Using Human-Centered Systems Engineering to Reduce Nurse Stakeholder Dissonance

Elizabeth A. Samaras and George M. Samaras

Editor's Note: *Stakeholder dissonance (SD) is a term for the conflict between the needs, wants and desires of different stakeholders. It is evidenced by errors, workarounds, and threats to patient safety and organizational profitability. Nurses are principal stakeholders for patient care technology. This article discusses three examples of new technologies that resulted in nurse SD: computers on wheels, bar coded medication administration, and infusion pumps. Conceptual models, concrete tools, and strategies are offered to resolve, reduce, or mitigate nurse SD across the lifecycle of new healthcare delivery products, processes, and services.*

The Institute of Medicine (IOM) reported on its collaborative initiative with the Robert Wood Johnson Foundation: *A Summary of the October 2009 Forum on the Future of Nursing: Acute Care*.[1] Dr. Marilyn Chow, a nurse, offered these cautionary words: "The acute care environment is being reshaped by technologies, business models, and human needs. New acute care models will either emerge haphazardly by default or coherently by design." The report offers a nursing perspective and vision regarding the central role nurses may play to narrow the gaps in care, reduce patient risks, and achieve the promise of the IOM's earlier quality initiatives.[2,3]

The report comes as the United States begins a multibillion dollar investment to fund comparative effectiveness research priorities and offer incentives to private practitioners and hospitals to adopt and meaningfully use healthcare information infrastructure, such as electronic health records (EHRs).[4] These efforts promise to reshape the acute care environment and add new levels of complexity to healthcare delivery.

Safety, effectiveness, efficiency, and satisfaction are the top-level needs, wants, and desires (NWDs) of all healthcare stakeholder groups.[5] They are influenced profoundly by the development and deployment of new technologies. Ignoring or misjudging their influence leads to stakeholder dissonance (SD)—a lack of agreement, consistency, or harmony among various stakeholders. SD is a term for the conflict between the NWDs of different stakeholders as evidenced by errors, workarounds, and threats to patient safety and to organizational profitability.

The Nurse Stakeholder

According to the American Association of Nurses, nursing is the "protection, promotion, and optimization of health and abilities, prevention of illness and injury, alleviation of suffering through the diagnosis and treatment of human response, and advocacy in the care of individuals, families, communities, and populations."[6] Nurses have a foundation of shared ethics in the adherence to the ethical principles of non-malfeasance or "Do No Harm," and in their professional Code of Ethics for Nurses with Interpretive Statements,[7] with the specific mandate to serve as a patient advocate.

Registered nurses (RNs) are a heterogeneous group, but with shared values and demonstrable core competencies. They must abide by a fundamental scope of practice and complete the minimum educational requirements as mandated by state nurse practice acts. All must pass a national standardized examination required for licensure as an RN. According to a recent U.S. Department of Health and Human Services report,[8] there are more than three million licensed RNs living in the United States, with approximately 85% of these actively employed in

