ACCE News

Newsletter of the American College of Clinical Engineering

In this issue

President's Message (from ACCE Board)

Ilir Kullolli, President, ACCE

Happy (recent) Healthcare Technology Management Week to all of you! On behalf of the ACCE Board, thank you for your tremendous efforts and commitment to the clinical and patient care community.

For our members who aren't aware of it yet, it is with regret that we inform you that Priyanka Upendra has resigned from her position as President of the American College of Clinical Engineering. We are grateful for the time and effort that Priya has contributed to our organization, and we wish her all the best in her future endeavors.

As we move forward, the Board of Directors is working diligently to ensure a smooth transition of leadership. The Board met to discuss the next steps and, as per our bylaws, appointed Ilir Kullolli, who was currently serving as Immediate Past President, to be ACCE President until the term is over in August. In addition, the Board appointed Arif Subhan (a past president) to serve as Immediate Past President until the end of the term in August.

In the meantime, please join us in thanking Priya for her service and dedication to our organization. Her contributions have been invaluable, and we will miss her leadership and guidance at ACCE. She wanted to share with the ACCE Community that it was an honor for her to serve in this position and she looks forward to what's next for ACCE.

This is the first time that ACCE has had to face the challenge of a President resigning. However, our bylaws and policies, set in place by different ACCE Boards throughout the years, have helped us navigate this process smoothly!

Now, back to business – last month, ACCE hosted an insightful webinar following a request at the HIMSS CE-IT symposium to address CE-IT collaboration in cybersecurity. We had experts from H-ISAC, Sodexo, UI Health, Intermountain Healthcare, and ECRI discuss the processes, procedures, and workflows that have proven beneficial in their organizations. There is another webinar coming up focusing on ultra-high frequency passive radio frequency identification technology. This is a topic of interest in many health systems as the focus has shifted greatly towards efficiency and speed of care delivery.

ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING

CCE Exam Prep: Personnel Management

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 11. Note that the instructors for the ACCE CCE Prep courses, and the writers for this column, do NOT have any affiliation with the CCE Board of Examiners and have no access to the actual exam questions. If you have specific topics you would like us cover please contact editor@accenet.org.

Personnel Management

Question 1: As a new manager of a clinical engineering department, you realize from CMMS records that one of your technicians has documented many more PMs then he could have reasonably completed in a given period of time. How do you as a manager handle the situation to determine if this tech has been falsifying records, and, as appropriate, to hold him accountable for his actions?

A. Fire the individual immediately.

B. Obtain documentation of the problem. Address the individual confidentially about the matter before jumping to conclusions. Perform a broad scope fact-finding and utilize outside resources if needed. Depending on the findings, discipline accordingly.

C. Call an outside investigative source to further look into the department's records.

D. Obtain the proper documentation and publicly call out the individual so the rest of the shop is aware of his actions.

Correct answer B: Obtain documentation of the problem. Address the individual confidentially. Perform a broad scope fact-finding and utilize outside resources if needed. Depending on the findings, discipline accordingly.

Explanation: Fact find first. Was this a documentation error or intentional falsification of records? Once the investigation is complete, train and/or discipline accordingly.

Question 2: As a new clinical engineering manger, you are given approval to hire four new techs, all at the same level (e.g. BMET 2). Human Resources (HR) has advertised and provided you with 20 "qualified" applicants. What is the best way to select which techs to hire?

A. Hire whomever HR recommends to hire.

B. Hold the interviews privately with you as the only individual to rate the interviewed applicants.

C. Create a panel of representative stakeholders. Have the panel determine who to interview based on resume review and published job requirements. Use a list of performance based and technical questions to ask to each interviewed candidate.

D. Hire individuals based solely on resume content and organization and past experience.

Correct answer C - Create a panel of representative stakeholders and use a list of performance based and technical questions to ask each interviewed candidate.

Explanation: Creating a panel of representative stakeholders removes personal bias and forces the use of a consistent and fair, hiring methodology. Asking job-specific, performance-based and technical questions allows the panel to more objectively evaluate the candidate's qualifications for the job.

Financial Management

Question 3: You are the manager of an in-house clinical engineering department in a non-profit hospital system that has been well integrated into the fabric of the hospital system for decades. A for-profit clinical engineering service organization has approached the hospital's CFO with a proposal to replace your clinical engineering department, with a promise to save a lot of money, and still give excellent service. What should you have done in anticipation of this day?

A. Gone over this scenario in advance with your boss so that she/he has helped you articulate why the current structure is the best one for the hospital system.

B. Met with the CFO periodically to go over your department expenses, and what is (or is not) included in those expenses (e.g., do you absorb parts costs or charge back to user departments).

C. Developed benchmarking data to show how your department fares against other similar facilities.

D. All of the above.

Correct answer D – All of the above.

Explanation: All clinical engineering departments need to have robust financial data, and need to share that data with relevant hospital leadership. Comparing your financial metrics to similar facilities with similar clinical engineering departments (i.e., benchmarking) is often more difficult, but also important.

Kim Greenwood
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ECRI Perspectives: AI at HIMSS

Hello from ECRI! We're looking forward to seeing some of our favorite people in Long Beach and stocking up on hand sanitizer and sunscreen.

