Optimizing Diabetes Care With the Standardized Continuous Glucose Monitoring Report

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Why Is Continuous Glucose Monitoring Considered an Improvement (or Necessary) in Diabetes Care?

Continuous glucose monitoring (CGM) technology has brought about a paradigm shift in defining glycemic control in diabetes management and research. A1C and blood glucose monitoring have been widely accepted measurements in diabetes care, yet each has limitations in its clinical utility. A1C is established as an indicator of population health and long-term risk for microvascular complications but is less useful in personalizing glycemic goals, guiding therapy changes, or understanding patterns of glycemic excursions (1). Furthermore, A1C has limitations in accuracy and reliability in the context of hemoglobinopathy, anemia, iron deficiency (2), pregnancy (3), and racial differences (4).

With increasing evidence regarding the relationship of glycemic variability with micro- and macrovascular risks, the definition of diabetes "control" is changing, and that change is bringing opportunity to tailor therapy decisions that truly improve outcomes (5).

Self-monitoring of blood glucose (SMBG) has been an important tool for calculating insulin doses and gaining an understanding of daily glucose patterns. SMBG provides the glucose level at a single point in time without the context of past or future directionality and carries a burden of pain and inconvenience for patients, further limiting the amount of data available to analyze (1). The accuracy of an SMBG reading is dependent on the user's testing technique and on the accuracy of the glucose meter itself; many glucose meters do not meet accuracy standards (6).

Although CGM provides a wealth of information that A1C testing and SMBG lack, adoption of and persistence with this technology have been limited (7). However, with the arrival of systems for personal use (real-time use for patients) and professional use (blinded for patients with retrospective analysis by clinicians) that are more affordable and user-friendly (i.e., that do not require SMBG calibration and are indicated as an alternative to SMBG for making treatment decisions), CGM use is growing among patients with diabetes (8).

What Is a Standardized CGM Report?

A key contributor to clinicians' reluctance to embrace CGM, particularly in the primary care setting, has been the large amount of data to interpret without a standardized report format to allow for efficient clinical application (7). To address this need, the Leona M. and Harry B. Helmsley Charitable Trust supported an expert panel to begin the work of standardizing CGM information in 2017. Since then, the work has continued and produced a series of consensus statements. The latest is an international consensus statement developed during the 12th Advanced Technologies & Treatment for Diabetes meeting in Berlin, Germany, in February 2019 (9) and has been widely endorsed by professional organizations such as the American Diabetes Association, the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, and the Endocrine Society. These consensus statements support systematic data evaluation and individualized clinical targets, broadening the adoption and utility of an ambulatory glucose profile (AGP) data graph and a standardized CGM report. The standardized CGM report, recommended to be compiled from 14 days of CGM data (10) and at least 70% of CGM data captured, consists of three sections: a summary, the AGP, and a daily glucose summary (7).

The summary (Figure 1) is a statistical report of the average glucose, time in range (TIR), coefficient of variation (CV), and standard deviation (SD). TIR provides numerical values to compare the glycemic profile over time and is more actionable than A1C values alone. The

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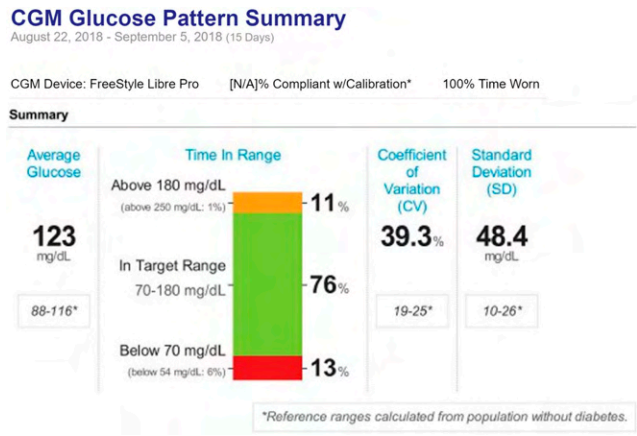


