



ACCE News

Newsletter of the American College of Clinical Engineering

July — August 2023

Volume 33 Issue 4

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President's Message



Ilir Kullolli, Interim President, ACCE

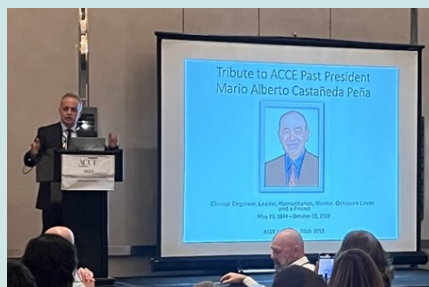
Dear ACCE Community,

I hope you all had a great Independence Day! Having lived in the US for the last quarter of a century and a better part of my life and seeing the events that have happened around the world and in the country over the last few years, I have come to appreciate this special day more and more every year. On this Independence Day, we not only celebrated the declaration of independence, but we also celebrated the diversity and resilience that defines us as a nation. I wanted to take a moment to express our gratitude to all the men and women who have dedicated their lives to defending our freedom and upholding the values we hold dear, and to the many clinical and biomedical engineers who served in the military. Their unwavering commitment and sacrifices inspire us to strive for a better tomorrow.

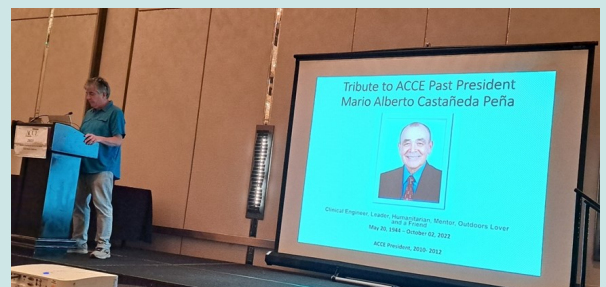
In June, we had great participation at the AAMI eXchange in Long Beach, CA. We had some exciting educational opportunities at the eXchange and in the CE Symposium. During the Symposium we discussed the ever-changing landscape around medical device security and wearable technologies. We had a great panel discussion about wearables where topics included how they can and will change the model of care and how Artificial Intelligence/Machine Learning is going to effect the adoption of wearable technologies.

In addition, we had many ACCE Members present at the AAMI eXchange. It was so exciting to see ACCE members at full force, taking the lead, and sharing their experiences and knowledge with the clinical engineering community. We also had a great membership event where we got to meet colleagues from all over the country and the world, made new connections, and had some good food! Significantly, we also took time to recognize many ACCE Members with various ACCE Awards.

One of the most special moments of the evening was the tribute to our past president Mario Castañeda, and presenting his ACCE 2023 Lifetime Achievement Award to his daughter, Sandra C. Dietrich. Thank you to everyone who helped make this message special!



Long time friend, Mark Manning, Vice President at Kaiser Permanente, paying his tribute to Mario



Steve Campbell, Chair, AAMI Foundation, reflecting on Mario's legacy in strengthening ACCE collaboration with AAMI.

President's Message (continued)

(Continued from page 1)

I also want to take a minute to give a shout-out to our ACCE Board members who were recognized at the AAMI eXchange with special awards.

Bhaskar Iduri – ACCE Treasurer – was recognized with the AAMI HTM Leadership Award. This award recognizes individual excellence, achievement, and leadership in the healthcare technology management (HTM) profession.

Katherine B. Navarro – ACCE Vice President – was recognized with the AAMI Young Professional Award. This award is presented annually to a professional under the age of 40 who exhibits exemplary professional accomplishments and a commitment to the healthcare profession.

Erin Sparnon – ACCE Board Member at Large – made a special appearance at the AAMI Wall of Heroes with the Best Column/Commentary with her article on *How to Find the Clinical AI at Your Facility and Govern It*.

Congratulations to all the award winners – you fully deserve these accolades and you make us all look good!

Switching gears, we just completed our ACCE Board elections! Please take a look at the results on [Page 9](#). We had a great slate of candidates for the positions and I look forward to a great year with the new Board! Thank you to the Nominations Committee for helping sort through the candidates and presenting them to the Board and the ACCE Community for approval. Also, much gratitude to the Board Members that have elected to continue serving ACCE over the next year!

With many 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.

Last, but not least, I want to wish ACCE a Happy 33rd Birthday! What an accomplishment for an organization that is member-supported, has been advocating for the profession for over 30 years, and continues to be the leading Clinical Engineering organization in the country and the world. Happy Birthday ACCE!

This is my last message as the Interim ACCE President! I want to thank you for being committed to our mission, for the words of encouragement over the last couple of months, and for your continued support for ACCE!

Sincerely,

Illir Kullolli
Interim ACCE President
American College of Clinical Engineering
President@accenet.org

ACCE Board
American College of Clinical Engineering



Sandra Castañeda Dietrich receiving, on behalf of her late father Mario Castañeda, the 2023 Lifetime Achievement Award

ACCE News

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

Managing Editor

Ted Cohen
tedcohen@pacbell.net

Co-Editors

Dustin Keith Telford
dustin.telford@gmail.com
Sonja Markez
sonja.markez@gmail.com

Circulation & Address Corrections

Suly Chi, ACCE Secretariat
secretariat@accenet.org

Advertising

Dave Smith
advertising@accenet.org

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CCE Exam Prep: Sample Review Questions

This column provides example questions and information regarding preparation for the CCE exam. The questions are based on topics from the ACCE Body of Knowledge survey and the CCE Study Guide, version 12. Note that the instructors for the ACCE CCE Prep courses, and the writers for this column, do NOT have any affiliation with the CCE Board of Examiners and have no access to the actual exam questions. If you have specific topics you would like us cover please contact editor@accenet.org

Question 1: What are important values achieved by standardizing common medical equipment used throughout a hospital (e.g., infusion pumps), and why?



