Viability of Biological Material Found in Sterilized Surgical Instrument Trays

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Abstract

Viability of microorganisms left in surgical instrument trays after use is a challenging topic to observe. The following paper outlines a study conducted that reviewed two main components of the Sterile Processing Department (SPD). Two of the main machines used through the SPD department are the washer-disinfector and steam sterilizer. The experiment conducted looked at the process breakdown or breach in protocol that can occur. Biological contaminants can be found from a previous case in the Operating Room (OR) prior to use on the subsequent case. To examine the viability of these contaminants biological material was run through the two machines outlined above (automated washer and steam sterilizer). The results showed that all samples that were run through these machines yielded no biological growth on aerobic, anaerobic, and yeast medium plates.

This demonstrates the effectiveness of the washer-disinfector and steam sterilizer. High heat in combination with physical impediment denatured the protein structure of the microorganisms rendering them unviable.

A breach in protocol can occur for a number of reasons and the reporting of these incidents play a pivotal role in developing solutions and identifying trends. A positive culture can lend itself to improved reporting, which as a result can help identify issues related to failures in procedure. The disruption these failures can have in cost and decision making can be impactful. Reducing reprocessing cost and the impact on labor cost can have future implications leading to improved practices for the sterile processing department.

Frontispiece

The life-Cycle of decontamination illustrates the relevant features of decontamination (Henry Schein Medical,2022)

Acknowledgments

I'd like to express my gratitude to everyone who has assisted me with this process and my research paper. This experiment would not have been possible without the support of the University of Colorado Hospital. The machines processing surgical instruments and equipment are challenging to use, but it was a learning experience. I am grateful to the University for providing me with access to these machines as well as time to work through test data samples for my research project.

For the experimental context, it was beneficial to simulate an operating room scenario. The ability to use these expensive resources was invaluable. I would like to further extend my gratitude to those who helped me review the work and provide feedback. There were a hand-full of nurses and healthcare professionals that provided comments and input to ensure that I expanded on topics where needed and added clarification.

Lastly, I would like to emphasize that I worked at the University of Colorado Hospital for six year in the Sterile Processing Department. I worked not only as a Manager for the department for 4 years but also as staff member. This allowed me to have specific knowledge regarding workflows and processes, as well as decision making regarding hospital policy and guidelines that were developed specific to breaches in protocols. This hands-on-knowledge created a framework for understanding the problem and the hypothesis formulated. This coupled with research available created the structure for exploration into this topic.

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Chapter I: Introduction

Background

Healthcare is a business, just like any other business based on productivity, efficiency, and throughput. Hospitals and healthcare systems are challenged in today's world with maximizing the number of patients treated on a daily basis. There are a number of elements that contribute to this, but the economics of healthcare plays a pivotal role. In the perioperative world many factors affect the process of how an operating room function. Staffing, surgical schedules, and sterile processing all play critical roles in the success or impairment of the ideal surgical strategy.

While the surgical world has switched predominantly to disposable single use items for many supplies, surgical instrumentation has remained multi-use over the years for multiple reasons. The material most instruments are made of allows them to be decontaminated, cleaned, inspected, and sterilized for safe use on another patient (Rutala & David, 2008).

If the procedures for reprocessing instrumentation are not followed completely, biological material that remains on surgical instrumentation after reprocessing could create multiple issues for the patient and those responsible for the patient's care. If found before a procedure has begun, new instrumentation would need to be obtained, which could potentially cause a delay. This delay could have a cascading effect (Rutala & David, 2008).

Surgery cases may need to be shifted or delayed, and as a result the cost in the operating room can be significant. Practices vary for each hospital organization regarding

procedure for bioburden discovered intraoperatively; however, typically it involves breakdown of all items involved in the procedure and a new setup. The organizational and logistical impact can be very substantial. Additionally, if the foreign material is not found before the surgical procedure begins, there may be risk of infection (Seavey, 2013).

The functions and workflows that exist through the sterile processing department are complex and have multiple steps and variables. There are four main components to a sterile processing department: decontamination, assembly, sterilization, and storage (ANSI/AAMI ST79, 2017) Within each of those areas there are varying subsets of processes and workflows that exist. The study focused on two machines (automated washer-disinfector and steam sterilizer), which exist in the decontamination and sterilization spaces respectively (Rutala & David, 2008).

The problem identified is the occurrence of a break in protocol resulting in biological debris being uncovered prior to use on a patient. While this occurrence is not drastically high, the impact that it can have is significant (Southworth, 2014). Surgeons and surgical staff take very specific steps to ensure sterility and clean parameters are met in the operating room. Therefore, being able to profess sterilized biological material as non-infectious would prove to be advantageous for procedural decision making in the future. This would also allow for certain factors regarding an increase in sterilization cost and labor cost for the sterile processing staff to be mitigated (Alfred et al, 2021).

Surgeons and staff are constantly making decisions throughout a procedure to establish the best possible outcome for their patient. Hospital policy dictates the decision making that goes into a contaminant discovery. Outside of decision or hospital policy that outlines protocols, the impact of foreign material on surgical delays and decreased

productivity in SPD is also significant (Baxter et al, 2006). There are quality assurance measures that help define specific protocols that are met in accordance with specific parameters or guidelines. Specific to this study there are tests that are done on the washer-disinfector to show a cleaning process has been met. There are also chemical and biological indicators that demonstrate parameters and cycle phases for machines are within appropriate parameters as well (Rutala, Gergen, Weber, 1998). These quality assurance measures are used by not only staff in SPD but also staff in the OR. Visual cues from chemical indicators can provide the staff in the room with a level of comfort that instrumentation was run through specific processes. (Rutala, Gergen, Weber, 1998)

There are complications that arise through the operating procedure, specifically with the reprocessing guidelines provided to SPD personnel (Spry, 2008). While complications are expected, it is important to understand the risk associated with these obstacles and how to overcome them. The guidelines given to the SPD department are formulated given certain criteria on the equipment. Surgical instruments are given classifications that outline the minimum required cleaning, decontamination, and sterilization. Non-critical, semi critical, and critical devices are divided by contact points with the patient and the risk of infection related to this contact (Rutala and Weber, 2016). One distinction between semi critical and critical is whether the device crosses the mucous membrane and enters the blood or breaks a tissue barrier. If the device crosses this membrane, it is designated as critical and must undergo a more rigorous cleaning and sterilization process (Rutala and Weber, 2016).

The Spaulding classification designate to an instrument creates a framework for the decontamination method required and this is coupled with FDA guidance for each

surgical instrument to formulate instructions for use (IFUs). These instructions provide the SPD personnel with the varying methods of decontamination and sterilization available. The hospital dictates which method will be followed although it is always recommended to follow the most rigorous process.

The process each surgical instrument must follow can impact the time it takes to fully reprocess an item. This variability in reprocessing methods can create misunderstanding between the OR and the SPD. This fractured trust creates a culture that is not working cohesively. This creates frustration from the OR staff resulting in underreporting of incidents related to surgical instrumentation. This can be an inaccurate number of instruments, wrong instruments, or unsterile instruments. The underreporting of these issues makes it difficult to understand a pattern but also the impact and severity of the problem. Collaboration between departments to define simpler tray construction and education into the complexities within SPD creates an open forum of mutual understanding. This would allow for collective thinking to solve problems and design new trays (Swanson, 2008).

Each department understanding the impact on the other would allow for the impact of each role to be clearer. For example, point-of-use cleaning really can reduce the backlog that can be seen in decontamination and would also mitigate the likelihood of contaminated instrumentation from being fully reprocessed (Percin et al, 2015). This all drives towards increased education at a high level for all parties involved in the process.

Increased knowledge regarding the efficacy and efficiency of equipment within SPD can also impact decision making. If manual steps fail, what is the outcome or viability of the microorganisms or bacteria remaining. There are roughly 46.5 million

surgical procedures in the United States (U.S.) each year (Rutala & David, 2008). These procedures involve contact by a medical device with a patient's tissue or mucous membrane. This action creates risk to the patient by potentially introducing pathogens which could lead to an opportunistic infection. This risk is increased exponentially if breach in protocol or a failure to properly disinfect or sterilize the instrumentation occurs (Rutala & David, 2008).

