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Managing Cybersecurity as a Patient Safety Function: Business and Governance Challenges in Surgical Sterile Processing Departments

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Abstract

Emerging networks of medical devices, for remote monitoring and data collection, are advancing efficiencies, while also introducing vulnerabilities in Surgical Sterile Processing Departments (SPDs). Cybersecurity efforts in SPDs should be guided by a new risk treatment paradigm – to be inextricably linked with patient safety risk mitigation, instead of remaining the sole purview of the information technology (IT) governance structures. Security vulnerabilities in sterilizers, washer-disinfectors, and tracking systems have the potential to bring entire operations to a standstill, impact the integrity of patient data, and even increase surgical site infections from the use of instruments processed with suboptimal outcomes. Using a narrative review methodology and assessing literature in academic, regulatory, and industrial spheres, this work aims to characterize the business and governance challenges faced by healthcare organizations in this effort. Such challenges may include the legacy composition of SPD device ecosystems, the budgetary silos of clinical, IT, and cybersecurity funding, the absence of SPD and clinical engineering cybersecurity subject matter experts, and the disconnect between regulatory and voluntary guidance frameworks. The review suggests that successful mitigation of these cybersecurity risks in SPDs will depend on shared accountability across clinical, operational, and IT leaders. Specific recommendations include a patient safety-oriented cybersecurity framework, an SPD-specific risk assessment, and structured communication across disciplines to enable business continuity, clinical outcome, and cyber resiliency alignment.

Keywords: Cybersecurity, Patient Safety, Sterile Processing, Surgical Site Infection, Medical Device Security, Healthcare Governance, Clinical Engineering

1. Introduction

Surgical Sterile Processing Departments (SPDs) are among the most important yet less visible nodes in the hospital's patient safety web. The invisible work and care that occurs behind the scenes is among the most crucial and also the most labor and resource-intensive. Surgical SPDs are solely responsible for the appropriate decontamination and sterilization of every single instrument used during a surgical procedure. In other words, every tray, every wrapped instrument, and every device used during a surgical procedure is the direct responsibility of the

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SPD personnel and must be 100% microbiologically safe upon delivery. The safety and completeness of the clean surgical tray is directly proportional to clinical outcomes (National Patient Safety Agency, 2009). Failures in decontamination or sterilization can and do lead to surgical site infections (SSIs), among the most common causes of hospital-acquired illness and its consequent avoidable morbidity, mortality, length of stay, and the associated billions of dollars in costs (World Health Organization, 2018; Ban et al., 2017).

Traditional risks in the SPD have been of mechanical, chemical, and human-factorial nature. Most work has been manual, and while there were always procedural controls and validations in place, the focus and the language of these validations were equally clinical and traditional. Despite automation of some steps in the process, the inherent risk in the department remained clinically focused, not only because the devices used in decontamination and sterilization were standalone units with no interconnections or communications with the hospital's IT system but also because the thought of a cyber attack was generally considered outside of traditional SPD risk management plans.

In a quest to increase efficiency, ease traceability, and meet regulatory compliance, surgical SPDs like many other operational departments in hospitals have turned to integrated, networked, software-dependent technologies and devices that can offer improved "audit trails" and near-perfect inventory management and tracking capabilities and are much easier to manage via central standardization protocols. Automated, network-connected washer-disinfectors, automated steam and hydrogen peroxide sterilizers with microprocessors that provide electronic biological and chemical integrator reports, and electronic instrument tracking systems using radio-frequency identification (RFID) or barcodes connected to a central database are just some of the devices now becoming very common in surgical SPDs (Alfa, 2019). The automation and attendant technology benefits in this traditionally manual department are tremendous and real, yet it has also opened the door for an entirely new, and potentially a more sinister, set of vulnerabilities: cyberattacks.

The integration of operational technology (OT) with traditional, more clinical IT devices on the hospital network and their integration with business networks have been a growing concern among cybersecurity and healthcare policy experts, as it often exposes these "life-critical" devices to security threats that had historically only affected administrative and financial systems in healthcare organizations. The malware code necessary to lock up a sterilizer, introduce malware into a PLC circuit board of a decontamination device, alter a digital record that proves a sterilization cycle was completed, or simply bring the entire tracking system to its knees and stop it cold may be just a ransomware infection, malware code, or accidental misconfiguration away. The implications of a "breach" in the cyber context can be profound as, unlike financial or personnel data, cyber threats now have the potential to directly and immediately affect clinical

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care by introducing the possibility of using non-sterile or sub-processed surgical devices and trays. Cybersecurity and its connotation, therefore, needs to be not just rethought but expanded to include its fundamental basis and its previously only tangential relation with patient safety in the clinical context.

