



What Hinders Lean Process Improvement in Healthcare

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Executive Summary

The Lean process improvement methodology has shown some success in improving processes and their outcomes in healthcare settings. However, replicating these successes on a broad scale has proven difficult, and even where successful, process improvement could be carried further. We argue that these problems result from Lean being developed in a manufacturing environment. Arbitraging the Lean package wholesale to healthcare is problematic because the context of healthcare differs greatly from manufacturing. To begin to address these problems, we define what exactly is Lean process improvement, which is often misunderstood in the healthcare arena. We then describe particular differences in the healthcare context from manufacturing that hinder the application of Lean process improvement in healthcare.

Introduction

Healthcare has many problems: It is hugely expensive, its outcomes are much poorer than desired; and it is often not patient-centered. Over the past two decades, many have tried to attack these problems by translating the methodology of Lean process improvement (or more simply “Lean”) into a healthcare context. The leaps in quality, productivity, and customer satisfaction in manufacturing industries as a result of Lean are indeed staggering. However, transplanting these benefits to healthcare has been problematic. As the CEO of a—highly innovative—integrated regional healthcare practice put it, “The results have been rarely effective, and when effective, very difficult to replicate.” (Anderson 2015a). Moreover, Lean, even in its original manufacturing context, is poorly understood within the healthcare industry. This paper addresses the root causes of these problems by first defining exactly what Lean and what it is not. Secondly it describes why translating Lean from a manufacturing into a healthcare context is anything but straightforward.

What is Lean Process Improvement?

Lean is often misunderstood in the medical community. Many in the healthcare industry, such as those the author has interviewed, think Lean is simply about reducing costs through eliminating employees. Nothing could be farther from the truth. Lean is instead a generic term for the Toyota Production System—and to some extent, Honda’s production system—that was coined by Womack et al. (1990) in their seminal study *The Machine that Changed the World*. In that book, they argues that the sources of advantage of some Japanese auto manufacturers over their Western rivals was in large part due to Lean process improvement.

Before beginning to describe Lean, many may be aware of the Six Sigma process improvement program. While many scholars and consultants will argue that it is different from Lean, Lean and Six Sigma grew out of many of the same principles.* Moreover, in recent years the Six Sigma—now Lean Six Sigma—movement, has embraced almost all the

* Particularly the inheritances from W. Edward Deming and the other Western exponents of quality improvement

other concepts of Lean as well. The only exception is that experts (“black belts” and the like) lead process improvement efforts rather than line workers. Even this difference is minimal, however. Successful Six Sigma practitioners almost always involves front line workers in their efforts, so the arguments in this paper will generally apply to Six Sigma as well.

Most importantly, it important to understand what Lean is not. Lean is not firing employees, but rather empowering mangers, line-workers, and suppliers so that they can improve the system in which they work through continuous improvement. Firing the employees or suppliers involved would only result in killing any further improvement (Repenning et al. 1997).

To understand Lean, the best place to start is to consider each of its main components, one by one in their original, manufacturing context as practiced by Toyota (Ohno 1988, Bellini 2016, Liker 2006). Then we will explain the challenges that hinder each component’s application to healthcare. Finally, in the discussion, we will describe some changes in healthcare practices that are necessary to drive forward the implementation of Lean. Other white papers in the Institute for Lean Healthcare’s series will flesh these changes out in more detail, so as to create an agenda for meaningful improvement in the healthcare industry.

Identify Customer Goals and Limiting Purchase Options

The first step in implementing Lean is to identify customer wants. Once identified, a Lean organization with then limit the number of potential purchase options to only those that will satisfy the bulk of customers. Prior to the emergence of Toyota in Western nations in the 1970s and 1980s, Western manufacturers concentrated on initial price and annual differentiation—through aesthetics, improved acceleration, and the like—to attract customers. They also relied on offering literally hundreds of option package combinations to the individual purchaser.* Toyota realized early on that many, if not most, customers craved reliability, durability, and low cost of ownership instead. For these customers, a car was merely transportation. Not being stranded on the road and repeated visits to auto repair shops was worth much more than having this years’ fins on the back of the car. Toyota also found that customers only needed a limited menu of options to choose from. A small number of models, each with only a few option packages, was enough to satisfy the bulk of customers. In fact, many customers preferred not being confused by a great number of options.

