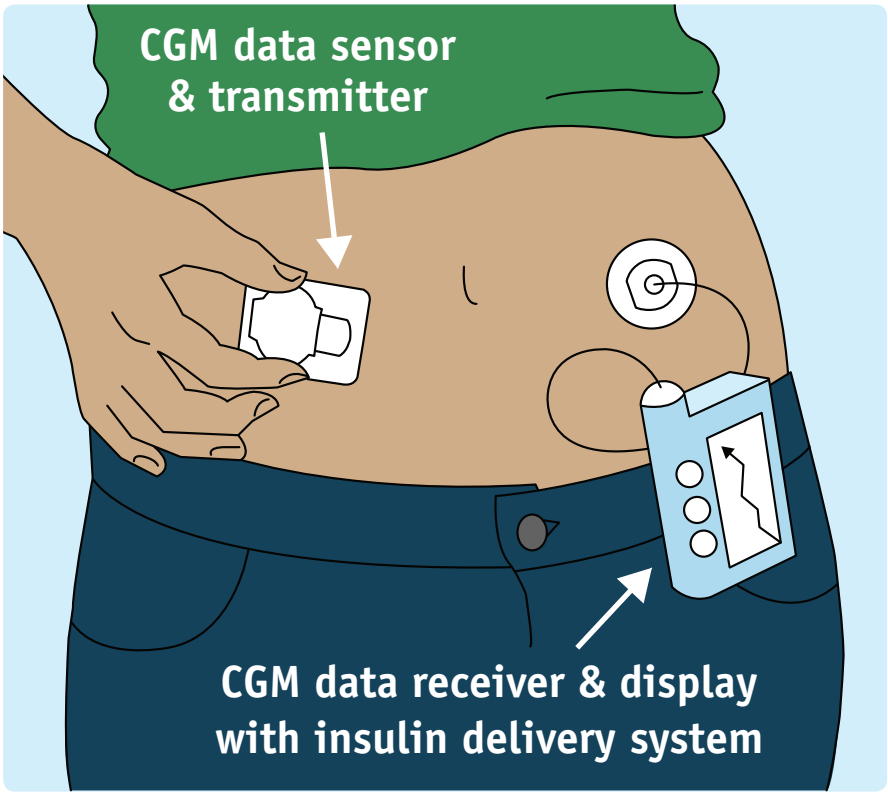
More Choices Available for Diabetes Management

Do you have diabetes? Do you notice that your blood glucose (sugar) levels rise or fall quickly? Has your doctor prescribed insulin to treat your diabetes? Are you comfortable with using a medical device?

If you answered yes to all of those questions, continuous glucose monitors (CGMs) and insulin pumps are tools that you and your health care professional might consider to assist you in achieving stable blood sugar levels.



There are many options available allowing patients with diabetes to monitor and manage their glucose levels. The continuous glucose monitor (CGM) shown here includes a glucose level sensor and transmitter, a data receiver which displays the patient's glucose levels, and an insulin delivery system.

Why managing blood sugar levels is important

Diabetes is caused by defects in the body's ability to produce or use insulin—a hormone that controls blood sugar levels and helps convert food into energy. If the pancreas doesn't make enough insulin, or if the insulin that is produced does not function properly, a person's blood sugar level becomes too high. Over time, that can lead to serious health problems, including:

- heart attack
- stroke
- kidney disease
- nerve damage
- loss of toes or feet
- digestive problems
- blindness
- gum problems and loss of teeth

Low blood sugar can also be dangerous, causing you to feel shaky or pass out.

Devices that can help you now

If you have diabetes, there are several types of devices that can help you keep your blood sugar level within safe ranges. Here are three options you and your healthcare provider may want to consider:

- an insulin pump, which is a computerized device that can deliver a steady flow of insulin, even while you sleep. FDA has cleared and approved many different insulin pumps. The pump, which is similar in size

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to a pager, is worn outside the body and is connected to a tube (catheter) that carries insulin from the pump to another tube (cannula) implanted just under the skin.

- a continuous glucose monitor (CGM), which uses sensors that measure glucose levels every five minutes in the fluid around your cells (interstitial fluid). The sensor readings, which are sent wirelessly to a receiver, show whether blood sugar levels are rising or falling. Blood glucose meters, which use drops of blood placed on test strips, are approved for use to monitor your blood sugar. The FDA has not yet approved CGM values alone to determine insulin dosing.
- There are also CGM-enabled insulin pumps, which can communicate wirelessly with a CGM sensor. The sensor readings are displayed on the insulin pump screen instead of on a separate receiver, which enables the user to carry one less piece of equipment.

There are currently two FDA-approved, CGM-enabled insulin pumps: the Medtronic MiniMed, approved in April 2006, and the Animas Vibe System, which was approved on Nov. 25, 2014. The Animas Vibe System combines the DexCom G4 Platinum CGM with an Animas insulin pump. This approval gives consumers more choices in the types of CGMs that can be integrated wirelessly with an insulin pump.

"These devices are an important technological advance to address some of the challenges people with diabetes face in managing their blood sugar," says Alberto Gutierrez, Ph.D., director of FDA's Office of In Vitro Diagnostics and Radiological Health. "As they become better integrated with insulin pumps, CGMs can ease the daily burden of people with diabetes who juggle the use of multiple medical devices."

The coming innovation: artificial pancreas

In addition, researchers are making significant progress towards the development of artificial pancreas device systems (APDS). These automated, closed-loop systems combine a continuous glucose monitor, an insulin infusion pump, and a "smart" system that monitors glucose levels in the body and automatically pumps appropriate doses of insulin when needed, with little or no input from the patient. The ideal APDS will be a system of devices that closely mimics the glucose-regulating function of a healthy pancreas. It will not only monitor glucose levels but also automatically adjust the delivery of insulin to reduce high blood glucose levels (hyperglycemia) and minimize the incidence of low blood glucose (hypoglycemia).

Currently many investigational studies involved in the development of APDS are using sensor enabled pumps, including ones that integrate the G4 Platinum System, as a component. The availability of an insulin pump that is already compatible with the G4 Platinum system will make the development and approval of APDS that use this technology easier. The FDA will continue to prioritize the development of an APDS and will continue to keep you and health care professionals informed of developments.

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