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Planning Medical Technology Management in a Hospital

By Y David¹ and EG Jahnke²

¹Biomedical Engineering Consultants, LLC, Houston, TX ²Baylor College of Medicine, Houston, TX

ABSTRACT

Appropriate deployment of technological innovation contributes to improvement in the quality of health care delivered, the containment of cost, and access to health care services. Hospitals have been allocating a significant portion of their resources to procuring and managing capital assets; they are continuously faced with demands for newer medical technology and are challenged to interoperate and manage legacy and newer generation of inventory simultaneously. To objectively manage this investment over it life cycle, hospitals are adopting medical technology management programs that need pertinent information and planning methodology for integrating new equipment into existing operations as well as for optimizing costs of ownership of all equipment. Clinical engineers can identify technological solutions based on the matching of new medical equipment with the hospital's objectives. They can review their institution's overall technological position, determine strengths and weaknesses, develop equipmentselection criteria, supervise installations, train users and monitor post procurement performance to assure meeting of goals. This program, together with cost accounting analysis, will objectively guide the capital assets decision-making process. Cost accounting analysis is a multivariate function that includes determining the amount, based upon a strategic plan and financial resources, of funding to be allocated periodically for medical equipment acquisition and replacement. Often this function works closely with clinical engineering to establish equipment's useful lifespan, prioritization of acquisition, upgrade, and replacement of inventory within budget confines and without conducting time-consuming, individual financial capital project evaluations. The clinical engineer's skills and expertise are needed to facilitate the adoption of an objective methodology for implementing the program, thus improving the match between the hospital's needs and budget projections, equipment performance and cost of ownership. Systematic planning and execution will result in a program that assures appropriate inventory level at the lowest life-cycle costs at optimal performance.

Keywords – clinical engineering, equipment assessment, technology management, equipment planning, technology evaluation, program methodology, cost accounting, life cycle, capital asset, budget.

INTRODUCTION

The appropriate deployment of technology contributes to improvement in the quality of health care delivered, the containment of cost and to increased access to services offered by the health care system. Over the past one hundred years, the dependence of the health care system on medical technology for the delivery of its services has continuously grown. In this system, the technology facilitates the delivery of the "human touch." All medical specialties depend to varying extent on technology for achieving their goals. Some specialties more than others, use medical technology, be it in the fields of preventive medicine, diagnosis, therapeutic care, rehabilitation, administration or health-related education and training. Medical technology enables practitioners to collaboratively and timely intervene together with other caregivers with patients in a cost-effective and efficient manner. Technology also enables integration and continuum care in a way that improves the level of overall health indicators. Hospital and clinical administrators are faced with the expectation for return-on-investment that meets accounting guidelines and financial pressures.

Society's expectations for quality care and for the containment of the cost of care, as expressed in relationship to the Gross National Product brought the need for even better integration and control into the public debate arena. The U.S. government, in 1983, attempted to contain runaway health care costs through Federal regulation. These regulations established a new method of reimbursement, called the prospective payment system, which encouraged hospitals to manage their resources more effectively. Reimbursement methodology continues to influence innovation, development, and adoption of medical technologies.

As a result, routine methods for delivering care are being replaced with alternatives, such as the growth of outpatient clinics, ambulatory surgery and telemedicine. Conventional as well as alternative, sites of health care services are expected to meet a specific set of goals and objectives. These goals and objectives include administrative, clinical, financial, and regulatory parameters that influence how the integration of medical technological tools are planned for, funded, and executed. It also guides how these tools are selected, installed, trained for, integrated, safely operated, serviced, upgraded, and retired or replaced. These are essentially the phases of all technology, including medical technology. The application of knowledge about the optimal management of various life cycle phases of capital assets will maximize system utilization during each one of the phases. Capital assets management, one life cycle phase, the process of selecting and acquiring medical technology, has not been well coordinated in most hospitals until recently.¹ In addition,

financial evaluations, which rely upon net present value (NPV) and internal rate of return would consume an enormous amount of a manager's or director's time and may in fact be questionable when put in their proper context.² NPV is an important evaluation tool that needs to be integrated with a clinical engineering assessment when evaluating new rather than existing demand-based service lines of business or large program comparisons of alternatives based on cost efficiencies. Examples include, the proposed addition of a diagnostic imaging center or the comparison of major system software packages. Examples of equipment not needing NPV analysis, existing assets include: defibrillators, infusion pumps, and anesthesia machines. In this case, a typical health care organization may have an inventory encompassing thousands of individual pieces of equipment. However, in their attempt to improve allocation of resources to medical equipment, the majority of health care executives have been making significant capital expenditure decisions with growing involvement of clinical engineering expertise and costof-ownership information.³

