I hope everyone had a great Healthcare Technology Management (HTM) week (May 19 - 25)! It is that time each year where we acknowledge the work of our professional community. On behalf of the ACCE Board of Directors, I would like to say thank you for your continuing efforts throughout the last year to improve patient care through the provision of reliable, innovative, and safe healthcare technology.

In line with our commitment to continuing education, we are offering a webinar on Managing Clinical Engineering Projects on June 6th. Please remember to register in advance for this session. This webinar session, like the entire series, is complimentary to ACCE members thanks to the support of our co-sponsors.

Arif Subhan and I attended the Canadian Medical and Biological Engineering Conference (CMBEC 46) in Toronto, Ontario where we co-presented a session on Certification in Clinical Engineering on Tuesday, May 28, 2024. We also presented, on behalf of the ACCE, the certificate to the 2024 ACCE student paper competition/Master Division winner, Maryam Sangargir, University of Ottawa, since Maryam is unable to attend the 34th ACCE awards reception in Phoenix. I personally have always been pleased with the fact that the ACCE has this competition in place to encourage young Clinical Engineers in training to develop a technical paper and have it published in a journal. I believe this competition is great encouragement at the start of one’s career.

Work continues as we prepare for our participation in the upcoming AAMI eXchange 24 in Phoenix, Arizona, and as in previous years, ACCE is an official conference contributor. One of the best ways to keep updated with the latest conference changes and news is to check both the AAMI and ACCE websites. If you have not registered yet, I encourage you to do so, and use this registration form to qualify for the ACCE member’s discounted rate.

I hope to see all of you at this year’s AAMI eXchange where we can keep up to date both professionally and personally. This venue is always one of the best opportunities we have for exchanging our thoughts on the latest trends.

Please remember the deadline for submitting your CCE renewal is fast approaching on June 30th. Don’t forget to action this task and please submit your renewal application to avoid late fees or cancellation of your certification.

Finally, on behalf of the ACCE Board of Directors, I hope all of you had a happy HTM week and thank you for your commitment to our mission and shared values in the healthcare community.

Kim Greenwood, President
American College of Clinical Engineering
greenwood@cheo.on.ca
Renew your 2024 CCE Certification by June 30th

Clinical Engineering Certification Program
Renew your 2024 CCE Certification by June 30, 2024

All active certified individuals with a Renewal Expiration Date of June 30, 2024, must complete the 2024 CCE Renewal Application form and submit it electronically to the HTCC via email at certification@accenet.org. The three year renewal fee is $150 if paid by June 30.

Late Renewal (deadline: September 30)
Late renewals will be accepted through September 30th for an additional $150 late fee. For more information, please reference the 2024 CCE Renewal Handbook.

No applications will be considered after the Late Renewal Deadline and will result in loss of certification.

Retired and Emeritus Status
Any active CCE with a renewal expiration date of June 30, 2024, who wishes to change his/her certification status to Retired or Emeritus, must submit the 2024 application by 06/30.
Please refer to the Retired and Emeritus Status Change handbook for additional details.
The Retired Status application fee is $100, while the Emeritus status application is free of charge.

2024 CCE Renewals:
All active Certified Clinical Engineers (CCE) with a June 30th, 2024 renewal date must complete their 2024 CCE Renewal Application form and submit it electronically to the HTCC via email at certification@accenet.org. The three-year renewal fee is $150 if paid via PayPal by June 30. Late renewals will be accepted through September 30th for an additional $150 late fee.

For more information, please reference the 2024 CCE Renewal Handbook.

Retired and Emeritus Status Changes:
Any active CCE with a Renewal expiration date of June 30th, 2024, that wish to change their certification status to Retired or Emeritus Status, must submit the 2024 application by June 30th, 2024. Please refer to the 2024 Handbook and Application for Retired and Emeritus Status Change for additional details.
This column provides example questions and information regarding preparation for the CCE exam. The questions are based on topics from the ACCE Body of Knowledge survey and the CCE Study Guide, version 12. 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.

CCE Study Guide Section 5.1.C Project Management

1. Which of the following elements is one of the two major functions of Project Management?
   A. Personnel evaluations
   B. Project Monitoring
   C. Project Selection
   D. Team member selection

2. Which of the following tools are not typically part of a Project Management Plan?
   A. Work Breakdown Structure
   B. Risk Analysis
   C. Cybersecurity Risk Assessment
   D. Documentation and Configuration Management Plan

CCE Study Guide Section 5.1.J Device Integration Planning

3. Using standards is an important component of ensuring seamless interoperability. Which of the following standards would not be applicable in medical device integration?
   A. HL7 2.X
   B. FHIR
   C. DICOM
   D. SWIFT

CCE Study Guide Section 5.1.O Return on Investment (ROI) Analysis

4. Which of the following costs would be considered ‘Recurring’ expenses that would need to be considered as an annual expense when performing an ROI analysis?
   A. Vendor service contracts
   B. Original equipment purchase
   C. Equipment installation costs
   D. Building infrastructure costs required for installation

(Answers on page 18)
ACCE is a Contributing Organization for AAMI eXchange 2024. ACCE members are eligible to register for the conference at AAMI members discounted rate. Just download and complete this [pdf form](#).

Mark your calendar and join ACCE at AAMI eXchange. See you in Phoenix!

