

## PHARMACIST CE:

# Review of Continuous Glucose Monitors: Technology and Beyond

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**T**echnology is a blessing for managing chronic diseases, such as diabetes, that require significant patient involvement for monitoring and tracking to optimize health outcomes. Blood glucose monitoring devices help ensure patients are receiving the optimal therapy and meeting the blood glucose goals required to minimize the risk of complications secondary to uncontrolled diabetes. The technological advances in monitoring blood glucose at home have been tremendous. In 1925, Benedict's solution was introduced as the first reagent for detecting glucose in the urine at home.<sup>1</sup> The solution showed the patient's glucose level, based on the color change observed. The Ames Company introduced the first blood glucose meter, called the reflectance meter, in the 1970s.<sup>2</sup> It was exclusively used by medical professionals in conjunction with the first blood glucose test strip, the Dextrostix. It was not until 1981 that self-monitoring blood glucose (SMBG) meters were available for at-home use.

Fast-forward to today, and we have revolutionized the technology to monitor blood glucose, allowing for better diabetes management and patient outcomes. There are many devices that allow patients to be

## Abstract

Blood glucose monitoring technology is constantly evolving. The advances have led to the development and enhancement of continuous glucose monitors (CGMs). Currently, two different categories of FDA-approved CGMs are available in the market: real-time CGMs (rtCGMs) and intermittently scanning CGMs (isCGMs). Available literature indicates their efficacy in controlling blood glucose, reducing hypoglycemia, and improving quality of life. The use of these devices is further supported by major guideline recommendations. Pharmacists are vital in providing comprehensive care to patients with diabetes, including assistance with CGMs. As more and more patients embrace CGMs for glucose monitoring, it is imperative for pharmacists to continuously update their knowledge regarding CGMs.

## CE FOR PHARMACISTS

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## Learning Objectives

- List functions of the basic components of continuous glucose monitors.
- Describe different types of continuous glucose monitors available in the US market.
- Compare and contrast the features and capabilities of the available continuous glucose monitors.
- Summarize the evidence for use of continuous glucose monitors in the management of diabetes.
- Identify the role pharmacists play in selection of continuous glucose monitors and provision of education to patients and providers.

self-empowered in managing their diabetes. According to the Diabetes Forecast, there are about 87 different blood glucose monitoring devices available in the US market.<sup>3,4</sup> Choosing the right device depends on many patient-specific factors: patient preference, cost, accessibility, and ease of use. The frequency of testing blood glucose varies depending on the person, as well as their health status. For example, patients with multiple daily insulin injections (MDI) and those with higher hypoglycemia risk have higher blood glucose testing requirements.<sup>5</sup> Continuous glucose monitors (CGMs) can help make monitoring easier for those requiring rigorous blood glucose monitoring. These devices have allowed individuals with diabetes to better control their glucose swings and overall quality of life by limiting the need for fingerstick blood glucose monitoring.

The purpose of this article is to provide a detailed overview of the available CGMs for patient use, their differences and similarities, their place in therapy and evidence for use, and the role pharmacists play when using this technology for patient care.

## Available Devices

Two different categories of CGMs are available in the market for patient use: real-time CGMs (rtCGMs) and intermittently scanned CGMs (isCGMs). The latter are also commonly known as flash glucose monitors (FGMs). Understanding the differences in features and capabilities for each device is important when deciding which CGM is best for the patient. Important key features of these devices are summarized in Table 1.

### CGM Technology

Both rtCGMs and isCGMs use an enzyme-coated wire, which measures interstitial glucose through the generation of an electrical current when glucose reacts with the enzyme glucose oxidase.<sup>6</sup> The generated current is proportional to the interstitial glucose level measurement, which is then converted to an estimated glucose level by an algorithm. Sensors for these CGMs measure interstitial glucose every 5 minutes. Basic components of a CGM include a sensor, a transmitter, and a display device, also referred to as a receiver or a reader.<sup>6,7</sup> The sensor is a small wire probe inserted into the skin where it

monitors glucose in the interstitial fluid. The transmitter is the wireless component that works with the sensor to communicate glucose data to the display device. The display device is a small device that receives and displays data received from the sensor/transmitter combination. Some manufacturers use their own technology to receive the data from the monitor, while others use third-party app technology that lets the user see the data on their mobile device or on a smart watch.<sup>8-12</sup> The sensor/transmitter combination must be removed before the patient undergoes imaging procedures such as MRIs, CT scans, and X-rays, or an electrical heating treatment such as diathermy. Many of the sensors also have limits for water exposure, such as depth and duration; therefore, the user guide of each device should be consulted for these specific requirements. Both rtCGMs and isCGMs require an external source or app to review glucose data; therefore, there is a need for extensive patient education to understand how to use these devices. The biggest difference between rtCGMs and isCGMs is the way patients receive their glucose values. The rtCGMs allow for passive glucose monitoring, where the data shows up on the display device in real time, including any alerts for concerning glucose values. For isCGMs, the data is not automatically transferred; patients have to manually scan the sensor using the reader device in order to receive glucose values. The newest isCGM does include the option to turn on alerts for concerning values.<sup>12</sup>

