ADCES PRACTICE PAPER

The Diabetes Care and Education Specialist's Role in Continuous Glucose Monitoring

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Continuous glucose monitoring (CGM) includes a sensor that is inserted subcutaneously under the skin, a transmitter, and a receiver.[1] Most devices permit real-time glucose display to allow the individual to respond to changes in glucose values; all can generate reports for later download and review. CGM is recognized as an important tool to enhance diabetes management and is recommended by the American Diabetes Association's Standards of Medical Care for adults and children with diabetes.[2] Evidence of benefits continues to grow for both type 1 and type 2 diabetes. [3,4] There are two types of CGM: personal CGM for home use and professional CGM which is specifically designed for use by healthcare professionals and is worn by the person with diabetes on a short-term basis.[4]

The goal of this paper is to outline topics that should be covered by diabetes care and education specialists when teaching people with diabetes (PWD) and their families or support persons in the utilization of CGM and interpretation of the data. It is imperative that the diabetes care and education specialist understands the advantages of CGM as compared to blood glucose monitoring (BGM) and hemoglobin A1C and maintains a high level of expertise in this area to best support the growing number of PWD that use these devices. The identify, configure, collaborate model and DATAA tool can help the diabetes care and education specialist to integrate CGM into their practice and optimize care for PWD.

Benefits

Data from research studies have demonstrated that use of CGM leads to clinically significant reductions in hypoglycemia compared to a BGM alone in individuals with type 1 diabetes.[5-6] In a multicenter, randomized control trial (RCT) of 239 individuals, persons with type 1 diabetes on multiple daily injections who utilized CGM experienced a 38% overall reduction in hypoglycemia and a 40% reduction of nighttime duration of BG < 70 mg/dL.[7] In an additional RCT of 224 individuals with type 2 diabetes, the 149 individuals assigned to the intervention arm of the study experienced a 43% reduction in BG <70mg/dl with a 54% reduction in nocturnal hypoglycemia.[8] Additional randomized controlled trials show significant A1C reductions in adults[9-10], older adults[11], and children[12]. Use of CGM drives A1C reduction regardless of the type of insulin delivery system.[13] Empowerment and quality of life have also demonstrated improvements with CGM use.[14]

Professional CGM

Continuous glucose monitors measure interstitial sensor glucose (SG), providing valuable information that is unattainable using finger stick capillary BGM. Professional Continuous Glucose Monitors can be used by healthcare professionals to guide treatment decisions due to the availability of a large amount of data for pattern identification and management. The professional CGM devices are worn to collect information that will

be downloaded and reviewed by a healthcare professional, providing retrospective data. There are currently three approved professional CGM devices in the U.S. The data cannot be integrated with insulin pumps or smart pens. The sensor glucose (SG) readings are recorded every one to fifteen minutes depending on device. There are some differences between devices which are important for PWD and healthcare professionals to understand (Table 1). The following paragraphs describe the features the diabetes care and education specialist should be aware of when considering professional CGM use.

a. Blinded versus Unblinded

Blinded CGM means that the PWD cannot see the SG readings in real time while wearing the device. This is intentional so that the PWD 1) does not alter their behavior based on the numbers they are seeing and 2) can wear the device for a short period of time to gather retrospective glucose data on downloads to enhance treatment decision making by or with their healthcare provider. Unblinded means the PWD can see their glucose readings in real time. There are advantages to each approach. In the blinded option, individuals are not aware of their glucose readings and may be more likely to go about their normal routine and activities rather than making corrections to hyperglycemia and hypoglycemia when the data is visible. This may provide more realistic data for the healthcare professional to make medication and treatment adjustments. All three professional CGM devices are available in blinded mode.

