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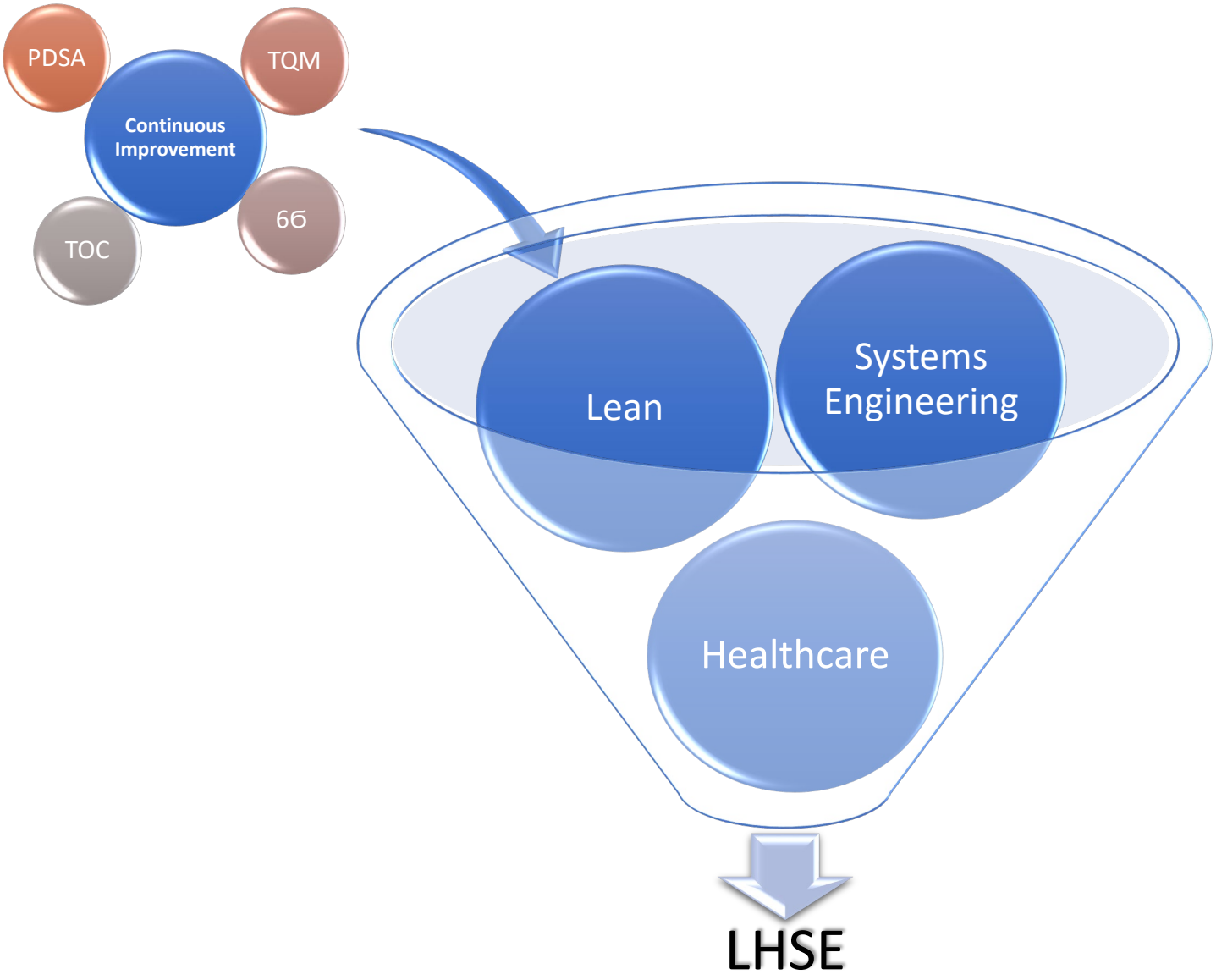

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INCOSE Healthcare Working Group

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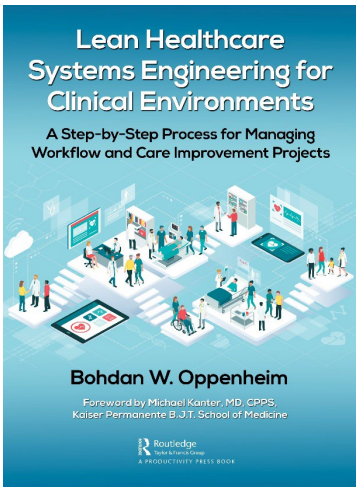

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Comparison of Lean Healthcare Systems Engineering Process (LHSE) for Healthcare Improvement Projects with Earlier Improvement Initiatives

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INCOSE Healthcare Working Group

Table of Contents

Summary

A new process called Lean Healthcare Systems Engineering (LHSE) recently invented for improving healthcare workflows and designing new care is reviewed and compared to previous quality initiatives: PDSA, TQM, Six Sigma, Lean, Theory of Constraints, and several others. LHSE is applicable to workflow improvement or new care design projects in clinical environments, including hospitals, operating suites, emergency departments, clinics, imaging and clinical laboratories, pharmacies, population health, and telemedicine. LHSE integrates the strengths of Lean Six Sigma and Systems Engineering (SE). Lean's overarching philosophy of "do what is necessary to deliver the value and reject everything else as waste" governed the tailoring of the classical SE process to healthcare, eliminating the many bureaucratic and wasteful activities, and leaving only the steps that truly are needed in healthcare improvement projects. Utilizing tools from SE, LHSE presents several powerful improvements over previous approaches, in particular system optimization reducing the trial-and-error effort and cost; and increasing the predictability of outcomes. LHSE provides consistent logical rigor to projects, reducing iterations and failure, and is particularly effective in elimination the notorious fragmentation in healthcare systems.

1. Introduction

It has been almost 20 years since the Institute of Medicine released the seminal report titled Crossing the Quality Chasm [Institute of Medicine, 2001]. They identified six domains of care quality (safe, timely, effective, efficient, equitable, and patient-centric) and noted a huge gap between the current state and the desired state. Although this report received a great deal of attention, sadly there has been little progress in these areas. In the United States, healthcare still has huge disparities, is inefficient, fragmented and demonstrates delays in care that are often unsafe. Most U.S. citizens are expected to suffer from a diagnostic error sometime during their lifetime [NASEM, 2015], not receive a large fraction of recommended care [McGlynn et al., 2003], and pay for one of the most expensive systems in the world [Davis et al., 2014]. Problems occur in all clinical environments and at every level. Challenges due to increasing complexity of medical and healthcare systems are growing at the rate exceeding the ability of workforce to adopt.

Improvements in workflows and new care implementations are usually carried out as improvement projects. Starting with the Plan-Do-Study-Act (PDSA) method, over the last 70 or so years, projects relied on several improvement methodologies with mixed success. Often, driven by consultants, a new method is promoted and displaces the previous one as "fad". That has been the history of approaches such as PDSA, Total Quality Management (TQM), Theory of Constraints (TOC), Six Sigma, until the recent Lean and integrated Lean Six Sigma[1]. The experience of the present authors is that each approach made positive contributions to the quality and efficiency of healthcare operations, some more than others, and the approaches are not mutually exclusive but rather complementary and evolutionary. It is with this viewpoint that we review a new general process for improving projects in healthcare operations, called Lean Healthcare Systems Engineering (LHSE) Process. It is described in detail in Section 3, after [Oppenheim, 2021]. The process adds critically important selected Systems Engineering steps and tools to the above improvement approaches. First, in Section 2 we review the former approaches as a context for the LHSE method. For each, we discuss and summarize the history and main points, strengths and weaknesses. We identify three critical shortcomings of all these earlier approaches: the lack of a unified and consistent systems rigor and approach in projects; inability to avoid unnecessary and wasteful trial and error methods, and inability to integrate highly fragmented care elements and stakeholders into a continuum of care that both patients

[1] For completeness, in the following text we also briefly mention the special case of the Model for Improvement (MFI).

and providers need.

In Section 4 we summarize the nearly 100 student Master's Capstone projects that have been executed using the LHSE process in actual healthcare settings by students at LMU in the program of Healthcare Systems Engineering. In Conclusions in Section 5 we summarize the significant superiority of LHSE.

The paper is limited to the design and improvements of healthcare delivery workflows and care elements practiced in clinics, hospitals (including emergency departments and operating suites), clinical and imaging laboratories, pharmacies, population health, and telemedicine.

In the present considerations we exclude healthcare activities other than delivery operations, specifically: large healthcare projects with thousands or many hundreds of requirements, such as creation of healthcare informatics or electronic health record (EHR) software, (but EHR modifications to support a clinical process improvement are included); national public health; pandemic management (except as it relates to local delivery environments); politics and economics of national, state or military healthcare; medical device development (but the integration of medical devices in clinical care is included); and pharmacological industry activities. In the Conclusions section we also discuss the limits of project size for using LHSE, and the challenges in learning LHSE in healthcare systems.

2. Evolution of Process Improvement Initiatives

We review here the most popular process improvement methodologies used in healthcare delivery operations, including historical notes, summaries and philosophical underpinnings, main tools, strengths and weaknesses. Each of the discussed methods has been used in thousands of healthcare projects. The quality and scope of the outcomes created with the different methods vary widely depending not only on the inherent capabilities of a given method, but also on the experience and competence of the team using it; the organization culture; the level of challenges in the project; and personal experiences and biases, good and bad, with the individual methods. In view of these powerful variabilities, a comprehensive review of the methods and their successes is beyond the scope of this paper. We limit the discussion to those characteristics which are relevant to the comparison of each of the above method with the LHSE process described in this paper, including the ability to reduce systems variability, ability to remove waste, ability to remove process bottlenecks, ability to apply rigor throughout the entire project, ability to integrate across interfaces in a fragmented system, ability to reduce project iterations, cost and effort, and the focus on system's approach. We also comment on the inherent promotion or lack thereof of leadership engagement, and failure to perform a high-quality literature review in each approach. The engagement is important because in several former approaches the leaders just brought in outside consultants to implement the method, but were themselves not engaged in the process, with poor results (according to personal experiences of the first two authors). The lack of literature review in projects may have the following negative outcomes: 1) trying things that have already been tried and shown to fail; 2) testing out things already known to work 3) testing out things that have a low likelihood of success based on prior knowledge. After a brief general description of each method, we explicitly summarize these characteristics in a standardized table, so that the different methods can be easily compared.

2.1. Plan-Do-Study-Act

The basis of this method was created by Walter A. Shewhart in the 1920s, and popularized by Edwards Deming in the 1950s ["PDCA," 2021] who named it the "Shewhart Cycle" to honor his mentor. The method is also known under several other names: the Japanese "Kaizen" [Imai, 1986], Continuous Improvement (CI), and "Deming Wheel" or "Deming Cycle". The PDCA Cycle was initially used in production as an iterative CI process, but quickly became a main process improvement method in healthcare industry [Taylor et al., 2014]. A prominent example of PDCA success was Mayo Clinic which demonstrated a decrease of

the median test turnaround time from 7.3 to 3 hours, and a reduction of inventory of clinic stock by 31% [Sladen et al., 2019]. The four phases of PDCA include "Plan" that defines project goals based on organization's mission and values; "Do" representing the plan execution; "Check" which includes verification that project objectives have been made and identifies successes and failures for future iterations; and "Act" implementing corrective actions. Deming modified the "Check" phase to "Study", emphasizing the need to study at depth and not only check the processes; and the process name was changed to PDSA [The W. Edwards Deming Institute, 2021]. A well-run organization is supposed to engage in continuous improvement of operations and make it a part of routine operations. The iterative PDSA Cycle is intended to produce better outcomes in each cycle.

PDSA should be credited for popularizing the profound fact that no process is ever perfect and can always be made better, as well as for initiating quality trends across the U.S. industry and across products, processes, and services, including healthcare. Shewhart and Deming promoted studies of process variability using Statistical Process Control (SPC) and Statistical Quality Control (SQC) [Deming, 1982]; and Taguchi [Roy, 1990] promoted Design of Experiments (DoE)[2] as elements of PDSA. The severe weaknesses of PDSA were the excessively general formulation of the steps, with process variability statistics being the only rigorous elements of PDSA; and the lack of explicit rigor needed for efficient project execution and optimal results, leaving all implementation steps to the project team interpretation. Thus, the outcomes of PDSA projects varied strongly between projects, teams, and organizations. Also, PDSA did not formally involve the customer feedback in its iterations, was totally oblivious to interfaces and fragmentation in healthcare, ignored explicit systems approach, and lacked the ability to explicitly identify process wastes and bottlenecks. By definition, PDSA was an iterative method, consuming resources and time in each iteration. Table 1 summarizes these characteristics.

