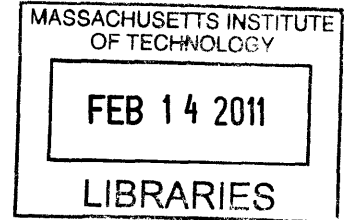


Adapting the Lean Enterprise Self Assessment Tool for Health Care

By

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S.B., Aeronautics and Astronautics
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Submitted to the Systems Design and Management Program
in Partial Fulfillment of the Requirements for the Degree of
Master of Science in Engineering and Management

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By Cynthia Hernandez

Submitted to the Systems Design and Management Program in Partial Fulfillment
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Management

Abstract:

The Lean Enterprise Self Assessment Tool (LESAT) is a product of the Lean Advancement Initiative (LAI) and the Massachusetts Institute of Technology. This tool has been applied by many organizations to gage their progress toward lean enterprise management, however applying this tool in health care organizations has been inhibited by language and underlying assumptions from product manufacturing. An adaptation of the LESAT specifically for health care is proposed. Review of the literature and special reports on health care are used in determining the recommended changes. "Product life cycle" is reinterpreted as a health care service cycle and context specific enterprise level processes and practices are presented. Comparison to other industry measures shows the content the LESAT for health care to cover all key issues and practices for high quality health care delivery.

Thesis Advisor: Deborah Nightingale

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To all my friends, old and new, I am happy to know all of you and thankful for your friendship. To the SDM crowd: Bonds built under stress are usually the strongest; I hope they continue to flourish after the stress is gone. Special thanks to a couple of families who housed me at critical times. Thank you for your hospitality and tolerance.

I want to express my gratitude to Jim Utterback, who first agreed to advise me. He gave me very wise advice indeed and graciously let me go when I decided to take a different direction.

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To Jordan Peck, Jorge Oliveira, and Nathan Perkins thank you for your ideas, your perspectives and the contacts you provided. Best of luck to you all in your own work, and I hope that others will be as generous with you.

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1 Introduction

Motivation

Health care is one of the “new frontiers” for systems engineering. Researchers and practitioners are looking to the tools developed in industries such as aerospace and automotive to provide the understanding and advancement seen in those industries. At first glance, health care may not seem to have much in common with engineering and manufacturing in these industries. When one recognizes health care as a complex socio-technical system itself, similarities become more evident.

For example, see the comparison of the aerospace and health care industries presented by Nightingale. Both industries are driven by an overarching commitment to excel. Both have historical mindsets and emotional components as well as financial constraints to overcome. Both are inherently complex industries.

Table 1: Cross-Industry Enterprise Challenges (Nightingale D. , 2009)

Aerospace	Health Care
Overarching commitment to ensure global peace and security	Overarching commitment to provide world class medical care
Incumbent “higher, faster, farther” mindset	Incumbent overuse, underuse, and misuse mindset
Declining defense dollars after Cold War (fewer military aircraft programs; industry consolidation)	Overburdened health care expenditure as a % of GDP (proliferation of fragmented disjointed providers)
Inherently complex industry: <ul style="list-style-type: none">• Multiple stakeholders with misaligned objectives and numerous constraints• Capital intensive• Complex product development	Inherently complex industry: <ul style="list-style-type: none">• Multiple stakeholders with misaligned objectives and numerous constraints• Capital intensive• Complex service provision
Uncertain outcome in contract awarding	Uncertain outcome in value sharing
Emotional impact (patriotism)	Emotional impact (personal health)

I have experience in both the aerospace and the automotive industry. The Systems Design and Management program has given me a deeper understanding of phenomena and behaviors I have witnessed as an engineer in these industries. It has also given me a new perspective and a

new tool set. I wanted to explore the impact that systems thinking and systems engineering practices can have in this “new frontier” of health care. Since it is new for me as well as new for systems engineering, it is twice as interesting. Health care has such a critical role in our society, and many challenges to be faced, including an imminent surge in demand as “baby boomers” age and need more care.

Lean Enterprise Thinking, as promoted by the Lean Advancement Initiative at MIT, takes lean practices to the enterprise level, which is a system level view. Health care needs this system level view to see the full scope of its challenges and to be able to address them effectively. Sometimes, though, the language and underlying assumptions that come with the practices from product manufacturing industries can stand as barriers to adoption. This thesis aims to remove these barriers for the Lean Enterprise Self Assessment Tool (LESAT), taking a first step toward creating a version adapted for the health care context.

Having worked at a tier 1 automotive supplier, I am familiar with lean principles and the benefits they have provided. I chose this thesis topic as an opportunity to leverage what I know from the automotive industry and my coursework, while learning about the health care industry and application of these tools there.

Overview

Section 2 lays out a roadmap for development of a health care LESAT. This followed by section 3, giving some background about the need for change in health care and the history of the Lean Advancement Initiative (LAI) and it’s work to facilitate lean transformations in other industries. Section 4 makes the case for a health care LESAT.

Sections 5,6 and 7 outline the changes made in adapting the LESAT for the health care context. Section 5 addresses the underlying architecture of the LESAT. Section 6 presents the proposed summary level of the LESAT, with key practices and characteristics. Section 7 discusses the modifications made, and provides supporting references from literature. In Sections 8 and 9 the content of the LESAT for health care is reviewed against industry measures and by lean

practitioners in health care organizations. Conclusions are given in section 10; recommendations for future work in section 11.

2 Roadmap for Development of a Health Care LESAT

Core LESAT as a Foundation

The Lean Enterprise Self Assessment Tool (LESAT) was developed as an aid for self-assessing the present state of leanness of an enterprise and its readiness to change. (Lean Advancement Initiative) It is not intended to be a basis of comparison between organizations. The practices and maturity levels for the core LESAT were developed through a series of meetings and conference calls with representatives from industry, government and university members of the LAI Consortium. (Nightingale D. a., 2002)

This thesis is not trying to prove (or disprove) the validity of the core LESAT or the Lean Enterprise Model upon which it is built. The core LESAT is accepted as a useful measure and guide toward the desired future state of an enterprise. The work of this thesis takes the first steps toward adapting this tool for more effective application in health care enterprises, as identified in the roadmap outlined below.

Structure of the LESAT

The approach used for assessment is a capability maturity model (CMM). To create a CMM one must first determine the most important factors relative to an organization's performance. Then for each factor, "levels" are defined, such that progressively greater levels of capability are reflected as an organization "matures" in its performance on that factor. (Nightingale, 2002) In the core LESAT, specific level descriptions were developed for each enterprise practice, incorporating best known practices and giving examples of behavior that indicate maturity in that practice. Table 2 gives the generic definitions of maturity levels used in the LESAT and an example of practice specific definitions.

Table 2: LESAT Maturity Levels

Level	Generic Definition	Example specific definition (practice I.A.1 Integration of Lean in Strategic Planning Process)
Level 1	Some awareness of this practice; sporadic improvement activities may be underway in a few areas.	Concepts and benefits of lean principles and practices are not evident in culture or business plans
Level 2	General awareness; informal approach deployed in a few areas with varying degrees of effectiveness and sustainment	Lean is recognized, but relegated to lower levels of the enterprise and application is fragmented.
Level 3	A systematic approach/methodology deployed in varying stages across most areas; facilitated with metrics; good sustainment.	The growth implications of lean are understood and lean implementation plans are formulated, but not integrated into the strategic plan.
Level 4	On-going refinement and continuous improvement across the enterprise; improvement gains are sustained.	Transitioning to lean is adopted as a key enterprise strategy and included in the strategic plan.
Level 5	Exceptional, well-defined, innovative approach is fully deployed across the extended enterprise (across internal and external value streams); recognized as best practice.	Strategic plans leverage the results of lean implementation to achieve growth, profitability and market position.

Figure 1 shows an excerpt from the LESAT. For each practice maturity levels are described and examples of maturity indicators are listed. The evaluator marks both the current state (C) and the desired state (D) for the enterprise. Comments may be added to support the ratings selected.

I.A. Determine Strategic Imperative - the decision to pursue an enterprise transformation is strategic in nature. Its impact throughout the enterprise is profound and pervasive, affecting all business practices and processes. The enterprise will behave in a fundamentally new manner, significantly eliminating waste and enhancing relationships with all stakeholders.							
Diagnostic Questions	<ul style="list-style-type: none"> • Are enterprise leaders familiar with the dramatic increases in competitiveness that many companies have realized as a result of transforming? • Are enterprise leaders fully aware of the potential opportunities (i.e. greater growth, profitability and market penetration) that can be realized within their own organization as a result of transforming? • Has a suitable strategy for growth been identified to utilize resources freed up by improvements? • Does “stakeholder value” strongly influence the strategic direction? • Has full leverage of the extended enterprise stakeholders been incorporated into the strategic plan? 						
	LP #	Enterprise Practices	Capability Levels				
			Level 1	Level 2	Level 3	Level 4	Level 5
	I.A.1.	Enterprise Transformation is Integrated into Strategic Planning Process <i>Enterprise transformation is a key ingredient for achieving strategic objectives.</i>	Concepts and benefits of enterprise transformation principles and practices are not evident in organizational culture or business plans.	Enterprise transformation is relegated to lower levels of the enterprise and application is fragmented.	Enterprise transformation plans are formulated, but not integrated into the strategic plan.	Coordination and synergistic relationship exists between transformation and strategic planning.	Strategic plans leverage the results of transformation improvements to achieve enterprise objectives..
			C D	C D	C D	C D	C D
	<i>Indicators (Examples)</i>	<ul style="list-style-type: none"> • Enterprise transformation implementation is included explicitly in the enterprise strategic plan. • Strategic planning makes allowance for anticipated gains from transformation improvements. 					
	<i>Evidence</i>						
	<i>Opportunities</i>						

Figure 1: Excerpt from Core LESAT

Adaptation to Health Care

When the assessment method for the LESAT was chosen, there were other options evaluated along with CMM. While CMM was rated the highest both overall, and for key functional attributes (“Assesses degree of ‘lean-ness’ for an enterprise and all its core processes”, “Provides feedback for improvement”), one may note that CMM scored low on the characteristic “scaleable/flexible for different users.” In fact, evidence from LESAT evaluations completed in health care organizations show that evaluators did not understand or see the relevance of some questions. Adapting the LESAT for health care will make adoption of this tool easier and more attractive.

One other adaptation of the LESAT has already been created – the Government Lean Enterprise Self-Assessment Tool (GLESAT). The GLESAT is focused on government program offices and government organizations with multiple functions needed to fulfill their mission. It is 60-70 percent similar to the LESAT. Differences are primarily in terminology, making the wording more appropriate for use in government settings. All of the concepts from the core LESAT were retained. (Lean Advancement Initiative)

Approach

Figure 2 illustrates the general approach for adapting the LESAT for health care. The goal is a meaningful transition from the context of the core LESAT – product manufacturing – to the

context of health care. This happens by way of three stages. The first is examining the underlying conceptual architecture and principles of the LESAT. Through review of the core LESAT and LAI information and research, the architecture, principles and practices are understood. A review of the literature regarding the health care industry reveals terminology, priorities and characteristics of health care in the United States, as well as experiences and examples from health care organizations that have already begun applying lean thinking. The underlying concepts are translated to a conceptual architecture and principles in the health care context. This leads to changes to the generic enterprise architecture, particularly the product life cycle. Some of the principles are adjusted as well, in accord with priorities and desired behaviors for health care organizations.

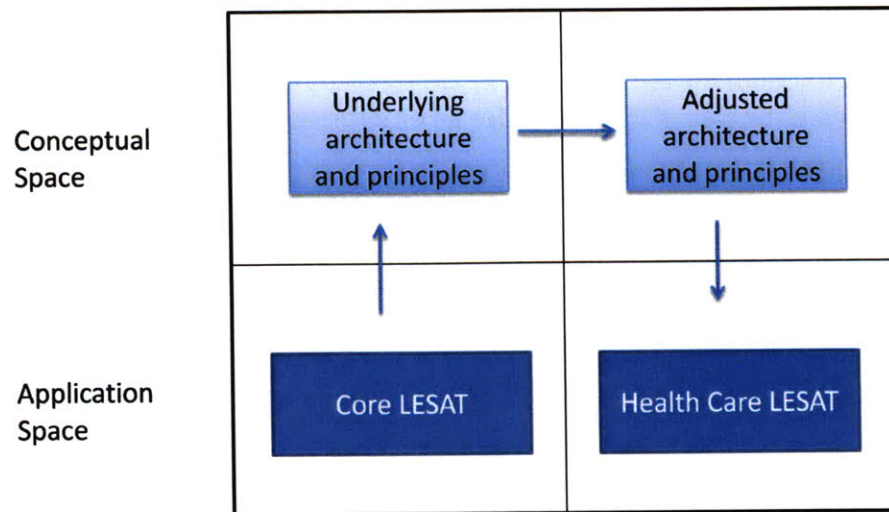


Figure 2: Approach for Adaptation of LESAT

This approach is inspired by the generic design process shown in Figure 3. (Quayle, 2009)

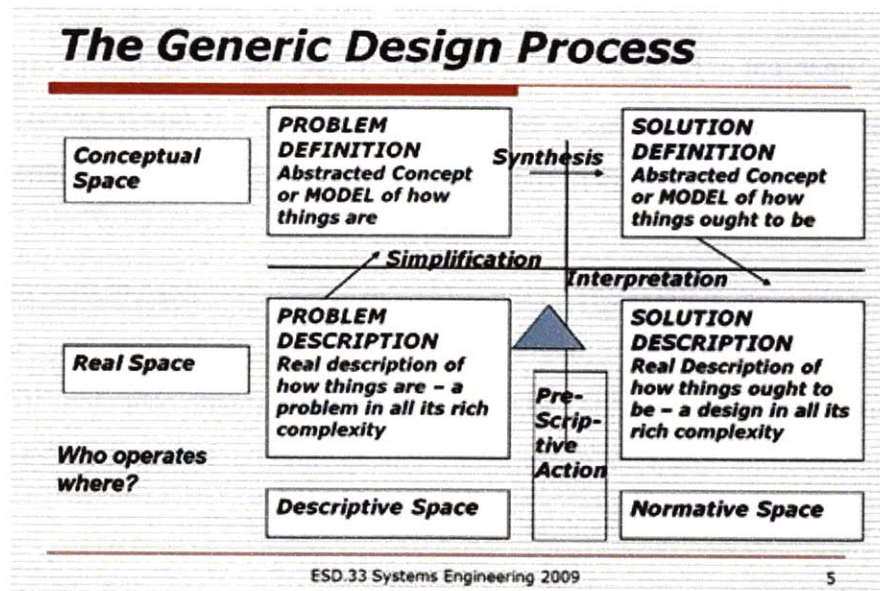


Figure 3: Generic Design Process

The roadmap for developing a health care version of the LESAT builds on the general approach above, as shown in Figure 4. The context specific conceptual architecture becomes the foundation for the enterprise practices and characteristics. New descriptions use vocabulary and concepts familiar in the health care context, based on literature review and discussions with practitioners in the field.