The concept of management of capital assets is a far-reaching one that goes beyond merely acquiring or maintaining medical equipment and generally includes market-based demand forecasting as a method of estimating future demand for a health care organization's services.⁴ Changing payment methodology and existing inventory operations and maintenance costs are important factors in planning the deployment of new equipment; these are management issues that merge together in the clinical environment.⁵ This paper describes the emerging process for managing medical technology in the hospital and the role that clinical engineers are fulfilling.

THE TECHNOLOGY MANAGEMENT PROGRAM – ACHIEVING GOALS

The health care delivery system is going through a transition that is led by three major driving forces: cost, technology, and social expectations. The impact of these forces may change from time to time, as does their relative significance. In addition, the human factor that interacts with these forces is not constant either, thus submitting an important subject for public debate. Nevertheless, the

system is being subjected to mounting pressures from the needs to first identify its goals, secondly select and define priorities, and finally allocate the limited resources.

Hospitals' rising investment demonstrates their belief in the importance of and the benefit from the deployment of technology. Health care organizations have been using a variety of evaluation methodologies to provide alternatives in the delivery of care. They are driven by medical innovation, prospective reimbursement, and societal expectations. In this environment, evaluation methodologies only work if an organization is truly prepared to cancel a project after the initial investment. The flaw in the theory is not its complexity, as some have said, but in the fact that it ignores the psychological and political realities of capital investments.⁶ It becomes imperative for providers to make good resource allocations decisions at the outset of their capital budgeting process and often those decisions are biased towards equipment that has a positive impact on reimbursement. Health care providers spent \$8.25 billion on capital equipment in 1988, compared with \$8.21 billion in 1987.⁷ A survey of hospitals' spending plans for capital budgets, one that includes equipment and construction, indicates that spending rose during 1992 by 15%, reaching \$23.6 billion.⁸

However, the increasing scarcity of available resources within the hospital community on the one hand and the demand for quality health care on the other, promoted a public debate and awareness of such a paradoxical economic perspective. New tools for cost and outcomes management include disease management and patient safety initiatives.⁹ It is in such an environment that hospitals have begun to manage their fixed assets (i.e. capital investments) and equipment-related operation expenditures better than ever before. As the deployment of medical equipment continuously evolves, its impact on the hospital operations and on the consumption rate of its financial resources increases. The ability to forecast and manage this continual evolution and its subsequent implications has become a major component in all health care decisions. In a survey of three large hospitals in Houston, Texas, with a combined licensed capacity of about 1400 beds, the average number of medical devices being used per licensed bed has increased between 1982 and 2002 from four devices per bed to over 17 devices per bed.¹⁰ This illustrates that hospitals are experiencing a continual increase in the number of medical devices used on a per bed basis. It is therefore imperative that in an industry where the only constant is change, there is a program that:

- a. provides for a guiding strategy for allocation of limited resources
- b. maximizes the value provided by resources invested in medical technology
- c. identifies and evaluates technological opportunities or threats
- d.optimizes priorities in systems integration, facility preparation and staff planning
- e. meets or exceeds standards of care
- f. reduces operating costs
- g.reduces risk exposurecreates
- h.better care environment.

Whereas both knowledge and practice patterns of management in general are well organized in today's literature, the management of the health care delivery system and that of medical technology in the clinical environment is more fragmented and has not yet reached that level of integration. However, we are beginning to understand the relationship between the methods and information that guide the decisions regarding the management of the medical technology that is being deployed in the highly complex environment of the health care delivery system, including the variances among users, applications and cultures from one hospital to another.

The health care delivery system presents a very complex environment where strategy, facilities, equipment, drugs, information and the full range of human interventions are interacting. It is in this clinical environment that patients in various conditions, staff, temporary skilled labor and the wide variety of technology converge. The technology that has been developed for and is deployed in the health care delivery system ranges from the "smart" facilities within which care is being provided to the products that are used around the provision of healthcare services, and to its regulation and management. "Technology means merely the use of tools, that is, the involvement of any agent which assists in the performance of a task."¹¹ Such tools have been introduced at an increasing rate during the past 100 years and include the use of techniques, instruments, materials, systems, and facilities. Of all the factors and resources that will shape the future of the health of mankind, the one that most often stretches the imagination is medical technology.¹⁰ But yet, it is also blamed for contributing to the escalation of health care costs without receiving recognition for improving access to and quality and efficiency of the system.

