FEATURE STRATEGIC PLANNING

Healthcare Technology Challenges 2020

Defining a Framework for Success

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ABSTRACT

Over the next 10 years, healthcare technology will give us the possibility of transforming healthcare delivery in ways that can offer unprecedented quality, timeliness, effectiveness and availability. Some of these technologies include integrated clinical information systems, robotics, imaging, genomics, telemedicine and nanotechnologies.

However, these technologies are increasingly complex and integrated. Most organizations do not have the infrastructure to adequately deal with the proper selection, deployment or support of these new and emerging tools. These healthcare organizations must adopt strategic processes to ensure they select technologies appropriate to their missions and goals. These organizations must also evolve existing services, such as clinical engineering and information technology, into a seamless support service for medical and information technologies by adopting a common governance framework. Implementing a strategic technology selection process and evolving the technology support infrastructure (staff, processes, tools) are necessary to achieve the substantial benefits to patient care and economic sustainability.

KEYWORDS

Clinical engineering, medical technology, healthcare technology, governance, technology assessment, infrastructure.

WE ARE in a period of great change in healthcare. Much of what we have seen in recent years and much of what we are likely to see is attributable to the healthcare industry's adoption and use of rapidly evolving technologies, including medical devices/systems, information systems and telecommunications. These tools are critical to existing and future gains with respect to the quality, timeliness and effectiveness of patient care. That healthcare technology has and will continue to play a critical role was acknowledged in the Institute of Medicine's seminal report *To Err is Human*, where it was stated that going forward, "technology ... has to be recognized as a 'member' of the [healthcare] work team."[1] In the IOM's 2010 report *The Future of Nursing*, they acknowledge "there is perhaps no greater opportunity to transform [healthcare] practice than through technology."[2]

We have come to heavily depend on technology—this "member" of the healthcare team—and our ability to deliver care can be severely compromised when this team member is not ready and available. We also note that these technologies, on which we

have become increasingly dependent, have come at the expense of significant increases in both healthcare complexity and cost.

Increased complexity. A *Networking and Information Technology Research and Development* (NITRD) program report from 2009 describes how "older generations of mechanical, analog and electromechanical devices ... have been largely replaced by devices and systems based on information technologies" and how these devices/systems are "often connected to other devices in increasingly complex configurations, potentially creating systems of systems that span scales from tiny ... to ultra-large."[3]

Formerly passive technologies have largely been replaced by new *systems of systems* (SoS) that actively control critical physiological processes and functions.

Increased cost. Healthcare technologies are major contributors to increasing healthcare costs. Technology-associated gains have come at a significant financial cost to this industry. The 2008 U.S. Congressional Budget Office (CBO) estimates that nearly half of the annual double-digit increases we have experienced in healthcare over the previous decade are the direct result of our adoption and use of new technologies.[4] One of the largest U.S. healthcare enterprises, Kaiser Permanente, reported that between 1997 and 2007 their spending on health technologies and related procedures increased by 830 percdent.[5]

By the end of 2011, annual spend by the U.S. healthcare industry for information technology is expected to reach $40 billion ... with an estimated 24 percent compound annual growth rate (CAGR) between 2012 and 2014.[6] Estimates are that industry will spend an additional $105.8 billion for medical devices/systems for that year.[7] These numbers help put in perspective the relative size of the financial implication of technology on healthcare costs—and also indicate how the technology spent is portioned between information and medical technologies, as depicted in **Figure 1**.

Fully realizing the benefit of new medical devices/systems, information systems and telecommunications technologies will require that we understand and address the full impact of these technologies, including the consequences of increased complexity and cost, as well as the increased benefits.

In what follows, we more fully lay out some of the most promising categories of evolving healthcare technology as well as some of the key elements in a new infrastructure paradigm that is designed to similarly evolve with and appropriately support these new technologies.

THE PROMISE OF HEALTHCARE TECHNOLOGY

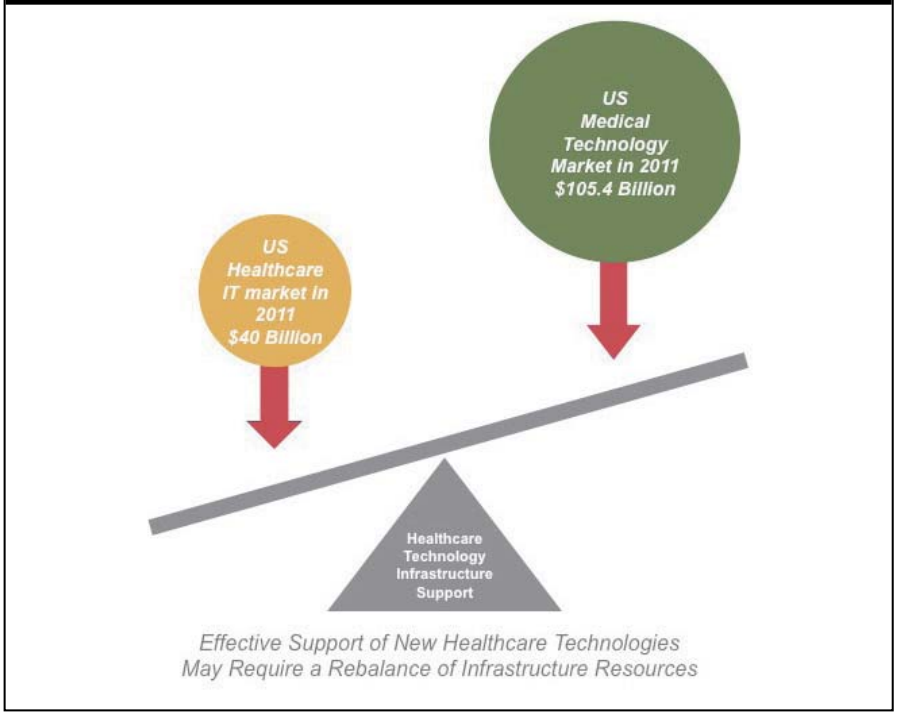
Technology has the potential to play a transformational role in healthcare delivery. If appropriately selected, deployed and used, technology can be a major enabler for clinicians in advancing patient care. It can positively influence work processes, facilitate seamless exchange of data and provide critical information to clinicians, enabling them to deliver more appropriate and timely patient care.

