A Practicum for Biomedical Engineering & Technology Management Issues, Edited by Les Atles

Chapter 13
Medical Equipment Replacement: Planning, Factors, Methods and Outcomes

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Introduction
The purpose of the biomedical/clinical engineering (CE) department is to ensure that safe, cost-effective medical technology is available for the highest-quality patient care. This involves support of devices through maintenance, education and safety actions, and involvement in the planning of new technologies and replacement of current devices. At a point in a device’s life cycle, it crosses over from being beneficial to the institution’s patient care mission to being detrimental.

Medical equipment replacement should not be a political process or knee-jerk reaction to isolated events. Unless a quantified, defensible system with clear reporting of replacement needs and priority is developed for equipment replacement, unplanned subjective replacement requests or events will occur. Examples include the following:

- A physician returns from a conference and states to the CEO, “Our CT scanner technology is obsolete and must be replaced.”
- At the capital budget meeting, a department head states, “My monitoring equipment never works right, and we need a new system.”
- During a major repair of a critical item, it is found that parts are no longer available.
- After a serious adverse event with an infusion pump, the FDA MAUDE search shows many similar events have occurred at other sites, and the manufacturer has not resolved the issue.

Replacement planning is linked to the overall institutional or system strategic plan. The strategic plan involves clinical and nonclinical factors in determining the healthcare organizational direction. New services may require technologies unique to the organization, or current health services may see a paradigm shift to a different technological modality. Technology planning involves both these new technologies and replacement of existing devices, as shown in Figure 13.1. The capital planning process may oversee medical device replacement. It is well known that limited funds are available for equipment purchases. There is no set percentage for new technologies versus replacement equipment costs. Some facilities “ballpark” the average medical equipment replacement cycle as 7 to 10 years.

Typically, planned equipment replacement will involve a number of health systems personnel. Administration, clinicians, supply chain, facilities, and biomedical/clinical engineering (CE) should have involvement in the process. The CE role focuses on our technical expertise, resource library, equipment database ownership, and other resources, such as networking with other CE departments, governmental (e.g., FDA), and independent agencies such as ECRI. Also, our knowledge of device-patient and device-network systems is critical.
Replacement Factors
A number of factors should be taken into consideration in developing an equipment replacement plan. The following identifies these factors, related resources, and recommended prioritization, with some factors modulating the overall impact related to replacement.

Equipment Life References
- The American Hospital Association (AHA) publishes the Estimated Useful Lives of Depreciable Hospital Assets about every five years. Although this book can be used as an estimate, it is directed primarily toward financial administrators where depreciation timelines are used. This information is also available in the AHA Maintenance Management for Medical Equipment publication. Medium priority.
- A source compiled by the U.S. Army, Technical Bulletin (TB) MED 7, Appendix B—Life Expectancies, is more representative of the CE perspective, but was last written in 1992. Medium priority.

Maintenance
- **End of support date.** Support may include such things as field support by the manufacturer, service contract availability, accessibility of repair parts, service literature and/or test equipment from the manufacturer or their supplier, and availability of parts or service from third parties. Many manufacturers provide end of support dates on their Web sites. The receipt of an “end of support” notice from the manufacturer is an important guidepost in replacement planning, but is not inherently the last word for replacement. If there are alternatives to manufacturers service that are appropriate for the facility, then these may come into play and support the device quite well for a period of years after support has ended. If the facility has a substantial supply of repair parts, or access to them, then that also would help to extend the life of the device beyond the manufacturers support date. An information source in this area is the Medical Equipment and Technology Association (META) member Web site, which contains obsolete and end-of-support date by manufacturer and model for about 500 items. **High priority.**
- **No or limited parts availability.** This information is available from some manufacturers, but there are alternative parts sources that can extend equipment life. **High priority.**
- **Maintenance costs.** For departments with a long running computerized maintenance management database, cost data for parts and labor is available. The overall cost of the maintenance divided by the purchase or replacement cost can be used as a measure. Some feel that the cost trend or projected cost is a better gauge. **Medium to high priority.**
- **Reliability.** Most devices have reduced reliability as they age, and a sharp decrease in reliability at they near the end of their useful life. A simple way to measure reliability is to count the number of unscheduled repair work orders per year. A facility can calculate an aggregate reliability figure for all medical devices, and then break it down by device type, manufacturer and model, and individual device. The failure trend is an important factor. The failure type should be related to inherent device reliability, not lack of maintenance, abuse, accidental damage, or operator error. Device usage—portable, moveable, and fixed—is another consideration in this assessment. **Medium to high priority.**
• **Condition.** The device condition assessment by qualified CE staff is a factor. Excepting cosmetic problems, the condition should be scored based on reconditioning the device to a like-new condition by repairing defects and other corrective actions. *Medium priority.*

