A day in the life of Cmdr. Mike Krumlauf, a critical care nurse at the National Institutes of Health (NIH) Clinical Center, is a micro-cosm of a surging challenge in healthcare: managing battery-powered medical devices.

For Krumlauf, patient care routinely requires the use of a diverse collection of high-tech and low-tech medical devices and equipment. The long list of items includes: ambulatory infusion pumps, intravenous (IV) infusion pumps, blood pressure machines, oxygen saturation monitors, thermometers, glucometers, ventilators, suction machines, scales, portable telemetry, feeding pumps, defibrillators, automated external defibrillators (AEDs), sequential compression devices, portable electroencephalogram (EEG) and electrocardiogram (ECG) machines, patient transfer lifts, patient beds, ultrasound machines, and constant positive airway pressure (CPAP) and bilevel positive airway pressure (BIPAP) machines.

Like many healthcare providers in hospitals and other clinical settings, Krumlauf and his colleagues also rely on point-of-care support systems. For them, these systems include:
- Portable workstations
  - Laptop computer
  - Bar code scanner
  - Bar code printer
  - Portable data assistant (PDA) scanner
- Unit-based cellphones
- Medication dispenser or storage machines
- Supply cabinets for stock patient care items

All of these wired and wireless medical devices, equipment, and support systems feature a common component—batteries.

About the Author

Martha Vockley is principal of VockleyLang, LLC, a communications and marketing firm based in Reston, VA. E-mail: mmv@cox.net
But the challenges of battery-powered medical devices are myriad and diverse.

**What Could Go Wrong?**

“We rely heavily on battery-powered medical devices,” says Krumlauf, who is also a nurse consultant with the Research and Practice Development section of the Nursing Department at the NIH Clinical Center. “Frequent use leads to undercharging, with potential battery loss and failure. It’s very much a challenge to figure out how much power is left in all of the devices. Not every device has a battery indicator or an alarm. For patient safety during transport, by ambulance or through the hospital, you often have to send patients with two devices because you’re worried that one is going to fail.”

A small-sample qualitative survey of nine respondents from nine hospitals in a network of 250 healthcare facilities that participate in the U.S. Food and Drug Administration (FDA) Medical Product Safety Network, known as MedSun, sheds more light on the challenges posed by batteries. Up to 50% of service calls in hospitals surveyed are related to battery issues, according to the FDA's Antoinette Hazlett, manager of surveys, special studies, and research at the Center for Devices and Radiological Health (CDRH) Office of Surveillance and Biometrics, Division of Patient Safety Partnerships.

The small survey of hospital biomedical or clinical engineers, risk managers, nurses, and purchasing directors may not represent all device users’ experiences, Hazlett cautions. Still, the range of issues cited by just nine respondents at geographically diverse hospitals, which are shown in Table 1, is telling: failure to plug in battery-powered medical devices; inaccessible plugs or outlets; battery overcharging, undercharging, leakage, swelling, and loose connections; incorrect replacement; and confusion with the on/off button.

These issues can result—and have resulted—in premature battery depletion, loss of power, overheating, fire, and explosion. All of these outcomes are potentially serious hazards to patient care; some could cause injuries or even death to patients and anyone else in the proximity of malfunctioning batteries in medical devices. Moreover, Hazlett says, the devices cited most frequently by survey respondents are widely used for diagnostic, therapeutic, and, in some cases, life-support functions. They include large-volume infusion pumps, telemetry boxes, pulse oximeters, thermometers, electric beds, monitors, and portable or mobile devices.

At one hospital, severe weather caused a power loss. While an emergency generator kicked in within five or six seconds, a memory battery on an infant isolette did not back up the programmed temperature setting. The temperature reverted to the manufacturer’s default setting, and the isolette became too hot.

One hospital reported that a temporary external pacemaker provides no indication that the battery is low or depleting. But when the battery is depleted, the staff has just two to five seconds to replace it. “Insufficient charging of infusion pumps causes alarms,” Hazlett adds. The burden of too many alarms and alerts is already a major challenge in

---

**Table 1.** Types of Battery-related Issues and Challenges. (Source: Hazlett A. Overview of MedSun Survey. Presentation at the FDA Public Workshop, Battery-Powered Medical Devices: Challenges and Opportunities. July 30–31, 2013.)

