



ACCE News

Newsletter of the American College of Clinical Engineering

March—April 2022

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President's Message



Dear ACCE Community,

I trust that each of you continue to be safe and healthy! Healthcare technology management/clinical engineering (HTM/CE) needs you to be so that we can continue to grow rapidly. Professional development in our field is necessary to remain current with the growing technology and human resource management trends. Our education committee hosted several thought-provoking sessions this past quarter focusing on challenges with connected medical devices, regulatory compliance and Joint Commission updates, and managing policies and procedures in HTM/CE. Webinars are scheduled every month and can be viewed here: <https://accenet.org/NewsEvents/Pages/Webinars.aspx#past>

Our Education Committee co-chair Nader Hammoud is presenting to the Japanese Association of Clinical Engineering on May 15th on clinical engineering experiences during COVID-19 response activities. This presentation speaks to the collaboration our International Committee has set up with clinical engineering communities around the world that allow us to share practices and advance professional development.

Our International Committee, led by Binseng Wang, is making great progress exploring collaboration opportunities with the United Nations' Office for Project Services (UNOPS). Another collaborative and assistive agreement is being put together with the German Clinical Engineering Association (Fachverband Biomedizinische Technik e.V. - FBMT) and Lebanese Clinical Engineering Association (HTMA Lebanon) that will strengthen ties in our community in the form of education seminars, remote internship and job prospects, and mentoring in academic institutions. International Committee-organized webinars can be seen here: <https://accenet.org/International/Pages/Webinars.aspx>. If there is a topic that you would like to present to our international members, please contact Binseng Wang.

I'm thankful for the ACCE members that joined U.S. Senator Ron Wyden of Oregon on January 27th to discuss Right to Repair. With focus on ensuring continuous care delivery, maintaining medical devices with the least downtime, and facilitating access to all servicers, this topic is crucial to our industry. As medical device servicers, it is important for our community to voice our opinions at the state legislature level, build a coalition, and increase awareness on timely care delivery.

Our efforts to review and revamp the clinical engineering certification (CCE) and its process has taken full effect. On behalf of the ACCE Board, I am thankful for the expert advice from our auditors and collaboration with the HTCC, US, and Canadian Board of Examiners. This revamp will allow our certification process to accommodate US domestic and international applicants and allow us to incorporate current exam-taking practices.

In closing, I want to thank all ACCE Board members, committee chairs, and members for tirelessly working to support patient care delivery and ensuring professional development in our ACCE community.

Priya Upendra, President
American College of Clinical Engineering
president@accenet.org

ACCE Membership Renewal

Thank you for being an ACCE member! It's time to renew your membership. If you have not yet renewed for 2022, renewal is due now!

To renew your 2022 membership online with PayPal, please [click here](#) or go to <https://accenet.org/Members/Pages/default.aspx?from=login>.

To renew by postal mail, please remit your renewal check to:

ACCE
2880 Bicentennial Pkwy, Ste 100 #249
Henderson, NV 89044

If you need an e-invoice, please contact ACCE Secretariat at secretariat@accenet.org

ACCE News

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International Committee Report

The International Committee (IC) held an extraordinary meeting on February 18 to discuss possible future collaborations with the United Nations' Office for Project Services (UNOPS). During this meeting a variety of possible forms of collaboration methods were explored and subsequently conveyed to UNOPS for its consideration.

On March 18, 2022, IC held its second 2022 bimonthly meeting. At this meeting, the chair reported that the German CE association (Fachverband Biomedizinische Technik e.V. – FBMT) has agreed to sign a mutual collaboration and assistance agreement with ACCE. A draft agreement is being submitted to ACCE Board for review and approval.

In addition to following up on the discussion of possible collaborations with UNOPS, IC discussed potential collaboration and assistance to the Lebanese CE association (HTMA Lebanon) per its request. Some of the possible cooperation topics discussed were:

- Educational seminars with a certificate

of attendance jointly issued by ACCE and HTMA

- Remote internship and job opportunities
- Mentoring for university students
- Student paper competition exclusive for Middle East students
- Research/technical project competition

Several IC members are interested and willing to assist HTMA. A follow-up meeting will be arranged by Salim Kai with HTMA leaders to discuss how to proceed.

Per invitation by the Japanese CE association (JACE), the IC made arrangements for Nader Hammoud to make a presentation on "Clinical engineers involvement facing COVID-19" on May 15th. This presentation will be made through a pre-recorded video followed by a live, online Q&A session.

Additional webinars with other national associations are being planned but have not been scheduled. The current list of webinars being offered is available on the ACCE's website: <https://accenet.org/International/Pages/Webinars.aspx>. ACCE members who are not IC members are welcome to consider offering webinars they believe are of potential interest to our international 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 do not involve any honorarium.

Binseng Wang, IC Chair

international.chair@accenet.org

World Health Organization (WHO) Collaborating Center for Health Technology Management Update

On February 28th, the WHO rolled out a series of training videos for biomedical equipment used with oxygen delivery systems. The project was led by ACCE member Adriana Velazquez, Team Lead Medical Devices, and In Vitro Diagnostics, at WHO. The equipment covered includes **Oxygen Concentrators, Oxygen Cylinders, Mechanical Ventilators, CPAP/BiPAP machines, Pulse Oximeters and Patient Monitors**. 29 of the 32 videos were released at this time to provide equipment training over the life cycle: *Selection, Acceptance/Setup, Clinical Use, Decontamination, Maintenance (Preventive and Corrective), and Decommissioning*. A self-paced course covering all equipment and life cycle phases is available on OpenWHO – a free platform for learning and takes about 6 hours with certificates for successful completion. As of April 8th, 6,828 individuals have registered for the course. The videos are also on YouTube. The links are below:

[Rollout Webinar](#)

[OpenWHO](#)

YouTube Training

The WHO Collaborating Center for HTM at the University of Vermont (UVM), Technical Services Partnership was a prime contributor to the training videos with WHO acknowledged contributions from six UVM biomedical engineering student interns and two clinical engineers. ACCE members Bill Gentles and Tobey Clark, UVM WHO collaborating center co-director, were coordinators of the video series involving over 100 contributors from 20 countries.

