Dear ACCE Community,

I hope all of you and your loved ones are staying safe and healthy! With utmost humility and gratitude, thanks to all of you for electing me as President of the American College of Clinical Engineering. I am truly honored to serve ACCE and our community in this capacity. I have great shoes to fill and thank Ilir and Arif for their dedication, leadership, and commitment to ACCE, our community, and preparing me to serve in this capacity. I am very grateful for Arif’s leadership at ACCE over the past seven consecutive years. He served as the Vice-President (2014-2016), President-Elect (2016-2017), President (2017-2019), Immediate Past-President (2019-2021), and BoK Committee Chair (2014-2018).

I welcome the 2021-2022 Board and resonate with their dedication and commitment to lead with excellence. Members of the Board volunteer their time and expertise and help expand the knowledge base of our profession. I want to welcome Bhaskar Iduri to the ACCE Executive Board as the new ACCE Treasurer (replacing Samantha Herold). Ilir Kullolli moved to be the Immediate Past President, Kim Greenwood moved to be the President-Elect, and Samantha Herold moved to be a Member-at-Large.

Prior to the 2021-2022 Board elections, we named three key positions on the Education Committee and the Body of Knowledge/CE Certification Promo Committee; Nader Hammoud and Tony Cody are the Education Committee Co-Chairs and Jennifer Nichols is the Body of Knowledge/CE Certification Promo Committee Chair. Ilir Kullolli will be the Nominations Committee Chair. And these outstanding Committee Chairs agreed to continue leading for another term: Kevin Kreitzman, Advocacy Committee Chair; Juuso Leinonen, Membership Committee Chair; Binseng Wang, International Committee Chair, Jim Keller, CE-Hall of Fame Nominations Committee Chair; and Dave Smith, Advertising Committee Chair. I am thrilled to see the 2021-2022 full Board in place, and I am positive of our growth to facilitate ACCE’s goals and continued collaborations.

The last 18 months have been crucial for healthcare systems across the world and clinical engineers have been resilient and contributed in many innovative and cost-effective ways. We have truly pushed the limits, taking the integration of engineering and patient care delivery to its highest levels of perfection. Despite surge response efforts, we planned effectively and put together a very successful CE-IT Symposium at HIMSS21. Focused on Data Availability and Security in the Clinical Environment. The Symposium delivered timely content that was beneficial to clinical engineering programs and other healthcare stakeholders. We were also very happy to see our colleagues and friends after a long time!

Identifying the needs of our community, continuously establishing standards of competence, and promoting excellence in the profession are key focus areas of the Board and we are working to finalize the 2021-2022 goals. We will be increasing engagement in the industry and in academia, offering complimentary educational opportunities, and facilitating the adoption of vetted practices.

(Continued on page 2)
President’s Message continued:

(Continued from page 1)

I want to remind all ACCE members to come forward and participate in the ACCE Committees and sign up for the 2021-2022 Educational Webinar Series, which is complimentary to all ACCE members. ACCE submitted written comments to both the remanufacturing draft guidance and strengthening cybersecurity discussion papers on September 22nd. Our ability to advocate for clinical engineering programs and professionals in this space is unparallel, so I request each of you to share your expert insights.

In closing, thank you all for your support and continued contributions to the healthcare community. I am excited and looking forward to a fantastic year ahead!

Priyanka Upendra (Priya)
President, ACCE
president@accenet.org

MDSC Seeks Comments on White Paper on Technician Training Best Practices

The Medical Device Servicing Community (MDSC) has released a white paper outlining best practices for the training of medical device servicing technicians. Link to White Paper: Guidance for Technician Training Best Practices.

Commenting Period

The MDSC is soliciting comments from any interested party related to medical device servicing including but not limited to original equipment manufacturers (OEMs), independent service organizations (ISOs), hospital biomedical engineering, clinical engineering or healthcare technology management departments, professional organizations, and/or regulatory bodies. The white paper will be open for comments until 5pm EST on October 13, 2021.

AORN (Association of periOperative Registered Nurses) is participating in the development of and collecting comments on behalf of the Medical Device Servicing Community, a stakeholder coalition of volunteer organizations dedicated to advancing safety, effectiveness, and quality of medical device servicing. As a Steering Committee member of the Medical Device Servicing Community, AORN will work with AAMI and the MDSC to review and consider all comments on this document. If you are not a member of AORN, please register to gain access to the document for commenting.

Samantha Jacques, PhD
Samantha.Jacques@mclaren.org
ACCE Member Spotlight: VA CE/HTM Leader, Kurt Finke Retires

The Veterans Health Administration (VHA) is the largest integrated health care system in America. It provides care to 9 million veterans each year in over 170 medical centers and 1,100 outpatient clinics across the country.

For almost a decade, Kurt Finke managed over 8 billion dollars worth of medical equipment in VHA as the Director of Healthcare Technology Management (HTM). He was supported by 1,500 BMETs and clinical engineers.

Kurt recently retired after serving the veterans and the country for almost 4 decades. He was the role model for professionalism in HTM. He exemplified all that is good about Clinical Engineering and healthcare and promoted excellence at work.

Getting Started

Kurt became interested in biomedical engineering through family experiences. His father was an aeronautical engineer, and his mother was a nurse. As a child Kurt was interested in engineering, but when he heard about biomedical engineering, he thought it was the perfect fit for him. This led him to join Tulane University (one of the few schools that offered undergraduate degree in biomedical engineering at that time) and graduated in 1984.

After completing his degree, Finke joined the VA’s flagship Technical Career Field (TCF) training program in Biomedical Engineering. He later worked as the Chief Biomedical Engineer at VA medical centers in Baltimore, New Orleans, and Minneapolis.

Leader in the Field

Kurt has been a great promoter of the Clinical Engineering profession and the training of Biomedical Engineering staff throughout his career. In recognition of his efforts, he was selected for the 2011 Veterans’ Affairs Biomedical Engineer of the Year, ACCE 2012 Professional Achievement in Management Award/Managerial Excellence Award and the AAMI 2020 HTM Leadership Award. He also serves on the prestigious AAMI Board of Directors.

