



DEFINING THE BC PROVINCIAL PREVENTIVE MAINTENANCE PROGRAM: WORLD HEALTH ORGANIZATION DEVICE TYPE CLASSIFICATION

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ABSTRACT

There is no slowing down the perennial increase of in-hospital medical devices, which presents an ongoing challenge to BME departments with limited resources available for service demands. A computerized maintenance management system (CMMS) is a prerequisite for the execution and sustainment of a successful preventive maintenance (PM) program. Implementing a provincial database revealed that medical device inspections, PM schedules, and job procedures varied widely between provincial facilities. This paper will focus on the successful implementation of a Provincial PM program in British Columbia and the historical context to arrive at this point. It will also describe the risk and frequency of device types that constitute the PM schedule using the World Health Organizations "Medical Equipment Maintenance Programme" methodology. Over the course of 20 months, the British Columbia Biomedical Engineering (BCBME) CMMS team classified over 1,000 medical device types. Overall, the BCMBE program reduced the total number of device types for both *Critical* and *Normal* devices, and increased the number of *Not Scheduled* devices and improved the efficiency and efficacy of our PM program. It is our hope that others will find value in our approach and its implementation at a provincial level.

KEYWORDS

Preventive Maintenance, Scheduled Maintenance, World Health Organization, Computerized Maintenance Management System, Risk, Frequency

INTRODUCTION

There is no slowing down the perennial increase of in-hospital medical devices; this is the new reality. It is often assumed that biomedical engineering (BME) departments will undertake responsibility for these new devices and ensure they remain safe, accurate and can be relied upon to perform as intended by the vendor [1]. Traditionally, BME departments accomplish this by performing scheduled and unscheduled maintenance throughout the device life cycle.

A recent Canadian study found that most, if not all, healthcare organizations include all their medical equipment in their maintenance program and simply follow manufacturers' recommendations for preventative maintenance [2]. Preventive maintenance is an activity within the control of BME departments that does not receive sufficient scrutiny. In fact, some believe that clinical and biomedical professionals are still holding on to process measures rather than analyzing the outcome of maintenance despite experience from other industries, which shows traditional PM is often unnecessary, if not counterproductive [3].

This is hardly a new issue, and the debate as to what PM is necessary or desirable has been ongoing since the first formal clinical engineering departments were formed during the 1960s and 1970s [4]. The fact of the matter is that an increasing number of devices and their service demands presents an ongoing challenge to BME departments with limited resources available to do the work. Time spent

doing any unnecessary PMs is a lost opportunity [4] for the hospital. Biomedical engineering departments have struggled to optimize medical device risk management using various medical equipment management programs for 25 years [1]. It has been suggested that PM programs need to use actual postmarket device failure rates and causes collected from their inventory instead of premarket estimates from equipment manufacturers to make their risk assessment pertinent to their reality [5].

A maintenance program is defined by inspections, preventive and corrective maintenance. At its core, preventive maintenance aims to extend the life of medical equipment and prevent failure through periodically scheduled inspections that perform a variety of tasks such as calibration, parts replacement, and cleaning [6]. Preventive maintenance is also known as planned maintenance, periodic maintenance and scheduled maintenance. For the purposes of this paper it will be referred to as preventive maintenance.

British Columbia's (BC) PM program comprises two aspects: job procedures and preventive maintenance schedules. This paper will not discuss job procedures, nor will it debate the utility of the tasks associated with a PM or the effectiveness of a PM program. This paper will focus on describing the risk and frequency of device types that constitute the PM schedule. It is our intent that others will find value in our methodology and its implementation at a provincial scale.

