Bridging the gap between payer and provider perspectives

October 2014
Volume 20
Special Issue 13

THE AMERICAN JOURNAL OF MANAGED CARE®

Evidence-Based Diabetes Management™

From the Editor-in-Chief

Diabetes Management Key to Healthcare Solutions

Robert A. Gabbay, MD, PhD

Welcome to *Evidence-Based Diabetes Management* and a new era in the evolution of this journal. I am thrilled to be joining as editor-in-chief; my goal will be to ensure that the journal focuses on critical issues and innovations in the management of diabetes. The healthcare environment is evolving rapidly, and the management of diabetes stands at the forefront of many of these changes. The epidemic of diabetes continues to grow in the United States, with more than 26 million diabetes sufferers and an annual healthcare cost of $245 billion.[1] It is estimated that if we cannot rein in this dramatic rise, 1 in 3 Americans born in the year 2000 will develop diabetes in their lifetime. With a global prevalence of 347 million, the statistics for many countries are even more chilling. In China, for example, more than 11% of the population is currently enduring the disease.

No effort to rein in healthcare costs is likely to be successful without tackling the challenges of diabetes management. This is becoming increasingly apparent to policy makers, employers, public health experts, and payers. As a plethora of new medications, devices, and digital solutions become available, prudent examination of the value of these approaches will be critical.

Robert A. Gabbay, MD, PhD

In many ways, diabetes care has long been the harbinger of innovative care delivery models. The critical importance of patient self-management, recognized by Elliott Joslin over a century ago, has now become integral to the management of all chronic diseases. Team-based care, a mantra of the patient-centered medical home (PCMH), originated in the management of patients with diabetes. Similarly, early implementation of population management, the Chronic Care Model, and now the PCMH, all started with diabetes.

(continued on page SP389)

Drug Combination Update

Upending of Conventional Combination Therapy in Type 2 Diabetes Mellitus

Stanton R. Mehr

Rapid innovation in treating type 2 diabetes mellitus (T2DM) has challenged primary care physicians (PCPs) and endocrinologists alike to stay current. Clinicians have a high comfort level with prescribing metformin as a first step after changes in diet and exercise in a patient with newly diagnosed T2DM. However, monotherapy with metformin may work only for a short time for a few patients to sufficiently lower glycated hemoglobin (A1C) levels, owing to the deteriorating nature of beta-cell function.[1]

The typical second step, if hyperglycemia persists, has been to add a sulfonylurea (SU), like glipizide; however, clinicians often wait too long before adding the second medication, thus limiting its effectiveness.[1] As a result, consensus is growing to begin combination therapy earlier in treatment. This more aggressive approach to controlling glycemic levels early on, studies suggest, will preserve beta-cell function down the line; the goal is to prevent serious long-term consequences such as kidney disease, neuropathy, and glaucoma.

Although metformin and SU have long been the top choices for initial antidiabetic drug treatment, other noninsulin choices for step 2 therapy abound, from Actos (pioglitazone) to Victoza (liraglutide [rDNA origin] injection). To compound the choice facing clinicians, many manufacturers, when conducting mid-stage and late-stage clinical trials, include a monotherapy trial of their glucagon-like peptide-1 (GLP-1), dipeptidyl peptidase-4 inhibitor (DDP-4), thiazolidinedione, metglitinide, or sodium-glucose co-transporter 2 (SGLT-2) agent. These are often shown to be effective in placebo-controlled clinical trials.

Moving Faster to Effective Therapy

In its 2014 update, the American Diabetes Association (ADA) revised its Clinical Practice Recommendations for treating T2DM. A significant change from past recommendations is a shorter trial of noninsulin monotherapy to control hyperglycemia. According to the new guidelines, physicians should wait no longer than 3 months (instead of up to 6 months) in an average patient before moving to combination therapy.[2] If adopted, this practice would compel clinicians to decide earlier which second-line therapy is best for their patients. For many, this means prescribing an SU, which they have been doing for years in patients who do not have contraindications. For others, the more innovative choices can be both attractive and daunting.

(continued on page SP389)

Policy

Origins and Evidence Behind New ADA Recommendations for Pediatric A1C

Sejal Saraiya, PharmD

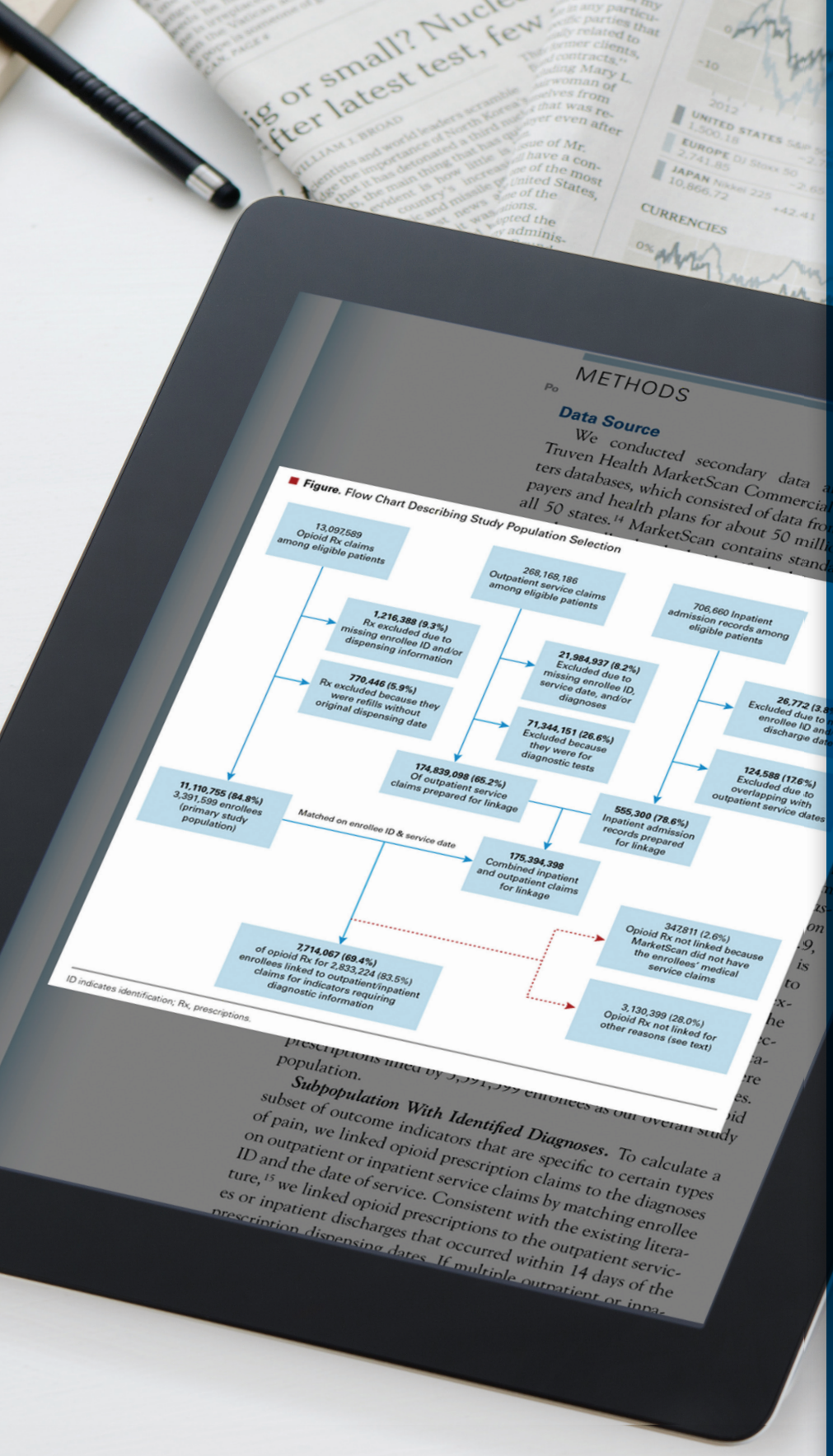
Type 1 diabetes mellitus (T1DM), or insulin-dependent diabetes, is a chronic condition in which the β-cells of the pancreas produce little or no insulin. It is an immune-mediated condition which requires lifelong management with exogenous insulin. Although the disease is often referred to as "juvenile diabetes," primarily due to the age of onset, a majority of people with T1DM are adults. In fact, of the estimated 3 million individuals with the disease, less than 200,000 are juveniles.[1,2] This could be explained by the improved survival of individuals with childhood-onset diabetes.[3] The American Diabetes Association (ADA) recently released a position statement to better manage T1DM and prevent complications associated with the condition.

(continued on page SP391)

Also in this issue...

Commentary
Tory Johnson, a business reporter for Good Morning America, discusses her journey with weight loss and what finally motivated her transition to healthy living (SP375).

***AJMC*'s ACO Coalition**
Excerpts from the Web-based meeting which featured Jeffrey Farber, MD, MBA, chief medical officer at Mount Sinai Care LLC. Farber introduced the attendees to the functioning of Mount Sinai Medical Center's Diabetes Alliance (SP387).



A One-Stop App for *Managed Care Professionals*

All our print and digital content in one place!

Access exclusive, original content from the industry's most trusted and most referenced managed care publication, *The American Journal of Managed Care* (*AJMC*). Whether on the road or in the home, managed care news and media are now at your fingertips—whenever you want it!

By downloading the *AJMC* app, you will gain access to exclusive content not seen anywhere else on the Web or in print. In addition to our peer-reviewed research, the app includes:

- In-depth author commentaries
- AJMCTV Peer Exchange videos
- CME resources
- Monthly "Payer Perspectives" Column
- And so much more

AJMC Tablet Edition

Download to your tablet today!

Available on the App Store

ANDROID APP ON Google play

THE AMERICAN JOURNAL OF MANAGED CARE®

AJMC.com

From the Publisher

With this issue, we proudly announce that Robert A. Gabbay, MD, PhD, chief medical officer and senior vice president at Joslin Diabetes Center, joins *Evidence-Based Diabetes Management* as its first editor-in-chief. Dr Gabbay was the keynote speaker at our recent conference, Patient-Centered Diabetes Care, and he is a leader in implementing value-based principles in healthcare delivery, as reflected in his work with the Patient-Centered Medical Home model. We look forward to Dr Gabbay's stewardship in bringing you important developments in research, therapeutics, and the ongoing effort to change the way persons with diabetes gain access to care in the United States.

Robert A. Gabbay, MD, PhD, chief medical officer and senior vice president at Joslin Diabetes Center, joins Evidence-Based Diabetes Management *as its first editor-in-chief. Dr Gabbay was the keynote speaker at our recent conference, Patient-Centered Diabetes Care, and he is a leader in implementing value-based principles in healthcare delivery, as reflected in his work with the Patient-Centered Medical Home model.*

As we have said before, change is all around us, and so is the concept of what constitutes a high standard of care. This was obvious at the 74th Scientific Sessions of the American Diabetes Association earlier this year in San Francisco, where leading scientists asked whether the future of care for type 2 diabetes mellitus (T2DM) would look more like care in cancer, in which major interventions come early, not late, in the process. This is the thinking behind research into new therapy combinations, which we discuss in our cover story. Approaches to how we measure health, especially in the youngest patients, are changingtoo. This issue examines new guidelines for glycated hemoglobin (A1C) for pediatric patients and debates whether body mass index (BMI) is the right way to gauge a young person's obesity status. BMI is convenient and easy, but it may not tell us what we need to know: are dangerous levels of fat present, and does this condition need to be addressed?

The relationship among T2DM, A1C, blood pressure, and cardiovascular measures matters more than ever because these metrics are now tied to the bottom line for accountable care organizations, an entity created by healthcare reform to ensure that we reward value in care. Leaders like Dr Gabbay have called on all of us to pay attention to whether patients get better, not whether they are subjected to a host of procedures. Today, Medicare is paying attention, too.

We hope you share our enthusiasm about Dr Gabbay's new role with *Evidence-Based Diabetes Management*. As always, we thank you for reading, and remind you to look to www.ajmc.com for updates.

Brian Haug
Publisher

EDITORIAL MISSION

To present policy makers, payers, and providers with the clinical, pharmacoeconomic, and regulatory information they need to improve efficiency and outcomes in diabetes.

Editorial Board

Fear of Fat Talk Kept Me From My Doctor for a Decade

Tory Johnson

Motivating overweight patients to lose weight and improve their health is among the most difficult challenges facing the healthcare system. In recent years, studies have examined the doctor-patient relationship, where many conversations about weight loss first occur. These encounters may set the course for an overweight person's overall experience with the healthcare system. In fact, a new survey from Johns Hopkins found that 21% of overweight patients felt judged by their primary care doctor and were less likely to trust that person's advice.[1] *To understand how such an encounter can affect an overweight patient—and what it takes them to change—*Evidence-Based Diabetes Management *invited Tory Johnson of* Good Morning America *and author of* The Shift *to share her experience.*

My doctor spent an hour with me on that hot summer afternoon. She knew I was nervous since my palms were sweaty in the air-conditioned room. During her exam, she calmed me by talking about work, motherhood, and careers. At the end, she told me to get dressed and said she'd be back in a few minutes.

Whew, I thought, I'd dodged the weight bullet! Not a single word during the exam. But then we had The Final Chat and she oh-so-gently recommended that I see her colleague who specialized in obesity. He's great, she said, slipping me a piece of paper with his name and number.

My face flushed and a feeling of intense humiliation surged through my body—even though she could not have been kinder or gentler with me.

Don't be a stranger, she said, and I nodded numbly: of course not.

Not only did I *not* go see her colleague, but I avoided her for the next 10 years.

Research shows that my experience at the doctor's office is not unique. Studies have shown that when an obese patient sees the doctor, more time is spent talking about weight, with less time spent on general health.

No mammogram, Pap smear, blood tests for cholesterol—all keys to women's health. Even though I had health insurance, I'd reached a stage where I was so terrified at being called fat that I avoided going to the doctor for an entire *decade*.

Just the thought of it makes me more determined than ever to make sure that my kids never retrace my footsteps. That they never fear time with a medical professional.

What finally got me to that place was losing weight—a lot of it. It took a very candid conversation to get me there.

As a weekly contributor on ABC's *Good Morning America*, I had always thought in the back of mind that it was just a matter of time before my size became an issue. But no anchor, producer, or executive ever said a thing for years. I got the false sense that my work was so good that it trumped any issues with my girth.

Then one day, Barbara Fedida, the executive in charge of all on-air talent at ABC News, asked me to coffee. Uh oh, I thought, the jig is up.

After 45 minutes of polite chitchat, it was. She said I didn't look my best, my clothes didn't do me justice, and she wanted to send me to a stylist.

Once again, like that day in the exam room, my palms became drenched in sweat. My heart began to beat fast and my head got fuzzy.

Barely, just barely, I managed to force these words from my mouth: *Of course! I'd be happy to see your stylist! Thank you!*

As I fled the building and walked out onto the street, I felt an incredible sense of relief. I knew my life was about to change. Someone had finally told me directly what I needed to hear in a way that suited me just fine.

Barbara didn't put me on the spot, embarrass, or humiliate me. She did not threaten me or say I had to lose weight. And the word obese never came up.

But I'm no dummy, and I took her words as they were intended: *Tory, TV is a visual medium and you must lose weight*.

Exactly 1 year later, on my own, I had lost 62 pounds.

I did it by realizing that what I put in my head is far more powerful than what I put in my mouth. That pills and potions are no match for patience and perseverance. I wrote about my journey in *The Shift*, which became a No. 1 *New York Times* bestseller, out in paperback with new updates this month.

Tory Johnson

Thanks to *The Shift*, I got to show off the new me on *Dr. Oz*. I told him that the fear of the scale—the specter of being weighed by a nurse in a doctor's office during a routine visit—was enough to keep me away my whole life.

He nodded in agreement and said he encourages physicians not to put women on a scale: any good doctor can look at a patient and know if they have a weight issue. No need, he said, to embarrass someone on the terrifying scale.

This is why viewers love you, I thought. I'll come back on your show anytime!

Research shows that my experience at the doctor's office is not unique, and it may be doing harm. Klea Bertakis, MD, MPH, of the University of California at Davis, studies doctor-patient relationships and has found that when an obese patient sees the doctor, more time is spent talking about weight, with less time spent on general health.[2]

Another study from Johns Hopkins found that overweight patients are more likely to repeatedly switch doctors, and researchers believe that off-putting comments or unsolicited weight advice play a role. Compared with normal-weight patients, these "doctor shoppers" are 85% more likely to end up in the emergency room.[3]

Incidentally, I had pledged to myself that I'd return to my doctor when I lost weight—and I did. She was happy to see me—and thrilled with the new me. All my tests were good.

Don't be a stranger, she said. I won't, ever again. **EBDM**

References

1. Gudzune KA, Bennett WL, Cooper LA, Bleich SN. Patients who feel judged about their weight have lower trust in their primary care providers [published online July 7, 2014]. *Patient Educ Couns*. doi:10.1016/j.pec.2014.06.019.