The collaborating center received a grant from the Pan American Health Organization (PAHO) to develop a policy and plan for healthcare equipment management for the Ministry of Health and Wellness (MOH&W) in Belize. Following many virtual meetings and an on-site survey of the health system, the proposed policy and plan was completed in July 2021. The MOH&W chief executive officer approved the plan in September and on-site training by the collaborating center on the policy and plan was conducted in October at all hospital sites. The policies have been implemented and phase I of the plan has

started with the employment of a web-based CMMS to be used in all hospitals. Additional training and interaction are planned for the Belize MOH&W.

Phase I of a PAHO healthcare technology management initiative for the Caribbean with five webinars and five country focused workshops was completed in December. Collaborating center staff played a key role in these activities. Phase 2 for 2022 is planned which will include 12-week HTM courses on the PAHO Virtual Campus for Public Health and continuation of the webinars and workshops.

Lastly, the University of Vermont, Technical Services Partnership's designation as a WHO Collaborating Center was renewed for another four years. UVM is the only WHO collaborating center focused on healthcare technology in the United States. Mike Lane, co-director, spearheaded the renewal process.

Tobey Clark tobey.clark@uvm.edu

Michael Lane Michael.lane@uvm.edu



Join us to congratulate the 2022 ACCE Advocacy Awards Winners





Thomas Judd
Lifetime Award



Ilir Kullolli
Professional Achievement
in Technology Award



Samantha Jacques
Professional Achievement
in Management Award



Richard Straub
Challenge Award



Arif Subhan
Tom O'Dea Advocacy Award



Priyanka Shah
Marv Shepherd Patient Safety Award



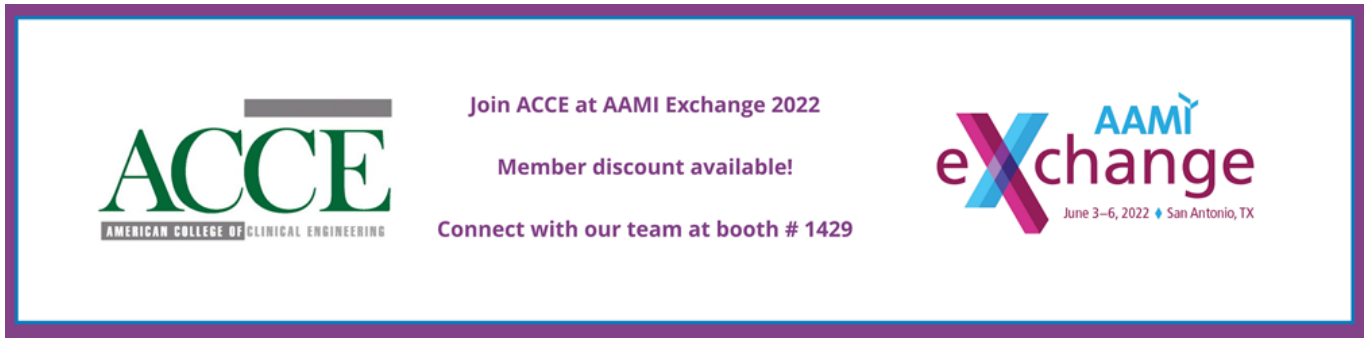
Lucio Brito
A. Hernandez International Clinical Engineering Award



Clinical Engineering Association of South Africa
International Organization Award



ACCE at AAMI Exchange 2022, San Antonio, TX



ACCE is a Contributing Organization for AAMI Exchange 2022. ACCE members are eligible to register for the conference at discounts off the non-member registration fees.

Attend these co-sponsored can't miss events at AAMI Exchange

The 3 R's Round Table – Recruitment, Retention, Recognition

Date: Saturday, June 04, 2022, 7:30AM-10:15AM

Location: Henry B. Gonzalez Convention Center, room 006A, B, C, D – San Antonio, TX

Theme:

Acquiring and retaining qualified HTM/CE professionals struggle is being felt by everyone across the field.

Tools and processes: how can we improve recruitment efficiencies, refine strategies for employment retentions? Aligning recognition with retention?

Time reserved for discussion and interaction with our panel of experts.

Education Session, presented by ACCE: The New Customer Service

Date: Sunday, June 5, 2022

Time: 9:15am – 10:15am

Location: Henry B. Gonzalez Convention Center

Speakers: Eric Aring, Mayo Clinic & Keith Whitby, Mayo Clinic

Description: With the rise of service automation customers expect speed, communication, and low friction service. While this may be getting easier to deliver it is in direct conflict with making customers feel valued and maintaining the customer connection which is a critical component to customer service and HTM operations. Join us to discuss how changes in technology and expectations have changed how we interact with our customers, discuss how we can use our processes, tools and emotionally intelligence to improve our customer experience.