### CGMs and Fingerstick Testing

Traditional CGMs need to be calibrated to relate glucose to the electrical current upon which the glucose measurements are based. The calibration for most CGMs involves corroborating the glucose value with a fingerstick test; however, the frequency and duration of calibration varies per each device. The CGMs monitor interstitial fluid glucose, which is about 5 to 10 minutes behind the actual blood glucose.<sup>13</sup> Therefore, in certain instances, it is necessary to check blood glucose via fingerstick. Some newer CGMs do not require this calibration step; however, fingerstick testing for a CGM user is needed when blood glucose is rapidly changing, such as during hypoglycemia, and when the symptoms of hyper- or hypoglycemia do not

match the readings of the CGM.

### Real-Time Continuous Glucose Monitors

There are a total of three rtCGM devices currently available in the US market: the Dexcom G6, the Guardian Connect System, and the Eversense sensor. Similar to isCGMs, most of the rtCGMs also include a combination of sensor/transmitter and a display device, but some systems do not have a separate display device; data is directly sent to a smartwatch or a smartphone. The sensor/transmitter automatically transmits glucose data to the display device and does not require the user to actively scan the sensor.<sup>6,7</sup> Patients see continuous and real-time glucose measures, including any alarms or alerts for concerning glucose values. In order for data transmission to occur, the transmitter and display device must be no more than 20-25 feet apart.<sup>4</sup>

Dexcom G6 was FDA approved in 2018 for ages 2 years and older.<sup>8</sup> Readings are updated every 5 minutes, providing glucose levels, trends, and alerts. The system can predict future highs and lows in glucose, so users can alter their behavior to help prevent hyper- or hypoglycemia. Patients who are using Dexcom G6 are able to share their results through a secondary application with up to 10 followers, who often include healthcare providers, family members, or friends. The sensor is approved to be placed on the abdomen for adult users and on the buttock or abdomen for users who are between 2 and 17 years of age. The sensor, however, does not require fingerstick calibration throughout its wear time of 10 days. Standard doses of acetaminophen do not interfere with the sensor, but doses higher than 1 gram every 6 hours may affect the system, and glucose values may be reported higher than the actual glucose values.

The Guardian Connect System is indicated for continuous or periodic monitoring of glucose levels in patients who are between 14 and 75 years of age.<sup>9</sup> The Guardian Connect System includes the Guardian Connect app, Guardian Sensor 3, and the Guardian Connect transmitter. The Sensor 3's wear time is 7 days and requires calibration during the initial sensor placement phase, as well as once every 12 hours. The Guardian Sensor 3 glucose values are not intended to be used directly

**TABLE 1. Characteristics of the CGMs Currently Approved for Use in the US Market<sup>8-12</sup>**

	rtCGMs			isCGMs	
	Dexcom G6	Eversense	Guardian Connect System	FreeStyle Libre 14 day	FreeStyle Libre 2
<b>Wear Length</b>	10 days	90 days	7 days	14 days	14 days
<b>Sensor Location</b>	Abdomen or upper posterior arm or upper buttocks <sup>d</sup>	Upper posterior arm <sup>e</sup>	Abdomen or upper posterior arm	Upper posterior arm	Upper posterior arm
<b>Fingerstick Calibration</b>	None	2 per day	2 per day	None	None
<b>Age Approved</b>	2 and older	18 and older	14 to 75	18 and older	4 and older
<b>Warm-up</b>	2 hours	24 hours	2 hours	1 hour	1 hour
<b>High/Low Alarm<sup>a</sup></b>	Yes	Yes	Yes	No	Yes
<b>Non-Adjunctive Labeling<sup>b</sup></b>	Yes	Yes	No	Yes	Yes
<b>Display Device<sup>c</sup></b>	Reader or Smart Device	Smart Device Only	Smart Device Only	Reader or Smart Device	Reader
<b>Drug Interactions</b>	Acetaminophen & Hydroxyurea	Tetracycline	Acetaminophen & Hydroxyurea	Vitamin C & Salicylates	Vitamin C