Healthcare technologies available today or in the near term have the prospect of significantly improving the quality, timeliness, and effectiveness of patient care; patient and staff safety; and business operations (e.g., management, scheduling, billing). Examples of technologies that either now impact or over the next ten years will impact patient care in a significant way include:

Integrated clinical and information technology systems. Information technology promises to play a greater role in the *clinical* aspects of healthcare, in addition to the business aspects. The number of diagnostic, therapeutic and information systems is rapidly rising with an overall synergistic effect. Benefits gained from integrating these systems can far exceed the benefits available when individual devices and systems are used in a standalone mode.

- As a consequence of our ability to increasingly integrate and use clinical and information technologies to gather growing amounts of data from medical devices about a patient's condition, there has been a corresponding need to process that data into information in a way that is meaningful to the diagnostician and therapist without causing them to suffer "data overload."

FIGURE 1: Effective Support of New Healthcare Technologies May Require a Rebalance of Infrastructure Resources



- New knowledge-based or evidence-based *expert* and *decision-support systems* are designed to collect data and suggest diagnoses and courses of treatment based on pre-selected rules for decision-making within specialized domains of knowledge.
- Intelligent communication technologies can insure the *right* information gets to the *right* provider at the *right* time to insure the *right* patient gets the *right* care.
- Increased reliability for critical patient care applications will be achieved by the incorporation of autonomic capabilities similar to the human body's involuntary nervous system (i.e., that allows the human body to adjust to environmental changes, external attacks and internal failures). As autonomic features are incorporated, these critical systems will increasingly:

1. Be self-aware.
2. Adapt to environmental changes.
3. Continuously adjust to optimize performance.
4. Defend against attack.
5. Self-repair.
6. Exchange resources with unfamiliar systems.
7. Communicate through open standards.
8. Anticipate users' actions.

The use of autonomic systems will enable us to realize the benefit of increasingly complex technologies that, without their autonomic abilities, would quickly overwhelm us with their need for management and support.[8-9]

- Integration has the potential to bring healthcare resources to any near or remote location and to facilitate medical data, voice and video communications between a combination of patients, providers and payers.

Digital imaging. Advances in imaging technology enable clinicians to view physical details that were not discernable with earlier imaging systems. New systems can even evaluate biologic processes and events as they occur *in vivo*. New images offered through advanced technologies give functional images of blood flow and metabolism essential to diagnoses and to research on the brain, heart, liver, kidneys, bone and other organs.

Telemedicine & telehealth. Improvements in telecommunications, information and medical technologies are greatly expanding opportunities for the application of telemedicine and telehealth. With the availability of high-resolution imaging, non-invasive telemetric sensors, robotics and high-speed broadband connections, providers have the capability of remotely monitoring, diagnosing and treating patients in a manner that both makes optimum use of clinicians' time and delivers care when and where needed by the patients.

Robotics. Use of robotics in patient treatment can facilitate both remote access by a provider to a patient as well as access to areas on or in the patient that may be otherwise difficult or impossible to reach by traditional methods. The provider's ability to operate more accurately may be enhanced, the patient's recovery time may be significantly reduced and access may be greatly improved.

- Accuracy. Robotic systems can perform procedures (e.g., surgery) more steadily than the human hand and with much greater control. Complex procedures will greatly benefit from the increased steadiness and control offered by these systems.
- Minimally-invasive procedures. Because robotic systems can operate in much smaller and more confined spaces than the human hand, these systems can be much less invasive and consequently require less recovery time and reduce the likelihood of complications (e.g., infection and blood loss).
- Remote procedures. Robotic systems are being utilized to treat patients when it is not feasible to have an operator at the patient's side

Micro- and nanotechnologies. Micro scale analytic systems are under development that will provide a "laboratory on a chip." The result will be a highly portable platform that is capable of remote screening and, as a consequence, accomplishing earlier detection in the disease process.