Tobey Clark from University of Vermont, who nominated Kurt for the ACCE award stated, “Kurt Finke is a national leader at the Veterans Administration hospitals who took the initiative to have 43 team CE members go through intensive CCE exam review sessions and take certification exam in 2011 greatly enhancing the quality of clinical engineering services at the VA.”

Training the Future Generations

To improve and enhance the career path for Clinical Engineering personnel in VHA, Kurt implemented a professional development and training program for all HTM staff. The VA paid for study materials, instructor-hosted webinars, and other technical training opportunities for the HTM staff. “The profession we’re in is rapidly evolving,” says Kurt. “If we don’t constantly refresh our skills and refresh our knowledge, we become stale and less effective than we should be.”

Impact on Others

Kurt has had a significant impact on the careers of many HTM professionals. He recruited, trained, mentored, and served as a role model to many HTM professionals who now hold leadership positions in the HTM world.

Retirement

Kurt and his wife have 6 children and 7 grandchildren. His favorite sports are hockey and baseball. We wish him well in his retirement!

Quotes from some of Kurt’s colleagues:

Galpin Kevin MD, Executive Director, Telehealth VHA: “Your efforts will have a significant impact on VA’s ability to deliver the highest quality services to Veterans long into the future.”

Tandi Bagian, Chief Engineer, VA National Center for Patient Safety: “Was a wonderful time to be in VHA - thanks for your vision and partnership Kurt, and may we all continue to work as ONE TEAM!”

Richard S. Schofield, MD, VA National Program Director, Cardiology: “I am particularly going to miss your level-headed approach to problems and your wise counsel on how to deal with them.”

Megan Friel, Acting Director, HTM, VHA: “Kurt Finke has a vision and passion that runs deep for Healthcare Technology Management. He spent his VA career dedicated to elevating the HTM career field, and increasing awareness of our profession’s direct impact on patient care. His love for HTM was always at the core of his decision-making as the VHA HTM leader.”

(Continued on page 4)
On a personal note, Kurt recruited me to the VA over a decade ago. He has mentored me over the years.

Arif Subhan, MS, CCE, FACCE, AAMIF
Past President, ACCE
Chief Biomedical Engineer, VA Greater Los Angeles Health Care System
ansubhan@icloud.com

Henry Stankiewicz, Jr., former VA Chief Biomedical Engineer, VISN1 and Consultant, Sigma Healthcare: “Kurt Finke brought both knowledge and extreme passion to the VA HTM Program in his long VA career. This past decade he led the growth of the VA HTM Program as its Program Chief. He and his team’s efforts resulted in an HTM community that is more professionally prepared for any health care reality, as demonstrated by the huge improvement in the VA’s response to medical equipment patient safety incident, recalls, cyber security threats, and Covid-19 challenges. His leadership and passion will be greatly missed in the VA community and by me. I suspect that passion will continue to make Kurt’s impact to our profession felt in his next chapter. His friendship and camaraderie are something I hope to continue at AAMI and social gatherings.”

On a personal note, Kurt recruited me to the VA over a decade ago. He has mentored me over the years.

Arif Subhan, MS, CCE, FACCE, AAMIF
Past President, ACCE
Chief Biomedical Engineer, VA Greater Los Angeles Health Care System
ansubhan@icloud.com

Nominations for the 2022 ACCE-HIMSS Excellence in CE-IT Synergies Award is now Open

Nominations for the 2022 ACCE-HIMSS Excellence in Clinical Engineering and Information Technology Synergies Award are being accepted between now and the deadline of October 19, 2021. Eligibility and criteria for nominations are as follows:

- Has demonstrated innovative leadership through effective use of technology in support of the strategic initiatives of his/her organization
- Represents the highest standards of leadership in health information technology
- Is respected and recognized as a role model to peers in the industry
- Has participated significantly in either leadership or organizational activities of ACCE or HIMSS (i.e., board of directors, board-appointed committee, task forces etc.)
- Has advanced the professional standards embraced by HIMSS and ACCE
- Has made outstanding contributions to the principles for which HIMSS and ACCE stand, including but not limited to: Supporting and participating in lifelong learning opportunities
- Supporting and promoting HIMSS and/or ACCE as a recognized thought leader in the industry
- Current membership in good standing of HIMSS and ACCE
- Is not currently serving on a HIMSS or ACCE Board.
- Cannot be currently employed by HIMSS, nor engaged in a consulting contract with any component of HIMSS or ACCE
- Award judges are ineligible to be nominated
- Previous award recipients are exempt from consideration

Submit your nominations online here by October 19, 2021.

Past award winners
Welcome ACCE’s 2021-2022 Officers, Board of Directors and Committee Chairs

