

# ACCE News

Newsletter of the  
American College of Clinical Engineering

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## President's Report



With only a few weeks left in the year - 2009 is just around the corner - I'd

like to use this space to reflect on some of ACCE's accomplishments this year:

### CE-IT Collaboration

CE-IT collaboration is probably one of the most talked about events in our profession this year (except for the NFPA 99 changes, but we'll get to that soon). In February 2008, ACCE, HIMSS, and AAMI signed an agreement to develop a community of CE and IT professionals that will, according to our press release:

- \* Foster further development of a united voice for IT and clinical engineering concerns, and provide a forum for its expression.
- \* Provide a mechanism for developing resources, guidelines, and best practices for the CEIT community, and provide education, research, certification, public policy, terminology, , mentoring, advocacy, networking, and career services.
- \* Explore appropriate collaboration of clinical engineering/IT functions.
- \* Develop a framework for repre-

senting the interests of clinical engineering and IT departments to the broader healthcare community

The initiative is already off to a great start with five active working groups all with deliverables designed to support collaboration between CE and IT environments. Please visit: <http://www.ceitcollaboration.org/default.asp> to learn more.

### NFPA 99 - we had to say something!

As part of the 2009 annual revision cycle, the National Fire Protection Association (NFPA) proposed a couple of changes to NFPA 99 - their safety standard for healthcare facilities. The first was a change to the definition of a 'wet location' to include all operating rooms based on the idea that there is a substantial amount of fluid spillage in operating rooms and therefore, a 'blanket' definition is warranted to automatically define these areas as wet. The substantiation for this proposal specifically calls for the installation of isolated power systems or ground fault circuit interrupters in all operating rooms and eliminates the possibility for the institution to perform risk assessment analyses for their procedure rooms and determine which electrical systems are, and are not, necessary to ensure patient and worker safety.

The second proposal that ACCE commented on was the proposal to 'delete chapter 10' -

the chapter in NFPA 99 that defines detailed maintenance documentation and suggests that vendors might not be required to provide maintenance manuals to their customers.

ACCE leaders Julio Huerta, Steve Grimes, and Paul Sherman all collected data from our peers. In August, we submitted the comment to eliminate this new wet location definition and to require vendors to continue to provide technical documentation to hospitals. Our official comments can be viewed on the ACCE website: <http://www.acenet.org> under Publications.

ACCE will continue to review proposed changes to standards that impact our profession. If you know of any standards that we should be reviewing, and commenting on, or if

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Jennifer Leigh Jackson, ACCE President, and her husband, Sergio Gaudio, celebrate their recent wedding in Palmi, Italy. Congratulations Jen and Sergio!

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## President's Report (cont)

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you would like to participate by sharing your opinions, e-mail me at [president@accenet.org](mailto:president@accenet.org).

### Professional Practice Guidelines

Our Professional Practice Committee was hard at work this year and as a result of their dedicated work, we have six new professional guidelines available to the membership. These guidelines are written by your peers to serve as everyday resources for the clinical engineering profession. New and revised publications for 2008 include: Expert Witness and Testimony (new), Promoting Health Care Health Savings (new), Support for BMETs (new), Medical Equipment Management Programs (revised), Incident Investigation (revised) and Design, Testing, and Manufacturing of Medical Devices (revised). Look for each of these soon on the webpage:

<http://www.accenet.org/default.asp?page=publications&section=practices>

### Advocacy and New Partnerships

This year, Eric Rosow, Pat Lynch, and Tom Judd all took on the leadership of the Advocacy Committee and they recently initiated a project to contact approximately 120 organizations in an attempt to foster new partnerships both within and outside of clinical engineering. Overall goals of the committee are to enhance the ACCE image while creating opportunities for mentoring and education for up and coming generations of Clinical Engineers. Some of the deliverables mentioned are a speaker's bureau, educational video development, article publication and the committee is really interested to hear ideas from our membership. So, if you want to unlock that inner scribe or would like to help future clinical engineers by sharing your expertise, please get involved by contacting Tom Judd at [judd.tom@gmail.com](mailto:judd.tom@gmail.com).

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## 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

## CCE Certification: New Applicants and Renewals

1. The next CCE exam will be given on November 7, 2009 in 28 cities around the US. The deadline for applications is September 12, 2009. Please see the website: <http://www.acce-htf.org/certification> to view the handbook and application for this exam.

2. In 2007, ACCE released the results of the new "Body of Knowledge Survey". The US Board of Examiners for Clinical Engineering, chaired by Patrick Lynch, made adjustments in the mix of questions based on that survey. The changes are included in the 2007 CCE Handbook which is available on the ACCE-HTF website.

3. Renewal: CCE renewal is required once every three years. The CCE Renewal Handbook and Renewal Application Form can be downloaded from the CE certification website:

<http://www.acce-htf.org/certification>. The renewal fee can be paid by check or by credit card on the ACCE HTF website.