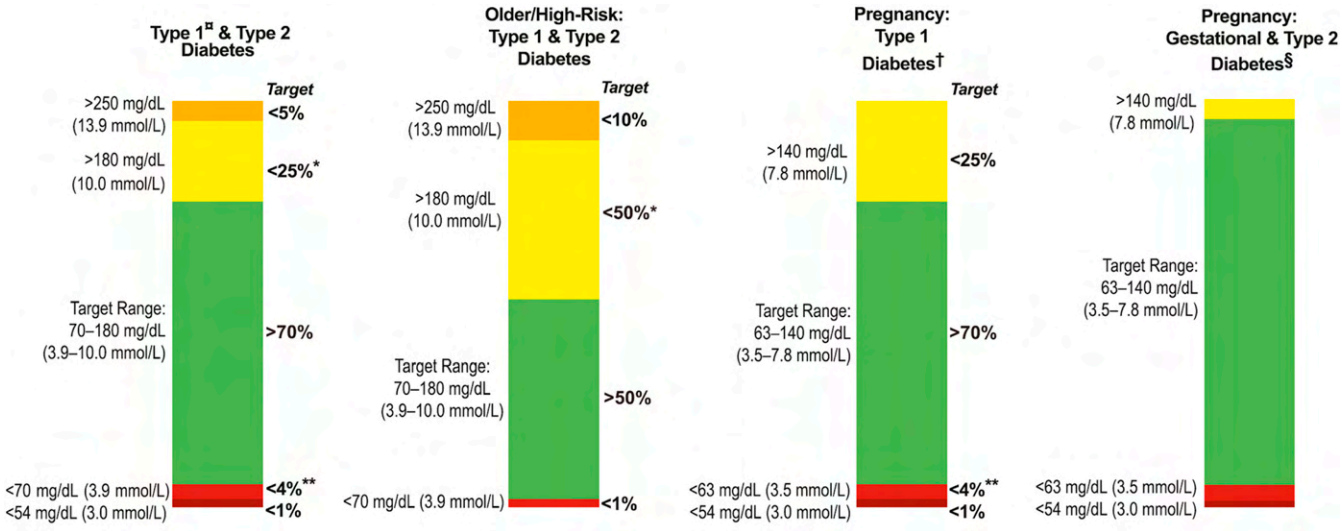
FIGURE 1 Summary, the first of three sections within the standardized CGM report.

glucose target range for most nonpregnant individuals with type 1 or type 2 diabetes is 70–180 mg/dL (9). Increasing evidence has shown correlations of the percentage of TIR of 70–180 mg/dL to diabetes complications (11,12) and A1C (13,14).

The goal for most nonpregnant patients with diabetes is to keep TIR to >70% and to minimize percentages of time below range (TBR) and time above range (TAR). TIR of 70% correlates to an A1C of ~7%, and each 10% increase in TIR corresponds to a decrease of ~0.5% in A1C (13,14). Priority should be given to minimizing time in hypoglycemia (goal: <4% of time at <70 mg/dL) and eliminating time at <54 mg/dL (goal: <1% of time at <54 mg/dL). Just as A1C goals are adjusted for certain populations, TIR goals are recommended to be individualized according to factors such as a patient's age, as shown in Figure 2 (9).

CV and SD are measures of glucose variability, and it is desirable for them to be as low as possible; CV should be <36% (9,15), and SD should be less than the average glucose divided by 3 (16). Mean glucose must be considered when interpreting the clinical relevance of SD, whereas CV may be considered a "relative SD" (CV = SD/mean), making it efficient to interpret.