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ACCE at AAMI Exchange2022, San Antonio, TX

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32nd Members Meeting/Awards Reception

Date: Saturday, June 04, 2022, 7:30PM-10PM

Location: Grand Hyatt San Antonio, 600 E Market St, San Antonio, TX 78205

Room: Lone Star A, B

[RSVP here](#)

Join us for an evening of networking with your peers and to congratulate the 2022 Advocacy Awards winners and the 2021 & 2022 Clinical Engineering Hall of Fame inductees.

2022 CCE Oral Exam



Date: June 2-3, 2022

Location: Grand Hyatt San Antonio, 600 E Market St, San Antonio, TX 78205

Rooms : Travis A, Travis B, Travis C, Travis D

Please confirm your Oral exam schedule with HTCC Secretariat certification@accenet.org

Stop by ACCE Booth at Exhibit Floor, Booth # 1429

- Learn about new educational webinar series
- Learn about the CCE exam
- Learn about the membership programs
- Learn about volunteering opportunities
- Learn about ACCE activities
- Connect with old and new friends
- Check/update your membership status



Plan your travel:

To receive the special conference rate, book your hotel no later than May 11. [Click here](#) for an overview of the hotels.

UCONN Clinical Engineering Internship Program

The last few years have been filled with ambiguity and change for the University of Connecticut (UCONN) Clinical Engineering Internship program. I could not be more impressed with the resilience of the interns and the adjunct faculty.

You may recall that I assumed the role of Program Director in the fall of 2019. The former director, Frank Painter, provided a wonderful transition including an in-person Clinical Engineering Week in October 2019. Shortly thereafter, the interns and I began planning the Spring 2020 Clinical Engineering Week agenda and content. Little did we know how much our collective knowledge and creativity would be challenged.

The spring 2020 Clinical Engineering (CE) Week was conducted virtually. We learned a lot about what we could and could not do with the video conferencing platform. We also learned a lot about how we function individually and collectively in a virtual conference – i.e., all day online feels much longer than all day in person. That said, the CE Week “host” interns did a great job of sharing information and images about their host health systems and their individual internship experiences.

Throughout those early days of the pandemic, the interns often found themselves on the frontlines helping their health systems expand capacity and learning how to “learn on the fly” side-by-side with their health system co-workers. After graduation in May 2020, the 2nd Year interns transitioned to full-time positions across the country.

May 2020 Graduates	
Ana Arreygue	Nicole Quintal
Bianca Wyman	Obiananma Nwokike Muon- eke
Cooper Schwabe	Shasha Graves
Lujain Elnihum	

The 2020-2021 academic year continued to challenge the UCONN CE Internship program and the interns. While the academic courses continued via the university’s formal distance learning platform and the diligence of the full-time and adjunct faculty, the Clinical Rotations courses were severely impacted by the clinical lockdowns. We took this challenge as an opportunity to expand our exploration to non-clinical departments that support our work as clinical engineers – e.g., Supply Chain Management, IT, Facilities Engineering, Finance. Again, CE Week was held virtually with adjustments based upon our spring 2020 experience. This academic year was particularly rough, because the interns did not have any opportunities to connect in-person. May 2021 brought graduation and new opportunities for the 2nd Year interns.

May 2021 Graduates	
Andrew Strong	Nicole Conley
David Doyle	Oliver Nigro
Emily Sizemore	Rima Viradia
Jacqueline (Jackie) Bertan	Shelby Johns
John (Jack) Casey	
Julia Podsen	
Kevin Cox	

The current academic year, 2021-2022, has continued the themes of ambiguity and resilience. Scheduling and completing clinical rotations remain challenging in some locations while other locations are settling into their “new normal.” The fall CE Week was held on the UCONN campus in a Biomedical Engineering conference room at the Bronwell Building because physical space capable of providing the necessary physical distancing was extremely limited and the “host” health systems still had many visitor restrictions in place. While we relied on virtual presentations from guest speakers at “host” health systems

and beyond, the interns were able to connect in-person with each other to begin building the core of their professional networks.

The delta and omicron variants introduced renewed challenges, so the spring CE Week was designed as a hybrid event. This allowed the interns to determine the most appropriate way for each of them to engage with the content whether that was in-person on the UCONN campus or via the video conferencing platform. Once again, we were fortunate to have the support of guest presenters from our “host” health systems and beyond who shared their expertise virtually with the interns.

Like the graduates before them, the current cohort of 2nd Year interns look to the broader clinical engineering community to help them transition from decades of life as students into their new professional lives. These interns continue to support their “host” health systems while they apply and interview for permanent positions as well as complete their final academic course work.

May 2022 Graduates	
Alexandria (Alex) Castillo	Joemart (Ian) Contreras
Caroline Lynch	Jacob Crisafulli
Dana Hamed	Olivia Zimmerman
Emily Borges	Renee Gordon
Hailey Michael	

I encourage you to reach out to all of these recent and about-to-be graduates of the UCONN Clinical Engineering Internship program. Congratulate them, get to know them, and share your experience and expertise with them.

I would be remiss if I did not thank the health systems that host the UCONN Clinical Engineering interns. These organizations derive great value from having the

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Critical first step for securing your IoMT devices

According to a recent [AllTheResearch](#) report, the global Internet of Medical Things (IoMT) market is growing annually at 24.4%, and will reach \$254.2 billion in 2026. This is one of the fastest-growing markets, with the number of IoMT devices having proliferated at a bewildering rate to [20-30 billion devices in 2020](#).

IoMT devices provide significant [business benefits](#) to Healthcare Delivery Organizations (HDOs) including improved patient care, lower per patient cost, improved patient experience, and reduced burden on practitioners. However, twin issues of management and monitoring of these devices have created new challenges for HDOs. In particular, securing these devices is critical to maximizing the business benefits.