2. Bertakis KD, Azari R. The impact of obesity on primary care visits. *Obes Res*. 2005;13(9):1615-1623.

3. Gudzune KA, Bleich SN, Richards TM, Weiner JP, Hodges K, Clark JM. Doctor shopping by overweight and obese patients is associated with increased healthcare utilization. *Obesity*. 2013;2(7):1328-1334.

ACO Concept Wins Praise, Though Early Results Are Inconclusive

Andrew Smith

How goes the most ambitious reform effort in the history of American diabetes management?

The early evidence shows mixed results from health service providers that are teaming up to coordinate patient care and wide disparities between the best and worst teams.

The early evidence, however, is paper thin.

CMS last released outcomes data for some accountable care organizations (ACOs) in February 2014. It was 1 of only 2 announcements the government has ever made about the performance of such operations, which now treat several million Americans, and the numbers were already more than a year old.

The dearth of information precludes detailed analysis of actual ACO results, leaving only a general consensus about the transformative potential of coordinated care and some anecdotal evidence about events on the ground.

"The ACO concept is extremely logical. Research clearly shows that people with diabetes and other chronic ailments enjoy dramatically better health, and consume dramatically fewer resources, when their various care providers intelligently coordinate treatment," said Robert E. Ratner, MD, FACP, FACE, chief scientific and medical officer of the American Diabetes Association (ADA).

"We just don't know many details about how this logical concept is working in practice. We can't make any general statements about where ACOs have done well and where they have done poorly. We can't say whether some types of ACO produce better results than others, or explain what separates the best and worst performers."

"All we can really say is that the initial results were encouraging and that we'd really like to see much more data. We think greater transparency, not just in the data the government collects but also in the internal data from the ACOs themselves, would benefit everyone by helping best practices spread far more quickly," added Ratner.

The Affordable Care Act actually provides for several different types of ACOs that are variations of the same general idea: healthcare providers that work together to coordinate wellness programs for chronically ill patients get 50% to 60% of the difference between expenditure benchmarks and actual outlays.

Unlike the traditional fee-for-service model, which pays caregivers more when patients get sick, the ACO payment model provides caregivers a financial incentive to keep patients healthy.

To keep those caregivers from reducing expenditures simply by skimping on care, CMS has created 33 quality measures for Medicare ACOs, and private insurers have created their own metrics for commercial ACOs.[1] During their first year of operation, providers need only report the percentage of patients that meet each target. Subsequently, providers that want to keep sharing in "savings" must demonstrate that they're meeting targets on each metric for ever-increasing percentages of their patients.

The initial word on ACO performance came last summer, when CMS reported the first-year results for 32 organizations that participated in Medicare's "Pioneer" program.[2]

All of the Pioneers had begun experimenting with the coordinated care model before CMS created its programs—an experience that made those groups an ideal model to prove the benefit of an ACO—and most of the Pioneers came through.

Costs for the more than 669,000 beneficiaries aligned to Pioneer ACOs grew less than half as much in 2012 as costs for similar patients with traditional care. Nearly half of the Pioneers beat cost targets enough to share in "savings" that totaled $87.6 million, and all but 7 of the 32 saved some money.

Better still, the Pioneer ACOs outperformed fee-for-service organizations in all 15 quality measures for which direct comparison was possible. Among diabetics, for example, the median rate of cholesterol control was 57% for ACO patients but only 48% for others.

Early this year, however, CMS released the first numbers from its larger group of ACOs— the Medicare Shared Savings Program—and the picture was decidedly mixed.[3]

Only 54 of the 141 ACOs in that program managed to keep costs below their targets, and only 29 of them kept costs low enough to share in savings. Most of the participating ACOs actually billed more for patient care than a typical fee-for-service provider.

CMS also released data on how the ACOs in the Shared Savings Program performed on 5 quality measures, 4 of which gauged diabetes care: aspirin use, tobacco non-use, glycated hemoglobin (A1C) less than 8%, and blood pressure less than 140/90 mm Hg.[4]

Overall, ACO performance exceeded comparable numbers from fee-for-service providers, and on average, the groups in the program met each target for 65% to 75% of their patients.

The gaps between the best performers and the worst performers, however, were dramatic.

An ACO in Wisconsin called Bellin-ThedaCare Healthcare Partners reported that 84% of its patients kept their A1C levels under 8%. Accountable Care Coalition of Maryland, on the other hand, reported that only 24% of its patients could maintain that target.

Success rates on the blood pressure target ranged from 33% to 88%. Success rates for tobacco nonuse were similar, but the variations in aspirin use were even more extreme. Several plans reported that all of their diabetic patients used aspirin, while several others reported that less than 30% did.

Those numbers may overstate the actual size of the gaps somewhat. Some of the lowest-scoring ACOs have announced that failure to collect data for some patients (and, in one case, failure to appropriately tabulate percentages[5]) deflated their scores. Still, the true gaps were substantial.

"The disparities from the Shared Savings plan make sense when you consider the huge variety among the ACOs that are participating," said Brett Erhardt, a director with a research and consulting firm called The Advisory Board.

"Some of them had been experimenting with coordinated care for years, but most had little to no experience with it. They were dipping their toes in the water and testing different concepts. Big gaps were to be expected across the board. Gaps were particularly natural on the quality measures because the numbers came from the program's first year, when ACOs have a reporting requirement but no performance targets. They were, quite rationally, focused on other matters," he added.

Another likely explanation for at least some of the performance gaps—or possibly even the majority of them—is variance among the patient populations of different ACOs.

Aggregate differences in age, education, income, and other demographic factors correlate strongly with differing propensities to keep using tobacco, quit using medications, or otherwise confound efforts to measure caregiver quality.[6]

Some caregivers think it's unfair to judge them on measures not completely under their control, and CMS is evaluating those complaints—looking for measures that everyone can support. Indeed, the agency has spent years working to settle disagreements, align conflicting goals, and build something approaching a consensus for its method of evaluating ACO performance.

The current system, then, is an attempt at compromise: a compromise between those who support fee-for-service and those who support population-based payments, a compromise between those who believe doctors should be measured by what they do and those who believe they should be measured by the outcomes they partially produce, and a compromise among countless other warring ideals.

Indeed, the diabetes measures illustrate the difficulty of the task. Even now, after years of work, the ADA takes issue with 1 of the 4 official measures. CMS wants caregivers to get A1C levels below 8% for all patients, but the ADA thinks a significant minority of patients fare just as well with higher levels.

Still, CMS has succeeded in creating a surprising amount of consensus by proving itself willing to consider complaints and tweak its system. For example, the agency originally proposed twice as many quality measures, but slashed the list following objections

over duplicate metrics and excessive reporting costs.

Despite several years of work, it's a work in progress. Just this past July, CMS added 4 new quality measures, eliminated an existing measure, and tweaked 2 others.[7]

Additional consensus-building efforts will probably result in further changes to the quality measures and may even lead CMS to adjust its performance targets on those measures.

Although the agency factors patient demographics into its cost targets for each ACO, it currently does not consider demographics in setting performance targets. All ACOs must meet the same performance targets to share in savings. Some observers expect CMS to concede the effect of demographics and begin customizing quality targets, while others expect it to eliminate targets entirely and demand a yearly improvement from each ACO instead.

CMS has not announced any plans on additional data-sharing on ACO performance, but the information that it does provide is likely to be at least 6 months old, simply because it takes at least that long for all claims to be processed and any savings to be tabulated.

Everyone recognizes the complexity of gathering considerable information, analyzing it, and making it public in anything resembling a timely manner; but many still think that if the ACO experiment is to provide maximum benefits to patients and taxpayers, CMS must share more.

The president's own Council of Advisors on Science and Technology believes that sharing information ranks among the 6 most important strategies for improving healthcare.[8] "Communicating the lessons learned can help those starting system-improvement efforts."

With little hard data on hand, observers must cobble together anecdotal evidence and independent research to combine with the 2 releases from CMS to estimate the general strengths and weaknesses of existing ACOs, and to surmise the difference between the best and worst performers.

The evidence they see suggests that nearly all ACOs, even the newest among them, have achieved the most important initial goal: identifying the neediest patients, the ones who end up in hospital several times a year because they cannot manage their conditions.

Research suggests that this small group of patients consumes much of the money spent on chronic illness each year, and thus represents much of the opportunity for improving health and cutting costs.

The potential for significant improvement certainly exists. One study of a coordinated care program launched more than a decade ago by the Veterans Health Administration found that it reduced the hospitalization rate of diabetics by 50% and reduced the average stay for people who were hospitalized by 3 days.[9]

Significant results of this order have generated widespread enthusiasm for coordinated care programs, but many experimental programs have failed to justify that enthusiasm. A large trial in Australia, for example, managed to produce moderate improvements to patient health, but overall expenditures rose significantly.[10]

For many new ACOs, though, the biggest initial challenges seem to be technological.

Coordinated care only works when information flows among all the caregivers on the team, even when all those caregivers work at different practices, with different initial software, and with different initial work flows.

"Most caregivers have struggled for years to make technology improve communication and increase efficiency at individual practices. Figuring out best practices for connecting multiple practices with health information exchanges and population health management software is clearly a work in progress," said David B. Muhlestein, PhD, director of research at Leavitt Partners, LLC.

ACOs made up entirely of caregivers who work for a single hospital or network of hospitals naturally enjoy the advantage of compatible software, and that's not their only advantage. Large organizations have larger capital budgets; some experience coordinating care between different types of doctors and clear chains of command to settle disputes that arise.

Hospital ACOs may also enjoy another advantage over ACOs made up of smaller independent practices: a greater ability to get patients to buy into the team concept.

"Patients have always thought about choosing individual caregivers rather than care teams. They find one doctor for this and one doctor for that, and they get comfortable with those doctors, and they won't change easily," said Muhlestein.

"Caregivers who work for ACOs will need to change that mind-set by explaining why teams can provide patients such better care than unconnected individuals. Getting patients to buy into the concept will improve everyone's numbers, and improving numbers will get more patients to buy in. It's a positive cycle, but one that will take years to play out," Muhlestein added. **EBDM**

References

1. ACO Shared Savings Program Quality Measures. CMS website. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Shared-Savings-Program-Quality-Measures.pdf. Accessed August 22, 2014.

2. Pioneer Accountable Care Organizations succeed in improving care, lowering costs [press release]. Baltimore, MD: CMS Newsroom Center; July 16, 2013. http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2013-Press-Releases-Items/2013-07-16.html.

3. Performance year 1 interim results for ACOs that started in April and July 2012. CMS website. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/PY1-InterimResultsTable.pdf. Accessed August 22, 2014.

4. ACO quality data. Data.Medicare.gov website. https://data.medicare.gov/Physician-Compare/Accountable-Care-Organization-ACO-Quality-Data/ytf2-4ept. Accessed August 22, 2014.

5. Rau J. Medicare data show wide differences in ACOs' patient care. Kaiser Health News website. http://www.kaiserhealthnews.org/Stories/2014/February/21/Medicare-Data-Shows-Wide-Differences-In-ACOs-Patient-Care.aspx. Published February 21, 2014. Accessed August 22, 2014.

6. Socioeconomic position and health among persons with diabetes mellitus: a conceptual framework and review of the literature. *Epidemiol Rev.* 2004;26(1):63-77.

7. Sullivan K. CMS proposes additional quality measures for ACOs for 2015. *The American Journal of Managed Care* website. http://www.ajmc.com/focus-of-the-week/0714/CMS-Proposes-Additional-ACO-Quality-Measures-for-2015. Published July 7, 2014. Accessed August 22, 2014.

8. Cassel CK, Saunders RS. Engineering a better health care system: a report from the President's Council of Advisors on Science and Technology [published online July 14, 2014]. *JAMA*. doi:10.1001/jama.2014.8906.

9. Chumbler NR, Neurgaard B, Kobb R, Ryan P, Qin H, Joo Y. Evaluation of a care coordination/home-telehealth program for veterans with diabetes. *Eval Health Prof.* 2005;28(4):464-478.

10. Battersby MW. Health reform through coordinated care: SA HealthPlus. *BMJ*. 2005;330(7492):662-665.

Diagnosis and Monitoring

Noninvasive Tests Could Ease Diagnosis and Monitoring in Diabetes

Surabhi Dangi-Garimella, PhD

A recent report in the *Journal of the American Medical Association*, based on research from the CDC between 2011 and 2012, found that 16.9% of youth and 34.9% of adults in the United States are obese. Although the prevalence of obesity has not changed significantly in the past decade,[1] it remains a substantial burden on the healthcare system, as obese youth are more likely to present risk factors for cardiovascular disease and obese adolescents are more likely to develop prediabetes.[2]

Diabetes necessitates a constant monitoring of blood glucose levels, with finger pricks several times a day. This can be quite distressing, especially for younger patients. The thought of the associated pain and discomfort can interfere with self-testing and negatively impact disease management. With this in mind, several research groups have been actively seeking noninvasive methods to diagnose individuals with diabetes and to efficiently monitor blood glucose in diabetic patients.

Salivary Biomarkers

One study published recently in the journal *PLOS One* evaluated adipokines as salivary biomarkers for the diagnosis of type 2 diabetes mellitus (T2DM).[3]

Adipokines, secreted from white adipose tissue, have been implicated in obesity, T2DM, and cardiovascular disease.[4] Of the 8319 Kuwaiti children (aged 10 to 12 years) whose saliva samples were collected for the experiment, expression levels of 20 hormones and cytokines were evaluated in a random cohort of 744 individuals. The study identified significant changes in 4 salivary biomarkers: insulin, C-reactive protein (CRP), adiponectin, and leptin, which were specifically upregulated in obese children. The authors conclude that an early diagnosis of these markers could help regulate metabolic diseases and evaluate prophylactic therapies in children.


William A. Petit, MD

A Salivary Glucometer?

The iQuickIt Saliva Analyzer, being developed by Quick, LLC, shows promise. The analysis requires placing a single-use Draw Wick in the patient's mouth to obtain a sample of their saliva, and then placing it in the analyzer for testing. The data generated following the test can be stored, as well as shared, with a smart device.[5]

In addition to internal evaluation, Quick is launching a clinical study of an iQuickIt Saliva Analyzer prototype in conjunction with the institutional review board of a leading healthcare network, according to William A. Petit, MD, chief scientific officer. Petit informed *Evidence-Based Diabetes Management* that there is no current estimate of when the product will be commercially available.

Regarding the device's accuracy, Petit said, "Once additional data from the clinical study are available in fall 2014, and following additional calibration of the product, we will be able to determine if occasional monitoring by other means will be recommended." He added that the device will be priced competitively with currently available glucometers, and that the company does not foresee any significant obstacles to the product qualifying for equivalent insurance reimbursement.


The iQuickIt Salivary Analyzer, Quick LLC.

Continuous Glucose Monitoring System

The emerging continuous glucose monitoring (CGM) systems are appealing in that they provide the user the ability to monitor his or her glucose levels in real time. Although the reviews from patients are mixed—some patients consider it an information overload that can cause anxiety, while others appreciate the ease of use, the ability to monitor hypoglycemia, and the relatively painless insertion[6]—the technology is definitely a step in the right direction. The **Table** lists some of the older devices available on the market, while the products described below are still under development:

Non-Invasive Device

Smart Lens

Novartis has followed Google's precedent for out-of-the-box approaches, this time in healthcare. Following "Google Glass," scientists at Google announced the development of an ocular monitoring device: the "smart lens."[7] Subsequently, in July of this year, the eye care division of Novartis, Alcon, announced its partnership with Google—a team within Google built to address global issues—to develop a lens that can address ocular conditions.[8]

In an e-mail response, Alcon representatives informed *EBDM* that the smart lens technology involves noninvasive sensors, microchips, and other miniaturized electronics embedded in the contact lenses. Alcon is currently focusing on utilizing the technology in 3 areas:

- Helping diabetic patients manage their disease by providing a continuous, minimally invasive measurement of the body's glucose levels via a "smart contact lens" designed to measure tear fluid in the eye and connect wirelessly with a mobile device;
- For people living with presbyopia who can no longer read without glasses, the "smart lens" has the potential to help restore the eye's natural autofocus on nearby objects in the form of an accommodative contact lens or intraocular lens as part of the refractive cataract treatment;
- In addition to patients living with presbyopia, the "smart lens" technology shows potential for addressing other critical eye health conditions, such as glaucoma.

Officials informed *EBDM* that exploratory clinical trials have been conducted by Google with regard to the glucose-sensing lens prototype, and additional clinical studies will soon be initiated as part of Alcon's development efforts. However, the product is in very early stages of development and may not on the market for some time.

