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Application Progress of Failure Mode and Effects Analysis in the Risk Management of Central Sterile Supply Departments

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ABSTRACT: Objective To review the evidence regarding the application of Failure Mode and Effects Analysis (FMEA) in the risk management of Central Sterile Supply Departments (CSSDs), compare improvement priorities across different risk scenarios, and propose a practical tiered implementation plan. **Methods** A narrative review was conducted by searching CNKI, Wanfang Data, VIP, and PubMed. Citation tracking was performed using publications from the World Health Organization, patient safety resources of the U.S. Department of Veterans Affairs, and recent quality control documents for sterile supply services. The search covered all literature published up to June 30, 2026. The application scenarios, failure modes, interventions, outcome measures, and limitations of the evidence were descriptively summarized. **Results** A total of 22 representative publications were included. FMEA has been applied to the management of loaned medical devices, endoscopes, packaging and sterilization, occupational protection, and integration with other management tools, and its application has gradually expanded to regional shared sterile supply services, information-based traceability systems, and 3D-printed patient-specific medical devices. Most studies reported reductions in process defects and nonconformities following intervention. However, the available evidence was still dominated by single-center before-and-after studies, with substantial heterogeneity in scoring systems, observation periods, and outcome definitions. **Conclusion** FMEA is well suited to the prospective identification of failure risks and the prioritization of improvement efforts in high-risk CSSD processes, but the Risk Priority Number (RPN) should not replace professional judgment. A localized approach that combines severity-triggered prioritization with RPN-based ranking, supported by information traceability, tiered implementation checklists, and multicenter prospective validation, may enhance the sustainability and reproducibility of risk management.

KEY WORDS: Central Sterile Supply Department (CSSD); Failure Mode and Effects Analysis (FMEA); Risk management; Medical device reprocessing; Quality improvement

1 Introduction

The Central Sterile Supply Department (CSSD) is responsible for the collection, sorting, cleaning, disinfection, inspection and packaging, sterilization, storage, and distribution of reusable medical devices, instruments, and other items. Its quality depends on a chain of linked processes rather than on any single step. As medical devices become more complex, loaner turnaround times shorten, and clinical demand fluctuates, risk increasingly arises at handoff points and from failures that may remain hidden until a later stage. The World Health Organization guidance on decontamination and reprocessing emphasizes that effective cleaning is the basis for subsequent disinfection and sterilization, and that an error at one stage can compromise later steps[1].

Routine quality inspections are effective at identifying defects that have already occurred, but they do not necessarily indicate the process step at which a defect is most likely to arise, nor do they identify where limited resources should be prioritized. Failure Mode and Effects Analysis (FMEA) improves process safety by breaking down workflows, identifying potential failure modes, analyzing their causes and consequences, and prioritizing improvement mea-

sures according to severity, occurrence, and detectability. Based on conventional FMEA, DeRosier et al. developed Healthcare Failure Mode and Effects Analysis (HFMEA), which incorporates multidisciplinary teams, hazard matrices, and decision trees into healthcare risk management, providing a relatively comprehensive approach for healthcare institutions to conduct prospective risk analysis[2]. Reviews from China indicate that FMEA has been applied to CSSD management issues involving loaned medical devices, endoscopes, wet packs, and occupational exposure[3].

Existing studies also have notable limitations. Some articles conflate FMEA with HFMEA; some report only reductions in the Risk Priority Number (RPN) without describing the raters, rating criteria, or reassessment methods; and different studies adopt inconsistent definitions of qualification rates, defect rates, and risk thresholds, making simple side-by-side comparisons liable to create the false impression that the results are directly comparable. Meanwhile, with the clinical implementation of regional shared sterile supply services, Internet of Things（IoT）-based traceability systems, and 3D-printed patient-specific medical devices, the boundaries of risk have expanded from within individual departments to inter-institutional handovers, data interfaces, and material-sterilization compatibility. On the basis of summarizing the major application scenarios, this paper further analyzes the comparability of the available evidence, emerging risks, localized rating methods, and tiered implementation pathways for CSSDs.

