What's New and Around the Corner in CGM?

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CONTINUING MEDICAL EDUCATION

LEARNING OBJECTIVES

At the end of the activity, participants will be able to:

- Describe new and emerging technologies in continuous glucose monitoring (CGM) use, including over-the-counter (OTC) CGM devices and continuous glucose-ketone monitoring.
- Interpret CGM data, such as the ambulatory glucose profile (AGP) accurately to inform changes in diabetes therapy and optimize glucose control.
- Initiate CGM in patients with diabetes who would benefit from enhanced glucose monitoring and better blood glucose control, including those with insulin delivery devices.
- Engage members of the health care team in collaborating on diabetes management to facilitate patients acquiring CGM devices.

KEY TAKEAWAYS

- The goal of therapy for glycemic control in diabetes is to reduce hyperglycemia without causing hypoglycemia.
- A lack of symptoms does not mean that patients are not experiencing dysglycemia.
- Glycated hemoglobin alone is an average glucose metric that is unable to reveal areas for therapeutic changes; self-glucose monitoring is limited as it only reveals a point-in-time metric and can be painful to obtain.
- The use of CGM allows for visualization of blood glucose patterns via the AGP, which can be understood by clinicians, patients, and caregivers.
- New and emerging CGM technologies include OTC CGM devices and continuous glucose-ketone monitoring devices.
- Clinicians should seek to involve members of the multidisciplinary healthcare team for optimal diabetes care, as appropriate.
- Consider expanding CGM use in adults with type 2 diabetes (T2D) treated with glucose-lowering medications other than insulin to achieve and maintain glycemic goals.

TARGET AUDIENCE

Clinicians who wish to gain increased knowledge and greater competency regarding primary care management of CGM.

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Dr. Miller serves as speaker and advisory board member of Abbott, Bayer, Boehringer Ingelheim, Eli Lilly, Embecta, Insulet, and Novo Nordisk, and as an advisory board member of Corcept and Dexcom.

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INTRODUCTION

Diabetes affects an estimated 38.4 million people in the United States, or 11.6% of the population.[1] The majority of the diabetes care burden falls to primary care practitioners (PCPs) as approximately 90% of diabetes care in the United States occurs in the primary care setting.[2,3] Progress in the understanding of diabetes pathophysiology and new treatments have advanced the care of patients with type 1 diabetes (T1D) and type 2 diabetes (T2D), yet many patients still do not achieve glycemic targets.[4] Furthermore, existing models of care are insufficient to provide optimal diabetes care. Diabetes care occurs continuously, with the majority conducted by patients and caregivers—between visits and outside of clinical encounters.[5]

Limitations of HbA1c and blood glucose monitoring

While it is helpful to monitor glycemic control in diabetes using intermittent approaches such as glycated hemoglobin (HbA1c) and fingerstick blood glucose monitoring, these modalities have significant limitations. The HbA1c provides a 30- to 90-day retrospective average of blood glucose data, but HbA1c alone may not be very helpful for patients to understand their diabetes control.[6] Fingerstick blood glucose monitoring only measures blood glucose at a single point in time.[7]

HbA1c has been considered the gold standard in monitoring of diabetes care, but it provides only an average of a patient's blood glucose history. HbA1c may underestimate or overestimate glucose control and does not indicate glycemic variability, including the extent or timing of hypoglycemia and hyperglycemia.[8,9] HbA1c values have limited utility for insulin dosing decisions and can be unreliable in patients with certain conditions such as hemolytic anemia, hemoglobinopathies, iron deficiency, or pregnancy.[8,9]

Metrics obtained from continuous CGM, such as time in range (TIR), which measures the proportion of time a patient's blood glucose is within a target range (typically 70 to 180 mg/dL), provide more actionable information than HbA1c alone and should be used to complement HbA1c.[10] Each 5% increase in TIR is clinically beneficial.[10] Equivalent HbA1c values do not translate to equivalent TIR (**FIGURE 1**).[10]

