Chapter 7

Human–Centered Systems Engineering:
Managing Stakeholder Dissonance in Healthcare Delivery

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ABSTRACT

Deploying new tools and technologies often results in creating new problems while solving existing problems. A root cause is the interaction between tool design and organizational deployment. One undesirable result is the creation of stakeholder dissonance (SD). SD is a term for the conflict between the needs, wants, and desires (NWDs) of different stakeholders. In healthcare delivery systems, it is evidenced by errors, workarounds, and threats to patient safety and organizational profitability.

Human-Centered Systems Engineering (HCSE) is the foundational paradigm for managing SD. HCSE emphasizes the criticality of the interfaces between humans, their tools, and their organizations, offering methods to recognize, measure, and control SD. It is complimentary to Lean, Six Sigma, Balanced Scorecard, and Quality Function Deployment approaches.

Managing SD requires recognition of all stakeholders and their NWDs, permitting discovery and mapping of potential conflicts. Prioritizing conflicts for mitigation relies on standard risk analysis and decision analysis methods. HCSE provides methods for measuring only those NWDs involved, once the critical conflicts are chosen. This permits the mitigations to be verified, and the deployment design to be validated in a pilot setting, prior to general release of the new tools and technologies into the organization.

INTRODUCTION

Effectiveness is the foundation of success –

Efficiency is a minimum condition for survival

after success has been achieved.

Efficiency is concerned with doing things right.

Effectiveness is doing the right things.

Peter F. Drucker (1909 - 2005)

I spend a considerable amount of my time haranguing my clients (the majority of whom are medical device manufacturers) that absent rigorous Design Controls (Samaras, 2010a) their products will have problems, will dissatisfy customers, and be potential sources of adverse events. What I conveniently forget to tell them is that, even though they may do everything perfectly, the way their products are deployed has a profound impact on meaningful use, patient safety, and profitability in the user organization. Why the concern with profitability? Because organizations that are not, by some measure, profitable will wither and die. Meaningful use, patient safety, and profitability in the user organization are three core issues for effective healthcare delivery.

Figure 1 shows two connected Venn diagrams. The upper Venn diagram depicts the interactions of hardware, software, and human factors issues in the design of tools resulting in tool-level problems; the locus of control is the manufacturer of medical devices, information technology systems, etc. The lower Venn diagram depicts the interactions of business, technical and regulatory issues in the user organization resulting in organizational-level problems; the locus of control is the hospital system, the nursing home, the physician's office, etc. In recent years, especially with increased emphasis on human factors engineering, manufacturers have become quite good at identifying

Figure 1. Source of errors from two levels of interaction
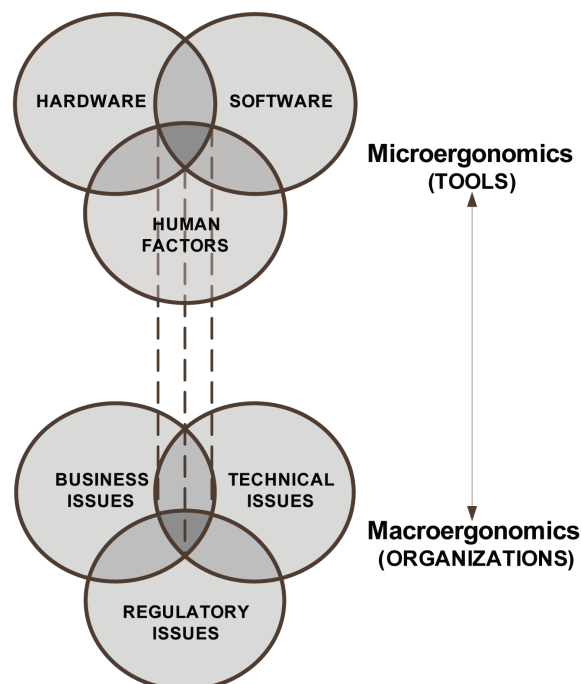
and mitigating tool-level problems. Businesses that deliver healthcare are quite facile at dealing with traditional organizational-level issues common to non-healthcare businesses.

The purpose of Figure 1 is to highlight the multi-level problem of the interaction of tool-use and organizational deployment of these tools in healthcare delivery. This class of problems leads to a phenomenon termed s*takeholder dissonance* (SD) – a lack of agreement, consistency, or harmony among the stakeholders (Samaras & Samaras, 2010). SD in the healthcare delivery system, results in decreased patient safety and decreased organizational profitability. In the jargon of human factors engineering, the two levels in Figure 1 are called *microergonomics* and *macroergonomics*. They are subdisciplines of human factors science and are practiced by different specialists, not unlike industrial versus electrical engineering.

SD is a management concept. It is not the concept of "cognitive dissonance" related to an inconsistency between beliefs and actions. SD is not related to negative drives; it refers to the conflicting needs, wants, and desires (NWDs) among different stakeholders. NWDs are not static; they devolve over time, so that what today may be a Desire tomorrow often devolves to a Want or a Need and is replaced by new Desires. Conflicts between the NWDs of various stakeholders, in the context of healthcare delivery, is evidenced by errors, workarounds, decreased motivation, decreased satisfaction, and even outright rejection of new products, processes, or services. SD is diagnostic for quality deficits.

So, how do we deal with SD in the delivery of healthcare? It is important to realize that SD never can be eliminated totally in any system, including healthcare delivery systems. SD arises from the intentional or unrecognized conflicts between the NWDs of the various system stakeholders. The Venn diagram of Figure 2 depicts the needs of four different stakeholder groups, how they align pair-wise, and how they align for all four stakeholders. It should be self-evident that complete

alignment of the NWDs of patients, clinicians, support staff, and management will be very rare, if not impossible.

So, how do we manage SD in the delivery of healthcare? Ask it another way. How do we measure and control SD, to manage it in healthcare delivery? One approach is to use the principles of human-centered systems engineering. This will allow us to characterize, quantify, prioritize, and control conflicts in the NWDs of the various stakeholders. In human-centered systems engineering, we go beyond the "voice of the customer" and recognize that all stakeholders (individuals and their organizations) are critical to safety, effectiveness, efficiency, and satisfaction.

Human-centered systems engineering is the foundational paradigm for addressing SD. Our objective in the application of human-centered systems engineering will be to *satisfice* all the stakeholders, which Simon (1957) defined as to obtain a good result that is good enough, though not necessarily the best, for each stakeholder. The term *satisfice* is presumed to be a contraction of the terms *satisfy* and *suffice*. Nobel Laureate economist and sociologist Herbert Simon first defined the concept of *satisficing* in an attempt to reduce the computational complexity of a linear programming problem for individual and

Figure 2. Alignment of stakeholder needs
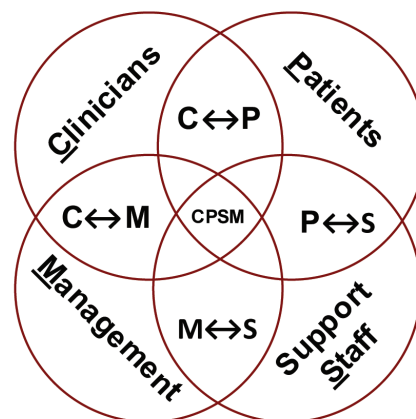
organizational behaviors. This SD reduction strategy is akin to "greasing the skids", thereby reducing known and unknown forces preventing realization of organizational goals. Solving the problems of *satisficing* ALL the stakeholders is a proper endeavor for management engineering,

A HUMAN-CENTERED APPROACH

Human-Centered System Engineering

Products, processes, and services are developed and maintained solely because their use by humans has real or perceived value that is utilitarian and/or esthetic. Even completely automated, unsupervised systems have human users (maintenance personnel) and maintenance is typically a significant portion of the Total Cost of Ownership (TCO). This is the fundamental justification and rationale for human-centered systems engineering (HCSE).

Classical systems engineering is a very powerful mechanism for reducing business and technical risks. It is a structured, systematic approach to the design, development, deployment, and replacement of products, processes, and services. HCSE extends systems engineering to expose the criticality of human actors and their organizations in the engineering process (Samaras & Horst, 2005). The HCSE process has an essential iterative nature (Samaras, 2010a), each new iteration (Figure 3) beginning with the (re-) identification of stakeholders and assessment of their NWDs (**N**eeds - basic needs or "*must haves*", **W**ants - performance needs or "*like to haves*", and **D**esires - latent needs or "*I'll know it when I see it*").