The AGP (Figure 3) is a graph visualizing all glucose data collapsed and displayed into a modal day (24-hour) view. The target glucose range in the AGP can be individualized depending on the current patient glucose range goals. This visualization is a powerful tool to help clinicians and patients understand the predominant pattern of glycemia, discouraging the tendency to focus on outlier glucose values. In the AGP, the median glucose is represented by the single dark blue line in the center and reflects the pattern of glycemic stability over the course of the day. The darker blue shaded region, delineated by the 25th and 75th percentiles, is called the interquartile range (IQR) and represents the middle 50% of the glucose values. The lighter blue shaded region, delineated by the 10th and 90th



¤ For age <25 yr., if the A1C goal is 7.5%, then set TIR target to approximately 60%. (See *Clinical Applications of Time in Ranges* section in the text for additional information regarding target goal setting in pediatric management.)
† Percentages of time in ranges are based on limited evidence. More research is needed.
§ Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed. Please see *Pregnancy* section in text for more considerations on targets for these groups.
* Includes percentage of values >250 mg/dL (13.9 mmol/L).
** Includes percentage of values <54 mg/dL (3.0 mmol/L).

FIGURE 2 CGM-based targets for different diabetes populations. Reprinted with permission from ref. 9.

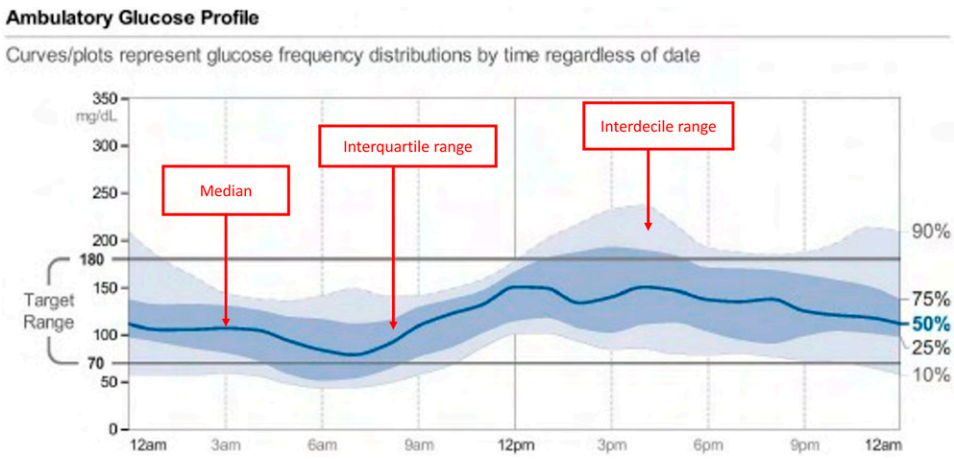


FIGURE 3 AGP, the second of three sections within the standardized CGM report.

percentiles, is called the interdecile range (IDR) and represents 80% of glucose values. The IQR and IDR are a visual representation of glycemic variability and provide insight into the consistency of patient behaviors (7).

The daily glucose summary (Figure 4) shows the glucose tracing from each individual day along with average glucose and TIR data. This data representation allows clinicians to discuss day-to-day events with patients to identify the effects of patient behaviors (e.g., eating and exercise) and medications and to develop action plans to improve glucose control.

How Is CGM Used in Clinical Practice? A Case Study

This case study of an actual patient will demonstrate the recommended approach (17) to using the CGM standardized report and illustrate its clinical value.

Presentation

D.B. is a 71-year-old man with type 2 diabetes who is taking metformin 750 mg twice daily, liraglutide 1.2 mg daily, and insulin glargine 30 units daily at bedtime. His A1C ranges from 6.4 to 6.9%. He performs SMBG once daily in the morning while fasting, and his

FIGURE 4 Daily glucose summary, the third and final section within the standardized CGM report.

FIGURE 5 Summary from the standardized CGM report of D.B.'s professional CGM study.

results are in the range of 80–110 mg/dL. He feels well overall and denies any symptoms or episodes of hypoglycemia.

