

JUNE 2020

THE LEADING MAGAZINE FOR ENDOCRINOLOGISTS

Endocrine news

INTERNATIONAL

From Bench to **BEDSIDE**

A Tale of Two Scientists

As the COVID-19 pandemic wreaks havoc around the world, many endocrine researchers have left their labs to care for these patients and help their clinician colleagues.

Endocrine News speaks to two endocrine scientists who put their own health at risk on the front lines of this global scourge.

BEST LAID PLANS:

Treating COVID-19 patients in a hospital setting

BACK TO THE BENCH:

How will research resume after labs start opening back up?

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Hormone Science to Health

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Advocacy Is Vital, Now More Than Ever

Many Endocrine Society members are familiar with the value of the Society's meeting and journals, but I want to stress the value of our advocacy, particularly during these difficult times.

The Endocrine Society has a robust advocacy program led by our Advocacy and Public Outreach Committee. The Society tackles some of the most difficult and pressing policy issues

“

Policy makers increasingly turn to the Society and our members as trusted advisors, and we are able to influence legislation and regulations that affect our members' professional lives. As the global community struggles with the effects of coronavirus, now is especially the time to raise our voices to share the value of science.

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such as: funding for biomedical research; access to care; diabetes and obesity; and regulation of endocrine-disrupting chemicals (EDCs). We advocate to U.S. policy makers and, in the case of EDCs, to European Union lawmakers as well.

The coronavirus pandemic has shuttered universities, businesses, restaurants, and recreation facilities across the

world. In Washington, D.C., the halls of Congress are closed; in Brussels, the EU Commission and Parliament are not open to the public. Yet, our advocacy efforts for our member researchers and physicians continue virtually. The Endocrine Society was one of the last groups in the U.S. Capitol before it closed in March — we brought researchers around the country to Washington to advocate during a Researcher Hill Day — and we were one of the first groups to implement a virtual Hill Day in April to advocate for provisions to be included in COVID-19 relief legislation.

During the spring, the Endocrine Society successfully advocated for expanded coverage for telehealth, additional funding for the Special Diabetes Program, and increased physician payment for audio-only visits — issues that really make a difference for our member clinicians, diabetes researchers, and patients. We continue to be a leading voice during the public health emergency advocating for adequate supplies of personal protective equipment (PPE), additional funding for the National Institutes of Health, and increasing the supply of diabetes test strips for patients.

Not related to the COVID-19 crises, during the past few months we have also advocated to provide access to affordable insulin, oppose anti-transgender legislation, support women's health research, and provide coverage of obesity treatment. Despite the pandemic closures, we have submitted congressional testimony to increase funding for the National Institutes of Health; submitted comments on new U.S. legislation to quicken access to cures; joined as an amicus to the U.S. Supreme Court case *California v. Texas* challenging the Affordable Care Act; participated in remote meetings with work groups of the Organization for Economic Cooperation and Development (OECD) to assist in the development of international approaches to regulating EDCs; and commented on Europe's Chemical Strategy for Sustainability and its Beating Cancer Plan.

Policy makers increasingly turn to the Society and our members as trusted advisors, and we are able to influence legislation and regulations that affect our members' professional lives. As the global community struggles with the effects of coronavirus, now is especially the time to raise our voices to share the value of science.

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Stand up, and be heard.
It takes all of us to make a difference.
Communicate to Educate.
Participate to Advocate.

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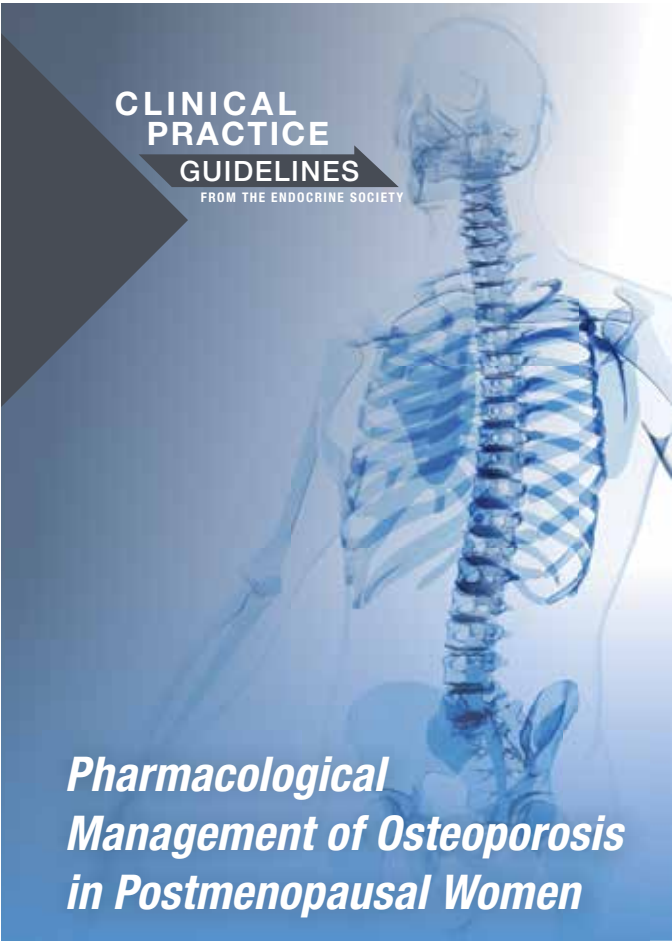
Stand up, and be heard. It takes all of us to make a difference.
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I urge you to join me in these efforts:

- ▶ Visit endocrine.org/advocacy for more information about our issues and activities.
- ▶ Contact advocacy@endocrine.org to find out how you can participate in upcoming virtual advocacy visits and activities.
- ▶ Go to endocrine.org/takeaction to join our current online advocacy campaigns.

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

Gary D. Hammer, MD, PhD
President, Endocrine Society



CLINICAL PRACTICE GUIDELINES

FROM THE ENDOCRINE SOCIETY

Pharmacological Management of Osteoporosis in Postmenopausal Women

A STANDARD FOR CARE UPDATE

Improve patient care with our new guideline update which recommends romosozumab under selective criteria as another pharmacological therapy to prevent osteoporosis and reduce fracture risk in postmenopausal women.

**READ THE GUIDELINE UPDATE AT
[ENDOCRINE.ORG/2020OSTEOPOROSIS](https://endocrine.org/2020osteoporosis)**

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FROM THE **EDITOR**

JUNE 2020

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Endocrine News informs and engages the global endocrine community by delivering timely, accurate, and trusted content covering the practice, research, and profession of endocrinology.

An Enormous Privilege

As the COVID-19 pandemic rages on, *Endocrine News* is devoted to providing you with the must up-to-date content from the world of research that we can get our hands on, as well as the stories from your colleagues about how their everyday lives have changed.

Two Endocrine Society members' lives that have changed significantly are those of Domenico Trico, MD, at the University of Pisa in Italy, and M. Furkan Burak, MD, at Brigham and Women's Hospital in Boston, Mass., two clinician scientists who were summoned from benches to bedsides to help treat COVID-19 patients, whom I interviewed for "Research Interrupted: Scientists Are Heeding the Call to Treat COVID-19 Patients" on page 32. Both were recipients of the Endocrine Society's 2020 Early Investigator Awards, featured in the May issue, and that's where I learned about their calls to action. I knew their stories would be important to *Endocrine News* readers.

"As someone who has dedicated most of his training in doing research, I was enthusiastic to serve the cause, but afraid of my limited clinical experience," Trico told me. "However, my fellow researchers and I were assigned to newly created hospital units where we received training and fundamental support by expert clinicians. After a few weeks of sharing this experience, we have all become a big family."

Speaking of scientists, Glenda Fauntleroy Shaw has provided an in-depth look at the steps researchers can take when it's time to reopen their laboratories in "Benched: Resuming Research After COVID-19" on page 46. One of her sources is Vivian Fonseca, MD, at Tulane University Health Sciences Center in New Orleans, La., who had plenty of experience reopening a shuttered lab; when Hurricane Katrina hit in 2005, he was doing clinical research in his small lab at Tulane as well as participating in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial — a multicenter National Institutes of Health (NIH) study involving 10,251 participants with type 2 diabetes. Fonseca's story is truly inspirational, and, as he says, "The most important thing is having the resilience to carry on and do the best you can. These are very important lessons for everybody in this crisis."

At the end of April, the first of a series of articles was published in the *New England Journal of Medicine* that contained recommendations for treating COVID-19 patients in a hospital setting. The authors are a group



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of healthcare professionals who actually came together as a group on WhatsApp when they reached out to one another to get advice and share their own information. Senior editor Derek Bagley spoke to one of the authors of these papers, Ricardo Correa, MD, from the University of Arizona College of Medicine in Phoenix, about the group's recommendations for best practices in "Best Laid Plans: Managing COVID-19 in Hospital Settings" on page 66.


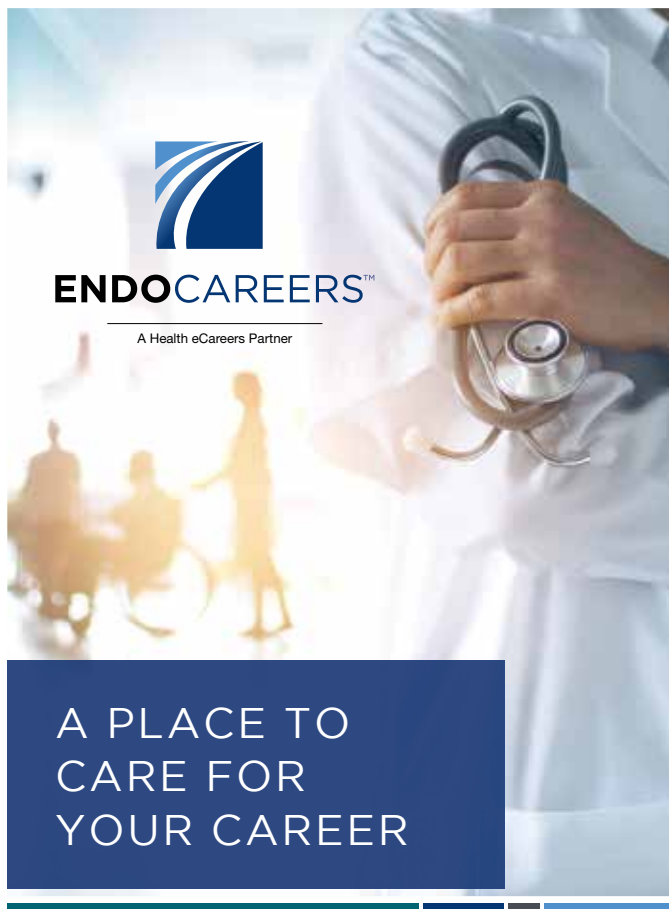
As many clinicians have learned firsthand during this pandemic, social distancing protocols can add yet another obstacle in treating many of their patients. The Endocrine Society is one of five bone health organizations that have joined together to collectively release a new set of guidelines for treating osteoporosis patients in the age of COVID-19. Endocrine Society member and incoming president of the American Society for Bone and Mineral Research (ASBMR), Suzanne Jan De Beur, MD, gave me some insight about these guidelines in "Osteoporosis & COVID-19: An Alliance Provides Guidance" on page 62.

More than likely, by the time you receive this issue of *Endocrine News*, **ENDO Online 2020** will be well under way. No doubt, you will be joining more than 18,000 of your endocrinology colleagues from around the world to check out the latest developments in endocrine science and treatment ... for FREE! And just in case you need to be further enticed, on page 42 we have provided a preview of one of the sessions as part of the "Barriers to Care" program entitled "Fair Trials" that details how a lack of representation in clinical trials could lead to inaccurate data for all patient populations. So if you haven't registered yet, there's still time; go to: www.endocrine.org/endoonline2020.

As we continue through this healthcare crisis together, rest assured that *Endocrine News* is prepared to provide you with important information as well as compelling stories from your colleagues around the world. The spirit of the endocrinology community is no better represented than in the words of Furkan Burak in the cover story: "When you look into [COVID-19 patients'] eyes, you see the fear and they are alone without any loved ones around. We, frontline workers, are the only ones who can relieve that fear and anxiety. I feel like that is an enormous privilege."

If you have stories you would like to share with *Endocrine News* about your experiences or even helpful ideas in dealing with the COVID-19 crisis, please feel free to email me at: mnewman@endocrine.org. Until next time, stay healthy and safe! 

— Mark A. Newman, Editor, *Endocrine News*



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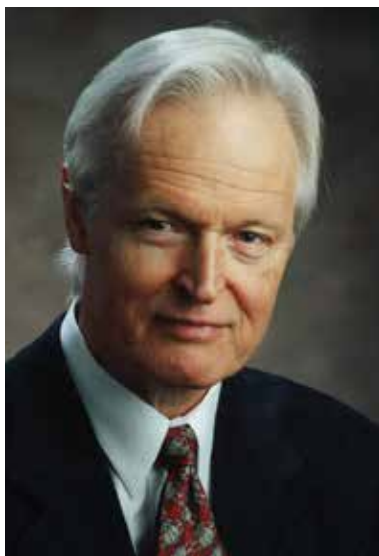
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ENDO International Travel Award Honors C. Wayne Bardin's Legacy



To pay tribute to C. Wayne Bardin, MD, and honor his legacy, the Endocrine Society is now raising money for an endowment fund to support an annual international travel award.

The C. Wayne Bardin, MD, International Travel Award has been created for young, outstanding endocrinologists to attend the annual meeting of the Endocrine Society. This award honors Bardin's longstanding interactions with endocrinologists around the world and his interest in recognizing and nurturing young researchers.

Bardin passed away in New York City on October 10, 2019, at the age of 85. During his scientific career, he contributed enormously to women's reproductive health by developing novel and effective contraceptive methods particularly applicable for use in underdeveloped countries. His key attributes included a passion to help provide reproductive services and training in underdeveloped countries as well as mentoring numerous trainees.

Bardin was strongly committed to serving the Endocrine Society and for many years contributed his efforts with a high level of enthusiasm. Highlighted leadership roles include: director of the Clinical Endocrinology Update Course for many years, membership on the Endocrine Society Council, and president of the Endocrine Society (1993 – 94).

Candidates for the travel award will be chosen based on the quality of his/her **ENDO** research potential. The grant will cover up to \$3,000 in travel, hotel, and per-diem costs for the annual meeting. The Endocrine Society will also waive the registration fee for the awardees. We encourage our membership to make donations for this worthy cause to the "In Memory of C. Wayne Bardin Fund" available on our website. Through private donations made prior to this announcement to the general membership, 40% of the total amount (\$100,000) needed to fund a named award in the Endocrine Society has already been received.

To contribute to this award, please donate to the "In Memory of C. Wayne Bardin Fund" at: www.endocrine.org/donation. Information on the award can be found at: www.endocrine.org/bardinaward.

Details on how to donate as well as Bardin's obituary published earlier in *The Journal of Clinical Endocrinology & Metabolism* and *Endocrine News*, and the Travel Award Plan, are also available on the website listed above. – Colleen Williams

New Online Communities Foster Connections, Knowledge Sharing Among Society Members

The Endocrine Society's new Special Interest Groups (SIGs) are member-led communities created to facilitate online interactions and in-person networking opportunities at Society meetings.

SIGs can be topic focused, based on career level, or other areas of interest to members. The inaugural SIGs were chosen by strong member interest and represent the broad scope of the Society. They are: Adrenal and Pituitary, Early Career, Entrepreneurship, and Transgender Research and Medicine.

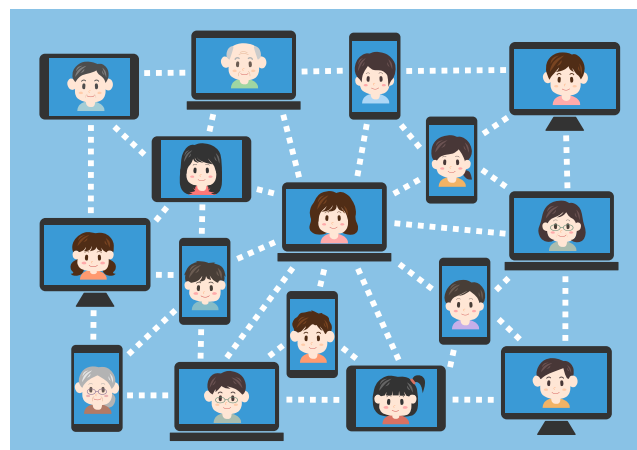
"The SIGs provide a direct opportunity for member-initiated activity focused on key areas of endocrinology that are timely and impactful. They were developed to meet member needs, enable networking through an online community platform, and to provide opportunities for leadership and other aspects of career development, meeting programming, and advocacy," explains Steve Rosenthal, MD, co-chair of the task force that launched these communities. "The SIGs are designed to be valuable for members at all stages of their careers."

The Transgender SIG has been off to a quick start, setting advocacy as a key priority and educating physicians and researchers on recent advances in care through new online courses and Transitions of Care documents. The work of the Transgender SIG is especially important during Pride month when many organizations are advocating and raising awareness around access to care for these individuals.

"The Transgender Research and Medicine Special Interest Group brings together both national and international providers who have an interest in healthcare for transgender and gender diverse people. Our goal is to collaborate with healthcare workers in the fields of research and clinical practice and to provide opportunities for member and trainee education," says Caroline Davidge-Pitts, MBBCH, co-chair of the group.


"In addition, we strive to become a trusted resource for patients and their families through close collaboration with the Hormone Health Network and beyond," adds Sean Iwamoto, MD, the other co-chair of the Transgender SIG.