We constantly hear of incidents and accidents that are alleged to be caused by human error, but which human error? *Use* error or *UseR* error? *Use* errors are attributable to the design and/or deployment of the system; they result from the myriad interactions of tool design errors and organizational deployment issues (Figure 1). The major causal factors associated with *Use* error (Samaras,

Figure 3. HCSE iterative deployment paradigm
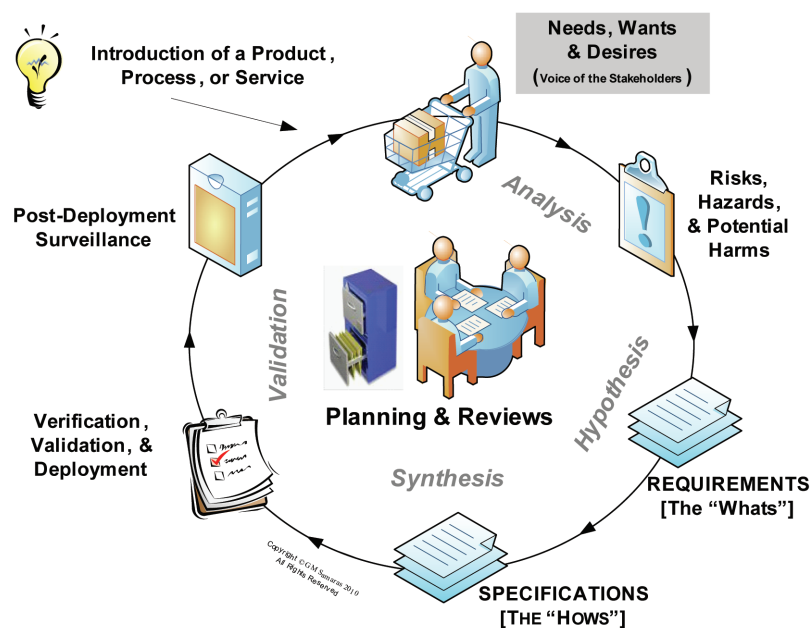
2010b) are improper management controls, improper design controls (at either the technology manufacturer and/or the deploying organization), inadequate non-financial risk management, and inadequate record-keeping controls (Figure 4). *UseR* errors are attributable to the internal or external human user environment, <u>excluding</u> the system itself (Figure 5); these are some of the "human factors" associated with the individual involved with the error (Samaras, 2010b). So, who is at fault? The human operators? Or, the human developers and deployers? Human *Use* errors are largely within the locus of control of system developers and deploying organizations. Even future *UseR* errors may be influenced by the developer and/or deploying organization (e.g., avoid confusing or frustrating the operator, avoid

undesirable physical or cognitive exercises, avoid delays and operator attention loss, avoid inappropriate workloads and work schedules).

In the healthcare arena, safe and effective healthcare delivery systems (products, processes, and services) are the goal. However, human stakeholders complicate the process at a myriad of levels from conceptualization through design, development, deployment, and replacement. Great care must be exercised in finding fault with end-users, when design and development, organizational deployment, or a combination (see Figure 1) may actually be the root cause. This is especially important, since from an organizational perspective, we have far less control over daily use by end-users than we do over organizational deployment or tool selection and acquisition

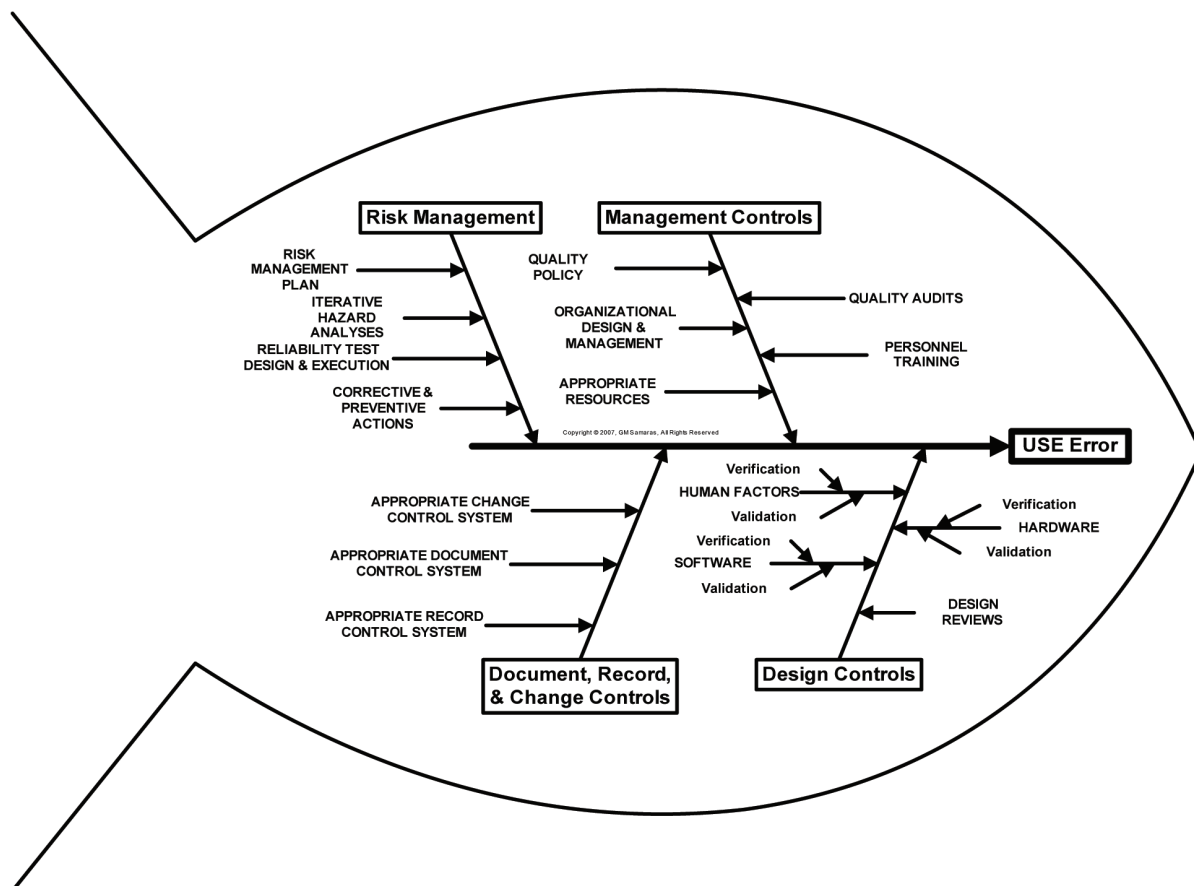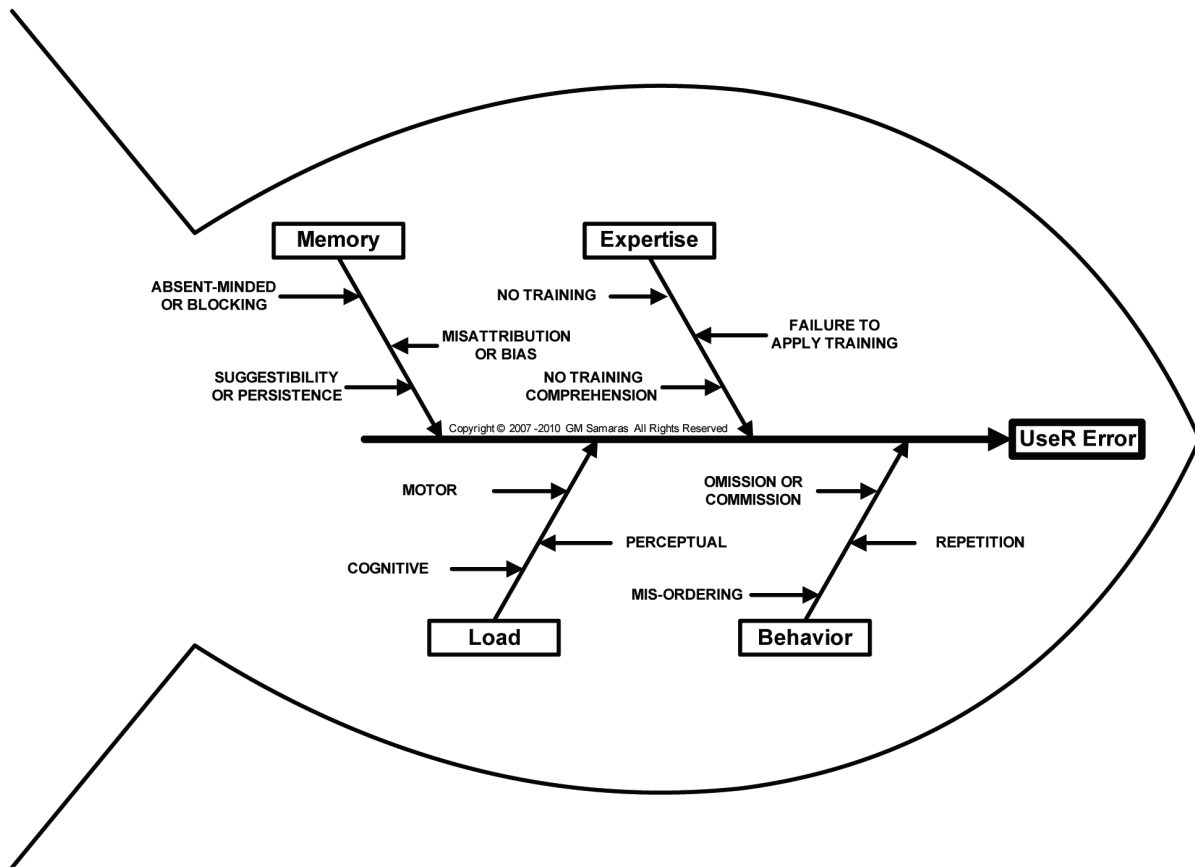*Figure 4. Use error root cause analysis (partial)*