Background

Biomedical Engineering departments in Canadian hospitals are not governed by a national regulating organization that prescribes PM strategies, or indicates when, how or what must be done during maintenance activities. The purview of operation and maintenance of medical equipment is beyond Health Canada's jurisdiction. Hospital accreditation remains the ultimate "test" of in-house PM programs. Accreditation Canada aims to "improve quality, safety, and efficiency" so hospitals can offer the "best possible care and service" [7]. Biomedical Engineering departments have a role in preparing for hospital accreditation. The 2017

handbook of Required Organization Practices states, "An effective preventive maintenance program helps ensure medical devices, medical equipment and medical technology remain safe and functional. It also helps identify and address potential problems with medical devices, medical equipment, or medical technology that may result in injury to team members or clients" [8]. BME departments have three main criteria that must be met [8]:

1. That there is a preventive maintenance program in place for medical equipment
2. That preventive maintenance practice is documented
3. There is a process to evaluate the effectiveness of the preventive maintenance program

Essentially, the responsibility to devise and sustain a PM program resides with the BME department. Most often, assets that require PMs are included in the CMMS to comply with accreditation requirements that service has been completed in accordance with the defined schedule, and documented appropriately [9].

British Columbia History

The implementation of BC's Provincial PM program has been a work in progress over the last 12-15 years. Its success is the result of a confluence of factors, namely: the evolution of provincial committee dialogue, successive iterations of a provincial PM strategy, the implementation of a common provincial computerized maintenance management system, and the adoption of a globally recognized risk-based classification strategy.

The BC Clinical Engineering Committee (BCCEC) was established in the early 1980s, prior to the Internet, to facilitate provincial dialogue on common BME issues [10]. In 2004, concern was raised that the absence of a provincial preventive maintenance standard was an unacceptable standard of care that left facilities at a higher risk of liability [10].

An assessment found that medical device inspections, PM schedules, and job procedures, varied widely between BC facilities. A paper titled "Development of a Standard Practice for Medical Device Preventive Maintenance in B.C.

Hospitals” was presented at CMBEC 28 [10]. Using a simple scoring system assigned to “utility” and “risk”, their method split medical equipment by device types into two categories: *Mandatory* and *Recommended* inspections. Scoring was subjective and the authors admitted “...there was a large range of opinion ...on a large number of devices types” [10]. This exercise resulted in agreement on 18 *Mandatory* device types and 29 *Recommended* device types. In 2006, the BCCEC drafted “*Minimum Standard for Inspection and Preventive Maintenance of Medical Devices*” and since then British Columbia’s Biomedical Engineering (BCBME) departments have more or less followed this adopted practice.

In 2011, the BCCEC decided to remove some of the subjectivity plaguing the existing standard, by considering an established methodology to give integrity, weight, simplicity and validity to the scoring. The World Health Organizations (WHO) “Medical Equipment Maintenance Programme” [6] provided a suitable framework to move forward.

Arguably, a CMMS is a prerequisite for the execution and sustainment of a successful PM program. In the fourth quarter of 2014, BC successfully implemented a common CMMS for the province [11]. In our experience, this was undoubtedly a precursor to the successful development of the BCBME PM Program. This occurred in two time periods, Q2 2013 go-live for the 4 Vancouver health authorities (HA), and the onboarding of 3 additional HAs Q4 2014. A initial decision was made to adopt the existing PM schedules in the CMMS (original 4 Vancouver HAs) as a common starting point. Except for the 47 device types agreed to in 2006, there had been no formal provincial agreement on other device types. The fragmentation of PM schedules, and the need to standardize them in the CMMS prompted the provincial classification.

Governance

In 2014, the creation of a council of federated directors changed BCBME leadership, and medical equipment data became transparent with a common CMMS. Both factors increased the flow of information and idea

sharing, which ultimately led to the obsolescence of the BCCEC, which was officially disbanded in 2015.

The BCBME CMMS team formed to support the provincial CMMS operations. It is composed of four full-time and two part-time database administrators and is led by a manager. The team meets biweekly; its primary purpose is data integrity and the evolution and development of provincial business processes. The team created the role of a Provincial ‘PM Engineer’, to assume responsibility for oversight of the PM Program. This role strives to achieve consensus when possible, and is authorized to make a decision on behalf of the program. Both the CMMS lead and the PM Engineer report to the council of federation directors to resolve issues and clarify the program direction.

