

JULY 2013

THE LEADING MAGAZINE FOR ENDOCRINOLOGISTS

# ENDOCRINE **NEWS**

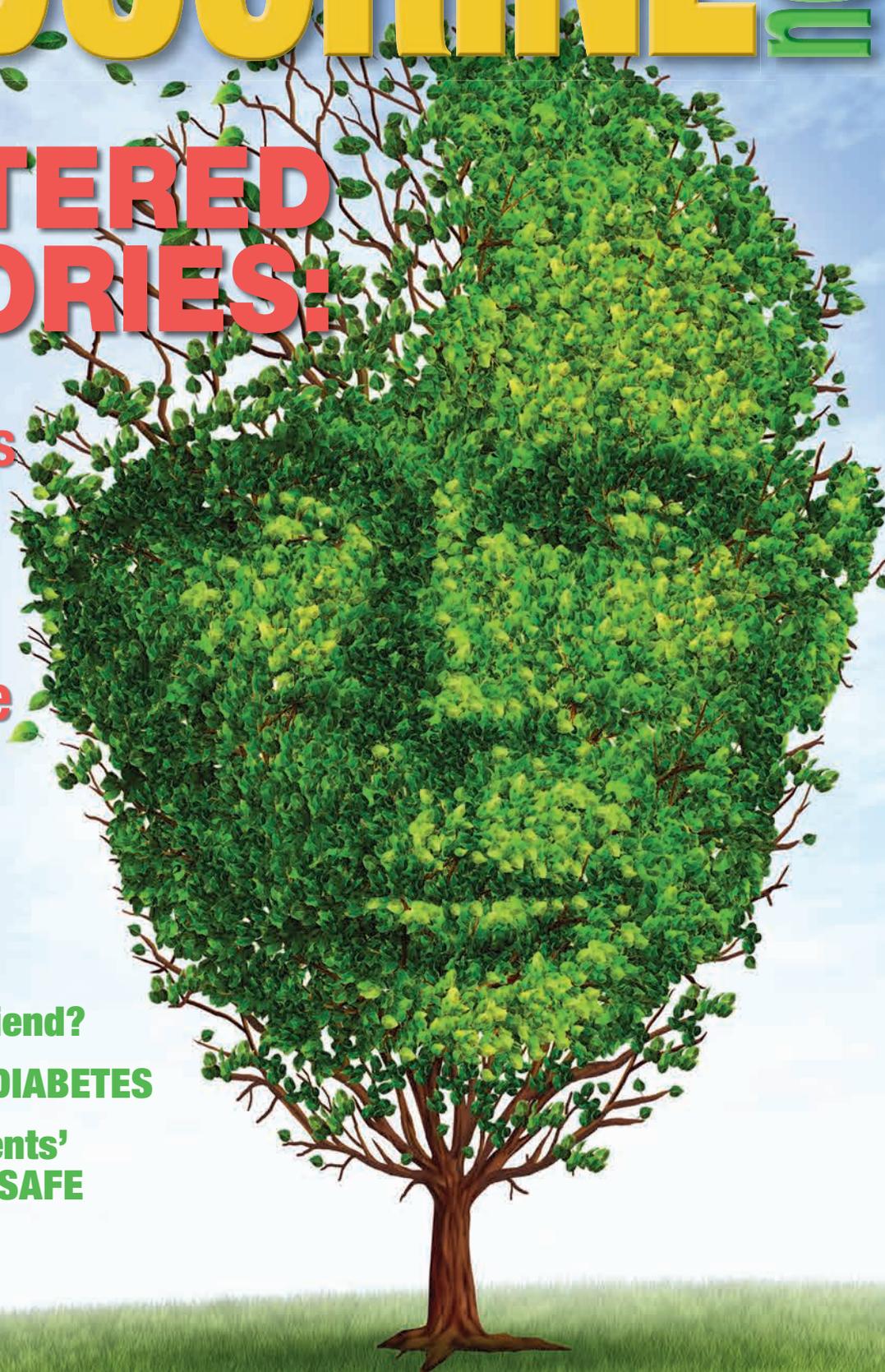
## SCATTERED MEMORIES:

Memory Loss  
and Other  
Side Effects  
Fuel the  
Statin Debate

**DIAMONDS:**  
A Sperm's Best Friend?

**The High Price of DIABETES**

**Keeping Your Patients'  
ELECTRONIC DATA SAFE**



# Victoza® vs sitagliptin—dig deeper into the differences.

Victoza® works like natural GLP-1 to treat type 2 diabetes.<sup>1</sup>

After 52 weeks—



## Greater HbA<sub>1c</sub> reductions vs sitagliptin

1.3% with Victoza® 1.2 mg to 1.5% with Victoza® 1.8 mg vs 0.9% with sitagliptin 100 mg<sup>2\*</sup>



## Greater weight reductions vs sitagliptin

2.8 kg with Victoza® 1.2 mg to 3.7 kg with Victoza® 1.8 mg vs 1.2 kg with sitagliptin 100 mg<sup>2†</sup>



More than 600,000 patients worldwide have been prescribed Victoza®.<sup>3</sup>

**VICTOZA®**  
liraglutide

\*Victoza 1.2 mg + metformin (n=155); Victoza 1.8 mg + metformin (n=176); vs sitagliptin 100 mg + metformin (n=166) over 52 weeks.

†Victoza 1.2 mg + metformin (n=155); Victoza 1.8 mg + metformin (n=176); vs sitagliptin 100 mg + metformin (n=166) over 52 weeks.

**References:** 1. Victoza® [summary of product characteristics]. Bagsvaerd, Denmark: Novo Nordisk A/S; 2012. 2. Pratley R, Nauck M, Bailey T, et al; for the 1860-LIRA-DPP-4 Study Group. One year of liraglutide treatment offers sustained and more effective glycaemic control and weight reduction compared with sitagliptin, both in combination with metformin, in patients with type 2 diabetes: a randomised, parallel-group, open-label trial. *Int J Clin Pract.* 2011;65(4):397-407. doi:10.1111/j.1742-1241.2011.02656.x. 3. Internal calculations based on IMS Midas Quantum data, May 2012.

### Prescribing information

Victoza® (liraglutide) 6 mg/ml solution for injection in pre-filled pen  
Victoza® 3 ml pen

1 ml of solution contains 6 mg of liraglutide.

**Indication:** Treatment of adults with type 2 diabetes mellitus in combination with metformin or a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of metformin or sulphonylurea monotherapy; or in combination with metformin and a sulphonylurea, or metformin and a thiazolidinedione in patients with insufficient glycaemic control despite dual therapy. **Dosage:** Victoza® is administered once daily by subcutaneous injection and at any time independent of meals however it is preferable to inject around the same time of day. Victoza® should not be administered intravenously or intramuscularly. Recommended starting dose is 0.6 mg daily, after at least one week, the dose should be increased to a maintenance dose of 1.2 mg. Based on clinical response, after at least one week the dose can be increased to 1.8 mg. Daily doses higher than 1.8 mg are not recommended. When added to existing sulphonylureas or in combination with metformin and sulphonylureas, a reduction in the dose of sulphonylurea may be necessary to reduce the risk of hypoglycaemia. Victoza® can be used in the elderly (>65 years) without dose adjustment but therapeutic experience in patients ≥75 years is limited. No dose adjustment for patients with mild renal impairment (creatinine clearance (CrCl) 60-90 ml/min). Due to lack of therapeutic experience Victoza® is not to be recommended for use in patients with moderate (CrCl of 30-59 ml/min), severe (CrCl < 30 ml/min) and end-stage renal disease or patients with hepatic impairment or children <18 years. **Contraindications:** Hypersensitivity to the active substance or any of the excipients. **Warnings and Precautions for use:** Victoza® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Victoza® is not a substitute for insulin. The addition of Victoza® in patients already treated with insulin has not been evaluated and is therefore not recommended. Limited experience in patients with congestive heart failure New York Heart Association (NYHA) class I-II and no experience in patients with NYHA class III-IV. Due to limited experience Victoza® is not recommended for patients with inflammatory bowel disease and diabetic gastroparesis. Victoza® is associated with transient gastrointestinal (GI) adverse reactions. GLP-1 analogues have been associated with pancreatitis; patients should be informed of symptoms

of acute pancreatitis if pancreatitis suspected, Victoza® and other suspect medicinal products should be discontinued. Thyroid adverse events, including increased blood calcitonin, goitre and thyroid neoplasm reported in clinical trials particularly in patients with pre-existing thyroid disease. Risk of dehydration in relation to GI side effects; take precautions to avoid fluid depletion. No studies on effects on ability to drive and use machinery. Patients advised to take precautions to avoid hypoglycaemia while driving and using machines, in particular when Victoza® is used in combination with sulphonylureas. In the absence of compatibility studies Victoza® must not be mixed with other medicinal products. **Fertility, pregnancy and lactation:** If a patient wishes to become pregnant, pregnancy occurs or is breast feeding, treatment with Victoza® should be discontinued; use of insulin is recommended instead. Apart from a slight decrease in number of live implants in animal studies no harmful effects on fertility observed. **Undesirable effects:** The most frequently observed adverse reactions which varied according to the combination used (sulphonylurea, metformin or a thiazolidinedione) were: Very common (≥ 1/10): nausea, diarrhoea, hypoglycaemia when used in combination with sulphonylureas, headache when used in combination with metformin and vomiting when used in combination with metformin and rosiglitazone; Common (≥1/100 to <1/10): vomiting, constipation, abdominal pain, discomfort and distension, dyspepsia, gastritis, flatulence, gastroesophageal reflux disease, gastroenteritis viral, toothache, headache, dizziness, nasopharyngitis, bronchitis, hypoglycaemia, anorexia, appetite decreased, fatigue and pyrexia. GI adverse reactions are more frequent at start of therapy but are usually transient. Patients >70 years or with mild renal impairment (CrCl 60-90 ml/min) may experience more GI effects. Consistent with medicinal products containing proteins/peptides, patients may develop anti-liraglutide antibodies following treatment but this has not been associated with reduced efficacy of Victoza®. Few cases of; angioedema (0.05%), acute pancreatitis (<0.2%), injection site reactions (usually mild, approx. 2%). Rates of thyroid adverse events - 33.5, 30.0 and 21.7 events/1000 subject years of exposure for liraglutide, placebo and total comparators; Thyroid neoplasms, increased blood calcitonin and goitres are the most frequently reported thyroid adverse events/1000 subject years of exposure were 6.8, 10.9 and 5.4 of liraglutide treated patients in comparison with 6.4, 10.7 and 2.1 of placebo treated and 2.4, 6.0 and 1.8 of total comparator treated. The Summary of Product Characteristics should be consulted for a full list of side effects. **MA numbers:** Victoza® 2 x 3ml pre-filled pens EU/1/09/529/002. Victoza® 3 x 3ml pre-filled pens EU/1/09/529/003. **Legal Category:** POM. **Basic NHS Price:** Victoza® 2 x 3ml pre-filled pens: £ 78.48. Victoza® 3 x 3ml pre-filled pens: £117.72. **Further prescribing information can be obtained from:** Novo Nordisk Limited, Broadfield Park, Brighton Road, Crawley, West Sussex, RH11 9RT. **Date created:** March 2012.

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0845 6005055). Calls may be monitored for training purposes.

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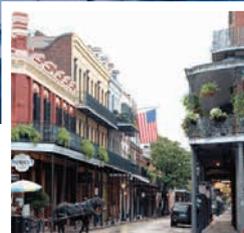
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To apply or for more information on the program, visit [www.endocrine.org/international/ambassador-exchange-program.cfm](http://www.endocrine.org/international/ambassador-exchange-program.cfm)



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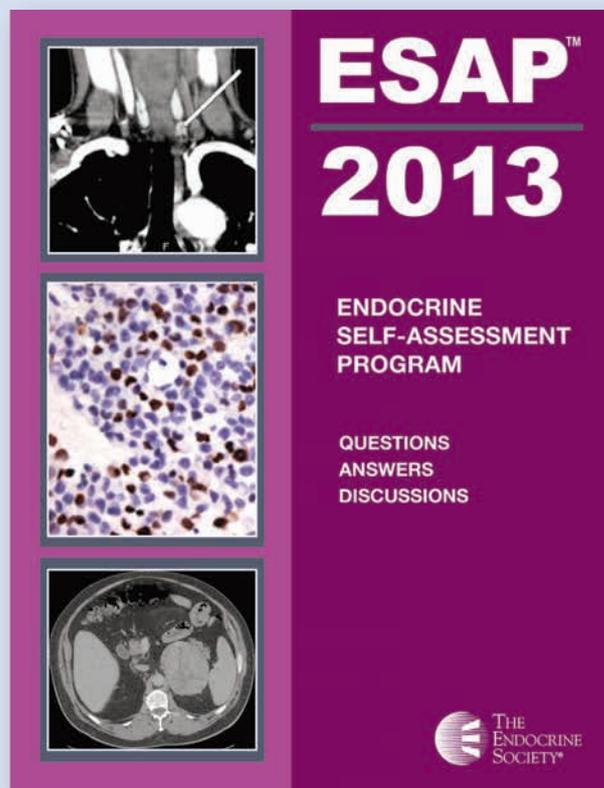
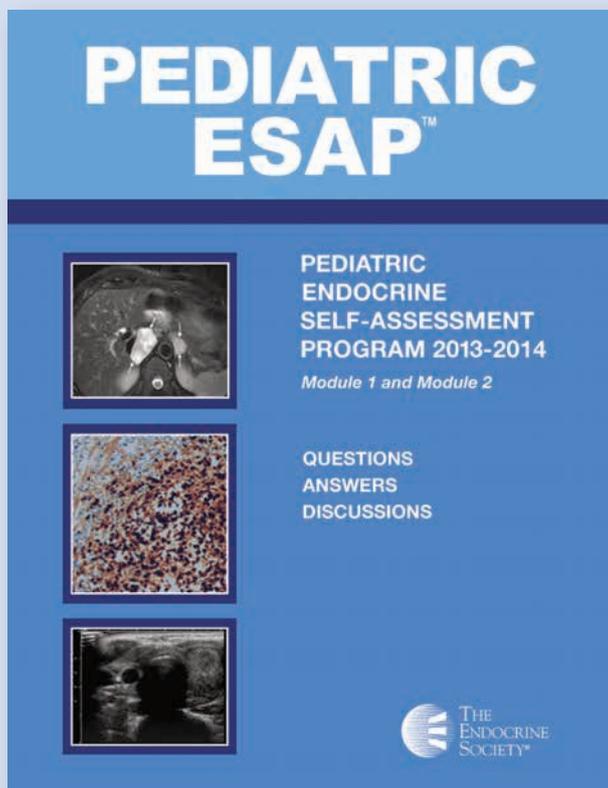
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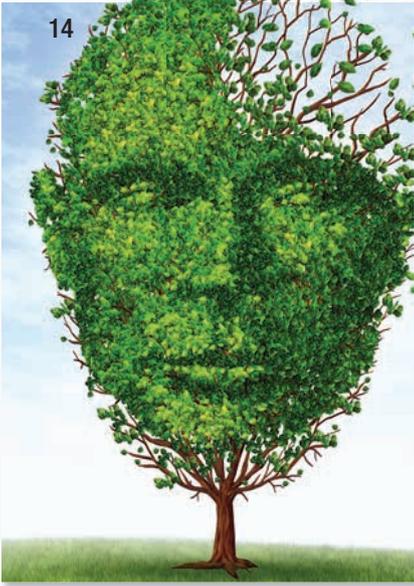


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**COVER Story**

**14 Statins: Rap Sheet or Bum Rap?**

*By Terri D'Arrigo*

Cholesterol-lowering drugs are taken by more than 20 million Americans, but the fears of possible side effects have sounded an alarm among patients and doctors. How do you see beyond the hype and the hysteria?