The model of this study is to focus on what is happening, specific to bacterial growth, when these breaches or failures occur. The hypothesis is that due to high-heat and pressure, the viability of any organism going through the process will be minimal. Organisms will not survive and the growth on various media plates will not occur. The remaining sections throughout the paper will review more in depth the role of SPD, the relationship between SPD and the OR, and empirical background tied to the hypothesis concluded. This will create the framework behind the resultant study conducted and the results and implications of this study will be discussed.

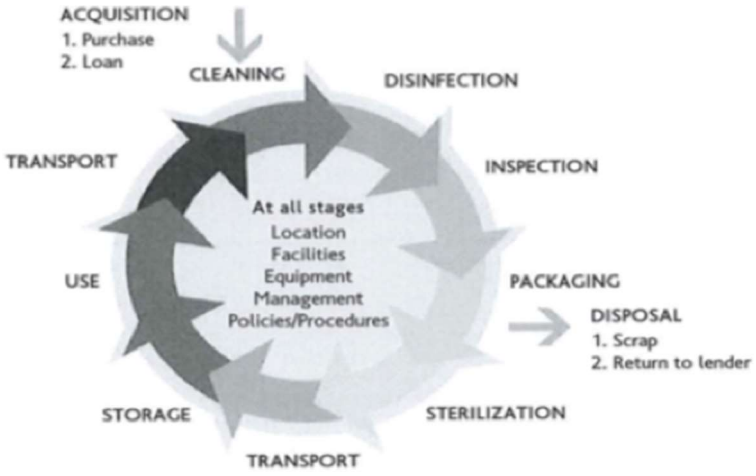
Role of Sterile Processing Department (SPD)

According to (Spear et al. 2021) staff members in the SPD department face a tough duty of processing sophisticated instruments, controlling expenses, and managing limited resources, and how they respond has a direct impact on patient safety care. The SPD is responsible for ensuring that surgical equipment is reprocessed according to the manufacturer instructions for use (IFUs), including decontamination, washing, assembly with human inspection, and sterilization of instrumentation. These are step-by-step instructions provided by the manufacturer on the cleaning and sterilization (if applicable) of the medical devices, equipment, and instrumentation.

It is important to note that each manufacturer is required to get FDA clearance regarding the reprocessing of items. Hospitals are required to follow the specific guidelines outlined, but they do have flexibility in which reprocessing method to follow if more than one is given. For example, certain items can be run through a low temp sterilizer (hydrogen peroxide) or steam sterilizer. It is best practice to choose a sterilization method that is more rigorous. Some items will have instructions for high level disinfection as well as low temp sterilization. In this instance the best practice method would be to follow the instructions for low temp sterilization (Mohapatra, 2017).

Decontamination is the process of physically removing and eliminating the gross contamination of biological material, most of the pathogenic microorganisms, aside from bacterial spores. The manual process of cleaning surgical instrumentation involves mechanical removal (i.e. scrubbing, brushing) and liquid chemicals involving enzymes and other reagents that dissolve biological debris (Rutala & David, 2008)

Figure 1. Decontamination Life Cycle



Decontamination life cycle illustrates the key elements of decontamination (WHO, 2018)

Disinfection is described as the total removal of vegetative forms of microorganisms from inanimate objects, with the exception of bacterial spores. This approach reduces the number of germs by 103 log CFU (Mohapatra, 2017).

Sterilization is a process that eliminates almost all forms of microbial life through either physical or chemical methods. An exception to this is prions. These misfolded proteins are highly structured and make them difficult to degrade (Mohapatra, 2017).

Point-of-use cleaning (cleaning performed at the time of use in the Operating Room), removes organic and inorganic load present (quantity of foreign material). This helps prevent cross contamination, protect sterile processing technicians, prevents pitting, and wear-and-tear on surgical instrumentation (Percin et al, 2015). Exposure time, the physical design of the medical device, temperature and pH conditions are all directly capable of impacting the efficacy of the decontamination/disinfection and sterilization phases. (Mohapatra, 2017). The cleaning process is not replaced by point-of-use cleaning. This is the first step in the cleaning procedure (WHO, 2016).

SPD Function

Organizations typically have sterile processing departments divided into four major areas: decontamination, assembly and sterile processing, sterile storage, and distribution (WHO,2016). The following section aims to outline the functions and flow of surgical instrumentation through sterile processing.

Once the instruments leave possession of the OR team, the first stop is in the decontamination area of SPD. The instruments, equipment and reusable supplies are cleaned with manual (hand washed) and mechanical (automated) methods depending on the Instruction for Use (IFUs). This is most often followed by a chemical disinfection

product which is capable of removing most biological residue and debris that might have been missed in the previous actions performed on the instrument. Instruments are now considered clean and should contain no bioburden (Rutala, Maria, and David, 2014)

Clean items are then received to an assembly area where trained staff will inspect, organize, and assemble the instruments into sets, trays or single packages. Instruments are not only inspected for bioburden, but also for function, repair needs, and preventative maintenance.

Next the instruments will go through an appropriate sterilization process, again referring to their IFU. The two most standard techniques in today's world are steam and chemical sterilization. There are high functioning machines that perform sterilization; they monitor conditions and parameters known to ensure efficacy of each technique. The instruments will next find themselves moved to an organized storage area until they are needed for a procedure (Rutala & David, 2008).

Decontamination Specifics

Used supplies and instrumentation should be collected and taken to the decontamination area in the SPD in a manner that prevents biological material being contaminated on personnel or throughout the hospital. This involves covering equipment in a closed system, either a bin with a locking lid or a case cart with closed doors or a cover (Rutala & David, 2008).

The individuals working in the decontamination area should be wearing Personal Protective Equipment (PPE). This includes a scrub uniform covered by a gown that is moisture-resistant, shoe covers, gloves, hair covering, safety goggles, and mask. Items will then be sorted so that they are ready for cleaning. This includes organization of the

items and minimal handling that may include removal of single-use or other disposables. Depending on the IFU from the manufacturer the items will be soaked and manually scrubbed in an enzymatic solution (Rutala, Maria, and David, 2014). The study conducted in this paper focused on stainless steel instruments which follow a more common practice of manual cleaning while in an enzymatic sink and then run through an automated washer (Rutala et al, 2014). A washer is used to clean heat-tolerant items. The cycle involves a series of washes and rinses followed by high heat. These cycles also involve a detergent solution that aids in the breakdown of biological materials. An ultrasonic may also be used which functions by converting high-frequency sound waves into vibrations that free debris from the surface of instruments or lumened items. The high frequency creates bubbles on the surfaces that implode and create small vacuums that draw out further debris. This process is known as cavitation.

Sterilization Specifics

Bacterial spores are some of the most resilient living organisms because of their ability to withstand external destructive agents. The chemical and physical processes that pathogenic microorganisms go through in sterilization allow them to be considered sterile when necessary, conditions have been met during the sterilization process (Rutala & David, 2008). Specifically, for many common surgical stainless-steel instruments this involves exposure of 4 minutes to 270 degrees at a pressure of 30psi. There are printed receipts that are reviewed to confirm these parameters were met as well as internal failsafe from the sterilization machines. For example, a chamber leak will cause the cycle to abort.

Steam sterilization involves using heat and pressure (Rutala & David, 2008). Moist heat in the form of steam under pressure causes denaturation and coagulation of protein or the enzyme-protein system within a cell. This is catalyzed by the presence of moisture, and steam sterilization focuses on the direct contact of this saturated steam. When steam enters the chamber under enough pressure it condenses with cold items once it makes contact, and wets all of the items. This provides the requisite of moisture and heat. No living item can survive saturated steam at 250 F longer than 15 minutes (Resendiz, Horseman, Hover, et al, 2020). As temperature increases, time can decrease. This creates a basis for parameters and a guidance determined by IFUs regarding cycle lengths and times. There is a dry time that is required as re-evaporation of water condensate must be removed (Resendiz, et al, 2020).