METHODOLOGY

BCBME WHO Tool

An excel spreadsheet was developed into a user tool integrating the WHO logic; it was later nicknamed the “WHO Tool” (see Figure 1). Its creation equips anyone in the BCBME program to assess or challenge the recommended risk classification and frequency of a device type in a standardized and repeatable fashion.

Table 1: BCBME WHO Review Timeline

Review	Timelines	
	Start-End Date	Months
Critical Device Types	Mar-Sept 2015	7 months
Normal Device Types	Nov 2015-Dec 2016	13 months
Final Review Signoff	Projected March 2017	

Project Phasing

The process of classification was split into two phases. Phase one, described in this paper, focuses on the classification of greater than 1,000 medical device types using the WHO framework. The enormity of this task cannot be fully described. The complete list of device types was taken from the CMMS, randomly divided amongst the team, and scored individually leveraging the expertise of the BCBME CMMS team. Over the course of 20 months (See Table 1) the team met to confirm

the risk and frequency of each medical device type.

Review priority was given to *Critical* device types first, followed by *Normal* device types. Four hour biweekly web-conference meetings were set to ensure sufficient time for discussion and information gathering (e.g. manufacturers' website and ECRI searches).

Phase two, the addition of a new device type to the CMMS, would be tested using the What Constitutes a Clinical Engineering Asset guideline to determine eligibility for the CMMS [9], and classified with the WHO Tool. This is out of scope for this paper.

Table 2 – WHO Evaluation Criteria, Function and Score

Evaluation Criteria	Score	Function Description	
Equipment Function	10	Therapeutic	Life support
	9		Surgical & intensive care
	8		Physical therapy & treatment
	7	Diagnostic	Surgical and intensive care physiological monitoring & ionizing radiation emitting devices (e.g. x-ray)
	6		Additional physiological monitoring, diagnostics & non-ionizing radiation medical imagine (e.g. ultrasound)
	5	Analytic	Analytical laboratory equipment
	4		Laboratory accessories
	3		Computers & related
	2	Miscellaneous	Miscellaneous patient related & others
Physical Risk Associated with Clinical Application	5	Death	
	4	Patient or operator injury	
	3	Misdiagnosis or inappropriate therapy	
	2	Equipment damage	
	1	No significant or identifiable risks	
Schedule Maintenance Requirement	5	Extensive	
	4	Above average	
	3	Average	
	2	Below average	
	1	Minimal (typ. replace rather than service)	
Equipment History	+2	Significant (more than one incident every 6 months)	
	+1	Moderate (one incident every 6-9 months)	
	0	Average (one incident every 9-18 months)	
	-1	Low (one incident every 18-30 months)	
	-2	Insignificant (less than one incident every 30 months)	

Risk Classification

The BCBME PM program uses three risk classifications (see Table 3). It should be noted that the term *Normal* was chosen to replace the term *Recommended* from the 2006 BCCEC guideline.

The WHO framework builds on the well-known Fennigkoh and Smith [12] model of equipment classification. The logic schematic for the WHO Tool is shown in Figure 2. The WHO Tool's four evaluation criteria (see Table 2) are scored and summed to generate an Equipment Maintenance number (EM#). If the *Schedule Maintenance EM#* (See Figure 2) is greater than 12, the device qualifies for PM. If the EM# is greater than 16, maintenance is considered *Critical*, scores of 13-15 are considered *Normal*, and scores less than or equal to 12 indicate the device does not require scheduled maintenance and is classified as *Not Scheduled*.

Table 3: Summary of the Risk Classification Scoring

Risk	Classification Score	
	Common Name	WHO EM# Score
Risk 1	Critical	≥16
Risk 2	Normal	13-15
Risk 3	Not Scheduled	≤12

Frequency

The frequency determination is largely based on the evaluation criteria of Scheduled Maintenance Requirement and Equipment History (See Table 2). *Critical* devices by default are scheduled for maintenance once per year, but can be twice per year if the Required Maintenance score is above average. *Normal* devices are scheduled for either annual or semi-annual maintenance as determined by their Required Maintenance and History scores.