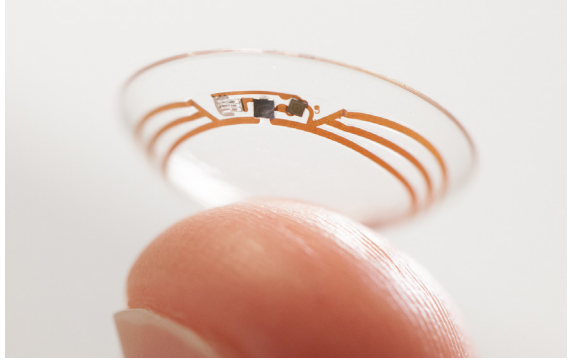
Invasive Devices

FiberSense/EyeSense

A diagnostic devices company called EyeSense, based in The Netherlands, has developed CGM systems fabricated with fiber optic material, with labeled biological molecules that act as glucose sensors within a hydrogel matrix. The sensor can be implanted either under the skin or under the conjunctiva of the eye to measure glucose in the surrounding tissue fluid. The readings are monitored with a fluorescent photometer attached to the skin (for FiberSense) or a photometer that reads varying emission wavelengths from the sensor (EyeSense).[9]

Advantages of CGM

The CGM products under development could prove a definite advantage for all involved—the patient, of course; the physician; and the insurance companies covering treatment. From the patient's perspective, CGM eliminates the need to remember to periodically test blood sugar levels, which could have a tremendous impact on quality of life. The device ensures that even as the patient sleeps, glucose levels are under surveillance. Additionally, the data acquired by most of the CGM systems can be sent to a smart device, which can keep the patient's provider updated in real time. The physician who cares for the patient can rest assured that the constant monitoring will prevent episodes of hyperglycemia or hypoglycemic shock. Hypoglycemia, a serious complication associated with diabetes treatment, leaves a significant mark on the healthcare system in the United States, as previously discussed in *EBDM*.[10]


The "Smart Lense": a Product of the Google-Alcon collaboration, Alcon Inc.

Scientists in the field are evaluating CGM as a method of diagnosing early dysglycemia (prediabetes), now recognized as a risk factor for diabetes. One such study, which used a CGM system to monitor first-degree relatives of diabetes patients who were obese but lacked symptoms of diabetes, recognized the presence of significant dysglycemia in these individuals.[11] As childhood obesity rapidly develops into a global epidemic, CGM systems can prove valuable in monitoring the younger high-risk population.

Disadvantages

As with many new technologies, these devices are a work in progress, and accuracy seems to be a major concern both for patients and for providers of care.

Drawbacks of these devices include a high rate of false-positive alarms and a lack of success in detecting episodes of hypoglycemia.[12] One such device, Medtronic's Minimed 530G with the Enlite sensor, was reviewed in *EBDM* by diabetic patient Brian Hegarty. Hegarty wrote that the sensor is inaccurate and the system as a whole is not well synchronized.[13]

The need for finger pricking is reduced—not completely eliminated—with CGM systems. The device needs to be calibrated, which means resorting to the traditional method of measuring blood glucose. Additionally, when the device detects hyperglycemia or hypoglycemia, reconfirming blood glucose levels before taking corrective measures is necessary.[14]

Compared with a glucometer, the devices have a lag in their glucose reading; this is because of the different modus operandi. CGM systems detect glucose levels in the interstitial fluid rather than in the blood. This argues for using the devices to monitor the trend in blood glucose levels, rather than using them to measure the actual levels at a point in time.[14]

Overall, though, when combined with intermittent self-monitoring, CGM provides diabetic patients an improved handle on their disease.

Where Does Reimbursement Stand?

CGM does not come cheap—the systems costs over $1000, and the sensors need to be replaced every few days.[15] The good news is that reimbursement woes are a thing of the past for these devices, at least on the commercial insurer front. Based on information on the websites of the major vendors Dexcom and Medtronic, most commercial health plans (including

evident at greater than or equal to 0.5 times clinical exposure from a 300 mg dose *[see Nonclinical Toxicology (13.2) in full Prescribing Information]*.

These outcomes occurred with drug exposure during periods of animal development that correspond to the late second and third trimester of human development. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. INVOKANA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known if INVOKANA is excreted in human milk. INVOKANA is secreted in the milk of lactating rats reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA showed risk to the developing kidney (renal pelvic and tubular dilatations) during maturation. Since human kidney maturation occurs *in utero* and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from INVOKANA, a decision should be made whether to discontinue nursing or to discontinue INVOKANA, taking into account the importance of the drug to the mother *[see Nonclinical Toxicology (13.2) in full Prescribing Information]*.

Pediatric Use: Safety and effectiveness of INVOKANA in pediatric patients under 18 years of age have not been established.

Geriatric Use: Two thousand thirty-four (2034) patients 65 years and older, and 345 patients 75 years and older were exposed to INVOKANA in nine clinical studies of INVOKANA *[see Clinical Studies (14.3) in full Prescribing Information]*.

Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300 mg daily dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were 75 years and older *[see Dosage and Administration (2.1) in full Prescribing Information and Adverse Reactions]*. Smaller reductions in HbA1C with INVOKANA relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA 100 mg and -0.74% with INVOKANA 300 mg relative to placebo) compared to younger patients (-0.72% with INVOKANA 100 mg and -0.87% with INVOKANA 300 mg relative to placebo).

Renal Impairment: The efficacy and safety of INVOKANA were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to less than 50 mL/min/1.73 m^2) *[see Clinical Studies (14.3) in full Prescribing Information]*. These patients had less overall glycemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR greater than or equal to 60 mL/min/1.73 m^2); patients treated with INVOKANA 300 mg were more likely to experience increases in potassium *[see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Adverse Reactions]*.

The efficacy and safety of INVOKANA have not been established in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m^2), with ESRD, or receiving dialysis. INVOKANA is not expected to be effective in these patient populations *[see Contraindications and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Hepatic Impairment: No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. The use of INVOKANA has not been studied in patients with severe hepatic impairment and is therefore not recommended *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

OVERDOSAGE

There were no reports of overdose during the clinical development program of INVOKANA (canagliflozin).

In the event of an overdose, contact the Poison Control Center. It is also reasonable to employ the usual supportive measures, e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as dictated by the patient's clinical status. Canagliflozin was negligibly removed during a 4-hour hemodialysis session. Canagliflozin is not expected to be dialyzable by peritoneal dialysis.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

Instructions: Instruct patients to read the Medication Guide before starting INVOKANA (canagliflozin) therapy and to reread it each time the prescription is renewed.

Inform patients of the potential risks and benefits of INVOKANA and of alternative modes of therapy. Also inform patients about the importance of adherence to dietary instructions, regular physical activity, periodic blood glucose monitoring and HbA1C testing, recognition and management of hypoglycemia and hyperglycemia, and assessment for diabetes complications. Advise patients to seek medical advice promptly during periods of stress such as fever, trauma, infection, or surgery, as medication requirements may change.

Instruct patients to take INVOKANA only as prescribed. If a dose is missed, advise patients to take it as soon as it is remembered unless it is almost time for the next dose, in which case patients should skip the missed dose and take the medicine at the next regularly scheduled time. Advise patients not to take two doses of INVOKANA at the same time.

Inform patients that the most common adverse reactions associated with INVOKANA are genital mycotic infection, urinary tract infection, and increased urination.

Inform female patients of child bearing age that the use of INVOKANA during pregnancy has not been studied in humans, and that INVOKANA should only be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Instruct patients to report pregnancies to their physicians as soon as possible.

Inform nursing mothers to discontinue INVOKANA or nursing, taking into account the importance of drug to the mother.

Laboratory Tests: Due to its mechanism of action, patients taking INVOKANA will test positive for glucose in their urine.

Hypotension: Inform patients that symptomatic hypotension may occur with INVOKANA and advise them to contact their doctor if they experience such symptoms *[see Warnings and Precautions]*. Inform patients that dehydration may increase the risk for hypotension, and to have adequate fluid intake.

Genital Mycotic Infections in Females (e.g., Vulvovaginitis): Inform female patients that vaginal yeast infection may occur and provide them with information on the signs and symptoms of vaginal yeast infection. Advise them of treatment options and when to seek medical advice *[see Warnings and Precautions]*.

Genital Mycotic Infections in Males (e.g., Balanitis or Balanoposthitis): Inform male patients that yeast infection of penis (e.g., balanitis or balanoposthitis) may occur, especially in uncircumcised males and patients with prior history. Provide them with information on the signs and symptoms of balanitis and balanoposthitis (rash or redness of the glans or foreskin of the penis). Advise them of treatment options and when to seek medical advice *[see Warnings and Precautions]*.

Hypersensitivity Reactions: Inform patients that serious hypersensitivity reactions such as urticaria and rash have been reported with INVOKANA. Advise patients to report immediately any signs or symptoms suggesting allergic reaction or angioedema, and to take no more drug until they have consulted prescribing physicians.

Urinary Tract Infections: Inform patients of the potential for urinary tract infections. Provide them with information on the symptoms of urinary tract infections. Advise them to seek medical advice if such symptoms occur.

Active ingredient made in Belgium

Finished product manufactured by:
Janssen Ortho, LLC
Gurabo, PR 00778

Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560

Licensed from Mitsubishi Tanabe Pharma Corporation

10282400 K02CAN13080B

janssen

Noninvasive Tests
(continued from SP378)

Table. Marketed Continuous Glucose Monitoring Devices

Product	Company
Dexcom G4	Dexcom
Enlite sensor	Medtronic
iPro Evaluation	Medtronic

Sources: http://dexcom.com/, http:// bit.ly/19ToBcf

Aetna, UnitedHealthcare, Humana, Kaiser, Blue Cross Blue Shield, and Anthem) cover the cost of the currently marketed devices.[16,17]

The uphill battle has been with Medicare. While the government insurer covers professional CGM, such as systems used in hospitals or clinics,[15] the personal CGM system has not earned similar acceptance. This could mean a big transition for retirees who switch to Medicare from employer-based private insurance plans—an important topic of discussion on several diabetes forums.[18,19]

Representative Carol Shea-Porter (D-NH) introduced a bill before the House Energy and Commerce Committee late last year to amend Medicare CGM coverage, which was subsequently referred to the Subcommittee on Health.[20] Additionally, organizations such as JDRF are spreading the word, asking people to support the bill.[21] The wheels are in motion, and hopefully, a decision will soon be made. **EBDM**

References

1. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. *JAMA*. 2014;311(8):806-814.

2. Childhood obesity facts. CDC website. http://www.cdc.gov/healthyyouth/obesity/facts.htm. Updated February 27, 2014. Accessed August 8, 2014.

3. Goodson JM, Kantarci A, Hartman M, et al. Metabolic disease risk in children by salivary biomarker analysis. *PLoS One*. 2014;9(6):e98799.

4. Kwon H, Pessin JE. Adipokines mediate inflammation and insulin resistance. *Front Endocrinol (Lausanne)*. 2013;4(71). doi:10.3389/fendo.2013.00071.

5. iQuickIt website. http://www.iquickit.com/iquickit/. Accessed August 7, 2014.

6. Continuous glucose monitoring system (CGMS): new technology advances diabetes care. Columbia University Medical Center website. http://nbdc.cumc.columbia.edu/news/continuous-glucose-monitoring-system-cgms. Published April 29, 2014. Accessed August 11, 2014.

7. Womack, B. Google unveils smart contact lens project to monitor glucose. Bloomberg website. http://www.bloomberg.com/news/2014-01-17/google-unveils-smart-contact-lens-project-to-monitor-glucose.html. Published January 17, 2014. Accessed September 3, 2014.

8. Novartis to license Google "smart lens" technology [press release]. Basel, Switzerland: Novartis; July 15, 2014. http://www.novartis.com/newsroom/media-releases/en/2014/1824836.shtml.

9. EyeSense website. http://en.eyesense.com/product/. Accessed August 11, 2014.

10. Dangi-Garimella, S. The persistent complication of hypoglycemia in diabetics. *Am J Manag Care*. 2014;20(SP8):SP251-SP252.

11. DeVries JH. Continuous glucose monitoring: coming of age? *Eur J Endocrinol*. 2012;166(1):1-4.

12. Soliman A, DeSanctis V, Yassin M, Elalaily R, Eldarsy NE. Continuous glucose monitoring system and new era of early diagnosis of diabetes in high risk groups. *Indian J Endocrinol Metab*. 2014;18(3):274-282.

13. Hegarty B. My initial impression of Medtronic's new pump. *Am J Manag Care*. 2014;20(SP4):SP119.

14. Medical devices: continuous glucose monitoring. Cleveland Clinic website. http://my.clevelandclinic.org/devices/glucose_monitoring/hic_continuous_glucose_monitoring.aspx. Accessed August 14, 2014.

15. Vashist SK. Continuous glucose monitoring systems: a review. *Diagnostics*. 2013;3:385-412.

16. Reimbursement. Dexcom website. http://www.dexcom.com/reimbursement. Accessed August 14, 2014.

17. CGM billing and reimbursement guide. Medtronic website. http://professional.medtronicdiabetes.com/docs/CGM-Billing-and-Reimbursement-Guide.pdf. Published 2014. Accessed August 14, 2014.

18. Community: adults living with type 1. American Diabetes Association website. http://community.diabetes.org/t5/Adults-Living-with-Type-1/Lost-Appeal-to-Get-Continuous-Glucose-Monitor-Sensors-Paid-for/td-p/272390. Accessed August 22, 2014.

19. Keeping it real on Medtronic's 530G. http://www.diabetesmine.com/2013/10/keeping-it-real-on-medtronics-530g.html. Published October 8, 2013. Accessed August 15, 2014.

20. H.R.3710 - Medicare CGM Coverage Act. https://beta.congress.gov/bill/113th-congress/house-bill/3710. Congress.gov website. Accessed August 14, 2014.

21. CGM coverage by Medicare. http://advocacy.jdrf.org/our-work/medicarecovercgm/. Accessed August 14, 2014.

Diabetes in the Geriatric Population Needs Improved Management

Surabhi Dangi-Garimella, PhD

Managing a diabetic patient is a delicate balance; finding that balance in an older patient is even trickier. Many older adults suffer from multiple comorbidities, which further complicates disease management. One very common problem encountered with the rigorous control of glycated hemoglobin (A1C) is hypoglycemia (blood sugar below 70 mg/dL). As examined in a previous issue of *Evidence-Based Diabetes Management*,[1] frequent episodes of hypoglycemia can lead to hypoglycemia unawareness—a condition where the body fails to generate the usual warning signs of an overcompensated blood sugar drop.

A recent study, published in *JAMA Internal Medicine*, highlighted the significance of this problem in the elderly population by conducting an exhaustive analysis of more than half a million patients enrolled within the Veterans Health Administration (VA) in 2009.[2] The patients evaluated were at least 75 years old, received insulin and/or a sulfonylurea, and had intensive glycemic control (in categories of less than 6%, less than 6.5%, and less than 7%). The conclusion: 11.3% of the patients had A1C less than 6%, 28.6% had A1C less than 6.5%, and 50% had A1C less than 7%, with a wide variation observed across the VA facilities. The study concluded that because patients treated with antidiabetic agents are highly susceptible to episodes of hypoglycemia, their glycemic management should be reevaluated, especially with respect to intensive therapy.[2]

A commentary exploring the study findings was published in *The Journal of the American Medical Association*. Its authors, while calling for a change in approach when treating the older population, elegantly highlighted some of the current barriers:

- The need to reconcile evidence-based data and patient-centered medicine
- Clinical inertia, which prevents therapy reduction
- Conflicting information and multiple guidelines, combined with commercial marketing, which can confuse both the patient and the physician
- The difficulty, for physician and patient alike, of discussing treatment de-escalation.[3]

The authors of the commentary also alluded to an important issue that has confronted the primary care realm for some time: the 20 minutes that the primary care physician can allocate per patient is not sufficient for a discussion of scaling back treatment.

James Sabin, MD, clinical professor of population medicine and psychiatry at Harvard Medical School and director of the Harvard Pilgrim Health Care Ethics Program, concurred with 2 of these arguments. On his blog entry for The Hastings Center, Sabin pointed out that acknowledging and accepting new practices that might contradict old ones meets with an immense amount of resistance from the physician. A contributing factor, he adds, is skepticism in the provider's mind about pharmaceutical industry–sponsored research. Sabin points out that reducing treatment would be an acknowledgment of vulnerability and mortality. Age increases sensitivity to insulin and oral diabetes medications, which puts the patients at an increased risk of hypoglycemia.[4]

How Do You Confront This Challenge?

