Improving Quality and Reducing Cost In the Sterile Processing Department with Lean

GOAL

The aim of this study was to show the impact of Lean in a sterile processing department.

SUMMARY

In this case study, a team of individuals with long experience in the application of the Toyota Production System (TPS) to industrial operations was engaged by a 400+ bed, acute care hospital to apply Lean principles to address SPD operational problems.

OUTCOME

The ROI for this six-month project exceeded 250%. The hospital saved $8,852 per month in replacement tool costs, as well as $31,360 per month in traveling staff costs. Cycle times were reduced from 21.6 hours to 12.8 hours (41% improvement), while errors per week were reduced from 32 to 17.7 (45%).

CASE STUDY OVERVIEW

The Sterile Processing Department (SPD) is often an "out of sight, out of mind" operation for many hospitals when things are going well, but this department can very rapidly become the center of attention when problems arise. For example, the situation may escalate rapidly into critical scenarios if SPD provides a contaminated instrument that can lead to infection or other adverse outcomes, or if the department is unable to provide an urgently needed sterile instrument in the midst of a life-threatening emergency. Even during normal operations, SPD errors may produce ongoing difficulties such as delayed surgery starts in the Operating Room (OR), surgeon dissatisfaction or turmoil in the OR from missing or poor-quality instruments.

Change management professionals often cite the benefits of a crisis to drive lasting improvement and culture change. In this Case Study, Operating Room personnel became increasingly aware of multiple errors in the instrumentation sets being supplied by SPD, including missing instruments, contaminated instruments, errors in the sterilization packaging, and mislabeled instrument sets.

In addition to these vital quality issues, SPD offers many opportunities to imbed hidden costs. For example, when SPD does not process instruments quickly enough to meet OR demand, a common way to keep up with OR requirements is to have extra instruments on hand. This approach "hides" the process inefficiency, but results in an excess inventory of instruments, which can represent a very substantial financial investment.

"Lean" is a proven method for process improvement that was developed and refined by Toyota over the last sixty years as the Toyota Production System (TPS), an approach that enabled them to become the world's highest quality, most productive automotive manufacturing organization. In the last ten years, several U.S. healthcare organizations have begun to employ Lean, with positive results in improved safety, quality, patient satisfaction, employee satisfaction, and cost. This paper describes how Lean has been employed to dramatically improve the performance at a hospital SPD. In this case study, a team of individuals with long experience in the application of TPS to industrial operations was engaged by a 400+ bed, acute care hospital to apply Lean principles to address SPD operational problems.[i]

As with all projects that are conducted in the true spirit of TPS, front-line workers from the SPD, OR and related organizations such as Facilities, IT, and Scheduling were fully engaged in this project. These individuals were given focused, hands-on training in the fundamentals of Lean, and then participated in front-line observations, mapping the current and future states, identifying improvement opportunities, and crafting the detailed Implementation Plan. The people who do the job know it best and are energized by the opportunity to participate in improving their daily work. Their enthusiastic acceptance of the Plan is critical to sustainability.

RESULTS

Figure 1 summarizes the results that were obtained in the first six months of this project. Annualized savings from reduced costs of temporary personnel ("travelers") were $376,320 and reduced costs of replacement instruments were $106,224. In addition, excess instrument inventory valued at over $100,000 was removed by selling some instruments, donating some to worthy organizations, and placing some in reserve to serve as future replacements. The ROI for this six month project exceeded 250%.

Measured Metrics	Project Start	6 Months Point	Improvement
Cycle Time	**21.6 hrs**	**12.8 hrs**	**41%**
Errors/Week	**32 errors**	**17.7 errors**	**45%**
Nurse Satisfaction (1-10)	**2.5**	**5.0**	**100%**
Surgeon Satisfaction (1-10)	**1.5**	**4.5**	**200%**
Replacement Tool Cost $ / month	**$19,844**	**$10,992**	**$8,852 / mo.**
Staff Cost (travelers) $ / month	**$71,104**	**$39,744**	**$31,360 / mo.**

Figure 1. SPD Results, First Six Months of Lean Process Improvement

Teams that are true to the core principles of Lean developed by Toyota focus on helping front-line workers learn the problem solving and process improvement skills that will help them on the path to continuous improvement. In this project, Lean coaches helped the SPD team develop the capability to make ongoing improvements after the consulting engagement was completed, including designing a revised workflow when new equipment was installed, continually reducing processing errors to a fraction of the original level, and implementing process efficiencies that eliminated the need for contract workers, or "travelers." In addition, one of the junior technicians that was a part of the initial improvement team performed exceptionally well and was eventually selected for advanced training and designation as one of the organization's internal Lean facilitators.

