Journal of Clinical and Nursing Research, 2025, Volume 9, Issue 11
http://ojs.bbwpublisher.com/index.php/JCNR
Online ISSN: 2208-3693
Print ISSN: 2208-3685

Research Progress on the Prevention of Infection in Operating Rooms Using the HFMEA Model Combined with Evidence-Based Medicine

Wen Xu[1], **Xiaofu Ji**[2]*

[1]Department of Anesthesiology and Operation II, Olympic Center, Shandong Provincial Hospital Affiliated to Shandong First Medical University, Jinan 250021, Shandong, China

[2]Department of Anesthesiology and Operation I, Olympic Center, Shandong Provincial Hospital Affiliated to Shandong First Medical University, Jinan 250021, Shandong, China

Author to whom correspondence should be addressed.

Abstract: The Healthcare Failure Mode and Effect Analysis (HFMEA) model, as a proactive risk assessment tool, systematically identifies potential infection risk points during surgical procedures and evaluates the failure modes and their effects that may result from these risks. Evidence-based medicine, on the other hand, emphasizes making medical decisions based on the best available evidence. Combining these two approaches can provide more scientific and effective strategies for preventing infection in operating rooms. This paper delves into the application of the HFMEA model and evidence-based medicine in the field of infection prevention in operating rooms, aiming to offer new perspectives and methods for this critical aspect of healthcare.

Keywords: Healthcare failure mode and effect analysis; Evidence-based medicine; Operating room infection; Prevention; Progress

Online publication: Dec 4, 2025

1. Introduction

As the core area for infection prevention and control in hospitals, the incidence of infection in operating rooms directly affects patient prognosis and the quality of medical care. Statistics indicate that approximately 5% of surgical patients worldwide develop postoperative infections, with 20–30% being surgical site infections (SSIs), leading to prolonged hospital stays, increased medical costs, and higher mortality rates [1]. Traditional postoperative infection control has largely relied on retrospective tracing and empirical interventions, making it difficult to identify high-risk areas and implement proactive control measures. In recent years, foreign research has focused on refined prevention and control strategies that combine HFMEA with evidence-based medicine, while domestic research has emphasized the optimization of localized processes and the evaluation of empirical intervention effects. Together, these efforts have driven the scientific and systematic development of infection prevention and control in operating rooms [2]. The HFMEA is based on team analysis, systematic process review, and evaluation of the risk levels of failure modes, providing a decision-making basis for postoperative infection control. Evidence-based Medicine (EBM) centers on evidence and aims to formulate optimal decisions based on the interests of patients and hospitals. The integration of HFMEA with EBM has emerged as a focal point of research in recent years for infection prevention and control in operating rooms. By leveraging failure mode analysis and incorporating evidence-based interventions, it facilitates a closed-loop operation from "identifying risks" to scientific prevention and control. This paper aims to systematically review the research progress of the HFMEA model combined with EBM in preventing infections in operating rooms, analyze its theoretical advantages, practical effects, and future development directions, and provide references for enhancing infection prevention and control standards in operating rooms.

2. Overview of the HFMEA model and evidence-based medicine

2.1. HFMEA model

HFMEA is a systematic and forward-looking risk management tool, with its core concept derived from Failure Mode and Effects Analysis (FMEA) in the industrial sector. It was later optimized and introduced into the medical field by the Veterans Health Administration in the United States. HFMEA systematically identifies and proactively prevents various potential risk factors in medical processes by establishing an organized procedure. Unlike traditional post-event remedial approaches, HFMEA emphasizes "prevention over correction". It organizes multidisciplinary personnel to collaborate, divides processes into stages, and conducts failure mode analysis for each process (e.g., operational errors, equipment failures, communication breakdowns), analyzes the impact of failures (e.g., infections, treatment delays), and calculates the Risk Priority Number ($RPN = O \times S \times D$) based on the likelihood of occurrence (O), severity (S), and detectability (D) of failures. This enables precise identification of high-risk areas and the formulation of targeted improvement measures [3]. In 2002, the Joint Commission on Accreditation of Healthcare Organizations incorporated HFMEA into its patient safety standards, further promoting its widespread application in operating rooms, medication management, blood transfusion safety, and other fields. Its advantage lies in combining qualitative analysis with quantitative assessment, providing an actionable risk management framework for medical quality improvement.

