The Future of Clinical Engineering:
The Challenge of Change

STEPHEN L. GRIMES

"It's not the strongest of the species that survives, nor the most intelligent, but the one most responsive to change."
—Charles Darwin

"It's not the progress I mind, it's the change I don't like."
—Mark Twain

"Change is good. You go first ..."
—Dilbert

Will Clinical Engineers Be Prepared to Meet the Challenges and Opportunities Brought About by Extreme Forces Poised to Change the Landscape of the Industry?

What will the future of clinical engineering look like? The question is an important one for clinical engineers to consider because the answer determines how they should be preparing now for that future. What level of education and what skill sets should be acquired? Anticipating the future enables us to effectively prepare ... to be proactive rather than reactive as changes take place in our industry.

Clinical Engineering's Future Linked to Developments in Healthcare

To reasonably predict the future role of clinical engineering, we must consider the future nature of healthcare. Clinical engineering services evolve within the context of our healthcare delivery system. Consequently significant changes in healthcare delivery are likely to result in a corresponding need for changes in the character of clinical engineering services.

We must recognize there *are* revolutionary changes occurring within the healthcare delivery system. These changes are the result of a combination or

0739-5175/03/$17.00©2003IEEE

confluence of technological, economic, cultural/demographic, and regulatory forces. Clinical engineering's ability to contribute or perhaps even survive professionally will depend on how effectively it adapts to the changes brought about by these forces. What follows is a brief overview of these *forces for change*.

Technological Forces

Today we have mapped the human genome. As we continue our research in this area we gain the ability to 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. And our understanding of the genome will enable us to refine our treatments. We will have the ability to develop some 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 makeup.

Significant scientific developments have been occurring in the areas of micro- and nanotechnology [1]. Nanoparticle vectors are being developed to aid in drug delivery and DNA modification. Micro- and nanoscale devices are being designed to function as artificial organs and surgical instruments. Micro- and nanosensors under development can serve as probes and detectors at an organ-, tissue-, cellular-, or even molecular-scale level. These technologies are designed to be minimally invasive, minimally disruptive, and to closely mimic the body's own natural systems.

Information technology promises to play a greater role in both the business and the clinical aspects of healthcare. As a consequence of our ability to use technology to gather more data about a patient's condition, there has been a corresponding need to process that information in a way that is meaningful to the diagnostician and therapist.

The capability and availability of the integrated circuit have dramatically increased since personal computers made their appearance in the early 1980s. Over that period of time, the processing power of the computer has roughly doubled every 12 months [2]. [In 1978, Intel's 8086 processor contained the equivalent of 29,000 transistors. When introduced 22 years later, Intel's Pentium 4 contained the equivalent of 42,000,000.] While the processing capability of each new generation of computer has grown exponentially over the past 20 years, the relative cost of those systems has dropped by half in the same period. In 1981, an IBM PC with a 4.77-MHz 8088 with 64 KB of RAM and 320 KB of storage sold for about US$3,000. A typical system in 2001 with a 2-GHz Pentium 4, 512 MB of RAM, 120 GB of storage also sold for approximately US$3,000—but that is the equivalent of US$1,454 in 1981 dollars.

Growing capabilities and falling cost of integrated circuits have led both to the proliferation of computers in medicine and to the widespread adoption of those integrated circuits in medical devices and systems. Incorporating these technological advancements has greatly increased the amount of diagnostic and therapeutic data these systems can collect, store, and process. Further, it is spurring the development of a broad array of experience and knowledge-based expert systems—systems that 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" [3]. In medical devices and systems, these advancements have had the added benefit of improving system reliability and incorporating self-diagnostic capabilities.

Connectivity is another trend that is rapidly transforming the healthcare technology landscape. The number of diagnostic, therapeutic, and expert systems being linked is on the rise. Clinical information systems are also tying into the business-oriented hospital information systems. The overall effect is synergistic, where the benefits gained from integrated systems far exceed the benefits available when the individual devices and systems are used in their stand-alone mode. Connectivity has also been advancing at another level. Networking and the Internet has the potential to bring healthcare resources to any near or remote location and to facilitate medical data and personal (voice and video) communications between a combination of patients, providers, and payors.

WHAT IS CLINICAL ENGINEERING?

Clinical engineering is generally considered a specialty of the biomedical engineering profession.

