SPECIAL ISSUE: DIABETES AND OBESITY IN YOUTH

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Evidence-Based DIABETES MANAGEMENT™

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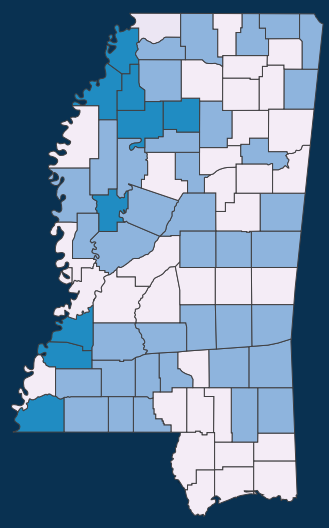

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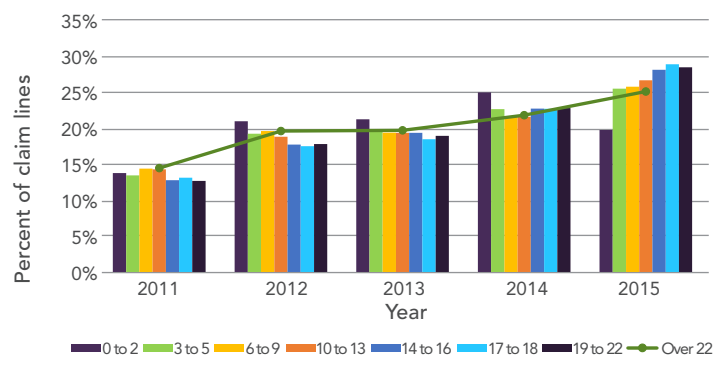
PAYER DATA

Obesity and Type 2 Diabetes in Young People: A Matter of National Concern

Robin Gelburd, JD

TYPE 2 DIABETES (T2D) was so rare in children that it was once called adult-onset diabetes to distinguish it from type 1 diabetes (juvenile diabetes). A growing body of evidence has shown, however, that the prevalence of T2D is increasing among the nation's young people and that a major contributor to this increase is the epidemic of obesity in the same population.[1,2] Our recent white paper, "Obesity and Type 2 Diabetes as Documented in Private Claims Data: Spotlight on This Growing Issue Among the Nation's Youth,"[3] examines these trends.

FIGURE. Annual Percent of Claim Lines With a Type 2 Diabetes Diagnosis by Age Group (in Years), 2011-2015.



Source: FAIR Health white paper. Obesity and type 2 diabetes as documented in private claims data: spotlight on this growing issue among the nation's youth. January 2017.

Consulting our FAIR Health database, which, at the time, included more than 21 billion privately billed healthcare claims nationwide (and has since grown to over 23 billion), we analyzed data from 2011 to 2015 to look for trends and patterns in obesity, T2D, and other obesity-related conditions in the nation's pediatric population, which we defined as youth aged 0 to 22 years. As a point of comparison, we also studied adults 22 years or older. Claims data are a useful means of investigating public health issues because they reflect actual healthcare utilization and the information provided on claims indicates the assessments of providers, who are better than laypeople at judging health conditions. What we found suggests that greater attention and new approaches are needed for prevention, screening, diagnosis, and treatment of obesity and T2D in the pediatric population. The age groups studied were 0-2 years, 3-5 years, 6-9 years, 10-13 years, 14-16 years, 17-18 years, 19-22 years, and 22 years or older.

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MENTAL HEALTH

Mental Health Care in Pediatric Diabetes: Overcoming Challenges and Barriers

Mary Pat Gallagher, MD

THE FINANCIAL BURDEN of poorly controlled diabetes in childhood and adolescence is not fully evident until complications occur during adulthood. In 2010, researchers estimated that the annual cost of type 1 diabetes (T1D) in the United States was $14.4 billion, including medical costs and lost income.[1] Prevention of diabetes-related complications requires that providers who care for children and adolescents with diabetes address barriers to good control soon after diagnosis and at frequent intervals as patients progress developmentally.

As a self-management disease, diabetes requires patients to adjust their insulin regimens based on blood glucose patterns they have recognized (in relation to exercise, illness, type of foods eaten, etc). This requires the synthesis of information from different sources and depends upon cognitive function and attention to detail. Even with the most advanced technology (insulin pumps, continuous glucose monitors, and hybrid closed loop systems),

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CONVERSATION

Joslin's Lori Laffel, MD, MPH, Explains the Challenge of Transitioning to Self-Care

Andrew Smith

AS CHIEF OF THE PEDIATRIC, Adolescent, and Young Adult Section of Joslin Diabetes Center, Lori Laffel, MD, MPH, has more than quadrupled the department's size and established it as a major center for both treatment and research. During this time, she has maintained a busy clinical practice and performed dozens of clinical trials designed to evaluate the efficacy of everything from new technology for automatic blood sugar management to new strategies for increased treatment adherence. Her achievements have won her

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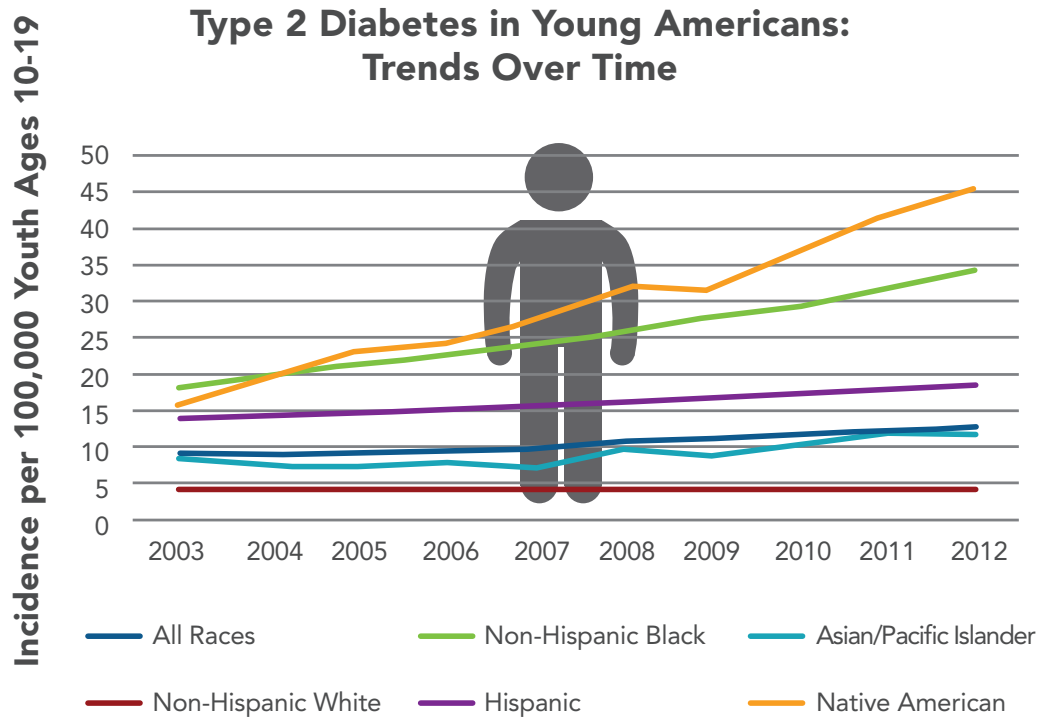

Model-Adjusted Incidence Estimates.
Shown are model-adjusted incidence estimates for the rate of new diagnosed cases per 100,000 youths. The incidence of type 2 diabetes was assessed among participants who were 10 to 19 years of age.
Source: CDC, National Institutes of Health.

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FROM THE CHAIRMAN

Trends Seen in Adults Showing Up in Youth


MIKE HENNESSY, SR

THIS ISSUE OF *Evidence-Based Diabetes Management*™ (*EBDM*™) looks at trends in diabetes management and obesity in children and adolescents, and finds good news and bad news. Unfortunately, the trends toward rising incidence and prevalence of diabetes and obesity that have been seen in adults for many years are showing up in youth.

This issue reports on brand-new epidemiological and claims studies that show these effects, which are particularly affecting racial and ethnic minorities. But there's good news, too. Places like Mississippi, where obesity and chronic disease have been most entrenched, have put prevention efforts in place and are starting to see the first signs of progress. As the article by Mississippi State Senator Brice Wiggins shows, sometimes the simplest ideas work best, and not all the solutions come from government. Private foundation grants helped schools replace deep fryers and purchase fruit prep equipment to make healthy food attractive to children, and without burdens on taxpayers.

This issue demonstrates the importance of prevention—if halting diabetes among the Medicare population can save $2650 per person over 15 months, as a recent YMCA pilot showed, think how much can be saved if we prevent type 2 diabetes and obesity among our youngest Americans? This issue also covers progress seen in caring for youth with type 1 diabetes (T1D); the greatest challenges here arise during the transitions from childhood to young adulthood, when parents gradually hand over the management decisions on food intake and insulin dosing. It's the time when glycemic control may be at its worse, as Joslin Diabetes Center's Lori Laffel, MD, MPH, describes in an interview. Dr Laffel has had a front-row seat for the rise of diabetes technology, but more importantly, she's an expert on the limits of what it can do.

Although the advances are significant and have contributed to better health for people living with T1D, day-to-day management still wears on young people. The need to pay attention to the mental health aspects of diabetes care led the American Diabetes Association to develop specific recommendations in this area, which Mary Pat Gallagher, MD, of NYU Langone Medical Center addresses from the pediatric perspective in her excellent cover article. Understanding how diabetes and obesity affect today's youth offers a glimpse into our healthcare obligations of the future.

We hope that you enjoy this issue of *EBDM*™ and thank you for reading. ◆

Sincerely,

Mike Hennessy, Sr
CHAIRMAN AND CEO

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FROM THE EDITOR-IN-CHIEF

Understanding What the Young Person With Diabetes Needs

Robert A. Gabbay, MD, PhD, FACP


GABBAY

WHEN WE TALK ABOUT THE RISING prevalence of diabetes in youth, those outside medicine often assume we are referring to type 2 disease (T2D). Certainly, T2D and coincident obesity are rising at alarming rates; T2D in youth was rare a generation ago, but today, the effects of sedentary lifestyles, too much screen time, and poor nutrition are evident. Old assumptions about what constitutes healthy eating for children are being set aside. A good example is the recent editorial by my colleagues here at Joslin Diabetes Center—Heather A. Ferris, MD, PhD; Elvira Isganaitis, MD, MPH; and Florence Brown, MD—called for an end to juice in the Special Supplemental Nutrition Program for Women, Infants, and Children.[1]

Within this issue of *Evidence-Based Diabetes Management*™ we discuss results from the first decade of the SEARCH study, which has found an increase in diabetes among youth. But it is not just T2D; type 1 diabetes (T1D), which gets less attention, is on the rise, too, and it is increasing among populations not historically associated with the disease.[2] SEARCH also showed us that youth are developing complications of diabetes at younger ages. These trends raise many new questions that ongoing studies will explore, according to Barbara Linder, MD, PhD, of the National Institutes of Health.[3]

Support for Psychosocial Care

In this issue, Mary Pat Gallagher, MD, of NYU Langone Medical Center, outlines the rising cost burden ($14.4 billion in 2010) of T1D, but as she explains, it is the psychosocial toll that demands greater attention, both from the diabetes care team and from the health system. As Gallagher discusses, the American Diabetes Association has brought attention to this aspect of the diabetes burden—and it is a burden—by endorsing a position statement on the providing high-quality psychosocial care that meets individual patient needs. Psychosocial care is not widely available and not accessed enough, in part because it is poorly reimbursed. Support for people living with diabetes must be ongoing through all of life's stages.

The Promise of Technology

Is there hope in better insulin pumps, improved continuous glucose monitors (CGMs), and the promise of an artificial pancreas? Of course, there is. Better tools and apps are wonderful, but they can also be overwhelming and burdensome, especially at first. As my colleague Lori Laffel, MD, MPH, shares in this issue, it is essential to manage expectations. Young adults may not always seek more information. Technology only helps if it is used (or if insurance companies pay). Clinical trials have shown us that CGMs are effective when used—but adherence in young people is often limited, and we need to understand why that happens.

THE AMERICAN DIABETES ASSOCIATION HAS ENDORSED A POSITION STATEMENT ON PROVIDING HIGH-QUALITY PSYCHOSOCIAL CARE THAT MEETS INDIVIDUAL PATIENT NEEDS.

Finally, there is the challenge of diabetes care for young people that can never come from an app, a gadget, or a pill. Learning to take responsibility for one's own care, to help parents let go, and to be the person asking questions at the doctor's appointment, is perhaps the most difficult part of learning to live with T1D. Evidence tells us this period is the time when young people with T1D have the worst glycemic control. Joslin and other health systems have programs for youth to help transition from pediatric to adult care, but these programs need to be more robust and ubiquitous. Our payment systems must support interaction on digital platforms—because this is what youth want.

For all the new tools that we have in diabetes care, the most important one for helping young people is the most basic: our ability to listen. ◆

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Diabetes Rates Rise Among US Youth, Especially Minorities

Christina Mattina and Mary Caffrey

ADDITIONAL RESOURCES

MD

Youth With Diabetes: Can Gaming Entertain, Educate, and Reward?

MORE AT: ajmc.com/link/1916.

RESULTS FROM THE FIRST DECADE OF a major study by the CDC and the National Institutes of Health (NIH) show diabetes incidence is rising rapidly among US youth, but especially among racial and ethnic minorities.

The findings from the Search for Diabetes in Youth Study (SEARCH), which began in 2000 and will continue until at least 2020,[1] were published in the *New England Journal of Medicine (NEJM)* in mid-April,[2] and were consistent with a claims study reported by FAIR Health earlier this year (see **Cover**).

The study is the first to analyze trends in new cases of both type 1 diabetes (T1D) and type 2 diabetes (T2D) among US youth younger than age 20 across 5 ethnic groups: non-Hispanic whites, non-Hispanic blacks, Hispanics, Asian Americans/Pacific Islanders, and Native Americans.

While the findings were not quite a surprise, the gap in disease incidence among ethnic groups, and the trends in the Hispanic population in particular, demand policy responses and increased levels of research, according to several experts who contacted *Evidence-Based Diabetes Management*™ (*EBDM*™).

The current findings report data from 2002-2003 to 2011-2012, and found the unadjusted incidence of T1D cases rose significantly by about 1.4% per year, but rates varied by demographic characteristics. For instance, new cases increased much more among boys than girls. After adjusting for age, sex, and race or ethnic group, the researchers found a 1.8% relative annual increase in T1D incidence. They also found that Hispanic youths had a significantly higher increase in new T1D cases per year (4.2%) compared with white youths (1.2%).

T1D is known to be caused by a combination of genetic and environmental factors, according to Jessica Dunne, MD, director of Discovery Research for JDRF. The rise in cases of T1D in ethnic groups beyond those Northern European countries associated with the disease suggests that the genetics could be changing, "or that there is a larger interplay of what those environmental factors may be," Dunne said in an interview with *EBDM*™.

When looking at unadjusted T2D incidence, the researchers observed a 7.1% increase in new cases each year among youths aged 10 to 19. After adjusting for demographics, they found white youths had a significantly lower increase in incidence compared with each of the other ethnic or racial groups. In other comparisons, Native Americans had a significantly higher average increase in incidence rates at 8.9% than Hispanics at 3.1%, but the CDC press release cautioned that the sample of Native American youths in this study was not representative of all Native American youths nationwide.

According to study authors, the findings, particularly those concerning T1D, indicate that racial and ethnic minorities are shouldering most of the burden of increasing youth diabetes rates. As such, the results "highlight the critical need to identify approaches to reduce disparities among racial and ethnic groups."[2]

SEARCH found that obesity had increased among Hispanic girls and black boys from 2003 to 2012, but had not increased for American youths overall. Along with further research on insulin resistance in children of different races and ethnicity, the researchers suggested that these disparities in risk factors like obesity might provide an opportunity to control the growing numbers of children developing diabetes, which the CDC described as a serious public health concern.

"Because of the early age of onset and longer diabetes duration, youth are at risk for developing diabetes related complications at a younger age. This profoundly lessens their quality of life, shortens their life expectancy, and increases health care costs," Giuseppina Imperatore, MD, PhD, epidemiologist in CDC's division of diabetes translation, National Center for Chronic Disease Prevention and Health Promotion, said in a statement.[3]

Ongoing efforts to clarify the drivers of diabetes rates include The Environmental Determinants of Diabetes in the Young (TEDDY) study[4] and the Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) study.[5] In addition to funding projects like TEDDY and TODAY that target the youth population, NIH is also conducting initiatives such as the Type 1 Diabetes TrialNet, which collects outcomes data and conducts research on preventing diabetes in Americans of all ages.[6]

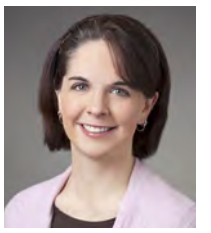
Dunne said diabetes researchers are waiting for the data from TEDDY to better understand what the viral triggers are that lead to the development of T1D. The overall rise of diabetes in the Hispanic and African American population suggests a complex mix of environmental factors are at work. "There hasn't been a single smoking gun, and I don't anticipate there will be," she said.

William T. Cefalu, MD, chief scientific and medical officer for the American Diabetes Association, said in an email that the SEARCH study and another study in the *NEJM* April 13, 2017, issue, "Mortality and cardiovascular disease in type 1 and type 2 diabetes,"[7] highlight both "the concerns about the increasing prevalence of diabetes, and the positive impact of research in managing the disease."