This paper will attempt to synthesize the existing literature on this emergent topic to highlight and make the case for this shift in semantics and to outline the formidable business and governance challenges healthcare organizations are confronted with as they try to secure this environment. This discussion will then serve as the foundation for this article to examine this new triad's unique challenges—clinical operations, medical legacy devices, and business silos. To understand and surmount the challenges that this creates in terms of defending healthcare's most visible patient safety risk from the invisible and insidious cyber threat that can have very visible and, more importantly, physical effects on patients.

Figure 1. Conceptual convergence of cybersecurity, sterile processing operations, and patient safety, illustrating how cyber failures in SPD can directly translate into clinical harm.

2. Methodology

A narrative literature review was conducted to synthesize evidence from multiple domains. We

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used a narrative literature review approach to integrate evidence from multiple fields. Literature searches were conducted in PubMed, IEEE Xplore, ACM Digital Library, and Google Scholar from 2015 to 2024. Search terms included: "sterile processing cybersecurity," "medical device security," "operational technology in healthcare," "patient safety and cybersecurity," and "healthcare governance cyber." Grey literature search terms included U.S. Food and Drug Administration (FDA), Cybersecurity and Infrastructure Security Agency (CISA), ECRI Institute, AAMI, and the International Association of Healthcare Central Service Materiel Management (IAHCSMM). Articles were included in this research if the technology, organization, or governance of SPD was associated with potential vulnerabilities in the cybersecurity process. Articles were also included if they addressed patient safety and outcomes. Themes of common business and governance challenges were explored through thematic analysis.

3. Literature Review

3.1. The Convergence of Cyber Risk and Patient Safety in SPD

The link between SPD function and patient outcomes is obvious. SSIs are related to ineffective sterilization. Sterilizer and SPD standards like those from AAMI (ANSI/AAMI ST79) have very prescriptive requirements for process control (AAMI, 2022). The use of networked devices is a new form of process failure vector. Kramer et al. (2021) showed how infection of a network-connected sterilizer with malware could result in it to changing its cycle parameters or fabricating electronic logs to falsely show successful sterilization, presenting a "trust" in sterility that does not exist. The FDA has become much more aware of this and now has pre and post-market cybersecurity guidance to advise manufacturers of medical devices that security is an aspect of device safety (FDA, 2022). CISA advisories regularly point to vulnerabilities in medical devices that are used in SPD. Due to how these devices are used, exploits can result in a denial-of-service condition rendering sterilization equipment unavailable (CISA, 2023).

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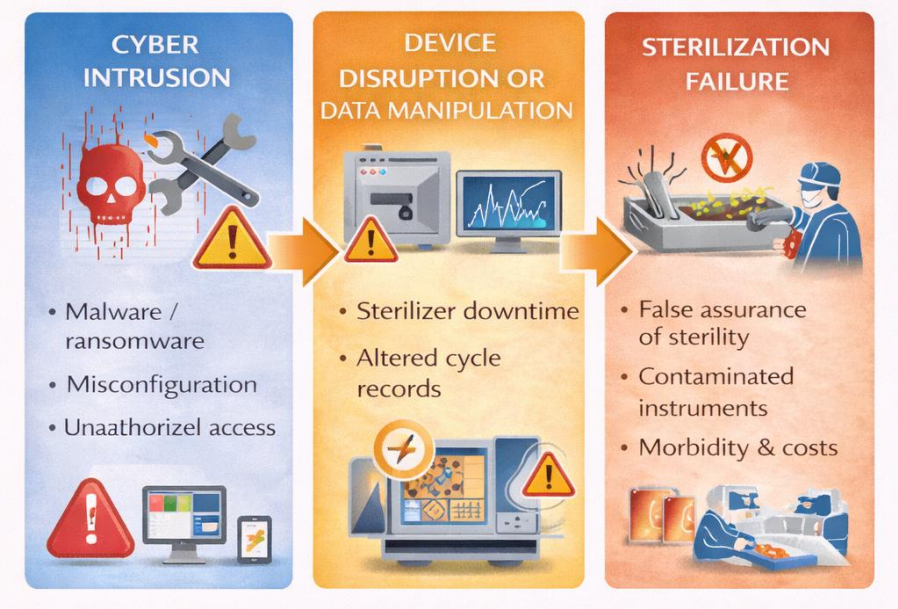

Figure 2. Causal pathway illustrating how cybersecurity incidents in networked sterile processing devices can compromise sterilization integrity and lead to patient harm.