Did you get to HIMSS? We braved the exhibits, marveling at the number of booths touting artificial intelligence-enabled solutions. There were AI-enabled algorithms from traditional medical device suppliers, from physiologic monitors to wireless stethoscopes to imaging systems. There were algorithms from providers hawking their homegrown wares or third-party vendors who built something cool. There were huge pools of data from EHR vendors and providers and third-party brokers to help train and validate the next wave of AI-enabled products. There were portal operators who provide neither data nor algorithms but instead interface and connectivity management, like a very expensive and complex version of the Amazon Fire cube that sits watch over our home television and lets us choose between apps. There was rampant giddiness about generative-AI chatbots outperforming physicians in both the quality and empathy of written responses to patient questions drawn from a social media forum. There were some pretty sweet giveaways, with cash-flush vendors partying like it was 2007. Even the more sober FDA-regulated medical device suppliers were buzzing about FDA opening the door to active learning in cleared medical devices and systems this April.

So AI is cool, yeah? There's still a lot to be done to make sure AI-enabled technologies work for the type of patients you're seeing, and aren't perpetuating or worsening inequalities and health disparities. Want to get some helpful talking points for your next conversation with a clinician and do you like waking up early? Come join me at the AAMI eXchange on Saturday morning for "How to Talk About AI So Clinicians Will Listen".

Can't get enough of ECRI's cybersecurity coverage? We've got your back. Brand-new ACCE Education Committee co-chair Juuso Leinonen joined the latest edition of ECRI Now to talk about why healthcare organizations are such tempting targets for cyberattackers and how facilities can make sure they are adequately protected.

Want to improve your sleuthing skills? An estimated one in four patients experience an adverse event, with nine percent of these events causing significant harm. Approximately one quarter of these events are preventable. To enhance patient safety and prevent event reoccurrence, identification and resolution of contributing factors is critical. However, some healthcare organizations struggle to develop an unbiased causal analysis process. ECRI PSO (Patient Safety Organization) has developed a robust curriculum of causal analysis for healthcare organizations that includes courses for Root Cause Analysis, both foundational and advanced, and Healthcare Failure Modes and Effects Analysis, a proactive causal analysis process.

If you're ever in the neighborhood, we'd love to show you around our gorgeous new laboratory space. But, in the meantime, wash your hands, keep on excelling, and, as always, tell us what you're seeing.

Erin Sparnon
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President's report continued

ACCE is excited to actively participate at the AAMI eXchange in Long Beach, CA. As always, we have exciting educational opportunities at the eXchange and in the CE symposium. This year, we have experts shedding light on crucial topics that address wearable technologies, their benefits and pitfalls, and how Clinical Engineering and HTM professionals can prepare for these "new" challenges to our field. We're also thrilled to recognize the 2023 award recipients, the 2023 Clinical Engineering Hall of Fame inductees, and the 2023 Fellow members, and to meet all our members at the 33rd ACCE Awards reception.

With upcoming events and activities, we encourage you all to take a look at the ACCE website and participate in the webinars, panel discussions, and other engagements that interest you.

We are looking forward to the Board elections and the fantastic lineup of candidates we have for the 2023-2024 Board.

With that, we hope you all had a Happy HTM week and thank you for being committed to our mission and demonstrating shared values in the healthcare community!

ACCE Board
American College of Clinical Engineering
board@accenet.org

Ilir Kullolli
President, ACCE
president@accenet.org

Marvin D. Shepherd and George I. Johnston Inducted Into CE Hall of Fame

The Clinical Engineering Hall of Fame celebrates the application of engineering and managerial skills to support and advance the application of technology to patient care. The Clinical Engineering Hall of Fame is an "outward facing" (to the wider public) virtual museum established to tell the story of clinical engineering, from its beginnings in the late 1960s to the present date, by honoring the visionaries, leaders, and luminaries who have contributed to the creation, evolution, and advancement of the profession. This year we honor two luminaries, Marv Shepherd, and George Johnston, unfortunately both posthumously, who made significant contributions to the initial establishment and advancement of the clinical engineering profession.

**Marvin D. Shepherd
(Posthumous Recipient)
May 18, 1932 - April 13, 2023**

Marvin D. Shepherd has been inducted into the Clinical Engineering Hall of Fame in recognition of his work and significant contributions to the development and advancement of the clinical engineering profession.

Marv began his career in the 1950s and is certainly one of the pioneers in clinical engineering. From 1958 through 1970 Marv worked in the physiology department at the Proctor Eye Research Foundation supporting investigators in physiology and eye research through the development, construction, and support of unique instrumentation.

Beginning in 1970 Marvin was the program manager in the Office of Environmental Health and Safety at the University of California, San Francisco Medical Center. While there he managed programs in fire safety, hazardous materials, physical safety, non-ionizing radiation, emergency response, medical device safety, and education and training. He retired from that position in 1991 and

established Devteq Consulting, providing consultation on medical device safety issues to hospitals, manufacturers, and government agencies. He also provided seminars on medical device safety, risk management and human error, and expert witness services on accidents involving medical devices.

Based on his contributions for over 50 years, he was absolutely one of the most influential pioneers and industry leaders in our profession. He had a substantial impact on its evolution since the profession's inception. He advocated by writing prolifically and speaking widely on topics related to a systems approach to safety, fire safety, electrical safety, human factors engineering, and incident investigation.

In the early days of clinical engineering, Marv's publications and presentations influenced young clinical engineers and ultimately his material became the foundation of our knowledge about how safety, human factors engineering, and incident investigation could contribute to patient care.

Marv's innovations in safety, human factors engineering, and incident investigation led him to develop two of what would become the clinical engineering profession's most referenced tools. One is Shepherd's System for Medical Device Incident Investigation and Reporting (Quest Publishing, 1992) and the other is the Electrical Safety Manual: A Comprehensive Guide to Safety Standards for Healthcare Facilities (AAMI).

