

# **ACCE** News

Newsletter of the American College of Clinical Engineering

March — April 2024

Volume 34 Issue 2

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### **President's Message**

Dear ACCE Community:



The first quarter of 2024 is gone and spring is here. I hope the winter months were productive for everyone. We have some key annual conferences behind and in front of us. The ACCE Education Committee and CE-IT Symposium Task Force members Juuso Leinonen, Mike Powers, Ousai Shikari, Keith Whitby, Martin Poulin, and Max Velez-Mejias, just completed a pre-HIMSS24 symposium on March 11th. The session titled "Implementing Emerging AI Tools and Medical Device Technologies in Healthcare" was well attended and provided insight into the issues we will face in the future.

Looking forward, AAMI eXchange will be held in Phoenix, Arizona from June 14th to 17th. ACCE is a Contributing Kim Greenwood, President ACCE Organization of AAMI eXchange24 and I invite you to register today. The CE Symposium Task Force members

Erin Sparnon, Jim Panella, Ashley O'Mara, and Charles Wickens are busy preparing for the eXchange symposium on "Navigating Homecare Technologies – Adapting to Shifting Patient Care and Tech Support Challenges at Home" which will be presented on Saturday, June 15th. This half-day session will give you a good overview of the home model, its specific support challenges, and strategies to overcome these obstacles. There will also be an opportunity for the audience to pose their own questions to the symposium's panel of experts. Please remember to note this event in your calendar.

Confirmation voting for the two candidates selected by the CE-HOF nomination committee is under way. I encourage all Individual/Fellow/Emeritus members to cast their confirmation vote by April 7th. If you can't find your ballot in your inbox, please contact Suly at secretariat@accenet.org.

Hopefully we will see all of you at our annual ACCE reception and awards ceremony on Saturday evening, June 15th. This is an opportunity to give well deserved recognition to our colleagues for their outstanding contributions to the CE profession. We will be inducting the class of 2024 into the Clinical Engineering Hall of Fame, and the 2024 ACCE Fellow members.

As always, ACCE will have a booth (#826) at the AAMI eXchange24 vendor exhibit hall and it will be staffed by member volunteers. Please drop by and visit us.

We will be posting conference updates on the ACCE website from now until opening day.

I hope to see all of you at AAMI eXchange24 in Phoenix!

Kim Greenwood ACCE President President@accenet.org



### Hope to see you at AAMI eXchange 2024

AAMI eXchange 2024, Phoenix AZ, June 14-17, 2024

ACCE is a Contributing Organization for AAMI eXchange 2024. Join us and your HTM peers for four days to learn, connect, and share the latest innovations and knowledge with the CE community. ACCE members are eligible to register for the conference at the AAMI member discounted rate. Just download and complete this registration <u>form</u>.



Attend these co-sponsored "can't miss" events at AAMI eXchange:

#### Clinical Engineering Symposium – Presented by ACCE: Navigating Homecare Technologies – Adapting to Shifting Patient Care and Tech Support Challenges at Home

Date: Saturday, June 15, 2024, 7:30AM-10:15AM Location: Phoenix Convention Center Light refreshments start at 7:15AM

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 line-up of speakers and facilitators will guide you through active learning on the following topics in order to prepare you for providing homecare support in your organization:

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

#### **Presenters:**

Priyanka Shah, MS, ECRI: High Level Trends and Considerations from ECRI Members Samantha Moriarty, MEng, BWH: Hospital in the Home Model, from Concept to Creation Samantha Holligan, MBA, BSN, RN, NE-BC, Mayo Clinic: Virtual Care Jacob Bartush, AS, VA HTM Program Office: VA Tele-Technologies

Click here to register.

(Continued on page 3)

### **AAMI eXchange: Other ACCE Events**



(Continued from page 2)

### Education Sessions, presented by ACCE

#### Going Through a Merger & Acquisition – Lessons Learned and Keys to Success Date: Monday, June 17, 2024

Time: 8:00 AM – 9:00 AM Location: Phoenix Convention Center Speakers: Tony Cody, Mike Powers

With the ever-changing HDO ownership landscape, mergers 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.

### Stop by ACCE Booth #826 on the Exhibit Floor

Stop by to visit colleagues, new and old, and learn about:

- Our new webinar series
- The CCE exam

- All of ACCE's membership programs and activities
- Check/update your membership status

<u>Registration</u> and <u>hotel</u> reservations are open.

See eXchange24 <u>Schedule-at-a-</u> <u>Glance</u> for the full AAMI education program.

We hope to see you in Phoenix!



2024 CCE Oral Exam June 13 - 14, 2024 Location: Sheraton Phoenix Downtown Please confirm your exam schedule with HTCC Secretariat at <u>certification@accenet.org</u>.

#### **ACCE News**

**ACCE News** is the official newsletter of the American College of Clinical Engineering (ACCE).

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**ACCE News** is a benefit of ACCE membership; nonmembers may subscribe for \$75 per year.

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### 2024 ACCE Advocacy Committee Awardees Congratulations to the Award Recipients

ACCE 2024 Professional Achievement in Management/Managerial Excellence Award: Carolyn Mahoney, MS, CCE, CHTM ACCE 2024 Professional Achievement in Technology Award: Carl Cross, MS





Carolyn Mahoney

This award is given to an individual for his/her contributions to the CE profession of a managerial nature, such as a paper of significance, solving of a problem or issue for the profession, or the application of new techniques to CE with measurable positive results.

The award winner this year is Carolyn Mahoney, CCE, CHTM, for her ongoing support and continued improvement to personnel management and equipment procurement tracking processes that have made a significant impact to the VA HTM community.

Carolyn started working for the Department of Veteran's Affairs (VA) after graduating from Worcester Polytechnic Institute (WPI) with her Master's in Engineering. Carolyn worked for the VA for over 31 years in a variety of locations including Seattle WA, Ann Arbor MI, and New England, before retiring in 2023. During her career with the VA, Carolyn worked to strengthen the regional clinical engineering programs by developing processes for consistent department reviews, standardizing equipment requesting and procurement tracking and working closely with sites to improve key performance measures.

