

Continuous Glucose Monitoring (CGM): Improving Outcomes for Patients with Diabetes

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Pathophysiology

Diabetes mellitus (DM) is a chronic complex illness that requires continuous medical care with an interdisciplinary team. DM results from defects in insulin secretion, insulin action, or both. In persons with DM, various genetic pathways and environmental factors result in the loss of β -cell function that presents clinically as hyperglycemia or elevated levels of blood glucose.^{1,2} The disease process can cause impaired fasting glucose levels and impaired glucose tolerance or prediabetes before progressing to a diagnosis of DM. In persons with DM, uncontrolled hyperglycemia can present as polyuria, polydipsia, and polyphagia, and weight loss may also be noted along with blurred vision.¹ Figure 1 shows the types of DM based on the cause.

DM has both direct and indirect medical costs and is associated with reduced productivity. People with DM incur average medical expenses of \$16,750 annually, of which \$9600 is attributed to DM. Indirect costs include increased absenteeism, reduced productivity at work, and inability to work due to disability.⁴

Over time, DM can lead to damage to the heart, vasculature,

kidneys, nerves, and eyes.⁵ These complications increase morbidity and mortality and reduce quality of life. The United Kingdom Prospective Diabetes Study provided strong evidence that hyperglycemia is a toxic state and that lowering blood glucose levels can decrease microvascular complications.³ Measures such as HbA1c (hemoglobin A1c), self-monitoring of blood glucose, and continuous glucose monitoring (CGM) can be used to assess glycemic control. However, one of the major limiting factors with HbA1c is the lack of a measure of glycemic variability or hypoglycemia.⁶ This highlights the importance of obtaining feedback from self-monitoring of blood glucose and from CGM. The feedback from blood glucose readings as an aspect of diabetes self-management education has been shown to prevent short- and long-term complications associated with DM. It has been shown to be one of the factors that impacts behavioral changes and enhances self-confidence in persons with DM.⁷

Role of glucose monitoring in achieving desired outcomes in the care of the patient with DM

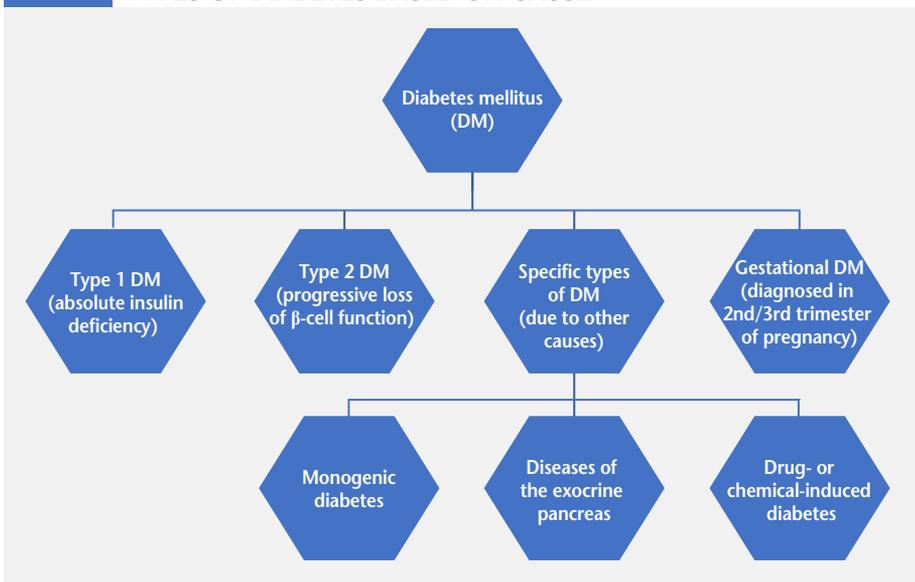
Self-monitoring of blood glucose (SMBG) has been an integral part in managing blood glucose levels for people living with diabetes. Although it has been a helpful tool for identifying both hyperglycemia and hypoglycemia, there are barriers associated with SMBG. These barriers include pain associated with performing a fingerstick, inconvenience, and lack of adherence. It is reported that only 1 of 3 patients adhere to an SMBG regimen suggested by their health care provider.

