

ACCE News

Newsletter of the
American College of Clinical Engineering

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President's Message: Healthcare IT in NYC

The summer in the northern hemisphere started on a busy note for ACCE. After recovering from all the



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exciting activities in Tampa, ACCE was invited to co-sponsor the HIMSS (Healthcare Information and Management Systems Society) *Leadership Summit: Achieving National Healthcare Transformation* at the beginning of June in New York City. The main focus of the summit was on interoperability, setting standards, RHIOs (Regional Health Information Organizations) and the implementation of EHRs (Electronic Health Records) nationwide within the next few years. The buzzwords, "interoperability" and "collaboration" amongst all stakeholders propagated through the heart of Manhattan.

The highlight of the HIMSS Summit was marked by the announcement by the [U.S. Department of Health and Human Services Secretary Michael O. Leavitt](#) of the formation of AHIC (American Health Information Community). AHIC, funded by HHS (Health and Human Services), will focus on standards and policies on health IT and interoperability, and will be chaired by Secretary Leavitt. This new venture will consist of 17 commissioner positions selected through a nomination process. The healthcare industry is moving into an era of "collaborative problem solving" that will require joint

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Foundation's Clinical Alarms Initiative Survey

Despite the inclusion of Patient Safety Goal #6, Clinical Alarms Improvement, in the JCAHO hospital accreditation standards from 2002-2004, incidents and events continue to occur due to a variety of causes including: alarm design, operation, and frequency, along with issues related to staffing, environment, response, communication, and staff taking appropriate action. For example, deaths and injuries reported to the FDA with the term "alarm" in the description increased from 189 in 2000 to 449 in 2004. At the same time, the technology has been enhanced (e.g., smart alarms and alarm integration

systems which add both improvements and complexities).

The American College of Clinical Engineering Healthcare Technology Foundation (AHTF) <http://www.acce-htf.org/>, in conjunction with a number of clinical and patient safety organizations, has put forth an initiative to improve clinical alarms. A survey has been prepared to collect data relating to clinical alarm issues, changes, and priorities for improvement. Feedback from clinicians, engineers, technicians, and practitioners is critical to enhancing the understanding of clinical

alarm management and integration. To take this survey please go to the link:

<http://www.surveymonkey.com/s.asp?u=339221233056>.

Please share this information with your clinical and biomedical staff. If you desire a printed version of the survey form, go to the AHTF website for the PDF file download. The website also has publications and educational materials on clinical alarms.

Clinical Alarms Task Force

http://www.acce-htf.org/clinical_alarm_task_force.htm

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Upcoming ACEWs

ACCE's International Committee, in conjunction with the Pan American Health Organization (PAHO) and other international organizations, continues to organize and implement Advanced Clinical Engineering Workshops (ACEW) throughout the world. (See the article beginning on page 8 on the recent workshop in Cartagena, Colombia).

These workshops help leaders, and soon to be leaders, in clinical engineering and healthcare administration learn best practices in healthcare technology management from ACCE faculty.

Upcoming ACEWs will take place in Nicaragua, El Salvador, Argentina, and, in conjunction with Project ORBIS, Ethiopia.

If you would like more information about ACEWs, contact Frank Painter.

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News Articles Wanted

The ACCE News editor team (Ted Cohen and Melissa Burns) are looking for material for future Newsletters. If you would like to contribute, please contact us at the e-mail addresses listed below. We can accommodate articles up to about 1000 words, and shorter articles are welcome. Articles can be technical or newsy, but remember we are not a peer-reviewed technical journal publishing research papers.

We are also looking to add a few small features such as publishing a list of recent publications by ACCE members, particularly in non-Clinical Engineering journals. If you have other ideas, please let us know. Thanks!

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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

ACCE Certification—What You Need to Know

- 1) The next CCE exam will be on November 19th, 2005.
- 2) The written exam will be given in twenty-eight cities around the US.
- 3) For an extra fee, the written exam can be given in almost any city in the US or in almost any major city in the world.
- 4) The deadline for having returned a completed application (application, references & transcripts) for the November 2005 exam is September 24th. This is a firm date, so we suggest that you get your application in well in advance of this date (e.g. September 1)
- 5) The handbook that describes the process and the application which needs to be completed can be found on the website www.accenet.org/certification/ or www.acce-htf.org/certificaton
- 6) The study guide has been recommended by several who recently passed the CCE exam and became certified. Walter Burdett of the VA Medical Center in Syracuse, NY said "The Study Guide was an excellent fit to the style, vocabulary, content and level of difficulty of the written exam. The bibliography was very useful."

ACCE News

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Perspectives from ECRI:

Behind the Scenes of an Infusion Pump Recall Alert

Publishing reliable and accurate information and recommendations about medical device recalls and corrective actions requires much work behind the scenes. In ECRI's experience, the recall information published by manufacturers and federal or state agencies frequently contains errors or is confusing. Compounding this problem, and adding to the equipment management and administrative burdens on clinical engineering departments, is the republication and list-serve postings of such original reports without fact checking and value-added analysis and clarification.

Presented here is an example of the pre-publication research, fact checking, corroboration, analysis, draft review, and re-review that is required to provide accurate recall information and clear action recommendations. It relates to a recent series of infusion pump recalls and related FDA notifications.