Carl Cross

This award is given to a single individual for his/her contributions to the CE profession. These contributions must be of a professional or technical nature, such as research or development of a new technique or product, a paper of significance on a technical issue, or "trailblazing" work in a new application of clinical engineering.

This year's recipient is Carl Cross for his innovative work on a Power-BI analytics portal for tracking medical device cybersecurity data for the entire VHA HTM community. This portal allows the development of enterprise-wide interactive cybersecurity reports to track and monitor remediation of cybersecurity vulnerabilities in the field.

Carl is a Biomedical Engineer with the VA Southeast Network of the Veterans Health Administration, where he serves as the Medical Device Cybersecurity Lead. He started his career with the VA in the Technical Career Field program at the Loma Linda VA Healthcare System. Later he joined the Ralph H. Johnson VA Medical Center in Charleston, SC, where he became the Assistant Chief of HTM. ACCE 2024 Lifetime Achievement Award: Thomas Bauld, PhD, CCE, FACCE, FAIMBE



Tom Bauld

This award is the highest award given by ACCE. It is presented annually to a single individual based on lifelong accomplishments and contributions to the clinical engineering profession.

This year's Lifetime Achievement Award is presented to Dr. Thomas Bauld, a Biomedical Engineer, Leader, Mentor and past ACCE President (1994-1996).

Tom had a long biomedical engineering career in various healthcare organizations. He started the first department of Biomedical Engineering at Sinai Hospital of Detroit in 1974, and later worked for the VA, retiring in 2017 from the VA's National Center for Patient Safety (NCPS) in Ann Arbor, MI. NCPS promotes best practices for safe and optimal patient care throughout VA.

Tom won numerous awards throughout his career including the AAMI Clinical Engineer of the Year Award in 1985 for his devotion to improving patient safety, and the Tom O'Dea Advocacy Award from ACCE in 2017, for his promotion of Clinical Engi-

### **2024 ACCE Advocacy Awards continued**

#### (Continued from page 4)

neering to people in other related fields. He was also instrumental in establishing the Michigan Society for Clinical Engineering.

#### 2024 Tom O'Dea Advocacy Award: Jennifer Nichols, MSE, CCE, CHTM



Jenn Nichols

The award is given to an individual who has written articles, given presentations, or led efforts that have advanced the field of CE – particularly in promoting the profession to people in other related fields.

The award winner is Jennifer Nichols for her profound interest in advancing clinical engineering and promoting clinical engineering certification among HTM professionals.

Jenn is the General Manager of

Clinical Engineering for TRIMEDX. Over the last decade, she has obtained a certificate in biomedical equipment technology, her CCE and CHTM certifications, and became involved in multiple industry associations to better enhance her technical abilities and leadership skills. Jenn has served as the ACCE Body of Knowledge Committee Chair since obtaining her CCE in 2021, hosted multiple webinars for the CCE Written Review Series, co-led the CCE Oral Review Webinar, recorded a webinar with Katherine Navarro on the CCE application and certification process, and authored and edited multiple chapters in the BoK Study Guide. In 2021, Jenn led the committee and completed the analysis for the 2021 Body of Knowledge Survey Results.

#### ACCE/HTF 2024 Marv Shepherd Patient Safety Award: Bruce Hansel, PhD, CCE

This award is given to an individual who has excelled in a 'safety' area related to the CE field. This is a joint award between ACCE and the Healthcare Technology Foundation.

The award recipient this year is Bruce Hansel. Bruce is the chief scientist in ECRI's Hi-TECH accident and forensic investigation group. Dr. Hansel developed ECRI's Accident Intelligence Pro-



Bruce Hansel

gram<sup>™</sup> in 2016 to promote ECRI's accident investigation services to the healthcare community. He also developed a Healthcare Incident Management and Investigation Course in 2019 that strengthened healthcare facilities' abilities to respond to medical device incidents. Dr. Hansel is committed to reducing medical misconnection. His efforts facilitated the adoption of EnFit<sup>™</sup>enteral-specific small-bore connectors in US hospitals, as well as advocating safe use of Luer connectors as published in the Anesthesia Patient Safety Foundation newsletter in 2021.

Congratulations to all the 2024 awardees!

### **ACCE Membership Renewal**

Thank you for being an ACCE member! It's time to renew your membership for 2024. To renew your membership online via PayPal, click <u>here</u>. To renew by postal mail, please remit your renewal check, payable to ACCE, to: ACCE 2880 Bicentennial Pkwy, Ste 100#249 Henderson, NV 89044 If you need an e-invoice, please contact ACCE Secretariat at <u>secretariat@accenet.org</u>

### **AAMI: FDA Cybersecurity Update**



On the last day of AAMI/FDA neXus, Jessica Wilkerson, Senior Cyber Policy Advisor and Medical Device Cybersecurity Team Lead at FDA presented on regulatory requirements for medical device cybersecurity.

Wilkerson opened her talk with a simple "Why?" The healthcare sector currently faces aggressive and increasing cyber threats and "Cyber threats can, have, and very much do, pose patient safety risks to the healthcare sector." According to Wilkerson, FDA's regulatory priorities do not come from a love of paperwork but out of concern for patient safety.

The most relevant legislation to medical device cybersecurity is the Food and Drug Omnibus Reform Act (FDORA), which was passed into law as part of the Consolidated Appropriations Act of 2023 and signed into law in December 2022. This incorporated Section 524B - Ensuring Cybersecurity of Medical Devices into the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Section 3305 of the Omnibus, Ensuring Cybersecurity of Medical Devices, applies to prospective submissions for 'cyber devices' under the 510(k), de Novo, PDP, and PMA pathways. It came into effect on March 29, 2023, 90 days after signing. Section 524B of the Act defines a 'Cyber Device' as a device that has these three concurrent characteristics:

- Includes software validated, installed, or authorized by the sponsor as a device or in the device.
- Has the ability to connect to the internet.
- Contains any such technological characteristics validated, installed or authorized by the sponsor that could be vulnerable to cybersecurity threats.