- Micro- scale diagnostic sensors are available that offer the ability to do minimally intrusive, continuous physiologic monitoring of ambulatory and non-acute patients
- Micro- and nano-sensors under development can serve as probes and detectors at an organ, tissue, cellular, or even molecular
- Micro- and nano-scale devices are being designed to function as artificial organs and surgical instruments
- Nano-particle vectors are being developed to aid in drug delivery and DNA modification level.

Genomics. Technologies under development will screen and identify individuals who possess genes that predispose them to certain diseases. Knowing who is predisposed to what disease will enable us to focus our preventive efforts on those most at risk. As our understanding of the genome improves, we will have the ability to develop treatments that target affected genes while still other treatments can be optimized for an individual patient based on what we know to be effective for someone of their genetic make-up.

If managed well, these technologies have the potential to make possible the efficient delivery of better quality healthcare at affordable costs in a greater variety of venues to a population that has been underserved. If not managed well, these same technologies can financially drain healthcare organizations, create workflow nightmares and pose major risks to the care and safety of its patients.

THE CHALLENGE OF REALIZING THE PROMISE

While healthcare technology has the potential to greatly enhance our ability to deliver safe, effective and timely patient care, these benefits are not automatic.

Technology must be strategically applied and aligned with the organization's mission and goals. The spectrum of healthcare technologies available now and in the near future leaves healthcare providers with a broad range of choices. These provider organizations must select from among those technologies based on an evaluation of their relative benefits and the degree to which the application of any of these technologies contributes to the organization's stated mission and goals. Anticipated benefits (e.g., improvements in care outcomes, patient/staff safety,

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increased revenue, reduced costs, operational efficiencies, demographics served, market perception) should be based on available evidence.

Effective technology implementations require process and workflow changes. To gain planned benefits, virtually all significant technology implementations require changes in workflow processes. In fact, often a major goal of new technology implementations is to achieve safer, more efficient and effective workflows. To insure these desired improvements are achieved, those processes and workflows should be analyzed and adequately planned with all relevant stakeholders (e.g., managers, users) prior to technology implementation.

Metrics enabling the organization to monitor the benefits gained must be established and employed. Prior to selecting and deploying new technologies, the organization should identify appropriate metrics to employ in determining the degree of success in achieving each of the anticipated benefits. The use of such metrics in assessing improvements in care outcomes, patient/staff safety, increased revenue, reduced costs, operational efficiencies, demographics served, market perception will help validate the planning process or focus attention on those process areas in need of improvement.

Technology also presents risks that must be anticipated and addressed if potential benefits are to be fully realized and the potential adverse affects are to be avoided. Some factors contributing to these risks and some consequences include:

Increased complexity associated with new healthcare technologies. Healthcare technology has grown considerably more complex over the last 20 to 30 years. The evolution of healthcare technologies can be summarized in three key trends:

- Most electronic medical devices are designed with microprocessors and essentially operate as special purpose computers.
- Computerized medical devices have an increasing number of features/options that enable them to collect, process and store increasing amounts of medical data. Given this increased complexity, clinician training (and re-training) on operating procedures, safety precautions, basic troubleshooting and backup procedures are critical.
- There is a growing trend is to integrate and interconnect/network disparate medical (and information) technology devices and systems to facilitate an increased exchange of medical data. A 2010 survey conducted by the College of Healthcare Information Management Executives (CHIME) concluded that 23 percent of medical devices in respondents' medical device inventories were already networked and an additional 8 percent, while not yet connected, were network-capable.[10] These interconnections further compound the complexity of these systems.

New technologies applied with without requisite changes in processes and workflows. New technologies usually require workflow and process changes and often are acquired specifically because of anticipated improvements in safety and efficiency. Failure to plan for new workflow processes or involve key stakeholders in implementing needed process changes can result in new technology implementations that are less safe, less efficient and more costly than the old technologies they replaced.

Introduction of new vulnerabilities: Single points of failure (SPOF) on clinical systems that can affect multiple patients. Discrete devices and components are generally more reliable today than their predecessors of 20 or even 10 years ago. However the interconnection of these devices/components often creates complex, integrated clinical systems potentially affecting many more patients than the standalone device. The interconnection also often introduces new vulnerabilities by incorporating devices/components that are *single points of failure* (SPOF). If these SPOF devices/components do fail, they have the potential to take down an entire system and affect the care and safety of many patients as well as business operations.

Increased dependence on new technologies. Due to the enhanced benefits these systems offer, clinicians' dependence on the information maintained and transmitted by systems for effective and timely diagnosis is likewise increasing. This dependence on integrated systems can have major implications on the clinician's ability to deliver patient care and on business operations if those systems should fail. And some systems are likely to fail with the potential for dire consequences for patient care, patient/staff safety, or operations, particularly if adequate steps are not taken to identify and mitigate the associated risks.

Convergence of clinical and informa-

The bottom line is that no organization can afford to acquire and deploy major new healthcare technologies without first giving appropriate consideration to the strategic clinical, operational, and financial implications of that acquisition.

tion technologies outpacing the development of adequate management and support services. While convergence of clinical, information and telecommunication technologies in healthcare has been rapidly accelerating for more than 20 years, the development of integrated services by healthcare providers to effectively handle the acquisition, deployment and support of these converged technologies has severely lagged. There is generally insufficient collaboration between clinical engineering, information technology and telecommunications services who continue to follow an operations model designed for the less complex and un-converged technologies of 20 years ago. As a consequence of inadequate collaboration and coordination, providers often incur unnecessary costs and experience inefficiencies in the acquisition and deployment, of new systems. They also often fail to realize the full benefit these systems once deployed and can experience compromises in the system performance and patient safety.