Utility of CGM for glycemic monitoring

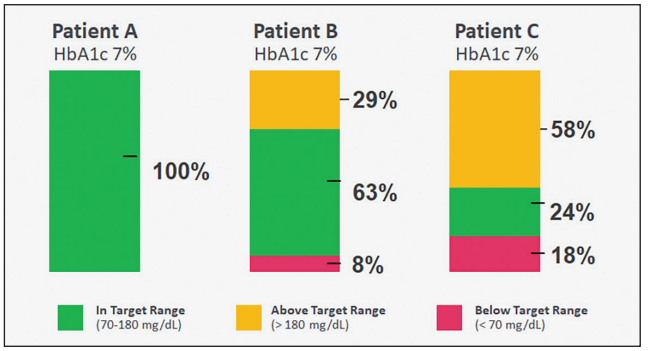
CGM allows clinicians and patients to move beyond traditional HbA1c and self-monitoring of blood glucose (SMBG) measurements, with access to more data obtained outside of the clinic, and more insights into patients' blood glucose patterns and detection of dysglycemia (**FIGURE 2**).

Diabetes technology such as CGM has improved overall care of patients with diabetes in recent years and has the potential to make a larger impact with optimal implementation in primary care settings.[11] The American Diabetes Association (ADA) and the American Association of Clinical Endocrinology recommend the use of CGM for many patients with diabetes and recognize the benefits of CGM use.[12,13] Specifically, the ADA *Standards of Care in Diabetes* recommend the following[12]:

- Diabetes devices should be offered to patients with diabetes.
- CGM should be offered to people with T1D early in the disease, even at the time of diagnosis.
- Recommend early initiation, including at diagnosis, of CGM depending on a person's or caregiver's needs and preferences.
- Real-time CGM or intermittently scanned CGM is recommended for diabetes management for people with diabetes receiving any insulin therapy.
- Consider using CGM in adults with T2D treated with glucose-lowering medications other than insulin to achieve and maintain glycemic goals.

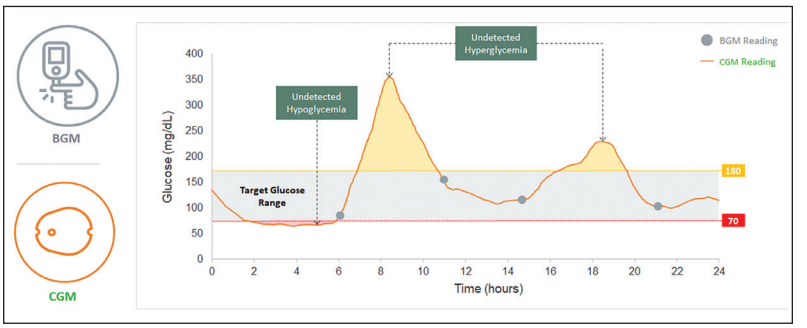
Furthermore, early use of CGM can support glycemic outcomes. Data indicate that CGM helps patients reach and maintain HbA1c targets in the first year of treatment and

FIGURE 1. Equal HbA1c values compared to different TIR values.[10]



