A LOOK AT ENDOON Ine2020 FROM AROUND THE WORLD!

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X-Ray VISIONS

Artificial Intelligence & Osteoporosis

- Lamenting to the "fractured" process
 of treating osteoporosis, Australian
 endocrinologists and software developers
 teamed up to create a tool that uses artificial
 intelligence to read X-rays.
- This new program XRAIT has significantly improved fracture detection and could change the future of osteoporosis treatment.

THYROID RESEARCH REVELATIONS:

Recent studies guide new treatments and stir old debates

SPATIAL RECOGNITION:

Social distancing tips back in the lab



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A Closer Look at the Endocrine Society's Flagship Basic Science Journal

n a year of ongoing unprecedented worldwide challenges, we head into the autumn with hopes and plans for better times ahead. In that spirit, I want to comment on the ongoing success, resilience, and future of our journals, available in almost 8,000 libraries around the world as well as numerous nonprofit research institutions in more than 100 developing countries. In particular, I want to give you a closer look into our flagship basic science publication, *Endocrinology*, as it undergoes a changing of the guard at the editor-in-chief position.

The Society thanks Teresa K. Woodruff, PhD, for her service as editor-in-chief these past few years, through June 2020. The energy, vision, and high standards that Teresa and her team brought to *Endocrinology* helped continue its long run as a global leader in hormone science and research, with more than 43,000 citations and 1.9 million article downloads each year.

We welcome Carol A. Lange, PhD, as the new editor-in-chief, who began receiving new submissions in July 2020. Carol is professor in the Departments of Medicine and Pharmacology at the University of Minnesota Masonic Cancer Center, and a 2020 Endocrine Society Laureate Award recipient for her distinguished service to the Society and the field of endocrinology, including her previous role as the editor-in-chief of *Hormones & Cancer* in 2011 when that journal was with the Society.

The vision for *Endocrinology* that Carol and her team bring to the journal reflects the Society's renewed dedication to its basic science community. We are moving ahead on the recommendations of the Society's Basic Science Advisory Group, which called for *Endocrinology* to re-double its focus on publishing the very best basic science research, especially in topic areas that were most often targeted for *Molecular Endocrinology* before that journal merged with *Endocrinology* in November 2016.

Carol welcomes the submission of original research investigating endocrine function in health and disease at all levels of biological organization, including molecular mechanistic studies of hormone-receptor interactions and hormone-regulated signaling events. *Endocrinology* encourages the submission of cross-disciplinary and integrative research in traditionally recognized fields of endocrinology as well as molecular studies in emerging areas not traditionally recognized as



Endocrinology encourages the submission of cross-disciplinary and integrative research in traditionally recognized fields of endocrinology as well as molecular studies in emerging areas not traditionally recognized as endocrinology.



endocrinology, including mechanisms of signal transduction, the biochemistry and structural biology of receptors or other signaling molecules, epigenetic mechanisms of gene regulation and transcription, mitochondrial biochemistry, bioenergetics, cellular metabolism, and stem cell biology/tissue regeneration.

With continuous online-only publication and monthly issues, the first eight pages free for members, no color charges, and article-level Open Access options, *Endocrinology* accepts format-neutral manuscript submissions and pre-submission inquiries.

I am also delighted that under Carol's leadership, *Endocrinology* is not only continuing the Early Career Reviewers program that Teresa initiated to mentor reviewer/author skills, but she is looking into coordinating that program with the Society's

highly successful FLARE program (Future Leaders Advancing Research in *Endocrinology*) for trainees and junior faculty from underrepresented minority communities.

In closing, I can do no better in encouraging Society members to read and submit their best research to the journal than to quote Carol as she comes on board to lead Endocrinology. Carol writes:

"I have dedicated my entire career to understanding the biochemistry and the molecular and cell biology of hormone action, and I look forward to continuing *Endocrinology's* commitment to publishing the best and most fascinating original research and molecular mechanistic studies on endocrine pathways, cells, systems, and diseases.

"One of the things that drives me is the desire to positively impact the field of endocrinology and promote the success of others within my circle of influence, both as individuals (authors and readers) and at the level of the Society. As a veteran scientist and member, much of my leadership experience has come from service to the Society. As such, I understand the unique strength and core identity of the Society, and I enjoy promoting and supporting a stimulating and rich professional environment that recognizes that everyone has something valuable to contribute and is culturally inclusive, diverse, and innovative.

"My charge is to strengthen our basic science base and help integrate this effort with the Endocrine Society annual meeting programming by collaboration with Endocrine Society leadership across the science and educational missions."

If you have any questions or comments, you can reach me at: president@endocrine.org.

Gary D. Hammer, MD, PhDPresident, Endocrine Society





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FROM THE **EDITOR**

Can Artificial Intelligence Change the Future of Osteoporosis Treatment?

very time I hear the phrase "artificial intelligence" I think of that Stephen Spielberg movie from 1997, A.I., where a couple replaced their late son with a robot equipped with, you guessed it, artificial intelligence, which, of course, seemed like a good idea at the time but there were consequences. (The Simpsons even did a great riff on the movie in one of its annual "Treehouse of Horror" episodes where Bart got replaced by a replicant. It did not end well.)

Fortunately, more and more success stories involving artificial intelligence are emerging in the world of medical research, such as in this month's cover story by senior editor Derek Bagley. In "More than Meets the Eye: Artificial Intelligence and X-Ray" (p. 30), he reports on how a pair of Australian endocrinologists teamed up with software developers to create a tool that uses artificial intelligence and natural language processing that can actually detect fractures three times more frequently than manually reading X-rays. This new technology, X-Ray Artificial Intelligence Tool — or XRAIT — has been a boon for fracture liaison services, which bone health experts agree are necessary to mending the fractures in osteoporosis treatment.

According to Jacqueline Center, MBBS, PhD, FRACP, from the Garvan Institute of Medical Research in Sydney, "this new technology is so vital because there is evidence that fracture liaison services result in decreased subsequent fractures," she says, adding: "So as long as you're engaging more patients to take treatment, if they've got osteoporosis, you will decrease further fractures. There's evidence for that."

Center's colleague, Christopher White, MBBS, PhD, FRACP, an endocrinologist at the Prince of Wales Hospital in Randwick, Australia, says that new technology is really all about quality improvement as he mentions certain medical problems that might get reported but are not acted upon, i.e., a shadow on the lungs. "Because if a fracture has been reported," he says, "and it was previously, and it's shown to be osteoporotic, you have actually haven't got a leg to stand on if you didn't respond to it."

It seems like people can't stop talking about the Endocrine Society's first ever all-virtual conference, ENDO Online 2020, which took place in

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June. While it is in no way a replacement for the traditional in-person ENDOs (nothing could ever replace those, am I right?), it certainly blazed a trail for a new type of meeting.

One of the biggest benefits of a virtual online meetup is that attendees are not barred based on the cost to travel from faraway places, much less visa, passport, or other transportation issues. Due to this easy access, ENDO Online 2020 welcomed visitors from around the world in record numbers. While some of these attendees had been to a number of in-person Endocrine Society meetings, for so many of them ENDO Online 2020 was their first exposure to the cutting-edge science and world-renowned legends of the endocrinology world who comprise the faculty.

On page 20, you'll see a roundtable discussion of a handful of Endocrine Society members from around the world sharing their thoughts about the all-new virtual ENDO Online 2020. While some of them lamented the fact that they didn't get

to see their friends and colleagues in person, by and large everyone was very enthusiastic about the conference, some of whom would not have been able to participate in an inperson meeting due to financial or timing considerations. Also, the fact that so much of the programming was ondemand made it even easier for these attendees to take part — either again or for the very first time — in an Endocrine Society meeting.

I'm sure this article will not be the last time we'll report about ENDO Online 2020; there was so much great science presented that we definitely want to share it with our readers in more future issues!

Until next month, stay safe and as usual, if you have any comments or story ideas, please feel free to reach out to me at: mnewman@endocrine.org.

- Mark A. Newman, Editor, Endocrine News



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Endocrine Society Announces 2021 Laureate Award Winners

ast month, the Endocrine Society announced it has chosen 15 leading endocrinologists as winners of its prestigious 2021 Laureate Awards, the top honors in the field.

Established in 1944, the Society's Laureate Awards recognize the highest achievements in the endocrinology field, including groundbreaking research and innovations in clinical care. The Endocrine Society will present the awards to the winners at ENDO 2021, the Society's annual meeting.

The Endocrine Society's 2021 Laureate Award winners are:



Phillip Gorden, MD FRED CONRAD KOCH LIFETIME ACHIEVEMENT AWARD

The Society's highest honor, this annual award recognizes lifetime achievements and exceptional contributions to the field of endocrinology. Gorden is director emeritus at the National Institute of Diabetes and Digestive and Kidney

Diseases (NIDDK) in Bethesda, Md.



Teresa K. Woodruff, PhD GERALD D. AURBACH Award for Outstanding TRANSLATIONAL RESEARCH

This annual award recognizes outstanding contributions to research that accelerate the transition of scientific discoveries into clinical applications. Woodruff was recently appointed

provost at Michigan State University in East Lansing, Mich., following a 25-year career at Northwestern University in Chicago, Ill. She is a past president of the Endocrine Society and the former editor-in-chief of Endocrinology. She has dedicated her research career to improving female fertility and largely defined oncofertility, a medical field created to maximize the reproductive potential of cancer patients and survivors.



Ambrish Mithal, MD, DM INTERNATIONAL EXCELLENCE IN ENDOCRINOLOGY AWARD

This award is presented to an endocrinologist who has made exceptional contributions to the field in geographic areas with underdeveloped resources for hormone health research, education, clinical practice, or administration. Mithal

is the chairman and head of the endocrinology and diabetes division of Max Healthcare Hospital in Delhi, India.



Richard J. Auchus, MD, PhD **OUTSTANDING CLINICAL INVESTIGATOR AWARD**

This annual award honors an internationally recognized clinical investigator who has contributed significantly to understanding the pathogenesis and therapy of endocrine and metabolic diseases. Auchus is a

professor of internal medicine and pharmacology at the University of Michigan in Ann Arbor, Mich., and the world's foremost authority on steroid-related diseases. His pioneering science has transformed fundamental principles of steroid biosynthesis, and his clinical investigation has repeatedly changed clinical practice for androgen synthesis, endocrine hypertension, and hypercortisolism.



Frances J. Hayes, MBBCh VIGERSKY OUTSTANDING **CLINICAL PRACTITIONER** AWARD

This annual award recognizes extraordinary contributions by a practicing endocrinologist to the endocrine and/or medical community. As the associate clinic chief of

endocrinology at Massachusetts General Hospital in Boston, Mass., Hayes has brought best practices and efficiency to the division, always with an eye to the best patient experience.



Ann Danoff, MD OUTSTANDING EDUCATOR AWARD

This annual award recognizes exceptional achievement as an educator in the discipline of endocrinology and metabolism. Danoff currently serves as chief of medicine at the Corporal Michael J. Crescenz Veterans Administration

Hospital and vice chair of medicine at the Perelman School of Medicine at the University of Pennsylvania in Philadelphia. She has been very active in educational activities at the Endocrine Society, including serving as chair of Trainee Day, chair of the Endocrine Board Review course, and most recently, physicianin-practice chair of the Annual Meeting Steering Committee, where she organized over 100 sessions.



Richard J.M. Ross, MBBS, MD, FRCP **OUTSTANDING** Innovation Award

This award recognizes endocrinologists who have demonstrated innovation and entrepreneurship to further endocrine research or practice in support of the field of endocrinology, patients, and society at

large. Ross is a professor of endocrinology at the University of Sheffield in the United Kingdom and an exceptional clinical scientist. His research on optimizing endocrine replacement therapy has focused on replacement of cortisol in patients with adrenal insufficiency and congenital adrenal hyperplasia.