4. Any questions can be directed to Cheryl Shaw, the certification program's secretariat, at [certification@acce-htf.org](mailto:certification@acce-htf.org).

## ACCE News

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# ACCE Healthcare Technology Foundation Report

## Foundation Registers as PSO

The ACCE Healthcare Technology Foundation is now listed with the Agency for Healthcare Research and Quality (AHRQ) as a Patient Safety Organization (PSO). Note that the official designation of an organization as a PSO is distinct from organizations who may otherwise be dedicated to patient safety. PSOs were authorized by The Patient Safety and Quality Improvement Act of 2005

(Patient Safety Act). The PSO concept is that additional patient safety information can be effectively collected from hospitals, with anonymity protected, and that this information can then be aggregated by the individual PSOs, and then by a central organization, to give a broader and more representative picture of patient safety incidents and issues. With respect to medical devices, you might note the parallel

here between PSO reporting and FDA MDR reporting. Reporting events to a PSO does not replace reporting the same event to the FDA, when applicable. Similarly, being part of MedSun (<https://www.medsun.net/about.html>) is distinct from being a PSO participating hospital. And for those of you with state reporting, you still have to do that as well. The “Final Rule” for establishing PSOs was published on November 21, 2008. Students of government and political science will note the significance of the effective date, January 19, 2009.

Participation in PSOs by hospitals is voluntary. It therefore remains to be seen whether there will be large scale buy-in from the hospital community. The web home for PSOs is <http://www.pso.ahrq.gov/index.html>.

PSOs, including ours, will work under contract with individual hospitals or healthcare organizations. If your hospital is considering participating in the PSO process, please keep the AHTF-PSO in mind. Since the Foundation is devoted to the support and enhancement of clinical engineering and patient safety, any funds derived from PSO activities will be directly used for our programs and toward our collective goals.

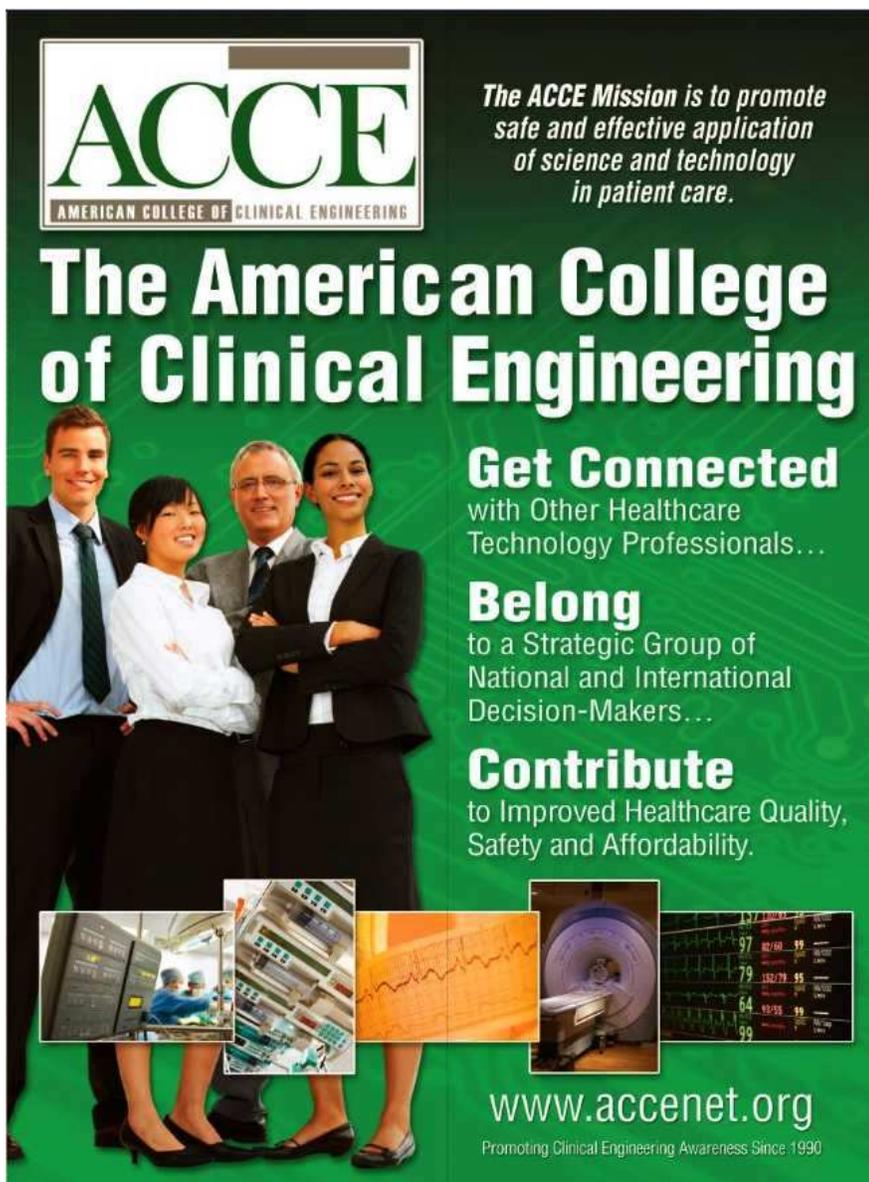
## Awards

Please remember the two awards administered by the Foundation. These are the Marvin Shepherd Patient Safety Award (co-administered by ACCE) and the Excellence in Clinical Engineering Leadership award. Further information on these prestigious awards can be found at the Foundation website: <http://www.accefoundation.org/>.

