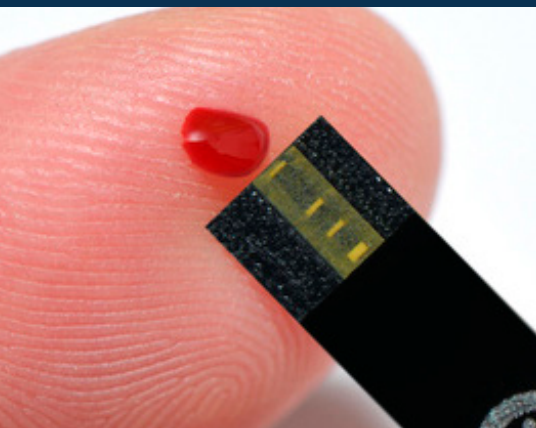


Evidence-Based DIABETES MANAGEMENT™

MARCH 2019
VOL. 25 • NO. 4

ALSO IN THIS ISSUE



A patient tests their blood glucose.

FROM THE EDITOR-IN-CHIEF

In this issue of *Evidence-Based Diabetes Management™* (EBDM), our Editor-in-Chief, Robert Gabbay, MD, PhD, FACP, calls on CMS to bring its Competitive Bidding Program to a halt until it can address the program's many flaws. Gabbay explains that while problems began with a poorly designed program, the real fiasco has been "a refusal to listen to patients and advocates—and even Congress—despite clear evidence that competitive bidding is not working," [SP115](#).



Q&A WITH ABBOTT LABORATORIES

EBDM sat down with Abbott Laboratories for an exclusive Q&A

to discuss Abbott's decision to distribute FreeStyle Libre through a different channel, and how payers have responded. [SP123](#).

UNITEDHEALTHCARE + MEDTRONIC

Almost 3 years after UnitedHealthcare named Medtronic its preferred supplier of insulin pumps for adults, a fresh wave of protest has erupted after the payer extended the pact to youth, starting at age 7. EBDM discussed this update in guidance with JDRF, the advocacy and research organization previously known as the Juvenile Diabetes Research Foundation, who had issued a statement calling on UnitedHealthcare to reverse the decision, [SP127](#).

CGM & DIABETES MANAGEMENT

Continuous Glucose Monitoring: An Emerging Standard of Care

John B. Welsh, MD, PhD; and Roy Thomas, PharmD

Background

Insulin is a foundation stone of diabetes therapy. It is the life-sustaining drug for everyone with type 1 diabetes (T1D) and an important treatment option in type 2 diabetes (T2D).

Whether given by multiple daily injections (MDI), continuous subcutaneous insulin infusion (CSII), or intranasally, insulin's low therapeutic index makes precise dosing difficult, even for experienced users. Its absence or deficiency leads to persistent hyperglycemia and vasculopathy, which are leading causes of morbidity and premature mortality, while the acute dangers of insulin-induced hypoglycemia remain the key obstacle to therapy intensification efforts.¹ Because insulin dosing decisions depend on knowledge of current and target glucose concentrations, as well as the individual's likely response to the drug, the ability to measure glucose plays a key role in understanding and managing diabetes.

With the development and commercialization of insulin, the need for glucose quantification increased and technology for measuring glucose in urine and blood improved throughout the latter part of the 20th century. Self-monitoring of blood glucose (SMBG) technology improved throughout the late 1980s with devices that did not require subjective color matching, required less blood and less time, and allowed for wider ranges of hematocrits.^{2,3} However, SMBG testing remains painful and obtrusive, many patients test at suboptimal frequencies, and individual test results do not provide important trending information.⁴



Dexcom G6 family of products with applicator.

CONTINUED ON SP116

MEDICARE COMPETITIVE BIDDING PROGRAM

Three Years After Advocates Report Flaws, Medicare Diabetes Test Strip Bidding Program Nears Collapse

Samantha DiGrande and Mary Caffrey

THREE YEARS AFTER RESULTS FROM A study in *Diabetes Care* revealed how flaws in CMS' Competitive Bidding Program (CBP) endangered Medicare patients who rely on supplies to test their blood glucose,¹ the federal government has allowed contracts to expire for the dwindling number of suppliers, raising fears that the program for seniors with diabetes has reached the point of collapse.

Self-monitoring of blood glucose (SMBG) is one of the fundamentals of diabetes care, and to do this, patients need test strips—the short, chemically treated pieces of plastic that are used just once to capture a drop of blood, then inserted into a meter to read the glucose level and offer guidance for dietary or medication adjustments. For individuals with

CONTINUED ON SP120

PRICING CGM

A New Era: Increasing Continuous Glucose Monitoring Use in Type 2 Diabetes

Tejaswi Kompala, MD; and Aaron Neinstein, MD, FAMA

PRECIS: Continuous glucose monitors (CGMs) are increasingly accessible and effective for patients with type 2 diabetes (T2D), and even those with prediabetes, as a means for real-time biofeedback and behavior change.

A convergence of several healthcare megatrends will lead to increasingly common use of CGM in people with T2D and even those with prediabetes: (1) improvements in CGM accuracy, size, and cost; (2) the ability to upload data to the cloud; (3) the availability of digital coaching tools and analytic software, and soon, artificial intelligence, and (4) a shift toward value-based care.

CONTINUED ON SP123

SPECIAL ISSUE
DEVICE AND SUPPLY UPDATE
MARCH 2019
VOLUME 25 ISSUE 4

FROM THE CHAIRMAN

Diabetes Management Starts With Monitoring Tools

THE COST OF DIABETES to the healthcare system and to our economy rises each time we measure it. The American Diabetes Association (ADA) reported that diabetes cost the United States \$327 billion in 2017, a 26% jump from 2012.¹ Of note, twice as much is spent on diabetes complications as is spent on the basic medications and supplies for managing the disease. Thus, to drive down the cost of diabetes, it makes one wonder: If we spent a little more money to help people with diabetes manage their condition, would we spend less on things like end-stage renal disease, amputations, or treatments to prevent vision loss?

No amount of doctor's care or magic pills will stem these costs in isolation; those with diabetes—both type 1 (T1D) and type 2 (T2D)—need tools, education, and support to manage a condition that never takes a day off.

Glucose monitoring is the foundation of diabetes management; a person with T1D or advanced T2D cannot make good choices about diet, exercise, or insulin use without accurate, real-time information about blood glucose levels. Although continuous glucose monitoring (CGM) has become the standard of care in T1D, patients' need for test strips so they can self-monitor their blood glucose in some circumstances does not go away; it is recommended after changing a sensor or when a CGM reading doesn't match patient symptoms.

It's not reasonable to ask someone to manage a disease they can't monitor. The good news is, today's management tools are better than ever. Other than improvements in both CGM and test strips, there are hundreds of apps, online support groups, and new therapeutic options and combinations. The bad news? For many patients with diabetes, the best monitoring tools cost too much, even for those with insurance. For those with T1D, payers might cover CGM, but sometimes choice is limited (see **SP127**) and cost sharing is expensive. As we report in this issue, test strip rationing is so common that a "gray market" has emerged for patients who can't afford or can't get the supplies they need from their insurer. For those with T2D, coverage for CGM can also be hard to find, even though it might help this group make the connection between diet and exercise and their blood glucose levels long before complications arise. Two years ago, at the ADA Scientific Sessions in San Diego, California, a leading researcher suggested that "renting" a CGM to patients with T2D once a quarter for 10 to 14 days might be enough to shift behavior without incurring long-term costs.²

As we read in this issue, CGM awareness is increasing and the integration of this technology with other health-related apps will likely lead to its use among more people with diabetes, even if they don't use insulin. Giving people with diabetes more information and control makes more sense than waiting for complications to arise. And it may even cost less in the long run. ♦

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Sincerely,

Mike Hennessy, Sr
CHAIRMAN AND CEO

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FROM THE CHAIRMAN Diabetes Management Starts With Monitoring Tools

MIKE HENNESSY, SR
CHAIRMAN AND CEO

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FROM THE EDITOR-IN-CHIEF Halt the Glucose Test Strip Bidding Program Until It Can Be Fixed

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CGM & DIABETES MANAGEMENT Continuous Glucose Monitoring: An Emerging Standard of Care

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MEDICARE COMPETITIVE BIDDING PROGRAM Three Years After Advocates Report Flaws, Medicare Diabetes Test Strip Bidding Program Nears Collapse

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PRICING CGM A New Era: Increasing Continuous Glucose Monitoring Use in Type 2 Diabetes

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FROM THE EDITOR-IN-CHIEF

Halt the Glucose Test Strip Bidding Program Until It Can Be Fixed



GABBAY

EVEN WHEN THINGS GO well, managing diabetes is not easy. Keeping tabs on this disease 24/7 takes planning, commitment, support, and the right tools. For years, a chief complaint among those living with diabetes has been that managed care nickel-and-dimes people over basic supplies, which are comparatively cheap—things like test strips and sensors for a continuous glucose monitor—but will shell out thousands for dialysis and amputations. In the years ahead, if Congress wants to understand rising costs for end-stage renal disease or an increase in emergency department visits for hypoglycemia, it should look directly to CMS' foray into competitive bidding for blood glucose test strips.

CMS' failure started with a poorly designed program, but the real fiasco has been a refusal to listen to patients and advocates—and even Congress—despite clear evidence that competitive bidding is not working. Seniors with diabetes are not merely inconvenienced by the complicated test strip procurement program; they cannot get their supplies in a timely manner, and many have simply given up trying. In a presentation dating as far back as 2015, Gary Puckrein, PhD, and his colleagues at the National Minority Quality Forum showed that people with diabetes in the initial CMS test markets had worse outcomes, that hospitalizations increased, and even that the test markets were associated with increased mortality. Puckrein et al published full results on the CMS pilot in 2016¹ and did a follow-up on the effects of the nationwide rollout last May. Their bottom-line conclusions are unchanged; the 2018 study found that disruptions had “persisted and worsened.”²

In other words, the government's bidding program for test strips is harming people. If a drug were shown to do this, it would be pulled from the market. Instead, CMS has expanded the bidding program to the rest of the country.

Now, as we report in this issue of *Evidence-Based*

Diabetes Management[™], the failure to stop the program and fix it has pushed it to the point of collapse. By driving prices for test strips below their actual cost, CMS has pushed out reputable suppliers—advocates told us that it seems all mail-order vendors have dropped out. Inattention created by changes in HHS leadership allowed durable medical equipment contracts to expire, and a new proposal excludes diabetes products because Congress demanded that CMS deal with them separately due to problems in the current program. But rather than admit defeat, CMS lets the current system linger on life support, refusing to admit that depending on where patients live, some have few options. (CMS has declined comment except to say it is preparing a new proposal for both mail-order and retail suppliers in diabetes care.)

Patients who lack the right testing supplies cannot properly dose insulin and are at higher risk of severe hypoglycemia; failing to test properly in the long term puts them at risk of multiple health problems. As Charleston, Mississippi, pharmacist Robert Salmon, RPh, tells us, it's foolish to increase barriers to glucose testing given the consequences. Yet CMS has done just that—all while declaring victory for achieving “savings.”

