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Trends in clinical engineering practices

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Abstract— Appropriate deployment of technological tools contributes to improvement in the quality of healthcare delivered, the containment of cost, and better access to healthcare systems. Hospitals have been allocating significant portion of their resources to procuring and managing capital assets; they are continuously faced with demands for new biomedical technology while asked to manage existing inventory for which they are not well prepared. To effectively manage their investments, hospitals are developing medical technology management programs that need expertise and planning methodology for safe and efficient deployment of healthcare technological tools. Clinical engineers are practitioners that can lead such programs and deliver technological solutions based on carefully determined needs and specified set of organization objectives and abilities. The successful practice of clinical engineering is dependent on the ability of these practitioners to transfer knowledge from the engineering and life sciences to the support of clinical applications. As rapid changes in the complexity and variety of technological tools and in the measurement of patient care outcomes taking place, it is best to facilitate transfer of such knowledge having well defined body of knowledge. This can be accomplished only when the goals of the profession are clearly described and uniformly accepted accommodating profession vision and commitment. Such a commitment must include the promotion of safe and effective application of science and technology in patient care and on the acceptance of professional accountability demonstratable by the achievement of competency recognition by national professional certification program.

To be ready, clinical engineers must participate in continuing education activities and maintain wide level of expertise, demonstrate ability for leading and effectively executing complex projects and functions, and be accountable for maintaining safe technological tools/systems used in the patient environment. As systems complexity and integration continues to increase, now is the time to demonstrate that the required competencies do contribute to desired outcomes.

Keywords— Biomedical technology, Capital budget, Clinical engineering, Healthcare technology planning, Outcomes, Professional certification, Program methodology, Technology assessment, Risk mitigation, Technology evaluation, Technology management program.

Resumen— La adecuada implementación y aplicación de herramientas tecnológicas contribuye al mejoramiento de la calidad en la prestación de los servicios de salud, la minimización de los costos de dichos servicios, y el aumento de la accesibilidad al sistema hospitalario. En las últimas décadas los hospitales han venido asignando una considerable porción de sus recursos al cuidado y administración de sus bienes de capital; enfrentan continuamente la necesidad de adquirir nuevas tecnologías biomédicas al tiempo que deben administrar la existente, situación para la que no están bien preparados. Con el fin de orientar eficientemente sus inversiones, los hospitales han venido desarrollando programas de administración de tecnología médica que requieren expertos en el tema y la aplicación de metodologías específicas para un aprovechamiento seguro y eficiente de estas herramientas en el sector salud. Los ingenieros clínicos son quienes pueden liderar estos programas al proveer soluciones tecnológicas basadas en las necesidades prioritarias, cuidadosamente establecidas, y en los objetivos organizacionales específicos. El éxito en la práctica de la ingeniería clínica radica en la habilidad de estos profesionales de transferir los conocimientos del campo de la ingeniería y de

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las ciencias de la salud al entorno hospitalario para servir de soporte en las aplicaciones médicas. A medida que se dan grandes y rápidos cambios en la complejidad y variedad de las herramientas tecnológicas disponibles y en las formas de evaluar el cuidado que se le brinda a los pacientes, la mejor forma de transferir dichos desarrollos es mediante un completo conocimiento del tema. Esto se puede lograr sólo cuando los objetivos de la profesión han sido claramente definidos y son coherentes con el compromiso y la visión profesional. Tal compromiso debe incluir la promoción del uso seguro y eficaz de la ciencia y la tecnología al servicio del cuidado de los pacientes y la aceptación de la necesidad de demostrar sus capacidades como ingeniero clínico al adquirir el reconocimiento de sus competencias profesionales mediante el programa de certificación profesional nacional.

Para estar preparados para estos desafíos los ingenieros clínicos deben participar en actividades de educación continua, mantener su pericia y habilidades profesionales, demostrar capacidad para liderar y ejecutar eficientemente proyectos y funciones complejas, y velar por el seguro mantenimiento de las herramientas y sistemas tecnológicos utilizados en el sector salud. A medida que aumenta la integración y la complejidad de los sistemas, es el momento de demostrar que las competencias de los ingenieros clínicos realmente contribuyen al cumplimiento de las metas establecidas.

Palabras clave— Tecnología biomédica, Administración de capital, Ingeniería clínica, Planeación de tecnología hospitalaria, Resultados, Certificación profesional, Metodología del programa, Evaluación de tecnología, Mitigación del riesgo, Evaluación de tecnología, Programa de gestión de tecnología.