SMBG only identifies a person's blood glucose level at that point in time and is

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FIGURE 1 TYPES OF DIABETES BASED ON CAUSE



Adapted from Classification and Diagnosis of Diabetes (2021)³

therefore a limited picture of a person’s glycemic patterns. Even with frequent SMBG tests, highs and lows can be missed.⁸ In the Diabetes Control and Complications Trial, intensive insulin therapy guided by frequent blood glucose monitoring resulted in delayed onset and slower progression of DM complications, although there was an increased risk of severe hypoglycemia.⁹ Although SMBG has improved glycemic control and quality of life in those treated with or without insulin, it is not able to predict impending hypoglycemia or to alert a patient about hypoglycemia.¹⁰ In both type 1 DM

and type 2 DM management, hypoglycemia is a major limiting factor.¹¹ With chronic hypoglycemia, the typical compensatory responses get dull, leading to hypoglycemia unawareness.¹² Integrating the results of CGM into management of DM can be an effective tool for guiding medical nutrition therapy, physical exercise, and medication management as well as for preventing hypoglycemic and hyperglycemic events.⁸ CGM measures interstitial fluid, which correlates with plasma glucose, although there may be a lag in times of rapid rise or fall in glucose. Lag time in devices can range up to

TABLE 1 COMMON PERSONAL CGM SYSTEMS AVAILABLE IN THE UNITED STATES

CGM system	Dexcom G6	Eversense®	FreeStyle Libre 14 day	FreeStyle Libre 2	Guardian™ Sensor 3
Company	Dexcom	Senseonics and Ascensia Diabetes Care	Abbott	Abbott	Medtronic
Sensor	Yes	Yes. Professionally inserted only, under the skin	Yes	Yes	Yes
Sensor “warm up period”	2 hours	24 hours	1 hour	1 hour	2 hours
Sensor wear	10 days	90 days	14 days	14 days	7 days
Transmitter	Yes. 90-day battery life	Yes. Removable, rechargeable, and water resistant	Yes. Built into sensor, making the system one piece	Yes. Built into sensor, making the system one piece	Yes. 1 year with charger (battery operated)
Receiver	Yes, or can use compatible phone app	Used with compatible phone app or smart watch	Yes, or can use compatible phone app	Yes, or can use compatible phone app	Insulin pump and phone app
Alerts	Yes	Yes	No	Yes	Yes
Calibration with fingersticks	Not needed ^a	Initialization phase: After warm-up, 4 fingerstick tests spaced 2–12 hours apart Daily: fingerstick every 12 hours	Not needed	Not needed	2–4 calibrations/day
MARD ^b	9.8%	8.5%	9.7%	9.2%	8.7%–10.6% (site dependent)
Integration with Pump	Yes	No	No	No	Yes
How often system measures blood glucose levels	Every 5 minutes	Every 5 minutes	Every 1 minute	Every 1 minute	Every 5 minutes
Age (y) of approved indication	≥2	≥18	≥18	≥4	≥2

Source: Adapted from Abbott.com, Medtronic.com, Senseonics Incorporated, Dexcom.com

^aFingersticks not required as long as you enter the code number when starting the sensor; otherwise fingersticks are required. <https://www.dexcom.com/safety-information>

^bMARD, mean absolute relative difference. This metric is commonly used when comparing CGM systems. The smaller the MARD, the closer the CGM readings are to the reference glucose values. A larger MARD indicates a wider range between the CGM values and the reference glucose values.⁸