**17 Price Gouging**

*By Kelly Horvath*

Baby boomers are seeing an increase in longevity. And so are the chronic ailments that afflict them, most notably diabetes. Diabetes costs will total almost \$250 billion annually. Before this staggering economic burden finally topples the healthcare industry, the key to curtailing costs lies in one simple word: Prevention.

**24 Gaping Holes Seen in Electronic Record Security**

*By Eric Seaborg*

Electronic health records could be a tempting target for hackers because the software is vulnerable, but workers' habits can be even worse. It's time for your practice to adopt a culture of security awareness.

**42 Hormone Health Network Fact Sheet:**

Goiter: Symptoms, Causes & Treatments  
Your Patients Need to Know

**DEPARTMENTS**

**8 President's Viewpoint**  
Introducing  
Teresa K. Woodruff, PhD

**9 Editor's Page**  
New editor highlights July issue

**10 Trends & Insights**  
News from the latest research

**20 Laboratory Notes**  
Diamonds may hold the key to extending the life of a sperm

**23 Practice Resources**  
Pediatric Self-Assessment Program: What is causing a toddler's sudden illness?

**26 Research Roundup**  
Studies in the Society journals

**27 InTouch**  
Society & member news

**40 Classifieds**  
Job opportunities



## Introducing the New President: TERESA K. WOODRUFF, PhD

The Endocrine Society is pleased to welcome its president for 2013–2014, Teresa K. Woodruff, PhD, who took office June 19. Woodruff is a leading expert in reproductive endocrinology and vice chair for research in the Department of Obstetrics and Gynecology at the Feinberg School of Medicine at Northwestern University. She coined the term “oncofertility” to describe her work researching female reproductive health and infertility and translating her findings to the clinical care of women who will lose their fertility due to cancer treatments. She has co-edited three books on the subject, detailing everything from procedural guidelines and best practices to the ethical, religious, economical, and legal implications of preserving fertility in cancer patients.

She also advocates for gender specificity in clinical trials in order to reach a better understanding of the effects that medicine has on women, and she founded the Women’s Health Research Institute at Northwestern University to develop programs to better serve women’s health. She has served on The Endocrine Society Council and has been recognized nationally, receiving numerous awards and honors for her work.

Woodruff succeeds William F. Young Jr. MD, MSc, as the Society continues its rotation of presidents who represent its core constituencies: basic researchers, clinical researchers, and clinical practitioners. “It was a tremendous honor to be selected by my peers to lead this organization for a short period of time,” she says. “As volunteer members, we all contribute to the health of our field, and I look forward to serving with the leadership and committee members.”

Woodruff joined The Endocrine Society 25 years ago, influenced by her mentors at Northwestern University, Kelly Mayo and Neena Schwartz, who also both served as presidents of the Society. “I’m somewhat homozygous for the endocrine science phenotype,” she says.

One of her first experiences as a Society member



Teresa K. Woodruff, PhD

was in New Orleans in 1988, where she admits she was a little star struck, presenting a paper on the cloning of the subunits for the hormone inhibin and showing how they were regulated during the reproductive cycle of the rodent “in front of a packed room of endocrinology super luminaries — folks that I had read about but never met.”

She says she was inspired by Society members almost immediately, discovering new avenues and concepts in member impact and value. “My first committee was on membership,” she recalls. “Gwen Childs was the chair [of the Membership Committee] and a real activist. I imprinted on her way of thinking outside the box.”

Now that she’s something of a super luminary herself, Woodruff plans to inspire Society members in the coming year, describing her goals of developing a new look for the Society, including a new logo that “refreshes the way we present ourselves to the world,” as well as creating a tagline “that has momentum and expresses our goals and our values.”

But it’s not just about aesthetics; she plans to introduce even more tangible member benefits, including new awards categories that reward members for their achievements, accelerating the careers of the newest society members, and creating a new program called “Leap” that represents the most innovative science and the best scientists in endocrinology. “Reward, Accelerate, Leap,” Woodruff says, “our bold new awards program that increases the visibility of people and ideas.”

Woodruff hopes these fresh approaches translate to new tactics and implementation plans for tackling the “grand global challenges” in endocrinology, including the colliding epidemics of obesity and diabetes, the increasing health risks of endocrine disruptors, the fulcrum between global population expansion and personal reproductive needs, and the support of endocrine science in a low-no- resource environment.

“We have to be a society about solutions,” she says. “We have to invest in next-generation innovators and advocate for them with funding agencies and governments around the globe.” **EN**

—Derek Bagley is associate editor of Endocrine News

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JULY 2013

# ENDOCRINE NEWS

THE LEADING MAGAZINE FOR ENDOCRINOLOGISTS

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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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Another ENDO has passed and as I'm sure you noticed if you made it to San Francisco, it was a roaring success, with attendance records being broken almost every single day. The sessions were nothing short of amazing in terms of the amount of information that was shared. For me, it was a great opportunity to meet so many of you in person, and I can assure you that I returned to the East Coast with more than my fair share of story ideas and sources for a dozen years' worth of *Endocrine News*!

And speaking of timely information, this issue is loaded with stories about topics currently in the forefront of our national consciousness. On page 14, Terri D'Arrigo delves into the controversies surrounding statins, those cholesterol-lowering drugs that are prescribed to over 20 million of us. These drugs are being blamed for a litany of side effects including memory loss and diabetes. Physicians are now determining whether these alleged "wonder drugs" are as wonderful as first thought. Are the possible side effects worth it? In many cases it simply boils down to what's worse, a heart attack or diabetes? Rest assured, this is an issue that won't be going away any time soon.

As the baby boomer population lives longer, the incidence of chronic maladies is also on the rise. None is more prevalent than diabetes, with an estimated 22 million people suffering from it in 2012. To no one's surprise, the financial burden of this disease is almost \$250 billion, according to a study by the American Diabetes Association. In "Price Gouging" on page 17, Kelly Horvath comes to the realization that the solution to stop these spiraling costs rests with the physician as well as with the patient. The old adage about "an ounce of prevention" has never been more relevant.

Apparently diamonds aren't just a girl's best friend anymore; they're also a sperm's. Former *Endocrine News* associate editor Jacqueline Ruttiman writes about research that shows how diamond-coated petri dishes improve the survival rate for sperm used in IVF procedures, thus increasing the success rates for parents-to-be (page 20). Of course, the addition of diamonds to the mix is only going to increase an already costly procedure, but hopefully it will reduce the number of procedures, thereby lowering costs in the long run.

Be sure to let me know what you think of the topics we're covering this month. Your thoughts and opinions and any feedback you want to offer are vital in ensuring the continued success and future growth of *Endocrine News*. You can always find me at mnewman@endocrine.org. I look forward to hearing from you. **EN**

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



Mark A. Newman,  
Managing Editor



## PAID DIETERS Lose More Weight

With obesity contributing to “presenteeism,” a lack of productivity while at work due to health problems, employers are looking for ways to combat this costly problem. A new study shows that one way they could save money is by paying their employees to lose weight.

Jeffrey Kullgren, MD, MS, MPH, at the University of Michigan, and his team of

researchers divided 105 obese dieters (body mass index 30–40 kg/m<sup>2</sup>) into three groups: a control group given links to an online weight-loss network to participate in monthly weigh-ins; a second group who were additionally offered a monthly \$100 incentive to meet their individual weight-loss goal; and a third, who were subdivided into groups of five to split \$500 among only those group members who met their goals (thus building in the possibility of a bigger payout if not all five met goals). In their paper, to be published soon in the *Annals of Internal Medicine*, the researchers report that

the third group lost on average 4.4 kg more weight than the non-incentivized control group and 3.2 kg more than the individually incentivized group after 24 weeks of dieting. However, 12 weeks post-incentive, the individual-incentive group had kept off an average of 2.7 kg more weight than the group-incentive group. **The researchers conclude that the prospect of a bigger cash reward among the group-incentive participants was the strongest motivator to lose weight. Maintaining that loss over the long term might also be more successful if the incentive plan is likewise continued.**

— Kelly Horvath



## STATINS OFTEN PRESCRIBED with No Likely Benefit

Statins cost the healthcare system more than \$20 billion a year and may be overprescribed to patients who are not at high risk for coronary heart disease (CHD).

Michael E. Johansen, MD, at the University of Michigan, Ann Arbor, and his team of scientists anonymously surveyed 202 family and internal medicine and cardiology physicians on their treatment choices in six clinical vignettes, each concerning a hypothetical patient ranging from age 40 to 75 years with various baseline risk factors for hyperlipidemia (e.g., high “bad” cholesterol or blood pressure level, diabetes, smoking), but none with existing CHD. In their paper, to be published soon in the *Journal of the American Medical Association: Internal Medicine*, the researchers report that most physicians (70%) would have prescribed a statin to even the patients with very low risk for developing CHD anytime soon yet fewer than half would have prescribed a statin for the diabetic patient who may have benefited most.

**The researchers conclude that physicians prescribe statins almost reflexively, focusing solely on cholesterol levels and without adequately weighing the risk–benefit ratio. Lifestyle modification (e.g., quitting smoking, eating well, and exercising) is most effective in many patients with high cholesterol but no other CHD risk factors, they add.**

— Kelly Horvath

## Group Clinics Improve Outcomes, **KEEP COSTS DOWN**

With chronic diseases such as diabetes requiring constant management and never-ending medical bills, group medical clinics (GMCs) have been shown to be effective at managing diabetes. Are they also cost effective?

George L. Jackson, PhD, MHA, at the Durham Center for Health Services Research in Primary Care in North Carolina, and his team of scientists recently studied 239 people with poorly controlled diabetes receiving either usual care or attending GMCs every two months for one year. GMC attendance included education and structured interactions among the up to eight group members, and the care team comprised registered nurses, certified diabetes educators, pharmacists, and general internists. Diabetes in the GMC group was more successfully managed, with lower systolic blood pressure and cholesterol levels. In their follow-up paper, to be published soon in the *Journal of the American Medical*



*Association: Internal Medicine*, the researchers report that having better controlled disease, the GMC group required fewer emergency room and primary care visits, thereby offsetting the annual \$460 GMC fee. Moreover, GMC participants reported greater satisfaction with the group experience than with conventional one-on-one care.

**The researchers conclude that cost-effective and clinically beneficial GMCs could be the new face of long-term care for certain chronic diseases in the United States.**

— Kelly Horvath

## FISH OIL LENGTHENS LIFESPAN Among Older Adults

Eating fish and seafood, foods that are unique in containing long-chain polyunsaturated omega-3 fatty acids, can improve cardiovascular and brain health. A new study examines for the first time whether these benefits might help us live longer.

Darius Mozafarrian, MD, DrPH, at the Harvard School of Public Health, Massachusetts, and his team of researchers analyzed blood level data of three types of omega-3 fatty acid from 2,692 healthy U.S. adults ages 69–79 years who participated in the National Heart, Lung, and Blood Institute's 1992–2008 Cardiovascular Health Study. In their paper, to be published soon in the *Annals of Internal Medicine*, the researchers report that docosahexaenoic acid lowered risk of coronary heart disease (CHD) death by 40%, eicosapenta-

noic acid lowered risk of nonfatal heart attack, and docosapentaenoic acid lowered risk of stroke death. Although none of the three omega-3 acids was strongly related to reducing noncardiovascular causes of death, those participants with the highest circulating levels of all three types had an overall 27% lower risk of mortality due to all causes. **The researchers say that the biggest benefit comes from increasing fish intake to about two servings a week. The gain is well worth it—on average, this amount increased lifespan by 2.2 years.**

— Kelly Horvath



## GUT MICROBIOTA Important for Healthy Metabolism

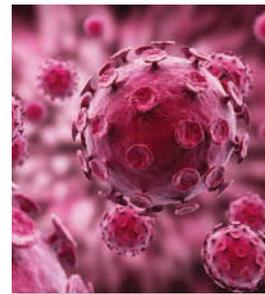
For years, scientists have wondered why roux-en-Y gastric bypass (RYGB), the most widely done form of gastric bypass surgery, results not only in rapid weight loss but also in an even faster return to normal glucose metabolism, suggesting that the latter effect is not due strictly to decreased caloric intake or absorption. A new study tests whether the changes RYGB causes in the makeup of gut microbes accounts for the additional effects.

Doctors Lee Kaplan, MD, PhD, at the Harvard Medical School, Massachusetts, and Peter Turnbaugh, PhD, at Harvard's Center for Systems Biology, and their team of researchers divided 23 mice into an RYGB group, a sham surgery group, and a sham surgery coupled with caloric restriction group, analyzing their fecal samples before

surgery and then weekly for 12 weeks. In their paper, published in *Science Translational Medicine*, the researchers report increases in proteobacteria and verrucobacteria and a decrease in firmicutes in the RYGB and the dieting groups, with more dramatic and rapid changes among the RYGB group. When proteobacteria and verrucobacteria were transferred to mice guts in the sham surgery group, rapid weight loss resulted.

**The researchers conclude that the changes in gut bacteria account for the metabolic benefits seen after RYGB, possibly by increasing levels of short-chain fatty acids, which speed up metabolism. Manipulating the gut microbiota without surgery could be a potential new therapy to address obesity in humans, they add.**

— Kelly Horvath



## LONGER CONCEPTION Time Leads to More Neurological Issues

Couples who take longer to conceive may be at higher risk of having children born with mild neurological problems, according to new research.

Babies born through in vitro fertilization (IVF) have an increased risk of being born prematurely or having a low birth weight, possibly leading to a developmental disorder. But what has been previously linked to the IVF treatments, the developmental problems actually may be connected to what initially caused the couples' infertility.

In an article appearing in *Archives of Disease in Childhood: Fetal & Neonatal* edition, researchers from The Netherlands examined 209 two-year-old children who were born to subfertile parents. The couples had taken between 1.6 and 13.2 years to conceive. More than half of the couples had undergone IVF.

The study, led by Jorien Seggers of the University of Groningen, assessed the children's neurological development by testing their movement, muscle tone, reflexes, gross and fine motor function, and hand-eye coordination.