This definition can include devices that do not have internet connectivity but do have ports (e.g., USB connection). Wilkerson stated that the Act also includes notable requirements for device manufacturers. Section 524B(a) requires that a sponsor do the following:

- Provide a plan to monitor, identify, and address, post-market cybersecurity vulnerabilities and exploits, including coordinated vulnerability disclosure and related procedures.
- Design, develop, and maintain processes and procedures to provide a reasonable assurance that the device and related systems are cybersecure, and ensure that a device has postmarket patching capability.
- Provide a software bill of materials (SBOM) including commercial, opensource and off-the-shelf software components.
- Comply with other regulations and demonstrate reasonable assurance of cybersecurity.

FDA's final premarket guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" was published in September last year, capping a nearly six-year development process. Wilkerson stated that the guidance is "intended to help manufacturers comply with requirements under Section 524B of the FD&C Act." Critically, the scope of the premarket guidance is much broader than the scope of 524B and will apply to more devices. Resources include a publicly available webinar, and the FDA's incorporation of the guidance into its device submission form system (eSTAR).

The guidance addresses how cybersecurity fits into Quality System Requirements and updated the 2022 draft by including Center for Biologics Evaluation and Research (CBER) submission types, considerations for combination products, and elements associated with Section 524B requirements. Structural changes include subsections in Security Risk Management meant to clarify premarket submission documentation deliverables including Cybersecurity Risk Assessments and interoperability. Citing patient concerns, Wilkerson stated that cybersecurity should not stand in the way of interoperability. Last, the document addresses software bill of materials (SBOMs) and aligns with the 2021 National Telecommunications and Information Administration (NTIA) SBOM Framing Document. However, FDA still asks for supporting materials, which can be submitted separately from an SBOM.

Of course, the total product lifecycle includes both the premarket and postmarket phases, and FDA's findings in one will influence the other. "When we see an issue in the post market, we will go back to the premarket cybersecurity guidance...and we will update our review criteria," Wilkerson said.

Regarding cybersecurity review, Wilkerson drew a key distinction, stating, "software engineering is about ensuring that certain things happen ... security is about ensuring that they don't." The ideal question to ask is "what can the device do?" What a device is able to do is far more important than what it was designed to do. Further, past performance does not equal future security. Cybersecurity threats evolve quickly, so past security is no guarantee of future safety. Wilkerson indicated that asking "who is ever going to do that?" in reference to a potential cyber threat, is neither relevant nor helpful. Cybersecurity concerns apply:

- If the device is or contains software.
- If the device meets the definition of a Cyber Device.
- Regardless of whether the software or software component was designed by a medical device manufacturer or a third-party.
- To the entire system, not just the end device.

Wilkerson also noted that the risks (<u>Continued</u> on page 7)

### **International Women's Day: Celebrate Women in CE**



Happy International Women's Day 2024 to all women in the HTM/CE Profession. Thank you for your dedication and contribution to the HTM/CE profession and to the ACCE mission!

And a special thank you to all the women who have served on an ACCE committee, task force or the ACCE Board over the years.

See <u>page 8</u> for the first edition of the new ACCE News series on Women in Clinical Engineering.

### AAMI Update continued

(<u>Continued</u> from page 6)

increase if the device has wired capabilities such as USB, ethernet, SD, CD, or RGA, as well as wireless capabilities such as Wi-Fi, Bluetooth, RF, inductive, or cloud connectivity. Cybersecurity considerations also apply to the entire system rather than just the end device, and will include software update infrastructure, cloud applications, and commercial devices.

Wilkerson also presented on the guidance document currently under review. Key issues include:

- Security risk management
- Security architecture
- Cybersecurity testing
- Labeling
- Cybersecurity management plan

Security risk management will apply to the context of the larger system, and end-to-end assessment of cybersecurity risks and controls. This is a parallel but interfacing process with ISO 14791 Safety Risk Management. AAMI TIR57:2016 is also a valuable resource.

Security risk management will require

threat modeling, cybersecurity risk assessment and a focus on interoperability. It should also involve addressing third-party software components, dealing with unresolved anomalies, and using security risk metrics.

While SBOM is not the sole issue for third-party software components, FDA recommends aligning with the October 2021 NTIA Multistakeholder Process on Software Component Transparency Document "Framing a Software Component Transparency: Establishing a Common Software Bill of Materials." Ideally, a machine-readable version will be provided.

Security architecture will optimally include an implementation of security controls, with security designed in, and including eight Control Categories. Wilkerson pointed to 524B Appendix 1 as a source of recommendations for each category. Architecture views should be included as well, with Wilkerson remarking, "Draw us a picture." FDA will want to see the global system view, the multi-patient harm view, updateability/ patchability view, and security use case view.

Regarding cybersecurity testing, Wilkerson stated that testing is recommended to include security requirement testing, threat mitigation, vulnerability testing, and penetration testing. Testing should be as close to the scope of the system as possible. Labeling is recommended to include 14 elements such as SBOM and labeling mitigations. In addition, risk transfer items may need to be included as part of the Human Factor Testing tasks. Ideally, users have sufficient information to manage security risks and updates.

Finally, a cybersecurity management plan is best if it focuses on cybersecurity throughout lifecycle vulnerabilities and incidents. Plans should include a Coordinated Vulnerability Disclosure process as described in the FDA 2016 Post-market Guidance. Plans can also include items like periodic security testing to test identified vulnerability impact, a timeline to develop and release patches as outlined in Section 524B, and patching capability on a reasonable timeline.

Dan Visnovsky Media Relations Manager <u>dvisnovsky@aami.org</u>

### Women in Clinical Engineering: A New Series

The first biomedical engineering program in the US began in the 1920s as a collaboration between engineers and healthcare professionals to advance healthcare treatment. It subsequently emerged as its own field of study with several subdisciplines. Today females represent about 15% of the engineering workforce and 20% of all engineering degrees are awarded to female students. However, around 40% of the biomedical engineering degree recipients are female.

We celebrate International Women's Month by introducing some of our very own female engineers from the ACCE community. They are members of the ACCE Advocacy Committee who support and promote the profession of Clinical Engineering and agreed to be interviewed to introduce this new series on Women in Clinical Engineering.