The good news is that help is available through a constellation of vendors that can help HDOs meet these challenges. But success depends on making the right pick. Technology provided by these vendors is complex, so picking the right vendor could be daunting. Consider the following 4 criteria before making your decision:

1. Secure before procure - the best miti-

gation strategy is to only buy secure devices. Technology can help in modeling risk for any new device before connecting it to the network. Your IoMT security vendor should provide secure configuration guidelines on how to connect and configure medical devices in the healthcare environment. Your IoMT security vendor should allow risk modeling to assess and quantify risk based on the potential future state of devices on the network.

2. Passive data collection - many IoMT devices are susceptible to malfunction if a procedure is performed concurrently with a vulnerability scan. Active scanning of devices can also jeopardize patient safety. Passive scanning ensures that data collection is non-intrusive and not resource intensive.

3. Identify exploitable vulnerabilities and prescribe mitigation strategy - just identifying the vulnerabilities is not enough. Technology has to calculate attack vectors to establish if a vulnerability can be exploited. Calculating attack vectors requires research on the vulnerability and real-time, deep analy-

sis of the environment and ecosystem specific to each device and hospital. If a vulnerability is exploitable, potential mitigation strategies should be suggested. Remember that segmentation or patching is not always the correct solution or the only solution.

4. Forensic data analysis - in an unfortunate event where an HDO has to endure a security breach or patient safety incident, a root cause analysis is required to ensure that a similar breach does not happen in the future. A security vendor needs to have the capability to collect all network and related data, including examination of raw packets for forensic analysis.

HDOs can greatly benefit by leveraging IoMT devices in improving operations. Realizing the full potential of IoMT devices is a journey and selecting the best-in-class IoMT cybersecurity provider is the critical first step.

Dinesh Katiyar, Head of Business Development, Assimily

dineshk@asimily.com

UCONN Clinical Engineering Internship Program (continued)

(Continued from page 6)

UCONN CE Internship Host Health Systems		
Baystate Health	Middlesex Health	VA Greater Los Angeles Medical Center
Boston Children's Hospital	UCONN Health Center	VA North Texas Health System
Geisinger Health	UMass Memorial Health	Yale New Haven Health
Hartford Health	Lifespan Health	
Kaiser Permanente	Massachusetts General Hospital	

interns as part of their teams but do so by providing great value to the interns.

I encourage you to reach out to me or the CE leaders at these health systems to learn how your health systems might benefit from hosting a UCONN CE intern.

Thank you for all you do every day. Be well.

Carol Davis-Smith, MS CCE FACCE AAMIF

Program Director – UCONN BME Clinical Engineering Internship Program

Carol.Davis-Smith@uconn.edu

Welcome New ACCE Members

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

Name	Class	Job Title	Organization	Country
Enrique Ortega	Individual	Sr. Field Service Engineer	Philips Healthcare	FL/USA
Mairead Smith	Institutional/Individual	Sr. Project Engineer	ECRI	PA/USA
Brad Bonnette	Institutional/Individual	Sr. Project Officer	ECRI	PA/USA
Neethu A. Mathew	Individual	IT-Enterprise Tech Services	Northwell Health	NY/USA
Brendan Gribbons	Individual	Regional Engineering Team Manager	Providence Health Care	Vancouver/Canada
Larry Roberts	Institutional/Individual	Associate Director, Instrumentation and Technical Services	University of Vermont	VT/USA
Brian Julius	Candidate	Supervisory Biomedical Equipment Support Services	Indian Health Service	SD/USA
Kevin Davis	Corporate/Associate	President	ERD-US	NV/USA

Congratulations goes to the following member who was upgraded to Individual Status:

Zachary Smith, Clinical Engineer at Houston Methodist Hospital, TX.

Welcome to our newest corporate member:

ERD Medical Equipment Solutions



ACCE Website Job Postings

For posting job opportunities, please contact Dave Smith at

advertising@accenet.org

ECRI Perspectives: A Busy Spring

Spring is in the air elsewhere, and Plymouth Meeting is enjoying Spinter, the season in which it swings from 62 degrees and sunny to 26 and whiteout blizzard overnight. Tank tops and parkas at the ready, here's what we're focused on this month:



1. We keep making a difference in medical devices. While investigating a problem reported by a member of ECRI's patient safety organization (ECRI and the Institute for Safe Medication Practices PSO), in which a Baxter infusion pump's upstream occlusion alarm failed to trigger, we found that the manufacturer was aware of the issue but was initially not planning to notify all users about it. Without an alarm, it is likely that an occlusion would not be noticed, and a patient could go an extended period without the medication. In response to this safety issue, ECRI began an investigation that resulted in the publication of a Hazard Report in December 2021. Spurred in part by ECRI's investigation, the manufacturer issued a field correction to notify all users. The issue was further escalated to an FDA Urgent Safety Communication in February and a Recall in March. This case is just one of many that exemplifies one of ECRI's core strengths: the ability to influence manufacturers to do the right thing.
2. We're so proud of our award-winning staff. Device Evaluation Principal Project Engineer Juuso Leinonen, BEng, was announced as the 2022 recipient of the ACCE-HIMSS Excellence in Clinical Engineering and Information Technology Synergies Award. This award recognizes leadership in promoting and implementing synergies between the clinical engineering and information and technology professions with contributions either professional or technical in nature. The recipient of the Excellence in Clinical Engineering and Information Technology Synergies Award is selected jointly by the Boards of Directors of the American College of Clinical Engineering (ACCE) and HIMSS, and Juuso was recognized during the 2022 HIMSS

Global Health Conference & Exposition in Orlando.

