Call for Assistance for Kosovo Biomedical Engineering

Background

In 2003, International Aid (IA), led by Bill Teninty, provided a nine-month course in basic medical electronics to a Team of 7 engineers and 21 technicians in Kosovo. IA led by senior BMET Teninty and volunteers has done this medical equipment training (MET) in many places around the world in recent years.

Since September 2003, the Team - part of the Kosovo Ministry of Health (MoH) - has provided medical equipment services at 7 public hospitals and 30 clinics serving the 2 million people in this war-torn country that occupies only 7000 square miles in the southern part of former Yugoslavia.

In October 2004, IA, MoH, and the World Health Organization sponsored a 5-day Advanced Clinical Engineering Workshop taught by ACCE faculty to 40 physician and nursing health leaders, and biomedical Team members from Kosovo’s 6 key regions. Faculty members included George Johnston, Sam Miller, Steve Grimes, Tom Judd, and Kevin Taylor.

Several critical improvement opportunities were identified; it was recommended by faculty to MoH that both short-term and longer-term clinical engineering mentors assist the Kosovo Biomedical Engineering Team and health leaders in addressing these medical equipment management (MEM) needs. For example, it was noted that well-intentioned donors have provided a diversity of medical devices since the 1999 war, making it difficult to obtain necessary parts, manufacturer-specific training, and service manuals to conduct proper preventive maintenance and repair.

Next Steps

Short-Term Mentors: 2 clinical engineers from Canada - Victoria Young (Toronto) and Sonia Pinkney (Vancouver) - will conduct a 3-week follow-up mission to Kosovo Nov. 30-Dec. 20, 2004, visiting key health facilities in the 6 regions, assisted by MoH, with IA’s Kosovar project manager/translator, and a local US NGO driver. They will assist in identifying critical repairs, spare parts, manuals and training needed.

Longer-Term Mentor: ACCE member George Johnston has agreed to come for 6 months in early 2005 to help the MoH physician leader and Biomedical Engineering Team (K-Team) implement these findings.

(Continued on page 2)
Kosovo Assistance
(Continued from page 1)

Assistance Needed Now

Mostly You: clinical engineers, biomedical equipment technicians, health technology managers who can offer advice to the K-Team via a Kosovo MEM Listserv for a wide variety of issues. Pass this request on to your colleagues and other appropriate Listservs.

Money: There is a $6,000 at-cost budget (travel, on-ground expenses) for the short-term mission; help us assist the K-Team before the end of ‘04 by sending a US tax-deductible donation: International Aid, “Account 1220-310 Kosovo MEM”, 17011 W. Hickory St., Spring Lake, MI 49456. The longer mission will be funded differently.

Questions and further information: Please contact Tom Judd (tjudd51@hotmail.com, 404-932-5551) or Sam Miller (bearwalker@verizon.net)

New Editors

We would like to introduce ourselves as the new co-editors of the ACCE Newsletter. Many thanks to Steve Grimes for his service as editor over the past year and his assistance in getting us off on the right foot.

There are great things ahead for ACCE, and we welcome the opportunity to bring you events and news from around the clinical engineering community. All suggestions welcome, and thanks for reading!

-Ted Cohen
theodore.cohen@ucdmc.ucdavis.edu

-Melissa Burns
mburns02@yahoo.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

Purchase a copy of the new ACCE Clinical Engineering Certification Study Guide

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

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

Or e-mail Secretariat@ACCEnet.org and include credit card information (name on card, type of card, card number, and expiration date).

The next examination may be given in May 2005 and will be given in November 2005. The deadline to apply for this examination is 10 weeks in advance of the exam date. The application form and 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

ACCE News

ACCE News is official newsletter of the American College of Clinical Engineering (ACCE). ACCE News is a benefit of ACCE membership; nonmembers may subscribe for $60.

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President’s Message: The End of the Year is Approaching ...

The summer has come to an end, the fall is well underway and some of us are already seeing the first signs of snow! The first November snow, in its full glory, at my parent’s backyard in Connecticut; what a sight! The leafless trees and the leftover sweet Halloween candy only reminds us now of the short days and long nights ahead. The winter is almost here....

