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Integration of Healthcare System with its Experts for Improving the Life Expectancy of Medical Devices : A Review

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ABSTRACT

This paper provides the structure of healthcare system in India and analyses recent developments in the derivation of bio-medical equipment's maintenance & management strategies, and proposes some specific points to consider and offer to perform them during operation. We also envisage the new challenges in the healthcare system in India which represent an important economic position and are subject of everyday optimization attempts. For this purpose by now exists a huge number of tools which conduce more likely to a complexness of the problem by a comprehensive implementation. In the future, we envision that new paradigms to be structured to overcome the present strategies which will benefit & upgrade the rural and urban healthcare system with reduction in patient risks, and in the longer term, provide an alternative source for maintenance and management of medical devices at hospitals in the form of biomedical engineering department.

Keywords: Biomedical equipment's, Hospitals, Healthcare Technology Management (HTM), Medical Devices, Medical Technology

I. INTRODUCTION

Health technologies are essential for a functioning health system. Medical devices in particular are crucial in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation. Recognizing this important role of health technologies, the World Health Assembly adopted resolution WHA60.29 in May 2007. The resolution covers issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices. By adopting this resolution, delegations from Member States acknowledged the importance of health technologies for achieving health-related development goals; urged expansion of expertise in the field of health technologies, in particular medical devices; and requested that the World Health Organization (WHO) take specific actions to support Member States. One of WHO's strategic objectives is to "ensure improved access, quality and use of medical products and technologies."

A medical equipment inventory provides a technical assessment of the technology on hand, giving details of the type and quantity of equipment and the current operating status.

In a modern hospital, most diagnostic, therapeutic, and rehabilitation activity is based on the extensive use of medical technologies. The management tools to make strategic decisions depend on the quality of information. One of the equipment manager's most critical duties is determining whether to repair or replace a piece of equipment [1]. Hospital is an integral part of a social and medical organization, the function of which is to provide for the population complete health care, both curative and preventive; the hospital is also a centre for the training of health workers and bio-social research (World Health Organization). Hospital is much more complex than other manufacturing organizations, for it undertakes medical and health responsibilities that deal with the lives of people, and it must also account for health economics which is different from economic production in important respects [2].The documentation

of equipment maintenance and risk ranking is an extremely important duty relating to these activities [3], [4]. A good maintenance system is required for almost all equipment in order to guarantee its performance, prevent failures and to extend its life expectancy [5].
The inventory provides the basis for effective asset management, including facilitating scheduling of preventive maintenance and tracking of maintenance, repairs, alerts and recalls. The inventory can provide financial information to support economic and budget assessments.

The inventory is the foundation needed to organize an effective HTM department. Items such as equipment history files and logbooks, operating and service manuals, testing and quality assurance procedures and indicators are created, managed and maintained under the umbrella of the equipment inventory. Furthermore, accessories, consumables and spare parts inventories are directly correlated with the main medical equipment inventory. Corrective maintenance is more costly and time intensive than preventive maintenance, but only occurs when a machine fails. A good preventive maintenance policy considers the trade-offs between more frequent preventive maintenances and the more expensive corrective maintenances [6].

On the one hand, the importance of medical equipment, effective management of such equipment, and advances of this technology in prevention, diagnosis, and treatment of diseases is evident. Without medical equipment, diagnosis and treatment will be done at very basic, insufficient levels. On the other hand, for years extortionate costs have been paid for procurement and maintenance of hospital equipment in the health and medical facilities and the equipment has been largely supplied by foreign countries. This certainly has had negative consequences for the country and necessitates attention, care, maintenance, and proper use of hospital equipment.
Moreover, incorrect use of medical equipment leads to detrimental consequences for the safety and health of the patient, and malfunctioning equipment due to inappropriate maintenance can affect the health of patients and the performance of hospitals.
The breakdown of medical equipment in service is of particular concern because of its possible use in critical conditions. The signs of equipment failure may not always be apparent to the clinical staff. Therefore scheduled inspections help ensure the safety and efficacy of the medical equipment [7]. Time series forecasting is an important area of forecasting in which past observations of the same variable are collected and analysed to develop a model describing the underlying relationship. The model is then used to extrapolate the time series into the future, with a promising application in the area of maintenance of medical equipment.

