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Management of medical technology for sustainable reliability

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ABSTRACT

Medical technology is constantly evolving to improve and prolong the lives of people. With the constant evolution of medical technology comes the constant challenge of managing the technology to ensure proper safety and function.

Purpose: This paper reports on an exploratory study conducted on New Zealand hospitals investigating how biomedical engineering departments can maintain reliability and meet growing demand for efficiency and safety.

Design/Methodology/Approach: This research is exploratory therefore a qualitative research approach using New Zealand public hospitals as case studies has been employed.

Findings: Discusses findings from two case studies and reports how hospitals can structure their biomedical engineering departments to efficiently manage medical technology to meet the growing demand and safety.

Originality/Value: This study provides valuable information on the management of biomedical technology.

Keywords: biomedical engineering; customer satisfaction; service quality; medical technology; healthcare; biomedical equipment.

INTRODUCTION

The growing complexity of healthcare organisations' diverse equipment needs, rapid technology development, and organisation-wide use of patient care equipment has made clinical/biomedical engineering's role both inevitable and necessary (Kortum, 2010). Today, hospitals are full of devices, instruments and machines that have been designed and produced by engineers working in collaboration with doctors, nurses, physicists, microbiologists and technicians. Examples range from the infusion pumps that administer drugs to patients and patient monitoring instruments that monitor heart rates and other vital signs, to complicated scanners that produce detailed three-dimensional images of internal body structures.

This research commences by reviewing the biomedical engineering department's role in public hospitals and the importance of service quality, internal customer satisfaction and safety. Methodology and data collection techniques used for this research are then discussed in order to explore how biomedical engineering departments in New Zealand hospitals currently manage biomedical technology to achieve quality and internal customer satisfaction. Data analysis and findings in six distinct areas of biomedical equipment management are then presented. The researcher concludes the paper by discussing recommendations and conclusions drawn from the research.

BIOMEDICAL ENGINEERING IN PUBLIC HOSPITALS

Biomedical engineers design and develop technologies for healthcare, usually in an academic or manufacturing setting. The growing complexity of healthcare demands the continual development of new technologies. The future holds new possibilities of providing advanced e-health services, new systems for home self-care, sophisticated new sensors, and new methods of patient care in healthcare institutions (Kortum, 2010). This indicates that there is no limit to what engineering can do to further revolutionise medical practice. In fact, the next generation of biomedical engineers will probably develop things we cannot yet imagine. This accelerating progress poses tremendous challenges to biomedical engineering departments in managing medical technology in public hospitals.

In hospitals, the key role of biomedical engineers is to meet technology management challenges that can be broadly defined as providing safe and effective management of technology used for patient diagnosis, therapy and patient monitoring (Zasimova and Shishkin, 2013). This implies involvement in all phases of the equipment life cycle including selection, acceptance testing, training in safe and effective use, equipment safety, maintenance and final disposal or replacement. Biomedi-

cal engineers are responsible for explaining new technologies and their impact on construction and operating costs, and for translating technological ideas, problems and concepts into a non-technical language so that a wide range of people (i.e. outside the biomedical field) can understand new technologies with ease. Frize (1988), Yi et al. (2014) and Zasimova and Shishkin (2013) suggest that hospitals'biomedical engineering departments usually perform the following tasks:

- Corrective maintenance and calibration of medical equipment.
- Incoming inspections (acceptance testing) for new equipment acquisitions and for equipment returned after an outside repair, before the equipment is placed in patient use.
- Preventive maintenance and periodic inspections of equipment as per medical equipment management standards (AS/NZS 3551:2012 for both New Zealand and Australia).
- Equipment safety checks such as screening hazard notices, performing equipment and electrical safety checks and generally contributing to a safer environment.
- Training users on the safe, effective use of new technologies and prevention of equipment misuse or abuse and accidents related to the misuse of equipment.
- Pre-purchase consultation, especially where the clinical engineering department is expected to repair the equipment after expiry of the warranty and sometimes even during the warranty period.
- Physiological measurements requiring personnel with a technical background, such as the catheterisation procedure and cardiac investigation studies.
- Clinical research and development, including equipment modification and design, because this activity transfers important skills to medical researchers and brings clinical engineers into closer contact with direct patient care, and also provides a multidisciplinary approach to problem solving and to the quality of patient care.
- Administration duties relating to the biomedical engineering departments' budgets, staffing, planning and training and development.

