AAMI eXchange REWIRED Success Promises ‘Bright Future’ Ahead

Brian Stallard

AAMI’s eXchange REWIRED online conference wrapped up on June 11, proving to be a rousing success. Attendees praised the event for delivering on the promise AAMI made to create an online event that was more than “just another virtual event.”

Well over 1,000 people participated in the five-day event in real-time. They now have access to recordings of the 61 education sessions from the event until 2022.

“None of us have done an event in this way before, and we are getting feedback from all over the place saying this is the best virtual event folks have seen,” said Robert Burroughs, senior vice president of education at AAMI, adding that one attendee even wrote they preferred the REWIRED experience to most live conferences. “That may be a bit of hyperbole, but I’ll take it!”

LIVE at eXchange REWIRED

The addition of a five-day livestream to the virtual conference proved to be a huge hit, and among the most popular content was “Good Morning HTM,” a live morning show broadcasted from AAMI headquarters. The broadcast, hosted by Burroughs and AAMI’s Danielle McGeary, vice president of healthcare technology management (HTM), introduced attendees to some of the event’s hottest topics and included live Q&As with special guests and surprise announcements.

The Gains and Pains of Digital Health

Jennifer Peters

During the COVID-19 pandemic, many patients and providers embraced telehealth options for the first time. The benefits of remote digital care are numerous.

“Digital health technologies allow health professionals to become much better equipped to do their jobs in an efficient and a collaborative way,” said Rob Turpin, Head of the Healthcare Sector for the British Standards Institute, at a session during AAMI eXchange REWIRED. “There’s an appetite amongst care teams to bring their services into the 21st century and ensure they’re fit for purpose in a modern society.”

Pat Baird, Sr. Regulatory Specialist at Philips, noted the most obvious perk: telehealth visits reduce the risk of infection that patients face when they encounter other sick people in the waiting room.

But there are other pluses. Telehealth allows patients access to their health data, like test results and prescriptions. And Baird

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AAMI Member Company Tackles Food Desert for Future Workers

If you heard that a grocery store was being built for a community in need, you’d likely think this was the good work of a charity, philanthropist, or entrepreneur. For Arlington Woods, a neighborhood in Indianapolis with limited access to fresh foods—a so-called “food desert”—it is instead medical device manufacturer and AAMI corporate member Cook Medical who is stepping in to meet the community’s nutritional needs.

“We believe it’s possible to do good business and do good in the community too,” Pete Yonkman, president of Cook Group and Cook Medical recently told AAMI News.

The project began with plans to build a Cook Medical-Goodwill medical device manufacturing facility in Arlington Woods, an area which Cook Medical says has some of the “highest levels of unemployment and poverty in [Indiana].” To address concerns that employees would have limited access to fresh foods, Cook made additional plans to construct a new 14,000 square foot full-service grocery store near the manufacturing facility.

According to Cook Medical, they’ve partnered with Goodwill of Central & Southern Indiana, The Indianapolis Foundation, IMPACT Central Indiana, Martin University, the State of Indiana, City of Indianapolis, and the United Northeast Community Development Corporation to support two Arlington Woods entrepreneurs, Michael McFarland and Markus Williams. Cook Medical will build the local store and IMPACT Central Indiana will provide startup capital.

It is a powerful example of corporate social responsibility in action that has gained national attention. You can learn more about the inspiring project through NPR’s All Things Considered.

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Announcing 2021 Members to AAMI HTM Leadership Groups

Seven AAMI members and leaders in the healthcare technology management (HTM) space have accepted roles on the Technology Management Council (TMC) and the Healthcare Technology Leadership Committee (HTLC) for a three-year term.

“I’m excited to start working with these leaders in the TMC and HTLC,” said Danielle McGeary, vice president of HTM, AAMI. “These are AAMI members who go above and beyond for the HTM field, offering their time, expertise, and passion to make the healthcare technology space better for everyone!”

AAMI’s TMC is an influential committee of HTM thought leaders working with McGeary to advance and support the field. This committee represents the interests of biomedical equipment technicians, clinical engineers, and other HTM professionals.

AAMI’s HTLC is an advisory committee of experienced HTM thought leaders seeking to develop the next generation of HTM leaders by nurturing leadership skills among HTM professionals and advancing the professional interests of HTM managers.

The following members will begin their three-year terms after the TMC’s next quarterly meeting on June 29 and the HTLC’s next quarterly meeting on June 30, respectively.

Joining the TMC

- **Rudy Flores**, South Texas Regional HTM Program Director at Universal Health Services. Flores joins the TMC with 27 years working in the healthcare industry under his belt. A certified CBET since 1995, Flores is familiar with the difficulties that his staff and shops face daily and brings new ideas to improve HTM department efficiency to the table.

- **Krishna Govindarajan**, HTM Consultant at DK Medical. Govindarajan is an independent medical device quality and regulatory professional with more than 25 years of experience in the digital health technology space. She plans to harness her in-depth knowledge of the medical device industry to help improve the safety and effectiveness of the HTM profession.

- **Axel Wirth**, Chief Security Strategist at MedCrypt. For the past 12 years, Wirth has focused his career in the health technology field specifically on healthcare cybersecurity and the unique challenges that come with making medical devices a secure and effective part of the Internet of Things. He seeks to work with AAMI and the TMC to change the imbalance between vulnerable technologies and the tools and know-how available to keep them secure.

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Announcing 2021 Members to AAMI HTM Leadership Groups

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Joining the HTLC

• Ali Youssef, Director of Medical Device and IOT Security for Henry Ford Health System. A specialist in medical device security and digital health with more than 20 years of experience, Youssef sought to join the HTLC to mentor future leaders for the HTM field. Through cross-training, he intends to help build crucial bridges between the increasingly overlapping fields of HTM and health IT.

• Andrew Ulvenes, Vice President of Clinical Technology & Cybersecurity for Kaiser Permanente. Self-described as a professional with “relentless customer focus,” Ulvenes’ priority is patient safety. He is joining the HTLC to help pave a clear path for HTM leaders in a changing healthcare technology landscape, as more effective HTM departments, he reasons, leads to a safer patient experience.

• Ivan Joyner, HTM Team Lead for Anaheim Regional Medical Center. After more than 30 years working in the healthcare technology field, Joyner has spent the last seven mentoring the next generation of HTM professionals. Now, he hopes to have an even larger impact on the future of HTM by helping to develop the next generation of HTM leaders.

• Michael Angel, Director of HTM COE for Sodexo. During his more than 21 years of experience in the healthcare technology industry, Angel has worked to educate students in how they can best leverage new knowledge to launch promising HTM careers. Until now, these efforts have been limited to local colleges in places he has lived. By joining the HTLC, Angel aims to grow the “HTM family” and help ensure it continues to have effective leadership.

NEW!

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• Medical device manufacturers conducting their own validation testing, or for use during the design phase to assist in developing devices which are “reprocessing friendly.”
• 3rd party reproprocessors to validate their cleaning and reprocessing methods for single-use devices.

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Nuvolo Sponsors New AAMI BMET Apprenticeship Program

Nuvolo, the world’s fastest-growing workplace software company, today announced it has partnered with AAMI to support HTM departments who enroll in AAMI’s new Biomedical Equipment Technician (BMET) Apprenticeship Program. The one-of-a-kind program, which combines online and classroom education with up to 6,000 hours of on-the-job learning time over the course of two years.

BMET apprentices participating in the two-year program have the opportunity to earn three industry-recognized credentials: the Certified Associate in Biomedical Technology (CABT), the Certified Biomedical Equipment Technician (CBET), candidate status; and CompTIA IT Fundamentals (ITF+) certification. Upon successful completion of the apprenticeship, participants also receive a nationally recognized certificate from AAMI and the U.S. Department of Labor.

To help HTM departments pay for the cost of certifying their BMET apprentices, Nuvolo has started the Nuvolo Apprenticeship Sponsorship Program. Here’s how the program works:

• The first seven health systems or stand-alone hospitals to enroll in AAMI’s BMET Apprenticeship Program by December 1, 2021 will be automatically eligible to receive up to $725 per apprentice for up to two apprentices.

• Hospitals and Health systems must officially register their apprentice(s) in AAMI’s BMET Apprenticeship Program by December 1, 2021. After this date, any remaining sponsorship spots will be offered up to other hospitals or health systems enrolled in the BMET Apprenticeship program.

• A total of up to 14 apprentices will have the cost of their certification tests covered by Nuvolo.

• Nuvolo will donate the funds to AAMI, who then will apply the donated funds as a reimbursement to the eligible participating

Helping HTM Departments Hire and Train BMET Apprentices

Nuvolo is proud to be the first company to invest in the new BMET Apprenticeship Program through a pledge of $10,000 to support HTM departments in hiring and certifying BMET apprentices.

The first seven health systems or hospitals to register for the program are eligible for certification funding for two apprentices who have enrolled by Dec. 1, 2021.

Learn about the Nuvolo Apprenticeship Certification Program here:
Connectedworkplace.nuvolo.com/apprenticeship-certification-program/

Enroll in the AAMI BMET Apprenticeship Program:
www.aami.org/BMETApprenticeship

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Nuvolo Sponsors New AAMI BMET Apprenticeship Program

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organizations once the apprentice passes each of the required certification tests by June 30, 2025.

- Additional program details can be found at connectedworkplace.nuvolo.com/apprenticeship-certification-program/.

“At Nuvolo, our teams are actively invested in the industries we support,” said Tom Stanford, Founder and CEO at Nuvolo. “Sponsoring the AAMI BMET Apprenticeship program is just the latest expression of that commitment. The need for skilled talent in the healthcare technology management industry is being felt across the board and Nuvolo is committed to addressing this need.”

To address the shortage of qualified HTM professionals in the hiring pool, some hospitals and other employers had been training their own BMETs from the ground up with no formalized way to ensure these BMETs are trained consistently or to a minimum standard.

This apprenticeship program will bring structure to that process and contribute to a solution for bridging the current skill gap in the field for entry-level employees. The availability of a formalized BMET apprenticeship, offering formalized training in a real work environment, is intended to attract new professionals to the field.

“AAMI wants to thank Nuvolo for coming up with this creative way to support the HTM community in addressing the BMET shortage and growing the field” says Danielle McGeary, Vice President of Healthcare Technology Management at AAMI. “This is a great way to financially support hospitals who want to participate in the BMET Apprenticeship Program but may have budget constraints. We hope more companies will follow Nuvolo’s example so that even more hospitals can hire BMET apprentices.”

Upon completion of the apprenticeship, participants receive a nationally recognized certificate, jointly issued by AAMI and the U.S. Department of Labor, signifying that the apprentice was trained to AAMI’s recommended minimum competencies and standards.

More information on how to become a BMET Apprenticeship partner can be found by visiting www.aami.org/training/bmet-apprenticeship.

United Airlines Introduces Telehealth-Observed COVID Self Testing

Fran Kritz

One of the largest airlines in the United States, United Airlines, announced that a telehealth-based collaboration to help travelers returning to the U.S. comply with Centers for Disease Control and Prevention requirements (CDC) requirements for a negative COVID-19 test taken within three days of travel.

“We appreciate the private sector proactively helping travelers have access to easy, reliable COVID-19 test options,” said CDC Director Rochelle P. Walensky, MD, MPH, in a press release. “Comprehensive testing that is easy, rapid, accurate and trusted is a fundamental strategy for preventing the spread of COVID-19.”

Under the collaboration with Abbot Laboratories (makers of a rapid COVID-19 test) and telehealth firm EMed, United travelers can purchase Abbot’s BinaxNOW test from the airline before departing and then use it before returning by accessing a telehealth visit with EMed.

Self-administered tests can be easier and less expensive for travelers than finding a testing center in the country being visited and getting those results back in the three-day window required by CDC.

CDC requirements for telehealth observed COVID-19 self-tests include:

- The test must be a SARS-CoV-2 viral test with Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA).
- The testing procedure must include a telehealth service affiliated with the manufacturer of the test that provides real-time supervision remotely through an audio and video connection.
- The telehealth provider must confirm the person’s identity, observe the specimen collection and testing procedures, confirm the test result, and issue a report [for the airline.]

“Now that the first self-test that uses telehealth has been approved to meet CDC entry requirements for air travel, we should see growth in use and promotion of telehealth enabled testing by many international airlines given the convenience and flexibility it affords travelers,” said Dave Ryan, senior advisor to the American Telemedicine Association.
High Value of Human Factors Engineer Embedded in the Clinical Setting

Jennifer Peters

Human factors engineers work to understand how human involvement impacts the use and usability of medical devices. But what can they add to the mix when embedded in a clinical setting?

A lot, according to Brittany Anderson-Montoya, a human factors specialist at Atrium Health, who with other embedded human factors engineers (HFEs) discussed their role in the clinical setting and the value of HFE embeds in improving patient health and medical device usability at the International Symposium on Human Factors and Ergonomics in Health Care.

HFE professionals are tasked with understanding how human involvement impacts the use and usability of medical devices, helping end users as well as manufacturers understand how to better design devices with actual application in mind.

“Medical device use errors really continue to contribute to adverse patient events despite a lot more focus from FDA and other regulators to make devices more user-friendly,” Anderson-Montoya said.

She explained that a common driver of adverse events is that new, sophisticated technology is causing medical devices to become more complex.

“I see sometimes where a very complex medical device that our teammates struggle to use appropriately actually goes home with our patients,” Anderson-Montoya explained. That then leads to the potential for an adverse event to occur when the patient is attempting to use the device.

But it isn’t only new devices that can be difficult for clinicians and patients to grasp. As devices are updated and tweaked, the opportunity for error is reintroduced. “I think any of us who are clinically embedded will state that even a small change, something that seems very innocuous... can have huge ramifications for the usability engineering of the device, and really can have deleterious consequences for patient safety,” Anderson-Montoya noted.

The big-picture issue, though, is the disconnect between the end users and the manufacturers. By encouraging more users—clinicians, HFEs, even patients—to actually report device-related injuries and errors, Anderson-Montoya hopes that a closed feedback loop can be created to better guide usage of potentially problematic medical devices.

Part of that starts with the procurement process, as Emily Rose, a biomedical engineer for Providence Health Care, discussed. Procurement focuses heavily on utility and cost, Rose explained, but what she has tried to do is “introduce this idea that there’s a third prong that needs to be considered, and that is usability.” Rose has worked with the Western Canada Human Factors Collaborative to help introduce this line of thinking to the organization handling medical device procurement for the Collaborative’s many members.

Rose noted that there are three main benefits of embedding the human factors approach into the procurement process:

- Identify design problems that may affect patient safety and quality of care.
- Provide additional information for decision-making (e.g., implementation concerns, troubleshooting).
- Quantify level of consistency between new device and current workflow, including the degree of standardization and error potential.

“There’s still a disconnect between the industry work and the applied work creating a ‘work as imagined’ versus ‘work as done’ confound,” Anderson-Montoya noted in her own presentation about the procurement process. The sentiment was echoed by Rose. “The nice thing about being embedded is that we can really bridge this gap. We can translate some of the theory to the applied setting, and we can really tailor our approach to the unique culture and environment of our system.”

By focusing on usability from the start of the process, providers can utilize the expertise of their embedded HFEs to help prevent medical device errors caused by human factors before they even pop up in the clinical setting.

“We were initially very academic in our application of human factors methodologies,” Rose explained. “We’ve since had to understand [how to] deliver very actionable results to our organizations.”

Another part of the process that benefits from HFEs is the analysis of errors after the fact. As noted by Chris Flewwelling, Associate Director of Medtech at Healthcare Human Factors, one of the most used causes still found in databases of medical device errors is “no fault found” (NFF).

“Usability-related design flaws manifest themselves as defective devices, resulting in an increase of ‘no fault found’ report generation,” Flewwelling explained. “The actual use environment actually amplifies any issues we’re seeing.”

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Flewelling recommended a three-step approach to ensuring that NFF reports become less common and the real issues—those potentially caused by human factors—are brought to light and corrected.

Flewelling’s approach involves:

• Ensuring human factors principles are considered during equipment procurement;
• Continuously analyzing medical engineering equipment maintenance data for devices associated with high NFF incident rate; and
• Discussing the results of the analysis with BMETs and conducting heuristics evaluations.