Recognizing the degree to which the healthcare providers are challenged in this area, the Joint Commission published a Sentinel Event Alert on *Safely Implementing Health Information and Converging Technologies* in 2008.[11] In this Alert, the Joint Commission warns that "as 'converging technologies' (the interrelationship between medical devices and health IT) are increasingly adopted by healthcare organizations, users must be mindful of the safety risks and preventable adverse events that these implementations can create or perpetuate."

"Not only must the technology or device be designed to be safe, it must also be operated safely within a safe workflow process." Joint Commission's Alert further warns of the following additional risk factors:

Failure to conduct adequate technology planning. Inadequate technology planning can result in:

- Poor product selection (i.e., selecting a product solution that does not adapt to the target clinical environment). Major factors contributing to poor selection can come about through failure to consult product reviews or alerts or the previous experience of others; and over reliance on vendor advice (without oversight of an objective third party).
- Insufficient testing or training.
- Failure to consider best practices.
- Failure to consider costs and resources need for ongoing-maintenance.

Failure to anticipate and mitigate for technology-related adverse events. Technology-related adverse events can happen when healthcare providers and leaders do not carefully consider the impact technology can have on care processes, workflow and safety. New technology systems can create new work, complicate workflow—and can result in events that can have a significant, adverse effect on patient care and safety.

Failure to integrate and regularly update systems. Manual transcription and re-entry of data significantly increases opportunities for errors. Safety is compromised when healthcare information systems are not integrated or updated consistently.

STRATEGIC TECHNOLOGY PLANNING SERVICES

Today's healthcare technologies have major implications for patient care, operations and finances. Because of their impact on patient care, their level of technical integration and their need for support, the deployment of *any* new healthcare technology can easily have a ripple effect on a wide range of an organization's clinical, support and business operations.

Corresponding to their growing impact on operations, healthcare technologies can also have a major impact on the organization's financial resources. In recent years, costs associated with healthcare technologies have been responsible for nearly 40 percent of the healthcare cost increases faced by providers. Inadequate consideration of *all* technology costs relative to technology's benefits can significantly compromise both the quality of an organization's financial investments as well as the hoped for benefit gains. The bottom line is that no organization can afford to acquire and deploy major new healthcare technologies without first giving appropriate consideration to the strategic clinical, operational, and financial implications of that acquisition.

To address the challenge of identifying new healthcare technologies for acquisition, some provider organizations are establishing a form of "strategic healthcare technology assessment" committee. This committee would be multidisciplinary and may include:

- Department chairs
- Chief Medical Officer (CMO)

- Chief Medical Information Officer (CMIO)
- Chief Nursing Officer (CNO)
- Chief Executive or Operating Officer (CEO/COO)
- Chief Financial Officer (CFO)
- Chief Technology Officer (CTO)

Additional support staff should include the senior experts in information services, clinical engineering, quality and risk management.

The role of such a committee is to serve as a the healthcare provider's gateway for new and emerging healthcare technologies (generally limited to those with an impact of capital-plus-first-year-operating impact of $100,000) by proactively examining which of these technologies provides benefits that best meet the mission and goals of the provider organization. These benefits may fall into one or more of the following categories:

- Improved care outcomes.
- Improved patient/staff safety.
- Regulatory compliance.
- Improved efficiency and workflow processes.
- Improved revenue, particularly revenues improvements associated with pay for performance (P4P) initiatives.
- Reduced costs.
- Broader demographic served.
- Market perception (reputation).

This committee should:

- Focus on—and provide the greatest weight to—evidence-based reviews of new technologies and seriously consider those that most further the service objectives of the organization.
- Charge appropriate stakeholders with the task of analyzing and planning workflow processes associated with effective deployment of new technologies and reporting findings back to the committee.
- Establish appropriate metrics to determine how well the new acquisitions achieve each of the benefits predicted... and should in turn adjust their decision-making processes when anticipated results are not subsequently achieved.
- Adopt a long, strategic view of its role and should promote the concept that healthcare technologies are not departmental, but organizational, assets that need to be properly integrated technically and operationally if the anticipated benefits those technologies are to be fully achieved.
- Avail itself of appropriate staff expertise, particularly from senior experts in clinical engineering and information technology who can identify required infrastructure associated costs (e.g., facilities, staffing, supplies, training, service/support); and conduct a risk analysis to identify vulnerabilities and the degree to which they can be reasonably mitigated.

