What are the biggest challenges facing clinical engineering and biomedical departments when it comes to medical devices? AAMI sought to find out with its first survey of that sweeping question, and more than 400 hospitals responded. The results underscore several points about the current state of medical technology and its professions.

One, information technology (IT) plays a huge and growing role in clinical engineering. In fact, three items on our list are IT-related. “The issue of medical equipment and computers, and how they interact, how they work together, and the paradigm shift for clinical engineering departments to shift focus in this very direction are very important for the industry,” says Jeff Hooper, director of the Department of Biomedical Engineering at Children’s National Medical Center in Washington, DC.

Two, the idea of interaction and connection extends well beyond devices and computer networks. It’s also about people. No single department or organization can operate in isolation when it comes to the delivery of top-notch healthcare, whether it’s the clinical engineer (CE) or biomedical equipment technician (BMET) who services the device, the IT specialist who supports the network, the clinician who uses the device, or the manufacturer who makes it. Ray Zambuto, president of Linc Health LLC—a Holliston, MA-based company specializing in solutions to healthcare technology—says there’s a marked change “in the functioning of the clinical engineering department from one whose focus has been the technical support of the equipment to one where the focus is the technical support of the care delivery system.”

Christopher Nowak, director of Clinical Engineering Services and Healthcare Technology Integration with Universal Health Services Inc., describes it this way: “Everything we do is for the benefit of the patient and impacts the outcome of their care.”

Finally, while change is ubiquitous in the medical technology field, there are also some constants. Some of the challenges—maintenance of batteries, for example—have been around for decades. They are “classic” challenges, according to Robert H. Stiefel, president of Baltimore-based RHS Biomedical Consulting LLC, reflecting the fact that there will never be a healthcare system that’s static. “There will probably be improvements in the design, materials, technologies, and/or construction of
these devices over time, but whether they are evolutionary or revolutionary, only time will tell,” says Stiefel.

In terms of solutions to these challenges, clinical engineering veterans and other professionals hit on the same broad themes: better education and training, stronger communication and cooperation among departments, and, often, a need for standards.

Does this list represent all of the device-related challenges out there? Absolutely not. But it gives you a good idea of what’s on the minds of the men and women maintaining, repairing, and teaching others about the medical devices that have become such a critical part of healthcare around the world. Hooper puts it another way, describing the survey results as “comforting.” What does he mean by that? “I am happy,” he explains, “that the same issues that are facing me in my hospital are those that my peers are facing.”

Here’s AAMI’s list:

1. **Interfacing Between Devices and Information Systems**

   A big category, this speaks to what Hooper calls the “huge transition” in clinical engineering, a point drummed home by others. “For a number of years now, the trend for clinical engineering has been to become increasingly intertwined with information technology ... This trend will continue,” says Stiefel.

   More and more, medical devices are being plugged into networks, and today’s successful biomed needs to have some grounding in IT training. “In general, it seems to be more effective to start with a good BMET and add the IT education and training, than to start with an IT tech and try to get them up to speed with biomedical engineering technology,” Stiefel says. “The best solution to the problem is to provide appropriate education and training.”

2. **Maintaining Computerized Equipment and Systems**

   Closely related to the first, this challenge encompasses things such as upgrades, updates, and virus protection.

A key ingredient in meeting the challenge of making sure devices work and “speak” to one another and the network as a whole is, according to the experts, developing a healthy relationship with the IT department. In fact, Dave Francoeur, vice president of operations with CREST Services near Dallas, says that whether IT-related issues are actually a challenge at your hospital is “completely dependent on your relationship with the IT component of your organization and your ability to work with them and ensure them you can bring value to the table.”

To be sure, there are other obstacles to integration, such as aging equipment and a lack of standardization at the point of purchase. Those who are facing these issues say it's critical for CE departments to weigh in early on purchasing decisions, share their expertise with clinicians, and play a big role in developing integration plans, especially with the move toward electronic medical records (EMR).

“The forward-thinking clinical engineering departments are quickly defining or refining their relationships with IT, clinical, and supply chain leadership so they can play a full and integral role in the EMR process,” says Carol Davis-Smith, a director with Premier Consulting Solutions in Phoenix.

**How Did We Compile the Top 10 List?**

AAMI's list of Top 10 Medical Device Challenges stems from a research survey commissioned in November. Conducted by the professional research firm, Stratton Publishing & Marketing Inc./Stratton Research, the survey was conducted via e-mail with questions sent to 2,522 hospital-based biomedical equipment technicians and clinical engineers, asking them to rank a list of 22 device-related challenges. Those challenges were identified by a task force of AAMI leaders and staff.