I. Introduction

The appropriate deployment of healthcare technology contributes to the improvement in the quality of healthcare delivered [1], the incorporation of new knowledge, the containment of costs and to increased access to services offered by the healthcare delivery system.

Over the past one hundred years, the dependence of the healthcare systems on biomedical technology for the delivery of its services has continuously grown. In this system, biomedical technology facilitates the delivery of the expertise and the 'human touch'. All medical specialties depend, to some extent on technology for achieving their goals. Some specialties more than others, use biomedical technology, be it in the area of preventive care, diagnosis services, therapeutic procedures, rehabilitation programs, administration or other health-related research, education and training. Biomedical technology enables practitioners to collaboratively intervene together with other caregivers to optimally manage their patient conditions in a safe, cost-effective and efficient manner [1]. Technology also enables research activities and systems integration in a way that contributes to improvements in the level of health outcomes. Yet, hospital and clinical administrators are faced with the expectation for return on investment that meets accounting guidelines and are dependent on guidance of technological expertise.

Society's expectations for access to quality care and for predictable outcomes is challenged by the costs of providing such services [2]. While various reimbursement methodologies have been tried, stake holders encouragement for professional management of biomedical technologies at the regional and hospital levels are yet to be recognized.

Decisions related to biomedical technology creation and adoption must be based on needs and local capability to safely deploy it. The state of the art versus the state of the science [3] presents a framework that provides for predictable outcomes only when clinical engineers are well prepared for their mission. Clinical engineering is a unique profession [4]. Only in healthcare can a technical professional be involved with such a wide spectrum of issues relating to ethics, human values, professionalism and decision making processes involved with life, the quality of living and death. As healthcare grows even more technology-intensive and its reliance on that technology increases, so the role of the clinical engineer becomes more vital. The healthcare team is consistent of many professional members, each well trained in their respective specialty; and it is the interrelationship between these individuals as well as with the technology they use that to a large extent determines patient's outcomes. Clinical engineers, as they create –select– install and manage technology, must practice their obligation to minimize the risk associated with the use of technology and thus facilitating the team success.

II. The technology management program─achieving goals

The creation and dissemination of sophisticated biomedical technology programs was not noted until 1971, when an article describing the technology-related hazards patients faced while being treated in US hospitals was published by R. Nader [5]. It suggested that 1,200 patients were injured in US hospitals from small amounts of electrical energy known as micro shock. The public, government and accreditation and regulatory agencies applied pressure to correct the situation and demanded safer environment. Skilled clinical engineers rose to the occasion and met the challenge by providing competent technology services. This was the beginning of the biomedical technology management program. Today, a result of the Institute of Medicine publication [6], in response to similar pressure to further eliminate care-related errors and to increase the overall level of safe-care in and out of the hospitals new applications such as electronic health record, bar code system, asset tracking and Telehealth are becoming to be part of the biomedical technology program.

The biomedical engineering department at Texas Children's Hospital in Houston, Texas, USA [7] was among the first programs to place its focus on risk mitigation methodology eliminating patient exposure to unsafe levels of micro shock energy and on the safe management of biomedical technology throughout its life cycle. Over the past twenty five years, under the leadership of Dr. Yadin David, the program's technology management methodology matured and added the expertise for expanded program that delivers equipment planning, technology evaluation [8], vendor negotiations, device development, installation services, commissioning tests, users training, comprehensive technology maintenance, upgrades and replacement planning. Throughout the stages of technology's life cycle, the program monitors the variation in the overall technological risk exposure, determines technological strengths and weaknesses, develops technology disaster recovery plans [9], establishes equipment-selection criteria, validates vendor provided services and installations, trains users and monitors post procurement performance to assure meeting of the institution's goals [10]. This program, together with financial analysis, objectively guides the capital assets decision-making process at the hospital [11]. Priority has been placed on replacing biomedical technology that required, more than normal, clinical engineering interventions or that fail to meet safety guidelines or standards. Often this function works closely with clinical users to establish projected equipment useful life and to prioritized acquisition, upgrade, and replacement of inventory within budget confines. Clinical engineering's skills and expertise facilitated the implementation of an objective methodology for program management, thus improving the match between the hospital's needs and available budget, between the cost-of-ownership and sustainable equipment performance. The result of systematic planning and execution is a program that assures the availability of safe and appropriate technological tools at the lowest life-cycle costs with the best possible performance.

