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Research Article

Assessment of the Quality of Finished Intravenous Infusions Using Failure Mode and Effects Analysis

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Abstract

Background: The post-dispensing process of Pharmacy Intravenous Admixture Services (PIVAS), including verification, packaging, transportation, nurse receipt and verification, and clinical administration, involves multiple high-risk steps associated with intravenous medication safety. However, existing risk management studies have primarily focused on internal preparation procedures within PIVAS, with limited attention to the external circulation processes after admixture preparation. **Methods:** Failure mode and effects analysis (FMEA) was applied to systematically identify, evaluate, and prioritize potential risks in the post-dispensing workflow of finished intravenous infusions. Risk priority numbers (RPNs) were calculated based on severity, occurrence, and detectability scores. High-risk failure modes were defined as those with an RPN ≥120 or a severity score ≥8. Targeted corrective interventions were subsequently implemented for these high-risk processes. **Results:** A total of six high-risk failure modes were identified across the post-dispensing workflow. Following FMEA-based interventions, the total RPN score of these six high-risk failure modes decreased from 707 to 394, representing a 44.3% reduction. In addition, the incidence of real-world risk events decreased significantly between 2020 and 2022 ($p < 0.001$), indicating substantial improvements in medication safety and process quality. **Conclusion:** FMEA is an effective and practical tool for extending quality control from internal admixture preparation to the complete post-dispensing process in PIVAS. The implementation of FMEA facilitated the establishment of a closed-loop risk management framework and improved the safety of intravenous medication administration.

Keywords: failure mode and effects analysis; Pharmacy Intravenous Admixture Services; intravenous medication safety; risk management; quality control

1. Introduction

Pharmacy Intravenous Admixture Services (PIVAS) is a specialized pharmaceutical unit that provides finished intravenous infusions ready for direct clinical use and serves as a critical component in ensuring the safety of intravenous medication administration throughout the hospital. Compared with traditional decentralized ward-based preparation models, PIVAS transforms intravenous infusion preparation from "ward-level self-preparation" into a centralized, standardized, and sterile compounding process under pharmacist supervision. Through pharmacist-led prescription review, standardized operating procedures, and the application of information and automation technologies, PIVAS systematically reduces the risks of contamination, preparation errors, and occupational exposure [1]. In addition, integrated information systems and barcode-based traceability support closed-loop medication management throughout the intravenous medication-use pathway.

However, after the preparation of intravenous admixture products within the PIVAS framework, products still undergo multiple post-dispensing stages, including verification, packaging, transportation, nurse receipt and verification, and clinical administration. A critical component of this process is the integration of electronic patient identification and verification systems to ensure the "right patient, right medication, and right time". During bedside medication administration, dual verification is performed by scanning both the patient's wristband and the drug barcode, while electronic medication records are simultaneously completed within the information system, thereby enabling full traceability and closed-loop management from prescription to administration. This process requires multidisciplinary collaboration and constitutes a highly complex healthcare delivery system. Therefore, the post-dispensing process should not be regarded as isolated operational steps, but rather as an integrated closed-loop medication-use system involving pharmacists, logistics staff, nurses, and patients. Any lapse during these stages may compromise drug stability, lead to medication administration errors, or even cause adverse events. Consequently, it is necessary to extend the scope of PIVAS quality management from internal preparation procedures to the entire post-dispensing process before the finished infusion reaches the patient.

Failure mode and effects analysis (FMEA) is a proactive and systematic risk management tool originally developed by the US military in the 1940s and subsequently adopted in industries such as aerospace to improve project safety and quality. The core principle of FMEA is the structured identification and evaluation of potential failure modes within a process. Each failure mode is assessed according to severity (S), occurrence (O), and detectability (D), and the Risk Priority Number (RPN) is calculated to determine the level of risk and intervention priority. As a preventive risk assessment method, FMEA can systematically identify potential problems before adverse events occur, thereby enabling early intervention and process optimization. In recent years, FMEA has been widely applied in medication management and intravenous medication quality control in healthcare institutions and has demonstrated significant effectiveness [2,3].

