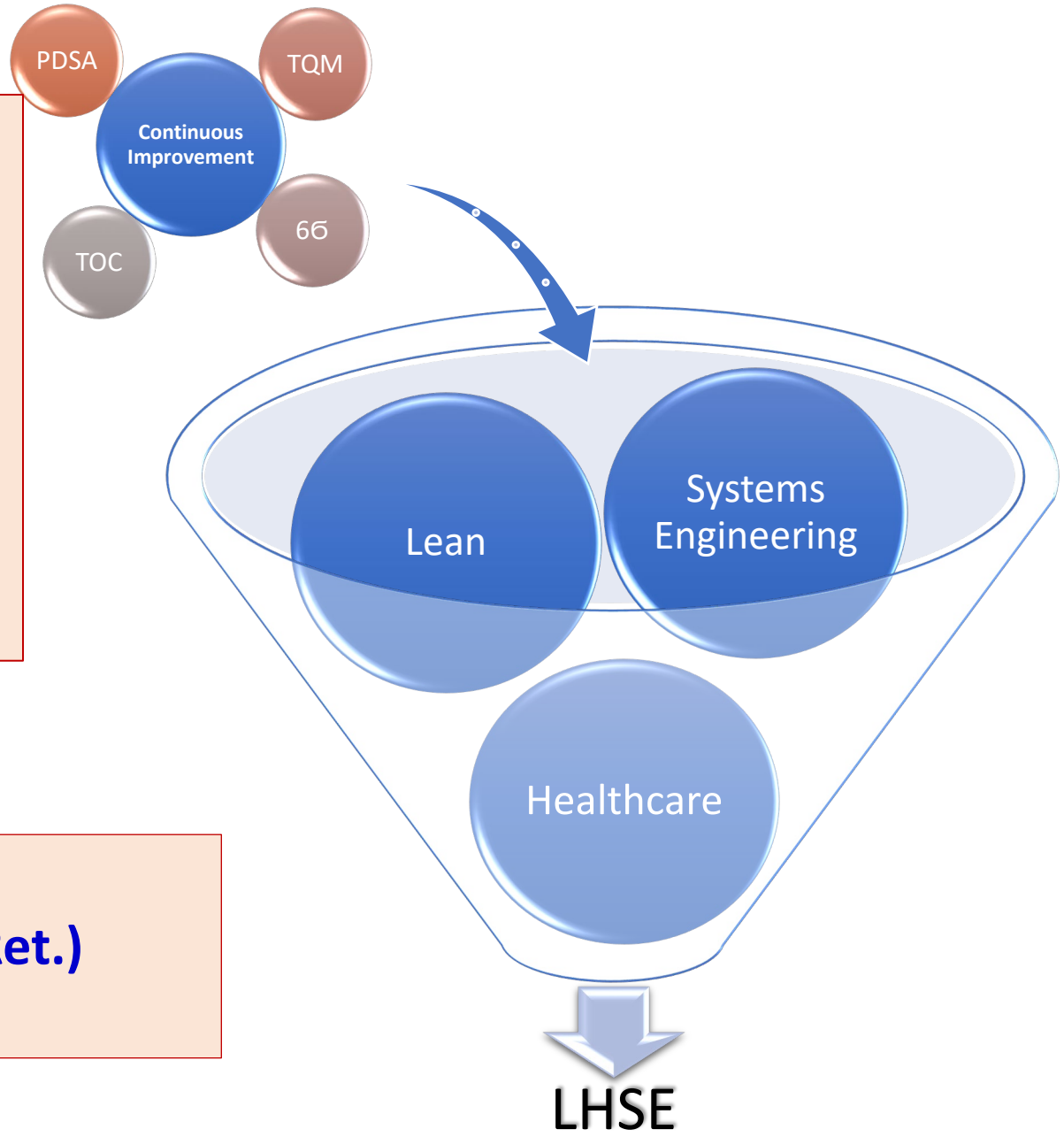
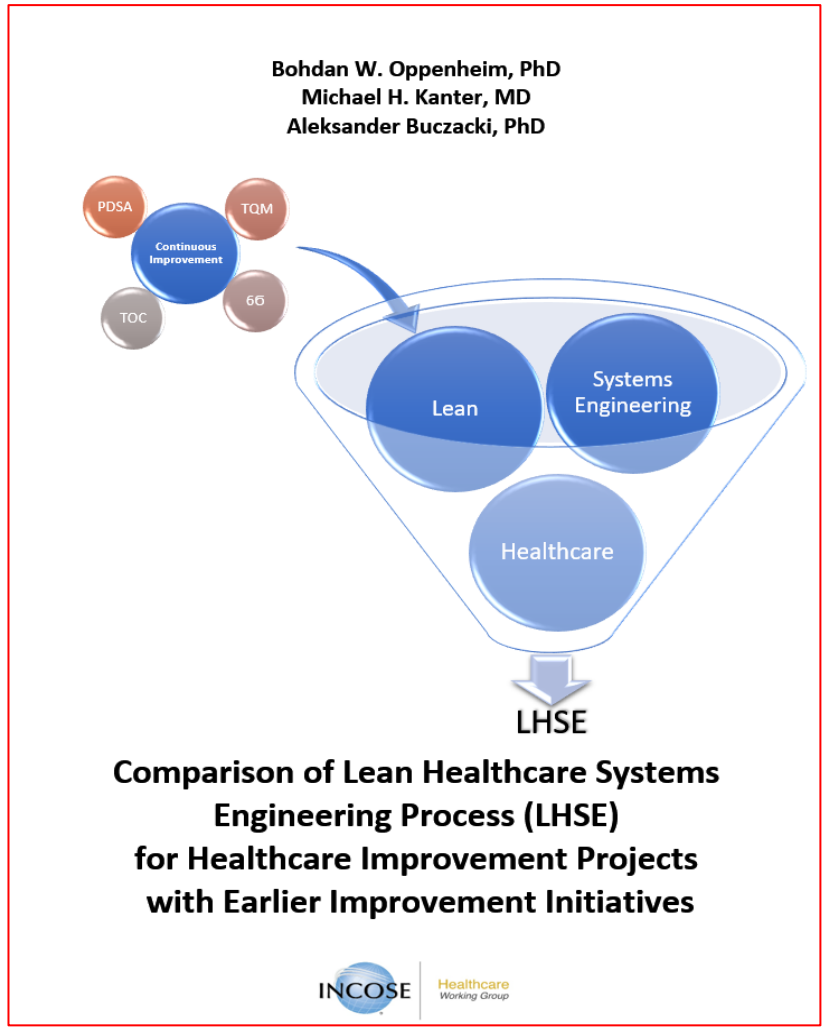
Comparison of the „Lean Healthcare Systems Engineering (LHSE)" Proces to the earlier quality methods: PDSA, TQM, Six Sigma, Teory of Constraints, Lean…



