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Clinical Research on the Effect of FMEA Risk Model in Improving the Management of Medical Equipment during Intra-hospital Transport of Critical Patients in EICU

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Abstract: *Objective To explore the application value of FMEA risk model in the management of transport equipment in the intra-hospital transport of critical patients in EICU. Methods FMEA risk model was used to analyze the failure modes related to transport equipment management during the intra-hospital transport of critical patients in EICU. According to the RPN values, 6 failure modes that must be intervened were selected, and corresponding improvement measures were formulated. The management effects before and after the implementation of FMEA risk management improvement measures were compared. Results Through the implementation of FMEA risk model management measures, the incidence that equipment was not fully charged, the incidence that equipment failed to alarm and the incidence that oxygen cylinders were insufficient, were significantly decreased ($\chi2=11.971$, $\chi2=22.900$, $\chi2=12.180$; $P<0.05$). At the same time, the incidence of pressure ulcers related to transport medical equipment of critical patients in EICU also decreased significantly ($\chi2=11.966$; $P<0.05$). Conclusions The use of FMEA risk model management measures to manage the transport equipment in the process of intra-hospital transport can effectively reduce the incidence of near-miss events related to transport medical equipment and the incidence of pressure ulcers related to transport medical equipment in EICU. FMEA risk model has great application value in the management of transport equipment during the intra-hospital transport of critical patients in EICU. This management model is suitable for promotion and application in the management of transport equipment.*

Keywords: *FMEA; Failure mode; Near-miss event; Pressure ulcer*

1. Introduction

Intra-hospital transport of critical patients is the process of transporting critical patients between different medical areas in a hospital for large-scale equipment inspection, specialized inpatient treatment, or surgical treatment [1]. In Chinese hospitals, transport tools mainly include transport beds, transport carts and wheelchairs. Patients who cannot get up for a long time are mainly transported by transport beds or transport carts, and patients who can sit up but cannot walk are transported by wheelchairs. During the transport process, both the patients and the transport medical equipment are in a moving state. If the transport medical equipment is not effectively managed and fails during the transfer process, it may cause injuries to the patients and cause medical device-related adverse events [2-4]. The management of transport medical equipment is an important part of medical equipment management in hospitals.

Failure Mode and Effect Analysis (FMEA) is a risk intervention model initiated by NASA. It is used to evaluate the risk degree of events, and put forward targeted improvement measures according to the assessment results to reduce the incidence of hazardous events and improve the quality of management [5,6]. This study attempted to use FMEA to analyze the risk factors related to the management of medical equipment in the intra-hospital transport process of critical patients in EICU, and put forward corresponding improvement measures to improve the management effect of medical equipment in the intra-hospital transport process.

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2. Research Materials and Methods

2.1. Research Materials

The EICU of a large hospital in Xi'an has 16 beds and 93 sets of medical equipment for intra-hospital transport, including transport ventilators, transport monitors, infusion pumps, micro-pumps, oxygen cylinders, negative pressure aspirators, defibrillators, etc. This study took these medical equipment for intra-hospital transport as the research objects.

2.2. Research Methods

Since July 2021, the EICU of the hospital had used the FMEA risk model to intervene in the management of the department's transport medical equipment, and the specific implementation process includes the following aspects.

2.2.1. Determine the Theme

After preliminary research, it was determined that the theme of this intervention was to use FMEA risk intervention model to analyze the possible failure modes of medical equipment management in the process of intra-hospital transport of critical patients, and to adopt effective measures for intervention [7].

2.2.2. Set up FMEA Team

The FMEA team was composed of EICU medical staff, clinical medical engineers and medical department staff. The FMEA team was led by the head nurse of EICU, and consisted of data record group, data analysis group, and implementation supervision group. Among them, the data record group mainly recorded the daily management behavior data and the implementation effect data of measures, the data analysis group was mainly responsible for the analysis of failure mode data and assessment index data, the implementation supervision group was mainly responsible for the effective supervision of the implementation of improvement measures. After the establishment of the FMEA team, quality management experts outside the hospital were invited to conduct FMEA management mode system training for FMEA team members.

2.2.3. Confirmation Process

Through more than two months of research and several meetings and discussions, the FMEA team members analyzed the existing management process of transport equipment for intra-hospital transport of critical patients, then they found out the failure modes that were prone to the occurrence of adverse events related to the transport medical equipment, and analyzed the possible adverse consequences.

2.2.4. Quantitative Evaluation of Failure Modes

The FMEA team quantified the failure modes of risk factors in the management process of transport equipment for intra-hospital transport of critical patients. The evaluation contents included the occurrence of failure mode-O(Occurrence), severity of failure consequence- S(Severity) and detectability of failure mode-D(Detectability). The scores of O,S and D ranged from 1 to 10, with a higher score of O indicating a higher occurrence of failures, a higher score of S indicating a more severe failure consequence, while a higher score of D indicating that the failure mode is more difficult to be detected[8]. All FMEA team members were trained on the failure mode quantitative assessment criteria before the assessment to ensure the uniformity and objectivity of the quantitative assessment criteria.

