

Application Effect Analysis of RCA on Improving the Management of Medical Equipment-Related Near-Miss Events in ICU of Hospital

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Abstract: **Objective** To explore the application value of RCA analysis method in improving the management of medical equipment-related near-miss events in ICU. **Methods** The ICU of a hospital in Xi'an used the RCA analysis method to analyze the medical equipment-related near-miss events. Firstly, the proximal causes of the medical equipment-related near-miss events were found out, and the root causes were found through brainstorming. Then, corresponding improvement measures were formulated according to the root causes, and the implementation of improvement measures were supervised. The management effects before and after the implementation of RCA analysis were compared and analyzed. **Results** After the implementation of RCA analysis improvement measures, in the statistics of the incidence of medical equipment-related near-miss events, the incidence of incomplete equipment accessories, the incidence of equipment self-test failure and the incidence of equipment alarm failure were significantly lower than those before the implementation of improvement measures ($\chi^2=5.701$, $\chi^2=5.128$, $\chi^2=6.652$; $P<0.05$). **Conclusions** RCA analysis method can significantly reduce the incidence of medical equipment-related near-miss events, so as to reduce the incidence of medical equipment-related adverse events. It can also improve the management quality of ICU departments and improve patients' satisfaction with inpatient services. RCA analysis can improve the management effect of medical equipment-related near-miss events in ICU. It is a scientific and effective medical activity management tool, and it has high application and promotion value in the management of near-miss events in hospitals.

1. Introduction

Near-miss events refer to events that may lead to accidents and injuries, but do not actually cause

injury or loss because such events are detected and handled in a timely manner. In medical activities, because near-miss events do not cause actual losses, medical staff often ignore the management of near-miss events. In fact, near-miss events are the early warning of adverse events, which have the same causes as adverse events, and there is a certain proportional relationship between near-miss events and the occurrence of adverse events [1-3]. By preventive management of near miss-events and reducing the incidence of near-miss events, the occurrence of adverse events can be prevented to a certain extent. As a management unit for the centralized treatment of critical patients, ICU needs all kinds of middle and high-end medical equipment to monitor and treat critical patients. Due to the medical staff's operation error of equipment, equipment failure and other reasons, the incidence of medical equipment-related near-miss events is high, which leads to the occurrence of medical equipment-related adverse events from time to time, causing a major impact on medical safety. In order to reduce the incidence of adverse events related to medical equipment in ICU, it is necessary to effectively manage the near-miss events.

Root cause analysis (RCA) is a standard and systematic method to analyze the causes. Through retrospective scientific analysis of the existing problems, the root causes of the problems are found out and corresponding measures are taken to prevent similar problems from happening again [4,5]. It is an organizational approach to problem solving that focuses not only on the problem itself, but also on identifying the root causes of the problems and solving them through an orderly, step-by-step analysis. RCA analysis method is widely used in the industrial field for retrospective analysis of error events, and in the medical field in recent years, it has also been used in the management of medical adverse events [6]. However, there are few studies on the management of medical equipment-related near-miss events. This study attempted to use RCA analysis method to manage medical equipment-related near-miss events in ICU of hospital, and verify the management effect of this method on medical equipment-related near-miss events.

2. Research materials and methods

2.1. Research materials

The medical equipment in ICU of a hospital in Xi'an was taken as the research object. The department had 30 beds, 17 doctors and 65 nurses, and 346 sets of various medical equipment, including ventilators, monitors, defibrillators, blood gas analyzers, cardiopulmonary resuscitation devices, bedside hemofiltration devices, infusion pumps, micropumps, mobile B-ultrasound, electrocardiogram devices, etc.

2.2. Research methods

The RCA analysis method was used to manage the high incidence of medical equipment-related near-miss events in general practice. The implementation of the RCA analysis method was divided into the following parts.

2.2.1. Preparation stage

1) The RCA management team was established, which was composed of head nurse, nurses in charge, doctors in charge and clinical medical engineers. The RCA management team first conducted in-depth study on the analysis method of RCA and the management theory of near-miss events.