RESULTS

Through the classification of over 1,000 device types, the BCMBE program experienced a net reduction in the total number of device types for both *Critical* and *Normal* devices, whereas the number of *Not Scheduled* devices increased. Table 4 provides a high level

summary of the before and after Risk classification. It should be noted that data cleaning occurred and some of the device types were retired from the CMMS, subsequently no scoring was done.

Table 4 – Summary Device Type Count Before and After Classification

	Risk Classification			
	<i>Critical</i>	<i>Normal</i>	<i>Not Scheduled</i>	<i>Total</i>
Before	216	519	300	1035
After	167	324	462	953
Retired	-	-	-	82

A detailed view of the device type classification changes by count is show in Table 5. This table shows the specific changes to each risk classification before and after classification.

Table 5 – Detailed Device Type Classification Changes by Count

	Risk Classification				<i>Total Before</i>
	<i>Critical</i>	<i>Normal</i>	<i>Not Scheduled</i>	<i>Retired</i>	
Critical to...	139	56	16	5	216
Normal to...	26	243	204	46	519
Not Scheduled to...	2	25	242	31	300
Total After	167	324	462	82	1035

A detailed view of the device type classification changes are shown in Table 6 as a percent. The "+" indicates an increase whereas a "-" indicates a decrease. For example, 39% of *Normal* device types were classified as *Not Schedule* following the provincial review, whereas 5% of *Normal* devices were classified as *Critical* following the review.

Table 6 – Detailed Device Type Classification Changes as a Percent

	Risk Classification			
	<i>Critical</i>	<i>Normal</i>	<i>Not Scheduled</i>	<i>Retired</i>
Critical to...	No Δ	-26%	-7%	-2%
Normal to...	+5%	No Δ	-39%	-9%
Not Scheduled to...	+1%	+8%	No Δ	-10%

DISCUSSION

CMMS Assignment

Each unique asset is defined with a manufacturer-model pairing (e.g. Covidien-840) and each manufacturer-model pairing is assigned a device category and device subcategory that defines the medical device in the database [13]. For the purposes of this paper, the terms device subcategory and device type are equivalent.

The PM schedule is defined by risk classification and frequency, and configured by device subcategory. By default, different manufacturer-model pairings with the same device subcategories will have the same risk classification and frequency. At a minimum, every *Critical* and *Normal* asset must have at least one maintenance schedule in the CMMS (risk class 3 is *Not Scheduled*). Multiple schedules per asset are permitted if the device requires different schedules for different tasks. Once a schedule is configured, staff can self-generate PMs individually by asset, or in batches as required. The BCBME program decided to use variable schedules (aka floating) rather than static schedules, for greater flexibility. Thus, the next due date is calculated using the last completed date and thereby the schedule is not fixed to a specific calendar date. Dashboard audits help supervisors manage due and overdue *Critical* PMs [11].

Implementation, Challenge Process and PM Exceptions

The classified device types were entered into the CMMS immediately, affecting the

workloads. Discrepancies between the reclassified and the existing risk score were treated as a challenge request. The challenger would score the device type using the BCBME WHO tool, which was then compared with the scoring by the PM engineer. This typically resulted in one of three pathways: 1) the reclassified risk score stands and the challenge is dismissed, 2) the risk score is rescinded to its original score, 3) a local (i.e. hospital based) exception is made.

Due to the limitation of the risk assignment by device type, exceptions can only be made to the frequency and not to the risk classification. Risk classification is defined for the entire device type, thus if a challenge requires a risk classification change, then a new device type must be created with the challenged score and the affected assets moved into the newly created device type.

A common reason for making exceptions in the CMMS are due to mandatory provincial regulations such as the College of Physician and Surgeons of BC's Diagnostic Accreditation Program (DAP), which includes both the Laboratory Medical Accreditation Standards and the Diagnostic Imaging Accreditation Standards [14 & 15]. This accreditation program often mandates the PM frequency for specific equipment, and exceptions are made in the CMMS to comply with DAP.