Helena Teede, MBBS, FRACP, PhD, FAAHMS OUTSTANDING LEADERSHIP IN ENDOCRINOLOGY AWARD

This annual award recognizes outstanding leadership in fundamental or clinical endocrinology. Professor Teede holds leadership roles across healthcare, research, and policy in

Australia, including as the director of Monash Centre for Health Research Implementation, School of Public Health and co-director of Monash University's Monash Institute of Medical Engineering, an endocrinologist at Monash Health,

and executive director of Monash Partners Academic Health Sciences Centre.



James R. Gavin, III, MD, PhD **OUTSTANDING MENTOR AWARD**

This annual award recognizes a career commitment to mentoring and a significant positive impact on mentees' education and career. Gavin is a clinical professor of medicine at the Emory University School of Medicine in Atlanta, Ga., and the Indiana University School

of Medicine in Indianapolis, Ind. He's also the chief executive officer and chief medical officer of Healing Our Village, Inc., a corporation that specializes in targeted advocacy, training, education, disease management, and outreach for healthcare professionals and minority communities.



Anne L. Peters, MD **OUTSTANDING** PUBLIC SERVICE AWARD

This annual award is presented to an individual who best demonstrates dedication to public awareness or public service in support of the field of endocrinology, and the patients who suffer from endocrine disorders. Peters

is a professor of medicine at the Keck School of Medicine of USC and director of the USC Clinical Diabetes Programs in Los Angeles, Calif. She has dedicated her career to serving underprivileged populations by educating and training minority and disadvantaged students, providing healthcare in clinics devoted to treatment of at-risk marginal populations, and volunteering in family medicine clinics.



Guillermo E. Umpierrez, MD **OUTSTANDING SCHOLARLY** PHYSICIAN AWARD

This annual award recognizes outstanding contributions to the practice of clinical endocrinology in academic settings. Umpierrez is professor of medicine in the division of endocrinology at Emory University

School of Medicine, director of the Grady Memorial Hospital

Clinical Research Network, Atlanta-CTSA, and director of the diabetes and endocrinology section at Grady Memorial Hospital in Atlanta, Ga.



Alexander S. Kauffman, PhD RICHARD E. WEITZMAN OUTSTANDING EARLY CAREER INVESTIGATOR AWARD

This annual award recognizes an exceptionally promising young clinical or basic investigator. Since joining the University of California, San Diego in La Jolla, Calif., as an associate professor in

2009, Kauffman has published 48 peer-reviewed articles and become an internationally recognized leader in reproductive neuroendocrinology research.



Tahaki Kadowaki, MD, PhD Roy O. Greep Award for Outstanding Research

This annual award recognizes meritorious contributions to research in endocrinology. Kadowaki is a professor at the University of Tokyo in Japan who discovered the adiponectin receptor and its function to understand the

molecular basis of type 2 diabetes and metabolic syndrome. Kadowaki's accomplishments have not only enabled essential understanding of the molecular mechanisms of adiponectin action but have reinvigorated adiponectin-based drug development programs for type 2 diabetes.

SIDNEY H. INGBAR DISTINGUISHED SERVICE AWARD

This award recognizes distinguished service to the Endocrine Society and the field of endocrinology. This year, the Society is honoring two members for contributions to basic science.

Sally A. Camper, PhD

Camper is a professor of internal medicine and the Margery Shaw Distinguished University Professor of Human Genetics at the University of Michigan Medical School in Ann Arbor,



Mich. She is an exceptional basic scientist who has successfully applied innovative genetic technologies to understand the pituitary gland. She has served in many different committees at the Endocrine Society since she became a member, including on the Molecular Endocrinology Editorial Board, the Basic Science Task Force, the Annual Meeting

Steering Committee, the Scientific Statements Task Force, the Scientific and Educational Programs Core Committee, the Nominating Committee and the Advisory Board.



Ursula B. Kaiser, MD

Kaiser is a senior physician at Brigham and Women's Hospital and a professor of medicine at Harvard Medical School in Boston, Mass. She has been involved in service to the Endocrine Society continuously since 1997 as member or chair on the Student Affairs Committee, the Publications Committee, the

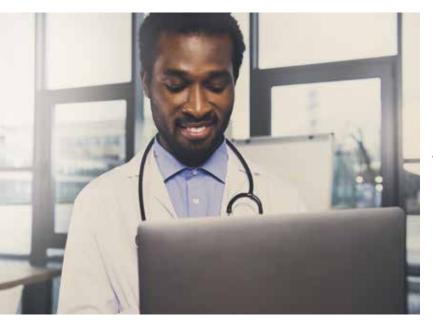
Laureate Awards Committee, the Annual Meeting Steering Committee, the Research Affairs Committee, and the Committee on Governance Affairs. She has also served on two **ENDO** Meeting Task Forces, the Laureate Awards Review Task Force, and currently on the Governance Task Force.

Nominations are being accepted for the 2022 awards cycle until December 31, 2020. Any submissions received after December 31 will be considered for the following year.

A multi-page feature is being planned for the December 2020 issue of Endocrine News.

For more in-depth profiles of the 2021 Laureate
Award recipients, go to:

wwww.endocrine.org/2021_Laureates



Endocrine Society Hosts Virtual Career Fair September 24

he coronavirus pandemic has created a lot of uncertainty for endocrinologists who are entering the job market or planning their next career move. Social distancing guidelines and bans on large group gatherings have also made in-person networking and communicating with potential employers a challenge.

To help job seekers find new opportunities during this difficult time, the Endocrine Society is hosting a Virtual Career Fair on September 24. This online recruitment event will connect endocrinologists with private practice employers, group practices, hospitals, health systems, and other recruiters around the country.

"The virtual fair is a great opportunity to find potential employers but also to network and guide others about different opportunities," says Ricardo Correa, MD, of the University of Arizona College of Medicine, Phoenix. Correa is attending the Virtual Career Fair as a mentor to guide early-career endocrinologists on entering the job search.

During the three-hour virtual event, job seekers can browse employer profiles and general endocrinology and subspecialty positions. Attendees will be able to visit different virtual booths, chat with recruiters, and network with colleagues and mentors.

"The Endocrine Society virtual career fair offers a diversity of opportunities for future jobs in different areas like academic and research that other fairs don't offer," Correa says. "I hope

to hear what opportunities are out there in the area of clinical research and to guide some of the fellows and junior faculties on deciding their first job and move in their career path."

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The Endocrine Society virtual career fair offers a diversity of opportunities for future jobs in different areas like academic and research that other fairs don't offer.

For more information on the event and how to register: https://www.endocrine.org/our-community/career-andprofessional-development/endocareers

Explore the Endocrine Society's online Career Center which contains over 180 jobs and a professional resource library with career tips and tools: https://www.healthecareers.com/ endocrine/search-jobs

TRENDS & INSIGHTS





We can get a full picture of what a child's glucose levels are doing without having to disrupt their play or sleep with painful fingersticks.

Next-Generation Integrated Continuous Glucose Monitor Now Available Following FDA Clearance

n integrated continuous glucose monitor (iCGM) is now available for adults and children (four-plus years) living with diabetes, following its clearance in June from the U.S. Food and Drug Administration (FDA). Abbot is marketing this new technology as the FreeStyle® Libre 2.

The FreeStyle Libre 2 system uses Bluetooth to automatically alert users when their glucose is high or low without needing to scan the sensor. Users also have the option of turning off the customizable, real-time alarms. The system has a combined mean absolute relative difference (MARD), a measurement of performance for CGMs, of 9.3% (9.2% for adults and 9.7% for pediatrics).

This new CGM system met or exceeded the FDA's rigorous iCGM special control standards.



The system is designed to digitally connect and communicate with other devices. This can allow people to tailor and potentially simplify how they manage their diabetes.

The sensor is worn on the back of the upper arm for up to 14 days and measures glucose every minute to help users and their healthcare providers make informed treatment decisions. With a one-second scan using a handheld reader, users can see their glucose reading, trend arrow, and eight-hour history.

"Innovations like FreeStyle Libre 2 will change the way people manage their diabetes, especially among children," says Endocrine Society member Larry Kurt Midyett, MD, a pediatric endocrinologist at Midwest Women's and Children's Specialty Group. "Using this technology can improve time in optimal glucose

> range and lower HbA1c because we can get a full picture of what a child's glucose levels are doing without having to disrupt their play or sleep with painful fingersticks. The alarms are a bonus because they provide parents a level of reassurance."

COVID-19 May Pose Blood Clot Risk in Pregnant Women

OVID-19 may increase the risk of blood clots in women who are pregnant or taking estrogen with birth control or hormone replacement therapy, according to a new manuscript published Endocrinology.

Authors Daniel I. Spratt, MD, and Rachel J. Buchsbaum, MD, both of Maine Medical Center in Portland, and Tufts University School of Medicine in Boston, Mass., point out that COVID-19 has an unusual array of pathological effects. "In addition to damage inflicted on the lungs, kidneys, heart, and other organ systems, reports have emerged of hypercoagulable states in patients hospitalized with COVID-19," they write. "Macro- and microvascular thrombosis in venous and arterial beds along with venous thromboembolic events (VTEs) occur with a troublesome frequency. A recent study found increased platelet activation and aggregation in patients infected with SARS-CoV-2, with increased expression of platelet adhesion protein P-selectin along with altered gene expression in multiple pathways, which may underlie platelet hyper-reactivity contributing to thromboinflammation in COVID-19 disease."

One of the many complications of COVID-19 is the formation of blood clots in previously healthy people. Estrogen increases the chance of blood clots during pregnancy and in women taking birth control pills or hormone replacement therapy. If infected with COVID-19, these women's risk of blood clotting could be even higher, and they may need to undergo anticoagulation therapy or to discontinue their estrogen medicines.

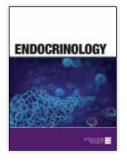
"During this pandemic, we need additional research to determine if women who become infected with the coronavirus during pregnancy should receive anticoagulation therapy or if women taking birth control pills or hormone replacement therapy should discontinue them,"



Spratt says. "Research that helps us understand how the coronavirus causes blood clots may also provide us with new knowledge regarding how blood clots form in other settings and how to prevent them."

Researching and understanding the cause of blood clotting in COVID-19, including the intersecting effects of estrogen therapy or pregnancy, has several hurdles and will require innovative animal and tissue models, the authors write. "Several issues complicate matters," Spratt and Buchsbaum continue. "COVID-19 has a variety of coagulation effects that appear to differ between individuals. Coagulation physiology in nonhuman animals differs from humans. Hypercoagulability with pregnancy (and probably estrogen therapy) does not naturally occur in other animals."

Findings: Conversations between clinicians and basic researchers and between endocrinologists and hematologists necessary to explore potential interactions between SARS-CoV-2 - the virus that causes COVID-19 — and pregnancy or estrogen therapy that could guide clinical management, the authors conclude.



Research that helps us understand how the coronavirus causes blood clots may also provide us with new knowledge regarding how blood clots form in other settings and how to prevent them.





Virtual 2020 Clinical Endocrinology **Update/Endocrine Review Board**

CEU 2020 EBR 2020 Sept. 10 – 12, 2020 Sept. 16 - 18, 2020

Every year, the Endocrine Society holds Clinical Endocrinology Update (CEU), which brings together hundreds of endocrine clinicians for a unique learning experience.

This year, due to concerns regarding the safety of both attendees and faculty stemming from the COVID-19 outbreak, the Endocrine Society is conducting these sessions in a virtual learning environment.

CEU 2020 offers an opportunity to stay up to date on the newest breakthroughs in clinical endocrinology. Expert faculty deliver a comprehensive three-day program covering a range of clinical practice areas using interactive, case-based learning.