In contrast, even when patients’ diagnoses are similar, identifying customer goals is difficult in healthcare. Current metrics, such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) and hospital readmission rates, measure only limited aspects of the value of healthcare to the individual customer. Each individual

* The author once studied the number of option combinations for the 1984 Pontiac Firebird while employed by General Motors. The resulting estimate was over 6 million potential combinations.

patient's health and priorities are different. No two individuals are the same. No two life experiences are the same. From my own experience, in high school I wanted to treat my asthma just enough so that I could “pull my weight” on the soccer team. Others, however, wanted to play well enough to have a shot at playing on a college team. Clearly our two needs were different. Wants also evolve over time. When I was 17 years old, I just wanted to play a hard game of soccer. At age 50, I don't play soccer, but I still want to have enough mobility so that I can backpack for a few days. When I'm 80 years old, I'll be happy to walk a few miles unassisted. In contrast, my mother, who is 80 years old has COPD and would be ecstatic just to be able to go grocery shopping without help.

Because patient needs are so diverse, limiting the number of “purchase options” is normally impossible in healthcare. There are exceptions. Lasik centers limit their services to correcting eyesight with laser surgery. Shouldice Hospital, outside of Toronto, limits their operations to the correction of internal hernias. Integrated practice units, such as those at the Cleveland Clinic, offer integrated services by limiting themselves to particular patient segments (Porter and Teisberg 2007). However, many other areas of the healthcare industry, such as general hospitals and private practices, must handle patients ranging from 20-somethings with broken arms, to pediatric cancer patients, to senior citizens with multiple comorbidities. Hence, diversity in wants will always hinder the creation of limited purchase options in healthcare.

The Mass Production Inheritance: Interchangeable Parts and Assembly Lines

Lean manufacturing, from which Lean Process Improvement is derived, is often presented as the opposite of mass production. However, no less a figure than Taiichi Ohno, one of the creators of Lean at Toyota, has stated that Lean is really an elaboration of Mass Production that builds on mass production's core assumptions. One core principle is minimizing variation, creating interchangeable parts, which underpinned the creation of the assembly line. To this day, Toyota continues to spend a great deal of time and effort improving interchangeability by continuously reducing variation .

In healthcare, interchangeability is impossible. Patients are not widgets. Even unrealistically assuming that patients all had the same wants, their health issues are very seldom identical, even in a “limited” specialist practice such as Maxillofacial surgery. Lack of interchangeability affects every area of healthcare. Even scheduling physician appointments has proven to be extremely difficult in most settings because of patient variability (James et al. 2015).

Another inheritance of mass production is the embedding of most professional knowledge in the equipment and layout of the assembly line. Prior to Henry Ford, a customer would pick one of a number of model plans to base their automotive order on. It is not too much of a simplification to say that the parts would be gathered together, put in a pile on the side of a workshop, and then skilled craftsmen would assemble it. The assembly was guided by the knowledge in the craftsmen's heads. The plans for the car would provide a rough guide, but as anyone knows who has followed the “instructions” in assembling a piece of unassembled

furniture, things seldom go to plan. To complicate matters, the customer would often request customizations inconceivable in mass production, such as a special fabric for the seats or even making the car a foot longer. Given that assembly was essentially artisanal work, in which cars were built by hand in any case, such customization was a minor issue.

Because of their spatial and analytical skills, the number of such capable artisans, however, was limited. Most of them today would likely be engineers. Henry Ford developed the assembly line in part so that he could make do with unskilled labor by embedding the knowledge of his skilled craftsmen into machines, jigs, and a layout in which each successive activity in the assembly process was standardized. This succeeded to such an extent that *unskilled* laborers could perform their steps every 60 seconds with minimal training. Essentially, Ford had separated the knowledge of the craftsmen from the production of the product.

In healthcare, there are few standardized “operations” because of patient variability. Moreover, patient problems often change “on the fly.” Hence, it is impossible to separate the artisan from the product. Nor is there enough volume of any one “product.” For these reasons, embedding the healthcare provider’s knowledge into equipment is extremely difficult, if not impossible. Neither can one separate the process of treating a patient into a fixed sequence of standardized activities that can serve all patients. The actions of a healthcare provider will necessarily be much more entangled with each other than in an assembly line. Hence, healthcare will always be much more an artisanal rather than manufacturing process, and applying Lean methods and tools, which were developed in a manufacturing setting, to such an artisanal environment will always remain problematic.

