ACCE News

ACCE Symposium Kicks Off AAMI 2005 Conference & Expo in Tampa

Sunny Tampa is the place to be May 14-17, 2005 for the annual AAMI Conference and Expo. AAMI 2005 is filled with exciting and enriching ACCE activities. This year many of our ACCE members will be recognized for their valuable contributions to the profession of clinical engineering. Once again, ACCE is one of the contributing organizations featuring presentations from many of our members.

The ACCE Symposium Planning Committee put together a highly stimulating half-day program entitled *Information Security for Medical Technology* which will be presented on Saturday, May 14th from 8 am to noon at the Tampa Convention Center.

Izabella Gieras is Manager of Clinical Engineering with Beaumont Hospitals in greater Detroit and *President* of ACCE

The symposium features speakers from ACCE, FDA, ECRI, VA, healthcare providers, medical systems manufacturers and consultants. As medical devices and systems increasingly become interconnected and computer-based, the vulnerability to security breaches increases. This poses a major risk to patient safety, confidentiality, and overall quality of care. The Symposium presents a review of the concerns and processes available for addressing medical device security issues. Case studies and methods on diverse mitigation initiatives of interest to Clinical Engineering and Information Systems personnel will be presented.

The symposium keynote address, giving a CIO's view of healthcare information security issues, will be presented by Mr. Gregory Walton, Senior Vice President and CIO at Carilion Health Services. Mr. Walton is also a past HIMSS board chairman. Other Symposium speakers include: Brian Fitzgerald, FDA; Lisa Gallagher, Healthcare Sector Coordinating Council; Dennis Seymour, VA Health Information Architecture Office; Scott Bolte, GE Healthcare; Nick Mankovitch, Philips Medical Systems; Denny Simmons, Cardi-

nal Health; Jim Keller, ECRI and ACCE board member; Ken Olbrish, Mainline Health System and Steve Grimes, GENTECH and ACCE President-Elect.

In addition to the Symposium, ACCE members are presenting several exciting educational sessions covering diverse areas of importance to clinical engineers. Topics include: The role of human factors engineering in patient safety, Successful and proven strategies for managing multi-hospital clinical engineering programs, Hospital networks, Technical iconoclast roundtable, CE/IT relationships, Update on JCAHO standards, Medical device integration, Wireless telemetry, The World Health Organization's (WHO) Essential Healthcare Technology Package, Computer security and patch management impact on patient safety, Service technology, Best of BI&T highlighting a culture of patient safety, a "town hall" meeting on clinical alarms and many more.

On Sunday evening, May 15th, ACCE will hold its Annual Membership meeting at the Wyndham Harbour Island Hotel, one block from the Tampa Convention Center. The evening will start at 6 pm

ACCE Members in the News and on the Move

The following membership applications and changes were approved by the ACCE board:

Individual Membership:

Matthew A. Clark (upgrade)

Todd Cooper

Susan Knapp

Ira Lipson (upgrade)

Frederick Montello

Associate Membership:

Kenneth M. Hart

Candidate Membership:

Diana B. Anderson

Members on the Move:

Bill Rice, ACCE Board Member-at– Large recently joined BSA Health System in Amarillo Texas.

Dave Francoeur was recently promoted to Vice President, Service Operations at TriMedx in Indianapolis.

Steve Grimes, ACCE President-Elect, has been advanced to Senior member status (SHIMSS) by the Health Information and Management Systems Society (HIMSS) .

Ron Baumann joined EQ International in Chicago as Senior Project manager in medical equipment planning.

Melissa Burns, ACCE News Co-Editor, also recently joined EQ International.

Please let us know about any job changes, personal and professional achievements and items of note to the ACCE community!

- Colleen Ward
secretary@accenet.org

AAMI 2005 Tampa ...

(Continued from page 1)

with a reception and an opportunity to network with your fellow ACCE members and special guests. The annual membership meeting will follow immediately after the reception. The meeting will provide ACCE members with an overview of this past year's diverse ACCE activities, presentation of the 2005 ACCE Advocacy, Best Student Paper, and Lifetime Achievement Awards as well as a description of new and exciting developments at ACCE.

Please take a moment to stop by at the ACCE Booth, #720 on the exhibit floor, for a friendly chat, a new brochure and to see our new banner! If you would like to volunteer for booth duty please contact Al Levenson at Secretariat@accenet.org.

For more information on the AAMI conference and the educational sessions, please check the AAMI website at www.aami.org. I look forward to seeing you all in Tampa!

- Izabella Gieras, President ACCE

igieras@beaumontservices.com

ACCE's New Season of Educational Teleconferences

May 19: Medical Device Security & HIPAA Compliance, **Steve Grimes**

June 16: Clinical Alarms, **Tobey Clark**

July 21: Cell Phone Developments, **Craig Bakuzonis**

August 18: Computer Security, **Colleen Ward and Rob Cadick**

September 15: CCE Exam Prep, **Tobey Clark**

October 20: JCAHO Changes, **Ode Keil**

November 17: RFID Developments, **Michael Fraai**

Programs are at Noon, Eastern Time, and 1 hour in length unless otherwise noted. A new teleconference host allows for improved audio quality and a controlled question and answer session.

$150 per session

Contact Joe Skochdopole at jaskochd@trimedx.com for more information.