Figure 5. UseR errors root cause analysis (partial)


(which ultimately controls design and development).

Human-Centered System Complexity

Introducing human actors (*actor* is a term of art in social science and economics that subsumes *user*) into any endeavor dramatically increases the possible number of incorrect or inappropriate responses of a "simple" hardware/software system. The ratio of "wrong to right" responses often is used to characterize the complexity of tasks; it also imputes the requisite level of expertise (training and experience) to execute a series of such tasks successfully by the operators (or groups of operators and/or their automated aides). Humans dramatically increase system complexity.

Complex systems have *emergent* properties – the result of component interactions at the interfaces – that are not readily predictable without appreciation of the system as a whole. It is now generally recognized that product, process, and service design-induced errors are a serious problem, a critical system safety issue, and an important source of reduced quality. They can rarely be alleviated simply with labeling or user training!

Not fully appreciating human-centered system complexity, especially in risk management, has been an important obstacle in the design and deployment of essential clinical systems (e.g., clinical decision support, medication management, and clinical information exchange). Using technology merely to solve identified problems often creates new, previously unidentified, problems (e.g., see

Figure 6. Factors for actors
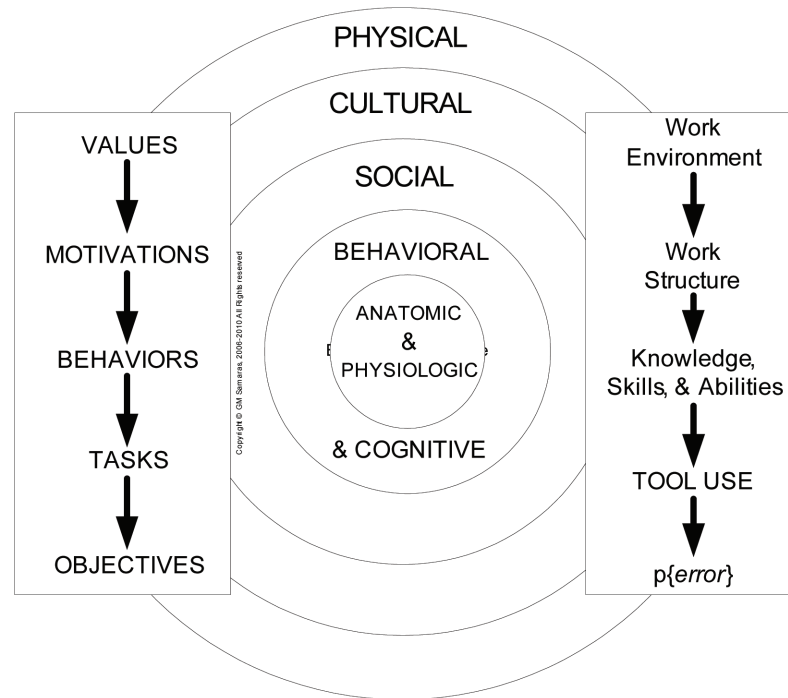
how a decade's difference dramatically altered perspectives of computerized physician order entry [Tierney et al, 1993 vs. Koppel et al, 2005]).

Stakeholders operate in a complex environment (Figure 6) that influences both what they achieve and how they err. Whether they are patients, clinicians, support staff, managers, or other stakeholders (e.g., 3rd party payers, regulators, stockholders, suppliers, manufacturers, competitors, etc.) their behaviors are determined in large part by their disparate values and motivations. How they work and how probable will it be for them to be involved with errors, is influenced not only by training and by experience, but also by the work environment and work structure (e.g., 8-hour shifts versus 12-hour shifts). These all are influenced by individual biological, behavioral, social, cultural, and physical environmental factors – yielding a complex environment and a resulting increase in overall system complexity.

Complexity arises at the interfaces. A human-centered approach requires a detailed appreciation

of the interfaces to actors and between actors. Otherwise, we remain unable to predict and control the critical human and organizational influences both on system design parameters and on system sensitivities to external factors.

Our fundamental need to study the system as a whole requires a model of human-centered complexity (Samaras & Samaras, 2009) from which we can derive an operationalization schema, a means of defining what needs to be measured and how it may be measured (Table 1). It offers a way of appreciating both the system components and their potential interactions.

In all cases, the interfaces consist of both overt factors (quantities we can detect with one or more of our five senses) and covert factors (quantities we cannot detect with our five senses). An engineering example would be the externally observed *distance* (an overt factor) a free body traveled versus the externally observed *acceleration* (the second time derivative of distance, a covert factor) of the free body. At the level of *individual* actors

Table 1. The interdisciplinary nature of measuring human-centered system complexity

	HCSE METROLOGY CATEGORIES			
	INDIVIDUAL		GROUP	
FACTORS	**PHYSICAL**	**BEHAVIORAL**	**SOCIAL**	**CULTURAL**
Overt	Anthropo-morpho-metry	Verbal & Nonverbal Behaviors	Communication & Coordination	Language & Artifacts
Covert	Biomechanical & Sensory Processes	Affective, Cognitive, & Physiological Behaviors	Conventions & Expectations	Beliefs, Customs, Ethics, & Morals

and their tools, the interfaces consist of overt and covert physical and information management behavioral factors. Here we are concerned with the static and dynamic "physical fit" of tools as well as the requisite behaviors involved in the decision-making processes of tool use. At the level of *groups* of actors and their tools, the interfaces consist of overt and covert social and cultural factors. These include communication and coordination, norms and roles, as well as language differences (e.g., the language of clinicians versus the language of engineering or business) and differing value systems (shared beliefs, customs, ethics, and morals that vary among stakeholders). Using this operationalization model supports comprehensive consideration of system, parameter, and tolerance design for engineering human-centered systems – an essential set of tasks in quality engineering.

In HCSE, the emphasis shifts to iterative discovery of stakeholders, iterative identification of their evolving NWDs, and iterative reconciliation of conflicts; the objective is to *satisfice* ALL the stakeholders (concurrent engineering is a subset of this approach). This precedes, and is the basis for, the requirements formulation process in each iteration (Figure 3). This shift in emphasis tends to mitigate errors and omissions early in the system deployment cycle, increasing effectiveness and efficiency. Absent robust HCSE, essential systems (e.g., clinical decision support, medication

management, and clinical information exchange) will continue to hinder rather than help, be economically inefficient, and be examples of poor quality. However, to manage this, we must be able to measure and control the interfaces.