Officers and Board of Directors, 2021-2022

Priyanka Upendra
President

Kim Greenwood
President Elect

Jim Panella
Vice President

Kamecia Bruce
Secretary

Bhaskar Iduri
Treasurer

Ilir Kullolli
Past President

Jim Caporali
Member at Large

Dave Braeutigam
Member at Large

Samantha Herold
Member at Large

Katherine Navarro
Member at Large

Committee Chairs, 2021-2022

Jennifer Nichols
BOK/CE Certification promo

Tony Cody
Education

Nader Hammoud
Education

Juuso Leinonen
Membership

Kevin Kreitzman
Advocacy

Binseng Wang
International

David Smith
Advertising

Ilir Kullolli
Nominations

Jim Keller
CE-Hall of Fame

Ricardo Silva
HTCC
Welcome New ACCE Members

We welcome our newest members, approved by the 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>
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<tr>
<td>Petroula Hansen</td>
<td>Individual</td>
<td>Biomedical Engineer</td>
<td>VA Midwest Healthcare Network, VISN 23</td>
<td>MN/USA</td>
</tr>
<tr>
<td>G. Blake Collins</td>
<td>Individual</td>
<td>Director, Clinical Engineering</td>
<td>Christiana Care</td>
<td>DE/USA</td>
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<tr>
<td>Abdelbaset Khalaf</td>
<td>Individual</td>
<td>Professor, Health Care Technology Program</td>
<td>Durham College</td>
<td>Canada</td>
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<td>Harrison Arciprete</td>
<td>Institutional/Associate</td>
<td>Clinical Imaging &amp; Integrations II</td>
<td>Yale New Haven Health</td>
<td>CT/USA</td>
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<tr>
<td>Caroline Chyc-Olesiak</td>
<td>Institutional/Associate</td>
<td>Clinical Imaging &amp; Integrations</td>
<td>Yale New Haven Health</td>
<td>CT/USA</td>
</tr>
<tr>
<td>Syed If tikhar Ali</td>
<td>Associate</td>
<td>Senior Medical Equipment Planner</td>
<td>Sidra Medicine</td>
<td>Qatar</td>
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<tr>
<td>Caitlin S. Young</td>
<td>Institutional/Individual</td>
<td>Clinical Engineer</td>
<td>Northern Light Health</td>
<td>ME/USA</td>
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<tr>
<td>Chris Bzovey</td>
<td>Individual</td>
<td>Regional Clinical Engineer</td>
<td>Winnipeg Regional Health Authority</td>
<td>Canada</td>
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<tr>
<td>Angelina Chiaracane</td>
<td>Institutional/Individual</td>
<td>Clinical System Engineer</td>
<td>Kaiser Permanente</td>
<td>Ca/USA</td>
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<tr>
<td>Dallas T. Sutton, Jr</td>
<td>Institutional/Individual</td>
<td>Manager, Clinical Engineering</td>
<td>WakeMed Health and Hospitals</td>
<td>NC/USA</td>
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<tr>
<td>Eric Sommers</td>
<td>Institutional/Associate</td>
<td>Biomed Engineering Tech 2</td>
<td>WakeMed Health and Hospitals</td>
<td>NC/USA</td>
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<tr>
<td>Shannon Hunter</td>
<td>Institutional/Associate</td>
<td>Biomed Engineering Technician</td>
<td>WakeMed Health and Hospitals</td>
<td>NC/USA</td>
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<tr>
<td>Sarah Kubik</td>
<td>Institutional/Associate</td>
<td>Biomed Engineering Tech 1</td>
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<tr>
<td>Ashley Wolf</td>
<td>Institutional/Associate</td>
<td>Biomedical Healthcare Technology Manager</td>
<td>The Christ Hospital Health Network</td>
<td>OH/USA</td>
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<tr>
<td>Douglas Wolff</td>
<td>Institutional/Associate</td>
<td>HTM Manager—MDIIS</td>
<td>The Christ Hospital Health Network</td>
<td>OH/USA</td>
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<tr>
<td>Tim Armstrong</td>
<td>Institutional/Associate</td>
<td>Lead Tech, Biomed</td>
<td>The Christ Hospital Health Network</td>
<td>OH/USA</td>
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<tr>
<td>Carl King</td>
<td>Institutional/Associate</td>
<td>Medical Systems Security Specialist</td>
<td>The Christ Hospital Health Network</td>
<td>OH/USA</td>
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<tr>
<td>Justin Illes</td>
<td>Student</td>
<td>Student, major in Biomedical Engineering</td>
<td>The College of New Jersey</td>
<td>NJ/USA</td>
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Congratulations to the following ACCE members who were upgraded to Individual level:

<table>
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<th>Organization</th>
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<tbody>
<tr>
<td>Jeff Mendoza</td>
<td>Individual</td>
<td>Medical Equipment Planner</td>
<td>NYU Langone Health</td>
<td>NY/USA</td>
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<tr>
<td>Emily Mengel</td>
<td>Individual</td>
<td>Clinical Engineer</td>
<td>WakeMed Health &amp; Hospitals</td>
<td>NC/USA</td>
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Welcome to our newest Institutional Members:
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<tr>
<th>Name</th>
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<th>Organization</th>
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</thead>
<tbody>
<tr>
<td>William Balhorn</td>
<td>CCE</td>
<td>MIM Software</td>
</tr>
<tr>
<td>Michael J. Ballintyn</td>
<td>CCE</td>
<td>Clinical Engineer, Hartford Healthcare</td>
</tr>
<tr>
<td>Andrew M. Blanford</td>
<td>CCE</td>
<td>Chief, Healthcare Technology Manager, VA Central Ohio Healthcare System</td>
</tr>
<tr>
<td>Michael S. Brilling</td>
<td>CCE</td>
<td>Manager, Clinical Engineering, Dartmouth-Hitchcock</td>
</tr>
<tr>
<td>Jennifer Boudreaux</td>
<td>CCE</td>
<td>Chief Clinical Engineer, Southeast Louisiana Veterans Health Care System</td>
</tr>
<tr>
<td>Luke Bowers</td>
<td>CCE</td>
<td>Supervisory Biomedical Engineer, VA Eastern Kansas Health Care System</td>
</tr>
<tr>
<td>Katelyn Greenbank</td>
<td>CCE</td>
<td>Biomedical Engineer, VA Capitol Healthcare Network</td>
</tr>
<tr>
<td>Jennifer L. Kizis</td>
<td>CCE</td>
<td>Chief Biomedical Engineer, Lexington VA Healthcare System</td>
</tr>
<tr>
<td>Tyler L. Moxam</td>
<td>CCE</td>
<td>Clinical Engr Supervisor, VA Connecticut Healthcare System</td>
</tr>
<tr>
<td>Jennifer Nichols</td>
<td>CCE</td>
<td>Division Vice President, TRIMEDX</td>
</tr>
<tr>
<td>Rebekah Paiser</td>
<td>CCE</td>
<td>Clinical Engineer, VA New England Healthcare System</td>
</tr>
<tr>
<td>Ashley Shramm</td>
<td>CCE</td>
<td>Clinical Engineer, Cincinnati VA Medical Center</td>
</tr>
<tr>
<td>Virginia Hall</td>
<td>CCE</td>
<td>Biomedical Engineer, VA VISN 20, Northwest Network</td>
</tr>
<tr>
<td>Kristy Sharma</td>
<td>CCE</td>
<td>Clinical Engineer, VA Boston Healthcare</td>
</tr>
<tr>
<td>Cheryl Shaw</td>
<td>CCE</td>
<td>Biomedical Engineer, VA VISN 20 Northwest Network</td>
</tr>
<tr>
<td>Anna Cristina Shivers</td>
<td>CCE</td>
<td>Sr. Clinical Systems Engineer, Kaiser Permanente</td>
</tr>
<tr>
<td>Natalia Tabares-Franco</td>
<td>CCE, Sr. Clinical Systems Engineer,</td>
<td>Clinical Engineering Manager, Massachusetts General Hospital</td>
</tr>
<tr>
<td>Tiffany Wang</td>
<td>CCE</td>
<td>Chief, Healthcare Technology Management, VA Puget Sound Healthcare System/Seattle</td>
</tr>
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ECRI Perspectives: Celebrating World Patient Safety Day & Calling on the FDA and Industry to Revisit COVID-19

