



ACCE News

Newsletter of the American College of Clinical Engineering

March/April 2010

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Make Your Plans for ACCE at AAMI Tampa

ACCE will be conducting a symposium on Saturday June 26 as part of the AAMI Conference and Expo. This year the Symposium topic will be "Medical Device Connectivity is mandated for 2013: Are you ready? Meaningful Use and Its Impact on Healthcare Technology Management".

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Reunion Celebrates 20 Years of ACEWs throughout the World

Clinical Engineers from throughout the world joined ACCE's very active International Committee and Advanced Clinical Engineering Workshop (ACEW) leadership in a celebration of the 20th anniversary of the ACEWs. The American College of Clinical Engineering (ACCE) started the Advanced Clinical Engineering Workshop program in 1991. For the past twenty years, workshops have been conducted around the world with support from entities such as the World Health Organization (WHO), the Pan American Health Organization (PAHO), and Orbis International. In twenty years, there have been 45 ACEWs, hosted by 28 countries, with over 4,000 participants



Clinical Engineers from throughout the world celebrated the 20th anniversary of the Advanced Clinical Engineering workshops from 63 countries attending, and more than 70 faculty members involved.

The goal of the meeting was to not only celebrate 20 years of successful health technology management (HTM) workshops/seminars with health leaders, but also to conduct a review of the program in an effort to capture their impact in our various communities. The meeting was designed to encourage an open discussion in several areas of interest including: the key components of an ACEW workshop, structure and methodology, content and materials provided, faculty and participant selection, and the development of HTM programs in countries after the workshop and how the workshop might have played a key role in 'kick-starting' national health technology policy implementation.

This meeting had 2 days of face-to-face discussion along with a dinner celebration. Since the meeting was conducted around the HIMSS Annual Conference, the participants were invited and welcome to join ACCE-sponsored conference activities. They were sponsored to attend the

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ACEW reunion at HIMSS continued

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HIMSS CE-IT pre-conference symposia, invited to attend the Exhibition area and Interoperability Showcase, and the ACCE Meeting & Reception.

The ACCE ACEW Reunion 2010 Organizing Committee (Mario Casteneda, Tobey Clark, Yadin David, Tony Easty, Antonio Hernandez, Jennifer Jackson, Thomas Judd, Frank Painter and Adirian Velazquez) would like to thank the WHO and PAHO for their generous

financial and planning support for this meeting. We would also like to thank the following people for joining the Organizing Committee as additional faculty for the meeting: William Gentles, Andrei Issakov, Roger Schmitt, Binseng Wang, Elliot Sloane, and James Wear. We would also like to thank the IFMBE CED for endorsing this meeting, as well as the meeting sponsors ACCE, WHO-PAHO, Orbis International, Cisco Systems, Aramark Healthcare and Kaiser Permanente.

Participants from throughout the world enjoyed a packed agenda that included: Country reports from several African, Central and South American, Caribbean, Asian and European countries; a WHO/PAHO update; and a workshop to answer the question: What tools, documents, education, networking opportunities, advocacy, etc need to be developed or rewritten to encourage sustainable implementation of healthcare technology management and how these resources should be realized?

Tom Judd

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Participants in ACEW Reunion in Atlanta

