Continuous Glucose Monitoring Backgrounder

Glucose monitoring in the management of diabetes

Since the late 1970s, when meters for self-monitoring of blood glucose (SMBG) were first marketed, glucose meters have increasingly become part of the fabric of daily life for millions of Americans with diabetes. People with type 1 diabetes as well as those with type 2 have come to depend on their own glucose meters to give them a blood glucose value in the moment, when needed. They use these values to help them make daily adjustments to their insulin, food, and exercise, in order to maintain glucose levels in a safe and healthy range. This involves constantly aiming to avoid low glucose (hypoglycemia) and its dangerous short-term effects ranging from shaking, loss of consciousness and seizure, while also steering clear of high glucose (hyperglycemia) to prevent long-term diabetes complications affecting the nerves, eyes, kidneys and heart.

Continuous glucose monitoring provides added visibility into glucose levels

Over the past decade, the innovation of continuous glucose monitoring (CGM) has emerged to help people with diabetes more diligently and actively manage their glucose levels than they could equipped only with glucose meters.

While glucose meters use a drop of blood to calculate and display a numerical result showing where the glucose level is at a single point in time, CGM systems are worn on the body, work around the clock, and measure glucose levels every few minutes. These continuous measurements help users see what their glucose levels were over the past few hours, what their current level is in real time, and where the glucose levels are trending in the near future. CGM systems also let the user know how rapidly these levels are rising or falling, which is very useful information for a person with diabetes.

All CGM systems have three essential components:

- A **sensor** inserted beneath the skin to measure glucose in the interstitial fluid found between the layers of the skin.
- A **transmitter** that receives glucose data from the sensor and sends it wirelessly to the system's receiver.
- A **receiver** that displays the glucose information and, in some systems, can alert the user to high or low glucose readings. Some CGM systems use the person's own smartphone as its receiver, while other systems have a separate, stand-alone, proprietary receiver.

Benefits of CGM for insulin-using people with diabetes

While efforts are under way to develop future systems that can be made more broadly available to all people with diabetes, current CGM systems are prescribed primarily for people who depend on insulin to manage their diabetes. All people with type 1 diabetes and many people with type 2 diabetes require insulin to manage their disease. In the U.S., there are 6.9 million people with diabetes who require insulin.[i]

The utility of CGM for insulin users has to do with the rapid changes in glucose levels that can happen with insulin use and the ability of CGM systems to forewarn users of such fluctuations. This ability to

identify rapidly changing glucose levels is an important benefit of CGM systems as this feature signals its user to treat with glucose or insulin if necessary.

The clinical value that CGM systems provide to people who use them has been proven through important health outcomes documented in research. For example, use of real-time CGM systems has demonstrated meaningful improvements in users' overall glucose control, as measured by HbA1c,[ii] and also in reduction of incidents of hypoglycemia.[iii] Adding to the research supporting CGM, a multi-center clinical trial launched in 2006 by the type 1 diabetes organization JDRF conclusively demonstrated that CGM use improved not only these same clinical measurements (reduced A1cs and hypoglycemic events) in people with type 1 diabetes of all ages, but also the amount of time their glucose levels stayed within the target range.[iv,v]

Medical need, demonstrated value, and underutilization drive CGM innovation

In the U.S., 70 percent of diabetes patients struggle to control blood glucose levels and hypoglycemia is prevalent among insulin users.[vi] Yet while research has repeatedly demonstrated real health outcomes with regular CGM use and healthcare professionals have clearly expressed that many U.S. patients could benefit from CGM,[vii,viii,ix] even still, the technology is significantly underutilized among the millions of people who use insulin and could be ideal CGM candidates.[x,xi]

Three out of four people with diabetes don't use CGM, and of those who try it, nearly a third abandon it within a year for a variety of reasons, including size, comfort, or problems with repeatedly inserting the sensor. [xii] To address the barriers to CGM use, companies continue producing innovations with an aim toward making CGM easier for the user.

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