SELF-STUDY SERIES

Toyota manufacturing processes in healthcare

An overview of lean transformation in sterile processing

by Monique L Jelks, BA, CRCST

There has not been a change in America’s healthcare system like the one ignited by the Patient Protection and Affordable Care Act (PPACA) of 2010 since Medicare and Medicaid became law in 1965. The PPACA not only requires that all Americans have healthcare insurance but that all healthcare organizations improve inefficiencies and provide quality healthcare that is affordable.¹ The requirements of the law have forced healthcare leaders to address deficiencies in quality and efficiency of their organizational processes for both direct and indirect patient care services. In order to address such concerns and meet the demand of the PPACA many top healthcare executives have chosen an approach successfully used in manufacturing known as lean transformation.

What is lean transformation?

Developed by Japanese automaker Toyota, lean transformation is an approach used to improve organizational processes by eliminating waste.² Lean transformation is a quality improvement process that incorporates less human effort, less inventory, less time to produce a product or service, and less space in order to be highly efficient and responsive to customer demands all while producing top quality products.³ For many healthcare workers, like sterile processing technicians, this sounds preposterous. After all, our number one customer is the surgery department where customer demand is high and changes are frequent; therefore we need more space, more resources and more time. Right?

Lean transformation is the process of changing something large into something smaller with a discipline of continuous improvement and respect for people.² If you are old enough to remember when cell phones first came out they were huge and there was no possible way it would fit into the back pocket of a pair of jeans. If you were to tell someone back then that one day in the near future you would be able to look at them while talking to them on the phone they would say that sounds preposterous. Eliminating waste, value stream mapping, rapid improvement events (RIE) and A3 problem solving are all lean tools and methods that can be used to successfully transform sterile processing departments into highly efficient service providers of quality sterile surgical instrument sets.

Eliminating waste

The process of continuous improvement involves the elimination of waste in the steps of a process.² The Japanese word for waste is muda.³ Waste is identified as non-value added steps from the perspective of the customer.⁴ While the patient is an indirect customer of SPD, the direct customers are patient care providers in surgery, L&D, and minor procedure areas that rely on SPD to provide terminally sterilized instruments to aid in the care of patients. To help remember waste as a non-value added process step, a lean acronym called DOWNTIME can be used to help identify forms of waste.⁴ (See Figures 1 and 2.) DOWNTIME is defined as follows:

- **Defects** — Products and or services that do not meet the needs or requests of customers. In SPD, defects are mislabeled sterilized instruments.
- **Overproduction** — Providing products or services that aren’t truly needed by the customer. For SPD, this could be instruments that are often requested for surgery and rarely used and require re-sterilization.
- **Waiting** — Idle time between processes also paired with delays. Waiting on biological test results in SPD is not uncommon and can potentially delay the start of surgery.
- **Non-utilized talent** — Under-utilized skills and potential of employees. This waste can exist in SPD when technicians are not trained to perform in all process areas. Technicians for instance who are only

**LEARNING OBJECTIVES**

- Explain lean transformation.
- Describe non-value added waste.
- Explain how lean tools are used for improving SPD.
- Describe lean problem solving techniques and methods.

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trained to perform decontamination and set assembly processes create limitations in the department’s ability to perform efficiently when productivity is high and staffing is low.

Transportation — The act of moving materials from one place to another. This form of waste in SPD can be the pick-up and delivery of clinic instruments from various locations.

Inventory — Excessive duplication of supplies in temporary storage areas (drawers, closets, etc.). A continuous review of frequently used packaging products for steam sterilization can help reduce the ordering quantity as well as reduce or eliminate products that are seldom used.

Motion — Unnecessary movement of people and or equipment. For SPD, this can be the frequent interruption of set assembly to search for and replace missing instruments.

Extra processing — Extra unneeded steps used to achieve a result. An example of extra processing in SPD could be the use of extended steam sterilization cycles for sterilization of all implants. Sterile processing leaders and technicians should always follow the manufacturer’s Instructions For Use (IFU) for each medical device to ensure the appropriate cycles are used to achieve sterility, and to eliminate unnecessary cycle extensions.