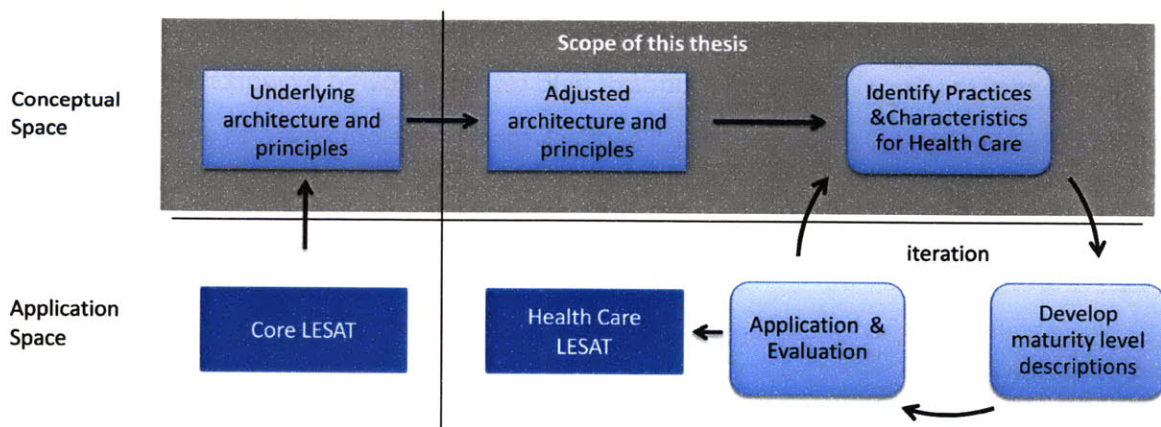


Figure 4: Roadmap for Development of Health Care LESAT

The steps shown in the shaded box in Figure 4 – identifying the underlying principles and architecture, adjusting these, and identifying practices and characteristics – comprise the scope of this thesis. The intent of these steps is to establish the content of the health care LESAT. Validation of the content determines whether the indicator – in this case the LESAT – adequately captures the full content of the concept to be measured. Are key elements missing? Are there elements included that should not be? (Adcock, 2001) Building on the underlying principles and architecture of the core LESAT takes advantage of the empirical validity that has been established through its development and application. Another measure of validity comes from comparing the health care LESAT content with other industry measures such as recommendations from the Institute of Medicine, and the Health Care Criteria for Performance Excellence from the Baldrige National Quality Program.

With enterprise practices and characteristics identified, maturity levels for each must be developed. (This step is shown at the lower right of Figure 4.) As with the core LESAT, five levels of increasing capability and maturity will be described. Development of the maturity levels for each enterprise practice will require further research, and would benefit from participation by a broad representation of health care organizations.

As with the core LESAT, iterative development of the LESAT for health care is anticipated. The cycle on the right side of Figure 4 illustrates this, with feedback from application and evaluation flowing back to the identification of practices, characteristics and maturity levels. During development of the Core LESAT, two rounds of field testing followed by workshops at MIT yielded LESAT version 1.0 in August 2001. Feedback forms were employed to determine LESAT's usefulness, ease of use and alignment with other business practices. Twenty companies from both the U.S. and the U.K. participated in field testing. (Nightingale D. J., 2002)

3 Background

Now that the path forward is laid out, this section steps back to give some background about the need for change in health care, LAI, and how LAI tools such as the LESAT can facilitate the kind of transformation that some health care organizations are seeking.

Need for Change in Health Care

In its landmark report, *Crossing the Quality Chasm*, the Institute of Medicine identified an urgent need for fundamental changes in the organization and delivery of health care in the United States. (Institute of Medicine, 2001) The urgency is driven by alarming statistics about the number of medical errors, other measures of quality of care, and the rising cost of providing even the level of care currently offered. 100,000 deaths per year are attributed to medical errors (Kohn, 2000). Adults only receive about 55% of recommended care (McGlynn, 2003), while over 45 million Americans are uninsured (Thorpe, 2007) and therefore have limited access to care. Costs are increasing, with already 17.3% of the GDP spent on healthcare (Truffer, 2010). Nearly 50% of these expenditures are focused on 5% of the population and these costs are forecasted to continue to rise, as the number of individuals over 65 is expected to increase by 20% by 2020 (Kaiser, 2007).

Cost and quality are symptoms of the problem, however. The IOM identifies four underlying reasons for the inadequacies in health care: the growing complexity of science & technology, increase in chronic conditions, a poorly organized delivery system, and constraints on exploiting the revolution in information technology. (Institute of Medicine, 2001) Another way of stating this is that the environment has changed, but the organization and management of health care has not kept up with the changes.

"Health care today is characterized by more to know, more to manage, more to watch, more to do and more people involved in doing it than at any time in the nation's history. Our current methods of organizing and delivering care are unable to meet the expectations of patients and their families because the science and technologies involved in health care - the knowledge, skills, care interventions, devices and drugs - have advanced more rapidly than our ability to deliver them safely, effectively and efficiently." (The Robert Wood Johnson Foundation, 1996) (Institute of Medicine, 2001)

Health care needs system level design and management tools – tools capable of coordinating and managing highly specialized and distributed personnel, multiple streams of information, and material and financial resources across multiple care settings. (National Academy of

Engineering and Institute of Medicine, 2005) The National Academy of Engineering's report, *Building a Better Delivery System*, recommends enterprise management and systems control tools needed to meet this challenge. The Lean Advancement Initiative at MIT incorporates a range of systems-engineering tools and management practices into products to aid enterprises who seek to transform into efficient, effective, financially strong organizations.

Lean Advancement Initiative

The Lean Advancement Initiative (LAI) at MIT is an open consortium of key government, industry, and academic members. LAI enables enterprises to effectively, efficiently, and reliably create value in complex and rapidly changing environments. (Lean Advancement Initiative)

LAI has grown out of a series of research studies coordinated by MIT, starting with the International Motor Vehicle Program (IMVP) research consortium that resulted in publication of "The Machine That Changed the World." Begun as the Lean Aircraft Initiative, the initial charter was to determine whether lean principles could be applied to military aircraft production.

Through several phases of research, LAI expanded its membership and the scope of its research, shifting from application on the factory floor to enterprise-level research. Figure 5 illustrates this expansion. In 2007, LAI's board approved a name change. "Lean Advancement Initiative" reflects growing interest from other industries. (Lean Advancement Initiative)

Today LAI's member list includes several U.S. government organizations; industry members from aerospace, automotive, and information systems; and a collaborative network of educational institutions.

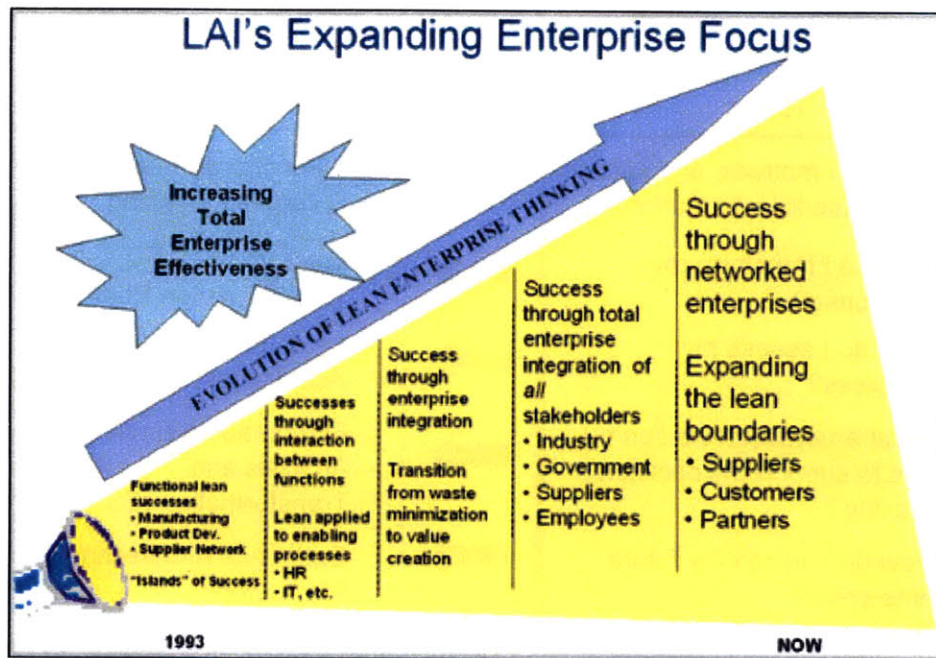


Figure 5: LAI's Expanding Enterprise Focus

LESAT Aids Enterprise Transformation

The mission of LAI is to “enable the focused and accelerated transformation of complex enterprises through collaborative stakeholder engagement in developing and institutionalizing principles, processes, behaviors, and tools for enterprise excellence.” (Lean Advancement Initiative) Through its research, LAI has created a set of tools to aid its members in this transformation. The Lean Enterprise Self Assessment Tool is a key element of this tool set, providing a way for organizations working on transformation to gage their progress. Figure 6 shows some of the key tools that LAI offers in its holistic approach to enterprise transformation. (Nightingale D. , 2009)

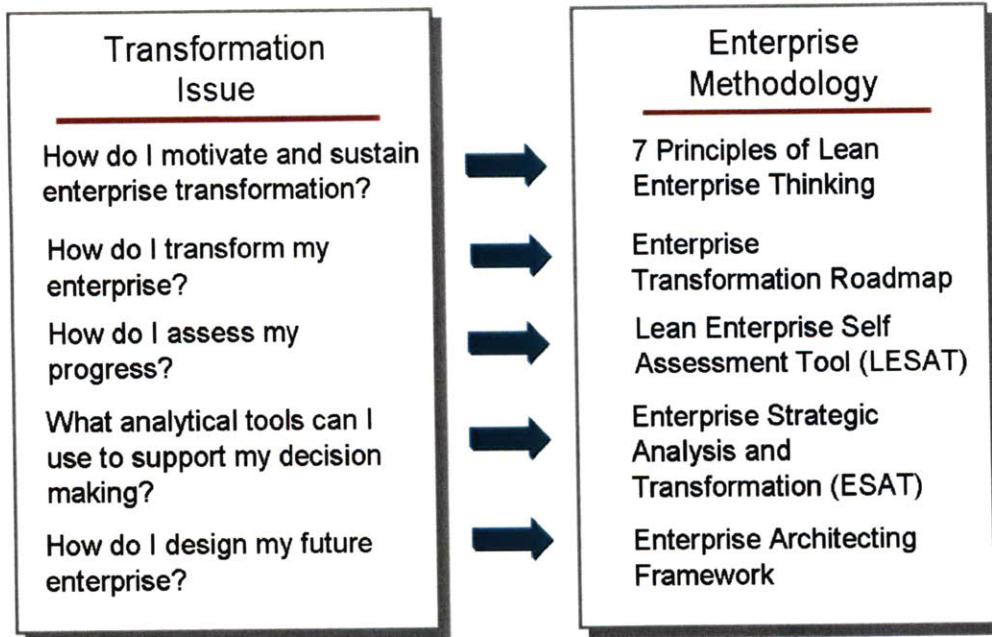


Figure 6: Holistic Approach to Enterprise Transformation

The principles of lean enterprise thinking – listed in Table 3 – provide an overarching guide to enterprise transformation. These principles are put into action through methodologies and tools such as the Enterprise Transformation Roadmap and the LESAT.

Table 3: 7 Principles of Lean Enterprise Thinking

1	Adopt a holistic approach to enterprise transformation
2	Secure leadership commitment to drive and institutionalize enterprise behaviors
3	Identify relevant stakeholders and determine their value propositions
4	Focus on enterprise effectiveness before efficiency
5	Address internal and external enterprise interdependencies
6	Ensure stability and flow within and across the enterprise
7	Emphasize organizational learning

The Enterprise Transformation Roadmap displayed in Figure 7 portrays the overall “flow” of action steps necessary to initiate, sustain, and continuously refine an enterprise transformation based upon lean principles and practices. (Nightingale D. , 2009)

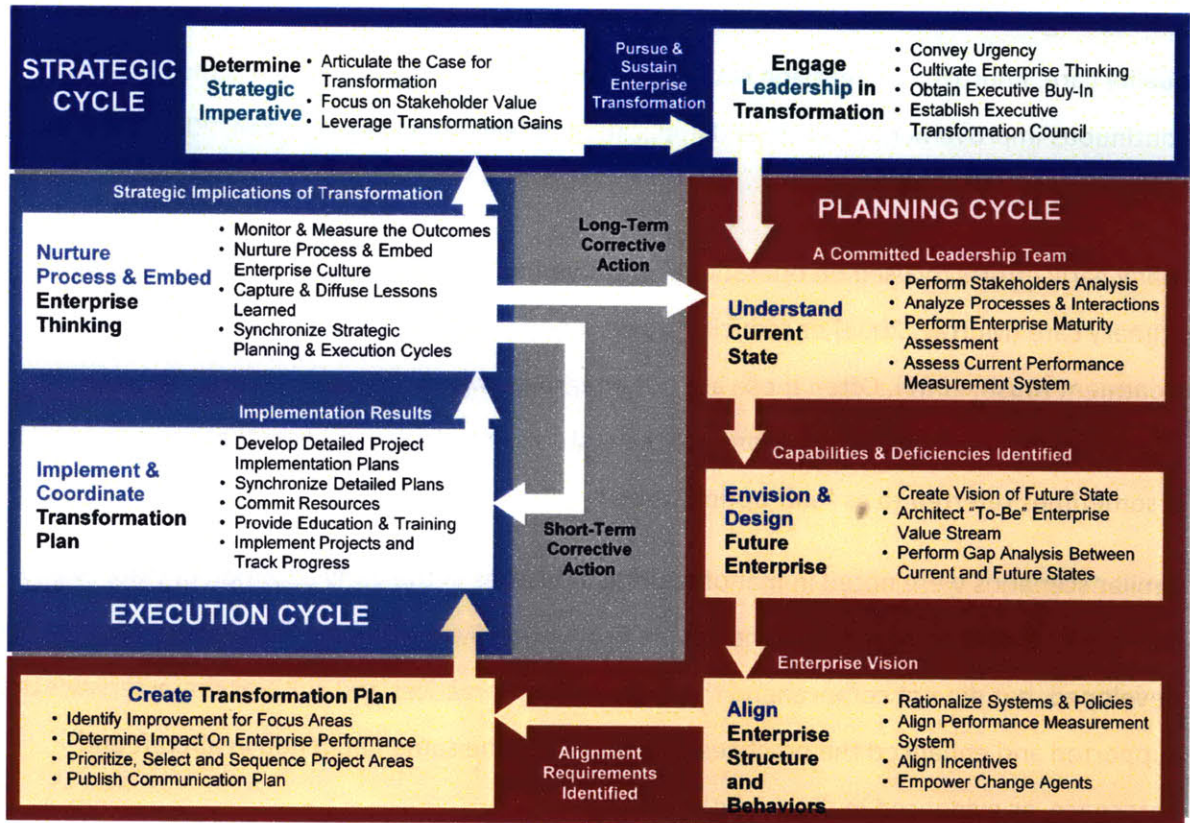


Figure 7: Enterprise Transformation Roadmap

LESAT is based on the Seven Enterprise Principles, and the practices it evaluates relate to the elements in the Enterprise Transformation Roadmap. By identifying both the current state of the organization, and the desired future state, the LESAT provides both a snapshot in time and a means of measuring progress as an enterprise transforms itself.