The other three Special Interest Groups have also been hard at work. The Early Career SIG is currently hosting webinars on negotiation and communication skills, and the Entrepreneurship SIG is surveying entrepreneurs from different backgrounds on a variety of topics to pursue. The Adrenal and Pituitary SIG just started a session titled "The Paper that Changed my Practice," which members can access in the online community.



"The SIGs allow members to engage with the Endocrine Society year-round. They provide an opportunity to meet members not only once a year during the **ENDO** meeting, but continuously through an online community platform. This can lead to new opportunities for collaboration, teaching, and mentoring," says Jenny Visser, PhD, another co-chair of the task force behind this initiative.

For a quick tutorial of the platform, check out endocrine.org/our-community/special-interest-groups and explore the different ways to engage with your colleagues including sharing and commenting on resources, posting videos, uploading articles, and participating in discussion boards.

Visit community.endocrine.org today, and log in with your Endocrine Society credentials to get started. – Colleen Williams 



BY DEREK BAGLEY
Senior Editor

New App Helps Improve Diabetes Care in Patients with COVID-19



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We observed changes in protocols, ways people are trying to be creative to care for patients and to protect our nurses and the community. So ... we decided to target this as our first effort and see where it would take us.

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Last month, *Endocrine News* ran a feature about the need for optimal glycemic control in patients hospitalized with COVID-19, which could require physicians treating these patients to take different approaches than usual. Now, an international group of healthcare experts have developed an app to help the providers on the front lines of caring for patients with diabetes who have been hospitalized with the novel coronavirus.

The app, called COVID-IN-DIABETES (Collaborative Open-Access Virtually Individualized Decision-Algorithms for Inpatient Diabetes — covidindiabetes.org) was developed with the goal of achieving glycemic control with a community-centered perspective, which means caring for patients while preserving personal protection equipment (PPE) and decreasing the spread of COVID-19. (The project is partially supported by the National Institute of Diabetes and Digestive and Kidney Diseases, grant number P30-DK-111024.)

Francisco J. Pasquel, MD, MPH, assistant professor of medicine in the Division of Endocrinology at Emory University in Atlanta, Ga., who developed the app and serves as its content editor, says that he and his colleagues had actually already been working on a project with the goal of individualizing therapy in the hospital, with recent experience they have gained in the inpatient setting and through knowledge gained through observational studies and clinical trials. “With COVID-19 there was actually an immediate need to learn how people were transforming care in the inpatient setting,” Pasquel says. “We observed changes in protocols, ways people are trying to be creative to care for patients and to protect our nurses and the community. So, along with Javier Szyzlican (developer) and Agustina Urrutia (post-doc fellow) we decided to target this as our first effort and see where it would take us.”

The site will have two main areas — Hospital Care and Diabetes Technology — and Pasquel and his team are still adapting this site to what they think people who use it might be interested in. Each section will have a repository to share protocols along with other experiences and knowledge, relevant literature, and a “news section.” “This initiative also represents our ‘response and mitigation’ efforts in a broader concept we are working on, which consists on adapting the Preparedness Cycle framework to understand transformations in diabetes care during the COVID-19 pandemic,” Pasquel says.

An upcoming section will focus on telemedicine, as the pandemic has forced many physicians to stop seeing patients in the clinic and adopt new technologies. “We are collecting several different experiences about the potential benefits of telemedicine and the gaps and barriers for optimal implementation,” Pasquel says. “I hope we can stimulate those discussions.”

Since releasing the app, Pasquel says they have received lots of feedback and interest from many investigators and physicians caring for patients with diabetes and COVID-19 in the U.S. and around the world. David Klonoff, MD, medical director of the Diabetes Research Institute at Mills-Peninsula Medical Center in San Mateo, Calif., and editor-in-chief of *Journal of Diabetes Science and Technology*, recently signed on as the project’s co-editor to help with the content.

“[We’ve received] recommendations about including sections that may be of interest, suggestions on the most relevant topics, and opportunities/ideas for collaborations,” Pasquel says. “We are very excited about other colleagues joining so we can hopefully have a place where it will be easy to access relevant information related to the transformations in care related to the interaction of diabetes, COVID-19, and advances in technology.”

FDA Approves Leuprolide Acetate for Injectable Suspension for Pediatric Patients with Central Precocious Puberty

The U.S. Food and Drug Administration (FDA) last month approved leuprolide acetate for injectable suspension for the treatment of pediatric patients two years of age and older with central precocious puberty (CPP). Tolmar Pharmaceuticals is marketing the drug as Fensolvi.

Leuprolide acetate is the most widely used treatment for CPP. Fensolvi utilizes a proprietary polymeric gel technology that forms an in-situ solid after injection and releases leuprolide acetate in a sustained and controlled manner over time. This technology enables a small volume of injection of only 0.375mL, subcutaneous administration, and a six-month dosing cycle.

FDA approval was based on results from a multicenter, open-label, single-arm Phase 3 study evaluating the efficacy, safety, and pharmacokinetics of leuprolide acetate (LA) 45 mg for injectable suspension in 64 children with central (gonadotropin-dependent) precocious puberty. The study achieved its primary endpoint, with 87% of children achieving a serum luteinizing hormone

concentration of <4 IU/L at six months post injection. The study also demonstrated that Fensolvi suppressed sex hormones to pre-pubertal levels and stopped or reversed the progression of clinical signs of puberty.

“Children with CPP require treatment for several years, and missing treatment or stopping treatment too soon may lead to significant short stature and misalignment between chronological age and physical and emotional development,” says Karen Klein, MD, associate clinical professor at the University of California, San Diego. “Fensolvi offers treating physicians and their patients with CPP a safe and effective treatment option that is administered twice a year with a small injection volume that has the potential to improve compliance.”

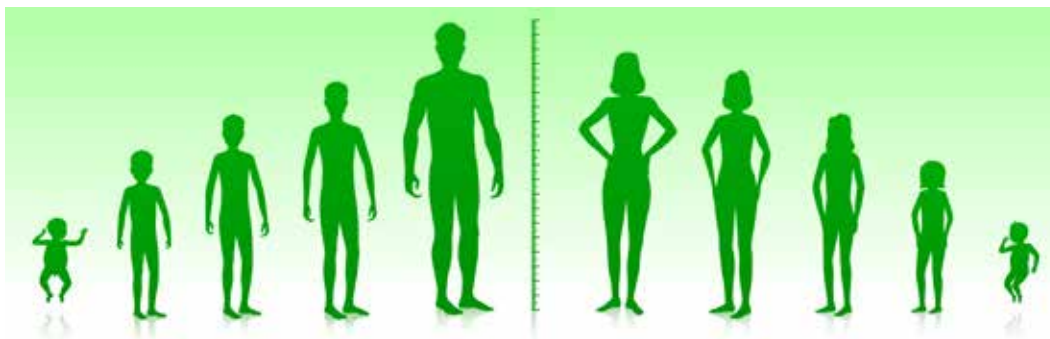
Treatment emergent adverse events (TEAEs) were mostly mild or moderate, with none leading to withdrawal from the study. The most common TEAEs were injection site pain (31%), nasopharyngitis (22%), and fever (17%).



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Children with CPP require treatment for several years, and missing treatment or stopping treatment too soon may lead to significant short stature and misalignment between chronological age and physical and emotional development.

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These results do not support the sweet uncoupling hypothesis. Rather, they suggest that sucralose consumption alters the metabolism of simultaneously consumed glucose to rapidly produce deleterious effects on metabolic health.

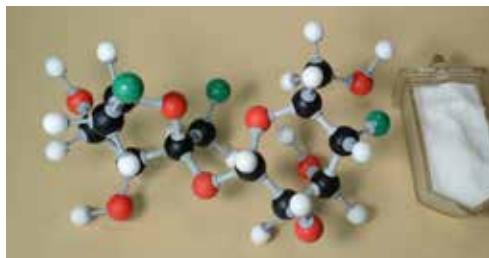
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Consuming Sucralose with Carbohydrates May Impair Insulin Sensitivity, Study Finds

Consuming sucralose-sweetened beverages with carbohydrates may impair insulin sensitivity, according to a study recently published in *Cell Metabolism*.

Researchers led by Dana M. Small, PhD, director of the Modern Diet and Physiology Research Center at Yale University in New Haven, Conn., point out that there is still significant controversy surrounding the effects of no- or low-calorie sweeteners (LCSs) on human health. These sweeteners have been positively associated with weight gain and weight loss, with diabetes, and with lower BMI, or they've been found to be unrelated to metabolic health. "A similar inconsistency exists in the animal literature, with three recent reviews reaching three different and mutually exclusive conclusions. Given the growing use of LCSs, especially in relation to the obesity and diabetes pandemics, it is of pressing importance to resolve the controversy surrounding LCS consumption," the authors write.

Small and her team write that several mechanisms have been proposed to resolve this controversy, including uncoupling sweet taste from energy receipt, which could lead to weakening conditioned responses to sweet taste. "Support for this uncoupling hypothesis comes from a series of studies in rodents reporting weight gain or glucose intolerance in rats consuming yogurts sweetened inconsistently with sucrose and LCSs compared to rats consuming yogurts consistently sweetened with only sucrose," the authors write.



For this study, the researchers wanted to test the sweet uncoupling hypothesis in humans. They enrolled 45 participants ages 20 – 45 years who don't typically consume LCSs and had them consume seven 355 mL of novel-flavored beverages over two weeks. The sweeteners were consumed as fruit-flavored beverages with added sucralose, with table sugar, or with maltodextrin added to their sucralose drinks as a control group. (The researchers chose maltodextrin, a non-sweet carbohydrate, to control for the calories of sugar without adding more sweet taste to the beverage.) The investigators conducted studies on the participants before, during, and after the testing period, including performing fMRI scans to look at changes in the brain in response to sweet tastes, as well as other tastes like salty and sour. They also measured taste perception and did an oral glucose tolerance test to look at insulin sensitivity.

Surprisingly, it was this control group that showed changes in the brain's response to sweet taste and the body's insulin sensitivity and glucose metabolism. Small and her team then added a second control group, in which the participants drank beverages with maltodextrin alone. They found no evidence that consuming maltodextrin-containing beverages over the seven-day period alters insulin sensitivity and glucose metabolism.

Findings: "These results do not support the sweet uncoupling hypothesis," the authors write. "Rather, they suggest that sucralose consumption alters the metabolism of simultaneously consumed glucose to rapidly produce deleterious effects on metabolic health. Since the extent of this exposure is very likely experienced in a natural setting, our results provide evidence that LCS consumption contributes to the rise in the incidence of impaired glucose tolerance."

New Research Explores Blueberries' Positive Effects in Men with Type 2 Diabetes

Intake of the equivalent of one U.S. cup of fresh blueberries (given as 22 g freeze-dried blueberries) resulted in clinically significant improvements in measurable indicators of type 2 diabetes — Hemoglobin A1c (HbA1c) and fructosamine — compared to a placebo, according to a study recently published in *Current Developments in Nutrition*. The study was conducted at the Stratton Veterans Affairs (VA) Medical Center in Albany, N.Y.

Researchers led by Kim Stote, PhD, MPH, RDN, who has a research appointment at the Albany Stratton VA Medical Center, point out that blueberries are dietary sources of polyphenols, specifically anthocyanins, which have been shown to reduce type 2 diabetes risk. However, human clinical trials evaluating blueberries' effects on patients with type 2 diabetes have been limited.

“To date few human clinical trials have evaluated the potential beneficial health effects of blueberries in populations with type 2 diabetes,” Stote says. “While the results cannot be generalized to all populations, they speak to the evidence that a dietary intervention with a realistic serving of blueberries may be an effective strategy to improve metabolic factors associated with type 2 diabetes.”

Over an eight-week period, researchers studied 52 overweight male participants between the ages of 51 and 75 who had a medical diagnosis of type 2 diabetes for at least six months as indicated by HbA1c > 6.5 and < 9 and BMI > 25 kg/m². During the study, non-insulin diabetes medications were prescribed to 100% of the participants. Other inclusion criteria for subjects included no insulin use and no heavy exercise.


Participants were randomly assigned one of two interventions: either 1) 22 g of freeze-dried blueberries (the equivalent of one U.S. cup/d fresh

blueberries) along with their regular diet or 2) 22 g of a placebo powder (matched in energy and carbohydrate content to the freeze-dried blueberries) along with their regular diet. Of note, fiber was not controlled in the study, which is known to influence glycemic response.

Fasting plasma glucose and serum insulin were not significantly different after eight weeks of consumption of freeze-dried blueberries, compared with placebo. Total cholesterol, LDL cholesterol, HDL cholesterol, CRP concentrations, blood pressure and body weight were not significantly different after eight weeks of consumption of freeze-dried blueberries, compared with the placebo.

The results also showed significantly decreased levels of serum triglycerides after blueberry consumption compared to placebo. Left untreated or uncontrolled, elevated blood triglyceride levels may increase the risk of serious complications such as cardiovascular disease — the leading cause of morbidity and mortality for individuals with diabetes.

“In conclusion,” the authors write, “the daily consumption of 22 g freeze-dried blueberries (equivalent to 1 cup fresh blueberries) may beneficially affect cardiometabolic health parameters in men with type 2 diabetes. Additional research is needed to determine whether polyphenol-rich foods reduce ASCVD by modifying glycemic control and dyslipidemia in those with type 2 diabetes without or with NAFLD.”

The research was funded by the U.S. Highbush Blueberry Council (USHBC). The USHBC had no role in study design, data collection, data analysis, data interpretation, or writing of the study. 



“

While the results cannot be generalized to all populations, they speak to the evidence that a dietary intervention with a realistic serving of blueberries may be an effective strategy to improve metabolic factors associated with type 2 diabetes.

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ENDOOnline2020

ENDO Online 2020

June 8 – 22, 2020

The Endocrine Society will host its largest-ever online meeting in June to ensure endocrine researchers and clinicians continue to have access to the latest scientific information, despite the COVID-19 pandemic. **ENDO Online 2020** will feature a mixture of on-demand and live programming for both clinical and research audiences.

Sessions will address a wide-ranging variety of endocrine topics. There will be both clinical and basic science content, as well as professional development sessions.

www.endocrine.org/ENDOOnline2020



ENDORSED BY



American Diabetes Association's 80th Scientific Sessions: A Virtual Experience

June 12 – 16, 2020

The Scientific Sessions offers researchers and healthcare professionals an opportunity to share ideas and learn about the significant advances in diabetes research, treatment, and care. Experience major lectures, symposia, Interest Group discussions, oral abstract presentations, ePosters, and a virtual exhibit hall. Receive continuing education credits for physicians, international physicians, physician

assistants, nurses, pharmacists, dietitians, and certified diabetes care and education specialists.

professional.diabetes.org/scientific-sessions

Nonalcoholic Fatty Liver Disease (NAFLD): Mechanisms and Novel Therapeutics - Virtual Event

June 30, 2020, 8 AM - 6 PM

The Nutrition Obesity Research Center at Harvard's 21st Annual Symposium presents Nonalcoholic Fatty Liver Disease (NAFLD): Mechanisms and Novel Therapeutics.

This educational all-day event will feature internationally recognized speakers addressing the topic of NAFLD and the genetics behind the disease, the global and clinical burden, and mechanisms and novel therapeutics for NAFLD. Registration is free of charge and required for access to livestream link.

www.norch.org

Heart in Diabetes

New York, New York

August 7 – 9 2020

This CME conference is a unique medical meeting that brings clinical leaders in

Before you make any travel plans, check with the sponsoring organization to make sure the events are taking place as scheduled.

diabetes and cardiovascular disease and practicing clinicians together to improve the care of patients at a high risk of cardiovascular, metabolic, and kidney diseases. This program is designed to evaluate the clinical science aspects of diabetes, obesity, and cardiovascular disease, focusing on the heart and kidney in diabetes. The goal is to develop appropriate, comprehensive clinical management plans aligning endocrinologists, cardiologists, nephrologists, and all other interested clinicians in their understandings of the impact of diabetes and CVD outcome trials on the clinical management of these very high-risk patients.

www.heartindiabetes.com

Obesity Week 2020

Atlanta, Georgia

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 ObesityWeek. 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



INTERNATIONAL ITINERARY

Endocrine Congress of Sri Lanka College of Endocrinologists (VIRTUA SLENDO 2020)

August 6 – 8, 2020

Virtual Event

The goal of SLENDO 2020 is to update and enhance endocrine knowledge among endocrinologists, physicians, trainees, and primary care doctors, both locally and internationally. SLENDO2020 will feature the participation of more than 50 eminent speakers from Europe, U.S., Canada, Australia, and New Zealand along with outstanding regional endocrinologists from South Asia. Deadline for abstracts: June 15, 2020.

<https://slendo.lk/>

ICE 2020: 19th International Congress of Endocrinology

Buenos Aires, Argentina

October 4 – 7, 2020

19th International Congress of Endocrinology (ICE 2020), 4th Latin American Congress of Endocrinology (CONLAEN) and 13th Congress of the Argentine Federation of Endocrinology Societies (FASSEN) 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 middle-income countries; preserving reproduction in cancer patients; and so much much more.

www.ice-2020.com

EndoBridge 2020

Antalya, Turkey

October 22 – 25, 2020

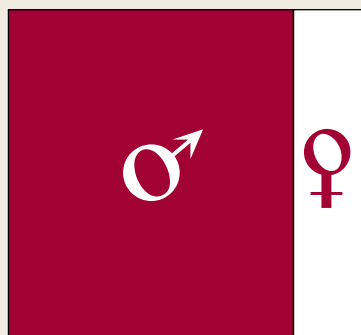
EndoBridge® is a unique initiative with the vision of bridging the world of endocrinology. EndoBridge® is co-hosted by the Endocrine Society and the European Society of Endocrinology in collaboration with the Society of Endocrinology and Metabolism of Turkey. The meetings are held in English with simultaneous 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

20
YEARS

Over the past 20 years, the rate of heart attacks, strokes, and other medical emergencies improved among people with diabetes, narrowing the gap in cardiovascular mortality rates between individuals with and without diabetes.