President's Message: Embracing Patient Safety

I cannot help but feel rejuvenated with the first signs of warmer weather, colorful tulips, chirping birds – everything and more that we have waited for so long has finally arrived; the long awaited spring is here! It is with the same feeling that we embrace our work as clinical engineers as we make our contributions to a safer healthcare environment.

Having just returned from the ACCE Healthcare Technology Foundation (AHTF) Annual Board of Director's meeting in Houston added to my feeling of rejuvenation. It was a highly stimulating and an extremely productive meeting with excellent discussions on AHTF governance and projects. The Foundation, under the leadership of Dr. Yadin David, continues to exemplify the true nature of clinical engineering with strong focus on patient safety and effective patient care. I have observed great passion, motivation and perseverance, making the work a great success for the Foundation, ACCE and our clinical engineering community.

On my way back from Houston, reading through the April *Medical Edge* section of the Northwest WorldTraveler magazine, I came across an interesting article on *New Dimensions in Heart Care*, a new 5-D imaging technology that helps physicians diagnose and treat arrhythmias, especially atrial fibrillation. As a clinical engineer, the article drew my attention. This new technology allows doctors to see in five dimensions: the heart's anatomic structure (three dimensions of space), the heart moving and pumping (fourth dimension of time) and the heart's electrical impulse patterns (the fifth dimension of function). The Mayo Clinic-developed technology provides a more detailed analysis of the heart by mapping the electrical activity of the heart walls leading to faster and more effective patient treatments.

Cutting edge technologies such as 5D imaging, the exciting work on medical device interoperability, medical device security, new professional relationships and, most importantly, the underlying focus on patient safety, are all necessary initiatives that should be incorporated into our daily lives as healthcare professionals. As clinical engineers we play many roles, from researchers, educators, mentors to consultants, and now an even more important role as safety advocates. More so than ever before, we need to ask ourselves the question: How can we make our healthcare system a safer place for our patients, families and employees? Putting patient safety at the forefront might be somewhat of a culture change. However, as with the first signs of spring, we welcome this change to our clinical engineering profession, embracing the new strengthened perspectives on patient safety. Please be sure to review the AAMI educational sessions at www.aami.org encompassing many different aspects of patient safety initiatives in healthcare.

ACCE has embarked on another successful year completing a great first quarter of 2005. The annual member survey produced fantastic results. Each committee member is taking a proactive role in pursuing ACCE members interested in learning more about the diverse organizational activities. The teleconference series presents once again a comprehensive and highly educational set of sessions supporting our members' current interests and hot topics in the medical device industry.

The February HIMSS annual conference was an absolute success in further pursuing the flourishing relationships between clinical engineers and IT professionals! ACCE looks forward to continuing this success at the *HIMSS Summit: Achieving Healthcare Transformation* in June 6-7 in New York City, www.himss.org.

I would also like to continue to encourage you to read the article published in the last ACCE News on Tsunami Relief efforts in South East Asia – call for volunteers. Please feel free to contact me if you would like to pursue these activities.

Please take a moment and read through the articles on ACCE activities at the AAMI conference this May. I look forward to seeing you all in Tampa.

- Izabella Gieras, President, ACCE
igieras@beaumontservices.com

Jennifer Jackson, New ACCE Board Member

Jennifer Jackson, new ACCE Board member

Jennifer Jackson, assistant Director of the Biomedical Engineering Department at Brigham and Women's Hospital in Boston, has been named as an "at-large" member of the ACCE Board. Ms. Jackson takes the position previously held by Ted Cohen, who is now an ACCE Vice President. Ms. Jackson is involved in several projects of interest to ACCE members including the Operating Room of the Future. The board welcomes Jennifer's participation and looks forward to working with her on a variety of upcoming ACCE activities.

View From the Penalty Box: Is HIPAA like Y2K?

In the past several months, we have seen some real problems with our healthcare system splashed across the front pages of newspapers and in lead stories on newscasts. We had a group of "physicians" recruiting patients to have needless procedures and splitting fees with them, estimated at about $100 million in unnecessary costs. We had a whole class of drugs with serious side effects withdrawn from the market; those costs will be in the billions before the lawyers are through. We had "healthcare" companies cooking their books so the top executives could get huge payouts. We saw a very public right to die fight in the courts and congress followed by another very public death watch. Rarely do we hear of successes in the press; it must be that good news does not sell!

We have a very real problem facing us that the ACCE has worked very hard on, but it seems that all too many healthcare providers have chosen to go with the "experts" who don't know how to handle the problems. I am referring to the HIPAA Security Rule. In the March issue of Health Information Privacy/Security (volume 9 #3) the author stated that *"someone from the IT department needs to be involved as well as the network administrator. Someone from the medical staff should attend as well. And no meeting is complete without the lawyers".*

In the next paragraph our own Steve Grimes was mentioned as explaining that clinical engineers should be included. This brings back some very bad memories of Y2K where the wrong people were involved for the wrong reasons, and when we got involved the equipment problems were very minor compared to the IT problems. If you remember the hype back then, all of our equipment was going to have problems and hospitals would need to spend billions on new equipment. What happened? For medical devices, most hospitals spent more on the paper work than on repair, upgrade and replacement, but for IT systems, hospitals spent huge sums to resolve Y2K problems. With the HIPAA Security Rule there will be some major equipment costs if we rely on the "experts" from IT, consulting and the legal professions, so as Steve so aptly put it *"Get Involved".* Hopefully the ACCE membership will **share** information on the various methods that they use in setting up the compliance programs at their institutions or systems. Everyone should not have to reinvent the wheel at every institution. Working collectively will save ever-tight healthcare dollars.