Participants Name	Affiliation	Country
ACEVEDO Francisco	Naval Hospital, Viña del Mar (Valparaiso)	Chile
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AGIBETOV Kazbek, PhD	MoH, Bishkek, Kyrgyzstan	Kyrgyzstan
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GONZALEZ Maria Luisa	MoH, CENETEC, Mexico City	Mexico
HAMID Azman	Healthtronics, Secy, CAHTMA, Kuala Lumpur, Malaysia	Malaysia
JALIAHVILI Irakli	Tbilisi, Georgia (working in Denmark)	Georgia
JENKINS Gabriela Munilo	CCSS, San Jose	Costa Rica
JUAREZ Salvador	ISSS, San Salvador	El Salvador
KEMPE Lutz	WHO Health Technology Consultant , TTM, Germany	Germany
KHALAF Baset	Tshwane University, Pretoria, South Africa	South Africa
MASANJA Richard	MoH, Dar es Salaam	Tanzania
MIDEKSA Mulugeta	MoH, Addis Ababa	Ethiopia
MISLA Oscar	CIRACET Corp., San Juan	Puerto Rico
MOLINA Tatiana	Universidad CES, Medellin	Colombia
PORTER David, PhD	WHO Health Technology Consultant, Nepal	Scotland
PRIMIC Victor	MoH, Buenos Aires, Argentina	Argentina
RICHARDS Keith	MoH, Montego	Jamaica
RIVAS Rossana	PUCP-CENGETS, Lima, Peru	Peru
SEMTIME Senait	MoH, Addis Ababa, Ethiopia	Ethiopia
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ACCE News

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Healthcare Technology Foundation: New Name for a New Era

The Healthcare Technology Foundation, Plymouth Meeting, PA, a 501(c)3 charitable organization, recently announced the adaptation of a new name and logo that reflects its new direction with respect to the safety of medical technology.

The Healthcare Technology Foundation, founded in 2001, was incorporated



exclusively for charitable, educational and scientific purposes associated with medical technology. Since 2001, the Foundation, through the service of volunteers, has sponsored conferences, white papers, patient education and professional development activities that focused on:

Improving healthcare delivery outcomes by promoting the development, application and support of safe and effective healthcare technologies through the advancement of clinical engineering research, education, practice and related activities.

“Our new name will create new opportunities in the healthcare

marketplace by clarifying that we are an independent organization with an independent mission.” said Healthcare Technology Foundation President William Hyman, ScD. “We expect that this will facilitate new collaborations while continuing to work closely with the American College of Clinical Engineering.”

In addition to Dr. Hyman, the Healthcare Technology Foundation’s executive leadership includes, Tobey Clark, Vice President, Jennifer Ott, Secretary, Henry Montenegro, Treasurer, Wayne Morse, Immediate Past President, and Yadin David, EdD, President Emeritus .

Certification in Clinical Engineering
(CCE) Exam



Exam Date November 6, 2010

US Application Deadline August 14, 2010
For those taking the exam within the US & Canada

International Application Deadline July 17, 2010
For those taking the exam outside the US & Canada

Visit www.acce-htf.org/certification/ for handbook, application and more information.

Email secretariat@acce-htf.org if you have any questions.

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ACCE Clinical Engineering Certification Study Guide

The American College of Clinical Engineering has prepared a Study Guide for the Clinical Engineering Certification examination offered by the Healthcare Technology Certification Commission established under the ACCE Healthcare Technology Foundation. The Study Guide is available through ACCE for \$30. To order a copy of the Guide, please make out a check payable to ACCE and send to:

Alan Levenson, ACCE Secretariat
5200 Butler Pike
Plymouth Meeting, PA 19462

Or e-mail Secretariat@ACCEnet.org and include credit card information (name on card, type of card, card number, and expiration date). Applications are now being accepted for the **November 2010** exam. Applications and the applicant handbook can be found at www.ACCEnet.org/certification

The ACCE Study Guide was written by an independent group of clinical engineers not associated with the exam process

Commentary: Some Considerations on Alarm Notification Systems

Alarms continue to plague healthcare as evidenced for example by the recent problems at MGH (http://www.boston.com/news/health/articles/2010/02/21/mgh_death_spurs_review_of_patient_monitors/), yet the alarm-off condition at MGH is just one of many alarm issues. The scope of the alarms challenge was addressed at length in the Foundation's white paper, Impact of Clinical Alarms on Patient Safety (<http://www.acche.org/White%20Paper.pdf>). Another much addressed issue is alarms actually reaching the caregivers in a timely and meaningful manner, and the caregivers actually responding appropriately.

