Review Article

Using Lean Process Improvement to Enhance Safety and Value in Orthopaedic Surgery: The Case of Spine Surgery

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Abstract

Lean methodology was developed in the manufacturing industry to increase output and decrease costs. These labor organization methods have become the mainstay of major manufacturing companies worldwide. Lean methods involve continuous process improvement through the systematic elimination of waste, prevention of mistakes, and empowerment of workers to make changes. Because of the profit and productivity gains made in the manufacturing arena using lean methods, several healthcare organizations have adopted lean methodologies for patient care. Lean methods have now been implemented in many areas of health care. In orthopaedic surgery, lean methods have been applied to reduce complication rates and create a culture of continuous improvement. A step-by-step guide based on our experience can help surgeons use lean methods in practice. Surgeons and hospital centers well versed in lean methodology will be poised to reduce complications, improve patient outcomes, and optimize cost/benefit ratios for patient care.

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The manufacturing industry developed lean methodology to increase output while decreasing costs. Lean methods revolutionized manufacturing in Japan, where productivity gains led to Japanese domination of the manufacturing industry in the late 20th century.[1] Today, American manufacturing companies that use lean methods include Boeing, Intel, Ford, Nike, Caterpillar, John Deere, and Kimberly-Clark. The service industry has also adopted lean methodologies, although the core strategies must be modified to fit the service paradigm. Prominent examples of service industry companies that have used lean management include Southwest Airlines, Taco Bell, Fujitsu, and Walmart. Motivated by the productivity and customer satisfaction gains made with the use of lean methods in the manufacturing and service sectors, several healthcare organizations have attempted to adopt these methods in patient care.[2]

Principles of Lean Methodology

Many of the principles of the lean methodology originated in Japan, particularly in the Toyota Production System (TPS).[3] Lean methods center around continuous process improvement through incremental change (*kaizen* in Japanese),[4] systematic elimination of waste, prevention of mistakes, and empowerment of every worker to stop the process if a deficiency is discovered in the system. TPS hinges on the just-in-time principle, whereby production should perfectly match customer demand. At a granular level of production, TPS aims to perfectly match demand at each step of production to prevent waste.

Lean management relies on the development of so-called standard work, which is based on the concept that any process can be categorized into discrete steps. Each work step is then detailed according to (1) the responsible operator, or the person conducting the work; (2) the task, or the work itself; and (3) a check process to ensure that the work is performed at the expected level. Taiichi Ohno, one of the originators of lean methods, famously said, "Without standards, there can be no improvement."[2] Any work process is thus defined by the standard work. Subsequent incremental improvements are made in each discrete step of the process to improve the entire process. Ohno defined five aspects of a lean process: (1) defining value, in which managers are responsible for identifying what is valuable to the customer; (2) value stream mapping, whereby managers outline the standard process from the standpoint of the value delivered in each step of the process; (3) flow optimization to maximize the value delivered at each step; (4) pull, whereby demand at the next step of a process drives the flow of the previous step in the process; and (5) continuous improvement through serial, incremental changes.[5]

In the service industry, the concepts of continuous improvement[6] and respect for people are central to the application of lean management. The focus remains on the reduction of waste. In the service and information industries, waste can be categorized into eight discrete types similar to the seven areas defined for waste in the manufacturing industry[2] (Figure 1). In health care, the principles of preventing mistakes and maximizing customer value are particularly important.[7]

Lean Methods in Health Care

Lean methods have been implemented in nearly every type of healthcare facility, from trauma hospitals to pediatric centers; in systems ranging from large health systems[8,9] and academic centers[10] to regional medical centers[11,12] and ambulatory centers;[13] and in fields such as nursing care,[14] laboratory,[15] pathology,[16] and radiology.[17] These methods have proved particularly powerful in surgical arenas, including implant procurement,[18] perioperative care,[19] and standardization of operating room management and work flow.[20]

One of the first healthcare institutions that implemented lean methods is Virginia Mason Medical Center in Seattle, Washington.[2] Beginning in 2002, the institution systematically applied lean methods throughout the medical center with dramatic results. The Virginia Mason Production System (VMPS)[21] is an adaptation of TPS to health care. As a result of the VMPS, the incidence of ventilator-associated pneumonia decreased from 34 cases with five deaths in 2002 to 4 cases with one death in 2004, with subsequent annual savings of $500,000.[2] Over the next decade, targeted value-focused improvements throughout Virginia Mason Medical Center led to systematic reductions in cost and medical errors,[20,22] extending into orthopaedic surgery and spine surgery.[23]

