



ACCE News

Newsletter of the American College of Clinical Engineering

November-December 2013

Volume 23 Issue 6

Nominate an outstanding colleague for the 2014 ACCE Advocacy Awards!

See [Page 10](#) for more information.

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President's Message



Pennsylvania and many other parts of the country got a blast of arctic air. It's been an unpleasant reminder that 2013 is rapidly winding down. I don't know about you, but I'm amazed that we're at this point in the year already. The busy life of clinical engineering really helps to make time go quickly.

I just finished a long string of work-related travel. I was on the road for six of the last seven weeks. I'm looking forward to a few weeks at home and in the office to get ready for the holiday season and for what I am sure will be another busy year. My travel this fall touched on a lot of the issues that will be defining the clinical engineering profession over the next few years.

The first trip was for the AAMI-FDA [Summit on Healthcare Technology in Nonclinical Settings](#) in Herndon, VA. ACCE was a co-sponsor of the event. I represented ACCE and ECRI Institute with a presentation on the "Environment of Use Considerations" as part of a panel that was asked to consider how we can ensure that the right technology is being used in the right environment. The general premise of my presentation was that use of health technology is rapidly growing in nonclinical settings. Just a few examples of these "migrating" technologies include infusion pumps, ventilators, beds, pacemakers, patient monitors, cell phones, dialysis machines, oxygen concentrators, etc. And they are being used all over the place. This can include the home, cars, planes, parks, stadiums, doctor's offices, schools, etc. Regarding the "right use in the right environment" question, I asserted that we have to assume that medical technologies will be used almost anywhere.

A big part of the summit's discussion revolved around how more and more hospitals are becoming responsible for deploying and managing the use of health technologies in "nonclinical" settings. Clinical engineering is a big part of that, and in my opinion it should be taking the lead in this area. Policies and procedures need to be developed for selecting these technologies, training of nonclinical users, monitoring for hazards and recalls, conducting service and preventive maintenance (as appropriate), and for managing and using the data that many of these devices/systems will be transmitting (e.g., patient monitoring). If oversight of homecare is not on your list of things to do you may want to start planning for it – because I expect it will be coming your way.

My next trip was to Chicago. I participated in a Group Purchasing Organization's meeting to discuss contracting for patient monitoring systems. A big part of the discussion at this meeting was how the convergence of information technology and medical devices was creating new challenges for purchasing-based decision-making for patient monitors. The "computerization" of patient monitors makes them very configurable. Clinical engineers can help their hospitals plan for the most appropriate and safest configuration for their clinical settings. As we all know, the computerization opens the door for connectivity. With connectivity, interfaces with information systems, and how well they work, has to factor into the purchasing equation. Clinical engineers can also work, in collaboration with their information technology colleagues, to identify best practices for connecting patient monitors to their IT systems. And, as many are already doing, they can lead the effort to manage these connections.

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President's Message

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After the Chicago trip, I travelled to Washington, D.C. to participate in a meeting for an ECRI Institute consulting engagement with the [PEW Charitable Trusts](#). We've been asked to help PEW investigate how new and innovative technologies become established on the market. One of the purposes of the project is to identify characteristics of those technologies that more quickly become established. It's believed that knowing these characteristics can help regulators better understand the impact of their premarket decisions and possibly lead to expedited premarket decision-making.

You might be wondering how the innovative technology project relates to clinical engineering. I see a key responsibility of the clinical engineering professional as being a resource and advisor for his or her hospital on all aspects of a technology's decision-making. That includes understanding what innovative technologies are in the pipeline and how they may fit with the hospital's strategic plans. Over the next 5-10 years I expect the pace of new and emerging technologies coming on the market to increase. Hospitals will need a lot of help from clinical engineering to select the best for them.

The next week I travelled to California to present ECRI Institute's Health Devices Achievement Award. This is the eighth year in a row that we've given out the award. Our award recognizes an outstanding initiative undertaken by an ECRI Institute member healthcare institution that improves patient safety, reduces costs, or otherwise facilitates better strategic management of health technology. This year's winner was Methodist Hospital of Southern California. Hospitals apply for our award and Methodist's winning submission described development of a new integrated systems management program that identifies equipment vulnerabilities

related to patient safety, information availability, and cybersecurity.

ECRI Institute's award selection committee was impressed with the forward thinking approach that Methodist Hospital took with its project, particularly surrounding the looming problem with cybersecurity. This has had some high profile coverage in the press recently. The revelation about the remote communication for Dick Cheney's pacemaker being turned off to avoid cybersecurity-related tampering is just one example. The cybersecurity risk with medical devices is a serious and emerging concern which most hospitals have yet to significantly address. The Methodist project, which was run by its biomedical engineering program, sets an excellent example for other hospitals to follow on how to tackle this issue. ECRI Institute will be publishing a detailed description of the Methodist project in January. Feel free to contact me if you would like any information about this project.

After my California trip, I was back in Washington, D.C. to attend ECRI Institute's [20th Annual Conference on the Use of Evidence in Policy and Practice](#). This year's conference was entitled "Data BIG and Small: What Healthcare Decision Makers are Using Now". It was a very high level meeting in an amazing setting at the [National Academy of Sciences](#). The meeting revolved around how big data is being used and should be used for healthcare decision-making. The discussions ranged from how big data is used to make policy-level decisions to more tactical decisions within individual healthcare institutions.

Use of big data is expected to impact all levels of healthcare, including clinical engineering. For example, one of the sessions of the conference talked about how healthcare providers are using EHRs to manage their hospital systems and determine how to deliver the best care to patients. An important part of the data set to be managed will be all of the device information that clinical engineers are helping to transmit into the EHR. It's a

daunting amount of information that our profession will be expected to help decipher. ECRI Institute's conference was free to the public, and the recordings are available at the conference web link in the previous paragraph.