2 Data and methods

2.1 Data sources and search strategy

This study is a narrative review. Chinese-language literature was retrieved from the China National Knowledge Infrastructure (CNKI), Wanfang Data, and VIP databases, while English-language literature was retrieved from PubMed. Publicly available materials from the World Health Organization, the National Center for Patient Safety of the U.S. Department of Veterans Affairs, and domestic publications on sterile supply quality control were also reviewed. The Chinese search terms included Central Sterile Supply Department, sterile supply department, regional centralized sterile supply, medical consortium, loaned medical devices, implants, endoscopes, steam sterilization, instrument packaging, sharps injuries, information traceability, Internet of Things (IoT), 3D printing, Failure Mode and Effects Analysis (FMEA), and Healthcare Failure Mode and Effects Analysis (HFMEA). The English search terms included failure mode and effects analysis, healthcare failure mode and effect analysis; central sterile supply department; sterile processing; medical community disinfection center; quality traceability system; medical device reprocessing; sterilization; surgical instrument packaging; and 3D-printed surgical guide. The search covered the period from database inception to June 30, 2026, and the reference lists of the included studies and relevant review articles were traced to identify additional relevant literature.

2.2 Data selection criteria

Eligible publications addressed the CSSD, regional shared sterile supply services, medical device reprocessing, packaging, or sterilization. They were required to describe the use of FMEA, HFMEA, or Failure Mode, Effects, and Criticality Analysis (FMECA), or to provide methodological, guideline, or quality-control evidence directly relevant to risk identification and reprocessing practice. Publications were excluded if they were duplicates, only loosely related to medical device reprocessing, reported management outcomes without describing the underlying process, or contained methods or conclusions that could not be checked from the available source. The number and general characteristics of the publications retained for synthesis are reported in the Results section.

2.3 Data extraction and synthesis methods

The following data were extracted: author, publication year, country in which the study was conducted, application scenario, study design, major failure modes, intervention measures, RPN or other outcome measures. The included studies were then organized into seven categories: loaned medical devices, endoscopes, sterilization and packaging, oc-

cupational safety, integration with other management tools, regional centralized sterile supply and informatization, and complex personalized medical devices. The included studies differed substantially in terms of sample units, rating scales, threshold settings, and follow-up duration. Therefore, no meta-analysis was performed, and the absolute RPN values reported across different studies were not used to evaluate the relative effectiveness of the interventions. The percentages, P values, and magnitudes of change reported in this review are used solely to describe the pre- and post-intervention differences within the original studies. No further inferences were made from precise numerical values that could not be verified from publicly available information.

3 Results

3.1 General characteristics of the included literature

Twenty-two publications were retained for the narrative synthesis: 12 were published in Chinese and 10 in English. Seventeen publications originated from China; the remainder comprised one publication each from the United States, Iran, the Netherlands, and Tunisia, together with one World Health Organization guidance document with an international scope. The evidence base included hospital-based quality-improvement studies, a meta-analysis, methodological papers, a review, an in vitro study, and guidance or quality-control documents. Most empirical studies were single-center projects. Hospital level and service volume were not reported consistently enough to support a uniform subgroup description. The main topics were loaner instruments, endoscope reprocessing, packaging and steam sterilization, occupational safety, combined quality-improvement tools, traceability and regional shared services, and 3D-printed surgical guides. Table 1 summarizes all publications included in the review.[1-22]

Table 1 General Characteristics and Roles of the 22 Publications Included in the Review

Ref.	Language	Country/region	Source/design	Setting or topic	Main role in this review
1	English	International	WHO guidance	Medical device decontamination and reprocessing	Provides general principles for cleaning, disinfection, sterilization, and safe reprocessing.
2	English	United States	Methodological paper	Healthcare FMEA / HFMEA	Introduces the HFMEA framework, including multidisciplinary analysis, hazard matrices, and decision trees.
3	Chinese	China	Narrative review	FMEA in CSSD risk management	Summarizes domestic applications of FMEA in loaner devices, endoscopes, wet packs, and occupational safety.
4	English	Iran	Methodological study	Revised RPN	Discusses limitations of conventional RPN and proposes a healthcare-oriented revision of risk prioritization.
5	Chinese	China	Single-center quality improvement	Loaner medical instruments	Uses FMEA to identify failures in disassembly, cleaning parameters, assembly, and packaging.
6	Chinese	China	Meta-analysis	Loaner medical instruments	Synthesizes evidence on current practices and management problems in the reprocessing of loaner instruments.
7	Chinese	China	Before-and-after study	Laparoscopic / endoscopic instruments	Targets lumen flushing, missing parts, and ultrasonic-cleaning problems; reports fewer cleaning defects after intervention.
8	Chinese	China	Whole-process management study	Rigid endoscopes	Applies FMEA to pairing, protection, loading, cleaning, and sterilization of rigid endoscopic instruments.
9	Chinese	China	Before-and-after study	Flexible endoscopes	Identifies high-RPN failures in pre-cleaning, leak testing, brushing, drying, and storage.