The Pittsburgh Regional Health Initiative similarly implemented lean methods centered around the reduction of defects in the region's medical centers. One of the most striking findings related to this effort of using lean principles was the reduction of central line infections by up to 90% within 1 year of implementation.[2] ThedaCare, a hospital group in Wisconsin, saw similar gains in productivity and quality through the implementation of lean methods[24] centered on the reduction of defects, improved efficiency, and a culture of change and respect for people. ThedaCare reported $3.3 million overall institutional savings attributable to reduced waste in 2004 through the implementation of basic lean principles.[24]

These examples demonstrate that successful implementation of lean management depends on the adoption of a culture that empowers each person to examine processes and implement incremental changes to enable continuous process improvement.

Dr. Sethi or an immediate family member serves as a paid consultant to K2M, NuVasive, and Orthofix; has received nonincome support (such as equipment or services), commercially derived honoraria, or other non–research-related funding (such as paid travel) from K2M; and serves as a board member, owner, officer, or committee member of the Scoliosis Research Society and the Washington State Orthopaedic Association. Dr. Burton or an immediate family member has received royalties from and serves as a paid consultant to DePuy Synthes; has received research or institutional support from Bioventus, DePuy Synthes, and Pfizer; and serves as a board member, owner, officer, or committee member of the Scoliosis Research Society. Dr. Bess or an immediate family member has received royalties from K2M and RTI Surgical; is a member of a speakers' bureau or has made paid presentations on behalf of and serves as a paid consultant to K2M; has received research or institutional support from DePuy Synthes, K2M, Medtronic Sofamor Danek, NuVasive, Stryker, and Zimmer Biomet; and serves as a board member, owner, officer, or committee member of the North American Spine Society and the Scoliosis Research Society. Neither Dr. Yanamadala nor any immediate family member has received anything of value from or has stock or stock options held in a commercial company or institution related directly or indirectly to the subject of this article.

