Healthcare's Horizon

FROM INCREMENTAL IMPROVEMENT TO DESIGNING THE FUTURE.

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Impressive examples over the past several years illustrate the value of utilizing Six Sigma and related best practices for healthcare quality and process improvement.

Providers, however, continue to face a daunting and escalating array of challenges. Regulatory pressures, increased competition, cost management issues, workforce shortages and rising consumerism all vie for attention and remediation.

Occupying an increasingly prominent place on the healthcare executive's radar screen are issues involving clinical quality and patient safety. Instances of overuse, underuse and misuse of healthcare services have been costly to patients, providers and payers.

Prompted by illuminating reports from the Institute of Medicine[1, 2] and scrutiny from groups such as Leapfrog, providers are seeking effective methods for both optimizing the care they deliver and documenting the improvements.

It is a pivotal moment in the history of medicine—one offering great promise through rapidly advancing technology and tremendous pressure to deliver better care to more people for less cost.

At this juncture, then, it seems an appropriate time for reflection—both on the progress made through Six Sigma applications and the realm of opportunities for the future. Drawing from research and organizational experience, we can evaluate achievements and explore the next phase in reshaping the industry.

Applications to Healthcare

The DMAIC (define, measure, analyze, improve and control) approach works quite well for any service line or process that can furnish measurable response variables.

Generally, four groups of metrics or response variables in healthcare may define a delivery system's performance:

- Service level.
- Service cost.
- Customer satisfaction.
- Clinical excellence.

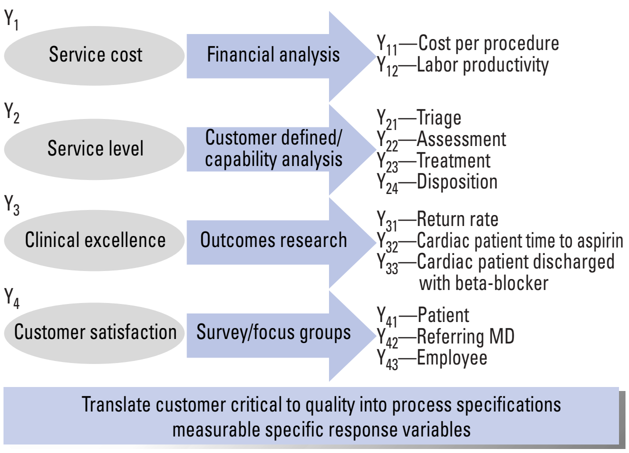
Service level metrics indicate the ability of the system's performance to meet the expectations of patients, referring physicians and other stakeholders—critical to quality parameters (CTQs).

Each set of metrics has specific parameters. Service level indicators may be generalized as access to care, wait time, service time and information conveyance time. Service cost indicators include cost per unit of service, labor productivity and other factors associated with the cost of providing service. Customer satisfaction indicators may be segmented into specific groups such as patient and family, referring physician, staff and payer.

Clinical excellence indicators may relate to a particular treatment pathway or department, such as compliance with guidelines for prescription of aspirin to myocardial infarction patients or reduction of rates of infection contracted in a hospital or other healthcare facility. Figure 1 illustrates sample metrics from an emergency department.

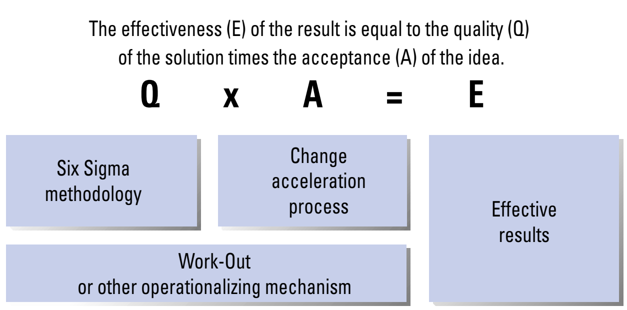
Most healthcare organizations measure performance using some combination from these four groups, but such analysis can be misleading since the metrics often represent an average. Customers rarely experience the average performance of a system—instead, they tend to experience the variability.

