The Growing Move Toward Clinical Systems Engineering

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In 2005, the Institute of Medicine (IOM) book *Building a Better Delivery System: A New Engineering/Healthcare System*,[1] made the case that a partnership between healthcare and engineering could lead to significant improvements in the healthcare delivery system, essentially by recognizing that it is, in fact, a system of interlocked systems, each with its own work flows, resources, overhead, and product. Some of these systems deliver care directly, such as emergency room queuing. Others are more behind the scenes, such as cycling of IV pumps or maintaining operating room (OR) sterile packs.

The IOM book, which was jointly drafted with the National Academy of Engineering, cites the need to apply systems engineering principles to the improvement of these systems. This is significant in that it gives recognition by the clinical community to the fact that solutions to complex problems in the healthcare environment sometimes derive from other disciplines.

More recently, Richard Schrenker reported in *IT Horizons*[2] that as clinical engineering (CE) and information technology (IT) have converged, they have exposed not only the complexity of the healthcare IT system as a system of systems, but have also demonstrated that the clinical engineer is positioned by training and experience to meet the need for systems engineering in the technological side of healthcare. He makes the argument that there are broader areas of healthcare where clinical engineering can similarly function; however, the very success of clinical engineering in the clinical information arena has tended to create a "blind spot," both in the profession and in the eyes of healthcare leadership regarding the broader application of clinical engineering in addressing the broader issues of healthcare delivery.

Clinical engineers have the opportunity and responsibility to demonstrate to leadership that just as they are overcoming the CE-IT problem of making technical systems work together, they are in place and capable of addressing other system-based challenges in healthcare. The IOM report notes that as of 2005, very little talent had been devoted to optimizing or improving operations, or measuring or developing quality and production. It postulated the need to develop and/or identify engineering tools and technologies to help deliver healthcare that is "safe, effective, timely, patient centered, efficient, and equitable." Unfortunately, five years later, very little progress has been made.

While the IOM report recognized the transformative value of a partnership between engineers and healthcare professionals to reconfigure the current loose collection of practices into a cogent system of systems, it did not recognize, as Schrenker does, the existing resource of clinical engineering. Further, while the IOM report outlined a series of standard systems analysis tools—such as statistical process controls, queuing theory, modeling and simulation, and human factors engineering—its recommendations were heavily weighted toward research and development based in academia and government agency. One IOM recommendation advocates the introduction of healthcare issues into the engineering curriculum, oblivious to the presence of healthcare, technology and systems engineering in most clinical engineering degree programs.

It should be noted that while most clinical engineers are exposed to the tenets of systems engineering during their academic development, few have developed significant practical skills or experience on the job. However,

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they do bring their powers of observation and communication to work every day, along with the ability to relate clinicians' needs for process improvement to the systems engineering community.

The IOM strategy is bold and long term. In 2005, the report encouraged development in the following more technical areas as indicative of the potential for improvement of healthcare performance:

- Voice recognition systems
- Human interface—communications technology system interfaces
- Systems that spread costs among multiple users
- Software dependability in critical systems
- Secure dispersed databases
- Measurement of the impact of information/communications systems on the quality and productivity of health care

These issues are all familiar to clinical engineering, but not in the context of a system of systems. Only the move to a Nationwide Healthcare Information Infrastructure[3] has taken on the mantle of a system of systems. The federal government's focus on this as a national priority since 2004 has generated not only attention, but also some of the funding needed to bring it to fruition. The consistent economic pressure on the healthcare system, coupled with the recent recession and uncertainty about healthcare reform, have certainly contributed to the lack of progress on the initiatives recommended by the IOM.