—SOURCE: THE JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM



80%—men
20%—women

Research suggests COVID-19 symptom severity may be due to the protective actions of estrogen in women, with intubation rates and death around 80% in men compared to 20% among women.

—SOURCE: HEALIO

New Patient Resources:

The FDA's updated Nutrition Facts label on packaged foods and drinks is the first major update in over 20 years. The goal of this update is to make it easier to make

informed food choices that contribute to healthy eating habits, a critical step in the management of diabetes.

Nutrition Facts	
8 servings per container	
Serving size 2/3 cup (55g)	
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	16%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

Calories are now displayed in larger, bolder font.

Daily values have been updated.

Added sugars, vitamin D, and potassium are now listed. Manufacturers must declare the amount in addition to percent of daily values.

—SOURCE: CDC DIABETES

MEMBER SPOTLIGHT



Christopher McCartney, MD

Christopher (Chris) McCartney, MD, has served the Endocrine Society in many capacities including Clinical Guidelines Committee Chair, APDEM President, and other leadership roles. He attended medical school

and completed his internal medicine training at the University of Mississippi School of Medicine. In 1999, McCartney began his career at the University of Virginia in Charlottesville, Va., first as an endocrinology fellow and then staying on as a faculty member.

McCartney previously served as a member of the Annual Meeting Steering Committee. In 2018, he was named as chair of the Clinical Guidelines Subcommittee, and under his leadership the Subcommittee was recently established as a full committee by the board of directors.

A champion for the Society's guidelines, McCartney is passionate about improving our guideline development methodology as well as about making guideline content more accessible to readers around the world. He has led a variety of improvements to our process, including more rigorous guideline reviews, improved formatting, and the implementation of national and international best practices in guideline production.

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

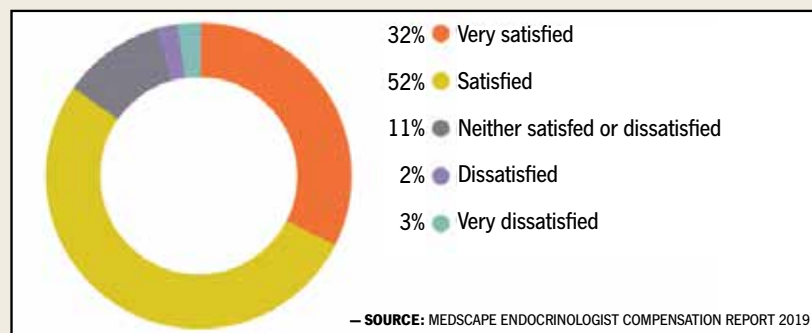
www.endocrine.org/member-spotlight

1/2

Almost half of patients with diabetes don't meet their related goals, including A1C blood glucose levels, blood pressure, and LDL cholesterol levels.

—SOURCE: NEW ENGLAND JOURNAL OF MEDICINE

How Satisfied Are Endocrinologists With Their Own Job Performance?



\$1,700

The average savings for patients using telehealth.

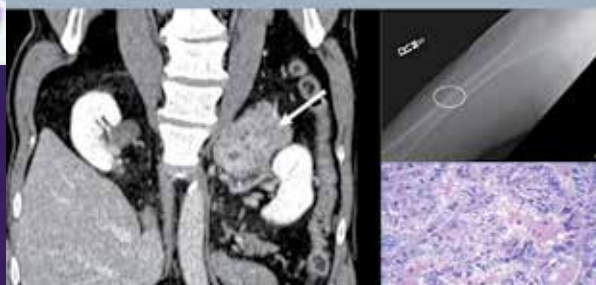
—SOURCE: JOURNAL OF MEDICAL INTERNET RESEARCH



"The Computer has a virus. Ironical, isn't it?"

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– Beth Cohen, MD

"Overall, nice diversity of endocrinology topics with isolation of
some problem issues in managing patients and their diseases"
– Lori Roust, MD

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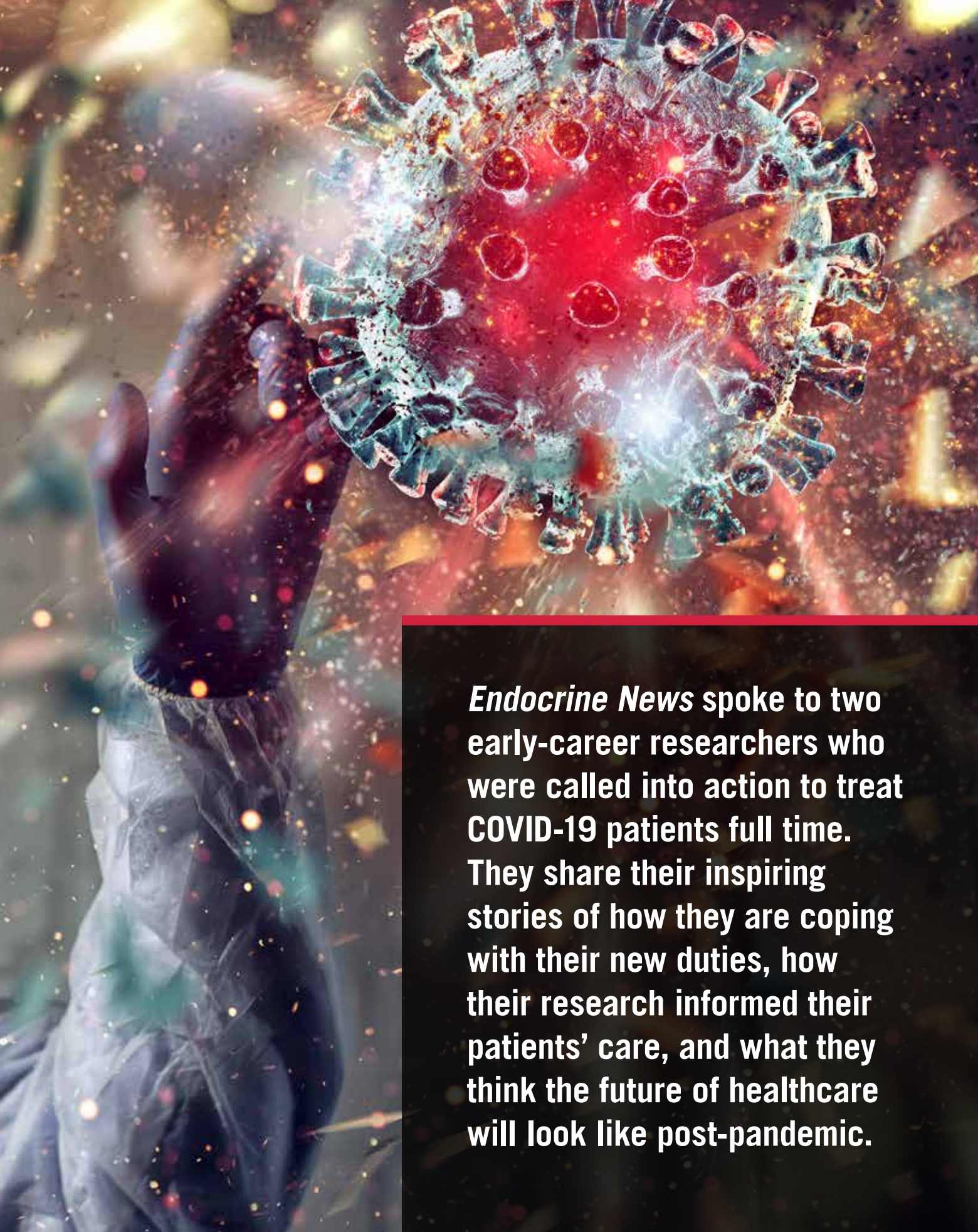
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Research **INTERRUPTED:**

BY MARK A. NEWMAN

**Scientists Are Heeding
the Call to Treat
COVID-19 Patients**



***Endocrine News* spoke to two early-career researchers who were called into action to treat COVID-19 patients full time. They share their inspiring stories of how they are coping with their new duties, how their research informed their patients' care, and what they think the future of healthcare will look like post-pandemic.**



M. Furkan Burak, MD, postdoctoral research fellow, the Sabri Ülker Center for Nutrient, Genetic, and Metabolic Research, Harvard T.H. Chan School of Public Health; Brigham and Women's Hospital; Harvard Medical School, Boston, Mass.

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Currently, we are writing a grant to study details of this relationship and specifically address targeting metabolism of immune cells for treatment of COVID-19 infection.

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Endocrine scientists routinely spend their days at the bench working to uncover the mysteries that seem to confound much of the healthcare world. Unlocking these mysteries has proven to be the key to improving human health in myriad ways. Seldom does a day in the endocrinology research lab go to waste as remarkable new discoveries evolve to change the way patients are treated around the world.

However, one thing that many researchers cannot change is the impact that the COVID-19 pandemic is having on their labs. As the virus began to spread, research labs around the world shut down, samples were stored, data was saved, and many scientists left their darkened labs not knowing when they would be able to return to their research.

But some scientists have found themselves squarely on the front lines of this pandemic, called into action to treat COVID-19 patients. *Endocrine News* readers learned about a couple of these scientists who left their research to treat patients in the article, “Laboratory Leaders: Talking to the 2020 Early Investigator Award Winners” by Glenda Fauntleroy Shaw in the May issue.

When asked about the effects of the pandemic on their research, all the researchers lamented the shutdown of their projects, but two added that they were now treating COVID-19 patients, suddenly thrust into new, daunting roles but eager to rise to the challenge. Domenico Trico, MD, at the University of Pisa in Italy, and M. Furkan Burak, MD, of Brigham and Women's Hospital in Boston, Mass., have put their research on hold to treat patients and come to the aid of their fellow physicians.



Domenico Trico, MD, assistant professor of internal medicine, University of Pisa, Pisa, Italy

“

Most COVID-19 patients requiring hospitalization are obese and have pre-existing medical conditions, including type 2 diabetes. In these patients, ... the COVID-19 infection can be harder to treat.

”

Leaving the Lab

Trico, currently in his first year as an assistant professor of internal medicine at the University of Pisa and a PhD candidate at the Sant'Anna School of Pisa, is a clinical scientist with a longstanding interest in diabetes and nutrition. His primary research focus is evaluating the effects of macronutrients on beta cell function and dissecting their potential pathogenetic role in type 2 diabetes development and progression in both adults and children.

At the time he started treating COVID-19 patients, he was involved in four ongoing clinical studies focusing on the effects of nutrient timing and circulating lipids on beta cell function and overall glucose homeostasis. Trico was also an attending physician in the Section of Dietology at the University Hospital of Pisa.

According to Trico, he is one of several scientists, researchers, and faculty members affected by this unprecedented action by the University Hospital of Pisa's board to put the scientists into treatment roles. "As someone who has dedicated most of his training in doing research, I was enthusiastic to serve the cause, but afraid of my limited clinical experience," Trico says. "However, my fellow researchers and I were assigned to newly created hospital units where we received training and fundamental support by expert clinicians. After a few weeks of sharing this experience, we have all become a big family."

Burak, a postdoctoral research fellow at The Sabri Ülker Center for Nutrient, Genetic, and Metabolic Research, Harvard T. H. Chan School of Public Health, is also a newly appointed member of the faculty at Brigham and Women's Hospital (BWH) and Harvard Medical School. He was set to begin his duties on July 1 after completing his three-year clinical/research endocrinology fellowship at BWH.

Burak's research focuses on the role of fatty acid binding protein 4 (FABP4/aP2) in obesity-related immunometabolic diseases such as diabetes, fatty liver disease, and asthma. "We are developing new therapeutic strategies against those diseases using anti-FABP4 agents," he explains. "We think that FABP4 plays a critical role in the pathogenesis of metabolically driven chronic low-grade inflammatory diseases, such as obesity, diabetes, asthma, fatty liver disease, and atherosclerosis, which share similar lipid derangements and immune-metabolic underpinnings. We are also investigating the role of FABPs in the metabolism of immune cells, which we think may have important connection to immune response upon infection as well."

For now, however, their research will have to wait. But for how long is anybody's guess.

The New Abnormal



Aside from pushing away from their research, Trico and Burak have had to adjust to a new way of dealing with patient care, as well as a new, more cautious approach to living their everyday lives.

"I try not to lose common sense, panic, or become paranoid," Burak says, "but I am very cautious about public places such as markets, post offices, and pharmacies, and avoid them if I can."

When he does go out in public, Burak always has his face covered. "Additionally, I keep delivery packages outside for a day before bringing into the house," he says. "Lastly, while working inpatient frontline duty, I move into a hotel for the entire week, thanks to Brigham and Women's Hospital, providing this opportunity."

"My biggest fear is not to get infected," Burak continues, "but asymptotically infect my parents now living with us, my family, or my patients."

According to Trico, in Italy, nearly 10% of infected patients are healthcare workers, and more than 140 doctors had died due to COVID-19. "Some of them were retirees who had voluntarily returned to service," he says. "Their sacrifice is a remarkable warning about the potential, extreme personal consequences of COVID-19 infection."

Even more importantly, Trico says, "protecting ourselves is the only way to protect our patients and loved ones from the infection. For these reasons, I always put a great effort and time into putting on and taking off personal protective equipment. I've even cut my hair and beard and have self-isolated from my family."

“As someone who has dedicated most of his training in doing research, I was enthusiastic to serve the cause, but afraid of my limited clinical experience. However, my fellow researchers and I were assigned to newly created hospital units where we received training and fundamental support by expert clinicians. After a few weeks of sharing this experience, we have all become a big family.”



Domenico Trico, MD, is one of several scientists, researchers, and faculty members affected by this unprecedented action by the University Hospital of Pisa's board to put the scientists into treatment roles.

No “Typical” Days

Like so many of us during this pandemic, researchers have their own version of a “new normal” and had to adapt to it as quickly as possible. While some of us have now become experts in social distancing and mastering the art of virtual Zoom or Skype meetings, these scientists were now face to face with a barrage of very sick patients suffering from a virus that is still not yet fully understood.

Before the pandemic, Trico dedicated half of his time to research and teaching activities and the other half to seeing patients. “My time for clinics was mainly devoted to the care of outpatients with metabolic diseases and malnutrition, with a few monthly shifts in the hospital’s internal medicine unit,” Trico explains. “After I joined the COVID unit, my time in the hospital has substantially increased. Outpatients with urgent needs can still reach me by phone or email because I don’t want to risk passing the virus on to them in case I’m a carrier.”

Burak says that as a physician/scientist, “this lifestyle is what I have signed up for” but admits that it is very unusual to totally shut down the lab and be re-deployed to general medicine to fight the infection on the front lines. However, in addition to being an endocrinologist, Burak is also a board-certified internist, which includes pulmonary/critical care and infectious disease management. “I feel a huge responsibility and desire to help my colleagues at the front line,” he adds.

Despite Trico’s new job on the front lines, he is still required to give online lessons and exams at the university during this time as well. “Academic activities have not been suspended, not even for clinicians caring for COVID-19 patients,” he adds.

COVID-19 Patients and Endocrine Conditions

Trico says that as he sees more and more COVID-19 patients, there are commonalities he has noticed: “Most COVID-19 patients requiring hospitalization are obese and have pre-existing medical conditions, including type 2 diabetes. Some develop glucose intolerance during hospitalization due to infection and use of steroids,” he says. “In these patients, it can be difficult to adjust the insulin to prevent the fluctuation in blood glucose levels and, most importantly, the COVID-19 infection can be harder to treat.”

As more patients are treated, Trico says that he and the other physicians and healthcare providers have become more and more aware of the importance of “nutritional support” for COVID-19 patients. “Older age and comorbidities are typically associated with malnutrition and sarcopenia, independently of BMI, which in turn can lead to worse clinical outcomes,” Trico explains. “Local guidelines for nutrition therapy in COVID-19 infections encompass oral and parenteral supplements that are individually tailored based on health status, comorbidities (e.g., diabetes or kidney failure), and disease severity.”



The Rise of the (Telemedicine) Machines

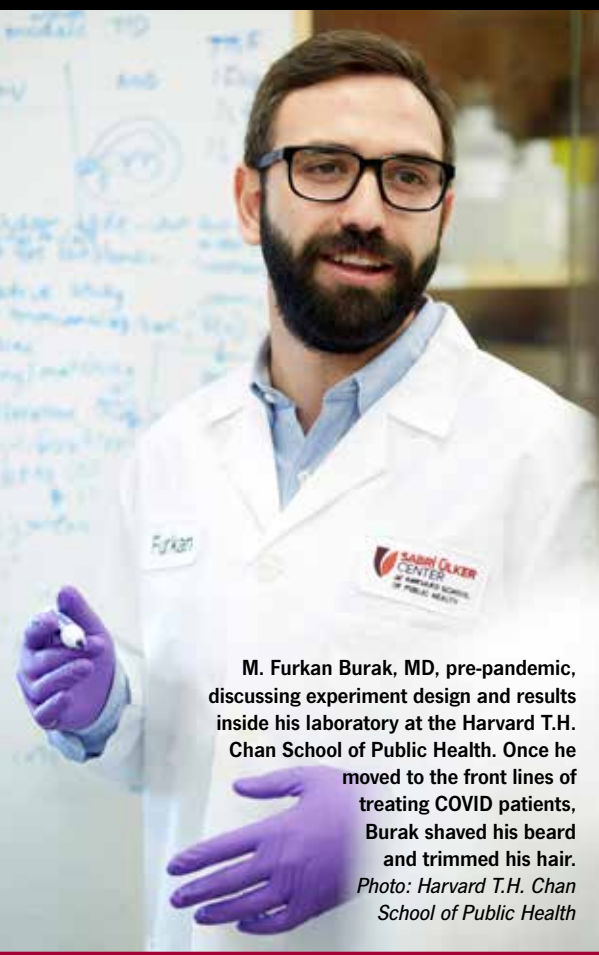


Throughout this pandemic, telemedicine has been overwhelmingly embraced to become the new norm, and everyone seems to agree that treatment via broadband is here to stay.

