Greetings ACCE members! First, I wanted to take a second to wish United States of America a Happy Birthday! On the 4th of July this year, US turned 244 years old! I hope you all celebrated safely and happily with your families and friends on this great occasion!

And last month, the American College of Clinical Engineering celebrated its 30th Birthday! What an accomplishment for us and the profession as a whole! We received many messages with birthday wishes; many of them from founding members and past presidents, committee chairs, board members, and different volunteers. We also received many messages from different international Clinical Engineering associations who couldn’t wait to join us in the celebrations! You can find a lot of these messages on our LinkedIn page, and you can see the videos sent to celebrate the 30th birthday on the ACCE Website. Thank you to all who took time out of their busy day to send us a message!

ACCE continues to keep an eye on the COVID-19 Pandemic. We have continued to be very active in helping our members and Clinical Engineering/HTM professionals throughout the country and the world with resources on COVID-19 as well as being an advocate for our profession and professional rights. Many of our members have participated in many different webinars with US PIRG to fight for The Right to Repair. The Right to Repair has been affecting many hospitals during the time of this pandemic; many manufacturers haven’t been able to send their technicians to hospitals to repair/PM equipment and our hospitals technicians weren’t qualified to service these devices because manufacturers wouldn’t provide training. We will continue to participate in different webinars to fight for this. In addition, I will kick off the PartsSource Summit on October with a presentation on The Right to Repair. I would like to invite all of you to provide input directly, so we can make sure to include all the concerns and be able to be an advocate for this basic right!

Due to COVID-19 we had to cancel many in-person activities. As a result, we have been able to provide different webinars free of charge to our members. Our next webinar, sponsored by Ordr, is on Thursday, August 27, 12-1 pm (EDT) where we will learn about Mayo Clinic’s Efforts to Secure Connected Medical Devices and HIoT. This is a great opportunity to learn about this very important topic, and we are very happy we are able to offer this to our members. In addition, the Education Committee is finalizing the topics for the 2020-2021 Webinar Series. I have seen a list of the topics and I am excited about them — they are filled with an exciting lineup of speakers and topics relevant to our profession.

Again, thank you for your continued support! Stay safe, wash your hands, wear a mask, and

Happy 30th Birthday ACCE!

Ilir Kullolli, President
American College of Clinical Engineering
President@accenet.org
Volunteers Wanted!

If you would like to volunteer for ACCE, please complete this volunteer survey.

Volunteers are needed to write ACCE News articles, participate on a variety of important committees and assist in various other roles.
International Committee Report

The International Committee (IC) held its 4th regular bimonthly meeting on July 24, 2020. Ray Dalton and Barbara Campbell, Chairman and Executive Director of the Relink Global Health (relinkglobalhealth.org), respectively, were our guest speakers. They made a presentation about their “Three Step Approach” to assist low-resource countries to leverage and improve their technology infrastructure in order to enhance the delivery of care to their populations. They shared an example of their project that is being conducted in Haiti. After several years of hard work collecting data on the existing infrastructure and establishing collaboration with the Haitian government and several international organizations they were able to achieve some excellent results. This project differs from most donation and technical training programs in establishing a commercial service company that provides services to local hospitals and clinics. They believe this approach will enhance the sustainability of their efforts in the long term.

Since the start of the global pandemic, the IC has been sharing information about COVID-19 efforts and experience accumulated by American CE professionals with the 12 foreign associations with which ACCE has established collaboration and mutual assistance agreements. These exchanges have been well received.

Due to cancellation of the 2020 AAMI Exchange originally scheduled for June 12-15, the IC was not able to participate in the Global Exchange of which ACCE is one of the event organizers. IC members also did not make the joint presentations with foreign collaborating members as originally planned. Hopefully these presentations will be conducted next year. In the meanwhile, the IC will continue to refocus its efforts in holding webinars and virtual interactions with the foreign collaborating organizations, as well as seeking opportunities for cooperation with international outreach organizations located in North America.

Binseng Wang, IC Chair
International.chair@accenet.org

For more information and to register, go to https://accenet.org/NewsEvents/Pages/Webinars.aspx

August Educational Webinar
"Systems Level Analysis, Creative Ways of Using Systems"

Date/Time:
Thursday, August 13, 2020
12:00pm - 1:00pm (EDT)

Presenter:
Prakhar Kapoor
Clinical Systems Engineering Manager
Brigham and Women's Hospital

For more information and to register, go to https://accenet.org/NewsEvents/Pages/Webinars.aspx
CCE Prep: Sample Questions

In this column we are providing sample questions and information regarding preparation for the CCE exam. The column is written by a group of certified clinical engineers who have taught CCE Prep courses. The sample questions are based on topics from the ACCE Body of Knowledge survey and the CCE Study Guide, version 9. Note that the instructors for the ACCE CCE Prep courses, and the writers for this column, do NOT have any affiliation with the CCE Board of Examiners and have no access to the actual exam questions. If you have specific topics you would like us to cover please contact editor@accenet.org.

