ACCE News

Newsletter of the American College of Clinical Engineering

March—April 2017 Volume 27 Issue 2

Join ACCE at AAMI 2017!

See Page 7 for more details

In this Issue:

President's Message

As I write this latest President's message my mind is full of thoughts about change and leadership.

I look outdoors here in Winnipeg and I see that all the snow has left the ground, the thermometer has been registering well above freezing for a few weeks, some rain has fallen in recent days, the sun has been shining, and the trees are starting to get a tinge of green on their branches. After a long cold winter, this is a very pleasant change. Other changes that are happening may not be as welcome … or should they be? My provincial health system will undergo more change this fiscal year than it has in the past 20 years combined as a result of a new government introducing a mandate for major health system transformation. The changes will be felt in every corner of the health system, including clinical engineering. What is the best response to this situation and to similar ones that you may have faced or are facing now in your own working environment? Should one resist change and try to preserve what was before? Or should one embrace change and see it as an opportunity for improvement, for growth?

I feel that anticipating change, seeing the opportunities that lie within it and becoming part of the new order are winning strategies. Over and over again I've watched capable individuals dig-in their heels against change only to be side-lined or run over by the change. In my own career, I've experienced continuous change and have always tried to be ahead of the curve by trying to anticipate what is going to happen, align myself to the future and lead those for whom I am responsible in that direction. It is here that change and leadership intersect for me; where they are inexorably tied together - leadership is all about change. As clinical engineers, we must do more than embrace change, we must actively look for change and put ourselves into leadership positions within the changing environment. Does change happen to you and you are surprised by it when it happens? Or do you lead the change, becoming part of the change leadership? Do you actively look for and associate yourself with people who lead or do you prefer to take a less "out front" position? Do you look for committees and projects in your workplace to be a part of or preferably to lead? In the broad healthcare delivery system, clinical engineering typically does not have a seat at the senior leadership table. Clinical engineers who want strategic technology decisions to be a part of regular senior management discussions have to find ways to work at that level and to bring the subject to that table. Leading change in organizations through leadership of committees and projects is one way to do this and thereby establish strategic relationships (which I've written about in the past).

Many books have been written about leadership. I am not convinced that any single book holds the secret to transforming a "regular" person into a leader. Engineers and other clinical engineering professionals are often very focused on reading literature about the latest technological developments and trends. It is important, in my view, to make room for reading books about leadership and managing change as these two subjects are the primary business of senior management. It behooves us to learn their language and to speak it. You don't need to be a senior manager to be a leader; being a leader is about what you do, not the formal hierarchical position you hold.

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President's Message (Continued)

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Over the coming months, the ACCE, AAMI and HIMSS will be evaluating the future direction of the Clinical Engineering – Information Technology Community (CE-IT Community). For a decade this Community has worked to forge closer connections between clinical engineering and information technology as these two technological worlds intersected increasingly. A tremendous amount of outstanding work has been done but the world is changing, and the Community needs to consider how it will continue to be a force for positive change and leadership. What should be the role of clinical engineering professionals in the integrated but cyber-vulnerable future? If you have ideas to share, please email the ACCE secretariat. Don't be shy, all ideas are welcome. If you are interested in becoming involved, to take up a leadership role, let us know.

I want to end on a celebratory note and recognize the leadership of a valued colleague. Congratulations go to Manny Furst for becoming a Fellow of the ACCE. His leadership over many decades is recognized in achieving this status. The "Manny" meetings, which he organized for many years, brought together clinical engineers to look into the future, discuss key changes coming and prepare attendees to lead the way forward. Thank you Manny.

Petr Kresta, President, ACCE
PKresta@dsmanitoba.ca

Congratulations to our newest Fellow member, Emanuel (Manny) Furst, PhD, CCE.

View from the Penalty Box

Well we got through the winter. Some got a lot of snow, rain or cold, but we made it through. We had the Patriots winning the Super Bowl for the 5th time, and here in New England the breweries had to work overtime to keep the parties supplied. The strange thing is that they did not raise the price of beer. They did not follow the lead of many of the drug manufactures. At least some critical suppliers of our needs are not out to squeeze us harder.

We hear a lot about the high costs of healthcare here in the US. It is not an alternate fact but true. The president of one of the New England's larger health insurance providers published an op-ed article in the Boston Globe. He stated that it would be cheaper to send a patient and companion to the Cayman Islands for the drug most commonly used to treat Hep C, bring them back and then send them back down for a week, when the drug regime was completed, than to treat the patient in the US. The insurance company would save over $8,000 for the treatment. This would cover the cost of what this same insurance company pays a hospital for a replacement hip, not including surgery and follow up. This includes just the hardware, which is reported to be twice what the supplier charges the hospital. I guess that we will always have "gotcha's". How do the auditors of hospitals justify this overbilling? For my wife and me, two people who are both in reasonable health, and over 70, our total healthcare costs for 2016 were $10,017.57, which is about 15% of our pensions and social security. No wonder why so many people have limited insurance coverage. They are betting that their health will be good and they can survive. Maybe if our senators and reps had to pay 16% of their salaries for healthcare, we would get some action on costs. Yes, I was working on my taxes and took a break to write this rant.