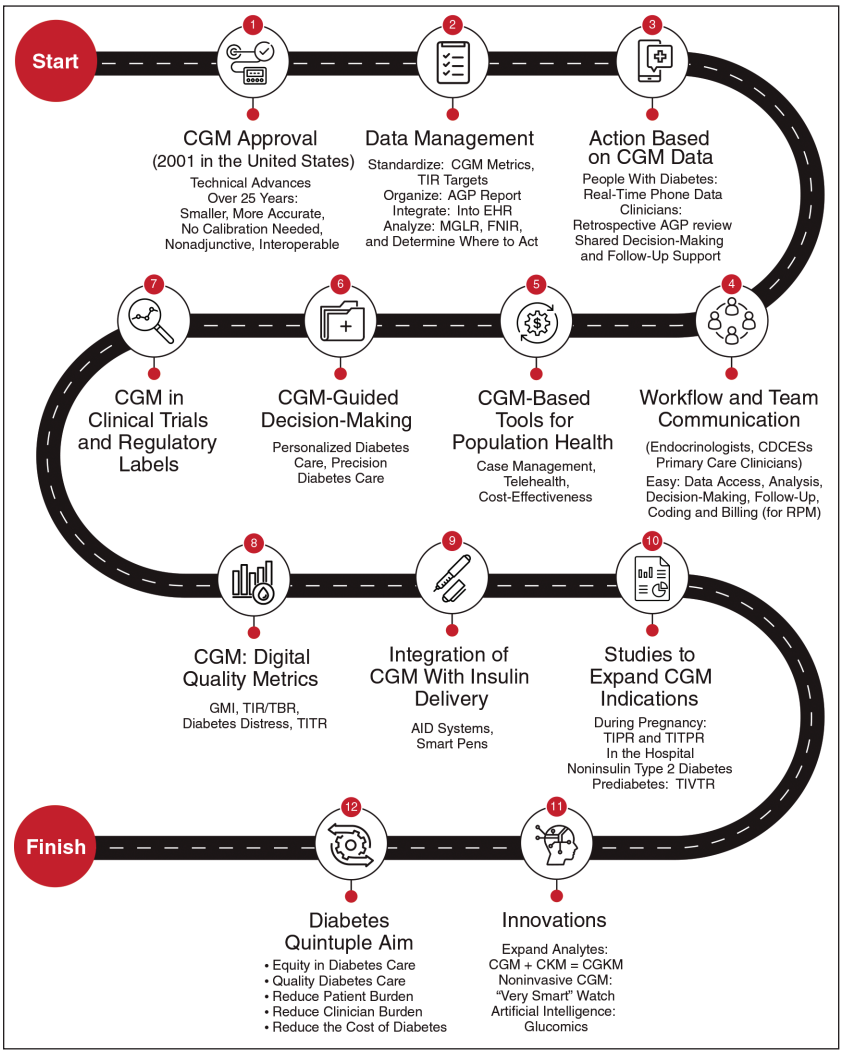
Abbreviations: HbA1c, glycated hemoglobin; TIR, time in range.
Not actual patient data; for illustrative purposes only.

FIGURE 2. Blood glucose monitoring vs CGM for detecting dysglycemia.



Abbreviations: BGM, blood glucose monitoring; CGM, continuous glucose monitoring.

FIGURE 3. Roadmap of the effective use of CGM: Innovation, investigation, and implementation.[15]



Abbreviations: AGP, ambulatory glucose profile; AID, automated insulin delivery; CDCES, Certified Diabetes Care and Education Specialist; CGM, continuous glucose monitoring; CGKM, continuous glucose-ketone monitoring; CKM, continuous ketone monitoring; EHR, electronic health record; FNIR, flat, narrow, in-range; GMI, glucose management indicator; MGLR, more green, less red; RPM, remote patient monitoring; TBR, time below range; TIPR; time in pregnancy range; TIR, time in range; TITPR, time in tight pregnancy range; TITR, time in tight range; TIVTR; time in very tight range.

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results in long-term health improvements, even when glycemic control wanes over time.[14] Patients with T2D who achieve glycemic targets soon after diagnosis are more likely to keep blood glucose within target range.[14] Additionally, managing glucose levels early in diabetes reduces the risk of complications.[14]

CASE STUDY

A 42-year-old woman presents to her primary care clinic for a follow-up appointment to discuss her T2D regimen. She states that she feels well today and has no complaints. Her HbA1c today is 7.5%, which is lower than it was 3 months ago (8%). She denies hypoglycemia and checks her blood glucose only when she does not feel well. She takes metformin 1000 mg twice daily and glipizide 10 mg twice daily, and she started dulaglutide 1.5 mg once weekly 2 months ago.