For more information:

**Registration Information**

**Registration form (pdf)**

**eXchange24 Schedule at a Glance**

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**Stop by the ACCE booth at Exhibit Hall Booth # 826**

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

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**2024 CCE-US Oral Exam**

**June 13 - 14, 2024**

Location: Sheraton Phoenix Downtown

Please confirm your exam schedule at [certification@accenet.org](mailto:certification@accenet.org)

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This two-day Expo Only pass ($100 value) includes access to the Expo Hall Saturday and Sunday.

To register, go to [www.AAMIeXchange.org](http://www.AAMIeXchange.org), select the “Expo Only” registration option and enter the coupon code: **ExpoOnlyGuestEX24**

The cost will be updated to zero.

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**Note:** Pass does **NOT** include Friday, lunches, receptions, or education sessions.
ECRI Update

Healthcare Technology Management Week

I hope you were able to celebrate Healthcare Technology Management (HTM) Week May 19–25. This yearly week of celebration is meant to promote awareness of — and appreciation for — the critical work of professionals who manage and maintain the vast assortment of health technology found in healthcare delivery organizations. I did my part by introducing clinical engineering to middle school students on career day.

Malfunctioning Plastic Syringes Made in China

The FDA has warned against using syringes made in China due to malfunctioning products that could cause patient harm. In response, ECRI released a comprehensive market analysis designed to help healthcare providers discontinue the use of the affected syringes and secure safe alternatives. The [report](#) analyzes hundreds of comparable syringes to determine which are considered functionally equivalent. ECRI was at the forefront of alerting members about this issue when it began late last year. We have made these reports available in the [ECRI Newsroom](#) so that all healthcare providers can access this information, regardless of ECRI customer status. In this way we aim to live our mission of doing all we can to reduce preventable harm.

The FDA has been warning healthcare providers and the public about malfunctioning plastic syringes made in China since November 2023. The affected syringes are leaking, cracking, and breaking — putting patients at risk of receiving incorrect doses of medication, and risking serious injury or death. While the FDA advises against using syringes manufactured in China, healthcare providers are working to secure safe alternatives which is a time-consuming process fraught with inefficiencies and delays. Since most of the syringes imported to the U.S. are made in China, this issue has the potential to cause serious supply chain disruptions.

ECRI has shared recommendations about mitigating the threat posed by these syringes since late last year. In an [ECRI Exclusive Hazard Report](#) from December 2023, ECRI advised its members to review their inventory of all plastic syringes to identify those made in China, contact vendors to request the original equipment manufacturer (OEM) identification, monitor recall notices to identify affected lots, and contact ECRI for help identifying alternative products or to request lot-specific quality testing of their syringe inventory.

Safe and Effective Use of Water for Processing of Medical Devices

Every day, hospitals’ central sterile processing teams rely on water as they clean and sterilize a variety of medical devices. This publicly available article on ECRI Blog outlines general considerations to support safe and effective water preparation and use:

[What Hospitals Need to Know: Using Water During Processing of Medical Devices](#)

Keep in touch and let us know your thoughts on how ECRI can better help the clinical engineering community.

Ismael Cordero
Senior Project Engineer, Device Safety, ECRI
icordero@ecri.org

Help Wanted: ACCE News Co-Editor

ACCE News is published six times a year (every other month) and each edition is 10-20 pages long. The ACCE News co-editor is responsible for editing 3 of these newsletters each year and those duties include the following:

- Notifying regular article contributors of the upcoming edition’s submission deadlines
- Editing submitted articles
- Editing photos and graphics
- Editing newsletter pages so that the articles fit on the page
- Writing headlines and sub-headings
- Submitting draft Newsletter for subsequent review and edit suggestions by the ACCE Secretariat, ACCE President, ACCE Co-editor, and ACCE Managing Editor
- Completing final editing for submission for publishing
- The co-editor may also on occasion write articles

Currently, the software used for this process is Microsoft Publisher. It takes approximately 10-20 hours per issue to complete the above-mentioned editor tasks.

If interested, please contact editor@accenet.org.
Clinical Engineering Symposium
Navigating Homecare & Virtual/TeleHealth Technologies - Adapting to Shifting Patient Care and Tech Support Challenges at Home

Saturday, Jun 15, 2024, 7:30 am - 10:15 am
Phoenix Convention Center, Phoenix, AZ

Date: Saturday, June 15th, 2024, 7:30 am -10:15 am
Location: Phoenix Convention Center, Room 129 AB
Light breakfast: 7:15 am

Description:
Whether we call it “Hospital in the Home”, “In-Home Services”, “Acute Hospital Care at Home”, or any other name, your patients are moving out of your facility and taking devices with them. This opens up new opportunities and challenges in ensuring patients have the right technologies considering their needs and activities, and ACCE is here to share what we have learned so far.

Join us for this half-day working session to share your experience and to hear from your peers on their hospital-in-the-home model. Learn to overcome homecare technology support challenges.

Our stellar line-up of speakers and facilitators will guide you through active learning on topics you just can’t miss if you want to be ready for homecare in your organization:

- Choosing the right homecare technologies
- Technology service and support
- Connectivity and Cybersecurity considerations
- New: Audience-generated discussion questions. Come with your own questions for our experts!

Registration form: Click Here.
34th Members Meeting and Awards Reception
Phoenix, Arizona

You are invited! Join us for an evening of networking with your peers and to congratulate the 2024 Advocacy Awards recipients, 2024 ACCE Fellows, 2024 Clinical Engineering Hall of Fame inductees, AAMI Foundation/ACCE Robert Morris Humanitarian Award recipient, and the 2024 Student Paper competition winners.