1. The Safe Medical Devices Act of 1990 (SMDA) requires a report to the manufacturer and/or the FDA whenever:

a) any medical device fails regardless of patient injury or death.

b) SMDA does not require reporting. Reporting is optional.

c) SMDA only requires reporting for patient deaths caused by medical devices.

d) a medical device fails and causes, or is likely to have caused, serious patient injury or death.

Correct answer: d

Explanation: In 1990, Congress enacted the Safe Medical Devices Act (SMDA) to increase the information that the FDA and manufacturers receive about serious problems with medical devices. Under SMDA, device user facilities (i.e., healthcare delivery organizations) are required to report deaths and serious injuries to which a medical device has or may have caused or contributed to that adverse event. Deaths are reportable to the FDA and the manufacturer. Serious injuries just to the manufacturer.

Reference:
https://www.slideshare.net/BMETWiki/smda accessed: 7/1/2020

2. Service manuals:

a) Vendors are required by U.S. federal law to provide service manuals for all medical devices.

b) It is a best practice for HDOs to require service manuals in purchase orders and to not pay vendors until the manuals are provided.

c) Service manuals are not needed anymore since this information can always be obtained on the internet.

d) Service manuals are usually provided without requesting them, and at no cost, upon delivery of the medical equipment.

Correct answer: b

Explanation: The FDA only requires service manuals for x-ray emitting devices (21CFR1020.30). Current interpretation of federal regulations is that service manuals for other, non-x-ray emitting medical equipment, is not mandated in the U.S. Service manuals are recommended in NFPA-99 and other AAMI and HTM-related publications but these are not referenced in federal regulations. Therefore, it is a best practice for HDOs to request service manuals in purchase orders, state the specifications for the manuals (e.g. include PM procedures, replaceable parts list, calibration procedures, service software requirements etc), and include in the device’s purchase terms and conditions that the purchase order will not be paid in full until the manuals are delivered.

Reference:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

FR=1020.30 accessed: 7/1/2020

3. The primary difference between a Root Cause Analysis (RCA) and Failure Mode and Effect Analysis (FMEA) is:

a) There is little difference. They are essentially the same.

b) FMEA is the obsolete version of RCA

c) FMEA is primarily looking for potential failure modes and their effects in a system and its components. RCA is looking at real failures during a review after an incident.

d) RCA is primarily looking for potential failure modes and their effects in a system and its components. FMEA is looking at real failures during a review after an incident.

Correct answer: c

Explanation: Two commonly used tools for analyzing medical device failures and near misses are FMEA (Failure Mode and Effect Analysis) and RCA (Root Cause Analysis).

Failure Modes and Effects Analysis (FMEA) is a systematic method for evaluating a device or process. It is typically used proactively - before a problem occurs - to attempt to predict the most common failure modes
Welcome New Members

We welcome our newest members, approved by Membership Committee and supported by the Board of Directors:

<table>
<thead>
<tr>
<th>Name</th>
<th>Class</th>
<th>Job Title</th>
<th>Organization</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ali Shaukat</td>
<td>Individual</td>
<td>Biomedical Quality Manager</td>
<td>SEHA Abu Dhabi Health Service Company</td>
<td>UAE</td>
</tr>
<tr>
<td>Prakhar Kapoor</td>
<td>Individual</td>
<td>Clinical Systems Engineering Manager</td>
<td>Brigham and Women’s Hospital</td>
<td>MA/USA</td>
</tr>
<tr>
<td>Sam Byamukama</td>
<td>Individual</td>
<td>Biomedical Engineer</td>
<td>Mark Biomedical Limited</td>
<td>Uganda</td>
</tr>
<tr>
<td>Sean Barnards</td>
<td>Associate</td>
<td>Clinical Engineer</td>
<td>Children’s Hospital of Philadelphia</td>
<td>PA/USA</td>
</tr>
<tr>
<td>Travis Morford</td>
<td>Individual</td>
<td>Clinical Engineer</td>
<td>Renovo Solutions</td>
<td>CA/USA</td>
</tr>
</tbody>
</table>

Congratulations goes to the following members who were upgraded to Individual Level:

<table>
<thead>
<tr>
<th>Name</th>
<th>Job Title</th>
<th>Organization</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jennifer Boudreaux</td>
<td>Acting Chief Clinical Engineer</td>
<td>Southeast Louisiana Veterans Health Care System</td>
<td>LA/USA</td>
</tr>
<tr>
<td>Supreet Kaur</td>
<td>Biomedical Engineer</td>
<td>Department of Veterans Affairs</td>
<td>OH/USA</td>
</tr>
<tr>
<td>Brandon Low</td>
<td>Biomedical Engineer</td>
<td>VA Greater Los Angeles</td>
<td>CA/USA</td>
</tr>
</tbody>
</table>

and their impact severity. It can be applied to likely failure of devices (e.g., wear-out of mechanical component, or electrical component failures) and processes and people.

