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ORIGINAL RESEARCH

Improving Pressure Steam Sterilization Quality Through Healthcare Failure Mode and Effects Analysis: A Pre-Post Intervention Study in Central Sterile Supply Departments

Yanrong Zhang[1,2], Ruixue Hu[1,2], Yanhua Chen[1,2], Xiaoxiao Liu[1,2], Jin Wu[1,2], Liangying Yi[1,2]

[1]Department of Sterile Processing Nursing, West China Second University Hospital, Sichuan University, Chengdu, Sichuan, People's Republic of China; [2]Key Laboratory of Birth Defects and Related Diseases of Women and Children (Sichuan University), Ministry of Education, Chengdu, Sichuan, People's Republic of China

Correspondence: Liangying Yi, Department of Sterile Processing Nursing, West China Second University Hospital, Sichuan University, No. 20 Section 3, South Renmin Road, Chengdu, Sichuan, 610041, People's Republic of China, Email yiliangying88@163.com

Objective: To evaluate the effectiveness of Healthcare Failure Mode and Effects Analysis (HFMEA) in reducing quality defects during pressure steam sterilization in the Central Sterile Supply Department (CSSD).

Methods: The study followed a structured HFMEA framework: (1) A multidisciplinary team (n=7) with CSSD expertise was established to analyze sterilization workflows, including instrument scanning, sterilization verification, and post-sterilization cooling. (2) Process mapping and risk prioritization were conducted using a 4-level severity/occurrence matrix (adapted from Australian clinical risk criteria) to calculate Risk Priority Numbers (RPN=Severity×Occurrence). High-risk failure modes (RPN≥8 or severity=4) were identified, including unlabeled "non-sterilized" packages (due to incomplete scanning), wet packages (from insufficient cooling<30 minutes), and unverified sterilization information. (3) Root causes were analyzed via fishbone diagrams (human, machine, material, environment, method). Targeted interventions included: optimizing the traceability system with department-specific alerts, standardizing scanning protocols, staff retraining on verification procedures, increasing instrument inventory and sterilizer racks, and implementing performance monitoring with 5W1H checklists.

Results: Pre-intervention, 87 defects were identified among 185,382 sterilization packages (32 unlabeled "non-sterilized", 10 wet packages). Post-intervention, defects decreased to 11/189,531 packages (χ^2=115.556, P<0.001), including 4 unlabeled (χ^2=374.951, P<0.001) and 2 wet packages (χ^2=8.889, P=0.003).

Conclusion: Systematic HFMEA application reduced sterilization defects by addressing critical workflow gaps, demonstrating its value in enhancing CSSD quality control and patient safety.

Keywords: healthcare failure mode and effects analysis, central sterile supply department, pressure steam sterilization, quality defects

Introduction

The central sterile supply department (CSSD) is an important hospital department that ensures the quality of medical care and controls infection.[1] This unit holds a central position in safeguarding the quality of medical and nursing care, as well as in mitigating the occurrence of hospital-acquired infections. Given the rapid progress in medical technology, sophisticated and precise medical instruments pose stringent requirements and challenges for pressure steam sterilization.

The term "adverse event of the CSSD" refers to a situation that occurs during the disinfection supply work and may have an impact on the regular operation of the hospital, the outcomes of patient diagnosis and treatment, the workload of the same department, and the safety of the staff.[2] Reprocessing of reusable surgical instruments depicts one of the multimodal exogenous sources of bacteria causing Surgical site infections.[3] Surgical instruments must undergo rigorous cleaning, disinfection, and sterilization procedures after usage. According to current Chinese standards, the sterilization

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process of surgical instruments must strictly adhere to the requirements for pressure steam sterilizers specified in *Technical Specifications for Cleaning, Disinfection, and Sterilization Operations in Hospital Central Sterile Supply Departments*.[4] Consequently, it is crucial to actively identify the pertinent risk factors affecting the sterilization effect of surgical instruments in CSSD and to implement preventive measures at the earliest possible juncture.