Education Session by ACCE

Going Through a Merger & Acquisition - Lessons Learned and Keys to Success

Date/Time: Sunday, June 16, 2024, 8:00 am - 9:00 am
Location: Phoenix Convention Center, Phoenix, AZ

Date: Monday, June 17th, 2024
Time: 8:00 am – 9:00 am
Topic: Going Through a Merger & Acquisition – Lessons Learned and Keys to Success
Speakers: Tony Cody, Sodexo HTM, Mike Powers, Intermountain Health & Ilir Kullolli, Stanford Children’s Health

Description:
With the ever-changing HDO ownership landscape, merger and acquisitions are a common occurrence with 53 instances in 2022. It is crucial to the success of HDO organizations to align with the new organization's principles to provide safe and effective access to medical equipment. In this session, attendees will be exposed to best practices and lessons learned.
Women in Clinical Engineering

In this issue, we are highlighting the journey of our female members of the ACCE Educational Committee. These female members of the ACCE Educational Committee support and promote the profession of Clinical Engineering and agreed to share their thoughts on their careers as Clinical Engineers.

Angelina Chiaracane, MS, CHTM: Angelina works as a Biomedical Engineer for the Department of Veterans Affairs in Tampa, FL and is a graduate of the University of Connecticut’s Clinical Engineering Master’s Program. She started volunteering with ACCE in 2020 and is an active member of the ACCE Education Committee.

Angela Bennett, BS, CHTM: Angela works for TRIMEDX at the FMOL Our Lady of the Lake Baton Rouge Market in Baton Rouge, LA. She joined the HTM field in 2014 through the United States Army. She has contributed to the ACCE Education committee since 2022.

Maryam Samiee, MSc, PEng: Maryam began her career as a Clinical Engineer in 2008 at the Health Sciences Centre in Winnipeg. The scope of her responsibility soon expanded, first to the regional level and subsequently throughout the entire province. The service eventually transformed into a provincial entity, where she continues to work to this day. She became a member of the ACCE Education Committee in September 2022.

Priyanka Shah, MS: Priyanka is a principal project engineer at ECRI where she evaluates medical technologies and integrates human factors engineering and safety science to help hospitals and health systems make decisions on technology selection, implementation, and risk mitigation. She joined ACCE in 2023 and has been actively involved with the Education committee.

What do you think of being female in engineering?

Chiaracane: I really enjoy the work I do each day serving the Veterans in our community, but I specifically enjoy being a female engineer because it is an opportunity to defy stereotypes. There are, and will be, some instances of implicit bias in any workforce, but this can be overcome by exemplifying our knowledge and confidence in our abilities to break stigmas! I find it so inspiring to see other females in leadership positions within my organization, and it shows how we can, together, empower each other to reach our max potential as women in engineering.

Bennett: It’s empowering and rewarding. To be able to work in a male-dominated industry and to be a leader in this industry is an honor. I love what I do and I could not ask for a better support system. I have a support system of females as well as males who have been my mentors and have truly helped me get to where I am today. The wisdom and knowledge that I take in daily is humbling.

Samiee: As a female Clinical Engineer in the healthcare industry, I am immensely proud of the role I occupy. Working within a sector that values competence and dedication above all, I have consistently felt respected and valued by all my colleagues, regardless of gender. The inclusive nature of our field is reflected in the diversity of its leadership, many of whom are women.

Shah: I’m part of a team and an organization where half of the workforce are women, and I’ve had strong female leaders. I’ve always felt supported by both my colleagues and the clinical engineering community.

(Continued on page 9)
Women in Clinical Engineering (Continued)

Who was your greatest influence/advocate for choosing clinical engineering?

Chiarcane: I was positively influenced by the careers of my parents – my Mom is a Nurse and my Dad is an Electrical Engineer. I enjoyed hearing about the fast pace and gratifying environment of the hospital but also the challenge and technical, critical thinking an Engineer needs to apply. When I found out about the Clinical Engineering field from an alumnus of my undergraduate University, it seemed like the perfect blend of the two career fields of my parents and an appropriate fit for my expectations in a career where I can apply interpersonal skills and technical knowledge while intersecting with healthcare.

Bennett: Honestly, when I joined the Clinical Engineering field, I didn’t know it existed. It was a gap that the US Army needed filled and I wanted to be in the medical field. So, I signed up and it’s been the best decision I could have ever made for my career and future. Since then, I have gained quite a few mentors in the field. One of them is AAMI’s VP Danielle McGearry. She inspires me every day to be the best leader that I can be in a constantly changing field.

Samiee: My path to a career in clinical engineering unfolded by chance. Initially, I wanted to become a physician but the lengthy educational commitment required gradually dissuaded me. This led me to explore engineering, where I stumbled upon biomedical engineering—a field that seamlessly combined my interest in medicine with engineering. It was during my tenure as a researcher that enlightening discussions with well-informed and friendly colleagues revealed the opportunities in clinical engineering.

Shah: Since high school, I’ve been fascinated by the intersection of engineering, medicine, and biology. I owe immense gratitude to my parents for noticing my interest in these subjects early on and encouraging me to pursue biomedical engineering.

What surprises you in clinical engineering?

Chiarcane: Each day is different: different challenges, different stakeholders, different learnings! This makes the role enjoyable, in my opinion, because it shows a Clinical Engineer is always growing and enhancing their skills.

Bennett: Nothing. Nothing surprises me in this field. The medical field is forever changing and I keep my mind opened and just adapt to the changes. And I encourage my team to do the same thing.