Answer:

- Fewer user errors and adverse events – Staff being familiar with equipment operation is especially important if the equipment is centrally distributed to many units or if clinical staff may be assigned to work in different units in the healthcare facility.
- Reduced training time and costs – Clinical and maintenance staff training is reduced if standardized equipment is procured.
- Better discounts for purchasing of equipment, consumables, & accessories - Volume discounts can be achieved along with more efficient ordering systems.
- More efficient maintenance – Fewer parts stock requirements will be necessary, more efficient ordering can be achieved, and timelier repair will result.

Question 2: What are key medical equipment support information and requirements to include in a vendor solicitation for new equipment?

Answer:

Example service information and requirements are:

- Multi-year service contract costs and specifications.
- Uptime guarantees.
- Time of coverage.
- Call back & on-site response time.
- Time & materials rates outside contracted hours - after hours, weekends, holidays, travel and zone charges.
- Vendor service technician qualifications.
- Service reports requirement.
- Costs for training, parts, service tools such as diagnostic software, codes, fixtures, and specialized test equipment.
- Service training equal to manufacturer personnel - on-site at the healthcare institution preferred in many cases.
- A discount biomedical screening of problems.
- Documentation with schematics, parts list, theory of operation, PM procedures, troubleshooting and updates.
- Service assistance via phone and online.
- Guaranteed availability of parts for seven years minimum.
- Shipment of critical parts overnight.
- Parts exchange policy.
- Software updates policy and costs.

Question 3: Rank downtime costs for the following equipment types based on average lost revenues of an exam. One (1) is the highest cost, and four (4) is the lowest cost.

- CT scan
- X-ray
- MRI
- Nuclear medicine

Answer:

1 – MRI, 2 – CT scan, 3 - Nuclear Medicine, 4 – X-ray

Explanation:

Although the costs vary widely depending on the specific exam, on average, MRI is the

most expensive, thus a down MRI unit results in the highest lost revenue per exam. CT scans are next, followed by Nuclear Medicine. X-ray is by far the least expensive exam. Lost revenue means more expensive downtime - and a higher maintenance priority when the device needs repair.

Reference: *Costs, charges, and revenues for hospital diagnostic imaging procedures: differences by modality and hospital characteristics* by C. Sistrom & N. McKay
<https://pubmed.ncbi.nlm.nih.gov/17411868/>

Question 4: Match the terms with their definitions.

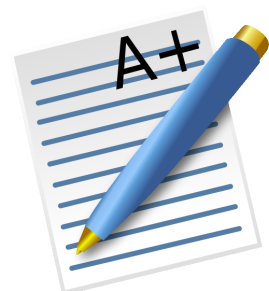
- A. Healthcare Technology Assessment
- B. Clinical Effectiveness
- C. Policy
- D. Accreditation

1. A statement of intention to do something, an orientation, a guide for action based on a set of guiding principles or values, aimed at influencing, and determining long term decisions and actions for healthcare technology.
2. An examination of safety, efficacy, cost-effectiveness, need, impact, ethical and legal issues associated with a new technology within the population context.
3. A voluntary process by which a government or non-government agency grants recognition to an organization which meets defined standards.
4. The extent to which a specific medical intervention, procedure, regimen, or service does what it is intended to do under ordinary circumstances, rather than controlled conditions.

Answer:

- A. Healthcare Technology Assessment – 2
- B. Clinical Effectiveness – 4
- C. Policy – 1
- D. Accreditation - 3

Tobey Clark
University of Vermont
j.tobey.clark@gmail.com



ACCE at AAMI eXchange 2023 — Long Beach

ACCE Board Meeting

The ACCE June Board Meeting was held in person on Friday, June 16, 2023 at Hyatt Regency Long Beach, with the entire Board and several committee members.



L-R: Jim Panella, Suly Chi, Erin Sparnon, Bhaskar Iduri, Amy Klemm, Michele Manzoli, Ashley O'Mara, Kim Greenwood, Sudhakar Nagavalli, Jenn Nichols, Kevin Kreitzman, Arif Subhan, Katherine Navarro, Ilir Kullolli

ACCE at AAMI eXchange 2023 — Long Beach

2023 Clinical Engineering Symposium, by ACCE: Saturday, June 17, 2023

The ACCE team once again organized a highly successful and informative Clinical Engineering Symposium at the AAMI eXchange 2023 in Long Beach, CA. This year, the CE Symposium focused on “Wearables and IoT - The Emerging Healthcare Technology Support Challenge”, which clearly piqued the interest of numerous AAMI attendees. Our expert speakers discussed topics ranging from cybersecurity to the practical challenges of managing wearable technologies in healthcare settings.



