IMPACT OF THE CONVERGENCE OF MEDICAL AND IT SYSTEMS

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Introduction

The convergence of Information Technology (IT) systems and medical equipment systems is changing the practice of Clinical Engineering, the priorities, the body of knowledge, and the scope of work. The “digital revolution” is fundamentally altering the perceived limits of Clinical Engineering practice, creating challenges and opportunities to extend Clinical Engineering’s impact on the healthcare system.

By the close of 2010, integrated digital systems will have replaced paper based systems, analog devices, and discrete digital components. Benefits such as single point of entry, artificially intelligent systems watching for outliers, and standardized vocabularies and phraseology are expected to improve patient safety and treatment quality and to reduce overall cost. While it remains to be seen if this great promise will be realized, clinical engineers have both roles to play and adjustments to make as the new paradigm evolves.

Perspective

In the 1960s, computers first began to make their way out of the laboratory and into industry. As this was occurring, other technologies were permeating healthcare, giving rise to a perceived need for professionals who understood the technology, its uses and ramifications in the health care setting. From this need, Clinical Engineering was formed.

“Clinical Engineering began as an applied discipline concerned with the application of engineering principles to the economic solution of clinical problems. It relied heavily upon a body of knowledge that drew on electrical and mechanical engineering, physiology, human factors, and chemistry.” (1)

The clinical engineer as a professional spoke the language of medical, administrative, and engineering personnel in hospitals and other institutions. S/he understood human factors, concepts of leveraging technology, and the special constraints of work in the hospital, such as sterile technique, which were missing from traditional engineering training. The Clinical engineer was seen as having an impact on patient care as well as technology, through input to the design of equipment, teaching of clinical staff, and promoting a safer environment.

As an interdisciplinary practitioner, the clinical engineer took on many roles, including: an advisor on technology selection; an incident investigator; a
partner in clinical studies. This developing role took a turn in the 1970s as a result of two external factors, the great electrical safety uproar and the economic downturn in healthcare.

- In April, 1970, Ralph Nader published an article asserting that at least 1200 Americans were being electrocuted annually during routine diagnostic and therapeutic procedures in hospitals. (2)

- A year later, the Emergency Care Research Institute issued a scathing report on the quality and effectiveness of medical devices. (3) These reports started a landslide of investigation and legislation which resulted in new standards; assisted in moving Congress to enact Public Law 94-641, the Medical Device Amendments to the Food, Drug, and Cosmetic Act (1976); and turned the attention of the healthcare industry to the clinical engineer as the medical device “guru” in the hospital.

- The second issue that bore on Clinical Engineering was the beginnings of financial constraints on hospitals. Since the end of World War II, healthcare had enjoyed a building and expansion boom, thanks to strong Veterans Health Administration and Hill-Burton programs, which aided the growth of technology as well as facilities. As these wound down, and hospitals began, for the first time, to live in a more conservative fiscal environment, the beginnings of cost containment were felt in the Clinical Engineering community as a de-emphasis on the softer Clinical Engineering services and a focusing on the areas of Joint Commission on Accreditation of Hospitals (now the Joint Commission on the Accreditation of Healthcare Organizations – JCAHO) compliance and medical equipment maintenance.

This turn toward equipment maintenance and management diminished the broader engineering role of Clinical Engineering and focused attention on the management of service shops, where they competed with senior biomedical equipment technicians (BMETs) – the people who actually serviced the equipment, for management positions. This was the primary role associated with Clinical Engineering through the turn of the century.
Advent of Information Technology

From 1960 to 1999, the primary use of information technology in healthcare was for billing systems. Medical records continued to be kept on paper. Diagnostic tests began to employ digital circuitry; the output typically remained as hard copy. Prescriptions continue to be written and processed by hand. While there were advances in the use of digital technology in medical equipment, they were usually confined to proprietary systems or discrete devices, notable exceptions being the advent of Picture Archiving and Communication Systems (PACS) in the imaging area, and the expansion of Digital Imaging and Communications in Medicine (DICOM) and Health Level 7 (HL-7) standards.

By 2001 however there were forces at work fostering the widespread application of information technology in healthcare.