According to Trico, the gradual ongoing transition toward telemedicine has greatly accelerated to minimize the risk of infection carried by traditional in-person care. “There are some advantages in the implementation of telemedicine which will make it difficult to return to the old medicine,” he says. “However, we should consider that access can be limited, particularly for the elderly, and long-term consequences are unpredictable.”

In order to limit disruption of COVID and non-COVID medical care, Brigham and Women’s Hospital “rapidly adopted to digital health transformation, telemedicine, virtual care, and E-consults for both inpatient and outpatient medicine, which really helped to continue our care with excellence,” Burak says. “Even with inpatient care, having tablets in patient rooms to keep frequent interaction with our patients without increasing risk of COVID transmission made both primary team and consultants constantly available.”

Burak feels that both physicians and patients found virtual care very efficient and convenient, adding “they are getting used to it, which might affect how we deliver care after the COVID-19 era.” As an example, he points to the number of far-removed patients who travel to the hospital, fighting traffic, and often having to endure long wait times that can result in a half-day commitment. The use of telemedicine lets them simply wait in their own living room to get connected. “Actually, given that doctors are constantly in front of computers,” Burak adds, “some patients feel like we are even more available now between clinic visits, and they are reaching out to us more frequently for their medical issues and getting timely online interventions.”



M. Furkan Burak, MD, pre-pandemic, discussing experiment design and results inside his laboratory at the Harvard T.H. Chan School of Public Health. Once he moved to the front lines of treating COVID patients, Burak shaved his beard and trimmed his hair.
Photo: Harvard T.H. Chan School of Public Health

“The COVID-19 era reminded researchers the importance of global collaboration and making a bigger impact by helping each other, sharing resources, opening access to confidential libraries and compounds, as well as raising awareness for more joint funding.”

Burak’s endocrine consulting team is seeing an escalating number of patients with diabetes and obesity whose conditions appear to worsen the course of COVID-19 as their glycemic patterns are atypical and therefore need some adjustments. “We prioritize endocrine conditions to help manage COVID-19 treatments, which could be a lifesaver,” he says. “Insulin requirements dramatically increase in COVID-19 patients with diabetes because of insulin resistance. There are also anecdotal new diabetes cases with COVID-19 infections, which are thought to be related to direct β -cell injury/loss from viral infection. With these additional challenges and more diabetic ketoacidosis (DKA) cases, our diabetes team leaders have created new protocols for DKA management with minimal patient contact to prevent the risk of infection during treatment.”

Trico adds that the endocrinology community in Pisa has a long tradition of having several eminent endocrinologists locally, many of whom have been assigned to the same COVID-19 unit. Because of this, clinical decisions regarding patients with underlying clinical conditions can be shared among his esteemed colleagues.

COVID’s Lasting Impact

The COVID-19 pandemic has changed everything, from how we interact with cashiers at Target to how we handle our incoming mail and package deliveries. Nowhere have these changes been more acute than in the world of medicine. Trico says that not only will both healthcare and research be dramatically affected by the pandemic, but social habits as well “at least until a vaccine or effective drugs are available.”

Burak feels that the pandemic has not only created new solutions to healthcare delivery — namely the advent of telemedicine (see “Rise of the [Telemedicine] Machines” sidebar, previous page) — but has also created a new set of problems regarding patients delaying or ignoring treatments altogether for underlying conditions. “In general, people are avoiding on-site hospital visits, having a very high threshold to go to the emergency room, and delaying their chronic disease care such as diabetes, hypertension, heart disease, cancer treatments and imaging, and perhaps not even refilling their prescriptions as regularly,” he says. “After the COVID era, we will likely need to deal with the consequences as a medical community and potentially observe higher mortality from chronic diseases.”

Reverence for Research

As the pandemic wears on, the entire world is tenuously hanging onto the hope that a vaccine will emerge sooner rather than later, which Burak says makes it clear to the whole world that the only way to conquer this pandemic is with science and medicine.


“Researchers and medical professionals are the new heroes,” Burak says, adding that this will further motivate scientists, increase the impact of scientific studies, and potentially raise more funding for science. “Additionally, the COVID-19 era reminded researchers the importance of global collaboration and making a bigger impact by helping each other, sharing resources, opening access to confidential libraries and compounds, as well as raising awareness for more joint funding.”

However, Burak fears that with the spotlight shining even more brightly on the need for fast results, there could arise a harmful side effect on scholarly publishing. “Nowadays, we start seeing articles first in the *New York Times* before a peer-review journal,” he says. “Bioarchive publishing platforms for pre-prints have become extremely popular and emerged as go-to publishers. We are facing some danger of losing the appropriate controls in research studies and only focusing on hypothesis and endpoints, of which bias might increase false results and could be misleading in many fields and eventually could damage trust.”

While their labs remain empty, Trico, Burak, and a host of scientists and researchers around the world lend their expertise and healing hands in the midst of this pandemic.

However, Trico says that research cannot remain idle for too long. “It is fundamental to conduct new research to better understand the many aspects of the transmission and pathogenesis of the new coronavirus that are still unclear,” he says. “Meanwhile, endocrinologists — and *all* clinicians — should be ready to switch to internal or even emergency medicine until the curve is not flattened as the waves of COVID-19 patients keep coming in to be treated.”

For his part, Burak is relying on his research background in immunometabolism, which he says is very relevant to the variable inflammatory course of COVID-19 infection. “My research about the metabolism of immune cells was warning me proactively about the worsening effect of hyperglycemia and obesity,” he explains. “Also, our research on how lipid mediators might have a significant role in worsening inflammation could be applicable in treating these patients.

From a recent night shift, Burak reflected on his duties and even though he misses not being able to continue his research at the moment, he considers it an honor to help the lonely and fearful patients he has been treating during the pandemic. “When you look into their eyes, you see the fear and they are alone without any loved ones around,” he says. “We, frontline workers, are the only ones who can relieve that fear and anxiety. I feel like that is an enormous privilege.” 

“ It is fundamental to conduct new research to better understand the many aspects of the transmission and pathogenesis of the new coronavirus that are still unclear. Meanwhile, endocrinologists — and all clinicians — should be ready to switch to internal or even emergency medicine until the curve is not flattened as the waves of COVID-19 patients keep coming in to be treated.”

Domenico Trico, MD, currently in his first year as an assistant professor of internal medicine at the University of Pisa and a PhD candidate at the Sant’Anna School of Pisa, is a clinical scientist with a longstanding interest in diabetes and nutrition.



— NEWMAN HAS BEEN THE EDITOR OF *ENDOCRINE NEWS* SINCE 2013. IN THE APRIL ISSUE HE WROTE “VIRAL LOAD” DETAILING HOW MIHAIL ZILBERMINT, MD, HAS ADJUSTED TO THE COVID-19 PANDEMIC AT SUBURBAN HOSPITAL IN BETHESDA, MD.



FAIR Trials

BY DEREK BAGELY

One of the biggest obstacles to medical research is the lack of a truly representative population in clinical trials. For his ENDO Online 2020 session, “Minority Participation in Research: Considerations of Urgency and Strategy,” James R. Gavin III, MD, PhD, will discuss needed steps researchers can take to ensure clinical trials are representative of all patient populations.

There is no debate among medical experts that when it comes to chronic conditions, minorities are overrepresented and disproportionately affected by the course and severity of these diseases. The problem here is that the healthcare community is still unsure why that is or what can be done about it.

If minorities aren't properly represented in something like a drug trial for a medicine to treat a disease that affects this population at a higher rate, then the data are in danger of being incomplete, since physicians won't know whether treatments or interventions shown effective in mitigating the effects of such conditions in others would have similar benefits — or adverse events — in minorities.

The first step to solving any problem is admitting you have one, which is why **ENDO Online 2020** this month will feature James R. Gavin III, MD, PhD, clinical professor of medicine at the Emory University School of Medicine, arguing for the dire need for more minority recruitment for clinical trials in his talk “Minority Participation in Research: Considerations of Urgency and Strategy,” part of the larger session on Breaking Barriers to Care.

“It is essential to have adequate exposure of such populations to the treatments and interventions under consideration in order to make informed judgments about the safe use of these approaches in minority population,” Gavin says. “For the healthcare provider, such knowledge, or its absence, will have an effect on the substance of the conversation the healthcare professional might initiate with the patient regarding what to expect from the proposed treatment plan.”

Cultural Competence

For his talk, Gavin tells *Endocrine News* that he will summarize the urgency for having a discussion of the best practices to recruit minorities into clinical trials and gathering real-world evidence in the clinical setting, both historically and right up to the current COVID-19 pandemic. “I will point out the learnings we have derived from working in this space for many years and outline some of the strategies we have used to increase recruitment and retention (it requires both to merit the designation of participation),” he says.

First and foremost, Gavin says that it's important to know the demographics of the patient population you're seeking for your research project, as well as the network of providers who serve them. “It is essential to establish networks of relationships that will assure trusted access to these populations, and it is essential that cultural competence training be provided for all persons engaged in such recruitments,” he says.



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We are entering a new era of unprecedented displacement and disruption. Many will have lost jobs and not have jobs to go back to. Different levels of pressure will emerge over fundamentals like transportation, childcare, and even food security.”

— JAMES R. GAVIN III, MD, PHD, CLINICAL PROFESSOR OF MEDICINE, EMORY UNIVERSITY SCHOOL OF MEDICINE, ATLANTA, GA.

Cultural competence training involves educating staff on how to properly engage with diverse population groups, to close the gaps in these patients' treatments. Culturally competent care, then, involves some self-reflection and acquiring cultural knowledge — it's important to be aware of diverse populations' different approaches to healthcare and how they view healthcare providers. For example, according to Gavin, African Americans tend to have a deep distrust of medical providers because of past experiences.

Gavin will provide some action strategies and approaches on how to break this barrier to care and for increasing minority participation in clinical trials, even as some of those trials may currently be disrupted by COVID-19, a virus that has also disproportionately ravaged minority communities.

Infected Relationships

The current COVID-19 death rate in New York City for blacks is 20 out of 100,000, and for Hispanics, the rate is 22 out of 100,000. The death rate in New York City for whites is 10 out of 100,000. In Michigan, where African Americans represent 14% of the population, their death rate is more than 40%.

What's more, the novel coronavirus pandemic may have infected relationships among minorities and their healthcare providers and researchers hoping to recruit diverse populations for clinical trials designed to help extend lifespans and improve the quality of those lives. Most protocols are set up for virtual meetings, and it's much easier to trust someone by sitting down with them and meeting face to face.

“The process of relationship building and cultivation, which are important long-term elements in the clinical research enterprise,

just cannot be easily done remotely,” Gavin says. “In many instances, subjects may not be technologically adept or equipped to fully engage virtually. Moreover, it takes time to properly teach about the dangers of this pandemic and the importance of fidelity to rigorous risk mitigation strategies.”

Unprecedented Displacement

And once this is all over, once things return to “normal” and it's safe to shake someone's hand or hug a loved one, Gavin says that priorities are different for everyone now, and will be for a very long time. “We are entering a new era of unprecedented displacement and disruption,” he says. “Many will have lost jobs and not have jobs to go back to. Different levels of pressure will emerge over fundamentals like transportation, childcare, and even food security.”

And researchers may have to change the ways they approach recruitment strategies once it's safe for clinical trials to be conducted in person. “Continued participation in clinical studies may become increasingly transactional and incentives will have to be thoughtfully considered,” Gavin says. “On the other hand, I fear significant levels of dropout.”

Still, the need for minority participation in these research projects and clinical trials is more urgent than ever, especially as COVID-19 has shown the healthcare community that it's imperative to understand why minorities are so disproportionately affected and adversely impacted by chronic conditions and global pandemics. “This type of recruitment is extremely urgent, doable, rewarding, has lots of learned or acquired elements embedded in the process of doing it successfully, and most importantly, requires legitimate patience and willingness to tolerate differences,” Gavin says. **EN**

— BAGLEY IS THE SENIOR EDITOR OF *ENDOCRINE NEWS*. HE WROTE ABOUT GLYCEMIC CONTROL IN COVID-19 PATIENTS IN THE MAY ISSUE.

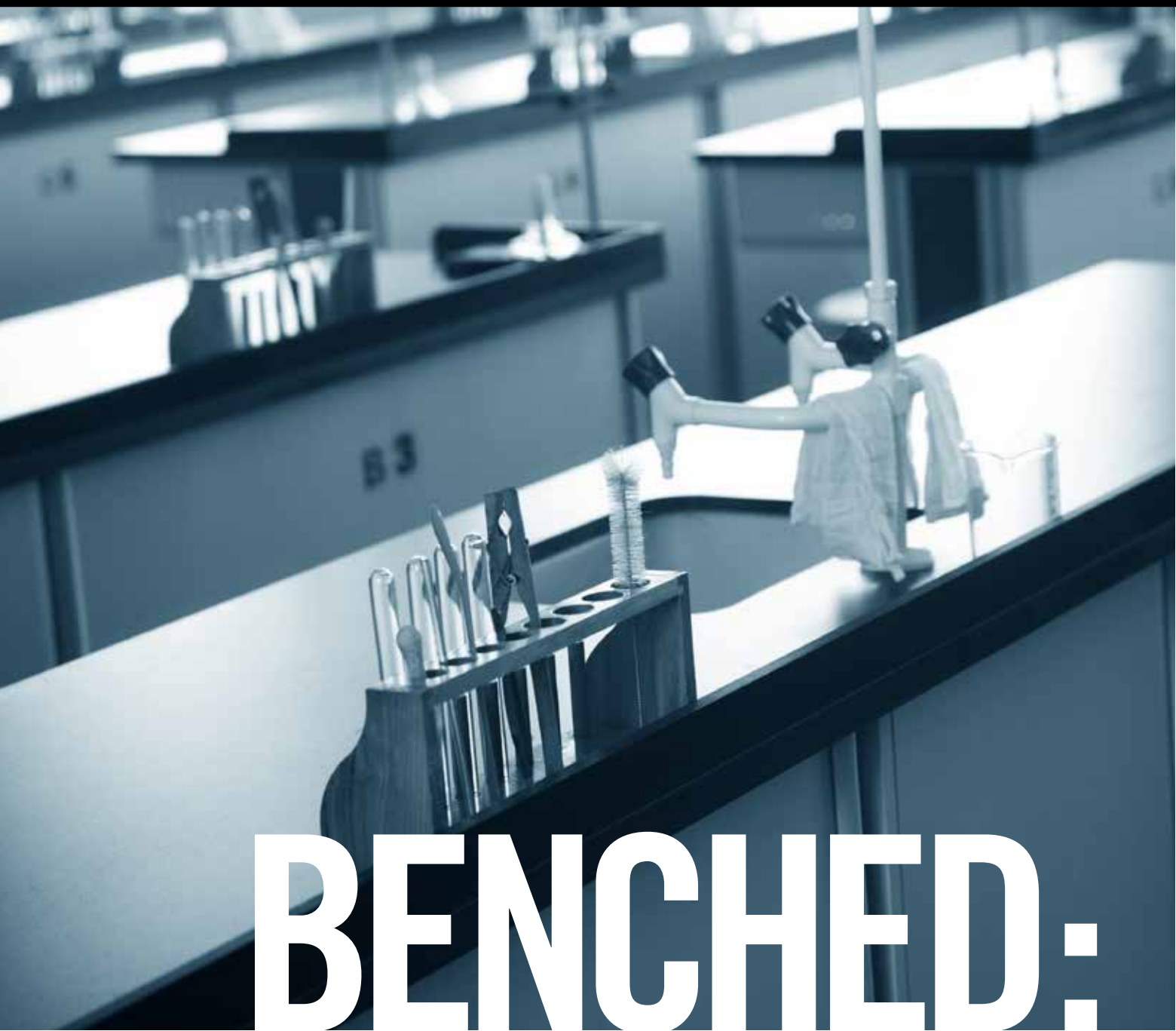


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BENCHED:

Resuming Research After COVID-19

BY GLENDA FAUNTLEROY SHAW

As researchers and scientists wait out the pandemic, lessons for restarting their labs can be learned from previous disasters that put a halt to research.

The devastation caused by the COVID-19 pandemic has reached every part of the globe and every industry. Countries such as France, Italy, New Zealand, and the U.K. have implemented some of the most restrictive mass quarantines, and about 90% of the U.S. was under either a state- or city-mandated shelter-in-place order as of mid-April. Governors, however, are making changes to their state's mandates by the day, leaving academic institutions and businesses to frequently adjust.

Most institutions have followed established emergency preparedness plans to guide staff through stopping research investigations or working remotely as much as possible. And those who have lived through a disaster before know that planning for a shutdown crisis is crucial long before the crisis arrives.

"As far as disaster preparedness goes, there is little difference between a disaster with notice and one without," says Tracy Wieder, senior manager of Research Support at UHealth Sylvester Comprehensive Cancer Center at the University of Miami.