Create A Management Culture That Surfaces and Solves Problems

When the author worked at the Ford Motor Company, it was often said that the first commandment of the factory was “Thou shalt not shut down the assembly line.” At Ford, our assumption was that doing so cost approximately \$10,000 per minute.* The rule makes sense at first glance. However, Lean firms believe that producing defects, because of rework—which usually has to be done by hand—and warranty costs made it more efficient to solve problems in production as soon as possible. Put another way, Lean firms calculate that **not removing defects** cost much more than stopping production. Losing five minutes production to fix several hundred or more defects was for Toyota an easy—though, at the time, out of the box—trade-off to make. In fact, instead of management ignoring problems, which is common in most firms (Daft and Weick 1984), Toyota has made it a priority to surface problems as soon as possible. The reason is that, without surfacing problems, there is no way to solve them. This has led many in Toyota to actually “treasure defects” and other mistakes because they reveal ways to improve their processes, make customers happier, and increase Toyota’s profits.

* Kruse estimated that a minute of shutdown cost automotive assemblers \$42,000 per minute in 2002. Kruse, E. (2004), “Why Does GKN Run Lean,” retrieved on March 13, 2017 from <https://scm.ncsu.edu/scm-articles/article/why-does-gkn-run-lean>.

Healthcare has a number of issues with this Lean approach. One is that healthcare cannot be standardized, nor can the care provider actions be easily separated from each other, as described earlier. Because of variability, applying the lessons from mistakes made in one patient's care to improving another's is, while not impossible, much more difficult. Another and perhaps more problematic issue is the inherent incompatibility of incentives between individual clinicians and the system in which they are embedded. Surfacing a problem in manufacturing is considered a "win" because of the cost trade-offs just described. Moreover, because the problem typically lies in the process rather than any individual worker, the line-worker who surfaces a problem is appreciated and often rewarded. At a higher level, a plant that can surface many problems quickly will be best able improve its overall quality by solving them. In contrast, if a clinician finds a problem, it is very likely the result of an error by himself or a coworker. Or, even if a problem is not a clinician's fault, it will still be attributed to him or her. Since there are professional repercussions from making errors—either lawsuits or even just a loss of professional reputation—there is a significant disincentive to reporting the error. This prevents systematically prevent repeats of the problem in the future. At a higher level, hospitals that report problems may suffer penalties or simply lose business (Rau 2012). This might also explain some of the lack of transparency in healthcare, which aggravates this issue still further. In the automotive industry, one can literally look up reports, such as those by J.D. Powers, that list the defect rate of every assembly plant that produces cars to be sold in the United States. As anyone knows who has tried, comparing healthcare institutions or practitioners is very difficult, if not impossible. Web ratings are of little help. Moreover, even if metrics were available, they would have to be adjusted by the percentage of their high-risk patients. For example, Cleveland Clinic would tend to look worse in comparison with a community hospital, because it treats many patients that cannot be treated anywhere else. For all these reasons, any progress in surfacing problems will always be an uphill battle because the incentives for an individual care provider and his or her organization will always hinder it.

Focusing on Processes to Reduce "Waste"

Lean firms believe that they have outstanding workforces. So they attribute problems to poor processes. This makes Lean firms obsessive about mapping how their processes work, understanding their weaknesses, and improving them in a continuous manner.

While there is no other industry in which the employees care more about their jobs' purpose, it is more difficult for them focus on processes than it is in manufacturing. One reason is that every clinician is—rightly so—focused on the patient he or she is currently treating. However, this orientation focuses on the issues peculiar to each patient, making it more difficult to see commonalities in a treatment *process*. Worsening this problem is that high-risk patients, such as those with multiple comorbidities, are going to demand the most time and attention, making them uppermost in clinicians'. This blots out any commonalities, making processes even harder to perceive. Finally, observing commonalities requires reflection time, which clinicians generally do not have because they are already overworked.

Without a focus on understanding processes, several issues occur. One is that evidence in most industries shows that problems occur most often at the gaps in a process. This is also true in healthcare. Most deaths occur during handoffs of patients from one area to another (Joint Commission 2014, Starmer 2014, McDaniel 2015). Only a deep understanding and focus on processes can reduce problems resulting from gaps. Another issue is that there is no separation of process from personnel as described earlier. Hence, clinicians' tasks are difficult to observe, which results in clinicians varying how they do any particular task from how other clinicians perform the exact same task. Another result of the inability to separate process from personnel is that when problems do happen, they tend to be blamed on personnel. For example, Wally Hopp and William Lovejoy described an emergency department in the American Midwest in which the rate of life-threatening mistakes from medication errors occurred in almost 30 percent of patients (Hopp and Lovejoy 2012). About one-third of these were attributed to personnel errors. In any other industry, a mistake rate of 10% would be a red flag that something was wrong with the process rather than the person acting within the process. Hence, many process problems remain ignored in healthcare.