**Downtime**

• *Equipment downtime measures are related to the time the device is out of service due to equipment failure.* This measure is clear for an imaging modality where patient exams are scheduled for a set time frame, but less clear for an infusion device where similar devices may be available and the repair is put on a routine priority. Back-up equipment affects this factor, along with criticality of need. *Medium to high priority.*

**Device Function and Criticality**

• *Device function.* Life support, critical, routine, or nonpatient care is a factor in the analysis. *Medium priority modulator.*

• *Criticality.* A second and more important factor is the device’s criticality to the healthcare organization’s patient care mission. Equipment such as a diagnostic CT scanner is an absolutely essential technology for every acute care hospital, whereas a noninvasive blood pressure unit for routine vital signs is not—manual measurements are an alternative. The range of criticalities range from nonimpact to stoppage of patient care. *High priority modulator.*

**Safety**

• *Adverse events.* Hospital incidents, recalls, and hazards are another factor. The weight of these factors depends on the magnitude of the hazards and if the hazard can or has been resolved. *Medium to absolute priority.*

• *Safety features.* The lack of inherent device safety features is a second important category. Examples would include poor return electrode monitoring for an ESU or no “guardrails” limits for dose in infusion devices. *High priority.*

**Clinical Use**

• *Acceptance.* The acceptance of the device or system by clinicians is a subjective factor determined by clinician interviews. This may be related to operation, clinical performance, or other factors. *Medium to high priority.*

• *Use.* A second factor is the frequency of use errors or other quantifiable data. This may point to human factors design issues. *Medium to high priority.*

**Standardization**

• Device standardization can reduce costs significantly, reduce training requirements and use errors, make it easier for caregivers to work interdepartmentally, and enhance support. *Medium to high priority.*
Standards of Care

- Many clinical professional organizations, such as the American Heart Association and American Academy of Pediatrics, publish standards of care for different procedures and treatments. These recommendations may involve technologies requiring certain features. An example is the *AHA Defibrillation Guidelines* specifying biphasic energy characteristics for defibrillation. *Medium to high priority.*

Medical Device Standards

- Device standards set by ANSI, AAMI, ASTM, NEMA, or IEC differ from clinical standards in that they focus on equipment characteristics. They are generally minimum standards. In some cases, they may be adopted by national, state, or local authorities, and they fall into the regulatory category. *Medium to high priority.*

Regulatory Requirements

- Regulatory prohibition is an absolute factor for replacement. A device may use a process or material that has been identified as being hazardous, and while the device is useful, reliable, supported, and clinically effective, it needs to be removed. In these cases, a process may need to be created to remove and replace the devices in a planned fashion at one time, or staged over a predetermined period of time. In this case, written verification of the removal of the device, and its disposition may be required. Examples are mercury manometers and thermometers, or the replacement of mammography systems in the 1990s related to federal MQSA guidelines. *Absolute priority.*

Technological Status

- The medical equipment may be emerging, current, mature, or obsolete on the life cycle curve. This factor must be scored through the use of experts knowledgeable about the technology. *Medium to high priority.*

