Familiar Themes in a Changing World
AAMI Survey Identifies Top Medical Device Challenges

Managing medical devices on the information technology (IT) network and integrating device data into electronic health records are the top device-related challenges for healthcare technology management professionals, according to a new survey commissioned by AAMI.

The survey results offer a microcosm of sorts of the changing world of an HTM professional—one in which routine duties, such as preventive maintenance (PM) checks, are part of a workday that increasingly contains more sweeping responsibilities, such as helping to implement a hospital-wide medical device integration plan, and often with fewer resources. One thing became abundantly clear in follow-up interviews with multiple biomeds: Their days are jammed packed, moving from one task to another with little, if any, time in between.

“There isn’t really a typical day for me as every day brings something new,” said Anthony McCabe, a radiology equipment technician with the Department of Clinical Engineering at the Ohio State University’s Wexner Medical Center in Columbus. McCabe and other professionals—biomeds, consultants, and manufacturers—responded to questions posed by AAMI after the survey to get a better sense of the challenges.

The survey results are very similar to those of the first AAMI survey on this issue last year, a reflection of the fact that many challenges are long term in nature, dealing with complex “systems” issues that often require the involvement of other departments. The results also underscore the evolving nature of healthcare in general as technology plays a bigger and bigger role in how both clinicians and HTM professionals do their jobs and, ultimately, in how patients are treated.

According to the survey results, the top 10 medical device challenges are:

1. Managing devices and systems on the IT network (72%)
2. Integrating device data into electronic health records (65%)
3. Broken connectors (50%)
4. Battery management (50%)
5. Alarm management (49%)
6. Maintenance of infusion pump systems (48%)
7. Cybersecurity of medical devices and systems (47%)
8. Setting preventive maintenance strategies (44%)
9. Medical device incident reporting and investigations (42%)
10. Medical devices brought in by patients (42%)

Respondents also cited the management of endoscopes and wireless technologies as significant challenges, as well as problems with vital signs monitors and dialysis equipment.

The vast majority of respondents, 82%, said they worked for hospitals, while 12% said they worked for independent service organizations. The majority of respondents were middle-aged or older. Close to 40% were between the ages of 45 to 54, and 37% were ages 55 to 64. Just 13% were between the ages of 25 and 44, and only 4% were younger.

About the Author
Sean Loughlin

How the Survey Worked
AAMI’s list of Top 10 Medical Device Challenges stems from a research survey commissioned by AAMI in April 2012 and conducted by Westat—a nationally recognized research and statistical survey firm. The survey was sent via e-mail to healthcare technology management (HTM) professionals in 1,900 different U.S. hospitals. Respondents were asked to rank how significant 18 specific device-related challenges are to their facility. Those challenges were identified by a task force of AAMI leaders and staff.

There were 188 hospitals who responded. With the results in hand, AAMI editors then interviewed numerous HTM professionals, seeking their input and analysis.
Matt Baretich, president of Baretich Engineering in Fort Collins, CO, said the mix of challenges listed likely reflects that different respondents have different responsibilities. “I suspect there are two large groups of respondents: some at the management level, dealing with large-scale, long-term issues, and some in the trenches—trying to keep the joint running,” he said.

That point was amplified in the follow-up interviews. While managers and directors may worry about projects that are months, if not years, in the making, the concerns of biomeds on the frontlines can be more immediate and tied to the task at hand.

“I think my biggest challenge is getting the parts at a decent price or just being able to get them,” said Mike Lindahl, a CBET with Baylor Medical Center in Carrollton, TX. “I have a lot of old pieces of equipment, and sometimes it’s hard to find parts.”

Rudy Modock, the president and owner of Buckeye Biomedical Services, an independent service organization (ISO) based in Louisville, OH, echoed that sentiment. “I would have to say in my little BMET world, the biggest device-related challenge is troubleshooting and repairing a device that is 20-plus years old, with no service manuals and no tech support, because the company went bankrupt 12 years ago!”

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Sound Familiar?

Seeking to get a better understanding of their responsibilities and challenges, AAMI asked some healthcare technology management professionals to share their daily routines. John Egan, clinical engineering technician 2, at St. Joseph’s Hospital Health Center in Syracuse, NY, provided this detailed answer:

“My typical day starts at 7:30 a.m., unless I have an equipment check-in at an offsite/satellite office or OR (which we rotate but usually at least once per week for me); then I am there anytime from 6:45 a.m. on. I come back to the office and attend our mandatory “huddle” in the morning…Then we hustle to do any equipment surprise check-ins for our main campus OR and put out any fires from the overnight staff. Two of us get to doing equipment PMs, while the third is left to do repairs for the day. If need be, one of the two techs on PMs will help out if repairs gets too daunting. Then there is always a plethora of new equipment to check in. I myself will attend meetings for projects, policy or whatever else I am asked to deal with.

And since we are trying to attain our ISO 9001 certification this fall per DNV [an accrediting body] regulations, I have been busy writing and revising both policies and guidelines for our department and the hospital. I am also a lead internal auditor for the hospital, so I have audits and paperwork and follow-ups to conduct. And then there are the follow-ups with departments that have issues that are unresolved or awaiting third party actions. Somewhere in there I take lunch. And at least once a month, I cover the on-call portion of our job.”

Overall, most experts who reviewed the survey results expressed little surprise in what respondents selected as their biggest challenges.

“Number 1 and number 2 are the concerns that I hear most about from our clients,” said Charles Schwandt, commercial manager of devices and services with GE Healthcare. “No surprise to me. This makes sense.”

