Elements for Medical Equipment Quality Assurance

Călin CORCIOVĂ, Dan ZAHARIA
Faculty of Medical Bioengineering,
University of Medicine and Pharmacy „Grigore T. Popa" –Iasi, Romania
calin.corciova@bioinginerie.ro

***Abstract* — Medical equipment quality assurance is part of an overall medical equipment management program for a healthcare facility or system. A complete program includes corrective maintenance or repair, equipment control, asset management, health care technology planning, education, and activities directed toward improving medical device-related patient safety. The purpose of this paper is to provide some guidance lines in establishing and managing a medical equipment quality assurance program and to present some procedures for inspection, maintenance, evaluation and performance testing for some medical devices. The results of this paper take into consideration the advances in device reliability, reduced preventive maintenance requirements and internal device surveillance (self-test) along with changes in standards. Due to the ongoing efforts at global harmonization, international standards are used and referenced where applicable, such as electrical safety testing references. A computerized medical equipment management system is described. The results demonstrate that it is a useful tool in tracking device inventory and maintenance history. Also risk classes have been designed for medical devices based on the time of testing, risk identification in relation to patient and staff member, clinical function, physical risk, problem avoidance probability, incident history, and regulatory manufacturer requirements.**

***Index Terms* — calibration, clinical risk, corrective maintenance, incoming inspection, life support equipment**

I. INTRODUCTION

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

The goal of any medical equipment maintenance program is to ensure that medical equipment is safe, accurate, and ready for patient use. Quality assurance is achieved with periodic checks of the equipment. The purpose of establishing risk-based maintenance intervals is to provide high-quality, cost-effective inspections based on risk and function, historical data on problems found, and the effect of maintenance on the reduction of problems. The inspection procedures should be based on need that includes the maintenance requirements of the device, risk classification, device function, and history of incidents.

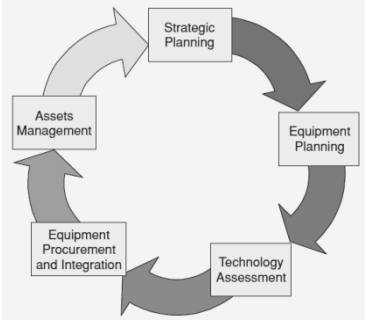

Fig. 1. The technology management process in medical services

Maintenance and performance inspections do not prevent random failures, particularly related to electronic equipment and low risk devices do not need performance verification at the same frequency or intensity of higher risk devices. Medical equipment should be evaluated to determine how often testing should be performed. If a device is not tested often enough, it may fail before the next scheduled maintenance or give erroneous results. If a device is tested too frequently, time that could be better spent maintaining other equipment is wasted. The biomedical professional's job is to achieve a balance between the time and effort needed for periodic functional testing and the safe use of medical equipment

The medical technology management model (Fig. 1), contents adoption of the strategically prescribed norms

took place, as well as the monitoring in accordance with a well-thought-out plan, equipped with know-how from a multidisciplinary team of users and the implementation of an agreed-upon policy. The multidisciplinary team has a similar approach toward the creation of definition of needs, scope, and objectives for a specific type of medical technology.

II. MATERIAL AND METHODS

Inventory equipment

Understanding what devices are in the facility in order to provide a quality maintenance program is critical. Inventory data is used for a variety of applications including establishing a maintenance schedule, tracking medical device hazards and recalls, and deciding when to replace aging equipment.

A computerized medical equipment management system is a useful tool in keeping track of the device inventory and maintenance history. Any medical equipment management software should track basic device information. At a minimum, the device type, manufacturer, model, and serial number should be tracked. This information is essential to the maintenance program. The clinical use of a device should be documented. Equipment used for life support needs to be given a higher priority for maintenance. Additionally, regulations on life support devices may be different. For example, in the United States, equipment used for life support to have a 100 % completion rate for scheduled maintenance. Our software developed in Visual FoxPro respect all these conditions above.

The equipment location is used to find the equipment for maintenance. Also, the location is useful to break up the maintenance schedules by department (Fig.2).

Fig.2. Access in to the system

Fig. 3 Track equipment

A record should be kept of all maintenance performed on equipment, including scheduled maintenance, repairs, software upgrades, and incident investigations (Fig.3). Dates of service should be included in this history (Fig.4).