Marv not only helped define key elements in what should be a comprehensive clinical engineering service, but he was effective in reaching out to the na-
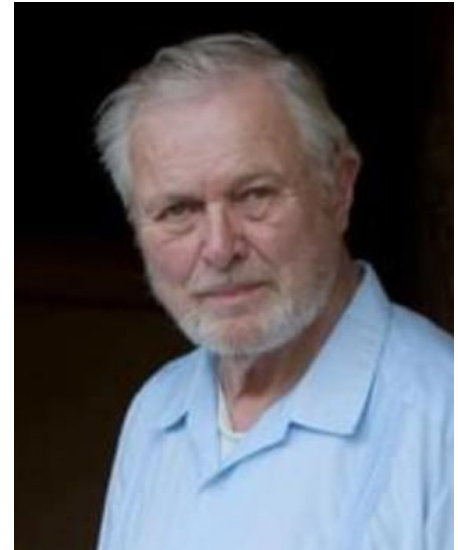
**George I. Johnston
(Posthumous Recipient)
May 29, 1929 - May 12, 2022**

George I. Johnston has been inducted into the Clinical Engineering Hall of Fame in recognition of his seminal work and significant contributions to the development and advancement of the clinical engineering profession. Beginning in 1958, he had had been one of the most influential pioneers and industry leaders in clinical engineering for six decades.

George's entry into the field of biomedical engineering came shortly after graduation from high school in 1948 when he was employed as a medical electronics technician at the Johns Hopkins School of Medicine. While working, he attended the Hopkins electrical engineering program part time and graduated in 1955. With his experience and new BSEE, George landed a job as a Biomedical Engineer in the Instrument Section of the National Institute of Health, where he authored his first publication and presented at two engineering conferences.

Johnston In CE HoF Continued

CLINICAL ENGINEERING
Hall of Fame

In 1958, George left NIH to start the Biomedical Engineering Support department at the University of Oregon Medical School, now called the Oregon Health Sciences University. He modeled the department after the NIH's Instrument Section and Johns Hopkins School of Medicine shop where he obtained his early experiences. He was a pioneer in the concept of bringing together technicians, engineers, and other skilled experts in a hospital-based team to collaborate and work with clinicians to develop and support new medical technologies that changed how patient care was being delivered.

All aspects of what George did as the leader of a new service were new and innovative. His close partnership with clinicians whose patients benefited from his technical innovations, his creation of a full-service, multi-disciplinary team, his engineering management and organization skills, all represented an innovative approach to a new clinical engineering service.

Word of George's multi-disciplinary approach toward technology support and technical support of caregivers got out and it soon became the industry model. In what was considered the "early days" of the profession, clinical/biomedical engineers looked to Oregon and George's program as a template for how to establish their own new clinical engineering services. George thus greatly influenced the generations of clinical engineers that followed. The impact he had on the clinical engineering profession was profound and continues to this day.

George's reach was both dramatic and widespread. During the 1970s George's department of biomedical engineering, like many others, experienced a significant shift in its customer base from a research focus to a hospital focus. Within 10 years, they became a hospital department and changed their name to Clinical Engineering. About that time, Project HOPE was introduced to George by Robert Morris, a renowned clinical engineering pioneer in his own right. The overseas experiences were both trying and a delight for George and his wife, Arlene, so much so that George retired from the Oregon Health Sciences University at the end of 1988. In 1989-1990, he took a long-term assignment with Project HOPE in China, and another long-term (1992-93) assignment in Guyana. After that, his humanitarian work took him to Belize, Guayaquil, Kenya, Kosovo, and beyond. After retirement, George continued to work with Dybonics, a biomedical engineering consulting firm he founded with two colleagues in 1967, to perform medical incident/accident investigations and provide related forensic testimony.

For more information on George's career and life, including personal recollections from his daughter, see ACCE News, Vol 32, No. 3 (May/June 2022), available to ACCE members at https://accenet.org/Membership/Memoriam/Pages/GeorgeJohnston.aspx.

Shepherd In CE HoF continued

tional and international community with his knowledge and expertise. He was a generous mentor to many in the field, meeting and sharing his knowledge and expertise at many domestic and international conferences and workshops. He further demonstrated his passion and dedication by creating and funding the Devteq/Shepherd Patient Safety Award. This annual award is now given jointly by the American College of Clinical Engineering (ACCE) and the Healthcare Technology Foundation (HTF) and is bestowed upon a single individual or entity who has excelled in the "safety" area related to the CE field. Potential recipients of the Devteq/Shepherd Award could be national investigators of accidents, inventors of a safety device, or authors of books on medical device hazards, etc.

For additional information on Marv's career, see https://accenet.org/HallofFame/Pages/MarvinShepherd.aspx

Volunteer Opportunity

ACCE News Co-Editor

ACCE News is published 6 times per year and each issue is 10-20 pages long. It takes the co-editor ~ 10-20 hours of work per issue. The ACCE News co-editor is responsible for editing 3 issues per year and duties include the following:

- Notifying regular article contributors of upcoming submission deadlines
- Editing submitted articles and editing layout so articles fit on page
- Following up with authors re article deadlines and corrections / clarifications
- Editing photos and graphics
- Writing headlines and subheadings
- Submission of draft newsletters for review and edit suggestions by ACCE Secretariat, ACCE President, ACCE Newsletter co-editor(s) and Managing Editor
- Completing final editing for submission for publication
- Occasionally writing articles

Currently the software used for this process is Microsoft Publisher

Min. Requirements: Member of ACCE and excellent command of written English

From the Editors' Desks

Welcome to our new co-editor, Sonja Markez.