In this case study, the patient may appear to have satisfactory, and improving, glycemic control and may need only minor medication adjustments. However, more information is needed to obtain the full clinical picture of this patient's blood glucose patterns.

NEW AND EMERGING TECHNOLOGIES IN CGM

CGM technologies began with the first CGM device approval in the United States in 1999 and have continued to evolve over the past few decades (**FIGURE 3**).[15,16] Notable recent advances in CGM include the emergence of over-the-counter (OTC) CGM devices, continuous glucose-ketone monitoring, and artificial intelligence biosensors for CGM.

OTC CGM devices

Three OTC CGM devices are currently approved: Libre Rio, Stelo Glucose Biosensor, and Libre Lingo (**TABLE**).[17-19] The Libre Rio is an OTC CGM device that is intended for adults ≥18 years who manage diabetes through lifestyle modifications and noninsulin antihyperglycemic therapy.[17] The Stelo Glucose Biosensor is an OTC device designed for adults with prediabetes or T2D who are not taking insulin and do not experience problematic hypoglycemia.[18] The Lingo OTC CGM is designed for adults to better understand and improve general health and wellness.[19] It tracks glucose and provides personalized insights to help create healthy habits and improve overall well-being.

Continuous glucose-ketone monitoring

Diabetic ketoacidosis (DKA) is a serious complication of diabetes that can occur in patients with T1D (25% to 40%) or T2D (up to 34%).[20] It is characterized by the triad of hyperglycemia, ketosis, and anion gap metabolic acidosis, with manifestations of ketones in the blood and a sweet smell on the breath.[20] Patients taking a sodium-glucose cotransporter-2 inhibitor are at increased risk for DKA.[20]

TABLE. Characteristics of approved OTC CGM devices.[17-19]

	Libre Rio[17]	Stelo[18]	Libre Lingo[19]
Characteristic			
Wear period/ sensor duration	Up to 15 days	Up to 15 days + 12 hour grace period	Up to 14 days
Reading interval	1 minute	5 minutes	1 minute
Glucose range	40 to 400 mg/dL	70 to 250 mg/dL	55 to 200 mg/dL
Alarms	No	No	No
Finger sticks	No	No	No
Insurance coverage	No	No	No
Reader	No[a]	No[a]	No[a]

[a]Transmits data to a smartphone app.

Measuring ketones in the blood or urine at home can help detect ketosis, which can help identify those at risk for DKA early, prompting further evaluation and potential intervention. Currently, urine ketone strips and blood ketone strips and meters are available to measure ketones at home, and—when testing is conducted properly—both have similar accuracy.[21]

Integration of continuous ketone monitoring and CGM in the same sensor platform is an important consideration for streamlining measurement of ketones and glucose.[22] Integrated CGM-ketone sensors are actively being studied in clinical trials; 1 device has received US Food and Drug Administration breakthrough designation status and may become clinically available in the future.

Artificial intelligence biosensors for CGM

In recent years, the growing popularity of artificial intelligence (AI) in various applications has prompted efforts to improve the performance of CGM biosensors with AI, in addition to other applications of AI in diabetes, such as detection of retinopathy and macular edema.[16] The primary applications of leveraging AI to improve CGM biosensors include closed loop control algorithms, glucose predictions, and sensor calibration (**FIGURE 4**).[16] As AI and CGM technologies continue to advance, additional innovations in their capabilities are likely.

USING CGM IN PRACTICE: THE AGP AND ADJUSTING TREATMENT

The ambulatory glucose profile (AGP) report is the primary method of obtaining blood glucose data from a CGM device.[12] The AGP contains a summary of metrics, values, and goals to help clinicians and patients assess the overall quality of glucose management. Most AGP reports will display daily glucose profiles, as well as an aggregated glucose profile for the time period (often 14 days). The daily glucose profiles can be helpful in determining causes of patterns or exceptions to usual patterns. The aggregated glucose profile shows variability in the mean glucose and patterned areas of highs and lows, displaying all values as if collected over a single 24-hour period.[12]