It is, therefore, expected that the only winners are those who use superior strategy and execution. Generally, a superior strategy is the result of the use of market-based demand forecasting. Market-based demand forecasting is a method of estimating future demand for a health care organization's services by using a broad range of data that describe the nature of demand within the organization's service area. This provides a fundamental link between strategic planning and financial planning and thereby provides a rational basis for assessing how many patients may be expected to use services and what level of capital resources is needed to provide those services.¹² This would define the types and volume of equipment needed to meet demand. Equipment is categorized by its function and owner department requirements in an assets list developed by the user and equipment planner as part of Biomedical Engineering validation of meeting appropriate clinical standards and institution integration prior to purchase recommendation. The plan must be layered with present organizational capital asset requirements for replacing and upgrading existing inventory to maximize effective use of the existing capital equipment matrix and for appropriate systemization of medical processes. At this point, it is the managers who have to link technical capabilities to clinical requirements. Too often planning is the result of a crisis, a situation that does not permit thorough analysis and usually it is a time when it is too late to begin a plan. Managers are expected to understand why their institution's values and mission are set as they are, to pursue their institution's strategy and business plan through that knowledge and to act in a way that effectively allocates resources for which they are responsible. One may not necessarily be a part of the organizational level that develops the institution's strategic plan; however, one must be familiar with it, one must understand and believe in it, to be able to develop an action plan at that level that supports the institution's mission.

To implement an effective plan, one will be expected to know how the present state of technological deployment should be assessed, and to have a good rapport with the research and development industry to be able to provide a forecast and review of emerging technological innovations, the impact that they may have on the particular institution, plus have the ability to articulate justifications and provisions for adoption of new technology or of the needs to enhance or replace existing ones. Because tomorrow's clinical devices are in the research laboratories today, a medical equipment manager should be considering visits to such sites as well as to the exhibits areas of the major medical scientific meetings. To facilitate the process, the current state of the health care organization's inventory should be assessed and quantified by the clinical engineer based upon numerous criteria. This process is aided by the existence of both Biomedical Engineering equipment and Finance capital equipment databases. The technology management process would include an assessment using a multi-year template of when and if equipment will need upgrading, replacement, and when new acquisitions are to be added. Clinical engineering should then calculate a life-cycle for each asset. Using cost accounting analysis that includes a review of the impact equipment has on reimbursement methodologies such as cost based or case based, and in conjunction with a market-based forecasting model, each prospective piece of equipment should be priced and an overall annual cost of maintaining the organizational inventory assessed as well as new additions supporting the strategic plan. Given the limits of an organization's resources, an overall prioritization can then be developed so that the most important medical technology related to the strategic plan are procured, thereby enabling the organization to satisfactorily meet its service obligations, maximize financial returns, and attain goals.

The past decade has shown a trend of increased legislation that supports more Federal regulations in health care. These and other pressures will require that deployment of, and justification for, additional or replacement medical technology is well planned. If you subscribe to the saying that you cannot manage what you do not measure, and you cannot measure what you do not define, then the need for the development and the maintenance of a systematic and comprehensive planning process for the adoption of medical technology in hospitals is obvious. A mixture of literature review and experience demonstrates that the rationale for technology adoption is derived from the following reasons:

Clinical Necessity

- meet or exceed medical standards of care
- impact care quality or level
- effect on life quality
- improve accuracy, specificity, reliability, timing and/ or safety of interventions
- change in service volume or focus
- response to community needs
- reduce errors or improve predictability of outcomes

Management Support

- better or more effective decision-making protocol for interventions
- improve operational and maintenance efficiency and effectiveness
- · facilitate development of or current offering of service
- reduce liability exposure
- increase compliance with standards or regulations
- decrease dependence on staffing and/or the skill level of personnel, improve staff retention
- effect on supporting departments
- improve return on investment or cash flow
- enhances integration and knowledge sharing
- improve patient throughput

Market Preference

- improve access to quality care
- increase customers' convenience and/or satisfaction
- enhance organization or service image
- improve financial or value impact
- reduce cost of adoption and ownership
- effect on market share
- improves community conditions
- facilitate continuum of care

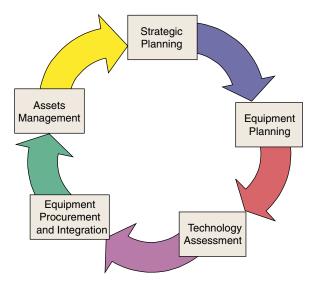


FIGURE 1. The technology management process at the Texas Children's Hospital.

