ACCE News

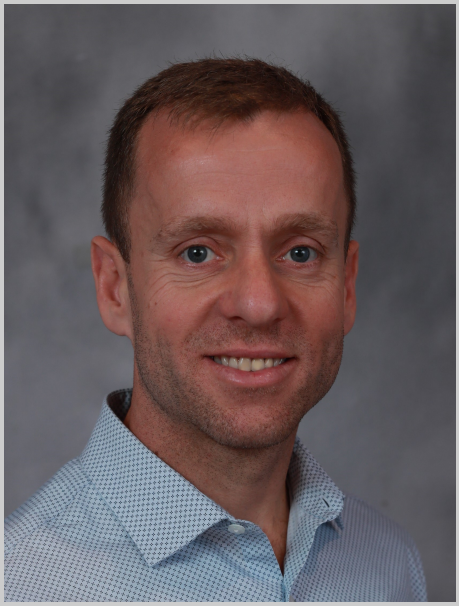
Newsletter of the American College of Clinical Engineering

January — February 2021 Volume 31 Issue 1

In Memoriam: Tom O'Dea

In this Issue:

President's Message



As this is the first message of the year, I want to wish all of you a Happy and Healthy New Year in 2021! Last year was hands down the most challenging year in my career, and I am sure that is the case for most of us. The insecurities highlighted by the COVID19 Pandemic, racial injustice and inequalities, and the elections were front and center throughout the year and affected all of us personally and professionally.

However, here we are – a year after this pandemic started. We have learned a lot, adapted, and can see a light at the end of the tunnel. Just last week I received the second shot of my COVID19 Vaccine. The politicization of the disease, and as a result of the vaccine, surely created doubts in my self-proclaimed scientific mind. However, the logical side won again and I received both shots of the vaccine. I can say the biggest side effect was the euphoria associated with it, and the fact that I cannot stop talking/writing about it! And I would encourage each and every one to trust science and take the vaccine as soon as you can!

In January we celebrated MLK Jr. day, celebrating the life and legacy of Martin Luther King Jr., who became the most visible spokesperson and leader in the Civil Rights Movement from 1955 until his assassination in 1968. While in the past I have had the opportunity to volunteer on this day, this time around and due to pandemic restrictions, I wasn't able to do so. However, both of my daughters have been learning a lot about this day in school and we set some time aside to discuss what they have learned and how we can apply the learnings from school and from MLK Jr., in our day to day activities. I was very surprised to hear the depth of knowledge and understanding from my 8-year old. And frankly, I learned a lot from her too! I believe, moving forward, this will be an MLK Jr. Day activity in our household!

Switching gears to ACCE's goals for 2021 – last week I had a chance to revisit some high level goals we had set for ACCE before the pandemic. I want to share with you where we are with some of these goals and what else we want to address and achieve in 2021.

Goal 1: Promote and increase ACCE membership

While we have experienced the challenges that many organizations have over the last year, we have been able to continue the growth of ACCE members. This has been all thanks to many free webinars, free articles, COVID19 Information, international collaboration agreements, and other activities which have been organized by our Education Committee, International Committee, our amazing secretariat, and our Newsletter editors.

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President's Message, Goals for 2021

(Continued from page 1)

This year we will continue to look for growth, nationally and internationally. We will do this by collaborating with different organizations in US and outside, and continue to provide as many free events and products as possible.

Goal 2: Enhancing educational opportunities for CE and developing closer ties with academic programs

Thanks to our sponsors (and endless efforts of our secretariat) we have been able to deliver many free webinars and other products/articles. Many webinars were delivered to address immediate issues (such as the different cybersecurity threats we experienced in 2020), and many others were organized with different leading organizations to deliver the information and tools needed to address the day's challenges.

This year, while continuing to provide educational opportunities, we will also look to increase our partnership with different academic programs to promote the profession of clinical engineering, and to increase awareness about ACCE.

Goal 3: International Outreach

I am proud to say that this has been a slam dunk in goal achievement. Our International Committee has signed Mutual Collaboration Agreements with 14 countries and several more are pending. This in turn has led to ACCE recognition throughout the world. Many international members participate in our webinars, and many others speak at our webinars and events. Last year we helped organize an international panel to address the pandemic with members of the Italian Society of Clinical Engineers, Chinese Society of Clinical Engineers, and American College of Clinical Engineering. This was a huge event attended by thousands of engineers throughout the world. And given its success, we will continue to plan more such events!

Goal 4: ACCE aiding succession planning and increase presence with HTM professionals

ACCE has recognized the need for better succession planning in the clinical engineering profession. As such, in 2021 we will develop a plan to help with retention and succession planning We will do this by organizing an effort from ACCE to partner with local HTM/ CE/ biomed/ BMES associations throughout the United States. In addition we want to build outreach efforts with college and high school career fairs in order to help with the next generation of clinical engineers.