Samiee: When I first entered the field of clinical engineering, I was under the impression that female engineers were in the minority. To my surprise, I have since discovered that this field is increasingly attracting female professionals. It’s been inspiring to see this shift towards greater gender diversity, reflecting a broader change in the engineering landscape.

Shah: I find myself not only surprised but also inspired by the unwavering perseverance of our community to tackle every facet of medical devices and technologies, always prioritizing patient safety while navigating the complex healthcare ecosystem.

What would you tell other women when considering engineering?

Chiarcane: Be a part of this supportive and bonded community of female engineers! The number of women in engineering is growing, so it is great to have other women serve as mentors or resources for overcoming relatable struggles. It’s inspiring to expand this community of female engineers and bring in so many other perspectives while also being an example for future generations.

Bennett: Do it!! It’s a very rewarding career and field to be in. You will learn something new every day! You will stay valued! You have the potential to grow and do things in the field you never thought would be possible. Stay focused! Stay adaptable! “If you love what you do, you will never work a day in your life!”

Samiee: I highly encourage them to explore the field of Healthcare Technology Management. It’s a realm where our skills can truly make a difference, merging technical expertise with healthcare applications.

Shah: Embarking on the path of engineering opens a world of diverse opportunities across various fields, while also equipping us with the skills to tackle any challenges, anticipated or not. I’ve always felt welcomed by the engineering community and found solid peers and mentors in this field. Join me as a fellow traveler on this exciting and fulfilling journey! Also, don’t hesitate to reach out to explore more about the field or connect further!

Erin Sparnon, MEng
Member, Advocacy Committee
Erin.sparnon@gmail.com

Erin Sparnon, MEng
AAMI Update

AAMI Releases Guidance on FDA CGMP’s for Combination Products

As the breadth and scope of combination products around the world continues to ramp up, are U.S. manufacturers equipped with the best design plans possible? A brand-new guidance document, released by the Association for the Advancement of Medical Instrumentation (AAMI), will assist manufacturers in aligning with the latest best practices for manufacturing combination products.

AAMI TIR48: 2024 Quality management systems (QMS) recommendations on application of the U.S. FDA’s CGMP final rule on combination products is designed to assist manufacturers with abiding by the Food and Drug Administration’s regulation on current good manufacturing practices (CGMPs) for combination products.

Combination products are defined as products that incorporate drugs or biologics with medical devices. However, the taxonomy and regulations surrounding these products may vary wildly from country-to-country, leading to confusion for manufacturers looking to stay compliant with U.S. requirements. AAMI TIR48 provides a comprehensive resource for manufacturers navigating FDA requirements for combination products and ensuring they can bring medical devices to market that will benefit patients.

AAMI TIR48 was produced by the AAMI Combination Products Committee, which is co-chaired by John Weiner, Director of the Office of Global Operations at FDA and Susan Neadle, an industry veteran and leading expert in the field of combination products.

According to Neadle: “Sometimes you’re using the exact same words for the drug world as you use in the device world, but the interpretation is different. That creates all sorts of confusion, not just for industry but also for health authorities. So, the inspection readiness piece of TIR48 will help you contend with that both internal to your organization and as you’re interfacing with health authorities.”

In short, AAMI TIR48 provides the most current industry guidance for combination product manufacturers as they deal with an increasingly complex regulatory environment. The standard is available for purchase in the AAMI store.

A “Colonial Pipeline” Moment – Axel Wirth on the Change Healthcare Breach

Last April, the House of Representatives Energy and Commerce Committee, chaired by Representative Cathy McMorris Rogers (R-WA), held a hearing on the fallout of the Change Healthcare cyber breach. According to KFF Health News, the attack was first made public on February 21, 2024, and resulted in Change Healthcare’s payment services becoming temporarily unavailable as well as impacting many hospitals’ and pharmacies’ ability to process prescriptions. At that time, doctors, pharmacists, and other healthcare professionals could not discern whether patients had health insurance and payments to healthcare organizations like pharmacies and hospitals were halted. In March, CBS News reported that healthcare delivery organizations across the industry could be losing a cumulative $100 million a day. The cost to UnitedHealth is already estimated at $872 million but is likely to exceed $1 billion and therefore would make it one of the most costly cyber losses for a single organization.

Change Healthcare worked to restore services, but periodic problems have persisted and the company has faced additional cyberthreats. The federal government also continues to take interest, with Senator Ron Wyden (D-OR) promising an April 30th hearing by the Senate Finance Committee.

To better understand the implications of this developing story, AAMI News spoke to Axel Wirth, longtime AAMI member, AAMI Fellow, and chief cybersecurity strategist at the medical device cybersecurity firm Medcrypt. The following represents Wirth’s views as a cybersecurity professional and a friend to the healthcare industry and do not necessarily represent AAMI’s perspective. Our correspondence has been lightly edited for length and clarity.

What are the long-term implications of this breach?

Many have identified the Change Healthcare breach as a paradigm shift for the healthcare industry, similar to the Colonial Pipeline event for the oil and gas industry. I would tend to agree and similarly, I would expect that governments’ and regulators’ efforts to improve healthcare’s cybersecurity posture will accelerate now.

(Continued on page 11)
AAMI Update (Continued)

Do you have any thoughts on the fallout of the breach and what weaknesses it revealed?
It is worth noting the sheer impact these events had on the larger industry. It was estimated that over 50% of US healthcare providers were impacted from a revenue cycle perspective and experienced the impact on their ability to process billings or prescriptions. This is pretty much a traditional single point of failure example but on a very large scale.