Because his A1C is on the lower side of his goal and given his advanced age and the fact that he is taking insulin, the clinician asked more detailed questions regarding possible hypoglycemia. He reported occasionally waking up with a headache, sweating, and feeling uncomfortable, all of which he related to "having bad dreams."

Evaluation

Based on his symptoms and the clinician's suspicion of nocturnal hypoglycemia, a professional (blinded) CGM study was completed. The clinician obtained the CGM report and interpreted the results in the following stepwise manner.

1. Evaluate the quality and quantity of data—the number of days and percentage of the time the device was worn (Figure 5). For D.B., data were captured throughout 14 days, and the sensor was worn 100% of the time, achieving targets of 14 days and >70% of time worn.
2. Review the summary section (Figure 5). D.B.'s average glucose was 123 mg/dL, which correlates to an A1C of ~5.9%. His TIR (70–180 mg/dL) was 76%, his TAR (>180 mg/dL) was 11%, and his TBR (<70 mg/dL) was 13%. The utmost priority is to minimize or eliminate the TBR given the nature of acute risk of hypoglycemia. The next step would be to lower the TAR. D.B.'s glycemic variability data showed a CV of 39.3% and an SD of 48.4 mg/dL. The goal would be CV<36% and SD less than the average glucose divided by 3 (123 mg/dL/3 = 41 mg/dL).
3. Inquire about the patient's daily routine (e.g., times of sleep, meals/snacks, medications, and exercise) and mark these events on the AGP to help you and the patient understand the correlation of glycemic patterns to behaviors (Figure 6). D.B.'s meals, medications, and exercise were noted.

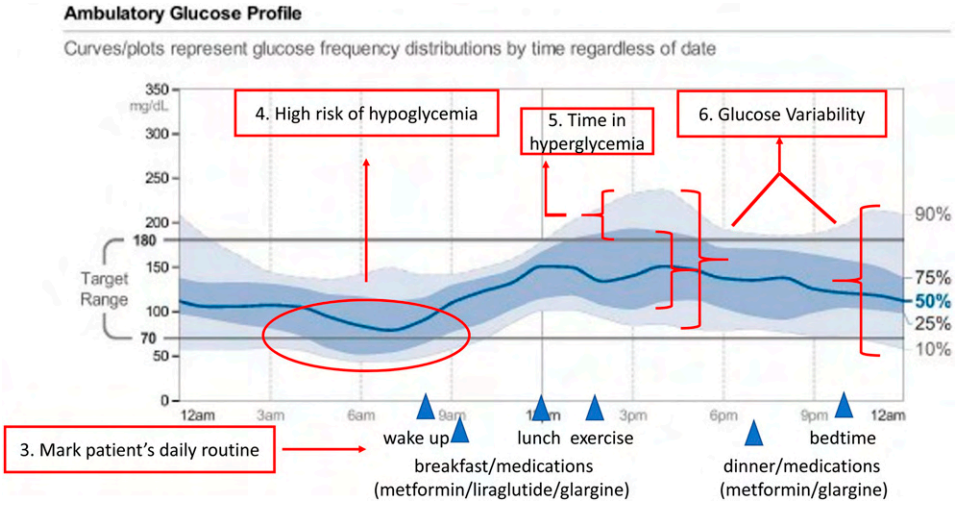


FIGURE 6 AGP from the standardized CGM report of D.B.'s professional CGM study.

4. Identify the times with highest incidence and risk of hypoglycemia (Figure 6). For D.B., the highest risk was overnight, especially between 4:00 and 8:00 A.M., likely because he was injecting excess basal insulin. Confirm these findings with the daily glucose summary (Figure 7), on which frequent nocturnal hypoglycemia is shown in red. The clinician made an action plan to lower the dose of basal insulin (insulin glargine) to 25 units and move the injection timing from every night at bedtime to every morning.
5. Identify TAR (Figure 6). For D.B., the median line stayed within the target range, and TAR was only

