Safety Verification Procedure in the Implementation of Alternative Equipment Maintenance at The Ottawa Hospital

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Abstract— **This paper explores the implementation of AEM at TOH, including risk analysis through safety verifications, focusing on optimizing resource use and maintaining patient safety. This methodology includes integrating World Health Organization (WHO) guidelines, establishing a dedicated AEM committee, and a safety verification process using CMMS work order data and failure codes. The paper includes a case study on TOH Civic Campus floor scales to illustrate the AEM safety verification process further.**

Keywords— **Alternative Equipment Management (AEM), Preventive Maintenance (PM), safety verification, risk-based prioritization, failure codes, Computerized Maintenance Management System (CMMS).**

I. Introduction

In response to the dynamic landscape of healthcare technology, TOH has defined the AEM project, aiming to strategically manage Preventive Maintenance (PM) practices, which 40 biomedical engineering Technologists are currently performing on over 22,000 medical devices. This paper explains TOH's approach to deviating from manufacturer PM recommendations, evaluating the shift from Preventive Maintenance recommended by the Original Equipment Manufacturer (PMOEM) to Preventive Maintenance recommended by the Alternative Equipment Management (PMAEM) (terms taken from [2]). It also explores critical questions surrounding the effectiveness of PMOEM, considering the unpredictable nature of some equipment failures.

The AEM project aims to identify cases where deviation from PMOEM recommended activities (what technologists should do during PM) or frequencies (when they should do it) can be justified. AEM is also relevant in scenarios where the manufacturer changes the PM activity or frequency, prompting the hospital management team to assess the necessity of the changes or in the case of privately owned medical devices (e.g., research equipment).

II. Background

The previous approach to Preventive Maintenance (PM) at TOH was strictly planned based on PMOEM. When a new device arrived at the hospital, the PMOEM recommendation was added to the PM schedule for that asset type in the Computerized Maintenance Management System (CMMS). Subsequently, any new similar device would adhere to the same PM schedule. Throughout the lifecycle of that device, there were no changes to PM frequency or tasks, despite the device's aging, potential changes in use cases, or variations in fleet size that might result in more or less backup equipment.

As each manufacturer recommends a minimum frequency for inspection, calibration, or maintenance, usually around every 12 months, the number of hours of maintenance due per year grows with every new piece of equipment entering the hospital. Generally, these 12-month recommendations do not take into consideration the actual usage of that device, as not many preventive maintenance tasks are based on a count of hours. With three campuses—the Civic, the General, and the Riverside—as well as multiple offsite smaller locations and over 1,800 beds at TOH, it is challenging to track equipment usage. The fleets of standard equipment are very large, and every change has a significant impact on resource allocation (for example, 2000 infusion pumps, 1800 vital signs monitors, 1300 thermometers).

Over the years, this PMOEM strategy showed a decline in the PM completion rate as the PM workload kept increasing with time and new equipment entering TOH. Technologists had a hard time prioritizing which PM tasks to complete, given the overwhelming load, difficult access to equipment, and the requirement to inspect every device almost every year. Even if a technologist suggested a change in PM frequency or activity, there was no procedure in place to document that change, despite having valid reasons for it. Instead of updating the maintenance plan, technologists would decide independently not to complete these PM tasks, resulting in a low completion rate, and the PM work orders would be generated year after year automatically in CMMS.

At TOH, we decided to follow the AEM process proposed by the AAMI AEM guide [2] to allow for a specific analysis of each medical device category requirement. We identified the following advantages in this approach:

- Avoiding the need to change the entire PM program frequency all at once is a significant effort and has a substantial impact on such a large institution.
- The ability to control what is being modified and how it is being adjusted based on user experience or technologist feedback.
- The ability to introduce a follow-up review to confirm that the changes adopted are producing the desired results.

III. Methodology

The AEM procedure at TOH is a detailed process per the AAMI AEM Guide [2], ensuring the safety and reliability of the devices are kept intact. This procedure encompasses the following seven key steps:

1. Formation of the AEM Committee:

An AEM-dedicated committee performs various steps throughout the AEM project. The committee comprises team members, including one manager, at least two experienced technologists for the specific device, and a Computerized Maintenance Management System (CMMS) coordinator. This multidisciplinary team thoroughly evaluates AEM procedures on a case-by-case basis.