Moreover, biomedical engineers are uniquely qualified to understand the many subtleties of medical devices and alarm performance. They tend to have a very good understanding of the inner workings of the devices and are good at picking out situations where clinical staff may run into trouble when using a certain type of device or feature (Keller, 2006).

SERVICE QUALITY

Chen and Lee (2006) have mentioned that service quality is more difficult to measure when compared with product quality. Parasuraman et al. (1988) have explained that service quality is defined as the

capability of a company to meet or exceed customers' expectations. They have further illustrated that customer satisfaction results from service being better than customer expectations. Hence, service quality is closely connected to customer expectations; in turn, expectations are viewed as a line or point that service performance must go beyond, due to the concept of disconfirmation (Kletz, 2001; Varma and El-Kafafi, 2011).

Furthermore, the core philosophy of quality management is to lead and to operate an organisation successfully through a systematic and transparent manner of direction and control (El-Kafafi, 2006). However, the meaning of the word quality has remained elusive, leading to misunderstandings and hindering efforts to improve healthcare (Campbell et al., 2000). McGlynn (1995) argues that a simple definition of service quality is the art of doing the right thing at the right time, in the right way, for the right person and having the best possible results. Quality is a word that evokes different concepts for different people.

Therefore, how to define quality within healthcare remains a major concern and is further complicated by the wide range of stakeholders, each holding differing perceptions of quality (Joss and Kogan, 1995). Quality management as opposed to Quality Assurance (QA) within healthcare has grown in importance in recent years, and this is due to the fact that hospitals believe that quality improvement programmes and methods will lead to higher quality patient care, improved patient satisfaction and enhanced employee morale and lower the cost of service delivery (Roshnee and Fawdar, 2005).

CUSTOMER SATISFACTION

In addition to service quality, customer satisfaction continues to be of significant managerial importance. There is mounting evidence to show that service quality is a crucial variable that leads to customer satisfaction. Several studies seem to conclude that customer satisfaction is an effective rather than a cognitive construct (Olsen, 2002). Healthcare is one of the many service industries where customer satisfaction has been an increasing focus of research. This is mainly because of the fact that the public healthcare sector is experiencing growing levels of competition from private healthcare providers (Cronin et al., 2000).

Despite extensive research in the years since Cardozo's classic article, "An experimental study of customer effort, expectation and satisfaction" (Cardozo, 1965), researchers have yet to develop a consensual definition of consumer satisfaction. For example, Rust and Oliver (1994) have defined satisfaction as the "customer's fulfilment response" (p.16), which is an evaluation as well as an emotion-based response to a service. This definition also indicates that satisfaction is an

indication of the customer's belief in the probability of a service leading to a positive feeling. Cronin et al. (2000) have defined service satisfaction using items that include interest, enjoyment, surprise, anger, wise choice and doing the right thing. For Johnson and Fornell (1991), "satisfaction is a customer's overall evaluation based on the entire purchase and consumption experience with a product over time" (p.274).

From the various definitions, it is clear that customer satisfaction has different levels of specificity. Although satisfaction with a product's attributes or a consumption experience may be desirable, satisfaction with a service product or its delivery (the 'core' service) is more fundamental, and therefore has become the focus of this research. As this research is specific to the healthcare industry, the expanded customer satisfaction definition provided by Johnson and Fornell (1991) can be regarded as particularly appropriate:

> "satisfaction is a customer's post-purchase evaluation of the overall service experience, including process and outcome. It is an affective state in which the customers' needs during the course of the service experience have been met or surprisingly exceeded" (p.274).

In the context of biomedical engineering, customer satisfaction is measured to determine how well biomedical engineering services meet or exceed internal customer expectations. These expectations often reflect many aspects of the biomedical engineering service and activities, and include how the department operates in the hospital environment. The measure of customer satisfaction is an overall psychological evaluation that is based on the internal customer experience.

METHODOLOGY

This study used a qualitative research method to collect data from four case studies (New Zealand public hospitals). Qualitative research focuses on a full and rounded understanding of organisational experiences and the situations of individuals within a group, gathering large amounts of rich information concerning a small number of people or organisations (Ticehurst and Veal, 2000). Since this was exploratory research, qualitative study was considered most suitable; in fact, very little has been written about biomedical management programmes in New Zealand public hospitals, and therefore, the researcher sought to listen to participants and to build an understanding based on their ideas (Creswell, 2003). This qualitative method provided biomedical engineers and hospital managers an opportunity to respond frankly to enquiries about their experiences in the management of biomedical/clinical equipment.