2.2.5. Calculate the Risk Priority Number (RPN) Value

The formula for calculating RPN is RPN=O×S×D, and the maximum value of RPN is 1000. When the RPN value is greater than 125, the failure mode is considered to require intervention [9]. After quantitative evaluation and RPN value calculation, 6 failure modes that must be intervened were selected, as shown in Table 1 below

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Table 1: Failure mode analysis of transport medical equipment during intra-hospital transport of critical patients

Failure mode	Adverse consequences	O	S	D	RPN value
Insufficient power of transport equipment and insufficient oxygen in oxygen cylinders	The equipment was shut down or oxygen could not be supplied during the transport	4	10	7	280
Transport equipment was not properly positioned	During the transport process, the equipment vibrated violently and fell, resulting in failure	7	9	4	252
Equipment accessories were not in good contact with the patients	During the transport process, the transport device was separated from the patients, and no monitoring data was available	9	9	8	648
The fixation of equipment accessories and patients was not reasonable	Pressure ulcers were caused during the transport process	6	8	10	480
The transport route planning was not reasonable	The uneven transfer route led to severe vibration and falling of equipment during the transfer process	7	7	8	392
Medical staff were not familiar with transfer equipment operations	Improper operation of equipment caused adverse events	5	10	8	400

2.2.6. Formulate Improvement Measures

In view of the 6 failure modes that must be intervened in the above analysis, corresponding improvement measures were formulated, mainly including the following aspects.

1) Clinical medical engineers and engineers from equipment manufacturers were invited to train medical staff on the operation and simple maintenance of transport medical equipment, so as to ensure that medical staff mastered sufficient operation and daily maintenance skills of the transport medical equipment. In the process of intra-hospital transport, medical staff could make good connection between equipment accessories and patients. At the same time, medical staff could make corresponding device parameter settings according to the patients' monitoring vital signs data.

2) Developed the preventive maintenance system for the transport medical equipment, and clinical medical engineers regularly maintained the transport medical equipment, replaced the aging consumables and vulnerable accessories, and replaced the accessories with potential risks inside the equipment.

3) Developed the daily management behavior system of the transport medical equipment, and the medical staff would check the equipment every day to ensure the normal operation of the equipment, charge the equipment with insufficient power in time, fill the oxygen cylinder with oxygen in time, and replace the damaged equipment accessories in time.

4) Transport management experts outside the hospital were invited to train medical staff on transport process management, including how to fix medical equipment during intra-hospital transport, how to reasonably connect equipment accessories with patients, and how to deal with emergencies during transport, so as to ensure that medical staff mastered equipment management skills during intra-hospital transport.

5) Invited the pressure ulcer prevention experts outside the hospital to train the medical staff on the operation of preventing pressure ulcers related to the transport equipment, so that the medical staff could have certain knowledge of preventing pressure ulcers nursing, which would minimize the incidence of pressure ulcers in the process of intra-hospital transport of critical patients.

6) Made intra-hospital transport route planning in advance. Through on-site investigation and comprehensive analysis, the FMEA team made all kinds of transport route planning, ensured that the transport route was smooth and safe, and the patients were timely transported to the corresponding place by the shortest route, and the effective transport route planning scheme was communicated to the medical staff in charge of transport through training.

2.2.7. Implementation of Measures

The implementation supervision group of FMEA team supervised the implementation of improvement measures, the data record group recorded the data in the management process, and the data analysis group analyzed the obtained data.

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2.3. Assessment Indicators

2.3.1. Comparison of the Incidences of Near-miss Events related to Transport Medical Equipment in Intra-hospital Transport Management

Near-miss event refers to a potential hazard event caused by personnel operation error or the failure of the equipment itself, and no substantial harm is caused due to the timely intervention of the human or the triggering of the protection device. It is a warning event before the occurrence of adverse events, and it has the same cause of occurrence as adverse events [10,11]. Before and after the implementation of FMEA risk model management measures, the near-miss events in the intra-hospital transport management of EICU for 60 days were statistically compared. The compared near-miss events included the times that equipment was not fully charged, the times that equipment failed to alarm during the transport process and the times that oxygen cylinders were insufficient.

2.3.2. Comparison of the Incidences of Pressure Ulcers related to Transport Medical Equipment in Intra-hospital Transport Management

Before and after the implementation of FMEA risk model management measures, the incidences of transport equipment-related pressure ulcers of critical patients during intra-hospital transport in EICU for 90 days were statistically compared.

2.4. Statistical Analysis

The data of 2.3.1 were input into SPSS20.0 software for processing. The times of near-error events was counted and analyzed by chi-square test. $P<0.05$ indicated statistical significance. The incidence of pressure ulcers in 2.3.2 was expressed as a percentage.