When gaps are identified in the LESAT, Enterprise Architecting (EA) views (strategy, policy, process, organization, knowledge, information, product and service) are a useful framework for analyzing the enterprise and designing a future state.

4 LESAT for Health Care

Some health care organizations have turned to the quality improvement methods that were initially developed for the manufacturing sector – lean thinking and Six Sigma. Organizations such as Virginia Mason, ThedaCare, and the Veteran’s Administration have reported higher quality care, improved patient and staff satisfaction, and reduced cost of care resulting from continuous improvement projects and application of lean principles. (Graban, 2008) (Toussaint, 2009)

Many early efforts focused on operational improvements such as reducing waiting and delays in primary care (Murray, 2003) or reducing travel required in the process of chemoradiation treatment (Bush, 2007). Often these are not integrated with other enterprise processes. Improvements are seen, but they are not the systems level improvements that are needed. This is sometimes referred to as “sub-optimization.”

Similar scenarios were noted in manufacturing industries in the early adoption of lean. Many companies that tried to emulate the Toyota Production System copied the practices Toyota had developed, but did not comprehend the management practices and cultural characteristics that supported and enhanced the practices. (Spear, 2008) The same happened in aircraft and aerospace, as evidenced in the evolution of LAI.

LAI’s analysis concluded that practices were being implemented in a bottom-up fashion and did not fit with the existing enterprise environment. “The full benefits of lean can be realized only by rethinking the entire enterprise: its structure, policies, procedures, processes, management practices, reward systems, and external relationships with customers and suppliers.” (Lean Advancement Initiative, 2001)

In health care, too, there is a need to progress past the isolated implementation of lean practices to the level of lean enterprise management. Health care organizations with the greatest success adopting lean have all committed to cultural transformation and leading the organization in a different way. (Bliss, 2009) LAI’s principles, methodologies and tools can help health care enterprises seeking to make that transition.

A version of the LESAT adapted specifically for health care will make it easier for health care organizations new to lean enterprise management to use it as an evaluation and planning tool. Many of the revisions will be related to the nature of healthcare as a service. While a patient is clearly a customer, or at least the primary beneficiary of the service, this enterprise to customer relationship is different than that in a product based enterprise. The patient is both an input to the process as well as an output, with health care seeking to change the condition of the patient for the better. This leads to the largest change in adapting the LESAT – rethinking the product life cycle.

5 Adjusting the Architecture and Principles

LESAT uses a generic enterprise architecture (shown in Figure 8) as an organizing framework. This architecture is comprised of three groups of enterprise level processes: enterprise leadership processes, life cycle processes and enabling infrastructure processes. Enterprise leadership processes are those that guide and manage the enterprise as a whole. These include strategic planning, selection of business models and organizational structure, and general management.

Life cycle processes are those that actually create the primary value or product for the customer. In product manufacturing firms, these are the processes that design, manufacture and distribute the product. Enabling infrastructure processes such as finance or facilities services do not contribute directly to the creation of the primary value but are necessary for the function of the enterprise.

This structure is evident in the LESAT. A section devoted to each group of enterprise level processes contains relevant enterprise practices. In the core LESAT, section two is dedicated to lean practices associated with the product life cycle. In a manufacturing or product oriented enterprise, this cycle encompasses steps for conceiving, designing, manufacturing, and operating the product. Best practice is to feed information from each stage in the cycle back into the conception and design of products. (Morgan, 2006)

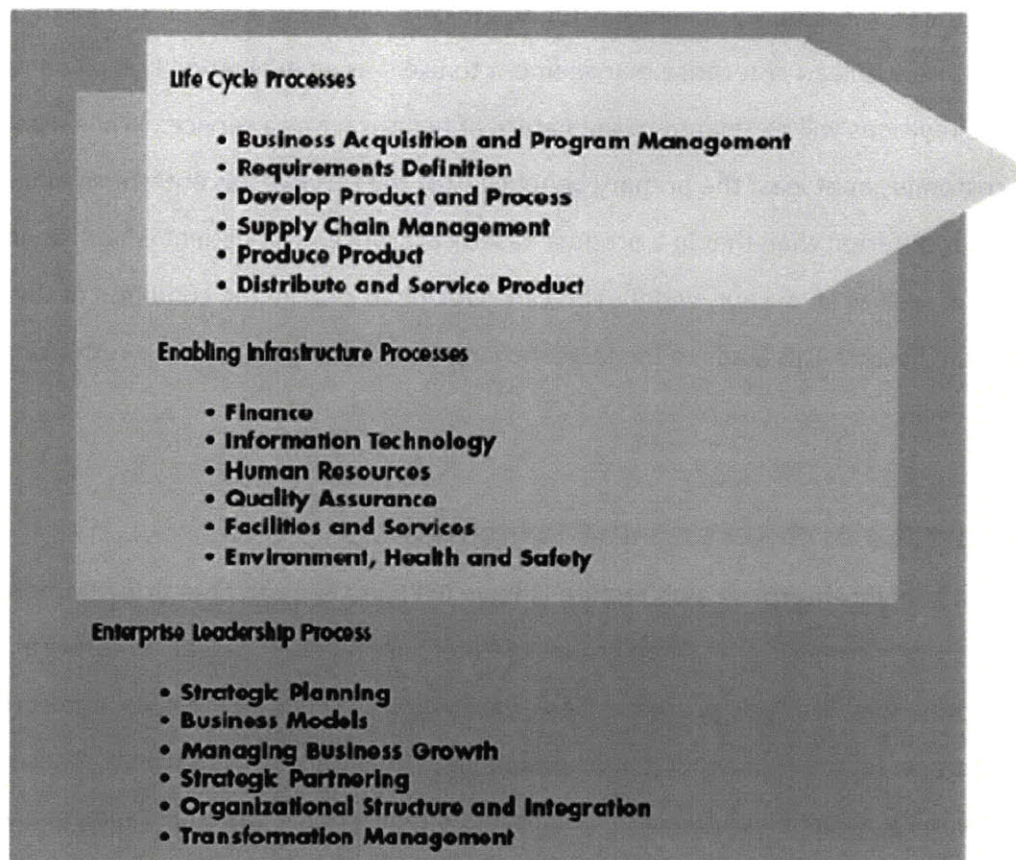


Figure 8: Generic Lean Enterprise Process Architecture (Lean Advancement Initiative, 2001)

The product life cycle encompasses activities beyond the initial manufacturing of a product. It looks at all stages of a product's life and use – sometimes described as “cradle to grave.” There is value in making a part easy to service or replace. There is value in flexibility, the ability to use a product for more than one purpose – such as a minivan that can carry people or cargo. The product life cycle and the value of “ilities” are so established in some industries (e.g. aerospace and automotive) that they are no longer recognized as the complex concepts they are. “The product life cycle” as outlined in the LESAT contains a set of assumptions built into the conceptual enterprise architecture.

People from the health care industry though, do not share these assumptions, foundations or terminology. (Life cycle has a different connotation in health care!) Health care in the U.S. is a fragmented industry and most enterprises provide piecemeal services, not connected or

continuous care. (Swensen, 2010) In aerospace or automotive a systems integrator or original equipment manufacturer (OEM) takes responsibility for coordinating the development of a large system, even when components or subsystems are designed or manufactured by multiple companies. (In U.S. health care, this systems integration or coordination role is rarely explicitly filled. It often falls to the patient or the patient's family to attempt this.)

Evidence from LESAT evaluations completed in health care organizations reflect this mismatch. Evaluators did not understand or see the relevance of some questions from the "life cycle process" section. One project manager from Greater Boston Medical Enterprise, a certified Lean Six Sigma Blackbelt, noted that major revisions will be necessary to make the LESAT suitable for healthcare in this section. (Hashmi, 2008) Notes and comments from the completed LESAT for another medical enterprise also focused on this section. (Schlosser, 2008)

In Section II.A there is concern with terms such as "business acquisition," questioning whether this is appropriate for health care organizations to pursue. It is not clear what managing risk and schedule mean in the health care context. Throughout section II, "product" can be reinterpreted as "service," but related questions and capability levels include references to warranty claims, product usage data, and manufacturing knowledge which are noted as not relevant or not understood. Section II.F, Distribute and Service Product, has no apparent relevance when the "product" is itself a service and there is no physical product to move through distribution.

Clearly, the product life cycle that applies so universally in product manufacturing does not fit as well to a service industry such as health care. Still, the concept of a cycle - a series of occurrences that repeats - is applicable. How is care conceived, designed, provided and maintained? What value can be created at each stage? This piece of the enterprise architecture must be modified to reflect the primary value processes in health care. Rather than a "life cycle," this will be referred to as the health care service cycle.

In health care, the process cycle can be viewed through two lenses: 1) the patient point of view (the consumption model) 2) the enterprise point of view (the delivery model). There are parallels between these two points of view, but different scale and focus.

The health care service cycle includes identification of care or service needs, definition of requirements, design of the service and the delivery process, coordination of the extended enterprise, delivery of care and post-care support and monitoring. The steps of this cycle were identified by combining two sources. The first source is the core LESAT life cycle processes. For each life cycle process key issues or concepts were identified. These key issues then were reconsidered in the context of health care. The second source is interviews with people in the health care industry, applying lean in their organizations.

Table 4 summarizes the life cycle steps in the original LESAT and service cycle steps in the health care domain.

Table 4 Life Cycle Processes Comparison

LESAT 2001 Life Cycle Processes	Key Issue	Health Care Patient View	Health Care Enterprise view
Business Acquisition and Program Management	What is our next product/service?	Need or condition arises	Identify Opportunities for Service
Requirements Definition	What do the stakeholders need?	Diagnosis	Define Requirements
Product/Process Development	How do we meet the need and create value?	Define / design treatment (the course of care for one patient)	Develop Service and Delivery Process
Supply Chain Management	With whom do we coordinate, and how?	Preparation and coordination	Manage Extended Enterprise
Production	How do we deliver the value efficiently?	Give treatment	Deliver Care (Operations)
Distribution and support	What additional value can we provide?	Assess outcome. Follow up and monitor patient.	Support and Surveillance

In “A User’s Manual for the IOM’s ‘Quality Chasm’ Report,” Berwick writes that the underlying framework analyzes the needed changes in American health care at four different levels: the experience of patients (Level A); the functioning of small units of care delivery (“microsystems”) (Level B); the functioning of the organizations that house or otherwise support microsystems (Level C); and the environment of policy, payment, regulation, accreditation, and other such factors (Level D), which shape the behavior, interests, and opportunities of the organizations at Level C. The model is hierarchical because it asserts that the quality of actions at Levels B, C,

and D ought to be defined as the effects of those actions at Level A, and in no other way.
(Berwick, 2002)

The IOM's level A corresponds to the patient view in the table above. As Berwick points out, this is the level at which the efforts at other levels come to fruition. Yet, to achieve the quality, effectiveness and efficiency desired, the processes at each of the other levels must be carefully designed and implemented.

Much of the literature addressing the application of lean to health care focuses on Level B, the microsystem level. This is where the work happens. Value stream mapping, eliminating waste, stopping the process to fix problems have all been applied with success at the micro-system level. (Murray, 2003) (Bush, 2007) (Tovim, 2007) (Toussaint, 2009) (Grout, 2010) However, as seen in automotive, aerospace and other industries, this is only the shallow surface of Lean. The strength, and greater benefit, lies in the enterprise level transformation – level C.

LESAT is focused on assessing the degree of maturity of an enterprise in its use of “lean” principles and practices to achieve the best value for the enterprise and its stakeholders.
(Nightingale, 2002)

For health care, we have now identified a new conceptual architecture, replacing life cycle processes with health care service cycle processes. This now becomes the structure for a health care LESAT, and we proceed to modifying the enterprise practices.

6 Health Care Enterprise Practices and Characteristics

Table 5 presents the proposed practices and characteristics for health care enterprises. For ease of reading, excerpts from this table will be included in the discussion sections.