Endocrine Board Review (EBR) is an essential course for endocrinologists preparing to take the boards or practicing physicians seeking an intensive knowledge assessment. The virtual program is designed as a mock exam, with rapid-fire, case-based questions emulating the format and subject matter of the ABIM's Endocrinology, Diabetes, and Metabolism Certification Examination. Attendees will have early access to topical on-demand presentations with detailed answer rationale (available in late August).

www.endocrine.org/ceu2020 • www.endocrine.org/ebr2020

CMHC Live Online October 21 - 24, 2020

For the first time in its 15-year history, the Cardiometabolic Health Conference (CMHC) will deliver a historic cardiometabolic educational event entirely online as the 2020 Annual CMHC Live Online: Evolving Paradigms in Cardiometabolic Care: Disparities & Advancements. Led by leading clinical experts, this conference will present the latest information and updates across the cardiometabolic healthcare industry as well as provide a deep dive into the intersection of social determinants of health and cardiometabolic care. Through an advanced learning structure, this offering will help you build a practical strategy through which to both keep your practice up to date and effectively navigate the challenges of inequity in healthcare. www.cardiometabolichealth.org

ObesityWeek® 2020

November 3 - 6, 2020

ObesityWeek® is home to the latest developments related to obesity from cutting-edge basic and clinical research to state-of-the-art treatment and prevention to the latest efforts in advocacy and public policy. Present your latest work and stay up to date on the latest advances in the field by attending the interactive, all virtual ObesityWeek 2020. The overarching theme for ObesityWeek 2020 will be Pathways to Precision Obesity Care. A key component in the development of precision care for obesity is recognizing and understanding the inherent heterogeneity in both the patterns of development and expression of obesity, and ObesityWeek 2020 programming will draw particular attention to these topics.

www.obesityweek.org

Diabetes and Its **Complications**

Livestream

November 12 - 14, 2020

Anyone who provides care for people with diabetes knows that these patients often have a myriad of comorbidities and complications, and that optimizing their care is frequently complex and challenging. It is with these challenges in mind that Harvard Medical School faculty have developed this CME program, which will provide comprehensive updates, practice recommendations, and the newest evidence-based strategies for the treatment and care of the person with or at risk for diabetes.

http://hmsdiabetescourse.com/

Project ECHO

Project ECHO events are live, interactive seminars using virtual platforms that allow participants to connect in real time to provide feedback on cases. Launched at the University of New Mexico in 2003, ECHO stands for Extension of Community Healthcare Outcomes, and it is built on the idea that while not everyone can be a specialist, all patients deserve access to specialty care.

Type 1 Diabetes Care and Management

Open to all clinicians, this virtual program seeks to educate primary care providers, care teams, and non-diabetes specialists in best practices for type 1 diabetes care and management. With many therapeutic and pharmacological options available, clinicians need additional resources to stay up to date. This program features live, interactive seminars and on-demand webinars, and will focus on evidence-based methods for addressing type 1 diabetes with a goal of improving health-related quality-of-life for patients and empowering clinicians to provide the best possible care.

www.endocrine.org/project_echo_ type1diabetescare

Approaches to Long-Term Weight Loss and Obesity Care

Open to all clinicians, this virtual program seeks to educate primary care providers, care teams, and non-obesity specialists in best practices in obesity care and management. The program will address the obesity epidemic and associated diseases by educating clinicians around the world in best practices and research directly from obesitymanagement specialists. There will be a total of 12 ECHOs throughout the next year, each focusing on a different aspect of obesity and associated comorbidities.

www.endocrine.org/project_echo_ type1diabetescare

INTERNATIONAL ITINERARY

EndoBridge 2020

Virtual Event

October 22 - 24, 2020

EndoBridge® is a unique initiative with the vision of bridging the world of endocrinology. EndoBridge® is co-hosted by the Endocrine Society and the European Society of Endocrinology in collaboration with the Society of Endocrinology and Metabolism of Turkey. The meetings are held in English with simultaneous translation into Russian, Arabic, and Turkish. Accredited by the European Accreditation Council for Continuing Medical Education (EACCME). this three-day scientific program includes state-of-the-art lectures delivered by world-renowned faculty and interactive sessions covering all aspects of endocrinology. EndoBridge® provides a great opportunity for physicians and scientists from around the world to interact with each other, share their experience and perspectives, and participate in discussions with global leaders of endocrinology. www.endobridge.org

AOCE-SICEM 2020

Virtual Congress

October 28 - 31, 2020

The 17th Asia - Oceania Congress of Endocrinology and the 8th Seoul International Congress of Endocrinology and Metabolism will take place in Seoul, Korea. AOCE - SICEM 2020 will provide a platform to network with colleagues, exchange ideas, discover novel opportunities, and increase professional knowledge. It will be held at the Swiss Grand Hotel in Seoul.

http://sicem.kr/main.asp

ICE 2020: 19th International Congress of **Endocrinology**

Virtual Meeting February 2021

19th International Congress of Endocrinology (ICE 2020), 4th Latin American Congress of Endocrinology (CONLAEN), and 13th Congress of the Argentine Federation of Endocrinology Societies (FASEN) is organized by MCI Group — Argentina. Topics to be discussed include: big data and its impact in health, human diseases, artificial intelligence, and big-data mining; thyroid cancer diagnosis and treatment; advances in pheochromocytomas and paragangliomas; the tsunami of diabetes in lower- and middleincome countries; preserving reproduction in cancer patients; and so much, much more.

www.ice-2020.com

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ENDO Online 2020 tried to bring all the complexity of debates and sessions that take place in a meeting in a traditional format. Unfortunately, it is impossible to replace the person-to-person interaction that is, in my opinion, one of the highlights of the in-person format. On the other hand, ENDO Online 2020 reached a much larger audience than the events in the traditional format."

- PAULO MIRANDA MD, PHD, assistant, Clinic of Endocrinology and Metabology, Santa Casa; coordinator, Endocrinology Service, Mater Dei Health Network; adjunct professor of medicine, UniBH; and director, Brazilian Society of Endocrinology and Metabology, who discussed his impression of the Endocrine Society's first ever all-virtual ENDO Online 2020 as part of the roundtable article, "ENDO Online 2020: The Views from Around the World" on page 38.

MEMBER SPOTLIGHT

Shlomo Melmed, MD



Shlomo Melmed, MD, compellingly impacts the practice of pituitary medicine by clinical leadership, educational initiatives, and major translational discoveries in pathophysiology and therapy of pituitary disease. He has elucidated mechanisms for paracrine pituitary growth factor

regulation and pituitary tumorigenesis and identified novel molecules for pituitary tumor therapy. His landmark papers demonstrated mechanisms for pituitary tumorigenesis and intrapituitary ACTH and GH control. He described ectopic GH acromegaly syndrome. discovered pituitary tumor transforming gene, and pioneered receptor subtype-specific analogs for neuroendocrine tumor therapy.

As past editor-in-chief of Endocrinology, he exemplifies an international pituitary scholar and leader. His exemplary publications in the very highest-quality basic and clinical journals reflect a dual combination of outstanding basic and clinical creativity underscoring his standing as a leading international clinical scholar of pituitary medicine and discovery.

Few scholarly physicians have contributed more to our fundamental and clinical understanding of pituitary tumor biology as it is applied to the practice of endocrinology.

To learn more about some of the Endocrine Society's outstanding members, go to:

www.endocrine.org/member-spotlight.



Cerebral palsy (CP) among IVF children decreased by more than 50% in the past 20 years (from 8.5 to 2.8 per 1,000 births). The rate of CP remained stable for IVF twins; however, indicating that multiple pregnancies heighten risk.

- SOURCE: EUROPEAN SOCIETY OF HUMAN REPRODUCTION AND EMBRYOLOGY



A new survey has found that one in four patients diagnosed with diabetes have rationed supplies to cut the cost of their diabetes care since the start of the COVID-19 pandemic.

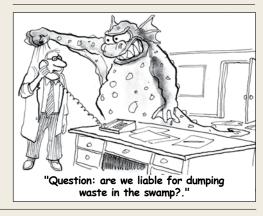
- SOURCE: AMERICAN DIABETES ASSOCIATION

84 million Americans have prediabetes and are at risk for developing type 2 diabetes.

90% of them don't know they have it.



- SOURCE: DIABETES.ORG





Testosterone Therapy in Diabetes

33% – Reduced testosterone concentrations are found in 33% of men with type 2 diabetes.

1/3 – In a recent study, one-third of men treated with testosterone saw remission of their diabetes.

83% In that same study, 83.1% of men treated with testosterone reached their target level of HbA1c.

- SOURCE: JOURNAL OF DIABETES. OBESITY. AND METABOLISM





www.endohighlights2020.com

HIGHLIGHTS OF ENDOON Ine 2020

INCLUDING PRESENTATIONS SCHEDULED FOR ENDO 2020

FOCUS ON DIABETES & COMORBIDITIES

AVAILABLE IN 4 LANGUAGES!











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- Video introduction
- International faculty interviews
- Virtual meeting presentations
- Expert overview on the latest scientific information presented
 - ENDO 2020 conference summaries from key oral presentations
 - Podcasts from poster sessions
 - Downloadable slide kit

Keep up with the latest advances in diabetology & endocrinology care from the convenience of your home and office!

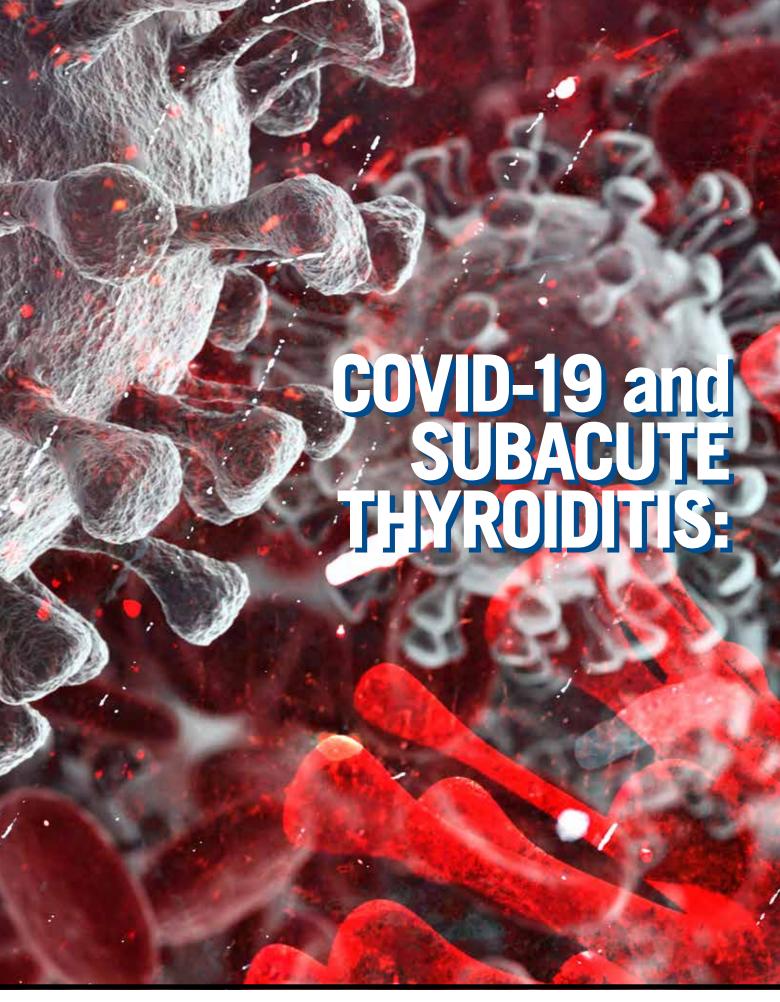
Visit www.endohighlights2020.com!

