Putting Medical Devices in the Center Ring

On September 9-11, 2010, Bangkok, Thailand played host to the World Health Organization’s First Global Forum on Medical Devices (GFMD). Over 100 countries sent representatives to network with each other, professional organization representatives such as ACCE, academia, and industry. We came together to learn how medical devices, when assessed, managed, and regulated appropriately, can make a difference in strengthening healthcare delivery systems.

The objectives of the GFMD were:

- To demonstrate evidence for the need for appropriate evaluation, prioritization, regulation, assessment, management and research strategies for medical devices;
- To share knowledge on available resources, guidelines, tools, strategies, policies and best practices at national and regional levels;
- To bring together policy makers, professional organizations, funding agencies, and key stakeholders to foster interdisciplinary partnerships and cultivate the aim of reaching a common goal of accessible medical devices.

(Continued on page 2)
This was a very important activity for ACCE. Since February, we had volunteers serving on the GFMD’s International Organizing Committee and were tasked with responsibilities such as identifying important themes and nominating speakers.

AACE members were invited to participate as Chair, Co-Chair, and/or Speaker during several of the tracks, as highlighted below:

**Session: The Role of Medical Devices to Improve Health Service Delivery**

**Track:** Meeting the Needs
ACCE Member: Mr. John Zienaa, Speaker

**Track:** The convergence of eHealth and Medical Devices: implications for the future
ACCE Member: Jennifer Jackson, Chair

**Session: Assessment and management: a continuous process**
ACCE Members: Ismael Cordero, Chair; Jennifer Barragan, Co-Chair

**Session: In search of appropriate and innovative technologies**
ACCE Member: Dr. Iyad Mobarek, Co-Chair

**Workshop: Medical Devices Management**
ACCE Member: Ismael Cordero, Workshop Leader

**Workshop: eHealth**
ACCE Member: Jennifer Jackson, Workshop Leader

Tobey Clark and Iyad Mobarek also presented posters at the Forum.

The GFMD was conceived by member Adriana Velazquez Berumen, Coordinator of the Diagnostic Imaging and Medical Devices team for WHO. Together with her brilliant and dedicated staff, including Jennifer Barragan, the event was considered a great success to all who attended. So much so that Dr. Carissa Etienne, Assistant Director General of WHO announced during her closing remarks that there would be a 2nd Forum.

Personally, I was proud to see so many ACCE members play prominent roles in the preparation and delivery of such a successful event.

Using as pretty handy little device call the SpotMe (http://www.spotme.com/), at the end of each session, the participants nominated and voted on the top three issues to use as recommendations to WHO. All of these recommendations are currently under review at WHO and will be addressed in the final report for the conference. Once this report is finalized, we will make it available to ACCE members. But will it just be the staff at WHO that carries out these recommendations? In his closing speech on Saturday, Thailand’s Health Minister, Dr. Suwit Wibulpolprasert stated that WHO is really just as strong as the supporting member states. He added that we, citizens of those countries, are the ones that will make the difference to change the world and so it is not our task to tell WHO what to do, but to instead to adopt our own recommendations, both in our national policies and our day-to-day practices. These words really touched me and reinforced my commitment to the field and to ACCE. There so many opportunities to improve lives with technology and WE, clinical engineers, are the ones skilled and trained on how to offer those improvements in the safest and most economic way. What the success of an event like the GFMD represents is that we are making a difference in people’s lives and we need to keep it going!

Jennifer Jackson
jljackson@accenet.org

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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). The ACCE Study Guide was written by an independent group of clinical engineers not associated with the exam process.
Images from the First Global Forum on Medical Devices

Mr. Abhisit Vejjajiva, Prime Minister of the Kingdom of Thailand, speaking during the inauguration session

Dr. Margaret Chan, Director-General, WHO, addresses participants

Tobey Clark (R) presenting his poster

Jennifer Jackson and Ismael Cordero with Albert Poon (center)

Tobey Clark and Jennifer Jackson listening to opening speech

Ismael Cordero having fun with a dancing puppet during the opening banquet
ACCE Board Election Results

Once again, I’d like to say that it has been my pleasure and privilege to serve as your President for the past two years.

With a heartfelt gratitude, I’d like to thank the Nominations Committee, led by Stephen Grimes, for their amazing work generating the 2010-2011 slate of officers. You, as the membership, cast your ballots and let your voice be heard!

