**JULY 2015** 

THE LEADING MAGAZINE FOR ENDOCRINOLOGISTS

## CLINICAL TRIALS: A GAME OF CHANCE OR LAST BEST HOPE?

Endocrine News looks at how clinical trials can offer hope to your patients with intractable conditions after other options have been exhausted. Whatever the outcome, these patients can still contribute to the growth of scientific knowledge.

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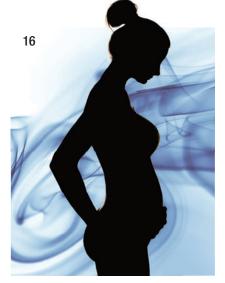
#### CLINICAL ENDOCRINOLOGY UPDATE SEPTEMBER 10-12, 2015

#### ENDOCRINE.ORG/MIAMI



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By Eric Seaborg

NIH funds billions of dollars in medical research each year and many of the studies will have profound effects on the practice of endocrinology. Here's an overview of some of the leading endocrine-related studies currently taking place.

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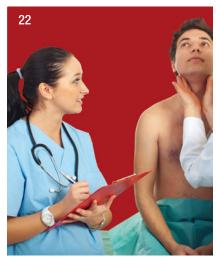
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#### Preparing to Celebrate 100 Years of the Endocrine Society in Boston



Lisa H. Fish, MD

One of the most exciting responsibilities of the President is to work with the members of the Annual Meeting Steering Committee (AMSC) to craft the scientific and educational components of the **ENDO** program. I am pleased to report that this committee is an impressive assemblage of bright and accomplished endocrinologists from around the world. Committee members travelled from near and far — from Asia, Oceania, Europe, the Middle East, and

across the Americas — for our recent planning meeting. I am especially grateful to the chairs of the committee Carol Wysham, MD, Overall Chair, Jenny Visser, PhD, Basic Science Co-chair, Gary Hammer, MD, PhD, Clinical Science Co-chair, and Mike McDermott, MD, Physician in Practice Co-chair, for their leadership and thoughtful contributions.

**ENDO** is our largest, most visible activity and reflects the breadth, depth, and diversity of endocrine research and practice. Adding to our responsibilities this year, **ENDO 2016** (April 1 – 4, 2016, in Boston) will mark the 100th anniversary of the first organizational meeting of our Society and thus will kick off the Endocrine Society's Centennial Celebration. Covering all the bases in current endocrine research and practice is just the beginning of what the Society is aiming to accomplish in Boston. As we take time to celebrate 100 years of discovery and advances in patient care, we will also chart our collective course for the next 100 years of progress.

Embracing our centennial theme, the AMSC has organized the plenary lectures to commemorate the accomplishments of Nobel and Lasker Prize-winning endocrine researchers. The Presidential Plenary Session will celebrate the accomplishments of Banting, MacLeod, their collaborators Best and Collip, and Sanger, for the initial discovery of insulin and the subsequent elucidation of its structure. In this special opening session, Douglas Melton will present his laboratory's latest advances in developing beta cells from induced pluripotent stem cells, and Edward Damiano will provide us with the very latest data from his group's development of an artificial pancreas. Our aim is to illuminate how basic science discoveries and their translation into practice have dramatically improved patient health. Following this model, other plenary sessions will celebrate the development of in vitro fertilization technology, the surgical treatment of thyroid cancer,

and the discovery of hormones and second messenger signaling pathways, including steroid hormones and hypothalamic-releasing hormones.

Among the cutting-edge scientific and clinical symposia planned by the AMSC is an array of Centennial Symposia. In each of these special sessions, the chairman will provide a brief historical perspective that will celebrate how far we have come in our century of discovery and practice. Speakers will be challenged not only to show their latest data but also to define priorities for future research and to predict the direction in which our field will go in the next century.

Our meeting will feature a diverse assortment of special sessions, including the perennial favorite, the Clarke T. Sawin History of Endocrinology lecture on 100 Years of Endocrinology, as well as a special Century in Thyroid review. In addition, the AMSC has planned a number of Year in Sessions, Master Clinician Sessions, and an Endocrine Debate. The **ENDO 2016** website will have all of the details.

As always, the committee has invited an impressive roster of physician educators to lead Meet-the-Professor (MTP) sessions. Mike, Carol, and I are particularly keen that these MTP sessions be true to their original intent — effective and engaging education. We are requiring the entire MTP faculty to deliver case-based and interactive sessions. The program will also feature Case Management Forum sessions in which clinician experts team up to test each other and you with particularly challenging cases.

**ENDO 2016**, with its special Centennial theme, will provide an opportunity for our community to take stock of our accomplishments and to set our top priorities for the future. We hope that you will be part of the best Endocrine Society Annual Meeting and EXPO ever, so please mark your calendars with the dates: April 1 – 4, 2016. The abstract submission deadline is November 10, and registration opens on October 5, 2015, with the early registration deadline for the lowest price ending on January 13. If you have any questions or comments, please contact me at *president@endocrine.org*. **EN** 

Luis Fichmo

Lisa H. Fish, MD President, Endocrine Society







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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.

The mission of the *Endocrine Society* is to advance excellence in endocrinology and promote its essential and integrative role in scientific discovery, medical practice, and human health.

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The statements and opinions expressed in *Endocrine News*' are those of individual authors and do not necessarily reflect the views of the Endocrine Society. Advertising appearing in this publication does not constitute endorsement of its content by *Endocrine News* or the Endocrine Society. This month, we are devoting a considerable amount of space to the topic of clinical trials. This idea was suggested to me last year by Mila Becker, the senior director of Advocacy & Policy Programs for the Endocrine Society. It sounded like a great idea, and it was something *Endocrine News* had never done in the past. Also, this further illustrates how well the Society staff work together in getting the most relevant information into the members' hands whether it's via email or an educational session at **ENDO** or a monthly magazine article. So, I'd like to include a special thanks to Mila for



Mark A. Newman

her very timely and interesting suggestion as well as to Joe Laakso, the Society's associate director of science policy, who reviewed the articles thoroughly before publication.

The first of the clinical trials articles by Eric Seaborg is "Great Expectations" (p. 10) and concerns the basic question: Why should a clinician consider a clinical trial for one of his or her patients? First and foremost, it is a chance to offer the patient hope when all other means have been exhausted. Second, regardless of the individual patient's outcome, the trial is doing its part to further the science of medicine. "I think patients benefit from being in clinical trials because the questions that we study arise when we really don't know whether one treatment is better than the other," Judith Fradkin, MD, director of the Division of Diabetes, Endocrinology, and Metabolic Diseases at the National Institute of Diabetes and Digestive and Kidney Diseases, tells Eric. "So people who are in clinical trials are really getting state-of-the-art treatment. The trials are comparing what we think is the best treatment or two different strategies when we aren't sure which is the best treatment, so people in clinical trials get very good care." Eric's second piece, "Coming Attractions: Top Endocrinology Clinical Trials at NIH" (p. 14), hones in on those trials being conducted by the National Institutes of Health that relate specifically to endocrine disorders. Not only did Eric work closely with NIH staff, but he also consulted with the Society's Research Affairs Core Committee. A special thanks to those experts as well.

Since endocrine-disrupting chemicals (EDCs) are a major threat to the hormone health of people around the world, we're including an article that focuses on the link between EDCs and women's reproductive issues, "Indecent Exposures: EDCs and Women's Health" (p. 16) by Kelly Horvath. "We need to be aware that these EDCs are in our everyday life, even if banned in the past, and they may be having an untoward effect on our ovaries, reproductive health, and overall wellbeing," says Amber R. Cooper, MD, with the Division of Reproductive Endocrinology and Infertility in the Department of Obstetrics and Gynecology at Washington University in St. Louis, Mo.

As always, I welcome your comments about what's in this issue as well as suggestions for topics you would like to see included in future issues. Feel free to contact me at *mnewman@endocgrine.org*. EN

By Derek Bagley

TRENDS & INSIGHTS

#### Mouse Model Pathways Could Predict **Prostate Cancer Progression**

Researchers have used mouse models to examine the complex interplay of several pathways to predict prostate cancer (PCa) progression, which can be difficult to analyze in humans. The study was published recently in *Hormones and Cancer*. The investigators, led by Diane M. Robins, PhD, of the

Department of Human Genetics at the University of Michigan, used mouse models designed to perturb sequentially androgen receptor (AR), ETV1, and phosphatase and tensin homolog (PTEN) pathways to examine the impact of common somatic mutations in PCa on AR signaling. The authors wrote that they humanized the mice with "AR (hAR) alleles that modified AR transcriptional strength by varying polyglutamine tract (Q-tract) length, and then these mice were crossed with mice expressing a prostate-specific, AR-responsive ETV1 transgene (*ETV1* <sup>Tg</sup>)."

They found that ETV1 strongly antagonized global AR regulation and repressed androgen-induced differentiation and tumor suppressor genes, and when PTEN was varied to determine its impact on PCa's progression, the mice lacking one PTEN allele (*Pten* +/-) developed more frequent prostatic intraepithelial neoplasia (PIN). "Yet," Robins and her team wrote, "only those with the ETV1 transgene progressed to invasive adenocarcinoma. Furthermore, progression was more frequent with the short Q-tract (stronger) AR, suggesting that the AR, ETV1, and PTEN pathways cooperate in aggressive disease." Upregulation of the gene *Cxcl16* (a strong inflammatory gene expression signature) was induced by ETV1. The researchers concluded that concerted use of these mouse models "illuminates the complex interplay of AR, ETV1, and PTEN pathways in pre-cancerous neoplasia and early tumorigenesis, disease stages difficult to analyze in man."

#### "Critical Window" of Menopause Hormone Therapy Examined

A new study from the University of Texas has looked at whether, when, and how long women should undergo hormone therapy for menopause. The results were published recently in *Endocrinology*.

