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LEARNING OBJECTIVES

- 1.) *Determine the foundations for sound quality management systems.*
- 2.) *Understand the relationship between quality assurance and efficiency.*
- 3.) *Execute effective quality management strategy planning sessions.*

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Education nation: Creating Sterile Processing Department SOPs

Sarah B. Cruz, CSPDT, CRCST, CHL

The Sterile Processing (SP) department has its own soundtrack. The sound of the cart washer door opening, the rumbblings of a full autoclave truck being pulled, and even the phone ringing are contributors to the Sterile Processing album. Even if we aren't in the department while we read this, some of us may think we hear the sterilizer beeping now. The hustle and bustle of the department professionals are a part of this chorus. Banter about weekend plans, discussion about a possible wet load, and conversations between the SP and the Operating Room (OR) happen regularly.

The tone and attitude that we use within our department reflects our standard operating procedures (SOPs). SOPs allow for the department and its professionals to work together because everyone knows what goals they are working towards. They are the difference between a reactive situation that has an outcome and a high-pressure moment with a proactive solution. As a vital part of a Sterile Processing department's quality management system (QMS), SOPs encourage everyone to move towards a solution together via clear expectations. The actions of the department rely upon SOPs to create harmony and flow towards positive patient safety outcomes.

The FAQ of SOPs

Standard operating procedures are the instructions that outline how to perform a certain process. The idea is that if the SOP is performed the same way, every time, then the same outcome can be expected. Therefore, they are an integral part of any effective quality management system. While the QMS addresses the needs of the organization (in this case the department), the SOPs outline the factors that contribute to the overall success of the department.

SOPs have a direct impact on patient safety because they are designed to guide the professionals towards a singular outcome. SOPs are a high-level overview of a process, which is why they should not be confused with exact or instructional step-by-step processes or "how-tos". The main objective of an SOP

is that all parties involved are made privy to the information necessary to perform said task effectively.

Standard operating procedures are designed to help break down the most complex processes so that even new technicians know the desired outcome of their task². There is no limit as to the number of SOPs that can be assigned in a Sterile Processing department. However, this does not necessarily mean that a department with hundreds of SOPs will operate more effectively than a department with fifty. In the case of an SOP, "effectiveness" is determined by the ability to perform a task consistently. An SOP is effective when the end results are achieved consistently within range and when there is an increase in:

- Staff confidence in process application
- Quality products
- Productivity
- Department safety

These factors must be considered when determining the realistic outcome of an SOP. If even one area is lacking at the expense of another area to thrive, the SOP cannot be considered effective.

For example, if a Sterile Processing professional can check ten instrument sets per hour on assembly, but the quality of each set decreases over time, the SOP is not effective. This may call for the SOP creators to reevaluate how they are defining the term "productive" and to address what physical indicators they are using to indicate that one is being such. The SOP does not suggest that one area of the process is more important than another; rather it demonstrates why all areas must be considered equally important when building out the processes to achieve it.

This ushers in the evident reminder that Sterile Processing professionals are *humans*, not machines. Machines don't require confidence or reassurance in their work performance to maintain focus on their end goal. The parameters of what is or isn't acceptable must provide a range that Sterile Processing professionals can work within and still be successful.

Variations due to interpretation

Standard operating procedures define what success is. They do so by removing emotional biases and preconceived notions of expertise and creating a foundation for application. Variations in SOP application are typically the result of the SP professional's interpretation of the process and its expectations. The SP professional will interpret how to achieve the SOP outcome through their own scope of job skills formed by workplace tenure, experience levels, and learned habits. Thus, SOPs level the playing field and give every SP professional the same foundation for evaluation.

It is possible to create SOPs that consider different professional levels and are only applied to those levels. However, using a high caliber SOP as the baseline for professionals with less experience is only setting up the department and our patients for failure. SOPs must be tangible; their tangibility measured by the success rate of those performing them.

