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Preventable Surgical Site Infections and the Critical Role of Sterile Processing Professionals in U.S. Healthcare Systems

Cynthia Nyakangu Gitau
Surgical Sterile Professional / Independent Researcher
cynthiagitau03@gmail.com

Abstract

Surgical site infections (SSIs) are a critical patient safety, clinical outcome, and cost burden in the United States, with many cases deemed preventable. Instrument reprocessing and management play a pivotal role in this. This literature review delves into the etiology and impact of SSIs attributed to sterile processing failures. Central Sterile Processing Departments (CSPDs) uphold an intricate, high-stakes workflow, and sterile processing (SP) professionals are an essential, but undervalued and under-resourced, node of the healthcare safety net. We discuss the top challenges facing the SP profession today, including workforce shortages, training deficiencies, ergonomic hazards, and systemic barriers to communication. The article closes with a set of evidence-based, implementation-ready recommendations for healthcare systems to begin the work of raising the stature of sterile processing through standardized education, technological innovation, interdisciplinary collaboration, and institutional investment to prevent avoidable harm and strengthen the entire surgical safety ecosystem.

Keywords: Surgical Site Infections (SSIs); Sterile Processing; Central Sterile Processing Department (CSPD); Healthcare-Associated Infections (HAIs); Medical Device Reprocessing

Introduction

Surgical site infections (SSIs) are the most common type of healthcare-associated infection (HAI), affecting an estimated 2–5% of patients undergoing inpatient surgery in the United States and resulting in approximately 110,000 to 500,000 cases each year (Centers for Disease Control and Prevention [CDC], 2024). In addition to the significant human suffering that comes from prolonged recovery times, readmissions, and in some cases, mortality, SSIs cost our healthcare system an additional $3.3 billion to $10 billion each year (Zimlichman et al., 2013). While SSIs have a number of causes, a key link in this safety chain is the assurance that every single instrument placed in a surgical wound is 100% sterile–the near-exclusive responsibility of sterile processing (SP) professionals.

Physically and all too often organizationally relegated to the basement of our hospitals, Central Sterile Processing Departments (CSPDs) are the epicenter of the surgical safety ecosystem. From a tiny needle holder to a $100,000 robotic arm, every device used in a surgical procedure must go through CSPD hands for cleaning, inspection, assembly, sterilization, and packaging for

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distribution to the point of care. A single failure in this complex, multi-step process can cause biofilm formation, prion transmission, or direct pathogen inoculation into a surgical wound with devastating and preventable patient harm (Ofstead et al., 2018). This review synthesizes the available evidence on the connection between sterile processing and SSIs, the indispensable and under-threat role of SP professionals, and how healthcare systems can close the gap to protect patients.

Medical Sterile Processing Workflow: A "Chain of Custody"

Figure 1. The sterile processing chain of custody illustrating sequential reprocessing steps and potential failure points contributing to surgical site infections

The transformation of a "dirty" surgical instrument into a "sterile" one is a complicated, scientific, and regulated process that includes multiple points of failure (but no room for failure).

1. Point-of-Use Treatment & Transport: Starting in the OR (cleaning instruments in the place they are used, as they should be, and preventing bioburden from drying onto

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instruments is important), wrong transport in non-permeable pouches can be an environmental and personnel hazard

2. Cleaning & Decontamination: The most important link in the chain, as the presence of residual organic soil can protect microorganisms from subsequent sterilization attempts. Manual cleaning should be followed by validated mechanical cleaning (e.g. ultrasonic cleaners, washer-disinfectors), using enzymatic detergents. Cleaning should be verified, both visually (requires magnification!) and through ATP bioluminescence testing, though the latter is not yet standard of care (Alfa, 2019).
3. Preparation & Packaging: Counting out instruments into instrument trays according to count sheets (right instruments in right quantities), and choosing the right packaging material (woven, non-woven, rigid containers, etc.) to allow penetration of the sterilant and maintain sterility until the point of use.
4. Sterilization: Main modalities in the U.S. are steam (autoclaving) and low-temperature (ethylene oxide, hydrogen peroxide plasma) sterilization. Cycles are monitored using physical (gauges), chemical (integrator strips), and biological (spore) indicators to assure that the necessary conditions for lethality were met (Association for the Advancement of Medical Instrumentation [AAMI], 2022)
5. Storage & Distribution: Sterile packages must be stored in specified environments, and distributed using first-in, first-out (FIFO) systems to ensure that shelf-life is not exceeded.

Breaking any of these links in the chain has inherent risks; for example, a recent study by Ofstead et al. (2018) revealed that 76% of "sterile" flexible duodenoscopes inspected by inspectors after cleaning still harbored moisture, blood and debris from prior procedures, related directly to failures in cleaning and reprocessing protocols.

