



ACCE News

Newsletter of the American College of Clinical Engineering

September - October 2016

Volume 26 Issue 5

Introducing ACCE President, Petr Kresta

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President's Message



Warm autumn greetings to all! It is my great pleasure to write my first message to you as President of the ACCE.

When I joined the ACCE very soon after it formed in 1990, I was very young in my career as a clinical engineer and I would not have predicted that I would be writing this article today. Life, both professional and personal, has a way of catching us by surprise from time-to-time. I am glad to say that in this case, it is a very pleasant surprise. In my time as an ACCE member, I've benefited greatly from the formal activities of the College. Even more significant, however, is the benefit I realized through the personal relationships that I've established with colleagues across North America and internationally through the ACCE. I have been inspired and mentored, not necessarily in formal ways but simply through association, by leaders in our field of work and I cannot overstate the importance of these

personal relationships in contributing to my career. When I was a young engineer, this value was not apparent to me. But now that I am older (hard to admit in some respects), I can see it clearly and I am eager to contribute to the work of the ACCE.

The number of exciting and important activities that ACCE does is truly impressive. Did you know that there are 11 formally established committees, 6 standing work groups (or equivalent); 7 formal liaisons with other significant organizations, and the list goes on? These committees, groups and liaisons are comprised of many dedicated ACCE members who work all year long to fulfill the mission of the ACCE, to promote the important role clinical engineering plays in healthcare. I encourage all ACCE members to reflect for a few minutes on this and look for ways to become involved. I can tell you from my own experience, the contribution you make will be returned to you many fold.

In recent weeks, the ACCE Board approved ACCE's support of and participation in the newly created Global Clinical Engineers Day. Conceived by the International Federation for Medical and Biological Engineering, Clinical Engineering Division, it will be celebrated on October 21, 2016 around the world. The event aims to educate and raise awareness of the expertise and benefits that clinical engineers bring to healthcare delivery systems by addressing challenges associated with the development and utilization of safe, effective, accessible and affordable technology. From the coordinated efforts of international organizations like IFMBE and the World Health Organization, and regional organizations, like ACCE, specific examples of CE contributions will be collected and posted on various websites. ACCE intends to create a presentation or video about ACCE and its activities. Further, ACCE will promote Global CE Day to its membership (all of you) and encourage you to participate in the day by creating and submitting examples of new CE/medical services,

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President's Message (Continued)

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improvements in safety, improvements in chronic disease management with instrumentation/technology, more accurate medical data, better technology assessment and maintenance, better use of equipment donations through appropriate deployment of technology management programs, and many other examples of the contributions CE makes to healthcare delivery systems. Start thinking about examples you can submit and watch for more details on how to participate. Tom Judd has kindly volunteered to assist ACCE in the organizing activities. Thanks Tom for your continuing leadership in CE!

Earlier this year, the FDA published on the Federal Register a Proposed Rule entitled, "Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments". The FDA justified the request for comments by saying, "...various stakeholders have expressed concerns about the quality, safety, and continued effectiveness of medical devices that have been subject to one or more of these activities that are performed by both original equipment manufacturers (OEM) and third parties, including health care establishments". Comments were requested by June 3, 2016. A task force was assembled to write comments on behalf of ACCE and a submission was made to the FDA (thank you again to Jim Caporali, Alan Lipschultz, Barbara Maguire, Malcolm Ridgway, and Binseng Wang (alphabetically) for their hard work on the submission). Not long afterwards, the FDA

announced that it would hold a workshop in October and opened up registration apparently on a first-come first-enrolled basis. ACCE heard from several members that their attempts to register resulted in them being placed on a waiting list. Action needed to be taken to ensure that ACCE members' views on this very important topic would be heard at the workshop. Paul Sherman and I submitted a letter (kindly drafted by Binseng Wang), to FDA formally requesting that ACCE have a seat "at the table" where discussion would take place. I am pleased to report that ACCE will have four members (Mark Bruley, Alan Lipschultz, Barbara Maguire and Malcolm Ridgway) participate formally in the workshop either as presenters and/or as panel members. The FDA plans to have a plenary session (15 minute presentations by organizations) and 4 panel discussions during the 2 day long workshop. This is an excellent example of the combined power of individual activity and organizational strength. Without both, I fear the voice of clinical engineers might have been silent on this occasion.

One of the most active committees ACCE has is the Education Committee. The Committee Co-Chairs, Jennifer DeFrancesco and Chris Falkner, and their entire team, have worked very hard to create outstanding education programs for ACCE members and others. Chris had to step down from the Committee recently due to expanded new responsibilities at his work. Congratulations Chris and thanks for all your work! I would not be surprised if ACCE knocks on your door in the future. I hope you will answer. Stepping up to join Jennifer in leading the committee is Rodney Nolan from the University of Minnesota Health where he works as Biomedical

Engineering Manager. Thank you Rodney for stepping up and taking on this important role. The current program of ACCE webinars organized by the Education Committee has a record number of subscribers, a tremendous milestone. Finally, the Committee is working to organize ACCE's educational activities for the upcoming HIMSS conference in Orlando (Feb 19 to 23, 2016). It is sure to be another outstanding event. Perhaps there is a way you can contribute...

I am going to close on a more "business" related topic. Earlier this year, the ACCE initiated a formal financial audit of its activities. This is a good step for our College to take and will provide an external unbiased assessment of how the financial affairs of the College are being managed. Information from the audit will be shared in the coming months. And with that important news, I wish all of you a happy and productive early autumn.

Petr Kresta, President, ACCE
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ACCE News

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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, w-hyman@tamu.edu, who is one of the editors of JCE, or send them to Michael Leven-Epstein at: michael.levinepstein@gmail.com.

AAMI Update

Pack a 'Brown Bag' for Free Young Professional Webinar Series

AAMI's Next Gen Task Force has launched a free "brown bag" style webinar series for students and young professionals.