The Whitaker Foundation (www.whitaker.org) defines biomedical engineering as *a discipline that advances knowledge in engineering, biology and medicine, and improves human health through cross-disciplinary activities that integrate the engineering sciences with the biomedical sciences and clinical practice.*

The American College of Clinical Engineering (ACCE) defines a clinical engineer as *A professional who supports and advances patient care by applying engineering and management skills to healthcare technology*.

The majority of clinical engineers work in a hospital or other healthcare provider environment. They may be employed by the healthcare provider or may be an employee of an organization that provides service to multiple healthcare providers. These clinical engineers are a part of the healthcare team along with physicians, nurses, clinicians, and other hospital staff. Their role is to insure that other team members have adequate and effective technology to insure the delivery of quality healthcare.

A smaller number of clinical engineers work in academic or industry settings. While not working directly in the provider environment, their focus nonetheless remains on developing services and programs to advance the effective use of technology in healthcare.

For additional information on clinical engineering and its future role, visit the ACCE website (www.accenet.org) and consider attending the ACCE Annual Symposium featuring the *Future of Clinical Engineering: Technology That Enables Improved Patient Care* being held on 14 June 2003 in Long Beach, California.

We need to be concentrating most of our efforts on the development of a healthcare system that provides long-term treatment programs for patients with multiple, chronic diseases.

The information technology industry is moving toward the development of what IBM calls "autonomic" systems [4], [5]. Like the involuntary nervous system that allows the human body to adjust to environmental changes, external attacks, and internal failures, future autonomic technical systems will:

- be self-aware
- adapt to environmental changes
- continuously adjust to optimize performance
- defend against attack
- self-repair
- exchange resources with unfamiliar systems
- communicate through open standards
- 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.

We have just identified several key technological developments affecting healthcare. These have included mapping the human genome, advancements in micro- and nanotechnology, the exponential growth in information processing capacity and availability, the connectivity of technologies, and finally the introduction of autonomic systems. These are emerging medical technologies that have the potential of greatly improving the quality and availability of healthcare and doing so at a reasonable cost [6].

As powerful forces for change, these emerging technologies will likely be critical in determining the future role of clinical engineering.

Economic Forces

The U.S. healthcare industry is experiencing a financial crisis. U.S. healthcare costs have been spiraling out of control in the past ten years. In 1997, 13.5% of the U.S. Gross Domestic Product (GDP) was spent on healthcare (considerably higher than Germany, Switzerland, and France, whose spending is the next highest as a percent of their GDP at 10%) [7]. Total U.S. healthcare expenditures rose from US$888 billion in 1993 to US$1,425 billion in 2001. Those expenditures are expected to further grow to US$3.1 trillion and 17.7% of the GDP by 2012 [8]. Spending on health benefits for their employees cost American companies US$177 billion in 1990, and by 1996 the amount had soared to more than US$252 billion (or rising at more than twice the rate of inflation) [9]. Health insurance premiums increased by 11% in 2001—the fifth straight year of rising premiums and the highest increase since 1993 [10]. Americans now spend more money on healthcare than any other nation, but their care ranks No. 37 in quality, according to a recent World Health Organization survey of 191 countries [11].

One study reported in the *New England Journal of Medicine* found that between 19 and 24% of U.S. healthcare expenditures go for administrative costs [12]. This compares with Canada where it is estimated administrative costs represent only 11% of total expenditures and most European countries where the average is 7%.

Adoption of new technologies has significantly contributed to industry cost increases. One recent study estimated that between 1998 and 2002, new medical technology contributed 19% of the increases in inpatient healthcare spending [13]. Another recent study conducted by University of California, Berkeley researchers on the true total cost of ownership (TCO) for computer-based systems calculated that TCO the first three years after acquisition now represents between 3.6 to 18.5 times the initial purchase cost of hardware and software [14]. The same study suggests that "a third to half of TCO is recovering from or preparing against failures." Without innovative design (e.g., autonomic systems) and careful management, the disproportionate relationship between the initial purchase and on-going support costs will only increase as new and more complex technologies are adopted.

Clearly these trends cannot continue if we are to have a healthy economy and a first-rate healthcare industry. We must find a means of reducing costs for the level of healthcare we are receiving, or if we cannot reduce these costs, we must be prepared to adjust our expectations and settle for the level of care we can afford.