HEALTHCARE TECHNOLOGY SUPPORT SERVICES

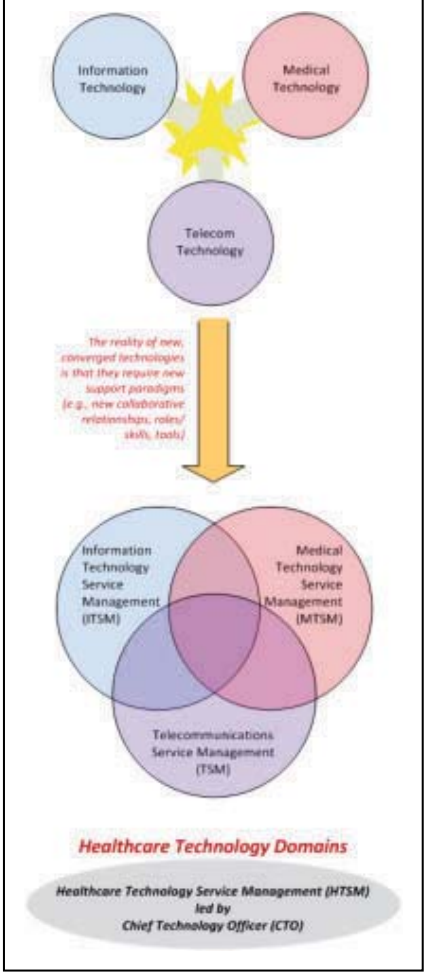
To achieve the promise of the new technologies, healthcare providers also need to develop an infrastructure that is conducive to the appropriate selection, efficient deployment and safe use of those technologies.

The increasingly complex nature of and expanding role of healthcare technology requires a corresponding increase in sophistication of that infrastructure. Infrastructures (i.e., support staff, services, processes, facilities, utilities) that were adequate to support technologies of 20 to 30 years ago are not adequate to support technologies of today let alone provide the support those healthcare organizations will need to deal with technologies in the near future. Going forward, healthcare organizations need to plan for the continual evolution of their infrastructures to meet the new challenges associated with these converging technologies. These organizations need to insure their infrastructures are both prepared to address the substantial increase that has occurred in deployed technologies and also better allocated between the support of medical and information systems (e.g., where the value of medical technologies acquired by U.S. healthcare organizations is reported to be more than twice the value of health IT acquired by those organizations).[12]

A critical aspect of the evolution of an effective infrastructure is the successful integration and collaboration between clinical engineering (CE), information services (IS) and telecommunications to support their converging technologies. Medical device/system support in healthcare organizations has traditionally been the domain of CE services. Information technology support has usually been addressed separately by IS. The reality of today's medical and information technology convergence is that CE and IS must harmonize their efforts if they are to effectively support these increasingly linked technologies.

Close collaboration and some integration is vital. It is also vital that healthcare organizations realize that, while the technologies are converging and the support model (i.e., clinical engineering, information services, telecommunications) needs to adapt (**Figure 2**), it is important that the best elements of each be preserved in the adaption and integration process. This is particularly critical when the CE and IS

FIGURE 2: Healthcare Technology Domains



are brought together in a shared reporting relationship. Because CE is usually significantly smaller (i.e., staffing, budget) than IS in most organizations, clinical engineering is more vulnerable to loss of its unique character in any "merger." Among the most important aspects of a typical clinical engineering service to preserve is their focus on the nuances of technology application at the *point of patient care*. As a consequence of their professional training and experience, clinical engineers (CE) and biomedical engineering technicians (BMET) generally understand those nuances to include:

- Patient safety issues.
- The benefits and risks of medical technology on the patient.
- Their primary role as supporting the clinicians who are responsible for delivering care.
- The interface between patient, device, clinician and environment.
- How response time in addressing medical technology issues can have a significant impact on patient safety and the delivery of care.
- Regulations and best practices associated with the use of medical technology in patient care.
- The management of medical device hazards and recalls.

Support of medical devices and systems cannot be rendered safely or effectively without this patient-centered perspective. However converging technologies bring new challenges into the medical technology support arena and the move from what were primarily discrete medical devices to integrated systems requires *another level of technology sophistication* for those who are involved in the selection, deployment and support of those integrated medical systems.

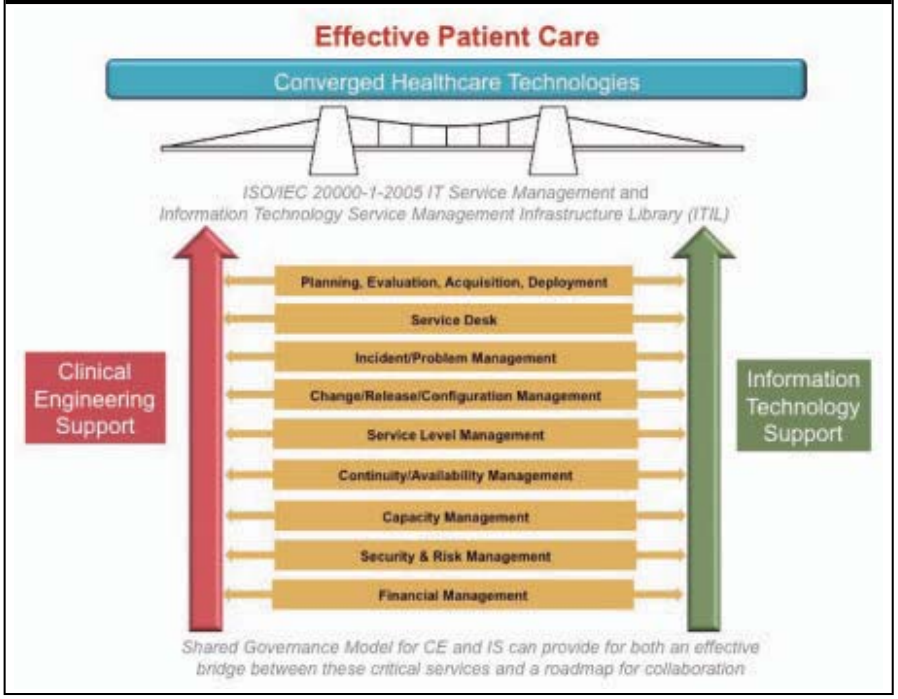
It remains critical to retain the patient focus when supporting these systems, but it also is critical to appreciate that these medical technology systems are typically more complex and may have implications for more than one patient's care or safety. Some of these medical systems may even be considered "life critical" in the same sense that some business systems are considered mission critical. Effectively supporting these integrated medical systems requires not only the above-described "patient focus" but also an understanding of the complexity inherent in a system of interconnected devices collecting, exchanging, and processing patient data. Those charged with the primary support of these integrated medical systems must evolve their service paradigm and their skills to account for the fact that these technologies are an integration of medical and information systems.