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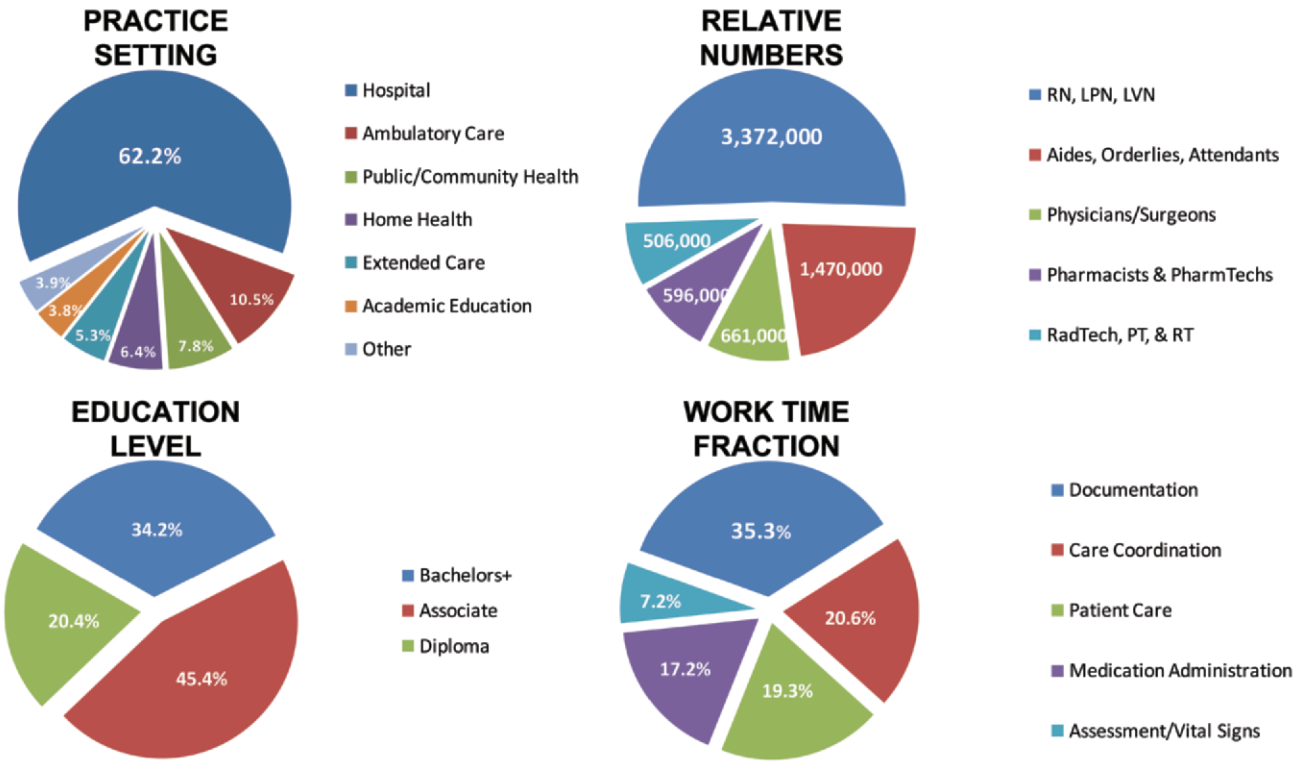

Figure 1. Nurses and Nursing (Practice Setting, Relative Numbers, & Education Level data from National Sample Survey of Registered Nurses, 2010)[8]; Work Time Fraction data from Hendrich et al. (2008).[11]

nursing positions. These numbers make RNs the largest group of healthcare professionals in the country (see Figure 1: Relative Numbers).

Those entering nursing come from a variety of educational backgrounds (see Figure 1: Education Level). More than a quarter of a million RNs reported they were additionally prepared as advanced practice nurses (APNs) in one or more advanced specialties or fields; more than 400,000 RNs reported having a master's or doctoral degree in nursing or a related field.

The average age of the RN population has been rising over the past two decades and was reported as 45.5 years in the 2010 report. In terms of gender, race, and ethnicity, the RN population does not mirror that of the U.S. population as a whole. Nearly 83% of RNs describe themselves as non-Hispanic white, compared to about 66% of the overall U.S. population. The vast majority of RNs are women. In the report, only 6.6% of all RNs were men; however, the relative percentage appears to rising with more men (9.6%) graduating as RN-eligible nurses since 1990.[8]

If one were to add licensed practical nurses (LPNs, also known as licensed vocational nurses or LVNs), the only other group legally recognized as nurses, more than three-quarters of a million additional individuals would be included.[9] The LPNs/LVNs have yet another set of educational and practice standards, with less formal training and a more limited scope of practice. They are instrumental in delivering nursing care in the United States and reflect an important part of the nurse stakeholder population.

Nursing characteristics are not homogeneous, which poses significant challenges for human factors practitioners.