Root Cause Analysis (RCA) is a process that is typically used retroactively (i.e., after an incident) to identify and understand the proximate cause(s) of the adverse event, and its underlying cause(s). An RCA report would typically include: defining the problem, failure, or adverse event; the methods used for determining causes; all known probable causes with the likelihood for each cause (i.e., probability that the cause contributed to the adverse event); and the supporting evidence for the reported causes and their likelihoods. Examples of a few RCA methods include FMEA (see above), Common Cause Analysis (review of prior similar device failures), Reenactment (e.g., for use errors), and Fault tree analysis.

References:
- [https://sixsigmastudyguide.com/fault-tree-analysis/](https://sixsigmastudyguide.com/fault-tree-analysis/)
- [https://www.fda.gov/media/71543/download](https://www.fda.gov/media/71543/download)

Ted Cohen, Co-Editor
ACCE News
tedcohen@pacbell.net

(Continued from page 4)
A Rookie Season – UCONN Clinical Engineering Internship Program

Who would ever guess that a girl who grew up in Louisville, KY and got her collegiate education in Dayton, OH and Tucson, AZ would end up as the director of a 40-year New England tradition? I am humbled and appreciative that Frank Painter and the UCONN Biomedical Engineering department leadership – Ki Chon, PhD and David Kaputa, PhD – entrusted the clinical engineering internship program and its students with me.

Who knew that the 2019-2020 academic year would be such an amazing, challenging, and confounding experience? The academic year began much like any other; however, what we found in the spring semester was community and a much deeper understanding of what clinical engineers bring to healthcare. Each of the interns found themselves in unexpected situations on the frontlines of the pandemic to remote assignments and everywhere in between. It was no longer an academic exercise, but real situations requiring application of their engineering, project management, and critical thinking skills to support their host clinical engineering departments and health systems. Similarly, with travel bans expanding almost daily, we pioneered a virtual means of experiencing Clinical Engineer Week. While we missed the in-person networking and camaraderie, we used the opportunity to expand our agenda to include report-outs from internship locations outside of New England as well as the locations originally scheduled to host our on-site visits. Additionally, we incorporated external presentations by content experts in the fields of forensic engineering, medical equipment planning for construction projects, and employment compensation packages.

Appreciation and kudos to the twenty-one graduate students who welcomed me into the UCONN community and would ultimately co-navigate the uncharted pathways of the COVID-19 pandemic.

Nine of those students were 2nd Year clinical engineering interns and represented diverse undergraduate perspectives – i.e., Rochester NY, College Station TX, Ft Myers FL, Santa Clara CA, Boston MA, Worcester MA, Monterrey Mexico, and of course Storrs CT. The eleven 1st Year interns brought further undergraduate diversity – i.e. Ann Arbor MI, Schenectady NY, Orono ME, Fayetteville AR, Dayton OH, and Kingston RI.

In May, the 2nd Year interns graduated and began the transition to full-time permanent positions across the country. Congratulations to them all as they begin the next phase of their professional journeys.

Similarly, the 1st Year interns began their transition to 2nd Year intern status with summer assignments at their host health systems. I look forward to reconvening with them this fall to welcome a new set of 1st Year interns and see what the future holds for us all.

Be safe, stay healthy.

Carol Davis-Smith, MS CCE FACCE AAMIF, Program Director
UCONN BME Clinical Engineering Internship Program
Carol@CDSAssoc.com
Loss of Sam Buhrow, Cybersecurity Leader and HTM/CE Advocate

It is with a heavy heart that we announce the loss of a cybersecurity leader and HTM/CE advocate, Sam Buhrow. Sam passed unexpectedly on Tuesday night, July 14, 2020 in his home with his wife and daughter.

Sam was a beautiful genius who was giving and always had a smile. He always presented with a curious and calm demeanor, positive attitude, and passion for cybersecurity. During his time at Banner Health, he actively participated in table top exercises and incident management for connected medical devices. Sam started his career in GTC and Xerox Corp. working on network and server hardening and moved into eDiscovery, Incident Response, and Forensics over a decade ago. He was active member of H-ISAC and ACCE and presented a webinar to the ACCE Community the Educational Webinar on Business Continuity and Disaster Recovery for CE-IT in March 2020. He was a sought after speaker in ISACA, RSA, Global Engage, various CIO Forums, Electronic Frontier Foundation, Cybersecurity Council of Arizona and presented in a 2-part MD EXPO session on table top exercises for HTM/CE professionals in October 2019.