2) The RCA management team consisted of three groups: RCA data collection group, RCA measure formulation group and RCA quality supervision group. Among them, the RCA data

collection group was responsible for recording the daily use of medical equipment, the daily operation and management of equipment by medical staff, the near-failure events, and the preventive maintenance of engineers. The RCA measure formulation group was responsible for the formulation and supervision of improvement measures. The RCA quality supervision group was responsible for the inspection and supervision of the implementation of improvement measures.

3) Summarize the medical equipment-related near-miss events of the whole department in the past year. The summarized medical equipment-related near-miss events in the past year mainly include: (1) damaged or incomplete accessories of the medical equipment to be used; (2) the medical equipment to be used failed the self-test; (3) the batteries of the medical equipment to be used were not fully charged; (4) the medical equipment to be used failed to alarm; (5) medical equipment consumables were aged and damaged; (6) the medical equipment was not properly connected to the patients; (7) medical equipment and accessories were disconnected from the patients during treatment; (8) the parameters of the medical equipment were not set correctly; (9) insufficient oxygen in the oxygen cylinder of the transport ventilator; (10) pressure ulcers due to contact between medical equipment accessories and patients.

2.2.2. Find the proximal causes

The RCA data collection group conducted a retrospective study on the medical equipment-related near-miss events in the past year to find out the proximal causes of medical equipment-related near-miss events, including five aspects: man, machine, material, method, and milieu [7].

1) Man

In terms of man causes, it mainly includes: (1) medical staff were not skilled in the operation of medical equipment and were not familiar with the performance of the equipment. They did not carry out simple maintenance of the medical equipment, did not tidy up the medical equipment and accessories every day, did not clean and disinfect the equipment every day, and did not check whether the equipment consumables need to be replaced; (2) medical staff were not familiar with the measures to prevent pressure ulcers and did not know how to reduce the occurrence of pressure ulcers in patients; (3) clinical medical engineers did not carry out preventive maintenance of medical equipment, which led to the failure of medical equipment.

2) Machine

In terms of machine factor, the main reason was that the parameters of the equipment were not set correctly, and the equipment was not calibrated and measured in time, which led to the occurrence of near-miss events.

3) Material

In terms of materials causes, it mainly includes: (1) materials of consumables that were easy to cause skin allergy of patients caused pressure ulcers where consumables contacted the skin; (2) the sheath material of the lead wire did not choose the material with high flexibility, which caused the lead wire sheath to be easily damaged, and the lack of protection to the lead wire might lead to damage to the lead wire; (3) the material of the breathing circuit must be non-toxic and resistant to high temperature disinfection; (4) the material of the transfer equipment was not selected to be shock-resistant, which might cause the transfer equipment to be easily damaged.

4) Method

In terms of method causes, it mainly includes: (1) lack of medical equipment management behavior system for medical staff; (2) lack of prevent pressure ulcer operation standard process for medical staff; (3) lack of patient transport process management system for medical staff; (4) lack of preventive maintenance system for clinical medical equipment.

5) Milieu

In terms of milieu factor, the main reason was that the dust in the ward environment entered the

inside of the equipment through the cooling holes of the equipment and adhered to the circuit control board, which led to the fault prone of the equipment.

2.2.3. Identify root causes

All members of the RCA team held an RCA quality improvement meeting to brainstorm the summarized medical equipment-related near-miss events and the proximate causes of near-miss events. They summarized the root causes of the high incidence of near-miss events, which mainly included the following aspects: (1) medical staff were not familiar with equipment operation and simple maintenance process; (2) medical staff lacked of knowledge on pressure ulcer prevention; (3) medical staff did not check and tidy up medical equipment every day; (4) clinical medical engineers did not carry out preventive maintenance of medical equipment in time.

