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IN THIS ISSUE

412 COVER STORY

Seek and You Shall Find?
Tracking Medical Devices in Healthcare Facilities

Chris Hayhurst

422 FEATURES

A Holistic and Collaborative Approach to Audible Alarm Design
Elif Özcán, Dilip Birdja, and Judy Reed Edworthy

433 RESEARCH

Frequency and Duration of Infusion Pump Alarms: Establishing National Benchmarks
Rachel R. Vitoux, Catherine Schuster, Kevin R. Glover, and Mark Dekker

442 Medical Equipment and Healthcare Technology: Health Vision 2050
Adhra Al-Mawali, Avinash Daniel Pinto, and Ali Talib Al-Hinai

452 The Modern Hospital Bed: A 'Prescription for Recovery and Wellness'
Annie Keller

DEPARTMENTS

402 FRONTLINES

404 THE ROUNDUP

408 DID YOU SEE?

409 TEN QUESTIONS WITH...

410 PEOPLE ARE SAYING

454 ROUNDTABLE DISCUSSION

Improving the 'Alarm Problem' Will Require Much More Than Just Reducing the Number of Alarms

462 VIEW FROM THE TOP

Staying Ahead of 'Enormous and Evolving' Cyberthreats Requires End-to-End Collaboration

464 BRIGHT IDEAS

A Life Cycle Approach to Medical Device Cybersecurity
Gavin Stern

467 CYBERINSIGHTS

Keeping Track of All the Moving Pieces
Axel Wirth

472 STERILIZATION

Straight Talk: Overcoming Subject Matter Snobbery: Knowing that You Don't Know Everything
Weston Balch

474 SETTING STANDARDS

What to Expect in the Third Edition of ST72
Carolyn Braithwaite-Nelson, Tami Benjamin, and Rodney D. Parker

477 TROUBLESHOOT IT

Multigas Monitors: Overview and Preventive Maintenance Essentials
Becky Crossley

478 FINAL WORD

Device Integration Specialists Are Needed to Fill Vital Support Gap
Corey J. Weeden
Precision Tracking

The decision to pursue a real-time location system (RTLS) solution in a healthcare facility is not one to be made lightly, according to the experts featured in our cover story (p. 412). RTLSs are expensive, compatibility with existing Wi-Fi architecture is difficult to navigate, battery management presents unique challenges, and shifting technology means it’s difficult to know when to pull the implementation trigger.

But when it’s working effectively, an RTLS solution can mean enhanced protection of assets and lowered chance of equipment loss, better productivity among staff (who aren’t searching aimlessly for missing equipment), improved patient flow, enhanced tracking of patient data (leading to improved analytics), better room turnover, optimized throughput, and greater satisfaction among patients.

The considerable expense of taking the RTLS plunge is worth emphasizing. To minimize costs, explained Mike Friesen, director of clinical engineering at the University of Virginia Health System in Charlottesville, most RTLS systems are built on a facility’s existing 802.11 platform. However, mapping access points and “turning them into geography” can become costly, as can remapping following renovations. Throw in additional costs, such as annual licensing fees and those related to planned obsolescence, and the price tag can be hefty.

“You really have to look at it all—the acquisition, the go-live cost, the annual management cost, and the replacement cycle—before you can know for sure if it makes sense,” recommended Friesen.

For Ali Youssef, principal mobility architect in the information technology department at Henry Ford Health System (HFHS) in Detroit, the RTLS journey began with a challenge many organizations face—finding and managing infusion pumps—then grew into the pursuit of a unified RFID strategy across the entire organization.

Working closely with vendors, HFHS took a phased approach to implementing its RTLS. Phase 1 allowed tracking of assets with floor-level accuracy, while phase 2 involved achieving room-level accuracy (on a case basis) through the use of battery-operated, infrared light–emitting devices in individual rooms that are picked up by nearby RTLS tags.

Another RTLS technology making waves is Bluetooth Low Energy (BLE), the proponents of which say could provide great value to healthcare. According to Rob Reilly, GE Healthcare’s vice president and general manager for services in the United States and Canada, BLE on a “Wi-Fi backbone” can provide “really good resolution with fairly minimal infrastructure.”

“We’re working on things like extending battery life and improving coverage area with our beacons. And we’re looking at ways we can incorporate passive and active RFID,” said Reilly.
2019 AAMI AWARDS

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Nominate yourself—or your peers!

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www.aami.org/awards
The Roundup

A compilation of items about healthcare technology news, regulations, and AAMI initiatives

Medtronic’s Earl Bakken, AAMI and Industry Pioneer, Dies at 94

Earl Bakken, a driving force in AAMI’s infancy and chairman emeritus of Medtronic, a multi-billion-dollar medical technology company that he cofounded in a Minneapolis, MN, garage, passed away at his home in Hawaii on Oct. 22. He was 94. A holder of dozens of patents and honorary degrees, Bakken’s influence on the growth of medical technology was enormous.

Bakken was “a soft-spoken giant in the industry,” said Mike Miller, AAMI’s first president and CEO. “Bakken supported AAMI from its conception. He was a member of the AAMI Executive Committee and Board of Directors for several years, supported AAMI financially, and encouraged his staff to participate in and support AAMI. I also heard that he was a very good ballroom dancer and rarely wore the same suit twice … a really nice guy.”

According to the Minneapolis Star-Tribune, Bakken created the wearable, battery-powered pacemaker in just four weeks in 1949. He also commercialized the first implantable pacemaker in 1960, according to The Associated Press.

In 2011, the AAMI Board of Directors honored Bakken with the AAMI Leadership and Achievement Award, making him only the sixth recipient of that award in AAMI’s history. Board members hailed his “long and exceptional service to AAMI and the medical device industry” and a career marked by integrity and positive impact.

FDA Issues Cybersecurity Premarket Guidance

In an effort to stay “a step ahead” of cybersecurity vulnerabilities, the Food and Drug Administration (FDA) has issued draft guidance to help manufacturers incorporate cybersecurity best practices into medical devices and address threats prior to entering the market. Crucially, the draft guidance recommends that premarket submissions include a “cybersecurity bill of materials” detailing the software and hardware components of a device that are susceptible to cyberattacks.

The draft guidance, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, encourages the creation of “trustworthy” devices, defined in part as those that are “reasonably secure from cybersecurity intrusion and misuse” and “provide a reasonable level of availability, reliability, and correct operation.”

“In particular, devices and systems should be designed to protect assets and functionality in order to reduce the risk of multi-patient harm due to the loss of authenticity, availability, integrity, and confidentiality,” the FDA wrote in the guidance document.

Drawing on design recommendations from the National Institute of Standards and Technology’s Framework for Improving Critical Infrastructure Cybersecurity, the draft guidance outlines what documentation manufacturers should include in their premarket submissions to demonstrate that their device has mitigated cybersecurity risks. That includes design documentation to show that the device is trustworthy in addition to risk management documentation.

Call for Papers: Sterilization and Reprocessing Horizons

Healthcare personnel face a constant challenge in properly sterilizing and reprocessing medical devices to protect patients from healthcare-acquired infections. That’s why the spring/summer 2019 issue of AAMI’s award-winning Horizons supplement will focus on the topic of sterilization and reprocessing.

Submission categories can include (but are not limited to) research articles based on scientific method or scholarly investigation; systematic reviews reflecting bodies of knowledge in relevant areas; case studies describing valuable real-world experience or innovations in practice; tools-based papers that detail emerging methods, measures, or instruments; and commentaries expressing an informed opinion.

Horizons articles undergo peer review and are indexed and searchable on PubMed. Article summaries are due by Dec. 4 and full-length manuscripts by Jan. 15, 2019. For more information, visit www.aami.org/callforpapers.
Technology Seeks to Reduce Heart Failure Readmissions

Carlsbad, CA–based ImpediMed has enrolled the first subject in a 200-patient trial to study a technology that is intended to reduce readmissions for heart-failure patients. The study will use ImpediMed’s SOZO bioimpedance spectroscopy technology—a small electrical current that’s sent through the body and analyzed—to identify fluid overload earlier.

“SOZO has the potential to significantly improve the quality of life for heart failure patients by enabling them to remotely monitor their fluid status so that clinical intervention can take place as soon as possible,” said A.J. Accardi, a physician at Scripps Memorial Hospital, in a statement. “This early intervention is critical to helping prevent the occurrence of rehospitalization.”

According to ImpediMed, about one-quarter of patients admitted for heart failure are readmitted to the hospital in less than 30 days. The study is being conducted at Scripps Memorial Hospital in San Diego, CA, and will follow patients at home for 45 days after discharge for a heart-failure–related hospital admission.

SOZO has been cleared by the Food and Drug Administration for use in heart failure patient monitoring. The study data are intended to support future marketing efforts.

“We believe SOZO’s ability to accurately and noninvasively measure and monitor small fluid changes in the human body has the potential to greatly improve these patients’ lives while also providing tremendous savings to the healthcare system,” said Richard Carreon, managing director and CEO of ImpediMed, in a statement.

AAMI Opens Nominations for Annual Awards

Who are your outstanding peers? Now’s the time to give them a chance to stand in the limelight by nominating them for an AAMI Award.

Each year, the healthcare technology management (HTM) community recognizes leaders and innovators who are moving the industry forward. AAMI needs your help! Nominate yourself or other leaders in the industry. Award winners will receive monetary prizes and plaques commemorating their achievements. Best of all, a celebration will be held at the 2019 AAMI Exchange, the name for the reimagined annual conference, in Cleveland, OH, next June.

Here’s a snapshot of several types of awards:

• AAMI Awards recognize patient safety innovators, leaders in HTM, biomedical equipment technician excellence, outstanding young professionals, top-notch volunteers, and exceptional HTM associations.

• AAMI Foundation Awards recognize an individual or group for a unique, major contribution to the advancement of healthcare technology and systems, service, patient care, or patient safety; humanitarian efforts to improve global human conditions with healthcare technology; or applied clinical engineering practices or principles to solve patient care problems or challenges.

• Standards Awards honor major contribution(s) to the development or revision of a specific standard and technical committee excellence.

“Encourage you to nominate all who are working to advance the profession,” said MaryJane Thomas, AAMI director of membership development.

For more information, visit www.aami.org/awards.

Philips, Ypsomed Partner on Medical Adherence Monitoring

Health technology company Royal Philips and Ypsomed, a Swiss-based developer of injection and infusion self-medication systems, have signed a memorandum of understanding that would combine Ypsomed’s connected self-medication devices with Philips’ digital, cloud-based HealthSuite platform.

The combination would allow for sophisticated self-medication adherence tracking and sharing of data across Ypsomed’s line of devices, which are used to treat chronic diseases such as diabetes, multiple sclerosis, and rheumatoid arthritis.

“Our partnership with Philips aims at embedding smart devices in a digital health ecosystem that simplifies access to therapy-relevant medication adherence data,” said Ulrike Bauer, senior vice president of Ypsomed Delivery Systems, in a statement.

A definitive agreement between the two companies is expected by the close of the year.

Cyberattacks Top ECRI’s List of Hazards

In its annual list of the top 10 health technology hazards, the ECRI Institute identified cyberattacks by hackers, who can exploit remote access to systems and disrupt healthcare operations, as the greatest threat facing the health technology community in 2019.

“Clearly, medical device cybersecurity has become a topic of significant relevance, and over the past months we have seen a number of valuable contributions being published,” said Axel Wirth, distinguished technical architect at Symantec Corporation. “One of the unique aspects of this problem is its complexity and the need to find a common
ACI Board Suspends Two Certifications

After assessing feedback and participation in its programs, the AAMI Credentials Institute (ACI) Board of Directors has decided to suspend exams for Certified Laboratory Equipment Specialist (CLES) and Certified Quality System Manager (CQSM) at the end of 2018.

Although ACI also was considering suspending the Certified Radiology Equipment Specialist (CRES) exam, the certification will continue to be offered as a result of increased interest by several organizations.

The ACI Board had announced in the summer that it was reevaluating those three certification programs and solicited reaction to its proposal. The comments it received were a key consideration in the decision to end the CLES and CQSM exams and continue with CRES.

“These decisions were not made lightly,” said Sherrie Schulte, AAMI’s senior director of certification and the AAMI Exchange. The Board considered many factors, including the low number of test takers, the cost of maintaining the exams, and interest level within the industry. The status of each exam will be reevaluated on an annual basis to determine if there are factors that would warrant reinstating some or all of the designations.”

Individuals who already hold the CLES or CQSM certifications will be able to continue to use the designations provided they maintain their certification by completing the necessary continuing education units and submitting the necessary renewal fees every three years. If the designation is revoked, there will not be any opportunities to retake the exams at this time.

FDA Launches Special 510(k) Program Pilot

The Food and Drug Administration (FDA) has kicked off a pilot program to test an expansion of the agency’s Special 510(k) premarket clearance process—an optional, and faster, pathway to clearance for certain well-defined modifications to a manufacturer’s own medical device. All Special 510(k) submissions received on or after Oct. 1, 2018, are included in the program pilot.

Under the proposed update, manufacturers making a design or labeling change to an existing device can apply for the faster Special 510(k) Program as long as:

- The proposed change is made and submitted by the manufacturer authorized to market the existing device.
- Performance data are unnecessary. Alternatively, if performance data are necessary, well-established methods for evaluating the change must be made available.
- All performance data necessary to support substantial equivalence need to be available for review in a summary or risk analysis format.

The FDA described the proposed expansion of the program in draft guidance titled The Special 510(k) Program.

“Special 510(k) Program Pilot” began with a process that includes several key steps, including the manufacturer verifying that their change is well-defined and only requires an added or changed part or a change to the labeling. The proposed change must also result in a device that is substantially equivalent to the approved device.

The FDA described the proposed expansion of the program in draft guidance titled The Special 510(k) Program.

The implementation of the Special 510(k) Program Pilot is expected to enhance regulatory efficiencies, which will benefit manufacturers and patients alike.

The nefarious exploits of cyber hackers topped ECRI’s list of health technology hazards for 2019.

language and form a common understanding across participating stakeholders.”

Wirth co-edited AAMI’s Medical Device Cybersecurity guide with Stephen Grimes, principal consultant for Strategic Healthcare Technology Associates, LLC. AAMI offers multiple standards and related documents that provide cybersecurity guidance to manufacturers, including the technical information report TIR57, which describes how to develop a cybersecurity risk management process for their products.

To order the guide or standards, visit the AAMI Store at www.aami.org/store.

Trusting Physicians to Detect Defects

Managers in medical device firms rely on physicians to detect product defects, in lieu of issuing a voluntary recall, according to a behavioral investigation of the factors that influence the decision to recall a defective product.

“The decision to recall a product can significantly affect an operations manager’s career, the credibility and financial performance of the firm, and the safety of customers,” wrote authors from the Indiana University Kelley School of Business and the University of Minnesota’s Carlson School of Management.

For their study, published online in the Journal of Operations Management, the authors interviewed regulators and industry professionals to identify factors that influence recall decisions, then tested the effect of these factors in an
experiment with managers from a Fortune 500 medical device firm.

“We find that a physician’s ability to detect a defect prior to product use decreases the likelihood to recall, while a manager’s understanding of the root cause of the defect increases the likelihood to recall,” because information, rather than intuition, shapes their decisions, the authors wrote.

Medical device industry managers “appear to trust physicians to screen out defects on behalf of the firm, meaning that when the defect is detectable to the physician, managers are less likely to recall,” said author George Ball to ScienceDaily. “This is because of a perception of increased patient safety when defects are detectable.”

**Wearable Patch Uses Ultrasound to Track Blood Pressure**

Researchers at the University of San Diego have developed a wearable ultrasound device that can provide continuous monitoring of central blood pressure. Although clinical applications are still a long way off, the technology holds promise for helping clinicians assess cardiovascular health and predict cardiac events, according to the researchers.

The small, silicone-based patch incorporates the parts needed to produce ultrasound waves with thin, spring-like copper wires, making it flexible. The patch can monitor central blood pressure more accurately than a blood pressure cuff—in major arteries up to 4 cm below the skin.

“This is like seeing just the tip of the iceberg,” said Sheng Xu, a professor of nanoengineering at the University of California San Diego Jacobs School of Engineering, in a statement. “By integrating ultrasound technology into wearables, we can start to capture a whole lot of other signals, biological events, and activities going on way below the surface in a noninvasive manner.”

The researchers described their work in an article published on Sept. 11 in Nature Biomedical Engineering.

**AAMI Partners with Singapore Group on Education, Certification**

AAMI’s portfolio of international partnerships is expanding, this time to Singapore. AAMI will collaborate with the Singapore Manufacturing Federation (SMF) to deliver educational programs, certifications, and events for the Singapore medical device industry.

SMF, a nonprofit organization established in 1932, champions Singapore manufacturing. With more than 3,000 corporate members, SMF has strong links with the nation’s government. The nation of Singapore plays a critical role in the Association of South East Asian Nations. The 150 medical device manufacturers in Singapore have generated approximately $14 billion a year—3.5% of GDP.

“AAMI is encouraged by the strong support of Singapore’s government, their medical device manufacturing community, and by the Singapore Manufacturing Federation,” said Brad Schoener, vice president of innovation at AAMI. “AAMI is looking forward to a strong and mutually beneficial relationship.”

The statement of intent between the two organizations calls for “promoting increased technical and educational ties between U.S. and Singaporean companies.”
Did You See?

The Food and Drug Administration released a highly anticipated draft guidance document intended to help manufacturers protect medical devices from cybersecurity threats.

*AAMI News* breaks it down at [www.aami.org/Cybersecurity_Guidance](http://www.aami.org/Cybersecurity_Guidance)

The latest episode of the AAMI Podcast detailed how virtual reality is poised to change the training of healthcare technology management professionals.

Listen in at [www.aami.org/Podcasts](http://www.aami.org/Podcasts)

You can get the latest healthcare technology news, career resources, standards information, and more delivered to your inbox with AAMI's e-newsletters.

Sign up at [www.aami.org/Enewsletters](http://www.aami.org/Enewsletters)

The AAMI Foundation published the SpO₂ Alarm Management Toolkit—a helpful resource to improve alarm management.

Get the toolkit at [www.aami.org/SPO2_Toolkit](http://www.aami.org/SPO2_Toolkit)

*AAMI News* detailed how standards leaders are preparing for how artificial intelligence will revolutionize healthcare technology.

Read about it at [www.aami.org/Al_Revolution](http://www.aami.org/Al_Revolution)
Ten Questions With ...

Steven Helms

What drew you to the healthcare technology management (HTM) field?
I’ve always loved working on electronics. As a kid, I would take my gaming machines or pretty much anything electronic apart to see how they worked. After working in the electronics field for a few years, I met Nathan Tucker, the owner of MedRepair Rx. He told me about the biomedical field, and he pulled me under his wing and showed me that I could make a real difference doing what I love.

What do you enjoy outside of work?
I’m a country boy at heart, and I love the outdoors. I enjoy everything from hunting and fishing to just spending time in nature. My favorite pastime would be sitting by the campfire with my family.

Who—or what—is your rock?
My rock is the Lord Jesus Christ and my wife (although she may tell you that my rock is my head!).

Why is it important to keep a sense of humor on the job?
Comedy is the best medicine. Are things not going your way? Don’t get mad and break something! Instead, take a break and laugh. When you go back to it, you will figure it out.

What is your favorite food?
I’ve always been a hunter, so my favorite food would be wild game, especially elk or deer.

Least favorite?
I am definitely not a fan of onions.

Where do you hope to be in 10 years?
In 10 years, I hope to be running a biomedical business, at the top of my field, and continuing to make a difference in people’s lives.

Tell us about your best day working in HTM.
My best day in HTM was when an old lady came into our shop who didn’t have any money. She needed her oxygen regulator repaired. We decided to give her a new regulator free of charge. When I told her that, she started crying and prayed to God, thanking us for this much-needed gift.

What would people be surprised to learn about you?
I’m a major animal lover. My wife and I have two dogs and two indoor cats, and we feed the stray cats in the neighborhood.

Where would you go, if you could go anywhere?
I would love to go to Ireland. That’s where my ancestors came from. I would love to be able to actually see what they saw and know more about where I came from.
People Are Saying

“A while attitude alone can’t win the day, it certainly makes me want to root for that person throughout the interview and candidate-selection process. The right and appropriate attitude is key to finding and being considered for a role in healthcare technology management.”
—Donald Armstrong, AAMI Blog. Armstrong is a senior biomedical engineering manager at Stanford Health Care in California and a member of the BII&T Editorial Board.

“The rapidly changing landscape in HTM provides challenges in servicing equipment. However, the focus should never change from the ones who need our help, the patients.”
—Larry Nguyen, AAMI Connect discussion group. Nguyen is CEO of Summit Imaging in Seattle, WA.

“When clinicians have the right equipment available, when they need it, and operating seamlessly across all available interfaces, I have done my job.”
—Leslie McGovern, AAMI Instagram account. McGovern is a clinical engineering site director at Northwest Community Healthcare in Arlington Heights, IL.

“Reprocessing tops risk list for device-related healthcare-associated infections, according to AAMI forum participants. Two years on, AAMI’s report [at www.aami.org/HAIs] is worth another read.”
—Susan Ramonat, AAMI Twitter account. Ramonat is CEO of Spiritus Partners in Edinburgh, UK.
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Seek and You Shall Find?
Tracking Medical Devices in Healthcare Facilities

Chris Hayhurst
As might be expected of a business founded by the world’s most famous auto pioneer, Henry Ford Health System (HFHS) in Metro Detroit is big, ambitious, and, in many ways, cutting edge. With six major hospitals and more than 100 clinics spread throughout southeast Michigan, the organization employs upwards of 30,000 people and amasses billions of dollars in revenue each year.

In September, a team of Henry Ford cardiologists became the first physicians in the United States to implant a device called a “reducer” in a patient with angina. In addition, the system’s neurosurgery division recently was awarded a $600,000 grant by the Department of Defense to support research on the molecular makeup of gliomas—the same type of brain cancer that killed Senator John McCain. HFHS has a lot going on. It’s the kind of place where change is always in the air—and those driving it are among the leaders in their professions.

One of those professionals is Ali Youssef, CWNE, PMP, CPHIMS, principal mobility architect in HFHS’s information technology (IT) department. Among relatively few in the healthcare technology management (HTM) community nationwide to earn certification as an enterprise wireless networking expert, Youssef is a member of the HFHS mobility team. The group covers Wi-Fi, cellular, “and any other frequency that’s in use within our hospitals,” he explained.

According to Youssef, his role encompasses a number of different areas, from monitoring the aforementioned frequencies and minimizing coexistence issues to ensuring that the Wi-Fi architecture is meeting the organization’s demands. “Part of that entails keeping an eye on the latest trends and technologies—making sure that we’re aligned with what’s out there and what’s available so we’re always leading the way in this space.”