Sam was a great supporter of students in STEM and mentored several who wanted to pursue careers in Cybersecurity. His family and partners at Business Partner Solutions Inc. will continue to honor his legacy with a scholarship to a student to attend a conference and learn, which is what Sam modeled. A GoFundMe page has been created to help support his family after a terrible loss.

Priyanka Upendra, priyanka.upendra@bannerhealth.com
Thank you for participating in the 2020 ACCE Officer and Board Election and casting your important vote. The election for ACCE’s new Board for the year 2018 has been finalized and the Board has approved the results.

The election ballot was emailed to 323 eligible members, who include Individual, Fellow and Emeritus members in good standing. Institutional/Corporate Fellow and Individual members also participate in elections. Of the 323 members, 79 votes were received between July 6 and July 19, 2020.

The new Board of Directors will take office as the governance body for ACCE on August 21, 2020. We are pleased to announce the 2020-2021 team and, as always, we look forward to serving you and your needs.

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
<th>Votes received</th>
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<tbody>
<tr>
<td>President</td>
<td>Ilir Kulloli, MS</td>
<td>79</td>
</tr>
<tr>
<td>President Elect</td>
<td>Priyanka Upendra, MS, CHTM</td>
<td>74</td>
</tr>
<tr>
<td>Vice President</td>
<td>Jim Panella, MBA</td>
<td>77</td>
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<tr>
<td>Secretary</td>
<td>Kamecia Bruce, MS</td>
<td>77</td>
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<tr>
<td>Member at Large</td>
<td>David Braeutigam, MBA, ITIL, CBET, CHTM</td>
<td>75</td>
</tr>
<tr>
<td>Member at Large</td>
<td>James Caporali, MS, CRES, SASHE, FACCE</td>
<td>76</td>
</tr>
<tr>
<td>Member at Large</td>
<td>Kim Greenwood, MASc, P.Eng., CCE, FEIC, FCMBES</td>
<td>78</td>
</tr>
<tr>
<td>Member at Large</td>
<td>Katherine Navarro, CCE</td>
<td>78</td>
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The following Board member will be continuing the second year of her second term:

<table>
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<th>Title</th>
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<tr>
<td>Treasurer</td>
<td>Samantha Herold, MS, CCE</td>
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The following Board member will remain as Immediate Past President when the President takes office for his second term:

<table>
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<th>Title</th>
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<tr>
<td>Immediate Past</td>
<td>Arif Subhan, MS, CCE, FACCE</td>
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Officers and Board, 2020-2021
In this column we normally share with you our latest thinking and approaches to safety in healthcare and evaluation of medical devices. In this issue we share our thoughts on another equally important set of issues: racial injustice.

Tightly woven into ECRI’s DNA is the imperative to speak truth to power, based on facts and evidence. The facts are that for centuries in the United States, racism has caused historic and acute trauma and untold pain, suffering, and justified anger. The senseless death of George Floyd in Minneapolis this past May has reignited a worldwide movement against racism, inequality, and inequity. This movement speaks volumes, as people from many nations raise their voices in unison and move to take action against racism.

Racism affects all areas of civil rights and liberties and endangers human life. It manifests in every walk of life: in fair housing, equitable opportunity in workplaces, and in financial, educational, and healthcare institutions. Racism has created and continues to create enormous disparities and barriers. Racism is pervasive and must be eradicated. This must begin with us.

Our President and CEO, Marcus Schabacker, MD, PhD, has strongly voiced his concerns about these events and reinforced our organization’s core values, which are compassion, integrity, impact, transparency, and innovation. These values provide important foundational blocks for an antiracist workplace. They emphasize that ECRI does not and will not tolerate racism of any kind.

Leading by example, Dr. Schabacker signed the CEO Pledge for Diversity and Action in early June, joining more than 1,000 CEOs who signed the pledge.

From our executive leadership committee to individual employees in offices in the United States and around the world, ECRI stands united to combat racism, discrimination, inequality, and inequity.

I feel very honored to work for an employer that is committing to these principles. And as an ACCE member I feel further encouraged that ACCE’s Board of Directors issued a statement condemning racism and intolerance on this year’s Juneteenth.

Let’s all each do our part!

Ismael Cordero, Senior Project Engineer
Device Evaluation, ECRI
icordero@ecri.org
Free Webinar

**Topic:** Mayo Clinic Efforts to Secure Connected Medical Devices and HIoT

**Description:** Hospitals have greater insight and more robust security controls for their printers than their networked medical devices that deliver direct care to patients. With nearly 15 IoMT and IoT devices per bed, organizations remain challenged to identify, monitor, and secure these mission-critical assets from cyberthreats. COVID-19 has also impacted medical device security as devices procured or deployed to address the surge of patients must now be brought into compliance.

In this webinar, learn from Mayo Clinic and ordr on the best practices to improve visibility into your medical device and HIoT fleet and improve the security of connected devices. Hear about strategies Mayo Clinic Healthcare Technology Management is implementing to transform cybersecurity practices across their organization.