<table>
<thead>
<tr>
<th>Issue/Challenge</th>
<th>Reported/Potential Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to plug in device</td>
<td>• Premature depletion</td>
</tr>
<tr>
<td></td>
<td>• Loss of power</td>
</tr>
<tr>
<td>Inaccessible plugs/outlets</td>
<td>• Premature depletion</td>
</tr>
<tr>
<td></td>
<td>• Loss of power</td>
</tr>
<tr>
<td>Overcharging</td>
<td>• Overheating</td>
</tr>
<tr>
<td></td>
<td>• Fire</td>
</tr>
<tr>
<td></td>
<td>• Explosion</td>
</tr>
<tr>
<td>Undercharging</td>
<td>• Premature depletion</td>
</tr>
<tr>
<td></td>
<td>• Loss of power</td>
</tr>
<tr>
<td>Leakage</td>
<td>• Fire</td>
</tr>
<tr>
<td>Swelling</td>
<td>• Explosion</td>
</tr>
<tr>
<td>Loose connections</td>
<td>• Premature depletion</td>
</tr>
<tr>
<td></td>
<td>• Loss of power</td>
</tr>
<tr>
<td>Incorrect replacement</td>
<td>• Leakage</td>
</tr>
<tr>
<td></td>
<td>• Increased heat</td>
</tr>
<tr>
<td></td>
<td>• Fire</td>
</tr>
<tr>
<td>Confusion with on/off button</td>
<td>• Premature depletion</td>
</tr>
<tr>
<td></td>
<td>• Loss of power</td>
</tr>
</tbody>
</table>

---

Up to 50% of service calls in hospitals surveyed are related to battery issues, according to the FDA.
Batteries in Implantable Devices

In December 2013, the FDA announced a pilot program focusing on implantable medical devices that use batteries. In collaboration with manufacturers and other stakeholders, the FDA will develop:

- A framework for determining specific manufacturing operations, design considerations, and controls that impact the quality and safety of implantable devices that use batteries
- An inspectional approach that focuses on these factors
- Outcome measures to evaluate the effectiveness of this approach

The pilot program is part of the FDA's Case for Quality initiative, which focuses on quality, enhanced data transparency, and stakeholder engagement. By looking at quality, the FDA aims to build on its operational model of ensuring regulatory compliance by also promoting “critical-to-quality” practices that correlate to higher quality outcomes.

An Escalating Challenge

Krumlauf, Hazlett, and others whose perspectives are captured in this article spoke at a public workshop on battery-powered medical devices convened by the FDA in July 2013. More than 700 people—including 400 who participated online from all over the world—attended the workshop, which was held at FDA headquarters in Silver Spring, MD.

The FDA hosted the battery workshop to raise awareness about battery challenges, and to engage many stakeholders—including healthcare providers, healthcare technology management (HTM) professionals, manufacturers, regulators, and patient safety advocates—in developing solutions.

In AAMI surveys of HTM professionals in hundreds of hospitals in 2011, 2012, and 2013, battery management emerged as a top 10 medical device challenge. In the 2013 survey, 50% of respondents cited battery management as a challenge, ranking it “higher than alarm management, infusion pumps, and cybersecurity,” as the FDA's devices and processes with an eye on improving patient care.

Challenges with battery-powered medical devices extend beyond hospitals and other clinical settings. “Many medical devices have migrated to homes, into environments for which they are not necessarily intended, with harsher use by people who don’t have healthcare training,” Maisel says.

Battery issues are migrating to homes and other nonclinical settings along with the devices. For example, the FDA’s Mary Weick-Brady, senior policy advisor at CDRH, cites a July 2013 case study of a home-use ECG machine with a lithium-ion battery recharging on a home kitchen counter. The family heard popping noises and found the “jumping battery” on the floor—and in flames. The patient’s son put the fire out by stomping on the battery. While no injuries resulted, the incident exemplifies a potential fire hazard in recharging batteries.

