Application of Healthcare Failure Mode and Effects Analysis (HFMEA) in Surgical Item Counting Management

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Abstract

Objective: To investigate the application effectiveness of Healthcare Failure Mode and Effects Analysis (HFMEA) in surgical item counting management.

Methods: Using a convenience sampling method, 98 surgical cases performed in the operating room of our hospital from June to November 2023 were selected as study subjects. Surgeries from June to July were designated as the control group, and those from October to November were designated as the experimental group. The control group followed conventional surgical item counting procedures, while the experimental group, in addition to the conventional procedures, applied the HFMEA management model to identify high-risk failure modes, analyze root causes, and develop and implement intervention strategies. The compliance rate of surgical item counting standards and the Risk Priority Number (RPN) values of high-risk failure modes were compared before and after implementation.

Results: Following HFMEA implementation, the compliance rate of surgical item counting standards increased from 73.47% to 95.92%, with a significant decrease in the RPN values of high-risk failure modes. All differences were statistically significant ($P<0.05$).

Conclusion: Application of the HFMEA management model to surgical item counting management can effectively improve compliance rates and enhance the quality and safety of operating room nursing care.

Full Text

Application of Healthcare Failure Mode and Effects Analysis (HFMEA) in Surgical Item Count Management

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Abstract

Objective: This study aims to explore the application effects of Healthcare Failure Mode and Effects Analysis (HFMEA) in the management of surgical item counting.

Methods: Using convenience sampling, 98 surgical operations conducted in our hospital' s operating room from June to November 2023 were selected for the study. Surgeries from June to July were designated as the control group, while those from October to November served as the experimental group. The control group utilized the conventional surgical item counting process, whereas the experimental group applied the HFMEA management model on top of the conventional process to identify high-risk failure modes, analyze root causes, and implement targeted intervention strategies. The compliance rate of surgical item counting standards and the Risk Priority Number (RPN) values of high-risk failure modes were compared before and after implementation.

Results: After applying HFMEA, the compliance rate of surgical item counting standards increased from 73.47% to 95.92%, and the RPN values of high-risk failure modes decreased significantly. All differences were statistically significant ($P < 0.05$).

Conclusion: The application of the HFMEA management model in surgical item counting management effectively improves compliance rates, enhances operating room nursing quality, and strengthens patient safety.

Keywords: surgical item counting; operating room nursing; Healthcare Failure Mode and Effects Analysis

Introduction

The operating room is a core department of hospitals, and operating room nursing safety management constitutes a critical component of hospital safety management systems. Surgical item counting encompasses the verification of surgical dressings, instruments, and special surgical items. Inaccurate surgical item counting represents a significant nursing safety issue that not only affects surgical procedures but can also endanger patient lives, trigger medical disputes, and impose substantial psychological burdens on medical staff.

Healthcare Failure Mode and Effects Analysis (HFMEA) is a healthcare quality management method advocated by the Joint Commission in the United States. It prospectively analyzes potential failure modes in healthcare processes, quantitatively assesses these modes to identify potential failure factors, and implements targeted improvement measures to systematically prevent failures and ensure medical safety. In April 2023, our department established an HFMEA project team to implement HFMEA management for surgical item counting, achieving favorable results as reported herein.

Methods

Study Design and Participants

Using convenience sampling, 98 surgical operations performed in the operating room of a tertiary Grade A hospital in Shandong Province from June to November 2023 were selected as observation subjects. Forty-nine surgeries from June to July (pre-process improvement) were designated as the control group, including 26 open surgeries and 23 endoscopic surgeries; 20 were first-scheduled surgeries and 29 were subsequent surgeries. Among participating nurses, there were 36 male and 62 female instances, with an average age of 32.43 $\pm$ 3.27 years.

Forty-nine surgeries from October to November (post-process improvement) were designated as the experimental group, including 25 open surgeries and 24 endoscopic surgeries; 22 were first-scheduled surgeries and 27 were subsequent surgeries. Among participating nurses, there were 40 male and 58 female instances, with an average age of 34.33 $\pm$ 5.07 years. Comparison of general data between the two groups showed no statistically significant differences ($P > 0.05$).

Inclusion Criteria: 1. **Surgeries:** Performed in the operating room; involved both circulating and scrub nurses; obtained informed consent from patients and families. 2. **Nurses:** Operating room nurses in our department; held valid nursing licenses; possessed operating room qualification; had more than one year of operating room nursing experience; voluntarily participated.

Exclusion Criteria: 1. **Surgeries:** Outpatient operating room procedures; surgeries with only circulating nurses; special requirement surgeries such as demonstration or teaching surgeries. 2. **Nurses:** Trainee, rotating, or student nurses; less than one year of operating room experience; nurses without operating room qualification; those who refused participation.

Control Group Procedures

The control group received conventional nursing measures. Before surgery, circulating nurses inspected the operating room environment, while scrub nurses performed surgical hand scrub 15-30 minutes in advance. Scrub and circulating nurses jointly executed surgical item counting procedures following the requirements and principles outlined in the *Operating Room Nursing Practice Guidelines*.

HFMEA Intervention

Based on conventional nursing care, the experimental group applied the HFMEA management model to improve surgical item counting procedures as follows:

Theme Determination In March 2023, the operating room nursing quality improvement team voted on potential improvement projects and ultimately iden-

tified optimizing surgical item counting procedures and improving compliance rates as the research theme.