"AAMI's Next Gen Brown Bag webinars are the big kickoff for our initiative to get more students and young professionals involved in healthcare technology. Our goal is to help launch our members' early careers by providing resources and networking opportunities," said Allison Rafti, director of membership marketing at AAMI and the staff manager for the Next Gen Advisory Task Force. "This supports AAMI's strategic priority to help young professionals develop in their careers and climb the ladder."

In October, the series will focus on the armed forces with two presentations. The first, by Jonathan Richardson, a federal government service sales manager at Siemens Healthcare, will provide advice on transitioning from military healthcare technology management to the private sector. Then on Oct. 31, Danielle McGeary, director of clinical engineering for the VA Boston Healthcare System, will talk about working for the U.S. Department of Veterans Affairs.

In November, Inhel Rekik, a clinical engineer at the University of Maryland Medical Center, will focus on how women in engineering can overcome challenges, and Angela Spillane, a consultant with Mainspring Healthcare Solutions, an Accruent Company in Boston, MA, will discuss taking on projects to advance your career.

To register and to learn about additional resources to help advance your career, please visit www.aami.org/nextgen.

Committee Looks to Standardize Technology Acquisition

AAMI's Medical Equipment Management Committee is developing a new standard on the acquisition of healthcare technology, with the goal of creating a consistent process for healthcare delivery organizations (HDOs) and a uniform set of topics that should be covered during the requisition process.

Capital equipment planning is becoming a bigger issue, and many hospitals are finding they are not making optimum decisions about med-

ical equipment, facts that are detailed in the July/August cover story of AAMI's peer-reviewed journal, *BI&T*.

Patrick Bernat, AAMI's director of HTM, said there is a need to establish clear protocols and policies. "Without a formal process in place for acquiring healthcare technology, and without involving the necessary players in the process, healthcare technology acquisition can become disorganized and disjointed," he said.

A formalized, streamlined approach to technology acquisition could help HDOs make more appropriate decisions, save time and money, and reduce end-user error.

"The industry would greatly benefit from a referenceable standard on healthcare technology acquisition that identifies the benefits/need for an effective acquisition process to HDO leadership, lays out an effective process with appropriate stakeholders engaged, and provides examples of tools that can help facilitate the acquisition process," said Stephen Grimes, managing partner of Strategic Health Care Technology Associates and a member of the Medical Equipment Management Committee.

The new standard is expected to cover service documentation, risk management files, processes for making purchasing decisions (including who should be involved in those decisions), depreciation schedules, monitoring of hazard alerts and product recalls, and identifying technical specifications. The committee is also aiming to develop a standardized request for proposals.

Interested in becoming an AAMI Faculty Member?

AAMI is looking for qualified applicants to join the faculty team for its Design Control Requirements and Industry Practice Course and Process Validation Requirements and Industry Practice Course. Interested individuals should complete the online application and submit the requested supporting documents by Oct. 31.

- This opportunity is suited for those who are:
- Interested in teaching medical device

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AAMI Names New CEO



Robert Jensen, AAMI's new President and CEO

AAMI's Board of Directors has named Robert D. Jensen, a longtime executive in the healthcare industry, as the association's third president and CEO.

Jensen, a former U.S. Marine, has been with the MITRE Corporation since 2003. He currently serves as vice president and director of the CMS Alliance to Modernize Healthcare (CAMH). He conceived of and established the MITRE Center for Transforming Health, dedicated to improving healthcare nationwide through systems thinking, advancing technology, and providing transformative services for government health-related organizations.

The selection of Jensen, 57, comes 10 months after outgoing President and CEO Mary Logan, 62, announced her planned retirement and just ahead of AAMI's 50th anniversary in 2017. Jensen is expected to officially start on Nov. 14. Logan will end her tenure with AAMI at the end of this year, Logan will serve in a supporting role during that time to help with the onboarding responsibilities.

For more information see: <http://www.aami.org/productspublications/pressreleasedetail.aspx?itemNumber=3859>

American Institute for Medical And Biological Engineering

The American Institute for Medical and Biological Engineering (AIMBE) headquartered in Washington D.C. is celebrating its 25th Anniversary this year. Founded in 1991, the AIMBE represents academic institutions, private industry, and professional engineering societies including more than 50,000 individuals and the top 2% of medical and biological engineers. AIMBE provides leadership and advocacy for public policy issues in medical and biological engineering for the benefit of society.

The Mission of the AIMBE is to coordinate and enhance interaction among scientific organizations in medical and biological engineering.

The AIMBE is structured in four parts:

The College of Fellows – Approximately 1,000 individuals who are the outstanding biomedical and biological engineers in academia, industry, and government.

The Academic Council – Universities with educational programs in bioengineering at the graduate or undergraduate level.

The Council of Societies – AIMBE's mechanism of coordinating interaction among professional and scientific organizations in medical and biological engineering.

The Industry Council – The voice for industry, acting on common interests that will advance the field of Medical and Biological Engineering and contribute to public health and welfare.

For many years, ACCE has been a council member of the AIMBE as one of the 18 organizations of the "Council of Societies (CoS)." The membership gives ACCE members access to AIMBE year-round activities such as participating in the collaborative forums in the field of medical and biological engineering; co-

ordinating activities with other member societies; participating in the advocacy presence in Washington DC; participating in the Advocacy activities and programs; and opening the opportunity for ACCE members to be nominated as candidates to the AIMBE College of Fellows or being nominated as candidates for the Society awards.

I had the honor to represent the ACCE at the CoS Meeting on April 3rd during AIMBE's Annual Event in Washington D.C. The primary purpose of this annual gathering was to receive feedback and discuss programming and communication opportunities for the coming year, as well as how to improve communication and coordination with AIMBE and the CoS organiza-

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AAMI continued

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industry professionals how to better understand requirements, regulations, and related standards.

- Capable of discussing challenges and solutions with course participants from around the world.
- Enthusiastic about teaching side by side with leading experts throughout the industry and from the Food and Drug Administration.
- Interested in gaining valuable experience.

The AAMI Faculty Review Panel will consider all applications and will invite selected applicants to attend the next train-the-trainer session, which will be held Jan. 26–27 in Arlington, VA. During this session, participants will have the opportunity to cultivate their instruction and facilitation skills with veteran faculty members.