**Speakers:**
Keith Whitby, Mayo Clinic, Section Head of Healthcare Technology Management Cybersecurity and Operations
Gnanaprakasam Pandian, Ordr, Chief Product Officer.

**Date/Time:**
Thursday, August 27 / 12-1pm (ET)

**Pre-registration required:**
To register, [click here](#)
PROHEALTH CHOOSES ORDR FOR MEDICAL DEVICE SECURITY

“Ordr automatically identifies all our network connected devices and then monitors the traffic of each device. This enables us to automate the creation of security ACLs which speeds up our entire segmentation process.”

- Joel Benson, Network Engineer for ProHealth

Read Case Study
**Global Clinical Engineering Response to COVID19**

**Situation**

The global COVID-19 pandemic has been a crisis that demands worldwide response, not only by countries and their health systems, but also by most individuals on the planet. This has been a time of incredible suffering, of new challenges, and also unprecedented opportunity for the clinical engineering global community to come together and share experiences - as well as learned and improvised best practices - for medical device management and related tools used to address the prevention, diagnosis, and treatment of COVID-19.

**Background**

In response to this crisis and the World Health Organization (WHO’s) request in March 2020, IFMBE CED has organized a series of global webinars and information tools to share clinical engineering (CE) learnings related to the COVID-19 pandemic.

This continues to be a rapidly changing situation presenting new challenges to CEs on the front lines all over the world. These events and the need to implement a CE knowledge network - that can quickly respond to and implement practical solutions has been driven by conversations with CED, WHO, and international colleagues. The network and its platform has facilitated both immediate communication via texts as well as planned training sessions via video conferencing like Zoom. The international community continues to search for practical solutions during these times to assist decision makers in their various health systems. CED’s knowledge network includes five components/channels that contribute to each other, as shown in Table 1:

1. Daily Q&A on a CED WhatsApp group.
2. Weekday CED Hacking COVID19 Blog
3. Monthly CED Board ad Collaborator meetings with a WHO focus.
4. Monthly WHO-CED global webinars on critical COVID19 topics, and monthly CE competency webinars. Table 2 illustrates the key Townhall CE-related discussion issues.
5. Monthly WHO Medical Devices Newsletter

**Recommendations**

Rapid and significant changes require the field of Clinical Engineering to network and share knowledge more than ever before.

It is critically important that, in spite of challenges - language - everyone is engaged including ACCE members. CED is thankful how ACCE has contributed locally and globally to fight the COVID-19 crisis.

(Continued on page 13)

### Table 1

<table>
<thead>
<tr>
<th>Channels</th>
<th>Global CED WhatsApp</th>
<th>Hacking Blog</th>
<th>CED B&amp;C</th>
<th>WHO-CED</th>
<th>WHO</th>
</tr>
</thead>
<tbody>
<tr>
<td>March</td>
<td>Forecasting critical C19 equipment, accessories, &amp; ICU beds needed</td>
<td>Established reliable C19 info on variety of CE-relevant sources</td>
<td>Identified global needs &amp; volunteer CE experts</td>
<td>Began enhanced partnership through regular B&amp;C and weekly updates</td>
<td>Identifying latest global guidelines</td>
</tr>
<tr>
<td>April</td>
<td>Oxygen delivery and C19 Decontamination (Decon) issues</td>
<td>Identified global C19 educational programs &amp; websites</td>
<td>Initiated with Adriana to have May C19 THs</td>
<td>Global C19 CE Day: CEs in 10 countries share Lessons Learned: <a href="https://ced.ifmbe.org/blog/ce-covid19day-2020.html">https://ced.ifmbe.org/blog/ce-covid19day-2020.html</a></td>
<td>CED joins EBC with WHO; assists C19 emergency facility planning</td>
</tr>
<tr>
<td>May</td>
<td>Shared access to recent and upcoming country C19 WBs</td>
<td>Daily examples with photos as global CEs addressed C19</td>
<td>Six THs doubles CED global contact countries</td>
<td>Townhalls: Oxygen, PPE, CPAP, Pulse Oximetry, Ventilators: 97 countries</td>
<td>Initiate global C19 device inventory</td>
</tr>
<tr>
<td>June</td>
<td>Gives voice to our Africa colleagues Q&amp;A as their C19 rates increased</td>
<td>Global C19 innovations in spotlight; LMICs hire new CEs</td>
<td>New TH: C19 Decon &amp; Disinf.: People, Assets</td>
<td>C19 generic training video prep., as CED provides 2 graduate interns to WHO</td>
<td>Global device inventory results</td>
</tr>
<tr>
<td>July</td>
<td>Dissemination of global articles for early warning re latest C19 science</td>
<td>Continue to promote CE profession &amp; our C19 response</td>
<td>Review impact of WHO-CED C19 partnership</td>
<td>7/15: CE C19 Innovation competency WB</td>
<td>Newest global C19 related guidelines</td>
</tr>
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</table>

(Continued on page 13)
The search for and use of guidelines for the management of health technology should be reviewed by appropriate expertise, and then uniformly adopted by each locality.