I wanted to share these goals with everyone because I want all members to not only be aware of what we are doing, but to help us achieve these goals, and ultimately to hold us accountable to deliver on them. None of those are too small – especially for a volunteer organization. And without your help we wouldn't be here today, never mind delivering on these ambitious goals!

In closing, I want to wish everyone again a Happy and Healthy New Year! Thank you for all you do to support healthcare, and for your continued contribution to the clinical engineering profession!

Ilir Kullolli,
President, ACCE
president@ACCE.net

ACCE Membership Renewal

Thank you for being an ACCE member! It's time to renew your membership. If you have not yet renewed for 2021, renewal is due now!

To renew your 2021 membership online with PayPal, please click here or go to https://accenet.org/Members/Pages/default.aspx?from=login .

To renew by postal mail, please remit your renewal check to:

ACCE
19825 N Cove Road, #175
Cornelius, NC 28031

If you need an e-invoice, please contact ACCE Secretariat at secretariat@accenet.org

ACCE News

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

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

ECRI Perspectives: Focus on Safety

A very warm, but socially distant, new year's greeting to all.

ECRI closed out 2020 by adding vaccine-specific guidance to our free COVID-19 Resource materials, launching a whole new Vaccine Portal available at https://www.ecri.org/covid-19-vaccine-information/. As a kickoff for this resource, over 2,000 attendees from around the world tuned in on December 16 to hear our clinicians, engineers, and supply chain staff lay the groundwork for efficient handling and distribution of the COVID-19 vaccine. Of course we addressed how to handle, prepare, and administer the vaccine; critical supplies to have on hand, and lessons learned from the UK's earlier roll-out of a vaccine program. But perhaps the most surprising segment was guidance on how to store and handle the dry ice required to store the Pfizer vaccine and maintain its cold chain. Outside of research labs, many facilities aren't used to handling dry ice, and we reviewed All the Ways Dry Ice Can Hurt You, namely:

Frostbite: Due to its very cold surface temperature, dry ice can cause severe frostbite if users come in direct contact with either the dry ice itself or the vapors coming off of it.

Asphyxiation: As dry ice warms up it changes directly into CO2 gas, which can reduce the oxygen concentration in the area by displacing room air. Breathing higher-than-normal concentrations of CO2 can cause headache and drowsiness. Extremely high concentrations can lead to tremors, loss of consciousness, or even death.

Explosion: When stored in airtight containers with inadequate temperature control, CO2 gas can pressurize the container, causing it to burst or rupture, potentially leading to serious injuries.

To avoid these hazards, we recommend the following Do's and Don'ts of Dry Ice:

Do:

Handle dry ice only in large, well-ventilated areas.

Use insulated or cryogenic gloves when handling dry ice.

Use safety eyewear such as goggles, eye shields, or face shields to protect the eyes, especially if cutting or chipping dry ice.

Store dry ice in insulated containers or specially designed freezers.

Dispose of dry-ice by placing it in a well-ventilated space at room temperature.

Do Not:

Handle dry ice with bare hands or exam gloves.

Store in airtight containers. The container can burst or rupture.

Dispose of dry ice in sinks, toilets, or drains. It can cause structural damage.

Dispose of dry ice in the trash/garbage or leave it unattended in minimally ventilated areas.

We also got a from-the-trenches view on our attendees' readiness. With over 600 responses to our in-session polling, 70% of respondents were concerned that they did not have adequate supplies of dry ice and cryogenic gloves on-hand, and 35% rated their current confidence in their ability to handle and administer COVID-19 vaccines as "fair" or "poor". You can view the lab webcast and a very nice tip sheet on dry ice safety in our free COVID-19 resource center: https://www.ecri.org/landing-webcast-covid-19-vaccine-distribution-and-administration

Take care, wash your hands, and stay tuned for the upcoming release of the Top Ten Technology Hazards for 2021,

Erin Sparnon
Senior Engineering Manager, ECRI
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Looking for a new job? Check out ACCE's job listings.