The Dexcom G6 Pro is the only professional CGM device that can be viewed in real time by the PWD and is also approved to make treatment decisions in real time. An advantage to unblinded, real-time visual CGM readings is that PWD can see and react to a low glucose before it becomes severe and potentially prevent hypoglycemia through use of alerts, if desired. The individual can also treat hyperglycemia sooner with the addition of high alarms and/or visual cues. Using unblinded CGM can also allow the user to see in real time the effects of food, medication, activity and stress without waiting for the report to be downloaded. Wearing and discussing the results of professional CGM is a great way to introduce the individual to personal CGM to consider purchasing one for themselves. The Dexcom G6 Pro requires that a person have a compatible smart device and download the G6 mobile app to use in unblinded mode.

b. Cost

Cost can be a consideration when determining which device to purchase for the clinic. One system has a transmitter that is reused in between PWD (Medtronic IPro2) which is more costly to replace if lost or damaged. If one PWD is using the device or has not returned it on time, then the device is not available for another PWD to use. The transmitter must be cleaned and disinfected between uses, which requires additional steps and consideration when scheduling, adding to staff time and supply costs.

The other two available professional CGM devices have a one-time use sensor and transmitter and re-usable reader. There is a minimal expense if the sensor is lost or not returned. Sites can order a supply of the sensors so that they always have some in stock, but should be wary of expiration dates. When the sensor is returned, the stored information should be downloaded and reviewed with the PWD to note SG trends over the duration of wear and discuss management strategies.

c. Wear Time and Accuracy

The wear time is slightly different among devices and ranges from 6 to 14 days. The accuracy, reflected by the mean absolute relative difference (MARD)[15], is also slightly different between devices (see Table 1). Some practices have the PWD mail back the trannsmitter. Once received, the sensor can be downloaded and the information shared. When using the Dexcom G6 Pro in unblinded mode, the PWD could download the Clarity app and data can be viewed remotely. An appointment should be made to review the data with the PWD, in person, by phone or virtually. See Section G on reimbursement. Of note, the Dexcom G6 Pro must be downloaded within 30 days of starting the session to retrieve data.

d. Sensor Insertion and Training

Diabetes care and education specialists must be trained on the proper insertion technique as well as cleaning and disinfecting the equipment between PWD if applicable. Product manufacturers may have a certification program to document that healthcare professionals have completed the training on the device. Diabetes care and education specialists also have an important role in counseling PWD about certain restrictions during use of the device. Examples include: avoidance of CTs, MRIs , diathermy and x-rays for all CGM devices. Certain medications can interfere with readings in some CGMs. The diabetes care and education specialist should refer to the user guide of the device for potential contraindications. The diabetes care and education specialist is poised to provide the additional teaching needed for systems such as setting alerts for high and low values as agreed upon with the individual. They can also review how to document events such as insulin doses, grams of carbohydrates, exercise and health-related issues such as illness and infection, which may influence glucose values. Documenting events into the mobile app may be too complex for some individuals and can be handwritten instead. This information is very beneficial when interpreting the downloaded data.

e. The Importance of Keeping a Food/Activity Log

Professional CGM is useful for teaching PWD about the effects of food, medications, physical activity and stress on their BG levels. Individuals are encouraged to track their food intake, physical activity and medication-taking behaviors which provides much richer data when interpreting the CGM report. According to the AACE/ACE position statement on glucose monitoring[16], glucose pattern analysis may be used as an educational tool to demonstrate the relationship between an individual's glucose levels, their medication, and other therapeutic interventions. The three professional CGM companies have food and activity logs available, which can be obtained from company representatives, online or a general log could also be created and distributed. There are many mobile apps also available, some of which allow the person to take pictures of their food[17].

f. Individualizing Device Selection

All of the sensors and transmitters are waterproof and can be worn in the shower and bathtub regularly. It is important to note that while the sensors and transmitters can be worn in the pool as well, data may not transmit during this time because of signal interference created by being submerged underwater. Diabetes care and education specialists can help healthcare providers identify which CGM device would be best for each individual. PWD may experience many challenges including visual impairment, dexterity issues or other barriers to monitoring blood glucose. In these cases, a product that is easily inserted does not require calibration and does not demand frequent interaction may be the best choice.

