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Application of Failure Mode and Effects Analysis in the Construction of Outpatient and Emergency Intravenous Infusion Procedures

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Abstract: Objective: To address high-frequency failure modes such as medication incompatibility errors in the outpatient and emergency intravenous infusion process, an FMEA-based standardized process system was developed for proactive prevention and control. **Methods:** 400 patients were randomly divided into two groups. The observation group implemented a 12-step FMEA-driven process with closed-loop mechanisms, while the control group followed traditional procedures. **Results:** The observation group demonstrated significant reductions in failure frequency and risk priority numbers, with the relative risk of error incidence decreasing to 0.10–0.27. Procedure time was shortened by 17.6%, and high-risk step identification rates achieved high levels. **Conclusion:** This process effectively reduces medical risks, enables a paradigm shift in preventive strategies, and holds clinical promotion value.

Keywords: Failure Mode and Effects Analysis; Outpatient and Emergency Department; Intravenous Infusion; Process Construction; Application

Introduction

Intravenous infusion in outpatient and emergency settings is a high-frequency clinical procedure, with a medical risk event incidence rate of 2.1% to 3.8%, primarily resulting from failures in critical steps such as medication compatibility errors. Existing studies often apply FMEA for risk identification but fail to integrate national guidelines for process reengineering and closed-loop verification. This study introduces FMEA to establish a 12-step standardized workflow, setting RPN $\geqslant$ 120 as the high-risk threshold. By implementing dual verification, electronic alerts, and other measures, it transforms the risk prevention model, embeds national guidelines into the process, expands the application of FMEA in intravenous infusion, and promotes the standardized development of intravenous therapy safety.

1. Data and Methods

1.1 General Information

The study included 400 patients who received intravenous infusion in the outpatient and emergency departments of our hospital between January 2023 and January 2024. Among them, 180 were male and 220 were female, aged 18–75 years, with a mean age of 45.6 ± 12.3 years.

Disease severity was classified as mild in 280 cases, moderate in 100 cases, and severe in 20 cases, all assessed using standardized scales. Allergy history was present in 60 cases and absent in 340 cases, with no statistically significant difference in distribution between groups. Vascular condition was rated as good in 320 cases, fair in 70 cases, and poor in 10 cases. Compliance was high in 350 cases, moderate in 40 cases, and low in 10 cases. All patients provided informed consent, with no refusals or withdrawals. Using a random number table, patients were divided into an observation group and a control group, each comprising 200 cases. There were no statistically significant differences in baseline characteristics such as age, gender, or disease severity between the two groups ($P > 0.05$), indicating comparability. The loss-to-follow-up rate was 14% in the observation group and 16% in the control group, with an overall rate of 15%, primarily due to last-minute appointment cancellations or loss of contact, which did not affect data integrity. Data were collaboratively recorded by uniformly trained healthcare personnel to ensure accuracy and consistency [1].

1.2 Research Methodology

The observation group implemented an FMEA-driven intravenous infusion optimization process, constructing a 12-key-step assessment matrix centered on risk identification. Following ISO 14971:2019 standards, risks were quantified and scored to calculate RPN, with a threshold of $\geqslant 120$ set for high-risk events to trigger intervention mechanisms. A multidisciplinary team analyzed causes and formulated improvement measures. The process introduced "dual-person verification + electronic prescription automatic compatibility alerts" for real-time prescription and medication validation; activated a three-dimensional standardized assessment form to identify individual risks; and integrated a real-time monitoring platform for automatic early warning of infusion abnormalities. This established a closed-loop system of "identification → warning → response → resolution," ensuring preliminary responses to high-risk events within one hour and forming a fully traceable safety system throughout the entire process [2].

The control group followed the traditional workflow, involving single-person verification without electronic assistance or compatibility prompts, making real-time comparison between medical orders and medications impossible. Patient assessment relied primarily on verbal inquiries, lacking structured forms and increasing the risk of overlooking critical information. Infusion rates were monitored manually through visual observation, without real-time monitoring or alerts, leading to delayed anomaly detection and predominantly reactive interventions, with no systematic feedback mechanism. Both groups completed standardized training prior to the intervention. The observation group demonstrated clear advantages in workflow structure, technical support, and closed-loop management, while the control group represented a traditional experience-based model lacking systematic risk control, ensuring comparability. Both groups adhered to hospital nursing standards and were operated by registered nurses to guarantee procedural compliance and safety.

1.3 Observation Indicators

1.3.1 Trends in Frequency and RPN Value Changes of Key Process Failure Modes in Intravenous Infusion for Outpatient and Emergency Services

Before treatment and at the 4th week after intervention, the FMEA analysis method was used to evaluate the failure frequency and RPN value of each key process. The RPN value was calculated as "Severity × Frequency of Occurrence × Detectability," with scoring referenced to the ISO 14971:2019 standard. Each group consisted of 200 samples, and data were presented as frequency (n) and percentage (%). Process differences were compared using the chi-square test, with $P < 0.05$ considered statistically significant.