Quality Assurance

There are a variety of indicators that are used to determine whether parameters ensuring sterilization have been met during the process. The equipment used in this study had automatic controls monitoring the parameters of the automatic mechanical washer and the sterilizer. There are specific protocols and procedures that must be followed in order to maintain consistency in the sterile processing department (Blackmore, Bishop et al, 2013). Chemical indicators are another tool used to verify exposure to sterilization and provide a visual aid for the sterile processing staff as well as the staff in the operating room. This helps differentiate between sterilized and unsterilized items. The placement of these chemical indicators provides a visual cue for the OR staff to see if the instrument or tray has been run through the sterilizer. The chemical indicator will turn color, which denotes the exposure to high heat and pressure.

There are DART or challenge packs that are used for daily testing and monitoring as well. These packs will test to see if the parameters for the sterilizer have been met. It specifically is testing the air removal and steam penetration in pre-vacuum steam sterilizer at 270-273 F (ANSI/AAMI ST79, 2017).

A biological indicator consists of living spores resistant to the sterilizing agent (Rutala, Gergen, Weber, 1998). Sealed vials or ampoules of spores are most common, and a control is used that is not sterilized. Biological testing must be done at least once a week and with every load containing an implantable device such as screws or plates (ANSI/AAMI ST79, 2017).

Another quality measure implemented is testing materials for the automated washer. AAMI ST79 recommends that monitoring of the efficacy of the automated washer should be done weekly at minimum, but daily is preferred. There is a range in variability of rapid cleaning monitors available and some of them are outlined in the table below. There have been no specific benchmarks set to determine the efficacy of the washer but rather to test and document that the cleaning is being done in a manner that complies with the device manufacturers IFUs. For example, some of the tests have a small amount of liquid that mimics blood in a location that is hard to reach and clean. The test is considered passed if the testing material is visibly clean. The goal of these tests is to ensure that the automated washer is functioning appropriately and running on the correct cycles. As noted above, there is no documentation that supports this, however; it functions at the very least to denote that the cleaning was done.

Table 1. Cleaning Monitors for automated Washers

Application	Name of cleaning monitor	Manufacturer	Parameter monitored	Parameter
Automated washers with connectors for lumen instruments	Flexi check	Medisafe, UK	Fluid flow through lumen connectors	Color change of indicator strip positioned within lumen
Automated washers with connectors for lumen instruments	TOSI Lumchek	Perag, Germany	Fluid flow through lumen connectors	Removal of blood soil
Automated washers with connectors for lumen instruments	Lumen check	Medisafe, UK	Fluid flow through lumen connectors	Removal of blood soil
Automated washers used for Surgical instruments	Enzymatic Detergent Test	Serim Research Laboratories, Elkhart, IN	Presence of enzymatic detergent	Color change of indicator pad
Sonicator washers	Sono Check	Healthmark Industries, Fraser, MI	Functionality of ultrasonic transducers	Color change of liquid occurs when sonication breaks beads containing dye
Automated washers used for surgical instruments	STF Load Check	Steris, Mentor, OH	General fluid kinetics with detergent	Removal of red dye
Automated washers used for surgical instruments	Wash Check	SteriTec, Englewood, CO	General fluid kinetics with detergent	Removal of red dye
Automated washers used for surgical instruments	TOSI	Perag, Germany	General fluid kinetics with detergent	Removal of blood soil
Manual cleaning of flexible endoscope channels	Channel Chek	Healthmark Industries, Fraser, MI	Organic residuals in flexible endoscope channels	Color change of test pads detects protein, carbohydrate, and hemoglobin residuals
Manual cleaning of flexible endoscope channels and surfaces	3M Clean-Trace ATP Water Test for channel samples and 3M Clean-Trace ATP Surface Test for flexible endoscope surface samples	3M, Minneapolis, MN	ATP residuals in flexible endoscope channels or on the external surface of the endoscope	Level of ATP measured by relative light units
Manual cleaning of flexible endoscope channels and surfaces	Ruhof ATP test; uses a instrusponge to collect surface or lumen samples from flexible endoscopes	Ruhof Industries, Mineola, NY	ATP residuals in flexible endoscope channels or on the external surface of the endoscope	Level of ATP measured by relative light units

This table represents some examples and listing of cleaning monitors (Alfa, 2019)

Classification of Surgical Instrumentation

Roughly 60 years ago, Earle H. Spaulding came up with a rational method for classification of surgical instrumentation. This method has been refined and is still used by infection control professionals to this day. The main premise is to divide items into 3 categories based on the degree of risk of infection. The three categories were: critical, semi critical, and noncritical.

Table 2. Spaulding's Classification of Devices

Device/Item	Definition	Risk of Infection	Example	Reprocessing Procedure
Critical	Medical device that is intended to enter a normally sterile environment, sterile tissue, or the vasculature	High	Surgical instrument, cardiac catheter, implants, needle, ultrasound probes used in sterile body cavity	Sterilization by steam, plasma, or ethylene oxide
Semicritical	Devices that are intended to come in contact with the mucous membrane or nonintact skin	High/intermediate	Flexible endoscope, respiratory therapy equipment, manometry probes, diaphragm-fitting rings, laryngoscope blades	Sterilization desirable, high-level disinfectants
Noncritical	Devices come in contact with intact skin	Low	Blood pressure cuff, stethoscope	Intermediate or low-level disinfectant

Spaulding Classification which is the Instrument classification system used for reprocessing decisions (McDonnell and Burke, 2011).

Non-Critical items are those that contact skin but no mucous membrane. Intact skin functions as a sufficient barrier to many microorganisms, the sterility of items is non-critical. Examples of such items are as follows: blood pressure cuffs, crutches, bed rails, bedpans, etc. Many items in this category do not need to be moved or transported for cleaning or disinfection. These items are low-level disinfected and typically have an exposure time of one minute. The exposure time is the determined allotted contact length needed to ensure that the item being disinfected is rendered disinfected or sterile.

Critical items are labeled as such because of the high risk of infection if this item is contaminated with bioburden or microorganisms. If the item is contaminated there is a higher likelihood of disease transmission because the object is entering sterile tissue or the vascular system (McDonnell and Burke, 2011). Items in this category should be steam sterilized if possible or purchased sterile. If there is a heat sensitivity issue the items may be treated with ethylene oxide (ETO, hydrogen peroxide (HP) gas Plasa, or liquid chemical sterilant. Liquid chemical sterilant such as peracetic acid can only be relied on if the proper cleaning and process has been met (Rutala, Gergen, Weber, 1998). All of the visibly gross material and bioburden needs to be removed prior to liquid treatment. This ensures that all surfaces of the item contact the liquid sterilant. Another concern when using liquid sterilant is whether there is a required rinse time that renders the item near impossible to keep sterile. In addition, the item can't be wrapped (Halyard Sterilization Wrap) or placed in a container (Aesculap Sterilization Container) making it also challenging to maintain sterility.

Semi critical items are those instruments that come in contact with mucous membranes or non-intact skin. Some items that are included in this category are:

bronchoscopes, laryngoscopes, Endo cavity probes, cystoscopes, hysteroscopes, etc. These types of mucous membranes are generally resistant to infection by common bacterial spores but susceptible to other organisms such as viruses and alien bacteria (Ubhayawardana, et al, 2013). This classification of items has been noted to have a high reprocessing error, resulting in patient notification and further patient follow up. As a result, these items should have further education and guidelines behind the step-by-step process for reprocessing (Rutala and Weber, 2016).

The University of North Carolina ensured that this education was met by requiring all staff who handle and reprocess semi critical devices to attend a three-hour class on high level disinfection. This course includes the rationale behind why the reprocessing steps are imperative as well as a discussion around high level disinfectants and exposure times. Infection control and prevention teams should also make regular rounds on these areas as they are an area of higher risk (Rutala and Weber, 2016). The results from these rounds should be discussed and reported to unit managers. The University of Colorado would regularly use Joint Commission Tracers to round through a multitude of units throughout the organization. They had specific tracers for HLD and the rounding was done regularly. These reports were given to the unit manager to identify trends or educational gaps as needed. It is important to note that feedback is crucial because identifying pain points is what allows managers to not only identify trends and education gaps but also develop process changes or recommendations on equipment as needed. When discoveries are made that require follow up it is important to do so in a time efficient manner, meaning checking on the concern within two weeks of discovery.