The changes in seasons, however, did not put a stop to all the vibrant activities within the ACCE family. First and foremost, in October we welcomed our new Secretary, Alan Levenson. Alan will provide Secretariat services on behalf of ACCE, the ACCE Healthcare Technology Foundation (AHTF), and the Clinical Engineering Certification Program. We thank Matt Baretich for his work and dedication to the Secretariat activities and extend a warm welcome to Alan.

Another exciting activity within ACCE involved the new changes in the ACCE Newsletter editorship. We thank Steve Grimes for his wonderful work as the ACCE News-letter editor and welcome our new co-editors, Melissa Burns and Ted Cohen. They already had their contributions to the publishing of this newsletter issue and it looks spectacular! I encourage you to send them any ideas you might have for future newsletters. Over the past year we have seen new enhancements to the format of the newsletter making it less laborious for the editor and I can guarantee more will be coming our way. I am sure Steve is now looking forward to investing his full energy into HIPAA, medical device security endeavors and other interesting opportunities, not to mention his President-Elect duties! Thank you, Steve!

While we are on the subject of new editors, I would like to mention that 24x7 magazine also has a new editor, Kelly Stephens. She is very enthusiastic and eager to learn more about the profession of clinical engineering. Kelly is also interested in gathering materials for future articles.

Not to overdo the talk about editors but I had an interesting exchange of e-mails with Mike Hrickiewicz, editor of Health Facilities Management (HFM) magazine. Mike is interested in receiving ideas for potential articles to publish in the HFM magazine. He would also like to learn more about the intricacies of our profession, our uniqueness and distinction between Clinical Engineers and Biomedical Engineering Technologists. ACCE members in the past, including the HFM November cover story on “Out of the shadows - Clinical Engineers work to increase their visibility”, have provided great input on diverse clinical engineering related topics. Increased patient safety initiatives provide and will continue to provide endless opportunities for clinical engineers to increase their visibility and show value to healthcare administrators. Let’s make use of these opportunities!

Intertwined in patient safety is the increased emphasis on medical device security. This topic is going to be one of the main themes at AAMI 2005. To complement AAMI’s conference theme, ACCE is planning the 8th Clinical Engineering Symposium on “Information Security for Medical Technology”. Watch out for more information on the symposium as the ACCE Symposium Planning Committee finalizes the program. In addition, ACCE has recently endorsed the release of Healthcare Information and Management Systems Society’s (HIMSS) Manufacturer Disclosure Statement for Medical Device Security (MDS²) marking a monumental step forward for the medical device industry. The MDS² will serve as a user-friendly venue for collecting pertinent device information during medical device risk assessments.

So what else will winter bring? The list as always is endless....The ACCE

(Continued on page 8)
The year 2004 has been a strange one here in Eastern New England. The Pats win the Super Bowl and the weather turns cold; some thought that it might be Hell freezing over.

Now the Sox have won the World Series, and it is getting cold early around here. But I don’t think that Hell is freezing over because the Cubs still haven’t won. When the Cubs win, global warming will be reversed.

Ray Zambuto and I recently attended a 2 day workshop on indoor positioning systems and RFID. While the technology was interesting, we discovered that many of the people at this meeting had little knowledge of clinical engineers and what we do. Many of the people there were from software, construction, and insurance companies and venture capital companies. Ray and I spent most of our breaks and meals talking with various people about what a clinical engineer is and what we do. At first, we thought it might just be a geographical problem, but the people were from all over the country. We need to get the word out about what we do to everyone involved with healthcare. During a conversation with one person from the software industry, I discussed clinical engineering. When I finished, he said, “as you described it, a clinical engineer is like a product manager, total responsibility with no authority or budget.” Having been a product manager in the past and a clinical engineer, that is one of the better analogies that I have heard.

While visiting at a local hospital recently, I answered the phone, “Good morning, clinical engineering,” only to hear nothing on the other end until a small voice said “I thought I called the repair shop?” The next few minutes were spent explaining that, while the shop does repair work, they also handle many other technical problems in the hospital. While I think the person understood what we do, they still said that their computer printer was not working and they needed it fixed. At this hospital printers are in the domain of the IT group and we do not work on them, but I told the person that I would have someone check on the printer. A quick call to the IT department got me voice mail with instructions to leave a call back number and someone would be back to them that day. I left the message about the printer and went on to other tasks within the department. Heading out for a smoke, I ran into one of the IT guys and asked about the printer call, getting the response that they were too busy to get to it. About 3 hours later I asked again. This time there were 3 people sitting there reading about the Sox. The answer was, the day isn’t over yet. Heading to lunch about an hour later, our route took us past the printer problem, so I stuck my head in to ask if it had been fixed. The answer was no and the person had numerous reports to get out and was having a bad day because the printer wasn’t working. Trying to be helpful, we looked at the printer, cleared a jam and the printer was functioning well. During lunch the person and her boss came over to us to thank us for helping them out, in voices loud enough for the IT guys setting a few tables away to hear. We will probably pay for that good deed in the future.

