

Early Patient and Clinician Experiences with Continuous Glucose Monitoring

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Abstract

Fifteen years after publication of landmark studies that clearly demonstrated the benefits of intensive diabetes management, patients continue to fall short of glycemic goals. The risk of hypoglycemia remains a major barrier to optimal glycemic control.

Continuous glucose monitoring (CGM) can assist in overcoming some of the limitations of self-monitoring of blood glucose by providing the ability to track glucose levels 24 hours a day, observe glucose trends and patterns, and receive alarms or alerts for actual and impending hypo- and hyperglycemia. In the brief time it has been available, studies have already demonstrated an association between the use of CGM and less time spent in hypo- and hyperglycemia, reduced glycemic variability, and reduced hemoglobin A_{1c} levels.

Because little information exists in the literature regarding teaching and learning experiences to assist clinicians beginning to incorporate CGM into their practices, the training and user experience from a 12-week study of patients using the FreeStyle Navigator CGM system was evaluated. Through responses to questionnaires, clinicians indicated the ability to train easily on the CGM system, and both patients and clinicians felt that they were able to make more informed decisions on therapy adjustments based on information from the receiver and the data management reports.

It is important for clinicians and patients to understand the scope and limitations of this new technology to prevent unrealistic expectations. It is imperative to provide adequate training and education to effectively manage and use the large amount of data made available by CGM.

Fifteen years have elapsed since publication of the results of the Diabetes Control and Complications Trial (DCCT),¹ which clearly and definitively demonstrated the benefit of aggressive blood glucose control in type 1 diabetes. The trade-off at the time was the increased risk of hypoglycemia. The Epidemiology of Diabetes Interventions and Complications study, a follow-up to the DCCT published in 2005,² demonstrated a 57% reduction in the incidence of myocardial infarction and stroke for those in the intensive treatment group in the DCCT. The results of both studies speak volumes about the absolute benefit and incontrovertible evidence that blood

glucose control matters. Why, then, is glycemia not more aggressively controlled for all patients? The risk of intensive management has always been the possibility of causing a profound hypoglycemic reaction.

How can one hope to achieve better glucose control while reducing the risk of hypoglycemia? Enter the new technology of continuous glucose monitoring (CGM). It is not a cure, not a panacea, but another measure that may for some bring a far better level of glucose control while reducing the incidence and risk of hypoglycemia.

CGM is the first new glucose monitoring technology since the introduction of self-monitoring

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of blood glucose (SMBG) in the 1980s. Despite the initial concern that patients would not prick their fingers several times a day, the utility of SMBG technology won over skeptics and became the standard of practice for most individuals with diabetes worldwide. Although SMBG provides important information to assist in making diabetes management decisions, its usefulness is limited in several respects. Intermittent monitoring enables patients to view only a brief snapshot of their blood glucose values. These somewhat random determinations do not provide a true appreciation of glucose trends throughout the day and night. The utility of SMBG is also limited by the frequency with which patients are willing and able to perform blood glucose checks.

CGM is a technology that can assist in overcoming some of the limitations of SMBG by providing patients the ability to track glucose levels 24 hours a day, observe glucose trends and patterns, and receive alarms or alerts for actual or impending hypo- and hyperglycemia. In the brief time that CGM has been available, studies have already demonstrated an association between the use of CGM and less time spent in hypo- and hyperglycemia, reduced glycemic variability, and reduced hemoglobin A_{1c} (A1C) levels.³⁻⁵

Continuous glucose sensors are electrochemical sensors inserted in the subcutaneous tissue for a period of days that continuously measure glucose in the interstitial fluid. The devices use glucose oxidase, measuring an electric current generated by the sensor that is converted into glucose values. A transmitter attached to the sensor uses radiofrequency communication to send the sensor information to a receiver, which provides glucose information and alarms to the user.

The first generation of continuous glucose sensors approved for use in the United States were designed as a tool for health care providers to collect glucose data throughout a 3-day period during which the data were masked to the user. Health care providers would subsequently download the data for retrospective

interpretation and glucose pattern identification after the sensing period. Newer real-time sensors provide the opportunity for more immediate therapy adjustments by allowing users to observe glucose values and trends while they are wearing a sensor and make immediate decisions based on the glucose information as it happens. The technology, accuracy, and sophistication of features have steadily improved since the first real-time CGM sensor became available in 2000.