On March 15, 2005, Baxter Healthcare Corp. mailed an "Urgent Device Correction" about three problems with their Colleague infusion pumps. The notice was directed to biomedical engineers, with copies to directors of nursing. It was not presented or labeled as a recall. The problems involved: 1. Users inadvertently pressing the on/off key rather than the start key; 2. Communication port failures when pumps were hooked to certain types of hospital information systems; and 3. The need for pump inspection when any of several types of error codes were displayed. For the last problem, pumps that exhibited certain error codes could have disruption of infusion and cause a delay in delivery of life-sustaining drugs or fluids, although they would continuously alarm.

ECRI subsequently published a

Health Devices Alerts Action Item regarding Baxter's letter that clearly summarized the needed remedial actions to help hospitals address the reported problems (*Health Devices Alerts Accession Number A6238*, June 10, 2005). As with all *Health Devices Alerts* Action Items, the supplier, Baxter in this case, was given a pre-publication copy of our draft for review and comment. Baxter's review helped ensure accuracy and clarity of the final published information and, as a result, we received no comments expressing confusion about what to do.

On July 19, 2005, after considerable analysis, FDA classified Baxter's March 15, 2005, device correction as a Class I Recall and published it as such on July 19. A Class I Recall is the most serious type and involves situations in which there is a reasonable probability that use of the affected product will cause serious injury or death. The Class I Recall repeated the action recommendations from the March 15 manufacturer's notice. From ECRI's perspective, there were still no problems with clinical engineering departments understanding what needed to be done.

However, the next day, on July 20, 2005, Baxter initiated and published a separate "Urgent Product Recall" of Colleague infusion pumps for reasons closely related to its March 15 device correction. Similar descriptions of the infusion disruption problem were presented, but the error codes to look for were confusing: some were the same as the March 15 notice, some of the March 15 codes were deleted, and some new codes were added. Also, in this more recent July 20 notice, Baxter recommended that hospitals immediately remove from service any pumps that displayed any of the listed failure codes



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during use and any pumps that had any of the failure codes stored in their event history.

On July 21, 2005, FDA published a press release about the July 19, 2005, Class I Recall (i.e., the March 15, 2005, Baxter action). FDA press releases are typically mandated for all Class I Recalls. This press release did not address the Baxter July 20 recall and unintentionally resulted in significant confusion within the clinical engineering, materials management, and risk management communities. The press release was not clear about the fact that the pumps would continue to alarm if they stopped infusion due to an error code.

ECRI subsequently received numerous calls from CEs, BMETs, materials managers, and from Health Canada, asking for clarification about the Baxter July 20 recall and the FDA notifications. An ECRI team of four engineers and an editor worked with Baxter, FDA, Health Canada, and hospital based clinical engineering services to explore and clarify the issues and deter-

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ECRI continued: Infusion Pump Recall

(Continued from page 3)

mine the best approach to managing the problems with the Colleague pumps. Our team considered equipment management logistics and patient safety issues within the realities of the clinical setting. Numerous and lengthy discussions were held within the team and between the team and the other stakeholders. Baxter worked to revise and clarify the action needed.

In the end, after more than 120 hours of ECRI staff time were spent

resolving issues for just this one recall, we were able to deliver reliable and accurate information and comment in our abstract of the FDA and Baxter recall notices (Health Devices Alerts Accession Number A6520, August 5, 2005). We cannot readily calculate the time savings to CE departments from our efforts. But this example is worthy of consideration when the value of reliable recall alerting is debated.

The Health Devices Alerts Action Item discussed above can be viewed on

the members Web sites at <http://www.ecri.org> for ECRI's Health Devices, Health Devices Gold, and SELECTplus programs. Feel free to contact me if you would like to learn how to access this information.

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President's Message continued: US Government Shows Increased Interest in Healthcare IT

(Continued from page 1)

efforts of many stakeholders to achieve the desired goals.

Following Secretary Leavitt's announcement, Dr. David Brailer, MD, PhD, National Coordinator of Health Information Technology, announced the release of four RFPs (Requests for Proposals) to achieve interoperability in healthcare. The RFPs will focus on addressing HIT (Healthcare Information Technology) standards harmonization, certification of EHRs, NHIN (National Health Information Network) prototypes, and privacy and security legislation/regulation.

How does this all impact ACCE? ACCE has just recently endorsed HIMSS's collaborative response to the Standards Harmonization RFP (ONCHIT-1). It is imperative to search for ways to overcome the obstacles to interoperability of health information presented by disharmonious standards and multiple implementation processes. Please watch for future collaborative efforts between ACCE and HIMSS on this and many other endeavors.

I am also very excited to report on

the new collaboration between ACCE and the Italian Association of Clinical Engineers (Associazione Italiana Ingegneri Clinici, AIIC). I had the pleasure of attending the HTAi (Health Technology Assessment International) meeting in Rome, Italy towards the end of June. ACCE was invited by AIIC to present on "Clinical Engineering's Role in HTA: US Perspective" at the HTAi. The presentation was well received with great discussion on ongoing dialogue on clinical engineering and overwhelming interest in pursuing an international clinical engineering certification program. The room was filled with over 40 clinical engineers and technology assessment specialists from all over the world as speakers from the United States, South Africa and Italy addressed clinical engineering's role in HTA. AIIC is very interested in continuing the collaboration and plans on joining ACCE in Washington D.C. next June. I would like to once again acknowledge AIIC's support and thank them for their warm hospitality during my trip to Rome.

