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CONTROVERSIES in *Continuous Glucose Monitoring*

# Continuous Glucose Monitoring: Changing Diabetes Behavior in Real Time and Retrospectively

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## Abstract

Results of both the Diabetes Control and Complications Trial and the United Kingdom Prospective Diabetes Studies supported the role of tight glucose control in reducing long-term complications of diabetes. There is further evidence that glycemic variability may be better correlated with the risk for complications than sustained hyperglycemia. These studies reinforce the need to work toward improved glucose control with minimal variability in patients with diabetes. Continuous glucose monitoring technology offers a means of obtaining a more complete picture of glucose patterns and can be used to aid in identifying trends in glycemic variability, especially overnight and after meals when blood glucose testing is not usually performed. Increased access to retrospective trends, the addition of real-time glucose alarms, and prospective trend data can be advantageous in motivating and evaluating behavior change.

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## Introduction

Mounting evidence supports the role of tight glycemic control[1,2] with minimal glucose excursions in reducing the risk of diabetes complications.[3–7] The drive to improve glucose control places a burden on both patients and their health care providers (HCPs). Motivating behavior change can be challenging but it is an important component of helping patients achieve their diabetes care goals. Technology such as continuous glucose monitoring (CGM) can provide patients and HCPs with real-time, prospective, and retrospective data on glucose control. The increase in data can identify areas where glucose goals are not being met. CGM systems provide programmable alarms that can be used to alert the user when glucose rises above or drops below the programmed threshold, as well as prospective information, including the rate and direction of glucose change. These data provide immediate and retrospective feedback to the patient about how their glucose is affected by their behavior and therapy.

## About CGM Technology

Continuous glucose monitoring systems consist of three major components: (1) a sensor, which is inserted under

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**Abbreviations:** (BG) blood glucose, (CGM) continuous glucose monitor, (HCPs) health care providers

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the skin, and (2) a transmitter, which attaches to the sensor and sends data to (3) a receiver, which displays data. CGM systems do not measure blood glucose (BG), they measure glucose in the interstitial fluid. Rapid blood glucose changes may result in a 6- to 18-minute delay in interstitial glucose readings. About 6 minutes of the delay is due to a physiologic lag between blood and interstitial glucose levels, and up to 12 minutes of delay may be because of filters imposed on the glucose sensor to eliminate noisy readings.[8] CGM systems are currently approved for use as adjunctive technology to discrete blood glucose tests, meaning they do not replace the need for BG tests. In addition, CGM systems require a blood glucose meter for calibration. If an inaccurate BG result is entered as a calibration or if it is performed when the glucose is changing rapidly it can impact the accuracy of the CGM readings.

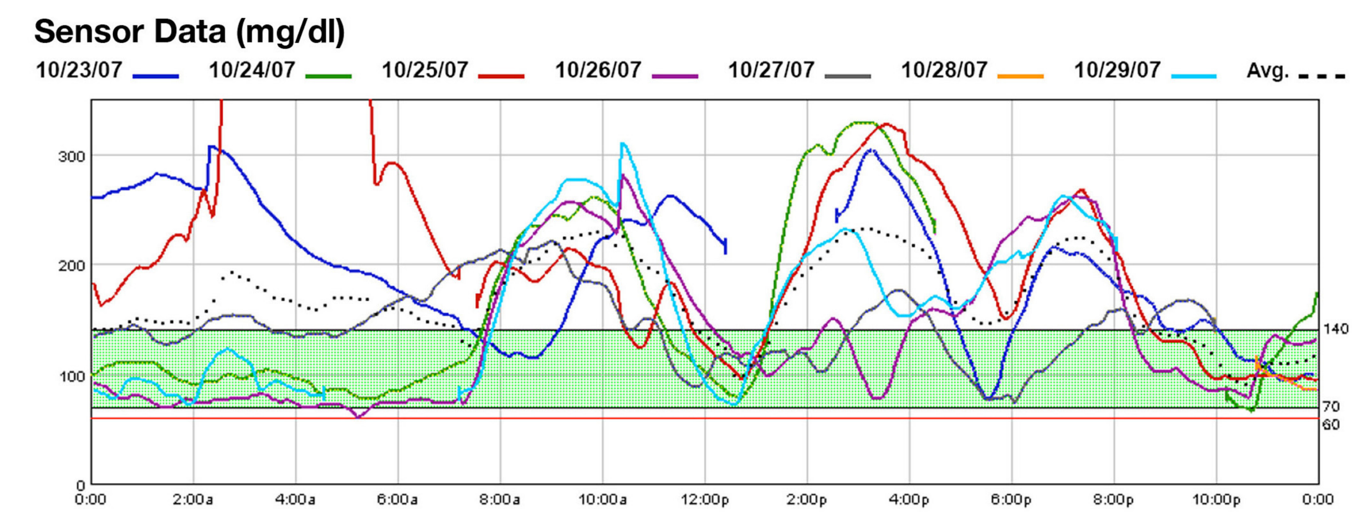
In addition to real-time glucose trend data and alarms, CGM systems offer both short- and long-term retrospective data. Without downloading data to a computer, CGM devices display short-term retrospective glucose data from the last few hours up to the last 24 hours depending on the system. CGM systems can also be downloaded to software programs that provide a variety of reports and statistics to analyze glucose trends (see **Figure 1**).