Against this backdrop, healthcare remains in need of a more systems-based approach to process. As process increasingly involves software, and technology becomes ingrained in process, the need for systems analysis of both areas will become critical to assure consistent quality of outcomes. Since the IOM report was issued, two additional dimensions of complexity have been added to the technical cornucopia—the growth of wireless communications as a force in healthcare, and the emergence of home care and other remote sites of treatment. Achieving economic justification for clinical engineering to address the system of systems is clearly a challenge. There are cultural challenges and, in some cases, structural barriers to clinical engineers moving beyond the comfort space of existing practice. This is no better recognized than in the "call to action" statement of the IOM report, which reads in part:

> *"As important as good analytical tools and information communications systems are, they will ultimately fail to transform the system unless all members of the community participate and actively support their use. Although individuals 'on the ground' (i.e. those doing the work) often know best how to improve things, empowering them to participate in changing the system will require that they understand the overall goals and objectives of the system and subsystems in which they work. Based on this understanding, they can contribute substantively to continuous improvements, as well as to radical advances in process. The communication of the overall system and subsystem goals to individuals and groups at all levels is a crucial task for the management of the organization and encouraging and recognizing individuals for their contributions to continuous improvements in operations at every level must be a principal operating goal of management."*

This, in effect, opens the door for clinical engineers to utilize their individual and collective expertise to take a more active role in improving healthcare quality by improving the technology-imbued systems that are critical to the robustness of the individual hospital and the system as a whole. To make the business case for this, clinical engineering must address issues that are of concern to leadership.

The National Priorities Partnership (www.nationalprioritiespartnership.org), made up of 32 "diverse, high-impact stakeholder organizations working to bring about healthcare improvement," has defined nine waste-reduction priority targets. Waste reduction is an indicator of system optimization. As such, it also provides a measure of improved value or reduced cost—essential drivers of a business case. While the partnership's waste reduction targets are clinically oriented—such as inappropriate medication use, unwarranted diagnostic procedures, and preventable emergency department visits and hospitalizations—they point out the national mindset that reduction of waste can simultaneously have a significant impact on the quality of care and its cost. In addressing waste, the tenets of lean manufacturing are often considered the benchmarks. Maureen Bisognano of the Institute for Healthcare Improvement[4] (www.ihi.org) has adapted these as follows:

- Delay—Idle time spent waiting for something, such as utilization reviews, insurer payments, test results, patient bed assignments, OR prep, medical appointments
- Re-Work—performing the same task a second time, such as retesting, re-scheduling, refilling lost forms, rewriting of patient demographic data, multiple bed moves
- Overproduction—manufacturing of products or information that's not needed, such as precautionary "defensive" medical tests, surplus medications, excessive levels of paperwork
- Movement—unnecessary transport of people, products, or information, such as requiring patients to see a primary care provider before seeing a specialist who is clearly needed
- Defects—design of goods that do not meet consumer needs, such as medication errors, wrong side surgery, poor clinical outcomes
- Waste of Spirit or Skill—failure to address the many hassles in our daily work, hunting and gathering, re-calling the same things every day

Bisogano identified eight "internal drivers" of the waste that drives cost up and quality down. They include: unreliable processes, unwarranted variation between cases and providers, limited patient-centeredness, and "one size-fits-all" processes. Each of these is concerned with the integrity of process—its repeatability, reliability, effectiveness, and relationship to other processes within the system of systems.

Reduction of variability, for example can be as simple as the design of uniform patient rooms that face the same way. With opposite facing rooms, a common design, there is a greater likelihood of cross-connected medical gas systems—and more work. Half of patient televisions will face the sun, frustrating patients and forcing extra steps to close and open window blinds. In an emergency, the position of controls, displays, and connections are reversed in 50% of the rooms, and actions taken on the headwall are right-handed vs. left-handed. Throughout the hospital, such examples abound of ways in which process could be improved within the context of existing systems, work flows, and architectural design.

The six technical issues of the IOM and the six tenets for improving productivity identified by Bisogano form a crosswalk of target opportunities where clinical engineers can apply their interdisciplinary knowledge and communication skills to impact quality of care—locally and across the healthcare system.

An Important Opportunity

Clinical engineers have a window of opportunity to demonstrate their capacity to analyze and improve these complex systems. That opportunity lies in the application of core-systems engineering skills to the new healthcare technology challenges present in today's emerging clinical–information technology systems. This window of opportunity, given the industry's pressing needs for effective healthcare technology management, will only remain open for a short time before the role is filled by someone.

