

Supporting Medical Devices during Unprecedented Challenges

Roundtable Participants



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Crothall Healthcare.

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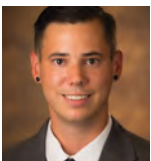
Clair College.

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Davis Medical Center.

Michael Marchant is health information technology director at UC



Dustin Smith, CHTM, is a senior solution consultant at Nuvo.

Gavin Stern The coronavirus pandemic has been putting tremendous strain on the healthcare system overall. What has your experience been, and how might this have changed the way you're servicing medical devices?

James Linton I teach at a college, and there have been large changes on how we're training people to work on equipment. We're going to continue these changes. While we'll still teach hands on, we are developing online learning for working on equipment. I've started focusing on customer service, and teaching students, "Here's how to give help over the phone."

We're trying to move to a world where we prepare for the pandemic and being able to work on equipment in a way that reduces site visits, and get better at communicating with staff on sites. We're also trying to build up our virtual reality (VR) right now, so we can try to train staff as opposed to sending people all over the world.

Jeffrey Ruiz The reallocation of devices is straining hospitals. This is coming pretty fast, and a lot of organizations just don't have the capital to say, "I need to order 50 patient beds," and start having them delivered and build an addition to the hospital. What you're seeing now is, what projects do we have right now, what can we hold off on, and what devices can we reallocate? Not only just reallocate those devices, how are we going to make them integrate with the systems that we have currently? We have electronic health record (EHR) scenarios, we have nurse notification systems. Not only is it taking it from one location to the other, we want to make sure that we're working with our brothers and sisters in the IT space, to make sure that we're communicating with them, making sure that these systems are tested and working properly in these new locations.

Michael Marchant On the IT side, we're trying to figure out how to do a lot more

things remotely. At UC-Davis, we have about 500 folks in our IT shop, and we went from about 50 people working remotely part time, to 450 people working remote full time, along with supporting 4,000–5,000 other staff members in the organization, who by rule in California, have been asked to shelter in place. We're investing in technology like VPN tunnels, Citrix clients, virtual desktops, and physical laptops. We have dual authentication security that requires you to authenticate with the device in your hand, so if they didn't have a health system issued cell phone, we needed to get them a phone so they could authenticate and maintain security policy. There are a number of things we are focusing on to just to continue normal operations, as well as things to support COVID-19 like surge capacity planning, increase in telehealth visits, and adding and/or integrating ventilators.

One the projects we're expediting that's been on our radar for a long time is our ventilator interoperability—getting data from the vents into our EHR—and by getting more vents integrated, that allows the respiratory therapists to review and document the data generated by the vent without having to go into the room and use personal protective equipment (PPE), which we know is in short supply. If we can get these vents up and running and integrated, we can minimize some of that usage for that particular purpose.

Jennifer DeFrancesco Within the past year, we've become a lot more proactive in capital planning, and that's paid unexpected dividends for our surge planning. We implemented a fleet management standard, in which we identified the fleets within the system that are most critical for continuity of operations, and have a phased replacement plan for those fleets. Many of those systems included key equipment needed for the COVID-19 surge. Much of that equipment was actually hitting our doorsteps as we started this surge, and we were able to retool equipment to provide additional capacity.

We focused on preparation through the

lens of critical system strengthening and learned from our brothers and sisters in China and Italy and what they had done. Much of my focus was on my clinical engineering IT team—strengthening that team, because it's one of my smaller teams, but also strengthening those systems, getting expanded training out, and leveraging our CE/IT CompTIA IT Fundamentals training, turning every biomed into tech level ones during a very short period of time.

Because Crothall has earned ISO 13485:2016 certification, we already had segregated areas set up for cleaning equipment and all of those things in place, which gave us a leg up on safety and sanitization. We were able almost immediately to test all of the off-label functions of anesthesia machines, vents, and other devices and we were able to reach out to our community partners and receive ventilators from other locations and check those in.

We also took steps to proactively preserve PPE through device setup. For some of our vents, we're able to take off the fronts and mount them to the IV poles outside of our isolation rooms. I think that's one of the most notable things I've recognized as a result of COVID-19, from clinical engineers and healthcare technology management (HTM) professionals, is the ingenuity and the problem solving that's going on.