3.2. Business Challenges

- Legacy Technology and Patching: Much of the capital equipment in SPD (think sterilizers) has a useful lifespan of 10-15 years. This equipment often runs operating systems that are now end-of-life (say Windows 7) or are embedded with firmware/software that cannot be patched or even easily updated. Vendors can be very slow to create (and validate for FDA clearance) a security patch as they may fear that the update would break device functionality and thus void FDA clearance (Fu & Blum, 2020). Known unpatchable vulnerabilities persist.

- Budgetary Silos and Cost Pressures: SPDs are usually cost centers and typically governed under perioperative or nursing services budgets. Cybersecurity budgets are in IT or Information Security (InfoSec). The cost of upgrading or hardening SPD equipment often falls into a grey area between central IT budgets (too “operating room specific”) and SPD’s own operational budgets (too capital equipment heavy to fund from operational budgets). Critical security investment funding is often just unavailable due to misaligned funding silos (Wicklund, 2022).

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- Lifecycle Management Disconnect: The purchasing, commissioning, monitoring, and decommissioning of medical devices touch clinical engineering, SPD, procurement, and IT. Cybersecurity is an afterthought on a procurement RFP. Without clear governance, lifecycle cybersecurity risk of a given SPD device is owned by no one (Sundaram, 2021).

3.3. Governance Challenges

- Fragmented Accountability and Knowledge Gaps: SPD technicians are experts in microbiology, sterility, sterilization science, but have had little exposure to cybersecurity topics. Conversely, hospital InfoSec teams are used to looking at network perimeter threats and have little knowledge of SPD and how critical the workflow and device uptime is to patient safety. Clinical engineers are the "grey hat" in the middle that understand both, but they may lack the ability to mandate policy from SPD. This results in gaps in risk assessments and incident response plans (Petrie & Evans, 2023).

- Regulatory and Standards Complexity: SPD operations have to align with clinical standards (say, AAMI, The Joint Commission) and cybersecurity efforts to outside frameworks (NIST Cybersecurity Framework, HIPAA). What parts of cybersecurity activities overlap with/are allowed under SPD device safety requirements and are not well-defined. A vulnerability scan initiated by the IT department against a SPD device that has no a priori engagement with clinical engineering might crash the device and violate patient safety standards (Johnson, 2022).

- Supply Chain and Vendor Management: SPD operations rely on many 3rd party vendors for equipment, software, and services. Many such devices need remote access for diagnostics and maintenance which can also be an attack vector. Contracts may not have explicit cybersecurity related service level agreements (SLAs) leaving hospital exposed to vendor-side hacks (ECRI Institute, 2023).

4. Results

The literature synthesis and reported event analysis have produced a remarkably consistent and disquieting picture of vulnerabilities. They can be condensed into four key thematic areas: technical, organizational, governance, and regulatory. We find repeated evidence of a near-complete lack of cybersecurity being considered as part of the clinical safety culture of SPDs.

Table 1. Summary of business and governance challenges contributing to cybersecurity vulnerabilities in surgical sterile processing departments.