Table 5: Enterprise Processes, Practices and Characteristics for Health Care

<u>Process</u>	<u>Enterprise Practice</u>	<u>Enterprise Characteristic</u>
Section I - Lean Transformation/Leadership		
I.A. Enterprise Strategic Planning	I.A.1 - Integration of process improvement in strategic planning process	Lean impacts growth, profitability and market penetration
	I.A.2 - Focus on customer value	The enterprise value stream is patient-centered
	I.A.3 - Leveraging the extended enterprise	Value stream extends throughout the extended enterprise, providing continuity of care
I.B. Adopt Enterprise Paradigm	I.B.1 - Learning and education in Lean for enterprise leaders	“Unlearning” the old, learning the new
	I.B.2 - Senior management commitment	Senior management leading it personally
	I.B.3 - Lean enterprise vision	New mental model of the enterprise
	I.B.4 - A sense of urgency	The primary driving force for Lean
I.C. Focus on the Value Stream	I.C.1 - Understanding current value stream	How we now deliver value to customers
	I.C.2 - Enterprise flow	“Single piece flow” of materials and information
	I.C.3 - Designing future value stream	Value stream to meet the enterprise vision
I.D. Develop Enterprise Structure and Behavior	I.D.1 - Enterprise organizational orientation	Organize to support value delivery
	I.D.2 - Relationships based on mutual trust	“Win-win” vs. “we-they”
	I.D.3 - Open and timely communications	Information flows freely to support informed decision making
	I.D.4 - Employee empowerment	Multi-disciplinary teams share responsibility
	I.D.5 - Incentive alignment	Reward the behavior you want
	I.D.6 - Innovation encouragement	From placing blame to creative problem solving
	I.D.7 - Lean change agents	The inspiration and drivers of change
I.E. Create & Refine Transformation Plan	I.E.1 - Enterprise-level Lean transformation plan	Charting the course across the extended enterprise
	I.E.2 - Commit resources for Lean improvements	Resource provision for lean
	I.E.3 - Provide education and training	Just-in-time learning
I.F. Implement Enterprise Improvement Initiatives	I.F.1 - Development of detailed plans based on enterprise plan	Coordinating lean improvements
	I.F.2 - Tracking detailed implementation	Assessing actual outcomes against goals
I.G. Focus on Continuous Improvement	I.G.1 - Structured continuous improvement processes	Uniformity in how we get better
	I.G.2 - Monitoring lean progress	Assessing progress toward achieving enterprise objectives
	I.G.3 - Nurturing the process	Assure executive level involvement
	I.G.4 - Capturing lessons learned	Ensuring that successes lead to more successes

<u>Process</u>	<u>Enterprise Practice</u>	<u>Enterprise Characteristic</u>
	I.G.5 - Impacting enterprise strategic planning	Results lead to strategic opportunities
Section II - Health Care Service Cycle Processes		
II.A. Opportunity Identification	II.A.1 - Leverage Lean capability for enhanced service	Exploiting new service opportunities arising from lean enabled capabilities
	II.A.2 - Optimize the capability and utilization of assets	Assets or capacity freed by process improvement are used to serve additional patients/stakeholders
	II.A.3 - Provide capability to evaluate and respond to changes in the clinical evidence and business environment	Success is achieved with value that meets the changing needs of patients/stakeholders
	II.A.4 – Allocate resources for program development efforts	Teaming for success
II.B. Requirements Definition	II.B.1 - Establish a requirements definition process that optimizes the value of the whole process cycle	Consideration for patient and stakeholder needs through the whole process
	II.B.2 - Utilize data from the extended enterprise to optimize future requirement definitions	Closed loop processes are in place to capture operational performance data (including external indicators)
II.C. Develop Service and Delivery Process	II.C.1 - Design the care and the delivery process to be knowledge-based, patient-centered, and systems-minded	Care based on the best clinical evidence, but allowing for patient preference or condition
	II.C.2 - Incorporate stakeholder values into service and delivery	Understanding internal and external stakeholders reduces waste and creates additional value
	II.C.3 - Integrate service and delivery process development	Breaking down of functional silos enables seamless communication and value flow
	II.C.4 – Information systems are designed with and in support of service and delivery	Information systems facilitate new processes
II.D. Manage Extended Enterprise	II.D.1 - Define and develop elements of the network	Coordination with internal and external organizations
	II.D.2 - Optimize network-wide performance	Services are delivered in a complementary and timely manner. Continuity of care crosses disciplinary and organizational boundaries (Haggerty, 2003)
	II.D.3 - Foster innovation and knowledge-sharing throughout the network	Promote innovation and sharing of best practices
II.E. Deliver the Care (Operations)	II.E.1 - Utilize workforce capabilities to strengthen the business and reputation	Investment in improving workforce knowledge and resource development
	II.E.2 - Establish and maintain an efficient operations system	Error free care paced by demand and continuous flow. (Christopher, 2009)
	II.E.3 - Manage physical goods supply chain in Lean fashion	Right product, right quantity at the right time
	II.E.4 – Align capacity and capability to demand	Monitor and anticipate service demand to maintain key flows

Process	Enterprise Practice	Enterprise Characteristic
II.F. Support and Surveillance	II.F.1 - Seamless transition of service into and out of the enterprise	Effective and efficient flow of information and materials (e.g. medication) to and from patients and stakeholders
	II.F.2 - Enhance value of delivered care and services to patients, stakeholders and the enterprise	Follow up and support to enhance care outcomes and patient experience
	II.F.3 - Provide post delivery support and monitoring	Performance measures are monitored to drive process improvements
Section III - Enabling Infrastructure		
III.A. Lean Organizational Enablers	III.A.1 - Financial system supports Lean transformation	Lean requires appropriate financial data
	III.A.2 - Enterprise stakeholders pull required financial information	Data on demand
	III.A.3 - Promulgate the Learning Organization	Learning organizations create a flexible workforce
	III.A.4 - Enable the Lean enterprise with information systems and tools	Facilitate the flow of information and knowledge
	III.A.5 - Integration of environmental protection, health and safety into the business	"Cleaner, healthier, safer"
III.B. Lean Process Enablers	III.B.1 - Process standardization	Strive for consistency and re-use
	III.B.2 - Common tools and systems	Assuring compatibility, reducing costs
	III.B.3 - Variation reduction	Reduce uncertainty by reducing variation

7 Discussion of Modifications to Enterprise Practices and Characteristics.

General Changes

Two changes are applied broadly through the LESAT. First, the term "customer" has been replaced with "patients and stakeholders." Second, "service" or "care" has generally been substituted for the word "product."

The patient is the most obvious customer of the health care enterprise, as the receiver of the primary benefit or value the enterprise provides. Other stakeholders should be considered when defining or designing services. Stakeholders may include the patient's family, employees, and insurance providers. The Malcolm Baldrige Health Care Criteria lists additional stakeholder groups: the community, insurers and other third-party payers, employers, health care

providers, patient advocacy groups, Departments of Health, and students. (Baldrige National Quality Program , 2009)

While “product” can be interpreted to include service as a product, the wording in the LESAT is biased toward physical, manufactured products. Health care is a service – more transformation than production. By explicitly referring to it as a service, no further interpretation is required. Since the LESAT for health care is not intended to apply to any enterprise in any industry, the generic wording can be replaced with appropriate specifics.

Section 1 – Lean Transformation Leadership

The enterprise level processes in this section are not specific to any industry and equally applicable in health care. A few changes have been made, primarily to revise wording where the original may have unfavorable connotations in the health care context.

I.A Enterprise Strategic Planning

I.A. Enterprise Strategic Planning	I.A.1 - Integration of process improvement in strategic planning process	Lean impacts growth, profitability and market penetration
	I.A.2 - Focus on customer value	The enterprise value stream is patient-centered
	I.A.3 - Leveraging the extended enterprise	Value stream extends throughout the extended enterprise, providing continuity of care

In the core LESAT, the characteristic for I.A.2 refers to “customers pull value.” For the health care version, this phrase was removed. Since the customer, generally the patient, is not at the receiving end of a production system, but rather in the process receiving service, the concept of pull is out of place. In the spirit of the practice, “focus on customer value,” this characteristic has been reinterpreted as a patient-centered value stream.

I.A.3 in the core LESAT again seems to rely on the perspective of the customer at the “end” of the production system. The characteristic was “value stream extends from the customer through the enterprise to suppliers.” Wording has been adjusted to be less unidirectional, allowing less linear relationships between the patient, the enterprise and other parts of the extended enterprise. The reference to suppliers has been replaced with the extended

enterprise. The extended enterprise will be discussed further in the context of section II.D, Managing the Extended Enterprise.

I.D. Develop Enterprise Structure and Behavior

I.D. Develop Enterprise Structure and Behavior	I.D.1 - Enterprise organizational orientation	Organize to support value delivery
	I.D.2 - Relationships based on mutual trust	“Win-win” vs. “we-they”
	I.D.3 - Open and timely communications	Information flows freely to support informed decision making
	I.D.4 - Employee empowerment	Multi-disciplinary teams share responsibility
	I.D.5 - Incentive alignment	Reward the behavior you want
	I.D.6 - Innovation encouragement	From placing blame to creative problem solving
	I.D.7 - Lean change agents	The inspiration and drivers of change

Three practices in this process section were revised: I.D.3, I.D.4 and I.D.6. The characteristic for I.D.3, “open and timely communications” was changed from “information exchange when required” to “information flows freely to support informed decision making.” The intent is much the same. The new wording is inspired by the need for transparency, one of the “new rules” for health care promoted by the IOM. (Institute of Medicine, 2001)

Previously the enterprise characteristic for II.D.4 Employee Empowerment read “decision making at the lowest possible level.” It now reads “multi-disciplinary teams share responsibility.” One LESAT evaluator suggested that this be clarified to focus on enterprise processes, rather than decisions regarding treatment or care. That distinction may not be necessary. Even in the process of providing care, which has been traditionally directed by physicians, the value of cross-disciplinary teams is being recognized.

The Institute of Medicine outlines stage of evolution in the design of health care organizations. In the lowest level, individual physicians craft solutions for individual patients. In higher maturity levels, the professional team formally shares roles and responsibilities among its members, and the physician emerges as a leader. (Institute of Medicine, 2001)

“The autonomous physician model of care is not only becoming obsolete, it is hazardous because it exposes patients to increased risks associated with transitions, hand-offs, and

communication failures. A different model—one that emphasizes collaborative practice and inter-professional teamwork—is needed.” (Lucian Leape Institute , 2010)

Another important aspect of employee empowerment in lean enterprises is the power and responsibility of each team member to stop the process when one sees a problem. While it requires some adjustment of traditional roles and responsibilities, this practice can be just as effective in health care as it has been in manufacturing enterprises. (Grout, 2010) ThedaCare has shown success with collaborative care teams comprised of a nurse, a physician and a pharmacist working together to coordinate a care plan. This approach has provided "dramatic improvement in patient satisfaction, quality performance and medication reconciliation." (Toussaint, 2009)

The enterprise characteristic for I.D.6 Innovation Encouragement was “from risk aversion to risk rewarding” in the core LESAT. To avoid misperception of encouraging risk that may endanger patient’s health, this characteristic has been reworded as “from placing blame to creative problem solving.” The intent is the same: focus on the process, rather than the individual, and correct root causes with creative solutions. An earlier IOM report, *To Err Is Human* attributed most patient injuries to systemic factors such as unrealistic reliance on human memory, poor communication systems, reliance on handwriting in a computer age, and so on. (Kohn, 2000) Systems should make it as easy as possible for individuals and teams to provide high quality care. Searching out the errant person instead of studying the process and identifying a root cause leads to low error reporting and unwillingness to be candid. (MacPhee, 2007)

I.B, I.C, I.E-G

No changes were made for the health care version.

Section 2 – Health Care Service Cycle Processes

Since the processes in this section have been changed through the redefinition of the conceptual enterprise architecture, the practices and characteristics have been changed as well.

II.A Opportunity Identification and Planning

II.A. Opportunity Identification	II.A.1 - Leverage Lean capability for enhanced service	Exploiting new service opportunities arising from lean enabled capabilities
	II.A.2 - Optimize the capability and utilization of assets	Assets or capacity freed by process improvement are used to serve additional patients/stakeholders
	II.A.3 - Provide capability to evaluate and respond to changes in the clinical evidence and business environment	Success is achieved with value that meets the changing needs of patients/stakeholders
	II.A.4 – Allocate resources for program development efforts	Teaming for success

“Business acquisition and program management” in the core LESAT has been recast as “opportunity identification and planning”. In many product oriented companies, the product is produced for a customer, often another enterprise. Business acquisition is the process of getting hired to do a job – designing and or producing a product or family of products. The “job,” and all the tasks required to complete it are referred to as a project or program. This way of doing things is not common in health care. Yet, the basic purpose of identifying what is next for the organization still must be fulfilled. In the LESAT for health care, this is referred to as Opportunity Identification and planning.

In this stage, the health care enterprise is determining what services it should offer. Key inputs or considerations include constituent patient population and stakeholder needs, clinical evidence base and medical research, the enterprise’s strategic goals and performance data, and external or environmental drivers. Are there changes in the patient population or marketplace that create new opportunities? Are there new treatment methods or technologies that the enterprise should offer?

The concept of innovation includes both technological and organizational innovation. The Baldrige Criteria for Health Care Excellence give examples: “Beyond specific health care provisions leading to desired health care outcomes, services might included extended hours, family support services, cost, timeliness, ease of use of your services, assistance with billing / paperwork processes, and transportation assistance.” (Baldrige National Quality Program , 2009)

In the core LESAT, II.A.1 and II.A.2 both refer to business growth. Business growth is a common indicator of success, but given the nature of health care, and health care organizations, it is helpful to redefine the parameters of business success. Business growth and competitive advantage can be perceived to be at odds with the altruistic nature that is expected in health care. While financial strength or profits are important to the enterprise, they are not the primary focus. In the LESAT for health care, “growth” is replaced with enhanced service, or service to additional customers.

Practice II.A.3 previously identified the enterprise practice as managing risk, with risk being tied to program cost, schedule and performance. This is in essence the program management function. In a product oriented enterprise, often a large portion of resources and attention are applied to the work of developing a new product. In health care, the majority of resources are applied in operations, delivering service. The new practice has been stated as “Provide capability to evaluate and respond the changes in clinical evidence and the business environment.” The associated characteristic focuses on responsiveness to the changing needs of patients and stakeholders.

II.B Requirements Definition

II.B. Requirements Definition	II.B.1 - Establish a requirements definition process that optimizes the value of the whole process cycle	Consideration for patient and stakeholder needs through the whole process
	II.B.2 - Utilize data from the extended enterprise to optimize future requirement definitions	Closed loop processes are in place to capture operational performance data (including external indicators)

Requirements definition outlines the intent and criteria for designing the service and the delivery process. At the enterprise level, this considers the needs of a patient population (e.g. stroke patients) or a class of stakeholders (e.g. families or insurance companies) rather than an individual.

As a starting point, the Institute of Medicine identifies six aims for improvement. These aims are listed below. For each aim, a requirement or target can be set to help guide the design of service and process. (Institute of Medicine, 2001)

1. Patient centered
2. Safe
3. Effective
4. Timely
5. Efficient
6. Equitable

As indicated in II.B.1 lean enterprise practice aims to optimize value over the whole process cycle. Requirements should take into account information from the opportunity identification phase, as well as stakeholder needs from the operations stage, the extended enterprise, support processes and post-service support. In the characteristic, “stakeholder pull” has been changed to “consideration for patient and stakeholder needs through the whole process.” As discussed in practice I.A.2, the concept of pull is not intuitive in a care delivery process.

Established models or practices, such as the Chronic Care Model (CCM), can be useful in defining requirements. The CCM is a guide to improving chronic illness management. Initial evidence demonstrates that the model can improve chronic care and in some cases reduce health care costs. (Bodenheimer, 2002)

Practice II.B.2 calls for using performance data from the extended enterprise to inform requirements for new services. External indicators such as standardized patient satisfaction and employee satisfaction surveys, participation in the Institute for Healthcare Improvement's 100k Lives campaign, and participation in the JCAHO accreditation are some sources available to help drive performance improvement. (Kitts, 2008)

II.C Develop Service and Delivery Process

II.C. Develop Service and Delivery Process	II.C.1 - Design the care and the delivery process to be knowledge-based, patient-centered, and systems-minded	Care based on the best clinical evidence, but allowing for patient preference or condition
	II.C.2 - Incorporate <i>stakeholder</i> values into service and delivery	Understanding internal and external stakeholders reduces waste and creates additional value
	II.C.3 - Integrate service and delivery process development	Breaking down of functional silos enables seamless communication and value flow
	II.C.4 – Information systems are designed with and in support of service and delivery	Information systems facilitate new processes

Just as with physical products there is a need to design both the product itself and the process by which it is produced, in health care there is a need to design both the care/service and the process by which that care is delivered.