"Seeing the rate of diagnosis rise among youth should draw everyone's attention to this epidemic," he said. "At the same time, we've been able to improve the lives of millions of people who are living with diabetes around the world through research leading to fewer incidences of complications."

Ted Kyle, RPh, MBA, founder of ConscienHealth and an advocate for people living with obesity, said in an email that while the *NEJM* articles did not include assessments for body mass index, there was little doubt that the current, historically high levels of childhood obesity—especially severe obesity—"will contribute to further growth of type 2 diabetes for years to come. The best hope for blunting this trend is better utilization of evidence-based obesity care, such as the Diabetes Prevention Program."

Kyle called for health plans to make smarter use of both diabetes prevention and obesity care for at-risk populations. ◆



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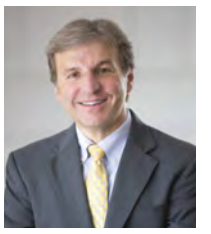

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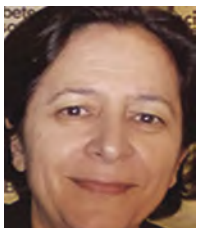

IMPERATORE

Jessica Dunne, MD, is director of discovery research for JDRF.

William T. Cefalu, MD, is the chief scientific and medical officer for the American Diabetes Association.

Ted Kyle, RPh, MBA, is the founder of ConscienHealth and an advocate for people living with obesity.

Giuseppina Imperatore, MD, PhD, is an epidemiologist in CDC's Division of Diabetes Translation.

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Mississippi Taking Steps to Reduce Childhood Obesity

Brice Wiggins, JD

WIGGINS

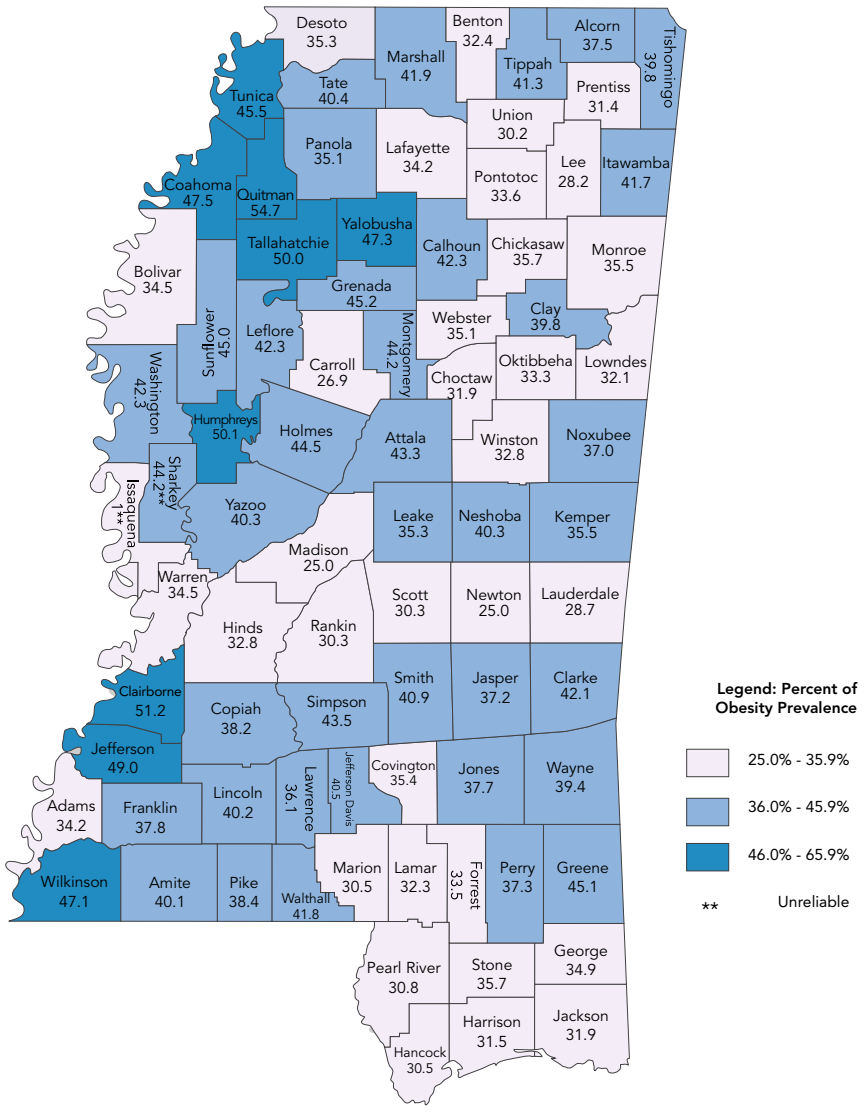
State Senator Brice Wiggins (R-Pascagoula) is the chairman of the Senate Medicaid Committee. He has been a state legislator since 2012.

MISSISSIPPI MAY LEAD THE NATION in prevalence of diabetes,[1] but several initiatives are moving us closer to the top in terms of fighting it among our youth and adults.

It is estimated that 41.8% of school-aged children and youth in Mississippi are overweight or obese.[2] The reasons for this are varied: household financial constraints that prohibit purchase of fresh fruit, vegetables, and proteins; lack of access to these items in rural areas; poor dietary habits; failure to take advantage of school breakfast and lunch programs; limited physical activity; and increased time in front of a television, tablet, or phone.

Thanks to a grant from the National Governors Association under the Healthy Kids, Healthy America Program, Mississippi conducted an extensive study and developed an action plan of implementable policies to curb the rate of obesity and diabetes in our children.[3] The program, Preventing Obesity with Every Resource (POWER), resulted in then-Governor Haley Barbour appointing a task force of 9 organizations and departments to guide these projects.[4]

FIGURE. Percent of Obesity Prevalence in Mississippi by County, 2011-2014 [2]



Thanks to the Child Nutrition and WIC (Women, Infants, and Children) Reauthorization Act of 2004,[5] each school was required to establish a Local School Wellness Policy. This led to adoption of stricter guidelines for what can be sold in school vending machines, adoption of improved nutrition standards, and new requirements for physical education and activities.

Through the Bower Foundation, schools were awarded Five Star Foods Grants to increase consumption of fruits and vegetables through the purchase of sectionizers and slicers, which made school lunch food more attractive to students. In addition, food service managers attended chef-led training sessions. Eighty schools from 25 school districts benefited from this program.[6]

The Bower Foundation Nutrition Integrity Grant[6] helped remove fryers from school kitchens and replace them with combination oven steamers. A total of 104 steamers were purchased in 41 school districts across the state.

The Committee to Move Grant provided 25 grants totaling $9400 to 21 schools to purchase physical education equipment and resources.[6] The Center for Mississippi Health Policy conducted an evaluation of these grant awards over 5 time periods from Spring 2008 to Spring 2010 to further study the relationship between fitness and academic performance. The Governor's Commission on Physical Fitness and Sports later gave recognitions of excellence to more than 260 schools.[7]

The TEAM Mississippi: A Partnership for Healthy Families was formed in conjunction with the University of Mississippi Medical Center. As reported in the journal *Obesity*, 450 children in grades 1 through 4 spent a year being educated on healthy eating habits; the results showed improvements in overall nutrition and weight and a statistically significant decrease in body fat over those who were not educated in health matters.[8] Finally, through the Health in Action initiative, teachers now have free access to an online database of 1300 health and physical education lesson plans.[9]

But many point to the passage, and funding, of the Mississippi Healthy Students Act of 2007, requiring schools to serve better and healthier meals, as a watershed moment in turning the tide on our obesity and diabetes epidemic.[10] This was further strengthened by:

- Restricting the advertising of unhealthy foods
- Increasing public service announcements for healthy foods
- Requiring state government food service to serve healthy foods
- Requiring Medicaid and private insurance to cover obesity treatments

As a result of all of these efforts, the Center for Mississippi Policy reported that rates of overweight and obesity among students in kindergarten through fifth grade fell from 43.6% to 37.3% from 2007 to 2011.[11] CDC data show our youngest children made early progress as well—obesity rates among 2- to 4-year-olds from low-income families dropped from 14.6% in 2008 to 13.9% in 2011.[12] More recent evidence in the *Journal of the Mississippi State Medical Association* found the combined share of overweight and obese students in kindergarten through 12th grade was 41.8% in 2013, compared with 43.9% in 2005.[13] (**Table**).

As chairman of the Mississippi Senate's Medicaid Committee, I am acutely aware of the financial need to continue to address this problem in our youth. Estimates show that Medicaid

TABLE. Overweight, Obesity in Mississippi Students[13]

2013	41.8%
2011	40.9%
2009	42.4%
2007	42.1%
2005	43.9%

Data show combined prevalence for grades K-12.

spending would be 11.8% lower in the absence of childhood obesity. And in a time where Medicaid overages are prevalent and state budget dollars are limited, we must remain diligent on this matter.[3]

In 2016, Mississippi announced a partnership with the Cleveland Clinic's Endocrinology & Metabolism Institute to build a state-of-the-art research facility to address the rise in diabetes and obesity in our state (**Figure**). By bringing private sector dollars to the table, along with state funds, the National Diabetes and Obesity Research Institute (NDORI) will develop the necessary infrastructure to offer clinical research, trials, disease-based registries, and treatment-based algorithms. A 300-acre medical campus is being developed in South Mississippi around NDORI with local and regional healthcare providers, leading medical educational institutions, and state and federal agencies sharing research and training tools to help fight this epidemic and educate future healthcare providers.[14]

But we are not stopping there. Mississippi currently leads the nation in telemedicine and is 1 of only 7 states to receive an "A" rating from the American Telemedicine Association.[15]

In 2015, Mississippi began one of the most aggressive research programs in the nation in the heart of the Delta through Intel-GE Care Innovations, the University of Mississippi Medical Center, and CSpire. The program treated 200 patients in the region with the most severe form of diabetes. Early results show not a single hospital readmission due to the disease and more than 10,000 miles of patient travel saved.[16,17]

In 2017, Governor Phil Bryant signed into law the Health Care Collaborative Act,[17] which will provide new opportunities for the University of Mississippi Medical Center to partner with rural hospitals to further expand medical services. Furthermore, the University of Mississippi Medical Center has formed partnerships to teach diabetes- and obesity-related curriculum in churches, doctors' offices, and civic clubs throughout the state. The state now has more than 500 trained individuals who can serve as screeners for diabetes and hypertension.

However, the realities of funding Medicaid remain top of mind. The continued expansion of Medicaid, especially to able-bodied adults, has left many states, like ours, fearful of the larger share of healthcare costs that we may have to bear.

By the Mississippi Division of Medicaid's own numbers, for the last 18 months, the number of Medicaid enrollees has gone down, yet the request for state dollars has continued to climb with this year's request totaling over $1 billion.[18] Managed care of Medicaid was implemented in 2014 to address these rising costs. During our 2017 legislative session, I called for the commissioning of a joint study to determine if the managed care organizations are performing as we hoped, what the savings have been if any, and what changes still need to be made. The services we provide are extensive, and necessary, to treat those who cannot help themselves and provide a safety net for our least fortunate. We need to look at whether those services are providing a return on investment by improving the health and well-being of the patients served and changing Mississippi's poor health behavior for the long term.

While there is hopeful talk that Congress will swiftly address Obamacare (the Affordable Care Act), I have found waiting on Congress to act is a losing proposition. The states have traditionally been the "laboratories of democracy," where grassroots efforts can effect change. For these reasons, I thank my fellow legislators for starting the important work of determining how to responsibly take care of our Medicaid population without breaking the bank, and proactively addressing the diabetes and obesity epidemic in our state. ◆

AUTHOR INFORMATION: State Senator Brice Wiggins, JD, is the chairman of the Mississippi Senate Medicaid Committee. A Republican from Pascagoula, Senator Wiggins has served in the Legislature since 2012.

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ADDITIONAL RESOURCES

AJMC THE AMERICAN JOURNAL OF MANAGED CARE

How Enhanced Primary Care Affected Diabetes Outcomes:

MORE AT: ajmc.com/link/1918.

Researchers Turn Attention to "Power" of Diabetes Camps

Mary Caffrey

WEISSBERG-BENCHELL

Jill A. Weissberg-Benchell, PhD, CDE, is a professor of psychiatry and behavioral sciences in the Feinberg School of Medicine at Northwestern University.

THREE YEARS AFTER the discovery of insulin, the first camp for children with diabetes opened in 1925, with the same goals that exist today: to give children with type 1 diabetes (T1D) a summer camp experience in a medically safe environment, where they can take important steps toward self-care and form bonds with other children like themselves.[1]

The Diabetes Education and Camping Association (DECA) reports that 20,000 children take part in camps in North America each summer[2]; while most have T1D, a growing number have type 2 diabetes (T2D), and DECA Executive Director Terry Ackley told *Evidence-Based Diabetes Management*™ (*EBDM*™) in an interview, "There are conversations about how to best serve these children and their families."

From the start, camp served as a place where children could learn to manage their diabetes, but for decades, research on the effectiveness of camp was sporadic, ranging from surveys, to reports, to more formal studies. The oldest abstracts listed on PubMed date to the 1950s, and research picked up in the 1980s and early 1990s.

In 2015, the American Diabetes Association (ADA) reported results from a 3-year study that found a 10% increase in campers confident to manage their diabetes, with the largest increase (19%) among those newly diagnosed. The ADA study also found:

- A 7% decrease in diabetes-related anger and a 6% decrease in diabetes-related sadness
- An 11% increase of overall knowledge of proper diabetes management
- A 9% increase in the number of children who knew how to figure the correct insulin dose.[3]

Jill A. Weissberg-Benchell, PhD, CDE, professor of psychiatry and behavioral sciences at Northwestern University, and her co-authors offered a review of recent studies in a 2016 paper, Camp for Youth With Type 1 Diabetes.[5] While the paper cited several studies that found increased diabetes knowledge in the months right after camp, the authors saw a great need for more research on the psychosocial aspects of camp, especially the long-term benefits.

"We know that the social support, the sense of not being alone, the shared experiences are very powerful," Weissberg-Benchell said in an interview with *EBDM*™. When a child with T1D finally has sense that there are others that "get you," it makes a difference, she said.

The 2016 paper called for longitudinal studies that compare quality of life, self-care, and family functioning among one-time and repeat campers.[4] Separately, Weissberg-Benchell led a study published in early 2017 that surveyed parents and campers to assess how camp attendance affected diabetes-specific emotional distress, diabetes-specific quality of life, and self-care behavior.[5] While the youth reported higher levels of self-care than their parents did, both parents and children agreed on a major benefit: camp is a place "where youth feel they are with others who really understand what it is like to live with diabetes."

This is not to be underestimated, said DECA's Ackley, who said Weissberg-Benchell's work is needed and welcomed. One of the greatest benefits of camp for children with diabetes, Ackley said, are the friendships that develop. Thanks to social media, children have an easier time staying in touch. "They don't feel isolated," he said. "The lifelong friendships that develop—really, it changes lives."

"One of the primary benefits is that children become capable of being more independent in their diabetes care," There are many "firsts" at diabetes camp—the first time a child injects himself with insulin, the first time changing the site of an insulin pump, the first time eating a new food. "There's formal and informal learning that takes place," he said.

Camps Contribute to Science

The surveys of parents and youth campers found that both saw exposure to new technology as a benefit of camp.[6] The 2016 paper had highlighted the enormous contribution that camps have made to clinical trials—they have served as the perfect laboratory for studying many of the modern technologies on the market today.[5] Camp studies have contributed to the development of continuous glucose monitoring (CGM) systems, to technology that allows remote monitoring of CGM, and to the "artificial pancreas" so eagerly awaited by those with T1D.[6-9]

Weissberg-Benchell also led a study that examined the psychosocial impact of this emerging technology on the children taking part in the clinical trial.[10] She and her co-authors found that children using the automated insulin delivery device in the trial reported "significant reductions" in hypoglycemic fear and regimen burden, but "expressed annoyance about carrying around the necessary equipment."

Few Minority Families Respond

While Ackley reports that children from low-income families are well-represented at camp, thanks to fund-raising and scholarships, Weissberg-Benchell said getting low-income minority families to respond to surveys for research purposes has been difficult. This was acknowledged as a limitation in her recent study, and she said despite redoubling efforts the following summer, the researchers still had very few responses from minority parents.

There are many reasons for this, from lack of internet access to the fact that the families do not know the researchers personally. "It's a moral and ethical issue," Weissberg-Benchell said, and one that researchers will keep working to address. "These are families whose voices are not as well heard," she said. ◆

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RESEARCH REPORT

Type 2 Diabetes: Changing the Paradigm From Management to Reversal

Sarah Hallberg, DO, MS

TYPE 2 DIABETES (T2D) has long been viewed as a chronic condition that can be managed but is inevitably progressive.[1] While clinicians may be increasingly more aware that T2D can be reversed, most think that is only possible through drastic means like bariatric surgery. With the recent findings from our ongoing clinical trial, which add to the existing literature, medicine may be on the cusp of a major paradigm shift for the treatment of T2D: from management to reversal without the use of surgery.

The published results highlight the first 70 days of an ongoing 2-year clinical trial collaboration between Virta Health and Indiana University Health in which 262 patients with T2D were enrolled in the Virta Clinic.[2] The clinic combines online education for behavior change, biometric feedback, peer support, and an individualized nutritional approach that promotes nutritional ketosis. After 70 days and greater than 90% retention of participants, mean weight loss was 7.2% and the mean glycated hemoglobin (A1C) reduction was 1%, with 56% of patients achieving an A1C below 6.5%.