World Patient Safety Day

At ECRI we celebrated World Patient Safety Day for the entire week preceding September 17. This year’s theme was Safe Maternal and Newborn Care. You may have seen social media and news reports promoting ECRI’s World Patient Safety Day Resource Center with free and shareable resources, but what you may not be as familiar with are the heartbreaking statistics. Worldwide: Nearly 6,700 newborns die every day; >300,000 women die from childbirth each year. In the United States, more women die from childbirth than in any of the 11 other developed countries measured. This is compounded by systemic racial and socio-economic inequity in the healthcare system. Behind these statistics are devastated children and families.

So what are we doing at ECRI to improve maternal and newborn health? A few examples:

Through our Health Resources & Services Administration (HRSA) contract, we provide extensive obstetric clinical risk management training, guidance, and expert one-on-one consulting to 28,000 individuals in federally qualified health centers. This helps them deliver safer, higher-quality maternal and newborn care to thousands of patients, many from vulnerable communities that otherwise lack access to perinatal services.

ECRI conducts in-depth analysis on millions of perinatal patient safety events submitted to the ECRI and Institute for Safe Medication Practices (ISMP) Patient Safety Organization.

We partner with hospitals and health systems in diverse communities across the U.S. conducting intensive, individualized assessments of their perinatal services.

Calling on the FDA and Industry to Revisit COVID-19 Medical Device EUAs as Shortages Ebb

As the coronavirus pandemic intensified in the U.S., the FDA granted emergency use authorizations for a slew of medical devices to fill shortages of crucial medical supplies when hospitals began filling up with COVID-19 patients.

The special authorizations were made for devices ranging from COVID-19 tests and personal protective equipment to ventilators and remote patient monitoring devices. EUAs allow products not yet cleared or approved to be used or allow devices to be used beyond their original indication to help address the pandemic.

Our CEO, Marcus Schabacker, believes that the use of EUAs can compromise patient safety because of the shortened review process and communication challenges when an EUA is revoked could lead to patients being treated with unsafe devices.

The FDA in rapid manner authorized hundreds, now over 1,000, consumables and devices with EUA. For ECRI, that was an alarm bell because for medical devices, in particular, we don’t believe that we still have found the right approach for clearing those devices for usage.

There are already safety concerns with the primary medical device review process — the abbreviated 510(k) pathway — and EUAs “shortcut the shortcut.”

While the delta variant of the coronavirus has sparked another surge across the U.S., the crisis has eased from levels seen last year and the EUA risks need to be addressed by regulators and industry.

In the early months of the pandemic as the FDA was issuing EUAs we started really getting into EUA risk analysis right away. The alarm bells went off because it looked very indiscriminate as to who got an EUA and who didn’t. When we then began discussing what were the biggest risks for this year, the EUAs came to mind.

Because in the eyes of the clinician, the device shows up on their shelf or on their floor as safe to use, and a lot of them don’t even know that the device never went through any proper procedure to be cleared for marketing. So, they use it with the assumption that it is a safe and effective device, and the FDA has no way through an EUA in determining that, particularly not if the agency pumps out hundreds of them.

ECRI does not blame the FDA. There were no supplies, there were new things we needed and there were products that we thought could be useful but didn’t have the proper indication. In an emergency situation, as we had a year ago, the FDA needs to do whatever they can to get the supplies to the people.

Now, we’re certainly not in a crisis anymore when it comes to supplies. And it behooves the FDA to really take a much more aggressive approach in looking at those EUAs using criteria such as if there is sufficient supply of an approved device, if there is a need for that device in the treatment of COVID-19, and if there have been any reports on issues of that device during the EUA.

(Continued on page 9)
WHO HTM Collaborating Center Update

The collaborating center at the Technical Services Partnership at the University of Vermont is spearheading a Pan American Health Organization (PAHO) initiative to advance healthcare technology management (HTM) in the Caribbean. The work includes a series of six interactive webinars on HTM topics. The first two webinars covered: 1) The Integrated Approach to Health Technologies: planning, policy/regularations, assessment, and management, and 2) Showing the Value of HTM. This topic was chosen based on a survey of the 100+ participants in the first webinar. Additional webinars will cover planning for support during acquisition, the value of standardization, effective procurement of parts and consumables, and more.

The second activity is country-specific workshops. Two workshops have been conducted for Trinidad & Tobago and Suriname with additional workshops planned for Guyana and Belize. The workshops focus is on high priority HTM issues specific to the country. For each country at least two workshops will be held to support solutions to their most pressing HTM problems.

The third activity, a 12 week course – Healthcare Technology Planning & Management, is being offered on the PAHO Virtual Campus for Public Health for the fourth time since 2015. The course has been translated into French for country-specific application to Haiti. Fluent French faculty include Rossana Rivas, Vermont collaborating center consultant and ACCE member, Evenel Osias, BMET, Biomedical Engineering Technology Aid (BETA) in Haiti, and Gabriela Jimenez Moyao, PAHO and WHO consultant. Tobey Clark is the coordinator. The course will start on September 20 and run to mid-December with 45 participants.

Continuing courses include the Essentials of Biomedical Technology course for Haiti sponsored by Health Equity International and the Dalton Foundation with the final evaluation session on October 5th. Evenel Osias, BMET, and Tom Monaghan, (Day job as a BMET at Massachusetts General Hospital), are the other faculty members who have added value to the course due to their experience in Haiti.

