**SPECIAL ISSUE:** TECHNOLOGY UPDATE

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# Evidence-Based DIABETES MANAGEMENT™

SEPTEMBER 2017
VOL. 23 • NO. 11

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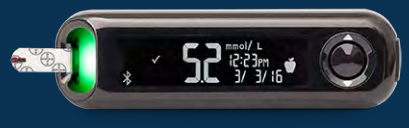
### MEDICATION ADHERENCE

While Intarcia Therapeutics awaits FDA approval for the ITCA 650 to treat patients with type 2 diabetes, researchers present evidence that the delivery system has value for payers, SP439.


### DIGITAL MANAGEMENT

In the past year, WellDoc has made a series of moves to allow its BlueStar technology for managing type 2 diabetes to reach a wider audience, including through health plans, SP443.




### CGM FOR MEDICARE

In a key development for Medicare beneficiaries with diabetes, Dexcom reached an agreement with Ascensia to include its CONTOUR NEXT ONE blood glucose meter (shown above) for shipment with the Dexcom G5 continuous glucose monitoring system to meet Medicare bundling requirements, SP447.

## PROVIDER PERSPECTIVE

# Omada's Paul Chew, MD: From Treating Chronic Disease to Prevention

*Mary Caffrey*

**FOR YEARS, PAUL CHEW, MD,** commuted from his New Jersey home to Paris, France, where the pharmaceutical giant Sanofi Pasteur has its headquarters. A cardiologist and former faculty member at Johns Hopkins, Chew served as senior vice president and global chief medical officer at Sanofi,[1] where he helped develop therapies to treat cardiovascular disease, the number one killer in the United States,[2] and diabetes, which has been on the rise for decades and now affects 30.3 million Americans.[3]

However, in January, Chew's career path took him in different direction—literally. He now travels back and forth to San Francisco, California, where he is the chief medical officer at digital behavioral health provider Omada Health. The company is harnessing technology to help people with prediabetes make lasting lifestyle changes to halt the chronic diseases that kill too many Americans, changes that evidence shows few can make on their own.




Tools that help Omada Health clients follow the Diabetes Prevention Program.

Chew visited *Evidence-Based Diabetes Management*™ (*EBDM*™) for an interview to discuss his transition from treating chronic disease to preventing it and how managed care companies—and employers—should weigh evidence when selecting a digital behavioral health provider.

Eighty-four million people have prediabetes, a condition of elevated blood glucose that falls short of a diabetes diagnosis.[3] Chew calls prediabetes "the waiting room" for chronic disease, but he says identifying it represents an opportunity. With the right lifestyle intervention, this condition can be reversed. Evidence going back to the original study of the Diabetes Prevention Program (DPP) showed the right combination of dietary changes, exercise, education, and support can reduce the likelihood of progressing to type 2 diabetes (T2D) by 58%.[4]

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## CONVERSATION

# After 20 Years of Watching Diabetes Tech, Kliff Eyes Smart Insulin Pens, CGM for Patients With Type 2 Diabetes

*Andrew Smith*

**ALTHOUGH CURRENT MEDICATIONS CAN** maintain healthy blood sugar levels in most patients who have type 1 (T1D) or type 2 diabetes (T2D), most patients don't use them correctly and therefore suffer the expensive and unpleasant complications of both hyper- and hypoglycemia. Less than half of all patients with T2D achieve glycemic goals advocated by the American Diabetes Association, and about two-thirds die prematurely of heart disease.[1]

Study results indicate that educational interventions can boost treatment adherence, at least among some patients,[2] but many experts believe the only hope for widespread improvement among real-world patients lies in new medications and novel technologies—products that dramatically reduce the pain and complexity of proper self-care.

David Kliff, who has run *Diabetes Investor* since he was diagnosed with the condition more than 20 years

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## PAYER UPDATE

# UnitedHealthcare's Medtronic Deal Sparks Furor, but a Year Later, Innovation Continues

*Andrew Smith*

**WHEN UNITEDHEALTHCARE (UHC)** announced in May 2016 that it would only cover insulin pumps made by Medtronic for most adults, patient advocates decried the news as both a major loss for those affected and, quite possibly, a harbinger of a world where exclusivity pacts stifled competitive innovation. Investors, it seemed, were in full agreement. Shares of smaller pump maker Tandem Diabetes Care immediately dropped 20% when news of the deal became public.[1]

CONTINUED ON SP455

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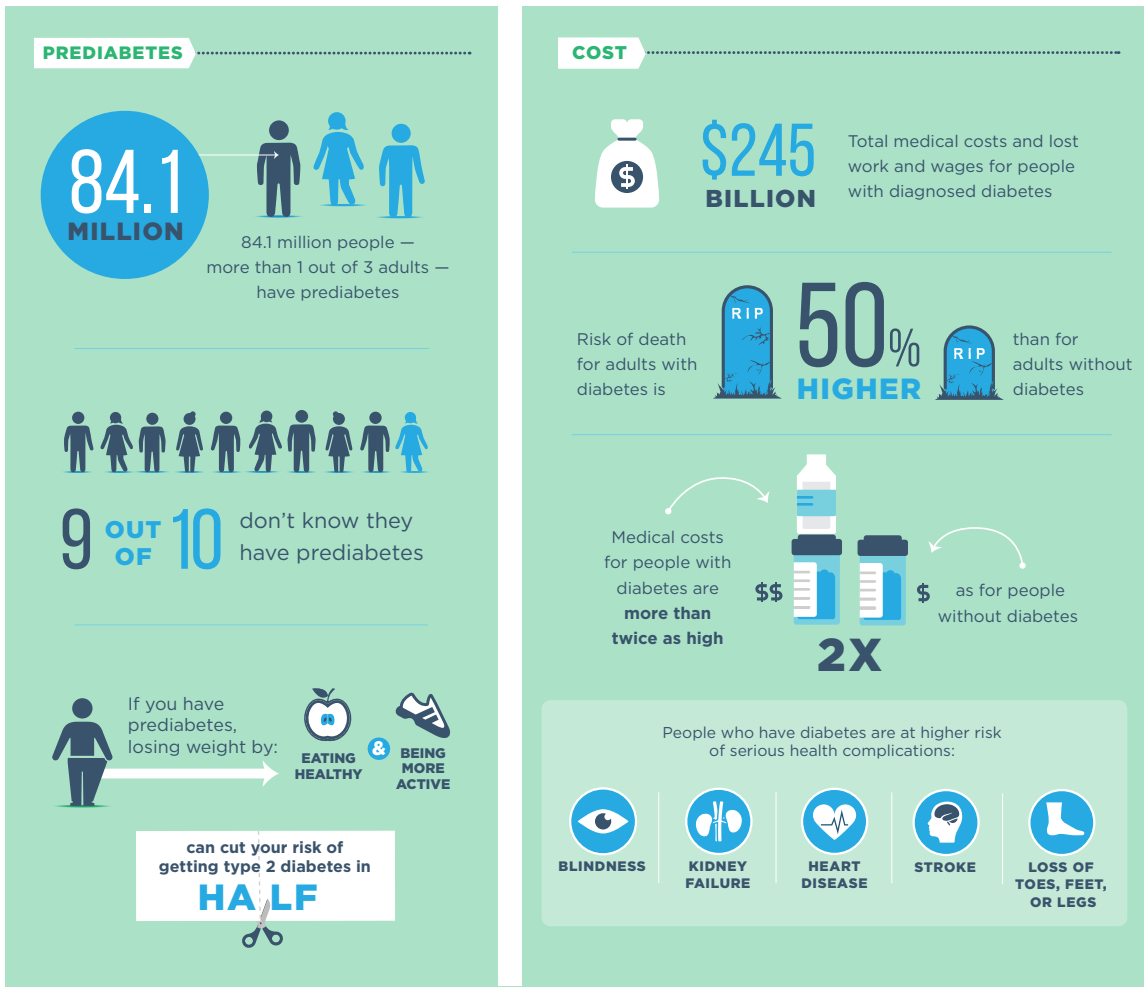
# SP448

## A Snapshot of Diabetes in the United States




Source : CDC

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## FROM THE CHAIRMAN

# In Diabetes Management, the Innovators Take Charge


MIKE HENNESSY, SR

**TECHNOLOGY'S ROLE IN HEALTHCARE** has been evident for some time, but few fields manifest the potential of self-care quite like diabetes. We've seen major advances in insulin pumps and continuous glucose monitoring (CGM) systems—and over the past year—new payer arrangements to fund them. Some say these designs could bring down costs, but patients worry they threaten choice and could stifle innovation, just as a new wave of smaller, more accurate, and less time-consuming tools is about to reach the market. A sticking point is government regulation. As the Government Accountability Office pointed out, CMS must update its standards to allow patients age 65 and older to use CGM with a smartphone and perhaps use disposable products.

Patients and advocates have moved the field forward, working with the FDA to ensure that the next generation of devices and drugs not only targets glycated hemoglobin but also reduces hypoglycemia and addresses the all-important time in range. As the number of patients with type 2 diabetes climbs, there are calls for more of them to embrace CGM to understand how their diet and exercise patterns affect their health. The goal is to keep people out of the hospital, and don't payers want that, too? Groups like JDRF are calling on payers to embrace what's coming, and soon, because there's a sense at diabetes meetings that the tipping point is at hand. It's driven first by the diabetes entrepreneurs, the patients and parents—such as the founder of Bigfoot Biomedical—who have hacked their way to solutions that they now seek to bring to others. It's happening because of the ubiquity of smartphones, and the sense that patients *can* get help managing diabetes—through companies like WellDoc—anytime, anywhere. It's happening because innovators, such as Abbott and Intarcia, are bypassing human imperfection to achieve perfect medication adherence and accuracy in glucose readings.

**Partnerships are forming all the time between startups and medical device mainstays, between pharmaceutical companies and tech giants like Google's Verily, which is working with Sanofi. It's all about the data, of course, and investors want in.**

Partnerships are forming all the time between startups and medical device mainstays, between pharmaceutical companies and tech giants like Google's Verily, which is working with Sanofi. It's all about the data, of course, and investors want in. Christopher J. Bergstrom, MBA, of Boston Consulting Group told the recent meeting of the American Association of Diabetes Educators that $700 million in venture capital went to CGM and digital health companies in 2016. Amid all the excitement, however, CDC released a new report showing the number of people with diabetes now exceeds 30 million, and 1 in 3 American adults will have the disease by 2050. Pharmaceutical and tech companies are also now working on ways to prevent diabetes, and that will be the next big challenge.

We hope that you enjoy this issue of *Evidence-Based Diabetes Management*™ and thank you for reading. ◆

Sincerely,

*Mike Hennessy, Sr*
CHAIRMAN AND CEO

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Display for Abbott Freestyle Libre Pro at AADE 2017.
Source : Abbott

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## FROM THE EDITOR-IN-CHIEF

# Dr Gabbay on Diabetes Technology, Payer Coverage, and Changing the Conversation

*Earlier this year, Robert A. Gabbay, MD, PhD, FACP, senior vice president and chief medical officer at Joslin Diabetes Center, who is editor-in-chief of* Evidence-Based Diabetes Management™ *took part in an interview and* Peer Exchange *on the growing role of technology in diabetes care. Below are excerpts from the interviews.*

**What developments in diabetes technology will we see in the next year?**

**DR GABBAY:** Diabetes technology is about to explode in terms of its impact on diabetes care, and I think there are a few different ways that's going to happen. One is in the realm of continuous glucose monitors; they're about to become cheaper and more accurate. A new one on the market doesn't require calibration—ultimately it has the potential, if it's inexpensive enough, to replace blood glucose monitoring as we know it with a lot more information. That added information could be used to help drive better outcomes for patients with diabetes.

The second one I'll mention is using that continuous glucose data to drive insulin pump changes, and the first step of that is the Medtronic MiniMed 670G, which will allow titration of insulin through the pump overnight to maintain near-normal glucose levels. It'll be a self-regulating system, the first time that's really been available. Initially it'll be only for a small subset of people, mostly those with type 1 and some with type 2 that are on insulin pumps, but I think that technology will continue to evolve and improve and become more widely available.

The third area that I'll mention, which I think is also very exciting, is the decision support tools and the ability to provide real-time information to patients, but also potentially to providers on how to better manage patients, and for patients how to better care for themselves. Being able to capture all the information—glucose levels, activity levels through step counting and other mechanisms, and dietary information—all on somebody's smartphone to help guide and coach them towards a better lifestyle could be very effective. Similarly, that information transmitted to providers in an intelligible and actionable way could also drive better care.

**Why does digital technology have hurdles in receiving payer coverage compared with a device, such as an insulin pump?**

**DR GABBAY:** I think one of the challenges for devices is that pathway of making iterative changes makes sense, and each thing is regulated and reviewed. But in these digital platforms, there are very few studies with, them but when they are done, usually the process of development is so rapid that in whatever they tested 2 years ago, they've got a completely different version—version 5.0. And so, our clinical trial system can't do the studies fast enough for the iterative changes in digital technology.

**Do we think these technologies change the conversation between patients and providers, and break down some barriers?**

**DR GABBAY:** I think they have the potential to. I think that's just beginning to be tapped. I think continuous glucose monitoring certainly helps. Even the simple ability of downloading blood glucose meter data and then looking at that with a patient, I think, is really helpful. But, I think there is a piece where we're not quite there yet.

One would imagine [a case where] someone has the glucose monitor on, something that's tracking their activities, something that's measuring all sorts of things and what they're doing, and then that data is fed back to their provider. Well, most providers don't want *all* that data. It's too much data. So, having some intelligent decision support tools that could analyze that data and flag individuals that need help is the piece that's happening at the margins. But, certainly, that's the next revolution.

To view the full Peer Exchange, "Technology in Diabetes Care, From Prevention to Disease Management," please see ajmc.com/link/2617. ◆

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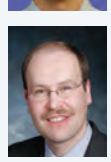

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# Digital Providers to Comment on Proposed CMS Limits for Medicare DPP Launch

*Mary Caffrey*

**FROM THE MOMENT WORD CAME** that Medicare would pay for the Diabetes Prevention Program (DPP), digital health providers have been eager to reach the 23 million seniors with prediabetes.[1,2] Many digital health providers have evidence their programs work just as well as face-to-face sessions, and industry leaders say CMS needs them to make a dent in diabetes care and management.[3,4]

No one blinked in June when a CMS official warned the original January 1, 2018, start date might be pushed back.[5] But what came next was a shock: on July 13, 2017, CMS proposed a Medicare DPP model that limited digital (or virtual) providers to giving makeup sessions only, all but leaving these providers out of one of the most important preventive health initiatives that Medicare has undertaken.[6]

Specifically, CMS proposed in the 2018 Physician Fee Schedule (PFS) that seniors must enroll in a traditional, in-person DPP program and that digital providers can only be paid for up to 4 make-up sessions. Although final comments are not due until September 11, 2017, as *Evidence-Based Diabetes Management*™ (*EBDM*™) went to press, published statements and interviews suggest digital providers will argue the proposal hurts seniors who live in the wrong places.