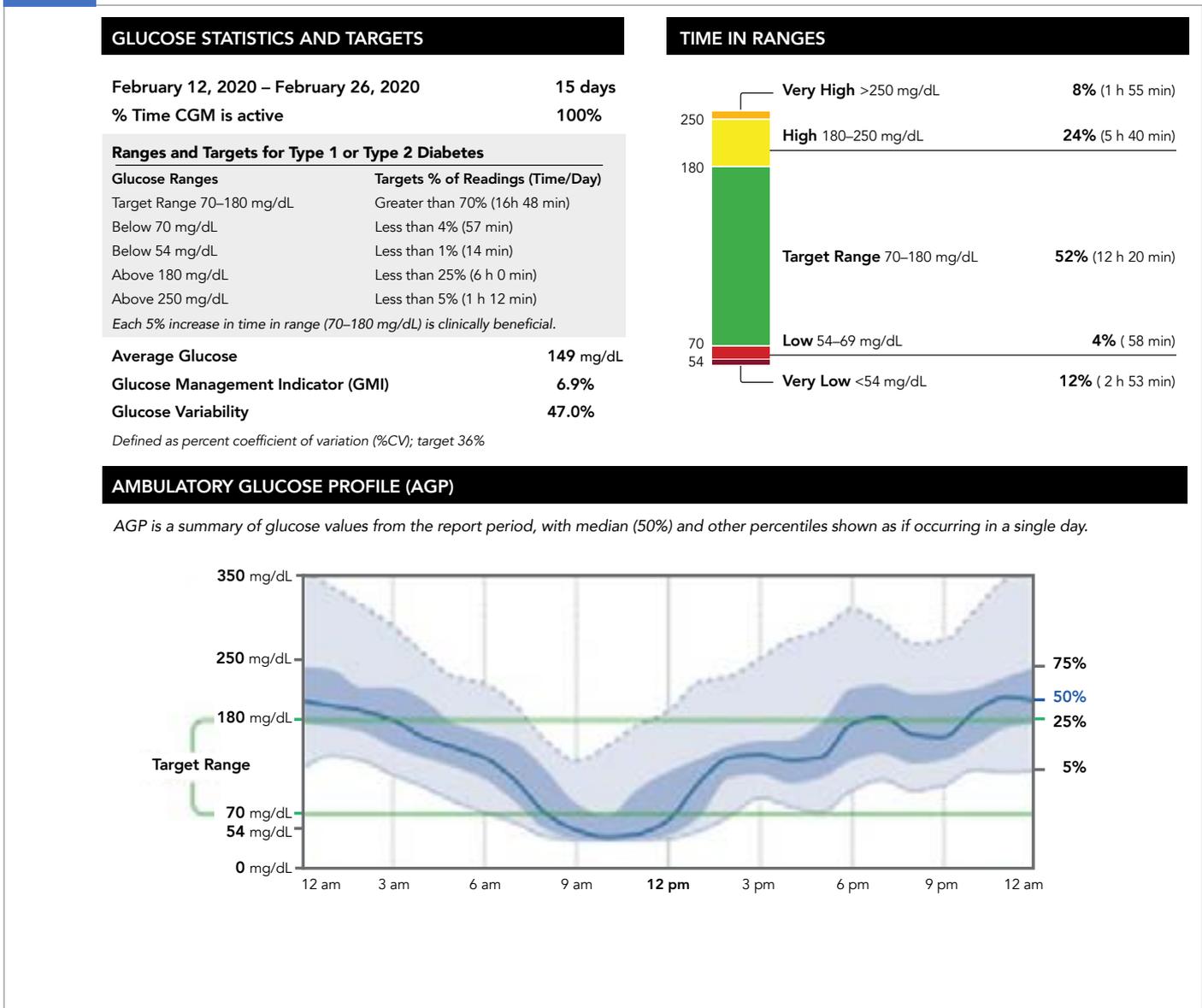
15 minutes but are typically less than that in current CGM systems because of algorithm adjustments. A person living with diabetes should have a glucometer to perform SMBG if values obtained from the CGM do not match signs and symptoms.

There are 2 types of CGM devices: professional and personal.¹ Professional CGMs are owned by the health care provider and, depending on the device, are worn 1–2 weeks and data can be visible or blinded. Data are uploaded from the device to view reports. The personal continuous glucose monitor is owned by the person living with diabetes and provides real-time data. Some devices have real-time streaming whereas other personal devices require the user to scan the sensor to obtain the real-time data. These devices can provide information that can help with decision treatments for therapy

and/or lifestyle modifications.¹³ Table 1 lists some personal brands of CGM available in the United States.

