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Major Article

The work of sterile processing departments: An exploratory study using qualitative interviews and a quantitative process database

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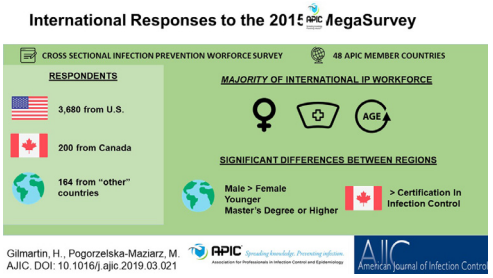

Key Words:
IUSS
Infection prevention
Hospital

Background: The sterile processing of surgical instruments and equipment is an essential part of surgical operations. Although clean instruments prevent infections, little is known about the departments that conduct this work. We sought to describe sterile processing departments (SPDs) and to identify factors impacting them.

Methods: We analyzed data from 22 qualitative interviews of staff and managers and a quantitative benchmarking database.

Results: Qualitative results indicated 4 primary factors impacting sterile processing work: (1) role and visibility, (2) relationships and communication with other departments and vendors, (3) staffing and management, and (4) technical problems and solutions. Quantitative analysis revealed significant differences in SPD responsibilities and scope.

Discussion: Relationships with operating room staff were of paramount importance in the ability of the SPD to accomplish its job and in staff motivations and feelings. Differences in management practices, communication strategies, and problem-solving resources were also emphasized. Both quantitative and qualitative data showed concern for the role of the SPD in patient safety, particularly concerning practices such as the use of immediate-use steam sterilization.

Conclusions: To more completely address adverse patient events and surgical patient safety, we must move toward examining the entire surgical process, including the vital role of SPDs.

Every day, millions of surgical instruments and pieces of medical equipment are cleaned and processed in the United States by over 50,000 central processing technicians (techs).[1,2] Reports of infection outbreaks draw attention to the sterilization of instruments and its importance in keeping patients safe and preventing infections.[3–5] An infection outbreak among patients in orthopedics and ophthalmology was directly linked to surgical instruments contaminated with coagulase-negative staphylococci and *Bacillus* spp.[6] In 2015, duodenoscopes used for endoscopic retrograde cholangiopancreatography were found to be the cause of an outbreak of carbapenem-resistant Enterobacteriaceae at the Ronald Reagan University of California, Los Angeles, Medical Center that sickened 7 patients, 2 of them fatally.[5,7] In another outbreak, this time of AmpC *Escherichia coli* from the same procedure, duodenoscope reprocessing was found to *exceed* the manufacturer's recommended guidelines—highlighting the complex nature of sterile processing work.[8]

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Sterile processing is an essential component of accreditation, operating room (OR)/procedure turnover times, and, most critically, patient safety.[9] Infection outbreaks draw temporary attention in the popular press to the work of instrument sterilization. Hospital leaders come up with ad hoc solutions to reduce patient harm based on the regulations and technical literature on the process of disinfection and sterilization techniques.[10–13] However, few studies have investigated the variety of management practices by which central processing personnel, sterilization, and instrument availability can be leveraged for infection prevention.[14–17] Our study analyzes data from qualitative interviews with 22 sterile processing department (SPD) managers and employees and a separate quantitative dataset of the Association for the Advancement of Medical Instrumentation (results only) to (1) describe the status of SPDs and their relationships with other parts of the hospital, and (2) highlight staffing and equipment management practices of interest to infection control professionals.

METHODS

Qualitative data collection

During the course of a larger surgical safety project designed to understand the importance of culture and the role of facilitators and barriers for improving surgical safety, in-person interviews were conducted with 22 employees responsible for sterilizing and cleaning instruments.[18] Although the larger project included over 300 interviews from 16 hospitals with individuals involved in the entire perioperative process (surgeons, scrub techs, circulators, nurse educators, etc), this article focuses solely on the transcripts of sterile processing workers and managers who worked in 12 of the hospitals, which were diverse based on region, rurality, size, ownership type, and teaching status. Secondary analysis of these deidentified sterile processing transcripts was conducted for this study.

Qualitative analysis

The transcribed interviews were analyzed using an inductive qualitative analysis approach with thematic analysis.[19,20] Two authors (initials removed from blinded copy) coded the interviews inductively, categorizing themes that emerged from the data. The analysts conferred regularly to discuss the emerging themes. Disagreements were resolved through discussion and with the help of the third author. This article reports on the 4 main themes that emerged, and we present them as key factors for sterilization work.