Toward that end, Youssef said, one of his main responsibilities in recent years has involved medical device tracking and the technologies and architecture behind real-time location systems (RTLSs). At the close of 2017, he said, he and his team completed the installation of an RTLS platform in HFHS’s largest hospital, as well as set up a “location services lab” for putting emerging location technologies to the test.

“Right now, on our Detroit campus, we’re just doing asset tracking and PAR-level [periodic automatic replenishment] management, but we’re looking to expand to other use cases as well,” he explained. “It’s a significant investment with a lot of considerations—you want to know what you need before you commit.”

HFHS’s “journey toward RTLS,” as Youssef described it, began with a challenge many healthcare organizations face: finding and managing infusion pumps.

“Our clinical engineering department wanted to track intravenous (IV) pumps and other key assets and where they were in the facility. We had tried doing it with Wi-Fi cards, but the problem there is when the device is powered off, all bets are off—there’s...
no way to tell in real time where it is.” In addition, Youssef said, they were running into issues with medical devices being lost: “Things were being accidently thrown down laundry and trash chutes. We had expensive devices disappearing, and sometimes we’d never see them again.”

In 2012, Youssef’s team started looking at radio frequency identification (RFID) tagging as a possible solution to its infusion pump problem. According to Paaske et al., there are two basic types of RFID systems: passive and active. The systems typically involve transponders (tags) attached to the device to be tracked, a transponder reader, and a database software application. Passive RFID technology relies on tags that don’t have batteries. The tags draw their energy from the transponder reader, which emits electromagnetic waves that create a current in an antenna built into the tag. With active RFID, on the other hand, the tag’s transmitter uses its own battery as its power source. In both cases—passive and active—the current that is induced by the energy source is used to send radiofrequency signals, and data from the tag, to the transponder reader.

“Data collected from the transponder reader is then sent through a local area network (LAN) to a database installed on a server,” stated Paaske et al. “Users can then retrieve the data using an application installed on the server.”

Youssef and his team considered both passive and active versions of the technology as they researched solutions that might work for their pumps. As part of that process, they reached out to more than a dozen RFID vendors. Meanwhile, he said, other departments within HFHS “were beginning to go down that same path, looking at buying their own RFID systems for their own unique use cases,” including patient tracking and infection control.

**Bluetooth Low Energy: An Alternative to RFID**

CenTrak’s RTLS product, noted Adam Peck, the company’s vice president of marketing, includes embedded Bluetooth Low Energy (BLE) technology that can be activated, for a licensing fee, on a case-by-case basis.

The cloud-based RTLS solution Encompass, which GE Healthcare launched in 2017 in collaboration with Zebra Technologies, was developed to resolve issues around expense and location accuracy, said Rob Reilly, GE Healthcare’s vice president and general manager for services in the United States and Canada. “With the low-energy Bluetooth on a Wi-Fi backbone, you can get really good resolution with fairly minimal infrastructure.”

In the past, Reilly noted, a 300-bed facility developing a tracking system might spend close to a million dollars hard wiring RTLS readers and beacons—a process that he described as being “super disruptive, running cables and putting antennae in every patient room.” GE Healthcare itself performed 50 or 60 installs in this manner around the country, he said. “But when you took a step back and asked what the return on investment is—well, the systems worked and the nurses and the biomedical equipment technicians (BMETs) liked them, but if you talked to the CFO, it just didn’t pass muster.”

A system that relies on BLE, on the other hand, can be implemented in around two weeks “in a much-less invasive way,” Reilly said. “You have your active tags that act like beacons, and then you have a combination of fixed and mobile receivers.” The fixed receivers might be placed in storage areas, for example, while the mobile ones can be placed on carts or carried by nurses and other clinical staff. “One important aspect of the system is the way it leverages crowdsourcing,” Reilly said. As staff move around a facility with their mobile receivers, those receivers “hear” the beacons in nearby storage rooms, as well as any tags attached to nearby devices and equipment. That information—as location data—is then fed over Wi-Fi to the Encompass application, which synthesizes the data to continuously update and map asset locations. “The crowdsourcing allows us to keep the infrastructure light,” Reilly said. “You’re literally talking about a handful of fixed readers on each floor, and then the rest is just training nurses and other staff to carry mobile receivers as they work.

Although Reilly estimated that just 40 to 50 hospitals have deployed Encompass thus far, he predicted that number will rise in the near future as the company refines the tracking platform. “We’re working on things like extending battery life and improving coverage area with our beacons. And we’re looking at ways we can incorporate passive and active RFID.”

GE Healthcare has its own “substantial” biomed organization of around 1,500 BMETs nationwide, according to Reilly, so they would benefit from any improvements as well. “We manage about 4 million pieces of equipment around the country. In the next couple of years, using this system, we’d like to have either active or passive ability to track every single one of those devices.”
“The more we looked at things and the more we talked to vendors, the more it became clear that a lot of these systems could do so much more than we originally had hoped. Temperature monitoring, patient duress, nurse call—the list goes on and on,” said Youssef. With that in mind, HFHS decided it would be best to create a unified RFID strategy across the entire organization. “If we could use one platform for everything that would be great—that would be the gold standard.”

Eventually, the health system did just that, settling on a product from the RTLS vendor CenTrak that would give them the ability to do real-time tracking. According to RFID Journal, a publication covering the technology and its uses across a number of different industries, RTLS “is any solution that can tell you where an asset, individual, vehicle or other object is located, in real time.” (There is some debate as to whether RTLS should stand for “real-time location system” or “real-time locating system.”) Many RTLSs use active RFID technology, the journal noted, with tags on devices, or any object, “set to send a signal every few seconds or minutes.” CenTrak’s literature describes RTLS as a kind of satellite-free “indoor GPS” that can be used not only for locating valuable assets, but also—through integration with other IT solutions (including computerized maintenance management systems [CMMs])—to “improve workflow, reduce costs and increase clinical quality.”

According to Youssef, HFHS “leaned heavily” on its RTLS hardware and software vendors to design a system that would work. Ultimately, the health system decided to split the project’s implementation into several distinct phases. Following its completion, phase 1 allowed them to locate assets with floor-level accuracy. Phase 2, he said, “was a little more complicated, and had to do with room-level accuracy and the use cases that depended on that.” (For that phase, he explained, they installed battery-operated devices in individual rooms; the devices emit infrared light, which in turn is picked up by nearby RTLS tags (see sidebar on p. 416.) Finally, Youssef said, the third phase—“our long-term goal”—will involve using the system to enhance workflow management. “That will require very precise location accuracy. We’re working on it, but we’re not there yet.”

Meanwhile, the current RTLS system is working as HFHS had hoped. The health system has saved thousands of dollars by catching tagged items that were mistakenly tossed in the trash, and its HTM team has reaped the benefits through better asset management. “It’s so much more efficient for the technicians to be able to go out and locate things, even at a floor level,” said Youssef. "No matter what else we do with this technology, that on its own has made it worth it to us."

Tag and Deliver
It’s a similar story at Children’s Mercy Hospital and Clinics in Kansas City, MO, where Ken Ervin and Steve Cazzell are the director and assistant director, respectively, of biomedical engineering.

Like the HTM professionals at HFHS, the Children’s Mercy team developed their tracking system “in stages” over a number of years, Cazzell said. They began by trialing several different platforms and decided that with those that relied strictly on wireless, “we never could be 100% sure where the equipment was.” They eventually chose to use CenTrak’s system for the same reasons as Youssef and HFHS. “The infrared,” Cazzell said. “You know exactly where everything is, down to the room, at all times.”

Today, Ervin said, all of the facility’s portable medical equipment is covered by the system, but so too are many “low- or no-tech items” like wheelchairs and transport wagons. “We started out wanting to track things like infusion pumps,” he said, “so if somebody orders a pump and we have nothing on PAR level, we can go in and say, ‘Oh, there’s a whole bunch of those up in X department—let’s go get some and redistribute.’"

Over time, however, that “morphed into a much larger animal” as others in the organization realized how tracking could help them. “It’s a huge inconvenience for our customers if they come in and they need a wheelchair or wagon and the people
at the volunteer desk don’t know where to find one.” The wagons in particular, Ervin said, often wind up in the facility’s parking garage or left in a far-off room following an internal hospital event. “Someone will use one to carry food someplace, and then who knows where it’s going to end up?”

Now that everything is tagged, Ervin said, situations like that are no longer an issue—“which is big when you think about patient satisfaction.” Their system also includes a staff-duress solution that allows anyone with a badge to alert security with a push of a button, as well as a sensor feature on certain tags that allows them to track temperature data on medications and vaccines. “And the best thing about it,” Ervin said, “is it all leverages the infrastructure we’ve put in place. So anytime we want to add something new to be tracked, all we really have to do is buy another tag.”

Moving forward, Cazzell added, the hospital’s tracking-related goals include integrating the system with its CMMS and using staff badges to track equipment cleaning and delivery. The CMMS project, he explained, will help clinical engineering when they get work requests, “so they know where to go to pick up this equipment as it’s transferred from one department to the next.” When it comes to equipment cleaning, on the other hand, the system should allow them to automate data collection—a process currently prone to unintentional error.

“Right now, when someone from Medical Equipment Management Services cleans a device, they record that interaction in a database by hand,” Cazzell said. “Our plan is to use the tags to track who cleaned it, when they put it away, when and where it was delivered—everything.” In the future, he explained, when a nurse calls down and complains to them that nobody delivered the equipment they asked for, “we’ll be able to look in the system and say, with proof, ‘It was actually delivered at this exact time, and it was placed right there at the front desk.’”

RTLS: Challenges and Solutions

Ali Youssef, principal mobility architect with Henry Ford Health System (HFHS), said that his team has had to overcome several challenges in order to 1) decide on the right RTLS vendor, 2) get their new tracking system up to speed, and 3) stay abreast of the latest that the technology has to offer while looking ahead to the future.

1. **Compatibility.** HFHS’s Wi-Fi platform is from a California company named Extreme Networks. As Youssef and his team considered potential RTLS vendors, most had completed interoperability testing of their systems with Cisco Wi-Fi platforms only. “Cisco is probably 80% of the market, so that made sense,” he said. “But it meant that we had to ensure that whatever we got would work for us, because there’s a very specific Wi-Fi design methodology you have to use.”

2. **RTLS interface.** His team originally expected they’d be able to manage their RTLS system from one interface. “We had this concept of having a ‘single pane of glass’ for everything. But we learned that’s not really a feasible thing to do based on how diverse the different platforms and use cases are,” explained Youssef.

3. **Phased approach.** Completing implementation in phases made sense financially and logistically, Youssef said, but it also led to challenges “from a communication standpoint and with setting expectations for our end users.” For instance, during phase 1, as word got out that they had an RTLS system in place, “everyone immediately expected room-level accuracy—that this thing should be able to tell me exactly where I am at any point in time.” In reality, however, that first phase merely provided floor-level location. “For biomed, that was good enough; now, instead of having to search a whole building, they could narrow their search down to a floor. But there were others who were disappointed at first, because they had their own use cases they wanted to use it for, and this wasn’t enough for them.”

4. **Shifting technology.** Setting and sticking to a long-term implementation strategy has been difficult because RTLS technology is moving so quickly, Youssef noted. “Already I’m looking at a BLE-based [Bluetooth Low Energy] product in our lab to see if using it would make more sense for some of our smaller clinics rather than using the system we deployed for our hospitals.”

5. **Battery management.** The batteries in active RFID tags tend to last anywhere from two to five years, depending on how often the tag is signaling, and when a battery dies, the tag must be replaced. “For now, we’re outsourcing that job,” Youssef said.
**Better Vision for VISN**

Another organization that is investing in RTLS is the Department of Veterans Affairs (VA), which in 2011 announced its plans to use the technology “to provide tools to assist in the automation and improvement of operations and healthcare services VA provides to our Veterans.”

The program, which spans more than 150 medical centers in the 21 Veterans Integrated Service Networks (VISNs), also uses the CenTrak platform, as well as RTLS software from Intelligent InSites. “It’s a solution that is meant to improve workflow,” explained Cheryl Shaw, MS, PMP, VISN 1 RTLS program manager at the West Haven VA Medical Center in Connecticut. (VISN 1 includes eight VA medical centers in the New England region.)

In the VA’s case, they don’t tag everything “because there’s no proven return on investment in that approach,” Shaw said. Instead, the VA follows a general rule of thumb: If an item is mobile and space for a tag exists, it gets tagged. However, items that are bolted down or can’t be easily removed (e.g., magnetic resonance imaging machines) do not get tagged. Tagged items currently include stretchers, beds, and computers, and although VISN 1 intended to include telemetry monitors on that list, the tags that they purchased were too big. “We’re looking into other options now,” Shaw said.

Biomedical equipment technicians can see where a tagged device is in their facility by entering its inventory control number into the tracking application on their computer. “There’s a map view and there’s a list view,” Shaw explained. “The list view includes a room number, while the map view shows an icon where it’s displayed on the map.” When a new device is purchased or an old device is decommissioned, the facility’s logistics department handles tagging or tag removal, she said. “It’s a really simple process, and we can reuse the tags—we don’t have to throw them out.”

Although installation of the new system was completed only recently, most feedback has been positive thus far, Shaw said. “I don’t have metrics yet to capture data to show that it’s improved efficiency, but I know from discussions with people in biomed and logistics that it’s been very helpful.” Clinicians, she said, have been a

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**The CenTrak System**

Many healthcare organizations, including several featured here, are relying on RTLS equipment from CenTrak, a Pennsylvania-based company that also has locations in California and Europe.

According to Adam Peck, CenTrak’s vice president of marketing, most of the healthcare organizations with which the company works are already using some kind of tracking system. “Some are using barcoding; others are using passive RFID. They come to us because of the limitations with those systems.” Because such technologies are not “active,” he explained, they can only provide readings when they’re physically scanned, or when they pass through a “choke point” where their data can be captured. “And after that, it could be in a lot of different places—it’s like the wild, wild west when you don’t have RTLS.”

With CenTrak’s platform, Peck said, users can rely on one of two different communication-protocol backbones: Wi-Fi or 900-MHz ultra-high frequency (active UHF). “If our technology ‘hears’ that 900-MHz frequency, it will use that band; if it doesn’t, it will attempt to make contact via Wi-Fi.” That’s important, he explained, because many organizations already have Wi-Fi built in, and deploying active UHF often requires additional infrastructure. “Active UHF is much more efficient and uses less power, so it’s preferable when it comes to battery consumption. But if you have Wi-Fi, you have what you need to deploy RTLS right away with very minimal start-up cost.”

CenTrak’s platform uses a supplementary technology the company calls “Second-Generation Infrared” (Gen2IR). Infrared (IR) light, which is invisible to the naked eye, does not pass through walls, Peck explained. CenTrak’s Gen2IR system relies on battery-operated devices the size of smoke detectors installed inside of individual rooms, in hallways, or elsewhere within a facility. The devices emit IR light, which can be detected by any tags in the space. In its literature, the company describes Gen2IR technology as “ideal” for “certainty-based (100% accurate) room-/bed-/bay-level locating, a requirement for the automation of healthcare workflow applications.” For biomed, Peck added, the technology is perfect for PAR-level [periodic automatic replenishment] management: “With sensors in your supply closets, you always know exactly what’s in there and what’s available.”
little slower to come around, in part because they’re not accustomed to using inventory control numbers. “There are things we’re still working on, but I think the experience overall has been great.”

A Different Perspective
Although organizations like the VA, HFHS, and Children’s Mercy Hospital and Clinics have had great success with RTLS, the technology’s utility is still an open question for others.

“So far,” said Mike Friesen, director of clinical engineering at the University of Virginia (UVA) Health System in Charlottesville, VA, “we don’t feel like we’re really getting a lot of value out of it.”

The 650-bed hospital has had a facility-wide RTLS system in place for several years, he explained, and over that time, “numerous medical devices” have been tagged to enable tracking. The health system’s original hope was that end users, including nurses and patient care technicians, would rely on the system’s Internet-style portal to easily locate devices. That hasn’t happened, however, for what Friesen said are several different reasons.

“First, there’s the fidelity of the system. It’s an 802.11-based tracking system that triangulates using access devices that are maybe 30 or 40 feet apart,” he said. Although that gets an end user to a certain geography, “they still have to search the area room by room to actually find the device.” Friesen’s team has considered installing IR beacons to “add detail” to the system, “but as we’ve explored that, we have yet to come up with a clear business case for that expense.” And RTLS systems “are expensive,” emphasized Friesen. “The tags are expensive, the licensing fees are expensive, and battery maintenance is expensive.”

Currently, UVA Health System’s biggest pain point when it comes to locating equipment involves its infusion pump fleet. With 3,500 IV pumps and modules scattered across the facility, Friesen estimated the cost of putting RFID tags on every device for use in a system using IR “would be somewhere in the range of $300,000 to $400,000.” That price “might be worth it if it allowed us to know utilization,” he said, “but the reality is that it would only give us location, and location on its own has very little value.”

As a result, Friesen’s team tracks pumps the way they always have: by eye and by hand as they do their preventive maintenance sweeps. “The real problem is not with us finding the pumps; it’s can we put a pump in the hands of the caregiver when they need it? And without utilization, we just send people looking for a dot on the map with no idea of whether or not they’ll be able to retrieve it.”

So is there a better way? According to Friesen, the health system is exploring its options, and RTLS may or may not be part of the equation. “We have our pump infrastructure—the servers that track the entire fleet and allow a pathway to our electronic health record (EHR). And we have the EHR itself, and each patient’s

Cost Considerations
Mike Friesen, director of clinical engineering at the University of Virginia Health System, emphasized that anyone considering an RTLS platform should first understand the various costs associated with the technology.

Most RTLS systems, he said, are built on a hospital’s existing 802.11 platform, which minimizes infrastructural costs. “But mapping those access points and turning them into geography—that can start to get expensive, and then you have the costs of ownership,” such as the cost of remapping following a facility renovation project, the cost of annual licensing fees, or the hidden costs that may come with planned obsolescence.

“Some of these systems now come with batteries that will get you about a year of high-fidelity data before they need to be replaced,” Friesen said. “So you have to think of that as another asset you need to manage, as well as the hands-on time that requires.” Meanwhile, other devices come with nonreplaceable batteries, “so every three or four years, they need to be replaced,” he said.

Organizations should “add it all up” before making any decisions, he recommended. “You really have to look at it all—the acquisition, the go-live cost, the annual management cost, and the replacement cycle—before you can know for sure if it makes sense.”
medication administration record, which includes their name and location.” If they can integrate each of those technologies so that whenever there’s an active order for IV therapy it’s associated with the patient’s location as shown in admissions data, “that would be the holy grail,” Friesen said.

“We’ve talked to vendors about this, and there is one that has taken a location engine and paired it with the IV pump infrastructure, but to date, we really haven’t found that product to be what we want it to be.” Meanwhile, Friesen said that UVA Health System also is considering the generational replacement of its current RTLS, but they’re not rushing the decision.

“We’re trying to ask the question: What will it be when it grows up? How will it be a management tool rather than just floor plans with dots on them? And that’s our quandary,” Friesen said. “We don’t want to throw good money at an RTLS system that doesn’t derive a lot of value.”

Dare to Dream
From the point of view of Cazzell and Ervin, they have yet to identify a need at Children’s Mercy for the level of asset visibility that a “utilization window” might provide.

“Everybody wants RFID to do everything, when it really has only one purpose,” Cazzell said. “And that’s to tell you where something is at.” Nevertheless, he said, when a pump is running, for example, the drugs it administers are recorded by the pharmacy, “and that information is entered into a database somewhere.” Could they track utilization? They could, he said, if they had the right tools. “We’d probably just need a third party to pull the data together. The technology is there; it’s just deciding you want to do it.”

In fact, according to Cazzell, both he and Ervin believe the sky is the limit when it comes to the ways RFID might be put to work. Their facility’s central sterile processing department is using its system to track
endoscopes, for example, and biomedical engineering itself may soon start placing RFID tags on cables.

“So instead of having to reorder a $1,000 set of cables every time someone said they can’t find them, we could just look it up and say, ‘It’s in this room somewhere,’ and then start going through drawers” until it turns up. The biggest challenge they’ve had with their tracking technology has had nothing to do with system deficiencies, he added.

“Our only problem has been our lack of imagination, and not thinking about the possibilities that might come with integration. I think that’s where we really need to focus: on dreaming up new things for it to do,” said Cazzell.

References


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Audible clinical alarms have been an indispensable component of patient monitoring since the 1950s.\(^1\)\(^2\) During the previous 15 years, and particularly since the clinical alarms summit in 2011,\(^3\) several initiatives by regulatory agencies, hospital management, and medical equipment producers have sought to optimize the use of alarms and audible alarm signals in an effort to overcome their negative effects (e.g., alarm fatigue, delirium, postintensive care syndrome) on clinicians, patients, and visitors. Although the field of alarm and alarm signal design is gaining momentum in creating more human-centered alarms, current technological advances (e.g., biosensors, smart wearables, remote monitoring) and the ways in which society is engaged with technological solutions (e.g., continuous tracking of heart rate, sleep, or healthy behavior) bring new challenges and opportunities for monitoring health data and warning users regarding out-of-limit values and other conditions for which alarms might be appropriate.\(^4\)

Current trends and developments will influence how alarms are used and experienced in the future, and the number and range of stakeholders who have an interest in, and influence on, the nature of alarms will increase. Already, many stakeholders who are involved with health technology have limited exposure to, knowledge of, and concern for optimal and appropriate audible alarm design. With the increase in technology such as middleware and wearable devices, health professionals’ interest and involvement in audible alarms is likely to expand exponentially. Thus, considerable thought needs to be given to the alarm design process in a broad, inclusive sense to capitalize on the knowledge and expertise that exist in this area.

In this article, the future of audible alarm design is considered from the perspectives of technological trends and cultural and societal demands. We discuss why the health technology field needs a holistic and design-centered approach and propose collaborative ways to design for future healthcare applications. Current trends in audible alarm design are discussed, and good practices demonstrating inclusive collaborations from intensive care units (ICUs) are described, as medical audible alarms, patient monitoring, and patient data are instrumental to critical care. Moreover, this article considers a broader approach in terms of future applications that will represent less critical settings/environments in which new technology is likely to be used.

**Future Trends and Demands Related to Alarms**

Medical devices are becoming increasingly personalized and tailored to the patient or user. In general, people are becoming more aware of the data that they produce (through smartphones, smartwatches, and dedicated health wearables) and demand that health professionals add value to these data in terms of lifestyle guidance, treatment, and even early recognition of diseases. Device manufacturers, as well as Internet giants, are addressing this demand by developing cloud- or app-based platforms that give developers the opportunity to capitalize on the value of patient data by bringing together health professionals and patients. As a result of this collaboration, patients are provided with a sense of data ownership and management.

Sensor technology for monitoring vital signs is also developing rapidly. Manufacturers are producing small wireless sensors for hospital contexts and vests that have built-in sensors. In addition to providing comfort for patients, sensor technology can make patients aware of oncoming complications through early-recognition algorithms (e.g., vests that act as defibrillators by detecting cardiac events). Moreover, such small-sized medical devices will be used in domestic
contexts, allowing patients and nonmedical caregivers to interact with medical procedures. With more data to process (remotely or in hospital), hospitals will also change their data management strategy to centralized intensive patient data monitoring in addition to the intensive care provided by nurses.

