New Roles & Responsibilities of Hospital Biomedical Engineering

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Abstract— Over the last decade the changing healthcare environment has required hospitals and specifically Biomedical Engineering to critically evaluate, optimize and adapt their operations. The focus is now on new technologies, changes to the environment of care, support requirements and financial constraints. Memorial Sloan Kettering Cancer Center (MSKCC), an NIH-designated comprehensive cancer center, has been transitioning to an increasing outpatient care environment. This transition is driving an increase in-patient acuity coupled with the need for added urgency of support and response time. New technologies, regulatory requirements and financial constraints have impacted operating budgets and in some cases, resulted in a reduction in staffing. Specific initiatives, such as the Joint Commission's National Patient Safety Goals, requirements for an electronic medical record, meaningful use and ICD10 have caused institutions to reevaluate their operations and processes including requiring Biomedical Engineering to manage new technologies, integrations and changes in the electromagnetic environment, while optimizing operational workflow and resource utilization.

This paper addresses the new and expanding responsibilities and approach of Biomedical Engineering organizations, specifically at MSKCC. It is suggested that our experience may be a template for other organizations facing similar problems. Increasing support is necessary for Medical Software - Medical Device Data Systems in the evolving wireless environment, including RTLS and RFID. It will be necessary to evaluate the potential impact on the growing electromagnetic environment, on connectivity resulting in the need for dynamic and interactive testing and the growing demand to establish new and needed operational synergies with Information Technology operations and other operational groups within the institution, such as nursing, facilities management, central supply, and the user departments.

Keywords: Biomedical Engineering, evolving technology, technology management, equipment management, regulatory, MDDS, electromagnetic spectrum, connectivity,

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INTRODUCTION

Memorial Sloan Kettering Cancer Center (MSKCC), located in New York City, is dedicated to the improving the management of cancer through patient care, research and education. MSKCC is operationally composed of the Memorial Hospital for Cancer and Allied Diseases and the Sloan Kettering Institute for Cancer Research. In addition to the main campus, there are 17 off-site and regional network facilities located within a 60 mile radius of Manhattan, providing consultations, outpatient treatment and other special procedures. Memorial Hospital is a 469 bed hospital, which manages approximately 24,598 yearly admissions, and 541,474 outpatient visits. As part of its intensive cancer treatment program, Memorial performs in excess of 391,187 x-ray exams and special procedures, 110,765 radiation treatments and 19,691 surgical procedures annually. To test and evaluate innovative cancer therapies, over 550 clinical trials are ongoing. The research programs at Sloan Kettering Institute involve research on the basic understanding and mechanisms of cancer, often leading to direct translation into the clinic. This rapid transition of research and technology to practical clinical application has maintained MSKCC as a leader in cancer care.

Traditional Biomedical Engineering operations have been focused on the repair, preventative maintenance, calibration and regulatory compliance of medical devices. The increasing wireless applications, medical device integration / connectivity and new support requirements have driven Biomedical Engineering operations to deal with new areasof concern and responsibility.

Biomedical Engineering at Memorial Sloan Kettering Cancer Center (MSKCC) is structured as a clinical service within the Department of Medical Physics. It maintains a combination of clinical responsibilities, support and regulatory roles and research.

Specifically, Biomedical Engineering has adapted its operations and functional responsibilities to meet the expanding technology, clinical, engineering and business
As a result of this dynamically changing environment and ever changing focus, the following new areas of responsibility and management are specifically addressed within this publication:

1) Medical Device Data Systems & Medical Software
2) Electromagnetic Environment

3) Dynamic Simulation Laboratory
4) Big Data – Alarm Management
5) Real Time Location Systems (RTLS)
6) New Synergies and Collaborations

Specific operations were critically evaluated delegating specific lower risk operations to 3rd party or other support operations, with management and over sight performed by Biomedical Engineering.[1,2]

This enabled some reallocation of resources while new positions with varying types of expertise were created.

1: Medical Device Data Systems (MDDS) and Medical Software Management

In Feb. 2011, the FDA issued its final determination and rules to reclassify middleware hardware and software. These rules were developed to address the risks associated with MDDS, including the potential for inaccurate, incomplete and untimely data transfer, storage, conversion or display of medical device data.

Medical Device Data Systems (MDDS) were specifically identified as hardware and / or software products that transfer, store, convert formats, and display medical device data. An MDDS does not modify the data or its display, and does not by itself control the functions or parameters of any other medical device. An MDDS is defined by one or all of the following criteria:

1. The electronic transfer or exchange of medical device data from a medical device, without altering the function or parameters of any connected devices.
2. The electronic storage and retrieval of medical device data, without altering the function or parameters of connected devices.
3. The electronic conversion of medical device data from one format to another in accordance with a preset specification.
4. The electronic display of medical device data, without altering the function or parameters of connected devices.

