristics of suspected fatal ADR cases at DHQ Hospital Charsadda, identify the principal medicines and fatal manifestations, assess causality and preventability, examine available forensic evidence, and determine factors associated with potentially preventable reactions. The findings may support targeted medication-safety interventions and strengthen hospital-based pharmacovigilance reporting.

METHODOLOGY

A retrospective observational study integrating forensic medicine and pharmacovigilance assessments was conducted at District Headquarters (DHQ) Hospital Charsadda from January 2025 to June 2025. The study reviewed deaths in which exposure to a medicine was suspected to have caused or contributed to the fatal outcome. Information was retrieved from inpatient files, emergency department records, intensive care documentation, medication charts, death certificates, adverse drug reaction reporting forms and available medico-legal records. Postmortem, histopathological and toxicological reports were also examined where available. As this was a retrospective record-based investigation, no intervention or alteration in patient management was undertaken.

Total-enumeration sampling was used, where all cases eligible in the six-month study period were evaluated. Sample size was not calculated separately as the study was to include the entire available population of suspected cases of fatal ADRs and was not intended to take a sample of a larger population. 134 cases were identified through screening of the available records against the eligibility criteria for the final analysis, leaving 86 cases. Cases were considered eligible for

the case when the patient had been exposed to one or more medicinal product prior to clinical deterioration, the possible reaction was responsible for or contributed to death and adequate clinical or forensic data were available to determine the temporal relationship between the exposure to the medicinal product and the fatal event. Cases of intentional poisoning, recreational drug toxicity where death was clearly due to trauma and records missing key medication or clinical information were excluded. If multiple medicines were suspected, the medicine that showed the most temporal and clinical relationship was considered the chief suspected medicine and the other medicines were reported as concurrent or interacting medicines.

A structured extraction form was designed for this study to collect data. Demographic data recorded comprised age and sex, area of residence. Clinical data included the initial diagnosis, associated comorbidities, renal or hepatic impairment, previous history of allergy or ADR, hospital department and length of hospital stay (LOS) and number of medicines received. Polypharmacy" was defined as the use of 5 or more medicines at the same time. Details about the suspected medicine were generic name, therapeutic class, indication, dose, frequency and other route and duration of administration. Prescription status, self-medication, overdose, inappropriate dose selection, failure to modify dose for renal/hepatic dysfunction, medication errors and potential clinically significant drug–drug interactions were also documented.

The clinical pattern for each reaction was determined by the symptoms, physical findings, laboratory tests, X-rays, and/or treatment record. The delay between drug administration and onset of the reaction, and between recognition of the reaction and death were recorded when available. Fatal reactions were classified by the main toxicity consisting of major haemorrhage, anaphylaxis, severe hypoglycaemia, acute kidney injury, acute liver failure, respiratory depression, cardiac arrhythmia, severe cutaneous reactions or bone marrow suppression. An ADR would be considered fatal if death was directly caused by the reaction, or if the reaction played a significant part in the chain of events that caused death. If a death took place during treatment, it was not necessarily accepted as a fatal ADR unless a reasonable temporal and clinical association with the medicine suspected to have caused the death was established.

The WHO-Uppsala Monitoring Centre system was used to assess causality, with the following categories: certain, probable/likely, possible, unlikely, conditional/unclassified, unassessable/unclassifiable. The time of drug exposure, drug plausibility, alternative explanations, and drug withdrawal effects and laboratory or toxicological findings were all taken into account. Rechallenge was not required as this would typically not be clinically useful or available in a fatal case. Reactions were also classified as Type A if they were predictable and relate to the established pharmacological activity of the medicine, Type B if they were unpredictable, and other if they were prolonged, delayed, withdrawal or therapeutic failure. The criteria of modified Schumock and Thornton were used to assess preventability and it was determined as "definitely preventable", "probably preventable" or "not preventable". Definitely and probably preventable reactions were counted as "potentially preventable" in the regression analyses.