## How Can CGM Technology Help Motivate Behavior Change?

### *Using CGM Data in Real Time*

Glucose alarms, continuously updated glucose data, and short-term trend graphs on the device provide immediate feedback to the user on the effects of food, medications, exercise, stress, and other variables on glucose control. The instantaneous feedback increases the likelihood that the patients will take action to correct glucoses that are above or below their target when they are verified by BG tests. Patients can also utilize the trend information provided by on-device reports, as well as pending alarms to intervene and ideally prevent glucose from dropping below or rising above the threshold.

Real-time glucose alerts, especially those for low glucose, are an attractive feature of CGM technology. A study evaluating the impact of the Diabetes Control and Complications Trial findings on patients living with diabetes cited that fear of hypoglycemia was a barrier to improving glucose control in almost 70% of patients.[9,10] CGM alarms for actual or pending low and high glucose values are not perfect and should not be relied upon as the sole means for detecting glucose excursions. When used in conjunction with blood glucose tests, the use of




| | Tue Oct 23 | Wed Oct 24 | Thu Oct 25 | Fri Oct 26 | Sat Oct 27 | Sun Oct 28 | Mon Oct 29 | Average / Total |
|---|---|---|---|---|---|---|---|---|
| # Sensor Values | 263 | 221 | 285 | 288 | 264 | 15 | 210 | 1,546 |
| High SG (mg/dl) | 308 | 328 | 400 | 282 | 220 | 110 | 310 | 400 |
| Low SG (mg/dl) | 78 | 66 | 94 | 60 | 74 | 86 | 72 | 60 |
| Average SG (mg/dl) | 196 | 157 | 216 | 138 | 145 | 94 | 167 | 170 |
| Standard Dev. | 61 | 81 | 84 | 65 | 33 | 7 | 68 | 73 |
| MAD % | 25.2 | 8.9 | 25.9 | 30.8 | 23.4 | N/A | 19.6 | 23.4 |
| # Valid Calibrations | 7 | 5 | 7 | 6 | 4 | 1 | 4 | 40 |

**Figure 1.** Medtronic CareLink™ sensor daily overlay report. SG, sensor glucose; MAD mean absolute deviation.

CGM trend data and pending alarms offers the potential to reduce hypoglycemia while maintaining good glycemic control. The ability to use trend and projected glucose alarms to prevent hypoglycemia when possible is an exciting prospect. The timing and amount of treatment rendered to prevent hypo- or hyperglycemia should be tracked to identify patterns that may warrant lifestyle or medication adjustment.

