Benefits of Departmental Connectivity

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LEARNING OBJECTIVES

1. Identify the benefits of connectivity in the Central Service/Sterile Processing department as it pertains to operational readiness
2. Explain how connectivity drives compliance and standard work to support departmental quality management systems
3. Discuss the importance and benefits of a single platform to streamline workflow and simplify troubleshooting issues

Work smarter, not harder should be a mantra for all Central Service/Sterile Processing (CS/SP) departments as they strive for continuous operational readiness. In some cases, following that mantra is easier said than done; however, it is certainly achievable given today's advancements with departmental connectivity.

Imagine working in a CS/SP department where visual dashboards, priority notification, compliance, and standard work supporting the department's quality management system were a daily norm, and where work flow and troubleshooting issues were streamlined, thereby, making root cause analysis simpler. All this can be made possible with the adoption and implementation of medical device and equipment connectivity.

Objective 1: Identify the benefits of connectivity in the Central Service/Sterile Processing department as it pertains to operational readiness

As healthcare professionals, we have a profound responsibility to the roles we play and the contributions we make toward supporting quality healthcare to the patients in our respective organizations. These responsibilities include reducing or eliminating healthcare-associated infections (HAIs), remaining in a state of operational readiness, and managing HAIs.

Medical device connectivity is the establishment and maintenance of a connection through which data is transferred between a medical device, such as a sterilizer, and an information or workflow management system. The term "medical device connectivity" is used interchangeably with biomedical device connectivity or biomedical device integration. By implementing departmental connectivity and eliminating the need for manual data entry there are potential benefits that include, but are not limited to, faster and more frequent data updates, diminished human error, and improved workflow efficiency.[1]

In 2016, the Association for the Advancement of Medical Instrumentation

(AAMI), in collaboration with the American Hospital Association (AHA), Centers for Disease Control and Prevention (CDC), US Food and Drug Administration/Center for Devices and Radiological Health (FDA/CDRH), and The Joint Commission (TJC), held a forum on preventing device-related HAIs. The forum was organized to facilitate the exploration of how and why these device- and equipment-associated transmissions occur and identify solutions to the problem.[2]

The CDC estimates 46.5 million surgical procedures are performed in hospitals and ambulatory settings each year; this includes approximately 5 million gastrointestinal endoscopies. Each of these procedures involves contact with a medical device or surgical instrument.[3] A substantial risk of procedures is the introduction of pathogens that lead to infection. Additionally, one cannot rule out the risk of developing an infection from contact with medical equipment, devices and supplies while seeking other health services. Failure to properly clean, disinfect or sterilize and use or store medical equipment, devices and supplies not only poses risks for the person seeking health services, but also carries the risk for person-to-person transmission of infection.[3]

Several strategies and prevention protocols identified by forum stakeholders spoke to the perceived risk of the role of people and the environment of care, the role of the physical environment of care, role of devices and equipment, as well as the role of the device and equipment design.

It would be no surprise then to learn the results from the pre-forum survey of stakeholders (N=415) that associated high or very high-risk percentage with reprocessing reusable devices (cleaning, disinfection, sterilization), maintenance and repair, as well as quality systems and risk management.[2]

There are many steps involved in the cleaning, disinfecting and sterilizing of medical equipment, devices and supplies. It is critical that healthcare workers follow standardized practices to minimize infection risks related to those steps. Reliable systems exist for controlling these processes and can assist CS/SP departments in implementing effective orientation, training and competency of the healthcare workers who are processing medical equipment, devices and supplies; helping establish proper levels of staffing and supervision of the healthcare workers who are processing medical equipment, devices and supplies; assisting with standardization of process, regardless of whether it is centralized or decentralized; reinforcing the process (e.g., the use of placards that list the steps to be followed, according to manufacturer's guidelines); and performing ongoing quality monitoring.[3]

Several AAMI standards speak to competency, education and training, and call out the importance for healthcare organizations, specifically device processing areas, to identify and define requirements for job functions. In addition, device processing areas in healthcare organizations shall establish, document and maintain procedures for providing adequate education and training.[5]

Departmental connectivity is a simple solution for auditing and inspecting employee education and training records; it shall be reviewed on a scheduled basis as determined by the facility. Where required, employees and their immediate supervisors shall create an education and training plan to develop and maintain the skills and competencies needed for ongoing effective job performance.