Examination of Table 1 indicates the measurement methods belong to a wide range of scientific disciplines – from biomechanics to cultural anthropology. These are well-established measurement techniques in each scientific discipline; therefore, threats to construct validity are minimized, although not eliminated. Physical measurements include essentially static human characteristics as well as dynamic measurements used in biomechanics and sensory physiology. Behavioral measurements use traditional techniques of experimental psychology. Techniques of social anthropology, social psychology, and sociology are used for social measurements. Cultural measurements use techniques of linguistics (for language), archaeology (for tools and other artifacts), and cultural anthropology (for value systems). Some practical examples to illustrate application of this measurement schema are shown in Table 2.

At a workshop related to HCSE that I teach annually, I am invariably asked, either in dismay or cynically, "You don't really expect us to do all these measurements; we do not have the cognitive psychologists, sociologists, and cultural anthropologists on staff!" My answer is invariably, "I do not expect an industrial engineer to program

Table 2. Measurement examples for table 1 metrology categories

INDIVIDUALS	PHYSICAL	**Overt factors** – the static size and fit of an individual (e.g., the range of adjustment of an operating table for the comfort of individual surgeons of different heights and reach)
		Covert factors – biomechanical factors (e.g., the weight and balance of an individual surgeon's tools) and sensory factors (e.g., multiple audible alarms in the operating theater interfering with recognition of a high priority alarm)
	BEHAVIORAL	**Overt factors** – verbal and non-verbal information management behaviors (e.g., verbalization and mouse/trackball operation while using a computerized provider order entry system)
		Covert factors – affective (e.g., a surgeon's frustration with multiple simultaneous alarms), cognitive (e.g., difficulties comprehending which alarm has the highest priority), and physiological behaviors (e.g., increased heart and respiration rate due to time pressures and frustration with discrimination of the alarms)
GROUPS	SOCIAL	**Overt factors** – communication and coordination (e.g., a physician putting medication orders or other directives in an inappropriate location of the computerized provider order entry system)
		Covert factors – conventions and expectations (e.g., the buyer routinely selects the diagnostic radiology device based upon the radiologist's desire for high image quality, erroneously expecting that the technicians and nurses – the actual users, not the readers – will deliver high productivity and profitability, regardless of the choice of device)
	CULTURAL	**Overt factors** – language and artifacts (e.g., clinical users and clinical engineers do not speak exactly the same language and patient safety problems often arise when there are gaps in communication due to language difficulties; what may be obvious to the engineer may not be obvious to the clinician and omission leads to miscommunication)
		Covert factors – shared values, such as beliefs, customs, ethics, and morals (e.g., the classical example of covert cultural factors is the discrepancy between clinical professionals and business professionals, both of whom are well-meaning but neither of whom recognize that they are starting with different assumptions and value systems)

a computer operating system and I do not expect YOU to do all these measurements, but I do expect that you will require some of these types of measurements for any particular deployment". What needs to be measured depends upon the particular circumstances and what needs to be measured should be measured.

If you are deploying a new infusion pump, your primary focus probably will be on individual factors. Are the displays intuitive, are the screens easy to read, or are the manual controls laid out well? If not, what can you do to minimize the impact on workload, how do you reduce the probability of medication errors, and is the TCO of the new infusion pump you are planning to buy consistent with your strategic objectives? Alternatively, if you are deploying a new medical record or provider order entry system, your primary focus will most likely be on group factors. How will this impact communication and coordination among physicians, pharmacists, and nurses? What "normal" conventions might undermine success of the deployment? What are the expectations of these stakeholder groups for the impact of this deployment on their workload, probable medication errors, and the TCO to the organization? In both these cases, TCO can no longer include just initial purchase price or maintenance costs, but also must include the cost of reduced clinician efficiency, increased medication errors, and the cost of not being reimbursed, if the deployment does not satisfy the "meaningful use" criterion.

Managing requires measuring. What gets measured depends specifically on what you are trying to deploy. Who needs to do the measurement is determined by what needs to get measured, not the other way around. The assessment and validation of human interface attributes is a process that is inescapably multi-disciplinary (Samaras, 2006).

Human-Centered Quality

HCSE takes a different approach to quality definition and quality management (including improvement). The definition encompasses, for example, all of Holpp's (1993) eight definitions of quality in healthcare and subsumes all six of Berwick's (2002) dimensions of healthcare performance. HCSE defines quality as *the degree to which the needs, wants, and desires of <u>all</u> the stakeholders have been satisficed* (Samaras, 2010b). With this quality definition, quality (Q) and SD are related concepts: zero SD corresponds to total quality (Q = 1 - SD). Under this definition, total quality (SD = 0) is unachievable, except in the most trivial cases. Reducing SD is the means to increasing quality. Furthermore, a quality improvement intervention – even if successful in the short term – can never be expected to endure without additional effort, because the system of humans (the organization) is dynamic, not static. Because SD can never be eliminated totally, the *satisficing* task, as first put forth by Simon, is a linear/nonlinear programming question and a classical management engineering problem.

There exist a myriad "definitions of quality" and many believe that the concept of quality is elusive. Holpp (1993) offered eight definitions of quality in healthcare that endure today. He stated that quality is customer satisfaction, meeting requirements, continuous process improvement, teamwork and empowerment, outstanding service, cost control and resource utilization, doing the right things right the first time, and (finally) how we do business.

The HCSE definition of quality encompasses all of Holpp's eight definitions; each of the eight definitions may be derived from the single HCSE definition: Stakeholders include both internal and external customers; *satisficing* their NWDs results in their satisfaction (although not necessarily their delight). Requirements (design inputs) in HCSE are defined as the subset of identified or discovered NWDs that are economically and technologi-

cally feasible at a given point in time (Samaras & Horst, 2005; Samaras, 2010a). Continuous process improvement, also called corrective and preventive action (CAPA) or continuous quality improvement (CQI), is a central element of the HCSE lifecycle, whose objective is to *satisfice* stakeholder NWDs. *Satisficing* the NWDs of all the stakeholders promotes teamwork and empowerment, outstanding service (we are *satisficing* the NWDs of both internal and external customers), and cost control and resource utilization (we are *satisficing* the NWDs of managers and business staff). *Satisficing* the NWDs of all the stakeholders moves us closer to doing "the right things right the first time". Finally, if you are *satisficing* the NWDs of all the stakeholders, that is how you do business.

All stakeholders have the same top-level NWDs (Samaras & Samaras, 2009); they are: **S**afety, **E**ffectiveness, **E**fficiency, and **S**atisfaction (SEES). The first three are objective measures (safety, effectiveness, and efficiency). The fourth (satisfaction) is a set of five subjective measures (perceived effectiveness, perceived efficiency, engaging, error tolerant and easy to learn). While these are the top-level NWD categories, their specific meaning varies by stakeholder (by the frame of reference).

Etzioni's (1964) defines "The actual *effectiveness* of a specific organization is determined by the degree to which it realizes its goals. The *efficiency* of an organization is measured by the amount of resources used to produce a unit of output."

Dubin (1976) asserts that effectiveness has a different meaning based on whether the organization is viewed from the inside (efficiency) or from the outside (social utility), which begins to get to the contemporary issue of "meaningful use". As you change the frame of reference from that of a single stakeholder to a stakeholder group, then to multiple stakeholder groups, and then to ALL the stakeholders, the effectiveness criterion is transformed. As you alter the system boundaries, the computation of efficiency is changed, because

only resources that cross the system boundary are considered.

Where you decide to draw the system boundary, while always considered arbitrary, has profound consequences. The reference frame is crucial. For the patient, safety may mean that their health status is not degraded further; for the clinician, safety may mean that they are not injured/infected during the course of providing care; and for the healthcare delivery organization, their safety will most likely be expressed in financial terms. Similarly, the clinician and the healthcare delivery organization may disagree on both objective and subjective efficiency: management is satisfied that fewer clinicians are required to service a fixed number of patients, whereas clinicians are dissatisfied that their workload is above the generally accepted professional norm.