- In 2001, the Institute of Medicine (IOM) published its second report on quality in the nation’s healthcare system, “Crossing the Quality Chasm – A New Health System for the 21st Century.” This report stated that the “development and application of more sophisticated information technology systems is essential to enhance quality and improve efficiency” and called for a national commitment to build an information infrastructure capable of supporting all facets of health care delivery.

- The Leapfrog Group, a coalition formed by the Business Roundtable of over 135 organizations that provide health care benefits, focused national attention on three quality of care issues in response to the first IOM report on patient safety. One of these issues was Computer Physician Order Entry (CPOE). Leapfrog argued that prescriptions in hospitals should be automated with doctors entering orders directly into a computer. The prescription can then be read accurately and the medication checked for appropriate dosage, indications, contraindications, allergies, and adverse effects in combination with other drugs in use. Leapfrog estimated that this type of system could serious medication mistakes by up to 86 percent. A side benefit, not touted by Leapfrog was that automating this process would reduce the number of human interactions, and hence the cost of filling physician orders.

- In 1996, Congress passed the Healthcare Insurance Portability and Accountability Act (HIPAA). HIPAA was enacted as a health insurance reform measure to protect health insurance coverage for
workers and their families when they change or lose their jobs. In order to accomplish this, HIPAA contains Administrative Simplification provisions that allow for the “portability” of health information to occur. These provisions established national standards for electronic health care transactions and national identifiers for providers, health plans, and employers. While much public debate has focused on the privacy and security provisions of HIPAA, the administrative simplification is, in effect, moving healthcare to widespread use of electronic data interchange. (9)

- Within industry, as the number of digital systems began to proliferate and hospital information technology departments began to consider IT backbones for the next century, it became apparent that there was little, if any, standardization with regard to the movement of digital information. As a result, two major professional societies, the Radiological Society of North America (RSNA) and the Healthcare Information Management Systems Society (HIMSS) used their combined influence to create a project called Integrating the Healthcare Enterprise (IHE). (10) The project, begun in 1999, has brought together over 30 major vendors of imaging systems in a collaborative effort to improve the way computer systems in healthcare share information. IHE promotes coordinated use of established communications standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care in a vendor neutral environment. IHE has now extended its program beyond radiology to include cardiology and other areas.

Convergence

In 1990, the American College of Clinical Engineering (ACCE) compiled the following generally accepted definition of a Clinical engineer: “A Clinical engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology.” (11) This corresponded to the origins and legacy training of clinical engineers and was the first widely accepted statement that the clinical engineer’s role extended well beyond managing the medical equipment. By 1997, healthcare trends pointed to a Clinical Engineering paradigm shift “from a focus on technology to a focus on information.” (12) After a quarter century in which Clinical Engineering was dominated by equipment management and compliance issues, information technology was driving a shift for clinical engineers to extend their scope as communicators and problem solvers.
As IT began to move out of the business office, it encountered a new set of challenges within the clinical environment that it had not dealt with previously. The relatively ordered world of information systems clashed culturally with the fast paced world of the clinician and had fundamental disconnects regarding speed, customer service, and flexibility. As the applications of digital technology reach all corners of the clinical world, their complex technologies require communication, collaboration, and interfacing of IT, facilities, clinical and administrative interests in a sea of technologies and priorities that are not always in harmony.

- At the same time that IT is reaching out to the facility, the nature of care is moving from a facility centric model to a patient centric model.

- As Personal Digital Assistants (PDA’s) and wireless applications explode on healthcare, the electronic noise of the environment and limits imposed by the configuration of buildings must be accounted for.

- New technologies like remote robotics and telemedicine that share physical backbones with imaging and business systems, even though separated logically, need to have clearly established bandwidth priorities to assure clinical performance and safety.

- The eventual convergence of the various disparate systems into a single computerized patient record will require significant resources to assure a seamless integration.

Overlaying all of these is the need for policies, procedures and protocol, to communicate information quickly, accurately, and with appropriate safeguards of privacy and security; all in an environment where the number of caregivers is decreasing while the number of patient encounters is growing.