The Centers for Medicare and Medicaid Services (CMS) and accreditation organizations, such as AAAHC, DNV-GL and TJC also speak to the importance of education, training and competency, and departmental connectivity is certainly a proven solution to helping departments meet this requirement. In addition, orientation and education of medical equipment users can describe or demonstrate capabilities, limitations and special applications of equipment; operating and safety procedures for equipment use; equipment procedures in the event of an equipment failure; and reporting procedures for equipment problems, failures or use errors.[4]

Healthcare Technology Management (HTM) professionals can demonstrate or describe knowledge and skills necessary to perform maintenance responsibilities and processes for reporting equipment management problems, failures and use errors.[4] Recent survey results point to a number of areas causing CS/SP departments to become jammed with their accreditation surveyors during inspection. Connectivity is a solution that can manage these opportunities in the healthcare facility.

Objective 2: Explain how connectivity drives compliance and standard work to support departmental quality management systems

As ANSI/AAMI ST90 states, the healthcare organization shall periodically monitor and measure the characteristics of the medical device or equipment to verify that cleanliness, safety and functionality requirements have been met according to all manufacturers' written instructions for use (IFU). The CS/SP department shall maintain documented evidence of conformity with all manufacturers' IFU and department-written acceptance criteria. Records shall identify the person(s) authorizing the release of the device or equipment.[5]

Release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed. The healthcare organization shall record the identity of personnel performing any inspection or testing.

CS/SP departments shall conduct performance testing and maintenance of all sterilizers. These activities should be documented and include daily, weekly, monthly and/or quarterly cleaning and routine maintenance performed by operators, per the manufacturer's operation manual. Departmental connectivity provides a visual dashboard of status and is capable of housing such records. It should be maintained to provide evidence of conformity to departmental processes, patient safety practices and QMS requirements, as well as the effective operation of the quality management system.

Connectivity promotes the controls needed to review and revise forms used to record conformity evidence, ensure records are clearly identifiable and remain legible and retrievable, and define and follow a record retention program that meets the healthcare organization's policies and local and national regulations.

Implementing connectivity measures makes is easier for accreditation organizations to verify that CS/SP departments are maintaining records of process parameters for the sterilization process used for each sterilization cycle. Connectivity also helps ensure that sterilization records can be traced back to each sterilization cycle used to process surgical sets or other medical devices.

Connectivity, in addition to electronically managing documentation and record keeping (including sterilizer and washer tape data, biological and chemical indicator results), may also provide stakeholders with up-to-the-minute priority requests and processing parameters for each tray entering the CS/SP department. Connectivity reporting can also help manage documentation, including recall and productivity reports, IFU, count sheets and labels, as well as on-screen assembly and count sheet management for all instrumentation.

It is important to ask whether the CS/SP department takes action to minimize or eliminate identified safety and security risks in the physical environment. Stated another way, does the department respond to the risk assessment and correct the identified risk (e.g., wet packs, high-level disinfection/sterilization, and equipment maintenance)?

Preventing loss is the goal. Risks can be difficult to predict and are often hidden. CS/SP departments should start with a list of activities, systems and processes that are used in their department. Next, they should go through the list and ask the question, "What can go wrong?" Finally, the CS/SP department should make a list of significant failures that have occurred within the past three years and use this to identify additional potential risks.

In reality, most CS/SP departments are so busy with the day-to-day events that many do not set time aside to perform necessary risk assessments – and when they are performed, it usually occurs as a result of a crisis situation involving many stakeholders. When in a crisis situation, people are almost always operating with incomplete or incorrect information. Connectivity provides the necessary data to assist in CS/SP department risk assessments.