What can healthcare delivery organizations and cybersecurity professionals learn from these events?
The lesson learned for us is that we really shouldn’t be looking at security risks as an issue for individual systems or even the individual hospital. It really has become an issue of regional and even national criticality as it affects, due to scale, our larger public health system.

Why all the concern? Was the Change Healthcare breach simply bigger than most attacks or does it imply innovation on part of bad actors?
A noteworthy aspect is the speed and scale of the attack relative to what we have seen in the past. On one hand, this established a new precedent of the level of impact on the industry. On the other hand it is a continuation of increasing attack severity and malice trends as we have been observing over the past years when analyzing HHS “Wall of Shame” breach reporting data.

So, while the attack demonstrated new capabilities from malign actors, this is also part of an industry-wide trend?
Sure. For example, despite 733 breaches reported, 2023 stayed relatively flat compared to the two previous years. However, the number of breached records set a new all-time high, exceeding last year by a factor of 2.5. Further, breaches reported now show 80% classified as “Hacking/IT Incident”, which aligns with my previous statement about increase in targeted and malicious attacks.

Another important trend to note is that of cyber adversaries using strategies to maximize their profits. For example, in the Change Healthcare case, in addition to the initial ransom demand (rumors have it pegged at $22 million) we now see additional extortion affecting patients, with attempts to wholesale the data in the underground markets.

AAMI Staff
Dan Visnovsky
Media Relations Manager
dvisnovsky@aami.org

Congratulations to the 2024 AAMI Foundation & ACCE Robert Morris Humanitarian Award Recipient: Clement Appiah, MS

Clement Appiah sets a good example for all of us in the CE/HTM field with his continuing dedication to our profession in an under-resourced part of the world. He has provided years of selfless support to several international healthcare NGOs (such as Mercy Ships, Operation Smile, Ghana Medical Help) as they carry out their humanitarian efforts in Ghana. He is an excellent role model for young people starting out in our field.

Clement Appiah is a deserving choice for the 2024 Robert Morris Humanitarian Award.

Kim Greenwood, ACCE President
Update from the UCONN Clinical Engineering Internship Program: Spring 2024 CE Week

Winter descended in full force as I arrived on the UCONN campus for the Spring 2024 Clinical Engineering Week (February 13-16, 2024). This was no “walk in the park” for this central Arizona girl! Nevertheless, we had a great week of learning, sharing, and networking lined up so we stayed calm and carried on in spite of the snowstorm!

Day 1 – Spring 2024 CE Week

Day 1 was a return to the virtual CE Week format since roads were too dangerous for travel and the university was closed for the day. We were able to stay engaged and made the best of the snowy day through.

In the morning, we heard from alumni of the UCONN CE Internship program – Dana Hamed, Hailey Michael, Elena Buckley, and Tyler Moxam – who shared insights to growing your career over the long term. In particular, they emphasized that finding your first job is certainly important but it is only the first step in your professional journey.

In the afternoon, Jason Landers and Erin Sparnon coordinated presentations by ECRI team members that provided glimpses into their Device Evaluation work. Their rigorous investigations inspired us to use our own engineering capabilities to support our healthcare organizations to make strong technological decisions.

We wrapped up the day with 1st Year Intern presentations, we heard from FIVE guest speakers! It was a jam-packed day.

The 1st Year interns shared … “The most important thing I learned during my first semester was …. In addition to technological insights, several of the interns shared things they learned about themselves and soft skills that were clearly going to be important to their success in the internship.

We were also joined (virtually) by three friends/colleagues from the VA health system - Arleen Thukral, Arif Subhan, and Clarice Holden. They provided an excellent overview of the VA HTM program along with clarifying information about relevant positions for the UCONN CE interns upon graduation. We all learned a lot - thank you!

We wrapped up our day with a high-energy, super practical LinkedIn presentation by Samantha “Sam” Moriarty. Several of us made adjustments to our LinkedIn profiles that evening.

Day 3 - Spring 2024 CE Week

In addition to wrapping up the last of 1st Year Interns presentations, we heard from FIVE guest speakers! It was a jam-packed day.

Elisabeth George shared her career journey and insights into the quality and regulatory requirements imposed upon medical device manufacturers. We all agreed that the more we learn about the regulatory environment as clinical engineers, the better we can serve our healthcare delivery organizations and collaborate with our industry partners.

Since the 2nd Year Interns were deep into the job search, we had a virtual visit from Michele Manzoli who presented the 2023 Clinical Engineering Salary Survey supported by ACCE - American College of Clinical Engineering. The information was extremely helpful to everyone, but especially to those graduating in May 2024.

While most of our guest speakers joined us remotely, we were happy to have Erin Coon join us in person to share an overview of Crothall Healthcare and the Clinical Engineer (Project Manager) position recently posted for her account in Providence, RI. Similarly, we were pleased to have Dana Hamed join us in person to provide an overview of Middlesex Health’s clinical engineering department and her vision for the team.

We wrapped up the day with a presentation by Jennifer Ott about medical equipment planning within the context of construction and renovation projects. This role seems to be steadily growing as a non-traditional career path for clinical engineers.

Day 4 - Spring 2024 CE Week

After the fall 2023 CE Week, the interns and I decided to invite Frank Painter back to share his career journey and his most interesting projects. Perhaps the most interesting aspect for me was that Frank had never been asked to share his journey, which is

(Continued on page 13)
Update from the UCONN Clinical Engineering Internship Program (Continued)

(Continued from page 12)

extremely unfortunate because it was a fascinating presentation. We were inspired and entertained – photos from the 1970s are like nothing else!