2. AEM Eligibility Assessment:

The committee thoroughly investigates predefined criteria in this initial step, ensuring that only eligible medical devices undergo the AEM methodology. There are specific cases where AEM on certain categories of medical devices is not allowed, and mandatory PMOEM is required [2].
Ineligible devices are life-support devices, imaging and radiologic devices, medical lasers, devices subject to a law (e.g., accreditation) that mandates adherence with manufacturer-recommended maintenance activities or frequencies, or devices new to TOH with less than three years of history.

3. Calculating the Equipment Management Number:

This AEM project integrates the WHO's guidelines for PM prioritization [1], offering a risk-based management method and a tiered process for efficient use of the resources. The prioritization approach provides:

- Different levels of PM priorities.
- Inspecting equipment based on workload and available staff.
- Enabling the hospitals to ensure staff readiness before expanding the equipment inspection scope.

The WHO's introduced scoring system includes criteria of four scores described below:

- ***Function Score:*** Assesses the essential function and role of the medical device.
- ***Application Score:*** Evaluates the physical risk associated with clinical application in case of device failure.
- ***Maintenance Requirements Score:*** Examines the maintenance needs and complexity of medical device maintenance.
- ***History Score:*** Considers the device's historical performance and reliability.

Table 1 provides the details of WHO scoring criteria.

Table 1 WHO's Scoring Criteria

Factor	Category	Description	Score
Equipment Function	Therapeutic	Life support	10
		Surgical and intensive	9
		Physical therapy and treatment	8
	Diagnostic	Surgical and intensive care monitoring	7
		Additional physiological monitoring and diagnostic	6
	Analytical	Analytical	5
		Laboratory accessories	4
		Computers and related	3
	Miscellaneous	Patient-related and other	2
Application (Physical risk associated with clinical application)	Potential patient death		5
	Potential patient or operator		4
	Inappropriate therapy		3
	Equipment damage		2
	No significant identified risk		1
Maintenance Requirements	Extensive: routine calibration and part replacement required		5
	Above average		4
	Average: performance verification and safety testing		3
	Below-average		2
	Minimal: visual inspection		1
Equipment Incident History	Significant: more than one every 6 months		+2
	Moderate: one every 6–9 months		+1
	Average: one every 9–18		0
	Minimal: one every 18–30		-1
	Insignificant: less than one in the past 30 months		-2

The summation of the four mentioned scores for each device category calculates the Equipment Management Number (EM#) [1] defined in equation 1:

EM # = Function # + Application # + Maintenance # + History # (1)

The AEM committee utilizes an automated AEM form (designed as a part of this project) to calculate the Equipment Management Number (EM#). The form also generates WHO's recommended PM frequency based on the criteria from Table 2. If the EM# is less than 12, no preventive maintenance is needed, and corrective maintenance suffices. For EM# greater than 12, WHO outlines specific frequency ranges for maintenance activities, ranging from every four months to annually. These evaluations are crucial inputs for implementing the AEM approach in TOH.

Table 2 WHO's Recommendation for Frequency if EM#>=12

Criteria	Range	PM frequency
#EM	19-20	Every four months
#EM	15 -18	At least every six months
Maintenance Requirement	4-5	Six months
Maintenance Requirement	3,2,1	Annually

4. Safety Verification:
The safety verification assesses the likelihood of preventable or predictable failures for ensuring the safety of AEM through an approach thoroughly described in section III.

5. *Decision Making:*
The AEM committee makes decisions by considering the manufacturer and WHO recommendations on PM and the results of the safety verification process. Modifications to PM activities/frequencies are decided based on these comparisons. Once the committee calculates the EM# and the WHO's recommended PM frequency, the under-study medical device category will undergo the AEM-decided PM frequency/activity.

6. Documentation:
Comprehensive documentation is integral to the AEM process. The AEM committee documents the process step by step in an AEM form. The development of this automated form and the associated Standard Operating Procedure (SOP) was a part of this project. It includes different sections to keep records of data analysis and captures the rationale behind decisions during the AEM process.

7. Applying AEM-Decided PM Activities/Frequencies in CMMS:
The CMMS coordinator modifies CMMS with the committee's conclusions for future PMs on the device.

8. Scheduled Follow-up Reviews:
The AEM program emphasizes scheduled follow-up reviews to validate ongoing safety. After enough successive years of PMAEM, there is a need to re-check the measures to ensure safety is maintained.