Keynote Address

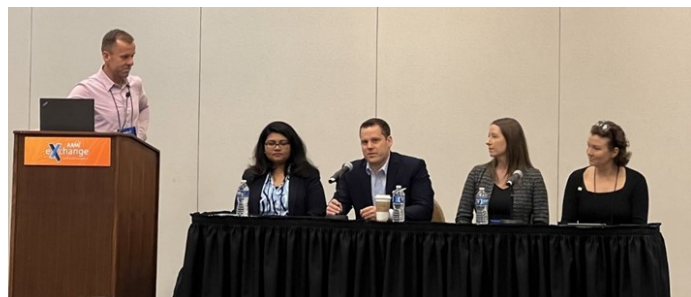
The keynote address, “Telehealth Cybersecurity: Secure Remote Patient Monitoring Ecosystem”, highlighted the excellent work done by the team at the National Cybersecurity Center of Excellence (NCCoE) in securing Remote Patient Monitoring (RPM) systems.



Sue Wang and Ryan Williams from MITRE/NCCoE shared the NCCoE team’s development of a reference architecture for securing RPM systems, providing insightful information about RPM data flows, and applicable security controls.

Wearables and IoT

The symposium’s second session was a panel discussion on wearables. Expert viewpoints from HDOs, a manufacturer, and ECRI were included in the panel. Ilir Kullolli from Stanford Children’s moderated the session and posed questions to the panelists, including some from the audience, to delve into key questions about wearables and their impact on Clinical Engineers. The expert panel of speakers included Priyanka Shah, MS, Sr. Project Engineer from ECRI; Eric Airing, MBA, HTM Program Manager from Mayo Clinic; Katrina Jacobs, MS, CCE, Sr. Clinical Systems Engineer from Kaiser Permanente; and Jennifer Jackson, MS, CCE, Sr. Director, Business Development from Masimo Co.



The use of wearables and IoT devices in healthcare organizations is rapidly expanding. This technology shift offers intriguing new opportunities but also presents several practical technology management and support challenges. If you missed the CE Symposium, the presentation slides are available for download on the [ACCE web-site](#). ACCE looks forward to continuing its coverage of wearables in healthcare through our upcoming educational webinars.

Leadership

On Sunday morning, the ACCE Education session was delivered by Mike Powers, Nader Hammoud & Tony Cody, on “Focusing on What’s Important – Leadership Evolution in HTM/CE.”

This panel was attended by many and the healthy participation and discussion caused the session to run beyond the allocated time... definitely a topic to be continued!



ACCE at AAMI eXchange 2023 — Long Beach

2023 Members Meeting / Awards Reception:

2023 Awardees received congratulations and plaques from Ilir Kullolli, ACCE Interim President.



Student Paper Competition:
Kordell Tan



2023 Class, Fellow member:
Hank Stankiewicz, FACCE



2023 Class, Fellow member:
Steve Juett, FACCE



Joan Brown, EdD receiving the 2023 Professional
Achievement in Technology Award



2023 Class, Fellow member:
Marc Brody, FACCE



ACCE at AAMI eXchange 2023 — Long Beach

2023 Members Meeting / Awards Reception: Saturday, June 16, Hyatt Regency Long Beach, California

Hall of Fame



Marvin Shepherd (h.c.)
2023 Inductee



George I. Johnston (h.c.)
2023 Inductee

The 2023 Class of Hall of Famers: [Marv Shepherd](#) & [George Johnston](#), were inducted to the [ACCE Clinical Engineering Hall of Fame](#)

Absentee Honorees

Unfortunately, a few of the awardees were unable to travel to Long Beach for the ceremony. We extend our congratulations to:

- Angela Bennett, the 2023 Professional Achievement in Management/Managerial Excellence Award
- Ernesto Antonio Ibarra, the 2023 Antonio Hernandez International Clinical Engineering Award
- ABEClin, the 2023 ACCE/HTF International Organization Award
- Simin Nazeri, the 2023 Student Paper Competition, Master Program Division
- Julianne Boughton, the 2023 Scholarship winner

Congratulations to all the awards recipients!

and

Thank You!

Thank you to our evening co-sponsors:

[PYCUBE](#), [Medigate by Claroty](#), [NESCE](#), [Phoenix Data Systems](#), [Schiller Americas](#)

Thank You to Our Member Volunteers at AAMI eXchange 2023 — Long Beach

Thank you again for taking time from your busy schedules while at AAMI eXchange 2023 to staff the ACCE booth, set-up, dismantle, and package and ship booth material.

Our immense gratitude to the following wonderful volunteers as we couldn't have done without their help: Eric Aring, Kim Greenwood, Michele Manzoli, Kevin Kreitzman, Jennifer Nichols, Juuso Leinonen, Katherine Navarro, Ashley O'Mara, Kwaku Offori, Sirvart Karaoglyan, Jim Panella, Alan Lipschultz, Elkin Lara-Mejia, Eunice Santiago, Daisha King and Binseng Wang.

The traffic at the ACCE booth was heavy during this year's event, with members and non-members from the US and around the world.



L-R: Sirvart Karaoglyan, Kwaku Offori,
answering questions to conference participants



L-R: Alberto Lanzani, Italy &
Michele Manzoli



L-R: Eric Aring, Sirvart Karaoglyan, Michele Manzoli,
Jennifer Jackson, Ted Cohen, Suly Chi



L-R: Juuso Leinonen, Tony Cody, Frank Painter, German Giles



L-R: Juuso Leinonen, Jim Panella, Ashley O'Mara, Ilir Kullolli

2023 ACCE Officer and Board Election

Thank you for participating in the 2023 ACCE Officer and Board Election and casting your important vote. The election of ACCE's new Board for the year 2023 has been finalized and the Board has approved the results.