A mixture of literature review and experience demonstrates that the rationale for technology adoption is derived from the following reasons [12]:

(a) Clinical necessity

- (i) meet or exceed medical standards of care.
- (ii) effect on care quality or level.
- (iii) effect on life quality.
- (iv) improve accuracy, specificity, reliability, timing and/or safety of interventions.
- (v) change in clinical service volume or focus.
- (vi) response to community needs.

(b) Management support

- (i) better or more effective decision making protocol for interventions.
- (ii) improve operational and maintenance efficiency and effectiveness.
- (iii) effect on development of new or current offering of service.
- (iv) reduce liability exposure.
- (v) increase compliance with regulations.
- (vi) decrease dependence on staffing and/or the skill level of personnel, improve staff retention.
- (vii) effect on supporting departments.
- (viii) improve return on investment (ROI) or cash flow.
- (ix) enhances integration and knowledge sharing.

(c) Market preference

- (i) improve access to quality care.
- (ii) increase customers' convenience and/or satisfaction.
- (iii) enhance organization or service image.
- (iv) improve financial or value impact.
- (v) reduce cost of adoption and ownership.
- (vi) effect on market share.
- (vii) improves community conditions.

Hospitals are experiencing, as recorded over the past 25 years at Texas Children's Hospital, a continual increase in the number and complexity of medical devices used on a per patient-bed basis. It is therefore imperative [13] that in an industry where the only constant is change, there is a program that:

- (a) establishes focal point for technology management issues.
- (b) provides for a guiding strategy for best allocation of limited resources.
- (c) maximizes the value provided by resources invested in healthcare technology.
- (d) identifies and evaluates technological opportunities or threats.
- (e) optimizes priorities in systems integration, facility preparation, equipment planning, and staff development.

(f) meets or exceeds standards of care.

(g) reduces operating costs.

(h) reduces risk exposure and adverse events. And

(i) able to support clinical research activities.

Whereas both knowledge and practice patterns of management in general are well organized in today's literature, the management of the healthcare delivery system and that of healthcare technology in the clinical environment is more fragmented and has not yet reached that level of common integration. However, we are beginning to understand the relationship between the methods and outcomes that guides the decisions regarding the management of the healthcare technology [14]. Technology management program is critical for sustainment of operations since it is deployed in life critical environment dependent upon complex integration of legacy and new systems, on direct and derived physiological measurements, on tethered and wireless environment, on utilities unpredictable conditions in addition to variances among users competency, work processes and cultures from one hospital to another.

III. The role of the clinical engineer

According to the definition of the American College of Clinical Engineering (ACCE) [15] "a clinical engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology" [16] and the professional clinical engineer recognizes his practice as a calling requiring specialized knowledge and often long and intensive academic training with primary attributes consisting of expertise, responsibility and accountability [17]. Such attributes will support the understanding of clinical systems, the role of technology in disease management, maintaining technological vision, strategy consideration for sustainment of operations, implementation of process improvement plans, the examination of outcomes measurement and ability to achieve transparent integration between legacy and new systems and devices. The field demands strict technology management skills in addition to technological expertise in order to properly assess and mitigate risk, to predict impact on clinical operations and processes by technology adoption, and the impact of regulatory compliance issues.

Based on academic input and practitioners survey, the Healthcare Technology Foundation (HTF) of the American College of Clinical Engineering (ACCE) established standards of competence for achieving professional recognition through certification program and for developing model of best practice in clinical engineering leadership, the ExCEL award program [18]. According to the ACCE report, the main content of the body of knowledge for the certification examination consists of technology management, service management, risk and safety management, product development testing and evaluation and professional development activities. While the body of knowledge continues to expand academic programs regressed. On the leadership role, the ExCEL award program seeks to combine two areas, that of general leadership attributes and performance measures. The leadership attributes consists of knowledge, organization, communication skills, coaching and ability to marshal and manage resources. The performance measures includes ability to solve diverse and important institutional problems, reflection of high ethical behavior, and inspiration for team effort. All attributes are recognized as significant competencies that hospitals need from a skillful clinical engineer.