Sonja Markez is a Clinical Engineer at the University Health Network (UHN) in Toronto, Canada. Prior to joining UHN, Sonja worked in Regulatory Affairs and Quality Assurance for various medical device manufacturers with sales in Canada, the US, and Europe. She has an undergraduate degree in Mechanical Engineering, a Master's degree in Clinical Engineering from the University of Toronto, and is a licensed professional engineer (P.Eng.). Sonja has earned a certificate in both Regulatory Affairs and Technical Writing. She holds a number of other professional certifications: Project Management Professional (PMP), Certified Medical Device Auditor (CMDA), Regulatory Affairs Certification (RAC) for US, Canada and EU, and is currently in the process of obtaining her Certification in Clinical Engineering (CCE).

Thank you to our out-going co-editor, Ismael Cordero, and out-going Managing Editor Jim Keller

We thank Ismael Cordero for his years as ACCE News co-editor and wish him well. We also thank Jim Keller for his more than 20 years as Managing Editor.

Moving on, Ted Cohen will be the ACCE News Managing Editor and we are recruiting for a new co-editor. Ted will continue as co-editor, along with Sonja, until a new one is recruited and trained.

Ted Cohen

editor@accenet.org

ACCE at AAMI eXchange2023 – Long Beach

ACCE is a contributing organization for AAMI eXchange 2023. ACCE members are eligible to register for the conference at AAMI members discounted rate. Just complete this <u>registration form</u>.

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

<u>Clinical Engineering Symposium – Presented by ACCE</u>

Title: Wearables and IoT - The Emerging Healthcare Technology Support Challenges

Date: Saturday June 17, 2023, 7:30AM - 10:15AM
Location: Long Beach Convention Center

The use of wearables and IoT devices in healthcare organizations is rapidly expanding. This technology shift is providing interesting new opportunities, but also presents a number of practical technology management and support challenges. Healthcare facilities are increasingly faced with the use of patient owned wearables. Many clinicians are leveraging bring your own device (BYOD) policies and utilizing their own medical devices and IoT to deliver care. The home use of medical devices is also rapidly ramping up with the expansion of telehealth. Many of these wearables and IoT medical devices are also network connected, exchange patient data, and utilize various cloud services. How do we stay on top of managing these new clinical use cases and expanding fleets of wearable and IoT devices? What are the related roles and responsibilities of HTM departments? How do we ensure these systems are used safely and the associated security risks are controlled?

Join this ACCE symposium to hear about the latest trends and best practices regarding the use, management, and support of wearables and IoT in healthcare. During this symposium we will discuss the common use cases for wearables and IoT in the healthcare setting and review the best practices in managing them. Learn the latest from the leading industry experts in panel discussions and hear education sessions from healthcare organizations about their successes and challenges in adopting wearables and IoT.

Click <u>here</u> to register

ACCE Symposium at AAMI continued

Agenda:

7:15am light refreshments, sponsored by Masimo

7:30am – 7:45am - Opening Comments

7:45am – 8:45am - Keynote - Telehealth Cybersecurity: Secure Remote Patient Monitoring Ecosystem
Description: The National Cybersecurity Center of Excellence (NCCoE) published a practice guide discussing approaches in applying privacy and cybersecurity measures in safeguarding a telehealth remote patient monitoring (RPM) solution. The speakers will describe the RPM ecosystem and discuss where security and privacy challenges may exist based on a risk assessment, approaches needed to understand those risks and a means to mitigate risks in serving their remote patient community. Healthcare technology practitioners will learn about complexities associated with deploying RPM solutions and take away concepts that may apply to their own RPM deployments.

8:45am – 9:00am - Break

9:00am -10:15am – Wearables Panel Discussion
Moderator – Ilir Kullolli, Stanford Childrens; Panelists: Priyanka Shah, ECRI; Eric Airing, Mayo Clinic; Katrina Jacobs, Kaiser Permanente; Jennifer Jackson, Masimo
The use of wearables and IoT devices in healthcare organizations is rapidly expanding. This technology shift is providing interesting new opportunities, but also presents a number of practical technology management and support challenges. Healthcare facilities are increasingly faced with the use of patient owned wearables. Many clinicians are leveraging bring your own device (BYOD) policies and utilizing their own medical devices and IoT to deliver care. The home use of medical devices is also rapidly ramping up with the expansion of telehealth. Many of these wearables and IoT medical devices are also network connected, exchange patient data, and utilize various cloud services. How do we stay on top of managing these new clinical use cases and expanding fleets of wearable and IoT devices? What are the related roles and responsibilities of HTM departments? How do we ensure these systems are used safely and the associated security risks are controlled? Join this ACCE symposium to hear about the latest trends and best practices regarding the use, management, and support of wearables and IoT in healthcare. During this symposium we will discuss the common use cases for wearables and IoT in the healthcare setting and review the best practices in managing them. Learn the latest from the leading industry experts in panel discussions and hear education sessions from healthcare organizations about their successes and challenges in adopting wearables and IoT.