There were 418 responses, and the poll results have a margin of error of plus or minus 4.62%.

With the results in hand, AAMI editors then interviewed numerous clinical engineering veterans and other medical technology professionals, seeking their input and analysis. With that feedback, we took the results to craft a top 10 list, combining some categories when there was significant overlap.

“Everything we do is for the benefit of the patient and impacts the outcome of their care.”

—Christopher G. Nowak, Universal Health Services Inc.
In other words, once that “interface” is established, how do you keep things running smoothly? Guarding against viruses and other malware is a big concern of hospitals and other healthcare facilities. Axel Wirth, the healthcare solutions architect at Symantec Corp., a global software and services company, says that medical devices “form a unique exposure profile to cyberthreats”—at a time when such threats and attacks are on the rise.

But protecting against viruses can present its own problems. “An anti-virus program can negatively impact a device, most often by slowing down the operation of the device to the point that it’s ineffective,” says Kenneth Maddock, vice president of clinical engineering and telecommunication services for Baylor Health Care System in Dallas. Manufacturers, Maddock says, can play a crucial role here by validating “their equipment/systems with the most popular anti-virus programs” and by providing clear instructions on how to install anti-virus programs on particular devices.

In today’s hospitals, technicians must understand that they’re rarely working on a piece of equipment by itself. Maddock gives the example of a patient monitor that works fine when it’s not plugged into the network, but malfunctions once it is plugged in. “A technician who is an expert on the device, but doesn’t have networking troubleshooting skills is at a loss and unable to resolve the problem,” Maddock says.

Survey respondents cited the issue of alarms a number of ways, including alarm fatigue in which clinicians grow virtually immune to alarms because there are too many of them going off too often; alarms that can’t be heard; and similar-sounding alarms. Alarms management is far more than an academic debate about sounds. It’s a matter of life and death with documented cases of patients who died because alarms were either ignored or could not be heard. Hooper sees an opportunity here for CE departments to shine by educating and training the clinical staff about the setup, default settings, and proper use of alarms.

Mindy Gonzales, with the VA Medical Center in Alexandria, LA, says technicians should also instruct clinicians that accessories to a device can impact alarm function. “Many clinicians just assume it is the device and won’t check accessories as often as they should—even if told to,” she says. “This takes a great deal of building rapport in order to educate clinicians without them feeling insulted.”

Manufacturers, say biomeds, have a big role to play in continuing to improve the design of devices, so the alarms themselves can’t be ignored or turned off. Craig Baku- zonis, director of clinical engineering at Shands HealthCare in Gainesville, FL, says biomeds can help manufacturers by sharing feedback with them on alarm performance in the work environment.

AAMI takes a comprehensive look at the issue of alarm systems in an upcoming issue of Horizons, due out this spring.

4 Maintaining and Processing Endoscopes

Just say the word “endoscopes” and you’re likely to elicit a spirited reaction from biomeds. “A nightmare,” says one clinical engineering veteran.

Whether it’s questions over how to properly clean them or how to maintain them as part of an inventory, endoscopes have become a huge issue for many clinical engineering departments and hospitals in general. “Endoscopes are important because there are a lot of them, they are expensive, they break easily and often, and because of the sensitivity of the issue in hospitals,” says Francoeur. “Doctors get angry when scopes don’t work.”

The Joint Commission’s announcement in 2010 that endoscopes are considered medical devices means that CE departments should include them as part of their inventory. That’s a particular challenge for rigid endoscopes as they are replaced frequently, making them difficult to track.

The commission’s move stems from a broader effort to manage and clean the devices, which have been the subject of alarming news stories about cross contamination and patients being infected with transmittal diseases, such as hepatitis, after undergoing endoscopic procedures with instruments that likely hadn’t been properly cleaned.

Another challenge for many CE departments has been transitioning to a new sterilization system after the U.S.
Food and Drug Administration (FDA) in 2010 questioned the safety of the popular Steris System 1, used to sterilize endoscopes. While Steris disputed FDA’s assertions, the company last year agreed to a recall and transition plan for System 1 customers.

Francoeur says issues with endoscopes represent an “opportunity” for CE departments to help solve a big problem for hospitals. “If handled properly, it can be a great win,” he says.

Broken Connectors

“Virtually all medical devices have some sort of connector,” says Maddock. “They are not built to be very sturdy and they can be difficult to replace.” The sheer volume of broken connections may be one reason this is such a headache for CE departments.