The only thing CMS should be declaring is an emergency. It should scrap the current system and take steps to get new suppliers in the market temporarily while it fixes the program. Budget language from Congress shows its intent on this matter is clear, and as the evidence shows, lives are at risk. ♦

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Robert A. Gabbay, MD, PhD, FACP
EDITOR-IN-CHIEF

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

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CGM & DIABETES MANAGEMENT

Continuous Glucose Monitoring: An Emerging Standard of Care

John B. Welsh, MD, PhD; and Roy Thomas, PharmD

continued from cover



WELSH

John B. Welsh, MD, PhD, is a physician who writes about diabetes technology and has had type 1 diabetes since 1976.



THOMAS

Roy Thomas, PharmD, is a pharmacist and a medical science liaison at Dexcom.

The potential value of continuous monitoring of blood glucose⁵ and the enzyme-based electrode that underlies continuous glucose monitoring (CGM) in the subcutaneous tissue⁶ were described in the 1960s. In 1999, the FDA approved the first “professional” CGM system, which stored data over 3 days for later retrieval and analysis. However, many patients (even volunteers in CGM-based clinical trials) found early-generation systems uncomfortable and difficult to wear.^{7,8} By contrast, current systems are more accurate, provide customizable alerts and alarms, are easier to use⁹ and less likely to cause skin irritation,¹⁰ resist interference from acetaminophen,¹¹ allow for real-time data to be shared and remotely monitored,¹² and are stable enough so as not to require periodic calibrations with SMBG values. Single-use transcutaneous sensors from Abbott, Dexcom, and Medtronic last for up to 14 days, while implantable sensors from Senseonics last up to 90 days. Systems are also distinguished by whether or not data are transmitted automatically to a receiving device or rely on the receiving device being brought into proximity with the transmitter. The latter “intermittently scanned” configuration is used by the Abbott FreeStyle Libre system and does not allow for automatic generation of alerts in response to abnormal glucose concentrations.

CGM has revolutionized the way diabetes, especially T1D, is managed. According to several contemporary experts,¹³ CGM is second only to insulin as the most important advance in caring for those with T1D. When used appropriately, modern CGM can guide decisions leading to average glucose concentrations that are closer to the normal range, reduce the severity of and worry associated with hypoglycemic events, and drive reductions in the cost of complications. Population-level statistics from the T1D Exchange Registry¹⁴ show that its adoption is rapidly increasing (from 7% in 2010-2012 to 30% in 2016-2018) and that CGM users with T1D, regardless of insulin delivery method or age, achieve lower glycated hemoglobin (A1C) levels than patients not using the technology.

Nonetheless, only a minority of adults and youth with T1D achieve goals outlined by the American Diabetes Association (ADA) for A1C¹⁴ and many patients face barriers when contemplating or continuing CGM use. CGM systems include multiple components, which have variable lifespans, prices, and reimbursement schedules. The extent to which clinical practices advocate for CGM usage and reimbursement also varies, and some practices may mistakenly associate CGM use with the requirement for adoption of a sensor-augmented pump system. Beyond these initial tasks of obtaining and paying for the system, there are additional requirements for long-term success with the technology: wearing the sensors consistently and incorporating CGM data into the daily routine.

The Evidence Base for CGM

Evidence for the clinical benefits of CGM comes from randomized controlled trials (RCTs), patient-reported

outcomes, and observational studies. RCT results allow for quantification of prespecified outcomes, such as A1C reduction and hypoglycemia mitigation, for CGM users compared with usual care with SMBG. The **Table**¹⁵⁻²² summarizes several RCTs using current-generation devices; 3 recent reviews²³⁻²⁵ offer additional commentary. A1C reductions among adults using MDI were studied in the DIAMOND Type 1,^{15,26} DIAMOND Type 2,¹⁶ and GOLD^{17,27} studies. In these studies, CGM use was associated with significant reductions in A1C, independent of participant age, education, diabetes numeracy, or hypoglycemia awareness. In the DIAMOND study, A1C reduction was larger for subjects with the highest baseline A1C levels.²⁸ The DIAMOND Type 1 and GOLD study results also illustrated that CGM use was associated with significantly reduced time spent in and episodes of hypoglycemia, particularly overnight.

Hypoglycemia reductions among hypoglycemia-prone adults with T1D were studied in the HypoDE¹⁹ and I HART CGM^{18,29} studies. The HypoDE study reported a 72% reduction in the incidence of hypoglycemic events (defined as a series of glucose values ≤ 54 mg/dL for ≥ 20 min) for participants in the CGM group. The I HART CGM study highlighted the value of real-time CGM compared with intermittently scanned CGM, in that users of the real-time system experienced larger reductions in hypoglycemia than users of the intermittently scanned system, presumably because of the automatically generated alerts in the former configuration. The impact of CGM use in pregnant women with T1D on neonatal outcomes was recently documented in the CONCEPTT trial, with findings that demonstrated that CGM use improved maternal glycemic control with lower rates of neonatal complications in both insulin pump and MDI users.^{22,30}

Patient-reported outcome studies of CGM have documented the favorable experiences of patients and caregivers. Data collected with the DIAMOND Type 1 study demonstrated a broad satisfaction with the device for participants within the CGM group, which was associated with significant reductions in diabetes distress and hypoglycemia fear, as well as significant increases in hypoglycemia confidence and well-being.³¹ The reduction in hypoglycemia fear associated with CGM use in adults has been reported in multiple studies.^{27,32-34} For parents and caregivers of children with T1D, CGM, particularly with remote monitoring, has been found to improve multiple quality-of-life measures, reduce family stress, reduce overall worry and stress, and improve parental sleep.^{34,35} Although the effects of CGM data sharing among adolescents can vary,³⁶ parents of youth who consistently use CGM report high general quality of life for their children.³⁷

Observational studies have consistently associated higher device utilization rates with improved outcomes. Associations between device interactions and favorable decreases in mean glucose levels were observed by Dunn et al³⁸ (over 6 million data points from users of the Abbott FreeStyle Libre system)

TABLE. Selected Randomized Clinical Trials of CGM¹⁵⁻²²

Name (reference)	Population	Design	Goal(s)	Device(s)	Key Outcome(s)
DIAMOND Type ¹⁵	T1D A1C 7.5%-9.9%	Randomized 2:1 to CGM (n = 105) or usual care (n = 53) for 24 weeks	A1C reduction	Dexcom G4	Between-group difference of 0.6 percentage points in favor of CGM (P < .001). Significant reduction in hypoglycemia in the intervention group.
DIAMOND Type 2 ¹⁶	T2D A1C 7.5%-9.9%	Randomized 1:1 to CGM (n = 79) or usual care (n = 79) for 24 weeks	A1C reduction	Dexcom G4	Between-group difference of 0.3 percentage points in favor of CGM (P = .022).
GOLD ¹⁷	T1D A1C ≥7.5%	Crossover CGM vs usual care; Randomized 1:1 to 26 weeks of CGM before (n = 82) or after (n = 79) 26 weeks of usual care	A1C reduction	Dexcom G4	Between-group difference of 0.43 percentage points in favor of CGM (P < .001). Significant reduction in hypoglycemia in the intervention group.
I HART CGM ¹⁸	T1D GOLD score ≥4 or recent severe hypo	Randomized 1:1 to CGM (n = 20) or flash glucose monitoring (n = 20) for 8 weeks	Hypoglycemia reduction, CGM vs flash glucose monitoring	Dexcom G5, Abbott FreeStyle Libre	CGM reduces hypoglycemia more effectively than flash glucose monitoring.
HypoDE ¹⁹	T1D History of impaired hypo awareness or severe hypo in past year	Randomized 1:1 to CGM (n = 75) or usual care (n = 74) for 26 weeks	Hypoglycemia reduction in high-risk individuals	Dexcom G5	Incidence of hypoglycemic events fell by 72% for CGM group (P < .0001).
Comisair ²⁰	T1D/MDI or CSII A1C 7.0%-10%	Nonrandomized: CGM (n = 27) or SMBG (n = 38) for 52 weeks	A1C and hypoglycemia reduction	Dexcom G4, Medtronic Enlite	Comparable reductions in A1C and hypoglycemia in CGM/MDI and CGM/CSII groups
IN CONTROL ²¹	Adults T1D/MDI Impaired hypo awareness (Gold score ≥4)	Randomized crossover: CGM then SMBG (n = 26) or SMBG then CGM (n = 26)	Hypoglycemia reduction in high-risk individuals	Medtronic Enlite	Periods of CGM use associated with more TIR, less time in hypo- and hyperglycemia, fewer severe hypoglycemic events
CONCEPTT ²²	T1D with existing or planned pregnancy	Parallel arms, to 34 weeks in pregnant women; for 24 weeks in those planning pregnancy	A1C reduction	Medtronic Guardian REAL-Time	Between-group difference of 0.19 percentage points in favor of CGM (P = .02) in pregnant women; no difference in women planning pregnancy. CGM group had fewer LGA babies, fewer ICU stays of >24 hours, and fewer neonatal hypoglycemia events

A1C indicates glycated hemoglobin; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; ICU, intensive care unit; LGA, large for gestational age; MDI, multiple daily injections; SMBG, self-monitoring of blood glucose; T1D, type 1 diabetes; T2D, type 2 diabetes; hypo, hypoglycemia; TIR, time in range (70-180 mg/dL).

*Dexcom G4 Platinum CGM System with an enhanced algorithm, Software 505, the same algorithm used in Dexcom G5

BOX 1. ADA Recommendations for Real-time CGM Supported by A-level or B-level Evidence⁴³

- Should be considered in children and adolescents with T1D, whether using multiple daily injections or CSII, as an additional tool to help improve glucose control and reduce the risk of hypoglycemia. Benefits of CGM correlate with adherence to ongoing use of the device.
- When used properly and in conjunction with intensive insulin regimens, is a useful tool to lower A1C in adults with T1D who are not meeting glycemic targets.
- May be a useful tool in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes.
- Should be used as close to daily as possible for maximal benefit.
- May be used effectively to improve A1C levels and neonatal outcomes in pregnant women with T1D.

A1C indicates glycated hemoglobin; ADA, American Diabetes Association; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion T1D, type 1 diabetes.

BOX 2. CGM Coverage Criteria for Medicare Beneficiaries^{47,48}

- A diagnosis of T1D or T2D and a requirement for therapeutic CGM
- Frequent (4 or more per day) SMBG testing
- Three or more injections of insulin per day or use of an insulin pump
- An insulin regimen that requires frequent adjustments on the basis of the CGM data, which requires that the CGM be classified as a “therapeutic” device
- An in-person visit with treating practitioner within 6 months of ordering the CGM to evaluate their diabetes control and determine if the above criteria are met
- An in-person meeting with the treating practitioner every 6 months to assess adherence to their CGM regimen and diabetes treatment plan
- Use of a receiver classified as durable medical equipment to display glucose data, alone or in conjunction with a compatible smart device

CGM indicates continuous glucose monitoring; SMBG, self-monitoring of blood glucose; T1D, type 1 diabetes; T2D, type 2 diabetes.

and Battelino et al³⁹ (10,501 users of Medtronic sensor-augmented pump systems). Welsh et al reported on 10,000 individuals who transitioned from Dexcom’s G5 to its G6 system.⁴⁰ Patients who transitioned to the G6 system experienced fewer glucose readings in the hypoglycemic range than during their tenure as G5 users, which was attributed to a new G6-specific “Urgent Low Soon” alert triggered by impending hypoglycemia. A separate observational study reported on 15,000 youth with the ability to share their real-time G5 data with 1 or more remote monitors (“followers”).¹² The presence of at

least 1 follower was associated with significantly more sensor wear time and higher percentages of glucose values in relative euglycemia. This study’s results support the value of patient engagement and shared responsibility advocated elsewhere^{41,42} for successful T1D management. Although large patient numbers provide high levels of statistical significance in these studies, they are subject to selection bias and cannot be used to assert causal relationships.