I was back in the D.C. area for one last road-trip in 2013. This one was the [Center for Business Innovation's](#) fifth annual [Medical Device Connectivity Conference](#) in Herndon, VA. ACCE was a conference partner, and I represented ACCE and ECRI Institute as the moderator of a keynote panel discussion patient safety and HIT. This conference provided an opportunity for ACCE members to shine. ACCE member presenters included Past-Presidents Jennifer Jackson and Steve Grimes; current Board Member-at-Large Jim Welch; and Julian Goldman, MD, Bridget Moorman, Ken Fuchs, and Shelly Crissler. In addition to my panel, other topics included the regulatory future for health IT, mobile applications, and interoperability; governance related to HIT and connectivity; the impact of standards on connectivity; management of cybersecurity; and clinical alarm fatigue. It was a great meeting that helped set a blueprint for how healthcare organizations manage connectivity for years to come.

I was pleased to have the opportunity to participate in such a stimulating set of meetings and projects, especially since they were so connected to where clinical engineering will and needs to be going over the next several years. However, I'm definitely ready for a break from all the travel and time away from home. Best wishes to you and your family for a wonderful holiday season. I'm looking forward to working with many of you in the next year.

Jim Keller, President, ACCE
president@accenet.org

Welcome New Members

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

Candidate Members:

Anna Cristina Shivers—Clinical Engineering Intern/Graduate Student, UMASS Memorial Health Center/UCONN, Worcester, MA

Angela Czesak—Clinical Engineering Intern/Graduate Student, UCONN Health Center/UCONN, Farmington, CT

Emily A. Bonazelli—Clinical Engineering Intern/Graduate Student, Baystate Health/UCONN, Springfield, MA

Max Whitfield—PhD Candidate, George Washington University, Washington, D.C.

Individual Members:

Vladimir A. Sequera—Chief Warrant Officer II/Clinical Engineer, US Army

Associate Members:

Ratish Kumar M.V.— Biomedical Engineer,

SRI Ramachandra University and Research Institute, India

Daniel J. Adams—Manager/Clinical Engineering, Adventist Health, CA

Institutional Members:

IEB-UFSC, Florianopolis, Brazil (Main representative: *Dr. Renato Garcia Ojeda*, Director)

Allison Tolloti—Clinical Engineer (Associate Member)

Carlos Alexandre Beckert—Clinical Engineer (Associate Member)

Ronaldo Nunes—Clinical Engineer (Associate Member)

Diego Schirmer Spall—Clinical Engineer (Individual Member)

Marcelo Massaki Hayashide, MBA—Clinical Engineer (Individual Member)

Priscila Sousa de Avelar, MSBE—Clinical Engineer (Associate Member)

Rafael Briese, MSBE—Clinical Engineer (Associate Member)

Renan Feltrin, MSBE—Clinical Engineer (Associate Member)

Renato Zaniboni, MSBE—Manager of Technology (Individual Member)

ECRI Institute, PA, US (Main representative: *Jim Keller, VP Health Technology Evaluation and Safety*)

Eric Sacks—Director, Healthcare Products Alerts (Individual Member)

Ramya Krishan, MSBE—Project Engineer (Individual Member)

Christian Lavanchy, BSME—Engineering Director (Individual Member)

Jeremy Suggs, ScD—Engineering Manager (Individual Member)

ACCE Would Like to Thank....

Bill Betts

The ACCE International Committee would like to recognize the contributions and work of our friend and colleague Bill Betts to the initiatives and activities of the committee. Bill worked with the IC from 2011 to 2013 and was a very active and hard-working contributor who brought a great deal of experience and knowledge to different projects. His contributions were instrumental in crafting the "General Guidelines for Activities of the ACCE International Committee" document. We thank you, Bill, and look forward for your input on the IC activities on support to the clinical engineering international community.

Antonio Hernandez
ACCE International Committee Chair

Dr. Robert Malkin

Dr. Robert Malkin is retiring from the ACCE Membership Committee due to additional responsibilities at Duke University. He has been a part of the Membership Committee for the past three years and has helped improve the procedures for accepting new members into ACCE. He has always made recommendations on new applications in a timely manner. His services will be missed especially by the Membership Chair.

James Wear
ACCE Membership Committee Chair

ACCE News

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AAMI Update:

Steam sterilization standards, small-bore connectors and alarm competency training

Popular Steam Sterilization Standard Updated

Those looking for information on steam sterilization wrapping will have additional guidance as a result of an updated version of ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

The updated standard contains a new amendment, published as Amendment 4:2013, which provides four revised figures of sterilization wrap drawings and a new annex on moisture assessment. Rose Seavey, president and chief executive officer of Seavey Healthcare Consulting, LLC, said the revised figures will serve as improved guides for sterilization professionals.

“The updated figures are much better pictures and more intuitive,” Seavey, a member of the AAMI Steam Sterilization Hospital Practices Working Group, said. “We also added wording to each of the drawings to describe each step in the four different techniques for sterilization wrapping.”

Cynthia Spry, an independent clinical consultant and co-chair of the working group, added that the drawings will make it more clear to professionals how to wrap packages for sterilization.

In addition to the drawings, Annex P on moisture assessment will serve as “a very valuable annex for healthcare facilities experiencing wet packs or wet loads,” Seavey said.

Spry noted that ST79 previously did not contain much information about wet packs, including why they occur or what to do when they become wet. Sterilization professionals found that this information was scattered throughout the document and offered little assistance on how to fix the problem. With the new annex, however, sterilization professionals will have a clear resource for guidance.

The updated standard will be available for purchase at my.aami.org/store/. The price is \$140 for AAMI members and \$280 for nonmembers. The amendments (without the full standard) will be available in print (\$40 for AAMI members and \$80 for nonmembers) and as a free download.

FAQs Address Small-Bore Connectors

AAMI, patient safety groups, and other stakeholders released a resource this fall intended to help the healthcare community prepare for upcoming changes to medical device small-bore connectors that are designed to prevent tubing misconnections and enhance patient safety.

“Stay Connected” is a comprehensive list of 23 frequently asked questions (FAQs) related to small-bore connectors, which have long posed a threat to patient safety because of a design issue. A commonly used type of small-bore connector, called the Luer connector, has a universal design that allows the tubing of one medical delivery system to be connected to an unrelated system—a potentially fatal flaw. New design standards are in the works for small-bore connectors and the new FAQ document explains the changes and their impact.

The FAQ document answers questions such as:

- What changes are coming?
- What products will be impacted by the new standards?
- How should organizations prepare for the changes?