Vendor Status

- The device may be the latest model, a model still currently sold, but not being advanced, or a model no longer offered by the company. *Medium priority.*
- A second factor is the ability of the device to be upgraded to the state-of-the-art through software and hardware. *Medium to high priority modulator.*
- Refurbishment is an option in some cases. This action will bring the device to its original performance status. *Medium priority modulator.*

Interfacing and Network Compatibility

- Today, device networking and linkage with hospital networks is critical. An example would be an ultrasound’s DICOM compatibility or an IEEE 802.1 wireless link for an infusion pump. *Medium to high priority.*
Utilization

- Device utilization is an important factor in determining the need for replacement for many devices. The utilization can range from very high for a linear accelerator used 16 hours a day to very low for a surgical laser used once a year. For devices with only emergent need, such as a defibrillator, the levels will be lower, but will be relative to similar devices. *Medium to high priority modulator.*

Backup Equipment and Spares

- The availability of back-up equipment and spares play a role in determining the need for equipment replacement. *Medium to high priority modulator.*

Non-equipment Factors

- Other medical equipment replacement factors that are typically not directly addressed by CE departments are the important area of referrals from physicians and organizations, physician recruitment and retention, marketing, malpractice and other insurance advantages, cost advantages of new technologies, particularly in the area of consumables, staffing, payer reimbursement, and other efficiencies, and tax advantages related to depreciation.

Methods for Determining Medical Equipment Replacement Recommendations

Over the years, various methods, from basic to advanced complexity, have been published (see references 1, 5, 6, 7, 8, 9, and 10). The use of these methods depends on the resources available to the CE. The key element is the equipment management database. This may range from no availability to a very robust, accurate, multiyear, multifaceted database. Also access to outside resources such as life expectancy data, FDA/ECRI safety information, standards and regulations, manufacturers, and clinicians—along with CE internal staffing levels and expertise—will influence the method utilized. With this background in mind, three increasingly complex methods are presented to come up with a medical equipment replacement plan and report.

Basic Level

For institutions where a robust equipment management database and necessary resources do not exist, a basic methodology can be used to develop an equipment replacement report. This system can use a simple, hand-written or computerized spreadsheet and basic data derived from free sources to prepare a first-order equipment management plan. This approach is a derivative of that published by Robert Dondelinger in 2003.\textsuperscript{ix}

For any equipment replacement plan, the first element that is needed is a device inventory, including location, device type, manufacturer, model, and serial number. The next piece of information to be researched is the device age. This may be determined through hospital records such as purchase orders, asset lists, or the CE department’s files. Another way is through communication with the manufacturer’s customer service organization. Many times, the serial number is related to the manufacture date. Next, the life expectancy must be determined from the AHA, U.S. Army, or other resource file. A retirement date may be determined by subtracting the device age from the life expectancy—many times, a negative number—and converting it to a date. The next important item to determine is the replacement cost. This can be determined from manufacturer’s quotes or various databases for equivalent equipment.
Review the list for any absolute or high-priority replacement issues shown in Figure 13.2—regulatory prohibition, unresolved safety issues, parts no longer available, or devices that you know are disasters and will not make it through the next budget year. These items should be put at the top of the spreadsheet list for recommended replacement, as shown in Figure 13.3. The remaining items would be sorted by projected retire date.

The replacement costs are added in the Cumulative Costs column for the list in Figure 13.3. If an amount has been budgeted for medical equipment replacement, a “cut line” can be established. In Figure 13.3, an amount of $100,000 has been established for equipment replacement. Based on priority, items whose cumulative total is less than $100,000 are on the replacement list—items cumulating to an amount greater than $100,000 (shaded section in Figure 13.3) will be deferred for replacement.

This basic method is a beginning, but does not include many of the factors previously discussed. Also, it does not show a multi-year replacement plan. With a good computerized maintenance management system (CMMS) (see Chapter 11) and some additional resources, a more comprehensive replacement report can be developed. A follow-up paper by Dondelinger discusses a more complex process.

Comprehensive Level—Use of Computer Databases and Analysis
The Technical Services Program at the University of Vermont (UVM) has been providing equipment replacement reports to 23 member institutions since the mid-1980s (see references 1, 8, and 10). This system uses a CMMS (HEMS ®, EQ2, Inc. Burlington, VT), a standardized reference database for manufacturer and model information, and analysis and reporting software.