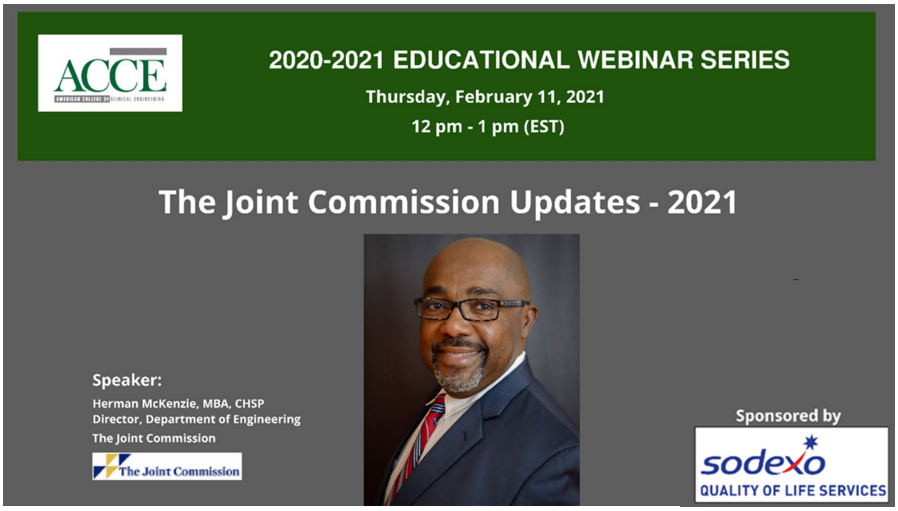
From the Education Committee Desk

The 2020-2021 Education Webinar series continued with 2 additional sessions: The first was held on December 10th, with panelists Martin Poulin of Island Health-Canada, Bill Gentles of CESO-Canada, Matt Baretich of Baretich Engineering-US, and moderated by Arleen Thukral. The panelists discussed different approaches to Preventive Maintenance applied in Canada, US, and internationally.

For our second session on January 14th, we had David Guffrey of Mass General Brigham as our returning speaker, and Christine Vogel was our moderator. David presented an overview of tabletop and laboratory -based risk assessment processes for medical device systems. Additionally, he presented methods for using assessment data to reduce organizational risk via integration of findings into procurement language and contract development.

Don't miss our upcoming Educational webinars for the months of February, "Joint Commission Update", and March, "Transitioning Culture, the Change to CE-IT" .

To register or for more information, go to https://accenet.org/NewsEvents/Pages/Webinars.aspx or complete the registration form to receive an e-invoice for online payment.



Hear what's new in Joint Commission standards related to medical equipment management

Working together with IT to bridge the communication and process gaps. Change management, disaster recovery and converged systems.

If you missed last month's webinar, you can view it here.

IFMBE CED Update

Welcome to the Clinical Engineering Division of the International Federation of Medical and Biological Engineering (IFMBE CED) update.

We are glad to be co-hosting with AAMI the 4th International Clinical Engineering and Health Technology Management Congress from September 27-29, 2021 at Disney World Florida.

Thanks so much to those who submitted over 370 Abstracts from about 60 countries covering the wide spectrum of the CE and Health Technologies field, including nearly 70 students! And over 50 abstracts were submitted by ACCE members. The review by our Scientific and Student Papers Committee began in mid-January and the program will be finalized in February and March. Make plans to participate and begin your preparations now! Registration begins in February. Travel, visa, exhibitor, and program information can be found at: https://www.aami.org/events/icehtmc2021.

Other IFMBE CED updates and upcoming events:

After a challenging 2020 for all, your global CE-HTM colleagues – like you – are hoping and preparing for a better 2021. All of our ACCE colleagues are invited to join us and learn about our many activities/resources at the links below:

- A review of 2020 Global Clinical Engineering (eg, CED supporting WHO; CED providing COVID19 tools; individual & team honors) & plans for 2021: https://ced.ifmbe.org/blog/2020-clinical-engineers-potential.html
- WHO COVID19 Health Technologies projects, December 2020-January 2021; see information about Global Clinical Engineering Alliance (GCEA) involvement at https://ced.ifmbe.org/blog/who-newsletter-dec-2020.html.
- A January 27 CED Webinar: COVID19 Vaccines & Global Clinical Engineering: How Can We Help?; information found here: https://ced.ifmbe.org/resources/courses/gurupcategs.html; with ECRI and CEs around the world reporting.
- A February 24 CED Webinar: Global Clinical Engineering COVID19 Day part 2: all 2020 learnings ; 11 am – 12:30 EST; register here: https://us02web.zoom.us/webinar/register/WN_iMckvN7hSlynaCjqEj3FxA similar to April 2020 Global CE COVID19 Day part 1: https://ced.ifmbe.org/covid19/guruPrograms/16-covid19/15-globalce-covid19day-2020.html

Tom Judd, IFMBE CED Chair
Judd.tom@gmail.com

CCE Prep: Sample Questions

In this column we are providing sample questions and information regarding preparation for the CCE exam. The sample questions are based on topics from the ACCE Body of Knowledge survey and the CCE Study Guide, version 9. 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.

Sample Questions:

1. List at least three advantages and at least three disadvantages of manufacturer service contracts versus hospital clinical engineering department service.