g. Downloading CGM Data

Each device has a different software system into which the data is downloaded in clinic. There are slight differences in reports depending on the system used for download. All have the capability to show the CGM key metrics including time in range, time spent below range, and time spent above range. There is also glucose variability, glucose management indication (GMI) and the number of days worn. A graph superimposing all days of use also called an ambulatory glucose profile (AGP) helps to determine trends and patterns. The complete AGP reports also includes a day-by-day breakdown.[18]

h. Professional CGM Billing/Reimbursement

For the purpose of data analysis and insurance reimbursement, professional CGM devices must be worn for at least 72 hours. Many insurance plans will cover professional CGM, but the process varies among plans with some requiring prior authorization. It is recommended to verify insurance coverage prior to use. The device is inserted on the first visit which involves the use of a simple insertion process. In 3 to 14 days the PWD can either drop off the device for download or return for a follow up visit and review the results with the diabetes care and education specialist or their diabetes healthcare provider. After documentation of a minimum of 72 hours of data, the provider can bill using the code 95250. Per reimbursement guidelines,

interpretation can be done remotely; so results can be mailed, discussed by phone, sent via Electronic Medical Records (EMR) or discussed through a virtual visit. Per Medicare guidelines, the final interpretation must be done by a nurse practitioner, PA or physician, and is billed using a CPT code of 95251. Depending on state laws, pharmacists may also be able to perform the interpretation through a collaborative practice agreement. Diabetes care and education specialists can review the download and make recommendations to the healthcare provider, who can then review and bill for the evaluation.

Personal CGM

a. How it Works

The personal CGM device collects data every 1-5 minutes and records data every 5–15 minutes, depending on the device. The device displays SG and rate and direction of change, and may have the option to alarm the user about low and high SG levels. This real-time data can help inform treatment decisions, give advanced warning of rapid glucose changes and motivate PWD to enhance their diabetes self-management.[19] There are currently four companies that produce personal CGM devices available in the U.S.

b. Considerations/Limitations

CGM minimizes the need for BG monitoring. However, finger stick BG checks are warranted in the following situations:

- A calibration or blood glucose symbol appears on the device.
- Symptoms or expectations do not match CGM readings.
- CGM readings are suspected to be inaccurate or used for an off-label indication like pregnancy.
- Determining an insulin dose for a correction if the device is only FDA approved for adjunctive therapy (See table 2).

However, there is the risk of increased distress in some individuals especially with devices that cause multiple alarms.[20]

Systems are not approved for pregnant women, persons on dialysis, or critically ill populations. Although currently not a standard of care, recent research studies support the utilization of CGM in these populations.[21-25]

c. Diabetes Care & Education Specialist's Role

Diabetes care and education specialists well versed in CGM are poised to help in the selection of appropriate candidates, educate regarding device options, and instruct on sensor utilization. While evaluation of results is billable only by a physician, nurse practitioner or PA, the diabetes care and education specialist may assist with downloading the devices and interpretation of the results. Providing information, skills and support will result in empowered individuals who can embrace this innovative technology. Comprehensive engagement includes management of CGM technology, evaluation of the results, and assessment of the needs and goals of the individual.[26]

Key teach-back points should include:

- Sensor site selection.
- Insertion of the sensor.
- Attachment (and charging) of the transmitter to the sensor, if required.
- Required taping/securing of the sensor/transmitter.

- Connection of the transmitter to the receiver.
- Difference between SG and BG.
- Understanding CGM data and trends.
- Calibration including timing, frequency and importance of accurate meter/finger stick technique if required.