*a The real-time continuous glucose monitors can also predict future highs and lows.  
b Allows the CGM to be used for insulin dosing and does not require a fingerstick reading.  
c Smart device consists of compatible mobile devices and smart watches.  
d Age-based sensor location: 2-17 years old → upper posterior arm, abdomen, or upper buttocks; 18 years and older → on upper posterior arm or abdomen only  
e Sensor is implanted subcutaneously and is surrounded by a silicone collar containing 1.75 mg dexamethasone acetate used to reduce inflammation around the sensor.  
isCGMs, intermittently scanning continuous glucose monitors; rtCGMs, real-time continuous glucose monitors*

for making therapy adjustments. While the system does not include a separate display device, the transmitter directly transmits glucose data to an app on compatible mobile devices. It can predict future highs and lows in glucose and users can receive alerts 10 to 60 minutes before such glucose changes occur. The app stores sensor glucose data and provides a user interface for sensor calibration, entering exercise and meal data, and uploading information to the CareLink, a data management software. These advanced features of the app require users to have sufficient experience with adjusting the mobile devices' auto and notification programming.

The third rtCGM system on the market is the Eversense sensor.<sup>10</sup> This system offers a very unique sensor. The pill-sized sensor is implanted into the skin by a healthcare provider. The sensor is considered ready for monitoring glucose 24 hours after insertion; it can be worn up to 90 days. It requires fingerstick blood glucose calibration with this initial sensor placement period, as well as once every 12 hours. A new transmitter is applied daily, using a gentle adhesive

right over the area of skin where the sensor is inserted. The system uses a smartphone as the display device; data is transferred directly to the Eversense Data Management System app on the phone. It allows data to be shared with 5 different individuals. The sensor and transmitter combination vibrates on the arm when glucose values are above preset high or low thresholds, even when the smartphone is not nearby. The system can predict future highs and lows in glucose. It is the only CGM system that is approved for use during an MRI.

**Intermittently Scanning Continuous Glucose Monitors**

There are two FDA-approved isCGMs available in the US market for patients with Type 1 and Type 2 diabetes mellitus: the FreeStyle Libre 14 day and the FreeStyle Libre 2. These isCGMs include a sensor/transmitter and a stand-alone touch-screen display device (or “reader”). The sensor continuously communicates with the reader, but in order to obtain a reading, it requires the patient to scan the sensor with the reader device from a minimum

1.5 inch distance.<sup>8-12</sup> A compatible mobile device with FreeStyle LibreLink app can also receive real-time sensor data which can be uploaded to LibreView account and shared with healthcare providers. At minimum, the sensor should be scanned once every 8 hours, otherwise the sensor data is lost.<sup>5,11,12</sup> Scanning it more frequently during fasting, post-prandial, and periods of physical activity can provide more information about changing glucose and allow for proactive therapeutic interventions.<sup>8-12</sup> The sensor is worn on the back of the upper arm. The maximum sensor wear time is 14 days, which means patients have to replace the sensor after 14 days. Once the sensor is placed, it is ready in an hour to start capturing data. Fingerstick SMBG is not required for calibration or for making treatment adjustment decisions; however, the reader device has a built-in SMBG glucose monitor for times when patients are required to confirm the readings with the fingerstick method. For example, a magnifying glass with a blood drop symbol may appear on the display device, which means that the patient must check

fingerstick blood glucose in order to make treatment adjustments.

The FreeStyle Libre 14 day system is approved for use in acute and long-term therapy for diabetic patients ages 18 and up.<sup>11</sup> This device does not have alarms to indicate episodes of hyper- and hypoglycemia. There are certain substances that interfere with and alter the FreeStyle Libre sensor readings, including doses of ascorbic acid (Vitamin C) > 500 mg, which may result in falsely elevated sensor readings; and salicylic acid (aspirin) doses > 650 mg, which may result in falsely lower sensor readings. However, according to the manufacturer's data on file, aspirin 81 mg and aspirin 325 mg did not show any interference. If patients are taking such interfering substances, fingerstick SMBG may be required to confirm the glucose readings.

The FreeStyle Libre 2 is the newer of the two FreeStyle Libre systems approved for both acute and long-term use for detection of hyper- and hypoglycemia in diabetic patients ages 4 and up.<sup>12</sup> Compared to its predecessor, it has had several updates and improvements. It is an isCGM with optional capability for providing real-time alerts to patients, as long as the reader is within 20 feet of the sensor. However, unlike most rtCGMs, the alarms will not automatically tell a patient their glucose value. The sensor must be scanned with a reader to display glucose readings. Like the 14-day system, ascorbic acid in doses > 500 mg may produce falsely elevated sensor readings with the Libre 2, but salicylic acid does not interfere.