With that, we wrapped up Spring 2024 CE Week. We had an intense week of weather, learning, networking, and even a bit of fun. It was time, though, for us all to return to our hospitals and prepare for finals.

May 2024 – Graduation

Fast-forwarding to the present, our 2nd Year Interns are becoming graduates. As in years past, they’ve worked hard and grown immensely. They have forged bonds with each other and with many of you – the ACCE community. Please take a moment to congratulate them on this achievement.

<table>
<thead>
<tr>
<th>2nd Year Intern</th>
<th>Host Hospital / Health System</th>
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<tbody>
<tr>
<td>Hannah Aseltine</td>
<td>Brigham &amp; Women’s Hospital</td>
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<tr>
<td>Anna Cooper</td>
<td>Yale New Haven Health</td>
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<td>Jackie Cooper</td>
<td>Lifespan / Rhode Island Hospital</td>
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<td>Allie Fabian</td>
<td>VA Greater Los Angeles Health System</td>
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<td>Kaity O’Brien</td>
<td>Geisinger Health / ISS Solutions</td>
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<td>Taylor Recaido</td>
<td>Kaiser Permanente – Northern California</td>
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A huge ‘Thank You’ from me to the host hospitals and health systems that provide the real-world experience that is so valuable to our interns.

Once again ... Thank you to everyone who shared my posts with your networks! That sort of visibility is so very important. Reach out to me if you’re interested in learning more about the UCONN Clinical Engineering Internship program or if you would like to hire one of our talented students!

Carol Davis-Smith, MS CCE FACCE AAMIF
Program Director – UCONN BME Clinical Engineering Internship Program
Carol.Davis-Smith@uconn.edu
M.Eng.: Biomedical Engineering with Concentration in Clinical Engineering

We are thrilled to announce the launch of our poster promoting the Master of Engineering (M.Eng) program in Biomedical Engineering with a concentration in Clinical Engineering at the Ottawa-Carleton Institute for Biomedical Engineering (OCIBME). As a collaboration between Carleton University and the University of Ottawa, OCIBME combines academic resources from both institutions with clinical engineering expertise from leading hospitals and research institutions. We invite all interested candidates to explore this exciting opportunity to advance their careers in Biomedical Engineering with a focus on Clinical Engineering. Please take a moment to check out the poster (next page) for more information and help us spread the word within your network!

The 2-year M.Eng. program offers students a comprehensive foundation for a career in Clinical Engineering. It includes coursework in Biomedical Instrumentation, Medical Imaging Modalities, Introduction to Biomedical Engineering, Clinical Engineering, and Fundamentals of Policy I: Policy Analysis. Additionally, students will undertake an 8-month practicum/internship supervised by Certified Clinical Engineers and complete a Clinical Engineering project under the mentorship of a Professional Engineer.

Which school should I apply to for the Clinical Engineering Concentration?
You can apply to either school. The program is jointly offered by the University of Ottawa and Carleton University: OCIBME.

How do I get admitted?
The selection process will be conducted during the summer. The students who are admitted into the MEng program and have expressed their interest in the CE concentration will be contacted in the early summer with instruction about the selection process. The admission to the CE program is selective and competitive, and a limited number of the M.Eng. students are admitted into the CE program each year.

For more information about the application process, Click Here.

Marie-Ange Janvier, PhD, PEng, CCE mjanvier@cheo.on.ca

Where are graduates working now?
There have been 12 graduates of the program in the past 10 years. Most graduates seek jobs in clinical engineering departments in hospitals, but some are employed by independent service organizations, equipment-planning firms, or medical equipment manufacturers in clinical technology management, technology support, quality or design roles.
What is a clinical engineer?

“A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology.” -ACCE Definition,

“Professionals who are qualified by education and/or registration to practice engineering in the health care environment where technology is created, deployed, taught, regulated, managed or maintained related to health services” - IFMBE CED Definition

Clinical engineers work in hospitals, medical device companies, government or regulatory bodies or as consultants. You can find out more about this profession by reviewing organization websites associated to the profession below.

What is the M.Eng Biomedical Engineering with concentration in Clinical Engineering Program?

The Ottawa-Carleton Institute for Biomedical Engineering (OCIBME) offers a M.Eng Biomedical Engineering with concentration in Clinical Engineering degree. OCIBME is a multi-disciplinary institute combining academic resources from Carleton University and University of Ottawa as well as medical expertise from a number of well-established hospitals and medical research institutions.

The 2-year M.Eng Biomedical Engineering with concentration in Clinical Engineering degree provides students with a foundation for a career in Clinical Engineering. Students take courses in Biomedical Instrumentation, Medical Imaging Modalities, Introduction to Biomedical Engineering, Clinical Engineering and Fundamentals of Policy 1: Policy Analysis, complete an 8-month practicum/internship designed by Certified Clinical Engineers and complete a Clinical Engineering project under the mentorship of a Professional Engineer.

What is the Clinical Engineering internship?

The Clinical Engineering (CE) Internship is an 8-month placement for M.Eng students enrolled in the BME program. It provides students an in-depth, rigorous, clinical experience that builds on the engineering expertise gained in the classroom. The primary objectives of the internship are to provide:

- Opportunity to apply engineering principles to healthcare in the hospital environment.
- Exposure and understanding of the hospital environment.
- Experience working with hospital staff, including administrators, clinicians, technologists, etc.

