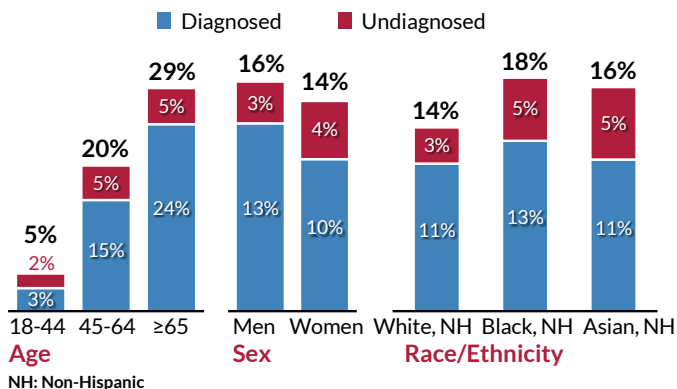


## Introduction

Diabetes mellitus is a growing global health crisis, with an estimated 537 million adults affected worldwide in 2021 — a number projected to reach 783 million by 2045.<sup>1</sup> In the United States (U.S.) alone, diabetes prevalence has reached 38.4 million people, representing 11.6% of the population, with an additional 96 million adults having prediabetes.<sup>2</sup> As shown in Figure 1, the prevalence of diabetes extends across ages, genders, races and ethnicities, with undiagnosed cases a substantial burden across all demographics.<sup>2</sup> This chronic metabolic disorder significantly increases the risk of cardiovascular disease, neuropathy, nephropathy and retinopathy, contributing to substantial morbidity, mortality and economic burdens for patients, their caregivers, health care systems and society as a whole.

**Figure 1. Prevalence (%) of Diabetes in the United States, 2017-2021<sup>2</sup>**

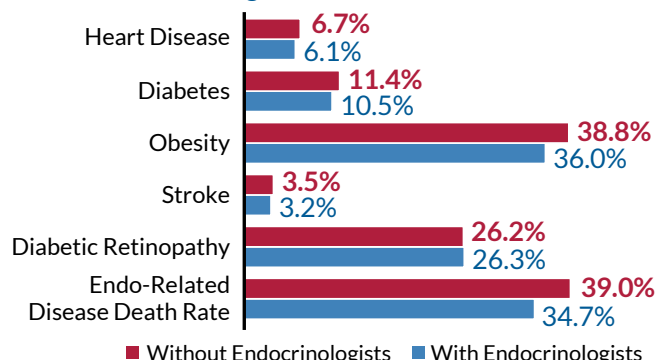


Of the individuals who have been diagnosed with diabetes, only half are at the recommended hemoglobin A1c goal of  $\leq 7.0\%$ , underscoring the need for improved access to optimal care.<sup>3</sup> Unfortunately, data indicates that approximately 75% of U.S. counties lack an endocrinologist, leaving millions of individuals dependent on primary care providers for diabetes management.<sup>4</sup> Patients in these regions, referred to as “endocrinology deserts,” often experience delayed diagnoses, inadequate access to advanced therapies and poorer health outcomes compared to those in areas with readily available specialist care, as shown in **Figure 2**.<sup>5</sup>

The shortage of endocrinologists and the rise of endocrinology deserts have underscored the need for alternative health care solutions, particularly in primary care settings. Nurse practitioners (NPs) have become pivotal in addressing these gaps, particularly in rural and underserved communities. Studies show that diabetes patients managed

by NPs in primary care settings achieve comparable or superior outcomes compared to those managed by physicians, particularly in areas such as glycemic control, adherence and reduced hospitalizations.<sup>6-8</sup>