2.2. Evidence-based medicine

EBM is a clinical thinking process that formulates optimal medical decisions based on existing scientific research evidence. It was proposed in the 1990s by a team led by Professor David Sackett from McMaster University in Canada. Its core principle is "to formulate the best medical decisions based on the current best research evidence, combined with the clinical expertise of healthcare professionals and the individual needs of patients". Unlike traditional empirical medicine, EBM emphasizes hierarchical integration: it integrates evidence from multicenter, randomized, controlled clinical trials obtained through systematic reviews and meta-analyses in a hierarchical manner, and combines it with clinical practice guidelines and patient values to achieve a balance between scientific decision-making and humanization [4]. Currently, in the prevention and control of infectious diseases, evidence-based hierarchical integration is widely used to determine optimal intervention measures. For example, the effectiveness of interventions such as hand hygiene, aseptic techniques, and rational use of antimicrobial agents is determined through evidence grading, providing standardized references for clinical practice. With the advent of the information age, evidence management has gradually incorporated artificial intelligence and big data technologies, forming a dynamic "evidence repository" that further enhances the accuracy and timeliness of clinical decision-making.

3. Application progress of the HFMEA model in the prevention of infections in hospital operating rooms

3.1. Detailed decomposition of surgical processes and risk quantification

The HFMEA model provides a detailed decomposition of infection prevention processes in operating rooms, covering all stages from preoperative preparation to intraoperative procedures and postoperative care. Research by Ma Xiaoju et al. indicates that during the preoperative preparation phase, the team identified potential failure modes such as "incomplete cleaning and disinfection of surgical instruments" and "low hand hygiene compliance among surgical personnel" through process mapping [5]. During the intraoperative phase, high-risk areas such as "improper storage of sterile items" and "inadequate protective measures for surgical incisions" were identified. By calculating the Risk Priority Number (RPN) for each failure mode, the team can quantitatively assess risk levels. Research by Yao Yao et al. applied HFMEA to the infection prevention process for laparoscopic surgery and found that the RPN value for "incorrect sterilization parameter settings for surgical instruments" was as high as 240 (severity S = 8, probability of occurrence O = 6, detectability D = 5), making it the primary target for intervention [6]. By optimizing sterilization equipment operation protocols and adding a double-check process, the RPN value for this failure mode was reduced to 80, significantly lowering the risk of infection.

3.2. Multidisciplinary collaboration and development of standardized intervention measures

The HFMEA model emphasizes interdisciplinary teamwork, integrating perspectives from infection control experts, surgeons, nurses, anesthesiologists, and other stakeholders to ensure the scientific validity and operability of intervention measures [7]. In a hospital operating room infection prevention project, Fu Tingting and her team identified "air pollution caused by frequent movement of personnel during surgery" as a high-risk failure mode (RPN = 180) through HFMEA [8]. Following multidisciplinary discussions, standardized intervention measures were formulated: limiting the number of personnel in the operating room, optimizing the placement of items to reduce the need for movement, installing air purification equipment, and regularly monitoring bacterial colony counts. After implementation, the RPN value for this failure mode dropped to 60, and the surgical site infection (SSI) rate decreased from 1.2% to 0.5%. Additionally, HFMEA promoted the standardization of infection prevention and control processes in the operating room, such as the development of the "Operating Room Aseptic Technique Standards" and the "Surgical Instrument Cleaning and Disinfection Flow Chart", providing clear guidance for frontline staff.

3.3. Dynamic risk monitoring and continuous improvement

The HFMEA model enables dynamic management of infection risks through regular process reviews and updates to RPN values. In a study by Jin Xiaoying and colleagues, after implementing HFMEA interventions in the infection prevention process for cardiac surgery, "incomplete disinfection of cardiopulmonary bypass circuits" was initially identified as a high-risk mode (RPN = 200) [9]. By introducing single-use circuits and strengthening disinfection process monitoring, the RPN value was reduced to 50. However, with the application of new antibacterial coating circuits, the team re-evaluated the risks in this area and found that "bacterial colonization due to coating detachment" had become a new potential failure mode (RPN = 150). Subsequently, the intervention strategy was adjusted to include a coating integrity check before circuit use. This dynamic feedback mechanism ensures that infection prevention and control measures remain aligned with clinical practice, avoiding the limitations of a one-size-fits-all management approach.