Demographic/Cultural Forces

The United States is undergoing significant cultural and demographic changes that will have an important impact on the healthcare industry. Within the next decade, the "baby-boomers" will begin reaching the age of retirement. Between 2011 and 2030, the number of Americans age 65 and older will jump from 13% to over 20% of the total U.S. population [15]. As this group reaches 65, they can look forward to the prospect of living much longer lives than previous generations due to advancements in medical science and technology. Due to the aging population, there is a growing shift from acute, episodic care to care for chronic conditions [16]. 100 million Americans are now treated for chronic conditions. Of these, 100 million, 40% have multiple chronic conditions [17]. Today, the medical care costs of people with chronic diseases account for more than 60% of the nation's medical care costs [18]. By the year 2020, 157 million Americans will have a chronic condition and 80% of the country's total medical care

spending will be associated with treatment of these individuals [19]. As a consequence of these trends, we need to be concentrating most of our efforts on the development of a healthcare system that provides long-term treatment programs for patients with multiple, chronic diseases.

Given their exposure to advances in technology and the Internet, today's consumers are better informed and have higher expectations regarding healthcare quality and availability than any previous generation. These consumers will demand that industry and government work together to insure that quality healthcare is readily available at a reasonable cost. As the U.S. population looks forward to a longer lifespan and the prospect of long-term treatment for chronic diseases, the availability of effective and affordable healthcare becomes a critical *quality of life* issue.

Regulatory Forces

In recent years, issues related to healthcare quality and costs have led to government and industry initiatives directed at improving the quality and availability of healthcare and at reducing its costs.

In the early 1990s a respected industry group reported to Congress that US$73 billion per year could be saved if healthcare organizations would adopt the use of standardized data formats to exchange patient information [20]. Congress reacted by including the administrative simplification provisions in the Health Insurance Portability and Accountability Act (HIPAA) and passing this legislation in 1996 [21]. In the HIPAA legislation, the Department of Health and Human Services (HHS) was directed to develop regulations requiring healthcare organizations to adopt the use of standardized data, to insure privacy of patient-related health information, and to implement safeguards to insure the integrity, availability and confidentiality of that data. The various provisions of HIPAA were scheduled for implementation between 2002 and 2005. Adoption of these provisions should help facilitate the exchange of data between a rapidly growing array of information and biomedical technology systems.

In 2001, the Institute of Medicine (IOM) released its watershed report—*Crossing the Quality Chasm: A New Health System For The 21st Century*—that examined the state of the U.S. healthcare system [22]. That report details recommendations for the industry including a number of major recommendations on "applying advances in information technology to improve clinical and administrative processes." In fact, many of the report's main recommendations can be accomplished only through the effective integration of information and clinical or biomedical technologies. A year earlier, the IOM had released another major report—*To Err is Human: Building A Safer Health System*—which suggested as many as 98,000 Americans die annually as the result of medical errors [23]. In this report, the use of increasingly sophisticated and complex technologies is cited as a contributory factor in many of these errors. The report goes on to say that technology must be recognized as a member of the healthcare team and that among its roles are enhancing human performance and automating processes so as to remove opportunities for humans to make errors. However, system failures can occur, and where technology is employed humans must still find ways to effectively monitor the processes they automate. Both of these IOM reports have had a major impact on the healthcare industry and are very likely to influence federal legislation and industry initiatives for the foreseeable future.

In 1999, an industry-sponsored initiative called *Integrating the Healthcare Enterprise* (IHE) was launched. IHE brought together medical professionals and the healthcare information and imaging systems industry "to agree upon, document and demonstrate standards-based methods of sharing information in support of optimal patient care" [24]. The initiative was sponsored by the Radiological Society of North America (RSNA) and the Healthcare Information and Management Systems Society (HIMSS). After successful efforts in medical imaging, this program is now attempting to broaden its scope into clinical laboratory, cardiology, and other areas that would benefit from the effective integration of biomedical and information technology systems.

HIPAA, the IOM reports, and IHE represent perhaps the most significant regulatory and pseudo-regulatory initiatives impacting the adoption of technology in healthcare industry in current times. As we look to technology to help address healthcare's growing number of problems and issues, they will undoubtedly turn out to be only the precursor of many future initiatives.