#### Jennifer C. Ott, MS, CCE, FACCE:

Jennifer has worked for 16 years at Northstar Management as a Senior Project Manager / Medical Equipment Specialist doing medical equipment planning for healthcare construction projects. She has been involved in ACCE since 1991, joined the board in 1996, and has been involved in some capacity ever since.

Clarice Holden, BSE: Clarice works as the Chief Biomedical Engineer for the Department of Veterans Affairs, Heart of on the position of Director, Clinical Engi-Texas Healthcare Network (VISN 17). She started volunteering with ACCE in 2016, and has contributed to the Education, Membership, and Advocacy Committees.

Erin Sparnon, MEng, CSSBB: Erin has worked for over 20 years evaluating medical technologies and reducing patient harm through research, education, and advocacy. She joined ACCE in 2004, and has been involved with the Education and Advocacy committees as well as the Executive Board.



Jennifer C. Ott, MS, CCE, FACCE



Erin Sparnon, MEng, CSSBB

#### **Bokang Motlotle, MS, CCE, PMP:**

Bokang joined Beth Israel Deaconess Medical Center six years ago as a Sr. Manager in Clinical Engineering. Once Lahey and Beth Israel merged, she took neering & Technology Planning for a system of 14 hospitals. She joined ACCE the best clinical engineers! in 2001, and has been involved in several different areas including participation in the Education and Advocacy Committees, CCE Board of Examiners, and the Healthcare Technology Certification Commission.

#### What do you think of being female in engineering?

Ott: I have found it to be incredibly rewarding. I have enjoyed watching the medical field evolve over the years and



Clarice Holden, BSE



Bokang Motlotle, MS, CCE, PMP

seeing more and more women in leadership roles, and not necessarily coming from nursing. Has it had some struggles? Sure, but all in all, I have been wonderfully supported by my colleagues both at work and professionally. I still firmly believe that Moms make

**Holden:** It isn't lonely! Both the Director and Deputy Director of HTM in my organization are female, as are about half the regional Biomedical Engineers. The leadership makeup has changed over the past decade, but my graduating class was about 50% female too.

**Sparnon:** I've never felt lonely! My last team was all-female and my department was about 50% women. I've also (Continued on page 9)

### **Women in Clinical Engineering continued**

(Continued from page 8)

seen the power of mentoring and networking, with other ACCE women being so generous with their time and advice.

**Motlotle:** As one of the few girls who chose to go into a technical field during my early University of Botswana days, I found it very intimidating. But I got to realize very fast once I joined the professional world that we, women, provide a different perspective, and it's a much-needed balance to our male counterparts. I felt like I too had a voice and it needed to be heard. Today I see more women doing the same, and it gives me great pleasure to know that more of us are out there providing that different perspective and that balance for the benefit of our patients.

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

**Ott:** Certainly my parents. My mother was a nurse and my father an engineer. I combined their careers! Also Barbara Lavin who was my supervisor during my co-op program at Marquette University at the North Chicago VA. She proved to me that a woman in clinical engineering can be a successful force of nature in what was then a male dominated world.

**Holden:** My dad is an electrical engineer, and I always enjoyed life science subjects. I knew I wanted to focus on engineering and medicine, and Clinical Engineering/Biomedical Engineering was the best mix.

**Sparnon:** I lucked into the field. I graduated with electrical and biomedical engineering degrees in the great tech bust of 2002, and Jim Keller recruited me to my first job evaluating medical devices at ECRI. But I quickly saw the accomplishments of ACCE from women like Izabella Gieras, Jennifer Jackson, and Jennifer Ott, and stayed for the opportunity to make patients safer. **Motlotle:** Back in high school in Botswana, I had an awesome Physics teacher who was very passionate about electronics. He ran an Electronics Club and had us build working models that we got to display at different conferences competing with other schools. That's where I was introduced to instrumentation. Although I was the only girl in the group, he never overlooked me and always judged me as an equal, and gave me as many opportunities as he gave the boys.

#### What surprises you in clinical engineering?

**Ott:** How we still fly under the radar after all this time. We are so important to the success of a healthcare organization but we still have to explain what we do. It is like a black cloud we cannot shake. I appreciate every advocacy effort ACCE and AAMI do to increase awareness. It is something that we just cannot quit and have to continue to grow.

**Holden:** The fact that we are a "best kept secret" in engineering – still! When I joined the field in 2012, it was because of a single presentation made to my senior design class. Often, students are still discovering the Clinical Engineering field through networking alone (not a wider dispersion of the opportunities).

**Sparnon:** The sheer breadth of responsibility that clinical engineers take on every day. A good CE knows medicine and physiology, devices and information technology, and how to translate between clinical, technical, and business stakeholders.

**Motlotle:** As my old boss used to say "Clinical Engineering is a thankless job." Somehow, we always manage to make the headlines when something has gone really wrong, otherwise "no news is good news." And we have gotten very comfortable with that. We do a great

job, come in and out quietly, and manage to call very little attention to ourselves and to the great work that we do. I'm very appreciative of different groups that bring awareness to our profession. I would like to see us doing more at the grass roots level to promote our daily work as we tackle issues and put out fires.

### What would you tell other women when considering engineering?

**Ott:** Don't be scared. Ignore the suggested male dominance. That is NOT the case! Engineering is a great field for women, especially Clinical Engineering. I am always willing to talk about the road I have traveled.

**Holden:** It's the perfect mix for both the technical and personal skillsets.

**Sparnon:** Just do it! It's one of the few undergrad majors where you can find great jobs right out of school, take advantage of tuition reimbursement programs, and build any number of careers over time. Want to go into research and development? Regulatory? Business? Sales? Medicine? Start with engineering!

**Motlotle:** Think of the great rewarding work that you would be doing for the patient. In Clinical Engineering the results are tangible! I walk around in the hospital and see the new technology that my team and I helped bring into the institution. I also see the new workflows that we advocated to introduce, as well as the technology that supports it, and the new tools that we have built to help leadership make better decisions in multi-year capital planning. The list is endless. I see all these and think, "this is really a great place to be." So, certainly, come on in and share the joy!

