Chapter 12
Clinical Engineering

Joseph F. Dyro
Biomedical Resource Group, USA

ABSTRACT

Clinical engineering supports and advances patient care by applying engineering and managerial skills to healthcare technology. Since the 1970s, as medical device technologies have proliferated, increasingly impacting the cost and quality of healthcare, the clinical engineering profession has matured to play a significant role in healthcare technology management. It increases the cost-effectiveness, safety, and optimal utilization of medical devices. This chapter provides a comprehensive overview of the clinical engineer's body of knowledge. It is addressed to international clinical engineering researchers, faculty, and students, as well as clinical engineering practitioners, medical device technology managers, hospital administrators, clinical and technology support personnel, regulators, and manufacturers. The chapter provides a solid foundation upon which healthcare systems can utilize methods for managing the ever-increasing number and complexity of medical device technologies and systems.

12.1. CHAPTER OBJECTIVES

This chapter, which reveals the essential elements of the clinical engineering profession, serves as a basis for a comprehensive educational curriculum for the student and a desk reference and resource for the practicing engineer concerned with medical device technologies in health care. It explains the management and technical concepts of the profession and their relevance to the rapidly advancing field of medical device and other health care technologies. It presents the origins, development, present status and future of this applied branch of Biomedical Engineering. Most of the material in this chapter is drawn from the experience of clinical engineering in the United States. Differences do exist in clinical engineering practice and education from country to country (Jackson *et al.*, 2010). The intent of this chapter is to provide a framework for growth of clinical engineering where it does not currently exist, and for the modification of existing models where appropriate.

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The chapter begins with an introduction and a definition of clinical engineering followed by a historical background and literature overview. Next, clinical engineering practice is described beginning with a delineation of the many and varied roles and responsibilities of clinical engineers, most of whom work primarily within hospitals with the remainder supporting and advancing healthcare as manufacturers, regulators, educators, researchers, and consultants. Clinical engineers working in hospitals, hospital networks, extended care facilities or service companies manage medical device technologies. The various ways in which they serve the needs of the healthcare industry and the wide range of medical device technologies are detailed herein.

Included within the scope of clinical engineering practice are clinical application of technology, health technology management, standards and regulations, research and development, patient safety, failure analysis, human factors, education and training, and professionalism and ethics. Clinical engineers extend their expertise beyond medical devices and into medical systems of interconnected devices, information technology, and clinical facilities and utilities.

A further objective of this chapter is to look to future directions, such as the convergence of clinical engineering and information technology, the need for clinical systems engineers, a return to clinical support, and maintaining expertise in evolving technologies and sciences; e.g., nanotechnologies, materials, diagnostic sensors, and surgical techniques. Finally, professional societies and organizations are described, and resources and references are listed.

12.2. INTRODUCTION

Clinical engineering emerged from the realization that engineering attributes, i.e., analysis and synthesis, are relevant and necessary to improve health care (Caceres, 1977). Some engineering aspects of the profession eroded over the years as hospital administrators and engineers themselves viewed the primary clinical engineering activity as medical device inspection, maintenance, and repair. Fortunately, the original concept of clinical engineering has reemerged, largely in response to the driving forces of cost-control, utilization optimization, regulatory requirements, patient safety and human error awareness, and increasing complexity of the technological environment. For example, among the forces of change were the revelations of inadequacies in the so-called healthcare delivery system (Kohn *et al.*, 2000). Systemic ailments in this system cry out for re-engineering. No longer can clinical engineering be content with following routine maintenance and repair procedures when the need is so great for making engineering changes in the healthcare arena; changes that will support and advance patient care.

The value of clinical engineering to the healthcare community is clearly recognized and enthusiastically embraced. The enormous potential of highly competent, well-educated, talented, and skilled clinical engineers is now tapped for inventions, technical development, and systems analysis. Clinical support, engineering at the bedside, healthcare delivery process improvement, enhanced technology utilization and patient care, and device design are at the core of the clinical engineering discipline. The listing of the many facets of the discipline of Clinical Engineering is shown in Figure 1.

Within the complex environment of the modern hospital, clinical engineering is primarily concerned with medical devices, but recognizes that interactions between drugs, procedures, and devices do commonly occur and must be understood and managed to ensure safe and effective patient care.

Engineers who are active in the healthcare sector contribute to long-term quality development by developing new techniques or improving existing ones. By working daily with medical