The immediate and underlying cause of death, manner and place of death, gross postmortem findings and histopathological examination and toxicological results (if available) were used as the basis for forensic evaluation. Only when reliable toxicological reference ranges were documented, the concentration of the suspected drug was classified as therapeutic, toxic or lethal. After an analysis of the clinical, pharmacological and forensic evidence, the suspected drug was deemed to have been a primary cause of death, contributing to the cause, or of uncertainty. The correlation between clinical and forensic cause of death was checked in the cases for which post mortem data was available. These cases were evaluated by relevant qualified reviewers from clinical pharmacology/pharmacovigilance and forensic medicine, respectively, independent of each other. Disagreements were settled by discussion and by review of the entire transcript.

The obtained data were analyzed in IBM SPSS Statistics version 26.0. The Shapiro–Wilk test and the visual inspection of the histograms were used to check the normality of continuous variables. Variables that were not normally distributed were reported as median ± interquartile range (IQR) and those that were normally distributed were presented as mean ± standard deviation. Categorical

variables were presented as frequencies and percentages. The comparison of potentially preventable and non-preventable fatal reactions was done by Fisher's Exact test or Chi Square test, whichever was applicable. Those variables that had p-values < 0.20 in univariate analysis, and were clinically relevant, were included in a binary logistic regression model. Odds ratios (with 95% CIs) were computed to determine independent factors associated with potentially preventable fatal ADRs. All the adjusted estimates were evaluated for multicollinearity and model fit prior to interpretation and a two-sided p-value of < 0.05 was deemed significant.

RESULTS

A total of 86 deaths were included in the study, where an adverse drug reaction (ADR) was suspected. The average age was 58.6 ± 16.4 years and ranged from 18 to 88 years. The age group of greater than 60 years old was the largest, with 42 (48.8%) cases. There were 48 (55.8%) males and 38 (44.2%) females. Fifty-seven (66.3%) patients lived in rural areas. Forty-eight (55.8%) patients had hypertension and 34 (39.5%) had diabetes mellitus. Cardiovascular disease, renal impairment and hepatic impairment were documented in 23 (26.7%), 20 (23.3%) and 11 (12.8%) patients, respectively. Eight (9.3%) patients had a history of drug allergy or adverse reaction. 51 (59.3%) of cases had five or more medicines being used concurrently.

Table 1. Baseline Characteristics of the Study Population (N = 86)

Characteristic	Result
Age, Years	58.6 ± 16.4
Age ≤40 Years	13 (15.1%)
Age 41–60 Years	31 (36.0%)
Age >60 Years	42 (48.8%)
Male	48 (55.8%)
Female	38 (44.2%)
Rural Residence	57 (66.3%)
Urban Residence	29 (33.7%)
Hypertension	48 (55.8%)
Diabetes Mellitus	34 (39.5%)
Cardiovascular Disease	23 (26.7%)
Renal Impairment	20 (23.3%)
Hepatic Impairment	11 (12.8%)
Previous Allergy Or ADR	8 (9.3%)
Polypharmacy	51 (59.3%)

The most common suspected drug category was anticoagulants and antiplatelet drugs, with 20 (23.3%) deaths attributed to these. The most common antimicrobial agents were implicated in 18 (20.9%) cases, with insulin and other glucose-lowering medicines implicated in 12 (14.0%) cases. Ten (11.6%) cases involved analgesics, opioids and non-steroidal anti-inflammatory drugs. A total of 12 patients (14.0%) had consumed the assumed drug without a prescription. In 25 (29.1%) cases a medication-related error was identified and in 23 (26.7%) cases potentially clinically significant drug interactions were found.

Table 2. Distribution of Suspected Drug Classes

Drug Class	N (%)
Anticoagulants And Antiplatelet Medicines	20 (23.3%)
Antimicrobial Agents	18 (20.9%)
Insulin And Other Glucose-Lowering Medicines	12 (14.0%)
Analgesics, Opioids And Nsaids	10 (11.6%)
Cardiovascular Medicines	9 (10.5%)
Antineoplastic Medicines	6 (7.0%)
Antiepileptic Medicines	5 (5.8%)
Anaesthetic Agents	4 (4.7%)
Other Medicines	2 (2.3%)

Total	86 (100.0%)

Major bleeding was the most common fatal reaction, seen in 20 (23.3%) patients. Of the 15 cases of anaphylaxis (17.4%), 11 were cases of severe hypoglycaemia (12.8%). Acute kidney injury or significant electrolyte disturbance occurred in nine patients (10.5%) and acute hepatic failure occurred in eight (9.3%). Other serious adverse outcomes were: respiratory depression, cardiac arrhythmia and severe cutaneous reactions and bone marrow suppression due to infection, all of which were fatal. The median time from exposure to the suspected medicine to the onset of the reaction was 2.0 days (interquartile range: 1.0 - 5.0 days). The median time to death, following clinical recognition of the reaction, was 11 hrs (IQR 4–29 hrs).