It is extremely important to note that this reduction in A1C was achieved while medications were reduced. At baseline, 89% of the patients were taking one or more diabetes medications, and at 70 days 58% of patients had either reduced or eliminated their medications. This is unlike treatment strategies aimed to lower A1C in the past. For example, in the ACCORD trial,[3,] where A1C levels were lowered with aggressive medication use, the most aggressively treated patients had worse outcomes. Specifically, the intensive glycemic control group who were prescribed more medications, which often included insulin with multiple oral agents, had significantly more weight gain, more episodes of severe hypoglycemia, and greater mortality than the standard group.

Many were led to conclude from the ACCORD trial that strictly lowering glucose could be detrimental. However, it may be that how glucose is lowered is a critical consideration. In the Virta 70-day trial, there were no serious adverse events and no episodes of serious symptomatic hypoglycemic events requiring medical intervention.

The concept of reversing T2D by nonsurgical means is relatively new, but is gaining attention in both the scientific literature and popular press.[4,5] So, what does reversal of T2D mean? It means that patients who previously were on medications to control elevated blood glucose now maintain blood glucose below the diabetes threshold despite reducing or eliminating the need for hypoglycemic medications. This is exactly the opposite of what was thought to be the inescapable progression of a disease that puts patients at high risk for so many complications, including cardiovascular disease, blindness, renal failure, and amputations.

A major reason that the concept of management to slow progression of T2D has prevailed for so long is the standard nutritional recommendations, which focus dietary macronutrient intake on carbohydrate. Basic physiology dictates that carbohydrate ingestion causes blood glucose to rise, particularly in the face of the insulin resistance that underlies T2D. In fact, the most recent edition of Nutrition Therapy Recommendations for the Management of Adults With Diabetes[6] from the American Diabetes Association states that "total amount of carbohydrate eaten is the primary predictor of glycemic response." This makes basic science sense, and the practical response would be to decrease dietary carbohydrates if the goal is to decrease blood glucose. This approach has been shown to be effective in improving glycemic control while reducing or eliminating medications in prior smaller studies.[7-9]

In addition to adjusting dietary carbohydrate to each patient's level of insulin resistance, patients need individualized support and medical management. The Virta Clinic specializes in being able to provide the personalized treatment needed on a personalized schedule. While barriers exist to convenient and accessible care in a brick-and-mortar clinic, the Virta Clinic overcomes these by providing a full medical specialty clinic online. Each patient receives a health coach who guides patients through appropriate nutrition changes while considering lifestyle, cultural, and financial barriers. Specialty-trained physician supervision for each patient ensures that medications are decreased safely and efficiently.

Ultimately, our current trial will add to the compelling evidence that:

1. Diabetes can be reversed while reducing medication and without risk, cost, or side effects of bariatric surgery and
2. Reversal can happen in a large percentage of patients, not only in outliers.

At the very least, our results beg the question: has the medical profession been approaching the dietary management in T2D all wrong? I firmly believe the dialogue must change educate patients that reversal is possible. By not doing so, we are complicit in the continued staggering rise of this disease.

With the increasing cost of healthcare, we must look for solutions. In doing so, we must be willing to acknowledge that there have been past shortcomings in both dietary recommendations and treatment goals. Our patients deserve the opportunity to gain control of their health. They want more than just another prescription or procedure. To help them, we need to change the dialogue. We need to talk about reversal and provide the knowledge and support to achieve it. ◆

HALLBERG

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PEER EXCHANGE™

Nearly Two Years Later, Unpacking Details From Empagliflozin Results

Mary Caffrey

SCANLON

INZUCCHI

BLOOMGARDEN

GABBAY

SNOW

Dennis P. Scanlon, PhD, is professor of health policy and administration and director for the Center for Health Care Policy and Research in the College of Health and Human Development at Pennsylvania State University.

Silvio Inzucchi, MD, is medical director for Yale Diabetes Center.

Zachary Bloomgarden, MD, is clinical professor in the Division of Endocrinology, Diabetes, and Bone Disease of the Department of Medicine at Mount Sinai, New York.

Robert A. Gabbay, MD, PhD, FACP, is senior vice president and chief medical officer, Joslin Diabetes Center, Boston.

Kenneth Snow, MD, MBA, is a medical director for Aetna.

On April 6, 2017, The American Journal of Managed Care® *convened its Diabetes Stakeholders Summit, which featured 3 Peer Exchange™ panel discussions. An excerpt from the discussion, "Diabetes Therapy and Cardiovascular Outcomes: An Update," appears below.*

IN SEPTEMBER 2015, results from the EMPA-REG OUTCOME trial stunned the medical world: for the first time in diabetes care, a treatment for type 2 diabetes, empagliflozin, was found to have cardiovascular benefits.[1] The good news about the sodium glucose co-transporter-2 (SGLT2) inhibitor did not end there, however. Researchers have continued to pore over data, finding evidence of additional benefits.

The results were the focus point of conversation in April at *The American Journal of Managed Care®*'s second Diabetes Stakeholder Summit. The Peer Exchange™ panel discussion, Diabetes Therapy and Cardiovascular Outcomes: An Update, was led by moderator Dennis P. Scanlon, PhD, professor of health policy and administration and director for the Center for Health Care Policy and Research in the College of Health and Human Development at Pennsylvania State University. Joining him were Silvio Inzucchi, MD, medical director for Yale Diabetes Center and the lead investigator for the EMPA-REG OUTCOME trial; Zachary Bloomgarden, MD, clinical professor in the Division of Endocrinology, Diabetes, and Bone Disease of the Department of Medicine at Mount Sinai, New York; Robert A. Gabbay, MD, PhD, FACP, senior vice president and chief medical officer, Joslin Diabetes Center, Boston; and Kenneth Snow, MD, MBA, a medical director for Aetna.

Inzucchi explained that for years, diabetes providers had been frustrated by the fact that correcting a fundamental feature of the disease—hyperglycemia—had little or no effect on cardiovascular outcomes. "We can reduce retinopathy, and nephropathy, and probably neuropathy," he said. "But when you look at studies over many decades, it's been very difficult to demonstrate that lowering glucose with a specific strategy or any drug actually benefits the heart."

EMPA-REG OUTCOME didn't set out to find a cardiovascular benefit. The trial's purpose was to show that empagliflozin was safe, after events in the mid-2000s caused FDA to seek proof diabetes and obesity therapies were safe for those at high risk of heart attacks or stroke.

Inzucchi made an important distinction about what the trial did and did not find. "I think what EMPA-REG OUCOME showed us is that you can improve cardiovascular outcomes, perhaps not through lowering glucose, but through using a glucose-lowering therapy," he said. This was the first time a drug was shown to have an effect on cardiovascular mortality, and it was associated with a 38% reduction.

"I must say, when I saw these results—and I was on the steering committee for the trial—I almost fell out of my chair," Inzucchi shared with the panel. He was struck that a diabetes therapy that was effective, but not hugely powerful, in lowering blood glucose, could bring such a result on reducing cardiovascular death.

As much as researchers are still gleaning from EMPA-REG OUTCOME—and still learning about SGLT2 inhibitors—the trial is a breakthrough and changes the thinking about treating diabetes in many ways, Gabbay said.

Snow agreed. "Certainly, one of the major driving forces for why we treat diabetes to begin with, and why payers pay for the treatment of diabetes is not so much because we want to see lower blood sugar, but because we want folks to live longer, healthier lives," he said. "And ultimately, these types of outcomes trials, particularly if we are seeing reductions in major cardiovascular events, are exciting."

What Do We Know About SGLT2 Inhibitors?

The SGLT2 inhibitor drug class has a completely different mechanism from other anti-diabetic therapies, in that it targets a protein that normally reabsorbs glucose in the kidney, and instead blocks this function and causes excess glucose to be expelled in the urine. Scanlon asked Gabbay what researchers have learned about the mechanism of action of SGLT2 inhibitors that explains the results found in EMPA-REG OUTCOME.

"It's a great question," Gabbay said, adding that the results surprised many. There's been a lot of "thinking backward," to truly understand how SGLT2 inhibitors work, and therefore, how they achieve what they do.

"What we do know about SGLT2 inhibitors is that they result in a little bit of dieresis and volume contraction, and that, certainly, could be one of the factors (particularly in terms of congestive heart failure incidences and hospitalizations for congestive heart failure), for which they saw a benefit. There's also a small amount of weight loss, which could also be a factor."

As Gabbay explained, regression models using data from the EMPA-REG OUTCOME trial estimated that about half the effects could be related to volume. Another correlation that merits further study involves uric acid levels.

"There's another finding of the empagliflozin trial, which is fascinating and may shed light on this—the effect on renal disease," said Bloomgarden. EMPA-REG OUTCOME showed that empagliflozin was not simply a diuretic, but also acted on sodium secretion; it worked in the kidney "in a lovely way with angiotensin blocking agents," Bloomgarden said.

"So, at the level of the macula densa, delivering more sodium to that part of the kidney seems to then potentiate the benefit of not having so much angiotensin action on board," he said. "Well, this fits very nicely into a lot of our clinical knowledge of what's good for heart failure and our theoretical ideas of what's good for the heart and what's good for the kidneys."

A New Indication

Scanlon asked about a recent decision by the FDA to add a new indication to empagliflozin to reduce cardiovascular death in patients with type 2 diabetes.[2] What are the clinical decision-making implications?

Payers face challenges, Snow said, in deciding if the effect is just for empagliflozin or a class effect for all SGLT2 inhibitors (at press time, other trial results were pending). "Is it in all patients, or only those with preexisting heart disease?" he asked. "These are research questions that are still in the process of being answered, and somehow, in the process there needs to be a decision on coverage."

"At the very least, there are now data out there about the population of folks who clearly got a benefit with a particular agent," Snow said. "And now, really the question is, is it unique and is it unique to that population?" ◆

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Report: Secret Apple Team Creating Glucose Sensors That Don't Pierce the Skin

A WIDELY CITED REPORT[1] states that Apple has assembled a confidential team to create something that has eluded the biomedical field thus far: a blood glucose sensor that doesn't pierce the skin.

This step would be a game-changer for people with type 1 diabetes, as well those whose type 2 disease has reached a stage where continuous glucose monitoring (CGM) is recommended. Those who use sensors must change them regularly, which adds to the cost of living with diabetes. Failure to do so could cause the CGM to be inaccurate or lead to scar tissue, due to the skin puncture.

The report, which appeared April 12, 2017, on CNBC, said the project was the vision of the late Apple CEO and co-founder Steve Jobs. CNBC claims that the designers and engineers have reached a point where Apple is pursuing feasibility trials and hiring people to help the company navigate the FDA's regulatory process.

Other companies have tried and failed to create a needle-free sensor, and some are still trying. Aspire Ventures, through its Tempo Health subsidiary, is working on a microfluid biosensor that would monitor blood glucose levels in sweat, its chief product officer told *The American Journal of Managed Care*® in a recent interview.[2]

Google's Verily team is developing a contact lens that could measure blood glucose levels via the eye.[3] Also, there have been a string of new partnerships between traditional consumer technology companies and medical device makers to improve the reliability, design, and user experience of diabetes technology.

For a company like Apple to offer such a product would instantly disrupt the market, however, given its size and marketing reach. The CNBC story said that such a leap would convert the Apple Watch from a "nice-to-have" to a "must-have" for people with diabetes.[1]

The timing of the news came almost exactly 10 years after Amy Tenderich, founder of the website Diabetes Mine, penned the essay, An Open Letter to Steve Jobs." Tenderich called on the Apple CEO to bring the same level of innovation and creative design to diabetes devices that he had brought to the iPod, as iPod sales reached the 100-million mark.[4] Tenderich's piece went viral and sparked discussion about the lack of user-friendly choices for people living with diabetes.

If the CNBC report is correct, Jobs listened. CNBC reported that about 30 people are working on the project, and it cites Apple's onboarding of experts from Medtronic, C8 Medisensors, Sano, and other companies. According to the report, Apple did not respond to requests for comment.[1] ◆

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JDRF-Funded Study Finds Target to Control Immune Response to Implanted Medical Devices

A RECENT STUDY IN *Nature Materials* sheds light on how the body reacts to implanted biomedical devices, and this could lead to advances in the equipment that people with diabetes use to manage their disease.[1]

People with diabetes, especially those with type 1 disease (T1D), use insulin pumps that feature infusion sets and continuous glucose monitors that work with sensors, which are inserted in the body. Parts of these systems that penetrate the skin must be replaced once the body's immune response creates what is called a fibrotic cascade, causing a reaction against the device that no longer allows the insertion point to be "read" correctly. After a certain number of days, the device can no longer deliver insulin or read blood glucose.

The cost of replacing sensors and infusion sets affects both people living with diabetes as well as payers. After a time, scarring from past infusion sites can make finding new ones a challenge. Immune response to biomedical material is not only an issue for current devices—it's also a challenge for researchers designing cell encapsulation devices that would allow insulin to be delivered in a "pill."

The study, funded by the JDRF and the Leona M and Harry B. Helmsley Charitable Trust, identified colony stimulating factor-1 receptor (CSF1R), which increased significantly when biomedical materials were implanted in rodents and nonhuman primates, indicating a strong immune response. Researchers tested materials such as ceramic, polymer, and hydrogel.

"FOR PEOPLE LIVING WITH TYPE 1 DIABETES, THESE ADVANCES COULD HELP IMPROVE INSULIN PUMP INFUSION SETS, CONTINUOUS GLUCOSE MONITORS AND ENCAPSULATION THERAPIES."

—Aaron Kowalski, PhD

By contrast, inhibiting CSF1R improves the body's receptiveness to biomedical material, reducing the scarring, known as fibrosis, without limiting healing. "Our results indicate that targeting CSF1R may allow for a more selective method of fibrosis inhibition, and improve biomedical biocompatibility without the need for broad immunosuppression," the authors wrote.[1]

JDRF Chief Mission Officer Aaron Kowalski, PhD, heralded the findings in a statement.

"For people with type 1 diabetes, these advances could help improve insulin pump infusion sets, continuous glucose monitors and encapsulation therapies," he said. "By understanding how to target and prevent unnecessary immune responses to the materials used in medical devices, we can provide therapies that work more effectively and with fewer negative side effects. That would be an incredible step forward in JDRF's mission to cure, prevent, and treat T1D."[2] ◆

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Strong Link Between Obesity, High Blood Pressure for Hispanic Teens

RISING RATES OF OBESITY among teens are a problem across ethnic groups in the United States, but for Hispanic teens, the connection to high blood pressure is especially severe, according to research from McGovern Medical School at the University of Texas Health Science Center at Houston.

The findings, published in the journal *Pediatrics*,[1] don't explain why Hispanic teens who are obese are far more likely to have high blood pressure than teens who are white, African-American, or Asian. Increasing body mass index (BMI) was associated with increased risk of high blood pressure among obese teens across all major ethnic groups:

- Hispanic teens were 6 times more likely to have high blood pressure if they were obese, compared with normal-weight teens.
- Among white teens, the rate was 4 times higher.
- Among Asian teens, the rate was 3 times higher.
- Among African-American teens, the rate was twice as high.

The stronger connection between BMI and high blood pressure among Hispanic teens is worrisome, as it puts them at higher risk for diabetes. According to the CDC, 50% of Hispanics are likely to develop type 2 diabetes over their lifetimes, compared with 40% of all US adults.[2] This puts Hispanics at higher risk for complications such as kidney failure and retinopathy. According to the National Kidney Foundation, Hispanics are 66% more likely to be diagnosed with chronic kidney disease than white Americans.[3]

Given those statistics, identifying which teens are most at risk is important to help them prevent progressing to having diabetes and cardiovascular disease. "We believe we are the first to compare adolescent blood pressure to body mass index in these 4 major ethnic/racial groups," lead author Joshua Samuels, MD, MPH, said in a statement.[4] Samuels is a pediatric nephrologist and a professor in the Department of Pediatrics at the medical school.

"WE BELIEVE WE ARE THE FIRST TO COMPARE ADOLESCENT BLOOD PRESSURE TO BODY MASS INDEX IN THESE 4 MAJOR ETHNIC/RACIAL GROUPS."

—Joshua Samuels, MD, MPH

Findings came from an analysis of 21,062 adolescents taking part in a high school blood pressure screening program that McGovern Medical School operates. Testing took place at 27 schools in the Houston area between 2000 and 2015.

The contrast between Hispanic teens who were obese and those of normal weight was notable. "The prevalence of high blood pressure among Hispanic adolescents rises sharply with weight gain," Samuels said. "Normal-weight Hispanic adolescents had the lowest level of high blood pressure among the four groups, but obese Hispanic adolescents had the highest."

For study purposes, high blood pressure was defined as being in the 95th percentile or higher for 3 consecutive screenings. Those in the 85th to 94th percentile of BMI were designated as overweight, while those at the 95th percentile or higher were categorized as obese. ◆

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Young Children Gain Glycemic Control in Artificial Pancreas Study

A SMALL STUDY OF elementary school-age children with type 1 diabetes (T1D) has shown that an artificial pancreas system can offer better control of blood glucose levels with fewer cases of hypoglycemia.

