Application of Failure Mode and Effect Analysis in the Emergency Management Process of ECMO in Children

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Abstract [**Objectives**] To analyze the application effect of failure mode and effect analysis (FMEA) in the management of ECMO emergency treatment procedures in children. [**Methods**] The FMEA project team was established, the theme was determined, the workflow diagram of ECMO was drawn, the failure mode of the emergency treatment process management of children was determined, the root cause of the failure mode was analyzed, and improvement measures were formulated and implemented. [**Results**] Compared with before the improvement, the time of ECMO personnel in place, item preparation time, pipe prefilling time and bedside catheterization time were significantly shortened (all $P < 0.05$), and the satisfaction of medical and nursing cooperation and parents of the children were significantly increased (all $P < 0.05$). [**Conclusions**] FMEA can optimize the emergency treatment management process of ECMO, shorten the start time of ECMO, improve medical cooperation and parental satisfaction, and help improve the success rate of ECMO treatment in children.

Key words Failure mode and effect analysis, Children, ECMO, Process management

1 Introduction

Extracorporeal Membrane Oxygenation (ECMO) involves draining a patient's blood from the body, oxygenating it through a membrane lung, and then returning it to the body using a centrifugal pump to provide extracorporeal respiratory and/or circulatory support[1]. It has become the primary mechanical support modality for critically ill pediatric patients[2]. However, nursing management for pediatric ECMO is characterized by complex procedures, multiple challenges, significant difficulty, and a lack of established nursing protocols[3]. Failure Mode and Effects Analysis (FMEA) is a proactive management tool that effectively identifies and mitigates potential system risks to prevent adverse events[4]. To address the high complexity, high risk, and high complication rates associated with pediatric ECMO, this study applied FMEA to achieve continuous quality improvement in the pediatric ECMO emergency management process, with notable effectiveness.

2 Methods

2.1 Topic identification Identify the improvement theme: Optimize the "One Patient, One Team" ECMO emergency management process.

2.2 Establishment of the FMEA Project Team A multidisciplinary pediatric ECMO management team was established under the overall guidance of the deputy president in charge. The team consisted of core members from administrative departments including the Medical Affairs Office, Nursing Department, and Hospital Infection Control Office, as well as clinical departments such as the Pediatric Department, Emergency Department, and Intensive Care Unit. All members held intermediate or higher professional titles, had received FMEA training, and possessed proficiency in applying FMEA as a quality improvement tool.

2.3 Flowchart plotting and identification of failure modes and causes The team members systematically reviewed the pediatric ECMO process management procedures, ultimately identifying 5 main processes comprising 21 sub-processes, as shown in Fig. 1. Using on-site observation and brainstorming methods, the team analyzed the function and failure modes of each sub-process and conducted a potential cause analysis for the identified failure modes.

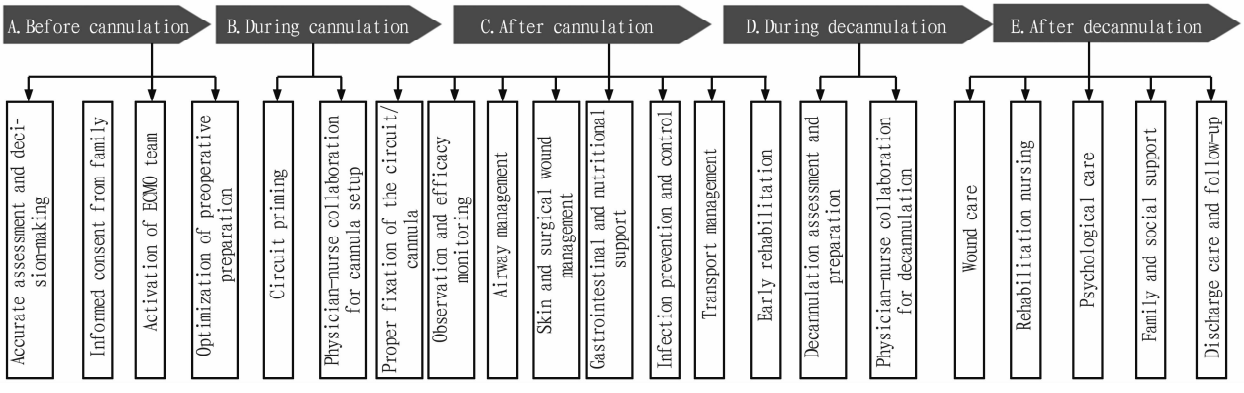

Fig. 1 Flowchart for ECMO management in children

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2.4 Calculation of Risk Priority Number (*RPN*) values and prioritization of failure modes The risk level of a failure mode