Previous studies have confirmed the applicability of FMEA in various medication management scenarios, including intravenous admixture preparation, high-alert medication management, infection prevention, and outpatient dispensing optimization. Liu et al. [4] applied healthcare failure mode and effect analysis (HFMEA) to optimize the insulin preparation process and reduced the overall risk value by 67%. Fei et al. [5] used FMEA to identify and address nonstandard operations within PIVAS, effectively reducing the risks of contamination, preparation errors, and occupational exposure. Pu et al. [6] systematically evaluated the full-process risks associated with antineoplastic drugs in PIVAS and demonstrated that FMEA significantly reduced the RPN values of high-risk steps, thereby improving preparation quality and medication safety. Other studies have further extended FMEA to the management of psychotropic drugs, monoclonal antibody medications, hospital infection control, and interdisciplinary management of high-value drugs [7,8,9,10,11]. Collectively, these findings indicate that FMEA can effectively identify high-risk failure points, quantitatively evaluate risks, and provide structured strategies for quality improvement in complex pharmaceutical service processes.

However, most existing studies have primarily focused on internal operational procedures within the PIVAS framework, with insufficient attention paid to the transitional stages after finished infusions leave PIVAS and before they reach the patient. These stages involve cross-departmental and cross-regional collaboration, multiple manual operations, and frequent information transfer, making them vulnerable to communication gaps, management blind spots, and risk accumulation. To date, few studies have systematically evaluated the risks associated with the complete external circulation process of finished intravenous infusions after preparation.

Therefore, this study extended the FMEA framework from internal PIVAS preparation procedures to the complete post-dispensing workflow of finished intravenous infusions, including verification, packaging, transportation, nurse receipt and verification, and clinical administration. The study aimed to identify and prioritize high-risk failure modes, reduce RPN values, and real-world incident rates through targeted interventions, and establish an evidence-based closed-loop management model for PIVAS.

Accordingly, this study addressed the following research questions:

(1) What are the major high-risk failure modes in the post-dispensing process of finished intravenous infusions within the PIVAS framework?

(2) Can FMEA effectively identify and prioritize these risks through RPN assessment?

(3) Can targeted interventions based on FMEA significantly reduce RPN values and real-world incident rates?

(4) Can the application of FMEA be extended from internal preparation procedures to a closed-loop, full-process management model in PIVAS?

2. Methods

2.1 Study Setting and Data Source

Quality tracking data of finished intravenous product infusions were collected from the PIVAS of the Chenggong Hospital District of the First Affiliated Hospital of Kunming Medical University and Yan'an Hospital of Kunming Medical University, between January 2020 and December 2022. The study was approved by the ethics committees of both institutions. Owing to its retrospective nature and use of anonymized medical records, informed consent was waived. The study adhered to the FMEA implementation guidelines issued by the European Association of Nuclear Medicine(EANM) [12].

2.2 FMEA Implementation Procedure

2.2.1 Risk Assessment Using FMEA

Failure mode and effects analysis (FMEA) was applied to identify and evaluate risks in the post-dispensing process of intravenous infusions. The RPN was calculated using the formula:

$$RPN = S \times O \times D \tag{1}$$

where severity (S) reflected the potential clinical consequences of a failure mode, occurrence (O) represented the likelihood of the failure occurring, and detection (D) indicated the probability that the failure could be identified before affecting the patient. Higher RPN values indicated greater risks and higher intervention priorities [13,14].

The identified failure modes are summarized in Table 1. Each dimension was scored on a 10-point scale according to predefined criteria. Detailed scoring standards for severity, occurrence, and detection are presented in Ta-

bles 2,3,4. The scoring criteria were adapted from ASHRM guidelines and previous FMEA studies and were further refined according to the operational characteristics of the PIVAS workflow and expert consensus. Severity scores were primarily determined based on the potential impact on patient safety and clinical outcomes, occurrence scores based on historical event frequency, and detection scores based on the likelihood of identifying the failure before patient exposure. Final scores were determined through multidisciplinary consensus discussions involving pharmacists, nurses, and quality management personnel. High-risk failure modes were defined as those with an RPN ≥120 or a severity score ≥8. The severity threshold was established in accordance with ASHRM recommendations, which emphasize prioritizing failure modes associated with serious patient harm [15]. In addition, previous studies have suggested that traditional RPN calculations may underestimate high-severity but low-frequency risks because of mathematical limitations [14]. Therefore, an independent severity criterion was introduced to avoid underestimation of clinically critical risks.

The threshold of RPN ≥120 was adopted as a reference standard for identifying high-risk processes in PIVAS [16]. Although no universally accepted RPN cutoff currently exists, combining the RPN threshold with the severity criterion enabled a more practical and clinically oriented risk stratification approach. Accordingly, failure modes meeting either criterion were prioritized for intervention.