Heidi Horn One of the things that happens in these types of crises is that you have to coordinate between multiple departments. In talking to our clients, we're seeing a lot more of them having to put up, for example, temporary patient care areas that were not being used for patient care areas before, and having to work with the facilities departments, with the IT department, with the HTM department. More than ever, we're seeing this essential coordination between all the different groups happening.

Another challenge that we've heard from international companies is when we have all these people working from home, we take for granted in the U.S. that people can easily set up a home office with Wi-Fi. That's not always the case in other countries, where it's not as common to have that infrastructure.

Gavin Stern As this pandemic grows and the response to it grows, healthcare systems are taking on lots of new devices in a really short period of time (e.g., ventilators). What are some of the strategies to support all that equipment that's coming in, while addressing existing needs?

James Linton In the education setting, a lot of students had their internships cancelled and that's sad. Recently, I mentioned to a local hospital that I have 30 grads looking for work. That hit home with them—could these graduates work on an emergency basis? I put together a list and reached out to other hospitals. I've had a tremendous response! Within days, more than half of my students got job offers, because hospitals are starting to realize that biomed students get sick, too. Losing even a couple can be horrifying. Plus, it really doesn't hurt to pay a young biomed to do some of the lighter lifting, which frees up senior techs during this pandemic.

Jeffrey Ruiz We heard of a lot of joint ventures between ventilator manufacturers and nontraditional healthcare manufacturers. When we have tens of thousands of ventilators hitting the market—are we going to inspect those when they hit the door? Some of our other hospitals in our state have received ventilators from the Federal Emergency Management Agency that are ready to roll, but the oxygen and med air supply lines were not there. That has led to a last-minute scramble to source for parts and supplies. There's a lot of work that's going on right now to try to make sure that these machines have everything they need so they are operating properly and safe for use.

James Linton Jeff is right to be concerned. As much as industry wants to make a medical device, they do tend to step on the biomed. They don't always want to listen to our concerns. If you're buying a medical device from an auto manufacturer, it is going to cause a strain on biomed. We need to have very strict incoming inspections and guidelines and even look at their PMs.

These companies are getting into medical, and they seem to not understand

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the strict guidelines. It's my belief that a lot of these companies don't actually have biomed staff that are looking through it and saying whether everything is up to code or not.

Michael Marchant The ability to communicate clear requirements is essential. That's one of the things that we're dealing with as we add new equipment, or we add new devices and testing. We went from no COVID testing to doing 200 to 1,000 tests a week in a relatively short period of time. People underestimate the need for clear leadership and project oversight and communication on those things. That's a main barrier that causes some of these initiatives to fall or be implemented in a less optimal way.

Before we deploy technology, it becomes our responsibility to ask those questions, make sure we've got clear requirements, document those things, and clearly communicate to the organization.

Jennifer DeFrancesco We had ample time to prepare and see how clinical engineers were so crucial to COVID-19 response, particularly in Italy. That gave us an opportunity to go back to basics—to work ahead and do everything we can to prepare for the uncharted territory ahead of us. A lot of biomed staff will wait until the last few weeks of the month to get their PMs done—we started seeing our teams start within the first week getting 60% done.

Another area that really helped was having a solid, well-established process to intake equipment and to get it into our inventory quickly and accurately. We also realized the importance of our process for tracking where we're transferring items within our system. That process has been instrumental in making sure that we can locate equipment, and know when it's due for maintenance after we get through this surge.

Gavin Stern How is meeting Joint Commission deadlines for 100% PMs for critical devices working during this crisis? Do you feel that additional AEM guidance is needed in this area?

Dustin Smith The Joint Commission is big on documentation. If you have policies in place governing the way you're going to handle "do not locate" or it was on a patient at the time the PM is supposed to be done—if you're closing out your work order within the appropriate period—you're still meeting that 100% documentation. You will need to go back and redo the PM. The biggest thing is having an awareness of exactly what's going on.

As Jennifer said, it's key to work ahead right now. Do not wait until the end of the month to do the PMs, because that's when you're going to be caught off guard, and when you're not going to have the ability to fulfill. If you have a leadership team that is prioritizing, start the PM when the asset is available. If we're proactive as a community, we can stay on top of this.

