



ACCE News

Newsletter of the American College of Clinical Engineering

March-April 2014

Volume 24 Issue 2

President's Message

2014 ACCE
Advocacy Award
Recipients
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This is a great time of the year for ACCE. We're coming off a very successful [HIMSS conference](#) with many notable ACCE activities. We're in the midst of preparing for what is always an extremely busy [AAMI conference](#) for ACCE. I'm particularly looking forward to this year's AAMI conference since it will be in Philadelphia. For a change, I won't have to travel far to the meeting. ACCE will also be hosting a virtual membership webinar on April 30th, 2014. I think that these virtual meetings are such an important part of the services we provide to members, especially those who are not able to participate in ACCE's educational and networking activities at the HIMSS and AAMI conferences.

The HIMSS conference started off with the ACCE sponsored pre-conference symposium on Medical Device Security Risks and Challenges. I was tied up with another symposium commitment that day so I didn't get to participate. But I heard from several ACCE members that the program was well attended with very interesting and lively discussion.

The security pre-conference symposium was complemented by ACCE's educational session on practical considerations for medical device cybersecurity during the main part of the HIMSS conference. I did attend this session and served as its moderator. I was impressed with the large number of Health IT professionals in the audience. I was less impressed with how many in the audience admitted to not being familiar with an important medical device security-related tool and resource (the [IEC 80001](#) standard). Of course even fewer admitted to actually using 80001. Erin Sparnon from ECRI Institute did an excellent job highlighting the kinds of medical device security problems that hospitals have been having. One [example](#) from FDA's MAUDE database shows how complex medical device cybersecurity can become. It involved antivirus software on a patient monitoring system. The monitor manufacturer had validated an antivirus application for its device. So if a hospital loaded the software onto the monitor the manufacturer's warranty would still apply. However, the validated version of the software is reportedly no longer supported by or available for purchase from the monitor manufacturer. The currently sold and supported antivirus version is reportedly not validated and if loaded onto the device it could void the manufacturer's warranty. It's like being stuck between a rock and hard place. No good option.

I attended a HIMSS [pre-conference symposium on patient safety](#) that was led by ECRI Institute. It was subtitled "Making Healthcare Safer - IT Challenges and Solutions". One of the most interesting parts of this meeting for me was a panel discussion on challenges and successes with pursuing interoperability. It covered multiple levels of interoperability from health information exchanges, intra-hospital integration of EHRs with other systems, and the growing number of networked medical devices. Discussion revolved around how each level of integration poses unique hazards that can impact patient care and looked at ways that provider organizations have addressed or can address them. One of the presenters highlighted the integration challenges and benefits associated with medication management. This is of course an area in which many clinical engineers are taking the lead (i.e., related to integrating infusion pumps with the EHR). For those who are not involved with integration, this is typically an area where you can get started and really help your organization while also expanding your horizons.

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President's Message

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There were lots of other highlights from the HIMSS meeting. Two of my favorites, from an ACCE perspective, were the very well attended Clinical Engineering & IT Community/ACCE Awards Reception and the HIMSS awards banquet. At the reception we had a great time connecting with ACCE members, meeting prospective members, and honoring two recipients of our Advocacy Awards. The awards banquet is – for many – a black tie affair honoring the amazing achievements of our colleagues in the HIT profession. As many of you know, ACCE and HIMSS have collaborated on an award that is appropriately named the ACCE-HIMSS Excellence in CE-IT Synergies Award. I was very pleased to be the formal presenter for this year's recipient - my good friend and colleague Manny Furst. The presentation ceremony was a big deal. Manny and I were required to attend a practice session 90 minutes before the banquet to review its Oscars-like production, learn where to stand during the presentations, and for the presenters – to practice using the on-stage teleprompters with our speeches. Congratulations Manny! It was fun.

My favorite HIMSS highlight – from a personal perspective – was the last-day keynote by [Erik Weißenmeyer](#). Erik is blind and has climbed the highest peaks on every continent. He is an excellent and very funny motivational speaker. One of his most amazing stories described his mountain climbing partnership with Mark Wellman and Hugh Herr. Mark is a paraplegic from a mountain climbing fall. He uses a special pulley-based rig to do hundreds of pull ups to literally will his body up sheer cliff faces. Hugh is a double leg amputee who lost his legs after getting lost in a blizzard on Mount Washington. Hugh is an engineer and runs the Biomechatronics Group at the MIT Media Lab. He designed his own custom made prosthetics specifically for mountain climbing. Here's a [link](#) to a YouTube video of Erik, Mark, and Hugh climbing

the 800 foot desert tower in Moab, UT. What they were able to do together is mind boggling. After the Moab climb Erik, Mark, and Hugh started an organization called No Barriers. It's a non-profit organization with a goal of promoting innovative ideas, approaches, and assistive technologies to help people with disabilities push through their own personal barriers to live full and active lives. Erik's keynote showed how anyone can overcome barriers and major adversity to do great things, whether it's climbing Mount Everest or successfully deploying health information technology. Truly inspirational.

One of the goals of my ACCE Presidency has been to increase our organization's engagement with its members. Our upcoming virtual membership webinar is an opportunity to help make that happen. All ACCE members and prospective members are invited to participate. I'll kick off the webinar by highlighting some of the major activities of ACCE. We'll then have an overview of ACCE's cybersecurity presentation from the HIMSS conference. This will be followed by commentary from ACCE President-Elect Paul Sherman on Integrating the Healthcare Enterprise. We're calling this part "IHE and What it Means to Me". We'll wrap up with a Q&A/discussion session in which we hope members will share their perspectives about our presentations or provide ideas for how we can improve ACCE. Please join us. For more information on joining the webinar, visit the ACCE website [here](#).