IV. Safety Verification Process

Ensuring safety is a paramount consideration in AEM. The concept of risk, encompassing the probability of failure occurrence, forms the basis for safety verification.

A. Metrics for Measuring Equipment Safety

Various approaches, including failure rate (device failures per year), meantime between failures, downtime (hours per device per year relative to required uptime), and failure codes, can be integrated into the AEM program for safety verification. Failure codes introduced by Wang et al. [3] provide a good categorization of the failures. In this project, it was decided that the failure codes defined by the AAMI [4] would serve as the metric for measuring safety, as they represent the latest combined failure codes that best address the needs of each institution.

In 2017, AAMI introduced a series of standard codes [4], as listed in Table 3, which can be defined in the hospital CMMS and should be assigned by front-line technologists to each work order.

Table 3 List of TOH adopted list of Failure Codes [4]

Failure Acronym	Failure Code
FACC*	Accessory or Disposable
CAL*	Calibration Failure
BA*	Component Failure (Battery)
COM*	Component Failure (Not Battery)
FM*	Failure Caused by Maintenance (e.g., over-voltage)
FAB	Failure Caused by Abuse or Negligence
NE	Network or Connectivity Failure
SO	Software Failure
UE	Use Error (Use Failure)
UT	Failure Caused by Utility System
ENV	Failure Cause by Environmental Factors
nID	Failure Could Not be Identified
nRE	Failure Not Diagnosed—Device Not Repaired
nFA	No Failure Associated with the WO

*= PM-related failure

According to AAMI [4], only the five failure categories are considered preventable or predictable through improved PM practices, including failures in accessory or disposable parts (FACC), calibration failure (CAL), component failure (COM), battery failure (BA), and failure caused by maintenance (FM).

AAMI suggests that these five specific failure types indicate cases in which better PM could avoid or anticipate the failure, implying that other failure categories are not PM-preventable or predictable. This idea helps to limit our safety investigations to the five categories of "PM-related failures".

B. The Index for Measuring Safety

The risk assessment seeks to determine the likelihood of occurrence for the five categories of failure codes (FACC, CAL, BA, COM, FM), which could have been predicted or prevented through PM.

The index used in this project for measuring safety is the Annual PM-Related Failure Probability (APMFP). The AEM form designed as a part of this project automatically computes this index over the five years of data using equation 2:

$$\text{APMFP} = \frac{\text{FACC} + \text{CAL} + \text{BA} + \text{COM} + \text{FM}}{\text{Total number of devices in that year}} \qquad (2)$$

C. Safety Calculations:

The steps involved in the Safety Verification process are outlined below:

1. A qualified staff extracts the "*PM-related*" failure codes associated with the intended asset category from the TOH CMMS for Corrective Maintenance (CM) and Preventive Maintenance (PM) work orders spanning the last five years of data. The goal is to investigate:
   - How many actual incidents have happened to this category of devices according to CM data?
   - How many failures were discovered by the technologists during the PMs according to PM data?

In cases where less than five years of data are available, the AEM committee will assess the sufficiency of data, considering the quantity of devices. They will also evaluate whether a comparable device history can be employed for analysis. Work orders lacking assigned failure codes will be manually categorized by qualified staff.

2. The APMFP index and the related graphs are calculated automatically by the AEM form for both PM and CM data.

3. The committee analyzes the graphs of APMFP over an accepted period to assess the annual PM-related failure probabilities. An increasing trend may be a sign of a rise in preventable or predictable failures, indicating a need for "improved" PM practices. In such instances, modifying the PM frequency would involve an "increase." Conversely, a decreasing APMFP trend may imply that changing the PM frequency would demand a "decrease."

4. Scheduled Follow-up Reviews: Safety verification will be repeated based on the frequencies assigned by the committee. By repeating the safety verification, any increase in Annual PM-related failure Probability (APMFP) after the effective date of the changes prompts a reassessment of PM practices. The success of the AEM program is reflected in a decreasing trend after each follow-up, signifying the sustained enhancement of equipment safety after the initiation of the AEM process. Consistent and thorough follow-ups are vital to the overarching goal of upholding and advancing equipment safety standards. The TOH AEM committee will repeat the safety verification process in one year, two years, and five years after initiating the AEM.

V. AEM CASE IN TOH

After considering suggestions from technologists and evaluating historical data, the TOH biomedical engineering department decided to start AEM on the potential case of patient floor scales at the Civic campus (one of the three campuses of TOH). The Civic campus has 51 active floor scales (ECRI Category 13461).