Lithium-ion batteries offer much higher energy density than other alternatives, providing long run times with less frequent recharging required. They also do not suffer from the so-called “memory effect,” which means that a battery holds less charge after repeated recharging. Lithium-ion batteries can be charged, fully or partially, at any time, greatly simplifying battery maintenance. Still, if overheated or overcharged, lithium batteries can rupture and combust.

In nonclinical settings, Weick-Brady says, the environment of use, users, and devices are even more highly variable than in clinical settings—and few patients or family caregivers are prepared to head off or troubleshoot battery issues. “What may be innocuous to [healthcare technology experts] may be an emergency to a user,” she says. To learn more about issues related to the use of healthcare technology in nonclinical settings, including emergency considerations, see the AAMI publication, A Vision for Anywhere, Everywhere Healthcare, available for free at www.aami.org/summit2013/index.html.

‘Mixed Bag of Challenges’

Dave Marlow, a certified biomedical equipment technician with the University of Michigan Health System, has been working with and testing medical device batteries in most hospitals. “Some hospitals have stopped using some of these devices.”

Even in a highly controlled acute care setting, Krumlauf considers “what happens when the lights go out” during routine power checks and in emergencies—when generators and batteries power medical devices for critically ill patients. “If you were me, a nurse or a healthcare provider, and the power is out,” he says, “you’d wonder, ‘How long will the power be out? Can you plug in all devices? Which devices should you plug in? What do we do next?’”
hospitals for more than 35 years. He categorizes the “mixed bag of challenges” with batteries as follows:

- Different battery technologies
- Manufacturers with different approaches
- Different applications
- Different levels of criticality
- Medical facilities with different capabilities
- User training and experience differences

At the FDA workshop, several presenters expounded on these challenges. The sheer number and variety of battery-powered medical devices compound the challenges in both clinical and nonclinical settings. The evolution of miniaturized, low-powered electronics; the demand for portable, mobile, and wireless devices; and the convenience of avoiding software boot-up time are contributing to the surge in battery-powered medical devices, ECRI Institute’s Lavanchy says.

The quest for smaller batteries comes at a cost. “The persistent demand to reduce battery size, increase longevity, and add device features continues to drive batteries with more power and energy in a smaller package, which inherently adds risk,” says Dominick Frustaci, vice president of R&D and product development engineering at Greatbatch Medical, a company that designs and manufactures batteries and other components for healthcare technology.

There are many types of batteries—for example, lead acid, lithium-ion, nickel cadmium, nickel–metal hydride—each with different chemistries, characteristics, and charging and maintenance requirements, depending on the manufacturer. Some batteries are built into medical devices and are hard to access, or require battery support systems to manage and service them.

Battery applications and levels of criticality in these applications vary considerably as well. Some batteries are the primary source of power, as with implantable devices. Others provide secondary, redundant, or backup power or functionality for devices or device accessories.

For some applications, such as defibrillators, transport ventilators, heart-lung machines, ventricular assist devices, and intra-aortic balloon pumps, batteries are vital, Lavanchy says. For others, such as patient lifts, infusion pumps, surgical saws, suction pumps, and mobile X-rays, they are helpful. But he sees the use of batteries in other devices, such as patient scales, sequential compression devices, stationary infant incubators, and operating rooms, as questionable. Batteries can be a “blessing” or a “burden,” he says.

“There is a tradeoff between the convenience of battery power and the burden to maintain them,” he says. “Maybe it is a bit of a luxury factor in having all these devices with batteries. Maybe we’re putting batteries in devices just because we can.”

The maintenance challenge is exacerbated by the reality that medical facilities and users differ in their capacity for proper battery use, servicing, and supportability. Clinicians might not know that the intended use for batteries in some medical devices is for backup power only. Operating a ventilator, for example, in battery mode might result in exceeding the recommended battery backup time.

Medical facilities also are increasingly burdened with the service requirements of battery-powered medical devices and equip-

---

A patient monitor that was damaged from a battery fire. There was no harm to the patient, but the monitor was totaled. An investigation pointed to a problem with the battery’s safety circuit.