These classifications have acted as guiding principles for best practice sterilization methods for medical equipment. It is important to note that there are minimum recommendations provided from the manufacturers regarding acceptable methods of sterilization, however; it is always best practice to use the highest degree of sterilization when possible. Providing the highest possible quality patient care should be at the forefront of every healthcare organization.

Relationship between OR and SPD

One of the objectives of any healthcare organization is the safety of the patient and of their staff. The perioperative team shares this ideology and understands that everyone plays a role. There have been several articles written in AORN (Association of perioperative Room Nurses) that discuss the need for improved relationships between departments (Swanson, 2008).

SPD is typically a department that works behind the scenes. The staff don't provide direct patient care, however; they handle the instrumentation used directly and, in many instances, intraoperatively on a patient. A component that one article emphasizes is an establishment of trust between the OR and SPD (Seavey, 2010).

One way this is accomplished is by mitigating instrument set errors. Groups of instruments that are used in a surgical procedure are organized according to a pre-fixed recipe sheet to be completed and followed by the sterile processing staff. This recipe will contain the type of instruments as well as the quantity. This is meant to act as an order form for the following instrument tray (Stewart, 2004). Instrument trays can be organized by surgical specialty and surgical function.

The number of instruments is important as well as the contents itself. Deviation from this can result in unwanted stress during the procedure. This includes making these recipes simple to follow when possible so that it can be completed efficiently and accurately. Many of these mistakes will lead to a level of mistrust between departments. This leads to an inability to cultivate positive relationships and can ultimately have significant harm to a patient (Stewart, 2004). The delay in the surgical case that may result from these errors may result in the need for an alternative surgical plan or simply just unnecessary time under anesthesia.

It is important to note that communication is key in fostering this relationship (Seavey, 2010). This includes explanations when it comes to policy or process changes. Sterile processing is expected to be agile in relation to regulation changes and adjustments (Swanson, 2008). This can have an impact in processing capabilities as well as instrument usage. All parties need to have an open mind to process change. Maintaining a discussion forum where both departments can express their concerns, be educated about changes and have opportunity to ask questions, will lead to a positive culture. Southworth denotes that a push in creating a more comfortable environment for reporting is necessary. Operating room personnel should feel empowered to report incidents so that processes can be evaluated effectively.

There are certain regulations and protocols that can't be altered, but everyone needs to be on the same page regarding the understanding of these rules. The two departments would benefit from understanding each other and being able to work cohesively. Honest and clear dialogue can allow this to be accomplished (Seavey, 2010).

Swanson (2008) used the expression of "tearing down the wall". This image provides a great example of an obvious barrier between two departments that work hand in hand but are disconnected (Swanson, 2008). Miscommunication often creates stress for both departments. SPD staff find themselves working on instrumentation blindly, unsure of the priority or needs for the next shift, day or even week. The expectation from the surgical department is that everything is reprocessed at the exact moment possession changes to SPD. When in real life, most SPD departments do not have the resources to complete such ambitions. A complete reset after every surgical day is ideal, however, other challenges arise that make this reality impossible. Aside from staffing shortages, often departments are outdated and do not have the physical space or equipment available to process items in a timely manner. Some instrumentation requires tending to from a medical company representative in order to make the set complete for the next patient. During the inspection stage of reprocessing, damage and repairs to instruments could delay the turnaround time. Shear volume of instrumentation flow can disable a department until a slower time, often the weekend, arrives and allows the SPD to "catch up."

This metaphorical wall should be nonexistent, and all teams should work in unison. This ideal state may seem challenging but if the above culture is created steps can be made in the right direction. It is also crucial that the education provided and resources for the SPD staff is improved. The role of a sterile processing technician or central service technician historically has only required a high school diploma or GED along with a certification that can be acquired on the job. Much of the training for SPD staff is achieved hands-on, and as a result, much of the education is done hands-on. The

orientation program for SPD staff would benefit from being more rigorous so that they can feel empowered to ask the right questions and have a strong foundation (Stewart, 2004). This ties directly in with the resources provided to the team and the continual training that is needed. The complexity of instrumentation varying across a multitude of specialties requires not only vast resources, but also subject matter experts (Seavey, 2010).

Being able to think critically is not only imperative in the OR but also SPD. There is a vast collection of knowledge required to transpire into a contributing and beneficial SPD employee. Learning the names of thousands of instruments in conjunction to the cleaning practices for each of them is no small feat. Additionally, there are various roles within the department, which have specific hospital defined protocols under the guidance or recommendation of various accrediting bodies.

Education and communication could go a long way in improving the relationship between the OR and the SPD department. One article noted that oftentimes staff are trying to work through knowledge or communication gaps to solve problems (Swanson, 2008). This is to say that in order to cultivate an appropriate relationship the foundations for staff need to be bolstered and the dialogue improved.

Chapter II: Methods

Empirical Background and Data

Southworth compiled articles and incidents relating to a break in protocol specific to decontamination by searching Medline and Embase databases for specific parameters listed below (Southworth, 2014). A number of relevant studies involved disinfection of surgical instruments rather than sterilization which is the recommended method outlined by the WHO (Southworth, 2014). There are instrument decontamination failures that involve cleaning, disinfection and rinsing; however, no particular trend is identified.

Southworth was able to review the reported incidents in these two databases and noted a discrepancy in event reporting (Southworth, 2014). The reluctance to report failures or breaches may allow them to go unnoticed. Surgical volume and the number of errors restrict the realistic time available to report and catch some of these breaches in decontamination protocols. This level of underreporting is what the author noted to be most striking. There is a certain level of stress associated with owning a mistake or a failure, specifically in the operating room. This is a result of the complexity involved but also the lack of open dialogue regarding concerns and issues (Seavey, 2013). The variability in reporting of a breach creates inconsistency when looking through data sets as well. Examples of this are as follows: dirty tray in a sterile storage area, or standard cycle used for sterilization rather than enhanced cycle (Southworth, 2014). Both scenarios outline a failure in process and both trays are classified as unsterile, but the point at which they are reported may vary.

An interesting takeaway is that there was no distinct trend identified in a specific instrument type, we can assume that all surgical instruments are susceptible to a breach.

With this discovery, we can assume the data set for this paper is representative of all instruments despite focusing on a few specific instrument types. This article was reviewed because it looked at a comprehensive number of articles looking for identifiable trends or patterns (Southworth, 2014). It also establishes a baseline for the hypothesis that the risk of cross-transmission due to unsuccessful decontamination would be low. Even though the incidents seem to be underreported the proportion is still extremely low.

Another study was looking at evaluating the efficacy of a washer (Rutala et al, 2014). A washer-disinfector acts like a dishwasher and uses a combination of water spray, heat, cavitation, detergents, and a drying process to eliminate bioburden and microorganisms. This study examined the efficacy of washers in the process outlined above. This evaluation was achieved by looking at surgical instruments exposed and non-exposed surfaces after they went through the automated process. The researchers disabled the detergent phases of the cycle to look at the effectiveness of the washer in the absence of enzymes and detergents (Rutala et al, 2014). There are five main phases that are relatively standard for an automated washer: pre-wash involving enzymatic for 1 minute, wash involving detergent solution for 4 minutes, ultrasonic or cavitation for 4 minutes, thermal rinse with lubrication (varying time length), drying for 4 minutes at a high temperature (250 F). Quantitative assays have shown that the range of CFUs after clinical use in the operating room is 4415 CFUs. These instruments after going through the washer-disinfector had bioburden levels lower than 1000 CFUs in 88% of the assays (Rutala et al, 2014). This denotes the effectiveness of the washer process regarding the removal of specific colony forming units.

The results from this study noted that the washer-disinfector was effective in significantly reducing the bacterial load and spores even in the absence of enzymatic cleaner, except in the hinges or parts of the instruments that were harder to see or reach (Rutala et al, 2014). The study had also noted that there was no notable difference in the bacterial load removal or efficacy with or without the use of detergents and enzymes. The conclusion drawn was that high heat water and mechanical automated cleaning was an effective measure at removing microorganisms, but not in crevices or less exposed areas of the surgical instruments (Rutala et al, 2014).