Bohdan W. Oppenheim, PhD
Professor *Emeritus* and Director (Ret.)
HSE, LMU, Los Angeles

This presentation is based on:

White Paper



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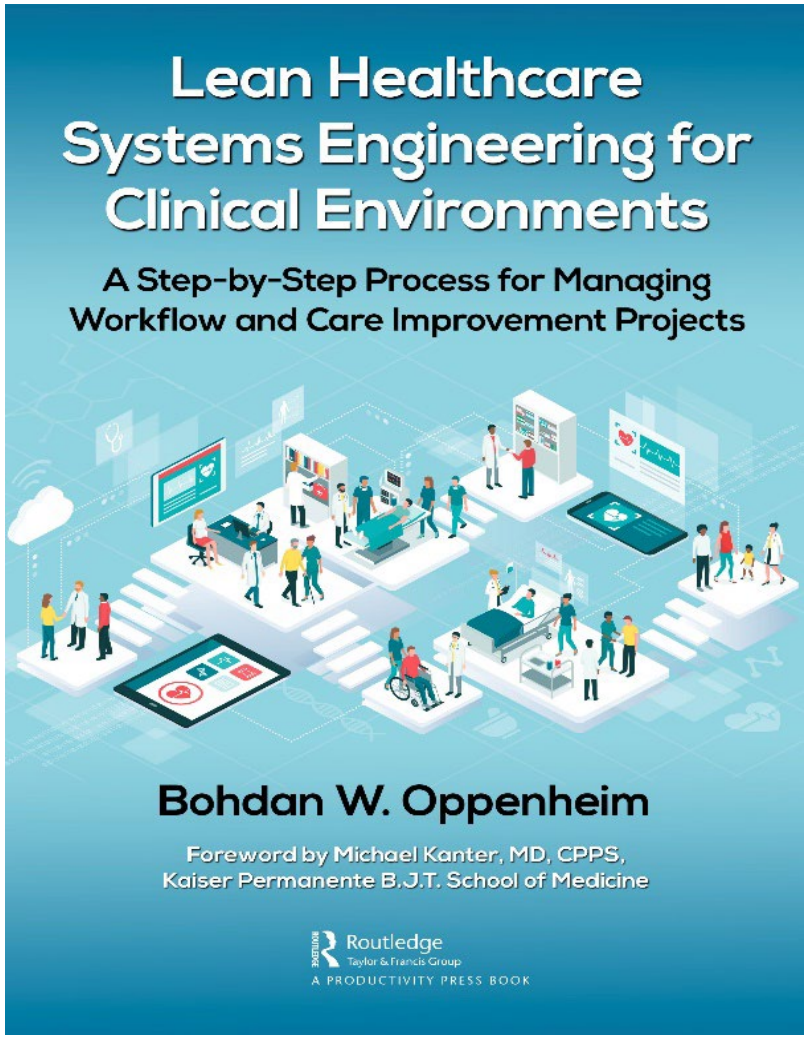
Book