One emerging example is the telehealth program of the Emory University Critical Care Center in Atlanta, GA. Through a collaboration among Emory Healthcare, Royal Perth Hospital in Australia, and the health technology company Philips, the Emory Electronic ICU Center, which aims to monitor patients remotely during a 24-hour span, was established.\(^5\) Such monitoring centers or data management departments will also require the expertise of more technical personnel (e.g., information technologists) who can make valuable connections among variables regarding patient data.

These developments are paving the way toward a more strategic handling of patient data and personal use of medical devices. Considering these broader technological advances, harnessing advances in audible alarm implementation is of vital importance.

Broader Context in which Alarms Are Used

Since the clinical alarms summit in 2011,\(^3\) high-profile and concerted efforts have been made to reduce the problem of alarm fatigue. Although alarm fatigue has not been clearly delineated and a full understanding has not been achieved, the general idea that clinicians are overwhelmed with alarms has considerable traction and various solutions have been sought. Measures, such as setting parameter limits in a more patient-specific fashion, ensuring that leads and sensors are regularly checked and changed, and ensuring that alarms are disconnected, have led to reductions in false alarms. The implication is that alarm fatigue is reduced as a result.\(^5-12\)

At a broader level, however, cultural and sociotechnical issues also play a part in how alarms are used. For example, one of the few studies that attempted to find predictors of alarm fatigue showed that variation among the “big five” personality traits influenced objective measures of alarm fatigue, whereas the number of alarms (i.e., the most obvious factor to be expected to correlate with alarm fatigue) did not.\(^7\) Thus, to address the issue of alarms and alarm fatigue, both individuals and the cultural status quo need to be considered.

Audible alarms have socio-technological relevance, and the use of alarms might also be observed and studied using ethnographical approaches (i.e., by focusing on the individual, the individual’s behavior, and the social and cultural constraints affecting that behavior). Because humans are creative, they will find ways to use audible alarms in ways that were not intended. For example, they might use an audible alarm as a monitoring signal as patient data fluctuate in and out of the acceptable range of a physiological variable. Although creative ways of using alarms may not necessarily be prescribed by the regulatory agencies, understanding why humans choose different uses for alarms can inform designers and researchers by providing insights into new roles for alarms. As technical objects, these cultural and social consequences of alarms suggest that in addition to engineering, other disciplines should be included in the design and evaluation of alarms.
New Perspectives on Alarm Design

The following section discusses the alarm design process from the perspectives of interested stakeholders, as well as describes emerging technologies and their potential contributions to the field. In Figure 1, the major stakeholders and their involvement in the context of alarm design, as well as their ability to change alarm norms, are illustrated. The figure shows that many people who have direct issues with alarms (e.g., patient delirium, postintensive care syndrome, alarm fatigue) have little authority to change alarms, whereas actors who do have this authority typically have only indirect knowledge about alarm issues (through hospital management or equipment producers). Ideally, patients and clinicians, regulatory agencies, manufacturers, and hospital management would participate equally in the development of new alarms and related emerging issues.

In many cases of alarm design and implementation, stakeholders investigate alarm issues independently of other issues due to the complexity of the event and the various types of expertise required. However, it is this very complexity that calls for a collaborative approach. Currently, the instances of collaborative approaches in this field are scarce. If and when stakeholders interact with each other during the process of alarm design and implementation, they typically contribute in a linear but circular way, meaning that the alarm is both the problem to address and goal to achieve. Linear interactions cause sequential interpretation and handling of the alarm issues from different perspectives.

Figure 2 illustrates this linear but collaborative approach to alarm design, in which users, knowledge institutes, public actors, and private actors take part in a stepwise fashion. First, issues with critical alarms are exposed through the experiences of users. Then, these experiences are studied (often in laboratory conditions) by knowledge institutes (academic hospitals and academia representing technical and social sciences) to gain deeper insights and demonstrate evidence-based research. The issues proven are raised to the public actors through scientific publications, public awareness through published media, and lobbying. Private actors (e.g., health technology companies) then respond to the directives published by regulatory agencies with the aim of solving the issues of the target group.

Although the framework in Figure 2 effectively captures the essence of desired activities, the order of interactions, and focus on users, this framework still needs to be...
"future proofed," allowing for innovation in critical alarm design to occur along with developments in emerging technologies. Stepwise collaboration can interrupt the innovation process and delay the placement of novel products at the service of patients and clinicians; thus, a substantial time gap can occur between discovering user needs and those users benefiting from novel solutions. Considering how fast technology is evolving, the actors in the field of alarm design will need to find ways of shortening the alarm development process.

Overall, the current issues with critical alarms derive from alarms being a symptom representing an intertwined problem with numerous sources (e.g., sounds, devices, patients, clinicians, patient rooms, data management algorithms, rules and regulations) and various stakeholders (Figures 1 and 2). Although a health professional only hears "an alarm," that particular alarm has to be designed from multiple perspectives so as to satisfy a range of requirements in order to be a reliable and effective part of the healthcare system. Issues with critical alarms will be even more of a problem as new technologies with untested and unforeseen effects are introduced in healthcare practice. To be more proactive and prevent undesirable consequences of critical alarms in future contexts, the field of critical alarm design would benefit from evolving into a collaborative approach that brings multidisciplinary knowledge together in one hub accessible by all contributors.

**Alarm Signal Design**

Symptomatic of the consequences of the linear, constrained approach described above is the way audible alarms for medical devices typically have been designed and implemented. It is important not to underestimate the extent to which the audible signals that signify alarm conditions themselves contribute to adverse experiences of alarms. This is likely to get worse as medical devices flood the home and other nontraditional environments. Here, technology lags far behind what is possible and indeed desirable. Despite the fact that digital technology allows almost any sound to be used as an alarm signal, with few exceptions, medical devices of all sorts cling to old-style "beep" and "ping" sounds. The use of these sounds creates a raft of problems, including lack of distinctiveness, acoustic aversiveness, and lack of meaning. Expensive medical devices often remain equipped with the most basic of audible alarms, while smartphones—devices that new medical technologies might wish to emulate—are equipped to provide a near-endless variety of sounds (via ringtones, SMS messages, or other alerts) and are supported by sounding devices that are of sufficient quality for us to identify almost any kind of sound.

To be more proactive and prevent undesirable consequences of critical alarms in future contexts, the field of critical alarm design would benefit from evolving into a collaborative approach that brings multidisciplinary knowledge together in one hub accessible by all contributors.

**Collaborative Approaches in Critical Alarm Design**

In Figure 3, an updated version of the framework shown in Figure 2 is proposed. Figure 3 shows the individual and collaborative roles of the different stakeholders in, and their role in contributing to, the future development of audible alarms. This framework illustrates a nonlinear collaborative approach, with the aim of being inclusive in decision making by taking a holistic view of the alarm issue and emerging technologies. The framework in the figure consists of three parts: 1) actors (i.e., stakeholders); 2) the knowledge, skill, and research and development activities of actors; and 3) a living lab for observing the context of alarm use.

The actors (i.e., clinicians/visitors/patients, knowledge institutes, public and private actors), representing different disciplines or backgrounds and having varying concerns regarding critical alarms, can equally seed knowledge into, and gain knowledge from, in situ experience of critical alarms. These actors can coparticipate in various research and design activities by exploring, experimenting, cocreating, and...
evaluating critical alarms before the alarms are put into practice. The coparticipation takes place in a living lab environment, which is the natural habitat of clinicians using alarms and people who are exposed to alarms (i.e., patients, visitors, or even clinicians not using the alarms).

The research activities in this human-centered framework are multidisciplinary by nature and focus on ethnography, emotions, and behavioral tendencies; ergonomics and usability; engineering; innovation; and policy making and regulations. While ergonomics research tackles patient safety and effectiveness of alarms, the ethnographic stance is crucial to ensure the positive role of critical alarms in users’ daily activities and their fittingness to users’ concerns.9 Ethnographic research into alarms requires observations and interviews with clinicians, patients, and families in order to document the clinical and nonclinical use of critical alarms and predict their impact on the well-being of people in a medical setting.21 Results of such research may be more valid if observations are based on real-life contexts. Therefore, in this article, the living lab concept22,23 is proposed as an inclusive hub that allows equal and simultaneous exchange of information among stakeholders, with a focus on the active participation of clinicians and patients, including their visitors (Figure 3).

In a living lab dedicated to improving audible alarms, new types of alarms and novel equipment (particularly new technologies) can be explored and conceptualized from the users’ perspective and new ideas can be tested with and against evidence-based scientific approaches found in healthcare and technology institutions. These ideas can be cocreated with users and influence the long-term policies of regulatory agencies. In addition, equipment producers can have first-hand knowledge of the requirements of alarm or equipment design and evaluate the results of joint efforts with target users. This approach also will involve the application of cutting-edge research relevant to the project. The living lab could be seen as an organism with the purpose of fostering a distinct way of thinking: Alarms are desirable objects.

Similar initiatives have emerged that exemplify the need for transforming healthcare via a holistic and inclusive approach. For example, in the Netherlands, a network called Medical Delta24 has been established that connects partners from life sciences, computer sciences, medical technology, and local governments in living labs to work toward a common purpose (e.g., health aging, care robotics).

In the United States, within Sibley Memorial Hospital, which is part of Johns Hopkins Medicine, an innovation hub was created to improve patients’ hospital stays. Using design approaches with a focus on users, the Sibley Innovation Hub encourages tackling pain points for both staff and patients, from prototyping soundscapes for the staff’s Tranquility Room to reducing alarm fatigue throughout the hospital.25,26

On a smaller scale, partnerships (e.g., personnel exchange, educational or doctoral collaborations) among hospitals, health technology companies, and design schools also are trending in the Netherlands. These partners are seen as complementary to Figure 3. Framework illustrating the proposed holistic context of alarm design, with stakeholders equally and simultaneously contributing to the development of future alarms and medical equipment in living labs designated for critical alarms.
achieving innovation in the complex domain of healthcare (e.g., Medisign MSc specialization and Critical Alarms Lab of Delft University of Technology (TU Delft) collaborating with Intensive Care Department of Erasmus University Medical Center [Erasmus MC]).

Below, three recently or nearly completed projects pertaining to future solutions to ICU alarms are showcased. In addition to demonstrating the multistakeholder collaborations taking place in settings similar to the living labs concept, these projects exemplify how emerging technologies are fertile grounds for innovation in alarm signals and systems. Thus, the projects suggest that the norm for alarms, as well as the systems used to deploy them, will fundamentally change in the future and that this change will be more substantial and better integrated with simultaneous input from involved stakeholders. These early examples, though at times not fully meeting the collaboration flow proposed in the framework of Figure 3, indicate the need for, and a movement toward, a holistic and collaborative approach.

**Designing alarms for global standards.** ANSI/AAMI/IEC 60601-1-8:2006 & A1:2012 is a global medical device standard dealing with various safety issues related to medical devices and, therefore, holds considerable importance for stakeholders concerned with the safety of medical devices.28 The case study reported here is concerned specifically with the audible alarms described within the standard (called "reserved" sounds). To be compliant with the standard, a manufacturer either needs to use these alarms or demonstrate that those that will be used are at least as effective as those indicated in the standard.

The alarms specified in 60601-1-8 fail the alarm design framework described here (Figure 2) in that the main input came from the regulatory bodies themselves (more specifically, from members of the standards committee, who were both clinical practitioners and who had some skill and interest in music and sound). Therefore, almost no input was provided from the stakeholders indicated in section 2 (knowledge institutes) of the framework, with limited input from those indicated in sections 1 (users) and 4 (private actors). Unsurprisingly, the reserved alarms have been shown to be considerably less than optimal.15,16,18–20

Over time, the importance of updating these alarms became apparent, as did adopting a multidisciplinary, transparent, collaborative project in which all relevant stakeholders work toward a common goal consistent with the framework shown in Figure 3. The revision of 60601-1-8 has taken this path, and as a result, when the standard is updated toward the end of 2019, it should specify new auditory alarms that are much easier to learn and localize, are resistant to masking, and are less inducing of alarm fatigue. The scientific evidence supporting these features is available in the public domain via peer-reviewed publications, and the adoption and acceptance of the new alarms through the appropriate regulatory bodies has been open and transparent to anyone who wishes to follow the project.17,29–32

In addition to representing a new, more inclusive way of developing alarms for standards, the sounds that will be described in the revision of 60601-1-8 will be very different from those currently in use. The research indicates that "auditory icons" are much easier to learn and recognize than traditional abstract tones and beeps; therefore, it is expected that alarm sounds with an iconic relation to their sources will be adopted in the new version of the standard.17,29,32 Auditory icons typically are real-world sounds that act as metaphors for the events that they are portraying. For example, a sound that in some way resembles or mimics an actual heartbeat might be an appropriate auditory icon for a cardiovascular sound. Once these sorts of sounds start to be adopted, the soundscape of medical alarms will change, which also will have consequences for future technologies.

Because the new sounds represent a move away from using precisely specified abstract sounds towards sound as metaphor, much greater potential exists for tailoring sounds to
a specific context or person. For example, many versions of a heartbeat sound could be used to signify a cardiovascular event, but all of the sounds can be recognized as signifying heartbeats. The metaphor is important in recognition and learning, whereas the specific acoustic details of the sound can to some extent be tailored to specific contexts (e.g., a noisy background, the need for the patient to have a quiet environment). This opens up numerous possibilities for audible alarms, giving users some level of choice in tailoring alarm signals to their needs.

This approach fulfills the recommendations of the framework in a comprehensive fashion, with interaction among the various stakeholders representing the four sections (users, knowledge institutes, and public and private actors) shown in Figure 3. The process of revising 60601-1-8 began with interactions between sections 2 and 3 of Figure 3, in the form of university academics collaborating through standards committees (representing public actors). Then, input was provided by medical device manufacturers (section 4) and clinical users (section 1), both through scientific studies and as public actors (section 3; relevant standards committees with their varied representation, including medical device manufacturers). Through publication of articles demonstrating the progress of the findings, the work is essentially opened up to scrutiny by the academic community (section 2) and, where access is possible to the relevant research, other stakeholders. Some groups of users, particularly patients and family members, have had little involvement in revising 60601-1-8. However, the goal is to engage these stakeholders before revision of the standard is completed.

**Intensive care alarm system.** The Intensive care alarm system (ICAS; Figure 4) is the result of a collaboration funded by the Delft Health Initiative of TU Delft. One of the conditions for funding research was to bring technology and medical partners of the Medical Delta Program together (see above). As a result, design engineers of TU Delft interacted with clinicians of the Adult Intensive Care Department of Erasmus MC. A designer led the project alongside a clinician, with all observations and evaluations conducted at Erasmus MC. The aim was to prevent unnecessary noise in patient rooms by designing a user-sensitive patient monitor that is by default silent in the patient mode but becomes active and alive when recognizing a clinician in the vicinity. The need for such a monitor was based on the authors’ observations and interviews with ex-ICU patients, as well as clinicians’ concerns that their work needs disturb patient sleep and may even induce delirium.

![Figure 4](image-url) Illustration of the intensive care alarm system, which is a user-sensitive patient monitor that silences the alarms in the patient room by default but activates them only for clinicians, ensuring a more comfortable resting environment for patients.
ICAS uses Internet-of-things technology, together with detection algorithms and machine learning so that systems triggering alarms are sensitive to user needs and alarms target the designated person entering in the patient room (i.e., clinician, patient, visitor) by choice. This targeting of alarms can go as far as differentiating between an intensivist and a nurse, as well as between the patient's clinicians and supporting clinicians. ICAS paves the way for personalizing the display of information (audible alarms or visual alerts) even in critical contexts, which is in line with the trend of personalized medicine and e-health. Such personalization would be based on roles rather than personal preferences.

Because alarms are inherent to all electronic and sensing equipment in patient rooms, the next goal is to upgrade the connectivity of devices by incorporating other alarm-producing devices. At the time of this writing, the team behind ICAS was setting up a larger collaboration with a pediatric ICU and multiple medical equipment manufacturers (of monitoring and support devices, such as mechanical ventilators and intravenous pumps). The team will apply for a clinical trial with the hypothesis that in quieter rooms, patients’ sleep quality will increase and the chance of delirium will decrease. The expectation is that positive results might convince the regulatory authorities that alarms belong to clinicians, whereas patients need to be free of them.

ICAS has partially met the recommendations of the proposed framework shown in Figure 3. The project was initiated by knowledge institutes (section 2), such as a design school (TU Delft) and an ICU (Erasmus MC), to address the concerns and needs of users (section 1), especially patients and clinicians. Interactions among these stakeholders were successful in practice, in the sense that a proof-of-concept of a product with a working prototype was created. However, direct input from public actors (section 3) as to what is realistically possible was not gathered. Also, private actors (section 4) were represented only by technical staff who maintain and support the use of medical devices at the hospital—not by engineers or managers from health technology companies.

A full collaboration with the involvement of the stakeholders in all four sections might bring a better integrated product solution. However, the outcome of the collaboration drew the attention of a health technology company that is concerned with the requirements of regulatory agencies, as well as inspired other research institutes that want to substantiate the safety and reliability aspects of the created concept.

**CareTunes: music as a nurse’s work tool.**

CareTunes is an international collaboration funded by DesignUnited, the Dutch federation for design schools. It brought together the knowledge and skills of designers, researchers, artists, engineers, and clinicians in a unique and creative way (Figure 5).

![Figure 5. CareTunes, which was designed as a work tool for monitoring of patients by nurses, is a continuous musical stream that summarizes patient vital signs.](image-url)
Dutch partners (TU Delft, Erasmus MC and New Compliance) were interested in interaction and system design in healthcare, and U.S. partners (Vanderbilt University Medical Center in Tennessee and SenSound in Virginia) were interested in medical utilization and musical quality.

CareTunes was developed as a continuous musical stream that summarizes patient vital signs and presents them in a coherent, logical, and pleasant way to clinicians. The objective of CareTunes is to provide clinicians with a clear understanding of the overall criticality of patient status, its trend toward recovery or deterioration, impulsive changes in the vital signs of patients, and the history of changes in vital signs. The aim of the project was to draw the attention of the public actors and create awareness in patient organizations that designing pleasant yet informative, rather than aversive, sounds as work tools was possible. CareTunes has been selected for the Embassy of Health Exhibition of the Dutch Design Week in 2018, which will facilitate further involvement of additional actors.

The CareTunes project fulfills the recommendations of the proposed framework in Figure 3. The project was initiated by DesignUnited as a public actor (section 3) with the broader vision of supporting innovation in healthcare. It involved design researchers and designers from TU Delft, clinicians from Vanderbilt University (section 2), and private actors from NewCompliance (a technology company) and SenSound (a musical art studio) (section 4). Erasmus MC supported the project by permitting its clinical staff to take part in cocreating and evaluating the concept (section 1). The outcome of this project aligns with the initial call for daring and fresh design solutions that are beyond classical views on what alarms should be like.

Conclusion
The conservative approach described in Figure 2 has, up to now, been used in almost all alarm design domains. In this article, we have argued that the multidisciplinary and multistakeholder field of alarm design presented in Figure 1 will need to keep up with technological advances and user demands for more personalized, intelligent care and seamless interactions with advanced medical equipment.

Moreover, as novel devices and new functionalities are introduced into critical care, alarms will be quite different from those used presently. New alarms, novel devices, and complex infrastructures are likely to provide challenges in development, testing, and user evaluation. Thus, it also is expected that the nature of academic research into alarms, as well as clinical trials, will undertake new techniques as part of our proposed and tested collaborative and holistic approach. For example, ethnographic and behavioral research might well be in demand in order to predict user responses, and high-fidelity prototypes will be used as part of clinical trials. Furthermore, the established fields of interaction design and experience-driven design will provide much needed perspectives on human-centered innovation.

Although innovative processes often belong to industry, because of the complexity of the alarm design process, it is suggested that innovation might take place openly and in collaboration. This approach allows any stakeholder to initiate the design and innovation process, while also allowing for collaboration with partners who can bring a more holistic view on alarm issues. By allowing for a more rooted and simultaneous integration in the ecology of health systems, this inclusive and holistic approach will likely improve the extent to which clinicians, patients, and visitors experience interactions with alarms and consequently with health technology.

References


Reduction of clinical alarms is a priority due to alarm fatigue and the high incidence of nonactionable alarms, especially those generated from physiological monitors. However, research on infusion pump alarm types and frequencies is limited. The purpose of this study was to establish a baseline for infusion pump alarm frequencies and duration in the hospital setting. Frequency and duration of alarms across 29 hospitals using 11,410 infusion pumps revealed 987,240 alarms associated with 568,164 infusions during a consecutive 60-day period. Pump alarms accounted for only 0.8% of infusion time, with an average of 1.74 alarms per delivery and 0.18 alarms per hour. Average alarm duration was 0:02:38 (h:min:s), with 60% of alarms being addressed within 0:01:08.

The most frequent alarms were keep vein open (33.77%), hold expired (27.18%), and downstream occlusion (22.94%). The medical/surgical and intensive care unit (ICU) care areas had the highest number of alarms (41.66% and 39.70% of total alarms, respectively), but pediatrics/neonatal ICU had the highest frequency of alarms per delivery (4.91). Intravenous fluids accounted for 47.16% of total alarms, with an average of 3.03 alarms per delivery, whereas parenteral nutrition and propofol had 6.77 and 6.74 average alarms per delivery, respectively. A higher average number of alarms per delivery occurred on Saturdays (1.74) and Sundays (1.73) compared with weekdays. Infusion pump alarm data collected and analyzed were sufficient to establish a reasonable baseline of infusion pump alarm types and relative frequencies for the device.

Healthcare facilities and patient rooms contain many devices (e.g., physiological monitors, ventilators, pulse oximetry machines, infusion pumps) with audible alarms competing for caregivers’ attention. The variety of bedside alarms in intensive care units (ICUs) has increased sixfold during the previous three decades, resulting in reported frequencies of bedside alarms as high as 40 times per hour.1

Most evidence on device alarms has focused on electrocardiogram, physiologic monitors, and pulse oximetry in the telemetry and ICU, where alarm incidence is thought to be highest.1–4 Of these alarms, 80% to 99% have been reported as nonactionable (i.e., defined as true but requiring no clinical intervention). For example, narrowly set monitor thresholds may cause true but clinically insignificant alarms to sound.2,4 Generally, the high frequency of nonactionable alarms may lead to alarm desensitization among staff, which is universally described as alarm fatigue.2,5–7

Without proper management, alarms meant to alert clinical staff to potential problems may actually put patients at risk for delayed clinician response or nonresponse to actionable alarms (i.e., alarms that are true and require clinician intervention to address or resolve).8–10

Although many physiological monitor alarms are nonactionable and/or self-correcting, infusion pump alarms typically are actionable, indicating a specific condition (e.g., air in line, occlusion, infusion complete), and they will continue to alarm until addressed. Yu et al.7 reported 10 months of alarm data from one pump at one institution, resulting in a total of 64,511 minutes of alarm activation. Mean resolution times for 83% of alarms were one minute or less; however, 3% of alarms took more than four minutes to resolve. The researchers were concerned about the high prevalence of alarms and longer resolution times during night shifts but did not specify types of alarms. They suggested future work to link pump alarm events to patient safety events. Clearly, more research is required to identify
the quality of care, patient safety issues, and staff workflow dynamics associated with low proportion, but highly actionable, infusion pump alarms.