Other topics that should be addressed are:

- Setting and managing alerts including high alert, low alert, high snooze, low snooze, rise rate, fall rate, and predictive alerts.
- Problem solving for site adhesiveness.
- Support with coping and problem solving related to individual behavioral issues that can improve management.
- Possible interference of products that include acetaminophen, hydroxyurea, tetracycline, salicylic acid and high-dose vitamin C.
- Education to prevent overcorrection of high glucose (some people will correct every 5 min or every 30 min when they see the numbers are not going down as quickly as they would like, which could lead to hypoglycemia).
- Sharing data; how and when to involve others in diabetes management.
- Understanding CGM reports including the ambulatory glucose profile and time in range.

d. Downloading Personal CGM and Sharing Data

People with diabetes who utilize a personal CGM can download their reports at home or view on a compatible smart device. The reports can be shared with their healthcare team by linking their individual account to the clinic's account. For those using a smart phone app, Bluetooth connectivity allows nearly constant download of real-time data. The data can also be downloaded during in-person clinic visits. See Table 2 for more information on downloading personal CGM device data.

e. Interoperability

The FDA has an approval pathway that allows interoperability or use with other devices such as insulin pumps, closed loop systems, smart pens and mobile apps to qualify for expedited approval. Integrated CGM devices (iCGM devices) including the Dexcom G6 and Libre 2 have a less cumbersome approval process if they meet certain criteria.

f. Understanding CGM Data and Trends

It is important for individuals to focus not only on glucose in real time, but the **direction** and **speed** of the glucose trending. This includes not only proactively preventing hypoglycemia when blood glucose is still in target ranges, but also when the direction and speed of the SG indicate a downward trend. Upward trending arrows and significant hyperglycemia can also be noted with potential for insulin pump or insertion site malfunction, insufficient insulin or omission of a meal bolus, or the need to change the timing of pre-meal insulin. Diabetes care and education specialists have an important role in discussing these concepts with the PWD so that the individual can improve their time in range and reduce time spent in hypoglycemia and hyperglycemia. Glycemic variability should be assessed when downloading CGM data and should be included in patient discussions and recommendations for improvement.[27] There is an international consensus statement that provides guidelines for CGM metrics. This includes a target range of 70-180mg/dL

for all non-pregnant people with diabetes. The goal for most adults with type 1 or type 2 diabetes is to spend over 70% time in range. The goal is to minimize time spent in hypoglycemia with no more than 4% of the time with glucose <70mg/dL.[28]

There is a CPT code for training PWD on personal CGM devices (CPT code 95249). CPT code 95250 is still the appropriate code for diagnostic or professional CGM. Although diabetes care and education specialists and/or RDs can perform services associated with CPT codes 95249 or 95250, the billing must be done under a physician, nurse practitioner or PA. Medicare and most commercial payers limit RDs billing under their own NPI to diabetes self-management training (DSMT) and/or medical nutrition therapy (MNT) services.

g. Use of CGM in Acute Care

The use of CGM in the hospital setting is not an FDA approved indication, although the FDA has allowed CGM use in hospitals during COVID-19[29]. This allows for remote monitoring of patients to track episodes of hypoglycemia and hyperglycemia and can save personal protective equipment (PPE) and time in sanitizing glucose meters.

The benefit of a CGM device that alerts nurses that a patient's glucose is rapidly rising or falling or that the insulin infusion rate needs to be titrated would be of tremendous value. In the meantime, individuals may come to the hospital wearing their personal CGM device. The device should not be used for management decisions such as meal-time insulin dosing or hypoglycemia treatment in the hospital setting. In addition, only the hospital BG meter should be charted in the electronic health record. CGMs that require calibration could be calibrated to the hospital meter so that the results are similar. Patients should be instructed to ask the nurse to verify the current SG with the hospital meter for meal time and correction insulin dosing and treatment of hypoglycemia.