Some Basics

- Recall: SE was created to help integrate fragmented elements in complex aerospace systems.
- Wise people knew that complex systems tend to fail at the interfaces. Individual subsystems/elements may be perfectly designed by disciplinary experts, but do not integrate well at the system level. So, they invented SE.
- The name SE is misleading as it suggests engineering and math. Not so. The name „engineering" is historical; because it was first used in engineering systems.
- At its basic, SE is a rigorous logical proces of managing information assurance across interfaces across fragmented elements of the system.

Fragmentation in Healthcare

- Every healthcare employee is painfully aware of the notorious poor communication and coordination in all clinical environments.
- The fragmentation occurs in all areas of care, from diagnosis and treatment to home care, long-term care, chronic care and preventive care.

Economic Times

The forces driving fragmentation in Healthcare

- Two powerful forces drive the fragmentation:

  1) Traditional medical education emphasizes doctor's autonomy and specialization but ignores care continuum and information flow across the entire patient-centered system.

  2) The complex network of distributed institutions and organizations, fragmented into general and specialty clinics, hospital departments, private individuals, laboratories, pharmacies and payers.

- The elements to integrate (coordinate) in healthcare are people (patient, doctors, nurses, technicians, admins…), electronic nodes (Electronic Records, other IT), devices (MRI, X-Ray, U-Sound, Cat-scan…) and processes.

The need for SE in Healthcare

- None of the previous Quality methods (PDSA, TQM, Six Sigma, Lean Six Sigma, Theory of Constraints…) addressed fragmentation directly
- SE applies ideally for Healthcare applications which is known as the most fragmented system in human civilization.
- But what kind of SE is needed in Healthcare?

Systems Engineering evolved in Aerospace/Defense to become a gigantic bureacracy. Healthcare Delivery Operations need vastly smaller projects than Defense

	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, often 1	10,000s-100,000s
Project duration	Weeks to months	Decades
Driving incentive	Streamline a workflow or care in a local clinic or hospital or lab	Cost-plus federal funding and jobs.

So, in healthcare we need something radically simpler: Lean SE

Lean Healthcare Systems Engineering (LHSE) Proces

- Described in the book above.
- Perfected in over 100 projects in major healthcare organizations in Southern California during 2015-2022.
- Adopted the best elements from the previous Quality Improvement methods and rejected their faults.
- Developed for healthcare applications but is fully applicable in any other domain.
- In clinical projects we typically deal with only a few requirements. So, MBSE not needed. Applications outside of Healthcare may need to add MBSE.

Lean Healthcare Systems Engineering "V"

1. Background, literature review

2. Analysis of Current State

- System of Interest (see next slide)
- In scope, out of scope, subsystems, externalities
- Process map or Current State VS Map
- Fishbone diagram
- Stakeholders and Other Nodes
- N^2 Matrix, Interfaces, Fragmentation
- Other sources: SPC, statistics, surveys…
- Problem Statement

3. Design of Future State

- Goal Statement
- Requirements and Verifications,ConOps
- Analysis of Alternatives
- Design of Future State
- Systems Architecting and SIPOCs
- Risk Management
- Verification and Validation

4. Implementation

The System

- In Healthcare, the system is the collection of people, organizations and nodes interacting to help the given patient. E.g. in Adolescent Oncology, the system elements include:
  - Family MD
  - Oncologist
  - Radiologist, if used
  - Mental health person
  - Fertility preservation staff
  - Social worker
  - Transportation worker
  - Nurses and technicians directly involved with the patient
  - Electronic Health Records
  - Other IT tools used

Previous generic Quality Improvement methods popular in Healthcare (chronologically)

- Plan Do Study Act (PDSA)
- TQM =Total Quality Management
- Six Sigma
- Theory of Constraints
- Lean
- Lean 6 Sigma

The tables below will be discussed in a summary form: yellow highlights.
Please read the White Paper for details.