Quantitative data and methods

The Benchmarking Solutions—Sterile Processing platform (Association for the Advancement of Medical Instrumentation, Arlington, VA) is a product developed as a collaboration between the International Association of Healthcare Central Service Materiel Management and the Association for the Advancement of Medical Instrumentation. It provides a digital platform designed to assist SPDs in managing their operations and provides benchmarking information. We used the results-only version of the database for fiscal year 2017 and calendar year 2017 as downloaded on May 2, 2018. Data are voluntarily reported by departments and aggregated for the results-only version. The Benchmarking Solutions tool results-only version does not allow hospital-level data to be linked across types of information at the observation level. Additionally, no hospital names were available from either the qualitative or quantitative data, so we do not know if any of the data overlap. There are several domains available: facility information, scope and responsibilities, compliance policies and procedures, immediate-use steam sterilization (IUSS) procedures, processing procedures, sterilization loads, anomalies, and staffing. The number of responses varies by question. Only the average number of responses is listed in the results-only version for each domain. Because the risk of bias increases with smaller sample size (the hospitals answering the questions in domains with few respondents are likely quite different from those who choose not to answer), we opted to not present these results in case they were misleading and include only domains with an average of 15 responses per question. Given the limited and nonrandom sample, percentages will be used to describe the results.

Table 1
Summary of key factors

Key factors	Definition
Role and visibility	Visibility of department staff and work of the department within the hospital; understanding of the role of sterile processing work
Relationships and communication	Relationship to OR; relationship to vendors; microinteractions and how these interactions affect work and workflow
Staffing and management	Hiring, training, licensing, ladder, turnover, hours, leadership structure
Technical problems and solutions	Equipment needs and problems; regulations about how to do work; workflow processes; responses and solutions to technical problems

OR, operating room.

RESULTS

Qualitative results

Through the course of conducting the qualitative work, it quickly became apparent that SPDs vary quite a bit in physical size, personnel, volume of instruments processed, types of instruments, position in hospital, et cetera. However, 4 key factors did emerge as consistently important across the 12 hospitals in which we conducted site visits: (1) role and visibility within the hospital, (2) relationships and communication with OR staff, (3) staffing and management, and (4) technical problems and solutions. We address each in more detail in the following paragraphs, and all 4 are equally important (the different section lengths do not indicate a difference in weight) (Table 1).

(1) Role and visibility within the hospital

During interviews, most SPD staff talked about their department's relationship with the rest of the hospital. In many hospitals, the SPD is physically located in the basement and is somewhat disconnected from the rest of the hospital activity happening on floors above. This reality of the physical location could isolate an SPD. One manager talked about how nice it was that his SPD was (unusually) located near the OR: "I would continue to rather have [the SPD] on the same floor because I've go[ne to] the places where sterile processing has become disconnected. It's like another place somewhere else, and we don't see those faces, and we don't know who those people are. And it really doesn't matter. It's good that they know who these people are and it matters. It's just like a team. You need to know who your players are, so I would always want it to be on the same floor."

The physical isolation also contributed to a sense of feeling underappreciated, invisible, or misunderstood. One interviewee explained how the SPD had been traditionally overlooked: "We're the department nobody knows about. Even today, people say, 'Sterile processing? What's that? What do they do?' They can't even tell you where

they are in the hospital . . . So we're a behind-the-scenes department, but everything we do touches every patient."

The SPD staff we talked to were absolutely convinced of their value. One interviewee even described the role of the SPD this way: "Well, we're kind of like the heartbeat." However, they also communicated the frustration that other parts of the hospital took their role for granted. An SPD supervisor explained that she realized "these people [in the SPD] don't get the appreciation they deserve." Without their work, surgeries and procedures would come to a standstill. This perceived lack of recognition about the importance of SPD also strained communications and relationships with other departments, which we address next.