The Institute for Healthcare Improvement uses MFI, [Langley et al., 2009] as the framework to guide improvement work. The MFI is a simple extension of PDSA, intended to accelerate improvement by starting projects with the following three questions: "What are we trying to accomplish", "How will we know that the change is an improvement", and "What change can we make that will result in improvement". Since MFI is so similar to the original PDSA, no separate discussion of this method is included here.

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[2] In non-healthcare industries besides SPC, DoE was promoted as a second tool for variability reduction and setting a process on target. In this text we omit DoE because in healthcare it is nearly impossible to actually get multiple different care factors active at the same time in a precise fashion needed for DOE.

Table 1: Characteristics of PDSA

Characteristic	Description
Main steps, tools, emphases	Cyclic iterations: Plan, Do, Study, Act, recommends Statistical Process Control.
Strengths	Culture of CI and relentless quality improvement
Weaknesses	Excessively general formulation of the steps, with process variability statistics being the only rigorous elements of PDSA. Lacking explicit rigor needed for step-by step project execution. Lacking customer feedback in its iterations.
Cost and effort of implementation	High due to iterative method with limited progress in each iteration.
Ability to reduce system variability	High for individual tasks of a process, poor for the entire process
Importance of literature review	None.
Ability to remove waste	Poor, focusing on quality and not on wastes.
Ability to eliminate bottlenecks	Poor
Ability to apply rigor across the entire project	Poor, highly dependent on the project team skills.
System's approach	Poor. Does not consider systems, subsystems, interfaces, etc.
Ability to Integrate across interfaces of fragmented system elements	Totally oblivious to integration across interfaces in fragmented system.
Ability to reduce project iterations	Poor, the method is iterative by definition.
Promotion of leadership engagement	Poor, project left to project team.

2.2. Total Quality Management

As [Oppenheim, 2021] described, in June 24, 1980, NBC TV broadcasted a special two - hour program titled "If Japan can why can't we?" opening U.S. eyes to a new management paradigm called TQM that started sweeping U.S. industry by storm. Led by [Deming, 1982] this was an attempt to adopt successful Japanese industrial management methods to U.S. industry. A profound message of TQM was that pursuit of higher quality is compatible with lower costs. TQM emphasized *total* approach to quality. It was based on PDSA, including continuous improvement of all processes, and process variability reduction using SPC. It

added several critical new characteristics: focus on business strategy; explicit customer satisfaction; strong, purposeful and unifying leadership and management; designing quality into both products and processes (rather than relying on the final inspection to identify defects); mutually beneficial supplier relations; bottom - up employee suggestion system; self - motivation and empowerment of employees; and corporate culture based on respect for people. It also popularized quality circles and quick reaction *Kaizen* teams. TQM received strong support from the U.S. federal government, including Department of Defense, [*DoD,* 1988]. In 1987, following the Japanese E. Deming Award, the Department of Commerce initiated the Malcolm Baldridge Award as a motivational recognition of the best U.S. companies in three categories: manufacturing, service (including healthcare) and small business. In 2000, the International Standards Organization (ISO) issued a quality standard denoted ISO 9000:2000, which captures many of TQM elements.

TQM was highly popular in healthcare industry, e.g., [Alzoubi et al., 2019; Chiarini & Vagnoni, 2017; Nicolay et al., 2012]. But the application of TQM in U.S. industries had mixed outcomes. While quality improved, especially in the auto[3] and service industries, profits did not follow proportionately, and high costs were attributed to the huge scope of TQM activities that needed to be implemented for success, yielding the perception that "TQM takes away from the bottom line". Even the quality improvements alone failed in many companies that tried TQM, [Paton, 1994]. The significant effort and cost of implementing TQM, combined with lack of widespread business success made TQM vulnerable to criticism and opened the way to new ideas. Business Week [Byrne, 1997] declared TQM as a "dead fad", blaming TQM's excessive costs and "lack of teeth" in implementation. While today the term TQM has receded, many of the key elements of TQM have endured and are integral to Lean, [Murman et al., 2002]. In retrospect, now we can see that TQM attempted to include the entire enterprise as a system to improve but lacked the focused ability to improve interfaces in fragmented workflows, remove wastes and bottlenecks, and provide rigorous approach to improvement projects. Table 2 summarizes these characteristics.

[3] Cynics say that any quality initiative would have improved the notoriously poor quality of the cars made in the U.S. in the late 1900s.

Table 2. Characteristics of TQM

Characteristic	Description
Main steps, tools, emphases	Total approach to quality across the entire enterprise. Quality circles and quick reaction *Kaizen* teams addressing problems. Focus on business strategy; customer satisfaction; strong, purposeful and unifying leadership and management; designing quality into both products and processes (rather than relying on the final inspection to identify defects); mutually beneficial supplier relations; It also popularized, quality circles and quick reaction *Kaizen* teams.
Strengths	Change of culture towards enterprise-wide quality. Evidence that pursuit of higher quality is compatible with lower costs. Bottom- up employee suggestion system; self - motivation of employees. Corporate culture based on respect for people and employee empowerment.
Weaknesses	Focus on underperforming work elements at the expense of the overall flow. Excessive scope of TQM activities that needed to be implemented for success. Lack of focus on project steps.
Cost and effort of implementation	Huge, not translating into the bottom line.
Ability to reduce system variability	Good use of SPC. Applicable to individual processes/tasks; poor for the entire value stream.
Importance of literature review	None.
Ability to remove waste	Poor, focus on quality and not on wastes.
Ability to eliminate bottlenecks	Poor, focus on quality and not on impediments to flow.
Ability to apply rigor across the entire project	Poor, TQM scope is too big, too unfocused.
System's approach	Poor for specific workflow and care systems, instead focus on entire enterprise.
Ability to integrate across interfaces of fragmented system elements	Totally oblivious to integration across interfaces in fragmented system.
Ability to reduce project iterations	Poor, the method is iterative by definition.
Promotion of leadership engagement	Often none; implementation led by consultants.

2.3. Six Sigma

As [Oppenheim, 2011] described, in the early 1990's TQM evolved into another quality initiative called Six Sigma [Harry et al., 2000], arguably with "better teeth". According to [Wedgwood, 2006], "Six Sigma is a systematic methodology to home in on key factors that drive performance of a process, set them at the best levels, and hold them there for all time." Originating at Motorola and relying on rigorous measurement and control, Six Sigma focused on systematic reduction of process variability from all sources of variation: machines, methods, materials, measurements, people, and environment, [Murman et al., 2002]. Like TQM, Six Sigma aims to achieve predictable, repeatable and capable processes and defect free production, where parts and components are built to exacting specifications. But unlike the motivational TQM, it achieves this by rigorous data collection and statistical analysis, as well as rigorous training of leaders[4]. Six Sigma was not free of problems: it often was implemented with a costly bureaucracy, introducing *the waste of measuring waste* and was criticized for being too top - down, and for displacing two other critically important continuous improvement tools of TQM: small quick - reaction *Kaizen teams*, and the bottom - up employee suggestion system, which Toyota credits for a half of its success. Six Sigma can also be prone to sub optimization by focusing too narrowly on process improvement for a process that may not be needed. [Murman et al., 2002] described this deficiency as "a focus on *the job being done right*, but not necessarily on *the right job*". It was the next step in the industrial evolution, called Lean that provided the unified focus on *the right job* and *doing the job right*, and also on the management culture needed for both. Table 3 summarizes these characteristics.

[4] Following the *ju - jitsu* language, Six Sigma leaders are designated by "belts" of various colors denoting different levels of training and experience.

Table 3. Characteristics of Six Sigma

Characteristic	Description
Main steps, tools, emphases	Rigorous statistics applied to processes, rigorous training of practitioners.
Strengths	Better discipline of work than TQM. Systematic reduction of process variability from all sources of variation. Focus on convergence on exacting specifications.
Weaknesses	Costly bureaucracy, introducing the waste of measuring waste. Top down, displacing *Kaizen* approach and the bottom - up employee suggestion system. Focus on *the job being done right*, but not necessarily on *the right job.*
Cost and effort of implementation	High, costly bureaucracy in the Six Sigma application.
Ability to reduce system variability	Excellent, main focus of the method.
Importance of literature review	None.
Ability to remove waste	Poor, focus on variability reduction and not waste elimination.
Ability to eliminate bottlenecks	Poor, focus on variability reduction and not impediments to flow.
Ability to apply rigor across the entire project	Moderate: focus on process and not on project.
System's approach	Poor for specific work systems; instead focus on process variability.
Ability to integrate across interfaces of fragmented system elements	Totally oblivious to integration across interfaces in fragmented system.
Ability to reduce project iterations	Poor, focus on iterations for minimum variability.
Promotion of leadership engagement	Poor, statistics not accessible to many leaders.

2.4. Lean

The term Lean as an industrial paradigm was introduced in the United States in the bestselling book "The Machine that Changed the World, The Story of Lean Production" published by the MIT International Motor Vehicle Program [Womack et al., 1990], and elegantly explained and popularized in their second bestseller "Lean Thinking", [Womack &

Jones, 1996]. The authors identified a fundamentally new industrial paradigm based on the Toyota Production System. The paradigm is based on systemic and relentless elimination of waste from all workflow operations. Lean strives for minimum waste to deliver high quality and defect - free products meeting customer demand just - in - time, at the rate ordered, with minimum inventories, at minimum cost and in minimum time. Lean is driven by a unique management culture of respect, empowerment, openness, and teamwork, turning all front - line workers into problem solvers to eliminate waste (here we recognize the contributions of TQM). The Lean process has been captured into six "Lean Principles" named Value (to the customer, to achieve at the end of the workflow), Value Stream Mapping as a tool to identify wastes in the process, Flow (of work across all tasks, without backflows or stoppages)[5], Pull (where the output of a previous task should be pulled by the next process rather than pushed by the previous task, to eliminate batches), Perfection (to identify all imperfections and apply improvements accordingly), and Respect for People (similar to the TQM-promoted culture of workforce empowerment and engagement). The value stream represents the linked end - to - end activities necessary to create services or products needed by the customer (e.g., the patient). Waste represents those activities that do not directly contribute to customer (patient) value (health). Waste is categorized into: overprocessing (processing more than needed), inventory (batches of items or patients), waiting waste (a massive source of waste in healthcare), overproduction (working on non-value-added tasks, such as bureaucracy); motion (of people and goods) and excessive transportation waste; defects; and the waste of human potential, pervasive in healthcare in the form of overburden. Lean looks not only at individual activities in a workflow but also at the waste occurring between the activities, such as waiting. In contrast to previous approaches, companies adopting Lean observed direct and dramatic improvements of operations and increases in profits. Womack and Jones, [Womack & Jones, 1996] described six manufacturing case studies that demonstrated reductions of cost, lead time and inventory of up to 90%, with simultaneous improvements in product quality and work morale across a wide range of company types and sizes. More dramatically, lead time and cost reductions on the order of 30 - 50% were realized routinely after only a few days of implementation by simple rearranging of activities into the flow [LEI, 2007]. After the multi - year implementation efforts of TQM, or Six Sigma, this was a revelation. Within a few

[5] Some might ask how the focus on flow differs from Henry Ford's moving line mass production or from "rhapsodized industrial engineering". Indeed, there are common elements. However, there are important distinctions. Lean emphasizes the importance of the front-line workers as problem solvers, unlocking the enormous human resource potential for process improvement. Lean also focuses on *single piece flow* with minimum inventories, which leads to cellular work arrangements. This is contrasted to the method of *batch and queue* practiced in traditional production.

years, Lean production has become the established manufacturing paradigm pursued by all competitive factories, and evolved into other domains [Oppenheim, 2011]. Lean entered healthcare operations with a big bang due to the publication of the bestseller Lean Hospitals [Graban, 2008]. Soon, Lean evolved to a mainstream paradigm practiced in most hospitals, clinics, and auxiliary departments. Yet, Lean was not free of problems. It lacked the ability to explicitly reduce variability of workflow tasks and eliminate the impediments to flow, except indirectly, via waste analysis. It was poor in identifying interfaces in a fragmented system and integrating such systems. It also suffered from frequent misinterpretation, appearing to force workers to work faster and harder, while it is meant to speed up workflows by elimination of frustrating impediments to flow. Emphatically, Lean does not expect anyone to work faster or harder, but everybody is expected to work smarter [Oppenheim, 2021]. But the most important contribution of Lean to workflows, particularly applicable in healthcare, is the very definition of waste: “anything other than what is absolutely required to deliver value to the patient or patient proxy, such as a provider” [Oppenheim, 2021]. Table 4 summarizes these characteristics.

