DEVELOPMENT OF A STANDARD OF PRACTICE FOR MEDICAL DEVICE PREVENTIVE MAINTENANCE IN B.C. HOSPITALS

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ABSTRACT

This paper describes the process to establish a recommended minimum standard of practice for medical device preventive maintenance (PM) and performance assurance (PA) inspections in B.C. hospitals. This is a project embarked by the Clinical Engineering Committee of B.C. (CECBC) in 2003/04 to assist biomedical engineering departments to assess their medical device PM/PA requirements. A simple ranking system based on risk and utilization of each type of medical device was developed as a first level criterion to determine PM/PA requirements. Based on this ranking system, each hospital region then reviewed their list of medical devices and assigned their own ranking scores and PM/PA intervals. The scores and intervals were reviewed by the CECBC to arrive at a consensus of the minimum mandatory and recommended PM/PA interval for each of the common device types. The result for this exercise is included in this paper. In addition, a list of essential PM/PA procedures for each device type is being developed as part of this project.

INTRODUCTION

Hospitals in B.C., like many others across Canada, have been faced with frozen budgets or even cutbacks for a number of years. In the same period, Biomedical Engineering Departments (BMED) continue to support more equipment without budget increases to match the actual service needs. The result is that managers have been forced to shift the workload associated with scheduled maintenance to demand repair work. The result is the increased risk of premature or catastrophic equipment failure. The biomedical engineering group is relied upon by hospital administrators to make professional decisions regarding which medical equipment requires preventive maintenance (PM) or performance assurance (PA) inspection as well as the frequency and extent of the inspection.

The author was asked in 2003 by the Clinical Engineering Committee of B.C. (CECBC) to lead a project to define a Standard of Practice in B.C. for medical device inspection to which all members present would adhere. The benefits of obtaining consensus from the members on a minimum Standard of Practice include:

1. CECBC members would all be consistent on the level of risk assumed, and
2. It provides this group with a strong argument to approach hospital administrators for additional resources, if required, to maintain an absolute minimum level of PM/PA inspection of medical devices.

This paper describes the results of this exercise and the methodology used to arrive at this accepted Standard of Practice.

METHODOLOGY

There are many publications in the past suggesting ways to define inclusion criteria and frequencies for medical device PM/PA inspections. The most commonly adopted inclusion criteria were originally proposed by Fenningkoh and Smith[1] using an equipment management (EM) number calculated from adding the numeric values assigned to three parameters: the function, the physical risk and the maintenance requirements of the equipment. A similar approach was described by Chan[2] which takes into account overdue inspections to prioritize PM/PA inspection frequency. The experience of implementing a system based on the EM rating and device service history was reported by Brewin, Leung & Easty[3]. Instead of inspecting all devices that meet the inclusion criterion and ignoring the rest, Rice[4] proposed a risk based sampling approach based on established statistical techniques to determine the sample size of equipment that requires inspection. Such an approach has the potential to reduce the PM/PA workload while providing sufficient level of confidence that the device population is safe and effective. Equipment ranking using these approaches often varies from one facility to another as the assigned scores are subjected to the

perception of the individual assigning the scores and to the different natures and needs of the facilities.

A simple assessment methodology for determining minimum PM/PA requirements was developed by one of the CECBC members, Tim Rode[5], during his tenure as Manager of Biomedical Engineering for the Simon Fraser Health Authority. This methodology was adopted by the CECBC for this project as a first level criterion to determine minimum PM/PA requirements. The methodology consists of a simple ranking system of each device type based on two scores: "Risk" and "Utility".

The "Utility" is an estimate of the actual value of completing an inspection, or "will the inspection actually do anything useful?" "Risk" is the risk to the patient, operator, or hospital if the device fails. The "Utility" and "Risk" must be considered together to make the final determination. If either the "Utility" or the "Risk" is negligible, in most cases there is no benefit in performing the inspection. For example, if an inspection will do nothing to prevent a device failure, it does not matter how much risk is associated with the device.

The following elements are to be reviewed to set the score for "Utility":

- Part Replacement useful
- Cleaning is useful
- Lubrication is useful
- Calibration is required
- Adjustment is required
- Functional Check required
- Electrical Safety required

The following elements are to be reviewed to set the score for "Risk":

- Immediate Injury is a possibility if failure occurs
- Misdiagnosis is possible
- No back-up device is available
- The repair cost may be higher
- Revenue may be lost with downtime

Each element of 'Risk" and "Utility" is assigned a value, N-None, L-Low, M-Med or H-High. The highest value from the list of elements is chosen to be the score. The scores of the "Risk" and "Utility" are combined to form the rating, for example, LM stands for Low Risk – Medium Utility.

Based on this ranking system, each hospital region (there are currently 6 health regions in B.C.) reviewed their list of medical devices and assigned ranking scores and PM/PA intervals. As expected, there was a range of opinion regarding the final ranking score on a large number of device types. Therefore, the list of medical devices with their range of rankings was reviewed by the CECBC members. Through discussion and debate, a consensus was reached on the PM/PA requirements of a list of medical device types.

The resulting rank was either PM/PA Mandatory or PM/PA Recommended with a minimum frequency of inspection defined. In general, if the rating is HH, HM or MH, inspection is considered mandatory. If the combined rating is LM, ML, MM, HL or LH, the CECBC group generally ranked PM/PA as recommended. The CEC members drew on their experience to contribute to the final recommendation. These device types are separated into two groups: one requiring mandatory PM/PA while the other stating the recommended minimum PM/PA interval.