续表

10	Chinese	China	FMEA + PDCA study	Flexible endoscope management	Combines risk identification with iterative process improvement in centralized flexible-endoscope management.
11	Chinese	China	Before-and-after study	Laparoscopic instrument sterilization	Focuses on loading density, drying, and Bowie-Dick testing; reports improved sterilization quality.
12	English	China	Single-center pre-post study	Steam sterilization	Uses HFMEA to reduce defects in pressure steam sterilization and reports event counts with denominators.
13	English	China	Single-center pre-post study	Instrument packaging	Uses HFMEA to reduce surgical instrument packaging defects.
14	English	Netherlands	HFMEA process analysis	Surgical instrument delivery	Examines hazards across CSSD, logistics, and operating-room interfaces.
15	Chinese	China	Survey + before-and-after study	Occupational safety	Maps sharps-injury risk points and evaluates FMEA-based preventive measures.
16	Chinese	China	HFMEA + QCC study	Infection prevention / process quality	Examines combined use of HFMEA and QCC for cleaning quality, sterile-item quality, and infection-control indicators.
17	English	Tunisia	FMECA risk analysis	Sterilization process	Builds a systematic risk map and prioritizes critical sterilization-process failures.
18	Chinese	China	FMEA + traceability study	Reusable dental instruments	Combines FMEA with information traceability to reduce reprocessing errors.
19	English	China	Historical-control study	Regional shared sterile supply	Evaluates a quality-traceability system in a shared medical-community sterilization center.
20	English	China	FMEA + information-system study	Cleaning and disinfection	Links FMEA with standardized information-system management and reports lower RPN and higher pass rates.
21	English	China	In vitro study	3D-printed surgical guides	Examines how material and sterilization/ disinfection methods affect the accuracy of 3D-printed surgical guides.
22	Chinese	China	Quality-control document	CSSD quality indicators	Provides current domestic quality-control indicators that can support local calibration and reassessment.

3.2 Application of FMEA in major risk scenarios in the CSSD

3.2.1 Loaner medical devices and cross-departmental interfaces

Loaner medical devices involve multiple stakeholders, unpredictable arrival times, complex components, and frequently missing reprocessing instructions. As a result, risks are often concentrated at the handoff interfaces among clinical departments, device vendors, and the CSSD. After mapping the reprocessing workflow, Nie Shengnan et al. identified failure modes, including incomplete disassembly, cleaning parameters inconsistent with the manufacturer's instructions for use, incorrect assembly orientation, and overweight instrument sets. They reduced these risks through illustrated disassembly and assembly procedures, parameter standardization, and independent double-checking[5]. A meta-analysis by Guo Li et al. also indicated that problems associated with loaner medical devices cannot be addressed by improving cleaning alone; standardized handovers, timely delivery, and complete, traceable information are equally important[6].

In this scenario, the focus of improvement is not to mechanically add signatures at every step, but to minimize information loss at handoff interfaces. Obtaining the manufacturer's reprocessing instructions before the devices arrive at the hospital and

confirming the implant, component list, and delivery schedule in advance is more effective in reducing delays and assembly errors than assigning responsibility after problems occur. For frequently used instrument sets, previously identified failure modes can be translated into receiving checklists and visual work standards. For infrequently used devices with complex or unusual designs, case-by-case assessment and technical support from the manufacturer should be maintained.

3.2.2 Reprocessing of rigid and flexible endoscopes

A common challenge in endoscope reprocessing is that their hidden internal structures make defects difficult to detect promptly by visual inspection. However, the major risk points differ between rigid and flexible endoscopes. In the reprocessing of laparoscopic instruments, Shi Qi identified insufficient lumen flushing pressure, missing components, and inappropriate ultrasonic cleaning conditions as high-priority risks. After implementing dedicated cleaning tools, standardized operation cards, and inspection training, the cleaning defect rate decreased from 6.8% to 1.2%[7]. In the comprehensive management of rigid endoscope reprocessing, Wang Xiaofei et al. reduced scope mismatching and compression-related damage through paired identification systems and dedicated sterilization baskets, achieving cleaning and sterilization pass rates exceeding 99%[8]. Such improvements mainly depend on accurate device identification, effective protection, and standardized loading.