Despite the diverse methods proposed in current literature for reducing defects in sterilization, most of them focus on post-occurrence rectification and remedial measures, lacking a comprehensive analytical framework for proactive analysis of the entire process and preemptive risk management strategies.[1,5,6] Healthcare Failure Mode and Effects Analysis (HFMEA) is a proactive risk management tool for identifying the possible failure modes of a system, process, product or service, analyzing the causes and effects of the failures, and eliminating or reducing the most significant ones by proposing risk mitigation actions.[7] The use of HFMEA in the healthcare setting has become increasingly popular over the last decade, being applied to a multitude of different areas.[8,9] So this study aims to address the gap in quality management of pressure steam sterilization in CSSD by introducing the HFMEA method, thereby enabling the formulation and implementation of proactive and effective intervention measures to significantly enhance the overall quality of sterilization work.

Materials and Methods

Study Setting

We conducted a thorough retrospective analysis and risk assessment of the pressure steam sterilization process based on the HFMEA framework. The analysis consisted of 7 steps: determining the subject, team formation, process mapping, hazard analysis, establishment of a checklist, implementation of interventions, and evaluation.

Between April and July 2023, 185,382 sterilization packages were selected as the control group. Through a decision tree model, we identified the process steps requiring action and accordingly formulated improvement plans. From August to November 2023, 189,531 sterilization packages were selected as the experimental group to test the effectiveness of the improvement plans.

Basic Steps for Implementing HFMEA

Determining the Subject

The workflow of the CSSD encompasses ten pivotal stages: collection, sorting, cleaning, disinfection, drying, inspection and maintenance, packaging, sterilization, storage, and distribution of sterile instruments. Within this sequence, the pressure steam sterilization procedure assumes paramount significance owing to its crucial role and associated high-risk potential. Following a thorough evaluation of the quality control data from 2022 conducted by our department's quality assurance team, coupled with a deliberative discussion on nursing-related adverse events, we have identified "mitigating the occurrence of quality deficiencies in pressure steam sterilization" as the focal point of this study, utilizing the brainstorming approach to formulate our research objective.

Team Formation

In April 2023, an HFMEA team was assembled comprising seven experienced professionals from our hospital's Central Sterile Supply Department (CSSD). The core members included a head nurse (project supervisor), a chief nurse (project leader), a deputy chief nurse (implementation overseer), a research nurse (literature review and data analysis), two nurse backbones, and a sterilization technician. While engineers were not permanent members of the team due to their external affiliation with the hospital, sterilizer manufacturer engineers were actively consulted throughout the study to provide technical guidance on equipment operation, maintenance, and troubleshooting. For instance, during discussions on sterilizer-related failures such as incomplete vacuum cycles or temperature deviations, the team collaborated with these engineers to analyze root causes and develop solutions. All core team members possessed over five years of CSSD experience and underwent unified HFMEA methodology training prior to the project to ensure rigorous implementation and evaluation. This hybrid structure balanced internal expertise with external technical support, aligning with HFMEA's multidisciplinary principles while addressing practical constraints.

Process Mapping

Through interviews with project team members and clinical characteristic discussions, seven pressure steam sterilization workflows were systematically mapped. A standardized flowchart with numbered steps and sub-processes was developed (see Table 1).

Hazard Analysis

A comprehensive hazard analysis was conducted through brainstorming sessions and fishbone diagramming to identify potential failure modes in the pressure steam sterilization process. The analysis evaluated risks from five perspectives: human, machine, material, environment, and method. Each failure mode was systematically numbered and linked to root causes and consequences. Biological indicators (Geobacillus stearothermophilus spores) and chemical indicators (Class 4/5) were routinely employed to monitor sterilization efficacy, with results integrated into the risk assessment framework.