Consensus guidelines for use of CGM were proposed at The Advanced Technologies & Treatments for Diabetes conference. CGM reports create an ambulatory glucose profile that provides data on time in range (TIR), percentage of time spent below and above range, and variability.⁸ It allows the provider to assess patients with DM for hypoglycemia, hyperglycemia, and glycemic variability.¹¹ The use of continuous glucose monitors in patients with DM has helped decrease the burden of care because of better patient satisfaction, consistency with device use and medication therapy, and increased awareness by clinicians. Personal CGM devices have both current glucose level and rate of change trend arrows, which

FIGURE 2 FREESTYLE LIBRE REPORT: 14-DAY WEAR



indicates the directions and rapidity of glucose change.¹⁴

The International Consensus on the use of CGM recommends some key factors to keep in mind when assessing a CGM report.¹ These include the following:

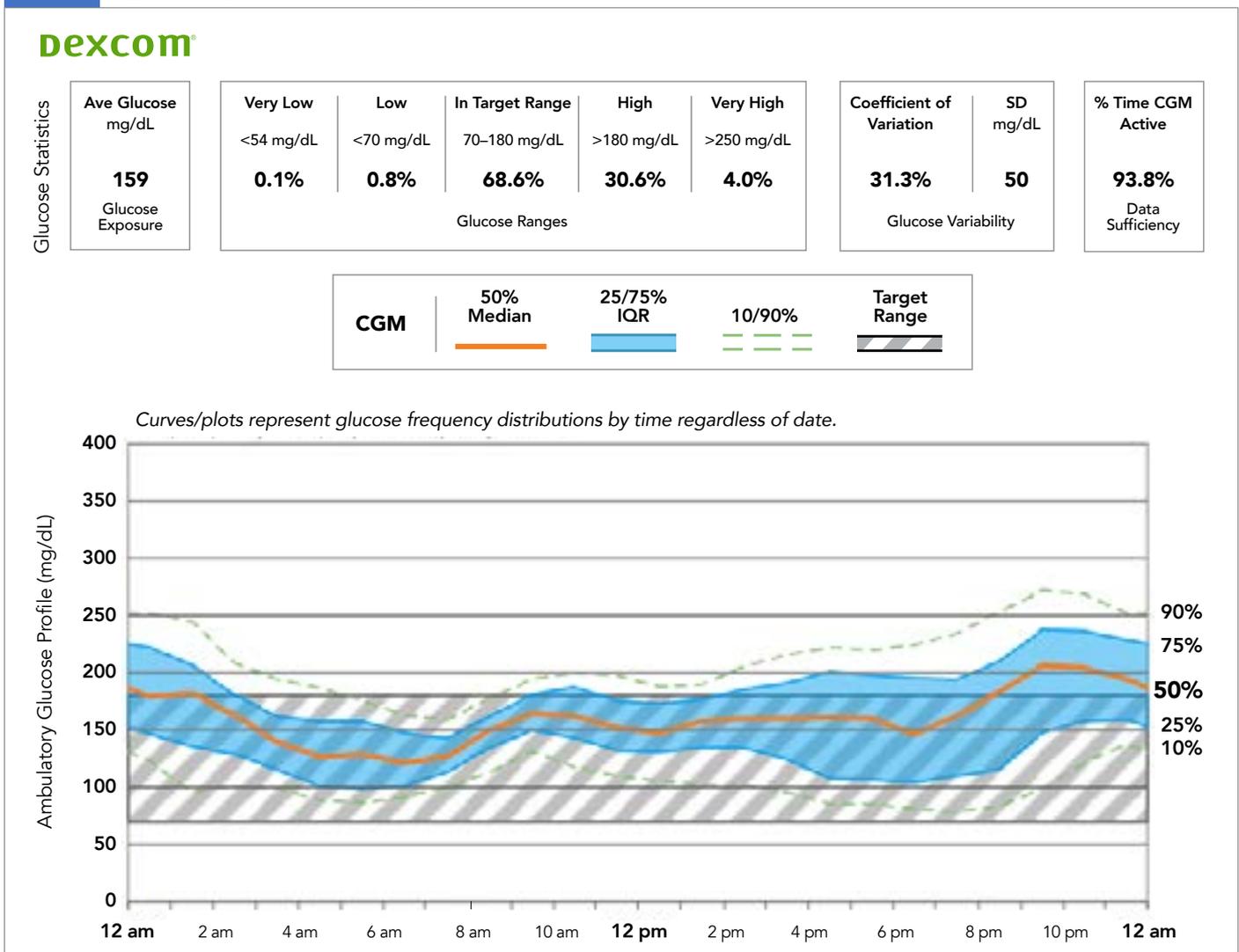
- Mean glucose level
- Percentage of time in level 2 hypoglycemia range (<54 mg/dL)
- Percentage of time in level 1 hypoglycemia range (<70–54 mg/dL)
- Percentage of time in target range—default as 70–180 mg/dL, although these can be individualized based on pertinent factors
- Percentage of time in level 1 hyperglycemia >180 mg/dL
- Percentage of time in level 2 hyperglycemia >250 mg/dL
- Glycemic variability
- Average glucose