Berwick (2002) identifies six dimensions of healthcare performance cited in the IOM report *Crossing the Quality Chasm*: safety, timeliness, effectiveness, efficiency, equity, and patient-centeredness. These IOM's six dimensions or domains translate to only four independent quality dimensions – safety, effectiveness, efficiency, and satisfaction. Safety is not just a matter of avoiding physical, psychological, or socioeconomic injuries to patients, but also avoiding such injuries to other stakeholders including clinicians, support staff, and healthcare delivery organizations. Effectiveness is not only provision of evidence-based "treatment", but also provision of that treatment to all where (location) and when (timeliness) they can benefit; "treatment" needs to be understood in the broadest sense for all stakeholders (not just receiving a pill, but also having your work structure changed, your reimbursement terms altered, etc.). Efficiency is about avoiding waste, but as Dubin indicated, it is totally dependent upon where you draw your system boundary (your frame of reference). Timeliness is not an orthogonal quality dimension; it is an element of effectiveness (providing treatment when there will be benefit), efficiency (not wasting time),

and satisfaction (because, as previously stated, satisfaction is a function of perceived effectiveness and perceived efficiency). Patient-centeredness (while the *raison d'être* of healthcare delivery) is not an independent dimension of quality; it is but one of a number of foci of the complete set of stakeholders that must be balanced in the implementation of a rational healthcare delivery system. Finally, equity (providing care invariant over demographic and socioeconomic status) does not survive careful analysis as an independent quality dimension (even though it is very attractive from a social justice perspective). Inequitable distribution of care jeopardizes the safety of some patients, is ineffective from a public health perspective (think of herd immunity), is inefficient from a national economic perspective (think of who is paying for whom to go to the emergency room), and is dissatisfying to many of the stakeholders (not all of whom are merely recipients of the inequitable care).

A basic premise of management engineering is that you *cannot manage what you cannot define*. The HCSE definition of quality is neither *ad hoc* nor "elusive", but contained, constrained, and quantifiable. It is derived from the fundamental principles of human-centered systems engineering and it is susceptible to effective management. Attempting to meet some or all the stakeholder NWDs is the sole purpose for system development and system deployment. The degree to which you are *satisficing* all the stakeholder NWDs is the fundamental measure of quality.

DIFFERENT PERSPECTIVES

Management engineering, like all other engineering disciplines, may be characterized by a set of tools, often borrowed from other scientific disciplines. Some of the more widely used (albeit, less rigorous) tools are identified and compared to HCSE.

Lean Approach

"Lean" got its name from a bestseller (Womack, Jones, & Roos, 1990) discussing how automobile manufacturing moved from craft production to mass production to lean manufacturing. Healthcare delivery is fundamentally a lean engineering problem characterized by the inherent tension between the search for high throughput and the involvement of primarily professional workers. The basic principles of lean engineering process optimization are simple to understand, but often difficult to achieve: (1) add nothing, but value (eliminate waste), (2) organize based upon people who add value, (3) create flow from pull (delay commitment), and (4) reduce barriers by optimizing across organizations. Critical to the lean engineering process is the recognition and analysis of the value stream (the flow of increasing value). Mapping out the value stream facilitates identification of waste and facilitates identification of stakeholders, including not only those who add value, but also those who might add barriers. Adding value and eliminating waste are central NWDs of all stakeholders. While lean engineering practitioners normally focus on adding value that an internal or external customer cares about, there is no reason it cannot be extended to adding value for all stakeholders.

Balanced Scorecard Approach

The first balanced scorecard was created in 1987 at Analog Devices, Inc. (Schneiderman, 2006). It achieved "balance" by adding non-financial measures that characterize progress towards the organization's strategic objectives. It considered five major stakeholder groups (communities, customers, employees, stockholders, and suppliers) focusing on gaps in their satisfaction that could be mapped to internal process improvements. The original balance was achieved by considering four perspectives (financial, customer, internal processes, and innovation & learning). Over time, more

rigorous design methods have evolved (Lawrie & Cobbold, 2004) including the strategic linkage model (connecting strategic objectives with scorecard measures and targets to yield strategy maps) and the incorporation of a strategic goal or end-state definition (the "Destination Statement"). These improvements have tended to make the selection of perspectives, measures, and targets more closely linked to the actual organizational strategy designed to serve the stakeholders.

Six Sigma Approach and DMAIC

In 1988, Motorola, Inc. received the Malcolm Baldrige National Quality Award in part for their six sigma program (Pyzdek, 2003). The Six Sigma (6σ) approach is fundamentally about a process quality objective used for defects reduction by reducing process variability. It is now viewed as a method for improving organizational performance through the reduction of variability and elimination of waste. It focuses on control of a process to $\pm$ six standard deviations (6σ) from a target, which translates to about 2 defects per billion opportunities (3.4 defects per million opportunities $= \pm 4.5\sigma$, so you must be willing to accept an additional 1.5σ drift). It assumes a "normal" or Gaussian distribution, a frequent simplifying assumption of industrial practitioners, which may or may not always be true, but is often a good first-order approximation. The major impact of Six Sigma is that Motorola and subsequent practitioners fundamentally changed the acceptable quality level discussion - from performance levels measured in percents to performance levels measured at least four orders of magnitude smaller.

Like the Lean approach, Six Sigma is a framework for increasing value, decreasing variability and eliminating waste; Lean focuses on flow, whereas Six Sigma focuses on variability. Both Lean and Six Sigma can benefit from the application of sophisticated mathematical and statistical analyses; both also can be applied with simple arithmetic. The Six Sigma paradigm is based upon

on a 5-step process: Define, Measure, Analyze, Improve, and Control (DMAIC). DMAIC refers to a measurement-dependent, data-driven quality strategy for process improvement. Central to the DMAIC approach is defining the "Customer", their "Critical to Quality" issues, and core business processes.

Quality Function Deployment (QFD) Approach

QFD is a key practice in Design for Six Sigma (DFSS). Broadly defined (Akao, 1990), it is a method that "converts user demands into substitute quality characteristics …, determines the design quality of the finished good, and systematically deploys this quality into component quality, individual parts quality, and process elements and

their relationships." The QFD lifecycle may be directly mapped on to the classical systems engineering lifecycle (Samaras, 2006). In this schema, the 'Voice of the Customer" (Figure 7) appears as a subset of the "Voice of the Stakeholders" (Figure 8); other than that, everything appears basically the same. A powerful tool of QFD, the "House of Quality" is a mechanism for selecting and verifying the relationship between Design Inputs (Requirements or "Whats") and Design Outputs (Specifications or "Hows").

HCSE Approach

HCSE is a general paradigm that applies to both the development and deployment of products, processes, and services. A wide variety of lifecycle models, published over the last quarter century,

Figure 7. QFD mapped to HCSE lifecycle
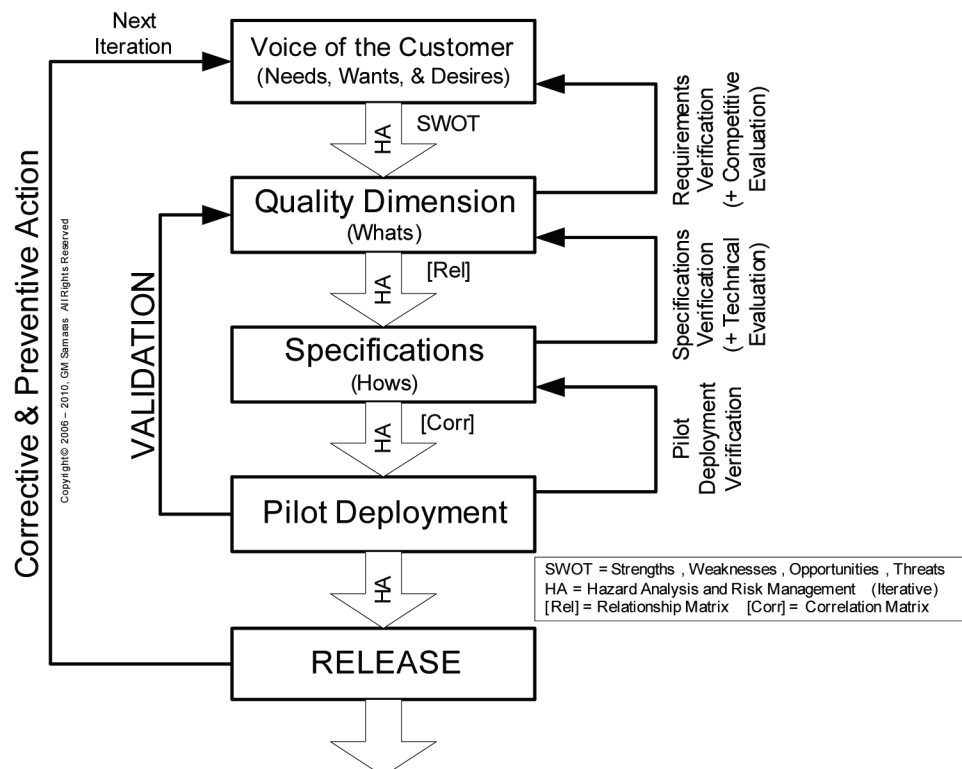
directly map to the classical systems engineering lifecycle model (Samaras & Horst, 2005). The primary difference between the classical systems engineering lifecycle and the HCSE lifecycle is the iterative emphasis on identifying all stakeholders and their NWDs (Figure 8).

