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IMPLEMENTATION OF EVIDENCE-BASED MAINTENANCE AT THE UNIVERSITY OF OTTAWA HEART INSTITUTE TO OPTIMIZE BIOMEDICAL ENGINEERING DEPARTMENT MAINTENANCE STRATEGIES

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INTRODUCTION

The healthcare industry is rapidly growing. There is a corresponding increase in the variety and number of medical devices deployed into hospitals and other healthcare institutions. The number of devices present in an institution can range anywhere from 1000 for smaller community hospitals to over 10 000 for larger teaching hospitals [1]. Medical devices require equipment maintenance to ensure they continue to perform their intended function and remain safe to the user and patient. There are two main categories of equipment maintenance: 1) *scheduled maintenance*, and 2) *unscheduled maintenance. Unscheduled maintenance activities* are not planned or scheduled, and include corrective maintenance (CM), which involves restoring the equipment back to operational specifications, and replacement, which involves replacing equipment if it cannot be repaired or it is not economical to repair [2]. *Scheduled maintenance activities* are planned and scheduled, and include preventative maintenance (PM), which involves detecting existing or potential failures, monitoring parameters that are used to predict failures, or performing some act that will prevent future failures [2]. Each medical device may require a methodical approach composed of multiple scheduled maintenance activities, and this collection of activities is referred to as a *maintenance strategy* [2].

Unfortunately, with the growing variety and number of medical devices becoming present in a hospital, more time is needed to keep up with all the maintenance strategies (recommended and required by the equipment manufacturers). In conjunction with restrictive and potentially decreasing financial resources, it is becoming increasingly difficult for the biomedical engineering (BME) and clinical engineering (CE) departments to keep up with the demand. Currently there have been few studies performed to analyze and monitor the effectiveness of the implemented maintenance strategies for medical devices [2] [3] [4]; however, experience from other industries has shown that PM's are often counterproductive [2] [5]. This is because recommendations from manufacturers often err on the side of caution due to liability concerns and revenue desires [5]. Determining alternative maintenance strategies that are more efficient, is desirable to alleviate this burden. Such strategies would require data to indicate equivalent safe and effective outcomes as those recommended by manufacturers. This data-based methodology is called *evidence-based maintenance (EBM)* and was developed by Fedel and Wang [6].

EBM is defined as "a continual improvement process that analyzes the effectiveness of maintenance resources deployed in comparison to outcomes achieved previously or elsewhere, and makes necessary adjustments to maintenance planning and implementation" [6]. The objective of this research was to measure and monitor the effectiveness of the BME maintenance strategies at the University of Ottawa Heart Institute (UOHI) by implementing the *EBM* technique that was presented in the paper "Evidence-Based Maintenance" [2]. It was also to identify any issues and barriers for EBM implementation in order to provide in site and assistance to other hospitals wanting to monitor the effectiveness of their maintenance strategies.

Table 1: List of failure codes adapted from [2].

Source	Activity	Code	Code Definition
Equipment	***Corrective Maintenance (CM)***	UPF	*Unpreventable failure*, evident to user, typically caused by normal wear and tear but is unpredictable
		PPF	*Preventable and Predictable failure*, evident to user, typically caused wear and tear that can be predicted or detected
		USE	*Failures induced by use*, e.g., abuse, abnormal wear and tear, accident, or environment issues
		SIF	*Service-induced failure*, i.e., failure induced by corrective or scheduled maintenance that was not properly completed or a part that was replaced and had premature failure ("infant mortality")
	Scheduled Maintenance (SM)	PF	*Potential failure*, i.e., failure is either about to occur or in the process of occurring but has not yet caused equipment to stop working or problems to patients or users
		EF	*Evident failure*, i.e., a problem that can be detected but was not reported by the user without running any special tests or using specialized test/measurement equipment
		HF	*Hidden failure*, i.e., a problem that could not be detected by the user unless running a special test or using specialized test/measurement equipment
	CM and SM	NPF	*No problem found*, including alleged failures that could not be duplicated ("cannot duplicate" [CND])
Accessories	***CM or SM***	BATT	*Battery failure*, i.e., battery(ies) failed before the scheduled replacement time
		ACC	*Other accessory failures*, excluding batteries, evident to user typically caused by normal wear and tear

IMPLEMENTING EVIDENCE-BASED MAINTENANCE

In order to implement the EBM technique a small set of failure codes was derived by Wang *et al.* and are found in Table 1 [2]. These failure codes are assigned by the BME professionals when completing a PM or CM work order for all medical devices [2]. Currently at the UOHI there are 9500 medical devices that are managed by the BME department. BME staff at the UOHI were trained to use these failure codes through presentations, and meetings. They were also provided two flowcharts that were created as supplementary material (see Fig. 1 and 2 in [2]).