Following virtual meetings and an on-site survey of the healthcare system and facilities in Belize, the final Revised Model Plan and Policy for Healthcare Equipment Management was provided to the Ministry of Health and Wellness (MoH&W) and PAHO. The final step in the process will be training on the plan and policy with MoH&W leaders and staff.

Work for the World Health Organization has included contributions to the publication Compendium of Innovative Technologies for Low Resource Settings which was released in August 2021, and functioning as Co-coordinator, with ACCE member Bill Gentles, of the WHO COVID-19 Priority Medical Device training videos. The long-term project involves the production of 34 videos covering life cycle activities for six priority medical devices utilized by COVID-19 patients. The work entails writing and editing video scripts/scenes, coordinating videoographers and reviewers globally, producing videos, working with digital producers, reviewing videos, and bi-weekly meetings. The videos will be placed on the OpenWHO educational website and be available on YouTube.

Tobey Clark
Tobey.clark@uvm.edu

ECRI Perspectives continued
(Continued from page 8)

The medical technology industry should help determine whether some of these EUAs are still necessary and safe, especially considering the additional workload the FDA is dealing with during the pandemic. The industry got those EUAs, and they have an obligation now that the crisis is over to be proactive and provide the necessary data to the FDA.

They can provide the use data for that product, adverse events that were captured and lab tests that would have been provided if it were a 510(k) or premarket approval application. Be proactive about it. Don't wait for it. You have a moral obligation to provide FDA with these data sets.

Hospitals have an obligation, too, under the EUA. Hospitals need to manage these devices very differently. They need to keep track of them and know where they are. And if an EUA gets revoked, it’s like a recall, you have to ensure that product gets removed from the shelf. If it’s been used to treat a patient, you can finish the treatment of that patient. But after that, you need to make sure it gets locked up with a big yellow sign on it saying, "Not for human use." And you need to document that you have done that because you are liable if something happens.

It’s not an unsolvable problem, but it won’t go away by itself, and it can potentially be dangerous because we have hundreds and hundreds of EUAs out there.

ECRI is concerned that going forward devices will be used to treat patients after an EUA is revoked. It could be an issue that these devices are not safe and putting patients in danger. That’s why the medical technology industry, hospitals, third parties like ours, the FDA and other government agencies need to work together to make sure that patients stay safe.

Ismael Cordero,
Senior Project Engineer, ECRI
icordero@ecri.org
A U.S. national BMET Apprenticeship Program recently launched by the Association for the Advancement of Medical Instrumentation (AAMI) has gained valuable new support through the College of Biomedical Equipment Technology and Fluke Biomedical. The backbone of hospitals and even laboratories, BMETs routinely service the medical devices that are needed to monitor patient health or record important data. Unfortunately, AAMI estimates that nearly half of the current healthcare technology management (HTM) workforce is over the age of 50. As more BMETs retire and the number of college programs to train new HTM professionals dwindles, healthcare systems will find it increasingly difficult to fill these crucial positions.

That’s why AAMI’s BMET Apprenticeship Program, recognized by the U.S. Department of Labor, guides employer partners in training the next generation of HTM professionals. The program combines traditional education with up to 6,000 hours of on-the-job learning. Prospective BMETs are matched with program partners in their area, who provide them with training and paid work experience, and cover expenses for the requisite educational courses.

Now, the cost of supporting an apprentice may prove lower than employers expect!

Discounted Access to Exclusive College Courses

The College of Biomedical Equipment Technology is an online college that offers biomedical equipment technician (BMET) and healthcare technology management (HTM) training at the certificate and associate degree levels. The college is offering all participants in the Apprenticeship Program access to A&P and mathematics courses at a 20% discount for organizations taking on AAMI BMET apprentices.

“Typically, only students enrolled in their degree program can take those classes, but they are opening them up to any AAMI BMET Apprentices,” explained Danielle McGeary, vice president of HTM at AAMI. “We view the Apprenticeship Program as a unique opportunity to bridge a critically important gap in education and serve a segment of the workforce that might otherwise struggle to gain entry into an incredible career field,” said Dr. Richard L. “Monty” Gonzales, president of the College.

According to McGeary, “since the College of Biomedical Equipment Technology’s courses are entirely online, its support solves three potential problems our Apprenticeship Program’s partners may face.”

1. Employer partners might not already have a relationship with a local community college for providing classroom learning.

2. Employers/Apprentices located in rural areas of the country are sometimes hours from a physical college, making it hard for apprentices to access the necessary classes.

3. Not everyone can attend face-to-face school at night after working a 40-hour week, due to other commitments.

“With this new option, apprentices can do it all online at their own pace,” said McGeary, who serves on the College’s advisory board.

Free Industry Training

Support from Fluke Biomedical is covering another important corner of the BMET Apprenticeship curriculum. A manufacturer of biomedical test equipment and training software, Fluke is offering free Advanced Training Courses to participating apprentices.

The courses add up to an estimated 22 hours of free training and count towards the ‘Medical Equipment Training from Industry Sources’ requirement in the Related Instruction section of the new U.S. national apprenticeship program’s curriculum.

“Year one requires 30 hours of medical equipment training from industry sources, so this 22 hours of content will complete a majority of the requirement at no cost to organizations participating in the BMET Apprenticeship Program,” explained Danielle McGeary, vice president of HTM at AAMI. “The content contains a lot of training around their biomedical test equipment, which is perfect for the apprentices who are brand new to the field and need to learn about test equipment and electrical safety.”

“AAMI wanted to provide some quality free training options as we know budgets are tight for everyone right now,” McGeary added. “We are very appreciative of Fluke’s support.”

“It turns out the program was the perfect application for our immense library of educational content,” said Michael Raiche, senior portfolio manager for Fluke Biomedical. “What better way to influence the test and measurement market than to educate the next generation? It’s important that we all understand the clinical applications of medical devices, the risks if they fail, how to test them and share industry best practices.”