(2) Relationships and communication with OR staff

Several interviewees specifically talked about their relationship with the OR staff, whom they interacted with frequently. Communication between the OR staff and the SPD was not always smooth, especially when instruments were needed urgently and there was little understanding about delays. One SPD supervisor we interviewed had previously worked in the OR as a nurse, and her perspective provides a useful one in elucidating some of the common perceptions and barriers to good communication between the SPD and the OR: "You know, as an OR nurse, you think you know sterile technique, but you really don't. I mean, the detail that goes on [in the SPD] behind the scenes is just, you know, I was really shocked. Those manufacturers' instructions for use are very complex, just the equipment, all the different processes they have."

She also explained that a little bit of understanding and appreciation for the work of the SPD could go a long way in communications. She explained: "One thing I would do differently when I called downstairs for a tray of instruments and say, 'What's taking so long?' Because now I know. A lot of times I do apologize to them—'Oh, I'm so sorry.' And same thing since I've been down there. We've been working on educating SPD on what the OR does and the OR what SPD does, and I think just the relationship there alone has really improved."

Multiple respondents talked about feeling like their OR colleagues ignored or overlooked them until there was a problem (eg, an instrument was needed but not available). Then, there was little patience or understanding about the complex work of the SPD but rather demands for sometimes unrealistic response times.

At 1 hospital we visited, the relationship between the SPD and OR staff was positively impacted by a unique staffing arrangement in which OR surgical techs actually floated to work in the SPD when the procedure volume was high. Surgical techs at this hospital were specialized to a particular service line (orthopedics, neurology, etc) and were very familiar with the assembly and disassembly of the instruments they worked with. According to 1 surgical tech, this arrangement helped improve teamwork and communication between OR and SPD: "If they need help here, we'll just come and help here. If . . . some of us are free, we'll come and help SPD, so we're pretty close and tight with everybody around both areas."

From the management perspective, this staff floating arrangement was made possible through the chain of command—the manager of this SPD also supervised OR staff: "We're able to have a close relationship with sterile processing in the operating room because I kind of manage both. . . . Now, if they've had a busy day yesterday and I have spare surgical techs . . . I would float them over . . . to call center and send them over there. So [name] . . . will probably . . . be in the operating room tomorrow doing cases, but today I could afford to bring her over there and help them catch up." The manager reported really appreciating this arrangement "because that also creates a little bit of camaraderie. And also empathy for what the other person is doing."

(3) Staffing and management

We found several different managerial approaches among SPD directors. One manager, for example, focused primarily on education and marketing her department. She thought the most important thing was to continuously "reinforce, reiterate" information about sterile technique and safe behavior. Although "everybody knows about surgical site infections," people may have gaps in education or may forget something, and continuous education is key. She wanted to focus on "modifiable behaviors" to achieve this goal. She also organized an open house during SPD week that took place during OR in-service time, that is, when the OR staff receive their weekly educational updates. OR staff came with the nurse educator to the SPD and stopped at each station and observed the work done in SPD.

Another SPD director had a different approach to education of his staff. In that SPD, the manager installed cameras and watched the previous night's shift every morning while drinking his coffee. In his eyes, every small transgression might lead to an adverse event, and he would do anything to avoid those: "So I'll come in the morning . . . and I'll get a second, get my cup of coffee, and I'll review last night. And I'll say, okay, who's in instruments? What did they do? Who's in decontam[ination station]? Did they use proper PPEs [personal protective equipment]? Were they protecting themselves? . . . Were they using the proper safety stuff? . . . What are they doing with the objects? How are they doing? How are they handling it? . . . And as long as everything looks good, then we're good to go, and I can look back, I think, about 2-3 weeks, and then I'll dump off, and then if I want to save something, I can always burn it and save it and then show it to them later on . . . So I use that to monitor the shifts I'm not there for."

Notably, cameras were installed in this SPD *before* the administration was planning to install cameras in the OR. This manager also introduced a unique process aimed at reducing human errors: a double sign-off for assembled instrument trays to create redundancy. According to the manager, this helped reduce errors because "when everybody knows they've got each other's back on that, it makes it easier for that person . . . instead of having just one person take all the weight on that, we said, 'Have your buddy check it out too.'" Although this may be a very useful process innovation for smaller hospitals, large hospitals with high volumes of procedures and instruments may never have enough staff to implement it.

One SPD director decided to hire only people with experience and required that all of the sterile processing techs be certified within the first year. Because only a few states require certification, choosing to hire only people with experience is a luxury that not every hospital may be able to afford. For example, small rural hospitals may not have a pool of applicants who have worked in sterile processing before to choose from.

