



Healthcare Technology Challenges

Defining a Framework for Success

By Stephen L. Grimes, FACCE FHIMSS FAIMBE

Executive Summary

Technology has the potential to transform the entire healthcare delivery system over the next decade. Technological advances in clinical information systems, robotics, imaging, genomics, telemedicine and nanotechnologies could yield unprecedented improvements in patient care quality and in the economics of care.

Since these technologies are often complex and require an unprecedented level of integration, the improvements are not automatic. Because of their impact on patient care, the deployment of any new healthcare technology can easily have a ripple effect on a wide range of clinical, support and business operations. To realize the anticipated benefits, healthcare leaders must insure that technology adoption is done strategically and is properly aligned with their organization's mission and goals. Implementing a strategic technology selection process and evolving the technology support infrastructure (e.g., staff, processes, and tools) are also necessary to achieve the substantial benefits to patient care and economic sustainability.

This white paper from ABM Healthcare Support Services provides a look at the critical strategic, clinical operations and financial implications that CIOs and healthcare leaders need to consider before they acquire and deploy new technologies.

Overview

We are in a period of great change with respect to healthcare. Much of the change 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 healthcare technologies are critical to drive existing and future gains in 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 of 2000, "To Err is Human," where they stated that going forward "technology ... has to be recognized as a 'member' of the [healthcare] work team."¹ In the IOM's 2010 report on "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 only at the expense of significant increases in both healthcare complexity and cost.

Increased complexity

Healthcare technologies are increasingly complex. A 2009 Networking and Information Technology Research and Development (NITRD) Program report 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 (GBO) 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%.⁵

The U.S. Healthcare IT market is slated to grow at a CAGR of nearly 22% during 2013-2017, driven by factors such as the rising adoption of EHRs/EMRs.⁶ At an estimated \$120.4 billion in 2012, the U.S. medical device

1 To Err is Human: Building a Safer Health System, Committee on Quality Health Care in America, Institute of Medicine, 2000.

2 The Future of Nursing: Leading Change, Advancing Health. Institute of Medicine, 2010.

3 High-Confidence Medical Devices: Cyber-Physical Systems for 21st Century Care. Networking and Information Technology Research and Development (NITRD) High Confidence Software and Systems Coordinating Group. February 2009

4 Congressional Budget Office. "Technological Change and the Growth of Health Care Spending." <http://www.CBO.gov/doc.cfm?index=8947>. Accessed June 2011.

5 Halvorson, George. Health Care Will Not Reform Itself. CRC Press. 2009

6 US Healthcare IT Market Outlook to 2017. RNCOS Industry Research Solutions. May 2013

market is already the world's largest.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 spend is portioned between information and medical technologies (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, offer a detailed lay out of 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.

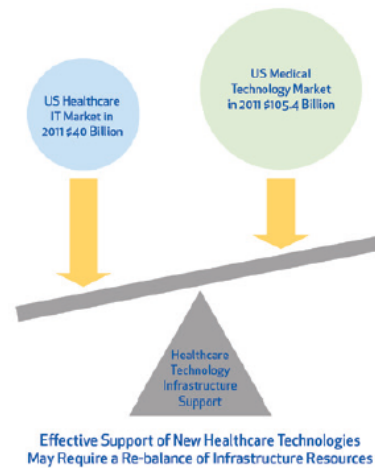


Figure 1

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 & staff safety
- Business operations (e.g., management, scheduling, billing)

Examples of technologies that are now impacting or have the potential to significantly impact patient care over the next decade include:

Integrated Clinical and Information Technology Systems

Information technology promises to play a greater role in the clinical aspects of healthcare as well as 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,

⁷ The Medical Device Market USA – Opportunities and Challenges, Espicom Business Intelligence, Q2 2013. http://www.espicom.com/Prodcat2.nsf/Product_ID_Lookup/00000110?OpenDocument

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”

- 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 payors.

Digital Imaging

Advances in imaging technology enable clinicians to view a patient’s 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 of the human body.

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,

8 Autonomic Computing, IBM, <http://www.research.ibm.com/autonomic/overview/elements.html>, accessed May 21, 2011

9 W. Gibbs, “Autonomic computing” *Sci. Amer.*, May 6, 2002.

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 & 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 Nano-Technologies

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 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 level.
- 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.

Genomics (the "mapped" human genome)

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 with their genetic make-up.

If managed well, these technologies have the potential to enable 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 Challenges 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 those technologies based on an evaluation of their relative benefits and the degree to which the application will contribute to the organization's stated mission and goals. Anticipated benefits (e.g., improvements in care outcomes, patient/staff safety, 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. 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 20-30 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% of medical devices in respondents' medical device inventories were already networked and an additional 8%, 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 are often 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 information 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.

¹⁰ Networked Medical Devices – Security and Privacy Threats. Symantec White Paper. 2011

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 2008¹¹. In this Alert, the Joint Commission warns that “as converging technologies (the interrelationship between medical devices and HIT) 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
- Over reliance on vendor advice (without oversight of an objective 3rd 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 health care information systems are not integrated or updated consistently.

¹¹ Safely implementing health information and converging technologies. Sentinel Event Alert Issue 42. The Joint Commission. December 11, 2008. http://www.http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_42.htm. Last accessed June 17, 2011.

Strategic Technology Planning Services

Today's healthcare technologies have major implications for patient care, operations and finances.