The practice II.C.1, “design the care and delivery process to be knowledge-based, patient-centered, and systems-minded,” is based on redesign principles outline by the IOM.

Knowledge-based care means using the best scientific and clinical information available in the service of the patient. Patient-centered care puts each patient in control of his or her own care. The aim is customization of care, according to individual needs, desires, and circumstances. Systems-minded care assumes responsibility for coordination, integration, and efficiency across traditional boundaries of organization, discipline, and role. (Berwick, 2002)

Practice II.C.2 incorporates multiple stakeholders’ values into the design of both service and delivery. Many organizations need to consider requirements for suppliers, partners, and collaborators at the work system and work process design stage. Overall, effective design must take into account all stakeholders in the continuum of care. (Baldrige National Quality Program , 2009) In the core LESAT, the characteristic for II.C.2 referred to downstream stakeholders. This has been revised to “internal and external” stakeholders as a reflection of the more networked form of extended enterprise likely in health care.

II.C.3, “integrate service and delivery process development,” highlights the value of integrated development, also called concurrent engineering. Concurrent engineering – designing both the product (or service) and the process to provide it – has been identified as a best practice in manufacturing industries, and offers benefits in health care as well. “Simply defined, concurrent engineering is an attempt to break down silos in an enterprise through effective teamwork. ” (National Academy of Engineering and Institute of Medicine, 2005)

Three categories of knowledge are needed to design good care and delivery: (Schlosser, 2010)

1. Knowledge of the science, this is from the literature and “research” institutions
2. Knowledge of the organization - local knowledge about the current system capabilities and constraints
3. Knowledge of the patient - local knowledge about both the populations of patients usually served and the individual knowledge of discrete patients needing care.

“Knowledge of the organization” speaks to the importance of designing the care and the delivery process together. What the process can do informs the service that can be offered, just as the service needs help define the requirements for process design.

Here are two examples of how the knowledge of the organizational capabilities or constraints may factor into design. If the enterprise doesn’t have a cardiac surgery service, the design of a cardiac care system will be different than if it did. If the enterprise is limited by ICU beds, then handling of ED patients would be designed differently. (Schlosser J. M., 2010)

Practice II.C.4, “information systems are designed in conjunction with and to support service and delivery”, is added. While information technology (I.T.) is covered generally in section III, it is added here to reinforce the value of including it explicitly in concurrent design.

“I.T. without process redesign is only adding cost. Implementing the same lousy process in electronic format will do nothing except add the cost of the I.T. infrastructure to the budget. We must study the processes of care and then design I.T. solutions that support the new process not the other way around.” (Toussaint J. S., 2008)

II.D Manage the Extended Enterprise

II.D. Manage Extended Enterprise	II.D.1 - Define and develop elements of the network	Coordination with internal and external organizations
	II.D.2 - Optimize network-wide performance	Services are delivered in a complementary and timely manner. Continuity of care crosses disciplinary and organizational boundaries (Haggerty, 2003)
	II.D.3 - Foster innovation and knowledge-sharing throughout the network	Promote innovation and sharing of best practices

In the core LESAT, this process is “manage the supply chain.” The standard view of the supply chain leaves out an important consideration in health care – especially in the U.S. That concern is the coordination across elements of the network - both internal and external to the enterprise. Internal elements may be departments or specialties, or multiple facilities or locations such as hospitals and clinics with in a larger health organization. Even the physicians who practice at a hospital may be considered elements or partners, since many hospitals do not directly employ the physicians who practice there. External elements may include primary care facilities, outpatient clinics, specialist offices and suppliers that provide goods (pharmaceuticals, tools, etc.) or services (I.T.) (Schlosser J. , 2010)

The term “extended enterprise” in intended to encompass all of these elements. While an enterprise can refer to multiple organizations working together for a common business purpose, for clarity the health care LESAT uses the term “enterprise” to mean the organization of interest and the term “extended enterprise” to include other organizations with which the enterprise must coordinate.

Traditional supply chain management is still a critical task for health care organizations. There are many physical items and pieces of equipment that are necessary in providing care. Linens, bandages, thermometers and surgical instruments are just a few examples. Because operating within an extended enterprise is such an important consideration, this section of the health care LESAT has been dedicated to practices supporting that. Physical supply management has been moved to section II.E as part of operations.

The challenge to a lean enterprise is to help the extended enterprise to operate like one system. First one must identify the components of the network (II.D.1) and encourage development of the capabilities needed to be part of an efficient enterprise network.

"Moving from the current conglomeration of independent entities toward a 'system' will require that every participating unit recognize its dependence and influence on all other units. Each unit must not only achieve high performance but must also recognize the imperative of joining with other units to optimize the performance of the system as a whole." (National Academy of Engineering and Institute of Medicine, 2005) Practice II.D.2, "optimize network-wide performance," recognizes this aim.

In the realm of health care, network-wide performance includes the concept of the continuity of care. Continuity is how individual patients experience integration of services and coordination. The desired standard is "Services are delivered in a complementary and timely manner. Continuity of care crosses disciplinary and organizational boundaries." (Haggerty, 2003)

There are three types of continuity to consider: informational, management and relational. Providers will consider the importance of each differently in the context of care being provided.

Informational continuity requires the availability of information on past events and personal circumstances to make current care appropriate for each individual. Management continuity offers a consistent and coherent approach to the management of a health condition while being responsive to a patient's changing needs. Relational continuity maintains an ongoing therapeutic relationship between a patient and one or more providers. (Haggerty, 2003)

Ideally, all three types of continuity and the stakeholders in the extended enterprise will be considered in the design of health care services and delivery processes.

The final practice in managing the extended enterprise is fostering innovation and knowledge-sharing (II.D.3). The core LESAT characteristic references technology transfer. Although "technology transfer" is not such a big concern and has been replaced with "sharing of best practices," the underlying purpose is the same in health care as in other industries.

II.E Deliver the Care (Operations)

II.E. Deliver the Care (Operations)	II.E.1 - Utilize workforce capabilities to strengthen the business and reputation	Investment in improving workforce knowledge and resource development
	II.E.2 - Establish and maintain an efficient operations system	Error free care paced by demand and continuous flow. (Christopher, 2009)
	II.E.3 - Manage physical goods supply chain in Lean fashion	Right product, right quantity at the right time
	II.E.4 – Align capacity and capability to demand	Monitor and anticipate service demand to maintain key flows

In the core LESAT, section II.E was labeled “Produce Product,” the primary operation of the enterprise. For health care, this primary operation is “deliver the care.”

Both the practice and the characteristic have been changed for II.E.1. In the core LESAT, the practice was “utilize production knowledge and capabilities for competitive advantage.” In the health care context, both “production knowledge” and “competitive advantage” need to be reconsidered.

Production knowledge for the health care context is reinterpreted as “workforce capabilities.” The Baldrige Criteria for Health Care describes workforce capabilities as “your organization's ability to accomplish its work processes.” This includes clinical knowledge and training, but also the knowledge of the local patient population and the procedural knowledge and coordination skills of the people or team providing care. This drives the enterprise characteristic of “investing in improving workforce knowledge and resource development.”

Because of the financial/payment structure of health care in the U.S., lean improvements and workforce capability do not always result in the “competitive advantage” or financial benefit seen in other industries. Most frequently, payment is based on volume (e.g. number of days in the hospital) or pre-set rates for specific services (e.g. an MRI). Examples have been published (ThedaCare, Henry Ford Health System) in which improvements led to reduced payments (from Medicare or other payers), and thus financial penalty. (Toussaint J. , 2009) (McCarthy & al, 2009) In the aggregate, lean practices do serve to strengthen the business long term, improve

quality and thus enhance the reputation of the enterprise. These measures of success seem to be a suitable stand in for growth and competitive advantage.

Practice II.E.2 is “establish and maintain an efficient operations system.” The characteristic “defect free production pulled by the customer” has been reinterpreted as “error free care paced by demand and continuous flow.” (Kim & al, 2009) Much of the available literature is focused on this section – how to incorporate lean practices into health care operations. An “efficient operations system” encapsulates a much larger body of work and detail: eliminating waste, improving flow, error free work, standardization where reasonable, measurement and reporting of performance.

Creating value requires both effectiveness and efficiency. Value is benefit at cost. An effective system achieves its goals; it provides benefit. An efficient system provides that benefit with minimum use of resources.

Two key practices have been added to this section: movement of physical items (II.E.3) and the concept of matching capacity to demand (II.E.4). While moving material does not have the same critical focus in services as it does in product manufacturing, it is still an important aspect of operations. Availability of necessary items such as tools, bandages, bed linens or medication will impair or prevent the timely delivery of health services.

Matching demand and capacity (II.E.4) is addressed in core LESAT section II.F. as “aligning marketing and sales to production.” It is now in the operations stage because for services, there is no separate distribution/sales activity. One example of this practice is open access scheduling. By matching supply and demand, and reducing backlogs primary care practices have reduced waiting times and increased the percentage of patients able to see their own physician. (Murray, 2003)

II.F Support and Surveillance

II.F. Support and Surveillance	II.F.1 - Seamless transition of service into and out of the enterprise	Effective and efficient flow of information and materials (e.g. medication) to and from patients and stakeholders
	II.F.2 - Enhance value of delivered care and services to patients, stakeholders and the enterprise	Follow up and support to enhance care outcomes and patient experience
	II.F.3 - Provide post delivery support and monitoring	Performance measures are monitored to drive process improvements

One of the key considerations in the classic product life cycle concerns what happens after the sale: what responsibility does the manufacturer have, and what support must be provided. This might manifest as warranty repairs or service parts. In health care, too, there is a need to consider what happens after care has been provided. Accordingly, “distribute service and product” from the core LESAT has become “support and surveillance.”

"A surgical procedure may be performed perfectly, but if there is inadequate post-operative care, follow up care, home care, or other supports, the patient may encounter complications that compromise the quality of the episode of care." (Crossing the Quality Chasm, p 98) Taking this from another direction, it says that post-operative or post-care support can increase the value to the patient/stakeholders by improving outcomes and avoiding cost and waste associated with complications.

In practice II.F.1, “distribute product in a lean fashion” has been replaced by “seamless transition of service into and out of the enterprise.” As a service, health care does not require distribution in the way physical products do. However, there is a transition that occurs as a patient exits the service of an enterprise. Whether the patient has an ongoing relationship with the enterprise (as in the case of a primary care office) or not (as may be the case for an urgent care visit), the transition out is an important step. The enterprise characteristic desired is “Effective and efficient flow of information and materials (e.g. medication) to and from patients and stakeholders.”

Practice II.F.3 addresses what the enterprise does to enhance the value of delivered care. Follow up and support enhances care outcomes and patient experience. Health care tasks that

may be "post service support" include interval or between visit services, follow up appointments, annual reminders for tests, immunization, etc. (Schlosser J. , 2010) Post service support may also include administrative tasks such as billing and insurance claims processing.

Surveillance refers to monitoring the health care outcome and other performance measures, which is practice II.F.4. Both internal performance measures and external indicators should be monitored to drive continuous improvement.

Section III - Enabling Infrastructure

III.A. Lean Organizational Enablers	III.A.1 - Financial system supports Lean transformation	Lean requires appropriate financial data
	III.A.2 - Enterprise stakeholders pull required financial information	Data on demand
	III.A.3 - Promulgate the Learning Organization	Learning organizations create a flexible workforce
	III.A.4 - Enable the Lean enterprise with information systems and tools	Facilitate the flow of information and knowledge
	III.A.5 - Integration of environmental protection, health and safety into the business	"Cleaner, healthier, safer"
III.B. Lean Process Enablers	III.B.1 - Process standardization	Strive for consistency and re-use
	III.B.2 - Common tools and systems	Assuring compatibility, reducing costs
	III.B.3 - Variation reduction	Reduce uncertainty by reducing variation

III.A Lean Organization Enablers

No changes to the practices and characteristics in this section are proposed.

III.B Lean Process Enablers

No changes to the practices and characteristics in this section are proposed. However, the capability levels for each of these practices will likely benefit from some adjustment.

Practice III.B.1, "process standardization," is a basic tenet of lean thinking. While there are examples of the benefits of standardization, there is also some caution. "One must be careful, however about oversimplifying the parallels between health care and manufacturing and other services industries. Because of the complexities of disease process, variations in human physiology, and difficulties in restoring health, simple cut-and-copy approaches to improving health care processes will not suffice." (National Academy of Engineering and Institute of

Medicine, 2005) The capability level descriptions and examples may need to address what is appropriate standardization.

One of the engineering principles referenced by the IOM is relevant to the discussion of standardization – the 80/20 principle. It is also stated as “Design for the usual, but recognize and plan for the unusual.” (Institute of Medicine, 2001) The more predictable the work, or the more evidence there is to support a care protocol, the more it makes sense to standardize it. Examples of standardization include emergency room response protocols for cardiac arrest patients (Toussaint J. , 2009) or equipment bundles (Graban, 2008).

Standardization is an important tool in process design for safety. It can prevent errors and make mistakes more visible.

People can't be controlled like machines. People are a major source of variation. (George, 2003) This is true both of the variation of patients and their conditions, and of the variation in processes created by care providers. Not all of the variation can be eliminated. The indicator examples for practice III.B.3 ,“variation reduction,” can be revised based on examples from successes in the health care industry.

Summary of Changes

Table 6 shows an overall comparison of the practices as described in the core LESAT and the health care LESAT. Arrows indicate where practices were changed.