SHARED GOVERNANCE FRAMEWORK

The reality of medical and information technology convergence has led a growing number of healthcare organizations to bring their clinical engineering and information services together under a common organizational framework in order to foster collaboration and coordination of efforts on technology issues in an increasingly common workspace. While there is growing recognition of the need for collaboration, the industry has yet to arrive at a consensus on how best to achieve it beyond changing lines on the organization chart. The best solution for effective collaboration (regardless of reporting relationships for CE and IT) is likely to be found in the adoption of a common governance framework such as the *Information Technology Infrastructure Library* (*ITIL*) or ISO/IEC 20000-1:2005 *Information Technology – Service Management*.

In *The Gartner Group's* 2008 report on "Top 12 Actions for the CIO," they insist that healthcare organizations who have not done so seriously consider the adoption of ITIL.[13] As a proven set of IT best practices, Gartner says ITIL provides a framework for delivering services in healthcare organizations where those information technology services are increasingly critical to all aspects of the organization's operations. An advantage in adopting either ITIL or an ISO/IEC 20000-1 governance model is that both clinical engineering and information technology share common elements in those models. By adopting and adapting elements in such standard governance models, clinical engineering services map well to the respective processes in informa-

FIGURE 3: Shared Governance Model for CE and IS can Provide Both an Effective Bridge Between These Critical Services and a Roadmap for Collaboration



tion services (**Figure 3**). Both clinical engineering and information services could and should retain their unique aspects (i.e., clinical engineering's focus on patient safety and the clinical environment) but through a shared governance model, both would have a bridge that could help ensure seamless support for converging technologies.

A spectrum of service elements make up a comprehensive clinical engineering or medical technology service (**Figure 4**). Ideally every healthcare provider would have access to these services to insure effective support. In practice, many healthcare providers fragment the responsibility for services and assign or leave the responsibility for some elements to other departments or vendors. As a result of this fragmentation, some of these service elements are either delivered inconsistently or not delivered at all. As the number of complex, integrated, converged systems increases, the need to consolidate infrastructures and offer a comprehensive CE and IS that work together seamlessly becomes vital.

Adopting one of the aforementioned governance frameworks can help identify any gaps critical gaps in the infrastructure and insure there is effective integration of medical and information technology services.

NEW HYBRID ROLES

Another consequence of the need for evolving infrastructures is likely to be new *hybrid* of roles that build on critical elements from both clinical engineering and information services. Among the most important of these growing new hybrid professionals are:

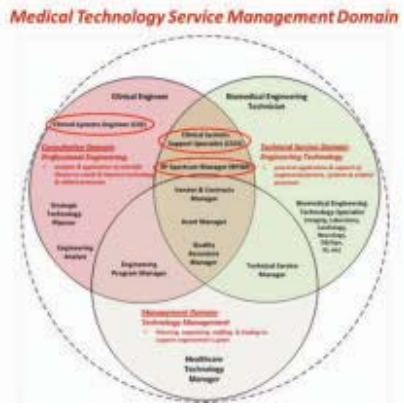
- Clinical systems engineers (CSE) who will focus on strategic planning and management services associated with increasingly complex integrated medical systems.
- Clinical systems support specialists (CSSS) will focus on technical services such as installation, configuration, repairs of these integrated medical systems.
- Radiofrequency spectrum managers (RSFM) 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.

FIGURE 4: Spectrum of Medical Technology Services Required to Support New Technologies

Figure 5 is a Venn diagram that illustrates the relationship between clinical engineering (medical technology service management) professional domains (i.e., technology management, professional engineering and engineering technology) and their sub-and cross-specialties.

Position descriptions outlining possible roles, responsibilities, and qualifications for clinical systems engineers (CSE), clinical systems support specialists (CSSS), and radiofrequency spectrum managers (RFSM) are provided in **Table 1**.