Figure 1. **Response Variables**



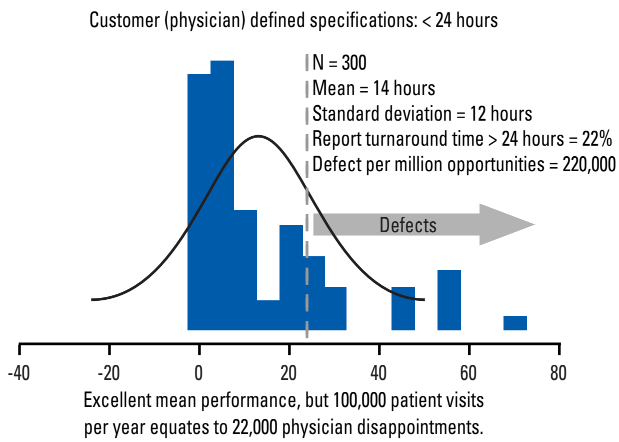
Source: GE Medical Systems

Figure 2. **Formula for Effective Results**



Source: GE Medical Systems

Figure 3. **Capability Analysis: Report Turnaround Time**



Source: GE Medical Systems

From Manufacturing to Medicine

Six Sigma came slowly to healthcare and initially was met with some skepticism. This hesitancy stemmed in part from disparities between processes driven by humans vs. automated or engineered processes.

In manufacturing, it's quite possible to eliminate most—if not all—human variability through automation, creating precise measurement of assignable causes of variation. In healthcare, however, the delivery of patient care is largely a human process, and the causes of variability are often more subtle and difficult to quantify.

The challenge for healthcare institutions and staff as they begin to embrace Six Sigma is to find a way to leverage the data to drive human behavior. Where the approach seems to have had greatest success, providers combined a strong technical strategy (Six Sigma) with a strong cultural strategy, such as change acceleration process, and a sound operationalizing mechanism, such as GE Medical Systems' Work-Out, Motorola's Leadership Jump Start, lean, Pareto analysis or decision trees. This is illustrated in Figure 2.

Leveraging all three aspects has led to notable results. Most projects, however, involved optimizing existing processes and retaining systems and structures bound by capital investment and traditional grouping by function. A hospital's IT system, for example, may not fully support changing a given process, but the facility might decide to simply optimize around it until the investment is retired.

CUSTOMERS RARELY FEEL THE AVERAGE PERFORMANCE OF A SYSTEM—INSTEAD, THEY TEND TO EXPERIENCE THE VARIABILITY.

Service delivery methods in healthcare have also become entrenched and often run counter to the notion of customer centricity. It's common in many facilities, for instance, to take the patient to the care rather than bring the care to the patient. Clearly, we need new models to create a system that genuinely meets patient needs.

A Brief Overview of DMAIC

To implement the right solution to a problem, you need to understand the degree to which different factors may impact the variability of the project's response variable (Y) before specific solutions are designed. Projects tend to focus on response variables from the four groups mentioned earlier.

The initial define and measure phases of a project essentially involve translating the voice of the customer, or CTQs, into measurable response variables. Customer expectations—whether patients, referring physicians, staff or payers—are then used to establish process specifications for those response variables. A measurement of the process capability to meet CTQs is performed, and the end result is expressed as a sigma level or defects per million opportunities (DPMO). This concept is shown in Figure 3, using cycle time for reporting radiology results.

In the analyze phase, the team identifies the causal factors (X's) likely to have the greatest impact on the response variable (Y). These factors are classified as either controllable or uncontrollable. If a factor (X) is controllable and contributes significantly to variability in the response variable (Y), then an opportunity to achieve a better result presents itself by controlling the causal factor.

On the other hand, if the primary causal factors are uncontrollable, a new process must be built to withstand that variability to the degree possible. Many factors in healthcare are quite predictable, though uncontrollable—such as arrival rate at the emergency room. See "Common Emergency Department Critical to Quality Factors."