The annual AAMI conference is fast approaching. Our half-day clinical engineering symposium is coming together nicely. We'll be focusing on what I think is the next big thing for clinical engineering. It's how to best utilize the "Big Data" we are gathering from medical device/EHR integration, real time location system implementations, data mining of clinical alarms, and many other sources. The data we are gathering has so much potential to help improve patient safety and patient care in general. Clinical engineering can be a big player in

this game. But we'll need the resources to understand how to best do this. The symposium is a good way to start that. Thanks to ACCE Education Committee Chair Jacob Johnson, ACCE Vice President Ilir Kullolli, and the rest of the planning committee for their hard work on this program.

If you are planning to attend the AAMI conference please mark your calendars for ACCE's annual membership reception on June 1st. This will be an excellent opportunity to meet ACCE members, get to know our organization's leadership, and to recognize winners of our Advocacy Award. Also please stop by ACCE's conference booth to say hello. I hope to see you in Philadelphia.

Feel free to contact me at the e-mail address for ACCE's President (president@accenet.org) if you have ideas that you'd like me to share in my next President's report or if you have any suggestions or feedback for ACCE's Board.

Jim Keller, President, ACCE
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Journal of Clinical Engineering Subscriptions for ACCE Members

ACCE members receive a discounted subscription to the [Journal of Clinical Engineering](#) for only \$99! (Originally \$222) Visit [LWW.com](#) and enter code WDKI36ZZ at checkout.

Welcome New Members

We welcome our newest members, approved by the Membership Committee and supported by the Board of Directors:

Individual Members:

Dan Zhou, DBA—Vice President, People's Liberation Army General Hospital (PLA), China

Michael M. Hamid—Sr. Clinical Engineer, The Children's Hospital of Philadelphia, PA

Ciro Roberto Rios—CEO, Clinical Engineer, CRR Biomedical (SUCURSAL), Spain

Christopher Falkner—Integrated Environment Manager, Kaiser Permanente, CA

Tony Tai Chi Wah—Deputizing Hospital Administrator, Hospital Authority Hong Kong, China

Associate Members:

Martine J. Janicki, PhD—Senior Project Manager, StarFish Medical, Canada

James R. Knight—Clinical Systems Engineer, Biomedical Engineering Services & Training, CA

Cuichao (Kurt) Li—President, Ling Star Technology, CA

Paul R. White—Senior Engineer, Comcast Cable, NJ

Institutional Members:

EIA-CES, Escuela de Ingenieria de Antioquia CES, Colombia (Primary representative: *Dr. Jesus Soto Castano*)

Tatiana Molina Velasquez—Biomedical Engineer (Individual Member)

Carolina Castano Portilla—Biomedical Engineering Director (Associate Member)

Robinson Torres Villa—Biomedical Engineering Professor (Associate Member)

Brigham and Women's Hospital, Boston, MA (Primary representatives: *L. Michael Fraai, Director; Michael Wheeler, Assistant Director*)

Kevin Kreitzman—Assistant Director, Clinical Engineering (Individual)

Ernst Daniel—Clinical Engineering Manager (Individual)

MediMizer, Inc., Encinitas, CA (Primary representative: *Mark Woodruff, President, Sales & Development*)

Gus Sakis—Vice-President, Sales (Associate)

Jennie Whitt—Exec Administrator (Associate)

Tonya Pilcher—Technical Support (Associate)

Jeff Clark—Senior Development/Architect, Development (Associate)

University of Michigan Health System, Ann Arbor, MI (Primary representative: *Salim Kai*)

Chris E. Peters—Clinical Engineer (Associate)

ACCE News

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Anniversary Logo Results

Next year will mark the 25th anniversary of ACCE. To commemorate the event, ACCE solicited logo designs from members. Eleven entries were submitted by the deadline, and voting closed on April 10th. With 25% of the 92 votes, the following logo was determined to be the winner.



The anniversary celebration will kick off at AAMI in June. Look for the anniversary logo to be featured on the website and in advertising. Thank you for participating!

AAMI Update:

Fall Summit to Focus on Ventilator Technology; Industry, Clinicians Get Help for Postmarket Surveillance; AAMI University to Launch this Summer

Since 2010, AAMI and the U.S. Food and Drug Administration (FDA) have focused the spotlight on a number of problems related to the safety of healthcare technology, devices, and systems. This fall, the two will tackle the issue of ventilation technology used in operating rooms, critical-care units, and other healthcare delivery settings.

Scheduled for Sept. 16 and 17 in Herndon, VA, the summit will bring together regulators; leaders from the medical device industry; healthcare technology professionals; clinicians, including physicians, nurses, and respiratory therapists; and other experts. These participants will work together to identify challenges, set priorities, and discuss next steps to addressing the issues related to ventilation technology, which helps patients who are unable to breathe sufficiently on their own.

Ventilator technology has become increasingly complex over the years, incorporating monitors and alarms to alert clinicians if there is a problem. However, certain challenges have been associated with use of the technology, including ventilator-associated pneumonia.

Furthermore, the technology is not just used in healthcare delivery organizations, but also in nonclinical settings, such as the home. In such an environment, ventilators are placed in the hands of untrained professionals, posing additional challenges for both the user and the care provider.

The ventilator technology event will mark the sixth time that AAMI and the FDA have joined forces to host a summit on a pressing issue in healthcare technology, and it is expected to follow the format of its predecessors.

"We're excited to bring those who work with ventilation technology on a daily basis together to examine common problems and work toward possible solutions," said AAMI President Mary Logan.