In this study, an infusion pump alarm is defined as an audible and visual signal during pump operation that requires intervention from the user for it to be silenced. This is different from a dosing alert, which is a single, nonrepeating message when attempting to program outside the drug library limits.

The purpose of this study was to establish a baseline for infusion pump alarm frequencies and duration in the hospital setting. A robust alarm analysis of thousands of infusion pumps across multiple hospitals is reported. The alarm analysis details the frequency and duration of 987,240 alarms associated with 568,164 infusions during a consecutive 60-day period. Data were collected between April 2014 and February 2017. These data will initiate the necessary benchmarking of infusion pump alarms, allowing evidence-based recommendations to improve actionable clinical alarm management.

Methods
Data were collected and analyzed from 29 hospitals located primarily (n = 25) on the East Coast (Pennsylvania, New Jersey, New York, Maryland, Virginia, North Carolina, and Florida), with the remaining hospitals (n = 4) located in Kentucky, Iowa, and California. The hospitals included 28 short-term acute care hospitals with 62 to 934 staffed beds and one 25-bed critical-access hospital. The departments involved in the study included critical care, emergency, trauma, obstetrics, oncology/infusion, transplant, medical/surgical, operating room/postanesthesia care, catheterization laboratory/special procedures, pediatrics, neonatal intensive care, and palliative care.

All hospitals were using the same large-volume infusion pump (smart pump) model with a proprietary infusion data software application that collects, stores, and displays infusion data in real-time views and reports (Outlook 400ES Safety Infusion System and DoseTrac Infusion Management Software; B. Braun Medical Inc., Bethlehem, PA). This smart pump is intended for use with adult, pediatric, and neonatal patients and is equipped with smart pump dose error reduction software and two-way wireless communication. All hospitals had been using the pump and associated software for a minimum of one month prior to transferring a database copy containing up to 18 months (April 2014 to February 2017) of infusion pump data to the investigator. Data were imported and sent via secure file transfer protocol to a secure central server protected by firewalls, then HIPAA (Health Insurance Portability and Accountability Act) deidentified (as necessary) and merged with a dedicated, secure data repository.

A subset of these data containing a consecutive 60-day time frame (i.e., same quantity of days) for each hospital was used in the statistical analyses. For each hospital, the most recent 60 consecutive days of data available to the researchers were used. Microsoft SQL Server (2012; 11.0.5343.0 X64) was used, and unique code was written to sort the data to complete the descriptive analyses (percent, mean, median, mode, range, and/or frequencies, as appropriate).

The data elements analyzed are listed and defined in Table 1. Eleven types of alarms produce an audible tone and visual message on the pump screen and alarm repeatedly until resolved by a clinician. To be included in the analysis, alarm records had to be complete and have consistent data elements from alarm start to alarm stop. For example, elements such as pump serial number, drug category, rate, dose, volume, and care area cannot be changed during a single alarm state. If any data elements were different or missing from alarm start to stop, the alarm record was excluded.

In addition, all data were cleaned of clinically nonsignificant alarms (i.e., data with little to no clinical value), such as alarms that were greater than 60 minutes or three or fewer seconds in duration. Prolonged alarms are likely to occur outside the patient care area (i.e., while a patient is ambulating off the unit or during biomedical testing and service) and can inappropriately skew the data, resulting in a deceptively higher average alarm duration. Momentary alarms that are three or fewer seconds in duration are likely occurring during pump
programming and, deceptively, can lower the average alarm duration. No additional measures were undertaken to determine whether individual pumps were operating correctly.

Collating data across multiple hospitals and running queries on those data required intricate management of enormous amounts of complex data. A validation protocol was used to direct the collating, cleaning, and assembling of data to ensure the process was valid and reliable. This validation protocol included testing of exclusion criteria using random sampling of infusion records, followed by comparing the data assembly tool output with the data management software database record for the same infusion, testing metrics using a randomly selected day, and comparing the data assembly tool extraction with the data management software database records for the same time period.

**Results**
A total of 29 hospitals using 11,410 infusion pumps were included in the study. During the 60 consecutive days of use, 568,164 deliveries occurred. The pumps were in an active delivery state for 5,508,384 hours, representing the total potential time the pumps could alarm. The pumps were in an alarm state 0.8% (SD unknown) of the time (43,598 hours) and in a nonalarm state (run and hold) 99.2% (SD unknown) of the time (5,464,786 hours). From a total of 1,036,371 reported alarms, 987,240 were included in the analysis following data cleaning. A total of 49,131 alarms (4.7%) were excluded (37,902 due to incomplete or inconsistent alarm records, 9,884 for duration ≥60 min, and 1,345 for duration ≤3 s). Average alarms per delivery were 1.74, and average alarms per hour were 0.18. Average alarm duration (h:min:s) was 0:02:38 ± 0:05:27 (mean ± SD), with a median duration of 0:00:43. Of alarms, 20% were addressed within 0:00:11, 40% within 0:00:28, 60% within 0:01:08, and 80% within 0:03:19.

The most frequent alarms (Table 2) were keep vein open (KVO; 33.77%), hold expired (27.18%), and downstream occlusion (22.94%). The alarms with the longest average duration (h:min:s) were downstream occlusion (0:03:58), battery empty (0:03:48),

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Operational Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of hospitals</td>
<td>Number of individual hospitals reporting into each database</td>
</tr>
<tr>
<td>Number of pumps in use</td>
<td>Number of unique pump serial numbers in use during the 60-day time frame</td>
</tr>
<tr>
<td>Number of deliveries</td>
<td>Number of unique medication deliveries (a single infusion from start to stop) running in the 60-day time frame</td>
</tr>
<tr>
<td>Number of alarms</td>
<td>Total number of alarms during the 60-day time frame</td>
</tr>
<tr>
<td>Active delivery state</td>
<td>Total time and percent of time pumps in hold, run, alarm, and KVO state; total time from run to off that pump can alarm</td>
</tr>
<tr>
<td>Alarm state</td>
<td>Total time and percent of time pumps in alarm and KVO state</td>
</tr>
<tr>
<td>KVO state</td>
<td>Total time and percent of time pumps in KVO state</td>
</tr>
<tr>
<td>Average alarms per delivery</td>
<td>Total number of alarms/total number of deliveries</td>
</tr>
<tr>
<td>Average alarms per hour</td>
<td>Total number of alarms/total time</td>
</tr>
<tr>
<td>Average alarm duration</td>
<td>Cumulative duration of all alarm states/total number of alarms</td>
</tr>
<tr>
<td>Alarm frequency and duration by alarm type</td>
<td>Number of alarms, percent of total, and average duration for each alarm type (air in line, bag empty, battery empty, check set, door open, downstream occlusion, hold expired, KVO, low flow from container, system error, upstream occlusion)</td>
</tr>
<tr>
<td>Alarm frequency and duration by drug category</td>
<td>Number of alarms, percent of total, alarms per delivery, and average duration for each drug</td>
</tr>
<tr>
<td>Alarm frequency and duration by care area</td>
<td>Number of alarms, percent of total, alarms per delivery, and average duration for each care area (user selected drug library)</td>
</tr>
<tr>
<td>Alarm frequency and duration by day of week</td>
<td>Number of alarms, percent of total, alarms per delivery, and average duration for each day of week</td>
</tr>
</tbody>
</table>

Table 1. Alarm data elements with operational definitions. Abbreviation used: KVO, keep vein open.
and bag empty (0:03:01). The medical/surgical and ICU areas had the highest alarm frequency based on total alarms (41.66% and 39.70% of total alarms, respectively), but pediatrics/neonatal ICU (NICU) had the highest based on the number of alarms per delivery (4.91) (Table 3). The medical/surgical care areas also had one of the highest average alarm durations (0:03:25).

The top three drug categories within the drug library with the highest number of alarms based on percent of total were intravenous (IV) fluids (47.16%), heparin (5.58%), and IV piggyback (IVPB; 4.76%), with average alarms per delivery of 3.03, 4.74, and 0.82, respectively (Table 4). Parenteral nutrition and propofol had the highest alarm frequency at 6.77 and 6.74 average alarms per delivery, respectively.

A higher average number of alarms per delivery occurred on Saturdays (1.74) and Sundays (1.73) compared with weekdays (1.29–1.38) (Figure 1). Average alarm duration (h:min:s) by day of the week ranged from 0:02:36 to 0:02:42.

### Discussion

The relatively low incidence of pump alarms (0.8% of total infusion time, 1.74 alarms/delivery, 0.18 alarms/infusion hour) is consistent with other published reports addressing the percent of infusion pumps compared with other medical devices (e.g., physiological monitors). However, because pumps are used on nearly every patient in the hospital, and nearly all pump alarms are actionable, improving actionable alarm management based on the evolving data is important. The sheer number of infusion pumps used and nature of these alarms may contribute to patient harm if staff hesitate to respond due to alarm fatigue.

Direct comparison of various study alarm results should be done with caution. Alarm data are complicated by treatment of data (e.g., inclusion/exclusion principles), pump alarm type and capabilities (e.g., model of infusion pump, number of alarms available), and pump configurations (e.g., pressure settings, KVO and pre-alarms enabled/disabled). A previous study of 131 large-volume pumps infusing 362,778 hours in an acute care hospital found that pump alarms accounted for approximately 5% of total infusion time, which is a much higher percentage of infusion time than the 0.8% across all hospital units reported in the current study. Yu et al.7 reported 60,773 alarm

<table>
<thead>
<tr>
<th>Care Area</th>
<th>No. of Deliveries</th>
<th>No. of Alarms</th>
<th>No. of Alarms per Delivery Mean ± SD</th>
<th>Percent of Total</th>
<th>Average Duration (h:min:s) Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical/surgical</td>
<td>95,126</td>
<td>204,803</td>
<td>2.15 ± 4.80</td>
<td>41.66</td>
<td>0:03:25 ± 0:06:12</td>
</tr>
<tr>
<td>ICU</td>
<td>72,106</td>
<td>195,210</td>
<td>2.71 ± 6.11</td>
<td>39.70</td>
<td>0:01:30 ± 0:03:31</td>
</tr>
<tr>
<td>ED</td>
<td>8,919</td>
<td>24,684</td>
<td>2.77 ± 5.01</td>
<td>5.02</td>
<td>0:02:46 ± 0:05:21</td>
</tr>
<tr>
<td>Pediatrics/NICU</td>
<td>4,840</td>
<td>23,741</td>
<td>4.91 ± 8.98</td>
<td>4.83</td>
<td>0:01:03 ± 0:02:24</td>
</tr>
<tr>
<td>Oncology/infusion</td>
<td>9,628</td>
<td>15,200</td>
<td>1.58 ± 3.39</td>
<td>3.09</td>
<td>0:01:31 ± 0:03:17</td>
</tr>
<tr>
<td>OB/L&amp;D</td>
<td>7,340</td>
<td>12,222</td>
<td>1.67 ± 2.84</td>
<td>2.49</td>
<td>0:01:42 ± 0:03:34</td>
</tr>
<tr>
<td>Step down/telemetry</td>
<td>3,621</td>
<td>9,876</td>
<td>2.73 ± 5.55</td>
<td>2.01</td>
<td>0:03:50 ± 0:06:55</td>
</tr>
<tr>
<td>OR/PACU</td>
<td>2,739</td>
<td>4,573</td>
<td>1.67 ± 4.10</td>
<td>0.93</td>
<td>0:00:59 ± 0:02:26</td>
</tr>
<tr>
<td>Cath lab/special procedures*</td>
<td>1,034</td>
<td>1,129</td>
<td>1.09 ± 2.29</td>
<td>0.23</td>
<td>0:01:33 ± 0:04:07</td>
</tr>
<tr>
<td>Therapy specific†</td>
<td>200</td>
<td>224</td>
<td>1.12 ± 1.31</td>
<td>0.05</td>
<td>0:03:46 ± 0:06:40</td>
</tr>
</tbody>
</table>

Table 2. Alarms (n = 987,240) by type and duration. Abbreviation used: KVO, keep vein open.

Table 3. Alarms by care area selected within the drug library (n = 491,662). *Includes imaging and interventional radiology. †Includes epidural, antibiotics, irrigation, and dialysis. Abbreviations used: Cath lab; catheterization laboratory; ED; emergency department; ICU, intensive care unit; L&D, labor and delivery; NICU, neonatal intensive care unit; OB, obstetrics; OR, operating room; PACU, postanesthesia care unit.
events across 44,798 infusion processes, which would calculate to 1.36 alarms per delivery—a slightly lower number than the 1.74 alarms per delivery reported here.

Looking at alarm frequency per hour, Gorges et al.,13 in an observational study, recorded an average of 0.74 infusion pump alarms per hour in a single ICU, which is higher than the 0.18 alarms per hour that we measured using hospitalwide data. The difference in alarm frequency is not surprising, as it would be expected that ICUs typically would use the most pumps. Kurnat-Thoma and Shah14 evaluated two weeks of IV pump alarm/alert data across six units and reported 8,761 alarms/alerts and an average of 623.6 alarms/alerts per 24 hours, which would calculate to 26 alarms/alerts per hour. The number of deliveries or infusion processes was not reported.

Data were handled differently among previously published studies. Lee et al.12 removed files that contained errors and significantly high numbers for each error code, indicating possible software corruption (n = 7). Yu et al.7 used the entire pump data set. Gorges et al.13 collected observational data only (as opposed to pump records). Other than Lee et al.12 describing the removal of seven corrupted files, the other studies mentioned no exclusion of data based on clinical relevance or otherwise; therefore, whether the data were cleaned or modified in any way is unknown.

### Table 4. Alarms by drug category selected within the drug library (n = 448,748). Drugs are listed in order of percent of total alarms, only including top 25 drugs. Abbreviations used: IV, intravenous; IVPB, IV piggyback; KCl, potassium chloride; RBC, red blood cell.

<table>
<thead>
<tr>
<th>Drug category (Top 25)</th>
<th>No. of Deliveries</th>
<th>No. of Alarms</th>
<th>No. of Alarms per Delivery</th>
<th>Percent of Total</th>
<th>Average Duration (h:min:s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV fluids</td>
<td>76,469</td>
<td>232,015</td>
<td>3.03 ± 5.61</td>
<td>47.16</td>
<td>0:02:53 ± 0:05:40</td>
</tr>
<tr>
<td>Heparin</td>
<td>5,790</td>
<td>27,470</td>
<td>4.74 ± 8.07</td>
<td>5.58</td>
<td>0:03:09 ± 0:05:57</td>
</tr>
<tr>
<td>IVPB</td>
<td>28,703</td>
<td>23,434</td>
<td>0.82 ± 1.93</td>
<td>4.76</td>
<td>0:03:00 ± 0:06:19</td>
</tr>
<tr>
<td>Propofol</td>
<td>3,447</td>
<td>23,231</td>
<td>6.74 ± 13.25</td>
<td>4.72</td>
<td>0:01:10 ± 0:02:35</td>
</tr>
<tr>
<td>Antibiotic</td>
<td>23,607</td>
<td>21,429</td>
<td>0.91 ± 2.05</td>
<td>4.36</td>
<td>0:02:19 ± 0:04:24</td>
</tr>
<tr>
<td>Parenteral nutrition</td>
<td>2,486</td>
<td>16,839</td>
<td>6.77 ± 10.57</td>
<td>3.42</td>
<td>0:01:46 ± 0:04:27</td>
</tr>
<tr>
<td>RBCs</td>
<td>4,379</td>
<td>11,648</td>
<td>2.66 ± 3.06</td>
<td>2.37</td>
<td>0:01:52 ± 0:03:58</td>
</tr>
<tr>
<td>Norepinephrine</td>
<td>3,032</td>
<td>10,027</td>
<td>3.31 ± 6.32</td>
<td>2.04</td>
<td>0:01:00 ± 0:02:16</td>
</tr>
<tr>
<td>Insulin</td>
<td>2,410</td>
<td>8,632</td>
<td>3.58 ± 8.63</td>
<td>1.75</td>
<td>0:01:11 ± 0:02:41</td>
</tr>
<tr>
<td>KCl</td>
<td>3,603</td>
<td>7,227</td>
<td>2.01 ± 2.55</td>
<td>1.47</td>
<td>0:02:15 ± 0:04:29</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>1,402</td>
<td>6,945</td>
<td>4.95 ± 8.53</td>
<td>1.41</td>
<td>0:01:05 ± 0:02:19</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>1,060</td>
<td>6,266</td>
<td>5.91 ± 13.32</td>
<td>1.27</td>
<td>0:00:59 ± 0:01:56</td>
</tr>
<tr>
<td>Pantoprazole</td>
<td>949</td>
<td>5,755</td>
<td>6.06 ± 7.56</td>
<td>1.17</td>
<td>0:02:18 ± 0:04:47</td>
</tr>
<tr>
<td>Magnesium sulfate</td>
<td>3,662</td>
<td>5,506</td>
<td>1.50 ± 2.13</td>
<td>1.12</td>
<td>0:02:16 ± 0:04:29</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>3,604</td>
<td>5,345</td>
<td>1.48 ± 1.95</td>
<td>1.09</td>
<td>0:00:52 ± 0:02:10</td>
</tr>
<tr>
<td>Nicardipine</td>
<td>1,178</td>
<td>5,037</td>
<td>4.28 ± 7.87</td>
<td>1.02</td>
<td>0:01:15 ± 0:02:45</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>1,420</td>
<td>4,736</td>
<td>3.34 ± 5.10</td>
<td>0.96</td>
<td>0:01:27 ± 0:03:09</td>
</tr>
<tr>
<td>Diltiazem</td>
<td>1,378</td>
<td>4,230</td>
<td>3.07 ± 5.29</td>
<td>0.86</td>
<td>0:02:25 ± 0:04:53</td>
</tr>
<tr>
<td>Oxytocin</td>
<td>3,204</td>
<td>4,214</td>
<td>1.32 ± 2.30</td>
<td>0.86</td>
<td>0:01:40 ± 0:03:27</td>
</tr>
<tr>
<td>Phenylephrine</td>
<td>1,013</td>
<td>4,089</td>
<td>4.04 ± 7.81</td>
<td>0.83</td>
<td>0:01:03 ± 0:02:11</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>3,590</td>
<td>3,934</td>
<td>1.10 ± 1.86</td>
<td>0.80</td>
<td>0:02:17 ± 0:04:34</td>
</tr>
<tr>
<td>Piperacillin-tazobactam</td>
<td>3,183</td>
<td>2,935</td>
<td>0.92 ± 1.58</td>
<td>0.60</td>
<td>0:02:49 ± 0:05:30</td>
</tr>
<tr>
<td>Midazolam</td>
<td>777</td>
<td>2,838</td>
<td>3.65 ± 6.98</td>
<td>0.58</td>
<td>0:00:56 ± 0:02:00</td>
</tr>
<tr>
<td>Milrinone</td>
<td>490</td>
<td>2,763</td>
<td>5.64 ± 12.09</td>
<td>0.56</td>
<td>0:01:55 ± 0:04:26</td>
</tr>
<tr>
<td>Vasopressin</td>
<td>933</td>
<td>2,203</td>
<td>2.36 ± 4.46</td>
<td>0.45</td>
<td>0:00:47 ± 0:01:39</td>
</tr>
</tbody>
</table>
After excluding what we defined as clinically nonsignificant alarms (duration ≤3 s and ≥60 min), the mean duration of infusion pump alarms was 0:02:38 (h:min:s), with a median of 0:00:43. Gorges et al.\textsuperscript{13} reported a substantially lower mean infusion pump alarm duration (43 s [range 1 s to 17.25 min]) using observation in a 12-bed medical ICU. Yu et al.\textsuperscript{7} reported that mean alarm resolution was one minute or less for 83% of alarms for a single hospital, while 60% of our alarms were addressed within 0:01:08.

The differences in study methodologies (including sampling and treatment of data) makes it difficult to compare results across studies. Creating standardized operational definitions and measurement methodologies for reporting alarm data will help to better understand and compare infusion pump alarms.

The majority (83.89%) of our study’s identified alarms were KVO, hold expired, and downstream occlusion. These alarms potentially can be reduced. KVO and hold expired alarms are anticipated; they alarm based on programmed volume to be delivered and user programmed hold time. Both can be mitigated by the user modifying programmed volumes and adjusting the hold time duration (e.g., to allow time for an IV restart, getting a new IV bag). Assuming each delivery reaches its programmed volume, one would expect approximately one KVO alarm per delivery. Excessive KVO alarms could be due to how clinicians conceptualize the infusion process, what type of infusion is being delivered, the unit environment, and the individualized effect of anticipated alarms on workflow.\textsuperscript{15} For example, clinicians might program pumps with volumes that are less than actual bag volumes, due to bag overfill not accounted for, as an intentional buffer to prevent the bag from running dry and air entering the line, or to cause a KVO alarm as a call-back feature.

Downstream occlusion alarms are unanticipated alarms that unexpectedly interrupt delivery. They can be caused by a clamped, kinked, or occluded IV tubing or catheter, IV site placement at a joint (e.g., antecubital, wrist), clogged filter, rapid IV push administration, narrow diameter catheters, and downstream pressure thresholds that are set too low.\textsuperscript{16}

Lee et al.\textsuperscript{12} looked at another pump model and found that the three most frequent alarms were “occlusion below pump,” “on hold,” and “no flow above pump.” Similar to our study, Kurnat-Thoma and Shah\textsuperscript{14} (pump model not identified) found the three most...
common alarms/alerts were “infuser idle 2 min,” “distal occlusion,” and “line A VTBI complete.” Frequency of alarms by alarm type were not reported in the other studies. Of note, each model of infusion pump comes with a unique set of alarm types and capabilities; therefore, it is problematic to make direct alarm comparisons between different models of pumps.

The medical/surgical and ICU areas had the highest percent of alarms (81% of alarms combined), and these areas had the most infusion deliveries (167,232 combined, 81% total). However, pediatrics/NICU had the highest ratio of alarms per delivery (4.91). The high pediatric/NICU alarm ratio might be related to this population having smaller lumen catheters, nonpreferred IV sites/tiny veins, crying, and uncontrolled movement, which could increase downstream occlusion alarms. Further exploring alarm characteristics in these care areas will be important to understanding why the alarm ratio is so high. At the time of this analysis, only one study reporting pump alarm data by care area could be found: Kurnat-Thoma & Shah14 found that the majority of alarms/alerts occurred in the surgical (30.6%) and critical care (25.5%) units. This example signifies the importance of looking at both total alarms and alarms per delivery. Both are important metrics and can help identify where to target alarm management interventions.

