

A Clinical Engineer

is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology.

ACCE Definition, 1992.

The convergence of medical and information technology systems has changed the practice of Clinical Engineering. Those changes include an expanded focus on systems of systems, a broadened scope of work, and a substantial increase in the underlying body of knowledge required.

The clinical environment has moved from standalone medical devices to a world dominated by complex clinical systems, intimately bound to IT by network connections and the tight integration and flow of data between various systems. In this new arena, clinical engineers and IT professionals must regularly interact at many levels.

For clinical engineers, new challenges have evolved. Strategic issues of technology acquisition, systems integration and support for the flow and security (i.e., integrity, availability and confidentiality) of patient information have sharply risen.

Clinical engineers are responding to these changes by broadening their skills and developing strong relations with IT in their organizations. Working together, they can achieve the maximal levels of efficacy and safety as these new technologies are deployed.

American College of Clinical Engineering

Founded in 1990, ACCE is a non-profit professional society committed to enhancing and advocating for the profession of clinical engineering worldwide. With members from the U.S. and around the world, ACCE is widely recognized for its contributions to patient safety and the effective use of healthcare technology.

Mission of ACCE

- To establish a standard of competence and to promote excellence in clinical engineering practice.
- To promote safe and effective application of science and technology in patient care.
- To define the body of knowledge on which the profession is based.
- To represent the professional interests of clinical engineers.



ACCE

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Relationship between CE & IT

The evolution of technology in healthcare is accelerating. Integrated clinical information systems, robotics, imaging, genomics, telemedicine and nanotechnologies are only some of the transforming technologies that are impacting clinical engineering practice. While these integrated medical and information systems are significantly advancing our capabilities to deliver care, they also are adding layers of complexity which can challenge patient safety, clinical practice, and technology management. As a result, the scope of clinical engineering practice now includes aspects of integration management, the impact of software on workflow, human factors, and interaction between systems. Many healthcare providers do not yet have the infrastructure to adequately deal with this emerging reality of healthcare as a "System of Systems." Clinical engineers engage this transition by fostering collaboration with healthcare Information Technology (IT) to create a seamless support service for medical and information technologies. By jointly developing appropriate tools, processes, and positions, substantial benefits to patient care and economic sustainability are being attained.

Device Integration

The days of discrete, stand-alone medical devices are gone. Some recent studies suggest that more than fifty percent of a healthcare provider's medical inventory is network capable. Examples of some medical devices that have been integrated are ventilators, cardiac output computers, extracorporeal therapy systems, infusion pumps, vital signs monitors, electrocardiographs, infant incubators, blood gas analyzers, and even smart beds. The potential benefits of medical device integration on patient care and patient safety are substantial. Integration not only allows automatic and accurate charting of data from medical devices to the electronic medical record (EMR), it will also enable possibilities like establishing systems where outputs of diagnostic devices (e.g., heart rate monitors & pulse oximeters) can affect input on therapeutics devices (e.g., infusion pumps). Integration also facilitates remote management of medical devices (e.g., monitoring data flow integrity/continuity, error code monitoring, remote diagnostics, software updates).

IT Collaboration

While there is growing recognition of the need for collaboration, the industry has been challenged on how best to achieve it beyond changing lines on the organization chart. Clinical Engineering and IT have fundamental differences

in their cultures - differences which can be highly complementary. As they work together to improve the deployment and management of integrated systems, both clinical engineering and IT can and should retain their uniqueness (e.g. clinical engineering's focus on patient safety and the clinical environment). Clinical engineers will need to understand some of the management frameworks used by IT, however, such as the Information Technology Infrastructure Library (ITIL) or ISO/IEC 20000-1:2005 Information Technology – Service Management, since elements of these models are common to clinical engineering. Regardless of the physical or operational structure adopted by the organization, the most successful implementations of these high technology systems of systems will be where clinical engineering and IT work side by side to devise policies, protocols, and joint skill sets. This is essential to ensure seamless support for all converging technologies.

Patient Safety

Patient safety takes on new importance in the integrated environment. It can be compromised at any of the interfaces between the patient, equipment, caregiver, and environment. The progressively complex nature of integrated systems significantly increases the challenge of detecting safety risks. Clinical engineers must be particularly sensitive to the subtleties of complex systems; of software or hardware errors that could impact a patient; of hidden program errors that do not surface for weeks or months after deployment; or, of errors introduced into the system by poor human factors design, or clinician information overload. By combining their strengths and harnessing their diverse backgrounds, Clinical engineers and IT professionals can reduce the occurrence of medical errors and improve patient safety.

Standards & Standardization

As the technologies grow increasingly complex and integrated, clinical engineers must become knowledgeable of the standards used for communicating information between devices and systems. IT professionals are familiar with DICOM (Digital Imaging and Communications in Medicine) - the image exchange standard for networked devices, and HL-7 (Health Level Seven)—the data exchange protocol for healthcare messaging. Wireless networks are governed by IEEE standards 802.11 a/b/g/n; short

range wireless devices follows the Bluetooth standard; the Wireless Medical Telemetry Standard (WMTS) defines the frequency band allocation for medical telemetry; and electronic communication between devices is governed by a range of standards developed by IEEE and other bodies. The IHE (Integrating the Healthcare Enterprise) initiative sponsored by HIMSS, ACCE and many other professional organizations has been identifying standards for connecting and exchanging data between disparate medical devices and systems in order facilitate processes that contribute to the effective and efficient delivery of patient care.

Risk Management

The use of increasing use of complex and integrated medical technologies has created both greater dependence by providers on the use of these technologies and more severe implications should these technologies fail. Clinical engineering and IT need to coordinate efforts and work with clinicians and other stakeholders to identify risks and mitigate against failures ... particularly those single points of failure (SPoF) that can lead to compromise or shutdown of major critical systems.

Medical Device Cybersecurity

A significant consequence of the convergence of medical and information technologies is an increasing risk to the security of data being transmitted to/from or stored in medical devices. The rapidly growing number of computer-based medical devices and systems being networked has increased the vulnerability of the data to disruption. With diagnostic and therapeutic signals potentially sharing the information systems backbone, risks extend beyond patient privacy. Compromises to diagnostic or therapeutic signals can impact patient care and well being. Clinical engineers and IT professionals are increasingly focusing and coordinating their efforts in this critical area. ACCE has been a leader in the advancement of medical device security through its work with HIMSS, AAMI, IEEE, and other societies.

As Medical and Information Technology worlds continue to converge, clinical engineers will assist in the integration of the new technologies into the healthcare system, foster the acceptance by the clinical communities, and remain vigilant to the needs for patient safety and clinical information security.