REVIEW ARTICLE

WEARABLE DIGITAL HEALTH TECHNOLOGIES IN MEDICINE

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Digital Technology for Diabetes

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THIS REVIEW ARTICLE PRESENTS THREE TRUE-LIFE CLINICAL VIGNETTES that illustrate how digital health technology can aid providers caring for patients with diabetes. Specific information that would identify real patients was removed or altered. Each vignette is followed by a discussion of how these methods were used in the care of the patient.

VIGNETTE 1: USE OF DIABETES TECHNOLOGY FOR TYPE 1 DIABETES

Leo, a 22-year-old man who received a diagnosis of type 1 diabetes at 17 years of age, has struggled to meet glucose targets. As a young adult, he has many competing priorities, and diabetes is not first among them. He works in a restaurant kitchen and does not have private insurance. He has been receiving multiple-daily-injection (MDI) insulin therapy with glargine as basal insulin, but fingerstick glucose measurements and mealtime injections are often forgotten. Leo regularly has an evening snack without insulin because of his fear of nocturnal hypoglycemia. For the past 2 years, his glycated hemoglobin levels have ranged from 9.0 to 13.2%, putting him at high risk for long-term complications. His diabetes team prescribed a glucose sensor, also called a continuous glucose monitor (CGM), which provides interstitial glucose values every 5 minutes, but approval was denied because he did not perform at least four fingerstick glucose meter measurements each day. Approval for an insulin infusion pump was also denied because of missed insulin injections and a high glycated hemoglobin level.

When Leo enrolled in a study testing an automated insulin delivery (AID) system, his glycated hemoglobin level was 11.2%. He was initially provided with both a glucose sensor and an insulin pump, but according to the study protocol, insulin delivery was not yet automated. His glycated hemoglobin level decreased to 8.5% in 2 weeks. This striking improvement was attributable to several factors. First, the glucose sensor measures glucose levels every 5 minutes, providing immediate feedback and alerts. By sharing these real-time readings and alerts with his partner, both Leo and his partner became more comfortable with lower glucose values, especially overnight. Second, the insulin doses were easier to deliver, since the pump calculated meal and corrective doses and eliminated the need for manual injections. Finally, wearing the pump around the clock ensured that basal insulin was present and was not affected by missed manual injections.

After 6 months, as specified in the protocol, Leo transitioned to the use of an AID system (Fig. 1). He quickly learned to trust the system, and his anxiety regarding nocturnal hypoglycemia dissipated. After 3 months of using the AID system, his glycated hemoglobin level was 6.9% (Fig. 2A).

The AID system integrates communication between the glucose sensor and insulin pump and uses an algorithm to automatically decrease or suspend insulin delivery for predicted hypoglycemia, increase basal insulin for predicted hyperglycemia, and deliver corrective doses for higher glucose values while accounting for previously delivered insulin. These automatic real-time decisions are made every 5 minutes, coinciding with each new sensor glucose value. AID algorithms are typically stored on the pump, which communicates with a cell phone to send data to the cloud. Cloud-based programs offer patients, family members, and health care providers the ability to visualize integrated glucose and insulin delivery data, allowing identification of patterns that can be used to modify settings and behaviors. Table S1 in the Supplementary Appendix (available with the full text of this article at NEJM.org) provides examples of adjustable factors with some of the current systems.

The standard glycated hemoglobin goal is typically set at less than 7.0%, but levels below 7.5% are also associated with a low risk of long-term complications.[1] Although the glycated hemoglobin level is the current reference standard for assessing the long-term risks of complications,[2] it is an indirect surrogate marker of mean glucose levels and is strongly influenced by red-cell life span, medications, and genetic ancestry.[3,4] Glucose sensors now provide a direct measure of interstitial glucose, which bathes tissues where nonenzymatic glycosylation and the formation of advanced glycosylation end products occur (the process leading to many of the long-term complications of diabetes).[5] Glucose sensors also generate measures of the risk of hypoglycemia that are not provided by measurements of glycated hemoglobin. As the technology has advanced with glucose sensors, sensor-augmented pumps, and AID systems, it has become easier and safer for people to meet glycemic goals in order to prevent short- and long-term complications of diabetes (Table 1).

Data show that diabetes technology is effective in improving glycemic and quality-of-life outcomes.[11] Initial AID systems had many alarms and safeguards that created additional burdens