The benefits of all this work? Fewer problems caused by human factors.

Tandi Bagian, Manager and Program Analyst for the Veterans Health Administration, added that one of the biggest reasons to embed HFEs in the clinical setting is to avoid running into the same problem over and over across facilities. “If Hospital A learned something, why should Hospital B have to experience the same thing to learn it?” she said.

Especially at the 150 facilities that comprise the Veterans Health Administration, being able to track trends across environments and usages, and to get an understanding of any human factors involved, allows them to not only get a complete picture of the problems they’re facing, but to get a clear view of how to resolve the issue as well, whether that’s through conversations with the manufacturers, new usage guidance, or even a recall.

“It’s been really rewarding to see the patient care improve because people are willing to share when something doesn’t look right,” she added.

“We have a first-hand view of medical devices in our environment,” Anderson-Montoya noted of embedded HFEs. “The reality is that a lot of the usability testing is still being done in an ideal environment. It’s very different when you get it into your clinical environment.”

By having HFEs available continuously in the clinical setting, healthcare providers and medical device manufacturers benefit from the continued oversight and troubleshooting they provide while also having the opportunity to prevent future errors.

Find additional AAMI News coverage of the HFES symposium at www.AAMI.org/AAMINews.

High Value of Human Factors Engineer Embedded in the Clinical Setting

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In Memoriam: Ruey Dempsey

The AAMI and health technology communities mourn the passing of Ruey C. Dempsey.

Dempsey served for more than 13 years as Vice President of the medical device trade association, AdvaMed. Prior to her time in industry, Dempsey conducted research at the University of Pennsylvania. She carried this passion for thoroughly understanding a problem over into medical device development, working with scientists, engineers, and innovators alike.

Dempsey served as a member of AAMI’s Radiation Therapy working group for three years and later offered insights and advice to AdvaMed’s sterilization and biocompatibility experts working with AAMI standards developers.

“Ruey was a dedicated champion for the medical device industry and worked with our membership to help educate our lawmakers on what is best for patients and our industry,” said Phil Cogdill Vice President of Technology and Regulatory Affairs at AdvaMed and 2021 AAMI Fellow. “She will be greatly missed.”

“Ruey did an amazing job bringing industry and FDA together to resolve key challenges and advance policies to help patients get access to life saving devices,” added Maureen Sundeen, who first met Dempsey through medical device advocacy working groups. “She was such a kind and caring person that had such a positive impact on so many lives.”

Marjorie Shulman, Assistant Director, Device Determinations and Custom Devices Lifecycle Team at FDA, remembers Dempsey specifically as a guiding voice during important discussion within the FDA/Industry 510(k) working group.

“Because of her leadership, we always were able to have constructive conversations and solve many issues with total respect for all parties involved,” she said. “Because of this working relationship, we became friends, and she will be missed.”

In recognition and appreciation for Dempsey’s impact on the medical device field, the CDRH and FDA Statisticians donated a large flora arrangement for Dempsey’s funeral mass, held on May 22.
Human Factors Experts Seek Trust and Safety for AI/ML Medical Devices

Gabrielle Hirneise

Healthcare is an innately human experience, but with the introduction of artificial intelligence and machine learning, keeping healthcare delivery human-friendly can be a challenge. It was a lesson brought up time and time again during the recent 2021 HFES International Symposium on Human Factors and Ergonomics in Healthcare.

Though it’s undeniably a burgeoning field in the healthcare industry, there exists some apprehension in regards to AI/ML usage. That’s why human factors experts have found themselves working at the very foundation of this doubt, devising new ways to make AI/ML-enabled medical devices more trustworthy and facilitating human-AI collaboration.

Trust in AI

The first step to enabling trust is providing insight into how algorithms reach a decision. That’s at least according to Yuval Bitan, a human factors engineer and lecturer at the Ben-Gurion University of Negev, who spoke during the HFES Symposium.

“One of the things that affects trust is the fact that all these algorithms are basically a black box, and we in human factors, need to try and find ways to change this black box algorithm to a clear box,” said Bitan.

Another element of trust is user interaction, namely information relevancy and interactivity. If the information and the way it’s displayed by the device does not fit the needs and objectives of the clinician, then the device is of little use. As for interactivity, ideally, the device would allow for some interaction or customization of the user interface by the clinician.

Bitan and his research team were able to study such factors in a simulation where an AI was aiding the detection of bacteria in the bloodstream. Their preliminary data, which will be published at a later date, suggests that displaying relevant information and interactivity are an important element of trust in AI/ML-enabled medical devices.

“We really could see that when the physicians felt that if they had relevant information, they felt more confident about the system and had more trust in the system. We [also] saw that when they had more interactive work with the device, they had more trust in the system,” Bitan added.

Data Quality and Transparency

Though AI and ML have become more widely accepted and efficient with time, they are not considered entirely reliable, as there are more factors to be considered.

Emily S. Patterson, associate professor at the Ohio State School of Health and Rehabilitation Sciences, presented an example of this during the symposium.

Radiation of the spinal cord has been a treatment method utilized on head and neck cancer patients; however, too much radiation can result in paralysis. If an algorithm were to dictate the treatment plan, and patient anatomy features were to fall outside the bounds of the AI/ML-based model, or a patient had already been exposed to radiation previously without the algorithm knowing, there would be an increased risk of paralysis.

In order for physicians to lean on such devices to inform treatment strategies, data quality, data diversity, and transparency must be emphasized.

“If we want to have voluntary hospital-level patient safety improvements in this space… One thing we can do is share our code,” Patterson said.

Patterson pointed out that in light of human lives being at risk, there is no benefit to competition between algorithms. As a result, the healthcare industry can benefit from open-source code, predetermined validation of the models, and patient population characteristics. Such accessibility could promote higher data quality and could bring to light differences in efficacy for different populations.

“If we share our models, we can also share the findings about how well those models fit,” she said.

Learn more about Patterson’s research into sharing ML-based algorithms between hospitals safely and effectively: Read the latest!

The biases we see in the collection of data and databases used to train AI/ML algorithms are a large contributor to data quality. If the training dataset only represents one demographic, it can only serve that one demographic.

This was exhibited in a study completed by Duke University, COVIDidentify, which utilized data from wearable devices to create a software that could predict COVID-19 and flu infection through the analysis of prevalent biomarkers.

Peter Cho, one of the PhD students leading the study, observed that although the study was cost effective for the researchers because it prompted participants to send their own devices in,

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it was cost or access prohibitive for the participants. This meant that the data collected only represented the narrow demographic that could afford such devices, and it was also found that the participants generally only represented the white population in the U.S. This presented a prime opportunity to apply human factors concepts to achieve the data quality and diversity needed for a safe and effective AI/ML-enabled device.

“Since one major barrier was the cost and skepticism of the value added by the device, we also purchased wearable devices and distributed them to underrepresented groups,” Cho said.

Stakeholders to Consider
To better understand how to utilize AI/ML technology, human factors experts are compelled to consider the relationships between different stakeholders.

Anne Miller, a lead human factors researcher with Cerner Corporation, utilized Norman’s Gulfs of Execution and Evaluation to demonstrate the relationships between different parties. The theory dictates that the success of a system depends on how designs represent the world and how the system interacts with its users.

“So, what happens when we put machine learning into the mix of this,” Miller asked. “We create some more gulfs—the gulf between the world and the database, [where] the database is simply a reflection of the world … Then you have the representation of that database in a model, which is another interface … Then of course you have the representation of both the world (that is the patient in the case of healthcare) in the user interface, and you have the representation of the model in the user interface, and all of this has to be communicated to the clinician, who is expected to perceive the world through these interfaces.”

As a complex network of stakeholders, it’s a challenge to ensure nothing is lost in translation, especially in representing the patient’s needs in the algorithm and sufficiently conveying them to the physician. More specifically, Miller brought to light the problem of correspondence, or the “degree of faithfulness with which these interfaces reflect the world,” and the coherence problem, or “how well that representation fits the goals, intentions, the experience, and the expectations of the users.”

Human factors experts were able to get first-hand experience with the demand for patient representation in a project completed by Shimeng Du, a product design engineer at SpectraIMD.

Du communicated that there are about 50,000 burn wounds that require hospitalization in the U.S. per year, with roughly 4500 deaths. With such a high lethality rate and a shortage of burn specialists, there is a demand for solutions, and because the subdiscipline requires “heavy decision making in a short period of time,” such a field would benefit from AI assistance.

In response to this, Du’s team is developing an AI-enabled device to assess healing potential for burn wounds through imaging technology. In developing the device, the researchers accounted for human factors and usability engineering.

To start, they established all the stakeholders and their relationship to one another. The first loop of relation was between the user, patient and device. Upon reviewing this relationship, they realized changes needed to be made.

“We extended this framework into considering the need for the algorithm’s parents, the developers or the data scientists … There is a second loop which is between the algorithm and the developers/engineers. We realized that there are a lot of gaps between these two loops,” Du said.

To mediate this and because the pre-existing image orientation resulted in a lack of consistency and thus poor quality data, the researchers evaluated ways to make the device more user and patient oriented.

“First of all, we changed the shape of our camera head by adding more polarity to it,” Du said. “We are also using a cable from this camera head instead of using a hard crane arm to connect with the device, so that highly increased the flexibility … of the camera head. Also, in our software UI workflow, we provided the ability to perform the rotation of images by the users themselves … instead of having the engineers do it later.”

This project highlighted the importance of adding all the necessary stakeholders in the early stage of development and offered a testament to usability engineering’s ability to bridge the gap between software developers and clinician users.

AI- and ML-enabled medical devices hold great promise for the future of healthcare; however, human considerations are key in further implementation. Without such considerations, data quality and patient outcome may suffer.
FDA Advises on Cybersecurity Concerns in Annual Forum

Gabrielle Hirneise

As most information is stored and exchanged via our devices, cybersecurity is a growing concept of concern. Kevin Fu, acting director for medical device cybersecurity and program director for the DHCoE at the FDA, spoke to this topic at the 2021 FDA Science Forum, addressing recent headway the FDA has made in guiding cybersecurity regulations and overcoming recent challenges within the medical device landscape.

“The FDA has elected not to approve and not to clear medical device submissions on cybersecurity concerns alone,” Fu said. “The reason why, simply stated, is because cybersecurity is safety. It’s extremely difficult to have a safe and effective medical device if there are cybersecurity risks of clinical relevance.”

However, the FDA does not enforce stipulations alone—they also provide solutions and guidance. Over the last decade, the FDA has assembled documents, regulations, and educational materials for medical device manufacturers, encouraging them to provide built-in cybersecurity defenses in lieu of adding them as an afterthought.

“There are two primary documents available—a premarket guidance document finalized in 2004 and a second document finalized in 2016 called the post-market cybersecurity document, and that I would consider more of a social engagement document,” Fu said. “It talks about how medical device manufacturers and organizations can work together to share information about not only vulnerabilities in a medical device but actual incidents … such as ransomware … and how to communicate that with stakeholders across the medical device ecosystem.”

In line with the constant evolution of cybersecurity, the release of a new draft of the premarket guidance is to be released later in 2021. Amongst such guidance is a call for threat modeling, which would eliminate the uncertainty associated with taking on a new medical device.

“It’s very difficult to make scientific claims about cybersecurity if a manufacturer does not provide a reasonable and reputable threat model specific to the medical device,” Fu said.

Threat models do what their name implies: model what cybersecurity threats one can expect with a given device or software. This eliminates any speculative arguments as well as unforeseen risks.

“The main idea behind threat modeling and good cybersecurity science is to get away from judgment assessments, or just statements of belief, and move much more toward a verifiable security design control,” Fu added. “In my opinion, it’s impossible to make scientific claims of computer security without a reputable threat model.”

To further emphasize the importance of threat modeling, the FDA arranged boot camps, where those who perform threat modeling could educate others within the industry on how to do the same.

Amongst other forms of safeguards against cybersecurity threats, there is the International Medical Device Regulators Forum (IMDRF), which works to “harmonize different standards” between countries, as well as the Software Bill of Materials (SBOM), which “is effectively an ingredient list of what third party software is inside” a given device.

The SBOM allows manufacturers to pinpoint which devices are at risk if a third-party software is compromised.

Although there are plenty of guidance documents for assessing cybersecurity threats amongst the various markets developing devices, the Joint Security Plan (JSP) serves to provide guidance on cybersecurity threats specific to medical devices.

However, Fu urged manufacturers to pay particular attention to the Cybersecurity Engineering Principles published by IEEE in 1975. The principles provide a framework for making devices secure and safe from cybersecurity attacks.

Amongst the eight key principles, two stood out to Fu as the most important: the open design principle and the principle of least privilege.

“The open design principle, it’s extremely important to not depend on the ignorance of an attacker or what we call ‘security by obscurity’ where you just hope for the best.”

Because attackers have become clever, creative, and financially motivated, one should “assume the adversary knows everything about your system except, for instance, a small manageable cryptographic key that could be kept physically secure.”

For the second one, the Principle of Least Privilege (PQLP), is “the idea is that when you are creating a computer program, use the least number of privileges necessary to complete that function.”

This is based on the idea that attackers will inherit whatever privileges were encoded in the software. This will minimize the liberties they will have upon infiltrating the device.

Though much work has been done within the cybersecurity landscape, in the coming year Fu hopes to further integrate security principles via the CDRH Total Product Life Cycle, continue to educate stakeholders and industry members, and foster further collaborations across the federal government.
Device to Improve Post-Stroke Hand Grasping Gets De Novo Authorization

Fran Kritz

The Food and Drug Administration (FDA) has granted De Novo authorization for a new device that combines a brain-computer-interface and exoskeleton to help stroke patients regain the use of their hand, arm, or wrist.

Developed by Neurolutions, the IpsiHand Upper Extremity Rehabilitation System (IpsiHand System), also received a breakthrough device designation, which helps expedite the development and review of devices that address critical needs. The specific goal of the device is to help stroke patients improve grasping.

According to the company, the system translates brain signals from the uninjured (i.e., ipsilateral) hemisphere of the brain, into movement of the exoskeleton. As a result, when the patient thinks about opening their hand, the device physically opens the patient's impaired hand, which provides muscle reeducation and can improve upper extremity rehabilitation.

The authorization “offers certain chronic stroke patients undergoing stroke rehabilitation an additional treatment option to help them move their hands and arms again and fills an unmet need for patients who may not have access to home-based stroke rehabilitation technologies,” said Christopher M. Loftus, M.D., acting director of the Office of Neurological and Physical Medicine Devices in the FDA’s Center for Devices and Radiological Health, in an FDA press release.

The FDA assessed the safety and effectiveness of the IpsiHand System device through clinical data submitted by the company, including an unblinded study of 40 patients over a 12-week trial. All participants demonstrated motor function improvement with the device over the trial.

“Progress in improving rehabilitation outcomes for stroke patients has historically been challenging, but the market authorization of the IpsiHand System promises to usher in a bright future for our stroke patients and allows us to support their recovery throughout the rehabilitation process,” said Eric Leuthardt, MD, Chief Scientific Officer of Neurolutions and Chief of Division of Neurotechnology and Professor of Neurosurgery and Neuroscience at Washington University, in a company press release.

According to the company, approximately 800,000 American adults experience a stroke each year, of which approximately 300,000 are left with upper extremity movement dysfunction. The device is expected to become available later in 2021.

FDA Warns that Strong Magnets May Affect Pacemakers and Other Implied Medical Devices

Randolph Fillmore

The FDA’s Center for Devices and Radiological Health (CDRH) issued a May 13 statement warning consumers that high field strength magnets used in cell phones and smart watches may affect pacemakers and other implanted medical devices, such as cardiac defibrillators, causing them to suspend normal operations until the magnet is moved away from the medical device.

Some implanted devices have a built-in “magnetic safe mode” which allows for safe operations during certain medical procedures, such as an MRI. However, some devices with a magnetic safe mode could stop working or have their normal functions altered when a strong magnet is placed nearby.

Accordingly, FDA recommended keeping cell phones and smart watches at least six inches away from a medical device and not carrying consumer electronics in a pocket over a medical device as the magnets may cause a cardiac defibrillator to be unable to detect tachycardia events.

Although FDA said the risk is low and that the agency is not aware of any associated adverse events, they are “monitoring all relevant scientific information.”