Nuvolo Sponsorship Program

In addition to help from Fluke Biomedical and the College of Biomedical Equipment Technology, AAMI previously announced the support of Nuvolo.

Through the Nuvolo Apprenticeship Sponsorship Program, the first seven health systems or stand-alone hospitals to enroll in AAMI’s BMET Apprenticeship Program by December 1, 2021 will be... (Continued on page 13)
ACCE at HIMSS21: CE-IT Symposium

ACCE was a collaborator of HIMSS21 and hosted the CE-IT Symposium, a pre-HIMSS21 event focused on “Data Availability and Security in the Clinical Environment”.

The symposium included education sessions that expanded the CE-IT knowledgebase through expert insights around program assessment using the NIST Cybersecurity Framework, incident management, contracts management, and ongoing industry trends and best practices.

The day-long agenda included:

- Keynote: The Importance of Business Continuity and Disaster Recovery and Operational Support, Data Impact on Clinical with Data Availability, by Bill Hudson
- Discovering and Disclosing Vulnerabilities, by Mike Powers and Nader Hammoud
- Aligning NIST Cybersecurity Framework with Clinical Engineering Operations, by Matt Dimino
- Balancing Priorities During and Following a Cyber Attack, by David Finn
- Overview of Cybersecurity Resources, by Mike Power
- Getting Ahead of Cybersecurity Risk with Contract Language, by Christopher Falkner

Special thanks to John Muir Health, ECRI, First Health Advisory, CynergisTek, Intermountain Healthcare, and Kaiser Permanente for having its leaders share their expertise. The CE-IT symposium provided attendees with tools, information about vetted practices, and frameworks required to start or improve their medical device cybersecurity programs.

If you missed this symposium, you may download the presentation slides at https://accenet.org/publications/Pages/Symposiums.aspx

ACCE is grateful to the 2021 ACCE CE-IT Symposium co-sponsors. With their support the symposium was offered free to all attendees.
Fuchs winner of CE/IT Synergies Award

The ACCE-HIMSS CE-IT Synergies Award recognizes leadership in promoting or implementing significant synergies between the clinical engineering and information technology professions with contributions either professional or technical in nature. The Board of Directors of both organizations jointly select the recipient.

The 2020 Award winner is Ken Fuchs, MBA, MEng. Due to the cancelation of the HIMSS20 conference, Ken was recognized at the 2021 ACCE awards reception at HIMSS21—Las Vegas, by ACCE President, Ilir Kullolli.

Ken is the Senior Standards Consultant at Draeger Medical Systems, Inc. a manufacturer of electronic medical devices such as patient monitoring, ventilation, anesthesia and warming therapy systems. Ken is currently responsible for coordination of Drager Medical’s participation in US and International standards development activities. He is also personally active in medical device clinical- as well as interoperability-related standards. He currently serves as

Contreras Receives ACCE Scholarship

Congratulations to Joemart Contreras, the recipient of the 2021 ACCE Student Scholarship award. Joemart is a graduate student in the Biomedical Engineering/Clinical Engineering program at UCONN.

The following is an excerpt from Joemart’s Scholarship entry essay:

The value and importance of learning has been instilled in me from an early age. As my parents would say, knowledge is the only thing that no one can take away from you. Adhering to their advice hasn’t always been easy, but I’ve realized that it is easier to learn about something you care about. The challenging semester courses felt effortless because I cared about the material and its application to my career. Having to move to a completely new environment by myself, balancing my time between my responsibilities, and figuring out how to be a young adult during a chaotic time did not make my academic life any easier. However difficult it may have been, I was able to achieve academic excellence and secured a 4.0 GPA. The grades I earned mark my resilience and drive to obtain a valuable education in clinical engineering.

I am pursuing a graduate education in clinical engineering because I want to work in a field that not only fits my career goals but that also offers a practical approach to affecting patient outcomes through hospital technology oversight and development. With technology on the forefront on how patients are cared for, it is exciting to be within a profession that will be important in navigating through it. I have been fortunate enough to be able to see cutting edge technology be implemented into the VA such as the Accuray CyberKnife which is making cancer treatment for our radiation oncology patients safer, more efficient, and more affordable. I look forward to getting certified as healthcare technology manager and clinical engineer in the future to enhance my abilities to contribute to the profession and achieve my goal of becoming a chief operations officer of a hospital.”

ACCE thanks its sponsor, ASIMILY, that helped make this year’s HTA/ACCE awards reception at HIMSS21 a success.
International Committee Report

The International Committee (IC) held its fifth 2021 regular bimonthly meeting on September 13, 2021. At this meeting we welcomed the addition of Dr. Abdelbaset (Baset) Khalaf to IC as the replacement for Jennifer Jackson, who resigned due to heavy workload.

Dr. Khalaf was born in Palestine, lived for many years in South Africa and is currently teaching in Canada. He has worked in clinical engineering in Palestine and served as the Deputy Director of Health Technology Policy for the Department of Health of South Africa. There he also taught at the Tshwane University of Technology before transferring to Durham College in Canada, where he is a Professor of Health Care Technology Management. He has earned a BSc-EE from the Middle East Technical University, Turkey, a MTECH and DTECH from the Tshwane University of Technology, and a PhD-EE from the Université De Versailles Saint-Quentin-En-Yvelines, France.

At this meeting, IC members discussed the progress made in establishing collaboration and mutual assistance agreements with foreign associations. One of them, with the Association Françaises des Ingénieurs Biomédicaux (AFIB), has been submitted for review to and approved by the ACCE Board. Others agreements being explored include the associations of Bosnia and Herzegovina, Greece, and Ireland.

IC members also discussed the webinars that are being offered to our collaborating associations. A webinar entitled “Clinical Engineering – An Overview and Future Perspectives,” was delivered by Binseng Wang & Julio Huerta to the Asociación Colegio de Ingeniería Biomédica de El Salvador (ACIBES) on July 29, 2021. Another one, entitled “Medical Equipment Planning - An Overview of the Process” will be delivered by Avinash Konkani to The Clinical Engineering Association of South Africa (CEASA) on Oct. 19, 2021. A few additional ones are also being arranged. The list of webinars being offered also has been augmented with new subjects and is available on ACCE’s website: https://accenet.org/International/Pages/Webinars.aspx.