2.2.2 Formation of the FMEA Team

A multidisciplinary FMEA team was established, comprising the PIVAS director, senior pharmacists (with ≥3 years of experience and intermediate or higher professional title), and logistics personnel. All team members received standardized FMEA training before study implementation. The team was responsible for process mapping, failure mode identification, risk scoring, and the development of improvement measures.

To ensure the reliability and objectivity of the scoring results, a structured consensus-based evaluation process was adopted. For each failure mode, the S, O, and D scores were determined through multiple rounds of discussion and collective review. Team members contributed perspectives from clinical practice, pharmaceutical management, and operational procedures before consensus on the final scores was reached.

2.2.3 Process Mapping and Risk Identification

A detailed flowchart describing the post-dispensing workflow was developed, covering verification, packaging, transportation, nurse receipt and verification, and clinical administration (Fig. 1). On the basis of this workflow, a comprehensive risk assessment table (Table 1) was established, including 25 potential failure modes identified across all stages of the process. Each failure mode was evaluated and scored by the FMEA team during consensus meetings according to the criteria presented in Tables 2,3,4.

2.2.4 Intervention and Monitoring

For high-risk failure modes (RPN ≥120 or S ≥8), root causes were analysed using brainstorming and onsite observation. Targeted corrective measures were designed and assigned to responsible personnel. The implementation was monitored continuously, and RPN values were re-evaluated periodically until values fell below the risk threshold.

2.2.5 Statistical Analysis

The data were analysed using IBM SPSS Statistics version 29.0 (IBM Corp., Armonk, NY, USA). The incidence rates of risk events were compared across years (2020–2022) using the chi-square test. The Bonferroni method was applied for multiple comparisons (adjusted significance level $\alpha = 0.017$). A p value < 0.017 was considered to indicate statistical significance.

3. Results

3.1 Identification of High-Risk Failure Modes

The post-dispensing process of finished intravenous infusions was systematically evaluated using FMEA, covering five major stages: verification, packaging, transportation, nurse receipt and verification, and clinical administration. A total of 25 potential failure modes were identified across these stages (Table 1).

According to the predefined prioritization criteria (RPN ≥120 or severity score ≥8), six high-risk failure modes were identified as priority targets for intervention. These included failure to verify finished infusions, delayed delivery of drugs to the wards, prolonged storage before administration, incorrect administration sequence, failure to protect light-sensitive medications from light exposure, and inappropriate medication titration rate. Although severity scores reflect the intrinsic clinical impact of failure modes and remained unchanged after intervention, risk reclassification was determined based on RPN values.

As presented in Table 5, root cause analysis revealed that most high-risk failure modes were associated with workflow coordination problems, insufficient staff awareness, inadequate labeling or reminder systems, and deficiencies in communication between PIVAS and clinical departments. Based on these findings, targeted corrective measures were developed and implemented for each high-risk process.

3.2 Effectiveness of FMEA-Based Interventions

Following the implementation of targeted corrective measures for the six high-risk failure modes identified in Table 5, all risk items demonstrated substantial reductions in RPN values and were reduced below the predefined high-risk threshold (RPN < 120).

Table 1. Post-dispensing quality risk assessment table for finished product infusion.

Serial number	Risk segment	Failure mode	Potential impact	Risk assessment			
				S	O	D	RPN
1	Verification	Infusion leakage not identified	Medication errors and safety risks;	7	4	2	56
2		Failure to verify finished infusions	Increased medication risks	8	4	3	96
3		Residual drugs not checked	Reduced medication quality	3	4	2	24
4		Batch confusion	Delayed treatment	2	5	2	20
5	Packaging	Sorter failure	Sorting errors and delays	2	5	1	10
6		Sorting error	Medication loss and delayed administration	6	2	7	84
7		Incorrect bagging	Wrong ward delivery	3	4	4	48
8		Irregular bagging	Inadequate medication precautions	2	5	2	20
9		Incorrect ward boxing	Delayed administration	3	5	4	60
10		Unsealed transport containers	Drug safety risks	2	3	2	12
11		Failure to count outgoing medicines	Medication discrepancies	2	3	2	12
12		Delayed drug return	Billing and inventory discrepancies	3	4	2	24
13		Unscanned packaged drugs	Reduced traceability	3	5	2	30
14	Transportation	Delayed delivery to wards	Delayed treatment	5	6	4	120
15		Infusion leakage during transport	Delayed administration	4	4	3	48
16		Missing transport records	Inadequate traceability	4	5	1	20
17	Nurse acceptance and verification	Incomplete drug verification	Medication discrepancies	3	6	6	108
18		Missing sign-off records	Inadequate traceability	2	5	2	20
19	Clinical administration	Drugs cannot be located	Delay in patient treatment	5	2	5	50
20		Prolonged storage before administration	Reduced drug efficacy and infusion safety risks	6	7	3	126
21		Incorrect administration sequence	Fluctuating drug levels, reduced efficacy, and adverse events	6	4	5	120
22		Failure to protect light-sensitive medications	Degradation of the drug, reducing its efficacy, or producing toxic reactions	5	6	4	120
23		Incorrect infusion rate	Affecting treatment outcomes and even inducing adverse events	5	5	5	125
24		Drug discoloration or turbidity	Adverse drug events	7	2	4	56
25		Adverse drug reactions occurring	Serious adverse events threatening patient safety	7	2	5	70