Moving on to another pet peeve, electrical safety testing or leakage. The new issue of NFPA 99, 2016, leaves out the requirement for electrical safety testing on a scheduled basis. It is close to 40 years since people trying to justify some "alternate facts" that over 40,000 people per year died in hospitals due to electrical leakage from devices they were connected to. Have any of you ever seen a patient electrocuted from a device? Most of the articles reporting this "alternate truth" were not peer reviewed. Will it be another 40 years before we determine that PM's are not generally needed on 90% of medical devices, but performance testing is needed on all devices and probably PM's on the devices with moving parts? Of greater concern to me is who is looking at all the IT equipment making sure

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ACCE News

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View from the Penalty Box (Continued)

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that it is running correctly? That includes moving the data to where it needs to go and receiving data needed for patient care. I have heard of far too many screw-ups with IT systems that no one seems to want to address, and that is not an "alternate fact".

In one of the newsletters I receive every day was a short piece on the Joint Commission which is considering having no scheduled inspection time. Instead, they would just show up at the door unannounced. In the article, it was stated that they felt that they would find more problems than if the hospitals were given notice, like now, that the "sea gulls" are coming. They mentioned that once the system is in place, the hospitals would spend more time keeping their policies and procedures up to date and everyone would know what is in them. Remember the line from the TV show Get Smart, "Would you believe"? No, it is doubtful that it will have any meaningful benefits to the patients or the staff taking care of them, but it will keep a large number of administrative personnel employed doing nothing to benefit healthcare. But the sea gulls will be happy. I use the sea gull reference because a sea gull generally flies in, craps all over everything, and flies off.

I was recently introduced to an engineer who works for a medical device company. After about the second beer, he began asking questions on how clinical engineering groups got new information and shared information. At about beer four, he asked why clinical engineers are not open to talking with people who are designing new equipment. I had no answer to that question. We need to get more people involved with our technology suppliers and have our concerns as part of the new product, not something that happens after the product is on the market. All too often our "watchdogs" seem to be at the hydrants and not looking at what is needed.

Have fun in Texas. If it is going to be your first time there it will be an eye opener.

Dave Harrington
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Welcome New Members

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

Name	Class	Job Title	Organization	Country
Lola Lyttle-Hill	Institutional/Associate	Clinical System Engineer	Kaiser Permanente	MD/USA
Tyler Moxam	Institutional/Associate	Clinical Engineer	Kaiser Permanente	CA/USA
Patrick Garzon	Institutional/Associate	Clinical Engineer	Kaiser Permanente	CA/USA
Abe Ahala	Institutional/Associate	Senior Clinical System Engineer	Kaiser Permanente	CA/USA
Bryan L. Gros	Institutional/Associate	Clinical System Engineer	Kaiser Permanente	CA/USA
Nimmy Christopher Samraj	Associate	Assistant Officer	FORTIS Hospital, Mumbai	India
Jose R. Flores	Institutional/Associate	Clinical Engineer	Eastern Maine Medical Center	ME/USA
Gerald (Jerry) McNeil	Institutional/Associate	Supervisor	Eastern Maine Medical Center	ME/USA
Majdi Sami Samain	Individual	Sr. Biomedical Engineer	Dar Al-Handasah	MI/USA
Jennifer Boudreaux	Institutional/Associate	Clinical Engineer	Southeast Louisiana Veterans Health Care System	LA/USA
Christopher Arciga	Institutional/Associate	Biomedical Engineer	Portland VA Medical Center	OR/USA
Paula Andrea Berrio-Molina	Individual	Chief of Clinical Engineering Dept.	Hospital Pablo Tobon Uribe	Colombia
Alberto Lanzani	Associate	Operations Area Manager	Tecnologie Sanitarie Spa	Italy

Congratulations to the following members - upgraded to Individual Member Status:

Name	Job Title	Organization	Country
Leslie M. Baggesen	Clinical System Engineer	Kaiser Permanente Clinical Technology	CA/USA
Austin Hampton	Chief, Biomedical Engineering	Gulf Coast Veterans Health Care System	MS/USA

AAMI Update

AAMI Annual Conference to Spotlight Cybersecurity, Big Data, and Accreditation Requirements in Healthcare Technology

With more interconnected medical devices being introduced into healthcare facilities—and more threats to that technology emerging in the cyberworld—the questions of how this equipment is purchased, maintained, and used are more important than ever. So too are the healthcare technology management (HTM) professionals who manage these activities, serving a crucial role in patient safety and healthcare outcomes.

During the AAMI 2017 Conference & Expo, set to run June 9–12 in Austin, TX, the HTM professionals who service and support a dizzying array of complex and often life-critical medical devices and equipment will have the opportunity to learn what they need to stay on top of the latest innovations, advances, and risks. The Expo will allow attendees to see the latest upgrades and advances in medical technology from nearly 200 manufacturers.