Based on the results, I’m delighted to present to you the 2010-2011 Board of Directors:

- Mario Castañeda, President
- Jennifer Jackson, Past President
- Jim Keller, President-Elect
- Jim Welch, Vice President
- Julio Huerta, Treasurer
- Jon Blasingame, Secretary
- Izabella Gieras, Member-at-Large #1
- Arif Subhan, Member-at-Large #2
- Michael Fraai, Member-at-Large #3
- Colleen Ward, Member-at-Large #4

The Outgoing and Incoming Boards will hold a transition meeting this month. We started many projects last year that must be sustained, as well as many new opportunities for the future. We will continue to share our ideas with you using our newsletter and website. As we share this information with you, please send us your input. I look forward to working with many of you in this new capacity as Immediate Past President.

I wish you all health and happiness in the coming months!

Best regards,

Jennifer Jackson
jljackson@accenet.org

Healthcare Technology Foundation News

Home Hemodialysis Safety: A Patient Guide Brochure

The Healthcare Technology Foundation (HTF) and ECRI Institute have completed the brochure entitled “Home Hemodialysis Safety: A Patient Guide”. This is a free tri-foldable download that is available on the HTF website http://thehtf.org/publications.asp. It is available in English and will be available in Spanish.

The brochure is written for the patient that needs hemodialysis. The following topics are presented:

- How does home hemodialysis treatment work?
- What are the risks?
- What can I do to keep myself safe?

In addition to being on the HTF website, a limited number of printed copies will be available.

The HTF is currently looking for distribution channels for this brochure. If you are aware of any organization that might use this brochure at a meeting or place it on their website, let James Wear know at james.wear@gmail.com.

This is the third brochure in the home medical device patient safety series from the HTF. The two previous are “Fire Safety & Oxygen: A Patient Guide” and “Can I bring my own medical device with me to the hospital?”.

These are available from the HTF website as free tri-foldable downloads in both English and Spanish. Limited numbers of printed copies remain available. Co-branding opportunities are also available with prior permission. Please remember these resources if these issues come up in your hospital, or be proactive and bring them to the attention of appropriate personnel. Suggestions for additional brochure topics are welcome, especially if you want to help write one!

James Wear
james.wear@gmail.com

Secretariat Services

The Foundation is in the process of looking to recruit a Secretariat replacement. We are looking to fill this role by December 2010. Most of the work involved is with the Certification program and averages out to be around 15 hours per month. What a great way to stay connected with Foundation activities plus make a little money. Please contact Jennifer Ott, secretary@acce-HTF.org, if you are interested.

James Wear
james.wear@gmail.com
The View from the Penalty Box:

Is anyone in charge, anymore?

Once upon a time in a place far, far away people took responsibility for their actions and when needed made decisions as to what was to be done, by whom and when it was to be completed. Now it seems that no one person, group or agency can make a decision without first getting permission from multi other persons, groups, or agencies. We have seen our government in action with an oil spill that probably was caused by someone not following what should have been done but looking for the easy way to finish up. Once the spill started one government agency after another got involved and it often took days to get a simple decision on what to do while the oil spilled out. But we sit back and say that type of a problem would never happen in our field.

Recently there was a major recall of eggs. While I do not know all the facts in this recall it seemed to be clear that the company involved had less than a sterling record over the years. It also came out that the Department of Agriculture was not monitoring the company and that once people started getting sick the FDA got involved and was portrayed as being less than knowledgeable with what was going on. To my way of thinking the FDA got a bum rap on this one as they were way down the list of who should have made the call. To their credit the FDA did step in and took action. Now let’s see if the corrective actions are still in place in six months.

In the September issue of a popular “bathroom reader magazine” was a multi page article on medical devices and problems with them. One of the sources for the information in this article was a “think tank”, advocacy group or who knows what, working out of a Boston area hospital. Since I had never heard of this group I made some calls to engineers and Biomeds that I knew who worked at this hospital, some former students, and guess what, they had not heard of the group either. If someone is doing research on device safety at a hospital you might think that they would at least be known by the technology staff there. Much of the information in the article was old, some from the 1990’s and problems mentioned have mostly been corrected but there was one critical point made by the article which we all have to get more involved with. That point was that a very low percentage of device problems are promptly or in many case ever reported to the FDA. Why are not more problems reported? The simple answer is lawyers. Everyone is so afraid of being sued that too many people do the Sgt. Shultz routine of “I know nothing!!!!”