As CGM systems have evolved over the last few years, metrics have been adjusted to provide for data that is most relevant to looking at pattern management.

Figures 2 and 3 demonstrate a FreeStyle Libre and a Dexcom report, respectively. A lot of information can be gleaned from these reports, which guide both the provider and the person with DM to make actionable changes. While interpreting data from a continuous glucose monitor, it is important to consider the glycemic variability as well as the fluctuation of glucose levels within day (intraday) and day-to-day (interday) variations. This glucose variability has been associated with cardiovascular damage and endothelial markers. Hence, providers must pay attention to both the wide range of glucose variability and time outside a target range.⁹

Continuous glucose monitors that are attached to the skin can be associated with side effects such as contact dermatitis (both irritant and allergic). Tape irritant may need to be eliminated to ensure consistent use of CGM to maximize its benefit for persons with DM.⁸

FIGURE 3 DEXCOM REPORT: 10-DAY WEAR



Diabetes mellitus (DM) has both direct and indirect medical costs and is associated with reduced productivity. People with DM incur average medical expenses of \$16,750 annually, of which \$9,600 is attributed to DM. Indirect costs include increased absenteeism, reduced productivity at work, and inability to work due to disability.

Coverage for CGM

Alarming approximately 73.1% of the costs associated with DM are the costs of treating complications of DM and indirect costs from lost productivity. Of total DM costs, only 1.1% are directed towards diabetes supplies. Even then, private and public payers seem to focus on making eligibility criteria for DM supplies challenging, especially those for continuous glucose monitors, which appears to be counterproductive. The Centers for Medicare & Medicaid and private insurers have eligibility requirements for coverage of CGM. Recently CMS updated their guidelines and removed the 4 fingersticks a day requirement and expanded coverage for individuals who use inhaled insulins by permitting multiple daily administration of any insulin.¹⁵ It also requires adjustment of insulin by the patient based on blood glucose levels and being on multiple daily insulin injection therapy at least three times a day. The conundrum created by a lack of transparency with regard to coverage for CGM by payers makes DM care restrictive for both patients and providers. As evidence-based research highlighting the benefits of CGM has grown, there is a need to make this tool more readily available to persons with DM irrespective of diabetes type and history of self-monitoring blood glucose.¹⁶

Outcomes

CGM may significantly improve both clinical outcomes and quality of life for persons with DM and their caregivers. CGM enables the healthcare team to help patients identify glucose trends and make informed treatment decisions. Although the CGM device alone cannot improve any outcomes, the data interpretation that leads to lifestyle changes or medication adjustments is crucial to achieving glycemic goals and lessening the burden of managing DM.¹⁷

CGM increases patient engagement and enhances self-efficacy.

The advent of CGM technology has eased the burden of traditional glucose monitoring, improving quality of life and making DM management more convenient. CGM has also been shown to reduce DM distress and ameliorate anxiety about potential hypoglycemia or taking fingersticks with a glucometer.¹⁸ CGM can provide persons with DM a greater understanding of their individualized treatment regimen. Persons with DM who use CGM technology feel more confident that they can respond to blood glucose fluctuations in a timely manner, whether they are experiencing hypoglycemia or hyperglycemia.¹⁸ Patients who have real-time data feel empowered to make decisions regarding exercise and food choices. Greater satisfaction is reported among persons with DM who use

CGM compared with traditional glucose monitoring because of the ease and convenience of CGM.¹⁸

