ABM Healthcare Support Services

The Next Evolution of Clinical Engineering

Is Your Clinical Engineering Service Truly Meeting Your Needs?

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Executive Summary

The question of whether or not healthcare organizations are well served by their existing clinical engineering (CE) services has become a common one over the past decade. For many, the answer is often "no" … or at least, "not well enough."

The pace at which new technology is being introduced into healthcare delivery has grown exponentially in the past decade. Surgical robots, radiosurgery systems, hybrid ORs, complex integrated medical systems, clinical decision support systems, and electronic health records are examples of some of the new technologies that represent both great advances in healthcare delivery as well as great challenges to healthcare costs and infrastructure. Many hospitals today are spending 8 to 10 times more than they were 10 years ago on medical capital equipment. Because of this, properly selecting, deploying and maintaining new healthcare technologies is critical and poses several challenges.

What readers will learn:

- A brief History of Clinical Engineering and the evolution of Medical Technology
- How Clinical Engineering must advance to support today's sophisticated healthcare technologies
- The steps necessary to align organization objectives with Clinical Engineering services
- How to strategically plan for the next decade of healthcare technology advancements

Brief History of Clinical Engineering and the Evolution of Medical Technology in the U.S.

Clinical engineering, including professional clinical engineers and biomedical equipment technicians, largely came to the healthcare industry in the late 1960s and early 1970s. Prior to that time, the use of diagnostic and therapeutic technologies in most hospitals was relatively sparse. Much of what did exist was either mechanical (e.g., anesthesia and suction machines), electrical (e.g., x-ray machines), or some unsophisticated combination thereof.

With the practical application of biomedical research conducted post-World War II and particularly during the period of the "Space Race," more sophisticated monitoring, diagnostic, and therapeutic technologies became available and were applied in the delivery of healthcare (e.g., physiologic monitoring, clinical laboratory, ventilators, heart-lung bypass systems, defibrillators and pacemakers). Along with the growing influx of these technologies, concerns began to rise regarding whether patient safety was being adequately addressed; companies producing new medical equipment were not exercising appropriate caution in the manufacturing process.

In 1970, consumer advocate Ralph Nader wrote an article claiming 1,200 patients per year were being electrocuted in hospitals because of faulty equipment and inadequate precautions. In his article, Nader recommended that hospitals retain qualified engineers and technicians who could help ensure the safe use and maintenance of medical equipment. Around the same period, the Joint Commission (formerly known as the Joint Commission for the Accreditation of Hospitals) mandated hospitals test quarterly ALL medical equipment for electrical safety (never mentioning performance testing). A few years later, Congress passed the Medical Device Amendments of 1976, which gave the United State Food and Drug Administration (FDA) the power to regulate manufacturers so as to help ensure only safe and effective products were brought to market.

Largely as a result of these events, in the ensuing decades the ranks of clinical engineering professionals grew and medical device related regulations evolved dramatically. Now, all healthcare organizations in the U.S. have equipment management programs, staff or contract technicians who perform testing and repairs, and engineers who evaluate and plan for the deployment of new (and replacement of old) medical systems.

Today's Clinical Engineering Service

To ensure clinical engineering services are performed correctly, clinical technology experts in the healthcare setting should be involved in all phases of the medical device/system life cycle.

Qualified clinical engineers understand new and replacement equipment planning, effective acquisition processes, compliance requirements, risk/vulnerability assessments and mitigation, device security management, alarms management, device integration, and service management using in-house and vendors in a manner that maintains quality while minimizing costs. Qualified biomedical engineering technicians are specialists who understand how to conduct or monitor the safe installation, operation, testing and repair of a wide range of medical devices and

systems. More than ever before, clinicians rely on technicians and engineers to be the healthcare organization's technical resources so that they can focus exclusively on providing patient care.

Clinical Engineering's Support of Healthcare Technology Today

Clinical engineering services used by many U.S. hospitals have not kept pace with the influx of increasingly sophisticated and complex technologies. Many clinical engineering services still focus on a technical role of safety testing, preventive maintenance and repair. This focus fails to take into account that the medical technology in use today requires a very different type of technical role.

Today's technology tends to be less mechanical (i.e., less affected by "wear & tear"), more reliable, and more capable of self-diagnosis. Regular equipment testing and preventive maintenance, which traditionally represented about 50% of a biomedical equipment technician's work time, is far less important today because a dwindling percentage of medical equipment failures are detected or prevented by routine testing or scheduled maintenance.