“AAMI and its stakeholder partners are excited to move this project forward,” said AAMI President Mary Logan. “Too many tragedies have resulted from misconnections, and we all hope the new connectors will significantly reduce the number of adverse events.”

The “Stay Connected” document can be downloaded for free at www.aami.org/

hottopics/connectors/index.html. That page also contains others AAMI resources related to the small-bore connectors challenge.

Paper Highlights Alarm Competency Training

A new paper from the AAMI Foundation’s Healthcare Technology Safety Institute (HTSI) looks into how a facility developed alarm competency training for staff, resulting in enhanced patient safety across a large health system.

The 11-page paper, titled Simple Solutions for Improving Patient Safety in Cardiac Monitoring—Eight Critical Elements to Monitor Alarm Competency, is the latest from HTSI’s Safety Innovations series. Each paper explains how leading healthcare organizations have solved a specific technology-related safety issue.

This paper focuses on the University of Pittsburgh Medical Center (UPMC) Presbyterian, a 737-bed hospital known for organ transplantation, cardiology, cardiovascular surgery, critical-care medicine, neurosurgery, and trauma services. It is part of a multi-facility system with more than 20 academic, community, and specialty hospitals.

As with many facilities, staff at UPMC Presbyterian experienced problems delivering quality patient care as a result of excessive alarm noise. In 2006, the facility went about identifying and quantifying the types of alarm signals to see if they could make improvements.

A team subsequently set up a pilot project and initiated alarm competency classes that taught nurses within the medical cardiology and progressive care units how to adjust alarm signals appropriately based on a patient’s condition, as well as how to communicate these changes from one shift to another. The facility also held nursing grand rounds on how to address

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International Committee: Florianópolis Brazil ACEW Workshop

The fifth Advanced Clinical Engineering Workshop in Brazil (also known as Tec-Saúde 2013) was held in Florianópolis, at the Instituto de Engenharia Biomédica (IEB) of the Universidade Federal de Santa Catarina (UFSC), on October 8-10, 2013. This workshop was organized by IEB/UFSC, the American College of Clinical Engineering (ACCE), and the Pan-American Health Organization (PAHO/WHO). Financial support was provided by the Brazilian Ministry of Health and Fundação de Amparo a Pesquisa de Santa Catarina (FAPESC). Also contributing to the event was the Engineering in Medicine and Biology division of the Institute of Electrical and Electronics Engineers (EMBI/IEEE), and the Latin American Regional Council on Biomedical Engineering (CORAL) of the International Federation for Medical and Biological Engineering (IFMBE).

This workshop is part of a long series of workshops held in various developing countries by ACCE. The workshop was lead by a team of American faculty members comprised of (in alphabetic order): Antonio Hernandez (consultant), Thomas M Judd (Kaiser Permanente), Kenneth Ross (ECRI Institute), and Binseng Wang (ARAMARK Healthcare Technologies). In addition, two PAHO regional advisors, Alexandre Lemgruber and Pablo Jimenez, participated as speakers in the event.

The following health authorities and experts (in alphabetic order) gave presentations and/or chaired sessions:

- Rubia Alves – CEGED, IEB-UFSC, Brazil
- Elsa Elena Arellanes—CENETEC, Mexico
- Eduardo Assis—DECIT/SCTIE, Brazilian Ministry of Health
- Priscila Avelar—IEB-UFSC, Brazil
- José Luis Ciani—Univ. Entre Rios, Argentina
- Murilo Contó—CONITEC/COAINF, Brazilian Ministry of Health
- Cristian Dias—CTH, Chile
- Renan Feltrin—CEGED, IEB—UFSC, Brazil
- Alexandre Ferreli—Brazilian Association of Clinical Engineering (ABEClin)
- Eric Laciari—Univ. San Juan, Argentina
- Jefferson Brum Marques—Professor, Biomedical Engineering, IEB—UFSC, Brazil
- Sérgio Mühlen – Brazilian Society of

Biomedical Engineering (SBEB)

- Daniela Suzuki – Associate Professor, Biomedical Engineering, IEB-UFSC, Brazil
- Luis Vilcahuamian – CENGETS, Peru
- Renato Zaniboni - CEGED, IEB-UFSC, Brazil

Attendees included representatives from hospitals, universities, and industry. There were a total of ~70 registered participants. Ten persons and institutions from as far as Argentina, Mexico, Peru, and India also attended via real-time Internet broadcast.

The workshop covered a wide range of technology management and maintenance issues such as strategic equipment incorporation, equipment management, maintenance management, human resource management, medical device regulation, CE department performance management, human factors, CE-IT integration, international safety standards, technology assessment, patient safety and risk management, and ACCE international activities. Two workshops with break-out sessions were held in addition to the traditional lectures. These break-out sessions and subsequent plenary reports allowed participants to

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Florianópolis Brazil ACEW Workshop Faculty and Invited Speakers

International Committee: Florianópolis Brazil ACEW Workshop

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share their experience related to equipment incorporation and patient safety and risk management.

Although some of the participants have had several years of CE experience, the majority said that they learned a lot from the lectures and enjoyed the discussions held at the break-out sessions. Detailed workshop evaluations were obtained from 35 of the participants, who rated the

workshop overall with the score of 3.60 out of the maximum of 4.00 points (i.e., 90%), with standard deviation of 0.56. The most appreciated strength was the quality of the faculty (expertise and experience), while the range of topics covered came second. The most citing weakness was lack of time for discussion after the presentations, with the long commute between the hotel and the venue a close second. Among the comments, several indicated that they would like to have received more detailed information on medical device regulation, benchmarking,

maintenance planning, risk management, and technology incorporation.