For all these reasons, a process view is more difficult to achieve in healthcare than in manufacturing. The focus on individual patients, lack of reflection time, and inability to separate process from personnel all present significant hurdles to employing Lean concepts in healthcare.

Empowering Personnel to Continuously Improve Quality

To enable all these improvements to occur, Lean requires an exceptional and empowered workforce. At Toyota, any worker can stop an assembly line if she detects a problem. At that point, her manager and a small group of her fellow workers collaborate to band-aid the problem immediately. They then reflect later on the root cause of the problem to create a long-term solution. Upper line management also participates on an ongoing basis. Quality is everyone's job.

There are many barriers to empowering personnel to continuously improve quality in healthcare. In manufacturing, most manufacturing jobs are unspecialized, and all operations are thoroughly documented and standardized. So front-line workers can easily collaborate with each other. If needed, there are also engineers that understand the system as a whole who can always be called on for help. Finally, management is typically composed of former manufacturing engineers, particularly in firms with complex processes. Hence, collaboration among all employees to solve problems in manufacturing is relatively straightforward. In healthcare, responsibilities and knowledge are much more fragmented, and the knowledge of individual tasks is often restricted to one particular specialty or another. Complicating this, administrators are often not clinicians. So collaboration to improve quality is difficult, and employing everyone to solve problems yields much less in healthcare than in manufacturing.

One crucial way that Lean empowers personnel is through the use of a set of simple visual tools. Some improve the visualization of statistics for process metrics. (Lean employs metrics as much as possible.) Other tools serve to facilitate brainstorming, prioritizing potential causes of error, and validating any improvements made. Yet other tools enforce scientific reasoning through the proposal, analysis, and testing of process improvements. Many of these were adopted from the pioneering statistical process control researchers such as Walter Shewart and the legendary W. Edwards Deming, often called the Godfather of process improvement. Others were developed by Toyota itself, or its suppliers, particularly Denso. Unfortunately, clinicians often cannot use tools designed to facilitate process improvement in manufacturing because healthcare differs in numerous ways. For example, as previously discussed, variability is higher, fragmentation of knowledge is greater, and knowledge is more embedded in clinicians. Hence, a different set of tools is necessary for healthcare, but remains undeveloped.

A separate issue inhibiting continuous improvement is that many processes are locked into place by electronic health record (EHR) systems. Given that they were originally developed purely as billing systems, EHRs tend to lock processes into inefficient states. Moreover, the ability of employees to improve a process when its information systems cannot accommodate change is very, very difficult (Glaser 2006).

In short, there exist a number of natural barriers, as just described, to empowering clinicians to continuously improve healthcare. Foremost of these are the peculiar aspects of the healthcare context relative to that of manufacturing, in which Lean was initially developed.

Mistake Proofing and Visual Management

As just described, Lean firms improve their processes by first using a number of tools to find out the root cause of any problem in the process. Then they “mistake-proof” the problem so that any recurrence of it becomes impossible. If mistake-proofing cannot be done, the process is designed so that problems are made manifest immediately. For example a rod for a part that is too long will not fit into the jig for the next step of the process. Another method is the use color or other visual means to make it easier for workers to avoid mistakes, referred to as Visual Management.

Mistake proofing and visual management in healthcare are hindered because determining root causes is much more difficult. Hence, mistake proofing is hindered as well. If one knows exactly how a patient is treated, the number of potential “suspects” for the root cause of a problem is reduced. As any detective will tell you, reducing the number of suspects is integral to any investigation. However, knowing how a process is performed is difficult in healthcare because standardization is lacking. Moreover, process knowledge, separating employees from process problems, incentives to surface problems, and appropriate tools to solve problems all facilitate mistake proofing and visual management in manufacturing. For reasons discussed earlier, these are also absent in healthcare. Hence mistake proofing and visual management is problematic in a healthcare environment.