Currently participating hospitals include the:

- University of Ottawa Heart Institute (Ottawa, ON),
- The Ottawa Hospital (Ottawa, ON),
- The Children’s Hospital of Eastern Ontario (Ottawa, ON) and
- The University Health Network (Toronto, ON).

These internships occur with the supervision of qualified staff in the Healthcare Technology Management departments at these hospitals. The students work as Clinical Engineering Interns, familiarizing themselves with the healthcare environment and typical clinical engineering duties and projects. The student has a pre-determined work schedule and is treated as a department employee with accountability and assigned responsibilities.

The internship includes a stipend.

To learn more about the program, please reach out to Fabio Variola, Director, University of Ottawa, email: fabio.variola@uottawa.ca or Yuu Ono, Associate Director, Carleton University, email: yuuono@sce.carleton.ca
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>State/Country</th>
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</thead>
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<tr>
<td>Gina Roy, MSN, MBA</td>
<td>Institutional Associate</td>
<td>Lead Project Manager</td>
<td>Kaiser Permanente</td>
<td>CA/USA</td>
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<td>Lauren J. Higgins, MBA</td>
<td>Institutional Associate</td>
<td>Clinical Systems Engineer</td>
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<td>Valeria N. Mondo, BA</td>
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<td>Consultant III</td>
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<td>Taylor Recaido</td>
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<td>Patrick S. Mellady, CCE</td>
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<td>Jada Plummer</td>
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<td>Madison M. Arciga</td>
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<td>Alexandria Castillo, MS</td>
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<td>Heather Heindenreich, MS</td>
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<td>Gurneet Singh, MSPM</td>
<td>Institutional Associate</td>
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<td>Juliann Record, BS</td>
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<td>Michael Cauthen, BSBME, MBA, CBET</td>
<td>Individual</td>
<td>Technical writer/editor</td>
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<td>Harper Cash, CHTM, CBET</td>
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<td>Banner Healthcare</td>
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<td>Agustina Krivoy, PEng</td>
<td>Institutional Individual</td>
<td>Dir., Provincial Equipment Planning</td>
<td>Shared Health</td>
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<td>Bindu Matthews, Eng,L</td>
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<td>Regional Clinical Engineer</td>
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<td>Rebecca Autman, PhD, PEng</td>
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<td>Mgr, CE-Imaging Support Services</td>
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<td>Paul Prowse, MSc, PEng</td>
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<td>Sydney Lyda, BS</td>
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<td>Paul E. Dorregaray</td>
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<td>Antonio Carlos de Andrade Moreno</td>
<td>Institutional Associate</td>
<td>Jr. Electronic Engineer</td>
<td>Hospital Israelita Albert Einstein</td>
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<td>Jesus Enrique Quintero Lopez, MS</td>
<td>Individual</td>
<td>National Biomedical Engineering Manager</td>
<td>FMedical</td>
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<td>Barbara Strain Consulting, LLC</td>
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<td>Gary Barkov</td>
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<td>V.P., Clinical Engineering-Operations</td>
<td>Advocate Health</td>
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<td>Camilo Nogueira</td>
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<td>Clinical Engineering Technologist</td>
<td>Rede D’Or Sao Luiz</td>
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<td>Rodrigo de Oliveira Martin</td>
<td>Individual</td>
<td>Biomedical Engineer</td>
<td>TPF Engineering</td>
<td>CE/Brazil</td>
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Congratulations to the following member who was upgraded to Individual Level:

Bryan I. Gros, PhD, Project Manager/Clinical Technology at Kaiser Permanente

Congratulations to the Emeritus members:

Paul Sherman and Steve Grimes. Enjoy your retirement!

Welcome to our newest Institutional Member: Shared Health
Mark E. Bruley has been inducted into the Clinical Engineering Hall of Fame in recognition of his significant contributions to Clinical Engineering.

He is a distinguished clinical engineering consultant and renowned internationally for his expertise in accident and forensic investigation. Patient safety with medical devices has been the focus of Mr. Bruley’s work since beginning at ECRI in 1975. His initial work as a project engineer focused on the clinical and laboratory evaluation of medical devices. During his career he frequently consulted and lectured on medical device safety, medical technology accident investigation, and recall and problem reporting programs. The Joint Commission, state departments of health, the FDA, standards committees, professional societies, and foreign governments have all relied on Mr. Bruley for his expertise for decades.

Dr. Monique A. Frize been inducted into the Clinical Engineering Hall of Fame in recognition of her significant contributions to Clinical Engineering in many areas.

She is a trailblazing Canadian clinical engineer with a formidable array of academic qualifications and professional credentials. She has significantly advanced the safety standards of medical equipment in Canada and globally. In 1966, she became the first woman to graduate in electrical engineering from the University of Ottawa with a B.A.Sc. degree, marking the beginning of her groundbreaking journey. Through her unwavering dedication, she has paved the way for numerous women in the field of engineering. During her academic career, spanning over 3 decades, she was awarded approximately CAD$3 million in research grants, supervised 48 master’s students, five PhD students, two post-doctoral students, and 35 undergraduate theses. She has published over 200 papers, of which 155 were in peer-refereed conferences and 36 in journals, 11 book chapters and six complete books as a single author. She discovered the major causes of electro surgical burns during surgery and received a patent for electrode design in 1987.

Congratulations to the 2024 ACCE Fellow Members

Please join us in congratulating the new 2024 ACCE Fellow Members: Samantha Jacques and Erin Sparnon! They will receive their Fellows credentials/plaques at the ACCE 34th Members Meeting/Awards Reception on June 15th in Phoenix, Arizona.