Prior to the workshop, Tom Judd and Binseng Wang visited the State Regional Hospital in São José and the Cardiology Institute to learn how the IEB/UFSC teams are managing and maintaining equipment there. The senior executive leadership at both sites expressed great satisfaction at the services provided, lamenting only that the state can only provide them with 20 hours of clinical engineer assistance per week at each site in spite of repeated requests for

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Visit to [Instituto de Cardiologia de Santa Catarina](#). From left to right: Tom Judd (ACCE), Juliano Martins (IEB-UFSC Supervisor), Eng. Felipe dos Santos Rosa (IEB-UFSC Coordinator), Sr. Romualdo Leone Tiezerin (Hospital Administrator), Binseng Wang (ACCE)



Prof. Fernando Mendes de Azevedo (Director of Electrical Engineering Department, UFSC), Eduardo Assis (Brazilian Ministry of Health), Alexandre Lemgruber (PAHO), Renato Garcia (Director of Institute of Biomedical Engineering, UFSC), Binseng Wang (ACCE Faculty), Prof. Walter Celso de Lima (founder of IEB)



Workshop session delivered by Alexandre Lemgruber, PAHO



Workshop session delivered by Ken Ross, ECRI Institute

International Committee: Florianópolis Brazil ACEW Workshop

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full time deployment. Most of the repairs and scheduled maintenance are performed by vendors as each site only has one full-time technician. Repairs usually take a long time (as long as 30 days), due to the lengthy paperwork approval process.

Representatives of the Brazilian Ministry of Health expressed interest in having more workshops for many Brazilians who could not attend. Similar desire was expressed by participants from other Latin American countries. Alexandre Lemgruber offered a suggestion that some of the training material could be presented via Internet to allow broader coverage at lower costs. Almost all participants agreed that higher level health authorities need to be involved and engaged to enable better management of health technologies in its entire lifecycle, from research and development, through regulatory approval, post-market surveillance, maintenance and management within healthcare organizations and consumers environment, and until retirement from service. In addition to assistance from North America, cooperation among these countries will be key in developing sustainable and appropriate solutions.

It is clear that some Latin American countries like Brazil and Mexico are quite advanced in CE, while others are catching up quickly. However, all of them still have a lot to do to ensure that medical equipment is managed safely, efficiently and supporting the overall goal of equitable access for everyone. This workshop certainly helped the participants in progressing toward these goals.

The faculty and participants wish to acknowledge the support of the following patrons:

- Prof. Fernando Azevedo, Chairman of the Electrical Engineering Department, School of Engineering, UFSC
- Prof. Walter Celso de Lima, founder of the Biomedical Engineering Group that was the forerunner of IEB-UFSC

Above all, the faculty would like to express its appreciation to Professor Renato Garcia and his efficient team for the hospitality that they provided, the participants for their enthusiasm, and the sponsors for their generosity.

Binseng Wang

AAMI Update

(Continued from page 4)

alarm fatigue and improve alarm recognition and awareness.

Word of the team's efforts spread across the hospital system, so Kate Hileman, then-unit director for a medical cardiology unit, and Anne Ward, Presbyterian Hospital's unit director for Neurology, searched for commonalities in alarm management across departments. The result: an evaluation tool known as "Eight Critical Elements to Monitor Alarm Competency."

Staff are required to show they know how to perform the following functions:

- Admit a patient in the cardiac monitoring system
- Discharge a patient from the system.
- Review alarm settings
- Customize alarm settings and document them in an electronic health record
- Properly place leads on a monitored patient
- Correctly load electrocardiogram paper in the machines
- Appropriately put monitors in standby mode versus alarm signal suspend mode
- Set monitors to identify a pacemaker-implanted patient correctly

To read more about UPMC's experience, go to www.aami.org/htsi/safety_innovation.html and download the paper for free.

AAMI staff



Group photo with participants in front of IEB-UFSC (Universidade Federal de Santa Catarina)

View from the Penalty Box

As 2013 comes to a close, we have seen and heard about a lot of proposed changes to healthcare but few real facts to back up all the hot air floating around the topics. We have software that doesn't work, we have conflicting requirements from accreditation agencies, and we have "experts" coming out with new numbers of people that die because of malpractice or malfeasance but in many cases no hard facts. As engineers, we deal with FACTS, using them to create better devices, treatments or to hold down costs. Our ability to get and use the FACTS is getting harder every year. It is the engineers that will lead the way to better healthcare and lower costs. All we need is the FACTS to make things happen.

In recent weeks, we have seen professional athletes described as bullies, being insensitive to others, being only concerned about themselves and out for the money. Unfortunately, this description also fits too many physicians, administrators and IT personnel. This makes progress on problems more difficult to accomplish. We can make healthcare less expensive, easier to use and understand, but we all have to be willing to work together as a team. The Red Sox proved that talent alone does not win world championships, but talented people working together can make a difference. Talented people not working together for the betterment of everyone is called Congress and as my favorite bumper sticker says, "Go Green, Recycle Congress".

ACCE has very talented people working together, but we need to get more involved with the overall picture not just concentrating on their own hospitals. We need to share our knowledge to solve problems keeping healthcare moving forward. We need to look at new technologies, new applications of older technologies and importantly the removal of obsolete technology from the healthcare process. From reports in various newsletters, the iPhone is fast approaching a diagnostic tool that will allow for quick testing of patients. It is coming down to the point where the average physician will

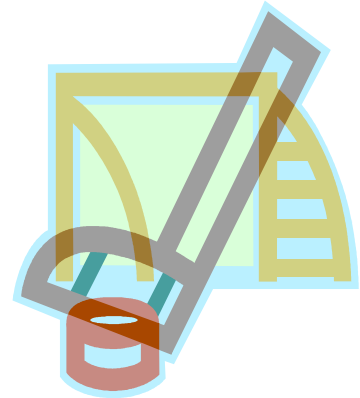
have more instrument applications on their cell phones than a hospital had in total less than 10 years ago. Technology is advancing faster than the medical field can get comfortable with it, and it will be getting faster every year.

I recently spent time with medical and engineering personnel from West Africa. I spent some additional time with medical and engineering personnel from South East Asia. While separated by many miles and cultural differences, their problems closely mirror ours. They are very focused on selecting the right hardware for their needs, being able to support that hardware, and to afford the capital costs of the equipment. What surprised me was that the capital cost of the equipment was not their first priority but their third after selecting the right equipment and being able to maintain it.

About 3 months ago, I did a little consulting for a hospital in this area, and they were looking for something that would give them a competitive edge, even if it was not used much and the capital cost, while important, was less than the "cutting edge technology" that they want to market. Unfortunately, this cutting edge technology is quickly becoming bleeding edge technology as it is very expensive to operate and maintain. But it looks good in their marketing package. Clinical Engineers will probably get blamed for the costs even though we were against the purchase of the device.