Similarly, when looking at alarm frequency and duration by drug category, results can vary widely based on the metric used. For example, IV fluids had highest number of alarms (n = 232,015) and percent of total (47.16%) because they are the most frequently delivered. However, parenteral nutrition and propofol were associated with a higher number of alarms per delivery (6.77 and 6.74, respectively); therefore, investigating drugs with a higher ratio of alarms, in order to determine whether variables exist that make these drugs more prone to alarms, may be more clinically relevant. For example, propofol and total parenteral nutrition with lipids may be associated with more downstream occlusion alarms due to higher viscosity and/or clogged filters. Downstream occlusion alarms also be caused by IV push administration of drugs such as propofol. Because some drug categories, such as IV fluids, IVPB, antibiotic, parenteral nutrition, red blood cells (RBCs), and chemotherapy, represent groupings of drugs/infusions, discerning which individual drugs in these groupings are primarily contributing to the alarm incidence is not possible. For example, some facilities selected the drug category label RBCs for infusing multiple blood products and chemotherapy can contain a large subset of patient-specific chemotherapeutic agents.

The higher average number of alarms per delivery on Saturdays (1.74) and Sundays (1.73) warrant further investigation. The weekend staff-to-patient ratio may be higher and/or weekend staff may be less experienced than weekday staff. Similarly, Yu et al. observed a higher risk for infusion pump alarm resolution based on care area and time of day, with alarms resolved significantly faster ($P < 0.001$) on day shift (6 a.m. to 6 p.m.) than night shift. A search of available literature revealed no like studies that reported incidence of alarms by day of week or shift.

Limitations
The current study had several limitations. Although the data were from 29 different hospitals, they were from one model of infusion pump. Whether other pump models would generate similar results is unknown. Variation in hospital bed size, acuity, number of pumps, and number of deliveries could affect results. Although data from the same total number of days for each hospital was analyzed, the datasets varied in size due to the number of deliveries. A possible alternative approach would be to limit datasets based on total number of deliveries per hospital rather than days.

Conclusion
The infusion pump alarm data collected and analyzed in this study from 29 U.S.-based hospitals using the Outlook 400ES Safety Infusion System via DoseTrac was sufficient to establish a reasonable baseline of infusion pump alarm types and relative frequencies for this device. The results
represent one model of infusion pump; thus, generalizing the results to all other pump platforms should be done with caution. Alarm frequency and characteristics can vary widely depending on pump model, variety of alarm types, selected configuration options, and alarm thresholds set. Therefore, comparing alarm data across different pump models, and even comparing hospitals within a system using the same pump model but with different alarm configurations and clinical practices, is difficult. Establishing consistent industrywide benchmarks for measuring and reporting alarms will be key, as will each hospital establishing its own unique baseline.

Collecting, analyzing, and cleaning pump data should follow research principles to ensure accuracy and validity. Inconsistencies with wireless communication, data capture, and major biomedical repairs can result in gaps or inconsistencies in pump alarm reporting and should be addressed. Clinically nonsignificant data require clinical and operational insight to assess and resolve; alarms that occur while the user is programming the pump may skew alarm duration averages to appear much lower overall. We attempted to control for this by eliminating alarms that were three seconds or less or 60 minutes or longer. Creating and establishing standardized metrics, operational definitions, and processes for measuring and reporting alarm data is the first step to understanding and identifying key issues of infusion pump alarms and will promote the growth and development of this area of study.

With benchmark data on pump alarms, we will be better positioned to evaluate whether technological changes can improve alarm management. Possible changes include alarm prioritization, alarm forwarding and delays, real-time monitoring, incorporating patient-specific configurations or options to personalize to hospital practices, and creating more autocorrect features. However, we also need to consider that the addition of technology could increase operational complexity and associated alarm fatigue by adding additional user prompts, programming steps, alerts, or alarms. Further research is critical to understanding the characteristics of pump alarms and how they affect clinicians and patient care so that industry and clinicians can work toward reducing alarm burden in the healthcare environment.

References


Medical Equipment and Healthcare Technology: Health Vision 2050

Adhra Al-Mawali, Avinash Daniel Pinto, and Ali Talib Al-Hinai

Abstract

To address the demands of worldwide demographic and epidemiologic changes and globalization, as well as their effects on population health, the Ministry of Health in Oman developed a long-term plan for its health system called Health Vision 2050. The plan was shaped by international consultants, who sought to augment the vision with up-to-date evidence and achieve alignment with international standards. The Health Vision 2050 main document was anchored by 24 separate strategic studies covering different dimensions and pillars of the health system, one of which was the strategic study of medical equipment and healthcare technology (MEHT). This study analyzed the current status of MEHT, highlighted the achievements and bottlenecks, anticipated future challenges, and determined the future vision through pragmatic, contextualized, and actionable objectives and strategies that will provide a platform for comprehensive MEHT planning. Of note, pharmacological technologies, pharmaceutical drugs, and information technology have not been covered under the scope of this vision. By shedding light on this important strategic study about MEHT, the aim of this article is to assist other countries that are seeking to improve their MEHT based on the latest international guidelines and standards.

The provision of equitable, reliable, efficient, and cost-effective healthcare to any population requires a robust system of properly managed resources. A high standard of healthcare cannot be achieved without medical equipment and healthcare technology (MEHT), which serves as a pillar of modern healthcare. Combined knowledge of planning, engineering, management, and financial skills has become integral to the complex system of MEHT. Embracing rapid advances in technology and integrating them through the application of engineering methods and informatics are vital elements of effective healthcare delivery.¹

In the delivery of healthcare, MEHT plays a vital role in, for example, disease prevention, earlier diagnosis, less invasive treatment options, and reduced hospital stays and rehabilitation times.² Innovations in MEHT are fundamentally transforming the healthcare landscape, providing new solutions to address chronic diseases and revolutionizing the way treatments are administered.

Finding the optimal mix of cost-effective interventions to meet the needs of growing populations with evolving disease burdens while staying within cost parameters and ensuring service sustainability can be a formidable challenge. Achieving this optimal mix requires adequately resourced processes, systems, and structures for managing the complete life cycle of MEHT—from needs assessment, planning, and budgeting to formal evaluation, procurement, warehousing, distribution, utilization, maintenance, replacement, and disposal—all of which must be overseen by governance systems for asset, cost, risk, and quality management.

Challenges of MEHT

Healthcare technology has become an integral and increasingly important component of the health sector in governments around the world, especially those witnessing demographic and epidemiological transitions. However, ensuring access to MEHT (due to various factors, including lack of availability, cost, and remote area accessibility) for specific epidemiological purposes has been challenging.

The costs of healthcare are multidimensional and complex, and medical technologies represent a considerable portion of overall spending. Trends during the previous two to three decades show that MEHT-related costs continue to increase as a result of the mushrooming of high-end technologies (e.g., advanced diagnostic imaging, laboratory-based analytical techniques, cancer treatment).
Before resource ceilings are reached, an evidence-based MEHT assessment will be needed to ensure optimal acquisition and utilization of proven, cost-effective medical technologies. Of note, the top 10 healthcare technology hazards identified by the ECRI Institute in 2018 included ransomware and cybersecurity threats, flaws in medical networking, improper cleaning causing device malfunctions, and inadequate use of digital imaging tools. The weaknesses facing Oman include a cumbersome tendering process, acquisition of technology without any health technology assessment (HTA), and lack of a long-term strategy for MEHT. These potential risks and challenges need to be minimized through the development of a policy and careful management of technologies. To this end, a SWOT (strengths, weaknesses, opportunities, and threats) analysis (Figure 1) was carried out.

**Vision 2050 for MEHT**

Predicting the future of healthcare delivery can be fraught with uncertainty and risk, especially given the high number of determinants (e.g., demographic, political, economic, social, technological, environmental, legal) affecting healthcare. With the help of international consultants and guidance from the World Health Organization (WHO), the Omani Ministry of Health created a long-term plan for the health system called Health Vision 2050. The slogan for the vision is “Quality Care, Sustained Health.”

The Health Vision 2050 main document is anchored by 24 strategic studies covering different dimensions of healthcare. Overarching issues, such as health equity, safety, quality of service, and innovation, are addressed in this vision for MEHT. The strategic study has a vision of “attainment of state-of-the-art healthcare technologies and the highest technological competencies” and a mission of “facilitating the planning, development, and implementation of sustainable national healthcare technology programs and guidelines that are safe, reliable, efficient and cost effective.”

To regulate healthcare technology and ensure efficacy, quality, and safety, it was determined that the Ministry of Health should adopt suitable quality standards for all aspects of healthcare technology. In addition, systems should be established to ensure that standards are met and that wide-ranging policies covering all aspects of the planning, utilization, effectiveness, and safety of healthcare technology are considered. To achieve the vision, establishing systems to ensure that these policies can be implemented was thought to be of paramount importance. (Of note, surgical and therapeutic procedures, pharmaceutical drugs, and information technology were not included in the scope of this vision.)

To achieve the vision and mission for MEHT, the following eight objectives, which are further described below, were developed:

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**Figure 1. SWOT analysis for healthcare technology in Oman. Abbreviation used: HTA, health technology assessment.**

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Well-established hierarchical structure with services at different levels of the healthcare delivery system</td>
<td>• No clear development of a comprehensive and dedicated asset management system and related online medical equipment database for easy access and consultation</td>
</tr>
<tr>
<td>• Transparent tendering process</td>
<td>• Cumbersome tendering process</td>
</tr>
<tr>
<td>• Existing country-wide health information system</td>
<td>• Lack of long-term strategy for healthcare technologies</td>
</tr>
<tr>
<td>• Existence of well-established health facilities with good infrastructure that can cope with advanced healthcare technologies</td>
<td>• Insufficient continuous professional development for staff at all levels</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Threats</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Wide scope of specialties within the field of healthcare technology</td>
<td>• Legislative and political environment</td>
</tr>
<tr>
<td>• Well-established information technology infrastructure</td>
<td>• Equipment pricing, competition, inflation, exchange rate fluctuations, and economic slowdowns</td>
</tr>
<tr>
<td>• Partnerships and collaboration with reputable institutes, both internally and externally</td>
<td>• Possible adverse effects of high demand and availability of medical devices</td>
</tr>
<tr>
<td>• Medical device innovation</td>
<td>• Recalls of medical devices</td>
</tr>
<tr>
<td></td>
<td>• Monopolization of the global market by medical device manufacturers</td>
</tr>
<tr>
<td></td>
<td>• Protecting medical devices from cyberattacks</td>
</tr>
<tr>
<td></td>
<td>• Patient privacy and security needs</td>
</tr>
</tbody>
</table>

www.aami.org/bit 443
1. Developing comprehensive national policies
2. Developing regulations
3. Performing a needs assessment
4. Building capacity for deployment, management, and maintenance
5. Developing a healthcare technology management (HTM) system
6. Developing a financing system
7. Supporting and promoting research and development (R&D)
8. Establishing an advanced monitoring and evaluation system

**Developing Comprehensive National Policies**

Public policies should complement the drive toward universal health coverage and service delivery reform. Policy making must be based on the core values of the health system, and wide-ranging policies must be established to cover all aspects of the planning, utilization, effectiveness, needs assessment, and safety of healthcare technology. Policies also must be reviewed periodically to respond to the ever-changing nature of healthcare technology and incorporate suitable modifications. Figure 2 illustrates the role of medical devices within the national health policy via their interlinked functionality with various phases (i.e., R&D, regulation, management, assessment) and expected outcomes (i.e., safety, quality, universal coverage, equity).

**Developing Regulations**

The Ministry of Health oversees efforts of manufacturers to ensure that medical devices are effective and safe. The safety and continued performance of MEHT are two critical elements that encompass the need for appropriate and stringent regulations. To achieve this, an autonomous regulatory body—with a specific focus on MEHT—must be established to develop national norms and standards for quality assurance, as well as to design an accreditation system. A national coordinating agency (which, preferably, should be the same agency that regulates the manufacture and distribution of medical devices) must also be established to receive and manage problem reports from all sources, thereby providing valuable feedback for the agency to improve its decision making.

Vendor control must be established to allow the government to have knowledge of the devices sold by manufacturers, with the goal of communicating with vendors in case of adverse events and regarding their after-sales responsibilities. A robust postmarket surveillance system also should be introduced.

Promotional activity by the Ministry of Health must be carried out to encourage cooperation among all stakeholders, enforce compliance, and reduce burden of enforcement. This will be achieved through proper dissemination of the policy to stakeholders by the regulatory authority and user education that addresses the misuse and misrepresentation of medical devices.

Regulations should be set to establish accreditation of hospitals and clinical engineering departments. Some hospitals in Oman have sought international accreditation. For example, the Royal Hospital, a large, tertiary-level, acute care hospital of the Ministry of Health, recently received Qmentum International Accreditation from Accreditation Canada. In addition, a quality assurance center is responsible for monitoring the quality of healthcare services among Ministry of Health institutions. The Ministry of Health must help ensure regional cooperation through the facilitation of interactions among regulators. It also should set priorities for regulatory program development according to the needs of the country.

**Performing a Needs Assessment**

A needs assessment can help determine and address gaps between a current and desired state. By incorporating a number of variables, a needs assessment allows decision makers to prioritize and select appropriate medical devices at a national, regional, or hospital level. A thorough needs assessment by the Ministry of Health should include the potential impact on performance of medical equipment users and their facilities, as well as on delivery of services within the context of health system capabilities and service delivery priorities. Before MEHT is purchased, the needs assessment should take into account the overall objectives of the institution, existing facilities and infrastructures, long-term plan of use, research studies, cost effectiveness,
innovation, and human resources (HR) development. Considering the needs of end-users during the assessment is also critically important. Overall needs are determined by the gaps that are identified.

To achieve this objective, baseline information needs to be acquired by evaluating suitable health service delivery requirements based on epidemiological needs (disease priorities), population issues (current demographics and trends), protocols/national recommendations, internationally recognized guidelines on prevention (e.g., WHO medical device guidelines), diagnosis and treatment of various diseases, and prioritization of healthcare needs. Baseline information on health service availability must be acquired by constructing a map that includes availability and accessibility, gathering opinions on health service delivery from the target population and providers, and devising a map that includes the number, type, geographical location, conditions, and current staffing levels of facilities.

Baseline information will be needed on medical device inventory, including availability, status/condition, and related infrastructure. From the outset, the inventory should be cataloged using a unified nomenclature with specific information and parameters. Similarly, information related to HR (e.g., creating a staffing plan, devising an education and training map) must be gathered and developed. An outline of HTM positions, including the types of jobs, managerial structure, and responsibilities, also should be devised. Finally, baseline information on finances must be collected by assessing the budget and expenses from previous periods, as well as by assessing the current budget, performing budget forecasts, and determining a system for monitoring/controlling the budget.

The needs assessment objective also should include a strategy for comparing the current inventory lists with internationally or regionally recognized guidelines (that use a unified nomenclature) for the type of facility and/or intervention being reviewed. Then, the respective gaps need to be assessed with careful adaptation to the local setting. Resource gaps need to be prioritized to determine areas of greatest need, and operational targets should be set based on the goals of the management team and the healthcare facilities. The operational plan should be integrated into the overall plan for healthcare technology, appraising the various options by weighing the evidence and implementing strategies through use of an action plan and timetable.

**Building Capacity for Deployment, Management, and Maintenance**

To achieve this objective, infrastructure capacity for MEHT must be enhanced by improving the financial, human, and material resources capabilities of the Medical Technologies department in the Ministry of Health. Infrastructure capacity should be further strengthened by establishing an appropriate unit for healthcare technology in all regions of the country, as well as by improving the design and development of facilities hosting biomedical equipment. A robust infrastructure also will include improved coordination with other ministries and agencies, with the goal of achieving cost savings. Another important
aspect of this objective is developing a nationwide organizational structure for the deployment of MEHT.

HR capacity must be fortified through the development of an educational infrastructure that will generate qualified technical personnel. This will be done by collaborating with universities, as well as with other nations, on the development of formal degree programs and providing continuing education for technical personnel. In Oman, the Ministry of Higher Education requires that each university be affiliated with an international university. Graduate studies and internships abroad also would be helpful means of enhancing HR capacity.

Further enhancements should include the support of management personnel in providing leadership to set department policies, provide budget recommendations, supervise technical staff, arrange for training, set priorities for department activities, and administer overall programs. Promoting good clinical practice during operation of healthcare technology through self-study, training, and workshops led by national and international experts also will be beneficial in building capacity.

Developing an HTM System

HTM encompasses a wide range of functions, beginning with input from the regulatory, assessment, and innovation stages and ending with the safe and effective support of clinical services. HTM is a field that requires the involvement of staff from many disciplines (e.g., technical, clinical, financial, administrative). The Ministry of Health should manage MEHT through its five phases: 1) strategic planning, 2) procurement and commissioning, 3) inventory management, 4) maintenance program management, and 5) decommissioning.

The strategic planning phase is the foundation of a comprehensive HTM process. Planning and acquisition of medical equipment, collectively called technology incorporation, is centered on a conceptual framework consisting of in-depth analysis of the basic principles that govern each stage of the technology life cycle. The planning step involves establishing a plan using data collected from an existing technology audit and cost-benefit evaluation. The acquisition step involves implementing the plan and procuring the assets through selection based on technical, financial, and regulatory considerations.

The procurement and commissioning phase would involve restructuring the current administrative and procurement processes by following the five rights of procurement: 1) right product or service, 2) right quality, 3) right price, 4) right time, and 5) right place. Future procurement needs for health technologies must be estimated by building an asset management system to track equipment status and include various parameters (e.g., operation, reliability, return on investment, patient safety, repair cost, useful life). Guidelines also should be set for establishing, and in some cases limiting, the numbers and geographic distribution of “big ticket” items (i.e., high-value equipment with implications toward national wealth control), consistent with the “Certificate of Need” mechanism recommended by the WHO.

Through electronic data interchanges and web-based bidding, a system of electronic procurement—with an eye toward the future—must be developed. Proper management also requires that ethics are upheld during the procurement of medical devices. A procurement strategy that could be followed is to allow for autonomy and decentralization in the procurement of medical equipment by large hospitals (≥500 beds). In Oman, some major regional hospitals already function as autonomous entities, each with a separate management board constituted by the Ministry of Health. These hospitals have budgets of their own and enjoy a certain degree of financial and administrative autonomy.

The inventory management phase requires updating and standardizing the current medical equipment inventory at the national and regional levels through an appropriately linked digital system. An adequate system of inventory management, following the three
stages of initial data collection, information update, and annual audit/review, also should be followed. Risk assessment inclusion criteria, using algorithms and models such as Wang’s collective risk management model, should be adapted and followed.

The “golden rule” approach can be considered for assessing overall asset status in terms of age, as the current inventory list assumes a five-year lifetime for MEHT. Although the golden rule method is overly simplistic, it provides an initial approach to assess asset status for replacement planning. From this initial assessment, considerations such as equipment usage, reliability, availability of backups, and availability of replacement parts, will allow for more objective replacement planning. Equipment that is aged up to five years reflects the current state of technology and offers opportunities for economically reasonable upgrade measures. Equipment aged between six and 10 years is still fit for use but requires replacement strategies to be developed. Equipment older than 10 years is no longer state of the art, meaning that replacement is essential. From these rules and the experience of studies into the age profile of medical equipment, a set of golden rules should be used as a guideline for investment policies and budget allocation (but not purchases).

To ensure the safe and effective functioning of medical equipment, an equipment spare parts inventory should be implemented. This process also could be useful in estimating the annual maintenance costs of the medical equipment stock. The main inventory should be further defined by cataloging other inventories (e.g., workshop tools and test equipment inventory, industrial and hospital equipment items inventory, safety equipment inventory, radioactive and hazardous materials, waste). The medical equipment inventory also should be used in forecasting and developing budgets, planning and equipping technical workshops, determining required staffing, identifying training needs, managing service contracts, planning for spare parts and consumables, developing replacement and disposal policies and goals, developing purchasing goals, planning for disasters and emergencies, performing risk analysis, determining management and mitigation, and helping to identify potential benefits in standardizing equipment.

An effective medical equipment maintenance program consists of three main elements. First, the Ministry of Health must identify the medical devices that need to be included in the maintenance program. This planning should consider providing autonomy to large hospitals to enable them to plan and implement their maintenance programs. Second, appropriate management for the maintenance program must be achieved through effective financial management, personnel management, operational management, performance monitoring, and performance improvement. In addition to the performance of maintenance activities, the safety and reliability of the maintenance program must be evaluated to ensure its success. Third, proper implementation of the maintenance program by the Ministry of Health is critical to ensuring optimal equipment functionality. This involves using pre-established procedures for equipment maintenance and inspection and preventive maintenance activities.

The process of decommissioning equipment when it is no longer safe or useful should focus on clinical considerations, type of equipment, quality, safety, reliability, repair cost, and life expectancy. As appropriate, redistributing equipment to areas of lower demand may be a means of reducing capital investment need.

### Developing a Financing System

Effective financial management is essential to proper MEHT management. To achieve this objective, healthcare technology needs should be prioritized based on the available budget. The operational plan must consider the financial resources required for implementation of MEHT at the national and regional levels and those required for equipment management activities. Effective budgeting as a financial planning tool is needed to ensure accurate forecasts of expenditures during operational activities (both direct and indirect operational expenditures).

The financial system must make sound financial decisions and take appropriate actions based on analysis of available funds and use of financial management tools and strategies.
economic concepts. To this end, the Ministry of Health should follow three steps: 1) analyze financial data and make financial decisions; 2) set a multiyear follow-up plan according to population needs and expected price changes due to inflation, technology evolution, and other international and local factors; and 3) continuously monitor progress. Also of note, achieving this objective requires allocation and improvement of financial resources for capacity development programs, in order to better respond to training needs at the national and regional levels.

**Supporting and Promoting R&D**

To realize this objective, the R&D capabilities needed to drive innovation would need to be developed by transforming R&D infrastructure to meet changing healthcare facility needs; attracting, motivating, and mobilizing the best talent; and developing innovative products/healthcare technologies that offer benefits over existing therapies. Solutions appropriate to the local MEHT needs in Oman must be developed, which also would lessen the dependence on imported technology. This objective would involve setting a strategy to improve productivity and performance through appropriate research on maintenance and implementation techniques, medical instrumentation, diagnostic imaging, biomaterials, and bioengineering, as well as supporting the use of research evidence in developing health policy.

Oman has a number of engineering colleges, including Sultan Qaboos University, Salalah College of Technology, Nizwa College of Technology, and Higher College of Technology. Some of these institutions already offer biomedical engineering specialization.

Another key component is ensuring that ethical considerations for medical device R&D are followed by setting guidelines and measures.