Many hospitals are reformulating their technology management process, which starts with the strategic planning process, thus demonstrating clearer support for the prescribed management of medical technology. It is a process in which the understanding of the key issues and the critical success factors are followed by a more defined task of resource allocation, and assignment of the responsibility for sustained improvement in technology's performance through attainment or progression toward measurable technology utilization rate goals. This is a planned process that may be unique for each organization and is essentially a prescription for the way to look ahead. Although it may be different for every organization, all are faced with the following five similar questions: What are we? What do we want to be? Where are we going? What will be our role? And, how will we do it?

PLANNING AND MONITORING THE DEPLOYMENT OF MEDICAL TECHNOLOGY

As we developed our medical technology management program model (Figure 1), adoption of the strategically prescribed norms took place, as well as the monitoring in accordance with a well-thought-out plan, equipped with know-how from a multidisciplinary team of users, and the implementation of an agreed-upon policy. The multidisciplinary team has a similar approach toward the creation of definition of needs, scope and objectives for a specific type of technology, such as the equipment.

The question is no longer whether a medical technology management plan is worth the effort, but rather can we afford not to implement it, and do we have the adequate tools to execute it? If we do then the hospital will be able to make informed decisions regarding deployment of new technology as well as monitor its utilization.³

The need for clinical engineering involvement in such a team became evident when the following problems were repeatedly encountered:

- recently purchased equipment not sufficiently used
- ongoing user problems with equipment
- excessive downtime and ownership cost
- lack of compliance with accreditation agencies and regulations
- high percentage of equipment failing and awaiting repair
- maintenance costs emerging as a large single expense
- medical equipment upgrading, replacement, and planning are not intertwined
- use errors and near-miss events

A further analysis of these symptoms using a system performance analysis technique would likely reveal.¹³:

- a lack of a central clearing house to collect, index and monitor medical technology performance for resolving current issues and for future planning purposes
- the absence of strategy for identifying emerging technologies for potential integration
- the lack of a systematic plan for conducting technology assessment, thereby not being able to maximize the benefits from prioritization of the deployment of available technology
- an inability to benefit from the organization's experience with a particular type of technology or supplier
- the random replacement of medical technologies, rather than a systematic protocol based on a set of well-developed criteria

- the lack of integration of technology forecasting into the strategic planning of the hospital
- limited opportunities for interdisciplinary exchange between engineering-related and clinically-related professionals

To address these issues a technology assessment plan was initiated with the following six objectives: (1) Accumulate pertinent information regarding decisions about medical equipment. (2) Develop a multi-year plan for technology replacement and associated costs. (3) Communicate replacement selection criteria that is supported by users. (4) Create an ongoing assessment methodology with outcomes measurements. (5) Improve the capital budget process by integrating the status of current technology with long-term needs relative to surgical-medical services goals. (6) Integrate the competency of clinical engineering into patient safety goals.

Because the program provides for both the management of the existing inventory of medical equipment aiming at the lowest reasonable life-cycle cost, and for the recommendations relating to procurement, it is mandatory to integrate trended operational and utilization information with the projected budget strategy into the technology management plan.

At the Texas Children's Hospital, the Biomedical Engineering Department has been accumulating pertinent information and has developed indicators for measuring medical equipment performance.¹⁴ A Medical Technology Evaluation Committee (MTEC), which is chaired by the Director of Biomedical Engineering, began developing analytical selection criteria and life-cycle costs information. The membership of the committee includes representatives of the medical and nursing staff, high-tech users, administration, equipment planning, risk management, safety, and materials management departments. Another clinical engineer from the same department with nursing training experience serves as the committee's designated coordinator for all evaluation tasks. Once the committee accepts a request for review (RR), it identifies other users who may have an interest in it and authorizes the coordinator to assemble a task force of users specified by the committee. This task force then serves as an *ad hoc* committee responsible for the evaluation of the

equipment described on the RR form. During any specific period, there may be multiple task forces, each focusing on a specific equipment protocol.