Another study reviewed bioburden left in cannulated orthopedic instrumentation (Smith et al, 2018). The study looked at bone cores removed using cannulated instruments. The objective was to use these drill bits with bone and have them run through the autoclave. They were mixed with specific strains of bacteria to be able to track accurate growth (Smith et al, 2018). The results showed that there was some growth on the agar plates that could be tied back to the initial strains. An important note from this study is that the sample size was small, leading to a poor statistical significance. The bioburden was from the cannulated drill bit, which is going to have very limited exposure or ability to have contact with steam in the chamber (Smith et al, 2018). There were only fifteen samples collected and plated. Smith et al was able to denote that the instrument complexity can play a role in the ability of steam to penetrate throughout the instrument if biological debris is present.

Southworth looked at biofilm specifically. The experiment inoculated instruments with bacteria, and they were left to dry over a specified amount of time. The study looked at wrapped versus unwrapped instrumentation, and inoculation that occurred prior to

sterilization. It was noted that wrapped instrumentation still yielded CFUs. The limitation of this study was the sample size of only 60. The inoculation and timing for these bacteria created a level of biofilm that became difficult to remove from the process of sterilization. This inoculation was left to sit on the instrumentation for over 24hrs to dry before being placed into the sterilizer. This helps to establish the need for immediate removal of gross bio debris from surgical instrumentation. In the experiment designed for this paper we did not allow biofilm to build as the surgical instruments were immediately sent to decontamination for processing.

The bacterial load also dictates the time required for a cleaning agent or disinfectant to eliminate biological material. This can partly be a result of the heterogeneous bacterial populations. There is limited data on the types of contamination on used surgical instruments. The following study looked at the relationship between bacterial load on stainless steel instruments and the amount of time before decontamination commenced (Percin et al, 2015).

The results concluded that within the first six hours there was no significant change in bacterial load, however; after the six hours the bacterial count increased logarithmically (Percin et al, 2015). The study noted the lag phase to be the first six hours. This means that bacteria are adjusting to the new environment and no real growth occurred. After this time the increase in bacterial load can have an impact on the cleaning practices of surgical instruments (Percin et al, 2015).

This is relevant to surgical procedures because cases can last longer than six hours but also the time from when an item is used and cleaned can be variable. Many organizations have been practicing instrument point-of-use cleaning throughout the

surgical case to help mitigate the start of the lag phase. The time from when instrumentation is finished being used and it begins to enter the manual cleaning process can also have a wide range. Instrument pre-cleaning helps to begin breaking down the contaminants left of surgical instrumentation. This is useful for the SPD as bottlenecks can occur in the decontamination space. This can occur as cases begin to finish in a hospital setting and the timing creates multiple instrument sets needing to be processed through decontamination at the same time or within a small window of time. This backlog of instrument sets needing to be cleaned is a result in part due to staffing but is also a limitation of the machine throughput. This creates a bottleneck in reprocessing as the instrument sets will sit for large periods of time before they are processed.

Similarly, remote departments that use surgical instruments that are also cleaned by the SPD require a transport time or even pickup which can contribute to this lag phase.

The summary of these studies created a framework for the study conducted in this paper. Biofilm builds up over time when a surgical instrument is used and then left uncleaned for a long period of time. This biofilm is not only hard to clean but also as an indirect result lead to a backlog in the decontamination space. It has also been established that the washer-disinfector is a good tool to remove microorganisms and bacteria due to the fact that it is a consistent mechanical clean at high heat. In addition, this research outlined a framework for the disconnect that exists with reporting of incidents and the need for improved relationships (Southworth, 2014).

Discussion of Methods of Collection and Results

The following section outlines the collection methods for the results obtained. In reducing the variability of the results collected all samples were obtained through the same collection method.

Figure 2. Reducing the Variability: Collection Methods

Example of sterile equipment used for collection

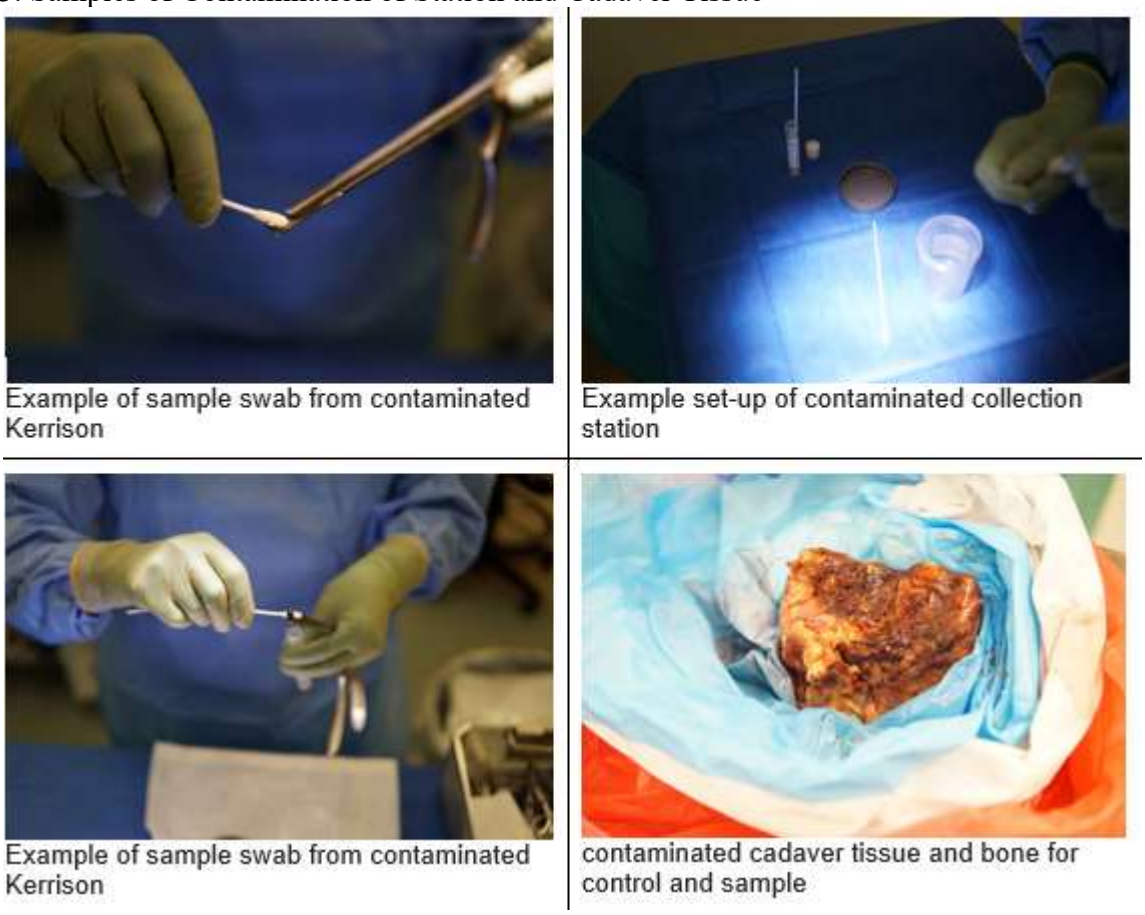
Positive samples collected

Contaminated instrument set loaded into washer-disinfector

Contaminated instrument set loaded into steam sterilizer

Different stages of Collection Methods

Figure 3. Samples of Contamination of Station and Cadaver Tissue



Samples of contaminated Swab, Station, and Cadaver Tissue and bone.