Risk quantification utilized a decision tree model, calculating Risk Priority Numbers (RPN) as RPN = Severity (S) × Occurrence (O). Severity reflected the impact on medical devices/operations (eg, compromised sterility), while occurrence frequency estimated failure likelihood. Based on medical risk management standards, both parameters were stratified into four levels with corresponding scores (Table 2).[9] Based on these classifications, an HFMEA hazard scoring

Table 1 Breakdown Diagram of Pressurized Steam Sterilization Process

First-level	A: Pre-Sterilization Inspection			
Second-level	A1: Check Sterilizer Media	A2: Check Sterilizer Performance	A3: Sterilizer Preheating	A4: B-D Test
Third-level	A1a: Check Power Supply A1b: Check Water Pressure A1c: Check Steam Pressure A1d: Check Compressed Air	A2a: Verify Sterilizer Pressure Gauge at "0" Position A2b: Check Sterilizer Seal for Flatness and Damage A2c: Verify the sterilization cabinet's condensate drain is clear and the door safety latch functions properly.	A3a: Turn On Sterilizer Power Switch A3b: Select Program, Ensure Jacket Pressure Reaches 3000 mbar for 20 Minutes.	A4a: Inspect B-D Test Pack A4b: Open and Place Test Pack Correctly in Sterilizer A4c: Select B-D Test Program and Start
First-level	B: Loading			
Second-level	B1: Scan Sterilization Items	B2: Load Sterilization Items	B3: Place Monitor Products	
Third-level	B1a: Transport Items to Be Sterilized to Rack B1b: Scan Items to Be Sterilized by Department B1c: Verify Exchange Sheet with Information System to Confirm Details	B2a: Load Items to Be Sterilized on Rack According to Standards B2b: Double-Check Sterilization Information	B3a: Check Quality of Monitor Products B3b: Place Monitor Products on Rack	
First-level	C: Sterilization		D: Unloading	
Second-level	C1: Select and Start Sterilization Program	D1: Unload Sterilized Items	D2: Cooling and Storage	D3: Sterilization Quality Confirmation
Third-level	C1a: Confirm Sterilization Program C1b: Select and Start Sterilization Program C1c: Observe and Record Operating Parameters and Equipment Status During Sterilization	D1a: Wear Heat-Resistant Gloves D1b: Unload Sterilized Items	D2a: Transport Items to Cooling Area, Avoiding Direct Airflow D2b: Allow Sterilized Items to Cool for Over 30 Minutes	D3a: Check Physical Print Parameters D3b: Inspect Batch Monitoring D3c: Check External Chemical Monitor of Packages D3d: Verify Package Integrity D3e: Check for Moist Packages

Table 2 The Failure Mode Evaluation Tool for Pressure Steam Sterilization

Classification/Items	Definition		
	Severity	Occurrence	Score
I	The failure hardly produces significant adverse outcomes, or the impact is minimal.	The failure hardly occurs, or the likelihood of occurrence is extremely low.	1
II	The failure may lead to minor adverse consequences, such as an extended sterilization time.	Failures rarely occur, but there is still a possibility of them happening.	2
III	The failure may lead to moderate adverse consequences, such as substandard sterilization effects.	Failures occur sometimes, but the frequency is not high.	3
III	The failure may lead to serious medical accidents, such as the spread of infection.	Failures occur frequently, or there is a high likelihood of them happening.	4

Table 3 Potential Failure Modes Within Quality Defects of Pressure Steam Sterilization

Process	Potential Failure Modes	Possible Causes of Failure	Severity	Occurrence	RPN
B: Loading	B1: Scan Sterilization Items	B1a: Failure to promptly use the transfer cart to load items to be sterilized next to the sterilization rack	1	3	3
		B1b: Failure to scan items to be sterilized one by one by department	4	4	16
		B1c: Failure to verify sterilization item information by comparing the exchange form with the information system	4	4	16
	B2: Load Sterilization Items	B2a: Failure to load items to be sterilized onto the sterilization rack according to standards	2	4	8
		B2b: Failure to verify sterilization item information by comparing the exchange form with the information system	4	4	16
D: Unloading	D2: Cooling and Storage	D2a: Failure to promptly transfer sterilized items to the cooling area	1	3	3
		D2b: Sterilized items not cooled for over 30 minutes	4	2	8

matrix was developed, with a total score ranging from 1 to 16. Failure modes with a hazard index of 8 or above, or a hazard index below 8 but with a severity score of 4, were considered high-risk modes. Later the failure modes requiring immediate action were identified presented in Table 3.