**Figure 2. Prevalence (%) of Comorbidities in Counties With vs Without Endocrinologists<sup>5</sup>**

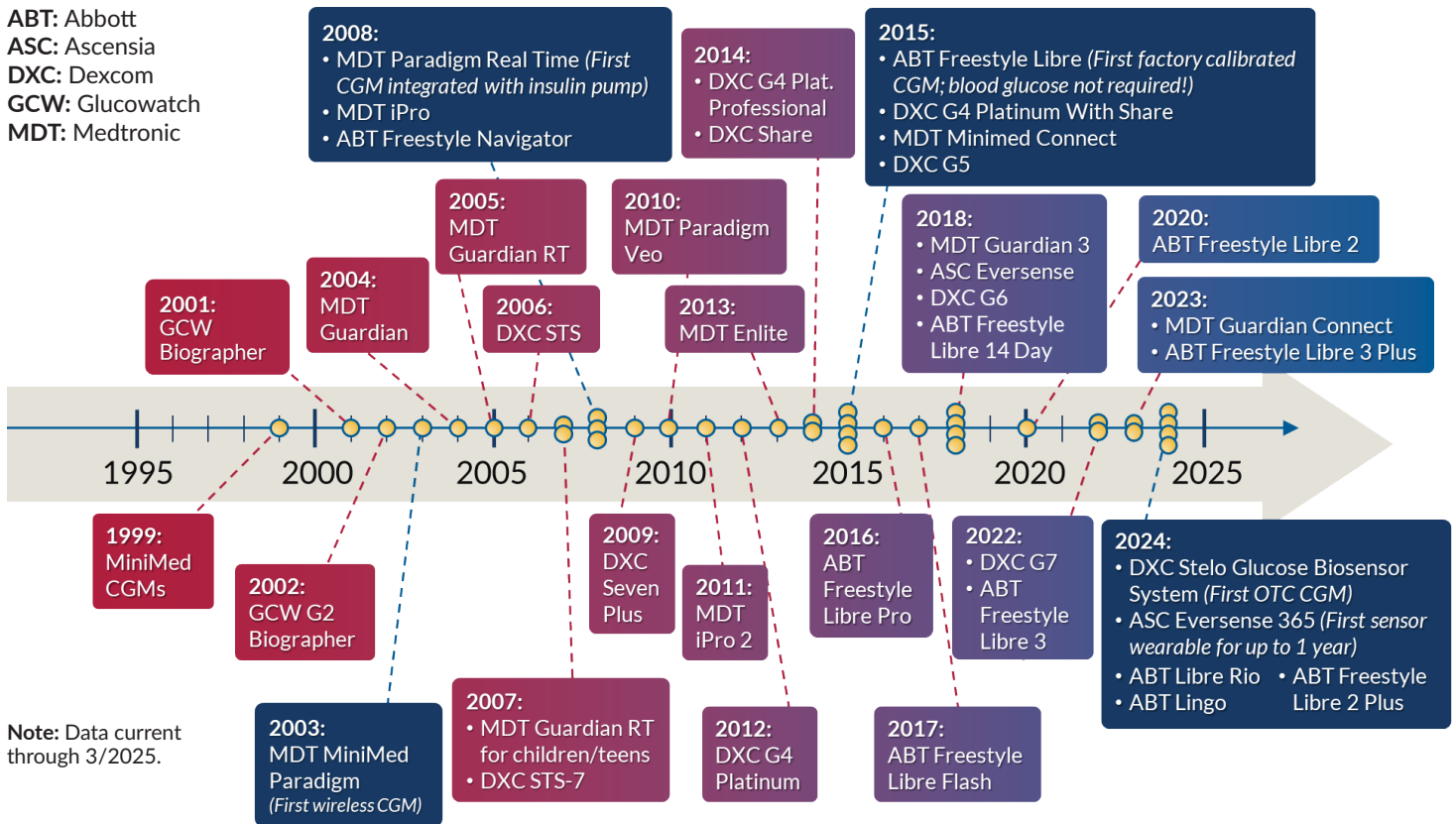


Continuous glucose monitoring (CGM) emerged as a transformative tool in diabetes management, offering real-time insights into glucose fluctuations and enabling proactive therapeutic adjustments.<sup>9</sup> Although initially developed for individuals with type 1 diabetes (T1D), technological advancements combined with substantial clinical evidence propelled CGM into the care of all patients with diabetes, both T1D and type 2 diabetes (T2D), regardless of insulin dependency. CGM use has been shown to improve glycemic outcomes, reduce hypoglycemia and enhance patient confidence in disease management.<sup>10-12</sup> By providing continuous glucose data, CGM enables early intervention strategies aimed at preventing disease progression and minimizing complications.<sup>1</sup> More recently, CGM use has expanded beyond diabetes care, driven by growing interest in personalized nutrition, athletic performance and metabolic health. Fitness enthusiasts and individuals seeking early detection of metabolic dysfunction have increasingly adopted CGM to gain real-time insights into glucose variability, dietary responses and insulin sensitivity.<sup>13</sup> **Figure 3** (next page) highlights milestones in CGM innovation, including the release of various devices from different manufacturers, with key firsts represented by dark blue.<sup>14-18</sup>

As CGM adoption continues to expand, NPs play a crucial role in integrating this technology into primary care, educating patients on real-time glucose monitoring, interpreting trends and personalizing treatment plans. Their ability to provide patient-centered diabetes management makes NPs essential in bridging the gap left by the limited number of endocrinologists, ensuring that more individuals receive high-quality, technology-driven diabetes care.

**Figure 3. CGM Devices and Year of FDA Approval<sup>14-18</sup>**

ABT: Abbott  
 ASC: Ascensia  
 DXC: Dexcom  
 GCW: Glucowatch  
 MDT: Medtronic



Note: Data current through 3/2025.

## CGM Basics

CGM provides real-time glucose readings, trends and alerts, offering a significant advancement over traditional self-monitoring of blood glucose (SMBG). Unlike finger-stick glucose testing, which provides only single-point measurements, CGM continuously tracks glucose levels throughout the day and night, allowing for proactive diabetes management and personalized treatment adjustments, as shown in **Figure 4 (next page)**.<sup>9</sup>

### Components of a CGM Device

CGM devices consist of three primary components, as shown in **Figure 5**:

- 1. Sensor:** A small device inserted subcutaneously, typically in the upper arm or abdomen, that measures glucose levels in interstitial fluid rather than blood.
- 2. Transmitter:** Attaches to the sensor and wirelessly sends glucose data to a receiver or compatible device, such as a smartphone or insulin pump.
- 3. Receiver/Display Device:** A standalone monitor or a mobile app that presents real-time glucose readings, historical trends and predictive alerts for hyperglycemia or hypoglycemia.