The study from researchers at the University of Virginia—among the world's leading sites for research on this technology—found that a dozen children aged 5 to 8 years spent more time in range when using the system, which connects an insulin pump and continuous glucose monitor through an algorithm to automatically dispense the right amount of insulin.[1]

YOUNG CHILDREN WITH TYPE 1 DIABETES REACHING SCHOOL AGE ARE IN PARTICULAR NEED OF MORE RELIABLE DIABETES MANAGEMENT TECHNOLOGY.

Results were presented by Mark DeBoer, MD, MSc, MCR, an associate professor at the University of Virginia School of Medicine in Charlottesville, at the recent meeting of the Endocrine Society in Orlando, Florida. In the study, children using the artificial pancreas technology kept their blood glucose in range 73% of the time, compared with 47% with usual home care. The target range for blood glucose was 70 to 180 mg/dL.

The children also cut the amount of time with high blood glucose levels in half. Those using the technology were above 180 mg/dL only 25.8% of the time, compared with 51.5% for those with usual care.

"Up until now, parents and doctors have had to decide how much insulin to give young children throughout the day to avoid dangerously low or high blood sugars," DeBoer said in a statement.[2]

Earlier work has shown that artificial pancreas systems are safe and effective for adults and teenagers with T1D. The first FDA-approved system, the Medtronic's MiniMed 670G, will start shipping to priority access customers in June 2017.[3]

While the study was small, DeBoer said it shows promise for the technology's use in young children. "In the future, this type of technology is likely to become the standard of care for type 1 diabetes control for children in this age range," he noted.

Young children reaching school-age are in particular need of more reliable diabetes management technology, as many school systems create barriers to these children to participate in sports or school functions that involve food, despite laws against these practices.[4] Many elementary schools no longer have a school nurse, and there have been several civil rights cases in recent years against districts that try to pull children from their neighborhood school to one with a nurse.

A study in *Diabetes Care* last year asked parents about their acceptance of an artificial pancreas system after their young children took part in a trial for a new device at summer camp. The study found that 70.5% of the parents found the technology easy to use and 67% felt it was useful in improving glucose control. Almost all (94%) intended to use the artificial pancreas technology long term.[5] ◆

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The Canadian study found a pet's presence favorably affects a developing infant's gut bacteria.

Pets During Pregnancy Trigger Gut Bacteria Changes for Infants That May Cut Obesity Risk, Study Finds

IS HAVING A PET AT HOME WITH a pregnant mother-to-be a good thing? Results of a study done by Canadian researchers showed that a furry pet's presence favorably affects a developing infant's gut bacteria, and it could help the child ward off potential allergies and obesity.

The study, funded by the Canadian Microbiome Initiative, was part of a larger analysis, the Canadian Healthy Infant Longitudinal Development Study (CHILD). Researchers looked at 746 infants taking part in CHILD whose mothers were pregnant with them between 2009 and 2012. The study was published in the journal *Microbiome*.

The mothers were asked whether the family had a pet at home during the second and third trimesters; if so, what kind; and whether the pet remained in the home for 3 months after the baby was born. Fecal samples were collected from the infants to profile their gut bacteria through rRNA sequencing. Most of the pet owners had dogs; second most popular were cats.

More than half the infants were exposed to at least 1 furry pet during either the mother's pregnancy or after birth. Of the study group, 8% were exposed during pregnancy only and 46.8% were exposed before and after birth.

Being exposed to furry pets increased the likelihood that infants would have high levels of 2 key bacteria, *oscillospira* and *ruminococcus*. The results of other studies have associated *oscillospira* with reduced risk of obesity, while *ruminococcus* has been linked to reduced risk of having allergies. In addition, the CHILD study's authors found that pet ownership during pregnancy was associated with a lower risk of streptococcal colonization, which the authors say may reduce the risk for childhood metabolic disease and atopic disease.

The benefits of pet ownership are many, the authors wrote, and the question of having a pet is "a common one for pregnant women."

More research is needed, they noted, to definitively link gut bacteria changes to the presence of a pet, and to further link exposure to furry pets while *in utero* or in infancy to long-term positive changes in health outcomes. ◆

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Pilot Diabetes Prevention Study Shows A1C Drops in At-Risk Youth

A PILOT PROJECT THAT tested a lifestyle modification program on 33 poor, mostly Hispanic youth successfully helped nearly half of them bring their glycated hemoglobin (A1C) under control, according to a report in *Diabetes Care*.[1]

The small study was led by researchers at the University of Tennessee in Memphis, a city with one of the nation's highest rates of childhood obesity.[2] The pilot tested a program called Insulin Superheroes Club, a modified version of the Diabetes Prevention Program (DPP) designed for children from culturally diverse, minority backgrounds. CDC data show that children who are overweight are at increased risk of developing obesity and diabetes as adults, and poor children are at increased risk for both.[3] The mean age of the children in the pilot was 10.8 years.

THE CHILDREN TOOK PART IN A MODIFIED VERSION OF THE DIABETES PREVENTION PROGRAM, WHICH WAS CREATED FOR YOUTH FROM DIVERSE MINORITY BACKGROUNDS AT HIGH RISK OF DIABETES AND OBESITY.

The program's design captured children who had a parent with impaired glucose tolerance who was simultaneously enrolled in the DPP; the Superheroes Club has a similar yearlong design to the CDC-recognized program for adults: an initial phase of 16 weekly classes, then 3 biweekly classes, followed by 6 monthly classes.[1]

The youth participants had 60 minutes of physical activity and 30 minutes of education, which included lessons in nutrition, physiology, mindfulness, exercise, and stress reduction. Children took hands-on cooking classes and engaged in role play, while also learning specific exercises, playing basketball, or taking part in dance or yoga.

All 33 youth who started the pilot had low socioeconomic status, including 76% receiving government food assistance. They were 59% female and 88% Hispanic, and they came from 16 households, so most had a sibling in the program in addition to having a parent enrolled in the DPP. More than half the group were at least overweight, meaning they had a body mass index (BMI) of at least 25 kg/m^2; 24% were overweight (BMI 25 to < 30 kg/m^2) while 39% were obese (BMI 30 30 kg/m^2 or higher). Five youth were lost to follow-up, but their baseline A1C was similar to the rest of the group.

From baseline to the 16-week mark, A1C for the remaining youth improved significantly; the percent with an A1C 5.7% or higher dropped from 61% to 15%. Measures of BMI, body fat, diastolic blood pressure, a right-hand grip test, and a 6-minute walk test all improved to a lesser degree. Results at the 12-month mark will be reported later.

"The beneficial outcomes suggest that a family-based program that involves lifestyle education, behavior modification, and goal-driven exercise can be effective in a predominantly Latino population," the authors wrote. ◆

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Digital Health Provider Noom Wins Full CDC Recognition for Mobile, Online Applications

NOOM INC, A NEW YORK CITY–BASED digital behavioral health company, announced on April 12, 2017, that it had received full CDC recognition for its mobile and online applications of the Diabetes Prevention Program (DPP), becoming the first virtual provider to achieve this status.[1]

Artem Petakov, Noom's president and co-founder, said the confirmation came directly from the CDC via email. This step comes 4 years after Noom created the program and 2 years after the CDC began accepting applications for recognition from digital providers.[2]

"We know that the program is above the requirements," Petakov said in an interview with *Evidence-Based Diabetes Management*™. The CDC requires that 40% of participants lose 5% of their weight, and Noom demonstrated that 51% achieved 5% weight loss, he said. "It's been a big team effort."

DPP is a year-long, evidence-based lifestyle management intervention for people who meet clinical criteria of prediabetes. The program has been shown to reduce the chances of progressing to type 2 diabetes (T2D) by 58%,[3] and a pilot program offered through the YMCA under the Center for Medicare & Medicaid Innovation (CMMI) showed a savings of $2650 per Medicare beneficiary over 15 months. That prompted Medicare to fund the program starting in January 2018.[4]

HAVING FULL CDC RECOGNITION IS KEY, BECAUSE MEDICARE'S FIRST ROUND OF RULES REQUIRES PROGRAMS TO HAVE THIS STATUS TO RECEIVE REIMBURSEMENT WHEN IT STARTS PAYING FOR THE DIABETES PREVENTION PROGRAM NEXT YEAR.

Until now, only programs that offered face-to-face instruction had achieved full recognition, a lengthy process that requires following an approved curriculum and submitting 2 years of data on patients' participation and weight loss. Online programs offer the potential to scale the DPP to the estimated 86 million Americans with prediabetes.[5] Right now, 175 programs listed on the CDC website have partial recognition, which means they are working toward full recognition.[1]

More and more, these providers are publishing studies in academic journals to gain acceptance from payers as a way to prevent chronic disease or slow its march, in an effort to keep diabetes, obesity, and cardiovascular disease from consuming ever-larger portions of the healthcare dollar. Already, diabetes accounts for $1 of every $3 spent in Medicare.[6]

Noom's philosophy, "Changing your body by changing your brain," offers customers a digital health coach and a customized program that aims to reveal—and change—the behaviors that lead to unhealthy eating. The program seeks to change eating habits for the long haul, and for its business clients, it offers outcomes-based pricing.[7]

Having full CDC recognition is key, because Medicare's first round of rules requires programs to have this status to receive reimbursement when it starts paying for DPP next year. The next round of rules, which is expected to cover specifics for digital providers, is set to come out in June. Digital providers are core members of the Council for Diabetes Prevention, which has organized to ensure DPP access and program quality.[8]

While the implications for Medicare reimbursement are important, Petakov said gaining full recognition from the CDC is also key for demonstrating the program's value to payers, large employers, and individual consumers who are driving the company's growth. "It's really a myth that consumers will not pay for their own care," he said. "They will pay if the product is right, if it is presented not in medical terms but in layman's terms."

Noom employees practice what they teach with healthy lunches created by an in-house chef.

Consumers, for example, are asking when the Medicare program will be available, and some are asking their doctors about it and whether their health plans cover it, Petakov said.

While Noom boasts that it has served 45 million clients, Petakov said in the interview that the current focus is on the 3 billion data points it has gathered, which are allowing the company to continually refine its behavioral-driven programs, tailoring directives and reading material to users based on feedback. Petakov said Noom is not only developing data that correlate certain materials with success in certain groups, but that it's reaching the point of developing causal data.

"That's been keeping us busy," he said. "There are a lot of ways to mine the data and shape the program."

Petakov said Noom appeals to consumers who have tried and failed to lose weight on other diets or through medication. "Customers are smart," he said. "A lot of these people have tried the pills or the unsustainable solutions, the crash diets—they've tried everything in the book and it hasn't worked. They're coming to this with full awareness looking for something different." ◆

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Regular Bedtimes for Toddlers Linked to Less Obesity Later, Study Finds

KEEPING YOUNG CHILDREN ON A SCHEDULE—with consistent mealtimes, limited screen time, and especially a regular bedtime—may shield them from obesity as they get older, new study results have found.

Ohio State University's Sarah Anderson, PhD, along with colleagues from her own university and the United Kingdom, found a link between a lack of a routine and weight problems as children neared their teens. Consistent schedules appear to foster greater emotional self-regulation, and the effects last for years, according to the study results published recently in the *International Journal of Obesity.*[1]

Scientists seeking answers for the global epidemics of diabetes and obesity have increasingly looked at sleep as a lifestyle factor that should be managed along with diet and exercise. Too little sleep, or rotating sleep schedules as seen in shift work, have been linked with weight gain and insulin resistance, putting those with interrupted sleep at risk of diabetes.[2]

"Sleep is so important, and it's important for children in particular," Anderson said in a statement. "Research is increasingly finding connections between obesity and poor sleep."[3]

The Ohio State study is the first to examine connections between sleep schedules in early childhood and self-regulation, along with their links to obesity in older children. Researchers evaluated data from 10,955 children born between 2000 and 2002 who took part in a long-term study in the United Kingdom.

At age 3, 41% of the children always had a regular bedtime, 47% always had a regular mealtime, and 23% were limited to an hour or less of TV or videos. By age 11, 6.2% of the children were obese. The 3 household routines studied were all associated with greater emotional self-regulation, which was computed through parents' responses to how much their children become frustrated or agitated. The less self-regulation, the more likely the children were to become obese.

INCONSISTENT EARLY CHILDHOOD BEDTIMES WERE AN INDEPENDENT RISK FACTOR FOR OBESITY.

"We saw that children who had the most difficulties with emotion regulation at age 3 also were more likely to be obese at age 11," said Anderson, an associate professor of epidemiology in the School of Public Health.

After controlling for socioeconomic differences, the researchers found that each unit on a scale measuring emotional self-regulation at age 3 increased the overall risk of obesity at age 11 by 38%.

Inconsistent bedtimes were an independent risk factor of obesity; Anderson and her colleagues found this factor was associated with an 87% increased overall risk of obesity by age 11. Differences arose even if a child's bedtime was "usually" consistent, compared with "always" consistent.

"This research allows us to better understand how young children's routines around sleep, meals, and screen time relate to their regulation of emotion and behavior," Anderson said. Future work should examine the role of emotional self-regulation in obesity generally, and how bedtimes contribute to its development; policymakers should take note of these effects.

"As a society, we should consider what we can do to make it easier for parents to interact with their children in ways that support their own and their children's health," she said. ◆

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Diabetes Prevention Program Has Promising Results Over First 4 Years

EARLY RETURNS ON THE National Diabetes Prevention Program (DPP) show it's working and that the higher the level of participation, the better the results.

A study published May 12, 2017, in *Diabetes Care* evaluated data from 14,747 adults who took part in the yearlong program between February 2012 and January 2016, and found that participants took part in an average of 14 sessions over an age of 172 days. The average weight loss was 4.2%, and the median weight loss was 3.1%. The study also found that 41.8% met the physical activity goal of 150 minutes per week.[1]

The study found a direct connection between the number of classes a person attended and the results: for every additional session attended and 30 minutes of physical activity, participants lost 0.3% of body weight. This may have important implications for program design, as both CMS and groups that offer the DPP look to boost retention rates.

The DPP seeks to help participants with prediabetes lose between 5% and 7% of body weight, a level that that is considered "transformational" because evidence shows it greatly reduces the likelihood that the person will progress to type 2 diabetes (T2D).

The National DPP was launched in 2010, after the National Institutes of Health developed the program and published the results from a clinical trial on its effects in 2002. Those findings show he program reduced the risk progression to diabetes by 58%, and by 71% for those 65 and older.[2]

As the population ages, CMS is looking for ways to reduce the share that ends up with T2D, because already $1 of every $3 in Medicare spend is on diabetes—a percentage that officials have said is not sustainable. An estimated 86 million people in the United States have prediabetes, but 9 in 10 have no idea.[3]

Based on a pilot program with the YMCA, CMS announced in March 2016 that it would begin offering the DPP through Medicare, after its actuary found that the government could save $2650 over 15 months for each person enrolled in the program. CMS has issued some rules on how the program will operate in Medicare, and another round is expected in June, which should contain specifics for digital providers. DPP is set to start in Medicare in January 2018.[4]

DPP takes place over 12 months. In its original, in-person format, participants meet for weekly sessions for the first 16 weeks, known as the "core sessions." After that, participants met monthly for maintenance sessions.

There is hope that digital providers will help the DPP reach more men, since the population in the *Diabetes Care* study was 81% female. Brenda Schmidt, CEO of Solera Health, which offers technology and support services for DPP programs, said in a previous interview with *The American Journal of Managed Care®* that digital programs could offer significant opportunities for closing the gap with men.[5]

The study authors wrote that focusing on reasons why some delivery methods have better retention than others may help reduce disparities and bring better overall results.

"Further program expansion is needed to continue lowering the burden of type 2 diabetes nationally," they wrote. ◆

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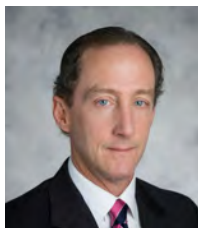
Quality Is the "New Currency in Healthcare Delivery," UVA's Shannon Tells PQA

Mary Caffrey



SHANNON

Richard Shannon, MD, is executive vice president for Health Affairs at the University of Virginia.

WHEN PRESIDENT LYNDON B. JOHNSON signed the law that created Medicare more than 50 years ago, there were 20 million beneficiaries and the typical one lived just 3 years beyond age 65 and cost the government $287 a year. Today, there are 40 million beneficiaries and the typical one lives 13 years beyond age 65 and costs $8300.

With the number of beneficiaries forecast to double again over the next decade, Medicare's costs are not sustainable without a radical rethinking of how healthcare is delivered to ensure that errors and waste are squeezed out and that the system only does things that help people, according to Richard Shannon, MD, executive vice president for Health Affairs at the University of Virginia (UVA). Shannon's address, "Building a Culture of Quality to Transform Patient Care," capped the opening day of the 12th annual meeting of the Pharmacy Quality Alliance, taking place in Baltimore, Maryland, from May 17 to 19.

While the quality care movement has been in place for some time, it picked up steam with the Affordable Care Act (ACA) and is now entering a new phase, said Shannon, who called quality "the new currency in healthcare delivery."

Besides the shift in demographics, Shannon said the nature of what healthcare does has shifted over a half-century. Decades ago, medicine's chief concern was infectious disease—but vaccines and treatments have largely eradicated these threats. Today, instead of short, intense encounters with the healthcare system, patients suffer chronic disease and interact with health systems for decades—at great cost.

PEOPLE WHO COME TO THE HOSPITAL WANT TO KNOW THEY'RE GOING TO GET BETTER, SO A HOSPITAL MUST BE ABLE TO ANSWER QUESTIONS LIKE, "WHAT'S MY CHANCE OF HAVING A COMPLICATION? WHEN CAN I GO BACK TO WORK?"