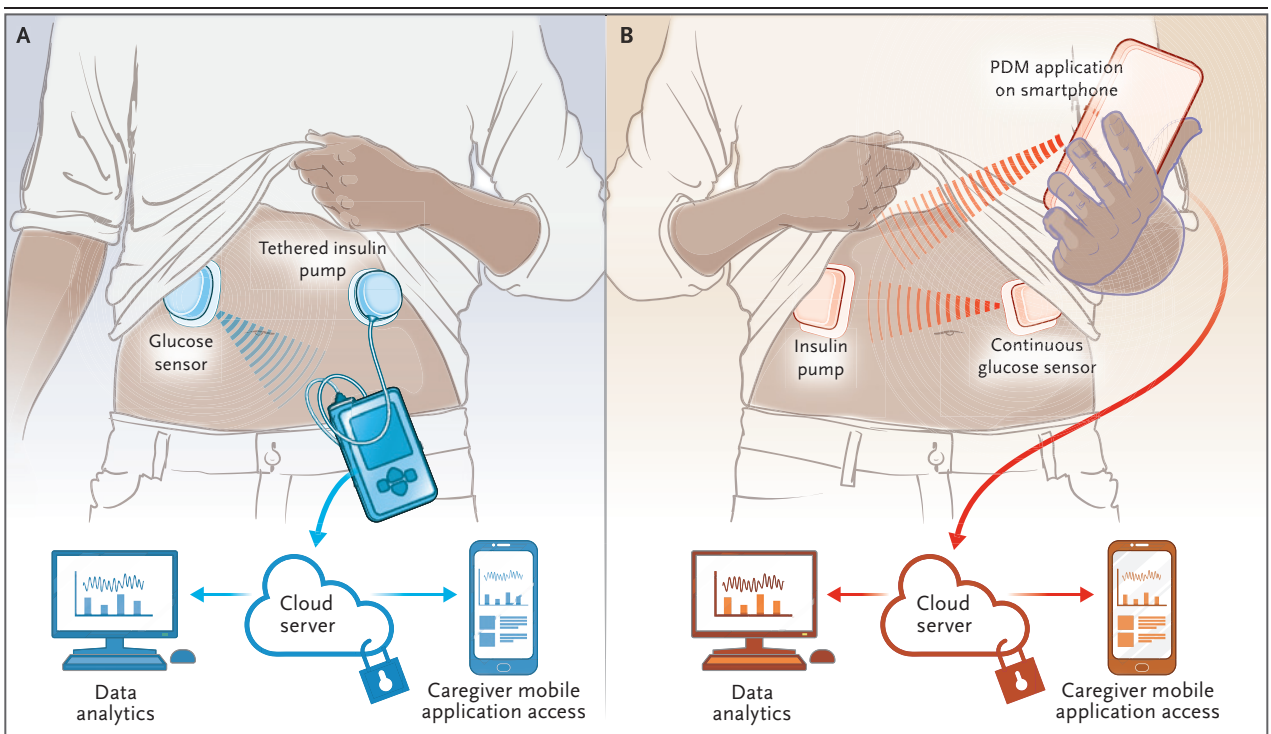


Figure 1. System Configurations for Automated Insulin Delivery (AID).
Panel A shows a system using a "tethered" insulin pump, and Panel B shows a system using a tubeless or "patch" insulin pump. PDM denotes personal diabetes manager.

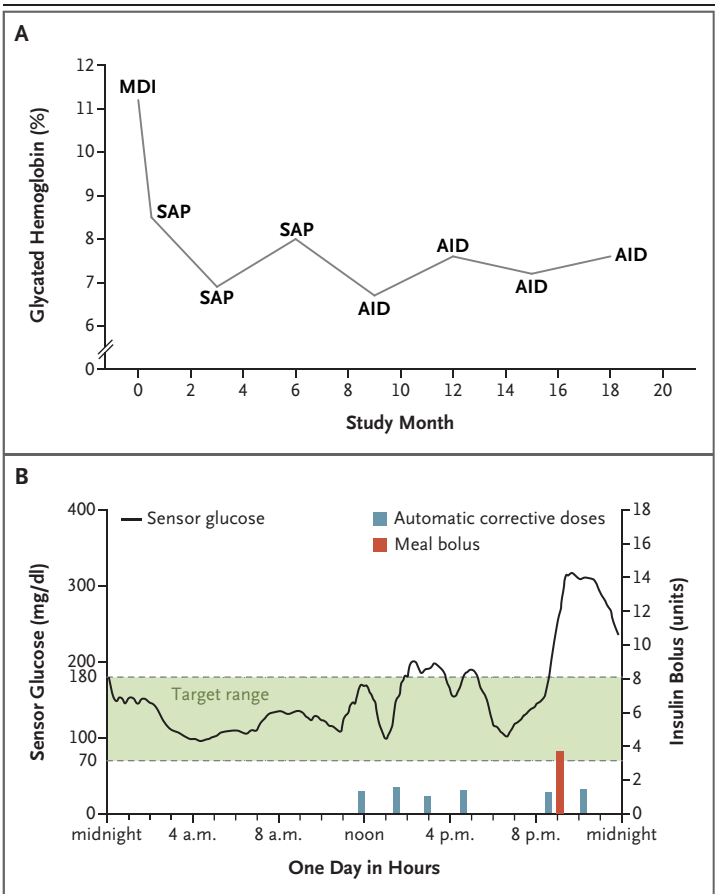


Figure 2. Trends in Leo's Glycated Hemoglobin Levels and an Example of Hourly Glucose and Insulin Tracing on AID.

