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DEVELOPING A SYSTEM TO SUPPORT EQUIPMENT REPAIR VERSUS REPLACEMENT DECISION MAKING

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ABSTRACT

As part of the life cycle management of medical devices, the Clinical Engineering (CE) Program is responsible for assessing the status of failed medical devices and determining appropriate corrective action. However, when faced with a major equipment failure, there was no formal system in place to guide the process of deciding whether the device should be repaired or replaced.

A literature review was conducted to search for established replacement policies and repair history analysis was done to learn more about the predominant failure patterns for sample fleets of medical devices.

A process was developed to support CE in following a consistent, methodical approach to repair versus replacement decision making. This approach is intended to improve the confidence of decision makers and equipment owners, and provide adequate supporting evidence, when CE makes a recommendation to proceed with either a costly repair or equipment replacement.

BACKGROUND

A literature review on repair versus replacement approaches used in healthcare technology management was conducted. There was no established best practice identified, and in fact very little published on this topic.

A significant body of work exists regarding established maintenance and replacement policies; however, the bulk of this theory is applicable only to deteriorating systems [1]. Deteriorating systems are those with increasing failure rates over time, and in theory at some age the equivalent annual costs of preventative and corrective maintenance will surpass the projected equivalent annual cost of replacement [2].

In the literature, there are different theories regarding the failure patterns that may be applicable to medical devices. One view is that these are subject to deterioration with usage and age [3], and an alternate view is that failures occur independent of age, based on the general conviction that electronic equipment has a constant failure rate [4].

In order to determine which approach better describes our equipment inventory, and therefore which existing replacement policies we could employ, a repair history analysis was necessary.

METHODS

A variety of failure occurrence analysis methods were investigated [2, 5, 6, 7] and two were found to be useful for this analysis [6,7].

Wang et al [6] developed the measure of Global Failure Rate (GFR) as a valid measure of the output or value of a CE Department, and further suggested that GFR can be used to evaluate the relative condition of a specific device against a group of similar devices. The authors state that device replacement should be recommended if the failure rate exceeds the baseline accumulated and the repair costs exceeds a certain threshold [6]. In our application, we adapted the GFR method to determine how the failure rate of a group of equipment changed over time.

Jardine and Tsang [7] proposed the Short Term Deterministic Optimization approach to determine an optimal replacement policy that would minimize the sum of operating and replacement costs per unit time. In theory, if the equivalent annual cost of maintenance, ownership (replacement), and total cost (sum of maintenance and replacement) is plotted we will find a point where the total cost reaches a minimum and then begins to rise. This would suggest that for this type of equipment, the device should be replaced at the age at which the minimum total equivalent annual cost was achieved. Although this method was developed for deteriorating equipment, it was applied to the sample data as an examination of failure pattern and optimal replacement time.

These failure analysis methods were employed on four sample fleets of medical equipment (see details in Table 1).

Table 1: Details of devices included in analysis

Device	Qty	Repair history (years)
Defibrillator	42	9
Electrosurgical unit	44	7
Syringe pump	59	8
Vital signs monitor	29	9

The device populations selected for data analysis are a subset of devices selected by Wang et al [8] and likewise "intentionally selected to cover a wide range of applications".

The selected device populations also met the following criteria:

- Large (> ~30), homogeneous fleet,
- Same assets in use over a long period (>7 years),
- CE performs repairs in-house,
- Single component systems, and
- Subject to scheduled maintenance.

A complete repair history review was conducted to tabulate all hard and soft failures [4] and associated costs by device age in days.

RESULTS

Similar trends were observed for all four fleets analyzed. Results will be presented here for the vital signs monitor fleet only. For the GFR analysis it was observed that the GFR in the first 3 years of use was typically lower than later years, however, the GFR in years 4 and later was relatively stable. There was no clear indication of systematic deterioration with increasing age; when a peak was observed in the annual GFR is was typically between years 5-7 years, and then stable or declining thereafter.

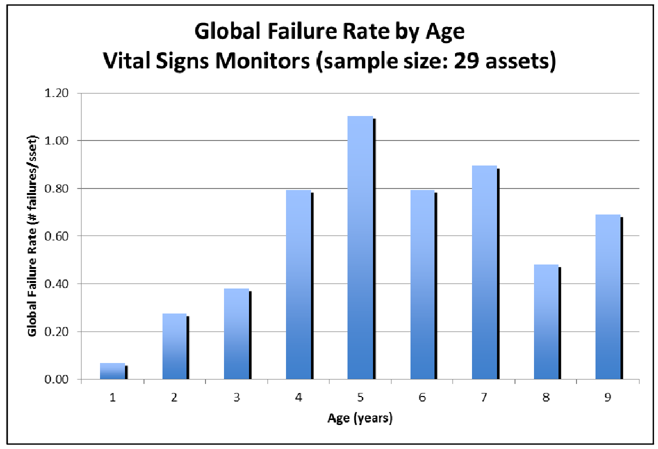

Figure 1: Global Failure Rate versus age for fleet of 29 vital signs monitors

For the deterministic optimization plot, we did not find a point within the recorded equipment life where the total cost reached a minimum and then began to rise. Despite a slight increase in maintenance costs over time, the total equivalent annual cost decreased continually with each passing year (Figure 2). Furthermore, through projection of best fit curves in attempt to predict when in the future the lines might cross, we found that it was not until greater than 20 years of age – long past the age when almost all devices are replaced in practice.

In summary, we found:

- A general trend of modest increases in repair costs with age over the study period, but
- The modest increases did not have sufficient magnitude to increase the overall cost of ownership over time and prompt device replacement.

