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It is a pleasure to introduce *A Practicum for Healthcare Technology Management*, which was originally assembled and edited by my late colleague and very good friend, Leslie R. Atles, and published in 2008 under the title *A Practicum for Biomedical Engineering & Technology Management Issues*. When Les passed away in February 2013 after a very short illness, I resolved to do all that I could to ensure that his passion for the new generation of healthcare technology management (HTM) professionals would live on. Les’ wife, Linda Atles, and I offer our thanks to those colleagues who have made this continuation of Les’ vision possible.

This edition includes a whole new chapter on the evolution of reliability-centered maintenance and its relevance and potential application to HTM. Fast-developing topics such as collaboration with information technology professionals, picture archiving and communication systems, and radio frequency identification (RFID) have all been updated and refreshed. Useful information on two new technologies related to RFID—near field communication and body area networks—has also been added.

The chapters in the original edition that were adapted from the material initially published by Marquette as the *Affinity Reference Guide for Biomedical Technicians* have not been included because this particular material has been republished by GE Healthcare since they acquired the Marquette organization. A few of the other original chapters have also been omitted for a variety of reasons.

The staff at AAMI, particularly Steve Campbell, chief operations officer, and Melissa Coates, special projects editor, have been wonderful to work with, and Linda and I wish to thank them for all of their hard work, dedication, and professionalism in making this updated edition possible.

*Malcolm G. Ridgway, PhD, CCE, FAIMBE*
Chapter 1

A Brief History of Clinical Engineering and Biomedical Equipment Technology

Tom O’Dea, PE (retired), CCE, SASHE, PhD

Overview

The history of clinical engineering can be described by outlining the controversies that have arisen during the brief history of the profession. Many of these remain unresolved. However, one fact is universally agreed on, both by practitioners in these fields and by those patient care providers that need their services: medical equipment management services are integral to patient care in the modern healthcare services. However, many different models of the extent of these services and the manner in which they will be provided exist today and will probably continue for the foreseeable future. It is the purpose of this overview to outline these controversies and the ways they have been resolved over the last 60 years.

In the Beginning

In the late 1950s and early 1960s, dependence on devices in patient care increased rapidly. Medical imaging was one of these areas. For example, interventional radiology depended on radiographic and fluoroscopic units of increased resolution and dependability, multichannel cardiac monitoring systems, and analog recording systems. In addition, bedside monitoring systems in the cardiac, surgical, pediatric, and neonatal intensive care units allowed continuous monitoring of ECG, arterial blood pressure, and later cardiac output, as well as more specialized parameters. Technology became more prominent in patient treatment as well. The use of ventilators, kidney dialysis machines, neonatal warmers, and specialized patient units became commonplace, not
only in metropolitan medical centers but, to a limited degree, in community hospitals. Even patient beds became electrically powered. In the operating room, cardiac bypass, specialized anesthesia delivery and monitoring systems, and electrosurgery units became commonplace. Finally, laboratory technology—especially using multichannel analyzers and high throughput hematology systems—replaced manual analytic method for patient laboratory tests.

However, the existing technology depended on vacuum tubes and electromechanical relays and stepper switches. Constant surveillance and frequent maintenance was required because of high operating temperatures, voltages, and currents, as well as sensitivity to dust and dirt. In addition, proliferation of standalone bedside and operating room devices overwhelmed the number of outlets and the electrical capacities of healthcare facilities. The result was a tangle of carts and “jerry-rigged” electrical systems in close proximity to the patient bedside or operating table.

The situation was brought to the attention of the healthcare community with the publication of Dr. John Bruner’s article, “Hazards of Electrical Apparatus” in the March/April 1967 issue of Anesthesiology. As concern grew, estimates of the number of hospital deaths due to electrocutions were made at 1,200 to 12,000 annually, and public awareness led to regulatory bodies, especially the local code officials, paying particular attention to the electrical safety issue.

Voluntary organizations, such as The Joint Commission (TJC), Underwriters Laboratories (UL), the Association for the Advancement of Medical Instrumentation (AAMI), and the National Fire Protection Agency (NFPA), issued documents and recommendations, which were adopted by regulatory agencies and quickly went from voluntary to mandatory standards. Although these were quite far-ranging and sometimes conflicting, there were four basic areas of discussion:

1. A value for the maximum current (termed leakage current), which could be transmitted to patient from the device. This varied from 500 microamps (μA) to 1 μA, depending on patient circumstances and other factors.
2. A testing interval and methodology for testing leakage current. Intervals varied from monthly to annually at various times.
3. Facility system issues such as number of outlets per bed, integrity of grounding (not only for outlets but also for all metal surfaces within the patient vicinity), and the availability of emergency power to outlets. This led to the marketing of safe power centers for the patient bedside.
4. The necessity of isolated power to operating rooms, wet locations such as physical therapy, and dialysis units and to intensive care units. Since a single line to ground fault would pass unnoticed within an isolated power system, line isolation monitors were required to ensure system integrity.