During the 18-month study, Leo's glycated hemoglobin levels improved, as shown in Panel A. Switching from multiple-daily-injection (MDI) insulin therapy to a sensor-augmented pump (SAP), which provided communication between the glucose sensor and insulin pump but without AID, led to an initial improvement during the first 6 months of the study, which was further enhanced when the two systems were allowed to communicate as an AID system. Panel B shows an example of a single-day tracing while Leo was using AID. Only one meal bolus was given, at approximately 9 p.m. (red bar). However, the algorithm called for six automatic corrective doses (blue bars) to help provide insulin for other meals, including lunch and afternoon snacks. To convert the values for glucose to millimoles per liter, multiply by 0.05551.

for the patient. However, current systems have reduced alarm burdens, use glucose sensors that do not require calibration, and provide automatic corrective doses of insulin with the use of improved adaptive algorithms. These changes have also resulted in improved sleep[12] and have lessened other burdens of diabetes by providing a degree of forgiveness for late or missed meal boluses, as observed in Leo's case (Fig. 2B). A recent review article[11] provides further information about current AID systems, results of pivotal trials, and suggestions for initiating and managing these systems. The hope is that future types of technology will further reduce burdens for patients and their families with the use of smaller glucose sensors, more durable and comfortable infusion sets,[13] and elimination of the need for patients to "announce" meals to the system and to count carbohydrates.[14]

A majority of insulin pumps sold in the United States and Europe are now equipped with AID technology, and these systems have been tested in patients who are 2 to 81 years of age.[11,14] Initiation of both a glucose sensor and an AID pump can be completed in a single visit lasting approximately 3 hours, so that patients can transition directly from MDI insulin therapy to AID, either in person or remotely. Patients and their family members are taught how to insert the devices, program their pumps, interpret data in real time, and connect the system to a cell phone. In a recent randomized trial that initiated AID in young children (2 to 5 years of age), 81% of the families of children who were assigned to AID were trained remotely, and the participants included children and families across the United States who lived in areas that were far from major diabetes centers, with 26% of the participants from groups that are often underrepresented in health care delivery settings.[15]

In the vignette, Leo's lack of private insurance hindered his access to diabetes technology. This illustrates a common obstacle posed by the well-established disparities and health care inequities that characterize insurance coverage in the United States, even though the use of diabetes technology is the recognized standard of care for patients with diabetes for which insulin is warranted.[16] Disparities in use of and access to technology have worsened over the past decade and are implicated in disproportionately higher glycated hemoglobin levels among persons from low socioeconomic and underserved racial and ethnic groups.[17,18] Drivers of inequitable access — such as payer coverage, provider bias, and limited language options in device interfaces — are often outside patient control. Public payers and high-deductible insurance plans are implicated in interruptions of glucose sensor use that compromise glycemic outcomes.[19,20] Studies have shown that bias based on both race or ethnic group and insurance status affects recommendations re-

Table 1. Effects of Technology on Reaching Glycemic Targets.*

Target and Diabetes Technology	Glycated Hemoglobin Level	Glucose Sensor Metrics		
		Glucose Level, 70–180 mg/dl	Mean Glucose Level	Glucose Level <70 mg/dl
	%	% of time	mg/dl	% of time
Target[6]	<7	>70	154	<4
MDI insulin therapy and blood-glucose meters[7]	8.2	45	189	5.5
MDI insulin therapy and glucose sensors[7]	7.6	51	180	4.8
Pump and glucose sensors[8]	7.4	59	170	2.2
AID[8-10]	6.8–7.1	71–75	148–156	1.3–2.3

* To convert the values for glucose to millimoles per liter, multiply by 0.05551. AID denotes automated insulin delivery, and MDI multiple daily injection.

garding the use of technology.[21,22] Changes in national, institutional, and payer coverage can help bridge disparities and increase access to diabetes technology.[23] Diabetes technology has been associated with improved outcomes in economically diverse settings in resource-rich countries.[24] Although this vignette highlights structural barriers to equitable access that are specific to the United States, similar barriers in other countries also warrant system-level changes. Globally reliable access to insulin, blood-glucose monitoring, and diabetes technology is limited and is a major cause of avoidable illness and death.

VIGNETTE 2: USE OF DIABETES TECHNOLOGY FOR TYPE 2 DIABETES

Eli was advised to go to the emergency department after a routine blood test showed a high random glucose level of 640 mg per deciliter (35.5 mmol per liter). Although type 2 diabetes had been diagnosed 4 years earlier, he was not treated with medications. His glycated hemoglobin values, measured once or twice a year, had ranged from 6.7 to 7.2%. A new measurement showed that the glycated hemoglobin level was 16.3%. Eli also had worsening urinary frequency and thirst. In the emergency department, treatment with subcutaneous insulin and intravenous fluids led to the resolution of a concomitant mild anion gap acidosis. A glucose sensor and instruction in the use of injectable insulin were provided by the on-call certified diabetes care and education specialist, and a follow-up clinic visit was arranged. Eli was discharged home after he received a prescription for glargine insulin and a recommendation for the use of insulin treatment indefinitely.