Team Formation An operating room HFMEA management team was established, comprising 3 operating room head nurses, 6 specialized operating room nurses, 3 nursing graduate students, and 1 surgeon (total 13 members). All team members received systematic HFMEA training and demonstrated understanding and mastery of HFMEA methodology.

Process Mapping and Failure Mode Identification Based on the existing *Surgical Item Counting Procedure*, team members further mapped the surgical item counting process through site visits. The counting process was divided into four main phases: before surgery, before cavity closure, after cavity closure, and after skin suture, encompassing nine sub-processes.

The team used site tracking and brainstorming to analyze potential failure modes and their effects for each sub-process, and employed brainstorming and fault tree analysis to identify root causes as potential failure causes.

Risk Priority Number Calculation A hazard scoring table was developed to number failure modes and potential causes. Each team member independently scored potential failure modes in the surgical item counting process based on clinical experience and the hazard scoring table. RPN values were calculated using the HFMEA risk matrix: RPN = Severity (S) $\times$ Occurrence (O). Higher RPN values indicate greater failure risk; RPN $\geq$ 8 indicates significant process hazards and is classified as a high-risk failure mode.

Decision Tree Analysis High-risk failure modes with RPN $\geq$ 8 were subjected to decision tree analysis based on three criteria: whether it represented a single point of weakness, whether existing control measures were effective, and whether it was easily detectable. This analysis determined whether further improvement was required for high-risk failure modes. The decision tree evaluation results are presented in .

Improvement Measures Based on HFMEA action strategies—elimination (removing failure opportunities), control (establishing barriers for easy detection), and mitigation (reducing harm severity)—countermeasures were developed for potential failure points receiving "yes" determinations in the decision tree analysis. The countermeasure formulation is presented in .

Observation Indicators

1. **Surgical Item Counting Compliance Rate:** Calculated as (number of surgeries with standardized item counting / total sampled surgeries) $\times$ 100%.

2. **RPN Values of High-Risk Failure Modes:** Risk Priority Numbers for high-risk failure modes in surgical item counting.

Statistical Analysis

Data were analyzed using SPSS 26.0. Normally distributed continuous data were expressed as mean ± standard deviation and compared using independent samples t-test or paired samples t-test. Categorical data were expressed as frequency (percentage) and compared using chi-square test or Fisher' s exact test. The significance level was set at $\alpha = 0.05$, with $P < 0.05$ considered statistically significant.

Results

Compliance Rate Comparison

After HFMEA implementation, surgical item counting compliance rate significantly improved from 73.47% to 95.92%, with statistically significant difference ($P < 0.05$), as shown in .

RPN Value Comparison

Following HFMEA implementation, RPN values for high-risk failure modes in the surgical item counting process decreased significantly, with statistically significant differences ($P < 0.05$), as presented in .

Discussion

This study applied the HFMEA management model to optimize surgical item counting procedures. Results demonstrated significant improvement in compliance rates compared to pre-implementation ($P < 0.05$), consistent with findings from Zhang Jie and Wu Xian' s studies using quality control circle activities to standardize surgical item counting behaviors. While various management tools are applied in clinical nursing management, HFMEA' s distinctive prospective approach emphasizing prevention over retrospective analysis has gained increasing recognition.

This study followed HFMEA methodology to systematically map the surgical item counting process, identified potential failure modes through brainstorming and site tracking, scored these modes based on clinical experience to calculate RPN values, and applied decision tree analysis to ultimately identify 11 high-risk failure modes. Using brainstorming, 15 countermeasures were developed and categorized into three bundled nursing interventions: (1) optimizing standardized surgical item counting procedures; (2) strengthening training and departmental safety culture development; and (3) implementing process monitoring and quality control. This established a tripartite quality management system integrating process, personnel, and quality control, ensuring sustainable

implementation and forming a long-term mechanism that effectively improved compliance rates.

RPN values for high-risk failure modes decreased significantly after HFMEA implementation ($P < 0.05$), aligning with Pan Xiaoling et al.' s research. The HFMEA model effectively identifies weak links in surgical item counting processes, enabling control and improvement of high-risk failure modes through targeted interventions. To address time constraints in emergency surgery counting, we established emergency surgical kits (emergency cesarean section kits, Type A aortic dissection emergency kits, and general emergency kits), saving nurses' preparation time while ensuring completeness. This approach significantly improved operating room efficiency and created valuable time for item counting.

Additionally, standardized management processes were applied to surgical item counting management, establishing standardized positioning for specialty surgical items with detailed preoperative, intraoperative, and postoperative positioning standards, standardized surgical instrument integrity checks, standardized procedures for adding/removing surgical items intraoperatively, and optimized surgical instrument kit configurations. These measures effectively alleviated nurses' counting pressure, achieved homogeneous management of surgical item counting, and significantly reduced risk indices for high-risk failure modes. Conducting surgical item counting skills competitions, establishing operating room safety culture walls, and implementing surgical item counting management dashboards enabled real-time awareness of management metrics for both nurses and surgeons. Ranking departments by cooperation level in item counting maximized healthcare personnel engagement, thereby ensuring surgical item counting safety and improving nursing quality.

In conclusion, the HFMEA management model effectively reduces failure risks in surgical item counting procedures, improves compliance rates, enhances surgical nursing quality, and further ensures patient safety, warranting clinical promotion and application. However, this was a single-center study, and variations across different hospitals and operating rooms limit sample representativeness. Future multi-center studies involving multiple hospitals are recommended. Additionally, the three-month implementation period requires long-term observation to evaluate the sustained effectiveness of certain interventions.

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Note: Figure translations are in progress. See original paper for figures.