The FDA said it has conducted testing on some products using high strength magnets and confirmed that the magnetic field is strong enough to turn on the magnetic safety mode of some medical devices. Their findings, said the agency, are also “consistent” with some publications identifying this potential problem.

On May 20, the agency issued final guidance that makes recommendations on testing the safety and compatibility of medical devices in the magnetic resonance (MR) environment and provides a format for MRI safety information in medical device labeling.
FDA Issues Updated Facility Inspection Report
Fran Kritz

The Food and Drug Administration (FDA) recently issued a new report, **Resiliency Roadmap for FDA Inspectional Oversight**, to outline its plans for inspecting facilities it oversees in the months ahead.

In March 2020, as cases of COVID-19 increased in the U.S., the FDA announced that it was temporarily postponing all domestic and foreign routine surveillance facility inspections, though the agency continued “mission critical” inspections when possible. Such inspections were done when possible, for example, in cases of drug shortages, for approval of novel drugs or drugs related to COVID-19 and to support of premarket and prelicense applications.

“Like most organizations around the world, the FDA experienced unprecedented and unique challenges during the SARS-CoV-2 pandemic, said Acting FDA Commissioner Janet Woodcock, M.D. “In particular,” said Woodcock, “our inspection, surveillance and compliance activities were significantly impacted. The FDA fully understands the importance of getting back to a more consistent state of inspectional capacity. This plan provides…a transparent picture of both the successes and challenges we’ve faced in these areas over the past year, as well as our plan moving forward.”

The FDA began resuming prioritized domestic inspections in July 2020 using the agency’s **COVID-19 Advisory Rating system**. The new report includes information on inspections the agency was unable to complete during the past year due to travel restrictions or inability to ensure the safety of workers.

**Key facts from the report:**

- From March 2020 through March 2021, the FDA conducted a total of 821 mission-critical inspections, including 29 in foreign countries.
- The FDA conducted a total of 777 prioritized domestic inspections since resumption of that work in July 2020.
- The FDA used alternative tools and approaches where inspections weren’t possible including remote interactive evaluations (remote livestreaming video of operations, teleconferences or screen sharing) and records requests.

Looking ahead, the agency says that in the short term “inspections considered critical to the FDA’s mission will remain the primary focus and that when planning routine surveillance inspections, the FDA will be prioritizing higher-risk facilities which means there may be a longer time between inspections for lower risk facilities “as the FDA adjusts to the impact of the COVID-19 pandemic.”

The agency will also soon begin a review of inspection approaches using next-generation assessment technologies and improvements. The FDA is also establishing an agency-wide FDA Inspectional Affairs Council that will plan and coordinate inspection activities.

FDA Updates Premarket Notification Submissions Guidance for Peripheral Atherectomy Devices
Randolph Fillmore

The Food and Drug Administration (FDA) updated its **Premarket Notification Guidance** for peripheral vascular atherectomy devices aimed at removing atherosclerotic plaque from diseased arteries by cutting, shaving, sanding, or vaporizing.

The final guidance, **Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions**, reviews four design categories for atherectomy devices—directional, rotational, orbital and laser—and makes premarket submission recommendations.

The scope of the updated guidance is limited to atherectomy devices used in the peripheral vasculature regulated under 21 CFR 870.4875 with the product code and regulation number MCW 870.4875 Intraluminal Artery Stripper.

Premarket submission recommendations include device description details and predicate device description if needed. Device description should include identifying the device by regulation and product code as described in section III of the revised guidance as well as identifying all accessories and describing their function(s). Submissions should also include:

- Description of device operation mechanism
- Description of technological characteristics
- Listing of materials
- Identification of coating and images or engineering drawings
- Description of device operation mechanism
- Description of technological characteristics
- Listing of materials
- Identification of coating and images or engineering drawings

The FDA recommends describing the technical and performance data for the device and providing a brief device design description. According to the guidance document, the submission should describe all device models and configurations if the submission is for multiple device models. In addition, include information on how the device reaches its desired rotational speed and relevant information on device functional physical and environmental considerations.

Predicate device comparisons should also be included for devices reviewed in 510(k) processes to compare new devices to those already marketed and demonstrate substantial equivalence and how the new device is similar to, or different from, the predicate device. The FDA noted that “side-by-side” comparisons are desirable where possible.

The agency is accepting comments at [www.regulations.gov](http://www.regulations.gov), docket FDA-2018-D-2494.
What HTM Professionals Need to Know about Wireless Technology

Chris Hayhurst

Looking for an easy way to get three CEU (continuing education unit) credits? Or how about answers to some really tough questions involving wireless management, maintenance, and security?

Healthcare technology management (HTM) professionals in need of either have a new resource, a just-released webinar (free to AAMI members) on medical device connectivity featuring insight from four wireless technology experts.

Hosted by AAMI Vice President of HTM Danielle McGeary and led by Steve Baker of AlphaBravo Connectivity, the free presentation covers everything from the latest industry trends to wireless device procurement in healthcare settings.

Noting that the number of Bluetooth devices in existence can (almost) be compared to the number of stars in the galaxy, Baker points out in his introduction that “wireless is everywhere,” especially in healthcare. “Our architectures and our planning need to take this into consideration,” he said.

Joining Baker for the one-hour discussion were Bill Salzstein, principal at Code Blue Consulting; Ali Youssef, principal mobility architect at Henry Ford Health System; and Travis Ruthig, a medical device security analyst with Clinical Engineering Services at Allina Health. The four worked together earlier this year to update the AAMI Medical Connectivity FAQs, a document first published in 2014 to answer frequently asked questions about wireless issues commonly seen in the healthcare environment.

Wireless, Baker explained, is “undeniably, unambiguously, uncontestably unreliable in its base form. That's why we have the FAQs.”

After explaining the differences among various wireless technologies, Baker, Salzstein, Youssef, and Ruthig used the information contained in the FAQs to highlight best practices for wireless device management. Their key points and advice included the following:

• How the medical device supports your organization's specific HIPAA (Health Insurance Portability and Accountability Act) policy.
• Whether the device includes an enterprise-class radio.
• How they will ensure that any security issues are addressed in a timely manner.
• About the risks that patients will face in the event of a connection failure while they're relying on the device.
• Whether the device supports the latest versions of, for example, Bluetooth, Wi-Fi, and WPA3.
• About the processes they have in place for detecting and assessing new vulnerabilities.

“It's extremely important to have a formal procurement and onboarding process for these types of devices when they come into your health system,” explained Youssef.

One common and highly effective approach, he said, is to organize a “cross-functional group” of HTM, clinical, and other stakeholders who can “scrutinize the purchase and make sure you're asking the vendor the appropriate questions.” Many organizations develop a standard questionnaire to use for this purpose, said Youssef. They then take the answers they get from prospective vendors to ensure their devices conform to established best practices.

Youssef and his colleagues pointed out that medical connectivity is a complicated subject and that it's likely to become even more complicated in the future. On the other hand, they noted, the modern HTM professional is perfectly positioned to understand this wireless world. Success just depends on knowing where to start—and for that, this discussion could be tough to top.

Brad Montgomery is not afraid to address the emotional toll of the pandemic on our community. Of course, work in the healthcare industry was already high-stress, and the pandemic compounded that condition.

In the first keynote speech to the 2021 AAMI Exchange REWIRED, Montgomery explored themes of resilience and explained how social and emotional support in the workplace leads directly to positive performance results both for the individual and the company/organization.

“You have a greater ability to create positive change in others than you sometimes remember,” Montgomery said. “I’m here to remind me that you have even more bandwidth to create even more positive change in others.”

In a nod to the trend of increased working from home during the pandemic, Montgomery walked attendees through his home as he related stories of how positive reinforcement, acknowledgement, and recognition can dramatically change performance.

Many of the stories began with an anecdote of how negative reinforcement depresses performance and how authority figures can greatly influence behavior including the on-the-job behavior of employees and colleagues. Brad used relatable stories about sports, first jobs, and parenting to illustrate how these behaviors are not out of the ordinary and can easily be brought into the workplace.

Social and emotional needs are the “soft chewy center” in each of us, Montgomery explained, that responds to positive reinforcement. This can be conveyed easily through simple communications and small moments both from peers and supervisors. He provided the audience with a reminder to extend that culture of caring and concern as much to each other as to the patients and services that we provide.

In short: “Everybody needs to be told that they are awesome.”
On the first day of AAMI eXchange REWIRED, Dr. Christoph Lehmann, Director of Clinical Informatics at UT Southwestern Medical Center, joined the hosts of “Good Morning HTM” as a special guest to talk about combining clinical informatics and medical devices for better patient care.

Lehmann, who is also a pediatrician and professor in clinical science at UT Southwestern, said he started his foray into clinical informatics in a way that’s hard to talk about.

“It’s a difficult story for me to tell because it starts with the death of a patient,” he explained.

At just 18 months old, Josie King died at Johns Hopkins Hospital due to a number of medical errors made during her care. This terrible moment triggered several events—most notably, the founding of the Josie King Foundation for patient safety and a rapid transition among hospital systems in how they account for and prevent medical errors.

These events also ultimately created a patient safety center that Lehmann found himself a part of.

“That was my first opportunity to spend time on developing informatics solutions that could improve the quality and safety of patient care,” he said. Since then, Lehmann has been working to improve patient safety and reduce costs of care using the immense amounts of data that are part and parcel to the modern healthcare system.

Turning Data into Knowledge

“It has been more fun than work. With informatics, we can turn this data into knowledge that helps us understand what works and functions better for patients and then turn those lessons into powerful applications,” Lehmann said.

An example of this powerful field applying to medical devices, Lehmann offered, is an automated calculator for infusion pumps. First, a physician will use the calculator to order the appropriate infusion speed and concentration. This also informs the printing of the correct label. Finally, a pump is used that similarly calculates the rate given the correct data. Nurses are trained to start an infusion only if the rate on the pump is identical to the rate on the order and also identical to the rate on the label.

“This drastically reduced the number of infusion errors we had been seeing,” said Lehmann.

However, overall, he wants to see much for of this kind of “cross-fertilization” between medical device design, informatics, and device end-users.

“I see devices coming up with solutions to problems that really don’t exist,” he said, “but the fact that I’m here talking today with you and the AAMI community is a really good first step!” He added that he’d love to see a future where there is a seamless integration between medical health records and medical devices.

“And the communication has to be bi-directional,” he added, envisioning a device which can update records in real-time.

AAMI eXchange co-host Danielle McGeary, whose career started on the front lines as a biomedical equipment technician (BMET), was thrilled by the possibilities.

“It’s all about safety,” said McGeary, VP of HTM at AAMI. “In an emergency where there’s very little time to set up a device… if there’s decision support available, you want it right there at the point of care!”
What to Expect in Today’s HTM Hiring Landscape

Martha Vockley

While COVID-19 upended daily work, one aspect of the healthcare technology management (HTM) career has remained constant: Jobs are plentiful, and recruiters are hiring.

“It’s still a very strong HTM market, with lots of positions opening,” said Ashley O’Mara, VISN1 chief clinical engineer at the Veterans Administration, in an education session on the first day of AAMI eXchange REWIRED.

“We know that those in the healthcare technology field were incredibly important to the successful outcome of COVID and getting us all through that,” said Leah Salamon Curry, recruitment manager at Sodexo. “We didn’t see fewer positions available. In fact, we saw our business growing and our clients needing us more than ever. There are many, many opportunities and lots of candidates still in the job market for us to engage with and hire."

“The pandemic really showcased for me the healthcare technology management industry,” said Erica Cuthbertson, corporate recruiter at Agiliti, who expects increased hiring to continue this year. “We saw an expansion in the need that our customers had for our services. We are really seeking candidates, searching them out, and trying to find new ways to introduce individuals to the biomedical technology career path. We hope that our continued recruiting efforts and advocating for this great career path drives more people into our field.”

The pandemic did spur people to reflect on what they want in their lives and careers—and that can impact their career choices.

“As we make our way out of the pandemic, it’s been a time of reflection for a lot of candidates,” Salamon Curry said. “Everyone’s taken time to self-reflect and say, ‘Does this company really match my core values? Is it the company culture that I like and that aligns with my quality of life, personal values, desires, and goals?’

Work life is expected to continue to be more flexible as well, with technology providing opportunities for teleworking and better work–life balance, O’Mara said.

Tips for Job Candidates

The three panelists offered this advice for standing out in as a job candidate:

• Put your best foot forward in your résumé—and put the most relevant information on the top half of the page.

• Create or update your LinkedIn profile. “If you don’t have a LinkedIn profile and if you’re not connecting on social media, you’re really missing a big, big opportunity to connect with people outside of your résumé,” Salamon Curry said.

• Research the company and position and apply directly through the company website.

• Come to the interview prepared to ask questions to find out if you’re a good match for the company and position.

• Skill up by becoming certified as a biomedical equipment technician, healthcare technology manager, or clinical engineer.

• Join local biomed associations for networking and learning opportunities.

Visit jobs.aami.org to find job postings and the AAMI Career Center for career planning resources.
‘We Know What We’re Doing!’
an International Comparison of Device Maintenance Incidents

Brian Stallard

Preliminary results from a study conducted by health technology professionals across the globe show that less than 1.5% of all medical device related issues reported each year can be attributed to medical device maintenance or service.

“My assumption is that this is because we [the HTM community] know what we’re doing, and we’re doing it in a consistent, systematic way!” said Jean Ngoie, Head of Instrumentation and Clinical Engineering at NHS Tayside, Scotland, in an education session during AAMI eXchange REWIRED.

For the session, “International Comparison of Maintenance-Related Medical Equipment Incidents,” Ngoie was joined by fellow presenters Binseng Wang (VP, Program, Management at Sodexo CTM) and Frank Rothe (Head of Service Management Europe, Vamed Management und Service GmbH in Germany).

The researchers specifically looked at records of medical equipment related incidents in Germany, Canada, Scotland, and the United States. Those countries keep relatively thorough data on these events which are accessible via public record or a Freedom of Information Act request. Records ranged between the early 2000s to 2020, with the United States having assorted records (including those from the FDA) starting as early as 1977.

Of the four countries, Canada and Scotland appear to have particularly effective maintenance programs, according to the researchers. With a grand total of 355,972 health incidents reported to Health Canada within the last decade, the analysis results showed that a mere 0.004% were attributed to poor device maintenance or servicing.

Ultimately, the researchers determined that of all device-related incidents resulting in death, injury, potential for injury, or even incidents without any adverse consequences for the patient’s health, only 1.6% were related to maintenance or servicing in Canada. Similarly, only 2% of the medical device related incidents reported in Scotland over the last five years can be attributed to poor maintenance or servicing.

However, it’s worth noting that Scotland’s data has to be obtained through a request with the Scottish government and did not show how these incident numbers compared to all reported health incidents over those same five years.

Germany showed a maintenance-related incident rate of only 1% among all reported incidents, according to data from the German Federal Institute for Drugs and Medical Devices (BfArM).

Perhaps most interesting of all is that the number of incidents reportedly related to device maintenance in the United States may range between around 18 and 172 incidents each year, added Wang, who attributed the result to a discrepancy between FDA data and those reported by The Joint Commission. This placed the U.S. in a gray area, either at the same impressive 0.004% rate as Canada boasts or a more humbling 3% rate.

“The differences in how countries and organizations report incidents, collect data, etcetera, all can influence these results,” Wang added, “but the important take away from these results is that the number of incidents per year in these countries is very, very small.”

Wang compared the healthcare device maintenance numbers to those touted by airlines, with their comprehensive alternative maintenance programs to limit incidents.

“At this time, we don’t see a need for additional regulations for device services,” he concluded. “We are really doing a very good job!”
Training for the Future with VR

Martha Vockley

Hands-on learning is a hallmark of training for a career in biomedical equipment technology. But hands-on learning has its limits. Now, virtual reality (VR) can deliver hands-on—and minds-on—learning experiences in engaging, cost-effective ways. Moreover, virtual reality can help students, particularly those who struggle with tough concepts, learn more.

“VR is the future of biomedical training,” said James Linton, program coordinator and professor of biomedical engineering at St. Clair College, in an education session at AAMI eXchange REWIRED. “The minute you gamify something, everyone’s fighting to get the top score.”