Evaluating manufacturer service contracts versus in-house services depends upon your particular reality. Typical "factors" and their advantages and disadvantages are summarized in the following table:

Factor	*Manufacturer Service Contracts*	*Hospital Clinical Engineering Department Services*
Response time	Disadvantage: Rural sites may have long waits especially off hours.	Advantage: Immediate response to emergent issues; personnel in the facility or local on-call
Expertise	Advantage: Generally a high level of expertise, but need to evaluate vendor staff prior to service contract signature	Disadvantage: In-house primarily generalists; Including service training with parts access at the time of purchase adds value here
Experience	Advantage: May work on product regularly	Disadvantage: In-house covers many device types thus in-house typically doesn't have significant experience
Parts	Advantage: Full and rapid access to all parts	Disadvantage: Some vendors require prior authorization for parts access. Advantage: Research required for 3rd party parts but may be less costly
Price	Disadvantage: Typically highest price.	Advantage: Typically lowest price if reasable cost training is available.
Value added	Advantage: Point of sale contracts can include product up-grades; clinician perception of gold standard service	Advantage: No profit margin concerns; clinical staff more likely to work with in-house staff to reduce costs and improve quality
Flexibility	Disadvantage: Least flexible. Locked into single vendor	Advantage: Maximum flexibility; option for any service provider – in-house, 3rd party or manufacturer on time and materials
Complexity	Advantage: Easy to sign contract. Easier to access trained technical staff.	Disadvantage: Moderate complexity of management required to show value of in-house program and meet accreditation

2. List at least three steps to take to manage vendors providing service contracts on medical equipment.

Possible answers and their explanations include: Vendor service staff check-in/check-out procedures, monitor repairs, communicate with the vendors regularly through meetings and asking questions, track all updates, upgrades and modifications to equipment, require written service documentation, and have vendors justify and require CE department service work approval if outside of the service contract.

3. In starting a clinical engineering program at a new hospital, what is a reason to match a medical device inventory item to its maintenance source, costs and services provided?

a. To meet Joint Commission requirements for cost of service

b. To determine if the maintenance level is appropriate for the devices in the inventory

c. To meet World Health Organization requirements

d. To insure that all equipment is under a manufacturer service contract

Correct answer: b

Explanation: To determine if the maintenance level is appropriate for a particular device, the starting point is to match the inventory to the maintenance provided including vendor, cost, scope of maintenance service, satisfaction of regulatory and accreditation requirements, staff survey of satisfaction with service, etc. Once this is accomplished, a plan for maintenance can be implemented.

The Joint Commission does not typically address source or cost of service. The WHO does not have requirements for hospitals regarding matching maintenance to equipment items. And there is no requirement for all equipment to be under manufacturer service contract.

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Welcome New ACCE Members

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

Name	Class	Job Title	Organization	Country
Brennon Cucullu	Individual	Chief Biomedical Engineering	New Mexico VA Health Care System	NM/USA
Sonja Markez	Associate	Clinical Engineer	Toronto General Hospital	ON/Canada
Ranjana Singhal	Individual	Senior Clinical Development Engineer	UC Davis Health	CA/USA
Stuart Kozlick	Individual	Strategic Adviser, Executive-In-Residence	Fasken Martineau Du-Moulin	Quebec/ Canada
Marc Heroux	Institutional/Associate	Clinical Engineering Manager	CHEO	ON/Canada
Brose Joel	Institutional/Associate	Manager, Biomedical Engineering Services	CHEO	ON/Canada

CCE Prep: Sample Questions continued

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4. What actions should be taken if a nursing unit has a significant number of use errors and no problem found results in the medical equipment work order reports?

a. Meet with nursing leadership to review their procedures related to the device in question

b. Determine if staff training is required on the device

c. Identify training source(s) (e.g. vendor, in-house Clinical Education staff, Clinical Engineering)

d. Continue to monitor the issue to see if the problem has been resolved

e. All of the above

Correct answer: e. All of the above

Explanation: If use errors and no problem found causes are reported, meeting with nursing unit leadership to review their procedures and staff training is needed. If problem areas are identified, changes in procedures and/or training can be arranged. Training may come from nursing educators, vendors, or the clinical engineering department. Other reasons for no problem found problem causes could be device reliability issues, which need to be addressed with the vendor, or poor human factors design. Also, continual usability problems need to be considered in equipment replacement planning.

AAMI Update: : Remote-Controlled Hospital Devices Get COVID-19 Guidance

Remotely controlled hospital wards may sound like something out of science fiction, but they're already becoming reality, and an innovation that could save time and even lives during the COVID-19 pandemic.

That is why the Association for the Advancement of Medical Instrumentation (AAMI) has published a new consensus report (CR) detailing guidelines for the implementation of remote control for many critical medical devices. Notably, the U.S. Food and Drug Administration (FDA) has already issued emergency use authorizations for many remote devices.

AAMI CR511, Emergency use Guidance for Remote Control of Medical Devices, is the latest in a suite of consensus reports that represent the combined expertise of clinicians, the medical device industry, and regulators on AAMI's COVID-19 Response Team.

"We're following where the greatest need is," said Dr. Julian Goldman, an anesthesiologist at Massachusetts General Hospital (MGH), medical director of biomedical engineering for the Mass General Brigham health network, and co-chair of the Response Team. "We started when a demand for inexpensive ventilators created what was basically a 'wild west' of innovation. Since then, the situation has evolved. We've provided emergency design and user guidelines for resuscitators, BiPAP, ventilatory helmets, and now remote-control capabilities."

