COMMENTARY

5 Things to Know About Continuous Glucose Monitors

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DISCLOSURES | April 05, 2024

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Dexcom Stelo Glucose Biosensor System is the first continuous glucose monitor (CGM) approved by the US Food and Drug Administration (FDA) for use without requiring a prescription. With this approval, here are five things to know about CGMs.

1. CGMs were previously FDA-approved only for people with either type 1 or 2 diabetes.



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Currently, four major CGMs are available and approved by the FDA in the United States: Medtronic, Dexcom, FreeStyle Libre, and Eversense. All of these devices evolve in accuracy, wearability, and function, such that new versions are released every few years.

Most importantly, they are all FDA-approved for use in people with type 1 diabetes or type 2 diabetes, and specific CGMs (ie, Dexcom G7, Libre 2, and Libre 3) have been approved for

gestational diabetes.

CGMs are intended to provide users an estimate of blood glucose that is accurate enough to make treatment decisions based on the numbers (eg, administer insulin). This most recent approval allows anyone to purchase a CGM.

2. Several factors affect accuracy.

CGMs provide only an estimate of blood glucose. They do not measure it directly the way glucometers or lab tests do. CGMs measure the subcutaneous interstitial glucose concentration — the glucose level in the microscopic fluid spaces just beneath the surface of the skin. For this reason, CGM glucose readings can be erroneous.

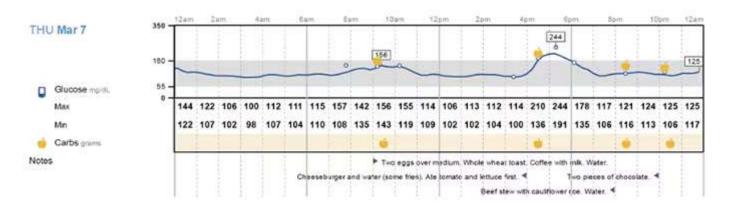
A term to become familiar with is "mean absolute relative difference" (MARD). MARD is a measurement of accuracy, and it is the average difference between the glucose measured by CGM vs the glucose measured by a lab in venous blood. The lower the MARD, the better the CGM. The current industry best is the Dexcom G7, with a MARD around 8%.

However, accuracy can decrease on the basis of sensor location (the upper arm is generally better than the abdomen), how long the sensor has been worn (ignore any data from the first day), how stable the blood glucose is (rapidly increasing or decreasing levels affect accuracy), and the glucose level itself (less accurate at extreme highs or lows). MARD can be as high as 20% in some cases; in other words, if it says your glucose is 100, it might actually be 80 or 120 mg/dL.

3. Pay attention to relative changes, not just absolute numbers.

The greatest clinical benefit of CGMs is the information they provide patients on how behaviors (eg, nutrition, physical activity) affect their glucose levels. To underline this point, the people who garner the most benefit are those who pay attention to their behaviors.

Here is an example of one patient who carefully recorded his activities and gave permission for me to share his information:



His A1c has consistently been in the low 6s, meeting the criteria for "well-controlled diabetes," but the CGM offers more granular data to further optimize

his glucose control. Research has consistently demonstrated that adding a CGM to a patient's diabetes management can reduce A1c by about 1%.

4. You are not (only) what you eat.

Despite the treasure trove of nutritional feedback a person can access with CGMs, remember that food is not the only determinant of health. Significant variability can occur even when a person is consuming the same exact food. Healthcare professionals do not rely solely on CGM data to determine disease risk. We interpret the data in the context of other information, such as blood pressure and lipids, to develop a comprehensive understanding of a patient's overall health status and risk for disease. Researchers, too, recognize that other inputs (eg, microbiome, anthropometrics) are necessary for more accurate risk stratification.

5. Information is not the same as education.

The FDA recently approved the first CGM to be available without a prescription, which increases access to this powerful tool to potentially "healthy users." Individuals who choose to use CGMs without the guidance of a healthcare professional may find that information is not the same as education. Timing of a meal, sequence of food groups consumed, and timing of exercise to food intake can all affect CGM readings. Day-to-day reproducibility can be poor. Observing glucose peaks and troughs may cause unnecessary anxiety if the variability is caused by a malfunctioning sensor, or it may provide insight into a person's unique glucotype. Users must educate themselves on the limitations of CGMs and seek advice from professionals when needed.

CGMs are excellent tools for people to learn how behaviors can affect glucose levels. They are a component of the burgeoning movement of personalized medicine. The increased access to personal glucose data provided by an overthe-counter CGM creates an opportunity for investment in preventive medicine.