Because CGM is still in its infancy, very little information exists in the literature regarding teaching and learning experiences to assist clinicians beginning to incorporate CGM into their practice settings. The training experience from the study presented here offers insight into some of the lessons learned from the perspective of both health care practitioners (HCPs) and patients using the FreeStyle Navigator CGM system (Abbott Diabetes Care, Alameda, Calif.).

FreeStyle Navigator System

The CGM system is composed of three components: a miniature electrochemical sensor placed in subcutaneous tissue at ~ 5 mm depth, which is delivered via a disposable sensory delivery unit; a radio frequency transmitter; and a handheld receiver that receives sensor signals and displays continuous glucose recordings every minute. The system is a stand-alone monitoring unit that is currently not integrated with an insulin pump.

The system includes two types of glucose alarms. A threshold alarm is designed to alert users if the glucose level crosses a preset high or low threshold. A projected alarm provides an early warning alarm to alert users 10, 20, or 30 minutes before an anticipated low or high glucose event to enable them to take appropriate corrective action. For example, users may decide to administer more insulin if glucose levels are rising too rapidly or to consume a source of carbohydrate if levels are declining too quickly after performing a confirmatory blood glucose check. The direction and rate of change of glucose is

displayed with trend arrows on the main screen of the receiver indicating increasing glucose with upward arrows and decreasing glucose with downward arrows.

Study Design

The user evaluation assessed 12-week user experience with the CGM system after subjects were trained using a uniform training method. The study was conducted at nine clinical sites throughout the country, with 90 adult subjects with type 1 diabetes. Among the inclusion criteria were diagnosis of type 1 diabetes ≥ 2 years, age 18–64 years, and treatment with either insulin pump therapy or multiple daily insulin injections. Subjects wore a sensor in either their upper arm or abdomen at the subject's discretion for a total of 90 days, changing sensors approximately every 5 days. The initial training averaged ~ 2 hours in duration, with the subjects performing the first two sensor insertions under supervision. Subsequent sensor insertions were performed by subjects at home.

Subjects were requested to complete their usual SMBG checks and to perform a confirmatory blood glucose check with the meter that is built into the CGM receiver before taking any corrective action based on CGM readings. Subjects were encouraged to record their insulin, meals, exercise, and health events in the receiver's electronic log and were offered the use of the data management software program CoPilot for FreeStyle Navigator to evaluate data.

At days 5, 30, and 90, participants returned to the clinic for the upload of electronic data compiled by the receiver. Data included continuous glucose values recorded every 10 minutes and blood glucose levels from the built-in meter. To properly assess user satisfaction and experience with the CGM system, subjects and health care providers completed written questionnaires at baseline, day 30, and day 90.

Results

Study subjects

Of the 90 enrolled subjects, 56% were female, average age was 42

years, and mean duration of diabetes was 23.1 (SD 10.1) years, and 73% used insulin pump therapy. All subjects had completed high school or its equivalency, and 72% had a 4-year college degree. Of the 90 enrolled subjects, 88 completed the 90-day study.

Subject questionnaires

The subject questionnaires consisted of various types of questions, including ranking, rating, and multiple choices. For rating questions, the evaluation used a 6-point Likert scale, in which 1 corresponded to “strongly disagree” and 6 corresponded to “strongly agree.”

Initial impression and ease of use

At the time of initiation, 94% of the respondents indicated a strong sense of need for a CGM system (mean Likert score 5.3). A similar percentage indicated that “I will know in advance if my blood glucose is dropping or rising” (mean 5.3). As many as 99% expressed their hope that with the device, “I can know which way and how quickly my glucose levels are changing” (mean 5.5). At the time of the 30-day questionnaire, 100% of subjects responded positively to the statement, “It is easy to understand the direction and rate of change of my continuous glucose levels (mean 5.5).”

Important features and benefits

Study subjects rated the following features of the system most important to them at the end of the study: the 1-minute glucose readings, the high and low glucose alarms, and the trend arrows. The most important benefit of the system changed from “improvement in my glucose control” at Day 1 to “understand the changes and variability in my daily glucose levels” at Day 90.