In fact, access could be especially poor in areas where diabetes rates are highest, based on CDC data.[7] Study results published earlier this year show this mismatch has already played out with diabetes self-management education and support programs. Unless CMS changes course, digital providers say, this could be repeated with the DPP when it launches April 1, 2018.[6,8]

The losers will be seniors and taxpayers, Omada Health CEO Sean Duffy argued in a recent commentary. "Diabetes and diabetes-related treatment is one of the biggest drivers of rising health care costs for every payer—with Medicare spending more on treating those with the disease every year. This is particularly true in rural America, as the prevalence of diabetes and coronary heart disease is approximately 17% and 39% higher in rural areas than urban areas," he wrote for *Morning Consult*.[9]

The DPP is a yearlong, evidence-based lifestyle program with a CDC-approved curriculum; it features 16 weekly core sessions, followed by a maintenance period of monthly sessions. Evidence shows the program stops prediabetes from progressing as participants make modest changes and lose 5% to 7% of body weight. In a landmark study by the National Institutes of Health, the program showed a 58% reduction in participants progressing to diabetes.[10]

HHS' decision to offer DPP in Medicare followed a successful pilot program the Center for Medicare & Medicaid Innovation (CMMI) conducted with the YMCA, which showed a savings of $2650 per beneficiary over 15 months.[1] The finding showed that DPP could help Medicare slow spending on diabetes, which currently consumes $1 of every $3 Medicare spends.[11]

Letting in-person programs form partnerships with digital providers for make-up sessions could be helpful. Evidence shows that once DPP participants miss 2 sessions, the inability to make them up is a chief reason people drop out.[12] Some say excluding digital-only programs is a missed opportunity to attract seniors who are unable or unwilling to take part in a weekly, in-person program. For example, most DPP participants thus far have been women, and digital programs may attract more men.[13]

Neal Kaufman, MD, MPH, founder and chief medical officer of Canary Health, said in a recent interview with *EBDM*™ that achieving widespread DPP delivery requires both in-person and digital programs. "Digital is ubiquitous, 24/7. The person doesn't need to get in their car to get to the appointment. They can access it from the privacy of their home, they can come in for 5 or 10 minutes if that's all they have that day, or they can spend an hour or longer if need be," he said. "It identifies and helps people who don't like to join groups."

In the proposal, CMS argues that the CMMI demonstration was based on an in-person program and that a 100% virtual DPP program is untested, at least within Medicare. "Instead, we are considering a separate model under CMS' Innovation Center authority to test and evaluate virtual DPP services. Our intention is that any separate model test of virtual DPP services would run in parallel with the MDPP Expanded Model. Consistent with our regular practice for Innovation Center models, we would release details on the model test for virtual DPP services separately."[6]

This argument overlooks the fact that CDC created a process for digital providers to submit data and achieve recognition status the same way traditional programs do. This has allowed digital providers to offer commercial payers and employers proof that their programs meet evidence-based standards and CMS has access to this data.[14]

The proposed PFS makes other changes that promise more flexibility to Medicare clients—notably a maintenance period that can last up to 2 years if the person meets weight loss and attendance goals. There's strong emphasis on performance-based payment, with a detailed schedule of fees for different benchmarks. CMS has called for 50% of Medicare payments to be value-based by 2018.[6]

Anne Woodbury, executive director of the Council for Diabetes Prevention, which represents both digital and in-person providers, said the group will also seek clarity on what happens with DPP programs that are already included within some Medicare Advantage policies. In an interview with *EBDM*™, Woodbury said the proposal points up a broader issue within HHS: "How do we maximize the use of new technology in the delivery of care?" Old regulatory structures can't accommodate the levels of innovation that are changing the way care reaches patients, she said. "It's a real challenge, and Medicare DPP is feeling that friction right now." ◆

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COST SAVINGS

# Glytec Moves Beyond Clinical Results to Touting Savings

*Mary Caffrey*

McFARLAND

RHINEHART

BOOTH

*Raymie McFarland is vice president of Quality Initiatives and Clinical Excellence for Glytec.*

*Andrew S. Rhinehart,MD, FACP, CDE, BC-ADM, CDTC, is chief medical officer for Glytec.*

*Robby Booth is senior vice president of Research and Development for Glytec.*

**THIS JUNE, GLYTEC CAME TO** the American Diabetes Association (ADA) Scientific Sessions with a new story to tell.

In years past, Glytec came ADA armed with data showing that eGMS, a cloud-based glycemic management decision support system, offered a superior way for hospitals to manage insulin therapy for patients.[1] Company officials brought a new focus to the 77th Scientific Sessions in San Diego, California, saying that it's not enough to offer better time in range. Glytec wants to show how its results translate into what matters most to payers—and a hospital's bottom line.

"We know we can get the glucose under control," said Andrew S. Rhinehart, MD, FACP, CDE, BC-ADM, CDTC, chief medical officer of Glytec. "Now, the issue is: How does that intermediate outcome turn into a hard outcome—lower readmissions?" And that translates into financial savings.

"Does fixing glucose really fix everything else?" Rhinehart asked rhetorically during an interview with *Evidence-Based Diabetes Management*™ (*EBDM*™). It turns out that stabilizing blood glucose levels can fix a lot of things, leading to shorter hospital stays, fewer readmissions, and lower infection rates among patients—all factors that hospitals are graded on in this era of value-based care.

Rhinehart credited the shift in strategy to Raymie McFarland, vice president of Quality Initiatives and Clinical Excellence, who previously led quality improvement processes for Sanofi. Glytec's FDA-cleared algorithm suite, known as Glucommander, can assist providers with glycemic management at all points on the continuum of care, which will be increasingly important as health systems work to comply with the Medicare Access and CHIP Reauthorization Act (MACRA).

The growing importance of quality ratings will put pressure on hospitals to meet ADA standards without extra manpower. As a practical matter, there aren't enough endocrinologists to meet demand, due to lagging incomes in the field and a rise in the number of people who need these specialists. "As the market moves toward value-based reimbursement, we're there—we're ready for it," Rhinehart said.

Robby Booth, senior vice president of Research and Development at Glytec, noted a distinguishing feature: Glucommander can interact with major electronic health record systems, a hurdle that has kept many digital providers from making headway. (Glytec has reported case studies involving integration with Epic Healthcare Solutions, which is used by many of Booth's clients.[2])

## Partnerships Are Key

In an interview with *EBDM*™, Booth said that Glytec has formed key partnerships with other technology companies—AgaMatrix, maker of a Bluetooth glucose meter, as well as Livongo and Telcare, which make cellular meters—to capture glucose data from the cloud. Glytec has shown that, instead of needing 18 months' worth of appointments to help patients reach their glycated hemoglobin goal, physicians can use the system to titrate patients in 11 or 12 days. "We want to be able to get that patient titrated to goal as quickly as possible," Booth said. "[To be] able to do that remotely, it's really critical to have that data from the patient [who] is testing in the home environment."

The gradual development of skill sets, from the early focus on critical care patients to the ability to help care for noncritical patients, has positioned Glytec for growth as MACRA arrives. "After 11 years, we're an overnight success," Booth said.

## Results From the Kaweah Delta Medical Center

Showing how glycemic management fits into a quality care strategy offers a context for the results Glytec presented at ADA, McFarland said.

A decade ago, the ADA called for hospitals to shift from sliding scale to subcutaneous basal-bolus insulin therapy for non–critically ill patients. However, concerns that staff could not keep up with the dosing demands kept most hospitals from upgrading to the standard of care.

Earlier in 2017, Glytec presented data highlighting how eGMS offered hospitals a way to meet the basal-bolus standard, reducing the number of days patients were out of range.[3] At the June ADA meeting, Glytec offered proof that the system not only improves glycemic control but also saves time and money.[4] The data came from Kaweah Delta Medical Center in Tulare County, California, where 13.2% of the county has diabetes. After struggling to convert to basal-bolus insulin, the hospital succeeded with help from Glucommander, an electronic-guided insulin dosing system.

In 2015, researchers matched 1039 patients who received usual care with 3200 patients treated during the first year after the switch to eGMS (March 2016 to March 2017). The results showed an overall savings in the first year of $7.1 million, including $2.6 million achieved by cutting the average length of stay from 7.18 days to 5.51 days.

The share of patients with hypoglycemia (<70 mg/dL) was lower with Glucommander (20.10%) than with usual care (30.31%), even though the Glucommander brought a reduction of 69,256 insulin adjustments. The calculated time saved per patient was nearly 200 minutes; the time saved per shift, 30 minutes.

Before the hospital implemented the Glytec system, basal-bolus insulin was used only 5% of the time; afterward, the situation was reversed, with basal-bolus used 96% of the time—particularly noteworthy, given how much the hospital had struggled to make the switch before engaging Glytec, McFarland said. While basal-bolus is the standard of care, "it's difficult to do this for every patient with no endocrinology support," he said. ◆

*Christina Mattina contributed to this report.*

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# Latest Results on Intarcia's Mini-Pump Show "Clear Value to Payers," Says Study Author

*Mary Caffrey*

**WHILE WAITING FOR THE** FDA's decision on its novel mini-pump to treat type 2 diabetes (T2D),[1] Intarcia Therapeutics has presented a fresh round of evidence aimed at a different audience: payers.

The results of a pair of studies presented in June at the 77th Scientific Sessions of the American Diabetes Association (ADA) in San Diego, California, showed that patients with T2D who used Intarcia's ITCA 650, a matchstick-size pump that delivers microscopic doses of exenatide, were less likely than patients taking sitagliptin to need an additional drug to control their diabetes.[2,3]

The author of one of these studies, Robert R. Henry, MD, professor of medicine at the University of California, San Diego, said in an e-mail to *Evidence-Based Diabetes Management*™ that the findings add to the evidence that show "clear value" for payers. Not only can payers avoid the cost of additional medication, but by ensuring compliance, he said, they can also reduce the likelihood of complications that send patients to the hospital.

Results from other studies presented at ADA in June showed that ITCA 650 was safe to take alongside common drugs such as birth control pills, acetaminophen, and statins.[4,5] These results are important because the ITCA 650 is designed to be inserted under the skin and left in place for up to 6 months.

By the time the FDA accepted Intarcia's new drug application in February, the company had presented results showing twice the reduction in glycated hemoglobin (A1C) as sitagliptin, 3 times the weight loss, as well as top-line results that showed ITCA 650 met end points of a cardiovascular (CV) safety study.[1,6,7] What sets ITCA 650 apart in the market is the possibility of tamper-proof persistence for patients whose T2D was not controlled with metformin. For those unwilling or unable to take a pill or injectable on schedule, this "is one of the major features of ITCA 650 [that] make it so valuable," said Henry, who is also the chief of section, Diabetes, Endocrinology & Metabolism, and director at the Center for Metabolic Research, VA San Diego Healthcare System.

As Henry noted, compliance has vexed every drug on the market—both oral and injectable—and in the real world, no therapy has been able to overcome the problem of certain patients who simply don't stick with a regimen and develop costly complications. (For similar reasons, Proteus Digital Health is working on a pill with a digestible sensor to monitor compliance.[8])

Henry has studied the ITCA 650 for some time and was the lead author of an abstract that pooled data from 39-week and 52-week studies to compare patients on ITCA 650, sitagliptin, and placebo. Patients began with an average A1C of 8.6%, and there were predefined protocols for including additional oral antidiabetic therapies if patients' A1C was not maintained below 8%. Most patients on ITCA 650 maintained glycemic control below this threshold, the abstract said (**FIGURE**).[2]

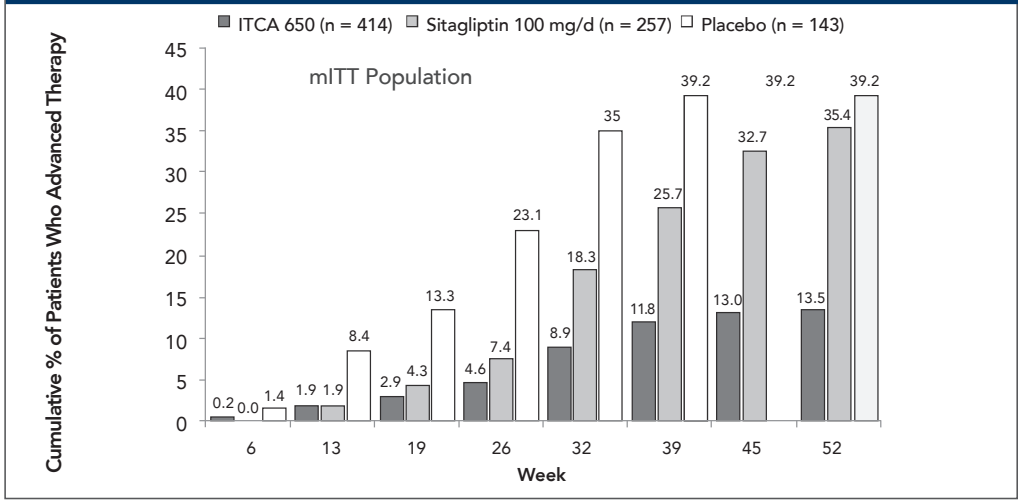
"An increase in [antidiabetic therapy] occurred in all groups at week 26, but 88% of ITCA 650 patients remained on assigned therapy at week 39," the authors wrote. "In contrast, there was a progressive increase in the need for [antidiabetic therapy] in the placebo and sitagliptin groups at week 26."[2]

In the e-mail, Henry said the ability to ensure constant delivery of exenatide, a glucagon-like peptide-1 (GLP-1) receptor agonist, stands apart from the normal delivery method for this powerful drug class. "All other GLP-1 agonists are given by subcutaneous injection and are frequently associated with noncompliance for numerous reasons, despite the fact that aside from insulin, they are the most efficacious glucose-lowering agents," Henry said.

Compliance issues cause patients to miss out on weight-loss benefits and, in some cases, CV-risk benefits, he said. Ensuring persistence, Henry said, offers "clear value to payers—not only the immediate cost of not having to use other medications, many of which may be less effective or also associated with noncompliance."

Just as important, or perhaps more so, "ITCA 650 use translates to overall better glycemic control compared [with] noncompliant use of medications, with lower risks of complications, mainly microvascular and perhaps macrovascular disease," he said. "I believe these features make ITCA 650 very attractive to payers." ◆

**FIGURE.** Percentage of Patients Who Advanced Antidiabetes Therapy on or Before Certain Weeks.




ITCA 650 included FREEDOM1 and FREEDOM2; Sitagliptin was from FREEDOM2 and Placebo was from FREEDOM1.
mITT indicates modified Intent-to-treat.

HENRY

*Robert R. Henry, MD, is professor of medicine at the University of California, San Diego, and chief of section, Diabetes, Endocrinology & Metabolism, VA San Diego Health System.*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# Experts Offer Perspectives on "What's Now and What's Next" for Artificial Pancreas Systems

*Christina Mattina*

**AT A SYMPOSIUM DURING THE** 77th Scientific Sessions of the American Diabetes Association, researchers discussed the progress that has been made in developing hybrid closed-loop (HCL) insulin delivery systems—and what challenges remain.

Also known as an "artificial pancreas," an HCL system consists of an insulin pump and sensor that uses an algorithm to continuously monitor glucose and adjust insulin dosing. These systems aim to reduce glycemic variability and make it easier for patients with diabetes to stay in their target glucose range.[1]

HOVORKA

Roman Hovorka, PhD, of the University of Cambridge, kicked off the symposium by presenting the perspective from Europe, where recent study results demonstrate promising outcomes with HCL systems in outpatients with diabetes. The technology is such a hot topic that a question about the artificial pancreas appeared on the General Certificate of Secondary Education exams taken by 16-year-old students in the United Kingdom.

Hovorka highlighted the promising results of several European trials that saw patients with diabetes improve their time in target glucose range and lower their rate of hypoglycemic events when using HCL systems. For instance, the Pediatric Artificial Pancreas project tested such a device in children with type 1 diabetes (T1D) attending an overnight camp in Italy and found that their time in hypoglycemia was 3-fold lower than when they used a standard insulin pump.[2]

Another study he discussed tested HCL insulin systems in pregnant women with T1D in the United Kingdom and found that the systems improved the time in target glucose range and reduced incidences of hyperglycemia compared with standard pump therapy, both overnight and over a 24-hour period.[3] Even when the women went into labor, there were no instances of hypoglycemia during the 24 hours before and 48 hours after delivery. Notably, the women reported improved sleep, reduced worry, and feelings of empowerment and reassurance while using the HCL system to control their glucose levels.

When taken together, Hovorka said, these study findings provide evidence that HCL systems can increase time in optimal glucose range and are well tolerated by users and in pediatric populations and their guardians.