Previously, the UOHI had been utilizing a different set of failure codes seen in Table 2. It was decided to combine data from the old work orders with the new work orders that have the new failure codes to enlarge the data set. This merger required mapping the old failure codes to the new failure codes, however this was not a direct one to one mapping. Therefore, to categorize the old work orders, those that were not coded with a No Problem Found (NPF) were evaluated individually and assigned a new failure code based on the comments and description of the problem that arose with the device.

Table 2: UOHI old failure codes.

Failure Codes	
Battery Failure	No Fault Found or (NPF)
Calibration Loss	Operator Error
Component Failure	Patient Related
Cord/Cable Failure	PC Board
Damage – Accident	Power Failure
Damage – Attrition	Reboot/Reinitialized
Mechanical	Software/Hardware
Network Related	

Once a collection of approximately two years of work orders was obtained, estimates of the average *Annual Failure Probability (AFP)* for each of the failure codes associated with PM's was calculated on the medical devices that had sufficient work orders collected within that time span for the results to be considered statistically significant. These averages can be "interpreted as estimates of the probability of finding the respective failure codes for each PM" [2]. Subsequently, estimates for the CM failure codes per device was calculated by multiplying each AFP estimate by the *Equipment Type Failure Rate (ETFR). ETFR* is "the ratio of CM work orders to the average total number of units within the equipment type" [2]. The ETFR was considered to ensure that the units that had no failures are accounted for, as CM work orders only arise when a unit has failed [2]. After calculating AFP values for all failure codes both the AFP values for CM's and PM's were combined to obtain the *AFP distribution (AFPD)*. The *AFPD* is a signature of a particular type of equipment's failure pattern in a particular hospital [2].

Table 3: Grouping of failure codes according to potential actions by BME adapted from [7].

Failure code	BME Responsibility	Action Group
NPF	None	
UPF	Advise purchasing	Future
ACC	Guide users and purchasing	Indirect
BATT	Guide users and purchasing	Indirect
USE	Guide users and facilities	Indirect
EF	Guide users	Indirect
SIF	Educate staff and advise original equipment manufacturers	Direct
HF	Review SM program	Direct
PF	Review SM program	Direct
PPF	Review SM program	Direct

Failure Code Grouping and BME Actions

After obtaining the AFPD the AFP for each failure code was combined into three groups based on potential actions that can be taken by BME (Table 3): 1) direct, 2) indirect, and 3) future [7].

Any medical device with a high direct AFP value should either: 1) not alter its current maintenance strategy, or 2) possibly strengthen it. Devices with low direct AFPs should have their maintenance strategies downgraded [7]. Not only are the direct AFP results valuable but the indirect and future AFP results can be used to determine if the equipment being purchased is reliable, or if better parts or more adequate training needs to be provided based on the AFP values obtained for each medical device [7]. Note that if changes are made to the maintenance strategy it is important to carefully monitor with EBM to prove that failure types and rates have not been significantly affected [7], or if they have been significantly affected, only in a positive manner.

RESULTS

Currently, the UOHI BME department has completed one full analysis on External Cardiac Pacemakers and the AFPD can be seen in Figure 1. This work is a preliminary phase undertaken by a subsequent comprehensive analysis of the life support equipment.

The AFP for external cardiac pacemakers at the UOHI for future actions that BME can take is 2.15%, for indirect actions is 4.57% and for direct actions is 0.00%.