The purpose of this document is to provide an overview of health-care technology inventory for people working within the health-care field. It is important to understand that maintaining an accurate inventory is not the end of the HTM process. Rather, the inventory serves as an input to the many different activities within the HTM cycle (Figure 1). The role of an equipment inventory in each step of the cycle is discussed in order to emphasize the importance it plays in all facets of HTM.

This paper maps out the situation of service management as well as facility management of medical technology and demonstrates a new integrative approach to optimize consisting downtime service maintenance. The concept arose against the backdrop of foreseeable social and technical developments. As a result of social change acting, hospitals and medical technology (equipment and services) providers have to rise to new challenges at the healthcare market.

In this paper the brief model of healthcare system at different levels in fully functional way is analysed to predict the future status of medical equipment to support decision making. The models are based on real data observation to determine some key parameters of the medical equipment such as Availability, Reliability, Management and Performance Efficiency.

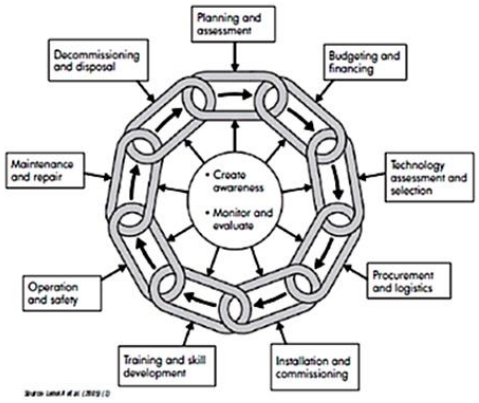

Figure 1: Healthcare Technology Management cycle

II. HEALTHCARE IN INDIA

The equipment inventory is an important input in determining the tools and test equipment required for maintenance and the budget required for acquiring, calibrating and maintaining the instruments [8]. It is imperative for any organization intending to run an effective medical equipment management programme to have and maintain an equipment inventory. The inventory serves as the basis for the programme. Intervals for inspection, testing and maintenance are defined by the initial risk analysis that determines a piece of equipment's inclusion in the inventory. All equipment has an expected lifetime and will eventually need to be replaced or disposed of. Service histories associated with inventory items can be assessed to determine when equipment is no longer serviceable, relevant, safe or cost-effective.

This information can help to develop policies for the replacement or disposal of equipment. Subsequently, this information can be used to prepare budgets for new capital purchases, repair services and so on.

Despite of having huge budget in healthcare, India is lacking the healthcare technology maintenance and management in comparison with other developing nations. The two initiative taken by the Health department, the National Health Systems Resources centre (NHSRC) at central wing and the Drug and medical supplies corporations at state level draw attention towards the poor attribute towards the technical and management strategies in the hospitals leading to huge loss and risking the patient lives at different levels.
The prospective study of availability and utilization of major equipment at District Hospital Gurgaon, Haryana by O.P. Lathwal, Alok Banerjee [9] was carried out in nine different departments and ten service areas in order to find out their availability and utilization of various major equipment's in the respective areas. The actual utilization of available equipment's was found to be only 39.3%, the rest were either non-functional (35.5%), or not in use (25.2%) and kept as reserve. Majority of the non-functional/breakdown equipment were just lying for condemnation (28.2%), only 7.3% kept for repair, out of the available total equipment of 369.

The initiative taken by NHSRC in the recent years on biomedical equipment's known as Project Mapping on biomedical equipment's inventory, across the nation.
This project is based on collecting the data of biomedical equipment's and reviewing the status of medical devices in the hospitals. This initiative is still in progress and as per experts working says that the conditions of equipment's are extremely poor and the devices are calling the maintenance experts for their care.
Wang and Levenson (2000) [10] emphasized that the consideration of mission criticality and utilization rates is essential when deciding which equipment should be included in an inventory. Mission criticality identifies how important the equipment is to the overall goal of the hospital.