is represented by the RPN, calculated using the formula: $RPN = S \times O \times D$, where S, O, and D denote the severity of the failure consequence, the probability of occurrence of the failure mode, and the detectability of the failure mode, respectively. Each variable is assigned a value on a scale of 1 to 10. A higher *RPN* indicates a greater potential safety risk. Failure modes were prioritized based on their *RPN* scores, followed by decision analysis. Given the involvement of multiple departments and limited research resources in this study, the eight failure modes with the highest RPN values were selected as the key issues for improvement in this initiative. These were: insecure fixation of the ECMO circuit/cannula, inadequate observation and monitoring, prolonged ECMO cannulation time, insufficient preoperative preparation, non-standard priming procedures, incomplete infection prevention and control measures, suboptimal psychological care outcomes, and prolonged team response time (Table 1).

Table 1 Failure mode analysis in the emergency management process of ECMO in children

Main process	Sub-process	Failure mode	Potential risk cause	*S*	*O*	*D*	*RPN*	Risk priority order
Before cannulation	A1 Accurate assessment and decision-making	Prolonged assessment time	Lack of specialized knowledge; incomplete test results	8	4	4	128	14
	A2 Informed consent from family	Discrepancy between family expectations and actual outcomes	Insufficient information provided to the family	8	3	5	120	15
	A3 Activation of ECMO team	Prolonged team response time	Lack of a daily team management mechanism	9	9	5	405	8
	A4 Optimization of preoperative preparation	Insufficient preoperative preparation	Absence of a preparation checklist; inadequate skin preparation of the pediatric patient; difficulty in establishing arteriovenous access	8	9	6.45	464	4
During cannulation	B1 Circuit priming	Non-standard priming procedure	Non-standard priming method; lack of proficiency in circuit priming procedures	8	7.75	6.25	436	5
	B2 Physician-nurse collaboration for cannula setup	Prolonged ECMO cannulation time	Noisy environment; lack of specific division of responsibilities; absence of emergency command leadership; unclear role definition for nurses	10	8	8	512	3
After cannulation	C1 Proper fixation of the circuit/cannula	Insecure fixation of the ECMO circuit/cannula	Ineffective rounding; improper cannula/circuit fixation method; patient agitation; lack of prevention and control measures	9	7.75	7.25	562	1
	C2 Observation and efficacy monitoring	Inadequate observation and efficacy monitoring	Incomplete specialty indicator monitoring content; lack of proficiency in observation and monitoring methods Delayed emergency response; absence of a communication mechanism	8	8	7.75	558	2
	C3 Airway management	Improper airway care outcomes	Failure to perform timely and effective suctioning; failure to implement oral care; non-compliance with aseptic technique standards	8	7.45	6.25	373	10
	C4 Skin and surgical wound management	Skin care measures	Ineffective pressure relief during cannulation; insufficient nursing attention; lack of nursing knowledge regarding wound care	8	4.5	3	108	18
	C5 Gastrointestinal and nutritional support	Nutritional deficiency	Inaccurate assessment; patient intolerance to parenteral nutrition; inadequate intravenous nutrition supplementation	10	3	3	72	21
	C6 Infection prevention and control	Incomplete infection prevention and control measures	Lack of knowledge; poor patient resistance; suboptimal ward environment; failure to implement aseptic technique	9	7	6	420	6
	C7 Transport management	Insufficient risk prevention during transport	Lack of professional assessment	8	7	6	378	9
	C8 Early rehabilitation	Insufficient assessment of rehabilitation exercises	Lack of specialized knowledge; outdated concepts	6	7	6	336	11
During decannulation	D1 Decannulation assessment and preparation	Insufficient preparation of supplies	Unclear about the supplies required for decannulation	7	5	3	90	19

(To be continued)

(Continued)