3. We're publishing new science in the field of duodenoscope cleaning safety and workflows. Device Evaluation Principal Engineer Amanda Sivek served as lead author for a landmark survey of hundreds of frontline staff involved in the precleaning and reprocessing of duodenoscopes. We found:
 - a) Most respondents experience pressure to work faster when cleaning duodenoscopes.
 - b) Most finish pre-cleaning in ≤ 10 minutes and manual cleaning in 16-to-30 minutes.
 - c) Cleaning duodenoscopes caused body fatigue or discomfort for >75% of respondents.

Want to support your colleagues in Central Sterile? Check out our article, Healthcare Worker Feedback on Duodenoscope Reprocessing Workflow and Ergonomics, in the American Journal of Infection Control.

4. We're expanding our global reach again. Our Asia-Pacific Office in Kuala Lumpur is busy ramping up for a big year of device evaluations after a hiatus due to COVID. This evaluation lab provides an opportunity for us to get our hands on products that are not available in the U.S. Keep an eye out for our upcoming coverage of ventilators, high-flow oxygen, O₂ concentrators, and vital signs monitors.
5. We're reaching out to our colleagues in Risk and Safety. ECRI just released our annual Top 10 Patient Safety Con-

cerns in conjunction with our affiliate the Institute for Safe Medication Practices (ISMP), to help organizations identify imminent patient safety challenges. The 2022 edition of our list features many first-time topics, and emphasis is on potential risks that could have the biggest impact on patient health across all care settings. The number one topic on this year's list has been steadily growing throughout the COVID-19 pandemic and impacts patients and staff on all levels: staffing shortages. Prior to 2021, there was a growing shortage of both clinical and non-clinical staff, but the problem has grown exponentially. In early January 2022, it was estimated that 24% of US hospitals were critically understaffed, while 100 more facilities anticipated facing critical staff shortages within the following week. Want to help your friends in risk and safety? Point them to these safety concerns and systems-based approaches to eliminate them. <https://www.ecri.org/top-10-patient-safety-concerns-2022>

I hope we're able to connect in person soon! But, in the meantime, wash your hands, support your precious staff, and tell us what you're seeing.

*Erin Sparnon,
Senior Engineering Manager,
Device Evaluation, ECRI
esparnon@ecri.org*

AAMI Update

Introducing AAMI's New President and CEO

Following an eight-month search and the evaluation of more than 300 candidates, the AAMI Board of Directors announced Pamela Arora, a respected healthcare leader, as its next president and CEO. Arora, who serves on the AAMI Board, most recently served as Senior Vice President of Strategic Technology at Children's Health System of Texas, where she was Chief Information Officer for 14 years.

"I'm honored to lead AAMI as its next president and CEO. I first moved into the healthcare technology field for several reasons, including the industry's readiness to adopt technological transformation. But the most important reason is the mission of using technology to improve the health and livelihood of those around us. That's the goal of AAMI's many stakeholders, and it's at the very heart of AAMI's role as a trusted, neutral convener," Arora said.

At Children's Health, Arora was responsible for directing technology efforts to support capital projects planned and underway at the system. Before joining Children's Health in 2007, Arora served as SVP and CIO at UMass Memorial Health Care in Worcester, MA, CEO of LiquidAgents Healthcare, and CIO of Perot Systems in Dallas, TX.

"As a leader, the most important lesson I've learned is that you can't do it all by yourself—you must surround yourself with team members who work well together toward a common goal. I am very much looking forward to working with AAMI staff, volunteers, and members in our shared mission," Arora added.

"Over the past several years, AAMI has invested in the people and systems necessary to support the needs of our members as we continue to advance the field of health technology. With Pamela on board, we are poised to begin an era of greater growth and extraordinary possibility," said Steve Yelton, chair of the AAMI Board of Directors and Professor Emeritus at Cincinnati State Technical and Community College. "I also want to extend our appre-



ciation and gratitude to Steve Campbell, who served as acting president and ensured that AAMI continued to dutifully fulfill its mission."

Arora's history as a longtime supporter and active AAMI participant was a major benefit in her selection as AAMI's next president, "as well as her impressive record of leading both healthcare and non-healthcare related technology organizations as an executive," said Prust, Global Standards Director with 3M Health Care. "I am excitedly looking forward to collaborating with her and the AAMI team to evolve the organization and lead the way for safe and effective use of healthcare technology."

After more than a year serving as acting president, Steve Campbell plans to remain engaged with AAMI, where he will work on the transition and his roles as AAMI's COO and executive director of the AAMI Foundation.

"Despite the challenges that all organizations have faced the past year, AAMI is financially strong, our membership is growing, and our mission is as important as ever. I'm confident that this organization is on the right path and—with its new CEO—in good hands," Campbell said.

AAMI members can look for more ways to get to know the organization's CEO, including a meet and greet at the AAMI

eXchange in San Antonio this June.

AAMI Comments on Proposed Quality System Regulation Change in FDA Meeting

In a virtual [public advisory committee meeting](#) of the FDA's Device Good Manufacturing Practice Advisory Committee on March 2, committee members and the public discussed a [proposed rule](#) with far-reaching implications for the medical device industry—an alignment of the FDA's Quality System Regulation (21 CFR 820) with the international consensus standard for devices, [ISO 13485:2016, Medical devices—Quality management systems—Requirements for regulatory purposes](#).

The change has been a long time coming, said Ariel Seeley, associate director of regulatory documents and special projects in the Office of Policy at the FDA's Center for Devices and Radiological Health.