A. WHO's Recommendation - Floor Scales

By the decision of the AEM committee, the floor scale category receives an EM# of 7, and WHO recommends "no PM" on them.

B. Detection of PM-related Failure Codes in CM and PM work orders

For the safety verification, qualified staff detected the PM-related failure codes in 38 CM work orders and 165 PM work orders from the past years of available data extracted from CMMS.

C. Calculation of PM-Related Failure Probabilities in the Civic Campus Floor Scales "CM Data"

A detailed analysis of PM-related failures in CM work orders of the Civic campus floor scales is presented in Table 4, outlining the AMPFP (equation 2) over the years. A positive approach towards AEM in this device category can already be noted here, as there were only 38 incidents reported in four years of available data of these scales.
Figure 1 illustrates the failure probability graph showing a good decreasing trend after the second year of data.

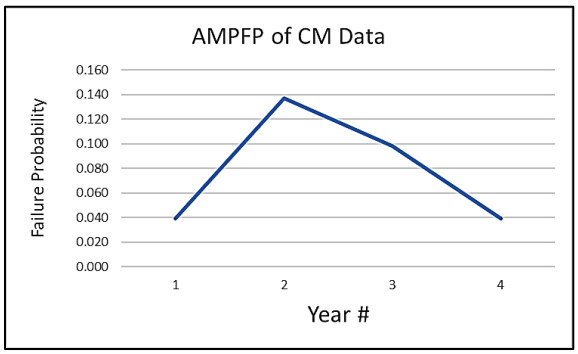

Fig. 1 PM-Related Probability Graph of CM data

D. Calculation of PM-Related Failure Probabilities in the Civic Campus Floor Scales "PM Data"

In 165 PM work orders, PM-related failures were found in 33 cases, with 16 related to battery replacements and 17 to other failures. The PM-related probability calculations and the associated graph are shown in Table 5 and Figure 2 (upper graph), respectively.

Table 4 PM-related failure probabilities in "CM work orders" of the Civic campus floor scales

CM DATA Year#		# Devices	Counts of Failure Codes for Each Date Range/Year					Annual PM-Related Failure Probability (APMFP)
			FACC	CAL	BA	COM	FM	
Year 1	2019	51	0	2	0	0	0	0.039
Year 2	2020	51	0	3	3	1	0	0.137
Year 3	2021	51	0	2	1	2	0	0.098
Year 4	2022	51	0	0	1	1	0	0.039

Table 5 PM-related failure probabilities in "PM work orders" of the Civic campus floor scales

PM DATA Year#		# Devices	Counts of Failure Codes for Each Date Range/Year					Annual PM-Related Failure Probability (APMFP)	AMPFP without the battery failure
			FACC	CAL	BA	COM	FM		
Year 1	2020	51	0	3	3	0	0	0.118	0.059
Year 2	2021	51	0	3	4	3	0	0.196	0.118
Year 3	2022	51	0	1	7	3	0	0.216	0.078
Year 4	2023	51	0	3	2	1	0	0.118	0.078

E. Updating the PM Failure Probability Graph by Excluding the Failures Related to the Batteries

In the case of Civic Campus floor scales, excluding battery failures would lead to a more pronounced decrease in AMPFP trend after the third year of analysis. The following reasons justify the exclusion of battery failures in the AEM case of floor scales:

- There were few instances of battery replacement in the PM work orders (16 cases in 4 years).
- Floor scale batteries are user accessible.
- Some floor scales are pluggable into AC power.
- Swapping the battery with a spare unit would not impact patient care or significantly disrupt clinical workflow.

The result of regenerating the AMPFP graph of PM data while excluding battery failures is shown in Figure 2 (lower graph), indicating that the decrease becomes more evident by excluding battery failures from the probability graph.

F. Decision of AEM on Floor Scales

Following the described AEM steps, the AEM Committee will have the following inputs to decide about the implementation of AEM on TOH Civic campus floor scales:

1- WHO recommendation for the floor scale is "no PM, repair only" due to the EM#.

2- Floor scales are "AEM eligible" according to AEM eligibility criteria.

3- The safety verification calculations on PM-related failures show a decreasing trend in both CM and PM data.

Based on the presented data, the committee might decide that AEM on floor scales at the TOH Civic campus may be feasible, and this category might be removed from the PM schedule.