### Types of CGM Systems

CGM technology can be categorized based on usage into professional CGM and personal CGM.<sup>9</sup>

- ♦ **Professional CGM:** Used in clinical settings (and owned by the clinic, not the patient), professional CGM devices collect glucose data over a specified period (e.g., 10-14 days) usually without patient access. This retrospective data helps health care providers assess patterns and adjust therapy.
- ♦ **Personal CGM:** Designed for daily use, personal CGM devices provide real-time glucose readings and alerts, empowering patients to manage their diabetes proactively.

**Figure 5. Components of a CGM Device**

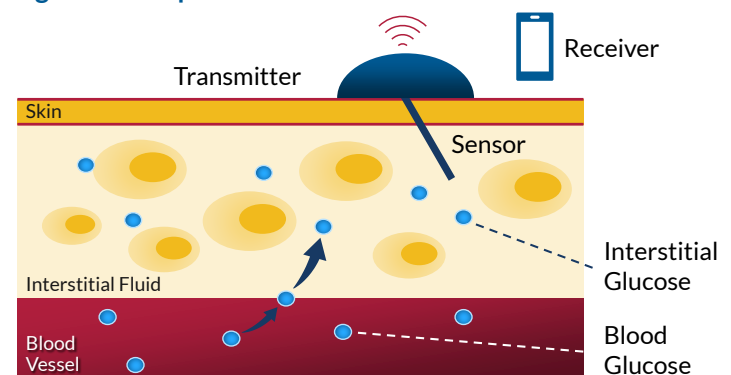
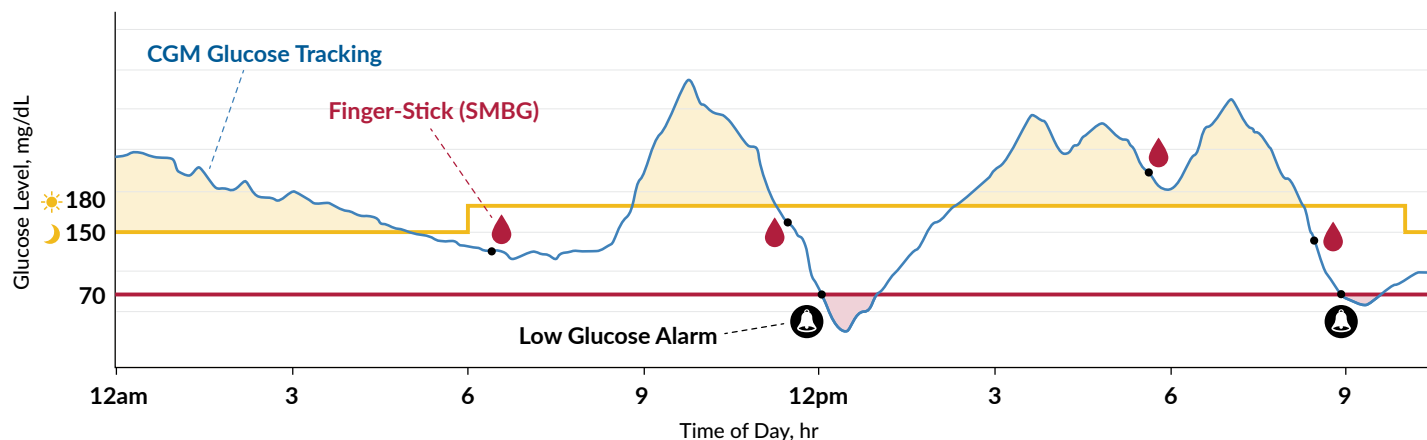


Figure 4. Comparing Finger-Stick vs CGM Data<sup>18</sup>



Personal CGM systems are classified into:

- ♦ **Real-time CGM (rt-CGM):** Continuously transmits glucose readings to a display device and provides customizable alerts for hypo- and hyperglycemia.
- ♦ **Intermittently scanned CGM (is-CGM):** Requires users to scan the sensor periodically to obtain glucose data rather than transmitting continuously.

### CGM Accuracy and Calibration

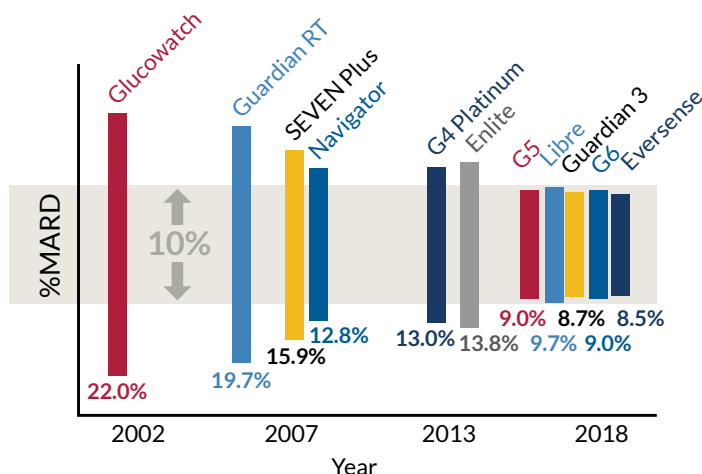
Mean Absolute Relative Difference (MARD) is a key metric reporting CGM accuracy, representing the average percentage difference between CGM readings and reference blood glucose values. The lower the MARD, the better accuracy of the device. As shown in **Figure 6**, modern CGM systems achieve MARD around or below 10%, comparable to SMBG, improving reliability for real-time insulin dosing.<sup>19</sup>

