A Roundtable Discussion…

New Community Aims to Provide Guidance, Leadership on CE-IT Issues

Ray Laxton, Moderator

This year, three national organizations joined forces to create the CE-IT Community, a collaborative effort to help healthcare technology management professionals grapple with the challenges and opportunities resulting from the convergence of medical technology and information technology (IT).

Recently, leaders from the three organizations—the Association for the Advancement of Medical Instrumentation (AAMI), the American College of Clinical Engineering (ACCE), and the Healthcare Information and Management Systems Society (HIMSS)—took part in a roundtable discussion to explore the big-picture issues driving these changes and the implications for medical device professionals. What follows are highlights of that discussion.

Ray Laxton: Let's start from the beginning. What prompted this collaboration?

Joyce Sensmeier: All three groups were previously working on a number of initiatives that intersected. We felt that this collaboration was a wonderful opportunity to pull together our resources and leverage them to create a space for the clinical engineering and the IT communities to work together.

There are many challenging problems emerging now related to medical devices. New standards and regulations are being developed, and we need to provide input. There is a lack of integration between technologies, between systems and hospitals, and within hospital departments. There is also a need to develop best practices in these areas.

Steve Grimes: There is a shared area of interest because of the convergence we're seeing in medical, IT, and telecommunications technologies. We need to better understand the implications of this convergence for our industry and how to address some of the challenges associated with it. We want to ensure that we can deploy and support these systems that combine IT and medical technologies safely and effectively.

John Hughes: This group has the opportunity through this arrangement to be the consensus-building organization and to open the necessary lines of communication among providers, IT professionals, clinical engineering professionals, manufacturers, and other stakeholders to find the best solution to deploy this technology and man-

Roundtable Participants

Ray Laxton is executive director of client services with ARAMARK Healthcare CTS. He was the founding chairman of AAMI's Technology Management Council, and currently serves on AAMI's Board of Directors. He was previously a member of the BMET Task Force.

Ted Cohen, CCE, manager of clinical engineering at UC Davis Medical Center in Sacramento, CA, is an authority on deploying and supporting medical device networks. He has presented and written extensively on a variety of clinical engineering subjects. He is a former member of the boards of directors of AAMI and ACCE and currently the co-editor of *ACCE News.*

Izabella Gieras, MS, MBA, CCE, CSSBB, is director of technology management for Beaumont Hospitals in Royal Oak, MI. She also heads up Beaumont's usability center, which focuses on helping medical device manufacturers improve their products before they are released to market. She is a member of AAMI, ACCE, and HIMSS.

Stephen L. Grimes, FACCE, FHIMSS, FAIMBE, is the immediate past president of ACCE and vice president of enterprise resource planning with Technology in Medicine, based in Holliston, MA. Grimes is an authority on security and risk assessment of networked/integrated systems.

age it in our facilities.

It's incumbent on all of us—whether we are clinical engineers, biomedical equipment technicians, or IT professionals—to understand the issues and to collaborate to find solutions.

We have an opportunity with these three groups to model the way we would like to see the industry behave in approaching this issue.

Laxton: Are any of you undertaking activities that tie into this initiative at your own facilities?

Rick Hampton: Partners HealthCare has several projects that fall in this realm. We have formal committees working to converge these technologies and getting them to function in the real world. We're ready to begin testing on several projects to see how we can connect various medical devices and IT systems with actual hardware and software, working under IEC 80001, *Application of risk management for IT-networks incorporating medical devices.*

Bob Stiefel: At the University of Maryland Medical Center, we've got a few interesting projects under way with IT and a research lab in conjunction with the military. They involve combining medical, IT, and telecommunications technologies to develop applications for the hospital and for this research lab. It has been a great opportunity to work with a variety of highly technically competent people from other professions.

Izabella Gieras: At Beaumont Hospitals we're starting a joint project among clinical engineering, IT, and telecommunications to look at the impact of the integration of medical technologies with our communication technologies. We're specifically looking at how the different alarms are managed between physiological monitors, nurse call systems, infusion pumps, and so on, and how they integrate with our communication devices, such as Spectralink phones, Vocera voice badges, and pagers. Ultimately we're hoping to examine the impact that this integration has on the caregivers' workflow and on patient safety at the end of the day.

