

January 2018

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LEARNING OBJECTIVES

1. Explain the relevance of 100%³ for today's SPDs.
2. List the five basic elements of successful SPD production.
3. Discuss the real-world issues that challenge 100%³.

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SELF-STUDY SERIES

Is 100%³ still relevant for hospital SPDs?

by John Kimsey

In the healthcare environment, as in other aspects of life, some things stay the same while others change for the worse. For example, in infection prevention circles, antibiotic-resistant organisms have been a threat for years. But recent data shows that patients in 2018 face even greater health risks from the exponential mutation of antibiotic-resistant organisms. Importantly, many patients become exposed to these pathogens while under care in a hospital or other healthcare facility. "New data show that far too many patients are getting infected with dangerous, drug-resistant bacteria in healthcare settings," said former CDC Director Tom Frieden, MD, MPH, in 2016.¹

A fact sheet updated in 2017 by the World Health Organization (WHO) states:

"Antibiotic resistance is rising to dangerously high levels in all parts of the world ... A growing list of infections — such as pneumonia, tuberculosis, blood poisoning and gonorrhea — are becoming harder, and sometimes impossible, to treat as antibiotics become less effective ... Without urgent action, we are heading for a post-antibiotic era, in which common infections and minor injuries can once again kill."²

In light of this worsened threat, WHO offers some time-honored commonsense guidance for healthcare administrators, environmental services teams and sterile processing professionals to address this heightened risk:

1. Improve surveillance of antibiotic-resistant infections.
2. Strengthen policies, programmes [sic], and implementation of infection prevention and control measures.
3. Prevent infections by ensuring your hands, instruments, and environment are clean.

Although these goals are not new, and they seem straightforward, achieving them remains a complex, daunting, daily effort in many healthcare facilities.

Improvement through a factory model

In 2005, as a way to help hospitals better manage infection risk, improve sterile processing process quality and increase

productivity, we introduced a new process improvement methodology for healthcare providers called 100%³, which takes advantage of the similarities among all "factory" type processes and applies the same principles. The goal was for sterile processing departments (SPDs) to provide end product to their "customers" that was 100% complete, 100% clean and sterilized, and 100% on time, by applying quality controls, effective process management and continuous improvement programs. Since then, this type of method has been shown to be the best way to optimize medical device reprocessing, particularly for preventing avoidable infections. As a 2016 study³ showed, well documented and managed programs enable process teams to track data and key information, reduce process variability, and achieve repeatable results. This, in turn, significantly improves processes and reduces the risk of avoidable errors that, in the case of healthcare, can cost lives.

How is 100%³ doing in the real world?

The fact is that sterile processing quality and process management is more important today than ever before, and is even more relevant than 12 years ago. SPDs face greater task complexity, manufacturer and regulatory requirements, and clinical compliance issues than they ever have before. The question is: how well are they faring today, and have they made any progress overall?

From the SPD perspective, 100%³ is still relevant because it's in demand: the surgical department (OR) wants their case trays and reusable devices to be 100% complete, 100% clean and sterilized, and 100% on time. The five basic elements of factory production are still relevant as well. Let's take a look at where sterile processing departments are at implementing them.

1. Raw material quality control

The principle applied here is that the quality of the end product is directly related to the quality of the raw materials supplied. For hospitals, this step is unique in that the end user of the product (the OR) is also the

raw material supplier. It would appear to be in their best interest to supply the best possible raw material in order to receive the best possible end product. In an ideal world, the OR would return all instruments that were pulled for a procedure to the SPD in their original containers and with signed count sheets documenting the instruments being returned.

Unfortunately, the handling of dirty surgical instruments in the OR has seen little improvement in the last 12 years. While some ORs return instruments to the correct trays and provide “raw material” to the SPD that meets expectations, most ORs are pressured for quick turnovers, or feel that it’s more financially and operationally efficient for an SPD technician to reassemble the trays. In these cases, many SPDs attempt to keep all trays used in the same procedure together throughout decontamination and into the assembly process, in hopes of putting the puzzle of mixed up instruments back together. This is a sub-optimal process that can slow things down and impede the “on-time” goal, which in turn can affect OR scheduling.

2. Process flow design

Process flow can support or hinder a department’s productivity goals. Workflows must be designed to support the operation’s objectives (100%) and to react to changing customer requirements. They must have clearly definable and measurable process functions, and support quality improvement and documentation requirements. They must minimize product and employee movement and effort (be ergonomic), and maximize the use of automation and information technology (IT) support.