Nursing Practice Settings and Work Complexity

Registered nurses work in a variety of settings. Most RNs reported that they worked in hospitals;[8] the remainder reported working in ambulatory care, public/community health, home health, nursing or extended care facilities, academic education, and "other" (such as insurance, benefits, utilization review, or medical device/pharmaceutical manufacturers; see Figure 1: Practice Setting).

The hospital acute care setting is quite varied including, but not limited to, general pediatric or adult medical-surgical floors, intensive care units, and specialty units (neurology, oncology, dialysis, emergency and operating

room). Each has its own anticipated patient population and acuity, cadre of providers, routine activities, procedures and priorities, disruptions and emergencies, nurse-patient ratios, physical layouts, unit-specific subcultures, and a host of other factors that prevent easy generalization across practice environments.

Including the broad range of community-based practice settings where nurses are found and patient care devices are used increases the complexity of defining the use environment. At any point in time, in any practice setting, we may encounter a broad spectrum of nursing skill and experience from novice to expert.[10] Nurses are not a uniform, one size fits all, stakeholder group.

Hendrich et al.[11] conducted a time and motion study that documented how nurses in a 36-hospital study spent their time (see Figure 1: Work Time Fraction). It demonstrates the enormous indirect effort (>50%) currently required of nurses relative to direct patient care.

Krickbaum and colleagues coined the term "complexity compression" to describe "what nurses experience when expected to assume additional, unplanned responsibilities while simultaneously conducting their multiple responsibilities in a condensed time frame."[12]

Ebright, Patterson, Chalko and Render[13] describe the constant change, patterns of work complexity, breakdowns in communication, and the way nurses respond cognitively to these factors. They assert that the work environment can both "support and hinder" the decision-making processes of the RN. They observed certain cognitive behaviors and categorized them as goal, knowledge, and management of care patterns. They describe "proactively monitoring patient status" as one such pattern, and "stacking" or moving on to other activities to prevent down time while waiting for resources or processes as another.

Potter and colleagues[14] measured nurse stacking by tracking patient care tasks and priorities over time, with activities and priorities added or subtracted sequentially as they were identified or completed. They illustrate the way nurses must "cognitively shift" attentiveness between one patient and another, graphically depicting these cognitive pathways, as well as the associated physical behaviors (e.g., movements between locations). These authors also consider the frequent interruptions nurses routinely encounter and ways these disruptions may impact the cognitive work and cognitive load of the nurse, thereby contributing to errors and omissions in care.

Ebright[15] argues that failure to understand the ways that RNs make their care decisions within the complex and often-unpredictable healthcare delivery system will contribute to the design of processes and technologies that further complicate the decision-making and work of the RN, leading ultimately to unsafe care.

Like human factors engineering, nursing is patient-centric; both focus on humans within the context of their environment (e.g. hospital, home/nursing home, workplace, and community). The nursing process—assess, diagnose, plan, implement, evaluate—is a systematic, interpersonal, iterative, and dynamic series of cognitive processes and behavioral activities that parallels the systems engineering process.

Human-Centered Systems Engineering

Classical systems engineering is a structured, systematic approach to the development, deployment, and replacement of products, processes, and services. Systems engineering is a very powerful mechanism for reducing business and technical risks. Human-centered systems engineering (HCSE) extends systems engineering to emphasize the criticality of human actors (*actors* is a term of art in the social sciences and economics that subsumes *users*) and their organizations in the engineering process.[16] Like the nursing process, the HCSE process has an essential iterative nature,[17] each new iteration beginning with the (re-)identification of stakeholders and assessment of their NWDs: needs (basic needs or *"must have"*), wants (performance needs or *"like to have"*), and desires (latent needs or *"I'll know it when I see it"*).