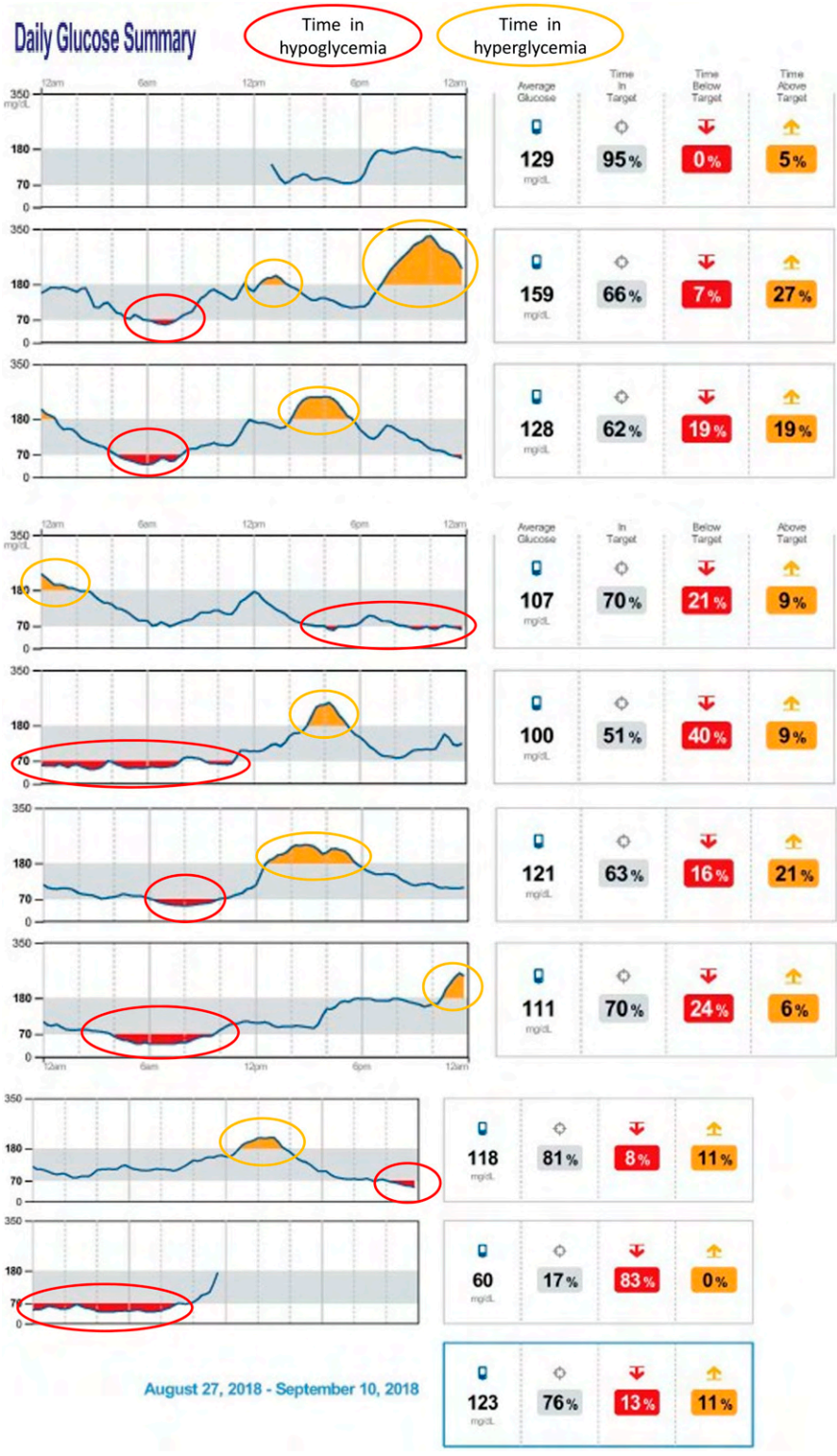


FIGURE 7 Daily glucose summary from the standardized CGM report of D.B.'s professional CGM study.