To me, helping a person who has a problem is all part of a good clinical engineering service, even when the problem is not ours. Too many of the departments within a hospital are territorial and do not or will not go out of their way to help another department. This is one of the contributing factors of healthcare costs. As clinical engineers, we are open to solving problems first rather than looking for someone else to take it on. As clinical engineers, we work hard to provide a safe environment for the patients, staff and visitors without big titles or budgets. As clinical engineers, we work to get the next generation of engineers and technicians up to speed to they can continue the process of improving healthcare.

These next 4 years will determine what our healthcare system will be for our retirement and that of our children. We cannot keep
ECRI recently reported on a very serious problem in which hoses from noninvasive blood pressure monitors and sequential compression devices were inadvertently connected to needleless Luer ports on intravenous administration sets. In one case, a patient died from an air embolism when a noninvasive blood pressure monitor cycled on and injected air into the patient’s intravenous line. These problems were able to occur because the hoses on the blood pressure monitors and sequential compression devices used Luer-type connectors, allowing them to be mistakenly connected to the intravenous lines.

ECRI also recently reported on the death of a ventilator-dependent child that was being cared for in the home. The child died because the ventilator was configured such that it did not alarm when the patient’s tracheostomy tube became occluded with pulmonary secretions.

If you are like most clinical engineers, you or your department have responsibility for managing and addressing hazards and recalls for medical devices. The two incidents described above are typical of the types of problems that clinical engineers should be responsible for dealing with. If you or your department has this responsibility, you should be able to say that (1) you know about the gas embolism and ventilator problems; (2) you have a good understanding of how they can occur; (3) you have a good understanding of how they can be prevented; (4) you have taken actions to prevent these problems from happening at your facility or facilities; and (5) you can show your administrator, a JCAHO surveyor, or even a lawyer documentation on when and how corrective or preventive actions were taken.

One of the solutions to the gas embolism problem is to eliminate any Luer-type hose connections for noninvasive blood pressure monitor or sequential compression device from your facility. Have you checked your hospital’s inventory for these devices? Is this information even recorded in your inventory? If not, you or someone else in your institution may need to do a physical check of all noninvasive blood pressure monitor and sequential compression device hose connections.

With the ventilator problem, have you verified that your hospital’s ventilators have alarms to warn of tracheostomy tube occlusions? The problem reported by ECRI occurred during the use of pressure controlled ventilation. ECRI’s report discusses the fact that the low-minute-volume alarm must be used and set properly during pressure controlled ventilation in order to detect the occlusion that caused the patient’s death. Has this information been communicated to the caregivers providing ventilator support at your institution? Can you point to documentation that verifies that this information was provided? If so, does the documentation show who this was communicated to?

The measures discussed above are just a few of the best practices ECRI has defined for managing medical device hazards and recalls. These measures revolve around identifying critical device-related safety information, communicating the information to the right people at the right time, and resolving the problems so that they never happen at your institution. Are you achieving these best practices?

ECRI published a comprehensive discussion of its best practices for managing medical device hazards and recalls in its February 2004 issue of Health Devices. ECRI’s reports on the gas embolism and ventilator problems were published in the June and September 2004 issues of Health Devices. Feel free to contact me at ECRI (jkeller@ecri.org or (610) 825-6000, ext. 5279) if you would like to discuss our perspectives on management of hazards and recalls for medical devices or if you would like to discuss the gas embolism or ventilator problems. Members of ECRI’s Health Devices and SELECTPlus Systems can view the articles mentioned above on their member Web pages at www.ecri.org.