Continuing to perform unnecessary work is one part of the problem for many of today's clinical engineering services. Arguably the greater problem is that other, more critical needs are going unfulfilled. Redirected CE efforts could greatly contribute to the safer and more effective use of medical technology in healthcare. These new needs are the result of the introduction of increasingly complex and integrated medical technologies. The redirected efforts should include:

- Strategic capital planning – ensuring objective information is available to consider the effect of new system deployments, and that objective information is available to prioritize and drive multi-year capital replacement plans
- Acquisition of new technology – ensuring all necessary preparations are made and that stakeholders are appropriately engaged
- Total service management – managing both in-house and vendor resources in a manner that ensures safety and quality service are delivered in the most cost effective manner
- Risk and vulnerability assessments – working with appropriate stakeholders to identify those critical clinical systems with significant vulnerabilities and to establish and manage a plan to mitigate those risks
- Collaboration with information technology on integration, security and other areas for the rapidly growing number of networked medical systems
- Compliance – including new Joint Commission, CMS, ONC, and AAMI standards and requirements

Needs Alignment

How can a healthcare organization determine whether its current clinical engineering service is aligned with its needs? Organizations should start by asking if their clinical engineering service:

- Contributes objective and useful information to the capital planning process (including replacement planning)
- Routinely participates in all medical device/system evaluations and acquisitions (including laboratory, imaging, surgical, etc.) Does CE provide a list of materials required from the vendor?
- Manages and documents all medical equipment service regardless of source (i.e., in-house, manufacturer, third-party)
- Works with clinicians, risk management and other stakeholders to identify an organization's critical medical systems to establish and execute a plan to mitigate identified vulnerabilities
- Collaborates with information technology on medical device integration (e.g., into an organization's EHR), medical data security (e.g., identifying and protecting ePHI containing in many medical devices)
- Has a clear understanding regarding:
  - The Joint Commission's 2014/2015 National Patient Safety Goal on alarms management
  - The ANSI/AAMI/IEC 80001-1:2010 Application of risk management for IT networks incorporating medical devices standard
  - The 2013 CMS update to memo S&C 12-07 regarding equipment maintenance practices and the associated changes Joint Commission and DNV accreditation standards
- Staff are members (or participate in activities) of AAMI, ACCE and/or HIMSS and whether the engineers are certified clinical engineers (CCE) and technicians are certified biomedical equipment technicians (CBET)

If the answers to these questions are predominantly "no," there is likely a considerable 'gap' between what existing resources are delivering and the short and long-term needs of the organization.

Bridging the Gap

The "good news" is that the vast majority of clinical engineers and biomedical equipment technicians are conscientious and passionate about their contribution to quality and safe healthcare; what many lack, however, is adequate direction and support. This has led to a gap between what many clinical engineering services are delivering and what their organizations truly need.

If a gap exists, organizations should conduct an assessment of their technology plans and needs over the next 5 to 10 years. Once strategic technology plans have been identified, they should assess what resources and infrastructure are going to be needed to adequately support the new medical technology landscape. Completing this assessment involves meeting key stakeholders (e.g., clinicians, finance, supply chain, information technology, clinical engineering, risk management, facilities, principle vendors, etc.) to identify

needs and "pain points." It also requires a review of current resources (e.g., organizational structure, policies, procedures, workflows, staff, contract services, space, equipment, etc.) to ensure those resources are optimal and capable of meeting the need. The assessment should result in a description of the gap and a detailed roadmap on how it can be bridged.

Many organizations will need to seek a consultant or consulting organization that can adequately identify their most pressing needs and establish an effective roadmap. If using a consultant or consulting organization, healthcare organizations should be sure to research backgrounds for evidence of appropriate experience and expertise.

Conclusion

Medical technology will continue to have major implications for the ability of healthcare organizations to deliver quality and economic care in the future. Only with access to a robust and fully engaged clinical engineering service can those organizations hope to achieve that goal.

Author info

Stephen L Grimes, FACCE FHIMSS FAIMBE is Chief Technology Officer of ABM Healthcare Support Services. Mr. Grimes has more than 30 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. Mr. Grimes is a frequent author and speaker at both national and international venues. He is a Fellow of the Healthcare Information and Management Systems Society (HIMSS) where he currently chairs their Medical Device and Patient Safety Task Force. He was also named a Fellow of the American Institute of Medical and Biological Engineering (AIMBE) a Fellow of the American College of Clinical Engineering (ACCE) where he is a past President. In February 2011, he received the joint industry ACCE/HIMSS Excellence in Clinical Engineering & Information Technology Synergies Award. Mr. Grimes is a graduate of Purdue University's Biomedical Engineering Program.

About ABM Healthcare Support Services

ABM Healthcare Support Services works in partnership with over 300 hospital clients throughout the United States, employs thousands of well-trained specialists and has revenue approaching $500 million. Additionally, for three of the last four years, HHA Services has been selected as one of Modern Healthcare's Best Places to Work.

ABM Healthcare Support Services is uniquely positioned to help healthcare industry facilities provide a new standard of care, which starts with a comprehensive, on-site facility assessment, including a thorough analysis of current operations and costs. Then ABM Healthcare Support Services will prepare a detailed business plan outlining a vision for future operations and recommended improvements to the current budget and existing service delivery model to improve overall patient satisfaction and safety while reducing overall costs.

ABM Healthcare Support Services is part of ABM (NYSE: ABM), a leading provider of facility solutions with revenues of $4.8 billion and 110,000 employees worldwide.

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