



Trends-in-Medicine

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by D. Woods

SUMMARY

- ◆ Use of CGMS is progressing like a tortoise.
- ◆ Reimbursement is miserable, but even with good reimbursement, usage is expected to grow slowly.
- ◆ DexCom is holding its own against Medtronic based on price, but doctors are keeping an eye on Abbott's device, which could be a game changer if it lives up to its hype.

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CONTINUOUS GLUCOSE MONITORING SYSTEMS (CGMS)

Endocrinologists and an RN were interviewed to determine how Continuous Glucose Monitoring Systems are being accepted by doctors and patients. Medtronic's Guardian RT was approved by the FDA in August 2005 and is undergoing a controlled rollout in the U.S. DexCom's DexCom STS was approved in March 2006 and is widely available. Abbott's FreeStyle Navigator is awaiting FDA approval.

Many doctors are recommending CGMS, but to only a few patients, largely because of reimbursement problems, but there are also availability issues. An Illinois endocrinologist said, "I recommend it (CGMS) to patients who would benefit, especially those with hypoglycemic unawareness, if they can afford it or are willing to try and fight for coverage." A Virginia doctor said, "We are going to have some patients do CGMS, though none have CGMS yet due to issues of insurance coverage." A Maryland doctor said she has prescribed the Medtronic device to three patients, but they couldn't get the devices, "Medtronic gave me a letter in April saying that the devices were available and to start prescribing them, but three patients told me the device isn't available, and they won't be able to get one until December. Apparently, they are on back order."

Device preference

Doctors were mixed as to device preference. Half said they had no preference, with patients using both Medtronic and DexCom.

- *Illinois:* "If the patient is already on a Medtronic pump, we suggest the Paradigm Real-Time (which integrates Guardian and an insulin pump). We have had patients try both (CGMS devices), and if the patients are cost-sensitive, they have opted for the DexCom. However, both have reliability and accuracy issues."
- *Virginia #1:* "I'm not aware of any patients using any other CGMS besides (Guardian)."
- *Virginia #2:* "I have no particular brand preference, though there are differences between the systems that are important. However, prices will trump much of this since it will be relatively expensive overall."
- *Massachusetts:* "We are doing trials with both the DexCom and Medtronic devices, and both have bugs."

Doctors said that they will wait to see how Abbott's Navigator works before prescribing it, providing that it is approved in the next several months. An Illinois doctor said, "Using Navigator will depend on how good it is. I am concerned that the buzz (about Navigator) may not reflect reality." Another Midwest doctor said,

"I'm waiting to see what the Navigator will be like. I think that it will have a lot more answers. I think we need to be very careful with picking and choosing. Right now, insurance companies aren't paying for them, and I want to make sure that they're good...I have a couple of patients on DexCom, however, I'm waiting (before writing any more prescriptions) ...I want the choice of all three (devices) and not just two." A Virginia endocrinologist said, "The Abbott technology has seemed superior to some of our investigators, but we expect it may take a while for reliable data to reach publication on whether there is superiority of one system over the others."

Patient demand and candidates

Patients are starting to ask their doctors about CGMS. A Virginia doctor said, "Patients are indeed asking – mostly those currently with pumps." A Maryland endocrinologist said, "Most of my patients who want it (CGMS) are already on pumps for the same reason – they have hypoglycemia – and the device can at least help them make more rapid changes in their insulin delivery."

Type 1 diabetics and those with hypoglycemic unawareness are the best candidates for CGMS, according to these doctors. An Illinois doctor said, "At this point, Type 1 patients with hypo/hyperglycemia or any patient with GMD (gestational diabetes mellitus) – but we see only a few of these. The obstetricians have not yet caught on and often don't refer back to us." A Virginia endocrinologist said, "Patients would be mostly those with Type 1 with marked instability in their blood glucose and problems with hypoglycemic unawareness." Another diabetes expert said, "It's mostly for patients with a pump. This is particularly true for (1) patients with HbA1c values that don't jibe with their home glucose monitoring, (2) patients with nocturnal hypoglycemia (the alarm component will be critical), and (3) patients with hypoglycemic unawareness." A Maryland doctor said, "Patients who have hypoglycemic unawareness, or live alone (are the best candidates). If they have events, and there's no one else who can take action for them, especially in the middle of the night, the devices can have an important role – but they're not for everyone. I recommend them for both pumpers and non-pumpers, and the majority are Type 1." A Michigan doctor said, "Type 1 patients on multiple daily injections or insulin pumps (are the candidates). If a patient is tightly controlled, that patient doesn't want a surprise."