**Results showed that minor neurological dysfunction (MND) was present in 16 children (7.7%). In the children with MND, couples took an average of 4.1 years to become pregnant compared with an average of 2.8 years in couples with children born without MND. Taking longer to get pregnant was linked with a 30% higher risk of having a baby with MND.**

— Glenda Fauntleroy





## Adolescent Bariatric Surgeries Decline While **OBSESITY RATES SOAR**

With childhood obesity at an all-time high — one in three kids is overweight or obese — effective strategies to combat this epidemic and its comorbid diseases are vital. Is adolescent bariatric surgery one such strategy?

Deirdre C. Kelleher, MD, at the Children's National Medical Center, Washington, D.C., and her team of scientists

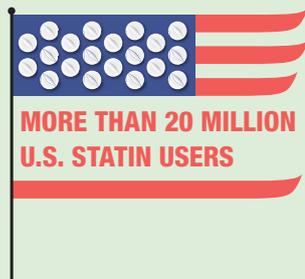
retrospectively analyzed data from the Healthcare Cost and Utilization Project Kids' Inpatient Database for the decade 2000–2009 to determine rate of bariatric surgery in adolescents (ages 10–19 years) and characterize related trends. In their paper, to be published soon in the *Journal of the American Medical Association: Pediatrics*, the research-

ers report that procedure rates increased considerably during the first three years (from 328 to 987) but subsequently plateaued. Type of procedure, length of hospital stay, and complication rates also changed: Minimally invasive (i.e., laparoscopic) procedures are now more likely to be done than open procedures, reducing both hospital stay and complications.

The researchers also found that males and younger adolescents are less likely to undergo the surgery than females age 17 years and older with private insurance. Those with low socioeconomic status and on Medicaid are also in the minority. Their data underscore the disparity between obesity rates and use of low-risk, minimally invasive bariatric surgery that could improve or even save many lives.

— Kelly Horvath

## Fast **FACTS** About Statins



6 out of 100,000 patients on statins suffered from rhabdomyolysis, which causes permanent muscle death.



Approximately 130 people need to take statins for a year to prevent just one unwanted health outcome.



500 people have to take statins to prevent a single death.

JAY T, PH.D.  
PRINCIPAL SCIENTIST  
PROTEIN TECHNOLOGIES

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# STATINS:

## Are the side effects from cholesterol-lowering drugs worth the risk?

By Terri D'Arrigo

When the Food and Drug Administration (FDA) announced labeling changes to cholesterol-lowering statins in February of last year, the media were quick to sound the alarm. Headlines proclaimed that statins raise the risk of diabetes and cause memory loss. Debate arose about side effects and whether statins, taken by more than 20 million Americans, were overprescribed. Suddenly, an entire class of wonder drugs wasn't so wonderful anymore.

But more recent evidence suggests that there's more to the statin story. Analyses of three major trials — including one the FDA cited in its warnings about diabetes — revealed that increased rates of diabetes in statin users depended on whether they already had risks for the disease before starting the drugs. Another study demonstrated that not only were statins well-tolerated in patients who had previously stopped taking them because of side effects, but that reports of memory problems in particular were rare. Yet this news did not garner as much attention in the mainstream consumer media.

### What gives?

“A lot of media attention focuses on things that create sensation,” said Anne Carol Goldberg, MD, FACP, associate professor of medicine at the Washington University School of Medicine in St. Louis. “But what physicians have to do is educate patients on the reality, which is that these drugs



### AT-A-GLANCE:

- In 2012 the FDA announced labeling changes to cholesterol-lowering statins to include warnings about diabetes risk and memory loss.
- Analyses of the JUPITER, TNT, and IDEAL trials revealed that increased rates of diabetes in statin users depended on whether they already had risks for the disease before starting the drugs.
- A study published this year in the *Annals of Internal Medicine* suggests that memory loss from statins is rare and that statins are well-tolerated.

save lives, particularly among people at high risk for cardiovascular disease.”

Goldberg said she encounters resistance to statins among her patients, in part because of what they hear anecdotally or in the news. “People are afraid of them and think they cause bad effects. I will show patients figures from the Cholesterol Treatment Trialists Collaboration [CTT] and explain what we actually see in terms of benefits,” she said.

The CTT is a group of physicians and researchers in the United Kingdom who conduct periodic meta-analyses of large randomized trials of lipid-lowering treatments. In the November 13, 2010, issue of *The Lancet*, the CTT published a meta-analysis of 26 randomized trials involving more than 169,000 participants wherein they found that reducing LDL cholesterol by 38 to 77 mg/dl via statins reduces the risk of vascular events such as heart attack, coronary revascularization, and stroke by 40% to 50%. More recently, in the August 11, 2012, issue of *The Lancet*, the CTT published a meta-analysis of 27 randomized trials involving more than 174,000 patients, which revealed that even low-risk patients who would not normally be considered for statin therapy derive as much risk reduction for vascular events from statins as high-risk patients do.

### Diabetes Risk

The labeling for statins now includes a warning that there have been reports of increased blood glucose and A1c measurements in people who take the drugs. Among its reasons for the warning, the FDA cited findings from the Justification for the Use of Statins in Primary Prevention: An Intervention Trial Evaluating Rosuvastatin (JUPITER) trial, which noted a 27% increase in investigator-reported diabetes in patients who took rosuvastatin compared to those who took placebo.

In light of the warnings, JUPITER researchers further analyzed data from the trial’s 17,603 participants to

weigh the benefits of statins against the risk of diabetes. As noted in the August 11, 2012, issue of *The Lancet*, they found a 28% increase in diabetes among statin users who already had one or more major risk factor for the disease. The team also learned that 134 vascular events or deaths were avoided for every 54 new diagnoses of diabetes, leading them to conclude that the cardiovascular benefits of statin therapy exceed the risk of developing diabetes.

A more recent analysis of data from two other studies with a combined 15,056 participants, Treating to New Targets (TNT) and Incremental Decrease in Endpoints Through Aggressive Lipid Lowering (IDEAL), yielded similar results. In this analysis, published in the January 15, 2013, issue of the *Journal of the American College of Cardiology*, researchers compared 80 mg/day of atorvastatin with 10 mg/day atorvastatin or 20–40 mg/day of simvastatin to assess vascular benefits and diabetes risk. They saw a 24%

**“...Physicians have to... educate patients on the reality, which is that these drugs save lives, particularly among people at high risk for cardiovascular disease.”**

— Anne Carol Goldberg, MD, FACP, associate professor of medicine at the Washington University School of Medicine in St. Louis.

increase in high-dose participants who already had two to four diabetes risk factors, and no increased diabetes in high-dose participants with no or only one risk factor for diabetes, compared to low-dose participants. Yet compared to low doses, the higher dose reduced the number of cardiovascular events in patients regardless of how many diabetes risk factors they had.

It boils down to severity, said David Waters, MD, professor emeritus at the University of California — San Francisco and lead investigator in the TNT/IDEAL analysis. “If you think about diabetes and cardiovascular disease, the two really aren’t equivalent. Developing diabetes is bad, but having a heart attack or stroke and dying is worse.”

Although diabetes itself raises the risk of cardiovascular disease, populations at risk for both tend to overlap, Waters said. “These are people with high blood pressure, higher than normal fasting glucose, high BMI, and [bad] family histories. Either way, they’re going to benefit from statin therapy.”



### STATINS AVAILABLE IN THE U.S.

- Atorvastatin (Lipitor)
- Fluvastatin (Lescol)
- Lovastatin (Mevacor, Altoprev)
- Pravastatin (Pravachol)
- Rosuvastatin Calcium (Crestor)
- Simvastatin (Zocor)

### COMBINATION MEDICATIONS THAT INCLUDE A STATIN

- Atorvastatin and amlodipine (Caduet)
- Lovastatin and niacin (Advicor)
- Simvastatin and ezetimibe (Vytorin)

Source: The American Heart Association

Like Goldberg, Waters has patients who hesitate to take statins. He addresses their concerns by emphasizing risk minimization. “Say a patient has a high BMI. They’ll say they’re afraid taking a statin will give them diabetes. But if they lose weight, they can cut their risk of developing diabetes right there.”

Waters has a bone to pick with what he sees as a bias against statins. “A lot of other drugs out there increase the risk of diabet-

es, like beta blockers, diuretics, HIV drugs, and steroids, but people rarely want to talk about that. They say they don’t want to take a statin because they’re against big bad drug companies, so they’ll take niacin instead. Well, niacin doubles your risk of getting diabetes.”

## The Question of Side Effects

Statin labeling now includes a warning that cognitive effects such as memory loss and confusion have been reported in people who take the drugs. The FDA based its warning on reports received through its Adverse Event Reporting System (AERS), where clinicians and patients voluntarily report what they feel to be side effects of the drugs, and noted that the reports generally described people in their 50s or older who experienced noticeable, if poorly defined, memory loss or impairment that disappeared when they stopped taking statins.

However, a study by researchers in the April 2, 2013, *Annals of Internal Medicine* suggests that memory loss from statin use may actually be rather rare. In the study, which was designed to ascertain the reasons for statin discontinuation and the role of statin-related events in routine care settings over eight years, memory loss was reported in only .06% of participants, or less than 1 in 1,000.

Among the 107,835 participants in the study, 18,778 patients, or 17.4%, had documented statin-related side effects. Muscle pain was the most common side effect, experienced by 4.71% of patients in the study overall. Of those who had side effects, 11,124 stopped taking statins.

Then 6,579 began taking statins again. The drugs were well-tolerated the second time around for these patients, as 92.2% of them were still taking statins a year after resuming therapy.

Alexander Turchin, MD, MS, associate physician at Brigham and Women’s Hospital, assistant professor of medicine at

Harvard Medical School in Boston, and the senior author of the study, acknowledges that there is a discrepancy between clinical trials’ reported rates of adverse reactions such as muscle pain and what physicians are observing anecdotally in routine care. “If you talk to doctors on the front lines and their patients, you’re constantly hearing about these reactions,” he said. “But in the clinical trials, their incidence is similar between statin and placebo arms.”

This could be for a number of reasons, he said. “Clinical trial participants who pass eligibility criteria tend to be healthier overall. On the other hand many of the symptoms that are reported as attributable to statins are not very specific, such as muscle pain. Sometimes the symptoms are specific to an individual statin or a higher dose. Other times the symptoms might not be from statins at all, but another underlying condition. We think our data implies a range of explanations.”

Turchin added that the older age of many statin users can make it difficult to root out whether their memory loss is actually from statins. “Older patients are at higher risk for vascular dementia from multiple strokes and for the onset of Alzheimer’s disease. This can paint a mixed picture both clinically and pathologically. It’s not an easy diagnosis to make.”

William James Howard, MD, MACP, director of Med-Star Washington Hospital Center’s Lipid Clinic and Lipid Consultation services in Washington, D.C., cautioned against awareness of potential side effects becoming a self-fulfilling prophecy. “One of the problems is that we have created a monster,” he said. “Most people get some muscle or joint pain as they get older, and they tend to ignore it.

**“Developing diabetes is bad, but having a heart attack or stroke and dying is worse.”**

— David Waters, MD, professor emeritus at the University of California — San Francisco

But if it’s in the back of your mind because you’ve been warned about it in commercials and the news, if you have muscle pain, you’ll think, ‘Oh, it’s the statin,’ when really it might be because you’re 60 and 60-year-olds tend to have a few aches and pains.”

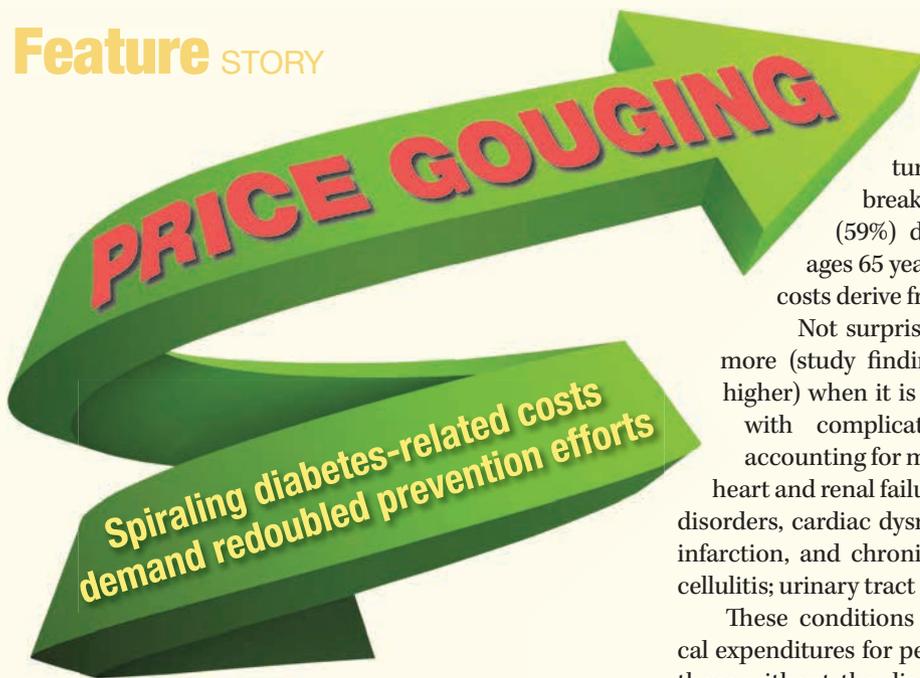
Howard counters the power of suggestion by having patients keep a diary for a few days before starting statin therapy. They record whether, where, and when they have pain or other symptoms so that both physician and patients know what kinds of issues already existed before starting the statin.

The sheer number of people who take statins makes compiling statistics tricky, Howard said. “If you have millions of people on any drug, you will have associations with anything imaginable, whether it’s memory loss, insomnia, peripheral neuropathy, and so on. But that doesn’t mean there’s a cause-and-effect relationship,” he said. “As we move forward with the research, we really need to separate out causation versus association.”

And so the statin story will continue to unfold. **EN**

—D’Arrigo is a health and science writer based in Holbrook, N.Y., and a regular contributor to Endocrine News





By Kelly Horvath

An aging baby boom population coupled with increasing human longevity has combined to dramatically increase incidence of chronic disease, particularly diabetes. Increasing by 5 million in just five years, 22.3 million people were living with diabetes in 2012.

The economic burden of diabetes grows even faster than its incidence. Diabetes costs, both direct and indirect, will total around \$245 billion for 2012, according to the April 2013 Scientific Statement by the American Diabetes Association (ADA), “Economic Costs of Diabetes in the U.S. in 2012.” This staggering figure reflects a five-year increase in diabetes costs greater than the overall cost of medical care as a whole (which holds true even after adjusting for inflation). The ADA last undertook an economic burden study in 2007; at that time, diabetes costs were \$174 billion. (Other costs not included in the ADA figure include undiagnosed diabetes, which is estimated to cost another \$18 billion; prediabetes, another \$25 billion; and unknown hidden costs, such as those incurred by nonpaid caregivers or by family members living with diabetes patients.)