"As with the previous summits, we will offer a free report summing up the main points of the event."

For more information about past AAMI summits, please visit www.aami.org/meetings/summits.

For device manufacturers, clinicians, and lay users, little guidance exists for conducting postmarket surveillance if something goes wrong with a device. A new technical information report (TIR) developed by AAMI's Human Factors Engineering Committee is designed to change that.

The U.S. Food and Drug Administration's Center for Devices and Radiological Health receives about 100,000 medical device reports each year, with roughly one-third of them mentioning "error" on the part of device users. However, given the lack of documentation, analyzing the data that are intended to guide future product development is difficult.

TIR50:2014—Postmarket surveillance of use error management provides guidance to clinicians and manufacturers on how to collect and assess postmarket use error data, in order to improve device safety. It is written with two audiences in mind: those making medical devices and those who use those products. The document notes that the challenges and needs of each group is different, so they wrote the document to engage each audience in different ways.

"This TIR packages rich information regarding the motivation behind and value in a well-designed, passionately executed postmarket surveillance process regarding use error with medical devices," says Janine Purcell, lead human factors engineer at Philips Healthcare. "It provides knowledge and tools that empower users of devices and manufacturers to develop meaningful insights from product use to enhance safety and usability."

The TIR advises manufacturers to lever-

age use error information discovered during the development process through risk management and usability efforts. It also suggests that manufacturers have a follow-up usability evaluation in the initial months after a product's launch. Doing so would allow for a controlled evaluation in a number of use settings.

From the clinical perspective, there is a culture of blame or punishing people when they report use events, including close calls. The TIR maintains that this culture must change. "Reporting of close calls and device dissatisfaction can go a long way to improve efficiency, reduce costs of care, and improve patient safety and overall user satisfaction with medical devices."

This year will mark the launch of a major new initiative at AAMI, one that promises to help professionals in the medical device industry and healthcare technology advance their careers. Four years in the making, AAMI University is set to "open its doors" this June.

The university is designed to serve as the go-to training center for medical device and healthcare technology management (HTM) professionals. Its programs will consist of a mix of face-to-face trainings, webinars, and online offerings, and students will have the opportunity to earn certificates indicating they have specific knowledge and skills for certain areas. A certificate for quality engineers will be the first one offered.

"There are many great education offerings that we want to make easier for our members to find," said Deborah Reuter, AAMI's senior vice president of education. "AAMI University will be the 'go-to' learning place that makes it easy for busy professionals to keep current with industry issues."

AAMI has long served as a resource for industry training and is showing its contin-

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AAMI Update

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ued commitment by launching seven new courses through AAMI University this year alone. These programs are designed for the busy professional, as students can access sessions on demand, reducing the need for travel.

AAMI University will offer a central location (<http://university.aami.org>) to access curriculum and view online programming. The online courses are organized into different modules, allowing students to concentrate on specific areas of training.

Sessions will consist of lectures, quizzes, and interactive exercises to engage the user and build community. Instructors for new industry offerings were selected after completion of AAMI's rigorous "Train-the-Trainer" program that assessed their knowledge and presentation skills.

Ultimately, AAMI University will serve as the repository for webinar recordings, replacing the currently available CD option. Interested parties will have the ability to buy and stream webinars on their computers. In addition, AAMI intends to stream popular sessions from its Annual Conference & Expo so that students can

access them after the event.

Those interested in learning more will have an opportunity to check out AAMI University at the AAMI 2014 Conference & Expo just before its official roll out on June 16.

AAMI staff

Manny Furst and the HIMSS Interoperability

Showcase

The HIMSS 2014 conference and exhibition was held Feb 24-27th in Orlando, FL. One of the popular and growing events in the conference over the past several years has been the Interoperability Showcase. HIMSS Interoperability Showcases™ are unique events in collaboration with Integrating the Healthcare Enterprise (IHE) where healthcare stakeholders come together to demonstrate the benefits of using standards-based interoperable health IT solutions for effective and secure health data information exchange.

Following this year's conference, I had the chance to talk with Emanuel (Manny) Furst who is one of the key figures in leading efforts in medical device interoperability. Manny is currently the project manager for the IHE Patient Care Device (PCD) Domain and has years of experience working in the industry as a healthcare technology expert. He has held various positions including the Director of Biomedical Engineering at University of Arizona Health Sciences Center and provided consulting services to many organizations including FDA, ECRI and Pan American Health Organization. In addition to many awards and honors that he has received throughout his years in the industry, Manny was recently awarded the "ACCE/HIMSS Clinical Engineering – Information Technology Synergies Award". Manny holds a PhD in Biomedical Engineering from Worcester Polytechnic Institute, Masters in Electrical Engineering from Columbia University and Bachelor of Electrical Engineering from Clarkson College.

I asked Manny several questions about Interoperability, IHE and this year's Showcase:

What does Interoperability in Healthcare mean exactly? What are its benefits?

Interoperability means that messages from device/system A will be accurately and unambiguously interpreted by device/system B when A and B conform to requirements. This is often harder to accomplish than it may ap-

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pear. For example, if additional software development is required there could there be gaps/errors in identifying all possible data. "Open", i.e. Standards-based interoperability, adds the requirement that the messages conform to published, available standards and thus may be implemented by any vendor willing to adopt the standards. This way if you are connecting two or more systems, you don't need to have a third party system to translate the messages between these systems. These systems would communicate without the development costs associated with developing multiple proprietary systems to accommodate multiple vendors. .

What does IHE mean and how is it related to Interoperability?

Integrating the Healthcare Enterprise (IHE) is described as "... an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively." I urge the readers to check www.ihe.net to learn more about the mission of IHE, the latest news, events about IHE and its domains.