Eda Cengiz, MD, MHS, FAAP, associate professor of pediatrics at Yale School of Medicine, offered her take on "what's now and what's next" in HCL systems from the American perspective. She highlighted the evident need for better glucose management, as a majority of patients with diabetes have poorly controlled glycated hemoglobin levels and the dangers of complications are ever-present.

CENGIZ

After providing an overview of the terminology associated with continuous glucose monitoring systems, including HCL systems, Cengiz discussed the findings of a study on Medtronic's MiniMed 670G, the first HCL system to enter the US market.[4] This insulin-only system increased time in target glucose range for adults and adolescents with T1D by reducing hyperglycemia and hypoglycemia and was shown to reduce glycemic variability.

The study, which was conducted while patients were at home and did not require meal restrictions, found that the MiniMed 670G was well tolerated and that patients reported high satisfaction and quality of life while using the device. No events of diabetic ketoacidosis or severe hypoglycemia were observed in either the adults or adolescents.

Eda Cengiz, MD, MHS, FACP, discussed new findings on Medtronic's MiniMed 670G, the first "artificial pancreas."

Cengiz also described several studies that tested the HCL systems with exercise or other challenging conditions. For instance, the Type Zero DiAs system was tested while users were skiing and among typical adolescents who may forget to deliver an insulin bolus; results showed that it reduced time in hypoglycemia and resulted in better glycemic metric outcomes.[5] Researchers observed some alarm burnout, but 100% of participants described the system as beneficial.

> **"There is a digital revolution everywhere in our lives, and it's unrealistic to think that diabetes will be isolated from this technology revolution."**
>
> —Eda Cengiz, MD, MHS, FAAP, associate professor of pediatrics, Yale School of Medicine

With these successful findings in mind, Cengiz acknowledged some opportunities for artificial pancreas systems to improve. She said they need to be tested in broader, more representative patient populations and noted that after-meal glucose control could be better achieved through the use of ultra–fast acting insulins. Finally, the burden to the patient needs to be alleviated by creating more user-friendly systems and providing more device training and support. HCL systems, Cengiz said, represent a new, team-based approach to diabetes management that requires patients and providers to think of technology as an ally.

"There is a digital revolution going on everywhere in our lives, and it's unrealistic to think that diabetes will be isolated from this technology revolution," she concluded. ◆

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# CGM "Debate" Finds Benefits, Barriers to Uptake in Type 2 Diabetes

*Mary Caffrey*

**THE MOOD WAS LIGHT**—where else do presenters' slides feature the back side of a rhinoceros and a smiling monkey—but the message was serious: after decades of trying and more than 40 drugs with FDA approval, large numbers of patients with type 2 diabetes (T2D) still have poor glycemic control.

Could broader use of continuous glucose monitoring (CGM) be the answer in T2D? For the right patients, yes, but the challenge is identifying those patients, according to Jeremy Pettus, MD, and William H. Polonsky, PhD, CDE, both from the University of California at San Diego, the host city for the 77th Scientific Sessions of the American Diabetes Association (ADA), which took place June 9-13, 2017.

PETTUS

POLONSKY

The ADA session, Should Continuous Glucose Monitoring Be Prescribed for People with Type 2 Diabetes? A Pro/Con Discussion, was styled as a debate, but Pettus and Polonsky turned it into a lively exchange of evidence that supports CGM for patients with T2D, along with research gaps and practical barriers to bringing the technology to more patients.

They started with a key ground rule: they had refused to debate CGM use for patients with type 1 diabetes (T1D) because it's the standard of care, but they took note of the recent Medicare rule change that would soon bring Dexcom's G5 to beneficiaries on intensive insulin therapy, which affects most patients with T1D and some with T2D.[1]

After Polonsky took the "con" position for sections on patients who use insulin, he and Pettus switched sides—and suit jackets—to debate CGM use for those with T2D using oral medication, who represent most patients with diabetes. Pettus started with an update from the DIAMOND study, which had previously shown that CGM was just as effective for patients with T1D using multiple daily injections of insulin as those using pump therapy.[2] New data from patients with T1D and T2D who use CGM show that it helps those using daily injections across both patient groups.[3]

The question about CGM, Pettus posed, is, is it worth the burden and the cost? It's worth noting, he said, that patients associate how sick they are with the number of medications they take. Unlike medication, CGM has "no side effects."

There are concerns about patients learning to use CGM, especially if they develop T2D when they are older and less tech savvy. Pettus said there's other evidence that shows that with limited instruction, a 1-page handout, patients with T2D learned to use CGM and it made a difference. What's more, he said, it made the biggest difference in patients with glycated hemoglobin above 9%, a group that "we might write off as hopeless." For these patients, seeing what certain foods and exercise does to blood sugar proves an eye-opener. "People seeing it in real time is empowering," Pettus said.

Many assume CGM will require more of a doctor's time, but it could require less in the long run. "We have a paternalistic view of medicine, and that's just not the case with CGM," Pettus said. Armed with better tools, patients "might not need us, and that's OK."

Polonsky said the main challenge is that patients with T2D with the most severe hypoglycemia haven't been studied—and they should be. He read from one of Pettus' papers to raise the question whether patients had the confidence to actually use their CGM consistently. "Maybe," Polonsky said, "but we need more evidence."

Pettus sought to dispel several myths about CGM and basal insulin: (1) titration with self-monitoring isn't perfect; (2) people will use the results, as seen in one study that showed patients using CGM ate fewer calories, lost weight, and exercised more; (3) hypoglycemia is a significant problem in T2D, and tests with CGM showed people had events that might have gone unnoticed, but the CGM allowed them to act.

In response, Polonsky said a 2014 study involving CGM in patients with T2D on basal insulin produced great results—but also involved frequent contact with the patients. There were 10 visits over 6 months, more than would happen in the real world.[4] "Was it the CGM or the remarkable support these folks got?" he asked.

When Pettus and Polonsky switched sides to discuss CGM use for those on oral agents, Polonsky—who is an advocate of advancing CGM in the right populations—presented data to show the dismal picture of T2D, despite the ever-increasing number of medication choices. "Why is it that so many folks have a tough time taking medications?" he asked. "Nobody is unmotivated to want to live a long life. We are, at best, ambivalent."

"We know there are active fears about medication," he added. By contrast, CGM can offer a chance "to become engaged and stay engaged." The use of feedback, he said, "is the most underutilized tool we have."

For some patients, CGM doesn't have to be all the time or forever. Polonsky envisions that some patients with T2D could "rent" a CGM device for a month, then maybe a few weeks a year, to get in touch with the patterns of their behavior and the effect on glycemic control.

Polonsky knows there's an argument that patients will never understand the data. That's the wrong way to think, he said. "What if we provided help and support so they know what these numbers mean? Can we help people have this 'Aha!' experience?" he asked.

He read a case study of a patient with T2D who started using CGM and now couldn't imagine going back to "being blind" managing his diabetes without it. "The government might not think I need this," the person wrote, referencing Medicare's old policy, "but you'll have to pry it from my cold, dead hands."

Pettus ended with a photo of a crowded waiting room, likely in a primary physician's office. The practical reality, he said, is that time constraints and insurance barriers make it too easy to just write a prescription than to take time to teach patients how to use CGM.

Pettus and Polonsky agree that CGM should only be tried in patients who show some willingness. Tthe question is how to identify who they are, and they agreed more evidence is needed. CGM costs would need to come down, and the technology would have to become even easier to use. Insurance coverage will remain a barrier until there's more evidence that the technology is cost-effective.

Polonsky said the idea that patients with T2D might not use CGM because doctors are too busy, "makes me very sad." ◆

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**Diabetes Management Guidelines: What Pharmacists Should Know**

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# For Diabetes Educators, Technology at Every Turn

*Mary Caffrey*

**FROM THE ENTHUSIASTIC CROWD** at the keynote address, "Let's Get Digital," to an exhibit floor where device makers consumed more real estate than drug companies, there was no missing technology's rise in diabetes management. And there's more to come, along with policy questions, said speakers at the annual meeting of the American Association of Diabetes Educators (AADE), held August 4-7, 2017, in Indianapolis, Indiana.

Digital health attracted $450 million in venture capital and continuous glucose monitoring (CGM) grabbed another $250 million in 2016, according to Christopher J. Bergstrom, MBA, an associate director at Boston Consulting Group, who spoke on August 6. Technology's role in both treating and preventing diabetes is crucial, notwithstanding CMS' early decision to leave digital providers out of the 2018 launch of the Medicare Diabetes Prevention Program.[1]

BERGSTROM

"There's one thing I know," Bergstrom said. "Digital *will* be part of it. Why? There [are] 84 million people with prediabetes!"[2]


Abbott Freestyle Libre Pro.
Source : Abbott

He noted the alliances that have formed between startups and medical device mainstays, and between tech giants, like Google's Verily and pharmaceutical giant Sanofi. The marriage of healthcare and data will bear dividends that have yet to be fully understood. "The new data sets are the patient-centered data sets," he said.

What can insurance companies learn about diabetes and depression from scanning 30,000 social media posts? Companies like Medtronic are asking, "How do we go beyond the pill?"

## Role of Diabetes Educators

Diabetes educators are the foot soldiers who teach patients to use blood glucose meters, CGM systems, and digital tools that let patients track their personal data or share it with providers. The era of population health—and accountability for patients' glycemic control—made for a standing room-only crowd at Abbott's presentation on the FreeStyle Libre Pro, which lets an educator or physician collect 2 weeks' worth of data with no effort from the patient. FreeStyle Libre Pro won FDA approval 1 month after last year's AADE meeting, just one of many technology developments over the past year.[3]

Also at the meeting, many educators wanted details on how to bill Medicare for Dexcom's G5 continuous glucose monitor—and why CMS won't let patients use their smartphone.[4] And on August 7, MannKind Corp, maker of inhaled insulin Afrezza, announced at the meeting it would be part of a clinical trial with One Drop, the digital device platform, evaluating its effectiveness in combination with the management tool.[5]

Not every digital health tool can serve every purpose, but various ones on the market can:

- Track patient data, which clinicians can use to make medication adjustments
- Offer reminders to take medication
- Offers AADE's curriculum through a smartphone,[6] such as what WellDoc's BlueStar system can do.
- Provide real-time feedback for patients managing their disease

## Digital Health and the Triple Aim

On Sunday afternoon, Kevin Clauson, PharmD, associate professor of Lipscomb University, addressed how diabetes educators can harness the potential of digital health. As digital tools become smaller, less expensive, and better connected to health systems, they have the potential to improve self-care, deliver a better patient experience, and lower costs. The catch, he said, is that patient data will become a commodity. Clauson said educators must be mindful of this when their patients have opportunities to use free or low-cost options.

He reviewed more up-and-coming technological tools, many of which could improve medication adherence. Proteus Digital Health, which received attention throughout the meeting, can include a digestible sensor in a pill, which offers the first fool-proof way of measuring adherence. Type 2 diabetes and hypertension are high on its list of target conditions.[7] Apple, he said, also is working on another step: "middleware" will let health systems connect all of the data from thousands of apps and wearables into usable information that can be integrated into an electronic health record.

However, the questions here are not just technical. Health systems are concerned about being overwhelmed with patient data and being held liable if they fail to act on something that lands in patient record.

> **"There's one thing I know," about Medicare's Diabetes Prevention Program. "Digital will be part of it. Why? There are 84 million people with prediabetes!"**
>
> —Christopher J. Bergstrom, MBA, Boston Consulting Group

As Bergstrom said in his morning talk, the ethical and policy questions will come faster than anyone realizes. The next generation of tools is at the doorstep. "There's going to be a tipping point, right before we know it," he said. ◆

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# WellDoc's BlueStar Seeks to Empower Patients With Type 2 Diabetes Through Real-Time Coaching, Provider Feedback

*Mary Caffrey*

**IT'S ONE THING TO GIVE PEOPLE** with type 2 diabetes (T2D) information on their blood glucose trends and send them on their way. It's quite another to give them access to real-time coaching and let them share their data by pressing a button, possibly heading off an episode of hypoglycemia.

This more intense level of support is the idea behind WellDoc's BlueStar digital diabetes products, which look like apps on a smartphone but have FDA clearance to do much more.[1] BlueStar is on the comprehensive end of an array of solutions in diabetes self-care, which address what clinicians say is their biggest challenge: what happens between visits.

Harnessing technology to give patients advice in the moment, to record what they eat in real time, or to automatically take their blood sugar may do more than remove the guesswork for physicians. There's hope that if technology usage becomes the norm in diabetes care, patients will finally connect the dots between specific foods and behaviors and the effects on their health. Today, BlueStar offers 3 products: the flagship product that connects patients with T2D with coaches and caregivers, a prescription-only product that features an insulin bolus calculator, and a consumer-focused lifestyle app, available through Samsung Health.[1]

Over the past year, WellDoc has made a series of moves to reach a wider audience and bolster key partnerships, most notably with the American Association of Diabetes Educators (AADE).[2] The biggest change came in January, when the FDA allowed WellDoc to offer the mainstay BlueStar app without a prescription, which opened the door to reach patients directly through health plans and wellness programs.[3]

These changes position the company to not only deliver better care, but also to help physicians make strides toward population health as they face new requirements under the Medicare Access and CHIP Reauthorization Act (MACRA). Since September 2016, WellDoc has also:

- Finalized a commercial partnership with LifeScan, a Johnson & Johnson company, that allowed BlueStar to integrate its digital platform with LifeScan's OneTouch VerioFlex glucose monitoring system and the OneTouch Reveal digital system (see **SP444**).[4]
- Announced a far-ranging partnership with AADE that puts the professional association's curriculum on the app.[2]

WellDoc unveiled a second piece of the partnership at AADE's annual meeting in August, when it launched its Diabetes Digital Health Learning Network to share best practices for gathering patient health data to improve population health.[5]

In a wide-ranging interview with *Evidence-Based Diabetes Management*™, WellDoc vice president of clinical advocacy, Malinda Peeples, RN, MS, CDE, FAADE, a past president of AADE, described the evolution of the WellDoc platform as an "interventional solution," compared with the "trackers" that some patients with T2D use.

Although BlueStar "looks and acts like an app," Peeples said, "We have real-time feedback messaging based on when people enter data. Then we have trending messages that are looking at patterns and are engaging patients in self-management and problem-solving around those patterns. We're also providing weekly summaries."

Patients can examine their diet, activity, and sleep to change behavior or reach out to their doctor if they need help. There's also a 12-week self-management curriculum and a resource library within the app, she said.

Janice MacLeod, MA, RDN, LDN, CDE, director of clinical innovation for WellDoc, said the individualization of the feedback is key. "The individualization is not just in the messaging. As BlueStar is learning and growing with the patient, it's also individualizing the prompts and reminders of what to track and when. And then the [care] team gets the information it needs."

WellDoc has learned plenty about how patients with diabetes respond to mobile technology compared with other forms of learning, Peeples said. "For us, the exciting part of the mobile platform is that it has forced us to be smart about that. How do you display a nugget of content on a screen that someone can read in 30 seconds?"

## Working With Payers

Although technology holds great promise in diabetes care, WellDoc and other digital providers are new players in the reimbursement arena. Payers have years of experience evaluating drugs or devices, like insulin pumps or stents, but what is the best way to evaluate an app? BlueStar regularly presents evidence at the American Diabetes Association and other professional meetings, showing proof of patient engagement,[6] or results from a pilot study with a patient-centered medical home (PCMH).[7]

For Peeples, BlueStar's value isn't just in what it can do for patients on an individual basis, but also in what it can do to help health systems gather information to improve population health. "We can provide summary data for all your BlueStar users," Peeples said. Claims data won't offer insight into what happens before patients end up in the hospital or the emergency department, but this type of data will, she said.