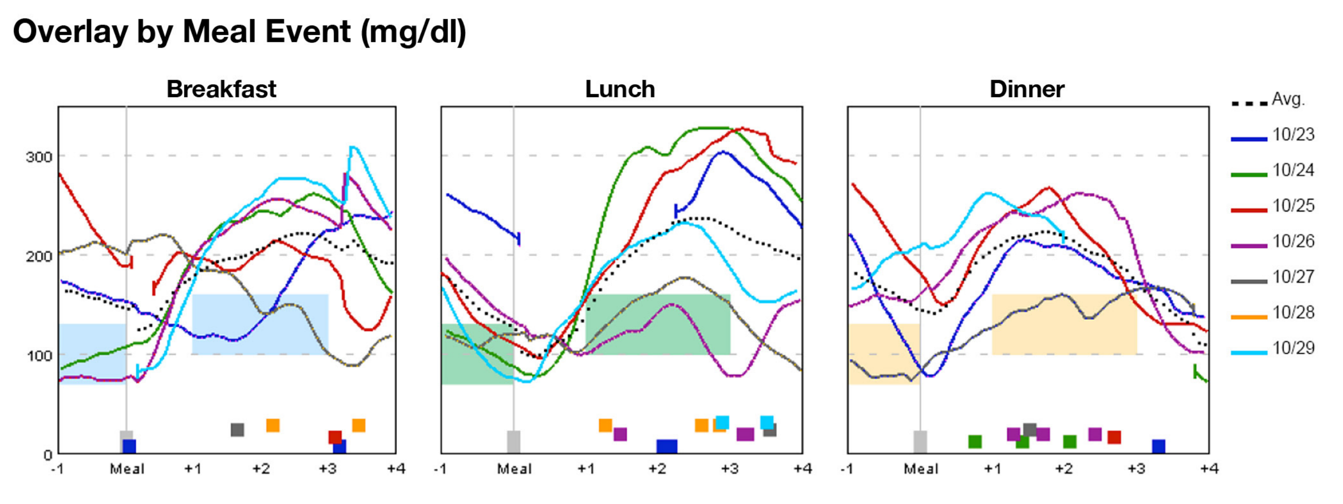
### *Using CGM Retrospectively*

Evaluation of retrospective trends is an important component of using CGM. Retrospective data can be used to identify consistent trends and make modifications to lifestyle and diabetes medications. Most CGM systems can all be downloaded to review retrospective glucose trends. Systems that offer event markers or integration with pump data provide additional information about the cause of the trend as shown in **Figure 2**. In this example the CGM and BG rose rapidly in the afternoon with no bolus likely caused by a missed meal bolus. The same system can align boluses given at different times within the morning, afternoon, and evening time frames to evaluate postprandial responses as shown in **Figure 3**.

## Expectations and Interactions

The combination of more complete retrospective data and the addition of prospective glucose data offered by CGM technology is still a relatively new concept in diabetes care. Access to so much information places patients in the position of having "naked" diabetes where almost all of their variability is not only identified but recorded. Taking a nonjudgmental approach and viewing glucose excursions as data that can be learned from and not personal failures can help give patients perspective.


**Figure 2.** Medtronic CareLink daily summary report.




| | Sleeping 3:00 AM - 6:00 AM | Before Breakfast | After Breakfast | Before Lunch | After Lunch | Before Dinner | After Dinner | Evening 11:00 PM - 3:00 AM | All Time Periods |
|---|---|---|---|---|---|---|---|---|---|
| Range | 100 - 150 | 70 - 130 | 100 - 160 | 70 - 130 | 100 - 160 | 70 - 130 | 100 - 160 | 100 - 150 | |
| Average SG | 167 | 155 | 205 | 146 | 212 | 162 | 209 | 125 | 170 |
| High SG | 400 | 282 | 276 | 262 | 328 | 272 | 268 | 400 | 400 |
| Low SG | 60 | 74 | 106 | 76 | 78 | 74 | 128 | 70 | 60 |
| Standard Dev. | 102 | 63 | 46 | 50 | 72 | 54 | 41 | 60 | 76 |
| # of Readings | 199 | 60 | 144 | 72 | 130 | 60 | 108 | 240 | 1,013 |

**Figure 3.** Medtronic CareLink overlay by meal report. SG, sensor glucose.

HCPs should help patients set realistic goals with a plan to achieve them and utilize CGM data to help evaluate their effectiveness. While not desirable, fluctuations in glucose are expected. Perfection is not a realistic goal given current technology and medications; continued improvement should be the benchmark for success.

## Patient Education

With all of the additional information that CGM provides it is important that both patients and HCPs have a good understanding of how to use data safely and effectively. Patients considering CGM should receive education about the technology itself as well as the impact of lifestyle, food, medications, stress, and other variables on glucose control. This includes information about the onset, peak, and duration of diabetes medications. Patients learning CGM should understand how lag time, calibration errors, and rapid changes in glucose can affect CGM data. CGM does not replace BG testing and should not be used as the only means of alerting patients to low or high glucose values. BG testing should be done as indicated, and additional CGM data and alerts may, in fact, prompt increased BG testing. In order to make continued improvements in glycemic control, education should emphasize periodic evaluation of retrospective trends. This will facilitate recognition of consistent patterns that may benefit from permanent regimen changes and may decrease the frequency of real-time alarms.

## Special Considerations for Hypoglycemia and Hyperglycemia

Patients should be taught to verify all CGM data and alarms with a meter BG before making treatment decisions. For high glucose values, patients need to take into account the insulin that is already present from previous insulin doses. If they do not take into account active insulin it places them at risk for subsequent hypoglycemia. This highlights the importance of educating patients on the onset, peak, and duration of all the medications they are using to manage their diabetes to prevent overcorrection and reduce the risk of hypoglycemia as a result of overcorrection.