Because of their impact on patient care, the level of technical integration and 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 forty 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 anticipated 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 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 & 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 department but rather 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).
 - 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 20-30 years ago are not adequate to support technologies of today let alone provide the support those healthcare organizations that need to deal with technologies of 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 US healthcare organizations is reported to be more than twice the value of healthcare 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 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

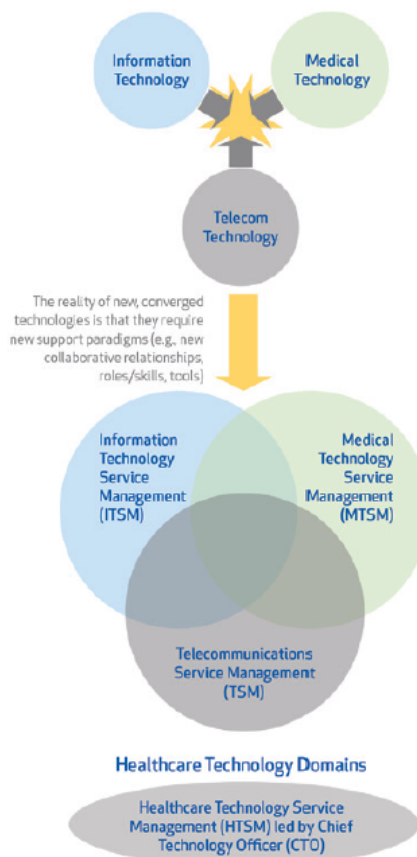


Figure 2

¹² Ibid. 6,7

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 & 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 Gartner’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 of such standard governance models, clinical engineering services map well to the respective processes in information 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 ensure 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.

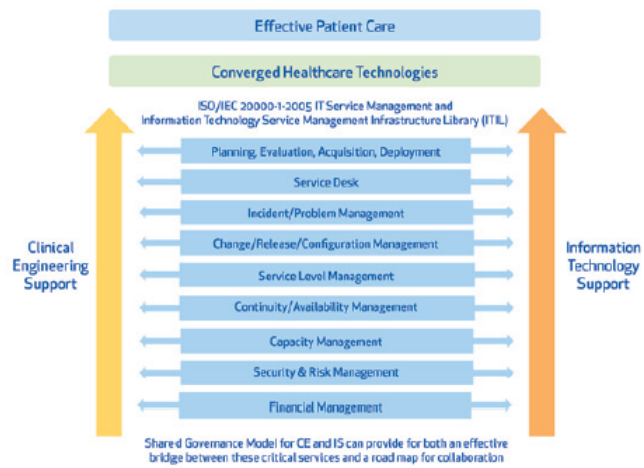


Figure 3



Figure 4

13 Gartner Reports, Top 12 Actions for the CIO, 2008, March 26, 2008. As of 2005, over 15,000 companies worldwide has adopted ITIL, including Microsoft, IBM, Hewlett-Packard, Boeing, Shell, Proctor & Gamble and the US Internal Revenue Service.

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

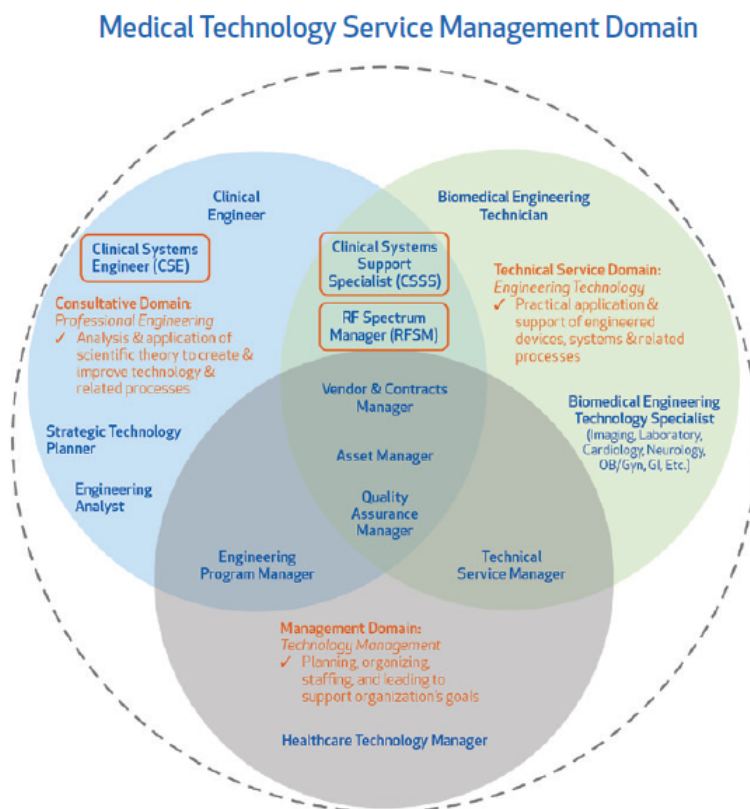


Figure 5: CE-IT Hybride Roles Circled in Red

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 the Appendix.

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:
 - Establishing policies
 - Providing adequate resources (e.g., financial, staffing) to conduct meaningful risk management
 - 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 will be responsible for providing:
 - Instructions on integrating a medical device into an IT-network
 - Information regarding any known risk vulnerabilities
 - 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 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 ensure 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 ensure 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.

Author

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.

Mr. 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).

Mr. 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. Mr. Grimes is a graduate of Purdue University's Biomedical Engineering Program.

Mr. Grimes is the 2010 recipient of the joint industry ACCE HIMSS Excellence in Clinical Engineering and Information Technology Synergies Award