This tells us that our data does not fit the typical pattern of deteriorating equipment, and increasing maintenance costs will not be a primary driver of equipment replacement.

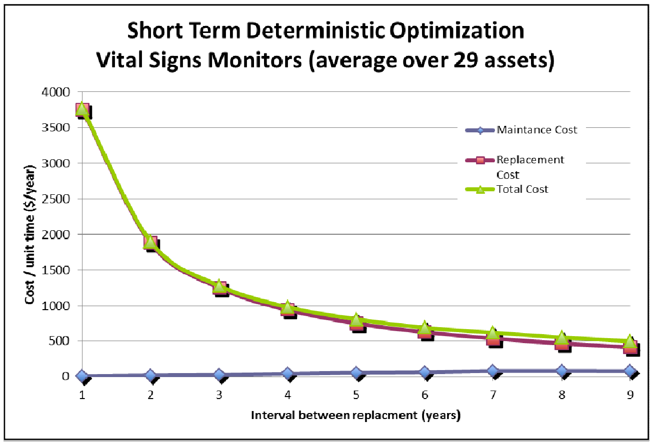

Figure 2: Short Term Deterministic Optimization for fleet of 29 vital signs monitors

DEVELOPING THE DECISION MAKING PROCESS

In the absence of a readily available established replacement policy, a two-phase process for repair versus replacement decision making was developed.

Phase 1: Repair cost limit

The first phase relies on a single repair cost limit to flag the most costly repairs for further review, a method commonly attributed to the U.S. Army TB MED 7 document [9]. The repair cost value of 50% of acquisition cost has been selected as the repair cost threshold at which device replacement should be seriously considered. This value is near the mid-point of the range suggested for similar systems reported in the literature (see Table 2).

In our case the limit applies to parts and external labour costs only (i.e. not in-house labour costs), and considers the estimated costs of the current repair only (not cumulative over the life of the device), and is therefore additionally conservative.

Phase 2: Further evaluation

The second phase incorporates factors identified through literature review as being useful for equipment replacement prioritization [12, 13, 14, 15, 16]. Here the factors are evaluated for a failed piece of equipment, to help assess whether or not it is a good candidate for replacement.

Table 2: Evidence of global maximum repair cost limits in the literature

Source	**Replace if …**	**Exceeds …**	**Of …**
U.S. Army [9]	Repair cost	38% (avg) 65% (max)	Replacement cost
Duke [10]	Cumulative cost of all repairs	50%	Replacement cost
Wang [11]	Repair cost	35%	Replacement cost
Drinkwater and Hastings [2]	Repair cost	50%	Acquisition cost

Ten (10) criteria were selected for this evaluation: age, past labour cost, past reliability, labour effort required (for this repair), current status of manufacturer support, estimated useful life remaining, projected reliability, condition, past usage intensity, and future usage intensity. Each of the factors is assessed on a five point Likert scale with customized endpoints, where a lower rating supports proceeding with the repair of the device in question, and a higher rating supports replacement (Figure 3).

Factor	Supports Repair	Rating	Supports Replacement
1. Age	< 6 years old	1 2 3 4 5	≥ 15 years old
2. Past labour cost	< 1% of purchase cost over last 3 years	1 2 3 4 5	≥ 4% of purchase cost over last 3 years
3. Past reliability	No repairs in last 3 years	1 2 3 4 5	≥ 4 repairs in last 3 years
4. Labour effort required (for this repair)	Minimal labour effort (1 hr or less)	1 2 3 4 5	Extreme labour effort (5 hrs or more)
5. Current status of manufacturer support	In production and supported by manufacturer	1 2 3 4 5	No longer supported by manufacturer
6. Estimated useful life remaining	Four (4) or more years remaining	1 2 3 4 5	Minimal useful life remaining
7. Projected reliability	Expected to function reliably	1 2 3 4 5	Multiple failures expected
8. Condition	Excellent condition	1 2 3 4 5	Poor condition
9. Current usage*	Has been lightly used	1 2 3 4 5	Has been heavily used
10. Future usage*	Will be lightly used	1 2 3 4 5	Will be heavily used

Figure 3: Excerpt from repair versus replacement worksheet

Each of the ten factors needs to be assessed by the technologist assigned to the repair request, with assistance from their manager and the device owner as required.

Following the evaluation of all relevant factors, the technologist and manager work together to assess whether the overall situation supports repair or replacement of the device in question and communicate their recommendation to the device owner.

DISCUSSION

This process and worksheet will facilitate repair versus replacement decision making following a major failure. The process is intended to be lead by CE, but is a joint responsibility of CE and the equipment owner.

All repairs with an estimated cost greater than 50% of acquisition cost deserve further review, however, the worksheet can also be used to examine the validity of a costly repair that is under this predefined limit. The repair cost limit threshold of 50% was selected as our starting point and future review will assess whether this limit is a good fit for our equipment mix.

In some cases, additional factors may support repairs in excess of the repair cost limit. These include, inability to replace with same make/model in a standardized environment, no suitable replacement available, and an anticipated quick turnaround of repair versus lengthy procurement process.

Additional failure analysis may produce different results for other equipment populations which may exhibit a dominant failure pattern due to a poor quality component or mechanical wear. However, the process presented here is not dependent on any specific failure pattern and can still be effective.

In order to support this new process a CE standard operating procedure, evaluation worksheet, and communication template were developed. Since the initial rollout, an electronic form analogous to the paper worksheet has been created. This will be integrated into the CMMS work order function to further facilitate this process within a repair request work order.

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