To manage their investments effectively, to identify priorities, to attain goals (according to a financial plan) and to maximize financial returns, hospitals need to develop medical technology management programs. These programs can integrate relevant information and a planning methodology for the purchase of new equipment, and for optimizing equipment inventories: upgrades, replacements, annual expenditures related with equipment repairs, among others. This efficient management of medical technology will enable the specialization, differentiation and innovation of medical organizations. In turn, this will improve the delivery of healthcare and allow the recruitment and retention of high quality professionals, along with increasing research and revenues (Orlikowski, 2000) (Brach et al., 2008) (Teplensky et al., 1995)[11] [12] [13]. So, due to the increasing dependence of such equipment's, it is fundamental to create and implement assessment and management methodologies of technologies, including medical hospital equipment (Jahnke and David, 2005) [14].

According to the Mapping project, the outcomes at certain places was found that more than 50% of medical equipment's were non-functional unless being maintained and around 30% of equipment's were defunct and condemn. Wang et al. (2006) [15] discuss further different strategies for determining equipment to be included in an inventory and within a medical equipment management programme. In a medical equipment inventory, each piece of equipment is assigned a unique number to allow it to be identified

from among all other pieces of equipment in the inventory.

The Association for the Advancement of Medical Instrumentation (AAMI), in its widely recognized standard recommended practice for a medical equipment management program [16], requires that inventory inclusion criteria take into account the function of the equipment, the physical risks associated with the equipment, the maintenance requirements of the equipment and the incident history of the equipment. The biomedical engineering department determines the identification numbering and labelling system to be used within the organization, which, the department is not found in any healthcare institution in India.

III.PROCUREMENT OF MEDICAL DEVICES

Cost effectiveness is of major importance in providing technology support services to hospitals. United States experience in the wake of the global financial crisis is that considerable cost savings and efficiency gains can be made by reverting to in-house biomedical/clinical engineering services responsible for equipment specification, procurement, commissioning, quality management and maintenance as against outsourced or externally managed services.

When equipment is replaced or disposed of, it usually needs to be replaced through purchase or donation [17]. Tracking inventory levels and trends over time in conjunction with performing a needs assessment of required technologies can help the health-care facility identify equipment that it needs to acquire. This information can be developed into a purchasing plan, identifying critical equipment that needs to be purchased in the short term, and establishing goals for future acquisition.

The procurement of medical equipment's in hospitals are directly managed and procured by management committee comprising the members of specialized doctors, head of the institution , some management members etc., without consulting or having any technical member in the procurement board. The reason behind lagging the technical person in the committee is the absence of biomedical engineering department in the hospitals or in any zonal health department.

Assessment might show that standardization would lead to lower spare parts prices, lower costs required for training more individuals on one type of technology, and lower costs for tool and equipment purchases.
As economic constraint bites there is a trend to replace outsourcing with in-house services as being more cost effective and this can apply to both small and large organizations.

Reporting from a "small" organization, Lolos [18], the assistant administrator (medical) from a multispecialty clinic indicated operational savings in the order of $500,000 p.a. over 8 years from developing an in-house Biomedical Engineering (BME)/Clinical Engineering (CE) Unit to manage services. During the period where asset value increased within the range $15.5 million to $29 million, service and maintenance costs reduced from 6.6% to 4.2% of the asset value. At the other end of the spectrum, the manager of a clinical engineering organization [19] within a 13 hospital medical service, when confronted with budget cutbacks worked with management to re-engineer practices to achieve the required savings; in this case set as $2.5 million in two years.

IV.MAINTENANCE & HEALTCARE MANAGEMENT

Medical hospital equipment's are systems employed in healthcare delivery to general population, and are typically operated by physicians, nurses or technicians. These equipment's usually carry mechanical, electronic, hydraulic and pneumatic mechanisms, and incorporate software (Carmo et al., 2007) [20]. They can be used in prevention, diagnosis, treatment or in the creation of the necessary comfort for the patient and medical personnel when performing diagnostic, therapeutic and prophylactic measures (Kabatov, 1970) [21].