Figure 1

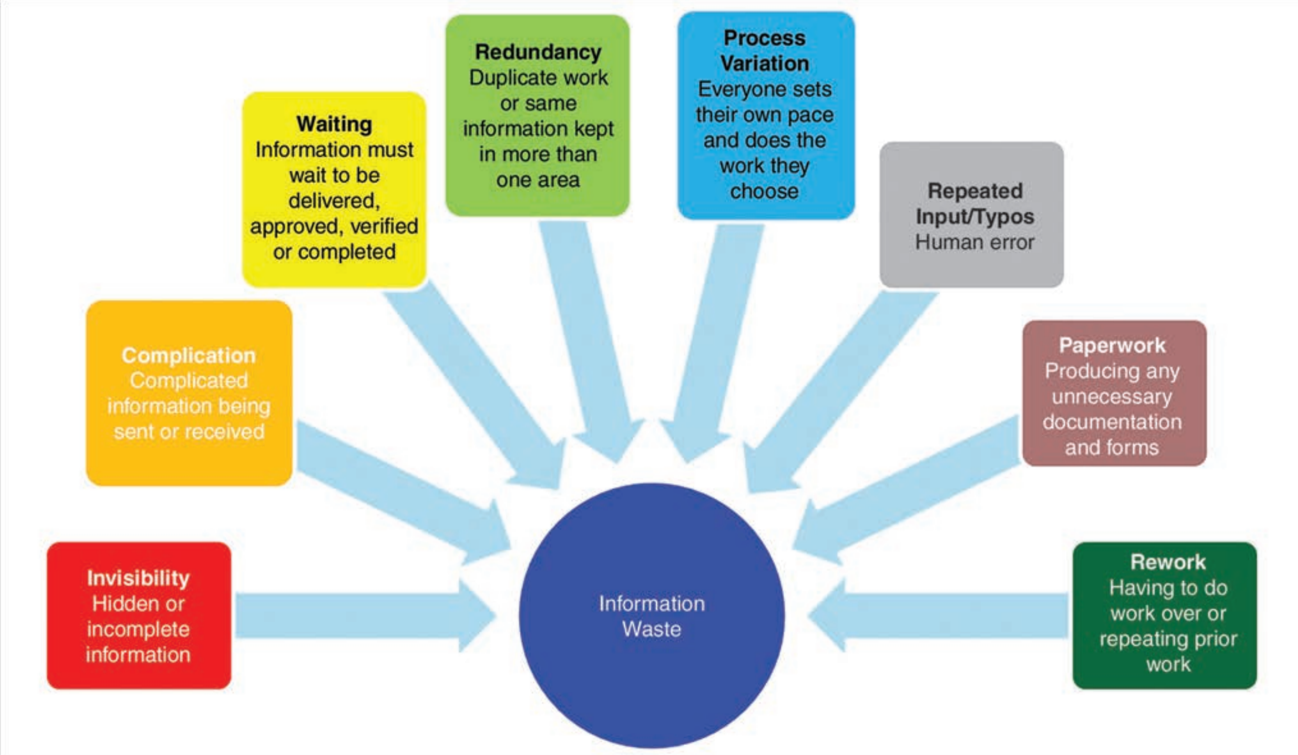

Diagram showing the eight types of information waste, adapted from Taiichi Ohno's original seven areas of waste.

The highest levels of leadership within the lean system must be involved in creating and supporting a culture of change within the organization. Leadership within the lean system must also enable a systematic approach to analyzing current processes, devising changes, and assessing the results of process improvements. Because lean processes are continually evolving, the VMPS uses a system to track implemented changes and the subsequent effects of these changes on the work process over time.

Lean Methods in Spine Surgery

Reported rates of intraoperative adverse events in complex spine surgery and spine deformity surgery are as high as 10%.[25-32] Overall complication rates range from 25% to 80%,[33] including intraoperative and postoperative mortality; transient and permanent neurologic deficits; myocardial infarction; systemic infection, including pneumonia and urinary tract infection; and surgical site infection. Therefore, the standardized protocols that are part of lean process improvement offer potential benefits in the field of complex spine surgery. The Seattle Spine Team approach is an example of the systematic utilization of lean methods in complex spine surgery.[34] Although many centers have developed individualized protocols to address individual complications,[35-39] the Seattle Spine Team approach[40] uses a value stream map that incorporates preoperative, perioperative, and postoperative care into a single process to improve the quality and ultimately the value of care delivered to the patient (Figure 2).

In the Seattle Spine Team approach, the first goal is defining value, as is the case in all forms of lean methodology. This process requires a multidisciplinary approach involving the key service providers (eg, surgeons, anesthesiologists, physiatrists, internists, pain specialists, nurses, operating room staff, physician assistants) and the customer (ie, the patient). Participating together in a rapid process improvement workshop, the key service providers collectively define the value, which in this approach is defined as delivering the safest and most effective complex spine surgery at the lowest cost.

The next step involves the creation of a value stream map, which delineates each of the steps involved in delivering the defined value (see Supplemental Digital Content 1, Current state map showing the discharge process after complex spine surgery, http://links.lww.com/JAAOS/A55). This iterative process results in the creation of a current state map. Each area is studied in detail to identify waste in the process. Depending on the focus of a particular improvement process, each step is delineated as broadly or as specifically as necessary. For example, in the value stream map depicted in Supplemental Digital Content 1, the patient's intraoperative care is delineated broadly, whereas the postoperative care is depicted granularly (see Supplemental Digital Content 1, Current state map showing the discharge process after complex spine surgery, http://links.lww.com/JAAOS/A55). Thus, this particular value stream map allows focused intervention at the level of the patient's postoperative care. Each part of the postoperative care is delineated with respect to the person performing the task, the task performed, how it is performed, and how it is evaluated. The first step, as depicted in the value stream, is performed by the admitting nurse (RN) on postoperative day (POD) 0. The nurse carries out admission documentation and regular patient checks as depicted in the box. Each step in this value stream may be performed in parallel or in series with respect to the other steps, and hence they are not depicted with any particular ordering scheme. All steps must be completed for the discharge process to take place.

After a value stream map is created, each step is studied rigorously. A method such as the VMPS involves the assessment of waste from the standpoint of time, resources, and personnel. Managers quantify the time, resources, and personnel required for each step and identify any sources of waste in the process. Next, areas of possible intervention for improvement are identified and visually overlaid onto the value stream map (see Supplemental Digital Content 2, Clouds overlaid on the current state map, http://links.lww.com/JAAOS/A56).

The mapping of areas for improvement requires direct communication with the personnel involved in each process to ensure best-practice process improvement. The people involved in the tasks (eg, nurse, physician assistant, physical therapist) are interviewed in the setting of a process improvement workshop. They identify areas where tasks are hindered by the existing processes. These insights are documented as clouds on the value stream map as seen in Supplemental Digital Content 2 (see Supplemental Digital Content 2, Clouds overlaid on the current state map, http://links.lww.com/JAAOS/A56). Color coding allows stratification of areas for improvement according to any number of subcategories, including by the operator, the location of the task, or the timing of the task.

