HEALTHCARE PURCHASING NEWS

SELF-STUDY SERIES

Documentation do's and don'ts for SPD quality

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LEARNING OBJECTIVES

- ***Review the importance of quality management to sterile processing technicians, the operating room (OR) team, surgeons and patients.***
- ***Examine quality guidelines in evidence-based standards.***
- ***Discuss policies for record keeping.***
- ***Discuss key performance indicators for Sterile Processing's critical business functions and how to record them.***

Discussing quality in Sterile Processing may seem vague and overwhelming. However, you do not have to be an industrial engineer to learn the ropes and jargon to develop, implement and participate in a successful quality management program.

Quality is an integral part of patient safety. In the surgical environment, it is important to have a system of checks and balances for each role or group of caregivers. For example, let's compare some checks and balances among Sterile Processing, the OR team, and the surgeon during a surgical procedure.

OR team and Sterile Processing:
The OR team inspects the instruments from Sterile Processing to check for bioburden, indicators and package integrity. In turn, the Sterile Processing team verifies that used instruments are returned safely and appropriately to the decontamination area.

Sterile Processing and surgeon:
The surgeon expects clear communication about turnover times and status updates for instruments. The Sterile Processing team needs accurate pick lists and instrumentation needs prior to the case.

Surgeon and OR team:
The OR team expects the surgeon to participate in time-outs. The surgeon expects that the OR team will be able to get the instruments and supplies they need when they need it.

These examples of checks and balances are tools and practices that are used to reduce the risk of harm to the patient during their procedure. Developing a quality management system can help identify critical processes and areas for improvement.

To further explain how processes and tools can help tighten corners and decrease the risk of patient harm, let's use Jim Reason's "Swiss cheese" model.

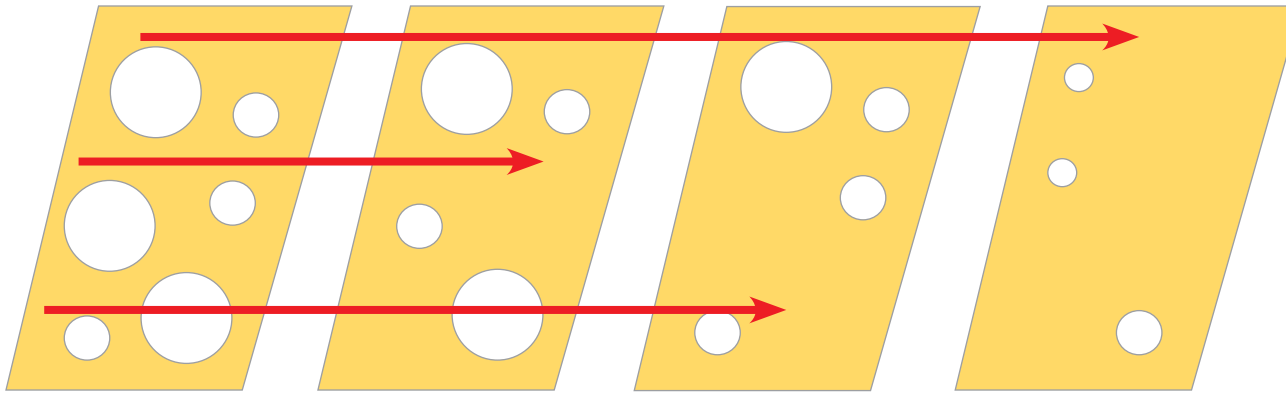
Swiss cheese model

Consider that each slice of Swiss cheese is a process, tool or practice that is put in place to prevent a mistake or safety event. Because no process is perfect or 100% error-proof, there are holes in the Swiss cheese that represent errors that may occur. A quality management system will help identify processes that need another slice of cheese.

A great example of the Swiss cheese in action is the set of recommended COVID precautions (which, frankly, we are all way too familiar with).

- The first precaution, or slice of cheese, is wearing a mask. We understand that it isn't possible to wear a mask 100% of the time. Masks must come off to eat or drink, some people can't medically wear them and some people refuse to wear them. Therefore, that process is not 100% reliable and there are "holes" that can lead to the risk of transmission.
- The second precaution is social distancing. Without some sort of force field surrounding you, it is impossible to maintain social distancing at all times, which can lead to the risk of transmission.
- The third precaution is cleaning and disinfection. Reducing the viral load on surfaces will help reduce the risk of transmission.
- The final precaution is hand washing, which helps prevent transferring and pathogens from your hands to your nose or mouth.

As you can see, none of these processes is perfect alone. But as you continue



stacking more risk-reducing processes, you greatly reduce the risk of harm.

Next, we'll look at the Sterile Processing-specific example of missing indicators. This mistake has plagued operating rooms for years. We all understand that each set and package need at least one indicator – but we're human and the mistake of not adding an indicator can and has happened! There are several strategies that Sterile Processing departments have tried to prevent this from occurring. Let's look at a combination of those in a Swiss Cheese model.

