In AAMI’s 2012 survey of the top medical device-related challenges, healthcare technology management (HTM) professionals placed battery management as the fourth biggest concern. That’s not surprising: Virtually all HTM professionals have to deal with medical device batteries and their associated issues.

The U.S. Food and Drug Administration (FDA) understands that batteries are a major issue for the entire medical device industry. This past summer, the agency convened a two-day workshop to explore the challenges and opportunities posed by battery-powered medical devices. The workshop drew approximately 200 attendees (plus several hundred additional virtual attendees) from industry—medical device manufacturers, battery manufacturers, and third-party battery distributors—and the clinical and regulatory worlds, including nurses, HTM professionals, and FDA staff.

The FDA’s online summary about the workshop highlights the ubiquitous nature of batteries in modern healthcare. “Batteries play a significant role in the overall safety, performance, and reliability of many life-saving and life-sustaining medical devices,” the FDA says. “As more medical devices become computerized, compact, and mobile, the number of battery-powered medical devices will continue to increase. While many different components can potentially impact the safety and effectiveness of medical devices, the battery is one of the most critical components. Unexpected depletion or failure of the battery can cause the device to stop functioning properly, preventing the device from delivering life-sustaining or life-saving therapy.”

The summary goes on to say: “While the FDA has confidence that medical devices currently being marketed will continue to function appropriately, there are opportunities to further improve their overall performance and safety.”

**AAMI Presentation**

I was asked to make a presentation on behalf of AAMI at the FDA workshop. Since the FDA knew that many of the industry attendees also would be AAMI members, they asked the association to focus on the HTM perspective for the presentation. In preparation, I worked with the AAMI staff to poll the HTM community about some of its practices regarding battery management. Because of a tight schedule, the survey was only open for about 90 hours. In spite of this relatively small window, 226 individuals responded. The survey responses becomes the basis for my presentation.

The first question on the survey asked, “Do you or does your HTM program routinely replace batteries at specified intervals, without waiting for failure?” Eighty-four percent of respondents replied in the affirm-
tive. Those respondents who replied “yes” were then asked for details about the types of equipment, intervals, and criteria used for battery replacement. Those details were provided by 176 participants. Figure 1 summarizes the types of equipment mentioned.

It should be noted that the percentages add up to more than 100%. That’s because many respondents listed more than one category in their responses. Only about half of the affirmative respondents to the first question provided any detail about the interval at which they replaced batteries. Their answers follow:

- Fifty-six percent said their replacement schedule followed the recommendation from each original equipment manufacturer (OEM).
- Thirty-five percent said they replaced batteries every two years.
- Fourteen percent said they replaced batteries every three years.
- Four percent said they replaced batteries as recommended by the OEM, and by what their own department experience had taught them.
- Two percent said they replaced batteries every year.

The second question on the survey asked, “Do you routinely purchase replacement medical device batteries from a third-party distributor? (Answer “no” if you always use the OEM.)” Ninety-one percent of the respondents answered “yes.”

A text box was provided with the following instructions: “If yes, do you simply trust your vendor to supply equivalent batteries, or do you do your own technical evaluation? If no, is that because of a bad experience with a third party distributor or advice from risk management, or a generally conservative approach?”

A total of 191 respondents filled out the text box. A summary of their responses follows:

- Eight percent said they bought OEM batteries for some key pieces of equipment, such as defibrillators or life support equipment, but used third-party party distributors for most other equipment.
- Three percent said they bought from third-party party distributors, but specified the same battery manufacturer/model that came with the device originally.

**DO YOU OR DOES YOUR HTM PROGRAM ROUTINELY REPLACE BATTERIES AT SPECIFIED INTERVALS, WITHOUT WAITING FOR FAILURE?**

![Diagram showing the battery replacement rates for different types of equipment](image)

**Figure 1.** Types of Equipment Cited by Survey Respondents

- 64% Defibrillators and/or automated external defibrillators (AEDs)
- 49% All life support equipment
- 20% IV pumps
- 20% UPS systems
- >10% Transport physiologic monitors, intra-aortic balloon pumps (IABP), battery-operated suction, ceiling lifts, transport incubators and/or portable X-ray machines.
- 6% All medical devices with rechargeable batteries.
- A few Sealed lead acid batteries on a scheduled basis.
- One Removed all batteries during scheduled maintenance (SM), and tested them, and replaced those found to be bad. Another respondent tested a sample during SM.
One respondent to the AAMI survey about batteries recommended a website from MHRA (Medicines and Healthcare Products Regulatory Agency), which is the United Kingdom’s equivalent of the U.S. Food and Drug Administration. The MHRA maintains a page that offers guidance on “the safe and effective use of batteries and chargers for medical devices.” The website URL is: www.mhra.gov.uk/Publications/Safetyguidance/Device-Bulletins/CON2022469

It should be emphasized that the guidance on this page is not official U.S. guidance. The author believes HTM professionals would be well served if the FDA developed a similar site.