In addition to these stand-alone CGMs, there are other CGMs available that directly connect to an insulin pump (CSII).<sup>4</sup> When worn in conjunction with an insulin pump, the pump can be programmed to suspend insulin delivery upon receiving an alert for hypoglycemia from the rtCGMs. One example is the Dexcom G6 transmitter, paired with one of two different t:slim pumps by Tandem. The Guardian Sensor 3 of the Guardian Connect System is also compatible with the MiniMed 670G and the MiniMed 630G insulin pumps, but it uses a different transmitter than the one used in the Guardian Connect System.

## Evidence for Use

The available studies for CGMs have

evaluated their effectiveness, looking at outcomes such as difference in HbA1c, time in range, glycemic variability, and hypoglycemia. Most studies have compared CGMs to traditional fingerstick testing, but some have compared rtCGMs to isCGMs. One randomized controlled trial looked at CGMs' effect on HbA1c as well as diabetes-related emergency visits. Mulianacci and colleagues found that early use of CGM devices in patients with Type 1 diabetes, regardless of the type of insulin delivery, resulted in statistically significant lower HbA1c as well as fewer diabetes-related emergency department visits due to hyper- or hypoglycemia.<sup>14</sup> The sections below further break down the evidence for CGMs based on their types.

### *Real-time Continuous Glucose Monitors*

Four randomized controlled trials (RCTs) of adult patients with Type 1 diabetes on CSII or MDI, comparing rtCGM to conventional fingerstick test monitoring, produced a between-group HbA1c difference.<sup>15-18</sup> This difference, noted across all four trials, was statistically significant and ranged from 0.43% to 0.6%, favoring rtCGM use. Two of the studies also show that higher adherence to sensor wear time was associated with greater improvement in HbA1c.<sup>18,19</sup> Studies including similar patient populations showed significant reduction in hypoglycemia with rtCGM use.<sup>20-22</sup> The use of rtCGM has been particularly valuable in patients with frequent hypoglycemia or hypoglycemia unawareness. A small study comparing rtCGM and isCGM for hypoglycemia found that adult patients using rtCGM spent less time in hypoglycemia compared with patients using isCGM.<sup>23</sup> In the pediatric population with Type 1 diabetes, the data from an RTC show no improvement in HbA1c due to poor sensor wear time adherence,<sup>19</sup> but an observational study in this population demonstrated improved adherence and increased parental satisfaction with CGM use in general.<sup>24</sup>

Two RCTs including patients with Type 2 diabetes taking oral agents, with or without basal insulin, and one RCT including patients with Type 2 diabetes on MDI therapy compared rtCGM use to conventional fingerstick glucose monitoring.<sup>25-27</sup> The between-group HbA1c

difference was statistically significant and ranged from 0.8% to 1.1% across these three studies, favoring rtCGM use. The DIAMOND2 trial included patients with Type 2 diabetes on MDI therapy only using rtCGM.<sup>27</sup> When compared to the conventional SMBG monitoring, there was reduction in HbA1c, but no difference in hypoglycemic episodes was found.

Due to increased turnover of red blood cells during pregnancy, HbA1c results are less reliable in pregnancy.<sup>28</sup> Using mean glucose values from CGMs is proven to be more accurate than the estimated HbA1c derived from various methods. In an open-label RCT, a group of pregnant patients with Type 1 diabetes using MDI or CSII were placed on rtCGM monitoring in addition to the standard of care (fingerstick SMBG).<sup>29</sup> When compared to the SMBG group alone, those using rtCGM in addition to fingerstick SMBG spent more time in target glucose range (68% vs. 61%,  $p=0.0034$ ) and less time in hypoglycemia (27% vs. 32%,  $p=0.0279$ ). This group of patients also reported decreases in length of hospital stay, and decrease in neonatal outcomes such as macrosomia and neonatal hypoglycemia.

