ENHANCING PATIENT SAFETY
The Role of Clinical Engineering

a white paper prepared by the

American College of Clinical Engineering

Opportunities for enhancing patient safety exist within the healthcare delivery system. Individuals and groups throughout the system are actively pursuing these opportunities. The profession of clinical engineering has a unique role to play in enhancing patient safety, particularly with regard to medical technology as it is applied in our healthcare delivery system.

The American College of Clinical Engineering was established in 1990 to represent and advance the profession of clinical engineering. ACCE has prepared this white paper to share its vision of the role of clinical engineering in enhancing patient safety. We address the white paper to our colleagues within the healthcare delivery system.

Our message is that clinical engineers, individually and collectively, will continue to work to improve patient safety. Our message is also that ACCE is taking a leadership role in pursuing opportunities for clinical engineering to contribute even more effectively in the area of patient safety. We seek the cooperation and active support of all our clinical, technical, and administrative colleagues in this pursuit.

Patient Safety

Over the past decade there has been steadily increasing concern regarding patient safety. Results from the Harvard Medical Practice Study focused attention on the incidence of adverse events in healthcare delivery (Brennan *et al.*, 1991; Leape *et al.*, 1991). Subsequent studies provided additional quantitative data (Thomas *et al.*, 2000). In a landmark report, "To Err is Human: Building a Safer Health System," the Institute of Medicine (2000) estimated that medical errors cause 44,000 to 98,000 deaths annually in U.S. hospitals.

One response to the concern for patient safety has been an effort to improve reporting systems for medical errors – including "near misses" in which errors could have caused death or injury but, fortunately, did not. The objective is to learn from these errors and find ways to prevent them from recurring. Such efforts have been hampered by controversies regarding mandatory versus voluntary reporting, confidentiality of data, and professional liability.

Another response has been to identify existing knowledge and resources that may be applied to the problem. In some cases the relevant knowledge and resources lie outside the healthcare delivery system. For example, past improvements in the safety of commercial aviation may serve as a model for healthcare delivery. In other cases, however, valuable knowledge and resources may be found within the healthcare delivery system itself. In this regard, improved cooperation and coordination among healthcare professionals is considered vital.

Of immediate impact on hospitals and other components of the healthcare delivery system are new patient safety standards promulgated by the Joint Commission on Accreditation of Healthcare Organizations (2001). The new patient safety standards cut across disciplinary boundaries in an attempt to make safety a fundamental principle of patient care. These standards are linked to long-standing safety-related standards regarding infection control, the environment of care, and other disciplines.

In a follow-up to its earlier report the Institute of Medicine (2001) has published "Crossing the Quality Chasm: A New Health System for the 21st Century." This report places patient safety within the broader context of quality and calls for a healthcare delivery system that is safe, effective, patient-centered, timely, efficient, and equitable. Underlying many of the report's specific recommendations is a concern that the healthcare delivery system is fragmented in ways that produce the opposite of these qualities.

What can be done now to enhance patient safety? First, we can improve our ability to learn from mistakes. Skillful investigation of incidents and responsible sharing of data will help us identify the root causes of error. Second, we can improve our ability to anticipate mistakes. Cooperation among healthcare professionals of all disciplines will augment our capacity to probe the weaknesses in the system.

Finally, we can improve the healthcare delivery system itself. All of us within the healthcare delivery system can work with other stakeholders to reconfigure the structure of the system, to realign the incentives that guide the system, and to build the resources the system draws on to produce high quality patient care.

Medical Technology and Patient Safety

A defining characteristic of the modern healthcare delivery system is the ubiquitous use of medical technology. Broadly speaking, medical technology includes not only medical devices, drugs, and biologics, but also the medical and surgical procedures they enable and the organizational and support systems within which they are used. Diagnosis, monitoring, treatment, and rehabilitation all rely on complex and sophisticated medical technologies.

In today's healthcare delivery system the patient is at the center of an intricate network of clinicians, medical devices and other elements of the system. Every interface between a human being and a machine contains opportunities for error: information may not be

accurately acquired, recorded, or communicated; necessary actions may not be safely and effectively carried out; adverse events may occur.

The healthcare delivery system has been criticized for its "culture of blame" in which culpability for failure has been attributed to the human elements of the system: people make errors; therefore people must change their behavior to reduce errors. However, numerous researchers (Bogner, 1994; Cook, 1998; Perrow, 1999) have found that human errors are more generally associated with latent causes hidden within systems and processes. Current thinking places the responsibility for "human error" squarely on the shoulders of latent (root) causes that can be prevented only by adjustments to systems and processes.