Introducing human actors 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 is used often 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 user (or groups of users and/or their automated aides). Humans dramatically increase system complexity. Complex systems have *emergent* properties, the result of component interactions, 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 user training. Not fully appreciating human-centered system complexity, especially in risk management, has been

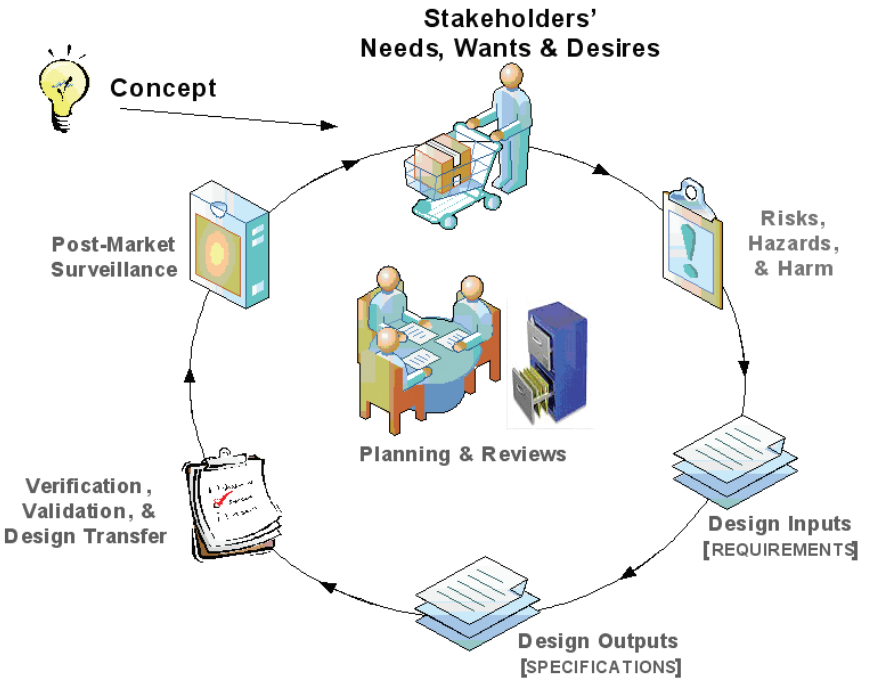

Figure 2. HCSE Iterative Development Paradigm, adapted from Samaras, GM (2010).[17] Copyright © 2008-2010, GM Samaras, all rights reserved.

an important obstacle in the design and implementation of essential systems. Merely applying technology to solve identified problems often creates previously unidentified problems (e.g., see how a decade's difference dramatically altered perspectives of computerized physician order entry in Tierney et al, 1993 vs. Koppel et al, 2005).[18, 19]

A human-centered approach requires a detailed appreciation of 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.

Identifying and Quantifying Stakeholder NWDs

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*[20] all the stakeholders, which means to obtain a good enough result, though not necessarily the best, for each stakeholder. This precedes, and is the basis for, updating and reformulating the engineering requirements (design inputs) in each iteration (Figure 2). Engineering requirements are the subset of *all* the stakeholder NWDs that are technologically and economically feasible at a given point in time.

This shift in emphasis tends to mitigate errors and omissions early in the system development and deployment cycles, reducing the final cost. Absent robust HCSE, essential medical systems (e.g., clinical information exchange, medication management, and clinical decision support) will continue to hinder rather than help, be economically inefficient, and be examples of poor quality. To manage this, we must be able to measure and control the interfaces.

The measurement methods belong to a wide range of scientific disciplines. 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). The assessment and validation of human interface attributes is a process that must be multi-disciplinary.[21]

Reducing Errors and Workarounds

Many incidents and accidents are alleged to be caused by human error, but the question is: Which human(s) made the error? One way to consider this question is through the lens of *use* error v. *user* error. *Use* errors are attributable to the design and/or deployment of the system; they result from the myriad interactions of design errors and organizational issues. User errors are attributable to the internal or external user environment, excluding the system itself. So which humans are we blaming—the human operators or the human developers/deployers? (For a nursing-specific example, see Waterworth, 2003.[22])

Human *use* errors of a system 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 deployer (e.g., avoid confusing or frustrating the operator, avoid undesirable physical or

cognitive exercises, avoid delays and operator attention loss, avoid certain workloads and work schedules).