Jim Welch, vice president of patient safety initiatives at Masimo Corp., a global medical technology company based in Irvine, CA, says broken connectors are the most common cause of “no problems founds (NPFs)” when a clinician raises a concern about a device and then a technician checks it out. In other words, the problem is the connector as opposed to a malfunctioning device.

Every connector, he explains, has a finite life, a limited number of connections before its reliability becomes uncertain. When it starts to fail, it doesn’t just break immediately. It fails intermittently, working sometimes and not others.

One solution? His company has put a timer in connectors. Once a predefined number of connections has been reached, the instrument displays a message: “You need to replace the connector now.”

Design improvements, Welch says, will extend the life of connectors, but he believes the lasting solution will only come when hospitals go completely wireless. That, or course, presents its own set of challenges.

Battery Management

“Batteries! A biomed’s nemesis,” says Gonzales. She suspects many survey respondents didn’t even bother to rank batteries as a challenge “because we are so used to this being par for the course.”

David Stiles, director of the Biomedical Engineering Department and Central Equipment Services at Long Beach Memorial Medical Center in California, says the fact that so many different types of portable devices rely

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—Dave Francoeur, CREST Services

Infusion Pump Challenges

The AAMI survey asked respondents to rank separately the biggest challenges related to infusion pumps, those devices stationed alongside nearly every hospital bed, delivering medication and nutrients to patients.

Named as the biggest challenges:

• Wear and tear on infusion pumps
• Use errors
• Battery management
• Lack of knowledge and effective training
• Uploading and managing drug libraries

An AAMI infusion device safety council—a byproduct of an AAMI/FDA summit held last fall—is already looking at those issues and more. For more information, visit www.aami.org/infusionsummit.
on batteries, underscores how critical it is for healthcare facilities to have a good handle on effective battery maintenance.

“Failure of facilities and personnel to remember to manage their batteries will result in more medical equipment failure,” he says.

How should facilities accomplish this? By including battery maintenance and replacement in their budgets and by making sure it’s part of the preventive maintenance (PM) program for each piece of equipment. “Training the staff to properly stow and charge all returned devices is also a clinical engineering goal,” Stiles says. (For more tips from Stiles, read the sidebar that accompanies this article.)

Stiefel sees some progress in improved battery technology, but he and others say there’s a long way to go.

Gonzales wants manufacturers to “design battery circuits for medical devices that are less dependent on plugging in” and would also like docking stations with “quick-change” batteries “for all medical devices that are critical to care, especially IV pumps.”

Hooper says recent natural disasters, such as hurricanes and earthquakes, underscore the importance of battery maintenance in any healthcare facility. “This is a huge issue for us to constantly be on top of,” he says.

**Problems With Patient Monitors**

The variety and the sheer number of patient monitoring devices can pose a challenge to those biomeds who must maintain them. Hospitals often have many models when it comes to patient monitors, translating into more time when it comes to training and troubleshooting.

“Mostly, there’s a need for standardization with the same manufacturer, the same model whenever possible,”

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**All Charged Up Over Batteries**

Given that batteries impact a multitude of medical devices, we asked one expert for his advice on solutions to effective battery maintenance. Here are some tips from David Stiles, director of the Biomedical Engineering Department and Central Equipment Services at Long Beach Memorial Medical Center in California:

- Set up and establish replacement or reconditioning schedules for battery operated devices. For example, anticipate replacement of lead acid batteries from 18 to 24 months depending on usage and service. In some cases, such as large capacity transport isolette batteries, replacement may be needed in only 12 months.
- Ensure that the users have all the tools and space needed to plug their devices in after battery operation. Many battery failures occur simply due to no AC outlets being available. Provide users with additional replacement battery packs and chargers as in the case of transport physiological monitors and defibrillator devices. These prove beneficial in areas with many transports ordered throughout the shift.
- If portable devices are distributed from a central equipment source, ensure that time is allowed for charging and testing the devices’ battery levels.
- Plan and budget equipment inspections that will include battery replacement. As an example, schedule similar equipment to include battery replacement in the same month. This will minimize the time that new batteries are left on the shelf, and battery replacement can be ordered prior to work starting. Have the battery replacement schedule included in the preventive maintenance (PM) work orders when they are due for service or replacement.
- Focus on the design of the equipment itself. Many times, we find external chargers or power supplies that come equipped with only a slip on power connector. Many battery failures result from these slipping from their receptacle due to transport or cleaning. Provide strain reliefs and securing methods to minimize these connection systems. When evaluating new equipment, specify the security of external chargers. We can also consider equipment with integral power supplies and secured AC line cords to prevent inadvertent disconnects.
says Izabella Gieras, director of clinical technology at Huntington Memorial Hospital in Pasadena, CA. “We often still have different vendors, different models, and different vintage of equipment in the hospitals.”