In healthcare, the improve and control phases can be most challenging since they often involve changing human behavior. It probably comes as no surprise to healthcare professionals that organizational structure can actually inhibit process thinking. Inherently, there are multiple silos across a typical facility and few examples of big picture oversight to unify conflicting agendas and constituencies.

Common Emergency Department Critical to Quality Factors

Quality.

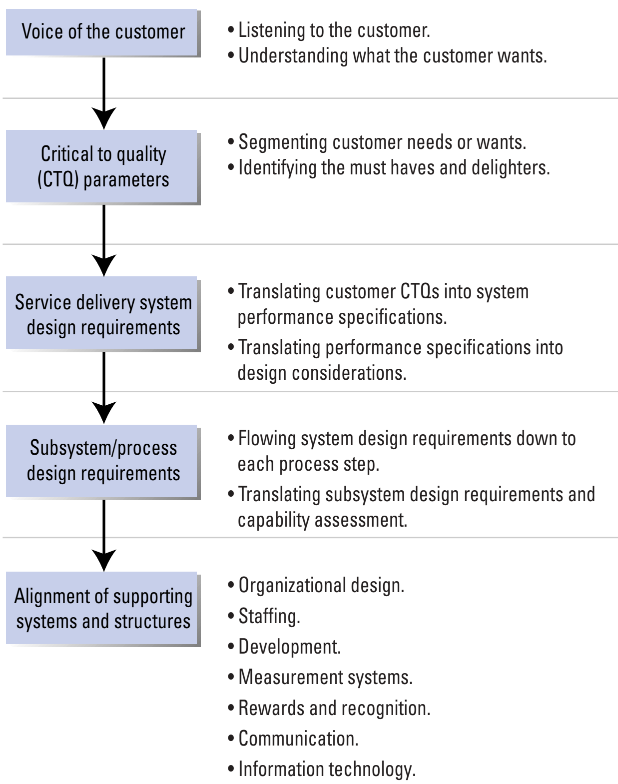
- Accuracy of diagnosis.
- Appropriateness of treatment.
- Timeliness of service
- Wait times.
- Exam and treatment.
- Testing and report turnaround.
- Staff availability.
- Bed availability in emergency department and hospital.
- Responsiveness to squads.

Satisfaction of patient and referring doctor.

Cost of operations.

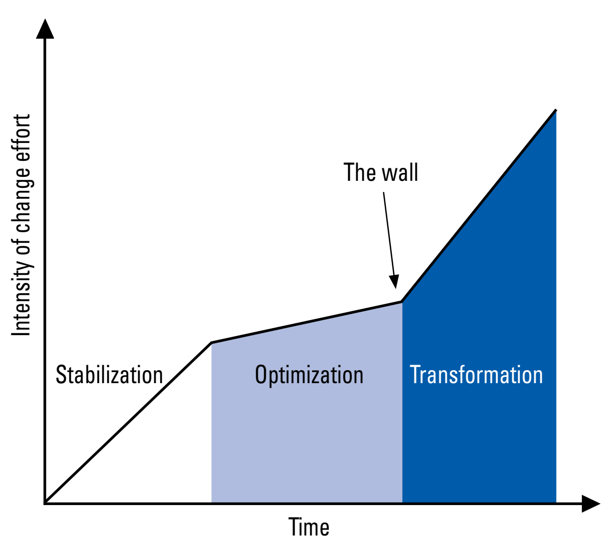
Productivity and workflow.

Figure 4. **Design Process Map**



Source: GE Medical Systems

Figure 5. **The Wall of Change Efforts**



Source: GE Medical Systems

The control phase, therefore, may require dismantling root-bound bureaucracies growing around ancient processes. To achieve long-term success, this must be accompanied by new control measures and process metrics to drive behavior changes.

Another challenge for healthcare is to institutionalize the wins—in other words, to translate the results from one area to another. For example:

- Adopt best practices to improve bed turnover time from a given inpatient unit to all hospital units.
- Translate ventilator weaning protocols from one intensive care unit to another.