Accurately interpreting the AGP report is essential to making treatment adjustments. Steps to quickly review and interpret CGM data from the AGP report might include the following:

1. "Riding the waves"
    a. Ask the patient to explain what patterns they see
    b. Identify occurrences of hypoglycemia (if any)
    c. Identify occurrences of hyperglycemia (if any)
    d. Identify any clear glucose patterns
2. "Peaks and valleys"
    a. Assess variability in glucose—more peaks and more valleys indicate greater glucose variability
3. "Compare with previous"
    a. Compare the AGP report with a previous report (if available) to identify similarities and differences

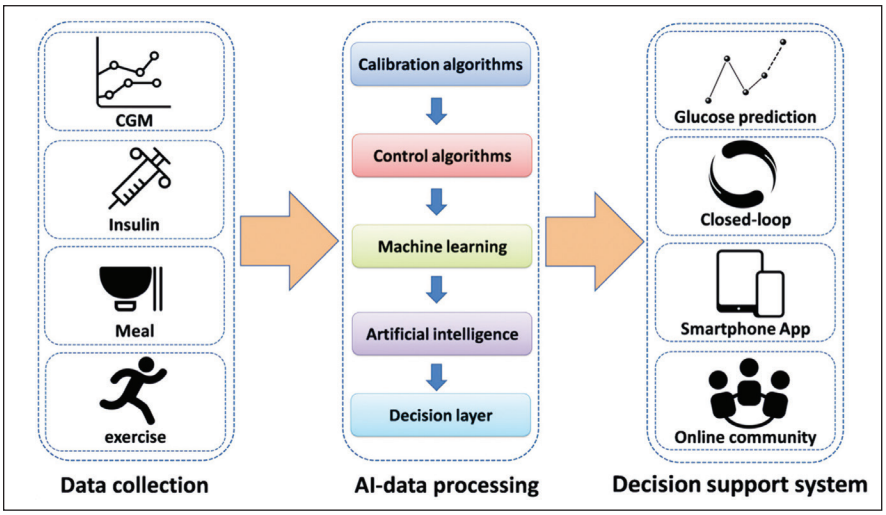
CASE STUDY (CONTINUED)

The patient started using a CGM device about 2 months ago, and her most recent data are shown in **FIGURE 5.** The AGP report indicates patterns of fasting hypoglycemia overnight and hyperglycemia in the late morning, afternoon, and evening. Her TIR is 58%, below her ideal TIR of >70%.[10] Time below range and time above range should also be reduced to <4% and <25%, respectively.[10] Obtaining additional information about the patient's dietary habits and providing counseling and careful medication adjustment would help improve this patient's TIR and reduce hypoglycemic and hyperglycemic episodes, resulting in better overall glycemic control.

IMPLEMENTING CGM IN PRIMARY CARE

While there are many benefits of using CGM, implementing this technology is not always straightforward. Benefits of CGM for patients with diabetes include improved health behav-

FIGURE 4. Representation of artificial intelligence applications in CGM.[16]



Abbreviations: AI, artificial intelligence; CGM, continuous glucose monitoring.