Study compliance

Participants in the study wore a sensor for an average of 76 (SD 17) days. Seventy-two percent of the subjects had good compliance, defined as wearing the sensor for > 75 of the 90 days in the study.

Data management software

Forty-seven of the 90 subjects elected to use CoPilot, the computer-based data management system, during the study. Ninety-six percent indicated that it was easy to use, including uploading the device and viewing the reports. The most frequently used report by subjects at the end of the study was the Glucose Modal Day report, a visual overlay of multiple days of data, followed by the Glucose Average report. More than 91% of subjects indicated that they were able to identify glucose patterns from these reports.

Overall experience

At the end of the study (day 90), the subjects rated the device on a scale of 1 (do not like it at all) to 6 (liked it very much). Thirty-eight subjects of 86 (44.2%) rated the device a 6; 20 participants (23.3%) rated it a 5; 17 subjects (19.8%) rated it 4; and one rated it a 1. Interestingly, the number of subjects who “liked it very much” increased between day 30 and day 90 from 19 of 82 to 38 of 86 subjects (23.2 vs. 44.2%).

Future purchase and usage of CGM device

When asked if they would be likely to purchase and use the CGM system when it became available, 86.5% indicated they were “somewhat likely” to “extremely likely” to purchase a system if insurance coverage was available, and 60.7% were likely to purchase and use it without insurance coverage.

HCP questionnaires

For rating questions, a 5-point Likert scale was used, with 1 corresponding to “strongly agree” and 5 corresponding to “strongly disagree.”

Overall training materials and content

HCPs gave a high rating of the usefulness of the Trainer’s Guides and User’s Guides for the CGM system (mean 1.8) and the data management system (mean 1.9).

Individual versus group training

Six HCPs trained study subjects individually on the system, whereas

three trained subjects in groups of two to three subjects. Only one HCP out of nine trained subjects in groups on the use of the data management system.

Study Outcomes

Glycemic analysis

Differences were assessed between the CGM data collected on the first 15 days of study participation and on the last 15 days of study participation. A total of 69 subjects recorded at least 100 hours of CGM data in both the first 15 days and the last 15 days of the study period. The most notable significant and clinically meaningful difference was that the number of hypoglycemic episodes per day between the first 15 days and the last 15 days in the study decreased from 1.3 to 1.0 ($P = 0.0025$) (Figure 1).

A1C analysis

The percentage of subjects with A1Cs < 7.0% increased from 38% at baseline to 54% at day 90. At 90 days, both subjects with a baseline A1C of $\geq 8.0\%$ ($P = 0.0036$) and subjects with a baseline A1C of < 8.0% ($P = 0.0001$) had a significant decrease in their A1C level.

Measurement accuracy

Each blood glucose measurement was paired with an interpolated CGM value corresponding to the time of the glucose measurement. Of 19,389 paired data points, 72.6% were within the clinically accurate zone A, with only 17 readings in the E zone (0.1%).⁶

CGM Experience in One Clinical Setting: Dr. Bloomgarden and Ms. DeRobertis Share Their Experience

As one of the nine clinical sites for the study, we were able to experience the use of the system along with our patients. Working with patients who used the system proved to be extremely beneficial in helping us to make decisions that resulted in improved blood glucose control and overall diabetes management. Review of data on follow-up visits was useful in making adjustments in basal rates for those on insulin pump therapy and adjusting basal

insulin, either glargine or detemir, for those on a multiple daily injection insulin regimen. Reviewing data also enabled patients to better understand how their boluses covered postprandial hyperglycemia. We found the system very helpful in assisting us, along with our patients, in modifying insulin-to-carbohydrate ratios and adjusting insulin sensitivity factors.

The patients with whom we worked were more aggressive with control as they became more comfortable in their ability to rely on glucose alarms or trend arrows that indicated that glucose levels were approaching either too low or too high a level.

Setting realistic expectations

It is important that patients understand the scope and limitations of CGM before purchasing and using this technology. The amount of information patients receive from CGM may help them make more informed treatment decisions, but they need to understand that wearing a monitoring device cannot improve diabetes control by itself. They have to interact with the system and make decisions based on the device readings. Providing access to printed literature or online materials on CGM technology can help patients get a basic understanding of what to expect from CGM so they are not disappointed if their diabetes is not “fixed” in a given

period of time. We found through our experience that explaining about the lag time between interstitial fluid glucose and blood glucose is crucial because this may otherwise be the cause of frustration during the first weeks of wearing a sensor.