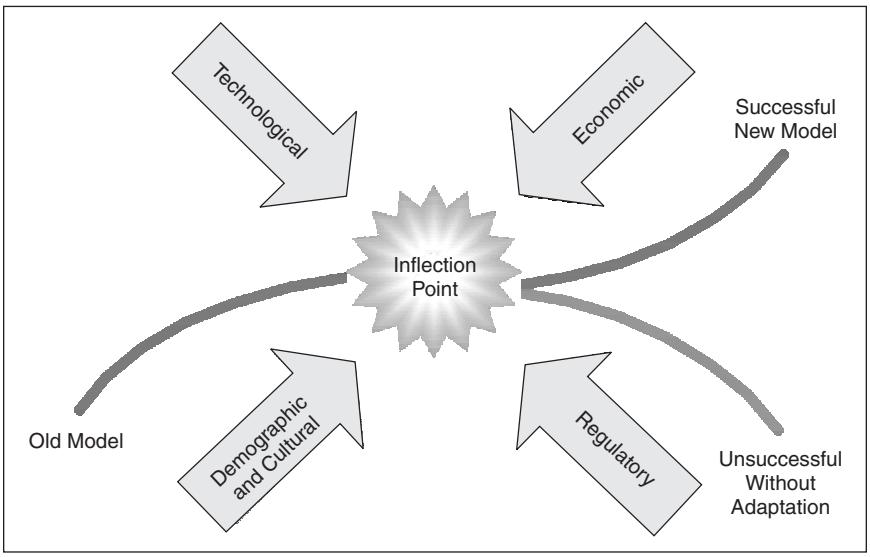

Fig. 1 Technological, economic, regulatory, and cultural/demographic forces create a strategic inflection point for clinical engineering.

Net Impact of These Forces

Due to forces described above, healthcare in the United States will undergo substantial changes within the next 5 to 20 years. The healthcare industry will increasingly focus on the long-term treatment of chronic conditions for an aging patient population. This population will expect high-quality care that is both readily available and reasonably priced. Technological advances will facilitate the industry's ability to meet these demands and regulatory pressures will foster better integration.

Clinical engineering programs are arriving at a strategic inflection point. The long-term viability of clinical engineering as a distinct profession and service depends on the model clinical these engineering programs adopt for the future.

A Strategic Inflection Point for Clinical Engineering

Andrew Grove, Intel's chairman, defined *strategic inflection point* as a term that describes the time in which extreme forces forever alter the landscape of an industry, creating both opportunities and challenges [25].

In Grove's model, businesses and industries progress along at a steady, smooth fashion until hitting a subtle point where the business dynamics force a change in the curvature of that progression. At this "inflection point," the transition is so smooth and subtle that there are no obvious profound, major, or cataclysmic signs. However, depending on the actions it takes, a business will progress through the inflection point along a path to potentially unprecedented heights—or find itself going down the path toward obscurity. If a business misses the opportunity and begins the descending branch of the curve, it is exceedingly difficult to reset the progression and correct for the action not taken at the inflection point. It is therefore extremely important to anticipate and act before reaching that inflection point.

Clinical engineering programs—and perhaps the profession—are arriving at a strategic inflection point. The long-term viability of clinical engineering as a distinct profession and service depends on the model clinical engineering programs adopt for the future. Selecting the right model ensures clinical engineering's future role as a successfully productive and important element in healthcare. Selecting the wrong model will result in a declining role until whatever clinical engineering function remains is assimilated by other technical service programs.

A Historical Perspective

Clinical engineering encountered another strategic inflection point in the past. Beginning in the mid to late 1960s, hospitals began to significantly increase their adoption and use of biomedical instrumentation. In 1970, the consumer activist Ralph Nader wrote an article for *Ladies Home Journal* claiming that at least 1,200 Americans were electrocuted annually in hospitals during routine diagnostic and therapeutic procedures [26]. The Emergency Care Research Institute (ECRI), a nonprofit organization evaluating the safety and effectiveness of medical devices, reported that "a disturbing proportion of ... medical devices is demonstrably ineffective, of inferior quality, or dangerous" [27]. ECRI's reports of medical equipment quality issues along with Nader's comments on electrical safety served to raise public interest and a series of Congressional hearings were subsequently held on medical device safety. Over the next five years the Food and Drug Administration (FDA) [Congress passed PL94 in 1976 giving the FDA the power to require medical device manufacturers to demonstrate a product's efficacy before marketing that product in the United States], the Joint Commission on Accreditation of Hospitals [JCAH, subsequently renamed Joint Commission on Accreditation of Healthcare Organizations (JCAHO)], the National Fire Protection Association (NFPA), Underwriter's Laboratories (UL), the Association for the Advancement of Medical Instrumentation (AAMI), and many states adopted standards or regulations pertaining to the design, manufacture, and/or testing of medical devices.