The exact nature of the new healthcare technology challenge was well articulated in a 2009 Networking and Information Technology Research and Development (NITRD) Program report, "High-Confidence Medical Devices: Cyber-Physical Systems for 21st Century Health Care."[5] The report, which is based on a series of workshops attended by industry scientists and experts, contrasts how today's healthcare technology is clearly an order of magnitude more capable, sophisticated, and

complex than previously experienced.

> *"With the advent of microprocessors, miniaturization of electronic circuits, wired and wireless digital networking, and new materials and manufacturing processes, older generations of mechanical and analog electromechanical devices used in patient diagnosis, monitoring, and treatment have largely been replaced by devices and systems based on information technologies across the diverse array of contemporary medical devices. They are often connected to other devices in increasingly complex configurations, potentially creating systems of systems that span scales from tiny (e.g., an ingestible digital camera with real-time video) to ultra-large (e.g., scanning and irradiation equipment and geographically distributed electronic records systems). The emerging classes of IT-enabled medical devices mark a significant paradigm shift: What used to be essentially passive devices controlled by a human operator are now complex computing systems whose embedded sensors and actuators not only monitor, but actively control, critical physiological processes and functions. The embedded computing, sensing, modeling, communications, and deep integration with physical elements and processes allow these new "cyber-physical systems" to achieve levels of functionality, adaptability, and effectiveness not possible with simpler passive systems."*

Both the 2009 NITRD and 2005 IOM reports recognize there is a need to apply multidisciplinary science, engineering, and education to develop new industry standards and to effectively design new interoperable clinical technologies. However both reports fall short in recognizing the healthcare provider's role in selecting, deploying, and effectively supporting those technologies. Most of us in clinical engineering have seen that regardless of how well standards are defined and technical systems are designed, technology's use in a clinical setting can lead to catastrophic results for patients and for healthcare operations if the appropriate preparations are not made and the appropriate support services are not maintained by providers. We know how clinical engineers were needed to address real issues of safety and support when discrete medical devices began appearing in the clinical environment in significant numbers some 35 to 40 years ago. However, the idea of a "discrete" medical device is largely disappearing. Also disappearing are many of the problems associated with those earlier devices (e.g., electrical issues, predilection for mechanical and thermal related failures), which have largely been "designed out" through technological advances.

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Today, those discrete devices are giving way to integrated systems and "systems of systems" (SoS) of such sophistication and complexity as to be beyond the ability of most providers and existing clinical engineering services to effectively manage.

What is to be done? It is time to recognize the need for a new healthcare technology management paradigm for healthcare providers. And it is time to recognize the need for the next major evolution in clinical engineering … the clinical *systems* engineer.

There are several key elements that are absolutely critical to the industry's and clinical engineering's ability to adopt an effective new technology management paradigm. They are:

1. Planning for change

Charles Darwin said that "It's not the strongest of the species that survives, nor the most intelligent, but the one most responsive to change." Technological developments in recent years have shown us just how much change has become a constant part of our personal and professional lives. In 1971, you could put the equivalent of 2,300 transistors on an integrated circuit.[6] A few years earlier, an Intel scientist conceived of Moore's Law, which predicted that industry would double the processing power of integrated circuits every 2 years. In 2010, Moore's Law is still in force as Intel just announced the first integrated circuit with the equivalent of 2 *billion* transistors.[7] We have seen extraordinary improvements in miniaturization and speed due in large part to this increased processing power, as well as the ability to store vast amounts of data in increasingly smaller volumes. These have led to huge advances in areas such as medical imaging, laboratory diagnostics, and micro-surgery. At this ever accelerating pace, the onslaught of new, more sophisticated, capable and complex systems is likely to continue. Healthcare

providers and clinical engineering must be "responsive to change" if we are to successfully adapt to this changing environment.

Too many clinical engineering services are still focused on the tactical aspects of medical equipment support. As a consequence, those clinical engineering services operate much as they have 20 to 30 years ago. To be a truly effective clinical engineering service, we must adopt a strategic approach to healthcare technology management where we focus appropriate resources on addressing the real challenges to effective selection, deployment, and support of these technologies. We must:

- Identify the nature of the technological challenges we face.
- Identify the resources (i.e., people, skills, technologies, environment, processes) required to meet those challenges.
- Apply and manage those resources, monitor their effectiveness, and constantly adjust as necessary.