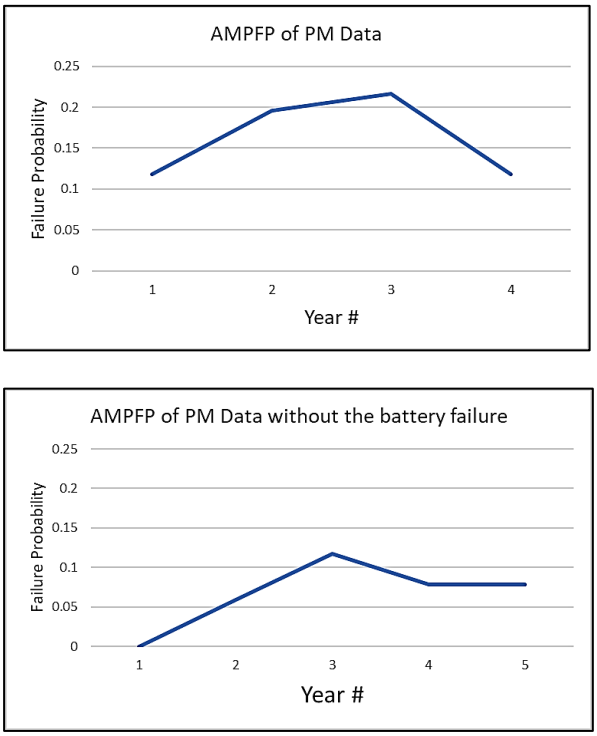

Fig. 2: Failure probability graphs in Floor scales "PM" data: The upper graph shows AMPFP considering battery failures, while the lower graph represents the same calculations without the battery failures.

VI. Conclusion

The primary objective of AEM is to uphold and, where possible, enhance patient safety. It seeks to achieve a harmonious balance, where patient safety is prioritized, and resources are utilized effectively to ensure the reliability and functionality of medical devices.

The ability to adjust PM schedules and tasks through AEM will enable the team at TOH to prioritize the necessary PM tasks better, take control of the PM program, and improve the PM completion rate. Such an approach will significantly impact biomedical technologists' well-being and job satisfaction, involving them in the process and providing a sense of control over the PM program, ensuring they are working on "the right thing". Furthermore, the end users will experience less disruption in their workflow with the reduction of non-critical PM tasks. The AEM strategy will empower the Biomedical Engineering management team to explain better decisions on maintenance schedules and the resources needed to achieve completion goals. Most importantly, for the equipment, it will ensure that more critical devices are prioritized over less critical ones.

TOH will follow the safety verifications described above to actively contribute to the promotion and enhancement of safety standards within the hospital. The follow-up reviews will allow us to confirm that the decisions made in the AEM project are moving the PM quality in the right direction.

VII. Future work

The writers believe that every hospital biomedical engineering team should undergo a subsequent phase in completing the AEM project. The AAMI AEM guide is a helpful tool for starting the AEM process. However, there is potential for refinement in the WHO's scoring criteria by adding factors such as the availability of backups and the age of the medical devices, tailoring the scoring system to the hospital's specific needs. Recognizing that the availability of backups ensures minimal downtime for medical devices and reduces associated risks, this step contributes to the overall effectiveness of the AEM program.

The time investment required to conduct a single AEM project on one asset category is minimal compared to the benefits in terms of time, cost, the quality of PM, and resources that could be gained over the lifecycle of that device category fleet. That is why the AEM project has every reason to be continued and expanded to multiple devices throughout the hospital. The AAMI failure codes should be integrated directly into the CMMS work order closure process to avoid manual review of large quantities of work orders.

If multiple organizations start AEM analysis on their medical devices, using similar failure codes and similar methodology, we could think about sharing data to have more accurate results and faster analysis to an extent where AEM results could be shared based on asset type or just by make model of the device.

VIII. Acknowledgment

The writers would like to thank Andrew Ibey and BCLMBE [5] for the guidance provided in the WHO section of the project.

Maryam Sangargir would like to extend thanks to Joël Brose, the project supervisor, for exceptional mentorship and guidance through this project, Hung Tan for the valuable internship opportunity at TOH, Stephanie Liddle for sharing the experience of AEM in the University of Ottawa Heart Institute, Marie-Ange Janvier for unwavering support in organizing OCIBME internship opportunities, and the TOH Biomed Team for their collaboration during this project.

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