The election ballot was emailed to 300 eligible members, who included Individual, Fellow and Emeritus members in good standing. Institutional/Corporate Fellows also participated in the elections. Of the 300 members, 92 votes were received between July 6 and July 24, 2023.

The new Board of Directors will take office as the governance body for ACCE on August 18, 2023. We are pleased to announce the 2023-2024 team and, as always, we look forward to serving you and your needs.

Title	Name	Votes received
President	Kim Greenwood	85
President Elect	Katherine Navarro	86
Vice President	Qusai Shikari	82
Treasurer	Bhaskar Iduri	85

The following Board member will be continuing their terms:

Title	Name
Secretary	Michele Manzoli
Member at Large	Jim Panella
Member at Large	Kevin Kreitzman
Member at Large	Erin Sparnon
Member at Large	Ashley O'Mara

The following Board member will remain as Immediate Past President when the President takes office for his second term:

Title	Name
Immediate Past President	Illir Kullolli

Michele Manzoli
ACCE Secretary
secretary@accenet.org

Congratulations

Welcome New ACCE Members

Name	Class	Job Title	Organization	State/Country
Anthony Angelo	Individual	Supervisory Biomedical Engineer	Defense Health Agency	MD/USA
Irshad Ali Mohammed Ali	Individual	Manager Clinical Engineering	Aldara Hospital & Medical Centre	Saudi Arabia
Sarah Kelso	Individual	Clinical Engineer	Shared Health Manitoba	Manitoba/Canada
Hemanthkumar Revali	Individual	Managing Director	Biontrics Medtech PVT LTD	Qatar
Albert Choi	Individual	Facility Manager	Princess Margaret Hospital, Hospital Authority	Hong Kong/China
Dana Hamed	Institutional/Individual	Supervisor, Clinical Engineering	Middlesex Health	CT/USA
Grete Gartz	Institutional/Individual	Senior PACS Analyst and CE	Middlesex Health	CT/USA
Simon Tereszko	Candidate	BMET	Prime Healthcare	NJ/USA
Chris Roure	Associate	Manager	Shared Health Manitoba	Manitoba/Canada
Michele Berthelette	Associate	Regional Clinical Engineer	Shared Health Manitoba	Manitoba/Canada
Esmeralda Ramirez	Institutional/Associate	Biomedical Engineer	VHA- Phoenix VAMC	AZ/USA
Carolyn Mahoney	Individual	Healthcare Technology Manager	Sigma Health Consulting	NH/USA
Paul Lapre	Institutional/Associate	Clinical Engineer	Middlesex Health	CT/USA
Kyle Cagnoli	Institutional/Associate	Clinical Engineer	Middlesex Health	CT/USA

Middlesex Health Medical Center



Cincinnati Children's Hospital



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

Congratulations to the CCE Class of 2023!



Ghaith B. Hasan
 Assistant Chief Biomedical Engineer
 VA Chicago Healthcare System



Bimal N. Dholakia
 Biomedical Engineer
 VA Sierra Pacific Network



Raghotham Malipeddi
 Manager, Medical Technology Planning & Implementation
 NYU Medical Center



Ian Garcia
 Clinical Engineering Supervisor
 Brigham and Women's Hospital



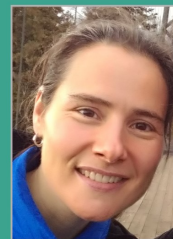
Syed Iftikhar Ali
 Senior Medical Equipment Planner
 Sidra Medicine



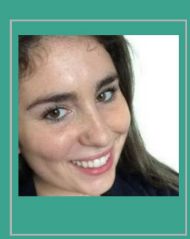
Mary Shine
 Clinical Engineer
 Mass General Hospital



Kwaku Ofori-Atta
 Medical Equipment Planner
 New York University Langone Health



Sonja Markez
 Clinical Engineer
 University Health Network



Anikke Rioux
 Coordinator & Biomedical Engineer
 CISSS de la Montérégie-Centre

From the Education Committee Desk

The Education Committee would like to thank our speakers/panelists from the 2022-2023 Educational Webinar series. They made it possible to have a very successful Webinar Series. We had a lot of distinguished speakers from all over the country, representing manufacturers and hospital staff. These included clinical engineers, IT representatives, managers, directors, administrators, etc. 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!



The 2022-2023 Educational Webinar series was delivered **complimentary to all ACCE members** with the support of the following sponsors: Crothall, Medigate/Claroty, ORDR, Renovo & Sodexo.



From the Education Committee Desk (continued)

The Education Committee is working to finalize the line-up of topics for the 2023-2024 Webinar series. Stay tuned!

The 2023-2024 series will kick off on September 14th covering the Topic: Wearables and Value-Based Care.

The ACCE Board continues to work to maintain the goal of providing accessible education, and thanks to our generous supporters, the Education Committee can continue to provide the 2023-2024 Educational Webinar Series FREE to all members.

If you are interested in supporting this upcoming series, please contact us at: secretariat@accenet.org



2023-2024 Educational Webinar Series

Wearables and value-based Care

FREE for MEMBERS

Pre-register today and join this ACCE Educational Webinar to learn more about how Value-based care (VBC) aims to meet the healthcare challenges of an aging America. The answer could be already on patients' wrists.