Positive controls were taken from the orthopedic surgery cadaver lab. Cadaver tissue was left out for a minimum of 48 hours. Pieces of this tissue were placed in the sterile set and pieces of bone were bitten with surgical instrumentation such as rongeurs, Kerrison and other surgical instruments, and placed in another sterile set. Cultures were taken and sent to the lab. The tissue was plated onto different types of media plates to look for growth. The types of plates used were aerobic, anaerobic, and yeast. The biologically infected tissue used was placed into a broth containing a multitude of bacterial and other infectious proteins. Biological material was harvested from the

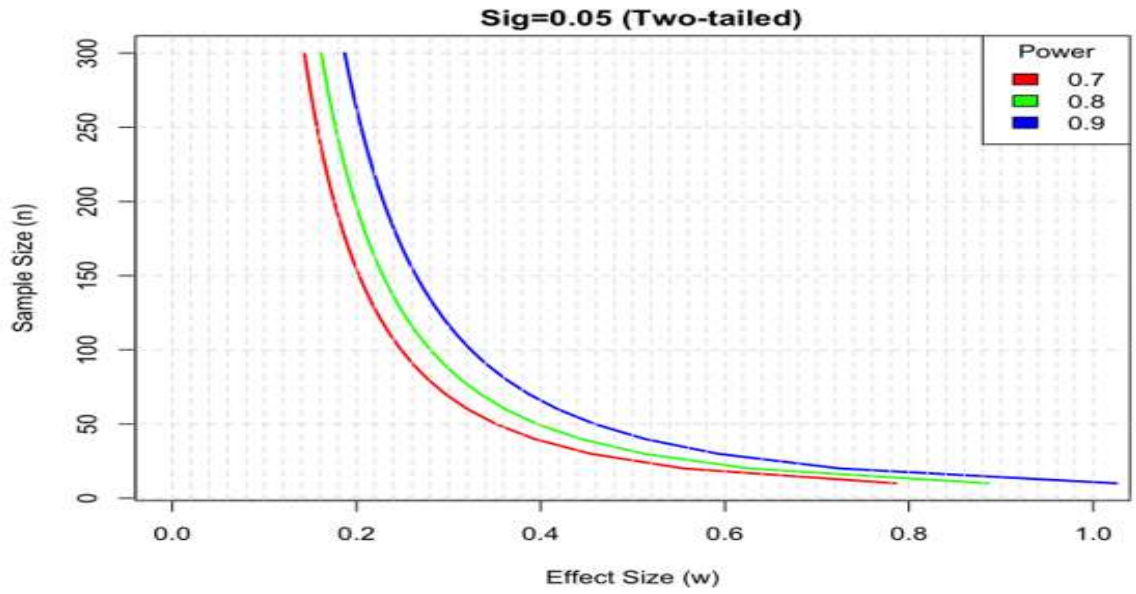
cadaver specimen and separated into two categories. The categories were bone and soft tissue for placement within clean surgical sets. These items were placed in a way that is typically seen when they are received in the operating room. The instruments were either clamped or had a cover to ensure the biological material was not lost from its original location. The surgical instrument tray was removed from the sterile environment and brought to the sterile processing department. The surgical instrument tray followed a typical sterile processing workflow involving a decontamination process and then a sterilization process.

The steps that followed are mimicking a breach in standard protocol for instrument reprocessing. The objective for this is to truly test the worst possible conditions. Two critical steps were taken regarding the processing. The surgical instrumentation was placed through an automated washer as well as an autoclave steam sterilization machine. The machines reach a specific temperature range and use a specific chemical enzymatic makeup as well (Chu, 1999). After this sterilization process the tray was brought back to the operating room. The set up in the operating room was a mock surgical procedure where it was handled in a sterile manner. The tissue or bone was found and sent for culture as described. There was a total of three samples for all the sets including the swab of the surrounding surface area.

The variable power graph below demonstrates the sample size estimate needed to achieve 70%, 80%, and 90% power. If the study were to achieve 90% power this would mean that 90% of the time, we would get a statistically significant difference between our two sample groups. In this case, the groups would be either sample sent through the protocol and samples that were not. The assumptions made for the study are that the

effect size would be drastically different. The analysis below assumes that we are rejecting the null hypothesis, which would be that there would be no difference between samples run through the protocol and samples that were not run through the protocol. As a result, the difference between the means between the two groups would be large resulting in a large effect size. A larger effect size would result in a smaller sample size being needed. In order to run this experiment to determine if these assumptions would hold true another experiment would need to be run. This would look at sending more samples out for controls to see if the results from plated growth remained consistent along with a larger sample size that is run through the protocol. The measurement of growth can be calculated through CFUs and the resulting variance in means would help dictate the next appropriate statistical tests.

Figure 4. Sample Size Estimation for Chi Square



Experiment Results Showing in Figure 4.

Chapter III: Results

The results from the experiment showed no growth on any of the samples that were run through the protocol and the instrumentation used to demonstrate this test is outlined in the table below.

Table 3. Bone and Soft Tissue Sample Summary

Soft Tissue		**Bone**	
Section	**Tissue**	**Section**	**Tissue**
1	Fibrous tissue-pickups	1	Rongeur
2	Fibrous tissue-pickups	2	Rongeur
3	Fibrous tissue-pickups	3	Rongeur
4	Fibrous tissue- pickups	4	Rongeur
5	Fibrous tissue- pickups	5	Rongeur
6	Fibrous tissue-tonsil jaws	6	Kerrison 4mm
7	Fibrous tissue-tonsil jaws	7	Kerrison 4mm
8	Fibrous tissue-tonsil jaws	8	Kerrison 4mm
9	Fibrous tissue-tonsil jaws	9	Kerrison 4mm
10	Fibrous tissue-tonsil jaws	10	Kerrison 4mm
11	Mushroom Punch	11	Kerrison 5mm
12	Mushroom Punch	12	Kerrison 5mm
13	Mushroom Punch	13	Kerrison 5mm
14	Mushroom Punch	14	Kerrison 5mm
15	Mushroom Punch	15	Kerrison 5mm

Bone and Soft Tissue sample summary

Table 4. Plate Results after 7 Days of Observations

Sample Anaerobic Testing	**Biological Sample**	**Underneath Biological Sample**	**Close to Biological Sample**
Soft Tissue 6	*NO*	*NO*	*NO*
Soft Tissue 7	*NO*	*NO*	*NO*
Soft Tissue 8	*NO*	*NO*	*NO*
Soft Tissue 9	*NO*	*NO*	*NO*
Soft Tissue 10	*NO*	*NO*	*NO*
Sample Anaerobic Testing	**Biological Sample**	**Underneath Biological Sample**	**Close to Biological Sample**
Bone 6	*NO*	*NO*	*NO*
Bone 7	*NO*	*NO*	*NO*
Bone 8	*NO*	*NO*	*NO*
Bone 9	*NO*	*NO*	*NO*
Bone 10	*NO*	*NO*	*NO*
Sample Yeast Testing	**Biological Sample**	**Underneath Biological Sample**	**Close to Biological Sample**
Soft Tissue 11	*NO*	*NO*	*NO*
Soft Tissue 12	*NO*	*NO*	*NO*
Soft Tissue 13	*NO*	*NO*	*NO*
Soft Tissue 14	*NO*	*NO*	*NO*
Soft Tissue 15	*NO*	*NO*	*NO*
Sample Yeast Testing	**Biological Sample**	**Underneath Biological Sample**	**Close to Biological Sample**
Bone 11	*NO*	*NO*	*NO*
Bone 12	*NO*	*NO*	*NO*

Bone 13	*NO*	*NO*	*NO*
Bone 14	*NO*	*NO*	*NO*
Bone 15	*NO*	*NO*	*NO*
Control Data	**Aerobic**	**Anaerobic**	**Yeast**
Bone Positive	*Yes*	*No*	*Yes*
Soft Tissue Positive	*Yes*	*No*	*Yes*

Detail of Data Collection results

The above table outlines the data collected regarding the positive controls. This means that these cultures were not run through the washer-disinfector or the sterilizer. Each swab was plated onto plates to identify growth of anaerobes, aerobic, and yeast. There was growth on all plates except there was no positive growth in any anaerobic plates. In addition, each sample set was swabbed directly where the biological material was located, underneath the biological material, and in a separate area of the tray not touching biological material. The goal was to see if there was an impact on the other areas of the tray if biological material was left on an instrument.

There were 30 instrument sets used that were run through the protocol. This resulted in 5 tests for each location type with 3 types of test completed. The cadaver tissue and bone from all instrument sets yielded no results. This means that there was no growth on any of the media plates. The fact that there was no growth among any of the samples demonstrates the effectiveness of the sterilizer and washer-disinfector.

Chapter IV: Discussion

Conclusion

The study was focused on looking at the potential growth of aerobic, anaerobic, and yeast if there was a mimicked breach in protocol. The break in protocol was the point of use cleaning that should occur in the operating room, and the manual cleaning that would have occurred on the assembly side. Seemingly the heat and automated washer made all of the microbes non-viable. As a result, the media plates showed no growth outside of the positive control. The data showed that the high heat and automated process killed or denatured the bacteria and microorganisms to the point where there was no observable growth.