### *Intermittently Scanning Continuous Glucose Monitors*

Evidence in favor of isCGMs is more prevalent in observational studies, compared to RCTs.<sup>5</sup> These observational studies, including children and adults with both types of diabetes, show that isCGMs' use results in lower HbA1c, lower incidences of hypoglycemia, and improved quality of life when compared with fingerstick SMBG. The evidence for reduction in hypoglycemia for patients with Type 1 diabetes at higher risk of hypoglycemia is mixed.<sup>20,30</sup> An RCT of patients with Type 2 diabetes on MDI therapy, using an isCGM, showed statistically significant reduction in HbA1c in the isCGM group versus the conventional SMBG group (0.82% vs. 0.33%,  $p=0.005$ ).<sup>31</sup> This study did not note increased frequency of hypoglycemic episodes. On the other hand, another RCT in Type 2 diabetes patients on various types of insulin treatments showed no improvement in HbA1c, but time spent in hypoglycemia decreased by 43% with the use of an isCGM ( $p=0.0006$ ).<sup>32</sup> With varying results from RCTs, there are a few

**TABLE 2. Recommendations for CGM Use from Major Practice Guidelines<sup>5,36</sup>**

<b>ADA</b>	<p><b>Grade A<sup>#</sup></b></p> <ul style="list-style-type: none"> <li>• Use of rtCGM in youth and adult patients with MDIs and CSII</li> <li>• Wearing rtCGM devices close to daily for those with MDIs and CSII</li> <li>• Scanning isCGM devices frequently, at least every 8 hours</li> </ul> <p><b>Grade B<sup>^</sup></b></p> <ul style="list-style-type: none"> <li>• Use of isCGM in youth and adult patients with MDIs and CSII to replace SMBG monitoring</li> <li>• Use of CGMs as adjunct to the standard of care, pre- and post-prandial SMBG monitoring, in pregnant patients with diabetes</li> </ul> <p><b>Grade C<sup>&amp;</sup></b></p> <ul style="list-style-type: none"> <li>• Use of either types of CGMs in youth and adults with other forms of insulin therapy</li> </ul>
<b>AACE</b>	<p><b>Grade A<sup>#</sup></b></p> <ul style="list-style-type: none"> <li>• All persons with diabetes treated with intensive insulin therapy (&gt; 3 or more insulin injections per day or CSII use)</li> <li>• CGMs recommended for:             <ul style="list-style-type: none"> <li>» All individuals with problematic hypoglycemia</li> <li>» Children/adolescents with Type 1 diabetes</li> <li>» Pregnant women with Type 1 diabetes and Type 2 diabetes treated with intensive insulin therapy</li> </ul> </li> </ul> <p><b>Grade B<sup>§</sup></b></p> <ul style="list-style-type: none"> <li>• CGMs may be recommended for:             <ul style="list-style-type: none"> <li>» Women with gestational diabetes mellitus on insulin therapy</li> <li>» Persons with Type 2 diabetes who are treated with less intensive insulin therapy</li> </ul> </li> <li>• rtCGM is recommended over isCGM for those with problematic hypoglycemia</li> </ul>
<p><small>#Clear or supportive evidence from well-conducted adequately powered RCTs, compelling nonexperimental evidence  <sup>^</sup>Supportive evidence from well-conducted cohort studies  <sup>&amp;</sup>Supportive evidence from poorly controlled or uncontrolled studies  <sup>*</sup>Evidence from RCTs or meta-analysis of RCTs  <sup>§</sup>Evidence from meta-analysis, nonrandomized controlled trial, prospective cohort study, case-control study, cross-sectional study, epidemiological study, open-label extension study, or post-hoc analysis study            CGM, continuous glucose monitors; ADA, American Diabetes Association; rtCGMs, real-time continuous glucose monitors; MDIs, multiple daily insulin injections; CSII, continuous subcutaneous insulin infusion (insulin pumps); isCGMs, intermittently scanning continuous glucose monitors; SMBG, self-monitoring blood glucose; AACE, American Association of Clinical Endocrinologists; RCTs, randomized controlled trials.</small></p>	

systematic reviews evaluating multiple types of trials available for isCGMs. The results of these systematic reviews also vary; however, some reviews suggest that isCGMs might replace the conventional fingerstick SMBG method for monitoring glucose in certain patients, due to their positive impact on HbA1c and hypoglycemia.<sup>33-35</sup>

**Recommendations from the Guidelines**

The American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE) have weighed in on the available evidence for the use of CGMs and provided recommendations in their guidelines.<sup>5,36</sup> The summary of their main recommendations can be found in Table 2.

Additionally, in March 2020, the FDA expanded the use of certain non-invasive remote monitoring devices, which

included CGMs, to monitor patients' blood glucose while they are hospitalized.<sup>37</sup> This allowed for contact-less monitoring of diabetes patients in the time of COVID-19 pandemic.