An example to illustrate the concept of exceptions is the use of the device type CENTRIFUGES. The reclassified scoring from the WHO Tool resulted in a Risk Score 3, or *Not Scheduled* with no PM schedule. One hospital challenged this scoring, due to the fact that there is a Laboratory Medicine Accreditation Standards that take precedence and overrule the WHO Tool scoring. The PM Engineer made a decision to change the device type risk score to 2, having a frequency of 365 days.

Large sample sizes for the WHO Tool

A significant advantage to using a provincial CMMS database is the opportunity to amass large sample sizes by either manufacturer-model pairings or device types to feedback into the Scheduled Maintenance Requirement and the Equipment History of the WHO Tool. As

discussed herein, these evaluation criteria predominantly define the Frequency.

Similarly, BC's HAs use a common safety event reporting system. The Patient Safety Learning System enables the aggregation of hazard and safety event information [16]. This information can be incorporated into the WHO Tool Physical Risk Associated with Clinical Application to obtain greater precision than an educated guess.

Accreditation Canada

The BCBME program has been through several iterations of Accreditation Canada assessments. Anecdotal feedback from those involved indicate that accreditors were very satisfied with the WHO based risk scoring and the ability of the provincial CMMS to obtain PM schedules, work history, asset records, and reports such as PM compliance for any selected asset.

Future Initiatives

It is known that there are inherent flaws defining the risk classification by the WHO framework. The BCBME program will continue to scan the literature and devise a better system to monitor postmarket failures, as proposed by Wang [5] to further refine their PM Schedule.

CONCLUSION

The BCBME successfully implemented a provincial PM program using the WHO Medical Equipment Maintenance Programme framework. To the authors' knowledge, this achievement marks the first time that a provincial PM strategy has been developed and implemented at this scale, in Canada.

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Cat or SubCat Code:		BMET completes Green Sections	BME Asset Tag Req'd: NO
UMDNS Description:			Scheduled Maintenance Req'd: ↓
Evaluation Criteria: <i>Risk evaluation method based on World Health Organization guidelines.</i>			
Equipment Function Therapeutic, Diagnostic, Analytical and Miscellaneous equipment categories are considered. <i>Note: This score is NOT based on equipment location (e.g. ICU) rather you are being asked whether the equipment's FUNCTION is Therapeutic, Diagnostic or Analytical regardless of it's physical location. For example a thermometer has a diagnostic score of 6, even though it may be located in a critical care area, while a defibrillator has a score of 10 even if located in a general ward.</i>			Scheduled Maintenance Required: NO
Physical Risk Associated with Clinical Application Lists the potential patient or equipment risk during use.			Priority: NONE
Scheduled Maintenance Requirement Describes the level and frequency of "scheduled maintenance" required as noted by the Manufacturer or through experience.			Frequency: NONE
Equipment History Any information available regarding service history that should be considered <i>(repair frequency, patient incidents, device alerts)</i>			<i>Note: The above calculated result determines whether an equipment category/sub-category is to be included as Scheduled Maintenance in the BC BME CMMS.</i> Unscheduled Maintenance occurs after equipment repairs &/or as determined by local BME supervisors.
Request a review: <i>If BMET disagrees with the calculated Scheduled Maintenance Result; request a review by completing the Review Tab (below) and put an R in this box-----></i>			
Brief Comment: (optional):			After completing this form • Save as: <UMDNS Code>.xls on your computer. • Email completed forms to: DBMTeam@bcbiomed.org
Health Authority Mandated (This field is set by the reviewing BME Risk Mgr/Engineer) <i>Purpose: To override the scored Priority & Frequency. (typically used to increase the Priority &/or Frequency due to a Corporate Directive or unique local need where a BMET Requested a Review.</i>			