## CGM as a Standard of Care: A Review of the Evidence

### CGM in Patients With T1D

Clinical trials evaluating CGM in T1D have consistently demonstrated improved glycemic control, reduced hypoglycemia and enhanced patient quality of life. An early study, the STAR 3 trial, established the superiority of sensor-augmented pump therapy over SMBG in lowering HbA1c levels.<sup>20</sup> The IN CONTROL trial demonstrated that CGM use significantly reduced diabetes distress and increased treatment satisfaction compared to SMBG.<sup>21</sup> In the HypoDE trial, hypoglycemic events per 28 days decreased by 72% in the rt-CGM group (from 10.8 [SD 10.0] to 3.5 [4.7]; IRR 0.28 [95% CI 0.20-0.39],  $p < 0.0001$ ), while reductions in the SMBG group were negligible (14.4 [12.4] to 13.7 [11.6]).<sup>22</sup> A 2022 meta-analysis of 21 studies involving 2,149 patients with T1D showed that CGM significantly decreased HbA1c vs SMBG (-2.46 mmol/mol [-0.23%],  $p = 0.0005$ ), with the most pronounced effects in those with baseline HbA1c above 8% (-3.83 mmol/mol [-0.43%],  $p < 0.0001$ ).<sup>12</sup>

Figure 6. MARD of CGM Devices Over Time<sup>19</sup>

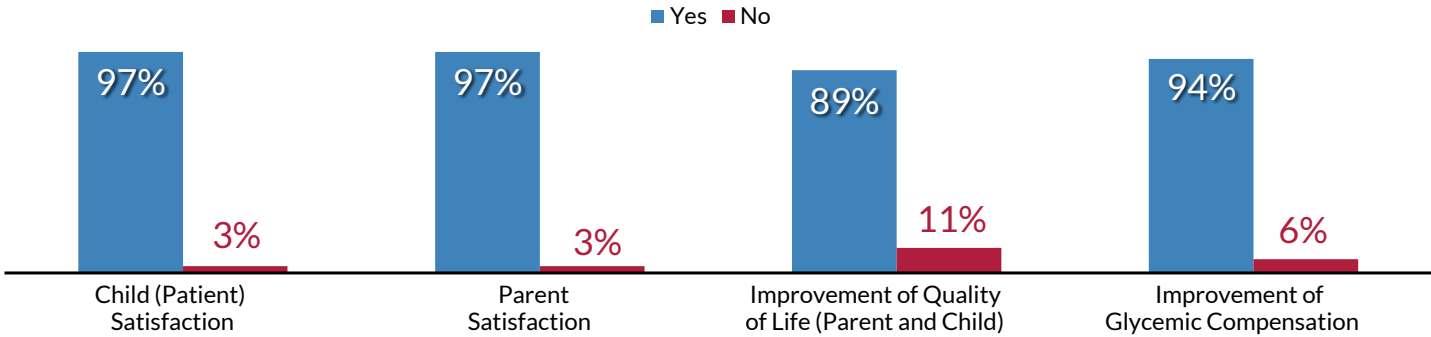


Zhou et al. demonstrated that rt-CGM improved absolute time in range (TIR) by 7% compared to is-CGM in patients with T1D. The study highlighted that rt-CGM was particularly beneficial for optimizing glucose control by providing proactive alerts for hypo- and hyperglycemia, further solidifying its role as the preferred CGM modality in T1D management.<sup>23</sup> Additionally, CGM use has been shown to significantly improve the quality of life of children with T1D and their parents/caregivers, as shown in **Figure 7 (next page)**.<sup>24</sup>

### CGM in Patients With T2D

Evidence supporting CGM in T2D has grown significantly over the past decade. The DIAMOND study demonstrated that CGM use in insulin-treated T2D patients significantly improved TIR and reduced glycemic variability compared to SMBG.<sup>25</sup> In the MOBILE study, CGM users with insulin-dependent T2D spent 15% more time in the target glucose range (59% vs 43%;  $p < 0.001$ ), had 16% less time above 250 mg/dL (11% vs 27%;  $p < 0.001$ ) and had lower mean glucose levels (179 mg/dL vs 206 mg/dL;  $p < 0.001$ ).<sup>26</sup> A narrative review of 11 studies of CGM use in 5,542 patients with T2D reported that compared to SMBG, CGM use was associated with greater reductions in HbA1c, body weight

Figure 7. Participants' Perceptions About Aspects and Effects of Using CGM<sup>24</sup>



and caloric intake, as well as higher adherence to dietary plans and increased physical activity. CGM combined with behavioral counseling further enhanced these benefits, while compliance to CGM wear-time was high (>90%).<sup>27</sup> A 2024 meta-analysis of 14 RCTs comprised of 1,647 individuals with T2D found that CGM use resulted in an average HbA1c reduction of 0.32%, with significant improvements in patient adherence and self-care behaviors.<sup>28</sup>

As shown in **Figure 8**, the majority of health care providers report being comfortable using the CGM system, with most finding it "Very Easy" or "Easy" to use. In addition, providers reported monitoring glucose values more frequently with CGM, and a significant proportion found that CGM made their work easier. While some providers experienced problems, 93% preferred CGM over SMBG, citing increased efficiency in monitoring glucose remotely.<sup>29</sup>

Clinical Uses for CGM Beyond Diabetes

CGM has revealed significant glycemic variability (GV) in individuals without diabetes, demonstrating its potential for early disease detection and risk assessment.