WellDoc's work with payers includes the PCMH demonstration with Horizon Blue Cross Blue Shield New Jersey, which found that if practices can get patients to start using BlueStar, most will stick with it and see results. Of the 89 patients with T2D who were offered the opportunity to receive telephone coaching and use the BlueStar technology, 43 accepted. Of these, 86% both used the app and filed a report, known as a SMART report, with their doctor. Patients logged an average of 6.5 entries per week. For those active with health coaching (70%), the combination reduced glycated hemoglobin by 1.7%, from a baseline of 9.7%.[7]

## Helping the Primary Care Physician

According to Peeples, the headwinds of MACRA have physicians looking for ways to help patients do 2 things: better manage their diabetes between visits and understand their disease so they can better engage their care team.

Peeples described a meeting with a primary care practice in search of a solution to "train" its patients with diabetes so that it could take some of the burden off the practice. "The practice needs to deliver the outcomes," she said. The historic, paternalistic thinking in medicine is giving way to the realization that getting patients to take charge is in everyone's interest.

"We are underestimating the power of the individual patient," she said. ◆

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# J&J's OneTouch Reveal: Connecting Diabetes Patients With Physicians, Managed Care

*Mary Caffrey*

**AS MICHAEL WEINBERGER EXPLAINS,** diabetes self-care technology has turned a critical corner: everybody's using it.

The senior director of digital product development and innovation for Johnson & Johnson Diabetes Care Companies demonstrates the new version of the free app, OneTouch Reveal, which can be downloaded from the App Store or Google Play. With this update, someone with diabetes can instantly sync a blood glucose reading from a meter to the app, sending the result to the top of the Facebook-like feed. A color-coding system shows if the person's blood glucose is in normal range or in a range that's considered hypo- or hyperglycemia.

It's simple and intuitive. No one needs instructions to understand that "green" means blood sugar is in range and "red" means it's high. A quick look at a chart full of readings will reveal if there are too many reds or blues, the latter signaling low blood sugar—always bad news for people with diabetes.

It wasn't always this way. Early on, diabetes technology—including early versions of OneTouch Reveal—overwhelmed patients with numbers but didn't always offer context, Weinberger said, when *Evidence-Based Diabetes Management*™ visited the Johnson & Johnson offices outside Philadelphia. Just as personal computing finally jumped from early hackers to systems that were friendly enough for everyone to put at their desk, diabetes technology is doing the same, and Johnson & Johnson thinks OneTouch Reveal 3.0 will open that door for new groups of patients, especially the majority with type 2 diabetes (T2D), who, until now, may have shied away from apps.[1]

"It's recognition that our users and our patients are like everyone else—they are impacted by digital technology," Weinberger said. "They want digital to be a part of everything that they do in their life, to make everything they do more effective, efficient, and convenient."

That's not to say that OneTouch Reveal won't still provide blood glucose patterns or tables in traditional formats. "The beauty of the Reveal app is that it can be simple or it can be a little more complex for those patients who want a little more complexity," said Brian Levy, MD, chief medical officer for Johnson & Johnson Diabetes Solutions Companies.

It's a revolution with huge possibilities for both individual care and population health, as it promises to tackle the problem that most vexes physicians: engaging patients between visits to catch cases of severe hypoglycemia before they results in a hospital visit. For this latest version of Reveal, Johnson & Johnson will promote a new feature: getting patients to connect their data with their physicians' practices so panels of diabetes patients can be monitored from afar and adjustments can be made well ahead of the 3-month appointment.

Saleem Ahamed, vice president, Global Franchise Organization, LifeScan, Inc, the Johnson & Johnson subsidiary that makes OneTouch diabetes products, said the effort to connect physicians and patients began this summer in the United States and Canada, will launch in 9 European countries in September, and will reach India by the end of 2017.

Johnson & Johnson has a partnership with WellDoc, which offers the BlueStar therapeutic app, including one version that sets insulin doses and requires a prescription (**SP443**). The BlueStar product offers round-the-clock coaching and individualized feedback based on the data the patient provides. Although OneTouch Reveal doesn't do this, it does offer engagement and, more importantly, a much easier way to understand the patterns that accompany high or low blood glucose so that patients can start thinking about how their behavior affects their health.


The OneTouch Verio Flex meter, at left, shows the ColorSure system that tells people with diabetes if their blood glucose is in range or too high or too low. Blood glucose data can be sent directly to the OneTouch Reveal app, shown on a smartphone at right.
Source: LifeScan

"What it does is help patients gain insight into what their numbers mean," Levy said. More importantly, by giving patients a free way to share data, it offers a way for physicians to get the information they need. Patients who need full-time coaching and more intense intervention would use BlueStar, Levy said, but once the patient's glycated hemoglobin (A1C) gets under control, he or she could use OneTouch Reveal to monitor blood glucose patterns.

Levy was a co-author of a recent study that found using the app makes a difference. Published in the *Journal of Medical Internet Research*, the study randomly assigned 137 patients with diabetes (A1C ≥7.5% to ≤ 11%) to use either the OneTouch Verio Flex meter or the meter along with the OneTouch Reveal app, for 24 weeks. The difference in A1C among patients with T2D using the meter with or without the app was significant: patients using the meter saw their A1C drop 0.58% while those using both who received at least 10 text message saw their A1C drop 1.05%. The biggest improvements were seen in patients with T2D who received the most messages from a healthcare professional.[2] The qualitative results generated claims that show the color-coding system is easy for patients to follow, Levy said.

Ahamed said besides physicians, Johnson & Johnson is sharing these results with health plans. "What payers are looking to do overall is to reduce costs, and a direct way of doing that is to help patients better manage their disease," he said. "This kind of system not only gives the patient a number, but it helps them to understand what the number means so they can make a more informed action. Hopefully, that will get the patient in better control and reduce costs to the system."

Weinberger said with a patient's authorization, managed care plans can have access to the information to intervene as needed. Pharmacies are working with Johnson & Johnson to have access to the information as well, with 1 partnership involving Walgreen's. Levy said the pharmacy offers patients incentives to take blood glucose readings regularly and upload them to the app.

Future healthcare will inevitably involve technology, Ahamed said. "Technology is not the objective, but it's what the technology enables you to do to help patient. That's the objective."

"It's not an option," Weinberger said. "If we want to be relevant and bring the most meaningful products to the market right now, technology has to be part of it." ◆

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# GAO Reviews Medicare's Approach to Covering Medical Equipment, Including Insulin Pumps

*Mary Caffrey*

**A RECENT REPORT FROM THE** Government Accountability Office (GAO) calls for a review of Medicare's policies for covering durable medical equipment (DME), and asks CMS to consider changes that would extend coverage to novel devices and encourage innovation. The report became public July 17, 2017.[1]

Historically, Medicare will not pay for devices that don't meet the DME test: the device must serve a medical purpose, can withstand repeated use, and have an expected life of 3 years. As technology advances, however, the lines are blurring between durable and disposable technology. Some devices that combine the 2, with potential to help patients achieve better glycemic control or greatly improved sleep, will fall outside current definitions. In the report, GAO predicts missed opportunities to keep patients healthy, and thus wants to review DME payment policies.

Allowing payment for disposable medical equipment—or asking Congress to create a new benefit category—might prevent situations like a decision the report cites: Earlier this year, CMS made a breakthrough policy change when it ruled that certain seniors with diabetes could have a Dexcom G5 continuous glucose monitor (CGM).[2] But then a Medicare administrative contractor said seniors could only be reimbursed if they didn't use the Dexcom monitor with their smartphone.[3]

That ruling, reported by *The American Journal of Managed Care®*, was specifically cited by GAO as an example of how "CMS has already faced issues accommodating new technology."[1]

The report found that CMS' challenges with technology will only increase as devices, such as new versions of the artificial pancreas or next-generation CGM, get closer to completion. Increasingly, traditional medical device companies are working with technology giants like Google and Apple[4,5] to create products that require minimal interaction from patients with diabetes and chronic disease. For example, Dexcom CEO Kevin Sayer said last year that the company is working with Verily, a division of Google, on a CGM transmitter that functions like Band-Aid, which patients "can peel off and throw away."[4]

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The GAO report cited an example of Medicare refusing to pay for an insulin pump that appeared to be Insulet's Omnipod.

**Six of the 21 stakeholders interviewed for the Government Accountability Office report said medical device technology is advancing, and 5 specifically cited CMS' definition of durable medical equipment as a disincentive to technological innovation, such as development of disposable substitutes.**

The goal: if medical devices have the usability of smartphones and Band-Aids, patients will stick with them and stay healthy, while feeding data to their doctors and health systems. Thus, devices will easily track progress at both the individual and population health level. For several years now, device and technology companies have formed partnerships with these goals in mind. Devices will become smaller and cheaper,[6] which should also appeal to Medicare.

GAO's report examined several types of devices: durable and disposable insulin pumps, infusion pumps, and blood glucose monitors. Insulin pumps that have both durable and disposable components present the current challenge, because Medicare has refused to pay for at least 1 popular pump (which appears to be Insulet's Omnipod based on the description in the report) after ruling its insulin delivery mechanism is disposable even though the bulk of the device lasts more than 3 years. This is the type of hair-splitting where GAO sees future problems. Six of 21 stakeholders interviewed for the report said medical device technology is advancing, and 5 "specifically cited CMS' definition of DME as a disincentive to technological innovation, such as the development of disposable substitutes."

"As advancing technology results in changes to the functionality of devices, including the development of disposable substitutes, CMS will likely have to consider how its benefit coverage policies will apply to them," the report stated.

Disposable substitutes for DME can have certain advantages: some disposable models are lighter and quieter; with certain patients, disposable products can promote adherence if it's not necessary to clean and transport supplies, as it is for durable products. In some care settings, disposal products reduce nurses' workloads and prevent infection. On the downside, DME varieties are preferred when dosing needs to be highly specific.

The GAO report goes into detail on several potential DME substitutes, with their potential benefits and limitations; it outlines the current incentives and disincentives for developing disposable DME substitutes. Lack of Medicare reimbursement for disposable equipment topped the list of barriers.

What can be done? The GAO recommended the following:

- CMS should evaluate the possibility of paying for disposable devices, including the potential for overall cost savings.
- If necessary, CMS should ask Congress to authorize a new benefit category if the current options would be inadequate to pay for disposable equipment.

GAO reports that HHS, which includes CMS, believes this type of evaluation is premature. But GAO says it "continues to believe an evaluation is needed to help HHS anticipate and plan for significant changes using a forward-looking process." ◆

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# "Beyond A1C" Pinpoints the Metrics That Matter to Patients in the FDA Process

*Mary Caffrey*

**IN DIABETES CARE,** glycated hemoglobin (A1C), which reflects a 3-month average of blood glucose levels, is the benchmark for tracking everything from how well a patient is doing on a diabetes care regimen to how well a health system is caring for its population.

For the FDA, A1C is the gold standard for measuring whether therapies or devices help people with diabetes manage the disease. But for patients, it's not the whole story: A1C tells nothing about how they are doing throughout the day. If FDA is to weigh other metrics, however, what would they be? Could professional groups agree on standards? How would these new measures be put into practice?

CLOSE

CEFALU

On July 21, 2017, the diaTribe Foundation convened luminaries in diabetes research, regulation, and advocacy for a daylong session, "Glycemic Outcomes Beyond A1C: Standardization and Implementation." The session, led by diaTribe founder and chair, Kelly Close, was a follow-up to a 2016 summer workshop, which then-FDA Commissioner Robert M. Califf, MD, attended in person.[1]

There's consensus that the FDA should measure how well drugs and devices control hypoglycemia and time in range. Based on the meeting, there's growing support for using continuous glucose monitoring (CGM) to gather data in clinical trials. Attendees also discussed whether the FDA should measure patients' ability to get more consecutive hours of sleep, since artificial pancreas technology offers this promise.

"We all know the very high dangers of hypoglycemia, but only by speaking with 1 voice—as researchers, clinicians, and patients, with leaders from different professional organizations—can we stay ahead of those dangers," Close said in an e-mail to *Evidence-Based Diabetes Management*™. "To achieve that, we hope that CGM is used more often in clinical trials and then that information is used to guide care for patients. If our goal is to improve outcomes at lower costs—and minimize hypoglycemia—that path will take us there."

Not only does reducing hypoglycemia and improving time in range lead to improved health and safety outcomes, but these factors matter to patients and caregivers and could lead to better quality of life. Richard Wood of dQ&A, a diabetes market research firm, presented data from 3455 patients who have either type 1 diabetes (T1D) or type 2 diabetes (T2D), including patients who used insulin and those who did not. Across the board, reports on quality of life were dismal. "Fewer than a third of the patients feel their diabetes care is very successful," Wood said. "It's clear we have a lot of work to do, despite all the therapies we have today."

> **"We all know the very high dangers of hypoglycemia, but only by speaking with 1 voice—as researchers, clinicians, and patients, with leaders from different professional organizations—can we stay ahead of those dangers."**
>
> —Kelly Close, founder and chair, diaTribe Foudation

As one patient said in the survey, "Time in range defines my daily experience."

This hardly means that A1C is meaningless. As Robert Ratner, MD, FACP, FACE, retired chief scientific and medical officer of the American Diabetes Association (ADA), explained, the landmark Diabetes Control and Complications Trial found that a 2% reduction in A1C was associated with a 60% reduction in retinopathy, nephropathy, and neuropathy.[2] But as has been seen in subsequent trials, reductions in A1C don't always translate into macrovascular benefits.

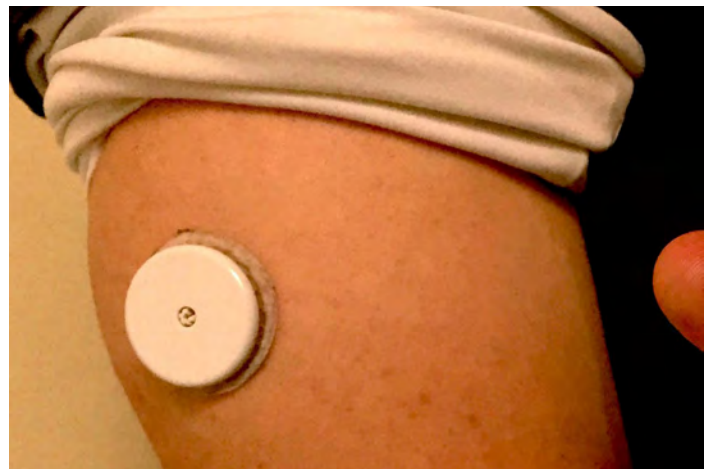
RATNER

HOME

More recently, with the DEVOTE trial, a cardiovascular (CV) trial that compared insulin glargine and insulin degludec (Tresiba),[3] "How you achieve A1C lowering become critically important," Ratner said. This head-to-head trial showed that both insulins were safe from a CV standpoint, but insulin degludec offered a larger drop in severe hypoglycemia, especially at night.

The meeting featured researchers and regulators from Europe, as diaTribe seeks to foster alignment between the FDA and the European Medicines Agency (EMA), so pharmaceutical and medical device companies developing new metrics will have a common set of standards. The rising role of technology was clear. ADA's chief scientific and medical officer William T. Cefalu, MD, said that the 2018 *Standards of Medical Care in Diabetes* will include a separate chapter on technology for the first time.

Philip Home, DPhil, of Newcastle University in the United Kingdom, said if CGM is to be used in research, issues arise about ensuring it is calibrated. If hypoglycemia is a metric, how do regulators define an event? If there are several within a short span, do they count as single incident?



Should clinical trials require continuous glucose monitoring throughout, or just for 14-day periods at the beginning and the end?

Bart Van der Schueren, PhD, of the EMA, discussed that agency's efforts to update metrics and said there is definitely a preference for including CGM data with applications, not just for T1D approvals. Even a week's worth of data for T2D approvals offers insight about glucose variability he said.

VAN DER SCHUEREN

The EMA is still exploring patient-reported outcomes, Van der Shueren said, but has not yet seen a validated measure it's ready to adopt. The need for alignment isn't about pleasing pharmaceutical companies. "We want companies to please patients," he said. To hold down costs and speed development, "There is a need to align internationally."