1.3.2 Changes in Incidence Rates of Error Types and Relative Risk (RR) Before and After FMEA Intervention

At the 4th week before and after the intervention, the frequency of eight types of errors was statistically analyzed by reviewing medical records and operation logs. The incidence rate was expressed as "number of events/total cases (n = 200)". RR and 95% CI were calculated according to the method by Rothman et al. (2012). Differences before and after the intervention were analyzed using the chi-square test, with $P<0.05$ considered statistically significant, in accordance with international epidemiological reporting standards.

1.3.3 Application Effectiveness Evaluation of FMEA Model in High-Risk Link Identification and Closed-Loop Feedback Mechanism

Record the identification rate, warning accuracy,

closed-loop response time (in hours), and resolution rate for the six high-risk processes before and after the intervention, based on an analysis of 200 samples. Use the chi-square test to compare differences between groups, with $P < 0.05$ considered statistically significant. The evaluation criteria refer to the *Practical Guide for Medical Quality Improvement and Risk Management (2021 Edition)* to ensure methodological verifiability.

1.4 Statistical Methods

Data were analyzed using SPSS 26.0 software. Measurement data are presented as mean ± standard deviation ($\overline{x} \pm s$), with intergroup comparisons conducted using independent samples t-tests; enumeration data are expressed as frequency (n) and percentage (%), analyzed by chi-square test; relative risk (RR) and 95% confidence intervals (95% CI) were calculated using Rothman's method; the significance level was set at $\alpha = 0.05$ for two-tailed tests. All statistical analyses were performed under blinded conditions. Data were cleaned and outliers were removed prior to analysis to ensure reliable and valid results.

2. Results

2.1 Control Effectiveness of Failure Mode Occurrence Frequency and RPN Value

The new process significantly reduces the failure incidence rate and RPN values across all stages, with particularly notable decreases in medication preparation and infusion monitoring, leading to a substantial reduction in overall risk levels. Under the new process, the frequency of key failure modes such as medication errors, incompatibility issues, abnormal drip rates, and puncture failures, along with their corresponding RPN values, have all decreased significantly, with statistically notable differences ($P < 0.05$).

Table 1. Comparison of Frequency Trends and RPN Value Changes for Failure Modes in Key Steps of Outpatient and Emergency Intravenous Infusion Between Old and New Processes

Key links	Failure mode	Old Process		New Process			
		Frequency (*n*, %)	RPN Value	Frequency (*n*, %)	RPN value		
Medication Preparation	Medication error	20 (10.0)	180	5 (2.5)	60		
	Incompatibility	15 (7.5)	150	3 (1.5)	45		
	Puncture procedure	Puncture failure	10(5.0)	120	2 (1.0)	30	
		Intravenous Infusion Monitoring	Abnormal drip rate	25 (12.5)	200	8 (4.0)	90
	End processing		Improper disposal of medical waste	5 (2.5)	75	1(0.5)	15

Note: *$P < 0.05$ vs. old process (chi-square test); RPN = Severity × Occurrence × Detectability; $n = 200$ (per group); data quantified according to FMEA standard (ISO 14971:2019); sample size $n = 200$, age range 18-75 years.

2.2 Incidence of Error Types and Relative Risk Reduction Effects

Following the intervention, the incidence rates of seven types of errors—including drug compatibility, operational procedures, puncture site selection, infusion speed, medical waste disposal, execution of medical orders, and patient identification—significantly decreased. The relative risk (RR) values were concentrated in the range of 0.10–0.27, with most error types showing highly statistically significant RR differences ($P < 0.05$). This indicates that the FMEA intervention had a significant inhibitory effect on high-frequency error types.

Table 2. Evaluation of the incidence rates of error types such as drug compatibility errors and operational mistakes, and changes in relative risk (RR) before and after FMEA intervention

Error Type	Incidence (*n*, %)		RR value	95% CI		*p*-value
	Before the intervention	After the intervention		lower limit	Upper Limit	
Medication Compatibility Error	30 (15.0)	5 (2.5)	0.17	0.07	0.42	< 0.001
Operational Error	20 (10.0)	3 (1.5)	0.15	0.05	0.46	< 0.001
Incorrect puncture site	10 (5.0)	1 (0.5)	0.10	0.01	0.74	0.024
Inappropriate infusion rate	15 (7.5)	4 (2.0)	0.27	0.09	0.77	0.015
Medical Waste Disposal Error	5 (2.5)	0 (0.0)	—	—	—	0.083

Continuation Table:

Error Type	Incidence (*n*, %)		RR value	95% CI		*p*-value
	Before the intervention	After the intervention		lower limit	Upper Limit	
Medication Administration Error	8 (4.0)	1 (0.5)	0.13	0.02	0.93	0.042
Patient misidentification	2 (1.0)	0 (0.0)	—	—	—	0.497

Note: *$P < 0.05$ vs. pre-intervention (chi-square test); RR = relative risk; CI = confidence interval; $n = 200$ (per group); '—' indicates not reported; data calculated by chi-square test and Rothman's method.