Thursday, September 14, 2023
12 pm - 1pm (EDT)



Kapil Parakh, MD, MPH, PHD
Medical Lead, Fitbit




If you are interested in volunteering within the ACCE Education Committee or its task force (symposiums), please complete this [volunteering form](#).

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

Suly Chi
Webinar coordinator
secretariat@accenet.org

CCE Written Exam Review Webinar Series




2023 CCE WRITTEN EXAM REVIEW WEBINAR SERIES

FREE for MEMBERS


Date: Wednesdays, Aug 09 - Oct 11, 2023, Time: 12:30 pm - 2:00 pm (EDT)

Register today and start preparing for your November Clinical Engineering Certification Written Examination


Faculty




kim Greenwood




Jenn Nichols




J. Tobey Clark




Kindall Druker




Arif Subhan



Chris Riha




Ted Cohen



Alan Lipschultz

To register: complete the online registration form _ <https://www.surveymonkey.com/r/2023CCE>

Disclaimer: This webinar is prepared and offered by individuals who are not involved in the preparation of the CCE Exam.



CASE STUDY

Europe's Leading Hospital Group Boosts Efficiency, Enhances Resilience, and Safeguards Care Delivery

Learn how Medigate by Claroty empowered Quirónsalud to overcome challenges such as fragmented visibility, complex infrastructure due to M&A activity, and zero tolerance for care disruption.

CLAROTY HEALTHCARE

CASE STUDY
QUIRÓN SALUD

Europe's Leading Hospital Group Boosts Efficiency, Enhances Resilience, and Safeguards Care Delivery with Medigate by Claroty

The Challenge

Quirónsalud is the leading hospital group in Europe and largest in Spain, where it operates more than 150 world-renowned centers that provide comprehensive patient care backed by innovative technology, advanced research, and decades of experience in all medical specialties. The group's deep commitment to patient satisfaction is a testament to its prestigious team of nearly 50,000 professionals — including Pau Giménez, Chief Biomedical Officer, and Javier Zapata, Chief Information Security Officer.

Mr. Giménez joined Quirónsalud in 2013 and is responsible for ensuring the thousands of medical devices that underpin care-delivery operations are available, well-maintained, efficiently utilized, and safe. Having long been concerned about the cyber risks facing these devices, he was pleased when Mr. Zapata joined in 2019 to lead a comprehensive cybersecurity plan to empower all Quirónsalud centers to continue providing quality care despite escalating risks.

This case study examines how Mr. Giménez, Mr. Zapata, and their respective biomedical and cybersecurity teams are working together with Medigate by Claroty to drive unprecedented resilience and efficiency while safeguarding care-delivery operations globally at Quirónsalud.

QUIRÓN SALUD
La salud primero a persona

Pau Giménez
Chief Biomedical Officer,
Quirónsalud

Javier Zapata
Chief Information Security Officer,
Quirónsalud

claroty.com

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

Training Videos

The WHO Collaborating Center for HTM at the University of Vermont (UVM), Technical Services Partnership (TSP) continues to work on the WHO COVID-19 Respiratory Equipment Training Videos project. The initiative is led by Adriana Velazquez, Team Lead Medical Devices, and In Vitro Diagnostics, at WHO. ACCE members Bill Gentles and Tobey Clark have been coordinators of the video series involving over 100 contributors from 20+ countries.

The 32 training videos, covering 7 different respiratory care devices over their entire life cycle from acquisition to decommissioning, have been translated to French by Humatem, a French NGO specializing in medical devices. This is important work as, in addition to France, 22 nations in Africa have a significant level of French speakers, and Africa is a primary focus of WHO. A webinar is tentatively set for August 17th to present the French training resources which will be available on the OpenWHO training site.

Another project that was just completed was updating three videos on clinical use of CPAP, BiPAP, and High Flow Nasal Canula devices. The English and French videos have been completed.

Over 16,500 individuals have enrolled on the English OpenWHO website for the training courses with many more expected when the French versions become available in August. The videos are also available on YouTube.

The links are below:

[OpenWHO \(English\)](#)



[Open WHO \(French\)](#)

[YouTube Training](#)

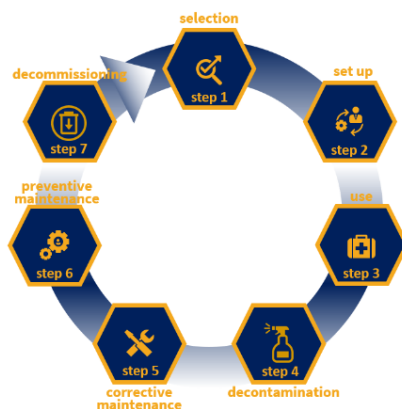


Figure 1 - The life cycle of medical equipment

Jamaica

In 2022, the Ministry of Health & Wellness in Jamaica developed a national policy for Maintenance Management of Medical Devices with support from the Pan American Health Organization (PAHO) and the UVM/TSP Collaborating Center for HTM. Over the period of June 4 - 9, 2023, Alfonso Rosales, DSc (BME), Technical Officer for PAHO Washington, DC and Tobey Clark worked on-site with the PAHO Jamaica office and the Technical Working Group at the Ministry of Health & Wellness to increase the scope via the development of an integrated health technology program. Presentations were provided on Healthcare Technology Assessment showing the results of RedETSA, the HTM network of the Americas, regulatory system development, HTM, quality assurance focused on acquisition, and priority medical devices for the first level of care. Related to this latter topic, which is a focus of PAHO in the Americas, six primary care healthcare facilities were surveyed over two days to adapt prior learnings to Jamaica. Next steps in Jamaica will be on finalizing the first level of care technology needs and standardization, along with aspects of the integrated approach to health technology.