What roles do AAMI, ACCE and HIMSS play in achieving Interoperability?

Several years ago some members of ACCE including Eliot Sloane, Ray Zambuto and Todd Cooper proposed to establish the Patient Care Device Domain. AAMI, ACCE and HIMSS now co-sponsor this domain of IHE. Sponsors provide administrative, financial and other support to domains.

Could you explain what IHE Profiles and Domains are exactly?

A profile is a technical document that is built on existing standards. Often, standards are very general as they are written for various applications. To build a profile, the standards are "constrained", meaning specific restrictions are applied and only retain elements that are essential for the specific profile. For example, IEEE and HL7 standards are two of most common standards used for PCD. As you know, HL7 is also available for applications other than medical devices.

Domains are areas within IHE that focus on specific areas in clinical care such as Radiology, Patient Care Devices, Laboratory and several more. There are also a few domains that support different clinical domains. For example, there is Information Technology Infrastructure (ITI) Domain which develop Profiles such as "Consistent Time" that are applicable to multiple Domains.

Every Medical device and HIT vendor claims that their systems are interoperable because they all can send their data out somehow. Is that interoperability?

I suppose vendors that enter into agreements to employ proprietary communications can claim interoperability, but that doesn't provide the developers or the purchasers with the benefits from truly standards-based interoperability. Each new integration, therefore, is a custom effort requiring months of effort using skilled engineers. Clinicians desiring to use a new device must wait for their vendors to develop new drivers. Additionally, safety issues can arise due to the sizable software effort and on-site customization required to integrate new systems. All these factors make system integrations a very costly effort for both providers and vendors.

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Manny Furst and the HIMSS Interoperability Showcase

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What are the main barriers on the way to achieve true interoperability?

The main barriers, in my view are:

- *Generating the demand from purchasers/users – which requires educating the purchasers about the short and long term benefits arising from demanding that their vendors provide IHE conforming products. PCD has developed a spreadsheet (available on the PCD ftp website) for purchasers that lists all the vendors with commercially available devices and systems that are part of IHE-PCD. Unless purchasers demand their vendors provide standards-based interoperability, vendors will not invest.*

- *Government prioritization – when Meaningful Use identifies, as a priority, the enormous amount of device data, its importance in the care of the patient and in control of costs the vendors will increase their investment. Currently there are talks about including some PCD messages in stage 3 of Meaningful Use. However, nothing has been added yet.*

Where are we now and where are we going with Interoperability?

We are witnessing significant increase in the number of vendors developing and commercializing IHE PCD profiles. An interesting element is that vendors that commercialized one product are now implementing additional products, implying that they believe that PCD conformance contributes to their development and that conformance will be important for future sales.

Even at this point, when almost all hospitals have an EMR system, there is a very high chance that when a patient comes into a new hospital, the hospital does not have “easy” access to the patient’s records elsewhere. Therefore, I think there is still a lot more work to do.

How do Interoperability and the coming changes affect Clinical and Biomedical engineers and their future roles in healthcare industry?

Interoperability will help technology managers acquire and support devices and medical record systems by reducing complexity, reducing the number of vendors responsible for getting a message from A to B (i.e., eliminating the need for the interface), and helping to reduce translation issues.

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Photos taken at the 2014 HIMSS Interoperability Showcase

Manny Furst and the HIMSS Interoperability Showcase

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In an area that is currently a work in progress, interoperability holds the promise of dramatically improving technology management. Consider that we can send out all the patient data from medical devices to medical record systems. Why can't we receive data about the device status itself? Why not have the medical devices report to us when they have a problem or send out their self-test results or other pieces of information that are important for technology management? In fact, many devices already do that but the data is only available through proprietary interfaces.

PCD is proposing two profiles: Location Services (LS) and Device Management Communications (DMC). The new profiles will be out in the next few months for public comment, and we are hoping that vendors will start to build and test these by early next year. We are going to have a live demonstration of the work in progress in the next AAMI meeting in the exhibit hall next to the ACCE booth.

What was the biggest highlight of the showcase this year?

It's not possible to single out one highlight. Highlights included:

- A much more impressive setting to demonstrate all IHE systems
- Focused clinical stories that improved the visitors' understanding of how various IHE profiles (technical requirements) contribute to patient care. These were described within several "clinical stories" that included medical equipment in the bigger picture with other systems, such as radiographic systems.
- A significant increase in the number of companies and medical devices demonstrating conforming medical equipment.

How did this year's showcase compare to the previous years', and what made this year's showcase better than last years and years prior to that?

There were more systems, there were more opportunities to integrate medical equipment in stories and overall there was more excitement. Approximately one-fourth to a third of the involved vendors participated in demonstrations with PCD devices and systems in the Showcase this year.

PCD demonstrated work in progress (at New Directions booth) for patient/device association/dissociation, standards-based location messages (RTLS) and the Device Management Communication effort that I mentioned above.

What do you expect to see in next year's show?

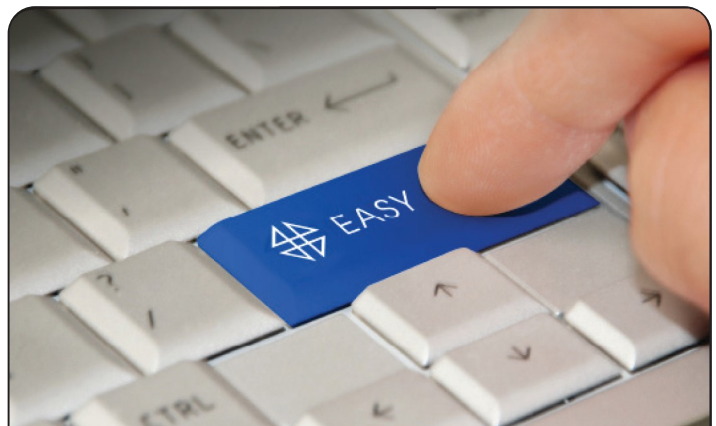
I expect to see more companies, more devices and systems. I also expect to see commercially available standards-based messages to CMMS.