Responding to trend arrows

The trend arrows were perhaps the most valuable feature of the CGM system because they allowed the subjects to see the direction that their glucose was heading. SMBG does not allow patients to know if their glucose is on the rise or on the decline. A patient may respond to a reading of 150 mg/dl by giving a correction dose of insulin. However, if the sensor indicates that the glucose is declining rapidly, the patient would have the information needed to bypass this correction dose, thus preventing potential low blood glucose. In our setting, we advised subjects to consider responding to an increasing glucose trend after confirming the glucose value with a blood glucose check by either giving a correction bolus, increasing the temporary basal rate for pump users, or increasing exercise at the time, taking into consideration “insulin on board” and the current glucose level. Depending on the glucose level, patients were advised to respond to a declining trend by either suspending their insulin pump for a short period of time, turning on a temporarily decreased basal

rate, or consuming 15 g of total carbohydrates.

Avoiding “insulin stacking”

Because most patients are not used to checking their blood glucose levels within the first hour of the postprandial period, they are often surprised to see the unexpected glucose excursions when they begin CGM. An initial response in some patients may be to frantically bolus and continue to bolus until glucose values return to the target range. This results in “stacking” insulin and increasing the risk of severe hypoglycemia. Because most currently available insulin pumps can track “active insulin” or “insulin on board,” patients will avoid over-insulinizing if they use this pump feature and follow the recommendation on the pump display. In our practice, we teach patients to avoid overreacting to sensor readings by encouraging them to wait at least 2 hours between taking any additional insulin injections or boluses and to verify CGM readings with a finger-stick blood glucose reading before making any treatment decisions.

Setting alarms

The alarms were a key feature that many of our subjects identified as a major reason they would choose to use a CGM system to alert them when their glucose was at or approaching a dangerous level. We asked study subjects to initially set high glucose alarms high enough (> 200 mg/dl) to avoid alerting them each time they ate.

Low alarms in our setting were often set in a range of 80–85 mg/dl to alert subjects before they reached the hypoglycemic state. However, this needs to be individualized, because some patients prefer to set them at a lower setting to avoid unnecessary disturbances, particularly at night.

The projected alarms, or early-warning alarms, were individualized based on how early subjects wanted to be alerted for potential high or low glucose levels. As they became more experienced, they often changed the settings based on their perceived needs and their awareness of hypoglycemic symptoms.

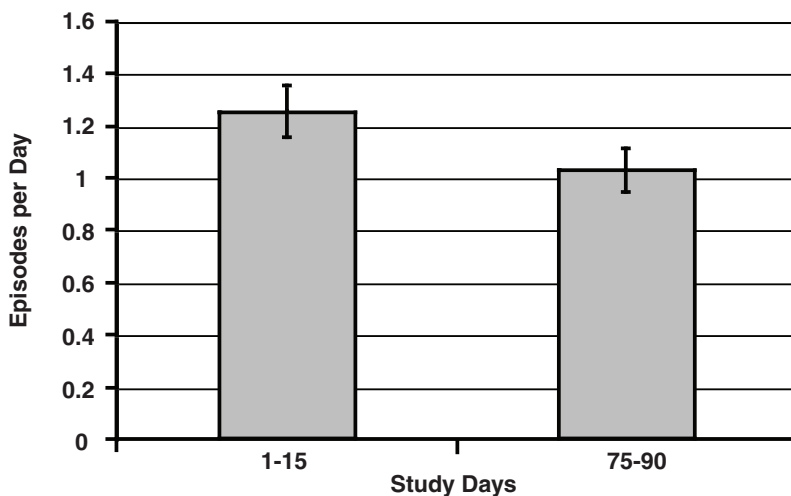


Figure 1. Number of hypoglycemic episodes.