PDSA

- Created by Shewart in 1950s, popularized by Deming.
- Also known as:
  - „Shewhart cycle”
  - “Kaizen”
  - „Continuous Improvement”
  - „Deming cycle”.
- Main idea: Cyclic iterations: Plan, Do, Study, Act. Recommends SPC

PDSA

Characteristic	Description
Main steps, tools, emphases	Cyclic iterations: Plan, Do, Study, Act, recommends SPC
Strengths	Culture of CI and relentless quality improvement
Weaknesses	Excessively general formulation, with process variability statistics being the only rigorous element. 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.

TQM

- Popularized by Deming in the 1980s
- Attempt to adopt the superb Toyota quality methods and culture to US
- Became hugely popular in USA
- TQM was the basis for the Malcolm Baldridge Quality Award and Quality Standards ISO 9000:2000.

TQM

Characteristic	Description
Main steps, tools, emphases	Total approach to quality across the entire enterprise. Quality circles and quick reaction Kaizen teams. Focus on business strategy; customer satisfaction; unifying management; designing quality into both products and processes (rather than relying on the final inspection to identify defects); mutually beneficial supplier relations.
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.

Six Sigma

- In the 1990s TQM was replaced by Six Sigma.
- „Putting teeth” into the ambiguous bottom-up TQM
- Systematic elimination of variability using rigorous measurements, statistics, and employee training (ju-jitsu model).
- Goal: predictable and repeatable processes, according to specifications.

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.

Lean

- Seminal book *Lean Thinking [Womack, 1996]* based on Toyota Production System introduced the Lean approach to the USA.
- Fundamentally new paradigm: systematic relentless elimination of waste from all work areas.
- Just-in-Tme work organization, minimal inventories, costs and time
- Rygorous identification of waste
- First ever for Quality methods: dramatic improvements in delivery/service time and costs. Displaced the earlier methods.
- Lean entered Healthcare: *Lean Hospitals [Graban, 2008].*
- In 2010s most US hospitals, clinics and medical labs adopted Lean (better or worse).

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.

Lean Six Sigma

- Integrated Lean and Six Sigma methodologies.
  - Lean accelerates work flow.
  - Six Sigma eliminates impediments to flow.
- We ignore the discussion for the sake of time. Please read the White Paper)

Teory of Constraints (ToC)

- Published by E. Goldratt in 1999.
- Focus: identification and elimination the current biggest bottleneck to flow
- After the bottleneck is eliminated, the flow speeds up to the speed limited by the next bottleneck…
- We then eliminate this next bottleneck, and so on.
- The goal similar to Lean: speed up the workflow,
  - Lean achieves this by elimination of all wastes simulatenously
  - ToC by elimination of bottlenecks to flow, one at a time.

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 on 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.

Summary

- The LHSE proces demonstrated success in over 100 projects in many healthcare institutions.
- It has been shown to apply to all clinical environments: clinics, hospitals, EDs, ORs, clinical and imaging labs, pharmacies, telemedicine and population health.
- LHSE does not require any engineering or math knowledge
- But it requires logical rigour.
- Often, the previous Quality methods presented a temptation to twist the results to show that the solution has been achieved. LHSE relies on rigorous Validation and Verification.

Summary

- The LHSE proces adopts many earlier tools and steps, and eliminates their weaknesses.
- All previous Quality methods ignored the damaging fragmentation in Healthcare. In contrast, LHSE uses powerful SE tools to eliminate the destructive fragmentation.
- Many projects start thinking that the problem is obvious and formulate the Problem Statement and Goals at the beginning. In contrast, LHSE requires that a comprehensive Analysis of Current State be performed before we formulate the problem and goals.
- Classical iterative methods (PDSA, TQM, ToC, Six Sigma, Lean) consume time and cost. In LHSE we formulate several alternative solutions and formally rank them. This eliminates wasteful interations.

Summary

- Traditional Healthcare projects often are short of success because no formal requirements were formulated.
- LHSE uses rigorous requirements, validation and verification.
- LHSE uses formal risk and opportunity analysis and mitigations – absent in previous methods
- LHSE promotes visual checklists (SIPOCS) which reduce miscommunications and facilitate coordination. Medical professions do not use such architecting tools. Workers love the tools!
- LHSE insists on literatire review, which should be obvious, but is ignored in earlier Quality methods – leading to a repetition of previous missteps.

All these factors support the thesis that LHSE is superior to the previous methods.

Summary

- All steps of LHSE are directly applicable to non-Healthcare projects, with the following modifications:
  - MBSE should be used in the requirements management, verification and validation if the numer of requirements is large
  - In projects requiring involvement of many sites, the LHSE steps should be compiled based on surveys from all the sites, and formal steps should be performed on a representative numer of sites.

Summary

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.
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
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

Thank you for your attention.