The remainder of this paper will describe:

- A Summary Description of Lean Process Improvement
- An Overview of a typical hospital Sterile Processing Department
- The specific work performed in this Lean SPD Case Study

SUMMARY DESCRIPTION OF LEAN PROCESS IMPROVEMENT

The purpose of Lean Process Improvement is to identify what is of value to the customer, and deliver it reliably, while minimizing the amount of material utilized and the amount of non-value-added effort expended. In the case of SPD, the mission is to deliver the correct sterile surgical instruments and goods to the Operating Room, Surgi-Center, or other areas requiring these items, in the right condition, and at the right time.

Lean is a competitive strategy, based on scientific principles, that is specifically designed to improve operational performance, eventually leading to a high level of performance called operational excellence. The Lean toolkit is a set of Principles, Systems, and Tools that are employed with deep respect for the people doing the work. The ultimate objective of Lean is continuous improvement through the relentless focus on the elimination of waste, by every person, at every level, on every process, every day. Mature Lean organizations have a built-in mechanism for coordinating these activities across the enterprise through a robust annual planning process.

To initiate the Lean journey in an operation such as SPD, experienced Lean practitioners use the process that was developed in the United States by Toyota in the mid-1990's to teach and sustain Lean in U.S. industrial operations. The Toyota Supplier Support Center (TSSC) called this process "shikumi", which roughly means "see as is; see as will be". This approach has been further developed and refined into the "VSAP", or Value Stream Analysis Process.

The VSAP differs fundamentally from the one-week "Rapid Improvement Event" featured by many consulting organizations in the United States. Deeply embedded issues may take much longer than five days to address, and instead may take many months of persistent effort to correct. Recognizing the importance of such longer-term issues, the Implementation Plan that results from a VSAP usually addresses action items that will take up to two years to complete. In addition, the objective of an effective Lean intervention is not limited to attaining a higher level of performance in the short-term and then merely sustaining it. The ultimate mission of Lean is to develop skills in the organization's employees that will enable them to embark on a path of continuous improvement. True Lean practitioners work shoulder-to-shoulder with client personnel to help implement the improvements, and then steadily decrease their involvement as client personnel develop the Lean skills to sustain and then continuously improve on the new level of performance.

Experience in healthcare has shown that front-line healthcare employees make greater progress on Lean Implementation Plans when they are helped by individuals who are experienced in Lean and who are focused specifically on the improvement effort. Healthcare professionals are fully capable of driving the improvements, but they work in a very dynamic and demanding environment, and may be confronted with urgent issues, unexpectedly and at any time. On the other hand, performance improvement requires a meticulous, relentless focus on implementing the improvements that have been identified. Teamwork between these front-line employees and an independent organization focused on Lean has proven very successful. The Lean organization may be an outside organization initially, but a key part of the organizational transformation must be for the hospital to develop its own internal Lean team as soon as individuals within the organization can receive the training, participate in a number of projects, and develop the skills to lead Lean process improvement activities successfully.

Another aspect of the partnership between the Lean team and healthcare professionals is the manner in which process changes are approved and implemented. People trained in Lean are knowledgeable in the methods for identifying and eliminating waste from a process; they are often not experts in the process details, particularly in the many diverse processes that exist in healthcare. Accordingly, the Lean team will be able to identify alternatives for improving performance, but the owners of the process technology must make the final decision on which changes can be made in compliance with all applicable legal requirements, industry standards and regulations.