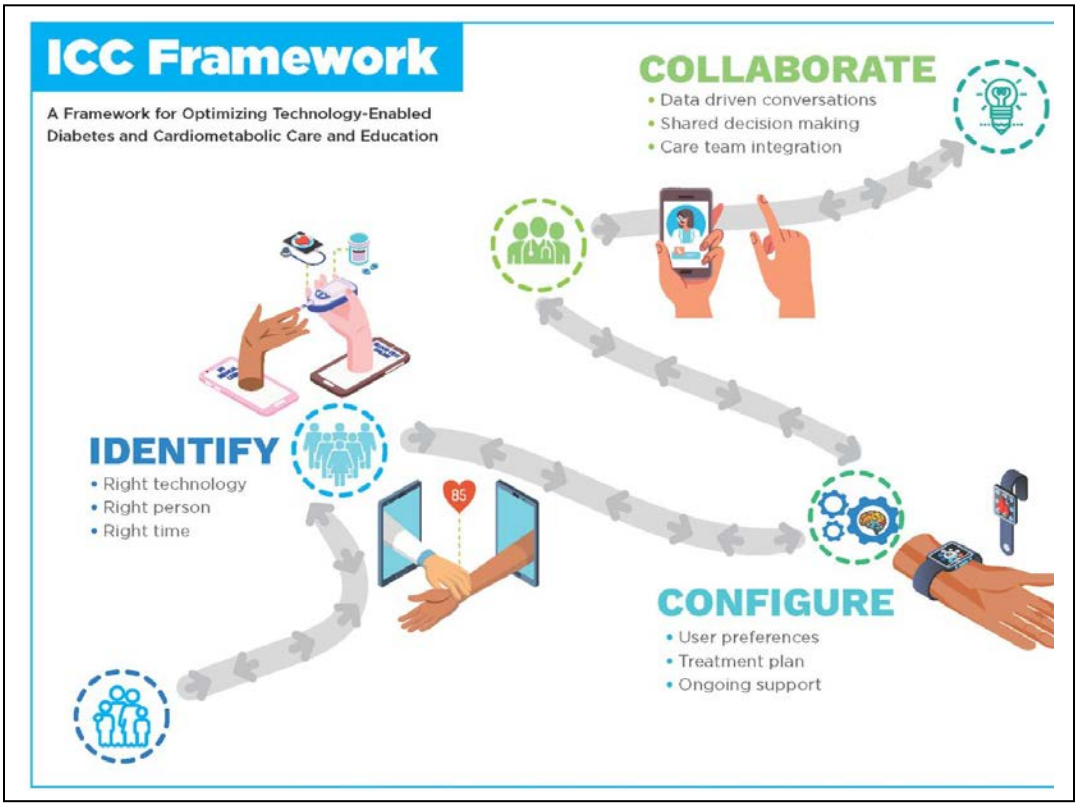
h. Use of CGM in Special Populations

As CGM technology becomes more common in the pediatric population, personnel within the schools, camps and daycares will benefit from education on the technology to obtain a better understanding of their role in keeping children safe. School diabetes medical management plans and 504 plans will need to be adapted to include the role of the CGM in the school environment and the responsibility of the school staff. Day and residential camps will need to determine how to utilize the sensor information, as well as how to care for the receivers and keep them safe. An additional discussion point is the role of cell phones as receiver in a camp environment. These issues are being reviewed and discussed nationwide, and you are referred to http://www.diabetes.org/assets/pdfs/advocacy/safe-at-school/cgm-guidance.pdf and www.diabetes.org/summercamp to follow the recommendations in regards to incorporating sensors into these environments.

i. Sensor-Enhanced Pumps

Sensors are increasingly being linked to insulin pumps. Data from the sensor can be seen on the pump screen, and some pumps will respond to sensor data through automated insulin adjustments to basal and correction doses. It is vital that the diabetes care and education specialist working with insulin pumps and sensors keep up to date on the options available to individuals and the functionality of the systems to increase the person's understanding of the tools to enhance their diabetes self-management skills. See the ADCES Practice Paper on Continuous Subcutaneous Insulin Infusion (CSII) Without and With Sensor integration for more details available at:

https://www.diabeteseducator.org/docs/default-source/practice/practice-documents/practice-papers/continuous-subcutaneous-insulin-infusion-2018.pdf?sfvrsn=10



Using the ICC Framework and DATAA Tools to Optimize Care

The diabetes care and education specialist can use the Identify, Configure, Collaborate (ICC) framework to optimize care for people with diabetes.[30] This includes identifying people with diabetes that would benefit from professional or personal CGM, and then helping them to configure the device. This step can include setting appropriate high and low alerts, troubleshooting site adhesives and skin sensitivities, and coming up with a plan for how to respond to the CGM numbers and arrows. The collaborate step is where diabetes care and education specialists and PWD have data driven conversations about the data and through shared decision making and come up with a plan to help increase time in target range. There is a tool called DATAA which can help the diabetes care and education specialist systematically go through the data. This stands for (download the data, assess safety or hypoglycemia, time in range-focus on days/times where time in range is highest and replicate the positive, areas for improvement, and action plan).