I am as guilty as anyone in that in the over 40 years I have been working with medical devices I have only ever filed 3 complaints with the FDA. In each of those cases the only reason I did send information to the FDA is that the manu-

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Wanted: Articles for ACCE News

Are you interested in practicing your writing skills? Do you desire to see your name and perspective in print? Do you have some “editorial comments” that you wish to “get off your chest”? Do you have some commentary, good or bad, about Clinical Engineering working with IT?

The ACCE News is looking for some good quality articles of interest to Clinical Engineers. Articles can be on any subject pertinent to the Clinical Engineering profession. Length should be from approximately 500 to 1500 words. Editorial and topic assistance is available from the editors. If interested, contact co-editors Ted Cohen or Ismael Cordero at Theodore.cohen@ucdmc.ucdavis.edu or ismael.cordero@orbis.org
Perspectives from ECRI Institute:  
Our Early History Now Part of American History

In the early 1960s, prior to the birth of ECRI Institute, Joel Nobel, MD, ECRI Institute’s Founder and President Emeritus, developed a resuscitation system called the Max Cart. ECRI Institute is pleased to announce that the Smithsonian Institution has accepted our donation of a prototype of the Max Cart to its National Museum of American History. It is such a great honor to have the Max Cart, which is an important part of ECRI Institute’s history, now also recognized as an important part of our Nation’s history.

Here are some perspectives from Joel Nobel on his development of the Max Cart:

“It was a response to the chaos of CPR at the time. It came into fairly wide hospital use in the United States and Europe. TIME, LIFE, Der Speigel and other lay publications did pieces on it. The design focused on human factors and prevention of operator errors and speed of operation. It was also used in Vietnam, and one was kept at the White House dispensary and there were rumors that there was one aboard Air Force One.

It was a simple concept--an assembly jig for resuscitation. It reduced the number of clinical staff needed and radically reduced the time needed to establish and maintain effective life support. It had a couple of technical innovations too, like a two-stage tuned air ejector to provide suction and a pistol grip and trigger to modulate suction. I worked with several engineers at Hamilton-Standard to develop it.”

Many of the lessons that Dr. Nobel learned during his development of the Max Cart were applied to his work at ECRI Institute. His process for evaluation and selection of acceptable products for use on the Max Cart were key progenitors for the comparative evaluation of medical devices and systems that we still publish today in the Health Devices journal.

Max was designed to help hospitals’ efficiency in emergencies by enabling doctors and nurses to save time, thereby increasing the chances of saving a life; the cart and its supplies improved response time and minimized errors. Max efficiently gathered all the life-saving materials and brought these to the patient, allowing for faster, better-executed treatment. These patient-centered qualities are now emphasized in today’s rapidly changing health-care system.

The prototype cart, 34 inches tall and 79 inches long when fully extended, is outfitted with the medical equipment and pharmaceuticals that were used in the late 1960s and 1970s, including a pneumatic cardiac compressor, electrocardiograph, respirator, pacemaker and intubation gear. The cart also recorded voice data, from the moment it was moved, and ECGs, facilitating later event analysis and systems improvements.

For those reading this newsletter online check out the links below which have announcements from ECRI Institute and the Smithsonian Institution about our donation of the Max Cart and more details about this great product.

Smithsonian Institution announcement
ECRI Institute announcement

Jim Keller
JKELLER@ECRI.org
International Report


This event reflects well on the growth of the medical technology management field in China. Centrally located, the event was opened by keynote addresses from the various medical associations, hospital administration, media, and invited guests. ACCE was well represented at this meeting, which took place in Shanghai, China, September 9-11, 2010. Mario Castaneda made a presentation at the opening ceremony for the meeting on September 10 as the official representative of the ACCE.

On September 9, Yadin David provided 3 hours of training and certification process review for the clinical engineers that were taking their certification examinations later that day. Of the candidates that applied for examination, 73 attended the review course and 60 of those qualified to take the written examination, which was in English. Thirty-seven candidates passed the written exam and took the oral examination. After the banquet, Yadin David, James Wear and Judy Wear graded the exams so they could inform the successful candidates who would continue to take the oral exams the next day.

The oral examination was done on September 10 by Yadin David and James Wear using translators and local medical devices regulatory issues. The certification program is in its 4th year and 3rd examination cycle and continues to demonstrate the level of commitment for professional development not seen in other clinical engineering societies in that part of the world.

In the afternoon of September 9 while the candidates were taking the written exam there was a Salon with presentations by Binseng Wang and James Wear as well as Chinese presenters. The Salon also had a discussion of curriculum issues for biomedical engineering education programs.