Afternoon sessions were set up as workshops to discuss the future of clinical trials and make concrete recommendations to the FDA. Questions debated included: (1) should hypoglycemia be an efficacy outcome, instead of a safety outcome, for US regulators? (2) Should CGM be required for an entire trial or just for 14-day periods at the beginning and the end? (3) What is the definition of nonsevere hypoglycemia? (4) What can be done about patients with hypoglycemia unawareness? ◆

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# Dexcom, Ascensia to Partner on Medicare Diabetes Bundle

*Mary Caffrey*

**ASCENSIA DIABETES CARE AND DEXCOM** reached an agreement on July 10 to speed delivery of Dexcom's G5 continuous glucose monitoring (CGM) system to eligible Medicare beneficiaries.[1] The deal gives Dexcom a partner for creating the "bundle" of a CGM and blood glucose monitoring system, which will meet Medicare shipping requirements and give access to those who meet CMS criteria for the system.

Earlier this year, Medicare announced it would pay for the Dexcom G5 for beneficiaries with diabetes who take insulin, use a home blood glucose monitoring system (BGMS), and perform finger stick tests at least 4 times a day. This covered virtually everyone with type 1 diabetes and many with advanced type 2 disease.[2]

For those who rely on CGM, this was historic news. Previously, turning 65 meant paying for the device out-of-pocket or giving up a tool that had helped bring unprecedented levels of glycemic control. Dexcom, and advocacy groups like JDRF, had worked for years on the policy change, which began with a July 2016 FDA hearing to show that it was safe to use the Dexcom G5 for dosing decisions. The Dexcom model is the only one approved by FDA for therapeutic use, which cleared the way for it to be covered by Medicare.[3]

The good news hit a snag, however, when Medicare suppliers refused to ship the Dexcom G5.[4] They wanted to know how to follow rules that require diabetes supplies to be shipped in a set, or "bundle." Because Dexcom doesn't make the BGMS needed to calibrate a CGM, it had to find a partner to meet requirements.

> **"For those people with diabetes who are eligible to receive the G5 through Medicare, Ascensia is thrilled to become the partner of choice for calibration of the Dexcom G5 CGM system."**
>
> —Robert Schumm, vice president and managing director, Ascensia Diabetes Care

According to a statement from Ascensia, "The complete bundle will be available to people who are covered by Medicare and qualify for therapeutic CGM." Ascensia Diabetes Care's Contour Next One BGMS will be included in the bundle. While separate blood glucose tests are no longer needed for each dosing decision, they are still needed twice a day to calibrate the CGM.

"For those people with diabetes who are eligible to receive the G5 through Medicare, Ascensia is thrilled to become the partner of choice for calibration of the Dexcom G5 CGM system," said Robert Schumm, vice president and managing director of Ascensia Diabetes Care. "We believe this combination will help improve diabetes management for people on Medicare who are eligible for therapeutic CGM."

Dexcom hailed the agreement as well. "In Ascensia, we saw a business partner that matches our own commitment to best-in-class products and services for people with diabetes. With this agreement, we are pleased to begin offering a complete bundle to Medicare-eligible patients, enabling access to the Dexcom G5 CGM system as efficiently as possible." ◆

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# CDC Report: US Diabetes Population Tops 30 Million

*Mary Caffrey*

**MORE THAN 30 MILLION AMERICANS** have been diagnosed with diabetes, and 100 million are living with diabetes or prediabetes, the CDC says in a new report that shows how this growing health emergency hits hardest those least able to manage the disease or its effects. At current trends, 1 in 3 American adults will have diabetes by 2050.[1]

Type 2 diabetes (T2D), in particular, is most common among the poor, minorities, those with less education, and those living in the South and Appalachia, including several states that did not expand Medicaid under the Affordable Care Act.[2] CDC updates diabetes data approximately every 2 years. The report released on July 18, 2017, includes data as of 2015 and shows that 30.3 million Americans, or 9.4% of the population, had diabetes, including T2D and type 1 diabetes (T1D).

The good news is that the rate of increase seems to be slowing, Ann Albright, PhD, RD, director of the CDC's Division of Diabetes Translation, stated. "Diabetes is a contributing factor to so many other serious health conditions," said Albright, who has made it a priority to find people with prediabetes, a condition that leads to T2D if left untreated.[3]

**While the rate of new diagnoses of diabetes might be slowing, better treatment methods and an aging population mean people can live many more years with the disease. This accounts for projections that a third of population could be living with diabetes by mid-century.**

The CDC report predicts there are 84.1 million prediabetic individuals, which is about 2 million less than previous estimates.[4] Working with the American Medical Association, Albright has made prediabetes the focus of a massive public health campaign. The CDC created the curriculum and recognition process for the National Diabetes Prevention Program (DPP), which Medicare will offer seniors with prediabetes in April 2018.[5] Medicare has estimated that diabetes accounts for $1 of every $3 it spends; thus, reversing trends in diabetes is crucial if Medicare is to stay solvent in the decades ahead.[6]

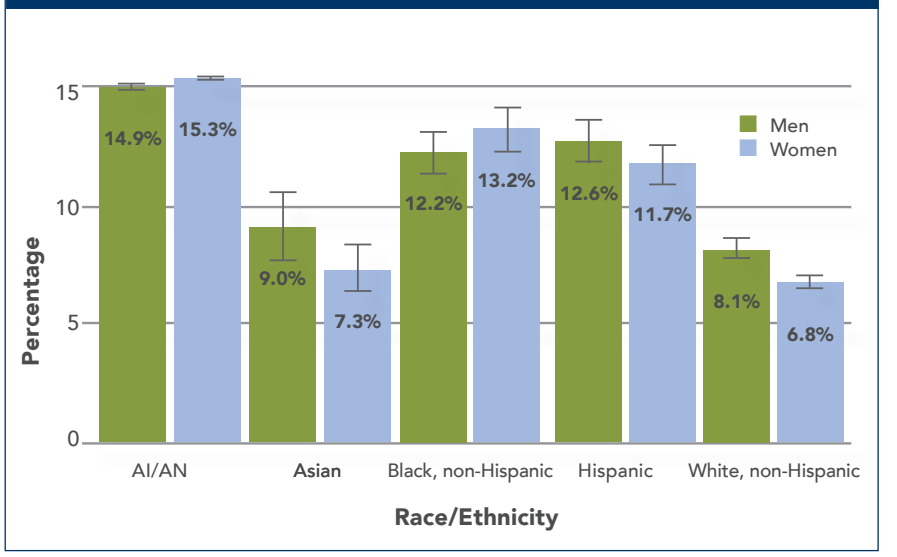
Key findings from the CDC report include:

- In 2015, approximately 1.5 adults received a new diagnosis of diabetes (aged 18 or older).
- Nearly 1 in 4 adults with diabetes (7.2 million people) didn't know they had the disease. Only 11.6% of adults with prediabetes knew they had it.
- The odds of being diagnosed with diabetes increases with age. Four percent of adults aged 18 to 44 years had diabetes, but that number jumps to 17% for those aged 45 to 65 years and to 25% for those 65 years or older.
- One if 4 Americans eligible for Medicare has been diagnosed with diabetes, although the actual number is believed to be higher.[1]

The report highlights significant disparities among those with diabetes and prediabetes, including:

- Native Americans and Alaska Natives had the highest rates of diabetes, at 15.1% of the population, followed by African Americans at 12.7% and Hispanics at 12.1%. By comparison, 8% of Asians and 7.4% of whites had diabetes.
- Adults with less education are more likely to have diabetes. Rates by level of education were: less than a high school diploma, 12.6%; high school education, 9.5%; some postsecondary education, 7.2%.

**FIGURE.** Percentage of Racial/Ethnic Groups With Diabetes, United States. 2015




AI indicates American Indian; AN, Alaskan Native.

Source: CDC

- Rates of prediabetes were higher among men (36.6%) than women (29.3%); this split held up across education levels and ethnic groups. The higher rate among men has frustrated those offering the DPP because thus far, the majority of program enrollees have been women. Virtual programs, seen as a way to engage more men, were not fully included in the Medicare DPP under a rule proposed last week.

While the rate of new diagnoses might be slowing, better treatment methods and an aging population mean people can live many more years with the disease. This accounts for projections that a third of the population could be living with diabetes by midcentury, which public health officials say is unsustainable.

Besides the complications associated with diabetes itself, such as retinopathy and amputations, there is growing evidence of links between diabetes and Alzheimer's disease—one of the costliest burdens in Medicare and Medicaid. The common thread of insulin resistance runs through both conditions, and preventing T2D is now seen as a way of stopping as least some cases of Alzheimer's. Right now, 5.5 million people have Alzheimer's disease, and that number is projected to grow to 13.8 million by 2050.[7] ◆

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# Gallup–Sharecare Survey Finds 11.6% of US Adults Have Diabetes, Tops CDC Study

*Mary Caffrey*

**THE DIABETES RATE REACHED 11.6%** among US adults in 2016, according to the results of a survey of 177,000 adults from Gallup and Sharecare. That rate, reported July 25, 2017, exceeds the 9.4% rate that CDC reported the same month, based on 2015 data culled from several sources.[1,2]


WITTERS


HOLCOMB

The survey figure climbed from 10.6% in 2008, which means approximately 2.5 million more people have diabetes now than if the rate had remained steady, Dan Witters, research director of the Gallup–Sharecare Well-Being Index, told *Evidence-Based Diabetes Management*™ (*EBDM*™).

According to a report on the survey, it simply asks, "Has a doctor or nurse ever told you that you have diabetes?" It does not distinguish between types 1 and 2 diabetes; if anything, survey administrators wonder if this method may miss people who know they take medication for "blood sugar" but don't realize they have type 2 diabetes.

While Gallup–Sharecare and the CDC each have their own methods of calculating US diabetes prevalence, including different data sets and different ways of weighting them, Witters said they share this bottom line about diabetes: "It continues to grow, and it continues to grow in a way that's pretty alarming."

Gallup–Sharecare and the CDC agree on several points: The likelihood of diabetes rises as education and income fall, and rates are highest in the South and Appalachia, where people are comparatively poor and less educated. Historically, residents there have had less access to healthcare, as well; while some states—including Kentucky, West Virginia, and, recently Louisiana— expanded Medicaid under the Affordable Care Act, most states in this region have not.[3]

The ongoing rise in diabetes is not a surprise, given the continued increase in obesity, Witters said: "Until obesity slows, diabetes is going to continue to go up. It can't help but go up." He said that from 2010 to 2013, it appeared that obesity was leveling off, and so was the diabetes rate. "But over the past 3 years or so, [obesity] is pushing its way back up again," he said. "I am personally not optimistic that this is flattening out." The reason: Obesity continues to increase among people in their prime working years.

**While Gallup-Sharecare and the CDC each have their own methods of calculating US diabetes prevalence, including different data sets and different ways of weighting them, Gallup's Dan Witters said they share this bottom line about diabetes: "It continues to grow, and it continues to grow in a way that's pretty alarming."**

## Some Occupations Hit Harder Than Others

A key feature of the Gallup–Sharecare study is the analysis by occupation. Workers overall are younger and healthier, and this is seen in a diabetes rate of 6.9%, compared with the 23.9% for people aged 65 and older. But transportation workers—a category that includes long-haul truck drivers—have a rate of 10.3%, compared with physicians, who have the lowest rate (5.1%). It's easy to understand why truckers are at risk—they sit all day, and many eat lots of fast food. But farmers and forestry workers? According to the results, the rate of 8.5% for farmers and forestry workers reflects their age, which doesn't offset their activity level. Smoking and drinking, which are more common among some types of workers than others, can offset the positive effects of physical activity.

**TABLE.** US Diabetes Prevalence by Occupation With Key Risk Factors, 2016.

| | % Diabetes Diagnosis | Risk Level of New Onset Diabetes | Obese | Heavy Alcohol Consumption* | Smoker | Low Exercise** | Low Healthy Eating*** |
|---|---|---|---|---|---|---|---|
| Transporation | 10.3% | Highest | 40.3% | 5.1% | 26.7% | 48.6% | 48.1% |
| Farming, Fishing or Forestry | 8.5% | Average | 26.0% | 6.1% | 17.9% | 33.2% | 41.0% |
| Service | 7.7% | Average | 27.8% | 4.0% | 23.3% | 44.3% | 47.2% |
| Clerical or Office | 7.7% | Average | 28.4% | 2.1% | 14.0% | 50.4% | 43.3% |
| Business Owner | 7.5% | Below Average | 22.5% | 5.7% | 15.4% | 41.2% | 38.1% |
| Manufacturing or Production | 7.5% | Above Average | 31.2% | 6.0% | 26.2% | 44.4% | 51.9% |
| Other Healthcare Professional | 6.8% | Average | 25.4% | 2.7% | 11.9% | 42.5% | 39.3% |
| Nurse | 6.8% | Average | 27.2% | 1.4% | 11.7% | 44.3% | 34.7% |
| Installation or Repair | 6.2% | Above Average | 27.4% | 8.7% | 27.2% | 41.9% | 51.1% |
| Teacher | 6.2% | Below Average | 25.3% | 2.0% | 5.2% | 44.5% | 36.5% |
| Manager, Executive or Official | 6.0% | Average | 27.6% | 4.9% | 14.9% | 43.7% | 42.3% |
| Professionals (except teachers and healthcare) | 5.7% | Below Average | 23.2% | 4.4% | 10.8% | 42.8% | 41.9% |
| Sales | 5.5% | Average | 25.0% | 4.5% | 17.6% | 44.9% | 47.6% |
| Construction or Mining | 5.5% | Above Average | 25.4% | 10.1% | 30.2% | 38.2% | 49.5% |
| Physician | 5.1% | Lowest | 13.8% | 2.7% | 2.5% | 41.5% | 36.7% |
| All U.S. Adult Workers | 6.9% | | | | | | |

*15 or more alcoholic drinks per week
**Did not exercise 30+ minutes 3+ days in the past week
***Did not consume 5+ servings of produce 4+ days in the past week

Source: Gallup-Sharecare Well-Being Index, 2016

What can employers do? "We have to take diabetes education outside the walls of the hospital," Sheila Holcomb, vice president of Sharecare Diabetes Solutions (formerly Healthways) said during an interview with *EBDM*™.

## Case Studies Show Effects of Benefit Design

An ongoing, longtime project in Florida, featured in the survey report, reveals how changes in benefit design—which require higher out-of-pocket costs for people with diabetes—affect outcomes and may cause employers to rethink cost-sharing arrangements for people with diabetes. Munroe Regional Medical Center, in Ocala, along with insurer Florida Blue, organized diabetes education for a group of school district employees with the disease. Classes took place at times that did not conflict with school hours, and participants received testing supplies and medication, including insulin, at no charge. Factoring in the cost of free supplies and drugs, the group had a 9% decrease in total healthcare costs, compared with a 39% increase for a second group that did not take part in the program. "Today, after 10 years, 47% of the participants remain active in the program and receive annual screening, program benefits, and 2 hours of follow-up education," the report states.

These results show the importance of lifelong diabetes education—which is the policy position of the American Diabetes Association and the American Association of Diabetes Educators—Holcomb said.[4] While coverage for education is better than it was 10 years ago, current benefit designs make co-pays too high for some. "Things will change. Medications will change," she said. "Patients need to have the opportunity to change through their life span." ◆

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# Abbott, Bigfoot Biomedical to Partner on Automated Diabetes Management System

*Mary Caffrey*

**THE PAIRINGS IN THE DIABETES** technology sector continue: On July 13, 2017, Abbott and Bigfoot Biomedical announced plans to work together on diabetes management systems that combine Abbott's Freestyle Libre glucose sensing technology and Bigfoot's insulin delivery systems.