We must be wary of complacency, and maintain a constant learning and adaptive mode to ensure we are prepared to address tomorrow's technology challenge as well as today's.

2. Gaining leadership buy-in

Effectively addressing today's healthcare technology challenges will require organizational commitment by providers to new strategic ways of thinking, new processes, and new infrastructure resources. Organization leaders and decision-makers (generally the "C-Suite") are typically intimately involved in the selection of new technologies. They also usually feel the operational and financial consequences of these decisions when they succeed—and particularly when they fail. However the decision-makers are often the least informed when it comes to what infrastructure (i.e., training, procedures, and technical support staff) is required for successful deployment, and use of new devices and systems. Leadership needs to be engaged and involved in a better-informed, decision-making process and made to understand strategic implications of adopting new technologies—their full risk, benefits and costs, including the extent of the infrastructure required to support them. To engage the decision-makers at both an organization and industry level, clinical engineering should work with academia, information technology, professional societies, and regulators to educate leadership on the need to adequately plan for new technologies and the consequences of not doing so.

3. Taking a strategic approach to healthcare technology assessment

Every healthcare provider should adopt a strategic approach toward the selection and adoption of new healthcare technologies. New technologies often compete for scarce financial resources and can have organizational implications reaching well beyond the department in which they're deployed. All stakeholders should adopt a strategic view and promote the concept that today's healthcare technologies are not a department, but rather an organizational asset. It is critical that key stakeholders (department chairs and top executives, such as the chief financial officer and the chief information officer) be engaged in the selection process, and that they seek the input of senior experts in CE, IT, risk management, etc. The benefits of acquiring new technologies should be measured against the organization's mission and goals. Do they improve care outcomes, patient safety, regulatory adherence, and revenues? Wherever possible, reviews of new technologies and their benefits should be evidence-based. Evaluate the need for and benefit of changes in process and workflows. Establish both the goals for new technology deployments and the metrics to monitor whether anticipated benefits are achieved.

4. Incorporating a systems engineering approach

Core engineering skills, particularly systems engineering, must be available to healthcare providers who hope to successfully respond to the challenges associated with today's healthcare technology. Many of the traditional tools and services previously used by clinical engineering are inadequate to deal with increasingly complex systems of systems. To remain relevant and in a position to appropriately support these systems, clinical engineering should acquire both systems engineering tools and the skills to use them—adopting a shared governance framework approach in CE-IT collaboration

A casual observer of technology's evolution will note how striking the convergence of information technology is with virtually every other form of technology, including communications, automotive, aviation, entertainment, and medical. The reasons for convergence are understandable—exponential gains in features and performance being among the most notable. While the healthcare industry was later than most to benefit from convergence, the trend is in full gallop now. One consequence of the changes in healthcare is that the two disparate groups that previously specialized in supporting

different areas—clinical engineering and information technology—increasingly work "elbow to elbow" on systems incorporating significant elements of both medical and information technology. The challenge is that clinical engineering's approach to dealing with patient-care equipment (some of which is life critical) and information's technology's approach to dealing with business systems (some of which are mission critical) could have highly nuanced differences. These differences and a lack of understanding about how they evolved often complicate the working relationship between the two groups. Yet both CE and IT are principally technology managers with many similar challenges. Ideally there should be a Rosetta Stone of best practices and syntax that could serve as a guide for both groups. Such a guide could facilitate their communications and collaboration in the support of technologies they have increasingly in common. It turns out, there are some excellent guidelines that, with some adaptation, might serve as a shared governance framework for both CE and IT. Two worth reviewing are *IT Service Management System* (ISO 20000-1)[8] and the *Information Technology Infrastructure Library* (ITIL v3).[9]Adoption of these guidelines has been increasing in many industries, including healthcare. Clinical engineering should review these and consider how they might be used to effectively integrate clinical and information technology service support.