This demonstrates that the instrumentation itself had no viable bacteria or microorganisms. This is not to say that there is no risk to a patient given that any bioburden would be a foreign body to the individual. It supports the notion that the risk of infection or the risk of contaminated instruments impacting the surrounding instrumentation is low. This information can be used by surgeons to effectively make decisions using more qualitative data. An example for how this can be interpreted can be as follows. A contaminated instrument is found in a set and there is no immediate available backup set and the case is already underway. Rather than holding the patient under anesthesia for a longer period of time the surgeon can decide to continue with the procedure while removing the contaminated instrument. The surgeon can do this knowing that while perhaps not an ideal situation, the risk of the contaminated instrument causing an infection is low, given the results of the study. I would like to be clear that the recommendation is not to use the results from this study to change any practice or

protocol already outlined at healthcare organizations, but rather provide qualitative metrics that can perhaps lead a discussion for adjusting emergent or urgent needs that occur at every healthcare organization.

The variability in the size of the bioburden was not able to be evaluated. The thought is that the larger the bioburden the higher likelihood of there being growth on the media plates. The steam won't be able to penetrate or kill the proteins in the center of the mass. As noted before, in order for the steam sterilization process to be effective all surfaces need to have contact with the vapor (Resendiz, Horseman, Hover, et al, 2020).

Rapid cleaning monitors have been developed to be used as a check and also teaching tool. These are devices such as ATP testing that can be done easily and quickly to determine if the manual cleaning process is being met appropriately. This type of testing uses specific thresholds to determine that a surgical instrument has been cleaned appropriately. These are currently being used in a variety of other methods throughout healthcare organizations such as environmental services. ATP testing has been used to determine if a room has been cleaned appropriately. It allows staff to randomly select challenging locations and test the cleaning process by the EVS Department. Similarly, this approach can be used on surgical instrumentation. After passing through the washer-disinfector the surgical sets can be randomly selected and the most challenging or hard to clean instruments can be spot checked. If the items pass the check, this demonstrates the proper steps have been met regarding the manual and automated clean. In the event that the items do not pass then the tray can immediately go back to decontamination to be cleaned again and education can be provided to the staff real time.

There are items such as suctions, lumened instruments, and complex instruments that require specific attention to detail and more scrutiny through manual cleaning. This tool can allow staff to be educated real time. The number of instruments and pieces of equipment that a sterile processing can see at a large healthcare facility in the course of a single day is tremendous. This real-time feedback for the staff would truly promote knowledge retention.

The incidents that can occur as a result of a breach in process can have significant costs impacts. Looking at labor impact to SPD and re-sterilization cost alone, we can see the exponential impact that these incidents have on cost. OR time is valuable, and delays or cancellations cannot only have downstream effects to scheduling, but also direct cost implications. The impact on workflow through the SPD department can not only impact productivity labor costs but also workload priorities and flow. Any errors that result in rework needing to be done only adds to the bottleneck effect in decontamination, but also pulls predictive hours away from a steady workflow.

Limitations

There has been much uncertainty post-COVID 2020 year. Science took a lot of scrutiny as healthcare organizations struggled to outline clear directives and provide informed guidance. The project in this study faced its set of challenges as labs were full of COVID testing and just when it seemed to get better variants became uncovered and labs retained focus on COVID testing. This proved to be specifically challenging for my project as it relied heavily on lab testing for the samples. Fortunately, there was a small window where data was collected, however; the number of samples and variability is not what I would have hoped for.

The study would have liked to look further into increasing sample size. This study retained value in that none of the samples had any growth. Increasing the number of samples would only help strengthen this argument perhaps. It was also limiting to conduct this study with resources that require a lot of technical skill. In trying to create mock OR settings the following steps were mimicked. The swabs themselves were collected in a sterile operating room to mimic the environment. The bioburden was then taken immediately to sterile processing and run through the washer and sterilizer following the protocol outlined. To further ensure that the biological contaminant remained on the instrument, tip protectors were used to prevent the material from falling off or being washed away. These methods really do mimic the setting in the operating room and another study could take this further and actually collect bioburden uncovered in the OR to be sent out to the lab for culture swabs and testing. The challenge with this is the availability of the lab on site.

We encountered this problem as outlined above and fortunately data collection had already begun despite needing to be halted. Further instrumentation with more lumens and cannulas would prove to be the next logical step as well. As noted from a previous study, the drill bits that were run through only the washer did have some growth occur. It would prove interesting to look at cannulated items such as suction or laparoscopic instruments to see if the harder crevices create complications for the high heat and pressure to denature all viability from the bioburden. Suctions tend to retain a large portion of debris from the nature of the design of the instrument. There are a couple different ways to test them and collect cultures but looking at instrumentation that is perhaps harder to clean or guarantee gross debris has been removed should be explored.

Despite the limitations outlined above the study was successful in lending some insight into the effectiveness of the combined processes of the automated washer and sterilizer. These two pieces of equipment when used in conjunction denatured the proteins of an microorganisms, and as a result there was no growth on any of the media plates (aerobic, anaerobic, yeast). This confirms the theory that high heat and pressure would effectively kill any living organism of concern. The study would have not only benefited from more samples being run through the control protocol but also working towards a homogenous origination sample for the control group and protocol group. In other words, instead of removing bone and tissue from one lump sum of biological material, the totality could be collected from one source and then homogenized through collectively grinding the material together. Measuring the growth through colony forming units would also allow for defined variances amongst means to be used for statistical analysis. In keeping the data being tested amongst both groups it would also be crucial to test the control group through the same methodology, meaning the swaps from under the sample and from another area in the tray should be collected. This allows for direct comparisons between the control group and the samples tested. This information can lead to further studies as outlined above and can also lead to improved decision making for surgeons and healthcare providers. Understanding risk is crucial when making decisions in the operating room. Improved data metrics and qualitative information can lend insight when needing to make critical decisions. Again, as mentioned before the objective is not to alter existing practices, but rather help drive informed decision making,

Impact to Cost

The cost associated with reprocessing is also crucial when looking at how surgical delays related to instrumentation contamination can impact hospital revenue and productivity. There are specific measurables regarding operating room cost per minute as well as specific costs tied to the reprocessing of instrumentation. An estimate for the cost to reprocess a single instrument is between $0.34-$3.00 (Knowles et al. 2020). The average cost of sterilization tied to a procedure range between $600 and $1000 (David M. Welker 2019). Some of the largest hospitals perform 13,004 and 25,605 surgical procedures annually. This leads to an estimated $7.8 million in cost related to sterilization. If items need to be re-run or replaced this creates a higher cost than previously expected. Bioburden found on instrumentation not only impacts the cost associated with supplies in the room that may need to be replaced but also the sterilization cost alone is now increased (Deshpande, Vinayak, et al, 2021). The results from this paper don't specifically decrease this sterilization cost, but the decision outcomes that could be affected, may lead to less re-sterilization cost.

In addition to the direct cost associated with the sterilization of instrumentation there is also the labor impact that reprocessing an item due to contamination can impact. The average wage for an SPD employee can vary, but for the hospital networks in Colorado this can be anywhere between $18 and $30 per hour depending on experience. The time to reprocess surgical instrumentation has a couple varying factors but looking at machine time alone, it can be estimated to take 45 minutes for the washer-disinfector and 1.5hrs for the sterilizer. This means that at least 2 hrs. and 15 minutes of time is strictly in the machine. This does not account for the manual process of cleaning as well as the

cooling time required after an item is removed from the sterilizer. It can be estimated that 3.5-4hrs is the time required for reprocessing of a surgical instrument. If an item needs to be reprocessed or a tray is needing to be reprocessed as a result of bioburden the associated time needed, pulls always from routine processing. Using 3.5 hrs. of reprocessing time for an item, this can equate to nearly half of a functional 8hr shift of an employee. Some variables can be more efficient when events like this occur, such as grouping instrument sets through the washer and sterilizer so process flow can continue. Looking at the average tray production for processing a tray member should functionally reprocess 4 trays per hour. Utilizing a $24 per hour rate of pay the cost for a single tray is 6$. If it is assumed that 5 incidents occur per week this can be extrapolated to be a labor cost of $1,560 annually for on hospital organization (Alfred et al, 2021). Another representation of this can be looking at the impact of a 15-minute delay as a result of bioburden or contamination. This can involve a new setup being required and gathering alternative instrumentation or a backup set. This 15-minute delay results in $300 OR time cost as a conservative estimate of $20 per minute for delays. The loss of productivity for the nursing staff would be 15 minutes of their average hourly rate of $40, which amounts to $10. This brings the total to $310 related to cost from the delay. If this breach 5 times a week this would equate to $80,600 (Farnworth et al, 2001). These figures, while small, represent only a fraction of the total impact of needing to reprocess a tray. There are several other factors that contribute to cost increases, such as increased time spent in the OR not related to surgery time and the case needing to cancel due to no available alternative or time for reprocessing.