Main process	Sub-process	Failure mode	Potential risk cause	*S*	*O*	*D*	*RPN*	Risk priority order
	D2 Physician-nurse collaboration for decannulation	Unfamiliarity with the decannulation procedure	Noisy environment; lack of specific division of responsibilities; absence of emergency command leadership	7	4	3	84	20
After decannulation	E1 Wound care	Delayed wound healing	Wound infection; improper care	7	4	4	112	17
	E2 Rehabilitation exercise	Failure to implement rehabilitation guidance	Insufficient attention; single-dimensional guidance approach	9	5	5	175	12
	E3 Psychological care	Improper psychological care outcomes	Low awareness of psychological care among nurses; failure to accurately assess the pediatric patient's mental health status	7	7.25	6.25	408	7
	E4 Family and social support	Lack of family and social support	Insufficient family involvement; negative emotions among family members	6	4	5	140	13
	E5 Discharge care and follow-up	Incomplete discharge instructions	Incomplete discharge guidance content; untimely follow-up with family members	8	5	4	120	15

2.5 Identification of root causes of failure modes Based on the Vincent Clinical Event Analysis Model[5], a problem analysis and summary were conducted from six dimensions: team factors, task factors, organizational management factors, environmental factors, individual factors, and patient factors. The root causes of failure modes in emergency management process of ECMO in children were identified as: inadequate linkage mechanisms, imperfect standard procedures, non-standardized cannulation management, insufficient professional knowledge, and lack of continuous quality improvement.

2.6 Development and implementation of improvement measures Through joint discussion and analysis by the team members, practicable measures were formulated for high-risk factors in each step and applied in clinical practice. The specific improvement measures and their rationale are as follows:

2.6.1 Before ECMO: establishing a rapid response coordination mechanism with four key measures to improve emergency response speed. (i) One-touch activation via a WeChat group to promptly place the project team on standby. (ii) One preoperative preparation checklist designed to ensure accurate and rapid supply readiness, capture key preparation priorities, implement proactive skin protection (using self-made neonatal water beds and advanced dressings to prevent pressure injuries) and facilitate ultrasound-guided cannulation to address critical preoperative challenges. (iii) One standardized priming protocol that integrates pressure monitoring channels before the pump, before the oxygenator, and after the oxygenator, enabling real-time pressure monitoring, providing a basis for volume assessment, and allowing evaluation of oxygenator performance. (iv) One programmed cannulation procedure chart that delineates roles, positioning, and steps, resulting in more precise and efficient cannulation.

2.6.2 During ECMO operation: Implementing integrated medical-nursing management with a focus on three key aspects to enhance management precision. Aspect 1: Circuit/cannula safety. (i) Utilize O + X fixation bandages, improve fixation methods, and apply foam patches for isolation to protect the patient's skin. Secure both the proximal and distal ends of the circuit/cannula simultaneously to ensure safety. (ii) Develop a routine circuit/cannula care procedure, establish warning lines and protective barriers, install audible and visual alarms for the safety range, use distinct color-coded markers, and implement emergency protocols for accidental dislodgement to achieve precise prevention and control of dislodgement risks. (iii) Integrate "effective assessment – standardized medication administration-innovative restraint" as a three-in-one approach to standardize sedation and analgesia, thereby ensuring secure fixation of the circuit/cannula. Aspect 2: Observation and monitoring. (i) Utilize specialized monitoring records and precision infusion pumps to achieve more accurate fluid intake measurement and more comprehensive documentation. (ii) Use self-made urine measurement containers and skin color comparison charts to achieve more precise measurement and observation; (iii) Conduct bedside examinations combined with a green channel to enable early access to test results; (iv) Identify potential equipment issues early through: first, checking the water level line; second, assessing the blood-to-gas ratio; and third, listening for pump head sounds; (v) Utilize standardized communication models for exchange, establish a three-tier (red-yellow-green) warning and management mechanism along with emergency protocols to enable timely problem identification and rapid response. Aspect 3: Infection prevention and control. (i) Strictly adhere to aseptic techniques and restrict personnel entry and exit; (ii) Expand the scope of hand hygiene and surgical skin disinfection—particularly in the NICU—extending hand hygiene to all areas that may come into contact with the patient or circuit, and ensure adequate availability of alcohol-based hand sanitizers; (iii) Use electric clippers specifically designed for infants to avoid skin injury; (iv) Utilize air purification systems in the ward, and disinfect equipment and floors in the morning and evening; (v) Closely monitor temperature changes and perform blood, urine, and sputum cultures as ordered; (vi) Place patients in single-room isola-

tion with dedicated physicians and nurses assigned to their care to maximize prevention of cross-infection.