Choosing Wisely for geriatric patients

Early last year, the American Geriatric Society issued guidelines, as a part of the Choosing Wisely initiative, which included recommendations for physicians on medication use and A1C control in older diabetic patients. The guideline clearly states that moderate glycemic control is better than tighter control: "Tight control has been consistently shown to produce higher rates

of hypoglycemia in older adults. Given the long time frame to achieve theorized microvascular benefits of tight control, glycemic targets should reflect patient goals, health status, and life expectancy. Reasonable glycemic targets would be 7% to 7.5% in healthy older adults with long life expectancy, 7.5% to 8% in those with moderate comorbidity and a life expectancy of less than 10 years, and 8% to 9% in those with multiple morbidities and shorter life expectancy."[5]

Clinical trials designed for the elderly

Despite a high incidence of diabetes among individuals over 65 years of age, clinical trials usually exclude older persons and even those who have multiple comorbidities. Data from the National Diabetes Statistics Report, released this year, show that 25.9% of seniors (over 65 years of age) suffer from diagnosed and undiagnosed diabetes mellitus.[6] The heterogeneity of their health status, combined with the lack of evidence from clinical trials, has resulted in a lack of standardization of intervention strategies for these older adults.[7]

Although retrospective studies have evaluated glycemic control, comorbidities, and hypoglycemic events in the elderly, very few prospective studies have been conducted in that population. One such study, completed last year, compared the efficacy and safety of 2 different insulin regimens in the management of nursing home patients with type 2 diabetes mellitus.[8]

Organized efforts to raise awareness

The American Diabetes Association convened a Consensus Development Conference on Diabetes and Older Adults in 2012, which addressed the heterogeneity of health status of older adults and the lack of clinical trial–based evidence to determine standard intervention strategies for older adults. By creating an overarching view of the disease epidemiology in older adults, including comorbidities, the conference aimed at developing guidelines to fill in evidence gaps. The experts who participated in the conference arrived at a consensus—following a review of all the available data and literature—that A1C goals should be individualized per each patient's needs and health status, rather than set down as rigid goals to meet (**see the Table**).[7]

To fill the existing gaps in the knowledge base on older adults with diabetes, the expert participants in the conference recommended that studies and trials should specifically include older adults who have dependent living situations and who might suffer from multiple comorbidities. Additionally, the recommendations called for using evidence from "real-world" settings to help develop treatment guidelines.[7]

Table. Framework to Establish Treatment Goals in Older Diabetes Patients[7]

Rationale	Reasonable A1C goal	Fasting glucose (mg/dL)	Bedtime glucose (mg/dL)	Blood pressure (mm Hg)
Longer remaining life expectancy	<7.5%	90-130	90-150	<140/80
Intermediate remaining life expectancy, high treatment burden, hypoglycemia vulnerability	<8.0%	90-150	100-180	<140/80
Limited remaining life expectancy makes benefits uncertain	<8.5%	100-180	110-200	<150/90

A1C indicates glycated hemoglobin.

Lack of Elderly in Trials: A Managed Care Burden?

Consider the following statistics:

- About 10.9 million adults 65 years or older (about 26.9% of that age group) were estimated to have diabetes in 2010
- Of the 65-years-or-older diabetic population, heart disease is noted on 68% of diabetes-related death certificates[9]
- Seniors use a sizable portion of services compared with individuals under 65 years of age, especially:
  - hospital inpatient days
  - nursing/residential facility days
  - hospice[10]

A diabetes model generated by the Institute for Alternative Futures predicts that by the year 2025, the total population of seniors with diagnosed and undiagnosed diabetes will present a 59% upsurge: from 10,821,600 in 2010 (estimated by CDC) to 17,191,000 in 2025. The expected medical and societal costs of this dramatic increase are estimated at $168 billion—up from $105.7 billion in 2010.[11] These costs are preventable. What is lacking is a solid evidence base and data, which can be accrued by including more seniors in clinical trials or by designing trials to specifically address diabetes complications in that population. Gaining a better understanding of prediabetes is another approach. Biomarkers that could identify the formative years of the disease—when symptoms are lacking—could help prevent or regulate the condition before disease complications set in. **EBDM**

References

1. Dangi-Garimella S. The persistent complication of hypoglycemia in diabetics. *Am J Manag Care*. 2014;20(SP8):SP251-SP252.

2. Tseng CL, Soroka O, Maney M, Aron DC, Pogach LM. Assessing potential glycemic overtreatment in persons at hypoglycemic risk. *JAMA Intern Med*. 2014;174(2):259-268.

3. Andrews MA, O'Malley PG. Diabetes overtreatment in elderly individuals: risky business in need of better management. *JAMA*. 2014;311(22):2326-2327.

4. Sabin J. Overtreatment of elderly diabetics. Over 65 blog: The Hastings Center. http://www.over65.thehastingscenter.org/overtreatment-of-elderly-diabetics/. Published July 7, 2014. Accessed August 28, 2014.

5. American Geriatrics Society: ten things physicians and patients should question. Choosing Wisely website. http://www.choosingwisely.org/doctor-patient-lists/american-geriatrics-society/. Released February 21, 2013. Accessed August 28, 2014.

6. Statistics about diabetes. American Diabetes Association website. http://www.diabetes.org/diabetes-basics/statistics/. Updated August 20, 2014. Accessed August 29, 2014.

7. Kirkman MS, Briscoe VJ, Clark N, et al. Diabetes in older adults. *Diabetes Care*. 2012;35(12):2650-2664.

8. Diabetes in the elderly: prospective study (DMElderly). ClinicalTrials.gov website. http://clinicaltrials.gov/show/NCT01131052.

9. Fast facts: data and statistics about diabetes. American Diabetes Association website. http://professional.diabetes.org/admin/UserFiles/0%20-%20Sean/FastFacts%20March%202013.pdf. Accessed September 3, 2014.

10. American Diabetes Association. Economic costs of diabetes in the U.S. in 2012. *Diabetes Care*. 2013;36(4):1033-1046.

11. United States' diabetes crisis among seniors: today and future trends. http://www.altfutures.org/pubs/diabetes2025/US_Diabetes2025_Seniors_BriefingPaper_2011.pdf. Institute for Alternative Futures website. Published 2011. Accessed September 3, 2014.

Body Mass Index: Not the Best Marker for Obesity

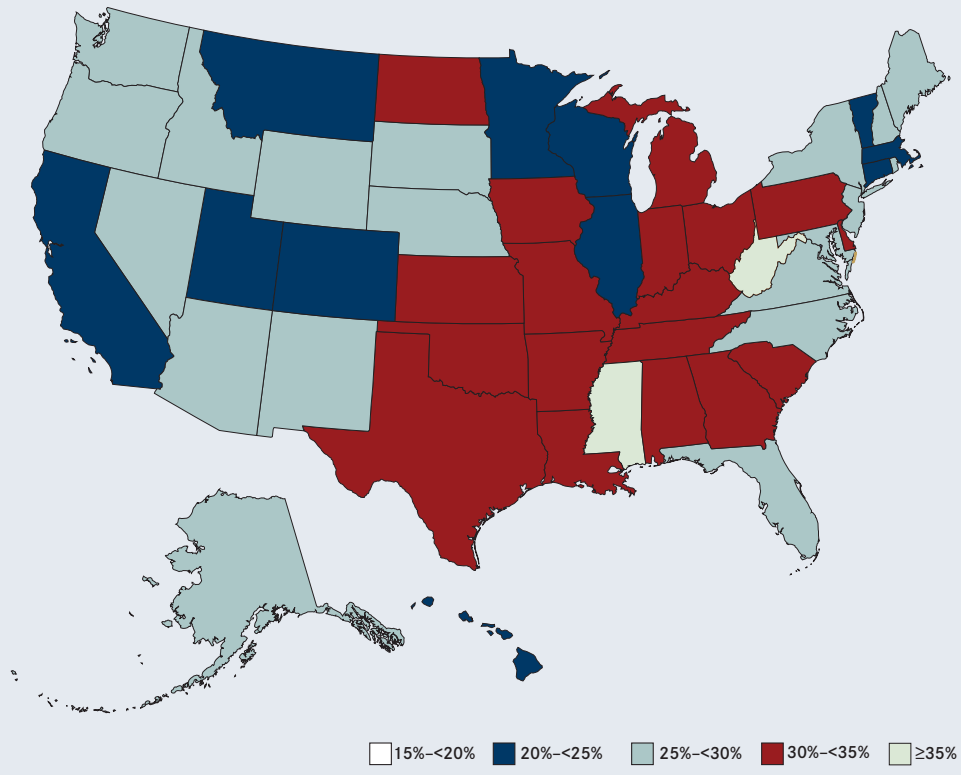
Surabhi Dangi-Garimella, PhD

Obesity is no longer an epidemic restricted to the United States—it has become a global phenomenon. While 34.9% of the adult population and 17% of youth in the United States were estimated to be obese based on a 2011-2012 census,[1] the World Health Organization (WHO) estimates that 11% of adults around the globe (>20 years of age) were obese in 2008. Additionally, WHO confirmed that nearly 40 million children under the age of 5 years were either overweight or obese in 2012.[2]

Obesity: The Source of All Diseases?

While the American Heart Association put forth a recommendation to classify obesity as a disease,[3] the American Medical Association went a step further and adopted policy to recognize it as a disease in 2013,[4] which can open doors for medical intervention to prevent or treat the condition. Why all the fuss over obesity? Because the condition has been

Figure. Self-Reported Obesity Across the United States, 2013



Source: Behavioral Risk Factor Surveillance System, CDC. http://www.cdc.gov/obesity/data/prevalence-maps.html.

identified as the root cause of numerous disease conditions: heart disease, stroke, type 2 diabetes mellitus (T2DM), kidney and liver disease, and cancer.[5,6]

The bottom line: extreme obesity can reduce life expectancy by up to 14 years, as a result of the secondary disease conditions. A study published in the journal *PLOS Medicine*, spanning 3 countries and 20 studies, discovered that adults with extreme obesity have an increased risk of dying early due to cancer, diabetes, heart disease, stroke, and kidney and liver diseases.[7]

All of these studies use a person's body mass index (BMI) to determine whether a person is obese. Obesity, defined as "BMI greater than or equal to 30," is an index of weight-for-height: it is the person's weight in kilograms divided by the square of his or her height in meters (kg/m^2).[2,7] In children and teens, BMI is interpreted after considering the child's age and gender, because the amount of body fat changes with age and gender.[7]

Is BMI the Right Indicator of Obesity?

That is the question being asked lately, and a universal BMI cut-off value for obesity—the one-size-fits-all attitude—is being examined. A meta-analysis of 37 studies, which included 53,521 children between 4 and 18 years of age, found that although highly specific, BMI was not very sensitive to identifying pediatric obesity. The authors point out that although adiposity measurements are driven by race and ethnicity, organizations like the American Academy of Pediatrics still recommend using BMI to diagnose pediatric obesity in the clinic. The meta-analysis recognized that the BMI measure has a 73% sensitivity, meaning that more than 25% of the children in these studies—who may have had excess adiposity—were not identified as being obese. Acknowledging this finding, the authors recommend that other tools that can measure body fat, such as dual-energy x-ray absorptiometry (DXA) and air-displacement plethysmography (ADP), be used as secondary measures.[8]

Characterizing the composition of body fat is important for diagnosing obesity, an element that is disregarded in the BMI calculation. Normal BMI does not necessarily indicate normal body fat—a major flaw with BMI as a marker of obesity.[8] The study concluded that if the BMI is higher than normal, the child is most definitely obese; but if the child has a normal BMI, secondary measures like ADP or skin-fold measurements should be used to confirm the results, especially in male children. The authors also point to other studies which indicated that the increase in BMI above normal is not proportional to increases in the percentage of body fat.[9]

An evaluation of the correlation between BMI and fat, muscle, and bone percentages of athletes found that BMI could not be used as a direct measurement of body fat content in athletes, who tend to have a lean body mass.[10] Another study that compared the National Institutes of Health's BMI-based obesity classification with the WHO's percent body fat (%BF)-based reference standard—in women of different racial backgrounds (namely Caucasian, African American, and Hispanic)—found that the BMI cutoff by the NIH failed to identify nearly half of the women who were classified as obese based on their %BF measure. This includes another variable in the BMI equation: race. The results beg the conclusion that BMI cutoff values should factor in an individual's racial background for a more accurate classification of obesity.[11] BMI could be used as a screening tool to determine the population's risk of obesity, but there is a need to follow up with secondary measures to confirm the absence of risk.

The CDC agrees that BMI should be used a surrogate marker for obesity, since it only measures excess weight and not excess fat. In a statement directed to clinical practitioners, CDC acknowledges that BMI is widely used primarily because it's a simple, inexpensive, and noninvasive test, the results from which can be used at the population level by public health professionals to generate models that span populations across time and geographic regions. Other measures of body fat, such as skin fold thickness, ADP, and DXA—although better indicators of body fat and risk of obesity-related health issues—can be expensive, intrusive, and not readily accessible. There's also a need for specialized equipment and trained staff to conduct these measures, which can prove challenging in routine clinical practice.[12]

What Are the Alternate Measures of Obesity?

Body adiposity index (BAI) is a measure developed by the laboratory of Richard Bergman, PhD, director of the Diabetes and Obesity Research Institute, Biomedical Sciences, at Cedar Sinai. BAI accounts for hip circumference and a person's height, without adjusting for gender. The study, which included Mexican American and African American men and women, identified %BAI as a direct estimate of the percentage of body fat.[13]

The index was also validated in a Caucasian population in Newfoundland. An evaluation of 2601 individuals of both genders identified BAI as a better index than BMI, as it reflected the gender difference in total %BF between men and women, correlated better with DXA, and performed well in normal weight and overweight subjects. Surprisingly, however, it was less accurate than BMI in the obese population.[14]

Contrave Gains Partial Approval for Weight Management

The FDA has finally approved the use of Contrave (naltrexone hydrochloride and bupropion hydrochloride tablets), manufactured by Orexigen Therapeutics, for chronic weight management. The regimen includes taking the drug coupled with physical activity and a reduced calorie diet.[1]

The fourth obesity drug to be approved so far,[2] Contrave has not yet received a complete clearance from the regulatory authorities. The FDA has a list of postmarketing requirements for the company to fulfill, which will assess:

- Cardiovascular risk
- Safety and efficacy in the pediatric population
- Effect on growth and development in an animal model
- Effect on cardiac conduction
- Dosing in patients with hepatic or renal impairment
- Drug interactions.[1]

Approved for use in obese or overweight adults who have at least 1 weight-related condition (hypertension, type 2 diabetes mellitus, or dyslipidemia),[1] the drug was rejected by the FDA back in 2011 due to concerns of cardiovascular safety on long-term use in the target population.[2] Additionally, bupropion is an anti-depressant.

Contrave has a boxed warning on increased risk of suicidal thoughts and behaviors. Some of the other effects of Contrave, observed in clinical trials that evaluated 4500 obese and overweight patients, include seizures, hypertension, and increased heart rate. Other adverse reactions observed were nausea, vomiting, dizziness, constipation, headache, insomnia, dry mouth, and diarrhea.[1] **EBDM**

References

1. FDA approves weight-management drug Contrave [press release]. Silver Spring, MD: FDA; September 10, 2014. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm413896.htm.

2. Nainggolan L. FDA approves bupropion/naltrexone (Contrave) for obesity. Medscape website. http://www.medscape.com/viewarticle/831513?src=wnl_edit_tpal&uac=217995HV. Published September 10, 2014. Accessed September 11, 2014.

Biomarkers of Obesity

Disease biomarkers that are reliable and can be identified using minimally invasive techniques are an ideal alternative to BMI or BAI measurements. An ideal biomarker would identify a high-risk obese individual, who might progress to develop cardiovascular disease or T2DM.

Partnering on one such project, scientists at Nestlé and General Electric studied the metabolic and lipid profiles in the plasma and urine of 40 overweight and obese females (25 to 45 years of age, with BMI between 28 and 40 kg/m^2). Additionally, their body composition and visceral fat distribution were analyzed using DXA and computerized tomography. On integrating the data from these various sources, a distinct pattern of amino acids and diacyl and ether phospholipids was identified in women with high visceral fat.[15] Such metabolomic profiles could vastly improve diagnosis of the disease.

What Are the Advantages of Early Detection?

Being able to identify individuals with a normal BMI as obese, using some of the secondary methods or %BAI (once validated), would open a window of opportunity for early intervention—clinical as well as lifestyle. In children, for example, parents could influence a child to maintain healthy eating habits and to exercise.

Obesity in adults can lead to health issues such as T2DM; cardiovascular problems and stroke, as well as influence breathing, resulting in sleep apnea and asthma. Additionally, obesity can lead to anxiety (**see Commentary on page SP375**) or more serious mental health conditions. The least we could expect is an accurate measure or test to diagnose obesity, with the hope of preventing a lot of these comorbidities, which are a huge drain on the healthcare system. **EBDM**

References

1. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. *JAMA*. 2014;311(8):806-814.

2. Obesity and overweight. http://www.who.int/mediacentre/factsheets/fs311/en/. World Health Organization website. Updated August 14, 2014. Accessed September 3, 2014.

3. Treating obesity as a disease. American Heart Association website. http://www.heart.org/HEARTORG/GettingHealthy/WeightManagement/Obesity/Treating-Obesity-as-a-Disease_UCM_459557_Article.jsp. Updated April 14, 2014. Accessed September 3, 2014.

4. AMA adopts new policies on second day of voting at annual meeting [press release]. Chicago, IL: American Medical Association; June 18, 2013. http://www.ama-assn.org/ama/pub/news/news/2013/2013-06-18-new-ama-policies-annual-meeting.page.

5. Adult obesity facts. CDC website. http://www.cdc.gov/obesity/data/adult.html. Updated July 9, 2014. Accessed September 3, 2014.