Added Izabella Gieras, director of Clinical Technology at Huntington Hospital, in Padadena, CA: “For the most part, the responses align with the industry.” Her hospital, in fact, is in the middle of a device integration plan, the initial phase of which deals with physiological monitors in surgical areas, along with the intensive and post-anesthesia care units. The biggest challenge so far? “Coordinating all the players on the projects, including the physicians,” Gieras said.

Tiffany Lemmen, director of clinical applications at Huntington, said careful planning is critical. “I would advise anyone starting on this path to do an integration assessment of your environment and equipment well ahead of starting a device integration project,” Lemmen said. “We are finding that some of our monitors will require upgrades in order to send/receive digital data.”

The notion of coordination and collaboration with others from outside HTM departments is a key aspect in understanding the challenges of managing devices on an IT network.

“We have to communicate with our IT department, medical device vendor, and user department for any integrations and network connection issues,” said Salah Alkhallagi, director of clinical engineering for King Abdulaziz Medical City in Jeddah, Saudi Arabia.

Depending on their specific job titles and responsibilities, some HTM professionals may not focus a lot on big-picture integration issues, but it’s a constant backdrop. For example, McCabe said he works closely with what his facility calls a “medical device IT interconnectivity manager.” That individual, said McCabe, “heads our Clinical Engineering Department’s efforts in device IT integration,” including implementation and testing of solutions in the clinical realm.

Lindahl estimated that he spends no more than 10% of his time dealing with integration issues, but he expects that will change soon. “By this time next year, I am sure the percentage will go up with the new systems being installed,” he said.

On the other hand, Joe Coughlin, a CBET with Saint Francis Health System South in Tulsa, OK, said he’s “always involved” when it comes to integration of medical devices, “specifically the hard-wire and wireless monitoring of patients and the networking of such systems across our hospital backbone.”

Several experts said there’s a need for breaking down traditional walls to address these challenges because the ramifications of a bad decision or a poorly executed one can extend far beyond any one department or even a single facility.

“We find that the networks have become more and more complicated over the years as patient monitoring has grown,” said Schwandt. “With these more complex systems, more challenges arise and the risk for failure increases.”

### A Deeper Understanding

With some specific challenges, the survey asked respondents to select the biggest issue for their hospital.

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Biggest Issue</th>
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<tbody>
<tr>
<td>Managing Medical Devices and Systems on the IT Network</td>
<td>Determining/assigning responsibilities across departments</td>
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<tr>
<td>Alarm Management</td>
<td>Alarm fatigue (too many alarms)</td>
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<tr>
<td>Broken Connectors</td>
<td>Connectors frequently break or don’t work properly</td>
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Dealing With Outside Equipment

Roughly 42% of respondents said that dealing with medical devices brought in by patients was a challenge. In follow-up interviews, it’s clear that how hospitals deal with the issue varies by facility.

John Egan, a clinical engineering technician 2 at St. Joseph’s Health Center in Syracuse, NY, said his facility is moving toward not allowing any such equipment into the hospital. Why? HTM professionals may not have “the correct testing equipment and knowledge” to deal with any such outside equipment, and clinicians may not be familiar with how to use it.

Egan also said there’s a concern that the hospital might not have any “needed accessories” for outside equipment, and it would not be cost effective to stock up. Finally, Egan said there was a basic infection control issue. “Simply put, we don’t know what is coming in on said equipment and may not be able to clean it effectively and do not want to put our other patients at risk.”

Other hospitals adopt a case-by-case approach. “Our department requires the caregivers to make a professional judgment call on the condition and operation of it,” said Anthony McCabe, a radiology equipment technician at the Ohio State University’s Wexner Medical Center. “If anything is in question, then we are consulted for further examination.”

Joe Coughlin, a CBET with Saint Francis Health System South in Tulsa, OK, said the criteria for what to do isn’t set in stone at his hospital. “My rule of thumb has always been: If the physician indicates it’s required for the patient and it passes the electrical safety codes, will not interfere with ancillary equipment, the hospital utilities, or staff, I have no problem with its use.”

The Challenge of Infusion Systems

For those respondents who identified infusion systems as a top challenge, the biggest issue was financial—the cost of replacement batteries. Many respondents also said that new device training was not a high priority for their employer. Other issues included the fact that preventive maintenance of these systems can be time consuming and the difficulty in determining who is responsible for downloading the drug library.

ADDRESSING CYBERSECURITY

Healthcare facilities and manufacturers are under increasing pressure to make sure their medical devices and networks are safe and secure—for both patient safety and privacy.

For one thing, there is the potential for bad publicity with more media attention on the claims of hackers who say they’ve been able to bypass security on devices such as insulin pumps. There’s also the threat of federal penalties for healthcare facilities that don’t adequately safeguard patient information. Under the Health Insurance Portability and Accountability Act (HIPAA), breaches of patient information could result in steep fines for healthcare facilities.

In looking at how to tackle the cybersecurity challenge, one expert from the manufacturing world urged all participants to consider the long-term impact of any decision, policy, or procedure.

“I’d like the industry to have a plan about how to approach this in a consistent, well thought-out way,” said Pat Baird, a systems engineer at Baxter Healthcare Corporation. “It would be very easy to have a knee-jerk reaction to all this and apply controls that will address the hype around cybersecurity, without actually increasing patient safety or security.”

In an article in the July/August 2012 issue BI&T on how to keep patient information secure on medical equipment, Richard Swim, manager of clinical technology with Baylor Health Care System in Dallas, advised: “Taking steps to secure this information will take some effort, but is well worth the investment to save time and money in the future, protect patients’ privacy, and help provide them the best experience while in your facility.”
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