Throughout AAMI 2017, industry experts and leaders will provide practical guidance and insights on the biggest trends and challenges in the healthcare technology sector, such as:

Moving Big Data to the Bedside. During the opening general session, J. Randall Moorman, a clinical cardiologist and University of Virginia professor of internal medicine, physiology, and biomedical engineering, will discuss how he and his colleagues have turned more than 100 terabytes of data collected from continuous electronic monitoring into a "risk estimation device" for deadly conditions, such as sepsis in premature infants and hemorrhage and acute lung failure in adults.

"I am completely committed to this idea that there are illnesses that we can detect early by analyzing the data that we already have," Moorman said.

Cybersecurity. During the prestigious Dwight E. Harken Memorial Lecture, Kevin Fu, CEO and chief scientist of Virta Labs, Inc. and an associate professor at the University of Michigan where he directs the Archimedes Center for Medical Device Security and the Security and Privacy Research Group, plans to probe the risks, benefits, and regulatory issues for medical device cybersecurity and provide insight into the development of trustworthy medical device software.

"I hope that people will come out of my presentation with a less sensational view of the issues and a more optimistic view of the future of medical device security," Fu said. "It's not about eliminating risk but about controlling and managing risk. It can be done—it's not impossible."

Stricter Joint Commission Requirements. On the final day of AAMI 2017, George Mills, director of engineering at The Joint Commission (TJC), will take the stage to provide the latest information on TJC's activities, discuss its plans, and explain how these will impact healthcare facilities. Attendees also will have the opportunity to pose their questions and concerns directly to Mills.

The full schedule of education sessions and events is available at www.aami.org/ac.

AAMI Publication Navigates the Noise of Clinical Alarms

AAMI has released the spring 2017 issue of its peer-reviewed publication, *Horizons*, with a focus on clinical alarm management.

Clinical alarms can improve care by arming clinicians with valuable information about their patients' current state. However, when too many nonactionable alarms occur, they can overwhelm and desensitize clinicians—a condition called "alarm fatigue."

This issue of *Horizons* explores several approaches for minimizing nuisance alarms and improving clinical alarm management, including:

- Using secondary alarm notification systems, such as middleware, to intelligently alert clinicians when intervention is needed.
- Examining how alarms should be classified.
- Initiating changes in culture and training to reduce nonactionable alarms.
- Looking to outside industries for lessons to manage clinical alarms.

This issue includes substantial contributions from members of the AAMI Foundation's National Coalition for Alarm Management Safety. To access this issue, visit http://www.aami.org/productspublications/horizonsissue.aspx?ItemNumber=4223

Two New Podcasts Available from AAMI

In one podcast, AAMI President and CEO Robert Jensen describes his vision for the association, how his time as a Marine officer helped prepare him for this job, and the opportunities (and challenges) he sees for the healthcare technology community.

In another podcast, two HTM professionals discuss their organization's initiative to safeguard its medical devices from viruses and hackers. They share tips, lessons learned, and advice for embracing cybersecurity management as an ongoing priority.

These AAMI podcasts, along with more than a dozen others, are available at www.aami.org/newsviews/podcasts.

AAMI Staff

ACCE 2017 Membership Dues Due Now!

ACCE Membership Dues for January through December 2017 is due now. To renew your 2017 membership online, please click here, or mail your renewal check to:

ACCE
5200 Butler Pike,
Plymouth Meeting, PA 19462

Perspectives from ECRI Institute

This issue features two contributions to the Perspectives from ECRI Institute Column!

Politics, Taxis, and Tight Living Quarters in Hong Kong

I recently returned from another international trip. This time I was in Hong Kong and Malaysia, each for about a week. In Hong Kong, I presented a three-day course on investigation of medical device adverse events. One of the attendees flew all the way from the Netherlands for the program. I was impressed. I also had business development meetings with clinical engineering, physician, and hospital administration colleagues from several hospitals in Hong Kong. In Malaysia, I presented a day-and-a-half course on hospital risk management, worked with ECRI colleagues at our Asia Pacific headquarters in Kuala Lumpur, and visited with a hospital development group. During the meeting with the hospital developer, we discussed its plans for seven brand new private hospitals in the Malaysian state that borders Kuala Lumpur.

Crowded living in Hong Kong

As you would probably guess, my international travels have been very interesting, on many different levels. I was in Hong Kong during its recent election, which selected a new Chief Executive. The Chief Executive is Hong Kong's highest-ranking official and reports up through the Chinese government. The new Chief Executive is Carrie Lam, who was chosen by a select group of about 1,200 voters. The group is derived from a mix of Hong Kong legislators and representatives of special interest groups like the financial and healthcare industry. Many in Hong Kong are not happy with this election model. It was fascinating to observe the tensions between citizens pushing for a more inclusive electoral process and those in support of the status quo.

I took a taxi from my Hong Kong hotel to the airport on my way to Malaysia. I was intrigued by the five smart phones mounted on my driver's dashboard. I have seen similar numbers of dashboard-mounted phones during many other taxi rides in Hong Kong. I actually heard about a driver with 13 phones on his dashboard. It turns out that Hong Kong taxi drivers often participate in multiple private cab-service networks or businesses that offer rides discounted below approved government rates. Each phone is typically used for one of the multiple networks the driver belongs to. So a driver takes calls/orders from prospective clients for each network he works for and helps with dispatching for each network. This is all done while driving on the road with customers. Is it safe? Probably not. Thankfully, I haven't experienced any serious near misses in a Hong Kong taxi. It is, however, efficient and definitely a sign of the times.