2.6.3 After ECMO decannulation: Implementing magnetic nursing extended services. Through coordinated efforts both within and outside the hospital, magnetic nursing extends care beyond the hospital setting. During hospitalization, a "Love Handbook" is used to understand the child's preferences, while nurses act as temporary mothers, providing companionship and compassionate care throughout to alleviate the anxiety and fear of hospitalized pediatric patients. Children who have been discharged from the unit are invited to return to the ward to help address any psychological concerns remaining from their hospital stay. After discharge, follow-up care activities, such as telephone calls, WeChat video consultations, and Internet Plus Home Care services, are conducted to provide comprehensive support and care for the child.

Based on the above measures, multidimensional empowerment is achieved through a training model that combines "online and offline approaches, theory and practice integration, and medical and nursing collaboration" to enhance ECMO expertise. By establishing pediatric ECMO quality management standards (including shift-by-shift handovers, daily consultations, weekly summaries and planning, and case-by-case analysis and improvement) and conducting real-time debriefings, a "One Patient, One Team, One Improvement" continuous quality improvement mechanism is established to ensure quality and safety.

2.7 Effect assessment The *RPN* values of each failure mode in the pediatric ECMO emergency management process were compared before and after the implementation of FMEA management. In addition, the ECMO cannulation-related time, as well as the satisfaction levels of medical staff and parents of pediatric patients, were compared between the two periods.

2.8 Statistical methods SPSS 21.0 statistical software was used for data analysis. Qualitative data were described using frequencies and percentages, and analyzed using the chi-square (χ^2) test or rank-sum test. Quantitative data were described using mean ± standard deviation ($\bar{x} \pm s$) and analyzed using the *t*-test. A *P*-value <0.05 was considered statistically significant.

3 Results and analysis

3.1 Effects of FMEA management on risks in the ECMO emergency management process in children After the implementation of FMEA management, the *RPN* values of the major failure modes in the ECMO emergency management process in children decreased compared with those before implementation. Among these, the *RPN* values for "prolonged team response time" and "suboptimal psychological care outcomes" showed the most significant reductions (Table 2).

Table 2 Comparison of RPN values of major failure modes in the ECMO emergency management process in children before and after implementation of FMEA management

Failure mode	Before implementation	After implementation
Insecure fixation of the ECMO circuit/cannula	562	352
Inadequate observation and monitoring	558	351
Prolonged ECMO cannulation time	512	370
Insufficient preoperative preparation	464	386
Non-standard priming procedure	436	206
Incomplete infection prevention and control measures	420	276
Bad psychological care outcomes	408	212
Prolonged team response time	405	130

3.2 Effects of FMEA management on clinical efficiency and satisfaction in ECMO in children Implementation of FMEA management led to significant improvements in clinical efficiency metrics for ECMO emergency management in children. Compared with the pre-implementation period, the post-implementation period showed markedly reduced times for team assembly, supplies preparation, circuit priming, and bedside cannulation, with all differences reaching statistical significance (all $P < 0.001$). In addition, both physician-nurse collaboration satisfaction and parental satisfaction were significantly higher following implementation (both $P < 0.05$). Detailed data are presented in Table 3.

Table 3 Comparison of cannulation time in the ECMO emergency management process in children before and after implementation of FMEA management

Implementation time	Cannulation time//min				Satisfaction//%	
	Personnel in place	Material preparation	Circuit priming	Bedside cannulation	Physician-nurse collaboration	Child parents
Before implementation	35.10 ± 2.56	66.0. ± 6.69	38.34 ± 5.07	56.14 ± 5.71	84.65 ± 2.71	91.54 ± 2.69
After implementation	15.16 ± 2.57	34.80 ± 5.92	18.60 ± 4.62	36.96 ± 4.46	93.09 ± 2.56	96.54 ± 2.47
T	12.282	7.950	6.437	5.92	5.061	−3.058
P	<0.001	<0.001	<0.001	<0.001	0.001	0.016