In healthcare delivery, safe and effective systems (products, processes, and services) are the goal. However, multiple human stakeholders complicate the process at a myriad of levels—from conceptualization through development, deployment, and replacement. Only recently has there been a concerted effort to include systematic consideration of human factors and ergonomics in the design process. Human factors and ergonomics must be, from beginning to end, a critical consideration in design, development, deployment, and replacement. While this is an objective of the medical device usability engineering standard ISO/IEC 62366,[23] the standard is limited to the usability component and is not intended to address the broader individual and organizational human factors issues of SD, especially during deployment and replacement.

HCSE Tools

HCSE is the foundational paradigm for addressing SD. HCSE is an extension of classical systems engineering and is an attempt to integrate human factors and ergonomics considerations throughout the system lifecycle—from "lust to dust." It is an attempt to consider the full range of human interfaces (physical, behavioral, social, and cultural) in a systematic manner, leveraging the measurement capabilities of a wide range of scientific disciplines, many of which are only now being considered useful for system development and deployment.

To anticipate and avoid nurse SD, a range of factors must be evaluated in a structured, systematic manner.[5] Some examples are:

- Micro-ergonomics *(physical ergonomics)* deals with the individual nurse using simple tools. Overt factors are static size and fit (e.g., nurse's fingers must fit the bandage scissors). Covert factors are dynamic "size and fit": biomechanics (e.g., the pressure a nurse must apply to depress syringe plunger) and sensory processes (e.g., a nurse wants to use a device under low light and minimally intrude upon sleeping patients; one audible alarm interferes with detecting another audible alarm).
- Meso-ergonomics *(information management ergonomics)* deals with the individual nurse using tools with automated features (e.g. tools with alarms, decision support, or autonomy). Overt factors are verbal and non-verbal behaviors (e.g., nurse uses verbalization or physically moves a mouse/trackball). Covert factors are affective behaviors (e.g. nurse's frustration programming an infusion pump; nurse's annoyance with multiple, simultaneous audible alarms), cognitive behaviors (e.g., nurse figures out the programming steps for the pump) and physiologic behaviors (e.g., nurse's heart rate increases due to time pressures and frustration with programming difficulties).
- Macro-ergonomics *(social ergonomics)* deals with groups of individuals operating within an organization (e.g., two or more nurses; a purchasing agent and nurses). Overt factors are communication and coordination (e.g., two nurses verifying drug and dosage settings for a patient-controlled analgesia device; a hospital purchasing agent not communicating or coordinating with nurse end users). Covert factors are conventions (e.g., the purchasing agent does not solicit input from nurse end users due to existing contracts with preferred vendors) and expectations (e.g., assuming nurse end users will "safely and effectively" work with any device purchased).
- Mega-ergonomics *(cultural ergonomics)* deals with groups of individuals operating in different subcultures (e.g. nurse vs. engineer). Overt factors are language (e.g. nurse-speak vs. engineer-speak) and tangible artifacts (e.g., the nurses' stethoscopes and patient charts versus the engineers' oscilloscopes and data sheets). Covert factors are shared values (beliefs, customs, ethics, and morals) such as the nurses' patient-centric emphasis versus the engineers' technology-centric emphasis.

Historical Examples

When nurse NWDs are ignored in favor of other stakeholder groups or are not recognized (not made obvious) due to inadequate understanding of nurse norms/roles, then conflicts arise and express as SD. Errors, workarounds, or outright rejection of newly introduced products, processes, or services are typical outcomes of SD. Bakken[24] has reviewed numerous examples in the context of applying informatics for patient safety. Here are three examples that led to nurse SD; they all are linked directly to healthcare delivery safety, effectiveness, efficiency, and satisfaction. In hindsight, the conflicts and missing nursing NWDs in the development and deployment of these products are obvious; they apparently were not obvious during initial development and deployment.

Computers on Wheels

The use of electronic medical/health records (EMR/EHR) throughout the United States and globally—with its computerized provider order entry, documentation, and other features—has made considering the right design and mix of mobile and stationary computing devices important. In one study's[25] settings, clinicians were able to choose from one of the following devices to perform computer-based tasks: stationary personal computers (PCs), tablet PCs, and two types of computers on wheels (CoWs)—the first, a generic CoW, consisting of a laptop mounted on a basic trolley; the second or "ergonomic" CoW with a specially-designed integrated computer and cart.