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Developed by





BY KELLY HORVATH

A paper published in *The Journal of Clinical Endocrinology* & Metabolism sounds an alarm for clinicians treating **COVID-19** patients to be on the lookout for possible cases of subacute thyroiditis post-infection.

An Alert for Endocrinologists

OVID-19 upended the world as we knew it in 2020, and its effects are continuing to be felt. New clinical sequelae are also emerging, not surprisingly, including subacute thyroiditis (SAT).

Researchers in Italy, the second country after China to be involved in the pandemic and, as some have speculated, possibly home to a particularly virulent strain of the coronavirus, were the first to report on post-COVID-19 SAT and published their findings in *The Journal of Clinical* Endocrinology & Metabolism online ahead of print in May.

Patient Case

In "Subacute Thyroiditis After Sars-COV-2 Infection," Francesco Latrofa, MD, of the Endocrinology Unit I, Department of Clinical and Experimental Medicine at the University Hospital of Pisa in Italy, and team describe an 18-year-old female patient who tested positive for COVID-19 via oropharyngeal swab on February 28, 2020, after her father (also her housemate) had been hospitalized for the virus. By March 14, 2020, she was no longer ill and twice tested negative for the virus. Suddenly, three days later, the patient experienced fever, fatigue, palpitations, and neck pain radiating to her jaw. On March 19, 2020, with the neck pain worsening, she was referred to Latrofa and team.

To backtrack a bit, the patient had previously experienced transient hyperthyrotropinemia, but imaging and testing on February 21, 2020, just before the onset of her viral illness, demonstrated that she was euthyroid, including a negative result for antibodies to thyroglobulin (TgAb), thus ruling out thyroid disease. Explains Latrofa, "The patient was asymptomatic, and measurement of thyroid-stimulating hormone (TSH) was part of the routine labs suggested by her family doctor. Hyperthyrotropinemia, when isolated (i.e., with no evidence of autoimmune thyroid disease) cannot be considered as an evidence of disease by itself but prompts reevaluation of thyroid function. Indeed, thyroid function was normal a few months later, shortly before the onset of SAT."

On examination on March 19, her heartrate was rapid and her thyroid tender to palpation. Given the association of SAT with thyroid dysfunction, which this patient had a history of,

We alert clinicians to look for this additional clinical manifestation related to SARS-CoV-2 infection. In some cases, the symptoms of SAT are mild, and therefore SAT could remain undiagnosed in patients with relevant symptoms of SARS-CoV-2 infection involving other organs."

> - FRANCESCO LATROFA, MD, ENDOCRINOLOGY UNIT I, DEPARTMENT OF CLINICAL AND EXPERIMENTAL MEDICINE, UNIVERSITY HOSPITAL OF PISA, ITALY

the team suspected SAT. Laboratory tests (thyroid hormone function tests) and ultrasound provided further evidence, and the patient was started on prednisone on March 20 while still in the acute phase of SAT to combat her symptoms as well as reduce the risk of recurrence. Within one week, the patient was no longer symptomatic, and within two weeks, clinical, biochemical, and imaging signs were back to normal.

Importantly, although the pathogenesis of SAT is not completely understood, it is thought to have a viral or postviral (inflammatory) origin in genetically predisposed individuals. SAT is often preceded by an upper respiratory tract infection or symptoms like malaise, fatigue, and lowgrade fever. It can occur seasonally, in the summer period, when the peak of infection by enterovirus occurs and has been also correlated with viral epidemics of mumps. The most relevant evidence for its viral origin is the detection of rising level of antibodies to viruses in convalescent patients.

However, the virus has been isolated from the thyroid of subjects with SAT in only a very few cases. Studies based on fine-needle aspiration of the thyroid from patients with SAT failed to isolate the virus. Although possibly associated with the de novo appearance of thyroglobulin autoantibodies TgAb-IgG to Tg as well as to the other thyroid autoantigens, SAT usually recovers without autoimmune sequelae.

In a study published in the June issue of *The Journal of Clinical*

Endocrinology & Metabolism, Latrofa and team showed that Tg leak associated with thyroid injury induces the production of specific TgAb-IgM, which, in turn, increases the clearance of Tg and might prevent the establishment of a persistent thyroid autoimmune response.

In the case in "Subacute Thyroiditis After Sars-COV-2 Infection," the confirmed prior thyroid disease-free status of the patient combined with the emergence of SAT 15 days after recovery from COVID-19 suggest that COVID-19 is likely the cause of her bout of SAT. Furthermore, "a second and a third case of SAT post-COVID-19 have now been published in the Journal of Endocrinological Investigation by a group of endocrinologists at the University of Insubria (in Varese, Italy) and a group of internal medicine doctors at the Ankara Hospital (in Turkey)," Latrofa says.

Ramifications

Although this patient completely recovered, "a common lasting sequelae of SAT is hypothyroidism, due to the damage of the gland," Latrofa says. Notably, autopsy of patients who have died after the 2002 SARS-CoV outbreak showed thyroid gland damage. "However, hypothyroidism is treated with levothyroxine, usually with no troubles, as the majority of cases of permanent hypothyroidism," he continues.

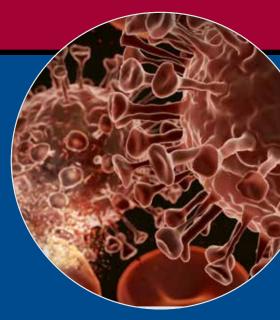
As for other postviral diseases that clinicians should look



out for, Latrofa cites recently reported cases of Guillain-Barré syndrome (a neurological disorder that has been associated with infectious agents) related to COVID-19.

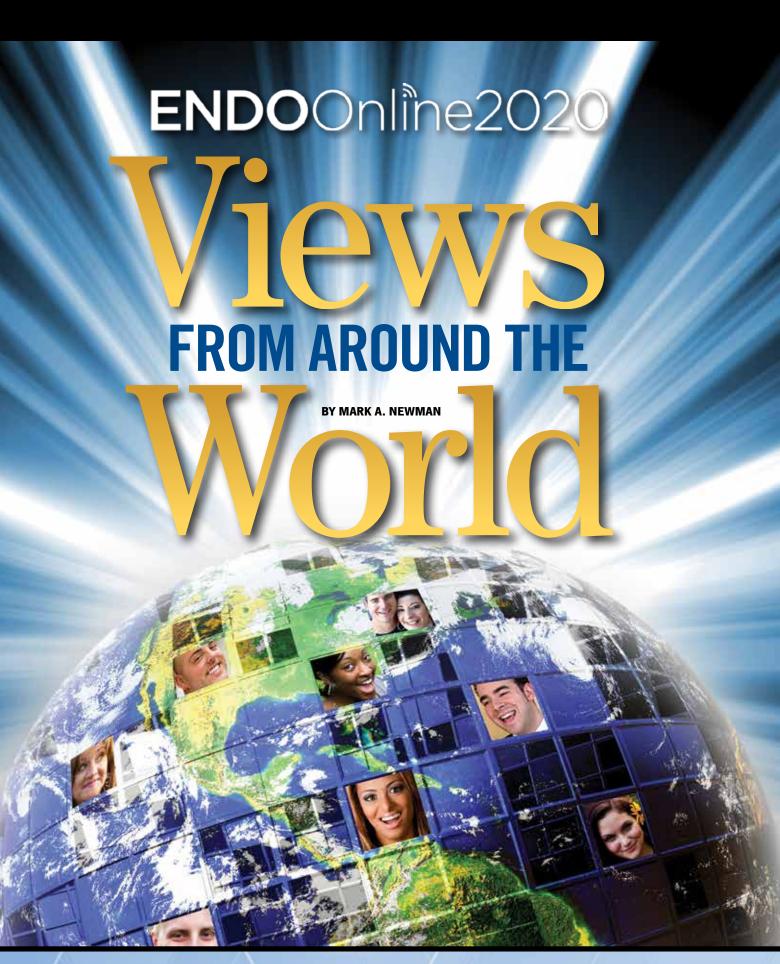
With COVID-19 infection continuing to spread worldwide, with more than 18 million cases reported at the time of this writing, Latrofa and team have an urgent message for endocrinologists. "We alert clinicians to look for this additional clinical manifestation related to SARS-CoV-2 infection. In some cases, the symptoms of SAT are mild, and therefore SAT could remain undiagnosed in patients with relevant symptoms of SARS-CoV-2 infection involving other organs."

With the ability of this coronavirus to trigger SAT, the probability is high that it can cause other postviral syndromes and damage other body systems. This case study has unveiled more of COVID-19's potential to do harm in unexpected ways.



AT A **GLANCE**

- In "Subacute Thyroiditis After Sars-COV-2 Infection," researchers report the first case of post-COVID-19 SAT infection that occurred in March 2020, in Italy; subsequent cases in Italy and Turkey have been reported.
- Researchers suggest that COVID-19 be added to the list of viruses with causal associations to SAT-like adenovirus. cytomegalovirus, dengue fever, Epstein-Barr virus, hepatitis E, HIV, mumps, orthomyxovirus, and rubella.
- Clinicians should be on high alert for SAT as well as other asvet undiscovered manifestations associated with COVID-19 infection.



The Endocrine Society's first all-virtual meeting, ENDO Online 2020, turned out to make history by being the biggest endocrinology conference in the world. Endocrine News reached out to a handful of the international attendees to see what they thought of this new phenomenon, what sessions were the most useful to them, and what they see as the future of scientific conferences.

uch has been written about the "new normal" \dots especially in the pages of Endocrine News. From grocery shopping to haircuts to the way we do our jobs, we've all had to adjust to an unfamiliar reality that, for many of us, has become a necessity. For example, some jobs are easier to do from home — magazine editor comes to mind — while others depend on brand-new protocols and especially brand-new technology.

As we've reported previously, the COVID-19 pandemic has brought the use of telehealth to the forefront with a fairly significant success rate, whether seeing patients in the comforts of their own homes, conferencing with colleagues on a challenging case, or even discussing research with fellow scientists, meeting via laptop or smartphone has become the new way to communicate with others.

When it was decided to hold a new, online-only conference this year, nobody knew what to expect or how it would be received by the vast endocrinology community. With more than 17,000 attendees showing up for ENDO Online 2020, nobody can argue that this event was anything but an unqualified success. For anyone keeping score, attendance at ENDO 2019 in New Orleans was roughly 7,000, so the numbers for this year's virtual meeting were phenomenal.

Endocrine News reached out to Endocrine Society members around the world to find out what they thought of this virtual get together, their own personal highlights, what sessions they found most helpful, and what they see as the future of online scientific conferences.

Answering our questions are Paulo Miranda, MD, PhD, assistant, Clinic of Endocrinology and Metabology, Santa Casa, Brazil; coordinator, Endocrinology Service, Mater Dei Health Network; adjunct professor of medicine, UniBH; and director, Brazilian Society of Endocrinology and Metabology; Jason Tan Liwag, an MS candidate in molecular biology and biotechnology, Molecular Endocrinology Laboratory, University of the Philippines, Diliman, Quezon City, Philippines; Rob Fowkes, BSc, PhD, PGCAP, FHEA, associate dean for post-graduate teaching and learning, Endocrine Signalling Group, Department of Comparative Biomedical Sciences Royal Veterinary College, London, U.K.; and Valeria de Miguel, MD, Endocrine and Nuclear Medicine Unit of Hospital Italiano de Buenos Aires, Buenos Aires, Argentina.



I think ENDO Online 2020 tried to bring all the complexity of debates and sessions that take place in a meeting in a traditional format. Unfortunately, it is impossible to replace the person-to-person interaction that is, in my opinion, one of the highlights of the in-person format. On the other hand, ENDO Online 2020 reached a much larger audience than the events in the traditional format."