Ted Cohen: At our facility we are already working to pull all these groups together. We in clinical engineering collaborate with our IT department, where we're trying to get our vendor partners to first document their best practices. We're comparing them to IT industry and medical device company best practices, and in joint meetings we evaluate them to identify where they're out of sync.

For more information about the CE-IT Community, a collaboration among AAMI, ACCE, and HIMSS, visit www.ceitcollaboration.org.

Laxton: What progress is being made in the area of integration of systems and devices in a multi-vendor environment, and what challenges remain to be tackled?

Sensmeier: The Healthcare Information Technology Standards Panel (HITSP), which is a government initiative, has received a Use Case this year focused on remote monitoring that presents a real opportunity to bring together those who are involved with developing standards around that topic. HITSP is a cooperative partnership between the public and private sectors formed for the purpose of harmonizing and integrating standards that

Rick Hampton is wireless communications manager at Partners HealthCare System in Boston, MA. His role is to ensure that wireless technologies, both old and new, function properly and, where applicable, increase the safety and efficacy of patient care.

John Hughes, MS, corporate director of contract administration with Bon Secours Health System Inc. in Marriottsville, MD is an industry pioneer and major proponent of CE-IT collaboration and integration. He is a member of AAMI, ACCE and HIMSS.

Joyce E. Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, is vice president of informatics for HIMSS, the country's largest healthcare association focused on information technology. She oversees clinical informatics, standards, interoperability, privacy and security, and professional certification.

Robert Stiefel, CCE, is director of clinical engineering at the University of Maryland Medical Center. A pioneer in the field of clinical engineering, he most recently served as chair of AAMI's Board of Directors.

will meet clinical and business needs for sharing information among organizations and systems. Representatives from the Continua Health Alliance, the Integrating the Healthcare Enterprise (IHE) initiative, and the Institute of Electrical and Electronics Engineers (IEEE) have been involved with these conversations. It's a great example of industry activities going on right now that require the multiple perspectives of those within this community to solve problems.

Hampton: The challenge that I keep running into is the different perceptions between the medical device industry and the IT industry. The IT industry seems to have a no-holds-barred attitude when it comes to making claims for their products. IT vendors come into a hospital and make claims like, "if you purchase our products and connect these things together, then look at all the miraculous solutions we can provide you."

On the other hand and contrary to the IT vendor's experience, the medical device manufacturers are held closely accountable in the regulatory arena for any claims they make. In the medical device world, there are significant issues to overcome concerning device connectivity and sending alarms, for example.

Now in the middle, the hospital will have to make up for the differences in expectations and risk management held by these two industries.

An enormous benefit of this collaboration would be to educate the IT world that it's not really as simple as connecting boxes together, and they must work with the medical device manufacturers and hospitals to properly set expectations and address the risks associated with the convergence efforts. My hope is this collaboration will help to address the differences between these two industries and bring them closer together.

Grimes: Conversely, on the medical device manufacturer side, we are challenged by manufacturers who still insist that their systems be deployed as individual systems, running on their own infrastructure, requiring us to buy not only the medical device but also the associated routers and servers. A medical center I worked at a few years ago had 140 servers all running on their own proprietary networks.

That's not manageable. We need to get the manufacturers to work with the IT industry to help us define standards so that if we build an infrastructure according to an agreed-upon standard, they would be willing to put their medical devices on it. That coordination would allow us to better manage these networks, as well as take advantage of some of the redundancy and robustness that we can get from having an integrated system that will allow multiple devices from multiple manufacturers to run on it.

Hampton: I think that old concept of separate proprietary networks is going by the wayside. We're seeing progress, but it's slow progress and there are challenges—specifically, the misunderstanding on the IT vendors' part that all you've got to do is just simply connect things together and they will work. Most of the device manufacturers I've been talking with agree we need to get away from the proprietary systems, but it can't happen simply by following the current marketing of the IT industry. Instead, they council much greater attention to planning and risk management.