I cannot end without sharing the wonderful news on the unveiling of the

new ACCE website. Please take a moment to visit the www.accenet.org to check out the new look! Please feel free to provide your comments and suggestions for further enhancements and future content to the ACCE Website Task Force, webtaskforce@accenet.org. Congratulations to the Website Task Force and to our developer for the job well done!

ACCE continues to grow in rich and diverse activities. Please visit the new ACCE website to learn more about those activities and perhaps find a committee that might catch your interest. Please do not hesitate to call on the committee chair.

And, as always, I welcome any of your comments and notes of suggestions on how ACCE can continue to serve you and the clinical engineering profession.

Enjoy the rest of the summer!

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Medical Device Security Update

“Security” ... What connotation that word has taken on in recent years! Mention “security” in almost any context and it is likely to draw attention and often evoke controversy.

In healthcare we are increasingly concerned with *data* security. As the technology that we rely on for quality, timely and affordable patient care grows and becomes integrated into large connected and interdependent systems, we need to insure that each technology component (including medical devices) preserves the security (e.g., the *confidentiality*, *integrity* and *availability*) of the data it receives, stores, acts on, or transmits. A security-related failure of even the smallest device in this web of integrated components can have major implications for healthcare quality and patient safety. If that small device is a critical medical device and other technology components (or people) assume that the *integrity* and *availability* of the data it maintains or transmits is intact, then diagnosis and treatment may be compromised. Put another way, when looking at integrated technical systems with medical devices, the “chain is only as strong as its weakest link.”

The concept of data security is relatively new to the healthcare industry ... and even newer to the medical device industry. Data *confidentiality*, *integrity* and *availability* were less vulnerable a few years ago when most medical devices were less sophisticated and rarely interconnected. With the sophistication of technology and interconnection of devices, the healthcare provider is becoming more reliant on the new capabilities these changes in technology bring. On the whole, this trend is a positive one resulting in better quality, more timely and widely available healthcare. On the flip side, the danger is that an increasing reli-

ance on sophisticated and integrated technologies introduces vulnerabilities for which we may not have adequately prepared. Hence the need for effective security and risk management to identify and mitigate where possible the data security risks associated with medical devices. The ACCE ECRI *Information Security Biomedical Technology Guide* published last year provides an effective approach for healthcare providers to address security and risk management of medical devices and their environment.

An increasing number of medical device manufacturers and their industry groups are aware that data security is a growing concern. Many manufacturers are incorporating data security features (e.g., data backup, data error correction, password protection, anti-virus software, etc) in their more critical devices. Last fall, the Health Information Management and Systems Society (HIMSS) published a Manufacturers Disclosure Statement for Medical Device Security (MDS²) that was designed as an information tool for manufacturers to share details about their devices’ security features and vulnerabilities with the device owner operator. If properly used, the MDS² can help the device owner operators make decisions on how and where the device should be used to achieve a desired level of security.

Ultimately the responsibility for data security lies with the healthcare providers. Manufacturers can design medical devices with a variety of security features, but in the end, data security will depend on such factors as how that device is used, the environment it is used in and the other devices and systems to which it is connected. These factors will always be largely under the control or management of the healthcare provider. The healthcare provider must develop a

secure environment for the operation of its medical devices. In the future, manufacturers will likely list operating specifications for medical devices that not only include its operating temperature ranges, space requirements, minimum services required (i.e., electric power, water, gas(es)), maintenance and consumable supplies required but also their *security requirements* or expectations. To aid healthcare providers, the HIMSS Medical Device Security Workgroup is developing guidelines and identifying minimum standards for a “secure environment.” Also through the *Integrating the Healthcare Enterprise* (IHE) initiative, HIMSS, ACCE and other industry groups are working to incorporate new guidelines for interconnecting devices that include making those devices “security aware.” *Security aware* devices will enable their various security features depending on the type(s) of devices they interconnect with.

While technological advances do hold great promise for improving the quality, timeliness and availability of healthcare, the industry must be vigilant in addressing data security in order to mitigate the risks inevitably introduced by these advances. This will be a major challenge for clinical engineering and one for which we should be preparing for now.

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View from the Penalty Box: Technology's Cost Impact?

Here in Massachusetts we are in the middle of an advertising campaign on changes in healthcare. Most of the ads revolve around costs, staffing and protecting turf that several hospitals have established on the "free care" pool.

It is interesting that some of the ads mention new technologies and techniques that can reduce costs. Others have blamed the rising healthcare costs on technology but they never explained how technology is the cost villain.

On the financial pages we read about the new technologies that are being developed, mostly computer based, but some are based on genetic engineering. One article stated that in the future, people will be able to get a pill that is expressly designed for them and the ailments that they have. In that article it was stated that all humans have 99.9% of the same genetic makeup. So, if this ever comes about, I can take a pill that will reduce my body mass, put cartilage back into my knees, get rid of my cataracts and keep me alive long enough so I can become a burden to my kids. All from one pill designed for me, sounds a "little-out-there" for us on the East coast.

While the future may bring the "magic potion" it will be a long time in coming. Just imagine the roadblocks that will be put up on such a potion. I can see drug companies, equipment suppliers, insurance companies plus many "religious" groups getting involved. The battle over stem cells is just the beginning; it will get very nasty but hopefully the benefits will so outweigh the downside that reason will prevail in the end.