Table 6: LESAT Practices, Core vs. Health Care

Core LESAT Practice	Health Care LESAT Practice
I.A Enterprise Strategic Planning	I.A Enterprise Strategic Planning
I.A.1 Integration of Lean in Strategic Planning Process	I.A.1 - Integration of process improvement in strategic planning process
I.A.2 Focus on Customer Value	I.A.2 - Focus on customer value
I.A.3 Leveraging the Extended Enterprise	I.A.3 - Leveraging the extended enterprise
I.B Adopt Lean Paradigm	I.B Adopt Enterprise Paradigm
I.B.1 Learning and Education in “Lean” for Enterprise Leadership	I.B.1 - Learning and education in Lean for enterprise leaders
I.B.2 Senior Management Commitment	I.B.2 - Senior management commitment
I.B.3 Lean Enterprise Vision	I.B.3 - Lean enterprise vision
I.B.4 A Sense of Urgency	I.B.4 - A sense of urgency
I.C Focus on the Value Stream	I.C Focus on the Value Stream

Core LESAT Practice		Health Care LESAT Practice
I.C.1 Understanding the Current Value Stream		I.C.1 - Understanding current value stream
I.C.2 Enterprise Flow		I.C.2 - Enterprise flow
I.C.3 Designing the Future Value Stream		I.C.3 - Designing future value stream
I.C.4 Performance Measures		I.C.4 Performance Measures
I.D Develop Lean Structure and Behavior		I.D Develop Enterprise Structure and Behavior
I.D.1 Enterprise Organizational Orientation		I.D.1 - Enterprise organizational orientation
I.D.2 Relationships Based on Mutual Trust		I.D.2 - Relationships based on mutual trust
I.D.3 Open and Timely Communications		I.D.3 - Open and timely communications
I.D.4 Employee Empowerment		I.D.4 - Employee empowerment
I.D.5 Incentive Alignment		I.D.5 - Incentive alignment
I.D.6 Innovation Encouragement		I.D.6 - Innovation encouragement
I.D.7 Lean Change Agents		I.D.7 - Lean change agents
I.E Create and Refine Transformation Plan		I.E Create and Refine Transformation Plan
I.E.1 Enterprise-Level Lean Transformation Plan		I.E.1 - Enterprise-level Lean transformation plan
I.E.2 Commit Resources for Lean Improvements		I.E.2 - Commit resources for Lean improvements
I.E.3 Provide Education and Training		I.E.3 - Provide education and training
I.F Implement Lean Initiatives		I.F Implement Enterprise Initiatives
I.F.1 Development of Detailed Plans Based on Enterprise Plan		I.F.1 - Development of detailed plans based on enterprise plan
I.F.2 Tracking Detailed Implementation		I.F.2 - Tracking detailed implementation
I.G Focus on Continuous Improvement		I.G Focus on Continuous Improvement
I.G.1 Structured Continuous Improvement		I.G.1 - Structured continuous improvement processes
I.G.2 Monitoring Lean Progress		I.G.2 - Monitoring lean progress
I.G.3 Nurturing the Process		I.G.3 - Nurturing the process
I.G.4 Capturing Lessons Learned		I.G.4 - Capturing lessons learned
I.G.5 Impacting Enterprise Strategic Planning		I.G.5 - Impacting enterprise strategic planning
II.A Business Acquisition and Program Management	→	II.A. Opportunity Identification
II.A.1 Leverage lean capability for business growth	→	II.A.1 - Leverage Lean capability for enhanced service
II.A.2 Optimize the capability and utilization of assets		II.A.2 - Optimize the capability and utilization of assets
II.A.3 Provide capability to manage risk, cost, schedule and performance	→	II.A.3 - Provide capability to evaluate and respond to changes in the clinical evidence and business environment
II.A.4 Allocate resources for program development efforts		II.A.4 – Allocate resources for program development efforts
II.B Requirements Definition		II.B Requirements Definition
II.B.1 Establish a requirements definition process to optimize lifecycle value	→	II.B.1 - Establish a requirements definition process that optimizes the value of the whole process cycle
II.B.2 Utilize data from the extended enterprise to optimize future requirement definitions		II.B.2 - Utilize data from the extended enterprise to optimize future requirement definitions
II.C Develop Product and Process	→	II.C. Develop Service and Delivery Process
II.C.1 Incorporate customer value into design	→	II.C.1 - Design the care and the delivery process

Core LESAT Practice		Health Care LESAT Practice
of products and processes		to be knowledge-based, patient-centered, and systems-minded
II.C.2 Incorporate downstream stakeholder values into products and processes	→	II.C.2 - Incorporate stakeholder values into service and delivery
II.C.3 Integrate product and process development	→	II.C.3 - Integrate service and delivery process development
		II.C.4 – Information systems are designed with and in support of service and delivery
II.D Manage Supply Chain	→	II.D. Manage Extended Enterprise
II.D.1 Define and develop supplier network	→	II.D.1 - Define and develop elements of the network
II.D.2 Optimize network-wide performance	→	II.D.2 - Optimize network-wide performance
II.D.3 Foster innovation and knowledge-sharing throughout the supplier network	→	II.D.3 - Foster innovation and knowledge-sharing throughout the network
II.E Produce Product	→	II.E. Deliver the Care (Operations)
II.E.1 Utilize production knowledge and capabilities for competitive advantage	→	II.E.1 - Utilize workforce capabilities to strengthen the business and reputation
II.E.2 Establish and maintain a Lean production system	→	II.E.2 - Establish and maintain an efficient operations system
		II.E.3 - Manage physical goods supply chain in Lean fashion
		II.E.4 – Align capacity and capability to demand
II.F Distribute and Service Product	→	II.F. Support and Surveillance
II.F.1 Align sales and marketing to production	→	II.F.1 - Seamless transition of service into and out of the enterprise
II.F.2 Distribute product in Lean fashion	→	II.F.2 - Enhance value of delivered care and services to patients, stakeholders and the enterprise
II.F.3 Enhance value of delivered products and services to customers and the enterprise	→	II.F.3 - Provide post delivery support and monitoring
II.F.4 Provide post-delivery service, support and sustainability	→	
III.A Lean Organizational Enablers		III.A Lean Organizational Enablers
III.A.1 Financial system supports Lean transformation		III.A.1 Financial system supports Lean transformation
III.A.2 Enterprise stakeholders pull required financial information		III.A.2 Enterprise stakeholders pull required financial information
III.A.3 Promulgate the learning organization		III.A.3 Promulgate the learning organization
III.A.4 Enable the Lean enterprise with information systems and tools		III.A.4 Enable the Lean enterprise with information systems and tools
III.A.5 Integration of environmental protection, health and safety into the business		III.A.5 Integration of environmental protection, health and safety into the business
III.B Lean Process Enablers		III.B Lean Process Enablers
III.B.1 Process standardization		III.B.1 Process standardization
III.B.2 Common Tools and Systems		III.B.2 Common Tools and Systems
III.B.3 Variation reduction		III.B.3 Variation reduction

8 Relationship of LESAT for Health Care to Industry Measures

In order to gauge the appropriateness and completeness of the practices and characteristics identified for the health care LESAT, they will be compared with other industry measures. Two major references for quality and innovation in health care will be considered: the Baldrige National Quality Program and Crossing the Quality Chasm, a report from the Institute of Medicine. Both are widely recognized and referenced in the industry.

Baldrige Health Care Criteria

LESAT and the Baldrige Health Care Criteria cover many of the same practices and principles. There are some key differences between the two. The Baldrige Criteria have no items that significantly address the extended enterprise, the value stream, and the enterprise organizational structure. Baldrige does specifically address legal and ethical behavior and societal responsibility, while LESAT does not.

The Baldrige National Quality Program, managed by the National Institute for Standards and Technology, recognizes U.S. organizations for their achievements in quality and performance and raises awareness about the importance of quality and performance excellence as a competitive edge. (National Institute of Standards and Technology) Awards are given annually in six categories: manufacturing, service, small business, education, health care and nonprofit. There are specialized versions of the Performance Criteria for both education and health care.

2009-2010 Baldrige Health Care Criteria for Performance Excellence build on a systems perspective of performance management. The framework shown in Figure 9 identifies the seven categories of criteria and how they are related.

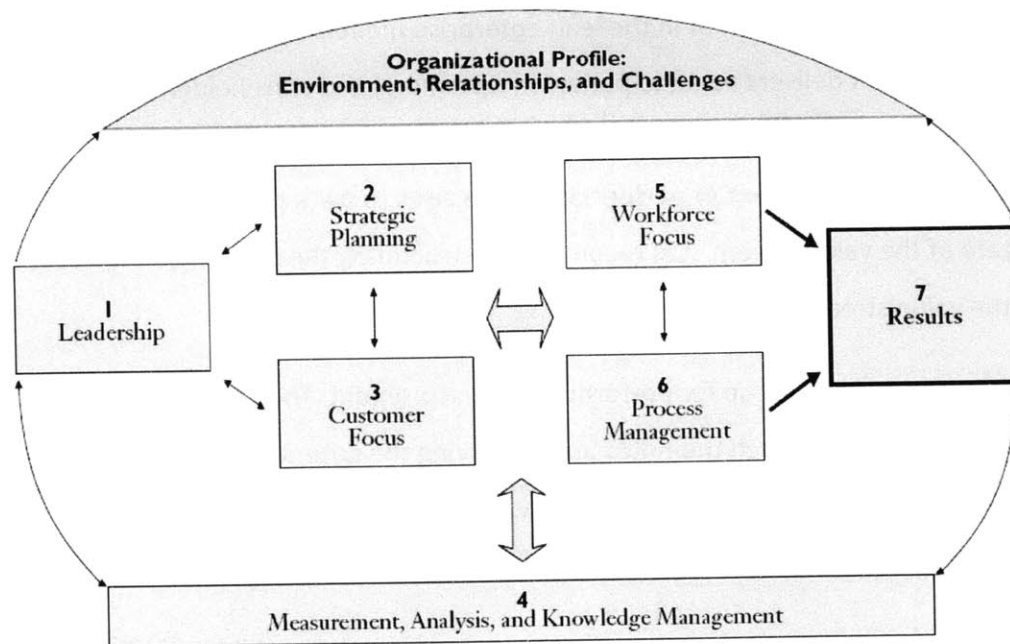


Figure 9: Baldrige Health Care Criteria for Performance Excellence Framework

One may note the considerable overlap between Baldrige Criteria categories, and LESAT structure. Baldrige combines categories one through three into the “leadership triad.” This correlates with Section I of the LESAT – Lean Transformation/Leadership. Baldrige does not make a distinction between primary business processes and enabling processes or infrastructure, as LAI does. Both primary and enabling processes are covered in the Baldrige categories five through seven, referred to as the “results triad.” In both the Baldrige framework and the LESAT, measurement and knowledge management play a foundational role. Per Baldrige, “Measurement, Analysis, and Knowledge Management (Category 4) are critical to the effective management of your organization and to a fact-based, knowledge-driven system for improving health care and operational performance and competitiveness.” Note that Category 4 provides the link from results back to leadership and the strategic planning process. Performance measurement plays the same role in the framework that underlies the LESAT, with performance measurement practices in each of the three sections.

There are three areas that are treated in the LESAT which receive little or no attention in the Baldrige Criteria: the value stream, the enterprise organizational structure, and the extended enterprise.

The value stream is a key concept in the lean enterprise model. The value stream is the core set of processes that delivers value to patients (customers) and stakeholders. Section I.C in the LESAT evaluates understanding of the current value stream, efficient flow of materials and information, and development of performance measures to track progress toward a desired future state of the value stream. LAI recommends structuring the enterprise organization around the value stream.

The Baldrige Criteria are set up for performance measurement. The results, rather than the method are primary. Although the notes accompanying the criteria give examples, no specific improvement method is recommended. Since value streams are a product of “lean thinking” or “The Toyota Way,” they have likely been left out in the name of neutrality.

Part of the enterprise organizational structure is related to relationships with suppliers and partners. LAI, and the LESAT, view the organization as part of a network or extended enterprise. The relationship with the extended enterprise can be a source of strategic advantage. The goal is to optimize performance throughout the network, as well as within the organization or enterprise of interest. Knowledge sharing and innovation support the whole extended enterprise.

The Baldrige criteria are focused on performance management within the organization. In the preface, there is a note that “Mechanisms for health care service delivery to your patients and stakeholders (P.1a[1]) might be direct or through contractors, collaborators, or partners.” (Baldrige) However, when the criteria do reference the extended enterprise – as “partners and suppliers” – the relationship is presented as one-way. How do senior leaders deploy your vision/strategy to key suppliers and partners? How do you make needed data available to your suppliers, partners and collaborators? Intentionally or not, the wording implies the enterprise as the locus of control, sending direction to its minions. The flow of information and innovation back into the enterprise is missing.

One of the changes to the Baldrige Criteria from 2008 to the 2009-2010 version is an “enhanced focus on sustainability and societal responsibilities and the senior leaders’ role.” (Baldrige) There is also a specific reference to legal and ethical behavior. While LESAT does not raise these

issues specifically, it does take a broad view of stakeholders. A thorough stakeholder analysis would include “society” – most likely in the form of the communities in which the enterprise operates, and relevant governing bodies – identifying those needs and including them in strategic planning and service development. Given the increased attention to the cost and politics of health care, and higher standards for corporate governance driven by the Sarbanes-Oxley Act of 2002, it may be well for the LESAT to make these standards more explicit.

A detailed comparison of the LESAT and 2009-2010 Baldrige Health Care Criteria for Performance Excellence is included in Appendix B.

Institute of Medicine Recommendations

In 2001, the Institute of Medicine published the final report of the Committee on the Quality of Health Care in America, titled *Crossing the Quality Chasm*. (reference) The committee had been appointed in 1998 to identify strategies for achieving substantial improvement in the quality of health care delivered to Americans. In the report, the IOM lays out a vision for the future of health care, and focuses on how the health care delivery system can be designed to innovate and improve care.

In “A User’s Manual for the IOM’s ‘Quality Chasm’ Report,” Berwick writes that the underlying framework analyzes the needed changes in American health care at four different levels: the experience of patients (Level A); the functioning of small units of care delivery (“microsystems”) (Level B); the functioning of the organizations that house or otherwise support microsystems (Level C); and the environment of policy, payment, regulation, accreditation, and other such factors (Level D), which shape the behavior, interests, and opportunities of the organizations at Level C. The model is hierarchical because it asserts that the quality of actions at Levels B, C, and D ought to be defined as the effects of those actions at Level A, and in no other way. (Berwick, 2002)

At Level C, the IOM committee identified six areas where health care organizations need better designs in order to support improvement at the microsystem level. (Berwick, 2002) (Institute of Medicine, 2001)

Table 7: IOM Recommendations for Redesign

1. Redesigned care processes
 - a. System design using the 80/20 principle
 - b. Design for safety
 - c. Mass customization
 - d. Continuous flow
 - e. Production planning
2. Effective use of information technologies
3. Knowledge and skills management
4. Development of effective teams
5. Coordination of care across patient conditions, services and settings over time
6. Use of performance and outcome measurement for continuous quality improvement and accountability

Essentially, these recommendations are driving toward a larger, system-level view of health care organizations. They identify how the organization must change to support the microsystem or working level changes that will drive improved quality, effectiveness and efficiency. What the IOM calls the organization level, LAI calls the enterprise. The LESAT is directed to the enterprise level, which makes it ideal for measuring and driving progress in the areas identified by the IOM.