Linton, who’s also pitching a VR education idea at Tuesday’s AAMI Alligator Tank, explained the spectrum of extended or augmented reality (AR) capabilities:

- **AR Absorb** is the equivalent of consuming content in new ways, but not changing it. The Google Translate app, for example, allows you to use your phone camera to translate text instantly, and Google Street View uses photographs to show virtual, 360-degree representations of your surroundings.

- **AR Blend** is the combination of actual reality and augmented reality. For example, uploading a picture into an app that turns it into a video or places it in a moving scene creates a new experience from existing content.

- **AR Create** is based on entirely virtual content, such as the Pokémon Go app.

AR Absorb is the simplest entry into this world. Linton has created a 360-degree video of a new facility that allowed people to walk around the building and get their bearings virtually. In his classrooms, he has created videos of a hospital morgue and a live surgery, to prepare biomedical students before they are called into such situations. “It lowers their anxiety,” he said.

AR Blend gives students the “amazing experience” of being able to look at, walk around, and manipulate medical devices that would otherwise be off-limits.

Jim Durocher, professor of biomedical engineering technology at St. Clair College, has used the Rumii app to help students understand how magnetic fields and flux work in MRI machines. Students can’t take MRI equipment apart, but in a virtual world, “they have the freedom to move and look into the magnetic coil and see the gradient coils and how they affect other objects,” Durocher said.

VR training also is a safer learning environment. Students can make mistakes without risk of hurting themselves or damaging equipment, Durocher said. And if they do make a mistake, they get as many do-overs as they need.

“Being physically engaged engages other parts of the brain and helps them remember,” Linton said. Student performance increased by more than 10% in the second half of a course with VR content, compared to the first half with no VR content. Notably, the gap between the highest- and lowest-performing students narrowed considerably, thus leveling the playing field.

“We’re seeing virtual reality and extended in schools and universities worldwide,” said Corinne Hoisington, professor of information systems technology at Central Virginia Community College and VR-certified trainer for ByteSpeed. “Now students can try so many different experiences have so many different experiences than you can possibly purchase or house within your schools.”

**Benefits of VR training include:**

- Excitement to learn (without having to travel)
- Engagement in learning
- Increased retention of knowledge
- Improved performance
- Ability to refresh or retest anytime
- Teacher engagement
- Cost savings
- Ability to “do anything”
How The Mayo Clinic Leads in Medical Device Cybersecurity

Gabrielle Hirneise

Cybersecurity issues took center stage during AAMI eXchange Rewired. In their education session, Kurt Griggs, information security manager at the Mayo Clinic’s Healthcare Technology Management (HTM) division and Cyber Tygr CEO Ty Greenhalgh detailed a framework and tools developed by The Mayo Clinic to evaluate and implement safeguards against common and even unforeseen cyberthreats.

This wasn’t always a focus, however. The American Reinvestment and Recovery Act of 2009 proved useful for advancing health IT, but it didn’t fully account for security. And with data breaches and the number of records breached on the rise, it is paramount that large healthcare organizations take action, especially considering the human lives that are at play.

“Medical device security is a patient safety issue,” Greenhalgh said. “People are hooked up to these devices, so if there is a problem with the device, it could have adverse outcomes.”

Fortunately, the Mayo Clinic’s HTM division, which was founded in 2019, has since taken a holistic approach to overcoming this challenge. With four different medical institutes and more than 50,000 network-connected devices, it was a challenge for The Mayo Clinic to maintain adequate regulation, specifically in the verification, maintenance, tracking, and documentation of devices and their associated components.

At its inception, Griggs said the HTM division’s goals included:

• Bringing diverse skills together and converging specialties
• Developing a program to align with industry standards
• Building out a mission statement and establishing some goals and objectives
• Leveraging next-gen tools

Griggs reinforced that these goals still hold true, and since the division’s start, headway has been made, particularly with the use of two tools: Ordr and Nuvolo.

“Ordr is a passive network monitoring tool that’s used to discover and support our process. It provides us with additional detail, especially from an inventory aspect, but it also provides some phenomenal abilities with advanced flow analytics, giving us daily tells into how we can actually segment the network,” Griggs said.

Nuvolo, on the other hand, is a computerized maintenance management system (CMMS) serving as a “day-to-day tool used by HTM for standard preventive maintenance features.” The plan, Griggs said, is to develop Nuvolo further to integrate a cybersecurity module, one that could identify emerging threats.

Although there are various other supplementary tools within the framework, at the core of its preventive workflow is the Proactive Security Model. This model dictates that for every device added there be a risk assessment request prior to purchase, then information regarding the vendor be compiled. Following this, a risk assessment would be performed, and if passed, a security profile would be built, and the device would be installed.

To better illustrate the current state of the industry that this framework addresses, Greenhalgh and Griggs used a sinking boat as a metaphor. Many of the approaches seen today involve throwing buckets of water out of the boat, or handling each preexisting threat on a case-by-case basis. However, the proposed solution is to “plug” the hole in the boat. That is, to stop devices from coming into an institution without proper vetting.

Outside of the Mayo Clinic’s efforts, the U.S. government is working towards the Software Bill of Materials (SBOM), which is “trying to identify the components and drivers and operating systems inside the devices” and providing guidance on how to navigate threats and their corresponding mitigation strategies.

Even with these efforts in place, there is still much work to be done to protect against cybersecurity threats.

“It’s a journey not a destination—it will take time,” Griggs said.

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HTM Professionals a ‘Key Piece of the Puzzle’ to Improving Medical Devices

Stephanie Rizk

The Medical Product Safety Network, called MedSun, is a way for those working at clinical sites to report medical device issues to the FDA’s Center for Devices and Radiological Health. But as the FDA’s Julie Morabito explained during a “Good Morning HTM” session at AAMI eXchange REWIRED, MedSun is much more than that.

Besides reporting adverse events, MedSun is also interested in information directly from the medical device users including usability, labeling, defects, and reliability concerns. The FDA relies on end users like HTM professionals to help them understand what’s going on in the field and how the medical devices are performing.

“We want to hear from HTM professionals, and we need to hear from HTM professionals! We need them to understand how important their perspective is,” said Morabito, supervisory biomedical engineer and assistant director of outreach and partnerships at FDA MedSun. “We don’t know until they tell us about an issue. We can take real steps to make the device better by working directly with the medical device manufacturer.”

HTM professionals can also help us understand the impact of regulatory changes we are considering so that we can make fully informed holistic decisions about changes to a medical device.

“HTM professionals are a key piece of the larger puzzle to help the FDA make holistic decisions that consider the input of all stakeholders,” she said.

AAMI will post data calls from MedSun on our website on the HTM resources page. Some examples of how input from HTM professionals have made a difference:

- Informing MedSun that a life supporting device wasn’t alarming when it was supposed to when it was not plugged into AC power. MedSun worked with the medical device manufacturer and initiated a recall and a software update for the device.
- Relating that a subcomponent on an infusion pump was failing prematurely and required constant replacement. MedSun discovered that there was actually a global supply chain concern with that component which MedSun would have never known about without the input of several HTM professionals.

It’s not just device concerns, MedSun also works with device manufacturers about the process and workflow for correcting device issues to ensure that the solution to the issue is feasible and reasonable for the HTM professional in the field to implement.

With New Wi-Fi on the Horizon, Is It Time for New Devices?

Brian Stallard

Wi-Fi has changed so much over the years. And a lot is about to change again!

“So, we thought it would be wonderful to do some forecasting for what is about to come,” said wireless technology expert Shawn Jackman, founder and CEO of Clinical Mobility. He joined “Good Morning HTM” as a special guest during AAMI eXchange REWIRED.

Wi-Fi as we know it previously made a transition from 2.4 GHz bandwidths to 5th generation (5G) capabilities. Now, just on the horizon, is WiFi-6E. Why’s that important?

Most of the time, when someone experiencing trouble connecting to a Wi-Fi network, spectrum congestion is the problem, Jackman explained. That is, too many devices are trying to connect over the same band of frequencies and compete for space to send data. With WiFi-6E, a new 6 GHz spectrum will introduce lots of new real estate for devices.

Confusingly, the “6” refers not to the frequency but to the name of the most advanced wireless standard, called “WiFi-6.” The “E” in Wifi-6E stands for “extended,” as in, an extended number of available bands.

“Marketing teams—I don’t envy them!” Jackman laughed.

Jackman also mentioned how the 802.11Ax-2021 standard, which encompasses WiFi-6 for 2.4 GHz and 5 GHz, and WiFi-6E for 6 GHz, is already a massive advancement unto itself.

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“The problem they tried to solve with 802.11Ax is the density issue,” he said.

With the 2021 Wi-Fi standard, devices can have “orthogonal frequency division multiple access” (OFDMA) capabilities. This mouthful of syllables means that when a device attempts to send a package of data, it can share that package with other devices that are simultaneously communicating on the network. Instead of networked devices competing for bandwidth, they are efficiently organized, much like a food delivery service picking up orders from multiple restaurants to then make deliveries in the same area.

It sounds like a dream come true for networked hospitals worried about any one device hogging bandwidth and slowing down other devices. However, there’s a catch!

“Your legacy devices don’t support it. It’s not a forward compatible technology. So, we’re going to need to buy new devices,” said Jackman.

“Is this something that HTM departments should be preparing for?” asked host Danielle McGearry, vice president of HTM at AAMI.

“Every time there’s a new infrastructure advancement like WiFi, it’s always better to buy new, compatible devices before you buy into the infrastructure itself,” Jackman replied.

This way, he explained, manufacturers will become aware of a demand for the technology and establish support systems for forward-thinking departments as soon as feasibly possible.

Making the Best BMET Internship for Students and Supervisors Alike

Brian Stallard

AAMI eXchange REWIRED attendees engaged in a discussion about making the best of biomedical engineering technician (BMET) internships. A survey recently conducted through Penn State New Kensington (PSNK) shaped the discussion, with a focus not only on student experience, but the value of an internship for employers as well.

“We really wanted to identify challenges for internships and discuss ways to address those challenges, but we also want to consider ways to ensure internships are a worthwhile experience for everyone involved,” said Joie Marhefka, the assistant teaching professor at PSNK, who led the research.

Marhefka and CTL Scholar Assistant Researcher Dalynn Park surveyed students who graduated from PSNK’s 400-hour internship program during the summer or fall of 2020 and professionals who have supervised students from that same program at any time between 2016 and 2020.

In some ways, Marhefka explained, the results were predictable. Students felt the most valuable parts of their internship program were the hands-on learning and experience troubleshooting new medical devices. Supervisors, on the other hand, felt it was most important for students to understand how health technology management (HTM) departments work, gain confidence, and learn how to work with others within a department.

“Making professional contacts, interestingly, was seen as least important overall for these in-person internships,” said Park. One explanation for this may be that both the students and supervisors are naturally forming connections by working together—it is a benefit that inherently comes with the experience.

These results also point to the number-one perceived value of BMET internships for employers: They see it as an opportunity to essentially “trial run” fresh talent to fill open HTM positions.

However, the duo also discovered that not every internship goes smoothly, especially with this misalignment in terms of what is valued most between students and supervisors.

“We don’t think of these supervisors as ‘teachers,’ but they truly have to be,” said Marhefka.

That can be a rude awakening for busy departments with very little time for explaining and hand-holding. Many students reported that when things got too busy, they found themselves sitting idle. Likewise, overwhelmed students may not have the communication skills required to seamlessly work themselves into a department’s processes, even if their technical know-how is up to par.

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Making the Best BMET Internship for Students and Supervisors Alike

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“The study has made me think there are two places where I, as an educator, can really influence how an internship goes,” Marhefka said. “By creating a clear checklist of requirements for students and their supervisors to meet, you’re ensuring they’re not just doing pump PMs every day. But likewise, you have to understand how busy things can get. Educators should be as flexible as possible with requirements without sacrificing the student experience.”

She also added that preparing student communication skills prior to the internship program can go a long way. Classes such as curriculum in professional email writing are easy prerequisites to set.

One surveyed student said the number-one value of an internship is to “bridge the gap between classroom and life.” It’s an incredibly apt description, Marhefka and Park said, for what all internships should aspire to be.

Secure Your Legacy Devices—Or Else!

Martha Vockley

If you’re not working proactively to protect legacy devices, you’re leaving your healthcare system vulnerable to cyberattacks.

“No one is immune,” said Samantha Jacques, vice president of engineering at McLaren Health, in a session at AAMI eXchange REWIRED. “If you haven’t heard of or been affected by an attack, just wait—your time is coming.”

Most healthcare technology management (HTM) professionals consider legacy devices to be those that manufacturers no longer support with upgrades or software patches, or those for which parts are no longer available. But the International Medical Device Regulators Forum has a narrower definition: A legacy medical device is one that cannot be reasonably protected against current cybersecurity threats.

There are two options for dealing with legacy devices, Jacques said:

1. **Keep them running, unsupported.** This can be a benefit if the devices still perform and function as designed. But it can be problematic because of cybersecurity risks, difficulty obtaining parts, and, for older devices, finding someone who is trained to repair them.

2. **Replace them with new technology.** The upside of new technology is that it typically comes with a newer operating system and support from the original equipment manufacturer (OEM). But most hospital systems don’t have unlimited capital to replace all legacy devices.

This is where HTM departments must play a proactive role. Clinical users and owners, such as cardiology or radiology departments, and even IT teams do not know as much about devices and risks as HTM professionals do. “They don’t know the cycle for OEMs to patch their devices, or whether a new software version has been approved by the FDA,” Jacques said. “We take responsibility for that.”

Because healthcare systems cannot replace all legacy devices, HTM professionals should collaborate with cybersecurity, IT, and finance teams, as well as organizational leaders, on replacement decisions, Jacques said. For legacy systems that are not replaced, HTM professionals should support solutions to mitigate or remediate cybersecurity threats and vulnerabilities, such as network configurations that provide more protection.

Cybersecurity attacks have caused real harm—a patient death in Germany last year, a clinic closure in Michigan after it chose not to pay ransomware in 2019, and lost revenue due to forced shutdowns of entire hospital systems. Mike Powers, clinical engineering director at Intermountain Healthcare, shared these statistics about cybersecurity in healthcare in 2020:

- 239.4 million cyberattack attempts
- An average of 816 attempted cyberattacks per healthcare endpoint
- A 9,851% increase from 2019
- 560 healthcare organizations impacted
- ~1 million healthcare records breached every month
- One breached service provider is estimated to be responsible for ~10 million breached records

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Creating a ‘Culture that Rocks’
to Earn Loyalty

Jennifer Peters

To create a successful company, a good product helps, but to earn the loyalty of your customers (and employees!) what you need is a culture that rocks. How does a company create that culture? Jim Knight, a former Hard Rock International executive, broke it down into eight easy elements in a keynote at AAMI eXchange REWIRED.

The ultimate outcome has to rock—that starts on the inside.

A few years ago, Knight was getting lunch at a chain restaurant in Florida. As he waited for his food, a little girl dressed as a princess approached the counter. The salesman took immediate notice and loudly announced, “All hail the princess.” At that moment, everyone working in the restaurant stopped what they were doing, bowed at the princess, and then went back to work.

“How much money did that take? Nothing. How much time did that take? A couple seconds,” Knight said of the employees’ actions. But that little girl will never forget that moment for the rest of her life. “You can’t teach that,” he said.

Celebrate heritage but focus on today (human behaviors).

According to Knight, “everything is culture.” What isn’t culture? The past. That little girl in the princess dress? She doesn’t know the company’s history. Her mom doesn’t know why that restaurant was great 20 years ago. What they both care about is that, on that day they visited, someone working for that company made them feel good.

Be like U2—everyone singing off the same sheet of music.

Think about U2, one of the biggest bands in the world. There are four members. Everyone knows Bono and The Edge, but who are those other guys? You may not know their names (Adam and Larry, for the record), but you’d certainly notice their absence. Without them, U2 doesn’t exist. Sure, they’re not the stars, but not everyone needs to be center stage. “Everybody has a part to play in the band,” Knight said. “We need Adams and Larrys.”

Learned behavior around “service” produces awesome results.