In recognition of the considerable RCT-based and cohort study–based evidence of the utility of CGM use, the ADA issued several

recommendations with regard to CGM in early 2019. These recommendations are excerpted in **Box 1**.⁴³ The International Society for Pediatric and Adolescent Diabetes (ISPAD) agrees on the utility and value of CGM. It asserts that CGM allows improved recommendations for insulin management for all individuals with diabetes and may particularly benefit those with hypoglycemic unawareness. The ISPAD recommendations also concede that CGM presents a more sophisticated glucose monitoring approach than home SMBG; CGM can identify times of hyperglycemia and times of increased risk for hypoglycemia.⁴⁴

Coverage and Potential Cost Savings of CGM

Three years ago in this journal, a Medicare beneficiary's quest for CGM coverage was described as a "never-ending story" of appeals and denials.⁴⁵ In 2017, CMS issued a ruling⁴⁶ that allows Medicare coverage for beneficiaries who meet certain criteria summarized in **Box 2**.^{47,48} Importantly, the CGM system must provide data that guide treatment decisions ("therapeutic" CGM), and a dedicated receiver must be used (alone or in combination with a smartphone app) to view the results. Many commercial payers limit CGM coverage to patients with T1D through a durable medical equipment provision. Only a few cover the technology for patients with T2D using intensive insulin therapy even though these patients' risk of insulin-induced hypoglycemia is comparable to the risk incurred by patients with T1D.

Coverage of CGM through the pharmacy benefit can allow patients with diabetes to readily pick up their supplies, treatments, and glucose monitors from the pharmacy and not risk being without appropriate monitoring while on insulin. Dexcom CGM systems and components are available on the national preferred formularies of most pharmacy benefit managers and can be provided as a pharmacy benefit if elected by the health plan or plan sponsor.

Improved coverage for CGM systems may result in cost savings in the long run. A recent study by Herman⁴⁹ showed that 30 years of excellent control in T1D can substantially reduce the incidence of complications, comorbidities, and death; improve quality-of-life; and reduce costs. Mitigation of severe hypoglycemic episodes that require third-party assistance and impose substantial costs on the individual and on the healthcare system is likely to be a significant component of overall cost savings. Even nonsevere hypoglycemic events impose significant costs in the form of workplace absenteeism and lost productivity.⁵⁰ Cost savings may also result from lower rates of end-organ damage (eg, retinopathy and nephropathy) and reductions in SMBG test strip utilization.⁵¹

Next Steps

CGM is revolutionizing our approach to insulin therapy and creating new opportunities for innovation and standardization. It offers patients, and those involved in their care, actionable information that leads to improved outcomes. In the context of clinical trials, CGM-derived metrics, such as time in range, may serve as validated outcomes,⁵² and CGM-derived average glucose values may reflect the adequacy of glycemic control with more robustness and precision than A1C.⁵³

Currently, there are no professional society recommendations regarding CGM-derived metrics; however, several proposals for optimal use of trend arrows have been made⁵⁴⁻⁵⁷ and there is a guide to integrating CGM data into clinical practice.⁵⁸ The Ambulatory Glucose

Profile is a standardized tool for summarizing and displaying large amounts of CGM data and provides an efficient way to identify behaviors or times for judicious therapy intensification.⁵⁹

In the near term, category awareness and adoption of CGM systems will likely increase, and systems with the "integrated CGM" designation will be used in a wider range of mobile health-related apps, decision support systems, and automated insulin delivery systems. The devices themselves are likely to become smaller, more accurate, more durable, and more cost-effective. Our expectation and personal experience is that CGM will continue to lessen the cognitive, emotional, physiologic, and economic burdens of insulin-requiring diabetes. ♦

AUTHOR INFORMATION.

John B. Welsh, MD, PhD, is a physician who writes about diabetes technology and has had type 1 diabetes since 1976. Roy Thomas, PharmD, is a pharmacist and a medical science liaison at Dexcom.

CORRESPONDING AUTHOR.

John B. Welsh, MD, PhD, Dexcom, Inc., 6340 Sequence Drive, San Diego, CA 92121; Email: john.welsh@dexcom.com.

DISCLOSURES AND FUNDING.

The authors are employees and shareholders of Dexcom, Inc. This work received no specific funding.

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MEDICARE COMPETITIVE BIDDING PROGRAM

Three Years After Advocates Report Flaws, Medicare Diabetes Test Strip Bidding Program Nears Collapse

Samantha DiGrande and Mary Caffrey

continued from cover

diabetes who are treated with insulin, monitoring glucose levels is vital to maintaining health and determining the proper insulin levels to be administered. According to the American Association of Clinical Endocrinologists and American College of Endocrinology, SMBG should be performed by all patients using insulin at least twice daily. More frequent SMBG after meals or in the middle of the night may be required for insulin-taking patients with frequent hypoglycemia.²

“Blood glucose testing for patients on insulin is critical to help them manage their diabetes effectively and remain safe. Access to glucose testing is critical in this population, foremost for their health but also given that hospital admissions for hypoglycemia have climbed and the highly effective way to prevent this is to ensure adequate home blood glucose monitoring,” said Robert Gabbay, MD, PhD, FACP, editor-in-chief of *Evidence-Based Diabetes Management*TM (EBDM) in an email to the journal.

Even before the CBP launched in 2011, patients and advocates questioned Medicare’s limits on how many strips patients could have per day, given that frequent testing is particularly recommended for seniors who use insulin.³ However, critics of the CBP said instead of savings for the government and consumers, the program created a “race to the bottom” in both price and accuracy, as low-quality test strips flooded the market, resulting in poor health consequences for seniors.⁴

In the initial implementation of the program, SMBG products were affected if they were obtained by mail order; single payment rates were reduced from \$34 to \$14 per vial of test strips.¹ A report from November 2017 found that the prices for the mail-order program had fallen 71%, to \$8.32 since the program began in 2011.⁵

A 2016 study by Puckrein et al, presented evidence that a CBP pilot for test strips had caused disruptions to the supply chain, and that changes were needed to protect patients.¹ However, CMS took the program nationwide anyway,⁶ and recent events show that problems with the CBP have continued:

- Researchers and advocacy groups say in interviews that payments for test strips are so far below market value that there is no incentive

TABLE 1. History of All Suppliers of A4253 With Claims Lines Allowed per FOIA-Provided Data to AAHomecare

Year	Suppliers	% Change	Claim Lines Allowed	% Change
2013	12,183		11,171,879	
2014	9836	-19%	10,517,295	-6%
2015	9276	-6%	9,929,460	-6%
2016	8743	-6%	8,996,193	-9%
2017	7977	-9%	5,941,421	-34%
Cumulative		-35%		-47%

FOIA indicates Freedom of Information Act. A4253 indicates blood glucose reagent strip. Data provided to the American Association for Homecare (AAHomecare) through FOIA.

to participate in the CBP, except to gain access to patients for other products. A CMS rulemaking last year brought an end to diabetes supply contracts on January 1, 2019⁷; the mail-order market has essentially bottomed out, and experts predict some retail suppliers may walk away, too. The advocacy group Diabetes Patient Advocacy Coalition reported in September 2018 that 98% of the program’s mail-order suppliers have been eliminated.⁸

- Data provided to EBDM by Tom Milam, founder and president of TrueLifeCare, show a 35% overall decline in test strip suppliers from 2013 to 2017, and a 47% decline in claim lines (Table 1). The data align with a follow-up study from Puckrein et al, who reported in May 2018 that CMS’ decision to take the CBP nationwide meant disruption to SMBG supplies has “persisted and worsened.”⁹
- An arrest in February 2019 of a former CVS employee exposed an apparent control problem in the CBP supply chain; CVS is revising prescribing protocols in a move it said is unrelated to the arrest.¹⁰
- Dan Patrick, a patient with type 1 diabetes (T1D) living in Ohio, told EBDM in an interview that he is required to bring his test results to his pharmacist in order to continue receiving test strips, but he has no idea what happens to his data. According to Christopher Parkin, MS, a coauthor on both *Diabetes Care* studies^{1,9} and the president of CGParkin Communications, this requirement affects patients who are prescribed to test more than 3 strips per day, which is the minimum amount that Medicare will cover. However, other experts told EBDM that sometimes when data are presented to a pharmacist, they do not reach physicians.
- On March 8, 2019, when CMS issued its updated proposal for durable medical equipment (DME) suppliers—which will address those contracts currently expired—diabetes supplies were left out.¹¹ A CMS spokesman told EBDM in an email that more time is needed to meet requirements imposed by Congress in February 2018.

When asked for comment on the effect of the gap period on patients with diabetes, CMS pointed only to the digitally available “Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program (DMEPOS): Temporary Gap Period Fact Sheet,” which includes instructions for patients ordering many types of supplies.¹²

The implementation of the CBP brought about consolidation in the marketplace. Where there were once dozens of suppliers with a share of the Medicare test strip market, a report published by the Office of the Inspector General in January 2019 found that “the top 2 test strips [types] accounted for 53% of the Medicare mail-order market,” and “the top 10 strip types accounted for 98% of the Medicare mail-order market.”¹³

New contracts are not expected before the end of 2020. According to a CMS statement, during this gap period, “People with Medicare may have to switch to another supplier if their current supplier isn’t willing to continue to provide the items on or after January 1, 2019.”¹²

Saving Money Was the Goal, but Stakeholders Found Flaws

In 2011, CMS launched the CBP in 9 test markets that included 2.3 million beneficiaries enrolled in fee-for-service Medicare across the United States.¹ The aim of the program was to lower the cost of diabetes testing products for both consumers and Medicare, and CMS quickly declared the pilot a success with plans to expand.¹ CMS published a report based on Medicare claims data from 2009 to 2012 that found that “the...competitive bidding

program has reduced overall Medicare spending without any negative effects on access to necessary supplies or beneficiary health indicators.”⁶

But critics of the program, including the National Minority Quality Forum (NMQF) and the American Association of Diabetes Educators (AADE), challenged CMS based on reports of patients’ inability to access supplies. Led by Gary Puckrein, PhD, president and chief executive officer of NMQF, in April 2016, they published a study in *Diabetes Care* that found not only had the pilot program disrupted patients’ ability to acquire the test strips they had been prescribed, but their inability to test as often had led to increased death rates, inpatient admissions, and higher costs.¹

“Their study [CMS] wasn’t good. It sure wasn’t science, I’m not sure what they’re doing. The [Government Accountability Office] took a look at that study and agreed that it wasn’t measuring what they [CMS] said it was measuring,” Puckrein told *EBDM*.

Parkin explained to *EBDM* that “CMS failed to establish (or report on) baseline values for DMEPOS acquisition behaviors and health status, thus making it impossible to determine whether changes in either measure occurred. CMS also failed to construct a ‘matched’ control group, which would have allowed them to determine whether changes in acquisition and health status was, in fact, the result of the CBP, and the significance of any changes seen compared to beneficiaries who were not affected by the CBP.”