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Although hospitals strove to implement these recommendations, intensive marketing efforts by electrical systems vendors to hospitals and also to regulatory agencies and voluntary standards organizations created uncertainty and concern among healthcare professionals and the public.

To the rescue came a group of engineers and technicians trained in university research laboratories and, especially, the military. These were often folded into existing departments such as anesthesiology, radiology, patient monitoring, and especially hospital facilities. But it became clear that the clinical engineering and biomedical equipment technology functions were not restricted to any particular hospital department, and that the freedom of action and accountability granted by independent departmental status was a definite advantage to medium- and large-sized hospitals.

Thus, by the early 1970s, the need for these two disciplines was firmly established and the stage was set for further controversies.

Definition and Accreditation

Although both clinical engineers (CEs) and biomedical equipment technicians (BMETs) worked side by side and often performed the same functions, the original difference between the two—that the CE had a college degree and thus might be classified in a managerial position, while the BMETs did not—swiftly became blurred. On the one hand, BMETs proved quite capable in managing departments and hospital functions, and frequently attained bachelors and advanced degrees. Conversely, many CEs proved both adept and interested in hands-on equipment repair. Thus, attempts to differentiate between the two proved imprecise. This has resulted in a laissez faire of atmosphere in hospitals, so that the appropriate individual, whether BMET or CE, manages the department.

On the other hand, the issue of qualification and training became paramount in both professions. A process of self-regulation through the International Certification Commission (ICC) was begun in the early 1970s for both BMETs and CEs. The ICC also certifies BMETs in clinical laboratories (CLES) and radiology (CRES). The American College of Clinical Engineering (ACCE) has a process for certification of CEs, in addition to the U.S. Department of Veterans Affairs (VA). A number of surveys have shown that certified BMETs are better paid than their uncertified counterparts, but CE certification compensation is less clear. The issue of professional engineering (PE) registration, while important in design and even facilities areas of healthcare, has not been required for clinical engineering practice. Liability and legal issues may lead more CEs working in hospitals to achieve this credential in the future.
New Functions of the CE and BMET in the Hospital

Although the initial emphasis of the two professions was the electrical safety of the patient care environment, the early 1970s saw both professions quickly branch out into other aspects of medical equipment management in the hospital setting. Motivation for these changes was frequently described as “emerging from the basement” and “achieving a window.” Also, the pressure to safely maintain direct patient care equipment was decreased by technological advances, especially the advent of solid-state technology in the form of discrete transistors. In addition to improving safety and reliability by decreasing the temperature, bias voltages, and current at which devices operated, use of solid-state technology decreased the number of mechanical relays and stepping switches, allowed combination of the numerous standalone boxes into modular systems, and decreased the size of displays. This relieved the clutter of devices at the bedside and the power drawn from electrical power systems.

Thus, CEs and BMETs sought to expand their horizons—both in seeking new technological areas to ensure device safety and reliability and also in exploring new areas of equipment management. Indeed, the term equipment management was coined at this time. These new areas brought these professions into contact with other disciplines within the hospital setting. The interconnection of devices into subsystems and interfacing with the fledgling hospital-wide data and communication systems required cooperation with both information management and facilities departments.

Although solid-state electronics greatly improved device and system reliability, troubleshooting and repair of such devices required new skills and a higher level of knowledge and manual dexterity. Items such as electric beds and televisions incorporating solid-state technology often became the responsibility of BMETs. Radiology and clinical laboratory equipment also increased in complexity, and a number of devices—including those used for image-guided invasive procedures in the radiology area—progressed from heart catheterization to other circulatory areas, such as neurological and peripheral vascular. All of these technology advancements increased the visibility and utility of the CE and BMET in these areas.