Table 4. Characteristics of Lean

Characteristic	Description
Main steps, tools, emphases	Optimization of entire workflow by relentless elimination of wastes. Philosophy that "anything other than what is absolutely required to deliver value to the customer is waste". General formalism of 8 waste categories and organization of work using 6 Lean principles. Batch minimization and focus on single piece flow of work elements (patients) per common takt time. Like TQM: Bottom-up employee suggestion system; self - motivation of employees; Corporate culture based on respect for people and employee empowerment.
Strengths	Changing front line workers into powerful problem solvers. Tangible improvement of bottom line. Cost, lead time and defect reduction by up to 90%. Capacity increase by up to 90%. Focus on workflow speed and organization.
Weaknesses	Inability to integrate across interfaces in fragmented system. Focus on flow speed but poor ability to improve quality of work elements.
Cost and effort of implementation	Significant training cost and effort, then relying on work teams. But overall strong improvement of revenue.
Ability to reduce system variability	Poor. Focus on workflow speed instead.
Importance of literature review	None.
Ability to remove waste	Excellent, this is the focus of Lean.
Ability to eliminate bottlenecks	Excellent, by balancing flow.
Ability to apply rigor across the entire project	Excellent for implementing the Lean Principles. Poor in analysis of alternatives, systems architecting, risk management, rigorous verification and validation.
System's approach	Limited to workflow system, ignoring externalities, subsystems, interfaces. Analysis of current state limited to value stream mapping.
Ability to integrate across interfaces of fragmented system elements	Poor, ignoring interfaces between work tasks.
Ability to reduce project iterations	Poor, only via waste analysis and elimination.
Promotion of leadership engagement	Excellent, systemic.

2.5. Lean Six Sigma

As [Oppenheim, 2011] described, Lean and Six Sigma both appeared in the post - TQM mid

1990s era as seemingly competing process-improvement approaches. Six Sigma, identified with Motorola and subsequently with GE, gained investor visibility and popularity. Lean identified with Toyota was incorrectly looked upon as limited to high volume manufacturing applications. While Six Sigma focuses on a disciplined, top - down approach to the elimination of all forms of variation, Lean focuses on speeding and optimizing the flow of work through the value streams by relentless elimination of waste. Six Sigma eliminates impediments to flow by variability reduction and quality improvements of workflow tasks, thus enabling faster flow. Thus, the basic principles of the two approaches are highly synergistic and complementary. By early 2000, most organizations adopted a blended version of the two bodies of knowledge and crafted them to meet their particular needs. Names such as Lean Six Sigma, Lean Sigma, and other less obvious name combinations appeared. Today, most organizations have harmonized Lean and Six Sigma. Many organizations now use the shorthand designation “Lean” when they mean “Lean and Six Sigma”, and the present authors have adopted this designation. Table 5 summarizes these characteristics.

In this text, for brevity, we will continue to use the Lean term and nomenclature, as meaning Lean Six Sigma, including the relevant parts of the earlier quality paradigms: PDSA and TQM.

Table 5. Characteristics of Lean Six Sigma

Characteristic	Description
Main steps, tools, emphases	Optimization of entire workflow by relentless elimination of wastes. Philosophy that "anything other than what is absolutely required to deliver value to the customer is waste". General formalism of 8 waste categories and organization of work using 6 Lean principles. Batch minimization and focus on single piece flow of work elements (patients) per common takt time. Like TQM: Bottom-up employee suggestion system; self - motivation of employees; Corporate culture based on respect for people and employee empowerment. Great ability to eliminate impediments to flow by task variability reduction.
Strengths	Changing front line workers into powerful problem solvers. Tangible improvement of bottom line. Cost, lead time and defect reduction by up to 90%. Capacity increase by up to 90%. Focus on workflow speed and organization.
Weaknesses	Inability to integrate across interfaces in fragmented system.
Cost and effort of implementation	Significant training cost and effort, then relying on work teams. But overall strong improvement of revenue.
Ability to reduce system variability	Excellent, via Six Sigma approach.
Importance of literature review	None.
Ability to remove waste	Excellent, this is the focus of Lean.
Ability to eliminate bottlenecks	Excellent, by balancing flow.
Ability to apply rigor across the entire project	Excellent for implementing the Lean Principles and Six Sigma. Poor in analysis of alternatives, systems architecting, risk management, rigorous verification and validation.
System's approach	Limited to workflow system, ignoring externalities, subsystems, interfaces. Analysis of current state limited to value stream mapping and process variability.
Ability to integrate across interfaces of fragmented system elements	Poor, ignoring interfaces between work tasks.
Ability to reduce project iterations	Poor, only via waste and variability analysis and elimination.
Promotion of leadership engagement	Excellent and systemic, via Lean.

2.6. Theory of Constraints

Introduced by [Goldratt, 1999] the Theory of Constraints (TOC) method promotes process improvement by identifying the biggest current constraint, or bottleneck, or impediment to flow, and elevating or eliminating it. Free of the impediment, the entire flow then speeds up, now constrained by the next (but smaller) impediment, which needs to be eliminated, and so on. Thus, it is similar to Lean in the intent to speed up workflows, but Lean does it by eliminating all seven wastes from the process, while TOC by eliminating the biggest impediments, one at a time. Probably because Lean has become the established paradigm in manufacturing, healthcare, and many other domains, it overtook TOC in popularity[6]. Table 6 summarizes these characteristics.

[6] Goldratt also promoted optimization of complex flow of value streams that merge together, by optimizing the critical chain among them [Goldratt, 1997]. This approach is ignored here as the other methods discussed herein are significantly more relevant to healthcare projects.

Table 6. Characteristics of TOC

Characteristic	Description
Main steps, tools, emphases	Optimization of entire workflow speed by identifying the biggest current constraint, (bottleneck, or impediment) to flow, and elevating or eliminating it.
Strengths	Ability to identify impediments to flow.
Weaknesses	Narrow focus in impediments, to the exclusion of all other aspects of projects, system, interfaces, and process variability.
Cost and effort of implementation	Low.
Ability to reduce system variability	Poor, unless the variability is the impediment to flow.
Importance of literature review	None.
Ability to eliminate bottlenecks	Excellent, the main focus.
Ability to apply rigor across the entire project	Poor. Limited focus on elimination of impediments to flow.
System's approach	Poor, ignoring system analysis, externalities, subsystems, interfaces.
Ability to integrate across interfaces of fragmented system elements	Poor, ignoring interfaces between work tasks, except for impediments to flow.
Ability to reduce project iterations	Poor, the approach is inherently iterative, one impediment at a time.
Promotion of leadership engagement	None explicit.

3. Lean Healthcare Systems Engineering Process

The LHSE process is an integration of Lean and Systems Engineering, with the latter heavily tailored for healthcare operations. The tailoring is explained in Section 3.1.

3.1. Systems Engineering

The first official call for use of Systems Engineering in healthcare was made by the Presidential Council of Advisors for Science and Technology [PCAST, 2014]. The call was motivated by the gap between the need and reality: on one hand the increasingly complex continuum of care steps needed by patients and providers, contrasted with the specialized education of medical professionals who are focused on prevention, diagnosis and treatment. Healthcare providers' lack of training in integrating fragmented healthcare workflows manifests when patients suffer from miscommunications, miscoordinations, open loops, "dropped balls", incompatible information, inability to access information, difficulty contacting the needed individuals, and many others.

To illustrate the fragmentation in healthcare, consider the treatment of adolescent and young adults (AYA) with cancer. The typical care involves up to 10 complex steps, including family medicine, oncology, pathology, surgery, radiation medicine, infusion centers, chemotherapy, fertility preservation, mental health, social work, financial advising, and even transportation [Speicher, 2019]. The young and frightened patients unfamiliar with the workflows tend to be lost in the complex steps, not knowing what to do next, who to contact, how to communicate, and experience the "dropped ball" syndrome with dire consequences for their health. While the providers tend to be empathetic and dedicated experts in their own area, they are usually unable to guide each patient through the individual longitudinal continuum of the needed care steps.

As [Oppenheim, 2021] described, the domain of SE was created specifically for integration of fragmented elements in complex systems. To the uninitiated, the term SE can be misleading as it conjures images of engineering and mathematical formulas. Not so. It is a historical term. The discipline of SE was created by Si Ramo and Dean Woldridge in 1954 to help with the development of ballistic missiles which had to work unconditionally [Jacobson, 2001]. It is a heuristic body of knowledge focused on managing flow of information in fragmented systems. Ramo and Woldridge realized that those missiles are too complex and too dangerous to rely on individual engineering disciplines of mechanical, aerodynamic, electrical, propulsion, etc., in isolation from one another [Brown, personal communication, 2009]. They understood that complex systems usually fail at the interdisciplinary interfaces (often interfaces among humans) rather than within single-

discipline elements. The individual elements going into a system may be perfectly designed by best disciplinary experts (analogy to expert medical professionals), but they fail the assembly into the system (analogy to continuum of care). The individual elements do not fit together physically, functionally, or in terms of human interactions - because disciplinary experts did not understand the interfaces between the disciplines, activities, or the people. Thus, some new process had to be invented to assure perfect integration of the elements across all interfaces. The word "engineering" in the SE name is historical, originating from the fact that the process was initially applied to engineering systems. In healthcare environment that word is somewhat unfortunate and misleading, scaring healthcare professionals with mental images of mathematical formulas. In fact, there is very little engineering in SE, even less mathematics[7]; it is more like a rigorous logical process for managing the flow of information throughout the project elements.

The SE process is not derived from natural sciences or mathematics. It is a heuristic body of knowledge more akin to Project Management (PM) but focused on managing flow of information in fragmented systems while PM tends to focus on management of resources, but there is some overlap between PM and SE[8].

The ability of SE to integrate fragmented elements maps superbly onto the needs of healthcare, which is recognized as one of the most fragmented domains in human civilization. Every healthcare worker is painfully aware of the frequent miscommunications occurring in all clinical environments: between different providers; between hospital departments; between providers, patients and payers; providers and laboratories; doctors and nurses; emergency departments and hospitals; hospital and post-hospital care institutions; and this is only a short list. Fragmentation occurs in all major care delivery activities, from diagnosis and treatment, to home care, long-term care, chronic care, and preventive care. Two powerful forces contribute to the fragmentation. One is the traditional medical education which emphasizes doctors' autonomy and specialization but not the efficient system-wide workflows in which correct information should flow reliably in a timely manner between various stakeholders and organizations involved in the patient care system. The second reason is the complex web of heterogenous health delivery institutions atomized into disjointed general and specialty clinics and hospital departments, individuals, laboratories, pharmacies, and payers. The fragmentation in the U.S. is particularly acute

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[7] Some exotic branches of systems engineering use mathematics, [Sage & Rouse, 2014] but these are ignored here, as they are of little practical use in healthcare operations.

[8] Modern trend [Rebentisch, 2017] is to integrate both SE and PM processes into one project management process, but this is outside of the scope of this text.

because of the fragmented collection of private, employer, local, state, federal and military organizations involved in healthcare. Due to these factors, healthcare systems, particularly in the U.S. have evolved to be highly stove-piped organizations optimized for the convenience of local stakeholders but not for the patient-centered care continuum.

Since the beginning in the 1950s, SE was used mostly in large engineering programs mostly in defense and aerospace, and to a lesser degree in infrastructure, energy, and automotive programs. The defense context of SE is important for our considerations because large defense programs funded and led the evolution of systems engineering. Besides technical capabilities, such programs are driven by powerful political and lobbying forces whose main objectives are jobs, cost-plus contracting, long-term profits, and risk aversion. In this environment, process efficiencies and streamlining have been a low priority. It is not unusual for a defense program to start with several hundreds of thousands of requirements [Carter, 2010]. Consequently, the biggest portion of a typical defense SE effort is spent on management of this huge number of requirements: formulating, iterating, deconflicting, clarifying, modifying, and verifying [Oppenheim, 2011]. The team involved in the execution of a typical defense development program involves hundreds of companies distributed nationally and even internationally with hundreds of thousands of stakeholders, plus a significant number of military or NASA workers. A typical large program lasts tens of years and creates hundreds of thousands or millions of program documents that comprise program requirements management and related activities, and subsequent system design [Carter, 2010]. To integrate and coordinate such vast programs, SE evolved into an inefficient bureaucracy of requirements management. Eric Honor, the 1997 President of International Council on Systems Engineering (INCOSE) named it "the bureaucracy of artifacts" [Honour, 2010].

A major development in the field of SE started in the early 2000s with the adoption of a computerized representation of program requirements, documents and models describing various system characteristics and elements. Named Model Based Systems Engineering (MBSE), it soon became a popular tool in requirements management, as it eliminated bulky paper documents with well-organized data structures. It was crowned in INCOSE's 2007 vision statement which promoted ubiquitous[9] use of MBSE in all programs by 2020 [INCOSE, 2007]. Indeed, many systems engineers practicing in large technology programs became enthusiastic about MBSE. But this was also the beginning of a serious "cognitive divorce"

[9] David Long, 2014-15 INCOSE President and the owner of a company producing important MBSE tools in his written communication to the first author stated that MBSE should not be regarded as panacea to all projects and programs and the term "ubiquities" should be applied judiciously.

between the mainstream SE users and healthcare practitioners, as follows.