Hughes: At Bon Secours Health System, we are currently implementing a system-wide clinical information system. As part of this project we did an inventory of all of the interfaces across the system. We found that more than 1,000 different interfaces were being maintained. Our IT folks and the project team are working diligently to reduce the number of interfaces that will be necessary, but this is a prime example of the effects of the lack of standards and the lack of real interoperability.

We are nowhere near plug-and-play interoperability. Until we can agree upon some standards for that interoperability, these challenges are going to remain.

Grimes: My hope is that this collaboration and these initiatives will result in a set of standards that will allow us to build an infrastructure that we would identify as a medical grade network, and all of the manufacturers will agree to have their products placed on that network.

Hampton: I agree with Steve, but caution that the system he describes with the term "medical grade network" is not equivalent to, nor should it be confused with, the system described by the same term in the current marketing campaign of one of the leading IT companies. There is still a lot of work to be done to achieve the system Steve describes.

Laxton: New standards and regulations are on the way. FDA has issued a proposed Medical Device Data System

(MDDS) rule that changes the way it regulates these systems, and a new draft standard—IEC 80001—is under development. How will these documents affect medical technology professionals?

Hampton: IEC 80001 is aimed at the hospital and how they should assess risk when they connect medical devices to the IT network. I have been involved in the preparation of that document and am already starting to put some of its requirements into practice. In my opinion, the changes impact the clinical engineering and medical device manufacturers less, and the IT industry and IT departments a whole lot more. Many of the risk management activities it requires are aimed strictly at making the IT network perform like a true medical device.

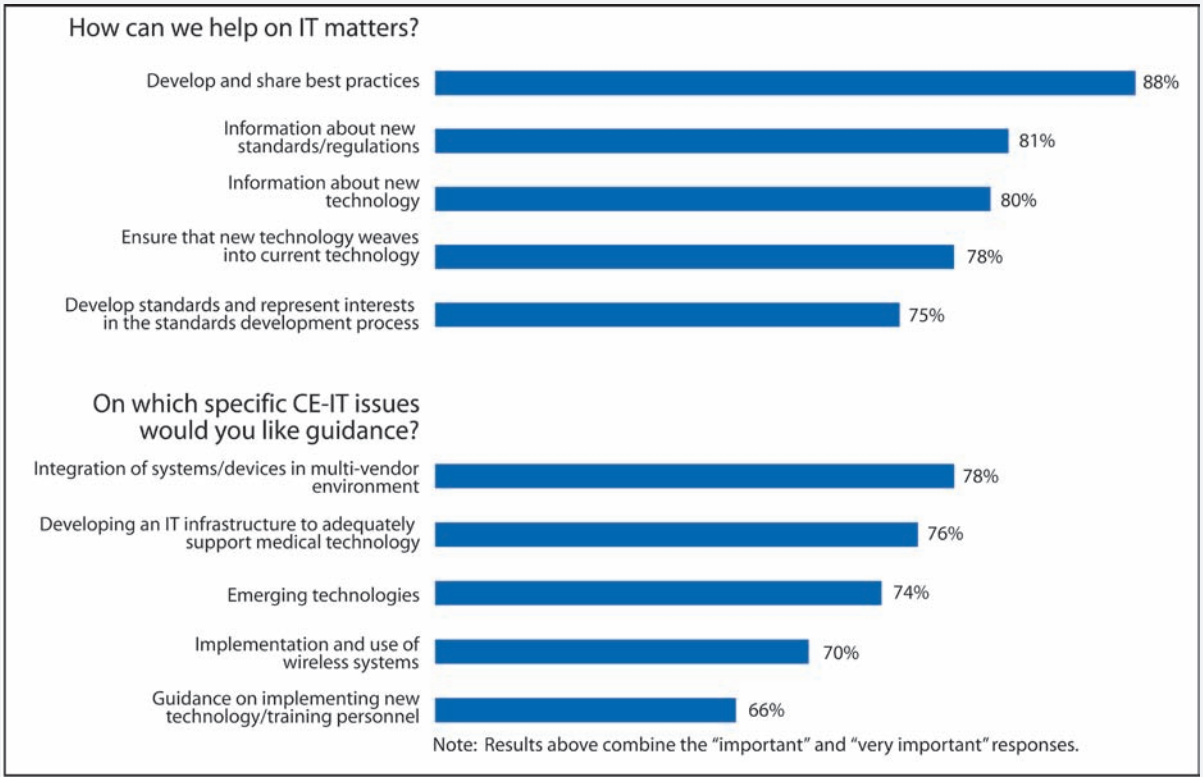
The new MDDS rule from FDA will have exactly the same effect. It is going to require the IT vendors, the IT industry, and the IT departments to start playing