In addition, involvement in the purchasing process and staff education in the safe use of clinical systems began to occupy a larger role in the daily work schedule of BMETs and CEs. These activities were supported by new equipment management computer systems, which served to track the service history of each clinical device and system. In addition to ensuring that devices did not get overlooked in the testing process, these systems allowed the tracking of trends. Thus, failure-prone devices and systems could be weeded out and the results used in future purchasing decisions. The success of planned and preventive maintenance in reducing failures could also be tracked, thus beginning departmental maintenance productivity measurements.
As a result of these departmental productivity measurements, and an acceleration of financial pressures on healthcare institutions brought on by more stringent reimbursement procedures, discussion began on appropriate parameters for describing the value of CEs and BMETs in financial terms to these institutions. Evaluation of productivity first demanded a definition of CE and BMET productivity in quantitative and customer satisfaction terms, then quantification of these definitions in readily measurable parameters, and finally publication of data in reputable journals. In this way, institutions and CE and BMET departments could compare their productivity and institutional value to the best practices, a process that became known as benchmarking.

The four financial criteria evaluated were as follows:
1. Maintenance cost per bed and/or operating room
2. Maintenance cost as a percentage of acquisition cost, perhaps adjusted by a depreciation factor
3. Maintenance cost per annual patient day, adjusted by patient intensity
4. Maintenance costs as a percentage of annual institutional budget

Some of the parameters targeted for benchmarking were controversial. Comparing maintenance costs among institutions, even with data available from an advanced computerized equipment management system, proved very difficult. Since departments had arisen under different circumstances, organizational structures, and scope of responsibilities, comparison often led to inexact conclusions. Some key CE/BMET functions—such as purchasing, educational, and research consultation—were not included in any financial benchmark.

As the financial pressure on hospitals increased, these benchmarks became more critical to the survival of in-house CE/BMET departments, especially in the light of the new mode of providing these services—the shared service. Shared services had been on the scene since the dawn of CE/BMET services as part of multihospital systems, but during this period, not only did the number of multihospital systems due to hospital mergers increase dramatically, but also the number of third-party equipment services increased. Companies that had specialized in building maintenance and environmental services aggressively marketed CE/BMET services to hospitals. In addition, large, original equipment manufacturers often bundled multidepartmental and multivendor repair contracts, thus providing further options to financially harried hospital administrators. Although the total job pool for CEs and especially BMETs remained relatively stable, those who enjoyed the hospital, rather than the corporate, environment found positions scarcer.

Technology also changed drastically in the 1990s. The microprocessor became the basis for most clinical devices. This required close cooperation between clinical/biomedical departments and information management areas. Software and firmware became a large component in maintaining system reliability. This resulted in these departments becoming united in organization as well as function.
Some new environmental and regulatory challenges also rose during these years. The ubiquity of cell phone and wireless networks (WiFis) required radio frequency measurements and threat assessments by CE/BMET departments. At the turn of the century, the millennium bug—a possible threat to all mainframe and microprocessor-based systems using a clock—threatened widespread system failure at the stroke of midnight 2000. This threat did not materialize, but anticipation of the problem led to a global reevaluation of existing software and firmware and probably resulted in avoidance of a number of potential software glitches. Nonetheless, the millennium bug remains one of the most dramatic cases of overreaction in the history of medical instrumentation—and, indeed, of all technology.

A general challenge similar in scope to the millennium bug was ushered in with the report on medical errors issued in 2000 and 2001 by the Institute of Medicine (IOM). The IOM cited numbers of deaths similar in scope to the original estimates of deaths from electrocution in hospitals; however, it remains to be seen whether the threat to patients from hospital errors is overstated. Nevertheless, the focus on improvement and calls to renewed efforts on behalf of patient safety again underscore the great contributions that the clinical engineering and biomedical equipment technician professions have made to patient care.

The reevaluation of preventive maintenance and electrical safety testing for devices using solid-state and microprocessor electronics called into question the efficacy of these procedures in enhancing patient safety. As reflected in TJC’s testing frequency standards, the threat of patient harm from electroshock was judged to have decreased and the equipment management process was called on to adapt a less rigid, more proactive approach, to incidents of potential patient harm. The implementation of such strategies continues to remain a lively area of discussion.

Today, the CE/BMET community gratefully acknowledges the great efforts made by our predecessors in the patient care area. Future CEs and BMETs, such as those using this book for their classes, can be proud to be a part of this community. There is no lack of challenges, both technical and organizational. We wish the student good luck in meeting them.