The results obtained from the study, despite the sample size, can lead to interesting thought-provoking ideas for the future state of sterile processing departments. Assuming that the automated washer-disinfector and steam sterilizer result in no microorganisms retaining viability, perhaps there can be adjustments in the workflow through SPD. The department could combine ATP testing on the assembly side of the department that can scan the instrument or tray and review for any biological or foreign material. This area can be split into almost a holding area for instrument trays to ensure that there is no cross contamination between the dirty and clean items. The manual process of scrubbing and cleaning instruments could be removed for less complex items and the focus for manual cleaning can be on items that are more challenging, such as suctions or complex spine instrumentation. This would significantly increase the throughput in decontamination and reduce the bottleneck that may occur. This theoretical state of SPD would require significant more testing, but the theory is that as automated machines improve the manual efforts that are put forth in sterile processing can become more targeted. This would shift the model of SPD from having multiple manual touch points and areas for human error, to one with targeted focus and more automation. The shift in automation can already be seen through sterilizers that unload themselves, and machines that integrate with computer systems to have parameters read. SPD staff used to read the biological test that would be run in the sterilizer manually to observe a color change. The biological reader now uses spectroscopy to determine if there has been a color or concentration change and the result is automatically integrated into the systems application used for tracking SPD processes.

This simple yet elegant example of an automated process demonstrates the removal for human error as well as improved efficiency. This concept can be extended to other workflows through the department as further experiments demonstrate the true efficacy of processes throughout the department. This experiment focused on a small fraction of the possibilities that can exist, however; the concept of determining the efficacy of existing automated machines should continue to be explored. This would require a huge culture shift throughout the frameworks that currently exist in the department, however; ideas that function as disruptors over time can have the largest impact.

Future Studies

The results from the study conducted in conjunction with the articles referenced lend to interesting future studies to be conducted. The suggested review regarding the impact of the size of the biological material would prove a logical next experiment. The size of the material should impact the ability for steam to penetrate not only through the contaminant itself but also the surface that is being covered by the bioburden. The experiment outlined would determine a relative threshold for the efficacy of steam sterilization in conjunction with the washer disinfector to degrade and denature proteins to make them nonviable.

The classification of bioburden is challenging in the setting of the operating room as any discrepancy or contaminant results in the surgical instrument or tray being considered unsterile. Suture found in a tray or pieces of a surgical glove left in a tray is considered contaminated. Another study looking at the impact of non-living foreign debris would prove insightful for decision making and guidelines that a hospital

organization can develop. These items come to the operating room in sterile packaging and can often be the contaminant found. An experiment that looked into the potential growth that may occur from these items being missed but having gone through the washer disinfector and sterilizer would help model the possible associated risk of infection for these non-living foreign debris.

This study focused on aerobic, anaerobic, and yeast microorganisms, however; viruses were not examined. A study that looked at the ability of high heat and pressure to eliminate viruses would be another perspective to analyze the efficacy of the steam sterilizer and washer-disinfector. Heat is commonly used to denature the secondary structure of proteins within viruses making them impaired. This detectability of the virus remaining can be accomplished through virus titers (Gamble et al, 2021). There are variables that can impact the possibility of this outcome, such as the suspension medium used and time and temperature of heat. Further research would need to be conducted to determine how to accurately mimic possible scenarios to the operating room.

Appendix 1

Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
CDC	Centers for Disease Control and Prevention
DART	Distress Assessment and Response
SSD	Sterile Service Department
ERCP	endoscopic retrograde cholangiopancreatography
ETO	Ethylene Oxide
FDA	Food and Drug Administration
HAIs	Hospital Acquired Infections
IFUs	Instructions for Use
IUS	Immediate Use Steam (sterilization)
OR	Operating Room
PPE	Personal Protective Equipment
RSUD	Reprocessed Single-Use Device
SPD	Sterile Processing Department
U.S.	United States
SSIs	Surgical Site Infection
WHO	World Health Organization

Appendix 2

Glossary of Terms.

Autoclave: An autoclave or sterilizer is a device used to sterilize equipment and supplies by subjecting them to high pressure and steam at 121ÆC or above. For the purposes of this document, the term autoclave refers to a large industrial sterilizer used in a central sterile services department.

Automated endoscope preprocessor: Machine designed to assist with the cleaning and disinfection of endoscopes.

Bioburden: The number of viable organisms that contaminate a device.

Biological indicator: Test systems containing viable bacterial spores providing a defined resistance to a sterilization process.

Chemical indicator: Test systems that reveal a change in one or more predefined variables based on a chemical or physical change resulting from exposure to the process e.g., color change.

Cleaning: The first step required to physically remove contamination by foreign material, e.g., dust, soil. It will also remove organic material, such as blood, secretions, excretions and microorganisms, to prepare a medical device for disinfection or sterilization.

Contamination: The soiling of inanimate objects or living material with harmful, potentially infectious or unwanted matter.

Decontamination: Removes soil and pathogenic microorganisms from objects so they are safe to handle, subject to further processing, use or discard. (Centers for Disease Control and Prevention [CDC] Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008).

Detergent: A cleaning agent that increases the ability of water to penetrate organic material and break down greases and dirt. Detergents are needed to allow effective cleaning to take place.

Disinfectant: A chemical agent that is capable of killing most pathogenic microorganisms under defined conditions, but not necessarily bacterial spores. It is a substance that is recommended for application to inanimate surfaces to kill a range of microorganisms. The equivalent agent, which kills microorganisms present on skin and mucous membrane, is called an antiseptic.

Disinfection: A process to reduce the number of viable microorganisms to a less harmful level. This process may not inactivate bacterial spores, prions and some viruses.

Dispersion: Breaking up of dirt aggregates into small particles.

Invasive procedure: Any procedure that pierces skin or mucous membrane or enters a body cavity or organ. This includes surgical entry into tissues, cavities or organs.

Medical device: Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, intended by the manufacturer to be used in humans for the purpose of the diagnosis, prevention, monitoring, treatment or alleviation of - or compensation for - an injury or handicap.

Monitoring compliance and effectiveness: A process of audit carried out by the infection prevention and control team or a similar group in order to measure the level of compliance with the policy outlined in this document. The audit activity will review both the environment and processes related to equipment decontamination in community health-care settings. Feedback will be supplied to managers to promote compliance with the policy.

Original device: A new, unused single-use device.

Prion: A small proteinaceous infectious unit that appears to cause transmissible spongiform ence- phalopathies. These are rare, fatal neurodegenerative disorders that occur in a wide variety of animals, including humans, and are highly resistant to disinfection and sterilization.

Quality assurance: A programme for the systematic monitoring and evaluation of the various aspects of a service e.g. decontamination, to ensure that standards of quality are being met.

Quality control: A system of maintaining standards by testing a sample against a defined specification.

Reprocessed single-use device: A reprocessed single-use device is an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient.

Reprocessing: All steps that are necessary to make a contaminated reusable medical device ready for its intended use. These steps may include cleaning, functional testing, packaging, labelling, disinfection, and sterilization.

Sterilization: A validated process used to render an object free from viable microorganisms, including viruses and bacterial spores, but not prions.

Validation: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently disinfect and sterilize instruments and other medical devices.

Verification: Confirm through the provision of objective evidence that specified requirements have been fulfilled.

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