The February 2005 issue of Health Devices has an excellent guidance article on electrical safety, I urge all of you to read it closely and maybe we can take some almost 40 year old misconceptions out of our workload.

I was recently asked by a friend to explain why he could go to one emergency room in Boston and be seen in 45 minutes or less but have to wait for up to 10 hours across town at another teaching hospital. The answer is very simple. At the first hospital, where most patients do not have private insurance, a decision was made to change its operating system to handle these patients quickly. The other hospital, where most patients have private insurance, looked at the emergency room as a bother to their structured patient care system. Guess which hospital makes money and which loses millions of dollars per year? Hint, it wasn't the one relying on private insurance payment.

Here in Massachusetts, the politicians are starting to act like it is time to do something about the cost of healthcare and healthcare insurance, as many working people cannot afford insurance. Massachusetts spends about one billion dollars a year in covering healthcare costs for the uninsured. Many companies and individuals wonder why they should provide or buy insurance if the state is covering the costs. To the politicians credit, they are pushing a law that says if a company does not provide health insurance it cannot bid on or get state contracts. One feature being pushed in the proposed plans is to develop a low cost insurance that doesn't cover everything, and steers the patients out of the emergency rooms where costs are high, into walk-in clinics where costs are much lower. One recent study showed that less than 2% of the patients in the Emergency Room needed that level of care. Unfortunately, all too many physicians use the ERs as dumping grounds for patients that don't fit into their schedule.

In closing, a little observation on my not so bright hockey player acquaintances. How can you tell the owners and fans in North America that you need a minimum salary of $1.5 million then go to Europe to play for $150,000 and face your fans? The sad part is that most of the players have agent/lawyers to advise them. Hopefully these are not the same lawyers involved with HIPAA security.

See you in Tampa!

- Dave Harrington

dharrington@techmed.com

Perspectives from ECRI: Colonoscope Reprocessing Issues

ECRI just published a Special Report article in its *Health Devices Alerts* publication (April 15, 2005) on a widely publicized problem related to the reprocessing of colonoscopes at a suburban Pittsburgh hospital. The problem had to do with the hospital's failure to reprocess the water-jet channel on two recently purchased colonoscopes. The hospital had been using similar colonoscopes that did not have a water-jet channel. Its technicians failed to recognize the design difference between the old and new colonoscopes and therefore continued to follow the hospital's reprocessing practices for the older colonoscopes. As a result, the water-jet channel for the newer colonoscopes was not disinfected for several months. Once the hospital learned of the error, it had to contact approximately 200 patients who had been treated with the colonoscopes to alert them to the problem and recommend testing for possible HIV and hepatitis infections.

Although no patients are known to have contracted infections from the reprocessing error, this issue became a huge problem for the hospital. The story was picked up by numerous national news publications and obviously raised major concerns among the patients who had to be contacted about the problem.

Unfortunately, the risk of cross-contamination from failure to properly reprocess endoscopes is a relatively common theme in today's healthcare environment. During the last few years, ECRI has written about similar incidents with bronchoscopes, rhinolaryngoscopes, and other flexible endoscopes. And, in fact, on February 28, 2003, we published a *Health Devices Alerts* Action Item on the same issue discussed above—the importance of reprocessing water-jet channels—involving the same model of colonoscope used at the suburban Pennsylvania hospital. ECRI's Action Item was based on a manufacturer's "Important Safety Notice" from February 2003.

The fact that this specific problem was reported on over two years ago emphasizes the need for hospitals to carefully examine their practices for managing hazards, recalls, and other safety notices for medical devices. ECRI has long recommended that hospitals search hazard and recall databases for outstanding problems before allowing new devices to be put in service. A search of ECRI's Health Devices Alerts database would have alerted the hospital for a need to change its reprocessing practices with its new colonoscopes. Clinical engineering departments are typically responsible for managing hazards and recalls for their hospitals. This responsibility should include searching appropriate databases for outstanding hazards, recalls, and other medical device problems for all new medical devices. Is this being routinely done at your hospital?

The *Health Devices Alerts* Special Report and Action Item discussed above can be viewed on the members Web sites at 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

Jim Keller is Director of ECRI's Health Devices Group, ECRI, and a Member at Large for ACCE's Board

this information or if you would like to discuss how you can search ECRI's databases for outstanding medical device hazards, recalls, and other important safety information before new devices are put into service. I can be reached at (610) 825-6000, ext. 5279, or at jkeller@ecri.org.

- Jim Keller

ACCE Seeks Nominees to FDA Panels

The ACCE is seeking volunteers to represent the interests of Clinical Engineers on various FDA Advisory panels as consumer members. These appointments generally require your attendance at meetings in the Washington DC area for 1 to 3 days per year. Travel, lodging and food costs are reimbursed and there is a stipend for each day.

The committees include: Anesthesia and Respiratory Therapy Devices, Circulatory Systems Devices, Clinical Chemistry and Clinical Toxicology Devices, Dental Products, GMP, ENT, Gastro/Urology Devices, General and Plastic Surgery Devices, General Hospital and Personal Use Devices, Hematology and Pathology Devices, Immunology Devices, Medical Device Dispute Resolution panel, Microbiology Devices, Molecular and Clinical Genetics

Devices, national Mammography QA Advisory committee, Neurological Devices panel, OB/GYN Devices, Ophthalmic Devices, Orthopedic and Rehab Devices, Radiology Devices panel, and Technical Electronic Product Radiation Safety Standards. Some of these panels have current openings, others will have vacancies in 1 to 3 years.