Le Creux Healthcare: 8 Wastes

- Defects: Efforts caused by rework, scrap, and incorrect information.
- Overproduction: Production that is more than needed or before it is needed.
- Waiting: Wasted time waiting for the next step in a process.
- Non-Utilized Talent: Underutilizing people’s talents, skills, and knowledge.
- Transportation: Unnecessary movement of products & materials.
- Inventory: Excess products and materials not being processed.
- Motion: Unnecessary movements by people (e.g., walking).
- Extra-Processing: More work or higher quality than is required by the customer.

Mapping out SPD processes

Lean transformation begins with a process called value stream analysis. A value stream is a lean mapping technique used to review workflow processes to ensure efficient delivery to customer demand by identifying excessive waste.\(^1\) There are many ways in which the map is physically designed. One of the most popular ways of designing a value stream map is by using 3M Post-it Notes of various colors to identify particular tasks and transitions in a process. (See Figure 3.) For example, decontamination Post-it Notes can be green while machine washed processes are yellow and manual cleaning is orange. The colors allow for great visual management of SPD process steps and the ease of explaining them to individuals who are not sterile processing professionals. The mapping process of the value stream is done by front line leaders and employees who actually do the work. After all processing steps have been identified, everyone must work together to locate both wasted and value-added steps in the process. Value-added steps are processes considered of great value for the customer.\(^4\) For SPD, value-added steps are those processes that are both required by regulatory agencies and customer satisfiers. For instance, value-added steps could be the placement of a lot control number on every sterilized package (as required by AAMI ST79) and sterilized sets that are complete with no missing instruments (customer). Lean transformation focuses on the improvement of value-added process steps for better performance, quality, and reduced cost.\(^4\)

Burning platform or simply room for improvement

Once value-added process steps are identified, the value stream mapping team members must put into place a plan to improve those steps identified. Prioritizing what to improve first will also be from the perspective of the customer as the team must ask the following question: Do we have a burning platform or simply room for improvement? A burning platform is a process that is in urgent need of problem solving. For SPD, this could be the lack of instrument sets available for the number of scheduled cases causing surgery delays, increased priority “stat washing” decontamination processes, high use of immediate use steam sterilization processes, and frustrated sterile processing technicians trying to keep up with the demand. Room for improvement in SPD could be the organization of the backup instrument area (cabinets, wall, drawers, etc.) to improve the ease of finding replacement instruments for sets that frequently return to the decontamination area of SPD missing instruments, such as towel clamps, adson forceps and allis clamps, just to name a few.

What makes a problem a burning platform versus room for improvement is determined by collecting data to analyze the frequency of the problem and the amount of subsequent barriers to performance that the problem causes. To extinguish the burning platform or reduce the room to improve, a four-day lean transformation event known as a rapid improvement event (RIE) is organized.

Rapid improvement event (RIE)

A rapid improvement event is a Toyota method used to facilitate continuous improvement by repetitive problem finding, problem solving and solution retention within four to five days.\(^5\) The Japanese word for continuous improvement is kaizen.\(^6\) An RIE involves a team-based method of front line leaders and employees who actually perform the processes in the map to eliminate waste, identify solutions, and perform experiments that test possible solutions for implementation of a lean transformed process.\(^9\) Stating the reason for action, a burning platform or need for improvement is the first step of the RIE. The following actions for the four-to-five-day event are mapped out using a lean document called an A3.
A3 problem solving
A3 is the form Toyota uses to improve the value-added process steps identified in the value stream map. A3 is a simple problem-solving approach that fits on a single sheet of paper. Interestingly, A3 is a form named after its large paper size (11 x 17 inches) used to outline the process that will be transformed. The A3 form has seven and sometimes nine boxes that guide the RIE team members through the problem solving process of lean transformation. (See Figure 4.) In the RIE, one person must serve as a team leader to ensure the boxes are followed step by step and the team remains focused on the problem to be solved. This can sometimes be a challenge as often times solving one problem will reveal more room for improvement. The following titles of seven A3 boxes in respective order guide the RIE team through the lean transformation process:

- Box 1: State the problem
- Box 2: Current condition (what issues do the problems cause?)
- Box 3: What’s the goal?
- Box 4: What's the root cause?
- Box 5: Proposed counter measures
- Box 6: Plan (What is the improvement plan?)
- Box 7: Follow up and Review.