Wieder was the manager for one of the largest research labs at the University of Houston Medical School when it was devastated by Tropical Storm Allison in 2001.

The storm dumped 32 trillion gallons of water on the city, and the Medical Center suffered about \$1.5 billion in damages when the basement of the medical school building was completely filled with water. The flood caused massive loss of research animals and destroyed backup generators that were all housed in the basement.

"Shutting down labs [during COVID-19] will potentially result in losses, even though we aren't dealing with an event like a hurricane, flood, or earthquake," Wieder says. "My primary concern during the current shutdown has been the potential loss of cell lines and other intellectual property that could happen if a freezer on campus were to go down during this time when staff are not on campus to notice."

Wieder says she hopes most institutions have made sure lab freezers are on alarm-monitoring systems at all times so if there is a sudden shutdown, lab managers will be notified. But then what?

"It's just as critical that labs know what procedures their institute will allow them to follow if there is such a freezer emergency," Wieder says. "Will any staff be allowed on site to move samples? If so, do they need special designation? Will repair techs be allowed on site to make repairs and, if so, are the vendors open and willing to come on site?"

Emergency preparedness plans should outline how to deal with sudden shutdown caused by a hurricane, fire, or pandemic, Wieder says. "You have to prepare for instances where people are not allowed to go back to work for an extended period of time," she adds.

Lessons from Katrina

Vivian Fonseca, MD, assistant dean for Clinical Research and chief of Section of Endocrinology at Tulane University Health Sciences Center, has also experienced the devastation of flood waters. For him, it was New Orleans' Hurricane Katrina in 2005.

When Katrina hit the city, Fonseca was doing clinical research in his small lab at Tulane as well as participating in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial — a multicenter National Institutes of Health (NIH) study involving 10,251 participants with type 2 diabetes.

“Our center had 180 people in the trial, and we lost everything,” Fonseca recalls. “For researchers at Tulane, not only couldn’t you go to work, but all your freezers went off, all your animals died, all your samples were lost. We’re talking about years of sample collection, both clinical samples as well as animal samples.”

“We moved to Houston, and Baylor University was very generous and gave us some space to function,” he recalls. “We moved the medical students there and did clinics in the VA Hospital.”

“NIH told me I had to do something for the 180 ACCORD participants who were on experimental treatments, so our coordinators did an incredible job,” Fonseca continues. “We went to various shelters in Baton Rouge and Houston with signs reading ‘if you are a patient in trials at Tulane, talk to me.’ We eventually found all but 10 or 15 people, and we saw them in some peripheral clinics, and we arranged for a pharmacy to ship them the study medications wherever they were.”

It would be almost one year before Fonseca was allowed to return to his Tulane office.

Fonseca says the university has implemented a host of new preparedness systems since Katrina. A major change was to have generators installed on the second floor of the parking garage and electricity placed in a section of the building called the freezer farm used by all researchers. The freezer farm houses all freezers in one space, all cataloged, and is on a generator back-up power supply.

Tulane also changed its clinical trial informed consent process. Patients are asked to carry a laminated card showing their clinical trial enrollment and must provide backup contact information in case of emergency. The information is stored on an offsite database that is backed up on a regular basis.

Pushing Through Despite Disruptions

Since Tulane shutdown for the COVID-19 pandemic, Fonseca and fellow researchers have stopped all trials and studies that were not providing a direct benefit to patients. “However, our clinical trials unit remains open and busy,” he says. “We are talking to our patients by telephone and FaceTime, but more importantly, we have started several COVID-related clinical trials.”

“This has been a novel learning experience for our clinical research nurses, who have stepped up and learned the principles of infection control and personal protection, while learning new protocols involving very sick patients,” Fonseca says. “We are



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The most important thing is having the resilience to carry on and do the best you can. These are very important lessons for everybody in this crisis.”

— VIVIAN FONSECA, MD, ASSISTANT DEAN, CLINICAL RESEARCH, CHIEF OF SECTION OF ENDOCRINOLOGY, TULANE UNIVERSITY HEALTH SCIENCES CENTER, NEW ORLEANS, LA.



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Based on our conversations, it appears that our priority will be to restart the pending mouse experiments that require a lot of time and effort to perform. Specifically, during the first couple of weeks, we plan to restart the mouse colonies and finalize some benchwork that is necessary for the publication of pending papers and completion of PhD theses of graduate students.”

— DIONYSIOS CHARTOUMPEKIS, MD, PHD, UNIVERSITY OF PATRAS, PATRAS, GREECE

very grateful for their dedication and determination. They have done it again, just as they did after Katrina.”

For Dionysios Chartoumpekis, MD, PhD, from the University of Patras in Patras, Greece, COVID-19 social distancing measures were implemented in early March. The shutdown halted his research program, mouse colonies had to be reduced, and experiments were postponed. Chartoumpekis is one of the Society’s 2020 Early Investigators Award Winners and is working remotely to continue as much research as he is able.

“During these challenging times, my colleagues and I have maintained communication through online platforms, and we have mainly focused on finalizing some writing projects and analyses that do not necessarily require our presence in the lab,” Chartoumpekis says.

“We are lucky to have dedicated technical personnel and a veterinarian in the School of Medicine animal facility who are taking good care of the mouse colonies during this crisis,” Chartoumpekis continues. “A designated person from each lab can enter once a week to perform some basic tasks such as genotyping of mutant mice offspring. In this way, we should have enough breeders to initialize new experiments once this pandemic crisis cools down.”

“Renewing the Sense of Membership”

Everyone wonders when life and work will return to normal. When will it be safe to go back to the office and laboratories? How do researchers and lab managers plan for the first day back?


Chartoumpekis says his team has discussed what items top the list.

“Based on our conversations, it appears that our priority will be to restart the pending mouse experiments that require a lot of time and effort to perform,” he says. “Specifically, during the first couple of weeks, we plan to restart the mouse colonies and finalize some benchwork that is necessary for the publication of pending papers and completion of PhD theses of graduate students.”

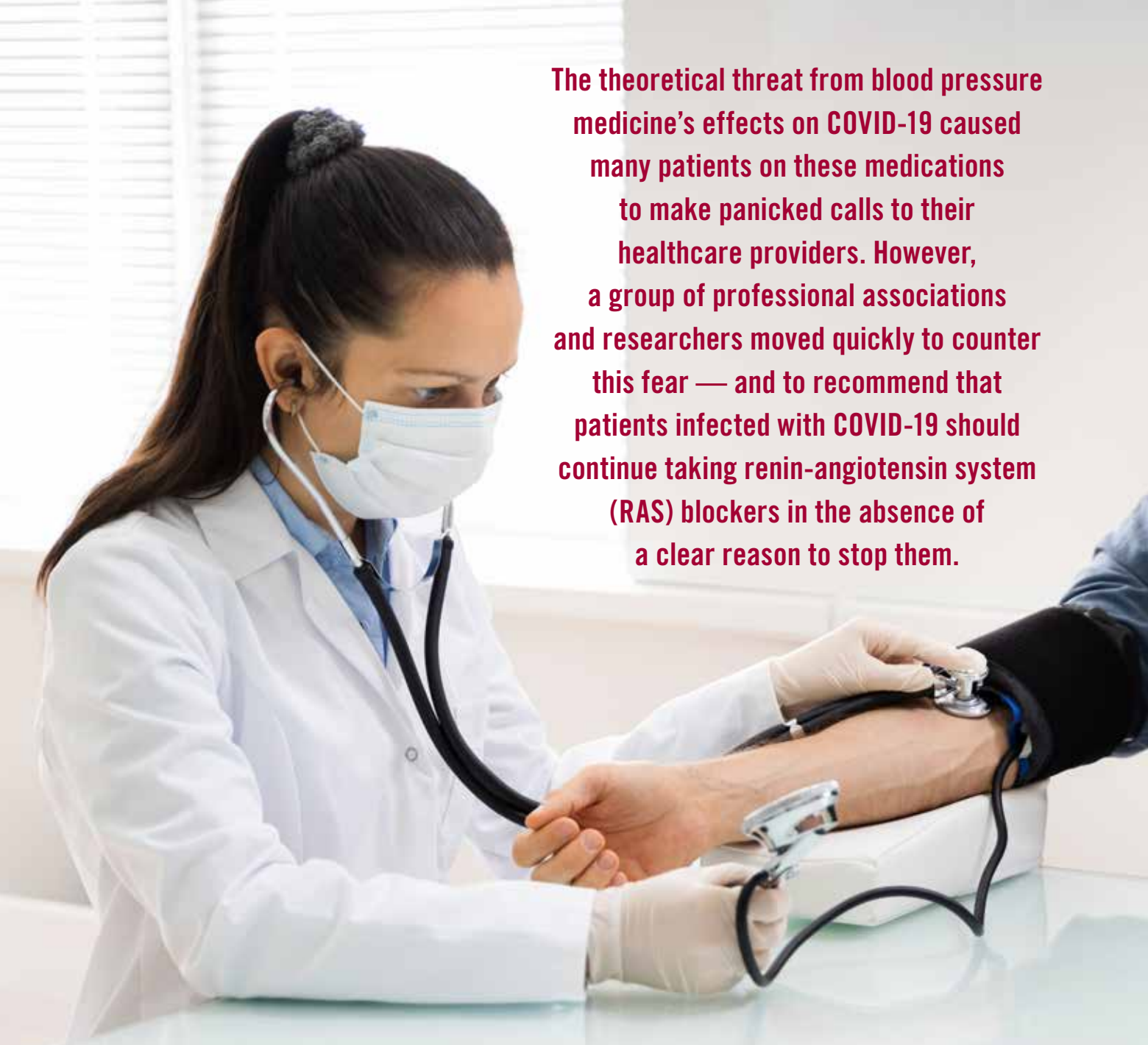
Wieder suggests teams also focus on reconnecting. “My primary advice is to allow staff ample opportunities to just sit down and talk as a group,” she advises. “Renewing the sense of membership in a team that cares for each other is going to be very important as we all move forward. Some people will be dealing with tremendous loss, grief, and trauma. Others who are not dealing with issues that are quite so serious can offer their help and support.”

“We used to think we had to come to work and keep our personal lives private and out of the work environment, but I encourage us all now, in this time, to let that idea go,” she adds.

Wieder and Fonseca share similar survivor sentiments.

“The most important thing is having the resilience to carry on and do the best you can,” Fonseca says. “These are very important lessons for everybody in this crisis.” 

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



The theoretical threat from blood pressure medicine's effects on COVID-19 caused many patients on these medications to make panicked calls to their healthcare providers. However, a group of professional associations and researchers moved quickly to counter this fear — and to recommend that patients infected with COVID-19 should continue taking renin-angiotensin system (RAS) blockers in the absence of a clear reason to stop them.

EXPERT OPINION:

COVID-19 & RAS Blockers

BY ERIC SEABORG



Patients on blood pressure medication that blocks the renin-angiotensin system (RAS) should continue taking their medication during the COVID-19 pandemic, and COVID-19 patients should continue these medications in the absence of a clear reason to stop them, many professional societies recommend.

The professional societies issued formal statements in response to the theoretical threat that angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs) could increase the likelihood of infections and worsen their severity by encouraging a potential pathway for the SARS-CoV-2 virus to enter lung cells. Contrary to the theoretical risk, the three largest observational studies to date found no signals of harm from continuing these medications.

“This has been an active debate and an example of how little bits and pieces of basic science can lead you down paths that can really get you twisted around,” says Stephen C. Textor, MD, professor of medicine with specialties in nephrology and hypertension at the Mayo Clinic in Rochester, Minn., who was on the committee that wrote the Endocrine Society scientific statement on hypertension.

“We had a lot of discussion about it,” says Gail Kurr Adler, MD, PhD, associate professor of medicine in the division of endocrinology, diabetes, and hypertension at Brigham and Women’s Hospital in Boston, Mass. “We decided that we should keep everybody on their ACE inhibitors and ARBs because there was not enough data to stop effective, good treatments, and there is a lot of cardiovascular risk with stopping them. The medical associations came out very quickly to say don’t stop them. Now there is good observational data that these medications are safe in COVID-19.”

The Theoretical Threat

A pair of letters in *BMJ* and the *Lancet* in mid-March raised two potential areas of concern that sparked the discussion.

One concern relates to how coronaviruses can gain access into cells. Like other coronavirus family members, SARS-CoV-2 has a spike protein on its surface that can attach to receptors on angiotensin-converting enzyme 2 (ACE2) and gain entry. Because some animal studies have shown that ACE inhibitors and ARBs increase the expression of ACE2 — which is expressed in the epithelial cells of the lungs — the writers proposed that this mechanism could contribute to more severe infections among patients taking the drugs.

Second, the investigators noted that patients with hypertension, diabetes, and cardiovascular disease were at highest risk for severe infection. Because these patients are likely to be taking ACE inhibitors and ARBs, they posed the question: Could the drugs be contributing to the severity of their infections?

The two letters “got so much press that patients were calling us and asking what to do. Some universities and practices actually released statements saying that you should be holding these medicines in anybody because of this theoretical risk,” says Jordana Cohen, MD, assistant professor in the division of renal-electrolyte and hypertension at the Perelman School of Medicine at the University of Pennsylvania.

The prospect that patients might decide on their own to stop taking their medications, just in case they became infected, was

a big concern. “The possibility of adverse events from stopping these drugs likely would outweigh any theoretical change in the COVID course if they were ever infected,” Textor says.

Professional Societies Push Back

A large group of professional societies quickly pushed back with official recommendations saying that there was no evidence to support the withholding of these medications, so they should be continued in the absence of indications for stopping them. At least 14 groups, including the European Society of Hypertension, American Heart Association, and Heart Failure Society of America, went on the record.

Cohen says that the first retrospective studies on the use of the medications in COVID-19 patients reported confusing outcomes — some found the medications were beneficial, some found them to be harmful, and some found neither.

Evidence Weighs In

The weight of evidence shifted when the May 1 *New England Journal of Medicine* published three of the largest observational studies yet, with none showing evidence of harm with the use of ACE inhibitors and ARBs.

One was a database study of 8,910 COVID-19 patients hospitalized in 11 countries on three continents. That study found that neither ACE inhibitors nor ARBs were associated with an increased risk of in-hospital death.

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— GAIL KURR ADLER, MD, PHD, ASSOCIATE PROFESSOR OF MEDICINE, DIVISION OF ENDOCRINOLOGY, DIABETES, AND HYPERTENSION, BRIGHAM AND WOMEN'S HOSPITAL, BOSTON, MASS.



A study in the Lombardy region of Italy compared 6,272 patients with confirmed COVID-19 with 30,759 controls matched according to age, sex, and municipality of residence. The study found no association between ACE inhibitors or ARBs with the likelihood of COVID-19 infection nor any association between the drugs and severe COVID-19 disease.

A study of more than 12,500 electronic health records of patients in the New York University health system found no positive association for ACE inhibitors or ARBs with either a COVID-19 infection or severe illness.

An editorial accompanying the studies said: “Professional scientific societies and experts have spoken with one voice in advising that patients should not discontinue ACE inhibitor or ARB therapy out of a concern that they are at increased risk for infection, severe illness, or death during the COVID-19 pandemic. These three studies support those recommendations.”

“The three *New England Journal of Medicine* observational studies had thousands of patients in each report. The results are quite consistent — from many different parts of the world, many different healthcare systems, and many different populations — all coming to the same general conclusion. I think that is extremely useful evidence for the patients who use these drugs and the physicians who prescribe them. There are millions of people taking these medications, and some of them would be understandably frightened. We can now give them a greater degree of reassurance,” says Daniel J. Drucker, MD, professor of medicine at the University of Toronto and editor-in-chief of *Endocrine Reviews*.

Need for Clinical Trials

Clinicians have little choice but to rely on observational studies on a topic that is rife with confounding effects that prevent the studies from answering basic questions such as: Are patients with conditions like hypertension, diabetes, and

AT A GLANCE

- ▶ Patients should continue taking angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers during the COVID-19 pandemic, professional societies agree.
- ▶ The theoretical threat that these medications could increase the likelihood and severity of COVID-19 infection led many institutions to re-examine policies on their use, but there is no evidence of harm from taking them.
- ▶ Observational studies have detected no signal of harm from the medications, and clinical trials are under way to give more definitive answers.

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The three *New England Journal of Medicine* observational studies had thousands of patients in each report. The results are quite consistent ...all coming to the same general conclusion. I think that is extremely useful evidence for the patients who use these drugs and the physicians who prescribe them. **There are millions of people taking these medications, and some of them would be understandably frightened. We can now give them a greater degree of reassurance.”**

— DANIEL J. DRUCKER, MD, PROFESSOR OF MEDICINE, UNIVERSITY OF TORONTO, TORONTO, CANADA; EDITOR-IN-CHIEF, *ENDOCRINE REVIEWS*

cardiovascular disease experiencing more severe COVID-19 because of these underlying conditions or because of the drugs they are taking to treat the conditions?

These kinds of questions emphasize the need for randomized clinical trials to help sort through the confounders and give more definitive answers, and these studies are on the way. Cohen is a co-principal investigator of a multi-center, international trial that plans to enroll 152 patients hospitalized with COVID-19 who are already using an ACE inhibitor or ARB. The patients will be randomly assigned to either stop or continue taking the medication, and their clinical course followed. The trial began enrolling patients on March 31 and is expected to run for three or four months. It is “essentially unfunded” with the healthcare providers and sites participating on a volunteer basis, Cohen says.

A large number of researchers must be stepping up in a similar fashion because more than 1,000 studies addressing various aspects of COVID-19 are registered at ClinicalTrials.gov, including more than 600 interventional studies and randomized clinical trials. At least a dozen of them are addressing the use of ACE inhibitors and ARBs.