The researchers, led by Andrea C. Gore, PhD, of the University of Texas, developed a rat model to test the "critical window" of the effects of timing and duration of estradiol (E2) treatment, since the loss of ovarian E2 necessitates the adaptation of estrogen-sensitive neurons in the hypothalamus to an estrogendepleted environment. They pointed out that "profound depletion of ovarian estrogens with menopause in women requires the resetting of, and adaptation to, a new homeostatic environment."

Gore and her team ovariectomized rats at two different ages (reproductively mature or aging), then gave the rats E2 or vehicle replacement regimes of differing timing and duration. They identified gene modules differentially regulated by age, timing, and duration of the E2 treatment and found that E2 status differentially affected suites of genes in the hypothalamus involved in energy balance, circadian rhythms, and reproduction. "In fact," the authors wrote, "E2 status was the dominant factor in determining gene modules and hormone levels; age, timing, and duration had more subtle effects." The authors concluded that these results "highlight the plasticity of hypothalamic neuroendocrine systems during reproductive aging and its surprising ability to adapt to diverse E2 replacement regimes." They also noted that this result is of particular importance because of the ongoing debates about E2 replacement therapy, and the study provides "novel insights into how the timing and duration of E2 treatment and

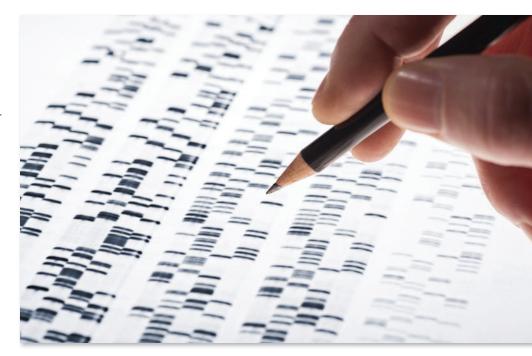
chronological age interact to affect expression of genes in the [arcuate nucleus (ARC) and the medial preoptic area (mPOA)] involved in neuroendocrine function."

#### Late-Onset Central Hypogonadism May Not Be Associated with Gene Mutation

A study presented at ENDO 2015 looked at the case of a healthy 16-year-old male who presented with hypogonadism, as well as fatigue, depressed mood, cold intolerance, and decreased libido, symptoms which had been occurring for nine months prior to evaluation. The patient also said he had been under a lot of stress, as well as exercising strenuously, and restricting his diet. The patient was diagnosed with central hypothyroidism (CeH) and hypogonadotropic hypogonadism (HH) and was prescribed levothyroxine 100 mcg/ day to determine whether his HH was secondary to CeH.

According to lead author Angela Delaney, MD, a pediatric endocrinologist with the Eunice Kennedy Shriver National Institute of Child Health and Human Development. the patient "had a remarkable response with resolution of all symptoms, improved growth, with an additional 4 cm gained over the subsequent year with final height and weight at the 50th percentile, consistent with familial height. TSH after six weeks was 0.36 mcIU/ml (0.3 - 5.0), T3 was 130 ng/dL (80 -200), and free T4 was 1.16 ng/dL (0.7 -2.0). After four months on therapy, he reported normal sexual function and libido and total testosterone was 376 ng/dL (262 – 1593). The patient has remained in good health on levothyroxine therapy."

The researchers then collected genomic DNA and sequenced the IGSF1 gene to determine the etiology of this clinical presentation of CeH with testicular enlargement despite biochemical evidence of HH. "No mutations in IGSF1 were identified," they wrote. This led the team to the conclusion that the patient's testicular volume was likely normal due to the onset of HH occurring in late puberty and did not represent macroorchidism in combination with CeH due to a mutation in the coding sequence of *IGSF1*. "This suggests that condition was reversible," Delaney says. "In the end, we believe it was a combination of significant stress... because once all those things reversed, he recovered," she says.



late-onset CeH may not be associated with *IGSF1* mutations," they wrote.

CeH usually presents much earlier, and Delaney and her team knew they would probably not find any mutations in the genes that they screened, because those phenotypes are usually associated with an earlier onset presentation. The *IGSF1* gene has been described as having a somewhat more variable presentation, and since the patient's symptoms pointed to the gene as a possible culprit, they thought it was worth screening. "We weren't surprised that he did not have a mutation in that gene," Delaney says, "because it didn't exactly fit the phenotype, but we were curious."

"What evolved and became more interesting over time was that his

The implications of the study, according to Delaney, is that we tend to think of this hypothalamic dysregulation as only occurring in women, but we know that stress, strenuous exercise, and/or a restricted diet can be associated with hypogonadism and can affect multiple hypothalamic hormones. "But we really don't think about it in a male population," Delaney says. "It's clearly not as common in men, but if you look back at the literature and cases like his, it's clear that it does happen in some cases, and so the implication is that we should think about it."

"Down the line, it'll be interesting to have a better understanding of what the factors are that might make one man susceptible to it, compared to the rest of the men who don't experience that," she says.

#### Prevalence of Metabolic Syndrome in the U.S. Has Leveled Off

According data from the National Health and Nutrition Examination Survey (NHANES), about 35% of U.S. adults had metabolic syndrome in 2011 – 2012, which is about the same rate as earlier samples. The results were published recently in a research letter in the *Journal of the American Medical Association*.

Researchers led by Maria Aguilar, MD, of the Alameda

Health System-Highland Hospital in Oakland, Calif., noted that from 1999 – 2006, the U.S. had a reported



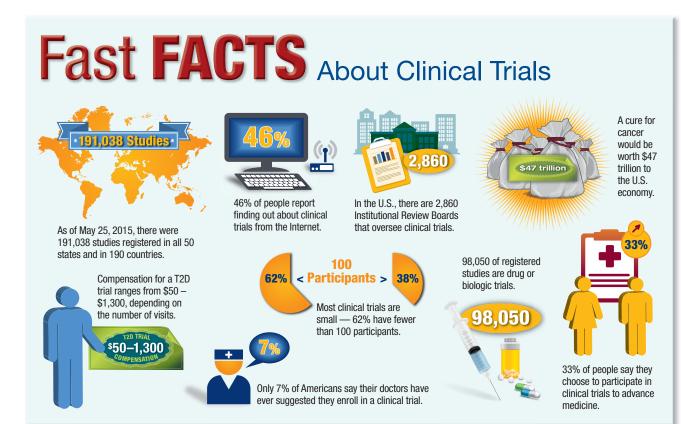
metabolic syndrome prevalence of 34%. "Understanding updated prevalence trends may be important given the potential effect of the metabolic syndrome and its associated health complications on the aging U.S. population," the authors wrote. "We investigated trends in the prevalence of the metabolic syndrome through 2012."

The researchers used 2003 – 2012 NHANES data and a definition of metabolic syndrome based on the National Cholesterol Education Program Adult Treatment Panel

III, updated by the American Heart Association, as having three or more of the following: a large waistline (35 inches or more for women; 40 inches or more for men), high triglyceride level (150 mg/dL or higher), low HDL cholesterol level, high blood pressure, high fasting blood sugar. They used weighted samples to get a better picture representative of the U.S.

> Aguilar and her team found that from 2003 to 2012, the overall prevalence of metabolic syndrome in the U.S. was 33%. From

2003 - 2004 the prevalence was 32.9%. That jumped to 34.7% in 2011 - 2012. The authors wrote that metabolic syndrome prevalence remained stable from 2007 - 2008 (36%) to 2011 - 2012 (34.7%). In 2011 - 2012, women showed a higher prevalence than men (36.6% versus 32.8%), and Hispanics had the highest prevalence of metabolic syndrome from 2011 - 2012 at about 39%. The data also show that metabolic syndrome prevalence appears to increase with age, which the authors called a "concerning observation in the aging U.S. population."



Sources: ClinicalTrials.gov, Institute of Medicine, the Center for Information & Study on Clinical Research Participation (CISCRP), University of Chicago

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# GREAT EXPECTATIONS

Clinical trials can offer hope for patients with intractable conditions when current medicine can't offer satisfactory treatment. Whatever the outcome, these patients can still contribute to the growth of scientific knowledge.



By Eric Seaborg

#### AT-A-GLANCE

- For patients with conditions for which there is no good treatment, a good option may be found among the thousands of clinical trials currently recruiting patients.
- Physicians should have in-depth conversations with potential trial participants to dispel misconceptions and make sure they understand the pros and cons.
- Trials can offer cutting-edge treatment and patient protections but do entail risks, with no guarantee that a treatment will work.

Certain patients may be among the most troubling in a clinician's practice. The diagnosis is clear. The disease is debilitating. But modern medicine has no good answer.

Endocrinology is replete with these conditions — consider Cushing syndrome, invasive pituitary tumors, nonresectable neuroendocrine tumors, many aspects of infertility, inborn metabolic defects, and glycogen storage diseases to name just a few. Even most treatments for the condition that dominates the field — diabetes — are aimed at staving off complications and comorbidities rather than effecting a cure.

One important alternative that a physician can offer these patients is a clinical trial. A clinical trial comes with no guarantees. But it offers the patient the important commodity of hope, at times can offer a breakthrough treatment, and always contributes to the growth of scientific knowledge.

"I think patients benefit from being in clinical trials because the questions that we study arise when we really don't know whether one treatment is better than the other. So people who are in clinical trials are really getting state-of-the-art treatment," says Judith Fradkin, MD, director of the Division of Diabetes, Endocrinology, and Metabolic Diseases at the National Institute of Diabetes and Digestive and Kidney Diseases. "The trials are comparing what we think is the best treatment or two different strategies when we aren't sure which is the best treatment, so people in clinical trials get very good care." Fradkin says that the benefits of a clinical trial can last for many years. The Diabetes Control and Complications Trial ran for 10 years and proved the benefits of tight control of blood glucose. Patients who received intensive intervention and achieved lower hemoglobin A1c levels are still displaying benefits years after the study ended in 1993. In the years since the study, the glucose control of both study groups has been essentially the same, but a recent study found the mortality rate of patients in the intervention group is half that of the control group.