11%. No action was needed to address hyperglycemia. Confirm this finding with the daily glucose summary (Figure 7). For D.B., some postprandial hyperglycemia showed in yellow, but overall his time above range was acceptable.
6. Identify the times with high glucose variability indicated by wide blue shaded regions (Figure 6). Look for areas with dark blue (25th to 75th percentile) and light blue (10th to 90th percentile) shades. D.B. had wider glycemic variation after lunch and close to bedtime, but overall, he was doing well. (His CV and SD from the summary section were also reasonable.) Confirm this finding with the daily glucose summary (Figure 7). This view showed that D.B. could further improve his glycemic variability by lowering his postmeal hyperglycemia (ideally by reducing his carbohydrate intake) and by avoiding nocturnal hypoglycemia.
7. Share a copy of the report and interpretation with the patient. The clinician gave D.B. a copy of his report and retained a copy in his patient chart to compare with future CGM data reports to evaluate the effectiveness of therapy or behavior changes over time.

Is CGM Covered by Insurance, and How Do Clinics Bill for It?

Coverage for personal and professional CGM has improved since the inception of the technology and continues to do so. Medicare now covers therapeutic CGM (CGM systems that can be used for making therapeutic decisions without SMBG confirmation) for patients who: *1*) are diagnosed with type 1 or type 2 diabetes, *2*) require intensive insulin therapy (three or more injections per day or insulin pump therapy), and *3*) currently perform SMBG four or more times per day (18). Commercial and Medicaid coverage rules vary by plan and geographic region.

CGM sensor placement and data interpretation are both billable services. Sensor placement (Current Procedural Terminology [CPT] codes: personal CGM 95249, professional CGM 95250) can be performed by health care personnel, including physicians, physician assistants (PAs), advanced practice registered nurses (APRNs), nurses, pharmacists, certified diabetes educators, or medical assistants if it is within their scope of practice. Sensor placement codes must be billed under the physician, PA, or APRN name. Sensor placement for a personal CGM (CPT code 95249) can be billed at the time of sensor placement and can only be billed once for the duration that the patient owns the data receiver. Professional CGM sensor placement (CPT code 95250) should be billed when the sensor is removed rather than when it is being placed and can be billed every time a professional CGM study is performed up to once per month (19).

CGM interpretation (CPT code 95251 for both personal and professional CGM systems) can be billed with a minimum of 72 h of data and must be billed by a physician, PA, or APRN. A face-to-face visit is not required to bill for data interpretation; patients can drop off or ship their professional CGM sensor to the clinic for download, and clinicians may easily access personal CGM sensor data uploaded into Cloud-based applications. Data interpretation can be communicated with patients either by phone or e-mail. If data interpretation is done during a face-to-face visit, regular evaluation and management (E/M) CPT codes can be billed with a modifier −25 if significant E/M service has been performed as well (19).

Summary

The standardized CGM report allows for individualized assessment and guidance in diabetes management that is efficient for clinicians and meaningful to patients. Patients can see the effects of medications, food, exercise, and other factors on their glucose levels. Easy to interpret information and reports are available at any time to patients who use personal CGM devices for ongoing behavioral feedback and improved engagement. Furthermore, benchmarks for diabetes management goals by professional organizations are rapidly transitioning to incorporate metrics beyond A1C, including TIR (10). The standardized CGM report has widened the application of personal and professional use of CGM to primary care and supports the movement of CGM toward becoming the new standard of care for diabetes management.

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DUALITY OF INTEREST

J.H.C. has served on an advisory board for Sanofi. M.S.O is employed by Abbott Diabetes Care. No other potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

The case study was provided by J.H.C. J.H.C. and M.S.O. researched, wrote, and edited the manuscript and are co-guarantors of this work and, as such, had full access to all the data presented and take responsibility for the integrity of the review.

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