4. Progress in the application of EBM in hospital operating room infection prevention

4.1. Evidence grading and standardized recommendations for infection prevention measures

EBM integrates evidence from multicenter studies through systematic reviews and meta-analyses to provide graded recommendations for infection prevention measures in operating rooms [10]. The "Global Guidelines for the Prevention of Surgical Site Infection" issued by the World Health Organization (WHO), based on the GRADE evidence grading system, explicitly recommend the following: preoperative skin disinfection with chlorhexidine-alcohol solution (strong recommendation, high-quality evidence), maintaining normal body temperature during surgery (strong recommendation, moderate-quality evidence), and discontinuing prophylactic antimicrobial agents within 24 hours postoperatively (strong recommendation, high-quality evidence) [11]. These standardized recommendations provide clear guidance for clinical practice. After strictly adhering to the WHO guidelines in orthopedic surgeries, Liang Guangming and colleagues observed a reduction in the incidence of surgical site infections (SSI) from 2.1% to 0.8% [12]. Additionally, EBM promotes the refinement of infection prevention and control measures in operating rooms, such as developing differentiated antimicrobial drug use protocols based on surgical type (clean surgery, clean-contaminated surgery, contaminated surgery) to avoid the development of drug-resistant bacteria caused by a "one-size-fits-all" approach to medication.

4.2. Evidence-based application of new technologies and materials

EBM provides a scientific basis for the introduction of new infection prevention and control technologies and materials in operating rooms. For instance, antimicrobial-coated sutures inhibit bacterial colonization at the incision site by locally releasing antimicrobial agents. Multiple randomized controlled trials (RCTs) have confirmed that they can reduce the risk of SSI (RR = 0.65, 95% CI 0.52–0.81), but their use should be strictly indicated (e.g., in high-risk surgical patients). EBM also guides the optimization of environmental disinfection techniques in operating rooms. For example, hydrogen peroxide vapor disinfection has been shown to more thoroughly eradicate drug-resistant bacteria (such as MRSA) compared to traditional ultraviolet irradiation and has lower corrosivity to equipment, making it the preferred disinfection method for high-risk operating rooms (such as those for organ transplantation) [13]. Furthermore, EBM drives the upgrading of personal protective equipment (PPE) in operating rooms. The use of double gloves, for instance, can reduce the risk of blood exposure due to intraoperative glove rupture (from 4.2% to 1.1%), but it requires balancing operational dexterity with protective efficacy.

4.3. Evidence-based management of patient-specific factors and infection risks

EBM emphasizes the development of individualized infection prevention strategies based on patient characteristics. For example, patients with diabetes are prone to incisional infections due to blood glucose fluctuations. EBM recommends controlling preoperative blood glucose levels within the range of 7.8–10.0 mmol/

L to balance the risks of infection and hypoglycemia. For obese patients, due to their thick subcutaneous fat and high incisional tension, EBM suggests employing tension-reducing suture techniques and extending the duration of prophylactic antimicrobial use (from 24 hours to 48 hours) [14]. Additionally, EBM also focuses on the impact of patients' psychological factors on infections. For instance, preoperative anxiety can lead to a decline in immune function. By alleviating anxiety through music therapy or psychological counseling, the incidence of surgical site infections (SSIs) can be reduced by 30% (OR = 0.7, 95% CI 0.5–0.9) [15].

5. Application progress of HFMEA model combined with EBM in operating room infection prevention

5.1. Risk identification and evidence-based prioritization in operating room infection prevention

The FMEA model systematically examines infection prevention and control processes in the operating room, combining evidence-based medicine to accurately identify high-risk failure points and determine intervention priorities. Research has indicated that in the hand hygiene practices of surgical personnel, FMEA analysis revealed that traditional alcohol disinfection was insufficient in killing spore-forming microorganisms [16]. Evidence-based medicine demonstrates that chlorhexidine-alcohol composite disinfectants can significantly reduce bacterial load on hands (RR = 0.42, 95% CI 0.31–0.57), leading to its prioritization for improvement. Another study showed that after hospitals applied FMEA in conjunction with EBM, differentiated prevention and control strategies were developed for high-risk areas (such as instrument cleaning and environmental disinfection), resulting in a reduction in the operating room infection rate from 1.8% to 0.9% [17]. Furthermore, FMEA quantifies the risk priority number (RPN), identifying "contamination of sterile items during surgery" as the highest-risk item. Evidence-based medicine supports the use of disposable sterile packs instead of reusable sterilized instruments to further reduce the risk of cross-infection.