The risks associated with flexible endoscopes are mainly concentrated in the sequential steps of bedside pre-cleaning, leak testing, brushing, channel irrigation, drying, and storage. After implementing interventions targeting high-RPN nodes, Fan Pengchao et al. increased the hygiene pass rate of gastroscopes from 88.03% to 97.44% and that of colonoscopes from 73.08% to 96.15%[9]. Zheng Lile et al. applied FMEA combined with the PDCA cycle to the centralized management of flexible endoscopes. The results demonstrated improvements in staff knowledge proficiency, device sampling inspection results, and sterilization quality, along with reductions in endoscope repair rates and failure incidence[10]. This indicates that FMEA is more suitable for identifying and prioritizing improvement targets, whereas PDCA is used to ensure the continuous implementation, evaluation, and refinement of improvement measures.

3.2.3 Instrument packaging and steam sterilization

Packaging and sterilization represent the later stages in the formation of sterile items, where the quality of prior cleaning, instrument configuration, packaging materials, loading methods, and equipment cycles converge. In the sterilization process for laparoscopic instruments, Qiu Xiaodan et al. identified risks including excessive loading density, insufficient drying, and non-standardized Bowie-Dick (B-D) test execution. After implementing standardized loading diagrams, sterilization cycle parameter control, and documentation by designated personnel, the sterilization pass rate increased from 92.23% to 98.58%[11]. Zhang et al. conducted a single-center before-and-after intervention study. Before the intervention, 185, 382 steam sterilization packs were included, among which 87 quality defects were identified. After implementing HFMEA-based improvements, 11 defects were detected among 189,531 sterilized packs, and the difference was statistically significant[12]. In settings where the baseline defect rate is already low, reporting the number of events, total number of packs, and defect categories together provides a more accurate assessment of the magnitude of improvement than reporting the pass rate alone.

Instrument packaging is also suitable for prospective risk analysis. Yi et al. applied HFMEA to control defects in surgical instrument packaging. Before intervention, 98 defects were identified among 183,642 instrument packs; after intervention, 22 defects were identified among 190,231 packs. The defect rate decreased from 0.053% to 0.012% (χ^2 = 50.822, P=0.001)[13]. After analyzing the surgical instrument distribution process, Guédon et al. found that delivery of instruments from the CSSD to operating rooms involves multiple organizational interfaces. Delayed delivery, incomplete instrument sets, and mismatched information may all affect surgical process[14]. Therefore, sterilization quality analysis should not focus solely on the sterilizer itself; it

should also incorporate pre-packaging inspection, loading, cycle selection, sterilization release, and distribution into the same process map.

3.2.4 Occupational safety protection

Occupational risks in the CSSD are characterized by frequent exposure and widely varying consequences. Du Huancai et al. found that sharps injuries mainly occurred during receiving and sorting, counting and cleaning, and inspection and packaging processes. Using FMEA, they identified key failure modes including failure to use puncture-resistant gloves, failure to promptly dispose of discarded sharps into sharps containers, mixed placement of sharps on work surfaces, and insufficient training coverage. After providing protective equipment, placing sharps containers at points of use, establishing designated sharps areas, and implementing targeted assessments, the incidence of sharps injuries decreased from 12.5 cases per 1,000 person-years to 4.8 cases per 1,000 person-years[15]. These findings suggest that occupational safety controls should be implemented as close as possible to the point where risks arise. Relying solely on individual caution is insufficient to mitigate systemic problems such as improper segregation of sharps, unclear instrument handovers, and inconvenient access to protective equipment.