S, severity; O, occurrence; D, detection; RPN, risk priority number.

Table 2. Scoring criteria for risk level of severity.

Level of severity	Criteria for evaluation	Score
Very serious	Directly causing death or serious injury to the patient	10
Serious	High likelihood of adverse medical events, resulting in serious patient injury	8–9
Moderately serious	Potential for adverse medical events, resulting in patient injury or prolonged hospitalization	6–7
Relatively slight	Injury to the patient may increase medical costs	4–5
Slight	Minimal damage to the patient	2–3
None	Basically no effect	1

As shown in Table 6, the total RPN value decreased from 707 before intervention to 394 after intervention, representing an overall reduction of 44.3%. Among the six high-risk failure modes, the greatest reduction was observed in "failure to verify finished infusions" (66.6%), followed by "Delayed medication delivery to wards" and "Failure to protect light-sensitive medications" (both 50.0%).

In addition, the reductions in occurrence (O) and detection (D) scores indicated that the interventions improved both process reliability and the ability to identify risks before adverse events occurred. These findings demonstrated that FMEA-based interventions effectively enhanced the safety and quality management of the post-dispensing process within the PIVAS framework.

Table 3. Scoring criteria for the risk frequency of occurrence.

Frequency of occurrence	Criteria for evaluation	Score
Extremely high	Very common; it happens all the time	10
High	Common, repeat occurrence	8–9
Moderate	Generally common	6–7
Relatively low	Occasionally happens	4–5
Low	It infrequently happens	2–3
Extremely low	Rare, basically never happens	1

Table 4. Scoring criteria for the degree of risk of detection.

Degree of detection	Criteria for evaluation	Score
Extremely low	Failure to detect potential failure modes	10
Low	Very low probability of detecting potential failure modes	8–9
Relatively low	Potential failure modes not easily detected	6–7
Moderate	High likelihood of detecting potential failure modes	4–5
High	Very high probability of detecting potential failure modes	2–3
Extremely high	Potential failure modes can be identified and detected	1