Conclusion

Diabetes care and education specialists who are well versed in professional and personal CGM devices are in a key position to promote and support this option for people with type 1 and type 2 diabetes. They can help identify those who would benefit from these devices, collaborate with their provider to facilitate obtaining an appropriate device, educate them on the utilization, and download the results to evaluate in order to maximize diabetes management outcomes. Diabetes care and education specialists provide the coaching needed to help PWD reap the benefits of the technology by utilizing the information to make *smarter* diabetes management decisions, reduce risk of hypoglycemia and hyperglycemia and thereby improve quality of life.

Table 1: Professional CGM Features Summary

	Abbott Freestyle	Dexcom	Medtronic
Professional version	LibrePro	G6 Pro	IPro2
Equipment needed	Sensor, reader, charger for reader.	Sensor, transmitter, reader, charger for reader, smartphone with G6 app (for unblinded).	Sensor, iPro2 recorder, Ipro2 dock, charger for recorder.
Blinded vs unblinded	Blinded	Both	Blinded
Maximum wear time	14 days	10 days	6 days
Calibration	None	None	3-4 per day
Downloading and data reports	LibreView	Dexcom CLARITY	Carelink-BG from meter, app or manually, must be entered at the time of download to appear on the report.
Reimbursement codes	95250 for removal with a minimum of 3-day wear; 95251 for interpretation by licensed healthcare provider.	95250 for removal with a minimum of 3-day wear; 95251 for interpretation by licensed healthcare provider.	95250 for removal with a minimum of 3-day wear; 95251 for interpretation by licensed healthcare provider.
Care between uses	Disposable sensors, one clinic reader for multiple users.	Disposable sensors, one clinic reader for multiple users.	Transmitter must be cleaned and disinfected.
Insertion	One-step process with auto inserter, the transmitter is incorporated into the sensor.	Two-step process; insertion of the sensor and attachment of the transmitter.	Multiple-step process with insertion of the sensor, taping the sensor, attaching the transmitter and taping over the transmitter.
MARD (accuracy-the lower the better)	12.3%	9%	11.05%
Alarms for high and low alerts	No	Yes, in unblinded mode.	No
Drug interactions	Vitamin C, Salicylic Acid	Hydroxyurea	Acetaminophen, Hydroxyurea

Table 2: Personal CGM Features Summary

	Abbott		Dexcom	Medtronic	Senseonics
Personal version	Freestyle Libre 14 Day	Freestyle Libre 2	G6	Guardian Connect	Eversense implantable
Insulin pump integration	No	No	Tandem T-slim X2 insulin pump as Basal IQ and Control IQ, Smart Pen (InPen)	Guardian 3; compatible with 630G/670G/770 G insulin pumps Guardian Connect: Smart Pen (InPen)	No
Equipment needed	Sensors, reader or compatible smart device.	Sensors, reader	Sensors, transmitter, receiver or compatible smart device.	Sensors, rechargeable transmitter, requires compatible smart device (no receiver).	Implanted sensor (in-office procedure to insert), removable, rechargeable, smart transmitter on the skin with on-body vibe alerts, requires compatible smart device (no receiver).
Maximum wear time	14 days	14 days	10 days	7 days	3 months
Warm-up and calibration	1-hour warm up, no calibration	1-hour warm up, no calibration	2-hour warm up; no calibration	Up to 2-hour warm up, 2 calibrations per day + occasional diagnostic calibrations required	24-hour warm up and 4 calibrations within 6-36 hours at start up; then 2 calibrations per day
FDA approved sites	Back of arm	Back of arm	Abdomen Upper buttocks (ages 2-18 years)	Back of arm, abdomen	Back of arm
FDA approved ages (years)	18 and up	4 and up	2 and up	Guardian 3: 2 and up Guardian Connect: 7 and up	18 and up
Downloading and data reports	LibreView; reader stores up to 90 days of	LibreView-stores up to 90 days of	CLARITY; Can also be	Carelink, mySugr, can also be	Eversense Data Management Software (DMS)