This is also the time to promote the Clinical Engineering profession and show the value of our contributions to government leaders, Ministries of Health, other healthcare team members, and the public.

CED invites and encourages the CE Community of ACCE and its various member countries to propose additional initiatives to address the COVID-19 crisis and to improve patient outcomes.

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**Table 2: WHO-CED Critical Townhall Discussion Topics**

1. Clinical requirements
2. Supply of necessary equipment & accessories, and operation/support
3. Availability of support/maintenance materials,
   a. e.g., Operator and Service Manuals in correct language,
   b. Including related donation issues, language, accessories, etc.
4. Training for operation and support
5. Coordination of various Critical Topic activities at care delivery & national levels
6. Systems approach and safety management for all of the above

---

Together We Can Make It Better!

Yadin David, EdD, PE, CCE, FAIMBE, FACCE, Editor-in-Chief, Global Clinical Engineering Journal, Past Chair, IFMBE CED
david@biomedeng.com

Tom Judd, MS, PE, CCE, CPHQ, CPHIMS, FAIMBE, FACCE, FHIMSS, Chair, IFMBE CED Board
judd.tom@gmail.com
AAMI Update

AAMI Foundation Awards 2020 Mary K. Logan Research Grants

The AAMI Foundation has named the 2020 recipients of the Mary K. Logan Research Award Program. Two grants, worth a total of more than $119,000, will support research initiatives that focus on improving patient safety and eliminating morbidity and mortality associated with the use of healthcare technology. The awards include:

A $69,565 grant to a research team at George Washington University, led by Ekundayo Shittu, assistant professor of engineering management and systems engineering. The group will explore the potential impact of utilization-based alternative equipment maintenance (AEM) programs. With the funding received by the AAMI Foundation, Shittu and his team are developing a software tool that will enable others in the HTM community to evaluate the effect their AEM programs have on patient safety, equipment availability and cost reduction.

A $50,000 grant to Poching DeLaurentis at Purdue University will help fund research that focuses on collecting data from smart infusion pumps and collaborates with clinicians who use them daily. DeLaurentis and her team aim to design and implement an infusion safety dashboard on the community-supported Regenstrief National Center for Medical Device Informatics (REMEDEI) web portal (CatalyzeCare.org). It will be powered by computational algorithms that evaluate infusion data from smart infusion pumps. DeLaurentis expects that the research will influence future smart pump management as well as device design and requirement.

“The AAMI Foundation is pleased to support these important research initiatives this year, and anxious to share the results of the researchers’ work with the entire healthcare community,” said Steve Campbell, executive director of the AAMI Foundation. “Competition for this year’s research funding was strong, but these two grant submissions stood out because of the depth and importance of the topics and the impressive proposals put forth by the researchers.”

The awards program, which was named in honor of AAMI’s former president and CEO, was established in 2016 with a gift from the association’s board of directors. Visit www.AAMIFoundation.org for more information.

‘Must-Have' TIR24971 Complements Risk Management Standard

A long-awaited technical information report (TIR) that provides state-of-the-art guidance on applying a fundamental risk management standard has just been published.

Already, AAMI/ISO TIR24971:2020, Medical devices—Guidance on the application of ISO 14971, has been a hot seller as a draft document. The TIR offers guidance on management responsibilities, components of a risk management plan, and the risk analysis and evaluation process. It is a companion piece intended to be used and applied together with the standard, ANSI/AAMI/ISO 14971:2019, Medical devices—Application of risk management to medical devices, which establishes a process for medical device manufacturers to identify, evaluate and manage risk.

However, the standard and its guidance report aren’t just useful for medical device manufacturers—they can be used to manage all risks, including those related to security and usability.

“‘The standard and TIR contain a very clear concept of systematic risk management. Any user of medical devices can use this process to develop a risk management system for their organization when the focus is on patient, user property, or environment safety,” said Tina Krenc, principal consultant for KTA Compliance Consulting, lead instructor for AAMI’s industry training course on Integrating Risk Management into the Product Life Cycle, and a member of the joint working group.

For more information, visit www.aami.org/TIR24971.

AAMI Mourns Loss of Noted Clinical Engineer George Panagiotopoulos

George Panagiotopoulos, dedicated clinical engineer, passed away on May 24 at the age of 60.

Panagiotopoulos started his professional life in banking but found his true calling in clinical engineering. He earned bachelor’s and master’s degrees in clinical science.
from California State University, San Francisco, and spent more than two decades working in biomedical and clinical engineering, including several positions within Kaiser Permanente’s National Clinical Technology Program. After taking early medical retirement two years ago, he remained active professionally by partnering with colleagues to start AdaptivMD, a telehealth and biometric data company.