### Direct and Indirect Costs

Of the \$245 billion, direct costs command the larger share at \$176 billion, and indirect costs come in around \$69 billion. Direct costs include emergency room care, hospital inpatient days, nursing/residential facility use, ambulance services, ambulatory visits, hospice care, podiatry, prescription medications, diabetic supplies, and other equipment and supplies, whereas indirect costs are associated with productivity loss from a combination of absenteeism (workdays missed due to health conditions), presenteeism (reduced work productivity while at work due to health conditions), reduced

workforce participation among those with chronic disability, and the productivity lost from premature mortality. Direct and indirect costs break down by age group as well, with most (59%) direct costs attributable to patients ages 65 years and older, whereas 88% of indirect costs derive from those younger than age 65 years.

Not surprisingly, the disease costs substantially more (study findings show from two to eight times higher) when it is poorly controlled and/or associated with complications. Diabetes-related conditions accounting for most of the overall direct costs include heart and renal failure; heart disease, such as conduction disorders, cardiac dysrhythmias, hypertension, myocardial infarction, and chronic ischemic heart disease; cataracts; cellulitis; urinary tract infections; and poor general health.

These conditions combine to increase annual medical expenditures for people with diabetes by 2.3 times over those without the disease. In fact, according to the ADA, “More than one in 10 healthcare dollars in the U.S. are spent directly on diabetes and its complications, and more than one in five healthcare dollars in the U.S. goes to the care of people with diagnosed diabetes.” Notably, hospital inpatient care is the largest piece of this spending, having risen to 48% (from \$58 billion in 2007 to \$76 billion in 2012), despite overall hospital inpatient care costs having decreased: of total direct medical costs, inpatient care dropped from 50% to 43% in the same five-year period.

How and why costs have skyrocketed by 41% in five years to \$245 billion seems to have less to do with specific economic factors (i.e., treatment costs rising) than with sheer disease predominance, according to the ADA. Diabetes prevalence reflects changing demographics (i.e., older adults show a greater prevalence, and the numbers of older adults are increasing both as baby boomers age and people live longer in general); increases in risk factors, especially obesity; decreasing mortality (i.e., people are living longer with disease due to improved treatments), and better disease detection. Some say that if incidence continues to burgeon, one in three people will be diagnosed with diabetes by 2050. Matt Petersen, managing director, Medical Information and Professional Engagement of the ADA, says, “I believe the key observation to make is that the increased cost from 2007 to 2012 is primarily a result of increased prevalence of diagnosed diabetes. One might think that the availability of new and often expensive medications would have contributed to that increased cost, but in fact the

#### AT-A-GLANCE:

- The ADA’s estimated costs of diagnosed diabetes have risen 41%, up \$71 billion from \$174 billion in 2007 to \$245 billion in 2012.
- Despite overall hospital inpatient costs having decreased from 50% to 43%, inpatient hospital costs for patients with diabetes increased — from \$58 billion in 2007 to \$76 billion in 2012.
- Diabetes prevention measures are the best way to lower these astronomic costs in the future, say the ADA and others.

proportion of the cost attributable to anti-diabetic agents remained flat during that time.”

Despite the availability of several new diabetes medications and despite double the use of such agents, overall pharmacy costs stayed more or less constant over a 10-year period at 12% of diabetes medical spending in 2012. Interestingly, prescriptions to treat diabetes complications cost significantly more than did prescriptions to treat diabetes — at 18% and 12%, respectively.

## Reducing Costs

Everyone agrees that this steadily increasing economic burden is overwhelming the U.S. healthcare system. Medicare currently shoulders the costs incurred by 14 million people living with diabetes — almost half of the diagnosed population. Among Medicare, Medicaid, and military programs, in fact, the U.S. federal government pays for 62% of diabetes-related costs. U.S. federal government 2014 budget proposals to reduce this outlay include shifting more costs to wealthier Medicare recipients and cutting about \$350 billion from providers and recipients. Opponents fear that such sweeping changes would limit care access for the biggest and most needy populations — low-income, older, and disabled diabetes patients — as well as cause an overall regression in public health. Other measures, such as the program hosted by the Centers for Medicare and Medicaid that allows patients to mail order their diabetes-related medications and equipment from suppliers who competitively bid to participate (commonly known by the acronym DMEPOS), saved only \$202 million in 2011.

The dilemma presented by these current and proposed measures (i.e., effectively reducing care access on the one hand and not saving enough money on the other) leaves many asking, how, then, do we pay this ever-

increasing bill? In the healthcare sector, however, many say we are approaching the issue from the wrong angle. We should not be looking at how to pay the bill so much as how to prevent the cost from being incurred.

“If the primary driver of the increased costs is increased prevalence, it’s a compelling argument that we should be looking at primary prevention of type 2 diabetes as the most important strategy for containing the costs,” says Petersen. “And prevention of course would not only reduce economic costs, but would also bring the quality-of-life benefits that would come from preventing diabetes in the first place.” Hospital inpatient care is the largest piece of the cost pie (one day is estimated to cost \$5,000), but preventing diabetes (or even effectively controlling it) would directly mitigate that expenditure by negating the trip to the hospital.

Thus, the answer to at least part of this problem is self-evident, say physicians and researchers, and is also long backed up by findings from the 2002 Diabetes Prevention Program (DPP). If 95%–98% of diabetes is type 2, and if the risk of developing type 2 diabetes is dramatically increased by obesity, then we need lifestyle interventions targeting obesity to prevent diabetes from developing and thereby stanch the increase in the diabetes base population, which some say is growing by 5,000 people a day.

“We feel prevention is paramount for reducing the future cost of the condition,” says Kelly L. Close, president of Close Concerns, a diabetes awareness organization, and editor-in-chief of *diaTribe*, an online diabetes news journal. For the other part of the problem, that is, those already diagnosed with diabetes, the answer is optimizing care, she says, adding, “We would like to move away from the ‘treat to failure’ model that so many patients get caught in and move toward new therapies. For example, exploration of annual use of continuous glucose monitoring so that poor management doesn’t escalate.”

The Endocrine Society is fully in agreement that prevention is paramount and urges the federal government to likewise recognize this necessity. The Society’s director of government and public affairs Stephanie Kutler says, “The Society has been working with members of Congress to secure full funding for the [DPP], and the new [ADA] data have helped to illustrate the urgency of our message. These costs will continue to grow unless we do something to prevent more people from developing diabetes, and the proven way to do that is through primary prevention programs like the DPP. But Congress and the Administration must make this a priority and fully fund the program.”

Investing in new drugs and technology as well as in public health programs on diabetes prevention seems to be the consensus among the healthcare sector. “More research into new prevention programs and treatments and cures” should also be a priority, adds Kutler. Perhaps legislators will realize that a twist on the old quote might apply here: “You must spend money to save money.” **EN**

—Horvath is a freelance writer in Baltimore, and a regular contributor to Endocrine News

**“We would like to move away from the ‘treat to failure’ model that so many patients get caught in and move toward new therapies.”**

— Kelly Close, president, Close Concerns; editor, *diaTribe*



**Direct Costs**  
**\$176 Billion**

- emergency room care
- hospital inpatient days
- nursing/residential facility use
- ambulance services
- ambulatory visits
- hospice care
- podiatry
- prescription medications
- diabetic supplies
- other equipment and supplies

**Indirect Costs**  
**\$69 Billion**

- Productivity loss from a combination of:
- absenteeism
  - presenteeism
  - reduced workforce participation among those with chronic disability
  - the productivity lost from premature mortality

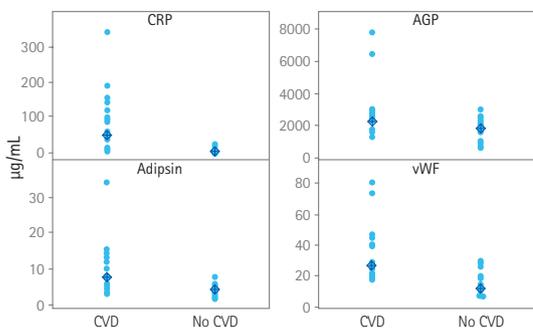
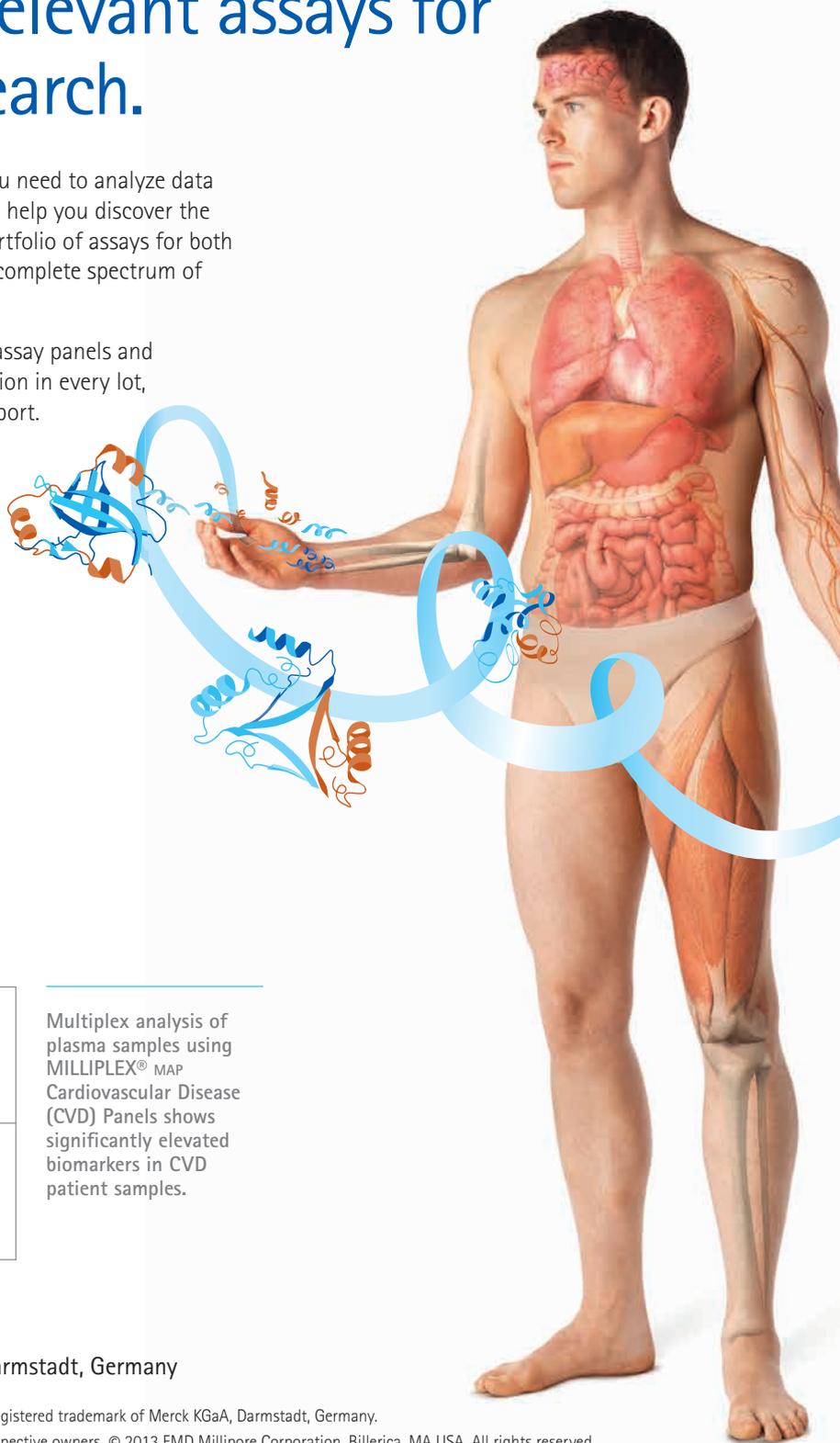
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# DIAMONDS in the Rough

By Jacqueline Ruttimann Oberst

**D**iamond-coated petri dishes protect sperm, thus improving IVF success rates. In vitro fertilization (IVF) already carries a hefty price tag—and the procedure may get costlier. A new method using nanocrystalline diamonds to carpet the bottom of petri dishes might ensure better survival and performance of sperm, improving IVF success, suggests a recent study in the *Online Proceedings Library* of the Materials Research Society.

“Our finding is likely to change the world of the petri dish,” explains Andrei Sommer, PhD, a materials scientist at Ulm University in Germany and the study’s lead author.

The average IVF cycle in the United States costs \$12,400, according to the American Society of Reproductive Medicine. Because its success rate remains rather low, at about 30%, couples often undergo multiple treatment rounds before they successfully conceive. “Poor sperm performance” is a common problem, which typically requires actual injection of sperm into an egg. Yet for decades a part of the solution was right in front of the reproductive endocrinologists’ eyes: the petri dish.

The majority of IVF clinics—about 99.9%—use disposable petri dishes made from polystyrene plastic. When cell medium is applied to these dishes, the surface softens, as verified by a material harness-measuring device called a nanoindenter. The liquefied surface facilitates the formation of reactive oxygen species (ROS) that is toxic to cells, including sperm, oocytes, and embryos.

Searching for ways to get around this problem, Sommer remembered the title of an American Chemical Society press release on his previous work titled, “Diamonds may have been life’s best friend on primordial Earth,” which suggested that the surface of natural diamonds might have provided the right conditions for life-creating chemical reactions. For his research, the title served as a “guiding light sentence” and stimulated the inclusion of nanodiamond-coated petri dishes.

Sommer’s team applied fresh sperm samples, at about 4.1 million/mL — lower than the typical male sperm con-



A new method using nanocrystalline diamonds to carpet the bottom of petri dishes might ensure better survival and performance of sperm, improving IVF success. However, since the average cost for an IVF procedure is already over \$12,000, the addition of diamonds to the process will only increase that price tag.

centration of 20–200 million/mL — onto four different types of petri dishes: polystyrene, quartz glass, sandblasted quartz glass coated with nanodiamonds, and quartz glass coated with nanodiamonds. After 42 hours at 37 degrees Celsius, about 20% more sperm survived in the pricey petri dishes, specifically the nanodiamond-coated plain and sandblasted quartz dishes, than the bargain polystyrene ones; the plain quartz containers without the diamond dusting yielded about 10% better viability than the polystyrene dishes.

The 42-hour time point could be important because, in IVF, after about 40 hours, the eggs are examined to see if they have become fertilized by the sperm and are forming embryos. The embryos are then placed in the woman’s uterus, thus bypassing the fallopian tubes, and hopefully ensuring pregnancy.

“During conventional IVF, sperm cells and oocytes both contact the bottom of the petri dish before the zygote is formed. These hours, and subsequent days prior to the transfer of the embryo into the recipient, are critical,” said Sommer, who added that sperm, while sensitive to ROS, are more robust to them than oocytes and embryos.

Bradley Anawalt, MD, chief of medicine at the University of Washington Medical Center and specialist in male reproductive physiology, who was not involved in the study, described the work as “a relatively simple and straightforward study that asks a simple question no one has asked before.”

He added that this research backs up prior findings that infertile men are exposed to ROS in their testicles and includes speculation that antioxidant therapies might



help these men. Given that banked sperm are often frozen in polystyrene containers, Anawalt posits that it is possible these containers could also affect the long-term viability of these frozen sperm.