Due to the prevalence of the COVID-19 pandemic in most countries, it is anticipated that these webinars will continue to be the primary means of collaboration between ACCE and the foreign associations with which ACCE has established collaboration and mutual assistance agreements. ACCE members who are not IC members are welcome to consider offering webinars they believe are of potential interest to our foreign colleagues. Interested persons should contact one of the IC members (see list on https://accenet.org/International/Pages/Default.aspx) and provide a short description similar to what is available on the ACCE webpage. Potential presenters are reminded that such activities are strictly voluntary and does not involve any honorarium.

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

AAMI Update continued

(Continued from page 10)

automatically eligible to receive up to $725 per apprentice for up to two apprentices. Additional program details can be found at connectedworkplace.nuvolo.com/apprenticeship-certification-program/.

“Our Apprenticeship Program continues to grow with the support of these incredible organizations,” said McGeary. “I’m excited to see even more companies join our growing list of employer partners paving the way for the next generation of exceptional BMETs!”

AAMI staff

Fuchs CE/IT Award continued

(Continued from page 12)

the chair of the IEEE 11073 Standards Committee for medical device communication, he co-chairs the AAMI MP working group for multi-parameter patient monitors and is involved in a number of other standards development efforts in ISO, IHE, HL7 and AAMI.

Ken’s background has been focused on networking, connectivity and system architectures at various point of care medical devices companies including Draeger Medical Systems, Siemens Medical Solutions, Mindray Medical and the non-profit Center for Medical Interoperability.

At HIMSS, Fuchs has been involved with the HIMSS Interoperability Showcase since 2005. When the first Patient Care Device demonstration was held. He was a member of the IHE USA Board of Directors as well as a PCD co-chair for a number of years. He has volunteered at the Interoperability Showcase in the past as well as for HIMSS20.

“Ken has been very involved in the CE-IT Community since its inception. His vision and leadership have helped define the scope of direction for PCD (Patient Care Device Domain) where he has been a leader from its very beginning. He has a great passion to collaborate across disciplines and to educate users’ community in order to provide much clarity for the complex architecture of network of systems and its dependence on standards to achieve and deliver safe true interoperability. Ken is well respected in the CE-IT Community; he has delivered a multitude of presentations and training workshops and has served on many committees in order to help deliver safe and effective patient care through technology. Ken is the true embodiment of CE-IT Synergies and we are extremely pleased he was awarded this Award”, said Ilir Kullolli, President of ACCE.
Updates from the IFMBE Clinical Engineering Division (CED), and the Global Clinical Engineering Alliance (GCEA):

1. **4th ICEHTMC**: As shared in the July 2021 ACCE News, CED and the ICEHTMC organizing committee decided to transform its upcoming 4th International Clinical Engineering and Health Technology Management Congress (ICEHTMC) into a virtual Congress, scheduled to be live-streamed October 23-26, 2021, on the Zoom Events platform. This Congress is now part of a week-long celebration of the contributions Clinical Engineers make around the world every day! **Free registration is coming soon!** Recordings of all the events will be available on the GCEA website. Here are some highlights for the upcoming virtual Congress, and related events:
   
a. **Keynotes (4):** WHO & the Global CE Community; Global CE Credentialing; COVID-19 Global CE Grand Challenges; Why GCEA.
   
b. **Global best practices:** Over 200 presentations from colleagues in 70 countries.
   
c. **Expected audience:** 1500 CEs from 120 countries.
   
d. **Global CE Week Global Celebration:** beginning in China Friday evening October 22 (New York time).
   
e. **Live streaming:** begins Sat Oct 23 at Noon-1 pm EDT: GCEA-sponsored Digital Health Roundtable & then 20 CE presentations.
   
f. **Continuing:** Sun Oct 24 with 9 am – Noon Global CE Summit; 12-3 pm Short Courses; and 6-9 pm Inaugural GCEA gathering.
   
g. **Congress:** Monday Oct 25 and Tuesday Oct 26; speakers in moderated 3-track sessions on many CE-HTM topics.
   
h. Click [here](#) for a complete ICEHTMC program

2. **For past CE week celebrations and country status reports, click Celebrations, or click Reports.**

3. **Global CE Summit 2021:** If you only have time for two events, try these:
   
a. **Global CE Summit:** issues most important to CEs globally:  
   
b. **Register and join the live-stream from Zoom Events for Sunday morning October 24, from 9 am – Noon New York time**

4. **Global CE Alliance Inaugural Gathering:** Sunday, October 24, from 6-9 pm New York time
   
a. Learn about CED & GCEA’s partnership in the production of the August, 2021 WHO compendium of innovative health technologies for low-resource settings 2021, COVID-19, and other health priorities ([https://www.who.int/publications/i/item/9789240032507](https://www.who.int/publications/i/item/9789240032507)).
   
b. Look for other exciting opportunities as GCEA provides “One Voice For All Clinical Engineering Professionals”.

Tom Judd, Board Chair, IFMBE Clinical Engineering Division (CED), [judd.tom@gmail.com](mailto:judd.tom@gmail.com)

Yadin David, Interim President, Global Clinical Engineering Alliance (GCEA), [David@biomedeng.com](mailto:David@biomedeng.com)
CCE Prep: Sample Questions

In this column we are providing sample questions and information regarding preparation for the CCE exam. The sample questions are based on topics from the ACCE Body of Knowledge survey and the CCE Study Guide, version 10. 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.