“George was welcoming to newcomers and forever supportive of his friends and colleagues. He exemplified the concept of lifelong learning more than anyone I’ve ever met,” shared Carol Davis-Smith, vice chair of clinical engineering on AAMI’s Board of Directors. “George shared ideas freely and listened intently to the ideas of others. He was a dedicated and compassionate son, father and husband. I know because we spoke often about our families and raising our kids in a complicated world. I am a better person for having known him.”

Panagiotopoulos was a member of AAMI’s Healthcare Technology Management (HTM) Benchmarking Task Force, which published the second edition of the HTM Benchmarking Guide in 2018. He also contributed articles to AAMI publications, including the peer-reviewed journal BI&T. Panagiotopoulos was involved with technology standards-setting groups and was a past member of the American College of Clinical Engineering (ACCE) Board of Directors.

**Winners of AAMI’s High School Essay Contest**

This year’s three winners of AAMI’s annual high school essay contest shared moving stories about the positive impact healthcare technology has had on their lives and the lives of their families.

The essay contest is part of AAMI’s Healthcare Technology Management (HTM) Week festivities and is designed to help spread awareness about HTM to and encourage students to consider pursuing a career in the field. AAMI’s Technology Management Council (TMC) selected the three winners from nearly 100 applicants: Ashlin Pfeifer-Winborn, first place, $500; Morgan Reupke, second place, $300; and Shiven Balaji, third place, $100.

“Members of the TMC were very impressed with this year’s submissions. The essays were thoughtful and covered many different types of healthcare technology and devices. AAMI staff will follow up with all students to encourage them to consider HTM as a career option,” said Danielle McGeary, vice president of HTM at AAMI.

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**Journal of Clinical Engineering Subscriptions for ACCE Members**

The Journal of Clinical Engineering is a compilation of articles, papers, and extensive manuscripts relevant to clinical/biomedical engineering or biomedical technology. Subject matter directly relates to the engineering or technology involved in patient care and treatment or technology in the broad field of healthcare delivery.

ACCE members receive a discounted subscription to the *Journal of Clinical Engineering* for only $99! (Originally $313). You must login to the ACCE website to view the code. Then visit LWW.com to enter code.
Welcome to our ACCE News feature celebrating job-related transitions for ACCE members. Please contact Suly Chi, ACCE Secretariat (secretariat@accenet.org), if you would like to be included in an upcoming issue or if you have a suggestion for another member who should be included. Congratulations Helen and James on their exciting new roles.

Helen H. Cheong, MS, CCE

**New Title:** Biomedical Engineering Department supervisor

**New organization:** First Health of the Carolinas (FHC), which serves 15 counties in mid-Carolinas.

**Responsibilities:** The Biomedical Engineering department is responsible for supporting and managing medical devices used by FHC employees, joint-venture, and contracted customers. Supervisors oversee the operation strategy and service performance of the biomed teams.

James L. Swiger, M.B.E.

**New Title:** Health Scientist Administrator in the Division of Digital Healthcare Research (DHR) in the Center for Evidence and Practice Improvement (CEPI).

**New Organization:** HHS/AHRQ (Agency for Healthcare Research and Quality). AHRQ’s role is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable. Formerly the Division of Health IT, DHR has broadened its scope to include more aspects of the digital healthcare ecosystem, including electronic health records that can be augmented with various forms of patient-generated, contextual, and environmental data to yield new insights for healthcare delivery via advanced analytics.

Prior to joining AHRQ, James worked at the U.S. Food and Drug Administration in the Center for Devices and Radiological Health (CDRH), Office of Product Evaluation and Quality (OPEQ). He was a Deputy Division Director in the Medical Product Safety Network (MedSun), a program that collaborated with a volunteer network of hospitals nationwide to identify, understand, and solve problems with the use of medical devices through a customized health IT platform. He was also a lead reviewer for pre-market orthopedic and spine implant submissions.
ACCE 30th Anniversary Messages

Messages from ACCE President, Committee Chairs and 2020 Student Winners

Messages from ACCE Past Presidents

Messages from ACCE President-Elect, Founding Members

Messages from our Collaborators and Supporters

Visit the ACCE YouTube channel - click here
Crothall Healthcare and Asimily Form Strategic Partnership to Provide World-Class Health Technology Management Services Providing Clients with a Complete End-to-End Cybersecurity and Connected Medical Device Risk and Lifecycle Management Services Portfolio

WAYNE, PA. (June 17, 2020) - Crothall Healthcare Technology Solutions (HTS) and Asimily, a leader in connected medical device inventory, cyber-security and operational management, are pleased to announce a strategic partnership. Crothall HTS is an ISO 13485:2016 certified industry leader in the field of Clinical Engineering and medical device life-cycle management.