Richard Rawlins, PhD, IVF laboratory director at Rush-Copley Center for Reproductive Health in Aurora, IL., mentioned that ROS scavengers are typically added to culture media to soak up any ROS in the dishes, yet perhaps these chemicals are not enough. He also called the study “a novel application of engineering helping out biology.”

Sommer’s group plans on testing the plates to see if it has any effect on sperm morphology and motility. They also want to ensure that the diamond coatings are biologically and chemically inert and do not release other toxic chemicals of their own.

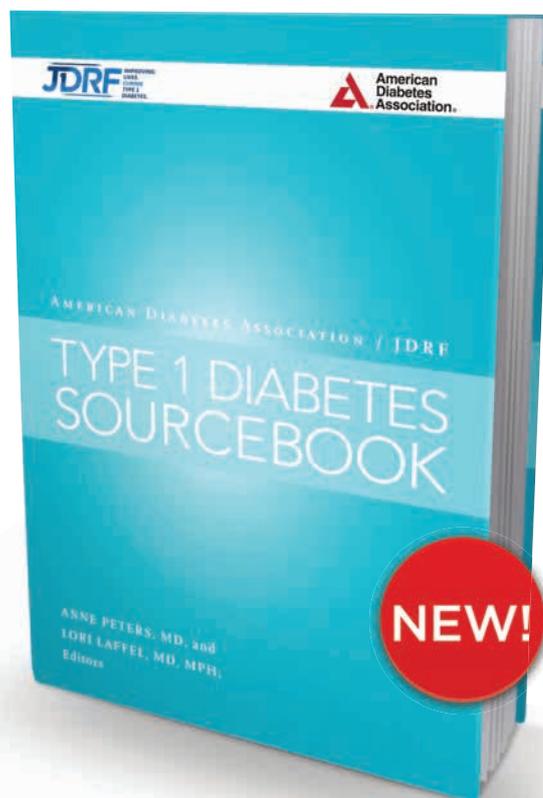
The diamond-coated petri dishes are not only sperm and egg’s best friend. They could also aid in culturing stem cells and cancer cells, suggested Sommer, whose lab previously reported greater growth success of P19 mouse embryonic carcinoma cells on the diamond-dusted quartz petri dishes’ substrates.

Although these dishes could theoretically be reused through sterilization techniques such as autoclaving, Sommer correctly points out that “neither the IVF community nor the patients will accept making babies in ‘used’ petri dishes.”

If Sommer’s future research continues to indicate that these plates show promise, companies could start manufacturing these dishes in the next couple of years. And IVF clinics that purchase these dishes would somehow transfer the costs to the patients. **EN**

—Ruttimann Oberst, PhD, is a freelance writer in Bethesda, MD and a regular contributor to Endocrine News

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# Replacing the SGR: A Physician-centered Approach?

**F**inding new ways to reimburse physicians is a critical next step in reforming America's healthcare system. Since 2002, physicians have faced potentially devastating payment cuts that have resulted from the flawed payment formula known as the sustainable growth rate (SGR). In 1997, the SGR was mandated by Congress in an attempt to stabilize federal spending and to balance the budget. Each year, target expenditures are established that take into account things like changes to physician service fees and the number of Medicare beneficiaries. If actual expenditures exceed that target, cuts to physician payments the subsequent year must take place to offset the difference.

While Congress typically passes short-term legislative patches to avoid these cuts, this approach to Medicare reimbursement is untenable. This year, physicians can expect to receive a 25% cut in Medicare payments if Congress fails to act. And in order to provide a permanent solution, Congress must find \$139 billion.

Because of the high price tag and the general divisiveness in Congress, an alternative approach to reimbursing physicians has not been given serious thought — until recently. Earlier this year, the House committees on Energy & Commerce and Ways & Means released a framework for reforming the Medicare payment system. Much like the trend toward patient-centered care, paying America's physicians may also be moving toward an individualized approach.

The current congressional proposals promise to give physicians a variety of reimbursement options, rather than taking a one-size-fits-all approach to replacing the SGR. Enabling physicians to choose how they get paid is a fresh take on a system that has long been shackled by formulaic considerations rather than improving the quality of patient care.

So how would this proposal work? First Congress

must decide the payment models from which physicians can select. Once these options have been decided, physicians would receive stable payments for several years to give them time to decide which option would work best for their practice. Physicians can continue to be paid under the fee-for-service (FFS) system or they can choose to participate in an alternative payment model that utilizes team-based care to streamline healthcare delivery. The FFS system will also see some changes during this time to integrate quality and performance measures so that future payment updates can take these considerations into account.

Throughout this process, the committees have engaged key stakeholders, like The Endocrine Society, to ensure the alternative payment models that are selected can benefit all specialties. The Society has long advocated for payment reform to better account for the undervaluation of the evaluation and management services that endocrinologists most often provide. The Society has also been supportive of both the SGR repeal and for physicians to be able to select a reimbursement option that is most suitable for their practice.

In comments to the committees regarding this framework, the Society has stressed the importance of working with physician organizations to ensure that there are relevant quality measures for all physicians. The Society also believes that providing flexibility during the selection process of an alternative payment model is a critical step in incentivizing physicians to try out new mechanisms for reimbursement. Comments on implementation, EHR adoption, clinical improve-

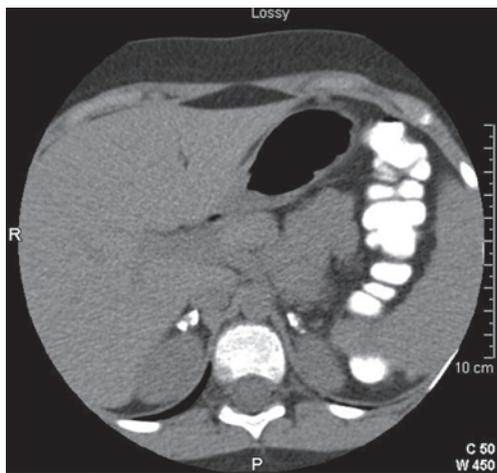
ment activities, alternative payment models, and resource utilization were also included in the comment letter, which can be found at [www.endocrine.org/advocacy/legislative/letters](http://www.endocrine.org/advocacy/legislative/letters). **EN**



## A TODDLER'S SUDDEN ILLNESS: A Case Study from Pediatric ESAP

A two-year-old boy is admitted to the hospital for spitting up and poor feeding. He was reportedly healthy until the week of this hospital admission, although his slow growth and lack of weight gain have been a consistent problem for which no definite diagnosis has been given. He was born after a full-term pregnancy to a 24-year-old primigravida woman. Gestation was complicated by early oligohydramnios and relatively poor weight gain, but the birth weight was 3,770 g (68th percentile) and birth length was 50.8 cm (62nd percentile). Although vaginal delivery was attempted, the use of forceps was unsuccessful and cesarean delivery was necessary after a difficult and prolonged labor. There were no other complications, and two days after delivery, the newborn was discharged with his mother.

There is no family history of disease, the child is not taking any medications, and he has not been exposed to any unknown substances. On physical examination, weight is below the fifth percentile and height is at the 10th percentile. He has no dysmorphic features, but he is dehydrated, pale, and lethargic. He has no trauma or rashes. He has normal male genitalia with bilaterally descended testes. An X-ray of the abdomen shows calcifications that are thought to represent kidney stones. Abdominal CT is shown.



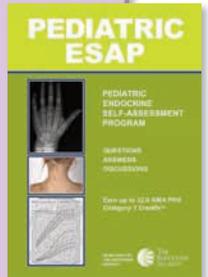
Laboratory test results:

- Sodium = 114 mEq/L (136-142 mEq/L)
- Potassium = 7.2 mEq/L (3.5-5.0 mEq/L)
- ACTH = 2,500 pg/mL (10-60 pg/mL)
- Cortisol = 1.2 µg/dL (AM serum cortisol, 10-20 µg/dL)
- 17-Hydroxyprogesterone = 35 ng/dL (AM 17-hydroxyprogesterone 60-300 ng/dL)
- Plasma renin activity = 86 ng/mL per h (0.6-4.3 ng/mL per h)

### QUESTION

The Pediatric Endocrine Self-Assessment Program (Pediatric ESAP™) is a self-study curriculum specifically designed for endocrinologists seeking initial certification or recertification in pediatric endocrinology, program directors interested in a training instrument, and clinicians seeking a self-assessment and a broad review of pediatric endocrinology. Pediatric ESAP is in both print and online formats with 100 multiple-choice questions in all areas of pediatric endocrinology, diabetes, growth, and metabolism. There is extensive discussion of each correct answer and references. Pediatric ESAP is updated biennially with new questions and now available is the new Pediatric ESAP 2013-2014.

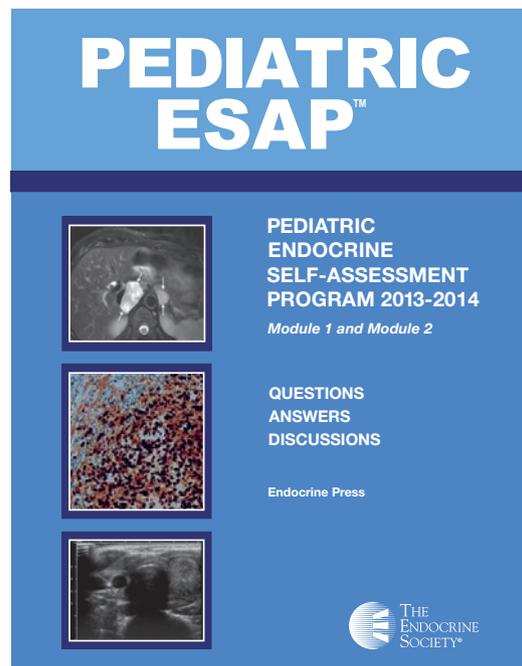
Learn more at [www.endoselfassessment.org](http://www.endoselfassessment.org).



*Which one of the following diagnoses is most consistent with the biochemical profile and CT image of this patient?*

- A Allgrove syndrome
- B Familial glucocorticoid deficiency
- C Congenital adrenocortical hyperplasia
- D Adrenal hemorrhage
- E Congenital HIV infection and adrenal insufficiency

*answer on page 30*



# GAPING HOLES

## Seen in Electronic Record Security

By Eric Seaborg

Computer-based medical records hold promise for improving treatment and efficiency, but experts say they are open to attack from hackers, malware, and even nosy employees.

The electronic health record (EHR) programs certified for use in medical practices and hospitals are far from secure, but the behavior of many practitioners exacerbates the risks.

“In terms of security management, the healthcare industry is particularly bad,” said Avi Rubin, PhD, professor of computer science at Johns Hopkins University and technical director of its Information Security Institute.

### Software Problems

Studies have found EHR software surprisingly vulnerable to potential hackers. A research team that examined a pair of EHR systems found very basic vulnerabilities, said team leader Laurie Williams, PhD, a computer science professor at North Carolina State University. The programs were open to “almost beginner level security attacks.”

Williams said that these vulnerabilities are not unusual compared with other kinds of software, but are troubling because the records contain such sensitive and personal information. Williams said that if credit card information is breached, a user can close an account and get a new credit card. “But with health records, if some-

one’s private information gets out, you can’t withdraw that knowledge,” she said.

Potential problems range from identity theft from the release of information such as Social Security numbers to tampering with records themselves. “You could possibly change someone’s blood type and then they’d get a transfusion of the wrong type,” she said.

EHR software users are at the mercy of the software developers and government regulators because they must buy a certified system, and Williams and Rubin agreed that the certification process has not paid adequate attention to security. They said that practitioners should pressure vendors and government regulators to make security a higher priority.

**“... with health records, if someone’s private information gets out, you can’t withdraw that knowledge.”**

— Laurie Williams, computer science professor, North Carolina State University

## 10 TIPS FOR IMPROVING PRACTICES in the Small Healthcare Environment

The U.S. Department of Health and Human Services’ cybersecurity website recommends the following:

- Use strong passwords and change them regularly.
- Keep anti-virus software current.
- Use a firewall, preferably a hardware firewall between a local area network and the Internet.
- Control access so that protected health information is accessible only to people who need to know it.
- Control physical access. The most common way protected health information is compromised is through the loss or theft of devices that contain it, including portable storage media, laptops, and handhelds.
- Limit network access, including operating wireless routers in encrypted mode.
- Plan for the unexpected by creating backups and having a data recovery plan.
- Maintain good computer habits, including uninstalling any nonessential software and keeping software up-to-date with security patches and new features.
- Protect mobile devices from physical theft and signal theft. Encrypt any information they contain.
- Establish a culture in which everyone takes security as seriously as practices like hand-washing and disinfection.

For more information, visit [www.healthit.gov/providers-professionals/cybersecurity](http://www.healthit.gov/providers-professionals/cybersecurity).

## People Problems

Rubin toured hospitals to observe their practices and was appalled to find a general disregard for computer security. He often saw passwords posted on computers by sticky notes. In one hospital, a nurse had the job of typing a physician's password into computers so the physician would not time out, which left the machines unattended and unprotected most of the time. The common practice of distributing to patients disks containing their X-rays—and executable programs for reading them—is dangerous because practitioners have no idea what is really on them when patients walk in with them. The disks could contain malware that could infect whole systems.

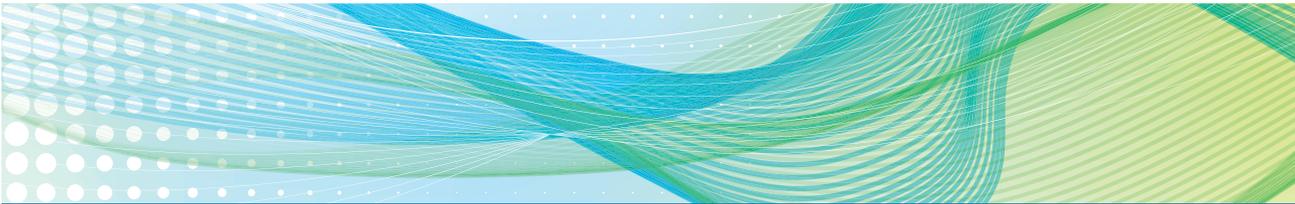
Williams noted that in the interest of making the transition to electronic records easier, some practices have been tempted to take shortcuts such as having a single

log-in ID for doctors and another for nurses, rather than having individual user IDs. "If they do that, they will have no way to trace who did what. So to use the blood example again, they should be able to go back and see who changed the blood type," Williams said.

## Tips for Improvement

Apparently, hackers have not set their sights on the medical establishment in a big way yet—most healthcare security breaches have resulted from mistakes such as the loss or theft of laptops. Rubin recommended engaging a security professional as a consultant or in-house in the case of larger institutions. **EN**

—Seaborg is a freelance writer in Charlottesville, VA, and a regular contributor to Endocrine News



# Endocrine Press

An Imprint of the Endocrine Society

Great ideas are only useful when you share them, so consider publishing your book with Endocrine Press: Endocrine Society's newly revamped book publishing program.

We are currently soliciting book proposals that provide important and cutting-edge information on a range of issues related to endocrinology.