Jim Keller is Director of ECRI’s Health Devices Group and a Member at Large for ACCE’s Board.
Medical Device Security Update

The Medical Device Security Workgroup of the Healthcare Information and Management Systems Society (HIMSS) has just published a Manufacturers Disclosure Statement for Medical Device Security (MDS²). The MDS² is designed to provide manufacturers with a standard format for reporting security-related information about both new and legacy devices. Since it specifies whether a device is capable of transmitting or maintaining electronic protected health information (ePHI) and describes a device’s security related features, this model-specific, manufacturer-completed form will provide healthcare providers with substantial assistance as they work to meet the April 2005 deadline for complying with HIPAA’s Security Rule. The Security Rule requires that all healthcare providers identify their sources of ePHI, determine the criticality of that information and the risks associated with any compromise to that information. Providers are then required to develop a plan to manage these risks. Since there are 3 to 4 times as many medical devices as information technology devices in a typical hospital, the MDS² should be a major benefit to providers. Prior to the MDS², hospitals had to either make a special request for this information to device manufacturers or attempt to compile the information themselves.

Several of the industry’s major manufacturers have already adopted the MDS² and will soon have it available for their current products (most will follow-up with their legacy systems as well). Industry support of the MDS² has also come from endorsements by ACCE, ECRI, and the medical manufacturers section of NEMA (the National Electrical Manufacturers Association). Some hospitals and hospital organizations have also adopted the MDS² as a requirement in their purchasing specifications. As more hospitals, manufacturers, and industry groups promote the MDS², it increasingly becomes the standard. The concept of the MDS² was derived from ACCE / ECRI guide for Information Security for Biomedical Technology and designed as a tool to work with that guide. The guide, which is being marketed by ECRI, lays out a comprehensive security management process that will meet the information security management requirements of HIPAA.


- Stephen Grimes
slgrimes@nycap.rr.com

View From the Penalty Box

(Continued from page 4)

spending at the rate that we are presently. In one article it said that our per capita healthcare costs in the US are $6,128.00. For that money, we do not have the longest life expectancy, the lowest infant mortality rate, or consistently good general health of the population. We have some chronic illnesses that, while treatable, consume huge percentages of healthcare funding. That sad part is that many of these chronic conditions are self inflicted. Look for groups like Leapfrog and others to be pushing for major changes in our healthcare system. One thing about Leapfrog is that they have the “power of the pen” in that they represent the big purchasers of health insurance and are looking for accountability and value.

So in closing, I would like to welcome our new editors and thank Steve for all his work on the ACCE News. The Harrington Clan wishes all a happy and peaceful holiday season.

- Dave Harrington
Dave@sbttech.com
ACCE 2005 Symposium planning is in full swing! Izabella reported that a Symposium Planning Committee has been put together. Committee members are Ray Zambuto, Steve Grimes, Ted Cohen, Jim Keller, Bill Rice and Bhavesh Patel. The topic that ACCE has submitted to AAMI for the Symposium is “Information Security for Medical Technology.” This is a very popular topic this year, and the Committee is working with the AAMI session chairs for the IT and Patient Safety tracks to ensure that content for the symposium and AAMI sessions has minimal overlap. We also have a new ACCE representative, Bhavesh Patel, on the AAMI Education Committee. Bhavesh attended the committee meeting on September 17th in Arlington, VA, and he will serve as the main liaison between ACCE and AAMI for Symposium-related issues.

The ACCE Board welcomed our new Secretariat, Al Levenson, and thanked him for joining us. As Secretariat, Al’s work will encompass a variety of ACCE, the Healthcare Technology Foundation, and Certification Program activities. Izabella proposed some ideas for Al’s ACCE activities including participation with the upcoming membership survey, updating ACCE’s membership database, streamlining the ACCE newsletter release, assistance with membership processing, ACCE Teleconference Series administration, preparation for HIMSS and AAMI conferences, as well as a variety of other administrative tasks.

Izabella provided the Board with an extract of an email written by Elliot Sloane on the subject of the recent natural disasters/hurricanes in the Caribbean and parts of the US. Elliot initiated this email to some of the individuals in the Caribbean as a way of offering the support of ACCE in their time of need. On behalf of PAHO, Antonio Hernandez thanked ACCE for our offer of assistance. He said that help will really be needed when they begin reconstruction. He has forwarded the ACCE offer of assistance to their task force, and he will be in contact with us when they know more about what is needed. Antonio will serve as the liaison between the Board and PAHO.