“For many healthcare systems, the rapid adoption of connected medical device technology expands the potential cyber-attack surface, and creates a significant cybersecurity gap, therefore making it difficult to scale device security,” said Shankar Somasundaram, Asimily’s founder and chief executive officer. “All of our clients will now have access to a world-class service portfolio that provides for the management and oversight of a hospital's entire life-cycle of connected medical devices and clinical technologies. This management and oversight include safety, cybersecurity, asset and risk management, technical support and financial stewardship.”

With the strategic partnership in place, Crothall and their clients will have laser sharp visibility into the client’s connected medical device profiles. Asimily’s state-of-the-art machine learning will then assess risk, prioritize actions and allow for the development of mitigation strategies to reduce security vulnerabilities.

“Our partnership will enhance Crothall’s medical device security offering with Asimily’s technical expertise in medical device security while Asimily will have the opportunity to access Crothall’s on-site expertise for identified vulnerabilities and risk mitigation,” said Jim Cheek, president of Crothall HTS.

This offering will allow Crothall and their clients to manage a full spectrum of capabilities: asset utilization; FDA recall notification; device vendor tracking; and user defined policy alerts in the environment. The partnership enhances the abilities of Crothall and its clients to manage devices from initial capital planning to end-of-life.

About Asimily

ASIMILY is a team with backgrounds in healthcare, security, machine learning and analytics. The team has launched solutions for connected devices at startups to Fortune 500 companies. The INSIGHT platform can comprehensively monitor and manage connected devices through their entire life cycle in the healthcare environment. Asimily is working with Health Systems across the country of different sizes. The INSIGHT platform permits different players in the healthcare ecosystem to focus on their core job of providing great patient outcomes in a safe environment. Asimily is headquartered in Sunnyvale, CA. For more information, visit www.asimily.com

About Crothall Healthcare, a Compass One Company

Crothall Healthcare Technology Solutions is the Clinical Engineering division of Compass One USA that is known for its specialized, high-quality, innovative, and responsive support services exclusively to the healthcare industry. Crothall HTS provides healthcare institutions with comprehensive management of their medical device life cycle through technology planning, service and maintenance, risk management, safety and device integration support, while ensuring financial certainty. Crothall serves many of the Top 100 Hospitals throughout its over 2100 healthcare service teams in 46 states. Crothall has been recognized as one of Modern Healthcare’s Best Places to Work and Best Places to Work in Pennsylvania since 2013 and Becker's Top 150 Places to Work since 2016. A division of Compass Group USA, the HTS division is ISO 13485: 2016 certified since 2019. Learn more at www.Crothall.com.
ACCE Calendar

For more detailed information and more events, go here.  

03 August 2020
Deadline to submit your registration for ACCE’s 2020 CCE written exam review webinar series: 10-session series

Location: Online
Registration form

12 August 2020 12:00 PM - 1:00 PM
CCE Review session 1: Technology Management I, Technology Assessment, Capital Planning, Healthcare Technology Strategic Planning, Product Selection / Vendor Selection, Usability/Compatibility Assessment

Location: Online
Faculty: Frank Painter, MS, CCET
Registration form

13 August 2020 12:00 PM - 1:00 PM
Educational Webinar - Systems Level Analysis - Moving Beyond the Device: Systems level troubleshooting moves beyond the device, from electronics to communication and even into human factors. Focusing on an individual device can create tunnel vision that isolates us from the true root cause of the problem. Moving beyond the Device we will take a step back and view systems as a whole.

Faculty: Prakhar Kapoor
To register, click here

19 August 2020, 12:00 PM - 1:00 PM

Location: Online
Faculty: Elena Buckley, MS, CCE
Registration form

26 August 2020 12:00 PM - 1:00 PM

Location: Online
Faculty: Ted Cohen, MS, CCE
Registration form

27 August 2020 12 - 1:00 PM (ET)
Free Webinar - Mayo Clinic Efforts to Secure Connected Medical Devices and HIoT: Hospitals have greater insight and more robust security controls for their printers than their networked medical devices that deliver direct care to patients. With nearly 15 IoMT and IoT devices per bed, organizations remain challenged to identify, monitor, and secure these mission-critical assets from cyber threats. COVID-19 has also impacted medical device security as devices procured or deployed to address the surge of patients must now be brought into compliance. In this webinar, learn from Mayo Clinic and Ordr, on the best practices to improve visibility into your medical device and HIoT fleet and improve the security of connected devices. Hear about strategies Mayo Clinic Healthcare Technology Management is implementing to transform cybersecurity practices across their organization.

Speakers: Keith Whitby, Mayo Clinic, Section Head of Healthcare Technology Management Cybersecurity and Operations. Gnanaprakasam Pandian, Ordr, Chief Product Officer.
To register, click here

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