In the US clinical engineering community, we've talked a lot about a new "sign of the times" with healthcare technology. It is the growing migration of medical devices into the home and other non-hospital settings. The rapid proliferation of cell phones and other internet-connected technology is one reason for why this is happening. Government incentives to keep patients from rebounding back to the hospital after discharge are another big factor. As a result, an important emerging responsibility for clinical engineering is to manage the technology used in patient homes. Common home use medical devices include oxygen concentrators, infusion pumps, ventilators, patient monitors, and hospital beds.

During my recent visit to Hong Kong, I asked a few colleagues if they have seen similar migration of medical devices to patient homes. Their response was no. They reminded me of the typical tiny home size in Hong Kong. In 2016, per capita living area for a Hong Kong resident was reported by the Hong Kong Housing Authority to be 141 square feet! I've seen descriptions of sub-divided flats to be as small as 50 square feet. Headlines like "In Hong Kong, the Apartments Are Fit for a Mosquito" clearly make the point. There is hardly room for anything in a Hong Kong apartment, let alone medical devices. Unless a medical device is as small as a cell phone, it will not likely be used in a Hong Kong home. Luckily for Hong Kong residents, more and more medical devices are being built into or integrated with cell phones. Maybe the tiny kitchen counters in Hong Kong flats (or apartments) will begin to resemble the dashboards of Hong Kong taxis.

Jim Keller, MS, FACCE
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New ECRI Content on Preventing Healthcare Acquired Infections

Happy Spring! Or winter, or summer, or monsoon season, depending on the time of day here in Plymouth Meeting, PA. Even though the weather hasn't settled on a particular season, it's time for some spring cleaning here at ECRI Institute. We're fielding an increasing number of calls about healthcare-associated infection (HAI) prevention and control topics from our member hospitals. We have roped in our in-house infection preventionists, biomedical and chemical engineers, statisticians, and environmental management specialists to help us answer the following questions:

Why is it so important to follow supplier-recommended cleaning practices?

ECRI regularly receives reports of damage related to use of either incompatible clean-

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Perspectives from ECRI Institute (Continued)

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ing agents or inappropriate cleaning methods. A simple substitution of a 1-minute wipe for a 3-minute wipe from the same supplier caused material degradation. Hospitals that weren't following suppliers cleaning instructions for infusion pumps and telemetry packs saw housing cracks, broken doors, and battery connector damage. Operating room tables experienced unintended table movement when fluid seeped into the control unit due to improper cleaning technique. While we're glad to see more attention being paid to making sure equipment is cleaned between patients, we want to help facilities avoid unnecessary increases in their repair and replacement budgets. We placed this issue on our Top 10 List of healthcare technology hazards for 2017 and are following up with guidance shortly. https://www.ecri.org/Components/Alerts/Pages/TrackingUser/AlertDisplay.aspx?AId=1629658

Should we be using UV light to disinfect mobile devices?

During our evaluation of tabletop UV disinfection systems, we assessed whether the ultraviolet-C (UV-C) dosages generated by tested systems was sufficient to achieve a 4 -log (99.99%) reduction in common strains of MRSA and VRE. We also wanted to see if these systems were safe for users to operate (i.e. did not leak UV-C radiation, could not operate with an open door/tray, etc.), and if they were easy to use and maintain. To further aid facilities considering this technology, we recently published guidance on considerations for clinical use of countertop UV disinfection systems. https://www.ecri.org/components/HDJournal/Pages/Eval-Background-Countertop-UV-Disinfection-Devices.aspx https://www.ecri.org/components/HDJournal/Pages/Considerations-for-Use-of-Countertop-UV-Disinfection-Devices.aspx

Do UV room disinfecting systems do the job?

We evaluated environmental disinfection systems that use UV-C light to disinfect rooms and spaces during terminal room processing. Among other issues like safety and ease of use, we wanted to determine whether these systems pack enough of a punch to kill sturdy organisms like *C.difficile* spores (*C.diff*). First, we measured the UV-C dose each unit delivered to various high-touch surfaces (e.g., bed rails) and hard-to-reach locations (e.g., under the bed) in our standardized patient test room. Then we needed a reliable way to estimate the level of pathogen reduction that we could expect from each tested unit. When there wasn't enough published information on how much UV-C dosage was needed to achieve at least a 3-log (99.9%) reduction of *C.diff*, ECRI partnered with an independent microbiology laboratory to establish our own UV-C dose-*C.diff* response curve. Now, we're able to comment on the how well each tested unit can reduce pathogen load on hard surfaces, and how use of these devices will impact Environmental Services workflow. Look for our results in early May, 2017.

Where does UV-C fit in with my environmental services plan?