(4) Technical problems and solutions

In a world that revolves around instruments, each of our interviewees shared stories of equipment challenges they encountered and ingenious ways of resolving them. For example, one manager discovered that an instrument manufacturer had 2 sets of different instructions on their website for how to sterilize an instrument. The manager proudly reported to us that she had pointed out this information to the company and the vendor quality control department had subsequently contacted her to thank her.

In another hospital, the manager wanted to address a problem with orthopedic instrument kits that were arriving in decontamination—the first area of SPD where all the dirty instruments initially arrive from the OR—with "bone and stuff caked on them." The manager realized that "if we just put them in the washer and expect the washer to clean them, we're kidding ourselves" and undertook to modify the cleaning process, starting in the OR. Their newly implemented process included rinsing the instruments in the OR before they reached SPD so the process of decontamination using enzymes could be started earlier: "After the case is done and the patient's out of the room, there's a rinse boat, so they take the instrumentation, the reamers, you know, the last tie with the reamers, the broaches, and those kind of things that have all the stuff and blood and bone and stuff on there, rinse them out, and put them then in a separate boat. So they're rinsed down . . . then put in another boat and sprayed with the enzyme so they stay moist. . . . So, it's a metal boat with fluid and enzyme, and they just, you know, under the water, you know, shake it around, get all the stuff out of it, and they take it out and put it in another boat so it's not sitting. . . . in the debris. They spray it with the enzyme and then send us everything back to SPD."

Many respondents mentioned waste in sterile processing. For example, sometimes large kits get reprocessed although half the instruments in the kit are rarely used. In 1 hospital, this happened often with robotic instruments. To reduce waste and improve efficiency, SPD managers asked OR nurses and surgical techs to return used and unused instruments separately. They planned to track which instruments are never used for particular surgeries to eliminate this extra work and thus accelerate reprocessing.

The daily surgical schedule also greatly impacted the volume and pace of work in the SPD, although the SPD typically had little control over the schedule. It was particularly challenging when similar surgeries (that required the same instruments) were scheduled back to back. To make it most efficient, many SPDs decided to purchase additional instrument kits necessary for that specific procedure to eliminate the need to use IUSS (quick cycle) or fast-track the instruments.

Several SPDs talked about reducing their rate of "flashing," or IUSS rate. IUSS is a sterilization technique that takes only about 20 minutes and allows OR staff to sterilize the necessary instrument quickly. Because this process is less thorough, it is believed to be potentially associated with infections and is an important quality metric in sterile processing. One SPD reported having an incredibly high flashing rate (27%). When they analyzed the data on the causes of IUSS, they realized that service line growth (hiring 2 new spine surgeons) had outpaced instrument purchasing (new instrument kits were never bought for those surgeons). Another manager assigned an SPD worker as the "runner" to get instruments quickly to OR teams in an effort to avoid flashing instruments unnecessarily (Table 1).

Changes in employment structure also affect SPD volumes. As 1 SPD director reported, the common transition of physicians from self-employed to hospital employees has had a major impact on SPD: "We started doing his pumps, but he used to do them in his office. Then, when he became a hospital employee instead of a private physician, that couldn't happen anymore."

Quantitative results

Response rates and sample description: response rates differed across questions and months. For questions concerning operational specifics, such as number of sterilization load runs, number of items processed, number of errors, number of IUSS events, and staffing analysis, the maximum number of respondents per month was 22. Across these questions, there was a pattern of responses, with fewer than 15 responses for most questions in August, September, October, and November—impeding our ability to look for seasonal trends. For categories that included more general questions, such as organizational policies, response rates were better, with average responses per question of 42-63.

