President’s Message

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!
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,

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

ACCE Board
American College of Clinical Engineering
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 – 1
X-ray – 2
MRI – 3
Nuclear medicine – 4

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

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

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.
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.

**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 website. ACCE looks forward to continuing its coverage of wearables in healthcare through our upcoming educational webinars.

**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.

**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!
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

The 2023 Class of Hall of Famers: Marvin 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 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 Karaoglanayan, Jim Panella, Alan Lipsultz, Elkin Lara-Meja, 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 Karaoglanayan, Kwaku Offori, answering questions to conference participants

L-R: Alberto Lanzani, Italy & Michele Manzoli

L-R: Eric Aring, Sirvart Karaoglanayan, 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.

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
<th>Votes received</th>
</tr>
</thead>
<tbody>
<tr>
<td>President</td>
<td>Kim Greenwood</td>
<td>85</td>
</tr>
<tr>
<td>President Elect</td>
<td>Katherine Navarro</td>
<td>86</td>
</tr>
<tr>
<td>Vice President</td>
<td>Qusai Shikari</td>
<td>82</td>
</tr>
<tr>
<td>Treasurer</td>
<td>Bhaskar Iduri</td>
<td>85</td>
</tr>
</tbody>
</table>

The following Board member will be continuing their terms:

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secretary</td>
<td>Michele Manzoli</td>
</tr>
<tr>
<td>Member at Large</td>
<td>Jim Panella</td>
</tr>
<tr>
<td>Member at Large</td>
<td>Kevin Kreitzman</td>
</tr>
<tr>
<td>Member at Large</td>
<td>Erin Sparnon</td>
</tr>
<tr>
<td>Member at Large</td>
<td>Ashley O’Mara</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Past President</td>
<td>Ilir Kullolli</td>
</tr>
</tbody>
</table>

Michele Manzoli
ACCE Secretary
secretary@accenet.org
Welcome New ACCE Members

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

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 Malipedi
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 Ofiri-Atta
Medical Equipment Planner
New York University Langone Health

Sonja Markez
Clinical Engineer
University Health Network

Anikke Rioux
Coordinator & Biomedical Engineer
CSSS 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

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

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

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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)

OpenWHO (French)

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 implementa-
The issue of cybersecurity has become so critical that the American Medical Association (AMA) has released a report highlighting the growing trend in healthcare data breaches. The HHS reports that healthcare data breaches “have consistently trended upward” over the last decade. Cybersecurity risks are 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 are more than double 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 cybersecurity.”

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
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.”

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 throughout 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 medical 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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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.

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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
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

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