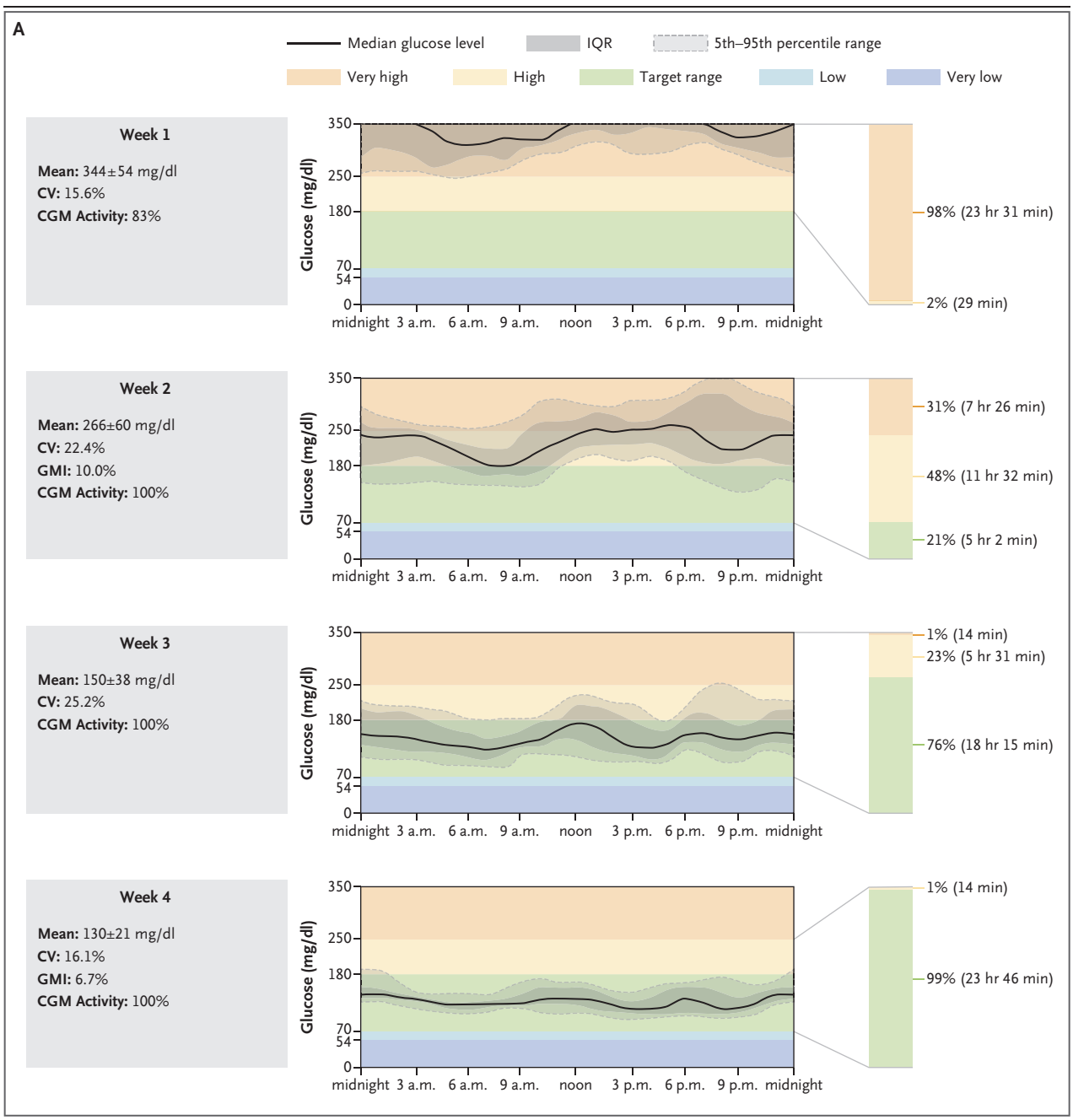
Interest in the use of glucose sensors in patients with type 2 diabetes has increased since data from two randomized clinical trials[25,26] showed greater improvements in glycemic outcomes with the use of real-time glucose sensors than with standard fingerstick glucose monitoring in patients with type 2 diabetes who were receiving insulin therapy. On the basis of these findings, clinical guidelines published since 2021 recommend that glucose sensors be considered for all patients with diabetes who are receiving insulin treatment.[27,28]