Effect on Clinical Engineering Body of Work

The same technology revolution that is spurring the problem solving side of Clinical Engineering is also driving down the demand for the legacy work of Clinical Engineering departments in preventive maintenance and repair. Newer generations of digital equipment are more reliable, requiring less calibration verification; and, when they do fail, they are more apt to be self diagnosing.
As the legacy equipment maintenance areas decline, it is important that the role of Clinical Engineering in the integration of IT be assigned those budget dollars no longer needed for preventive maintenance and repair. An additional factor in the economics is that the overall budgets associated with these new integrated systems are an order of magnitude greater than those associated with legacy medical equipment. With such a large investment at stake, it makes good business sense to assure that Clinical Engineering is heavily involved in the areas of strategic planning, systems support, and patient safety.

The successful planning and implementation of integrated systems will require an extraordinary amount of collaboration, a core competency of clinical engineers. New problems will require new solutions, but will draw on the existing basic skill set of Clinical Engineering. For example, where in the past, clinical engineers might resolve a problem between a device and its utilities, today, that person might mitigate a data problem between the device, the router, the backbone, or the telecom system. Where yesterday the clinical engineer might safeguard the design of a patient room by pointing up that the equipment would fit – but not the equipment and caregivers giving care; tomorrow, that clinical engineer might note that the frequency used by a proposed equipment locator system conflicts with that of the computerized physician order entry system.

The clinical engineer, by virtue of his/her background, and ubiquitous interfacing with technology in all clinical areas, and facility for working interactively with people in a demanding environment, is a very valuable person to have on any team assigned to implement tomorrow’s healthcare technology.

As new systems such as PACS, telemedicine, wireless terminal systems, and clinical information subsystems enter the hospital’s strategic plan, Clinical Engineering’s roll in the assessment of the new technologies and the evaluation of various vendor offerings should be an essential component of the process. The understanding which the clinical engineer has of the interrelationships between these new technologies and the operating environment will be a critical factor in assuring that expectations are met. For example, a high speed digital imaging system may be capable of rapid throughput of patient examinations, but if the infrastructure for patient transport cannot keep up, there will be insufficient supply to meet the capacity. Similarly, if the procedures for reading and interpreting test results cannot handle the increased throughput, a major benefit would be lost.
Support of the new technologies poses new challenges to Clinical Engineering. In addition to hardware service, integrated digital systems contain complex software, and the distinction between software and hardware failures is often subtle. While complex systems may require manufacturer support through either remote diagnostic or on site support, coordination and monitoring of these services to assure user satisfaction remains a Clinical Engineering function.

The life cycle support, assessment, and integration of these systems are expected to exceed six billion ($6B) dollars annually by 2005. Even assuming that a majority of that work falls to the IT department or outside contractors, the monitoring and quality assurance costs alone would exceed $500M per year, nationwide. This represents a substantial increase in the Clinical Engineering workload. This work cannot be consigned to Information Technology departments alone because every converged system has a patient at the input and or output and a clinician who needs to intuitively be able to enter and retrieve information that bears on care. Their best advocate in the system assessment, selection, and implementation is the clinical engineer.

The third area of impact on Clinical Engineering is directly related to the patient interface – safety considerations. Patient safety in converged digital-clinical systems is heightened by the complexity of the systems themselves. Problems can exist at a variety of levels, the patient-machine interface, the clinician-machine interface, the machine-system interface, and the machine-environment interface. This is typical of legacy equipment environments, but the potential for errors or harm and the detection of it is made significantly more complex in converged digital systems.

As diagnostic medical equipment evolves from stand alone units to systems, more and more clinical systems will be based on a “front end” client that acquires and digitizes patient information, middle level hardware using standard open systems architecture for signal processing and decision support, and a store-and-forward level somewhere in the IT server farm.

The emerging systems are based on thousands of lines of software which may have subtle hidden errors that can arise days, weeks, or months after new software is deployed. If an EKG interpretive computer is attached to a “dumb” signal acquisition front-end, and it makes a diagnosis which is used to prescribe medication, where does the computer begin and the medical device end? What is the role of software? If there is a software update that contains a subtle error, what quality assurance is in place – is quality assurance heightened during the software transition? These questions
become increasingly important as the system’s complexity outstrips the user’s understanding.