Establishment of a Checklist

The development of this checklist adopts a risk-driven, phased optimization approach through collaborative team discussions. Centered on whole-process risk management and sterilization quality improvement, it systematically establishes a workflow covering four critical stages: pre-sterilization inspection, loading, sterilization, and unloading. The structured development process includes: Step decomposition based on defect categories (preparation, loading, sterilization, unloading stages); Phase-specific inspection criteria established through equipment validation (steam quality testing, B-D tests), procedure standardization (scan-based registration, load capacity control), process monitoring (program parameters, preheating status), and post-sterilization verification (cooling efficacy); Tabular checklist formatting to display phased inspection items, results, and remarks. The system implements closed-loop management via a four-dimensional tracking mechanism (date, items, anomaly causes, responsible personnel) to enable root cause analysis and accountability verification. Dynamic process optimization is achieved through simulated testing and staff training,

ultimately ensuring traceable sterilization safety via full-process transparency, defect source tracking, and standardized documentation from preprocessing to quality review.

Establishment of an Action Plan

Through cause-and-effect diagram analysis, three critical issues in the sterilization process were systematically identified: departments' failure to independently scan sterilizable items, discrepancies between sterilization records and exchange slips, and insufficient post-unloading cooling (<30 minutes) of sterilized items, with root causes traced. Targeted countermeasures were developed using the 5W1H framework, specifying quality defect tracking (What), effectiveness verification (Why), implementation sites/timelines (Where/When), responsible personnel (Who), and operational workflow/item quality audit mechanisms (How). RPN-based prioritization determined improvement urgency for these issues. A 1/3/5 scoring scale evaluated corrective actions across cost efficiency, benefit potential, and team capabilities. Following the 80/20 principle, measures exceeding an 84-point threshold were selected for implementation (as detailed in Table 4).

Evaluation

Sterilization quality was evaluated via a composite endpoint consisting of: sterilization quality-defects, incidence of "non-sterilized" packages (failure to scan in traceability system), and wet packs (moisture retention post-sterilization).

Statistical Methods

Epidata 3.1 was used for dual-entry and management, and SPSS 26.0 statistical analysis software was employed for analysis. Chi-square tests were applied to compare the incidence rates of various indicators before and after the application. A P-value of less than 0.05 (two-sided test) was considered statistically significant.

Ethics Statement

This research was a quality improvement initiative that did not involve interventions with human subjects or the use of personally identifiable patient data. All analytical data were derived from routine sterilization process records of the Central Sterile Supply Department (CSSD) (eg, number of sterilized packages, types and incidence rates of quality defects), containing no individually identifiable information. All process improvement measures strictly adhered to CSSD internal operational protocols and impose no additional risks to staff or patient rights. Reviewed by the Ethics Review Committee of West China Second University Hospital, Sichuan University, it was determined that neither ethical approval nor related exemption documents are required for this study.

Results

The HFMEA-driven quality improvement initiatives demonstrated statistically significant reductions in sterilization-related defects across all monitored categories when comparing pre-intervention (From April to July in 2023) and post-intervention (From August to November in 2023) periods (all p-values <0.05). A comparison of the occurrence of quality defects in pressurized steam sterilization before and after the implementation of HFMEA is presented in Table 5.

Discussion

The Application of HFMEA Can Effectively Improve Sterilization Quality

After implementing HFMEA, the number of sterilization quality defects has significantly decreased, indicating that HFMEA is effective in improving sterilization quality. Yu et al's research has shown that after HFMEA, the qualification rate of overall monitoring process of disinfection quality improved from 16.5% to 78.7%, and the qualification rates of each monitoring step were all significantly improved.[10] Based on RPN, we have clarified the issues that require priority attention and implemented standardized management and improvements for key projects. We focused on reducing the chances and conditions for failure modes to occur, setting up barriers to make it easier to detect failures once they occur, and minimizing the severity of potential harm caused by failure modes. This has effectively reduced the frequency of failure modes such as failure to scan sterilized

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Table 4 HFMEA in the Pressure Steam Sterilization Process