OVERVIEW OF STERILE PROCESSING DEPARTMENT OPERATIONS

Recommended practices for SPD are provided by the Association for the Advancement of Medical Instrumentation and the American National Standards Institute in ANSI/AAMI Standard 79 ("ST79") "Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care

Facilities". The International Association of Healthcare Central Service Materiel Management (IAHCSMM) offers a certification for Certified Registered Central Service Technician (CRCST).

Figure 2 below depicts the layout and flow of instruments through a typical SPD.

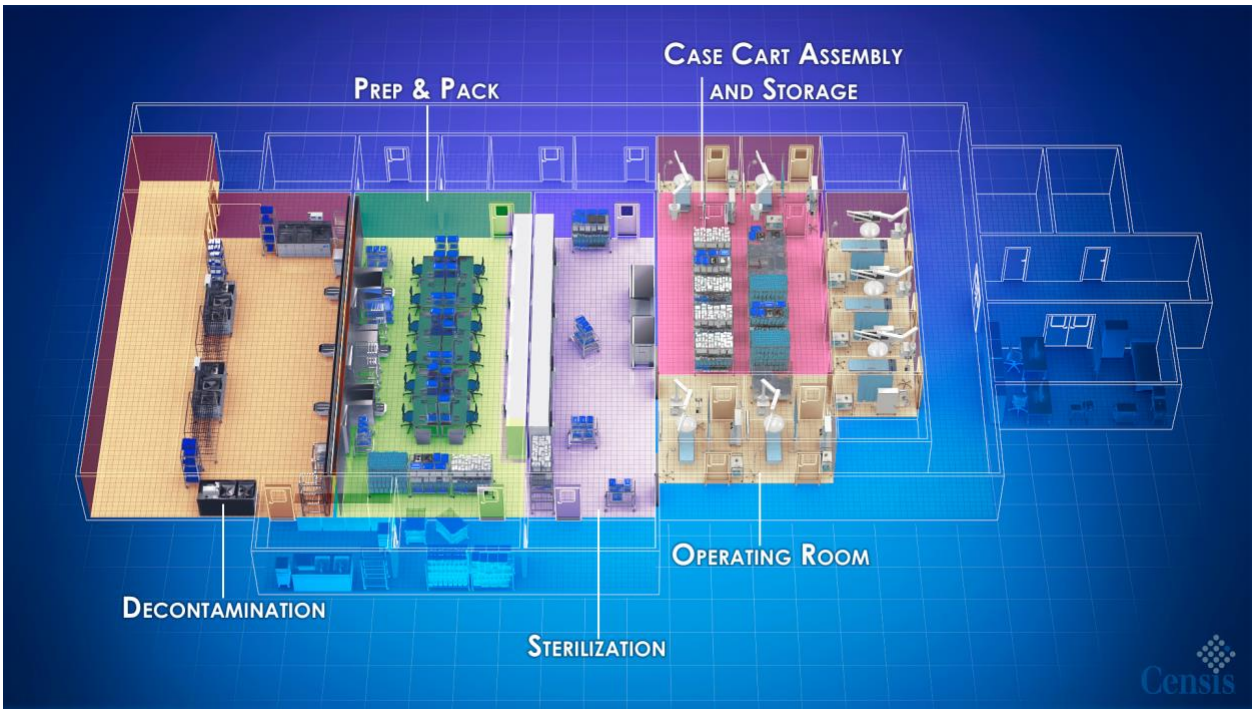


Figure 2. Typical SPD Layout and Work Flow [1]

The Decontamination area is pictured in orange. It is a "dirty" area, where contaminated instruments from the Operating Room (OR), Surgi-Center, or other areas that require sterile instruments are received and processed. The purpose of Decontamination, as defined by OSHA is:

> "The use of physical or chemical means to remove, inactivate or destroy blood borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is safe for handling, use or disposal." [2]

Workers must wear Personal Protective Equipment (PPE) for protection from the contaminants which instruments and other surgical support items have acquired during the surgery. Rigorous enforcement of PPE requirements must be practiced to prevent contaminants from being transmitted out of the Decontamination area. Workers in this area receive the instruments and other devices from the OR, break them down for cleaning, and perform a series of steps that includes a specified combination of hand-washing, ultrasonic cleaning, and processing through automatic washers. Most of the instrument sets pass through the automatic washers into the Prep

[1] "Principles and Design Considerations for Sterile Processes." Ron Blank and Associates, Inc.® 2008. An American Institute of Architects Continuing Education Program. Course Number: get11a (Getinge).
[2] OSHA CFR 1910.1030

and Pack area, with a small number of hand-cleaned items bypassing the washers and being passed directly to Prep and Pack.