"This is the time to innovate," added Sandy Weininger, co-chair of the Response Team. "The FDA has paved the way for innovation with very low overhead because the clinical need is recognized."

Weininger is a senior electrical/biomedical engineer at the FDA's Center for Devices and Radiological Health, which is responsible for the FDA's regulation of medical devices. In March, the FDA issued a new enforcement policy for non-invasive remote monitoring devices used to support patient monitoring during the COVID-19 emergency, followed by emergency use authorizations for certain remote or wearable patient monitoring devices. The rationale is straightforward: if a device or application can reduce how often healthcare providers need to be in the same room as their COVID-19 patients, it will be harder for the SARS-CoV-2 virus to spread. However, what remained unclear to device developers was where to begin.

"Early in the pandemic, there was uncertainty," said Weininger. "You had this perfect storm of scarcity of parts, testers who aren't in labs, and constructors trying to innovate in spaces they're not entirely familiar with. So, we've leveraged existing device standards while narrowing the scope, slicing up the apple and only taking the immediately useful parts."

CR511 focuses on highlighting common system elements for engineers and outlining safety and risk control measures that both manufacturers and caretakers should consider. The document also carefully defines what "remote-control" is when referring to medical devices.

For example, some mechanical ventilators are built with a detachable screen interface on a short cord.

"Some hospitals have figured out how to have that screen just outside a patient's room, so they don't have to don and doff PPE before adjusting device settings," Goldman explained. "Is that remote control? Actually, no. It's still the same device. It hasn't been modified to add remote control capability."

The document describes a remote-control innovation as an "auxiliary human machine interface" that allows caretakers to operate a medical device "from a location not co-located with the patient, device, or its primary interface." This even includes the concept of apps for controlling many devices installed on a common platform, such as a secure tablet.

It's a future for patient-care environments that Goldman has been envisioning for years. As part of a national initiative requested by the White House in 2014, Goldman and his colleagues at the Medical Device Plug and Play Interoperability & Cybersecurity Program at MGH first demonstrated how the remote control of medical devices would be ideal for patient care during an Ebola outbreak.

"We developed a reservoir of knowledge and working prototypes during the 2014 Ebola initiative. For instance, we know that it can take 10 to 15 minutes to put on PPE before going into a patient room. By then, a patient could be in dire straits if they're waiting for critically important treatment such as turning up the oxygen level on a ventilator or adjusting an infusion pump," said Goldman. "Fast forward to COVID-19, and now there's real interest."

"Now the opportunity is here to apply this knowledge expeditiously," added Colleen Elliott, director of standards at AAMI. "This consensus report resulted from a collaboration between AAMI's Interoperability Working Group and our COVID-19 Response Team. We deeply appreciate the subject matter experts and industry leaders who offered their knowledge for the sake of safe and effective medical device innovation."

AAMI CR511, Emergency Use Guidance for Remote Control of Medical Devices is available for download alongside more than a dozen freely available resources on the AAMI COVID-19 Emergency Guidance web page.

AAMI Explores Artificial Intelli-

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In Memoriam: Thomas Joseph O'Dea

"Clinical Engineer, active leader, and advocate for the Clinical Engineering Profession"

On Tuesday, December 8, 2020, Tom O'Dea, devoted husband and loving father and grandfather, passed away suddenly and unexpectedly at the age of 82. Tom was welcomed with open arms to heaven by his son, Patrick, his brother Patrick, and his parents, Beatrice and Patrick. He is survived by his wife Kay, daughter Christy and son-in-law Christian Busken, and grandchildren Marin, Maura, and Jack O'Dea and Melina Busken.

Born to Irish immigrants in the Bronx on July 7, 1938, he attended St. Jerome's Catholic school and entered the Christian Brothers, where he served as a high school science teacher for many years in upstate New York. He received his bachelor's degree in physics from the Catholic University, master's degree from State University of New York, and completed post-graduate studies in physics at Northwestern University in Chicago.

In 1969 in Chicago, he met the love of his life, Kay, and they were married on July 11, 1970. He was the Director the first Department of Biomedical Engineering at Evanston Hospital. After the birth of Christy and Patrick, the family moved to Shoreview, Minnesota, where Tom took a position as Director of Biomedical Engineering at the University of Minnesota. In 1993, after a long battle with brain cancer, his son Patrick went to heaven. Tom was a true lifelong learner, earning a PhD in medical imaging in 2001 at the age of 63. Even after retirement from the University of Minnesota, he continued his passion for biomedical engineering through many "projects" that he was constantly working on in the early hours of the morning and secured a number of patents for his work.

Tom was a supporter of many charities over his lifetime. In lieu of flowers, consider a donation to one of the following charities:

Wishes and More, Brothers of the Christian Schools, District of Eastern North America, Poor Clare Sisters, University of Dayton Campus Ministry or Totino-Grace High School.

Friends and family were welcomed to a virtual celebration of Tom's life and a virtual Irish wake on December 17, 2020. Funeral services were held at Good Shepherd Catholic Church in Montgomery, Ohio on December 18, 2020.