**Understanding the CGM Data Output**

Literature has recognized HbA1c as the key surrogate marker when assessing for complications relating to long-term diabetes in those with Type 1 and Type 2 diabetes. Unfortunately, HbA1c is unable to detect acute glycemic shifts and is therefore blinded to the resulting complications from hyper- and hypoglycemia.<sup>38</sup> Hemoglobin A1C interpretation can also be ineffective in the settings of anemia, hemoglobinopathies, iron deficiency, and pregnancy.<sup>39</sup> There has also been a report that the HbA1C

test can fail periodically and report false mean glucose even in the absence of the aforementioned conditions.<sup>40</sup> Monitoring glycemic control using HbA1c has been the approach for many years. While its utility is certainly noted, it will now serve as a complement to the glycemic data included in the CGM reports.

The Advanced Technologies & Treatments for Diabetes (ATTD) Congress assembled an international panel of clinicians and experts on CGMs to define and standardize the core metrics for assessing the CGM data.<sup>39</sup> Ten of these 14 core metrics are used to produce a standardized CGM report called the Ambulatory Glucose Profile (AGP). Figure 1 shows a sample AGP report for an adult patient with ideal glycemic ranges. The AGP report incorporates targets along with a 14-day composite glucose profile. Therefore, having at least a 14-day wear time is associated with more impactful data. The data generated in this report allows for meaningful conversations with the patient about the fluctuations in glucose levels and what may be contributing to the highs and lows, as well as patient-centered goals. For example, visualizing the impact of diet, exercise and medications on glucose values might be beneficial when the health care provider is collaboratively creating SMART (specific, measurable, attainable, realistic, and timely) goals with the patient.

Although it was agreed that CGM-based glycemic targets need to be personalized to meet the needs of each person with diabetes, the ATTD conceded on recommendations for particular glycemic target ranges: Type 1 and Type 2 diabetes (70-180 mg/dL) and during pregnancy (63-140 mg/dL).<sup>39</sup> With this agreement, the "time in range" (TIR) indicator was developed. The time in range is the percentage of time that a person spends within their target glucose range. As mentioned, even if different people have the same HbA1c, the actual fluctuations in blood glucose day-to-day will be quite unique. Some patients with a goal HbA1c may be experiencing many periods of hyper- and hypoglycemia, which can be correlated with negative health outcomes. There is evidence to suggest that lower TIR is associated with increased risk of microvascular outcomes.<sup>41</sup> Therefore, it is recommended that the TIR be > 70% for patients with Type 1 and Type 2

**FIGURE 1. Ideal Glycemic Ranges in a Sample AGP Report for an Adult Patient**

# AGP Report

## GLUCOSE STATISTICS AND TARGETS

Date Range (14 days)  
% Time CGM is Active

Glucose Ranges	Targets [% of Readings (Time/Day)]
Target Range 70-180 mg/dL.....	Greater than 70% (16 h 48 min)
Below 70 mg/dL.....	Less than 4% (58 min)
Below 54 mg/dL.....	Less than 1% (14 min)
Above 180 mg/dL.....	Less than 25% (6 h)
Above 250 mg/dL.....	Less than 5% (1 h 12 min)

Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

### Average Glucose

### Glucose Management Indicator (GMI)

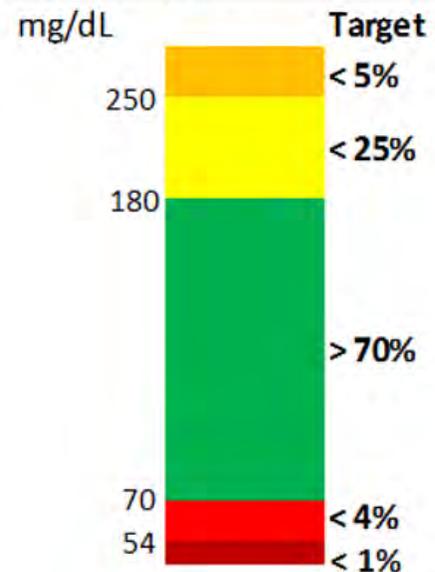
### Glucose Variability

Defined as percent coefficient of variation (%CV); target  $\leq 36\%$

*Adapted from Battelino et al.*

Name \_\_\_\_\_  
MRN \_\_\_\_\_

## TIME IN RANGES



diabetes and during pregnancy.<sup>39</sup> A slightly relaxed TIR, > 50%, is recommended for older patients or patients with high risk for hypoglycemia. The TIRs of > 70% and > 50% are equivalent to HbA1c of < 7% and < 8%, respectively.<sup>42</sup> In addition to TIR, the wear-time of CGM is an important factor to consider. Wearing CGMs over 70% of the time within 14 days is strongly correlated with 3 months of mean glucose, time in ranges, and hyperglycemia metrics.<sup>43,44</sup>

## Future Developments

The COVID-19 pandemic has certainly had an impact on diabetes management, by heightening the risk of serious complications in persons with diabetes who contract the virus.<sup>45</sup> New CGM technology is also feeling the effects of the virus, as the pandemic has slowed down research and development, as well as caused delays in FDA review and approval.