The Prep and Pack area is designated in green. Items in this area have been decontaminated and are being assembled for sterilization in the next step of the process. Workers in this area wear PPE to prevent cross-contamination from being carried into this area when they enter.

In the Prep and Pack phase, workers carefully inspect each instrument and assemble them into sets in accordance with a recipe card provided for each type of instrument set. The sets are then wrapped in a sterile protective material and sent to the Sterilization area.

Sterilization is defined by AAMI as a "validated process used to render a product free from viable microorganisms", which includes bacteria, spores, fungi, and viruses. AAMI describes a steam sterilizer as a "sterilizer that uses saturated steam under pressure as the sterilant".

The Sterilization area is depicted in purple. Here items are sterilized and are ready to be placed in Sterile Stores, where they can be drawn by the Operating Room or other personnel to support scheduled surgeries.

These major steps in the process are illustrated in Figure 3, which illustrates the flow of instruments between the OR, SPD, and Sterile Stores.

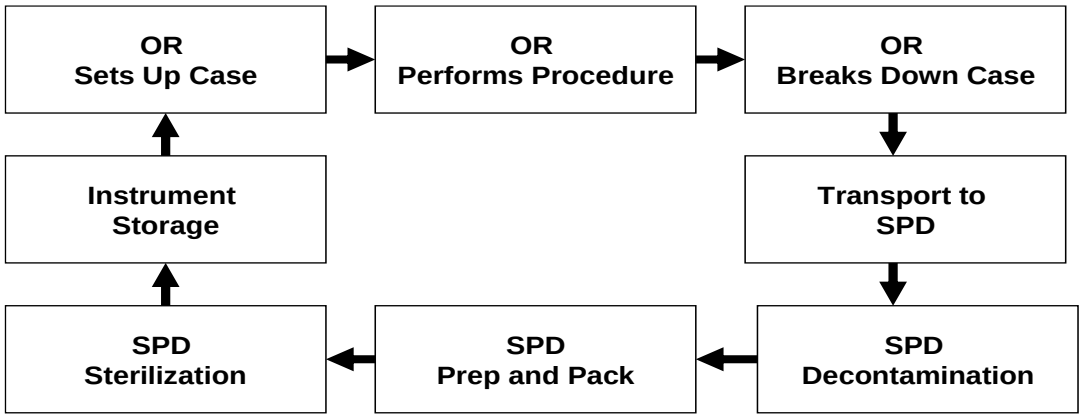


Figure 3. Overall Process Flow, OR-to-SPD-to-Sterile Stores Flow

Figure 3 illustrates the inter-connectedness of the OR and SPD, and consequently shows the opportunity for efficient operations through teamwork. For example, the OR team can make a tremendous contribution to good SPD operations by immediately placing instruments that have been used in the proper fluids to keep contaminants from solidifying before being delivered to SPD for processing. Similarly, SPD's close attention to recipe cards and other OR requirements can keep the OR team from having to search for missing instruments, often including drawing the SPD team away from their normal work to spend time helping the OR team on its search.

SPD SUPPORT SYSTEMS

Equipment reliability is an essential component of the high-performance levels achieved in a Lean process. Sterile Processing is a complex industrial operation that requires a reliable and ample supply of a number of high-quality elements to assure successful equipment operation. This includes:

- Pure water, either de-ionized or reverse-osmosis, as specified by equipment manufacturers

- Steam that meets the purity and chemical requirements specified by equipment manufacturers
- Electrical power and compressed air to fully support SPD operations

Facilities must also support SPD operations with many specific operational requirements. This includes lighting that has adequate power and proper placement to support effective quality inspections, and ventilation design and operation to support the isolation of various contaminants to their designated areas.