Comparing Perspectives

All five approaches share a number of distinct similarities. All focus on increasing value and target process improvement. All focus on some or all of the stakeholders' NWDs. All focus on core business processes to support the particular approach. Some are explicitly iterative, while others are implicitly iterative.

The Lean approach, with its historical roots in reconciling artisanship and mass production, is a good match for healthcare delivery's search for high throughput from highly skilled professionals. Six Sigma can stabilize gains from the Lean approach by reducing variability along the value stream. The Balanced Scorecard approach exposes the connections between organizational strategy and goal(s) with specific process measures and target values. Both the QFD and the HCSE lifecycles map directly to the classical systems engineering lifecycle and support design of products, processes, and services.

A crucial strength of HCSE is the focus on all stakeholders, rather than just a subset (i.e., customers), thus exposing previously unrecognized SD. Other strengths include the definition of quality and procedures for identifying, classifying, and operationalizing stakeholder NWDs. Recognition and quantification are prerequisites for measurement, control, and management.

Figure 8. HCSE lifecycle (HA = hazard analysis)
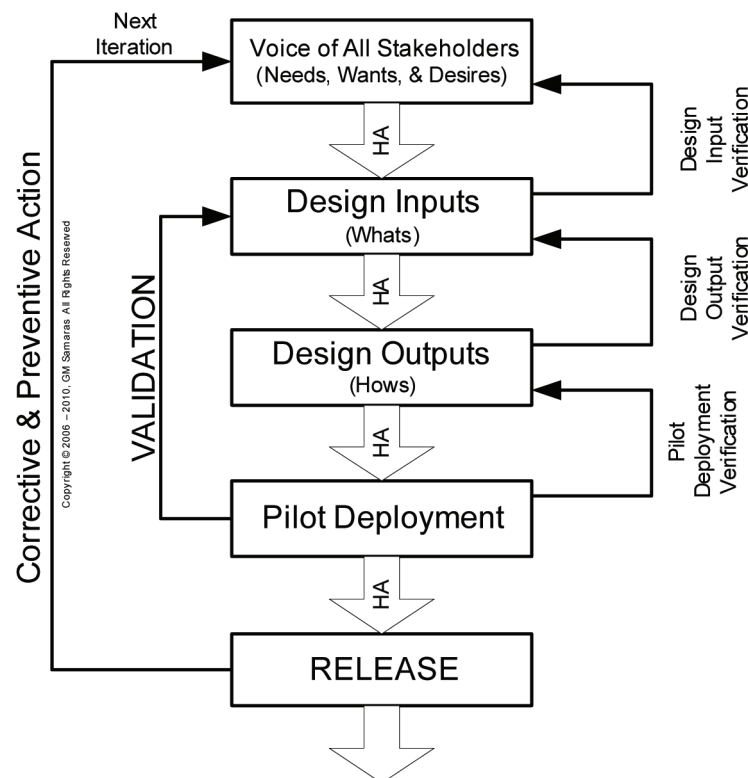
EXPOSING STAKEHOLDERS, THEIR NWDs, AND DISSONANCE

SD in a system never can be eliminated totally; it can only be reduced, except in the most trivial situations. SD arises from the intentional or unrecognized conflicts between the NWDs of the various system stakeholders. In order to manage SD, you must be able to control it. This requires that you are able to measure SD. Increased workload, increased errors, appearance of workarounds, and outright rejection of newly introduced tools are symptomatic of SD in healthcare delivery. While recognizing symptoms is important from a diagnostic perspective, treating (controlling) SD requires recognition and mitigation of the root cause - conflicting NWDs between stakeholders. The objective is SD reduction by reducing NWD conflicts among the stakeholders. Initially, this means identifying the stakeholders, soliciting and classifying their NWDs, and then searching for conflicts.

Identifying and Prioritizing Stakeholders

A stakeholder is any individual or group that potentially can threaten or cooperate in the deployment process (Savage, Nix, Whitehead, & Blair, 1991). Attributes of power, legitimacy, and urgency (Mitchell, Agle & Wood, 1997) are important elements for the identification and prioritization of stakeholders. Visualizing and mapping stakeholder influence (Bourne & Walker, 2005; Walker, Bourne & Shelley, 2008) is a critical step in identifying ALL the stakeholders, to avoid unrecognized NWD conflicts that may lead to SD. The degree to which the identification is more coarse-grained (e.g., clinicians) or fine-grained (e.g., physicians, nurses, pharmacists, occupational/radiation/physical therapists, nurse assistants, pharmacy technicians, aides/orderlies/attendants) will depend in part on the particular deployment and in part on the iteration in the deployment design process. There is little reason to begin in the first iteration with a very fine-grained analysis; however, as SD is mapped, the original course-grained analysis will very likely be expanded in future iterations for particular stakeholder groups.

Defining NWDs

We previously stated that NWDs may be envisioned as: **N**eeds - basic needs or "*must haves*", **W**ants - performance needs or "*like to haves*", and **D**esires - latent needs or "*I'll know it when I see it*". From the work of Kano (1984), we have a simple means of discriminating NWDs based upon stakeholder response (Figure 9). This stakeholder response matrix permits discrimination and identification of basic needs versus performance needs versus latent needs. However, it is not a good mechanism for soliciting NWDs from stakeholders. Most stakeholders do not readily relate to the terms "needs, wants, and desires" and encounter difficulties identifying their NWDs.

Soliciting NWDs

However, all stakeholders seem readily able and willing to discuss and give multiple opinions regarding safety, effectiveness, efficiency, and whether a tool is satisfying to use. This is convenient, because all stakeholders have the same top-level set of NWDs: the product, process, or service should be "Safe, Effective, Efficient, and Satisfying in a Specified Context of Use" (ISO/IEC, 2001). As previously stated (see section on Human-Centered Quality), the first three SEES elements are objective measures, whereas the fourth is a set of subjective measures encompassing perceived effectiveness, perceived efficiency, engaging, error tolerant, and easy to learn.

Figure 10 is an example of a worksheet for soliciting and organizing these across all stakeholder categories. The stakeholders' inputs are solicited in a number of different ways, including

Figure 9. Stakeholder response matrix

	POORLY MET	MET	VERY WELL MET
NEEDS (Basic Needs)	DISGUSTED	UNHAPPY	NEUTRAL
WANTS (Performance Needs)	UNHAPPY	NEUTRAL	HAPPY
DESIRES (Latent Needs)	NEUTRAL	HAPPY	DELIGHTED

Figure 10. Organizing commensurable stakeholder NWDs

TOP LEVEL NEEDS, WANTS, & DESIRES			STAKEHOLDER CATEGORIES			
			CLINICIANS	PATIENTS	MANAGEMENT	STAFF
	OBJECTIVE MEASURES	SAFETY				
		EFFECTIVENESS				
		EFFICIENCY				
	SUBJECTIVE MEASURES	SATISFACTION				
		Perceived Effectiveness				
		Perceived Efficiency				
		Engaging				
		Error Tolerant				
		Easy to Learn				

one-on-one interviews, structured focus groups, questionnaires, technical conferences (where participant stakeholders are invited to comment on relevant presentations), and traditional best practices benchmarking of competitors. No one particular technique appears totally adequate, but since the process is iterative, different techniques may be used in different iterations. Furthermore, an initial analytic effort to forecast stakeholder responses tends to expedite the process.