5. Establishing a new infrastructure

While today's technology offers potentially great benefits to improving patient care and the overall delivery process, the infrastructure necessary to support that technology is substantial. The skills, processes, and tools that worked in the past are generally not going to work in the future. There needs to be a revamping of the infrastructure to ensure we achieve the benefits of the new technologies.

a. Skills

To address converged medical and information technologies, new skills are needed. These are likely to be found in new *hybrid* roles that build on critical elements from both clinical engineering and information services.[10] These new hybrid professionals include:

- clinical systems engineers (CSE), who will focus on strategic planning and management services associated with increasingly complex integrated medical systems
- clinical systems support specialists (CSSS), who will focus on technical services such as installation, configuration, and repairs of these integrated medical systems
- radiofrequency spectrum managers (RSFM), who will focus on monitoring and managing the influx of an increasing number of electromagnetic energy sources that compete for available spectrum and that, without effective management, could have a severe adverse affect on patient care or safety

b. Processes

Due to the strategic implications and complexity of today's technology, new processes related to the selection, management, use, operation, and support often need to be developed and adopted. Among those processes are:

- Technology acquisition—re-engineer to ensure a strategic focus and participation from all appropriate stakeholders.
- Inventory and tracking—ensure all system components and their relationships are identified and all configuration data is maintained.
- Integrating the service desk—create single-source help for clinicians, coordinated management of service process between clinical engineering and information technology.
- Scheduled service—identify and deliver only those services which have demonstrated success in improving safe and effective use of technology (e.g., user education, replacement of worn parts, and testing of performance when known to drift).
- Medical technology replacement planning—establish replacement scores based on such factors as the degree of obsolescence, condition, criticality, availability of support, and reliability.
- Consolidating technical services—bring management of all healthcare technology, including imaging and laboratory, under one coordinating source to facilitate monitoring of quality, consistent and centralized management of technical services through use of service level agreements (SLA).
- Managing vendors—manage vendor services associated with all healthcare technology to ensure regulatory compliance and coordinated system services

c. Tools

Effective support of new technology often requires what amounts to a new set of tools for many clinical engineers. The complex and integrated nature of today's healthcare technologies will require new tools for the technicians who install, troubleshoot, and maintain the systems (e.g., network scanners and configuration database management software). It will also require these systems engineering tools to plan, model, manage, monitor, and analyze system performance. These tools facilitate:

- Process engineering
- Data mining and analyses
- System modeling and simulation
- Human factors engineering
- Reliability analysis and failure modes effects analyses (FMEA)
- Risk management (identification, analysis, control/mitigation, and acceptance)

While these tools are often associated with "system engineering," they are in fact the basis of many engineering disciplines, and now there is a need for them to figure more prominently in the clinical engineering toolkit. Academic and professional organizations serving the clinical engineering community need to offer education in these areas to both those planning on or currently working in technology management.

Summary

Clinical engineers bring many attributes to solving problems. They are, by nature and training, keen observers and immensely curious—continually looking for ways to improve the status quo. The American College of Clinical Engineering's very definition of a clinical engineer—"a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology"[11]—speaks to this. While we have traditionally viewed this definition as relating to the management of medical technology, clinical engineers are equipped to operate on a much broader plane. The clinical engineer empowers the thoughts and ideas of others. Because of his/her unique position within the healthcare organization, the clinical engineer receives input from nurses, physicians, administrators, engineers, IT, and financial professionals.

This empowerment can extend beyond the traditional medical equipment technology management role to encompass the broader range of problems. Starting with the application of clinical systems and advancing to the science of process improvement, the clinical engineer can actualize the IOM's call to empower the "individuals on the ground" and translate their observations along with his or her own to improve systems and processes in healthcare.

Right now, there's a window of opportunity open for clinical engineering. Healthcare providers are faced with major challenges associated with selecting, operating, and supporting increasingly complex systems. They are also challenged to improve productivity and processes in both technical and non-technical areas. Those providers need significant help if they hope to achieve the promised benefits of these new technologies—benefits that could significantly improve the quality, effectiveness, timeliness, availability, and economics of patient care. If clinical engineering prepares itself by taking a strategic and systems approach to today's technology challenges, it may yet pass through that window and play a larger role in the design of tomorrow's healthcare delivery.

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