Challenge Domain	Description	Patient Safety Impact
Legacy technology	Unpatchable OS, outdated firmware	Increased failure risk

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Budget silos	IT vs clinical funding disconnect	Delayed mitigation
Fragmented governance	No single accountable owner	Gaps in response
Regulatory mismatch	Clinical vs cyber standards	Risk avoidance behavior
Vendor dependency	Insecure remote access	Expanded attack surface

4.1 Ubiquitous and Unpatched Technical Vulnerabilities in Legacy and Networked Systems

The most common technical vulnerability is the widespread existence of legacy medical devices. High-dollar capital equipment (sterilizers, washer-disinfectors, high-use barcode printers, etc.) generally has a usable lifespan of 10 years or more and are running long-outdated software (Windows 7, embedded systems with no upgrade path) (Fu & Blum, 2020). Legacy medical devices were developed in a bygone era of air-gapped networks and have known exploitable features such as hard-coded passwords, unencrypted data-at-rest/transit, and intentionally disabled security capabilities to maintain uptime. They are also extremely difficult to patch. Vendor-created security patches must be re-validated for safety function (non-interference with sterilization process) and can take months or years to deliver (Johnson, 2022). SPDs may have known and exploitable Common Vulnerabilities and Exposures (CVEs) present on their network for years with no available mitigation.

4.2 Fundamental Organizational and Budgetary Disconnects

A theme common to both parts of this literature review is an organizational structure that is not aligned to the cross-cutting nature of clinical and cybersecurity operations. SPDs are generally clinical cost centers of a hospital, falling under perioperative or nursing leadership with budgets allocated to consumables, labor, device maintenance, etc. Cybersecurity and InfoSec risk is often budgeted and managed centrally as a hospital-wide IT cost center or, in larger organizations, an enterprise risk management team (Wicklund, 2022). The result is a "buyer-seller" funding gap in the middle, where it is not clear who is responsible for or willing to fund security. Segregating an SPD's device network on to a dedicated (more secure) virtual LAN (VLAN), purchasing a next-generation firewall for medical device traffic, or upgrading an OS on a legacy sterilizer all fall in to this perceived "no-man's land" of budgeting. Too clinical and narrow for the centralized IT capital budget, too large-ticket and technically complex for the SPD operational budget. It is a familiar story for many readers and leaves the organization with a perpetual backlog of needed investments and reactive/behind-the-curve "cowboy" security practices.

4.3 Lack of Consolidated Governance and Accountability

This naturally leads into the issue of a fundamental lack of governance over the cybersecurity of SPD devices. Accountable ownership for any aspect of cybersecurity is fragmented between at least:

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- SPD Management, who are beholden to throughput metrics, compliance with AAMI standards and immediate clinical function
- Clinical Engineering/Biomed, who are responsible for device function and preventive maintenance and may have vendor-management responsibilities, but often lack formal purview over or training in cybersecurity
- Information Security (InfoSec), who are charged with security of the network and technical controls but do not usually have clinical context to appreciate the patient safety impact of a device outage or operational concerns around patching for example

Reports in the literature show that in most organizations, there is no standing committee and rarely a single executive role with explicit responsibility for any part of the cybersecurity lifecycle of a medical device, from procurement (ensuring security controls are in the RFP process) to decommissioning (secure wiping of data at end-of-life) (Sundaram, 2021). The effect of this lack of consolidated governance in the organization is seen in our analysis as gaps in risk assessment, incident response plan, and cross-team communication.

Figure 3. Fragmented accountability across clinical, engineering, and IT functions contributing to unmanaged cybersecurity risk in sterile processing departments.

4.4 Regulatory and Cultural Mismatch

The final key issue with the current operational environment in SPDs is that it exists in a state of regulatory and cultural mismatch. On one hand, it is highly regulated clinically (what processes are used) and with regards to quality (ISO 13485 certification) and infection prevention (e.g. AAMI ST79 standards). Because of this, any action that can be construed as altering the base state, stability, or validation of a process in the SPD (unscheduled reboot, network scanning,

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software upgrades, etc.) can be seen as a hostile intrusion to that stability and non-compliant behavior (Petrie & Evans, 2023). At the same time, there is little guidance, as of yet, on how frameworks such as the NIST Cybersecurity Framework can be applied in a highly sensitive, real-time clinical environment.

The resultant risk-averse behavior is for the clinical or biomedical staff to reflexively reject and block requests or activity from IT staff for cybersecurity/privacy reasons for fear of an adverse event or accreditation citation. This means valid vulnerabilities often go unaddressed. There is also a tangled web of service/maintenance contracts with vendors for equipment in SPDs, but very rarely are their clauses addressing cybersecurity or delineation of risk responsibility in contracts for third-party vendor remote access or for sub-standard security practices on vendor premises (ECRI Institute, 2023).