The ACCE contact point for these panels is Kelley Garland, ACCE Advocacy Committee chair at kgarland@EQINTL.com. To apply, please include the following: CV, publications and presentations list and a list of your specific experiences related to the panel for which you seek nomination. The Advocacy Committee will review the applications and forward the information to the ACCE Board which will forward approved nominations to the FDA.

- Kelley Garland

ACCE to Co-sponsor HIMSS Leadership Summit in NYC

HIMSS (Healthcare Information and Management Systems Society) has invited ACCE to co-sponsor the HIMSS leadership summit on healthcare IT that HIMSS will be holding on June 6-7, 2005 in New York City. The Summit will be a high level event bringing together federal government, provider, vendor, and payer leaders who have major influences on the pace and direction of healthcare improvement through the deployment of information technology.

Keynote speakers will include **David Brailer**, MD, PhD, National Health Information Technology Coordinator, Department of Health and Human Services (HHS); **Carolyn Clancy**, MD, Director, Agency for Healthcare Research and Quality (AHRQ), HHS; **Newt Gingrich**, former Speaker of the US House of Representatives and founder, Center for Health Transformation; and **US Rep Patrick J. Kennedy** (D-RI).

During the HIMSS Summit, industry visionaries will engage success leaders, pioneers and adoptees in critical discussions on successful healthcare IT initiatives that are transforming organizations, communities and the nation. Bringing together forward-thinking industry leaders to share insight into current issues and collaborate on future strategies, the HIMSS Summit provides a platform for collaboration, debate and open dialog focused on the *electronic health record (EHR), interopera-* *bility* and *financing across the spectrum of the enterprise, ambulatory care* and *the wider community.*

ACCE's presence as a co-sponsor at the conference will display our organization as an important voice in the furtherance of healthcare IT to achieve improved care quality and patient safety. Attendees will come away with new perspectives on how to conduct business and a greater understanding on the impact national healthcare IT policy has on the industry.

The Summit Web site at http://www.himss.org/summit/ASP/index.asp includes session descriptions and registration information. ACCE members receive a discount on registration fees.

(Extracts taken from HIMSS March 2005 Chapter Leader eNews)

- Izabella Gieras

igieras@beaumontservices.com

HIMSS Summit
Achieving National Healthcare Transformation
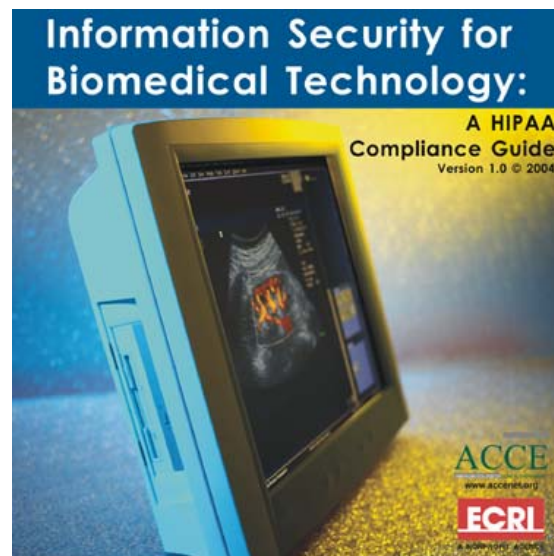June 6-7, 2005   Marriott Marquis   New York, New York   -   Register Today!

Highlights from the March/April ACCE Board Meeting

Izabella Gieras started the April 2005 Board meeting off with a warm welcome to our newest board member, Jennifer Jackson. Jennifer has accepted the vacant Member-at-Large position, and we look forward to her participation with ACCE in this new role!

It was announced that ACCE will hold it Annual Membership Meeting during the AAMI conference at the Wyndham Harbour Island Hotel on Sunday May 15th, from 6:00pm to 9:30pm. The Annual Meeting will be an opportunity to socialize and network with your fellow ACCE members, as well as an opportunity to hear about all of the activities ACCE has been involved in this past year. We'll also be bestowing a number of awards on deserving members, and discussing where ACCE is headed as an organization in the coming year. The Annual Meeting is bound to be an enjoyable and informative evening, so please come join us!

Kelley Garland and the Advocacy Committee have been hard at work preparing for the awards to be presented at the Annual Membership Meeting. Recipients have been selected for the following awards: Tom O'Dea Advocacy Award, Achievement in Management, Achievement in Technology, Challenge Award, DEVTEQ Award, Student Paper Award, and the Lifetime Achievement Award. Be sure to come to the meeting to see who the deserving recipients of these awards will be!

Izabella announced that Steve Juett attended his first FMDIC (FDA Medical Device Industry Coalition) meeting as the ACCE representative. Steve will be reporting to the Board on FMDIC activities.

It was reported by Ted Cohen, ACCE VP, that the Professional Practices Committee is currently looking for a chair. Any members interested in participating in, or knowing more about this committee, should contact Ted. Ted also reported that the Body of Knowledge Survey continues to move forward. It is currently being converted to a web format, and will be ready for release to the membership once the conversion is complete.

Ray Zambuto announced that plans are under way to hold Certification oral exams at AAMI. There will also be meetings of the Healthcare Technology Certification Commission (HTCC) and the US Board of Examiners for Clinical Engineering Certification during the AAMI meeting.