All six of these areas are addressed by elements of the LESAT. Relevant elements from the Health Care LESAT (under development) are shown in Table 8.

Table 8: LESAT Items relevant to IOM recommendations

IOM Redesign Recommendation	Relevant LESAT for Health Care Item
More robust systems for finding best practices and assuring they become organizational standards	I.A.1 Integration of process improvement in strategic planning process
	I.G.4 Capturing lessons learned (Ensuring that successes lead to more successes)
	II.D.3 Foster innovation and knowledge-sharing throughout the network (Incentivizing innovation and sharing of best practices)
	II.A.3 Provide capability to evaluate and respond to changes in the clinical evidence and business environment
Better use of information technology to improve access to information and support clinical decision making	I.D.3 Open and timely communications (Information exchanged when required)
	II.C.4 Information systems are designed to support service and delivery
	II.F.2 Seamless transition of service into and out of the enterprise (Effective and efficient flow of information and materials (e.g. medication) to and from patients and stakeholders)
	III.A.4 Enable the Lean enterprise with information systems and tools (Facilitate the flow of information and knowledge)
Investment in improving workforce knowledge and resource development.	I.D.6 Innovation encouragement (From placing blame to creative problem solving)
	I.D.7 Lean change agents (The inspiration and drivers of change)
	I.E.3 Provide education and training (Just-in-time learning)
	II.A.3 Promulgate the Learning Organization (Learning organizations create a flexible workforce)
More consistent development of effective teams and teamwork	I.D.2 Relationships based on mutual trust (“Win-win” vs. “we-they”)
	I.D.4 Employee empowerment (Multi-disciplinary teams share responsibility)
	II.A.4 Allocate resources for program development efforts (Teaming for success)
Better coordination of care both within and among organizations	II.B.1 Establish a requirements definition process that optimizes the value of the whole process cycle (Consideration for patient and stakeholder needs through the whole process)
	II.B.2 Utilize data from the extended enterprise to optimize future requirement definitions (Closed loop processes capture operational performance data)
	II.C.3 Integrate service and delivery process development (Breaking down of functional silos enables seamless communication and value flow)
	II.D.2 Optimize network-wide performance (Services are delivered in a complementary and timely manner. Continuity of care crosses disciplinary and organizational boundaries)
More sophisticated, extensive and informative measurement of performance and outcomes.	I.C.4 Performance measures(Performance measures drive enterprise behavior)
	I.G.2 Monitoring lean progress (Assessing progress toward achieving enterprise objectives)
	II.F.4 Provide post delivery support and monitoring (Performance measures are monitored to drive process improvements)

One can also consider the alignment of the IOM recommendations to the LESAT, as was done for the Baldrige criteria. For this exercise, the IOM recommendations have been summarized primarily by the six redesign recommendations referenced above and the ten “new rules” for health care set out in chapter 3 of the report.

Table 9: The IOM's Simple Rules for 21st Century Health Care Systems

1. Care is based on continuous healing relationships.
2. Care is customized according to patient needs and values.
3. The patient is the source of control.
4. Knowledge is shared and information flows freely.
5. Decision making is evidence-based.
6. Safety is a system property.
7. Transparency is necessary.
8. Needs are anticipated.
9. Waste is continuously decreased.
10. Cooperation among clinicians is a priority.

The IOM does not recommend specific organizational approaches. (reference) In this neutrality, it is similar to the Baldrige National Quality Program and so also does not include some of the LESAT elements that derive from lean management and transformation plans . The IOM also does not address financial elements or resource allocation. The majority of LESAT items, however correlate with one or more of the rules or recommendations from the OEM, or other sections of *Crossing the Chasm*. See Appendix C for a detailed comparison.

9 Response from Industry Representatives

A preliminary review was conducted with continuous improvement practitioners at the Veteran’s Administration VISN 1 in Massachusetts, and Trinity Health System in Michigan. Response was positive both from those who had previously completed the core LESAT, and those who had no prior experience with LESAT. Some language/vocabulary changes were recommended, and one reviewer said that providing definitions for some of the terms would

be helpful. The core LESAT does include a list of definitions, but there are some new terms for the health care LESAT, and some that are revised for this context.

These suggestions have been incorporated into the processes, practices and characteristics proposed. A list of definitions for use in the health care LESAT is given in Appendix D.

No changes to the content – additions or subtractions were noted. Of course, as development of the health care LESAT progresses, a larger group of reviewers will be needed to capture a broader range of health care organizations and their perspectives.

10 Conclusion

The principles and methodologies of Lean Enterprise Thinking developed by LAI have the potential to help health care enterprises make the transformation needed to achieve quality and cost improvements. Tools such as the core LESAT use terminology and built-in assumptions from product manufacturing that are not directly applicable to health care. An adaptation of the LESAT specific to health care has been proposed that preserves the principles and concepts, but interprets them in the context and language of health care. The work thus far identifies key enterprise level processes, practices and characteristics. This content compares favorably with other health care industry measures. While preliminary reviews from continuous improvement leaders in a few health care organizations are positive, additional work is required to establish relevant maturity levels for each practice, and vet these with a wider range of health care organizations.

11 Recommended Future Work

This thesis represents first steps toward creation of a health care LESAT. Additional work is required to identify five levels for each enterprise practice and conduct field trials to collect feedback on usefulness, ease of use and alignment with other business practices. The roadmap for development is shown again in Figure 10, with the work to be done highlighted. Field trials should include a broad range of health care organizations. Some possible categories of

organizations to include are hospitals, primary care offices, clinics, health systems or alliances of care providers, and outpatient surgical centers.

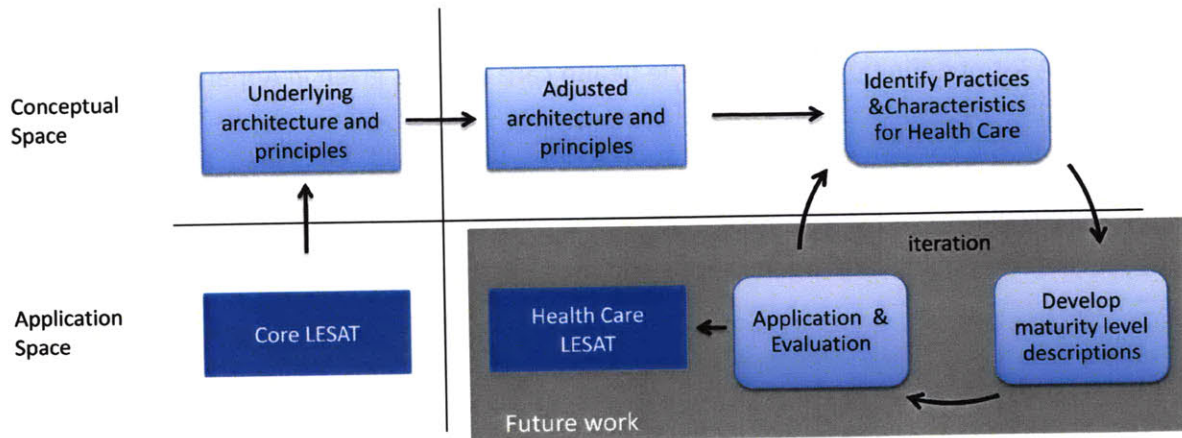


Figure 10: Roadmap for Development of Health Care LESAT

Both the core LESAT and the health care LESAT would be strengthened by validation of the scores generated. This would allow the LESAT score to be used in comparing organizations and methods they use for management and innovation.

One option is to show criterion-related validity – for example, how well does an enterprise’s health care LESAT score correlate with lean performance? Another option for validation is to show construct validity. This is the degree to which a measure relates to other variables as expected within a system of theoretical relationships. (Babbie, 2006) In the case of the health care LESAT, we expect that higher ratings on the LESAT will correlate to measures of financial strength and quality of care.

Validation might also require a study of the reliability of the LESAT score – how much variation is there among evaluators scoring the same organization, or how consistent is the score of one evaluator if repeated.

One way to demonstrate validity would be to compare LESAT scores from recognized or established leaders in health care quality or lean applications with those from organizations who have just begun to transition to lean. For example, one would expect winners of a Malcolm

Baldrige National Quality Award to score better than an organization that has just begun to implement lean thinking.

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Appendix A: Health Care LESAT Summary Sheet

LAI Enterprise Self-Assessment Tool (LESAT)				
Section I - Lean Transformation/Leadership				
Process Definition: Develop and deploy lean implementation plans throughout the enterprise leading to (1)- long-term sustainability, (2)- acquiring competitive advantage and (3) satisfaction of stakeholders.				
Roadmap Link	Enterprise Practice	Enterprise Characteristic	Capability Level	
			Current	Desired
I.A. Enterprise Strategic Planning	I.A.1 - Integration of process improvement in strategic planning process	Lean impacts growth, profitability and market penetration		
	I.A.2 - Focus on customer value	The enterprise value stream is patient-centered		
	I.A.3 - Leveraging the extended enterprise	Value stream extends throughout the extended enterprise, providing continuity of care		
	<i>Average</i>			
I.B. Adopt Enterprise Paradigm	I.B.1 - Learning and education in “Lean” for enterprise leaders	“Unlearning” the old, learning the new		
	I.B.2 - Senior management commitment	Senior management leading it personally		
	I.B.3 - Lean enterprise vision	New mental model of the enterprise		
	I.B.4 - A sense of urgency	The primary driving force for Lean		
<i>Average</i>				
I.C. Focus on the Value Stream	I.C.1 - Understanding current value stream	How we now deliver value to customers		
	I.C.2 - Enterprise flow	“Single piece flow” of materials and information		
	I.C.3 - Designing future value stream	Value stream to meet the enterprise vision		
	I.C.4 - Performance measures	Performance measures guide enterprise behavior		
<i>Average</i>				
I.D. Develop Enterprise Structure and Behavior	I.D.1 - Enterprise organizational orientation	Organize to support value delivery		
	I.D.2 - Relationships based on mutual trust	“Win-win” vs. “we-they”		
	I.D.3 - Open and timely communications	Information flows freely to support informed decision making		
	I.D.4 - Employee empowerment	Multi-disciplinary teams share responsibility		
	I.D.5 - Incentive alignment	Reward the behavior you want		
	I.D.6 - Innovation encouragement	From placing blame to creative problem solving		
	I.D.7 - Lean change agents	The inspiration and drivers of change		
<i>Average</i>				

LAI Enterprise Self-Assessment Tool (LESAT)

Section I - Lean Transformation/Leadership Continued...

Process Description: Develop and deploy lean implementation plans throughout the enterprise leading to (1) long-term sustainability, (2) acquiring competitive advantage and (3) satisfaction of stakeholders.

Roadmap Link	Enterprise Practice	Enterprise characteristic	Capability Level	
			Current	Desired
I.E. Create & Refine Transformation Plan	I.E.1 - Enterprise-level Lean transformation plan	Charting the course across the extended enterprise		
	I.E.2 - Commit resources for Lean improvements	Resource provision for lean		
	I.E.3 - Provide education and training	Just-in-time learning		
	<i>Average</i>			
I.F. Implement Enterprise Improvement Initiatives	I.F.1 - Development of detailed plans based on enterprise plan	Coordinating lean improvements		
	I.F.2 - Tracking detailed implementation	Assessing actual outcomes against goals		
	<i>Average</i>			
I.G. Focus on Continuous Improvement	I.G.1 - Structured continuous improvement processes	Uniformity in how we get better		
	I.G.2 - Monitoring lean progress	Assessing progress toward achieving enterprise objectives		
	I.G.3 - Nurturing the process	Assure executive level involvement		
	I.G.4 - Capturing lessons learned	Ensuring that successes lead to more successes		
	I.G.5 - Impacting enterprise strategic planning	Results lead to strategic opportunities		
	<i>Average</i>			

LAI Enterprise Self-Assessment Tool (LESAT)

Section II - Health Care Service Cycle Processes

Definition: Implement Lean practices through the whole service cycle.

	<u>Enterprise Practice</u>	<u>Enterprise Characteristic</u>	<u>Capability Level</u>	
			<u>Current</u>	<u>Desired</u>
II.A. Opportunity Identification	II.A.1 - Leverage Lean capability for enhanced service	Exploiting new service opportunities arising from lean enabled capabilities		
	II.A.2 - Optimize the capability and utilization of assets	Assets or capacity freed by process improvement are used to serve additional patients/stakeholders		
	II.A.3 - Provide capability to evaluate and respond to changes in the clinical evidence and business environment	Success is achieved with value that meets the changing needs of patients/stakeholders		
	II.A.4 – Allocate resources for program development efforts	Teaming for success		
		<i>Average</i>		
II.B. Requirements Definition	II.B.1 - Establish a requirements definition process that optimizes the value of the whole process cycle	Consideration for patient and stakeholder needs through the whole process		
	II.B.2 - Utilize data from the extended enterprise to optimize future requirement definitions	Closed loop processes are in place to capture operational performance data (including external indicators)		
		<i>Average</i>		
II.C. Develop Service and Delivery Process	II.C.1 - Design the care and the delivery process to be knowledge-based, patient-centered, and systems-minded	Care based on the best clinical evidence, but allowing for patient preference or condition		
	II.C.2 - Incorporate <i>stakeholder</i> values into service and delivery	Understanding internal and external stakeholders reduces waste and creates additional value		
	II.C.3 - Integrate service and delivery process development	Breaking down of functional silos enables seamless communication and value flow		
	II.C.4 – Information systems are designed with and in support of service and delivery	Information systems facilitate new processes		

LAI Enterprise Self-Assessment Tool (LESAT)				
Section II - Health Care Service Cycle Processes Continued...				
Definition: Implement Lean practices				
	<u>Enterprise Practice</u>	<u>Enterprise Characteristic</u>	<u>Capability Level</u>	
			<u>Current</u>	<u>Desired</u>
II.D. Manage Extended Enterprise	II.D.1 - Define and develop elements of the network	Coordination with internal and external organizations		
	II.D.2 - Optimize network-wide performance	Services are delivered in a complementary and timely manner. Continuity of care crosses disciplinary and organizational boundaries (Haggerty, 2003)		
	II.D.3 - Foster innovation and knowledge-sharing throughout the network	Promote innovation and sharing of best practices		
<i>Average</i>				
II.E. Deliver the Care (Operations)	II.E.1 - Utilize workforce capabilities to strengthen the business and reputation	Investment in improving workforce knowledge and resource development		
	II.E.2 - Establish and maintain an efficient operations system	Error free care paced by demand and continuous flow. (Christopher, 2009)		
	II.E.3 – Manage physical goods supply chain in Lean fashion	Right product, right quantity at the right time		
	II.E.4 – Align capacity and capability to demand	Monitor and anticipate service demand to maintain key flows		
II.F. Support and Surveillance	II.F.1 - Seamless transition of service into and out of the enterprise	Effective and efficient flow of information and materials (e.g. medication) to and from patients and stakeholders		
	II.F.2 - Enhance value of delivered care and services to patients, stakeholders and the enterprise	Follow up and support to enhance care outcomes and patient experience		
	II.F.3 - Provide post delivery support and monitoring	Performance measures are monitored to drive process improvements		
<i>Average</i>				