For more information about the application process, please contact DeDe George, AAMI's senior manager of industry training, at 703-253-8277 or dgeorge@aami.org.

A Call for Papers

AAMI will devote the spring 2017 edition of its award-winning supplement *Horizons* to clinical alarm management. Proposals are being accepted until Nov. 2.

Those interested in submitting a research article, systematic review, case study, commentary, or other type of paper should

email Senior Editor Gavin Stern at gstern@aami.org. Authors should specify in 200 words or less the topic of the proposed manuscript and describe how it will advance the literature on the subject.

Once submitted, manuscripts will undergo peer review. The content of *Horizons* is indexed and searchable on various healthcare and scientific databases, including PubMed.

Did You Hear? AAMI Podcast Series Turns Two

It was just two years ago that the AAMI podcast series made its first appearance. Since then it has racked up 18 episodes (and counting) and nearly 17,500 downloads.

The award-winning series, which is developed in partnership with the studios of Healthcare Tech Talk, explores today's most pressing healthcare technology challenges and the multidisciplinary approaches that are being used to clarify and resolve them.

"AAMI developed the podcast series to connect with the healthcare community in a new way. People may not always have the time to read a journal article, but they can enjoy a podcast while on the go. The conversations are always lively and informative," said Sean Loughlin, AAMI's vice president of communications. "We are excited about their growing popularity and have been fortunate to work with fantastic a host in Terry Baker."

To listen to the series, go to www.aami.org/podcasts. The podcasts are free.

AAMI staff

International Report: HTM in New Woman's Hospital in Guayaquil Ecuador

The Guayaquil Welfare Board (Junta de Beneficencia de Guayaquil – JBG) provides social and healthcare service to millions of low-income Ecuadorians with a network of hospital, clinics, relief homes, and asylums. The JBG is committed to improving the quality of life of those who are not covered by public or private health care, or those who do not have access to education due to extreme poverty.

The JBG provides institutional health services for everyone from newborns to the elderly. These services are provided by all of the following: Luis Vernaza Hospital, Children's Hospital, Dr. Roberto Gilbert E., Gineco-Obstetric Hospital, Enrique C. Sotomayor, and the Neurosciences Institute. The hospital infrastructure has 2,000 beds and is a reference network of institutions for the whole country due to the wide range of clinical specialties, the experienced medical professionals, the high-tech equipment, the well-trained and committed staff of clinical and hospital engineers, and the appropriate infrastructure to meet needs with quality and safety.

Five years ago The JBG decided to replace the 68 year old Gineco-obstetric Hospital, Enrique C. Sotomayor, located in downtown Guayaquil due to the obsolete infrastructure, limitation to expand, and difficult accessibility for the population. The new hospital overcomes these limitations and is located on the grounds next to the Roberto Gilbert Children's Hospital, thus combining to form the "Alejandro Mann" Hospital Complex. This is the largest such complex in Ecuador, with an over 1,000 bed capacity between both hospitals, which services women and children.

The new Alfredo G. Paulson Woman's Hospital facility, extended the previous gynec-obstetric services. The hospital is comprised of 463,000 square feet, has 553 beds, 18 operating rooms, and 8 delivery rooms. The facility has implemented the latest technology in medical equipment and shares laboratory and laundry services with the Children's Hospital. An elevated tunnel joins both buildings and is used for the transfer of newborns in need of specialized services.



Antonio Hernandez, working at the new hospital in Guayaquil, Ecuador

The summer before its inauguration, I was invited to visit the facility and conduct a technical evaluation of the infrastructure and the technology during the commissioning process. Being part of the process of the opening of the facility was a great experience, but most notable was the professionalism and confidence shown by the professionals responsible for the operation not only of the new facility, but the Hospital Complex at large.

The leader of the project and director of the Hospital Complex, Dr. Enrique Valenzuela, is an old friend and strong supporter of healthcare technology management. He has been close to the American College of Clinical Engineering (ACCE) since early 2000, when the Roberto Gilbert Children's Hospital was under construction.

With a clear vision of the need to appropriately manage the technology, Dr. Valenzuela sent a young and bright engineer, Freddy Matamoros Espinoza, to the 2000

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The new Alfredo G. Paulson Woman's Hospital in Guayaquil Ecuador

AIMBE continued

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tions. I had the opportunity to present the ACCE mission, vision, organizational structure, and main activities. This included the ACCE international experience and coordination with international engineering and technology societies. The experiences with other countries' professional societies was of particular interests of the participants. After the meeting and analyzing the work plan of IFMBE, the wide range of opportunities that AIMBE offers to the member societies became very evident. Particularly, how ACCE members could widely benefit from the AIMBE College of Fellows or by being nominated as candidates for the Society awards.

A detailed report with recommendations was presented to the ACCE President. The President appointed me as the ACCE liaison to the AIMBE and the Board concurred with the designation, with the objective of strengthening the relationship between the organizations.

Having a close and continued communication and coordination of activities will benefit not only the ACCE Members, but ACCE will also have the opportunity to share the clinical engineering and health technology management activities with the CoS organizations. On the other hand, it will facilitate informing ACCE members of resources, events, and information available on AIMBE.

Nomination of ACCE Members to AIMBE's College of Fellows is one of the most important options of the membership. Only AIMBE Fellow members and Council members can nominate candidates to the College of Fellows. Currently, ACCE only has ten AIMBE Fellow Members. One of the priorities is to establish a system to determine qualified candidates from amongst our membership, and to submit their names in nomination to the College of Fellows.

To advance this initiative, an ad-hoc group was established with the participation of AIMBE Fellow Members from ACCE, Binseng Wang and Steve Grimes. The other members are Elliot Sloane and Mario Castaneda. The participation of all fellows has been requested for the activities normally reserved to Fellow Members, such as nominating and voting of new Fellow Members. All of the activities will be in coordination with the ACCE Advocacy Committee.