On September 10, presentations were made by Mario Castaneda, Tobey Clark, Yadin David, Binseng Wang and James Wear.

The meeting had 1,200 participants and a sizable vendor show. The program was in Chinese except for our presentations from ACCE and a few other presenters from the US such as by Jeffrey C. Lerner, President of ECRI Institute and representatives of the German medical devices Standards Board.

James Wear
james.wear@gmail.com
Penalty Box (Continued from page 5)

facturers were stonewalling on getting the problem fixed. Should I have done more, yes? Why didn’t I do more? The only answer I have to that is I got the other problems resolved for the hospital that I was working for at that time and did not want to make problems for the vendors. Yes it was a mistake. Trying to do everything your self is not the best answer. Get others involved, even if it is a government agency.

As a profession and as also as an industry we need to take a critical look at what we do, how it gets done, and how much it costs. But most of all, the patient is our first concern. If the patient is not our first concern then we will all too often let things slide, or simply pass the problem on to someone else hoping that they do something. Maybe we need the “Joint” to put into their requirements that we have to provide detailed reports on each incident that occurs in our institutions, what occurred, what was done to correct the problem and what was done to prevent the problem from occurring again for starters. Maybe if the “Joint” doesn’t do it CMS will, but someone has to get more aggressive on problems with devices. Maybe ACCE should think about having a web site where problems can be posted and comments made on the problems that could lead to solutions. If nothing else such postings will get information out on problems. Feedback from others who have seen or had similar problems could be very beneficial to patient care and getting problems resolved. Just a thought and please send your thoughts in so something can get started.

Also I would like to thank our out-going office holders for all their hard work over the years and wish our incoming office holders and committee members success in achieving the ACCE objectives over the next years.

Lastly to all of the members of ACCE please continue the mentoring of new-comers to our profession, please make presentations at conferences and please publish articles on your work as we need to help our colleagues help the patients.

Have a great fall season

Dave Harrington
dave@sbttech.com

Looking for an ACCE Member to Give Guest Lecture

As part of its services to students, the Biomedical Engineering Honor Society at Florida International University periodically organizes a lecture series called "Industry Lectures", in which students are offered presentations from industry representatives discussing possible career options in biomedical engineering.

They have been considering having a lecture on the topic of Clinical Engineering, after learning about the American College of Clinical Engineering. They are hoping to be directed to a member of ACCE that they could contact to invite to give a guest lecture on Clinical Engineering and the ACCE. Please be aware that they are a student organization, and as such cannot provide monetary compensation for the lecture, only a small gift of appreciation. They can request some funding towards the lecture from the University, but this would probably not exceed $50. Thus, an ACCE member from the Miami, FL area would probably be the most feasible option. Those interested in representing clinical engineering and ACCE please write to aemb.fiu@gmail.com.

Alpha Eta Mu Beta FIU
Biomedical Engineering Honor Society
web.eng.fiu.edu/aemb
2010 ACCE/HIMSS Excellence in Clinical Engineering & Information Technology Synergies Award Call for Nominations

The 2010 ACCE/HIMSS Award Call for Nominations is now open! All nominations must be submitted to HIMSS by November 1st, 2010.

The award will be presented to one or more individuals, who in the opinion of the joint Boards of Directors, has best demonstrated leadership in promoting or implementing significant synergies between the clinical engineering and information technology professions. These contributions may be of a professional or technical nature, and may include research or development of a new process or product, a paper of significance, or ‘trailblazing’ work in a new application of clinical engineering and information technology.

The award may be made to an individual from the clinical engineering or information technology professions or may be shared between two individuals from the clinical engineering and information technology professions who have cooperated in their efforts. Click here for more information on the Award.

Past recipients include:
- 2009 Adrian Johnson, BTECH, BEPS
- 2008 Todd H. Cooper
- 2007 John D. Hughes, Jr, M.S.
- 2006 Elliot B. Sloane, PhD
- Raymond Zambuto, CCE, FASHE, FHIMSS

Award recipients will be recognized at the 2011 Awards and Recognition Banquet during the HIMSS11 Annual Conference and Exhibition in Orlando.

If you have further questions regarding awards please email awards@himss.org or call Megan McGuirk at 312-915-9269.

EMPLOYMENT OPPORTUNITY

The ORBIS Flying Eye Hospital (FEH) is a unique mobile teaching and operating facility on board a DC-10 jet aircraft that travels to developing countries worldwide to share the gift of sight. Our Flying Eye Hospital staff travel up to 45 weeks per year to countries such as Peru, Dominican Republic, Syria, Niger, Nigeria, Uganda, China, Cambodia, Indonesia, Vietnam, Laos and India.