As a consequence these devices now defined as medical devices need to conform to the rules and practices defined by regulatory bodies, such as the FDA and Joint Commission.

To manage this new class of medical devices these devices and associated components have been inventoried into the medical equipment database, with new data fields defined to accommodate these software- based systems. In addition each device is documented with a corresponding service history, identifying upgrades, software revisions, recalls, and verification cycles, similar to the service history of other medical devices.

Since these devices have been previously managed either by IT, the user department and / or biomed, a new synergy and interaction has been defined and established to optimize management of these systems.

2: Management of the Electromagnetic Environment

As with most hospitals, MSK has deployed a variety of wireless devices and applications throughout the institution. In addition patient telemetry systems operate at WMTS frequencies, communication devices, such as cell phones and VoIP systems operate interchangeably between 3G /4G and WiFi, depending on the availability and quality of the received signal. Deployment of Real Time Location Systems, including active RFID has provided real time location and tracking which has enabled optimized inventory management, and workflow metrics. These include a combination of WiFi based tags using triangulation for position, computation coupled with localization antennas using LF, IR, and / or ultrasound for room level / bed level resolution. Additional passive localized RFID solutions have been deployed for supply chain and resource management. These solutions have added significant RF emitting device density operating at a variety of radiofrequencies (RF) within the environment of care.

Since any RF system can introduce electromagnetic interference (EMI) to other devices and systems, whether wireless or not. it has become necessary to establish functions within Biomedical Engineering to manage the overall electromagnetic environment. At a minimum, this involves documentation of which applications / systems are in the environment, the operating frequencies, which are medical devices and mission critical, as well as a detailed antenna pattern layout diagrams. Any inadvertant changes to the antenna patterns of the individual systems, either as a result of construction or adding new antennae to support the base WiFi infrastructure has the potential of impacting the operational integrity of these systems.

Due diligence additionally requires examination of the overall RF environment, including an on-going review, testing and evaluation of potential interference. We perform several types of EMI testing, internal testing within the patient care environment and externally with organizations, such as the FDA at their EMI test facility (White Oaks, Virginia). Internal testing uses a newly designed and deployed MSKCC Simulation Laboratory (Figure #1) providing a dynamic and isolated test environment. The laboratory duplicates the hospital environment in terms of infrastructure, device compliment and applications operating within the current environment of care. To date, the laboratory has been extensively used to test potential RFID induced EMI and the potential workflow impact of new devices and operational complexities to the environment.

In 2012, we entered into a collaborative testing program with the FDA to further evaluate potential interference sources and interactions. Current testing is focused on RFID-induced interference on medical devices, including physiological monitoring, ECG systems and infusion pumps.

The electromagnetic environment, relative to medical devices and RFID applications is managed by Biomedical Engineering, by IT for VoIP, hand held devices and connectivity etc., This collaborations further demonstrates the growing need for a strong synergy and working relationship between the two groups.

3: Dynamic Simulation Laboratory:

Biomedical Engineering in collaboration with IT and Nursing developed a phase I dynamic simulation laboratory, operationally deployed in the second quarter of 2013. [See Figure 1.] The laboratory was designed to duplicate the patient environment in terms of infrastructure, both wired and wireless, medical device complement, hospital applications, RTLS and RFID deployment, as well as all integrations, connectivity and archival solutions.

Figure #1: Simulation Laboratory

The objective of the laboratory is to provide a dynamic and configurable environment with the following capabilities and functionality:

- Test hardware and software upgrades and revisions to existing infrastructure, devices and applications.
- Test device integrations, such as connectivity and device-to-device interfaces
- Test new and evolving technologies, devices and systems
- Provide a training platform, enabling comprehensive and interactive training of MSK staff.

The Simulation Laboratory was developed, deployed and is used jointly by Biomed, IT and Nursing providing a shared resource. The laboratory enabled comprehensive evaluation and testing outside of the actual patient care areas and other treatment environments, minimizing potential interactions, failures and overall risk to patient safety.

To date, the simulation laboratory has been extensively used for evaluation of upgrades to our physiological monitoring platform, RFID solutions, analysis of RTLS workflow, potential EMI, test device integrations, and the investigation of new technologies including environmental sensing and identification techniques. The largest utilization of the laboratory has been nursing training. The overall utilization has clearly indicated the need for a phase II expansion of the laboratory, separating simulation and testing functions from the training programs.