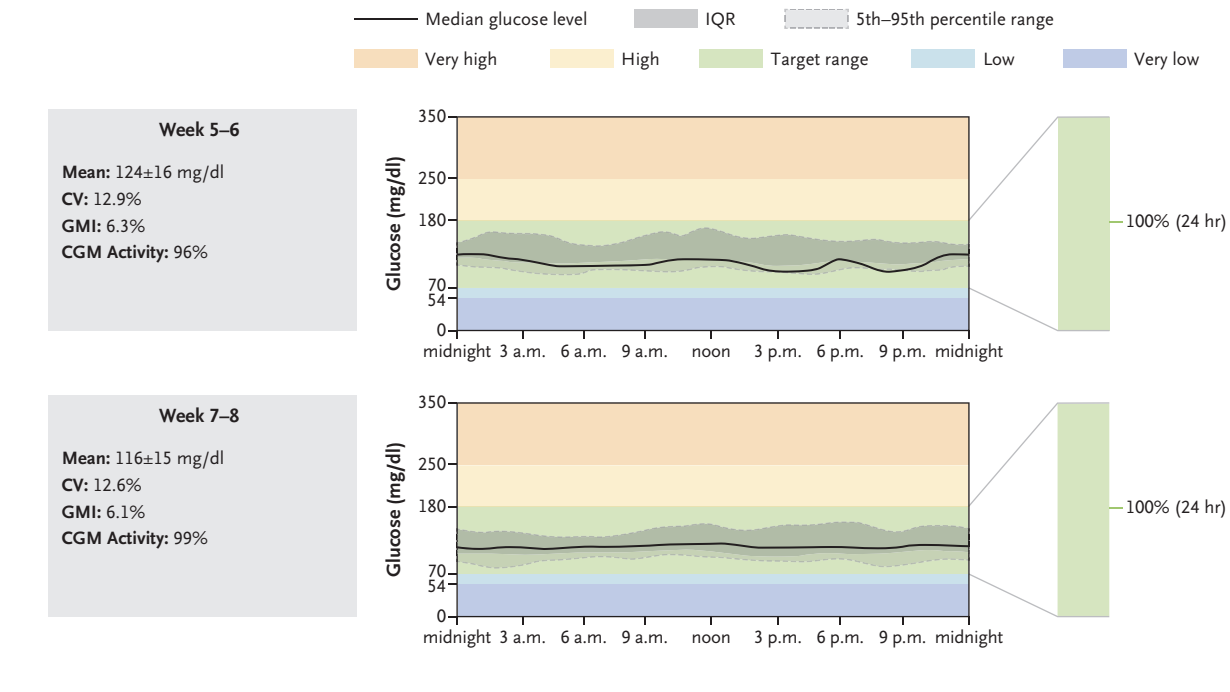
Eli initially expressed skepticism about the use of insulin, but as he watched his sensor glucose levels in real time at home, he recognized that glargine injections were warranted. On the basis of feedback from the glucose sensor, he independently eliminated foods that were causing pronounced glucose spikes; these changes resulted in improvements in glucose levels and reduced symptoms.

Exploring the potential for glucose sensor–related benefits with respect to behavioral changes remains a critical area for understanding how glucose sensors can serve patients with type 2 diabetes. This also applies to patients who are not receiving insulin treatment, particularly because lifestyle interventions are the cornerstone of management.[29] In the two aforementioned ran-

domized trials,[25,26] benefits with respect to glycemic outcomes were observed despite minimal or no changes in pharmacologic therapy, findings that suggest that the improvements in glycemic control may have derived primarily from sensor-informed behavioral changes. Use of the glucose sensor made Eli see that both insulin and dietary changes were warranted, even before he was seen in the clinic.

Four weeks after his emergency department visit, Eli had a diabetes consultation in the clinic. During this visit, Eli's physician reviewed the glucose sensor data with him on a computer screen, which helped to establish a collaborative foundation for discussion and shared decision making. The data revealed marked week-to-week reductions in hyperglycemia with the consistent insulin dose, indicating progressive islet recovery





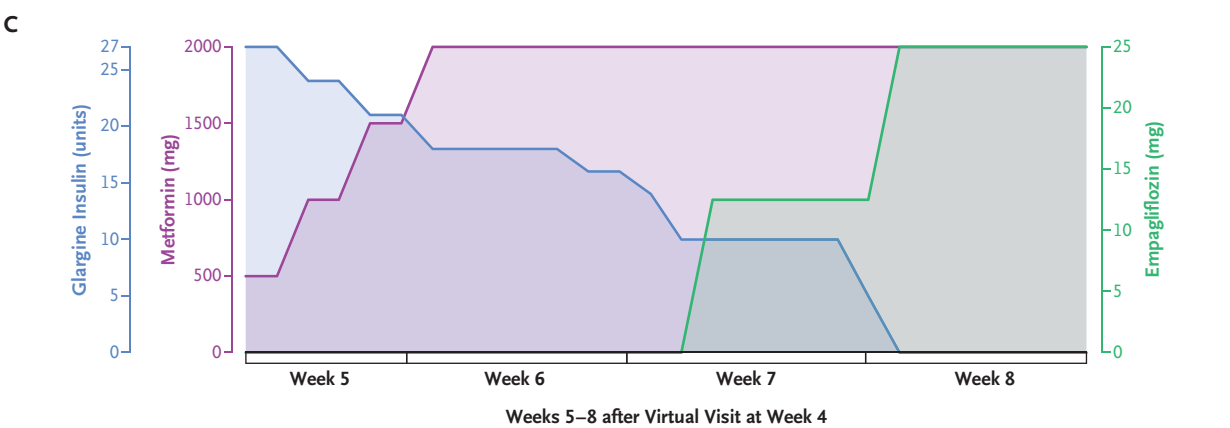


Figure 3. Trend in Islet Recovery and Medication Adjustments Informed by Glucose Sensor Data.