5. Discussion

The results of this review are striking: the cybersecurity of Surgical Sterile Processing Departments (SPDs) is shown to be a vital and under-supported patient safety function. The challenges identified in the results—technical, organizational, governance, and regulatory—are not individual gaps or weaknesses, but a sign of a misalignment of paradigm between the way healthcare organizations are expected to think and manage cyber risk, versus the true nature of the risk in SPD. Healthcare organizations are applying 20th century IT risk management approaches (data confidentiality, data availability) to 21st century, clinical risk (device and process integrity) with tangible and irrecoverable physical impact. In this discussion, I interpret the above findings to suggest that a fundamental change in approach is required to overcome the challenges, including the presentation of proposed models for cross-functional governance and holistic risk management.

5.1. Understanding the Risk: The Shift from Data Breach to Clinical Failure

The first major implication of the results is a reframing of the risk narrative: a cyber event on SPD must be interpreted not as "another cybersecurity incident to report to the InfoSec analyst" but with the same severity as a power outage in the OR or a tainted intravenous bag. As an outage results in canceled cases, inability to use core instruments and surgical equipment, or reliance on potentially non-sterile backup supplies (an all-too-common reality for medium to small facilities), and SSIs are a direct clinical outcome of these scenarios, the natural lens for cybersecurity risk assessment for SPD must be the clinical risk matrix. This means abandoning the classic cybersecurity framework of likelihood of impact in the form of data loss versus perceived impact severity for a:

- Clinical Impact Severity: Potential for patient harm (i.e., infection, death)
- Operational Criticality: Maximum offline time for the department or specific device before surgical capacity is impacted

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- Process Compromise: False negative or manipulability of the sterilization cycle

The reframing of risk from a data loss scenario to a patient safety event should force the SPD cybersecurity conversation out of IT department budget discussions and force it to its natural home: in executive boardroom meetings, quality & safety committees, and other cross-functional clinical governance forums where risk is discussed in terms of patient harm, not business interruption.

5.2. Proposed Model: The Cross-Functional Medical Device Cybersecurity Committee

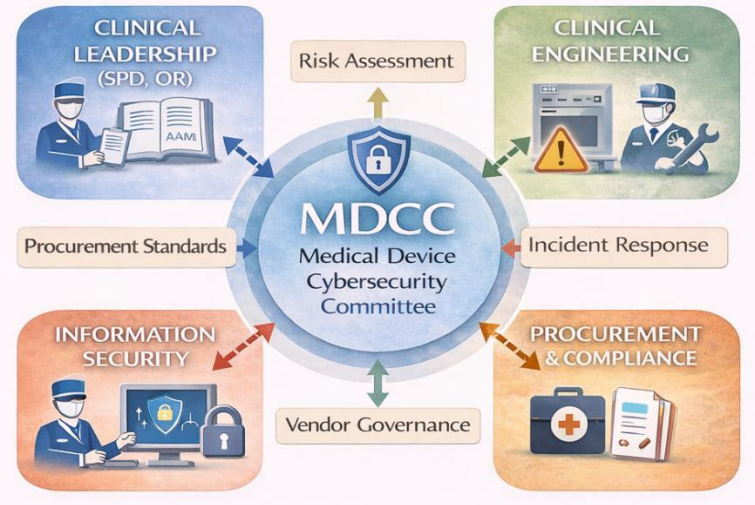

Figure 4. Proposed cross-functional Medical Device Cybersecurity Committee (MDCC) model for unified governance of cybersecurity and patient safety risks in SPD.

To overcome the governance and budgetary silos, hospital and health systems must create a permanent and executive-sponsored cross-functional Medical Device Cybersecurity Committee (MDCC) with direct scope and priority on SPD and other clinical departments. This committee must have equal representation from clinical, operational, and technical domains with authority at the executive level. The core functions of this committee should directly and logically counter the above challenges:

- Mandatory and Unified Policy and Procurement Governance: The MDCC should mandate in all medical device RFP and contractual language for medical device procurement a set of pre-requisite cybersecurity requirements, enforced upstream by technology procurement (IT). This should be written into as part of the security section of all RFPs for equipment, including minimum requirements for vendor reporting on SBOMs, predefined SLAs on patching / update windows, and support for key security features like RBAC. This upstream and in-built specification moves security from the implicit reaction to known vulnerabilities as a cost center to a key design feature, with

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well-defined investment justifications during capital planning.