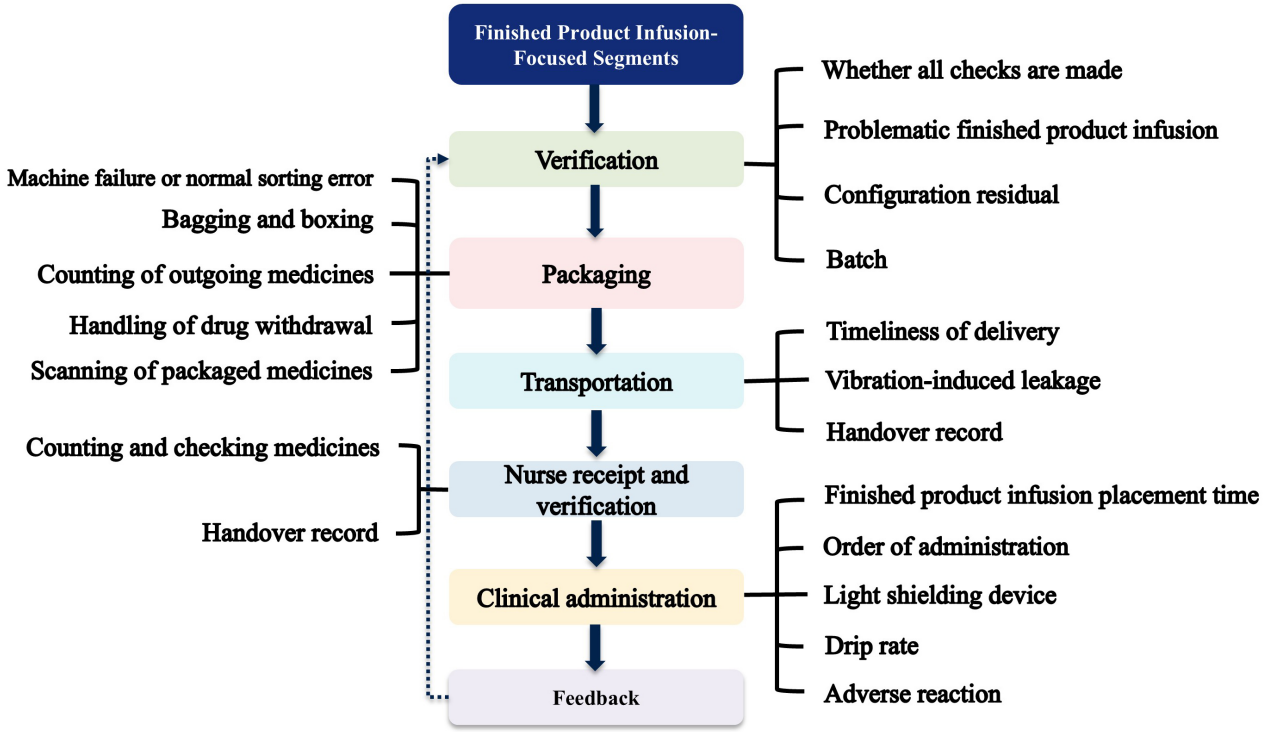

Fig. 1. Flowchart of quality risks in the post-dispensing process of finished product infusions.

3.3 Longitudinal Reduction in Real-World Risk Events

To further evaluate the real-world effectiveness of the FMEA-based interventions, the incidence rates of the six high-risk failure modes were continuously monitored from 2020 to 2022.

As presented in Table 7, the incidence rates of all six high-risk failure modes showed a progressive downward trend over the three-year study period. The total incidence rate decreased from 6.7288‰ in 2020 to 3.8673‰ in 2021 and further to 1.4649‰ in 2022. Among these failure modes, "finished product infusion being placed for too long" consistently exhibited the highest incidence rate, although substantial reductions were observed after intervention. Statistical comparisons of incidence rates across the three study years are summarized in Table 8. Significant differences were identified for all six high-risk failure modes (all $p < 0.001$), indicating that the observed reductions were unlikely to be due to random variation. Furthermore, pairwise comparisons between different years (Ta-

Table 5. High-risk failure modes and corresponding corrective interventions in the post-dispensing workflow of PIVAS.

Serial number	Failure mode	Main root cause	Key interventions	Risk assessment			
				S	O	D	RPN
2	Failure to verify finished infusions	Incomplete double-checking procedures; insufficient checking personnel	• Double-check workflow optimization • Increased pharmacist allocation • Staff training and performance assessment	8	2	2	32
14	Delayed medication delivery to wards	Insufficient transport staffing; elevator delays; poor workflow coordination	• Delivery schedule optimization • Elevator transport coordination • Additional transport personnel • Transport performance monitoring	5	4	3	60
20	Prolonged storage before administration	Early dispensing; insufficient nursing staff; delayed administration	• Standardized catalog for time-sensitive medications • Priority delivery management • Enhanced ward communication	6	5	3	90
21	Incorrect administration sequence	Improper batching; insufficient administration reminders	• Administration sequence guidelines • Infusion label reminders • Clinical staff education	6	3	4	72
22	Failure to protect light-sensitive medications	Lack of warning labels; non-standardized use of light-protective bags	• Light-protection labeling • Separate packaging for light-sensitive infusions • Distribution of protective bags	5	4	3	60
23	Incorrect infusion rate	Inadequate infusion rate reminders; inaccurate adjustment	• Infusion rate labeling • Intravenous medication safety rounds • Clinical communication and staff training	5	4	4	80

PIVAS, Pharmacy Intravenous Admixture Services.

Table 6. Comparison of RPN values before and after FMEA-based interventions.