• Four percent said they tested incoming rechargeable batteries upon arrival; some on random basis, some only for new battery types, and one tested all incoming batteries.
• Unprompted, 46% of respondents mentioned that, while they dealt with third-party distributors, they only used one or a small number of these distributors whom they trusted. Since the survey itself didn’t specially ask that question, I believe the percentage of those who have that view is probably substantially higher.

The third question asked, “Are there other significant medical device battery issues that should be raised at this workshop? If so, please include what your ideal solution would be.” A text box allowed respondents to write their answers. Likewise, the fourth question had a text box for the answer field and instructed, “Feel free to add any additional comments about battery management, battery-powered devices, or related issues below if you wish.” There were a total of 120 responses to the two questions. Common themes included the following:

• A need for better batteries and battery chargers.
• A belief that batteries cost too much and greater reliability is needed so not as many batteries would need to be replaced.
• Concern with user education: How can we convince users to plug in battery-operated devices when not in use?
• Calls for devices to be designed with a better indication of how much time before battery is exhausted.
• A desire for manufacturers to improve alarm strategy for when batteries need recharging and shutdown strategy when batteries are depleted.
• A belief that battery leakage and swelling is a problem, especially with UPS batteries. Enclosures in some cases also need a better design to allow access to change the battery.
• General confusion because of the proliferation of battery types with questions about how to handle and store the many varieties. At the end of my presentation, I asked

Data from ARAMARK

After hearing that I would be representing AAMI at the workshop, the national ARAMARK team contacted me to discuss some of the data it had collected. The ARAMARK team had sought to learn if there was any significant difference between failure rates when using OEM batteries versus third-party batteries. Salil Balar and Binseng Wang from ARAMARK put together this portion of my presentation.

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ARAMARK makes it a national practice at all of their accounts to replace rechargeable medical device batteries periodically as part of scheduled maintenance. The interval at which the battery is replaced depends on their national service experience with the manufacturer and model combination, not solely upon the type of equipment. ARAMARK allows the individual account customer to decide whether to purchase batteries from the OEM or from a third-party distributor. The national ARAMARK computerized maintenance management system (CMMS) requires technicians to categorize all work orders when completed so as to allow standardized analysis.

One of ARAMARK’s closing codes is “BATT”, which means “Battery(ies) failed before the scheduled replacement time.” For each manufacturer and model combination, ARAMARK calculates the battery-induced failure rate, which is defined as the number of BATT codes divided by the quantity of equipment over one year. ARAMARK compared battery-induced failure rates and standard deviations for
OEM and third-party batteries for three models of defibrillators, two models of general purpose infusion pumps, one model of a patient-controlled analgesia (PCA) pump, one model of Doppler, and one model of ventilator. (Figure 2)

The average battery-induced failure rates varied between approximately 4% per year to 70% per year. There was a wide variation in the standard deviation for all of these values. The ARAMARK team expects that the standard deviation is likely to lessen as more data is gathered over time. The data collected thus far does not indicate any difference between OEM-supplied batteries and those provided by a third-party distributor.

Infusion Pump A stands out as manufacturer/model with a greatly higher battery failure rate than the other models in the study. The manufacturer since has issued a recall on these infusion pumps because of battery issues.

ARAMARK intends to continue gathering information and compile a larger data sample to reduce the deviation. The ARAMARK team encourages other HTM groups to begin collecting data using the same methodology. It also recommends that
“multidisciplinary committee(s) to be created to establish standard practices acceptable to both OEMs and clinical users, as well as HTM professionals.”

**The Need for a Plan**

David Marlow, a certified biomedical equipment technician with the University of Michigan Health System, also delivered a presentation with an emphasis on the HTM perspective. Marlow made the important distinction, later repeated by others at the workshop, that primary batteries are very different from rechargeable batteries. Most of his talk focused on rechargeable batteries. Within rechargeable batteries, there are multiple chemistries. Within each battery chemistry type, there are many subtypes. Different manufacturers have taken widely different approaches to battery design and charging. The complexity is compounded by a variety of different applications and levels of criticality. Some rechargeable batteries are often used as primary power sources and some only as back-ups.

Marlow advocated that user facilities should have a battery management plan (BMP) covering battery purchase, inspection, storage, testing, replacement strategy and disposal.

Marlow pointed out that many HTM groups simply replace failed batteries without analyzing how often or why the batteries failed. The University of Michigan, however, does both of these things in order to adjust its BMP as needed. The cost of the equipment needed to test the batteries can be covered by the savings found in fewer battery replacements and fewer failures during use.

Marlow said that his battery test bench is equipped with four battery analyzers, each capable of monitoring four batteries simultaneously. The analyzers are linked to a software program that stores battery test protocols and testing results.

“Smart” battery systems used by some manufacturers can be very expensive, but they also have the potential to predict problems before batteries fail, reducing replacement costs and downtime.

**References**