Why should vendors participate and how can they do that?

If you look at a typical hospital today it likely has quite a few IT and software systems. The number of these systems has certainly grown in recent years but the number of devices in that same hospital still far exceeds the number of IT systems. This tells us that there are many more medical device companies that should consider implementing PCD requirements. They are not participating currently perhaps because they are unaware of what's going on or have chosen to hang back. Considering the way the industry is changing, we encourage them to participate now, before devices become part of Meaningful Use.

Participating vendors promote standards-based interoperability, educate purchasers to the benefits of purchasing conforming systems, and show their concern for the future of healthcare.

Most of the participating vendors can brag that they have tested their system with partners a recent Connectathon. The Connectathon is a voluntary and very beneficial opportunity for developers to send or receive conforming messages from multiple companies in a cooperative environment. They gain a level of confidence that they have met the technical requirements for interoperability and not when under the nervous eyes of the purchaser as they install their equipment or system.



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View from the Penalty Box

As I write this in March, with daylight savings in place, the baseball teams are getting ready for the upcoming season and Washington is still not doing much to pass the legislation that is needed to keep our country safe and be a leader in the world. It must be that the polar vortex has frozen the minds of our elected officials. The only thing that they seem to agree on is fund raising for their next election. Unfortunately, the brain freeze is also affecting various agencies, commissions and “study groups”, especially those charged with changing the way things get done.

The leadership in healthcare also seems to have a brain freeze. To illustrate that point, just look at some of the applications that are being touted on the iPhone platform. Every iPhone could be a “diagnostic center” with all the projected apps. How do we track all these “diagnostic centers”? What will CMS do with this technology? What will the Joint Commission do with this technology and finally what will we do to support the technology?

Hopefully we can find something better than HIMMS to get things working. Reading reports from the latest HIMMS meetings much of the discussion was on topics that were brought up over 20 years ago and are still not resolved. I got an email from a well-known company asking which of the approximately 18 listed software programs for medical records we used. Doing some digging, I found that the majority of these systems did not talk to each other. So much for sharing information across platforms; up go the costs and down goes patient care. One person was pushing the safety of the data from hackers. His system was so secure that many of the users of the system had trouble getting patient information to support their care for the patient. We need to keep and push the KISS process on to those trying to make programs work. (KISS means keep it simple stupid)

Many of us older members got our start in healthcare by designing and building

devices to support what physicians were trying to do. Once the FDA got involved most of the in-hospital design departments closed and the advancements on devices were mostly accomplished by small companies that were purchased or crushed by the big companies. It has been close to 40 years since and the progress of new technology reaching patients has slowed. Yes, there have been a lot of devices coming out but 99% seemed to be based off of old technology. With the new technology in computers, communications systems and 3D printing, the possibilities are endless and many of these items will reduce healthcare costs if they ever get by the FDA.

We might want to be pushing for a classification like the “orphan drug” where the items are restricted to a small population with a unique malady. We need to be open to this new technology and help in developing applications for this technology. Just think of all the application that the aspirin is used on or the Schmitt trigger circuit, or the micro pump. We were involved, and now we have to get involved or we will be the next IT department, never living up to what is expected or needed of us. On several occasions I have been asked why I am so negative in discussing IT departments and my answer has remained the same for years, they put technology first while I believe that clinical engineering puts the patient first. For the 99% of us that patient is always first, and for 1% remaining they will probably wind up in IT.

As much as we like to think that we can solve a lot of the healthcare cost problems by using the correct technology for the patient and by determining the true costs of a procedure, this is not what many want to hear from us. Case in point, I recently had a chest CT to determine if I had a problem with my aorta. I received a notice from CMS that the hospital charged \$1,377.00 for the procedure. They approved the \$1,377.00, but paid \$631.06. They said the maximum I could be billed is \$160.98. Where does the rest of the money come from? What



was the actual cost? Why the mark down of the cost? I am not a good customer as this was my second CT in 72 years.

We have to get more into the costs of healthcare and using those costs to develop fiscally sound and clinically valid capital replacement programs. Too many of our hospitals have 20 and 30 year old equipment that is rarely used but still needs to be maintained. These devices drive costs up and patient care suffers.

In closing, we spent a lot of cold hours in a hockey arena watching two grandsons play and two sons coach hockey teams. What makes it special is the knowledge that what I did as they grew up did have an impact on them and they in turn are doing their best with their sons. Both sons are doing their best unlike a recent team in the Olympics that was picked to win but came home with nothing. So please always do your best, and keep pushing to make healthcare better.

Thanks for your efforts.

Dave Harrington
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Healthcare Technology Foundation News

Managing Risk of Integrated Systems and Network Training Course

A clinical Engineering department supporting networked systems is not a new concept. However, the challenges of integrating and the evolving environment are presenting risk concerns.

Do you understand what you need to do to mitigate risks of integrated systems?

Are you prepared to manage the life cycle of all those integrated systems?

AAMI and HTF are proud to announce the joint training program developed to help Clinical Engineers and IT professional obtain the tools necessary for risk management methodologies and mitigation. Registration is open on the AAMI website. The course will be held on June 2nd in conjunction with the 2014 AAMI Expo in Philadelphia, Pennsylvania. This will be a **practical** one-day workshop that will provide an environment to learn real-life solutions.