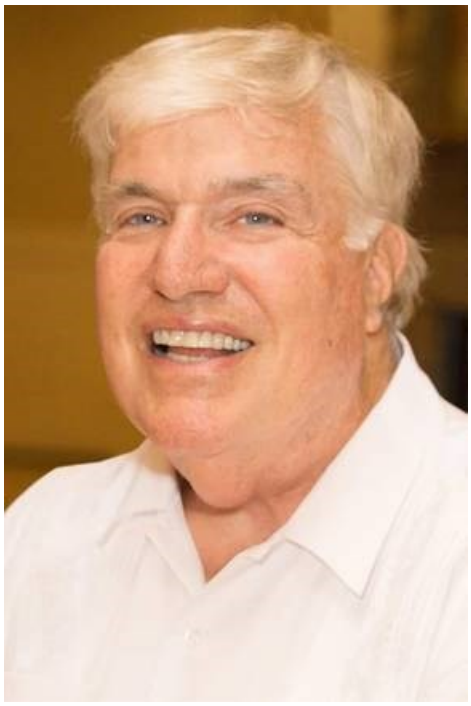
Our CE colleagues offer these thoughts and remembrances about Tom:

"Tom O'Dea was a gentleman and a gentle man. Always open to discuss a wide range of clinical engineering topics, and always well informed. Tom did not just serve as ACCE Advocacy Chair for five years, he was an active leader and advocate for the profession, writing articles, rebutting criticisms, and strongly representing the best in our profession - always with dignity and grace. It was in recognition of his contributions to advocacy, beyond the chair, that prompted the Board to establish the Tom O'Dea Advocacy Award. I was privileged to work with Tom as recently as last year and found he had not lost any of his fervor for ACCE or clinical engineering. May he rest in peace."
Ray Zambuto

I am shocked and saddened. I share Ray's description of Tom as a pillar of our community, quietly without taking the stage he was always kind and generous with his time and leadership.

We received an email recently - he and his wife had just moved closer to family – making this even harder to take.

Please add my name to message of condolence to his family.
Manny Furst



Tom O'Dea, , July 07, 1938 – December 08, 2020

I so enjoyed working with Tom. Ray really says it best above. I remember his passion and his wonderful distinctive voice that would rouse everyone's support!
Jennifer Ott

Tom and I served on the CE Board of Examiners when it was under AAMI maybe 25 years ago. He was a good man. A very happy and upbeat fellow.
Frank Painter

The clinical engineering profession lost a good man with the passing of Tom O'Dea. Tom was one of the most pleasant individuals that I have come across in our profession. I fondly remember his consistently insightful commentary and contributions to

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International Committee Report

The International Committee (IC) held its first 2021 regular bimonthly meeting on Jan. 11, 2021. Our guest speaker at this meeting was Dr. Alexandre Lembruger, regional advisor on Health Technologies for PAHO/ WHO. He described the activities that he is leading at PAHO on technology assessment, COVID-19 assistance to member countries, and training for CE professionals in Latin-America and the Caribbean region. We also discussed potential opportunities for ACCE to assist PAHO in response to medical equipment-related assistance requests from PAHO member countries, as well as how PAHO can help increase and intensify collaboration between ACCE and CE associations in those countries.

Since our last report (Nov-Dec 2020), ACCE signed two additional collaboration and mutual assistance agreements. The first one was signed with the Spanish Association of Clinical Engineering (Sociedad Española de Electromedicina e Ingeniería Clínica - SEEIC). The second was with the Biomedical Engineering College Association of El Salvador (Asociaci6n Colegio de Ingenierfa Biomedica de El Salvador – ACIBES).

In 2021, IC will continue to seek collaboration agreement opportunities with other national organizations. Unfortunately, the progress will continue to be challenging due to the ongoing surge of COVID-19 pandemic in most parts of the world and the slow progress of vaccination. Most CE professionals are still under extreme stress to keep essential equipment available for patient care and, thus, do not have time to work on collaborations with other groups or countries.

Also severely impacted by the pandemic are the national and regional conferences that IC members were planning to attend in person. The travel restrictions are likely to persist until the fall of 2021. Therefore, IC members have decided to intensify webinar offerings and other interactions via the Internet. One such event (with the Argentinean association SABI) is already scheduled for March 2021. Additional virtual events are being negotiated.

Binseng Wang, IC Chair
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Tom O'Dea continued

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our many years of mutual participation in AAMI's annual "Manny" meeting. I had the pleasure of recently reconnecting with Tom on ACCE's Hall of Fame committee. He was a great contributor to our deliberations about candidates and had a genuine interest in helping to raise the profile of our profession by helping to select well deserving members of the Hall of Fame. ACCE has rightfully named its clinical engineering advocacy award after Tom.