During this period, the combination of the rapid adoption of new technologies, rising public concerns about safety, and the promulgation of regulations resulted in the occurrence of an inflection point. This inflection point would have a significant effect on the growth of the relatively new field of clinical engineering. Very few of the nearly 7,000 U.S. hospitals had clinical engineering programs in the early 1970s. By 1975, JCAH (the largest hospital accrediting organization in the United States) had established a requirement that hospitals conduct incoming inspections of all new medical equipment and perform routine *electrical safety* testing of all medical equipment used in their facilities. When this inflection point occurred in the early 1970s, there were many opportunities for those individuals and businesses that were qualified and prepared to deliver biomedical equipment services. Larger hospitals employed clinical engineers and biomedical equipment technicians to develop and operate in-house medical equipment management programs. Smaller hospitals that could not afford to hire dedicated staff typically contracted with clinical engineering service organizations to obtain their medical equipment services.

The primary focus of clinical engineering services in the early years was on incoming and routine inspections (with an emphasis on electrical safety testing) and on repairs of biomedical equipment. While clinical engineering's role over the past 25 years has broadened, biomedical equipment inspection, electrical safety testing, and repairs still represent a substantial portion of most program efforts. Today, clinical engineering program services may include:

- Equipment management services
  - inventory management

Clinical engineers can be expected to develop organizational, project management, strategic planning, and investigative skills to ensure 24/7 availability of safe and effective healthcare technology.

- risk analysis
- evaluation of new devices and systems prior to acquisition
- vendor management
- compliance (e.g., government, accrediting standards)
- educational services (for equipment users and clinical engineering staff)
- device tracking (hazards and recalls)
- root cause analysis of adverse outcomes, incident investigation, and reporting:
- quality assurance

➤ Technical Services
- Inspection and testing (functional, safety, performance)
- calibration
- preventive maintenance
- corrective maintenance (repair).

Other than a broadening of the services offered, clinical engineering has not significantly changed. Given the technological, economic, cultural, and regulatory dynamics at work in the healthcare industry now, clinical engineering *will* be transformed over the next few years. The nature and success of that transformation depends on the action we as clinical engineers take now.

Take Action Now!

"If you want to prosper on the other side of a strategic inflection point, you must take action before you get there."

—Andrew S. Grove,
Intel chairman & co-founder

While still being mindful of our current business, we must lay the foundation for the future now. We cannot wait for events to overtake us or we risk irrelevance.

Clinical engineering must …

➤ **Adopt a systems and process approach.** Clinical engineering services have traditionally been oriented toward the management of discrete devices (i.e., *equipment* management). Systems and processes (i.e., *technology* management) were dealt with only marginally when they were dealt with at all. Consideration of systems and processes requires looking at the big picture—not focusing on discrete devices but understanding how individual devices must interconnect to accomplish a technical process. Clinical engineering must become more systems and process oriented. Increasingly, biomedical devices are becoming part of integrated technology systems. Technology will significantly contribute to quality of care, patient safety, patient outcomes, health data integrity, and availability issues. These issues involve processes and require a systems approach in their management.

➤ **Add basic information technology and telecommunications skills.** For years the trend has been for biomedical devices and systems to process increasing amounts of data and for these systems to be networked together to share this data. Today microprocessor, RAM, firmware, software, I/O port, and Ethernet are terms equally applicable to both biomedical and IT systems. This confluence of biomedical, IT, and telecommunications technologies will continue in healthcare. IT and telecommunication technologies will supply the backbone along which integrated biomedical systems will operate. Clinical engineering must develop basic proficiencies in IT and telecommunications. To insure support and coverage of these merging technologies, clinical engineering must also be prepared to integrate its services at an appropriate level with those of IT and telecommunications.