A motion to endorse the HIMSS Manufacturer Disclosure Statement for Medical Device Security (MDS^2) was passed by the Board. Steve said that this further cements the relationship that ACCE has with HIMSS in another area where we have common interests.

It was announced that we have two new, very enthusiastic ACCE Newsletter editors, Ted Cohen and Melissa Burns. Steve will be working with both of them on the transition.

Ron reported that George Johnston has accepted the position as the new chair of the Professional Practices Committee. George will be working with Marv Shepard in his transition to that new position.

Ray Zambuto reported that the IHE Taskforce is preparing for the HIMSS meeting in February 2005. ACCE is a co-sponsor of HIMSS and there will be a kiosk facilitated by ACCE on the exhibit floor. In addition, we will provide a 30-minute presentation in the IHE theater. Ray also put out a request for ACCE members to man the ACCE booth during the conference.

Jim Keller reported that sales of the HIPAA Compliance Guide have been good. In addition, it is expected that sales of the guide will increase due to exposure from the Manufacturer Disclosure Statement for Medical Device Security (MDS^2), as well as an agreement that is being finalised with HIMSS to promote the guide to its membership. The guide will also be promoted during the ECRI HIPAA Security Conference coming up in November.

Two new members were recommended for individual memberships in October. The Membership Committee also discussed having a membership drive, as well as looking at reviewing the Candidate, Associate and Fellow membership categories.

On the International front, an Advanced Clinical Engineering Workshop was held in Kosovo in October. This will be the last ACEW for the year. Antonio reported that they are working on next year’s workshops, as well as two workshops for 2006.

The Advocacy Committee has been working to fill some of the consumer member positions on the FDA Advisory panels with ACCE members. The Committee will be releasing a statement outlining which positions are available and what the process will be to get a nomination from ACCE. The Advocacy Committee will be responsible for the initial review of submittals, and recommendations will be forwarded to the Board for approval.

-Colleen Ward  
secretary@accenet.org
ACCE and ECRI publish new HIPAA CD-ROM

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.
Teleconference Schedule

The following Teleconference topics are scheduled for the balance of the 2004-2005 season. Teleconference topics, presenters and scheduled dates include:

- **Preparing for the CBET Exam**
  - presented by James Wear
  - December 16

- **Clinical Engineering’s Role in Telemedicine**
  - presented by Paul Ostrowski
  - scheduled January 20

- **PM Task Force: Update on Proposed JCAHO Equipment Management Standards**
  - presented by Binseng Wang
  - scheduled February 17

ACCE Advocacy Awards

On behalf of the ACCE Board and the ACCE Advocacy Committee, ACCE is happy to present the ACCE Advocacy Awards criteria for 2005. The Clinical Engineering profession has many distinguished individuals that fit the award recognition. Please take few minutes to review the criteria, which are now available on the ACCE website, www.accenet.org, together with a nomination form to help you recognize the individuals within your community.

Please complete your nomination form by **January 15, 2005**. Completed nomination forms can be sent directly to Kelley Garland, Advocacy Committee chair at kgarland@eqintl.com or regular mail as follows:

Kelley Garland
Advocacy Committee Chair
EQ International
1717 Pacific Ave.
Dallas, TX 75201

Please provide the nominee’s name, affiliation, title and contact information, type of an award he/she is being nominated for and corresponding supportive information.

Thank you for your contributions!

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Calendar of Events

November 28 - December 3, 2004
Radiological Society of North America (RSNA) 90th Scientific Assembly & Annual Meeting
Chicago, IL

November 29 - December 1, 2004
The Emerging Technologies and Health-care Innovations Congress (TETHIC)
Washington, DC

December 9, 2004
Planning Security Compliance—Including Biomedical Devices
HIMSS Audio Conference
http://www.himss.org

February 13-17, 2005
Healthcare Information and Management Systems Society (HIMSS) Annual Conference & Exhibition
Dallas, TX

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

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

October 2-4, 2005
Northeastern Biomedical Symposium
Southbridge, MA

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

November 28 - December 3, 2004
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Chicago, IL

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Is pleased to announce that it is now publishing and will continue to develop the groundbreaking manual created by Marvin Shepherd:

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