- Systems design, both for efficacy and safety must consider the policies, procedures, and human interfaces as well as the technology. Failure to consider these can result in unintended consequences ranging from inappropriate levels of trust in the technology to information overload of the user. An operator who becomes too trusting of the information provided by the system is in danger of missing the rare error that may occur. An operator who does not trust the system will forego its use or obviate the time saving benefit of automation with redundant manual operations. The operator who has information overload will make a mistake. Clinical Engineering, through input to the system design phase, selection phase, or training phase, and ongoing quality improvement processes can positively impact these concerns.

- New systems can create alternate scenarios for error with confusing controls and options that allow the user to “program” an event or outcome which is unexpected. This is particularly a concern where different vendor systems are used in the same institution. The differences between programming two different IV pumps is relatively straightforward compared with the subtle programming differences between different vendors affected by silencing an alarm.

- Interference is also a concern. Digital technology in the hospital includes a plethora of wireless devices. Cell phones are the tip of the iceberg. PDA’s are finding their way into clinicians’ hands throughout the hospital. Other wireless devices, whether for locating people or equipment, reporting lab results, patient telemetry, physician order entry, or patient communications will create an atmosphere rife with electronic noise, while being subject to potential loss of function due to interference, loss of signal, or bandwidth capacity.

Effect on Clinical Engineering Methodologies

The proliferation of digital technology will also affect how Clinical Engineering is practiced in the future. The automation of activities and the availability of more complex presentations of information are increasing the capacity of Clinical Engineering to effectively manage technology support throughout the hospital.
Among the emerging technologies available to improve asset management of portable medical equipment is equipment location technology. This is available in both radio frequency and infrared technologies, with each having its advantages. Totally wireless infrastructures which connect to the hospital’s existing network are significantly lowering the cost/benefit ratio of tracking mobile equipment. Gains in service turnaround time and reduction in inventories or rental costs can be realized from this approach.

Computerized Maintenance Management Systems (CMMS) have grown from the desktop to the local network, to web based systems, to handheld wireless terminals in less than 3 years. The new systems give users, managers, and department heads a new freedom to look at their equipment and review utilization, down time, training opportunities, and effectiveness of preventive maintenance with an eye to evidence based decision making.

A new generation of add-on tools makes possible digital dashboards, user portals, and the application of graphical based decision support software in evaluating financial as well as operational alternatives. These tools display multiple variables in a single presentation and use artificial intelligence to prompt the user based on outliers or trends.

Remote diagnostics reaching beyond the radiology department, simulations for the training and tracking of skill sets, and tools for real time tracking of life cycle costs are also on the horizon.

**Relating to the IT Department**

A number of clinical engineers have engaged actively in the support of integrated digital-medical equipment systems and in projects that created extensive interfaces and partnerships with the IT departments of the hospitals. Christiana Health Care and Hartford Hospital\(^{(14)}\) have explored alternative approaches to relating to the IT department, with Christiana developing a working partnership and Hartford merging Clinical Engineering directly into the IT department.

Each situation is different, as each hospital is different. In an integrated department, the communications can be maximized and the opportunity for Clinical Engineering to extend its knowledge base in digital technology will be extended.

There are however, significant cultural differences between Clinical Engineering and IT. The language is different, the view of customer service is different, and the priorities in a project are different. The checks and
balances of separate Clinical Engineering and IT departments collaborating as peers will reap more rewards in terms of long term success of overall system implementation than will be realized from a combined department. Whatever the structural relationship, however, Clinical Engineering and IT must develop a good working relationship, with mutual respect, if information for patient care is to be optimized in terms of efficacy, reliability, and safety.

Summary

Clinical Engineering is moving rapidly from an environment dominated by stand alone medical devices to a world dominated by clinical systems, intimately bound to the IT department by network connections and the two way flow of data. This change is altering the practice of clinical engineers by deemphasizing the traditional compliance functions of preventive maintenance and repair, and energizing the more strategic issues of information and communication. Clinical engineers must respond to this change by developing relations with the IT world at their hospitals and enhancing their knowledge of these new systems and the safety and efficacy challenges presented by the new technologies.
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