6. Kitahara CM, Flint AJ, Berrington de Gonzalez A, et al. Association between class III obesity (BMI of 40-59 kg/m^2) and mortality: a pooled analysis of 20 prospective studies. *PLoS Med*. 2014;11(7):e1001673.

7. Healthy weight – it's not a diet, it's a lifestyle. CDC website. http://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/index.html?s_cid=tw_ob064. Updated July 11, 2014. Accessed September 4, 2014.

8. Javed A, Jumena M, Murad MH, et al. Diagnostic performance of body mass index to identify obesity as defined by body adiposity in children and adolescents: a systematic review and meta-analysis [published online June 25, 2014]. *Pediatr Obes*. doi:10.1111/ijpo.242.

9. Wells JC, Coward WA, Cole TJ, Davies PS. The contribution of fat and fat-free tissue to body mass index in contemporary children and the reference child. *Int J Obes Relat Metab Disord*. 2002;26(10):1323-1328.

10. Garrido-Chamorro RP, Sirvent-Belando JE, Gonzalez-Lorenzo M, Martin-Carratala ML, Roche E. Correlation between body mass index and body composition in elite athletes. *J Sports Med Phys Fitness*. 2009;49(3):278-284.

11. Rahman M, Berenson AB. Accuracy of current body mass index obesity classification for white, black and Hispanic reproductive-age women. *Obstet Gynecol*. 2011.115(5):982-988.

12. Body mass index: considerations for practitioners. CDC website. http://www.cdc.gov/obesity/downloads/bmiforpactitioners.pdf. Accessed September 4, 2014.

13. Bergman RN, Stefanovski D, Buchanan TA, et al. A better index of body adiposity. *Obesity (Silver Spring)*. 2011;19(5):1083-1089.

14. Sun G1, Cahill F, Gulliver W, et al. Concordance of BAI and BMI with DXA in the Newfoundland population. *Obesity (Silver Spring)*. 2013;21(3):499-503.

15. Martin FP, Montoliu I, Collino S, et al. Topographical body fat distribution links to amino acid and lipid metabolism in healthy obese women. *PLoS One*. 2013;8(9):e73445.

Panel Finds Consistency in Evidence of Dietary Patterns to Prevent Diabetes, CVD, and Obesity

Mary K. Caffrey

If your mother told you, "Eat your vegetables," she knew intuitively what science continues to affirm.

The 2015 US Dietary Guidelines Advisory Committee (DGAC), charged with making recommendations to update the nation's policies for healthy eating, held its fourth meeting on July 16 and 17, 2014, in Bethesda, Maryland. During the meeting, a key subcommittee tasked with reviewing recent evidence on how dietary patterns affect health developed draft language on the relationships between what Americans eat and 4 major cancers—breast, colorectal, prostate, and lung—as well as chronic conditions such as type 2 diabetes mellitus (T2DM) and obesity. This is the first time that the DGAC's report will include recommendations on the connections between diet and cancer.[1,3]

Chaired by Barbara Millen, DrPH, RD, of Millennium Prevention in Westwood, Massachusetts, the 2015 DGAC consists of 15 scientists specializing in nutrition, cancer prevention, public health, and other fields who were appointed in spring 2013 to offer recommenda-

tions to the US secretaries of Health and Human Services (HHS) and Agriculture (USDA). As outlined by Congress, the process takes place every 5 years, with management rotating between HHS and USDA.[2,3]

DGAC's work remains in draft form until the final report goes to the secretaries, who then review it alongside comments from the public—which have in-person and online—as well the many "stakeholders," which include lobbyists for the food industry, some of whom have already appeared before DGAC during the public comment sessions.[3]

The final policy is released as *Dietary Guidelines for Americans*, a document that affects everything from the composition of school lunches, to the makeup of meals fed to the military, to the allotments that go into the Supplemental Nutrition Assistance Program. Fallout from the guidelines sometimes stirs controversy. The work of the 2015 DGAC continues as the National School Boards Association and other groups lobby Congress for relief from the Healthy Hunger-Free Kids Act of 2010, which revamped the rules governing what school districts receiving federal funds can serve in school lunches.[4,5]

In prior remarks and in her opening address to the committee on July 16, Millen discussed the committee's assignment of examining how the improvements to the American diet can reduce chronic disease. The committee, she said, "is charged with providing technical assistance on how food, nutrition, and physical activity can do 2 things: promote the health of the US population and help reduce the burden of chronic disease and other lifestyle-related problems, and also develop recommendations and best methods and practices, at the individual and population level."[1]

Millen said the emphasis on "dietary patterns" allows for several things: a review of how Americans eat now, a review of the evidence of what dietary patterns are associated with chronic disease and with cancers, and an analysis of "what works," which will provide practical recommendations for healthcare and public health officials.

The first day of the July meeting featured presentations from Frank Hu, MD, PhD, MPH, of the Harvard School of Public Health, and Steven Clinton, MD, PhD, of the Ohio State University. Hu presented draft language on the relationship between dietary patterns and cardiovascular disease (CVD), body weight/obesity, (T2DM), while Clinton presented language on the relationships between dietary patterns and 4 major cancers that account for half of the cancer incidence in the United States: lung cancer, prostate cancer in men, breast cancer in women, and colorectal cancer.

As Hu and Clinton outlined, and as committee members noted, there was a high degree of consistency across the evidence base when examining what dietary patterns were connected with lower or higher incidence of chronic disease. Among the 4 major cancers, evidence showed the strongest links between dietary patterns and colorectal cancer. More illuminating, however, was the fact that highly similar dietary patterns emerged in the draft recommendations for all 3 chronic diseases (CVD, body weight/obesity, and T2DM) (see **Table**). In summary, they are:

- A diet high in fruits, vegetables, and whole grains.
- A diet with regular amounts of fish, legumes, and low-fat dairy. Alcohol consumption in moderation was discussed in the draft statements on CVD and body weight only.
- A diet low in sugar-sweetened beverages, red and processed meats, refined grains, and saturated fats.

Table. Similarities in DGAC Draft Recommendations for Chronic Diseases[1]

CVD
The committee concurs with the NEL Dietary Patterns Systematic Review and AHA/ACC Guideline that strong and consistent evidence demonstrates that dietary patterns associated with decreased risk of CVD are characterized by: • Regular consumption of fruits, vegetables, whole grains, low-fat dairy, and fish, and are low in red and processed meat, refined grains, and sugar-sweetened foods and drinks. • Regular consumption of nuts and legumes and moderate consumption of alcohol are also shown to be beneficial in most studies. • Additionally, research that includes specific nutrients in their description of dietary patterns indicate that patterns that are low in saturated fat, cholesterol, and sodium and rich in fiber, potassium, and unsaturated fats are beneficial for reducing cardiovascular risk.
Body Weight/Obesity
The committee concurs with the NEL Dietary Patterns Systematic Review that moderate evidence suggests favorable outcomes related to healthy body weight (including lower BMI, waist circumference, or percent body fat),and risk of obesity with dietary patterns that: • Are high in fruits, vegetables, and whole grains • Include fish and legumes • Are moderate in dairy products, including low-fat dairy and alcohol, and • Are low in meats, particularly red and processed meats Nutrients that are components of dietary patterns that are associated with these favorable outcomes included high intakes of unsaturated fats and low intakes of saturated fats, cholesterol, and sodium.
T2DM
Moderate evidence suggests that the risk of developing T2DM is reduced by dietary patterns that are: • Rich in fruits, vegetables, and whole grains, and • Low in red and processed meats, high-fat dairy, refined grains, and sweets/sugar-sweetened beverages Evidence is lacking for the pediatric population.

ACC indicates American College of Cardiology; AHA, American Heart Association; BMI, body mass index; CVD, cardiovascular disease; DGAC, Dietary Guidelines Advisory Committee; NEL, National Evidence Library; T2DM, type 2 diabetes mellitus.

Frank Hu, MD, PhD, MPH

The consensus in the draft statements emerged from a rigorous process for all 3 chronic diseases. Hu said the process for CVD involved the Nutrition Evidence Library (NEL) Dietary Patterns Systematic Review Report, the highly publicized 2013 Guideline of the American Heart Association and the American College of Cardiology (AHA/ACC), and a review of 142 articles published since 2008, including 35 that appeared in 2 or more reviews. Hu noted that the articles reviewed included studies of the Mediterranean diet, the Dietary Approaches to Stop Hypertension (DASH), and vegetarian-style diets.[1]

The review for the draft recommendations for dietary patterns to combat obesity also involved the NEL review, and a separate guideline published in 2013 for the treatment of obesity from AHA, ACC, and The Obesity Society (TOS). The literature review included 81 studies, including 3 that appeared in 2 or more reviews. Draft language in the body weight/obesity recommendation includes a recommendation that overweight persons consult with a nutritionist or counselor to lose weight.

The draft language for the T2DM dietary pattern recommendation relied upon the NEL review, 1 comprehensive analysis, and 39 articles, including 13 that were in more than 1 review. Of note, Hu said that evidence for dietary patterns and T2DM is lacking in the pediatric population.

Hu noted that the 2013 AHA/ACC guidelines that informed both the CVD and body weight/obesity drafts relied largely on randomized clinical trials. To some degree, he said, minor inconsistencies between the draft statements across the different diseases reflect limits on what was included in clinical trials and studies available to the committee. Definitions of dietary patterns or terms such as "Mediterranean diet" varied from study to study. Of note, evi-

dence ratings for the CVD draft were strong. Evidence ratings were moderate for the dietary pattern portions of the body weight/obesity and T2DM statements, based on criteria Millen outlined, but the committee found strong evidence for its draft statement that weight loss is achieved through a balance of diet and exercise.

An important finding, Hu said, is that while there is consistency in the types of dietary patterns that reduce chronic disease, there is great variety in the individual foods that people can eat to achieve better health.

"People have been looking for the optimal diet," he said; however, "One size doesn't fit all.

This has important clinical and public health implications, he said, because it allows healthcare providers and nutritionists to adapt their recommendations to patient preferences, cultural needs, and the availability of local foods.

Even within the scientific literature, authors "used different methods to achieve healthy dietary patterns," Hu said. DASH, the Mediterranean diet, vegetarian patterns, and other methods received attention. Losing weight and reducing cardiovascular risk is possible, Hu said, "as long as the overall diet quality is high." **EBDM**

References

1. HHS. 2015 Dietary Guidelines Advisory Committee, Fourth Meeting, Day 1. http://videocast.nih.gov/summary asp?Live=14230&bhcp=1. Webcast July 16, 2014. Accessed August 30, 2014.

2. 2015 Dietary Guidelines Advisory Committee. 2015 DGAC members. http://www.health.gov/dietaryguidelines/2015-binder/2015/membership.aspx. Accessed August 31, 2014.

3. Caffrey MK. Dietary patterns, and effect on population health, get attention from panel. *Am J Manag Care*. 2014;20(SP4):SP111-SP112.

4. Evich HB. Michelle Obama fights to defend school lunch changes. Politico. http://www.politico.com/story/2014/05/michelle-obama-school-lunch-nutrition-changes-107121.html. Published May 27, 2014. Accessed September 1, 2014.

5. Gentzel TJ. Making school nutrition a political issue has distorted reality in our cafeterias. The Huffington Post. www.huffingtonpost.com/thomas-j-gentzel/making-school-nutrition-a_b_5630823.html. Published July 29, 2014. Accessed September 1, 2014.

Research Report

Exploring the Intersection of Chronic Disease, Adherence, and Life Expectancy

Stanton R. Mehr and Mary K. Caffrey

Multiple studies in recent years have discussed what happens when patients with chronic conditions do not take medications as prescribed. The impact of poor adherence on both health and healthcare costs is so well documented that CMS now asks accountable care organizations (ACOs) to take steps to ensure better adherence when patients leave the hospital, to help hold down readmission rates.[1]

Yet despite the attention to the problem of adherence, alongside data that show increases in life expectancy are hitting plateaus among older Americans,[2] it appears less attention has been paid to knitting together evidence on a related question. In this era of healthcare reform, is anyone asking whether challenges with adherence are contributing not only to poor health, but also to lower life expectancy?

> *"Living with multiple chronic diseases such as diabetes, kidney disease, and heart failure is now the norm and not the exception in the United States."*
>
> —Eva DuGoff, PhD

The question arises in the wake of a new study led by Johns Hopkins researcher Eva DuGoff, PhD, who in August published results that examined how having multiple chronic conditions at once affected life expectancy. DuGoff's analysis, based on records from 1.4 million Medicare enrollees and evaluating 21 conditions, found that on average, each chronic condition takes 1.8 years off a person's life after the age of 67 years.[2]

As DuGoff described in a statement released by Johns Hopkins, that average is based on its *cumulative* effect on older persons; the first disease takes off only a fraction from the life span, with the effect growing with each additional disease. The results showed that different diseases have different effects on the life span, too. But in her conclusions, DuGoff said the key finding—that there are limits to what can be done for patients who suffer from multiple conditions—was important for Medicare and Social Security administrators, who have a keen interest in knowing how long beneficiaries will live.[3]

"Living with multiple chronic diseases such as diabetes, kidney disease, and heart failure is now the norm and not the exception in the United States," DuGoff said. "The medical advances that have allowed sick people to live longer may not be able to keep up with the growing burden of chronic disease."

While DuBoff joined those calling for increased efforts to prevent chronic disease, left unanswered in her study is how patient adherence to multiple medications—needed to manage all those chronic conditions—factored into the life expectancy equation. Elsewhere, it has been demonstrated that taking medication consistently is linked to better health.

A review by Boswell and colleagues in *The American Journal of Pharmacy Benefits* found that the connection between adherence and positive clinical outcome varies depending on the chronic condition, but overall the pattern is consistent: there was a positive relationship between taking medication and good outcomes in 81% of the 79 outcomes evaluated.[4]

Simply put, while it may seem obvious, there's evidence that if you take your medication, it's better for your health. Boswell's review found taking medication was most important for patients who had suffered heart attacks and for those with hypertension, diabetes, high cholesterol, and schizophrenia.[4] Perhaps it's not a surprise that 8 of the 33 early measures of whether ACOs are delivering quality care—which Medicare will examine to determine reimbursement under its Shared Savings Program—are tied to diabetes and cardiovascular conditions.[1]

While adherence has received plenty of attention in the literature, much of the focus has been on the economic impact—in other words, the question asked is, "How does the failure of patients to take medication contribute to rising healthcare costs?"

For example, *Health Affairs* cited a $290 billion price tag for nonadherence.[5] A study from Excellus BlueCross and BlueShield found that in upstate New York alone, the cost of nonadherence was $2.87 billion just for depression, diabetes, hypercholesterolemia, and hypertension.[6]

Mona Chitre, PharmD, vice president and chief pharmacy officer at Excellus Blue Cross and Blue Shield, said, "The number of people who don't take their medications as directed is nothing short of astounding. This signifies a huge health improvement and cost savings opportunity for our upstate New York regions ($2.87 billion in this 1 part of New York alone). But as you know, the problem of nonadherence is a national issue, and not unique to upstate New York." A 5% or 10% increase in adherence can yield hundreds of millions in savings for patients suffering from multiple conditions.

For the majority of studies reviewed by Boswell and colleagues, the connection between adherence and death was not specifically measured or reported.[4] The connection between infarction or the need for revascularization may imply risk of death, but the direct relationship between nonadherence and risk of death has not been well explored.

A study published in the *Journal of the American Medical Association* did support such a link. In 2007, researchers studied the outcomes of more than 31,000

Table. Population With Chronic Disease by Age

Age	Percent With 1 Chronic Disease	Population With 1 Chronic Disease	Percent With 2 Chronic Diseases	Population With 2 Chronic Diseases	Percent With ≥3 Chronic Diseases	Population With ≥3 Chronic Diseases
18-44 years	19.4%	21.59 million	5.1%	5.62 million	2.0%	2.21 million
45-64 years	30.6%	25.10 million	18.5%	15.17 million	13.8%	11.33 million
≥65 years	25.0%	10.46 million	27.6%	11.57 million	33.2%	13.88 million

This table estimates the total population in the United States with 1 of 10 common chronic diseases: hypertension, coronary heart disease, stroke, diabetes, cancer, arthritis, hepatitis, weak or failing kidneys, current asthma, or chronic obstructive pulmonary disease.

Source: Ward BW, Schiller JS, Goodman RA. Multiple chronic conditions among US adults: a 2012 update. *Prev Chronic Dis*. 2014;11:130389.

older Canadian patients who had experienced a heart attack and who subsequently filled a prescription for a statin, beta-blocker, and/or a calcium channel blocker, which was considered a control medication for this study.[7]

The authors, who categorized the patients by their level of adherence, found that "Among statin users, compared with their high-adherence counterparts, the risk of mortality was greatest for low adherers" (adjusted hazard ratio [HR], 1.25; *P* =.001). The risk of mortality was also elevated among those with intermediate levels of adherence versus the low-adherence group (adjusted HR, 1.12; 95% CI, 1.01-1.25; *P* =.03). The authors found a similar relationship for patients who took beta-blockers. No such correlation was found with mortality in those taking calcium blockers.[7]

In 2014, Canadian researchers published a meta-analysis of studies involving populations taking statin medications. They found that nonadherence with statin medications resulted in up to a 2.54-fold increased mortality.[8]

How Many Have Multiple Chronic Diseases?