Helen Cheong Advocacy Committee Chair <u>helen\_cheong@baxter.com</u>

### **From the Education Committee Desk**





The 2023-2024 Educational Webinar Series will continue with session#8 on April 11, 2024 featuring Dean Skillicorn and Carol Davis-Smith sharing their thoughts on Medical Equipment Planning for Healthcare Organizations.

Navigating medical equipment planning can be a major challenge for any healthcare organization. Join this session to help optimize resource allocation and get tips on creating operational efficiencies in your Medical Equipment Planning efforts. ACCE Members (in good standing) and our collaborators, may register for <u>session#8 here</u>.

The series will continue with session#9 on May 09, 2024 in which Thomas Belda will share his presentation on New Technologies for Surgery/Surgical Simulations where he explores the cutting-edge landscape of new technologies used for surgeries.

A number of revolutionizing technologies (e.g., surgical robots, hybrid ORs), have become prevalent in many healthcare organizations. With new technology implementations also comes new technology management challenges. Join this session to learn more about managing these new surgical technologies. ACCE Members (in good standing) may register for <u>session#9 here.</u> The 2023-2024 series will conclude with session#10 on June 06, 2024. Register today and join Elizabeth Sayles, Shane Waltsak, and Katherine Leach to gain insights into Managing Clinical Engineering Projects.

Explore the multifaceted world of managing health care facility projects, from the ground up to the finishing touches, through both the lens of clinical engineering and the viewpoint of the vendor community. This journey offers a unique opportunity to uncover the gaps and gather valuable insights, allowing you to identify and implement improvements in your future projects. Embrace the power of project management principles to ensure a smooth and effective technology implementation, paving the way for

enhanced operational efficiency and improved patient care in health care facilities.

ACCE Members (in good standing) may register for <u>session#10</u> here. If you have not renewed your 2024 membership yet, please renew it via PayPal <u>here</u>, or contact us at <u>secretariat@accenet.org</u> to request an e-invoice for online payment via QuickBooks.

If you are not an ACCE member yet, please join us today! Just complete the membership <u>application form</u> and submit it to <u>secretariat@accenet.org</u>. Or if you prefer to register for a webinar as a non-member, please complete registration here.

Juuso Leinonen & Mike Powers Education Committee Co-chairs Education@accenet.org

Suly Chi, Webinar Coordinator Secretariat@accenet.org



### The ACCE CE-IT Symposium at HIMSS 2024 Implementing Emerging AI Tools and Medical Device Technologies in Healthcare

On the very first morning of HIMSS last month, AI was in the air. Every preconference symposium seemed to have at least a few tracks dedicated to it, and a good proportion of the 1100+ exhibiting vendors listed themselves as offering some flavor of AI or ML. But how many of the ideas had actually been implemented at scale? Over 100 clinical engineers, administrators, data scientists, and IT professionals gathered to talk about the practical realities of selecting, implementing, and governing AI-based technologies at the ACCE CE-IT Symposium. And here's what we learned:

The Digital-to-AI revolu-

tion looks a lot like the Analog-to-Digital revolution. Erin Sparnon started the day with a call to action for clinical engineering to recall the lessons CE learned the hard way over the last 20 years when we did things like massively adopt EHRs and move alerts from the bedside to clinician devices. The best exchanges of the session came during active learning:

- Data Scientist: "I'm trying to make a system that won't require clinicians to change their workflows."
- Clinical Engineer: "No way! We know your system will change clinical workflows anyway, so it's a good time to design better ones!"



ACCE Symposium speakers and panelists: Back row, L-R: Dr. Jamie Chow, Keith Whitby, Phil Englert, David Hilderbrand, Peter Shen; Front row, L-R: Tom Stanford, Kevin Littlefield, Rita Riso, Mark Nielsen, Erin Sparnon, Olivia Sanders

**Good AI Governance** looks a lot like Good Governance. Mark Neilson and Olivia Sanders shared their journey to robust internal development and governance of AI-enabled technologies at Intermountain Health. They championed "starting with the Why?", first establishing and validating the clinical need and context for any new systems, which serve as the source of truth for all following development and validation activities. Check out their <u>slides</u> for a detailed roadmap that facilities can use to assess their own organizational readiness and then build a framework for safe and effective AI implementations (whether homegrown or purchased) that align with organizational culture, leadership, and business priorities.

When it comes to **Evaluating Commercial AI Applications**, Dr. Jamie Chow, Clinical Lead of symposium sponsor Blackford Analysis, emphasized the importance of identifying clinical champions who can define and describe the clinical need, and then comparing feature sets to these clinical needs as part of the selection process.

**The Future is Bright:** Peter Shen and Rita Risto from Siemens Healthineers explored the current use cases of AI, including instant anatomical labeling for images and standardizing patient position during imaging to reduce re-scans. They then ventured into the near-future describing the development and use of a digital twin of a person to perform digital invivo treatments and maintain optimized health with predictive analytics and coaching/interventions.

(<u>Continued</u> on page 12)

### The ACCE CE-IT Symposium continued

#### (<u>Continued</u> from page 11)

Thomas Stanford of Nuvolo shared his vision of **Collecting Massive Pools of CMMS Data** to drive predictive parts sourcing and maintenance activities. Think about how many hours CE/HTM would save if community data indicated an uptick in circuit board failures in your model of a sequential compression device, and the boards arrived (with the right screws and all!) before the failure happened.

We Have Work to Do: Phil Englert's (VP Medical Device Security of symposium sponsor Health-ISAC) fast-paced panel discussion focused vendors and providers on their shared responsibilities for developing and deploying safe, secure AI-enabled technologies. As panelists and attendees talked through topics like data security, governance, and caregiver buy-in, it quickly became clear that we're still in the early stages. We don't have answers for everything, but we identified six key questions to take on for further exploration:

- What will be the downtime procedures when the AI application is down? How will frontline users know that a system is down, and what do they do next?
- How will patients, providers, and lawyers know how and when AI was used in clinical care? What does responsible disclosure look like?
- How will we deal with off label use or sideloaded use of AI? And for the vast majority of AI that falls outside of the FDA-clearable space, how do we establish reasonable expectations for use?
- Can AI be useful in generating "better" devices or applications when it comes to human factors or usability?
- What happens if/when we're hacked? Do we need to watermark or digitally poison PHI so it cannot be scrapped or abused in hacks?
- How much AI is out there? Is any entity creating an AI healthcare registry to track its deployment or performance?