Former US Representative Nancy Johnson of Connecticut, a Republican who was a cosponsor of the law that created the CBP,¹⁴ said the effects of the CBP on beneficiaries were immediately clear, and stakeholders came forward quickly. “People came to us [Congress] to get it stopped,” she said in an interview with *EBDM*. “Congress forced CMS to stop after 2 months. That’s unheard of, but the impact was so negative that there were 6 or 8 things we wanted to change, so we put in 1 or 2 [into a bill] and they only addressed the 1 or 2.”

“The program is now so complicated that you can break the law and not be held accountable,” said Johnson. Predictions of the race to the bottom were coming true. “The theoreticians were right, and we’re seeing the impact on patients,” she said.

Milam supplied data to *EBDM* (Table 1), which was obtained through a Freedom of Information Act request, that showed the number of claim lines for test strips have declined in utilization from 2013 to 2017 by 47%, and the number of available suppliers for test strips also saw a significant decline, from 12,183 in 2013 to only 7977 in 2017. This represents substantial consolidation in the marketplace, as several suppliers have simply left the Medicare marketplace or been forced out.

Milam, said for some, letting the contract

lapse was the last straw—it means there is no immediate hope that below-market prices will increase. Although the program is technically open to “any willing supplier,” none are willing to lose money at the prices Medicare will pay.⁸ At the start of the Trump administration, former HHS Secretary Tom Price, MD, who had served in Congress, had backed legislation to correct the problems, but once he resigned it languished. According to Milam, “[Price] had an interest in getting it fixed. His departure left things in limbo for quite some time. As a result, the gap was created, and the ‘improvements’ will certainly not be what he had envisioned and hoped for.”

“I can tell you, we worked with suppliers who

“Although we no longer had a ‘control group’ (comparator population) due to the national roll out, there is every reason to believe that the increased hospitalizations, mortality, and costs shown in our first report were experienced throughout the entire insulin-treated beneficiary population.”

— Chris Parkin, MS

were in the Medicare program providing SMBG to beneficiaries, and what they told us is that ‘we have no interest, there’s no money in this and we can’t provide the products at that price, we’d lose money and we’ll never participate again.’ Those were some large suppliers saying that.”

Cuts to Test Strip Payments Eliminate Other Services

Robert Salmon, RPh, tried as long as he could to make the CBP work, but in August he left the program due to CMS rejecting his bid more than 20 years after he began a mail-order business as a small sideline run from the back of his Charleston, Mississippi, pharmacy. The Diabetic Shoppe, now a separate business, is located in the state’s Delta region, an area with one of the highest diabetes rates in the country.¹⁵ Salmon sees the effects of the disease play out across generations. “What you have is socially, educationally deprived people who are also not eating right and doing the right things, and getting sick and overweight and handing that down through the children, and then the children are given to the same set of circumstances,” he said.

Treating diabetes is one thing, but Salmon aimed to teach his clients to break the cycle. At its peak, the Diabetic Shoppe employed 70 people—including diabetes educators, a certified disease state manager, and a dietitian. He ran seminars called Diabetic Days, “but that’s all gone by the wayside,” because he could no longer make it all work financially as payment for test strips went lower and lower.

Salmon said the CBP as designed works against clients like his, whom he described as some of the sickest in the country and least equipped to navigate Medicare without help

from a prescriber. “I have a college education and I couldn’t figure out how to get supplies off the internet,” he said. “Everyone in Medicare is over 65 and has a flip phone, so if I couldn’t do it, neither could they.”

“If you want to save money, the cheapest thing you can do is make sure they have enough testing supplies,” he said. It’s in CMS’ interest to make sure suppliers are legitimate businesses, “that have infrastructure and are not just trying to make money off [patients], but making relationships.”

Salmon said he still serves Medicare clients since the program lapsed in December, but he did not increase prices. “We lose money when we do it,” he said. His pharmacy continues to serve existing Medicare clients but doesn’t seek new ones.

CMS has not weeded out reselling test strips as it has reduced claim lines. Instead, Salmon said, seniors became frustrated and stopped trying to get their supplies through Medicare. Thus, they are either getting test strips elsewhere, or testing less frequently, if at all. Puckrein et al reached a similar conclusion in their 2018 follow-up

study in *Diabetes Care*, as they noted a 59% jump in beneficiaries who are full-time insulin users but only use SMBG part time or not at all. The authors wrote, “...we now have a large percentage of our cohort calculating their insulin dosages with inadequate (or no) SMBG to guide their therapy decisions.”⁹

“Although we no longer had a ‘control group’ (comparator population) due to the national rollout, there is every reason to believe that the increased hospitalizations, mortality, and costs shown in our first report were experienced throughout the entire insulin-treated beneficiary population,” Parkin told *EBDM*.

“The older people and the poor people—the people less likely to do what it takes and fend for themselves—these are the populations that have been mistreated and have had services taken away from them,” Salmon said. The worst part, he added, is that many commercial insurers are taking their cues from CMS on supply reimbursement. “Yeah, they pay for it, but they don’t pay as much as the product costs. In effect, they don’t pay for it. It’s too frustrating for patients, so they just give up and quit. I’m hoping someday CMS will see the light, but I don’t know what it would take.”

An Arrest Draws Attention to the Secondary Market

Many diabetes supply manufacturers make proprietary strips that only work with their meter, and if a patient changes meters (eg, because of a doctor’s recommendation or a change in insurance), a patient may have a supply of unused strips. The practice of reselling unused test strips has created a so-called “gray market,”¹⁶ which Medicare has tried to subvert. One recent

high-profile account did not involve a beneficiary, however. In February 2019, federal officials charged a former CVS employee, Antonio Rivera, with stealing diabetic test strips. Rivera, a former senior purchasing associate for CVS Pharmacy, is accused of ordering excessive amounts of test strips, intercepting the shipments and selling them to third-party retailers for personal gain.

According to an internal audit by CVS, the company could not account for 20,203 boxes of diabetic test strips ordered by Rivera, which amounts to a financial loss of \$2,535,307.63 for CVS.⁵ The charges— theft of preretail medical products, trafficking in stolen pre-retail medical products, and wire fraud— carry a maximum sentence of 20 years in prison and a \$250,000 fine.

EBDM reached out to CVS for comment on the arrest, to which CVS replied that it is “committed to supporting the health needs of patients who have diabetes while also complying with applicable requirements and guidelines.” Just before Rivera’s arrest, on January 29, 2019, CVS Pharmacy began limiting the quantities of diabetes testing supplies (DTS) covered under Medicare Part B to Medicare’s standard utilization guidelines in order to comply with medical necessity requirements.

“Under these guidelines, CVS will dispense DTS—including test strips and lancets—to non-insulin-dependent Medicare Part B patients for testing no more than once per day; and to insulin-dependent Medicare Part B patients for testing no more than 3 times per day,” Gary Serby, director of corporate communications at CVS Health, told *EBDM* in an email.

Serby also explained that leading up to the January 29 deadline, CVS contacted its Medicare Part B patients with diabetes and their prescribers to inform them of the change in guidelines. It is unknown how far in advance patients and prescribers were notified; however, importantly, “Medicare Part B patients with current DTS prescriptions that exceed the guidelines will require a new prescription that meets Medicare’s standard utilization,” he said.

This new requirement could affect patient access to DTS, as it will demand some current patients obtain new prescriptions from providers.

Rivera’s arrest illustrated demand for DTS on the secondary market, which is something stakeholders say exists in part because of challenges in the CBP. With the contract lapse and no date certain for a replacement, there are concerns that seniors who rely on Medicare for DTS will face fewer options.

Stakeholders Call for Changes to the CBP

As recently as September 2018, the AADE sent a letter to CMS stating, “AADE has expressed serious concerns with the CBP since its implementation in 2011. We continue to urge CMS to address the many flaws inherent to this program. The CBP, as currently designed and functioning, limits choice of testing systems for Medicare beneficiaries and reduces access to safe, effective, and high-quality products. This has resulted in diabetes-related complications, negative health outcomes, and healthcare costs.”¹⁷

In February 2018, after CMS had failed to act on earlier concerns about the program, Congress included language from the Protecting Access to Diabetes Supplies Act in the fiscal year (FY) 2018 to FY2019 budget. The language made several changes to the CBP, including strengthening the 50% rule, which requires suppliers to provide at least half the brands that beneficiaries use, and the anti-switching rule, which indicates that suppliers cannot entice beneficiaries to switch brands.

Specifically, the bill required the following¹⁸:

- Bidding suppliers must demonstrate an ability to obtain an inventory of strips consistent with the inventory mix provided in that supplier’s bid
- A surveillance program to be established to ensure the rules of the program, specifically the 50 Percent Rule, are followed
- CMS to use multiple data sources to measure compliance
- Codifying the anti-switching rule
- Allowing beneficiaries to interrupt the claims cycle by requiring suppliers to contact and receive a refill order not more than 14 days prior to dispensing a refill
- Suppliers to verbally provide beneficiaries with an explanation of their rights

However, despite these changes implemented by Congress, there was not enough time to evaluate the benefit before CMS allowed the CBP contracts to lapse.

“AADE has been closely tracking Medicare beneficiary access to safe, effective, and high-quality DTS. Since 2013, we have seen a marked decrease both in the number of Medicare claims submitted for DTS and in the number of suppliers (mail order and retail),” said Kate Thomas, director of Advocacy at AADE, in an email to *EBDM*. “This has created significant safety and access issues for Medicare beneficiaries trying to get the supplies they need.”

Patrick, the patient with T1D who spoke with *EBDM*, said CMS must do more than address availability of test strips—to keep patients safe, bids must be evaluated not just on price, but also on strict standards for accuracy and precision in measuring an individual’s blood glucose. “If they did that,” he said, “the program would look very different.” ♦

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PRICING CGM

A New Era: Increasing Continuous Glucose Monitoring Use in Type 2 Diabetes

Tejaswi Kompala, MD; and Aaron Neinstein, MD, FAMIA

continued from cover

In 2019, estimates put more than 30 million Americans living with T2D and 84 million with prediabetes, and both numbers are rising. Direct US healthcare spending on diabetes, both type 1 diabetes (T1D) and T2D, is currently estimated at \$237 billion, with 1 in 4 US healthcare dollars going toward the care of people with diabetes.¹ The critical importance of early glycemic control to prevent acute complications and halt disease progression to prevent chronic complications only intensifies as these costs, including the rising costs of insulin, increase.

SMBG and A1C Are Inadequate

The ability for patients and providers to gauge glycemic control in T2D depends on tools that provide incomplete information: self-monitoring of blood glucose (SMBG) data and glycated hemoglobin (A1C). It is challenging to get more than a limited set of SMBG data due to the inconvenience and pain associated with fingersticks, cost of test strips, and unforgiving requirements for specific timing. Even in the best of circumstances, SMBG data can be challenging to interpret. Patients and providers must frequently extrapolate from a single fasting blood glucose (BG) value or from glucose values at scattershot time points without clear temporal relationships to the food, exercise, or other stressors that provide key context. It should come as no surprise that although SMBG remains commonly used in both insulin-treated and noninsulin-treated patients, study results in noninsulin-treated patients have struggled to show efficacy of SMBG in changing patient behavior or reducing A1C.²

While A1C provides a useful measure of overall control, it cannot, either in real time or retrospectively, reveal a person's specific behaviors and actions to more meaningfully inform patient and provider decisions. An A1C of 7% may underlie either exquisitely stable BG values or mask a roller coaster, coupling dramatic postprandial BG spikes with overly aggressive insulin use and resultant hypoglycemia.