Cost and reimbursement

Reimbursement is a huge issue, and only one doctor said she had any experience with patients receiving reimbursement, after fighting with insurance companies. She said, "We've seen reimbursement only on a case-by-case basis, where we have appealed denials." All other doctors said that problems with reimbursement make CGMS prohibitively expensive for patients. A Virginia doctor said, "Reimbursement is an issue that I don't have a current answer for, and the price has seemed, to all of us, rather steep." A Michigan doctor said,

"It's going to be very slow going unless there is approval or some reimbursement for patients." A Midwest diabetes educator said, "It's a big issue here. We're saying go ahead and put in for it and then fight when it's rejected."

The August 2006 meeting of the Medicare Coverage Advisory Committee (MCAC) raised questions about the future of reimbursement for finger stick strips, continuous monitors in Type 2 diabetics over age 65, and CGMS. An industry source described the discussions as "fairly negative." He said CMS wants more data and is trying to get companies to do outcome studies. He added, "Companies sometimes think they did their job getting a device covered (by Medicare), but doctors need to get reimbursed (for their time), too."

Only a small percentage of patients appear willing to pay out-of-pocket for the devices. A Virginia endocrinologist said, "We have a pretty big indigent care component, which is not to say that there are no paying customers, so some patients will pay the cost of the sensors on an ongoing basis. It is expensive, and insurance coverage in the future will be critical." A Maryland doctor said, "I'm told that out-of-pocket expenses are about \$2,000 or \$3,000 and maybe more." A Massachusetts doctor said, "A very small percentage of patients is willing to pay out-of-pocket, but there are some." A diabetes educator said that 10-15 patients at her hospital are taking advantage of a DexCom program which lets the patient use its device for four weeks free, and then the patient can buy the device for half price – about \$400. She said, "DexCom has the market right now. Patients love it, but you have to do a lot of training, and you don't want to throw away your regular blood glucose meter for a while."

Doctors agreed the \$35-\$37 sensor replacement cost is way too high for patients, which is both limiting use and causing intermittent use.

- *Virginia*: "\$12 a day is sizeable, especially in the long term. At the outside, I could see patients using the device intermittently. If there is a closed loop system where the CGMS 'talks' to the pump, then perhaps this becomes worth it as a full-time deal."
- *Maryland*: "From the perspective of the patient, the cost is going to limit the use. For most people, \$35 is going to be a lot of money, so it's going to limit use to people who have the available resources. I think patients will most probably wear the device intermittently unless they have hypoglycemic unawareness."
- *Illinois*: "It is unacceptable if the sensors only last three to four days. But some patients understand that using the units one or two times a month or less might also be useful."
- *Midwest*: "If the sensors only last three days, it's a heck of a chunk of change. If that gets extended to six or seven days, then maybe \$30 a week might not be as bad as \$90 a week."