We've pulled together engineers, infection preventionists, and end users to provide commentary on the use of UV-C systems for room and mobile device disinfection, and to help our member facilities decide if and how to incorporate these systems into their infection control protocols. We're holding a webinar, "Blinded by the (UV) Light" on April 26, 2017, to cover our latest findings. https://www.ecri.org/events/webinars/Pages/HD_webinar_UV_disinfect_2017-Apr-26/UV.aspx?tab=1

When it comes to interesting problems and issues with medical equipment, ACCE members are some of our best reporters. The next time you find yourself wondering, "has any other facility dealt with this?", please don't be a stranger.

Erin Sparnon
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ACCE Congratulates the 2017 Class of Fellows of American Institute for Medical and Biological Engineering (AIMBE)!

On March 20, 2017, ACCE Member: Elliot Sloane, PhD, CCE was inducted to the AIMBE College of Fellows Class of 2017 (FAIMBE), "*for demonstrated leadership in the development of standards and processes to ensure the safe and effective application of medical technologies based upon contemporary engineering and management practices.*"

He joined 150 new AIMBE Fellows this year, recognized as the top 2% of the medical and biological engineering community. Fellows are considered the life-blood of AIMBE and work towards realizing AIMBE's vision to provide medical and biological engineering innovation for the benefit of humanity. Fundamental to their achievements is the common goal of embracing innovation to improve the healthcare and safety of society.

Join ACCE at AAMI 2017, Austin

Clinical Engineering Symposium

Diagnostic Imaging: The Next Frontier

Saturday, June 10, 2017, 7AM-11AM
Austin Convention Center

A light breakfast will be available prior to the session, so plan to arrive 15 minutes early.

Description: Experts will discuss the current and upcoming trends in diagnostic imaging. Pertinent topics will allow attendees to have an in-depth view of current issues and the future of imaging. Increasing regulatory compliance and dose management considerations will be evaluated and discussed with a focus on how Clinical Engineering professionals can aid the healthcare team in their management. Experts will offer practical solutions for cost-effective management of radiological modalities and enhancing patient outcomes through improved diagnostic imaging support. Finally, the convergence of health information systems and imaging modalities and how organizations can manage them moving forward through support, industry innovations and future technology trends will be explored.

Keynote: David Berkowitz & Jennifer Myers, ECRI Institute

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27th Members Meeting/Awards Reception

Saturday, June 10, 2017, 7:30PM-10PM
JW Marriott Austin—Ballroom E

Network with your peers and congratulate the 2017 Advocacy Awards recipients and the 2017 Clinical Engineering Hall of Fame inductees

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XVII Italian Clinical Engineers Association (AIIC) National Meeting in Genoa

Italian CE Ready to Meet the Innovation Challenge

The Italian Clinical Engineering Association (Associazione Italiana Ingegneri Clinici – AIIC) held its XVII National Congress in Genoa on April 6-8, 2017. It was a very impressive conference with approximately 1,200 total participants, and nearly 1,000 of those being AIIC members. The rest were exhibitors and students. The Exhibitor Hall had several dozens of exhibitors, including many large international manufacturers, and numerous independent service organizations (ISOs).

From left to right: Yadin David, Lorenzo Leogrande, Binseng Wang, Suly Chi

The opening ceremony featured the Italian Health Minister, Ms. Beatrice Lorenzin, and numerous national and regional authorities. The scientific program had several parallel sessions, as well as dozens of posters. Among the ACCE members in attendance were Dr. Yadin David and Dr. Binseng Wang, as well as the ACCE Secretariat, Suly Chi.

Dr. David Co-Chaired a special session with Paolo Lago about the *Introduction of Innovation in Different Countries: The Point of View of European Clinical Engineers*. This session not only introduced the role of clinical engineer within the innovation process, but also initiated the introduction and exploration of collaboration between clinical engineering societies across Europe. Adriana Velasquez from the WHO opened the session via virtual connection, along with a representative from Spain. The French, Italian, and Dutch clinical engineering representatives gave in-person presentations and provided impressive descriptions of their associations' activities. Of unique interest was the presentation made by Barbara Vermeulen, an Italian-educated clinical engineer, who lives and works in Holland. Barbara noted that her clincal engineering organization represents 45 CEs from Holland, including herself. She mentioned that just 10 years ago there were no CEs in Dutch hospitals. She further described how the Dutch CEs started to get together and evolved into a full-fledged, active association.

From left: Joel Delonde, Paolo Lago, Yadin David, Barbara Vermeulen

The Italian organizers deserved credit for initiating this cross-European congregation of CE associations, and set an example for other continents to follow. In 2007, Yadin began to organize meetings of the Biomedical Advisory Committee of IFBME with individual CEs from across Europe together with Paolo Lago. However, this is the first case of collaboration for associations.

Ms. Velazquez set the tone at the beginning of the morning session when she identified the sustainable development goals of WHO and emphasized those that address human resources and innovation. She further emphasized the role of biomedical and clinical engineers throughout the strategy's four categories of Policies, Processes, Device Characteristics, and Outcomes, as well as in the different tools for innovation. These tools include Assessment, Design and Use Factors, Regulations and Safety, Intellectual Property, Technology Transfer, Manufacturing, Maintenance, and finally the business and affordability issues. Ms. Velasquez noted that there are 10,000 types of medical devices and 500,000

Binseng Wang

different products available commercially. She also spoke about issues of aging population, infection diseases, non-communicable diseases and refugees' health received proper recognition. She also mentioned the upcoming 3rd Global Forum on Medical Devices hosted by WHO and the 2nd International CE and HTM Congress scheduled to be held September 21-22, 2017, in Sao Paolo, Brazil.