ACCE at AAMI eXchange2023 continued

Education Sessions, presented by ACCE:

Focusing on What's Important – Leadership Evolution in HTM/CE

Date: Sunday, June 18, 2023: 8:00AM - 9:00AM
Location: Long Beach Convention Center
Speakers: Mike Powers, Nader Hammoud, Tony Cody

In the early 20th century, leaders were taught to manage their team so that the individual contributors performed essentially as robots taking inspiration from the introduction of the assembly line. As generations have come and gone, leadership has stagnated and not leveraged many changes in culture or work style. AAMI has projected that between 2020 and 2025 75% of the leaders in HTM would retire and need to be replaced. With such an influx of new talent, there is an opportunity to share Leadership Techniques for the 21st century, where people are appreciated for both who they are today and who they can be tomorrow. Join us in this round-table discussion as we share the foundations of successful leadership of our HTM/CE teams.

33rd Members Meeting/Awards Reception Saturday, June 17, 2023, 7:30PM - 10:00PM

Hyatt Regency Long Beach
Regency Ballroom DEFH
200 South Pine Avenue
Long Beach, CA 90802

RSVP here

Join us for an evening of networking with your peers and to congratulate the 2023 Advocacy Awards recipients, the 2023 ACCE Fellows and the 2023 Clinical Engineering Hall of Fame inductees.

2023 CCE Oral Exam

June 15 - 16, 2023

Location: Hyatt Regency Long Beach

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

Stop by ACCE Booth at Exhibit Floor, Booth # 731

Learn about new webinar series, CCE exam, membership programs and other ACCE activities. Connect with old and new friends and check/update your membership status.

AAMI Registration and Housing are Open!
eXchange23 Schedule at a Glance

MEDIGATE
by Claroty

WHITE PAPER

Understanding HHS Section 405(d) & Medical Device Security

Learn how Medigate by Claroty can empower your organization to achieve the highest caliber of medical device cybersecurity in alignment with the HHS 405(d) Program's Healthcare Industry Cybersecurity Practices.

AAMI Update: New Documents Provide Guidance on Artificial Intelligence in Medicine

If you're wondering how machine learning (ML) algorithms or any artificial intelligence (AI) will affect your healthcare institution, company, or career, the Association for the Advancement of Medical Instrumentation (AAMI) has you covered.

AAMI Releases Special Report on Artificial Intelligence

AAMI has recently released an in-depth report, "Artificial Intelligence, the Trust Issue," that provides expert insights for product developers, regulators, standards developers, hospital systems, healthcare technology management (HTM) professionals, risk managers, and clinicians. The report is the first of an ambitious new AAMI series of Medical Device Safety in Focus reports that will explore hot topics in healthcare technology.

According to AAMI's Joe Lewelling, Vice President of Industry, the digital report, which consists of an estimated 40 pages of content including informative videos, figures and expert insights, will serve as "an introduction for people in healthcare who need to know more about AI but are not necessarily specialists in AI."

"Artificial intelligence is something that the healthcare industry is going to be focusing on, and working with, and struggling with for the next decade or longer," said Lewelling "This document is not going to make an expert in artificial intelligence, but it is going to prepare you to make important decisions."

"Artificial Intelligence, the Trust Issue," tells a compelling story about the opportunities and risks of AI in healthcare—and provides wide-ranging perspectives on efforts to balance risks and opportunities. The report is presented in three sections:

The first section, Rehumanizing Healthcare with AI, sets the stage with a look at the potential of AI to remake healthcare—and what's driving high hopes.

"When done right, AI has enormous potential," noted report contributor Jesse Ehrenfeld, president-elect of the Ameri-can Medical Association, professor of anesthesiology at the Medical College of Wisconsin, and co-chair of AAMI's Artificial Intelligence Committee. "Digital medicine has enormous opportunity to improve health outcomes. There is tremendous enthusiasm about disruptive innovation as long as it's clinically validated. Where we hear concerns, and I hear this all the time, is around lack of transparency that will interfere with that trust, with understanding how these tools were designed and validated."

Inside AI's "black box" focuses on the myriad ways that AI-enabled health technologies could jeopardize patient health and safety, increase inequalities and inefficiencies, undermine trust in healthcare, and adversely impact the management of healthcare.

"The proliferation of developers who are good at developing artificial intelligence systems, but who've never done it in a life-sciences setting, can cause problems in terms of safety, efficacy, and unintended consequences," said contributor Scott Thiel, Global Head of Regulatory Policy and Intelligence, Hologic, Inc. "Frankly it can also cause compliance issues out of ignorance of the regulatory requirements for these systems."

The report includes practice guidance and an AI vendor checklist for HTM professionals. It also addresses an irony in the growth of AI health technology and the complex challenges associated with it: Everyone involved in developing, managing, and using it needs to bolster their knowledge and competencies.

"Communication buys grace," added Mike Powers, System Director of Healthcare Technology Management, Intermountain Healthcare, and a member of AAMI's Artificial Intelligence Committee. "The more manufacturers, AI developers, and organizations that have experience with AI products communicate the risks and benefits of AI technology, the more informed additional parties can be to make informed decisions."

At the root of the report are the insights of professionals who are invested in a future where AI is used to enrich, not burden, the healthcare space.

"We know that artificial intelligence is going to change the world. Those working with healthcare technology may be wondering where they fit in or what they can do about it. The best action you can take—right now—is to get informed," said Gavin Stern, MPH, MS, Editor in Chief at AAMI and the association's Director of Publications. "That's why we developed Medical Device Safety in Focus, a new kind of publication that provides an in-depth look at a specific healthcare technology topic. The first edition of MDSIF puts you in the room with the foremost experts working at the confluence of artificial intelligence and healthcare, from multiple fields and viewpoints. This is the AI primer you've been waiting for."