“I don’t want you to think of yourself as just an HTM—you’re a brand ambassador,” Knight said. When members of a company think of themselves as part of a unit instead of individuals, they begin to take ownership. They want to provide the best experience for the end consumer, whether that’s a screaming audience at a rock concert or a patient in a hospital.

Service trumps product, price, convenience, theme, tech, etc.—always has, always will.

“People need us first and foremost for some thing, so we start with the product,” Knight said, but almost every product can be offered by someone else.

Secure Your Legacy Devices—Or Else!

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COVID-19-themed cyberattacks began with the pandemic, which resulted in new ways of delivering care, and attempted cyberattacks increased throughout the year.

“The opportunities for healthcare organizations to be an attack vector for a bad actor have increased tremendously,” Powers said. “These attacks took the form of brute force efforts, and social engineering attacks.”

Jacques and Powers serve on the Healthcare and Public Health Sector Coordinating Council (HSCC), a critical industry advisory council led by private-sector large, medium, and small health industry stakeholders working with government partners to identify and mitigate threats and vulnerabilities affecting the ability of the sector to deliver healthcare services. A major component of HSCC is a Cybersecurity Working Group, which represents 300 healthcare organizations in the subsectors of direct patient care, medical materials, health IT, health plans and payers, laboratories, biologics and pharmaceuticals, and public health.

An HSCC Med-Tech Legacy Devices Task Group is developing business solutions, best practices, incentives, and policies for end-of-life product life management and replacement of legacy devices, as well as working through how to prevent future technology from becoming legacy.

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Creating a ‘Culture that Rocks’ to Earn Loyalty

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The thing that makes a company stand out to consumers is how you make them feel. “Nobody can copy the service mentality because you’d have to copy me, you’d have to copy my behaviors,” he explained.

Value matters—stellar interactions/experiences help justify cost. Make people feel seen as much as you possibly can. “It can’t be fake and prepackaged and programmed,” Knight noted. It needs to be authentic. And it can come from anywhere. He encouraged HTMs to think, “I might be working on a machine, but I’m going to rock someone’s world and they don’t even realize it yet.”

Stay grounded within (and crush) your circle of influence. It’s impossible to control everything, even if you work your tail off, so Knight advised that you focus on your circle of influence (all those things you can control) rather than your circle of concern (all those things you simply can’t control).

Bring the flamethrower every day... and light it up! You can celebrate your company’s past while still moving forward. “When the rock ballad comes on, it’s okay to hang out there, it’s okay to revel in it, but there is no concert that ends on the rock ballad,” Knight explained. “You’ve gotta absolutely bring the thunder... so you can leave the show on the mic-drop moment.”

Is Your CMMS Ready to Be Your ‘Source of Truth’?

Jennifer Peters

The computerized maintenance management system (CMMS) needs to be your source of truth.

With more devices and departments being connected by a shared CMMS, you get more good data, allowing you to gain “accurate insights into the assets you manage and how that translates into efficiency, value, and cost savings,” explained Carter Groome, CEO of First Health Advisory, in a session at AAMI eXchange REWIRED.

HTM professionals can then use the improved asset data, visibility, and insights as a tool to explore new ideas for using the information obtained by the interconnected devices.

“As you enrich these platforms with useful information, it becomes a part of your workflow... and this becomes even more important as the delivery of care continues to be virtualized in locations outside of the healthcare campus,” Groome explained. “You’re operating in essentially a borderless environment of care and you still have to figure out how to manage and protect those devices and those individuals that will benefit from you managing them. If you can do that well, there will be great opportunities for efficiency in many areas of your operations.”

That’s called “asset agility.”

The number-one key to benefitting from interconnected assets is getting accurate information into the CMMS. Determining what assets should feed data into that system is also vital. After all, why have 50,000 devices in your CMMS when only 6,000 are actually managed?

“Making sure you’re only collecting the data you want and can use—rather than collecting any possible data available—will help reduce friction when you implement controls,” Groome said.

“If there’s not good data in the CMMS, then everything else doesn’t work.”

When a CMMS works well, all that good data within can combine to create greater efficiency in three main areas:

- **Visibility.** With increased visibility, the supply chain can better track assets throughout their lifecycle. This allows your facility to obtain useful metrics that can help ensure that you’re staffed accordingly and allow you to integrate your workforce management system to better understand things like worker productivity.

- **Risk.** “You can highlight high-risk assets from a security standpoint and track them over time. It's essentially your own risk register,” Groome explained. Additionally, you can build analytics into your CMMS to help with lifecycle management decisions and capital planning. By knowing the value of your assets and having an associated cyber or security risk score, you can best gauge whether assets need routine service or replacement.

- **Workflow.** An accurate CMMS helps you to help other departments with asset information—for example, a configuration management database can be integrated with your CMMS for better workflow between HTM and IT departments. You could also integrate your system with systems from other organizations so you could receive information like product alerts and recalls. Additionally, you can track service needs and response, as well as asset reliability.

“If you integrate your assets properly, and that good information gets into the CMMS, we’re really just scratching the surface with this new data!”
Innovation in Ventilation for Healthcare

Martha Vockley

Living through a pandemic has made everyone hyper-aware that the air we breathe can be dangerous. Nowhere is this truer than in enclosed healthcare settings, including surgical suites, emergency departments, intensive care units (ICUs), and patient rooms.

Viral respiratory outbreaks like COVID-19 continue to pose pandemic threats—and the time between outbreaks is shorter. “So far in the U.S., we have seen more than 3,600 healthcare workers dying from COVID-19,” said Peter Hojerback, CEO of Avidicare AB, at an education session at AAMI Exchange REWIRED. “That inability to protect our own staff is supposed to be something that we cannot tolerate.”

Airborne transmission has been observed in enclosed spaces, with prolonged exposure to respiratory particles, and where ventilation is inadequate. “Airborne contaminants are not only contributing to respiratory or other kinds of viral diseases,” Hojerback said. “They’re also contributing to healthcare-acquired infections and, especially, the most deadly and most expensive of all—surgical-site infections.”

Hojerback cited evidence to back this point:

• Approximately one-third of all healthcare-acquired infections involve transmission by airborne pathogens.

• More than 60 years of peer-reviewed evidence supports the relationship between airborne transmission and surgical-site infections. Implants, including total hip and total knee replacements, are particularly prone to be associated with infections.

“As we get older, many of us will need hip or knee replacements because we want to remain active,” Hojerback said. “Infections are the primary reason for revisions of total joint arthroplasty. By 2030, surgical-site revisions for total hip replacement are projected to increase by 142%, and by 190% for total knee replacement. Power tools, hammers, and other surgical instruments used in orthopedic surgery can spread airborne particles and contaminate surgical wounds and implanted devices. Bacteria shed by healthcare workers’ skin can cause infections as well.

The Shortcomings of Standard Ventilation

Inadequate ventilation in high-risk areas is a contributing factor to the spread of diseases and infections. Currently in the U.S., the standard ventilation method in emergency departments and ICUs is turbulent mixed airflow. Based on the dilution principle, filtered air is streamed into a space and mixed with contaminated air, which eventually exits the space. But air moves unpredictably, based on pressure and temperature differences.

“It’s like there’s a lot of people in a room that needs to be evacuated, but nobody knows where the exit is,” Hojerback said. It’s an inefficient system that keeps airborne contaminants in the air, which doesn’t meet the medical, scientific definition of “ultraclean.”

In operating rooms, laminar airflow is the standard method of ventilation in the U.S. This method, which relies on air direction and velocity, does not result in ultraclean rooms either. The strong downward flow of air creates vortexes of contaminated air. Laminar airflow is no longer recommended by the Centers for Disease Control and Prevention, World Health Organization (WHO), or International Consensus Group on Periprosthetic Joint Infection, Hojerback said.

A New Solution to Inadequate Ventilation

Temperature-controlled Air Flow Technology (TcAF) is a novel ventilation alternative that is in use in 250 healthcare facilities in Europe. Designed for the modern operating room and other high-risk healthcare settings, it is a validated technology that achieves ultraclean conditions throughout the entire space, improves comfort for surgical teams, and optimizes energy use, Hojerback said. This solution also meets or exceeds ANSI/ASHRAE/ASHE Standard 170, Ventilation of Health Care Facilities.

Hojerback encouraged healthcare systems that are building or renovating facilities to design them for tomorrow with TcAF. TcAF works by slowly releasing cool air from the ceiling. “It’s about three degrees Fahrenheit cooler than room temperature,” Hojerback said. “This air is heavier, so it falls down itself by gravity. This counteracts all the warm air that rises from people, instruments, and other equipment and heat sources in the room. On the periphery, air is supplied to push the air to the exhaust.” Room temperature and humidity can be adjusted to the needs of the patient and comfort of the staff. Monitoring and analytics enhance reliability and support compliance with environment of care standards.

Hojerback also pointed out that, unlike emerging European Union and WHO standards, U.S. standards are silent on what constitutes an acceptable level of microbial contamination in an operating room. In addition, there are no requirements for testing of airborne microbial bioburden. Development of such standards would require leadership by a recognized standards development organization, such as AAMI.

“Current AAMI standards address instrumentation and water. Should air be next?” Hojerback asked.
In Their Words: Diversity in HTM

Chris Hayhurst

Ask 10 professionals in healthcare technology management (HTM) about the paths they took to their current jobs in the industry, and you’re guaranteed to hear 10 different stories. The HTM “career ladder” is more like a maze, with twists and turns—and the occasional dead-end—that everyone has to navigate in their own way.

With that in mind, Gavin Stern, editor in chief at AAMI, recently asked seven HTM professionals with diverse backgrounds to share their experiences in the field. Here’s a look at some highlights from that discussion, featured at AAMI eXchange REWIRED, which included both established and up-and-coming HTM leaders alike.

We also sat down with Mike Powers, a diversity & inclusion professional and clinical engineering director at Intermountain Healthcare, to provide context and expertise for this important topic. Watch our interview for free on YouTube.

Building a Better Workforce

Stern began by asking how HTM employers could encourage more diversity in the field. Colleen Haugen-Ortiz, an HTM quality specialist at GE Healthcare, said that she had recently returned to school and was taking an ethics class that encourages students to consider the world from other people’s perspectives.

“I think that is one thing that HTM employers should look at,” she noted. “The fact that bringing in other cultures and other values can strengthen your company and create a more diverse environment.”

Priyanka Upendra, an AAMI Fellow who has worked in compliance with both Intermountain Healthcare and Banner Health, said she agreed with Haugen-Ortiz. As a U.S. immigrant from India, Upendra said she’s had to adjust to the many cultural differences between the two countries, but she’s also decided she can use that background to advocate for a field that is more inclusive.

One of her “focus areas,” Upendra explained, involves developing a workforce “that is mindful of culture, competencies, skills, gender, age, as well as race and sexual orientation and beliefs.” In addition, she said, she’d like to see HTM professionals learn to recognize when their response to something they may not agree with is “biased based on prior experiences.”

Sheldon Freeman, regional director of operations at TRIMEDX, said he helps lead the “diversity conversations” that take place at his company, and that he’s a strong believer in “setting goals” meant to drive improvement. As a Black man in a mostly White profession, he added that “those goals have to start with you—you have to determine where you lack.”

Reginald Burrus, who is also Black, and a recent retiree from the U.S. Army with three decades of experience in HTM management, echoed Freeman when he said it’s important “to have the conversations about the tough topics.” Today an HTM subject matter expert working as a consultant with Capitali, Burrus said the military had made progress in this area, especially when it came to bringing women into its ranks.

“The Army and the technical fields,” including areas like HTM, “are very male dominated,” he noted, but the military was finally recruiting women for these positions, recognizing that such diversity is critical to having a “functioning team.”

Women in a “Nontraditional” Role

“One reason I’m in this field is because I got a scholarship for a woman going into a nontraditional role,” said Donna Marie Dyer, senior director of HTM at GE Healthcare and a mentor to many in the group. That was 26 years ago, she added, but it still seemed to her that certain things remained the same.

“I would like to see us be more aggressive” about bringing women to the career, Dyer explained. “We’re already having a problem in the HTM industry with the availability of people in general. We certainly don’t want people excluding themselves; we’ve got to be more welcoming than that.”

Fernanda Zamudio, a senior BMET at Tenet Healthcare, and Renee Gordon, a clinical engineering intern at Baystate Health, both agreed with Dyer that the profession would benefit from having more women at all levels of employment. In her case, Zamudio noted, she was the only woman to graduate from her degree program, and the shop where she currently works is the first place she’s ever had a female colleague who was also a tech.

Gordon said there were just three women in the HTM department at her Massachusetts facility, but the numbers in the clinical engineering program she attends at the University of Connecticut are much more encouraging. “There are lot more females than males, which is very nice to see.”

Nearly all of the women on the panel spoke about the challenges they’d faced working in a field predominantly filled with men, but Haugen-Ortiz shared how she had learned to overcome...
them. “One way I proved myself was, I was always willing to jump in and rip something apart if I needed to,” she said.

“We Need More People”
As the discussion continued, the panelists spoke about everything from work authorizations and the hiring of immigrants to misogyny and “forced diversity.” Burrus told his colleagues about a military mentorship program, while Dyer recalled her own experience with mentors when she was an intern trying to find her way. “It really does take a special person to look at somebody who’s struggling and step in in a way that is helpful and pulls that person along to where they need to be,” she said.

If she could offer any advice to someone considering a career in HTM, Dyer said, it would be “come aboard, we need more people; we need more people who can collaborate, people who care about the work they do.” And for those who may lack the technical skills for the job? “We can work with that,” she said. It’s what on-the-job training is all about.

Upendra, for her part, brought up a quote she attributed to Charles Sorenson, MD, the CEO Emeritus of Intermountain Healthcare. “He said, when you’re working in healthcare, people trust you with their lives, so you have to run your operations at a much higher standard than anyone else.” That certainly applies to HTM, Upendra noted, regardless of who you are or where you come from, or how long you’ve been in the profession.

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**A Shocking Vulnerability Demonstrated at eXchange REWIRED**

*Brian Stallard*

Can you imagine having your smart assistant getting hijacked with... light?

During AAMI eXchange REWIRED’s “Good Morning HTM,” The Archimedes Center for Healthcare and Device Security shocked the healthcare technology management (HTM) community with a live demonstration of a worrying vulnerability inherent in many smart devices.

During the demonstration, University of Michigan PhD student and Archimedes Center research assistant, Connor Bolton aimed a bright green laser at a Google Home smart assistant device. A few seconds later, and seemingly unprompted, the device announced the time to everyone watching the eXchange REWIRED live feed.

“Oh wow—there it went!” exclaimed co-host Robert Burroughs, SVP of Education at AAMI. “And you’re doing that with some very inexpensive equipment? I’m definitely keeping my blinds closed from now on!“

Bolton explained that he had modulated the light of a $20 laser pointer to carry a specific message—in this case, asking the smart assistant to tell the time.

“By varying the intensity of the laser in tune with the voice command we want to give, we’ve essentially embedded audio into the laser beam itself,” he said.

The researcher and his colleagues have tested the technique in multiple devices and at varying distances. In one video, the team has even managed to command a smart device to open a home’s garage door after shooting the laser from a bell tower, through a window, and into the home.

The vulnerability, first revealed by researchers from the University of Michigan and The University of Electro-Communications, Tokyo, raises important security questions even while medical device designers are becoming increasingly interested in the idea of digital healthcare assistants, “smart” wearables, and networked smart devices in the clinical setting.

It also highlights a worrying trend: As the advance of new technologies continues to speed up, it may begin to outpace device security. Fortunately, this is a concern that AAMI and the Archimedes Center have combined their efforts to address in a new collaborative effort.

“We’re bringing together healthcare providers, security experts, device designers… everyone you can think of” to anticipate problems and find the right solutions, said Bill Aerts, Executive Director at Archimedes Center.

The two organizations have connected their membership and partner networks to work on advancing security for life-saving devices.

Watch this video at [youtu.be/EtzP-mCwNAs](https://youtu.be/EtzP-mCwNAs).
VA Shares Improvement Benchmarks for HTM Success

Brian Stallard

What does it take to transform a good health technology management team into a great one? According to the U.S. Department of Veterans Affairs (VA), it’s easy once you know how.

In a session during AAMI eXchange REWIRED, healthcare technology management (HTM) leaders from the VA shared proven strategies designed to positively impact HTM benchmarks such as work order turnaround time, PM completion, training, and employee productivity.