Currently, the AIMBE's FLASH government affairs newsletter to member

societies is available to the ACCE Members on the ACCE website. There is also a link to the AIMBE website. We encourage the ACCE Members to visit the AIMBE website at <http://aimbe.org>.

Millan P. Yager, Executive Director of AIMBE, has been very supportive of the strengthening of the relationship and is routinely providing advice and information on AIMBE activities. I have requested to the ACCE President to invite Mr. Yager to the 2017 ACCE Annual Meeting and Award Ceremony in Austin, TX, to present an advocacy message and a briefing on AIMBE activities.

Antonio Hernandez, AIMBE liaison
aimbeliaison@accenet.org

Guayaquil continued

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Advanced Clinical Engineering Workshop (ACEW) in Panama. Matamoros not only learned but also committed with ACCE Faculty to apply what he learned to the new facility.

In 2002, during the second ACEW held in Ecuador, the faculty and students were invited by Dr. Valenzuela and Freddy to visit the hospital during the commissioning process. We were impressed at that time; Freddy had applied the concepts and methodologies he learned from ACCE and has continued to do so through the years. I have had the pleasure of following Freddy's career and his growth through the ranks. He is the Director of Engineering and Maintenance of the Hospital Complex and has a team of very competent engineers and technicians with the necessary workshops and tools for managing the facilities. He is an active ACCE Member and he is currently working toward certification.

In addition to the support of Dr. Valenzuela, Freddy has secured the collaboration of Raúl Barcia, the Director of Hospital Engineering at the Central Level of the JBG. The JBG and the network of

hospitals has biomedical and clinical engineers, but there is no access to a continuous educational program in Ecuador. JBG is looking for ways to train the engineers and technicians. As part of the ACCE collaboration, we approached the ESPO (Escuela Superior Politecnica del Litoral), one of the best universities in Ecuador for engineering programs. The Dean of the School of Electrical and Computational Engineering is our old ACCE friend, Miguel Yapur. Miguel who has trained more than 200 engineers in Medical Electronics and his vision is to have a solid program in Clinical or Biomedical Engineering.

A meeting was held between JBG and SPOL where ACCE was invited. The meeting was to prepare an agreement to organize a training program on CE between the university and the JBG. I expressed the support of ACCE for this program and contacted Tobey Clark and Frank Painter for collaboration in the design of the curricula. This is a work in progress and there is also interest in scheduling an ACEW for 2017.

Antonio Hernandez,
International Committee Chair
internationalchair@accenet.org

Perspectives from ECRI Institute: Risk Management Course

ECRI Institute has had an active online education service for several years. We recently launched a series of ten online course that we are calling “Risk Management Basics”. The courses cover all care settings and provide a common foundational understanding of the essential elements of risk management. These include risk identification, analysis, and mitigation, including the importance of establishing a culture of safety and following up on reported adverse events. They are geared towards risk management professionals but are also relevant to clinical engineers or other healthcare professionals who would like to better understand the principles of healthcare risk management. This knowledge can help clinical engineers and other health professionals support their risk management colleagues and perform the risk management-related elements of their own job.

The courses are grounded in adult learning principles—focusing on interactive content for users who want to do more than just read an article or a set of slides. In addition to full voice-over for every course, the courses are filled with interactive elements like matching games, drag-and-drop content, and sequence and process activities. Learners will be able to establish and execute complete risk management programs, better manage risks, improve patient outcomes, and reduce financial risk. Each course is based on the recommendations that ECRI has been making for more than 30 years in its risk management-related publications.

The ten courses are listed below:

Getting Started with Risk Management

The First Step in Risk Management: Risk Identification

Establishing a Culture of Safety

Setting Priorities: Evaluating and Analyzing Risk

Stopping Problems before They Start: Risk Prevention and Management

Getting Started with Patient Safety

Risk Mapping and Maintaining a Risk and Patient Safety Program

Everyone's a Risk Manager: Get Staff Involved in Patient Safety and Risk

Make Risk Management Part of Daily Operations

The Last Piece: Measuring and Monitoring Risk

I'd be happy to talk with you if you

would like to learn more about these courses or any of ECRI's other online course offerings. I can be reached at jkeller@ecri.org or at (610) 825-6000, ext. 5279. Also, feel free to share this information with your risk management colleagues. More information is available at the link below.

<https://www.ecri.org/components/Pages/Risk-Management-Basics.aspx?tab=1>

Interestingly in my new ECRI international role I've seen a lot of interest in our courses from our overseas colleagues.

Jim Keller, Past President
JKELLER@ECRI.org

Volunteers Needed for Connectathon in Cleveland

IHE USA is gearing up for the next IHE North American (NA) Connectathon 2017 taking place January 23 – 27, 2017 at the [Huntington Convention Center of Cleveland](#) and [HIMSS Innovation Center](#).

Help advance IHE, learn more about medical device/IT integration and put your clinical engineering, medical device and interoperability knowledge to good use by participating in testing the connectivity between medical devices and various “middleware”, EMR and other IT systems.

IHE USA recruits volunteer monitors to review and evaluate interoperability tests completed by participants at the

IHE NA Connectathon. Monitors gain exposure to the latest standards, cutting-edge technology, and the engineers developing health IT interoperability. IHE USA's unique, practical learning environment provides the experience you need to advance your career.

For more information and an application see <https://docs.google.com/forms/d/e/1FAIpQLSfz9uzcMpoxqar-J5-RtLMR0ECYZ3MoEcp6ETInWhhn6dne5Q/viewform>

If you have any questions, contact Paul Sherman, IHE PCD technical coordinator at paulrshermancce@gmail.com.

Enter the 2017 Student Paper Competition

Sponsored by ACCE

The ACCE Student Paper Competition showcases the extraordinary talents of Clinical Engineering Students and related graduate program students while encouraging them to develop and contribute towards Patient safety through the application of science and technology.

Eligibility:

- The Competition is open to current students, undergraduate, or graduate in a Clinical Engineering or related graduate programs. Submitted papers must show significant contribution to the body of knowledge in Clinical Engineering.