We will miss you. Thank you for all that you did to serve and advocate for our profession.
Jim Keller

It was a pleasure to see Minnesotan Tom O in action! Exemplifying his lifelong learning, here's a 2016 Tom email: "I have been working on a measurement of risk and risk avoidance as it pertains to patient care equipment. I will communicate with you and the group when the draft is finished. Otherwise, I continue working in the medical device development area and have some limited success in going to market. We reached the second stage so far in applying for NIH grants in the areas of measurement of the lifetime extension of stored whole blood with a local blood bank and an improved mucus clearance system for cystic fibrosis and other diseases, (with Mayo). We also met with Medtronic to work on the measurement of food flow times through the upper gastric system. Hope to report completion of these projects by 2018 (when I turn 80)."

You have to love Tom's breadth of interests and passion for our profession! This passion was contagious as the Advocacy Award named in his honor attests. Thank you so much Tom O for your enduring contribution. Early in his career, he worked with college football people to measure concussive forces to improve helmets. Catch Tom O'Dea speaking about this and Clinical Engineering early days in this ACCE 2011 documentary video (Tom is speaking at 3:25 and 13:25).
Tom Judd

Compiled by Suly Chi
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WHO Collaborating Center

WHO Collaborating Center for Health Technology Management Update

As the pandemic continues, the collaborating center at Technical Services Partnership, University of Vermont has continued to support the World Health Organization (WHO) and the Pan American Health Organization (PAHO). A primary project is the development of scripts and video production related to training on priority devices in the fight against COVID-19. Collaborating center staff is working with ACCE member Bill Gentles, CCE, who is coordinating global clinical engineers primarily in low and middle income countries in the production of videos covering acceptance, use, maintenance, and decontamination of ventilators, CPAP/BiPAP, oxygen concentrators and cylinders, high flow nasal cannulae, pulse oximeters, and patient monitors. Note, this project is part of a much broader initiative including medical device databases, nomenclature, best practices, and guidelines covering the health technology life cycle led by Adriana Velazquez Berumen, Team Lead for Medical Devices and In Vitro Diagnostics, WHO.

Through coordination by PAHO, virtual training on incoming inspection, safety, user and biomedical maintenance on oxygen concentrators for fourteen Caribbean nations took place in October. Oxygen concentrators are a critical device in countries that have limited availability of piped in oxygen. Collaborating center staff member Rick Barnes, CBET, contributed training on oxygen concentrator maintenance.

COVID-19 priority medical devices being considered for purchase in Dominica and Belize were evaluated using WHO/PAHO requirements and the best practices of the collaborating center. Due to device availability and/or restrictions on export from North America and European countries, these devices were primarily manufactured in other countries and were not sold in the US or FDA approved. This added to the challenge to support Dominica and Belize in combating the pandemic.

Other WHO and PAHO work has included product evaluation for devices being considered to be included in the WHO 2020 Health Priorities Compendium of Innovative Health Technologies for Low-Resource Settings, contributing HTM chapters to the PAHO Virtual Course on Assessment, Selection, Rational Use and Management of Health Technologies in the context of COVID-19; medical device disinfection presentation for Bangladesh, center overview for IEEE EMBS of Peru, and continuing with activities focused on medical technology assessment with PAHO's RedETSA – the HTA network for the Americas headed by Alexandre Lemgruber, Regional Advisor on Health Technologies. Related to HTA, Rossana Rivas, Senior Advisor to the collaborating center, has spearheaded the current project to assist the Peruvian National Institutes of Health (INS) in developing a framework for HTA of medical devices. This will also include pilot assessments and leadership training. Future projects of the collaborating center include providing HTM services and training for Haiti and serving on the scientific committee of the ICEHTMC to take place in September.

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AAMI Update

(Continued from page 8)

gence in New Standards Initiative

Taking an important first step towards artificial intelligence (AI) standards and guidance for much of the healthcare industry, AAMI is standing up a new AI committee consisting of representatives from the British Standards Institution, the US Food and Drug Administration (FDA), and developers of machine learning technology.