Ray also reported that ACCE will be a sponsor of the summer HIMSS Executive Summit in New York City. Izabella will be our official representative at this important event. Ray attended the annual HIMSS Advocacy Day in Washington DC earlier in April, and was part of a team that spoke with Congressional staffers about supporting the budget for Dr. David Brailor's Office of the National Coordinator for Health Care Information Technology (ONCHIT).

Ray also reported on the Integrating the Healthcare Enterprise (IHE) Task Force. This task force is planning its agenda and budgetary needs for the 2005 and 2006 calendar years. Co-chairs are Elliot Sloane, Todd Cooper, and Ray Zambuto. Additional members are Ted Cohen, Steve Grimes, and Ron Baumann. ACCE has been awarded Sponsorship of the Patient Care Devices Domain of the IHE. It is anticipated that most of this year will be taken up with educational efforts and the creation of a demonstration project for the 2006 HIMSS Meeting in San Diego, CA.

The ACEW (Advanced Clinical Engineering Workshop) faculty left for Kingston, Jamaica on Friday, April 8th. This is a joint ACEW between ORBIS, PAHO and ACCE. Participants from Antigua, Bahamas, Barbados, Belize, Guyana, Jamaica, St. Lucia, St. Vincent and St. Kitts & Nevis will be present at this ACEW, and Tony Easty is the team leader.

On July 11-14, a Technology Management Workshop will take place in Cartagena, Colombia. Tobey Clark is the team leader for this workshop.

Dave Francoeur submitted a Membership Committee report with recommendations for the approval of the membership applications and upgrades of seven individuals (See article on page 2). The Board voted on and approved each of these membership applications/upgrades. Congratulations and welcome!

- Colleen Ward
secretary@accenet.org

ATTENTION ALL ACCE MEMBERS:

The annual ACCE Membership meeting will be held on Sunday, May 15, 6:00PM , in the Peter O. Knight Meeting Room at the Wyndham Harbour Hotel, Tampa FL.

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ACCE to Co-sponsor AdvaMed Cybersecurity Workshop

AdvaMed will host a one-day workshop on Medical Device Cybersecurity on May 26, 2005 in Arlington, VA. The workshop is co-sponsored by ACCE, FDA and NEMA.

Presenters include: John Murray, FDA; Nick Mankovitch, Philips Medical Systems; David Hernsath, IBM; Steve Wexler, VA Healthcare; Jim Keller, ECRI; Paul Connelly, HCA and speakers from Microsoft and Cisco Systems.

The goal of the workshop is to provide industry stakeholders with a forum for identifying and discussing the various issues and points of view associated with the security of medical devices with special focus on those that contain commercial off-the-shelf operating systems. The stakeholders include medical device manufacturers, third-party software developers, commercial system vendors, FDA, medical device users/consumers, healthcare information technologists, clinical/biomedical engineers, and security and healthcare technology consultants.

This workshop will bring together members of each of these constituencies to explain their concerns, hear the concerns of the others, and discuss ways to more forward together to address them. To ensure the workshop's success, it is vital that all major stakeholders be there. We particularly want to encourage healthcare consumers, providers and their information technology and clinical/biomedical engineering representatives to attend. We encourage companies to send their IT staff to participate in these discussions, and we encourage them to urge their customers (e.g., healthcare consumers, providers and their information technology and clinical/biomedical engineering representatives) to attend this meeting.

The meeting will provide significant opportunity for open discussion and questions and answers. We are asking all registrants to submit questions that they would like to see discussed at the workshop.

For additional details see:

http://www.advamed.org/publicdocs/may2005_cybersecurity_wkshp.shtml

- Steve Grimes

slgrimes@nycap.rr.com

The Shadow: Who Bit the Kielbasa?

I couldn't attend the annual church supper the week after Christmas, but my Mom was kind enough to put a plate of food in a doggie bag, i.e. a 2004 World Series Champion Red Sox soda cup.

A couple days later, I eagerly dished out the bag's contents onto a plate and sat down for a feast. At first glance, the two pieces of *kielbasa* (Polish sausage) nestled against the pile of *kapusta* (cabbage) looked tasty. A closer look, however, gave me pause and no small concern. A bite had been taken out of each piece. I didn't know what to make of it. Did my mother pick partially eaten kielbasa off unfinished plates? Was the kielbasa not made properly? Did my mother take a taste to make sure it was good enough for her son? Did someone help themselves to a bite and then put a partially eaten piece bag in the cup? What started as a pleasant snack turned into a mystery and a Polish sausage became a busman's holiday. So, I put on my clinical engineer's hat and launched an incident investigation.

I measured and photographed the evidence. I examined the partially devoured kielbasa looking closely at the contours of the bite. I interviewed three witnesses, my mother and daughters, Laura and Carolyn. Laura took the doggie bag from the supper and put it in the refrigerator of Carolyn, who was unable to attend the supper. The chain of custody was verified: Mom to Laura to Carolyn to me. I consulted an expert in kielbasa preparation, my wife. I consulted the technical literature.