"Over time, regulatory bodies coalesced around the international standard for quality management systems for devices, ISO 13485," said Seely at the meeting. "With its current proposed rule, FDA is announcing its intention to take [the] next step to further ensure its [Quality System Regulation] remains harmonized with current global standards."

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Commit To Your Success

“If we did all the things we’re capable of doing, we would literally astonish ourselves.”

—Thomas Edison

We all go about our life day to day, marking things off our “to-do” list, getting our work done and hoping for a good day. When we face a challenge with our health, we go to the doctor or when we need to do our taxes, most of us hire an accountant. We don’t think about the cost but know that it must get done and a subject matter expert is the right choice. But rarely when someone is “stuck” or feeling miserable in their current job do they

If you answered “yes,” to at least two of these questions, you probably need to make some changes and assess your current situation more deeply.

Here’s the thing. A lot has changed about how to land that dream job with all the current technologies and competition. Interviews are now over Zoom or video and getting selected for an interview can be challenging without the right resume or approach. A bit of advice if you want to start exploring new job opportunities on your own:

- Dust off that old resume and update it to include only the last 10-12 years of work experience in the job section. Trust me 5+ page resumes are not met fondly.

ences, have a clear understanding of their credentials, years of experience and specialty areas. If you are an engineer, for example, you would want to engage with a coach that understands the various engineering specialties, roles, structure, and talent landscape. Knowing who’s hiring, in demand skill sets and the current employment market should be top of mind to any qualified coach.

A coach needs to commit to deliver their parts as much as you need to commit to doing any “homework” and attending all meetings. It’s a dual commitment. Think about what you really need and want to focus on to move forward. Most coaches offer a variety of services and packages that may include:



know who to call or where to seek help. Most of us that have faced this situation, call a friend, confident, parent or perhaps a mentor. While these are important people in our lives, they typically have little understanding of how to go about finding a new job or giving professional career advice.

This isn’t a call to action for everyone to immediately find and hire a career coach. First ask yourself a few questions:

- Are you feeling unmotivated at your current job? Have you been passed up for promotion?
- Does the thought of starting a job search seem daunting or completely overwhelming?
- Do you need to bring balance and joy back into your life?

- Make sure your key skills are bulleted at the top of your resume as most screening systems use algorithms to filter candidates looking for key words.
- Network and reach out to former colleagues to explore opportunities.
- PREPARE for your interviews!

If your job and life are too demanding or you’re not finding success on your own, consider finding a qualified career coach. A career coach can not only be a good investment in yourself but also eliminate wasted time and energy.

How to find a career coach and choosing the best one for you is very much like picking a new doctor. It’s important that you meet with them in person or via video to assess their style and if you two are a good “fit.” Be very careful to check refer-

- Resume & LinkedIn profile creation
- Coaching sessions in person or via video (2-3 months)
- Interviewing Preparation
- Goal Identification
- Cover letter(s)
- Job search strategy
- Networking
- Career guidance and support

Whether you pursue a new direction for your career alone or with a coach, please know that you must commit to your success. I will give the analogy of a person that plays a musical instrument and seeks

(Continued on page 13)



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AAMI Update

(continued)

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Global harmonization of regulatory requirements introduces great efficiencies, she added, “such as ensuring favorable marketing conditions to potentially support earlier access to devices, promoting competition and efficiency, and reducing unnecessary duplication of effort.”

In comments delivered to the public meeting, AAMI’s vice president of standards, Amanda Benedict, lauded the nearly three decades of work by standards professionals to make quality systems harmonization possible, as well as the numerous benefits that harmonization would allow. AAMI administers the Secretariat to ISO/TC 210, the international technical committee responsible for the development of ISO 13485, as well as the US Technical Advisory Group to ISO/TC 210, which is responsible for the U.S. national adoption of the ISO standard.

“Consensus-based uniform and systematic approaches to quality management across the world can improve the safety and performance of medical devices globally, which benefits patients, and also encourages innovation within industry and facilitates expedited and less costly introduction of products into new markets,” Benedict said. “AAMI has long believed that ISO 13485 should become the global quality system standard for medical devices worldwide, and we support efforts towards regulatory convergence. The adoption of the new rule by the FDA would essentially make this a reality, leading to improved safety, effectiveness, and availability of medical technology for all.”

Also providing feedback were the medical device trade association AdvaMed and Medical Imaging & Technology Alliance (MITA). Representatives from both organizations expressed overall support for harmonization with ISO 13485, citing re-

duced costs and greater efficiency for companies.

However, both groups sought clarification on the length and process of the transition period times and the role of ISO 13585 certification and inspections. For example, Jamie Wolszon, vice president of technology and regulatory affairs at AdvaMed, recommended “sufficiently long” transition period of two years to protect smaller medical device companies and provide opportunity for training.

The FDA is accepting comments on the proposed rule until May 24 at www.regulations.gov, Docket No. FDA-2021-N-0507. The proposed rule was published in the [Federal Register Notice](#).

Commit To Your Success

(continued)

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out a music teacher. The teacher can show you how to play the music, point out how to play the instrument better and show you other ways to improve your skills. However, if you don’t practice or implement the changes to make yourself a better player then you will stay at the same level of performance. This is the case with your career journey and finding your own success.

So, what might have started out as “I need to find a new job” could result in not only a better job but personal growth for you as a professional and person. Take the time to know what is missing in your current situation so you don’t run from one bad situation to another bad situation. A person that goes to work happy, 99% of the time, shows up strong and does better work. Definitely a win-win situation and formula for success.