#### How to Find a Trial

The go-to place to look for a trial is www.clinicaltrials.gov. Run by the National Library of Medicine, the website describes almost every clinical trial of consequence, including studies funded by the National Institutes of Health (NIH) as well as pharmaceutical company tests of new drugs. It currently lists 190,000 trials in 190 countries, with 46,000 of them currently recruiting participants. It includes information on a trial's objectives, inclusion criteria for participants, and contact information for the investigators and study sites. It describes what a participant can expect in terms of drugs to be taken, whether some participants will receive a placebo, and requirements for site visits. The website can be searched by key phrases and conditions, by institutions sponsoring the trials, by city, and more.

Fradkin recommends also visiting the NIH website to look for the "intramural" studies that the NIH conducts in-house. Although these may require visits to the NIH campus in Bethesda,

Md., or a satellite branch in Phoenix,

Ariz., sometimes they can pay for a patient's travel, particularly in cases of rare conditions.

Another route to finding a trial is old-fashioned networking with your colleagues and other experts, according to Richard Auchus, MD, PhD, professor of internal medicine at the University of Michigan Health System in Ann Arbor: "Email somebody that you know who is a leader in the field or who works at a place that has particular expertise in the condition."

"I contact someone who I know is an expert in the area to ask, 'Do you know of anything that

"I think patients benefit from being in clinical trials because the questions that we study arise when we really don't know whether one treatment is better than the other.

#### So people who are in clinical trials are really getting state-of-the-art treatment."

 Judith Fradkin, MD, director, Division of Diabetes,
 Endocrinology, and Metabolic
 Diseases, National Institute of
 Diabetes and Digestive and Kidney
 Diseases, Bethesda, Md.

"The only reason the investigators are doing the clinical trial is that they don't know whether the treatment is actually better, **so patients should not assume that the treatment is better."** 

— Nanette Santoro, MD, E. Stuart Taylor Chair of Obstetrics and Gynecology, University of Colorado School of Medicine, Aurora, Colo. is ongoing, to find out what is happening," says Nanette Santoro, MD, E. Stuart Taylor Chair of Obstetrics and Gynecology at the University of Colorado School of Medicine in Aurora.

#### **Prepping the Patient**

Deciding whether a trial is the best option for a patient "requires a pretty sophisticated discussion," Santoro says. Many patients harbor a "therapeutic misconception" and assume that they will benefit from a trial. A physician may need to explain the concept of randomization, and make sure patients understand that they may receive a placebo rather than an active drug — and that even if they receive the drug, the drug may not be effective, and can even be harmful. Patients need to understand that "the only reason the investigators are doing the clinical trial is they don't know whether the treatment is actually better, so patients should not assume that the treatment is better."

And a patient may not be a good fit for the conditions of a trial. "Sometimes as an investigator, you just have to say, I am not comfortable with having that patient on placebo, so I won't enroll them in that trial," Auchus says. "You have to make that judgment as the treating physician, as an investigator."

He adds that study designs must be approved by an institutional review board, which will consider how to ameliorate the consequences of receiving a placebo. For example, Cushing syndrome causes hyperglycemia and hypertension, so participants in a Cushing trial would be likely to receive medications to control glucose and blood pressure. "If the trial design does not provide some patients adequate treatment for the Cushing's, provisions must be in place to treat the comorbidities," Auchus says.

Studies contain other safeguards as well. For example, in the study of lanreotride for gastrointestinal neuroendocrine (carcinoid) tumors, if patients required a specified amount of rescue treatment to control diarrhea, the randomization code could be broken and they could be crossed over to the

active drug. "Many times placebo-controlled trials are designed such that if patients on placebo continue to the primary endpoint, then they can get crossed over to actual drug. So, many times patients will eventually get the drug, and often the sponsor will offer continued treatment to patients who respond well in an extension phase until the drug gets approved," Auchus says.

And of course, many trials do not involve placebos, but can be head-to-head tests to see which treatment is best and follow myriad other formats.

Patients also need to be aware that there can be costs of participating, such as having to take time off from work, travel to the study site, take a drug with little-known effects, and other inconveniences. Some of these costs may be reimbursed.

In some cases, participation can entail substantial financial benefits. "People can receive thousands of dollars of medicine as well as free blood testing, EKGs, and various other health measures," Auchus says.

Participants in a current NIH-funded comparative effectiveness study of diabetes drugs known as the GRADE study will receive seven years of diabetes medications and supplies, care visits, lab tests, and diabetes education at no charge. (See "Coming Attractions: Top Endocrinology Clinical Trials at NIH" on page 14.)

The cost issue can be important in reproductive medicine, but Santoro says that her specialty is somewhat unusual with respect to the patients' motivations to seek their own solutions: "We really are sort of emerging out of the dark ages with fertility treatments, because there has been so little evidence for so many of them. Patients will often come in recommending things that range from the utterly off the wall — stuff that is being advertised without proof — to things that have various levels of plausibility, but inadequate evidence.

In those kinds of settings, I encourage patients to participate in clinical trials because then not only will they get a possible exposure to the treatment, but it will actually contribute to the answer and make it better for the next person who has that same decision to make."

#### No Substitute for Experience

Patients must thoroughly understand and have their questions answered before they sign a consent form, and Santoro's final piece of advice is that physicians should consider participating in a trial themselves so they can tell their patients what it is like. She has done this "just so I know what I am asking people to do. Then I was able to tell people, this is what I am asking you to do. It gives you a whole new take on the burden of the trial."

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## Coming Attractions: **TOP** Endocrinology **NIH** Clinical Trials at **NIH**

NIH funds billions of dollars in medical research each year and many of the studies will have profound effects on the practice of endocrinology. Here's an overview of some of the leading endocrine-related studies currently taking place.

**By Eric Seaborg** 

Medical knowledge marches forward one study at a time. The National Institutes of Health (NIH) oversees perhaps the premier medical research program in the world, involving billions of dollars. NIH develops and tests many cutting-edge therapies, but also concentrates on plugging the gaps in knowledge that private entities will be unlikely to fund, such as new uses for generic drugs, the effectiveness of dietary supplements, and head-to-head comparisons of drugs made by different companies, says Judith Fradkin, MD, director of the Division of Diabetes, Endocrinology, and Metabolic Diseases at the National Institute of Diabetes and Digestive and Kidney Diseases.

Here is a very small sampling of the most intriguing and anticipated trials related to endocrinology, chosen in consultation with the Endocrine Society's Research Affairs Core Committee and NIH staff.

#### Sex Hormone Treatment

Testosterone supplementation has been advertised so heavily that "low T" has become a catch phrase, without much hard data about its efficacy. The multicenter Testosterone Trial involves men 65 years and older who have low blood testosterone and at least one accompanying problem. Some 800 men were randomized to receive testosterone gel or placebo in six trials of the treatment's effects on physical function, vitality, sexual function, cognitive function, anemia, and cardiovascular risk. Results will begin appearing later this summer, so physicians will have a better evidence base for responding to patients prompted to "ask your doctor."

The clinicaltrails.gov identifier: NCT00799617

On the women's side, Menopause Strategies: Finding Lasting Answers for Symptoms and Health (MsFLASH), is a network of researchers conducting randomized clinical trials to test a variety of approaches for treating menopausal symptoms like hot flashes, sleep disturbance, mood disorder, and sexual dysfunction. Most of the early findings have shown that many widely used over-the-counter treatments are ineffective — important findings because "these were things people were spending gazillions of dollars on," according to Nanette Santoro, MD, E. Stuart Taylor Chair of Obstetrics and Gynecology at the University of Colorado School of Medicine in Aurora.

Various studies are continuing to enroll patients at five research centers around the country.

For information, visit http://msflash.org.

#### Vitamin D Trials

"The rate of prescriptions for vitamin D has gone up astronomically. It has become a very popular treatment without a lot of hard evidence, so clinical trials are important," Fradkin says.

The VITamin D and OmegA-3 Trial (VITAL) is a randomized trial of almost 26,000 U.S. men over 50 and women over 55 investigating whether taking daily dietary supplements of 2000 IU of vitamin D3 or 1 gram of omega-3 fatty acids reduces the risk of developing cancer, heart disease, and stroke in people who do not have a history of these illnesses.

The study began enrolling subjects in 2010 and has filled its quota, with an expected completion date of October 2017.

The clinicaltrials.gov identifier: NCT01169259

Observational studies suggest that vitamin D may lower the risk of developing type 2 diabetes. The VITamin D and Type 2 Diabetes Trial is testing whether a vitamin D supplement can prevent or delay the onset of type 2 diabetes in adults 30 and older who have prediabetes. It should also improve understanding of how vitamin D affects glucose metabolism. Researchers at 20 sites around the country will randomize about 2,500 volunteers who have a BMI of 24 to 42 and other diabetes risk factors to receive either a once daily vitamin D3 soft gel or a placebo for three years. The daily dose of 4,000 IUs of vitamin D is much higher than the 600 to 800 IUs recommended by the Institute of Medicine. The study began enrolling subjects in late 2013, and enrollment will take about two years.

The clinicaltrials.gov identifier: NCT01942694

#### **Comparing Diabetes Treatments**

Metformin is the first choice among drugs for treating type 2 diabetes, but most patients will progress to needing another drug as well. There is a large variety of these drugs, but a dearth of information on which work the best with metformin. Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE) is open to patients 30 years and older on metformin who developed type 2 diabetes within the past 10 years. Participants will be randomly assigned to one of four commonly used glucose-lowering drugs in addition to their metformin: glimepiride, sitagliptin, liraglutide, or basal insulin glargine. They will be followed for up to seven years to determine the best combination for glycemic control, side effects, and overall health. Forty-four clinical sites have enrolled almost 1,700 of a projected 5,000 participants.

The clinicaltrials.gov identifier: NCT01794143

#### **Preventing Beta Cell Loss**

The Restoring Insulin Secretion (RISE) study is a set of small trials testing methods to improve and preserve the production of insulin in people who have prediabetes or have been recently diagnosed with type 2 diabetes.