From Here to Futurity

Mistakes can be costly in any industry, and there are essentially three ways to approach them. Ignore them and hope for the best (not advisable in most cases); find and fix them within existing processes; or prevent them from occurring in the first place by designing processes correctly from the ground up.

Using the DMAIC approach (the find and fix method), many institutions have seen significant improvement in various clinical and operational processes. When coupled with proven change management and decision making techniques, some have even been able to induce a beneficial transformation in the organizational culture.

But quantum leap changes in the delivery of healthcare (and the prevention of errors through ground floor development) will not come about until providers begin the process of actually designing for Six Sigma. In *Six Sigma: The Breakthrough Management Strategy Revolutionizing the World's Top Corporations*, author Mikel Harry discusses the limits of traditional Six Sigma initiatives:

> The closer companies come to achieving Six Sigma, the more demanding the improvements become. At 4.8 sigma, companies hit a wall that requires a redesigning of processes, known as design for Six Sigma.[3]

This wall is often felt at significantly lower sigma levels in healthcare and consists of bricks retained from old systems and structures. To get through this wall and create quantum leap change, healthcare will have to adopt breakthrough or revolutionary thinking in how systems are designed and built to optimize the interaction of people, processes and technology.

A Brief Overview of DFSS

The primary difference between DMAIC and design for Six Sigma (DFSS) is that statistical tools are used to design a new service delivery system, process or tool rather than to improve the existing system. Customer expectations are translated into process specifications and then into system design requirements. These, in turn, flow down into subsystem and process design requirements.

Elements such as service, the care delivery model, supporting systems and structures and facilities are aligned with the resulting design specifications. Similar to DMAIC, DFSS is a five-step process represented by the acronym DMADV (define, measure, analyze, design and validate). Figure 4 is a design process map, basically a criteria-rating matrix that translates iteratively into system design requirements and then into subsystem requirements—drilling down into each level in order to design the process correctly the first time.

Organizational Readiness for DFSS

It's important to note not all organizations are ready for DFSS. Healthcare institutions can be assessed for readiness along a change continuum, illustrated in Figure 5. Those at the far left have fundamentally unstable operations and service delivery processes. The environment is typically chaotic and repeatability is often dependent on the performance of a few who seem to understand the "magic" involved.

In these institutions, substantial improvement may be achieved through developing and operationalizing procedures that document the magic and begin moving it into the world of science.

This approach is often referred to in DMAIC as a PM/CE/CNX/SOP approach—simply a shorthand method of communicating the following:

- PM = process map.
- CE = cause-effect.
- CNX = controllable, not controllable, experimental variables.
- SOP = standard operating procedure.

The team first gains a common understanding through process mapping (PM). Brainstorming then follows to discover causes of process variability and assess the effect (CE). Drivers of variability are classified as controllable, not controllable or experimental (CNX).

In the analyze phase of a project, the contribution

Table 1. **Process Improvement/Solution Design Continuum**

Improvement objectives >>>	Stabilization	Optimization	Transformation
Methods	Work-Out Kaizen Quality circles	Six Sigma—DMAIC Lean thinking Total quality managment	Six Sigma—DFSS
When to use	Issues or drivers of variability are well understood. Primary concern is building consensus on solutions.	Causal factors or drivers of variability not well understood. Not in a position to build consensus on solutions.	White paper improvement initiative or development of new and future services designed to exceed customer expectations.
Examples	Stabilization of service level metrics such as wait time through role clarity and standard operating procedures.	• Optimization of operating room capacity utilization. • Optimization of emergency department or radiology throughput.	• New operating room pick sheet. • New service line. • Renovated facility. • New hospital.