- PAULO MIRANDA, MD, PHD, ASSISTANT, CLINIC OF ENDOCRINOLOGY AND METABOLOGY, SANTA CASA: COORDINATOR, ENDOCRINOLOGY SERVICE, MATER DEI HEALTH NETWORK; ADJUNCT PROFESSOR OF MEDICINE, UNIBH; AND DIRECTOR, BRAZILIAN SOCIETY OF ENDOCRINOLOGY AND METABOLOGY, BRAZIL

Endocrine News: What made you decide to attend **ENDO Online 2020?**

Paulo Miranda: I have participated in all editions of ENDO since 2009. I already had everything planned for the San Francisco edition. As we know, we all had to change our plans after the new coronavirus pandemic. It was a great surprise to receive the news that, despite all the difficulties, we would have an online version of ENDO this year. I did not think twice about signing up.

Jason Tan Liwag: I was initially supposed to present a poster for my study at ENDO 2020 earlier this year. However, the rising cases in San Francisco and in the Philippines made that impossible, and quarantine rules were soon implemented. ENDO Online 2020 gave me the opportunity to still attend the lectures I was looking forward to without risking my health.



66 I think the diversity in the topics and in the experimental approaches was really enlightening. I have undoubtedly learned some best practices to try out when I get back to the laboratory, and a number of new ways of approaching and reframing research questions."

> - JASON TAN LIWAG, AN MS CANDIDATE IN MOLECULAR BIOLOGY AND BIOTECHNOLOGY, MOLECULAR ENDOCRINOLOGY LABORATORY, UNIVERSITY OF THE PHILIPPINES, DILIMAN, QUEZON CITY, PHILIPPINES

Rob Fowkes: Partially to compensate for not being at ENDO in person, but certainly to 'attend' specific sessions.

Valeria de Miguel: The cancellation of ENDO 2020 in San Francisco due to the COVID-19 pandemic but still having the opportunity to attend an Endocrine Society meeting, even if it was in an online format.

EN: What surprised you the most about the ENDO **Online 2020** experience?

PM: I think what surprised me the most was the prompt engagement of everyone around the idea. We still had a limited view on the potential of meetings in a virtual environment. In this case, the virtual environment has shortened distances and the free registration allowed the participation of a larger number of people. Allowing access to people who previously saw ENDO as an event outside their reality. This was very noticeable in developing countries like Brazil. The number of participants was impressive. I really liked the platform and the time we had to plan.



I'm really glad that some early-career researchers got the chance to present, and I hope the Endocrine Society can provide further opportunities for this to happen in the coming year. I thought some of the workshops were great (teaching tools, resilience, for example)."

- ROB FOWKES, BSC, PHD, PGCAP, FHEA, ASSOCIATE DEAN FOR POST-GRADUATE TEACHING AND LEARNING, ENDOCRINE SIGNALLING GROUP, DEPARTMENT OF COMPARATIVE BIOMEDICAL SCIENCES ROYAL VETERINARY COLLEGE, LONDON, U.K.

JTL: That it was free and open to everyone! Yay for open science! Also, the Twitter engagement!

RF: I was pretty overwhelmed by the numbers of attendees, which was really impressive. And very happy with the opportunities to engage in real time.

VDM: The possibility of free registration and access from all over the world. The online platform was very user-friendly and easy to navigate. I also liked the mix of both live and ondemand sessions.

EN: If you ever attended a traditional ENDO meeting, how did ENDO Online 2020 compare?

PM: I think ENDO Online 2020 tried to bring all the complexity of debates and sessions that take place in a meeting in a traditional format. Unfortunately, it is impossible to replace the person-to-person interaction that is, in my opinion, one of the highlights of the in-person format. On the other hand, ENDO Online 2020 reached a much larger audience than the events in the traditional format.



The ability to access the content from around the world and from around the world without economic or financial barriers [was a benefit of ENDO Online 2020]. This is an ideal way to build a community."

> - VALERIA DE MIGUEL, MD, ENDOCRINE AND NUCLEAR MEDICINE UNIT OF HOSPITAL ITALIANO DE BUENOS AIRES, **BUENOS AIRES. ARGENTINA**

JTL: Unfortunately, I have not attended a traditional ENDO meeting. However, I would imagine that there are a lot of missed opportunities for networking and for collaboration. Though the online nature does open up the ENDO meeting to a wider demographic, I think that the kind of opportunities and partnerships formed when in a physical space together is just different. Additionally, the chance to experience cultural exchanges or best practices between laboratories is something that I think online spaces won't necessarily facilitate as well as being in proximity to one another.

RF: Personally, apples and oranges, so unfair to compare them. I really miss meeting up with friends and colleagues in person, and it is certainly a lot more effective to have in-person meetings for access to a large amount of content. But as my first online conference experience, I thought ENDO Online 2020 was excellent. Being in a different time zone, I did struggle to 'attend' a full day as I'd already done over half a day's work before the conference would start for the day.

VDM: I think that they are both very different, but both formats have distinct advantages. Having attended traditional, in-person



ENDOs from 2009 to 2017, I found the experience unique since I was coming from a significant distance (Argentina), so I combined my academic learning, socializing, and professional development with a fair amount of tourism. The process starts from the decision to register, renewing my membership, and the choosing some significant learning for an abstract presentation (for me, most of the time it was a clinical case report).

Of course, it is very exciting to experience the various U.S. cities where the in-person meetings take place with four days dedicated to the experience, meeting colleagues from all over the world to exchange experiences. Poster presentations allowed me to meet wonderful new colleagues with whom I established strong relationships.

ENDO Online 2020 was very practical and accessible to everybody. Since I was not able to attend live sessions in real time, I tuned in later to the on-demand sessions that interested me.

EN: What did you like better about **ENDO Online** 2020 compared to traditional, in-person meetings?

JTL: I definitely love the accessibility. As a middle-income graduate student from a developing country, international meetings are hard to get into because of the additional economic barriers (i.e., costs of flights, accommodations, etc.), and also the sheer stress of applying for a visa. Though there are certainly funding agencies and in-house support for these, they are limited and competitive in nature. Being from a drastically different time zone, I also appreciated the availability of the sessions even after the meeting on the ENDO website — which also allowed participants to potentially attend more lectures, as opposed to schedule conflicts brought about by traditional, in-person meetings.

RF: More access to catch-up sessions. This is something we should consider to supplement ENDO.

VDM: The ability to access the content from around the world without economic or financial barriers. This is an ideal way to build a community.

EN: What ENDO Online 2020 session — or sessions — "wowed" you the most?

PM: I enjoyed all the sessions I attended. I wish I could have watched them all. I can highlight two that I really liked. Prof. Mjrian Christ-Crain presented an excellent review of the best pituitary papers published in 2019 and Prof. Ana Claudia Latronico presented on international research networks. These are examples of the wide range of themes that were offered in the ENDO Online programming.

JTL: I really loved the online session on Healthcare of the Transwoman Across the Lifespan by Dr. Vin Tangpricha. Even though I am not a medical doctor per se, I thought it gave some really good insights into roadblocks to proper medical attention for trans individuals, especially here in the Philippines. It also presented interesting questions and gaps in knowledge with regards to long-term considerations in research for trans individuals. I also greatly appreciated the "professional development sessions" that centered around the underappreciated, more human aspects of research, as well as the discussions on COVID-19 and its impacts on endocrinology and telemedicine.

RF: I'm really glad that some early-career researchers got the chance to present, and I hope the Endocrine Society can provide further opportunities for this to happen in the coming year. I thought some of the workshops were great (teaching tools, resilience, for example).

VDM: Personally, this year I focused more on professional development and educational sessions, which I like very much. I would like to have more Meet the Professor sessions that are so prominent at the traditional, in-person **ENDO** conferences.

EN: Did you learn anything at ENDO Online 2020 that you can use daily?

JTL: I think the diversity in the topics and in the experimental approaches was really enlightening. I have undoubtedly learned some best practices to try out when I get back to the laboratory, and a number of new ways of approaching and reframing research questions. In retrospect, I thought of research as a somewhat "pocketed" endeavor. Even though our problems seem like giants, it is empowering to see that we are in a collective struggle toward understanding and solving these problems; that there is a face to this struggle. There is comfort in the knowledge that someone out there is willing to listen and help you better your research.

VDM: Yes, I learned that the virtual world allows us to build and create new possibilities. In my experience, we organized our annual meeting online, and we are organizing different workshops for patient education. Also, the importance of talking about professional development can never be underestimated. The session, "How to Build Resiliency and Manage Burnout," was very important, especially during these times when we all need support.

ENDOOnline2020

DON'T MISS OUT!

Unlike past in-person **ENDO** meetings, if you missed **ENDO Online 2020** – and you're an Endocrine Society member – you have access to the full program. Both the live and on-demand sessions are available at: www.endocrine.org/endoonline2020_session_recordings.

Sessions will be available until July 2023.



EN: Any memorable **ENDO Online 2020** experiences you'd like to share?

PM: ENDO Online 2020 enabled greater participation worldwide. From that, I was able to include the participation of my undergraduate medical students. It was an incredible experience. ENDO was part of our activities for the semester. The students later selected one of the sessions for them to present and discuss during our classes. It was a remarkably interesting activity. The experience expands their horizons. I believe that they will have a different view of research in endocrinology from now on.

JTL: This! I am incredibly grateful to *Endocrine News* for reaching out to me via Twitter, especially considering I am at an early stage in my career development as a molecular biologist and science communicator.

As the U.S. Food and **Drug Administration begins** the process of incorporating real-world evidence into regulatory decisions, researchers and clinicians alike are pondering the possibility of virtual clinical drug trials.

A Brave New (Real) World

BY ERIC SEABORG

66 We came to the conclusion that there is no difference in the cardiovascular risk between linagliptin and glimepiride, but we also found that there is a substantial benefit of linagliptin with regards to avoiding hypoglycemic events. So that is the exciting example of how real-world evidence may work at its best."

> - SEBASTIAN SCHNEEWEISS, MD. SCD. PROFESSOR OF MEDICINE AND EPIDEMIOLOGY, HARVARD MEDICAL SCHOOL: CHIEF, DIVISION OF PHARMACOEPIDEMIOLOGY, BRIGHAM AND WOMEN'S HOSPITAL, BOSTON, MASS.

s healthcare providers struggle to cope with unprecedented numbers of COVID-19 patients, researchers are searching for effective treatments. Clinical trials can be difficult to run during a pandemic, but valuable sources of information like electronic health records (EHRs) are accumulating at a rapid pace.

The knowledge of how to turn this data into the useful information known as real-world evidence (RWE) continues to progress. For example, EHR data have already contributed to COVID-19 treatment with papers that demonstrated the importance of hyperglycemia as a risk factor for severe disease. The pandemic gives new urgency to these kinds of findings.

The U.S. Food and Drug Administration (FDA) has been grappling with how to incorporate RWE into its decision making since the passage of the 21st Century Cures Act in 2016. That law requires the FDA to use RWE in its regulatory decisions, including approval of new indications for approved drugs. These new indications can gain approval more easily because the agency assumes that the clinical trials for the original approval established the drug's safety.

Data or Evidence

In December 2018, the agency published a "Framework for FDA's Real-World Evidence Program" that distinguishes between realworld data (RWD) and real-world evidence: "RWD are data relating to patient health status and/or the delivery of healthcare routinely collected from a variety of sources. RWE is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD."

The framework says that RWD can come from a variety of sources, including EHRs, claims and billing activities, product and disease registries, patient-generated data, and data from sources such as mobile devices.