- Unified, Clinically Informed Risk Assessment: Rather than have IT perform regular vulnerability scans and SPD perform standard clinical safety checks in parallel, the MDCC should set up combined clinical-informed assessments, where a cross-functional team of one InfoSec analyst, clinical engineer, and SPD manager all review a single device. For example, the InfoSec analyst reviews CVEs; the clinical engineer and SPD manager review the clinical workarounds if that device was down or unavailable (Is there a manual log that can be kept? Are there redundant devices in the hospital?), creating a shared and balanced risk picture.

- Pre-Defined, Orchestrated Incident Response and BC/DR: The committee also should develop SPD-scenario-specific incident response playbooks with clear clinical decision-making steps (triggered and communicated by SOC to SPD Floor): If the tracking system is down for X hours, what are the SOPs to validate manual checking of all instruments to ensure sterility, assembling of surgical kits, and other manual overrides to continue a case safely? These jointly developed and tabletop-tested plans ensure critical actions are coordinated, not made in isolation by clinical and IT teams during a crisis, when communication breakdowns are most likely.

- Vendor Risk Management: The MDCC should also establish and hold medical device vendors to a set of standardized contractual cybersecurity requirements. These can include "right to audit" evidence of the vendor's cybersecurity program (testing and validation processes, incident response), protocols for enabling secure remote access and support, and a commitment to provide vendors with vulnerability disclosure within X number of days.

5.3. Overcoming the Clinical "Change Control" Paradox in "Security by Safety"

The false choice of clinical stability vs. change via "updates" can be reduced by taking a "security by safety" approach, which is: all cybersecurity actions must be pushed through existing change control and QMS (Quality Management Systems) for SPD, including incidents response playbooks above. This means, instead of an unplanned patch pushed by an IT change request and performed outside SPD control, a "security update" is instead a planned change request to a medical device and pushed through the pre-established, managed pathway: validated in non-production environment, scheduled with agreed maintenance window (approved by SPD leadership) to limit business impact, implemented in production with back-out plans and validated post-implementation to ensure device safety / function not impacted. This path reduces the likelihood of unvalidated software patches being installed, overcomes the false "cybersecurity versus patient safety" tension by aligning cybersecurity maintenance and hygiene

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to the existing (strict!) change control environment SPD already has, and ingrains cybersecurity as a defined and repeatable process.

5.4. Limitations and Further Study

The above discussion is based on a narrative review of the emerging but still limited literature; direct empirical research on the link between particular cyber vulnerabilities in SPD and rates of patient harm remains at a nascent stage. This can be an area of further research on:

1. Building and validating a cybersecurity risk assessment framework for clinical operational technology like SPD equipment
2. Case study evaluations of the governance model for integrated cross-functional cybersecurity committees with emphasis on SPD.
3. Economic cost analyses of SPD cybersecurity incidents and impact vs. the costs of different mitigation approaches to build stronger business cases for cybersecurity investment.

The business and governance challenges in SPD cybersecurity are significant and complex but not insurmountable; a key source is remediable, and that is the false dichotomy of "cybersecurity" as separate from "patient safety." The solution requires an intentional re-engineering of the organizational structure. By creating cross-functional governance, reframing cybersecurity risk in clinical terms, and standardizing and managing cybersecurity actions as we would any other safety action, healthcare organizations can create a new baseline of resilient and safe sterile processing operations. And by that, protect not only their networks and data but, most importantly, their core commitment to their patients to "first, do no harm."

6. Conclusion

The digitalization of Surgical Sterile Processing Departments is creating an increasingly direct pathway between cybersecurity failure and patient harm. The confluence of business and governance factors (legacy technology, fragmented budgets, stove-piped accountability, and regulatory whiplash) presents considerable inertia, but is not insurmountable. However, this will require both an understanding that cybersecurity in a clinical context is a distinct discipline that must consider not just data protection but the integrity of a safety-critical process and for healthcare organizations to break out of the cycle of relegating SPD cybersecurity to the IT organization. It should instead be integrated with clinical quality and patient safety program efforts. Future research directions might include the creation of standardized risk assessment frameworks with clinical use cases, like SPD, in mind, and the impact of integrated governance models on both cyber resilience and patient safety outcomes.

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