Currently approved in Europe for patients ages 4 and up, the FreeStyle Libre 3 is one of the next CGMs in the pipeline for diabetes management in the US.<sup>46</sup> This sensor is still a 14-day sensor with optional alarms; however, the sensor scanning every 8 hours is no longer required. It has an “always-on” feature that sends minute by

minute readings directly to its application. The sensor size has been reduced by 70%, allowing for much more discreet wearability for patients. Medtronic is currently in the development stages of the Project Zeus Sensor.<sup>47</sup> The focus of the Project Zeus Sensor is to reduce burden for patients. This sensor has been designed to be a 7-day externally worn sensor that requires less fingerstick calibration. With an expected launch in the second half of 2021, Dexcom G7 will have several new features.<sup>48</sup> As opposed to a 3-month transmitter battery life, this product will have a disposable sensor and transmitter combination. This sensor was announced as a 10-day sensor; however, Dexcom is working on extending its life to 14-15 days. This model is about 60% smaller than Dexcom G6. Approved in Europe for patients 18 years old and up, Eversense XL is the world's first CGM system with a fully implantable sensor that lasts for up to 180 days.<sup>49</sup> The system does not replace fingerstick blood glucose monitoring, but it is used as an adjunctive. Similar to the currently available Eversense sensor, it can also be worn during MRI procedures.

## Role of the Pharmacist

Pharmacists play a pivotal role in

numerous areas of patient care, and providing guidance on selecting and using appropriate technology for glucose monitoring is no exception. Pharmacists often provide glucometers or CGM components; hear about various patient challenges, including insurance coverage and apprehension about testing blood glucose; and engage in conversations about patients' overall diabetes management.

CGM technology is ever evolving, and many of these CGM supplies, such as the sensors, are now becoming more accessible by being billed through the prescription health plans. Now that these components are finding their way into retail pharmacy and ambulatory settings, it is vital that pharmacists are staying up to date with this ever-changing field of medicine. Pharmacists can assist with device selection, new device counseling, and data interpretation to empower their patients to further understand the benefits of a CGM system.<sup>50</sup> Depending on the pharmacists' state-specific scope of practice, they might also be able to make treatment recommendations or changes.<sup>51</sup>

In order to educate patients regarding CGMs, pharmacists should be aware of:<sup>51</sup>

- How to attach the sensor and transmitter when applicable



- How and where to insert the sensor
- How to secure the sensor-transmitter to the application site
- How to set up the transmitter-receiver connection
- Interfering medication or substances
- How to distinguish between sensor glucose and blood glucose
- How to calibrate devices when applicable
- When to remove the device for select diagnostic tests
- How to interpret CGM data and trends
- What the up and down arrows mean and how to intervene
- How to adjust alarms

Medicare is continuing to update their recommendations to expand coverage of CGM with requirements such as diagnosis of Type 1 or Type 2 diabetes, treatment with multiple insulin doses or infusion, and the need to frequently adjust insulin doses. As the role of the pharmacist in diabetes care continues to be recognized and expanded, there might be opportunities for exclusive billing for the following CPT codes: 95249 (personal CGM training/download), 95250

(professional CGM insertion/download), and CPT 95251 (CGM interpretation).<sup>51</sup> Although the Medicare guidelines restrict CPT 95251 to advanced practice nurses, physician assistants, and physicians, pharmacists might have a cooperative with local clinics or set up collaborative practice agreements.<sup>52</sup>

Pharmacists might need to explore alternatives to optimize care, including when a monitor is not covered by the patient's insurance, contacting the provider for further documentation, and following up with the patient each step of the way. While not within the scope of this article, it is important to mention that patients who do not qualify for their own device many might qualify for a professional device, which is owned by a practice and loaned to the patient.<sup>53-55</sup>

## Conclusion

The market for continuous glucose monitoring technology is continuously evolving. Available data in patients with diabetes show that CGMs can assist with reduction in HbA1c and hypoglycemia, as well as improve overall satisfaction and quality of life. Having a proper

understanding of the various types of devices, and the evidence behind these devices, is essential when educating patients about these devices. Pharmacists play a key role in identifying patients who might benefit from the use of CGMs, discussing the various CGM options, assisting with troubleshooting, and helping patients understand the CGM data report. As pharmacists continue to play a pivotal role in diabetes management as part of the interprofessional healthcare team, a pharmacist's ability to create billable patient-care services is on the horizon, and in some practices, already a reality.