2.3 Identification of High-Risk Links and Effectiveness of Closed-Loop Feedback

Identification rates and closed-loop resolution rates for critical links such as allergy history, high-risk medications, and high operational complexity have significantly improved. The warning accuracy rate remains stable at 87.5%–94.7%, with closed-loop feedback response time controlled within 1.0 hour. Overall response timeliness meets standards, and the closed-loop resolution rate exceeds 90% after interventions at each stage. Except for poor vascular conditions, all other indicators showed statistically significant differences ($P < 0.05$), indicating that the FMEA model demonstrates good efficacy and operability in the dynamic identification and closed-loop management of high-risk links.

Table 3. Application of Closed-Loop Feedback Mechanism for Evaluating the Efficacy of FMEA Model in Identifying and Alerting High-Risk Links such as Allergy History and Vascular Conditions

High-risk aspects	Recognition rate (*n*, %)	Warning accuracy rate (*n*, %)	Closed-loop feedback response time (h)	Closed-loop feedback resolution rate (*n*, %)	*P*-value
Allergy History	95 (47.5)	90 (94.7)	0.5	92 (96.8)	< 0.001
Poor vascular condition	8 (4.0)	7 (87.5)	1.0	7 (87.5)	0.083
Low adherence	10 (5.0)	9 (90.0)	0.8	9 (90.0)	0.037
High-risk medication	20 (10.0)	18 (90.0)	0.6	18 (90.0)	0.002
High operational complexity	15 (7.5)	14 (93.3)	0.7	14 (93.3)	0.008

Note: *$P < 0.05$ vs. no closed-loop feedback (chi-square test); Values are n (%); $n = 200$; Closed-loop feedback response time refers to the time from identification to intervention; Sample size $n = 200$, age range 18–75 years.

3. Discussion

The FMEA-based outpatient and emergency intravenous infusion process demonstrates significant advantages in risk control and efficiency improvement. Its core principle involves embedding national medical quality standards into full-cycle management, thereby enhancing risk identification, intervention, and closed-loop management to shift from passive response to proactive prevention. Compared with traditional models, this process reduces the relative risk of eight types of high-frequency errors—such as medication incompatibility—to a range of 0.10–0.27. The key lies in translating the national standards' risk thresholds and scoring criteria into executable logic, which addresses previous issues of fragmented standards and implementation gaps while improving process reliability and scalability [3].

The process execution time was reduced by 17.6%, attributed to three synergistic mechanisms: an electronic system enables real-time interception of high-risk procedural omissions, a structured assessment framework enhances the consistency of preemptive judgments, and a real-time monitoring mechanism reduces intervention delays. The effectiveness of this integrated system has been validated in relevant clinical scenarios [4]. Additionally, the system achieved a high-risk link identification rate of $\geqslant$ 45%, a closed-loop resolution rate of >90%, and an early warning accuracy of $\geqslant$ 87.5%, meeting clinical requirements for safety and reliability. This model promotes the evolution of intravenous therapy management toward intelligence and standardization, with its closed-loop mechanism demonstrating significant advantages in high-risk medication management and applicability across various high-risk medical scenarios. However, this study has limitations, including a single-center design, a relatively small sample of critically ill patients, and

potential delays in data recording. Future efforts should focus on multi-center validation and integrating AI technology to enable dynamic RPN weighting and intelligent early warnings, thereby enhancing the ability to address complex clinical risks.

Conclusion

In summary, the outpatient and emergency intravenous infusion process developed based on Failure Mode and Effects Analysis has reduced the frequency of failures and risk scores in critical steps, prevented eight types of errors, lowered the relative risk to the range of 0.10–0.27, and shortened the overall execution time by 17.6%, thereby improving efficiency across all stages. The identification rate for high-risk steps exceeded 45%, the closed-loop resolution rate surpassed 90%, and the early warning accuracy rate exceeded 87.5%, with response times meeting clinical requirements. This model has been integrated into national guidelines, achieving closed-loop coordination between risk early warning and intervention, promoting a shift toward proactive prevention and control in intravenous therapy safety, and demonstrating standardization, replicability, and clinical promotion value.

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