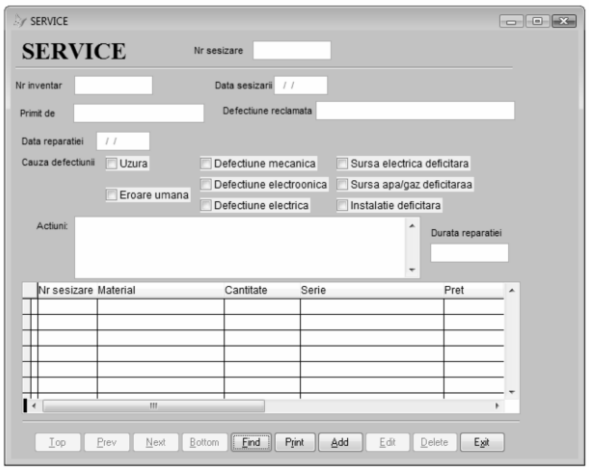

Fig. 4. Module record of servicing equipment

Risk-based inspection intervals

In order to maintain an efficient maintenance program, the frequency of inspection must be determined. Effort should be spent on equipment where testing is likely to have an impact on the continued safe operation of the medical device. We developed a risk-based system for determining the maintenance frequency. Intervals are established for equipment inspection based on risk, requirements, logistics, and history. Written criteria are used to identify risks associated with medical equipment per the Maintenance Strategy Module. The risks include equipment function, physical risks associated with use, and equipment history as it relates to patient safety. Life support equipment is specifically identified and receives the highest priority for actions

The risk criterion is divided into five categories: clinical function, physical risk, problem avoidance probability, incident history, and regulatory or manufacturer requirements. Devices are given a score for each of these categories. The scores for each category are added up and a total score is given for each device type. Maintenance strategies are determined based on the total score. A combined score of 12 or more is justification for semiannual testing, a score of 9-11 is justification for annual testing, and a score of 8 or less is justification for less than annual testing, either bi-annual or no scheduled testing, depending on clinical application. The result is a more cost-effective test program that will result in improved patient care through less equipment downtime and more money for direct patient care activities.

The risks identified are used to assist in determining the strategies for maintenance, testing, and inspection of medical equipment. In addition, the identified risks are used to guide the development of training and education programs for staff that use or maintain equipment. All medical equipment is screened at the time of delivery and appropriate training and testing of new equipment takes place prior to use on patients.

Clinical function is how invasive the equipment is to the patient. At the low end of this category is a device that does not make patient contact. The high end of this

category is a device used for life support, such as a ventilator.

Physical risk is an evaluation of what will be the outcome if the device fails. At the low end is low risk; failure is more of an inconvenience than actual harm such as an otoscope. At the high end is severe injury or death of the patient such as ventilator. Failure of this type of equipment can have a serious effect on the patient's outcome.

Problem avoidance probability is based on historic data related to medical equipment repair and maintenance. The low end of this category is maintenance or inspection having no impact on the reliability of the device; the high end is common device failures are predictable and can be avoided by preventive maintenance. This category also has an additional level, specific regulatory manufacturer's requirements that dictate preventive maintenance or testing.

The device incident history is also based on historic data. This category only has two scores, and is answered as yes or no.

III. CASE STUDY PRESENTATION

To illustrate risk criteria we discussed the two types of equipment used extensively in healthcare: apnea monitor and pulse oximeter.

Apnea is defined as the absence of breathing. An apnea monitor is designed to detect this condition. The apnea monitor senses by measuring changes in the electrical impedance of the thoracic cavity during respiration. Typically, electrodes are attached to the patient with lead wires connected to the monitor. The monitor will usually display the patient's heart rate and respiration rate, with the limits of these parameters adjustable by the user. An audible alarm will sound when the alarm limits are exceeded or if the monitor or when an apnea condition is detected. These types of monitors are typically used to monitor high-risk infants (Fig. 5).

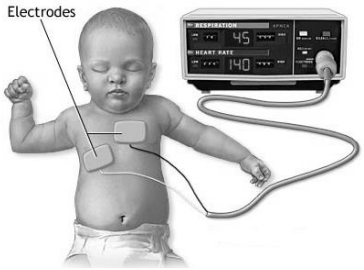

Fig.5. Apnea monitor system

TABLE I SAMPLE RISK ASSESSMENT FOR APNEA MONITOR

Criteria	Risk	Score
Clinical function		
No patient contact	1	
Device may make contact with patient non-critical	2	
Device is used for patient diagnosis or direct monitoring	3	**3**
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure fill result in inappropriate therapy, diagnosis, or loss of monitoring	3	
Device failure could result in severe injury or death of patient or user	4	**4**
Problem avoidance probability		
Maintenance would not impact reliability of the device	1	
Common device failure modes are unpredictable	2	
Common device failure is predictable and can be avoided by preventive maintenance	3	**3**
Specific regulatory requirements dictate preventive maintenance or testing	4	
Incident history		
No History (NO)	1	**1**
A significant history of incidents exists (YES)	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	
There are requirements for testing	2	**2**
TOTAL		**13**
Times per year tested	**2**	