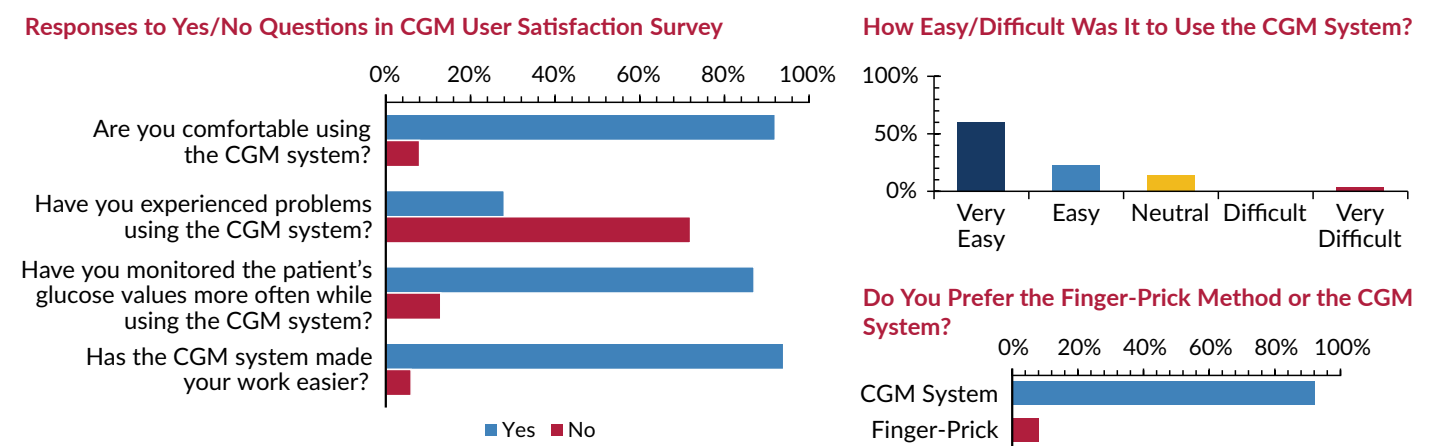
Large-scale data from over 7,000 individuals without diabetes showed that a substantial proportion experienced glucose levels exceeding impaired glucose tolerance thresholds multiple times daily, with 10% spending more than two hours per day above these levels.<sup>30</sup> Additionally, GV was found to be higher in individuals with prediabetes and was inversely associated with beta-cell function,

suggesting a role in the early detection of metabolic dysfunction.<sup>31</sup> Furthermore, GV was linked to coronary atherosclerosis progression, with individuals exhibiting greater glucose fluctuations showing a higher incidence of cardiovascular events.<sup>31</sup> These findings suggest CGM could be a valuable tool for stratifying cardiovascular risk, even in those without diagnosed diabetes.

Beyond metabolic health, CGM has provided critical insights into glucose dysregulation in specialized populations. Among patients recovering from acute ischemic stroke, Fountouki et al. found that persistent hyperglycemia correlated with worse functional outcomes, yet for every one-point increase in TIR, authors noted an expected 1.5% lower odds of having a worse outcome. Authors go on to conclude that CGM could aid in achieving glycemic control and potentially extend life expectancy.<sup>32</sup>

Among kidney transplant recipients, CGM detected early post-transplant hyperglycemia, with 43% of patients spending more than 12 hours per day above 7.7 mmol/L (138.7 mg/dL) in the first four days post-surgery.<sup>33</sup> This early hyperglycemia was associated with a 3.6-fold increased risk of developing post-transplant diabetes and a higher rate of graft failure.<sup>33</sup> In individuals with chronic kidney disease, CGM revealed that standard glycemic markers like HbA1c underestimated glycemic burden due to altered red blood cell turnover, highlighting the need for direct glucose measurements.<sup>34</sup>

Figure 8. Health Care Provider Perceptions About Aspects and Effects of Using CGM<sup>24</sup>



Additionally, CGM data demonstrated that sleep patterns and diet significantly impact glucose fluctuations, with certain individuals experiencing postprandial spikes exceeding 180 mg/dL despite consuming identical meals.<sup>30</sup> These findings illustrate CGM’s role in refining personalized health interventions, optimizing treatment strategies for at-risk individuals and broadening our understanding of glucose metabolism beyond traditional diabetes management.

Over-the-Counter CGM

The availability of over-the-counter (OTC) CGM devices has expanded access to real-time glucose tracking beyond diabetes, enabling broader use for metabolic health monitoring. These devices, now available without a prescription, allow users to assess their glycemic responses to diet, exercise and lifestyle factors, fostering a more personalized approach to wellness.<sup>30</sup> In 2024, the FDA approved three OTC CGMs: Abbott Libre Rio, Abbott Lingo, and Dexcom Stelo, marking a significant shift in glucose monitoring accessibility.<sup>35,36</sup> Abbott’s Libre Rio is intended for individuals with non-insulin-dependent T2D, offering an accessible tool for tracking glucose patterns and making lifestyle adjustments, whereas Abbott’s Lingo is positioned more broadly for the general wellness market, designed to help health-conscious individuals optimize metabolic health by providing insights into glucose fluctuations and their responses to diet and exercise.<sup>35</sup> Dexcom Stelo, intended for individuals with prediabetes, non-insulin-dependent T2D or those without diabetes, provides real-time glucose data without requiring finger-sticks or calibration.<sup>36</sup> As consumer interest in metabolic optimization grows, OTC CGMs have the potential to

reshape preventive health care by identifying early signs of glucose dysregulation and guiding behavioral interventions before clinical disease develops.<sup>30</sup>

Currently Available Devices

Table 1 provides a snapshot of all currently available CGM devices, both prescription (Rx) and OTC, highlighting their key features and accessibility.