Failure Mode	Cause of Failure	Consequences of Failure	Rectification Measures
The items to be sterilized have not been scanned individually and separately by department.	Without sorting items to be sterilized by department during the scanning process, the traceability system lacks prompts for departmental classification; there is no relevant reward and punishment system; the Standard Operating Procedure (SOP) for sterilization scanning operations is incomplete; sterilization operators consider scanning by department cumbersome and believe that not sorting items by department during scanning does not affect sterilization.	Failing to scan items to be sterilized by department makes it inconvenient to verify the names and quantities of this batch of items. Unscanned items are difficult to detect, and after sterilization, the information system displays them as "not sterilized". When quality issues arise with sterile packages, it becomes challenging to trace and achieve "one-to-one" recall.	We have discussed with engineers to set up departmental classification alerts in the information system; we will improve the performance evaluation guidelines for sterilization personnel positions, as well as relevant reward and punishment systems; further refine and perfect the SOP for sterilization scanning and display it next to the computers at the sterilization posts; strengthen training on the importance of sterilization scanning to enhance operators' scanning awareness, and strengthen supervision by managers and quality control inspectors.
The exchange slips have not been verified against the information system to confirm the sterilization item information.	There is a lack of clarity on which specific details need to be checked for the sterilization items; unawareness of the importance of accurate sterilization item information; and, due to the concentration of sterilization items in a particular time period, it is not feasible to carefully check each exchange slip.	If the verification is not conducted, any missing scans of items to be sterilized may not be detected, resulting in the information system displaying them as "not sterilized" after the sterilization process. This causes difficulties in tracing and achieving "one-to-one" recall when quality issues arise with sterile packages.	To address these issues, training will be strengthened to reinforce the learning and implementation of the verification system, ensuring that everyone is proficient in its use. The importance of checking sterilization item information will be emphasized. Quality control supervisors will conduct daily spot checks to ensure that sterilization personnel are verifying the sterilization item information. The number of surgeries scheduled for the next day will be tallied in the information system daily, and if there are a large number of surgeries, additional staff will be arranged to assist the sterilization personnel in scanning and loading. Reasonable and flexible scheduling will be implemented to increase staffing during peak periods of sterilization item concentration. The performance Evaluation guidelines for sterilization personnel will be improved, and relevant reward and punishment systems will be perfected, especially with non-compliance with the verification system being considered a one-strike disqualification.
Sterile items unloaded without cooling for over 30 minutes	Due to the limited quantity of instruments and the urgent need of surgical departments with multiple surgeries, the next batch of sterilization cannot wait for more than 30 minutes of cooling as sterilization racks are insufficient and need to be loaded promptly.	Occurrence of wet packages resulting in re-contamination of sterile parcels	Increasing the base number of instruments and purchasing additional sterilization racks.

Table 5 Comparative Analysis of Defects in Pressurized Steam Processes

Date	Number of Packages to be Sterilized	Sterilization Quality Defects	Number of "Unsterilized" Packages	Number of Wet Packages
April to July 2023	185,382	87	32	10
August to November 2023	189,531	11	4	2
χ^2	–	115.566	374.951	8.889
P	–	<0.001	<0.001	0.003

items by department, inaccurate checking during loading, and unloading of sterilized items without cooling for more than 30 minutes. Consequently, the overall quality of the pressurized steam sterilization process in the CSSD has been improved.

The Application of HFMEA is Beneficial for Continuous Improvement of Sterilization Quality

Surgical instruments, devices, and items serve as indispensable tools for surgical treatments, and their sterilization quality is paramount for surgeons to successfully complete surgical procedures. HFMEA is an effective tool that eradicates sterilization quality defects from the outset. The proposed model is applied in the case of the central sterilization unit of a tertiary national reference centre of dental treatment, where its efficiency is evaluated compared to the classical approach.[11] In this study, a dedicated project management team was established to oversee the execution of improvement measures. The head nurse of the CSSD spearheaded the formulation, revision, and quality monitoring of systems and procedures. Quality control personnel within the department provided comprehensive training to all staff and conducted daily quality checks on both the sterilization process and the final products. The regional team leaders were entrusted with the implementation of these procedures and systems. The project management team regularly and irregularly reviewed the project's progress, reporting and emphasizing its advancements and requirements during departmental meetings, thus facilitating continuous quality improvement.