Two of the trials will examine whether these patients should be treated sequentially — adding drugs as needed — or whether more aggressive initial treatment could give the insulin-producing beta cells a chance to rest and restore function.

A trial for adults will compare a placebo to three drug regimens: metformin alone, metformin plus liraglutide, and glargine used for three months before switching to metformin.

The clinicaltrials.gov identifier: NCT01779362

A trial in youth aged 10 to 19 will compare metformin alone to a regimen of using glargine for three months before switching to metformin.

The clinicaltrials.gov identifier: NCT01779375

#### A Gout Drug for Kidney Disease?

Preventing Early Renal Loss (PERL) in type 1 diabetes is the kind of study that no pharmaceutical company could profit from: a new use for a cheap drug used

#### AT-A-GLANCE

- NIH studies often answer questions that profitmaking entities can't afford to ask — such as which is the best diabetes drug to accompany metformin.
- Supplements and vitamins often become popular based on epidemiological studies that cannot show cause and effect. Clinical trials of vitamin D will provide hard data on its true benefits.
- A special appropriation for research into type 1 diabetes is permitting ambitious research that could return big dividends in prevention.

to treat gout for 30 years. Diabetic kidney disease is a huge problem, and studies indicate that moderately elevated serum uric acid may play a pathogenic role. Allopurinol has been used for many years to decrease high blood uric acid, so this trial will test its efficacy in maintaining kidney function in people with type 1 diabetes early in the course of kidney disease. The international trial began enrolling patients in early 2014, aiming for 480 patients at 13 diabetes centers. Patients are randomly assigned to take allopurinol or placebo for three years to see whether the drug slows the loss of kidney function.

The clinicaltrials.gov identifier: NCT02017171

**Special Funding for Type 1 Diabetes** NIH has a special annual \$150 million appropriation recently extended through 2017 — advocated for by the Endocrine Society — for research into type 1 diabetes that is allowing it to undertake "big bold things that we would not otherwise be able to do," NIH's Fradkin says.

In one initiative, researchers screened almost half a million newborns to find people with the high risk HLA genotype, which led to the enrollment of 8,000 children to monitor and analyze environmental factors that might contribute to the development of type 1 diabetes.

Another study has screened some 1.5 million family members of people with type 1 diabetes to enroll people in several ongoing trials of strategies to prevent the progression from autoimmunity to type 1 diabetes. The studies are run under the auspices of an international network of researchers known as TrialNet, which includes 18 centers running clinical trials and more than 150 participating medical centers and physicians' offices.

For information, visit www.diabetestrialnet.org/studies/

NIH is also investing millions in trials testing the development of several "artificial pancreas" models, but space considerations dictate that these important trials will be covered in a future issue of *Endocrine News*. EN ENDOCRINE News • JULY 2015

 Seaborg is a freelance writer based in Charlottesville, Va. He wrote about the microbiome in the May issue.

### Feature story

#### Indecent Exposures: EDCS AND BODE AND WOMEN'S HEALTH The evidence is endocrine-distriand their link to reproductive pro problems is going avoiding certain

The evidence is stacking up against endocrine-disrupting hormones and their link to a variety of female reproductive problems. Reducing these problems is going to take more than simply washing fresh produce and avoiding certain pre-packaged foods.

#### **By Kelly Horvath**

A ccording to the recent Introduction to Endocrine Disrupting Chemicals (EDCs): A Guide For Public Interest Organizations and Policy Makers published jointly by the Endocrine Society and IPEN, almost 100% of the world's population has detectable amounts of EDCs — phthalates (plasticizers), bisphenol A (BPA), polychlorinated biphenyls (PCBs), etc., in their bodies — chemicals that did not even exist prior to the 20th century.

"Studies on human populations show associations between the presence of certain chemicals and higher risks of certain endocrine disorders such as impaired fertility, diabetes and obesity, and cardiovascular disorders," says Andrea C. Gore, PhD, professor at the University of Texas at Austin and lead author of the guide. "Chemicals that interfere with hormone actions - even at low doses - are particularly detrimental when exposures happen during development. This 'developmental origin of health and disease' hypothesis is absolutely critical to consider."

For women, EDCs can be especially tricky substances, impairing reproductive functions across the life cycle, from causing problems with development of the oocyte pool to inducing early puberty to increasing rates of miscarriage and infertility. "We know this from animal studies in the lab, from research on wildlife that have been exposed to EDCs (especially pesticides), and from population studies in humans," Gore says. "Along with reproductive function are increases in reproductive cancers — breast, ovarian, and endometrial cancers are on the rise and are associated with EDC exposures."

#### Early Menopause and EDC Exposure

In "Persistent Organic Pollutants and Early Menopause in U.S. Women," published online in PLoS ONE, study authors led by Amber R. Cooper, MD, MSCI, Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, Washington University in St. Louis, Barnes-Jewish Hospital, St. Louis, Mo., sought to determine whether earlier age of menopause is also associated with EDC exposure. Although menopause timing might not seem like the gravest potential negative health impact from EDC exposure, in fact, it could have far-reaching individual and population-wide effects. Earlier menopause not only reduces a woman's fertility but also puts her at risk for earlier cardiovascular disease and osteoporosis development. On a societal scale, decreased fecundity raises difficult questions for human reproduction.

Thus, to more fully elucidate this problem, Cooper and her research team surveyed National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2008 to evaluate the serum or urine levels of dioxins/furans, phytoestrogens, phthalates, PCBs, phenolic derivatives, organophosphate pesticides, surfactants, and polycyclic aromatic hydrocarbons (PAHs) in 31,575 U.S. menopausal women older than age 30 years with intact reproductive organs. Of the eight categories of EDCs studied, 111 individual chemicals were analyzed, 15 of which demonstrated a significant association with loss of ovarian function. Specifically, women with the highest levels of  $\beta$ -hexachlorocyclohexane; mirex; p,p'dichlorodiphenyldichloroethylene; 1, 2, 3, 4, 6, 7, 8-heptachlorodibenzofuran; mono-(2-ethyl-5-hydroxyhexyl) and mono-(2-ethyl-5-oxohexyl) phthalate; and PCB congeners -70, -99, -105, -118, -138, -153, -156, -170, and

#### AT-A-GLANCE

- Biomonitoring demonstrates that nearly 100% of the world's population now carries a chemical body burden due to the astronomical amounts of chemicals produced globally.
- Evidence that EDCs are the likely culprits behind increasing incidence of a host of female reproductive problems abounds. Most recently, an association was found between menopause onset 1.9 to 3.8 years earlier with exposure to one or more of nine PCBs, three pesticides, one furan, and two phthalates, as compared to menopause onset in women with lower levels of these chemicals.
- Because intake is a primary route of EDC exposure, a diet of chemical-, hormone-, antibiotic-, and pesticide-free food is recommended to avoid as much new EDC exposure as possible. Washing fresh fruit and vegetables with tap water removes most chemicals.

-183 experienced menopause 1.9 to 3.8 years earlier than those with lower levels. It's important to bear in mind, according to Cooper, that "we looked at everyday exposures across the United States, not experimental conditions. We need to be aware that these EDCs are in our everyday life, even if banned in the past, and they may be having an untoward effect on our ovaries, reproductive health, and overall well-being." The team also found that increasing serum or urine EDCs is associated with earlier ages of menopause, not just high absolute levels. Another strength of their approach is the number of lenses through which they made their observations, first examining the highest levels of EDC

exposure, then considering the dose-response relationship as both a continuous log-transformed variable and as a continuous variable based on decile of EDC level, and, finally, performing a secondary analysis of the 15 suspicious chemicals in a younger cohort of women to confirm their findings.

The team suggests several possible causes for the ovarian insufficiency, such as damage to the follicular pool happening over time, *in utero* exposure preventing development of adequate numbers of oocytes, and premature depletion of the follicular pool from recruitment of excess follicles. Although the causal mechanism has yet to be pinned down, Cooper says, "The bottom line is, I hope that this study increases awareness and promotes future research. It shows an association between increasing environmental exposures and earlier age at menopause, earlier than what has been linked with tobacco smoke in past studies. It does not prove cause and effect but warrants much more research."

#### **Cleaning Up Our Acts**

"It is surprisingly difficult to determine the extent of 'known exposures' because most of us are exposed to various chemicals throughout our lives," Gore says. "Most

"Studies on human populations show associations between the presence of certain chemicals and higher risks of certain endocrine disorders such as impaired fertility, diabetes and obesity, and cardiovascular disorders. Chemicals that interfere with hormone actions — even at low doses — are particularly detrimental when exposures happen during development. This 'developmental origin of health and disease' hypothesis is absolutely critical to consider."

- Andrea C. Gore, PhD, professor, University of Texas, Austin

of them are not overtly toxic, but the cumulative effects of exposures to mixtures of many chemicals at low doses but often of unknown identity, is hard to quantify." Yet given the profound biochemical disruptions they are linked to, finding some way to mitigate the effects of pervasive exposures seems imperative. "At this point, identifying and minimizing risk is the best we can do. Research is very important for trying to arrive at new therapies, so by understanding the mechanisms by which the chemicals act in our bodies, we will someday be able to do more efficient interventions," Gore says.

In the meantime, as she says, "avoiding exposure in the first place is, of course, the best case scenario."

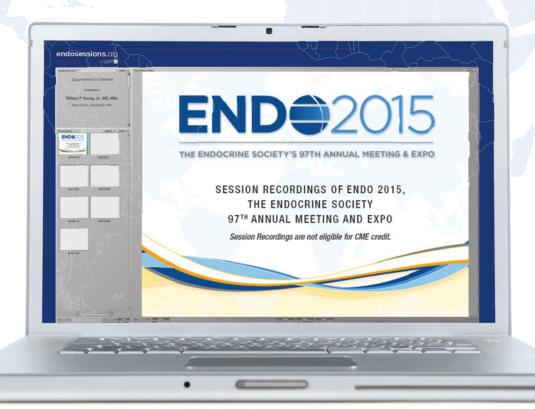
Because diet is the primary route for chemical exposure, "cleaning up" the food source is a good place to start. Exposure avoidance can mean advising patients to make simple lifestyle changes such as eating fresh rather than processed foods for obvious — and not so obvious - reasons. "Food contact materials such as cans, packaging, and plastic bottles, are not intended to leach chemicals into food and beverages, but this can happen, especially at hot temperatures (e.g., hot cars, microwaving, and heating food, etc.). Even if you're careful not to let your plastic water bottle get hot, you don't know whether it was transported across the country in an un-air-conditioned truck that sat out in the summer heat. The bottle may be nice and cool when you buy it at the supermarket, but leaching could have happened earlier," Gore explains.