One approach aimed at improving alarm responsiveness is the addition of an automatic or semi-automatic alarm notification systems. Typically such systems capture alarm data from medical devices, process the alarms to varying degrees, and then communicate the alarms to what are presumably the appropriate personnel. A variety of third party vendors or combinations of third party vendors are interested in this arena. The FDA is also interested as evidenced by the still pending Medical Device Data Systems (MDDS) proposed rule.

I recently had the occasion to develop a series of questions for such vendors. What follows is some of these questions with a few comments.

What is the FDA regulatory status of the vendor's system? Are they registered with the FDA and is their system listed? What FDA class is their system? If it was cleared through the 510(k) process, what is the 510(k) number? An assertion by the vendor that their system does not require FDA regulatory activity is an assertion that it is not a medical device. Such an assertion must be viewed with suspicion. See for example the discussion accompanying the MDDS proposed rule.

Does the vendor have references? How long has the reference had the system? How does the reference's internal tech-

nical support capability compare with yours (honestly)? Is the vendor likely to still be in business in one, two, five years?

Can the system be maintained in house without the vendor, or will you be forever vendor dependent? And what happens if forever turns out to be short term if the vendor doesn't survive the marketplace?

What device alarms will be included in the system? How will the system capture all the signals? What will it do with the information it captures, including how will it be processed and prioritized, and how will the caregivers actually be notified? Will this well defined in advance or is it going to be figured out after you sign the contract? The latter type of arrangement is probably one to be avoided. It is perhaps like agreeing to buy a new car and then determining the options that are included after the deal has been made.

How will new devices be added, and by whom? Is it user upgradeable or only vendor upgradeable? What will add-ons cost?

Is the system reliable with a low bug rate? Can an alarm not get captured and communicated, even though the intent and fair expectation is that it will be? Will expectations of being notified degrade user vigilance? What is the capacity of the system and can it get swamped?

Will there be alarm filtering and prioritizing, and if so what is the reliability of the algorithms? Note here that alarm filtering and prioritizing probably increases the FDA classification above class I where MDDS are proposed to be.

Is the vendor "stepping up" and calling it a primary alarm or "hiding behind" secondary? How do you intend to use it and is this consistent with the vendors assertions and disclaimers?

What will the level of call traffic be and

in turn how is a real life nurse in the real life environment supposed to function if her phone (or whatever) is yapping at her all the time? It is well known that today's alarm noises are commonly ignored, at least for some time. How will the new system be better than the old in this regard? What is a nurse supposed to do if she is actually busy doing something when her device sounds? What happens if she ignores the incoming traffic because she is busy dealing with the situation at hand? Will there be variable alerts depending on message acuity? Who will set these levels and sounds? And note that whatever the acuity and sound, they still might actually be legitimately busy.

What is the communication device? How does the nurse carry and use it? How will it be physically related to the other nurse carried devices? How many devices is a nurse supposed to be carrying and using? For example there may be multiple communication devices and maybe a few different bar code readers.

If the new communications messages are to be integrated into other devices who will be doing that? Are the details of doing so known in advance or to-be-determined?

Does the sending system know if the message is not received and/or acted on, and can it then alter or escalate the distribution?

What happens if the nurse with the device goes to lunch, or goes home? Is it up to the user to let the system know they are unavailable, or is this automated? If it is user operated what anticipated time period constitutes being busy? In real life does this mean that every time the nurse is about to begin a task they have to indicate "I'm busy" and then "I'm now available"? Think about having to do that at your desk or workplace.

How will implementation take place,

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Perspectives from ECRI Institute: New Activities with Social Media

You may have heard that ECRI Institute recently purchased Biomedtalk. After thirteen years of running the valuable listserv for the clinical engineering community Mike Kauffman was ready for a break. Biomedtalk has been an excellent forum for biomedical equipment technicians and clinical engineers to discuss and share technical matters on equipment repairs, accreditation concerns, issues surrounding device safety and performance, helpful hints for finding spare parts, and so on. The clinical engineering community is very grateful for the wonderful service that Mike has tirelessly provided for so many years. Thanks Mike! ECRI Institute is pleased to be able to carry on Mike's legacy and is looking forward to using Biomedtalk to help us become better connected with the clinical engineering community.