Jeffrey Ruiz At our hospital, we split our team into two "3 × 12" shifts, where each works three days a week for 12 hours each day. With the added coverage at the end of the day as well as the extra day on the weekend, and coinciding with the hospital reducing elective surgeries, it's actually given us better access to PMs. Especially those areas that have been traditionally busy. Mind you, this was after we already had performed a series of "flash" projects to prepare for COVID patient surge.

Jennifer DeFrancesco We really decided to be incredibly transparent as to the impact of COVID-19. Crothall instituted a code for PMs impacted by the pandemic so that we could easily identify which devices vendors couldn't come out to PM due to the novel coronavirus. We are documenting these, but not lumping them into our general "unable to locate" or "in use" so we can report them separately through the EOC and other governance structures and document for regulatory compliance. We also split our teams into two working from 6:00 a.m. to 1:00 a.m. daily, which allows the second shift to focus on the PMs and urgent calls.

Gavin Stern What would you say is the greatest servicing and support-related issue that you're facing right now?

Jennifer DeFrancesco Our biggest servicing issue right now is intaking all of the new devices we are receiving, identifying if they're usable, if they are coming from alternate sources (e.g., from community), and fixing them. They're off-brand devices from our normal system standard, they're things we're not used to, which requires additional learning, education, and parts supply chain.

Jeffrey Ruiz In our state, we're facing the definition of what is essential work and what is nonessential. We're working with the vendors we have service agreements with and getting notified that due to Coronavirus, they can only perform essential work on our devices. We're working very well with these vendors in getting documentation indicating their restrictions. We are using this documentation to support why a PM may be open.

Dustin Smith One of the issues that we frequently ran into in my previous role at Intermountain Healthcare is that you continue to have more and more network-connected assets, you're starting to see more and more remote monitoring and troubleshooting solutions. The OEMs, unfortunately, often are not willing to give up access to that. You can't access the same tools that they have. I think it inhibits our ability to do our best work.

James Linton In the school environment, I'm teaching students how to conduct PMs, and I'm sometimes unable to get manuals to just teach my students how to use the equipment. It feels like we're still fighting that age-old right-to-repair battle.

Gavin Stern We've heard in the past of difficulty with receiving documentation from manufacturers. Has that situation changed? If you saw improvements, were there strategies that you used to help make that work better?

Jennifer DeFrancesco There's been kind of a priming of the pump with this, with The Joint Commission including one of the

Elements of Performance in the EC chapter that we have a document library. That's supported us in our ability to get manuals, and we are fortunate to have a subscription to a vendor who pulls this together in a repository. However, we still run into the oddball items where we cannot find repair manuals.

During the Coronavirus, vendors of critical equipment have been more forthcoming with solutions, such as how to use a device off label. You really couldn't imagine that happening if we weren't in emergency.

The only negative I've seen during the crisis is that sometimes enthusiastic engineers from a vendor have solved problems and can offer you a solution, but their legal team isn't ready to officially take that on and provide you with something in writing.

Gavin Stern What's been your experience regarding the availability of training for new equipment? Have any of you seen cutbacks or investments when it comes to that training?

Dustin Smith When it comes to training, get that written into the purchase order or the contract that governs the acquisition of the assets you want to be trained on, and have it priced in. Oftentimes, that's going to be the easiest time to get training, and you can often get it at a discounted rate.

When you have the clinicians on board saying, "This is the asset I want," and if you can work with supply chain to leverage the clinician's desire, then you can often get that training built into that actual acquisition, and then you don't have to think about it after the fact. If it's rolled into the capital purchase, now you're not going to be trying to delve into your own operational funds to figure that out the next year, or two years afterwards, and that also gives you the ability to do first looks, while you're under warranty.

James Linton I agree. If you ask for it during the sales pitch, it's going to get thrown in because that sales person just wants to make the sale. You don't want a dime holding up a dollar. It's vital to make sure that a biomed is sitting at the table for capital planning. As far as the availability of

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training on new equipment, it seems to be a lot more available. However, it seems like it's a lot more expensive now. I noticed that there is more training available in online or VR settings. You pay for the VR training, but then you don't get to keep it and retrain yourself later, either.

In my role outside of the college, I always pushed a lot of cross-training, because training is expensive, especially if you don't put it in that initial purchase request.

Heidi Horn One trend I noticed is that you go to the training, but it's only good for a limited time, and then you have to get your staff retrained in order to get the support and benefits you need from that.