Serial number	Failure mode	Pre-control				Post-control				RPN drop (%)
		S	O	D	RPN	S	O	D	RPN	
2	Failure to verify finished infusions	8	4	3	96	8	2	2	32	66.6
14	Delayed medication delivery to wards	5	6	4	120	5	4	3	60	50.0
20	Prolonged storage before administration	6	7	3	126	6	5	3	90	28.6
21	Incorrect administration sequence	6	4	5	120	6	3	4	72	40.0
22	Failure to protect light-sensitive medications	5	6	4	120	5	4	3	60	50.0
23	Incorrect infusion rate	5	5	5	125	5	4	4	80	36.0
	Total				707				394	44.3

FMEA, failure mode and effects analysis.

ble 9) demonstrated statistically significant reductions between 2020 and 2021, between 2021 and 2022, and between 2020 and 2022 (all $p < 0.017$). These results suggested that the implementation of FMEA-based risk management strategies not only reduced theoretical risk scores but also achieved sustained improvements in real-world medication safety outcomes.

4. Discussion

4.1 Major Findings

In this study, FMEA was systematically applied to the complete post-dispensing workflow of finished intravenous infusions within the PIVAS framework, including verification, packaging, transportation, nurse receipt and verification, and clinical administration. A total of 25 potential failure modes were identified, among which six were classified as high-risk failure modes requiring priority intervention.

Following the implementation of targeted corrective measures, the total RPN score decreased by 44.3%, and the real-world incidence rates of all six high-risk failure modes showed significant reductions from 2020 to 2022. These findings demonstrated that FMEA effectively improved medication safety, process reliability, and quality management in the post-dispensing stage of intravenous medication administration.

Table 7. Annual incidence rates of six high-risk failure modes from 2020 to 2022.

Serial number	Failure mode	2020		2021		2022	
		Number of cases (times)	Incidence (‰)	Number of cases (times)	Incidence (‰)	Number of cases (times)	Incidence (‰)
2	Failure to verify finished infusions	73	0.5265	44	0.3001	20	0.1344
14	Delayed medication delivery to wards	215	1.5506	120	0.8185	40	0.2688
20	Prolonged storage before administration	370	2.6684	227	1.5483	86	0.5779
21	Incorrect administration sequence	57	0.4111	34	0.2319	15	0.1008
22	Failure to protect light-sensitive medications	117	0.8438	73	0.4979	31	0.2083
23	Incorrect infusion rate	101	0.7284	69	0.4706	26	0.1747
	Total	933	6.7288	567	3.8673	218	1.4649

Note: Incidence (‰) = number of cases of this failure mode/total number of infusions dispensed for that period.

Table 8. Comparison of incidence rates of six high-risk failure modes across the three study years.

Serial number	Failure mode	Year	whether or not		Total	χ^2	p	V	p
			Yes	No					
2	Failure to verify finished infusions	2020	73	1386510	1386583	35.131	<0.001	0.003	<0.001
		2021	44	1466102	1466146				
		2022	20	1488105	1488125				
14	Delayed medication delivery to wards	2020	215	1386368	1386583	137.050	<0.001	0.006	<0.001
		2021	120	1466026	1466146				
		2022	40	1488085	1488125				
20	Prolonged storage before administration	2020	370	1386213	1386583	199.488	<0.001	0.007	<0.001
		2021	227	1465919	1466146				
		2022	86	1488039	1488125				
21	Incorrect administration sequence	2020	57	1386526	1386583	28.437	<0.001	0.003	<0.001
		2021	34	1466112	1466146				
		2022	15	1488110	1488125				
22	Failure to protect light-sensitive medications	2020	117	1386466	1386583	56.995	<0.001	0.004	<0.001
		2021	73	1466073	1466146				
		2022	31	1488094	1488125				
23	Incorrect infusion rate	2020	101	1386482	1386583	48.917	<0.001	0.003	<0.001
		2021	69	1466077	1466146				
		2022	26	1488099	1488125				

Importantly, this study extended the application of FMEA beyond traditional internal admixture preparation procedures to the entire external circulation process before finished infusions reached patients, thereby supporting the establishment of a closed-loop medication safety management model within PIVAS.

4.2 Interpretation of High-Risk Failure Modes

Among the six high-risk failure modes identified in this study, most were associated with workflow transitions, cross-departmental coordination, and human-dependent operations. These findings suggested that the post-dispensing process represented a vulnerable stage within the intravenous medication-use pathway because it involved multiple personnel, information transfers, and operational handoffs.