Research data from sources, source was collected for validity and for the purpose of cross-checking in order to build a coherent justification of the themes (Bryman and Bell, 2007; Creswell, 2003). Data collection techniques are discussed in the following section.

Data collection techniques

For this research, case study methodology was used to collect rich and detailed information from four case studies (New Zealand public hospitals). The main focus was on biomedical engineering departments and their services to the hospitals' clinical areas, and the engineers' relationships with their internal customers.

Face-to-face interviews: the researcher used live interviews as the main data collection instrument, because this method yields rich insights into people's experiences, opinions, aspirations, attitudes and feelings (Creswell, 2003; Neuman, 2003). Members of the biomedical engineering department of each case study were interviewed. The participants were a mixture of technical, administrative and equipment managers. The technical members consisted of biomedical engineers and technicians who were actively engaged in repair and preventative maintenance, installation and day-to-day handling of biomedical equipment. The administrative staff were those who updated equipment databases, prepared equipment status reports and provided administrative support to technical staff in ordering spare parts,updating service procedures and data entry. The equipment managers were involved in assisting hospitals in capital equipment planning and purchasing processes, new technology trials and management of hospitals' biomedical equipment. Interviewing staff in a wide range of roles gave the researcher an opportunity to understand all stages of the biomedical equipment management cycle in a public hospital, from the planning stages through to the trialling, purchasing, installation and the final decommissioning stage.

To guide the interviewees, 20 semi-structured questionnaires were developed. The questions were focused on biomedical service activities, equipment handling, and equipment management and internal customer service. These questions were written in a structured format, which the interviewer followed strictly, as recommended by Bryman (2004). During the interviews, the researcher also discussed departmental documents to better understand their contents. Additionally, information gleaned from these interviews was also used to confirm information contained in hospital documents by using the process of triangulation.

Documents: document review was the second technique used for data collection. Both internal hospital documents and written materials external to the hospital were used to gather information on asset/

equipment database management, hospital policies, equipment maintenance procedures, test and calibration procedures, annual reporting, internal and external communication strategies, reporting systems, traceability and other departmental activities relating to biomedical engineering. The focus was on clinical equipment handling and management, traceability, quality and internal customer-related processes.

DATA ANALYSIS

This study used pattern-matching and cross-case analysis strategies for analysing case study data. These strategies involve looking for recurring patterns in the case study data to identify and compare similarities between different empirical patterns evolving from each data source (Creswell, 2003).

This strategy involved four stages. The four stages of the analytical procedure used for data analysis in this research were as follows:

1. The first stage consisted of creating a draft transcription of all information collected from tape recordings of interviews and transcription of information obtained from hospital documents. A primary review of the draft was undertaken to ensure accuracy and completeness. Then, the first draft was reviewed again to better understand content from both data sources.
2. In the second stage, keywords, opinions or themes relating to the key elements of the biomedical service were categorised into groups. Relevant keywords or themes from document review data were also categorised in order to compare those keywords or themes, as well as supporting information collected from interviewees. During this stage, the data were also reviewed in a bid to distil data from the first draft by using categorising keywords to create the second draft.
3. In the third stage, data from the second draft were analysed by relying on the theoretical proposition (distinct areas of clinical equipment management programmes) to identify and describe the individual event or pattern of key biomedical engineering activities within the hospital.
4. In the fourth stage, clinical equipment management events or activity patterns were compared to identify similarities and differences between overall patterns by using a cross-case analysis technique.

The findings from this analysis yielded the overall pattern of key elements of biomedical engineering services in the four case study hospitals, and were grouped into six emerging areas that are explained further in the findings section.

FINDINGS

From the data analysis, six distinct areas were identified as important arms of biomedical engineering departmental structure:

- Biomedical equipment management systems
- Biomedical equipment identification
- QA and preventive maintenance
- Biomedical equipment repairs
- Communication and feedback and
- Training and development

Management systems: All case study hospitals had a quality manual that outlined departmental policy and procedures, QA programme, complaint handling, traceability and equipment commissioning and decommissioning processes as part of an overall quality management system.