- The first strategy is adding indicators to the count sheet. We know that sometimes even instruments are missed on the count sheet, so this strategy is not 100% error-proof.
- The next strategy is delivering your assembled set to another technician, who adds indicators and wraps the set.
- The third strategy is having another technician do a "buddy check" to verify that indicators are in the set.

This may seem like overkill, and extra steps may seem like a waste of time to the team. However, you can see that using multiple strategies can help reduce the risk of a missing indicator.

Comparing processes to cheese makes them seem simple, but there are so many critical processes in Sterile Processing that can lead to mistakes and patient harm that it's hard to know where to start. You may also be hearing statements from the OR using words like "a lot," "never" and "always." What does it mean if you have "a lot" of missing indicators or dirty instruments? What is that relative to? This is where a quality management system comes into play.

A quality management system will help identify your most frequent mistakes and defects. It will give you a place to start for improvement work and you will be able to measure whether changes to your processes are working. It will also give you reportable performance information to share with the OR, infection prevention, risk, etc.

It may seem like an optional choice to begin developing a quality management system. However, our guidance in ANSI/AAMI ST79:2017 with Amendments A1, A2, A3 & A4:2020 Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities says otherwise. Section 14 provides guidelines for a "Continuous Quality Improvement program," which includes a risk analysis of all aspects of steam sterilization that should be performed annually and a planned, systematic and ongoing process for verifying compliance with procedures. Accreditation surveyors will ask questions about improvement initiatives and department metrics, such

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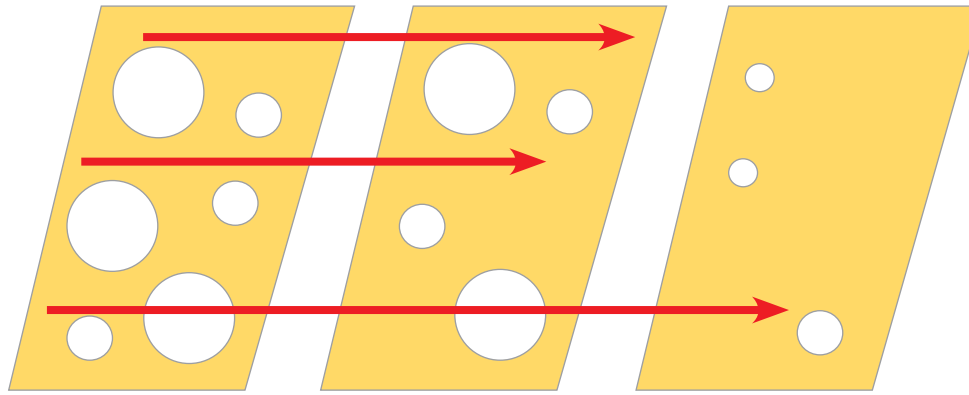

Strategy:
Adding indicators to count sheet.
Indicator on count sheet is skipped.

Strategy:
Set is passed to another tech to add indicator and wrap.
Busy tech forgets to add indicator

Strategy:
Another tech does a "buddy check."
Catches the missing indicator and adds it to the set.

Self-Study Test Answers: 1. D, 2. A, 3. D, 1. A, 5. A, 6. B, 7. D, 8. A, 9. D, 10. C

as immediate-use steam sterilization (IUSS). Luckily, we have additional guidance documents from AAMI.

ANSI/AAMI ST90:2017 Processing of health care products—Quality management systems for processing in health care facilities is a guideline designed specifically for Sterile Processing departments. It is intended to promote quality processes and methods and to assist healthcare personnel in their proper application to achieve acceptable and reproducible results. ST90 covers several major elements in Sterile Processing, including:

- Documentation requirements
- Management responsibilities for policies and planning
- Managing resources like staff competency, infrastructure and work environment
- Performing product quality assurance testing, how to add new devices and traceability to patient
- How to effectively measure, analyze and improve department performance

For practical guidance, the annexes of ST90 include detailed information about performing the following work mentioned in ANSI/AAMI ST79:2017 with Amendments A1, A2, A3 & A4:2020:

- Performing risk assessments
- How to perform product quality assurance testing
- How to create and implement a Quality Management System or Continuous Quality Improvement plan

A cornerstone of any quality management system is tracking key performance indicators, or KPIs. A KPI is a quantifiable measure used to evaluate the success of an organization, employee, etc. in meeting objectives for performance. The following examples are KPIs that relate directly to Sterile Processing:

Safety

Track events and injuries caused by workplace hazards or poor ergonomics. This could include things like sticks from sharps or employee injuries from lifting, pushing or pulling. Record when disposable sharps are returned to the decontamination area from the OR. These have the potential to cause injury, so it's important to partner with the OR to share these safety concerns.