Selection of winners: Winning papers will be selected by the Advocacy committee and Board of Directors based on, among other factors:

- **Relevance:** Relevance to current and future concerns in patient management.
- **Fundamentals:** Author's fundamental understanding of the subject.
- **Familiarity:** Author's familiarity with other relevant work in the field.
- **Application:** The application of author's topic in the profession of clinical engineering or related.
- **Analysis:** Appropriateness

of the methods of analysis

- **Structure of delivery:** The presentation/format of the oral/written work by the student

Conclusion: The ability of the results and discussion to support the conclusion.

To enter the competition:

Complete this [entry form](#)

Submit it along with a copy of your Paper to advocacychair@accenet.org

Deadline for submitting papers: 9:00 pm EST, December 23, 2016

AAMI Invitation to Participate in Standards Development

AAMI has invited ACCE members to put forward their names to work alongside others on the development of several new AAMI standards. The formal invitation from AAMI to ACCE to work collaboratively on standards is a significant event. The ACCE Board strongly encourages members to put their names forward for this important work. If you are interested in this opportunity, please send your name, contact details and reference to the standard on which you would like to work to the ACCE Secretariat.

Equipment acquisition standard:

The New Work Item Proposal was submitted last fall. It was formally approved for work to move forward in June of this year. The purpose is to provide guidance for healthcare delivery organizations on the acquisition of healthcare technology, with the goal of

having a consistent process and standardized set of topics that should be covered in the requisition process. Ultimately, standardization will benefit both healthcare delivery organizations and vendors. Topics may include service documentation, risk management files, processes for making purchasing decisions (including who should be involved in those decisions), depreciation schedules, monitoring of hazard alerts/product recalls, and identifying technical specifications, and a standardized request for proposals (RFP).

Service terminology standard:

This was also approved for work to move forward in June of this year. Its purpose is to help address the FDA's request for definitions of service-related terms. AAMI recommends that the FDA not attempt to define

these terms, because any such regulatory oriented definitions would not be consensus-based.

Compendium/reference standard:

This proposal is to be submitted for consideration this fall. It is intended to be a comprehensive reference standard that will point HTM professionals to key existing resources, standards, guidance, etc.

If interested in participating, please contact Suly Chi at sulyc@accenet.org.

Petr Kresta, President, ACCE
PKresta@dsmanitoba.ca

The View from the Penalty Box

Well we are almost done with the 2016 election cycle and only a few weeks until the 2020 election cycle starts. Why is it that most countries have short election cycles while we, here in the US, always seem to be in an election cycle? These continuous election cycles may be the big reason that the US ranks number one in healthcare costs, but is not in the top ten when it comes to life expectancy, infant mortality and so many other measures of quality healthcare.

What are the reasons for this less than stellar healthcare system? Is it the 535 senators and congressmen? Is it the Supreme Court? Is it the President? It is “yes” to all of these questions, plus the FDA, CMS, NPPA, Joint Commission and all the other groups that write the codes and regulations that we are trying to follow, even when they conflict with another code.

It seems that these groups have forgotten the most important item in healthcare who we lowly clinical engineers bust our butts trying to help. That neglected group is our patients. All the codes seem to be about data and not the patient. I read recently in a non-medical publication that the leading cause of deaths in the US are medical errors, not heart or cancer or auto accidents or if you live in Chicago, gun shots. As a profession we need to return to our roots and work with companies to make better products to serve the patients. We also need to jump all over the FDA and get them to move quicker on technologies allowed in other countries but not here in the US.

To illustrate this point, what do Bart Starr, John Brodie and the late Gordie Howe have in common? All were over 80 years old when they had major strokes, were wheelchair bound and could not speak, but got relief with stem cell treatments. These treatments were developed in San Diego, possibly with NIH backing, but are not approved for use here in the US. So these three men went to a clinic in Tijuana, where

they received injections of stem cells, grown in San Diego. Guess what? All regained their speech, were able to walk again, and got the majority of their bodily functions back. Is it a good thing that the stem cell therapy is not approved here in the US or are we too stupid to see cures and treatments that help those in need? Maybe we need to look at other ways of doing the testing for approvals. Should we use age as a factor, should we use past health issues, should we use international standards? Just think of the potential cost savings for patients who are herded into nursing homes because of strokes if they could stay in their own homes.

Let's think about international standards and what that would save. The EpiPen has been in the news as the price has moved up about six times in the recent past. The company said “why not” and talked about patents, FDA approvals, funding of additional research but not greed. We know that the patent on Epinephrine was us up about 30 years ago, so that must mean the pen design is patented. Look at the EpiPen and an insulin injection system. There is not much of a difference except that the insulin system is better marked and easier to use. As an engineer, how long would it take you to come up with an EpiPen based off of the insulin pen design? A couple of hours? How long to get the design approved by the FDA? 18 months to 2 years and close to \$100,000 in “legal” costs?

Moving on to another topic. I saw a line in some publication that said **“Horse and buggy to the moon in 70 years”**. Think about it. In 1899 we had the first commercial production of aspirin, a wonder drug back then, and still finding more uses for it in 2016. Another event in 1899 was the organization of the Ford Motor Company. As we all know, it's still around today. As engineers we have to be very proud of our past triumphs and we have to regain what we had and lost, so these next 70 years see progress in all the areas we are involved with. Remember, getting to the moon involved very little computer work and a tremendous amount of slide rule math and communication between engineering groups. It meant trying different materials, techniques and technologies. It meant communicating with peers to get answers, direction and the en-



couragement that we were headed in the right direction.

Maybe if we communicate better we can get the FDA closer to what is needed now, not what was needed in 1976. And we need to better understand that data for the sake of data is a waste of time and effort. Also the computer people need to design systems that always work the same, not sometimes one click or two or three or some other combination. Our goal is great patient care at a reasonable cost and we can do it if we are allowed to by others who will also put the patient first.

Remember to vote and those of you in Chicago, no more than 5 times, please.

