Case Study

A Lean Six Sigma Intervention to Optimize Sterile Processing

WakeMed Health Sees Faster Surgical Instrument Turnaround, Improved Employee Engagement and Savings from New Stryker Program

*WakeMed Health and Hospitals – Raleigh, North Carolina*
At a Glance

WakeMed Health and Hospitals in Raleigh, N.C., was an early client for the new Stryker Sterile Processing Optimization Program, a comprehensive process improvement solution designed to help transform the decontamination, cleaning and repacking of surgical trays and case cart build processes using Lean Six Sigma methodologies.

A baseline assessment of WakeMed’s Sterile Processing Department identified several improvement opportunities, including:

- Waiting time for the decontamination process was a staggering 884 minutes per surgical tray
- Instruments were placed in the wrong trays coming out of surgery, causing technicians to search for the “missing” instruments and adding five to 10 minutes of wasted labor per tray
- Time wasted in the case cart build process looking for available carts
- Finding specific trays needed to complete a set
- Filling out manual shortage sheets

Through an Assessment Phase and an Implementation Phase of the program, which included “Kaizens” targeting specific improvement opportunities, waiting time for beginning the decontamination process was reduced by 50% and direct labor was reduced by 25%.

Overall, WakeMed surgical and sterile processing leaders reported high satisfaction with the value of the Stryker engagement in helping to solve wait times, reduce the use of flash sterilization in the operating room and lower the cost of labor.
The Organization

WakeMed Health and Hospitals is an 870-bed not-for-profit health system with multiple facilities in the metropolitan Raleigh, N.C., area. The flagship WakeMed Raleigh Campus is a Joint Commission-accredited tertiary care regional referral hospital. It features Wake County’s first primary stroke center, a chest pain center, a Level I trauma center and a Level IV neonatal intensive care unit. Specialty facilities include a heart center, a children's hospital, a rehabilitation hospital, adult and children’s emergency departments and multiple high-level intensive care units.

Survey data for the latest year available shows that 162,171 patients visited the hospital’s emergency room. The hospital had a total of 36,062 admissions. Its physicians performed 9,710 inpatient and 16,330 outpatient surgeries.

Background

Sterile Processing Departments (SPDs) are typically divided into four major areas to accomplish the functions of decontamination, assembly and packing (“press and pack”), sterile storage and distribution.¹

In the decontamination area, reusable equipment, instruments and supplies are cleaned and decontaminated by means of manual or mechanical cleaning processes and chemical disinfection.

Clean items are received in the assembly and packaging area from the decontamination area and are then assembled and prepared for issue, storage or further processing.

After assembly or sterilization, items are transferred to the sterile storage area until it is time for them to be issued.

Several major functions are carried out in the distribution area: case cart preparation and delivery; exchange cart inventory, replenishment and delivery; telephone-order and requisition-order filling; and, sometimes, patient care equipment delivery.

With concern about hospital acquired infection on the rise, sterile processing departments today are the subject of higher levels of focus from the Association for the Advancement of Medical Instrumentation (AMMI) and the Joint Commission, which seek validated and standardized cleaning procedures and outcomes. One common thread is the potential overuse of Immediate Use Steam Sterilization (IUSS)—using an autoclave in the OR to “flash” sterilize surgical instruments rather than wait for an item from central processing. A major concern regarding IUSS is that its convenience may lead to nonemergent, inappropriate use. This abuse of IUSS has the potential to increase risk for development of surgical site infections, increased healthcare costs and even direct thermal injury to the patient.²

“Essentially when you are flashing instrumentation, you are taking shortcuts in the cleaning process,” said Clarence Byrd,
WakeMed’s Sterile Processing Department Manager. “So (standards agencies) really look at that and they look for track records of infection associated with use of IUSS and so forth. So yes it’s a big deal, and it’s something we really focus on heavily here at the hospital.”

Another issue of concern in today’s healthcare environment is a poor relationship between Surgical Services and the SPD.

“The traditional relationship between the operating room and the sterile processing/central service department is complex,” wrote Joseph F. LeBouef, who has served as both a certified surgical technologist and a sterile processing manager, and taught both topics. “The term ‘love/hate relationship’ has been uttered by many involved from each of these two teams. The two departments have an almost symbiotic existence, completely dependent on each other for success, yet communication and cooperation between them is often quite strained. Sometimes that communication can actually be quite hostile, if it really occurs at all.”

A New Solution

The new Stryker Sterile Processing Optimization Program is designed to help transform SPD processes using a comprehensive consultative solution to drive efficiencies, cost containment and process optimization by leveraging Lean Six Sigma methodologies.