CGM has clinical benefits to reduce HbA1c and glycemic variability

While traditional glucose monitoring only captures one moment in time, CGM provides the ability to see patterns and trends, including any fluctuations or glycemic variability. Numerous studies have demonstrated that CGM use in patients with type 1 and type 2 DM reduces HbA1c.¹⁹ Among patients with DM that is managed with multiple daily insulin injections, CGM use demonstrated a 0.6% reduction in HbA1c levels over 24 weeks.²⁰ Evidence supporting the efficacy of CGM utilization for individuals with type 2 DM who are not receiving intensive insulin therapy is growing. In a recent randomized control trial of 175 adults with type 2 diabetes, there was a more significant HbA1c reduction with CGM than with blood glucose monitoring (-1.1% vs -0.6%).²¹

In another randomized controlled trial in non-insulin-using patients with type 2 DM, the CGM group demonstrated a 0.43% reduction in HbA1c at 12 weeks compared with a 0.30% reduction for the blood glucose monitoring group, and the CGM group continued to have a -0.46% reduction in HbA1c at 24 weeks.²²

Reduced HbA1c levels are associated with reduced vascular complications. Greater glycemic variability and greater fluctuations in blood glucose levels are associated with greater risk of retinopathy and nephropathy in persons with DM.²³ Greater glycemic variability is associated with greater inflammation, endothelial dysfunction, and risk of microvascular and macrovascular complications. Use of CGM consistently demonstrates reduced glycemic variability, which can reduce the risk of long-term complications from DM.²⁴

Safety and reduced incidence of hypoglycemia

In a clinical trial, patients with type 2 DM who were receiving multiple daily injections of insulin reduced the incidence of hypoglycemia by 43% overall and 54% at night.²⁴ This can be attributed to the alarms that are standard features of personal continuous glucose monitors, which can quickly prompt treatment. Individuals with DM can often experience hypoglycemia while sleeping, which poses a significant risk, especially as many can experience hypoglycemia unawareness. For many persons receiving multiple daily injections of insulin, use of CGM can also lessen the burden on caregivers. Since many persons with type 1 DM do not experience signs and symptoms of low blood sugar, the alarms on CGM devices can lessen fear and anxiety for the family and

Continuous glucose monitoring (CGM) may significantly improve both clinical outcomes and quality of life for persons with diabetes mellitus (DM) and their caregivers. Although the CGM device alone cannot improve any outcomes, the data interpretation that leads to lifestyle changes or medication adjustments is crucial to achieving glycemic goals and lessening the burden of managing DM.

caregivers.²⁵ Use of CGM is also associated with reduced acute complications and hospitalizations related to diabetic ketoacidosis, hypoglycemic coma, and hyperosmolar hyperglycemic syndrome.²⁶ The reduction in these complications and hospitalizations can have a profound impact on reducing overall medical expenditures related to DM.

Role of the Care Manager

The care manager plays an integral role in DM self-management education by identifying barriers to care, providing an individualized treatment plan, and facilitating SMART (specific, measurable, attainable, relevant, and timely) goals. The care manager, including registered nurses, social workers, registered dietitian nutritionists, and other allied health professionals, have valuable tools to guide patients towards taking an active role in managing their DM and using problem-solving tools when analyzing CGM data.

The care manager can assist with identifying prerequisites for insurance coverage, determining copays, and facilitating communication with the provider to obtain a prescription for the CGM device. It is important for the patient to understand their insurance coverage and to receive financial assistance if cost is a barrier.

The care manager can provide resources to assist the patient with technical support, including the CGM manufacturer's contact information. Each manufacturer has instructional videos, resources on their websites, and 24/7 customer support assistance.

In addition to proper insertion and use of a professional or personal continuous glucose monitor, it is helpful for the patient to understand their glucose targets and TIR goal.¹¹ Patients should be encouraged to maintain a log of activity, meals, carbohydrate intake, and other factors such as sleep and stress. Analyzing the TIR bar graph can help the patient identify opportunities for lifestyle changes and adjustments to achieve glycemic goals.