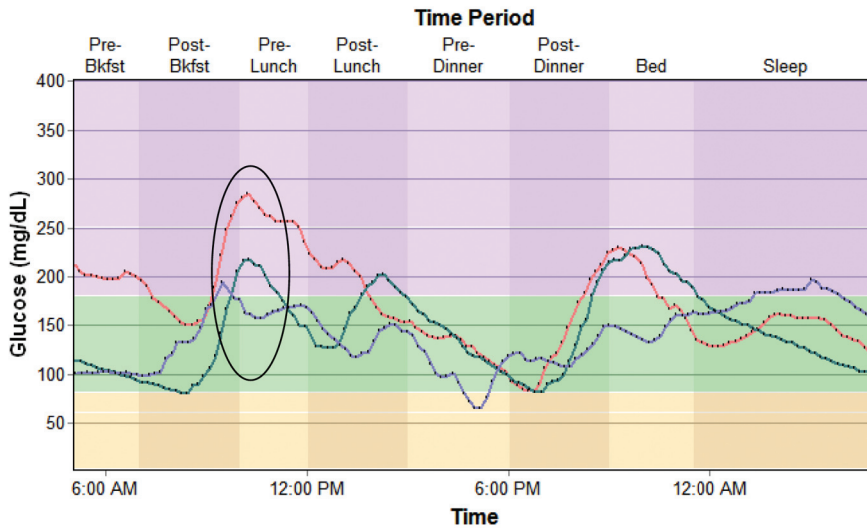


Figure 2. Glucose Modal Day report.

Data management reports

The most commonly used CoPilot report in the study by both subjects and HCPs and the one we used most frequently at our site was the Glucose Modal Day report. This report helped us identify glucose patterns throughout the day and gave us information to determine basal rate changes for patients on insulin pump therapy. An important point in evaluating the Modal Day report is to narrow the date range to look at a manageable period of time. We limit the data period to 3–7 days for most patients (Figure 2).

The Glucose Pie Chart (Figure 3) illustrates the percentage of glucose values below, within, and above a patient’s target range at each meal and was very helpful in evaluating mealtime glucose control.

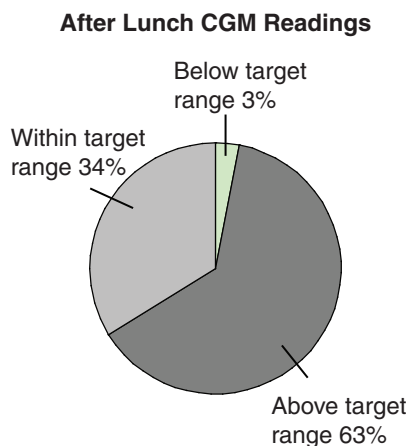


Figure 3. Glucose Pie Chart.

The first step was to ensure that basal insulin coverage was adequate. If the report revealed that glucose levels were above or below target range > 50% of the time, we would ask the subject to skip that meal. If elevated glucose levels continued during the time period without food, we would increase the basal insulin as needed.

The next step was to evaluate insulin for meal coverage. If the percentage of glucose values above the target range was high after a meal, this would indicate a need for reinforcement of carbohydrate counting, an increase in the insulin-to-carbohydrate ratio at the meal, or an adjustment in the timing of the insulin bolus. If elevated glucose levels continued after the meal and before the following meal, we would evaluate the insulin correction factor or insulin sensitivity factor and again look at basal rates for that period of time. The Glucose Pie Chart makes it very clear how to prioritize and communicate to patients the changes that need to be made to optimize glucose control.

Subject experiences

Subject K.E. K.E. is a 48-year-old woman on insulin pump therapy who was diagnosed with type 1 diabetes at age 30. She stated that the CGM system was very helpful in allowing her to better understand the frequent high glucose levels she experienced in the morning. The CoPilot Glucose Modal Day

report was helpful in identifying this pattern of hyperglycemia that began during the night and continued into the morning hours. Because K.E. was not eating during this time, her basal rate was gradually increased from 0.5 to 0.6 units at midnight and from 0.9 to 1.1 units at 3:00 a.m.

K.E. is an avid exerciser, but she was often frustrated by unexpected glucose fluctuations during and after exercise, resulting in the need for extra snacks to prevent and treat hypoglycemia. The CGM system helped enable her to increase her workout frequency or intensity and maintain close-to-target glucose levels with less risk of hypoglycemia during and after her exercise routine. The information provided by CGM helped determine that she should temporarily reduce her basal rate for a period of time before exercise to increase her glucose levels to an appropriate level for exercise without the need to eat a snack.