Figure 1: Screen shot of BCBME WHO Tool User Interface

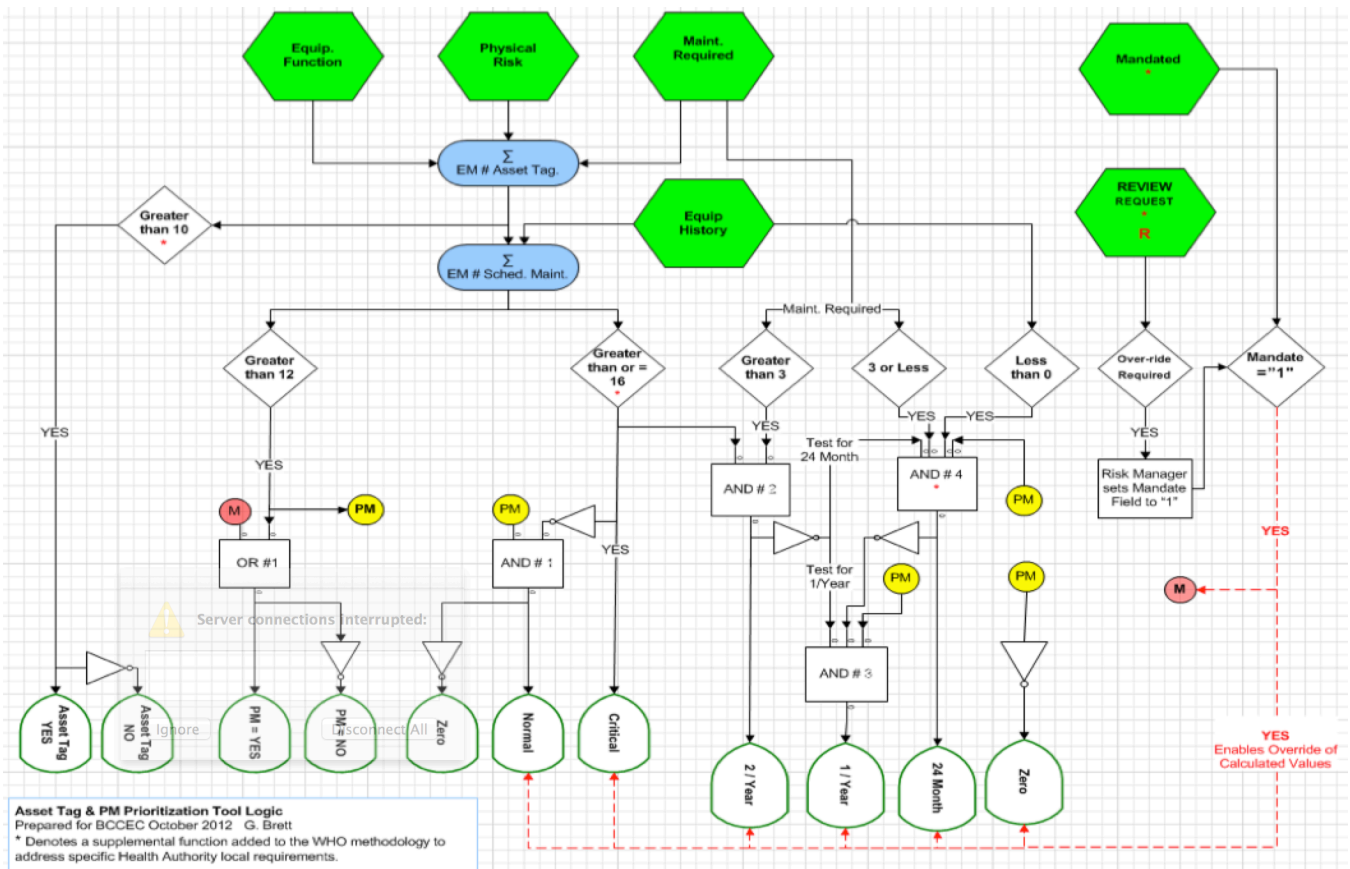


Figure 2: Screen shot of BCBME WHO Tool Logic Schematic

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