Physicians should also prompt patients to be aware of the contents of other household chemicals, such as toiletries, she says. Furthermore, "keeping our homes clean and plugging holes under the sink reduces pests and minimizes the need for spraying with pesticides. There are also organic alternatives to chemical pest control." **EN** 

 Horvath is a freelance writer based in Baltimore, Md. She wrote about the myths of pediatric thyroid cancer in the June issue.

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## **GUTTED:** Tips and Trends in Laboratory Renovation

Whether it's to make room for new equipment or to adhere to upgraded energy standards, if your lab hasn't been redesigned in over a decade, you might be due for a change.

#### **By Melissa Mapes**

Laboratories require valuable real estate, of which institutions generally have a finite amount. Scientists must often compete with peers for space to pursue their projects, and when they do secure a location, they have to find a way to repurpose the facilities to make sense for their research. Sometimes, the only answer is renovation.

Bob Mitchell, of the Mitchell Architectural Group in Southbury, Conn., has been involved in over 250 laboratory development projects — the vast majority of which were renovations. "Labs go out of date primarily due to equipment configurations and layouts that no longer meet the evolving protocols of the laboratory functions," he explains.

The fast pace of science requires a design that can change and adapt with it. Thus, a quality remodel will make flexibility a foremost priority.

#### **Pliable Planning**

Mitchell encourages institutions to think about configurations that can be easily adjusted to fit new requirements in the near future (and likely save significant funds down the road).

"Assume anything you construct now will be wrong five years from now," Mitchell explains. "Develop a plan and infrastructure to allow reconfigurations and renovations to occur without shutting you down."

He recommends planning an organized, generic, and flexible facility to the greatest extent possible. Some examples include arranging fume hoods as anchors of lab activity and adding modular components to the design.

These improvements can be impeded by out-of-date and rigid standards set forth by facilities departments, resulting in a laboratory that is still better suited to old functions, despite recent renovation. Mitchell encourages institutions to embrace innovation instead. "We want the client not only to think outside the box — but to throw the box away," he says.



This academic laboratory at Hunter College in New York had not been updated in nearly 50 years. The concept of turning it into a high-level research facility required the project team to look at every aspect of the lab, and in particular the MEP distribution systems. The final design was developed using a phenolic casework system, allowing for custom dimensions, which were required due to exiting conditions, and an open ceiling plan to accommodate the MEP systems. Windows were retained and incorporated into the casework design.

#### The Price of Progress

Depending on the age of the building and the level of renovation needed, the cost of implementing a new design may vary. Mitchell has worked on jobs ranging from small retrofits to biosafety level (BSL) containment, and he claims that the largest issues are generally infrastructure upgrades. "These can seriously impact the cost and time frame for the renovations," he says.

Depending on the level of work needed, Mitchell estimates the price of a typical lab renovation to fall between \$280 to \$450 per square foot, not including new equipment. A highly specialized and complicated project can reach as high as \$1,200 per square foot. In



These research labs at Mount Sinai Medical Center in New York had long outlived their useful life and were completely renovated to support the needs of the cell and molecular biology units at the medical center.

terms of time frame, the construction usually takes about six to nine months.

#### Less Is More

To maximize the results of a renovation, it is crucial to keep efficiency in mind. Energy efficiency, efficient use of space, efficient use of funds, and efficient use of time are all markers of a well-conceived lab redesign.

Planning can start by estimating the number of people who use the lab. To make sure every person has a seat, it is often necessary to decrease the amount of space per individual.

According to Barbara A. Carpenter, associate principal at Tsoi/Kobus & Associates, a Massachusetts-based architectural firm, the typical lab bench assigned to each individual has shrunk from eight feet long to five feet long over the past 30 years. Carpenter described this trend as "densification" in an article she authored for *Laboratory Design* magazine,

"The idea of fitting 'more' in less space is an economic driver that has translated into the following commonly observed design themes: the shrinking of linear feet of bench assigned to each researcher, the elimination of small customized labs, the sharing of expensive scientific equipment, and the centralization of core functions," she wrote.

Some colleagues might resist the idea of smaller stations at first, but Carpenter says that including certain perks can make the concept more appealing. She suggests adding glass walls between workstations and the break area, so food and drink can be consumed without having to take one's eyes off the lab.

#### Find the Weak Spots

Without unlimited funds, only a certain amount of improvements can be made. The current conditions of the laboratory should be thoroughly investigated before making any redesign commitments. Once there is a list of upgrades, the committee can pick the top items possible while still staying within budget.

New survey equipment allows architects to make pretty accurate guesses as to the state of a building's innards, but it is next to impossible to identify every potential issue. Sometimes, tearing into the walls may reveal good surprises, like boarded doors or windows that can be reopened. But, that is rarely the case.

"Having a construction budget contingency to address unforeseen conditions is critical and should be part of the original budget development," Carpenter explains.

Energy consumption may be another factor influencing the importance of an upgrade. Some changes can lead to plentiful savings in the long term by reducing utility bills. This economic incentive could help convince leadership to boost the renovation budget.

The committee should identify sources of wasted energy in the laboratory. Old equipment is often an issue, as is an aging HVAC system. Even lighting design and the types of bulbs in place can have an effect. In addition to reducing energy costs, such upgrades will make the lab more sustainable and eco-friendly, offering wide appeal to groups both inside and outside the institution.

Eventually, every lab requires renovation. Through smart planning and forward-thinking design, the improved facilities can offer lasting power, keeping future overhauls at bay and creating a more organized, effective work environment for all involved. EN

> — Mapes is a Washington D.C.-based freelance writer and a regular contributor to Endocrine News. She wrote about the artificial pancreas in pediatric patients in the May issue.

## Trends in Lab Design at the **UNIVERSITY RESEARCH LEVEL**

- Generic, flexible labs
- Links to industry with corporate lab models
- Plan for more intense equipment usage and less bench space
- Limit the specific lab type not usable by another discipline. For example, chemistry and biology labs are becoming bio-chem labs.

 <sup>(</sup>Provided by Bob Mitchell, Mitchell Architectural Group Southbury, Conn.)

The following studies, among others, will be published in Endocrine Society journals. Before print, they are edited and posted online in each journal's Early Release section. You can access the journals at *www.endocrine.org*.



Glucose Metabolism in High Risk Subjects for Type 2 Diabetes Carrying the rs7903146TCF7L2 Gene Variant • Giuseppe Daniele, Melania Gaggini, Mario Comassi, Cristina Bianchi, Giuseppina Basta, Angela Dardano, Roberto Miccoli, Andrea Mari, Amalia Gastaldelli, and Stefano Del Prato • *In subjects at risk for T2DM, the* 

TCF7L2 polymorphisms were associated with reduced Raex into systemic circulation causing reduced post-prandial blood glucose increase and, in turn, lower insulin secretion rate with no impairment in beta cell function. The reduced Raex is likely due to greater glucose retention in the splanchnic area.

Association of Sleep Duration and Quality with Alterations in the Hypothalamic-Pituitary Adrenocortical Axis: the Multi-Ethnic Study of Atherosclerosis (MESA) • Cecilia Castro-Diehl, Ana V. Diez Roux, Susan Redline, Teresa Seeman, Sandi Schrager, and Steven Shea • Shorter sleep duration, lower sleep efficiency, and insomnia are associated with alterations in diurnal cortisol levels consistent with changes in hypothalamic-pituitary-adrenal regulation.

The Effects of Recombinant Human Insulin-like Growth Factor-I/Insulin-like Growth Factor Binding Protein-3 Administration on Body Composition and Physical Fitness in Recreational Athletes • Nishan Guha, Simon P. Nevitt, Michael Francis, John A. Woodland, Dankmar Böhning, Peter H. Sönksen, and Richard I.G. Holt • rhIGF-I/rhIGFBP-3 administration for 28 days improves aerobic performance in recreational athletes but there are no effects on body composition.

Post-Gastric Bypass Hyperinsulinemic Hypoglycemia: Fructose is a Carbohydrate Which Can Be Safely Consumed • Anne E. Bantle, Qi Wang, and John P. Bantle • People with post-gastric bypass hypoglycemia can consume a meal sweetened with fructose with little risk of hypoglycemia. Treatment with rapid acting insulin before a carbohydrate containing meal did not prevent hypoglycemia.



Neuroendocrine Function Following Hypothalamic Depletion of Glucocorticoid Receptors in Male and Female Mice • Matia B. Solomon, Matthew Loftspring, Annette de Kloet, Sriparna Ghosal, Ryan Jankord, Jonathan N. Flak, Aynara C. Wulsin, Eric G. Krause, Rong Zhang, Taylor Rice, Jessica McKlveen, Brent Myers, Jeffrey G.

Tasker, and James P. Herman • Overall, these findings reveal pronounced sex differences in the PVN GR depen-

dence of acute stress feedback regulation of HPA axis function. In addition, these data further indicate that glucocorticoid control of HPA axis responses following chronic stress operates via a PVN-independent mechanism.

#### Glucagon Receptor Blockade with a Human Antibody Normalizes Blood Glucose in Diabetic Mice and Monkeys

 Haruka Okamoto, Jinrang Kim, JohnPaul Aglione, Joseph Lee, Katie Cavino, Erqian Na, Ashique Rafique, Jee Hae Kim, Joyce Harp, David M. Valenzuela, George D. Yancopoulos, Andrew J. Murphy, and Jesper Gromada
 In summary, the glucagon receptor-blocking antibody REGN1193 normalizes blood glucose in diabetic mice and monkeys but does not produce hypoglycemia in normoglycemic monkeys. Thus, REGN1193 provides a potential therapeutic modality for diabetes mellitus and acute hyperglycemic conditions.