It is important for engineers to appreciate that subjective measures may be as important as, or

even more important than, objective measures. Our natural inclination as engineers is to tend to discount "feelings" and other "human" things we are not trained to measure. However, from the point of view of the individual stakeholder, if they feel the tool is not working for them or if they feel it is increasing their workload, they will perceive it as ineffective or inefficient, regardless of what your objective data may indicate. Their "subjective" perception invariably will lead to workarounds or rejection of the tool, both of which are diagnostic for SD.

A very good example is the work on "ergonomic" versus "non-ergonomic" computer carts (Anderson, et. al., 2009). Nurses overwhelmingly rejected a slick ergonomic design in favor of a generic trolley that had a larger work surface and storage space for medications, papers, and other nursing artifacts. However, it has been my personal observation that a different group of clinicians (physical and occupational therapists), whose professional artifacts are mostly large and immobile, routinely use the modern, ergonomically designed computer on wheels.

Whether or not the ergonomic cart is perceived as effective and efficient is dependent upon the stakeholder group (on their frame of reference), in this case two subgroups of clinicians. In fact, the meaning and priority of each of these top level NWDs vary according to the specific (sub-) category of stakeholder. In our attempt to achieve SD reduction, we are not directly interested is SEES, but in the identification of basic needs, performance needs and latent needs for each specific stakeholder group and how they might conflict. Only a subset of all these NWDs will be translated into the design requirements for the deployment of the product, process, or service.

Classifying NWDs

In any given iteration, once we have a SEES set, it is relatively simple to classify each of the members of the SEES set as Needs, Wants, or De-

sires. For each given stakeholder group (actually their sampled representatives), we ascertain their response on a scale from addition to elimination of the particular design requirements, couched in terms that permits them to respond based upon whether the putative requirement is poorly met, met or very well met (see Figure 9).

Consistent with good survey and questionnaire practices, once you have constructed the questions based upon the subject matter, you need to randomize their sequence and ensure that you have both a balanced presentation (positive and negative interrogatories, as well as any other internal controls deemed necessary). The responses may be elicited in writing, in group sessions, or in any number of other formats. What is important, as with every other scientifically–based investigation, is that bias is minimized (use multiple representatives, minimize self-selection, avoid leading questions, do not suppress discussions and other interactions among stakeholder representatives in a group setting, etc.)

Since HCSE is inherently an iterative process, it is both unnecessary and inefficient to "get it right the first time"; that definition of quality does not apply here! Trying to complete the effort in a single iteration is usually counterproductive (Samaras, 2010a); the optimal design will usually change with each iteration. Attempting to "finalize" any subsystem will usually constrain future decision-making options and yield suboptimal results. The key, as in any iterative and agile endeavor, is to preserve flexible decision-making, maintain a high tolerance for ambiguity and uncertainty, and enforce short time intervals for each iteration.

Discovering and Mapping Potential Stakeholder Dissonance

SD arises from the intentional or unrecognized conflicts between the NWDs of the various system stakeholders. The best kind of SD is the intentional kind; the very worst kind is the result of unrecognized conflicts – especially with one

or more stakeholders being unknown. In order to avoid unintentional or unrecognized SD, we need to analyze and map potential conflicts between different stakeholder NWDs.

I am unaware of any structured, systematic approach for discovering potential SD. At present, it seems that only a tedious, subjective analysis is available. The analysis benefits from visualization by simple mapping of both agonistic and antagonistic NWDs from the different identified stakeholders. While this reveals an important weakness, it is by no means fatal for the approach. Any potential SD that can be discovered or predicted before deployment is one less cause of reduced safety, effectiveness, efficiency, and/or user satisfaction.

Risk Analysis

Once potential sources of SD have been identified, they need to be prioritized for mitigation. Not all SD can or will be mitigated. A well-established initial method for mitigation prioritization is risk analysis. Frequently used is the FMEA (Failure Modes and Effects Analysis); this is a "bottom up" approach that yields a risk prioritization in-dex. However, this inductive analysis relies not on quantitative, historical data, but on subjective, experiential input provided by the analyst. Using this technique alone is dangerous, in that it does not identify nearly all the actual hazards. Wetterneck et al (2006) report data that indicates less than 75% of infusion pump failure modes identified in actual practice were captured, in advance, by their FMEA. When historical, quantitative, failure rate data are not available (this is very often the case), improving the reliability of the risk analysis can be achieved by iteratively combining inductive and deductive analyses (e.g., FMEA and RCA, see Figure 11). The combined use of the "top down" and the "bottom up" analyses usually gives greater coverage, compensates for inherent weaknesses in each of these analytic techniques, and assists the analyst by providing two points of view (not unlike depth perception for a biological visual system).

Prioritizing Stakeholder Dissonance for Mitigation

Prioritizing SD for mitigation initially is based upon risk analysis. However, unless financial

Figure 11. Risk analyses

	Input Data	
	Historical, Quantitative	**Subjective, Experiential**
Top Down (Deductive)	Fault Tree Analysis (FTA) Event Tree Analysis (ETA)	Root Cause Analysis (RCA)
Bottom Up (*Inductive*)	Failure Modes , Effects and Criticality Analysis (FMECA)	Failure Modes Effects Analysis (FMEA) Hazard & Operability Studies (HazOp) Hazard Analysis & Critical Control Points (HACCP)

Analytic Technique

and technical risks are included in the initial analyses, further prioritization based first upon technical feasibility (can we do anything about it?) and then based upon cost-benefit (is it actually worth doing?) is required to arrive at a final prioritization list.

While technical feasibility is always used to eliminate candidates for priority, unless cost is the only optimization criterion, we must then turn to the general category of decision analysis methods. They can be as simple as Pareto, paired comparison, grid, force field, or decision tree analysis (Pyzdek, 2003). When multiple criterion optimization is sought, well-established techniques routinely used in business are of value. These include linear or non-linear programming (depending upon the shape of the constraints) and multiple criteria decision-making (cf., Dyer et. al., 1992; Zeleny, 1998).

QUANTITATIVE DESIGN INPUTS FOR SYSTEM VALIDATION

An un-validated system deployment is a "shot in the dark" and an unknowable risk to the organization. System validation is the demonstration that the deployed system actually conforms to the system design inputs (the system requirements). Requirements in HCSE are defined as the subset of identified or discovered NWDs that are economically and technologically feasible at a given point in time. One critical attribute of system requirements is that they must be measureable, which means they must be unambiguously operationalized, so they can be quantified.

The general outline for managing SD is shown in Figure 12. The approach may be used both for technology deployment as well as for deployment of other processes and services. Figure 12 provides a high-level overview, depicting it as three interlocking process cycles: a technology (re-) development cycle, a deployment (re-) design cycle, and a post-deployment surveillance cycle.

These activities are drawn as cycles to emphasize that they represent iterative processes – a key feature of HCSE.