Will there be cutbacks or investments in HTM? It will be interesting to see what happens after the dust settles with COVID-19, because revenue generators like surgeries and diagnostic imaging studies are getting postponed or canceled altogether. Obviously, I think the prediction is that a lot of the hospitals are going to be in a world of hurt as far as revenue and covering their costs.

Unfortunately, in HTM, the biggest expenses are always the staff and the training. Experience has been that, when push comes to shove as far as cutting staff versus training, the training is what gets cut. It'll be interesting to see if this will be the case at a lot of hospitals and HTM departments going forward.

Gavin Stern How are HTM departments innovating when it comes to servicing devices, as costs increase and budgets are shrinking?

Heidi Horn A couple things need to happen. One, HTM departments need to understand the value of standardization and the value of truly coming up with standardized, centralized processes for doing things. Especially if it's a large health system and you have multiple HTM managers at different locations, they'll often spend their time reinventing the wheel. If you can centralize and standardize those processes, and you have a valid procedure that works, you are saving yourself a ton of time and effort and money just doing that.

The other piece I think is important is the value of the AEM program itself. AAMI released an AEM guide that was looked at and approved by many folks in the industry as a valid process for servicing your equipment. What it tells us is that you don't necessarily have to follow the manufacturers' PM guidelines on devices where it does not make sense. Obviously, that excludes the diagnostic imaging, lasers, and new equipment. Sometimes, many of these PM procedures and frequencies don't make a lot of sense. As anybody who has been in the industry for a long time has found, a large number of PM tasks that we do, I would say, are "busy work."

Validating and analyzing what are the PM needs of certain equipment, what are the frequency needs, and addressing the needs versus what you just think you have to do because it's in a manual somewhere, is important. By doing that, you can significantly cut down your workload of "busy PM work" that doesn't improve the equipment's safety and reliability and focus on those PMs, CMs, and other activities that are absolutely critical to get done. That's my high horse, and I'll get off of it.

James Linton I would echo everything Heidi said. When I was national director, I had 10 shops across the country and a big gripe of mine was, I'd go out to the East Coast and we'd do a PM completely different than the West Coast. One of the main reasons I was hired in that role was to change that.

I set up so that a biomed would come to a piece of equipment, scan it into the computerized maintenance management system (CMMS), and it would bring up step one of the PM. They'd click pass or accept, put in the value, then go to step two. That really standardized everything, but it also allowed me to see who is cutting corners, how long should it take, and it allowed for so much more pulling of metrics to say, "You know what? In all of these IV pump PMs, we're only seeing problems show up every one and a half years on average. Maybe they don't need to be a six-month PM like the vendor says."

Jennifer DeFrancesco In the spirit of “back to basics,” similarly leveraging our CMMS data, we have a huddle every morning where we’ve customized reports and we go through pretty much everything you can possibly think of, our calls from the day before, how many were closed, how many are still open. We’ve added and amended those, based on COVID right now. How many vent repairs we have, how many vents are in use, other emerging critical device alerts. I think in many ways just kind of that look at the basics and say, “How do we use all this data? How do we distill a lot of that data into a super impactful five or ten minutes every morning so that we can escalate that up?” That information actually gets summarized and sent up to C-suite leadership on a daily basis, just so they have a high level of what’s going on with our entire fleet of equipment.

Dustin Smith The biggest thing is to leverage data. I think the HTM community is finally getting around to that and essential standardizing. People are taking it seriously, and we’re starting to see the fruits of that work, because it’s a hard task. Another thing—make sure you have the right talent to the right task. You can have a PM engineer and they’re not going to have to have the same capabilities as an engineer that’s doing corrective maintenance.

It’s also important to share resources. A lot of healthcare delivery organizations (HDOs) are incredibly large, and you’re covering either large campuses or geographic regions; don’t be afraid to talk to other managers and supervisors. Jennifer mentioned that all of her engineers are now level-one techs who can work with IT. That gives you the capability to essentially move the resources where they need to be.

Jeffrey Ruiz Along with a robust cloud-based CMMS, the ability to have technical resources available to the technicians at the right time is huge. Instead of a technician dragging a service manual to the device, we now have capabilities of virtual service manuals (specific to the hospital) and key technical checklists. Essentially a master service manual in your pocket.