Table 2. **Quality Function Deployment for New Emergency And Trauma Center—Requirements**

Y's		X's
Customer expectations	**Importance**	**System requirements**
No delays to service due to parking	1	Parking and location signage well identified
Ease of entrance identification and location	1	Dedicated emergency room parking within 100 yards of emergency department
Ease of triage identification and location	2	Internal building signage clearly identifies location
Comfort and safety of wait area	3	Standardized triage process
Minimal wait time to see doctor	4	No triage delays
Minimal wait time to receive treatment	4	Door to doctor time under 30 minutes
Privacy	3	User friendly concentric wait area
To be kept informed of process status	4	Metal detectors at entrance
Quality care	5	Staffing by arrival pattern demand
Positive caregiver interaction	5	Patient communication model designed and caregivers trained
Understand aftercare requirements	4	Mechanisms to ensure staff accountability
		Accurate diagnostics
		Diagnostic cycle time specifications
		Quality therapeutics
		Decision to disposition cycle time less than 15 minutes
		Coordination of aftercare by emergency department
		Frequent patient contact and information exchange
		Privacy of triage spaces
		Privacy of treatment spaces
		Availability of treatment supplies at point of care
		Point of care testing

to variation of the experimental variables is quantified, but the institution may not realize immediate gains by developing SOPs targeted at controllable variables.

In the second stage, processes are stabilized but not yet optimized. The performance service delivery may be stable and repeatable, but still fail to meet customer expectations or operate at lower efficiency and higher cost. In these cases the application of DMAIC will provide the mechanism for process optimization. This occurs by developing a sound understanding of the mathematical relationship between specific response variables (Y's) and their causal factors (X's).

Organizations eventually reach the previously mentioned wall where further optimization of existing systems and structures is no longer feasible. The wall is unavoidable as customer expectations increase and the retention of legacy systems restricts improvement. Design then becomes an important component of the strategy for transformation.

When considering the application of DMAIC or DFSS to a process, the following considerations become relevant:

- To what extent does the current process meet customer expectations?
- Does it require decreased variability alone or a radical shift in mean?
- How committed are you to current legacy systems that support this process?
- What new developments are on the horizon? For example, new pick sheet of materials needed for operating room cases; new service line or center of excellence; renovation of facility or new facility.

An example of a process improvement or solution design continuum is shown in Table 1 (p. 21).

DFSS may be the better approach in cases where in which the process is simply too broken to satisfy customer expectations or further optimization is constrained by legacy systems and structures. The development of new opportunities also invites DFSS as a mechanism to design specifically for customer CTQs as opposed to cloning old processes that may fall short.

The DMADV Process

The define and measure phases of a DMADV project are similar to those of DMAIC in collecting and using voice of the customer data to develop process performance specifications.

The difference with DMADV is that we're often dealing with new products or services, so measuring existing performance against specifications is not possible. With DMADV, the goal is to predict the performance of the new product or service and facilitate evaluation and selection of the best design alternative.

To accomplish this ambitious task of translating voice of the customer data into actionable design criteria, there is a commonly used tool known as quality function deployment (QFD). QFD is an advanced criteria rating matrix, used in DMADV to:

- Identify customer needs or CTQs (the whats).

Figure 6. **Quality Function Deployment for New Emergency and Trauma Center—Results**

Customer expectation	Importance	Staffing by arrival pattern demand	Accurate diagnostics	Mechanisms to ensure staff accountability	Quality therapeutics	Door to doctor time under 30 minutes	Coordination of aftercare by emergency department	Frequent patient contact and information exchange	No triage delays	Patient communication model designed and caregivers trained	Diagnostic cycle time specifications	Decision to disposition cycle time less than 15 minutes	Standardized triage process	Availability of treatment supplies at point of care	User friendly concentric wait area	Metal detectors at entrance	Privacy of triage spaces	Privacy of treatment spaces	Internal building signage clearly identifies location	Point of care testing	Parking and location signage well identified	Dedicated emergency room parking within 100 yards of emergency department	Total
Positive caregiver interaction	5	H	H	H	H	M	M	H	M	H	L	M	L	M	L	L	L	L		M			390
Quality care	5	H	H	M	H	H	H	M	M	L	H	M	M	M	L	L	L	L		M			400
Minimal wait time to receive treatment	4	H	H	M	M	H	L		H		M	L	M										200
Minimal wait time to see doctor	4	H		M		H			H				M										132
To be kept informed of process status	4	M		H		L	H	H	L	H	L	M	M										192
Understand aftercare requirements	4		H	M	H		H	H		M	M	M											192
Comfort and safety of wait area	3	L		L						L					H	H			M			L	75
Privacy	3			L				L						M			H	H		L			72
Ease of triage identification and location	2																		H				18
Ease of entrance identification and location	1																		H		H	M	21
No delays to service due to parking	1																				H	H	18
Total		177	162	138	138	136	136	135	106	101	78	58	56	39	37	37	37	37	36	33	18	15	