Translating CGM Data Into Real-World Clinical Benefit

Improving Patient Outcomes Through Effective Communication

Shared decision-making (SDM) is a critical component of optimizing CGM-driven outcomes, as it ensures that patients actively participate in their diabetes management. The SHARE Approach, developed by the Agency for Healthcare Research and Quality (AHRQ) and shown in Figure 9 (next page), outlines essential steps for engaging patients in treatment decisions, including seeking the patient’s perspective, exploring treatment options, assessing values and preferences, reaching a decision and evaluating outcomes.<sup>48</sup> Effective SDM involves patient and caregiver education on new therapies or therapeutic intensifications based on CGM data, as well as personalized lifestyle counseling and resource provision.<sup>11</sup> The Ambulatory Glucose Profile (AGP) is a standardized, visual summary of CGM data, typically collected over a 14-day period. This report (example shown in Figure 10 on page 7) is instrumental in evaluating overall glycemic control by offering a comprehensive view of glucose trends and patterns.<sup>49</sup> Furthermore, clinicians who have firsthand

Table 1. Currently Available CGM Devices<sup>37-47</sup>

| Device                        | Rx or OTC? | CGM Type     | Approval | Accuracy (MARD) | Insulin Pump Compatible? | Wear Time |
|-------------------------------|------------|--------------|----------|-----------------|--------------------------|-----------|
| Abbott Lingo                  | OTC        | Real Time    | 2024     | Not Available   | No                       | 14 Days   |
| Abbott Libre Rio              | OTC        | Intermittent | 2024     | Not Available   | No                       | 15 Days   |
| Ascensia Eversense 365        | Rx         | Real Time    | 2024     | 8.8%            | No                       | 1 Year    |
| Dexcom Stelo                  | OTC        | Real Time    | 2024     | 8.3%            | No                       | 15 Days   |
| Abbott Freestyle Libre 2 Plus | Rx         | Intermittent | 2024     | 8.2%            | Yes                      | 15 Days   |
| Medtronic Guardian Connect    | Rx         | Real Time    | 2023     | 9%-10.5%        | No                       | 7 Days    |
| Abbott Freestyle Libre 3 Plus | Rx         | Real Time    | 2023     | 8.2%            | Yes                      | 15 Days   |
| Abbott Freestyle Libre 3      | Rx         | Real Time    | 2022     | 7.9%            | No                       | 14 Days   |
| Dexcom G7                     | Rx         | Real Time    | 2022     | 8.2%            | Yes                      | 10 Days   |
| Abbott Freestyle Libre 2      | Rx         | Intermittent | 2020     | 9.2%            | No                       | 14 Days   |
| Abbott Freestyle Libre 14     | Rx         | Intermittent | 2018     | 9.4%            | No                       | 14 Days   |
| Dexcom G6                     | Rx         | Real Time    | 2018     | 9.0%            | Yes                      | 10 Days   |

Note: Data current through 3/2025.

Figure 9. The SHARE Approach<sup>47</sup>



experience using CGMs can enhance patient counseling by better explaining sensor wear, alerts and troubleshooting while also improving their ability to interpret glucose trends and guide patients through lifestyle adjustments.<sup>50</sup>

### Insurance and Cost of CGM

The cost of CGM systems varies based on the brand and specific components required. Insurance coverage for CGMs varies across different providers and plans. Medicare Part B covers therapeutic CGMs for individuals with diabetes who use insulin or have a history of problematic hypoglycemia, provided specific criteria are met. Most commercial insurance plans also offer coverage for CGMs, though the extent and specifics can differ.<sup>51</sup>

For those without insurance coverage of CGM, several manufacturers and organizations offer affordability programs:

- ♦ **Abbott:** Through the MyFreeStyle program, Abbott provides one free sensor for their FreeStyle Libre systems.
- ♦ **Dexcom:** For those without CGM coverage or facing high copays, Dexcom offers a pharmacy savings program.
- ♦ **CR3Diabetes:** This organization supplies equipment, including insulin pumps and CGMs, to individuals living with diabetes and accepts donations for insulin pump supplies.
- ♦ **Insulin Pumpers Foundation:** Assists individuals lacking financial resources to purchase an insulin pump.
- ♦ **Insulin for Life USA:** Accepts donations for insulin pump and CGM supplies and distributes them to people globally. Notably, donated insulin must be unexpired by at least 90 days.
- ♦ **Pharmacy Discount Cards:** Some discount programs, such as GoodRx and SingleCare, help reduce CGM costs.

These programs aim to enhance access to essential diabetes management tools, ensuring that cost does not impede optimal care.