Dr. Wang made two presentations: "Evidence Based Maintenance – Are we there yet?" and "Future challenges and solutions in Health Technology Management".

In addition to the large quantity and high quality of the presentations, he was

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XVII Italian Clinical Engineers Association (AIIC) National Meeting in Genoa (Continued)

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particularly impressed by the heated discussions in many sessions, proving the dynamic nature of CE in Italy. He reported that another remarkable aspect of Italian CE is the large number of ISOs present, some of which are now not only European in scope but also present in other continents.

The AIIC Conference was celebrated with a magnificent dinner at the Genoa Aquarium on the evening of April 7. The food was of course terrific, after all, this is Italy! Attendees also enjoyed appetizers while viewing colorful fish and had dinner in front of the dolphin tank. It was an unforgettable experience.

This greatly successful conference is the fruit of hard work by the AIIC President, Lorenzo Leogrande, and the Organizing Committee lead by Andrea Fisher. Among the prominent collaborators are Stefano Bergamasco (ACCE Member), Umberto Nocco, Alberto Lanzani (ACCE Member), Paolo Lago, Danilo Gennari and Paolo Pari.

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Call for Volunteer Biomedical and Clinical Engineers at Orbis

Orbis is a leading global non-governmental organization that has been a pioneer in the prevention and treatment of blindness for over 30 years. Orbis transforms lives by delivering the skills, resources and knowledge needed to deliver accessible quality eye care. Working in collaboration with local partners including hospitals, universities, government agencies and ministries of health, Orbis provides hands-on ophthalmology training, strengthens healthcare infrastructure and advocates for the prioritization of eye health on public health agendas.

Orbis operates the world's only Flying Eye Hospital, a fully accredited ophthalmic teaching hospital on board an MD-10 aircraft. For more information, please visit: www.orbis.org

As medical technologies play an essential role in ophthalmology, Orbis strongly believes that Healthcare Technology Management Professionals play a vital role in its mission. At Orbis, we provide training to BMETs and engineers around the world. Currently, we are looking for healthcare technology management professionals with extensive hands-on experience with maintaining and managing medical technologies. Particularly, we need individuals who have experience with medical and surgical ophthalmology equipment, lasers, anesthesia machines, patient monitors and other widely-used medical technologies. Our volunteers teach the technicians and engineers at our partner hospitals by running hands-on workshops during Orbis sponsored programs.

If you are interested to learn more about

these opportunities or to become a Volunteer Teaching Faculty, please contact Mohammad Baharvandy at mohammad.baharvandy@orbis.org and include a copy of your CV/resume.

Mohammad Baharvandy, MS
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Brexit and Possible Impact on Medical Device Regulation

Before the US Presidential election one of the big news items was the vote for The United Kingdom to leave the European Union (EU). The United Kingdom is made up of England, Scotland, Wales and Northern Ireland. Without getting into the politics of either, there is a real issue affecting medical devices as well as other important issues tied to the vote to exit the EU.

Currently the EU uses CE marking to indicate that medical devices have been approved. The CE marking is the manufacturer's claim that the product meets requirements of all relevant European medical device directives. Like the FDA approvals in the US, it is a way to make sure that devices are safe and effective.

The UK, as part of the EU, uses the CE marking. The question is, what happens when they leave the EU? What is the process for approval? Who will set the standards? What does this mean for manufacturers who sell to the UK, or from the UK to the rest of Europe?

For manufacturers selling into the EU, CE marking will continue. For the time being, CE marking will continue in the UK. For a UK based manufacturer, they will need to support CE marking for EU sales, FDA for US and "to be determined" for UK sales. When and how this change will take place is probably more than a year away.

The most likely "TBD" is to rely on the BSI Group. Also, known as the British Standards Institution, it is currently the national standards body of the UK. Accreditation is done by the Medicines and Health Care Products Regulatory Authority (MHRA). The challenge is that the MHRA is recognized by the EU as a European Competent Authority. Once the UK leaves the EU, that will go away and therefore they are no longer an approved European Competent Authority. There is confusion as to what will happen.

The BSI as a group has been around for quite a while and played a role in the rise of the Great Britain to a major power. The challenge is that they sometimes take a different approach to things. If you have ever worked on an older British car, then you most likely had to deal with Whitworth bolts. The very different approach to sizing bolts and nuts required two completely different set of tools for metric and whitworth. For anyone not familiar, metric tools are sized to fit the diameter of the head of a bolt (flat-to-flat diameter), whereas whitworth is sized by the diameter of the screw.

Other issue to be dealt with is the UK losing influence on the CE mark standards, and yet will have to abide by them without any input. The UK will need to decide if they will keep "Harmonized European Standards" or shift to British Standards. Because the UK is part of the CE Mark system today, we can simply agree to be instantaneously part of it after Brexit. Almost certainly this will happen, or should happen.