The finance and market groups seem to be able to get around the regulation while we try to conform. We get beat up, and they come off looking like visionaries. That may be the first sign of a politician; talk long and loud about an idea, no matter how bad it is, and people will start to demand that device or service even if there is no medical reason for the device or service. But it looks good in the marketing package.

I suggest that all of you have a look at ECRI's list of Top Ten Health Technology Hazards for 2014. Many of the items have



been on the list for several years and little gets done about them. Maybe as a society, we should pick one problem off the list and have some people from around the world come up with a solution to that specific problem, then push the solution to the FDA and insurance companies so the solutions actually get implemented and problems get corrected. We cannot rely on companies or colleagues to get this accomplished unless they have something to gain. The old version of the Golden Rule applies, "He who has the gold makes the rules", and those with the gold are the FDA and insurance companies. So let's get them involved.

So have a great end of year, celebrate long and hard, enjoy a few hockey or football games and look to our future challenges and set personal goals on what to do about those challenges.

Dave Harrington
dave@sbtttech.com

Healthcare Technology Foundation News

Welcome new Board Members!

HTF extends a warm welcome to ACCE member Tony Easty, PhD, Senior Scientist, University Health Network, Toronto, ON. He will attend his first meeting in December. We look forward to his contribution on HTF initiatives.

Respiratory Response to the Alarm Survey

The article evaluating the 2,071 responses from respiratory therapists to HTF's 2011 National Survey on Clinical Alarms, has been published in the November edition of [American Association of Respiratory Care AARC Times Journal](#)[†]. Many thanks to our AARC colleagues Shawna Strickland and Crystal Dunlevy for making this a reality!

American Association of Critical-Care Nurses Article Published

The American Association of Critical-care Nurses (AACN) published an article in its *Bold Voices Journal*: [Healthcare Technology Roundtable: Alarms Systems Management](#) on the HTF/AAMI HTSI roundtable discussion at the 2013 AAMI Annual Meeting. Thank you to HTF Board Member, Marge Funk, for seeing this to fruition.

ECRI Institute and HTF Continues Partnership

The Home Infusion Safety English [brochure](#) is complete. The Spanish translation should be finished shortly, see brochure link. In addition, ECRI Institute made a [video](#) on the brochure. This has taken our partnership to whole new level and we hope to continue to improve upon the methods of getting these safety messages out to our public audience.

Current assessment of future topics is leaning the group towards beds utilized in the home setting. If you have any suggestions on patient education materials please contact Jennifer Ott at secretary@thehtf.org.

Philips Healthcare Interviews HTF President

Philips Healthcare recently interviewed HTF President, Tobey Clark, on Alarm Fatigue in the September issue of [The Trace Journal](#). Go Tobey!

Poster Presentation on HTF at the 2nd Global Forum on Medical Devices

Yadin David and Tobey Clark manned the HTF poster session at the World Health Organization's [2nd Global Forum on Medical Devices](#) in Geneva, Switzerland, at-



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

tended by over 500 participants from 110 Member States. Yadin was a presenter in several other sessions at the forum. Tobey was part of the ACCE International Committee team who conducted a pre-conference workshop focused on ACCE's global impact.

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!

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[†] Posted with the Permission and Approval of the American Association for Respiratory Care. ©2013, All Rights Reserved.

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 [LWWW.com](#) and enter code WDK136ZZ at checkout.

ACCE Job Opportunities

To view information on available job opportunities, visit the [ACCE Job Postings site](#)
For information on posting job opportunities, please contact Dave Smith at advertising@accenet.org

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 Leven-Epstein at: michael.levinepstein@gmail.com



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2014 ACCE Advocacy Awards: **Call for Nominations**



The ACCE Board and Advocacy Committee recognize the [past award winners](#) and are pleased to announce that nominations are now being accepted for these awards. View the [awards criteria](#).

Please take the time to nominate worthy colleagues today and contact students to submit their papers. Just email the nomination form with recommended individual(s), justifications, and/or papers to advocacychair@accenet.org by January 17, 2014.

These awards will be presented at the 2014 ACCE Awards Banquet to be held at HIMSS in Orlando, FL in February 2014. Awardees will also be recognized on Sunday June 1, 2014 at the AAMI conference- ACCE membership meeting in Philadelphia PA.

Thank you for submitting nominations!

Illir Kullolli
ACCE Vice President

Developing HTM Capacity for Haiti

By Tom Judd, Pat Lynch, and Jean Chery

Private and public initiatives are underway to build HTM capacity in Haiti, but there is a long way to go.

PAHO and expert HTM teams are developing a short and long-term strategy in 2013 to address identified medical device and HTM needs, with the Ministry of Health (MoH). 32 BMETs have received training via [Tripartite](#), but not hired.

Although there are many smaller projects, the most systematic has been that of [Rotary Houston](#), along with its Haiti community partners, who have trained 46 BMETs in a 2-year training program since 2011. Most have been hired into private hospitals from many cities. The primary objective of this program is to develop regional training centers.

Haiti's healthcare system faces many hurdles, particularly since the January 2010 earthquake. [PAHO Haiti's web listing of public and private health facilities](#) monitors the location and distribution for health service response. However, many internal and external sources note the challenge of ensuring available and appropriate medical devices for care delivery at these sites. WHO-PAHO, NGOs (non-profits), professional societies, other countries and many healthcare workers are assisting initiatives to build or rebuild HTM capacity in the country. View more on the NGO healthcare efforts at <http://haiti.ngoaidmap.org/sectors/8>.

Meetings were held in January 2013 with 20 private hospital leaders in Port-au-Prince (PauP) and Milot, located in the north near Cap-Haitien. The Houston Rotary along with an expert HTM team,

including Tom Judd and Jean Chery, discussed the following topics:

- BMET workspace, tools and test equipment
- Repair, parts and supply challenges
- Device inventory management tools
- Donations
- Ongoing management (hospital leader) and BMET training
- Hospital leader partnerships (regional and national) for HTM

The team toured Haiti's University and Educational Hospital (HUEH), a major public tertiary hospital, along with various private hospitals in the PauP area. Extensive HTM needs were discovered. The team met with the MoH who affirmed this segment of HTM capacity building. In recent years, NGOs, such as TriMedX Foundation (USA), have periodically sent teams to individual hospitals and systems to train BMETs and provide HTM support.