Table 2
Facility locations

Region	%
Southeast (AR, LA, MS, AL, GA, FL, SC, NC, VA, WV, KY, TN)	40
Midwest (MN, WI, MI, IN, OH, IL, IA, MO, KS, NE, SD, ND)	18
West (CO, MT, WY, UT, NV, ID, CA, OR, WA, HI, AK)	17
Southwest (TX, NM, AZ, OK)	11
Northeast (DC, DE, MD, PA, NY, NJ, CT, MA, VT, RI, NH, ME)	14
Degree of rurality	
Rural	48
Urban	27
Suburban	25

NOTE. Average number of responses = 63.
AK, Alaska; *AL*, Alabama; *AR*, Arkansas; *AZ*, Arizona; *CA*, California; *CO*, Colorado; *CT*, Connecticut; *DC*, Washington, DC; *DE*, Delaware; *FL*, Florida; *GA*, Georgia; *HI*, Hawaii; *IA*, Iowa; *ID*, Idaho; *IL*, Illinois; *IN*, Indiana; *KS*, Kansas; *KY*, Kentucky; *LA*, Louisiana; *MA*, Massachusetts; *MD*, Maryland; *ME*, Maine; *MI*, Michigan; *MN*, Minnesota; *MO*, Missouri; *MS*, Mississippi; *MT*, Montana; *NC*, North Carolina; *ND*, North Dakota; *NE*, Nebraska; *NH*, New Hampshire; *NJ*, New Jersey; *NM*, New Mexico; *NV*, Nevada; *NY*, New York; *OH*, Ohio; *OK*, Oklahoma; *OR*, Oregon; *PA*, Pennsylvania; *RI*, Rhode Island; *SC*, South Carolina; *SD*, South Dakota; *TN*, Tennessee; *TX*, Texas; *UT*, Utah; *VA*, Virginia; *VT*, Vermont; *WA*, Washington; *WI*, Wisconsin; *WV*, West Virginia; *WY*, Wyoming.

Despite the small number of responses, there was substantial variation in facilities. The median number of beds was 280, with an interquartile range (IQR) of 105-402. As can be seen in Table 2, there is a plurality of facilities in the Southeast region, with nearly half in rural areas.

SPDs also varied in terms of personnel. The median number of full-time employees was 15, with an IQR of 4.5-25.8 (average number of responses = 50). The number of "leaders," or individuals with supervisory responsibilities was much lower with a median of 2 and an IQR of 1-3. Few facilities reported having full-time employees work outside of the SPD but at the same facility.

Responsibilities of the SPD (average number of responses = 61): at each facility, there were multiple floors, clinics, and units that received SPD services, with a median of 12 and an IQR of 7-24. Most of these appeared to be ORs, with a median per facility of 12 and an IQR of 6-22, but there was also a median of 3 labor and delivery rooms (IQR, 1-10) and a median of 2 endoscopy rooms (IQR, 1-4).

Responsibilities were roughly consistent across the sample, with 98% of facilities reporting being completely responsible for surgical instruments and 94% reporting being responsible for reusable treatment trays. Half reported being responsible for patient care equipment, and slightly more than half (55%) reported being responsible for case carts. Fewer SPDs (27%) reported being responsible for providing consumable supplies to nursing units.

SPDs also seem to have greater control over the selection and acquisition of products when they are more closely related to the core tasks of surgery and decontamination, as can be seen in Table 3. Endoscopes were a notable exception, with only 56% of SPDs reporting a significant role in their selection and acquisition.

Policies, processes, and quality improvement (average number of responses = 58): of the 9 different organizations and agencies that produce policies and procedures for compliance and related areas, none had fewer than 31% of SPDs reporting following their policies and procedures. Most of the organizations producing policies and procedures had at least 60% of SPDs reporting following them. Nearly all SPD respondents (81%) reported having a formal system to record, investigate, and resolve issues, and 12% reported planning to have such a system in the future.

IUSS is handled by SPDs in 70% of the reporting facilities and by ORs in 27% (the remaining 3% are listed as other). IUSS cycles are

Table 3
SPDs and their role in selection and acquisition of equipment

Equipment	% reporting routine consultation in selection and acquisition of equipment
Sterilization process indicators	94
Surgical instruments	92
Decontamination equipment	89
Packaging	89
Powered equipment (eg, electrically powered surgical instruments)	79
Containment devices	73
Storage equipment	61
Specialty equipment (eg, robotics)	60
Endoscopes	56
Distribution equipment	42
Other	16

NOTE. Average number of responses = 61.
SPDs, sterile processing departments.

considered in different circumstances (Table 4). SPDs also reported on whether there were policies in place to decrease the use of IUSS (Table 5). Monitoring and tracking were occurring in virtually all departments, with increased instrument purchases occurring in 78% of reporting SPDs.