## Patient and Clinician Resources

### American Academy of Family Physicians (AAFP)

- ♦ <https://www.aafp.org/family-physician/patient-care/care-resources/continuous-glucose-monitoring.html>
- ♦ Offers patient handouts in English and Spanish, along with educational videos on CGM.

### American Diabetes Association (ADA)

- ♦ <https://diabetes.org/advocacy/cgm-continuous-glucose-monitors>
- ♦ Provides a compilation of resources for patients and health care professionals regarding CGM use.

### National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

- ♦ <https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/continuous-glucose-monitoring>
- ♦ Features comprehensive information on how CGMs work, their benefits and considerations for users.

### Memorial Sloan Kettering Cancer Center

- ♦ <https://www.mskcc.org/pdf/cancer-care/patient-education/about-your-continuous-glucose-monitor-cgm>
- ♦ Provides a detailed PDF guide titled "About Your Continuous Glucose Monitor (CGM)," covering usage instructions and safety information.

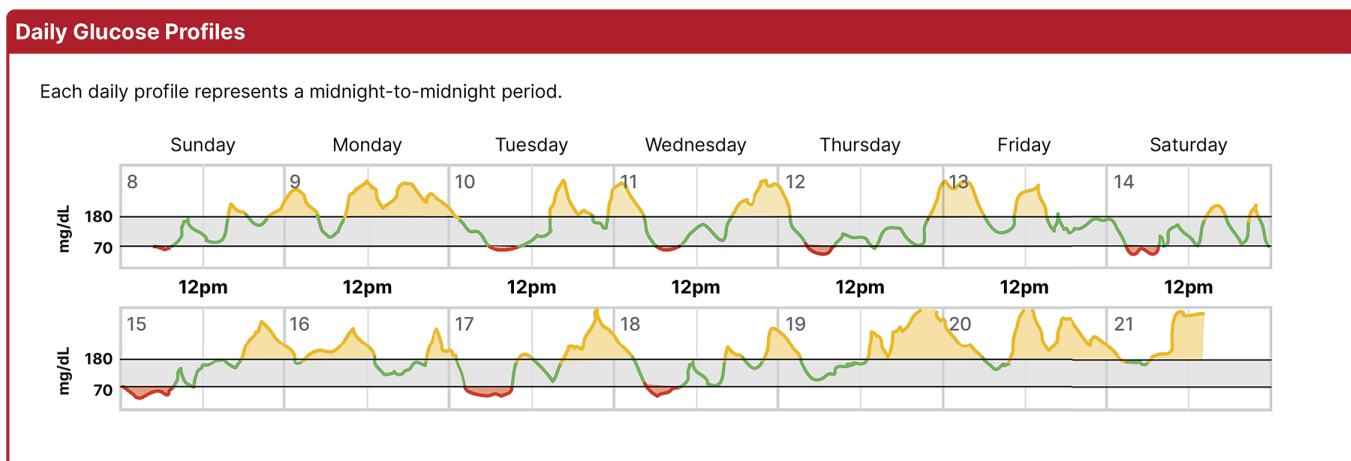
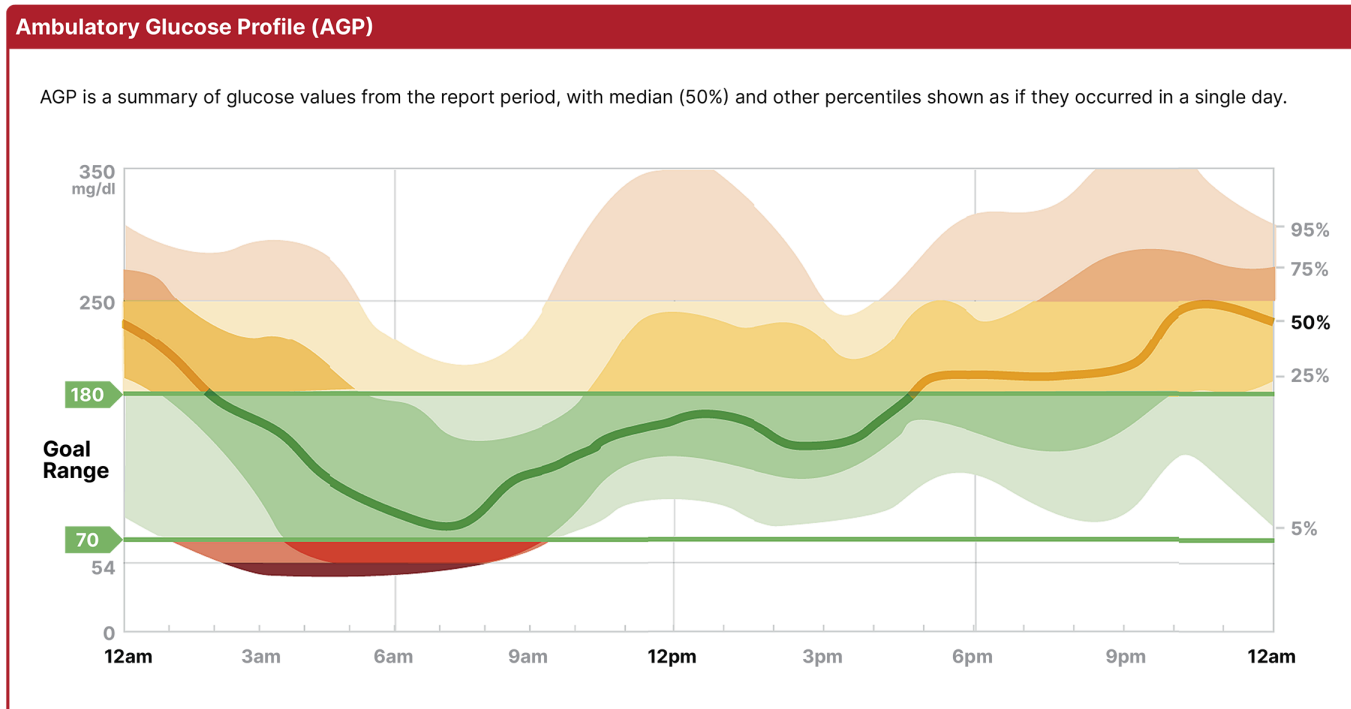
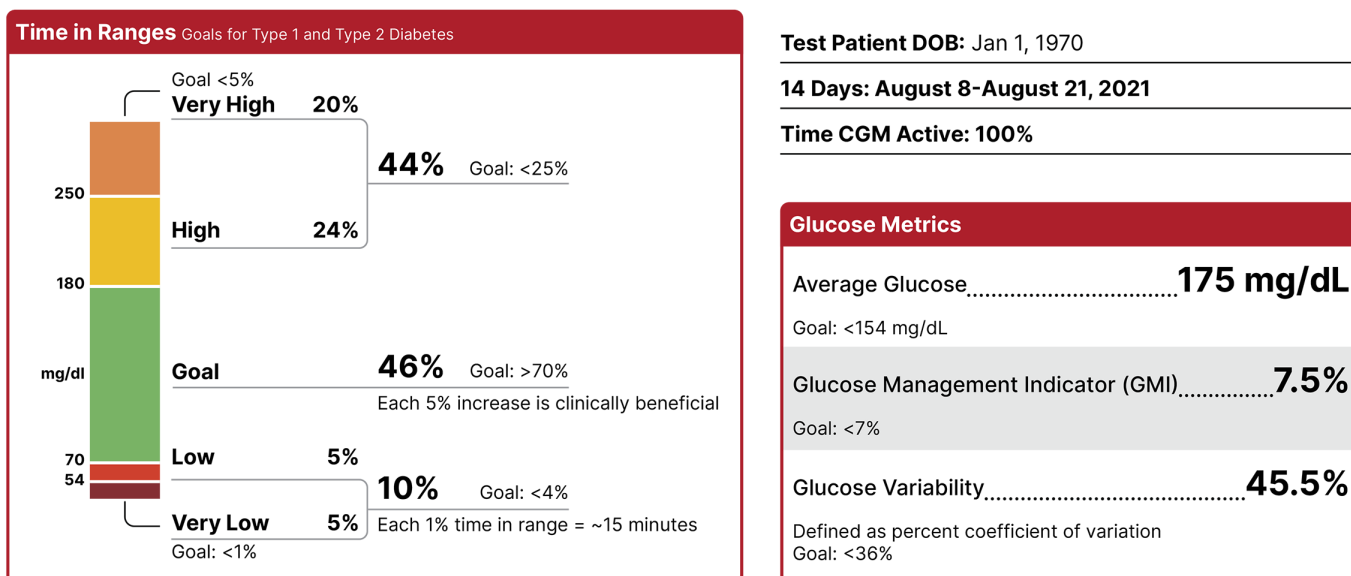
### Cleveland Clinic