After the 2014 PCAST appeal to systems engineers to come to the rescue of healthcare, and seeing the huge size of the U.S. healthcare industry (at $4 trillion, four times larger than defense and by far the largest segment of U.S. economy), systems engineers eagerly anticipated similarly big work opportunities in healthcare. Numerous initiatives were attempted to apply SE in healthcare delivery projects using MBSE. The first two authors of this article participated in several INCOSE Healthcare Working Group conferences [INCOSE HWG, 2021] in which healthcare executives described their needs and systems engineers presented the MBSE approach, resulting in a decidedly poor mutual match. The disappointments were driven by the significant differences between the defense and healthcare domains. Large defense programs are funded by the federal government, cost billions of dollars, employ tens or hundreds of employees in nationally distributed supply chains, while typical healthcare delivery projects focus on improving some aspect of workflow or care in a local setting, e.g., in a local clinic, hospital, laboratory, or pharmacy. The typical healthcare delivery projects involve a few individuals (often only one) working for a few weeks or months with small budgets or even no explicit budgets (working as a part of their regular duties), and the projects start with only a few (or even only one) requirements. The following are examples of typical projects in healthcare delivery operations:

- Reduce patient discharge time from a hospital
- Improve on-time starts in operating rooms
- Streamline patient admission from emergency department to hospital
- Reduce burnout of residents and nurses dealing with conflicting medical orders issued by operating surgeon and recovery intensivist
- Reduce no-shows and overbooking in a clinic
- Reduce patient throughput time in a clinic
- Reduce turnaround time and cost of clinical tests
- Reduce transportation time of samples between collection clinics and central laboratory
- Increase capacity of imaging laboratory without adding resources or working faster
- Reduce alarm fatigue in hospital
- Increase the use of online portal among patients.

Some population health projects dealing with chronic care, wellness, and preventive care may have a huge impact on large patient populations served, and require large teams in the care delivery phase, but the projects themselves designing the new care would still be small

in terms of schedule, budget, and the project team size [Kanter et al., 2013]. Examples of such population projects involve development of effective procedures for:

- Increasing vaccination rate
- Decreasing disparity between Caucasian and minority populations receiving vaccinations
- Reducing obesity or A1C in patients with diabetes

Such typical projects in healthcare are several orders of magnitude smaller than defense programs, as shown in Table 7.

Table 7. Scale of Healthcare vs Defense Programs

	Typical Healthcare Delivery Project	**Typical Defense Program**
Number of requirements	Under 10	1000-100,000
Budgets	$ 10,000-100,000	$ billions
Number of employees involved	Under 10	10,000-100,000
Project duration	Weeks to months but possibly 1-2 years	Decades
Driving incentive	Streamline a workflow or improve care in a clinical setting	Cost-plus federal funding and jobs.

The bifurcation of interests between the SE and healthcare communities should not come as a surprise when we observe the divergent incentives (last row of Table 7). The application of MBSE designed for managing tens of thousands of requirements to only a few requirements needed in healthcare would be a monstrous overkill and cause unacceptable cost increase, requiring a long learning curve to master MBSE because healthcare workers tend to lack the prerequisite technical background. And the benefits would be negligible. This dramatic difference in project scope was the source of the main disappointment on the part of many traditional systems engineers who wanted to undertake healthcare delivery projects, and on the part of healthcare managers eager for help from systems engineers. This was the main reason why for several years after the PCAST report, not much progress was made in the applications of SE to healthcare operations.

The creation of the LHSE process aimed at changing this situation, starting with a simplified definition of SE: **SE is a rigorous time-proven process for managing and coordinating information and work flow for all relevant elements of the system of interest, and strong focus on the system integration. It is a process of rigorous integration of complex fragmented elements so that they work together as a system, perfectly, as intended.**

3.2. LHSE Process

The overarching aim for the creation of LHSE process was to create a maximally useful, practical tool which would be general enough to be applicable to all care delivery operations yet would be easy to learn and use. Another intent was to avoid the weaknesses and combine the strengths of the previous approaches, and add the strengths of SE. In order to achieve this, the process had to adopt the rigorous (but non-mathematical) steps and include only those steps which are absolutely required to deliver value, and to ignore all the bureaucratic, wasteful steps which have evolved in systems engineering used in defense industry.

The LHSE process is shown in Fig. 1. It has four phases: Background, Analysis of Current State, Design of Future State, and Implementation, arranged graphically as a symbolic letter "V", following the SE tradition [Oppenheim, 2021]. Each phase includes a number of steps, as summarized below (detailed descriptions can be found in [Oppenheim, 2021].

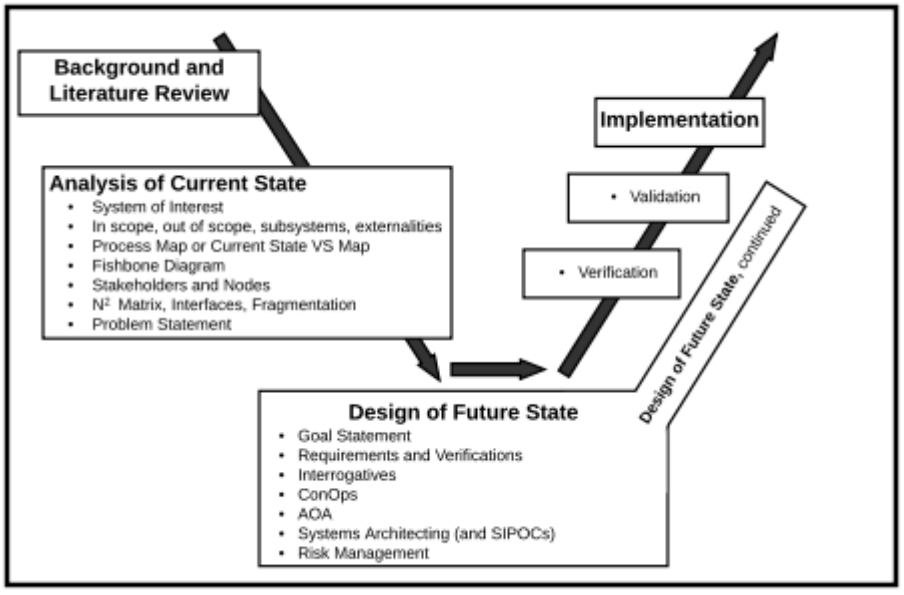

Figure 1. LHSE Process [Oppenheim, 2021]

3.2.1. LHSE Phase 1: Background

Starting a new project with a description of the project background provides an important common context for current and future workers and stakeholders. The background section should include a description of the project environment, location, main characteristics relevant to the project, such as the number and demographics of patients served, the

number and type of employees of different levels, relevant union organizations represented, ancillary facilities, cooperating vendors, etc. Any applicable regulatory and resource constraints (for example, budget and available staff) should be listed, if relevant.

The reason(s) why this project is undertaken should be named. However, it is important not to "jump the gun" and attempt to state the project goals right away – that will be done after the Analysis of Current State phase is completed, as an informed statement. At the project beginning, normally there is insufficient evidence to state the project goal precisely. "Not jumping the gun" is a part of the project rigor and contrasts with the other improvement methodologies mentioned above.

Next, the opportunities for improvements or new solutions should be presented. The current challenges: frustrations, burnout, gaps in quality, safety, cost, process time, fragmentation, miscommunications, etc. should be described. This is the place to cite the existing literature and summarize former/similar solutions.

In the spirit of Lean, one should balance the amount of information provided in the Background phase with the waste of information overproduction and over processing. The right amount is that which facilitates subsequent communications between project stakeholders and sponsors, avoids miscommunication, and promotes project success and implementation. Example of information to include in the background section is presented in [Oppenheim, 2021].

3.2.2. LHSE Phase 2: Analysis of Current State

The main objective of the Analysis of Current State (AoCS) is to gather evidence with data (Balestracci, 2015). Here the project dives into the current challenges, wastes, and frustrations, and seeks to understand root causes of problems. The last step of the AoCS is the Problem Statement which will serve in the next phase of the project: Design of Future State as the starting point for designing the solution with a high degree of rigor.

The AoCS is quite open-ended in terms of the format and tools used. Typically, tools from several disciplines are used, as applicable and as convenient: SE, healthcare management; Lean and Six Sigma; Quality, including PDSA methodology; SPC; TOC; TQM and other methods to study variability, and project management. If needed, expertise from medicine, IT, engineering, and law may have to be brought in. The overriding objective is to gain the needed knowledge of our system rather than discipline purity. The subsequent paragraphs describe some of the more popular tools taken from the domains of SE and Lean Six Sigma, but they should not be interpreted as exclusive or mandatory. This open-ended character of the AoCS may appear to contradict the LHSE rigor which we emphasize so heavily. Indeed,

the rigor should come in the depth of understanding of our problem and the formulation of the Problem Statement rather than the type of tools used towards this goal. The reader will find a higher degree of tools rigor in the next project phase, Design of Future State.

3.2.2.1. Stakeholders, System of Interest, Project Scope, and Externalities

The first step in the AoCS is to select our System of Interest (SoI), project scope, and system elements including both human stakeholders and non-human nodes, for example, EHR. These selections should be performed early in the project because the choice will affect our subsequent in-scope and out-of-scope project activities, the level of effort, project duration, and budget. The selections of system, stakeholders, and scope are related because changing one affects the others. The selection may be iterative; we start with one of the three, whichever is easiest, then identify the others; and consider the effect of our choice on project effort, budget, and duration. Fig. 2 illustrates the SoI, its elements, and in-scope activities as well as externalities for the project of patient discharge from a hospital. Major interfaces (interactions) are shown as thick arrows. In this example, they represent negotiations between the entities shown.

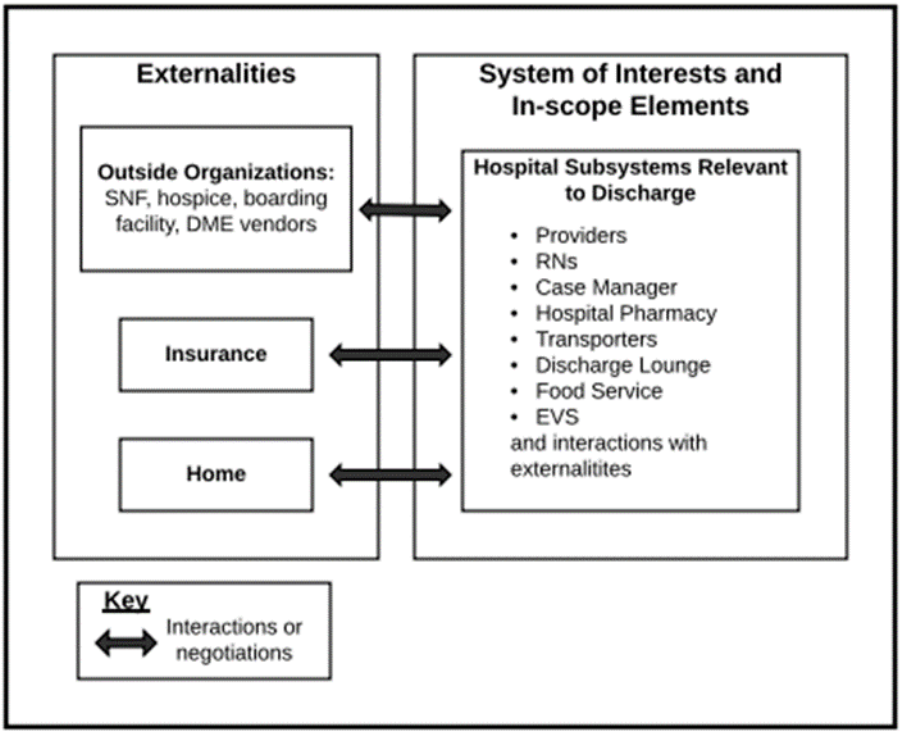

Figure 2. Example of System of Interest [Oppenheim, 2021].

The selection of the SoI size is often iterative. It is intuitively obvious that selecting too big a system leads to excessive project size, insufficient granularity, unaffordable costs, and duration. Too small a system risks missing important system characteristics or interfaces.

3.2.2.2. Fragmentation and the N^2 Matrix

As stated above, fragmentation is recognized as one of the biggest evils of healthcare [Elhauge, 2010] in all healthcare systems. LHSE manages fragmentation by identifying and fixing all imperfect interfaces between the relevant fragmented elements within the SoI and those with externalities. SE provides one of the most powerful tools for interface identification, called the N^2 matrix, where N is the number of elements in the system. The selection of N elements of the system is often not obvious when dealing with human beings and organizations. One of the critical questions that comes up in every project is what level of granularity should be used when listing the elements. Too high a granularity will yield a large N and the N^2 number will be so large that it becomes unmanageable, drowning the solution in irrelevant details. Too few elements may hide important interfaces.