Table 3. Clinical Manifestations of Fatal Adverse Drug Reactions

Clinical Manifestation	**N (%)**
Major Haemorrhage	20 (23.3%)
Anaphylaxis	15 (17.4%)
Severe Hypoglycaemia	11 (12.8%)
Acute Kidney Injury/Electrolyte Disturbance	9 (10.5%)
Acute Liver Failure	8 (9.3%)
Respiratory Depression	7 (8.1%)
Cardiac Arrhythmia	6 (7.0%)
Stevens–Johnson Syndrome/Toxic Epidermal Necrolysis	5 (5.8%)
Bone Marrow Suppression With Infection	3 (3.5%)
Other Reactions	2 (2.3%)
Total	86 (100.0%)

Reactions that were found to be certain or probable or likely by the WHO–UMC causality system were 7 (8.1%) and 44 (51.2%), respectively. Thirty (34.9%) cases were classified as possible and 5 (5.8%) as unlikely. Of the deaths, 57 (66.3%) were Type A and were predictable and dose dependent. 19 (22.1%) reactions were definitely preventable and 32 (37.2%) were probably preventable according to preventability assessment. Thus, a total of 51 (59.3%) of the fatalities were taken as potential preventable. Under clinical or laboratory monitoring was found in 28 (32.6%) cases. Inappropriate dosage was found in 21 (24.4%) and failure to adjust doses based on renal and/or hepatic function was found in 15 (17.4%). Of the 18 (20.9%) adverse reactions that were presented that resulted in death, only one had been reported to a pharmacovigilance centre.

Table 4. Causality, Mechanism and Preventability of Fatal Reactions

Assessment	**N (%)**
WHO–UMC Causality	
Certain	7 (8.1%)
Probable/Likely	44 (51.2%)
Possible	30 (34.9%)
Unlikely	5 (5.8%)
Reaction Mechanism	
Type A	57 (66.3%)
Type B	22 (25.6%)
Other Types	7 (8.1%)
Preventability	
Definitely Preventable	19 (22.1%)
Probably Preventable	32 (37.2%)
Not Preventable	35 (40.7%)
Formally Reported To A Pharmacovigilance Centre	18 (20.9%)

Post mortem examination was carried out in 52 (60.5%) cases and toxicological testing was done in 44 (51.2%). In 84.1% of the 44 cases tested, the suspected medicine or a metabolite

of the suspected medicine was found. After a joint discussion of the clinical records, Forensic findings and Pharmacovigilance assessment, the medicine was determined to be the primary cause of death in 54 (62.8%) cases. In 26 cases (30.2%), it was thought to be a contributing factor, and uncertain in 6 cases (7.0%). In 52 postmortem examinations, there was a 82.7% agreement between recorded clinical cause of death and the forensic cause of death.

Table 5. Forensic and Toxicological Findings

Finding	N (%)
Postmortem Examination Performed	52 (60.5%)
Toxicological Testing Performed	44 (51.2%)
Suspected Medicine Detected, N = 44	37 (84.1%)
Medicine Identified As The Primary Cause Of Death	54 (62.8%)
Medicine Identified As A Contributing Factor	26 (30.2%)
Contribution Remained Uncertain	6 (7.0%)
Clinical–Forensic Agreement, N = 52	43 (82.7%)

Medication error was the most significant independent predictor of preventability in the adjusted regression analysis (AOR = 8.14; 95% CI: 1.65–40.15; p = 0.010). Poor monitoring also was independently associated with preventable fatal reactions (AOR = 4.72; 95% CI: 1.30–17.10; p = 0.018). Patients receiving 5 or more medicines were at about 3 times the risk of having a preventable fatal reaction compared to patients not exposed to polypharmacy (AOR = 3.21; 95% CI: 1.15–8.95; p = 0.026).