There have been improvements in new sterile processing workflow designs as a result of ongoing education, in the design community and among hospital SPD staff. All parties have learned more about how to create the most productive sterile processing workflow and how to advocate for the appropriate space and layout in their facilities. Departments have improved their physical workflow designs and put more thought into process designs and balancing the workflow. The introduction and use of LEAN concepts has also improved in the last 12 years, but there are still opportunities for greater improvement. Here’s what’s going on in specific workflow functions:

- **Push of decontamination and pull of assembly:** the push method is best utilized in the decontamination area, where the objective is to remove biohazardous material as

quickly as possible to improve processing outcomes and reduce safety hazards to personnel. The pull method is best for the assembly area, where items can be pulled and assembled to meet OR scheduling needs. Unfortunately, there hasn’t been significant progress in the understanding and application of this concept. We continue to see a range of performance. Well-run departments are managing the process flow so that the decontamination function keeps up with all dirty items being “pushed” through from the OR, while their assembly areas are ensuring items are “pulled” based on prioritized need and/or processed in a continuous flow so there are no backlogs. However, many departments are still struggling with daily backlogs because of inadequate staffing at peak volume times, or inadequate facilities for handling the work. Poor staffing affects timely handling of push volumes, effective tray prioritization based on OR schedules, and management activities such as quality measurement and continuous improvement activities (management may have to fill in to process trays instead of performing management tasks).

There is one piece of good news: prioritization of instruments has improved. Some facilities have implemented better manual methods, or installed instrument scanning software tied to OR scheduling systems that automatically determines priorities.

- **Minimizing product and employee movement:** We still find technicians facing frequent interruptions, having to walk to find missing items, and working in non-linear environments. Some SPDs have successfully assigned “navigator technicians” in decontamination and assembly areas who help maintain product flow, which allows other technicians to stay at their stations and focus on their work.
- **Segregating non-conforming from conforming product:** We’ve seen some improvements in this area as departments have incorporated processes to manage missing instruments and instrument trays waiting for ordered instruments. But there’s still plenty of room for improvement.
- **IT solutions to reduce variability, improve quality, and measure performance:** Unfortunately, IT systems are not being utilized as fully as they could be. Many departments are only using them to track volumes and sterilization information rather than leveraging the technology for process and workflow management.

- **Providing flexibility to meet requirements:** Due to staffing shortages and other set-backs, many departments have been forced to be reactive rather than proactive. They are working to keep up with the changes being forced on them, including new instrumentation (with new reprocessing instructions), new regulatory mandates and guidance, and changing or increasing customer expectations.
- **Measuring product and process quality, backlogs, throughput and productivity:** The process of measuring is where it was in 2005. SPD managers frequently produce counts of the quantity of items processed (as in 225 trays processed today), and they report errors, but proactive measurements of process quality, productivity and other factors continue to be a struggle. These higher-level functions are hampered by chronic insufficient staffing, which causes managers to be reactively “fighting fires” and jumping in to get work done. Many SPDs are still run as a day-to-day operation, providing what the OR needs today rather than developing a proactive, continuous improvement process based on metrics.

3. Quality management through process control

“Measure, measure, measure” – this is the mantra of quality management. Not surprisingly, SPDs still struggle to accomplish this at a level of detail that can lead to improvement. Improving quality through process control means understanding each process step, measuring performance, and then making improvements. This is a future goal for most SPDs rather than a current one. Examples of where they could be, but aren’t, include: documenting missing instruments by OR service, by tray, and by assembly technician, to better identify where improvement is needed; tracking productivity and product quality by staff and by assignment; and measuring compliance to manufacturers’ instructions for use (IFU) in the decontamination function. There are many opportunities to utilize IT to help measure and improve processes.

4. Asset management

The SPD’s assets include their equipment and their people, and the goal is to keep them all working as efficiently and productively as possible. To do this, the concept of *line balancing* was introduced to achieve the highest possible level of process quality. In the SPD, line balancing is achieved by optimizing the available capacities of the decontamination,

assembly, and sterilization functions while meeting the production demand from the OR. But in the last 12 years, most departments have maintained the same equipment and staffing level while being required to take on more and more work. In fact, staffing may have actually gotten worse. Recruiting and keeping qualified staff is a struggle that almost all SPDs face, and because of this their ability to staff their departments to maintain process flow suffers. Not only are they unable to fully staff their departments in general; they are unable to provide staff to coordinate with the arrival times of incoming work. This has led to a capacity strain in many hospitals across the nation. SPDs can no longer keep up with the demand, and are therefore backlogging daily. Determining whether the department is capacity balanced from decontamination through assembly to sterilization is no longer a priority, since every process step is overwhelmed and operating under capacity constraints.

In general, we have observed that the decontamination function in most SPDs is under-capacity for equipment and space, and is typically also understaffed; the assembly area is almost always understaffed to keep up with the workload, and thus requires 3rd shift staff to help and/or work overflows into the weekend; but the capacity of the sterilization function is still relatively good. However, the staff they do have doesn't align with the arrival of work, and managers are staffing too many technicians on 2nd or 3rd shift, so departments are still creating their own backlogs and struggling to keep up with customer demand.

The biggest area of concern that has emerged is in the decontamination area, where the increase in tray volume and the complexity of devices and cleaning requirements has left many SPDs incapable of complying with the IFU for their device inventory, or unable to keep up with unacceptable backlogs of work. This is a problem because errors made or rushing the decontamination steps for complex devices could result in residual contamination and ineffective sterilization, which increases the risk of cross-contamination and infection.