Other Work for PAHO

Other work for PAHO in this region over the first half of 2023 included a virtual workshop with Belize MOH&W to assess imple-

mentation of the national HTM policy developed in 2021 and to provide training on HTM. Also, the development of an HTM policy for Suriname based on past work in Jamaica and Belize is planned for later in the year. This will be a cooperative activity between the three nations.

Other News

In other Collaborating Center news, through the efforts of Michael Lane, Co-Director of the Collaborating Center and Director of TSP, Kenichia Charles, former international clinical engineering intern from St. Vincent and the Grenadines in the Caribbean, will be starting as a clinical engineer at the TSP in September. Kenichia received her education from the University of the West Indies in St. Augustine, Trinidad & Tobago. And lastly, Julianne Broughton, UVM biomedical engineering master's student and biomedical engineering intern at TSP, received the *ACCE Student Scholarship Award for 2023*. Her CE training started with the UVM BME 296 Clinical Engineering course taught by Tobey Clark and was mentored by Mike Lane during the internship.

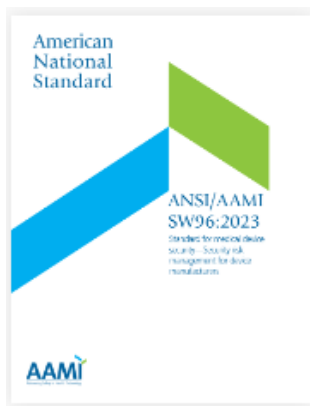
Tobey Clark
tobey.clark@uvm.edu

Michael Lane
michael.lane@uvm.edu



The University of Vermont

AAMI Update



ANSI/AAMI SW96 Helps Manufacturers Comply with FDA Guidance

The AAMI Medical Device Security Working Group recently developed a new standard on security risk management for device manufacturers - ANSI/AAMI SW96 - adding to the foundation of two Technical Information Reports (TIRs) on the same subject.

[ANSI/AAMI SW96:2023, Standard for medical device security—Security risk management for device manufacturers](#), is the first consensus standard to provide specific requirements for managing security across a product's entire life cycle. The document is based on guidance previously published in AAMI's TIR57:2016 and TIR97:2019.

[AAMI TIR57:2016/\(R\)2023; Principles for medical device security—Risk management](#), focuses on security risk during product design. [AAMI TIR97:2019/\(R\)2023; Principles for medical device security—Postmarket risk management for device manufacturers](#), relates to managing security risk during and after production.

The publication of ANSI/AAMI SW96:2023 comes at a time when managing medical device security risks is becoming more difficult by the day. A [study](#) from 2022 in *The Journal of the American Medical Association* found that ransomware attacks against healthcare organizations more than doubled between 2016 and 2021. Also, a [2023 cybersecurity report](#) by the U.S. Department of Health and Human Service's Office of Information Security noted that healthcare data breaches "have consistently trended upward" over the last decade. Cybercriminals, the HHS reports, "are continuously seeking to make their attacks more resilient, more disruptive, and harder to counter." The issue of cybersecurity has become so critical that the [2023 "omnibus" bill](#) signed into law

by President Biden includes a section on "Ensuring Cybersecurity of Medical Devices" that amends product submission requirements spelled out in the Federal Food, Drug, and Cosmetic Act. Responding to the amendment this March, the [FDA published new guidance](#) on medical device security that advises manufacturers to submit "a plan to monitor, identify, and address...postmarket cybersecurity vulnerabilities and exploits" and to "design, develop, and maintain processes and procedures to provide a reasonable assurance that the device and related systems are cybersecure."

While SW96 was developed before the FDA guidance came out, the standard provides device manufacturers with a road map to comply with its recommendations. Postmarket monitoring of device vulnerabilities and exploits, for example, is among the topics addressed in SW96, as are important cybersecurity measures like patching and creating a Software Bill of Materials (SBOM).

In a summary of the standard and its implications written by four industry leaders who played major roles in its development ([Charles S. Farlow, et al., Biomedical Instrumentation & Technology](#)), the authors say SW96 strengthens security risk management by focusing on several "elements" that are key to the risk management process. One section of the standard addresses security risk analysis while another covers the evaluation of "overall security residual risk acceptability." "General Requirements for Security Risk Management" explains what manufacturers must include in their security risk management plans. Clause 10, "Production and Post-production Activities," specifies that device makers must establish "a process for identifying and managing security incidents."

The authors also note that TIR57 and TIR97 enjoy a broad following as resources for industry stakeholders. Yet TIRs are reviews of technical issues and statements of expert opinion, and do not include any requirements that medical device manufacturers must follow.

Now, with ANSI/AAMI SW96:2023, device makers have a playbook they can use to stay ahead of existing and emerging cyber-threats while adhering to federal guidance on the subject. For years, manufacturers had a foundation, but now they finally have a house built to last.

FDA Officially Recognizes New AAMI Guidance Documents

AAMI is pleased to announce that the FDA has added [13 guidance documents](#) produced by AAMI or its standards committees to its database of [Recognized Consensus Standards](#). The official recognition of these documents both increases their visibility and will make compliance with their requirements and suggestions easier.