For some, population health has become a euphemism for shifting risk from payers to providers. Simply cutting payments to providers won't work; eventually, it causes some providers to refuse new patients on Medicare. But doing things differently can redirect up to a third of nation's healthcare tab—back to providers, to employers, and some to patients, he said.

"If we eliminate those things that add no value, I believe there will be sufficient resources to deliver care," Shannon said, with affordable access for all.

He outlined 4 issues that are essential going forward, for payers and health systems alike: (1) understanding the drivers of the delivery system, (2) understanding how public reporting shapes the agenda, (3) asking if reform can be achieved through payment reform alone, and (4) getting to the point of measuring what matters.

Not all the ways CMS has measured quality so far are fair or measuring the right things, he said. While the rise of accountable care organizations (ACOs) has helped the most inefficient systems rapidly improve, they've been less helpful for those already doing a good job.

And Shannon notes the reporting system has created some perverse incentives. UVA, a safety net hospital, had more than one-third of the patients who died there transferred from other hospitals last year. "They're sending patients to us 24 hours before they die so the mortality lands on us," Shannon said, "and I can't tell you how many arrive in a helicopter."

ACOs are great for "cherry-picking," Shannon said. "This movement has become a cottage industry. But is it generating meaningful data?"

So, what's the better way?Shannon called for an intense focus on changing processes, 1 that looks each day at what went wrong and asks why. It takes a team approach—involving a doctor, nurse, and pharmacist, and "lead coach," a navigator position.

"Every death, every pressure ulcer, every worker injury, every event gone wrong yesterday," Shannon said, "must be reported today and investigated today."

The message must go from both the top down and the bottom up. "Workers have to see their leaders acting in a different way," and they should benefit from "new tools and new skills."

So, not only will savings come from eliminating hospital acquired infections that add days to patient stays and cause more readmissions, but staff time will be saved if hospitals make sure nurses aren't running around looking for out-of-stock items. Hospitals save money if they prevent worker injuries, and workers benefit, too.

It's an intense approach, one that tackles a half-dozen target items at a time and focuses on them intensely until the hospital or health system masters them perfectly, Shannon said. He shared lists of items from the UVA system with dollar amounts, as well as a list of a target items that the Commonwealth of Pennsylvania had targeted for improvement, with significant improvement.

Most of all, he said, it's essential for each health system measure things that matter—compare yourself to others, and compare yourself to yourself over time. While some obscure statistics don't matter to the public, there are some bottom-line things the public wants to know. People who come to the hospital, want to know they're going to get better, so a hospital must be able to answer questions like, "What's my chance of having a complication? When can I go back to work?"

According to Shannon, those were the most common questions being asked at the senior center, so UVA started answering them. By taking intense steps to improve responses to heart attacks—including giving away new equipment to emergency medical services workers—UVA reduced mortality from a heart attack from 4.13% in 2015 to 3.6% in 2016. Its rate of complications is down, too, and its 5-year survival rate for breast cancer is up. "You can use data like this to drive process improvement," Shannon said.

Finally, he said, health systems must find ways to get understand the biggest barrier to care today: affordability. He shared the story of a woman who worked for UVA who kept ending up in the emergency department with asthma attacks. Through a program called BeWell, she told a pharmacist she could not afford the inhaler a doctor had prescribed. But she worked with that doctor, and didn't want to admit it.

"People are struggling mightily in their lives," Shannon said. ◆

Getting From Patient Reports to Measured Performance

Mary Caffrey

INCREASINGLY, VALUE-BASED INITIATIVES look for ways to bring the patient's voice into the equation. But that can be harder than it sounds. Panelists at the 12th annual meeting of the Pharmacy Quality Alliance, May 17 to 19, in Baltimore, Maryland, shared ideas on converting patient input into meaningful performance measures.

Led by moderator Molly Ekstrand, RPh, BCACP, AE-C, manager of the Medication Management Program at Park Nicollet Health Services, the discussion featured Jason Goldwater, MPA, senior director of the National Quality Forum (NQF); Eleanor Perfetto, PhD, MS, senior vice president for Strategic Initiatives at the National Health Council; and Angela Stover, PhD, health services researcher at the Department of Health Policy and Management, University of North Carolina at Chapel Hill.

The first thing to understand is the distinction between patient-reported outcomes (PROs), which offer information with no interpretation; patient-reported outcome measures (PROMs), which collect information told by the patient, again without interpretation; and, finally, patient-reported outcome performance measures (PRO-PMs), which aggregate the patient reports into "a reliable, valid measure of performance." This last one must be tested before it can be used.

Perfetto said that to create measures that truly matter, it's important capture the right information. "Just because it's patient-reported, doesn't mean it's patient-centered," she said.

In 2009, the FDA published a guidance on the use of PROs in labeling claims,[1] which Perfetto described as a key benchmark for whether a measure is a "legacy" measure—one that may or may not represent things patients say are important.

"We really ought to make sure the legacy measure is a good measure," she said. Understanding a measure's pedigree—where it came from—is key.

Goldwater, whose organization does not develop measures but endorses them, worked at the precursor to CMS during the infancy of measure development—when it nearly impossible to get reporting data from hospitals, let alone the patients receiving care.

"Patient engagement has become much more important in the years since then," he said. "Having a dynamic in where they are actively engaged with their provider—that can have a tremendous long-term effect on their health."

He agreed with Perfetto assessment about patient-reported measures—and as a corollary, said there are vast new ways of getting at what patients want. Social media offers tremendous clues. Goldwater offered an example of his efforts to develop questions to turn into a PRO-PM in chronic obstructive pulmonary disease (COPD). His NQF colleagues were skeptical, but he used a simple Twitter search to come up with 3 key issues that merited further exploration.

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"VERY OFTEN, PATIENTS HAVEN'T BEEN ASKED TO THE TABLE, AND THAT CAN MAKE AN IMPORTANT DIFFERENCE IN THE WAY PATIENTS THINK ABOUT CARE."

—Eleanor Perfetto, PhD, MS, National Health Council

Stover is working on measures in cancer care with the American Society of Clinical Oncology, and before that was a developer of the National Institutes of Health PROMIS (Patient-Reported Outcomes Measurement Information System) across a variety of health conditions. When testing PROs for patients in chemotherapy, there are important considerations—such as making sure the developers are not "gaming the system" by picking patients who are the least sick and the most educated.

In her current work in North Carolina, the researchers are careful to use an interactive voicemail system, since some patients in the state's Outer Banks do not have the internet. They are careful to capture patients in both academic settings and community clinics.

Perfetto said this approach is important. "Very often, patients haven't been asked to the table, and that can make an important difference in the way patients think about care," she said.

Goldwater said this was his thinking in using his Twitter experiment to start the work on the COPD measure. By itself, it would not have been sufficient, but he saved time and captured information on a medication causing anxiety, and the fact that there's confusion over the difference between COPD and asthma.

Who else needs to be involved? Stover said there's a need to make payers part of the PROs conversation, as well as pharmacists. Perfetto strongly recommends that measure developers not be afraid of learning from the professionals in market research. "They do their jobs really well," she said.

Stover said that with so much of healthcare happening between visits, the next wave of PROs should more accurately measure things like nausea or other side effects.

Most of all, the experts agreed that the days of bombarding patients with questionnaires in the doctor's office has passed. With wearables or other technology, there are alternative that can allow health systems to collect information without wasting precious office time. "It needs to fit into the person's life," Perfetto said. ◆

GOLDWATER

PERFETTO

STOVER

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Eleanor Perfetto, PhD, MS, is senior vice president for strategic initiatives at the National Health Council.

Angela Stover, PhD, is a health services researcher at the Department of Health Policy and Management, University of North Carolina at Chapel Hill.

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PAYER DATA

Obesity and Type 2 Diabetes in Young People: A Matter of National Concern

Robin Gelburd, JD

continued from cover

GELBURD

Robin Gelburd, JD, is the president of FAIR Health.

Obesity

During the study period, claim lines (the individual services or procedures listed on an insurance claim) with an obesity diagnosis increased in all age groups, from infants and toddlers (aged 0-2 years) to people of college age (19-22 years) to adults 22 years and older. The increase varied by age group, but after 5 years of age, it became greater for each successive age group. For example, the increase was 139% in individuals aged 17 to 18 years and 154% in those aged 19 to 22 years.

This finding contrasts with a report from the CDC, which found that the prevalence of obesity remained fairly stable for children and adolescents aged 2 to 19 years from 2011 to 2014.[4] The studies differ in that FAIR Health's results are based on health insurance claims for the privately insured population whereas the CDC results are based on surveys using interviews and physical examinations of a cross-section of the civilian, noninstitutionalized US population.[5] Because our study population had private insurance and excluded those with Medicaid, the results show that pediatric obesity is a problem not only for low-income children on Medicaid, who are often the focus of childhood obesity research,[6] but also for those with sufficient economic advantages to have private health insurance.

Type 2 Diabetes and Other Obesity-Related Diagnoses

According to our data, claim lines with diagnoses for T2D more than doubled from 2011 to 2015 in the pediatric population, for an average increase of 109% across all age groups. As with obesity, the increase during the study period tended to be greater among older individuals, reaching between 120% and 125% among youth aged 14 to 22 years. However, even among preschoolers (aged 3-5 years), the increase was 90%.

When we examined other obesity-related diagnoses in the pediatric population, we found trends similar to that of T2D. Claim lines with diagnoses of obstructive sleep apnea rose 161% from 2011 to 2015 and those with hypertension diagnoses rose 67%. Curiously, of the pediatric population, children aged 10 to 13 years had the greatest increase of claim lines associated with obstructive sleep apnea (218%) and elementary school students (aged 6 to 9 years) had the greatest increase in claim lines associated with hypertension (103%).

Because our study period spans the years before and after availability of subsidized coverage under the Affordable Care Act, it is possible that some of the increase in claim lines associated with obesity or obesity-related diagnoses can be attributed to the influx of newly insured people. The increased utilization nonetheless highlights a trajectory of growth in those diagnoses.

THE INCREASE IN TYPE 2 DIABETES AMONG YOUNG PEOPLE BRINGS WITH IT THE PROSPECT OF DECADES OF TREATMENT AND ITS COMPLICATIONS FOR A LARGER POPULATION THAN PREVIOUSLY ANTICIPATED.

Gender Patterns

Gender was found to be a factor in obesity, T2D, obstructive sleep apnea, and hypertension in the pediatric population. Except for those aged 10 to 13 years, claim lines with obesity diagnoses occurred more frequently in females than males. The greatest disparity was in the 19-to-22 years age group, in which the gender distribution of obesity diagnoses was 72% female to 28% male. However, in all but 2 groups (aged 10-13 and 19-22 years), claim lines with T2D diagnoses occurred more frequently in males than females. The greatest disparity was in the group aged 0 to 2 years, in which the gender distribution of T2D diagnoses was 62% male to 38% female. Claim lines with obstructive sleep apnea or hypertension diagnoses also were generally more common in males than females.

State-by-State Patterns

The prevalence of pediatric T2D appeared to vary by state. Comparing the percent of claim lines with pediatric T2D diagnoses to that of claim lines for all pediatric medical claims by state, we found pediatric T2D to be most prevalent in Ohio, Pennsylvania, North Dakota, Utah, and South Dakota. It was least prevalent in New Hampshire, Vermont, Delaware, Hawaii, and Rhode Island.

Claim lines with nondiabetic, obesity-related, pediatric diagnoses followed a similar pattern. They were most prevalent in Ohio, New Jersey, North Dakota, Pennsylvania, and West Virginia, 3 states of which have the highest prevalence of claim lines with pediatric T2D diagnoses, as previously noted. Claim lines with nondiabetic, obesity-related, pediatric diagnoses were least prevalent in Vermont, New Hampshire, Rhode Island, Delaware, and California, a group that includes 4 of the states with the lowest prevalence of claim lines with pediatric T2D diagnoses.

Implications

Our findings indicate that both obesity and T2D appear to have increased in prevalence in the pediatric privately insured population from 2011 to 2015, as did other obesity-related conditions, such as obstructive sleep apnea and hypertension. The implications for researchers, providers, payers, policy makers, and parents are profound. The increase in T2D among young people brings with it the prospect of decades of treatment and its complications for a larger population than previously anticipated, with all of the accompanying economic and social costs. Reversing this trend, and the rise of other pediatric obesity-related conditions, requires reversing the increase in pediatric obesity. That task will require the effort of all healthcare stakeholders.

Childhood obesity researchers Heidi M. Blanck, PhD, and Janet L. Collins, PhD, wrote: "Obesity-related health behaviors, such as nutrition and physical activity, are shaped by multiple sources of influence and environments, including the home, early care and education, school, healthcare, and other community settings. Therefore, a host of … stakeholders who influence these settings, including government, education, the private setting, nonprofit organizations, and families, have a role to play in creating healthier communities."[7]

Researchers must investigate the etiology, prevention, and treatment of pediatric obesity. Pediatricians must apply evidence-based means to prevent, screen for, diagnose, and treat this disease. Medical school curricula should prepare pediatricians to be alert to obesity and armed with skills and strategies to treat it. Payers may need to

alter their benefit designs and provider networks to ensure that a full range of services, specialties, and treatments are covered that are necessary for prevention, screening, diagnosis, and treatment of pediatric obesity. Policy makers can have an influence on pediatric obesity through their decisions affecting cities, schools, and people's way of life. For example, good urban planning can ensure that there are enough parks and playgrounds to encourage outdoor exercise and educational policy can encourage healthful physical education curricula and nutritious school meals. Parents can realize that their child's weight is both a cosmetic and a health issue and do all they can to instill healthy diet and exercise habits in their children.

Similar measures must be taken to address T2D in the pediatric population. Noting the clinical differences between T2D in young people compared with adults and the inadequacy of available treatment options, a recent consensus report of the American Diabetes Association and other organizations stated: "Comprehensive, coordinated, and innovative strategies for the investigation, prevention, and treatment of youth-onset type 2 diabetes are urgently needed."[8]

Even as research into T2D in young people continues, pediatricians must be alert for the signs and symptoms of the illness and be prepared to screen for and treat it with available means. Medical schools must prepare pediatricians to take on this challenge, and parents should be made aware of the signs and symptoms that they should bring to the attention of their child's doctor. Payers need to ensure coverage for services necessary for screening, diagnosis, and treatment of pediatric T2D.

By addressing obesity in the pediatric population, we have an opportunity to avoid much greater burdens in the future. And by addressing T2D in the same population, we have a chance to minimize the complications that can arise from inadequate management of this disease. ◆

DISCLOSURES

AUTHOR INFORMATION: Robin Gelburd, JD, is the president of FAIR Health, New York, New York, a national, independent nonprofit with the mission of bringing transparency to healthcare costs and insurance reimbursement. FAIR Health oversees the nation's largest collection of healthcare claims data, which includes a repository of more than 23 billion billed medical and dental procedures that reflect the claims experiences of 150 million-plus privately insured individuals and separate data representing the experiences of more than 55 million individuals enrolled in Medicare. Certified by CMS as a Qualified Entity, FAIR Health receives all of Medicare Parts A, B, and D claims data for use in nationwide transparency efforts. Ms. Gelburd has no conflicts of interest to disclose.

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Mental Health Care in Pediatric Diabetes: Overcoming Challenges and Barriers

Mary Pat Gallagher, MD

HASSENFELD CHILDREN'S HOSPITAL OF NEW YORK AT NYU LANGONE

continued from cover

GALLAGHER

Mary Pat Gallagher, MD, a pediatric endocrinologist, is the first director of the Robert I. Grossman and Elizabeth J. Cohen, MD, Pediatric Diabetes Center at NYU Langone Medical Center.

neurodevelopmental and behavioral issues can interfere with a child's ability to master diabetes self-management skills.[2]

Prevalence of Mental Health Issues in Pediatrics

The prevalence of mental health issues in the general pediatric population is high, increasing in frequency from childhood through adolescence. Data from the National Health and Nutrition Examination Survey show that the 12-month prevalence of mental health disorders for children aged 8-15 years is 13.1%. The National Institute of Mental Health indicates that the *lifetime* prevalence of mental health disorders in children aged 13-18 years is 46.2%, with the *lifetime* prevalence of "severe disorders" being 21.4%.[3] In decreasing order of frequency, this grouping of mental health disorders includes:

- Attention-deficit hyperactivity disorder
- Mood disorders
- Conduct disorder
- Dysthymia
- Anxiety disorders
- Panic disorders
- Eating disorders

Prevalence of Mental Health Issues in Pediatric Diabetes

An increased risk for mental health disorders has been well recognized in adults with diabetes.[4] Although published data are mixed, larger studies and meta-analyses indicate that the prevalence of mental health disorders in children and adolescents with diabetes is higher than in those without.[5-7] In children with mental health disorders, the task of diabetes self-management becomes more complex. Indeed, symptoms of mood disturbance and anxiety are themselves associated with increased glycated hemoglobin (A1C) levels.[8]

Even in the absence of a recognized mental health disorder, it is common for families to experience a significant amount of conflict as they transition the responsibilities of diabetes management from the parent to the child. Diabetes-related conflict is associated with decreased engagement in disease management, decreased adherence, and increased A1C levels.[9-11]

American Diabetes Association Recommendations for Psychosocial Care in Practice

The American Diabetes Association (ADA) recognized the important role that behavioral health plays in the successful management of diabetes. In 2016, the ADA released a position statement on psychosocial care of people with diabetes. It states,

> *"Practitioners should identify behavioral/mental health providers, ideally those who are knowledgeable about diabetes treatment and the psychosocial aspects of diabetes, with whom they can form alliances and use for referrals in the psychosocial care of people with diabetes (PWD). Ideally, psychosocial care providers should be embedded in diabetes care settings. Shared resources such as electronic health records, management data, and patient-reported information regarding adjustment to illness and life course issues facilitate providers' capacity to identify and remediate psychosocial issues that impede regimen implementation and improve diabetes management and well-being."*[12]

The ADA listed recommendations for psychosocial care, along with the level of evidence assigned. Level A evidence comes from randomized controlled trials, level B evidence comes from well-controlled cohort studies, and level E is from expert consensus.