Cheaper and Better CGMs

The first CGM was released by MiniMed (now Medtronic) in 1999. These early systems were rarely used due to cost, painful insertion, bulky size, poor accuracy, and the requirement for numerous fingerstick calibrations. However, as the technology has improved, data have shown improved glycemic control and decreased rates of hypoglycemia in those using CGM, leading both the Endocrine Society and American Diabetes Association to state that CGM use represents standard of care in T1D.^{3,4} CGM in Americans with T1D is now on an exponential growth curve, rising from 6% in 2011 to 12% in 2014 to 24% in 2016 to 38% in 2018.⁵

High costs and uncertainty over efficacy and necessity have kept CGM from widespread use in people with T2D. However, the newest CGM models, the Abbott Freestyle Libre and Dexcom G6, have begun to overcome many of these technical barriers to use of CGM systems. The sensors are inserted painlessly, are small enough to fit easily under clothing, can remain in place for 10 to 14

FreeStyle Libre CGM Sees Rising Use With Pharmacy Chain Distribution

Mary Caffrey

When the FDA approved Abbott's FreeStyle Libre Flash continuous glucose monitoring (CGM) system in September 2017, diabetes advocates hailed the move as long overdue and one that might lead to greater penetration of glucose monitoring technology for those with type 2 diabetes (T2D).¹

The Flash CGM, which is also available in a Pro model for use by physicians,² was the first product that allowed people with diabetes to see how what they ate and drank or how exercise affected their blood glucose levels without the need for a daily fingerstick test to calibrate the device. Users wear a sensor on their upper arm and wave a reader over it to record blood glucose data (see **Figure**).

Although some patients with type 1 diabetes favor sensors and alarms on competing products, pricing and cost-sharing decisions by payers have sometimes put traditional CGM systems out of reach. For patients with T2D, payer coverage has been even harder to come by; when Medicare added CGM coverage, it was limited to those performing at least 4 finger-stick tests per day.³

The Abbott CGM system includes a 1-time cost of \$69 for the reader and \$120 for a pair of 14-day sensors; those with insurance pay between \$40 and \$75 a month.⁴ Aaron Neinstein, MD, director of clinical informatics at the University of California at San Francisco Center for Digital Health Innovation (see **Cover Story**), wrote earlier this year that Abbott's price point was more affordable than most CGM systems but could be still out of reach for many with diabetes.⁵

FIGURE. Flash Continuous Glucose Monitor



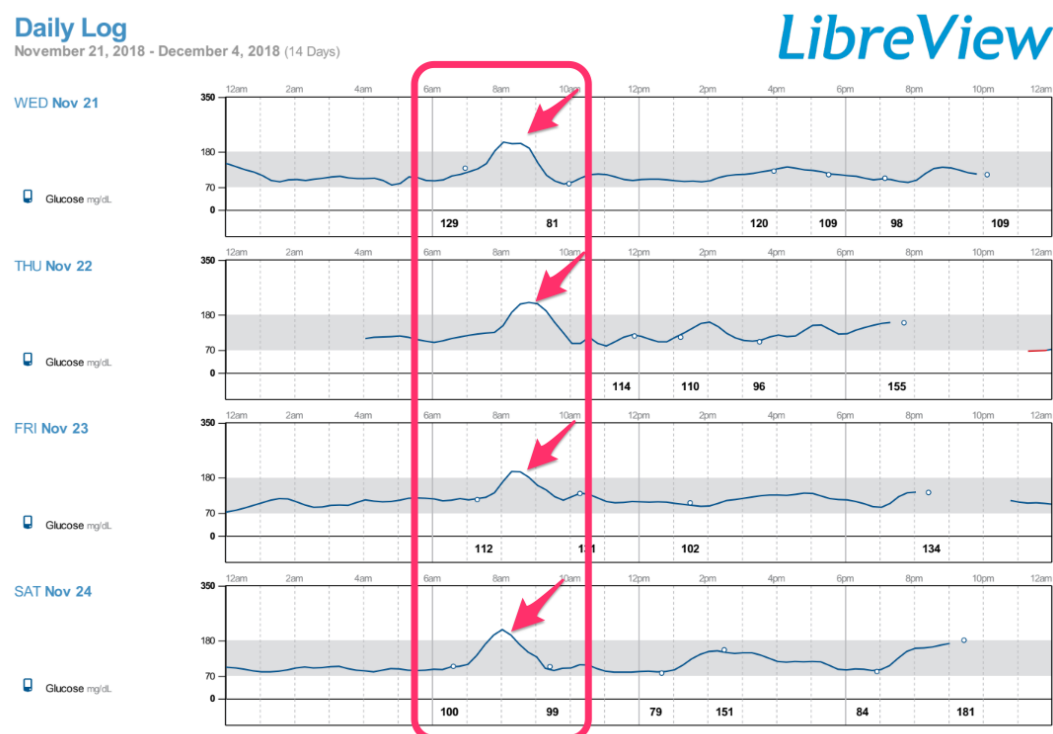
KOMPALA

Tejaswi Kompala, MD, is currently a clinical fellow in Endocrinology at the University of California, San Francisco. She is interested in diabetes prevention and improving diabetes care delivery.



NEINSTEIN

Aaron Neinstein, MD, FAMIA, is assistant professor of medicine at the University of California, San Francisco, with an active clinical practice in Endocrinology, and director of clinical informatics at the UCSF Center for Digital Health Innovation.

FIGURE 1: CGM (Abbott Freestyle Libre) Data Captures Daily Postbreakfast Glucose Spike^a

days, and are FDA approved as sufficiently accurate to use in lieu of fingersticks to make insulin-dosing decisions. Overcoming another significant barrier to use, data can now be seamlessly and continuously uploaded wirelessly to the cloud via a user's smartphone. Of note, the Libre is a flash glucose monitor, requiring the user to scan the sensor to reveal glucose information and recent trends. Although it cannot alert a person to acute hyperglycemia or hypoglycemia in the middle of the night, this is a nonessential feature for the majority of people with T2D. Perhaps most importantly, Abbott has introduced a new, lower-pricing category with Libre, at around \$75 to \$150 each month for sensors (2 sensors that last 14 days each), translating to \$900 to \$1800 per year compared with what is typically \$3000 to \$5000 per year for traditional CGM.

Real-time Biofeedback Enables Behavior Change

CGM affords 2 major benefits over the current standard of SMBG coupled with A1C testing: first, a vast increase in the quantity of blood glucose information, which provides a more comprehensive view of glycemic control. Rather than snapshots in time, continuous information allows us to capture important metrics like time in range, time in hypoglycemia, glucose variability, and many other emerging "glycometrics." These additional metrics cannot be captured with SMBG, even in the most diligent patients. A CGM recording BG every 5 minutes will record 105,120 BG readings per year compared with between just 1000 to 2000 in a person doing frequent SMBG.

Second is the ability of CGM systems to provide real-time biofeedback. With real-time data now

seamlessly available on a user's mobile device and the internet, easily visible trends and trajectories can help a person understand their own glycemic response in a more meaningful way. Patients can observe which foods and exercises affect them the most. Iterative exposure to this immediate biofeedback allows patients to learn about their own bodies and physiologic responses.

For example, we recently saw a 70-year-old man with T2D and heart disease, with an A1C of 7.5%, who takes metformin but had resisted making any changes to his diet. When he saw his graph of Libre data (Figure 1), he immediately identified the daily morning spike in his glucose level and its source: his daily glass of orange juice and banana. He cut these from his diet and reported an immediate improvement in his glucose levels. Also noteworthy is that had he used traditional fingersticks, he would have been completely unaware of these significant glucose spikes. His postbreakfast CGM scans showed readings of 81, 114, 131, and 99 mg/dL (Figure 2).

Clinical study results demonstrate that CGM in T2D is powerful for behavior change, a critical pillar in management. Patients adhere to exercise recommendations more consistently^{6,7} and decrease their caloric intake when using CGM systems.⁷ In addition, patients with T2D using CGMs have less hypoglycemia⁸ and, importantly, they have A1C reduction without intensification of their existing treatments.⁹

Based on information shared with investors, it appears payers and people with diabetes are responding to both the price point and a decision to distribute the product through the pharmacy chain.^{6,7} During the company's January 23, 2019, earnings call, Abbott reported that global sales of the FreeStyle Libre increased \$1 billion in 2018, up 100% from the prior year; the company reported 300,000 new users in the fourth quarter of 2018 alone, bringing worldwide users to 1.3 million.⁶

The pharmacy chain has proved increasingly popular for diabetes products. After struggling for years with barriers to receiving coverage for its popular Omnipod insulin pump as durable medical equipment under Medicare Part B, Insulet gained coverage through the pharmacy chain under Medicare Part D last year.⁸

The FreeStyle Libre Flash CGM is approved for users 18 years and older in the United States.¹ In October 2018, the FDA approved the FreeStyle LibreLink, an app that works with iPhone 7 and later, running iOS 11 and later.⁹

Evidence-Based Diabetes Management™ (EBDM) asked Abbott officials about progress with pharmacy chain distribution and how payers have responded:

EBDM: Can you discuss the thinking that led to pharmacy chain distribution? What were the pros and cons?

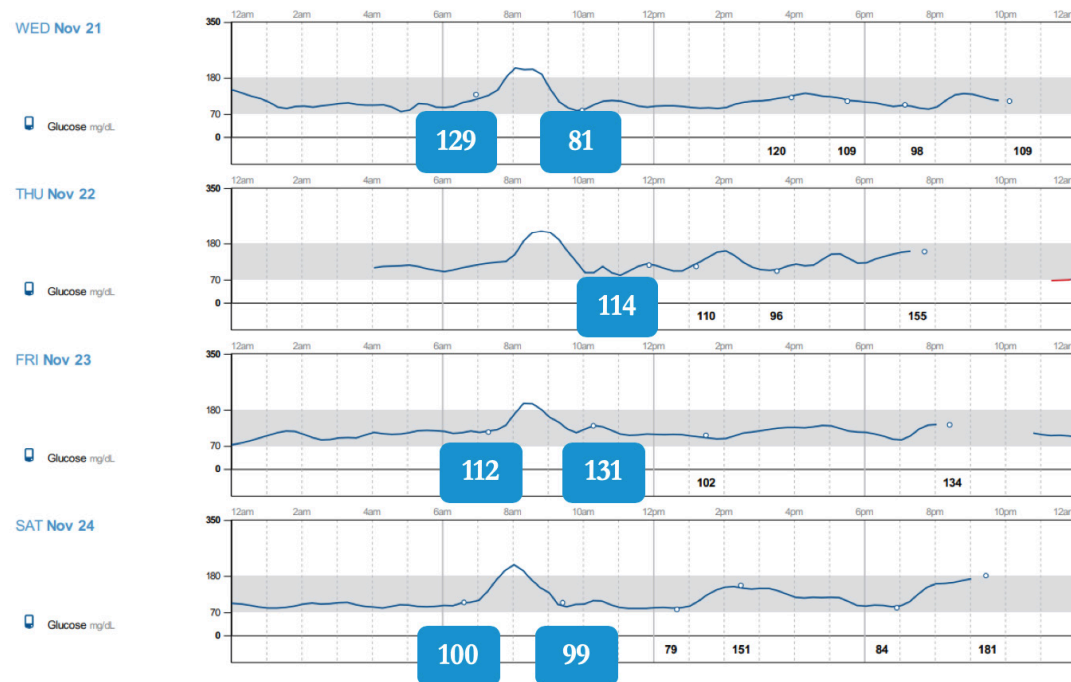
ABBOTT: At Abbott, we believe that access to information about your health should be painless, easy, and convenient. Many patients with diabetes use the pharmacy as a primary source for obtaining testing supplies today, and we wanted to enable patients to be able to continue to access their CGM supplies in the channel they find most convenient. In addition, eRx [e-prescription] prescribing systems are broadly used by physicians today, so prescribing the FreeStyle Libre system in pharmacy can be seamless, which has enabled broad uptake of [the] FreeStyle Libre system without the hassle of paperwork.