Consider the evil of fragmentation in a routine case of a patient seeing a Primary Care Provider (PCP) with a complaint of a persistent moderate abdominal pain. Before making a final diagnosis, the doctor orders blood work. A local phlebotomist is supposed to prepare the labels, draw blood samples into a few vials, attach the labels, and send them to a nearby clinical laboratory. The samples are to be transported to the lab, sorted with numerous other samples, analyzed, resulted, and the result automatically sent back to the ordering physician using EHR. This appears to be a simple, totally routine activity involving the following elements in our SoI: patient, physician, physician's nurse, phlebotomist, and clinical lab. In this example, for the sake of simplicity, only a shortened list of stakeholders is listed, ignoring clinic scheduler, receptionist and nurses, lab equipment maintenance technicians, equipment engineers and manufacturers, data entry clerk in the labs, transport driver(s), billing clerks, and hundreds of others. Once the five main system elements have been identified (N=5), the next step is to construct the N^2 matrix, listing the elements as both rows and columns, as shown in Fig. 3. Ignoring the cells on the main diagonal, the remining N(N-1) cells (20 in this example) show a possible interface or interaction (bi-directional or symmetric) between any pair of the elements. **Each cell represents an opportunity for the shown interface to go wrong.**

	Patient	PCP	Nurse	Phlebotomist	Clinical Lab
Patient					
PCP					
Nurse					
Phlebotomist					
Clinical Lab					

Figure 3. The N^2 Matrix for a Routine Medical Visit [Oppenheim, 2021].

In this simple routine clinical test any interaction may go wrong, including: the patient left the clinic before giving blood (bad interaction between the patient and the nurse who was supposed to inform the patient of the need to see a phlebotomist); the sample was taken but was placed in a wrong vial (a bad interaction between the phlebotomist and PCP); the label came off the vial or the vial was lost (bad interaction between phlebotomist and the lab); the sample was resulted, but the system failed to send notification to the ordering PCP (bed interaction between the lab and PCP); the test was positive but the PCP failed to follow up (bad interaction between PCP and the patient), and so on. Each of the above events has a low but not zero probability[10], and each has potentially fatal consequences if ignored especially if the test were positive for a serious disease. Each cell in the N^2 matrix should be labelled with a unique agreed letter code (e.g., T for phone interface, F for face to face, E for communication via EHR, etc. The quality of each interface should be marked in the cells with colors: green = working well, yellow = problematic, red = broken. Each red or yellow should be addressed in subsequent requirements for the SoI. The reader is invited to compare the rigor of this approach to the traditional approach, where only those interfaces would be identified and acted upon which created some kind of a visible trouble: patient harm, a legal or disciplinary action, or such. Others tend to remain in hiding. The LHSE provides rigorous and rich identification of all interfaces, showing the means of communications (e.g. by phone, huddle, face to face, text, email, etc.) using letter codes, and the quality of each (e.g., working fine, problematic, dysfunctional) using colors. [Oppenheim, 2021] contains examples.

3.2.2.3. Architecting the Current State

Good graphical representations of systems and work processes in healthcare projects

[10] The first two authors were involved in a year-long study of a major clinical laboratory and confirm from first-hand experience that each of the fragmentation events listed above actually took place.

cannot be overstated. SE uses architecting charts for that purpose. Most of architecting charts are useful in the next phase of the LHSE process, Design of Future State, where the solution is illustrated. However, some charts are also useful in the AoCS, as follows.

The Process Map, or if the data on waste is available, the Current State Value Stream Map (CS VSM) are used to illustrate the current workflow. The CS VSM is like a process map but with added information about wastes and timing measured at different workflow points. Ideally, all eight waste types used in Lean should be addressed. In healthcare projects one rarely has the luxury of time and budget to measure all eight accurately. In healthcare workflows the dominant category of waste is waiting: patients waiting for activities, activities waiting for patients, providers waiting for other providers or information, etc. So, just focusing on waiting waste alone usually leads to vast improvements. But other wastes may be important too. Patient safety depends on avoidance of defects because in healthcare they can have deadly consequences. Poorly architected clinic and hospital spaces can yield motion and transportation waste, which is easy to analyze using the so-called spaghetti and time charts. Poorly designed, especially bureaucratic tasks and processes can yield overproduction and overprocessing waste. Poorly managed inventories of supplies and medicines can yield inventory waste, and poorly scheduled medical activities can yield patient batching which transforms into the waiting and human-inventory waste. And the waste of human potential manifests itself in the form of provider's burnout, an increasingly critical characteristic of healthcare work. So, there is a lot of information that can be captured and shown on the CS VSM. Once this map is available, the Design of Future State will be so much easier to create, and much more effective. But if data on waste and timing is not available, or not relevant to the project, a Process Map alone should be used. Figure 4 illustrates example (simplified for this article) of a CS VSM. Other popular tools of PDSA/TQM such as the root cause analysis, including Ishikawa Diagram and the 5 Whys are popular in this phase [Oppenheim, 2021].

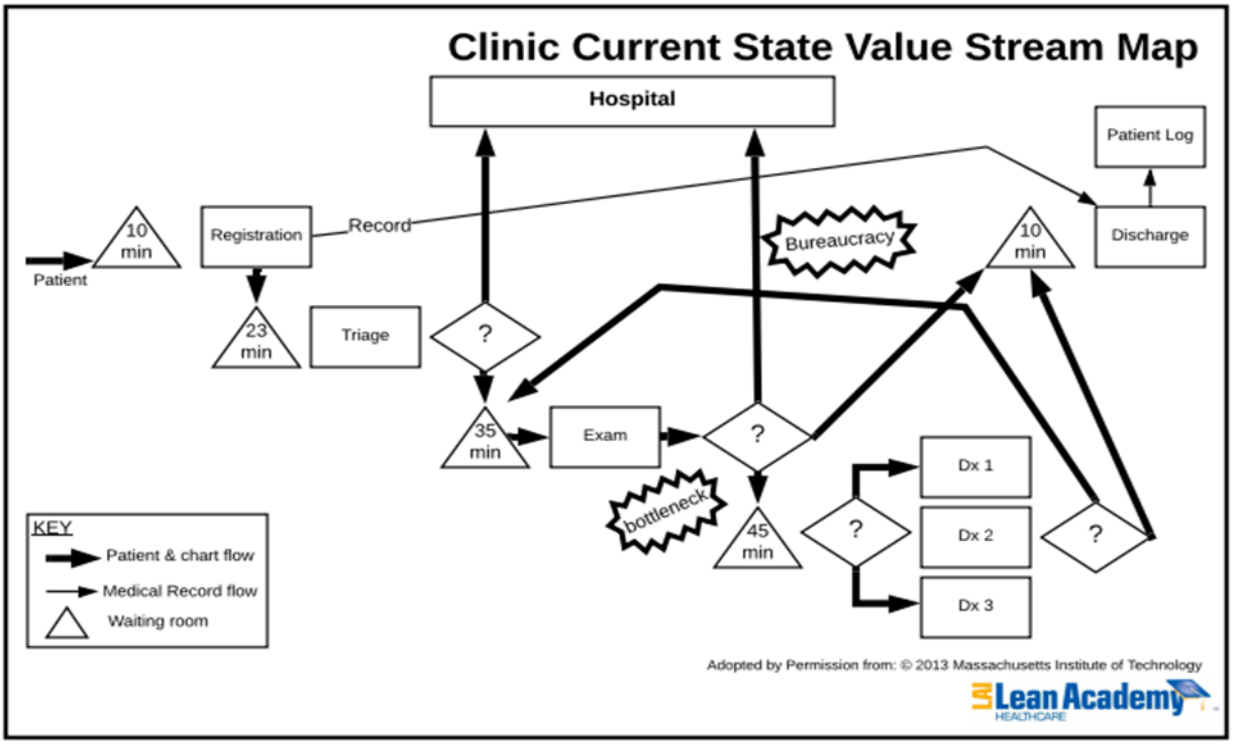

Figure 4. Example of CS VSM

More examples will be shown in the Design of Future State.

3.2.2.4. Problem Statement

The Problem Statement should be the last element of the AoCS. It is the "big bang" of the AoCS. At this step, the project team must have a near perfect, complete, clear, unambiguous, qualitative, and quantitative understanding of the system of interest, its problems, wastes, fragmentation, frustrations, miscommunications, etc.

The Problem Statement is a brief statement precisely summarizing the problem(s) to be addressed in the project. It is a critical element in the LHSE process rigor because it will drive all project steps in the subsequent Design of Future State. In LHSE, the Problem Statement is informed by a great deal of analysis prior to its formation, which is an important differentiator of LHSE from other improvement methodologies. A poorly formulated Problem Statement almost guarantees imperfect project outcome.

When formulating the Problem Statement, one should be inspired by Lean thinking: not trying to solve "the whole healthcare universe", not listing everything that is wrong in the institution; and in healthcare any halfwit can list numerous frustrations, grievances, and

problems. The focus should be on a specific problem or set of related problems that will lead to realistic feasible solutions. The Problem Statement should be limited to stating the problem and should be "solution agnostic," i.e. not attempt to present or suggest any solution. An example of a good Problem Statement is presented in [Oppenheim, 2021].

Formulating the Problem Statement at the end of the AoCS is conducive to a mature informed statement. Some healthcare projects state the problem at the beginning, in the Background section. For example, an excessive discharge time from the hospital is a problem that is usually well known to stakeholders even before the project is started and authorized, so there is a natural temptation to state it right at the beginning of the project. But the LHSE rigor requires that in the Background section we just state it as perhaps a "principal goal," e.g. "reduce excessive discharge time," but do not attempt to be too precise before we have a chance to analyze the problem at depth. Doing so assures that we do not "jump the gun", follow the rigor, and end up with a well-informed Problem Statement.

3.2.3. LHSE Phase 3: Design of Future State

In the Analysis of Current State, besides healthcare and systems engineering, tools from a mix of other knowledge domains are often used: Lean Six Sigma (and earlier quality approaches), project management; perhaps also medicine, IT, engineering, and law. In contrast, the steps used in the Design of Future State (DoFS) are limited mostly to systems engineering and Lean tools.

3.2.3.1. Goal Statement

The AoCS phase ends with a well-informed Problem Statement. The DoFS should begin with a realistic and feasible Goal Statement, which is a mirror image of the Problem Statement, just changing "what is wrong" to "what we need to do to fix it." It should be a concise statement on what this project is to accomplish. It should be formulated with the same clarity as the Problem Statement.

The Goal is different from a requirement; it is only meant as a starting point in formulation of the corresponding quantitative and verifiable requirement(s). The Goal represents the project objective but does not include the pass/fail verifiable and legally enforceable details. Goals are to be validated in the last step of the DoFS. In other words, follow this rule: Requirements must be verified; Goals must be validated.

The number of Goals should be small, often only one; having too many goals risks prolonged iterations and conflicts among stakeholders. It is better to split a project with too many

goals into several smaller projects each with only one or a few goals. An example of a Goal Statement is presented in [Oppenheim, 2021].

3.2.3.2. Requirements

Rigorous formulation of project requirements is a critical step of LHSE, as it is for any SE project. Requirements interpret Goals into precise characteristics of the desired Future State. LHSE provides the project rigor as follows:

- The Problem Statement is informed by a comprehensive Analysis of Current State, summarizing "what is wrong".
- The Goal Statement is a "mirror image" of the Problem statement informing what this project is to achieve, that is "what to fix".
- The Goal Statement logically leads to precise and verifiable Requirement statement.

This sequence of logically rigorous steps of Problem-Goal-Requirements contributes to a high probability of successful outcome. Requirements should be achievable but solution agnostic. In other words, when writing a requirement, one should not be constrained by how it might be implemented. Concerns regarding implementation will be handled in the subsequent risk analysis. However, requirements must be achievable; it would be counterproductive to write a requirement that we know *a priori* to be impossible to achieve.

Each requirement must be objectively verifiable. This implies that each requirement must be written with sufficient precision, clarity, lack of ambiguity and single meaning, so that every stakeholder will understand it in the same manner, and that the verification can only be binary: pass/fail. Each requirement must have the word "shall" in it, as in "…the patient discharge time shall be reduced to…". One should not combine several different aspects into a single requirement because verification may then be difficult, confusing as to which aspect is being verified and to what degree. Fig. 5 illustrates a bad requirement, the reasons why it is poorly written, and a corrected, verifiable requirement.

Bad requirement: The discharge time from hospital X and from the hospital ED will be reduced to be below the value of competitive hospitals.
Why is this a bad requirement? • Not verifiable, ambiguous, unclear • Lacking the word "shall" • Convoluting two different discharges: from hospital and from ED. • Not clear how the time is to be measured. As average? And if so, measured over what period? As a maximum? And measured during what period? • What is the value being compared to? Which other hospitals are being considered? • By what date is this to be accomplished?
Good requirement: The average discharge time of all patients from hospital X measured over a 30-day period starting on [specific date] shall be reduced to under two hours. The discharge time to be measured from the time of issuing discharge orders by the attending MD to the moment when the patient is wheeled outside of the hospital building. The reduction shall be demonstrated by [specific date].