Thanks to all the speakers and attendees who joined us in Orlando!

You can find the 2024 CE-IT Symposium presentations on the ACCE website here.

And a special thanks to the CE -IT Symposium task force for organizing the event and our sponsors Blackford Analysis and H-ISAC.

## <u>Blackford</u>





Maximiliano Velez-Mejia, Erin Sparnon, Suly Chi Contact: <u>suly@accenet.org</u>

### In Memoriam: Patrick (Pat) Kelly Lynch



A Tribute to the HTM Chief Do-Gooder, a Mentor, a Colleague, a Friend, and a Fellow ACCE



Patrick Kelly Lynch, CBET, CCE, FACCE (June 25, 1953 - March 1, 2024)

ACCE Fellow and HTM "Chief Do-Gooder", Patrick Kelly Lynch, passed away on March 1, 2024 in Fort Mill, South Carolina, after a lengthy battle with pancreatic cancer.

Pat was a clinical engineer for over fifty years, beginning his career at Charlotte Memorial Hospital. He was a highly respected member of the profession and received numerous awards and accolades over the years including, only a month before his death, the 2024 TechNation's Lifetime Achievement Award. He graduated from University of North Carolina – Charlotte and obtained an MBA from Kennesaw State University. During his career, he managed biomedical departments in several large hospitals, created and served in new biomedical state and regional societies and served as ACCE's Advocacy Committee chair from 2008-2010. Pat also traveled to many developing countries to bring and repair much-needed medical equipment such as infant incubators and heart monitors.

Patrick was the son of Sylvia Hogan Lynch and Lowell Lynch and grew up in Charlotte, NC with his three brothers, John, Steven, and Mark and his sister, Sharon Lynch. Patrick is survived by his wife, Patricia; his mother, Sylvia Hogan Lynch; his three daughters, Christy, Erin, and Eva; eight grandchildren, Nate, Hailee, Trevor, Iyanna, Lashay, Bryson, Alayah and friends, and colleagues.

#### Tributes from colleagues and friends

survived by Diane

Lynch, mother of

Christy and Erin.

Donations can be

made to the Charlotte

<u>Community ToolBank</u> or the local charity of

vour choice. Patrick

will be dearly missed

by all who knew him, but his legacy will live

on through his family,

#### **David Braeutigam:**

RIP Pat. I have lots of great memories of us hanging out at AAMI with a cigar. Condolences to the family. Pat is an icon in the biomed field.

#### Larry Fennigkoh:

Oh my and what sad news to hear; my deepest, heartfelt condolences to Pat's family and to all of those within our HTM community who were blessed to have crossed paths with him. We shared the same June 25th birthday and so I always felt an extra special connection. May you now rest in peace Pat and with an eternal thanks for all you've shared and given to our profession.

#### Tom Judd:

So thankful for this visionary leader, Chief Do-Gooder, great dad, and friend. My prayers are also with his family at this time. May others learn from the passion he brought to our profession.

#### James Knight:

I will always remember him! He was a true groundbreaker and forefather of our industry.

#### Greg Goll:

RIP Pat, prayers for your family. You are missed.

#### Parker. Patrick is also **David Francoeur:**

So sorry. He was the best. He did so much for our community and profession. He was the first person to hire me in this industry. Prayers to the family.

#### Paul Kelley:

My sincere condolences to the family. I loved Pat like a brother. RIP, my friend; you will be missed.

#### **Eben Kermit:**

I am so sorry to hear this news. Such a loss of a wonderful, intelligent, caring and thoughtful leader. My condolences.

#### Scot Mackeil:

I am profoundly sad. Above my bench is my CBET certificate with Pat's signature on it. Whenever I needed a guiding star to get me through a tough job, I looked there and asked what would Pat Lynch do? I was always inspired by his writings and spirit. He may have left this world today but I feel his spirit as strongly as ever. I will do my job in the OR with his memory in my heart always....RIP Pat.

#### Yadin David:

Pat, RIP, left us a unique vision for how each one of us, regardless of their position or their backers, can find passion to help others just as he did so persistently and successfully. All the many friends that he elevated and encouraged will never forget how wonderful a man Pat was. He created many specialty titles, all to promote others. My prayers and thoughts are with the family during this difficult time, and I feel blessed to have gotten to know him.

#### **Binseng Wang:**

You have done a lot for your colleagues, patients and humanity. My most sincere condolences to the family. RIP Pat.

For more information click <u>here</u>.

### **CCE Prep: Sample Questions**

In this column we are providing sample **Answers** 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 12. Note that the instructors for the ACCE CCE Prep courses, and the writers of 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 the ACCE Body of Knowledge (BoK) Committee chair at jennie nichols@yahoo.com.

#### **Question 1: To establish priorities for** risk mitigation, how can risk be calculated?

A. Severity X Probability **B.** Severity X Function C. PM Schedule X Probability D. Age X Probability

#### Question 2: What are the three factors of the project management triple constraint model?

A. Task, Cost, and Skill B. Time, Cost, and Skill C. Time, Cost, and Scope D. Time, Risk, and Scope

#### Question 3: The energy delivered by a defibrillator is measured in?

- A. Voltage= Current X Resistance B. Joules= Watts X Seconds C. Hertz = Wave Velocity/Wave Length
- D. Joules= Watts/Seconds

#### **Question 4: The proper Failure Mode** and Effects Analysis (FEMA) has how many steps in the process?

- A. 3
- B. 8
- C. 6

D. 4

Question 1: Correct answer: A Risk is generally defined as a combination of the potential severity of harm and the probability of the harm. Risk = Severity X Probability. On a graph, Probability is on the Y-axis and Severity is on the X-axis. The higher the score, the greater the risk.