Now let's look at costs in hospitals. If a patient has no insurance and has a hip replacement they are billed about \$36,000, if they have one of the major health insurance programs the insurance company will pay about

\$26,000, if the insurer is a minor player they might pay \$28,000 but if Medicare or Medicaid pays it will be closer to \$16,000. The hospital probably has no idea what the true cost is of the procedure. What is worse is that most don't even seem to care, but ask for a repair part that costs more than \$1,000 and you have to do all sorts of justification.

As clinical engineers, we are going to have to look at costs more than ever. We have good data on repair costs, we have decent data on life expectancies, but we have poor data on utilization of most technology in the hospitals. In many hospitals 20 to 30% of the devices could be removed with little or no impact on productivity. All too often when we bring in new technology or techniques we don't get rid of the technologies being replaced. These obsolete items remain in our inventory which costs the hospital money. Most people, when they get a new car or TV, let the old ones go, but in healthcare a new EKG recorder means that we have another old one as a back up. I was in one hospital where they had several "back-up" EKG recorders but no paper in house for them. In this case, there were un-used and un-useable assets taking up space and budget money. My motto has been "when in doubt throw it out"; if I could only get my wife to do that I would have much less "stuff" in the house.

We need to actively push to down-size our inventories of unused devices. We need to push the replacement of devices that are no longer supported by the manufacturer and especially of devices where the manufacturer is out of business. We seem to do it in other area but not in instrumentation.

There are two books that you should consider reading, both are fiction with a few facts mixed in. One is the DaVinci Code by Dan Brown. It is interesting reading in that you can

see why some people got so worked up about it, but it is fiction and challenges some long held beliefs. The other is State of Fear by Michael Creighton. This is about global warming and all the politics and hype that are involved. Towards the end he has several statements that are so true in our field.

Three themes emerge. The first is "once we make up our mind that something is true it is impossible to change most people's minds regardless of the data presented". Does electrical safety testing come to mind?

The second is "most researchers arrive at a conclusion then develop the experiment to support the already arrived at conclusion". There is a whole list of items on this one in our field.

The third one was "researchers do not want to solve a problem because if they do the funding goes away".

We need to work hard at cost reductions to avoid the old quote from Walt Kelly's comic strip Pogo where one character says to another "we have found the enemy and it is us".

Have a great rest of the summer.

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ACCE Foundation: A Progress Report

The ACCE Healthcare Technology Foundation has been making serious progress on a number of key initiatives: 1) Fundraising, 2) “Doers”, 3) Patient Safety and Education Committee, 4) Clinical Alarm Management and Integration, and 5) Professional Credentialing Committee.

Fundraising: Financially the ACCE Healthcare Technology Foundation continues to be strong; however, it is imperative to keep projects funded and initiatives moving forward, therefore, the Board of Directors continues to focus on fundraising. We have been successful in securing many corporate sponsors and are working diligently to add a few more this year. Individual donations are also critical. The support from ACCE members has been tremendous and the commitment of the ACCE Healthcare Technology Foundation Board of Directors has historically and continues to maintain 100% participation. As always any support is greatly appreciated and if you would like more information please visit our website: <http://www.acce-htf.org>

Doers: The success of the ACCE Healthcare Technology Foundation initiatives depend upon those who chair and volunteer their time and effort in support. “Doers” is a term coined at our April annual meeting. There is funding to support projects and leaders to organize them but it takes many individual “doers” to make it happen. Therefore, we are embarking upon a campaign to locate additional “doers”; those people who can assist in small and large tasks assigned by the chair to help carry the project forward. We received feedback and names at the ACCE annual meeting and following various Clinical Alarm Task Force activities. Are

you interested in making an impact - be a “doer”? Do you like the initiatives we are pursuing and think you can volunteer some time and effort? If so please contact Dr. Yadin David or Jennifer Ott (see contact information below). Be a “Doer”.

Patient Safety: The Patient Safety and Education Committee has been hard at work continuing the process of educational module development on specific safety topics that can be shared with the public and used for a variety of patient educational activities. They have secured a legal review of the process and assignment to ensure copyright issues are addressed. The group has set a goal to complete one education module development in 30 days: “Patient Devices Brought from Home”. The goal is to submit this module at the August ACCE Healthcare Technology Foundation Board meeting. If all goes well further modules will be pursued through the solicitation of authors and bids.

Alarm Management: The Clinical Alarm Management and Integration project has also made some significant progress over the past few months. It began with the first town meeting held at AAMI in June 2005, followed shortly thereafter by an ACCE Teleconference. There is now a formal Clinical Alarms Task Force who meet to review feedback from these two meetings, discuss specific institution alarm tools, and develop additional articles and educational material to promote the activities of the task force. The biggest portion of their time has been the development of a clinical alarm survey tool. This tool has been reviewed by other national clinical groups, such as the American Association of Critical Care Nurses (AACN), and will be utilized

to gather information on overall alarm issues. Look for further information as we solicit our ACCE partners to assist in data collection. The goal is to gather as much information in various settings and user groups to develop a white paper on issues, guidance, and best practices.

Professional Credentialing: A Clinical Engineering Certification exam was held in June 2005. The second 2005 exam will be held in November. You will see a greater emphasis on promotion for this exam through many channels such as publications and websites. The biggest promoters are those who have recently taken the exam. They have expressed many positive comments on the exam process and the material covered. All clinical engineers are encouraged to pursue certification and to maintain their certification through the renewal process. The Clinical Engineering Board of Examiners continues to develop questions for the test bank.