## New Patient Safety Brochure

The latest patient safety brochure from the Foundation is “Fire Safety & Oxygen: A Patient Guide”. This brochure is available from our website as a free tri-foldable download in both English and Spanish. This brochure joins the previous one, “Can I bring my own medical device with me to the hospitals?” which is also available at the

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The ACCE Mission is to promote safe and effective application of science and technology in patient care.

# The American College of Clinical Engineering

**Get Connected** with Other Healthcare Technology Professionals...

**Belong** to a Strategic Group of National and International Decision-Makers...

**Contribute** to Improved Healthcare Quality, Safety and Affordability.

[www.acenet.org](http://www.acenet.org)  
Promoting Clinical Engineering Awareness Since 1990

The poster features a group of four diverse professionals in business attire standing together. Below them are several small inset images: a person in a surgical mask, a hospital hallway, a medical monitor displaying a waveform, a CT scanner, and a financial data screen.

The ACCE Advocacy Committee is on a campaign to increase ACCE membership to 1000 and to increase the number of ACCE's partners to 50. This poster, introduced at AAMI in June 2008, is one of several “tools” being used to promote ACCE.

# Linking International Healthcare Technology Management to Morbidity and Mortality- An INFRATECH Discussion

During the past few months a very interesting discussion took place on INFRATECH, the global healthcare technology management discussion list.

Jennifer Barragan, a Program Manager for Medical equipment with the Clinton Foundation in Ethiopia, asked ... "if anyone in the group had information that showed the impact of healthcare technology management on rates of morbidity and mortality".

The following selected and summarized expert comments represent the wide range of replies to Jennifer's important question and demonstrate the challenge that our profession encounters in trying to link healthcare technology management (HTM) or clinical engineering (CE) to the outcomes of health care interventions:

**Andrei Issakov, Coordinator, Health Technology and Facilities Planning (TFP), WHO.** Dr. Issakov was quick to reply that "there is very little, if any, evidence on the impact of HTM on health status and outcomes. And there are many reasons for that, particularly as the causal pathway between HTM and health outcomes is not that straightforward, and there are lots of other factors influencing this." Issakov went on to say that "WHO is working on this, including linking HTM with service delivery outcomes and quality of care, and developing indicators to evaluate and measure these."

**Mladen Poluta, Director of HTM Program, University of Cape Town, Dept. of Human Biology, South Africa**

"The approach we have taken is a 2-step process, i.e. linking HTM to Quality of Care (characterized as being safe, timely, patient-centered, equitable, effective and efficient - IOM, 2001) and then Quality of Care to morbidity and mortality. Also, if healthcare technologies are to have optimal impact, they need to meet the criteria of Availability, Accessibility, Affordability & Acceptability (please refer to [www.htm-matters.com](http://www.htm-matters.com) for further details).

Also, a framework linking medical devices to morbidity and mortality is being developed as part of the WHO project on Priority Medical Devices.

We have also recently installed a basic X-Ray medical imaging system - with digital capability - at a primary-level health facility (Community Health Centre) in Cape Town; one of the studies planned is precisely to address/answer the issue/question you raise."

**Binseng Wang, Senior Director, Program Support & Quality Assurance, ARAMARK**

"To link healthcare technology management (HTM), not simply medical equipment, to morbidity and mortality is perhaps a noble cause but probably very difficult, if not impossible." Wang's experience in developing countries has taught him "not to use morbidity and mortality as justification for HTM, even though these could be used sometimes for equipment planning and acquisition. I have found it easier to justify investment in HTM using financial metrics and analogies of healthcare to industrial production. Some data are emerging on the true costs of HTM (aka clinical engineering) and how they relate to healthcare output such as patient discharges and patient days."

**Björn Fahlgren, Technical Officer, Department of Essential Health Technologies, World Health Organization**

"I think we can only prove up to a certain point the value of HTM, probably somewhere short of the clinical outcome. If we insist on trying to prove an effect on clinical outcome it is likely the results will systematically not be significant because we would mainly be recording noise.

It may be better to attempt to look at the negative consequences of the lack of HTM rather than the positive consequences of their existence, in order to be able to observe significant differences. Experimentally we would have to look at a situation where "everything else" is functional and HTM either functions or not. Obviously you cannot "inactivate" an HTM department for some period for the purposes of the research."