In addition, Rotary has had an influence with its BMET training and repair center initiative in which two cohorts have 4 two-week training sessions per year for two years since 2011. Through this initiative, over 40 BMETs have been placed and are beginning to succeed in positions at private hospitals. Also, in the fourth quarter of 2013, Rotary will be assisting the Hôpital Universitaire de Mirebalais (HUM), HTM leader and Carrefour Hospital to establish a PauP area joint Central/West Service Center for participating private hospitals.

The HTM expert team, Pat Lynch and Jean Chery, went on a PAHO mission in October of 2013. They met with public hospital leaders and toured hospitals located in North Haiti, such as Hôpital Justinien in



A primary clinic in Hinche.

Cap-Haitien. The team also toured the public Hôpital Universitaire La Paix (HoP—Hospital of Peace in PauP) and met with senior MoH officials. The following observations were made:

- Lack of (fully) trained BMETs—too few and/or lack of experience. This is an issue in private and public hospitals, even in almost all developed hospital systems in Haiti (except HUM)
- Focused BMET training—based on specific hospital inventories; fast troubleshooting methods

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Developing HTM Capacity for Haiti

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- Inventory—HTM team suggested methods to collect; consider use of cellphone picture attached to electronic device inventory
 - Self-Sufficiency—although we want to empower hospital leaders and BMETs to be able to work at the single hospital level, the HTM model recommended requires significant management and technical partnership. This is required at the regional and national level, across both public and private hospitals. The HTM team will need to create the *Role of BMET in HTM at Hospital* and *Role of Hospital Director in HTM* guidelines.
 - Access to spare parts—optimizing what is needed and how to efficiently procure the parts
 - Scope of HTM—what services are provided for what devices: Surgery, ICU, Lab, Imaging, etc.
 - Donations—storage solutions when not in use. What resources, accessories, and consumables are lacking for deployment?
 - Hospital directors—frustrated with HTM status; lack of funding, sharing of resources, etc. Need clear HTM job responsibilities for directors and BMETs, and career growth opportunity plan for BMETs
 - Logistics—storage space for devices awaiting repair. If unused donated devices are shared with regional service center, could they get credit to be used as needed?
 - Use existing HTM resources—e.g. HTM Director Monette Valliere at HUM (and others in Haiti) to serve as advisors to service centers; consider stipends based on level of involvement
 - Funding—How to structure a national or regional HTM model (business plan) to enable:
 1. Human resources—paid national service center manager and volunteer BMETs, etc.
 2. Parts (related participating hospital inventories) and device-related supplies
 3. Tools and test equipment—clarify if hospital or BMET owned, and whether used outside of hospital
 4. Envision external funding for national/regional HTM model that provides incentives to hospital directors to invest and make the model self-sufficient after a number of years
 - Five year and longer-term HTM program plans—will be important for acceptance in the Haitian culture
- The following were some of the desired HTM initiatives over the next 5 years, as proposed to PAHO in April, 2013:
- Equipment Support
- Make best use of existing trained BMETs (Rotary partnership—46, Tripartite partnership—32):
- Additional training cohorts to be determined by public/private hospital demand for BMETs
 - Technician training only without a *Management Support* component is not sustainable
- Develop a Health Technology (HT) Unit, using best HTM practices, such as use of Service Centers, with public-private partnership (PPP) in the capital, with regional satellites, e.g., North, West, and South Haiti.



The Hôpital Universitaire de Mirebalais (HUM) is a Tertiary Public Hospital located in Mirebalais.



A Secondary Private Hospital in PauP.

- Paid HT Manager, and volunteer BMETs (5-6) “on-loan” from local hospitals
 - Satellite units (3-4) staffed by volunteer BMETs (2-3) locally “on-loan” under HT Manager oversight
 - Best practice HTM developed jointly by paid HTM Coordinator (USA-based) and Haiti HT Manager, under Partnership Advisory Board oversight
- Management Support
- Maintain a network of public and private health leaders to guide HT Unit (s) and provide rotating volunteer BMETs, formalized through the Partnership Advisory Board.
 - Develop and enable ongoing training for health leaders and BMETs.

Project Support

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Perspectives from ECRI Institute: Big Data



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

Among the topics that Jim Keller discussed in this month's President's Message was big data in healthcare, the theme of ECRI's 20th Annual Conference on the Use of Evidence in Policy and Practice last month. Big data will present Clinical Engineers with increasingly complex challenges, but also with opportunities to improve patient care and contain costs in very meaningful ways.

So how can you prepare yourself and your organization to be at the forefront of leveraging big data to improve healthcare? By examining the ways the best Clinical Engineers have always used the information available to them, you can assess how well you are performing today. You can start to plan how to ramp up and improve on current best practices to handle the much larger sets of data, both signal and noise, that we certainly face in the future.

Clinical Engineers have always had a unique window on medical device use patterns. Repair work orders illuminate device misuse and abuse patterns. Incident investigations oftentimes demonstrate that some clinical users have inadequate proficiency with certain medical technologies and lack awareness of important safety issues.

Over time, individual Clinical Engineers

and BMETs develop hunches about technology pitfalls that are creating unnecessary maintenance expense and exposing patients to unnecessary risk. Comparing notes with colleagues, they confirm their suspicions and develop plans to help clinicians and technologists to use medical technology more effectively and safely.

Such plans can emerge in a variety of settings: during lunch with colleagues from your own hospital department, during discussions with colleagues at AAMI, ACE, and regional clinical engineering society meetings, and through collaboration with ECRI's Problem Reporting Network. Indeed, hospital-based Clinical Engineers have oftentimes been ECRI Institute's eyes and ears in researching of medical technology safety.