5. Order-based processing

IT tray-tracking software has helped this function to the extent that it has been implemented. However, the backlogs, lack of staff, and other issues facing today's SPDs have put them in a position of having to fulfill orders for what the OR needs within hours, rather than being able to plan for tomorrow or the next day. Order-based processing is meant to provide a proactive method to

ensure that customers have what they need when they need it. For example, there is an instrument tracking system available that, in addition to building in the OR schedule to help prioritize trays to process, also keeps track of instrument usage by day of the week, so it can proactively prioritize typically used trays beyond the OR schedule requirements and have them ready. Using this technology could help a department in multiple ways.

Facing the future

The last 12 years has seen the overall state of instrument reprocessing operations becoming more challenging for workers, supervisors, managers and hospital executives. With an uptick in hospital consolidations, it's no surprise that many systems are faced with what to do with five, eight, twelve, or even more SPDs in a system that are struggling. There has been a deterioration in available staff, which has had a negative impact on multiple fronts. Capacity has been stagnant, but work complexity and clinical compliance requirements have increased and all SPDs are struggling to handle the new challenges. And although there has been an increase in overall knowledge and use of lean concepts, there has not been enough progress to say that process management is now commonplace in SPDs.

On the good side, we have seen improvements in IT, process design and planning for new SPD construction and renovations. In addition, some facilities have implemented successful programs and been able to document process and quality improvements. For example, one SPD manager in Kentucky led a process improvement initiative aimed at providing 100% complete trays to the hospital's surgical department. The SPD documented tray completeness and the number of individual missing instruments through their instrument tracking system, and through their process improvement initiative were eventually able to show that 100% of their trays had achieved the goal of being 100% complete. Other facilities have achieved some success at streamlining processes and eliminating bottlenecks. These before and after photos featured on the right are the result of a department implementing the following process management techniques:

- Balancing the production lines
- Staffing technicians according to the workload arrival pattern to maintain continuous flow
- Assigning a technician as a "navigator" in decontamination and assembly areas to allow other technicians to stay at their work stations and work uninterrupted

- Ensuring on-the-floor supervisors have dedicated time to manage people and process versus being forced to process trays
- Measuring staff performance and work continuously to improve performance and productivity, and ensuring all staff understand the department's goals and their role in fulfilling them



Before



After

However, in order to fully benefit from sterile processing quality systems and continuous improvement, healthcare management needs to advocate for the importance of the sterile processing function as a key hospital productivity and patient safety component. There is a great need for well-trained SPD supervisors and managers who understand process management and are empowered to supervise and manage rather than doing the technicians' work. Once hospitals invest in SPD assets, IT platforms and quality improvement efforts, they can achieve greater process control, quality improvement and productivity. This, in turn will help them to achieve the goals and benefits of 100%. **HPN**

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3. <http://www.ormanager.com/process-improvements-raise-spd-standards-quality/>

CONTINUING EDUCATION TEST • JANUARY 2018

Is 100%³ still relevant for hospital SPDs?

Circle the one correct answer:

1. The World Health Organization recommends that hospitals strengthen policies and programs, and implement infection prevention and control measures, to better address the growing threat of antibiotic-resistant organisms.
 - A. True
 - B. False
2. In today's healthcare environment, SPDs are facing:
 - A. Manufacturer and regulatory requirements
 - B. Greater task complexity
 - C. Clinical compliance issues
 - D. All of the above
3. 100%³ includes what three basic surgical customer requirements?
 - A. 100% complete, 100% on time, 100% available
 - B. 100% complete, 100% clean and sterilized, 100% on time
 - C. 100% cleaned, 100% assembled, 100% sterilized
 - D. None of the above
4. In SPD production, the raw material supplier is also:
 - A. The manager
 - B. The reprocessor
 - C. The end user
 - D. The assembly technician
5. 100%³ is still relevant for SPDs because the surgical department wants their instruments to be 100% complete, 100% clean and sterilized, and 100% on-time.
 - A. true
 - B. False
6. Which healthcare department is accountable for poor raw material quality?
 - A. SPD
 - B. Device manufacturers
 - C. Surgical
 - D. None of the above
7. Soiled instruments should be pulled through the decontamination area according to customer demands, to remove biohazardous material as quickly as possible. Then the assembly area team can push the instruments through to sterilization.
 - A. True
 - B. False
8. Line balancing is achieved by:
 - A. Having definable and measurable process functions
 - B. Optimizing the available capacities of the decontamination, assembly, and sterilization functions
 - C. Being ergonomic
 - D. None of the above
9. Poor staffing affects
 - A. Effective tray prioritization
 - B. Management activities such as quality measurement and continuous improvement activities
 - C. Timely handling of push volumes
 - D. All of the above
10. Order-based processing is meant to provide a proactive method to ensure that customers have what they need when they need it. _____ can facilitate it.
 - A. Instrument tracking systems
 - B. More managers
 - C. Different processing equipment
 - D. A manual process

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