Stephen Grimes, vice president of enterprise resource planning with Linc Health LLC, says the most important decision on monitors comes at the point of purchase. “Providers today can ill afford to select and deploy monitoring systems in one department without considering the implications of how that monitoring systems will integrate into the enterprise’s EMR and other systems,” he says.

The evolving technology used in monitors also underscores the need for an increasingly collaborative approach in making sure they function properly. “As with all critical systems, clinical engineering must work with clinicians, IT, and appropriate stakeholders to ensure they have established a risk management process that identifies vulnerabilities associated with these monitoring systems and mitigates all significant risks,” he says.

Monitors, he predicts, are likely to become an even bigger issue with their increasing use, “not just for the majority of in-hospital patients, but also for monitoring the chronic conditions of patients in the home, at work, and around the community.”

**Problems With Dialysis Equipment**

These life-sustaining machines can, in the words of Lane McCarthy, a technical/facility manager with Rubin Dialysis Center Inc. in Troy, NY, “pose special hurdles to a clinical engineering group.”

Why? They are complex and the nature of their extended use by patients makes it something of a challenge to schedule preventive maintenance (PM) service. “A standard PM will take between three to five hours, depending on the device and the age of the equipment,” McCarthy says. That doesn’t even take into account the possibility of finding potential problems that need to be fixed, adding more time to the process.

“We’ve found that it is best practice to review the service schedule with clinicians and nurse managers responsible for dialysis service in advance of scheduled maintenance,” McCarthy says. Another advantage of such consultation, he adds, is learning of problems that had not been reported. “How may times have you heard a new service request start with the statement, ‘The _____ has been having this problem for weeks.’”

Gieras says maintenance of dialysis equipment is often outsourced, but this could be an opportunity for a CE department to demonstrate its value and expertise to a hospital by taking this in-house. “If not, ensure there is a collaborative partnership between the outsourced company and the CE department as all the documentation still needs to be available for Joint Commission compliance purposes.”

**Managing the Radiation Dose From Computed Tomography (CT)**

A valuable diagnostic tool, CT scanners also deliver potentially dangerous levels of radiation. In fact, the ECRI Institute identified “radiation overdose and other dose errors” as its top health technology hazard for 2011.

Whether the cause is human error, software-related problems, or inexperience with new technology, the consequences of improperly administered radiation can be devastating, “from causing critical damage to normal tissue and organs, which can lead to severe morbidity and death, to creating an avenue for disease recurrence through improper or incomplete treatment of a tumor,” says ECRI. What’s the challenge for biomeds? Keeping up the maintenance of radiation therapy devices and systems, ensuring that the equipment meets performance specifications.

“As technologies like these change and our understanding of both the beneficial and adverse effects of the application of these technologies evolve, clinical engineering needs to work with clinicians and other stakeholders to identify and adopt evolving best practices,” Grimes says.

**Conclusion**

AAMI’s Top Ten List of Medical Device Challenges is by no means the final word in addressing the issues that matter most to professionals in the medical tech-

The forward-thinking clinical engineering departments are quickly defining or refining their relationships with IT, clinical, and supply chain leadership so they can play a full and integral role in the EMR process.”

—Carol Davis-Smith, Premier Consulting Solutions
nology field. In fact, it’s probably better to think of this list as the start of a conversation, one colored by those broader challenges that every healthcare facility faces, such as budgetary constraints and staff shortages.

“The number one concern that I hear in the Cincinnati area is that CE managers are not able to hire the people that they feel they need to adequately maintain biomedical systems,” says Steve Yelton, program chairman of the ET and IT divisions at Cincinnati State & Technical Community College.

In the end, the most important challenge for CE departments may well be proving their value to hospital administration—and getting more support in return. Says Nowak: “The impact that a clinical engineering department has on a medical facility can be staggering, not only from a financial perspective, but also from a quality of care perspective.” (For more on Nowak’s perspective, see the Final Word column in this edition of BI&T.)

“Virtually all medical devices have some sort of connector. They are not built to be very sturdy and they can be difficult to replace.”

—Kenneth Maddock, Baylor Health Care System

Continue the Conversation

What do you think of our list? Would you add something else? Prioritize it differently? What kind of solutions do you employ at your healthcare facility?

Become a part of the discussion at one of AAMI eforums AAMI’s eforums (www.aami.org/tmcconnect/discussiongroups.html) or on AAMI’s LinkedIn community (www.linkedin.com/aami).

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