**When Wall Street trader Bryan Mazlish's 5-year-old son was diagnosed with T1D, he used his knowledge of how algorithms could replace human decision making to hack his way to a better glucose management solution with existing technology.**

The collaboration comes as people living with diabetes get closer to the holy grail of finger-stick free insulin delivery and glucose management, or the "artificial pancreas." Every person with type 1 diabetes (T1D), and more and more with type 2 diabetes, must have daily insulin injections to control blood glucose levels; in a statement, Bigfoot put this number at about 6 million in the United States.[1]

The story of Bigfoot Biomedical is one of the most compelling in the diabetes technology sector: when Wall Street trader Bryan Mazlish's 5-year-old son was diagnosed with T1D, he used his knowledge of how algorithms could replace human decision making to hack his way to a better glucose management solution with existing technology. Mazlish's wife, a physician also living with T1D, offered ideas and feedback.

From there, Mazlish set about to commercialize technology that would free people with T1D from finger sticks and parents of T1D children from waking up multiple times a night for glucose checks. Bigfoot has both injection and infusion pump-based insulin delivery systems in development.[2]

Abbott, meanwhile, has pioneered technology that records up to 14 days' worth of data without finger sticks or patient interaction, which is invaluable for physicians seeking a real look at glucose levels without relying on patients to record blood glucose readings or properly operate a device.[3]

Under the agreement:

- Abbott will supply glucose management sensors for Bigfoot's insulin systems in the United States, becoming the exclusive sensors.
- Bigfoot will develop and commercialize multiple systems using Abbott's Freestyle Libre sensors, including those for automatic insulin titration and delivery.

Financial terms of the deal were not disclosed. ◆

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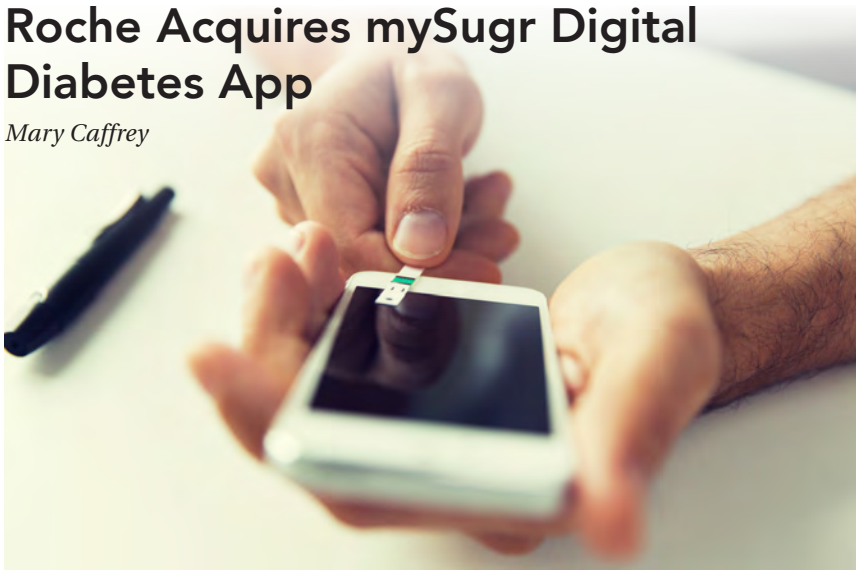
# Roche Acquires mySugr Digital Diabetes App

*Mary Caffrey*



**ROCHE HAS ACQUIRED** the diabetes management app mySugr, which offers data tracking and coaching services for people living with type 1 or type 2 diabetes. In a statement, Roche described mySugr as "one of the leading mobile diabetes platforms in the market," with more than 1 million users.[1]

The June 30, 2017, agreement lets Roche combine the mySugr mobile management tools with the company's diabetes diagnostics business. "The acquisition allows Roche to expand its leading position in the area of diabetes management," the company said in a statement. Terms were not disclosed.

Despite growing numbers of people with diabetes, both the pharmaceutical and technology sectors have been challenged by pricing pressure. Some have predicted consolidation in the digital health sphere, as multiple competitors have emerged before payers have completely figured out how to evaluate reimbursement criteria.

There are also good reasons for traditional device makers to pair with digital health companies to tech giants as big data become more important in healthcare. Medtronic has partnered with Glooko[2] and Canary Health,[3] and Dexcom, maker of continuous glucose monitors, has partnered with Google[4] to make these devices smaller or even disposable, more like a Band-Aid.

The Roche acquisition grew out of a partnership with mySugr that started in 2014, which Roche said revealed "an excellent cultural fit."

"Both our companies are passionate about taking diabetes management to the next level," Roche chief executive officer Roland Diggelmann said in the company's statement.

Frank Westermann, mySugr chief executive officer and cofounder, said the company was started with the purpose of using smartphones to solve everyday problems with diabetes management: "The mySugr team has filled a gap for over 1 million loyal users so far, and with Roche's diabetes expertise and global network, mySugr will become an indispensable companion for hassle-free life."

Roche is based in Basel, Switzerland, and makes the well-known Accu-Chek blood glucose meters, insulin delivery systems, and lancing devices; mySugr is based in Vienna, Austria, with offices in San Diego, California. ◆

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PROVIDER PERSPECTIVE

# Omada's Paul Chew, MD: From Treating Chronic Disease to Prevention

*Mary Caffrey*

*continued from cover*

Companies like Omada are built on the idea that the flood of Americans headed for T2D is too staggering to wait until people are sick to treat them. With an aging population and more proof of diabetes' links to Alzheimer's, failing to invest in prevention means diabetes will eventually lay claim to more than the third of the Medicare budget it already devours.[5,6]

Yet 15 years after the original DPP study, and more than 7 years after the CDC launched the National DPP to make the program more accessible,[7] uptake remains limited. There are many reasons: Physicians may be unaware, managed care plans may not be promoting DPP, but most of all, traditional face-to-face programs simply don't fit into schedules or are located too far from rural residents where diabetes rates are high.

That is where there is hope for digital health—it has the potential to scale DPP to the millions who need it.[8] Chew said Omada has worked with groups like the American Diabetes Association and the American Medical Association to help digital DPP reach places where face-to-face programs will never go. This is the case that Omada and other digital health providers will make in the coming weeks, as they try to convince CMS that they must be included when Medicare offers the DPP starting in April 2018.

As Chew points out, Omada has published peer-reviewed research to show its programs produce both transformational weight loss and rapid return on investment, making the case to payers and employers that the investment is worth it.[9-11]

Chew is optimistic. Despite the issues digital providers face, CMS' decision to fund DPP in fee-for-service Medicare is a breakthrough. And the implementation of the Medicare Access and CHIP Reauthorization Act (MACRA) will give physicians more incentive to refer patients to diabetes prevention, especially if they use the Merit-Based Incentive Payment System (MIPS) in the early going.

Compared with his days in the pharmaceutical sector, Chew says success in the world of preventive medicine is defined differently. When a new therapy is created, "it's 1 patient at a time and 1 pill or 1 injection at a time. The physician and the patient can see the benefits very quickly, and that was very gratifying," Chew said.

"When you talk about prevention," he added, "you're talking about a much larger group of people. Eighty-four million people have prediabetes in the United States; 90% don't even know it. Diabetes prevention through a digital platform can approach this problem on a population level and in a very patient-centric way, through diet, exercise, lifestyle intervention, and counseling. All of these are safe, effective approaches for most people who can participate. So this is quite different, in the sense that the patient is part of the solution."

## Adoption of Diabetes Prevention Strategies in the Era of MACRA

***EBDM***™**: The CDC just announced that 30.3 million Americans have diabetes. Prevention clearly needs to be priority, but there is a lack of provider awareness about available options. The health system has been slow to integrate prevention into routine care. How can payers work with providers to build awareness about prevention?**

**CHEW:** What's not known is that 12% of Americans have diabetes, and 35% have prediabetes. It's even more amazing that 90% of those who have prediabetes don't know it.[3] The problem we have is that there's lot of clinical literature that shows that behavioral counseling and dietary management can reduce the incidence of diabetes in those at risk by more than half. The problem we have is not the lack of literature but the fact that it has not been translated into practice for the benefit of people and to prevent them from becoming patients.

The main reason is that there is a system that has not been reimbursing or recognizing the value of prevention. The other issue is that this problem is so massive, with more than 84 million Americans having prediabetes, that it is literally impossible to address it in the old, traditional way. So we need proven digital approaches, where return on investment and publications can validate the approaches to make this a reality. Finally, one of the bright spots is that CMS will be encouraging prediabetes testing and prediabetes referrals, so that sort of alignment of the medical need, the incentives, and benefits can be brought closer into harmony.

***EBDM***™**: Has the implementation of MACRA increased provider awareness or sped adoption of digital health? Conversely, is there any concern that the "pick your pace" approach with smaller and rural providers will slow adoption in areas where diabetes rates are highest?**

**CHEW:** One of the most significant advances for the problem of prediabetes will be the MACRA and MIPS incentives for referral to programs—validated Diabetes Prevention Programs—as well as testing for prediabetes through the MACRA and MIPS initiatives. People at risk for diabetes live all over the country; some are closer to Diabetes Prevention Programs than others. So to reach the more than 84 million people at risk, we need a combination of both face-to-face as well as digital programs.

***EBDM***™**: Beyond just the financial, what are the costs—for providers, patients, payers, and health systems—of the lack of adoption of diabetes prevention?**

**CHEW:** One of the things we learned in medical school was that diabetes can affect you literally from the top of your head to the bottom of your feet. Diabetes is the leading cause of stroke—in your head—and it's the major cause of blindness in adults. It can cause heart attacks. It can also cause kidney failure and neuropathy—from the top of your head to the bottom of your feet. And the reason for that is the effect of diabetes on your whole vascular system. So that is the biggest medical problem. It's the leading cause of nontraumatic amputation as well. Prediabetes is the best bad news you could get because it allows you the opportunity—through lifestyle, diet, and exercise—to reduce that risk [of diabetes] by more than half. A digital Diabetes Prevention Program will allow this sort of benefit to reach people who are inaccessible to face-to-face programs, who may not want to go to face-to-face programs, and who are more comfortable with a self-paced program.

***EBDM***™**: Beyond the clinical benefits of preventing progression to T2D and heart disease, what are the other positive effects from Omada's intervention?**

**CHEW:** One of the reasons I went to Omada is that it is a research-based program. We're seeing not only the clinical benefits of diabetes prevention but also the financial benefits. Omada has published articles showing the return on investment[9] and the reduced need for prescription drugs and hospital interventions.[10] »

omada

CHEW

*Paul Chew, MD, is the chief medical officer of Omada Health.*

So it's important [to ask] when you select a Diabetes Prevention Program, "Has it been validated for its clinical endpoints as well as its financial return on investment?"

## The Role of Employers in Diabetes Prevention

***EBDM™*: Why is it important to engage employers in diabetes prevention?**

**CHEW:** Omada is approaching a problem that is found with every workforce. We estimate that 30% to 40% of people in the American workforce may be at risk for prediabetes. What elevates the risk? If you're 45 or older, if you have a close relative with diabetes, if you're a member of a minority group, and if you're overweight or obese. Those factors are found in a large number of Americans in the workforce. We feel strongly that the workforce, where you spend so much of your time, is a great opportunity for employers to reduce their costs and to improve the overall health, well-being, and enthusiasm of their employees.

***EBDM™*: How should an employer evaluate a digital health program?**

**CHEW:** One of the most important things that face employers—in fact, the nation overall—is the ballooning cost of healthcare. For employers, I would suggest they look at their organizations for the major healthcare costs, and I'm sure it will be diabetes, cardiovascular diseases, and obesity at the top. They should look at potential solutions that can reach the broadest number of people when they need it, when they want it, at home, at the office, or even at restaurants, where they can access a digital program. They should look for publications that validate [their corporate approach] in terms of clinical outcomes and return on investment. They should also look at a digital solution or a face-to-face solution that can be accessed and help the employer reach as many of their employees as possible. We know there are initiatives that are not taken because the approach or engagement of employees is just not there.

## The Role of Managed Care in Diabetes Prevention

***EBDM™*: How does an intensive behavioral counseling program like Omada's differentiate itself from weight-loss programs or apps?**

**CHEW:** The most important concept we must realize is that diabetes prevention is more than just weight loss. It's a change in your lifestyle in terms of healthy eating, exercise, and a change in mind-set. It's not a cosmetic approach but an approach that will internalize the benefits of these interventions to reduce your risk of chronic disease—not only of diabetes but the risk of cardiovascular disease as well.

***EBDM™*: One of the big obstacles for digital health has been integrating into the physician and care team workflows. How has Omada approached this problem?**

**CHEW:** Integration into the medical workflow is very important. Working as we have at Omada through optimizing the patient portal, [mediating] between the patient and the physician so they can communicate more effectively is one way. We also work with the electronic health record—these are initiatives we have under way.

***EBDM™*: What specific roadblocks have you seen within managed care settings?**

**CHEW:** Managed care settings have so many competing priorities nowadays that we must be very clear that the coming tsunami is one of the biggest ones they must address—and that is chronic disease. More money is spent on chronic disease than infectious disease. As the population ages, the cost of chronic disease will be even greater. Diabetes prevention can reduce the cost of cardiovascular disease, kidney disease, and neurologic disease, and it's something that can be seen—with the publications that we have, we've modeled the [return on investment] to be within a couple of years.[10,11] It's a clear and present danger. And we believe it's a clear and present return on investment.

**"The most important concept we must realize is that diabetes prevention is more than just weight loss. It's a change in your lifestyle in terms of healthy eating, exercise, and a change in mind-set. "**

—Paul Chew, MD,
chief medical officer, Omada Health

***EBDM™*: Where have managed care organizations "gotten it right" when it comes to digital health adoption?**

**CHEW:** It's a very early area, so it's hard to say there's a successful digital adoption [in managed care]. The ability to make an appointment through a patient portal or to get refills—those are rudimentary digital approaches to healthcare. We have found, for example, that wearable devices, though helpful, need to be supported by intensive behavioral change. That's why we believe Omada—with its publications, approaches, and 120,000 participants to date—is one solution that should be considered when it comes to diabetes prevention and cardiovascular disease prevention.

## Implementing the Medicare Diabetes Prevention Program

***EBDM™*: As you know, CMS has proposed delaying full participation of digital health providers in the Medicare DPP when it launches in April 2018. Is the CMS' call for more evidence legitimate, or is this barrier emblematic of others that digital health has encountered?**

**CHEW:** One of the greatest innovations in the digital approach or the diabetes prevention approach has been the CMS program that will go into effect next April. As you may know, at this stage [the CMS is] approving and reimbursing DPP programs that have been approved or certified by the CDC. They are still getting comments for digital diabetes prevention. We feel very strongly that the evidence base for seniors is already strong for diabetes prevention. We've published 2 articles on the effectiveness of the Omada program with results that are even better than the YMCA program's, which is the basis for the CMS program. The second [study's results] showed that the return on investment is even sooner than the 1-to-2-year time frame for seniors.[11] So overall, we feel the evidence base is there.

Most important, if the CMS benefit is to [reach] its full realization for seniors, we have to access seniors who may not have the ability or the desire to go to a face-to-face program once a week. We have to be able to provide access digitally for those participants, and we also have to recognize that there's only a very thin slice of time you spend in a face-to-face program, whereas in a digital program, it's constantly accessible—when you need it and where you need it.

***EBDM™*: Where do you see digital health and the DPP heading in the next 5 years?**

**CHEW:** The next 5 years are going to be very important as we go forward in digital health because we will get a critical mass of experience. It will become even more clear that diabetes prevention is needed. The CMS program and the MACRA and MIPS initiatives to encourage screening, I believe, will make it easier for physicians and other healthcare providers to recognize and refer patients with prediabetes. ◆


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CONVERSATION

# After 20 Years of Watching Diabetes Tech, Kliff Eyes Smart Insulin Pens, CGM for Patients With Type 2 Diabetes

*Andrew Smith*

*continued from cover*

ago, is a leading spokesman for this view. His livelihood depends upon being able to predict how patients will behave (and, therefore, what they will buy), and he scoffs at the notion that any affordable intervention produces significantly better outcomes with traditional treatment tools. He believes that better tools can produce better outcomes, that several significantly better tools have recently hit the market, and that more are coming soon.