One indication that an SOP should be evaluated is that the result isn't being achieved due to multiple observed process deviations. The key term in that sentence is "observed". Assumptions have no place in SOP creation, implementation, management, or assessment. Process observation can be performed through direct observation of the process, data analysis, and even conversations with the frontline SP professional performing their duties. While a good hypothesis can serve as the starting point for investigation, it must remain that until proven true or false. This proposed assumption was based on the limited evidence made available and easily becomes true if we allow our bias to lead its investigation.

Niche training

Another way to tell if SOPs need to be created or evaluated in a Sterile Processing department is by the awareness of niche training. "Niche" defines the area in which one can offer a tremendous amount of insight on a certain topic¹. Niche training is the concept that only a few individuals can perform a certain duty because they have excelled in the tasks outlined in said area. As a result, they are the only ones assigned those duties.

This is common in facilities experiencing a high employee turnover rate. As professionals come and go, the desired outcomes still need to be achieved. This results in the designated tasks and applicable knowledge becoming stagnant in one or a few specific individuals. Thus, the information and skills specific to these areas are not transferred

to new professionals. While these particular assignments in the department have become suitable for one or few professionals, niche training has caused information and professional knowledge to become limited to those expert(s). This perpetuates the cycle of insufficient training of new professionals due to the time necessary to hone these skills.

Let's observe niche training in the case cart SP assignment. In this area, the professional is responsible for interpreting a preference card based on the surgical procedure it is intended for. For this example, we'll focus on the instrumentation that is requested. The preference card lists every single type of set that may be necessary for the procedure, including multiple duplicated sets that are to be provided by different instrument companies. An experienced SP professional may be able to see the doctor's name and know what company they use due to their accumulated knowledge on the case cart assignment. A new SP professional may pick every single instrument set that is itemized on the preference card, resulting in excessive equipment. The case cart is hence assembled incorrectly. The experienced professional reviews the cart and tells the new technician to remember that this doctor only uses this specific equipment. Time goes by and the inaccurate case cart assembly happens again but for a different doctor. The trainer says that they went over this with the trainee and the trainee only recalls the previous event with a different doctor. Unfortunately, this will cause the trainer and trainee to become frustrated and impatient. The trainee views the trainer as incapable of teaching because they are only being corrected after the error and told to remember yet another fact amongst hundreds. The trainer will think "they just don't get it" and that they may not care about the job responsibilities or take them seriously.

SOPs will help limit niche training because the process outlined is based on the overarching task. They undermine the niching process by depersonalizing the actions used to achieve the outcomes. The professionals experiencing the effects of niche training have taken the job duties and made them apply to how they perform the task. Hence intertwining their personal perception, professional experience, and even their own view on workplace success. The trainer in this example looks to their learned subject matter expertise; a wealth of knowledge that has taken them their entire professional career to acquire. The expectations for the new technician are not only to

gain and retain this vast amount of knowledge during the short training period, but also demonstrate it in all the new moments that require it. The end results will vary in accuracy and consistency when a new technician is expected to achieve the same results the way their trainer has. The trainee and their manager may also begin to expect the desired outcome, based on the trainer's success measurements. Instead of allowing this to happen, an SOP can clearly define the goals, tasks, and resources required and leave no room for ambiguity.

Create Valid Expectations

SOPs are necessary to create a clearly defined expectation. However, we would do no justice to our SP team or the patient if we just grab an outcome out of thin air. Like in our previous example of inspecting ten sets an hour on assembly: Where did we get the number ten from? How did we determine that ten was a benchmark number we should use to measure productivity? These benchmarks must have a sound basis in logic. This is what makes them reasonable and therefore tangible. Without this, performance expectations can be perceived as biased, unrealistic, and frankly unfounded. Hence, several regulatory, industry, and facility-based requirements and recommendations must be considered in SOP creation. For a Sterile Processing department, this includes:

- Hospital policies
- Regulatory agencies
- Recommendations through accredited sources
- Facility documents
- Interdisciplinary groups

Determining key players, as in the FDA, AAMI, and even the facility's Infection Prevention and OR team, is important in SOP creation. As we have come to experience, industry benchmarks in Sterile Processing vary and may not even exist in some areas. Because of this, the specific department's data and workflow become even more vital when determining and creating credible figures used in SOPs.