Figure 5. Example of bad and good requirement [Oppenheim, 2021]

Each requirement shall be accompanied by a specification of how it will be verified. Verification must be done by one of the four following methods: test, measurement, inspection, or analysis [Walden et al., 2015]. Table 8 represents an example of organizing the requirements and their verifications into a table.

Table 8. Requirements Table

#	Requirement text	Owner / Justification	Verification means
1			
2			
3			
Etc.			

3.2.3.3. Project Interrogatives

If the project involves a team of people, it might be useful to borrow a tool from the project management domain, called Project Interrogatives [Spewak et al., 1993]. It is a set of six questions symbolically described as "who, what, where, when, why, and how" – which, when answered, make it clear how the project execution responsibilities are distributed:

- Who: who is to do it?
- What: what action is to be done or is needed?
- Where: where is it to be done or needed?
- When: when is it to be done or needed?
- Why: why is it to be done or needed?
- How: how is it to be done?

This information injects clarity and accountability into the project execution. This step of LHSE is optional and should be left to the project manager to decide whether to use it or not. Very small teams (1-2 people) probably do not need it. Similar interrogatives may also be used in the project Implementation phase, as the individuals implementing the project results may be different than those executing the project.

3.2.3.4. Concept of Operations

A Concept of Operations (ConOps) is a text document describing the intended use or operations of the system. It may include verbal descriptions how the future SoI should be used, by whom, when, under what circumstances, subject to what limitations; what training will be required to use it, etc. [Walden et al., 2015]. ConOps are formulated as informative narrative rather than imperative sentences. [Oppenheim, 2021] includes a comprehensive example.

3.2.3.5. Analysis of Alternatives

Once the requirements are defined, the project can proceed to the solution creation. It is critically important not to "jump to a conclusion," selecting a particular solution right away without first considering all reasonable solution alternatives. The Analysis of Alternatives (AoA) is an important step of LHSE, used to identify the solution candidates, agree on the means to evaluate them objectively, and select the best one. The AoA includes the following steps: identification of candidate solutions, selection of measures of effectiveness, and the candidate selection.

Among the candidates one should always include "do nothing," in other words, keep the current state. Including it as an alternative enables the team to compare other proposed candidates to the current state using the same measures. Typically, in healthcare projects, 2-4 candidate solutions are identified (in addition to "do nothing"), all of which appear reasonable and have a good chance to satisfy the requirements. The candidates are

proposed by stakeholders of the system based on their experience, creativity, benchmarking with competition, as well as solid understanding of the requirements. It is important to allow junior team members to propose their candidates and not to permit the authority gradient to stifle creativity. Surely, experience plays an important role, however, junior members' creativity is often invaluable, especially when dealing with modern technologies, IT, electronics, etc. [Oppenheim, 2021] includes a detailed example of the alternatives considered in the patient discharge project.

After selecting the candidate solutions, the next step of the AoA is to specify Measures of Effectiveness (MoE) that we will be applied to rank and judge candidate solutions as objectively as possible. Typical MoEs are: safety, cost, level of effort, turnaround time, wait time, ease of use, time to implement, patient acceptance, stakeholder acceptance, perhaps union acceptance, strengths, weaknesses, threats, opportunities, etc. Not all of them need to be applied in a given AoA. The choice should be driven by common sense and experience, as well as Lean Thinking ("do what is required to create value and no more"). A common practice is to use ranking scales for the MoEs, typically 1-5, with 1 being the least attractive and 5 being the most attractive, but other scales can be used if desired (e.g., popular Pugh scale from -2 to +2). The allocation of particular values to different alternatives is, of necessity, somewhat arbitrary, an "educated guess". Experience in the project domain is invaluable here. The exact value is not critical if the relative rankings are correct. The AoA in healthcare delivery projects is not meant to be a huge effort, consuming precious project budget and schedule. Educated guesses are usually "good enough." Performing detailed quantitative analysis of the measures appears to be an overkill and contradicts the Lean approach. Usually, it is fairly evident what measure value should be assigned to a given candidate alternative.

Even though educated guesses rather than science-based values are used on the ranking scales, the rigor of the AoA process is higher than an arbitrary decision at the project beginning to use only one solution idea.

3.2.3.6. Future State Design

Once a single alternative is selected, the project can proceed to detailed design of the SoI future state. Normally, this step represents a major effort of the project. The step is sometimes iterative: start with a design of the selected alternative, architect it (i.e., illustrate it graphically), and iterate it until acquiring certainty that all requirements can be verified, and all project goals validated. The knowledge utilized in this step is the healthcare and medical knowledge of the project subject rather than LHSE. The LHSE process provides

the necessary rigorous inputs into the design (goals, requirements, ConOps, and AoA), and will use the design outputs to rigorously architect, analyze for risks, verify, validate, and implement the designed SoI. But the design itself is specific to a given clinical environment of the SoI, so it should be left to healthcare and medical experts among the project stakeholders.

3.2.3.7. System Architecting

In healthcare delivery projects, design of a SoI usually involves a redesign or a new design of a workflow or care. The architecting step of LHSE is highly useful illustrating the new information flow among the SoI stakeholders. The process is often iterative, beginning with brainstorming the best possible design that, one hopes, will satisfy the requirements and architect it, and the architecting provides efficient visual and logical feedback to the design, which then can be improved, and so on.

The role of the architecting views or charts is to graphically present in an easy-to-understand way, the relevant information about the system elements, workflows, and interfaces, including the flow of information "from-to." The graphs are there to help the team understand the design, improve it, explain it to stakeholders, and avoid miscommunications. The most common architecting views used in healthcare delivery projects are as follows.

- Future State Stream Map (FS VSM) – a tool of Lean. (Graban, 2008; Jimmerson, 2009) provide useful instructions for VSM in healthcare.
- The Department of Defense Architectural Framework (DODAF) views [DODAF, 2009], are highly useful in illustrating design architecture. The DODAF offers 25 different system architecting views showing the system structure, interacting nodes, interfaces, information flows, data flows, and many others. In typical healthcare projects only need a few, even only one, are needed. At the risk of displeasing DODAF purists, the authors believe that it is perfectly acceptable to combine more than one view on a single chart. The most common in healthcare projects are Operational View 1 (OV1), Systems View 1 (SV1), and Data Flow View 1 (DF1). SV1 shows hardware subsystems and interfaces, OV1 shows high level tasks and activities, and DF1 is convenient for illustrating high level data flows between system elements. Details can be found in [Oppenheim, 2021]. Fig. 6 illustrates an example of a combined OV1/DF1 view for the hospital discharge problem.

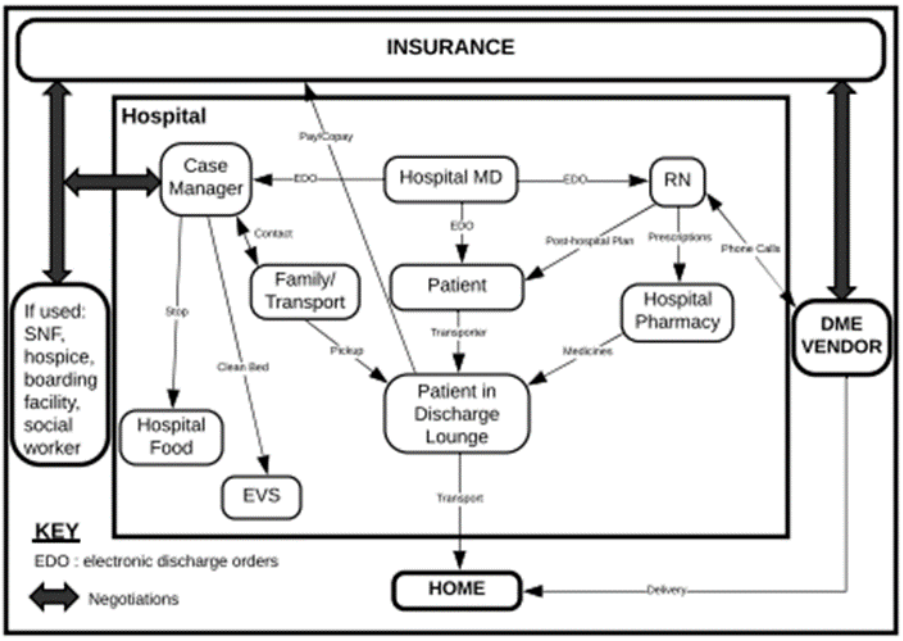

Figure 6. Combined OVI/DFI for Hospital Discharge [Oppenheim, 2021]

The Source-Inputs-Process-Outputs-Customers (SIPOC) diagram is of special importance in fragmented healthcare operations. It is ideal for precise illustration of inputs and outputs of a given activity (process, or task). The diagram shows the input information flows from sources to the process of interest, as well as the output information created by the process and the customers or destinations where the outputs are sent. It is critical that each diagram must describe only a single process, task, or activity[11]. Inputs and outputs are information. Sources and destinations can be individual human beings, organizational nodes (e.g., clinical laboratory), departments, or EHR. If the process is subject to an approval or "signature" of a supervisor, this should be indicated by a control box in the diagram. SIPOCs have proven themselves in the common situations where a provider (often a nurse or a hospital administrator) must repeatedly interact with many different stakeholders for each patient, receiving information (inputs) from some stakeholders (sources), processing the information (process), and sending the outputs to other stakeholders (customers or destinations). A SIPOC temple is included in [Oppenheim, 2021]. Fig. 7 illustrates an example of a hospital nurse managing the patient discharge process. The nurse receives patient

[11] Some practitioners tend to show several SIPOCs convoluted on one graph; for clarity's sake, the present authors argue against it.

discharge orders from the attending MD, and creates several outputs that go to the patient, a DME vendor, pharmacy, transporters, and EHR. The work of the Discharge Nurse is supervised by the Charge Nurse (for simplicity, we omitted destinations of SNFs and other continued care facilities).

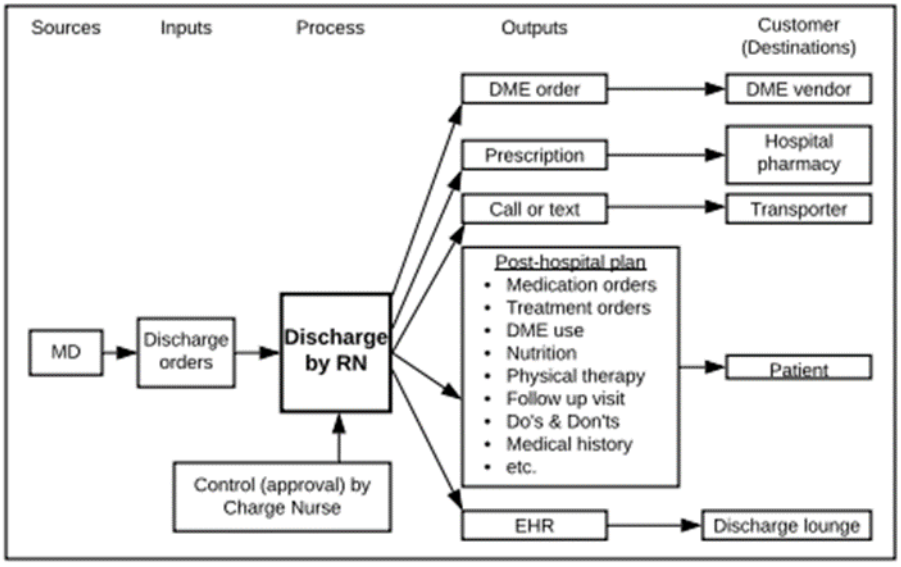

Figure 7. SIPOC Example for Patient Discharge from Hospital [Oppenheim, 2021].

SIPOCs have demonstrated their exceptional utility in the fragmented healthcare processes in which a stakeholder, typically the MD in charge of the patient or his/her RN, or Nurse Coordinator (often called nurse navigator), or an administrator repeatedly has to be in contact with a large number of stakeholders for a large number of patients. A simple SIPOC tends to "clean" the activities, making it self-evident what information is expected and who is to provide or request it. The present authors have seen clinic and hospital organizations where operations without SIPOCs caused significant errors, chaos, delays, "dropped balls," frustrations, provider burnout, and patient safety risks.

SIPOCs can be shown in a series of subsequent processes, or as a network, where an output from one serves as an input to another.