➤ **Monitor technological, regulatory, economic, and other developments**. Clinical engineering must monitor the developments likely to impact the value of its contribution to the organization. Clinical engineering services should be structured so as to take these developments into consideration and provide the maximum value. Clinical engineering should become proficient at new key technologies, be prepared to address new regulatory pressures, and to account for economic issues in its technology planning.

➤ **Become conversant in the "business" of technology.** Clinical engineering must acquire expertise in the economic nuances pertaining to the adoption and use of technology, including cost/benefit analyses, return on investment (ROI), and life-cycle cost analyses. These considerations are typically the prima facie support for technology-related decisions made by healthcare executives. Clinical engineering must be prepared to supply these decision makers with this information.

➤ **Plan for the integration of existing and new medical technologies.** Existing (i.e., *legacy*) and new technologies will be integrated. Clinical engineering must anticipate the need for integration, understand the implications, and possess the skills necessary to successfully manage the integration process.

➤ **Develop systems and infrastructure to support technology in nontraditional venues.** Healthcare will in-

creasingly be delivered outside traditional venues (e.g., hospitals and clinics). Clinical engineering must be prepared to incorporate and support medical technology in nontraditional locations (e.g., patient's home, assisted living facility, office, school, and public areas) by developing the necessary systems and infrastructure.

- **Closely examine existing clinical engineering services and practices.** Clinical engineering must closely examine its existing services and practices to determine which are necessary for the future and which should be discarded. Clinical engineering cannot afford to expend resources and continue providing services for which there is little or no demonstrable benefit.
- **Incorporate continuing education.** The pace of the healthcare technology revolution is quickening. Clinical engineering's only hope of making a contribution to the successful adoption of new technologies is to embrace a regimen of continuing education. Such education should include programs offered by universities, professional peer organizations, trade groups, and manufacturers. This education should also include regular literature research to identify current developments in technology and issues related to its adoption.
- **Build relationships with other stakeholders**. Teamwork is critical if the healthcare industry has any hope of effectively dealing with the technological, economic, regulatory, and social issues it must address in the coming years. Clinical engineering should identify stakeholders in the technology implementation process and should work to establish effective relationships with these key individuals and groups.
- **Develop a plan to transition from existing to future services.** Clinical engineering must develop and begin implementing a plan to transition from existing to future services. The plan must provide for acquisition of necessary skills and resources, education of clients as well as staff, and schedules to insure the transition is smooth.
- **Formulate a vision for clinical engineering within the organization.** Clinical engineering must develop and articulate a clear vision that is closely aligned with the vision and mission of the organization(s) served but in any case insures the vision promotes *quality*, *service*, and *innovation*.

Future Scope of Clinical Engineering Services

The clinical engineer's education and experience typically endow him or her with a fundamental understanding not only of relevant technologies but also of the physiological systems on which that technology is applied, of the healthcare environment in which the technology is used, and of the regulatory framework in which the technology exists. Clinical engineers can be expected to develop organizational, project management, strategic planning, and investigative skills to ensure 24/7 availability of safe and effective healthcare technology.

Given the forces for change and the clinical engineer's inherent and unique aptitudes, clinical engineering's future services are likely to include the following areas.

Management and Consulting Services

Inventory and Asset Management

To remain viable, any business must effectively manage its assets, and an accurate inventory is a fundamental component of any effective asset management program. Clinical engineering has in the past assumed, and should continue assuming, primary responsibility for maintaining the detailed inventory information on medical devices and systems. The basic inventory information includes quantity, type, owner, acquisition/warranty dates, and monetary value of medical devices and systems. Additionally, clinical engineering needs to regularly assess and update a broad range of information on these devices and systems including:

- current location
- associated devices and systems (i.e., a record of interconnections to other devices and systems)
- current physical and operating condition
- degree of obsolescence
- operating and service requirements and responsibilities
- operating & service history
- safety risk to patients/staff associated with device/system misapplication, failure, or lack of availability
- financial risk to organization in case of device/system failure (i.e., is device/system *mission critical*?)
- history of recalls and reported hazards.

Once collected, clinical engineering should *use* the above asset information to:

- provide a document trail regarding the condition, use, and servicing of devices and systems
- prepare capital budgets and schedule upgrades or replacements of worn or obsolete devices and systems
- encourage the standardization of devices and systems
- facilitate integration between other devices and systems
- plan the type, schedule, and source of service (i.e., calibration, inspection, and preventive maintenance)
- prepare service and operating budgets for medical devices and systems
- conduct risk analyses and facilitate risk mediation efforts (including disaster planning)
- analyze performance, integrity, and reliability of devices and systems
- analyze quality and effectiveness of technical services provided to devices and systems
- establish the real financial value for the organization's medical technology assets.