Quality manuals described enhanced effectiveness and customer satisfaction as targets that could be achieved through quality monitoring and by making improvements to services. The quality manuals were supported by a series of departmental procedures that described the detailed workings of each part of the quality control system. Biomedical engineering departments also had documents describing policies, procedures, technical, operational and behavioural subjects. These documents formed the core values to which the four case study biomedical engineering departments subscribed.

This research revealed that the current management of quality involves many aspects of the biomedical engineering service. The four hospitals' biomedical engineering departments all work towards ensuring that departmental functions inter-relate and work efficiently and effectively. The findings also revealed that biomedical engineering departments were following the International Organisation for Standardization (ISO, 2000) 9000 total quality concept, and furthermore, were using the ISO-9000 series of standards for quality management to reduce non-conformance and to fulfil customer expectations by providing cost-effective biomedical services within the departments' capacities. Processes relating to biomedical engineering services were described in procedures, and defects such as equipment faults and complaints were also regulated by detailed procedures and specific job instructions.

The findings also showed that case studies (New Zealand public hospitals) use different types of management systems to reach biomedical engineering objectives. For example, case study A was using a continuous improvement system to achieve its objectives at the time this research was conducted. Case study B was using a service management system, while case studies C and D were using a risk management system.

Biomedical equipment identification: Data analysis revealed that currently, all clinical and non-clinical equipment is recorded in a single database per hospital. When new equipment is purchased, it is asset registered and acceptance checked; a QA check sheet is prepared, the equipment details are loaded into the equipment database and then, the equipment is commissioned for patient use. It was noted that obsolete or faulty clinical equipment that was uneconomical to repair was decommissioned, removed from asset registers and was written off for disposal. This process was confirmed from document reviews and through face-to-face interviews. It was noted by the researcher that although all biomedical/clinical equipment was loaded into the hospitals' respective databases, the equipment categories were not explicit. For example, refrigerators were not clearly identified by function as sample, blood, drug or food storage refrigerators.

QA and preventive maintenance: Data analysis suggested that performance verification checks (QA checks) and preventive maintenance on clinical equipment are the most visible aspects of clinical equipment management. The researcher established from interviews with biomedical engineers and technicians that corrective maintenance only should not be the primary maintenance strategy for medium and high-risk equipment. Simply put, this is because the equipment might have drifted from its original calibration settings, but may still be functioning, and clinicians may then think that the readings obtained from the instrument are correct. Un-calibrated equipment can compromise operator and patient safety and can even lead to incorrect diagnoses. Therefore, a combination QA and preventive maintenance programme is important. This combination approach also can minimise breakdowns, allowing for maximum uptime use of the clinical equipment or system at minimum maintenance cost (Healy, 2007).

Biomedical equipment repairs: Although preventive maintenance and performance verification checks are carried out at regular intervals, it is inevitable that some equipment will experience failure because it is regularly moved with patients between wards. Therefore, skills and knowledge are important in maintaining quality of service and customer satisfaction. This research found that hospital biomedical engineering departments have limited resources, because public hospitals experience high demand for technological support in terms of equipment management, technical assistance in equipment operations, maintenance and technical advice. Therefore, at times, equipment downtime is longer than expected.

Communication and feedback: Findings from this research suggest that biomedical engineering departments in the case study hospitals are continuously working towards improving their service quality by establishing, evaluating and prioritising their internal customers' needs and

expectations. This study revealed that biomedical engineering staff actively promote good working relationships with clinical teams, specialists and clinicians. Biomedical engineering teams keep their internal customers well informed about equipment status via good communication and feedback. Common methods of communication and feedback include verbal and telephone discussions, e-mails, formal written reports and group meetings. Both interviews and available documentation reveal that case study hospitals rely on two methods of customer feedback.

1. *Informal internal customer feedback*: telephone dialogue and verbal discussions at the patient's bedside in the medical wards regarding equipment malfunction, the technical operation of clinical functions on equipment, technical advice and support.
2. *Formal internal customer feedback*: in the form of written service reports, meetings, training reports and e-mails.