**Establishing an Advanced Monitoring and Evaluation System**

For a proper system of follow-up and control to exist, the Ministry of Health needs a mechanism to advise on planning, selection, use, and evaluation of health technology. Linking knowledge with action is one of the greatest challenges of the global health system. This linkage often is achieved through innovation, which usually starts with basic research that is translated into new health technologies. These technologies must be delivered to the system appropriately.

HTA provides a basis for priority setting and informed decision making and has become a key tool for supporting the core functions of an effective global health system. HTA is the systematic evaluation of properties and/or effects of health technology. Its chief purpose is to inform technology-related policy making in healthcare, thereby improving the uptake of cost-effective technologies while bypassing technologies that are of doubtful value to the health system.

Health technology regulation, HTA, and HTM are linked and complementary functions that ensure the appropriate introduction and use of medical devices. Thus, the Ministry of Health can rely on HTA to guide policy that is accountable to the population. Rather than finding information, the greatest challenge is developing the capacity to use existing HTA information considering the country’s circumstances and needs.

To achieve this objective, an HTA unit must be established within the medical technology department to provide recommendations on public policies regarding medical devices (based on the needs of the population and national priorities). The health system should be strengthened by ensuring the central role of evidence-based decision making, both at the level of service delivery/community intervention and for planning and policy-making purposes. The HTA unit would need to develop the appropriate use of HTA by linking it to the resource capacity of the country. It also should be responsible for finding solutions to lower and balance costs of establishing and maintaining HTA functions and capabilities. HTA focal points (e.g., national research organization, universities) must be allocated for advancing the use of HTA for good governance in policy and decision making. The basic role of the HTA focal point would be to develop awareness of HTA and increase the uptake and appropriate use of HTA within the country.

A progressive approach to disseminating knowledge and skills associated with HTA could involve organizing workshops for health professionals to become familiar with the
concept, methods, and results of HTA; participating in HTA and policy networks; improving individuals’ capabilities in accessing, assessing, applying, and contextualizing HTA for specific settings; and building self-sufficiency in the knowledge and skills through mentorships, distance education, in situ graduate study, and postdoctoral work.\textsuperscript{17}

A toolkit also could be used to facilitate adaptation of HTA reports for different contexts. The use of toolkits, such as the WP5 toolkit from EUnetHTA,\textsuperscript{11} could benefit the Ministry of Health by providing time savings and an up-to-date collection of resources. The toolkit would provide checklists and resources for the HTA report domains, such as technology use; development, safety, efficacy, and effectiveness; and cost effectiveness.\textsuperscript{11}

Patient and public involvement in HTA programs by the Ministry of Health will help ensure relevant topics and identification and prioritization of processes.\textsuperscript{32} Joint HTA in the region, following the model of EUnetHTA, also could be a future opportunity. Joint HTA uses existing networks or links for HTA across countries, thereby allowing the countries to share resources and provide assistance. Social, economic, and political ties in the region could lead to greater collaboration and perhaps joint HTA for allocating healthcare resources.\textsuperscript{33}

**Conclusion**

The Health Vision 2050 for MEHT necessitates continuous planning and management of infrastructure that is vital to Oman’s ability to keep pace with rapid advancements in healthcare technology. This vision seeks to prioritize the most pressing health challenges and consider, for example, financial resources, material resources, personnel needs, and healthcare trends. An important part of healthcare technology is developing solutions appropriate to local needs.

The vision described in this article supports the use of research evidence, as well as building and promoting R&D capabilities, in an effort to drive healthcare technology innovation. MEHT plays an invaluable role in the delivery of healthcare, and by drawing on a wealth of experience from around the world in the creation of Health Vision 2050, the Ministry of Health is poised to realize its true potential.

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HTM Resources
Developed with You in Mind

AEM Program Guide: Alternative PM for Patient Safety
Product Codes: AEM and AEM-PDF

Medical Device Cybersecurity: A Guide for HTM Professionals
Product Codes: MDC and MDC-PDF

Computerized Maintenance Management Systems for Healthcare Technology Management
Product Codes: CMMS and CMMS-PDF

Electrical Safety Manual
Product Codes: ESM4 and ESM4-PDF

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Product Codes: EQ56 and EQ56-PDF
Available as HTM eSubscription

ANSI/AAMI EQ89:2015, Guidance for the use of medical maintenance strategies and procedures
Product Codes: EQ89 and EQ89-PDF
Available as HTM eSubscription

For details and to order, visit www.aami.org/store or www.aami.org/eSubscription.
To a layperson, the hospital bed may seem like the last thing that would be affected by new technology. Other than side rails and the ability to go up and down, what else might it need?

The truth, however, is that the common hospital bed has evolved from a fairly simple piece of furniture into a high-end medical device. Parallel with these advancements, healthcare technology management departments largely have taken over many of the responsibilities for maintaining these evolving pieces of equipment.

**Hospital Bed Maintenance: Greetings from Bermuda**

Bed management is a crucial part of any hospital’s work. If beds are managed properly, they can improve patient flow and treatment, reduce errors and diagnostic mistakes, and promote faster recovery with fewer subsequent readmissions.

“The maintenance of the beds in our facility is handled in house by our biomedical department, where our biomedical technicians (BMETs) have been trained by the manufacturer,” said E. Michael Smith, a senior biomedical technologist for the Bermuda Hospitals Board in Paget Parish, Bermuda.

“During daily ward rounds, our BMETs perform a general visual inspection of medical devices, including beds, ask the ward clerks and/or department managers about any issues that have arisen, and decide on a plan of action,” said Smith. He added that the BMETs primarily use a corrective maintenance approach and that maintaining beds can be a time-consuming process, with the most significant issues being labor time, availability and accessibility of parts and tools, and knowledge of estimated time before failure.

“The major challenges we have faced related to maintaining hospital beds have been the cost of parts and hospital bed replacement,” said Smith. Because the hospital at which Smith works is located in Bermuda, additional complications come into play. Every part must come from the mainland, meaning the turnaround time is longer than that for hospitals with greater ease of access.
“Small parts are set up before vendor parts arrive, and all inventory is maintained so that few parts remain unused,” explained Smith. “This is done so that nothing sits around for a long period of time.”

To maintain continuity of care, spare beds are kept at the ready. “In order to assist us in our repair service, we also have a small fleet of beds that we have identified as ‘biomed spares,’” said Smith. “We use these to replace a faulty bed so that we can have the bed removed from the ward, minimizing interruption to clinical service.”

According to Smith, consultation with other hospital stakeholders is vital to keeping the correct beds in place. “I believe it is very important, where possible, to standardize the type of bed to be purchased,” he said. Following the consultation, the right bed—for the right clinical use and with the correct features—can be purchased at the best price point.

“A hospital bed should be looked at as part of the patient prescription for recovery and wellness,” added Smith.

Bed Tech Innovations

Smith has borne witness to dramatic advancements in bed technology at his hospital.

“When I came to our facility some years ago, we still had some manual wind-up foot and head lift beds,” he said. “All beds were maintained by our facility management department at that time, but the introduction of more computerized beds with advanced mattress flotation technology proved to be more challenging as beds became less electro-mechanical.”

The lifting of patients is a common source of injury in healthcare facilities. Although mechanical lifting equipment has made the task easier for clinicians, beds that perform total lifting functions have eased the burden even further.

One type, the Flexbed, is brimming with tech. It adjusts to seven different positions and doesn’t need to be pushed or pulled; instead, it uses robotics to move anywhere it’s directed. The bed also is equipped with a tracking camera and laser sensors that can prevent collisions. Because the Flexbed can move itself into multiple positions, it can save nurses and physicians from moving a patient from one bed to another. Furthermore, radio-frequency identification chips can be put into beds to allow them to be tracked throughout a facility.

Another key innovation is the “smart bed,” which continuously monitors sleeping patients and can adjust medical devices if their welfare is affected. For example, a smart bed might adjust if a drop in blood pressure occurs and can even distinguish between “true drops” and temporary changes caused by shifts in position. These beds also may be equipped to signal patients to shift to avoid bed sores and to adjust automatically if sleep apnea symptoms are detected.

Although hospital beds may not be the most attention-grabbing devices in a patient’s room, they remain vitally important to the well-being of patients and effective delivery of care. With up-and-coming bed technology making life easier for patients and clinicians alike, keeping an eye on innovations in hospital beds is well worth the effort.


Improving the 'Alarm Problem' Will Require Much More Than Just Reducing the Number of Alarms

Joe Sheffer
How would you characterize the current state of clinical alarm management?

Maria Cvach
I have worked on alarm management at Johns Hopkins Hospital for the past 11 years. I would say that the current state of clinical alarm management is one of heightened awareness of the potential for alarm fatigue. There's been a lot of publicity about alarm fatigue over the past five years. I think people are aware of the problem, particularly since The Joint Commission (TJC) put out its National Patient Safety Goal (NPSG) on clinical alarm safety.1

Emily Patterson
I would like to define what human factors engineering is in order to say where I'm coming from. Human factors engineering applies theoretical frameworks and systems thinking to enable experts in complex technologies. Since that's my framing, I would say that the current state is that all clinical alarm management systems that I'm aware of are not effective in terms of being able to be used to meet their mission.

We define that in three ways. One is in terms of discrimination power, meaning that you can have a nurse discriminate what is the most urgent against the background in a reliable fashion. The next is informativeness, meaning that there's at least a 70% likelihood that a signal signifies what it's meant to signify and that it's worthy of directing your attention, as well as actionable, in that you can do something once you get the signal. The third is workload management, meaning that our time expectations for how quickly nurses will respond to alarms are reasonable and can be met while they are able to get other work done, particularly given the overall volume of alarms. In terms of being able to easily use them, they pretty much can use the alarm systems in terms of recognizing what the signals are and turning them off. But I would say that it's still a little bit too difficult to change the individual patient threshold settings, which could reduce false alarms by about 50% if we could redesign the systems to have it be done with fewer steps. I think the biggest bright spot in this area is analytics. A lot of these clinical alarm systems now allow us to capture data. The AAMI Rules & Algorithms Working Group, of which I am a member, recently completed a report on identifying and monitoring respiratory compromise.2 In the article, we describe how you can identify cohorts of patients who might be at risk for respiratory compromise and change the threshold settings to better protect that group, given that they are at higher risk of respiratory failure. Similarly, at the Ohio State University Wexner Medical Center, we have put out clarifying guidance that DNR-CC (“do not resuscitate comfort care”) patients should not have any monitoring, unless they specifically request it, which can make the overall systems better.

Judy Edworthy
My background is in sound. My particular interest is the alarm signals that come at the end of the monitoring process. But of course, everything that happens before the alarm signal itself is what most people are interested in right now. I've got a couple of things to say that are related to that. The first is that we all understand intuitively what alarm fatigue means. But when I see approaches purporting to deal with the problem, they are always presented along the lines of, “Well, we've dealt with the alarm fatigue problem because we've cut down the number of alarms.” Cutting down the number of alarms is only one dimension of the potential problem. The problem is only partly caused by false alarms. Of course, if you cut down the number of alarms, you're probably going to cut down the number of false alarms—but this isn't necessarily so.
There are some other issues we need to consider. When people talk about the problem of alarm fatigue, they always make reference to the alarm sounds. Although the problem is seen to be the sounds, the solution of doing much about the actual sounds—other than to reduce their number—is never considered. From my perspective, all these things are happening to reduce what we think causes alarm fatigue, but we should be looking to make better visual and auditory signals to go with that improvement, so that we address the sound (and possible visual) problem as well.

And what I see, partly from standardization work that I’ve been doing, is that there’s finally a real move to improve auditory alarm signals as well. I also see manufacturers really starting to think about how they’re going to improve not just the way that they process the information, including the way their engineering works to cut down the number of false alarms and to make the devices more intelligent, but also thinking about how to convey that to the clinician at the other end. That includes the auditory signals, the visual signals, and so on. I think there’s a real movement toward manufacturers thinking more about the fact that they’ve got this very expensive piece of equipment, so they should be doing more than make it just go beep when there’s an alarm.

There’s certainly a heightened awareness of trying to make the whole interface more user friendly and to think about how the alarms are from the point of view of the clinician.

Joe Sheffer What approaches are needed to improve our understanding of alarms overall?

Maria Cvach Approaches to improve our understanding of alarms depend on many factors: type of medical device, population for which the device will be used, environment of care, and staffing—to name a few. Monitor companies are doing a great job in trying to improve technology that will help minimize alarm fatigue. However, just because the latest and greatest features are available on the market does not mean that hospitals are able to purchase that equipment as soon as it becomes available. Even if the hospital is able to purchase the new equipment, staff may not know how to use features intended to reduce alarms. A good example of that might be the use of monitor profiles. There is great potential to reduce alarm fatigue using monitor profiles. For example, age-specific profiles for pediatric patients are very useful in preventing unnecessary alarms when a vital sign parameter breaches a set limit. There are many other examples where this can be useful. It is important for units to study the issue. Don’t accept out-of-the-box default parameters without understanding if the alarms are appropriate for the population to be monitored.

We do not currently have a way to measure alarm fatigue. Generally, as Judy discussed, the idea is if you reduce alarms, then you are going to reduce alarm fatigue. However, we really don’t know for sure if this is true. If evidence-based measures, such as alarm customization, altering alarm parameters, and timely discharge from the monitor are used to reduce alarms, we should expect that total alarms will be reduced.

Emily Patterson One point I’d like to make is that alarm fatigue is not a scientific concept with any utility whatsoever. The term alarm fatigue is not appropriate in the sense that it seems to imply that the main issue falls with people and their motivation, and whether or not they’re willing to slow down for safety. It is also not the case that nurses do not like alarms at all. In fact, we were recently told how important the cardiac crisis alarm is to the nurses in a focus group, where they did not want us to change the sound. But the real issue is that the devices and alarm systems themselves don’t have enough information to make it worth responding to. I think the alarm problem exists, and it probably should be called the “alarm problem.” And my answer is that the alarm problem is both more and less of a problem than in the past.

There have been some successes. For example, at the Ohio State Wexner Medical Center, we followed the American Heart Association (AHA) risk stratification suggestions, which suggested that certain

"Although the problem is seen to be the sounds, the solution of doing much about the actual sounds—other than to reduce their number—is never considered."

—Judy Reed Edworthy, full professor of applied psychology at Plymouth University in Plymouth, UK
categories of patients are Class III. That means that cardiac monitoring is not indicated because the risk for these patients is so low that monitoring does not give a therapeutic benefit. There are groups of patients, such as early post-op following surgery patients without an active cardiac disease, who do not need to have cardiac monitoring.

At Ohio State, we implemented that policy in our electronic health records with the orders that people made in the alarm settings. We were able to improve the response times to critical alarms. Emergency department boarding times went down for patients. We had, just generally, a positive response from a lot of people because if you increase the prior probability that the signal will be informative, the system overall improves by taking off patients who likely don’t need the monitoring. And I would say from that perspective, at least at our hospital, there is less of an alarm problem. But then, at the same time, you have more and more alarm systems going in, like nurse call systems and ventilator alarms. The more devices and the more escalation systems you have, the more things you have making sounds. From that sense, the number of sounds have gone up on the units, even if it's from fewer original alarms at the bedside that are then sounded again at the central monitoring station and then again on nurses’ hospital cell phones.

Maria Cvach We’ve covered them pretty thoroughly. First, it’s important to look at alarm parameters as they relate to the population to be monitored—don’t just take something out of the box and accept those default settings. Next, use features that are intended to decrease the quantity of alarms, such as monitor profiles and monitor delays. Finally, decide if a monitor is needed at all. Unnecessary monitoring results in nonactionable alarms.

Alarm integration technology has potential to reduce unnecessary alarms. This technology integrates alarms so that rather than alarming on isolated vital sign parameters or rhythms, the device uses augmented intelligence. Alarms are based on multiple parameters rather than single isolated parameters. I know a lot of work is being done in this area.

Maria Cvach To supplement what Emily had said, the AHA published updated guidelines in 2017 that offer new criteria for electrocardiographic monitoring indications.4

Joe Sheffer For the past several years, and particularly since the 2011 AAMI/Food and Drug Administration (FDA) Summit and, as Maria mentioned, the TJC’s NPSG on clinical alarm safety,1 many initiatives have occurred to improve alarms and audible alarm signals. In addition to what we’ve already discussed, what other noteworthy efforts to reduce nonactionable alarms and alarm fatigue have occurred in recent years?

Maria Cvach We did the same thing. Emily. We set high and low heart rates to alarm instead of bradycardia and tachycardia. There is no reason to have both. I would agree with you that the bed alarm is definitely considered a clinical alarm on the units. And in fact, for that one, you almost have to rely on the local alarm as opposed to it going through a secondary device. The reason it’s loud is for people in the immediate vicinity to hear it and quickly respond.

"It’s important to look at alarm parameters as they relate to the population to be monitored—don’t just take something out of the box and accept those default settings."
—Maria Cvach, director of policy management and integration at Johns Hopkins Health System in Baltimore, MD
Sending it to a secondary device may not make sense because you might be too far away and not able to get to the patient in time.

I often wonder, with some alarms, do you even need to send them through a secondary device if the goal is to get whomever is in the immediate vicinity to get in there as quickly as possible? In one respect, I wonder about making the alarm softer. Will it get the people in the immediate area to respond in time? On the other hand, I have personal experience with a family member who was in the hospital and got very upset with the sound of the fall alarm. It was very loud, it scared her, and she asked that we turn it off because it was so loud. I hear what you’re saying, but part of me thinks that with a fall alarm, you really need those in the immediate area to get in the room as quickly as possible instead of relying on a secondary device, which might take too much time to get to that patient.

Emily Patterson We actually might be agreeing about the trade-offs regarding when to send alarms directly to a specific nurse as opposed to broadcasting it out to everyone. We need to be thoughtful about who exactly needs each type of alarm and what’s the best way to send one. And it might depend on local factors. I also wanted to mention that for bradycardia, we did the same thing. We only have the low heart rate alarm now.

Joe Sheffer How would you characterize the current body of literature on alarm management? Are there gaps in the literature that need to be filled? Moreover, what sort of research approaches are needed to deepen our understanding of clinical alarms?

Judy Edworthy The key thing that I’ve been working on with many other researchers and designers is that of making alarm signals that are easier to learn, easier to localize, and less aversive and irritating than the existing ones. And we’ve done that through what will be the update of an important medical device standard: ANSI/AAMI/IEC 60601-1-8. The key thing we’re doing in addition to designing and testing the alarm signals themselves is to document the research evidence as much as possible in the peer-reviewed literature so that they have provenance as well. That’s never really been done before, and certainly not with alarm signals. But as a model of how to go about documenting anything we need to do with alarm fatigue, alarm management, and so on, it would be nice to see the same kind of process applied in other areas. Of course, the people that typically work in these areas are not people that have huge amounts of time or inclination to write scientific papers because that’s not what they do on a day-to-day basis.

Maria Cvach Last year, I was part of a group that performed a systematic review regarding approaches for managing alert fatigue. Most of what’s out there is quality improvement versus research. There really aren’t a lot of high-level, randomized control trials on this subject. It seems like the literature primarily consists of “before and after” studies, qualitative research, and observational research. There aren’t a lot of valid and reliable ways to measure this problem. We couldn’t do a meta-analysis because there are no standard ways to measure outcomes and a variety of nomenclatures are used.

We just completed a ventilator study, in which we used two different ventilator types and documented the frequency of alarms and set parameters. With two different ventilators, nomenclature varied substantially. The same alarm was considered high priority by one manufacturer and low priority by another. I really think it’s going to be hard to research alarms until we can agree on some standard nomenclature, measurement criteria, and outcomes.

Emily Patterson In our next year of research funded by the Association for Healthcare Research and Quality, we’ve been considering a couple ideas. I’m not sure yet that we’re ready to commit to either one at this time, but both are good ideas. Overall, our charge is to address the clinical alarm overload issues in our hospital.

“We need to be thoughtful about who exactly needs each type of alarm and what’s the best way to send one. And it might depend on local factors.”
—Emily S. Patterson, associate professor at The Ohio State University in Columbus, OH
One idea is related to the fact that our nurses are going to get smartphones provided by the hospital during their shift. Currently, existing technology allows you to change the default setting so that you can display a strip of four or five patients at once on the smartphone display, then potentially collapse alarms into a thread for one patient. So rather than each alarm going off at one time, you could have five lines that summarize the cardiac strip output along with the reading that triggered a specific alarm so that you can have a sense of the history of your patients when you get an alarm. Therefore, it’s possible that the technology is not quite there yet to do this. But from the first initial discussions we had, it sounded like it might be possible with only changing some defaults that are decided at the level of the hospital.

The other idea that we're considering is trying to predict who is at high risk for opioid-induced respiratory compromise in our hospital by using some sort of data mining or exploratory machine learning techniques. If you can identify that a cohort of patients are at particularly high risk, then you can start to say, "Let’s change the alarm parameters, or let’s send these alarms to the nurses’ cell phones that are currently filtered out." At least in our hospital, we don't currently escalate the low oxygenation alarm to all of the nurses' cell phones for all of the patients because it's such a high false alarm rate, such as when the sensor comes off of the patient’s finger and it reads as a low oxygen level.

Joe Sheffer Are manufacturers and clinical end users collaborating to reduce alarm fatigue? What efforts are occurring, or need to occur, in terms of user-centered device design and other human factors considerations?

Maria Cvach We have had robust discussions between the AAMI Alarm Committee and manufacturers in the past. I haven’t been involved in discussions with manufacturers over the past two or three years since that committee disbanded.

Judy Edworthy I’ve talked to a number of manufacturers, and recently, those discussions have focused on their alarm signals. I’ve heard reports of two or three manufacturers that certainly want to improve their auditory alarm signals. And I think that that goes with them improving the technology that underpins when and how the alarms signal. But, of course, the problem with industry is that they don’t necessarily talk to one another. They keep everything to themselves because of commercial sensitivities, so one manufacturer doesn’t necessarily learn from another. So they’re all doing their own thing—sometimes these things overlap and have a shared goal, but often they don’t. As a result, progress can be very piecemeal, but it’s a shame that they don’t talk to one another a bit more. Of course, that’s not likely to happen because it’s a competitive commercial market.

Maria Cvach And that's why, Judy, it was so good when we had the AAMI alarms summit and were able to bring multiple manufacturers in with the clinical staff to collaborate.²

Emily Patterson I would be slightly more optimistic. Ohio State University Wexner Medical Center is collaborating with our manufacturers to share our data, after it has been deidentified in a variety of ways. We’re sharing our hospital’s data with the manufacturers so that they can have a better feel for what is actually happening in the hospital and therefore can improve their designs. Historically, few hospitals have been willing to share their data with manufacturers, so we are proud that we’ve overcome that barrier to improvement.

There are human factors people at just about every important device manufacturer or vendor, and those human factors engineers are valued. My understanding, however, is that sometimes their scope is limited. By that I mean maybe they’ll go to hospitals, observe, and make some recommendations for how the hospital can change their policies. But they won’t change the design of the interface or device on the basis of those observations. I think some of that is due to worrying about getting FDA approval.