**Thyrostimulin Regulates Osteoblastic Bone Formation During Early Skeletal Development** • J.H. Duncan Bassett, Anne van der Spek, John G. Logan, Apostolos Gogakos, Jayashree B. Chakraborty, Elaine Murphy, Clementine van Zeijl, Jenny Down, Peter I. Croucher, Alan Boyde, Anita Boelen, and Graham R. Williams • *These studies identify thyrostimulin as a negative but indirect regulator of osteoblastic bone formation during skeletal development.* 

#### Testing the Critical Window Hypothesis of Timing and Duration of Estradiol Treatment on Hypothalamic Gene Networks in Reproductively Mature and Aging Female Rats Weiling Yin, Sean M. Maguire, Brian Pham, Alexandra N. Garcia, Nguyen-Vy Dang, Jingya Liang, Andrew Wolfe, Hans A. Hofmann, and Andrea C. Gore • *These results highlight*

the plasticity of hypothalamic neuroendocrine systems during reproductive aging and its surprising ability to adapt to diverse E2 replacement regimes.



Overexpression of the FoxO1 Ameliorates Mesangial Cell Dysfunction in Male Diabetic Rats • Guijun Qin, Yingni Zhou, Feng Guo, Lei Ren, Lina Wu, Yuanyuan Zhang, Xiaojun Ma, and Qingzhu Wang • Together, these findings shed light on the novel function of FoxO1 in inhibiting ECM deposition, which is beneficial to ameliorate MC dysfunction.

Minireview: Emerging Concepts in Islet Macrophage Biology in Type 2 Diabetes • David L. Morris • The intent of this review is to introduce the reader to emerging concepts of islet macrophage biology that may challenge the perception that macrophage accumulation in islets is merely a pathological feature of type 2 diabetes. PRACTICE RESOURCES

# Unconventional **WISDOM**

Endless curiosity and the ability to communicate with patients and other specialists are just two of the many duties of a good endocrine nurse.

#### By Kurt Ullman

Being an endocrine nurse can be a very challenging experience. It requires very strong observational skills and an ability to sift through mountains of information to find the most important indicators.

"Endocrine nurses are involved in a very holistic type of practice," says Margaret Eckert-Norton, PhD, FNP-BC, and certified diabetes educator at SUNY Downstate, Brooklyn, N.Y. "You have to be able to integrate technology with the whole person." This can be especially important considering the fact the endocrine diseases do not always (or perhaps even often) present with a clear path to the diagnosis.

"In most cases in medicine, we are trained to look for horses when we hear hoof beats," Eckert-Norton says. "In endocrinology, we are often zebra clinics seeing the rare disorders. We need to be able to see past the usual presentations."

She also notes that listening skills play a role in



endocrine nursing. "We have to get their entire story right to help find a proper diagnosis," Eckert-Norton notes. "You have to hear what they have to say in the context of their lives."

#### Understanding the Complications

A good understanding of pathophysiology is integral to the specialty.

"The endocrine system is a very complicated system of feedback loops and lots of different factors playing off one another, says Michelle Gurel, RN, BSN, a nurse at Massachusetts General Hospital's Neuroendocrine Clinical Center in Boston. "It takes a person who is fascinated by intricate processes."

Lots of data are usually available by the time a person gets to the endocrinologist's offices. Because of their multi-faceted nature, many tests will have been done, often by many different specialties before the diagnosis is made.

"There is a lot of detective work involved in the specialty," says Gurel, who is currently president of the Endocrine Nurses Soci-



#### "Many endocrine disorders are seen in patients with multiple comorbidities.

Because of this, we often have to work with practitioners from more than one additional specialty. We have to be not only able to translate endocrinology to the consumer but also translate endocrinology to the other specialists."

— Michelle Gurel, RN, BSN, Massachusetts General Hospital's Neuroendocrine Clinical Center, Boston their own injectable medications. This means that nurses have to be able to work with patients in multiple places and under differing circumstances.

All of this is a prerequisite for one of the more important functions of endocrine nursing, the ability to take the complex and make it understandable. But an understanding of how the endocrine system works is not enough.

"Many endocrine disorders are seen in patients with multiple comorbidities," Gurel says. "Because of this, we often have to work with practitioners from more than one additional specialty. We have to be not only able to translate endocrinology to the consumer, but also translate endocrinology to the other specialists."

She also notes that these same communications skills are important in dealing with patients.

"One of the keys of this specialty is the ability to say to your patient that while this is a very complex system, I'll break it down for you," Gurel says. "I want to make it not only understandable,

ety (ENS). "Because of this, persistence and attention to detail is an important part of an endocrine nurse's make up."

In addition, endocrine diseases may present with a group of symptoms that are similar to other disorders. For example, those with pituitary diseases may complain of weight gain, body aches, and fatigue that can be attributable to a number of distinct diseases across many systems.

"It is definitely a matter of doing your due diligence," Gurel says. "Listening to your patients can lead to that one special detail in their constellation of symptoms that help in establishing a diagnosis."

#### **Flexible Thinking Required**

A certain amount of flexibility in thinking is an important part of being an endocrine nurse. More than many other specialties, this one focuses on chronic care in the home and is more clinic-based. It is also one of the few where patients in the community are tasked with giving but manageable for my patients. They then become a part of the entire process of their own care."

Those interested in endocrine nursing have many educational opportunities available to them. One avenue is through membership in the Endocrine Nurses Society (*http://endo-nurses.org*). ENS provides endocrinerelated learning experiences and sponsors an annual meeting and exposition as well as presenting topics at the Endocrine Society meetings yearly. For those wanting to work with children, Pediatric Endocrine Nursing Society (*http://pens.org*) has similar services.

"One of the concerns of nursing in general is the increasing average age of nurses and the imminent retirement of many," Eckert-Norton says. "We need to grow a new crop of nurses in this and most other specialties." EN

— Ullman, RN, MHA, is an Indiana-based freelance writer with nearly 30 years of experience. He wrote about medical scribes in the June issue.

#### ADVOCACY

#### Society Members Participate in European Commission Conference on EDCs, Meet with Members of the European Parliament, Share New Position Statement

On June 1, R. Thomas Zoeller, PhD, co-chair of the Society's EU and Global EDC Task Forces presented during the European Commission (EC) Conference on Endocrine Disruptors: Criteria for Identification and Related Impacts and told the European Commission that current approaches to identify EDCs are not effective because they do not take into account critical endocrine principles.

The one-day conference, organized by the European Commission Directorate General for Health and Food Safety (DG SANTE), gathered stakeholders to "inform Member States, Members of the European Parliament (MEPs), third-country representatives, and stakeholders about the on-going impact assessment on criteria to identify endocrine disruptors and to provide a platform for further exchanges of views." The Endocrine Society was invited to present our scientific perspective on EDCs following our submission of comments to the European Commission in response to its public consultation on EDCs. Participants at the conference discussed scientific aspects of the criteria to identify EDCs, the EU legislative framework for EDCs, and potential impacts on industry, consumers, trade, agriculture, health, and the environment. The conference ended with little agreement on a path forward; however, several stakeholders emphasized that there exists a broad scientific consensus on the definition for EDCs and that further regulatory action is needed.

Society EU Task Force members Jean-Pierre Bourguignon, MD, PhD, Barbara Demeneix, PhD, Richard Ivell, PhD, Giancarlo Panzica, PhD, and Rémy Slama, PhD, also participated in the conference. The conference was limited to nearly 280 participants; however, stakeholders worldwide could watch a live webcast of the conference. The Endocrine Society actively generated additional attention through dedicated social media efforts. The Society's media twitter account featured live tweets of the conference and prompted interaction from EU scientists, journalists, public interest groups, and members. @EndoMedia added 10 followers as a result, including MEP Pavel Poc. In response to the Society's press release, coverage from Endocrinology Advisory highlighted Zoeller's presentation.

Following the conference, the Society's EU Task Force members met with several MEPs to discuss the Society's messages on EDCs and emphasize the importance of taking action and avoiding additional delays. The meetings also offered a chance for MEPs to learn more about the Endocrine Society's response to the



Endocrine Society EU EDC Task Force Members at the European Commission Conference on EDCs *(left to right)*: Joseph Laakso, PhD, Endocrine Society's associate director, science policy; Giancarlo Panzica, PhD; Jean-Pierre Bourguignon, MD and EU EDC Task Force Co-Chair; Rémy Slama, PhD; Barbara Demeneix, PhD, DSC; and Richard Ivell, PhD.



Endocrine Society member and co-chair of the EU EDC Task Force, R. Thomas Zoeller, PhD, delivers a scientific presentation called "Identifying EDCs for Public Health Protection: The Endocrine Perspective."

Commission's public consultation on EDCs and why a "potency" cutoff as part of the criteria for identifying EDCs is not scientifically justifiable.

In November 2015, the Commission intends to organize a workshop focusing on the development and evaluation of test methods for identifying EDCs. Additionally, a screening study will examine the impact and consequences of establishing various criteria for the identification of EDCs. The Commission anticipates that the process will continue through 2016. The Society will remain engaged to ensure that the perspective of endocrinologists is incorporated into the ongoing debates. To help advance the discussion, the Society recently issued a Position Statement on EDCs in the EU with specific policy positions and recommendations for regulators to consider moving forward. The Position Statement is available on the Society's website *www.endocrine.org*.

#### Society Supports NBHA Response to British Medical Journal Bone Fragility Paper

The Endocrine Society supports the U.S. National Bone Health Alliance (NBHA) response to the May 26 *British Medical Journal* paper, "Overdiagnosis of bone fragility in the quest to prevent hip fracture," disputing the paper's authors' argument "that evidence for stratifying risk of fracture and subsequent drug therapy to prevent hip fracture is insufficient to warrant our current approach."