The clinical engineer responsibility stretches throughout the stages of technology life cycle with the technology management program serving as a focal point for integrating the inputs from clinicians, administrators, informatics, technicians, quality and risk professionals. The clinical engineer must document decision making criteria for considering these inputs for evaluation protocols, for maintenance guidelines, for adverse event investigations, and for measuring the program performance. The concept of management of capital assets is a far-reaching one that goes beyond merely acquiring or maintaining medical equipment and generally includes forecasting as a method of estimating future demand for a healthcare organization's technology and for services needed for its support [4]. Improvement in service quality and risk mitigation should be reported periodically and variations investigated. The engineer also needs to guide staff training and development, and incorporate procedures for the use of tools and test equipment. Outcomes are better when program has well trained staff and test equipment [19].

Clinical engineers practice in a system that is subjected to mounting pressures to first identify its goals, secondly select and define priorities, and finally allocate the limited resources and to take advantage of systems integration and reduction of waste. That is where engineers enter. Hospitals' rising investment demonstrates their belief in the importance of and the benefit from the deployment of technology. However, clinical engineers must serve as conductors assuring that each note is heard without missing the rhythm. Variety of evaluation methodologies are available to guide optimal decision in the selection of technological solutions, one maybe better than other for particular application, the clinical engineer who is familiar with their hospital can select and apply the right methodology for meeting objectives driven by new medical knowledge, by technological innovation, users competency, budgetary guidelines, and societal expectations [10]. This will lead to management of assets and equipment-related operation better than without such a program. As the deployment of biomedical technology continuously evolves, its impact on the hospital operations and on the consumption rate of its resources increases. The ability to forecast and manage this continual evolution and its subsequent implications has become a major component in all clinical engineering decisions. To implement an effective plan, one will be expected to know the present state of biomedical technology innovation, 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 their particular institution, and have the ability to articulate justifications and provisions for adoption of new technology and the needs to enhance or replace existing ones. Because tomorrow's clinical devices are in the research laboratories today, a clinical engineer 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 hospital's inventory should be assessed and quantified by the clinical engineer and the users with the use of quantified criteria. This process is aided by the existence of both biomedical 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 [20]. 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 it's service obligations, maximize financial returns, and attain goals.

The need for clinical engineering expertise became evident when the following problems were repeatedly encountered:

(a) recently purchased equipment is under used.

(b) on-going user problems with equipment or use.

(c) excessive downtime and ownership cost.

(d) lack of compliance with accreditation agencies and regulations.

(e) high percentage of equipment failing and awaiting repair.

(f) maintenance costs emerging as a large single expense.

(g) medical equipment upgrading, replacement, and planning are not intertwined.

(h) increasing use errors and near-miss events.

(i) lack of integration between systems and applications.

A further analysis of these symptoms using a system performance analysis technique would likely reveal [21]:

(i) a lack of a central clearing house to collect, index and monitor medical technology performance for resolving current issues and for future planning purposes.

(ii) the absence of strategy for identifying emerging technologies for potential integration.

(iii) 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.

(iv) an inability to benefit from the organization's experience with a particular type of technology or supplier.

(v) the random replacement of medical technologies, rather than a systematic protocol based on a set of well developed criteria.

(vi) the lack of integration of technology forecasting into the strategic planning of the hospital.

(vii) 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 objectives:

(1) to accumulate pertinent information regarding decisions about medical equipment.

(2) to develop a multi year plan for technology replacement and associated costs.

(3) to communicate replacement selection criteria that is supported by users.

(4) to create an ongoing assessment methodology with outcomes measurements.

(5) to improve the capital budget process by integrating the status of current technology with long-term needs relative to surgical-medical services goals.

(6) to integrate the competency of clinical engineering into patient safety goals.

(7) to adopt criteria for user training and competency validation.

(8) to implement equipment service program that meets or exceeds quantified goals.

The Texas Children's Hospital, Biomedical Engineering department has been recognized by third party, by the hospital executives and by vendors as best practice model for achieving excellence in health technology management program [22].

IV. Conclusion

Clinical engineers need to broaden their skills to include technological visioning, system management and leadership attributes [23]. Through continued education and participation in meetings and conferences they can develop network of experts that will help them in overcoming the challenges associated with biomedical technology management such as systems selection, design, integration and servicing. The stages of biomedical technology life cycle must be all managed and monitored. While the challenge is not small, the reward is much larger.

The skilled clinical engineers, now more than ever, will be able to lead this new responsibility of achieving biomedical technology performance assurance within guidelines.

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