"The recognition of these standards affirms AAMI's leadership in the development, management, and use of safe and effective health technology standards. Additionally, it allows industry members to submit declarations of conformity to these FDA-recognized consensus standards, that may reduce the amount of supporting testing documentation needed in a premarket submission," said Matt Williams, vice president of standards at AAMI.

Document of Interest:

[ANSI/AAMI PC76:2021, Active implantable medical devices – Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging](#), builds on previous guidance documents such as ANSI/AAMI/ISO TIR10974:2012. The standard applies to "transvenous pacemaker, ICD [implantable cardioverter-defibrillator], and CRT [cardiac resynchronization therapy] systems intended to be used in patients who undergo a magnetic resonance scan," and provides testing guidelines to demonstrate that a device conforms to its MR Conditional [Magnetic Resonance Conditional] labelling.

The addition of these guidance documents to the FDA's Recognized Consensus Standards database is a boon to medical device manufacturers and healthcare delivery organizations. Their inclusion raises their profile and will make compliance with their guidance easier.

AAMI consensus standards are developed by volunteer experts from around the world. For more information about AAMI standards and how you can participate, visit www.aami.org/standards. If you would like to contribute your expertise to one of the committees that produces these guidance documents, please contact us at membership@aami.org.

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

ECRI Update



We really appreciated the chance to see some of our favorite colleagues in Long Beach last month, where the hugs and fist-bumps almost outnumbered the great ideas we'd all been storing up for discussion since San Antonio. A key highlight for me was the sweet and thoughtful tribute to legendary clinical engineer Mario Castañeda at the ACCE reception, which reminded me how much I truly value this community.

Here's what's going on at ECRI:

- What does BD's recent clearance of the [Alaris](#) infusion system mean for the infusion marketplace? Have you been waiting on a replacement project, or awaiting mitigations on the cybersecurity issues announced over the past few years? We will be actively tracking the market and would love to hear about your experiences.
- Have you ever wanted to join the ECRI team? Do you like getting to the bottom

of challenging technical issues and seeing how different models stack up against each other? Check out our [careers](#) page!

- Are you concerned about how proposed changes in ethylene oxide sterilization could affect your supply chain? Last month, ECRI submitted public comments to the Environmental Protection Agency (EPA) about their proposal to [remediate commercial sterilization facilities](#). While we fully support reducing harmful emissions, EPA's hurried timeline could result in widespread shortages of critical medical supplies, increased costs to healthcare facilities, and significant patient harm. See our [position statement](#).
- Is your facility considering virtual sitter technology to reduce fall risks? A recent ECRI and ISMP [webinar](#) highlighted the impact technology – like videos and AI driven platforms – can have on fall de-

tection to help keep residents safe and improve their quality of life. Such technology also sheds light on fall-related incident facts and data that might otherwise go unknown, especially in memory care units. As with any technology, it is a tool and not a “solution” in and of itself. The right technologies used in the right way can be an effective part of an overall falls management program- check out the webinar recording to see how.

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

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

33rd Japan CE Conference July 21-23 Hiroshima



On July 23, 2023, ACCE member Scott Skinner, Ph.D., MBA, FACHE, participated remotely in the JACE (Japan Association for Clinical Engineers) 33rd Annual Clinical Engineering Conference, during a session on the role of HTM in disaster relief. The session was led by Dr. Hirayama, Okayama University and Dr. Kashiwa, University of Tokyo, JACE International Exchange Committee.

Dr. Skinner shared his insights through his presentation “Coordinating Medical Equipment Donations through an NGO: Lesson Learned from Kentucky, United States.” In it, he highlighted the importance of triage to carefully determine priorities before developing a detailed donation plan and stressed the importance of coordination and communication to ensure successful donations. Dr. Skinner described example donations that had a positive impact in Ukraine and Ghana but also explained the challenges of assisting in disaster-stricken areas through the experience of the Kentucky hurricane. Many people quickly donated useful resources and rushed to the area for rapid assistance to the affected area. However, people flooding into the region soon became a source of confusion and created a second emergency situation. The fact that donated supplies were still unused more than six months later made Dr. Skinner realize the need for prioritization and triage, a concept commonly used in the medical field.

This was in contrast to Dr. Skinner's more successful and smooth experience of coordinating the donation of medi-

cal resources to Ukraine and Ghana through International SOS and NGOs, of which he is a board member. Lastly, he spoke about the need for BME involvement in the management of medical equipment. Emphasizing the importance of communication and coordination with the local community to ensure the success of delivering appropriate donations, Dr. Skinner noted that sending items that do not meet the needs of the local community can burden them.

The JACE International Exchange Committee would like to thank Dr. Skinner and the ACCE International Committee, who recommended Dr. Skinner as a guest speaker for this session. Thank you for all your support.

Other presenters from this session shared their experiences in disaster relief:

- Dr. Inaba delivered a presentation on “NGO Peace Winds Japan.”
- Mr. Osin, BME with WHO, presented “Ukraine: Impact of Russian Invasion on Healthcare in Ukraine from the Perspective of Biomedical and Clinical Engineering.”
- Ms. Matcovschis spoke about the change in Healthcare in Moldova in her presentation, “The Republic of Moldova - The Health System in the Context of the War in Ukraine and the Refugee Crisis.”