The NBHA is a public-private partnership of 48 organizations, including the Endocrine Society, and five U.S. federal government agency liaisons, co-chaired by the American Society for Bone and Mineral Research (ASBMR) and the National Osteoporosis Foundation (NOF). The NBHA's goal is to enact the recommendations outlined in the "2004 Bone Health and Osteoporosis: A Report of the United States Surgeon General" to reduce osteoporosis-related fractures.

The NBHA response disagrees with the paper's authors — that treatment of osteoporosis is futile — and points out that this premise is contrary to the worldwide consensus that the fracture liaison service (FLS) model of care is the mechanism to get at the post-fracture diagnosis, screening, and treatment gap. The NBHA and its partners are focused on identifying those individuals at greatest risk for a second fracture: those who have already suffered from a previous osteoporotic fracture. Through the widespread implementation of FLS programs, the goal is to identify and treat osteoporosis in high-risk individuals. The response also identifies that treatment of individuals who have already experienced a fracture is effective and prevents secondary spine and hip fractures.

#### Society Works with Diabetes Congressional Caucus to Spur Support for Diabetes Legislation; Endorses Legislation to Eliminate Disparities in Diabetes

The Endocrine Society is working with the Diabetes Congressional Caucus to increase support for various diabetes-related bills. On June 8, the Society participated in a Diabetes Congressional Caucus legislative briefing to provide information to congressional staff on diabetes legislation in the 114th Congress and to increase the number of co-sponsors on diabetes legislation. The Society gave a presentation on new legislation, the Eliminating Disparities in Diabetes Prevention, Access, and Care Act (HR 2651).

The briefing included background information for congressional staff on the challenge of diabetes and the legislative goals of the caucus as well as information about the following caucus leadership-sponsored bills:

- Protecting Access to Diabetes Supplies Act (HR 771)
- Medicare CGM Access Act (HR 1427)
- Preventing Diabetes in Medicare Act (HR 1686)
- Access to Quality Diabetes Education Act (HR 1726)
- Eliminating Disparities in Diabetes Prevention, Access, and Care Act (HR 2651)
- Medicare Safe Needle Disposal Coverage Act (HR 1727)
- National Diabetes Clinical Care Commission Act (HR 1192)
- Medicare Diabetes Prevention Act (HR 2102)

The Endocrine Society was one of the first advocacy groups to support the Eliminating Disparities in Diabetes Prevention, Access, and Care Act. This bipartisan bill promotes diabetes research, treatment, and prevention in minority populations. The bill includes provisions to increase research at the National Institutes of Health, enhance treatment and prevention programs administered through the Centers for Disease Control & Prevention, and increase efforts by the Health Resources and Services Administration to strengthen the health workforce in underserved areas.

#### Endocrine Society – IPEN Guide on Endocrine-Disrupting Chemicals Now Available in Spanish

Last December the Endocrine Society and IPEN, a leading global network of 700 non-governmental organizations (NGOs) working to establish and implement safe chemicals policies and practices, collaborated on the publication of *Introduction to Endocrine-Disrupting Chemicals (EDCs): A Guide for Public Interest Organizations and Policy Makers.* The purpose of the Guide is to raise global awareness about EDCs and help global policy makers, government leaders, and public interest organizations better understand what EDCs are and the impact EDCs have on human health. Authors of the Guide are Endocrine Society members: Andrea Gore, PhD, David Crews, PhD, Loretta Doan, PhD, Michele La Merrill, PhD, MPH, Health Patisaul, PHD, and Ami Zota, ScD, MS.

We are pleased to announce that the Guide is now available in a Spanish translation. Copies of the guide in English and Spanish are available at *http://www.endocrine.org/edcguide*.

The Endocrine Society and IPEN are disseminating the Guide and hope that greater awareness gained by its information will lead to additional programs to enhance knowledge of EDCs, to foster new research into the effects of these chemicals, and to promote a greater appreciation for the critical need for endocrine principles to be applied in formulating EDC policy and regulations. EN

## AstraZeneca Named *Endocrine News* Advertiser of the Year at ENDO 2015



On March 6, AstraZeneca LP was presented with the Endocrine News Advertiser of the Year Award at a ceremony held during ENDO 2015 at the Hilton San Diego Bayfront. Pictured are (I to r): Eva Tsalikian, MD, chair of the Development Committee; Curtis Carter, director of Advocacy, U.S. Medical Affairs, Metabolics, AstraZeneca, LP, Richard Santen, MD, past-president of the Endocrine Society; John Yee, MD, MPH, VP, and U.S. head of Medical Affairs, Diabetes, AstraZeneca, LP. AstraZeneca is a Diamond Leadership Donor in addition to receiving the Endocrine News Advertiser of Year and Online Advertiser of the Year awards. Special recognition was also given to the Journal Advertiser of the Year (Boehringer Ingelheim Pharmaceuticals, Inc. & Lilly USA, LLC). - PHOTO: David Tulchinsky

## Sundeep Khosla Named to NIAMS Advisory Council



Sundeep Khosla, MD, a past chair of the Society's Clinical Endocrine Education Committee, the Annual Meeting Steering Committee, and the Laureate Awards Committee, has been named to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) advisory council. Part of the National Institutes of Health (NIH), the council comprises scientific and lay members who have expertise in the

mission areas of the institute. Council members provide advice to the institute on broad policy issues and make recommendations on research proposals.

Khosla is the Dr. Francis Chucker and Nathan Landow Research Professor, a Mayo Foundation Distinguished Investigator, and the dean for clinical and translational science at the Mayo Clinic College of Medicine in Rochester, Minn. As principal investigator on a number of NIH grants, Khosla's research projects include investigating the mechanisms of bone loss in women and men, sex hormone action on bone, and the biology of osteoprogenitor cells (those involved in the growth or repair of bone) and stem cells.

Aside from his duties as a past committee chair and member, Khosla has seved on the **ENDO** Editorial Board, the *Journal of Clinical Endocrinology & Metabolism* Editorial Board, and is currently on the Advisory Board for *Endocrine Reviews.* **EN** 

#### Society Journal Sites Gets Upgraded

The Endocrine Society journal sites are in the process of moving to a responsive web design, which will optimize the journal content viewing experience for readers.

This new responsive design will allow readers to view content on your smartphones, tablets, and a variety of other devices. With this user-friendly shift, the journals are doing away with the current journals app and will cease production within the next few months.

If you have questions or concerns about this, please contact Maggie Haworth, associate director, Publishing Operations, at *mhaworth@endocrine.org*.

#### ICE/ENDO 2014 Honored by **TRADE SHOW EXECUTIVE**

Honored as one of the 50 Fastest-Growing Shows of 2014

It appears that not only was **ICE/ENDO 2014** a record breaker for the Society, but it was also an award-winning event, according to *Trade Show Executive* magazine. The publication bestowed three separate "Fastest 50" awards on **ICE/ENDO 2014**: Fastest Growing Medical Meeting, Greatest Percentage Growth in Attendance, and Greatest Percentage Increase in Exhibits.

Society executive director and CEO Barbara Byrd Keenan says that the Society is honored to receive these awards. "The staff and members work very hard to develop an outstanding scientific meeting, and it is clearly meeting the needs of our membership," she says. "And we are very grateful to our industry partners and suppliers!"

The awards were presented at the Fastest 50 gala on May 21 at the Hyatt Regency in Chicago.

#### HHN's Cheretta Clerkley Recognized by the ASAE

Cheretta Clerkley, MBA, CASE, director of the Endocrine Society's Hormone Health Network (HHN), has been chosen as one of the American Society of Association Executive's (ASAE) Diversity Executive Leadership Program (DELP) scholars for the class of 2015 – 2017.

DELP provides individuals from underrepresented segments of the association community an opportunity to advance into the ranks of leadership in the association profession by offering access to ASAE educational programs, career guidance, mentoring, volunteer service, and networking opportunities. Clerkley is one of 12 scholars chosen as part of the 2015 – 2017 class, a two-year program that includes a dynamic learning experience that will prepare the scholars for future leadership roles.

"I'm so thrilled to be selected as one of ASAE's DELP Scholars," Clerkley says. "I'm looking forward to the professional development opportunities the program will afford me, the chance to participate in open dialogue about diversity and what it means for an organization to truly champion, and most importantly, to represent the Society and promote the importance of communicating effectively about diversity commitments. It's such an honor and one that I humbly accept."

Clerkley came to the Society in November 2013 to oversee HHN after serving as director of marketing and corporate relations with the American Society for Parenteral & Enteral Nutrition (ASPEN) from 2011 to 2013. Prior to that, she was the corporate client services manager with the American Diabetes Association where she was charged with driving full-scope corporate communications and serving as project lead for the Annual Corporate Sponsor Summit. Other experience includes the Children's National Medical Center, Kingsbury, and Prince George's County (Md.) Health Department. A 2005 graduate of Temple University, Clerkley received her MBA from University of Maryland University College in 2011.

Since coming to the Society in 2003, Clerkley has overseen remarkable growth in the programs that HHN offers in its mission to increase patient awareness. Among the initiatives she has set in motion are: Secured funding for a new patient initiative for Diabetes University from BI Lilly Diabetes Alliance and Janssen Pharmaceuticals, Inc.; developed and launched an updated Menopause Map with an accompanying extensive social media campaign; redesigned HHN's fact sheets to create a new line of easily digestible infographics; launched new International Resource Center on hormone.org to

support global patient education and the Society's global initiatives; and wrote and submitted a successful Strategic Plan Initiative (SPI) proposal to Council for the Journey Through the Endocrine System a 21st century solution that will enhance the understanding of the intricacies of the endocrine system through the use of contemporary technology to tell a comprehensive story of the endocrine system and its related conditions.