Biomedtalk's transition to ECRI Institute took place on March 1, 2010. For any existing members, the transition should have been pretty seamless. However we have made a few changes. Biomedtalk is now free and is no longer accepting fees for advertising. We've spruced up and updated Mike's FAQ page and transferred this information to an ECRI Institute Web site at <https://www.ecri.org/biomedtalk/Pages/default.aspx>. You can find information at this site on how to sign up for Biomedtalk, send messages, view archives, customize your personal settings, and much more. To sign up for Biomedtalk simply e-mail your name, title, institution, city, and state to biomedtalkapp@ecri.org.

For the near term we plan to keep Biomedtalk pretty much as it is. However, we'll be soliciting ideas from the Biomedtalk community on ways it would



Jim Keller is ECRI Vice President for Health Technology Evaluation and Safety, and a past Member at Large for ACCE's Board

like to see the listserv improve. ECRI Institute has also begun to use other forms of social media. So we'll be investigating how Biomedtalk relates to these other social media tools.

Regarding other social media, you can now follow ECRI Institute on Twitter, Facebook, and LinkedIn. We hosted a very successful Webinar on CT radiation dose last month and sent out a variety of Tweets to our Twitter followers on useful information from the program. The headlines for our Health Devices Alerts hazard and recall information are now being made available via RSS feeds. We have also begun using discussion forums on the member Web pages of our Web site. We have discussion forums related to risk management, the Steris System I sterilizer, and surgical robotics. Starting with the March 2010 issue, all new online articles from the *Health Devices* journal will have their own discussion forums. The journal article discussion forums can be used to discuss our evaluation findings, share your experience with the products we evaluate, and comment on the recommendations and other information in our guidance articles.

Feel free to contact me at (610) 825-6000, ext. 5279 or jkeller@ecri.org if you would like to discuss our new social media tools or if you have comments or suggestions about how we can improve Biomedtalk.

Jim Keller

Alarms continued

(Continued from page 4)

how long will it take (which should then be multiplied by at least two), and who will be available to do it? Are there clear performance criteria for when the system is accepted? How will problems be resolved? For example suppose the current ventilator really can't be integrated into the system. In this regard I once heard a mostly proud presentation in which it was said that the vendor's engineers were on site "finagling" the system to make it work. If this is the case was such finagling documented? Is it extendable and repeatable? (P.S. Finagle generally has a negative connotation denoting trickery or deceitfulness making it a strange word choice in this regard, or was it an honest word choice?)

How much training will be required? When will take place and who will do it? Will it be demo-and-go, or will it be careful and competency based? How will new

and temporary nurses get trained?

If the system turns out to be a dud, how can you back out of it both financially and technically? I know a new hospital that had a pneumatic tube system installed throughout the building. After never getting it to work correctly, they sealed it up for future urban archeologists to discover.

There are no doubt many other considerations. For all of them it is preferred that all the answers be known pre-contract as opposed to sign-up-and-then-we-will-figure-it-all-out. More generally this is another example of why hospitals, with clinical engineering's help, need to be smarter and more diligent consumers.

William A. Hyman, President
Healthcare Technology Foundation

The View from the Penalty Box:

Spring, Politics and IT Idiots

Spring is starting to make itself known here in the Northeast, the snow is pretty much gone, the flowers are coming up and the politicians are still not getting it. I am not sure who said it but the quote “you can overcome ignorance, but stupid is forever” sure describes our politics at all levels.