After calculating the risk score of equipment builds its verification procedure that must contain: electrical safety (check ground wire resistance, chassis leakage and lead leakage), performance inspection (verify unit operates on battery, heart rate accuracy, respiratory rate accuracy, apnea alarm function, apnea alarm delay time, 60 bpm rejection of ECG artifact, alarm function). The heart rate and respiration rate should be within 5 % of the set rates. For a simulated heart rate of 120 bpm, the displayed rate should be between 114 bpm and 126 bpm. For a respiration rate of 60 breaths/min, the displayed respiration rate should be between 57 breaths/ min and 63 breaths/min.

Before returning to use, return any alarms that were adjusted to their original settings. Ensure the volume of the audible alarms is loud enough to be heard in normal

operating conditions. Plug in the power cord to ensure the battery remains charged.

A pulse oximeter non-invasively measures the oxygen saturation of a patient's blood. A pulse oximeter consists of a red and an infrared light source, photo detectors, and probe to transmit light through a translucent, pulsating arterial bed, typically a fingertip or earlobe. Oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (HbH) absorb red and infrared light differently. The percent saturation of hemoglobin in arterial blood can be calculated by measuring light absorption changes caused by arterial blood flow pulsations.

TABLE II SAMPLE RISK ASSESSMENT FOR PULS OXIMETER

Criteria	**Risk**	**Score**
Clinical function		
No patient contact	1	
Device may make contact with patient non-critical	2	
Device is used for patient diagnosis or direct monitoring	3	**3**
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure fill result in inappropriate therapy, diagnosis, or loss of monitoring	3	**3**
Device failure could result in severe injury or death of patient or user	4	
Problem avoidance probability		
Maintenance would not impact reliability of the device	1	
Common device failure modes are unpredictable	2	
Common device failure is predictable and can be avoided by preventive maintenance	3	**2**
Specific regulatory requirements dictate preventive maintenance or testing	4	
Incident history		
No History	1	**1**
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	**1**
There are requirements for testing	2	
TOTAL		**10**
Times per year tested	**1**	

Verification procedures for this equipment include: electrical safety (check ground wire resistance and chassis leakage), verify unit operates on battery, heart rate accuracy (for a simulated heart rate of 80 bpm, the displayed heart rate should be between 76 bpm and 84 bpm.), O_2 accuracy (for a simulated SpO_2 of 96 %, the displayed value should be between 93 % and 99 %), alarm function.

IV. CONCLUSION

The purpose of this paper is to provide some guidance lines in establishing and managing a medical equipment quality assurance program and to present some procedures for inspection, maintenance, evaluation and performance testing using sample risk assessment for two type of medical equipment. Implementing this system is just beginning, involving a small number of included equipment. In the future will go on a maintenance software development to play automatically each risk class for equipment from database.

Proper attention to appropriate planning and preparation for equipment supplies, maintenance, training and repairs can mean the difference between success and failure.

REFERENCES

[1] J. F. Dyro, *Clinical Engineering Handbook*, Elsevier Academic Press, 2004.

[2] World Health Organization, Introduction to medical equipment inventory management, Geneva, 2011.

[3] World Health Organization, Computerized Maintenance Management System Overview, Geneva, 2011.

[4] J. F. Dyro, Meditation on Ethics in Clinical Engineering Practice, *IEEE Engineering in Medicine and Biology*, 7(2):77-80, 1988.

[5] Y. David, E. G. Jahnke, Planning Hospital Medical Technology, *IEEE Engineering in Medicine and Biology*, 2004.

[6] Y. David, T. M. Judd, Healthcare Technology Management - Spacelab's Medical – Medical Biophysical Measurement Book Series, 1993.

[7] S. Woolhandler, D. U. Himmelstein, The deteriorating administrative efficiency of the U.S. health care system, New Eng. J. Med., vol. 324, pp. 1253-1258, 1991.

[8] H. D. Banta, *Assessing Medical Technology*, National Academy Press, Washington DC, 2005.

[9] World Health Organization, Priority medical devices, http://www.who.int/medical_devices/access/en/index.html