FIGURE 5: Medical Technology Service Management Domain



A STANDARD FOR CONDUCTING RISK MANAGEMENT ON MEDICAL DEVICE NETWORKS

A recently adopted ANSI/AAMI/IEC standard establishes guidelines and also defines key roles necessary for managing the challenges associated with increasingly complex and integrated medical technologies. The standard, *ANSI/AAMI/IEC 80001-1:2010 Application of risk management for IT networks incorporating medical devices,* outlines a risk management approach to managing the acquisition, deployment and support (addressing the entire life-cycle) of these integrated medical technologies. Among its most significant provisions, the standard defines these required roles and responsibilities:

- The health delivery organization's *top management* (i.e., management of the organization owning/operating the system) is responsible for

1. Establishing policies.
2. Providing adequate resources (e.g., financial, staffing) to conduct meaningful risk management.
3. Periodically review the performance of the risk management process.

- The medical IT network risk manager (e.g., clinical systems engineer) is responsible for the execution of the risk management process and for ensuring the safety, effectiveness, data/system security, and interoperability of integrated medical technologies—and for engaging appropriate stakeholders in this process and reporting results to senior management.
- The manufacturer be responsible for providing:

1. Instructions on integrating a medical device into an IT-network.
2. Information regarding any known risk vulnerabilities.
3. Information on device security features that would be useful in any mitigations.

Taken together with an appropriate governance frameworks like ISO 20000 (on which 80001-1 was in part based) and ITIL, this standard's refocusing of clinical engineering (and appropriate IT) resources on a

TABLE 1: CE-IT Hybrid Roles

Clinical Systems Engineer (CSE)

Coordinates an organization-wide program to insure the effective deployment, integration and support of interconnected medical systems

Responsibilities

- Maintains current inventory of networked and integrated medical systems (including catalog of services, features, interconnections)
- Coordinates security management process including risk (e.g., criticality & probability) and vulnerability analysis and related documentation associated with interconnected/integrated medical systems
- Coordinates with stakeholders a process to prioritize, develop and implement plan to manage/mitigate identified risks associated with interconnected/integrated medical systems by applying appropriate administrative, physical & technical safeguards
- Maintains the integrity of FDA approval for interconnected / integrated medical systems
- Works with stakeholders to insure effective deployment, integration, and support of new medical systems into legacy systems and non-medical elements of the organization's information infrastructure.
  - Works to assure systems are deployed into an optimum (i.e., secure & supportive) environment.
  - Continually reviews system components to determine which are obsolete or otherwise no longer adequately supportable and then
  - Plans for and implements component upgrades/replacement in a timely manner.
- Identifies and manages appropriate software upgrades, security patches and anti-virus installs for interconnected/integrated medical systems according to industry best practices
- Manages Root Cause Analysis (RCA) and Failure Mode Effects Analysis (FMEA) on incidents involving integrated medical systems and reports findings to appropriate stakeholders for follow-up action
- Monitors and adopts industry "Best Practices" to insure integrity, availability & confidentiality of data maintained and transmitted across interconnected and integrated medical systems
- Educates stakeholders on security and other implications associated with the proliferation of interconnected and integrated medical technologies.
- Supervises clinical engineering, clinical systems support specialists and other staff as necessary in clinical systems integration and infrastructure support (e.g., hybrid reporting structure, project supervision)

Qualifications

- Baccalaureate degree in Biomedical or Clinical Engineering (Master's preferred)
- 5-10 years experience in clinical engineering and information systems
- Project management and planning skills/experience
- Strong communication and team building skills across functional areas
- Certification (completed or in process) preferred in one or more of following:
  - Certified Clinical Engineering (CCE)
  - Certified Information Systems Security Professional (CISSP) by (ISC)2
  - Cisco Certified Network Associate (CCNA) or Network Professional (CCNP)
  - Microsoft Certified Systems Administrator (MCSA) or Engineer (MCSE)

Works with stakeholders

- Information Services (including network support, disaster recovery)
- Clinicians (system users including physicians, nurses, technologists, etc))
- Medical system manufacturers/vendors
- Risk management
- Information Security
- Procurement/purchasing/materials management
- Clinical engineering

Clinical Systems Support Specialist (CSSS)

Responsible for providing engineering support of specialized medical devices and systems (e.g., cardiology, neurology, surgical, monitoring). This support may include installation, integration, clinical training, operation, diagnostics, technical service, and vendor management in these specialized areas.

Responsibilities

- Maintains accurate inventory (including configuration information) of all devices, systems and components in their assigned areas.
- Coordinates deployment of new medical technologies in assigned areas including planning, needs analysis, evaluations, installation, integration and training
- Manages other special projects associated technologies considered for or currently used in assigned area(s).
- Monitors operational effectiveness of medical devices and systems in assigned area(s) and
  - insures devices/systems are effectively maintained by judicious application of scheduled & corrective maintenance, upgrades and overhauls as appropriate
  - acquires, deploys and utilizes appropriate hardware/software tools to monitor and manage device & system performance
  - develops or acquires and deploys administrative, technical and physical safeguards to maintain integrity and availability of clinical information maintained or stored by medical devices & systems
- Develops and provides operational and service training to clinicians and support personnel on devices and systems in assigned area(s)
- Provides consultation to clinical staff on capabilities and limitations of available technologies
- Represents technology perspective for assigned area(s) as needed at meetings with other stakeholders
- Monitors medical device hazard/recall reports for their assigned area(s) and insures appropriate follow-up (i.e., communication, corrective action, follow-up)
- Monitors regulatory developments affecting devices & systems in assigned area(s) and identifies/coordinates implementation of appropriate compliance measures
- Maintains technical library and database with information critical to the support of devices and systems in assigned area(s)
- Participates in the development and maintenance of a capital equipment plan (for existing and new operations) for assigned area. Basic plan elements should include needs analysis/ assessment, total cost of ownership (TCO) analysis, and comparative evaluations of technologies.
- Consistent with the needs of clinical engineering and other team members, may perform other duties as requested or assigned.