Question 2: Correct answer: C A project as defined by the Project Management Institute (PMI) is "a temporary endeavor undertaken to achieve a particular aim into which project management could be applied regardless of project size budget or timeline." Project management is defined as "the discipline of organizing and managing resources in such a way that said resources deliver all the work required to complete a project within a • defined scope, time frame, and cost constraint."

The triple constraint is often represented by a triangle where scope is one side of the triangle, time is another side of the triangle, and cost is the third side of the triangle. Scope is defined as the deliverable or service as a result of the project being completed. The second constraint is time which represents a schedule in which the project may be completed. Cost is the third constraint.



Question 3: Correct answer: D A defibrillator delivers energy in the form of joules. The energy delivered is designed to repolarize the heart by stopping an uncontrolled beating that is life-threatening. In electrical terms, the joule equals one watt-second-for example, the energy released in one second by a current of one ampere through a resistance of one ohm.

Question 4: Correct answer: B Failure Mode and Effects Analysis (FEMA) is a method deployed to reduce the occurrence of unanticipated adverse events. FEMA provides a systematic step-by-step method for identifying system vulnerabilities. There are 8 steps in the process.

- Step 1: Mapping the process
- Step 2: Identifying the process • failure modes
- Step 3: Identifying and quantifying the severity of the possible adverse consequences of the process failure modes
- Step 4: Identifying and quantifying the probability that the failure mode will actually occur
- Step 5: Identifying and quantifying the detectability of these possible failure modes
- ٠ Step 6: Combining these factors into a composite measure of seriousness or criticality
- ٠ Step 7: Identifying the possible cause of failure
- Step 8: Identifying how the vulnerabilities revealed in the process can be eliminated or reduced through control measures and at what relative cost.

Jenn Nichols Chair, ACCE Body of Knowledge Committee Jennie.nichols@yahoo.com

Triple constraint

### **Welcome New ACCE Members**

Welcome to our newest members, approved by the Membership Committee, and supported by the Board of Directors:

Name	Class	Job Title	Organization	State/ Country
Jason Launders	Individual	Medical Imaging Expert	Self-employed	PA/USA
Zachary Dane	Individual	Assistant Chief Bio- medical Engineer	Minneapolis VA Health Care System	MN/USA
Karen Haberland	Individual	Senior Project Officer	ECRI	PA/USA
Mukui Mutunga	Associate	Senior Project Officer	ECRI	PA/USA
Phil Englert	Associate	VP Medical Device Security	Health – ISAC	FL/USA
Woot Lervisit	Associate	Project Manager	Retractable Technologies, Inc.	TX/USA
Abel Villanueva	Institutional Associate	Biomed III	UI Health	IL/USA
Miguel Santos	Institutional Associate	Biomedical Engineer	UI Health	IL/USA
Alonso Topete	Institutional Individual	Clinical Engineering Manager	Intermountain Health	UT/USA

#### Congratulations to the following member who was upgraded to Individual Level:

Ghaith Hasan, CCE, Assistant Chief Biomedical Engineer at Jesse Brown VA Medical Center

Amy Klemm, MS, CCE Membership Committee Chair <u>Amy.s.klemm@gmail.com</u>

### **Student Paper Competition Winners**

Congratulations to the 2024 Student Paper Competition Winners:

#### US/Canada Master Division, Maryam Sangargir:

Graduate Student at University of Ottawa, Canada and International Undergraduate Division for "Safety Verification Procedure in the Implementation of Alternative Equipment Maintenance at The Ottawa Hospital."

**International Undergraduate Division, Antonio Carlos de Andrade Moreno**, Specialization in Clinical Engineering Student at Centro de Ensino Einstein, Brazil for "Analysis of the Return on Investment after the Implementation of the RFID System at Hospital Israelita Albert Einstein."



Maryam Sangargir



Antonio Carlos de Andrade Moreno

Read the winning papers here.

### ECRI Update: Celebrating Patient Safety Awareness

During March 10–16 healthcare professionals around the globe celebrated Patient Safety Awareness Week to highlight the importance of actions healthcare professionals can take to make care safer for all patients.

The World Health Organization estimates that 134 million adverse events occur each year due to unsafe care, resulting in approximately 2.6 million deaths. To help the healthcare community focus on this issue, ECRI is sharing its annual Top 10 Patient Safety Concerns <u>report</u> that identifies critical threats confronting the healthcare industry.

ECRI's <u>Top 10 Patient Safety Concerns</u> identify imminent safety challenges for patients and staff that we believe require maximum focus for the coming year. More importantly, it offers actionable recommendations to remedy these challenges.

The 2024 edition of our Top Ten report features many first-time topics and emphasizes potential risks that could have the largest impact on patients. The number one topic in this year's report was exacerbated by the COVID-19





pandemic and subsequent workforce shortages: challenges transitioning newly trained clinicians from education into practice.

Trends in employment rates for new clinicians were positive through 2023, with 96% of new nurses finding work. However, there is growing concern about the difficulty of transitioning new clinicians from education to practice in the face of several factors brought on by the recent global pandemic. Without sufficient preparation, support, and training, new clinicians can experience loss of confidence, burnout, and reduced mindfulness around the culture of safety. The combination of these factors may lead to preventable harm.

The report also includes workarounds with barcode medication administration systems. In addition, several topics reflect challenges that have arisen as a result of the stresses associated with adapting clinician workflows to new technologies, steering through changes in care delivery settings, mitigating complex risks like staff burnout and workplace violence, and navigating an uncertain economic and global political climate. Other topics include:

- Barriers to access maternal and perinatal care
- Unintended consequences of technology adoption
- Decline in physical and emotional well-being of healthcare workers

To effectively understand where vulnerabilities lie, leaders must examine all elements of the system—people, organizations, tasks and processes, tools and technology, and the physical environment. Each topic in this year's Top Ten represents a failure in at least one of these areas. In fact, many overlap and their roots are found in multiple areas.

Tell us what you're seeing concerning patient safety trends and challenges. And as always, if you're ever in the Plymouth Meeting, PA neighborhood we'd love to show you around our beautiful laboratory space.