Nearly half of SPDs (47%) reported having a formal continuous quality improvement program in place for at least some of their processes. Slightly fewer (39%) reported having such a program for "nearly all" of their processes. Of the remaining SPDs, 8% reported that such a program was planned, and 5% reported not having a program in place.

DISCUSSION

Using qualitative and quantitative data and analysis, we have shown the incredible variety of tasks, responsibilities, and processes followed by SPDs, describing what is known about their work. We also identified several key factors that impact SPD work. We found that SPDs have low visibility and status within the hospital hierarchy. From the interviews, the relationships with the OR, OR staff, and hospital were of paramount importance in the ability of the SPD to accomplish its job and in the motivations and feelings of the SPD staff. Differences in management practices, communication strategies, and resources to solve problems were also highlighted in the interviews. SPD managers use creative approaches to control their staffing flows, such as floating surgical scrubs between the OR and SPD, installing cameras in the SPD, employing double sign-off for completed instrument kits, and hiring only certified techs. SPD managers also constantly review their supplies and equipment stock purchasing additional equipment and introducing a "runner" in the sterile core to eliminate the need for flash sterilization.

Both quantitative and qualitative data showed a concern for the role of the SPD in patient safety, particularly as it concerned practices,

Table 4
When IUSS is considered

Circumstance	% SPDs reporting (categories not mutually exclusive)
Life- or limb-threatening	80
Insufficient instrumentation	75
Scheduling issues	59
Physician demands	52
Loaners	23
Other	16

NOTE. Average number of responses = 58.
IUSS, immediate-use steam sterilization; *SPDs*, sterile processing departments.

Table 5
Policies in place to reduce IUSS usage

Policy	% SPDs reporting (categories not mutually exclusive)
Monitoring and tracking use of IUSS	93
Purchasing more instruments	78
Increasing staff education on problems with IUSS	66
Establishing quality improvement initiatives	57
Other	10

NOTE. Average number of responses = 58.
IUSS, immediate-use steam sterilization; *SPDs*, sterile processing departments.

such as the use of IUSS. Existing literature on flash sterilization, or IUSS, acknowledges that IUSS has been sometimes abused (eg, flash sterilized instruments were used for later cases): "Confusion surrounding flash sterilization has led to abuses and shortcuts in some operating rooms, which could lead to improperly processed instruments being used on patients."[21]

Limitations

As with any voluntary reporting, response rates in the quantitative analysis differed per question and by time of year. Using the results-only version of the database, there was no way to tell when different facilities reported. For example, each month could have zero overlap in which facilities reported data or complete overlap—there was no way to know. This has serious implications for the results, in that they are not generalizable and may be biased, although the direction is unclear. The small sample size and deidentified nature of the transcripts analyzed here prevent us from drawing any conclusions based on hospital characteristics.

There are limited data available about SPDs. Given the tremendous importance of these departments, additional data collection would yield a much more complete picture of SPDs, their roles within health care facilities, and their effects on patient safety. The incredible amount of variation in physical location, processes, relationships with the OR, communication, responsibilities for equipment, staffing, and management highlights the need for additional work in this area to address the human factors—rather than the purely technical nature—that affect the work of the SPD. Additional research into SPDs could also help quality improvement efforts, particularly as SPDs are already accustomed to solving technical problems with feasible solutions. Although we were unable to connect the information gleaned in these interviews and metrics with standardized infection ratios, future work to collect data on SPDs that can be linked to standardized infection ratio metrics would elucidate the connection between SPDs and infections.

CONCLUSIONS

Efforts to reduce patient harm are ongoing in medicine. Much of this work is focused on technology or the processes and people involved in direct patient care. Although some work has shown the importance of processes and staff—such as cleaners—who do not provide direct patient care for the spread of health care–associated infections, there is very little research on how these nonclinical professionals try to improve safety and quality of patient care.[22] Our study highlighted some creative approaches of staff and equipment management in sterile processing of interest to infection control professionals. To more completely address adverse patient events and surgical patient safety, we must move toward examining the entire surgical process, even—and perhaps especially—the parts that occur outside the OR. Future research using statistical methods that combine institution-level outcome data on infections, process measures such as IUSS rates, and institutional metrics on staffing and number

of processed instruments will help establish areas in which causal links might exist. Qualitative studies at the same institutions will help establish mechanisms by which these correlations might be explained, informing new infection control interventions.

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