It’s also great to see that many technical

community resources and list serves that are out there today for the HTM field to ask and answer technical questions. And, with the prevalence of smartphones, technicians can have video chats with their fellow technicians for real-time virtual support.

Gavin Stern As healthcare systems are continuing to grow in size and scope, what are some of the cutting-edge practices that you see, when it comes to managing all those different devices over such large distances?

Dustin Smith A lot of this is going to continue to evolve around data. We need to be able to also integrate the CMMS to the EHR, for example, so we can start utilization tracking. That’s going to be a massive benefit. Then in terms of being able to get the assets where they need to be, HDOs need to have real-time location services. Those are two data elements that will dramatically change the way we’re doing business and our ability to effectively get assets to the patients that need them.

As we continue to get the CMMSs more and more loaded—more robust—as we increase our reports, our sophistication level goes up, and we’re going to be able to make engineers more and more effective as we get additional data points.

Michael Marchant As the COVID-19 crisis has lead to an increase and acceleration of organizational telemedicine initiatives, we’ll need to look at the sophistication of our technology and the types and number of devices that will be deployed outside of the organization. We will need to ensure they have the capacity to be remotely monitored. We’ll also need to address how we remotely maintain and monitor equipment that might be out in the world in patient or provider homes or businesses. As we add new devices, and add new real-time clinical data elements generated by those devices, we need to make sure it is getting back to its home provider, chart, and EHR. Whether it be patient monitoring, new social determinants of health, or new devices that don’t exist today, there must be a collaborative effort that creates a capacity to

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—Jeffrey Ruiz, HTM director at Holland Hospital.

bring those devices into an organization, make sure that they're maintained appropriately, and ensure there's consistency and accuracy of data as it gets back into the health system.

Gavin Stern Are there any other topics that we haven't covered yet?

Heidi Horn What AAMI does is great as far as bringing people together. But as an industry, we still could do a lot more to learn from each other and share information and best practices. It amazes me, especially in my role working with so many HTM departments nationally, the variety of ways HTM professionals are trying to solve problems that other organizations solved five years ago.

You would never see an airline say, "I'll figure out on my own how to fly, how to build a plane, or how to do this sort of thing." And yet we still try to figure out everything ourselves, whether it's the proper way to inventory equipment, to risk-score devices, and even what to call ourselves—HTM, clinical engineering, or biomed. Getting to a point where we can truly start identifying best practices, start sharing best practices, documentation, procedures, all of those things, so that we can elevate the entire profession—that's my dream for our industry.

Michael Marchant Part of the art and science behind the blending of devices and the data from those devices that create clinical information is creating an environment where traditional IT and the engineering groups work better together in a more collaborative environment. The preponderance of organizations, including my own, have an organizational structure with HTM and IT groups as two separate, non-integrated departments who follow separate processes, and manage information and technology differently. As we move forward, device and data interoperability will become the care standard and organizations will need to create structures and processes that bridge those gaps and ensure they are operating as effectively and efficiently as possible.

Jeffrey Ruiz I share the same concern Michael has on the relationship between HTM and IT. We are very fortunate at our hospital that HTM reports up to IT. I know we will always have break/fix repairs, but as we see more and more systems integrating, we are being called to troubleshoot these systems. The relationship between HTM and IT is more important than ever before.

But we also cannot overlook our HTM and facilities relationships as well. As we are seeing today with the COVID crisis, there is a lot of collaboration that occurs between HTM and facilities as far as opening floors, ensuring rooms are negative pressure, and confirming the med-gas infrastructure can supply all the ventilators connected to them.

The HTM community is right in the middle of it all. Let's be there for one another, share our stories, and show the world what HTM is all about.

Jennifer DeFrancesco One of the things that we have been really cautious about is all of the off-label items that are in our future phases, if this surge hits harder than anticipated in our area. We put together all of the off-label items and we walked through them with clinicians. We thought through what consumables we'd need, and what safety issues we can take out of the equation. For example, we identified several consumables that need to be replaced more frequently if anesthesia machines are used off label as ventilators. We also unhooked all of the anesthetic gases and connections as an additional precaution.

Biomed should make sure they have a plan put together well before you're in the surge. Make sure you think through what you may need or additional challenges that may be posed to clinicians and to you. Obviously, make sure the hospital's legal team has reviewed and approved it as well.