Healthcare Technology Trainer
The Healthcare Technology (HT) Trainer plans, designs, and implements training programs for biomedical engineers, clinical engineers, biomedical equipment technicians and other hospital personnel who participate in FEH programs around the world. He/she also works with the Biomedical Engineer to set-up, calibrate, maintain, and repair the medical and office equipment on board the aircraft and to direct ORBIS team members in the proper use of these tools. As a participant in the ORBIS MD-10 Team, he/she will advise the team on the biomedical specifications of the new Flying Eye Hospital. This position requires up to 45 weeks of worldwide travel per year, mostly to developing countries and between trips the FEH staff members work from home.

ORBIS welcome applicants who meet the following profile:
- Bachelors Degree or equivalent degree in Biomedical Engineering, Electrical Engineering, or Mechanical Engineering. Master’s degree in relevant field highly desirable.
- Minimum 4 years engineering work experience a hospital environment.
- Demonstrated expertise in Clinical Engineering and/or Healthcare Technology Management. This includes: (1) Proven in-depth familiarity with different types of equipment and modern health care technology management practices. (2) Operating knowledge of computerized medical equipment management systems, quality assurance and technology planning systems, and (3) the ability to demonstrate repairs and maintenance of medical equipment. Previous experience with ophthalmic equipment is a plus.
- Hands-on training and teaching skills and the ability to apply adult and participatory learning methods. Extensive training delivery experience highly preferred.
- Prior international work experience desirable.
- Excellent interpersonal, communication, and diplomacy skills and the ability to mentor and teach others.
- Solid analytical and problem solving skills with attention to detail.
- Team-oriented work style, with a proactive, open-minded, and flexible approach.
- The ability to function effectively in a demanding, fast-paced and constantly changing work environment.
- Oral and written fluency in English – working knowledge of a second language is a plus.
- Ability to lift equipment weighing up to 50 lbs.
- Ability to travel to developing countries up to 80% of the time. This includes having no significant disqualifying factors that would preclude approval of entry visas in the countries on the FEH travel schedule.

For more information about ORBIS and this employment opportunity, please visit our website: www.orbis.org. To apply, email your resume or C.V. and cover letter to HR@orbis.org.
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ACCE News is a benefit of ACCE membership; nonmembers may subscribe for $60

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Executive Director - Clinical Engineering

Cleveland Clinic is a world leader and model for the future of healthcare. We seek an exceptional executive for a once-in-a-lifetime professional opportunity to lead the clinical engineering function of the most technologically advanced healthcare system in the world.

Cleveland Clinic's physician-led, Institute model of care uniquely joins clinicians, researchers, academics and administration in optimizing collaboration for delivering world-class patient care. Reporting directly to the Chief Operating Officer, the Executive Director of Clinical Engineering will oversee the clinical engineering function of the Cleveland Clinic main campus, 10 regional hospitals and 17 community health and surgery centers. You will champion the clinical engineering vision and articulate the clinical engineering strategy to all levels of the organization.

We seek a recognized leader with an outstanding clinical applications background; demonstrated engineering skills in instrumentation design and functionality; ability to manage complex, large-scale systems implementations; proven inclusive leadership and managerial skills and the ability to interact and communicate effectively with clinicians and administration.

A Ph.D degree in clinical or biomedical engineering is required along with a minimum of 10 years of direct experience in the field plus 5 years of senior management experience in a major hospital environment.

Qualified applicants should send an introductory letter and curriculum vitae to the following:

John H. Petre, Ph.D.
Chair, Search Committee
petrej@ccf.org

Scott M. Simmons, MBA
Director
simmons1@ccf.org

Cleveland Clinic is proud to be an equal opportunity employer. Smoke/drug-free environment.

Calendar of Events

ACCE Teleconferences:

1. **October 21, 2010**
   PACS Administration

2. **November 4, 2010**
   Networking Basics

3. **November 18, 2010**
   Incorporating Standards Into Your Practice

4. **December 2, 2010**
   Networking Basics 2: Wireless

5. **December 16, 2010**
   Clinical Engineers Can Make Healthcare Safer

1. **January 6, 2011**
   CE-IT: New Job Opportunities

2. **January 20, 2011**
   New PM Paradigms

February 20-24, 2011
HIMSS 2011 Conference
Orlando, Florida

June 25-27, 2011
AAMI 2011 Conference
San Antonio, Texas