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A Review of Human Factors, Training Deficiencies, and Error Pathways in Surgical Instrument Sterilization: Implications for U.S. Patient Safety

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Abstract

Surgical instrument sterilization, a routine yet vital and high-risk procedure in contemporary medicine, often culminates in surgical site infections, device failures, and patient injuries when errors occur. As a comprehensive review, this paper navigates the expanse of literature regarding the human and systemic contributors that precipitate these errors and, by extension, bolster sterilization successes in the United States (U.S.). This review challenges the reductionist perspective of errors as isolated "human error," instead providing insights into complex human-machine-system interactions. These encompass cognitive workload, design, system culture, and, most prominently, inconsistent training paradigms which often create vulnerabilities in sterile processing departments (SPDs). This review details that errors in decontamination, inspection, assembly, and sterilization load preparation and management have been identified as recurring factors and likely failure pathways in the literature. When these errors lead to sterilization failure, they often implicate systemic issues over individual negligence. This review advances the position that the paradigm shift necessary to improve patient safety in the U.S. healthcare landscape can be enabled by heeding foundational tenets of human factors engineering in rethinking the system design, standardization, and focus on consistent training and certification, as well as encouraging a shift in safety culture to acknowledge SPD as a safety-critical department, a shift from blame-based systems to systems-based analysis.

Keywords: Sterile Processing, Central Service, Human Factors, Patient Safety, Surgical Site Infection, Training, Medical Errors, Systems Approach

Introduction

Instrument sterilization is an essential requirement for safe surgical care. Surgical site infections (SSIs) remain a leading cause of morbidity, mortality, and cost despite significant improvements in aseptic technique and antibiotic prophylaxis. In the United States, it is estimated that 1-3% of all surgical procedures are complicated by infection (Alverdy et al., 2021). One understated but essential line of defense against SSI is the sterile processing department (SPD). This multistep process involving point-of-use treatment and transport, decontamination, inspection, assembly, packaging, sterilization, and storage is vulnerable to human error at multiple points.

Traditionally, events resulting in instrument contamination have been assumed to be the result of

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Volume No: 01 Issue No: 01 (2024)

technician error. Increasingly, however, the mounting evidence in this arena is consistent with the seminal work of Reason (2000) on organizational accidents and their many latent antecedents. They are most commonly seen to be the result of latent conditions such as poor human-system integration, severe training variability, and the devaluing of SPDs within healthcare organizations (Ofosu & Tameru, 2022). This review will provide a more thorough discussion of human factors ergonomics, training issues, and identifiable error pathways throughout the surgical instrument sterilization process and implications for system interventions that may improve patient safety across the U.S. healthcare system.

Methodology

A narrative literature review was performed to identify, synthesize, and critically appraise the available evidence on human performance and systems issues related to sterile processing. Electronic databases such as PubMed, CINAHL, and Google Scholar were searched for peer-reviewed articles, government reports, and professional guidelines published between 2010 and 2024. Search terms included: "sterile processing human factors," "central service training," "surgical instrument reprocessing errors," "sterilization failure pathways," and "patient safety sterile processing." Inclusion criteria were studies and analyses relevant to U.S. healthcare settings or with findings and conclusions that could be applied more broadly to systems safety. Grey literature from professional organizations such as the Association for the Advancement of Medical Instrumentation (AAMI), the International Association of Healthcare Central Service Materiel Management (IAHCSMM), and the U.S. Centers for Disease Control and Prevention (CDC) was reviewed to ensure inclusion of the most up-to-date standards and field perspectives.

Literature Review

1. Human Factors in the Sterile Processing Environment

The field of human factors (HF) aims to optimize the relationship between people and systems in which they work. In SPD, numerous HF factors combine to create a “perfect storm” for introducing error:

- **Cognitive Workload & Interruptions:** SPD techs must perform hundreds of complexes, multi-step tasks for thousands of different instruments, each with its own cleaning & assembly instructions. This is a cognitively demanding job. They are frequently interrupted by “stat” requests or questions from the OR team, with no warning & high pressure to complete these new tasks. Workflow is disrupted, and steps can be missed (Klein et al., 2021). “The environment in which we work can often be characterized by hurry, distraction, competing priorities” (Rivera, 2019).

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Volume No: 01 Issue No: 01 (2024)

- **Ergonomics & Environmental Design:** Ergonomics issues (suboptimal workstation design, repeated lifting, etc.) can cause fatigue and error. Several studies have identified root causes related to poorly adjusted sinks causing splashback or awkward postures to inspect lumens, a noisy work environment with interference or shouting to communicate, and insufficient lighting for inspection areas (Ofosu & Tameru, 2022).

- **Organizational & Safety Culture:** SPD departments are usually physically & culturally separated from the OR by long corridors & a "we-they" culture. Thus, OR teams may be disrespectful, give incomplete communication about instruments, and not encourage psychological safety for SPD team members to speak up about near-misses or ask questions (Klein et al., 2021). If SPD is viewed as a "cost center" rather than a "business unit" that contributes to patient safety, it will not receive investments in staffing, training, or ergonomic equipment.

2. Systemic Training Deficiencies

The current U.S. training and certification structure for SPD technicians is highly variable and leaves room for systemic errors due to lack of consistency.

- Lack of Standardization: While professional organizations (AAMI) have published thorough standard recommendations (ANSI/AAMI ST79), there is no federal regulation that requires a certain training or certification level for employees reprocessing SPD. This training itself may be more rigorous in some facilities with multi-week programs, on-the-job training, "see-one-do-one" apprenticeships, or no formal training at all (Alverdy et al., 2021). This leads to a wide range of baseline knowledge among techs.