ASAE is a membership organization of more than 21,000 association executives and industry partners representing 9,300 organizations. Its members manage leading trade associations, individual membership societies, and voluntary organizations across the U.S. and in nearly 50 countries around the world. **EN** 



#### Society Proposes Revisions to New Chemical Safety Legislation

The Endocrine Society has proposed several changes to new chemical safety legislation under consideration in the Senate.

Recently, several stakeholders contacted the Endocrine Society for its perspective on the Frank R. Lautenberg Chemical Safety in the 21st Century Act, a new bipartisan attempt to reform the Toxic Substances Control Act (TSCA), which was implemented in 1976 and gives the Environmental Protection Agency (EPA) authority over chemical substances and mixtures. After a careful review of the bill by expert members of the Endocrine Society, the Society wrote a letter to the sponsors of the bill, Senator Tom Udall (D-NM) and Senator David Vitter (R-LA), acknowledging that the Society is unable to support the legislation as it currently stands.

In the letter, the Society outlined key concepts that should be revised in the final legislation:

- The draft bill emphasizes "standardized test designs and methods" and relies heavily on Good Laboratory Practices. The Society asked that the legislation be clarified to ensure that regulatory agencies are able to use high-quality academic studies that have been subject to peer review.
- At the time this was written, the legislation prioritizes

chemicals that result in "high hazard" and "widespread exposure." The Society recommended more inclusive criteria, such that chemicals could be prioritized due to "high hazard and/or widespread exposure" and also prioritized when exposure or hazard impacted "pregnant women, infants, and/or children."

 The Society was concerned that the fees added by the draft legislation would be insufficient to cover the expanded scope of activities by the EPA. The Society therefore recommended that caps on fees be removed or increased to ensure that EPA would be able to effectively conduct new regulatory activities.

The legislation has generated significant momentum in recent months; on April 28, the Senate Committee on the Environment and Public Works voted to pass an amended version of the bill. The Endocrine Society will continue to monitor progress on this legislation and keep members informed of developments.

If you have any comments on TSCA reform efforts in Congress, please contact Joe Laakso, associate director, Science Policy at *jlaakso@endocrine.org*. EN

#### InTOUCH

#### **Society's Accurate Insulin Decisions** Recognized by ASAE with Prestigious Award

#### Event CALENDAR

SEPTEMBER 8 – 12, MIAMI Clinical Endocrinology Update www.endocrine.org/ceu

**OCTOBER 9 – 12, SEATTLE** American Society for Bone and Mineral Research Annual Meeting **www.asbmr.org** 

OCTOBER 17 – 21, CHICAGO Neuroscience 2015 www.sfn.org

#### New Endocrine News Website to Debut in Fall

The online version of *Endocrine News* is undergoing a significant redesign that will totally change the way the magazine is accessed electronically.

Currently, the magazine's sole online representation is in the form of an e-book that allows users to click through page by page. The new site will be contemporary, modern, interactive, and updated in real time. In other words, as news breaks, *Endocrine News* can actually share this information with Society members and other relevant audiences.

"In its current form, the *Endocrine News* site is simply an easy reference to the print magazine," says the magazine's editor, Mark A. Newman. "The plan for the new website is to have it updated on a daily, if not hourly basis, and be fully interactive with the members. We often get news items and other information that we would like to share immediately, but presently there's not an appropriate outlet to do so. That will change soon, and change in a very big way with the new website."

The website is being created essentially from scratch by Matrix Group International, Inc., a website design company based in Arlington, Va. No stranger to the needs of membership associations, Matrix's clients include the American Counseling Association, Goodwill Industries International, NECA, Independent Insurance Agents & Brokers of America, as well as the Endocrine Society's own Hormone Health Network.

Newman adds that there will also be a number of social media applications that will accompany the new website, all in an effort to keep *Endocrine News* and the members of the Endocrine Society better informed and better connected.

According to Newman, the new website should be rolled out in the fall.  ${\ensuremath{\mathsf{EN}}}$ 

The Society just received the 2015 Power of A Gold Award for its Accurate Insulin Decisions (AID) program by the American Society of Association Executives (ASAE). The Power of A Award recognizes and celebrates the extraordinary contributions associations make to society by enriching lives, creating a competitive workforce, preparing society for the future, driving innovation, and making a better world.

AID offers decision support tools and educational resources on mealtime insulin to help people with diabetes better manage the disease. This program is designed to help patients set realistic goals and decide if mealtime insulin can help them achieve these goals based on their lifestyle and other priorities. AID is a joint initiative with the American Diabetes Association. American Association of Diabetes Educators, American College of Physicians, American Osteopathic Association, American Pharmacists Association, and Diabetes Nation.

There were only 30 Gold winners this year out of more than 140 entries. By receiving the Power of A Gold Award, the Society is also in consideration for one of six Summit Awards — ASAE's highest honor for associations.

The Society also received two 2015 Power of A Silver Awards for its "Pathways to Diversity, Inclusion, and Excellence" and "ACA Implementation: Impact on the Patient with Diabetes" programs. "ACA Implementation: Impact on the Patient with Diabetes" was a day-long summit held at the Ronald Reagan Building in Washington D.C. September 12, 2014. "Pathways to Diversity, Inclusion, and Excellence" is the Society's multi-tiered program that emphasizes underrepresented minority groups and includes a suite of EndoCareers initiatives, including the Minority Access Program, the Future Leaders Advancing Research in Endocrinology program, and others.

The awards will be presented on September 30.

## *New York Times* Highlights **Society Transgender CPG**

The *New York Times* recently profiled a transgender teen and pointed to the Endocrine Society's clinical practice guideline from 2009 that helped legitimize the protocol for administering puberty-blocking drugs to transgender adolescents.

The 2,800-word story details the teen's painful journey changing from a male to a female, including her depression and fear before her operation and her struggle after the surgery. Reporter Anemona Hartocollis quotes Norman P. Spack, MD, of Boston Children's Hospital, one of the members of the task force who wrote the guideline. Spack, who has treated more than 200 children since 2007, tells Hartocollis that he first learned about puberty blockers in transgender adolescents 15 years ago in Europe. Puberty blockers are administered to children and adolescents to help them decide whether they are truly transgender – the drugs can be reversed; surgery cannot be. However, treatments are not always covered by insurance, and as Spack tells Hartocollis: "That's where the dilemma came in: Who the hell could afford it?"

The article points out that advocates "say that extending treatment will alleviate depression and suicide"in the transgender population and that Oregon's Medicaid now covers "the gamut of treatment, regardless of age," but goes on to note that the "evidence is mixed."



Ηi,

I'm Eric

## BARIATRIC SURGERY AND ADOLESCENTS

**Meet Eric.** Eric is one of 12.5 million children between the ages of 2 and 19 who are overweight. That number is growing every year.

# 12.5 MILLION CHILDREN

Overweight and obese children are at greater risk for getting serious health conditions, including:



Eric and his family have been eating a healthier diet and getting more physical activity into their daily routine. But Eric's body mass index (BMI), a measure of a person's weight as compared to a person's height, is over 40, in spite of everything he's done.



Bariatric surgery can help get weight down to a healthier level.

- It is an option when adolescents reach what is sometimes called "skeletal maturity"—about the age of 13 for girls and 15 for boys.
- Eric's doctor tells Eric and his family that while bariatric surgery is a good idea for Eric, it's only one step in the process to getting to a healthier weight.
- Bariatric surgery is not a magic bullet. Eric will have to change the way he eats and keep getting plenty of physical activity, among other changes he may have to make.



Eric's BMI= over 40

There are two types of bariatric surgery that are performed on young people:

	Roux-en-y gastric bypass (RYGB) surgery	Adjustable gastric band (AGB) surgery
Description	Staples or plastic band are used to create a small pouch at the top of the stomach. The new smaller stomach is connected directly to the small intestine.	Adjustable silicone band is placed around the top of the stomach, creating a small pouch that holds much less food. When the pouch is filled with food, feelings of hunger go away.
Pros	Most frequently performed type of bariatric surgery in teens (80% of cases). Has been performed for many years and has a high success rate.	Lower rate of complications. Faster recovery time. Vitamin deficiencies are rare because the intestine is not affected.
Cons	Involves cutting through the intestine, so it has a longer recovery time than AGB surgery. Cannot be reversed.	May not take off as much weight initially as RYGB surgery. May require replacement surgery at a later date.
Possible side effects	Bleeding; anesthesia reactions; infections at the incision points; blood clot in the lung; bowel obstructions; "leaky" stomach or abdominal area, possibly leading to infection	Bleeding; infection; slippage of the band; erosion of the band into inside of stomach; spontaneous deflation of band due to leakage; enlargement of stomach pouch; blockage of the stoma (stomach outlet)

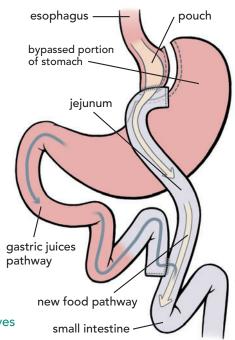
Eric's new, smaller stomach is able to hold much less food than his "old" stomach could. It may only hold 1 cup of food at a time, as opposed to as much as 8 cups in the old stomach.



After Eric recovers and returns home, he:

- Will eat many smaller, low-calorie, low-fat, high-protein meals throughout the day, eat more slowly, and avoid high-fat and highsugar foods.
- May have **side effects** from the surgery, such as pain in his stomach area, diarrhea, vomiting, or acid reflux (heartburn).
- May experience what is called **"dumping syndrome,"** which happens when the food moves too quickly through his digestive system.
- Will need to take vitamin and mineral supplements. By eating smaller amounts of food, Eric may not get all the nutrients he needs.

Today, Eric's weight is in a much healthier range. He's sticking to his new diet and getting more physical activity into his daily routine.



**RYGB** surgery



He's feeling better than ever, and he's happy that his risk for diabetes and serious heart problems has gotten much lower than it was.

#### Patients have questions. We have answers.

The Hormone Health Network is your trusted source for endocrine patient education. Our free, online resources are available at hormone.org.







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2014 ENDOCRINE SOCIETY





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