The equipment inventory workshops are not established in the hospitals, hence we cannot find the properly maintained work orders and service history records to identify equipment failures, malfunctions and misuse due to inadequate training. Training deficiencies may be identified by equipment (such as new technology that is difficult to learn to use), by department (such as incorrect application of the technology) and by person (such as where an error is repeated by the same person) [22]. It is important to note that training may be for

either or both technical and clinical staff. Where clinical staff members are expected to maintain and update equipment inventory records (such as in small clinics and other resource-limited settings), training on inventory recordkeeping is essential. Additionally, the arrival of a new piece of equipment typically sparks a series of training activities within the health-care facility, such as appropriate use and technique (required for clinical staff but also useful for maintenance staff), general maintenance, proper cleaning and storage of the equipment (for both clinical and maintenance staff). For specialized equipment, the initial inventory inclusion data for new equipment can be used to schedule periodic mandatory refresher training sessions for all personnel.

In healthcare system, most of times support from external service providers is required to undertake the service and repair activities for medical or test equipment. This is often the case for highly specialized equipment and equipment under warranty. The inventory can help identify which equipment needs external service and can also assist in determining the budget required and available for such service.

It is imperative for any healthcare organization intending to run an effective medical equipment management programme within the presence of biomedical engineering department to have and maintain an equipment inventory. The inventory serves as the basis for the programme. Intervals for inspection, testing and maintenance are defined by the initial risk analysis that determines a piece of equipment's inclusion in the inventory.

V.CONSEQUENCES OF POOR HEALTHCARE

The ineffective use and subsequent poor operational performance of medical equipment and the chronic lack of functioning medical equipment is generally regarded as an important contributor to the poor quality of health care delivery in India.

A study conducted in low and medium income economies, indicate that as much as half of the equipment in urban and rural medical institutions is inoperable and not in use. As a result the efforts of medical and para-medical personnel are seriously impaired.

Despite progress been made over the past few decades, the fact remains that a large proportion of the population in India does not have access to adequate health care. Recent statistics show that infant mortality is still as much higher than in other developing nations. High incidence of disease and high mortality rates contribute to a poor quality of life. The economic consequences of poor health are also considerable, in that a poor state of health directly and indirectly contributes to the economic burden carried by the country. This concern is expressed in a recent publication by The World Bank.

The poor state of healthcare in India has led the specialized medical personnel to opt to go other countries to work in better healthcare standard. The reasons given are multiple and often complex. McKie [23], for example, attributes the medical equipment problem in developing countries to poor management of health care technology. He states that "shortcomings in managerial procedures and practices are familiar and often described, however the root causes of the disease are seldom probed". He also speaks, in this respect, of a "disease with multiple causes".

VI.MONITORING OF BIOMEDICAL INVENTORY

Monitoring workflow applications have been already deployed in many enterprises related to manufacturing process. But maintenance of medical equipment's has some particularities that require a special infrastructure.

The monitoring process consists on the following steps:

1) Acquire the data required for monitoring;
2) Data processing to obtain monitoring parameters;
3) Condition monitoring, i.e. evaluation of parameters of condition and determination of their status with respect to their nominal operation conditions;
4) Perform a reactive action in case of failure; and
5) Perform a proactive action to improve the maintenance workflow.

In addition, the start-up of the monitoring process should be also considered.

A. Data Acquisition

The required data to track maintenance workflows is related to actors, events and steps, as stated above. Thus, data acquisition is related to obtain these data, as for example,

-a device status information,
-a spare part has arrived,
-an in-house technician is absent or ill.

This data should be acquired directly from the medical equipment and the hospital information services. Thus,

the key issue here is to build an appropriate interface to connect medical equipment and hospital information services in a common infrastructure that enables the maintenance workflow monitoring.