- ♦ <https://my.clevelandclinic.org/health/articles/continuous-glucose-monitoring-cgm>
- ♦ Offers an article explaining what CGM is, how it works and its role in diabetes management.

### Association of Diabetes Care & Education Specialists (ADCES)

- ♦ <https://www.adces.org/education/danatech/glucose-monitoring/continuous-glucose-monitors-%28cgm%29/cgm-selection-training/cgm-training-topic-checklist>
- ♦ Provides a simple training checklist to ensure comprehensive patient education on CGM usage.

Figure 10. Example AGP Report<sup>52</sup>



Patients can check their coverage details for CGM devices based on their insurance provider, plan type and state of residence at the following site:

**CGM Insurance Coverage Tool (Click Here)**

## Conclusion

CGM has transformed diabetes management by providing real-time glucose data, improving glycemic control and enhancing patient engagement. For individuals with diabetes, CGM has been shown to significantly reduce hypoglycemia, increase TIR and lower HbA1c levels. Beyond diabetes, CGM has gained popularity among individuals who seek insights into metabolic health, personalized nutrition, and athletic performance.

Large-scale studies have shown that glycemic variability in non-diabetic individuals is linked to early metabolic dysfunction and cardiovascular risk, highlighting CGM's potential role in preventive health care. Despite these benefits, barriers such as insurance limitations, financial constraints and healthcare disparities persist. OTC devices and affordability programs have helped bridge these gaps, making glucose monitoring more accessible. With a shortage of endocrinologists leading to increased demands for diabetes management through primary care practices, the role of NPs is crucial in effectively integrating CGM technology into routine care, ensuring that patients receive the education, support and resources needed to maximize its benefits.

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