**Shauna Mullally, Head of Biomedical Engineering, MRC Laboratories, The Gambia**

"I agree completely with all who have suggested that a direct causal relationship between HTM and patient outcomes (morbidity and mortality) is difficult if not impossible to study because of the presence of so many confounding variables.

A useful construct that I worked with was the following: Organizational Factors (hospital org structure, health policy, financing etc.) -> Clinical Engineering / HTM Effectiveness -> State and Functionality of Medical Equipment -> Patient Outcomes (morbidity and mortality) where '->' signifies a somewhat causal relationship, based on past research and/or expert knowledge. In my opinion, the last relationship (between equipment state and patient outcomes) is the one that is so difficult to study, for all of the reasons listed above.

However the relationship between CE / HTM effectiveness and indicators that describe the state of medical equipment (proportion of equipment that is out of service, repairs/yr, other work requests/yr, safety/incident investigations/yr, etc.) can be studied more easily. In fact I did some preliminary analysis of this relationship at the hospital level in my thesis.

Relating equipment state to patient outcomes is still challenging, for all of the reasons covered above. However, I believe using this construct is useful (a) because it moves the analysis one step closer to patient outcomes (and also removes one level of confounding variables that interfere with the relationship between HTM effectiveness and equipment state) and (b) because the relationship between the state of medical equipment and patient outcomes is more tangible and more easily intuited by policy makers and administrators. If a large proportion of your equipment is non-functional, you know patient outcomes will be affected."

**Tom Judd, National Project Director, Kaiser Permanente**

"I have wrestled with this issue with colleagues for awhile. The quality mantra is

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# Linking HTM to Morbidity and Mortality continued

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"Structure, Process, Outcomes." How does this apply to HTM improving outcomes? Here is one perspective among many.

As part of a study I did with several HTM colleagues and an experienced physician (internist, infectious disease, a lot of international work) in southern Africa a few years ago, I developed a matrix of technology needs called Targeted Health Technologies for Key Conditions.

What is the matrix's meaning and application to this topic?

**1. Structure:** If delivery of care in a designated health system is focused on delivering accepted evidence-based care (of course depends on who it has been accepted by, e.g. whose evidence and under what conditions)

**2. Process 1:** If care is delivered according to evidence-based clinical procedures (let's assume this is based on WHO evidence or consensus based practice guidelines or protocols and pathways at primary care clinic and secondary care hospital levels).

**3. Process 2:** Then if the medical device (and related supplies and consumables) have been shown to be the evidence-based "best" devices/systems to accomplish these

procedures (of course this is the part that generally has not been done so far, although one could argue that ECRI Institute evaluations are among the best at measuring whether a device/system functions as intended in clinical and business sense and could be considered "best" according to some definition). This is what is meant by "targeted health technologies" in the matrix I developed.

**4. Outcomes:** Then one could measure the sustainable outcomes for diagnoses and treatment of certain conditions, one could attribute improved outcomes to the "best" mix of clinical procedures using "best" health technology that was made sustainable by other HTM measures, e.g. the equipment is efficient for the purpose intended, its availability is high because it is supportable, etc."

Being relatively new to the field, Jennifer did not realize how sensitive a topic this was and confesses "I certainly did not expect to spark such a discussion. However, I was quite pleased with such an outpouring of responses as it really educated me on

this topic and helped me to further understand the difficulty in selling the importance of clinical engineering in less developed nations. I do agree with the respondents that there is difficulty in creating a direct correlation between HTM (or medical equipment) and morbidity/mortality due to a large number of confounding factors. However, being in Ethiopia and seeing hospitals unable to perform surgeries for weeks or months because they don't have one critical item, then I pause to consider if it is possible to collect data on patients admitted with certain conditions and reasons for their lack of treatment or death. Perhaps I am oversimplifying, but even if there are a number of reasons leading to the lack of treatment or death of a patient, if one reason is lack of availability of medical equipment then rationale for support of HTM programs is strengthened and support from donors (who think in terms of saving lives and not necessarily cost savings) would be more likely." What is important is getting this information out of the immediate HTM community and ensuring that it is disseminated to those with the power to give money, make decisions, and implement change such that they recognize the problem is not simply lack of medical equipment but more importantly the maintenance and management of that equipment."

## Foundation Report continued

(Continued from page 3)

website. Limited numbers of printed copies are also available, as is co-branding of the brochure with prior permission.

### Donations to the Foundation

Donations to the Foundation in support of its programs in clinical engineering are always welcome and encouraged. In addition to your personal support (and employer matching), donations to the Foundation can also be made "in honor/recognition of..." with the honoree receiving an announcement to this effect from the Foundation. Consider this professionally relevant means of recognizing your colleagues and others who support clinical engineering. All donations are tax deductible since the Foundation is a

registered 501(c)(3) charitable organization.