3.2.3.8. Risk and Opportunity Management

Risk and Opportunity Management (RAOM) is a well-established SE tool. At its simplest, RAOM proactively identifies "what might go wrong" with the system design and operations,

and prevents it. Risk is a potential problem or threat that could affect the project ability to deliver satisfactory SoI, meet its performance, cost, schedule, or other objectives [Lockheed Martin, 2017]. Proactivity, the mantra of good management, assures that project team will not be surprised by bad outcomes and will have enough time to prevent them or to mitigate them **before they occur**. The alternative to risk management is to do nothing, a reactive management, also called crisis management, where adverse events are allowed to occur and only then corrective actions are attempted, if not too late and if possible. And adverse events are usually not static: they tend to expand to crisis proportions; one problem generates others, etc. Popular heuristic indicates that reactive management requires dramatically more resources, higher level of expertise to deal with the resultant crisis, and causes delays, budget overruns, and frustrations for all involved.

In the context of risk, decision making is classified into three knowledge categories: complete uncertainty, relative uncertainty, and complete certainty. In complete uncertainty, one deals with "unknown unknowns" that is, one does not even know what one does not know. Even the best risk management will not help in this situation. In relative uncertainty, it is known that a risk exists and some partial information is used to assess and mitigate it. This is where risk management is the most useful. Complete certainty should be included in the project plan and not be a part of risk analysis.

Risk is described by two variables: Likelihood and Impact, both usually estimated with educated guesses [Oppenheim, 2021]. Each identified risk should be mitigated (prevented, if possible, or reduced) by a well-defined action, and each risk monitoring must be allocated to an individual as an ongoing responsibility until the risk is resolved. The individual should be responsible for tracking the risk, applying effective mitigations in a timely manner, alarming the project stakeholders at the first sign of the risk appearance, and reporting when it no longer exists.

Opportunity management is the "mirror image" of risk management. Opportunity is the potential enhancement or positive impact that could improve the project ability to deliver the SoI or to meet its performance, safety, cost, schedule, or other objectives [Walden et al., 2015]. The opportunities are characterized by the same likelihood and impact scales with the same numerical values 1-5, with 5 denoting the worst risk and the highest opportunity. A template of Risk Management Table and Graphical Matrix and example for discharge presented in [Oppenheim, 2021].

3.2.3.9. Verification and Validation

As Fig. 1 illustrates, at this phase of the project, a SoI has been created, architected, and

analyzed for risks and opportunities. Now comes the time to check if it is good enough, using the well-established SE activities: verification and validation, colloquially called V&V. An informal explanation of the difference between the two is (a quote often attributed to Peter Drucker: “Managers do things right. Leaders do right things):

- Verification verifies system requirements to ensure the system was built right
- Validation validates system goals to ensure the right system was built.

The purpose of the **Verification** process is to provide objective evidence that a system or system element satisfies its requirements. If any requirement fails verification, the SoI must be redesigned. Once all requirements pass their verifications, the project can advance to Validation. **Validation** confirms that project Goals have been achieved, that is that the SoI delivers the expected functionality and performance. Validation is a process of attaining and documenting sufficient evidence to give reasonable (The word “reasonable” has legal meaning and is used in legal cases, denoting that “a reasonably experienced, educated and competent individual would confirm that…”.) assurance that the SoI does (or will do) what was intended and needed [INCOSE, 2019]. Good practices of V&V are described by several authors in a joint edition of [INCOSE, 2019].

3.2.4. LHSE Phase 4: Implementation

Implementation is the final phase of the LHSE process, putting life the new Future State Design. This may involve the following or similar activities:

- Preparation of implementation plan “what needs to be done” (what, when, by whom, how, where). One can define similar Interrogatives for the Implementation phase as those shown in the AoCS.
- Preparation of training materials (slides, videos, manuals, checklists, procedures, standards, etc.)
- Purchase of relevant equipment, materials, or supplies.
- Selection of the trainers and users to be trained, and actual training of the users.
- Ensuring that the training objectives have been achieved (tests at the end of the training if the process is critical).
- Monitoring and mentoring users during the pilot phase or initial activities.
- Coding of the relevant portion of the system IT/EHR.
- Implementation of a helpline if the project involves difficult IT or equipment or

steps.

- Measurements of the outcomes for validation purpose.

Besides validation, a highly desired closure of each LHSE project is an explicit summary comparison of relevant system characteristics between the Current State and the Implemented Future State. Examples of characteristics include:

- Safety aspects of patients, health workers, and public.
- Medical efficacy of the new system.
- Cost, effort, throughput times, waiting.
- System capacity.
- Degree of burnout of providers.
- Statistics of satisfaction of stakeholders (best judged by a well-designed survey).

3.2.4.1. Change management

Every LHSE project introduces some changes into the Current State. Inevitably, there will be individuals who feel comfortable operating in the Current State, and they will be less than enthusiastic about making changes to it. Changes may be scary; the "new and unknown" may frighten some individuals. Folks doubt if they will be "up to it" and how they will be able to learn new ways on top of performing their regular work. They may question the need for new solutions and their efficacy. At the time of this writing, many have never heard the term SE. Therefore, a part of the LHSE process is to be able to persuade all stakeholders that investment of time and energy in the new system will be beneficial to patients, stakeholders, and the institution. Medical and healthcare professionals tend to be well educated and accepting of evidence. Strong evidence for improving patient safety, worker safety, or quality of care is usually sufficiently persuasive. If the project has strong financial aspects, evidence can be provided by a business case, comparing the cost of doing nothing (and paying for consequences of inaction) with the cost of implementing the proposed solution. Simple Payback Period and Return on Investment are two popular metrics used in business cases.

Change Management, the body of knowledge on how to accomplish the change from the Current State to a Future State is beyond the scope of the present text and can be found easily in numerous textbooks and Internet postings. It is a standard component of Lean transformations. Good examples can be found in [Graban, 2008] for hospitals and in [Womack & Jones, 1996] for non-healthcare companies. [Gladwell, 2002] provides a

fascinating discussion of persuasion techniques.

3.2.4.2. Spreading Success Across the Organization

As stated earlier, healthcare projects are often performed by a small team at a single clinic, hospital department, laboratory department or a local pharmacy. Other projects are designed from the start with the idea of spreading throughout the system. After validating project results, it makes sense to share it with all sister organizations in the same medical system. Sharing is the least expensive method of dissemination. It can rapidly bring the new capabilities or performance to all units in the institution, thus, increasing the competitiveness of the entire institution. The sharing replaces unhealthy rivalry with positive energy of teaming. It also prevents the high costs of "re-inventing the wheel". The institution incentives should strongly promote such sharing. The present authors recommend that each large medical system should have an infrastructure for the sharing, including a means of announcing successful projects, for example a dedicated website, or a newsletter; electronic means for online training of stakeholders in sister institutions; shared electronic database for dissemination of the materials; periodic meetings of like stakeholders from sister institutions to compare their operations, challenges, and achievements; a person in charge of coordinating the above activities; and if a given project is particularly successful, the project team should be incentivized to present it as a professional journal or conference presentation.

3.2.4.3. Ethics

Assuring patient wellness and treating sick patients is surely among the most ethical human activities. The LHSE process would not be complete without mentioning the ethical aspects. In every project an explanation should be included why the project (or the SoI) is based on a solid ethical framework, and whom and how it will benefit. Since there is no distinct "healthcare" or "LHSE" code of ethics, the next closest thing, namely the Code of Medical Ethics, can be used, including:

- Principles of Medical Ethics (autonomy of patients in decision making, nonmaleficence, beneficence, and justice)
- Ethics of Patient-Physician Relationships
- Ethics of Consent, Communication & Decision Making
- Ethics of Privacy, Confidentiality & Medical Records
- Ethics of Genetics & Reproductive Medicine

- Ethics of Caring for Patients at the End of Life
- Ethics of Organ Procurement & Transplantation
- Ethics of Medical Research & Innovation
- Ethics of Physicians & the Health of Community
- Ethics of Processional Self-Regulation
- Ethics of Interprofessional Relationships
- Ethics of Financing & Delivery of Health Care

3.2.5. Definition of LHSE

Two terms are often confused: the SE body of knowledge [Sage & Rouse, 2014] and the SE process [Walden et al., 2015]. The former is a large body of knowledge, still poorly defined, broadly used to create and study complex systems. The SE process is a part of that body of knowledge. It is a step-by-step technique of executing SE in projects and programs. The present text is limited to the process. A similar situation exists with Healthcare Systems Engineering: the huge body of knowledge includes subjects such as health IT, patient safety systems, population health, public health, health analytics, Lean healthcare, modelling in healthcare, medical device systems, etc. This knowledge is taught at a graduate level in academic programs typically called Healthcare Systems Engineering[12]. The HSE process is a step-by-step technique of executing healthcare projects. This text is limited to the process, specifically the Lean-inspired process of executing Healthcare Systems Engineering projects, which we named LHSE, and define as follows:

Lean Healthcare Systems Engineering (LHSE) is a SE process tailored for improving healthcare workflows and care in all clinical environments, such as clinics and hospitals of all types, including emergency departments, operating suites, and ancillary departments; imaging and clinical laboratories; pharmacies; telemedicine; and population health. The LHSE process contains only those steps which are critical to healthcare project success, free of the burdens, constructs, and procedures which are not essential to the healthcare project success. LHSE uses selected steps of SE to enable rigorous and efficient pass through all project activities so that the intended outcomes (workflow, diagnosis, treatment, cure, wellness, or illness prevention) are assured. LHSE relies on Lean Healthcare (including Six Sigma and earlier approaches) to identify waste and streamline operations. LHSE relies on

[12] For example, see the LMU graduate program https://cse.lmu.edu/graduateprograms/hse/

SE to rigorously define project goals and requirements, the system of interest, subsystems and externalities; architect solutions, fix interfaces and integrate fragmented elements of the care system, reduce project iterations by early use of analysis of alternatives, perform risk and opportunity analysis; and formally verify, validate and implement the solution while paying attention to the ethical elements of the project, and utilizing prior literature.

Table 9 summarizes LHSE characteristics in the same format as the that used in Tables 1-6.

Table 9. Characteristics of LHSE

Characteristic	Description
Main steps, tools, emphases	Rigorous SE process tailored for projects in healthcare operations improvement or care design. The tailoring accomplished using Lean methodology (include only what is needed to deliver value). LHSE relies on Lean (including Six Sigma) to identify waste and streamline operations. LHSE relies on SE to rigorously define project requirements, the system of interest, subsystems and externalities; architect solutions, fix interfaces and integrate fragmented elements of the care system, reduce project iterations by early use of analysis of alternatives, perform risk and opportunity analysis; and formally verify, validate and implement the solution while paying attention to the ethical elements of the project.
Strengths	Rigor, generality of use, ability to integrate fragmented elements, validation and verification of project goals and requirements, optimization of solution via analysis of alternatives, prevention of problems via risk and opportunity management, ease of implementation via architecting sketches, development of easy to implement information flows among stakeholders via SIPOC diagrams. Ethical elements.
Weaknesses	None identified.
Cost and effort of implementation	Manual of 62 pages with precise step-by-step instructions, and numerous illustrations and examples.
Ability to reduce system variability	Excellent, via variability-reducing tools such as Six Sigma, SPC, and other statistics included in LHSE elements.
Ability to remove waste	Excellent, via Lean tools.
Importance of literature review	Strongly emphasised.
Ability to eliminate bottlenecks	Excellent, via Lean tools.
Ability to apply rigor across the entire project	Excellent, one of the main strengths.
System's approach	Excellent, SE approach.
Ability to integrate across interfaces of fragmented system elements	Excellent, one of the main strengths.
Ability to reduce project iterations	Excellent, via rigorous progression of steps, analysis of alternatives, requirements, architecting, and risk management.
Promotion of leadership engagement	Excellent, via Lean.

4. Results

The LHSE process is a result of an evolution of using Lean (including the strengths of the previous approaches, as described above) and SE tailored for healthcare operations, as an integrated methodology. The evolution started in 2013 with 10 projects in various healthcare institutions and was completed in 2020 with the publication of [Oppenheim, 2021]. To the authors' knowledge, prior to this work such an integrated approach has never been used for improvement of healthcare delivery operations.

At the time of this writing, nearly 100 projects described on the website [LMU HSE Projects, 2021] have been completed using the LHSE process[13] at several Southern California medical centers of AltaMed, Cedar Sinai, Kaiser Permanente, Providence St. Joseph, UCLA Health, USC Keck/County Hospitals, Veterans Administration, and a large number of smaller healthcare facilities. Many of the projects displayed on this website contain full project presentation slides and details. All projects were executed by the LMU HSE Master's students as their capstone research projects, with close mentoring by the first author who served as academic advisor or co-advisor, and by a preceptor from the given healthcare institution. Besides the preceptor, each student typically had access to all key stakeholders in the institution for numerous day-to-day questions and Gemba walks. The interviews lasted until the student gained sufficient understanding of the current state to be able to draw a detailed process map and Current State VSM. Each project extended over approximately 20-30 weeks[14]. Each project was validated by the industry preceptor and his/her stakeholder colleagues. The students were required to formally present all projects with full details, and all projects were rigorously evaluated on ten following scoring scales by both faculty and managers from the healthcare institution: literature review, mastery of the LHSE process, effectiveness in identifying critical issues, benefits to the healthcare community, originality, evidence, quality of recommendations, advantages when implemented, quality of presentation materials, and oral delivery. These presentations represent a significant repository of healthcare improvement projects.