Visual examination revealed evenly spaced triangular indentations along the margin of the bite (see Figure 1). The witnesses affirmed that they had not taken bites of the kielbasa, that nobody else had access to the kielbasa after it was placed in the cup, and that the kielbasa was not taken off the plate of a diner, who may have taken a bite. The interview with my mother was a bit tense as she resented the implication that

anything but the highest quality kielbasa was suitable for her son. My wife provided the key kielbasa clue, i.e., the bite pattern was that typically seen when toothed grasping tongs are used to remove kielbasa from the pot in which they are boiled. When the kielbasa is not completely in the jaws of the tongs but only partially grasped, a "bite" is typically taken out of the edge of the sausage. This occurs especially when strong Polish women are hurrying to serve the hungry hoards waiting at the tables in the church hall, filled to capacity.

Dankelman et al (2005), report that during bowel resection, tissue is damaged if the jaws of graspers do not have a large contact area and rounded edges and grasp only a small portion of the bowel. Kielbasa consists of spices, a kind of meat, and other ingredients stuffed into lamb's intestine. After it has been cooked and while still in the pot, kielbasa is soft and friable. Haste and visual obscuration by the cloudy emulsion of water and fat contribute to the partial grasping of the kielbasa and, hence, the bite. Mystery solved.

Applying knowledge and skills to everyday mysteries, hones the clinical engineer's investigative technique. Writing a report for publication improves one's communication's skills and gives the reader the benefit of the incident investigation. We may one day discover who stole the *kiszka*.

References:

Dankelman J, Grimbergen CA, and Stassen HG. Engineering for patient safety: The clinically driven approach. *Biomedical Instrumentation & Technology*.
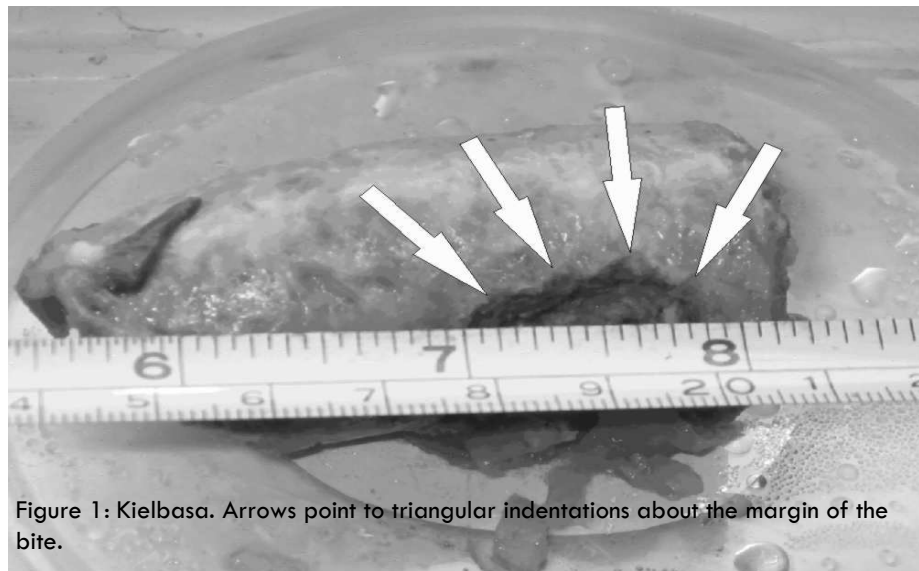

Figure 1: Kielbasa. Arrows point to triangular indentations about the margin of the bite.

ACCE 2004-2005 Member Survey Results

The 2004-2005 Member Survey results are in! 103 members took this year's survey and we'd like to take this opportunity to share the results with you.

Who are your fellow members? 75% of those completing the survey identified themselves as Individual members, 10% as Associate members, 5% as Fellows, 4% as Emeritus members and 2% as Candidate members. The majority of the respondents (54%) have been with ACCE for more than 5 years, and just under 10% are new to ACCE (less than one year). 35% of respondents indicated that they are Certified Clinical Engineers, with the vast majority of these certifications taking place through the ACCE/ICC certification program.

Continuing Education and Medical Errors/Patient Safety topped the list of issues and activities that are most important to our members with 69% and 65% of respondents, respectively, indicating that these issues were Very Important to them. Other issues that garnered a large number of Important and Very Important votes were Advanced Clinical Engineering Workshops, ACCE Networking Activities, Clinical Engineering Certification, the ACCE News, Converging Technologies, and our Annual ACCE Symposium.

Although the survey showed that just over one-third of our members were not aware of the ACCE Healthcare Technology Foundation (34.1%), those that were familiar with the Foundation indicated overwhelming support for its mission (82.2%), and felt that the Foundation was an Important or Very Important ACCE activity (74%). Nearly 50% of these members indicated a willingness to support Foundation activities with a donation of time and/or money.

ACCE members attend numerous conferences throughout the year. AAMI draws the largest percentage of ACCE members with 49% of respondents indicating that they will be attending this year. RSNA, HIMSS and ASHE will each also draw greater than 10% of our members to their annual conferences.

The ACCE Website Task Force was established to consider updates to the ACCE website. Responses to the survey indicated that links to patient safety information, white papers on technology management and related topics, and the online ACCE member directory were the items that were seen as most urgently needed on an updated website.

Thanks again to all who took the time to participate in the survey. These results are very important to ACCE because they have provided valuable information about the ways in which ACCE can best meet our members' needs, as well as how our organization can best serve our profession.

- Colleen Ward

secretary@accenet.org

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Association for the Advancement of Medical Instrumentation

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May 14–17, 2005 • Tampa, FL

Plan now to participate in the premier conference for healthcare technology management.

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- Get personal-development tips that will help you advance your own career.
- Share your own experiences and develop lasting relationships with your peers.
- See the latest products from the world's leading medical equipment manufacturers.