For example, delayed transportation of medications to wards and prolonged placement of finished infusions were mainly related to communication inefficiencies, insufficient staffing, and inadequate coordination between PIVAS and clinical departments. Similarly, inappropriate administration orders, failure to protect light-sensitive medications from light exposure, and inappropriate medication titration rates were primarily associated with insufficient reminder systems, inconsistent nursing practices, and a lack of standardized operational guidance.

Table 9. Pairwise comparisons of incidence rates among different study years.

Serial number	Failure mode	Year of comparison	χ^2	p
2	Failure to verify finished infusions	2020, 2021	8.906	0.003
		2021, 2022	9.360	0.002
		2020, 2022	34.110	<0.001
14	Delayed medication delivery to wards	2020, 2021	32.527	<0.001
		2021, 2022	41.205	<0.001
		2020, 2022	132.956	<0.001
20	Prolonged storage before administration	2020, 2021	42.732	<0.001
		2021, 2022	65.648	<0.001
		2020, 2022	197.788	<0.001
21	Incorrect administration sequence	2020, 2021	7.174	0.007
		2021, 2022	7.653	0.006
		2020, 2022	27.593	<0.001
22	Failure to protect light-sensitive medications	2020, 2021	12.803	<0.001
		2021, 2022	17.597	<0.001
		2020, 2022	56.313	<0.001
23	Incorrect infusion rate	2020, 2021	7.949	0.005
		2021, 2022	20.112	<0.001
		2020, 2022	49.819	<0.001

The substantial reductions in RPN values after intervention indicated that workflow standardization, barcode-based traceability, staff education, warning labels, and interdisciplinary collaboration were effective strategies for reducing operational variability and improving process safety. In addition, the observed reductions in occurrence and detection scores suggested that the implemented interventions not only reduced the likelihood of failures but also improved the ability to identify risks before patient exposure.

These findings further emphasized that medication safety in PIVAS should not be limited to sterile compounding quality alone, but should instead encompass the entire medication-use process after finished infusions leave the pharmacy [17].

4.3 Comparison With Previous Studies

Previous studies have demonstrated the effectiveness of FMEA in improving medication safety and pharmaceutical quality management in various healthcare settings. Fei et al. [5] applied FMEA to optimize the management of high-alert medications within PIVAS and reported significant reductions in medication-related risks after intervention. Pu et al. [6] similarly demonstrated that FMEA effectively reduced risks associated with antineoplastic drug management, while Liu et al. [4] reported improvements in insulin preparation safety after the implementation of HFMEA.

In addition to medication preparation processes. FMEA has also been applied in various healthcare settings, such as haemodialysis facilities and perioperative anticoagulant management, as well as in methodological and decision-making research [18,19,20,21]. Collectively, these studies confirmed that FMEA is an effective proactive risk management tool for identifying high-risk failure points and supporting targeted quality improvement measures.

However, most existing studies primarily focused on internal operational procedures within PIVAS, such as prescription review, drug compounding, or management of specific medication categories. In contrast, the present study focused on the complete post-dispensing circulation process after finished infusions left PIVAS and before reaching patients. This process involved complex interactions among pharmacists, logistics personnel, nurses, and patients, as well as multiple workflow transitions and information transfer procedures.

Therefore, our findings further expanded the application scope of FMEA from internal preparation quality control to full-process, closed-loop medication safety management.

4.4 Practical Implications for Closed-Loop PIVAS Management

This study provides a practical framework for healthcare institutions seeking to establish closed-loop risk management systems for intravenous medication administration. By systematically identifying high-risk failure modes and implementing targeted interventions, hospitals may improve medication safety, reduce operational risks, and enhance workflow efficiency.

Several interventions implemented in this study demonstrated particular practical value, including barcode-based medication verification, electronic traceability sys-

tems, standardized warning labels, nurse sign-off procedures, and interdisciplinary communication mechanisms. These measures strengthened process transparency and facilitated full-process traceability from prescription review to bedside administration.

Furthermore, the sustained reduction in real-world incident rates over the three-year study period highlighted the importance of continuous quality monitoring, standardized workflow management, and multidisciplinary collaboration in maintaining long-term medication safety improvements. These findings were also consistent with previous studies emphasizing the importance of process standardization and interdisciplinary cooperation in pharmaceutical quality management [17,22].