Randomized clinical trials (RCTs) remain the gold standard for assessing new drugs and treatments, but they have their limitations, according to David Klonoff, MD, medical director of the Diabetes Research Institute at Mills-Peninsula Medical Center in San Mateo, Calif., who has published extensively on RWE.

One limitation is the ability to spot rare side effects. If a side effect such as a cardiovascular event occurs in only one patient in a thousand, there might be only two or three reports in an RCT with 3,000 participants. But if the drug is approved and used widely, there may be hundreds of reports of the side effect. The analysis of EHRs or insurance claims could be a key to identifying the association.

An example of this after-approval discovery happened when concerns were raised about the cardiovascular safety of diabetes medications such as rosiglitazone after their approval and widespread use. The risk led to the FDA's decision in 2008 to add postmarket long-term cardiovascular outcomes trials as another safety step for glucose-lowering type 2 diabetes agents.

Ideal vs. Real

A related aspect is reflected in that "real world" name. Clinical trials show the power of a drug under rather artificial conditions, with a nurse at hand to supervise and overcome obstacles such as



patients remembering and being willing to take the drug as well as keeping on the correct schedule and dosage. Those conditions can tell you how well a drug can work, but real-world data give evidence of how likely it is to work in the hands of the average patient, Klonoff says.

Research has shown that the way diabetes treatments work in the real world can differ significantly from what is seen in clinical trials, according to Henry Anhalt, DO, a member of the Endocrine Society board of directors who practices pediatric endocrinology in Hackensack, N.J.

"We cannot rely on traditional RCTs alone to yield this type of data, because their closely monitored - some would say artificial - conditions are not necessarily reflective of how patients use the treatments in real life," Anhalt says.

Another weakness of RCTs is a systemic under-representation of people of color. "Mexican-American and Puerto Rican communities have a diabetes prevalence rate that is twice that of their white counterparts, yet they make up 4% of diabetes study participants," Anhalt says.

Approvals of New Uses

RCTs are also very expensive to conduct, so one first step the FDA is studying is whether RWE can be used to facilitate finding new uses for approved drugs. Obviously, an unapproved drug has no track record, but once a drug is in use, can researchers sift through thousands, even millions, of patient records to match participants for a virtual clinical trial?

To that end, the FDA has contracted with Brigham and Women's Hospital and Aetion, an RWE-analysis company founded in 2013, to run virtual clinical trials, according to company cofounder Sebastian Schneeweiss, MD, ScD, who is also professor of medicine and epidemiology at Harvard Medical School and chief of the Division of Pharmacoepidemiology at Brigham and Women's Hospital, Boston, Mass.

The team has a contract to use RWE to replicate the findings of 30 previously published RCTs. But an even more challenging contract is to identify seven ongoing phase-IV RCTs and predict what their outcomes will be before they are published.

Gone to CAROLINA Virtually

The first of these projects was to predict the outcome of the CAROLINA trial, an RCT to compare major adverse cardiovascular outcomes in type 2 diabetes patients taking the dipeptidyl peptidase-4 (DPP-4) inhibitor linagliptin vs. patients taking the established sulfonylurea glimepiride. The challenge for Schneeweiss' team was to mine insurance claims data to predict the outcome of the CAROLINA trial before its results were published.

Schneeweiss and his team registered a protocol at clinicaltrials. gov, submitted their paper to Diabetes Care months before the CAROLINA trial findings were published, and presented their predictions at the American Diabetes Association meeting shortly before the CAROLINA findings were unveiled.

The RWE findings were "spot on" to the RCT findings, Schneeweiss says. "We came to the conclusion that there is no We cannot rely on traditional [randomized clinical trials] alone to yield this type of data, because their closely monitored — some would say artificial conditions are not necessarily reflective of how patients use the treatments in real life."

- HENRY ANHALT, DO. BERGEN COUNTY PEDIATRIC ENDOCRINOLOGY, HACKENSACK, N.J.

difference in the cardiovascular risk between linagliptin and glimepiride, but we also found that there is a substantial benefit of linagliptin with regards to avoiding hypoglycemic events. So that is the exciting example of how real-world evidence may work at its best," he says.

But it's not difficult to find examples of researchers using RWD to come to questionable conclusions. For example, the goal of the CVD-REAL study was to use RWD to extend the findings of the clinical trials of SGLT-2 inhibitors in type 2 diabetes patients, comparing them with "other glucose-lowering drugs." The CVD-REAL claimed that SGLT-2 inhibitors were associated with a decrease in all-cause mortality that was inconsistent with the findings of the RCTs and so large as to be "unrealistic" as a causal effect, Schneeweiss says. He cites an analysis published in Circulation explaining how the mortality discrepancy could arise from researchers miscounting the SGLT-2 patients survival time in an effect known as immortal time bias (also known as survivor treatment selection bias).

Perhaps with these kinds of pitfalls in mind, the FDA has been moving cautiously. In May 2019, it published a draft guidance on submitting documents using RWD and RWE for drugs and biologics that it has not yet published in final form (https:// www.fda.gov/media/124795/download).

As this process moves forward, many experts have said that RWE could have a particular impact in diabetes treatment. With the number of new diabetes drugs becoming available and the plethora of combinations they make possible, it is unlikely that RCTs will be funded to sort out questions about which work best — but there will be ample EHRs and insurance claims data for running virtual clinical trials.

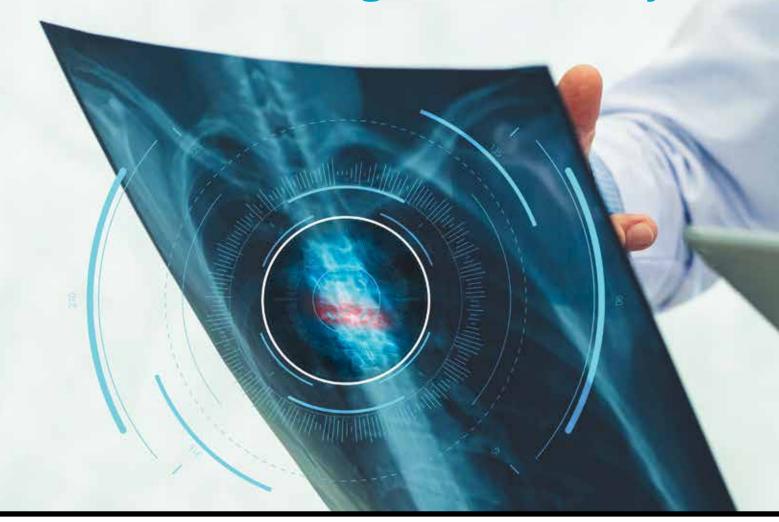


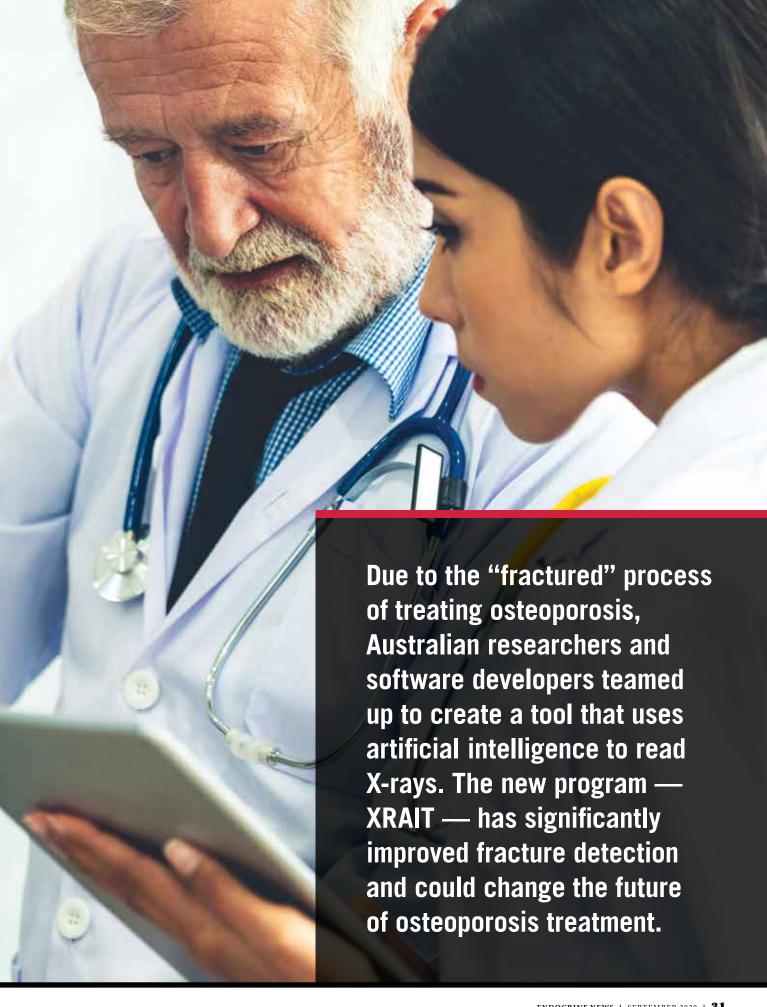
AT A **GLANCE**

- Randomized clinical trials remain the gold standard for answering questions about drug and treatment effectiveness, but they are expensive and have limitations.
- ► The FDA is exploring ways to include real-world evidence from sources such as electronic health records and insurance claims data into its regulatory decision making.
- Virtual trials using real-world evidence are already being tested for their ability to predict the outcomes of drug clinical trials.

More than Meets

Artificial Intelligence and X-Ray







HRISTOPHER WHITE, MBBS, PHD, FRACP, AN ENDOCRINOLOGIST AT PRINCE OF WALES HOSPITAL IN RANDWICK, AUSTRALIA, WAS TRYING TO RECRUIT PATIENTS FOR A CLINICAL TRIAL STUDYING HOW THE DRUG ROMOSOZUMAB AFFECTS PATIENTS WITH OSTEOPOROSIS, BUT HE FOUND THAT THE RECRUITMENT PROGRAM WAS VERY RIGID — THE SPONSOR WANTED NOT JUST PATIENTS WITH LOW T SCORES WHO MET THE CRITERIA FOR OSTEOPOROSIS, BUT EVIDENCE OF VERTEBRAL COMPRESSIONS AS WELL.

White was confident he'd meet his criteria; after all, he treats patients with osteoporosis regularly. He looked through discharge data, for patients with vertebral compression fractures, and figured even if he only found 10% of these patients, or had 10% referred to him, he could recruit with plenty of patients to spare. But despite his best efforts, he didn't meet his recruitment targets, and the study closed.

It turns out, when these patients were discharged from the Prince of Wales Hospital Emergency Department, they were sent to respite care, White says, and none was sent to him.

The current situation is something like this: An 80-year-old may present to the emergency room with vertebral compression fracture, but because of the patient's age and condition and competing pressure in a busy ER, physicians will only want to deal with the immediate fracture, then send the patient to respite care and eventually home.

Or a patient may present with breathlessness, and the radiologist sees a vertebral crush fracture. "The query on the X-ray report is, query pneumonia or heart failure," says Jacqueline Center, MBBS, PhD, FRACP, the head of the Clinical Studies and Epidemiology Lab at Garvan Institute of Medical Research in Sydney, Australia. "The report comes back as mild evidence of COPD, or something like that, but no evidence of pneumonia. They don't even bother reporting the fracture because no one even thinks about it."

Even when the vertebral crush is reported by the radiologist, the ER physician is focused on the immediate problem and will treat the pneumonia or heart failure and leave the fracture for "someone else" to deal with at a later time.