Results from the CE-IT Community Survey

Medical technology and information technology (IT) professionals are hungry for information on emerging technologies and guidance on the integration of IT systems in the healthcare environment, according to the results of a major new industry survey. The online survey was conducted recently by the new CE-IT Community, a coalition of AAMI, ACCE and HIMSS. The survey—which attracted more than 470 respondents—was developed to identify the major needs facing the members of the three organizations, so that the CE-IT Community could then address those needs through several specific projects in the months ahead.

According to the survey results, the overwhelming majority of the respondents want the CE-IT Community to develop and share best practices and to be kept informed about new standards and regulations and new technologies. In addition, respondents said it would be helpful if the CE-IT Community helped ensure that new technology weaves into current technology without precluding connectivity in the future.

The respondents also expressed strong support for sharing business plans, goals, and mission statements between IT and clinical engineering groups, and a desire to gather diverse stakeholders to discuss IT issues of mutual interest.



according to the same rules as the clinical engineering department and medical device manufacturers.

Cohen: There's a benefit too that it forces the IT companies, and perhaps IT departments, to get educated about what the FDA requirements are and are not.

On both sides people use FDA as an excuse. In some cases the IT industry doesn't understand and in many cases does not want to get involved in anything that has to do with FDA. They move up to that edge as close as they can, and then they back off.

Gieras: These documents could present an opportunity for the clinical engineering and IT departments to come closer together, to strengthen those partnerships as they are forced to work together on some of these initiatives. The clinical engineering departments have experience dealing with FDA and different medical device-related standards and regulations, while the IT side hasn't had that type of exposure. As we look outside to the relationship between vendors and the hospital we also need to make sure that we are ready internally with our own partnership between the medical device professionals and the IT side.

Hampton: There will be ample opportunities for educating the clinical engineering staff as well. While CE departments have dealt with FDA in many different ways, very few hospitals have dealt with FDA in the role of an actual device manufacturer, and that's possibly where the MDDS may take us.

Grimes: IEC 80001 applies the risk management process to the full life cycle of the device—from development and manufacturing through use and deployment in healthcare facilities. It's one more excellent guideline that we can use to examine the implications of deploying some of these complex devices that, because they are part of a system, have additional vulnerabilities that standalone devices don't have. All of these documents are pushing in the same direction of focusing on risk management and security management of the systems and the information that's exchanged between them.

Hampton: The MDDS rule and IEC 80001 are essentially two sides of the same coin. At Partners we're actually looking at how to address the MDDS requirements using 80001.

It's imperative that the IT and medical device industries see those documents linked in just that way. The clinical engineering groups and the IT groups in hospitals are going to have to work together to understand how to meet all those goals. We are already working on educating our organizations about these two documents as part of our integration operations.

If we really want the MDDS and 80001 to become an integrating function, then the IT industry and IT departments need to see that their intended functions are as important as rolling out an electronic medical record (EMR), or determining how to work the billing cycles. I would like to engage chief information officers (CIOs) in these issues as heavily as clinical engineers are engaged.

The requirements for convergence are going to hit the IT community as hard, if not harder, than the clinical engineering community because the cultural changes for IT will be greater. We need to have the CIOs sitting in on some of these presentations so they understand what's coming down the tracks at them. If we get the CIOs involved, we will have more participation in these efforts and we will actually be able to make some headway.