The process to create an equipment replacement plan depends on the existence of a good historical database of the medical equipment. If one is using a packaged computer program for medical equipment management, then the replacement assessment process may require an additional spreadsheet or database in order to manage the replacement information. The first step is to verify the accuracy of the inventory. Ensure that all devices that have been already removed from service have been so noted on the inventory. The credibility of the equipment replacement recommendations is often undermined if the inventory is not accurate.

In the database of the spreadsheet, each item has created for it a field for the basic CMMS information (control number, department, type, make, model, serial number, purchase cost, and date placed in service), plus the age of the device, reliability value, level of support available, and notes regarding clinical obsolescence, and data related to the total number of repairs, cost, and, if possible, the types of failures recorded. The University of Vermont (UVM) uses a basic mathematical algorithm to provide an estimated replacement year for the device. This is based primarily on age and reliability. Once the basic projection has been determined, each item is evaluated manually to adjust the replacement year to be provided to the department. From the manufacturer and model database, regulatory prohibition, unresolved safety issues, and no support will modify the items as high priority for replacement.

The replacement year is then adjusted up or down based on subjective factors. If a device is part of a system with multiple replacement years, then it would be best to align all of the devices with a single recommended replacement year. There may be factors from the capital budgeting process related to available capital funds, or a need to align a replacement with a building project or other purchase. This is the part of the replacement process that consists of art, compromise, and strategic planning.
The subjective aspect of the ERP is important, but should always be justifiable back to the basics of age, support, and reliability. The person that is preparing the recommendations should be aware of the overall organizational status of the clinical departments and the whole facility. The most common adjustments to the recommendations are related to a number of a single make and model of a device, where the ages and histories would direct the replacement of a portion of the fleet over a number of years. If the product line is current, and the hospital wishes to continue with that device, then that is appropriate. If, however, the hospital should consider a complete change of product, then the replacement years of the entire fleet may need to be aligned into a single year.

The other common subjective change of recommendations is most often associated with a physiologic monitoring system, where the end of support dates of various components is spread over several years. If a component is critical to the function of the entire system, and cannot be supported by the facility after a particular date, then the replacement date for the entire system should be aligned to this early replacement date. Systems with components of diverse dates of manufacture should receive the most ongoing support inquiry each year, so that a failure of single component does not jeopardize the entire system. Systems that span multiple departments often require multiyear capital funding requests in order to become approved. As medical equipment becomes more integrated into other systems in the facility, coordination of acquisition and replacement is more complex.

Some aspects of the device data can be difficult to manage. The aforementioned process works best if all of the maintenance data for each device are being loaded into the computerized maintenance software. In order for the total cost of the device to be valid, it would be necessary for the labor value to be included in the database for each repair. In the same way, the value of each service call for devices under a service contract should be included as well. If the database documents the repair costs in different ways for different device types, it predisposes the system to inaccuracies. The clinical engineering management should take this into account when defining how labor and parts are recorded for all work, whether tallied as time and materials, contract, first look, or in-house.

No process is perfect, and some areas for improvement have been noted. One phenomenon that occurs periodically is what can be termed inventory creep. In this case, a device is recommended for replacement, and a new device is acquired. The old device either remains in service or goes temporarily into storage. Over time, the device is back in service, and then suffers a failure that requires expenditure. The device is repaired if possible, shows up on the next year’s replacement recommendations, and is “replaced” again. This, of course, short-circuits the value of replacement planning. It is important to note in the device history the status of the replacement process, so that this situation can be avoided.
Reporting
As a check and balance, the clinical engineer’s report should be reviewed by the biomedical technicians responsible for servicing the equipment before it is published to the departments. This helps to catch errors and omissions, as well as to ensure that recently deleted devices do not show up on the report. The report is provided to the department in a timeframe to allow for the information to be used in the preparation of the upcoming capital budget.