Research from the National Center for Health Statistics and CDC estimated that approximately 117 million American adults have at least 1 of 10 common chronic illnesses.[9] This estimate, based on self-reports from the 2012 National Health Interview Survey, does not consider chronic disease in children, in addition to several other important chronic disorders, including mental health diseases, autoimmune diseases such as inflammatory bowel disease, and multiple sclerosis. This same review estimated that 1 in 4 adults have more than 1 chronic disease,[9] and that the likelihood of having multiple chronic diseases increases with age (**Table 1**).

By the age of 65 years, it is more likely that Americans will have 3 or more chronic diseases than 1 or 2.[9] The magnitude of this phenomenon in the United States was identified by the Johns Hopkins study, which found that nearly 80% of Medicare beneficiaries (aged 67 years or more) have at least 2 chronic conditions, more than 60% have 3 or more chronic conditions, and more than 33% have at least 5 chronic illnesses.[2] A rise in multiple chronic disease overall, coupled with its increased prevalence among older Americans, appears to already be making an impact on the flattening of life expectancy in the United States relative to other developed countries, based on what the Johns Hopkins researchers found.[2]

Reasons Behind Multiple Conditions, Poor Adherence

If adherence is a recognized problem, is the problem worse when a patient has multiple chronic conditions? Does being older further complicate things? And if so, how?

Preventing nonadherence in the elderly is a difficult challenge, according to Thuy-Tien Dam, MD, assistant professor of medicine at Columbia University Medical Center, New York.

"Barriers to nonadherence in the elderly include cognitive impairment, which can impact 'executive function' such as paying bills and deciding which mail should be kept and which should be thrown away," she said, "Adhering to medications also becomes an issue with early or mild cognitive decline, which is very common with aging. Most people over age 65 years who are living in the community are taking at least 3 medications, and these regimens can be confusing for older individuals."

Nonadherence can also be related to other critical factors, Dam said. "For example, physicians may not have the time to explain to patients why they need to take the medication and how it will help them. Second is the possibility that side effects or drug interactions are causing patients to discontinue the regimen," she said.

Questions about the ability to pay for medications often arise in studies on adherence. But prescription co-payments are not always be the only issue, or the main issue. In an important 2011 multicenter study of patients who had suffered a heart attack, adherence with pharmacologic therapy ranged between 36% and 49%.[8] They also found that even if the patients had full coverage for their medications in this study (without any co-payments), adherence rates rose only a maximum of 6 percentage points. However, even with this small increase, the rate of vascular events was still significantly less than in the group with lower adherence (who had usual coverage).

Consider this effect in the older patient with multiple drug regimens for several comorbidities. Said Dam, "I think that nonadherence for several diseases is synergistic, although there's not much evidence to support this specifically. If you have high cholesterol and hypertension, and you're nonadherent with 3 of your medications (for any reason), then the risk of having negative cardiovascular outcomes is greater.

"With polypharmacy, the instructions to the patient may be more complex, and it is to be expected that patients will have more difficulty in adhering to their medications. They will also experience more side effects, which can influence patients to stop taking their medication, also resulting in negative health outcomes," she said. Examples of complex instructions include "Don't take this medication without a meal," or "Don't take these 2 together."

A study by HealthPartners in Minneapolis[10] reported similar findings when it asked patients with diabetes or asthma to self-report barriers to adherence. Other barriers included failure to get timely refills and simply that there are too many pills to accurately track.

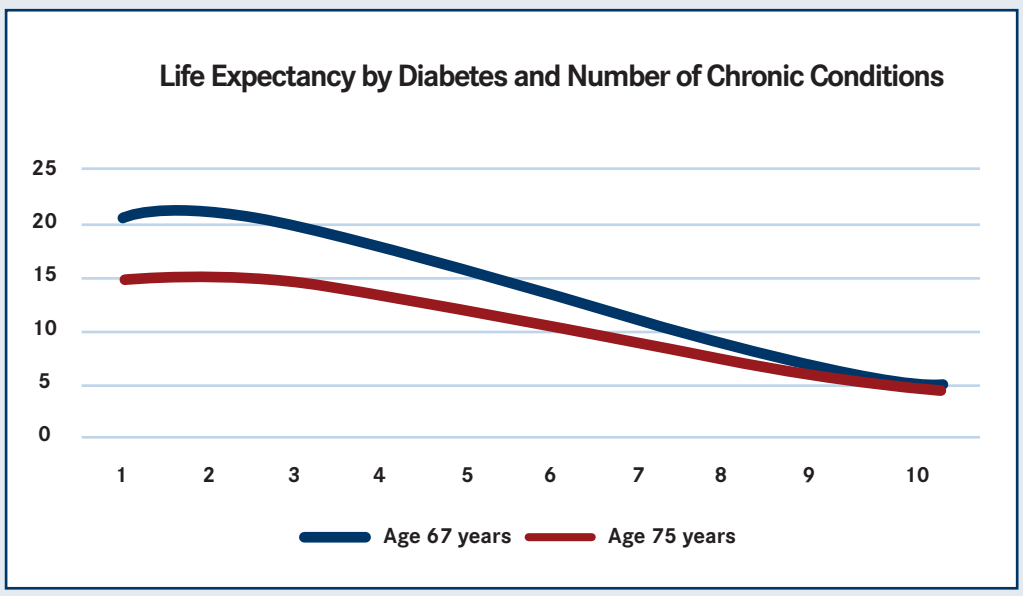
Polypharmacy is one of the greatest challenges in caring for the elderly, according to Renae Smith-Ray, PhD, research scientist at the Center for Research on Health and Aging, University of Illinois at Chicago. She told *Evidence-Based Diabetes Management*, "One of the main causes of falls among older adults is polypharmacy, and this results in a great deal of disability. It is very unusual to meet an older adult who doesn't take any medications. Most are taking 3 or more."

This issue of "nonadherence" affects health promotion as well. In her research on behavioral change, Smith-Ray found that "Adherence to behavior change programs is notoriously difficult. Some reasons may be intuitive—we're creatures of habit, and making abrupt change is difficult. Although most people know that physical activity is necessary for maintaining good health, physical activity takes considerable exertion relative to other health behaviors.

"We know that the initial phase of behavior change is most challenging; that is, when one first begins the new behavior. Consider an adult with arthritic knee pain: the most tempting thing to do is to keep your feet up on a sofa and remain immobile to prevent pain. It is much easier not to begin an exercise program, and there may be a mistaken perception that exercising will cause more arthritis-related pain. However, we have found exactly the opposite to be true, that improving endurance and lower-extremity strength removes pressure from weight-bearing arthritic joints, which decreases pain."

Smith-Ray believes that cognitive

Figure. Additional Years of Life Expectancy At Age 67 Years and At Age 75 Years For Patients With Diabetes by Number of Additional Chronic Conditions[2]



training programs can also be a useful tool for improving many aspects of health. "Through our research, we found that many participants report a noticeable difference in attentiveness to daily tasks following a 10-week intervention for cognitive training done in a classroom setting." Perhaps one of these tasks can be taking medication and following other medical recommendations.

"Nonadherence Affects Length of Life"

"Medication adherence is strongly related to both disease progression and control," stated Vittorio Maio, PharmD, MS, MSPH, associate professor, Thomas Jefferson University School of Population Health. "As former surgeon general C. Everett Koop said, 'Drugs don't work in patients who don't take them.' There is no doubt, therefore, that poor adherence is consistently associated with poor clinical, economic, and utilization outcomes. Nonadherence affects length of life."

Maio affirmed, "Clearly, adherence to treatments would become even more important in patients with multiple conditions, a quite common situation in the elderly, because these patients are already at much greater risk of poor outcomes. In these subjects, poor adherence to prescribed treatments would lead to suboptimal clinical responses to medications, which could in turn largely increase the onset of medical (and often lethal) complications as a consequence of poor therapeutic control." **EBDM**

References

1. ACO shared savings program quality measures. CMS website. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Shared-Savings-Program-Quality-Measures.pdf. Accessed August 22, 2014.

2. DuGoff EH, Canudas-Romo V, Buttorff C, Leff B, Anderson GF. Multiple chronic conditions and life expectancy: a life table analysis. *Med Care*. 2014;52(8):668-694.

3. Life expectancy gains threatened as more older Americans suffer from multiple chronic conditions [press release]. http://www.jhsph.edu/news/news-releases/2014/life-expectancy-gains-threatened-as-more-older-americans-suffer-from-multiple-medical-conditions.html. Baltimore, MD: Bloomberg School of Public Health; July 23, 2014.

4. Boswell KA, Cook CL, Burch SP, Eaddy MT, Cantrell CR. Associating medication adherence with improved outcomes: a systematic literature review. *Am J Pharm Benefits.* 2012;4(4):e97-e108.

5. McKethan A, Benner J, Brookhart A. Seizing the opportunity to improve medication adherence. *Health Affairs* blog. www.healthaffairs.org/blog/2012/08/28/seizing-the-opportunity-to-improve-medication-adherence/. Published August 28, 2012. Accessed August 2, 2014.

6. Medication adherence among upstate New York adults: a multi-billion dollar health improvement opportunity. Excellus BlueCross BlueShield website. (https://www.excellusbcbs.com/wps/wcm/connect/e3a05c81-35d2-466f-a71a-f8bba660f978/Rx+Adherence+FS-EX+FINAL.pdf?MOD=AJPERES&CACHEID=e3a05c81-35d2-466f-a71a-f8bba660f978). Published August 12, 2014. Accessed August 18, 2014.

7. Rasmussen JN, Chong A, Alter DA. Relationship between adherence to evidence-based pharmacotherapy and long-term mortality rate after acute myocardial infarction. *JAMA.* 2007;297:177-186.

8. Choudhry NK, Avorn J, Glynn Rj, et al. Full coverage for preventing medications after myocardial infarction. *N Engl J Med*. 2011;365:2088-2097.

9. Ward BW, Scholler JS, Goodman RA. Multiple chronic conditions among US adults: a 2012 update. *Prev Chron Dis*. 2014;11:130389.

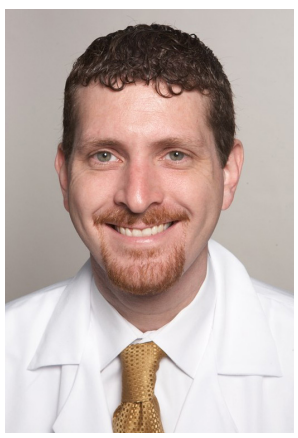
10. Rolnick SJ, Asche S, Pawloski PA, Bruzek RJ, Hedblom B. Barriers to and facilitators of medication adherence. *Am J Pharm Benefits*. 2013;5(5):209-215.

AJMC ACO Coalition

Coalition Invites Mount Sinai ACO to Share What It's Learned About Improving Diabetes Outcomes

Mary K. Caffrey

If the term "chief happiness officer" starts to work its way across the healthcare landscape, give credit to Jeffrey Farber, MD, MBA, chief medical officer at Mount Sinai Care LLC.



Jeffrey Farber, MD, MBA

Farber shared that phrase with a group of fellow healthcare leaders to describe how he met the needs of a diverse group of 280 primary care physicians. These physicians work in 26 practices that make up Mount Sinai Care, an accountable care organization (ACO) that formed in 2012 and expanded this year with the addition of the Beth Israel, St. Luke's, and Roosevelt practices.

In 2010, the Affordable Care Act created ACOs, which pursue the so-called "triple aim" of improved health for populations, better patient experiences, and lower cost of care. Earlier this year, *The American Journal of Managed Care* created the ACO and Emerging Healthcare Delivery Coalition, which now includes 100 stakeholders from across the healthcare spectrum. The Coalition gives groups like Mount Sinai Care a chance both to share what is working and to learn from others, as these new entities proceed in a changing landscape that measures healthcare outcomes in a different way, and in some cases connects reimbursement with those outcomes.

The ACO Coalition involves payers, providers, ACOs, integrated delivery networks (IDNs), pharmaceutical manufacturers, and specialty and retail pharmacy representatives, among other organizations. Coalition members are engaged in transitioning from a fee-for-service reimbursement model to one that rewards value.

In a Web-based meeting on August 18, 2014, Farber described Mount Sinai Medical Center's Diabetes Alliance, a management collaboration of the Mount Sinai ACO and the Mount Sinai Health Network. This initiative was designed to improve diabetes outcomes, which Farber said matters, because diabetes care is in the first group of measurements that the federal government tracks for Medicare reimbursement.

Farber walked a group of participants through Mount Sinai's new process for deploying care coordinators and diabetes educators into practices, to not only identify at-risk patients but to get them to change their behavior.

At its core, Mount Sinai's model involves transferring the relationship a doctor has built with a patient over to a certified diabetes educator (CDE). CDEs have more time to do the low-key follow-up and training in areas like nutrition, exercise, or social service interventions that are preventing progress. Connecting the CDEs to patients is the job of 24 care coordinators, who have 500 care "encounters" with at-risk patients per week. Patients receive customized treatment plans with a goal of avoiding unnecessary hospital admissions.

The approach is as much art as science. "Our care coordination model is nonclinical," he said. The coordinators are social workers, not nurses. Their job is to target patients whose numbers or history show they need contact with a CDE, who have both clinical and motivational training. Farber described the approach as "a lot of high touch, not necessarily high tech."

In 2 of the basic clinical indicators of diabetes—glycated hemoglobin (A1C) and cholesterol—clinics where the intervention has occurred started out with health measurements that were worse than New York City averages, to allow them to surpass city averages. Blood pressure measurements in the clinics have improved, too. Almost half the targeted patients have lost weight (46%), and more patients who should lose weight are self-monitoring—78% compared with 66% before the intervention.

What makes it work? "The preimplementation meeting is critical," Farber said. Mount Sinai wants to be certain that primary care physicians understand the role of the CDE and embrace the care coordinator concept. After that, it helps when doctors see their patients improve."

Farber's presentation was one of 3 at the session. More presentations and hands-on workshops will take place October 16-17, 2014, in Miami, when the ACO Coalition presents a live meeting featuring keynote speaker Thomas

Graf, MD, chief medical officer for Population Health and Longitudinal Care Service Lines, Geisinger Health System.

As ACOs and other emerging delivery and payment models evolve and move away from traditional fee-for-service system models toward cost-effective and value-based care, the need to understand how these models will evolve is critical to building long-term strategic solutions. The mission of the Coalition is to bring together a diverse group of key stakeholders, including ACO providers and leaders, payers, IDNs, specialty pharmacy, and pharmaceutical manufacturers to work collaboratively to build value and improve the quality and overall outcomes of patient care. Coalition members share ideas and best practices through live meetings, Web-based interactive sessions, and conference calls. Two distinguishing features are the Coalition's access to leading experts, and its small workshops that allow creative problem-solving. **EBDM**

To learn more or register for the Miami meeting of the ACO and Emerging Healthcare Delivery Coalition, visit http://www.ajmc.com/acocoalition.

Nutrition

US Kids and Teens Eat Too Much Salt, CDC Finds

Mary K. Caffrey

US school children and especially teens are eating too much salt, and they're doing so with the staples of the American diet–things like pizza, bread, snacks, chicken nuggets, cheeseburgers, and Mexican food.

Children aged 6 to 18 years consumed 42% more sodium on average than needed, with teens consuming nearly 60 percent more than recommended levels, according to a 2009-2010 survey released September 9, 2014, by CDC.[1]

In raw numbers, schoolchildren consumed 3279 mg of sodium daily on average, with teens taking in 3672 mg a day. The daily recommended amount is 2300 mg.[1]

Higher sodium intake has consequences beyond poor health for US children and teenagers. A study published in August 2014 in *The American Journal of Managed Care* found that a child with hypertension cost the healthcare system an extra $1000 a year on average.[2]

While most of the sodium intake by kids took place off campus, school lunches were not off the hook—the CDC study found that among kids who ate a meal at school during a day of the survey, 26% of the sodium intake came from food consumed at school. That's important, given the timeline of the survey, which occurred just prior to sweeping changes to the school lunch program following a 2010 law designed to make the meals healthier.

Leaders of the National School Boards Association and some members of Congress have pushed to roll back some of those changes, saying they have created wasted food and that school cafeterias are losing money.[3] First Lady Michelle Obama, meanwhile, is pressing to keep the 2010 law intact.[4]

Release of the CDC sodium survey comes at a critical time: next week is the September meeting of the Dietary Guidelines Advisory Committee, which is wrapping up its work before it makes recommendations to the US secretaries of Health and Human Services and Agriculture for the document that will become national nutrition policy for 2015-2020. Recommendations from the panel and subsequent changes to the 2010 *Dietary Guidelines for Americans* informed the law that is now under fire (see page **SP383**).