Source: GE Medical Systems

- Weight customer needs by order of importance.
- Identify product and service features that meet CTQs (the hows).
- Evaluate the ability of each feature to satisfy each need.

For a new hospital service line, this process would be repeated three times. The first iteration would match customer needs with specific service line features. In successive efforts, the hows become the whats.

The second iteration matches the features against system level requirements. In the last iteration, system level requirements are translated into subsystem level requirements. A QFD for a new emergency and trauma center illustrates the concept in Table 2.

Customer expectations are brainstormed and weighted in the left-hand column. Potential system requirements to satisfy these expectations are brainstormed in the right-hand column.

Each system level requirement is evaluated for its ability to satisfy each customer requirement using a high, medium and low scoring system, as in Figure 6. The system requirement score in the bottom row of the table indicates its relative importance. The customer expectation score in the table's right-hand column indicates the extent to which this expectation is

WHEN APPROPRIATELY IMPLEMENTED WITH LEADERSHIP SUPPORT AND THE UTILIZATION OF CHANGE MANAGEMENT TECHNIQUES TO ADDRESS CULTURAL BARRIERS AND BUILD ACCEPTANCE, SIX SIGMA HAS ACHIEVED MEASURABLE SUCCESS.

covered by the listed systems requirements and can be compared to the weight of the associated customer expectation.

System design requirements can then be sorted in order of importance, as in the Pareto chart in Figure 7. The system design requirements become the expectations (Y's) for the next flow down, and the process is repeated two more times.

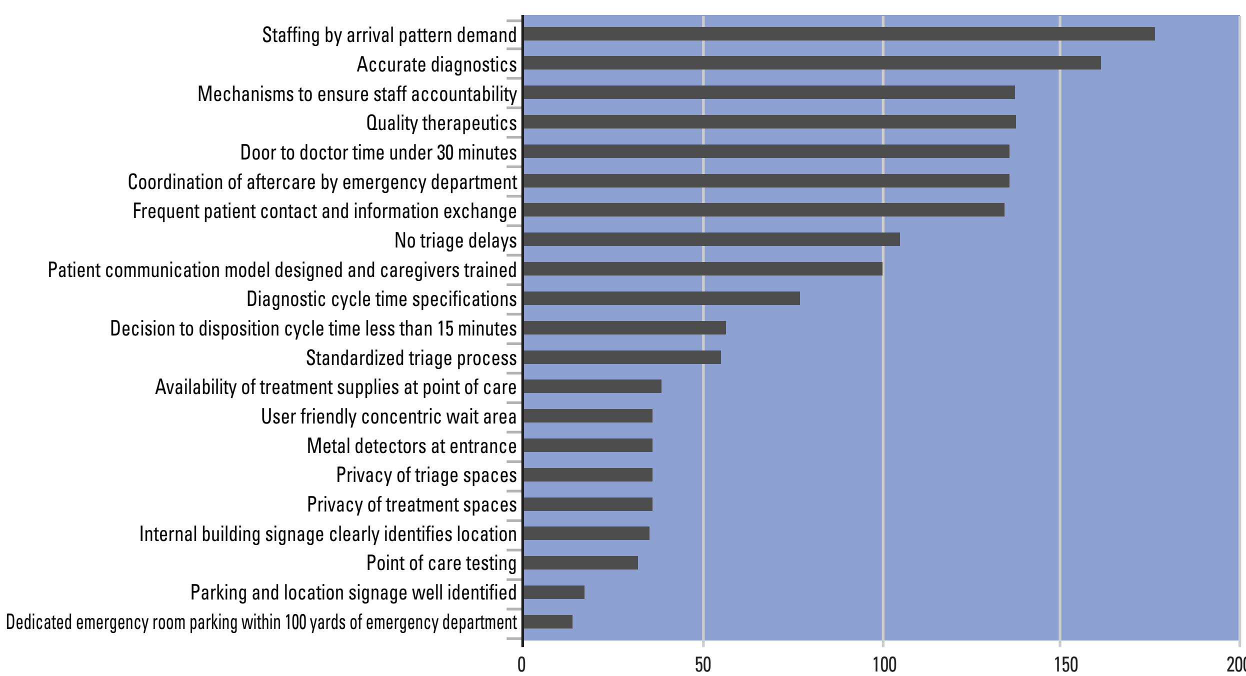
On the surface, this process may seem arbitrary and subjective. If executed correctly, however, using voice of the customer data to drive the importance of the whats and sound capability data to impact the hows, a very clear picture of overall design requirements and the trade-off between competing interests will emerge with clarity.