Kliff is not alone in his general optimism, but his specific predications differ from those of many others who think technology is about to revolutionize diabetes care. For example, Kliff said he doubts that any of the "artificial pancreas" devices currently under development will have any major impact on patients with T1D in the next decade. He thinks the real opportunity for improved outcomes lies in better glucose monitors and smart insulin pens. What's more, unlike many, he thinks that better technology (rather than just better medication) will greatly improve outcomes for patients with T2D.

There is an underlying theme to nearly all of Kliff's thinking about what will and won't succeed in attracting customers, improving outcomes, and reducing costs for patients with diabetes: ease of use. The majority of people simply cannot or will not make proper use of any product that is physically or intellectually demanding. So, the more a system requires of patients, the less they will use it and the more mistakes they will make when they do use it. Any tool that makes life simpler for patients (at an affordable price) has a good chance of winning widespread adoption and improving outcomes.

*Evidence-Based Diabetes Management™ (EBDM™)* interviewed Kliff about what's coming in diabetes technology and which innovations he believes have the greatest chance of success.

**EBDM™: What new and pending technologies most excite you?**

**KLIFF:** The next generation of continuous glucose monitors (CGMs). The current CGM from Dexcom is already a game changer. Although it must still be calibrated with a finger stick, the sensor was approved to allow patients to make insulin dosing calculations without verifying CGM readings with a finger stick.[3] Annual worldwide sales of finger sticks have already fallen from $6 billion to $4 billion, and I think that the ongoing flurry in CGM innovation will bring that number down to $1 billion in the next 3 years. This is a major shift. CGMs will not only be faster and more comfortable than finger sticks, [they] will be cheaper and more accurate as well, and that will end finger sticks.

The next generation sensor from Dexcom, which seems to be the innovation leader in this market, is slated to be about the size of a dime and capable of self-insertion and self-calibration. All patients need to do is put it on a new piece of skin every 3 days, touch a button, and the device does the rest. That would be a game changer.

**EBDM™: What does it do for patients, other than saving them finger sticks?**

**KLIFF:** Saving finger sticks is a big deal on its own, as anyone who has ever done multiple finger sticks a day will tell you, but the real advantage is the extra information. The switch from finger sticks to [using a] CGM gives patients more information. More importantly, it also provides more information to their doctors, who can use it in real time, either to tweak a patient's treatment protocol or to alert them that they're failing to control their blood sugar. Perhaps most importantly, [continuous glucose monitoring] gives data to smart software that can then calculate exactly how much medication patients need and exactly when they need it.

The only FDA-approved software that currently uses CGM data to automatically calculate insulin doses is the software that operates Medtronic's 670G system,[4] but other companies are working on the same sort of intelligent software. Dexcom has partnered with Verily, which doesn't sound like a huge alliance unless you know that Verily is a part of Google, which obviously has enormous experience with both: the necessary analytics and making user-friendly software.

KLIFF

*David Kliff is the publisher of Diabetes Investor.*

**EBDM™: So, the CGM will send a constant stream of data to some program, located either in a phone or a standalone device, and the software will tell the patient how much insulin to take and when to take it?**

**KLIFF:** Yes. We're not there yet, but that's almost certainly where it's going.

**EBDM™: Wouldn't it be easier for patients if the software sent the info to a pump, which delivered the insulin automatically?**

**KLIFF:** In theory, yes. In practice, not for a long time. Pumps just aren't the right solution for most people with type 1 diabetes. Pumps require more work for the patient initially, and these devices can, and do, malfunction, which can be dangerous, as they deliver a lethal drug. And that's why only a tiny fraction of the people who could use a pump actually do use a pump.

**"The current CGM from Dexcom is already a game changer. Although it must still be calibrated with a finger stick, the sensor was approved to make insulin dosing calculations without verifying CGM readings with a finger stick."**

—David Kliff

Significantly more than 90% of insulin users deliver their medication with insulin pens, which haven't improved nearly as much as glucose monitors in the past decade, but they're on the cusp of a big leap forward with the first generation of smart pens starting to hit the market.

**EBDM™: What do smart pens do, and how do you expect them to improve outcomes?**

**KLIFF:** Functionality varies from maker to maker. Some of them are just cases or caps for standard insulin pens. Those are able to keep track of when patients use insulin and tally their total usage. Patients who use traditional pens are supposed to keep detailed manual records of all that stuff, which most of them don't, so it's pretty much impossible for their doctors to evaluate their treatment adherence. Automating all that record keeping will give doctors the first accurate record they've ever had concerning patient behavior, and that's certainly a first step toward »

improvement. If patients keep failing to take proper doses at the proper times, the pens can alert doctors, who can nip problems in the bud rather than waiting 3 months for the patient's next appointment.

A few of the smart pens go further, though. They're fully engineered devices that, once doctors have programmed in a treatment protocol, will automatically size doses and notify patients when it's time to use them. The only time patients need to do anything more than insert new needles and insulin is at meal times, when patients provide information about their food and the pen software calculates how much extra insulin they need.

There are a bunch of companies working in this space. Companion Medical has a complete pen that is already FDA-approved.[5] There's a company called Common Sensing in Cambridge, Massachusetts, that is doing clinical trials at Joslin.[6] Bigfoot (Biomedical) just acquired a company called Timesulin that's working on another.[7]

***EBDM™*: Do these smart pens use the information from CGMs to calculate how much insulin you use?**

KLIFF: Not yet, but once again, that is almost certainly where this will end up. Dexcom has said that it has reached out to the companies that are making these pens about integrating the data from both devices. Presumably, all the other CGM makers have done likewise, and presumably, some company will make the software that combines the basic protocol that each doctor prescribes with the data from both pen and monitor to make the pens dial up the proper doses for each patient. All patients will need to do—other than adding new needles and insulin cartridges—is hold the pens in the right places when their smartphones tell them to do so. The whole thing will be a cheaper and simpler version of the artificial pancreas idea that most people are talking about, like an artificial pancreas light.

The interesting question is, who will write the software that controls everything? It may be a company that makes some actual piece of equipment, or it may be a big technology company that wants to get into the healthcare market. Apple, Google, Amazon, and Samsung have all expressed interest in diabetes, and I think they will probably end up making the big competing platforms that individual devices work with and support.

***EBDM™*: How much of this must come together before the new technology begins improving outcomes?**

KLIFF: None. The new toys that are already on the market do more than enough to change outcomes—if they're used properly. Existing smart pens and CGMs connect to the internet, so they can already tell doctors exactly which patients do and don't comply, more or less, with prescribed treatments. This alone can inform doctors when poor results require new protocols and when they require better patient compliance. That's a leap forward. Up until now, it has been very hard to tell whether poor results stem from the shortcomings of the protocol or the patient.

The real question is how aggressive we, as a society, will be about using the data to motivate patients to change their behavior. We already have auto insurers that use technology to monitor how their policy holders drive and then offer very cheap rates to people who drive safely and very high rates to those who drive aggressively. Would we be willing to use CGMs and smart pens to monitor diabetic patients and offer discounted premiums to those that complied religiously with treatment protocols?

**"The interesting question is, who will write the software that controls everything? It may be a company that makes some actual piece of equipment or it may be a big technology company that wants to get into the the healthcare market. Apple, Google, Amazon, and Samsung have all expressed interest in diabetes, and I think they will probably end up making the big competing platforms that individual devices work with and support."**

—David Kliff

***EBDM™*: Do you think that would be a good idea?**

KLIFF: I think it would be far more effective in changing behavior than any intervention that's been studied to date or any app that's designed to motivate people to change their behavior. There are at least  companies that are working on changing behavior, and I don't think any of them will have any real success. People won't change their behavior unless there is a real reason to do it, unless you make it significantly easier to do the right thing or significantly harder to do the wrong thing. Charging higher premiums to nonadherent patients and lower premiums to adherent patients would improve outcomes for a huge number of people, and it's certainly something we could do now, if we decided the benefits justified the invasion of privacy.

***EBDM™*: How else can the data from CGMs improve outcomes for people with T1D?**

KLIFF: This isn't just for people with T1D. Monitors have already gotten to the point that they probably make sense for people with T2D, and if they're not there yet, then they certainly will be by the next generation, which, in addition to its other advantages, should be cheaper than the current generation.

The same data that can tell doctors whether type 1 patients do or don't comply with their treatment protocols can tell doctors whether type 2 patients are complying with their treatment protocols. It doesn't matter whether the medication is insulin or something else. The data will show an experienced eye when patients take medicine. It will also give doctors more data than they've ever had about how narrow a range of blood sugar each individual patient can maintain with any protocol, and that will give doctors more feedback and more ability to fine tune than they have ever had before.

All CGM makers want to expand to the type 2 market because it is so much bigger. Really, all companies that can conceivably make their products helpful for type 2 patients will make such patients a priority. It's simple math. ◆

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MD MAGAZINE

**UCLA's Karol Watson, MD, discusses the value of liraglutide in reducing cardiovascular risk in diabetes care**

Read more here: **ajmc.com/link/2606**.

PAYER UPDATE

# UnitedHealthcare's Medtronic Deal Sparks Furor, but a Year Later, Innovation Continues

*Andrew Smith*

*continued from cover*

Such predictions, however, may prove overly dramatic. The past 16 months have seen Medtronic sign an outcomes-based payment agreement with another insurer, but no insurer has followed UHC's lead and signed exclusivity pacts with Medtronic or any other pump maker. If UHC patients are protesting the policy, they have been less visible in recent months. The exclusivity deal helped inspire a campaign by JDRF (formerly the Juvenile Diabetes Research Foundation),[2] but the early media coverage has waned.

As for the deal's impact on UHC patients, outsiders are forced to guess. UHC has declined to disclose any figures related to the policy: how many of its policyholders use insulin pumps, what pumps they chose before the transition, or how many have switched to Medtronic after preferred pumps broke or were out of warranty.

An estimated 1.25 million[3] (0.4%) of the nation's 325 million people[4] have type 1 diabetes (T1D). Estimates of the percentage of American patients WITH T1D who use a pump vary, but the JDRF currently reports the figure at 40%.[5] Roughly 75% of all pump users have a Medtronic pump. The vast majority have T1D, although a very small number have type 2 diabetes.[6] Still, it's hard to get a precise handle on the number of patients affected by the UHC decision, since the policy excludes Medicare Advantage patients, those younger than 18, and enrollees of UHC Sierra Life and Life Commercial.[7] Based on UHC's combined commercial and Medicaid population of 36.5 million, the number of people who might be asked to switch pumps is likely between 10,000 and 12,000.[8]

Eventually, nearly all adult Medicaid and commercial UHC patients who refuse to buy other pump brands out-of-pocket will have to switch, either to a Medtronic pump or to insulin injections. Those who used their benefits to buy a non-Medtronic pump before the policy took effect can still get coverage for supplies so long as the pump keeps working and remains under warranty. Warranties typically last 4 years, so the transition probably has yet to affect more than one-third of UHC patients who prefer non-Medtronic pumps.

Such numbers only tell part of the story. It is impossible to know the strength of patient preferences overall and for individual patients.

Michele Hynes, who is covered by UHC, switched from Medtronic to Animas more than 4 years ago because the Animas pump was waterproof (as some Medtronic models now are) and because it had a remote control. "As a woman, I often don't have access to pockets if I am wearing a skirt or dress. As such, in these cases, I generally clip my pump to my bra. It is SO convenient to be able to dose from my meter and not have to leave the table or grab my pump out of my bra," she wrote to *Evidence-Based Diabetes Management*™ (*EBDM*™) in an email.

An even bigger deal for Hynes is the sensor. The 41-year-old mother of 2 young children wants an integrated system that automatically delivers insulin based on readings from a continuous glucose monitor (CGM), but she wants a system that works with a Dexcom sensor. If she moved to a Medtronic pump, the only way to automate delivery would be to move to a Medtronic sensor as well.

"In general, I have found that anyone who has used Dexcom is less than impressed with Medtronic sensors. And as such, I am hesitant to switch—to the point I am still using an out-of-warranty Animas pump," she wrote. "I will probably concede defeat and order a new pump in the next 2 months."

Looking beyond patient preferences, the other important metrics for evaluating the policy are, obviously, health outcomes, total cost savings, and how any savings are distributed among UHC, premium payers, and pump-using patients. UHC, again, declined to disclose any details.

"Patient safety, service, and cost were key considerations in our decision-making process to partner with Medtronic," wrote UHC spokeswoman Kristen A. Hellmer in an emailed response to *EBDM*™ to requests for specific numbers. "We have finalized a value-based agreement, which rewards improved outcomes for UnitedHealthcare members on insulin pumps and places greater focus on quality rather than the volume of care delivered."

Some observers have argued that patients might suffer worse outcomes after being pushed away from first-choice machines and toward devices they found less intuitive or less suited to their needs,[9] but there's no trial data connecting current Medtronic pumps to inferior outcomes. There is, on the other hand, solid evidence tying Medtronic's most advanced pump system to superior outcomes.

Medtronic's MiniMed 670G, the first system to receive the FDA designation of "artificial pancreas,"[10] became available to US patients in June. It combines a pump with a CGM and software to automate many dosing decisions. Even in manual mode, it automatically suspends insulin delivery when blood glucose levels fall dangerously low (and resume it when they rise). In auto mode, the system uses CGM readings to adjust insulin delivery levels every 60 seconds. It's nowhere near perfect, but trial data strongly suggest that the automation—which is unique to Medtronic's system—significantly improves outcomes. Among 124 patients in a 3-month trial, auto mode reduced the following: average glycated hemoglobin (A1C) from 7.4% to 6.9%, dangerous hypoglycemia by 40%, and r time spent with excessive blood glucose by 11%.[11]

"Although we are in favor of more, rather than less, patient choice, there's good reason to believe that this UnitedHealthcare policy doesn't change that much negatively. It's likely that most UnitedHealthcare pumpers already use Medtronic, that those pumpers will be among the earlier ones to upgrade, and that outcomes will be as good or better with most that are in line to shift from another brand. Medtronic has shown that this product will improve outcomes, that's what matters to payers in this era of value-based healthcare, and there's good reason to think that UHC's policy will deliver on outcomes," said diaTribe Foundation founder Kelly L. Close, who advised patients who don't want Medtronic to raise their voices, especially on social media.

"Assuming it's true that Medtronic systems improve outcomes, the question would then become, which is more important: patient choice or better outcomes? The math would say better outcomes, but I also doubt that deep down, Medtronic or UnitedHealthcare wants this controversy," Close said in an interview.

There is no definitive proof that the 670G produces superior results in real-world settings. Obviously, Medtronic has not had time to complete a postmarketing study required by the FDA. Until it does, the only indicator of efficacy comes via anecdotes from early adopters and testers, which have generally been positive. Close spends much of her time talking to people about medical devices for T1D, and she says she rarely hears a negative review from anyone who has lived with the 670G. Even the people who are nervous about surrendering dosing control to an algorithm, people who are predisposed to be cautious about turning control over to a system, or even to dislike the system, usually end up telling her that it doses them better than they can dose themselves.

Medtronic, moreover, appears confident that the 670G will improve real-world outcomes and save money for payers. In June, Medtronic announced a deal with Aetna that ties payment rates for its systems to the results those systems produce in patients who switch over from insulin injections.[12] The companies declined to disclose the financial details of the deal, but Medtronic said that the achievement of A1C targets will be the first metric used to determine payments. Other metrics, such as reductions of hypoglycemic episodes, could be added later.[13]

"This agreement is an important first step as we look to broadening our partnership to facilitate patient access to the most advanced diabetes management solutions across the care continuum that not only ensure outcomes, but lower the overall cost of care for this chronic and burdensome disease," said Suzanne Winter, vice president of the company's Americas Diabetes Group, in the press release that announced the deal.[14]

In June, Medtronic said that it is negotiating specific benchmarks and payment levels for a similar outcomes-based compensation plan with »

UHC—a plan that is now in place—and other, unnamed insurers.[13] The Aetna deal, unlike the agreement that Medtronic struck with UHC, does not eliminate coverage for pumps from other makers. Indeed, no pump maker has signed an exclusivity pact with any payer since that first deal became public and generated dozens of stories about patients and patient advocates who were outraged by the loss of choice. After those stories died down, protecting and expanding patient choice became a major point of advocacy when the JDRF announced its 2017 priorities a few months later.