Dave Harrington
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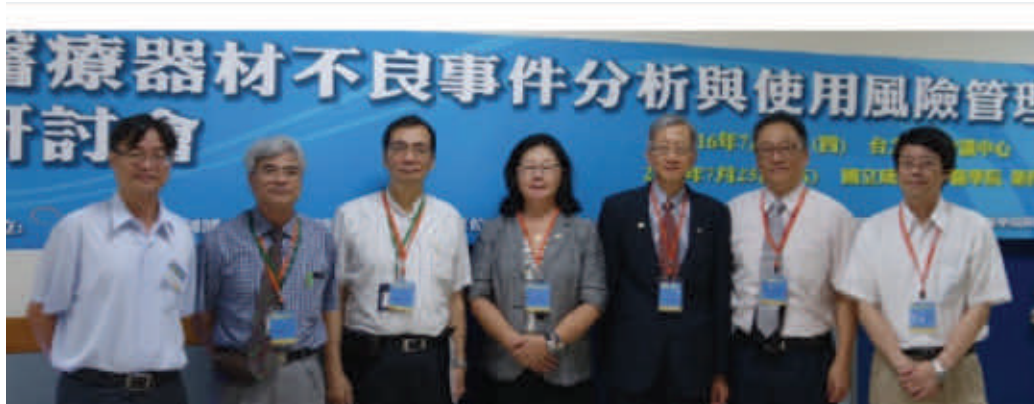


International Report: Clinical Engineering Progressing Well in Taiwan



Two conferences on Risk Management and Adverse Device Reporting were organized by the Medical Device Tech-

nology Translation Center, Chung Yuan Christian University (CYCU) and National Cheng Kung University Hospital



At National Cheng Kung University Medical College, Tainan

From left to right: Wei-Yang Lu (Director of Dept. of Biomedical Eng., National Cheng Kung University Hospital), Cheng Kuo-Sheng (Professor of Dept. of Biomedical Eng., National Cheng Kung University), Prof. Chyun-Yu Yang (Superintendent of National Cheng Kung University Hospital), Suly Chi, Binseng Wang, Kang-Ping Lin (Distinguished Professor of Dept. of Electrical Eng., Chung Yuan Christian University; Director of Technology Translation Center for Medical Device Development center; Secretary General of IFMBE) and Chia-Hung Chien (Senior Technical Specialist of Taiwan FDA, Ministry of Health and Welfare).



At The National Taiwan University's International Convention Center, Taipei

From left to right: Shiang-Lin Chu (Director of Dept. of Biomedical Eng., Cathay General Hospital), Hsin-Tai Chen (Director of Dept. of Biomedical Eng., Tungs' Taichung Metro Harbor Hospital), Shao-Liang Chang (Director of Dept. of Biomedical Eng., Lo-Hsu Foundation, Inc. Lotung Poh-Ai Hospital), Chia-Hung Chien (Senior Technical Specialist of Taiwan FDA, Ministry of Health and Welfare), Suly Chi, Binseng Wang, Kang-Ping Lin (Distinguished Professor of Dept. of Electrical Eng., Chung Yuan Christian University; Director of Technology Translation Center for Medical Device Development center; Secretary General of IFMBE), Cheng-Lun Tsai (Associate Professor of Dept. of Biomedical Eng., Chung Yuan Christian University), Siah Chee Shing (Senior Engineer of ECRI Institute, Asia Pacific) and Teso Chen (Coordinator of FlySheet Med-Informatics Co., Ltd.)

(NCKUH), with sponsorship from the Food and Drug Administration of Taiwan (TFDA), Ministry of Health and Welfare in July 2016. These conferences were flawlessly organized by Professor Kang-Ping Lin, Distinguished Professor of the Dept. of Electrical Eng. – CYCU and Secretary General of IFMBE, and his CYCU team. The invited speakers were: Suly Chi – ACCE Secretariat, Siah Chee Shing – ECRI Institute Asia-Pacific Office, and Binseng Wang – WRP32 Management, Inc. The first conference was held in Taipei at the National Taiwan University's International Convention Center, while the second was held in Tainan at the College of Medicine, NCKU.

In the first conference the topics covered were: (1) Evidence-Based Maintenance, (2) ACCE's national and international activities, (3) Healthcare Risk & Patient Safety, and (4) Risk Management & Incident Investigations. The second conference had an additional topic of Clinical Engineering Benchmarking.

In addition to these two conferences, Binseng Wang gave a presentation at the Changhua Christin Hospital on Evidence-Based Maintenance and participated in a workshop afterwards discussing risk management for medical equipment. Finally, he gave a presentation at T-FDA office on the Collective Risk Management Model for Medical Devices to the staff of its Medical Devices division and some guests from universities and professional associations.

During these conferences, Suly Chi

(Continued on page 11)

Military Health System Research Symposium

The Military Health System Research Symposium was held mid-August in Kissimmee Florida.

The premier gathering of the US military health system and those of many other nations was intended to share lessons learned, what works, what doesn't and what changes are to come.

The meeting ran for four days and included topics on care at the point of injury, transport and stabilization, definitive care and return to quality of life issues. It was a fascinating meeting that included military and civilian presenters.

A key issue the military is dealing with is how to keep the high level of delivered care as so many providers are leaving the military due to retirements and downsizing. Working to assure that the same level of care is available both in our current deployments and for the next ones is a major issue and is driving innovation, new technologies, decision support and work on Autonomous Care Systems.

Another key issue is maintaining the level of support and research as downward pressures on budgets cut programs and those that remain find themselves with less money or competing for fewer resources. This is occurring in all segments of the economy and the military is not exempt.

This is of real concern for us noncombatants as many of the innovations and improvements in care become part of civilian EMS and medical care. Many of the products that were developed to be used in combat, translate easily into civilian care and save our lives as well.

Other areas for research are related to improving the overall health of the wounded warrior, and caring for their bodies and their minds. It remains a troubling statistic that the suicide rate for soldiers is very high and a great deal of work is being done to stop this and to provide care for these soldiers.