If you're a biomedical equipment technician (BMET), clinical engineer, biomedical engineer, or asset manager, or are otherwise involved in the management of healthcare technology, then you should attend AAMI 2005.

For details, visit www.aami.org/ac

Updates on Medical Device Security and HIPAA

This past March 4, the Chairman of the National Committee on Vital and Health Statistics (NCVHS) sent a letter to the Secretary of the Department of Health and Human Services (HHS) on the subject of medical device security and its implications for organizations who must comply with HIPAA's Security Rule. The letter was the result of testimony given to the committee by various industry stakeholders last November and their written follow-up comments supplied in December.

This letter is significant because NCVHS is an influential public advisory body to HHS and because it contained recommendations that it felt HHS should address with respect to medical device security. The issues, as described by NCVHS, are:

- *"medical equipment in use today either stores protected health information (PHI), or connects to a network with other systems that store PHI, such medical equipment needs to comply with the Security Rule"*

- *"Computer errors, resulting either from a computer virus or a provider inappropriately performing a software update, may cause medical equipment or devices to malfunction, potentially resulting in patient harm"*

The NCVHS letter goes on to make the following four recommendations:

- *HHS should provide guidance to covered entities to assist them to bring medical equipment into compliance with the Security Rule and to otherwise take appropriate steps to make medical equipment secure (e.g. protection from viruses that may impact the proper functioning of the medical equipment).*

· *HHS should provide clarification regarding the compliance obligations of covered entities with non-compliant and non-upgradeable legacy medical devices. A range of options should be considered based on the nature of the equipment, its replacement cost and life expectancy, patient safety implications, security problems, and the possibility of protecting the security of PHI through other means.*

- *HHS should develop guidance to assist medical device manufacturers to provide medical device functionality consistent with the Security Rule, as well as address reasonable security risks.*

- *HHS should support industry efforts to have medical device manufacturers self report the capability of their medical devices consistent with the Security Rule*

I have proposed that ACCE, the Healthcare Information and Management Systems Society (HIMSS) and ECRI respond to the letter and its recommendations with a joint reply. While a final version of the response is still being considered, it will likely make the following points:

The letter perpetuates two fallacies:

1). *"medical equipment needs to comply with the Security Rule"*. The truth is that equipment (or any technology) <u>cannot be made compliant</u> with the Security Rule, rather, it is *processes* that are associated with technology use that must be adjusted to insure a healthcare provider is compliant.

2). *"it is the responsibility of the medical device manufacturers to design their devices to enable covered entities to comply with the Security Rule"*. Medical device manufacturers are not obligated, other than by market pressure, to design their products in a manner that would facilitate a covered entity's (i.e., healthcare provider's) compliance with the Security Rule. And as previously pointed out, only covered entities can be made compliant with the Security Rule... <u>not</u> their medical devices.

We agree there is a need for guidance documents and standards that would address the NCVHS recommendations regarding medical device security. ACCE, HIMSS and ECRI are organizations that have taken the lead in developing most of the existing guidelines in this area to date. These same organizations could, in a joint effort with adequate funding, effectively lead the development of additional guidelines and standards as necessary.

Attend our May 14 Symposium in Tampa on *Information Security for Medical Technology* and watch this column for further developments.

Go to http://www.ncvhs.hhs.gov/050304lt.htm for the complete text of the March 4 letter.

-Steve Grimes, President-Elect
slgrimes@nycap.rr.com

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 Foundation Meets in Houston

The ACCE Healthcare Technology Foundation held its third Annual Board of Directors Meeting this past April in Houston, Texas. Over the weekend, members of the Board adopted a growth strategy, reflected on how we got this far, where are we going, and enjoyed bonding and socializing activities as well. The Foundation's President, Yadin David, was the consummate host planning a variety of rich activities that helped to spur plenty of discussion and passion for the continued mission.

Financially, the ACCE Healthcare Technology Foundation is strong thanks to corporate and individual sponsors, many of whom are ACCE members. Since its inauguration, the Foundation has raised over $90,000. The Board of Directors focus is on ensuring that adequate governance is in place to continue to guide the Foundation's work for many years to come. Board members provided reports on projects that have received approval for implementation.

A facilitator, Professor William Hyman, helped guide a discussion on how to focus more clearly on where the ACCE Healthcare Technology Foundation is going, and on how to address accountability and the management issues of various endeavors approved by the Board of Directors. One thing is for certain, to succeed there must be serious commitments by serious and productive people, strategy must be aligned and consistent, there must be sufficient funding and there must be tangible accomplishments.

We had a roundtable discussion with a senior hospital administrator, Randall Wright, about the role and perceived value of Clinical Engineering. We discussed what can be done to further the profession in the eyes of administrators, what successes can be shared, and how do we determine value? The goal was to understand what was necessary from the administrator's point of view and also to further educate us on various projects and planned endeavors for the ACCE Healthcare Technology Foundation and what role it could play.

There was also a second roundtable with a manufacturing representative to discuss protocol standards, patient safety practices, electronic data management, managing equipment failure, upgrades and interoperability. It was an opportunity to really think "outside the box" in a futuristic way that could meet the needs of a manufacturer and support personnel alike.

The Public Awareness and Patient Safety Education Committee is working to address specific safety topics. An educational model has been finalized. The next steps include the solicitation of authors and bids to work on specific modules. Once the modules are developed they can be shared with the public and used for a variety of patient educational activities.