Program Objectives

- Identify methodologies for risk management of dynamic systems of integrated devices
- Understand the overall the concepts of ANSI/AAMI/IEC 80001-1 Application of risk management for IT Networks incorporating medical devices – Part I: Roles, responsibilities and activities
- Apply project management principles to developing, implementing, and managing networked systems
- Identify tools and resources to sustain safe integrated systems related to networked environment

Please see this [link](#) to learn more and to register.

HTF continues to receive requests on 2011 Alarm Survey

Alarm Management is at the top of a lot of lists. As clinical folks grasp analyzing their individual institutions and plan for the National Patient Safety Goal, HTF continues to receive requests to utilize the survey questions. We are happy to share. Our only request is that they complete and submit a proposal as to how they will be utilizing the questions and recognize HTF as the source.

[Click here to open the attached file to submit your own proposal.](#)

Completed proposals can be sent to the HTF Secretary, secretary@thehtf.org.

Board members in the News

HTF Congratulates James Wear! HTF Board Member, James Wear, PhD has been awarded the Lifetime Achievement Award by ACCE. See [page 11](#) for more details.

George Mills, Director of the Department of Engineering at The Joint Commission, is joined by ACCE President and HTF Advisory Board Member, Jim Keller, along with HTF President, Tobey Clark, in addressing Alarm Systems Safety in the January 31st issue of 24x7: [Taming the Clinical Alarm Hazard](#).

HTF Board Member Marge Funk provides a focus on alarm management for the February AAMI News: [Experts See Marked Improvement in Alarms Management Awareness](#).

The AAMI Foundation's Healthcare Technology Safety Institute's January webinar on [Alarm Systems Management Use of Middleware in Alarm Management: Ancillary Notification and Obtaining Alarm Data](#) included participation from two HTF board members – Paul Coss, RN and Marge Funk, PhD. The webinar covered:

- A. Definition of middleware and how it works
- B. Overview of ancillary alarm notification systems including: necessary components for implementation, use



Improve healthcare delivery outcomes by promoting the development, application and support of safe and effective healthcare technologies.

of these systems for alarm integration of multiple devices, and process for sending alarms to communication device

- C. Human factors considerations
- D. How to use middleware to acquire alarm data
- E. How to determine the best ancillary alarm notification approach for your organization , including selection of wireless communication device
- F. A case study on use of ancillary alarm notification system for alarm integration of monitor, ventilator, bed exit and nurse call system alarms

Please see the [AAMI website](#) for further resources including the slides and recording of this and other webinars.

Be sure to visit the HTF website to see all the latest news from the foundation, our programs, and resources. While you are there, feel free to hit the DONATE NOW button. We will accept them anytime and they are always tax deductible!

Tobey Clark, MSEE, CCE, President
president@thehtf.org

Jennifer C. Ott, MSBME, CCE, Secretary
secretary@thehtf.org

ACCE Announces the 2014 Advocacy Award Recipients

For more information about the ACCE Awards Recipients, visit the [ACCE website](#).

ACCE 2014 Challenge Award



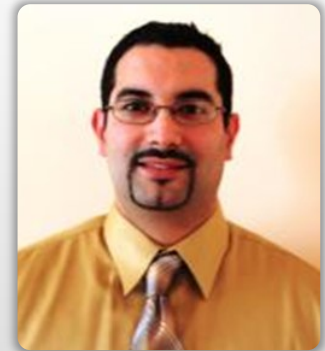
George Mills, MBA, FASHE, CEM, CHFM, Director, Department of Engineering, The Joint Commission (TJC)

ACCE/HTF 2014 Marv Shepherd Patient Safety Award



Bruce Hansel, PhD, CCE, Executive Director, Accident and Forensic Investigation, ECRI Institute

ACCE 2014 Tom O'Dea Advocacy Award



Robert Hijazi, PhD, MS, MHA, CCE, CBET, Chief CE at the William Jennings Bryan Dorn Veterans Administration (VA) Hospital in Columbia, SC

ACCE 2014 Lifetime Achievement Award



James Wear, PhD, CCE, CHSP, FACCE, FASHE, and FAIMBE, Professor Wear has been and continues to be a contributor to the CE community for the past 45 years. His major contributions include teaching, publishing, and consulting in areas of professional skills development, both technical and managerial.

ACCE 2014 Professional Achievement in Technology Award/Professional Development Award



Ken Fuchs, MEng, MBA, Executive VP, Interoperability R&D, Center for Medical Interoperability



Erin Sparnon, MEng, Engineering Manager for the Health Devices (HD) Group, ECRI Institute

2014 Advocacy Award Recipients (continued)

For more information about the ACCE Awards Recipients, visit the [ACCE website](#).

ACCE 2014 Professional Achievement in Management Award/Managerial Excellence Award



Purna Prasad, MS, PhD, CCE,
CE Director at Stanford University
Medical Center



Mark Thomas, MPH, BSE, PE, Na-
tional CE Director, Indian Health Ser-
vice-IHS, & a Captain in US Public
Health Service

ACCE 2014 Student Paper Competition



Winner: **Katherine Chan,**
University of Toronto



Runner-up: **Christine Vogel,**
University of Connecticut



Runner-up: **Michelle Hanbidge,**
University of Toronto

All papers are available for view-
ing from the [ACCE website](#).