The report is free for AAMI Members and available for purchase at aami.org/MDSIF-AI. Interested parties may read the executive summary for free at aami.org/MDSIF-AI-summary.

AAMI, BSI Join Forces to Publish Guidance on Artificial Intelligence

AAMI and the British Standards Institute (BSI) have jointly published guidance documents on performing risk management for ML or AI incorporating medical devices.

AAMI Technical Information Report (TIR)34971:2023, Application of ISO 14971 to machine learning in artificial intelligence – Guide, derives from a 2022 AAMI consensus report (CR). The U.S. Food and Drug Administration recognized the CR as a guidance document "appropriate for meeting requirements for medical devices under the Federal Food, Drug, and

Shauna Mullally: 2023 AAMI Foundation and ACCE Robert L. Morris Humanitarian Awardee

Congratulations to Shauna Mullally, MASc, 2023 AAMI Foundation & ACCE Robert L. Morris Humanitarian Award recipient.

This award, honoring the late clinical engineer and humanitarian Bob Morris, recognizes individuals or organizations whose humanitarian efforts have applied healthcare technology to improving global human conditions.

Since late 2016, Shauna Mullally has been in the Canadian sub-arctic overseeing medical equipment planning and procurement for the Northwest Territories' 34 communities' health facilities, and health and long-term care services.

Having also worked with communities in Gambia, Zambia, Denmark, Guinea, Guinea-Bissau, and London, Mullally has showcased how healthcare technology management practices can enrich low-resource healthcare systems around the world.

Among her proudest achievements is the development of a birthing house for and with the women of the village of Penyem, Gambia. Over 200 babies have been born at the facility since then, and it is now a full health center for the village with a visiting nurse and doctor.

"I was drawn to engineering because I loved math and science, and once I got there I was drawn to biomedical and clinical engineering because I wanted to work in an area that was people focused," Mullally told AAMI. "There was no turning back once I saw first-hand what a lack of safe, available health technologies means to patients and caregivers in low-resource settings. There is a tremendous amount of good our profession can do in the world, particularly in places with very few resources," she said. "It is meaningful for me to join the past recipients of this award, many of whom have been mentors to me. I believe in the work of AAMI and the ACCE in this area and feel very humbled to be recognized."

"Shauna has elevated the HTM/CE service delivery by educating HTM practitioners to adopt cost-efficient and time-efficient practices, globally impacting HTM projects, outreach efforts, volunteerism – all of which make her a passionate and positive role model in our industry. She is collaborative, professional, approachable, and committed to what our industry currently needs and where we strive to progress over the coming years. Her volunteer work to expand visibility to our field has allowed her to work with various NGOs in the developing world and collaborate their efforts with governmental and international organizations. This volunteering with NGOs has extended to her work at the World Health Organization supporting COVID-19 respiratory equipment training courses. Shauna

Shauna Mullally, 2023 AAMI Foundation & ACCE Robert L. Morris Humanitarian Award recipient.

has been a technical role model as well, in building workplans and templates for the COVID-19 relief project, which now has over 14,000 active participants across the globe.", said Priyanka Upendra.

Advocacy Committee
Advocacy@accenet.org

AAMI continued: Artificial Intelligence Committee

Cosmetic Act." Developed in collaboration with BSI, the CR was the first AI-related guidance to receive this level of recognition from the Agency. The new TIR and Standard designations carry more weight—and the British Standard Institute will extend the reach of the guidance.

Rather than reinvent the wheel, the AAMI Artificial Intelligence Committee applied the standard risk management process to the elevated or unique safety-related vulnerabilities and risks of AI- and ML-enabled medical devices, including: Data management; bias; data storage, security, and privacy; overtrust; and, adaptive systems.

"The risk management process is the same, but there are new ways to fail, different concerns, and different risk controls to consider," said Pat Baird, Senior Regulatory Specialist at Philips and co-chair of the AAMI Artificial Intelligence Committee, in AAMI's inaugural Medical Device Safety in Focus report, "Artificial intelligence: The Trust Issue". "Recognize the fact that AI systems, data, and clouds are going to change and that is outside your control. Plan for it. Don't wait until something bad happens and then try to figure out what you're going to do about that. Have the infrastructure and mechanisms in place."

AAMI and BSI are planning to propose TIR34971 as an international standard through International Organization for Standardization (ISO)Technical Committee (TC) 210, Quality management and corresponding general aspects for products with a health purpose including medical devices, and IEC (International Electrotechnical Commission) Subcommittee (SC) 62A/Common aspects of medical equipment, software, and systems.

AAMI Staff

From the Education Committee Desk

2022-2023 Educational Webinar Series
CMMS Standardization and Implementation - best practices and lessons learned
Thursday, June 08, 2023; 12 pm - 1pm (EDT)
FREE for MEMBERS
Panelists
Tom Toczlowski — Assistant Director, Alerts — ECRI
Jane Boal — Regional Manager — Providence Health Care
Ted MacLaggan — Manager, Biomedical Engineering — Island Health

2022-2023 Educational Webinar Series
Lessons learned: 2023 CE-IT Symposium: Securing IoMT Proactively
Thursday, May 11, 2023; 12 pm - 1pm (EDT)
FREE for MEMBERS
Panelists
Philip Englert — Director of Medical Device Security — Health-ISAC
Shawn Anderson — Manager, Cybersecurity Architecture — Intermountain Health
Chris Falkner — Sr. Director of HTM Digital Strategy — SODEXO HTM
Jim Panella — Director of CE/IT — UI Health

Complimentary webinar — Sponsored by PYCUBE
Moving Passive RFID Solutions into Mainstream Healthcare Use:
Practicality, Affordability and Powerful Performance Deliver an Advantage
Date/Time: Thursday, May 18, 2023, 12pm - 1pm EDT

Join us for an insightful and engaging presentation that dvelves into the fascinating world of Ultra High Frequency (UHF) Passive Radio Frequency Identification (RFID) technology. The presentation will provide an in-depth overview of UHR Passive RFID, illustrating its capabilities and exploring its numerous applications for healthcare.