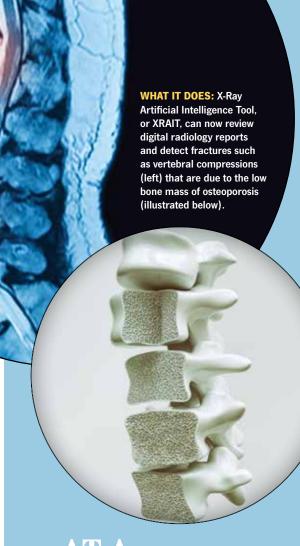
"The process of treating osteoporosis is fractured," White says.

Introducing X-Ray Artificial Intelligence Tool

About 44 million Americans are at risk of osteoporosis and have an increased risk of fractures because of low bone mass. Only two in 10 older women in the U.S. who sustain a fracture receive testing or treatment for osteoporosis, according to the National Osteoporosis Foundation. Although many hospitals have implemented fracture liaison services to identify patients whose fractures could be due to osteoporosis, Center says that manually reading the radiology records of referred patients misses some people at risk of osteoporosis or detects them too slowly.

So White had an idea. He decided that he could do for fractures what he did for bone density. He can already screen for a number. Why not screen for a diagnosis, using artificial intelligence (AI). He secured a relatively small grant to design a pilot program with a friend who develops software. "We played around with it, and it kind of worked," White says. "We just had a pilot [software program] that would read radiology reports. We took out some samples, and it seemed to work. Then I applied for a local grant, AU\$100,000 grant at my hospital, to build it and install it."

White and his team dubbed this new technology X-Ray Artificial Intelligence Tool, or XRAIT. This search tool uses natural language processing software



AT A **GLANCE**

- Because of some significant gaps in care and limited resources, the process of treating osteoporosis is currently "fractured."
- A team of endocrinologists and software developers in Australia created a tool that uses artificial intelligence and natural language processing that can detect fractures at a three-fold higher rate than manual reading of X-rays.
- The new detection tool has been a boon for fracture liaison services, which bone health experts agree are necessary to mending the fractures in osteoporosis treatment.



to understand human language and make communicating smoother and more uniform. "We all speak differently, so that's why I had to go towards natural language processing, to be able to interpret and learn the nuances in dialect, for instance," White says. "Australians speak differently to North Americans. We can understand each other. But there are differences in reporting, and in style."

To test XRAIT, White, Center, and their team had the tool search 5,089 digital radiology reports from patients over 50 years of age who went to a hospital's emergency department and had bone imaging over three months. The researchers compared XRAIT's results with manual review of the records of the 224 patients referred to the hospital's fracture liaison service in the same period. XRAIT was able to detect 349 people with fractures likely due to low bone mass compared with 98 people identified by the manual method, an over three-fold higher detection rate.

The researchers then tested XRAIT on the digitized radiology reports of another population of Australian adults over age 60 from the Dubbo Osteoporosis Epidemiology Study. From 327 reports of confirmed known fractures and non-fractures, XRAIT accurately identified fractures nearly seven of 10 times and correctly screened out patients without fractures more than 90% of the time.

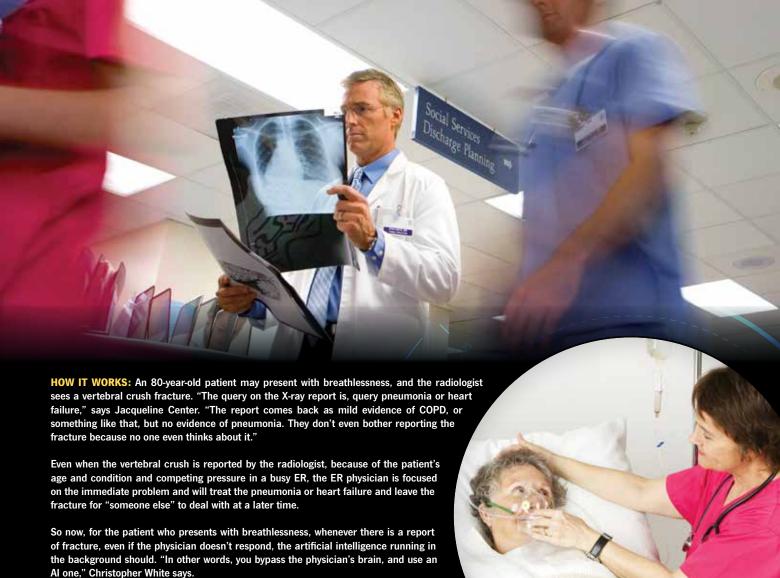
So now, for the patient who presents with breathlessness, whenever there is a report of fracture, even if the physician doesn't respond, the artificial intelligence running in the background should. "In other words, you bypass the physician's brain, and use an AI one," White says.

Almost Works Too Well

White and Center were supposed to present their findings at ENDO 2020 in San Francisco this past March, but the COVID-19 pandemic hit and threw everything into disarray. In the months since, White has continued using XRAIT at his hospital, and Center says that her team uses a similar tool. They both say that patients have been mostly impressed with the level of care they've received. "The people that we reached out to, who had their fracture treated, gone home, and then we've called them up, and said, 'Hey, your bones might be sort of at risk of having another fracture, let's assess you, and decide whether you need any treatment for underlying osteoporosis," Center says.

White tells Endocrine News that the program almost works too well; those who treat and study osteoporosis see the value in fracture liaison services, which up until now had been underutilized. "Now it's swamped by the massive numbers," White says, "about a fourfold increase in the number of patients that we're identifying, using AI."

"There is evidence that fracture liaison services result in decreased subsequent fractures," Center says "So as long as you're engaging more patients to take treatment, if they've got osteoporosis, you will decrease further fractures. There's evidence for that."



A Quality Improvement Project

White has a licensing agreement with Abbott Diagnostics, so anyone interested in implementing XRAIT in their local healthcare system can contact that company to get started. For now, XRAIT only "speaks" English, but other countries can develop their own natural language processing with help from biomedical engineers. From there, physicians will be able to identify more patients at risk for osteoporosis. "The long-term gain is that with adherence, provided there is that adherence to therapy, you should be seeing a decrease in fractures."

For White, this project is a quality improvement one. He points to medical problems that might get reported but not acted upon, like say, a shadow on the lungs. "Because if a fracture has been reported," he says, "and it was previously, and it's shown to be osteoporotic, you have actually haven't got a leg to stand on if you didn't respond to it."

6 The process of treating osteoporosis is **fractured**."

> - CHRISTOPHER WHITE, MBBS, PHD, FRACP, **ENDOCRINOLOGIST, PRINCE OF WALES** HOSPITAL, RANDWICK, AUSTRALIA

- BAGLEY IS THE SENIOR EDITOR OF ENDOCRINE NEWS. HE WROTE THE AUGUST COVER STORY ABOUT NEW RESEARCH THAT LINKS ENDOCRINE-DISRUPTING CHEMICALS TO CARDIOVASCULAR DISEASE.

LABORATORY NOTES

SPAC

As labs reopen around the world, researchers are finding new ways to collaborate while maintaining proper social distancing procedures. *Endocrine* News takes a look at some viable solutions when you go back to the bench.



he COVID-19 pandemic has turned work at research laboratories upside down across the globe. While initial lab shutdowns created panic and confusion on how to continue and preserve researchers' life work, lab reopenings have now led to a new set of challenges.

Some U.S. universities have started allowing researchers to resume oncampus work. However, principal investigators and facility managers must comply with COVID-19 safety guidelines that are crucial to limiting the risks of employees contracting and spreading the virus.

Wearing masks and maintaining good personal hygiene are two of the easiest guidelines lab employees are asked to follow. But maintaining a six-foot physical separation between individuals is more difficult.

BY GLENDA FAUNTLEROY SHAW

Everyone is back at the bench, however, things are different and what is unavoidably missing is the opportunity for quick discussions about an experiment or a project that usually occurs each day through unscheduled interactions in the lab."

> - DONALD MCDONNELL. PHD. GLAXO-WELLCOME PROFESSOR OF MCB AND CHAIR OF THE DEPARTMENT OF PHARMACOLOGY & CANCER BIOLOGY. DUKE UNIVERSITY, DURHAM, N.C.

So, what are the best ways researchers can create the minimum safe distance in their laboratories?

A Reopening Plan That Works

At Duke University School of Medicine, the lab of Donald McDonnell, PhD, is now fully operational after a March 19 shutdown.

"Everyone is back at the bench, however, things are different and what is unavoidably missing is the opportunity for quick discussions about an experiment or a project that usually occurs each day through unscheduled interactions in the lab," says McDonnell, the Glaxo-Wellcome Professor of MCB and chair of the Department of Pharmacology and Cancer Biology.

"The system the school put in place to manage activities and to help faculty, staff, and trainees weather the storm worked exceptionally well, and I was impressed at how everyone adapted to the 'new normal," he adds. "Operations ran in maintenance mode for approximately 10 weeks, and then a ramp-up plan was implemented that has allowed us to get our research up and running."

At Arizona State University, the reopening plan includes multiple communications to alert researchers to the most current campus COVID-19 guidelines.

"We have communicated via email, training, and other online methods," says David R. Gillum, senior director of Environmental Health and Safety at Arizona State University. "Our guidelines are posted on our website that is updated as new guidelines are proposed or changed by CDC and other authorities."

Gillum's office created a standard signage package with signs posted at building entrances, elevators, labs, and other campus spaces.

Researchers at Arizona State have raised the most concerns about how to manage social distancing challenges while working in a lab and that face coverings are "uncomfortable and make it difficult for them to concentrate," Gillum adds.

Increasing Distance

Since he is not physically involved in research, McDonnell says he was requested to limit his presence on campus to help keep density down. "Working from home has not been too disruptive, however, and I have had time to catch up on writing and submitted two new grant applications," he says.



This poster was created by the Environmental Health and Safety Department at Arizona State University and posted at building entrances, elevators, labs, and other campus spaces.

66 Researchers are working around the clock in shifts. Early birds are coming in really early, and the night owls are staying very late. All meetings are by Zoom, and quick chats are managed with Microsoft Teams."

- DONALD MCDONNELL. PHD. GLAXO-WELLCOME PROFESSOR OF MCB AND CHAIR OF THE DEPARTMENT OF PHARMACOLOGY AND CANCER BIOLOGY DUKE UNIVERSITY, DURHAM, N.C.

"Researchers are working around the clock in shifts," McDonnell continues. "Early birds are coming in really early, and the night owls are staying very late. All meetings are by Zoom, and quick chats are managed with Microsoft Teams." To increase the physical space between lab team members, safety officials at institutions offer many suggestions:

- **Work remotely when possible.** Perform non-lab work activities, such as computer or paperwork, at home if there are ongoing lab activities nearby.
- **Create shifts.** Have half the staff come in the morning and half in the afternoon. Or, have half the staff work from home on odd days and the other half on even days. Consider scheduling use of shared facilities and equipment.

Be smart. Do your part.

Follow these basic guidelines to help keep ASU a healthy place to live, learn and work. We are all in this together, Sun Devils.



Stay six feet apart.

Practice social distancing and stay at least six feet away from other people in public spaces



Wear a face cover.

Cover your nose and mouth, especially when social distancing cannot be maintained.



Wash your hands frequently.

Scrub with soap and water for 20 seconds or use an alcohol-based hand sanitizer



Obey occupancy rules on the elevator.

Maintain a four person maximum on the elevators



Stay home if you are sick.

Take care of yourself and contact your health provider or ASU Health Services for medical attention.



Go home if you get sick at work.

Leave the office immediately to avoid spreading illness. Cont act your supervisor for instructions on next steps.



Keep a clean workspace.

Declutter your desk and disinfect your workspace regularly to kill germs.



Work and visit with others remotely.