SPD equipment such as ultrasonic cleaners, automatic washers, and steam sterilizers require a well-designed, rigorous preventive maintenance program, performed by highly trained and experienced technicians to assure that the equipment is ready to operate properly when needed in the process.

Lean Process Improvement aspires to meet customer needs reliably, and to do so with the fewest possible non-value added actions and minimal materials. The support systems identified in this section are essential components of SPD's mission to deliver the correct materials to the OR, in the right condition, at the right time.

LEAN SPD CASE STUDY

The key elements of the Lean SPD Case Study were:

- Value Stream Analysis Process
- Process Flow Analysis
- Implementation Plan
- Problem Solving

Value Stream Analysis Process (VSAP)

Planning for the VSAP begins several weeks before the actual event, as the hospital Executive Sponsor and Project Sponsor are designated, preliminary walk-throughs of the designated space are conducted, the appropriate team is assigned to the effort, and facilities such as a conference room and needed supplies and audio-visual capabilities are designated. It is vital that this planning proceed thoughtfully and methodically, as each component mentioned has a vital effect on the success of the effort.

The goal of the VSAP is to achieve the following objectives:

- Develop one consistent and universally accepted view of the process by integrating the disparate system understanding of different observers
- Specify in detail the Current State of a process, including detailed information on the times required for various process steps, the throughput for each step and for the entire process, and identification of process constraints
- Lead a detailed investigation and brainstorming for how the process can be improved
- Set specific project goals for improvements in the appropriate combination of safety, quality, patient satisfaction, employee satisfaction and cost parameters
- Build a detailed Implementation Plan for the improvements, including responsibility and time frame for accomplishment
- Develop a vision of the Future State of the process, which drives the goals for the process improvement activity

The VSAP for an SPD typically requires five full days of effort by a multi-disciplinary team that includes representatives from all areas that touch the process, for example:

Director, Perioperative Services*	Director, Materials Management*
OR Nursing Manager*	OR Surgery Tech
Ambulatory Surgery Nursing Manager	SPD Manager; SPD Supervisor*
SPD Technician(s)	Case Cart Coordinators
IT	Senior Union Representative (as appropriate)
Surgeon(s)*	Executive Management*

Individuals designated with an asterisk are in leadership positions and typically attend a meeting at the start of each day, have lunch with the team, and attend the end-of-day meeting. It is essential that they attend the final Report-Out on the last day of the VSAP. This approach permits these individuals to stay fully abreast of project developments and still spend most of the day attending to their assigned responsibilities.

Highly interactive, cross-department discussions form the core of the VSAP. In virtually every case, representatives from different departments and operations enter the process with little belief that they will learn anything new. However, people very quickly begin to realize that their view of the process is tightly focused on their own area, and they have not previously had the opportunity to think deeply about how their actions affect others, or how the actions of others affect them. This thorough, detailed mapping of the "as is" process is heavily sprinkled with visits to the workplace for first-hand observations and measurements. This very strongly reinforces the Lean principle to "go see" the problem in the workplace, as opposed to just sitting in a comfortable conference room talking about it. In the case of Lean projects in SPD, process observations require donning PPE and spending considerable time in the Decontamination, Prep and Pack, Sterilization, Sterile Stores, and OR areas.

Process Flow Analysis

A key Lean concept is One-Piece-Flow, which essentially means that in the ideal state, material (in the case of SPD, instruments) moves constantly through the process without having to wait at any step. Visualizing this perfect state helps the process analysts to see the waste that is keeping material from being in constant forward movement.

One of the first observations in this SPD project was that the OR was waiting until several surgeries had been completed before taking the instruments down to SPD, the step that is shown as "Transport to SPD" in Figure 3 above. The instruments are moved in large stainless-steel surgical carts called Case Carts. It seemed logical to wait to take the Case Carts down to SPD until a few had accumulated, because this minimized the number of times that OR personnel had to travel on the elevator down-to and then back-up-from SPD. This is called waiting for a "batch" of material to accumulate before moving it to the next step in the process.

However, the process is inter-connected, and the result of taking Case Carts to SPD in batches gave SPD very wide swings in their workload. The team was either completely underutilized with no processing work to do while several Carts accumulated upstairs in the OR, or they were flooded with work when all of a sudden, a deluge of carts appeared. Not being able to work at a steady pace caused considerable dysfunction in Decontamination operations, which resulted in errors, inefficiency, and frustration on the part of the workers.