Why ask why?
While boxes one through three are pretty self-explanatory, boxes four through six are where the problem-solving process really begins. Box four, the root cause analysis, is the process of getting to the root cause of the problem. The method of getting to the root cause of a problem is by asking why five times. For example, for the problem of frequent immediate use steam sterilization (IUSS), the five whys are as follows:

**Why #1:** Why are we frequently using IUSS?
**Answer:** Because surgery needs instruments urgently.

**Why #2:** Why does surgery need instruments urgently?
**Answer:** Because the patient is on the table.

**Why #3:** Why is the patient on the table without available instruments?
**Answer:** Because SPD does not know when cases are added to the schedule.

**Why #4:** Why doesn’t SPD know when cases are added to the schedule?
**Answer:** Because the electronic schedule does not show surgery cases added after 4:00 p.m.

**Why #5:** Why doesn’t the electronic schedule show surgery cases added after 4:00 p.m.?
**Answer:** Because the surgery scheduling office closes at 4:00 p.m.

After asking why five times, we learn that the root cause is no one is in the scheduling office to add the patient to the electronic schedule that is viewed by SPD. The root cause is the real problem that RIE team members must aim to transform.

Experimenting with possible solutions
Box five is “proposed counter measures.” Counter measures are the possible action or actions taken to prevent routine mistakes. The Japanese word for mistake proofing is *Poka-yoke.* During the RIE, the team will identify and experiment with possible solutions to reduce or eliminate the problem. In order to be certain that the solution has a high probability of improving the process, the RIE team members must go where the work is done and perform experiments with the proposed solution. Once experiments prove successful, a plan (box six) for implementing the new lean transformed process is organized.

Box six is the plan for implementing the most successful experiment. The first step of the plan is to communicate the implementation plan to all employees directly involved with the work to be done. A great plan is subject to fail if no one knows about it. An RIE creates change and new processes. A major concern with change is learning about the change and adapting to the changes made; therefore all members of the RIE must be involved in communicating the new lean process to fellow employees as well as help their team members to adapt to the new process.

Box seven is follow up and review. Lean transformation is a change process and successful change takes time. Therefore, an ongoing follow up is needed to ensure the changes are adaptable and sustainable. As everyone begins to perform the new process, there may be a need for some adjusting. Therefore, weekly reviews and communication with employees who are doing the work is key for lean success. Continuous improvement and respect for people is the core around which a successful lean production system is built; therefore, everyone’s ideas, suggestions, and opinions are equally important. Engaged employees are dedicated and productive; so remember to celebrate the success of your lean transformation.

Summary
Healthcare organizations are forced to improve quality, efficiency and cost by the PPACA. Organizations that seek such improvement may benefit from the successful approaches that exist in other industries like lean transformation used by Japanese manufacturers. Toyota’s lean transformation approach is a continuous improvement process of eliminating waste and involving employees who do the actual work in problem solving and implementing newly improved processes. Whether the need for improvement is a burning platform or just room for improvement, there are many lean tools that can be used to facilitate a lean transformation. The best way to ensure a successful lean transformation is communication.

Conclusion
Sterile processing can easily be considered the manufacturing hub of every hospital and surgery center where instrument sets and equipment go through a standard of care in reprocessing daily. The non-regulatory standards created by SPD leaders, technicians and customers make for a great opportunity to use lean transformation to eliminate waste and improve quality, efficiency and cost. A philosophy of continuous improvement and respect for people can assist SPD technicians with their goal of providing its customers with complete and terminally sterilized instrument sets at the point of need.
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Circle the one correct answer:

1. Lean transformation is a quality improvement process that eliminates waste.
   A. True   B. False

2. Lean transformation was developed by Japanese automaker Toyota.
   A. True   B. False

3. The Japanese word for money is muda.
   A. True   B. False

4. Asking the word why five times will not get to the root of the problem.
   A. True   B. False

5. A value stream is a lean mapping technique used to review workflow processes.
   A. True   B. False

6. One popular way of designing a value stream map is with the use of 3M Post-it Notes.
   A. True   B. False

7. Value-added process steps are considered of great value for the customer.
   A. True   B. False

8. An RIE is a really involved employee.
   A. True   B. False

9. An A3 is a simple problem-solving approach that fits on a single sheet of paper.
   A. True   B. False

10. All members of the RIE team are responsible for communicating the implementation plan of the new lean process.
    A. True   B. False

References:
9. Cardillo JK. Tools of Toyota Lean/Rapid improvement events which are successful and contribute to quality improvement in a hospital. California State University, Long Beach; 2010.

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