"We recognize the important role that health plans make in coverage, affordability, and choice for type 1 diabetes therapies," wrote JDRF spokesman Christopher Rucas in an email about the group's opposition to exclusivity deals. "We have put together a campaign we're calling Coverage2Control, which will call on insurance companies to provide members with diabetes 3 things to give them control."

Rucas outlined the elements:

1. Predictable and reasonable out-of-pocket costs for insulin and diabetes management tools.
2. Freedom to choose an insulin pump that makes sense for the individual, which means no exclusive agreements with pump makers that limit choice.
3. Coverage of all life-saving devices, including artificial pancreas technology.

Rucas said the JDRF is "engaging directly with health plans, but also wants to provide the T1D community with opportunities to take action." The JDRF and other patient advocates believe that widespread coverage for all FDA-approved pumps benefits patients not only by letting them choose whatever current machine works best for them, but also by spreading revenue enough to encourage competition and innovation. There is a widespread belief among both patient advocates and financial analysts that at least 1 smaller player, possibly more, could soon drop out of the market.

Tandem Diabetes Care lost nearly $24 million in the first quarter of 2017 as pump shipments fell 30% to 2816.[15] The company lost more than $83 million in 2016 and more than $72 million in 2015.[16] Johnson & Johnson has said it is considering selling its diabetes care business, including Animas, a pump-making subsidiary that's based in suburban Philadelphia.[17] This comes after the Animas deal won FDA approval in December 2016 for the OneTouch Vibe insulin pump, the first to integrate with the Dexcom G5 CGM.[18] Also in the mix is Insulet, which has struggled to convince Medicare to offer reimbursement for its tubeless Omnipod pump.[19] And in August, the remaining patients using pumps from Roche Diabetes Care were turned over to Medtronic for ongoing support after Roche announced plans to stop selling its Accu-Chek pumps in the United States.[20]

Such a situation would not be historically unique. The number of pump makers has waxed and waned considerably over the past 40 years. New entrants have kept coming in with new technology, trying to dethrone MiniMed, the dominant player purchased by Medtronic for $3.7 billion in 2001.[21] None have succeeded, but their efforts have helped fuel a steady improvement in pump technology. Pumps have gotten considerably smaller, more discrete, smarter, easier to use, and more reliable since they first appeared in the 1970s.[22]

There is reason to believe that more players will enter the market with new ideas. For example, Bigfoot Biomedical is performing clinical trials on a system that includes a pump that has no controls on its body because it is controlled through a smart phone app.[23]

Even if fewer new companies enter the market and the pace of traditional pump development slows, patients will see differences. Today's models are good enough that observers like Close see little need for dramatic hardware improvement, regardless of how competitive the pump market is. Mechanical improvement will continue, she thinks, but more of the value will come from the brains of the pump.


UnitedHealthcare's exclusive arrangement with Medtronic could ultimately give patients with type 1 diabetes access to the 670G, the first product that meets FDA criteria for the label "artificial pancreas."
Credit: Medtronic photo

"Insulin is an incredibly dangerous drug, and a machine will always figure out dosing better than patients or parents or partners. Automation is where we're going, and it's all about the algorithms and who can make the easiest-to-use systems—take away steps, make things easier to use and smarter. That could come from the largest pump manufacturer, but it doesn't necessarily have to. It can come from another company or academic or even hobbyist who wants to write it," said Close, who gave the interview while testing a system that used software written by 1 individual to control her insulin.

"I can't wait to try the 670G, and I can't wait until it's widely available. For now, having a smart algorithm in a box that costs $126 and keeps me between 80 and 120 all night every night is pretty excellent. Medtronic raised the bar with its new pump and the outcomes that they have proven (mainly less hypoglcyemia)—and they shouldn't, and won't, take their eye off the ball because the field will keep raising the bar ever higher." ◆

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PRODUCT THEATER

# Experts Present Evidence and Advice on Canagliflozin


MENDE


MILLER


WYSHAM

*Christian Mende, MD, FACP, FACN, FASN, FASH, is clinical professor of medicine at the University of California, San Diego.*

*Eden Miller, DO, is a practitioner of family medicine and co-director, Diabetes Nation, Bend, Oregon.*

*Carol Wysham, MD, is clinical professor of medicine at the University of Washington.*

**THREE PHYSICIANS, 2 IN ACADEMIC MEDICINE** and 1 in family medicine, recently reviewed studies involving the type 2 diabetes (T2D) therapy canagliflozin, a sodium glucose co-transporter-2 (SGLT2) inhibitor sold by Janssen Pharmaceuticals, Inc, as Invokana.

The review included a 2016 meta-analysis of 38 studies, which found the 300-mg dose of canagliflozin reduced glycated hemoglobin (A1C), fasting plasma glucose, and systolic blood pressure better than other drugs in the class "at any dose."[1] The review also covered new results from the Cardiovascular Assessment Study (CANVAS) and CANVAS Renal (CANVAS-R) trials, which were presented June 12, 2017, at the 77th Scientific Sessions of the American Diabetes Association in San Diego, California.

The combined results of CANVAS and CANVAS-R trials, reported in the *New Journal of Medicine* (*NEJM*), found a 14% reduction in the combined primary endpoint of nonfatal heart attacks, nonfatal strokes, and cardiovascular (CV) death.[2] These results also found that patients taking canagliflozin had a lower risk of hospitalization for heart failure, less loss of kidney function, and a lower risk of progression to albuminuria.

Janssen officials said at that time the CANVAS and CANVAS-R results showed "a positive risk-benefit profile" for both CV and renal endpoints.[3] One commentator called these results highly statistically significant for noninferiority and statistically significant for superiority.[4] Since the CANVAS results were announced, CVS Caremark has listed canagliflozin as the preferred SGLT2 inhibitor on its 2018 formulary.[5]

The physicians' presentation, which welcomed questions from family practice physicians who treat most patients with T2D, featured Carol Wysham, MD, clinical professor of medicine at the University of Washington; Christian Mende, MD, FACP, FACN, FASN, FASH, clinical professor of medicine at the University of California, San Diego; and Eden Miller, DO, a practitioner of family medicine and a codirector of Diabetes Nation in Bend, Oregon.

SGLT2 inhibitors, which thus far are approved only for the treatment of T2D, have a unique mechanism of action that causes the body to excrete excess glucose through the urine. Reviewing the mechanism, Mende said that for a person with diabetes, the result can be the loss of 100 mg of glucose a day.

Mende and Wysham explained that canagliflozin goes to work immediately, and physicians must instruct patients to drink water and eat while taking the drug. In many cases, physicians should reduce or eliminate antihypertensive therapy, especially diuretics.

Patients starting canagliflozin "should drink an extra quart of water a day to stay hydrated," Mende said. If a patient must fast for a medical procedure, such as a colonoscopy, canagliflozin should be stopped temporarily. The rule of thumb, he said, is: "No food, no drink, no drug."

Canagliflozin, sold as Invokana, is available in 100 mg and 300 mg doses.

The physicians covered results from both randomized clinical trials and real-world evidence. Miller, the family physician, said real-world evidence includes claims, registry, and observational studies, which she said can be examined with clinical trial results to "synergistically inform us to make better decisions."

Results included the following:

- In lowering A1C, canagliflozin outperforms sitagliptin, a top-selling dipeptidyl peptidase-4 inhibitor, and patients on canagliflozin lost about 5 pounds.[6]
- Real-world results show patients were more likely to stay on canagliflozin than comparators.
- Safety data showed that canagliflozin compared well with its competitors, except for an increased risk of hypoglycemia if patients were also on insulin and sulfonylureas.

## Results From the Meta-analysis

A 2016 study funded by the United Kingdom's National Institute for Health Research reviewed results from 38 randomized controlled trials for the 3 approved SGLT2 inhibitors—canagliflozin, empagliflozin (Jardiance), and dapagliflozin (Farxiga). The meta-analysis involved 23,997 patients in trials that lasted at least 24 weeks.

Wysham noted that while the trials differed in some of the reported metrics, all recorded changes in A1C, and the average baseline A1C was within a narrow range of 8.0% to 8.2%. Citing an article by Zaccardi et al that appeared in *Diabetes, Obesity and Metabolism*,[1] the physicians explained that the meta-analysis found the following mean A1C reductions, compared with placebo:

- -0.9% (95% CI, -1.0 to -0.8) for canagliflozin 300 mg
- -0.8% (95% CI, -0.9 to -0.7) for canagliflozin 100 mg
- -0.7% (95% CI, -0.8 to -0.6) for empagliflozin 25 mg
- -0.6% (95% CI, -0.7 to -0.5) for empagliflozin 10 mg
- -0.7% (95% CI, -0.7 to -0.6) for dapagliflozin 10 mg
- -0.6% (95% CI, -0.6 to -0.4) for dapagliflozin 5 mg

"Comparisons among SGLT2 inhibitors showed greater [A1C] reductions with canagliflozin 300 mg compared with all SGLT2 drugs…and no significant differences between dapagliflozin and empagliflozin at different doses," the authors found.

## CANVAS and CANVAS-R

Both CANVAS and CANVAS-R arose from a 2008 FDA requirement that manufacturers of new diabetes, obesity, and cholesterol therapies conduct CV outcomes trials to show that the drugs are safe. As Wysham explained, the CANVAS started before canagliflozin was approved in March 2013,[7] while CANVAS-R began after approval.

In total, the 2 studies covered 10,142 patients, making the pool of patients larger than a comparable study of empagliflozin.[8] Patients' mean age was 63, and their mean time living with T2D was 13.5 years.

Wysham explained that because CANVAS was created to find out whether the drug was safe for high-risk patients, by design the population was sicker than the typical patients physicians will see in family practice: To participate, patients had to have a history of atherosclerotic CV disease or be at least 50 years old with 2 or more CV risk factors. In the canagliflozin group, close to a third had a diagnosis of neuropathy (30.8%[2]), 17.2% had nephropathy,[2] and Wysham said half were on insulin; 2.3% had already experienced an amputation.[2] (According to the *NEJM* study, the mean body mass index for the canagliflozin group was 31.4 kg/m$^2$.)

While all arms of the study started with baseline A1C of 8.2%, the canagliflozin group dropped to a mean of 7.5% at week 26 and then slowly rose over the long follow-up period while maintaining a difference of -0.58%, along with a mean body weight difference of -1.60 kg.

Wysham stated that the findings showed an increased risk in lower limb amputations, of the toe and forefoot; she clarified that while the risk was double that of placebo, the overall numbers were extremely small (6.3 vs 3.4 participants per 1000 patient years[2]).

PRODUCT THEATER

Miller explained the significance of CANVAS to family physicians who see the typical patient with T2D. "One thing CANVAS and CANVAS-R really did demonstrate was this 3-point MACE [major adverse CV events, which is a composite measure of reduction in heart attacks, strokes, and hospitalization for heart failure]. We saw these positive benefits from it, including a signal in the reduction in hospitalization for heart failure. This really matters at the primary care level and for treating all their comorbidities."

"The endocrinologist treats the sugar, but it's the primary care physician who keeps the patient alive," she said.

## Clarifying Amputation Risk

During the question-and-answer period, Amy Carroll, PhD, medical science liaison for Janssen, asked Wysham to further clarify what the amputation risk means for physicians in family practice.

Wysham emphasized that the patients in CANVAS, as a group, were very high risk, including those with established peripheral vascular disease who were at risk for amputation. "These individuals were pretty sick to begin with," she said. Wysham noted that this signal did not emerge in the earlier phase 3 and phase 4 trials for the drug.[9]

Trial protocols in CANVAS called for seeing the full effects of canagliflozin on blood pressure and lipids, which Wysham said "was actually probably not the best advice."

Wysham and Mende said it is apparent the problem was a volume depletion issue, and Mende added that there were amputation signals in trials for other SGLT2 inhibitors, just not the differential with placebo. "To me, it's a placebo issue," he said.

For family physicians, the best advice is to emphasize the importance of drinking water, especially when starting canagliflozin, and Wysham emphasized the need for regular foot exams.

## "Excited About the Kidney"

CANVAS confirmed previous results of increased rates of infections of male genitalia and mycotic genital infections in women. The physicians agreed that almost all these infections occur when patients are starting the drug, and physicians typically send patients home with a prescription for a barrier cream or one to treat the infection, in case it is needed. "A very small percentage are at risk of recurrent yeast infection," Wysham said.

In addition to the positive CV data, the renal results seen in CANVAS-R are promising. Both Mende, a nephrologist, and Miller say they are encouraged by the opportunity to preserve renal function with the drug. Miller said the purpose of CANVAS was to show cardiac safety, "and the data are showing there's some protective effect…but I'm just as excited about the kidney [function] and hospitalizations for CHF [congestive heart failure]."

Mende said he, too, is looking forward to the results of the CREDENCE (Evaluation of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Participants With Diabetic Nephropathy) trial, which is ongoing and expected to conclude in June 2019.[10]

Janssen's Carroll asked the physicians: What sets canagliflozin apart from other SGLT2 inhibitors?

"It was the first, it's had the greatest, by far, experience, it has the best A1C reduction overall," Wysham said. Because it is on most formularies, "I use what's easiest to get, with the understanding that Invokana is going to give us the greatest A1C reduction."

Added Mende, "You look at the data, and you have to make your own decision," For nephrologists, there's going to be a lot of news about renal data, he said. "Stay tuned."

"It's going to give us the biggest bang for the buck," Miller said. "I'm looking for more than blood sugar control." ◆


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RESEARCH

# Study Finds Genetic Links Between Diabetes, Heart Disease; Reveals Potential Drug Targets

*Mary Caffrey*

**CONNECTIONS BETWEEN TYPE 2** diabetes (T2D) and coronary heart disease (CHD) are well-established—so much so that when a drug is developed to treat one condition, at some point researchers study what happens to patients who have both conditions at once.

But what if scientists could find the common genetic thread and treat both conditions at once? Genome sequence information from 250,000 people has allowed researchers at the University of Pennsylvania's Perelman School of Medicine to do just that. Reporting in *Nature Genetics*, the team has identified 16 previously unreported loci for T2D and 1 new loci for CHD; the analysis also uncovered 8 variants that affect both conditions, according to the abstract.[1]

The findings not only raise the possibility of identifying a single common pathway to treat both diseases, but they also help explain puzzles like why some treatments for low-density lipoprotein (LDL) cholesterol can increase risk for T2D. The work opens the door for studies into treatments that can help both conditions without raising new risks for either one, according to the study's co-senior author, Danish Saleheen, PhD, a Penn assistant professor in Biostatistics and Epidemiology.

"Identifying these gene variants linked to both type 2 diabetes and CHD risk in principle opens up opportunities to lower the risk of both outcomes with a single drug," Saleheen said in a statement. «From a drug development perspective, it would make sense to focus on those pathways that are most strongly linked to both diseases."[2]

Besides identifying potential new treatment pathways, the study confirmed some existing targets, such as icosapent, an omega-3 fatty acid found in fish oils, which is sold in a prescription strength dose. The study also uncovered dual-risk loci for the area that includes the gene FABP4 (fatty acid binding protein 4), which is already being studied as a drug target. Mouse studies are under way that block this gene's protein to combat hardening of the arteries and fight diabetes and obesity.

Not all the diabetes-related gene variants worked the same way. According to a statement from Penn Medicine, CHD risk was elevated more by variants linked to obesity and high blood pressure than those that affected insulin or blood glucose levels.


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