## What CGM Research Tells Us about Behavior Change

Many studies on the use of real-time CGM demonstrated improved glycemic control as evidenced by a reduction in hemoglobin A1c or the percentage of time spent above or below the target range.[11–14] In two of these studies, an improvement in glycemic control occurred without guidance from the health care team.[11,12] In a study of DexCom's Seven® System with no guidance on the use of CGM, patients averaged a 21% reduction in the time spent <55 mg/dl, a 23% reduction in time >240 mg/dl, and a 26% increase in the time spent between 81 and 140 mg/dl.[11] Subjects using the FreeStyle Navigator® investigational CGM system for 20 days with no guidance on data use showed a 47% reduction in time spent <55 mg/dl,a 19% reduction in time spent 55–80 mg/dl, and a 19% reduction in time spent >240 mg/dl.[12] Both of these studies involved only a short duration (9 and 20 days) of access to real-time data.[11,12] The short duration of both studies does little to support the long-term impact of CGM use on glucose control. Both studies demonstrated the impact of real-time CGM data and alarms on improving glucose control and motivating change that resulted in an increased amount of time spent euglycemic.

A randomized study on the use of the Medtronic Guardian® REAL-Time in both adults and children with type 1 diabetes using intensive insulin management in poor glycemic control (hemoglobin A1c ≥8.1%) showed improved hemoglobin A1c in patients using real-time CGM. At baseline, all subjects were testing BG an average of 4.6 to 5.1 times per day. With the addition of CGM, half of the subjects reduced hemoglobin A1c by at least 1%, and a quarter of subjects reduced hemoglobin A1c by at least 2%. This study showed no overall change in the total daily dose of insulin, yet many subjects made changes in their food, lifestyle, and treatment based on real-time data.[14] A pilot trial of the FreeStyle Navigator investigational CGM system in children with type 1 diabetes was performed by the Diabetes Research in Children Network.[14] In this study, 30 children and their families used the FreeStyle Navigator continuously for 3 to 6 months. They were provided with instructions on how to use real-time data and software to view retrospective trends at home. At baseline the mean hemoglobin A1c was 7.1% with 52% of the values in the target range of 71 and 180 mg/dl. After 13 weeks of real-time CGM use the mean hemoglobin A1c was 6.8% and 60% of the values fell within the target range. Over 70% of subjects and parents found that the CGM made it easier to adjust insulin, made them more sure about diabetes decisions, clarified the effect of lifestyle on glucose levels, and identified glycemic patterns they were not previously aware of.[15] Both of these studies provided guidance and recommendations on how to adjust therapy and lifestyle in response to data and support the value of CGM data in improving glucose control.[14,15] Long-term studies on how to best utilize CGM technology and maximize the impact of the technology on glucose control are still needed.

While there is little published on the specific changes made to diabetes management as a result of CGM use, anecdotal experience with the technology has taught the author many things.

- It is important to balance real-time responses with retrospective analysis of data.
- Patients tend to tire of responding to alarms if they do not have the tools to make long-term changes to prevent their occurrence.
- CGM is a great addition to standard diabetes care but it is not a replacement. It is also not a closed loop. To improve glucose control patients must be willing to make changes based on the trends.
- The temptation to overcorrect is great with real-time alarms, and proper education about insulin pharmacodynamics is key.
- CGM can help fine-tune the appropriate timing of meal boluses and the composition of meals to minimize glycemic variability.
- Retrospective trend information is helpful in identifying the impact of exercise, stress, and different activities on glucose control and in determining appropriate insulin doses for each situation.

## Conclusion

The choice to use CGM should be made collectively by the health care team and the patient. Use of CGM is a team effort that is best utilized when both the patient and the health care team are knowledgeable about the technology and its limitations. Teaching patients how to interpret data from CGM monitoring is an important step in empowering patients and motivating behavior change. By combining real-time glucose information and associated prospective trend data with retrospective analysis, CGM provides considerably more information to the patient than has previously been available. If patients are not given the tools and education they need to modify their therapy in response to the trends identified by the CGM system and confirmed by the BG meter, then CGM may become just a means of alerting people to times they have not achieved their goals. Better education and more research on the type of education and tools needed to interpret data will enable patients to work toward improving their control by continually modifying their behavior and diabetes therapy in response to data.

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