We are particularly interested in books with scopes and subject matter relative to the Endocrine Society's mission of advancing excellence in endocrinology to promote its essential and integrative role in scientific discovery, medical practice, and human health.

Key topics of interest include the following:

- Adrenal
- Bone & Calcium
- Cardio Metabolic
- Diabetes
- Lipids & Obesity
- Neuroendocrinology
- Pediatric Endocrinology
- Pituitary
- Reproductive
- Thyroid

## SPECIAL CALL FOR MANUSCRIPTS ON HEALTH DISPARITIES IN ENDOCRINE DISORDERS

Submit a book proposal or pitch your own topic by contacting Maxine Aldred at [maldred@endocrine.org](mailto:maldred@endocrine.org). For more information about Endocrine Press, please visit <http://www.endocrine.org/endocrine-press>.

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](http://www.endocrine.org).



**Hypoglycemia and Diabetes: A Report of a Workgroup of the American Diabetes Association and The Endocrine Society**

Elizabeth R. Seaquist, John Anderson, Belinda Childs, Philip Cryer, Samuel Dagogo-Jack, Lisa Fish, Simon R. Heller, Henry Rodriguez, James Rosenzweig, and Robert Vigersky *The workgroup reconfirmed previous definitions of hypoglycemia in diabetes, reviewed the implications of hypoglycemia on both short- and long-term outcomes, considered the implications of hypoglycemia on treatment outcomes, presented strategies to prevent hypoglycemia, and identified knowledge gaps that should be addressed by future research.*

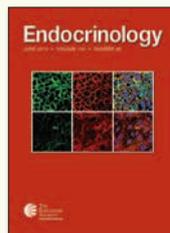
**Clinical Outcomes and Molecular Profile of Differentiated Thyroid Cancers with Radioiodine-Avid Distant Metastases** M.M. Sabra, J.M. Dominguez, R.K. Grewal, S.M. Larson, R.A. Ghossein, R.M. Tuttle, and J.A. Fagin *RAIA metastatic FCDTC are overrepresented with RAS mutations, whereas RAI refractory metastatic thyroid cancers are enriched with BRAF mutations.*

**Approach to the Patient With Hypogonadotropic Hypogonadism** Letícia Ferreira, Gontijo Silveira, and Ana Claudia Latronico *The precise and early diagnosis of HH can prevent negative physical and psychological sequelae, preserve normal peak bone mass, and restore the fertility in affected patients.*

**The Effect of Obesity on the Relationship Between Serum Parathyroid Hormone and 25-Hydroxyvitamin D in Women** Sue A. Shapses, Esther J. Lee, Deeptha Sukumar, Ramon

Durazo-Arvizu, and Stephen H. Schneider *These results suggest that if PTH is suppressed at a lower serum 25OHD in the obese compared to the entire population, the lower average 25OHD concentrations in the obese may not have the same physiological significance as in the general population.*

**Approach to Testing Growth Hormone (GH) Secretion in Obese Subjects** Vera Popovic *GH stimulation tests should be avoided in obese subjects with very low pretest probability.*



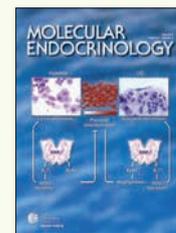
**Increased Bone Mass in Mice Lacking the Adipokine Apelin**

Lalita Wattanachanya, Wei-Dar Lu, Ramendra K. Kundu, Liping Wang, Marcia J. Abbott, Dylan O'Carroll, Thomas Quertermous, and Robert A. Nissenson *The increased bone mass in mice lacking apelin suggested complex direct and paracrine/endocrine effects of apelin on bone, possibly via modulating insulin sensitivity. These results indicate that apelin functions as a physiologically significant antianabolic factor in bone in vivo.*

**Renal Protective Effects of Toll-like Receptor 4 Signaling Blockade in Type 2 Diabetic Mice** J.J. Cha, Y.Y. Hyun, M.H. Lee, J.E. Kim, D.H. Nam, H.K. Song, Y.S. Kang, J.E. Lee, H.W. Kim, J.Y. Han, and D.R. Cha *GIT27 treatment improves insulin resistance and protects against the renal injury that occurs in type 2 diabetic nephropathy through both metabolic and antiglomerulosclerotic mechanisms, which suggests that TLR pathway inhibition might play a direct protective role in diabetic kidney disease.*

**cAMP-Responsive Element Binding Protein: A Vital Link in Embryonic Hormonal Adaptation** Maria Schindler, Sünje Fischer, René Thieme, Bernd Fischer, and Anne Navarrete Santos *Transcription factors CREB and ATFs vitally participate in embryo-maternal cross talk before implantation in a cell lineage-specific manner. Embryonic CREB/ATFs act as insulin/IGF sensors. Lack of insulin is compensated by a CREB-mediated adiponectin expression, which may maintain glucose uptake in blastocysts grown in diabetic mothers.*

**Age Increase of Estrogen Receptor- $\alpha$  (ER $\alpha$ ) in Cortical Astrocytes Impairs Neurotrophic Support in Male and Female Rats** Jason M. Arimoto, Angela Wong, Irina Rozovsky, Sharon W. Lin, Todd E. Morgan, and Caleb E. Finch *The persisting effects of ovarian acyclicity in vitro are hypothesized to arise from steroidal perturbations during ovarian senescence, which suggests that increased astrocyte ER $\alpha$  expression during aging contributes to the E2 desensitization of the neuronal responses in both sexes.*



**Estrogen-Related Receptor  $\gamma$  (ERR $\gamma$ ) Regulates Oxygen-Dependent Expression of Voltage-gated Potassium (K $^{+}$ ) Channels and Tissue Kallikrein**

during Human Trophoblast Differentiation Yanmin Luo, Premlata Kumar, and Carole R. Mendelson *ERR $\gamma$  mediates O $_2$ -dependent expression of genes involved in human trophoblast differentiation, function, and vascular homeostasis.*

## RECORD NUMBERS FOR ESAP™-ITE 2013

This year the Endocrine Self-Assessment Program In-Training (ESAP-ITE) exam was a great success! The Self-Assessment Committee is happy to report that 560 endocrine fellows from 134 training programs worldwide have completed the exam during the month of April. Of those 134 training programs, seven new training programs registered their fellows, including four international programs. “We designed ESAP-ITE to assess fellows’ knowledge across a broad range on endocrinology topics,” says Alan Dalkin, chair of the Self-Assessment Committee. “The exam has become an essential tool for fellowship training program directors domestically, and the addition of SI units to the 2014 exam will increase applicability to international training programs as well.” Learn more about ITE on [endoselfassessment.org](http://endoselfassessment.org).

Is there a topic that you would like to learn more about at ENDO?

## THE 2014 ANNUAL MEETING STEERING COMMITTEE



THE ENDOCRINE SOCIETY'S 96th ANNUAL MEETING & EXPO

welcomes suggestions for the joint 16th International Congress of Endocrinology/The Endocrine Society's 96th Annual Meeting & Expo

To submit suggestions, visit [www.ice-endo2014.org](http://www.ice-endo2014.org). The deadline to submit suggestions is July 24, 2013.

## Introducing THE 2014 ANNUAL MEETING STEERING COMMITTEE!

The 2014 Annual Meeting Steering Committee (AMSC) will have the large task of planning the joint 16th International Congress of Endocrinology/The Endocrine Society's 96th Annual Meeting & Expo. President Teresa Woodruff, PhD, will work with the chairs and AMSC members to create an exciting and comprehensive program. The first clinician-in-practice chair, Carol Wysham, MD, PhD, will bring special attention to the interests of the practicing clinician members of the Society.

### Derek Leroith, MD, PhD, ENDO 2014 Chair

Matthew Ringel, MD, PhD  
Clinical Science Chair

Kevin Grove, PhD  
Basic Science Chair

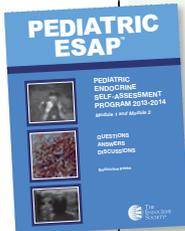
Carol Wysham, MD, PhD  
Clinician-in-Practice Chair

Richard Eastell, MBBS, MD  
Michael Levine, MD  
Steven Smith, MD  
Jane Reusch, MD  
Bernard Robaire, PhD  
Erica Elizabeth Marsh, MD  
Jorma Toppari, MD, PhD  
Nelly Mauras, MD  
Adrian Lee, PhD  
Louis Luttrell, MD, PhD  
John Cidlowski, PhD

Kristy Brown, PhD  
Stephanie Lee, MD, PhD  
Gal Omry, MD  
Wiebke Arlt, MD, DSc,  
FRCP, FMedSci  
Gregory Brent, MD  
Laura Calvi, MD  
Cheri Deal, MD, PhD  
Patricia Elizalde, PhD  
Ghada Fuleihan, MD, MPH  
Ashley Grossman, MD, FRCP  
Annette Grueters, MD, PhD  
Robert Handa, PhD  
Anthony Hollenberg, MD  
Malcolm Low, MD, PhD  
Christopher McCartney, MD  
Robert Millar, PhD  
Sue Moenter, PhD  
John Newell-Price, MD, PhD, MRCP  
Pere Puigserver, PhD

Elliot Rayfield, MD  
Charles Roberts, Jr., PhD  
Donald Simonson, MD, MPH, ScD  
Frances Sladek, PhD  
Jenny Visser, PhD  
Humphrey Yao, PhD  
Philip Zeitler, MD, PhD  
Daniel Marks, MD, PhD

In addition, eight members of the International Society for Endocrinology will be joining the AMSC this year.  
Peter Ebling, MBBS, MD  
Teresa Sir Petermann, MD  
Weiqing Wang, MD  
Philippe Chanson, MD, MS  
Subhanker Chowdhury, MD, MS  
Moises Mercado, MD  
Augustine Ohwovoriole, MD, MS  
Elizabeth Paz-Pacheco, BS, MD



## PEDIATRIC ESAP™ 2013–2014: Increased Benefits to Board Certified Pediatric Endocrinologists

The American Board of Pediatrics (ABP) has begun transitioning toward the new “continuous” Maintenance of Certification (MOC) model, requiring physicians to earn 40 Part 2 MOC points per five-year MOC cycle. To address this increased regulatory need, Pediatric ESAP 2013–2014 has been redesigned and ABP-approved to offer 40 MOC Part 2 points, which is twice the number of MOC Part 2 points offered by its predecessor, Pediatric ESAP 2011–2012. This new offering, developed by the Pediatric Self-Assessment Committee, includes two 50-question interactive modules and a printed book. Learn more about the benefits of Pediatric ESAP 2013–2014 on [endoselfassessment.org](http://endoselfassessment.org).

## Event CALENDAR

**AUGUST 7-10: PHILADELPHIA**  
American Association of Diabetes Educators (AADE)  
[www.diabeteseducator.org/](http://www.diabeteseducator.org/)

**SEPTEMBER 19-22: MILAN, ITALY**  
9th Joint Meeting of  
Pediatric Endocrinology  
[www.jointmeeting2013.org/](http://www.jointmeeting2013.org/)

**SEPTEMBER 23-27: BARCELONA**  
European Association for the  
Study of Diabetes  
[www.easd2013.com/](http://www.easd2013.com/)

**SEPTEMBER 24-28: NEW ORLEANS**  
Endocrine Board Review,  
Pediatric Endocrine Board Review, and  
Clinical Endocrinology Update  
[www.endocrine.org/nola](http://www.endocrine.org/nola)

## ENDOCRINE SOCIETY and HORMONE HEALTH NETWORK Launch New Websites

Visit the new websites of The Endocrine Society and the Hormone Health Network for an improved user experience, including new designs and improved layouts, to help you find the information you need, fast.

The Society website, [endocrine.org](http://endocrine.org), provides you with all of the tools and information you need to succeed in your work environment. Log on and stay up-to-date on important events; find products, services, and meetings to help advance your work; learn about hot topics in public policy; and more.

Created for patients, backed by the Society’s clinical and scientific expertise, [hormone.org](http://hormone.org) is your partner in endocrine patient education. With more than 100 free resources in English and Spanish, [hormone.org](http://hormone.org) educates patients and improves communication. Visited by 2 million people a year, The Hormone Health Network gives your patients a better understanding of hormone, health, disease, and treatment. The Network’s goal is to help providers move patients from educated to engaged, creating active partners in their healthcare.

## Submit Your Nominations for the 2013 EARLY INVESTIGATORS WORKSHOP

Did you know that The Endocrine Society annually hosts a workshop specifically designed to provide young investigators an in-depth introduction into the foundation for building successful careers in research at the Early Investigators Workshop? The two-day workshop offers early career investigators career development talks, small group presentations, and networking opportunities with peers and faculty. This year, the Society will hold the Early Investigators Workshop on October 21–22 in Indianapolis, Ind. This workshop is a must-attend for clinical fellows and post-doctoral fellows planning for independent research careers.

Here’s what participants of the 2012 Early Investigators Workshop shared with *Endocrine News* about their experiences.

**Dr. Michael Stitzel**, senior post-doctoral fellow at The Johns



Hopkins University School of Medicine, was drawn to the workshop by the basic science offerings and sessions focusing on grant writing,

lab management, negotiation, and mock study section: “I was expecting two intense days of scientific and professional advice and I was not disappointed. The personal and professional experiences that the faculty advisors shared were enlightening. I left San Francisco with a much better perspective of the “black box” of Study Section and scientific review of grants and with eyes wide open to the challenges and techniques in negotiating for a faculty position.”

He shared additional insights into the workshop’s networking opportunities: “Networking opportunities are usually difficult to facilitate in such a short, two-day workshop,

but I felt I the organizers, and particularly the participating faculty, made this a goal. I have found at other meetings that it can be difficult to penetrate the cliques that naturally occur. At this meeting, the faculty did a great job distributing themselves at meals and during the break amongst the trainees. I don't know if this was a conscious effort, but I did greatly appreciate it! Networking with other fellows who are at the same or similar stages of their careers was an added bonus."



**Dr. Irina Bancos**, fellow from Mayo Clinic, shared her perspective on the workshop: "I would highly recommend the Early Investigators Workshop to my colleagues! My advice would be to consider presenting a proposal that is in the early stages of development as it is most likely to be thought-provoking

to attendees. I also believe that first-year fellows would highly benefit from the workshop as this experience is likely to teach a better way to design research and avoid possible mistakes. Insightful and motivating!"



**Dr. Justin Gregory**, pediatric endocrine fellow at Vanderbilt University, also joined in the discussion: "I was given some great suggestions for my research after I gave a short presentation about what I am doing in the lab right now. One helpful suggestion was to look into some surgical

literature that I had not considered looking into that has some applicability for my research in hypoglycemia in T1DM. During some of the talks, the speakers had some great words of advice about how to effectively write research grant proposals. I am applying these as I write my F32 grant application. I also really appreciated the insights shared by the speakers about effective time management and balancing life as a physician and as a spouse and parent."