Nurses overwhelmingly chose the generic CoW (93.1% of the time) to perform their tasks, over its "ergonomic" counterpart and the other computer device options combined. The generic trolley had a larger work surface and more storage space for medications, papers, and/or other equipment. Nurses viewed it as more versatile in terms of task performance (e.g., with its convenient storage space for medication and tools for medication administration) and mobility (e.g., it could be used everywhere, including at the bedside); these benefits appeared to outweigh some of its disadvantages, such as reduced battery time.

Bar Coded Medication Administration

Medication errors have been a longstanding problem with great publicity resulting from the 1999 IOM report "To Err is Human."[2] The goal of bar coded medication administration (BCMA) is to support the six "rights" of medication administration: right patient, right drug, right dose, right route, right time, and right documentation. Failure to use BCMA systems properly facilitates errors in each of these six parameters.

Koppel et al.[26] observed 15 different workarounds (e.g., putting barcodes on computer carts, scanners, and the nurse's person) and 31 causes of workarounds (e.g., unreadable medications and medications that were not bar coded, poor or intermittent wireless connectivity, and failing batteries).

Vogelsmeier et al.[27] observed workarounds related to blockage or disruption in workflow arising from the technology design and/or the organizational implementation.

Ross[28] reports a collaborative effort to implement BCMA modeled on an organizational change approach with nursing, pharmacy, and information technology, involving group processes, and resulting in improved outcomes in patient safety. While preventing large numbers of monthly medication errors, the root cause(s) of these errors were not identified or directly mitigated.

Bargren and Lu[29] 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.

Weckman and Janzen's[30] report involved nurses in each phase of the Shewhart cycle (Plan-Do-Study-Act) during introduction of BCMA. They concluded "it is nurses who are in the best position to identify the clues needed to resolve underlying systemic issues and offer ideas for possible resolution." However, they also report the nursing staff (and local biomedical engineering staff) overlooked the need for brakes on the medication cart, which we interpret as the absence of structured, systematic risk management.

Infusion Pumps

Infusion pumps (IPs) have long been the "poster-child" for human factors failures and nurse SD. From a human factors perspective, IPs are highly complex medical devices of great clinical value, but prone to many *use* and *user* errors. IPs are associated with tens of thousands of adverse event reports, continue to have multiple product recalls, and are alleged to have caused many deaths and injuries. The problem is so pronounced that the U.S. Food and Drug Administration (FDA) recently ordered destruction of about 200,000 IPs.

Ergonomic difficulties encountered by nurses are well known (e.g., non-intuitive operations, hard-to-read screens, hard-to-understand menus, incorrectly sized icons/numbers, poor design/layout of manual controls, poor labeling, nuisance/too many/too frequent alarms, and the compounding of these problems by combining individual devices into multiple channels). Incorporation of wireless communication and increasingly complex safety systems (e.g., user programmable drug libraries, integration with BCMA and EMR) will further challenge development and deployment of these important clinical tools, creating new sources of nurse SD and resulting in new types of errors, workarounds, threats to patient safety, and threats to organizational profitability.

The draft of a new FDA IP improvement initiative[31] indicates increased scrutiny for premarket clearance