The ACCE Healthcare Technology Foundation continues to move forward on many projects. We again would like to thank our supporters! Please let us know if you have any questions or an interest in a particular project. We thank you for your support of the Foundation’s mission either personally or through your daily contacts. More information is available at our website: <http://www.acce-htf.org>

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ACCE Healthcare Technology Foundation



ACEW Colombia- ACCE's 29th Healthcare Technology Management Workshop

The first Healthcare Technology Management and Clinical Engineering workshop in Colombia was held in the historic, northern seaport city of Cartagena. Colombia was settled in the early 1500's with Cartagena being the primary port city. Today, Cartagena is made up of a historic walled inner city, a peninsula beachfront with modern high rise buildings, and a business/residential area including a large shipping center. Colombia's population is nearly forty-three million - making it larger than Canada. Current President Alvaro Uribe has made great strides in working cooperatively with the US, improving the economy and healthcare, reducing drug production, and making Colombia a safer place.

Nearly one hundred enthusiastic participants from Colombia, Argentina, El Salvador, Costa Rica, Mexico, Uruguay, and Panama came to the Hotel Almirante on July 11-15, 2005. The workshop was a collaborative effort of the Pan American Health Organization (PAHO), the National University of Colombia, Ministry of Social Protection, and INVIMA, the national regulatory authority. Faculty included:

- *Yadin David, PhD, Director of the Biomedical Engineering Department at Texas Children's Hospital, Houston*
- *Tom Judd, Director Quality, Kaiser Permanente, Atlanta*



Yadin David presents on technology planning to eager participants..

- *Petr Kresta, Technical Director, Diagnostic Imaging Program, Regional Director, Clinical Engineering Program, Health Sciences Centre, Winnipeg, Canada*
- *Frank Painter, Director, Technology Management Solutions LLC, Assistant Professor, University of Connecticut, Storrs*
- *Kok-Swang Tan, PhD, Medical Devices Bureau, Therapeutic Products Directorate, Health Canada, Ottawa*
- *Claudia Cárdenas, Clinical Engineering Professor, Universidad Iberoamericana, México*
- *Antonio Hernandez, Regional Advisor, Health Services Engineering and Maintenance, Pan American Health Organization (PAHO), World Health Organization (WHO), Washington, and*
- *Team Leader - Tobey Clark, Director, Instrumentation & Technical Services, Faculty, Biomedical Engineering, University of Vermont, Burlington*

Considerable planning preceded this workshop. PAHO provided excellent background materials on Colombia with a fifteen page report on the healthcare situation in the country including efforts in the area of healthcare technology and its management. Mortality causes in Colombia include circulatory system disease, external causes (homicide, car accidents, etc.), malignant neoplasms, and communicable diseases in that order. There is a mix of public and private healthcare coverage in the country.

Three months prior to the workshop, the ACCE faculty group put together a focused twenty-four question survey on healthcare technology management policy, planning, safety, maintenance, CE department operations, and special topics of interest to the country: telehealth, EMI and regulations, and academic programs. The survey was sent to country health lead-

ers to gauge areas of need and emphasis to assist in customizing program development. The curriculum was developed, and faculty dove into preparing presentations and developing materials which were sent to Colombia for copying (paper and CD). A full description of the workshop objectives and sessions can be found at the World Health Organization website http://www.who.int/patientsafety/events/colombia_workshop/en/index.html.

Hurricane Dennis delayed some faculty traveling to Miami on the way to Cartagena - the only direct flight to the seacoast city is from southern Florida. All were welcomed on the first morning of the workshop by representatives from national and local health authorities, government and university leaders including the Ministry of Social Protection, INVIMA, and National University. Antonio Hernandez spoke about the rich history of successful healthcare technology management workshops and the PAHO/WHO vision, structure, and new efforts in the area of e-health and global harmonization. Tobey Clark provided an overview of the



Tom Judd, Petr Kresta, Yadin David and Frank Painter show the positive mood of the Cartagena workshop.

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ACEW: Advanced CE Workshop Colombia continued

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workshop purpose, objectives, schedule, format, and introduced the faculty. In the afternoon, a high impact summary of the benefits of each area of healthcare technology management was made by all faculty members. In particular, Claudia Cárdenas, spoke about the great progress of clinical engineering efforts in Mexico following PAHO-sponsored workshop participation. Clinical engineers are working at the health ministry level in Mexico. Participants submitted questions at the end of the day for faculty to mull over and answer/discuss the next day.

The second day provided two venues for participants. Those planning on attending the entire week began the full curriculum sessions. The group started out with the "homework" assignment description. The participants were assigned to present a real life, home-grown, case study involving healthcare technology management using the principles presented in the workshop. They voluntarily chose to participate in the team exercise in one of four areas: 1) *Technology planning*, 2) *Maintenance and technical operations*, 3) *Safety, risk and quality*, and 4) *Regulations and standards*. The participants were to work on the case studies in groups of about ten during breaks, lunch and after the day's presentations. Each group's deadline was Friday morning where each would make a presentation, act out the problem with role play, or use other communication means to:

1. *Define example clearly looking at significant areas of technology management*
2. *Collect the information e.g. facts, issues, situation...*
3. *Analyze the problem using techniques from the workshop and develop solutions to determine the best course of action*

The remainder of the day covered the topics of planning, acquisition, and medical equipment maintenance management.

Directors, administrators, physicians, and managers staying for only two days attended a separate, high level full day session covering big picture issues in healthcare technology and its management. Tom Judd, Yadin David, Petr Kresta and Kok-Swang Tan presented a lively session on policy, planning, telehealth and regulations including EMI.