Partnering with the Supply Chain

Lean considers suppliers part of a firm's processes. Toyota is highly conscious of all their suppliers and often their suppliers' suppliers. Because Toyota realizes that it makes up a relatively small portion of the "value-add" when the entirety of the supply chain is considered, it actively makes suppliers part of Toyota's Lean system. Toyota managers, engineers, and quality control experts literally have spent millions of hours training their suppliers in the "Toyota Way," including all of Toyota's philosophies and tools (Mishina and Takeda 1992). Because of these tight relationships, Toyota managers have commented that a supplier relationship should be like a marriage. If there is trouble, Toyota will spend a great deal of effort trying to bring the supplier back up to standard. It will only end a relationship with a supplier as a last resort.

In healthcare, supply chain management is more difficult. Supply chains include in-home nursing, rehab clinics, assisted living facilities, as well as the many interconnections between primary care providers, specialists, hospitals and, perhaps most importantly, patients (Hernandez 2016). Complicating these issues is the lack of interoperability of electronic health record systems, which hinders communication between healthcare organizations, further fragmenting the supply chain. (In manufacturing, electronic data interchange to facilitate supply chain management began in the 1970s!) Because the relationships in healthcare are patient-specific, ephemeral in nature, and highly fragmented, the supply chain for any patient is unique. Another problem is that Lean manufacturers have striven to reduce their number of suppliers for decades. Both of these reasons make "supply chain management" much more difficult in a healthcare environment. Finally, since Lean is difficult even within the four walls of a healthcare organization for the reasons previously described, exporting Lean to suppliers is a non-starter. Thus, there exist significant barriers to applying Lean to healthcare supply chains that do not exist in manufacturing.

Create Continuous Flow Through the Process

Another Lean goal is to level the workload so that everyone is productive, but no one is overtaxed. Not only do Lean organizations such as Toyota try to level the production rate of each of its plants every day as a whole, they try to do this at a more micro level. For example, if a Lean plant produces a coupe, a roadster, and a sedan, that plant will produce in sequence one coupe, then one roadster, and then one sedan. It then repeats the cycle continually. Part of the reason behind leveling is consistency, as workers never get too used to one product in a way that will be detrimental to others. Lean firms also level production so that their suppliers can level their own production and *hence be Lean themselves*. As discussed in the prior section on supply chains, enabling Lean at its suppliers is a major goal of Toyota's.

Some aspects of healthcare might benefit from leveling such as public health, private practice appointments, and perhaps elective procedures. However, emergency departments and in-patient care at hospitals will never be able to level “production” because patients need acute care when they need it. It simply cannot be scheduled. In these areas of healthcare, implementing leveling will always prove to be difficult.

Conclusion

We have discussed in the paper that Lean production is essentially the Toyota Production System. Because that system was developed in manufacturing, applying it to healthcare without adjusting its principles and tools is problematic. Some aspects of healthcare such as diagnoses are so idiosyncratic to the patient that these areas may possibly never benefit from Lean. In addition, some principles of Lean in areas of healthcare such as leveling may prove impossible. However, while all Lean principles are constrained to some extent by the uniqueness of healthcare, there is stillroom for much improvement. Empowering employees to perform continuous improvement is an excellent example. To some extent continuous improvement in healthcare will always be limited by the uniqueness of each patient. This makes processes more variable and harder to map by employees, limiting the plateau achievable by continuous improvement relative to what can be achieved in manufacturing. That said, empowered employees can improve processes significantly from current levels. Given appropriate time for reflection, they can map out their processes to a much greater extent than is current practice and understand such patient commonalities as that do exist. Armed with this process knowledge, clinicians can meaningfully standardize many aspects of each patient’s experience, such as discharge and handoffs, and use mistake-proofing and visual management to improve these processes still further. Electronic health records can assist in mistake-proofing such as flagging medication errors. Consciousness of processes can also help assign many perceived clinician mistakes to processes instead of personnel, which will ameliorate to some extent incentive incompatibility problems preventing the surfacing of problems. Any improvement of supply chain awareness will also clearly be of value. All of this is possible with today’s Lean tools. Armed with visualization and problem-solving tools adapted to the healthcare environment, clinicians can drive these improvements much further.*

Most importantly, however, is that none of this can occur in the healthcare environment without the participation of everyone involved. Healthcare organizations’ leadership must support and encourage the implantation of Lean as well as facilitate the development of new tools. Each clinician must also participate to enable Lean. Because of the fragmentation of knowledge in healthcare, mapping and improving processes requires the knowledge and collaboration of every clinician. Even though it is difficult, they must drive process improvement forward, for no one else has the understanding to do so.

*Many other adaptations of Lean principles to healthcare can be found in papers at the Institute for Lean Healthcare.

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