The deployment design cycle, the subject of this chapter, consists of 10 sub-processes (the last of which is deployment validation in a pilot setting prior to general release) and 2 critical decision points (see Figure 12). The first five sub-processes consist of:

a. identifying and mapping all the stakeholders,
b. soliciting stakeholder input on SEES,
c. translating the SEES to NWDs,
d. identifying and mapping dissonance among stakeholders, and
e. conducting risk analyses to help prioritize dissonance mitigations.
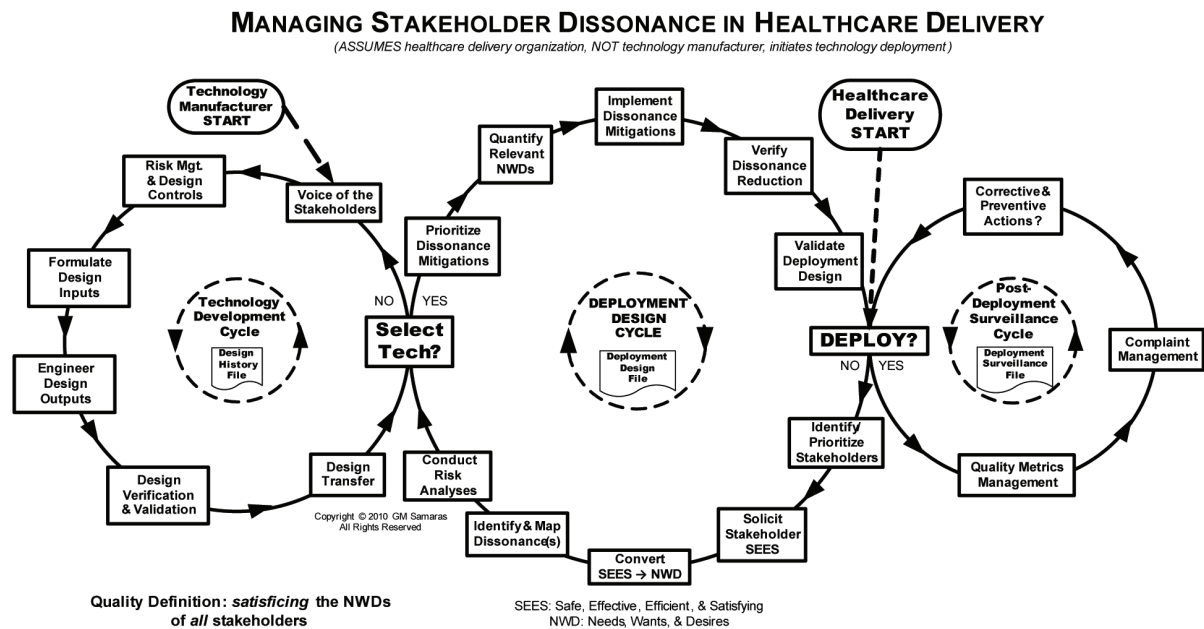
At this juncture, if technology is involved, a critical management decision is made whether or not the candidate product is acceptable; if not, technology redesign or selection of a different vendor may be warranted. The last five sub-processes of the deployment design cycle are:

f. prioritizing identified dissonance mitigations,
g. operationalizing and quantifying only the relevant NWDs involved in the selected mitigations,
h. implementing the selected dissonance mitigation(s),
i. verifying in a pilot setting that the selected dissonance was actually reduced, and
j. validating the deployment design in that pilot setting.

At this juncture, the second critical management decision is made whether or not to deploy the product, process, or service throughout the organization.

The seventh step in the process (step g of the deployment design cycle) requires quantification of the relevant NWDs, which we discussed in detail in the section on human centered system complex-

Figure 12. Three interlocking cycles of the SD management process

MANAGING STAKEHOLDER DISSONANCE IN HEALTHCARE DELIVERY
(ASSUMES healthcare delivery organization, NOT technology manufacturer, initiates technology deployment)

ity. There we identified how various **p**hysical, **b**ehavioral, **s**ocial, and **c**ultural (PBSC) factors may be operationalized. The relevant NWDs are those NWDs expected to lead to critical SD and have high priority for reduction or elimination. The reason we need to quantify these particular NWDs is that once we have applied a proposed mitigation, we must have a means to ascertain whether the SD was actually reduced, and then we need to validate that the selected NWDs (those transformed into system requirements) were actually met by the deployment design.

It is at this point that we can answer the question "what do I need to measure" and it is at this point that the measurement techniques in Table 1 (the previously defined PBSC measures) finally are used. Those NWD conflicts identified by prioritization for reduction or elimination are operationalized and quantified using the scientific measurement techniques identified in Table 1. Who (what individuals) will do the measurements depends solely upon what areas of expertise you have in-house; for measurements outside their

areas of expertise you will have to turn to academics, consultants, etc.

Consider the deployment of a new infusion pump. NWD conflicts will probably arise among management, purchasing, nursing, and biomedical engineering. Among all four stakeholder groups, we will likely be dealing with covert social factors (conventions and expectations) related to efficiency and effectiveness that require measurement skills from social psychology and sociology. Between purchasing and nursing stakeholders, we will likely be dealing with overt and covert information management behaviors related to workload, safety, and ease of use issues associated with pump programming that require measurement skills from cognitive and physiological psychology. Between nursing and biomedical engineering stakeholders, we will most likely be dealing with overt social and cultural factors related to language differences and safety/risk communication; there may also be conflicts related to differences in shared values between these two stakeholder groups. Prior to full deployment, you will need

to demonstrate that some or all of these potential NWD conflicts have been adequately mitigated; if not, validation fails and deployment throughout the organization is ill advised.

In the next section, using 20-20 hindsight, we look back at healthcare delivery system deployment situations (computerized provider order entry and bar coded medication administration) where SD occurred, subsequently became evident, and where some SD might have been avoided by the application of the principles of human-centered systems engineering.

RETROSPECTROSCOPY

Campbell et. al. (2006) have identified nine unintended consequences of computerized provider order entry (CPOE) systems deployment: more or new work for clinicians; unfavorable workflow issues; never-ending system demands; problems related to persistence of paper orders; unfavorable changes in communication patterns and practices; negative feelings toward the new technology; generation of new types of errors; unexpected changes in an institution's power structure, organizational culture, or professional roles; and overdependence on the technology. These correlate well with the findings of Koppel et. al. (2005). With the possible exception of "never-ending system demands", we can be quite confident that the remaining eight issues would have surfaced in structured interviews and structured focus groups of clinicians seeking to solicit stakeholder's SEES opinions. The extent to which SD could have been reduced would depend upon the deploying organization's conclusions regarding their risks. It would also depend upon their ability to delay deployment, until a validated deployment process design was achieved. Weighing the risks of delays versus the risks of failures is a critical management engineering activity.

Patterson, Cook, and Render (2002) identified five negative side effects of deployment of Bar Code Medication Administration (BCMA): nurses confused with automated removal of medications; reduced communication and coordination among physicians and nurses; nurses skipping steps (e.g., wrist band scanning versus entering patient identification) to reduce workload at peak times; increased prioritization of timely medication administration during goal conflicts; and difficulty modifying routine tasks. Koppel et. al. (2008) report a variety of BCMA-related workarounds, including omission of process steps and unauthorized BCMA process steps, all of which appear to have the intent of workload leveling. Bargren & Lu (2009) conducted a detailed case study analysis of altered nursing workflow following introduction of a BCMA system, reporting that the number of steps (a measure of workload) nearly doubled for their inpatient unit. Rothchild & Keohane (2008) assert that unintended consequences of healthcare technologies "more commonly are due to design flaws related to human factors and real world use, unexpected or unaccounted cultural and behavioral interactions, and inadequate training and implementation." While BCMA has the potential to improve patient safety by supporting the five "*rights*": *right* Patient, *right* Drug, *right* Dose, *right* Route, and *right* Time, failure to deploy BCMA systems properly facilitates errors in each of these five parameters. Deploying a system that adversely impacts actual or perceived workflow results in undermined communication & coordination, challenges conventions, expectations, and shared values, and results in stress that compromises covert physical and behavioral factors (see Table 1); clearly, this was never the intent of the deploying organization. Proper application of HCSE would have permitted mitigation of many of these problems.

CONCLUSION: ADDING THE RIGHT VALUE RIGHT AWAY

No matter how well a tool is designed (and there is always room for improvement), how the tool is actually deployed in a particular organization will always be a rate-limiting step in progress towards excellence in healthcare delivery. Value is what each stakeholder cares about, regardless of the views of all other stakeholders. *Satisficing* the NWDs of all the stakeholders provides a balanced local definition of value objectives. SD is "waste" and we attempt to reduce it to minimize its adverse effects on the value stream. Pre-deployment SD recognition and mitigation offers an opportunity to improve healthcare delivery by supporting **S**afe, **E**ffective, **E**fficient, and **S**atisfying organizational operations. The focus on identifying all the stakeholders and satisficing their NWDs provides a powerful mechanism for adding the right value right away. As healthcare delivery cost constraints intensify and sensitivity to TCO increases, avoiding costly errors, misjudgments, threats to patient safety, and threats to organizational profitability will require increasingly rigorous approaches for development and deployment of new technology. Human-centered systems engineering offers a powerful tool for management engineers.

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