The CDC report on school-age children also follows an uproar this spring over an Institute of Medicine report that said the evidence was inconsistent to support cutting sodium back beyond 2300 mg to 1500 mg, as recommended by the American Heart Association.[5]

Among the findings in the CDC study:

- Approximately 43% of sodium came from 10 types of food: pizza; yeast bread and rolls; cold cuts/cured meats; savory snacks, which include chip and pretzels; sandwiches like cheeseburgers; cheese; chicken patties, nuggets, and tenders; pasta mixed dishes (including spaghetti with meat sauce but excluding macaroni and cheese); Mexican-mixed dishes such as burritos and tacos; and soups.

- Although foods from grocery stores contribute the majority of sodium intake, foods from fast-food/pizza restaurants continue to contribute higher amounts of sodium per calorie. Fast food and restaurant foods also contribute to higher proportions of total sodium among teens compared with younger children.[1] **EBDM**

References

1. Cogswell ME, Yuan K, Gunn JP, eta. Vital signs: sodium intake among US school-aged children, 2009-2010. *MMWR* 2014:63(36);789-797.

2. Gilner TP, O'Connor PJ, Sinaiko AR, et al. Impact of hypertension on healthcare costs among children. *Am J Manag Care*. 2014;20(8):622-628.

3. Gentzel T. Making school nutrition a political issue has distorted our cafeterias. Huffington Post. http://www.huffingtonpost.com/thomas-j-gentzel/making-school-nutrition-a_b_5630823.html. Published July 29, 2014. Accessed September 9 2014.

4. Evich HB. Michelle Obama fights to defend school lunch changes. Politico. http://www.politico.com/story/2014/05/michelle-obama-school-lunch-nutrition-changes-107121.html. Published May 14, 2014. Accessed September 9, 2014.

5. Hellmich N. Report questions reducing salt intake too dramatically. *USA Today*. http://www.usatoday.com/story/news/nation/2013/05/14/salt-diet-sodium-intake/2156143/. Published May 14, 2013. Accessed September 9, 2014.

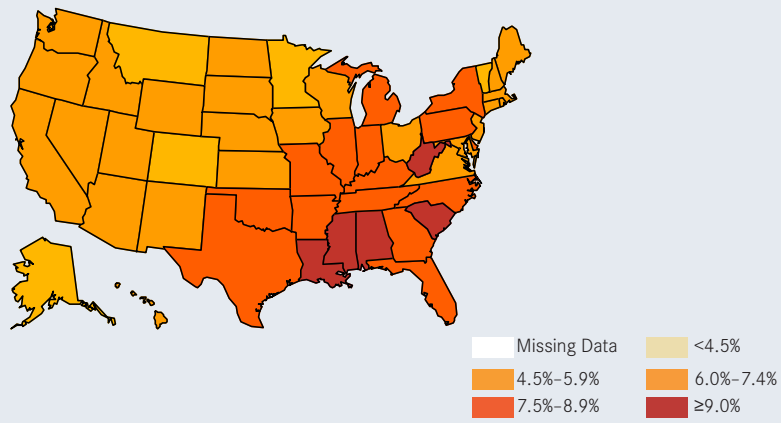
Diabetes Management Key to Healthcare Solutions
(continued from cover)

The good news is that the last 2 decades have brought a greater understanding of approaches to prevent complications of diabetes—the primary driver of diabetes costs. Appropriate control of blood glucose, blood pressure, and cholesterol, along with early screening for complications, have been clearly shown to decrease the potentially devastating long-term complications of diabetes, which include kidney failure, amputation, blindness, and cardiovascular disease. The challenge has been to ensure that those with diabetes meet these evidence-based goals. Much of the work in this arena will be based on improving our healthcare delivery system, making wiser choices regarding treatments, engaging patients, and achieving better coordination of care. *Evidence-Based Diabetes Management* will focus on covering this evolving field to better guide all of us in making the optimal choices in the management of this challenging disease. **EBDM**

Reference

1. American Diabetes Association. Economic costs of diabetes in the U.S. in 2012. *Diabetes Care.* 2013;36(4):1033-1046.

Figure. Age-Adjusted Prevalance of Diagnosed Diabetes Among US Adults in 2005



CDC's Division of Diabetes Translation. National Diabetes Surveillance System. http://www.cdc.gov/diabetes/statistics.

Drug Combination Update

Upending of Conventional Combination Therapy in Type 2 Diabetes Mellitus
(continued from cover)

In its 2014 standards of medical care, the ADA provides open-ended advice: "If noninsulin monotherapy at maximum tolerated dose does not achieve or maintain the A1C target over 3 months, add a second oral agent, a glucagon-like peptide 1 (GLP-1) receptor agonist, or insulin."[3] In other words, there is little specific information (and evidence) to help providers choose.

In these studies, insulin-based combinations, rather than metformin/SU, are used as the first drug combination. (Some of these studies were previously reported in *Evidence-Based Diabetes Managmenent*.[4])

This change is being driven by an overarching clinical and physiological philosophy, according to John Anderson, MD, of the Frist Clinic in Nashville, Tennessee: Stop beta-cell deterioration by getting patients to goal A1C levels as soon as possible. He said that ideally, one would screen patients with prediabetes and treat them at that point with lifestyle interventions or metformin.

"By the time patients are diagnosed with diabetes, we need to get them to glycemic goal as quickly as possible and keep them there as long as you can to reduce beta-cell damage and the long-term risk for micro- and macrovascular disease," Anderson said.

However, patients are infrequently diagnosed with prediabetes, and may have significantly elevated A1C levels when they are first seen by the clinician. Anderson explained, "If you can get them to goal on metformin monotherapy, that's fine, but if the patient is first diagnosed with an A1C of 8.5% or 9%, you have precious little chance to get them to goal with 1 treatment. In that case, we need to make changes to their treatment as soon as is feasible. For that patient, you may need to start out not on monotherapy, but on combination therapy."

Sparing beta cells or limiting beta-cell deterioration has long been an ultimate objective of T2DM care.[1] New studies have demonstrated that using insulin early in the natural history of the disease can actually produce short remissions in hyperglycemia and slow beta-cell dysfunction. Furthermore, investigators found that this occurred after only a few weeks of therapy.[5] This offers patients the possibility of using insulin early, but not continuously injecting it for the rest of their lives. In this scenario, GLP-1 treatment (which seems to have positive effects on beta-cell number and function)[6] would be used as maintenance therapy over the long term. This concept is based on an innovative way of thinking about the origins of diabetes, involving the interaction of fatty acids and glucose—a "glucolipotoxicity."[4]

Insulin and GLP-1 Combination

Novo Nordisk has already developed the idea of a full-fledged combination of insulin and GLP-1, called Xultophy. This combination comprises Novo Nordisk's new insulin formulation (degludec) and the company's already approved GLP-1 injectable (liraglutide). The company has filed for approval of the drug combination in Europe, where insulin degludec is already approved. One interesting benefit of this therapeutic combination is that liraglutide's ability to induce weight loss may help offset insulin's common side effect of weight gain.

At the recent ADA Scientific Sessions, investigators reported the 1-year results of using Xultophy (IDegLira). Researchers reported that 78% of those taking the combination achieved an A1C level of 7% compared with 63% of those taking insulin degludec alone or 57% of those trying liraglutide monotherapy. The main trial included more than 1600 patients, and the study extension to 1 year, more than 1300. In this investigation, patients taking the combination therapy lost a mean 0.9 pounds compared with a mean 5.1-pound gain for those taking insulin degludec only. Additionally, those taking the combination treatment used an insulin dose that was 37% lower than the dose used by those taking insulin degludec alone. The rate of hypoglycemia was also 37% lower with Xultophy than with the basal insulin alone.[7]

Another study at ADA presented 52-week findings using a different insulin–GLP-1 combination: insulin lispro and dulaglutide, a once-weekly GLP-1 injection. They demonstrated that insulin lispro given at mealtime, along with dulaglutide, offered better glycemic control than basal–bolus therapy with insulin glargine and insulin lispro (ie, 58% of patients attaining A1C levels less than 7% vs 49% using basal/bolus therapy; 1.48 point decrease in A1C vs 1.23 point decrease for the basal/bolus treatment), with a similar side effect profile. Hypoglycemia rates were 31 events/patient/year for the dulaglutide 1.5 mg/lispro combination vs 35 events for the dulaglutide 0.75 mg/lispro combination; the control group, with the lispro/glargine combination, had 39 events.[8]

Said Anderson, "We're just learning about this combination, but we do know that many things work well in combination with basal insulin. If a person is already taking basal insulin, it might be easier to intensify their regimen with a single shot of a GLP-1 than with 4 bolus shots each day. We don't have any long-term outcome studies on the comparison between the 2 regimens, however."

Anderson, who is also the immediate past president of medicine and science at the ADA, added, "You can say that the 26-week data on dulaglutide and basal insulin yielded better results than basal–bolus treatment in getting to A1C goal. We don't know what the results may look like 10 years down the line, but we don't have reason to believe the long-term benefit won't be reflective of the short-term findings announced at ADA."

SGLT-2 and DPP-4 Inhibitors

Combining 2 medications with different mechanisms of action seems to bear fruit in the control of T2DM. Boehringer Ingelheim and Eli Lilly have filed a new drug application with the FDA for a single pill combination of its recently approved SGLT-2, empagliflozin, with its DPP-4 inhibitor, linagliptin. In this case, the SGLT-2 acts on the kidney to release extra blood glucose into the urine, combined with the DPP-4 inhibitor's slowing of glucagon release, and increasing insulin production when food is ingested.

Compared with treatment with its individual components (398 patients), the combination (269 patients) caused a significant reduction in the A1C levels in a phase 3 trial **(see Table 1).** In addition, the percentage of patients taking the

Table 1. Results of an Investigational SGLT-2/DPP4 Combination Therapy (empagliflozin/linagliptin) Versus Component Monotherapy, at 24 Weeks[9]

	EMPA 25 mg/LINA 5 mg (n = 134)	EMPA 10 mg/LINA 5 mg (n = 135)	EMPA 25 mg (n = 133)	EMPA 10 mg (n = 132)	LINA 5 mg (n = 133)
A1C					
Change from baseline at week 24 (percentage points)	–1.08	–1.24	–0.95	–0.83	–0.67
Subjects with A1C <7% at week 24 (percentage)	55.4%	62.3%	41.5%	38.8%	32.3%
FPG (mg/dL)	-29.6	-28.2	-24.2	-22.4	-5.9
Change from baseline at week 2					

A1C indicates glycated hemoglobin; EMPA, empagliflozin; FPG, fasting plasma glucose; LINA, linagliptin.

medication combination who attained an A1C less than or equal to 7% after 24 weeks was far greater than those taking either component alone (odds ratio, 1.9-4.3). Interestingly, in combination, the lower dose of empagliflozin seemed to be more effective than the higher-dose combination.[9]

More in the Arsenal and More Varied Choices

In some ways, diabetes therapy may resemble cancer care in the future. A laundry list of treatments are available, with different mechanisms of action, and it will ultimately be left up to the clinician to choose what he or she believes will work best for the individual patient; specifically, to spare beta cells by reaching glycemic goals rapidly. Of course, payers will continue to exert due caution with regard to both untested therapies and the cost of treatment. For this reason, some clinicians may not retreat from step therapy or prior authorization approaches to diabetes treatment. There may be hand-wringing if inexpensive, generic metformin–SU treatments are replaced en masse with higher-cost combination approaches.

Table 2 shows diabetes prescription data provided by IMS Health, in which the utilization of various diabetes drug categories has changed between 2010 and 2013. While metformin prescribing dominates and has grown slowly over the years, the prescription of other drug categories has changed significantly. For instance, the use of fixed-dose biguanide–SU combination therapy has dropped off, as has the utilization of glitazone-biguanide combination therapy, but the prescription of DPP-4-biguanide combinations had grown substantially until this past year. Although it is not possible to say from these data whether other non–fixed dose combinations are being tried in increasing volumes, it is almost certain that if a combination of 2 agents seems to produce a clinical benefit, the biopharmaceutical industry will work on a new formulation to fill this demand.

Anderson believes that physicians may be willing to move away from SUs but not metformin. He said, "Even today, physicians add sulfonylureas somewhat reluctantly, because they have the potential for hypoglycemia, are associated with weight gain, and may be harmful to beta cells (in theory but not yet proved)." He added, "Yet, they still cost very little, so we know that patients can afford them and can access them. The SUs may be falling out of favor, in favor of combinations of metformin and DPP-4s and other biguanide combinations."

Anderson added, "When I started in practice, there were hardly any choices. Today, we have many more options with which we can tailor therapy to the individual patient. But it is difficult for diabetes physicians—much less PCPs—to keep up. But we have a diabetes epidemic on our hands, and 90% of the diabetes population are treated by PCPs. We need to learn how to use these various agents and get good at it." This means not only figuring out which therapies will get specific individuals to goal quickly, but when to move on to the next step in treatment.

EBDM

References

1. Zinman B. Initial combination therapy for type 2 diabetes mellitus: is it ready for prime time? *Am J Med*. 2011;124(1):S19-S34.

2. Summary of revisions to the 2014 clinical practice recommendations. *Diabetes Care*. 2014;37(suppl 1):S4.

3. Standards of medical care in diabetes–2014. *Diabetes Care*. 2014;37(suppl 1):S5-S13.

4. Caffrey MK. Can early use of insulin, GLP-1 halt diabetes progression? *Am J Manag Care*. 20(SP10):SP300.

5. Retnakaran R, Kramer CK, Choi H, Swaminathan B, Zinman B. Liraglutide and the preservation of beta-cell function in early type 2 diabetes: a randomized, controlled trial. *Diabetes*. 2014;63(suppl 1): Abstract 328-OR.

6. Mudaliar S, Henry RR. Effects of incretin hormones on beta cell mass and function, body weight, and hepatic and myocardial function. *Am J Med*. 2010;123:S19-S27.

7. Gough SCL, Guse JB, Woo VC, et al. One-year efficacy and safety of IDegLira in patients with type 2 diabetes. *Diabetes*. 2014;63(suppl 1): Abstract 65-OR.

8. Jendle J, Rosenstock J, Blonde L, et al. Better glycemic control and less weight gain with once-weekly dulaglutide vs once-daily insulin glargine, both combined with premeal insulin lispro, in type 2 diabetes patients (AWARD-4). *Diabetes*. 2014;63(suppl 1): Abstract 962-P.

9. Lewin A, DeFronzo R, Patel S, et al. Fixed-dose combinations of empagliflozin/linagliptin for 24 weeks in drug-naïve patients with type 2 diabetes.

Table 2. The Changing Diabetes Combination Marketplace

In 1000s:	YEAR 2013 Total Dispensed Scripts	YEAR 2013 Total Dispensed Scripts % Growth Over Year 2012	YEAR 2012 Total Dispensed Scripts	YEAR 2012 Total Dispensed Scripts % Growth Over Year 2011	YEAR 2011 Total Dispensed Scripts	YEAR 2011 Total Dispensed Scripts % Growth Over Year 2010	YEAR 2010 Total Dispensed Scripts
BIGUANIDES, ALONE	72,836	7	67,809	15	59,106	4	56,981
SU ALONE	37,093	0	37,215	9	34,161	–3	35,163
ANALOGUES OF HUMAN INSULIN, LONG ACTING	24,226	6	22,773	10	20,618	8	19,162
ANALOGUES OF HUMAN INSULIN, FAST ACTING	14,683	6	13,795	7	12,834	8	11,898
DPP-4 INHIBITORS, ALONE	11,898	4	11,409	22	9389	21	7760
GLITAZONES, ALONE	5706	–18	6977	–40	11,600	–21	14,721
DPP-4 INHIBITOR/BIGUANIDE COMBINATIONS	4958	6	4674	32	3548	28	2766
HUMAN GLP-1 ANALOGUES, ALONE	4117	12	3660	22	3008	21	2482
BIGUANIDE/SU COMBINATIONS	3101	–15	3662	–7	3950	–11	4447
ANALOGUES OF HUMAN INSULIN, COMBINATIONS	2856	–2	2906	1	2872	–2	2936
GLINIDES, ALONE	1232	–7	1329	–7	1431	–11	1602
GLITAZONE/BIGUANIDE COMBINATIONS	881	–24	1164	–42	1989	–26	2699
ALPHA GLUCOSIDASE INHIBITORS, ALONE	403	4	389	5	372	–2	381
HUMAN INSULINS, FAST ACTING	240	14	211	15	184	23	149
HUMAN AMYLIN ANALOGUES	94	–28	132	–22	168	–14	195
GLITAZONE/SU COMBINATIONS	54	–33	80	–54	175	–46	325
DPP-4 INHIBITOR COMBINATIONS, OTHER	26	99	13	>999	1	N/A[a]	
GLINIDE/BIGUANIDE COMBINATIONS	6	–23	8	–34	12	–31	18

National Prescription Audit reporting–as of January 2014–reflects the addition of a large amount of mass merchandiser data, with restated periods from January 2012 to January 2014, replacing data previously projected. The mail channel prescription volumes are also impacted by the large payer data disruption, which results in a trend break beginning in mid-2013.