"We're sharing our hospital's data with the manufacturers so that they can have a better feel for what is actually happening in the hospital and therefore can improve their designs." —Emily Patterson
approval with any changes. In some cases, they may have been told by their companies to limit the scope of their suggestions to what the hospitals can do without changing the device design.

In the newer application areas, the human factors people seem to be more excited to work with those groups and these companies. We might see some compelling research and development in the next five to 10 years, but I don’t see anything changing substantially with the FDA-approved bedside monitor technology anytime soon.

Judy Edworthy The big companies are using human factors people, but I’m surprised about how recent a development that is. I would have imagined that they would have had human factors people for the last 20 or 30 years, but that doesn’t seem to have been the case. And of course, when those people do start working for device manufacturers, they’re involved in every project, you know. And so it’s very busy for human factors people working in these areas and difficult for them to pursue individual projects.

Joe Sheffer We’ve touched on the need for common nomenclature surrounding alarms. What other approaches are needed across healthcare to arrive at a more synchronized understanding and appreciation for alarm management?

Maria Cvach I am really happy to see more emphasis on augmenting clinical intelligence with machine learning. Looking at trends and trying to determine when a patient is headed down a deteriorating path may allow us to intervene more quickly.

Judy Edworthy I think Maria is completely right about that. I would like to see more people from different work domains involved in the work, not just human factors people but psychologists, for example, because they’re the experts at extracting information from experts about how they think about problems and their solutions, what their mental models are like (which should influence how expert systems are developed), and how they use the information and expertise that they have. Doing things like this is much more difficult than it appears at first sight.
**Emily Patterson** What I would like to start with is avoiding over-responding to a single unfortunate incident at a hospital by pushing all alarms to a high urgency or criticality setting. So, for example, if you have a no-signal alarm, which I think asystole could be characterized that way, it could be that the patient’s heart has stopped or that there’s no signal because the leads have come off of the patient. It’s quite possible that nurses have been trained over time that an asystole signal is usually not informative other than putting leads back on the patient. So if there’s an unfortunate event, we have to look at how informative these signals are for most situations, and not say, “Well, we’re never going to let that happen again.” Therefore, that alarm should not always be pushed to the top of the priority list, as it makes the entire alarm system not work because you have this “cry wolf” effect where nobody will respond to it quickly anymore.

The other thing I’d like to see, along the same lines of what Maria was talking about, is the use of multiparameter combinations of data as a filtering strategy. For example, for lower-risk patients, the low oxygenation (SpO₂ low) alarm could be combined with the high carbon dioxide (end-tidal CO₂) reading before a nurse gets an alarm escalated to the phone. Or maybe a cardiac alarm is combined with the respiratory alarm before an alarm sounds. The idea is that based on your knowledge of the kinds of patients you have and the kind of patient this person is based on what you know about his/her history from the electronic health record, you might combine some parameters before an alarm sounds or is escalated.

**Maria Cvach** The other thing I hear when I do alarm consults with other hospitals is how difficult it is for them to get data. It should be a relatively easy thing. I don’t care if it’s a ventilator, a monitor, an infusion pump, or a bed alarm. You should be able to get your data so that you can make educated decisions about how to configure your devices to minimize alarms.

**Joe Sheffer** Before we wrap up our discussion, is there anything further that should be mentioned or any points that need to be clarified?

**Judy Edworthy** On the topic of multiparameter monitoring, I think there are one or two companies who can do that with their monitoring devices. I’ve certainly seen devices—for example, manufacturers in Oxford, UK—that produce a five-parameter composite score for each patient.

**Maria Cvach** Judy, I think you’re right that they do exist. But the question is, “Do you turn off the alarms on the individual device and rely on the alarm integrative device?”

**Emily Patterson** My understanding is it was done at a hospital in the United States, though I don’t have permission to name the facility. It was done in collaboration with a vendor, and it worked. The results were highly positive, but both the vendor and the hospital were concerned about risk for liability for their organizations. So they turned it off.

Also, to clarify, a lot of people get confused by the term “machine learning.” Honestly, it’s just using well-known statistical methods, such as logistic regression on data, that were not specifically collected for a research study. We don’t necessarily need a highly complicated artificial intelligence deep-learning algorithm to help us to identify patterns in data and high-risk groups of patients who might benefit from alarms more than others.

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**References**


Staying Ahead of 'Enormous and Evolving' Cyberthreats Requires End-to-End Collaboration

As a newly appointed member of the AAMI Board of Directors, you have mentioned how your work with MITA, H-ISAC, and AdvaMed can be leveraged to increase awareness of the vision and mission AAMI across a broader constituency in the healthcare domain. From your unique vantage point, what are some ways in which you these organizations can benefit by synchronizing their efforts?

Great examples of how best to leverage the synchronization of organizations often are found within standards consensus. As a member of multiple industry forums on standards, I have the ability to bring common topics and information to these various groups in improving communication horizontally.

In addition, organizational collaboration and synchronization are very helpful when attacking common challenges in need of standardization, such as our communication vehicles (e.g., the MDS2 [Manufacturer Disclosure Statement for Medical Device Security] form and the need to standardize the information inquiry in order to be both comprehensive and effective).

Standardizing a common software bill of materials (SBoM) also is needed. We need to be holistic in our approach to standards and organizationally collaborative across the end-to-end ecosystem. Synchronization and collaboration across organizations will further our mutual goal to strengthen the industry.

At this point, the dangers surrounding cyberthreats are well known, with the ECRI Institute ranking “Ransomware and Other Cybersecurity Threats” as its number one health technology hazard of 2018.1 What are the most urgent best practices and solutions that need to be implemented to combat this sharply escalating threat landscape?

From my perspective, members of the healthcare ecosystem need to apply best practices to inventory their assets, and that goes beyond the physical to include SBoM. Absent best practice inventory management, defining the threat landscape or establishing the defense, maintenance, mitigation, and remediation necessary to provide comprehensive cybersecurity is not possible. Again, we are a community that needs to be working together on these threats, as I had mentioned in my Oct. 4 opinion piece for the Morning Consult.

I would go further to recommend the development of a comprehensive coordinated vulnerability disclosure program, as well as to reassure customers and consumers that proper procedure and efforts are consistently applied to the repair of all vulnerabilities and prevention of future damage.

What’s one cutting-edge advancement in technology that shows promise in bolstering healthcare cybersecurity?

We see lots of promise within blockchain technology for opportunities (e.g., Keyless Signature Infrastructure) to augment traditional deployment solutions (e.g., Public Key Infrastructure) and reduce the risks of surveillance. A blockchain-decentralized network can definitely play a role in securing sensitive medical data, both at rest and in transit. Blockchain also has the potential to help us reduce human factor vulnerabilities and the risks of single points of failure.

What practical approaches should healthcare technology management professionals be implementing to protect medical devices from cyberthreats?

Identifying your end-to-end inventory assets is at the top of the list. This is foundational. With the defined inventory in hand, we as a community, both manufacturers and healthcare delivery organizations (HDOs), can then tackle the challenges of purging the end-to-end environment of legacy devices that represent enormous vulnerabilities.
You used the term "security ninjas." in a presentation you gave in 2016. What are security ninjas, and how do they factor into the landscape or medical device security?

Security ninjas are our own internal “white hat” hackers. Within our Security Center of Excellence, we have teams of talented cybersecurity professionals dedicated to hardening our products and services via both static and dynamic testing. As a manufacturer, we also fully embrace the external community of researchers. This embrace of external white hats or security ninjas is an important part of a holistic cybersecurity program, in that no one entity in isolation will be able to secure the environment against the evolving threat landscape. It will take the entire community working toward the same results for safety, security, and privacy.

You have asked, "How many believe that responsible 'coordinated' disclosure is a contact sport?" Can you please explain this? In what ways does the culture of disclosure need to change?

My contact sport metaphor relates to seeing some within the community of health technology manufacturers and HDOs taking a defensive posture with researchers. This is based on the incidental frictions that are part of that interactive relationship.

We all need to be open and transparent, recognizing and embracing the importance of external challenges to the security of our products and services; otherwise, we will be vulnerable and put our customers, consumers, and patients at risk.

Researches are our allies in arms against a common enemy; we must embrace their contributions, in order to reinforce our capacity to build a secure medical infrastructure that can deliver safe and affordable healthcare.

Along similar lines, you have espoused the need for transparency and clear communication among device makers, healthcare facilities, regulators, and security professionals regarding cybersecurity. What’s one shortcoming this broader dialogue would seek to address?

As mentioned previously, no one entity in isolation will be able to secure the environment against the evolving threat landscape. If any one player believes they can compete on the “security” of their own offering, they are sadly mistaken.

Cybersecurity threat and defense requires comprehensive transparency and clear communication across the end-to-end ecosystem. Any one device maker or healthcare facility can bring down all systems within and adjacent to its own enterprise business processes for suppliers, shipping, records management, etc. We also need open and honest communication with our regulators and security professionals to establish the capacity to defend against a landscape of perpetrators ranging from "attic room" hackers to organized crime and even nation-states.

The challenges ahead are enormous and evolving; to stay in front, we are dependent on the collaborative cooperation of all—throughout the end-to-end ecosystem.

Any closing thoughts?

I would just like to add my appreciation for the vote of confidence reflected in my recent election to the AAMI Board of Directors. I look forward to contributing, specifically regarding the cybersecurity issues facing the industry and to the more than 50-year legacy of the association’s impact on the development, management, and use of safe and effective health technology.

References


A Life Cycle Approach to Medical Device Cybersecurity

In 2016, the University of Vermont’s Technical Services Partnership (TSP) made the decision to align itself with the cybersecurity recommendations of the Medical Device Innovation, Safety & Security Consortium (MDISS) and its effort to build safer, stronger, more secure medical devices.

Utilizing MDISS’s best practices and information gleaned from cybersecurity resources, including the ANSI/AAMI/IEC 80001 series of information technology (IT) risk management standards, and resources from the Health Information and Management Systems Society (HIMSS) Global Conference & Exhibition, TSP would design and implement a comprehensive program at its main teaching hospital, the University of Vermont Medical Center in Burlington, VT, to proactively and continuously address the cybersecurity risks inherent in connected medical devices throughout the healthcare delivery organization (HDO).

This high-level plan—TSP’s cybersecurity management model—sits atop the group’s previously established healthcare technology life cycle (Figure 1). As part of the plan, TSP has integrated medical device cybersecurity and the defense of protected health information (PHI) into its day-to-day management of approximately 70,000 medical devices—and made device cybersecurity a fundamental aspect of its healthcare technology management (HTM) practice.

Today, TSP staff are focusing on implementing this plan throughout the network hospitals of the University of Vermont Health Network.

“We have a medical device working group that is really is trying to look at the big picture related to medical device security,” said Tobey Clark, engineering supervisor of instrumentation and technical services at TSP. “This effort really starts with looking at our inventory, what devices are connected to the network, and cataloging those attributes. Secondly, we’re assessing those technologies for the risks that they pose and what can be done about them in terms of controls. We’re not exactly in the infancy, but we are at a starting point for really getting a handle on the problem of medical device cybersecurity.”

Figure 1. The Health Care Technology Life Cycle at the University of Vermont Technical Services Partnership (TSP), with the inclusion of a cybersecurity risk management model. Image courtesy of TSP.
Challenge
Addressing and mitigating potential cybersecurity issues is essential, as more and more equipment in HTM’s purview is being connected to the HDO network. That evolution means that considerable vulnerabilities are being introduced into the healthcare environment, whether through hard-wired connections that could compromise protected health information, Bluetooth radios that could transmit data or provide access into systems over short ranges, WiFi, and more.

In addition, healthcare technology increasingly requires software updates and patches in order to keep it protected from cybersecurity threats.

“In the last few years, there’s been a couple of really high-profile cases of cybersecurity threats entering hospital networks. So, more and more, manufacturers are focusing on cybersecurity. We’re seeing lots of recalls in security alerts around that, which requires mitigation,” said Leah Francoeur, a clinical engineer at TSP.

Knowing all of the potential avenues and threats, the staff at TSP decided to create a cybersecurity-based framework to add to its healthcare technology life cycle to ensure that cybersecurity best practices are part of its day-to-day operations.

“This effort looks at cybersecurity from a comprehensive perspective to address the risks that are being put forth in the environment,” said Michael Lane, director of TSP.

“We then work with our team to be key players in the mitigation strategies for medical device connectivity. We train our staff to be aware of what those vulnerabilities are and put practices into place to allow us to reduce those risks, as well as work to educate our clients and customers about those vulnerabilities.”

Solution
Challenged by the rapidly advancing nature of cyber risks associated with medical device management, TSP’s comprehensive approach seeks to elevate the importance of cybersecurity throughout the entire device life cycle, from the request to procure a device all the way through to decommissioning.

TSP has developed and implemented a cybersecurity management model that sits on top of its Health Care Technology Life Cycle.

For Francoeur, who provides purchase consultations with TSP’s community hospitals, integrating cybersecurity risk management into the health technology life cycle often means the early collection of device data from manufacturers, so that cybersecurity risks can be addressed prior to the purchase of the equipment. The common way of doing that is via the HIMSS Manufacturer Disclosure Statement for Medical Device Security (MDS2) form.

“I’ve been trying to collect data upfront from the manufacturers. Once we attach the MDS2 form to our device history, we gain a wealth of information, such as the type of data the devices are collecting, the type of software they’re running, the version of SQL (structured query language) they’re using, and their operating system,” Francoeur said.

The biomedical staff document relevant parameters (e.g., Internet Protocol [IP] addresses, MAC addresses, network configurations) in the HDO’s computerized maintenance management system (CMMS), from which staff also can receive notifications about devices that contain protected health information.

TSP participates in a detailed equipment review through a committee known as the Technology Standards Review Board (TSRB), which is headed by Information Services, and includes representatives from HTM and several other hospital departments.

“It’s easier to deal with new equipment as it comes in because we have the ability to vet it before it goes into the building,” Lane said.

“The TSRB does a full review of basically any type of device that will be touching the hospital’s network, whether it’s clinically related or business related.”

For any devices that are connected to the network, staff are required to enter the operating system, the revision of the software that’s in that particular device, IP addresses for the device, and any switches to which the device is connected. That information allows for a map of the system within the IT network. When devices are decommissioned, further standard operating
procedures take into account the need to clear account passwords or PHI that might be retained on the device before disposal.

**Results**

TSP’s updated Health Care Technology Life Cycle now utilizes the Medical Device Risk Assessment Platform (MDRAP), which was developed by MDISS to help automatically conduct risk assessments and cybersecurity analyses of medical devices. By entering medical device attributes into the system, the software determines the level of cybersecurity risk for a given device.

“The output allows us to understand the risks that are within the control of the HDO and those that might need to be taken into consideration by device manufacturers,” said Lawrence Robert, associate director at TSP.

Under TSP’s cybersecurity model, key stakeholders are informed of the cybersecurity risks of the medical devices directly in the CMMS (e.g., alerting staff that the device contains PHI). Thus far, according to Lane, 22 MDRAP assessments (affecting 955 devices) have been completed.

**Conclusion and Next Steps**

Today, TSP, director of TSP has an established method and a standard nomenclature for adding new medical devices to the hospital network—and it continues to use this model to integrate cybersecurity best practices into its standard operating procedures.

Although it’s still being developed, TSP’s model has been used with the MDRAP tool to conduct risks analysis on physiological monitoring systems and identify systems that pose the greatest risk of cyberattack. One of the major obstacles for TSP going forward is generating awareness for cybersecurity issues, particularly within clinical departments. While cybersecurity commands the attention of many in HTM and IT, it may not be as great a priority for health professionals more sharply focused on clinical care.

“It’s been challenging to get awareness for this really serious problem. Our clients usually know about the WannaCry ransomware attack. But outside of that, there isn’t a whole lot of news coverage,” Clark said. “You may get something in the newspaper about somebody hacking a pacemaker or an infusion pump. But for the most part, the customers of our services aren’t aware that this is a high-priority problem that needs to be addressed.”

To help spread awareness, TSP organized a one-day workshop on medical device cybersecurity. The effort brought together key stakeholders within the HDO, outside cybersecurity experts, MDISS representatives, and TSP’s clinical engineering team.

Ultimately, the biggest ongoing challenge for TSP is simply working through the vast amount of connected medical devices—tens of thousands—that are within the HDO’s inventory, all while new devices are acquired and brought onto the network each month.

“We’re trying to make individuals aware of the value of the data carried in medical devices and the methods that folks can use to get in, whether that is to steal PHI or cause issues,” —Laurence Robert, associate director at the University of Vermont’s Technical Services Partnership in Burlington, VT

“...It’s been challenging to get awareness for this really serious problem...”

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Keeping Track of All the Moving Pieces

Although it wasn't that long ago, it's difficult to remember the days when cybersecurity wasn't at the forefront of our minds.

One morning back in 2008, shortly after having started my new healthcare cybersecurity–focused job at Symantec, by pure chance I ran into the vice president of regulatory affairs from a medical device company I had worked for until 2002.

We caught up on our professional whereabouts, and when he heard that I had started a job in cybersecurity, he said: “Smart move. You know, some researchers at the University of Massachusetts just hacked into a pacemaker. Nothing is sacred anymore, and the medical device industry will never be the same.” (Or something to that effect—his actual language may have been a little less suitable for print.)

He was referring to an article by Kevin Fu and colleagues, in which the authors described a hack of an implantable medical device—an implantable cardiac defibrillator in this case.1 It was the first article of its kind to appear in the literature.

Well, my former colleague was right and wrong at the same time. He was certainly right that this research would change the medical device industry, affect standards and regulations, and in a way, impact all of our jobs. However, he was wrong that it would happen any time soon.

In the next few years, other researchers demonstrated similar vulnerabilities of other types of devices, but not much happened until the Government Accountability Office's report in 20122 and the Food and Drug Administration's (FDA's) premarket cybersecurity guidance in 2014.3 Then, things really seemed to pick up after the FDA's postmarket cybersecurity guidance was released in 2016.4

The increased focus on cybersecurity in recent years can be illustrated in several ways. For example, one can look at the growing number of job postings by healthcare delivery organizations (HDOs) and device manufacturers looking to hire medical device cybersecurity specialists. Another interesting measure was recently described by MedCrypt in a whitepaper analyzing the number of ICS-CERT (Industrial Control Systems Cyber Emergency Response Team under the Department of Homeland Security) advisories specific to medical devices.3 MedCrypt reported that from October 2013 to December 2016 (i.e., prior to the FDA's postmarket guidance), the number of disclosures was much lower than that from December 2016 to August 2018 (i.e., after the postmarket guidance appeared).

Specifically, the report showed that the number of advisories grew from 12 in the three years prior to December 2016 to 35 in the 19 months since, corresponding to 37 disclosed vulnerabilities before versus 85 since. (Note: One advisory can list several vulnerabilities.) In other words, the number of vulnerabilities disclosed per month grew from just shy of one (0.95) to more than four (4.47). Similarly, the number of companies affected by the respective disclosure grew from six to 18.

This is pretty much in line with other indicators, such as the number of industry events focusing on the topic or the growing number of presentations/panels/roundtables taking place at events.

A Lot Is Happening

At the AAMI Annual Conference & Expo in Long Beach this past June, the association released Medical Device Cybersecurity: A Guide for HTM Professionals.6 Stephen Grimes (managing partner and principal consultant for Strategic Healthcare Technology Associates, LLC) and myself had the honor to be the lead editors on the publication. With the help of many respected contributors from HDOs, industry, and government, we produced an introductory guide to help educate stakeholders (as appropriate for their role) on the topic. In addition to providing insight and education, we attempted to detail the state of resources and information on this highly complex topic.

Not surprisingly, less than six months later, that list of resources could use an update. Here are a few examples of newly published and highly relevant documents.

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Incident Planning and Response

Most recently (October 2018), MITRE, in cooperation with the FDA, published a document that specifically addresses the need for incident preparedness and response. The report provides a common framework that allows for the creation of communication and action plans within an HDO, as well as (for example) the interaction between medical device manufacturers and an HDO, the actions they may take, and the resources that are available to support their response.

Incorporation of medical device cybersecurity into an organization’s emergency response plan enables HDOs to assess and mitigate the impact of a medical device–related incident. Besides HDOs, other stakeholders and resources are provided through state departments of health, medical device manufacturers, information-sharing and analysis organizations, and government agencies.

The playbook offers valuable resources for developing a customizable framework that HDOs can leverage as a part of their emergency response plans, with the goal of limiting disruptions in care delivery and reducing the risk of patient harm resulting from a medical device cybersecurity incident.

Internet of Things Security

In a previous article, I had discussed whether medical devices could be considered part of the Internet of Things (IoT). I concluded that although the argument could be made either way, from a cybersecurity perspective, no real difference exists because the underlying cyber-risk fundamentals are quite similar. Further, besides networked medical devices, HDOs have started to realize that care-disrupting cyber events could equally be caused by networked IoT devices like building or security systems, HVAC, patient entertainment, and the like.

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Legislative Action

Continuing the topic of IoT: In late September 2018, the California State legislature approved the nation’s first cybersecurity bill specifically addressing the risks of network-connected devices. California Bill no. 327 seeks to provide a baseline cybersecurity standard for IoT devices, requiring manufacturers to provide “reasonable security feature or features.” Even though it does not specify these features in detail, it does mandate (for example) that connected devices have unique and user-changeable passwords.

Beginning on January 1, 2020, a manufacturer of a connected device is required to equip the device with reasonable security features that are appropriate to the nature and function of the device; appropriate to the information it may collect, contain, or
transmit; and designed to protect the device and any information contained therein from unauthorized access, destruction, use, modification, or disclosure, as specified.

Interesting enough, this new law does not apply to any device that is subject to security requirements under federal law, regulations, or guidance promulgated by a federal agency pursuant to its regulatory enforcement authority. Therefore, FDA-regulated medical devices would be exempt, whereas other IoT devices that may be used in the healthcare environment, as discussed above, would be subject to this law.

**How Big Is the Risk?**

Obviously, with medical device cybersecurity being a topic of increasing importance and relevance, one should ask the question: How big is the risk, really? Although, to date, no reports of patient harm due to a cyber incident have surfaced, we do have many reports of medical device incidents contributing to care delivery impact (most recently during the WannaCry malware outbreak) or cases where medical devices were used as a beachhead for an advanced attack on other systems.

It is exactly that concern (i.e., the potential that a remote actor can disrupt care delivery via an attack on medical devices or health IT systems) that led the ECRI Institute to proclaim “Hackers Can Exploit Remote Access to Systems, Disrupting Healthcare Operations” as its greatest health technology hazard for 2019. Summarizing from the publication, ECRI’s analysis states:

“Cybersecurity attacks that infiltrate a network ... remain a significant threat to healthcare operations. Attacks can render devices or systems inoperative, degrade their performance, or expose or compromise the data they hold, all of which can severely hinder the delivery of patient care and put patients at risk.