The information was taken from FDA’s website which features presentations from the agency’s July 30-31, 2013 workshop on battery-powered medical devices.

**A Mismatch between Battery And Device Life Cycles?**

Why can’t batteries last as long as the projected life cycles of the devices they power? That question arose repeatedly during the FDA workshop on battery-powered medical devices.

Aligning battery and device life cycles will require innovation and multidisciplinary collaboration. Such open innovation efforts could be spurred by incentive prizes such as those offered on Challenge.gov, the federal government’s platform for open innovation, according to Cristin Dorgelo, assistant director for grand challenges at the White House Office of Science and Technology Policy.
What can HTM professionals do now to help with the effective maintenance of battery-powered devices?

- Ask manufacturers and third-party battery vendors to supply manuals, instructions for use, and/or labels with recommendations on how to manage batteries.
- Develop a repository of labels for battery-powered medical devices with simple battery instructions for clinicians and/or patients (e.g., “Plug In!”).
- Develop and follow a battery management plan—and adjust the plan as needed.
- Ensure that workbenches have appropriate equipment and tools for inspecting, testing, charging, and replacing batteries.
- Maintain an inventory of spare batteries and accessories.
- Provide consistent and ongoing education and training to staff responsible for the use, maintenance, charging, and replacement of battery-powered medical devices.
- Provide staff with information about the cost implications for replacing batteries.

A Closer Look

Experts say the many challenges with battery-powered medical devices generally fall into these four areas: purchase and replacement; charging; testing; storage, transportation, and disposal.

Purchasing and replacing. As they do with sourcing and replacing many components and parts of medical devices and equipment, most HTM professionals rely on both original equipment manufacturers (OEMs) and third-party vendors for batteries. Most also use one or more trusted vendors, according to an AAMI survey of HTM professionals on battery issues.

“Some hospitals say they use OEM batteries in the highest-risk applications,” Lavanchy says. “Most are concerned about risk and liability.”

That is certainly the case for Nationwide Children’s. “When children are burned, that makes the news,” Bradley says. The hospital used to change batteries only upon failure—until a scorched patient monitor led to changes in that process. The monitor battery, which had failed 30 days prior to that event, had been replaced with a new, non-OEM battery when an apparent safety circuit failure occurred while the monitor was in use in a patient room. The patient was not harmed; the monitor was totaled.

Now, all batteries are replaced every two years at Nationwide Children’s. Only OEM batteries are used for life-safety and critical equipment. The hospital also has limited the number of vendors from which it procures batteries, and attends to evaluating battery quality during preventive maintenance and when batteries are removed.

It’s unclear, however, whether or how OEM batteries differ from those of third-party suppliers. An analysis by ARAMARK of OEM vs. non-OEM batteries revealed wide variability in battery-induced failure rates (from approximately 4% to 70% per year) and wide variation in standard deviations on the tested values, in three models of defibrillators, two models of infusion pumps, one model of a patient-controlled analgesia (PCA) pump, Doppler ultrasound, and ventilator, respectively (Lipschultz, 2013). But the data on these devices did not indicate any difference in failure rates between OEM and non-OEM batteries.

“The ARAMARK conclusion is that the primary cause of premature battery failure seems to be a mismatch between the OEM expectations and clinical users’ understanding and ability to care for the batteries,” says Alan Lipschultz, president of Healthcare Technology Consulting, who presented the ARAMARK findings at the FDA workshop.

Finances are a significant issue as well when it comes to battery procurement and replacement. “The cost of changing batteries is expensive,” Bradley says. “We probably spend $100,000 a year changing batteries.” Healthcare technology managers need to weigh cost, value, quality, and reliability of OEM vs. non-OEM batteries.

Charging. Like Goldilocks in the children’s fairy tale, it can be difficult for healthcare providers and other device users to find the “just right” charging level for batteries. Batteries can be overcharged, which can lead to battery (and device) damage, loss of power, swelling, leakage, or explosion. Undercharging batteries can result in premature depletion and loss of power. Older batteries tend not to hold a charge as long as newer ones. Some batteries require a full charge–discharge–charge cycle periodically—and that process needs to be tracked and managed.