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4: Big Data – Managing Alarm Types & Setting Limits

The evolution of medical devices and clinical applications exploiting advanced business logic has resulted in large scale increases in the quantity and types of data available.[6,7] Connectivity solutions have enabled new combinations of data to be presented adding additional parameters and data volume to the environment. The problem with big data is that it is mostly raw data in nature and not effectively processed or presented. The needed intelligence and algorithms are still being developed

As an example, considering patient alarm data from physiological monitoring based devices, whereas a decade ago 10-20 clinical parameters and alarms where generally available, today approximately 3-4 times that number are delivered. In addition to the increase in parameters themselves, increased patient acuity results in an increase in the frequency of alerts and alarms. New methodologies including alarm delivery to the point of care have the potential of helping to manage this large volume of information, however, without precise workflow this can only add to the workload of clinical staff. [8]

5: Real Time Location Systems (RTLS)

The deployment of Real Time Location (RTLS) solutions has continued to expand enabling the extensive set of use cases / applications to be implemented. These have included the unique identification, dynamic locating and tracking and association of hospital resources (inventory and staff)[3], supply management, and applications focused on workflow and process optimization and verification.

Radio Frequency Identification (RFID) is a method of remotely storing and retrieving data using a technology that communicates via radio waves (oscillating electromagnetic fields) to exchange data between a reader and an electronic tag. RFID comes in 2 primary forms; passive, using energy harvesting techniques from an antenna to power and receive broadcasted tag data; and active which is self powered and broadcasts at regularly programmed intervals. Passive solutions typically require close proximity to antennas and is commonly used for localized applications, such as supply chain, sample collection, sponge counting, surgical instruments tracking, process validation etc. Active solutions are commonly used for dynamic and real time tracking of assets whether it be devices, inventory, staff, or patients. An optimized and effective hospital RTLS solution will use both passive and active technologies. as illustrated in figure #2.

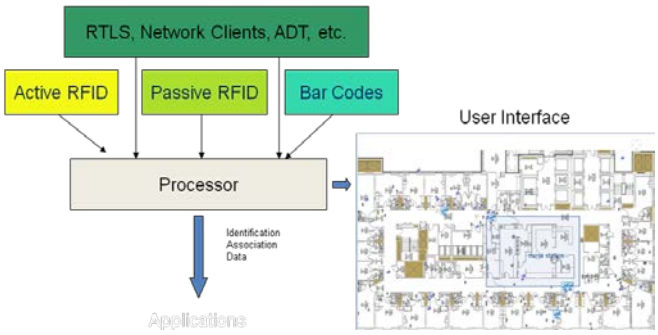

Figure # 2: Hospital RTLS Solution

At MSK a variety of solutions have been deployed both active (> 10,000 Tags) and passive components. The active solutions have focused on inventory, utilization management and optimization.[3,4,5] The passive have focused on process validation and inventory management and optimization. Additionally, Biomed has performed multiple pilot studies to evaluate workflow optimization metrics, applications and ROI.

The management and support of RTLS represents a new and evolving role based on the overall integrity of each of the applications. The overall success of any RTLS solution is largely dependent on the quality and integrity of the supporting inventory processes. Any errors in associating the inventory to the RFID tag / systems immediately impacts the results provided by the system.

6: New Synergies & Collaborations:

As was indicated above, Biomedical Engineering not longer manages stand-alone medical devices, but now deals with devices having significant connectivity and integrations involving other organizations. In or order to better manage the support of these systems, the user departments require at a minimum a single source of requesting service and support.

At MSKCC, an expanded help desk (request for service hot line) was established enabling any user within the hospital to call a single request line for service 24 x7. Specific scripts were developed to enable the responder to quickly assess which service would be the best provider of the initial response The user is required to identify a specific call for service, i.e. Cardiology, Operating room, or identify specific applications, such as connectivity or RTLS. All the staff, both IT and Biomed, carry devices enabling requests to be routed to specific staff as well as provide escalation and notification ot other staff as necessary.

CONCLUSION

In conclusion, Memorial Sloan-Kettering Cancer Center continues to take significant steps to strengthen its position as a leader in patient care, research, and education. To support this institutional effort, Biomedical Engineering has focused its specific expertise to provide leadership and innovation in order to rapidly bring new technologies to clinical use, while maintaining and supporting the existing medical equipment and technology currently used in the institution. Biomedical Engineering has become a strategic team member in the planning of long term clinical and technological objectives of MSKCC in planning, equipment replacement, product standardization and new construction or renovation programs.

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