Whether you're technology enthusiast, industry professional, or simply curious about the possibilities of UHF Passive RFID technology, this presentation will equip you with the knowledge to better understand and harness the power of wireless connectivity.

Don't miss this opportunity to stay informed and get inspired by the potential of UHF Passive RFID.

Dr. William Howden — Chief Revenue Officer — Pycube, Inc.

2022-2023 Educational Webinars Supporters

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The last ACCE Educational Webinar in the 2022-2023 series, will be on June 8th, covering the topic "CMMS Standardization and Implementation - best practices and lessons learned"

ECRI will expand on the importance of CMMS standardization and the use of a common nomenclature system to extract meaningful reports from your CMMS. Representatives from an HDO in British Columbia, Canada, who use a common CMMS, will review some of their CMMS improvement initiatives and standardized processes associated with their PM Program.

Members register for Free here

The Education Committee held their May 11th webinar session: "CE-IT Symposium, Lessons Learned from HIMSS". In this presentation the expert team of panelists shared their experiences of attending and presenting at the Pre-HIMSS Symposium. The speakers shared their key takeaways and discussed about the content covered during the in-person event. The team also shared their insights about our first ever cybersecurity tabletop exercise held during the symposium.

On May 18th, Dr. Bill Howden from Pycube presented "Moving Passive RFID Solutions into Mainstream Healthcare Use: Practicality, Affordability and Powerful Performance Deliver an Advantage." If you missed the live session, look for the recording and presentation slides on the ACCE Website.

The Education Committee would like to thank our speakers from the 2022-2023 Webinar series. These distinguished speakers, representing manufacturers and hospital staff, are what made this a successful series. We had clinical engineers, IT representatives, managers, directors, and administrators present. We would like to thank all of them for taking time out of their busy schedules to share with us their knowledge, help us advance the Clinical Engineering profession, and support ACCE through the Webinar Series. From all of us on the Education Committee – THANK YOU!

Last but not least, the Education Committee, and the ACCE community, would like to thank these generous sponsors who made it possible to offer the series FREE to all members!

Have a happy Summer and stay tuned for the 2023-2024 educational webinar series coming this Fall.

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

IFMBE Clinical Engineering Division

Clinical Engineering and Innovation

Clinical engineering is a field that focuses on the application of engineering principles to healthcare technology management. The scope consists of designing, developing, and maintaining medical equipment and assessing the safety and efficacy of medical devices. As technology advances, innovation in clinical engineering becomes increasingly crucial in providing high-quality patient care, where the possible areas of advancement include medical devices, services, and processes.

One of the most significant areas of innovation in clinical engineering is the development of new medical devices. Advanced technologies such as robotics, artificial intelligence, and nanotechnology integrate into medical devices to improve their effectiveness and efficiency. For example, robots assist surgeons in complex procedures, while AI analyzes information, signals, and/or images for diagnostic and treatment purposes. On the other hand, nanotechnology is being used to develop innovative drug-delivery systems targeting specific cells or tissues within the body.

The possibilities multiply when considering the interactions between the different developments and the tools available for their optimization.

Another area of innovation in clinical engineering is the use of telemedicine. With telemedicine, patients can receive medical care from the comfort of their homes, reducing the need for hospital visits and minimizing the risk of exposure to infectious diseases. Telemedicine is also used to provide medical care to patients in remote or underserved areas with limited access to healthcare. Social, economic, and health contingencies represent a scenario that can become common. The challenges that arise demand timely and quality services that telemedicine can provide through technological and process innovations.

The development of personalized medicine is another field for innovation.

This new field involves tailoring medical treatment to the individual characteristics of each patient. This approach can be highly effective in treating conditions such as cancer, in which each patient's tumor has unique features that require personalized treatment, or diabetes, where the patient's profile demands a customized strategy for treatment that can be supported by technology. Clinical engineering provides those tools to develop and implement personalized medicine, including genomic sequencing, bioinformatics, and advanced imaging techniques.

Another area of innovation in clinical engineering is big data analytics. With the increasing digitization of healthcare records, vast amounts of data are being generated that can be used to improve patient care. Big data analytics involves the use of advanced algorithms and machine learning techniques to analyze large datasets and extract insights that can be used to improve patient outcomes. For example, big data analytics can identify patients at high risk of developing a particular condition, allowing healthcare providers to intervene early and prevent the condition from developing.

Finally, clinical engineering is critical in developing more sustainable and environmentally friendly healthcare technologies. With the growing recognition of the impact of healthcare on the environment, there is a need for technologies that minimize waste and energy consumption. Clinical engineers are developing new technologies such as energy-efficient medical devices, sustainable packaging materials, and environmentally friendly disinfection processes.

Clinical engineering is at the forefront of the healthcare industry's transformation, from developing new medical devices and personalized medicine to using big data analytics and sustainable technologies. As technology advances, the role of clinical engineering in healthcare will only become more critical, and we can expect to see even more exciting developments in the years ahead.