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IFMBE — CED Update

Integration of Artificial Intelligence (AI) in a Primary Clinical Engineering Function: Maintenance and Monitoring

Artificial Intelligence (AI) has emerged as a transformative technology in various industries, and healthcare is no exception. In recent years, the integration of AI in Clinical Engineering has gained significant attention due to its potential to revolutionize healthcare technology management. Various applications cover different aspects of Clinical Engineering functions, and one of the most relevant is maintenance and monitoring.



AI can enable predictive maintenance and real-time monitoring of medical devices and equipment. AI-powered systems can analyze vast amounts of data generated by medical devices, including sensor readings, operational parameters, and historical performance data. By utilizing advanced machine learning algorithms, AI systems can identify patterns and trends in this data, allowing them to predict potential failures or deviations from normal operating conditions. This predictive capability enables Clinical Engineers to proactively address issues before they escalate into critical failures or unexpected downtime. This proactive approach helps prevent unplanned downtime, optimize maintenance schedules, and ensure equipment availability for critical patient care.

One of the key advantages of AI-powered predictive maintenance is its ability to detect subtle anomalies that may go unnoticed by traditional monitoring systems. By continuously analyzing data in real time, AI systems can identify early warning signs of equipment deterioration or impending failures that may not be apparent to human operators. This

early detection empowers Clinical Engineers to intervene promptly, schedule maintenance activities, and make informed decisions on equipment repairs or replacements. The optimization of maintenance schedules is another benefit of AI integration in predictive maintenance. By analyzing historical data and equipment performance patterns, AI systems can identify the most efficient maintenance intervals for different types of devices. This data-driven approach eliminates the need for routine maintenance tasks that may be unnecessary, reducing operational costs and minimizing disruptions to clinical workflows. It also ensures that critical equipment is serviced optimally, maximizing uptime and availability for patient care.

In addition to this, AI-powered equipment monitoring systems provide real-time insights into the performance of medical devices. Clinical Engineers can remotely access data dashboards or receive automated alerts when equipment parameters exceed predefined thresholds or deviate from expected values. This real-time monitoring allows for timely intervention and troubleshooting, thus preventing potential safety risks or adverse effects on patient care. It also facilitates proactive decision-making regarding equipment maintenance or replacement, ensuring clinical operations run smoothly and uninterrupted.

In summary, integrating AI in predictive maintenance and equipment monitoring revolutionizes how Clinical Engineering manages medical devices. By analyzing data patterns and utilizing machine learning algorithms, AI systems enable early detection of anomalies, optimize maintenance schedules, and provide real-time insights into equipment performance. This proactive approach enhances patient safety, reduces unplanned downtime, and maximizes the availability and reliability of critical medical equipment.

The synergy between AI technology and Clinical Engineering expertise empowers healthcare organizations to deliver high-quality care while optimizing operational

efficiency. In the Division, we have been following the advancements of AI in optimizing maintenance and monitoring of the technologies, with particular attention to ethical considerations and data privacy, to ensure the responsible and effective integration of AI.

Clinical Engineering Division
IFMBE
Fabiola Martinez
boardchair@ced.ifmbe.org



(Continued from page 16)

33rd Japan CE Conference (Continued)

- Mr. Sugiura, a CE who serves as a Japanese ODA (Official Development Assistance) coordinator in medical equipment donations overseas, introduced his experiences.
- Mr. Miki, a Japanese CE, lectured on disaster response cases and daily preparedness as a Japanese CE in the Japan Disaster Relief Team (JDRT) and Japanese Disaster Medical Assistance Team (DMAT).

Cheers to the JACE-ACCE Mutual Collaboration Agreement.

Tomokazu Nagasawa
JACE



Scott Skinner, Ph.D., MBA, FACHE

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.



ACCE CALENDAR

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

05 August 2023 : Last day to submit your nominations for the 2024 ACCE-HIMSS Excellence in CE Synergies Award

2023 CCE Written Exam Review Webinar Series:

09 August 2023 - 11 October 2023 | 12:30 PM - 2:00 PM

[Pre-registration is required.](#)

AUGUST / SEPTEMBER 2023 Sessions

- 09 August, Session#1: Technology Management I
Faculty: Kim Greenwood, CCE-CA
- 16 August, Session#2: Service Delivery Management II
Faculty: Tobey Clark, CCE
- 23 August, Session#3: Service Delivery Management I
Faculty: Jennifer Nichols, CCE
- 30 August, Session#4: Technology Management II
Faculty: Kindall Druker
- 06 September, Session #5: Technology Management III
Faculty: Arif Subhan, CCE
- 13 September, Session #6: General Management
Faculty: Chris Riha, CCE
- 20 September, Session #7: IT / Telecommunications I
Faculty: Ted Cohen, CCE
- 27 September, Session #8: IT / Telecommunications II
Faculty: Ted Cohen, CCE

15 August 2023 - 17 August 2023: 45th Annual Symposium of the North Carolina Biomedical Association (NCBA)

Location: Pinehurst Resort, Pinehurst, NC

[Click here for schedule](#)

17 August 2023, 1:00 PM - 2:00 PM: Complimentary Webinar: Next Level IoMT Security: Incident Response, Business Continuity and Disaster Recovery

Faculty: Mark Elliott / Asimily & Eric Maze / RUSH University Medical Center

[Click here to register](#)

18 August 2023, 1:00 PM - 2:00 PM: 2023-2024 Board to take office at Full Board meeting

*All times in Eastern Time Zone

ACCE

AMERICAN COLLEGE OF CLINICAL ENGINEERING

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