We also have distribution through the durable medical equipment [DME] channel, as [the] FreeStyle Libre system is covered under the medical benefit. This channel has seen particularly strong uptake for government insured patients, such as [those covered by] Medicare.

Overall, our goal at Abbott is to be able to have broad availability for FreeStyle Libre patients whether it is in pharmacy or through the DME channel.

EBDM: How is pharmacy chain distribution going at this point? What do CGM users like about this method? What unexpected issues still need to be corrected?

ABBOTT: So far our pharmacy distribution has been successful. [The] FreeStyle Libre system is available in all pharmacy channels, and from our data, we are the primary providers of CGMs to this distribution channel. Abbott is investing a significant amount of resources in education of pharmacists since CGMs is a new category to pharmacies. It is critical for pharmacists to be knowledgeable about this

FIGURE 2: SMBG Misses Postbreakfast Spike^a

BG indicates blood glucose; CGM, continuous glucose monitoring; SMBG, self-monitoring of blood glucose; T2D, type 2 diabetes. CGM (Abbott Freestyle Libre) data obtained from a 70-year-old man with T2D on metformin, showing the pre- and postbreakfast BG from the patient actively scanning the Libre, missing the post-breakfast glucose spike.

New Opportunities for Data Analysis and Coaching

Another challenge to date has been the lack of delivery system capacity to review, analyze, and interpret data, and then coach people with T2D based on their day-to-day glucose levels, a constraint which could potentially be magnified with the increased data provided by CGM. However, tech-enabled digital coaching services are emerging to help provide on-demand, accessible support for people with diabetes and prediabetes. Companies like Omada Health, Canary Health, Lark Health, Livongo, and others provide multiple touch points with enrolled patients to use biometric data (eg weight, blood pressure, blood glucose) for coaching and behavior change. Several of these services are already certified by CMS to provide digital diabetes prevention programs (DPP), and the availability of cheaper CGM means they will soon have access to rich, continuous BG data to be able to guide patients in interpreting and acting upon them. This will soon enable a capacity and scale for diabetes coaching that has never before been possible using the traditional care delivery system. The emergence of artificial intelligence tools to aid in data interpretation and even to automate some of the coaching via “chatbot” will only make this more efficient and cheaper.

Cost Implications of CGM Use in Type 2 Diabetes

One study looked at long-term cost-effectiveness for CGM use in people with T2D based on A1C reduction, projecting decreased rates of diabetes associated complications.¹⁰ Although we anticipate that A1C reduction through lifestyle changes by CGM users could prevent the addition of costly

new medications or dose intensification of existing treatments, more study is needed to test this. This matters: Studies looking at A1C compared with healthcare costs have found significant impacts.^{11,12} In one case, a 1% or more decrease in A1C was associated with \$685 to \$950 per year lower total healthcare costs,¹³ and in another, a 1% increase in A1C was associated with a 7% increase in healthcare costs over the next 3 years.¹⁴

There are likely to be cost savings for people switching from frequent SMBG to CGM. Given that a person using 4 test strips a day at a cost of \$1.30 per test strip—costs can vary widely from \$0.10 to \$2.00—is consuming \$156 per month in test strips, not to mention other consumables like lancets, the direct cost of CGM might actually be lower in this population in some cases, assuming these patients can largely eliminate their use of test strips. For those using much less frequent SMBG today, such as those not on insulin or with prediabetes, the incremental costs of CGM may seem imposing—but this doesn’t need to be the case. If one were to use a Libre for only 14 days every 3 months, the cost of sensors would be \$300 per year, at most, equivalent to about 4 to 5 test strips per week (at \$1.30 per strip), and we would argue the CGM would be of substantially higher value. Periodic CGM use enables treatment regimen changes, but more importantly, as seen by Vigersky et al, observations people make and behaviors they change while using CGM result in lower blood glucose levels even after they have stopped using CGM.¹⁵

technology to provide the right guidance to patients. We see this as an ongoing need as we continue to increase adoption of our FreeStyle Libre 14-day system. In addition, patients like the convenience of being able to pick up their CGM supplies along with their other prescriptions.

EBDM: Are payers receptive to this method of distribution? Do you see use of the pharmacy chain expanding as use of technology and digital health tools increase? Do payers have the right personnel on their end to work with you on these transactions?

ABBOTT: We have found that payers are very receptive to managing CGM through the pharmacy channel. Use of the pharmacy channel offers significant cost savings, the ability to easily track utilization and to offer their members a simple and convenient place to get their product. We have extensive experience working with payers, based on our blood glucose monitoring business, and we’ve been able to leverage this knowledge and experience to continue to secure access for CGMs.

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We believe that intermittent CGM use paired with coaching will provide much more impetus for lifestyle change than the current standard of every-3-months A1C with sporadic SMBG.

Summary

With rapidly improving CGM technology, wireless data upload, lower-cost CGM devices, and the availability of digital coaching tools, we believe the time is ripe for CGM use in a much broader population, including those with T2D who are on oral medications and those with prediabetes. Although additional studies will need to be done to demonstrate benefit in these populations, costs will likely continue to fall and technology will continue to improve, only further strengthening the value proposition for wider CGM use. ♦

AUTHOR INFORMATION.

Division of Endocrinology, University of California, San Francisco (TK, AN); UCSF Center for Digital Health Innovation (AN).

CORRESPONDING AUTHOR

Aaron Neinstein, MD
University of California, San Francisco
1700 Owens Street, Suite 541
San Francisco, CA 94158
aaron.neinstein@ucsf.edu
415-476-5397

FUNDING

There are no relevant funding sources.

DISCLOSURES

Dr Neinstein has received research support from Cisco Systems Inc. and The Commonwealth Fund. He has been a consultant to Steady Health, Nokia Growth Partners, WebMD, and Grand Rounds and has received speaking honoraria from Academy Health and Symposia Medicus. He is an uncompensated medical adviser for Tidepool.

Dr Kompala has no disclosures.

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PATIENT ADVOCATE PERSPECTIVE

JDRF Alarmed by Extension of UnitedHealthcare–Medtronic Pact to Youth With Type 1 Diabetes

Mary Caffrey

NEARLY 3 YEARS AFTER UnitedHealthcare set off a firestorm among the type 1 diabetes (T1D) community by naming Medtronic its preferred supplier of insulin pumps for adults,¹ a fresh wave of protest has erupted after the payer extended the pact to youth, starting at age 7. The change was announced in a UnitedHealthcare bulletin February 1, 2019.²

The change follows the FDA's expanded approval for the Medtronic MiniMed 670G for people with T1D aged 7 to 13 on June 21, 2018. The 670G, a hybrid closed-loop system, was previously approved for people with T1D aged 14 and older.³

JDRF, the advocacy and research organization previously known as the Juvenile Diabetes Research Foundation, issued a statement February 4, 2019, calling on UnitedHealthcare to reverse its decision, saying insurance restrictions “are bad for people with T1D, bad for children and their caregivers, and bad for our healthcare system.”⁴ In 2017, JDRF launched a campaign, Coverage2Control, to highlight the need for people with T1D to have choices in insulin, diabetes technology, and supplies like test strips, so that each person with T1D can select the products that best meets his or her needs.⁵

As was the case with the original policy change, the T1D community was taken by surprise, Cynthia Rice, vice president for advocacy and policy for JDRF, said in an interview with *Evidence-Based Diabetes-Management™* (EBDM). Expanding the policy to include youth aged 7 and older happened despite extensive talks with the payer that took place after the May 2016 decision, she said.

“This really does matter to our community,” she said. “These technologies are important to managing type 1 diabetes. People feel strongly they want to use what works for them, and they should make this decision themselves with their doctor.”

In an email, a UnitedHealthcare spokeswoman told EBDM that patient safety and helping those with diabetes avoid dangerous high and low blood glucose levels were the key factors in the decision to make the MiniMed 670G system the preferred product for people with T1D who are age 7 and older. The policy applies to those prescribed an insulin pump for the first time and those whose pump must be replaced after an older pump is out of warranty, according to the policy.

“Pediatric patients who are currently using a non-Medtronic pump may remain on that pump in conjunction with the physician's treatment plan,” UnitedHealthcare spokeswoman Tracey Lemper said.

A fact sheet provided by the payer stated that there is no change in coverage for those using nondurable tubeless pumps. However, UnitedHealthcare declined to clarify what happens if a person temporarily stops using a nondurable pump and uses multiple daily injections instead. Some people with T1D occasionally switch back to injections if they cannot afford the cost sharing to replace a pump or if they want to maintain the ability to manage their diabetes with insulin injections.

As it did in May 2016, UnitedHealthcare announced a clinical review policy that will allow physicians to appeal for their patients to use other pumps in special circumstances.² However, Rice said in the interview that successful appeals are rare, and UnitedHealthcare declined to release figures on the rate of successful appeals.

The UnitedHealthcare fact sheet stated that 9 of 10 enrollees who use an insulin pump already use a Medtronic pump. It is not clear how many youths with T1D will be affected by the new policy.

In July 2018, UnitedHealthcare released results from 6000 participants

who used Medtronic pumps over the first year of the preferred arrangement. The statement said there were 27% fewer preventable hospital admissions compared with UnitedHealthcare beneficiaries using multiple daily injections.⁶

However, JDRF's Rice told EBDM that statistic only measures how Medtronic users compare with those who aren't using insulin pumps. A more meaningful analysis would examine how people fared after they were forced to switch once a warranty ran out or how the outcomes of this group compared with those from a payer that allows people with T1D to use the insulin pump of their choice.

Rice said thus far that no one has released a study comparing outcomes for different insulin pump brands head-to-head. But advocates have been clear that the issue is not Medtronic's technology. Many leaders in the T1D community credit the company for pursuit of the 670G. The issue, they say, is that different products emphasize different features, such as alarms or alerts to family and caregivers, and features that matter greatly to one person may matter less to others.