The Case for Beneficial Effects

And while clinicians await these results, they can also consider the unsettled science surrounding ACE2 expression and activity. While some studies have shown that the RAS blockers increase

ACE2 levels, others do not. And although there is a theoretical risk from raising ACE2 levels, there is also an important possibility that the opposite could be true.

A *JAMA Cardiology* paper noted that ACE2 “plays a major anti-inflammatory role in RAS signaling by converting angiotensin II, the quintessential perpetrator of inflammation, to angiotensin 1-7, which carries anti-inflammatory properties.” ACE2 production declines with age such that “older individuals, especially those with hypertension and diabetes, have reduced ACE2 expression and upregulation of angiotensin II proinflammatory signaling.” The authors posit that lower levels of ACE2 could contribute to making COVID-19 worse, so by restoring them to earlier levels, ACE inhibitors and ARBs could have a beneficial effect.

Cohen notes that some studies show that these medications reduce inflammation in viral pneumonia, and Adler points to data suggesting that ACE2 is beneficial in some experimental models of lung disease.

In the face of the theoretical pros and cons, clinicians must make decisions based on the available evidence. Like Adler and her colleagues at Brigham and Women’s, Textor says that at the Mayo Clinic they “dug into the issue” and concluded that “it is a mistake to react to the theoretical issue when there has been no observed effect at all.” ^{EN}

— SEABORG IS A FREELANCE WRITER BASED IN CHARLOTTESVILLE, VA. IN THE MAY ISSUE, HE WROTE ABOUT RECOMMENDATIONS FROM THE EDITORS OF *THE JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM* REGARDING TREATMENT OF CERTAIN COVID-19 PATIENTS WITH UNDERLYING ENDOCRINE CONDITIONS.



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A New Addition:

Revised ADA Guidelines Include SGLT2 Inhibitors for Type 2 Diabetes Patients

SGLT2 inhibitors were designed to lower glucose, but clinical trials uncovered unexpected cardiovascular and renal benefits. Updated guidelines from the American Diabetes Association now recommend their use in many type 2 diabetes patients.

BY ERIC SEABORG

The evidence is clear that SGLT2 inhibitors should be added to the drug regimen of many type 2 diabetes patients, according to recent revisions of the American Diabetes Association's (ADA's) standards of care for diabetes.

Sodium-glucose co-transporter 2 (SGLT2) inhibitors interfere with glucose reuptake in the proximal tubules of the kidneys, increasing urinary excretion of glucose and thereby lowering glucose in the bloodstream. The drugs were brought to market with the thought that lowering glucose levels through this new mechanism should have favorable effects in treating diabetes.

But they've been found to have unexpected benefits — a discovery that has been called serendipitous. In 2008, the U.S. Food and Drug Administration (FDA) added long-term cardiovascular outcomes trials (CVOTs) as another safety step in the approval process for diabetes agents because of the possible adverse cardiovascular effects of some diabetes drugs that came to light well after they had been approved.

The CVOTs for SGLT2 inhibitors had unexpected results that quickly got people's attention when they began to appear in 2015. The first published trial tested empagliflozin against placebo among type 2 diabetes patients at risk of cardiovascular events — nearly all of whom had established cardiovascular disease — who were receiving the standard of care. Among the benefits were a significant reduction in the risk of cardiovascular mortality and a 35% relative risk reduction in hospitalization for heart failure. The CVOTs published for canagliflozin in 2017 and dapagliflozin in 2018 reported similarly positive heart failure outcomes.

A meta-analysis of the CVOT results published in the *Lancet* in January 2019 concluded: "SGLT2 inhibitors have moderate benefits on atherosclerotic





major adverse cardiovascular events that seem confined to patients with established atherosclerotic cardiovascular disease. However, they have robust benefits on reducing hospitalization for heart failure and progression of renal disease regardless of existing atherosclerotic cardiovascular disease or a history of heart failure.”

In the year since that analysis, more results have appeared that have generally reinforced and broadened the benefits as the drugs have been tested in more diverse patient groups.

What the New Guidelines Say

SGLT2 inhibitors are now part of the mix for glucose lowering in the section of the standards on glycemic treatment. But perhaps the most significant references come in section 10 (“Cardiovascular Disease and Risk Management”) of the 2020 guidelines, which recommend:

- “Among patients with type 2 diabetes who have established atherosclerotic cardiovascular disease or established kidney disease, a sodium–glucose cotransporter 2 inhibitor or glucagon-like peptide 1 receptor agonist with demonstrated cardiovascular disease benefit is recommended as part of the glucose-lowering regimen.”
- “In patients with type 2 diabetes and established atherosclerotic cardiovascular disease, multiple atherosclerotic cardiovascular disease risk factors, or diabetic kidney disease, a sodium–glucose cotransporter 2 inhibitor ... is recommended to reduce the risk of major adverse cardiovascular events and heart failure hospitalization.”

Jennifer Green, MD, an endocrinologist at Duke University and member of the ADA professional practice committee that regularly revises the standards, says that metformin remains the recommended first-line treatment for type 2 diabetes. But she says that when it comes to adding another drug, “the main change this year was the removal of a need for tighter glycemic control to add a medication with cardio-renal benefit. If you have a patient with established atherosclerotic cardiovascular disease, or, in particular, with chronic kidney disease or heart failure, you should preferentially add an SGLT2 inhibitor irrespective of the need for additional glucose lowering. The reason for the change is that the benefits of the drugs don’t seem to be mediated through glucose lowering. Benefits were seen irrespective of patients’ hemoglobin A1c at baseline, and in fact some of the benefits may extend to patients without diabetes. So, it is important for endocrinologists — and even more important for primary care doctors, nephrologists, and cardiologists — to think about using these drugs early in many patients with diabetes. The indications for the use of SGLT2 inhibitors are expanding rapidly.”

“ Many cardiologists now see these medications as drugs to prevent heart failure and cardiovascular death, with purely incidental effects on blood glucose. **Their real benefit, and the reason we should use them, is because of their effects on heart failure, diabetic kidney disease, and cardiovascular death.**”

— BRENDAN M. EVERETT, MD, MPH, ASSOCIATE PROFESSOR, HARVARD MEDICAL SCHOOL, BOSTON, MASS.

Solid Evidence Base

The decision to include SGLT2 inhibitors in the ADA guidelines was not difficult because it is based on consistent and solid evidence from large, well-conducted outcome trials, according to Mikhail Kosiborod, MD, of Saint Luke's Mid America Heart Institute in Kansas City, and an American College of Cardiology representative on the ADA committee.

He says that additional information has come from the DAPA-HF trial, which studied the effects of dapagliflozin in patients with heart failure and a reduced ejection fraction. The study included patients with and without diabetes and found similar cardiovascular benefits — significant reduction in the risk of cardiovascular death and worsening heart failure — regardless of the presence of diabetes. The findings provide additional evidence that the drugs provide benefits not related to lowering glucose and could have as-yet unestablished mechanisms of action conferring direct cardiovascular benefits. The speed with which benefits manifest — in relatively short-term trials — is another piece of evidence that they are not due to lowering glucose or hemoglobin A1c.

Which Drug to Choose?

The outcomes benefits are pretty consistent across the SGLT2 inhibitor class, Green says, so the choice of which SGLT2 inhibitor to prescribe may well be guided by the patient's insurance coverage and ease of access. For example, the VA includes one SGLT2 inhibitor on its formulary and Medicaid coverage varies by state. Private insurance often specifies one drug in the class for coverage or lower copayments, and discovering which drug is covered can be a hit-or-miss process of writing a prescription for the patient to take to a pharmacy.



AT A GLANCE

- ▶ The latest update of the American Diabetes Association's standards of care recommends use of SGLT2 inhibitors in type 2 diabetes patients as an additional agent for lowering glucose — and perhaps more importantly, for lowering cardiovascular and renal risk in patients predisposed to these complications.
- ▶ SGLT2 inhibitors' positive effects do not seem to be mediated through their glucose-lowering action and may extend to patients without diabetes.
- ▶ SGLT2 inhibitor's benefits were revealed unexpectedly in cardiovascular outcomes trials as part of the drug-approval process.

“ It is important for endocrinologists — and even more important for primary care doctors, nephrologists, and cardiologists — to think about using these drugs early in many patients with diabetes. The indications for the use of SGLT2 inhibitors are expanding rapidly.”

— JENNIFER GREEN, MD, ENDOCRINOLOGIST,
DUKE UNIVERSITY, DURHAM, N.C.

The Expense Hurdle


Like many other new drugs, the value of SGLT2 inhibitors has been questioned because of their high price. But Green notes: “There are currently patients with diabetes being treated with other expensive medications without a demonstrated cardiovascular outcomes benefit. It may be worth turning a critical eye on the regimen of patients at risk for cardio-renal complications to see if you could substitute an SGLT2 inhibitor for an existing expensive medication without a demonstrated outcomes benefit, for a financially net neutral change, but a positive change with respect to their risk of serious complications.”

Reasons for Caution

Of course, like any drug, SGLT2 inhibitors have their contraindications and side effects. In 2015, the FDA added warnings to their labels about the risks of urinary tract infections and ketoacidosis. The FDA has consistently turned down applications for the use of SGLT2 inhibitors in type 1 diabetes, with the main concern being an increased risk of ketoacidosis in these patients.

Green notes that a canagliflozin study raised concerns about an increased risk of fractures and amputations, so she is cautious about starting an SGLT2 inhibitor in a patient already at high risk for amputation, such as a patient with ongoing foot ulceration.

The nephrology community has greeted SGLT2 inhibitors with enthusiasm because of strong evidence that the drugs slow the progression of diabetic kidney disease. However, as kidney decline continues, their use is not recommended when a patient’s estimated glomerular filtration rate drops below 45 or 30, with the cutoff number varying by drug.

Brendan M. Everett, MD, MPH, an associate professor at Harvard Medical School and co-chair of the American College of Cardiology’s expert clinical decision pathway committee on the use of these drugs, also endorses the ADA’s new guidelines: “In the empagliflozin CVOT, there was a 40% reduction in cardiovascular death, and that drove a reduction in all-cause mortality. That’s important clinically to both doctors and patients. That finding has been validated in trials of canagliflozin and dapagliflozin. The benefits of these drugs for the cardiovascular system are so substantial that they have changed the way we think about treating patients who have both diabetes and cardiovascular disease. Many cardiologists now see these medications as drugs to prevent heart failure and cardiovascular death, with purely incidental effects on blood glucose. Their real benefit, and the reason we should use them, is because of their effects on heart failure, diabetic kidney disease, and cardiovascular death.” 

— SEABORG IS A CHARLOTTESVILLE, VA.-BASED FREELANCE WRITER AND A FREQUENT CONTRIBUTOR TO *ENDOCRINE NEWS*. HE WROTE ABOUT THE BENEFITS OF MEDICARE COVERAGE FOR CONTINUOUS GLUCOSE MONITORS IN THE APRIL ISSUE.



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OSTEOPOROSIS & COVID-19:



An Alliance Provides Guidance

Endocrine News speaks with Endocrine Society member and president-elect of the American Society for Bone and Mineral Research (ASBMR), Suzanne Jan De Beur, MD, about new recommendations from a coalition of bone health organizations that provide guidance for clinicians treating patients with osteoporosis during the COVID-19 pandemic.

BY MARK A. NEWMAN

The COVID-19 pandemic has impacted all aspects of life, most notably how healthcare is delivered. The endocrinology community has been quick to respond with new treatment protocols in this ever-evolving era.

One new set of guidelines was born from a medical society's webinar, but has now become a coalition of five leading bone health organizations that came together to release recommendations for healthcare professionals who treat patients with osteoporosis in the era of COVID-19. "Joint Guidance on Osteoporosis Management in the Era of COVID-19" was created through a collaboration by the American Society for Bone and Mineral Research (ASBMR), American Association of Clinical Endocrinologists (AACE), Endocrine Society, European Calcified Tissue Society (ECTS), and National Osteoporosis Foundation (NOF).

The creation of the guidelines was led by ASBMR Professional Practice Committee (PPC) chair Matthew Drake, MD, PhD. He assembled

a diverse group of osteoporosis experts for an April 2020 webinar on the care of osteoporosis in the time of COVID-19, according to Suzanne Jan De Beur, MD, associate professor of medicine at Johns Hopkins School of Medicine and incoming ASBMR president. These experts included Elaine Yu, MD; Elena Tsourdi, MD; Bart Clarke, MD; and Douglas Bauer, MD.

“This was so well received that a document summarizing the recommendations was drafted, approved by our PPC and Executive Committee,” Jan De Beur explains. “I recommended that we build a coalition of societies to review, adopt, and disseminate the recommendations. We were thrilled with the input and collaboration we got from the five societies that adopted and endorsed the recommendations.”

The overriding goal for creating these recommendations was to provide the most timely, evidence-based, and expert guidance to help clinicians manage patients with osteoporosis when direct, face-to-face medical care may be limited during this time of social distancing, according to Jan De Beur. “We recognize that there are a number of professional medical organizations that serve clinicians that treat patients with osteoporosis,” she says. “Creating a coalition of societies is the most effective means to rapidly disseminate this important and timely guidance to clinicians.”

Jan De Beur shares more insights about these new guidelines with *Endocrine News*, including the impact of patients missing or delaying treatment, the effects of social distancing, as well as an in-depth look at alternate care delivery methods.

Endocrine News: Since the osteoporosis patient population is overwhelmingly older, what is the danger for these patients in the event they delay or miss treatments altogether?

Suzanne Jan De Beur: Providing medical care to older adults in the time of COVID-19 requires a delicate risk-benefit assessment. It is important for patients to maintain osteoporosis treatment to prevent fractures, which increase both morbidity and mortality. Some osteoporosis treatments are extremely time sensitive and delaying or skipping treatments can result in bone loss and, in some cases, fractures. However, in many instances, care can be provided remotely or safely delayed. These recommendations help the clinician navigate which treatments must be continued and how they can safely be continued, and which can be delayed or modified.

EN: How much of an impact do social distancing treatment standards have on managing patients with osteoporosis?

SJDB: Social distancing impacts our ability to see patients face-to-face, our ability to administer injectable or IV osteoporosis medication, and our ability to screen and monitor osteoporosis by DXA (dual X-ray absorptiometry). These recommendations help clinicians assess when the benefit outweighs the risk of a face-to-face encounter for medication administration or bone density testing.

EN: Are there some patients who are easier to treat while still maintaining social distancing standards, i.e., telemedicine,

“Some osteoporosis treatments are extremely time sensitive and delaying or skipping treatments can result in bone loss and, in some cases, fractures. However, in many instances, care can be provided remotely or safely delayed.”

— SUZANNE JAN DE BEUR, MD, ASSOCIATE PROFESSOR OF MEDICINE, JOHNS HOPKINS SCHOOL OF MEDICINE; DIRECTOR, BALTIMORE, MD.

than others? What conditions would necessitate seeing certain patients in person?

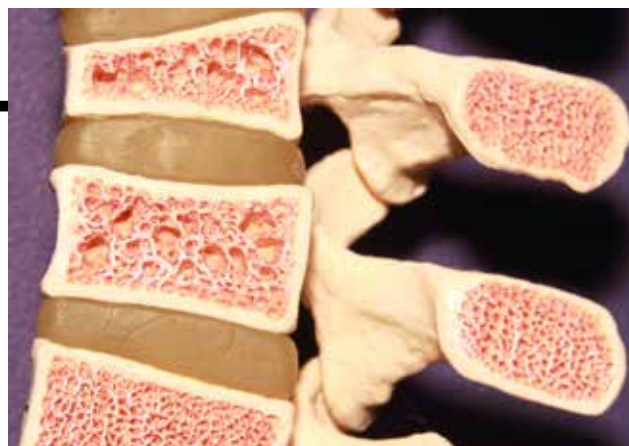
SJDB: Certainly, patients on oral agents such as oral bisphosphonates, raloxifene, and estrogen are the simplest to manage with telemedicine. Those on IV bisphosphonates, many times, can safely delay infusions for up to six months or a year. Denosumab and romosozumab are especially time sensitive and bone loss can occur if injection is delayed for more than a month for denosumab or two to three months for romosozumab.

The guidance in this document provides several solutions to consider in patients that need these injections such as off-site clinics, home delivery, self-injection, and drive-through administration. Teriparatide and abaloparatide are self-administered, but if continued treatment is not feasible, delay in treatment should not exceed two to three months. In cases where delays exceeding the recommended time period are anticipated with denosumab, teriparatide, abaloparatide, or romosozumab, therapy may need to be temporarily changed to an oral bisphosphonate.

Continuing Treatments

When possible, patients should continue their prescribed osteoporosis regimens, according to the guidelines. Specific recommendations for patients who are unable to receive their next dosage of non-oral osteoporosis medications during the COVID-19 pandemic include:


- ▶ For patients who are taking denosumab (Prolia®), experts recommend considering a delay in treatment. If the delay exceeds one month (i.e., is seven months from the most recent prior injection), consider temporary transition to oral bisphosphonate.
- ▶ For patients who are taking teriparatide (Forteo®), abaloparatide (Tymlos®), or romosozumab (Evenity®), experts recommend considering a delay in treatment. If the delay exceeds three months, consider temporary transition to oral bisphosphonate.
- ▶ For patients who are on IV bisphosphonates, delays of even several months are unlikely to be harmful.



EN: Can you give us some details on what the guidelines describe as alternate care delivery and which methods work best for certain patients?