	data, must be scanned every 8 hours to avoid gaps in data; Can also be downloaded into Tidepool	data, must be scanned every 8 hours to avoid gaps in data	downloaded into Glooko, Tidepool	downloaded into Tidepool	program; Can also be downloaded into Glooko
Reimbursement codes	95249 for removal with a minimum 3-day wear; 95251 for interpretation by licensed health care provider	95249 for removal with a minimum 3-day wear; 95251 for interpretation by licensed healthcare provider	95249 for removal with a minimum 3-day wear; 95251 for interpretation by licensed healthcare provider	95249 for removal with a minimum 3-day wear; 95251 for interpretation by license healthcare provider	Insertion code used by approved provider; 95251 for interpretation by licensed healthcare provider
Remove for MRI/CT-Scan/Diathermy	Yes	Yes	Yes	Yes	Remove transmitter, implantable sensor ok to leave in
FDA approved for insulin dosing	Yes	Yes	Yes	No	Yes
Data sharing	Mobile app	Mobile app	Mobile app	Text messaging	Mobile app
Insertion	One-step with auto inserter	One-step with auto inserter	One-step process with auto inserter, then attach transmitter	One-step with auto-inserter; attach and tape transmitter, charge in between use	Provider inserted and removed every 3 months. Smart transmitter charged daily and placed on skin with adhesive
MARD (accuracy-the lower the better)	9.4%	9.4%	9% adults and 7.7% pediatrics	9.64% with 3-4 calibrations per day; 10.55% with 1-2 calibrations per day	8.5%
Alarms for high and low alerts	No except during a scan	Yes, must be within 20 ft of reader	Yes, absolute and predictive alerts, must be within 20 ft of receiver or Smart device	Yes, absolute and predictive alerts, must be within 20 ft of Smart device	Yes, absolute and predictive alerts, on body vibration or must be within 24.9ft of Smart device
Interfering substances	Salicylic acid and Vitamin C	Vitamin C	Hydroxyurea	Acetaminophen, Hydroxyurea	Tetracycline
Interoperable	No	Yes	Yes	No	No

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Other resources:

1. Freestyle Libre Professional CGM. Available at https://provider.myfreestyle.com/freestyle-libre-pro-product.html
2. Medtronic IPro2. Available at https://www.medtronic.com/us-en/healthcare-professionals/products/diabetes/continuous-glucose-monitoring-systems/ipro2-professional.html
3. Dexcom G6 Professional CGM User Guide. Available at https://dexcompdf.s3-us-west-2.amazonaws.com/Dexcom-G6-Pro-User-Guide.pdf
4. Senseonics Eversense. Available at http://www.eversensediabetes.com
5. Guardian Connect. Available at https://www.medtronicdiabetes.com/products/guardian-connect-continuous-glucose-monitoring-system
6. Dexcom G6. Available at https://www.dexcom.com/g6-cgm-system
7. Libre 2. Available at https://www.freestyle.abbott/us-en/products/freestyle-libre-2.html
8. Libre 14-day system. Available at: https://www.freestyle.abbott/us-en/products/freestyle-14-day.html

Personal CGM Playbook

Available at: https://www.diabeteseducator.org/docs/default-source/practice/educator-tools/cgm-playbooks/personal-cgm-playbook.pdf?sfvrsn=2

Professional CGM Playbook

Available at: https://www.diabeteseducator.org/docs/default-source/opencms_test/prof-cgm-playbook.pdf?sfvrsn=2

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