K.E. stated that, as she became more comfortable and experienced with the system, she gained a greater sense of confidence and became better at problem solving. She began working with a trainer, which enabled her to do more exercise while she was able to more effectively manage her glucose levels. Recently, K.E. has decreased the upper limit of her target glucose from 120 to 100 mg/dl.

Subject C.L. As a businessman, C.L. related that the CGM system was helpful in preventing hypoglycemic events when attending the frequent meetings in his schedule. Looking at his receiver before attending a meeting helped him determine what adjustments he needed to make, if any, to prevent his diabetes control from becoming his primary focus during the meeting. Instead, he could direct his attention to the meeting at hand, knowing that at a moment’s glance, he could see his glucose level and the rate and direction it was going, and his projected alarm could alert him if he was headed toward hypoglycemia.

Although C.L. felt that the nighttime alarm was sometimes a

Table 1. Tips for Clinicians Getting Started With CGM

- Discuss expectations with patients, especially the differences that can occur between blood glucose and interstitial fluid glucose. Explain that CGM is another tool that may help patients achieve better control, but that such an achievement may take some time and require close work with the health care provider to learn to make subtle adjustments.
- Stress the importance of calibrating, using proper glucose monitoring technique only when glucose levels are stable to improve accuracy and prevent failed calibrations.
- Review responses to glucose information and identify key points to address first.
- Consider training patients in groups for initial sessions, with individualized follow-up visits to review reports and make therapy decisions.
- At follow-up visits, review the most recent data from the past 1–2 weeks for analysis of glucose patterns. This can assist in adjustment of basal rates, insulin-to-carbohydrate ratios, and insulin sensitivity factors.

nuisance, he admitted that it was helpful in preventing serious low blood glucose reactions during the night. He agreed that it was important to know his glucose level before doing anything that could potentially cause an unexpected low or high glucose. He expressed that wearing the CGM system was “truly an excellent experience.”

Based on our experience with CGM, Table 1 gives some tips for clinicians beginning CGM therapy. These are some of the important areas that we feel should be emphasized when initiating CGM.

Summary

CGM is an exciting new technology that has the potential to transform diabetes care. With any new technology, there is a period of time before health care practitioners accept and use the new products. This study reported early experiences of clinicians and patients in the training and use of a CGM system.

Study subjects were confident in their use of the system based on the training they received. They reported the major benefit of the technology was the ability to make day-to-day

decisions based on the 1-minute glucose readings, threshold and projected glucose alarms, and the glucose trend arrows that allowed them to observe the rate and direction of glucose change. Clinicians demonstrated that they could train patients easily on the use of the system and, along with the patients, make more informed decisions on therapy adjustments based on information from the receiver and data management reports.

With the plethora of glucose data available from CGM systems, training and education are key to managing and using the data. It is important to ensure that patients and clinicians understand the scope and limitations of the new technology to prevent unrealistic expectations and subsequent disappointment. Although studies have shown that the use of CGM has resulted in less time spent in hypoglycemia, reduced glucose excursions, and improvement in A1C levels, improvement in diabetes control depends on the willingness of patients to use this information to modify their diabetes management.

Acknowledgments

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References

- ¹DCCT Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 329:977–986, 1993
- ²DCCT/EDIC Study Research Group: Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes. *N Engl J Med* 353:2643–2653, 2005
- ³Garg S, Zisser H, Schwartz S, Bailey T, Kaplan R, Ellis S, Jovanovic L: Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care* 29:44–50, 2006
- ⁴Deiss D, Bolinder J, Riveline JP, Battelino T, Bosi E, Tubiana-Rufi N, Kerr D, Phillip M: Improved glycemic control in poorly controlled patients with type 1 diabetes using real-time continuous glucose monitoring. *Diabetes Care* 29:2730–2732, 2006
- ⁵Kovatchev B, Clarke W: Continuous glucose monitoring (CGM) reduces risks for hypo- and hyperglycemia and glucose variability in T1DM and insulin-treated T2DM. *Diabetes* 56:23A, 2007
- ⁶Clarke WL, Cox D, Gonder-Frederick LA, Carter W, Pohl SL: Evaluating clinical accuracy of systems for self-monitoring of blood glucose. *Diabetes Care* 10:622–628, 1987

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