Senior biomedical engineer Rabeh Hijazi, who presented during the session, was quick to admit that work order turnaround times used to be embarrassingly long at the Detroit VA Medical Center (VAMC) when he first joined the HTM team in 2013.

“The VAMC had an average work order turnaround time of 17 days,” he said, “and if that sounds excessive… it is.”

For comparison, the national metric for HTM work order turnarounds is only one week.

After measuring various aspects of the VAMC’s work order process and analyzing the resulting data, Hijazi was able to identify a number of fault factors that can hobble the efficiency of an HTM department. Specifically, he found that the Detroit department suffered from limited part availability and training opportunities. Alarmingly, the staff was largely unaware of their own repair time metrics.

Hijazi also discovered that some technicians were keeping repair parts at their individual desks. While a seemingly harmless habit, this was making it difficult to keep track of part availability and may be a lesser-known problem that can disrupt inventory planning.

Hijazi’s first priority was to address this parts inventory problem. Aside from making a new policy that required parts to be kept and catalogued in a communal storage area, the Detroit team reviewed what their most common repairs were to better inform part orders. The VAMC also took on interns to help barcode and organize parts.

As for training, Hijazi and his colleagues learned to take advantage of moments when purchasing new products to negotiate discounted training classes with vendors.

“We also started pairing up staff based on skill level or specialty,” he said. “Having only one person familiar with a certain task or department can become a major problem when they’re on leave.”

Paired training is a tactic that Emily Sizemore, a VA biomedical engineer based in the Greater Los Angeles (GLA) area, is very familiar with. She noted that the VA now encourages departments to set a goal of 20 training hours per employee every year, recognizing continuous education as an important HTM benchmark. However, she also noted that it can be understandably difficult for a department to consistently reach the 20 hour goal.

“One great strategy is to simply increase the frequency of training opportunities,” Sizemore said.

Similarly to VAMC’s strategy, Sizemore’s GLA team have started paring technicians together for cross-training, helping to diversify skillsets. Holding weekly presentations on education topics hosted by a rotating roster of GLA staff was another strategy for increasing training hours while simultaneously helping VA employees become aware of what skills they may lack.

According to Hijazi, these HTM benchmarks are not independent of one another. Thanks to the VA training strategies, a focus on improved inventory, and greater awareness among employees of their own capabilities, the VAMC was able to drastically improve productivity. By 2020, repair turnaround time had dropped to an average of only three days.

The presenters urged other struggling HTM departments to apply their current benchmarks and strategies to other difficult situations. And while one size may not fit all, they said, assessing one’s department for strengths and weaknesses can only help serve the ultimate goal of an informed and productive department.
Preparation for Medical Device Incidents

Brian Stallard

They may be rare, but Frank Painter, adjunct professor of biomedical engineering at the University of Connecticut, warns that medical device incidents and adverse events are inevitable even for the most competent healthcare technology management (HTM) department. He joined two other HTM thought leaders in exploring the best ways for a department and its healthcare system to be prepared.

“Accidents will occur, so being prepared to investigate that next adverse event, no matter how rare, is important,” Painter said in an education session at AAMI eXchange REWIRED.

In the event of a medical device incident, HTM departments will join forces with a hospital’s risk management team to determine the root cause of the incident and prepare a report. Why report it?

“One very good reason to conduct an investigation is that The Joint Commission requires it,” Painter said.

But that’s not all. Painter explained that by conducting an investigation, HTM professionals can determine what kind of mistake was made, creating an opportunity to learn from that mistake. Additionally, knowledge gleaned from a report can better inform manufacturers, the FDA, and even other HTM departments, helping to prevent similar incidents in the future.

“A smart person always learns from their mistakes, but a wise person learns from the mistakes of others,” commented Arif Subhan, Chief Biomedical Engineer of the VA’s Greater Los Angeles Healthcare System.

“Importantly, the report also provides clear, unambiguous, straight-forward answers for an affected patient and their family,” Painter added.

To be prepared for such an investigation, Painter suggested that the experienced BMET prepares an “investigation tool kit” that has everything they’ll need to quickly assess the scene of a medical device incident.

Some suggested tools for the kit include a digital camera, a backup memory card for the camera, and a tape measurer with large, clear numbers to serve as a size reference in the resulting photography. Painter also recommends that the kit be a noticeably different color than the other toolboxes found within an HTM department.

“You will have just seconds to grab the right kit,” he explained, “You don’t want to show up with a box full of wrenches instead of a digital camera!”

Alan Lipschultz, president of HealthCare Technology Consulting, LLC, said that once on the scene, a BMET needs to collect as much evidence as possible. This will require not only taking hundreds of photos, but also collecting error codes and data logs from the devices involved before they are unplugged.

Lipschultz also emphasized the importance of using the term “use error” and not “user error” when applicable in any resulting report.

“You want to be very careful about using the term ‘user error’ because it is a conclusion,” he said. “It assigns blame.”

Saying an incident was because of user error will also rule out other important factors that should be considered, such as inadequate device design or labeling.

He pointed to a study conducted by HHS Medicare in 2012 that found that incident reporting systems in hospitals were capturing an estimated 14% of all medical device incidents. The prevailing reason HTM departments were never notified, the study found, was because staff placed the blame squarely on user error.

Communication was also an important theme brought up by all three presenters, with an emphasis on working with crisis managers, determining when the investigating professional may have a conflict of interest, and ensuring clinicians know how to react to a device incident to preserve settings and other evidence even while ensuring the safety of a patient.

“And please resist the urge to fix the equipment,” said Subhan, acknowledging that the best BMETS are often eager to solve problems the second they arise. In this case, he explained, it is best to take things slowly, preserve evidence, and communicate thoroughly.
Clinical Engineering’s Role at Sírio-Libanês Hospital (Brazil) during COVID-19

Martha Vockley

For a clinical engineering department in Brazil, battling on the front lines of COVID-19 began as a struggle to reduce damage and improve the effectiveness of the hospital’s response to the pandemic. Now, the department is emerging from its most challenging days with unexpected benefits that will outlive the pandemic, including increased efficiencies, new partnerships and collaborative relationships, and nationwide recognition of the vital role of the healthcare technology management (HTM) profession.

When the pandemic hit, the clinical engineering department at Sírio-Libanês Hospital in São Paulo, Brazil, leaned into meeting the emergency demands of a large, complex hospital. “The pandemic moment brought the challenge to clinical engineers to quickly respond to several demands to combat COVID-19 and all its impact—not only healthcare issues, but technical and economic issues also,” said Marcello Dias Bonfim, manager of clinical engineering at the hospital, during AAMI eXchange REWIRED.

On the healthcare front, the hospital and clinical engineering department combined forces with Hospital das Clínicas, also in São Paulo. They collaborated to create safe patient care areas for COVID-19 patients and for patients who did not have the virus, and a system to decide where patients should go. The clinical engineering departments made quite an impact to operationalize these patient care areas in a short amount of time:

• Set up a 14-bed intensive care unit—including equipment, supplies, people, and training—in one week
• Reconfigured patient care areas and air pressures
• Assembled beds to add 200+ beds dedicated to COVID-19
• Rented 60+ ventilators, bringing the total ventilator count to 180+
• Installed 60+ multiparametric electronic monitors
• Sourced and deployed infusion pumps, pulse oximeters, portable X-ray machines, dialysis equipment, ECMO (extracorporeal membrane oxygenation) machines, thermometers, and more
• Donated beds, equipment, supplies, and training to public hospitals

Shortages of equipment and supplies led the clinical engineering department to pivot from sourcing products globally to locally. “We preferred to rent most equipment,” Bonfim said. “The clinical engineering staff evaluated new manufacturers and different models of equipment from our normal models, with new players and a new end user mindset.”

The HTM professionals also participated in crisis committee meetings seven days a week, with many participating virtually, to review dashboards of data about hospital occupation, availability of mechanical ventilators, consumption and availability of oxygen, hospital supplies, and more. They also supplied millions of gloves, aprons, surgical masks, and N95 masks to protect employees—and visited hospital units to reinforce the importance of using masks, hand-sanitizing gel, and social distancing practices.

Like the typical clinical engineering department, Sírio-Libanês Hospital’s would have toiled in obscurity—until Você S/A, a major professional magazine in Brazil, picked up the story. “The clinical engineering position was introduced to all of Brazil for the very first time,” Bonfim said. “This publication helped a lot of professionals to consider this career and, most importantly, motivated students to go into this profession.”

Results

• Reduced contracts for medical equipment by $1 million in 4 months
• Optimized the use of equipment
• Increased internal maintenance
• New equipment and new relationships with manufacturers
• Cultural change with greater collaboration among teams for faster resolutions
• Increased prominence of clinical engineering in the media after the pandemic
Being an Expert Witness for Medical Device Cases

Jennifer Peters

For professionals looking for a new way to help patients, hospitals, and device manufacturers, working as an expert witness in court cases is a unique—and lucrative—option.

Frank Painter, adjunct professor of biomedical engineering at the University of Connecticut, has worked as an expert in the investigations of more than 300 medical device–related incidents. At AAMI eXchange REWIRED, he offered guidance on how HTM and other medical industry professionals can get started as expert witnesses.

Court is “a real adversarial environment,” Painter warned future experts, and not just anyone can work as an expert witness. “You can’t just hire someone off the street… to come in and be an expert,” he explained. A good witness is “someone who can summarize the data and all the information into teachable points.” You need to be a teacher, a technologist, and an investigator. And you need to be “likeable.”

While likeability isn’t an expert-level skill, having a likeable expert is important to the lawyers hoping their side wins. As Painter explained, “Jurors rely on their opinion of the expert more than the expert’s opinion on the [subject].”

Along those lines, an advanced education isn’t a requirement to be a good expert witness. While a bachelor's degree is generally desired, advanced degrees are not always vital. “At some point, experience outweighs education in the eyes of many in the court system,” Painter explained.

Experience on the stand is also beneficial. If you’ve never served as an expert witness, one way to get that experience is by serving as a “fact witness.” A fact witness is someone who has direct knowledge of the facts of an incident and can tell the judge and jury exactly what happened. For example, if you were in the room when the incident occurred, or have specific knowledge about the device in question, you could serve as a fact witness.

Another way to gain the kind of experience that is valued in an expert witness is by working on in-house investigations at your hospital, such as doing root cause analysis or a failure mode and effects analysis.

Once you’re ready to work within the legal system, you’ll need to throw your hat in the ring for opportunities. Painter recommends connecting with other witnesses and letting them know you’re interested and available to offer your analysis. You can also advertise in legal directories or create your own website to share your availability.

When you’re contacted by a lawyer, you’ll be asked to work as a consulting expert or a testifying expert. A consulting expert is a third party hired by a lawyer to help investigate what happened and determine whether there’s a case. In 70 percent of cases, this is what lawyers really need. Only about 25 percent of cases go to deposition, and fewer than 10 percent go to trial. Painter noted that the majority of his 300-plus investigations were conducted as a consulting expert.

If a case goes to deposition or trial, you’ll be working as a “testifying witness.”

As a testifying witness, it’s important to remember that “you’re really working for the court system, not the lawyer, even though the lawyer is paying you,” Painter said. Your job is to explain the facts, not give a specific opinion. “That keeps your conscience clean and keeps your reputation intact,” he added.

And don’t be afraid to say “no.” If there’s something you don’t know or that’s outside your realm of experience, be honest and transparent. As Painter noted, “Your reputation is all you have.”
Efficiency in Field Repair with Live Video Support

Martha Vockley

“If a picture is worth a thousand words, live video is worth even more,” said Wayne Werner, manager of technical support and escalation at Dräger, Inc.

In an AAMI Exchange REWIRED education session, Werner explained how Dräger field technicians who are stumped by a problem when they’re performing preventive maintenance, for example, can get help on the spot via live video with more experienced technicians.

“With video, you can show the piece of equipment from different angles and zoom in to see what’s going on, which can be difficult with a single picture,” Werner said. “With these capabilities, you can also broadcast service manual pages, parts listings, and other details of the equipment, so that it is much easier to guide the tech to what the root causes of the problem may be—and then to a quicker resolution.”

Using a secure app, tech support agents can connect less experienced technicians, who may be encountering a problem for the first time, in a two- or three-way call with colleagues who can help troubleshoot to make the repair. Or they can bring in a total productive maintenance or training professional, making this another opportunity to learn.

Why would original equipment manufacturers, independent service providers, and clinical engineering departments want to consider live video support? For Dräger, this solution mitigates the challenges of field service:

- Field technicians spend a lot of time traveling to distant customer sites. Dräger wants to make sure that time is productive and resolves equipment issues quickly.
- New hires may not be familiar with all the company’s equipment.
- Training schedule constraints, especially in the era of COVID-19, mean that it can take months or more to train new people on a variety of equipment.

- Mentoring by more experienced technicians impacts their valuable time.
- Uncertainty about parts identification and miscommunication in voice calls can lengthen equipment downtime. “Voice-only communication is not as effective with less experienced field technicians,” Werner said.

Why not just use FaceTime or Skype? “The simple answer is that many, many hospitals and companies have restrictions about using them,” Werner said. “There are concerns about personal and protected health information—and then there are bandwidth concerns.” This type of video app, which is available from several vendors, is encrypted and configured to work even in basements where bandwidth can be spotty.

Dräger has bottom-line goals with video support:

- First-visit resolution of problems
- Reduced equipment downtime
- Reduced need for return visits
- Improved customer satisfaction
- Cost savings
Social Media Proves Useful for Training in Healthcare

Gabrielle Hirneise

With the dawn of social media and smartphones, we saw a sizable shift in the way information is consumed. Although some find this new way of life a challenge, there are certainly some advantages to the increased accessibility to learning materials at our fingertips.

Such platforms could be of particular use in training individuals in the healthcare space, as illustrated by Michelle McKinley, senior clinical education specialist at STERIS, in a session at AAMI eXchange Rewired.

“Our learning objectives are to identify historical trending and education techniques, understand how new technology can assist in ongoing education and learning, identify challenges moving into a more technology-based learning platform, and identify tips on how to navigate and develop a successful learning program in the social media age,” McKinley said.

Regarding the history of healthcare training, McKinley pointed out that training was once confined to in-person meetings held before or after a shift, with potential for interruptions from the OR, time constraints, and conflicting schedules caused by holidays, vacation, etc.

If the training materials were to be accessible in a new, online format, some of these challenges would be ameliorated. Similarly, there is the question of different learning styles, which range from auditory to physical to visual. Not everyone learns in the same way, so why teach them in the same way?

Lastly, there is the question of generational differences in learning and information consumption. You have your traditionalists, baby boomers, Generation X, Generation Y, and Generation Z, all with different influencing factors and degrees of technological competency.

“More new hires will be from this millennial generation who simply learned differently and have different learning expectations that the current training processes can’t offer anymore,” McKinley said.

So how do you meet the needs of all? We add social media into the mix. Whether it’s a private social media platform, in which only the members of a specific group or institution have access to the information disseminated, or whether it’s a public social media platform like Facebook, YouTube, Twitter, LinkedIn, or Instagram, social media will provide the means to share news, engage socially (which is advantageous for social learners), and consume training materials from a wide variety of sources.

That doesn’t mean adding social media into training protocols doesn’t come without challenges, however.

“Adding variety does provide the old challenges of where you need equipment and space for in-person staff meetings for example, and it also brings new challenges to consider [like] generational variance in the use of technology. Baby boomers may be inexperienced with newer technology and require further training in its use [while] millennials may become bored with long lectures hampering their ability to retain the information,” McKinley said.

Additionally, the information provided on these platforms may not be accurate, credible, or up-to-date, and there could be misuse of these platforms. Although this can be ameliorated through the use of a private platform, in which information is controlled by some guiding power like IT, only so much can be done to prevent misinformation and misuse.

Despite such disadvantages, industry experts remain convinced that a combinatorial approach will be the best way to teach the masses and ensure that operational deficiencies are minimized.

“Combining traditional facility training methods with social media tools allows the material to work for the greater variety of learning styles,” McKinley concluded.
Telehealth on a Shoestring: Lessons from COVID-19

Jennifer Peters

At the start of the COVID-19 pandemic, many healthcare facilities found that, in addition to an increased need for care, there was an opportunity to help keep patients safe by finding ways to provide at least some of that care remotely.