They challenge is a key point. Because of British perceptions of exceptionalism, they will probably be unable to resist a "tweak" to create a "better" medical regulatory system. That will destroy the UK as an entry point into Europe, and slow down adoption of new tech into the NHS. Good luck to us all.

Paul Cross, President
Healthcare Technology Foundation
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New CCE Renewal Options: Retired and Emeritus Status

Renewing CCE certificants now have the option of applying for retired or emeritus status in lieu of the full certification renewal. The retired status is for any active certificant who has decided to leave active employment in the Biomedical field, but wishes to maintain his/her certification in Clinical Engineering. The emeritus status is for any active certificant who has decided to retire from full-time employment in the biomedical engineering field and has met qualifications for lifetime achievement. Both options require a formal application to the Board of Examiners.

The fee for maintaining retirement status is a one-time payment of $100. The retired status of certified clinical engineer shall be listed as CCE-R, and is not recognized as an active CCE. Once granted, additional renewals or activity diaries are not required. Status can be reversed by completing a renewal application including the required activity diary and fees.

Those who qualify for emeritus status have 30 or more combined years as certified and actively working in the Biomedical Engineering field or show at least a continuous listing of fifteen or more years of active certification. The emeritus status of certified clinical engineer shall be listed as CCE-E, and is not recognized as an active CCE. No fees, renewals or activity diaries are required. Status cannot be reversed.

For more information and a copy of the application, refer to the 2017 Handbook and Application for Retired and Emeritus Status Change.

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Chairperson, Healthcare Technology Certification Commission
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Healthcare Technology Foundation News

HTF Board Members Participate at MD Expo

The MD Expo took place on April 9-11, 2017 in Irvine, California and was filled with a great diversity of educational sessions and the exhibits for the Healthcare Technology Management (HTM) community.

Izabella Gieras, chair of the Alarms Workgroup for the Healthcare Technology Foundation presented on "Alarm Management Strategies – The Journey to Support TJC NPSG and Beyond. The session focused on clinical alarms and how it continues to be a high priority within HTM. Clinical alarms have made the top list of the ECRI Institute's "Top 10 Health Technology Hazards" for several years now, making it one of the most researched and worked on initiative in hospitals. Izabella addressed the long journey in clinical alarms in healthcare, reviewed specific case studies, undertakings from various professional organizations as well as shared resources and tools to support the ongoing NPSG from TJC.

Izabella also co-presented with Jennifer Jackson on "Women in Engineering". The field of engineering has traditionally been dominated by men. Over the past 20 years, we started to see more women enter the field, especially in the Healthcare Technology Management arena. The presenters provided a historical overview of women in engineering, shared their own experiences in the field as well as well as highlighted other successful women in the field and their contributions.

Tobey Clark led two sessions as well:

BMET Education and Internships for Career Changers

The Technical Services Partnership at the University of Vermont has been offering biomed work experiences to students for over 40 years. Today, a full online course sequence is available to train those with a technical or clinical background in biomedical technology. This sequence, combined with a new formal internship framework and a developing apprentice program, has molded career changers into productive BMET staff. The opportunities, process education and mentoring to develop BMET staff from diverse backgrounds were presented in an interactive session.

Comparing Compliance Requirements: TJC, DNV, HFAP

Significant changes have taken place in the CMS regulatory requirements for medical equipment over the past five years. Contracted accreditation programs such as TJC, DNV and HFAP have adopted these requirements. Although the base regulatory requirements have to be implemented, each accreditation agency approaches medical equipment management differently. For example, DNV is based on ISO 9000 and has a strong emphasis on test equipment calibration and measures to take if test equipment was found out of calibration. This course covered the CMS regulations and provided crosswalks between the varying accreditations agencies. Measures to meet the guidelines of CMS and the accreditation groups were presented in an interactive discussion.

HTF Board Members Attend National Coalition

The goal of the National Coalition to Promote the Safe Use of Complex Healthcare Technology is to develop a compendium of best practices for selecting, educating and assessing complex technology. The AAMI Foundation convened its first meeting of the coalition on April 12-13 in Annapolis. The majority of the attendees were from the nursing profession with others from respiratory care, medicine, government, associations, clinical and human factors engineering, and industry which sponsored the event. HTF board members Jill Marion (FDA/CDRH), Erin Sparnon (ECRI Institute), and Tobey Clark (Univ. of Vermont) attended the workshop. Jill, who is the director of the Medsun program among other duties, presented the Purchasing for Safety initiative developed in conjunction with the VA hospital system. The CDRH starting point is the development of a checklist which focuses on ventilators, defibrillators and ESUs. Other presentations included the business case for training and other aspects of the initiative, competency, and usability. Notable talks were

HTF Healthcare Technology FOUNDATION

Improve healthcare delivery outcomes by promoting the development,

application and support of safe and effective healthcare technologies.

those by the American Society of Anesthesiologists and Boston Medical Center. The meeting ended with breakout sessions on principles to be included in a national training program and team reports. More to come on this multi-year initiative http://www.aami.org/newsviews/newsdetail.aspx?ItemNumber=4578

HTF Sponsors AAMI Horizons

The spring 2017 issue of *Horizons* – Clinical Alarms, Managing the Overload is now available online (at www.aami.org/horizons) and in print for AAMI members. In addition, a press release describing the issue has gone out. HTF is a proud sponsor as we have been working closely with AAMI and various groups on this topic.