The third and fourth day continued the healthcare technology management curriculum. Departmental operations, telehealth, safety/risk management/quality, and the important area of professional development were presented in very interactive sessions. Frank Painter covered US certification of clinical engineers while Claudia Cárdenas discussed the program in Mexico. Lastly, a special session on medical device regulation offered by Kok-Swang Tan drew a large attendance especially from those from INVIMA - the FDA of Colombia.

Friday was the most satisfying day for the faculty. The participants made wonderfully insightful and in some cases, dramatic presentations in their case studies. The faculty and program sponsors voted on the best presentation using the following criteria:

1. *Clarity of presentation*
2. *Use of principles and processes from the workshop.*
3. *Development of a working, successful solution to the problem*
4. *and Creativity of approach*

There was a very close vote with the Regulations and Standards team winning the voting based on their dramatic role play involving the corrupted approval of an unsafe defibrillator introduced into the health system, the fatal results and how the problem would be rectified using knowledge and techniques gained from the workshop.

The workshop ended with ceremony, pictures and sad goodbyes between the faculty, sponsors, and partici-



A physician, nurse and INVIMA investigator huddle around the "dying" patient, played by ACEW faculty member, Antonio Hernandez, in a case-study dramatization of medical device (mis) - regulation.

pants. Yadin David left early that day, invited to visit a impressive example of telehealth implementation at Hospital Universitario De La Samartina in Bogotá. Yadin said, "The hospital was very clean and well maintained, but it reminded me of the Tale of Two Cities..... on one hand - patients lay in old mechanical hospital beds watching TV with broken rabbit ears antenna, and on the other - completely wireless infrastructure supporting electronic medical records, lab and radiology where radiology is not digitized as of yet. Everyone (nurses, administrators, physicians, lab tech) are on the network pushing orders and results back and forth. The hospital is almost completely paperless!"

Continued communication and work will take place in the future between ACCE, PAHO and the participants via the linkages set up at the workshop.

The workshop was not without networking and social events. Daily luncheons and coffee breaks helped with the introductions. Dinners out included many members of the group discussing everything from medical device donation to soccer scores to seafood recipes. A performance by El Colegio del Cuerpo, an athletic dance group made up of youth from poor areas of Colombia was a highlight. A special evening event was held at a

(Continued on page 10)

ACEW: Healthcare Technology Education in Cartagena Colombia continued

(Continued from page 9)

high rise, rooftop entertainment area with a clear view of the entire city. Dancing, traditional food and camara-



Mexican and Colombian engineers and administrators enjoy the evening social event.

derie were included with Tom Judd taking over the ACCE faculty dance award from Kok-Swang Tan. Tourist highlights included the San Felipe Castle, the largest Spanish fort in the “new kingdom”, La Popa Candelaria Convent sitting high on the hill above the city, and the harbor and islands around Cartagena.

Lastly, it was a privilege for all ACCE faculty to be part of the first PAHO healthcare technology management workshop held in the native country of Antonio Hernandez, the individual responsible for the great improvement in healthcare technology management in Latin America through his efforts with PAHO. This

was Antonio’s twenty-second workshop benefiting Latin America, and we hope the best one yet.

Tobey Clark

Tobey.Clark@uwm.edu



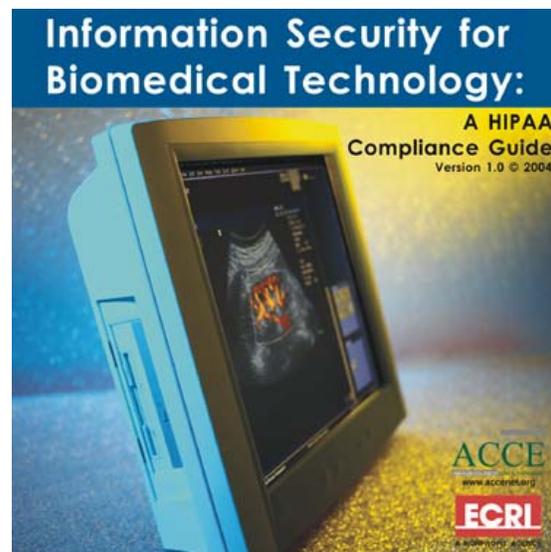
ACCE and ECRI publish new HIPAA CD-ROM \$200 discount for ACCE members!

Information Security for Biomedical Technology: A HIPAA Compliance Guide is a must-have tool for any healthcare facility’s data security program. The CD-ROM emphasizes best practices and contains an extensive overview of the HIPAA Security Rule, reviews necessary compliance measures for medical technology, and provides recommendations for implementing the rules with specific medical technology-related examples.

“The HIPAA Compliance Guide will help healthcare organizations identify and address information security issues,” says James P. Keller, M.S., director of ECRI’s Health Devices Group. “It includes valuable tools and resources, including downloadable forms, customizable worksheets, checklists for inventorying and analyzing risks, tools for setting priorities and implementing a mitigation plan, and much more.”

“Time is running out for organizations to comply with the security requirements of HIPAA,” says Stephen L. Grimes, FACCE, chair of the ACCE HIPAA Task Force. “This guide can help organizations save precious time and money because a majority of the hard work has already been done and is included in the CD-ROM.”

To order, call ECRI at +1 (610) 825-6000, ext. 5891, or visit www.ecri.org or www.accenet.org for more information.