Jennifer Garcia, CPCC
President, My Career Calm
www.mycareercalm.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 cover please contact editor@accenet.org.

Scenario for the following CCE Prep questions: You're the manager of a Clinical Engineering (CE) department at a large hospital. You are conducting a review of work order problem trend data for the last year and these questions are related to your findings.

1. You find that on a certain in-patient floor (20 East), there has been a significant increase in the following Work Order Resolution codes for certain medical devices compared to last year and compared to other comparable departments: No Problem Confirmed, Control Setting issue (i.e. Knobology problem), and other Use(r) Error codes. How do you approach solving this issue?
 - a. Schedule a meeting with the Nurse Manager for 20 East to explain your findings and discuss how you might reduce these problems.
 - b. Report the problem to the Chief Nursing Officer (CNO)
 - c. Discuss with the BMET(s) who have worked on these workorders to gather additional details and their impression of what is causing these problems.
 - d. Do nothing
 - e. a and b

Correct answer: "c"

Discussion: The best answer is to first talk to the BMETs who worked on these workorders, and then talk to the Nurse manager. Try to research further to see if equipment aging, consumable problems, training or other issues are at the "root" of the problem. See Question 2 below for more discussion.

2. At the meeting with the Nurse Manager, they explain that their department has been very busy and understaffed. They have started to use more float pool nurses, traveling nurses, and new graduates. Also, the nursing staff is frustrated with some of the older equipment. After further research, you agree that additional training may help the problem. You look at training options. Which option(s) probably makes the most sense in this situation?
 - a. A mandatory three hour comprehensive, on-site in-service for ALL 20 East nursing staff by the manufacturer/vendor of the equipment most impacted by the problem.
 - b. A series of short (e.g., 5 minute) on-line videos explaining some of the significant issues and how to mitigate them that can be viewed by any staff when they have time, and/or shown during on-boarding, huddles, department meetings etc.
 - c. No training. Wait and eventually funding will be available to replace the older equipment.
 - d. A comprehensive on-site in-service for a few key staff, who can then act as trainers and resource nurses for other staff.
 - e. b and d

Correct answer "e": (b and d)

Discussion: Training is needed but this department is too busy to demand that all staff attend a three hour in-service. By providing short on-line video inservices that anyone can view when they have time some will take advantage of that and may learn something new about operating the equipment, and hopefully, reduce some of the problem. Also, by providing additional comprehensive information to a few nurses who can relay that information to other staff, hopefully, some improvement will take place. In addition to communicating this problem to the Nurse Manager, CE's role might be to produce the 5 minute videos.

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

Education Committee Report

The 2021-2022 ACCE Education Webinar series (free for ACCE/Collaborating members) continued with these 2 additional sessions:

- On February 10th with speaker Herman McKenzie, moderated by Binseng Wang. The speaker outlined The Joint Commissions' Role in Accreditation, Survey Preparation and Documentation and answered attendees questions.
- On March 10th session with speaker Priyanka Upendar and Darwin Fontanares, moderated by Tony Cody. We had a discussion on Developing and Managing Policies and Procedures in HTM/CE.

If you missed any of the live sessions, check the on-demand recordings at <https://accenet.org/publications/Pages/ACCEWebinars.aspx>

The image is a promotional graphic for a webinar. It features the ACCE logo (American College of Clinical Engineering) in the top left. The main title is '2021-2022 Educational Webinar Series' followed by 'An Objective Capital Equipment Planning Method'. A blue cloud-shaped badge in the top right says 'FREE for MEMBERS'. The date and time are 'Thursday, April 21, 2022; 12 pm - 1pm (EDT)'. A text box on the left describes the webinar's focus on capital equipment planning during the COVID-19 pandemic, listing four variables: clinical impact, safety, condition, and supportability. Below this, it states that a replacement plan can be adjusted to meet hospital priorities. On the right, under the heading 'Speakers:', there are two headshots. The first is Morgan Ayers-Comegys, BBA, MHA, Director of Capital Equipment Planning at Sodexo HTM. The second is Binseng Wang, ScD, FACCE, Vice President, Program Management at Sodexo HTM.

ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING

2021-2022 Educational Webinar Series

FREE for MEMBERS

An Objective Capital Equipment Planning Method

Thursday, April 21, 2022; 12 pm - 1pm (EDT)

The COVID-19 pandemic has heightened the awareness of healthcare executives to be extremely judicious in their capital spending on medical equipment. Gone are the days when physicians and nurses can get equipment replaced because it has reached "useful life," or new "bells and whistles" are now available. To assist them an objective model has been developed considering 4 sets of variables:

- (1) clinical impact: mission criticality and patient impact,
- (2) safety: recalls, patient incidents and cybersecurity,
- (3) condition: physical state, reliability and age, and
- (4) supportability: parts and service availability and costs.

This method provides a replacement plan that can be adjusted to meet hospital priorities, thus reducing unnecessary capital expenses and, most importantly, lessening patient risks and delay/denial of care.

Speakers:



Morgan Ayers-Comegys, BBA, MHA
Director of Capital Equipment Planning
Sodexo HTM

Binseng Wang, ScD, FACCE
Vice President, Program Management
Sodexo HTM

Register today, so you don't miss the upcoming Educational webinars for the months of April and May:

Pre-registration is required!