### Mission Statement

It is a good idea to periodically review mission statements. The Foundation's mission is:

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

Your input on Foundation activities, and your participation in its projects, is always welcome.

William Hyman, ScD, PE, Secretary

[whyman@tamu.edu](mailto:whyman@tamu.edu)

Wayne Morse MSBME CCE, President

## about INFRATECH

Infratech is a listserv established to provide a centralized international discussion mechanism on CE/HTM issues. ACCE has a contract with WHO to manage the listserv. Bill Gentles from Toronto, Canada is the listserv administrator. To subscribe to the list, send the following message in the body of an email: subscribe infratech "Your Name" (Substitute your own name). Send the message to:

[LISTSERV@LISTSERV.PAHO.ORG](mailto:LISTSERV@LISTSERV.PAHO.ORG)

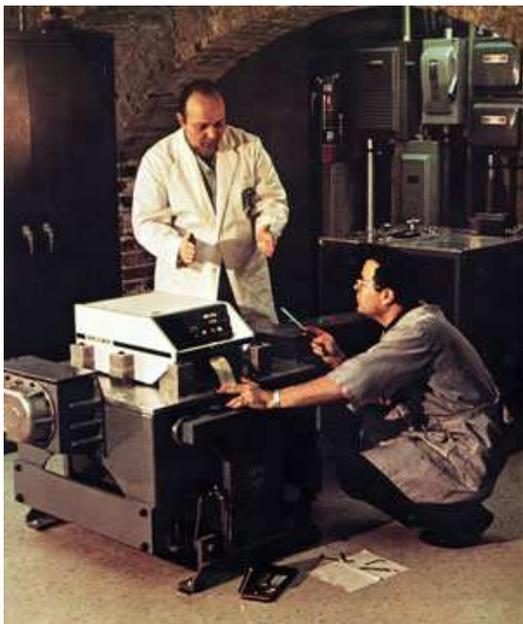
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# Perspectives from ECRI Institute: 40th Anniversary

“During my internship a four-year old boy died in the E.R. of ventricular fibrillation secondary to airway obstruction and I was furious because the defibrillator failed to work—and I’d reported it broken several times over the previous week. Anger is a great source of energy and I focused it on improving resuscitation technology and organization. That’s how we started.” Joel J. Nobel, MD, Founder and President Emeritus, ECRI Institute. Forty years later ECRI Institute is celebrating its fortieth anniversary, looking back on a tremendous number of accomplishments that have helped to improve healthcare in countless ways.

Joel J. Nobel, M.D., founded ECRI Institute by asking questions like: “Does it work? Is it safe? Is it Reliable?” Using Consumers’ Union as his model he developed the *Health Devices* journal with its comparative evaluations of medical devices. The first issue of *Health Devices* was launched in 1971 with an evaluation of manually operated resuscitators. Nine of the 18 brands of resuscitators tested were



Joel Nobel (white lab coat) testing a defibrillator with a colleague at one of ECRI Institute’s early laboratories.

found to be ineffective and were rated “Unacceptable.” As a result of ECRI Institute’s evaluation, eight of the “Unacceptable” models were removed from the market by their manufacturers; the ninth was later seized by FDA. Also, several products were improved by their manufacturers to address our concerns. Because of this one study, tens of thousands of ineffective “life-saving” products—devices that were supposed to save someone’s life but that would not—were removed from the market.

*Health Devices* is now in its thirty eighth year and continues to publish comparative evaluations of medical devices. In the decades since that first Evaluation, significant improvements in technology, new regulatory oversight, and the use of quality-systems processes by manufacturers have changed the medical device landscape for the better. Nevertheless, ECRI Institute continues to identify meaningful differences among evaluated models which helps hospitals avoid unsafe products, find less expensive alternatives to costly medical devices, or identify products that will be the best fit for their clinical staff.

Over the last forty years ECRI Institute has grown from a small group of dedicated, idealistic, and probably a little obsessed, collaborators with Dr. Nobel, to over 300 strong. ECRI Institute has also evolved from an initial focus on the *Health Devices* comparative evaluation program to producing a wide variety of products and services. They include product pricing databases, hazard and recall alerting services, problem reporting systems, technology assessment, risk management services,



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

equipment planning, accident and forensic investigation, and a new designation as a federally certified Patient Safety Organization.

ECRI Institute has developed a Web site ([www.ecri.org/40years](http://www.ecri.org/40years)) to help celebrate its fortieth anniversary. The Web site chronicles much of Dr. Nobel’s early work, includes the very first issue of *Health Devices*, has a cute animated video that reviews a few things you may not know about our organization, reviews our history and growth, and has some reflections from several of Dr. Nobel’s early collaborators. I hope that you’ll take a chance to check out the Web site. And, if you’ve worked with us or think that we’ve helped you out in any way over the last forty years, we’d like to hear about it. The Web site has a page where you can pass on memories that you may share about your experiences with ECRI Institute.