HTF Future Projects

Have a great idea to share? Please let us know if you have any suggestions on projects for HTF that will meet our mission:

Be sure to visit the HTF website, www.thehtf.org to see 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!

Paul Coss, RN
President, HTF
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Jennifer C. Ott, MSBME, CCE, FACCE
Secretary, HTF
secretary@thehtf.org

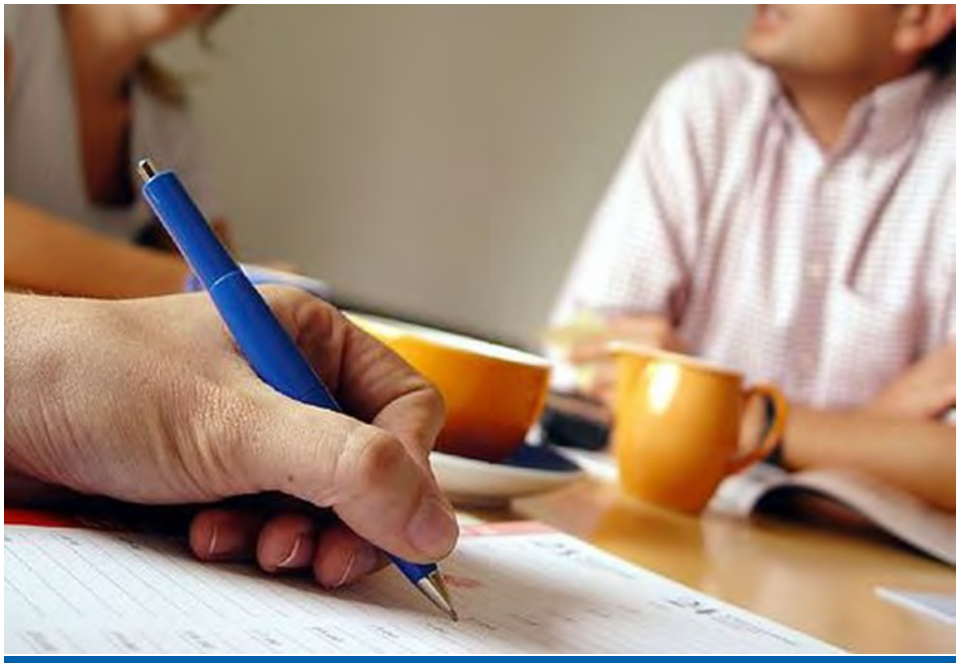
ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING

June 8-9, 2017 – Austin, TX

Prep for Certification in Clinical Engineering Exam (CCE) @ pre-AAMI 2017

Clinical Engineering and CCE Review Course

Prepare for the November Certification in Clinical Engineering Written Exam. This class will be presented by a group of ACCE Faculty who are experienced CCEs. The class will outline and present the material in each of the main subject areas covered on the exam. A mock exam as well as a session on the oral exam will be presented.



Disclaimer: This course is prepared and offered by individuals who are NOT involved in the preparation of the CCE Exam.

Going to AAMI?

—

Thinking about Getting your CCE but need a refresher?

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Sign up Today for our CCE Prep Course to learn from the experts!

Click here to download the registration form!

To register, please contact Suly Chi, ACCE Secretariat: secretariat@accenet.org

Thursday and Friday – June 8 and 9, 2017
Time: 8:30AM-4:30PM
Austin, Texas

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

Journal of Clinical Engineering Subscriptions for ACCE Members

The Journal of Clinical Engineering is a compilation of articles, papers, and extensive manuscripts relevant to clinical/biomedical engineering or biomedical technology. Subject matter directly relates to the engineering or technology involved in patient care and treatment or technology in the broad field of health care delivery.

ACCE members receive a discounted subscription to the Journal of Clinical Engineering for only $99! (Originally $265). You must login to the ACCE website to view the code. Then visit LWW.com to enter code.

ACCE Job Website Job Postings

For posting job opportunities, please contact Dave Smith at advertising@accenet.org

ACCE Calendar

May 10, 2017, 12-1:15PM
CCE Oral Exam Webinar
More Info

May 11, 2017, 12-1PM
ACCE Webinar: HTM 2.0—Where are We 5 Years Later
More Info

June 8-9, 2017
CCE Oral Exam
Location: JW Marriott Austin

June 8-9, 2017
CCE Review Course
Location: JW Marriott Austin
Registration Form

June 9-12, 2017
AAMI Annual Conference & Expo
Location: Austin, TX

June 10, 2017, 7-11AM
CE Symposium by ACCE: Diagnostic Imaging—The Next Frontier
Location: Austin Convention Center, TX

June 10, 2017, 7:30-10PM
27th Annual members meeting/Awards Reception
Location: JW Marriott Austin

June 15, 2017, 12-1PM
ACCE Webinar: Patient Safety—Case Studies and Mitigating Strategies from the Trenches
More Info

ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING

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