Not all batteries, or battery-powered medical devices, provide an indicator of battery status—and those that do can be hard to decipher or even wildly inaccurate, notes Bruce Adams, vice president of sales, Cadex Electronics Inc., a battery charger and analyzer manufacturer. Not all battery indicators give users sufficient advance notice that the battery power is running low.

Excessive heat, cold, dampness, and debris in the environment of use can cause failures in batteries, wiring, and connections, such as early deterioration, overheating, short circuits, corrosion, swelling, leakage, or premature discharge.
Any of these issues can delay treatment, or result in inappropriate treatment or hazardous situations, in patient care.

**Testing.** Procurement, replacement, and charging challenges underscore the importance of testing batteries for reliability and predicting device performance. “A battery test is important,” Adams says. “It tells you where the battery is in its life cycle, removes a risk, provides a time and date stamp for quality assurance. It’s important to make testing part of best practice in the healthcare market.”

Testing should begin with manufacturers and third-party battery vendors—through the processes of battery and device design, development, and production—and continue with HTM professionals when battery-powered medical devices are in the field. As batteries become smaller and more sophisticated, the testing regimen has become a greater challenge for both.

At Cadex Electronics, “the battery gets treated like a medical device,” Adams says, with tagging and tracking of battery data and serial numbers and supplier information. Battery testing is essential even for new batteries. “Not all new batteries perform,” he says. Over time and with use, “smart” digital batteries drift away from optimum capacity levels; routine testing and calibration during preventive maintenance can correct this issue, extend battery life, and reduce replacement costs.

Battery testing is time consuming and requires a dedicated workbench, testing tools, procedures, and trained personnel, says Marlow of the University of Michigan Health System. Most clinical facilities cannot test every battery; some prioritize testing of batteries used in life-critical applications and of non-OEM batteries, and test samples of other batteries. This is not a fail-safe approach, however: Even batteries from the same supplier and lot can differ in their readiness for use and in their performance, says Alex Fay, senior business development manager, Quallion LLC, a manufacturer of lithium-ion batteries for medical, aerospace, and military applications.

The one type of battery that should always be tested, Marlow says, is the failed battery. “You learn more from failed batteries than from new ones,” he says.

Primary batteries used in implantable medical devices, such as pacemakers and defibrillators, pose special testing challenges for manufacturers and healthcare providers. Implantable medical devices can be designed to last 10 years or more; testing to ensure that their batteries will last that long is vital for evaluating reliability and predicting device performance, according to Michael Root, science fellow at Boston Scientific, a medical technology company.

“Extensive testing is done at all stages of the product life cycle,” Root says, including discharge, electrical, and environmental testing during design and manufacturing. “Predicting the end of life of a battery is a challenge. It’s often impractical to test devices and batteries for 10 years. There’s an important role for battery bench testing.”

“Once in the marketplace,” Root adds, “patient follow-ups are important to monitor their condition and their device. Remote monitoring at home can be done more frequently than clinic visits. Cardiac rhythm systems and other implantable systems have home monitoring systems.” But patient compliance with monitoring can be a challenge, Root says.

Both Fay and Root cite battery component and materials sourcing as a challenge for implantable battery cell manufacturers. “Supply chain quality risks are real,” Fay says. He points out that 90% of the world’s cell production is for consumer products, not for high-reliability, high-risk applications such as healthcare technology. “Many suppliers refuse to supply in the medical device space due to concerns about litigation, small market opportunity, and unique materials,” adds Frustaci of Greatbatch Medical.

“Cell and material quality vary,” Fay says. “Variations in production lots of materials can be very difficult to identify,” which underscores the need for strict oversight of materials suppliers, full traceability of materials and finished cells, sampling multiple lots of key materials, and long-term testing of retained samples from each lot.

What Would Help Hospitals?

Ken Maddock is vice president of facility support services with Baylor Scott & White Healthcare in Dallas, TX. He offered the following suggestions for how battery performance could be improved.