3. Results

3.1. Comparison Results of the Incidences of Near-miss Events related to Transport Medical Equipment in Intra-hospital Transport Management

Before and after the implementation of FMEA risk model management measures, the statistical analysis results of the incidences of near-miss events related to transport medical equipment in intra-hospital transport management of EICU for 60 days are shown in Table 2 below. It can be concluded that through the implementation of FMEA risk model management measures, the incidence that equipment was not fully charged, the incidence that equipment failed to alarm and the incidence that oxygen cylinders were insufficient, were significantly decreased ($\chi2=11.971$, $\chi2=22.900$, $\chi2=12.180$; $P<0.05$).

Table 2: Statistical comparison results of near-miss events related to transport medical equipment in EICU intra-hospital transport management [n (%)]

Group	Times of intra-hospital transport for 60 days	Times that equipment was not fully charged	Times that equipment failed to alarm	Times that oxygen cylinders were insufficient
Before	265	48(18.11)	83(31.32)	36(13.58)
After	273	9(3.30)	15(5.49)	4(1.47)
$\chi2$	-	11.971	22.900	12.180
P	-	0.001	0.000	0.000

3.2. Comparison Results of the Incidences of Pressure Ulcers related to Transport Medical Equipment in Intra-hospital Transport Management

Before and after the implementation of FMEA risk model management measures, the statistical results of the incidences of pressure ulcers related to transport medical equipment in the intra-hospital transport management of EICU for 90 days are shown in Table 3 below. It can be concluded that the incidence of pressure ulcers related to transport medical equipment of critical patients in EICU decreased significantly through the implementation of FMEA risk model management measures ($\chi2=11.966$; $P<0.05$).

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Table 3: Statistical results of the incidences of pressure ulcers related to transport medical equipment in intra-hospital transport management of EICU

Group	Times of intra-hospital transport for 90 days	Times of pressure ulcers related to transport equipment	Incidences of pressure ulcers related to transport equipment
Before	394	65	16.49%
After	406	7	1.72%
χ^2	-	-	11.966
P	-	-	0.001

4. Discussion

In the current hospital equipment management system, the medical equipment management in the process of intra-hospital transport is often the weakest link. In the actual management, due to the urgent task of transporting patients, the limited number of medical staff in the department, and the heavy treatment task of the department, the transport process is often completed by many new medical staff or even interns without transport expertise, and the transport medical equipment is not effectively managed and maintained. As a result, the transport equipment is not properly placed during the transport process, the medical equipment is not properly connected with the patient, the transport route is not properly planned, and various emergencies are not properly dealt with during the transport process, which eventually leads to a variety of near-miss events related to the transport medical equipment, and even leads to the occurrence of adverse events. It affects the operation efficiency of treatment process and medical safety. In the process of intra-hospital transport, the effective management of transport equipment is an important guarantee to improve the efficiency of treatment and ensure medical safety.

In this study, the FMEA risk model was used to analyze the failure modes related to the management of transport medical equipment during the intra-hospital transport of critical patients in EICU. Firstly, the FMEA team was established to analyze the management process of transport equipment for critical patients and find out the failure modes that were likely to lead to adverse events related to transport medical equipment. The O, S and D values of the failure modes were objectively scored, and the RPN values of each failure mode were calculated. Then corresponding improvement measures were formulated and supervised for the 6 failure modes whose RPN values were greater than 125.

During the implementation of the improvement measures, as the medical staff in charge of the transport received the operation and simple maintenance training of the transport medical equipment, the medical staff mastered the management skills of the transport medical equipment. The medical staff carried out the boot inspection and daily management maintenance of the transfer medical equipment every day, and the clinical medical engineers carried out the preventive maintenance of the transport medical equipment. The medical staff carried out start-up inspection and daily management and maintenance of the transport medical equipment every day, and the clinical medical engineers carried out preventive maintenance of the transport medical equipment. During the transport process, the medical staff chose the transport route planned by the FMEA team. As a result, the incidence that equipment was not fully charged, the incidence that equipment failed to alarm and the incidence that oxygen cylinders were insufficient, were significantly decreased ($\chi2=11.971$, $\chi2=22.900$, $\chi2=12.180$; $P<0.05$). At the same time, as the medical staff in charge of transport received training on the prevention of pressure ulcers related to transport equipment, and the contact between medical accessories and patients was effectively handled, the incidence of pressure ulcers related to transport medical equipment of critical patients in EICU decreased significantly ($\chi^2=11.966;\ P<0.05$). FMEA risk model management significantly improved the management effect of transport medical equipment in EICU.

5. Conclusions

In conclusion, the use of FMEA risk model management measures to manage the transport equipment in the process of intra-hospital transport can effectively reduce the incidence of near-miss events related to transport medical equipment and the incidence of pressure ulcers related to transport medical equipment in EICU. FMEA risk model has great application value in the management of transport equipment during the intra-hospital transport of critical patients in EICU. This management model is suitable for promotion and application in the management of transport equipment.

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