Registration for the Early Investigators Workshop is now open to post-doctoral and clinical fellows wishing to grow their research knowledge base and develop skills that will help further their research careers. Registration will be open through August 19, 2013. Space for this event is limited so apply today! **EN**

For more information, please visit the 2013 Early Investigators Workshop website, [www.endocrine.org/awards/ConfTravelGrants/clinical\\_investigators\\_workshop/index.cfm](http://www.endocrine.org/awards/ConfTravelGrants/clinical_investigators_workshop/index.cfm).



## CALL FOR NOMINATIONS AND APPLICATIONS FOR EDITOR-IN-CHIEF OF JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM

The Endocrine Society is seeking candidates for the position of Editor-in-Chief of *Journal of Endocrinology and Metabolism* for a five-year term beginning January 1, 2015. This position requires a dynamic, nationally recognized clinician who has a broad background in the field and is committed to maintaining the journal's reputation for publishing cutting-edge science. *Journal of Clinical Endocrinology and Metabolism* provides an international forum for papers enhancing the understanding, diagnosis, and treatment of endocrine and metabolic disorders. It is the world's leading peer-reviewed journal for endocrine clinical research and cutting edge clinical practice reviews.

### RESPONSIBILITIES

The Editor-in-Chief of *Journal of Clinical Endocrinology and Metabolism* receives editorial and administrative support from The Endocrine Society's Managing Editor and editorial office staff in Chevy Chase, MD, as well as an honorarium. The Editor-in-Chief oversees the peer review process and content development:

- Selecting his or her Deputy Editors, Associate Editors (6), and Editorial Board (47)
- Providing direction for the journal and its content features and identifying emerging "hot" areas of importance and soliciting papers for submission
- Participating in meetings of the Publications Core Committee
- Participating in meetings with the editors-in-chief of the Society's other journals

### NOMINATIONS

All members of The Endocrine Society are encouraged to suggest the names of potential candidates by contacting Scott Herman, Group Managing Editor — Associate Director, Publications for The Endocrine Society, at [sherman@endocrine.org](mailto:sherman@endocrine.org). Please submit your suggestions by **August 30, 2013**.

### APPLICATIONS

Applicants for the position of Editor-in-Chief of *Journal of Clinical Endocrinology and Metabolism* should submit the following materials:

- Description of qualifications
- Statement outlining how the candidate plans to oversee the journal, including goals for content, target readership, acceptance criteria, and editorial policy
- Proposed Associate Editors, areas of expertise, and process for editorial decision-making
- Discussion of the present status of the journal, opportunities for growth and enhancement, and plans to achieve goals
- *Curriculum vitae*

Applications are due by **September 30, 2013**, and should be emailed as PDF attachments to Scott Herman ([sherman@endocrine.org](mailto:sherman@endocrine.org)). Please call 301.951.2615 to ensure that your submission has been received. Selected candidates will be contacted by the search committee chair and asked to provide more details. The Publications Core Committee will interview finalists in person at its March 2014 meeting and choose a candidate to recommend to The Endocrine Society Council.

### PUBLICATIONS CORE COMMITTEE

The search process is being undertaken by the Publications Core Committee, and the chair of the search committee is Janet Schlechte, MD. The other members of the committee are: Margaret Shupnik, PhD, Chair; Dennis Baskin, PhD; Joanna Burdette, PhD; Kerri Burnstein, MD; Martin Fassnacht, MD; Sandra Licht, MD; Jeffrey A. Sandler, MD; and Daniel Spratt, MD.

## A TODDLER'S SUDDEN ILLNESS: A Case Study from Pediatric ESAP

### ANSWER

#### The Pediatric Endocrine Self-Assessment Program (ESAP)

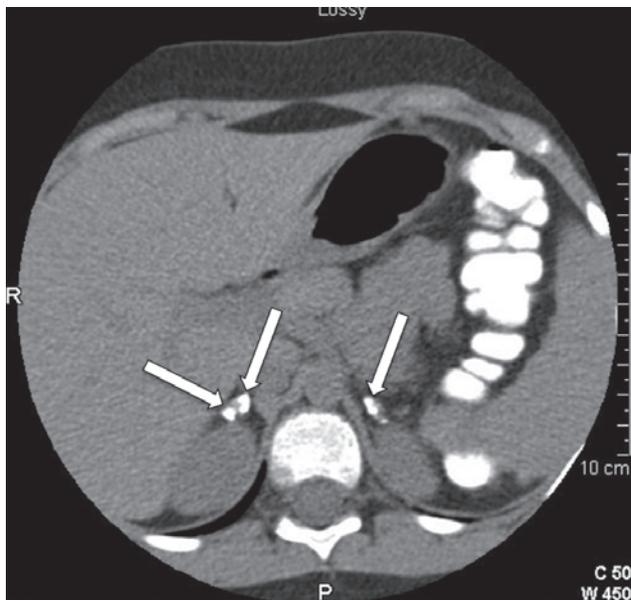
Enjoy this case? Access the NEW Pediatric ESAP 2013-2014 by visiting [endoseffassessment.org](http://endoseffassessment.org) today. Self-assessment products from The Endocrine Society offer CME credits and MOC points. Visit [endoseffassessment.org](http://endoseffassessment.org) and use the personalized "My Modules" dashboard to manage your CME and MOC needs.



question on page 23

### The answer is: D. Adrenal hemorrhage

This patient has adrenal calcifications (see arrows) caused by adrenal hemorrhage (Answer D), a well-recognized obstetric complication of the newborn, which is an increasingly rare cause of adrenal insufficiency because of the improvements in care during labor and delivery.



However, it is still an issue, and unless diagnosed and treated early, it can lead to chronic, partially compensated adrenal insufficiency or adrenal insufficiency crisis or both. In about half of the reported cases, the bleeds are bilateral and occur at birth. Gradually, the affected glands develop calcifications. Risk factors include large birth weight, hypoxia, septicemia, coagulation defects, and thromboembolism. Other causes of adrenal calcifications include tuberculosis; autoimmunity; Wolman disease (familial xanthomatosis); Niemann-Pick disease; and masses including hemorrhagic and teratomatous cysts, ganglioneuromas, pheochromocytomas, neuroblastomas, and adrenocortical cancer. Adrenal calcification may also be an incidental finding, although then it is also attributed to perinatal adrenal hemorrhage. This patient's history and presentation are consistent with the cases with adrenal hemorrhage that have been described in the literature, with presentation of adrenal insufficiency not at birth or shortly thereafter, but rather later in the second or third year of life. Typically, these patients compensate for their adrenal dysfunction with high ACTH levels. Partial adrenal insufficiency should be suspected in any infant who has failure to thrive and difficulty feeding, but no primary gastrointestinal disorder. Their condition may decompensate during an infection, a bout of diarrhea, or the course of any other illness, and then they present with severe adrenal insufficiency like the child in this vignette.

Patients with Allgrove syndrome (Answer A) (also known as triple A syndrome) present with alacrima, achalasia, and adrenal insufficiency, but they never develop calcifications in their adrenal glands.

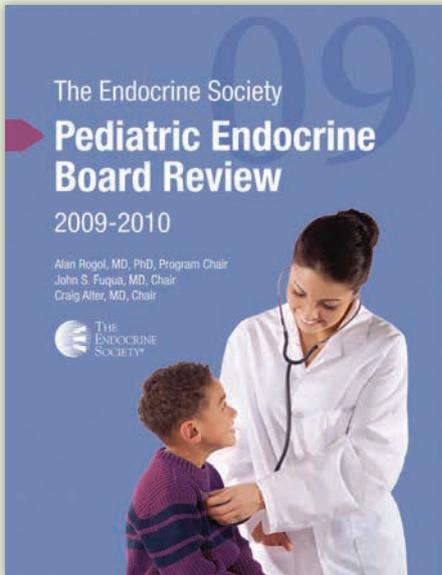
Allgrove syndrome and other causes of familial glucocorticoid deficiency syndromes (Answer B) also rarely cause mineralocorticoid deficiency.

Congenital adrenocortical hyperplasia (CAH) (Answer C) associated with mineralocorticoid deficiency is an unlikely diagnosis in a fully virilized male with low 17-hydroxyprogesterone levels. Although salt-losing 21-hydroxylase deficiency would be consistent with the biochemical profile in this male toddler, the 17-hydroxyprogesterone levels would be expected to be high. Also, CAH is not known to be associated with adrenal gland calcifications.

Finally, congenital HIV infection (Answer E) can cause adrenal insufficiency, but unless it leads to tuberculosis or parasitic infections (i.e., histoplasmosis), it would not be associated with adrenal gland calcifications. These calcifications tend to also be unilateral in patients who develop them secondary to an infection. **EN**