Hughes: I would like to challenge not only the folks in this discussion, but more importantly the membership of our organizations and the readers of this article to personally go and have these conversations with their CIOs and attempt to get them involved in the issues. If we got even two or three CIOs involved who really wanted to dig into this issue with us, we'd be much further ahead. Unless somebody creates that relationship and a sense of urgency around the issue, it's not going to happen.

Sensmeier: With this new collaboration, we now have a designated activity to get us focused on pulling together IT professionals with clinical engineering professionals. The main goal of this new collaboration is to do just that. We're forming working groups right now, focused on some of the key areas we learned in our survey across the CE-IT community. We can work together to get these issues addressed at all levels.

Hampton: One final note on the topic of IEC 80001: the 80001 standards group has heard very little from the hospital or the clinical engineering sector and virtually nothing from the IT industry. Even if you can't travel, you can

still participate. You can always submit written comments, and those are taken into consideration just as if you were there in person. People from both the IT world and the clinical engineering world need to get involved.

Laxton: How can we develop an IT infrastructure to adequately support these new technologies?

Hughes: One of the real challenges is going to be how to extend the infrastructure to the non-acute care facilities. So much of the growth in healthcare systems is going to come in the areas of long-term care, ambulatory care, ambulatory surgery centers, and imaging centers. Integrating the data from all of those facilities into the patient medical record and billing, for example, is an extreme challenge right now.

Hampton: Groups like the Continua Alliance are trying to take those networks out to the home, to the workplace, even to the street corner. Virtually every new, interesting application we can list is presenting problems for which no one really has answers. That's not necessarily bad, it's just the nature of the beast when you're inventing new technologies.

Grimes: To support these new technologies, infrastructures will have to be expanded, improved, or built from scratch. Our healthcare organizations will have to think more strategically. We're past the days when the deployment of a new device only affected its immediate area. Many of these new acquisitions have strategic implications, and we need to get much more strategic in our thinking on how we acquire and deploy them, and what the implications are for the rest of the organization.

Stiefel: We have run into many of these issues in dealing with the smaller startup companies that have very clever ideas. For example, it seems like all of the new robotics systems that we're interested in are coming from very small companies that don't have experience dealing with these issues. They will initially downplay questions about technical needs, hardware needs, and infrastructure needs, but when it comes to actually implementing the new technology, they say, "Oh, by the way, we need another server or we need a dedicated line."

This has happened to us more than once. It is yet another reason it's so important to develop appropriate standards or at least guidance documents for implementing technologies that combine medical hardware and IT hardware.

Hampton: And, of course, everyone in the hospital wants to be mobile, which requires wireless networking. On a day-to-day basis I work with medical device manufacturers to try to build honest-to-goodness medical grade networks and communications links using technologies that were developed for the consumer environment. We're convinced it can be done, but only with great care and planning.

Laxton: One of the things I'm hearing is that there's no place where you can really get answers, because this is the first time many of these questions are being asked. Do you see that as a potential opportunity for the CE-IT collaboration: to find ways to bring information from different sources together to help guide people as they tackle new technologies?

Gieras: It would be wonderful if we could do that. I would think that some of those tasks would fall under the different working groups that are being put together as part of the CE-IT collaboration. These different working groups could address bits and pieces of the problem, and package the solutions together for the community. ■

Working Groups Formed to Tackle Specific CE-IT Issues

The recently launched Clinical Engineering-Information Technology (CE-IT) Community has taken another step forward in pooling resources and knowledge by establishing working groups to address specific CE-IT issues.

The five working groups will focus on:

- IT infrastructure and wireless systems implementation
- Integration of systems/devices in multi-vendor environment
- Emerging technologies
- CE-IT convergence (policies on working with IT personnel, etc.)
- Risk Management

The CE-IT Community is the result of an agreement among AAMI, HIMSS, and ACCE to help improve patient care and safety and to boost the quality and cost-effectiveness of customer service.