A future state map is then created to identify the ideal value stream that is expected to exist after appropriate process improvements have been made. The future state value stream is codified as standard work, meaning that each part of the value stream is

Figure 2

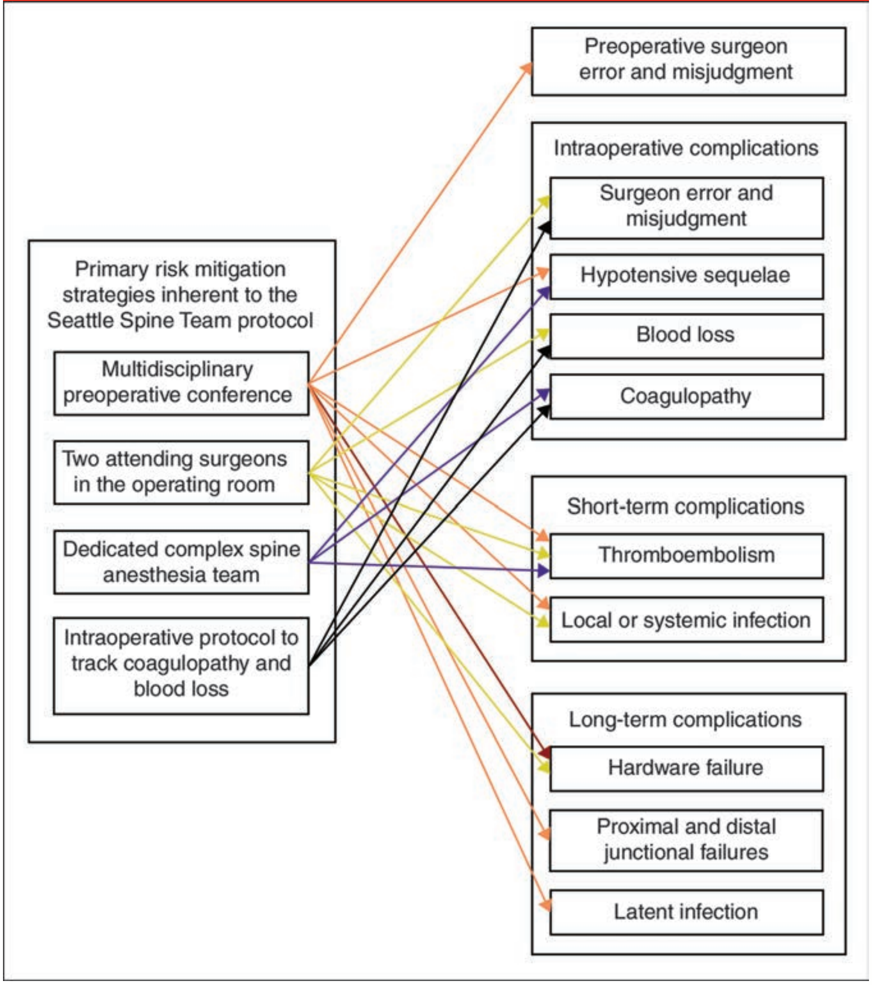

Diagram showing the key components of the Seattle Spine Team approach. Each process is designed specifically to optimize and standardize preoperative, intraoperative, and postoperative care for patients undergoing complex spine surgery. (Adapted with permission from Buchlak QD, Yanamadala V, Leveque JC, Sethi R: Complication avoidance with pre-operative screening: Insights from the Seattle spine team. *Curr Rev Musculoskelet Med* 2016;9[3]:316-326.)

Figure 3

Quality Check	Safety Precaution	Standard WIP
Purpose: Standardization of discharge process for complex spine patients		
Related Policies or Evidence:		
Roles/Work Units Who Must Adopt This Process: Spine clinic PA, RN, Inpatient RN		Task Time: 13 minutes

STEP Add quality, safety or WIP symbols as needed	OPERATOR List role responsible for each task	TASK DESCRIPTION	TOOLS/SUPPLIES REQUIRED Fill in as needed to explain use of specific tool or supply Add photos if valuable to provide clear instructions
1.	Outpatient RN	Track upcoming complex spine/fusion discharges	Chart notes, talk with PAs, attend weekly surgical team huddle
2.	Outpatient RN	Gather materials for discharge teaching	Print departure and postoperative pathway
3.	Outpatient RN	Do disharge teaching with patient, either day before or day of discharge	None
4.	Outpatient RN	Document teaching done in outpatient RN note using template	Computer
5.	Outpatient RN	Notify inpatient RN when teaching complete	None