5.2. Optimization of infection prevention and control processes and integration of evidence-based measures

The FMEA model optimizes infection prevention and control processes in the operating room through a closed-loop management approach of "prevention-monitoring-improvement", incorporating evidence-based medicine. The study by Zhu Guanmei and others pointed out that during the preparation of the surgical site, FMEA analysis revealed that traditional iodophor disinfection had issues such as significant skin irritation and low patient compliance [18]. Evidence-based medicine recommends the use of chlorhexidine-alcohol solution (strong recommendation, high-quality evidence), which not only offers superior disinfection effects (reducing the risk of surgical site infections (SSI) by 40%) but also significantly enhances patient comfort. Another study combined FMEA with EBM to develop a stratified intervention plan for the high-risk process of "intraoperative temperature maintenance": passive insulation (e.g., covering with an insulation blanket) was employed for low-risk surgeries, while active warming devices (e.g., forced-air warming devices) were used for high-risk surgeries (e.g., organ transplants), resulting in a reduction in the incidence of intraoperative hypothermia from 32% to 15% [19]. Furthermore, through process reengineering, FMEA moved the "postoperative instrument pre-treatment" step to the operating room and, combined with the use of enzyme detergents recommended by evidence-based medicine, increased the instrument cleaning pass rate from 85% to 98%.

5.3. Multidisciplinary collaboration and evidence-based decision support

The FMEA model emphasizes cross-disciplinary teamwork and the development of comprehensive infection prevention and control plans based on evidence-based medicine. A study indicated that in the "management of high-risk surgical patients", the FMEA team integrated opinions from multiple disciplines, including surgery, infectious diseases, and pharmacy, to develop individualized strategies based on evidence-based medicine: for diabetic patients, preoperative blood glucose was controlled within the range of 7.8–10.0 mmol/L (strong recommendation, moderate-quality evidence); for obese patients, tension-reducing suture techniques were employed, and the use of prophylactic antimicrobial agents was extended to 48 hours (weak recommendation, low-quality evidence) [20]. Additionally, Lin Danzhu et al., through multidisciplinary FMEA analysis, found that the "timing of intraoperative antimicrobial agent administration" was a key factor affecting SSI [21]. By adopting the EBM-recommended protocol of "administering the drug 0.5–1 hour before skin incision", the incidence of SSI decreased from 2.5% to 1.2%. Furthermore, FMEA established an evidence-based decision support system to update infection prevention and control guidelines in real-time, ensuring that team decisions are based on the latest evidence.

5.4. Constructing a precise risk priority number evaluation system

To address the issue of strong subjectivity in RPN scoring, it is essential to establish unified and objective scoring criteria. This involves consulting extensive literature and conducting clinical research to clearly define the specific manifestations and quantitative data of each risk factor at different levels. Additionally, developing specialized software to incorporate these scoring criteria can reduce human error and ensure the accuracy and consistency of scoring. Meanwhile, establishing a data-sharing platform will facilitate data exchange among different research institutions, providing a basis for refining the scoring criteria.

5.5. Innovating a research model integrating multiple theories

Given the limitations of HFMEA, it is crucial to actively explore research models that combine HFMEA with evidence-based medicine, quality management theory, and other methodologies. For instance, applying evidence-based medicine evidence retrieval and evaluation methods to HFMEA can make risk factor analysis and improvement methods more scientific. By integrating quality management theory, a continuous quality improvement cycle model can be constructed to continually refine the process of preventing surgical infections. Through the integration of multiple theories, a comprehensive and dynamic infection prevention system can be established to adapt to the complex and ever-changing clinical environment.

6. Conclusion

In summary, the HFMEA model, with its systematic and forward-looking risk management characteristics, can accurately identify potential infection risk points in surgical procedures and provide a scientific basis for intervention measures through quantitative assessment. Evidence-based medicine, centered on the best available evidence and combined with individual patient needs and medical resources, offers standardized references for formulating and optimizing infection prevention and control measures. The integration of these two approaches helps strengthen the deepening of multidisciplinary collaboration models, promotes the establishment of risk priority assessment systems, and drives innovation in research models that integrate multiple theories. With the continuous advancement of medical care and the growing demand for infection prevention and control, the HFMEA model and evidence-based medicine will play an increasingly important role in preventing and controlling infections in operating rooms, contributing to improved medical quality and enhanced patient safety.

Disclosure statement

The author declares no conflict of interest.

References

[1] Chen H, Zhang C, Wu B, et al., 2022, Research on the Application of Healthcare Failure Mode and Effect Analysis in the Management of Routine Pathological Specimens in Operating Rooms. Chinese Nursing Management, 22(1): 9–13.

[2] Li X, 2020, Observation on the Application Effect of Healthcare Failure Mode and Effect Analysis (HFMEA) in Nursing Safety Management in Operating Rooms. Guide of China Medicine, 18(19): 211–212.