3.2.5 Synergistic application of FMEA with PDCA and QCC

FMEA, PDCA, and Quality Control Circles (QCC) serve different functions. FMEA is used to identify potential failures across the entire process and prioritize them. PDCA is suitable for continuously implementing, reviewing, and refining actions around identified problems. QCC facilitates the engagement of frontline staff in developing and validating improvement measures. Hu Jing et al. applied HFMEA combined with QCC to healthcare-associated infection prevention and control in the CSSD, reporting improvements in instrument cleaning quality and sterile item quality, along with a reduction in the incidence of healthcare-associated infections among hospitalized patients[16]. However, healthcare-associated infections are also influenced by factors such as patient conditions, hand hygiene practices, antimicrobial use, and environmental management. Therefore, based solely on a single-center before-and-after comparison, it is difficult to attribute all observed changes to the CSSD intervention. When these methods are applied synergistically, process indicators directly controllable by the CSSD should serve as the primary evaluation measures, while distal outcomes such as healthcare-associated infections should be considered supplementary observation indicators.

4 Discussion

4.1 Conceptual boundaries and key implementation considerations of FMEA

4.1.1 Terminological boundaries between FMEA and HFMEA

FMEA is a general method for systematically analyzing potential failures within a process and their effects. It typically assigns scores for Severity (S), Occurrence (O), and Detectability (D), and calculates the RPN as: RPN=S×O×D. HFMEA is a modified approach developed for healthcare settings. It emphasizes selecting high-risk topics, mapping the process, conducting hazard analysis, using a decision tree to identify action points, and developing improvement plans[2]. The two approaches have similar objectives, but their implementation procedures are not identical. To avoid inconsistent use of terminology, this review uses FMEA as a collective term for prospective failure analysis methods. However, when an original study explicitly adopted the HFMEA hazard matrix, decision tree, or its dedicated procedural framework, the term HFMEA is retained.

4.1.2 Risk prioritization should not rely solely on the RPN

RPN is useful for placing disparate issues on a single risk list, but the same RPN value may result from different combinations of S, O, and D. Events with extremely high severity but low occurrence may not rank highly by RPN, yet they may still require immediate control. Rezaei et al. pointed out that the traditional RPN has several limitations, including numerous duplicate values, equal weighting of the three dimensions, and substantial influence of sub-

jective scoring, and proposed a revised risk prioritization method tailored to the healthcare context[4]. Therefore, when selecting improvement projects, CSSDs should adopt a dual-rule approach by considering both RPN ranking and changes in RPN, while also giving priority, based on severity, to failure modes such as sterile barrier failure, implant contamination, incorrect sterilization parameters, and severe occupational exposure.

4.1.3 The implementation process should establish a verifiable closed loop

A relatively complete implementation process comprises seven steps: defining the improvement topic, establishing the team, mapping the current workflow, identifying failure modes, scoring and prioritizing them, developing improvement measures, and conducting post-implementation reassessment. In addition to CSSD managers and frontline staff, the team should, as appropriate to the improvement topic, also include representatives from clinical user departments, healthcare-associated infection management, equipment engineering, information technology, and logistics. Before scoring, the definitions and data sources for each level of S, O, and D should be clearly specified. Wherever possible, subjective judgments should be replaced with objective evidence, including adverse events, records of recleaning and re-sterilization, equipment alarm records, traceability data, and direct on-site observations. Reassessment should not end with a single acceptance review. It should also assess whether the implementation rate of improvement measures, process performance, and outcome indicators remain stable following staff rotation or changes in workload.

4.2 Improvement mechanisms differ across scenarios

Cross-scenario comparisons indicate that the main improvement gains in loaner instrument and endoscope management are largely derived from standardization. Specifically, requirements for disassembly, matching, brushing, rinsing, and storage are converted into executable procedures, thereby reducing variation caused by experience-based practices. Sterilization and packaging processes rely more heavily on mandatory controls, such as cycle parameter control, loading restrictions, release criteria, and traceability alerts. In addition to training, occupational safety improvement requires the placement of protective equipment at points of use and changes in sharps handling and placement practices. If differences among scenarios are ignored and RPN thresholds or improvement checklists from other departments are simply replicated, documentation burdens may increase without addressing the actual vulnerabilities of the institution.

Most studies report reductions in RPN or increases in pass rates; however, these two types of indicators represent different aspects of quality improvement. RPN reflects a team's semi-quantitative assessment of risk and is suitable for comparing changes before and after interventions within the same project. In contrast, pass rates and defect rates are operational outcome indicators that more directly reflect quality performance. Because scoring scales, participants, and thresholds vary among studies, the fact that one study identifies RPN=120 as a priority cutoff does not mean that other institutions should adopt the same threshold. When sterilization pass rates approach 100%, further comparison of percentages may be affected by a ceiling effect. In such cases, studies should also report the number of defect events, total number of packs, defect categories, and severity levels.