As this project proceeded, training was provided in the form of a simulation that measured performance in a process of building in batches of 10, then batches of 5, and finally batches of 1 (or one-piece-flow, where workers "make-one, move-one"). It often seems counterintuitive, but the simulation proves conclusively that the one-piece-flow process produces the highest quality with the lowest cost compared to batch processing.

SPD performance improved significantly when the OR stopped batching their delivery of Case Carts to SPD. While any change like this naturally meets with resistance as employees have to alter long-established habits, SPD and OR leadership gave front-line support for this vital change, and the entire organization quickly began to understand and support the substantial quality, schedule, employee satisfaction, customer satisfaction, and cost improvements that resulted from this important step.

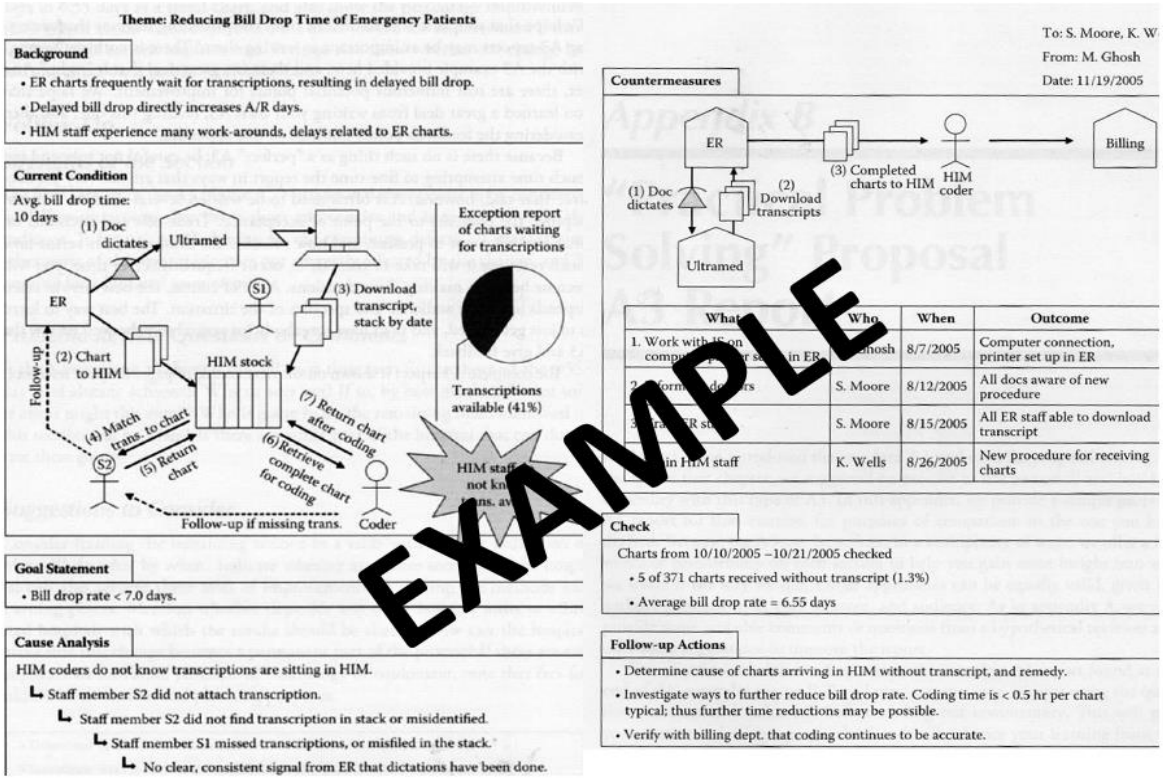
Implementation Plan

Each improvement that is identified during the VSAP is catalogued for future inclusion in the Implementation Plan. Once the entire list is completed, a comprehensive review may result in the combination of some items, or the development of additional items based on further discussion and review.