Quality

If you pick cases for the OR, case-picking accuracy is an excellent quality indicator to monitor. You can also review the rate of dirty or broken instruments sent to the OR and the amount of instrument repairs. In addition, the instances of instruments being sent to the decontamination area inappropriately (dry, not contained properly, delicate instruments being compromised, etc.) should be tracked and shared with the OR. Implementing a program to perform adenosine triphosphate (ATP) or soil testing and monitoring on flexible endoscopes will also help monitor cleaning and disinfection efficacy.

Production

The daily number of missing instruments can be tracked. In addition, it would be helpful to track the number of delays to procedure starts caused by missing instruments or supplies. Equipment repairs and downtime, like sterilizers and washers, can be documented to leverage performance issues with your equipment and repair vendors. The rate of complete sets versus incomplete sets is an important performance indicator that can be shared with your OR partners. And, one of the most important performance indicators, the IUSS rate, should be tracked and shared with the OR and infection prevention. Monitoring your IUSS rate by instrument or set can help justify purchases of additional instrumentation.

Once you know which KPIs you will track and how you will do it, you need to plan what you are going to do with the information. You should decide which information you are going to only use internally, and which indicators you will share with the OR, infection prevention, etc. If you are tracking information because of a state requirement, make sure your process to do so is robust. You should have a policy, competency testing for the specific process and, if necessary, a way to trace the information to the patient. The requirements for how long specific records must be kept is determined by state, so the policy should also outline how information will be archived.

Sharing specific KPIs with the Sterile Processing team is a fantastic way to garner engagement and generate ideas for fixing problems. Choosing to focus on one or two areas, like indicators or dirty instruments, will help get the team to keep those topics on their radar during their shift. This gets them actively involved in process improvement work.

There is no national benchmark for KPIs, like IUSS rate or assembly production. Once it's time to implement your quality management system, the following steps should be taken:

1. Identify critical business functions
2. Identify and document procedures for each business function
3. Identify and document records showing compliance to procedures – gather baseline data
4. Develop and communicate service expectations to customers
5. Set improvement goals based on current state and opportunities for improvement identified in steps 1 to 3, repeat.

In review, implementing or renovating a quality management system can seem overwhelming. Pick a few KPIs that make a big impact for your team and customers and start recording information. Work with infection prevention or risk to develop your system, share your information and ensure you're covering your bases from a liability standpoint. There is a wealth of resources out there, including AAMI ST79 and ST90, articles and your peers. Finally, the most important aspect of a quality management system is engaging the entire team to participate in process improvement work. Investing time into developing a quality management system is the best way to ensure we keep our patients safe. HPN

References:

- Reason, Jim. Human Error: Models and Management
- ANSI/AAMI ST79:2017 with Amendments A1, A2, A3 & A4:2020 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
- AANSI/AAMI ST90:2017: Processing of Health Care Products – Quality Management Systems for Processing in Health Care Facilities

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CONTINUING EDUCATION TEST • AUGUST 2021

Documentation do's and don'ts for SPD quality

Circle the one correct answer:

1. **A Quality Management System can:**
   - A. Provide reportable performance information
   - B. Help identify where to start a process improvement project
   - C. Provide a way to measure whether process improvements are effective
   - d. All the above

2. **Which ANSI/AAMI Standard is "Quality Management Systems for Processing in Health Care Facilities"?**
   - a. ST90
   - B. ST81
   - C. ST79
   - D. ST58

3. **ANSI/AAMI ST79 recommends a risk analysis of all aspects of steam sterilization be performed how frequently?**
   - A. Monthly
   - B. Bi-annually
   - C. Every three years
   - d. Annually

4. **Which of the following are NOT included in ST90?**
   - a. National benchmarks for productivity
   - B. Documentation requirements
   - C. Performing product quality assurance testing
   - D. How to effectively measure department performance

5. **Accreditation body, like The Joint Commission, may ask questions about improvement initiatives and department metrics.**
   - a. True
   - B. False

6. **What does KPI stand for?**
   - A. Key process initiatives
   - b. Key performance indicators
   - C. Key perioperative instruments
   - D. Key pandemic infections

7. **Which KPIs can be used for tracking department safety?**
   - A. Sharps injuries
   - B. Ergonomics injuries from lifting
   - C. Instances of disposable sharps returned to the decontamination area
   - d. All the above

8. **ATP or soil testing can be used in a Quality Management System to monitor cleaning efficacy.**
   - a. True
   - B. False

9. **Which of the following steps should be taken when implementing a Quality Management System?**
   - A. Identify key business functions
   - B. Document procedures for each business function
   - C. Identify and document records showing compliance to procedures
   - D. **All the above**

10. **Who determines how long sterilization records must be kept?**
    - A. AAMI
    - B. Federal Regulations
    - c. State Regulations
    - D. Joint Commission

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