How we talk to and about persons with diabetes while educating them about their condition is important. A collaborative approach is recommended, emphasizing open-ended questions, nonjudgmental language, and neutral words.²⁷

Some examples of neutral, open-ended questions include:

- What stands out when you look at the ambulatory glucose profile?
- Describe your activity and meals on the weekends
- What do you think contributes to higher glucose levels on Monday evenings?
- What are some goals you would like to work on?

The care manager can support patients with DM by observing glucose patterns and trends, by facilitating behavioral goals, and by assessing the effectiveness of lifestyle changes. Small changes such as reducing the portion of a starch with dinner or adding a brief walk in the afternoon can have favorable impacts on blood glucose levels.

Conclusion

The use of CGM technology can improve quality of life for persons with DM and reduce the healthcare burden associated with DM and its complication.²⁸ CGM is now recognized by the American Diabetes Association as a valid evidence-based method of assessing glycemic control. CGM is associated with a reduced incidence of hypoglycemia, reduced HbA1c, and reduced glycemic variability. The HbA1c test does not capture glycemic variability or episodes of hypoglycemia or hyperglycemia. The ambulatory glucose profile and TIR report provides a more personalized DM treatment plan.

The care manager plays an integral role in facilitating problem-solving skills to elicit behavior change. Care managers help patients adapt to new technology, gain a better understanding of their disease, and navigate the complex healthcare system. The care manager and patient should collaboratively analyze the TIR report to note any patterns and trends in blood glucose levels. This individualized approach will enhance the patient's confidence in managing DM and reducing overall DM distress. Ultimately, enhanced self-efficacy and self-management of DM improves clinical outcomes, reduces the prevalence of DM-related complications, and reduces overall medical costs. ■

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Questions

- Diabetes is a result of:**
 - Defects in insulin secretion
 - Impaired insulin action
 - Genetic pathways and environmental factors resulting in the loss of β -cell function
 - All of the above
- In persons with diabetes, uncontrolled hyperglycemia can present as:**
 - Polyuria
 - Polydipsia
 - Polyphagia
 - All of the above
- What is the average annual medical expense for people with diabetes?**
 - \$12,500
 - \$14,250
 - \$16,750
 - \$18,250
- Which of the following can be used to assess glycemic control?**
 - Hemoglobin A1c level
 - Self-monitoring of blood glucose
 - Continuous glucose monitoring
 - All of the above
- CGM measures interstitial fluid, which correlates with plasma glucose.**
 - True
 - False
- There are two types of CGM devices.**
 - True
 - False
- CGM reports provide or assess the following information:**
 - Time spent in glucose range
 - Percentage of time spent below or above glucose range
 - Hypoglycemia, hyperglycemia, and glycemic variability
 - All of the above
- What percentage of total diabetes costs are directed toward diabetes supplies?**
 - 0.8%
 - 1.0%
 - 1.1%
 - 2.0%
- Which of the following significantly improves clinical outcomes and quality of life for people with diabetes who use CGM and their caregivers?**
 - Increased patient engagement
 - Reduced hemoglobin A1c and reduced glucose vulnerability
 - Reduced incidence of hypoglycemia
 - All of the above
- The case manager's role in diabetic self-management includes:**
 - Identifying barriers to care
 - Providing an individualized treatment plan
 - Facilitating SMART (specific, measurable, attainable, relevant, and timely) goals
 - All of the above
- The case manager can facilitate insurance coverage for CGM by:**
 - Identifying prerequisites for coverage
 - Identifying copays
 - Obtaining the necessary prescription for CGM
 - All of the above
- In educating the patient with diabetes, the case manager should:**
 - Use open-ended questions
 - Use nonjudgmental language
 - Use neutral words
 - All of the above
- The case manager can support patients with diabetes by:**
 - Observing glucose patterns and trends
 - Facilitating behavioral goals
 - Assessing the effectiveness of lifestyle changes
 - All of the above

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Objectives

1. State the pathophysiology of diabetes mellitus.
2. Define the role that continuous glucose monitoring (CGM) plays in managing blood glucose levels in patients with diabetes.
3. State the two types of CGM devices.
4. Define the role of the case manager for patients with diabetes who use CGM.

Answers

Please indicate your answer by filling in in the letter:

1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8. _____ 9. _____ 10. _____ 11. _____ 12. _____

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