This figure shows Eli's glucose trends during the 8 weeks subsequent to his emergency department (ED) encounter and also includes the medication changes made during the month after his diabetes clinic visit, which took place 4 weeks after he was discharged home from the ED. For consistency, the data are labeled according to weeks since the ED visit, such that weeks 5–8 represent the month immediately after Eli's visit in the diabetes clinic. Eli's glucose sensor readings in the 4 weeks after his ED visit (Panel A, facing page) showed rapid and progressive reductions in his glucose levels, indicative of islet cell recovery. The glucose management indicator (GMI, calculated from 2 weeks of glucose data; see below) at week 2 was 10.0% and at week 4 was 6.7%. At Eli's in-person clinic visit, 4 weeks after his discharge from the ED, the 4 weeks of glucose data were reviewed with him, and a plan for how to progressively increase metformin and simultaneously decrease insulin glargine was made. Two weeks after the clinic visit (after weeks 5–6) (Panel B), the glucose sensor data were reviewed remotely by the physician with Eli. Together, they agreed on a plan to add empagliflozin while continuing to decrease the insulin. The results of this plan are shown in the subsequent 2 weeks (weeks 7–8), during which time empagliflozin was increased to the full dose and insulin was discontinued. The medication adjustments made in the month after his clinic visit are summarized (Panel C). These adjustments correspond to the continuous glucose monitor (CGM) data shown in Panel B from the same period, which allowed Eli and his physician to be comfortable with the swift dose adjustments. The GMI approximates glycated hemoglobin values on the basis of the mean sensor glucose using at least 2 weeks of CGM data (GMI %=3.31+0.02392×[mean glucose level in milligrams per deciliter]; GMI millimoles per mole=12.71+4.70587×[mean glucose level in millimoles per liter]).[30] CV denotes coefficient of variation.

(Fig. 3A). Eli preferred stepwise medication adjustments and agreed to begin with metformin. After 2 weeks, the maximum metformin dose was reached, and insulin doses had been decreased by half. The glucose sensor data were reviewed remotely with Eli, and empagliflozin was added. Over the following 2 weeks (weeks 7 and 8 since the emergency department visit), Eli was able to discontinue insulin while maintaining excellent glucose control. The glucose sensor data and medication dose adjustments during the 4 weeks after the clinic visit are shown in Figure 3B and 3C, respectively, with the remote review of the glucose sensor data occurring after the first 2 weeks.

This vignette highlights the ways in which data-informed medication adjustments can be made with glucose sensors. The glucose data were available for review remotely by the physician, who was able to make informed medication adjustments quickly by remotely checking glucose sensor results 2 weeks after the initial visit. Although telehealth services became reimbursable during the coronavirus disease 2019 (Covid-19) pandemic, glucose sensor review can be billed separately from clinic or telehealth services up to four times per year, but not more than once per month. Initialization (also billable) can be done in the clinic to ensure that glucose sensor data are available to health care providers in real time. Even with these advances, a lack of electronic health record integration means that clinical staff must manage multiple cloud databases to maintain updated data from glucose sensors and insulin pumps. Although some devices automatically transmit data to the cloud, others require manual data uploading by patients from home. If a patient has difficulty with this process, then data will be uploaded for review only at in-person appointments.

The remote monitoring capabilities and more detailed glucose data obtained from glucose sensors may be of particular benefit in underrepresented populations (including some racial or ethnic groups, patients with low socioeconomic status, and those with public insurance or no insurance coverage) who have a disproportionately higher incidence and prevalence of type 2 diabetes. Underrepresented younger persons with type 2 diabetes are emerging as one of the most vulnerable patient groups, with a rapid progression to diabetes complications.[31] Thus, it is imperative to strive for equitable access to diabetes technology as coverage continues to expand at the state level (Table 2), given the association between access and improved diabetes outcomes.[32]

Glucose sensors are a powerful recent innovation in the management of diabetes, and the marked improvements in glycemic control seen in patients with type 1 diabetes have prompted the use of sensors for treating other forms of diabetes.[33-35] In light of the evidence and guidelines,[25-28] we should consider carefully why any patient receiving insulin treatment is not using a glucose sensor. The benefits of these devices also seem likely to extend to patients who are not treated with insulin, although more data are needed to substantiate this idea.