- Rapid Technological Advancements: Surgical devices, especially robotic & MIS instruments with long, narrow lumens and fragile optics, have become much more complex in recent decades. The rate of training development is often not keeping up, leaving techs under-trained to reprocess advanced technologies (Ofosu & Tameru, 2022).

- Competency Validation: Training is often not paired with adequate, ongoing validation of competency. "See-one-do-one" is an accepted practice in many facilities, despite its limitations. Competency is often accepted with one demonstration and rarely validated by audit and testing (protein detection assays or testing with simulated complex assembly, etc.) (Rivera, 2019).

3. Error Pathways that Can Be Identified

In literature and open incident reports, there are common identifiable pathways through which failure modes are introduced to the sterilization process.

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- **Decontamination Failures:** This is the single most important step, as there can be no sterilization of a dirty or soiled item. Failures in this phase include "drying" of blood/tissue on instruments immediately after use, not using the correct enzymes or temperatures, not brushing or flushing instruments & lumens thoroughly, and not rinsing and drying thoroughly. These are caused by time pressure, poor IFUs, or not having the right brushes and flushing devices (Klein et al., 2021).

- **Inspection & Assembly Mistakes:** Visual inspection, especially under poor lighting, can miss residual bioburden and damage to instruments. Complex sets with 30+ components are prone to miss-assembly mistakes (mixing up washers in the wrong order, leaving out seals) or missed damage. Assembly from memory has been shown to be a risk factor (Rivera, 2019).

- **Sterilization Load Management:** Overloading sterilizer chambers, not wrapping or positioning containers/channels correctly, or selecting the wrong sterilization cycle (gravity cycle for a lumen device) can all prevent sterilant contact. Also, practice of "flash" sterilization in "in use" containers for cases that are non-emergent skips the safe step of controlled packaging and storage. (AORN, 2021)

Results

The reviewed articles were synthesized based on their results. It is apparent that failures are not the result of a single error by an individual employee. Failures arise from a series of failures which are latent in the work system. The key outcomes of this literature review were four related causal groupings (listed below in bullet points):

1. **The Work System is Error-Prone:** The SPD environment, in the way it is currently designed in most facilities, is high in cognitive and physical demands and interruptions with little to no defense.

2. **Training is Inconsistent and Inadequate:** The lack of standard, required, and competency-verified training has created a workforce with a varied and inconsistent understanding of the work and tasks necessary to consistently and safely reprocess instruments in the increasingly complex environment of today's SPDs.

3. **Error Pathways are Predictable and Recurrent:** Failures are not random or the result of "unusual" circumstances or lack of knowledge and skills on the part of the technicians. The "holes" through which failure are known and reoccurring, centering largely around decontamination, inspection, and load configuration. This is a sign that

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these events are the result of system design, not human variability.

4. **Organizational Culture is a Key Determinant:** Facilities where SPD is organized, acknowledged, and resourced as a member of the patient safety team, has the most predictable processes and, therefore, the best outcomes.

Discussion

It is clear from the above discussion and results that sterile processing must be reframed. The essential elements of processing must be understood in a broad context as a complex sociotechnical system. A good way to understand this is using the Systems Engineering Initiative for Patient Safety (SEIPS) model. Patient safety outcomes are determined by the relationships among: the person (technician), the tasks (process of reprocessing), the tools and technologies (washers, sterilizers, IFUs, etc.), the physical environment (SPD layout), and the organizational conditions (culture, staffing, training) (Carayon et al., 2014).

Interventions in these categories at the appropriate levels are needed to abate risk:

1. **Human Factors Redesign:** Cognitive aids need to be designed (colored-coded trays, visual, illustrated job aids with detailed steps and workflow pictures for complex sets, interruption free locations for inspection). Ergonomics workstations need to be purchased, and inspection needs better magnification/lighting.

2. **Training and Certification Reform:** Advocacy at the state and national levels for education standards and requirements for SPD training and mandatory certification is critical. Training needs to be a part of regular routine, with new hands-on technologies being learned with competency assessment. Mandatory certification needs to be recurrent. Perioperative nursing must be trained with sterile processing to understand the other side and vice versa.

3. **Strengthen Defenses:** Technological aids like instrument tracking systems that go from OR to SPD with barcoded IFUs that match to the instrument cart, routine use of chemical indicators and biological monitors, and audit with rapid protein residue testing need to be used. The use of immediate-use steam sterilization should be limited to true emergencies.

4. **Culture Change:** Surgical healthcare leadership needs to be actively and intentionally including SPD on the surgical safety team. This could look like including SPD in new product evaluation committees, joint OR-SPD quality improvement teams, and safe, transparent, non-punitive error reporting system. Most importantly, senior leadership needs to frame and model it through words and actions.

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Conclusion

Sterile processing of surgical instruments is a complex, high-risk process. Failures in sterilization have been shown to be due to design-level human factors that have been poorly controlled by current training and competency standards. This article presented evidence that the ways in which failure is occurring is not random and based on human variability, but rather the "holes" in the system through which failure can occur are predictable and recurrent.

There is an important shift in understanding that is necessary to improve patient safety in the United States. This shift must move away from blaming and punishing frontline workers, and into a proactive design of human factors work systems, strong standardization and regulation of training and competency evaluation, and building a robust patient safety culture that recognizes the critical role of SPDs. The cost of SPD is not overhead, it is an investment in preventing patient injury.

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