When ECRI member hospitals experienced scarcity of in-patient beds during the pandemic, they started “scrambling” to initiate telehealth options, said Erin Sparnon, senior engineering manager at ECRI Institute, during AAMI eXchange REWIRED. “There simply wasn’t enough space to bring in everyone who needed [thoughtful monitoring].”

Given the shortage of even the most basic medical supplies, Sparnon said hospitals were left wondering, “Does [remote monitoring] need to be so complex? What can we do for our patients without all this stuff?” They also didn’t know which vital signs were most important to monitor for the most complete picture of a COVID patient’s health.

Given that telehealth workflow challenges were sixth on ECRI’s 2021 “Top 10 Patient Safety Concerns,” and “rapid adoption of telehealth technologies can leave patients and data at risk” was third on the list of “Top 10 Health Technology Hazards,” there are a plethora of considerations to take into account when determining the best course of action for remote monitoring.

Priyanka Shah, senior project engineer at ECRI, noted that some of the ECRI facilities hardest hit were in rural areas where large portions of the COVID-positive population were not comfortable communicating in English.

“We had to figure out a way to monitor these patients in a way that is effective, but also that is easy for the patients to use,” Shah explained. And because of supply shortages, “the facilities’ device choices were driven by what was available in local pharmacies and retail outlets.”

The final solution was to courier pulse oximeters and blood pressure monitors to patients. Then, the patients were able to speak to a provider on the phone to learn how to use the devices and record the data.

“Based on your patient population, you may not need a very sophisticated solution… when a simple phone call could help manage patients better,” Shah explained. “If it requires too many sophisticated steps and the patient population isn’t comfortable doing it, maybe that’s not the [right solution].”

When choosing what solution would best serve your patient, the presenters suggested asking questions like:

- Does the remote monitoring solution require an Internet connection or use of a special app, and if so, does the patient have access to those things?
- Can the patient easily and effectively use the device without assistance?
- Does the device do what you need it to in order to provide the patient with the best possible care?
- Are there any factors in the home (other devices, for example) that could limit or impede use of the device?

Once ECRI patients were set up with their devices, follow-up “visits” could be conducted by phone, allowing them to get the care they needed without having to go to the hospital.

However, Juuso Leinonen, senior project engineer at ECRI, noted that “not every patient is a good fit for telehealth.” “Patient selection and support will be important,” he continued. “Having a patient-selection methodology that identifies the folks who are comfortable using telehealth is going to be important… Not every patient will have the technology access to partake in these solutions.”
New View: HTM from the Patient Perspective

Chris Hayhurst

Three people from different areas of the country with different work histories and areas of expertise. Three patients facing medical emergencies and unplanned journeys through their local healthcare systems. And finally, three stories with a common theme: They were all shared by leaders within the HTM community.

This special AAMI eXchange REWIRED session, “On the Other Side: HTM from the Patient’s Perspective,” includes stories and insight from three people who never imagined that they’d be the ones depending on the technologies that make healthcare possible:

Karen Waninger, executive director of clinical engineering at Franciscan Health in Indiana and Illinois, shared her story about surviving a horseback-riding accident that took place more than a decade ago.

Steve Campbell, acting president and CEO at AAMI, talked about the care he’s received for a heart condition diagnosed earlier this year.

Pamela Arora, senior vice president of strategic technology at Children’s Health in Texas, explained how she learned she had cancer right around the time COVID started to emerge.

In her case, Arora said, she was with a Children’s Health team visiting hospitals on the West Coast to gather ideas for new facilities her organization planned to build. “I had checked into the hotel after a full day of touring, and my physician had left me an urgent message to call her on her cell phone any time.” Her doctor told her she had an aggressive form of breast cancer, and recommended she see a specialist as soon as possible. She did so at the University of Texas Southwestern Medical Center, she said, and “over the last year, they saved my life.”

HTM “Superheroes”

Arora, Waninger, and Campbell each spoke about the emotional and physical rollercoasters they had to ride during their recoveries, and they talked about the support they received along the way from their families, friends, providers, and colleagues. But it was their respective backgrounds in healthcare technology—and their awareness of the role that HTM played in their personal trips through the medical system—that really came through as the session progressed.

“I could see the daily handprint of technology, device management, innovations making life better for the patients,” Arora noted. Campbell said that he was probably “the only patient in the ward who looked at inspection stickers on the equipment around me,” while Waninger said she was fascinated with the advanced tools and “cool toys” her therapists deployed during her rehabilitation.

“What I discovered,” Waninger added, “was not one time did I have to wait or have to be rescheduled, because that equipment worked all the time, every time, thanks to the work that our HTM professionals are doing all day, every day.” Arora, for her part, did experience one equipment issue: During a hospital visit for chemotherapy, the pump required for the procedure initially failed to work.

“They resolved that,” Arora recalled, “but it translated into an additional hour of my hands and feet in ice, and an additional hour with the sub-zero cold cap I was wearing on my head” to reduce hair loss from the treatment. The HTM professionals who showed up to take care of the problem as quickly as possible were, she said, “my superheroes.” She pointed to the work that HTM team did every day she was there, and noted that based on her experience, “without a doubt, they make a difference in people’s lives.”

Work that Matters

In their own lives, the three panelists said, things were looking up across the board. Campbell talked about an EKG device that used a smartphone app that allowed him to monitor his heart rhythm whenever he wanted, and said that while he was “wiped out” some days, it seemed like he was moving in the right direction. Arora said that she was about to undergo the final surgery that was part of her treatment plan. “Everything has been going very smoothly,” she noted. “I feel like I’ve come out of it at 100 percent.”

Waninger, who facilitated the discussion, also said she was “doing great,” although she still experiences double vision and other symptoms caused by the injury she suffered in her accident. “I can still tell every year that my brain is recovering, and my nerves are still healing. And so I think the underlying message is to never give up on your journey,” she said.

In bringing the session to a close, Waninger spoke for everyone when she expressed her gratitude to the people in healthcare who’ve made her recovery possible. “Everything that we have experienced with our journeys, even though they were not planned journeys, ties so closely back to the respect that each of us have for HTM professionals. And so for those of you who may be listening to this recording, we want to thank you…. You all do so much, and you care about the quality of your work, and it truly matters.”
AAMI eXchange REWIRED Success Promises ‘Bright Future’ Ahead

Continued from page 1

Shawn Jackman, founder and CEO of Clinical Mobility, explained to HTM professionals why now is the time to prepare for Wi-Fi6E technologies. Tietronix Software showed how they’re helping NASA develop easy-to-use healthcare solutions suited for space exploration. Sue Schade, principal at StarBridge Advisors and interim CIO at Boston Children’s Hospital spoke about the gender gap in HTM and the progress women are making in the field. In one of the show’s more fascinating moments, AAMI collaboration partner Archimedes Center for Healthcare and Device Security demonstrated a vulnerability in voice-activated devices in which a laser can be used to deliver silent, unbidden commands.

Attendees were able to chat with one another and presenters in real time during all the event’s live broadcasts and Q&As.

“I’m loving this morning show! ” one attendee wrote, while others commended about the friendly and often humorous dynamic McGeary and Burroughs brought to the broadcast. Attendees took their comments to social media as well. Nearly 150 social media posts used #eXchangeREWIRED during the conference week, earning 440 likes, comments, or shares between Facebook, LinkedIn, and Twitter.

The most-attended session of the entire week was a special two-hour livestreamed Q&A with Herman McKenzie, director of the Department of Engineering in the Standards Interpretation Group for The Joint Commission. McKenzie leads the team responsible for developing and interpreting the Life Safety and Environment of Care Standards and was well-prepared to take questions from his audience in real-time.

A Bright Future for AAMI eXchange

AAMI eXchange 2021—typically an in-person event featuring dozens of education sessions and a product Expo Hall—was transformed into a fully online event in the interest of attendee safety. The new event, named AAMI eXchange REWIRED, had less than three months to become something more than “just another virtual event”—a challenge AAMI Acting President and CEO Steve Campbell posed to his organization.

Now that the dust has settled, Burroughs is celebrating the event’s success and looking towards the future. After surveying attendees, presenters, and 37 sponsoring companies, Burroughs and his team are now making plans to implement the best of REWIRED’s successes into future in-person eXchange events.

“This success shows we can do ‘new’ and do it well,” he said. “The future is bright!”

The health technology and HTM communities will come together once again on June 3–6, 2022 for the next AAMI eXchange in San Antonio, TX. In-person once more, the event will be held at the beautiful Henry B. Gonzalez Convention Center, nestled alongside the world famous San Antonio Riverwalk.

Registration will be open soon, as will the call for proposals and Expo Hall sales.
noted a 2018 article he read in the *Journal of Patient Safety and Quality Healthcare* that stated that the 30-day readmission rate for patients with heart failure went from 16 percent to 3 percent with telehealth intervention.

Baird also noted a unique benefit of digital health: Sometimes patients are more willing to be honest with a piece of software than when they have to look their caregiver in the eye.

There are, however, also challenges. “One of the things we have to consider is whether it’s reasonable for a clinician to remember what these technologies can and cannot achieve when they’re already undertaking very, very stressful and busy jobs,” Turpin explained. “Have the solutions been properly designed with the end user in mind?”

Integration of digital tech into care pathways is also not a trivial matter. Providers need to consider the impact the digital option will have, not only at the point of contact, but how that telehealth option will impact the rest of the care environment, such as how it affects the facility workflow and how it will integrate into the patients’ lives.

Another challenge is regulatory practices related to telehealth. While technology advances at a rapid clip, regulations for safety and privacy “struggle to keep up with digital health innovation.” The most successful companies in the space, Turpin said, “put a lot of thought into ensuring safety, security, and performance of their solutions in order to protect the interests of patients and the wider public.”

Patients, too, present a unique challenge. While many patients have embraced digital and remote healthcare options, there are patients who prefer talking to an experienced provider in person, so the motivations and barriers to patient uptake are important to consider.

Equity is also a vital concern. First there’s equity of healthcare across facilities, as not each hospital is unique in the interoperability challenges it faces, and telehealth providers and developers need to consider how their options will work in different settings. But Turpin also highlighted a key equity issue, which is that digital healthcare “benefits certain parts of our society more than others, likely at the deficit of those who need healthcare the most.”

But the biggest challenge, Turpin said, is remembering that there is no definitive answer to how to respond to the increasingly remote nature of medicine. “Digital health cannot solve every healthcare challenge,” he said. “However, it can be a significant enabler for the future.”
Survey: Open Positions and Untapped Diversity for HTM

Brian Stallard

A survey of 71 healthcare organizations and more than 7,000 healthcare technology management (HTM) professionals has validated ongoing concerns while making some promising revelations. The first-of-its kind survey, conducted by AAMI, also clearly outlines areas where the HTM field may improve.

With just over 30 simple questions, the survey focused primarily on determining the current demographics of healthcare organizations, who responded anonymously. Responding groups ranged from standalone hospitals, multihospital healthcare systems, to large independent service organizations, and local HTM service providers.

Among the surveyed U.S. organizations, 5,861 HTM professionals were identified as biomedical equipment technicians (BMETs) or clinical engineers, making up 70% of the responding organizations’ staff. Those surveyed technicians represent more than one-tenth of all BMETs or “medical equipment repairers” employed in the U.S., according to the U.S. Bureau of Labor Statistics.

“We wanted to get a snapshot of the U.S. HTM community as a whole and define just how wide the field’s diversity gaps are,” explained AAMI’s Vice President of HTM, Danielle McGeary. “By participating in this survey, the respondents are helping to identify where the HTM field will best benefit from improvement. This data is critical as AAMI works to strategically plan future projects and initiatives with the goal of further elevating and diversifying the field.”

Diversity, HTM’s Untapped Resource

Perhaps most important was data pertaining to diversity within the HTM field. Among the 7,037 HTM professionals surveyed, 8.5% were black or African American, 7.7% were Hispanic/Latinx, and just over 10% identified as female. Among the respondents holding managerial positions, 14% identified as female.

Donna Marie Dyer, senior director of HTM at GE Healthcare and a mentor to many burgeoning HTM professionals, said that she’d like to see the field as a whole “be more aggressive” about introducing women and minority groups to HTM careers. She recently participated in a roundtable discussion among leaders who are working to help bring more diverse staff—and the fresh ideas and perspectives that come with them—to the HTM space.

“We’re already having a problem in the HTM industry with the availability of people in general. We certainly don’t want people excluding themselves; we’ve got to be more welcoming than that,” said Dyer, who is a member of the AAMI Board of Directors.

The Burden of Jobs Not Taken

Dyer echoes the thoughts of many HTM leaders, worried about a future where HTM departments are left with too many open positions —especially leadership roles—unfilled.

Of those surveyed, 47% of HTM staff are 50 or older. Among 618 respondents holding managerial positions, nearly 6 in 10 reported being 50 or order, with 95 managers (15.4%) over the age of 60. Meanwhile, the organizations polled reported being 8.5% understaffed (open vacancies) on average. Explaining for vacancies, one-third of those organizations reported that it takes two to four months to fill a position while another 30% reported that it takes longer than four months to fill a position.

“We also hope this data will be useful within organizations that employ HTM professionals as well, since up until now the field generally knew there were gender and racial gaps in the field, but we never had a quantifiable number to describe the magnitude of those gaps,” she added, explaining how identifying industry averages will help organizations acknowledge their own accomplishments and areas for improvement.

Read more: Diversity in HTM roundtable discussion.

Distribution of HTM positions within 71 surveyed healthcare organizations.

Age, race, and gender distribution of HTM professionals staffing 71 surveyed organizations.

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Survey: Open Positions and Untapped Diversity for HTM

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Across the U.S., we’re seeing job openings for BMETs not getting filled for months at a time and colleges are being forced to drop their BMET programs due to budgetary constraints,” said McGeary. “This only serves to widen a training gap between the county’s most senior and soon to be retiring BMETs and the next generation of HTM professionals.”

In 2020, AAMI helped gather responses for 24x7 Magazine’s 2020 compensation and job satisfaction survey. The publication, which focused on hearing from hospital-based BMETs, also asked for comments on this perceived training gap. The responses showed that those tackling work orders and preventative maintenance day-to-day are particularly aware of the growing divide.

Among the thousand-or-so respondents to 24x7’s Salary Survey, 52% characterized their workload as “heavy,” with a further 12% calling it “excessive.” “Only a miniscule number of those surveyed—2%—deemed their workload as ‘light,’” the magazine reported.

“There is always a high volume of work,” one survey respondent said. “Hospitals steadily climb in size and equipment count, but staffing can be slow to follow.”

“I teach biomed classes at the local community college and, this year, we will only graduate three students,” another commenter revealed. “This won’t replenish the aging workforce that is retiring.”

AAMI’s demographic survey revealed that on average, the surveyed healthcare systems have just under 1,500 medical devices per BMET, leading to more than 1,700 total work orders per BMET every year.

**Steps Towards a Better Workplace**

AAMI’s new BMET Apprenticeship program, approved by the U.S. Department of Labor and co-designed by McGeary and 2021 AAMI & GE Healthcare BMET of the Year Maggie Berkey, is a step towards addressing this problem. However, it will take the support of proactive organizations such as those who participated in AAMI’s demographic survey to pave this freshly blazed trail for prospective HTM professionals.

The U.S. military is also making strides towards creating HTM career opportunities for service members. The U.S. Army, for instance, offers 10 weeks of basic HTM training, 41 weeks of advanced individual training, and the support to pursue 20 relevant certifications. This career path is open not only to active-duty members, but Army reserve and the U.S. National Guard as well. The result? Of the 7,037 HTM professionals AAMI surveyed, nearly 38% reported being military veterans.

Still, consultant Reginald Burrus, a U.S. Army retiree with three decades of experience in HTM, said that it was only in recent years that women are being recruited for military BMET positions.

“Both the Army and the technical fields are very male dominated,” he explained during AAMI’s diversity roundtable at AAMI eXchange REWIRED. “It’s important to have the conversations about the tough topics” about where your organization is lacking and recognize that diversity is critical to having a “functioning team.”