ACCE Members, [register for free here](#)

Non ACCE members, [pay and register here](#)

(Continued on page 16)

Education Committee Report (continued)

(Continued from page 15)



2021-2022 Educational Webinar Series



Contracts Management in Clinical Engineering

Thursday, May 12, 2022; 12 pm - 1pm (ET)

This presentation will discuss the purpose and intent of contract as well as the different types of contracts Clinical Engineering departments may be involved in. The speaker will also review basic contracting terms and conditions as well as discuss which terms CE departments should review and possibly reject. Specific clinical engineering topics and terms will also be discussed for inclusion into standard contracts. Finally, other resources to acquire standard terms (specifically medical equipment cybersecurity terms) will be shared.

Speaker:



Samantha Jacques, PhD, FACHE, AAMIF
Vice President, Clinical Engineering
McLaren Health Care

Pre-registration is required!

ACCE Members, [register for free here](#)

Non ACCE members, [pay and register here](#)

For additional information, go to <https://accenet.org/NewsEvents/Pages/Webinars.aspx>

Tony Cody & Nader Hammoud,

Education Committee co-chairs

educationchair@accenet.org

Suly Chi,

Webinar coordinator

secretariat@accenet.org

The Global Clinical Engineering Alliance (GCEA) Update

Have you ever imagined that a single organization across the world might one day provide the stage to do so many things for our profession? Such as sharing knowledge, initiating point-of-care

research on the relationship between clinical engineering and patient outcomes, conducting global conferences, publishing a dedicated journal, organizing an annual global celebration recognizing our practitioners' contributions, creating an award program promoting collaboration between national societies, and serving as the best sound system to communicate all of that to the four corners of the world? Now that we created the Global Clinical

Engineering Alliance (GCEA), this is not imagination but rather reality in progress.

GCEA is the only global not-for-profit organization that was created by clinical engineering professionals, for the development of clinical engineering practitioners, and administered by clinical engineers. GCEA is an organization for national CE associations to come together and collaborate with other healthcare

stake holders (care providers, administrators, regulators, Ministry of Health leaders, academia, industry, and international NGO bodies) all for the mission of improving the patient experience and with predictable outcomes.

GCEA is working closely with IFMBE Clinical Engineering Division (CED) where projects jointly worked on already have produced important results. For example, developing

the methodology and data collection for the Technology and Engineering Management review of The World Health Organization

(WHO) evaluation of innovative health technologies submitted for addressing the COVID-19 pandemic challenges faced in countries considered Low-Resource Settings. During the past two years, GCEA and CED identified and recruited many dozens of CE volunteers who unselfishly donated their experience and time to judge the innovations. The results were published in two documents (available for free online) that are called the WHO Compendium on Innovative health technologies for low-resource setting 2020 and 2021, 1st released August 2021: <https://www.who.int/publications/i/item/9789240032507>.

Another major accomplishment resulted from collaboration between GCEA, CED, and AAMI who together administered the 4th International Clinical Engineering & Health Technology Management Congress originally scheduled for Disneyworld and due to the Pandemic last year was converted into virtual event held in October 2021 <https://www.globalcea.org/icehtmc> on the Global Clinical Engineering Day celebration. In a very short time, GCEA rapid growth has just been documented in its first annual report describing the initiation as well as early development of the organization. Impressive coverage **GCEA 1st Annual Report, January 2022** is a must read for the clinical engineering practitioner.

Additional success from such collaboration is the project led by Tobey Clark and Bill Gentles facilitating **WHO medical products Training Videos related to COVID19**, released in March 2022 <https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/management-use/trainings#>.

The **GCEA Webinar Series, has completed six (6)** webinars so far, and more are planned monthly throughout 2022, with the latest one on March 9, 2022, about *National Clinical Engineering Certification*: <https://www.globalcea.org/webinars>.

Together with CED, GCEA just posted the 500th vetting Issue of Hacking Coronavirus related manuscripts published daily since March 2020. For more information see the repository here: <https://mailchi.mp/iambiomedical/ced-march-2022-update>.

One of the unique tools that GCEA is promoting is the integration of the Health Technology Foundation (HTF) into GCEA - <https://www.globalcea.org/htf-home> thus turning its impact to the wider health population needs under the leadership of Elliot Sloane. The Foundation will issue a call for proposals that will produce evidence for the relationship between the work of clinical engineering professionals, the technology used at the point of care and patient outcomes. It looks to me that every national CE association should become a member of GCEA so our sound system will be loud enough to make a difference.

Welcome all to the Global CE Village!

Yadin David, GCEA Interim President

david@biomedeng.com





CALL FOR PAPERS



Global Clinical Engineering Journal

Health Technology & Innovation Improving Patient Outcomes

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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- Adverse events
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- Clinical engineering
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- Professional development & credentialing
- Quality and outcomes
- Regulation science
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- Software applications
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- Technology management methodologies
- Telehealth and telemedicine

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 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](#) to enter code.



ACCE CALENDAR

<https://accenet.org/NewsEvents/Pages/Calendar.aspx>

21 April 2022, 12pm - 1pm: Educational webinar: an Objective Capital Equipment Replacement Planning Method

12 May 2022, 12:00 PM-1:00 PM Session 9: Contracts Management in Clinical Engineering

02 June 2022-03 June 2022, 8:00 AM-5:00 PM, 2022 CCE Oral

3-6 June 2022, AAMI Exchange 2022, San Antonio TX

04 June 2022, 7:30 AM-10:30 AM, Clinical Engineering Symposium by ACCE (@AAMI Exchange 2022)

04 June 2022, 7:30 PM-10:00 PM, 2022 ACCE members meeting/awards

12 –17 June 2022, IUPESM World Congress 2022, Singapore

16 June 2022, 12:00 PM-1:00 PM, Session 10: Climbing the Clinical Engineering Career Ladder - Value of certifications and keys to gain management experience. Location: Online

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