LAI Enterprise Self-Assessment Tool (LESAT)				
Section III - Enabling Infrastructure				
Definition: To achieve a successful lean transformation, the enterprise infrastructure must support the implementation of Lean principles, practices and behavior.				
	<u>Enterprise Practice</u>	<u>Enterprise Characteristic</u>	<u>Capability Level</u>	
			<u>Current</u>	<u>Desired</u>
III.A. Lean Organizational Enablers	III.A.1 - Financial system supports Lean transformation	Lean requires appropriate financial data		
	III.A.2 - Enterprise stakeholders pull required financial information	Data on demand		
	III.A.3 - Promulgate the Learning Organization	Learning organizations create a flexible workforce		
	III.A.4 - Enable the Lean enterprise with information systems and tools	Facilitate the flow of information and knowledge		
	III.A.5 - Integration of environmental protection, health and safety into the business	“Cleaner, healthier, safer”		
		<i>Average</i>		
III.B. Lean Process Enablers	III.B.1 - Process standardization	Strive for consistency and re-use		
	III.B.2 - Common tools and systems	Assuring compatibility, reducing costs		
	III.B.3 - Variation reduction	Reduce uncertainty by reducing variation		
		<i>Average</i>		

Appendix B: Health Care LESAT and Baldrige Criteria Comparison

LESAT – Health Care

Baldrige

Section I- Lean Transformation/Leadership

I.A. Enterprise Strategic Planning

I.A.1 Integration of Process Improvement in Strategic Planning Process

2.1.a,b

I.A.2 Focus on Customer Value

3.1.b

I.A.3 Leveraging the Extended Enterprise

NSA*

I.B. Adopt Enterprise Paradigm

I.B.1 Learning and Education in “Lean” for Enterprise Leaders

1.1.a(3); 5.1.b

I.B.2 Senior Management Commitment

1.1.a.(1)&(2)

I.B.3 Lean Enterprise Vision

1.1.a.(1)

I.B.4 A Sense of Urgency

1.1.b.(1)

I.C. Focus on the Value Stream

I.C.1 Understanding the Current Value Stream

NSA*

I.C.2 Enterprise Flow

NSA*

I.C.3 Designing the Future Value Stream

NSA*

I.C.4 Performance Measures

1.1.b.(2); 2.2.a.(6); 4.1.a

I.D. Develop Enterprise Structure and Behavior

I.D.1 Enterprise Organizational Structure

NSA*

I.D.2 Relationships Based on Mutual Trust

NSA*

I.D.3 Open and Timely Communication

1.1.b(1),5.1.a(2)

I.D.4 Employee Empowerment

1.1.a.(2) weak

I.D.5 Incentive Alignment

5.1.a.(3)

I.D.6 Innovation Encouragement

1.1.b.(2); 5.1.a.(2)

I.D.7 Lean Change Agents

NSA*

I.E. Create and Refine Transformation Plan

I.E.1 Enterprise Level Lean Transformation Plan

NSA*

I.E.2 Commit Resources for Lean Improvements

2.2.a(3)?

I.E.3 Provide Education and Training

5.1.b(1)&(2)

I.F. Implement Enterprise Improvement Initiatives

I.F.1 Development of Detailed Plans Based on Enterprise Plan

2.2.a.(1)

I.F.2 Tracking Detailed Implementation

2.2.a.(4) &(6)

I.G. Focus on Continuous Improvement

I.G.1 Structured Continuous Improvement Processes

4.1.c

I.G.3 Nurturing the Process

1.1.a(3) ,6.2.c

I.G.4 Capturing Lessons Learned

4.2.a(3)

I.G.5 Impacting Enterprise Strategic Planning

2.1 all

Section II-Life-Cycle Processes

II.A. Opportunity Identification

II.A.1 Leverage Lean Capability for Enhanced Service

NSA*

II.A.2 Optimize the Capability and Utilization of Assets

5.2.a(3)&(4); 6.2.c

II.A.3 Provide Capability to Evaluate and Respond to Changes

4.1.a&b; 3.1.a(3); 6.2.a

II.A.4 Allocate Resources for Program Development Efforts

2.2.a(3)

II.B. Requirements Definition

II.B.1 Establish a Requirement Definition Process

3.1.a; 6.1.b(2)

II.B.2 Utilize Data from the Extended Enterprise to

NSA*

Optimize Future Requirements Definitions

II.C Develop Service and Delivery Process

II.C.1 Design Care and Delivery Process To Be Knowledge-based,
Patient-Centered, and Systems Minded

6.1.a; 6.2.a;6.2.b(2)

II.C.2 Incorporate Stakeholder Values into Service and Delivery

6.1.b(2); 6.2.b(1)

II.C.3 Integrate Service, Delivery Process and I.T. Development

6.2

II.D. Manage Extended Enterprise

II.D.1 Define and Develop Elements of the Network

2.1.a.(2); 6.1.a(1)

II.D.2 Optimize Network-wide Performance

4.1.c; 6.1.b(2); 6.2.b(1);

II.D.3 Foster Innovation and Knowledge-sharing throughout the Network

4.2.a(3);weak

II.E Deliver the Care

- II.E.1 Utilize Workforce Capabilities to Strengthen Business and Reputation 5.1.a(3); 5.2.a(3); 6.1.b; 6.2.a
- II.E.2 Establish and Maintain an Efficient Operations System 6.2.a&b
- II.E.3 Distribute Necessary Tools and Materials in Lean Fashion 6.2.a
- II.E.4 Align Capacity and Capability to Demand 3.2.c(1)

II.F Support and Monitoring

- II.F.1 Seamless Transition of Service Into and Out of the Enterprise 3.1.a(2)?; 4.2.a(3)
- II.F.3 Enhance Value of Delivered Care and Services to Patients, Stakeholders and the Enterprise 3.1a(1)&(2); 6.1.b
- II.F.4 Provide Post-Delivery Support and Monitoring NSA*

Section III-Enabling Infrastructure

III.A. Lean Organization Enablers

- III.A.1 Financial System Supports Lean Transformation 4.1.a(1); 7.3
- III.A.2 Enterprise Stakeholders Pull Required Financial Information 4.2.a(2)7.3
- III.A.3 Promulgate the Learning Organization 5.1.a&b;5.2 all
- III.A.4 Enable the Lean Enterprise with Information Systems and Tools 4.2 all
- III.A.5 Integration of Environmental Protection, Health and Safety 5.2.b.&1.2 all into the Business

III.B Lean Process Enablers

- III.B.1 Process Standardization 6.2 weak
- III.B.2 Common Tools and Systems NSA*
- III.B.3 Variation Reduction 6.2 weak

* Not specifically addressed

Appendix C: Health Care LESAT and IOM Recommendations Comparison

The IOM's Simple Rules for the 21st Century Health Care System: (from *Crossing the Quality Chasm*)

1. Care is based on continuous healing relationships.
2. Care is customized according to patient needs and values.
3. The patient is the source of control.
4. Knowledge is shared and information flows freely.
5. Decision making is evidence-based.
6. Safety is a system property.
7. Transparency is necessary.
8. Needs are anticipated.
9. Waste is continuously decreased.
10. Cooperation among clinicians is a priority.

IOM's Redesign Imperatives: (from *Crossing the Quality Chasm*)

1. Redesigned care processes
 - a. System design using the 80/20 principle
 - b. Design for safety
 - c. Mass customization
 - d. Continuous flow
 - e. Production planning
2. Effective use of information technologies
3. Knowledge and skills management
4. Development of effective teams
5. Coordination of care across patient conditions, services and settings over time
6. Use of performance and outcome measurement for continuous quality improvement and accountability

LESAT – Health Care	IOM recommendations
Section I- Lean Transformation/Leadership	
I.A. Enterprise Strategic Planning	
I.A.1 Integration of Process Improvement in Strategic Planning Process	
I.A.2 Focus on Customer Value	Rule 2: Customization based on patient needs and values. Rule 3: The patient as the source of control.
I.A.3 Leveraging the Extended Enterprise	Rule 10: Cooperation among clinicians.
I.B. Adopt Enterprise Paradigm	
I.B.1 Learning and Education in “Lean” for Enterprise Leaders	NSA*
I.B.2 Senior Management Commitment	leadership for managing change (p137)
I.B.3 Lean Enterprise Vision	“Leaders must be responsible for creating and articulating the organization’s vision and goals”
I.B.4 A Sense of Urgency	NSA*
I.C. Focus on the Value Stream	
I.C.1 Understanding the Current Value Stream	
I.C.2 Enterprise Flow	design for continuous flow (p124)
I.C.3 Designing the Future Value Stream	
I.C.4 Performance Measures	“a major tool [to assess performance] is to develop a balanced set of measures” (p136)
I.D. Develop Enterprise Structure and Behavior	
I.D.1 Enterprise Organizational Structure	NSA*
I.D.2 Relationships Based on Mutual Trust	Rule 7: The need for transparency
I.D.3 Open and Timely Communication	Rule 4: Shared knowledge and the free flow of information.
I.D.4 Employee Empowerment	developing effective teams (p130)
I.D.5 Incentive Alignment	“leaders can support reward and recognition systems that are consistent with and support the new rules set forth in Chapter 3...”(p139)
I.D.6 Innovation Encouragement	“Leaders of health care organizations may need to provide an environment for innovation that allows for new and more flexible roles and responsibilities...and supports the accomplishments of innovators despite regulatory, legal, financial and sometimes interprofessional conflict” (p138)
I.D.7 Lean Change Agents	NSA*
I.E. Create and Refine Transformation Plan	
I.E.1 Enterprise Level Lean Transformation Plan	NSA*
I.E.2 Commit Resources for Lean Improvements	NSA*
I.E.3 Provide Education and Training	“Leaders need to invest in their workforce to help them achieve their full potential, both individually and as a team, in serving their patients.”
I.F. Implement Enterprise Improvement Initiatives	
I.F.1 Development of Detailed Plans Based on Enterprise Plan	NSA*
I.F.2 Tracking Detailed Implementation	NSA*
I.G. Focus on Continuous Improvement	
I.G.1 Structured Continuous Improvement Processes	
I.G.3 Nurturing the Process	
I.G.4 Capturing Lessons Learned	
I.G.5 Impacting Enterprise Strategic Planning	
Section II-Life-Cycle Processes	
II.A. Opportunity Identification	
II.A.1 Leverage Lean Capability for Enhanced Service	Rule 8: Anticipation of needs.
II.A.2 Optimize the Capability and Utilization of Assets	Rule 9: Continuous decrease in waste.
II.A.3 Provide Capability to Evaluate and Respond to	“Leaders must ensure that their organization has the ability to

Changes	change. "(p138)
II.A.4 Allocate Resources for Program Development Efforts	NSA* (at the enterprise level)
II.B. Requirements Definition	
II.B.1 Establish a Requirement Definition Process	
II.B.2 Utilize Data from the Extended Enterprise to Optimize Future Requirements Definitions	Redesign 6: use of performance and outcome measurement
II.C Develop Service and Delivery Process	
II.C.1 Design Care and Delivery Process To Be Knowledge-based, Patient-Centered, and Systems Minded	Rules 1,2,3,5 & 6
II.C.2 Incorporate Stakeholder Values into Service and Delivery	Rule 2
II.C.3 Integrate Service, Delivery Process and I.T. Development	Rule 1: Care based on continuous healing relationships. Redesign 2: effective use of information technology
II.D. Manage Extended Enterprise	
II.D.1 Define and Develop Elements of the Network	
II.D.2 Optimize Network-wide Performance	Rule 10: Cooperation among clinicians. Redesign 5: coordination of care
II.D.3 Foster Innovation and Knowledge-sharing throughout the Network	Rule 4: Shared knowledge and the free flow of information.
II.E Deliver the Care	
II.E.1 Utilize Workforce Capabilities to Strengthen Business and Reputation	NSA*
II.E.2 Establish and Maintain an Efficient Operations System	Rule 9: Continuous decrease in waste. Rule 6: Safety as a system property. Redesign 1.b designing systems to prevent errors & 1.d continuous flow
II.E.3 Distribute Necessary Tools and Materials in Lean Fashion	NSA*
II.E.4 Align Capacity and Capability to Demand	Redesign 1.d continuous flow & 1.e production planning
II.F Support and Monitoring	
II.F.1 Seamless Transition of Service Into and Out of the Enterprise	Rules 1,4
II.F.3 Enhance Value of Delivered Care and Services to Patients, Stakeholders and the Enterprise	Rule 8: Anticipation of needs. Redesign 5: coordination of care
II.F.4 Provide Post-Delivery Support and Monitoring	Rule 1
Section III-Enabling Infrastructure	
III.A. Lean Organization Enablers	
III.A.1 Financial System Supports Lean Transformation	NSA*
III.A.2 Enterprise Stakeholders Pull Required Financial Information	Rule 4
III.A.3 Promulgate the Learning Organization	"The committee believes moving toward the health system of the 21 st century will require that health care organizations successfully address the challenge of becoming learning organizations." (p135)
III.A.4 Enable the Lean Enterprise with Information Systems and Tools	Rule 4
III.A.5 Integration of Environmental Protection, Health and Safety into the Business	NSA*
III.B Lean Process Enablers	
III.B.1 Process Standardization	Redesign 1.a 80/20 principle; "The more predictable the work, the more it makes sense to standardize care so that it can be performed by a variety of workers in a consistent fashion."
III.B.2 Common Tools and Systems	
III.B.3 Variation Reduction	"variation should be minimal when levels of certainty and clinical agreement are high"

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Appendix D: Definitions

Enterprise: One or more persons or organizations that have related activities, unified operation or common control, and a common business purpose (Black's Law Dictionary, 1999)

Extended enterprise: the network of organizations (internal or external) with which an enterprise must coordinate to provide quality health care services

Patient-centered care: care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions (Institute of Medicine, 2001)

Quality: "the degree to which health care services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge" (Institute of Medicine, 2001)

Stakeholder groups could include patients' families, the community, insurers and other third-party payors, employers, health care providers, patient advocacy groups, Departments of Health, and students. (Baldrige National Quality Program , 2009)

Value stream: The specific activities required to design, order, and provide a specific product, from concept to launch, order to delivery, and raw materials into the hands of the customer. (Womack, 1996)