“The reality is that we waste a lot of money by replacing batteries before it is absolutely necessary. Better diagnostic tools designed by the manufacturer specifically for their device that give you more accurate data on the condition of the battery and when it should be replaced, whether built into the device or available separately, would be a huge value.

“Associated with that is better error messages. The messages that come up when there are battery issues are often confusing to the customer and lead to unnecessary calls to the healthcare technology department and time spent by HTM technicians that could be better spent elsewhere. Messages that more clearly indicate the action that needs to be taken would lead to much greater efficiency and increased uptime.”
This kind of vigilance comes at a cost, Fay says, but this cost is probably worth it for batteries in life-critical devices. And it might save money down the line, and reduce the indirect cost and risk of surgery to replace batteries on implantable devices, costs of replacement batteries, staff time lost when a battery dies unexpectedly, maintaining an inventory of spare batteries and accessories, recharging equipment, and patient inconvenience.

**Storage, transportation, and disposal.** Healthcare providers and HTM professionals report that storage of batteries (and battery-powered medical equipment) is a problem. Backup batteries, and equipment that is not in use, take up space, but they need to be readily available when they are needed. Some batteries and devices have special storage requirements, such as temperature-controlled areas, and they might need to be tested or reconditioned after prolonged storage.

That’s an enormous challenge for the military, which stockpiles battery-powered medical devices all over the United States and the world. “We buy 1,000 infusion pumps and store them for a couple of years,” says Master Sgt. Curt Straub, CBET, non-commissioned officer in charge, U.S. Army Medical Materiel Agency, National Maintenance Program. “That’s what we do.” That equipment needs to be ready for deployment anywhere in the world at a moment’s notice. “Batteries are essential in a deployed environment to enhance power reliability,” Straub says. Diesel generators provide initial power until a stable electrical power grid can be erected. “Power reliability is questionable, especially at first,” he adds.

Temperatures in deployed environments can be brutal—well over 110°F in the summer in Kuwait and Iraq, for example, and as low as 25°F in the winter in Afghanistan, he says. Extreme environmental conditions impact battery charge capacity. For example, a sealed lead battery stored at 68°F takes 16 months to reach 50% state of charge; stored at 104°F, it takes only four to five months to reach that state of charge. Charging requirements during storage differ for different battery types as well; specifications range from fully charged to charged to discharged.

Transporting batteries and battery-powered medical devices also is problematic, for the military and for everyone else—particularly when large quantities are shipped. “Lithium batteries are regulated in transportation because they present chemical and electrical hazards and have more power than batteries with other chemistries,” says Kevin Leary, a transportation regulations specialist with the U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration. Lithium batteries, and some other types of batteries, must be carefully packed to protect against short circuits, damage, and excessive movement; labeled as potentially hazardous; and handled safely.

In addition, “transportation test requirements are required for all lithium and lithium-ion cells and batteries,” says Rich Byczek, the global technical lead for electric vehicle and energy storage at Intertek, a testing and certification provider. Individuals traveling with battery-powered mobility aids, personal electronics, and medical devices must meet special transport requirements as well. Mobility aids must be transported as checked baggage unless the battery is specifically designed to be removed during transit, Leary says. Users must verify that there are no obvious defects in the equipment, battery terminals are protected from short circuits, the battery is securely attached, and electrical circuits are isolated. Personal medical devices are permitted in checked or carry-on baggage; spare batteries are permitted in carry-on baggage only.

Finally, safe, proper disposal of batteries is a concern. Again, different batteries have different disposal requirements; some batteries can be tossed in the normal trash, others cannot. “Disposal issues are significant,” Lipschultz says.

**Potential Solutions**

Like many intractable challenges in healthcare technology, addressing multifaceted challenges with batteries and battery-powered medical devices will require multidisciplinary collaboration and commitment to achieve solutions. Participants at the FDA workshop offered these starting points:

**Standardized practices.** Multiple national and international standards and regulations for battery design, development, testing, certifica-
tion, and transport exist. But many standards apply to specific battery types, and they are not necessarily harmonized internationally.