Updates Since 2008

In the intervening years since this history was written for the book’s first edition, there have been changes in the areas discussed above, as well as whole new adventures in the area of clinical engineering and biomedical equipment technology with the melding of the two under the title of healthcare technology management (HTM). This update section is organized into the areas that have changed slightly, those that have seen massive changes, and those that hardly existed when this section was written.
**Areas With Slight Changes**

TJC has remained the premier inspection body for the efforts of HTM departments, but their standards have been heavily influenced by Centers for Medicare & Medicaid Services (CMS), the federal agency that determines standards for government reimbursement. Two manufacturer-linked issues relate to the CMS requirement that healthcare institutions follow exactly the manufacturer’s required planned maintenance requirements, versus its failure to mandate that manufacturers provide full maintenance information, both hardware and software. Spirited debate from the HTM community may reverse some of the more adverse effects of this conflict.

The issue of the preferred title and education of the HTM practitioner revolves around the twin issues of what is the role of these practitioners in the healthcare arena and what education is necessary for that role. CE title proponents state that the sobriquet “engineer” calls up the rich history of the profession and implies the ability to find solutions to both existing and future technical problems. Thus a technical degree at least at the bachelor’s level is preferred. Others feel that engineering is a small part of current requirements in the healthcare setting and thus a technical four-year college degree should not be mandatory. They believe that experience, along with an appropriate two-year degree, can be an effective precursor for departmental management success. Finally, the term HTM implies a broader range of responsibilities and a more administrative approach to the profession, perhaps including managing all or part of the technical services of the hospital data operations. This more accurately mirrors the systems approach discussed below. Education for the HTM professional is more administrative in nature and is probably an MBA or MHA taken by an experienced practitioner. Since the duties of the HTM professional vary widely from institution to institution, not to mention those involved in third-party organizations, the appropriateness of each title will vary.

Finally, the approach to technical problems encountered has become significantly broader in scope over the last six years, encompassing education, organization, and areas hitherto for the exclusive province of other departments, such as nursing or surgery. These elements of HTM practice are covered under the broad term *system engineering*. Two examples of these issues are operating room humidity control (building maintenance) and correct connection of intravenous tubing (nursing).

**Areas With Significant Technological Changes**

Two massive changes have occurred within the technical arena of operations for the HTM professional: the wireless environment and the microprocessor/software basis for most clinical devices and systems.
The replacement of wired systems with wireless has created both fertile ground for HTM expansion and new challenges. The wireless frequency spectrum was first defined and then expanded, the replacement of wired central systems with various wireless systems created the need for quality assurance for network integrity and freedom from “hacking,” and the ease of adding notification of alarm states to central and mobile locations brought about a rapid increase in the number of alarms. This has led to alarm overload and the project to prioritize alarms, control to whom they are sent, and eliminate false alarms. Additionally, the electronic medical record requires online recording of patient data and treatment information, thus further taxing the data transmission capabilities of data networks and bringing HTM further into the hospital administrative data area. Finally, the expansion of radio frequency ID tracking has required even more spectrum use and thus increased the opportunity for interference.

Interoperability and device tracking capability dramatically increases the ability of HTM personnel to find devices and to allow them to connect with each other. However, data security demands more intense attention and fosters close cooperation with the hospital data managers, both clinical and administrative.

**An Area With Significant Administrative Change**

The aforementioned systems engineering approach to solving technical problems broadens the scope of HTM while demanding knowledge of, and cooperation with, many areas of healthcare practice. This presents great opportunity for advancement, but also the challenge of a far broader knowledge of healthcare areas, and the ability to be an effective member or even leader of multidisciplinary teams that solve complex problems.

**Summary**

One would think that all these additional areas of responsibility would increase the profile and level of visibility for HTM personnel in the hospital setting. To some extent, the national conferences on interoperability have done so. However, many letters and conferences still mention the need to “get out of the cellar” or “enter into the C-suite.” Perhaps the change of title and more effective communication of these new roles to medical staff and hospital administration will effect a deeper appreciation for importance of HTM in the healthcare system.
Annotated Selected Bibliography

The following annotated bibliography contains review articles on the early development of clinical engineering and biomedical equipment technology. These sources may provide further information on specific topics.

Baretich M. Clinical Engineering Effectiveness From the Hospital Administrator's Perspective. ASHE Technical Document Series (February 1987).


Bruner JM. Hazards of Electrical Apparatus” Anesthesiology. 1967;28(2):396–425. This is the seminal article alerting the medical community to the electrical hazards. He later wrote a book on the subject, called Electricity, Safety, and the Patient (with PF Leonard). Yearbook Medical Publishers, Chicago IL.


Cardiologists start applying remedies for the problem.


This represents the view of the then Joint Commission on Accreditation of Hospitals (JCAH) authority on plant technology.


A specific application of quality principals by a pioneer in the field.