The task force coordinator cooperates with the Materials Management Department in conducting a market survey, in obtaining equipment for evaluation purposes, and in scheduling of vendor-provided demonstration and in-service training. After establishment of a task force, the coordinator analyses the evaluation objectives and together with input from the task force devises appropriate tests, and the associated evaluation feedback form. There are two stages to this phase: an engineering test to validate safety and performance issues, and a clinical trial to evaluate user interface issues and efficacy. Only equipment that has successfully passed engineering tests may proceed to a clinical trial. A clinical coordinator collects and reports the summary of experiences gained during the clinical trials to the task force. The committee coordinator then combines the results from the engineering tests and the clinical trials into a summary report and prepares recommendations for MTEC approval. In this role, the coordinator serves as a multidisciplinary professional, bridging the gap between the clinical, technical, and administrative needs of the hospital.

The technology assessment process actually begins as soon as a department or individual fills out a budget request and then the RR form already mentioned. The form is submitted to the hospital's Product Utilization and Review Committee, which determines if a previously established standard for this equipment already exists.

On the RR form, the originator delineates the rationale for acquiring the medical device. For example, how the item will improve patient care, generate cost savings, support the quality of service or improve ease of use, and who will be the primary user.

The form is sent to the MTEC if the item requested is not currently used by the hospital, or if it does not conform to previously adopted hospital standards. The committee has the authority to recommend either acceptance or rejection of any request based on a consensus of its members.

If the request is approved by the MTEC, then the requested technology or equipment will be evaluated using technical and performance standards. The role of the medical technology evaluation program in the purchase of medical equipment is threefold: (1) assuring that biomedical equipment facilitates the delivery of quality patient care, (2) assuring that the equipment purchased meets the needs of all users, and (3) establishing hospital standards for biomedical equipment. Medical technology evaluation occurs in two phases. Phase 1 is in the submission of recommendations for the purchase of new equipment. Phase 2 is the technical and clinical evaluation. This allows the hospital to validate equipment specifications, to obtain superior equipment at a competitive price and, in turn, consistently improve the quality of patient care. The evaluation process addresses pertinent issues regarding the medical equipment safety, user friendliness, and equipment performance history. Based on satisfactory evaluation results and feedback from the technical and clinical staff, a recommendation is made to purchase a specific equipment item. Following these product evaluation steps facilitates the standardization of the equipment selection process and, therefore, the standardization of biomedical equipment. This will allow the hospital to obtain superior equipment at a competitive price and, in turn, provide consistent, high-quality patient care.¹⁵ Upon completion of the review, a recommendation is returned to the hospital's Product Standards Committee, which reviews the results of the technology evaluation, determines whether the particular product is suitable as a hospital standard, and decides if it should be purchased. If approved, the request to purchase will be reviewed by the Capital Planning Committee (CPC) to determine if the required expenditure meets with available financial resources of the institution, and if or when it may be feasible to make the purchase. To ensure coordination of the technology evaluation program, the Chairman of the MTEC also serves as a permanent member of the hospital's CPC. In this way, technology evaluation is integrated with and impact budget decisions.

THE ROLE OF A CLINICAL ENGINEER

Advances in technology accelerated multidisciplinary approaches to healthcare management.¹⁶ Clinical engineering, a profession based on both engineering and the life sciences, developed in response. The recently created American College of Clinical Engineering provides a better

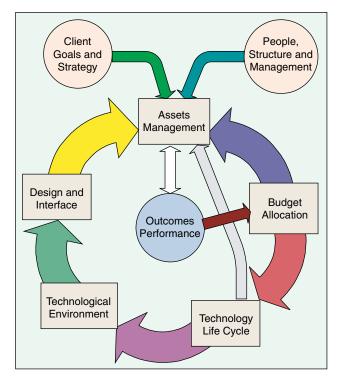


FIGURE 2. Medical technology management environment at Texas Children's Hospital.

understanding of the profession, and defines a clinical engineer as "a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology."¹⁷

The role of a clinical engineer is shared between planning for new equipment and optimizing the utilization of the existing inventory.¹⁸ The clinical engineer must be completely familiar with the procurement phase of medical equipment and with the synthesizing of clinical needs into a bid request document. This further includes bid specifications, vendor negotiations, installation preparation, acceptance criteria, user training and servicing of the installed base. The clinical engineer is also familiar with methods for assuring that medical equipment performance and risks are monitored, reported and managed. The process includes the assigning of criteria, i.e. values reflecting the evaluator or user preference, and measuring the degree to which those criteria are met in the daily routine of the clinical environment.¹⁹ Criteria could be the format and quality of information displayed at the

bedside physiological monitor, the set-up of minimum infused volume of an infusion pump, or the amount of work of breathing associated with one particular brand of mechanical ventilator compared with another.