It is important to note all customer needs are not created equal in this process. Features that currently exceed customer expectations and are considered delighters will quickly become expected must haves tomorrow.

This concept is illustrated using Kano's model in Figure 8 and must be considered carefully in assigning importance to customer needs. The model is followed by an illustration of the first iteration of the QFD process that matches features with customer needs.

The define and measure phase of a DMADV project may be summarized as a process of CTQ flow-down. The analyze phase can be summarized as a process of capability flow-up. This is where DMAIC and DMADV differ significantly.

Figure 7. **Emergency and Trauma Center Pareto Chart**



Source: GE Medical Systems

In DMAIC, an understanding of causal factors on a specific process outcome is quantified mathematically. In DMADV, a specific process supporting a service line feature and customer need may not exist. Where it does, capability can be measured directly as illustrated in the DMAIC section.

In cases involving new processes, systems and structures, the capability may be projected or forecast using modeling. In healthcare, the models most relevant to a new service line are those targeted at understanding capacity, patient queuing, provider resource allocation and patient routing. This concept is illustrated in Figure 9.

For a healthcare service line, the end result of the analyze phase of a DMADV project is twofold:

1. Develop a mathematical expression of customer needs translated to specific service line features, service delivery system, and service subsystem and process design specification.
2. Match needs and requirements against a mathematical expression of existing or forecast proposed process capabilities.

During the design phase, an optimal design is selected and implemented based upon the merging of the CTQ flow-down and the capability flow-up into an integrated design scorecard. Capability forecasting and analysis provides insight into how well design requirements will be met, and the QFD translates this into customer satisfaction. The result is a formalized, mathematical model for understanding customer impact associated with specific design alternatives and trade-offs.

Finally, in the validate phase, the actual performance from a subsystem is measured against predicted performance through the confirmation of customer satisfaction. In a manufacturing environment this is achieved through component, subsystem and system level testing.

In healthcare, however, the opportunity to test segments of the service line may or may not exist. What becomes more important in a healthcare application of DMADV is the degree to which appropriate controls are operationalized to consistently yield predictable results.

Full realization of designed service line entitlements depends on translating the vision of these entitlements to specific behaviors. This requires appropriately targeted changes in recruitment, staff development, measurement systems, performance evaluation, incentives, communication and information technology.

The validation phase of a DMADV project also affords the opportunity to rethink many institutional processes, systems and structures. For example, evaluating design alternatives for a new imaging department may indicate the existing patient registration process will not meet customer expectations. Redesign of this process should trigger rethinking of patient registration across the institution and, at the very least, provide a structured approach to institutional transformation of service.