One of the many benefits of equipment and process connectivity is the support for standard work. Standard work is the practice of setting, communicating, following and improving standards. Establishing standard work begins with creating, clarifying and sharing information about the most efficient method to perform a task that is currently known with everyone performing that process.[6] Once this information has been shared, everyone practices this standard consistently so the work is done the best way every time. This is where continuous improvement comes into play; standard work isn't a "set it and forget it" process, announced once and then permanently left unchanged. Instead, everyone should work to improve the standard and share new best practices as they are discovered.

Standard work creates stability and consistency within a continuous improvement system by providing the baseline upon which a process sits. This way, the team isn't constantly reinventing the wheel. Standardized work is one of the most powerful but least-used lean tools. By documenting the current best practice, standardized work forms the baseline for kaizen, the Japanese word that refers to continuous improvement. As the standard is improved, the new standard becomes the baseline for further improvements, and so on. Improving standardized work is a never-ending process.

Departmental connectivity supports the many benefits of standardized work to include documentation of the current process for all shifts; reductions in variability; easier training of new operators; reduction in injuries; and a baseline for improvement activities.

Connectivity platforms add discipline to the culture, an element that is frequently neglected but essential for lean to take root. Standardized work is also a learning tool that supports audits and promotes problem solving. The success of standard work lies in the documentation of the process. If the point of standard work is to get everyone performing a task to complete it in the most efficient, safe and effective manner, then getting the documentation correct is critical to their success.

Objective 3: Discuss the importance and benefits of a single platform to streamline workflow and simplify troubleshooting issues

Certified healthcare leaders should take a proactive role in managing their CS/SP department's equipment inventory and staff with enabling technologies to improve efficiencies and productivity. Supplying the department with real-time information enables the team to make the right decision at the right time. Connectivity provides the visual capability for the team to prioritize production at each process step and work station through real-time performance indicators; this helps drive productivity, compliance and quality.

Workflow management and connectivity is a crucial and important part of the healthcare organization's ability to establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required. Connectivity simplifies the healthcare organization's responsibility and need for traceability of surgical instrumentation and other medical devices through the entire processing system, including cleaning, inspection, decontamination, disinfection, sterilization, and distribution processes.

As part of a sound quality management system, a department's servicing activities may be performed by HTM facility employees or by an outside service provider and can include calibration, repair and routine/preventative maintenance. Equipment performance management shall be documented through established procedures, work instructions, reference materials and measurement criteria. Departmental connectivity can provide real-time equipment monitoring for maximum uptime, with auto fault notification to in-house HTMs and managers. The availability of real-time visual dashboards can provide proactive management for the CS/SP department's equipment with interactive tasks for daily preventative maintenance, cleaning and testing. The peace of mind gained knowing the CS/SP department's equipment is compliant to daily testing protocols is priceless.

The benefits for a connected department are vast; however, as with any new information received, the question often becomes, "What should we do next?" What follows are a few action items to consider and to generate conversation amongst CS/SP colleagues and other stakeholders involved with the processes that support quality device processing:

- Share this article with all stakeholders and ask the question, "What is the state of operational readiness as it pertains to our department's connectivity?"
- Set up several site visits to CS/SP departments with established and tested workflow management systems to fully appreciate the benefits of the equipment connectivity platform.
- Perform a gap analysis on the current data collection and tracking platform (a gap analysis examines current performance with the purpose of identifying differences between the current state of business and where the business should ideally go). Identify the options available and whether the team is taking full advantage of the existing system.
- Research new technology and advancements available today and identify opportunities to be implemented into the department's strategic business plans.
- Reestablish a clear vision of what is wanted for the department's connectivity system for the next one, three and five years, and then plan and budget accordingly.

Conclusion

CS/SP leaders have a choice to make and it is not about "if," but "when" they are going to embrace new technology for the benefit of their staff and, more importantly, how they will more efficiently and effectively communicate with available data to support quality patient care in the organization. It is essential that CS/SP professionals lead and nurture their team's vision for equipment and process connectivity in support of their department's quality management systems.

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