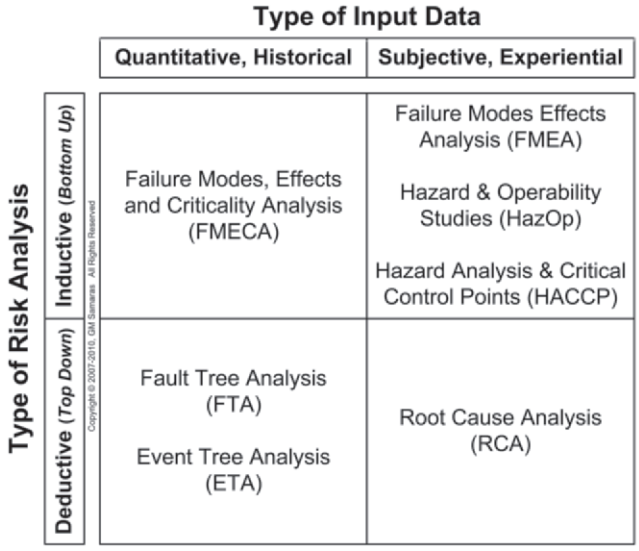

Figure 3. Some Types of Risk Analysis vs. Type of Input Data

and "suggests" conducting additional risk assessments, validating control measures, and presenting results to the FDA using an assurance case framework.

Risk management for these complex devices, especially with regard to human factors issues, can no longer be business as usual. Wetterneck et al.[32] report data indicating that less than 75% of infusion pump failure modes identified in actual practice were captured in advance by their failure mode effects analysis (FMEA). FMEA is a non-quantitative, subjective, and experiential technique (Figure 3), demonstrably inadequate based on decades of actual IP experience. It is worth noting that the medical device risk management standard ISO 14971[33] does not countenance using FMEA alone. A composite of inductive and deductive techniques, probably with greater analytical rigor, seems to be required.

Managing Stakeholder Dissonance

Quality in HCSE is "the degree to which the system *satisfices* the NWDs of all the stakeholders."[34] By this definition, we cannot eliminate all dissonance for all stakeholders; our objective must be to optimize the system based upon one or more criteria, such as patient safety, seller/purchaser cost, employee satisfaction, etc. You cannot manage what you cannot control and you cannot control what you cannot measure. Managing dissonance among stakeholder groups requires five iterative activities (I-A-D-P-R):

- Identifying all the stakeholders (not just those initially deemed important)
- Assessing stakeholder NWDs (to make them obvious) quantitatively
- Discovering SD within and among stakeholder groups
- Prioritizing SD for control using risk management
- Reducing overall SD in the system—resulting in a system that is safer, more effective, more efficient, and more satisfying to use.

This methodological approach has been applied experimentally in an actual study of stakeholders prior to a technology deployment; the report[5] details the approach, but also exposes the technical difficulties attempting to manage dissonance among stakeholders.

Identifying ALL the stakeholders is fraught with difficulty and only an iterative approach reduces omissions. Now we know that custodians and housekeepers are important stakeholders for sharps disposal; this was not obvious originally. It should be apparent that nurses are important stakeholders throughout the full lifecycle of patient care technology—from design and development to deployment and replacement. The evolving NWDs of nurses, in addition to those of many other stakeholders (physicians, regulators, purchasers, vendors, etc.), must be considered at each stage of design, development, deployment, and replacement.

Quantitative assessment of NWDs is not only a multidisciplinary endeavor, it is tedious and resource intensive. It may be expedited initially by analytical methods, but must be followed by empirical assessment (e.g., using structured focus groups followed by simulated/actual clinical validation trials). The increasing availability of simulated clinical wards used as training tools for nurses offers a new approach and venue for preliminary clinical validation studies; this cannot replace actual clinical validation studies, but it may provide a useful venue for exploratory studies and ranging experiments.

SD risk management cannot be simply subjective inductive analysis (e.g., FMEA). At a very minimum, a blend of expert opinion (e.g., hazard and operability studies) combined with deductive risk analysis methods (e.g., fault tree analysis or root cause analysis) are required to support the formulation and verification of the subjective FMEA (Figure 3) leading to a structured assurance case. At the very minimum, the analysis must include consideration of expected use, unexpected use, misuse, and abuse, so as to address not only product reliability, but also prevention of hazards that might lead to recalls and product liability. We expect that formal methods (mathematical modeling and simulation), well established in

other domains, will be adopted as a competitive business tool.

Systematically considering the nurse stakeholder in every phase of new technology design, development, deployment, and replacement is essential in mitigating many of these hazards. ■

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