In addition, there is a great deal of work being done on transplantation of arms, legs, and faces as well as dealing with complex pelvic injuries and associated body parts.

The conference was amazing. The work being done was impressive and the results even more impressive. It was an honor to attend.

One of the most interesting technologies coming out of this area is the development of Autonomous Care Systems. This is based on close loop technology that can regulate/control ventilation, fluid replacement therapy, temperature management, and other critical systems. While still early in development, we are seeing self-driving cars, cars that can park themselves and braking systems that deploy automatically. Autopilots in planes, heating and air conditioning systems are but two examples of

where this sort of technology already exists.

I stayed in a hotel recently where I had to turn the radiator on or off to control the heat. I lay in bed for an hour shivering before finally getting up and turning the radiator on at 2 in the morning. Then an hour later I had to deal with being too hot. Why are we so far behind in healthcare for even simple control systems? As patients become sicker and we struggle to keep enough clinicians in the field, systems like this will become standard in all sorts of settings.

*Paul Coss, President
Healthcare Technology Foundation
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Taiwan continued

(Continued from page 10)

and Binseng Wang were able to discuss the past accomplishments, current challenges and future growth of clinical engineering (CE) in Taiwan with the participants. Both were very impressed by the progress made thus far in Taiwan. In many respects, CE in Taiwan is comparable to CE in the USA. Most large hospitals have in-house teams with highly educated and competent staff (many with college or graduate degrees). There are also a few independent service organizations that evolved from formerly in-house teams competing favorably with OEMs and their distributors.

Several hospitals in Taiwan have achieved accreditation with the Joint Commission International and, thus, follow standards similar to those issued by The Joint Commission in the USA. While formal CE education is still in its infancy, undergraduate and graduate degrees in Biomedical Engineering have been offered in Taiwan for several decades.

In essence, CE is progressing well in Taiwan and exchanges between their and American CE professionals can be quite mutually beneficial.

*Binseng Wang
International Committee member*



Global Clinical Engineers (C.E.) Day

TOGETHER WE CAN MAKE IT BETTER

Global CE Day is a worldwide celebration recognizing the important contributions of clinical engineers to the improvement of the world population's health and wellness. It occurs annually on October 21st.

Join ACCE and our clinical engineering colleagues around the world on October 21, 2016, as we celebrate Global Clinical Engineers Day.

For 24 hours, this [website](#) will feature interviews with members of the US and global CE community, highlight events – either on-site or virtual - from associations around the world such as those events hosted by the American College of Clinical Engineering, include a chat room in different languages, and stream videos showcasing various CE roles and functions.

Members are invited to submit photos and short videos to be broadcasted throughout the day. Rotating around the world in each of the world time zones, delegates will be online, sharing their experiences

and responding to participants' comments. Short videos of up to three minutes are preferred, as well as such materials as brochures and professional success stories.

Please send your videos to Yadin David, Global CE Day chair, at da-vid@biomedeng.com and Tom Judd, IFMBE CE Division Secretary, at judd.tom@gmail.com.

References: [Country Presentation HTM](#) [Success Stories](#) [Success Story Invitation Letter](#)

[Health Technologies Resource 2016](#)

CCE study guide, V6.0—August 2016

ACCE would like to thank the volunteers who contributed over the past 20 years (1996-2016) to update the CCE Study Guide, which is today a complete guide.

Order your copy [here!](#)

Recent and previous contributors include:

V6.0 (August 2016): Matthew Baretich; Tobey Clark.

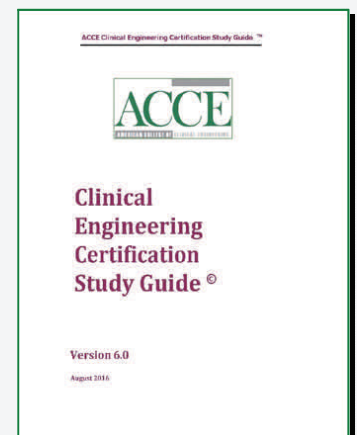
V5.0 (May 2016): Austin Hampton

V4.0 (July 2014): Jacob Johnson, Jennifer DeFrancesco

V3.0 (August 2012): Ilir Kullolli, Kindall Druker, Frank Painter

V2.0 (July 2007): Arif Subhan, Ismael Cordero, Evelyn Fan, Robyn Frick, Jennifer Jackson, Jeff May, Frank Painter, Bokang Rapoo

V1.0 (1996): Stephen L. Grimes, Jerry Anderson, Salil Balar, Ted Cohen, Vinnie DeFrancesco, Izabella Gieras, Frank Painter, Christine Ruther, Marv Shepherd



Education Committee Report: Welcome to New Co-Chair, Rodney Nolen

The Education Committee is extremely excited for the busy year ahead! The 2016-2017 webinar series kicked off with a presentation from Nathan Cinefro on Medical Device Patching and Sustainment that had over 200 individual and institutional members in attendance. The webinar had much discussion and tackled some of the unique challenges related to security and patch management across the field. The October webinar titled "Alarm Management: Balancing Clinical Appropriateness and Fatigue" promises to shed more light and open continued discussions on one of the ECRI Institute's Top Ten Health Tech Hazards of 2016. The education committee is working diligently to bring relevant material to your fingertips through the monthly webinar series. The upcoming webinars, listed below, still have room for registration!

The Education Committee is also excited to welcome a new co-chair Rodney Nolen! Mr. Nolen is the Manager of the Central Region of Biomedical Engineering for the University of Minnesota. Recently, he sat down for an interview with fellow co-chair (JD) to allow ACCE members to know a bit more about him:

JD: Rodney, how long have you been in the Clinical Engineering field and how did you get your start?

RN: I have been in the field over 26 years and I got my start at the United States Army Medical Equipment and Optical School (USAMEOS), Fitzsimons, CO.

JD: What are some of the main challenges you see as a Clinical Engineering manager?

RN: The changing and expanding role of the biomed technician always has my attention, however, I see one of our biggest challenges being the lack of a true staffing/FTE model. If we could develop a staffing metric that could eventually be supported and backed by regulatory agencies I would consider this a big win for the Clinical Engineering Industry.