Jim Keller

[jkeller@ecri.org](mailto:jkeller@ecri.org)

## *Eastern Caribbean Clinical Engineering Workshop in Barbados*

The Pan American Health Organization (PAHO) ran its first Eastern Caribbean Countries (ECC) *Technology Management and Clinical Engineering Workshop* in Bridgetown, Barbados, October 10-24, 2008. Hospital- and Health Ministry-based representatives from 15 English-speaking Caribbean nations including Anguilla, Antigua, Barbados, Belize, British Virgin Islands, Dominica, Grenada, Guyana, Jamaica, Montserrat, Nevis, St. Kitts, St. Lucia, St. Vincent, and Trinidad & Tobago participated throughout the week.

The format of this Workshop was somewhat novel in comparison to the other four that have been held in this region because the Workshop was designed to include three days of joint-morning sessions in which national delegates from different disciplines including administration, information systems, and clinical engineering were able to consider areas of – and opportunities for – collaboration. The morning sessions were followed by afternoon break-outs during which time many of the essential Clinical Engineering Workshop topics were covered.

This weeklong program was hosted by the Barbados-based ECC PAHO office in coordination with PAHO's headquarters in Washington, DC and the ACCE. During the first three days there were joint morning plenary sessions that included presentations by virtually every one of the participating nations, WHO Geneva, PAHO, ACCE, and guest experts from Canada and Venezuela. A wide range of important topics were discussed, including: technology planning, finance, regulation, policy and management, healthcare information technologies and electronic health records, architecture and public health and emergency response. These presentations provided extremely valuable information about novel ways that the individual nations are overcoming the challenges posed by each country's relatively modest size and national budget, and demonstrated many effec-

tive ways that the countries have successfully developed to support and expand the quality, cost-effectiveness, safety, and scope of the healthcare services that must meet both citizen and tourist needs.

The fast-paced joint morning sessions not only provided a very critical opportunity for networking between many widely different island nations but they also enabled some invaluable dialogs to begin between clinical engineers, purchasing agents, information systems managers, administrators, caregivers, and policy makers. As many participants pointed out, although each nation may only be a 40-minute airplane flight away from its neighbor, from a practical point of view, the diverse economic and political systems and the realities of travel delays and expenses often make the countries seem as far away from each other as they are from Miami! The participants seized every possible moment to seek and share each other's best practices in technology management. It became quite clear that a great deal of expertise exists within this region, and opportunities to collaborate on a longer-term basis were discussed.

The Clinical Engineering Workshop educational content was organized and presented by ACCE members Caroline Campbell, from Tri-Medix, Tobey Clark, from University of Vermont, Antonio Hernandez, from PAHO, and Elliot Sloane, from Villanova University. In addition to the many core Clinical Engineering topics from prior workshops, ACCE was asked to add supplemental discussions on two topics: ways to deal with the emerging clinical information system issues/opportunities, and the brainstorming on the possibilities of adapting lessons learned from past decades of shared services programs and services in the US. It was enlightening to learn about the similarities these countries are encountering with purchasing and supporting healthcare-related informa-

tion technologies to other world markets. It was also quite enlightening to understand some of the unique legal, cultural, economic, and technical considerations that these separate, sovereign nations must confront and ultimately overcome if they wish to gain the buying- and support-leverage that a shared service is designed to facilitate.

During the workshop, talks were initiated with the Barbados Community College about the potential to use distance learning materials for Clinical Engineers and Biomedical Equipment Technicians prepared by institutions like the University of Vermont. This approach is having success in Peru, and since Barbados is using the same open source distance learning software that is used in Colombia, Moodle, this may help transfer relevant knowledge and information in the region more cost- and time-effectively. Who knows; such discussions might make lifelong distance learning in our field more accessible and affordable to us all!

According to the exit-survey conducted among the workshop participants, they enthusiastically believed that their week had been well-spent, and they uniformly requested that additional Workshops on these topics would be valuable at least every two years. The ACCE faculty came away impressed with the caliber and commitment of these nation's healthcare technology managers, and expressed optimism about the bright prospects for this region to continue to make tremendous progress in the months and years ahead.

We are all indebted to the hard work and strong support of the PAHO Regional Office in Barbados, and their headquarters staff in Washington, for making this such a productive and successful week for the participants, and faculty, and the guest speakers.

*Elliot Sloan, PhD*

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## Searching the Web for Medical Device Info: CDRH Device Web-sites

The FDA continuously adds more and more medical device information to their web sites. There are at least 13 generic kinds of medical devices (see table below) that have their own multi-page web site at the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) web pages (<http://www.fda.gov/CDRH/>). Five of these (indicated by an asterisk) have direct links from the CDRH home page. The others are not necessarily easily found unless they are expressly searched for. The 13 main pages have varying "Last Updated" dates, ranging from July 2004 (Surgical staplers) to September 2008 (LASIK). In most cases these are consumer oriented sites. Only a few of the 13 devices fit within "traditional" clinical engineering interests (e.g. the three imaging entries, and possibly hospital beds), and at least one has little hospital presence (tanning). Whether clinical engineering should play a larger role with respect to implants (breast, cochlear, intraocular lens, wrinkle fillers), or disposables (staplers) is a good issue for discussion.