Chart showing the standard process for the work of the patient's nurse on the day of discharge. Each operator involved in a given process has an associated standard process that defines the specific operator's responsibilities within the overall process. PA = physician assistant, RN = registered nurse, WIP = work in progress

specifically defined at a granular level, a responsible operator is assigned for each step, and performance of proper quality checks is ensured (Figure 3). This codification of the work process ensures that the new value stream will actually be performed and that improvements will be maintained over time.

After the desired interventions are implemented by ground-level personnel, the time, resources, and personnel required for each step are again quantified. Assessment of these parameters over time enables managers to judge the level of improvement and its sustainability. When the future state is achieved, it becomes the new current state from which further improvements can be made in turn. Thus, the value stream map creates a guide for improvement, and the series of current state and future state maps provide a timeline of improvements in the process. This method allows for seamless integration of improvements in a way that individual improvement programs would not afford.

Although codification of the work process facilitates continual improvement through serial change, ultimately a culture of change at the organizational level is required to successfully implement this paradigm. At Virginia Mason Medical Center, where the Seattle Spine Team approach was implemented, the overall complication rate for complex spine surgery was reduced from 52% to 16%.[40,41] Importantly, this rate was sustained over a 5-year period through continuous improvement of preoperative screening, intraoperative communication, and postoperative care pathways.[35] Without the support of a culture of change and continued observation, these changes could have reverted over time.

One example of an area in which lean management can translate directly to success in complex spine care is reducing the need for unplanned secondary surgery.[40,41] The creation of value streams in which all team members are aligned can lead to enhanced communication preoperatively and intraoperatively. The optimization of preoperative communication means that important patient factors, such as obesity, smoking, and suboptimal bone density, can be appropriately managed before surgery. Intraoperatively, surgical teams can standardize their communication according to team-based protocols. We think that the implementation of these types of processes at Virginia Mason Medical Center ultimately explains the substantial decrease in complications leading to the need for secondary surgery.

The Future of Lean Methods in Orthopaedic Surgery

Systemwide improvements are crucial to the improvement of value in complex orthopaedic surgery.[6] The Seattle Spine Team experience demonstrates that lean methods are effective in reducing complications and improving the value of care delivered. Each center must develop its own value stream upon which to base its process improvements. Although the Seattle Spine Team approach offers a guide to the development of such a system, direct implementation of this approach without attention to an individual center's culture, practices, and patient population will likely lead to a suboptimal process. Individualized improvement processes at each center where complex orthopaedic surgery is performed will ultimately lead to global process improvement in the field.

Lean methodology can be employed first to reduce variation within orthopaedic centers. Implant inventory and processing is an important function in which the implementation of standard work processes can result in substantial reduction of waste and inefficiency.[20] A standard process has been developed at Virginia Mason Medical Center to understand the indications for both simple and complex spine surgery.[23] In this process, all proposed lumbar fusion and adult spinal deformity surgical procedures are expected to undergo a multidisciplinary approval process in which all healthcare professionals are given an equal voice and the indications are standardized according to the best possible implementation of evidence-based medicine. The equal votes of all healthcare professionals involved in the process embodies the concept of respect for people that is central to the lean methodology. Finally, lean methods can be applied to reduce variation among the order sets of orthopaedic surgeons in any given center, such as in the use of drugs (eg, antibiotics, tranexamic acid, pharmacologic thromboembolic prophylaxis), devices (eg, types of hip and knee implants), and postoperative mobilization protocols. The use of rapid process improvement workshops can allow for the variability that is necessary for safe patient care while eliminating unnecessarily variable processes that can add waste, contribute to inefficiency, and result in a negative patient experience.

Summary

Lean methodology has evolved from its origins in manufacturing and has been applied broadly in health care. Specific examples of implementation in complex spine surgery and orthopaedic surgery demonstrate that lean methods can assist surgeons and centers as they attempt to enhance the safety and value of orthopaedic care.

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Evidence-based Medicine: Levels of evidence are described in the table of contents. In this article, references 20, 28, 31, and 41 are level III studies. References 1, 2, 4-19, 21-23, 25-27, 29, 30, and 32-40 are level IV studies.

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