Sample Questions:

1. What is an example of a reason from the three areas below to replace an existing medical device and why?
   a. Safety  
   b. Maintenance  
   c. Standardization

   Answers
   a. Safety – Unresolved safety issues, adverse events, lack of safety features, doesn’t meet the standard of care, regulatory prohibition, no backups
   b. Maintenance – no parts available, poor reliability/excessive downtime, no support attributes, company “end-of-support”, high maintenance costs, high recent costs, BMET staff condition, device can’t be upgraded, high utilization,
   c. Standardization – user errors, enterprise interfacing for EHR, clinical acceptance, cost reductions, e.g. disposables, volume discounting, more cost-effective support

2. Healthcare Technology Assessment is:

Select ONE of the following possible answers:

a. the decision process to determine which vendor’s healthcare technology has the highest value for the healthcare organization
b. an examination of safety, efficacy, cost-effectiveness, need, ethical and legal issues associated with a new technology based on the context of application
b. a voluntary process by which a government or non-government agency grants recognition to an organization which meets defined standards
d. the extent to which a specific intervention, procedure, regimen, or service does what it is intended to do under ordinary circumstances, rather than controlled conditions

Answer

b. Healthcare technology assessment is an examination of safety, efficacy, cost-effectiveness, need, ethical and legal issues associated with a new technology based on the context of application. The context could be a country, health system or hospital. Answer “a” is acquisition when you are choosing between vendors, answer “c” is accreditation, and answer “d” expresses the clinical effectiveness. Healthcare technology assessment goes well beyond solely assessing the clinical aspects.

3. True or False: The time of maximum leverage with a vendor of medical equipment is during the warranty period of a device.

Answer: False - Prior to purchase of a medical device is the time of the maximum leverage with vendors where the healthcare organization can receive the most concessions. Negotiating the hospital’s requirements prior to purchase with data derived from the purchase analysis will provide leverage for the hospital to achieve its goals.

The warranty period is after the equipment is purchased therefore the leverage is limited. Unless there has been a warranty violation, the hospital does not have much leverage during the warranty period.

Tobey Clark
Tobey.clark@uvm.edu
The Education Committee announces their October 14th webinar session: “Adoption of AEM Strategies and Sustaining an AEM Program”. In this presentation the panelists will share their AEM experiences and discuss the benefits of a robust AEM program. They will also pass along the pitfalls they have overcome and the ones they may still be working on.

This is the second of ten webinars in the 2021-2022 series. The first one featured Chad Walters sharing the topic Successes and Pitfalls in Medical Device Cybersecurity”. If you missed the live session, you may access the recording on-demand here. Future webinars in this series will dig deeper into some of the issues that Clinical Engineering Departments experience globally. We have a great line-up of speakers for the upcoming webinars.

ACCE Members (in good standing), register for the October 14th webinar here. If you have not renewed your 2021 membership yet, please renew it here, or contact us at secretariat@accenet.org. If you are not an ACCE member yet, please join us today! Just complete the membership application form and submit it to secretariat@accenet.org. If you prefer to register as a non-member, register here.

The Education Committee would like to thank our speakers from the 2020-2021 Webinar series. These distinguished speakers, representing manufacturers and hospital staff, are what made this a successful series. We had clinical engineers, IT representatives, managers, directors, and administrators. We would like to thank all of them for taking time out of their busy schedules to share with us their knowledge, help us advance the Clinical Engineering profession, and support ACCE through the Webinar Series. From all of us on the Education Committee – THANK YOU!

ACCE Education Committee education@accenet.org
The open access Global Clinical Engineering Journal publishes high quality, timely, peer-reviewed manuscripts about the intersection of technology, engineering and informatics related to health, wellness, disease management, and patient-care outcomes around the world. Wider global community participation is further facilitated through this no-fee publication.

The vision of the Journal is to become the preferred international forum for facilitating the exchange, knowledge sharing, and engagement of practitioners across the globe. We will achieve that vision through a diverse range of high quality contributions of professionals from across the domains of clinical engineering, health-related technology, informatics and patient-care outcomes.

The purpose of the Journal is to collect, review, select, promote, and share original manuscripts, articles, technical papers, letters, scientific opinions, professional development tools, applications, and technical data relating to the clinical engineering and health technology fields.

The goal of the Journal is to advance and disseminate knowledge, to promote professional networking among practitioners and other stakeholders in academia, industry, government, and other decision-makers. We encourage work submissions by both young and senior researchers and practitioners. Our goal encompasses the promotion of education, training and ethical professional practice among members of this professional community.

EDITOR-IN-CHIEF: Dr Yadin David
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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 health care 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](http://LWW.com) to enter code.

### ACCE CALENDAR

[https://accenet.org/NewsEvents/Pages/Calendar.aspx](https://accenet.org/NewsEvents/Pages/Calendar.aspx)

- **13 October 2021, 12:00pm - 1:00PM EST**: ACCE CCE Webinar, last session: Product Development & Facilities Management
- **14 October 2021, 2:00 PM-3:00 PM EST**: ACCE Webinar #2: Adoption of AEM Strategies and Sustaining an AEM program
- **19 October 2021, last day to submit nominations for 2022 ACCE-HIMSS Excellence in CE-IT Synergies Award**, nomination form
- **21 October 2021, Global Clinical Engineering Day**
- **23-26 October, ICEHTMC, online**
- **25-29 October 2021, Global Health Equity Week/US National Health IT Week**
- **26 October 2021, 2:00 PM-3:00 PM**, FREE HTA Webinar: Digital Transformation in the Environment of Care
- **06-20 November 2021, CCE Written Examination period**
- **11 November 2021, ACCE Webinar #3, Maintaining Medical Devices in Anesthetizing Environments**
- **05 December 2021, last day to submit nominations for 2022 ACCE Advocacy Awards**, Nomination form
- **09 December 2021, 12:00 PM-1:00 PM, ACCE Webinar Session 4: HTM/CE Value to the Healthcare Organization**
- **01 January 2022**: ACCE Membership renewal due
- **13 January 2022, 12:00 PM-1:00 PM, ACCE Webinar Session 5: Wearables**
- **31 January, 2022, Student Paper Competition**: last day to submit your paper entry. Submit your paper [here](http://here)
- **10 February 2022, 12:00 PM-12:30 PM, ACCE Webinar Session 6: The Joint Commission 2022 Updates, sponsored by Sodexo**
- **14 –18 March 2022, HIMSS 2022, Orlando FL**
- **3-6 June 2022, AAMI Exchange 2022, San Antonio TX**
- **12 –17 June 2022, IUPESM World Congress 2022, Singapore**

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