ACCE 2014 Antonio Hernandez International Clinical Engineering Award



Zhou Dan, DBA, CCE, Vice Presi-
dent, Medical Management, PLA Gen-
eral Hospital, China

ACCE HTM Champion 2014 Award



Adam Darkins, MD, MPH,
FRSC, Chief Consultant for Tele-
health Services, Department of Veter-
an Affairs (VA), Washington, DC

2014 Advocacy Award Recipients (continued)

ACCE / HTF 2014 International ACEW Award

An Award given to the organization demonstrating significant improvements in national HTM structure and outcomes since ACCE and its partners conducted Advanced Clinical Engineering Workshops (ACEWs) in their countries.



The winner is **Ghana Health Service, Clinical Engineering Department (GHS-CED)**, led by Nicholas Adjabu, MD, Deputy Director, and Engineer John Zienaa, CE Manager.

Journal of Clinical Engineering Call for Papers

The Journal of Clinical Engineering prints selections of the ACCE News in each issue and is interested in papers from you. If you have an urge to write, and good clinical engineering activities or ideas to share, please consider JCE as one of your outlets. One type of article not seen in a while is the Department Overview which presents how your department is structured and how it performs its functions. Shorter "Perspective" pieces are also welcome. You can discuss manuscript ideas with fellow member William Hyman, who is one of the editors of JCE. Contact: w-hyman@tamu.edu.

Send manuscripts to William or Michael Levin-Epstein at: michael.levinepstein@gmail.com



Protecting medical devices –
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Today, more and more medical devices are integrated with general IT networks to improve efficiency and enable the exchange of information. We are creating new ways of delivering care, monitoring patients in the hospital and at home, and making decisions based on complex data sets. These medical devices are now exposed to a wide range of cyberthreats, yet they are often poorly protected and highly vulnerable, resulting in downtime and patient safety risks.

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Perspectives from ECRI Institute:

Trends in Medical Device Recalls



Eric Sacks, Director of ECRI Institute's Healthcare Products Alerts

Last month, FDA released its [Medical Device Recall Report FY2003 to FY2012](#) responding to a June 2011 GAO report that, among other things, requested that FDA to study trends in device recalls.

In its report, FDA states that:

- Medical device recalls had nearly doubled in a decade, increasing from 604 in 2003 to 1190 in 2012.
- Class I recalls had increased over the same time period from fewer than one per month to more than one per week.

FDA also reports progress in the recall process. For example, it states that the average time to complete Class I recalls (time to termination) dropped from nearly 600 days in FY2009 to 15 days in Q4 of 2012.

In its conclusions, FDA attributed the increase in the number of recalls to better reporting by manufacturers, specifically those firms cited by FDA for reporting

violations. That is to say, the increase

resulted from improved compliance with regulations rather than an increase in defective or otherwise problematic devices.

The report credited “CDRH and industry working together to improve the quality and safety of medical devices.” The report notes that the increase in Class I recalls was largely among “key device-type initiative areas” such as infusion pumps, AEDs, and ventilators that FDA has been scrutinizing more carefully. The report also asserts that the medical device industry had responded to FDA’s heightened post-market surveillance activities with initiatives that “are expected to improve device performance over time.”

While FDA has clearly demonstrated progress in its regulatory role in improving medical device safety and credits industry with having largely been a good partner, its report failed to fully recognize the role of healthcare providers, the patient safety and patient safety organization movement, and healthcare professionals such as Clinical Engineers in identifying problematic devices and, increasingly, combinations of devices with other devices and with other systems including HIT systems.

In recent years, ECRI has been collaborating with its member hospitals, and Clinical Engineers in particular, to publish on average 5 medical device hazard reports per month. Many of these reported hazards have later become the subjects of voluntary recalls by the affected manufacturers. In one recent example, ECRI published *Hazard Report H0228, Draeger Medical PS500 External Power Supply Batteries May Fail Prematurely, Resulting in Unexpected Evita V500 or Babylog VN500 Ventilator Shutdown* on January 30 of this year. The report which was developed in close collaboration between ECRI, reporting hospitals, and the manufacturer was followed by Draeger’s *Urgent Medical Device Recall*, in mid- to late February. FDA subsequent-

ly announced that it had classified the recall as Class I on April 2nd. With its claim that Class I recalls are being completed on average in 15 days, the question arises, why do they take so long to classify?

The fact remains that most recalls originate from the reported safety concerns of health care professionals on the front line. On behalf of ECRI Institute, I want to commend the Clinical Engineering community for its vigilance and reporting of medical device problems to manufacturers, ECRI, and FDA. We remain committed to working with you to aggregate the unique combination of technical and clinical knowledge of Clinical Engineers everywhere to improve the safety of medical technology. To make a confidential report of a problem you have identified with any medical device or supply item, please visit us at: <https://www.ecri.org/Pages/ReportADeviceProblem.aspx>.

Eric Sacks
ESacks@ecri.org

The International Corner:

An Update from the International Committee

The HIMSS14 Conference in Orlando last February was an opportunity for a face-to-face conversation with friends and colleagues. At the conference, there were an increased number of international clinical engineers attending the event with interest in the information technology field. This gave an impression that cooperation between CE and IT is increasing around the world.

I presented the “Implementation of IHE Colombia” as part of the “Lessons Learned around the Globe” in the Pre-conference Symposia “The Interoperability explosion: Where we are and where we’re headed” organized by Elliot Sloane. The presentation addressed not only the activities carried out to organize the IHE in Colombia, the first one in Latin America, but also the leadership of ACCE in promoting the interoperability and the use of standards developed by IHE.

During the presentation, the model developed the deployment of IHE organizations in a country and the strategies to support the sustainability of the organization were also addressed. This is particularly important in non-English-speaking countries.