WakeMed was the first healthcare organization to undergo both the Assessment and Implementation phases of the program.

The Assessment Phase begins with an onsite review of the SPD processes conducted by Stryker Lean Six Sigma and clinical experts to document current performance and identify improvement opportunities. Working with the Stryker team, the SPD uses the output from the assessment to create an improvement plan specifically tailored to meet its needs and those of its customers.

“This is essentially a consultative solution in which Stryker deploys two people, one who focuses on Lean Six Sigma and operational efficiencies, and another who focuses on clinical and chemical best practices—the latter provides the client with a kind of mini Joint Commission visit and assessment,” said Bill Higgins, Stryker’s Continuous Improvement Manager, who worked with WakeMed alongside Rod Parker, Stryker’s Senior Principal Scientist.

The Optimization Team goes on site with clients for four to five days, working alongside the supervisory staff as well as the general staff to really understand where the pain points are, what they’re doing right and not doing right, and whether they are using processes that are considered best practices. Then, the Stryker team works with the customer to develop an action plan to improve those processes.

The Sterile Processing Optimization Program Assessment includes the following elements:
• **Value Stream Analysis** of the information and product flows within the SPD processes, including queue times between process steps, for the purpose of identifying waste and quality issues.

• **Process Flow Analysis** of the area layout to help ensure the most efficient movement of people, information and materials to minimize the wastes of delay, motion and transportation.

• **Capacity Analysis** to determine if the SPD has sufficient manpower and equipment resources to satisfy customer demand.

• **A Clinical Compliance Assessment** provides an intensive review of equipment functions, cleaning, process flow and sterilization practices to determine compliance with the applicable clinical standards.

• **Chemical Analysis** focuses on current cleaning practice for optimal product longevity and performance.

• **Continuous Improvement Assessment** to establish a baseline of the Continuous Improvement Program maturity compared to benchmarks.

“From this we draw up a report and make a presentation on site to leadership regarding implementation of the changes,” Higgins said. “We may seek a cultural change from a Lean standpoint, and part of our offering are Kaizens (originally a Japanese management concept method of continuous incremental improvements). This is where we walk with them through the process of implementing change. We have a subset about 10 different implementations focused on sterile processing we can choose from.”

**The Challenge**

The Stryker team arrived on site at WakeMed in January 2015, and found a department in transition. A vendor had been running the SPD for many years, but WakeMed was in the process of taking the management of the department back in-house.

The value stream analysis of WakeMed’s sterile processing department found the waiting time for beginning the decontamination process was a staggering 884 minutes per surgical tray, the result of a series of downstream process problems. The value-added time for machine and operator cycle time was 120 minutes per tray. The ultimate goal is to eliminate queue time altogether and make the instrument sets available for the next surgery as quickly as possible.

Instruments being placed in the wrong trays coming out of surgery were causing the technicians to search for the “missing” instruments and adding five to 10 minutes of wasted labor per tray.
Eight to 10 minutes of labor per case, or six to eight hours per day, were being wasted in the case cart build process looking for available carts, finding specific trays needed to complete a set and filling out the manual shortage sheet.

The following observations were made during the Value Stream Analysis:

- Eliminated the past practice of 100% hand washing all instruments and limited hand washing to those instruments that are soiled or cannot be processed through the automated washers.

- There was a significant amount of operator to operator variation observed in how work was performed in both the decontamination and assembly areas. It was highly recommended that standard work be implemented for each of the major tasks to ensure each operator is performing the same work using the best method to improve efficiency and the quality of output.

- In the decontamination area the storage shelves next to the entrance door had trays, containers and pans stacked on top of each other, which is unsafe and creates a potential for instrument damage, requires multiple handling of trays and increases transportation distance due to the proximity to the wash stations.

- The decontamination technicians were instructed to manually clean tray containers even though the automated cart/tray container washer was idle most of the time.

- There was no visible process in place for linking work priorities in the decontamination area to customer demand.

**Before the intervention:** Case carts delivered to the Decontamination area were unloaded onto the shelves located near the entry door. At peak times, the shelves became overloaded, and trays were being stacked on top of each other, resulting in potential damage to the instruments and creating a safety hazard from falling trays.

**After:** Case carts containing six or more trays are no longer unloaded and placed on the shelf, which minimizes handling and eliminates stacking of trays on the shelf, preventing damage and eliminating a safety hazard.
There was also a culture of mistrust, said Sheldrick Streete, Director of Surgical Services for WakeMed. “People in the operating room felt as if the Sterile Processing Department should have full responsibility for all cleaning and handling of this rotation. There was not as much concern for whether we are in this together and all have some role to play in terms of cleaning and handling instrumentation. In addition, sterile processing also probably didn’t have as much respect for the work that was being done in the operating room to ensure that they would actually process instruments in a timely fashion.”