The Application of HFMEA Enhances Nurses' Evaluation of Sterilization Quality Defects and Team Cohesion

The results of this study show that during the optimization of the pressurized steam sterilization workflow in the CSSD, the HFMEA team used brainstorming to identify potential risk factors and improvement measures for failure causes, achieving favorable results. In this study, corresponding measures were taken for potential risk factors in key failure modes, improving nurses' evaluation of sterilization quality defects, enhancing team communication skills and cohesion, and creating a relaxed and favorable working atmosphere, effectively promoting the smooth implementation of nursing management.

The Adoption of HFMEA Can Further Standardize Pressure Steam Sterilization Procedures

This study identifies critical failure modes in the pressurized steam sterilization process that pose a significant risk. These include the failure to scan items for sterilization by respective departments, the oversight in verifying sterilization item information against exchange forms, and the premature unloading of sterilized items without a cooling period of at least 30 minutes. These deficiencies are primarily attributed to inadequacies in the tracing system, lack of standardized operating procedures among sterilization personnel, and suboptimal management practices. Such shortcomings can result in wet packages, packages labeled as "unsterilized", difficulties in tracing defective sterile packages, decreased clinical satisfaction, and adverse impacts on the utilization of clinical instruments and equipment.

To address these issues and prevent sterilization quality defects, the implementation of systematic control measures is essential. The HFMEA (Healthcare Failure Mode and Effects Analysis) team has refined the standard operating procedure for scanning sterilized items in the CSSD, aligning it with hygiene industry standards and evidence-based

practices. Additionally, a comprehensive checklist has been devised to document the current status of daily pressurized steam sterilization quality defects. The introduction of fine-grained management has enhanced the checking system and clarified job responsibilities for sterilization personnel.

Furthermore, the team has optimized collaboration by establishing long-term collaboration mechanisms with the boiler room, equipment department, and manufacturers.[12] This has strengthened the daily management of sterilization equipment and facilities, with dedicated personnel assigned for oversight. Regular inspections are conducted, timely feedback is provided, and prompt maintenance is performed to ensure the continuous operation of sterilization equipment and adequate monitoring of outcomes.

Limitations

While this study demonstrates the effectiveness of HFMEA in reducing pressure steam sterilization defects, several limitations should be acknowledged. First, as a single-center pre-post intervention study, the findings may be influenced by institutional-specific workflows, staff compliance, and equipment characteristics, limiting generalizability to other healthcare settings. Second, the 2-month intervention period might not fully capture long-term sustainability of improvements. Third, risk scoring (RPN calculations) relied on subjective team assessments of severity and occurrence, which could introduce bias despite standardized training. Fourth, the study focused on two measurable outcomes (unlabeled "non-sterilized" and wet packages) but did not assess latent risks like microbial survival rates or instrument functionality post-sterilization. Fifth, while staff training was implemented, the impact of individual competency variations and turnover rates on defect reduction remains unquantified. Finally, the Hawthorne effect may have temporarily enhanced staff adherence to protocols during the study period. Future multi-center studies with extended follow-up, objective biological monitoring, and mixed-methods evaluations of human factors are recommended to strengthen evidence for HFMEA's scalability in CSSD settings.

Conclusion

This study confirms the effectiveness of HFMEA in systematically reducing quality defects within pressure steam sterilization processes at the CSSD. The findings emphasize the critical importance of standardized operating procedures, enhanced traceability systems, and continuous staff training for maintaining sterilization quality. Furthermore, the structured HFMEA framework promotes cross-departmental collaboration, clarifies accountability, and enhances process transparency, aligning with overarching goals of patient safety and infection control. Although conducted as a single-center study, the results provide robust evidence for HFMEA implementation. Future multi-center studies with larger samples are warranted to validate its generalizability across diverse healthcare settings. In conclusion, the systematic application of HFMEA offers a replicable quality improvement model for CSSD and other high-risk clinical workflows. Its core principle of "prevention over remediation" establishes a new benchmark for medical risk management practices, demonstrating significant practical value in advancing healthcare safety.

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Disclosure

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. All interventions and analyses were performed independently by the CSSD team, with technical guidance from sterilizer manufacturer engineers strictly limited to equipment operation and troubleshooting. The authors affirm no personal, professional, or institutional affiliations that could influence the objectivity of this work.

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