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## Assessment Questions

- A wire probe inserted into the skin which detects interstitial glucose values is called:
  - Reader
  - Sensor
  - Transmitter
  - Receiver
- True or False:** Continuous glucose monitors completely replace the need for fingerstick glucose monitoring.
  - True
  - False
- The continuous glucose monitor that transmits glucose values in real-time along with alarms and alerts without user input is called:
  - Intermittently scanned continuous glucose monitor
  - Real-time continuous glucose monitor
  - Fingerstick blood glucose monitor
  - Closed loop insulin pump
- Which of the following continuous glucose monitors requires the user to scan the sensor using the display device?
  - FreeStyle Libre 2
  - Dexcom G6
  - Guardian Connect System
  - Eversense sensor
- Which of the following substances interferes with the FreeStyle Libre 14 day system?
  - Greater than 1 gram of acetaminophen taken every 6 hours
  - 500 mg or higher ascorbic acid (vitamin C)
  - Greater than 81 mg of aspirin
  - Tetracycline antibiotics
- Which of the following continuous glucose monitors require users to calibrate the sensor glucose values using fingerstick blood glucose?
  - FreeStyle Libre 2
  - FreeStyle Libre 14 day
  - Dexcom G6
  - Guardian Connect System
- Assessing a patient's Ambulatory Glucose Profile included in a continuous glucose monitor report, which of the following is a correct treatment goal for a 45 year-old patient with Type 2 diabetes?
  - More than 50% of glucose values between 70-180 mg/dL
  - More than 70% of glucose values between 70-180 mg/dL
  - More than 50% of glucose values between 80-130 mg/dL
  - More than 70% of glucose values between 80-130 mg/dL
- Which of the following statements regarding evidence for use of rtCGMs is correct?
  - Evidence for reduction of time in hypoglycemic range is consistent throughout all different types of diabetes.
  - Evidence for reduction in HbA1c is consistent throughout all different types of diabetes.
  - It has shown to reduce HbA1c only in the patients with Type 1 diabetes.
  - Use of rtCGM can replace the need for pre- and post-prandial SMBG testing in pregnant patients with diabetes.
- Which of the following most accurately describes the role a community-based pharmacist can play when assisting a patient using a continuous glucose monitor?
  - Educating patient how to make sense of various alerts
  - Troubleshooting when the sensor is not sticking to the application area
  - Educating patients about drugs that can interfere with sensor glucose values
  - All of the above
- Did the activity meet the stated learning objectives? (if you answer no, please email sarahs@pswi.org to explain)
  - Yes
  - No
- On a scale of 1 – 10 (1-no impact; 10-strong impact), please rate how this program will impact the medication therapy management outcomes or safety of your patients.
- On a scale of 1 – 10 (1-did not enhance; 10-greatly enhanced), please rate how this program enhanced your competence in the clinical areas covered.
- On a scale of 1 – 10 (1-did not help; 10-great help), please rate how this program helped to build your management and leadership skills.
- How useful was the educational material?
  - Very useful
  - Somewhat useful
  - Not useful
- How effective were the learning methods used for this activity?

- a. Very effective
  - b. Somewhat effective
  - c. Not effective
16. Learning assessment questions were appropriate.
- a. Yes
  - b. No
17. Were the authors free from bias?
- a. Yes
  - b. No
18. If you answered “no” to question 17, please comment (email [info@pswi.org](mailto:info@pswi.org)).
19. Please indicate the amount of time it took you to read the article and complete the assessment questions.

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- |                  |               |
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| 1) a   b   c   d | 11) _____     |
| 2) a   b         | 12) _____     |
| 3) a   b   c   d | 13) _____     |
| 4) a   b   c   d | 14) a   b   c |
| 5) a   b   c   d | 15) a   b   c |
| 6) a   b   c   d | 16) a   b     |
| 7) a   b   c   d | 17) a   b     |
| 8) a   b   c   d | 18) _____     |
| 9) a   b   c   d | 19) _____     |
| 10) a   b        |               |

July/August 2021

Review of Continuous Glucose Monitors:  
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