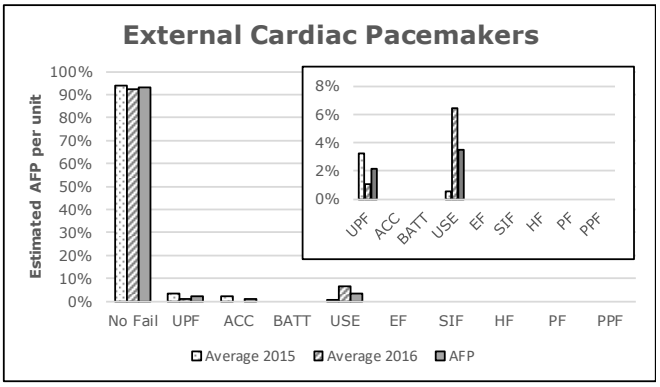

Figure 1: AFPD for external cardiac pacemakers at the UOHI. "No fail" means no failures and is not calculatd from NPF rather what remained from 100% after subtracting all the AFP estimates.The insert shows an enlarged scale.

DISCUSSION

This new methodology presented by Wang *et al.* has many advantages, which includes maintaining the safety and availability of equipment while possibly reducing labour and parts costs [2] [6]. This work presents the first reported implementation of EBM in Canada. The BME team at UOHI aim to generate interest in the Canadian BME and CE community to begin a discussion on the possibility of implementing EBM nationwide at other hospitals.

Due to the size of the institution and the smaller fleet of equipment, it has been difficult to obtain sufficient data in order to complete statistically meaningful analyses in a shorter period of time. As most medical devices on average are repaired once a year or less as was the case of the external cardiac pacemaker and receive between one or two PM's per year, a total average of two or three service records are obtained annually. Ideally, if a hospital has 100 devices that are the same model and brand, it is easy to accumulate a large enough sample size [6]. Contrarily a hospital with ten devices of the same model and brand would require several years to acquire sufficient data [6]. Which is why the UOHI currently has only completed the analysis on external cardiac pacemakers and will expand the analysis with subsequent medical devices when enough work orders are collected. This brings up a possible barrier in Canadian institutions; the vast majority of Canadian hospitals and facilities are relatively smaller in

size (unless a regional program) when compared to the USA, and may not have a large number of devices that are the same model and brand. Even though there are differences between hospitals such as practices, training and approaches to maintenance, in 2006 it was proven that CE performance can be compared and they have more commonalities than differences [6]. Therefore, to circumvent this barrier we propose that several Canadian hospitals agree to collectively implement EBM utilizing the same failure codes and share the data they collect with other hospitals [6].

The external cardiac pacemaker was the one device thus far to have enough data to complete an analysis. Based on the results from that analysis it was determined that the department could reduce the frequency of the PM's from six months to once a year because the direct AFP was 0%(extremely low). With reductions occurring in the frequency of PM's the department will be able to allocate resources elsewhere ultimately saving money.

Another barrier highlighted while implementing this model is the hesitation from the technologists/engineers to switch to the new failure codes. User feedback indicated that the new failure codes may be too generic and when a device is brought into the shop for repair they are no longer able to quickly get a sense of some of the specific problems that occurred previously with the devices (*e.g.*, PC board, component failure, or damage-accident). These failure classifications are based on parts replaced or specific corrective actions taken. While this information may be helpful to specific equipment manufactures to review their design or change components, it is not beneficial to maintenance strategy improvement [6]. Instead, it has been proven by EBM studies (e.g., [7] [8] [9]) that it is possible to focus on the smaller set of failure codes that are used to distinguish maintenance-related failures from those caused by normal wear and tear, abuse or accidents, batteries, accessories or random unpreventable failures [6]. Therefore, in order to satisfy the needs of both the technologists/engineers and the department heads the UOHI recommends implementing into the computerized maintenance management system a primary failure coding system and a secondary failure coding system; the primary system is for the new failure codes implemented for EMB (Table 1) and the secondary system for the old failure codes (Table 2) to use only for recollection of problems that have occurred previously.

CONCLUSIONS

This work presents the first reported application of EBM in Canada utilizing Wang et al.'s failure codes. Two years of work order data from the UOHIs external cardiac pacemakers was presented and the AFPD was computed for each failure code and grouped by actions to provide an example of how EBM is applied. This work highlights the necessity for a larger dataset in the analysis of EBM on medical devices and the need for Canadian institutions to collaborate on similar studies. It is important that a standardized set of failure codes are unanimously adopted by Canadian healthcare institutions such that appropriate inferences about the maintenance of medical devices can be determined. As such, institutions nation-wide might benefit from the alleviation of the increasing maintenance burden of medical devices ultimately saving hospitals money.

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