“It takes two to make this process run as efficiently as possible,” Byrd agreed. “It can’t just be the OR and it can’t just be the SPD; it has to be both. Our team spent so much time ordering new instrumentation because instrumentation was either misplaced or simply was not returned to us and we had staff wasting time looking for it. We were trying to work together on a process that would allow us to clean the instrumentation at the point of use.”

The Improvement Process

Following the onsite visit to the WakeMed Hospital Raleigh Campus to assess the SPD functions, interview staff and complete direct line observations, the Stryker Sterile Processing Optimization Team recommended a list of sterile processing optimization Kaizens. In each case a problem statement laid out the tangible and specific incremental improvement opportunity and a summary of the improvement.

Two examples include:

**Problem statement:** Trays were being unloaded from the case carts to a shelf rack, creating a potential safety hazard and resulting in increased transportation and multiple handling of the trays. The tunnel washer had insufficient capacity to process the daily volume of case carts and containers. And all instruments were 100% hand washed. The average distance the technician walked to process a tray was > 70 feet and the cycle time was four minutes per tray. Approximately 500 trays were processed through the decontamination area daily.

**Improvement summary:** Implemented the “Six Tray Rule”: If the cart contained six trays or more then the trays were left on the cart, which eliminated a potential safety hazard and multiple tray handling. Tray containers were removed from the OR prior to surgery, which minimized efforts required to disinfect the container and eliminated the tunnel washer bottleneck. One hundred percent hand washing was eliminated and only instruments that are excessively soiled or cannot be processed through the machine wash are being hand washed.

**Problem statement:** Case carts delivered to the decontamination area were unloaded onto the shelves located near the entry door. At peak times, the shelves became overloaded, with trays stacked on top of
each other, resulting in potential damage to the instruments and creating a safety hazard from falling trays. In addition, the process of unloading the case carts is causing multiple non-value added handling moving the trays to the shelf, consolidating trays on shelf, moving trays to cart, moving cart to sink.

**Improvement summary:** Case carts containing six or more trays are no longer unloaded and placed on the shelf, which minimizes handling and eliminates stacking of trays on the shelf, preventing potential damage and eliminating the safety hazard. The carts with six or more trays are moved directly to the sink for processing, minimizing walking distance for the decontamination technician.

“The interesting thing we learned was that WakeMed had already done an assessment of its issues with the OR and the SPD,” Higgins said. “They wanted us to come in and take a look and tell them what we saw without influencing us, and it turned out that what we identified as their main areas of opportunity were in line with what they had seen themselves.”

“I think with Stryker we pretty much knew what we were getting, but the surprise for us was how spot on Stryker was with their assessment, because it was what we had been saying all along,” Byrd said.

**Results**

Overall, the tray cycle time at WakeMed has been reduced by 50%. “This is something that we can actually see as we come into the department on a daily basis,” Streete said. “We used to have shelves basically loaded up with work in process. Now we walk through decontamination and those shelves are relatively bare. We have less need to have more storage space preparing trays because they are fewer dirty trays waiting to be cleaned. On the clean side the same thing exists. In the mornings we don’t walk in and see 50 or 60 trays dirty trays that are sitting from the day before, which then have an impact on the day of surgery where people spend a lot of time looking for trays and having delays occur as a result of that. We did at one point have that occur in the past.”

A total of a little more than $200,000 in direct costs annually were realized, though total savings in labor costs were far greater.

“The change in attitudes of the instrument technicians from our first visit is amazing,” Higgins noted. “Almost everyone seemed disengaged when we conducted the Baseline Assessment, but that totally changed after the improvements were implemented. Now everyone is engaged; they are excited about the improvements made so far, and they are talking about making even more changes. Best of all, they enjoy coming to work again.”
Some of the changes may appear minor, but had substantial benefit. “Visualization was something that Stryker pointed out for us, so we decided to color code our different containers by placing them on shelves that had the same color as the container lids, so that it would be easier for people when they came back to search for items to go to this location color,” Byrd said. “As a result, people are spending a lot less time searching for things.”
Overall, WakeMed OR and SPD leaders were impressed by the Stryker engagement. “I think the Stryker team that came to the site was very knowledgeable and had a full depth and breadth of the department and the process that should be occurring,” Streete said. “They were for the most part fully prepared to speak to accreditation issues and compliance issues and help walk us through some of those. So I’m very happy with the team that came out and were involved in the engagement.”