Fabiola M. Martinez-Licona
Chair: Clinical Engineering Division, IFMBE
fabimx@gmail.com

Welcome New Members

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

Name	Class	Job Title	Organization	Country
Krista Choe	Individual	Production Manager	MXR Imaging	USA
Jagadesh Kumar Dhayalan	Individual	Associate Biomedical Engineer	Tamilnadu Medical Services Corporation	India
Mary Shine	Individual	Clinical Engineer	Massachusetts General Hospital	USA
Majdi M. Noor	Individual	Biomedical Engineer	Galaxy Int'l Ventures LTD/Hayat National Group of Hospitals	Saudi Arabia
Heather Heidenreich	Student	Graduate Student	University of Connecticut	USA
Priyanka Shah	Institutional/Individual	Principal Project Engineer	ECRI	USA
Eunice Santiago	Associate	Biomedical Engineering Supervisor	UCSF @San Francisco General Hospital	USA
Phillip Jakubowitz	Institutional/Associate	Clinical Engineer	Beth Israel Deaconess Medical Center – BIDMC	USA

New Fellow Members

Please join us to congratulate the new 2023 ACCE Fellow Members! They will receive their Fellows credentials/plaques at the ACCE 33rd Members Meeting/Awards Reception on June 17th, in Long Beach, California.

Henry Stankiewicz Jr., FACCE

Mark Brody, FACCE

Steve Juett, FACCE

Join us to congratulate the 2023 ACCE Scholarship winner, Julianne Boughton

Julianne M. Boughton
Biomedical Engineering - Class of 2023
University of Vermont
Starting Master Program
Biomedical Engineering in Fall 2023
University of Vermont

An excerpt from Julianne's winning essay:

In many ways, healthcare workers are superheroes of our society, especially within the past few years. But this goes well beyond the doctors and nurses who work in hospitals and clinics. I was introduced to the clinical engineering field in January of 2022 when I began a course in clinical engineering taught by Tobey Clark. That same month, I also began my internship with Instrumentation and Technical Services (ITS) at the University of Vermont where I worked as a biomedical engineering intern. Through these experiences, I learned of the significance of clinical engineering and the value of the engineers and technicians who work to ensure the healthcare system stays productive and safe.

What really drew me to the field of clinical engineering is the attention to detail required on such a large scale. In my experiences with more traditional engineering roles, one may be focused on a component that will be a single piece of the entire system. Conversely, at the UVM Medical Center, there are tens of thousands of device types that each need maintenance schedules and procedures, scheduled updates, and disposal plans to name a few. Similarly, clinical engineers are responsible for every device from the acquisition stage until the decommissioning phase. Personally, I feel I would enjoy this broader range of responsibilities and diversity of challenges in my day-to-day duties in my career.

Another reason I am attracted to the field is the emphasis on human factors engineering. While this is a big must in all other engineering disciplines, none more so than clinical engineering. In many ways, our job is to bridge the gap between the anticipated needs of the device and the actual needs and environment of use. Most of the time, these demands cannot be quantified with numbers and instead require a more creative solution that fits within the resources of the hospital. By directly interviewing users of the devices, more intuitive systems can be created to avoid hazards or failures. I have greatly come to appreciate this side of design by bringing a more human touch to engineering.

…

Overall, I hope to continue my work in the field of clinical engineering beyond my college career and into my professional life. At least for now, I can appreciate the unsung heroes who work behind the scenes to ensure the best possible care for patients.

Application Deadline for 2023 CCE Exam is July 21

The computerized written examination for HTCC Certification in Clinical Engineering (CCE) will be available from November 4 through November 18, 2023. The deadline for applications is July 21, 2023.

Arrangements can be made to take the written exam in most major cities around the world at computer-based testing facilities managed by Prometric (https://www.prometric.com).

You may apply to take this exam by downloading the handbook and application form. After reviewing the Handbook, please contact Julia Mazzoleni, Secretariat for HTCC at certification@accenet.org, or by telephone (610-567-1300) if you have further questions.

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

ACCE Healthcare Technology Certification Commission

Clinical Engineering Certification Program (CCE)

The purpose of certification is to promote healthcare delivery improvement through certification and continuing assessment of competency of professionals who support and advance patient care by applying engineering and management skills to healthcare technology.

2023 Clinical Engineering Certification Examination

The computerized written examination will be available
from November 4, 2023 through November 18, 2023

Application deadline: July 21, 2023

For detailed information and to apply, go to:
https://accenet.org/CECertification/Pages/Default.aspx   or scan the QR code:

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 $351). You must login to the ACCE website to view the code. Then visit LWW.com to enter code.

ACCE CALENDAR

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

08 June 2023, 12:00 PM-1:00 PM
2022-2023 Educational webinar series, session10:
CMMS Standardization and Implementation - best practices and lessons learned

15 June 2023-16 June 2023
2023 CCE Oral Exam

16 June 2023-19 June 2023
AAMI eXchange

17 June 2023, 7:30 AM-10:00 AM
Clinical Engineering Symposium by ACCE @ AAMI eXchange23
Wearables and IoT - The Emerging Healthcare Technology Support Challenge

17 June 2023, 7:30PM - 10:00PM
ACCE 33rd Members Meeting/Awards Reception

30 June 2023
Last day to renew your 2023 CCE Certification

21 July 2023
Last day to submit your complete application package for 2023 CCE Examination

14 September 2023
ACCE 2023-2024 Educational Webinar series, session#1

October 2023
Cybersecurity Awareness Month

04 - 18 November, 2023
CCE Computerized Written Examination

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