The Q&A section reflected the interest of the audience (approximately 100 participants) in the topic and the interest of some on supporting this work. ACCE has included the IHE topic as part of the ACEW Syllabus and has been presented in the workshops since 2012.

The IHE-Colombia delegation led by Dr. Vladimir Quintero, Director of IHE-CO and Dr. Teofilo Ruiz, attended the event and provided feedback on the experience in organizing and strengthening the organization. The Interoperability Showcase gave the delegation the opportunity to witness the “Connectathon” in operation. This was crucial because IHE-CO is planning to participate in the Connectathon in Brazil later this year and organizing a small Connectathon in Colombia by the end of the year.

Some of the International Committee (IC) members accompanied the delegation in different meetings with IHE and HIMSS authorities. The delegation was invited to attend the Clinical Engineering & IT / ACCE Reception. ACCE will continue the collaboration with IHE-CO to strengthen the organization and will use this experi-

ence to work with other countries in the expansion of interoperability programs, use of standards and certification of the products. We want to congratulate the Colombian group for their outstanding work in such a short period of time. As a reminder to the readers, the process of IHE-CO started as a follow up activity after the ACEW held in Barranquilla, August 22-24, 2013.

There was also time for ACCE activities. At the ACCE Board of Directors meeting, I presented an update and the work plan for 2014. At the Clinical Engineering & IT / ACCE Reception, a summary of the IC activities was presented. Also, I had the privilege to join the group that accompanied Manny Furst in receiving his well-deserved ACCE-HIMSS Synergy Award presented in the HIMSS14 Awards Banquet. Congratulations to Manny.

In summation, the time was short and the agenda was full with activities, some pre-planned and others arranged on the spot to respond to the increased demand of cooperation between CE and IT in the international arena. Time spent involved attending the keynote speakers and some technical sessions. Some time was also allocated to visit the expo. We also took some time to chat with friends and attend some of the social events of the conference.

Next stop will be the AAMI2014 Conference & Expo in Philadelphia, PA from May 31 to June 2, 2014. Including, of course, the participation in Manny’s Meeting on May 30. I look forward for the opportunity to seeing all of you once again in Philadelphia.

Antonio Hernandez, Chair
internationalchair@accenet.org



Suly Chi, Manny Furst, Antonio Hernandez, Vladimir Quintero, and Mario Castaneda in the Interoperability Showcase.

ACCE at HIMSS 2014



ABM Healthcare Senior VP, Paul Monahan, and Steve Grimes, Chief Technology Officer addressing guests at CE-IT/ACCE reception



ACCE President Jim Keller opening the ACCE Meeting/Awards ceremony



Mark Thomas accepting the ACCE 2014 Professional Achievement in Management Award/Managerial Excellence Award.



Purna Prasad accepting the ACCE 2014 Professional Achievement in Management Award/Managerial Excellence Award with ACCE President, Jim Keller, and Advocacy Committee Chair, Tom Judd.

ACCE would like to thank ABM for their support at HIMSS 2014.



Jim Keller announcing Manny Furst as the recipient of the HIMSS/ACCE Synergy award.



Many more friends celebrating were with Manny Furst for his HIMSS/ACCE Synergy award, at the 2014 CE-IT/ACCE reception.

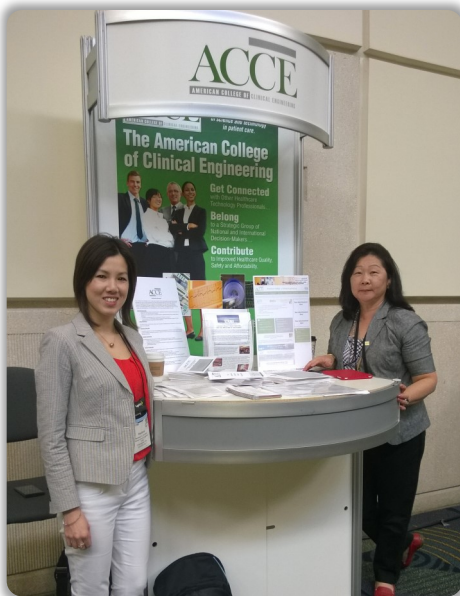
ACCE at HIMSS 2014



ACCE Education session: Are you covered? Practical Cybersecurity for Medical Devices.



Manny Furst, as accepts the HIMSS/ACCE synergy award.



ACCE Secretariat, Suly Chi, and member Mariana Hu.



Colleagues from ACCE and IHE were at the HIMSS award banquet to celebrate with Manny Furst, as he receives the HIMSS/ACCE synergy award.



ACCE member, Jared Ruckman, ACCE past president, Jennifer Jackson, and ACCE member, Darcy Del Dotto.



IHE Columbian delegation at ACCE booth along with ACCE president and committee chairs.

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- Reduce equipment loss
- Track rentals
- Streamline preventative maintenance

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ACCE Calendar

April 30, 2014

3rd ACCE Virtual Membership Meeting/Webinar
12PM - 1PM (EDT)

To join, click [here](#).

May 8, 2014

ACCE Educational Teleconference: Continuous Care Model (Home, Hospital and Back Again)

May 31-June 2, 2014

AAMI 2014, Philadelphia, PA

June 1, 2014

ACCE membership meeting & awards reception
Philadelphia, PA

June 12, 2014

ACCE Educational Teleconference: Hybrid OR—Emerging Technology

July 12, 2014

CCE written exam application deadline for applicants testing outside US & Canada

August 9, 2014

CCE written exam application deadline for applicants testing in the US or Canada

ACCE

AMERICAN COLLEGE OF CLINICAL ENGINEERING

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