SJDB: Directly from the guidance, alternative delivery methods include:

- ▶ Off-site clinics: Administration of treatments at locations geographically isolated from COVID-19 “hot-spots” should be considered whenever possible. However, recognize that this may disadvantage socioeconomically challenged communities if public transportation options are not available.
- ▶ Home delivery and administration: This is a feasible option if available and could include a visiting nurse, home health aide, home-visiting medical staff, or family healthcare provider.
- ▶ Self-injection of denosumab (and/or romosozumab) has been proposed and is reportedly available in some locales. However, there are important medical-legal issues to consider surrounding the proper product handling and administration, including the small risk of drug-related hypersensitivity reactions in the absence of a medical provider, although steps to mitigate such potential risks may be in place in some communities.
- ▶ Drive-through administration of denosumab and/or romosozumab: This may also be logistically difficult to arrange. Furthermore, it is recommended that patients be monitored by a medical provider for 15 minutes after injection in the unlikely event of a hypersensitivity reaction.

Read the full statement at www.endocrine.org/covid19osteoporosis. More helpful resources regarding COVID-19 from the Endocrine Society can be found at: www.endocrine.org/covid19. 

— NEWMAN HAS BEEN THE EDITOR OF *ENDOCRINE NEWS* SINCE 2013. IN THE APRIL ISSUE, HE WROTE “VIRAL LOAD” DETAILING HOW MIHAIL ZILBERMINT, MD, HAS ADJUSTED TO THE COVID-19 PANDEMIC AT SUBURBAN HOSPITAL IN BETHESDA, MD.

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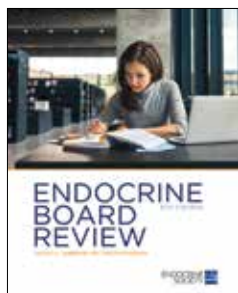
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MANAGING COVID-19 IN HOSPITAL SETTINGS

A series of papers to be published across a variety of journals provides a potential roadmap for treating COVID-19 patients within a hospital setting. It tells practitioners in these healthcare environments how to prepare for the unexpected.

BY DEREK BAGLEY

On April 30, an article appeared in the *New England Journal of Medicine* titled “Best Practices for a COVID-19 Preparedness Plan for Health Systems,” a collaborative effort among a national team of healthcare experts representing the Presidential Leadership Scholars, Aspen Institute Health Innovators, and Eisenhower Fellows.

This was the first in a series of papers written to address potential gaps in the healthcare system as the novel coronavirus continues to sweep over the U.S. “By acting early, health systems may avoid being crippled by crisis and continue to be operational and provide critically important care,” the authors write.

These papers were born out of a WhatsApp group of physicians and other healthcare leaders who were sharing their experiences on the front lines of treating patients with COVID-19. “We started talking about the needs we were seeing in different places around the country, [as well as] the needs of the healthcare system and how to prepare healthcare systems for something that we saw coming,” says Ricardo Correa, MD, EsD, FACP, FAPCR, FACE, CMQ, program director of the Endocrinology, Diabetes and Metabolism Fellowship at the University of Arizona College of Medicine, and one of the authors of these papers from the Presidential Leadership Scholars cohort.

As it turns out, these authors had a lot to contribute; initially, the paper was going to be a single publication, but the early draft of a Google document grew to around 20 pages, so the authors decided to release these papers as a series across several journals. (At press time, these papers had been accepted, but not published.) “When you have 18 to 20 people involved in this, everybody wants to give their own take,” Correa says.

For this NEJM article, Correa and his colleagues focused on the dire need for health systems to brace for the worst, even the unexpected, as we still know very little about this novel coronavirus, and we know even less about what might happen as the country begins to “reopen.” “The cornerstones of an effective COVID-19 preparedness plan for a health system are: (1) mitigating local transmission; (2) conserving, supporting, and protecting staff; (3) eliminating nonurgent strains on the system; and (4) coordinating communication,” the authors write.

“Health systems should not wait until they face a surge in COVID-19 cases to implement a comprehensive response,” they go on to warn.

Telemedicine: A Default Approach

The authors of the NEJM paper point out that patients are at risk of exposure to COVID-19 not just during their visit to a hospital but also while in transit to receive medical attention. In that case, patients should remain home unless it's an emergency.

“Instead, telemedicine should be utilized as the default approach,” the authors write. “Telemedicine allows continued care while reducing unneeded exposure to patients and healthcare workers.” The authors go on to write that while policy barriers have prevented more widespread adoption of telemedicine, recent legislation has relaxed some restrictions surrounding this still-emerging technology.

As an endocrinologist who adopted telemedicine relatively early (in 2015), Correa has seen the value of treating his patients via computer or smartphone. He primarily practices in the outpatient setting and says that telemedicine not only promotes more adherence to treatment, it allows for social determinant of patients' health. For example, Correa explains, if patients are no-shows, it's likely they didn't have the money to take a bus or taxi to the clinic, or they couldn't find someone to watch their kids, or they didn't eat the day before, and so on.

In his clinic, Correa sees many patients from underserved populations, but everyone has a smartphone, and when he connects with them through their smartphones, he can see some of their realities. “Sometimes they introduce you to their family, so you can see their caregivers are there,” he says. “You can talk directly to the family and tell them what they need to do to help care for a patient with diabetes. It creates an interpersonal relationship that might not otherwise exist in a traditional office visit where you would typically see the patient alone.”

Novel Conversations

Since the COVID-19 pandemic spread across the world, there have been myriad social media posts and viral videos thanking healthcare workers and first responders and



“

There is a lot of anxiety of what will happen in the future, but I think that we have to embrace technology as part of our life. **And this is the beginning of a new era where we will not stop the interaction because social interaction is so important.”**

— RICARDO CORREA, MD, ESD, FACP, FAPCR, FACE, CMO, PROGRAM DIRECTOR, ENDOCRINOLOGY, DIABETES AND METABOLISM FELLOWSHIP, UNIVERSITY OF ARIZONA COLLEGE OF MEDICINE, PHOENIX, ARIZ.

everyone else essential to maintaining some semblance of peace of mind for the rest of us. And while that's definitely deserved, providers are still reporting shortages of personal protection equipment (PPE) and other hospital resources.

It's more important than ever to protect and support those whose efforts have been saving lives. The NEJM paper authors write that the first documented case of community spread in the U.S. “resulted in 200 hospital workers being quarantined and unable to work for weeks.” Rotating staff, postponing elective procedures, and running virtual clinics will help preserve PPE, allow for anesthesiologists to provide care in the ICU, and conserve staff for when they have to take over for incapacitated colleagues, the authors write.

The novel coronavirus has impacted virtually every aspect of healthcare and has forced some novel conversations among providers about the best ways to protect themselves, even in a purely endocrine space. If a patient with thyroid cancer needs a fine needle aspiration, the discussion among thyroid experts is now whether this biopsy needs to be an aerosol procedure, Correa says. He goes on to say that he expects organizations like the Endocrine Society and American Thyroid Association to recommend the best decision, but if this procedure does need to be aerosol, it will totally change the approach. “If this is aerosol, we have to have complete PPE from face to feet, to the mask, to the gloves, everything,” he says. “They have to be in a room that is aerosol protected. You have to clean the room after each patient. So you will have to use a lot of PPE and if you are in a training setting, like I am, you have to provide the same thing to the residents and the fellows.”

A Virtual Renaissance

The authors of the NEJM paper write that this coronavirus crisis changes daily, which makes the need for effective communication crucial. They recommend forming central COVID-19 response teams, disseminating daily staff-wide information, and hosting virtual town halls, which should be recorded so those who can't leave the clinic can get the information later. Coordinating communication with patients is also just as important, since patients may need instructions on how to properly quarantine themselves.

Even communication among respective healthcare teams can be valuable — again, supporting staff, since healthcare providers are already prone to burnout, and COVID-19





has certainly heightened and sharpened that phenomenon. Correa says he calls his fellows at least once a day to check in (the fellows were all sent home March 15 to practice telemedicine), and provides meditation and other healthcare resources, as well as organizing Zoom happy hours to help decrease burnout and improve wellness.

Some states are beginning to see a decrease in cases, but as the country begins to reopen, Correa says he's not sure whether that trend will hold. "[If cases start to rise, we] will have to go back and attend to our plan, including those four points that the [NEJM] article mentioned — mitigation of transmission, all the isolation, the quarantine, the use of masks when you go out, the social distancing," he says.

For now, providers are adopting new technologies and even finding innovative uses for them. These emerging technologies got a jump start because of the pandemic, but as more providers warm to them, coordinating communication has become simpler thus providing easier access to vital information.

Correa points to the Endocrine Society's upcoming virtual meeting in June, which is on track to have 20,000 attendees, more than double the previous record. "People that were in the past unable to attend because of some X, Y reasons, always somebody had to stay in the hospital because you have to cover the hospital," he says. "There's a fellow who stays there, an attending who stays. Now with the opportunity of being online, they will be able to obtain the knowledge that otherwise they would lack."

Correa acknowledges there are still some wrinkles to iron out (his team was visited by a few "Zoom bombers" during a meeting — protections have been added since), but he says he tries to see the positive possibilities from all this uncertainty. "There is a lot of anxiety of what will happen in the future, but I think that we have to embrace technology as part of our life," he says. "And this is the beginning of a new era where we will not stop the interaction because social interaction is so important. However, now we have the opportunity to interact with many more people."

"Healthcare systems should realize that we are moving from the old paradigm to the new paradigm, and that everybody should get used to it — from the payers to physicians," Correa continues, "finding a middle line that everybody can benefit from." ^{EN}

Upcoming Papers

Quyen Chu, MD, MBA, et al., *Reallocating Ventilators During the COVID-19 Pandemic: Is it Ethical?*, *Surgery* (2020).

SreyRam Kuy, MD, MHS, et al., *Emphasizing Vulnerable Populations during COVID19*, *Academic Medicine* (2020).

Endocrine News talks with the 2020 Richard E. Weitzman Outstanding Early Investigator Award recipient, Andrew Dauber, MD, about his research in uncovering the underlying causes of growth deficits in children, the importance of a patient's family history, as well as what his lab has planned for the future.



Q&A:

The Road to Discovery

BY GLENDA FAUNTLEROY SHAW

Uncovering the cause of short stature in children became an early curiosity for Andrew Dauber, MD. Dauber is the chief of Endocrinology at Children's National Hospital in Washington, D.C., and in 2013, he discovered by whole-exome sequencing in families with central precocious puberty, the first human mutations in MKRN3. It proved to be one his many contributions to the understanding of growth and puberty.

As this year's Outstanding Early Investigator Laureate Award winner, Dauber and his fellow honorees unfortunately missed sharing the stage at the cancelled ENDO 2020. The spotlight

of recognition, however, hasn't dimmed. *Endocrine News* spoke with Dauber to learn more about the path that led to the honor.

Endocrine News: What did you first think when you heard of your Laureate honor?

Andrew Dauber: It really was a great surprise and I felt extremely honored. I've been attending the Endocrine Society meetings every year since I was a fellow and seeing the great physicians and scientists who have received the various Laureate Awards. I think I most appreciated that one

of my international collaborators [Ivo Arnhold, MD, PhD] nominated me for the award. I've really enjoyed having the opportunity to work with people from all over the world. Science is really a global phenomenon, and it's been some of my most rewarding experiences to collaborate with a diverse set of colleagues.

EN: How did the genetics of precocious puberty and short stature come to be your area of interest?

Dauber: Truthfully, it was somewhat the luck of my various career path opportunities. During my fellowship [at Boston's Children's Hospital], I had the good fortune to work with one of my mentors who has now continued to be a lifelong research mentor, Joel Hirschhorn. Joel happened to be the attending on the inpatient service one week when I was the first-year fellow, and together we encountered some really fascinating patients, including a patient with undiagnosed infantile hypercalcemia. At the time, Joel's expertise was in genomics and genomic studies, and I was an impressionable first-year fellow, and we decided to work together, using the latest genomic research technology to try and figure out what was going on with this child because we couldn't find the diagnosis. This subsequently led to figuring out that this infant had a gene mutation in a gene called the 24-hydroxylase gene, which at the time had never before been reported in a human. And that really got me excited about using exome sequencing, which at the time was a brand-new technology.

This work sparked my interest in applying genetic technologies to understanding pediatric endocrine disorders. So, during that fellowship, I decided to work with Dr. Hirschhorn. His major areas of research were height and obesity, and I was more interested in studying children with short stature, and that led to starting as a fellow with a cohort of children with undiagnosed short stature and applying sequencing technologies to them.

So as a fellow and then junior faculty, I had these amazing opportunities to apply exome sequencing and other genomic technologies, and I was working at Boston Children's Hospital and at the Broad Institute and one thing just led to another. We just kept finding the genes for growth, and then in

“ One thing I'm very interested in is trying to think about novel therapeutic approaches to kids who aren't growing well, especially as we're learning more about what are the specific genetic etiologies that are causing them not to grow.”

“ Science is really a global phenomenon, and it’s been some of my most rewarding experiences to collaborate with a diverse set of colleagues.”

collaboration with Ursula Kaiser at Brigham and Women’s Hospital and Ana Claudia Latronico at University of Sao Paolo, we made a major discovery of a gene called MKRN3, which is now the most common genetic cause of precocious puberty.

EN: How prevalent is the MKRN3 genetic mutation in the U.S. population?

Dauber: It’s not common in the U.S. population, but it probably underlies 1% – 2% of cases of precocious puberty and 30% – 50% of familial cases of precocious puberty.

The gene is a somewhat unusually inherited gene. It follows a pattern of genetic inheritance called imprinting, where it only manifests if it’s inherited from the father and not from the mother. So, that led to some very confusing family histories, as the father may or may not be affected, depending on if he inherited it from the grandmother or the grandfather. He would only be affected if he inherited it from his own father. This led to a complicated initial analysis of the exome data.

EN: What is the most common intervention at Children’s National Hospital for precocious puberty, and how are parents counseled through their understandable anxiety?

Dauber: There’s a class of drugs, gonadotropin-releasing hormone agonists, that are very effective at stopping the progression of puberty and preventing girls from having their first period.

Parents are often extremely nervous, especially about their daughter having her first period in first or second grade. I think providing reassurance that we have effective therapies, that we can figure out what’s causing this in some instances, and whether there’s anything they need to worry about can be very helpful. I also think dispelling some of the myths of the

cause is helpful, for instance, was it something they fed the child?

On the growth side, there really aren’t many effective therapies for treating some of the genetic growth disorders. One thing I’m very interested in is trying to think about novel therapeutic approaches to kids who aren’t growing well, especially as we’re learning more about what are the specific genetic etiologies that are causing them not to grow. Can we target those pathways and think about more targeted treatments for children with distinct genetic etiologies for their growth disorders?

EN: And what are your lab’s main goals for 2020?

Dauber: There are two big projects I’m working on now. One is a multicenter NIH-funded study where we’re trying to use searches of the electronic health record system here at Children’s National Hospital, but also at our collaborating hospitals, Boston Children’s and the Children’s Hospital of Philadelphia, to see if we can integrate these searches of the electronic health record with genomic techniques to identify children who are going undiagnosed with genetic growth disorders. We’re aiming to bring genetics into clinical practice and figure out what we are missing.

The other aim is to launch new clinical trials of targeted therapies for genetic forms of short stature. This is still in the planning phases, so I hope to have more to share about this in the near future. **EN**

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



Endocrine Society Maintains Influence on Global EDC Priorities

While the COVID-19 pandemic is understandably drawing the attention of policy makers around the world, the Endocrine Society remains committed to staying engaged regarding endocrine-disrupting chemicals (EDCs). Our members have continued to work with policy makers in the U.S., European Union, and around the world as they try to manage exposures to EDCs.

In the U.S., the Environmental Protection Agency (EPA) continues to advance a new rule on “Strengthening Transparency in Regulatory Science.” We have followed the development of the rule since the original 2018 notice of proposed rulemaking to ensure that the changes proposed by the EPA do not needlessly restrict the use of valuable scientific information for regulatory decisions aimed at improving public health and the environment.


The EPA recently released a supplement that further expands the scope of the rule without addressing our concerns about the rule’s effects. The Society’s U.S. EDC Task Force submitted comments to the EPA urging the agency to withdraw the proposed rule and instead adopt policies governing data sharing and access that are consistent with those of other research agencies such as the National Institutes of Health

Meanwhile, the EPA continues to implement the Frank R. Lautenberg Chemical Safety in the 21st Century Act, which made numerous updates to the chemical review process under the Toxic Substances Control Act (TSCA). As part of the law, the EPA must identify 20 high-priority chemicals for further review and several chemicals with effects on the endocrine system are among the initial high-priority list. Our task force members are guiding our input to the EPA on risk assessments for these chemicals so that they include findings from recent publications by scientists on the endocrine-related effects of these chemicals.

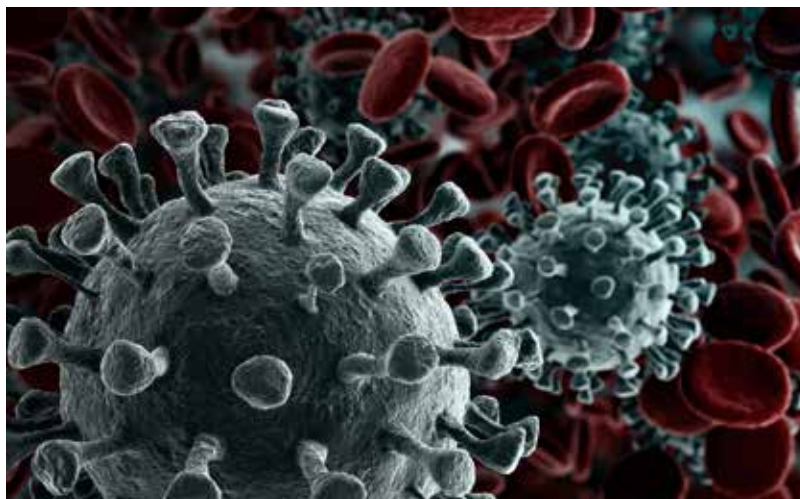
In the European Union, the Society’s EU Task Force is closely following several initiatives currently under development and providing expertise to policy makers guiding these projects. In May, a plan for the Chemicals Strategy for Sustainability was announced. This initiative will provide the political basis for further EU actions on chemicals including EDCs in 2021 and beyond. Our public comments on the plan call on the EU to prioritize minimizing exposures to EDCs as a key component of chemicals management.