Because of time limitation and constraints outside of student control some projects ended with only verbal validation of the recommendations prior to implemented results, but 24

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[13] Approximately half of the earlier projects used many but not all elements of LHSE as it was maturing and evolving.

[14] Nominally each project is one semester-long (15 weeks) in the senior year. Most projects, however, are intentionally initiated in the previous semester, to allow the student time for both, legal onboarding in the healthcare facility and early studies of the Current State.

projects provided subsequent feedback on actual implemented results, e.g. [Oppenheim et al., 2017].

The ideal evaluation of the effectiveness and utility of the LHSE process relative to the prior approaches (PDSA, TQM, Lean, Six Sigma, TOC) would have been to repeat the same project twice, using LHSE and at least one of those prior methods. This, of course, was not practical. This deficiency is a norm when evaluating new improvement methodologies, and a frequent source of unsubstantiated claims about the superiority of a new methodology relative to previous approaches, e.g. [Deming, 2000; Goldratt, 1999; Harry et al., 2000]. The situation with LHSE was different: in many projects preceptors had prior knowledge of at least one of the prior methods, often more than one, thus, were able to offer some basis, if somewhat subjective, for comparing it (them) to the LHSE. We summarize these comments in the Discussion and Conclusions, Section 5.

5. Discussion and Conclusions

Table 10 lists a summary of the data from Tables 1-6 and 9.

The above summary and the opinions of the users indicate the following superiority of LHSE:

- The LHSE process is general, applicable to all projects in most clinical environments, including: clinics, hospitals, including emergency departments and operating suites, clinical and imaging laboratories, pharmacies, population health, and telemedicine. It has been shown to work in about 100 typical improvement projects involved in a wide range of different aspects of healthcare in a variety of medical institutions.
- LHSE is a consistent step-by-step process, applying the same Lean and SE tools and steps for all projects, thus, easy to practice after the initial learning. Over 100 students have demonstrated that the process is not difficult to learn; it is described in detail in only 65 pages of [Oppenheim, 2021].
- The LHSE adopts logical rigor to the process steps from highly rigorous SE processes. The LHSE, although rigorous, does not require any engineering or mathematical expertise. It does, however, require some precision in thinking and reasoning. All of this rigor can be done without big resources and has the potential to create system improvements that have been carefully and rigorously analysed without “paralysis by analysis”. The advantage is that costly and time-consuming trial and error is minimized, and a more systematic approach is used.
- The former improvement methods apply tools in isolation, which may not always be powerful enough to address the needed quality improvement in healthcare. Instead, they offer a fragmented approach and result in a great deal of time-consuming and expensive trial and error. Oftentimes, the trial-and-error approach creates a huge temptation to torture the outcomes data until it looks like a solution has been achieved. On the other hand, LHSE creates a very systematic and rigorous methodology that uses these and other popular tools but organizes them into a systematic approach to problem solving.

Table 10. Summary of the data from Tables 1-6 and 9

Characteristic	PDSA	TQM	Six Sigma	Lean	Lean Six Sigma	TOC	LHSE
Main steps, tools, emphases	Cyclic iterations	Total approach to quality across the entire enterprise.	Rigorous statistics applied to processes, rigorous training.	Optimization of entire workflow by relentless elimination of wastes.	Optimization of entire workflow by relentless elimination of wastes.	Optimization by identifying the biggest current constraint and elevating or eliminating it.	Rigorous SE process tailored for projects in healthcare operations improvement or care design.
Strengths	Culture of CI and relentless quality improvement	Change of culture towards enterprise-wide quality. Pursuit of higher quality compatible with lower costs. Culture based on respect for people and employee empowerment.	Systematic reduction of process variability	Changing workforce into problem solvers. Tangible improvement of quality and bottom line.	Changing workforce into problem solvers. Tangible improvement of quality and bottom line.	Ability to identify impediments to flow.	Rigor, generality of use, ability to integrate fragmented elements, validation and verification of project goals and requirements, emphasis on both efficiency and performnce.

Characteristic	PDSA	TQM	Six Sigma	Lean	Lean Six Sigma	TOC	LHSE
Weaknesses	Excessively general steps. Lacking rigor. Lacking customer feedback.	Excessive scope of activities Lack of focus on project steps.	Costly bureaucracy	Inability to integrate across interfaces in fragmented system. Poor in improving process quality.	Inability to integrate across interfaces in fragmented system.	Exclusion of all other aspects of projects, system, interfaces, and process variability.	Lacking widespread use (new method)
Cost and effort of implementation	High due to iterative method.	Huge	High, costly bureaucracy	High, but worth the bottom line.	High, but worth the bottom line	Low	Low
Ability to reduce system variability	High for individual tasks poor for entire process	High for individual processes/tasks; poor for entire value stream.	Excellent, main focus of the method.	Poor. Focus on flow speed instead.	Excellent	Poor	Variability-reducing tools are LHSE elements
Importance of literature review	None	None	None	None	None	None	High
Ability to remove waste	Poor	Poor	Poor	Excellent	Excellent	Poor	Excellent
Ability to eliminate bottlenecks	Poor	Poor	Poor	Excellent	Excellent	Excellent	High
Ability to apply rigor across the entire project	Poor	Poor	Poor for project, focus on process	Excellent for implementing, poor in rigor	Moderate	Poor	High

Characteristic	PDSA	TQM	Six Sigma	Lean	Lean Six Sigma	TOC	LHSE
System's approach	Poor	None. Focus on entire enterprise.	Poor. Focus on process variability.	Limited to workflow system, ignoring externalities, subsystems, interfaces.	Limited to workflow system.	Poor	High
Ability to integrate across interfaces of fragmented system elements	None	Poor	None	Poor	Poor	Poor	High
Ability to reduce project iterations	Poor	Poor	Poor	Poor, but good results on 1st iteration.	Poor, but good results on 1st iteration.	Poor	High
Promotion of leadership engagement	Poor	Poor (defaulted to consultants)	Poor, stats not accessible to many leaders.	Excellent	Excellent	Poor	High

- Using a Lean philosophy of not creating an improvement system that is in itself wasteful (as the former TQM and Six Sigma often did), LHSE removes much of the waste and complexity of systems engineering used in large-scale engineering projects without removing their essential value and rigor needed in healthcare. These massive engineering projects involve many companies and people widely distributed in many locations who need to work together to solve complex coordination problems. The main conclusion from these projects is that healthcare needs a simplified SE process, stripped of all elements which evolved to deal with the massive size of teams, budgets and technical complexity of defense programs, and which would be wasteful in healthcare delivery operations. What is unique in LHSE is that these powerful system engineering tools are modified to be able to address much smaller healthcare problems that still involve similar problems in fragmentation and poor communication and coordination. Healthcare needs SE to provide logical rigor when integrating fragmented pieces, an assurance of high reliability, and the approach must be delivered in a manner which is user-friendly for healthcare stakeholders, supporting and facilitating their work without adding burden or cost.
- LHSE adopts the system approach to all projects. The system of interest, subsystems, externalities, and interfaces between them are rigorously defined. This approach avoids frequent problems in earlier methods, where these definitions were vague leading to confusions as to the project focus, scope and goals.
- Previous improvement methods used in healthcare, like PDSA do not address the fundamental nature of harmful fragmentation in healthcare. Although still widely used, such techniques have not lived up to their promise of creating a better healthcare system. SE was invented to integrate fragmented systems, and LHSE being its derivative also offers powerful ability to integrate the highly fragmented healthcare systems. It does so by identifying imperfect interfaces in human and electronic communication and coordination and fixing them.
- In LHSE, care is taken to not jump to a solution prematurely. Many traditional approaches to quality make an incorrect assumption that the problem is obvious and requires little thought to describe it, and formulate a problem statement at the project initiation. In contrast, LHSE requires that the formulation of problem statement be delayed until the completion of the analysis of current state, thus assuring that the problem to solve will be well understood and informed.
- Similarly, the classic PDSA cycle may just pick one solution and try it out, and work through subsequent iterations that consume time and resources. LHSE, on the other hand, requires the project team to create an analysis of alternatives

which is another novel approach not found in other healthcare improvement approaches. In LHSE, one identifies several candidate solutions and formally rates them prior to choosing an approach. This eliminates the need for iterations.

- LHSE emphasizes the need to list precise system requirements using SE rigor. The requirements that are stated in LHSE are often left off other healthcare improvement methodologies or are less formally stated and verified. Not systematically delineating requirements of a newly proposed system can lead to failure to address all of the important issues and result in inefficient trial and error. LHSE, by mandating that system requirements be clearly delineated adds more rigor. One of the main reasons a project may fail is that there are no requirements defined, and if there are, they are not achieved.
- Prior to implementation, LHSE requires an assessment of the risks and opportunities involved, mitigation strategy, as well as verification and validation of proposed solutions. These steps are absent in the prior approaches.
- LHSE promotes the use of "visual checklists" for workflow operations, such as SIPOC diagrams which define the recommended information flows among stakeholders and departments. Such diagrams reduce miscommunications and errors, facilitate coordination, and reduce harm to patients and frustrations to providers. Many stakeholders in the completed projects performed using LHSE expressed complements for making their work easier. Such diagrams are not used in the prior approaches.
- In the first phase of the LHSE process, a review of existing published literature is mandated, which should be obvious, but is not always done in other project applications, thus leading to projects that are ill defined and often repeat mistakes of the past.
- Summarizing, this paper presents arguments about the superiority of LHSE over the previous approaches. The LHSE process adopts many of earlier tools and approaches, but eliminates their weaknesses, and integrates them with the powerful rigorous systems engineering process strongly streamlined for healthcare applications and accessible to individuals who are not trained systems engineers. Every day that our healthcare systems malfunction, there is a huge opportunity cost in terms of money, mortality, morbidity, on-going health disparities, and patient frustration. The recently invented LHSE offers a big potential to solve many problems using less resources and less time.

As stated above, LHSE has been used successfully in about 100 healthcare delivery projects, each governed by fewer than 10 requirements. At this time there is no experience of using LHSE in large projects that rapid transformation of healthcare may need, e.g., design and application of genetics devices for personal medicine, AI systems,

redesign of EMRs, creation of health information exchanges, reform of payment systems, integration of home-use devices into EMRs, etc. Clearly, if the number of requirements is large (many tens or hundreds), the MBSE tool may become useful.

At the time of this writing, the present authors are completing a study of extending LHSE to large projects involving implementation of new processes at many hundreds of medical offices. The preliminary findings are that LHSE is totally applicable to such large systems, if two additional steps are included:

1) In the Analysis of Current State phase of LHSE, instead of a Current State Value Stream Map (CSVSM) and Ishikawa Diagram performed at a single clinical site, these items should be first created based on in-depth analysis and integration of information from several representative sites. Next, a survey tool should be created to be used at all other sites in the system (potentially hundreds) to capture the individual cases of operational variation, wastes, fragmentation problems and frustrations from all the sites, and subsequently integrated into a general CS VSM and ID applicable to all sites. This approach assures that no site has been ignored, yet the level of intensive discovery effort is limited to a few representative sites, plus the integration of the survey data. The subsequent steps of LHSE (current state architecting, problem statement, project goals, requirements, analysis of alternatives) are the same as in the standard LHSE method.
2) The Design of Future State, normally performed once at a given site, should instead be performed in three following steps:
    a. A draft of Future State design, including a strong degree of operational standardization, should be created. Next, the draft should be disseminated to all those clinical sites in the system, with a request for comments and edits.
    b. When collected these comments should then be integrated into the final Design of Future State, with a high level of standardization and verifications of requirements. It is important to formulate requirements in functional terms, defining and standardizing what the new system is to accomplish, leaving some operational freedom and autonomy to the local sites, an important factor in the culture of strong medical autonomy.
    c. After a reasonable period, the operational results from the local sites should be reviewed and the best practices incorporated into the final standard. The key is to produce a FS that would be accepted by all sites, and that would be based on best practices. The remaining steps of LHSE are the same as in the standard method.

The experience with learning LHSE is limited to the students in the LMU Healthcare SE

Master's program where they spend 20 hours learning it in a graduate course. The book [Oppenheim, 2021] devotes 60 pages to explaining LHSE, including many examples. But the experience of self-learning LHSE from the book, without additional tutoring is not currently available.

It is still an open question what it will take for health systems to implement LHSE. The fact that LHSE and SE are generally not known in the healthcare field outside of a limited number of organizations who benefited from the 100 projects, a few conferences and public presentations, and readers of [Oppenheim, 2021], is a challenge. The engagement of leadership and finding people with expertise in LHSE or training people in LHSE may be initially challenging. The present authors hope that this article may contribute to changing this situation.

List of Tables

List of Figures

References

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