From *Diabetes Care*[12]:

- Psychosocial care should be integrated with collaborative, patient-centered medical care and provided to all people with diabetes, with the goals of optimizing health outcomes and health-related quality of life. Evidence level: A.
- Providers should consider an assessment of symptoms of diabetes distress, depression, anxiety, disordered eating, and cognitive capacities using patient-appropriate standardized/validated tools at the initial visit, at periodic intervals, and when there is a change in disease, treatment, or life circumstance. Including caregivers and family members in this assessment is recommended. Evidence level: B.
- Consider monitoring patient performance of self-management behaviors as well as psychosocial factors impacting the person's self-management. Evidence level: E.
- Consider assessment of life circumstances that can affect physical and psychological health outcomes and their incorporation into intervention strategies. Evidence level: E.
- Addressing psychosocial problems upon identification is recommended. If an intervention cannot be initiated during the visit when the problem is identified, a follow-up visit or referral to a qualified behavioral healthcare provider may be scheduled during that visit. Evidence level: E.

It has been shown that behavioral interventions can improve regimen adherence and glycemic control, decreasing A1C levels by at least 0.5%,[13-15] which significantly reduces risk for long-term complications.[16] Interventions that target modifiable diabetes-related emotional or family processes and those that include training in problem-solving skills[14,15] had the largest effect on A1C levels. Decreasing the A1C level and, in turn, the rate of complications, will reduce the financial burden of T1D over time. It has also been shown that multisystemic treatment can decrease resource utilization in the present.[17]

Current Challenges

Numerous barriers prevent the delivery of behavioral healthcare. When practices refer patients elsewhere for care, only 50% follow through with making an appointment, and fewer remain engaged.[18] This may be driven by multiple factors:

- The stigma attached to seeing a mental health professional
- Difficulty identifying a provider who is familiar with diabetes
- Lack of insurance coverage
- Need for prior authorizations for visits when coverage does exist
- Lack of communication between the mental health professional and the referring provider

In a recent report from the Mental Health Issues of Diabetes conference,[19] a lack of trained mental health professionals who are knowledgeable about mental health issues as they relate to diabetes was identified as a significant barrier. To that end, another group

recommended increased clinical training programs for mental health providers focusing on the mental health needs of young people with diabetes as well as continuing medical education programs for endocrinologists on mental health topics to foster an integration of mental and physical healthcare for patients with T1D.[20]

The integration of behavioral health into the medical setting is advocated to remove some of the existing barriers to achieving the goals enumerated by the ADA. This model can help reduce the stigma attached to referrals and is associated with an increase in the number of appointments made after referral. Additionally, it strengthens the routine behavioral care that can be offered to patients and families.

However, there are barriers that persist even when practices use the onsite integrated behavioral healthcare model. These barriers are mostly related to the financial feasibility of the model. Billing for services is complex, and rules vary by state and by individual payer contracts. Psychiatric issues considered secondary to medical conditions cannot be billed under psychiatric coverage. Medicare has officially recognized behavioral medicine interventions for the treatment of a variety of medical disorders, outside of mental health disorders. This resulted in the creation of Health and Behavioral Assessment (HBA) codes in January 2002.[21] These codes are used to bill for services provided when a patient's behavioral function is affecting a health problem, as long as the patient's diagnosis is not a psychiatric one (the patient may have a co-existing psychiatric diagnosis but the visit being billed should address their medical illness). Their use requires a physical health diagnosis using *International Classification of Diseases, Tenth Revision, Clinical Modification* (not *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition).* Diabetes is among the diagnoses recognized as being responsive to behavioral interventions.

Health and behavior assessments (91650: initial assessment; 96151: repeat assessment) might include evaluation of patient adherence to medical treatment, management of symptoms, health-promoting behaviors, health-related risk-taking behaviors, and adjustment to physical illness.

Interventions (96152: individual; 96153: group; 96154: family with patient; 96155: family without patient) might include teaching self-monitoring, cognitive behavioral techniques, relaxation, visualization, coping and social skills, communication and conflict resolution, smoking cessation, relapse prevention, and diet and exercise, as prescribed by a physician.

HBA codes may be used by social workers, psychologists, or other nonphysician providers, but they must be within the scope of practice of the provider. Use of these codes does not require documentation of history, examination, or medical decision-making.

These providers may also render more complex services that are better suited to billing an evaluation and management (E&M) code. HBA codes should not be used when providing an E&M service on the same day. However, these codes may be used if another medical provider has seen the patient prior to the intervention, though this must be clearly noted in the medical record and the Current Procedural Technology code must be amended with an "S" (for "same day").

Summary

The management of diabetes in children and adolescents requires intensive psychosocial surveillance and interventions. While the cost of providing this care has been a barrier in the past, the reduction in resource utilization in the immediate and long term will decrease the economic burden of diabetes. Therefore, clinical practices should work together with their state's Medicaid programs and private payers to develop contracts for payment that will enable onsite integrated behavioral health programs to exist. ◆

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Joslin's Lori Laffel, MD, MPH, Explains the Challenge of Transitioning to Self-Care

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continued from cover

widespread recognition as an important innovator in the treatment of type 1 diabetes and formal honors such as the American Diabetes Association's 2015 Outstanding Physician Clinician Award.[1]

What is the focus of your research?

I pursue a diverse array of clinical investigations, but they all share the common goal of improving both clinical and psychosocial outcomes for pediatric, adolescent, and young adult patients with diabetes. I have worked with many collaborators locally, nationally, and internationally to explore ways to optimize disease management and outcomes, from dietary and exercise interventions to the design, implementation, and evaluation of new diabetes technologies. My team and I also spend a lot of time creating and evaluating educational programs and interventions designed to improve support for young persons with diabetes and their families. Research shows the benefits of a carefully orchestrated approach to diabetes management, one that starts with disease education and realistic expectations and relies upon positive support rather than blame and shame. Motivating family members to provide that support, particularly during the transition from family care to self-care, helps patients tremendously.

Why are you so interested in the period of transition between childhood and adulthood?

That is the period of life when disease control tends to be at its worst and, therefore, the period when patients most need better support. Blood sugar control in young children with diabetes tends to be close to goal because their parents are constantly around and providing care. There is some deterioration during the early school years and then more during adolescence. This is partially due to the fact that rapid growth during this period necessitates rapid adjustments to insulin dosing and other aspects of their treatment regimens, but an even bigger driver in this change is the transition from parental care to self-care. Glycated hemoglobin (A1C) levels actually tend to reach their highest, more than 9%, at age 19, when physical growth has already tailed off but the social and emotional challenges of transitioning from childhood to adulthood are at their highest. That number eventually falls toward 7.5%, but it takes until age 30. Anything that reduces the increase in adolescent A1C levels or enhances the improvement would be of tremendous benefit to patients in both the short run and the long run.

What does research and experience tell us about when and how the responsibility for disease management should move from parents to children?

It's not a jump from no self-care care to entire self-care; it's a gradual transition. Obviously, a very young child has parents or adult caregivers who do everything, just like a young child without diabetes has parents or other adults who do everyday tasks for him or her. As the child grows, one begins to give responsibility for very small diabetes management tasks, within the child's developmental abilities, with increasing responsibilities as the child matures. In many ways, you want to follow the normal developmental trajectory of the child as if he or she did not have diabetes. A child with diabetes should probably get to sleep over at a friend's house or decide what to pack for lunch at about the same time a child without diabetes would be able to do such things—if there are adults willing to assist the child with diabetes management when the child is away from home. You'd have the same talk about making good choices and selecting appropriate food, but you'd also talk about how different choices would affect the amount of insulin the child would need at lunch. A good first step might be seeing that the child can remember to take a snack to guard against low blood sugar when he or she starts going off alone with friends in the neighborhood. And, of course, the child would need to be able to check blood sugar levels when away from home. And then you go from there, one step at a time.

How should diabetes professionals advise parents to evaluate whether kids are doing well with each step in this transition from parental care to self-care?

Keeping up the dialogue within the family setting is probably the most important evaluation tool. That does not mean diabetes should be the only topic of conversation, or even the first topic of conversation, every time the child comes home from school. Diabetes management is obviously very important, but parents should not focus on it so much that children grow to think their disease is the most important thing in their lives. Parents should start by asking about the stuff that's important for all kids: how was the math test? How was the soccer game? But they do need to find out how their children are caring for themselves in addition to the other stuff, so they do need to ask questions about self-care: what was your blood sugar reading at lunch? It's also important to track the results of actual blood sugar tests. Continuous glucose monitors obviously give parents very complete glucose (sugar) data, especially when parents can stay connected remotely via mobile apps. Blood sugar levels, either episodically by finger-stick or continuous glucose levels using continuous glucose monitors, can indicate deteriorating diabetes disease control between clinic appointments with diabetes providers and before the A1C has time to rise.

But parents cannot do it alone. Healthcare professionals are a vital component in monitoring the transition to self-care. We recommend that children be seen at 3-month intervals. This would be true even with perfect adherence to treatment protocols because growth throughout childhood and especially during adolescence requires frequent changes to treatment regimens, and check-ups provide a huge amount of information about disease control, particularly when children are regularly seeing a whole team of caregivers: pediatric endocrinologists, pediatric nurses, pediatric dietitians, pediatric counselors and social workers, among others—like exercise physiologists. Also, every child needs eye exams, but it is particularly important for children with diabetes. The keys are making sure that health care visits are child-centered and offer family support. It can be very hard for patients and families to avoid "diabetes burnout" when it comes to diabetes care, so it is incredibly important to keep coming in every 3 months for visits, year in and year out.

How much potential is there for currently approved technology to improve diabetes care?

Insulin pumps and continuous glucose monitors, while improving all the time, are able to offer real benefits to patients in their current forms. The FDA has recently approved the first hybrid closed loop system that takes data from a continuous glucose monitor and uses the data to make some automatic adjustments to a connected insulin pump.[2] The device still requires a lot of work from patients, who must calibrate the continuous glucose monitor and provide information about carbohydrates and confirm bolus dosing, but it does automate some of the work, and such devices will almost certainly improve glucose control overnight.

Mobile applications that are designed to help people manage their diabetes can also be very helpful. Many patients get good results from programs that help them estimate the number of carbohydrates in a meal by comparing the size of portions they're eating with pictures of food. Even something as simple as an automated text message that reminds people to check their blood sugar levels at particular times of day can make a difference. We have studied that approach and found that it can reduce A1C levels in certain subsets of patients.

The thing about technology is that it should be considered within the context of an individual patient's needs. We have talked for years about individualized care, and technology is definitely an area where that comes into play. Technology that works brilliantly for some persons may be challenges for others to use and potentially add burden to their self-care. Technology's effectiveness can diminish over time, for example, as text message reminders may be helpful for a few weeks or a few months but then the effect may wane as patients tire from the constant reminders. That's an example of the burnout effect again. Diabetes care can wear people down, so we need to be innovative in our interventions and our approaches, and continually try different approaches that meet patients' needs. In other words, we need to keep coming up with new ways to keep patients and their families active and engaged.

What are the biggest limitations of today's technology?

New technology can certainly improve outcomes, but it may not make self-care easier for every patient. It can actually add more work and potential burden to our patients and families, as I noted before. So, it is important to consider when and if to introduce a new diabetes technology to a patient and family, carefully reviewing the time that would allow the patient and family to eagerly accept the extra time to learn a new management approach. Here are some examples of the extra work. When one uses a continuous glucose monitor, there is the need to insert the sensor, calibrate it against finger-stick glucose values, make sure that the alarms and alerts are set appropriately, and make sure that the data are downloaded and reviewed regularly and shared with the health care team appropriately. If one uses an insulin pump, there is a need to make sure that the infusion sites are changed and rotated appropriately, that the insulin reservoirs are filled appropriately, and that the insulin doses are selected appropriately. Every technology we have today—even those that are beginning to automate insulin delivery, all outstanding advances—still require effort from the person with diabetes or from the family member who is helping to support the care of that person.

Fortunately, a lot has improved. We are in an era when some of the technology that's available to patients can reduce some burden—if you start using this, you can stop doing that. For example, if you use a continuous glucose monitor with the right regulatory approval, you can use the glucose data as a replacement for finger-stick glucose checks to make diabetes management decisions.[3] If your continuous glucose monitoring device is calibrated appropriately, you can make management decisions directly from the readings produced by that device. You still have to calibrate the system at least twice a day with finger-stick glucose levels, but you may not have to check 6, 8, or 10 times a day as you once did.

What can providers do to inspire patients to put in the effort required to use technology effectively and enjoy the benefits it can provide?

The most important thing is setting realistic expectations. Patients have to know up front about the limitations of technologies and about the extra effort that may be required to use the technologies properly. It is also important to provide optimism as treatments are getting better and self-care will get easier because technology performance keeps getting better. It is worth putting in the extra effort for better health outcomes today as the future will bring tremendous improvements, likely with more automation and therefore less need for extensive self-care. And, we are always hopeful for biologic advances in addition to the advances we are seeing with diabetes devices and automated insulin delivery systems. We want our patients to remain healthy today and tomorrow so they can access the advances on the horizon. Our hope and optimism can be effective tools in motivating patients in their self-care and to keep them coming back for routine check-ups at the optimal intervals. The patients will see that each new appointment may bring some new tool or approach to help them manage their condition and improve their quality of life.

What research are you most excited about?

At this point in time, we are performing a lot of research in automated insulin delivery systems for automated glucose control, using systems that combine the data from a continuous glucose monitor with an insulin pump, merged together with special algorithms aimed at keeping glucose levels in range, thereby avoiding severe hypoglycemia as well as high glucose levels. These efforts appear to be especially effective overnight, and more advanced approaches in the future will be able to account better for food intake as well as stress and exercise. The current systems maintain glucose levels overnight and help control them during the day.

Other researchers at Joslin and elsewhere are trying to tease out what leads to the autoimmune destruction that leads to the loss of the insulin-producing beta cells. Others are working to create implantable stem cells that can become insulin-producing beta cells. The 2 remarkable efforts go hand-in-hand because if one figures out what destroys the beta cells and can prevent such autoimmune destruction, then implanted new beta cells would be likely to provide long-term insulin production.

"WE ARE IN AN ERA WHEN SOME OF THE TECHNOLOGY THAT'S AVAILABLE TO PATIENTS CAN REDUCE SOME BURDEN—IF YOU START USING THIS, YOU CAN STOP USING THAT."

Finally, other research efforts focus on preventing chronic complications in people with diabetes. Preserving vision and maintaining normal kidney function would provide enormous relief to people with diabetes and their family members. Recent years have witnessed tremendous opportunities to maintain vision and kidney function as long as patients continue to get routine care. Health care providers can identify eye and kidney problems early and at a stage when treatments can preserve function. In the future, there may be opportunities to identify genetic risk for complications, and genetic protection against complications, that would allow us to tailor diabetes management to a patient's risk level. We have optimism today and for the future for patients with diabetes and their families. ◆

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Value-Based Diabetes: Managing Costs Yet Improving Outcomes

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EDUCATIONAL OBJECTIVES

At the completion of this activity, the participant will be able to:

- Determine the appropriate treatment intensification strategy detailed by ADA and AACE to improve patient glycemic control
- Explain the different agents available, including new combination agents in the pipeline, and evaluate their place in therapy
- Identify quality measures and evaluate the potential impact of value-based decisions on diabetes care
- Examine quality and cost-effectiveness measures to identify areas of improvement that can be addressed in the future

ACTIVITY OVERVIEW

This activity will inform providers about the application of value-based care in type 2 diabetes. The activity will also provide information on different approaches to value-based care in managed care practice as well as a discussion on current guidelines on pharmacotherapy for type 2 diabetes.