“Remote access systems are a common target because they are, by nature, publicly accessible. Intended to meet legitimate business needs, such as allowing off-site clinicians to access clinical data or vendors to troubleshoot systems installed at the facility, remote access systems can be exploited for illegitimate purposes.

“Attackers take advantage of unmaintained and vulnerable remote access systems to infiltrate an organization’s network. Once they gain access ... attackers can move to other devices or systems, installing ransomware or other malware, stealing data or rendering it unusable, or hijacking computing resources for other purposes. ... Safeguarding assets requires identifying, protecting, and monitoring all remote access points, as well as adhering to recommended cybersecurity practices, such as instituting a strong password policy, maintaining and patching systems, and logging system access.”

Obviously, considering the prevalence of remote exploits and resulting data breaches, considering strong (two-factor) authentication would be advisable.

**FDA on the Move**

Also in October, the FDA published an updated draft of its cybersecurity premarket guidance. The document currently is open for public comment and, once final, will replace the previous premarket guidance from 2014.

Besides providing more granularity and detail on FDA’s expectations on cybersecurity features and processes that should be applied by manufacturers prior to market release, the document specifically calls out several new concepts, including the following:

The report introduces the concept of a CBoM (cybersecurity bill of materials) as “a list that includes but is not limited to commercial, open source, and off-the-shelf software and hardware components that are or could become susceptible to vulnerabilities.”

This concept is surprising for a few reasons. First, the FDA limits the content of the CBoM to security-relevant components, rather than requiring a complete SBoM (software bill of materials). This 1) reduces the complexity and 2) addresses intellectual property concerns manufacturers may have.

Second, it requires inclusion of security-relevant hardware components, which I’m assuming is due to several recently discovered hardware vulnerabilities affect-
ing commonly used chip sets. Specifically, the FDA recommends that “the device design should provide a CBoM in a machine readable, electronic format to be consumed automatically,” which is in line with recommendations provided by the Health Care Industry and Cybersecurity Task Force.

Obviously, manufacturers may have legal or intellectual property concerns. But considering the number of vulnerabilities in commercial software, as well as the increase of cyberattacks through the software supply chain, availability of complete configuration information via the CBoM is becoming a must. It does require, however, that HDOs can make use of this complex set of information across their entire device inventory, which, admittedly, is not trivial.

Further, the FDA document introduces the concept of cybersecurity tiers to allow for varying levels of controls depending on device security risk. Not to be confused with traditional FDA Class I, II, and III device classifications, these tiers only apply to considerations about cybersecurity risks:

1. Tier 1, “Higher Cybersecurity Risk”: devices that are capable of connecting and where a cybersecurity incident could result in patient harm to multiple patients.

Regarding device design, processes, and documentation, the FDA guidance specifically provides:

- Design recommendations to identity and protect assets and functionality.
- Labeling recommendations.
- Cybersecurity documentation.
- Recognized standards.

Overall, this document is a significant step forward and will be appreciated by healthcare organizations. I encourage everybody to review the provided draft and submit public comments by March 17, 2019.

I am working on a few comments myself, including some related to the document’s inconsistent or incorrect use of security terminology (e.g., terms such as threat, exploit, vulnerability, and incident often are used interchangeably). For further explanation of these terms, see chapter 3 of the AAMI Medical Device Cybersecurity guide.

Further, the FDA guidance positions antivirus as a possible security technology for some medical devices, which, in my opinion, is a poor technology choice. Antivirus is a reactive technology developed for the traditional endpoint use case (personal computers and servers—where it works well) and has serious shortcomings when used in embedded systems (e.g., resource impact, need of almost continual definition update, risk of false-positive detections). Current-day antivirus products make particular use of advanced features like behavior and reputation analysis, machine learning, and cloud-based processing to complement what can be done on the system.

A much better technology choice would be the so-called Host Intrusion Detection and Prevention Systems (HIDS/HIPS), as they are much lighter in resource requirements, more predictable in behavior, do not require signature updates, and have far less reliance on patching, thus alleviating lifecycle management pressures.

There is, of course, much more valuable insight provided in the guidance. I applaud the FDA as it continues its path towards making our medical device ecosystem a more secure and therefore safer place.

What Remains?

In summary, in the recent past, a lot of activity has occurred and much useful and important information has been published. However, attention is required in some areas. As such, there are plenty of opportunities to get involved (and plenty of material for future CyberInsights articles).

For example, one other topic that is starting to emerge is education of nontechnical stakeholders in an HDO. As daily users of devices, clinicians (e.g., physicians, nurses, other medical professionals) need to understand their role in cybersecurity—be it during the procurement process, as responsible device users, or as advisors to and advocates for patients in matters relevant to cybersecurity.

Clearly, we have our work cut out for us.
References


Overcoming Subject Matter Snobbery: Knowing that You Don't Know Everything

Somewhere along life's road, you've probably heard this pearl of advice: "Nobody likes a know-it-all."

Although that well-worn wisdom is true everywhere, it is especially true in the hustle and bustle of a busy decontamination room or in the midst of a teeming prep-and-pack area. In fact, all sterile processing professionals, whether they are brand-new technicians or seasoned leaders, should realize that acting like or claiming that they know everything is not only wrong-headed, it is potentially dangerous.

**Early Warning Signs: Are You Teachable?**

From the moment new technicians start orientation in a central sterile (CS)/sterile processing department (SPD), they also are starting to build their reputations as either teachable coworkers or hard-headed know-it-alls. Department educators and preceptors can identify these “reputation types” quickly after a training program has begun. New hires who make too many assumptions about how or why the job is done certain ways can give off signals that they are less interested in learning and more interested in doing it the way they think is best—even with the limited information they may possess.

When sterile processing trainers feel like they have a know-it-all in their midst, continuing to encourage and correct the new hire can be very difficult, sometimes as a result of sheer frustration from not being listened to throughout the orientation process. Depending on the mix of personalities in the department, some new-hire know-it-alls can unintentionally isolate themselves from any kind of corrective feedback or constructive criticism that others might have been willing to give them. When this happens, a new hire can be dangerously unequipped and unaware of their insufficient knowledge regarding department processes.

**Once Upon a Time, I Knew**

However, new hires are not the only ones in danger of not knowing how little they really know. Despite having a few years of work under their belts and perhaps a sterile processing certification or two, experienced frontline employees also can catch the dreaded know-it-all disease. At one time, these employees may have felt like they were at the top of the department food chain; everyone looked to them for advice. They fielded questions such as "What is this clamp called?" and "Where is that tray located?" They really did know more about the department and its processes than anyone else.

The problem is that learning in sterile processing is much more than a one-and-done endeavor. It’s not like getting a driver’s license, where the rules of the road stay more or less the same throughout one’s lifetime. Industry insights, guidelines, and improvements are constantly changing. Equipment is being updated and technology is disrupting; therefore, someone who knew a lot about sterile processing 10 years ago but knows little about what has happened since is no longer the expert they once thought they were. Although that person’s department may not have changed much in a decade, the world outside certainly has.

**Alone on a Leadership Mountain**

Frontline staff are not the only ones who can struggle with assuming they have a monopoly on sterile processing knowledge. Sometimes, the know-it-all syndrome can strike department managers and directors just as deceptively. In this scenario, a leader may come to believe that a mere title and office equals subject matter expertise in the realm of cleaning, disinfection, and sterilization. After all, they are the CS/SPD manager, so they must have all the answers, right? And what they decide should always be considered the correct conclusion—isn’t that true? These misconceptions sometimes are magnified by other hospital leaders who
expect and treat the CS/SPD manager as if they really do know everything about this complex and ever-changing industry.

Sterile processing leaders who let their position, title, or reputations go to their heads can put themselves and their departments in a potentially dangerous situation. Leaders who feel they can never be wrong are unable to evolve. Learning from their mistakes is not possible if they are incapable of acknowledging that they make mistakes. Leaders who can’t or won’t learn will be unable to keep up with the rapid pace of innovation and change that defines the sterile processing industry. And if a leader cannot keep up, their department will suffer as a consequence.

How to Re-Engage and Grow

So, what is the answer? How do we rescue ourselves, our coworkers, and our departments from the scourge of sterile processing subject matter snobbery? The answers are simple, yet profound: We must recover the virtue of professional humility and commit to continually and truly learning from each other every day. In a world where professional distinction is lauded and resumes are built on flashy buzz words such as “expert” and “thought leader,” the foundational concept of professional humility remains the great differentiator between industry leaders and mere charlatans.

A technician who is willing to learn has no barrier to how far and how fast they can grow. A leader who is willing to listen has no limit to the number of lives they can influence in a positive way.

The opportunities and outlets available to CS/SPD professionals who possess a lifelong commitment to learning are growing rapidly. In addition to industry guidelines, regional conferences, sterile processing periodicals, and even podcasts, our greatest asset for knowledge and insight are our people—the folks on the other end of the phone when you call a vendor hotline or at the other end of the table when you invite another manager out for lunch. When two people can Humbly open up a dialogue with each other—without any pretense or self-importance, for the sole purpose of sharing their passions for sterile processing excellence—entire industries can be changed. To win the battle for patient safety and safe surgical instruments, we need departments full of people who know what they do not know and are willing to do something about it.
What to Expect in the Third Edition of ST72

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When the revision process for ANSI/AAMI ST72:2011 began in April 2016, the goal of the Microbiological Methods Working Group (WG08) and its volunteer ST72 Endotoxin Task Group was to update the standard to reflect current industry and regulatory expectations for the testing of medical devices. Also known as the “nonpyromaniacs,” the ST72 Endotoxin Task Group includes WG08 members with a passion for the bacterial endotoxins test (BET) and helping to ensure safe, nonpyrogenic healthcare products.

In addition to other WG08 members, ST72 task group participants have been key contributors throughout the revision process, helping to map out the proposed changes. Several areas were identified as requiring clarification, guidance, and/or alignment with current regulatory BET guidance documents and expectations. Anticipated key changes are highlighted in Table 1.

Evaluating Implants with Nonintact Tissue Contact

During the ST72 revision process, one area of interest, controversy, and continual discussion pertains to the inclusion of the new requirement for endotoxins testing of implantable medical devices. An unforeseen change in regulatory requirements has triggered much concern and debate. After being exempt from bacterial endotoxins testing for more than 20 years, sterile implantable orthopedic products (e.g., artificial hips, shoulders, plates, screws) are expected to have BET results as part of Food and Drug Administration (FDA) regulatory submissions to minimize potential risks related to endotoxin exposure and nonsystemic pyrogenic events (localized responses).

In June 2011, BET changes were seen with the withdrawal of the 1987 FDA LAL (Limulus amebocyte lysate) guideline and 1991 interim guidance. Then, in June 2012, the FDA released guidance titled Pyrogen and Endotoxins Testing: Questions and Answers.2 In August 2015, changes were made to USP <161> Medical Devices—Bacterial Endotoxin and Pyrogen Tests, including removal of the exclusion for orthopedic products, latex gloves, and wound dressings. In January 2016, the FDA issued guidance titled Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile.3 BET changes in U.S. regulatory documents are highlighted in Figure 1 in the data supplement (available online at http://aami-bit.org/loi/bmit).

Meeting Challenges of New Implant Requirement

One challenge for WG08 has been to establish new technically sound requirements and guidance for implantable medical devices. In the absence of peer-reviewed endotoxin-related published data or recognized pyrogenic-linked responses, there is ambiguity associated with nonsystemic or subcutaneous routes of exposure. During several WG08 meetings, there were reoccurring debates about potential non–systemic-related patient risks and, if present, whether the BET could detect such risks. Could an acceptable bacterial endotoxin test result provide a false sense of security if localized risks are present? Clear-cut answers have been difficult to find, and the interpretation of reviewed literature references has not always been consistent.

Because the BET is a response-based assay that uses suitable tolerance limits for injectable parenteral drugs (5 endotoxin units/kg) adapted for medical devices (20 endotoxin units/device), whether a nonsystemic response will be detected for implantable medical device products that do not have direct or indirect patient contact with the intravascular, intralymphatic, or intrathecal systems is not known. In the future, WG08 members and the ST72 task group are hopeful that additional published data will emerge to justify the establishment of more defined guidance for implantable medical devices previously exempt from the BET with nonsystemic routes of exposure. It is conceivable that additional endotoxin data, as well as clinical or other supportive data, could be used to justify a less stringent endotoxin limit or the elimination of testing when it is not necessary to minimize risks for various nonsystemic routes of exposure.
Table 1. Examples of ST72 sections and proposed key areas of revision *Corresponding guidance provided in Annex B. Abbreviations used: BET, bacterial endotoxin testing; CSF, cerebrospinal fluid; OOS, out of specification.

<table>
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<tr>
<th>Section*</th>
<th>Example of Expected Clarification, Guidance, and/or Alignment</th>
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<tr>
<td>1</td>
<td>The scope of the standard will remain &quot;medical devices.&quot;</td>
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<tr>
<td>3</td>
<td>New definitions are being added.</td>
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<tr>
<td>4</td>
<td>Minor clarifications to general quality requirements.</td>
</tr>
<tr>
<td>5</td>
<td>New requirement and clarification for sterile devices and kits, including implantable medical devices that come in contact with nonintact tissue, which must be evaluated for bacterial endotoxin.</td>
</tr>
<tr>
<td>6</td>
<td>New section created to minimize confusion related to “nonpyrogenic” label claim considerations.</td>
</tr>
<tr>
<td>7</td>
<td>Clarification regarding sampling plans and family groupings for the testing of endotoxins.</td>
</tr>
<tr>
<td>9</td>
<td>Clarification and alignment related to extraction time/temperature conditions, maximum valid dilution terminology (which is more applicable to devices), and product and test method suitability.</td>
</tr>
<tr>
<td>10</td>
<td>Additional considerations for OOS and failure investigations.</td>
</tr>
<tr>
<td>11</td>
<td>Updates on the current expectations for alternatives to batch, such as having nonpyrogenic end product results.</td>
</tr>
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</table>

In the meantime, compromises have had to be reached and will continue to be needed in order to proceed with publishing the third edition of ST72. Examples of consensus include the use of “must be evaluated” instead of “must be tested” and the use of “batch tested” when referring to which medical devices are intended to be nonpyrogenic (as described in section 5.1 and B.5.1 of the draft version of ST72). This compromise removes the explicit mandate for endotoxin testing, and in the third draft of ST72 (in section B.5.1.2), explicit guidance is included stating that the term “evaluate” does not mean “testing.” However, many WG08 members are concerned that the BET will be conducted regardless of whether it is justified. As such, because implantable medical devices are such a broad category, WG08 and regulatory authorities must continue to work together to identify areas of possible exemptions for this requirement or the delineation of adequate risk assessment or endotoxin controls as an alternative to batch testing. Thus far, exemptions include implantable medical devices that have contact with intact tissue; specific examples will be provided in the new edition of ST72.

Consistent with applying alternatives to batch testing, the new Annex E contains several factors to be considered as part of a risk-based approach and examples intended to aid manufacturers and regulatory reviewers regarding the appropriateness of alternatives to batch sampling plans. As described in Annex E, the severity of a pyrogenic response and the ability of bacterial endotoxins to cause patient harm depends on several factors. The level of endotoxin exposure, rate of exposure, location of exposure (e.g., intravascular, intralymphatic, intrathecal, intraocular, etc.), and weight of the patient should be considered.

**Proposed Areas of Alignment and Harmonization Efforts**

Other key areas of focus during the ST72 revision process have centered on desired alignment with other BET regulatory documents (as noted above). Because it contains relevant instructions for medical devices, the WG08 co-chairs have been actively working to achieve alignment in the future with the next
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The updated ST72 standard will provide needed flexibility for supporting a risk-based approach to bacterial endotoxin testing, allowing for the continuous improvement required for medical devices and healthcare products in the future.

revision of USP <161>. In addition, retaining consistency with the harmonized general test chapter Bacterial Endotoxins Test <85> has been a desired outcome. A few specific points are as follows:

• The new edition of ST72 will provide clarification and changes related to inhibition, enhancement, and method suitability terminology, including the number of lots required for demonstrating suitability (and continued suitability) using various endotoxin testing techniques.

• Device extraction time/temperature conditions have been streamlined. The historically adequate, practical, and accepted required extraction conditions (e.g., devices filled/immersed in LRW [LAL reagent water] and held for not less than one hour at controlled room temperature) have been retained, as has the flexibility for alternatively validated conditions. However, directions related to using water initially heated to 37°C for extraction are not expected to be included in the updated ST72. This is because it is recognized by WG08 members that once the heated water is removed from its warming sources or when it contacts medical devices at room temperature, the ability to maintain water temperature at 37°C for even a short period of time is very limited. References within vertical standard/guidance documents with such requirements have been included as notes; therefore, users can be aware of special requirements for specific devices (e.g., ophthalmic devices).

• Harmonization on sampling plans, recommended number of sample terminologies, and other factors will be included in the revised standard.

Conclusion
Many changes, including new device requirements, BET clarification, and guidance for negotiating several of the new requirements, are driving the revision of ST72. The updated standard will provide needed flexibility for supporting a risk-based approach to BET, allowing for the continuous improvement required for medical devices and healthcare products in the future. Moreover, the new edition will seek to provide improved BET guidance to meet the needs of its users.

If agreement can be reached, the revision of ST72 is predicted to be published in 2019, following another period of comment and voting.

References


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Multigas Monitors: Overview and Preventive Maintenance Essentials

What is a multigas monitor, and what should I expect on a preventive maintenance (PM) inspection?

Multigas monitors or detectors are known by various names, including “gas modules.” Most often, they are called by their model name. Regardless of the name by which you know your multigas monitor, the function is the same: supplying information or monitoring a patient’s airway gas mixture. These monitors can be found in operating rooms, recovery rooms, outpatient departments, endoscopy areas, obstetrics departments, and emergency departments—essentially anywhere in which medications are used where patient “gas level” needs to be monitored.

When operations or certain procedures are performed, the patient is given oxygen, medical air, nitrous oxide, and some type of anesthetic agent (e.g. sevoflurane, isoflurane, desflurane, halothane). These gases are given to the patient in a certain mixture to ensure that they are sedated throughout the procedure and that they feel no pain.

By way of a sample line, the multigas monitor measures the gases being inspired and expired. The gases are delivered via a mask through a closed-loop system, with the sample line coming off of this loop. In most cases, these systems will have a water trap to collect and eliminate moisture from the line. This also serves as a way to keep moisture from entering the gas monitor. If moisture was allowed to enter the monitor, it could plug the internal lines or contaminate the chambers that measure gases, causing erroneous readings.

Multigas monitors can be stand alone or part of the anesthesia machine. They always will have a wide array of alarm parameters that allow the anesthesia staff to set limits to make them aware of problems. Some of these alarms include: inspired and expired oxygen, high and low oxygen saturation, high and low pulse limits, high and low end-tidal carbon dioxide (CO₂), high and low CO₂, apnea, and high and low anesthetic gas.

PM involves checking all gas measurements for accuracy. This is accomplished by using a canister of calibration gas and checking to make sure the delivered amount matches the canister. If the measurements do not match, the biomedical technician must calibrate them. (Of course, every manufacturer has different procedures, so the service manual must be consulted.) Calibration must occur before the monitor can be used again. Usually, if the calibration is off, the anesthesia provider will know and immediately notify biomedical engineering.

Each manufacturer has different guidelines regarding the frequency of PM and calibration for multigas monitors. Repairs include replacing inaccurate measurement devices and calibrating them after repair. Also following repair and PM, all alarms must be checked. Electrical safety also must be performed; this is done by measuring the ground resistance and chassis leakages. As technology has improved over the years, in addition to multigas monitors themselves becoming smaller, the measurement devices within the monitors have become smaller.

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<td>OUTSIDE BACK COVER</td>
<td>PAGE 461</td>
</tr>
</tbody>
</table>
Device Integration Specialists Are Needed to Fill Vital Support Gap

As technology changes and more devices are being integrated with electronic medical records (EMRs), a growing gap exists within the support model. No professional specialty has taken ownership of this vital behind-the-scenes environment, where transfer of information occurs among devices and with the EMR. This gap signals an opportunity for a new specialty within healthcare technology management (HTM): the device integration specialist.

This support area is characterized by unique security requirements, knowledge of in-play devices, and an understanding of the Health Level-7 (HL7) standard. The device integration specialist is capable of handling an entire spectrum of support services, from individual devices to the server, including patching, antivirus protection, integration and middleware, and device troubleshooting.

As many readers likely are aware, a vast difference exists between traditional information technology (IT) security and the security requirements of medical devices. Traditional IT security has three main areas of focus, with the following order of priority: 1) confidentiality (data must stay private), 2) integrity (ensuring data are correct), and 3) accessibility (data are available to those who need them).

Medical devices take more of an operational technology (OT) approach, where the order of priorities is 1) control (a strict method of how communication happens), 2) accessibility, 3) integrity, and 4) confidentiality. In addition to often being a point of contention, this inverse approach is indicative of why device integration systems need not be updated as often as IT systems. For example, many medical devices are running on legacy operating systems (OSs) that are the bane of system administrators' existence. However, it isn’t feasible for a hospital to buy a new computed tomography (CT) scanner just because the OS is outdated.

A specialization in device integration would include training in OT security, allowing these professionals to present better arguments and rationale to the hospital security team.

Security doesn’t stop at the device level; medical devices are required to transmit information across multiple platforms to an EMR. Vendor networks can incorporate many specialized devices and requirements, which may make them difficult to support and can lead to expensive contracts.

Considering these factors, a clear opportunity exists for HTM professionals to branch out from traditional technician roles. We understand the requirements and nuances of devices and can apply that knowledge to device networks and specialized servers.

Knowledge of devices is not the only consideration, however. An area of growth opportunity also lies in understanding HL7. HL7 is an American National Standards Institute–accredited standard that provides a comprehensive framework for the exchange of electronic health information (e.g., patient name, demographics, medical record number, vital signs data, other test results). This information flows from the device across the network and into the EMR. It can be a direct feed, go through some sort of middleware, or be translated within a server. To troubleshoot problems effectively, a device integration specialist has to have a basic understanding of the format of HL7 and be able to interpret the data within various systems.

In the past, branching out from traditional HTM roles has resulted in new certifications, such as the CRES (Certified Radiology Equipment Specialist), CLES (Certified Laboratory Equipment Specialist), and the new CHTM (Certified Healthcare Technology Manager). As HTM professionals take on the device integration role, it only follows that a certification should be created. The CDIS (Certified Device Integration Specialist) exam would test knowledge in the areas of device connectivity, middleware, networks, server administration, HL7, and both IT and OT security.

This path will allow device integration to remain within the HTM field and provide HTM professionals with a path to keep pace with growing technology.

Corey J. Weeden, CBET, is a clinical system analyst associate in information technology–ancillary applications at UCHealth in Colorado Springs, CO. Email: corey.weeden@uchealth.org
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