2.2.4. Develop improvement measures

According to the root cause of the medical equipment related near-miss events, the RCA measures formulation group should study and develop the corresponding operational improvement measures, and formulate the corresponding reward and punishment system to supervise the implementation of the measures. The improvement measures formulated include: (1) invite equipment manufacturer engineers to conduct systematic training on equipment operation and simple maintenance for medical staff, formulate daily medical equipment management code of conduct for medical staff, and require medical staff to maintain and tidy up medical equipment every day, clean the ward environment everyday; (2) invite experts to train the operation knowledge of preventing pressure ulcers, develop the operation process of preventing pressure ulcers for medical staff, and medical staff operate according to the operation process every day to reduce the incidence of pressure ulcers; (3) invite experts to train medical staff on the transfer process of patients, develop the management system for the transfer process of medical staff, and require medical staff to transfer patients according to the process system; (4) develop the three-level preventive maintenance system for clinical medical engineers, requiring engineers to implement three-level maintenance strictly in accordance with the maintenance schedule; (5) RCA quality supervision group shall regularly check the effect of the above improvement measures, and link the assessment results with the individual year-end assessment results.

2.3. Assessment indicators

Before and after the implementation of RCA analysis, the incidence of ICU medical equipment-related near-miss events for 30 days was statistically analyzed. The near-miss events included incomplete equipment accessories, equipment self-test failure and equipment alarm failure. The incidence of near miss events = number of near miss events/times of medical equipment used. The RCA data collection group was responsible for recording the use of medical equipment and the occurrence of near-miss events in ICU before and after the implementation of improvement measures for 30 days. The RCA data collection group aggregated the recorded data and calculated the near-miss event rate.

2.4. Statistical analysis

The above data were imported into SPSS20.0 software for statistical analysis. The times of medical equipment use and the times of near-miss events were counted data, which were analyzed by Chi-square test. $P < 0.05$ indicated statistical significance.

3. Results

Before and after the implementation of RCA analysis, the incidence of ICU medical equipment-related near-miss events for 30 days is shown in Table 1 below. It can be concluded that, after the implementation of RCA analysis improvement measures, in the statistics of the incidence of medical equipment-related near-miss events, the incidence of incomplete equipment accessories, the incidence of equipment self-test failure and the incidence of equipment alarm failure were significantly lower than those before the implementation of improvement measures ($\chi^2=5.701$, $\chi^2=5.128$, $\chi^2=6.652$; $P<0.05$).

Table 1: Statistics on the incidence of medical equipment-related near-miss events in ICU for 30 days [num, n (%)]

Group	Times of medical equipment use for 30 days	Times of equipment with incomplete accessories	Times of equipment self-test failure	Times of equipment alarm failure
Before	1962	165(8.41)	107(5.45)	183(9.32)
After	1979	13(0.66)	6(0.30)	17(0.86)
χ^2	-	5.701	5.128	6.652
P	-	0.017	0.024	0.010

4. Discussion

The safety of inpatients is very important, which is an important basis for the smooth operation of medical institutions. It is the consensus of hospital managers all over the world to ensure the safety of inpatients. Compared with the low incidence of medical equipment-related adverse events that cause serious injuries to patients or medical staff, there are a considerable number of medical equipment-related near-miss events in the clinical diagnosis and treatment process. Although these near-miss events do not cause great harm, they have similar causes with adverse events, and there is a certain proportion relationship with the occurrence of adverse events. Studies have shown that the incidence of near-miss events is about 3-300 times higher than the incidence of corresponding adverse events [2,8,9]. The management of medical equipment-related near-miss events can effectively reduce the occurrence of adverse events. However, in large hospitals of China, the number of patients is still increasing, and the purchase of medical equipment is also increasing. Hospital managers and medical staff focus on how to use advanced medical equipment to treat more patients, but ignore the prevention of medical equipment-related near-miss events. It was not until systemic management failures caused adverse events that resulted in certain personal injury or loss that intervention was taken. This kind of passive and backward management method is easy to cause the crisis of trust in medical institutions [10]. It is of great significance to take proactive preventive management of medical equipment-related near-miss events in line with the current management concept of prospective quality management and risk prevention in advance. The management of near-miss events has gradually become an important measure to ensure the safety of patients in hospital [11].