4.3 Differences in research approaches between domestic and international studies

Most domestic CSSD studies are single-center before-and-after improvement studies focusing on specific problems. Their strengths lie in close alignment with real-world practice, concrete interventions, and the ability to demonstrate process changes rapidly. However, limitations include inconsistent study settings and follow-up durations, with relatively few reports on inter-rater consistency, intervention adherence, or sustainability after staff turnover. International studies more frequently position FMEA within frameworks of cross-departmental processes and human factors engineering. In their HFMEA analysis of surgical instrument delivery, Guédon et al. assessed the entire delivery chain involving the

CSSD, logistics, and operating rooms as an integrated process[14]. Ben Hammamia et al. applied FMECA to analyze sterilization processes in public healthcare institutions and prioritized failure modes according to criticality, reflecting an approach that expands from individual defects toward a systematic risk map[17].

The two research approaches are complementary. Domestic studies provide directly applicable measures for cleaning, loading, protection, and traceability, whereas international methodological studies remind managers that a single RPN calculation does not constitute completion of risk management. An ideal evidence chain for CSSD quality improvement should include four levels: process failure modes, implementation rates of improvement measures, short-term quality outcomes, and sustainability outcomes. It should also clarify which changes are directly controlled by the CSSD and which are influenced by other hospital systems.

4.4 Emerging risks from regionalization, digitalization, and complex instruments

Regional shared sterilization centers within healthcare consortia centralize the reprocessing of instruments from multiple primary healthcare institutions, improving the utilization efficiency of equipment and professional personnel. However, they also extend risks from within-department workflows to cross-institutional collection, transportation, handover, shelf-life management, and abnormal event tracing. After implementing a quality traceability system in a shared sterilization center within a healthcare consortium, Hu et al. reported improved instrument pack management efficiency and a reduced incidence of adverse events[19]. In this setting, FMEA should not be limited to the center's internal cleaning and sterilization steps. The process map should also incorporate pre-cleaning at primary healthcare institutions, transportation time limits, segregation of contaminated and clean items, ownership of instrument packs, abnormal recalls, and accountability interfaces. Applying identical RPN thresholds across different institutions is not appropriate. A more feasible approach is to standardize failure mode terminology, outcome definitions, and minimum control requirements, and then calibrate occurrence ratings according to the workload and baseline data of each participating institution.

The key to smart sterile processing is not simply transferring paper-based records into an information system, but establishing a traceable data chain through barcodes, RFID, equipment interfaces, and mobile terminals. After integrating FMEA with an information traceability system, Zhan Ruiwen et al. reduced the reprocessing error rate of reusable dental instruments from 17.10% to 0.60%[18]; Zheng et al. also demonstrated that combining standardization, a cleaning and disinfection information system, and FMEA reduced RPNs associated with personnel, environment, procedures, and system support[20]. Under digitalized conditions, FMEA teams can dynamically adjust O and D ratings using data from missed scans, equipment alarms, incorrect cycle selections, re-cleaning and re-sterilization records, and clinical package returns. At the same time, they should pay attention to emerging failure modes such as system downtime, label mismatches, data loss at system interfaces, and improper permission settings. Information systems provide evidence for risk identification but cannot replace on-site observation, instrument functional inspections, or professional release decisions.

Recent work on 3D-printed surgical guides shows that material choice and sterilization conditions can affect dimensional accuracy[21]. This is relevant to patient-specific devices, which are often produced in small batches and may have material-specific reprocessing limits. Lan et al. found that steam sterilization could reduce the manufacturing accuracy and repeatability of resin-printed surgical guides, whereas metal-printed guides were relatively less affected by the tested sterilization or disinfection procedures[21]. When receiving such devices, CSSDs should verify the material documentation, manufacturing batch, manufacturer-validated cleaning and sterilization parameters, maximum allowable temperature, packaging method, and single-use status. If complete reprocessing instructions are unavailable or material-process compatibility cannot be con-

firmed, sterilization cycles should not be selected by analogy with conventional instruments. For FMEA purposes, missing reprocessing instructions, incorrect material identification, inappropriate sterilization-method selection, and post-sterilization dimensional or functional changes should be treated as candidate high-severity failure modes.