TARGETED AUDIENCE: Pharmacists
ACTIVITY TYPE: Application
RELEASE DATE: June 22, 2017
EXPIRATION DATE: June 22, 2018
ESTIMATED TIME TO COMPLETE ACTIVITY: 2.0 hours
FEE: *This lesson is offered for free at www.pharmacytimes.org.*

THE PROPOSED SOLUTION: VALUE-BASED DIABETES

The classification of diabetes, a disease of abnormal carbohydrate metabolism, includes several types: type 1, type 2, gestational, and other types that occur with less frequency. Type 2 diabetes (T2D) is by far the most common, affecting approximately 90% to 95% of those with any form.[1] Patients with T2D can experience a range of complications, particularly if their disease is not managed well. Complications may include nephropathy, neuropathies (particularly associated with the feet), and retinopathy, as well as cardiovascular events such as stroke and myocardial infarction.[2]

According to the Centers for Disease Control and Prevention, more than 9% of the US population (29.1 million people) have diabetes, with approximately 8 million of those undiagnosed.[3] Given the enormous prevalence of diabetes and its association with a host of health complications, diabetes poses substantial economic burden to the US healthcare system. A report by the American Diabetes Association (ADA) estimated that diabetes accounted for $245 billion in total medical costs in 2012; $176 billion and $69 billion were associated with direct and indirect healthcare costs, respectively.[4] Furthermore, diabetes accounted for an estimated $320 billion in the total US healthcare cost in the year 2015.[5] Diabetes ranks seventh in leading causes of death in the United States, accounting for 20.9 deaths per 100,000 population. It may contribute to other leading causes of death such as heart disease and stroke, the first and fifth leading causes of death, respectively.[6]

Importantly, increases in the cost of diabetes medications (particularly insulin, whose cost has more than tripled in the United States[7,8]) could force more patients to forgo critical drugs due to their financial situations.[9,10] For many payers, diabetes medications rank number 2 in overall drug spending, including specialty pharmacy, and it is the number-1 category of spending for nonspecialty drugs.[11] The societal and economic burdens of diabetes are substantial; effective tools to prevent and manage the disease, and to reduce its treatment costs, are critically needed to improve public health.

The drive to reduce the societal and economic burdens of diabetes includes efforts to change the healthcare payment model. Traditionally, the US healthcare system operates on a fee-for-service model, which pays healthcare providers for services provided. Spurred by directives in the Patient Protection and Affordable Care Act (ACA),[12] there has been a major

push to develop alternative payment and care models, including value-based healthcare, accountable care organizations (ACOs), and the patient-centered medical home (PCMH).[13] CMS helps to drive changes in these payment models primarily through the Medicare system. The concept of value-based insurance design (VBID) emphasizes the use of high-value services[14] so that the goal of the healthcare system to improve health is coupled with the goal to maximize resources. However, the initiatives in the ACA may change based on pending legislative efforts.

VALUE-BASED INSURANCE DESIGN

In VBID, priority is placed on therapies that reflect the best value for a patient. Such therapies may be offered at low or even no cost to drive patients and clinicians to use them. Theoretically, a single therapeutic agent may vary in cost dependent on the patient efficacy; a given treatment may provide benefit to some patients, or have no benefit or lesser degree of benefit in others.[14] The initiative for value-based care within Medicare, the Medicare Advantage Value-Based Insurance Design Model, began in 2017 in 7 states—Arizona, Indiana, Iowa, Massachusetts, Oregon, Pennsylvania, and Tennessee—with 3 additional states (Alabama, Michigan, and Texas) expected to begin implementing the model in 2018.[15] For 2017, the VBID model focuses on 7 targeted conditions, including diabetes, for innovations in benefit design for enrollees with the aim to foster the use of "high-value clinical services, those that have the greatest potential to positively impact enrollee health relative to cost."[16] Through high-touch counseling and coordination, pharmacists may play a key role in helping patients to understand the value of their medicines in order to prevent sequelae of their chronic conditions. With optimal implementation, this benefit design may contribute to more engaged patients while reducing financial medical risk for providers.

As with any model, the VBID model will not be a panacea; low-income patients and patients with higher-cost conditions (including diabetes) may be responsible for higher deductibles as costs are shifted towards increased patient costs.[17] In fact, the results of a study conducted by a group that included the originators of the VBID concept suggests that the increases in cost sharing within VBID "may worsen socioeconomic health disparities."[18] Recognizing that possibility, the group recommended that mechanisms should be in place to attenuate such an outcome.[18] In their recent position paper focusing on cost sharing in health insurance, the American College of Physicians (ACP) expressed support for VBID strategies that include mechanisms for reducing out-of-pocket expenditures for people in lower income brackets.[19] With unanswered questions about VBID, particularly with respect to potential effects on health disparities based on socioeconomic status, the ACP advises that large-scale studies be conducted.[19]

Accountable Care Organizations

An ACO is an organization of providers that is designed to coordinate and deliver healthcare to a group of Medicare patients in a manner that ensures quality care while driving down costs.[20-22] The rationale behind ACOs is that the ACO will reap the benefits of holding down costs by receiving a share of the Medicare savings that they generate, contingent on meeting certain quality benchmarks. CMS has 3 broad aims for ACOs: better care for individuals, better health for populations, and lowering growth in expenditures.[20] CMS allows for 2 models—1-sided and 2-sided—for sharing savings and financial risk. In the 1-sided model, the ACO benefits from shared savings at a lower rate while not being liable for shared losses. In the 2-sided model, the ACO benefits from shared savings at a higher rate, but is liable for shared losses.[21]

CMS's ACO initiatives began in 2012 with the Pioneer ACO Model, which was completed in 2016, and 2 additional programs: the Medicare Shared Savings Program and the Advance Payment ACO Model.[20] The ACO program evaluates ACOs based on 33 quality measures in 4 domains. Diabetes is addressed directly in 6 of the quality measures, 5 of which are grouped into the Diabetes Composite measures: glycated hemoglobin (A1C) control (<8%), low-density lipoprotein (<100 mg/dL), blood pressure (<140/90 mm Hg), nonuse of tobacco, and aspirin use. The other direct quality measure is the percentage of beneficiaries with diabetes whose A1C level is poorly controlled (>9%). Patients with diabetes will likely fall under other quality measures as well.[23]

In addition to Medicare ACOs, commercial ACOs have proliferated in recent years. More than 700 total ACOs were operational in 2015, divided roughly equally between Medicare and commercial models.[24] By January 2016, there were more than 800 US ACOs, with commercial ACOs covering more patients than Medicare ACOs.[25] At least 1 report suggests that commercial ACOs may be more efficient in providing care to patients compared with Medicare ACOs, which may be partly attributed to flexibility in organizational structure.[26] With a rapid increase in ACOs, conclusions on whether or not such organizations reduce costs and improve care, and to what degree, may not be fully clear for several years.[27]

Patient-Centered Medical Home

The PCMH is a model that can address shortcomings in current primary care practice and may have specific application in diabetes care.[28] Although the cost-effectiveness of PCMH in diabetes care is not entirely clear, improvements in diabetes outcomes can be achieved, along with increased patient and provider satisfaction.[29] A group of leading physician organizations—the ACP along with the American Academy of Family Physicians, American Academy of Pediatrics, and American Osteopathic Association—jointly outlined a set of principles to describe a PCMH.[30] Building on those principles, the Agency for Healthcare Research and Quality (AHRQ), a unit of the US Department of Health & Human Services (HHS), identified 5 functions and attributes that define a PCMH (**TABLE 1**[31]).[31] While an ACO must have a minimum of 5000 Medicare patients, PCMH concepts can be applied to a practice of any size. Multiple providers collaborate to provide comprehensive healthcare to patients (Table 1[31]).[31] Among those providers, pharmacists can participate in multiple ways, such as in medication therapy management, monitoring adherence to medication regimens, providing some aspects of direct patient care, and communication with the healthcare team.[32]

TABLE 1. Functions and Attributes of a Patient-Centered Medical Home (PCMH)[31]

1. Comprehensive Care – Through a team of care providers (physicians, nurse practitioners, nurses, physician assistants, pharmacists, etc), the PCMH provides comprehensive healthcare services to each patient.
2. Patient-Centered – Providing PCMH-based care requires that patients and their families are critical members of the healthcare team.
3. Coordinated Care – Coordination of care across the healthcare spectrum (specialty care, hospitals, home healthcare, etc) ensures continuity of care particularly during transitions, such as discharge from a hospital.
4. Accessible Services – PCMH team members are available through a variety of mechanisms to provide care and communication to patients.
5. Quality and Safety – The PCMH has commitment to quality and quality improvement through the practice of evidence-based medicine; shared decision making on treatment can be made with patients and their families.

Using Treatment Options to Avoid Clinical Inertia

In the continuum of care, instances of delayed treatment may occur. Clinical inertia is a phenomenon that, due to a combination of patient adherence and provider factors, stalls intensification of therapy. The delays in intensification of therapy can lead to clinical complications in subsequent years that hamper patient outcomes and limit cost-effectiveness of treatment.[33,34] Forestalling clinical inertia in the initial stages of diagnosis and treatment is particularly critical in patients with diabetes, who are vulnerable due to the substantial lifestyle changes expected of them.[34] Delays in therapy intensification can be substantial in patients with T2D who have suboptimal glycemic control, particularly regarding the addition of insulin—in this situation, the average delay exceeds 7 years.[33] The ADA and American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) guidelines support the early addition of insulin to patient regimens as needed to reduce A1C levels.[35,36] Clinical evidence supports the early initiation of insulin along with oral agents, but clinicians should be cognizant of the potential weight gain and risk of hypoglycemia that insulin introduction may raise.[37]

When preventing or treating T2D, the foundational approach is healthy lifestyle modification. Through modest weight loss and increased physical activity, T2D risk can be reduced.[38-40] Research in early detection and treatment, such as the Diabetes Prevention Program research trial, demonstrates that these efforts can effectively reduce the incidence of diabetes.[40] Reductions in diabetes incidence can have profound effects on quality of life for individuals and on the disease's socioeconomic impact.

TABLE 2. Overview of Medication Recommendations for T2D[a,35,36]

	ADA	AACE/ACE
Lifestyle management is the first step for a patient with prediabetes or T2D. If ineffective, progress to monotherapy.		
Monotherapy	Metformin	Metformin[b] *or* GLP-1 RA *or* SGLT2i *or* DPP-4i *or* TZD *or* AGi *or* SU/GLN
	If the patient is not at therapeutic goal after ~3 months progress to dual therapy.	
Dual therapy	Metformin + one of the following: SU TZD DPP-4i SGLT2i GLP-1 RA Basal insulin	Monotherapy agent + one of the following: GLP-1 RA SGLT2i DPP-4i TZD Basal insulin Colesevelam Bromocriptine CR AGi SU/GLN
	If the patient is not at therapeutic goal after ~3 months, progress to triple therapy.	
Triple therapy	Dual therapy + another agent *See guidelines for specifics*	Dual therapy + another agent *See guidelines for specifics*
	If the patient is not at therapeutic goal after ~3 months, progress to or intensify insulin combinations	
Insulin combinations	*See guidelines*	*See guidelines*

[a]This abridged outline of recommendations is for general information purposes only. Consult the full guidelines from the ADA and AACE/ACE for specifics.
[b]Agents in the AACE/ACE monotherapy section are listed in order of recommended hierarchy.
AACE/ACE indicates American Association of Clinical Endocrinologists/American College of Endocrinology; ADA, American Diabetes Association; AGi, alpha-glucosidase inhibitor; CR, controlled release; DPP-4i, dipeptidyl peptidase-4 inhibitor; GLN, meglitinide; GLP-1 RA, glucagon-like peptide-1 receptor agonist; SGLT2i, sodium-glucose cotransporter-2 inhibitor; SU, sulfonylurea; T2D, type 2 diabetes; TZD, thiazolidinedione.

Treatment and Clinical Inertia

Robust, detailed guidelines for the treatment of diabetes are published by the ADA, which include standards for all types of diabetes, and by the AACE/ACE, which focus on T2D. Both guideline sets emphasize lifestyle changes and obesity management as key elements in preventing and managing T2D.[35,36] Such interventions have been demonstrated to be effective both clinically and economically.[38,40,41] The ADA and AACE/ACE guidelines each use patient-centered approaches that allow for individualization of care with respect to pharmacotherapy and glycemic targets. While the AACE/ACE recommends a target goal for A1C levels of <6.5%, compared with the initial ADA recommendation of <7%, both guidelines call for flexibility in those goals based on patient characteristics.[35,36] The 2017 ADA guidelines have added psychosocial care as a point of emphasis throughout the recommendations.[42]

With lifestyle management as the foundation for treatment, the ADA guidelines recommend metformin for initial pharmacologic therapy,[35] while the AACE/ACE guidelines include a range of suggested medications for monotherapy (**TABLE 2**[35,36]).[36] The recommendations guide providers to add drugs of different mechanisms of action to optimize pharmacologic effect.[35,36] Frequent evaluation of each patient's therapy goals (eg, glycemic and body-weight goals) is recommended so that therapy can be adjusted on an individual basis. Progressive addition of additional drugs, including insulin, is prescribed in both ADA and AACE/ACE guidelines for T2D. The common drug classes used in the guidelines are:[35,36]

- **Alpha-glucosidase inhibitors**, including acarbose and miglitol. The inhibition of alpha-glucosidase in the intestine decreases carbohydrate digestion and absorption, leading to lower blood glucose levels.[35]
- **Biguanides**, including metformin, the mainstay of initial pharmacotherapy for T2D. Through activation of adenosine monophosphate-activated protein kinase and other cellular mechanisms, metformin decreases hepatic glucose production and improves insulin sensitivity.[35,43]
- **Dipeptidyl peptidase-4 inhibitors (DPP-4i)**, including sitagliptin, saxagliptin, linagliptin, and alogliptin. By inhibiting DPP-4, incretin (eg, glucagon-like peptide-1 [GLP-1] and gastric inhibitory polypeptide) levels are increased, leading to increased insulin secretion.[35,43]
- **GLP-1 receptor agonists (GLP-1 RAs)**, including exenatide, extended-release exenatide, liraglutide, albiglutide, lixisenatide, and dulaglutide. The GLP-1 RAs are mimetics of GLP-1 that activate GLP-1 receptors to promote insulin secretion, decrease glucagon secretion, and delay gastric emptying.[35,43]
- **Insulin**, the hormone now available in forms that include rapid-acting, short-acting, intermediate-acting, and long-acting analogues.[35,43]
- **Meglitinides**, including nateglinide and repaglinide. These short-acting agents block ATP-sensitive potassium (K_{ATP}) channels to stimulate insulin secretion.[35,43]
- **Sodium-glucose cotransporter-2 inhibitors (SGLT2i)**, including canagliflozin, dapagliflozin, and empagliflozin. By inhibiting SGLT2 in the proximal renal tubule, glucose reabsorption is blocked, and elimination of glucose in the urine is increased, leading to lower blood glucose levels.[35,43]
- **Sulfonylureas (SUs)**, including the second-generation SUs glyburide, glipizide, and glimepiride. By blocking K_{ATP} channels in the pancreas, SUs stimulate insulin secretion.[35,43]
- **Thiazolidinediones (TZDs)**, including pioglitazone and rosiglitazone. TZDs are agonists of peroxisome proliferator-activated receptor gamma to increase insulin sensitivity and increase glucose uptake in various tissues.[35,43]

Recommendations regarding which level therapy should be initiated are based on patient parameters. If A1C levels are ≥9.0%, the ADA suggests that dual therapy should be considered as the initial treatment level. The ADA guidelines also state that combination injection therapy should be considered if A1C ≥10%, blood glucose is ≥300 mg/dL, or if the patient is "markedly symptomatic."[35] In the AACE/ACE guidelines, the marker for starting dual therapy is an A1C level ≥7.5%, and the recommendation for triple therapy is based on A1C level ≥9.0%.[36]

For reasons that include ease of administration and complementary mechanisms of action, the newest diabetes drug products feature combinations of long-acting insulin and a GLP-1 RA. In these combinations, insulin provides control of fasting glucose while the GLP-1 RAs delay gastric emptying and decrease glucagon secretion, thus reducing spikes in postprandial glucose levels and potentially reducing weight gain. GLP-1 RAs also stimulate insulin release, thus potentially reducing required doses of exogeneous insulin.[44] These combination products—one combining lixisenatide and insulin glargine, and the other combining liraglutide and insulin degludec—were both approved by the FDA in November 2016.[45,46] In the DUAL trials, the combination of liraglutide and insulin degludec demonstrated efficacy and safety in patients with T2D, including lowering A1C with estimated treatment differences compared with controls of –0.59% (95% CI, –0.74% to –0.45%; P <.001)[47] and –0.94% (95% CI, –1.11% to –0.78%; P <.001).[48] The combination of lixisenatide and insulin glargine was studied in the LixiLan open-label trials and demonstrated efficacy when compared with insulin glargine controls with comparable safety.[49,50] In the proof-of-concept LixiLan trial with 323 total

TABLE 3. Comprehensive Diabetes Care Measures for ACO, PCMH, and Primary Care[71]

Quality Measure	Description
Poor control of A1C	Percentage of patients with diabetes in poor control whose most recent A1C level was >9.0%
	Percentage of patients with diabetes in control whose most recent A1C level was <8.0%
	Percentage of patients with diabetes in control whose most recent A1C level was <7.0% for a selected population
	Percentage of patients missing an A1C test
Eye examination	Percentage of patients with diabetes who received a retinal eye examination
A1C testing	Percentage of patients with diabetes who received A1C test
Foot examination	Percentage of patients with diabetes who received a foot examination that included a visual inspection as well as sensory, a monofilament exam, and a pulse exam
Medical attention for nephropathy	Percentage of patients with diabetes who received a nephropathy screening test or had evidence of nephropathy

A1C indicates glycated hemoglobin; ACO, accountable care organization; PCMH, patient-centered medical home.

participants, the treatment difference with the lixisenatide/insulin glargine combination compared with insulin glargine was –0.17% (95% CI, –0.31% to –0.04%; $P = .01$).[49] In the larger LixiLan-L trial with 736 subjects, the lixisenatide/insulin glargine combination group exhibited greater reductions in A1C from baseline compared with insulin glargine (–1.1% vs –0.6%, respectively; $P < .0001$) and a mean reduction in body weight of 0.7 kg for the combination compared with an increase in body weight of 0.7 kg for insulin glargine ($P < .0001$).[50] Combination products have demonstrated similar efficacy compared with insulin-only treatment, and have added potential to mitigate weight gain. In this way, combination products provide additional options for treating patients with T2D who have not achieved therapeutic goals.