Strategic Planning

The evolution of healthcare technology is rapidly accelerating on a number of fronts. As this increasingly wide array of technology becomes available, it has the potential to positively impact healthcare delivery by improving quality, safety, and availability while reducing costs. However these positive effects can only be realized through careful planning, adoption, and integration of appropriate technologies into the healthcare delivery process. Clinical engineering is uniquely suited to contribute to the strategic planning process. Clinical engineers must be prepared to use their unique abilities to:

- continually work to sharpen their awareness of existing and newly available technologies
- evaluate the technical strengths and limitations in the context of the intended applications
- apply their knowledge of the environment where the devices or systems are to be used to the appropriate selection and configuration of devices and systems
- plan for installation, integration with other systems, training, and on-going service
- contribute to cost-benefit and life-cycle cost analyses.

Quality and Safety

In recent years, quality and safety have become and are likely to continue to be a major concern of the U.S. healthcare industry. Technology has the potential to positively contribute to quality and safety but can have a negative impact if not properly managed. To insure technology's impact is positive, clinical engineering must:

- adopt a quality management system (e.g., ISO 9000, Six Sigma, Malcolm Baldrige, or similar) that will facilitate identifying:
  - performance criteria for technical systems and processes
  - target goals and objectives (benchmarks) associated with use of technology
  - methods for achieving these goals and objectives
  - techniques for measuring progress toward goals and objectives
  - a process for analyzing and improving effectiveness of methods used to achieve goals and objectives
- implement a risk management program including
  - an assessment program that identifies risks by evaluating the implications of failure of technical systems and their related processes on patient health, patient/staff safety, and the financial well being of the organization
  - a mitigation program that prioritizes identified risks and provides methods for reducing them to an acceptable level
  - provide root cause analysis, investigation, and reporting support when technology and technical processes are involved in adverse outcomes or incidents
  - identify contributing causes
  - propose recommendations to prevent reoccurrence.

Compliance

Government and industry produce an ever-changing array of regulations and standards that impact healthcare technology. A clinical engineer's role includes insuring compliance with the relevant government, accreditation, and industry standards and initiatives (e.g., FDA, SMDA, HIPAA, JCAHO, IOM, IHE). This requires they understand existing laws, standards, codes, and practices and remain current on changes. Clinical engineering must also take steps to insure technical systems and processes are used and maintained in a manner that insures compliance with all relevant regulations and standards.

Vendor Management

Vendors include medical technology manufacturers, distributors, and independent service organizations. Since healthcare organizations necessarily deal with vendors to obtain medical technology and technical services, clinical engineering needs to insure the working relationship is an effective one for all parties. Clinical engineering should serve as technical liaison, insuring that vendors have all the information and access necessary for them to deliver appropriate technology and services. Clinical engineering should also:

- evaluate vendors, their products and services, recommending those who best meet the needs and standards of the organization
- insure inclusion of necessary terms and conditions in agreements with vendor and regularly insure vendor compliance with those terms/conditions
- ensure vendor makes available any information, documentation, software, specialized tools, and education necessary to operate or service technology
- verify integrity of technology supplied
- monitor vendor quality and integrity of services delivered.

Support Services

Education

Clinical engineering's role in technical education should continue to evolve. It is important to train users in the proper operation of technical systems. Their expertise in technology and understanding of applications make clinical engineers uniquely well suited to complement application training with education of users on the effective use and basic trouble shooting of devices and systems.

Help Desk

Clinical engineering should adopt the *help desk* concept. The concept of a help desk comes from the information technology industry. The proliferation of business computers onto the desks of non-IT personnel resulted in the need for a readily identifiable and available source of technical expertise (i.e., the *help desk*). When computer users experienced the inevitable computer problems, they could telephone a software or hardware consultant at a help desk who could talk the users through a solution, thereby solving the problem more quickly and less expensively than could be done by a visit by IT personnel to the user's desk. The use of remote access and remote control software in recent years has further enhanced the ability of the help desk personnel to assist, troubleshoot and solve problems remotely. If clinical engineering were to adopt the help desk approach, it could complement existing services by providing some operating and basic technical support for system and device users (e.g., clinicians and patients). As more and more medical systems are connected via telecommunications, networks, and the Internet, the help desk can perform remote troubleshooting, diagnostics, and system upgrades. Senior technical personnel on the help desk would also be available to support less-experienced technical staff at remote locations.