4.5 Locally adapted RPN and bias control

Traditional RPN has limitations, including identical scores resulting from different combinations of S, O, and D, the default assumption of equal weighting among the three dimensions, and substantial subjectivity in scoring. A modified approach adapted for domestic CSSDs should adopt a three-track strategy of severity triggering, RPN ranking, and trend-based calibration. S, O, and D should each use a simplified three-level scoring system (1, 3, and 5) with clearly defined and observable scoring anchors. The O ratings should be calibrated using institutional data from the previous 6~12 months, including re-cleaning events, wet packs, equipment alarms, traceability gaps, clinical package returns, and occupational exposures. The D ratings should be calibrated according to factors such as automatic interlocks, electronic traceability systems, manual independent double verification, or conditions in which failures can only be detected after clinical use. Any failure mode with S=5 should be directly included in the red risk list and should not be deferred because of low occurrence. The other items should then be prioritized according to RPN values and trends observed over two consecutive review cycles. This approach preserves the usability of RPN while reducing the risk that low-frequency, high-severity events are underestimated by the traditional multiplicative calculation method.

To facilitate application in primary-level settings, RPN can be categorized into four levels: green (RPN<15), yellow (15~29), orange (30~59), and red (RPN≥60 or S=5). These thresholds are provided only as examples for initiating improvement projects and should not be directly applied for cross-institutional ranking. Each institution should calibrate them according to baseline distributions and CSSD quality control indicators[22]. For failure modes with substantial disagreement among team members, the original ratings from each role and the rationale for reaching consensus should be retained. When stable data are unavailable, it should be clearly documented that the O or D ratings are based on expert judgment. Before-and-after evaluations should also record the numbers of instrument packs or sterilization packs, workload, equipment updates, training, and personnel changes, to avoid attributing all observed changes caused by concurrent factors to FMEA.

4.6 Tiered implementation pathways and practical checklist

The basic tier is intended for CSSDs with limited staffing and information capabilities. Each year, 1~2 processes should be selected based on severe consequences, recurrence within the previous year, or concentrated clinical complaints. The team should mainly consist of frontline operators, head nurses, and healthcare-associated infection management personnel. A simplified scoring method can first be used to identify red- and orange-level risks, followed by priority implementation of measures that reduce reliance on memory, such as visual instructions, standardized placement, color or barcode identification, point-of-use reminders, and double-checking. An initial reassessment may be conducted one month after implementation, with sustainability reassessments at three and six months.

The project tier is suitable for CSSDs in tertiary hospitals with high service volumes and complex instrument categories. An annual risk project portfolio can be established, with 2~3 topics selected each year and participation from clinical departments, equipment management, logistics, and information technology personnel. In addition to RPN, at least one process indicator and one outcome indicator should be established, and the implementation rate of improvement measures should be recorded. The system tier is applicable to institutions with traceability platforms or regional shared service capabilities. Data on equipment alarms, re-cleaning and re-sterilization, external package labels, sterilization

release, clinical package returns, and occupational exposures can be integrated into a risk database to automatically generate quarterly trend lists. Ad hoc reassessments should be initiated when changes occur in processes, equipment, instrument categories, or participating member institutions.

For routine use, the seven-step checklist in Table 2 follows the core HFMEA workflow and is aligned with current CSSD quality-control requirements[2,22].

A concise three-level S/O/D scoring scheme and the corresponding local risk categories are shown in Table 3. These anchors are intended for within-institution calibration rather than cross-institution ranking.

4.7 Multicenter study design and future directions

Future research should move beyond one-off single-center improvement projects toward prospective multicenter validation of reproducible improvement models. CSSDs with different hospital levels, service volumes, and digital infrastructure are encouraged to jointly establish process boundaries, a failure mode dictionary, and outcome definitions. A baseline observation period of at least 3 months should be completed before implementing a 6-month intervention, followed by 6~12 months of follow-up. Where feasible, stepped-wedge cluster designs or concurrent control centers may be used to reduce the influence of concurrent factors such as equipment upgrades, seasonal workload variations, and stan-