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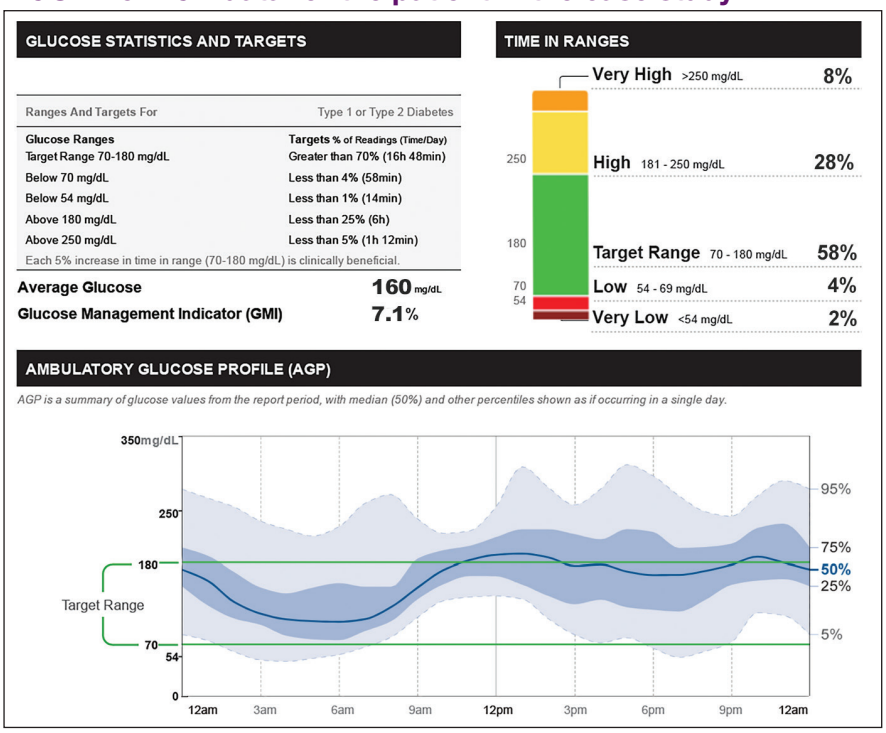
FIGURE 5. AGP data for the patient in the case study.



2-week range, time CGM active: 76%.

iors, reductions in HbA1c, less hypoglycemia, decreases in body weight, reduced caloric intake, increased physical activity, improved treatment satisfaction, and adherence to a personal eating plan.[11] For clinicians, CGM benefits include increased patient engagement, increased hypoglycemic awareness that can improve prevention, greater insight into therapeutic impacts on glucose management, and use of automated documentation to aid in data visualization.[23]

A primary barrier to CGM implementation is low rates of prescribing; one analysis using 2021 data estimated that only 13% of patients with T2D had used a CGM.[24] However, rates of CGM prescribing in primary care seem to be increasing.[24] Cost and insurance coverage can be additional barriers to CGM implementation, though coverage and reimbursement for CGM has improved in recent years. For example, the Centers for Medicare & Medicaid Services expanded coverage for CGM in 2023 to allow any patient using insulin to receive coverage for a CGM device.[25]

Employing appropriate coding and reimbursement strategies in clinics can help support clinic time spent on CGM implementation and monitoring. Coding for CGM may include the following[26]:

- 95249: personal CGM start-up and training
- 95250: professional CGM
- 95251: CGM interpretation
- 99212-99215: evaluation and management codes for patient encounters

Clinicians should also be sensitive to the potential effects of health disparities on CGM use and access, and should endeavor to involve the healthcare team in assisting with CGM access.[27,28] Indeed, CGM rates for patients in Federally Qualified Health Centers in the United States are estimated to be lower than the general population: 11% in patients with T1D and 1% in patients with T2D.[29] Health disparities that may affect CGM use include patients' location, socioeconomic status, racial and ethnic disparities, insurance coverage, technological challenges, and health literacy.[28] Involving other members of the care team such as diabetes educators, nutritionists, pharmacists, and nurses and offering

telehealth can improve patients' access to CGM and the overall quality of diabetes care.[30,31]

SUMMARY

PCPs play an increasingly important role in diabetes management in the United States, including in the use of diabetes technologies such as CGM. The use of CGM allows clinicians, patients, and caregivers to obtain more detailed information than what is available with HbA1c testing and traditional SMBG. CGM data visualization using the AGP helps mitigate the limitations of HbA1c and SMBG when evaluating a patient's overall glycemic control. New and emerging technologies in CGM include recently approved OTC CGM devices, the prospect of continuous glucose-ketone monitoring, and the use of AI in the CGM algorithm. As PCPs implement CGM in practice, with the involvement of other members of the healthcare team, patients are likely to have better access to CGM and improved glycemic control. ●

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