Experience has shown that the Implementation Plan resulting from an Censis VSAP can be an effective approach for driving process improvement for one to two years, after which time another VSAP is typically conducted to refresh information and continue on the path of improvement. The organization must have the capability and focus to keep working persistently on the Implementation Plan to achieve the full benefits of this work.

Problem Solving

Some of the items on the Implementation Plan are very straightforward and readily achievable, and these are called "Just Do It's". However, many of the items will require the use of a standardized Problem Solving approach, for which Toyota uses the A3 Problem Solving Methodology described in Understanding A3 Thinking: A Critical Component of Toyota's PDCA Management System by Professor Durward K. Sobek II and Art Smalley. The A3 approach is based upon the Plan-Do-Check-Act method of problem solving, and requires that those working on a solution distill their reports on to one page of A3 paper, as shown in Figure 6 below:



Ref: "Understanding A3 Thinking." Durward K. Sobek, II and Art Smalley. Productivity Press. 2008.

Figure 6. Example of an A3 Problem Solving Activity

The A3 Problem Solving Methodology can employ a number of problem-solving tools that help teams understand their problems more completely, identify the root cause, and then craft an implementation plan to eliminate the cause, test the results, and institutionalize the improvement once it has delivered the desired results.

Two of these tools that were particularly helpful in the SPD project described here are showing in Figures 7 (a Pareto Diagram of causes of customer dissatisfaction) and 8 (a Fishbone Diagram identifying all possible causes of Cannula Lumen Contamination).

In this SPD project, the Pareto Diagram illustrated in Figure 7 below was prepared from data that was consolidated from customer satisfaction surveys, and clearly indicated that the top issue was "missing instruments."

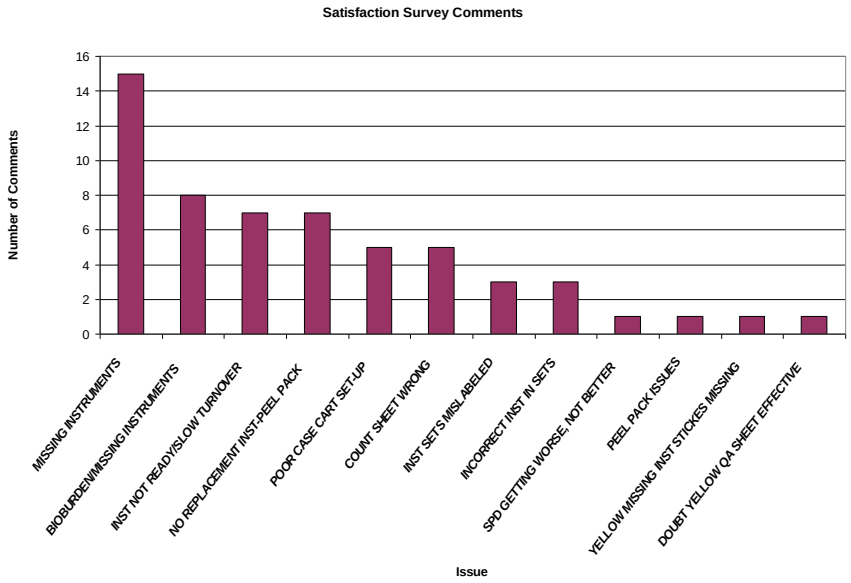


Figure 7. Pareto Diagram Showing Customer Satisfaction Survey Results

The Fishbone Diagram in Figure 8 below was developed through considerable brainstorming efforts on the part of the team to identify all possible causes of the recurring error of Cannula Lumen Contamination. This diagram then served as an effective tool for tracking the progress of subsequent problem-solving activities.