Another roadmap prepared by the European Commission earlier this year will inform Europe’s Beating Cancer Plan. While we appreciate that an approach to beating cancer will encompass many research objectives and strategies, our Task Force noted with concern that the roadmap did not include any specific mention of control of EDCs as a key factor in prevention of cancer. Our comments to the Commission on the roadmap focused on the prevention section and called for attention to reducing EDC exposures in this context.

Finally, the Society’s Organization for Economic Cooperation and Development (OECD) Task Force members continue to participate in remote meetings with OECD Work Groups to assist in the development of international approaches to regulating EDCs. The Society has weighed in on processes regarding the scientific review of adverse outcome pathways (AOPs) at OECD, and we have also participated in the review process for a Detailed Review Paper (DRP) on the retinoid system. Our input has provided an endocrine perspective and expertise that has been instrumental in improving these and other documents prepared by OECD for the international regulatory community.

The continued progress being made on EDCs despite the current pandemic illustrates the importance that policy makers around the world place on this issue, driven by years of advocacy by Endocrine Society members. 

COVID-19 Endocrine Advocacy



As the COVID-19 public health emergency (PHE) persists, the Endocrine Society continues to advocate on behalf of researchers, physicians, and patients.

Our issues have ranged from the need to increase funding for research at the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), to the need to support labs reopening to relief for physician practices to expansion of telehealth to additional health coverage and coding guidance.

As this issue of *Endocrine News* goes to press, Congress is deliberating on a fourth COVID-19 relief bill that would provide support to healthcare workers, researchers, medical students, universities, hospitals, and practices. The Endocrine Society is a leading advocate calling for additional emergency funding support for the NIH for endocrine research related to COVID-19, patient access to a 90-day supply of diabetes test strips, removal of copays for insulin, and adequate supplies of personal protective equipment (PPE). We also are working in broad coalitions to advocate for a myriad of issues including: Support to reopen labs, relaxation of immigration restrictions on physicians and researchers, and support for physician practices.

Take Action

Join our online advocacy campaign to urge Congress to support researchers, physicians, and patients by visiting endocrine.org/takeaction. Contact advocacy@endocrine.org to volunteer for advocacy efforts. Visit endocrine.org/advocacy to learn more about our advocacy program.

In previous relief legislation and regulations, our advocacy led to:

- ▶ **Expanded coverage for telehealth** — Our request to expand Medicare coverage for telehealth was included in the Centers for Medicare and Medicaid Services (CMS) emergency Interim Final Rule March 30.
- ▶ **Medicare waivers** — Our requests related to several Medicare waivers, including the three-month, in-person visit for patients with pumps and restrictions on telehealth across state lines was included in CMS emergency waivers released April 7.
- ▶ **Special Diabetes Program extension** — Our request to extend funding for the Special Diabetes Program was included in the CARES Act.
- ▶ **Physician assistance** — Our request to support the Public Health and Social Services Emergency Fund to reimburse providers for expenses and lost revenue attributed to COVID-19 was included in the CARES Act.
- ▶ **Social Distancing** — Our request to extend social distancing measures beyond Easter was agreed to by the White House.

We continue to work with both sides of the aisle in Congress and with the NIH and federal agency leadership. While economic pressures have reduced or cut advocacy efforts at other organizations, the Endocrine Society continues to be a leading voice. Our success shows that your letters and calls make a difference, and we urge you to participate in Endocrine Society advocacy efforts that will benefit scientists, physicians, and patients with endocrine diseases.

When the COVID-19 pandemic began to shut states down, one of our primary concerns was how this was affecting our members, and what we could do to help. We heard from many of our practicing clinician members about their need to expand telehealth coverage as this was the only way they could see patients. We also heard from members about their struggles with telehealth payment, developing telehealth best practices, and other issues that come with ramping up telehealth services during such a short period of time.

At the time of the outbreak, the Centers for Medicare and Medicaid Services (CMS) had restrictive rules for telehealth. The Endocrine Society shared our member concerns with CMS and with Congress and advocated for an expansion of telehealth services. As a result, one of the first actions CMS took to respond to COVID-19 was to open up the use of telehealth.

Unfortunately, at that time, CMS did not reimburse telephone-only and telephone with simultaneous video connection visits equally. Audio-only telehealth received a much lower rate. Consequently, we shared with CMS and Congress the problem and the fact that many beneficiaries did not have access to video. Physicians were still doing everything they could on a video call, and perhaps more, but were reimbursed at a much lower rate.



Endocrine Society Supports Changes to Telehealth Rules During COVID-19 & Provides Telehealth Education

Led by Senator Joe Manchin (D-WV), 39 senators sent a letter to CMS urging a change. This resulted in another round of regulatory waivers and rule changes on April 30 to provide flexibility to the healthcare system during the COVID-19 public health emergency. This included an announcement that CMS would be increasing payments for telephone-only visits to match payment for similar office and outpatient visits. Payments for these services would increase from a range of about \$14 – \$41 to about \$46 – \$110.

Now that telehealth is widely in use, we have heard from Endocrine Society members who need help navigating telehealth challenges. As a result, we hosted a telehealth webinar on May 20 titled “Telehealth in the Time of COVID-19.” During the webinar, a panel of clinicians discussed best practices, e-consultations, and how to make the rapid transitions to telehealth. The webinar recording is available for viewing in the Endocrine Society’s Center for Learning and is complimentary for all Endocrine Society members.

The Endocrine Society Government and Public Affairs team continues to advocate for you as Congress deliberates more COVID-19 relief bills. As the pandemic continues to evolve and new challenges arise, contact us at: advocacy@endocrine.org to describe issues that you are experiencing that we may be able to address through legislative or regulatory action.

For more information about Medicare changes to telehealth, please visit the Society’s COVID-19 member resources page at: endocrine.org/covid19.

The ENDO Store Is Open for Business!

Since **ENDO Online 2020** is kicking off this month, why not visit the **ENDO Store ... online?**

COMPILED AND WRITTEN BY COURTNEY CARSON

If you thought you missed your chance to stock up on new endocrinology gear at **ENDO 2020**, think again! We are pleased to offer some brand new items, as well as past favorites, that can be shipped straight to your door. And the best part? Your purchases help support the work of the Endocrine Society.

Grab some socks for yourself, a surprise for your furry friend, or a study resource for your clinic.

Place your order online at: www.endocrine.org/store.



Drink Up ▶

Cold brew or steamed latte? No matter your preference, our insulated travel mug will keep your beverage of choice the perfect temperature. This brand-new item is a beautiful blue stainless steel tumbler imprinted with the Endocrine Society logo in white.

\$25.00 Non-Member • \$22.00 Member • \$22.00 In-Training Member

◀ Walk This Way

Fido needs new gear, too. Walk your pet in style with this gland-imprinted dog leash, a brand-new item designed exclusively by the Endocrine Society.

\$25.00 Non-Member • \$20.00 Member • \$20.00 In-Training Member

▼ I Get By With A Little Help From My Glands

You've heard of wearing your heart on your sleeve, but what about your glands? This long sleeve t-shirt features gland illustrations on the sleeve and clever text on the back.

\$25.00 Non-Member • \$20.00 Member • \$20.00 In-Training Member



▲ Quiet As A Mouse

Want a new co-worker guaranteed not to make a peep? You need our (stuffed) laboratory mouse any researcher can love, complete with an Endocrine Society bandana. Inspired by the Knockout Rounds, one of the most popular events at **ENDO** each year, this Knockout Mouse will make the perfect gift for any researcher who spends most of their waking hours at the bench! \$11.00 Non-Member • \$10.00 Member • \$10.00 In-Training Member





◀ Rock These Socks

Don't say you don't need a pair! You don't have as many pair of socks as you think. How many are in your drawer without a mate? Choose from four designs exclusively from the Endocrine Society that are guaranteed to get compliments in the lab, clinic, or wherever you go.

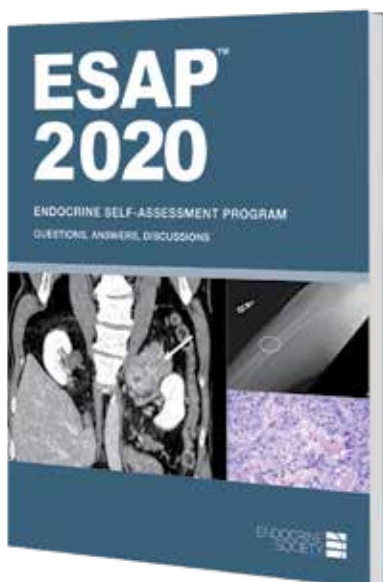
- Get an adrenaline rush every time you slip your feet into the adrenal socks. The soft, high-quality material will keep your feet protected and comfortable as you race around your lab, hospital, office, or home.
- The thyroid socks are sure to give an energy boost each time you put them on. No matter how active you are, these socks are perfect for your daily activities, whether you are playing sports, watching sports — or just watching a movie instead.
- Your serotonin levels are sure to rise once you slip your feet into the gland socks. The soft, high-quality material makes these socks just what the doctor ordered!
- You will feel extra sweet every time you wear the pancreas socks. These socks will keep your juices flowing throughout your day in the lab, hospital, or office.

\$12.00 Non-Member • \$10.00 Member • \$10.00 In-Training Member

Badge(holder) of Honor ▶

Are you one of the millions of healthcare workers that wears a lanyard every day? It's time you get one you love. Made with quality material and a gland-imprinted design, you can finally own a lanyard that's just your style.

\$15.00 Non-Member • \$10.00 Member • \$10.00 In-Training Member



◀ Study Buddy

Endocrine Self-Assessment Program (ESAP) is a self-study curriculum for endocrinologists determined to go beyond certification and provide the best in patient care. ESAP 2020 consists of 120 brand-new, multiple-choice questions in all areas of endocrinology, diabetes, and metabolism.

ESAP features three study modes:

ESAP 2020 Learning Mode: Use this traditional mode to answer 120 questions and receive immediate feedback and view the detail answer rationale. This mode must be completed in order to earn CME and MOC.

Mock Exam Mode: This is perfect for simulating an exam, which you can retake as often as you like. Each time the questions will be re-organized, and feedback will be provided after completion of the exam.

Topical Learning Mode: Questions are organized by topical area to offer another option for navigating the content.

\$350.00 Non-Member • \$250.00 Member

University of Alabama Health Services Foundation, PC, seeks **Clinical Assistant Professor** to participate in divisional meetings/lectures; teach UAB medical students, residents, and fellows; participate in outpatient services and on-call service; and provide patient care at the Endocrinology Clinic. Must have M.D. (or international equivalent) and have completed 36 months of residency training followed by 24 months of endocrinology fellowship training. Must be BC/BE in endocrinology. Work location is Montgomery, AL. Please send applications/resumes to Julia Embry at jsembry@uabmc.edu.

UAB MEDICINE

UAB HOSPITAL

UAB Medicine is an Equal Opportunity/Affirmative Action Employer committed to fostering a diverse, equitable, and family-friendly environment in which all faculty and staff can excel and achieve work/life balance irrespective of race, national origin, age, genetic or family medical history, gender, faith, gender identity, and expression, as well as sexual orientation. UAB also encourages applications from individuals with disabilities and veterans. UAB Medicine is active participant in E-Verify for the I-9 process.

An Exciting Opportunity for an Endocrinology Physician in the Southwest

San Juan Regional Medical Center in Farmington, NM is recruiting a second Endocrinology Physician to join a hospital-employed outpatient practice as a valuable member of our growing team of specialists.

You can look forward to:

- Compensation range of \$245,000 – \$250,000 base salary; productivity bonus; quality bonus
- Lucrative benefit package
- Student loan repayment
- Sign-on bonus and relocation package
- Quality work/life balance



Interested candidates should address their C.V. to:
Terri Smith | tsmith@sjrmc.net
888.282.6591 or 505.609.6011
sanjuanregional.com | sjrmcdocs.com

San Juan Regional Medical Center is a non-profit community-governed facility. Farmington offers a temperate climate near the Rocky Mountains with world-class snow skiing, fly fishing, golf, hiking and water sports. Easy access to cultural sites, National Parks and monuments. Farmington's strong sense of community and vibrant Southwest culture make it a great place to pursue a work-life balance.



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BROWSE JOBS NOW AT ENDOCRINE.ORG/ENDOCAREERS

GENDER AFFIRMING SURGERY INCONGRUENCE
ANDROGYNY TRANSITION
 GENDERQUEER DIFFERENCES OF SEX DEVELOPMENT (DSD)
GENDER ROLE SEXUAL ORIENTATION BISEXUAL
 TRANS MAN QUESTIONING
 INTERSEX **LGBTQIA+** CISGENDER
 HOMOSEXUALITY TRANSMASCULINE GENDER DYSPHORIA **HETEROSEXUAL**
TRANSGENDER PANSEXUAL ASEXUAL
 STRAIGHT **ALLY** TRANSFEMININE
 TRANS WOMAN GAY GENDER EXPRESSION
GENDER IDENTITY NON-BINARY **SEX** LESBIAN
 GENDER NON-CONFORMING QUEER
 GENDER FLUID SEXUAL MINORITY STRESS

THE MORE YOU KNOW

Gender-affirming healthcare for transgender and gender diverse people can sometimes be a challenge. Below are some tools to help you with your gender journey.

1. FIND AFFIRMING PROVIDERS

Affirming medical providers can advocate for your health and help navigate your gender journey.

2. BE PREPARED TO SHARE

Share your affirmed name, pronouns, and sex recorded at birth with your medical provider to avoid misgendering.

3. IDENTIFY FRIENDS OR FAMILY WHO CAN SUPPORT YOUR JOURNEY

It's important to have support from family, friends, and allies. Your support system can celebrate your triumphs and foster your well-being.

4. FIND A SUPPORT GROUP

Support groups offer a bond of understanding and empathy with others who have a shared experience. Support groups come in the form of face-to-face meetings or online communities.

5. KNOW YOUR MEDICATIONS

It's important to know the name and doses of medications and/or supplements you are taking and any allergies you may have.

6. GET THE PROPER SCREENINGS

Regular check ups and screenings are essential to longterm health. Screenings can identify conditions early and guide decisions with your healthcare provider.

7. HAVE COPIES OF YOUR MEDICAL HISTORY

Your medical history gives your provider a road map for your health needs. It helps your provider understand if you are at risk for any chronic diseases. Your health history can also guide gender-affirming therapies if you decide to pursue these.

8. EXERCISE REGULARLY AND MAINTAIN A HEALTHY DIET

It is important to eat well, exercise and maintain a healthy weight to reduce longterm health risks, especially if you are on hormone therapy. Eating well and exercising can improve health and well-being.

9. KNOW YOUR RIGHTS

Discrimination can come in many forms. Your healthcare provider can give you resources to help advocate for your healthcare rights.

10. ASK QUESTIONS

Asking questions and giving your provider feedback can improve your care. Having open discussions with your provider builds trust, satisfaction, and improves results.



You have questions. We have answers.

Editor: Caroline Davidge-Pitts, MBBCH, Mayo Clinic



Hormone Health
 NETWORK®
 FROM THE ENDOCRINE SOCIETY



KNOW YOUR HEALTHCARE TEAM

Decisions about medical care for transgender and gender diverse people should be a collaborative decision. Talk honestly with your healthcare provider about your goals.

PRIMARY CARE PROVIDERS FAMILY CARE PROVIDERS

- General medical care including regular check ups and health screenings
- Some primary care providers can provide hormone therapy for gender dysphoria
- Navigating insurance coverage
- Provide referrals to specialists



BEHAVIORAL HEALTH PROFESSIONAL

- Optimize trajectory of care
- Support for behavioral health issues
- Sexual health concerns
- Social work
- Family and school concerns
- Offer letters to acquire legal identity documentation (e.g. drivers license, passport etc.)
- Financial considerations



GYNECOLOGIST UROLOGIST REPRODUCTIVE ENDOCRINOLOGIST

- Breast/chest health
- Pelvic health including organ screening and evaluation/treatment of STIs
- Fertility
- Gender affirming surgeries



ENDOCRINOLOGIST OR PEDIATRIC ENDOCRINOLOGIST

- Medical care related to hormone therapy
- Initiation and monitoring of hormone therapy in adults and adolescents
- Sexual health
- Medical evaluations (before and after surgery)



DERMATOLOGIST

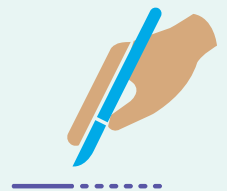
- Hair loss or unwanted hair
- Skin changes related to hormone therapy including acne



PLASTIC SURGERY

Gender affirming surgeries. Examples include:

- Chest and breast surgery
- Feminizing genital surgery
- Masculinizing genital surgery
- Facial feminization
- Tracheal shave



Remember you are the most important part of your medical team.
Know the facts and advocate for yourself.

ADDITIONAL RESOURCES:

hormone.org/find-an-endocrinologist
gottransition.org
wpath.org

VISIT HORMONE.ORG

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