In some cases the common name used for the main page does not correspond to the regulatory name, or names, reflecting an apparent effort to make the pages user friendly, while also reflecting the fact that regulatory names can sometimes be user unfriendly. For example, there is no regulatory category called Hospital beds, but rather a variety of listings for "Bed, ..." with varying subcategories, e.g. Bed, air fluidized.. Breast implants are officially listed as two types: "Prosthesis, Breast, Inflatable, Internal, Saline", or "Prosthesis, Breast, Noninflatable, Internal, Silicone, gel Filled".

Exactly why these 13 types of devices are singled out for their own web presence is not clear, but presumably they reflect areas of particular consumer interest (e.g. breast implants), or a large focused FDA effort (e.g. hospital beds). The updates, or lack thereof may

be related to there being no new information to post, or they may be a result of changing priorities and interests at the FDA. The 13 do not appear to be consistently related to devices that are of particular risk. The regulatory listing for Breast Pumps is "Breast pump, Kit" which has no entries in the MAUDE data base between 2000 and October, 2008. On the other hand "Stapler, surgical" (as opposed to surgical stapler) has 357 records just in the period January -October, 2008, yet this page has the oldest update.

These device specific materials are in addition to the extensive other medical device material found at the CDRH web pages. Of particular interest to clinical engineers are the MAUDE, Medical Device Reporting data base; recall data base and safety alerts.

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### Medical Devices with Their Own CDRH Web-Pages

Device	Web site URL	Last Update
Breast Implants*	<a href="http://www.fda.gov/cdrh/breastimplants/">http://www.fda.gov/cdrh/breastimplants/</a>	11/17/06
Breast Pumps*	<a href="http://www.fda.gov/cdrh/breastpumps/">http://www.fda.gov/cdrh/breastpumps/</a>	3/27/07
Cochlear Implants	<a href="http://www.fda.gov/cdrh/medicaldevicesafety/atp/101007-cochlear.html">http://www.fda.gov/cdrh/medicaldevicesafety/atp/101007-cochlear.html</a>	10/10/07
Contact Lenses*	<a href="http://www.fda.gov/cdrh/contactlenses/">http://www.fda.gov/cdrh/contactlenses/</a>	12/17/07
Hospital Beds	<a href="http://www.fda.gov/cdrh/beds/">http://www.fda.gov/cdrh/beds/</a>	4/21/08
Phakic Intraocular Lens	<a href="http://www.fda.gov/cdrh/phakic/index.html">http://www.fda.gov/cdrh/phakic/index.html</a>	4/22/05
Medical Imaging	<a href="http://www.fda.gov/cdrh/radhealth/products/byimaging.html">http://www.fda.gov/cdrh/radhealth/products/byimaging.html</a>	4/13/07
Surgical Staplers	<a href="http://www.fda.gov/cdrh/surgicalstapler/">http://www.fda.gov/cdrh/surgicalstapler/</a>	7/21/04
Tanning	<a href="http://www.fda.gov/cdrh/tanning/">http://www.fda.gov/cdrh/tanning/</a>	8/3/07
LASIK*	<a href="http://www.fda.gov/cdrh/lasik/">http://www.fda.gov/cdrh/lasik/</a>	9/18/08
Mammography	<a href="http://www.fda.gov/cdrh/mammography/index.html">http://www.fda.gov/cdrh/mammography/index.html</a>	11/10
Whole Body CT scanning	<a href="http://www.fda.gov/cdrh/ct/">http://www.fda.gov/cdrh/ct/</a>	10/12/05
Wrinkle Fillers*	<a href="http://www.fda.gov/cdrh/wrinklefillers/">http://www.fda.gov/cdrh/wrinklefillers/</a>	6/26/08

# View from the Penalty Box: CEs Matter

As 2008 comes to a close I can look back and be grateful for certain things, the election being finally over for one, and with some apprehension, the results of the election. We are also seeing that every publication, commentator and all the “Joe the Plumbers” have an opinion on what is needed to fix healthcare. Depending on which publication, commentator or “plumber” you listen to, technology is either the blame or the solution for health care’s high costs.

As Clinical Engineers we know that technology is the only way to reduce healthcare costs but to get to those cost reductions some cuts will have to be made in some areas of healthcare. As an engineer I look at Medicare which pays for 55% of hospital costs around the country, covers the most people and runs with a 7% overhead. The other healthcare plans covering about 40% of the hospital costs operates with a 30% overhead. The remaining 5% fall into the “free care” pool and those of us with insurance pick up a portion of those charges along with the state and federal government. In this present economy that 5% number may be growing rapidly but it will take several years for those keeping the statistics to confirm the trend.