Technical Services

Installation and Integration

Installation of new technology today frequently requires software/hardware configuration and integration into existing systems. The level of integration of medical systems will substantially increase in the future. Clinical engineering's expertise in a wide variety of technical systems and applications makes it well suited to provide guidance and technical assistance in installation and integration services.

Upgrades

System upgrades will become more commonplace as advances occur in medical hardware and software. Technology owners will attempt to curb costs by staggering upgrades of components and software rather than upgrading an entire system at once. Clinical engineering must be prepared to provide advice and assistance in this upgrade process.

Testing, Inspection, and Preventive Maintenance

The role of testing, inspection and preventive maintenance will significantly decrease. Devices and systems will still re-

quire testing and inspection on installation. However routine testing and inspection on devices and systems where it has been demonstrated that the test/inspection results never vary is questionable both in value and in the use of limited resources. Medical technology has become sufficiently reliable that visual inspections, operational checks, and monitoring of self-diagnostics by technical staff and users will largely replace traditional forms of inspection, testing, and preventive maintenance.

Repair

Clinical engineering will continue to offer repair services for medical technology, but the amount and nature of repair services will certainly change. Repair services will occupy fewer clinical engineering resources as the technology continues to become more reliable and incorporate self-diagnostics. Repairs will also increasingly focus on troubleshooting and solving problems associated with systems of interconnected devices.

Summary

Clinical engineering is at a *strategic inflection point*. Technical, economic, regulatory, and cultural dynamics are at work shaping the future of healthcare delivery. As the nature of healthcare delivery is transformed by these forces, the types and mix of technology management and support services needed by the industry are changing significantly. Clinical engineering has a relatively short opportunity to adopt a service model that will meet these changing needs. Delay or failure to adopt an effective service model as we pass through the inflection point will result in a diminished role for clinical engineering in healthcare technology management as other technical professionals move in to fill the need. The question is: *will clinical engineering rise to the challenge?*

Acknowledgments

The author gratefully acknowledges critique and suggestions from the following during the authors' preparation this article (listed in alphabetical order): Matthew F. Baretich PhD PE CCE CHFM, president, Baretich Engineering Inc; Joseph F. Dyro PhD CCE FACCE FAIMBE, president, Biomedical Resource Group; Izabella A. Gieras MSBME, clinical engineer, Beaumont Services Company LLC; David Harrington PhD MBA, president, SBT Technology Inc.; Barbara V. Laighton BA, manager, Center for Information Technology Services, Skidmore College; Raymond P. Zambuto MSB CCE FASHE, president, Technology in Medicine, Frank R. Painter MSEng CCE FACCE, president, Technology Management Solutions; Malcolm G. Ridgway Ph.D. CCE, senior vice president, Masterplan Inc.

Stephen L. Grimes is a senior consultant specializing in clinical engineering and technology management issues. He has served the past 18 years as president of GENTECH, a clinical engineering and computer services firm in upstate New York. Prior to that, he spent 6 years with ECRI and its International Shared Services group where he developed risk management and other consulting services and served as regional director for their New York operations. He is a graduate of Purdue University's Biomedical Engineering Program and a Fellow of the American College of Clinical Engineering

Address for Correspondence: Stephen L. Grimes, FACCE, Senior Consultant and Analyst, GENTECH, PO Box 800, Saratoga Springs, NY 12866 USA. Tel.: +1 518 587 4000. E-mail: slgrimes@nycap.rr.com.

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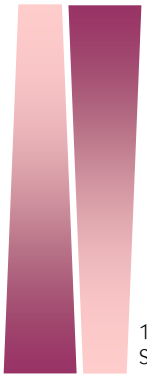

Strategic Health Care Technology Associates

Stephen L. Grimes, FACCE
Senior Consultant & Analyst

139 Henry Street
Saratoga Springs, NY 12886

Phone 518.441.5617
Fax 360.234.8894
slgrimes@nycap.rr.com