DPP-4 indicates dipeptidyl peptidase-4; GLP-1, glucagon-like peptide; N/A, not available; SU, sulfonylurea.

Information in the National Prescription Audit (NPA) is derived from IMS Health's Xponent service, one of the most complete, national-level prescription databases in the United States. Xponent captures roughly 70% market share of all prescriptions in the United States. IMS then uses a patented projection methodology from a stratified and geographically balanced sample to represent 100% market share coverage of prescription activity in the United States at retail, mail service, long-term care, and managed care outlets.

[a]No data for DPP-4 inhibitors in 2010.

Origins and Evidence Behind New ADA Recommendations for Pediatric A1C
(continued from cover)

ADA Pediatric A1C Recommendation

At the 74th Scientific Sessions of the ADA, held June 13-17, 2014, in San Francisco, the association released a position statement and simultaneously published it online in the journal *Diabetes Care*. ADA's first-ever policy statement on T1DM emphasizes changes in how patients and healthcare professionals should address and treat the disease. It also provides care recommendations for all age groups: children, adults, and older patients. The ADA had been working on this position statement for approximately 5 years from the time the decision for separate guidelines for T1DM and type 2 diabetes mellitus (T2DM) was reached. The first step in the development of the recently announced position statement was creating *The American Diabetes Association/Juvenile Diabetes Research Foundation (JDRF) Type 1 Diabetes Sourcebook*, which is an evidence-based reference work and consensus report outlining components of care for individuals with T1DM. The position statement itself contains the "practical pearls" from *The American Diabetes Association/JDRF Type 1 Diabetes Sourcebook*.[4]

One noteworthy change was the recommendation to lower the glycated hemoglobin (A1C) target to less than 7.5% for all T1DM patients under the age of 18 years. Previously, the A1C recommendations for pediatric patients were based on age groups: less than 8.5% for patients 5 years old and younger, less than 8% for those 6 to 12 years of age, and less than 7.5% for those 13 to 18 years of age. The reasons for the previous less-stringent targets in the younger age groups reflected concerns for the risk of hypoglycemia, which is associated with intensive management in young patients. Some of the primary concerns were the developmental consequences associated with severe hypoglycemia in growing children.[5] However, the ADA considered recent and ongoing research, which has dispelled these concerns regarding hypoglycemia and neurocognitive dysfunction.[6,7]

Recent evidence demonstrates that detrimental effects in neurocognitive function and the central nervous system are due to elevated blood glucose levels and glycemic variability in pediatric patients with T1DM.[8] Another reason for the shift toward a universal goal of less than 7.5% for all young patients is the ADA's recognition that today's modern treatment and monitoring abilities (eg, insulin analogues, "smart pumps," and continuous glucose monitoring devices) allow patients to more easily achieve improved glycemic control with fewer hypoglycemic events.[5] The recommendation of a single A1C goal of less than 7.5% for all pediatric age groups, based on clinical studies and expert opinion, is by no means revolutionary. This recent change by the ADA now aligns its recommendation with that of the International Society of Pediatric and Adolescent Diabetes (ISPAD) and the International Diabetes Federation.[9,10]

ADA Adult A1C Recommendation

While the ADA's recommendations for glycemic control in pediatrics intensified, the recommendations for older T1DM patients were relaxed. The ADA recognized that the older T1DM population has a number of comorbidities and highly variable life expectancy—defined by comorbidity and functional status—as opposed to just age.[4] Unlike the pediatric population, who would benefit from interventions such as stringent glycemic control, adult T1DM patients may not benefit, due to already advanced complications or because they don't survive long enough for the benefits to be realized. Additionally, the strict glycemic control recommended for younger, healthier adults may pose a higher risk of hypoglycemia and treatment burden in the older patients. Therefore, the final glycemic target recommendations for adults with T1DM are: A1C less than 7% for many nonpregnant healthy adults, less than 7.5% for healthy older adults, less than 8% for complex/intermediate older adults, and less than 8.5% for older adults with very complex or poor health. The age ranges for an "adult" versus an "older adult," however, are not defined.[4]

For individuals with T1DM, hypoglycemia is the most common acute side effect of insulin therapy and serves as one of the major barriers to optimal glycemic control.[11] Despite the overall guidance from the ADA that glycemic control should be approached aggressively, the organization makes it quite clear that it emphasizes individualization when choosing glycemic targets, focusing on the goal of achieving the best possible control—minimizing the risk of severe hyperglycemia and hypoglycemia while maintaining normal growth and development in pediatric patients. The goals for both pediatric and adult patients should be individualized based on duration of diabetes, age/life expectancy, comorbid conditions, known cardiovascular disease or advanced microvascular complications, hypoglycemia unawareness, and individual patient considerations.[5] All of these need to be factored into the discussion of the stringency of glycemic goals.

The ADA provides guidance on how to successfully monitor blood glucose levels in order to prevent hypoglycemia in T1DM. Self-monitoring of blood glucose (SMBG) allows patients to evaluate their individual responses to their prescribed insulin dosages, and to understand how nutrition and physical activity influence their glucose levels. Overall, frequent SMBG readings allow for insulin dosing adjustments that correlate with lower A1C levels.[12,13] The ADA therefore recommends that patients test their blood glucose prior to—and sometimes after—meals and snacks, at bedtime, before and after exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving.[4] The position statement points out that this may require patients to perform SMBG more than 10 times daily. In order to ensure the most benefit from SMBG, patients should be routinely educated on appropriate monitoring techniques.

An alternate approach to obtaining accurate blood glucose levels is through continuous glucose monitoring (CGM), which is a real-time measurement of interstitial glucose that parallels plasma glucose. CGM was described as an adjunct to SMBG, with CGM being recommended as a useful tool to reduce A1C levels in adults without increasing hypoglycemia, and as a way to reduce glycemic excursions in children. It is important to note that CGM sensors, which require calibration with SMBG, are not a replacement for self-monitoring. Also, SMBG is required for making acute treatment decisions, but patients can be alerted to hypo- and hyperglycemic excursions via CGM devices, which have alarms for designated absolute blood glucose levels and also for drastic rates of blood glucose changes.[4]

Discussion of the Landmark Study: DCCT

It is recognized that hyperglycemia is directly related to the incidence of complications, both short- and long-term. For this reason, glycemic control is fundamental to diabetes management. One of the more influential studies focusing on intensive glycemic control—referenced throughout the ADA position statement—was the Diabetes Control and Complications Trial (DCCT). A 10-year study published in 1993, DCCT was a prospective, randomized, and controlled study comparing intensive versus standard glycemic control in patients diagnosed with T1DM. The trial demonstrated that the intensive glycemic control group, which achieved a mean A1C of 7.4%, reduced the incidence of microvascular complications of T1DM compared with standard control, which achieved a mean A1C of 9.1% during the trial period. Specifically, compared with the control group, intensive glycemic control reduced the risk for retinopathy, neuropathy, and nephropathy by 76%, 60%, and 50%, respectively.[14] Additionally, the DCCT revealed that intensive therapy is not completely positive, being associated with an almost 3-fold increase in cases of severe hypoglycemia. The term was defined as an event with symptoms consistent with hypoglycemia, in which the patient requires the assistance of another person and which is associated with a blood glucose level below 50 mg/dL or with prompt recovery after oral carbohydrate, intravenous glucose, or glucagon administration.[15] It is worth noting that the DCCT only enrolled pediatric patients between the ages of 13 and 17 years. The lack of evidence in children below 13 years of age was one reason that the ADA has recommended a stratified treatment approach among the different pediatric age groups.[5]

The Follow-up EDIC Study

The DCCT was a landmark study in its own right; however some of the most intriguing data have resulted from its long-term follow-up study—Epidemiology of Diabetes Interventions and Complications (EDIC)—which began in 1994, the year after DCCT ended. The EDIC study, also referenced in the ADA position statement, astonishingly showed persistent microvascular and cardiovascular benefits in subjects who had previously received intensive treatment, even though their glycemic control had deteriorated over time.[16,17] Within 4 years of the DCCT trial ending, the mean A1C of patients, from both the intensive and conventional treatment groups, converged around 8%.[16] Nine years into EDIC, there was a 42% decrease in any cardiovascular event and a 57% reduced risk for nonfatal heart attack, stroke, or death from cardiovascular causes when comparing the patients who were originally assigned to the 2 treatment groups.[18] After 18 years, the overall prevalence of diabetes complications was 50% lower among the T1DM patients in the DCCT who were randomly assigned to intensive glucose control compared with those who received conventional treatment, despite the fact that A1C levels are no longer different between the 2 study groups.[19,20] When the patients who were enrolled in the intensive treatment group were compared with those enrolled in the conventional treatment group, the rate of retinopathy was 70% lower at 4 years after the DCCT trial ended, 53% lower at 10 years, and 46% lower at 18 years. Rates of ocular surgery, too, were lower at 18 years in the prior intensive group, with

differences of 48% in cataract extraction and 44% in vitrectomy or retinal detachment compared with those patients in the conventional treatment group.[19]

Summary

The ADA position statement, which focused solely on the management and treatment paradigm for T1DM, is a significant step forward in disease treatment, as opposed to T2DM, which is often addressed in tandem with T1DM. The statement was intentionally written in an easy-to-understand format, with evidence-based recommendations throughout. According to Lori Laffel, MD, MPH, chief of pediatric, adolescent, and young adult programs at Joslin Diabetes Center, "Previously, guidelines for the care of persons with diabetes didn't necessarily distinguish between patients with type 1 and type 2 diabetes. Often the guidelines that come out every January from the Diabetes Association are very long. They compile an entire journal. This particular guideline can be digested in a brief reading."[21] Laffel is the lead author on these guidelines. Beyond its discussion of glycemic targets, the full statement includes discussions on diagnosis, evaluation and follow-up, comorbidity management, blood glucose monitoring, and issues for special populations. **EBDM**

References

1. General diabetes facts. JDRF website. http://jdrf.org/about-jdrf/fact-sheets/general-diabetes-facts/. Accessed August 19, 2014.

2. Pettitt DJ, Talton J, Dabelea D, et al; SEARCH for Diabetes in Youth Study Group. Prevalence of diabetes in U.S. youth in 2009: the SEARCH for Diabetes in Youth study. *Diabetes Care*. 2014;37:402-408.

3. Scottish Diabetes Research Network Epidemiology Group. Life expectancy in type 1 diabetes : a Scottish Registry Linkage Study. EASD Virtual Meeting website. http://www.easdvirtualmeeting.org/resources/3906. Accessed August 1, 2014.

4. Peters A. How did the new ADA, Type 1 Position Statement get made? [interview]. Interview by Mark Harmel. https://www.youtube.com/watch?v=4CKk9Pe1owY. Published June 21, 2014.

5. Chiang JL, Kirkman MS, Laffel LM, et al. Type 1 diabetes through the life span: a position statement of the American Diabetes Association. *Diabetes Care*. 2014;37:2034-2054.

6. Cato MA, Mauras N, Ambrosino J, et al; Diabetes Research in Children Network (DirecNet). Cognitive functioning in young children with type 1 diabetes. *J Int Neuropsychol Soc*. 2014;20:238-247.

7. Marzelli MJ, Mazaika PK, Barnea-Goraly N, et al; Diabetes Research in Children Network (DirecNet). Neuroanatomical correlates of dysglycemia in young children with type 1 diabetes. *Diabetes*. 2014;63:343-353.

8. Barnea-Goraly N, Raman M, Mazaika P, et al; Diabetes Research in Children Network (DirecNet). Alterations in white matter structure in young children with type 1 diabetes. *Diabetes Care*. 2014;37:332-340.

9. Rewers M, Pihoker C, Donaghue K, Hanas R, Swift P, Klingensmith GJ. Assessment and monitoring of glycemic control in children and adolescents with diabetes. *Pediatric Diabetes*. 2009:10(suppl 12):71-81.

10. The global IDF/ISPAD guideline for diabetes in childhood and adolescence. International Diabetes Federation website. http://www.idf.org/sites/default/files/attachments/ISPAD-LFAC-Pocketbook-final-2.pdf. Published 2013. Accessed August 3, 2014.

11. Cryer PE, Fisher JN, Shamoon H. Hypoglycemia. *Diabetes Care*. 1994;17:734-755.

12. Miller KM, Beck RW, Bergenstal RM, et al; T1D Exchange Clinic Network. Evidence of a strong association between frequency of self-monitoring of blood glucose and hemoglobin A1C levels in T1D Exchange clinic registry participants. *Diabetes Care.* 2013;36:2009-2014.

13. Ziegler R, Heidtmann B, Hilgard D, Hofer S, Rosenbauer J, Holl R; DPV-Wiss-Initiative. Frequency of SMBG correlates with HbA1c and acute complications in children and adolescents with type 1 diabetes. *Pediatr Diabetes*. 2011;12:11-17.

14. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med*. 1993;329:977-986.

15. The DCCT Research Group. Epidemiology of severe hypoglycemia in the diabetes control and complications trial. *Am J Med*. 1991;90:450-459.

16. The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research group. Retinopathy and nephropathy in patients with type 1 diabetes 4 years after a trial of intensive therapy. *N Engl J Med*. 2000;342:381-389.

17. Martin CL, Albers J, Herman WH, et al; DCCT/EDIC Research Group. Neuropathy among the diabetes control and complications trial cohort 8 years after trial completion. *Diabetes Care*. 2006;29:340-344.

18. DCCT/EDIC Research Group. *N Engl J Med.* 2005;353:2643-2653.

19. Aiello LP. Diabetic retinopathy and other ocular findings in the diabetes control and complications trial/epidemiology of diabetes interventions and complications study. *Diabetes Care*. 2014;37:17-23.

20. de Boer IH. Kidney disease and related findings in the diabetes control and complications trial/epidemiology of diabetes interventions and complications study. *Diabetes Care*. 2014;37:24-30.

21. ADA Type 1 Diabetes Position Statement Changes A1C Recommendations for Pediatric Patients [press release]. Boston, MA: Joslin Diabetes Center; July 18, 2014. http://www.joslin.org/news/ADA-position-statement-changes-A1C-recommendations-for-pediatric-patients.html.

USPSTF Ruling, Medicare Policy Signal Shift in Linking Chronic Disease, Behavioral Health

Mary K. Caffrey

Two policy announcements in August, 1 from Medicare and another from the US Preventive Services Task Force (USPSTF), signal a shift toward understanding that America's battle with obesity and diabetes is not only a medical but also a behavioral health problem, and must be treated as such.

First, CMS announced that it would start paying primary care physicians $42 a month per patient next year to coordinate the care those with chronic diseases that include diabetes, heart disease, and depression. According to news accounts and The Advisory Board Company, the fee is contingent upon practices addressing patients' psychological and social needs.[1]

Then, the USPSTF followed up with a recommendation that obese or overweight patients with cardiovascular disease receive intensive behavioral counseling. The recommendations, published in the , apply to adults age 18 or older and carry a "B" recommendation, which means that it is a moderate benefit that should be offered to most patients.[2]

The policy announcements support the findings of a study published in August 2014 by which studied practices that spent extra time with Medicare patients upfront in an effort to avoid medical costs later.[3] The practices capped patient loads and featured many elements that will be required under the new CMS reimbursement model – such as 24-hour access and coordinated care. The study showed the model produced better health outcomes and cost savings for Medicare Advantage.

The Affordable Care Act requires that all preventive services rated B or higher be covered, and obesity screening and counseling coverage is already included for all but a few grandfathered plans. However, such counseling typically ends a preset number of sessions.

Reimbursing primary care doctors (PCPs) is likely to make bigger difference. Many PCPs often act as care coordinators without compensation, at a financial loss. The inability to be compensated for such coordination tasks is seen as a contributing factor to the shortage of PCPs nationwide, and to overcrowding in practices. Not only is the situation unpleasant for doctors and patients, but it is viewed as a contributor to the spiraling cost of healthcare. **EBDM**

References

1. Pear R. Medicare to start paying doctors who coordinate needs of chronically ill patients. *The New York Times.* http://www.nytimes.com/2014/08/17/us/medicare-to-start-paying-doctors-who-coordinate-needs-of-chronically-ill-patients.html. Published August 17, 2014. Accessed September 2, 2014.

2. LeFevre ML Behavioral counseling to promote a healthful diet and physical activity for cardiovascular disease prevention in adults with cardiovascular risk factors: US Preventive Services Task Force recommendation statement. *Ann Intern Med.* [published online August 25, 2014]. doi:10.7326/M14-1796.

3. Musich S, Klemes A, Kubica MA, Wang S, Hawkins K. Personalized preventive care reduces healthcare expenditures among Medicare beneficiaries. *Am J Manag Care.* 2014;20(8):613-620.

Documenting the future *of* American healthcare

ONLINE

Access to full text, online CME/CE programs, and editorial submission guidelines is now just a click away.

AJMC.com

Coming Soon

Jardiance®
(empagliflozin) tablets

Visit hcp.jardiance.com

Boehringer Ingelheim

Lilly