Today, Clinical Engineers have access to more data than ever. CMMS data from their own repair and preventive maintenance work make it easier to quantify your hunches about repair trends. Online resources from manufacturers and trade publications, including ECRI's Health Devices, provide details and guidance on topics that have been carefully analyzed by others. Blogs and discussion forums, such as BiomedTalk, make it much easier to compare notes with colleagues throughout the industry at any time. But are we doing any better than in the past at synthesizing all of this data into useful information and putting it to use to "help clinicians and technologists to use medical technology more effectively and safely"?

To assess how well you and your organization are leveraging medical technology data today, consider the following questions.

How effective is your organization at capturing the hunches of BMETs and other frontline technology management professionals and clinical users about problem trends with medical technology? Do you have a fully developed incident and near-miss reporting system implemented?

How effective is your organization at analyzing the data aggregated in incident re-

porting and maintenance management programs? You likely have a formal process for root cause analysis of major incidents, but are you really leveraging lower level signals that might allow you to predict and possibly even prevent the next major incident? Do you have a vision for how to analyze data captured from device systems in EHRs and other aggregating systems?

How effective is your organization at developing and implementing recommendations and guidance on safe and effective use of medical technology? How do you determine which users need to be informed or trained on safety and effective use of specific devices and systems? How do you document such training? How do you determine when refresher training is needed? Are per diem nurses getting the training and/or supervision they need?

And how effectively do you network with other technology management professionals, whether Clinical Engineers, IT professionals, or clinicians, to keep up with the latest ideas?

Going forward, remember that ECRI can support you in each of these areas. Report your hunches about safety problems and user experience trends to ECRI Institute's Problem Reporting Network. Put your ideas and questions on BiomedTalk. And by all means, call us when you need help talking through a technology management issue or in networking with other Clinical Engineers who have expertise on the technology in question.

Eric Sacks
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ACCE in Geneva

Our ACCE delegation to the World Health Organization (WHO) Second Global Forum on Medical Devices returned from Geneva after successfully delivering two workshops, one presentation, and a poster. Further, ACCE led a session and conducted strategic program meetings with organizations like IFMBE, HTTG, and CORAL.

Global Forums Background

The Global Forums objectives align with an unprecedented resolution by The World Health Assembly (WHA 60.29) adopted back in May, 2007. WHA 10.29 brought focus on health technologies and the critical medical devices used to deliver care within health systems. Further, the resolution placed Health Technology Management (HTM) at the center stage, and directed WHO resources to collaborate with non-governmental organizations to develop guidelines, recommendations and tools for better selection, management and use of medical devices. The WHO will then create a clearinghouse of guidance information for all countries and interested users.

Published objectives of the Second Global Forum:

1. To define methods of increasing access to priority medical devices under

the Universal Health Coverage initiative.

2. To share evidence on best practices in health technology assessment, management and regulation of medical devices.
3. To demonstrate the development and use of appropriate and innovative technologies that respond to global health priorities.
4. To present the outcomes of the implementation of the World Health Assembly resolution on health technologies (WHA60.29) and the status of actions resulting from the First Global Forum on Medical Devices.

ACCE Activities

Workshops—On the opening day, after the plenary session, Tobey Clark, Tom Judd, and I delivered the Workshop “Health Care Technology Management (HTM): ACCE Advanced Clinical Engineering Workshops.” The workshop focused on the best HTM practices to support the countries and organizations attending.

With an impressive record of 50 Advanced Clinical Engineering Workshops (ACEW) in 29 countries, ACCE faculty, 72-strong, has not only shared their

knowledge with 4,000 attendees, mostly in low-resource countries, but received feedback and facilitated the drafting of solutions and plans for building HTM capacity. We were poised to share with the audience the richness of the accumulated knowledge, and specifically the outcome of the last three ACEWs in Peru, Colombia, and Brazil.

We wrapped up with a Q and A exercise with high audience participation. The questions and comments can be summarized as follows:

1. French Speaking Countries, mostly in Africa, have not had ACEWs and requested ACCE considers bridging this gap.
2. New and more technology available is making HTM harder to address. While the ACEW results are excellent, there is a need to increase the number and frequency of ACEWs.

The afternoon ACCE workshop was delivered by Bill Gentles: “Computerized Maintenance Management Systems (CMMS): essential features and pitfalls to avoid.”

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Mario Castaneda presents at The Global Regulation of Medical Devices track.



Tobey Clark presenting at the HTM workshop based on case studies and experiences of over two decades of ACCE ACEWs around the globe.

ACCE in Geneva

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Bill gave an excellent presentation on the essential features of CMMS in small and large organizations. While the emphasis was in a low-resource setting, Bill discussed the process to select a CMMS that fits the organization, and the surprises that increase cost and timelines during system implementation.

Presentation—On behalf of Antonio Hernandez, who could not attend, I presented the talk “Single-use Medical Devices: Re-use and Re-processing.” The main points presented were as follow:

1. Reuse of single-use medical devices (SUD) is a growing worldwide tendency, and there are different reasons for this practice. The United States Food and Drug Administration (FDA) research shows that reprocessing of SUDs may be feasible, but it may be difficult to do and possibly dangerous.
2. The reprocessing of SUDs is considered a “Manufacturing Activity” by the regulatory authority and is regulated as such. The product should be labeled as a reprocessed
3. Due to the risk of reusing SUDs, this practice is a controversial activity and

is of public concern in countries that do not have strong medical device regulatory programs.

Poster—As an outcome of the ACEW in Colombia, the host, Universidad Simon Bolivar, submitted a poster to be co-presented with ACCE. The poster “Determining Health Care Technology Priorities during Health Policy Turmoil and System Changes” depicts the process used to address the challenge.

To move forward during a health policy transition, a group of leaders from the public, private, and academic sector under the facilitation of the Chamber of Commerce met to tackle the challenge.

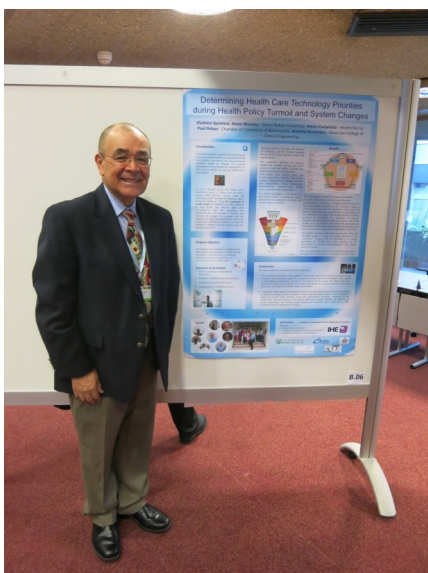
The group of leaders agreed on a plan to continue working on projects that would align with any rational health care program. One of the key components of the plan was for the leaders to understand Health Technology Management and Innovation. They invited ACCE to present an ACEW and fulfill this need.