JD: How do you see ACCE and the Education Committee fitting into professional development and continuous education?

RN: ACCE through the education committee provides very meaningful and real world professional development and education that has value to clinical engineering leaders at all stages of their careers from new leaders to the most seasoned of leaders.

JD: What do you expect to be your biggest challenge stepping into the co-chair role and

what do you want to bring to the group?

RN: Those who have come before me have done great work building a very effective program and I hope to continue the growth in a way that fits with ACCE's mission and goals. I bring a very diverse background to the role that includes government, consulting, and hospital operations at all levels and I just hope to use that experience and knowledge to help the organization.

JD: What is something that most of our ACCE members wouldn't know about you?

RN: I am a rabid Pittsburgh Steeler fan and native of the Pittsburgh area.

Jennifer.DeFrancesco
Jennifer.DeFrancesco@va.gov

10-Nov-16	Clinical Workflow Management: Implementing and Sustaining Health Information Systems Integration
8-Dec-16	Collaborative Support Models: IT, Informatics and Clinical Engineering
12-Jan-17	Clinical Engineering: Growing Competencies for Growing Responsibilities
10-Feb-17	Joint Commission Update
9-Mar-17	Translational Medicine: Moving Past Traditional Clinical Engineering Paradigms
13-Apr-17	Health Tech Equity: A Global Vision
11-May-17	HTM 2.0: Where is Clinical Engineering 5 Years Later
8-Jun-17	Patient Safety: Case Studies and Mitigating Strategies from the Trenches

ACCE Job Website Job Postings

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

Contributions to the ACCE Newsletter are always welcome. For ACCE Newsletter Guidelines, please go to: <http://accenet.org/publications/pages/newsletterinfo.aspx>

Thank You to 2016 CCE Review Webinar Series Faculty & Moderators From The Education Committee!

The Education Committee would like to thank our CCE Review Webinar Series' Faculty. We would like to thank these four faculty who had been taking time out of their busy schedule to share with us their knowledge and help Clinical Engineers to prepare for their CCE exam and advance the Clinical Engineering profession.



Matt Baretich, CCE



Tobey Clark, CCE



Ted Cohen, CCE



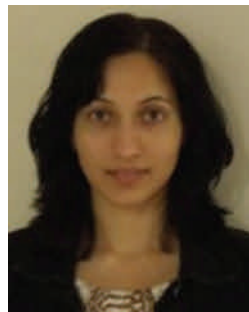
Frank Painter, CCE

Thanks also to our sponsor, Phoenix Data Systems, who made it possible to offer the webinar series at discounted rate to participants from many countries outside of the United States, including Brazil, the Bahamas, Canada, Chile, Ecuador, Honduras, Hong Kong, Saudi Arabia, and the United Arab Emirates.

We also thank our volunteer members who moderated the 2016 CCE Review Webinar Series:



Samantha Herold



Ketaki Muthal



Jared Ruckman

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 an exclusive discounted subscription rate to the Journal of Clinical Engineering, \$ 99! (originally \$265).

You must login to the ACCE website to view the discount code. Then visit the www.LWW.com , search for "Journal of Clinical Engineering" and enter the discounted code at checkout!

Welcome New Members

Dema Assaf	Candidate	Clinical Engineer	Universal Consulting Services	MD/USA
Hiroki Igeta	Associate	Clinical Engineer	Aso Izuka Hospital	Japan
Lesley Foster	Associate	Technical Services Engineer	Biotronik Incorporated	OR/USA
John Moore Jr.	Candidate	Clinical Engineer	Universal Consulting Services	MD/USA
Nehal Kapadia	Candidate	Grad Student/ Clinical Engineer Intern	UCONN/MGH	MA/USA
Alexis Henry	Candidate	Grad Student/ Clinical Engineer Intern	UCONN/Lifespan	RI/USA
Brittany Guerrero	Candidate	Grad Student/ Clinical Engineer Intern	UCONN/Hartford Hospital	CT/USA
Oreste C. Domond	Associate	Biomedical Engineer	Long Beach Memorial Medical Center	CA/USA
Ahmad Ateyat	Candidate	Grad. Student/ Clinical Engineer Intern	UCONN/Crothall Healthcare	MA/USA
Angelina Chiaracane	Candidate	Grad Student/ Clinical Engineer Intern	UCONN/Baystate Medical Center	MA/USA
Maraquia Atwood	Candidate	Grad Student/ Clinical Engineer Intern	UCONN/UCONN Health Center	CT/USA
Keith Barr	Individual	Self-Employed		NJ/USA
Shane Waltsak	Candidate	Grad Student/ Clinical Engineer Intern	UCONN/Brigham and Women's Hospital	MA/USA
Eric Aring	Institutional-Associate	Systems Engineer	Lucile Packard Children's Hospital	CA/USA

Welcome to our newest institutional member:

[Lucile Packard Children's Hospital](#)



Lucile Packard
Children's Hospital
Stanford

ACCE Calendar

August 10—October 12 (Wednesdays)

CCE Review Course—Webinar Series

October 13, 2016

ACCE Webinar: Alarm Management—Balancing Clinical Appropriateness and Fatigue

[More info](#)

October 21, 2016

Global Clinical Engineers Day (see article link)

October 27-28, 2016

FDA Workshop: Refurbishing, Reconditioning, Rebuilding, Re-marketing, Remanufacturing & Servicing of Medical Devices Performed by Third-Party Entities and OEMS

November 5-19, 2016

2016 CCE Written Exam

November 10, 2016

ACCE Webinar: Clinical Workflow Management—Implementing and Sustaining Health Information Systems Integration

[More info](#)

November 16, 2016

CE-IT Town Hall: Acquisition and Lifecycle Management of Integrated Systems

[Register](#)

December 8, 2016

Collaborative Support Models: IT, Informatics and Biomedical Engineering

ACCE

AMERICAN COLLEGE OF CLINICAL ENGINEERING

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