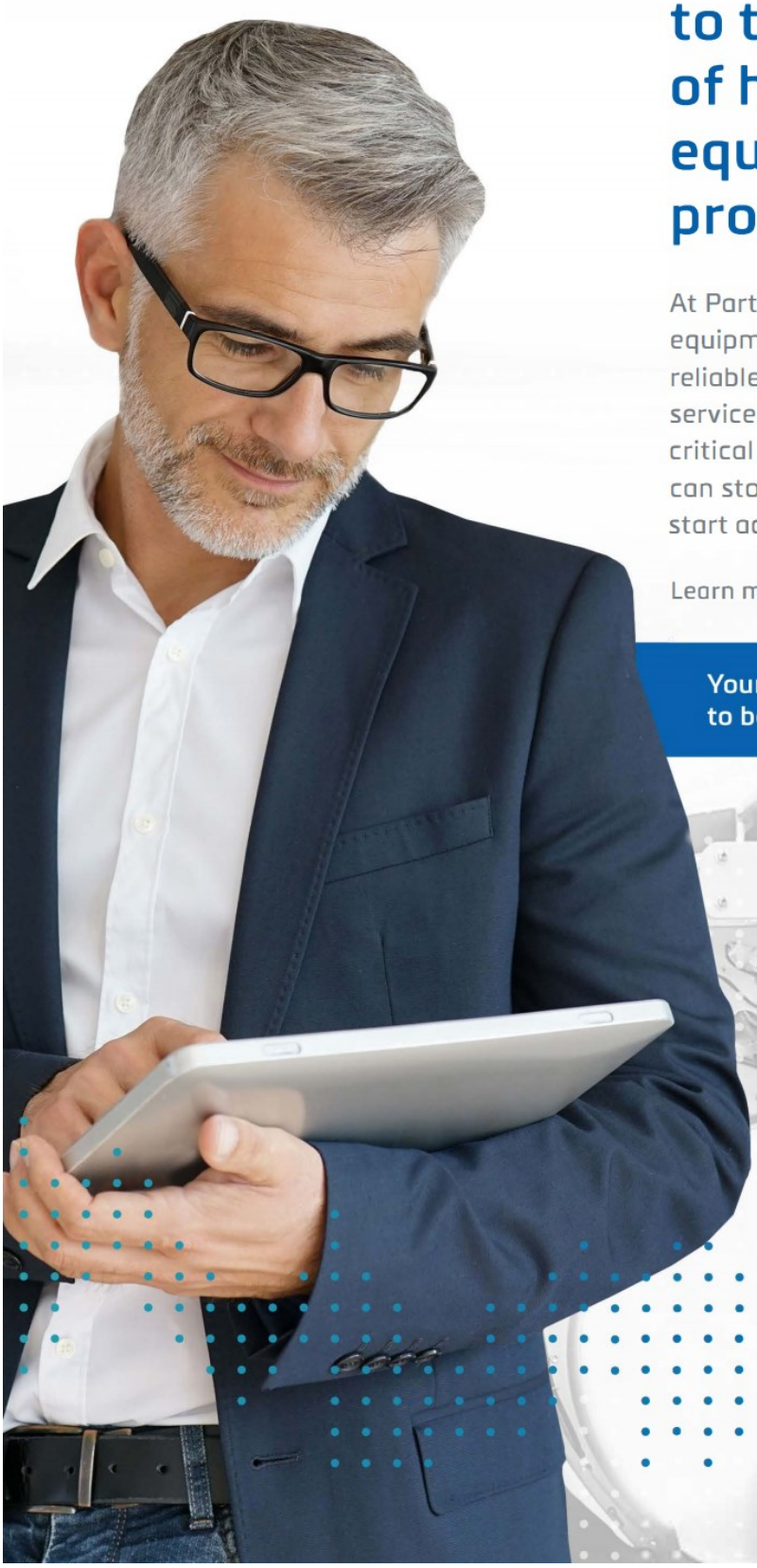
The AAMI AI committee and BSI are pooling experts to draft risk management guidance for AI and machine learning in medical devices. This new document will repurpose key lessons from an internationally known standard, ANSI/AAMI/ISO 14971, Medical devices—Application of risk management to medical devices, while leveraging the joint drafting committees' AI expertise.

"When we talk about AI in healthcare, we're talking about machine learning, data-driven systems that reach conclusions that we can't necessarily predict," explained Joe Lewelling, senior advisor on content and strategy at AAMI. "These are disruptive technologies in that they will change the way healthcare is designed, delivered, maintained, and even regulated."

In May 2020, AAMI joined forces with BSI to publish the position paper, Machine Learning AI in Medical Devices: Adapting Regulatory Frameworks and Standards to Ensure Safety and Performance, which examines how machine learning is different from traditional medical devices and software. It outlines a need for new standards and regulator initiatives to promote the safety, effectiveness, and availability of AI and machine learning in healthcare. The new AAMI AI committee will be responsible for developing the guidance documents and other work identified in the white paper.

The AAMI AI committee is accepting new participants on a rolling basis. Interested parties, including representatives of clinical practices, academia, regulatory authorities, and industry can find out how to get involved at AAMI.org or by contacting standards@aami.org.

AAMI Staff



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02/11/2021
Webinar: The Joint Commission Update, 2021

02/12/2021
Last day to nominate your candidate to CE-Hall of Fame

02/15/2021
Last day to apply for 2021 ACCE Student Scholarship

03/11/2021
Webinar: Transitioning culture, the change to CE-IT

06/05/2021
Clinical Engineering Symposium, by ACCE: The Clinical Engineer's Guide to Managing People, Cybersecurity, and Equipment

6/4/2021—6/7/2021
AAMI Exchange 2021, Charlotte, NC

8/8/2021– 8/13/2021
HIMSS 2021, Las Vegas, NV

9/28/2021– 9/29/2021
ICEHTMC-2021
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