The tangible outcomes of this effort were specific, viable, and actionable projects to address the health priorities in the community. Projects will be developed in a sample population of 200,000 lives, then scaled-up to the Barranquilla’s 2.5 million,

and subsequently to the Atlantic Coast of Colombia. This is a measurable success for the individual participant, the organizations represented in the program, and to the region.

Overall Geneva was a great success for ACCE, and at the same time a reminder of the unmet ever-growing need for many communities to access appropriate and well-managed health technology. We have seen results, and the closing words of the ACEW abstract captures how we measure our participation in world events: the value of ACCE activities is shown by actions taken by the participant organizations to improve health based on technological solutions and management of technology to enhance safety, reduce costs, and enrich quality.

Mario Castaneda
ACCE Immediate Past President



Mario Castaneda manning poster “Determining Health Care Technology Priorities during Health Policy Turmoil and System Changes”.



Tom Judd along with the poster presentation of the Universal Anesthesia Machine (UAM) prepared by ACCE colleague Ismael Cordero.



Leadership

Many of us entered the clinical engineering profession because of our passion for engineering, healthcare, or perhaps some other reason. Not too many of us studied and entered the field to become leaders. However, leaders are what we need, especially during these uncertain times for healthcare.

We need to reach outside of clinical engineering and see what opportunities await us; we need to leave our comfort zone. Clinical engineering as a profession has come very far, and we have provided much value to healthcare. We can offer more value and can apply much of what we learned to help our healthcare systems. We need to have situational awareness and look at problems and opportunities for improvement with a focus on a solution not just on clinical engineering. We should not be bound by our titles, we should use our passion for solving issues

and lead. We are all busy and have many responsibilities in clinical engineering, but we should leverage our knowledge and resources to help our healthcare system.

We have probably all read books on leadership, and we can probably all write down a list of traits a leader should have. Some of the common traits we could probably list are: having a vision; the ability to inspire others; having integrity; being trustworthy; having confidence; good or should I say great communication skills; being decisive, the list goes on. We certainly need a vision, a strategy, a plan to implement the strategy, and a team to make all this happen. Clinical engineering has solved many issues and our leadership can have a positive impact in other areas.

We don't want to change for the sake of change. We need to strive to make

change for the better and only when change is validated and needed.

We need to make sure we empower our teams, foster creativity let our staff know that it takes all of us to make things happen. We need to learn how to create positive deviance in our organization, develop the capability to lead positive change and acquire the ability to mobilize the capabilities of others in achieving positive change.

Leaders seem to make the most impact during uncertain times, so now is the time to show leadership.

Ken Schwarz
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Dr. Dziadek Lifts Spirits of Haitian Children

Our ACCE Fellow member, Dr. Joseph F. Dyro has devoted hundreds of hours in a labor of love for children who are victims of the terrible hurricane that struck Haiti in 2011. The world mobilized with relief supplies and manpower to assist in the reconstruction that destroyed much of what existed in Haiti. In addition to the physical and material aid, others have provided spiritual and artistic support.

Joe is friends with a radiation oncologist from his days as the Director of Clinical Engineering at Stony Brook University Hospital on Long Island. The oncologist has been heavily involved in relief efforts and travels often to Haiti. Joe decided to assist by providing hand-crafted name puzzles to dozens of children.

Joe created the first name puzzle 37 years ago when his first child, Carolyn was born. Six years ago he began giving presents to friends and relatives who became grandparents, including me. They are wooden puzzles with the name of the

grandchild. Sometimes each letter is a puzzle piece, other times the puzzle pieces are combinations of letters. Either way, they are artistically crafted, beautiful and very durable. He particularly enjoys receiving photos of the children holding their puzzles.

Now Joe, who is 100% Polish, has adopted the nom de plume of Dr. Dziadek, pronounced ja-dek, but, of course you knew that. In Polish, dziadek means grandfather which he is two times so far. In addition to spending considerable effort learning Polish as an adult, Joe is also partial to French, as some of you may recall from his delightful and amusing encounters with the wait staff in French restaurants.

I've included a few photos of the puzzles. One is a grouping of several puzzles. The other two are examples of specific names that I particularly like.

My hat is off to Joe. His generosity is an



inspiration for us all. I'm sure he would like to hear from you about his puzzle project for the Haitian children.

Tom Bauld
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Developing HTM Capacity for Haiti

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- Support hospital technology projects as encouraged by Partnership Advisory Board; e.g., BMET staffing, equipment user training, eHealth – mobile health, donation guidelines, etc.

About the Authors:

Pat Lynch and Tom Judd are ACCE members and Fellows, and have served as ACCE Advocacy Committee Chairs.

Jean Chery, a Haitian-American, has 3 Masters in Biomedical Engineering (University of Miami), Management, and Divinity. He has worked in medical device industry in the US, served in the US military, and is currently a management consultant, living with his wife in Atlanta. They also run a school for 200 children in western Haiti near Les Cayes where Jean grew up.

ACCE Calendar

December 12, 2013

ACCE Teleconference—Clinical Engineering Department Management

January 9, 2014

ACCE Teleconference—RTLS 2.0

January 27-31, 2014

IHE North America Connectathon
Chicago, Illinois

January 29, 2014

IHE North America Connectathon Conference

February 13, 2014

ACCE Teleconference—IHE/PCD: Advancing Products and Integrated Workflows

February 23-27, 2014

HIMSS 2014
Orlando, FL

February 24, 2014

CE-IT/ACCE awards reception
Orlando, FL

May 31-June 2, 2014

AAMI 2014, Philadelphia, PA

June 1, 2014

ACCE membership meeting & awards reception
Philadelphia, PA

ACCE

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