Comparison of Continuous Glucose Monitoring Systems

Issue	Abbott's FreeStyle Navigator	Medtronic's Guardian RT	DexCom's DexCom STS
FDA approval	Pending	Approved in August 2005 for adults age 18 and older	Approved in March 2006 for adults age 18 and older
Availability	Waiting for FDA approval	Controlled rollout	Widely available
Price	N/A	\$1,995 + \$395 docking station + \$35-\$40 per sensor	\$500 for receiver, transmitter, and 2 sensors plus \$800 for the unit and \$175 for 5 sensors.
Sensor life	Seeking approval for 5 days	Shuts off at 72 hours (FDA stipulation) but has gone longer in trials	72 hours
Size of sensor cannula	6 mm	14 mm	6 mm
Angle of sensor insertion	90 degrees	45 degrees	45 degrees
Insertion device available	Each sensor has a disposable inserter	Sens-serter, manual insertion also possible	DexCom STS applicator
Monitor size	3" x 2.5"	3.5" x 2.5"	3" x 2.5"
Start-up initialization time	10 hours	2 hours 20 minutes	2 hours
Calibration	Calibrate at 10, 12, 24, and 72 hours with no further calibration for final 2 days of 5-day wear.	First calibration is 2 hours after insertion, then 6 hours afterwards. Then every 12 hours. Will alarm if calibration value not entered.	Every 12 hours. With One Touch Ultra, cannot be entered manually.
Displays glucose numbers	Every minute	Every 5 minutes	Every 5 minutes
Displays directional trends	Yes. Always has directional and rate of change arrow. Can view 2-, 4-, 6-, 12-, and 24-hour graph. Can go back 28 days.	No. Must manually scroll backward and wait to upload data to software to make graphs.	Yes. Can display a 1-, 3-, or 9-hour glucose graph.
Displays rate of change	Yes. Sideways arrow means dropping at <1 mg/dL/minute. Up or down arrow means raising/dropping at >2 mg/dL/minute. 45 degree arrow means dropping/raising between 1 and 2 mg/dL/minute.	No	No
Alarms on vector technology	Yes. Will alarm on 10, 20, or 30 minutes before it estimates the patient will hit that number, based on the current trend. It estimates a future number by using algorithms and vector technology.	No	No
Alarm, vibrate, or both	Alarm or vibrate	Vibrate, escalating alarm, or both	Alarm or vibrate – low first vibrate, then alarm
Transmitter waterproof	Yes	Yes	No. Can shower with shower patch but shouldn't swim.
Transmitter batteries	Watch battery should be replaced monthly.	Non-replaceable. Transmitter life ~1 year (usually covered by insurance). Additional transmitter \$500.	Non-replaceable. Transmitter life unknown. Additional transmitter is \$250.
Monitor batteries	2 AAA batteries that need to be replaced every 3 months.	2 AAA batteries. Monitor alerts when change is needed.	Must recharge the battery every 5 days. Charge time is 3 hours.
Range of monitor to transmitter (factory stated)	10 ft.	6 ft.	5 ft.
Sensor storage	Room temperature, 4 month life	Refrigerated	Room temperature, 4 month life
Snooze alarm feature	Yes, 1 hour silence	Yes, only for high alarm, 1-12 hours	N/A
BG monitor	Built-in FreeStyle Flash Monitor	No	Must calibrate with One Touch Ultra
Computer software	FreeStyle CoPilot	Guardian Solutions	None yet
Warranty	N/A	1 year	6 month warranty for receiver and transmitter
Upgrade program	N/A	Medtronic Pathway Program	N/A
Developing technology	Open loop system with new Abbott Pump-Aviator.	Pump/CGMS monitor combination has been submitted to the FDA for approval and is already available in Canada.	Long-term (about 1 year/outpatient procedure) implantable sensor.

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- *Diabetes educator/nurse who wears a DexCom device:*
“The sensors are terribly expensive. I think it’s approved for five days now, but I use it intermittently because I can’t afford \$37 every 10 days. I wear it if I’m at a conference or if I’m going to travel or change pump settings. I’ll wear it, but then I’ll put it back in the drawer.”
- *Michigan:* “I don’t know why you would make that kind of investment just to use (the device) intermittently. Diabetes changes all the time – as we’re speaking – and so they’re going to want to get the most benefit, and that’s if it’s worn all the time. You want them to wear it all the time, and I’m not sure why you’d use it intermittently if you want to get the full benefit of the device.”

Outlook for future use

Most doctors said that CGMS use will increase only slightly (<5% of eligible patients) over the next six to 12 months unless there is reimbursement for the devices. If there were reimbursement, usage would increase but still stay below 10% of eligible patients. One endocrinologist said, “Right now, it’s less than 1%, and that won’t change very much over the next six months or a year. That will change if insurance companies pay for it...We have to fight harder for reimbursement, which might depend on publishing independent peer-reviewed studies showing clear evidence of improving HbA1c, fewer hospital admissions, or other clearly improved outcome data.”