The report that is provided to the department heads should be simple and easy to understand. UVM includes the basic device identification information, age, year of recommended replacement, and a justification code that supports the recommendation as shown in Figure 13.4. UVM uses at single letter for each justification, and there can be more than one. The UVM justifications include: A = Age; S = Support; R = Reliability; O = Obsolete; H = Hazardous material.

The justification codes can be seen on the sample page. Using a series of single letter codes allows for a single line to be used for the entire device record. A key is provided on each and every page to clarify the codes, even if the report is broken into sections for distribution. Reports in which a single device occupies more than one line were found to be confusing to the department leaders that were expected to evaluate and consider the recommendations.

UVM has provided equipment replacement planning to its member facilities for 20 years. During that time, it has become a sought-after report by the department managers. From year to year, the replacement recommendations need to be compared for uniformity. If the final recommendations for an item vary in value and justification from year to year, that can be confusing and undermine credibility. If an item is at a high priority for replacement for several years, then some additional interaction with the department may be necessary.

The effectiveness of the replacement planning process rests heavily on timing and distribution of the reports. They should be provided before the departments begin planning for the next year’s capital budget. The process also needs to ensure that each appropriate department manager, as well as the capital committee, gets the report. The reports to the department managers should list only devices from that department, arranged in increasing year of recommended replacement, and include only the devices scheduled for replacement over the next 3 to 5 years. A way to note devices that have been on the report for several years is also helpful. It is best if clinical engineering meets with each department head to go over the report, so that errors or questions can be resolved quickly.

Encourage challenges of the data and the recommendations. Although the database may be reliable, there may be information available from clinicians, department managers, or support services that would alter the recommendations. Changes of this type are frequent, and if they are justified, they serve only to strengthen the credibility of the report.

Equipment Replacement Planning also should be coupled with the hospital’s capital budget process. The clinical engineering department should be represented on the committee. The clinical engineer can answer questions concerning justification, and assist to ensure that budgetary replacement prices reflect reality and all aspects of the project. When used, this process is supportive to the department managers, who must provide justification for replacement or acquisition of new equipment.

It is important to include the replacement data not only in report form, but also as part of the device’s inventory data. The replacement year and justification should be included in inventory fields in the CMMS. A mechanism in the CMMS should exist to alert service staff when a work order is opened for a device that is due for replacement.
Advanced Level—Replacement Analysis for Major Medical Equipment

Inventory data, equipment histories of maintenance, costs, hazards and use problems, condition assessment, and life-expectancy databases when analyzed create an excellent replacement guideline for most medical equipment. One class of equipment where additional analysis may be necessary is for major medical equipment—imaging systems, laboratory analyzers, and other high-tech/high-cost systems. For these equipment types, factors such as utilization, clinical input, upgrades, projected maintenance costs and reliability, and technological status take on a greater weight in decision making and must be carefully analyzed.

Preliminary Equipment Replacement Plan

The Preliminary Equipment Replacement Plan, Malcolm Ridgway, xii is a strong program that analyzes seven key factors for reducing the evaluation of each item to a single figure of merit, which is then used to rank the candidates for replacement into a concise short list. The factor list includes:

- Age and condition
- Utilization level (Clinical staff)
- Clinical acceptability (Clinical staff)
  - For items deemed unacceptable, a justification letter is required.
- Technology status (CE assessment)
- Parts availability (manufacturer data)
- Projected reliability (analyze database)
- Projected annual maintenance cost (analyze database)
  - The rating is based on the cost trend information using a TWA algorithm.

Each item is examined with respect to each of the seven factors and classified into one of several broad categories (e.g., low, medium, high). Some categories are given replacement point (RP) scores of zero; others are given scores between 1 and 10 RPs. The sum of the RP scores for each of the seven factors is listed as the item’s total RP score. The higher the score, the higher will be the priority for replacement. This analysis not only provides historical information, but also projects costs and reliability.

The latest version of this program—the Dynamic Asset Replacement Planner—is Web enabled, providing real-time assessment of client-based replacement information.