B. Data Processing

This step consists on processing the acquired data so that the appropriate maintenance events can be generated. That is, data acquisition is related to raw data sent by different applications/ interfaces. This data should then be interpreted as maintenance events to be handled in the maintenance infrastructure. For example,

-from a device code a failure maintenance event is generated, and thus a maintenance workflow instance should be initiated,

-from a spare part arrival, a maintenance task should be either continued or started,

-from the information about the sick leave the maintenance escalation event should be activated and the maintenance task reassigned to another technician.

C. Condition Monitoring

Conditioning monitoring is related to determine the current status of a maintenance workflow instance. Three condition states can be detected:

-Start, when a workflow maintenance instance should be initiated due to a device failure or a device preventive maintenance operation (scheduled maintenance).

-Failure, if a delay is incurred.

-Predictive, when, for example, an overload due to an increase on maintenance operations can be detected and a possible delay on non-priority maintenance tasks can be predicted.

Each condition monitoring state requires a different actuation on the maintenance workflow. First, starting a maintenance workflow instance involves the initiation of a new monitoring process. Second, a failure should be corrected as soon as possible in what it is called the reactive maintenance. And third, a predictive state requires a proactive maintenance.

D. Monitoring Start up

For each maintenance workflow running a monitoring process should be started. Since several workflows should be controlled at a time, concurrent approaches should be followed when implementing the workflow monitoring. In this line, agent technology offers, for example, the possibility of organizing the different workflow instances according to several criteria, as the in-house technician responsible of the maintenances and the kind of medical equipment, among other. An additional agent should also assume the role of coordinator, dealing with possible preventive and predictive issues.

E. Reactive Action

When a failure occurs, there is a delay in the workflow progress. For this purpose the escalation procedure involved in the workflow should be activated. As a result, the workflow would be dynamically adapted to the new circumstances. This includes the actuation on the current patient scheduling so that the delays should be informed to the medical staff.

F. Proactive Action

When some information in the system predicts that there could be a failure in the current maintenance workflow instances, several actuations are possible among them, to dedicate more resources to the current maintenance operations, to give priority to some of them, and so on [26].

VII. STANDARDIZATION & DOCUMENTATION RISKS IN MEDICAL EQUIPMENTS

Importantly, the link between AS 3551, AS3200 [24] and IEC 60601[25] introduces the concept of “essential performance” or the performance necessary to achieve freedom from unacceptable risk; a concept not dissimilar to zero down time in IT and engineering terms. While this is fundamental to patient safety, it also places increased onus on the risk manager, preferably the clinical engineer, to be fully on top of the system at all times.

In a medical equipment inventory, each piece of equipment is assigned a unique number to allow it to be identified from among all other pieces of equipment in the inventory. All information gathered about this piece of equipment in the equipment management process, such as service history, preventive maintenance procedures and schedules, repair history and spare part usage, is linked to this identification number for optimal organization of data. Once the inventory identification number is assigned, each piece of equipment is labelled with that number. The clinical engineering department

determines the identification numbering and labelling system to be used within the organization.

VIII. COMPUTERISED INVENTORY MAINTENANCE & MANAGEMENT

Current advances in medical devices allow us to think in a scenario in which all medical equipment's involved in a hospital will be connected to a communication infrastructure. The maintenance operations related to all this devices can then be approached in an automated way taking advantage of the current hospital information applications, as for example, planning tools, data bases of human resources (technicians), etc. Thus, instead of dealing with a burden workflow execution based on manual interaction, the maintenance workflow can be controlled with a computer program.

The inventory may be integrated into a Computerized Maintenance Management System (CMMS), which generally combines inventory, repair and maintenance history, and work-order control into one system.

Other information as needed may also be included in a CMMS. A CMMS may have the capability to record all repair and maintenance history for a particular item included in the inventory. Work-order tracking is another important feature of a robust CMMS program. This tracks all work orders opened for maintenance within an entire clinical engineering department. For a health-care facility to have any intention of implementing a high-quality HTM programme, the first and most important step is to perfect the equipment inventory.

IX.ROLE OF BIOMEDICAL ENGINEERING

It is contended that biomedical engineering services, including the clinical engineering specialty, should be recognized primarily as a clinical support service, and should be aligned with the clinical services of the hospital for the purpose of representation, management and governance. By necessity, Clinical Engineers work across all clinical specialties and areas of medical practice within the hospital and their reporting structures within the organization should reflect this role if their contribution is to be fully realized.