VIGNETTE 3: USE OF DIABETES TECHNOLOGY IN THE HOSPITAL

Gia, who had lived with type 1 diabetes for 40 years, was admitted to the hospital with a nondisplaced hip fracture. She also had diarrhea due to *Clostridium difficile* infection and was receiving care with contact precautions. She had used an insulin pump for years and had a fear of hypoglycemia, which caused her to maintain high glucose levels. Two years earlier, she had started AID, and her fear of hypoglycemia had lessened. Her glycated hemoglobin levels were reduced to less than 7.5%.

On admission, Gia was transitioned from her AID system to MDI insulin therapy, an option that was more familiar to her primary admitting team. However, her glucose level was difficult to control. She expressed frustration about the lack of flexibility with MDI, particularly because her meals were often delayed or cold as she waited for a nurse to provide prandial insulin injections. Her anxiety about hypoglycemia also returned while she was receiving MDI therapy, and she regularly requested reduced doses of prandial insulin. At Gia's request, the AID system was restarted, and glucose control improved (Fig. 4). However, a facility that was willing to manage the AID system and also provide rehabilitation for her reduced mobility after the hip fracture was not available. To facilitate discharge, the AID system was again discontinued. MDI insulin therapy was restarted, and glycemic control once again worsened.

Both hyperglycemia and hypoglycemia are associated with increased risks of poor hospital

outcomes,[36,37] but avoiding both simultaneously can prove challenging.[38] Current inpatient glucose targets are conservative, typically 140 to 180 mg per deciliter (7.8 to 10.0 mmol per liter); these targets preferentially avoid the risks of hypoglycemia over those associated with hyperglycemia.[36,39] The current standard is to use a combination of long- and short-acting (basal–bolus) doses of insulin by means of MDI therapy.[36,39] However, glucose goals are often still unmet; one meta-analysis showed that glycemic targets were met in only 34 to 66% of patients, and 2 to 29% of the patients had hypoglycemic episodes.[38] Conventionally, these treatment protocols rely on point-of-care fingerstick glucose measurements, which must be performed at the bedside. There are no alerts for hypoglycemia, except symptoms. Management can be challenging because of the variability in insulin sensitivity (owing to stress, illness, medications, and reduced activity), changes in oral intake, and timing mismatches between food delivery and insulin administration. Thus, substantial demands are placed on hospital staff, particularly bedside nurses.[40] More aggressive goals or complex regimens may require more diligent oversight that is often provided by dedicated inpatient diabetes consultation services, which are not commonly available at community hospitals.[41,42] It is therefore not atypical to remove diabetes devices such as a glucose sensor, pump, or AID system when treatment teams and staff are unfamiliar with them.

Like Gia, many patients entering a hospital prefer to continue using their devices. Our institution was able to respond to Gia's request with infrastructural support and detailed guidance, including standardized criteria with protocols and documentation for use, interruption, and discontinuation of diabetes devices. Resuming use of the glucose sensor restored alerts for glycemic excursions, and her AID data were able to be reviewed by the inpatient diabetes service using the same cloud-based platforms used in the outpatient setting.

Although glucose control improved considerably when Gia transitioned back from MDI therapy to an AID system, studies are still needed to confirm the glycemic benefits of using diabetes devices in the hospital setting. Limited, mostly retrospective, data have suggested mild improvements in glycemic control with continued use of nonautomated pump therapy in carefully selected patients.[43,44] Similarly, the use of glucose sensors, without an associated delivery device, has been shown to be associated with mild reductions in periods when glucose levels are below 70 mg per deciliter (3.9 mmol per liter).[45,46] Clinical trials on the use of AID in the hospital have shown excellent results when a customized, fully automated system (with no meal input requirement)[47] or a commercial "hybrid" system (with meal input)[48] is used. By integrating the pump and sensor and implementing automated insulin-dose decisions every 5 minutes, AID offers the potential to proactively avert anticipated glycemic excursions arising from fluctuations in insulin sensitivity — a capability not possible with MDI therapy. However, it remains to be seen whether AID will become a primary insulin delivery tool for inpatient glycemic control in the future.

CONCLUSIONS

The three vignettes showcase the transformative changes that glucose sensors and AID technology have made in the management of type 1 and type 2 diabetes. However, the vignettes are not intended to provide a comprehensive review of the much broader landscape of digital technology for diabetes, which encompasses mobile health applications (apps) (mHealth, a name coined by Robert Istepanian[49]), insulin-dose adjustments, and decision-making support, as well as glucose monitoring and AID. Considerable work is ongoing in many of these areas. For instance, thousands of mHealth apps are now available on smartphones; these apps address nutrition, physical activity, and diabetes management. There is little evidence that mHealth apps can improve glycemic control in persons with type 1 diabetes; however, there is some evidence of improved lifestyle modification in those with type 2 diabetes.[50,51] Decision-making support tools such as cloud-based artificial intelligence can recommend adjustments in insulin doses for MDI insulin therapy or insulin pumps, but early clinical trials have not shown better glycemic control than that with the standard of care.[52-54]