The Clinical Alarm Management and Integration project is also moving forward with many activities in the near future. There will be a Town Hall Meeting at AAMI on Sunday, May 15th from 7:30am-8:30am. It will provide an overview of ECRI studies, other improvement efforts and new technology. There will be discussion between the moderators, Tobey Clark, Bob Steifel and Jim Keller and the audience on clinical alarm issues. On June 16th Tobey Clark and others will extend the town hall meeting format in an ACCE Teleconference again focusing on the same topics. The goal is to gather as much information in various settings and user groups to develop a white paper on alarm issues, guidance, and best practices.

The Professional Credentialing Committee has been very busy this year. With the help of the Healthcare Technology Certification Commission (HTCC) and the US Board of Examiners for Clinical Engineering Certification, 26 people took the CCE exam in Fall 2004. The 18 who passed are currently being scheduled for oral exams during the AAMI meeting. Interestingly, seven candidates were from Hong Kong. Two of the examiners were recently there to administer the oral exam to those candidates. Much appreciation is extended to Caroline Campbell for her leadership and guidance as Chair of the US Board of Examiners. Two exams will be held in 2005. Future plans include continuing to develop questions for the test bank and beginning research on international opportunities and other overall governance issues.

The Clinical Engineering Excellence (CE^2) program is heavily into the planning process. Much discussion occurred on the format for identifying clinical engineering programs that demonstrate excellence. There was focus on the development of eligibility and minimum requirements, the excellence criteria, review panels and judges, and the award and recognition process.

Overall it was a truly productive meeting with a wonderful format to encourage discussion and planning of the many activities of the ACCE Healthcare Technology Foundation We would be remiss to not once again thank our supporters who have both contributed monetarily and are working in various capacities on our projects. We ask that you continue this evolution and support the Foundation's mission either personally or through your daily contacts. More information is available at our website: **http://www.accefoundation.org**

- Jennifer C. Ott, MSBME, Secretary
secretary@accefoundation.org

- Yadin David, PhD, CCE, PE, HCSP, President
president@accefoundation.org

Join the effort to improve patient care...

Clinical Alarms Management & Integration:

Identifying issues and opportunities to improve clinical alarm design, integration, operation, response and actions.

Join your colleagues at AAMI for a "Town Hall" meeting to discuss this important issue

Sunday May 15, 7:30-8:30 AM

Tobey Clark and Bob Stiefel, Moderators

Overview presentation by Jim Keller, ECRI

For more information, contact Tobey Clark at Tobey.Clark@its.uvm.edu

Clinical alarm design, response and management are critical issues affecting patient care. Some examples include:

- *When presented with alarm sounds and asked to identify the source, anesthesiologists, OR techs, and OR nurses correctly identified the device producing the alarm only 33-54% of the time (Loeb, 1992).*

- *In February 2002, the JCAHO issued a Sentinel Event alert related to ventilator deaths and injuries. In 65% of the cases, there was a malfunction, misuse or inadequate audible alarm. Subsequently, in 2003, improving the effectiveness of clinical alarm systems became National Patient Safety Goal #6. Although Goal #6 was dropped for hospitals in 2005, JCAHO continues to look at this area as part of surveys.*

Healthcare provider shortages combined with the exponential growth of technology and systems increase the importance of alarm management strategies, device design, and system integration. Today's alarm systems not only include bedside and central audible and visual alarms, but have expanded to cell phone, pagers, nurse call, dashboards, tactile devices, and alarm prioritization systems. The ACCE Healthcare Technology Foundation has identified management and integration of clinical alarms as a key initiative for 2005-2006. One of the goals of this initiative is to *convene public meeting ("Town Meetings") at a variety of national patient safety, nursing, governmental, medical device industry, clinical engineering, and healthcare information technology annual meetings to stimulate discussion and gather best practices and ideas (e.g. AAMI, NPSF, HIMSS). Join us at AAMI for the first of these public meetings!*

AHTF Purpose: Improving healthcare delivery by promoting the development and application of safe and effective healthcare technologies through the public awareness and global advancement of clinical engineering research, education, practice and their related activities

ACCE Healthcare Technology Foundation (AHTF)
5200 Butler Pike
Plymouth Meeting PA 19462-1298
(610) 825-6067
www.accefoundation.org
AHTF is an independent, not-for-profit foundation

ACCE Healthcare Technology Foundation

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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

May 14-17, 2005
Association for the Advancement of Medical Instrumentation (AAMI) Annual Conference and Expo
Tampa, FL

May 14, 2005 (at AAMI**)**
ACCE Symposium
Tampa Convention Center

May 15, 2005 (at AAMI**)**
ACCE Annual Membership Meeting
Wyndham Harbour Hotel, Tampa

May 26, 2005
AdvaMed Medical Device Cybersecurity Workshop
DoubleTree Hotel, Crystal City at National Airport, Arlington VA

June 4-6, 2005
3rd Annual Conference on Ethical Issues in Biomedical Engineering
Alfred University, Alfred, NY

June 6-7, 2005
HIMSS Summer Conference
New York, NY

October 10-12, 2005
Northeastern Healthcare Technology Symposium
Southbridge, MA

November 20-25, 2005
3rd European Medical & Biological Engineering Conference
Praque, Czech Republic.

AMERICAN COLLEGE OF CLINICAL ENGINEERING

Newsletter of the American College of Clinical Engineering

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