Figure 8. **Kano's Model**

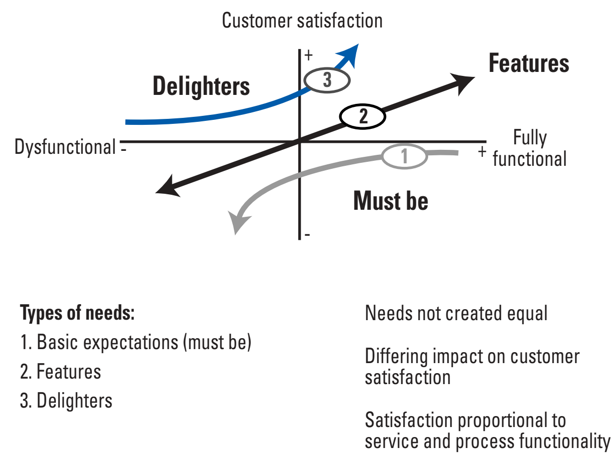
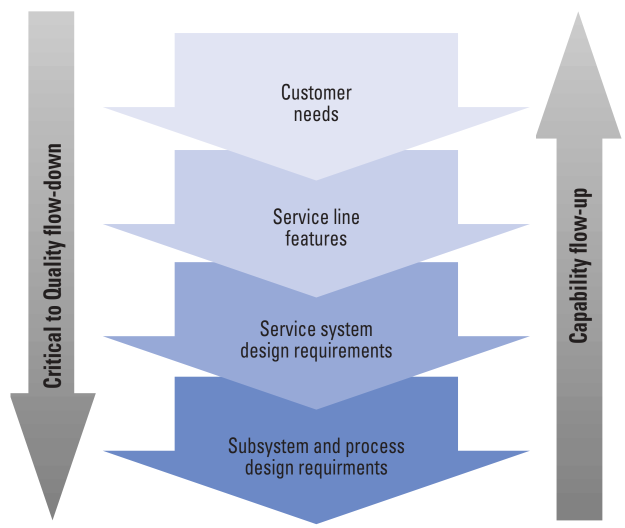


Figure 9. **DFSS Process**



Source: GE Medical Systems

The control phase may require dismantling root-bound bureaucracies growing around ancient processes.

Measurable DMAIC Successes

As a methodology for process and quality improvement, Six Sigma has demonstrated its ability to adapt to virtually any process—including patient care. Recorded achievements do not seem to be based on the type or demographics of the organization. Six Sigma has taken root in a wide variety of settings: within individual departments, throughout small, rural hospitals, within large teaching facilities and across multihospital systems.

When appropriately implemented with leadership support and the utilization of change management techniques to address cultural barriers and build acceptance, Six Sigma has achieved measurable success.

The DMAIC approach has been deployed in hospitals and health systems to improve service levels, cost productivity and customer satisfaction. Conceding the inherent distinctions between manufacturing and medicine, however, it's important to acknowledge the impact of human variability on statistical process control and the importance of cultivating acceptance for service based change initiatives.

What's Next?

Building on the success of the DMAIC model, the next platform for healthcare will likely follow the DFSS approach with continued emphasis on acceptance. DMAIC optimizes existing processes, while DFSS can be used to create and institute an entirely new model for healthcare. Both promises and pitfalls accompany current applications of Six Sigma within healthcare, and organizations will need to carefully assess their own unique needs and preparedness for either targeted or systemic change.

The 21st century healthcare organization faces multiple challenges. Some are complex, longstanding and unresolved issues, and others are emerging trends:

- Workforce shortages.
- Rising consumerism and patient expectations.
- The Health Insurance Portability and Accountability Act of 1996 and other compliance issues.
- Quality and patient safety.
- Reimbursement issues.
- Aging of the population.
- Regulatory constraints.
- Increasing acuity of illness.
- Disaster preparedness.

Driven by a confluence of such significant factors, the healthcare industry may soon gravitate toward an evidence based design of new systems and structures as a more verifiable and sustainable way to deliver optimal patient care.

There are no easy answers and no overnight solutions. It will take a considerable commitment and a concerted effort on the part of all stakeholders to embrace a new paradigm and build a better healthcare system by design.

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