Training and development: All four case study hospitals run a training and development plan for biomedical engineering staff. Engineers and technicians progress through a training plan and become competent on various types of clinical equipment. Once staff members gain product knowledge, experience and competency in one aspect of the equipment, they progress to the next level of training. Training needs are determined during an acceptance review of new equipment by senior staff, with the help of the manufacturer's recommendations. Once a training need is established, the staff who are likely to be working on the equipment are trained by the manufacturers or by the experienced members of the biomedical team. Interviews and documents revealed that due to the complexity of the equipment, budget constraints and lack of resources, biomedical engineering departments are currently facing difficulties in up-skilling their engineers and technicians.

Sometimes, training is conducted by the hospital's clinical educators to provide a clinical overview of the procedure in which the equipment will be used. Once the training is completed and the trainer/assessor feels that the engineer or technician is competent, then the trainee is allowed to work without supervision and is empowered to make decisions regarding clinical equipment. Furthermore, experienced team members share their skills and knowledge with other, less experienced members of the department in the form of in-service training. Training is delivered by two methods:

1. *On-the-job training*: occurs in a normal working environment, using the actual tools, equipment, documents and materials that staff use when fully certified. Training is conducted by a senior staff member through lectures and hands-on practice sessions.
2. *Off-the-job training*: occurs away from the normal workplace. This type of training is usually conducted in a classroom situation

on specific equipment. Occasionally, training is conducted by the manufacturer at the manufacturing site.

RECOMMENDATIONS

This research reveals that biomedical engineering professionals are facing difficulty in keeping up with myriad improvements in biomedical equipment technology, as well as keeping pace with increasingly high expectations from their internal customers for technological support. To continue maintaining the reliable functioning of complex medical technology, service quality and customer satisfaction in this fast-changing industry, this study makes the following recommendations:

Recommendations on improvements to service quality and customer satisfaction via staff training: Keeping in mind the myriad improvements in modern medical technology and the increasingly high expectations of clinicians for technological support, the researcher recommends that New Zealand public hospitals' biomedical engineering departments implement a more robust equipment management and training programme to improve staff technical skills. This will lead to improvements in service quality and internal customer satisfaction. Biomedical engineering departments should also be encouraged to allocate ample budgets to send more engineers and technicians to factory-level trainings on specialised biomedical equipment. Many medical device manufacturers have excellent training materials and other resources that can be used to help frontline engineers gain maximum knowledge in minimum time.

Recommendations for engaging outside contractors: Where hospitals depend on outside expertise to maintain high-tech equipment such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) scanners, management and senior staff should invest more time and resources in awareness training to ensure that everyone within the organisation understands the processes and procedures required to engage outside contractors when such equipment is down. This will avoid unnecessary delays in patient treatment.

Recommendations on upskilling biomedical engineering staff: E-health has made its way into the healthcare industry and is emerging around the globe. This term now seems to serve as a general 'buzzword' used to characterise not only Internet medicine, but also virtually everything related to the interface between computers and medicine. E-health is an emerging field in the intersection of medical informatics, public health and business, and refers to health services and information delivered or enhanced through the Internet and related technologies. This requires medical equipment to be networked be-

tween various types and models of equipment via hospital's Information and Communications Technology (ICT) network. Therefore, biomedical engineering managers should employ ICT specialists and should also attempt to upskill biomedical engineers and technicians in ICT areas that largely interface with medical equipment.

Recommendations on appropriate resourcing of biomedical engineering departments: Since biomedical equipment plays a crucial role in patient treatment and safety, public hospitals must review their biomedical equipment-related policies, processes, procedures and QA programmes regularly, and must work towards continual improvement.

CONCLUSION

This research concludes that the main function of biomedical engineering departments in public hospitals is to effectively manage biomedical equipment including preventative maintenance, repairs and inspections (acceptance testing) for new equipment, and to ensure patient and user safety.

Although several processes and procedures are in place in the four case study hospitals to ensure efficacious equipment management, gaps still exist in biomedical engineering services due to under-resourcing, inadequate staff training, budget constraints and the unrelenting pace of improvements in medical technology. Therefore, this research concludes that managing medical technology is clearly not a simple task. To maintain sustainable reliability in the fast-changing world of medical technology, it is important that not only the biomedical professionals should work together as a team, but that the biomedical professional and the clinical staff must work as a wider team. The most important aspect to creating a functional team is creating and maintaining relationships between all hospital staff. These relationships will help gain and maintain confidence in the abilities of the biomedical department staff, and will help prevent situations with potentially negative outcomes.

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BIOGRAPHICAL NOTES

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