Clinical engineering is at the point where significant additional change is necessary if it is to realize the potential for it to be an effective agent of change and a full partner in managing strategic planning of the medical technology asset in the healthcare sector into the future.

There is an oblique reference to biomedical engineering in the sister report from the Productivity Commission in 2005 looking at the "skills and availability of health professions and other complementary inputs", stating that the "use of medical technology at the very least requires the services and knowledge of a medical professional and may also require other inputs, such as other skilled professionals (e.g. technicians and nurses), capital equipment and infrastructure".

The Health Workforce Issues Paper 2 in 2005 [25] and a preceding study by Lehoux (Canada 2002) confirms the reference to biomedical engineering in relation to the health workforce, with the recommendation that training programs and CPD should be increased to strengthen the human capital (including biomedical engineers) required for the appropriate use and maintenance of the technologies, to guarantee technical compliance and to ensure appropriate staff resources.

The fact that the bureaucracy and government do not acknowledge biomedical engineers as being in the group with direct responsibility for the patient in areas of critical care, safety and treatment outcomes, must set the alarm bells ringing. This can mean two things; either hospital managers do not realize (or want to recognize) the risk involved in allowing management of the medical equipment inventory by other than competent clinical engineers or, the informed public knows so little of the critical role played by clinical engineers that the profession is simply not on the political radar. There is currently no requirement for a biomedical engineer with the appropriate qualification and experience to be responsible for this critical aspect of patient care.

A. Discussion and challenges on Role of Biomedical engineer in healthcare organization

In seeking to have influence, reporting relationships are important and in this respect, clinical engineering as a service entity in the hospital setting is vulnerable. It is

unlikely that clinical engineering will ever be one of the power blocks within a hospital, purely on weight of numbers and current incumbency. Hospitals are identified by the medical and nursing professions, to a lesser extent by allied health and increasingly, by the generic management professions linked directly to Treasury and Government.

The concern is to determine which of these organizational streams is most likely to respect the clinical engineering role and which of the streams will allow the clinical engineer to contribute in their own right and to set an independent and yet, supportive agenda.

The challenge in achieving this should not be underestimated as in many cases organizational trends have already been determined, possibly to the detriment of clinical engineering and its future. The risk in getting this wrong is that clinical engineers can find themselves relegated to the role of information provider only and distanced from the actual decision making process. Increasingly where this has happened, medical equipment is seen by executive management to be the province of the nursing officer, the IT consultant or the facilities manager and this "ownership" tends to become entrenched and isolating where the reporting authority itself is competing for recognition and influence in the organization.

The integration of biomedical engineering across hospitals and other healthcare facilities has been discussed in the context of operational flexibility and cost efficiency. The other advantage of integration is that it forms a presence and identifies biomedical engineering as an entity in its own right, avoiding or reducing the anonymity that can result if individual practitioners are dispersed and isolated within the organization.

X. CONCLUSION

Review of several available methods reveals that there are multiple paths that lead from management of medical equipment's to at least a maintenance of medical equipment's that more closely resembles lack of biomedical-clinical support in the hospital's. This apparent incomplete differentiation state likely results from our poor understanding of the mechanisms underlying the developmental shift from support staff to biomedical engineering wing. Moreover, the existing lack of standardization of specification, structure, and functional operations of medical devices has made comparisons between published papers challenging, if not impossible. In this review, we have illustrated the importance of extensive structural and functional operations in the healthcare institution and we encourage the community to apply various standards during in use medical equipment's. In addition, the use of well-documented and functional biomedical equipment's reference controls is key to the future improvement of maintenance and management strategy generation. This advance will lead to the rapid adoption of ecumenical paradigm and their use in a variety of applications including the study of the mechanisms of human disease and development, and, perhaps in the longer term, as a platform for biomedical/clinical engineering and to evaluate the efficiency and effectiveness of biomedical equipment's.

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