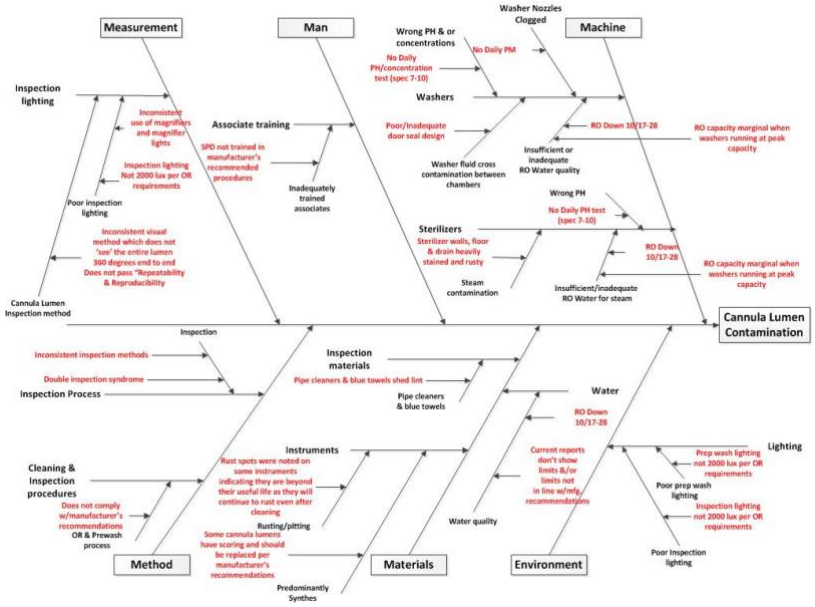


Figure 8. Fishbone Diagram; Possible Causes of Cannula Lumen Contamination

These problem-solving tools help steer the team to compile and rely upon data to develop and solve the root cause of the issue, and to proceed in a thorough, meticulous manner to develop robust solutions.

SPD BEFORE AND AFTER

A true Lean workplace is designed with effective Visual Management, meaning that any deviation from standard practice is instantly recognizable. The figures below illustrate the power of visual management through "before" and "after" pictures of various SPD areas. In Figure 9, the Decontamination area is cluttered with case carts that have been sent in a batch from the OR to SPD, instead of sending them using the principles of one-piece-flow.

Figure 9. Decontamination Area Before the Lean Project.

Figure 10. Decontamination Area After the Lean Project. [3]

Figure 10 is the same area after the completion of the Lean Project described in this paper. Key improvements include:

- The ability to see clearly the flow of instrument carts coming from the OR to SPD, which tells the team if they are ahead or behind in the work and if additional personnel are

[3] In Figure 10, the team has installed temporary tape on the floors to show where the case carts should be, which work is the next to be accomplished, and if work is being accomplished on schedule. The tape was a temporary expedient to implement the improvement and check its effectiveness. The hospital team is responsible for assuring Regulatory Compliance, and for implementing a permanent solution for these lines once the improvement has demonstrated its effectiveness

needed here to help meet customer demand; Removal of many unnecessary items from the workflow contributes immeasurably to this ability for all observer to "see" the process status immediately

- Designing a new position on the Decontamination Team whose job is to perform tasks that would take the worker away from working on instruments, which permits that worker to stay in one place
- Implementation of Standardized Work at all stations, and elimination of waste in process steps
- Integration of inspection tasks into the workflow, and implementation of improved facilities, such as brighter lighting, to support these vital inspections

Notice how much more orderly the area is in Figure 10 and how readily the process provides visual cues of whether the team is ahead or behind schedule.

CONCLUSIONS

Lean Process Improvement methods that have proven successful in industrial settings in the United States over the past thirty years are being introduced into healthcare, and offer a robust approach to improving safety, quality, patient satisfaction, employee satisfaction, and cost. The Processes, Systems and Tools that comprise Lean work well in healthcare settings, and are readily adapted by healthcare personnel. Development of a culture that supports the mindset of continuous improvement is essential to sustaining and extending the gains from Lean Process Improvement efforts. Strong leadership and vision from the top of the organization are essential to sustainment, and equally important are robust processes to encourage, support, and reward employee engagement.

This SPD Case Study details the exceptional results that have been achieved by applying this approach to the Sterile Processing Department of a 400+ bed acute-care hospital. The project contributed to dramatically improve quality and customer satisfaction, and it achieved a return-on-investment of over 250% in six months. Finally, by emphasizing the transfer of Lean skills and knowledge, the Lean coaches helped the SPD team develop the capability to sustain the new system and to embark on the path of continuous process improvement.

Censis™

[i] *All case study content provided through partnership with* Operational Performance Solutions, Inc.