Most importantly, do not forget to include SP leadership in the creation of Sterile Processing SOPs. Frontline contribution is vital to the implementation and continued practice of SOPs. If the bar is set based on a perceived workflow or half understanding of department responsibilities, the continued success of the SOP is in danger. Poor implementation of an SOP can be the result of a lackluster creation phase. Therefore, setting quality expectations and foundations is of the utmost importance and will affect the positive patient safety outcome.

How we've always done it

An SOP is a living document. It serves best when the document is consistently reevaluated for accuracy and relevance. The Sterile Processing industry, like much of healthcare, is always evolving. Facilities run the risk of performing tasks inadequately if "the way we've always done it" isn't achieving SOP outcomes or isn't synonymous with the facility's needs. Consider if:

- interdisciplinary roles have changed within the facility
- department employee turnover rate is high
- industry regulations and recommendations have been updated

These factors also contribute to how the SOP is being performed and encouraged in the department. Posting SOPs in their designated areas and making them easily accessible is vital to adherence. While having them electronically stored is nice and neat, being sure they can be accessed is a separate story. Technology and software training may be required to retrieve SOPs; and if they are all on one computer on Assembly, how does that serve the other areas throughout the department? Revisiting SOPs on an interim basis (determined by the department's needs) also keeps knowledge and practices on the forefront of the SP professional's mind.

Even the best written SOPs fail if they are not followed. The professionals required to interpret their outlined process need to understand why they are important. Department leaders create buy-in to process improvement based on their leadership style. While there are a lot of ways to promote adherence, creating opportunities for engagement will promote process consistency. Involving the SP professionals with *how* the SOP is achieved can create skin in the process improvement game. It also gives them a direct line to how their work impacts the patient. This can be achieved through department best practices, standard works, competencies, and in-services³.

Standard operating procedures are necessary for the department to function as an entire unit. They are a key component to the hum of productivity in the Sterile Processing department. SOPs contribute directly to the Sterile Processing professional's workplace experience, perception of value, and noted contributions to the department. Whether that is a positive or negative view is determined by how SOPs are created, implemented, and managed. By creating SOPs based on regulations, industry recommendations, facility policies, and incorporating leadership goals, everyone moves towards the SAME positive patient

safety outcome. They allow us to fine tune outdated practices, observe deviations, and even recognize the professionals that are excelling. When Sterile Processing professionals become silent in the department, this is a sign of disengagement, frustration, and unrest. By incorporating SOPs, leadership provides an actionable, tangible, and clearly articulated goal that gives everyone something to talk about. **HPN**

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References:

- 1) <https://www.merriam-webster.com/dictionary/niche>
- 2) <https://workflowautomation.net/blog/standard-operating-procedure-sop>
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Circle the one correct answer:

- SOPs are an abbreviation for:**
 - Strategically Outsourced Problems
 - Standard Operating Procedures
 - Standard Opportunity Practices
 - Strict Outline Procedures
- SOPs can create clearly defined expectations.**
 - True
 - False
- SOP “effectiveness” is determined by:**
 - When a SP professional clocks in or out
 - The ability to perform a task consistently
 - How long breaks are allowed to be
 - Regulatory agencies
 - All of the above
 - None of the above
- What are some factors that contribute to a facility risk of performing tasks effectively:**
 - Interdisciplinary roles have changed within the facility
 - Department employee turnover rate is high
 - Industry regulations and recommendations have been updated
 - All of the above
 - None of the above
- Niche training is a vital part to SOP implementation**
 - True
 - False
- Which is a factor as to how a Sterile Processing professional interprets and carries out an SOP?**
 - Job skills
 - Workplace tenure
 - Learned habits
 - All of the above
 - None of the above
- There are plenty of Sterile Processing industry benchmarks so facilities do not need to rely on their own data collection.**
 - True
 - False
- Standard operating procedures are part of a department quality management system.**
 - True
 - False
- A hypothesis is NOT an assumption.**
 - True
 - False
- Which of the following is NOT true?**
 - SOPs are living documents.
 - SOPs outline a certain process.
 - SOPs do not need to be evaluated for accuracy after creation.
 - All of the above
 - None of the above

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