Medical technology policy supported by an organized program of planning, implementing, monitoring and evaluation results in effective use of resources and reduction in operational risks. Medical Technology Management Environment at Texas Children's Hospital, outlines such a program (Figure 2). Positive outcomes affect allocation of capital and are dependent on the success of the assets management program, the impact of changes in the technology life cycle, the inherent design and quality of the technology as well as the environment within which the assets are deployed and serviced.

The methodology for the development and sustainment of medical technology management program must include properties that demonstrate the impact from each of these parameters on outcomes. Outcomes performance indicators include: cost effectiveness, compliance level, and client satisfaction and service leadership.²⁰ Performance indicators can include safety-related events such as the elimination or reduction in medical errors. Cost effectiveness can include return-on-investment analysis, reduction in cost per procedure, or improvement in uptime. Other indicators can represent the result of life cycle technology planning and the integration of technologies at the point-of-care measured by utilization rate and the level of satisfaction the caregivers team has with the environment of care.

The program needs to encompass all involved parties. This may at times extend the evaluation and provide for participation of professionals with different interests, which will require mediation between parties. The acceptance of the process is based on respect for their participation and at times will require a sequence of steps taken to pre-empt escalation of antagonistic attitudes among the parties participating in the evaluation. Often, one party seems to prefer an equipment feature that presents unacceptable conditions to another. The clinical engineer should provide the technical and cultural leadership needed to maintain the progress of the evaluation process in a participatory mode. The individuals participating should be representatives of the user groups, support groups, medical staff, nursing, engineering risk management, finance and administration.

Factors by which the equipment will be evaluated are selected, agreed upon, and a relative importance weight is assigned to them. Devices that pass the engineering bench test are forwarded to the clinical evaluation stage, which must be preceded by user training that is provided to all shifts by the clinical engineering staff and/or the vendor. During the clinical evaluation, the clinical engineer serves as a focal point for collecting users' problems as an indication for a possible mismatch between the equipment's real-life performance and user or system requirements. Following the evaluation, the clinical engineer collects the users' report documenting their experiences and presents it to the committee for a recommendation, while the cost accounting representative reviews the financial alternatives. Generally, to review financial alternatives, information is accumulated and developed into a capital equipment matrix that includes replacement cost, projected retirement, replacement, upgrade, and associated life-cycle dates. Based upon input from clinical engineering, equipment is prioritized regarding their role in the organization. This data is then compiled and provides a useful determination of expected capital costs for future capital budgets and can aid in the development of future strategic planning by providing specific costs by service component. Clinical planning thereby provides options for management in future years despite limited financial resources.

A period of time after equipment has been installed, for example between six and twelve months, a follow-up study of actual operational costs, service problems and utilization indicators relative to projections is performed. This activity supports and becomes part of the equipment planning and continuous quality improvement program. Many good lessons are learned this way. It is also important to review the implementation state and determine if it can be further optimized the next time. The clinical engineer, from that point on, continues with managing the other phases of the equipment life-cycle with proper attention to the planning for equipment upgrades, enhancements and replacement. The skills of the clinical engineer are needed now, more than ever, to manage this new responsibility: a responsibility for managing the medical technology program within guidelines that range from a strategic technology planning phase to the planning for systems replacement.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this paper.

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AUTHORS' BIOGRAPHY

Yadin David is principal at Biomedical Engineering Consultants, LLC and previously has been the Director of the Biomedical Engineering Department at Texas Children's and St. Luke's Episcopal Hospitals since 1982. He received his Master and Doctorate degrees from West Virginia University, is affiliated with the University of Texas School of Public Health, and previously also with the Department of Pediatrics, Baylor College of Medicine. He is Registered Professional Engineer and Certified Clinical Engineer. He is a member of the FDA Advisory and NFPA technical committees, and chairman of IUPESM HTTG group and member of the IFMBE Clinical Engineering Division.

Ernest Gus Jahnke is manager of Hematology/Oncology section at Baylor College of Medicine and holds MBA degree in business informatics and Bachelor's degrees from the College of Charleston, is a Certified Public Accountant licensed in the state of Texas, and is a Certified Forensic Accountant. Previously was the Manager of Finance at Texas Children's Hospital where he was the