4.5 Strengths and Novelty of This Study

This study had several notable strengths and innovative aspects. First, unlike most previous studies that focused primarily on internal PIVAS procedures, this study extended FMEA to the entire post-dispensing workflow, including verification, packaging, transportation, nurse receipt and verification, and clinical administration. This broader perspective addressed an important but previously underexplored stage of intravenous medication management.

Second, the study adopted a closed-loop management perspective by integrating electronic traceability, nurse verification, and process monitoring into the risk management framework. This approach enabled more comprehensive identification and control of medication-related risks throughout the medication-use pathway.

Third, this study combined theoretical risk assessment with real-world longitudinal outcome evaluation. In addition to reductions in RPN scores, significant decreases in actual incident rates were observed over a three-year period, thereby strengthening the practical validity of the FMEA-based interventions.

Finally, the study provided a reproducible and clinically applicable framework for implementing proactive risk management strategies in PIVAS settings, which may serve as a useful reference for other healthcare institutions and further support the implementation of risk management requirements proposed in current PIVAS quality management system research [23].

4.6 Limitations and Future Directions

This study had several limitations. First, this was a retrospective observational study based on historical quality management data, which limited the ability to establish direct causal relationships between interventions and outcome improvements. In addition, no parallel control group or randomized intervention design was included, and therefore potential confounding factors could not be completely excluded.

Second, although data were collected from two hospital campuses, both institutions adopted relatively similar PIVAS management models and information system frameworks. Therefore, the generalizability of the findings to other healthcare systems or institutions with different operational environments may be limited.

Third, the traditional RPN calculation model used in FMEA may oversimplify the interactions among severity, occurrence, and detection dimensions. Although multidisciplinary consensus scoring was used to improve scoring reliability, a certain degree of subjectivity inevitably remained.

In addition, this study mainly focused on process-related quality indicators and did not directly evaluate patient-centered outcomes, such as adverse drug events, patient satisfaction, or economic burden.

Future prospective multicenter studies incorporating intelligent information technologies, automated real-time monitoring systems, artificial intelligence-assisted warning systems, and advanced FMEA models such as fuzzy FMEA are warranted to further optimize closed-loop medication safety management within the PIVAS framework [20,24].

5. Conclusions

We identified six high-risk failure modes in the post-dispensing workflow of the PIVAS framework and demonstrated that FMEA-based interventions significantly reduced both RPN values and real-world incident rates. Following targeted corrective measures, the total RPN decreased by 44.3%, while the incidence of risk events showed a sustained downward trend from 2020 to 2022, indicating substantial improvements in medication safety and process reliability.

Importantly, this study extended the application of FMEA beyond internal admixture preparation procedures to the complete post-dispensing process, including verification, packaging, transportation, nurse receipt and verification, and clinical administration. This full-process perspective enabled more comprehensive identification and management of medication-related risks throughout the intravenous medication-use pathway.

Overall, the findings support the feasibility and practical value of establishing a closed-loop risk management framework in PIVAS. The proposed FMEA-based management model may provide a practical and reproducible reference for healthcare institutions seeking to improve intravenous medication safety and quality management.

Availability of Data and Materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Author Contributions

YNM and FYZ designed and executed the study, organized the experimental sessions, and were in charge of writing the main body of the manuscript. WC, JRL, YPY, and DLB conceived the study, participated in the research process, and assisted in drafting parts of the manuscript. MG was responsible for the data analysis of the project. YLH contributed to proofreading and explanation of the original manuscript, and also took charge of in the design of the graphic abstract. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

This study was conducted in accordance with the guiding principles of the Declaration of Helsinki. Ethical approval was obtained from The First Affiliated Hospital of Kunming Medical University (Chenggong Hospital District PIVAS) with approval numbers: (2025) Ethical Review L No.240 and Yan'an Hospital Affiliated to Kunming Medical University, with approval numbers: 2025-069-01, respectively. As this quality assessment study involved a retrospective analysis without direct patient contact and relied solely on existing anonymized laboratory data, the ethics committee approved the exemption from obtaining individual informed consent from participants. All data collection and procedures were strictly compliant with relevant ethical regulations and confidentiality requirements.

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Conflicts of Interest

The authors declare no conflicts of interest.

Declaration of AI and AI-Assisted Technologies in the Writing Process

During the preparation of this work, the authors used Deepseek to check spelling and grammar. After using this tool, the authors thoroughly reviewed and edited the content as needed and take full responsibility for the integrity of the publication.

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