Strategic Planning Committee Sets Agenda

The ACCE Strategic Planning Committee was chartered by the ACCE Executive Board to examine opportunities for ACCE to grow, increase the perceived value of Clinical Engineering, and increase the benefits to the members. The committee includes Ray Zambuto – Chair, Izabella Gieras, Steve Grimes, and Joe Skochdopole.

Since the Spring of this year, the committee has met by conference call and presented a report at the Annual Membership Meeting in Tampa. This report created an opportunity for feedback from the membership in attendance and a productive discussion was held which will be a model for issue oriented segments at future Annual Meetings.

The committee found that ACCE is doing well in meeting its Mission and has been growing increasingly visible in recent years, both in and outside the CE field. As a result of this success, the opportunities and demands on the College are increasing faster than we can respond at our current size and resources. The mission of the committee is to construct a formal strategy to assist ACCE as it takes the next steps in its growth and maturing.

The Committee has a draft vision statement for ACCE which reads: “The Mission of ACCE is to actively promote and foster the role of Clinical Engineering for the betterment of health care.” This Vision is articulated in four primary areas:

Advocacy – To promote the profession and clinical engineers

Representation – To provide a voice for CE within the healthcare industry

Value – To provide real value and support for the members, and

Education – To provide learning resources and benchmarks for the profession

Based on the committee’s discussions with the Board and the feedback from the members, one year goals are being shaped for each of these areas. These goals, along with three year goals, will be prioritized by the Board and assigned to various boards and committees

for implementation. It is not the intention of the Strategic Planning Committee to fully develop the goals, but rather to shape the direction for the Board and allow the committees to “fill in the blanks” as to how we hit the target.

Advocacy: In the area of Advocacy, we note that the Advocacy Committee has a robust program of Awards and Recognition, and they are developing tools and materials for clinical engineers to use in promoting the profession to high school and college students. At the annual meeting, it was suggested that we have some outside help in promoting the profession, perhaps a public relations firm. This is a good suggestion and is in the planning process.

Representation: Maintaining the Body of Knowledge is part of the Mission of ACCE. As such, the committee working on the Body of Knowledge should have more than ad-hoc status. The members told us that an annual updating is too often – 2 or 3 years is about right. Nevertheless, we should have a formal timetable and continuing process in place to assure that it is updated regularly.

Education: ACCE, in representing the profession and its interests, has been building bridges with many other groups. We need to concentrate our efforts and determine the most appropriate direction to pursue. In this regard, there has been considerable discussion regarding the AAMI relationship versus the HIMSS relationship. HIMSS has been most welcoming and receptive, and in the minds of many ACCE members, the information technology connection is where the future of clinical engineering lies. As ACCE expands its relationship with HIMSS, it must not lose sight of the benefit to the members which the AAMI connection brings.

Achieving such a balance at this time may require that ACCE present opportunities for members’ exposure to both HIMSS and AAMI. One way to do this is to gain exposure for the leaders of the profession by sponsoring a clinical engineering conference the day before HIMSS, concentrating on IT issues for clinical engineers.

Additionally the Professional Practices Committee should be encouraged to organize its plans for the year and promulgate its existing body of work, as this is in many ways a hidden jewel of ACCE.

Finally, the committee recognizing the variety of opinions on ACCE having its own journal, has tabled that idea for the present.

Value: Two near term areas were identified that will provide added value for the membership. The first is to establish a better process for inviting new members to participate in ACCE activities through committees or other work.

Second, all members would benefit from the full utilization of the new web site. A coordinated campaign is needed to encourage the use of the site on a regular basis.

As the year progresses, added goals will be developed and the existing goals evaluated for implementation and success.

Ray Zambuto

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Ray Zambuto is the ACCE Past President, President of Technology in Medicine, and is providing co-leadership on the ACCE IHE and Strategic Planning initiatives.

Integrating the Healthcare Enterprise (IHE) Update

Integrating the Healthcare Enterprise (IHE) is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. The IHE initiative was sponsored by the Radiological Society of North America (RSNA) and the Healthcare Information and Management Systems Society (HIMSS) in 1998. They have since been joined by the American College of Cardiology (ACC) as a major sponsor.

IHE is not itself a standard, but rather promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively.

The IHE endeavors to establish vendor neutral interoperability between clinical equipment and systems and the IT infrastructure of the healthcare organization. This creates many synergistic gains that would not be possible under a system of proprietary connectivity where each vendor owns its own protocol for connecting and passing information into the Electronic Medical Record (EMR) and is not able to communicate with other sys-

tems or devices on the network.

The organizational structure of the IHE initiative is by user groups or clinical specialties, referred to as "Domains." The primary domains in which there has been development to date are Radiology, Information Technology (IT), Clinical Laboratory, and Cardiology. A number of newer Domains are being established at this time, including "Patient Care Devices" (PCD), sponsored by the American College of Clinical Engineering (ACCE).

ACCE held an initial meeting of interested clinical engineers in Tampa on May 16th. Twenty-three (23) people participated and have signed up as the initial working group or task force. ACCE has named three co-chairs of this activity, Todd Cooper, Elliot Sloane, and Ray Zambuto. The IHE has named Jack Harrington, Sr. Director of Integrated Solutions at Philips Medical to be the mentor for the PCD. Since the May meeting, a number of additional actions have been completed. In June, Todd Cooper attended the OR of the Future Meetings in Cambridge MA. Ray Zambuto attended the IHE Educational Workshop in late June in Oakbrook IL, and the chairs have had weekly conference calls to prepare for the official kick-off meeting, September 29-30 in Washington DC. ACCE President, Izabella Gieras, has executed a

Memo of Understanding with HIMSS, RSNA, and ACC, naming ACCE as sponsor of the PCD.