Case one: In the last View I mentioned that I was going to try to attach to a pending bill in the state legislature that required car manufactures to supply auto repair shops with diagnostic software so the car owners would have options to have the same provisions apply to healthcare products. The committee did not see the benefit of having the bill cover healthcare products so it died quickly. As one person said to me, it sounds like it would save money but no one in politics wants to take up that fight right now.

Case two: Recently a major Boston Hospital had a patient die because the alarm on that patient’s monitor was turned off. It made the front page of the newspapers and the hospital put out a press release that all 1,100 cardiac monitors in the facility were tested and modified so that the alarms could not be turned off. Now think about this for a minute and what questions come to mind? Here are some that I have and I am sure that you can come up with more. First, 1,100 monitors in a hospital all checked and modified over a weekend? How long did it take to test and modify the monitors? Were all the monitors the same model? What was reported to the FDA? Why is there no advisory out on the problem from either the FDA or the manufacturer? As a side note, several days later a letter to the editor appeared in one of the Boston newspapers from a physician that trained at this hospital in 1969 saying that it was common back then to also turn off heart rate alarms. So where is the problem, bad equipment design, bad alarm criteria, bad training, poor or non existent oversight of medical products or what? This is at least a 41 year old problem that still has not

been solved.

Case three: A lot of press has been given to high levels of radiation exposure to patients getting CT scans, especially children. Now some of the companies are putting out advisories on exposure times based on the patient size. CTs have been around for over 40 years and the manufactures are just getting around to determine that one exposure rate does not fit all patients? Where were the people who were supposed to keep patients safe? Yes we can look in the mirror for one of the people who should have caught the problem.

It is widely believed that clinical engineering will become part of the IT departments in hospitals. But is this consolidation in the best interests of the patients? How many reports and stories have we heard about the IT personnel changing passwords preventing clinical people from getting needed information? Maybe there is a need to make these changes, but shouldn’t they inform those that are most involved with the patient needs?

The IT dweebs continually talk about mining all the clinical data from the equipment that we service but from what I have seen no mining is taking place. All that is happening is that patient equipment is becoming more complicated and expensive to purchase and maintain with very little if any benefits shown.

We need to forget the data mining and all the fancy bells and whistles on equipment until we, as clinical engineers, can assure the patients and clinical staffs that the equipment will work, will not sound alarms or change screen colors or print out strips for every transient event that happens with a patient. We, as a profession, need to push the manufacturers of equipment to keep it simple and easy to use because the **clinical personnel need to concentrate on the patient not the technology.** It is only the IT people that can do ctrl/alt/delete and get

out of a problem or reboot with the technology fails, not the clinician. When technology fails all too often the clinician has to call the morgue. So to the IT guys no more “ID 10 T” errors when dealing with patients, for those of you that do not know that error code just remove the spaces.

Have a great spring and keep watching hockey.

Dave Harrington

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Journal of Clinical Engineering – Call for Papers

The Journal of Clinical Engineering, which prints the ACCE News in each issue, is interested in papers from you. If you have an urge to write, and good clinical engineering activities or thoughts 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. He can be reached at w-hyman@tamu.edu. Completed manuscripts can be sent to William or Michael Leven-Epstein at

ACCE

AMERICAN COLLEGE OF CLINICAL ENGINEERING

ACCE Mission

1. To establish a standard of competence and to promote excellence in Clinical Engineering Practice
2. To promote safe and effective application of Science and Technology to patient care
3. To define the body of knowledge on which the profession is based
4. To represent the professional interests of Clinical Engineers

We are on the Web:

www.accenet.org

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 Body of Knowledge Committee Chair Open
 Strategic Development Committee Chair Izabella Gieras
 Secretariat Alan Levenson

Calendar of Events

June 26-28, 2010

AAMI Conference and Exposition,
Tampa FL

June 26, 2010

ACCE Symposium at AAMI
Tampa FL

September 16-17, 2010

Second Annual Medical Device
Connectivity Conference & Exhibition
San Diego, CA.



 = ACCE Teleconference