Glucose sensors are an important advance in management for persons with type 1 or type 2

Table 2. States with Public Payer Coverage for Glucose Sensors, 2019–2022.*

Patient Group	Coverage in 2019†	Coverage in 2022‡
	number of states	
Children with type 1 diabetes	35	41
Adults with type 1 diabetes	31	40
Children with type 2 diabetes	14	28
Adults with type 2 diabetes	14	27

* A total of 15 states in 2019 and 7 in 2022 had no public payer coverage for glucose sensors.
† Data are abstracted from https://diatribe.org/medicaid-and-cgm-whos-covered.
‡ Data are abstracted from https://www.chcs.org/media/Expanding-Medicaid-Access-to-Continuous-Glucose-Monitors_011222.pdf.

diabetes.[16] These sensors have led to the development of various applications for visualization and analysis of glucose sensor data in real time and retrospectively. The Ambulatory Glucose Profile[55] provides a standard presentation of glucose sensor data and has been widely adopted, along with the standardization of sensor glycemic targets to define hypoglycemia and hyperglycemia.[6,56] Mean glucose sensor values generate a glucose management indicator, which is strongly correlated with glycated hemoglobin levels.[30] Cloud-based access to diabetes data from glucose sensors, insulin pumps, or both during the Covid-19 pandemic made it possible to replace many in-person visits with virtual visits, which are now regularly used in clinical practice.

AID systems have also transformed diabetes care and have allowed a majority of users to meet or come close to meeting glycemic goals while decreasing some of the burdens of diabetes management.[11] Many AID applications continue to emerge, including AID support for persons with missed meal boluses[57,58] and AID use in persons with conditions such as cystic fibrosis–related diabetes and diabetes during pregnancy.[33,34,59] Although current AID systems have advanced substantially, they also have limitations, including unexpected insulin infusion-site failures, times when the accuracy of the glucose sensor is inadequate, requirements for frequent user input, issues with commercial smartphone compatibility, connectivity between devices, challenges in transmitting data to the cloud, and limitations in equitable access to diabetes technology.

It is not unreasonable to forecast that devel-

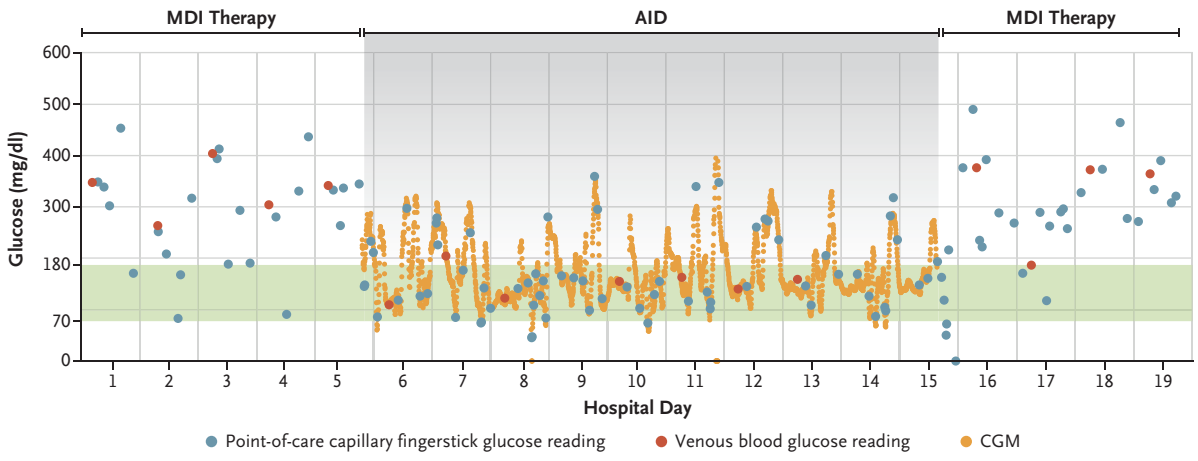


Figure 4. Trend in Daily Hospital Glucose Levels during Inpatient Diabetes Management.
When Gia was receiving MDI insulin therapy during her first 5 days in the hospital, she had fluctuating glucose levels that frequently exceeded 250 mg per deciliter. AID therapy was initiated on day 5, which led to improved glucose control. MDI insulin therapy was reinstituted on day 15 in order to facilitate Gia's discharge to a rehabilitation facility, and her glycemic control again showed greater fluctuation with higher glucose levels.

opments in diabetes technology will continue to improve glycemic control while decreasing the burdens for patients in managing diabetes. If widely adopted, these types of technology have the potential to improve the lives of both patients with type 1, type 2, and other forms of diabetes. The onus lies with the medical profession to help achieve greater and more equitable use of these methods.

Neither the *Journal* nor the Massachusetts Medical Society endorses any specific diabetes management technology. Examples of such technology appear in this article for illustrative purposes only and do not constitute an endorsement.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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