Table 6. Factors Associated With Preventable Fatal Adverse Drug Reactions

Factor	Preventable N = 51	Non-Preventable N = 35	AOR (95% CI)	P-Value
Medication Error	23 (45.1%)	2 (5.7%)	8.14 (1.65–40.15)	0.010
Inadequate Monitoring	24 (47.1%)	4 (11.4%)	4.72 (1.30–17.10)	0.018
Polypharmacy	37 (72.5%)	14 (40.0%)	3.21 (1.15–8.95)	0.026
Renal Or Hepatic Impairment	23 (45.1%)	8 (22.9%)	2.45 (0.88–6.84)	0.087
Important Drug–Drug Interaction	19 (37.3%)	4 (11.4%)	3.08 (0.85–11.19)	0.087

These findings indicate that fatal reactions were most commonly linked with anticoagulant, antimicrobial and glucose-lowering therapies. A considerable proportion appeared preventable, particularly when medication errors, inadequate monitoring and polypharmacy were present. Formal reporting to the pharmacovigilance system remained limited.

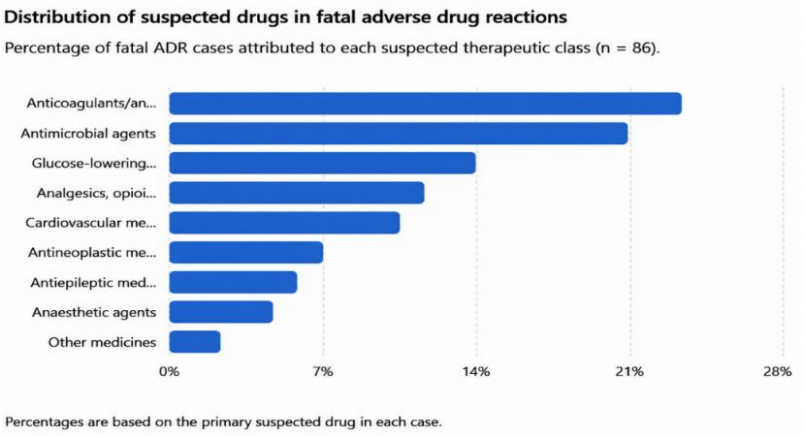

Figure 1. Distribution of Suspected Drug Classes Associated With Fatal Adverse Drug Reactions among the Study Population (N = 86).

Anticoagulants and antiplatelet medicines were the most frequently implicated drug group, followed by antimicrobial agents and glucose-lowering medicines.

DISCUSSION

The present study examined 86 suspected fatal adverse drug reactions through a combined clinical, forensic and pharmacovigilance approach. Nearly half of the patients were older than 60 years, and males represented a modest majority. Hypertension, diabetes mellitus, cardiovascular disease and renal impairment were common, while 59.3% of patients were exposed to polypharmacy. These characteristics indicate that fatal reactions predominantly affected patients with reduced physiological reserve and complex treatment requirements. A worldwide analysis of the WHO pharmacovigilance database similarly found that fatal ADR reports were more frequent among older adults and males [5]. A Korean national database study also identified advanced age, male sex and multiple concurrent medicines as factors associated with fatal events[7]. Conversely, an Iraqi analysis reported a younger mean age of 36 years, although males still outnumbered females [8]. Differences in age distribution may reflect variations in population structure, prescribing practices, disease patterns and the completeness of national reporting systems [18, 19].

In the present study, the most common category of medications suspected was the use of anticoagulants and antiplatelet medicines followed by antimicrobial agents and medicines used to lower glucose. The most common clinical symptoms were then major haemorrhage, followed by anaphylaxis, severe hypoglycaemia, kidney injury and hepatic failure. Anticoagulants may cause severe intra-cranial or gastrointestinal bleeding, especially if drug dosage, renal function and concurrent antiplatelet/anti-inflammatory medications are not thoroughly discussed. The drugs most commonly associated with hospital admission due to ADR were also identified in a prospective study in England [4] In the present study, antimicrobial agents were responsible for 20.9% of cases, which is similar to the 20.3% reported in the Korean pharmacovigilance database [7]. In the Iraqi VigiBase analysis [8], however, the biggest category was anticancer medicines. These differences suggest that local patterns of medicine use, referral practices and type of database analyzed, as well as underlying diseases, have a significant impact on the distribution of fatal ADRs.