The Association to Surgical Site Infections: A Preventable Outcome

SSIs are categorized as superficial incisional, deep incisional, or organ/space infections. Although patient comorbidities (i.e., diabetes, obesity) and operative factors (i.e., duration, technique) play a role, infection may be directly attributed to exogenous contamination from the environment and instruments, which is readily preventable. Examples of SSI outbreaks due to CSPD failures include:

- Inadequate Cleaning: This can include residual tissue or biofilm in lumened devices or joints of instruments and can result in SSI from a resistant organism such as Pseudomonas aeruginosa or Mycobacterium abscessus that is difficult to remove or sterilize.
- Sterilization Process Failures: Autoclaves can become overloaded, sterilization chemicals can be expired, and positive biological indicators can be overlooked when sending non-sterile sets into circulation. In one investigation by Cristina et al. (2018), an SSI outbreak

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of Bacillus cereus could be traced to insufficient steam sterilization cycles used for laparoscopic instruments.

- Breaks in Sterility: Damaged packaging, improper storage, or contaminated sterile water used for final rinsing can all re-contaminate processed instruments. The impact of effective sterile processing and infection prevention efforts are easy to see.

Table 1. Common sterile processing failures and their associated risks for surgical site infections.

Sterile Processing Stage	**Common Failure**	**Infection Risk**	**Example Pathogen**
Cleaning	Residual bioburden	High	*P. aeruginosa*
Decontamination	Inadequate detergent action	High	*Mycobacterium*
Sterilization	Overloaded autoclave	Severe	*Bacillus cereus*
Packaging	Compromised wrap	Moderate	Mixed flora
Storage	Environmental contamination	Moderate	Environmental bacteria

The correlation between following AAMI standards and employing a strong quality assurance program in the CSPD to overall lower SSI rates is well documented and tells the reader that investment in the CSPD is a worthwhile investment in patient safety (Huang et al., 2020).

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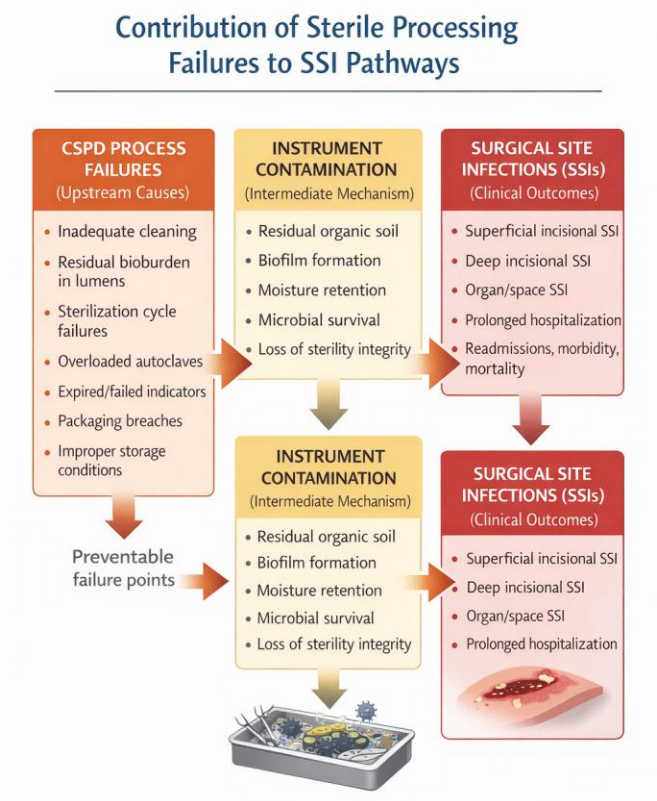

Figure 2. Pathway illustrating how sterile processing failures contribute directly to preventable surgical site infections.

Systemic Challenges Facing the Sterile Processing Profession

For all of the significant influence SP has on patient safety, the harsh reality is that many healthcare systems are not built to support this specialty and SP professionals are left vulnerable. Major risks include:

1. Workforce and education—There is no federal license for SP technicians; every state has different training and competency requirements. Shortage and turnover, particularly in rural and underserved areas, has led to a race to the bottom for salaries and career opportunities, increasing demand to "rush" processing and meeting compliance (Papadopoulos et al., 2021).
2. Ergonomics and environment—Heavy lifting, repetitiveness, and physically challenging cleaning and sterilization processes, in addition to exposure to bloodborne pathogens and infectious organisms, cleaning agents, and sometimes very hot sterilization equipment, contribute to job stress and burnout.