Removal Options

Although the conventional use of replacement planning is to identify devices that can be replaced one-on-one with a new device, this is not the only option.

- Depending on funding, a device identified for replacement could be designated as a back-up device, and kept in service with the understanding that if it fails, it would not be repaired.
- A device may be used in an area of lower acuity, especially if the issues are related to standardization or technological status.
- A device may be moved to a storage location if it might be used at a later date. It should be noted that the device will either have to be on the regular inspection program or evaluated closely prior to return to clinical service.
- Devices may be sold to a used equipment buyer, to another hospital, or other purchaser. Typically, devices are sold in an as-is condition, and your organization should have a sign-off form to reduce liability.
- Donation of medical equipment to mission-based organizations or direct to developing countries should not be viewed only as a tax write-off. Devices should be usable, have all components for clinical application, include user and service documentation and, if available, spare parts. Comprehensive sources of donation guidelines are the World Health Organization\textsuperscript{xiii} and the American College of Clinical Engineering.
- The device may be used for parts and may be “cannibalized.” Regardless, if the device is not to be used again, it should be disabled. Many locales have regulations regarding the type of materials that can be placed in a landfill. The clinical engineering department should remove any hazardous or regulated items from the device, including identifying marks and tags.

Summary
Equipment replacement planning does not need to be a cumbersome process. A facility that wishes to begin providing it should start small, with a small number of measurements and parameters. Age, support status, and reliability would be good initial parameters to review. If the facility maintains good-quality historical data, this can be incorporated as well. Caution should be exercised to ensure that the process does not become overly complex. The accuracy of the device information, and maintaining the material used to assess the equipment is what is most critical.

Trends and the Future
Current and future trends in replacement planning are driven by several factors. Clearly, medical devices are increasingly being included on the hospital or system network. Clinical information, images, alarms, and other data are commonly communicated. Devices that do not have interfacing hardware and software may not meet the hospital’s mission for information communication. With computer hardware still expanding exponentially, device computer “horsepower” must keep up with software upgrades that take advantage of hardware availability.

A second focus area in the twenty-first century is patient safety factors. After the 1999 Institute of Medicine report cited 98,000 deaths due to medical errors in healthcare and with the continued high level of reporting of adverse events related to medical devices, patient safety shortcomings are an increasingly important reason for replacement. An example is the change to infusion devices with internal drug libraries that alert caregivers when an out-of-range entry is made.

Cost-saving technologies are of increasing importance as hospitals look to meet bottom-line goals. The cost savings may come from a decreased costs of disposables, reduced utilities or space requirements, better reimbursement, or from other areas. Where a significant cost savings is available, medical equipment will likely be replaced.
Figure 13.1 Medical equipment replacement planning as part of the technology planning process
Figure 13.2 Weighting of factors in considering equipment for replacement

- **Heavy Weight**
  - Unresolved safety issues
  - No parts
  - Regulatory prohibition

- **Moderate Weight**
  - Opportunity for income
  - Documented poor reliability
  - Does not meet standard of care

- **Lesser Weight**
  - Anecdotal user problems
  - Age
  - More advanced technology
Figure 13.3 Example spreadsheet for a basic medical equipment replacement report

<table>
<thead>
<tr>
<th>Location</th>
<th>Type</th>
<th>Manf.</th>
<th>Model</th>
<th>Ser #</th>
<th>Flag</th>
<th>Age</th>
<th>Life Expectancy</th>
<th>Projected Retire Date</th>
<th>Replace Cost</th>
<th>Cumulative Costs</th>
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<td>Ugo</td>
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<td>933</td>
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Table 13.4 Sample page for operating room medical equipment replacement by year and justification code

**Justify codes:** 
- **A** = Age; 
- **S** = Support; 
- **R** = Reliability; 
- **O** = Obsolete; 
- **H** = Hazardous Material.

<table>
<thead>
<tr>
<th>Department</th>
<th>Control #</th>
<th>Device Type</th>
<th>Manufacturer</th>
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