Results from recent clinical trials with agents from the GLP-1 RA and SGLT2i classes may provide context with respect to the effect of pharmacotherapy on cardiovascular outcomes, which in turn may be helpful in addressing treatment inertia. For GLP-1 RAs, the LEADER trial investigated liraglutide versus placebo with a primary composite cardiovascular outcome of time to first occurrence of death from cardiovascular causes, nonfatal stroke, or nonfatal myocardial infarction. Liraglutide demonstrated benefits in the primary outcome (hazard ratio [HR], 0.87; 95% CI, 0.78-0.97; $P < .001$ for noninferiority; $P = .01$ for superiority) as well as death from cardiovascular causes (HR, 0.78; 95% CI, 0.66-0.93; $P = .007$) and rate of death from all causes (HR, 0.85; 95% CI, 0.74-0.97; $P = .02$).[51] On the other hand, the ELIXA trial studied the effect of another GLP-1 RA, lixisenatide, and found that the drug did not notably impact cardiovascular outcomes.[52] The EMPA-REG OUTCOME trial compared the effect of empagliflozin, an SGLT2i, with placebo on cardiovascular mortality and morbidity in patients with T2D who were at high risk of cardiovascular events.[53] Results from that trial demonstrated substantial reductions in deaths from cardiovascular events (HR, 0.62; 95% CI, 0.49-0.77; $P < .001$), in hospitalization for heart failure (HR, 0.65; 95% CI, 0.50-0.85; $P = .002$), and in death from any cause (HR, 0.68; 95% CI, 0.57-0.82, $P < .001$).[53] Such results were not observed with other SGLT2i agents.[54,55] The variable effects seen with different drugs emphasize the need to study the agents individually as well as in direct comparisons to provide the substantive evidence required for making value-based care decisions.

APPLICATION AND FUTURE OF VALUE-BASED DIABETES CARE

Applying value-based diabetes care can take different forms, including pharmacist-specific approaches such as the Asheville Project, formulary changes such as the Pitney Bowes example, or the application of more holistic approaches, such as the PCMH. With the varied approaches to the PCMH, the economic benefits can range from net savings to cost-neutral to net cost increases.[29,56-59] The impact on patient outcomes may also be mixed because of multiple factors that require resources and substantial changes to the current health system.[60] While the PCMH model may not substantially reduce costs in the near term, improved outcomes over an extended time frame may demonstrate cost-effectiveness.[29,57] In a retrospective analysis of 4595 patients with diabetes in New York State, application of the PCMH model resulted in increased use of PCMH services and reduction in A1C in patients with baseline levels >9.0% (reduction from 10.72% to 8.34%), but with a paradoxical and slight increase in A1C in patients with baseline levels ≤9.0%.[61] It is also important to prioritize the overall health benefits to patients in addition to economic considerations.[62] There clearly is no single approach to PCMH implementation, but it is crucial to establish clarity between the particular goals of PCMH and the metrics used to measure those goals.[63]

The impact of innovative pharmaceutical care on diabetes can be found in the Asheville Project and subsequent initiatives. The Asheville Project showcased the impact of community-based, pharmacist-led interventions on health outcomes for patients with diabetes.[64-66] The success of that project spurred other intervention programs such as the Diabetes Ten City Challenge.[67] One primary rationale for focusing on pharmacist interventions was pharmacist accessibility and frequent interaction with patients with diabetes.[65] The pharmacist interventions included monthly meetings with patients to monitor treatment goals, training on glucose monitoring, and counseling on medication adherence as well as physical assessments.[65]

In both the short term (7-9 months) and long term (up to 5 years), the pharmacist interventions in the Asheville Project produced desirable outcomes in decreased A1C levels, number of patients with optimal A1C levels, and improvements in lipid levels.[64,65] While the short-term results were mixed with respect to changes in healthcare costs (healthcare costs from all diagnoses decreased by 16% but did not reach statistical significance), the long-term follow-up demonstrated decreases in insurance claims that were slightly offset by increases in prescription claims. The overall effect in the 1-to-5-year range showed an overall decrease in total mean direct medical costs. Furthermore, the long-term data exhibited reductions in the number of sick days that patients used per year; 1 employer involved in the study estimated that increased productivity amounted to $18,000 per year. While the authors could not specify which pharmacist interventions were most effective, the results prompted the participating employers to implement the pharmacist-led interventions.[64]

Another perspective is found in the Pitney Bowes example. In this case, the company sought to address mounting health insurance expenditures when per-employee claims rose by double digits in the year 2000.[68,69] Through their analysis of total cost of care—medical costs as well as indirect productivity costs—they concluded that lack of medication adherence was a primary driver of rising costs. Based on this analysis, the company changed their employee prescription plan so that the cost of medications was reduced substantially for patients with diabetes, asthma, or hypertension. As a result, the company's total pharmacy costs increased, but patients with diabetes showed significantly increased medication possession ratios, while pharmacy costs decreased by 7%.[68] In addition, medical usage and costs decreased for patients with diabetes, and emergency department visits saw a 26% decline.[68] Short-term disability costs also decreased, from $7798 per claimant in 2002 to $1925 per claimant in 2004.[69]

The examples of the Asheville Project and Pitney Bowes demonstrate that pharmacy interventions can facilitate reductions in medical costs in patients with diabetes. In the Asheville Project, pharmacist interventions were the cost driver, while changes in prescription coverage were the cost driver in the Pitney Bowes example. Such examples demonstrate the potential for proactive methods to drive down healthcare costs. The complexities of the US healthcare system lend themselves to many possible approaches, and they highlight the need for coordination between multiple members of the healthcare team. Particularly in diseases such as diabetes in which drug utilization is a major component of care, pharmacists can be instrumental in educating patients and managing their pharmacotherapy.

QUALITY MEASURES

The Core Quality Measure Collaborative, which includes members from CMS, America's Health Insurance Plans (AHIP), chief medical officers from AHIP, and national physician organizations, as well as employers and consumers, has been developing core quality measures to assess quality of care.[70] Included in the set for ACOs, PCMHs, and primary care practices are quality measures for comprehensive diabetes care (**TABLE 3**[71]).[71] The National Committee for Quality Assurance (NCQA) manages

TABLE 4. HEDIS Measures for Comprehensive Diabetes Care[72]

In adults 18-75 years of age with diabetes, determine the number of patients with each of the following:
• A1C testing
• A1C poor control (>9.0%)
• A1C control (<8.0%)
• A1C control (<7.0%) for a selected population
• Eye examination (retinal) performed
• Medical attention for nephropathy
• Blood pressure control (<140/90 mm Hg)

A1C indicates glycated hemoglobin; HEDIS, Healthcare Effectiveness Data and Information Set.

the Healthcare Effectiveness Data and Information Set (HEDIS), a collection of performance measures for Medicaid, Medicare, and commercial health insurers, to allow performance comparisons across plans.[72] Diabetes is among the disease states that HEDIS highlights, with several parameters for A1C, eye examinations, blood pressure control, and nephropathy in their Comprehensive Diabetes Care Measures (**TABLE 4**[72]).[73]

TOOLS

Providers can access a wide variety of resources to help patients with T2D evaluate the various options for providing value-based care. For information on PCMH, the NCQA offers the Patient-Centered Medical Home Recognition Program, which grants recognition by NCQA to a clinical practice for meeting specified standards.[74] The AHRQ also hosts a webpage with a number of searchable resources for PCMH.[75] The Center for Medicare and Medicaid Innovation sponsors the Accountable Care Organizations Accelerated Development Program for those considering the ACO route in providing value-based care[76] (**TABLE 5**). In terms of medications, as providers take more financial risk for quality measures and cost of care, including pharmaceutical expense, there will be increased scrutiny of the value of both individual diabetes medications and combinations of such medications. These analyses by payers and providers will influence medication choice.

As the concept of value-based care progresses, alternative formulary designs may become more common and some forms of tier-based systems may be adopted (eg, the Pitney Bowes example). Such formulary decisions will need to be based on some form of value measure that may be as simple as cost per reduction in A1C. The value measures could come from health plans via internal or published studies. As an example of a value-based formulary study, Yeung et al observed the impact of formulary changes for 3 chronic disease states, including diabetes.[77] In this study, formulary changes were determined by an analysis of cost-effectiveness; investigators evaulated the effects of medication adherence on patient and health plan expenditures. The diabetes cohort demonstrated significant reductions in patient and overall expenditures ($5 and $9 per patient per month, respectively). However, as the authors noted, 1 major limitation of the study was that improvement in health outcomes was not measured.[77]

Full implementation of value-based care will surely require consideration of health outcomes, not only economic outcomes. Besides analyses within particular health insurance plans, independent value frameworks may prove worthwhile, such as those described by the Institute for Clinical and Economic Review (ICER), whose mission is "to conduct evidence-based reviews of healthcare interventions, such as drug, devices, and diagnostics, that help patients, doctors, and everyone else in the healthcare system know what works."[78] ICER uses a value assessment framework that was developed (and continues to be revised) based on input from multiple stakeholders; as such, perspectives are gleaned from patients, clinicians, pharmaceutical benefit managers, health insurers, and pharmaceutical companies.[78] Recently, ICER reviewed insulin degludec, taking into account the published evidence for the efficacy of the drug as well as the cost-effectiveness in patients with T2D. ICER concluded that "the long-term care value of insulin degludec exceeds commonly-cited cost-effectiveness thresholds."[79] As indicated in its summary, there were several limitations to its review, including underestimation of costs of managing hypoglycemia in the patient population considered, and use of wholesale acquisition costs in its analysis. ICER also indicated that part of the purpose of its study was "to determine the level of discount that may be required to achieve certain thresholds for both short- and long-term value."[79] By soliciting perspectives from multiple stakeholders and publishing their evaluation process, ICER provides a potential example for evaluating healthcare treatment value.

CONCLUSIONS

Rising costs for patients with diabetes may be reaching a crisis level. It is necessary to maintain high treatment quality and still manage costs. Government-driven programs, such as ACOs, will continue to influence the development of value-based approaches in diabetes care as well as the healthcare system in general. Such initiatives will likely affect the private sector as well.[14] Potential changes to Medicare and Medicaid may be expected due to changes in government administration, and clinicians should stay up-to-date on such changes. Through evidence-based medicine practices, quality can be maintained and costs may be managed via various mechanisms such as VBID, ACOs, and PCMHs. ◆

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TABLE 5. Additional Resources

Organization	Source
American Diabetes Association—Diabetes Pro–Professional Resources Online	http://professional.diabetes.org/
Centers for Medicare & Medicaid Services	https://www.cms.gov/
Patient Centered Medical Home Resource Center	https://pcmh.ahrq.gov/
Center for Value-Based Insurance Design	http://vbidcenter.org/
HEDIS Measure for Comprehensive Diabetes Care	http://www.ncqa.org/report-cards/health-plans/state-of-health-care-quality/2016-table-of-contents/diabetes-care
Institute for Clinical and Economic Review	https://icer-review.org/
American Diabetes Association Standards of Medical Care in Diabetes: 2017	*Diabetes Care*. 2017;40(suppl 1):S1-S135.
AACE/ACE Consensus Statement on the Comprehensive Type 2 Diabetes Management Algorithm—2017	*Endocrine Practice*. 2017;23(2):207-238.

AACE/ACE indicates American Association of Clinical Endocrinologists/American College of Endocrinology; HEDIS, Healthcare Effectiveness Data and Information Set.

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RELEASE DATE: June 22, 2017
EXPIRATION DATE: June 22, 2018

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PC-based participants
Required: Windows 7, Vista, XP, 2003 Server or 2000
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Posttest Questions

1. **LJ is a 57-year-old man with a history of hypertension controlled with a lisinopril (20 mg)–hydrochlorothiazide (12.5 mg) combination product. He is a social drinker (3-4 drinks per week) and does not smoke. He has a body mass index (BMI) of 26.3 kg/m^2 with a blood pressure of 124/78 mm Hg and pulse of 63 bpm. Recently diagnosed with type 2 diabetes (T2D), his fasting blood glucose level is 142 mg/dL and his glycated hemoglobin (A1C) is 8.3%. Using American Diabetes Association (ADA) guidelines, what would be an appropriate recommendation for treating his T2D?**
   - **a.** Lifestyle management and metformin
   - **b.** Lifestyle management and insulin
   - **c.** Lifestyle management and a sulfonylurea
   - **d.** Metformin

2. **LJ is a 57-year-old man with a history of hypertension controlled with a lisinopril (20 mg)–hydrochlorothiazide (12.5 mg) combination product. He is a social drinker (3-4 drinks per week) and does not smoke. He has a BMI of 26.3 kg/m^2 with a blood pressure of 124/78 mm Hg and pulse of 63 bpm. Recently diagnosed with T2D, his fasting blood glucose level is 142 mg/dL and A1C is 8.3%. Using American Association of Clinical Endocrinologists/American College of Endocrinology guidelines, what would be an appropriate recommendation for treating his T2D?**
   - **a.** Lifestyle management and metformin
   - **b.** Lifestyle management and a dipeptidyl peptidase-4 (DPP-4) inhibitor
   - **c.** Lifestyle management, metformin, and a DPP-4 inhibitor
   - **d.** Metformin and a DPP-4 inhibitor

3. **After 3 months of treatment with lifestyle management and metformin (1000 mg twice a day), LJ is evaluated again. His fasting blood glucose level is 125 mg/dL and his A1C is 7.8%. Using ADA guidelines, what would be an appropriate recommendation for treatment?**
   - **a.** Lifestyle management, metformin, and a glucagon-like peptide-1 receptor agonist (GLP-1 RA)/insulin combination product
   - **b.** Lifestyle management, metformin, and a sodium-glucose cotransporter-2 (SGLT2) inhibitor
   - **c.** Lifestyle management, metformin, and bromocriptine
   - **d.** No change in treatment

4. **Recently approved combination injectable products for T2D are generally reserved for advanced or uncontrolled cases of T2D. The combination products contain a GLP-1 RA and a long-acting insulin. The mechanism of action of GLP-1 RA complements that of insulin. Which of the following is a mechanism of action for GLP-1 RAs?**
   - **a.** Stimulation of glucagon secretion
   - **b.** Acceleration of gastric emptying
   - **c.** Increasing appetite
   - **d.** Stimulating endogenous insulin secretion

5. **BK is a 62-year-old woman who was diagnosed with T2D more than 8 years ago. Her current diabetes medications are metformin, a DPP-4 inhibitor (sitagliptin), and insulin glargine (14.6 units per day). She is 5′ 3″ tall, weighs 71 kg, and has a BMI of 27.7 kg/m^2. Her blood pressure is 130/81 mm Hg, and her heart rate is 67 bpm; her most recent A1C level was 8.6%. Given that her A1C level is not optimally controlled, which of the following treatment options would be most appropriate per ADA guidelines?**
   - **a.** Discontinue sitagliptin and metformin; start on lixisenatide/insulin glargine combination
   - **b.** Discontinue metformin; start on lixisenatide/insulin glargine combination
   - **c.** Discontinue sitagliptin and insulin glargine; start on lixisenatide/insulin glargine combination
   - **d.** Maintain current therapy

6. **There are many parameters that are common to both the comprehensive diabetes quality measures for health plans (HEDIS) and for providers (CMS measures). Identify the measure(s) that do not overlap between the sets.**
   - **a.** A1C poor control (>9.0%)
   - **b.** A1C control (<8.0%) and medical attention for nephropathy
   - **c.** A1C testing and eye examination
   - **d.** Blood pressure control (<140/90 mm Hg) and foot examination

7. **The accountable care organization (ACO) and patient-centered medical home (PCMH) are approaches to providing value-based care. Which of the following describes a major difference between the approaches?**
   - **a.** An ACO is organization centered, compared to the patient-centered focus of PCMH
   - **b.** An ACO must have a minimum of 5000 Medicare patients; PCMH can be of any size
   - **c.** An ACO must have a minimum of 500 Medicare patients; PCMH can be of any size
   - **d.** ACO and PCMH can be of any size

8. **One quality measure in the Comprehensive Diabetes Care Measures for ACO, PCMH, and primary care is "poor control of A1C." Which of the following is a parameter for this quality measure?**
   - **a.** Percentage of patients with diabetes in poor control whose most recent A1C level was >9.0%
   - **b.** Percentage of patients with diabetes in control whose most recent A1C level was <8.0%
   - **c.** Percentage of patients with diabetes in control whose most recent A1C level was <7.0% for a selected population
   - **d.** Percentage of patients missing an A1C test

9. **Which of the following should be considered when determining the value of an intervention?**
   - **a.** Indirect medical cost savings to insurer and employer only
   - **b.** Total cost savings only
   - **c.** Total cost savings and health outcomes
   - **d.** Health outcomes only

10. **The Institute for Clinical and Economic Review solicits input from several stakeholders in formulating their value assessment framework. Which of the following correctly lists the stakeholders?**
    - **a.** Patients, politicians, pharmacy benefit managers, health insurers, and pharmaceutical companies
    - **b.** Patients, clinicians, pharmacy benefit managers, health insurers, and pharmaceutical companies
    - **c.** Patients, clinicians, FDA officials, health insurers, and pharmaceutical companies
    - **d.** Patients, clinicians, pharmacy benefit managers, health insurers, and manufacturers of generic drugs

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6. Patient-focused drug development
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