“Solutions exist, but they are highly dependent on the type of device, the battery technology, and the intended use,” says Root of Boston Scientific. “It would be difficult to implement a single set of prescriptive standards or guidelines that could be applied to all devices.”

However, “general guidelines related to expectations of certain ‘bodies of knowledge’ for the battery selection/design and verification process may be useful,” says Craig Schmidt, senior director of energy systems research at Medtronic, a medical technology company.

Still, most workshop participants advocated for such standardized practices as incorporating battery charge indicators on devices, with actionable alerts that give clinicians, HTM professionals, or caregivers adequate time to change batteries without disruptions in patient care or safety hazards. As one respondent to the AAMI survey of HTM professionals on battery issues asked: “How much time before the device fails?”

Manufacturers also advocated for recognition of modeling methods for designing and testing batteries, particularly for batteries used in implantable medical devices. “For implantable batteries, it is necessary to test a new battery technology for many years before it can be designed into devices,” Frustaci of Greatbatch Medical says. “This results in slow adoption of new technologies.”

“Battery models are often an important component of the design/selection and verification process,” Schmidt says. Models are useful in translating device requirements to battery requirements, criticality, rationale, specifications, and design or selection; verification of testing strategies, plans, and data; simulating use conditions and labeling; accelerated tests of battery performance; and verification and validation of device performance.

“Adoption of these models by regulatory bodies in support of device submissions would help improve confidence and reliability, as it is not practical to have long-term—more than five years—of real-time test data available at the time of submission,” Frustaci says.

Human factors and systems approaches to design of battery-powered medical devices.

Poorly designed user interfaces on battery-powered medical devices contribute to use (not user) errors, says the FDA’s Ron Kaye, leader of the human factors premarket evaluation team with CDRH. Identified issues—such as confusion with on/off buttons, difficulty determining battery charge levels, insufficient response time when batteries need to be recharged or replaced, and battery reversion to default settings during power outages—could be resolved with attention to human factors during device design. “Human” human factors, Kaye says, include:

- Perception (e.g., visual, auditory, tactile)
- Cognition (e.g., interpreting meaning, recalling information, decision making, training, motivation, expectations)
- Actions (e.g., physical interactions, what users do and don’t do)

“Nonhuman” human factors are at play in healthcare settings as well, including noise, workload, number and variety of devices in the use environment, and the medical device user interface, Kaye says. Inadequate interfaces allow users to make errors that could be prevented, fail to orient users to problems in time to prevent them, and lead users to make errors.

“We need to know how these devices are used—not how the manufacturers want them to be used,” Kaye says. Manufacturers need to understand user expectations for how the device will work, how problems occur during use, and the critical tasks that users perform. That understanding can be gained through user-centered techniques such as focus groups and interviews with users, contextual inquiry, and simulated usability testing. Iterative, formative usability testing with prototypes can be used to improve interface design. Summative testing can provide data that validate usability.

Ensuring the safety of battery-powered medical devices requires an understanding of how the battery interacts not just with the device, but with the rest of the system, says the FDA’s Hamed Ghods, electrical engineer with the Division of Electrical and Software Engineering at the CDRH Office of Science and Engineering Laboratories.
He shared the case of a defibrillator that, after analyzing patients’ ECG waveforms and determining that a shock was needed, would sometimes shut down before delivering the shock. The device had a voltage monitoring circuit that was designed to shut the device down when the battery had insufficient charge remaining to deliver a shock. The manufacturer’s investigation revealed that this protective circuit would malfunction under certain conditions and shut down the device, even though the battery actually had enough charge to complete the operation.

“Our independent investigation uncovered a second design issue that had been overlooked by the manufacturer,” Ghods says. “The power conditioning circuitry of this defibrillator included several integrated circuits that converted the incoming battery voltage to different voltages needed by the system. By design, the voltage converter chip requires input voltages greater than 9 volts to operate. However, the battery voltage could drop as low as 7.7 volts during the run-up to delivering a shock. As a result, all of the downstream circuitry powered by this chip was likely to be adversely affected in the critical seconds immediately before the shock was delivered.