# Precious Patients, Require Specialty Care

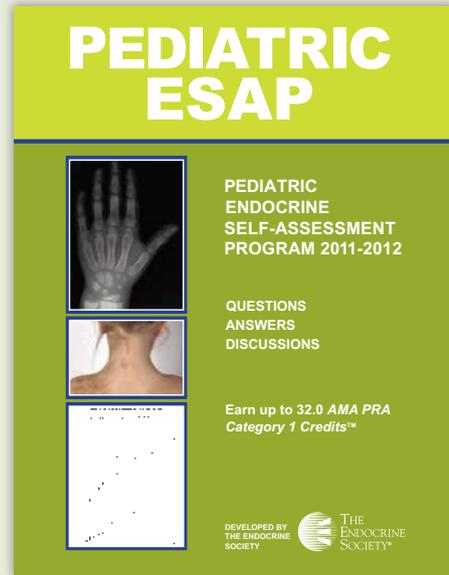
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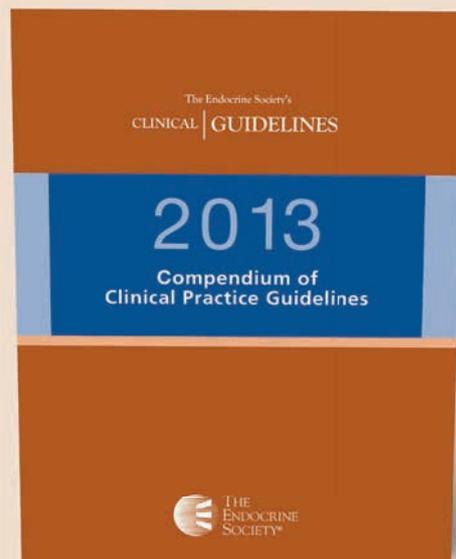
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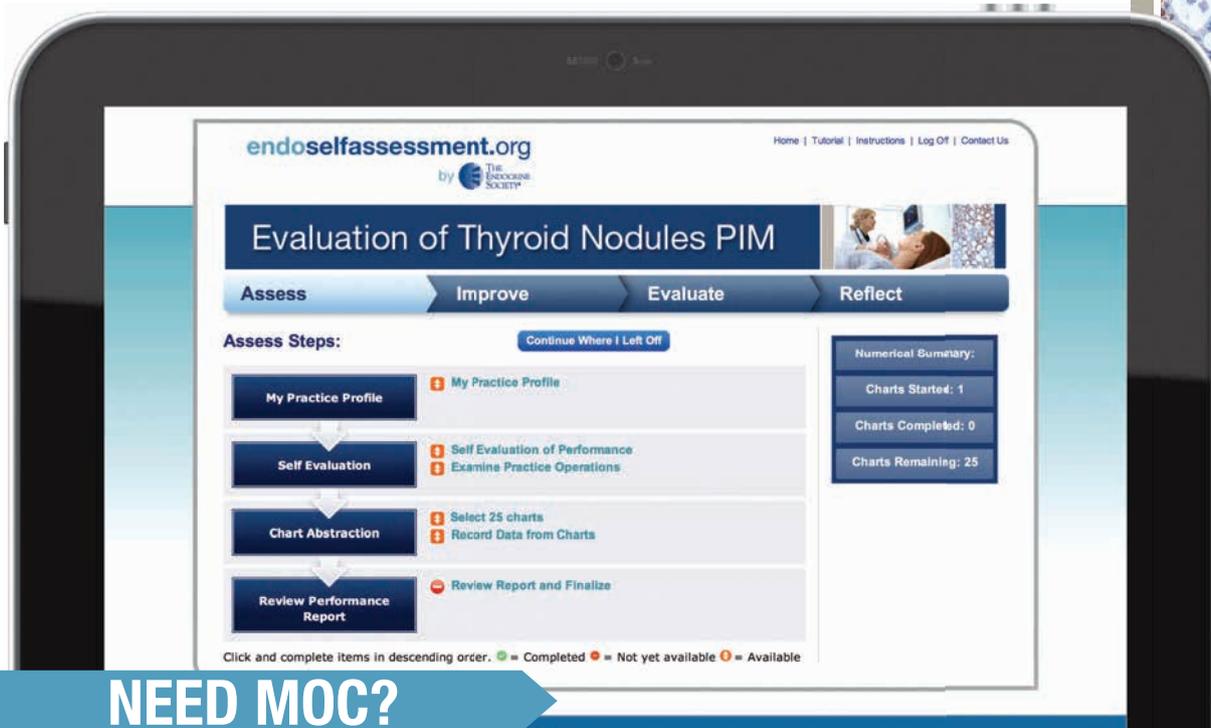
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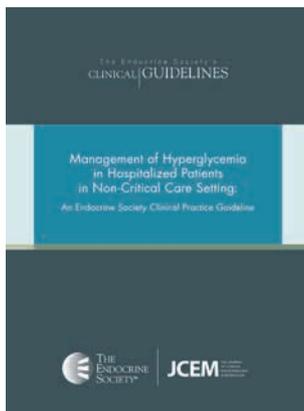
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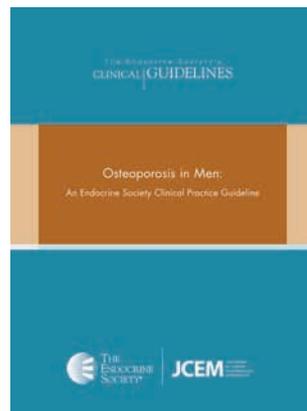
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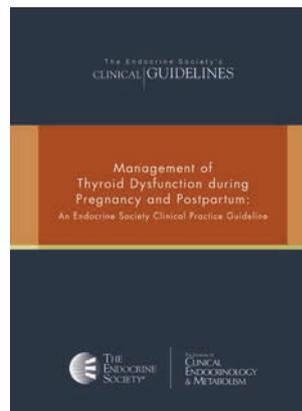
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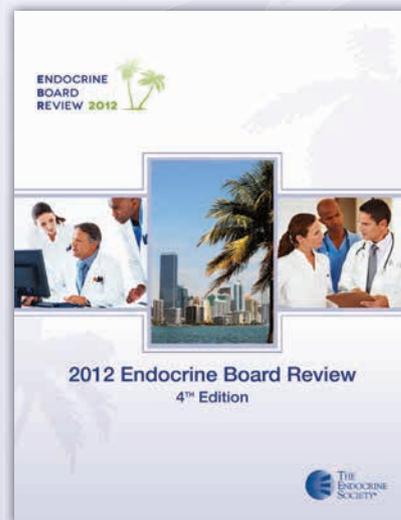
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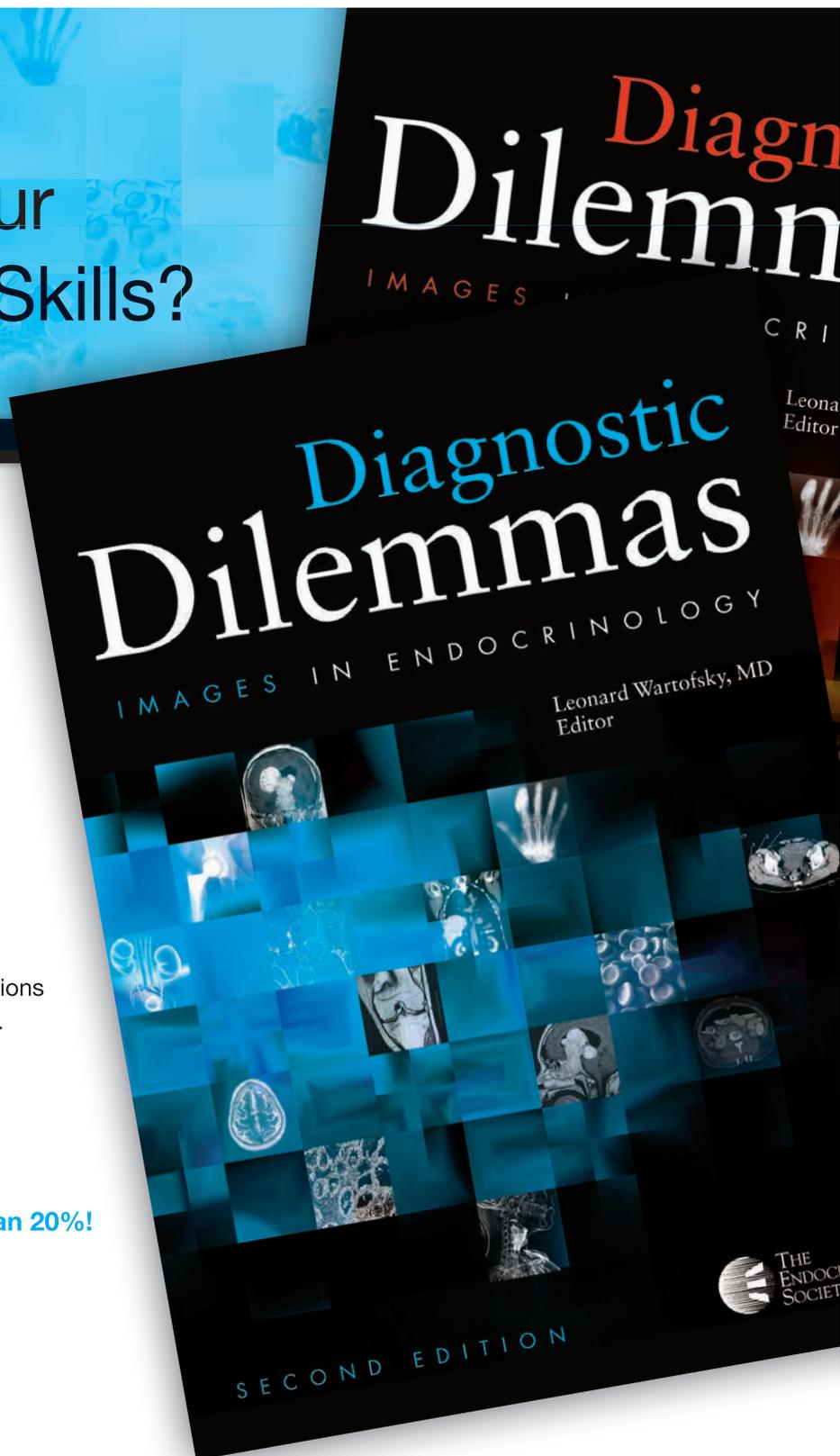
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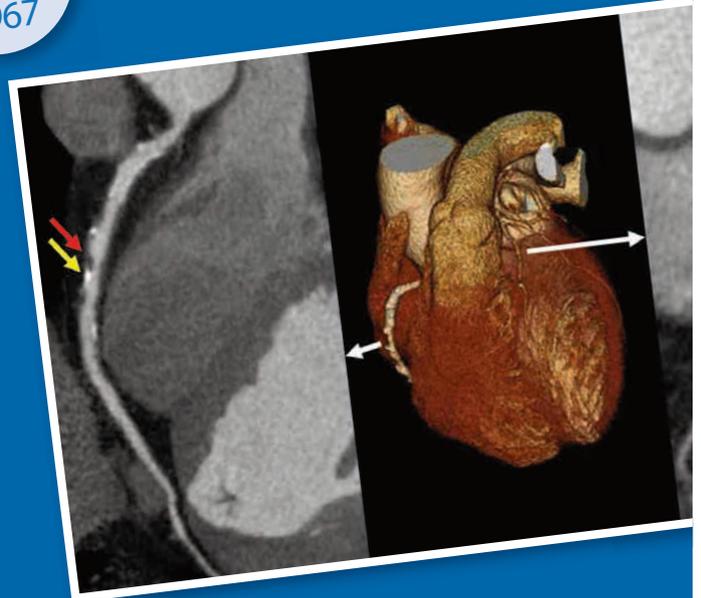
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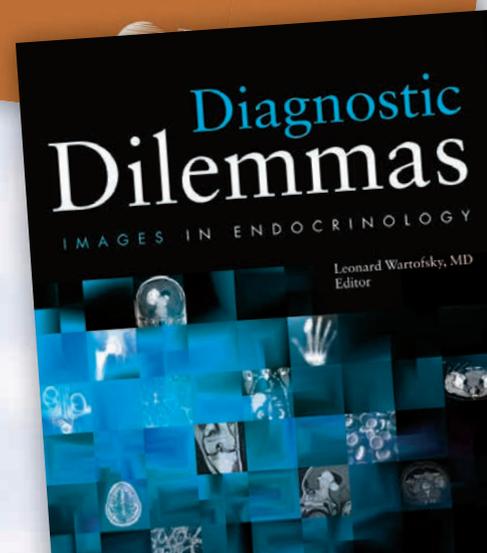
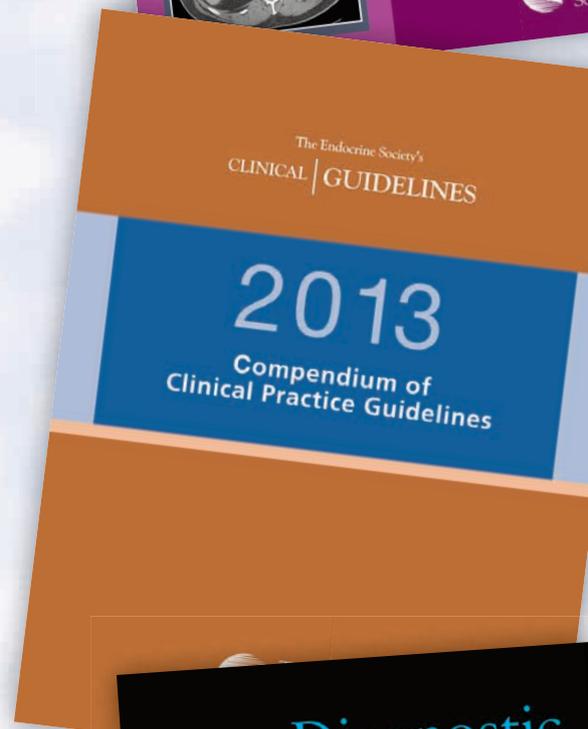
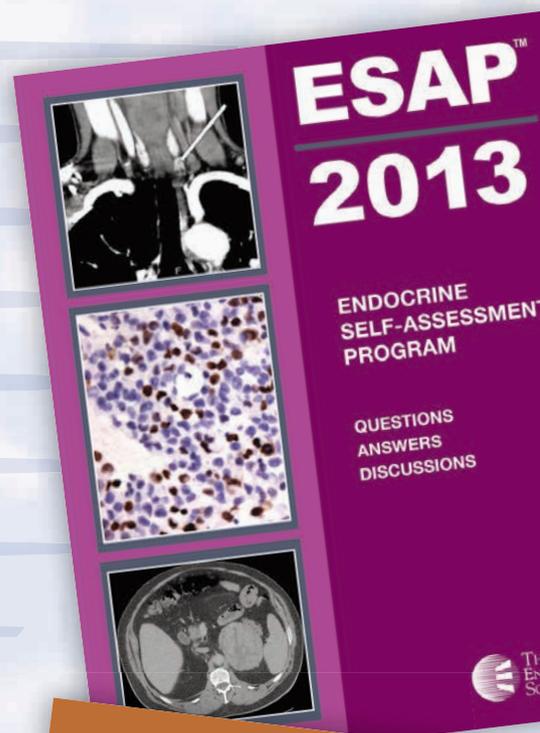
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# Goiter

## WHAT IS A GOITER?

A goiter is an enlarged thyroid gland. The thyroid gland, located in the front of your neck, makes thyroid hormones. When your thyroid gland is enlarged, it can produce too much, too little, or just enough thyroid hormone.

## WHAT DO THYROID HORMONES DO?

Thyroid hormones travel from your thyroid gland through the blood to all parts of your body. They control how your body uses food for energy, and help all your organs work well. Thyroid hormones affect your metabolism rate, which means how fast or slow your brain, heart, muscles, liver, and other parts of your body work.

If your metabolism is too fast or too slow, you won't feel well. For example, if you don't have enough thyroid hormone and your metabolism slows down, you might feel tired and cold. Or, if you have too much thyroid hormone, you might feel nervous and warm.

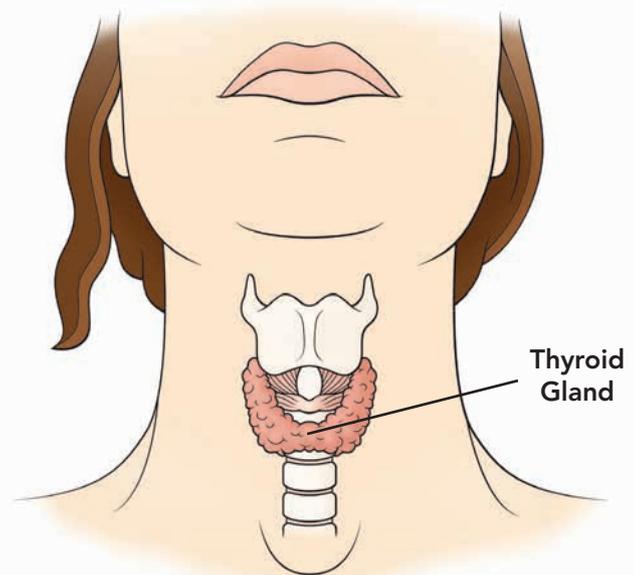
## DID YOU KNOW?

**The most common cause of goiter outside of the U.S. is a lack of iodine in the diet. Iodine is a substance in food (iodized salt and seafood) that the thyroid uses to make thyroid hormones. However, a lack of iodine is not common in the U.S. because iodine is added to salt and many foods.**

## WHAT ARE THE SYMPTOMS OF A GOITER?

You can have a goiter but have no symptoms at all, other than having some swelling at the base of your neck. Some people also may have

- Tightness in the throat
- Coughing
- Hoarseness
- Trouble swallowing
- Trouble breathing



## DEFINITIONS OF THYROID CONDITIONS

**Underactive thyroid gland:** when the thyroid gland doesn't make enough thyroid hormone; also called **hypothyroidism**. When the thyroid is underactive, the body's metabolism runs too slowly.

**Overactive thyroid gland:** when the thyroid gland makes too much thyroid hormone; also called **hyperthyroidism**. When the thyroid is overactive, metabolism runs too quickly.

**Hashimoto's disease** (the most common cause of underactive thyroid): when the immune system attacks and damages the thyroid gland; then the damaged gland no longer makes enough thyroid hormone.

**Graves' disease** (the most common cause of overactive thyroid): when the immune system attacks the thyroid gland and causes it to make too much thyroid hormone.

## WHAT CAUSES A GOITER?

In the U.S., the most common causes of swelling are

- Hashimoto's disease (leading to an underactive thyroid)
- Graves' disease (leading to an overactive thyroid)
- Nodules (lumps) on one or both sides of the thyroid gland

Less common causes include a hormone made during pregnancy that increases thyroid hormone production, inflammation of the thyroid, or thyroid cancer. A goiter also can be present in a newborn if his or her thyroid gland doesn't work properly before birth.

## WHAT FACTORS INCREASE THE RISK OF A GOITER?

Risk factors include

- Being a woman
- Being over age 40
- Being pregnant or in menopause
- Having a family history of autoimmune disease or goiter
- Having been exposed to radiation as a child or having had radiation treatment to your neck or chest
- Having a diet low in iodine

Some medicines also increase the risk of goiter.

## HOW IS A GOITER DIAGNOSED?

A goiter is often found during a physical exam when your doctor feels swelling in your neck. Your doctor also may use other tests to

find the cause of the goiter and to see how advanced it is, such as

- Hormone tests to show whether your thyroid gland is underactive or overactive
- Antibody tests for Hashimoto's disease and Graves' disease
- Ultrasound to see the size of your thyroid and whether there are nodules
- A thyroid scan to look at your thyroid, especially if your thyroid is overactive
- Other scans (CT or MRI) of the neck to check your windpipe
- A biopsy (using a needle to get a sample of your thyroid for testing)

## WHAT IS THE TREATMENT FOR A GOITER?

Treatment depends on the cause of the goiter, its size, and your symptoms. If your goiter is small and your thyroid is making normal amounts of thyroid hormone, your doctor might observe the goiter over time instead of starting treatment right away.

Possible treatments include

- Medicines for underactive or overactive thyroid
- Radioactive iodine for overactive thyroid (to shrink the goiter)

Surgery is rarely used. However, removal of the thyroid gland might be recommended for a large goiter, for one causing breathing or swallowing problems, for nodules, or for thyroid cancer.

## Questions to ask your doctor

- What is causing my goiter?
- What are my options for treatment?
- What are the risks and benefits of each treatment option?
- How long will I need treatment?
- Should I see an endocrinologist for my care?

## RESOURCES

- Find-an-Endocrinologist: [www.hormone.org](http://www.hormone.org) or call 1-800-HORMONE (1-800-467-6663)
- Hormone Health Network information about thyroid disorders: [www.hormone.org/Thyroid/overview.cfm](http://www.hormone.org/Thyroid/overview.cfm)
- Mayo Clinic information about goiter: [www.mayoclinic.com/health/goiter/DS00217](http://www.mayoclinic.com/health/goiter/DS00217)
- MedlinePlus (National Institutes of Health) information about goiter: [www.nlm.nih.gov/medlineplus/ency/article/001178.htm](http://www.nlm.nih.gov/medlineplus/ency/article/001178.htm)

## EDITORS

Bryan Haugen, MD  
James Hennessey, MD  
Leonard Wartofsky, MD

January 2013

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Goiter Fact Sheet



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