4 Discussion

4.1 FMEA provides proactive risk identification and effectively mitigates failure risks in pediatric ECMO management The pediatric ECMO emergency management process involves a wide range of areas, numerous steps, and complex circumstances. Standardized, normalized, and refined management is crucial for improving the effectiveness of ECMO treatment. This study applied FMEA to pediatric ECMO emergency management by map-

ping the process, prospectively identifying failure modes in the ECMO management process, identifying root causes, and developing bundled improvement measures for early intervention. This approach transforms passive post-event management into proactive pre-event intervention, thereby reducing the occurrence of errors and adverse events and improving management standardization and effectiveness. The study results showed that after implementation of FMEA management, the RPN values of failure modes in the pediatric ECMO emergency management process decreased significantly compared with those before implementation. This may be attributed to FMEA's ability to prospectively assess risks, predict potential failure modes, evaluate causes, and implement timely measures to control and prevent failures before they occur, thereby reducing failure risks[6].

4.2 FMEA enhances emergency efficiency and clinical operation speed of the pediatric ECMO team through process optimization ECMO is a high-risk, high-difficulty cardiopulmonary support technique characterized by a long learning curve and involvement of multiple disciplines[3]. At present, the development of pediatric ECMO technology in China remains uneven, and the relevant technical specifications and quality control still require further improvement[7], which contributes to the high risks associated with pediatric ECMO emergency management. In clinical practice, nurses often face issues such as incomplete supply preparation, lack of proficiency in assisting with cannulation, suboptimal aseptic technique, and inadequate capabilities in patient observation and management of emergent events due to insufficient ECMO training[8]. Therefore, it is necessary to implement more standardized nursing management for pediatric ECMO.

The results demonstrated that optimization of the pediatric ECMO emergency management process led to significant reductions in team assembly time, supplies preparation time, circuit priming time, and bedside cannulation time, with findings consistent with those reported by Luo *et al.*[9]. This improvement may be attributed to the application of FMEA for risk assessment, which helped identify key weaknesses and critical points across the workflow. Through the development of standardized protocols, revision of nursing routines, refinement of operational procedures, creation of checklists, implementation of systematic training, and enhancement of quality control oversight, each ECMO team member gained a clear understanding of their roles and responsibilities. Tasks were assigned based on actual circumstances, shifting the team from a reactive to a proactive operational model. This approach ensured that individual strengths were fully utilized and responsibilities were clearly delineated, thereby improving efficiency while reducing the disorganization, inefficiency, and errors often associated with ambiguous role definitions and uneven task distribution[10].

4.3 FMEA focuses on the specific characteristics of "pediatric" patients, implements precise and humanized management, and comprehensively improves treatment quality FMEA is a risk assessment, improvement, and process management tool that emphasizes "proactive prevention" over "reactive correction," focusing on system and process deficiencies rather than individual errors, thereby supporting continuous quality improvement[11]. This study applied FMEA to anticipate and manage risks in pediatric ECMO emergency management, refining both management and operational workflows. Pre-ECMO, four "One" strategies were introduced to accelerate team response times. During ECMO, integrated medical-nursing management was implemented around three critical areas, such as circuit safety, monitoring, and infection control. Post-decannulation, magnetic nursing services were delivered through coordinated in-hospital and out-of-hospital care, yielding positive outcomes. These results may be explained by FMEA's capacity to prospectively evaluate processes, uncover vulnerabilities in medical and nursing workflows, accurately identify failure modes and root causes, and develop targeted action plans with clearly defined outcome metrics, thereby enabling standardized management and measurable improvement[12-13]. Some studies suggest that applying FMEA at the system level to address potential risks from their source is a key strategy for reducing medical errors and ensuring pediatric patient safety[14-15].

4.4 Research limitations and prospects In summary, FMEA is an effective systematic and proactive quality improvement tool that assists management departments in implementing early control before risk events or problems become apparent, thereby reducing the occurrence of risk events during pediatric ECMO management and preventing problems before they occur. This study also has limitations. The RPN values may be influenced by team members' subjective perception, professional knowledge, management capabilities, and work experience, which may lead to inadequate analysis of certain process issues. Furthermore, the number of ECMO cases in children was relatively small and the observation period was short, warranting further investigation of the application effects.

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by increasing Ca^{2+} influx. This mechanism likely contributes positively to maintaining intestinal motility and overall gastrointestinal physiological function.

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