“The systems engineering approach can deal with this complexity and understand how parts interact with each other and with the patient,” Ghods adds. “The battery is one component of a complex system. It needs to be chosen correctly to assure that the host device meets its specifications. The device design needs to satisfy the operating requirements of the battery. The design engineer’s task is to know the failure modes of these components and design the system to fail safe if any of the components fail.”

Figure 1 shows a battery-powered medical device system, and some points at which system protections can be incorporated. From a systems engineering perspective, each component of the system has characteristics that introduce risk. A structured risk management process is used to identify the salient risks and corresponding protective measures. For example, overcurrent protection may protect the battery from a downstream short circuit. Over- or undervoltage protection may mitigate against a failure in the power conditioning circuitry, or shut down the system in an orderly way when the battery charge is no longer sufficient to assure that the system will perform correctly. In many real-world designs, these protective measures add quite a bit of complexity to the system, and some protective measures may introduce new risks that must be mitigated. A thorough understanding of how these components interact with one another, with the user and patient, and with the environment is essential.

**Battery management plan.** Given all the challenges with battery-powered medical devices, Marlow of the University of Michigan Health System recommended that healthcare facilities develop a battery management plan. That plan should cover such topics as prepurchase considerations, testing and maintenance schedules for batteries, procedures during power outages and emergencies, replacement and disposal policies, training, and equipment.

**Information, training, and education.** Clinicians and patients need more useful and consistent information to manage the battery-powered medical devices in their lives.
Instructions for use and labels are not very useful for people who are not device or battery experts—and they often are not available.

For example, clinicians need training, and reminders, to reinforce the need to plug in medical devices so battery power is not depleted, says Ron Charnock, chief operating officer, Kwikpoint, a communications firm. “New training material by itself will not change behavior,” he says. “How you package and deliver training and materials is as important, or more important.” For example, a short, colorful “Quick Start Guide” or “Plug In!” label on a device could be more useful and effective than lengthy, complex, and confusing instructions. In addition, he says, usability testing of information and training materials is important.

New media could help with communication, training, and education as well. Kwikpoint developed a social marketing campaign for the FDA to provide information to healthcare providers and individuals with diabetes on proper sharps disposal. “Battery change fits this model in terms of content and packaging,” he says.

Even HTM professionals who are comfortable working with batteries need training and education to keep up with new battery technologies and testing methods. “Understanding maintenance, how to maintain the stated charge—the education piece can be very complicated for all of us,” Frustaci says.

Innovation. Finally, manufacturers, HTM professionals, and regulators say that innovations and new science will be needed to improve batteries and battery-powered medical devices. Could new materials or different chemistries be used to increase battery longevity—or reduce or eliminate the need for battery charging altogether? Time will tell.

Or, perhaps, a true breakthrough will remake the battery landscape. That’s the direction in which researchers are headed. A team at the Massachusetts Institute of Technology (MIT), for example, experimented with wireless energy to power a light bulb. Now, an MIT spinoff, WiTricity Corp., is advancing that technology, known as highly resonant wireless power transfer. Highly resonant devices are tuned to the same frequency and exchange energy via an oscillating magnetic field, according to Colin McCarthy, sales engineer for automotive, industrial, medical, and military at WiTricity. Highly resonant coupling enables charging at a significant distance.

Elsewhere, Michael McAlpine, assistant...
professor of mechanical and aerospace engineering at Princeton University, and his colleagues are investigating the possibility of human-powered implantable or wearable medical devices. The idea is to harness and convert the mechanical energy that the human body produces with normal breathing and motion into enough electrical energy to power portable electronics.

The research—which is supported by the Army Research Office (ARO), Defense Advanced Research Projects Agency (DARPA), DuPont, and the Project X innovation fund—relies on nanotechnology, advanced materials, and plenty of advanced STEM (science, technology, engineering, and mathematics) know-how.

Such possibilities look promising. That’s good because the role batteries play in modern healthcare technology is omnipresent and crucial. Says the FDA’s Maisel: “It’s hard to think of a medical device component that is more important than a battery. It’s easier to generate a list of devices that don’t rely on batteries.”

---

**Resources and References**