In 2016, T1D advocates warned that the UnitedHealthcare–Medtronic relationship could affect competition and innovation in the diabetes technology marketplace. In 2017, Roche and Johnson & Johnson stopped selling insulin pumps in the United States and transferred their users over to Medtronic for customer service.⁷ However, in recent years Medicare has expanded coverage for continuous glucose monitors (CGMs). Dexcom followed by Abbott's Freestyle Libre received coverage after the CGM received FDA approval.^{8,9} Then Medicare covered the Omnipod insulin pump after years of interpreting durable medical equipment rules in a way unfavorable to the tubeless pump.¹⁰

Since the UnitedHealthcare decision, innovation has continued.¹¹ There is considerable anticipation about the partnership between Insulet, maker of the Omnipod pump, and Tidepool, which is working to get an automated insulin delivery app through the FDA, as well as Omnipod's work with Dexcom.¹²

Rice said it's important that payers remain open to covering different technologies. “The reason why a doctor might choose one insulin pump over another depends on a lot of factors—how well the sensor works, the emergency alerts to let people know they're about to have a severe low blood sugar,” she said. “UnitedHealthcare is really an outlier here... That's why we're advocating for them to join the rest of the industry.” ♦

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CGM IN RESEARCH

Bariatric Surgery Study Shows Potential of Using CGM in Clinical Research

Mary Caffrey

IN 2017, as advocates and researchers discussed the potential for continuous glucose monitoring (CGM) to become a tool in clinical trials, most of the discussion involved testing in new therapies.^{1,2} The discussion culminated in an international consensus on CGM, published in December 2017, that included standards for assessing hypoglycemia in clinical trials.³

From the start, the Abbott FreeStyle Libre Pro, approved in September 2016, appeared to be the default CGM choice for clinical trials: It is factory calibrated, does not require patient interaction, and allows healthcare professionals to download the glucose data after 14 days.⁴ In September 2017, the FDA approved the FreeStyle Libre Flash CGM for consumer use with a 10-day sensor; it approved the 14-day sensor in July 2018.⁵

“This finding, if replicated in a larger-scale, longer-term study, preferably a randomized controlled trial, would indicate a need for an early reduction in the dose of [T2D] medication.”

—Wysocki et al

In February, a small study published in the journal *Obesity Surgery*⁶ showed that CGM technology is already giving researchers the ability to not only track minute-by-minute data but also customize surgical or therapeutic interventions for individual patients.

In the study, researchers from Jagiellonian University Medical College in Krakow, Poland, used the FreeStyle Libre CGM to study patients with and without type 2 diabetes (T2D) who underwent 2 methods of bariatric surgery, laparoscopic sleeve gastrectomy and laparoscopic Roux-en-Y, also known as gastric bypass. Of the group, 16 patients had T2D and 16 did not; 18 had the sleeve procedure and 14 had gastric bypass. Patients were tracked for the 10-day postoperative period, from the day of surgery onward.

Patients in the study had a body mass index of 35 to 50 kg/m². Their diabetes was very well controlled: The median glycated hemoglobin (A1C) in the patients with T2D was 5.5%, which did not differ from that of the control group ($P = .460$). Preoperative daily blood glucose concentration between the 2 groups was also similar ($P = .622$).

Although the mean postoperative blood glucose concentration over the length of the study was similar between the 2 types of surgical groups and between those with and without T2D, use of CGM revealed different patterns, giving physicians insights into when diabetes therapy should be altered to prevent hypoglycemia.

The research team found the following results:

- Among the 32 patients, glucose concentration was within the target range of 3.9 to 6.7 mmol/L 68% of the time during the 10-day postoperative period.
- There were 12 ± 6 low-glucose events (<3.9 mmol/L) per patient, which were more frequent among the T2D patients than those without the disease (14 ± 5 events vs 9 ± 6 events; $P = .035$).
- After gastric bypass, patients with T2D had more low blood glucose episodes that lasted significantly longer than patients with T2D who had

the sleeve procedure ($P = .035$ and $P = .049$, respectively).

- Although mean daily glucose concentrations did not differ between the groups on days 1 to 3, by day 4, the CGM showed significantly lower CGM concentrations for patients with T2D who received gastric bypass compared with those who had the sleeve procedure; symptoms were seen in 4 patients with T2D who had gastric bypass that required glucose infusions.
- Just 2 patients did not have any hypoglycemia; both had the sleeve procedure. Low-glucose events, most occurring without symptoms, were seen in all the other patients at some point.

The authors noted that prior studies had tracked glucose status after bariatric surgery but for shorter periods; this pilot study was one of the first to use CGM to compare 2 surgical methods and follow patients for 10 days. The CGM showed that patients both with and without T2D had rapid rise in interstitial glucose concentration right after surgery, with a higher increase seen in those who had the sleeve procedure, although the difference was not statistically significant. This was consistent with prior study findings showing hyperglycemia immediately after surgery, which can result in complications and hospitalization.

The study's chief finding—pinpointing the drop in blood glucose levels after the third postoperative day for patients with T2D undergoing gastric bypass—is likely explained by greater incretin release following the procedures, the authors concluded. “This finding, if replicated in a larger-scale, longer-term study, preferably a randomized controlled trial, would indicate a need for an early reduction in the dose of [T2D] medication,” they wrote. Thus, they concluded, for these patients, therapy should be cut back even before weight loss begins.

Forthcoming studies will make use of the FreeStyle Libre Pro. Joslin Diabetes Center is leading a study that examines the relationship between blood glucose levels and retinopathy and nephropathy risk; participants who use the CGM are asked to mail the sensor to the coordinating center after wearing it for 14 days. Data collection is expected to be finished June 30, 2019.⁷ ♦

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Coverage by Laura Joszt, Kelly Davio, and Mary Caffrey



Drug prices continue to increase in the United States.

Senate Committee Discusses the Burden of High Drug Prices and Potential Solutions

INCREASED TRANSPARENCY, value-based pricing, and other policy reforms are necessary to ensure that Americans can access medications at affordable prices, a panel of experts said during a US Senate hearing January 29, 2019.

Douglas Holtz-Eakin, PhD, president of the American Action Forum; Mark E. Miller, PhD, vice president of healthcare for the Laura and John Arnold Foundation; and Peter B. Bach, MD, MAPP, director of Memorial Sloan Kettering's Center for Health Policy and Outcomes, joined Kathy Segó, the mother of a child with insulin-dependent diabetes, at a hearing on prescription drug prices before the US Senate Committee on Finance.

Segó relayed the heartbreaking story of her 22-year-old son, Hunter, who received a diagnosis of type 1 diabetes around his eighth birthday. Just before leaving for college, Hunter found out exactly how much his insulin cost his family when he went to pick it up at the pharmacy and was given a price tag of \$1700 for 4 vials. According to Segó, her son panicked at the thought of spending that much money, even with health insurance.

Later, she found out that he purchased just 1 vial and decided to ration it. In 2 weeks, he lost 20 pounds because he severely cut his food intake to match the amount of insulin he was taking. According to Segó, her son could have died. "I'm heartbroken to know my son thought he was a financial burden to us," she said. "Money over life is not the choice we want him to make."

At the beginning of the hearing, Sen Ron Wyden (D, Oregon), the ranking Democrat on the committee, highlighted what he called a "grotesque" practice by pharmaceutical companies: ratcheting up the price of older drugs.

He provided the example of Humalog, from Eli Lilly, which cost \$21 a vial in 1996 and is \$275 a vial today. That represents a 13-fold price increase for insulin, which was discovered in the 1920s. "Humalog is not 13 times more effective," Wyden said. "A vial does not last 13 times longer than it did in 1996."

Price increases by companies that have been left unchecked to set prices

on their own have "turned patients into beggars," he added.

Both Wyden and the committee chair, Sen Chuck Grassley (R, Iowa), noted that the heads of the major pharmaceutical companies had been invited to the hearing, and they all passed. According to Wyden, that is telling. In the past, even representatives of cigarette companies, which "make a product that kills people," he said, testified before the committee.

It is important to address the rising costs of prescription drugs because they are a basic necessity for many Americans and their loved ones, Grassley said. Although he acknowledged the need for a strong research engine to develop new treatments, he said there must be a discussion about the affordability of new drugs. "When it comes to drug pricing, you should not need a PhD in economics to understand how much your prescription costs," Grassley said.

Grassley added that he is in favor of more transparency and mentioned the idea of including drug prices in television ads. In October 2018,¹ President Donald Trump proposed requiring drug companies to include prices in ads as part of his blueprint, American Patients First.

According to Grassley, this is a logical step. Drug advertisers tell consumers about the benefits of the drugs and also are required to disclose side effects, "but they don't seem very gung ho to tell you how much a drug costs," he said.

Holtz-Eakin described the combination of supply and demand as a recipe for an economic crisis: Development costs about \$3 billion, and just 8% of drugs are ultimately approved; meanwhile, more than half of Americans take drugs; 60% have at a chronic condition and 40% have at least 2. He explained that policies need to address how to improve the supply side by lowering the cost, shortening the time between when a drug is tested and when it comes to market, and increasing the number of both branded and generic drugs. "There's nothing better than having multiple drugs," he said.

Miller highlighted the importance of protecting innovation and also lowering the cost for the patient and the taxpayer. "You have headroom between the prices being charged and being paid and how much is being spent on [research and development]," he said. "I think you can go after prices and go after spending and not immediately threaten innovation—but you should always keep that in mind."

Another solution is value-based pricing, which can address expensive drugs that have no current competition, Bach said. Through this mechanism, prices would be set based on the drug's benefits. The current healthcare system has little alignment between costs and benefits.

Bach also discussed value-based insurance design, which reduces the copayment for patients if the drug has higher value. "The notion is not that the patient should pay more," he said. "The notion is that the pharmaceutical company should capture a higher price if their drugs work better relative to if their drugs work less well." This would reallocate money away from drugs where the prices don't match the benefit and free up money for drugs that work better, he said.

The idea of drug reimportation was raised during the hearing after Segó said that during a visit to Hungary, her family found that there, a vial that would cost them more than \$400 out of pocket in the United States costs just \$10.

Although she wanted to stockpile vials, that wasn't a sustainable option. Her family couldn't visit another country every time Hunter needed more insulin.

Another committee member, Sen Debbie Stabenow (D, Minnesota), said that it's just a 10-minute drive for some of her constituents to cross the border to Canada, where drug prices can be 40% lower. She questioned how a company can argue that an FDA-approved drug is not as safe if it's bought in Canada: "We have trade on everything else, but we close the border on safe, FDA-approved drugs on both sides of the border."

Stabenow noted that Segó's situation is not rare, adding that she wished it was. She relayed that she heard about a similar situation from

a constituent in Minnesota, whose son died after rationing his insulin. What, Stabenow asked Sego, would she say to the drug company executives if any of those invited had shown up?

“As a mother, I would probably say to them: ‘I hope you know that there are people who are going without their medication, and because they’re going without their medication, they’re at risk of dying.’” Sego said. “I don’t know how any person would be OK with knowing that the medication [cost] is so high that you have to make a decision about life or death.”

Editor’s note: As Evidence-Based Diabetes Management™ went to press, leaders of several major drug manufacturers, including Sanofi, were scheduled to appear before the Senate Committee on Finance on February 26, 2019. ♦

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Judge Dismisses RICO Claims, but 3 Insulin Makers Still Face Drug Pricing Lawsuit

A US DISTRICT JUDGE in New Jersey has allowed a proposed class-action lawsuit against 3 major insulin makers to proceed.