The PCD addresses infrastructure as well as application. For example, one workflow might be to "analyze the vital signs chart", more fundamental issues would be associating a patient with a device, or setting protocol when a device is disconnected from the network and then reconnected in the same location or a different place.

Addressing these areas will require the group to work with IT, clinical, and vendor based professionals – something clinical engineers do well. It is a multi-year effort that will result in improved care, reduced error rates, and greater efficiency as the world moves closer to a true electronic medical record. The involvement of ACCE in the IHE presents a significant opportunity to raise the visibility of clinical engineering with the Information Technology profession and also with the major clinical societies.

The committee will continue to provide updates to this important activity in future issues of ACCE News. Anyone interested in joining in with this work should contact Ray Zambuto.

Ray Zambuto

rzambuto@techmed.com

Highlights of the July/August Board Meetings

Izabella Gieras reported that plans are already underway for the 2006 Clinical Engineering Symposium which will be presented during next year's AAMI conference.

On the international front, Izabella related that Frank Painter recently returned from an Advanced Clinical Engineering Workshop (ACEW) in Colombia with Tobey Clark (workshop leader), Petr Kresta, Yadin David, Kok-Swang Tan & Tom Judd. The program was a great success! The next ACEW will be in Nicaragua with Yadin David as leader, then another ACEW in El Salvador with

Matt Baretich as leader, and one in Argentina with Steve Grimes leading. A contract is being put in place with ORBIS for a workshop in Ethiopia. Kevin Taylor will be the workshop leader. Faculty members will include Jennifer Jackson and Bruce Barkalow. This workshop is planned for late October/early November.

Izabella also reported that she has been invited by PAHO to a meeting this August in Washington DC with an open agenda for ACCE to talk with WHO and PAHO of the current and future projects (ACEW, ACEW Sylla-

bus, INFRATECH, Patient Safety, etc). Frank Painter and Tobey Clark will be participating, as well as Ismael Cordero from ORBIS.

Steve Grimes announced that the new ACCE website is now up! Duane (our website developer) is currently working on transferring the member database, and expects that to be up soon. Steve requested that he be notified of any errors on the website, and also noted that he is continuing to solicit and develop additional content for the new website.

As part of ACCE's agreement with

(Continued on page 13)

July ACCE Board Meeting Minutes continued

(Continued from page 12)

our website host, ACCE has also subscribed to a fax service and now has a new fax number: (480) 247-5040.

Ted Cohen reported that Paul Sherman, the new Chair of the Professional Practices Committee presented the Board with some of the work that they've done so far. This work includes adoption of the General Considerations, adoption of the format used to create the guidelines, and the acceptance of the list of proposed guidelines. The Board requested time to look at the documents related to this work, and a motion and vote to approve the Committee's suggestions was made electronically. The motion passed by unanimous vote.

Ray Zambuto informed the Board

that Gary Evans has been elected as Chair-Elect of the Board of Examiners and will take over for Caroline Campbell at the end of her term.

Ray also reported that he attended the IHE Educational Workshop in late June in Oakbrook IL. A complete review was done of the IHE history, as well as plan development for the relative domains for this year and the future. The Patient Care Devices Domain is being well received, and it looks like the kick off will be in Washington DC in late September.

Ray provided details of the Strategic Development Group meeting on July 13th. This meeting served to follow up on the feedback from the Annual Meeting in Tampa and consider the work for this year. Some initial one-year goals were discussed. The areas of the discus-

sion centered on (1) expanding advocacy efforts to focus attention on clinical engineering, (2) strengthening the Body of Knowledge committee, (3) focusing our efforts in representing the profession through formal relations with other groups, (4) helping new members become active, and (5) helping all members maximize the benefits of the new website.

Finally, Joe Skochdopole reported on the 2005 ACCE Teleconferences, and stated that the recent Clinical Alarms teleconference was one of the best attended conferences we've ever had. More than 90 people dialed in!

Colleen Ward

ACCE Secretary

secretary@accenet.org

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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 and include credit card information (name on card, type of card, card number, and expiration date). Applications are now being accepted for the **November 2005** 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

Calendar of Events

- | | |
|--|---|
| - September 14-16, 2005
Virginia Biomedical Association
Omni Hotel, Charlottesville, VA | - October 2-4, 2005
Northeastern Biomedical Symposium
Southbridge, MA |
| - September 29-30
ACCE/HIMSS IHE Patient Care Devices, Kickoff Meeting
Washington, DC | - October 19-21, 2005
MD Expo
Stone Mountain, GA |
| | - November 20-25, 2005
3rd European Medical & Biological Engineering Conference
Prague, Czech Republic |

Teleconference Schedule

- | | |
|--|--|
| - September 15: CCE Exam Preparation 1.5 hour session (Tobey Clark) | Teleconference programs are at noon, Eastern time, and one hour in length unless otherwise noted. |
| - October 20: JCAHO Changes (Ode Keil) | \$150 per session |
| - November 17: RFID Developments (Michael Fraai) | Contact Joe Skochdopole at jaskochd@trimedx.com or register online at www.accenet.org . |



Newsletter of the American College of Clinical Engineering

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