Ismael Cordero Senior Project Engineer, Device Safety, ECRI <u>icordero@ecri.org</u>

### IFMBE — CED Update Navigating International Regulatory Changes in CE



One significant area of focus in recent years has been harmonizing medical device regulations across different regions. Regulatory bodies worldwide are increasingly working towards aligning their standards to enhance patient safety and streamline market access for medical devices. The European Union's Medical Device Regulation (MDR) represents a significant shift in regulatory requirements, with stricter guidelines for medical device manufacturers, importers, and distributors. Clinical engineers within the EU must adhere to these updated regulations to ensure compliance and uphold patient safety standards.

Similarly, the United States Food and Drug Administration (FDA) has been revising its regulatory framework for medical devices to address emerging challenges and technological advancements. The FDA's Digital Health Innovation Action Plan and Software Precertification Program aim to foster innovation in digital health technologies while ensuring product safety and effectiveness. Clinical engineers must stay abreast of these developments to navigate the regulatory landscape effectively, particularly in the rapidly evolving field of digital health.

Beyond regional regulations, international standards organizations play an essential role in shaping regulatory frameworks and ensuring interoperability of medical devices worldwide. The International Medical Device Regulators Forum (IMDRF) is a platform for collaboration among regulatory authorities from different countries facilitating the development of harmonized guidelines and best practices. Clinical engineering professionals can benefit from engaging with IMDRF initiatives to contribute to developing global regulatory standards and stay informed about emerging trends.

In addition to regulatory changes for medical devices, recent years have seen increased attention to cybersecurity in healthcare. With the growing integration of digital technologies and interconnected medical devices, cybersecurity vulnerabilities pose significant risks to patient safety and data integrity. Regulatory agencies are increasingly emphasizing the importance of cybersecurity risk management in medical device design, deployment, and maintenance. Clinical engineers must be well-versed in cybersecurity best practices and collaborate closely with information technology and cybersecurity experts to safeguard healthcare systems against cyber threats.

Moreover, the COVID-19 pandemic has underscored the importance of regulatory agility and preparedness in responding to public health emergencies. Regulatory agencies worldwide have implemented expedited approval processes and regulatory flexibilities to facilitate the rapid deployment of medical devices and technologies essential for pandemic response. Clinical engineering professionals have played a critical role in evaluating and deploying medical equipment and ensuring its

safe and effective use in caring for patients affected by COVID-19.

ical Engineering Division

As clinical engineering continues to evolve in response to technological advancements and changing healthcare landscapes, professionals in the field must remain proactive in monitoring regulatory developments and adapting to new requirements. Continuous education and professional development are essential to stay upto-date on regulatory changes and ensure compliance with evolving standards. By staying informed, engaging with regulatory bodies and standards organizations, and fostering collaboration across disciplines, clinical engineers can effectively navigate the complex regulatory landscape and contribute to enhancing patient safety and quality of care on a global scale.

Fabiola M. Martinez-Licona, MS, PhD Chair, IFMBE/CED <u>boardchair@ced.ifmbe.org</u>



### **Call for Nominations for ACCE Board Members**



Please send in your nominations for ACCE Board members by April 12, 2024. Per ACCE Bylaws, the Nominating Committee will confirm that anyone nominated is eligible for office, and is willing to serve if elected and attend Board meetings. Upon confirmation, the Nominating Committee will consider nominees eligible for the election.

There will be eight positions open for the 2024-2025 Board election:

President, 1-year term President-Elect, 1-year term Vice-President, 1-year term Secretary, 2-year term Member-at-Large 1, 2-year term Member-at-Large 2, 2-year term Member-at-Large 3, 2-year term Member-at-Large 4, 2-year term

Click <u>here</u> to propose your candidates.

#### Notes:

The Treasurer position is not open for 2024 election, as this officer will be serving the 2nd year of his two year term.

Current President, President-Elect, Vice-President, Secretary and Members at Large are completing their first term, and they are eligible to run for a second term.

Ilir Kullolli Chair, Nomination Committee <u>Ilir.kullolli@gmail.com</u>



### **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 <u>Journal of Clinical Engi</u>neering for only \$99! (Originally \$351). You must <u>login</u> to the ACCE website to view the code. Then visit <u>LWW.com</u> to enter code.



#### **HELP WANTED ACCE News Co-Editor**

The ACCE News co-editor is responsible for editing 3 newsletters each year and tasks include the following:

- Notifying regular article contributors of the upcoming issue's submission deadlines
- Editing submitted articles
- Editing photos and graphics
- Editing and formatting newsletter pages

- Writing headlines and sub-headings
- Submitting draft Newsletter for further editing
- Completing final editing for submission for publishing

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 <u>editor@accenet.org</u>.

#### ACCE CALENDAR

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

07—09 April 2024	MD Expo - Spring 2024 Location: M Resort Spa Casino, Las Vegas
11 April 2024 12:00 PM - 1:00 PM	ACCE 2023-2024 Educational Webinar Series Session#8: Medical Equipment Planning for Healthcare Organizations
09 May 2024 12:00 PM - 1:00 PM	ACCE 2023-2024 Educational Webinar Series Session#9: New Technologies for Surgery
19—25 May 2024	HTM Week
28 –30 May 2024	CMBEC46 / CESO 2024 Joint Conference Location: Doubletree by Hilton, Toronto, Ontario <u>Click here for more information</u>
06 June 2024 12:00 PM-1:00 PM	ACCE 2023-2024 Educational Webinar Series Session #10: Managing Clinical Engineering Projects
14—17 June 2024	AAMI eXchange24: Phoenix AZ ACCE members, please use the pdf registration <u>form</u> (not the online registration method) <u>Click here for more information</u>
14 June 2024 7:00 PM-9:30 PM	ACCE Board in-person meeting
15 June 2024 7:30 AM-10:15 AM	Clinical Engineering Symposium @AAMI eXchange: Navigating Homecare Technologies - Adapting to Shifting Patient Care and Tech Support Challenges at Home Location: Phoenix Convention Center

#### The ACCE Board and Committee Chairs

President	Kim Greenwood
President Elect	Katherine Navarro
Vice President	Qusai Shikari
Secretary	Michele Manzoli
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