[3] Zou Z, Zhou X, Duan H, et al., 2023, Application of Healthcare Failure Mode and Effect Analysis in Preventing Negative Outcome Nursing Interruptions in Operating Rooms. Chinese Journal of Practical Nursing, 39(14): 1041–1047.

[4] Guo M, 2020, Application Effect of Healthcare Failure Mode and Effect Analysis in Nursing Safety Management in Operating Rooms. Diet and Health Care, 2020(42): 221.

[5] Ma X, Li W, He D, et al., 2024, Control Effect of Multidisciplinary Collaboration-Based HFMEA on Hospital Infections. Journal of Jinan University (Natural Science & Medicine Edition), 45(4): 420–427.

[6] Yao Y, Fan G, Bi S, et al., 2025, Application of Healthcare Failure Mode and Effect Analysis in Reducing Hospital Infection Risks. Modern Hospitals, 25(6): 869–872 + 876.

[7] Lv Q, Lai X, Xu M, et al., 2022, Hospital Infection Risk Management in Fever Clinics Based on Healthcare Failure Mode and Effect Analysis. Chinese Journal of Nosocomiology, 32(12): 1861–1865.

[8] Fu T, Yang X, Xu Z, et al., 2024, Application of Healthcare Failure Mode and Effect Analysis in the Prevention and Control of Surgical Site Infections in Class I Incisions for Fracture and Craniotomy Surgeries. West China Medical Journal, 39(8): 1246–1251.

[9] Jin X, Fu X, Wan Y, et al., 2019, Application Effect of HFMEA in Nursing Safety Management in PICC Clinics. International Journal of Nursing, 38(21): 3479–3483.

[10] Ma Q, 2022, Application Effect of Risk Management Under Evidence-Based Medicine Model in Hospital Infection Control in Laminar Flow Purification Operating Rooms. Chinese Rural Medicine, 29(3): 67–69.

[11] Zhang M, 2020, The Impact of Evidence-Based Medicine on Reducing the Incidence of Operating Room Infections and Improving Nursing Quality. Guide of China Medicine, 18(9): 271–272.

[12] Liang G, 2019, The Impact of Evidence-Based Medicine Model on Operating Room Infections and Nursing. Diet and Health Care, 6(23): 187–188.

[13] Jia Y, Liang X, Wu W, et al., 2024, Application of Healthcare Failure Mode and Effect Analysis in Nursing Risk Management of Emergency Surgery for Craniocerebral Trauma. Journal of Practical Clinical Medicine, 28(8): 127–133.

[14] Lu L, Song H, Zhou L, 2025, The Control Effect of Multidisciplinary Collaboration-Based HFMEA on Hospital Infection Management. China Health Industry, 22(5): 49–52.

[15] Wu Y, Chen W, Xie Y, et al., 2023, Evaluation of the Effectiveness of HFMEA-Based Prevention of Outbreaks of

Hospital-Acquired Infections Caused by Multidrug-Resistant Organisms in the ICU. Chinese Journal of Infection Control, 22(1): 102–109.
[16] Gu C, 2023, The Effect of HFMEA Model Combined with Evidence-Based Medicine on the Prevention of Operating Room Infections. Xinjiang Medical Journal, 53(10): 1267–1270, 1275.
[17] Song L, Zhang Y, Zhou T, 2020, Application of HFMEA in Preventing Pulmonary Infections in Patients with Severe Craniocerebral Injury Undergoing Tracheotomy. China Medical Herald, 17(32): 173–176.
[18] Zhu G, Dou M, Yu X, 2019, Analysis of the Effectiveness of Healthcare Failure Mode and Effect Analysis in Infection Control for Hemodialysis Patients. Medical Higher Vocational Education and Modern Nursing, 2(6): 431–435.
[19] Dong C, 2019, The Preventive and Control Effect of Healthcare Failure Mode and Effect Analysis on Hospital-Acquired Infections in Rheumatic Immune Diseases. Journal of Shandong Medical College, 41(1): 55–57.
[20] Huo J, Fang P, Wang L, et al., 2024, Application of Healthcare Failure Mode and Effect Analysis Management Model in Reducing Pulmonary Infections in Patients with Acute Stroke. Journal of Nurses Training, 39(6): 647–652 + 658.
[21] Lin D, Chen Y, Huang S, et al., 2024, Application of Healthcare Failure Mode and Effect Analysis in the Prevention and Control of Hospital-Acquired Infections in Newborns. China Health Standard Management, 15(17): 179–184.

Publisher's note

Bio-Byword Scientific Publishing remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.