**Getting the Work Done**

What else helps a team function at its best? Continued learning. A more positive revelation from AAMI’s new survey is that once hired, employees are encouraged to expand their repertoire of HTM knowledge.

While only 19.7% of the organizations surveyed reported requiring their HTM professionals to be certified, nearly 80% incentivized certification with 70% reimbursing certification costs. As for strong incentives, 40% of the organizations reported granting a raise or bonus for a new certification, while 20% promote HTM professionals for obtaining the right certifications.

In a profession that regularly undergoes change, the importance of certification is undeniable. Certification programs recognize HTM professionals whose practice reflects a high degree of knowledge about medical devices and clinical practice as well as skill in implementing electro-mechanical talent in the repair and maintenance of devices used in the delivery of healthcare.

However, the AAMI Credentials Institute (ACI) is quick to point out that “certification is only as valuable as the standard it represents.” So long as a standard is maintained, it will go through updates. Therefore, regular recertification is important.

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And it appears that BMETs are indeed maintaining their competency—incentives or no. During the 2021 AAMI eXchange REWIRED conference, an international trio of HTM leaders revealed that less than 1.5% of all medical device related issues reported each year can be attributed to medical device maintenance or service.

“My assumption is that this is because we [the HTM community] know what we’re doing, said Jean Ngoie, Head of Instrumentation and Clinical Engineering at NHS Tayside, “and we’re doing it in a consistent, systematic way.”

“The good news is that we know the HTM community is full of people passionate about building a better field—better for HTM professionals, but also for clinicians and patients,” added McGeary. “These survey results reinforce our mission to enable a more diverse future where the next survey will hopefully leave us smiling at how far we’ve come.”
What to Do When You Receive Equipment with a Note Saying ‘Broken’?

Becky Crossley, CBET, is a BMET specialist in the Biomedical Engineering Department at the University of Pittsburgh Medical Center Susquehanna-Williamsport in Williamsport, PA.

Q We constantly receive equipment items with notes saying they are “broken.” Being a new technician, such notes can be frustrating because they do not adequately describe the problem. What is your approach in these situations? 

This has always been a joke in the healthcare technology management (HTM) field. When I was a newer technician, it used to anger me when problems were not written out. The troubleshooting process was not really emphasized in the technician school I attended. Biomedical equipment technicians, and others in the HTM field, lean heavily on the troubleshooting process. Over the years, I have developed a standard practice for troubleshooting equipment. I have noticed that regardless of whether I am told the problem, I still have a set path I follow when troubleshooting every situation of equipment.

The process I use follows these steps: (1) identify the problem, (2) eliminate things that are not relevant to the issue, (3) determine the cause of the problem, (4) fix the problem, and (5) test to make sure the problem is fixed.

The first thing I always do when I get a piece of equipment, even if it has a problem description, is to approach it like I am doing a preventive maintenance (PM) inspection. Start by setting the unit up as you would for a PM inspection, then walk through the PM steps. If there is a true problem, it will show up at some point during the inspection process. If a problem does not show up, you have completed the manufacturer-recommended PM and the piece of equipment is good to return to use.

At this point, I would go back to where I received the piece of equipment and talk with whomever reported the problem. Usually through this process, I discover that the problem was truly a user issue. I use this opportunity to teach the individual involved so that this does not continue to happen. I am always amazed at how a brief discussion, providing education to clinical staff related to equipment, can ward off a slew of future problems.

The next step is to eliminate things that are not the issue, and the PM inspection process also is helpful in this regard. If you do find a problem in the first step, this step allows you to drill down further on the specific issue and get to the one component that is the issue. Today, we have more computer-based pieces of equipment than ever before. It is during this step that you would also determine if the correct patches, drivers, and operating systems are installed.

It is totally feasible that staff are trying to use the piece of equipment in a way in which it cannot function because of software limitations. I can provide a good example of this from personal experience. We had two pieces of equipment that looked very much alike, and some staff assumed that the two pieces of equipment were synonymous with one another—they tried to use both pieces in the same manner. In fact, one of the items had an older version of software and therefore was not able to perform in the same fashion as the other item. Knowing software versions of all equipment can help during the troubleshooting process.

Receiving a piece of equipment with a note saying it’s “broken” may not be particularly helpful, but BMETs need not be deterred. A well-practiced troubleshooting process can determine the cause of and solution to the problem.

After you have determined that a problem does in fact exist, the next step is figuring out its cause. Did the problem emerge from an action by staff? Does it involve physical damage? Is it a failure resulting from overuse? Is it a repetitive failure? Knowing the cause of the problem can help educate staff, determine recall-type failures, and prevent many of the same types of issues.

Next, we must fix the problem, which in the field of HTM field, can be a challenging process. HTM departments commonly keep equipment going well past its intended life. We are very good at finding “the fix.” We are also good at finding workarounds. It is important to find solutions if parts are not available or if it will be weeks before they can ship. In my experience, a huge help is calling the representative from the company and seeing if they can offer a loaner unit or if they have a solution. You might be surprised at the help they can offer.

The last step is testing the unit to ensure that it is truly fixed. This is especially important with equipment that is touching a patient or being used on a patient. Doing a full manufacturer-recommended PM inspection will help to ensure the problem is indeed resolved. If you have the equipment and can allow it to run as if it was being used for patient care, this also can help ensure that it is fixed.

As you can see, although knowing the exact nature of the problem would be helpful, it isn’t necessary. Following a strong, well-practiced troubleshooting process will always lead BMETs down the path to resolving the issue. After you have a troubleshooting process that works well for you, the anxiety of not having any information about the problem will dissipate, along with any frustration.
Updated AAMI ST91 for Endoscope Reprocessing: An HTM Perspective

Jennifer Peters

Where endoscopes are used and processed in the healthcare facility varies greatly from one health system to the next, said Mary Ann Drosnock, Director of Clinical Affairs for Healthmark Industries, but “everyone needs to be in sync when it comes to what standard practices are.”

That’s why Drosnock and AAMI Working Group 84 are working towards an updated version of ST91. Drosnock explained what’s in store in an education session at AAMI eXchange REWIRED. The updated version of ST91, expected to be available in August, includes stronger guidance to help HTMs best work to ensure the safety of their facilities’ scopes.

“What’s great about ST91 is it covers all kinds of endoscopes, from bronchoscopes to ureteroscopes… to GI scopes, you name it,” Drosnock said.

Some of the updates include:

- Adding classification for high-risk scopes, such as bronchoscopes and ureteroscopes
- Changing guidance for drying of scopes, as well as proper storage and handling
- Recommendations against manual disinfection
- Guidance for testing water in automated endoscope re-processors (AERs) to avoid the final-rinse water re-contaminating the scopes
- Guidance for determining the length of storage, or “hang time,” that a scope can withstand before needing to be reprocessed

The updated document will also include “lots of references to support” the stronger guidance, making ST91 a more evidence-based document, Drosnock said.

In addition to ST91, there is also work being done on a technical information report, TIR99, which will cover the reprocessing of ultrasound probes and dilators. “[I’m] hopeful that next year we’ll have this… document, because there’s nothing that’s out there right now on how to properly process probes and dilators,” Drosnock said.

On April 1, the FDA issued recommendations to help providers deal with infections caused by or related to reprocessed urological endoscopes, noting that the agency “has received numerous Medical Device Reports (MDRs) which describe patient infections post procedure or other possible contamination issues associated with reprocessing these devices.”

Drosnock explained how healthcare facilities can best ensure their reprocessed scopes are as low-risk as possible.

“Carefully follow the reprocessing instructions for each scope found in their IFU (instructions for use), be aware that some products’ components may have separate reprocessing instructions that may not be found in the overall scope manual,“ and make sure that you’re carefully following precleaning, leak testing, and sterilization instructions, Drosnock said, adding that scopes “should be moved to sterilization instead of decontamination.”

It all starts with a visual inspection, preferably with lighted magnification, and ideally with a borescope. Once the visual inspection is complete, a leak test should be done to make sure the endoscope is ready for use.

“It is required that an endoscope be leak-tested every time it is used,” Drosnock said, noting that if a scope is too old to be leak-tested, it should be taken out of use.

Drosnock also offered guidance on leak-tester maintenance. “If you have a faulty leak-tester, you’re not going to know which scopes are leaking… and that is a direct infection control risk,” she said.
Sterilization-Related Challenges of Off-Site Transportation of Medical Equipment

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Medical devices and equipment increasingly are being transported from healthcare facilities to off-site locations for use or processing. The reasons for this transportation could include centralized processing centers being used to service off-site locations, a high-cost sterilizer located at one facility being used to sterilize items for several facilities, and/or healthcare facilities borrowing instrumentation and equipment (either on a scheduled basis or due to an emergency).

As these items are transported off site, maintaining their sterile integrity and proper functioning are concerns. Within a healthcare facility, the sterile storage environment is clean and monitored for temperature, humidity, and air flow. These factors are important because they affect the sterile integrity of a sterile package, as well as the functioning of medical devices and equipment. The environmental conditions of a sterile storage area are based on the standard ANSI/AAMI ST79:2017 & 2020 Amendments A1, A2, A3, A4 (Consolidated Text), Comprehensive guide to steam sterilization and sterility assurance in health care facilities, and the instructions for use from the manufacturer. While in the healthcare facility, the environmental conditions can be controlled and monitored; however, they may not be a consideration when transporting items from a healthcare facility, especially as a result of an emergency.

Challenges of Off-Site Transportation and Measures for Overcoming Them

Concerns related to off-site transportation may emerge. After a sterile item is transported away from the healthcare facility, it likely is exposed to uncontrolled environmental conditions that could cause damage or affect its sterile state. These uncontrolled conditions are present as an item is transported into and out of the healthcare facility and during its transportation. For example, if the transport vehicle is dirty, it could contaminate the item, and if the equipment is not secured, items could become dislodged, resulting in damage.

Medical device manufacturers test the transportation of their devices using standardized testing methods for the type of shipment required to move the product from the manufacturing plant to the end user. This often involves conditioning the shipping containers and devices to extremes in temperature and humidity, as well as shocks to the cartons from shaking and potential dropping of the shipping carton. This testing is done to ensure that a device reaches the healthcare facility in a condition that maintains its function for use.

Once at the facility, items are removed from the protective shipping cartons and placed into the system for processing and preparation for use. The packaging used at a healthcare facility is for sterilization (plastic peel pack, flat wrap, or sterilization container). Items are packaged as single items or in an instrument tray, an organizing set with holders, or a sterilization container. Of note, manufacturers do not test their devices outside of manufacturers’ shipping cartons in this manner to be transported over roadways to other facilities—unless this is a known requirement of the device’s use and is included in the device design requirements.

Rigid sterilization containers or organizing trays are designed to hold devices while undergoing sterilization processes. These same items are not designed to hold devices in a transportation truck to travel on roadways to another site. Use of these items may not protect the devices from shock and shaking to the same extent of that found with the original shipping carton. Medical devices are tested and challenged in numerous ways, and movement of them to other facilities may not immediately affect them during a few emergency transfers. However, frequent transfer—without the knowledge of the device manufacturer—may lead to functional or processing issues that may affect device use.

For example, a surgical power tool set with three tools, seven chucks, two collets, and an organizing case and tray is shipped to the healthcare facility in a total of 13 cardboard boxes that
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have been designed and tested for transport via truck or air shipment, in accordance with transportation standards. When they arrive at the healthcare facility, the cardboard cartons and internal packing material are removed and discarded. Those 12 medical devices that were shipped are placed in the tray and then the case and presented to the decontamination area for processing through the department. This configuration is tested to withstand the rigors of the processing for that equipment at the site; however, externally transporting it in this condition to another site, via truck or air vehicle, would lack the packaging as tested to withstand this type of transport.

The same holds true for the transport of flexible endoscopes. When flexible endoscopes are shipped from the manufacturer to the healthcare facility, they are packaged in tight-fitting foam, often in a suitcase type of container, to prevent breakage by holding them securely in place. This shipping case is kept in anticipation of future shipping of the endoscope (for instances such as repairs). Medical devices also may contain complex electronics, be fragile (e.g., microsurgical instruments), or have sharp edges that must be protected from becoming dull. Shipping of these types of devices without the appropriate packaging could damage the equipment, perhaps during the first instance in which it is transferred or after numerous transfers. The cause of damage may not be apparent to the manufacturer when sent for repair if the review of the external transport mechanism is not made known during the investigation.

Containers and organizing sets intended to be transported within a healthcare facility (e.g., between sterile processing and surgery) undergo a different type of transport testing. This testing is designed to mimic the conditions of healthcare facilities, which have controlled environments and fairly smooth-surfaced floors. In the previous example, the 12 items shipped to a healthcare facility in 13 boxes are placed into one organizing set and a container designed for sterilization, and this type of internal transport is considered as one unit. Devices within organized sets, such as k-wires, rongeurs, or cutters, could be delicate instruments with specific functions and sharpness requirements—requirements that would have been tested by the manufacturer under assumed normal use conditions. Unintended or undisclosed off-site transportation (over roadways) of these delicate items may limit the useful service of such devices if damage from this type of transport occurs.

As previously stated, device manufacturers are aware of intended distribution of items within a healthcare facility that has more standardized, controlled structures and environments; however, transfer or transportation of those same items to off-site locations, with or without the presence of a protective container or set with designated sections or bracketed positions, may not be the understood usage of a device and would not have been tested for such conditions. Off-site transfer of devices within uncontrolled transport vehicles has the potential to impart unintentional damage to a device that was not accounted for during the development process.

Communication and Setting Expectations
Consequently, communication becomes a key issue with the challenges of off-site transportation. If a healthcare facility does not have an internal sterile processing department (SPD) and understands that it needs to externally transport all devices for effective processing, this could directly affect the continued functionality or, potentially, cause damage to devices, depending on the shipping condition and awareness of the facility for transport care requirements. This is important information for the healthcare facility (as a customer) to share with device manufacturers to assess potential risks that might not have been addressed during product development. Continued communication between the healthcare customer and manufacturer could lead to scenarios where the healthcare facility that lacks an internal SPD conducts a risk assessment to determine the applicability of purchasing internal equipment for processing to avoid the burden and potential persistent damage to devices arising from external transportation.

Likewise, expectations of device transport to off-site locations are a key input for device manufacturers. Some configured sets (e.g., orthopedic instrument loaner sets) are easily identified and understood to be loaned equipment that travels over roadways to and from various facilities. For these sets, the device manufacturer designs the containment device to hold the set contents—following unboxing from original cartons and packaging—with brackets and holders for easier and safer

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transport. However, if the manufacturer sells sets of power tools or flexible endoscopes that were designed only with internal distribution within a single facility in mind, but the customer is shipping or transporting these devices to multiple off-site locations, this lack of communication and awareness could be detrimental to the continued use of those devices. Customer communication back to the manufacturer would aid the situation, allowing the manufacturer to proactively attempt to design a better system of transport and, potentially, a new containment device or case that could better hold and protect the equipment.

Conclusion

Shipping medical devices and equipment over roadways can negatively affect their functionality. This article has demonstrated how newly purchased medical devices are placed into packages that have been designed to protect them as they are shipped over roadways from the manufacturer to the healthcare facility. Once acquired by a healthcare facility, medical devices may only be shipped over roadways one time for an emergency situation or occasionally shipped over roadways. Conversely, some healthcare facilities use a centralized processing facility; this results in the continuous external roadway transportation of medical devices and could cause a device to be transferred over a thousand miles.

Healthcare facilities may transport medical devices off site using roadways for a variety of reasons, and it is prudent for the facilities to inform device manufacturers that their products are being shipped externally over roadways. The manufacturer may caution the facility that damage could occur to the item during transport. If the manufacturer is made aware, however, it may design a better containment system or even include external transportation as a design consideration.

As issues regarding processing medical devices continue to evolve, it is apparent that users (healthcare facilities) and device manufacturers need to communicate. At this time, many of the issues regarding external transportation of medical devices over roadways are unanswered. A new technical information report, AAMI TIR109, External transport of medical devices processed by health care facilities, is being developed by AAMI to address these issues. The content of this new TIR is based on collaboration among healthcare users, medical device manufacturers, and regulators to open conversations on these and other issues related to external transport—and to develop a method for healthcare facilities to transport medical devices safely and effectively over roadways.

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