Amy Klemm, MS, CCE
Membership Committee Chair
Amy.s.klemm@gmail.com

Samantha Jacques, FACCE
Erin Sparnon, FACCE
The computerized written examination for HTCC Certification in Clinical Engineering (CCE) will be available from November 2nd through November 16th, 2024. The deadline for applications is July 19th, 2024.

Arrangements can be made to take the written exam in most major cities around the world at computer-based testing facilities managed by Prometric.

You may apply to take this exam by downloading the candidate handbook and application form. After reviewing the Handbook, please contact Julia Mazzoleni, Secretariat for HTCC at certification@accenet.org, if you have further questions.

Also, additional information is available in this YouTube video, produced by the ACCE Body of Knowledge Committee, with step-by-step application and examination process instructions.

CCE Exam Prep: Answers

Question 1
Correct answer: B
Explanation: ‘Project Monitoring’ as noted in the Study Guide (ROI) as one of the two major functions of Project Management, (the other being Project Planning). While the Project Manager may have input into the Personnel Evaluation, and Team member selection, as well as the ability to select the project they would like to manage, those are not ‘major’ functions of Project Management.

Question 2
Correct answer: C
Explanation: While the Cybersecurity Risks may be listed in the Risk Analysis, the Cybersecurity Risk Analysis is managed by the cybersecurity technical subject matter expert.

Question 3
Correct answer: D
Explanation: SWIFT is a financial messaging standard; all the others listed are healthcare communication standards.

Question 4
Correct answer: A
Explanation: Vendor service agreements are considered an operating expense which are an annual (i.e., recurring) expense. Some vendors offer multi-year agreements with a discount if they are paid upon completion of the installation; however, those expenses would still be amortized throughout the multi-year agreement as required by accounting principles. The other expenses would be non-recurring or one-time capital expenses.

Chris Riha, CCE
Member, BOK Committee
cdriha@crihaconsulting.com
In the rapidly evolving field of clinical engineering, integrating user-centered design (UCD) principles in the development of medical devices is becoming increasingly critical. As healthcare technology advances, it is paramount to ensure that medical devices meet their users’ needs, preferences, and limitations — be they patients, clinicians, or technicians. This approach enhances usability and safety and profoundly impacts patient care, inspiring us to strive for better healthcare technology.

User-centered design places the user at the forefront of the development process. This approach involves understanding the users’ needs and contexts, designing solutions tailored to those needs, and testing and refining the design with user feedback. For instance, in the development of a new insulin pump, the design team would engage with diabetic patients to understand their daily routines, pain points, and preferences. The ultimate goal is to create intuitive, safe, and effective products in real-world settings.

The Key Principles of User-Centered Design in Medical Devices

Early and Continuous User Involvement: It is crucial to engage end-users early in the design process and maintain their involvement throughout the product lifecycle. This can be achieved through interviews, surveys, focus groups, and usability testing. For instance, the design team would involve radiologists, technicians, and patients in developing a new MRI machine to understand their diverse perspectives and needs. This collaborative approach helps identify potential issues and refine design solutions.

Contextual Inquiry: Observing and analyzing how medical devices are used in natural clinical environments provides invaluable insights. Contextual inquiry involves studying the workflow, identifying pain points, and understanding the environmental factors influencing device usage. This helps in designing devices that integrate seamlessly into existing practices.

Iterative Design and Testing: Iterative design involves creating prototypes, testing them with users, gathering feedback, and refining the design based on that feedback. This cycle is repeated multiple times to ensure the final product is effective and user-friendly. Your feedback, as users and developers, is crucial in this process, underlining the value and influence of your opinions in shaping the final product.

Emphasis on Usability and Safety: Usability and safety are paramount in medical device design. Devices must be intuitive, with clear interfaces and straightforward operation to minimize the risk of user error. Safety features should be integrated to prevent misuse and ensure the device performs reliably under various conditions.

Inclusivity and Accessibility: Medical devices should be designed to accommodate the broadest possible range of users, including those with disabilities or limited technical skills. This involves considering ergonomic factors, offering multiple modes of interaction (e.g., visual, auditory, tactile), and ensuring that devices can be used comfortably by all intended users.

Incorporating user-centered design principles in the development of medical devices is essential for advancing clinical engineering. By prioritizing the needs of users, designers can create devices that are innovative and effective but also safe, accessible, and user-friendly. As the field continues to evolve, embracing UCD will be vital in addressing healthcare technology’s complex challenges and opportunities, such as the increasing demand for personalized healthcare, the need for remote patient monitoring, and the integration of AI in healthcare.

Fabiola Martinez, MS, PhD
Chair, IFMBE/CED
boardchair@ced.ifmbe.org
2024 ACCE-HIMSS Excellence in CE-IT Synergies Award

Christopher Falkner is the recipient of the 2024 ACCE-HIMSS Excellence in Clinical Engineering and Information Technology Synergies Award. It was presented to him on March 11, 2024 during the ACCE CE-IT Symposium, pre-HIMSS24 by Tammy Kwiatkoski, HIMSS, Erin Sparnon, ACCE, and Jennifer Jackson, a past CE-IT Synergies award recipient and ACCE past president.

Tammy Kwiatkoski, HIMSS and Erin Sparnon, ACCE

Jennifer Jackson presenting the award to Christopher Falkner

What an interview of Chris Falkner by HIMSS host, Patty Enrado on HIMSS TV! Click here to play
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 $378). You must login to the ACCE website to view the code.