The suit, *Chaires v Novo Nordisk Inc*, was originally brought by a group of individuals who filed a 2017 complaint¹ against Novo Nordisk, Eli Lilly, and Sanofi. It was filed on behalf of the individuals themselves and a proposed class of insulin users who had paid for any part of the purchase price of several brand-name insulins.

The decision came after the Type 1 Diabetes Defense Foundation voluntarily dismissed *Boss v CVS Health* and related claims over its objection to an agreement entered into among law firms but not disclosed to an original plaintiff, Julia Boss.² The tolling agreement, discussed at length in the March 2018 issue of *Evidence-Based Diabetes Management™*, prevents prosecution of pharmacy benefit managers (PBMs) until a later date.³

The original complaint alleged that rising insulin prices are unrelated to rises in production costs and that “Sanofi, Novo Nordisk, and Eli Lilly have not only dramatically increased their insulins’ benchmark prices in the last 10 years, they have done so in perfect lockstep.”

According to the plaintiffs, in order to secure positions on PBMs formularies, the drug companies artificially inflated list prices, providing higher rebates to PBMs and forcing patients (especially those who are uninsured, have high deductibles, have high coinsurance rates, or are in the Medicare Part D coverage gap) to pay more out of pocket.

“In an industry where artificial benchmark price inflation has become common, Sanofi, Novo Nordisk, and Eli Lilly are [3] of the worst offenders,” read the complaint.

The plaintiffs also alleged that the drug makers violated the Racketeer Influenced and Corrupt Organizations Act (RICO). Novo Nordisk and Sanofi asked the court to dismiss the RICO claims, saying that the plaintiffs’ claims were barred by the “indirect purchaser rule,” a doctrine that states that a party cannot show that it was harmed by providing evidence only of purchases made indirectly.

The drug makers argued that the plaintiffs could not claim to have purchased their insulin directly from the companies because the products were sold to the patients by retailers (who in turn obtained the insulin from other members of the supply chain) and that the companies’ actions did not amount to a conspiracy under RICO.

In an opinion⁴ filed on February 15, 2019, Judge Brian R. Martinotti agreed with the insulin makers’ argument and dismissed the RICO claims.

However, he denied the defendants’ request to dismiss the suit for not having demonstrated a measurable loss to the plaintiffs, allowing the case to proceed.

The judge wrote in his opinion that the plaintiffs adequately pleaded a measurable loss in their contention that they were unfairly made to pay more than their share of the net prices of insulin. The court also held that the plaintiffs adequately alleged “fraudulent, unfair, or unconscionable conduct” on the part of the drug makers.

Attorney Steve Berman, JD, of Hagens Berman Sobol Shapiro LLP, co-lead counsel for the plaintiffs, said in a statement that Martinotti’s decision “clears the way for us to begin obtaining discovery from the manufacturers and PBMs so we can shine the light on exactly what has driven insulin prices sky-high.”⁵ ♦

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FDA Clears Phone App for d-Nav Insulin Guidance Service

HYGIEIA, A DIGITAL INSULIN management company, announced in late February 2019 that the FDA had given clearance to a phone app that works with its d-Nav insulin guidance service, designed to help people with type 2 diabetes (T2D) achieve optimal insulin doses to better control blood glucose.

The company claims in a statement¹ that the app is “the first insulin-management phone app able to titrate individualized doses for all types of insulin regimens, delivering recommendations directly to the patient.” Among its capabilities, it can connect to any glucose meter that shares data for the cloud, and it is available for both iOS and Android mobile phones.

The company, with headquarters in Livonia, Michigan, and Dundonald, Northern Ireland, aids patients by titrating individualized doses of insulin, which typically allows patients to use less insulin once they achieve glycemic control. The company’s website features a scenario of a patient who was using 90 units per day when he started with d-Nav and gradually increased insulin use during the first 2 months to 109 units, but then his insulin needs declined to 76 units by month 6. The website states² that without the d-Nav support system, such a patient could not achieve these results without frequent office visits for insulin dose adjustments.

The system relies on cloud-based technology backed by a team of healthcare professionals, according to the statement. Proprietary algorithms use patients’ glucose readings to offer personalized adjustments and make dosing recommendations. The system generated improved patient outcomes and cost savings over a 6-year period in Northern Ireland and it has been adopted by Blue Cross Blue Shield of Michigan (BCBSM). According to the company, at-risk patients with T2D enrolled in commercial BCBSM plans in southeast Michigan have access to the service.

Apps to assist patients with insulin dosing have existed for some time; the first product to offer personalized recommendations based on

individual data was Welldoc's BlueStar app,³ approved in 2013. For years, the FDA was reluctant to approve devices that did the dosing for patients, but that changed with the breakthrough decision to add a dosing indication to the Dexcom G5 continuous glucose monitor, which recognized how many people with diabetes were already using the technology.

Many more apps and insulin delivery devices⁴ that perform individualized dosing are reaching the market, leading some to believe that the traditional insulin pump may become obsolete. ♦

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New Look at VA Diabetes Trial Links Severe Hypoglycemia, Cardiovascular Events

A DECADE AGO, the *New England Journal of Medicine* published findings from the Veterans Affairs Diabetes Trial (VADT), which compared standard glucose control with intensive control on 2 groups of patients with longstanding type 2 diabetes (T2D).¹ Already, 40% had suffered a cardiovascular event. The study found no significant difference between the 2 groups in cardiovascular outcomes or most microvascular complications. This was important at the time, because the results differed from the ACCORD trial, which had stopped early because deaths had spiked among the intensive therapy group.

The VADT was significant because it looked specifically at the impact of glycemic control¹ rather than the effect of a specific agent. Now, with cardiovascular outcomes in T2D front and center among researchers, the VADT investigators have published a post hoc analysis in *Diabetes Care*, this time looking at differences among veterans who suffered severe hypoglycemia—and this group did see worse outcomes.²

The original trial involved 1791 veterans, almost all men but with good geographic and racial diversity. Their average age was 60.5 years, and they had lived with T2D and for an average of 11.5 years. Their condition was poorly controlled, with an average glycated hemoglobin (A1C) of 9.4% ± 2.0%. According to a 2015 interview with Peter Reaven, MD, a VADT lead investigator (and author on the new study), the treatment goal for the standard group was just below 7.0% for the intensive group and just below 8.4% for those receiving standard care—consistent with published findings that stated the 2 groups' targeted A1C goals were 1.5% apart.

During the study reported in *Diabetes Care*, veterans were seen every 3 months, and doctors recorded the number of severe hypoglycemia events, defined as a “self-reported episode of a low blood glucose value accompanied by confusion requiring assistance from another person or loss of consciousness.” Those data were missing for less than 0.5% of the participants (35 of 1791), who were excluded from the post hoc analysis.

Investigators found that the rate of severe hypoglycemia was higher in

the intensive treatment group: 10.3 per 100 patient-years compared with 3.7 per 100 patient-years in the standard treatment group ($P < .001$). Severe hypoglycemia within the past 3 months was associated with an increased risk of serious cardiovascular events ($P = .032$), cardiovascular mortality ($P = .012$), and total mortality ($P = .024$).

However, the analysis found a relatively greater increased risk of total mortality in the group that was treated to the standard goal compared with the group treated to the more intensive goal ($P = 0.019$). The association between severe hypoglycemia and cardiovascular events increased significantly as overall cardiovascular risk increased, based on the UK Prospective Diabetes Study risk score ($P = .012$).

Also, there were several independent predictors of severe hypoglycemia: insulin use at baseline ($P = .02$), protein in the urine ($P = .009$), and autonomic neuropathy, which can affect the cardiovascular system ($P = .01$). A higher body mass index had a protective effect ($P = .017$), a paradox observed in other studies. “Perhaps [this was] because of the associated insulin resistance providing some protection against the glucose-lowering effects of insulin or insulin secretagogues,” the VADT investigators wrote.

The new analysis shows the need to customize treatment to individual requirements, especially in older patients, according to the VADT investigators. “The serious consequences of these hypoglycemia-associated outcomes (cardiovascular events and mortality) emphasize the importance of careful selection of patients and medications when initiating intensification of therapy and close monitoring of patients for evidence of these events,” they wrote. ♦

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Alzheimer's Association Funds Extension of Study on Blood Pressure, Dementia Connection

More than 3 years ago, the National Institutes of Health ordered an early halt to the landmark SPRINT study (Systolic Blood Pressure Intervention Trial),¹ which found that aggressively lowering systolic blood pressure to 120 mm Hg instead of 140 mm Hg for patients with high blood pressure and another health risk led to fewer heart attacks, strokes, and cardiac deaths.

Investigators had good reason to take that step. The results were so clear that it would have been unethical to continue the trial; in fact, they have already prompted the American College of Cardiology and the American Heart Association to revise their definition² of what constitutes high blood pressure.

But stopping the study had an unintended consequence. The SPRINT MIND segment would end early, too, possibly leaving it underpowered to answer a different question: Does aggressively controlling blood pressure in certain patients with cardiac risks help prevent dementia?

Results from that truncated trial were published recently in *JAMA*. The findings suggest a connection but did not reach the level of significance.³ The authors stated that stopping the trial early meant there were simply fewer cases of dementia than expected. For that reason, the Alzheimer's Association announced that it will take the extraordinary step of awarding \$800,000 to fund SPRINT MIND 2.0, which will reengage the original participants and add 2 years of follow-up “to try to allow for a more definitive statement on reducing dementia risk,” according to a statement⁴ from the group.

The possible connection between cardiovascular disease (CVD) and dementia or Alzheimer disease has been studied for some time. An accompanying editorial in *JAMA* stated, “The mechanisms by which CVD risk factors and the risk of developing [Alzheimer disease] are most likely related to the important role in vascular health for β -amyloid and other neurodegenerative protein deposition, and observational studies have suggested that hypertension is associated with an increased risk of all-cause dementia.”⁵

What set SPRINT MIND apart was a plan for lengthy follow-up and a specific plan to look for both dementia and mild cognitive impairment, a separate state between normal aging and full-blown dementia. When the follow-up period was cut short, the planned year 4 cognitive assessments were done after primary care physicians again provided medications. The results showed that this difference rose to the level of significance, but the primary outcome of dementia did not.

Of the more than 9300 participants in the overall trial, 149 were in the SPRINT MIND intensive treatment group versus 176 in the standard treatment group. The latest data gathered in the SPRINT MIND trial showed that aggressively controlling blood pressure did result in a significant difference in these cases of mild cognitive impairment (14.6 cases per 1000 person-years in the treatment group vs 18.3 cases per 1000 person-years in the standard group, HR, 0.81; 95% CI, 0.69-0.95). When the trial ended with more than a year to go, the dementia cases were far fewer: 7.2 cases per 1000 person-years in the treatment group vs 8.6 per 1000 person-years in the standard group (HR, 0.83; 95% CI, 0.67-1.04).

The Alzheimer’s Association said in its statement that the group found the data “compelling.” Maria C. Carrillo, PhD, the group’s chief science officer, said in the statement that, mild cognitive impairment (MCI) “is a known risk factor for dementia, and everyone who experiences dementia passes through MCI. When you prevent new cases of MCI, you are preventing new cases of dementia.”

The group, she said, “is committed to getting clarity and certainty on the dementia outcome by following participants for a longer period of time.” SPRINT MIND 2.0 will begin early this year. ♦

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