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3. Increasingly complex technology and instruments—Miniaturization of surgical tools and complex electronics and optics often designed to be reprocessed in hospital reprocessing departments but requiring highly technical care when cleaning, such as long narrow lumens, tiny, fragile components, adhesives, specialty chemicals, and on occasion only one (sometimes single-use) instrument per procedure kit (set) places an untenable burden on CSPD technicians, especially in the absence of vendor support and facility investment in the appropriate reprocessing equipment.
4. Parallel power/education silos between OR and CSPD—Ongoing power dynamic and knowledge silos exist, where surgeons and perioperative nurses may not understand the challenges SP technicians face, or SP technicians may not feel empowered to report or raise concerns or explain delays, resulting in a breakdown of communication. In some cases, this results in the OR going "off-pack" with improvised "cook set" solutions that are not quality compliant, or it results in hostility when the CSPD rightfully withholds a set because it is not ready for patient use.

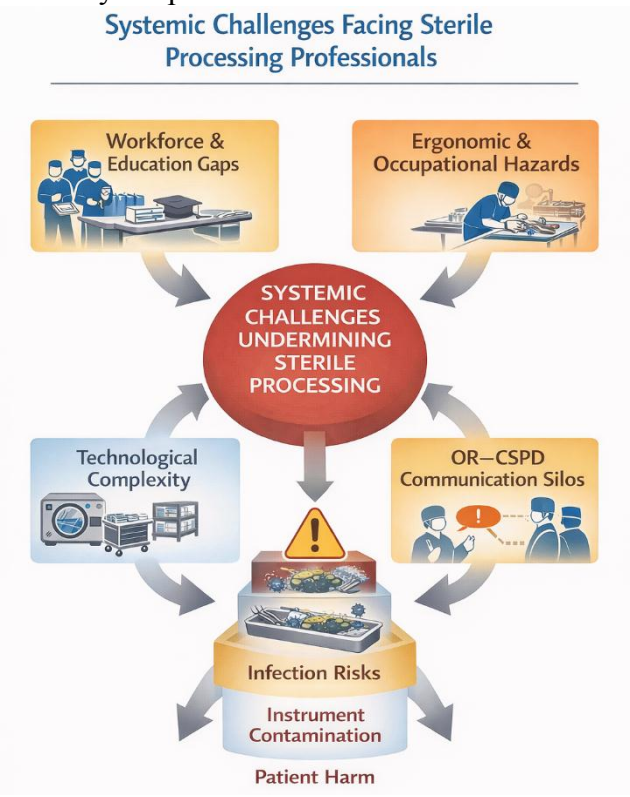

Figure 3. Interconnected systemic challenges undermining sterile processing effectiveness and increasing SSI risk.

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Recommendations / Ways Hospitals Should Be Investing in CSPD to Reduce SSI Risk

To properly support the CSPD and reduce SSI risk, clinical and hospital leaders must shift their thinking of sterile processing as an expense to be minimized to a safety net in which to invest.

1. **Professionalize**: Establish national education and certification/licensure requirements, with a clear career ladder that is visible and has commensurate pay.
2. **Technology, automation, and data are crucial; consider investing in:**
3. 1. Automated "track and trace" instrumentation systems to allow for ease of instrumentation accountability/visibility
   2. Washer-disinfectors with automated logging functions, allowing for standardization and computerized capture of wash metrics
   3. Scheduled use of ATP/verification testing and/or protein assays
   4. Continuous monitoring for sterilizers and storage monitoring for environmental factors.

4. **Shift culture**: Commit to breaking down professional silos with intentional communication bridges. Invite SP representation on perioperative committees and offer joint in-services for SP and surgeons (e.g., teaching surgeons how to care for and safely close instruments, then inviting SP staff to teach about instrument processing).
5. **Build mutual accountability**: Institute formal mechanisms to create safe environments for all perioperative staff to "speak up" and stop the process for a safety issue without fear of reprisal.
   5. **Invest in resources**: Commit to a budget that ensures the CSPD has adequate staffing and resources for staffing, education, equipment maintenance, and annual replacement of aging instrumentation and reprocessing equipment.

Conclusion

SSIs are completely preventable and the CSPD is the last line of defense against contaminated instruments; that process should be a robust one. The current state of U.S. healthcare, unfortunately, leaves much to be desired when it comes to supporting and investing in SP as a safeguard. With some realignment of perspectives and resources, hospitals and healthcare organizations can better position themselves to protect patients, the CSPD, and their facilities by elevating the importance of sterile processing, investing in the right resources to care for the supply, integrating technology where it can, and creating intentional communication opportunities and structures that break down silos in favor of a safety net of mutual protection.

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