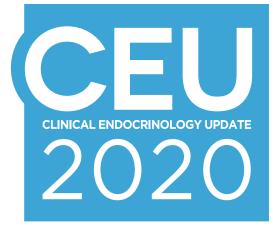
Avoid scheduling in-person gatherings or meetings and connect with people remotely whenever possible.



- Separate workstations by at least six feet. If this is not possible, use physical barriers, such as shields and curtains. If benches are back-to-back (with staff back to back), try closing down alternate workspaces on each bench to create a staggered workspace across all the lab benches in a zigzag pattern.
- Manage traffic flow. Labs that have more than one entrance can select one for entering and one entrance for exiting to establish a traffic flow pattern and reduce closeness of staff.
- Mark the floor. Use tape to identify six-feet separation on the floor for staff queuing up to use shared equipment.

- FAUNTLEROY SHAW IS A FREELANCE WRITER BASED IN CARMEL, IND. SHE IS A REGULAR CONTRIBUTOR TO ENDOCRINE NEWS.







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ADVOCACY



Latest Appropriations News: Deadline Looms to Pass Budget & Fund NIH

Endocrine Society Advocates for Increased funding for NIH, CDC

hile Congress has been wrestling with how to provide much-needed legislative relief during the COVID-19 pandemic, important deadlines for the fiscal year 2021 budget are also approaching quickly and the House of Representatives and Senate have not come to agreement on key funding decisions. Each year Congress must pass a series of appropriations bills to fund the federal government for the coming fiscal year, which begins October 1 and runs through the end of the following September. If Congress fails this task by the September 30 deadline, Congress can pass a short-term continuing resolution to fund the government at current levels for a period of time or the outcome is a partial or full government shutdown.

Every year, the Endocrine Society advocates for steady, sustainable increases in funding for our priorities. For fiscal year 2021, we requested at least \$44.7 billion for the National Institutes of Health (NIH) to support necessary advances in biomedical research to improve health; at least \$8.2 billion for the Centers for Disease Control and Prevention (CDC) to facilitate the translation of these advances to improve public health; and \$400 million for the Title X program to ensure that women have access to appropriate health services. While the

Take Action

Visit our online advocacy center at www.endocrine.org/ advocacy/take-action to join our campaign to urge Congress to complete the annual appropriations process and support increased funding for endocrine priorities.

NIH and CDC have seen additional emergency supplemental funding to address COVID-19-related priorities, it remains important to continue to advocate for increases to the base

If we have learned anything from our past efforts, it is that advocacy matters and that if the research community is vocal about its needs, we can ensure that increased federal funds for research are consistent and sustainable.

budget to ensure that other critical research and public health programs are able to continue to address other national priorities including chronic diseases and women's health.

Given the many competing demands for attention in an election year, we anticipate that the appropriations process will remain fluid right up to the September 30 deadline. We also expect that Congress will require at least a short-term continuing resolution to give them enough time to draft and pass a full complement of appropriations bills.

We have several upcoming opportunities for Endocrine Society members to advocate to support research and public health. As in previous years, the Society will be participating in the Rally for Medical Research on September 17, which will be a broad coalition of research, medical, and patient advocacy groups joining together to share the same advocacy message to Congress through virtual meetings with congressional offices. This year the meetings will take place via videoconference. If you are interested in joining the Rally, please contact advocacy@endocrine.org. We will also send an email alert to U.S. members to join our online advocacy campaign to send an email to your congressional delegation this September.

The Endocrine Society has had a history of successful advocacy for NIH funding by our members. Last year, we helped secure a \$2.6 billion increase for the NIH, continuing a trajectory of increases to the NIH budget. In previous years we also successfully pressured Congress to raise the budget spending caps that made these increases possible. We are proud of our victories and what they mean for the endocrine research community. If we have learned anything from our past efforts, it is that advocacy matters and that if the research community is vocal about its needs, we can ensure that increased federal funds for research are consistent and sustainable.

It is critically important, however, that members of Congress hear directly from you, their constituents, about the importance of funding biomedical research and public health programs. Continuing resolutions are an inefficient solution and introduce delays and uncertainty to the budget, which affects the ability of the NIH-funded researchers to apply for and receive grants. We all need to raise our voices to call on policy makers to stay focused, get the job done, and finish work on the appropriations bills.

Lack of Legislative Activity on Drug Pricing Results in Executive Action

The cost of prescription drugs has become an even more important issue for many Americans due to the COVID-19 pandemic. A recent study conducted by West Health and Gallup found that nine out of 10 people are concerned about rising drug costs as a result of the pandemic. The Endocrine Society has made prescription drug affordability an advocacy priority over the past several years. In particular, the Society has focused on this issue of the rising cost of insulin. However, the onset of the pandemic has forced Congress to re-shift its priorities in 2020 resulting in a lack of legislative action on this important issue.

Last year, Congress seemed poised to pass major legislation addressing high drug prices. In September, the U.S. Senate Finance Committee approved S. 2543, the Prescription Drug Pricing Reduction Act, which aims to lower drug costs for patients. In December, the House of Representatives passed H.R. 3, the Lower Drug Costs Now Act, which would give the Department of Health and Human Services (HHS) the ability to negotiate for lower prescription drug prices. However, since the pandemic, negotiations on drug pricing legislation have stalled because Congress has been focused on passing coronavirus relief legislation.

In the absence of legislation, the Trump administration has announced several executive orders in recent months to address high drug prices. Last month, the president signed four executive orders aimed at lowering drug prices. The first order signed by the president seeks to finalize a plan announced by the administration last year that would allow states to import certain drugs from Canada. The second



seeks to align the list price of drugs in the Medicare program to lower prices paid in other economically comparable countries. The third order would eliminate the rebate given to pharmacy benefit managers (PBMs) by drug manufacturers in the Medicare Part D program instead giving those rebates directly to Part D beneficiaries. The fourth order would require federally qualified health centers (FQHC) to pass the savings of insulin and epinephrine purchased through the 340b program directly to the patient. Many of the patients served by FQHCs are uninsured. Finally, the president signed another order in early August requiring certain essential medicines and medical supplies purchased by the federal government to be made in the U.S.

All of these orders are designed to lower prescription drug prices for millions of Americans. However, it is unlikely that any of them will actually be implemented. Executive orders do not carry the force of law and federal rulemaking needed to

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implement any policy changes. This process can take months to complete. Also, the orders could be challenged in court. Given this, legislative action is necessary to make substantial policy changes to lower the cost of prescription drugs. While it seems unlikely that Congress will advance comprehensive

46

The Endocrine Society will continue to advocate for lowering the cost of insulin and other prescription drugs.

drug pricing legislation before the November election, there is optimism that an agreement could be reached before the end of the year during the "lame duck" session or potentially in 2021 with a new administration.

The Endocrine Society will continue to advocate for lowering the cost of insulin and other prescription drugs. For the past three years, the Society has taken specific actions to lower the cost of insulin. In April 2019, Alvin Powers, MD, an Endocrine Society member, testified before the Energy and Commerce Oversight and Investigations Subcommittee at a hearing on insulin affordability. The Society has also called on Congress to eliminate patient co-pays for insulin during the public health emergency. We also recently updated our Insulin Affordability Position Statement (www.endocrine.org/advocacy/position-statements/ increasing-insulin-affordability), which details our work on this issue and recommendations for policy makers to lower the cost of this lifesaving drug. One notable recommendation calls for government negotiations to lower the cost of prescription drugs. We also provide an array of other recommendations such as lowering patient cost sharing, greater transparency throughout the insulin supply chain, and expedited approval of biosimilar insulins.

The Society will continue to update members on further developments as policy makers continue working to address this critical issue. For more information on the Society's advocacy on insulin pricing, please visit www.endocrine.org/insulin.

Medicare Proposed Physician Fee Schedule for 2021

n August 3, the Centers for Medicare and Medicaid Services (CMS) published the Calendar Year (CY) 2021 Proposed Rule for the Medicare Physician Fee Schedule (MPFS), which contains updates to the Quality Payment Program (QPP). The MPFS dictates Medicare rates and policies under Part B, while the QPP implements two value-based payment programs: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs).

Among the proposed changes, CMS has proposed to make permanent certain telehealth changes that have been implemented in response to the COVID-19 public health emergency (PHE), generally confirmed the evaluation and management (E/M) documentation guidelines and payment changes finalized in the 2020 MPFS, and proposed changes to the MIPS and APM participation options and requirements for 2021.

Of note, CMS has assessed the impact of the new coding for outpatient visits on various specialties. Endocrinology is estimated to come out the best of all specialties as a result of these new values with a projected 17% increase in reimbursement. However, the evaluation and management changes will be offset by a reduction in the conversion factor to maintain budget neutrality. Consequently, the potential gain for endocrinology will be partially offset by a reduction in the conversion factor. Other provisions of interest to endocrinology include proposed changes designed to increase the flexibility of the Diabetes Prevention Program, proposed values for implantable continuous glucose monitor codes, and a request for feedback on remote physiological monitoring codes.

The Endocrine Society is working with its Clinical Affairs Core Committee to assess the impact of the proposed changes and to develop comments on the proposed rule. For a comprehensive and detailed analysis of the proposed rule, please visit: www.endocrine.org/improving-practice/macra.

Comments on the proposed rule are due by October 5, 2020. Because of the PHE, CMS plans to implement the rule 30 days after it is finalized instead of the standard 60-day period. The Final Rule will likely be released in early December, providing little time for providers to adapt to changes before they take effect on January 1, 2021. We will keep members apprised of developments through the Endocrine Society website (www.endocrine. org) and through email alerts.



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FACT OR FICTION: PCOS MYTHS DEBUNKED

Polycystic Ovary Syndrome (PCOS) is the most common hormonal condition among women of reproductive age. Symptoms can include an increase of male hormone (androgen), excess hair growth on the face or body, acne, and weight gain or difficulty losing weight. The Hormone Health Network is here to debunk common misconceptions about PCOS!

MYTH 1

All Women with PCOS have Ovarian Cysts

Based on its name, many people think PCOS refers to cysts, but this is false. For many women, tiny follicles are present in the ovary and may resemble a "strand of pearls" on an ultrasound. The follicles may look like small cysts, but they are very different. These follicles aren't cancerous and do not cause pain. Not all women diagnosed with PCOS have follicles on their ovaries.

MYTH 2

Women Diagnosed with PCOS Can't Have Children

PCOS is a common cause of fertility problems for women, but that doesn't mean carrying a pregnancy to term is impossible. Many women with PCOS can conceive on their own or with the help of fertility treatments. Lifestyle changes and a healthier diet can also improve the chances of conceiving.

MYTH 3

An Irregular Menstrual Cycle Means You Have PCOS

PCOS is one cause of an irregular menstrual cycle, but there are so many other reasons! Typical cycles range between 21 to 35 days. Other factors such as stress, thyroid disorders or other endocrine conditions, fibroids, or extreme dieting can lead to an irregular cycle. If your cycle is irregular, speak to a doctor. Additional tests and exams will identify the cause.

MYTH 4

Women with PCOS Can't Lose Weight

Weight loss may be harder for women with PCOS, but it's not impossible. Many women with PCOS have a lowered sensitivity to insulin, a hormone that regulates sugar in the blood. This is known as insulin resistance, which is a risk factor for type 2 diabetes and may make it difficult to lose weight, even if you are following a healthy lifestyle. Working with a registered dietician and endocrinologist can also help with weight loss goals.

MYTH 5

All Women with PCOS Experiences Unwanted Hair Growth



Hirsutism is excessive growth of "male" pattern hair that may appear on a woman's face, back, chest, abdomen, or thighs. Hirsutism is usually an underlying sign of PCOS or another endocrine condition, but it's important to remember not every woman will have this symptom. Other factors, such as ethnicity, can increase the likelihood of a woman having excess hair growth.

REVIEWER

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