RESULTS

The following table (Table 1) reflects the medical devices reviewed which were determined to require mandatory PM/PA inspections. This table of device types with an inspection frequency represents the minimum level of inspection required. BMEDs are expected to use this list as a guide to set the inspection levels of similar device types taking into account the different manufacturers and models and unique site requirements (i.e., the inspection frequency can be increased to a more frequent interval if deemed necessary).

EQUIPMENT DESCRIPTION	SCHEDULE (MONTH)	RANK
ANAESTHESIA MACHINE	6	MH-HH
BLOOD PUMP CONSOLE	12	MH-HH
BLOOD PUMP MODULE	12	MH-HH
BLOOD WARMER	12	LH-HH
COMPUTER, CENTRAL STATION	12	MM-MH
DEFIBRILLATOR	6	MH-HH
ELECTROCONVULSIVE THERAPY UNIT	12	LH-HH
ELECTROSURGERY UNIT	12	MM-MH
HEATER COOLER - CARDIAC	12	MH
HEMODIALYSIS MACHINE	12	HH
HYPERTHERMIA UNIT – AIR MEDIUM	12	MM-MH
HYPO/HYPERTHERMIA UNIT – WATER MEDIUM	12	MM-MH
INCUBATOR	12	MM-MH
INTRA AORTIC BALLOON PUMP	12	MH-HH
LASER	12	LH-MH
OPHTHALMIC SURGICAL DEVICE, PHACO	12	LH-MH
TOURNIQUET	12	MH
VENTILATOR	12	HH

Table 1. Devices Requiring Mandatory Inspection

There was some debate amongst the members regarding the appropriate final rank of each device type. However, consensus was reached that these items should require mandatory inspections irrespective of the determination of a final rank. The ranges of the rankings are also recorded in the table. Note that all of the above devices in Table 1 contain at least an MH in the range of rankings.

Table 2 tabulates the medical devices reviewed which were recommended to have PM/PA inspections, but not mandatory. BMEDs are expected to use this list as a guide to set the inspection levels of similar device types taking into account the different manufacturers and models and unique site requirements (i.e., the inspection frequency can be increased to a more frequent interval if deemed necessary).

EQUIPMENT DESCRIPTION	SCHEDULE (MONTH)	RANK
APNEA MONITOR	12	LM
BLADDER SCANNER	12	MM
COAGULATION TIMER	12	MM-MH
CONTINUOUS PASSIVE MOTION UNIT	12	LM
ECG MONITOR/ELECTROCARIOGRAPH	12	LL-LM
ELECTROENCEPHALOGRAPH	12	LM
END TIDAL CO2 MONITOR	12	LM-MM
ENDOSCOPE, FLEXIBLE	12	LL-HM
FETAL MONITOR	12	LM-LH
HUMIDIFIER - VENTILATOR	12	LL-LH
INFUSION PUMP	24	MM-ML
INSUFFLATOR	12	LM-LH
INTERFERENTIAL THERAPY UNIT	12	LL
NIBP MONITOR	18	LM-LL
OPERATING MICROSCOPE	12	ML-HH
OXYGEN CONCENTRATOR	12	HL-MM
PACEMAKER	12	LL-MM
PATIENT MONITOR	12	LM
PULMONARY FUNCTION ANALYZER	12	HM-MM
RADIANT WARMER	12	LM
SMOKE EVACUATOR	12	LL-LM
SCALES, PATIENT, RENAL	12	LH
SUCTION PUMP	12	MM-MH
THERMOMETER, TYMPANIC	12	MM-HM
TRACTION MACHINE	12	LL-MM
TREADMILL	12	MM
ULTRASOUND THERAPY MACHINE	12	MM
UNINTERRUPTABLE POWER SUPPLY	24	MM
VITAL SIGNS MONITOR	18	LM-MM

Table 2. Devices with Recommended PM/PA Inspection

Note that despite the low rankings, some of the devices (e.g., physiotherapy equipment) are included in the table as they are mandated to have an annual inspection according to the professional standards of the clinical areas. Uninterruptable power supplies and infusion pumps were recommended for a 24 month inspection to ensure batteries are checked and/or replaced at this interval.

NEXT STEPS

Each department is expected to implement or update their PM/PA systems to model the minimum requirements defined. A review will be completed in a year's time at a CECBC meeting to determine compliance with this Standard of Practice. Other device types not included in the above list will need to be brought forward for review by the CECBC at a later time. Experience with complying to this Standard of Practice will also be reviewed to determine if some device types need to be moved from the recommended list to the mandatory list or vice versa.

A second objective of the PM/PA project is to establish, by consensus, a set of minimum inspection criteria for each device type. A preliminary set of minimum performance checks and mandatory part replacements has been defined for the device types noted above that require a mandatory PM/PA inspection. This preliminary list has been forwarded to members of CECBC to review and update for discussion at the June 2004 CECBC meeting.

CONCLUSIONS AND RECOMMENDATIONS

A simple, practical methodology has been adopted by the CECBC to determine a minimum Standard of Practice for PM/PA inspections of medical devices in B.C. This Standard of Practice was accepted by consensus by the members and will be implemented across B.C. to ensure a consistent level of medical device service.

By adhering to this Standard of Practice, BMEDs are able to reduce the level of risk assumed when trying to balance their budget and still provide a justifiable minimum level of service. The Standard of Practice also helps managers to argue for resources, if required, to meet this minimum level of service.

It is recommended that this approach be reviewed by biomedical engineering groups across Canada with the hope to establish a Standard of Practice across the country.

REFERENCES

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