One of the main results was that 51 (59.3%) reactions were definitely or likely preventable. Inadequate monitoring, and polypharmacy were the next strongest independent factors associated with preventability, with medication errors being the strongest independent association with preventability. The percentage was significantly higher than the 40% avoidable or potentially avoidable ADRs reported by Osanlou et al. [4]. The French IATROSTAT study also demonstrated that a significant proportion of the admissions for ADRs could have been avoided if the prescriptions and monitoring were safer [12] . The risks of therapeutic duplication, incorrect dosing and clinically significant drug interactions are increased in patients taking multiple drugs. Also, decreased renal or hepatic function increases the risk of drug exposure, if not adjusted for dosage. The fact that the majority of reactions were predictable type A reactions also lend support to the idea of prevention, since these reactions are usually associated with known pharmacological effects. Hence, there may be a significant number of lethal events averted by medication reconciliation, renal-dose adjustment, screening for medication interactions, and routine monitoring of coagulation, blood glucose, renal function, electrolytes and liver enzymes [20].

The combined assessment of the relationship between medicine exposure and death from both the forensic and the pharmacovigilance assessments was further reinforced. The postmortem examination was available in 60.5% and the suspected medication and/or suspected metabolite in 84.1% of the toxicological tests performed. In 82.7% of the postmortem cases there was agreement between clinical and forensic interpretation. However, toxicological findings cannot prove that a medicine was responsible for a death, as a drug could be present in a therapeutic range, or merely have contributed to deterioration that occurred due to an underlying disease. Therefore they must be considered in conjunction with temporal association, pharmacological plausibility, alternative causes, and post-mortem results and concentrations of toxicology. The majority of the reactions were graded as certain, probable and possible, in accordance to the

WHO–UMC grading system, but the number of unlikely cases highlights the inherent uncertainty of retrospective causality assessment. Modern investigations into the causes of fatal ADRs have also shown that retrospective or spontaneous reporting can uncover valuable safety signals, but do not on their own provide conclusive evidence of causation [7]. A similar study from Finland, conducted at a hospital setting, also highlighted the need for thorough review of the death record to find a drug-related cause of death [16].

Despite the severity of the outcomes only 20.9% of the suspected fatal reactions were reported formally to a pharmacovigilance centre, demonstrating the extent of underreporting. Not reporting fatal events can make the identification of local safety signals and limits timely and limit the recognition of patterns by regulatory authorities. Hence, hospital-based pharmacovigilance should be coupled with the meetings of mortality, medication safety committees and forensic case review. However, the results should be considered in light of a number of limitations. The study was retrospective, involved a single hospital and included only 86 cases over six months. The clinical, medication, autopsy and toxicological data may have been incomplete and influenced the assessment of causality and preventability. The lack of non-fatal ADRs or medicine-exposed controls resulted in the inability to estimate incidence and compare the risk; disease severity and indication were not fully controlled. The regression results are preliminary since some regression estimates were broadened confidence intervals. To conclude, future multicentre prospective studies are recommended to adopt standardized ADR forms, have an independent causality review and perform full toxicological testing and link with provincial or national pharmacovigilance databases.

CONCLUSION

Fatal adverse drug reactions at DHQ Hospital Charsadda mainly affected older patients with multiple illnesses and exposure to several medicines. Anticoagulants and antiplatelet agents were the most frequently suspected drug group, and major haemorrhage was the leading fatal manifestation. More than half of the reactions were potentially preventable, with medication errors, insufficient monitoring and polypharmacy emerging as important contributing factors. The limited rate of formal reporting further demonstrated the need to strengthen hospital pharmacovigilance. Regular medication review, dose adjustment according to organ function, early laboratory monitoring, prompt management of suspected reactions and systematic clinical–forensic investigation may reduce preventable medication-related deaths.

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