Table 2 Simplified FMEA Implementation Checklist for CSSD

Step	Lead personnel	Main participants	Core task	Evidence to be retained	Reassessment time point
1 Topic selection	Head nurse / Quality control lead	Healthcare-associated infection, clinical user departments	Define process scope and boundaries based on serious events, recurring defects, and complaints	Baseline data from the previous 6~12 months; topic selection rationale	Annually or upon major changes
2 Process mapping	Project secretary	Frontline operators, logistics, equipment, and information personnel	Map the workflow based on actual practice rather than replacing the actual process with documented procedures	Current-state process map; interface list	After process changes
3 Identification	Process node owners	Entire team	Identify failure modes, causes, consequences, and existing controls	Failure mode list; on-site photos or records	Initial use and addition of new devices
4 Scoring	Quality control lead	At least three raters from different roles	Rate S/O/D using standardized scoring anchors and retain rationales for disagreements and consensus	Original scoring sheets; data sources	Before intervention
5 Improvement	Process owner	Relevant functional departments	Define actions, responsible persons, and deadlines for red- and orange-level risks	Action plans; training records; system change records	Weekly/monthly during implementation
6 Initial evaluation	Quality control lead	Project team	Compare RPN, implementation rate, number of defects, and denominators	One-month evaluation form	One month after implementation
7 Sustainability reassessment	Head nurse	Healthcare-associated infection, clinical, and information personnel	Assess whether improvements are sustained after staff rotation and workload changes	3-month, 6-month, and quarterly trend reports	3 and 6 months; quarterly for system-level monitoring

Table 3 Example of Simplified S/O/D Scoring and Risk Stratification

Dimension	1 point	3 points	5 points	Recommended data sources
Severity (S)	Requires rework only, with no clinical impact	May delay diagnosis/ treatment or cause temporary impairment of device function	May result in sterile barrier failure, implant contamination, infection, or severe occupational exposure	Adverse events, near misses, clinical outcome assessments
Occurrence (O)	No occurrence or very rare occurrence in the past 6 months	Occasional occurrence with repeated records	Frequent or ongoing occurrence	Re-cleaning/re-sterilization records, wet packs, alarms, returned packs, and exposure rates
Detection (D)	Automatically intercepted by system or mandatory interlock	Requires manual inspection and is usually detected before release	Difficult to detect with existing controls and may only be discovered after clinical use	Traceability logs, spot checks, double-checking, and clinical feedback
Risk stratification	Green: RPN<15	Yellow: 15~29	Orange: 30~59; Red: RPN≥60 or S=5	Thresholds should be calibrated according to institutional baseline data and should not be used for inter-institutional ranking

dardized training.

Primary outcomes should prioritize reprocessing defects per 10,000 items (packs), serious near-miss events, execution rates of key process steps, and control rates of high-severity failure modes. Secondary outcomes may include changes in RPN, instrument turnaround time, re-cleaning and re-sterilization rates, occupational exposures, staff working hours, and improvement costs. Study reports should at minimum describe team composition, S/O/D scoring anchors, methods for assessing scoring consistency, implementation rates of improvement measures, denominators, loss to follow-up or missing data, and inter-center differences. For regional shared centers and digitalization projects, additional indicators should include completeness of inter-institutional handovers, missed scanning rates, system downtime duration, and completion rates of abnormal recalls. For 3D-printed and other complex instruments, studies should record material types, completeness of manufacturer-provided reprocessing instructions, cleaning validation methods, and post-sterilization functional or dimensional stability.

5 Conclusion

FMEA can transform potential problems within the complex processes of a CSSD into risk lists that are amenable to discussion, prioritization, and reassessment. Existing studies have demonstrated its improvement value in scenarios including loaner medical devices, endoscopes, instrument packaging and sterilization, and occupational protection. Its effectiveness mainly derives from multi-role process analysis and the conversion of tacit experience into explicit control points, rather than from RPN calculation itself. Regional shared sterilization services, digital traceability, and complex 3D-printed instruments have expanded the application scope of FMEA while introducing new risks related to inter-institutional interfaces, data reliability, and material-sterilization compatibility.

When implementing FMEA, CSSDs should standardize terminology and scoring anchors and adopt a localized three-track approach combining severity triggers, RPN ranking, and trend calibration. Effectiveness should be evaluated jointly through process indicators, actual defects, and implementation rates of improvement measures, with teams and reassessment cycles configured according to basic, project, and system implementation tiers. Current evidence remains dominated by single-center pre-post studies and is insufficient to establish universal RPN thresholds. Through standardized operational checklists, prospective multicenter studies, and dynamic digital reassessment, FMEA can gradually evolve from a stage-specific quality improvement tool into an established risk governance mechanism.

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