Qualifications

- Bachelors of Science degree in Biomedical or Clinical Engineering, Engineering Technology or related area
- 3 years experience in Biomedical or Clinical Engineering and clinical systems support
- Strong communication and team building skills across functional areas.
- Effective educator, mentor and role model.
- Demonstrated project management & planning skills
- Certification (completed or in process) preferred in Clinical Engineering (i.e., Certified Clinical Engineer / CCE) or Certified Biomedical Equipment Technician (CBET)

Works with Stakeholders

- Clinicians (system users including physicians, nurses, technologists, etc)
- Manufacturers/vendors
- Information Services
- Procurement/purchasing/materials management

Radio Frequency Spectrum Manager (RFSM)

The RFSM is responsible for enterprise-wide management and monitoring of the radio-frequency environment.

Responsibilities

- Maintaining an inventory of all R/F systems operating in or affecting the clinical environment
- Managing deployment and operation of R/F systems so as to insure regulatory compliance and to minimize adverse interactions between devices and systems
  - Advising in selection of compatible R/F systems
  - Planning for R/F allocation, deployment, integration and upgrades as necessary
  - Obtaining requisite licenses/permits and insure all are kept current
  - Investigating reports of possible adverse R/F affects on devices/ systems and identify appropriate corrective action as necessary
- Educating users and monitoring user practices associated with R/F system in order to assure their safe and effective operation

Qualifications

- Bachelors of Science degree in Electrical Engineering (relevant training may substitute)
- 5 years of experience in Spectrum Management, RF safety, license application process
- Knowledge of R/F related rules, regulations and best practices
- Strong communication and team building skills across functional areas.
- Proficiency with standard desktop applications such as Microsoft Word and Excel.

Works with Stakeholders

- Clinicians (system users including physicians, nurses, technologists, etc)
- Manufacturers/vendors
- Information Services
- Procurement/purchasing/ materials management

While convergence of clinical, information and telecommunication technologies in healthcare has been rapidly accelerating for more than 20 years, the development of integrated services by healthcare providers to effectively handle the acquisition, deployment and support of these converged technologies has severely lagged.

risk management approach to their support of medical technologies can substantially help clinical engineering and IT make the necessary paradigm shift to more relevant support models.

CONCLUSION

There is an opportunity for current and emerging technologies to play a major role in transforming healthcare delivery. We have mentioned clinical information systems, robotics, imaging, genomics, telemedicine and nano-technologies as being among the transformational technologies that can help achieve unprecedented improvements in the quality, effectiveness, timeliness and availability of patient care. However these technologies are often complex and require an unprecedented level of integration. Successfully achieving our patient care goals requires new strategic processes and an evolution in the infrastructure necessary to support these complex, integrated technologies. When selecting new healthcare technologies for deployment, we have discussed how organizations must adopt a strategic approach and insure appropriate consideration is given to the overall impact (e.g., clinical, operational, financial). We have also discussed how healthcare organizations must also look to evolve their technology support infrastructures to insure clinical engineering and information technology services share a common governance and that they are organized and staffed to adequately meet the challenges of the increasingly complex and integrated technology environment. Evolving technology is a steamroller that is even now changing the healthcare delivery landscape. All of us now have a short time to decide whether we'll be part of the steamroller—or part of the road. **JHIM**

Stephen Grimes is a Chief Technology Officer with ABM Health, a Boston area based healthcare technology consulting, management and service organization meeting the needs of over 250 clients throughout the U.S. There he specializes in technology management, medical and information technology convergence and integration issues and in medical device security and risk management. Grimes has nearly 35 years experience with hospitals, shared service organizations, and healthcare consulting firms. He is a nationally recognized authority on topics ranging from future challenges facing clinical engineering and healthcare technology integration to medical device security and risk management. He is a frequent speaker and author and serves as a healthcare technology management consultant to the World Health Organization (WHO) and Pan American Health Organization (PAHO). Grimes is a member of the American College of Healthcare Executives (ACHE) and a Fellow Member of the Healthcare Information and Management Systems Society (HIMSS) where he chairs the Medical Device and Patient Safety Task Force. He is also a Fellow of the American Institute of Medical and Biological Engineering (AIMBE) and a Fellow of the American College of Clinical Engineering (ACCE) where he is a Past President. Grimes is a graduate of Purdue University's Biomedical Engineering Program. Grimes is the 2010 recipient of the joint industry *ACCE HIMSS Excellence in Clinical Engineering and Information Technology Synergies Award.*

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