In this study, the RCA analysis method was used to analyze the near-miss events related to medical equipment in ICU. Firstly, the proximal causes of the near-miss events were found out, and the root causes were found through brainstorming. Then, corresponding improvement measures were formulated according to the root causes, and the implementation of improvement measures were supervised. During the implementation of RCA improvement measures, medical staff carried out simple maintenance and management of medical equipment every day, checked equipment

startup, sorted out accessories, adjusted parameter settings, and clinical medical engineers carried out preventive maintenance of medical equipment. As a result, in the statistics of medical equipment-related near-miss events, the incidence of incomplete equipment accessories, the incidence of equipment self-test failure and the incidence of equipment alarm failure were significantly lower than those before the implementation of improvement measures ($\chi^2=5.701$, $\chi^2=5.128$, $\chi^2=6.652$; $P<0.05$). RCA analysis method has a significant improvement effect on the management of medical equipment-related near-miss events in ICU.

5. Conclusions

In the medical management activities of ICU, RCA analysis method can significantly reduce the incidence of medical equipment-related near-miss events, so as to reduce the incidence of medical equipment-related adverse events. It can also improve the management quality of ICU departments and improve patients' satisfaction with inpatient services. RCA analysis can improve the management effect of medical equipment-related near-miss events in ICU. It is a scientific and effective medical activity management tool, and it has high application and promotion value in the management of near-miss events in hospitals.

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References

- [1] Ingole SJ, Chaudhary SN. Maternal Near Miss Events in Tertiary Care Hospital: A Retrospective Observational Study [J]. *Journal of Clinical and Diagnostic Research*, 2021, 15(4).
- [2] Aspden P, Corrigan JM, Wolcott J, et al. *Patient safety: achieving a new standard for care [M]*. Washington DC: The National Academies Press, 2004.
- [3] Wilson S, Barkun J, Bertens K, et al. A Canadian consensus definition of near-miss events in liver surgery for the real-time quality benchmarking of laparoscopic liver surgery [J]. *HPB*, 2020, 22: S88.
- [4] Lima L, Silva L, Dantas J, et al. Root Cause Analysis, Failures and Effects in pediatric total quality management: a scoping review. [J]. *Associação Brasileira de Enfermagem*, 2021 (6).
- [5] Usn D, Ret. J, Usn C, et al. Leadership Root Cause Analysis: Using a Formal Analysis Tool to Dissect and Promote Intrusive Leadership in a U.S. Naval Hospital [J]. *Military Medicine*, 2021.
- [6] Alrahbeni T, Alenezi ME. Root Cause Analysis of Medication Administration Error by Nursing Staff at a Number of Medical Institutes in Riyadh [J]. *Journal of Pharmaceutical Research International*, 2021.
- [7] Teymourlouy S, Choopani A, Kjnaghahi SU, et al. Root Cause Analysis of Falling out of bed in one of the Pediatric Hospitals in Tehran in 2019-2020 [J]. 2021.
- [8] Zaman NA, Ghani KS, Ruman MU. *Near Miss Obstetric Events and Maternal Death: Experience in Combined Military Hospital, Dhaka*. 2020.
- [9] Taylor MA, Reynolds CM, Jones R. Challenges and Potential Solutions for Patient Safety in an Infectious-Agent-Isolation Environment: A Study of 484 COVID-19-Related Event Reports Across 94 Hospitals [J]. *Patient Safety*, 2021, 3(2): 45-62.
- [10] Khodadadi V, Bakrani A, Vafaie MH. Factors Affecting Medical Equipment Management in the COVID-19 Pandemic Crisis: A Mixed Qualitative and Quantitative Study [J]. *Hospital Practices and Research*, 2021, 6(1): 23-28.
- [11] Et A, Gf B, Bt C, et al. The impact of antenatal care on maternal near-miss events in Ethiopia: A systematic review and meta-analysis – ScienceDirect [J]. *International Journal of Africa Nursing Sciences*, 2020, 13.