Simplistic models of adverse events involving medical technology have been based on a dichotomy between "device failure" and "user error." However, more sophisticated taxonomies have been developed that recognize numerous sources of error with the potential for complex interactions among them (ECRI, 1991). To emphasize the multifaceted nature of medical technology application some authors employ the term "use error" rather than "user error" (CDRH, 2000; Hyman, 1995). The critical point is that errors associated with the *use* of medical technology should not be automatically attributed to the *user*. More importantly, efforts to eliminate such errors should not focus on the user in isolation from the system in which he or she works.

In a recent report to Congress (Gardner and Flack, 1999) the U.S. Food and Drug Administration stated that under the requirements of the Safe Medical Devices Act medical device manufacturers reported a total of 980 device-related deaths in 1998. In a presentation to the Association for the Advancement of Medical Instrumentation (AAMI, 2000) a representative of the FDA Center for Devices and Radiological Health stated that one-third of the 80,000 incident reports it receives annually may involve medical equipment "use error." Medical technology is an integral component of the healthcare delivery system. Efforts to improve patient safety and the quality of healthcare delivery must take into account the omnipresence of medical technology.

The Clinical Engineering Profession

The American College of Clinical Engineering defines a clinical engineer as "a professional who supports and advances patient care by applying engineering and management skills to healthcare technology." Clinical engineering became a distinct profession in the 1960s in response to increasing use of medical technology in healthcare delivery. Since that time, clinical engineering has become a vital component of the healthcare delivery system, providing leadership in the safe and effective application of medical technology.

Throughout its history, clinical engineering has focused on medical devices as they are used in healthcare delivery settings: dealing with acquisition of appropriate equipment; inspection, maintenance, and repair; regulatory compliance; and related technical issues. Over time, clinical engineering has assumed a leading role in management of medical

equipment during its entire life span of use. As a result, clinical engineers have become deeply involved in quality improvement and risk management activities.

Clinical engineers are essential members of multidisciplinary hospital teams investigating incidents in which a medical device may have contributed to injury or death. The clinical engineering perspective can be instrumental in identifying root causes and solutions. An understanding of equipment design principles can produce insights that go beyond the standard behavior of the device in question. An understanding of equipment operation and maintenance can draw attention to likely failure modes and the effect of support systems of device performance. An understanding of systems theory and human factors engineering can shed light on the interaction between machines and humans.

Clinical engineers have also made contributions to patient safety beyond their own institutions in fields as diverse as anesthesia mishaps (Cooper *et al*., 1984), radio frequency interference with medical telemetry (American College of Clinical Engineering, 1998), and remarketing of medical devices (Hatem, 1999). Clinical engineers have advanced the literature of patient safety (Hyman, 1994; Shepherd, 2000) and incident investigation (Bruley, 1994; Dyro, 1998; Shepherd and Brown, 1992) Building on this history, clinical engineers have an important and unique role to play in efforts to improve patient safety.

In the future individual clinical engineers will continue to act within their own healthcare facilities to enhance patient safety on a day-to-day basis. Beyond this the clinical engineering profession will continue to work at all levels within the healthcare delivery system to improve patient safety and the quality of healthcare delivery.

The American College of Clinical Engineering

The American College of Clinical Engineering was established in 1990 to represent and advance the profession of clinical engineering, both in the United States and internationally. During that time it has acted both independently and in cooperation with other organizations to achieve its objectives.

For example, ACCE has worked with the U.S. Federal Communications Commission and the American Hospital Association to resolve radio frequency allocation conflicts that threatened the performance of medical telemetry. Similarly, ACCE has worked with the U.S. Food and Drug Administration and the Association for the Advancement of Medical Instrumentation to establish voluntary standards for remarketing of medical devices.

Since 1991 ACCE has also conducted numerous Advanced Clinical Engineering Workshops to educate clinical engineers in developing countries on the fundamentals of technology management. In addition, ACCE has recently assumed management of the clinical engineering certification program established in 1977 by the International Certification Commission on Clinical Engineering and Biomedical Technology.

The ACCE Board of Directors has established an ad hoc committee on patient safety. The committee advises the board of opportunities to advance patient safety in healthcare

delivery. The board has identified several strategies that it will adopt as opportunities occur:

- To seek partnerships at national and international levels to pursue common goals for enhancing patient safety.
- To provide formal endorsements of new strategies and methodologies designed to enhance patient safety.
- To prepare a directory of publications and other resources for reference and application by healthcare professionals in enhancing patient safety.
- To develop educational programs that improve the skills of healthcare professionals and their ability to participate in efforts to enhance patient safety.
- To review the body of knowledge for clinical engineering certification for inclusion of human factors engineering, root cause analysis, and other fields of study related to patient safety.

The first tenet of the ACCE Code of Ethics calls upon clinical engineers "to strive to prevent a person from being placed at risk of injury due to dangerous or defective devices or procedures." The American College of Clinical Engineering pledges itself to that duty in the far-reaching context of patient safety and high quality healthcare delivery.

For Further Information

For further information regarding the American College of Clinical Engineering and its efforts to enhance patient safety:

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