How come everyone else seems to get all sorts of time to come up with answers but Clinical Engineers are expected to have the answer to the problem before it happens? But administrators and politicians do not want to hear our answers until after the problem blows up. If you ever question that statement just spend some time listening to Sir Malcolm the Elder, (Malcolm Ridgway), on what he proposes and you will quickly become convinced that the Clinical Engineers are the best resource to get healthcare costs under control.

How do we get the word out that we are a large part of the answer to healthcare costs? That is a question that all too many Clinical Engineers do not want to think about but we have to. We have to become our own publicity agent, in the hospital by writing a short piece on new technology that has been installed in the hospital in the monthly

hospital newsletter. We have to ask people “have you seen” the new technology or techniques that are being used in our hospitals to physicians, nurses and others in the hospitals and even the sales people that come to call? Yes we need to talk with the sales people pushing our agenda and to find out what others are doing. Yes we have to write an article or even a letter to the editor of the local paper talking about technology in our hospitals and what it means to the general public. Yes we have to talk with the politicians on problems in healthcare and our views on how to solve them without just throwing money at that problem. We have to communicate with others in our field so a strong and clear message can be sent that Clinical Engineers are involved and not just in some basement lab doing who knows what.

That brings me to the last point

that I want to make on this rant. Here in New England we recently had a 3 day symposium with 7 tracks of programs every day. He had some 70 vendors with good food and drink. Several members of ACCE were very involved with the planning and doing presentation but many hospitals departments sent BMETS and not their Clinical Engineers. We had programs specifically for Clinical Engineers that were attended mostly by BMETS. We are still trying to figure out how do we get the Clinical Engineers and managers to sessions so we can share knowledge, any suggestions?

Lastly, I would like to wish everyone a great holiday season with peace and happiness and work harder in 2009 to get the word out that Clinical Engineers have answers and should be listened to.

Dave Harrington

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## President’s Report continued

(Continued from page 2)

Already we have started investigating new collaborations. IEEE EMBS would like our organization to sponsor a mini symposium- much like what we currently do at AAMI and HIMSS (both of which always sell out or are standing room only). This collaboration would open up new communications with the academic/research side of our profession and we are investigating the logistics of creating this symposium. To learn more about IEEE EMBS, please visit <http://www.embs.org/>.

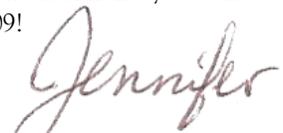
Also, I had the opportunity to attend the Annual Meeting of the International Union of Architects Public Health Working Group (UIA-PHG) last summer in Florence, Italy. This fascinating, diverse group of architects came together with the vision “that world public health can profit by the dedication of architects to provide efficient, safe and aesthetic health care buildings and an environment that can contribute to a more rapid healing of the patients as well as an improvement

in staff operations and satisfaction.” We continue to talk by email every now and then and perhaps we will find a common ground in which to pursue a partnership.

To learn more about UIA-PHG, visit <http://www.uia-public-health-group.org/>

This is only a summary of some of our activities in 2008. In 2009, we will continue to build on these activities and create new opportunities for our members. Use the above links for more information and to contact us. This is a membership-driven organization and I encourage you to get involved.

Have a wonderful holiday season!  
See you in 2009!



[President@accenet.org](mailto:President@accenet.org)

PS - when I wrote that the CE-IT Symposium at HIMSS always sells out, I wasn’t kidding. If you are going to HIMSS, make sure you register soon and buy that ticket to the “Clinical Engineering and IT Leadership Symposium”. As an ACCE member in good standing (dues are paid), you can register at the HIMSS member rate.

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**ACCE Clinical  
 Engineering Certification  
 Study Guide**

The American College of Clinical Engineering has completed 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](mailto: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 2009** exam. Applications and the applicant handbook can be found at [www.ACCEnet.org/certification](http://www.ACCEnet.org/certification)

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

**Calendar of Events**

April 4-9, 2009  
 HIMSS '09  
 (discount registration for current ACCE members)  
 Chicago, IL

April 4, 2009  
 2009 ACCE Clinical Engineering and IT Symposium in conjunction with HIMSS (separate registration required)  
 Chicago, IL

April 4-9  
 ACCE Annual membership meeting and awards ceremony (in conjunction with HIMSS 2009)  
 Chicago, IL

June 6-8, 2009  
 AAMI Conference  
 Baltimore, MD.

June 4-5, 2009  
 CCE Prep Review Course  
 Baltimore, MD.

November 7, 2009  
 CCE Exam  
 28 cities in US

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AMERICAN COLLEGE OF CLINICAL ENGINEERING

**Newsletter of the  
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We're on the Web!

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5200 Butler Pike  
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 (610) 825-6067

<http://www.accefoundation.org>

AHTF is an independent, not-for-profit foundation