Beyond A1C—Standardization of Continuous Glucose Monitoring Reporting: Why It Is Needed and How It Continues to Evolve

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Continuous glucose monitoring (CGM) systems are becoming part of standard care for type 1 diabetes, and their use is increasing for type 2 diabetes. Consensus has been reached on standardized metrics for reporting CGM data, with time in range of 70–180 mg/dL and time below 54 mg/dL recognized as the key metrics of focus for diabetes management. The ambulatory glucose profile report has emerged as the standard for visualization of CGM data and will continue to evolve to incorporate other elements such as insulin, food, and exercise data to support glycemic management.

Continuous glucose monitoring (CGM) technology has evolved since it was first introduced about 20 years ago. Current systems include both real-time and intermittently scanned CGM devices. With both, glucose values are displayed for users to see their current glucose level and glycemic trend to assist in glucose management. Retrospective review of CGM data also is extremely valuable for quantifying the amount of time that glucose levels are in, above, or below the target range and the degree of glycemic variability, as well as for visualizing glucose patterns to enhance ongoing glucose management decisions.

For retrospective review, 10–14 days of CGM data provide a reasonably good representation of a patient's time in different glucose ranges, provided that there have been no major changes in diabetes management (e.g., the addition of a new glucose-lowering medication) or in life events affecting the patient's glycemia during this time period (1). Ten days of CGM data are usually sufficient for an estimate of mean glucose, time in the target range (i.e., 70–180 mg/dL), and time in hyperglycemia; however, ≥14 days of data may be needed to estimate hypoglycemia and glucose variability if glucose levels have considerable fluctuation.

As CGM technology has advanced, it has become in many cases the first advanced technology prescribed for diabetes management (before an insulin pump), and comparable outcomes are achieved in type 1 diabetes when CGM is used in conjunction with a pump or multiple daily injections of insulin (2). For the management of type 1 diabetes, CGM now should be considered part of standard care. Thus, there is an ever-growing need for standardization of glucose metrics and data visualization.

CGM Glucose Metrics

Because CGM use has expanded to the degree that it could be considered part of standard care, particularly in type 1 diabetes, the need for standardization of glucose metrics and data visualization has become more imperative. Several organizations have published consensus statements on the role of CGM and specific metrics to use for assessing overall glycemic management, hyperglycemia, hypoglycemia, and glycemic variability, and a conference was held with representatives of all organizations to reach a consensus on these matters (3–5). The American Diabetes Association's *Standards of Medical Care in Diabetes—2021* recommends CGM for all adults and children with type 1 or type 2 diabetes who are receiving insulin (6).

Standard metrics that were established by consensus include five ranges (>250, 181–250, 70–180, 54–69, and <54 mg/dL) and certain other metrics (i.e., mean glucose and coefficient of variation [CV] and SD [measures of glycemic variability) (5). The percentage time in the range of 70–180 mg/dL is now commonly known as "time in range" (TIR). It is largely a measure of hyperglycemia in that, for most patients with diabetes, >90% of time outside of this range is >180 mg/dL. As such, TIR is highly correlated with the hyperglycemia metrics and with mean glucose (7). With respect to hypoglycemia, time spent with glucose <54 mg/dL has emerged as the most relevant CGM metric (8). Preventing glucose levels in the range of 54–69 mg/dL is

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https://doi.org/10.2337/ds20-0090

important to minimize the risk of even lower glucose levels, but it is glucose levels <54 mg/dL that have been demonstrated to have deleterious physiologic effects, including the development of impaired glucose counterregulation and reduced hypoglycemia awareness (9–11), which has been associated with an increased risk of severe clinical hypoglycemic events (12); cognitive function impairment (13–16); an increase in cardiac arrhythmias (mortality) (17-22); adverse effects on quality of life, including sleep (17-22); reduced work productivity (23,24); and impaired driving, with an increase in car accidents (25–27). Additionally, CGM-measured hypoglycemia has been associated with a subsequent risk of a severe hypoglycemia event (28).

With respect to the two metrics of glycemic variability, SD is highly correlated with mean glucose, and CV is associated with the amount of hypoglycemia (29–31). Thus, in most cases, neither variability metric provides information that is impactful for diabetes management, since actionable management changes are to reduce hyperglycemia, which will decrease mean glucose and SD, and to reduce hypoglycemia, which will decrease the CV.

Among the eight standard CGM metrics, then, overall glucose control largely can be defined by one measure of hypoglycemia and one measure of hyperglycemia. Time <54 mg/dL clearly is the important metric for hypoglycemia. TIR has emerged as the preferred hyperglycemia metric instead of time >180 mg/dL or mean glucose.

Surveys have shown that TIR resonates with people with diabetes and is valued as important (32). There are several reasons for this finding. First, a change in the percentage of time in a range, which can be described in minutes per day, is more readily understood than a change in glucose level, which is expressed in mg/dL. Second, improvement represented by an increase in a metric is more motivating than improvement represented by a decrease (as is the case with mean glucose and time >180 mg/dL). Finally, seeing a picture of one's usual daily pattern of glucose values throughout the day and night is much more informative and likely more motivating to make needed adjustments in medications or lifestyle than just having a single number (A1C), which represents the percentage of one's glucose attached to hemoglobin in the red blood cells.

CGM Metric Targets

In addition to consensus having been achieved for a standard set of metrics, consensus also exists for goals or targets for these metrics (Table 1) (33). For TIR, a goal of >70% has been established for both type 1 and type 2 diabetes and equates on average with an A1C of ~7.0%.

TABLE 1 Targets for CGM Metrics

CGM Metric	Target, %
TIR (70–180 mg/dL)	>70
Time >180 mg/dL	<25
Time >250 mg/dL	<5
Time <70 mg/dL	<4
Time <54 mg/dL	<1

Targets may differ for *1*) older adults with diabetes or those considered at high risk for hypoglycemia, for whom a lower target may be the goal, and *2*) pregnant women with diabetes, for whom the target may be 70% of values between 63 and 140 mg/dL.

Exceptions are for older adults with diabetes and those at high risk for hypoglycemia, for whom a lower target may be the goal, and for pregnant women with diabetes, for whom the target may be >70% of values between 63 and 140 mg/dL (7,34).

It is recognized, however, that many adults and children with diabetes have a TIR so far below this level that >70% is an unrealistic goal. As a result, in clinical care, emphasis should be placed on incremental improvements in TIR, with a 5% increase being a reasonable goal (33). Using Diabetes Control and Complications Trial (DCCT) data with standardized blood glucose measurements performed on 1 day every 3 months, Beck et al. (35) have shown that, for every 5% higher TIR, the risk of retinopathy was decreased by 22% and the risk of microalbuminuria by 15%, and for every 10% higher TIR, the risk decreases were 39 and 29%, respectively.

For time <54 mg/dL, the consensus target is <1%.

CGM Metrics and A1C

As CGM use has become widespread, there has been greater recognition of the limitations of A1C and the frequent discordance between laboratory-measured A1C and expected A1C based on mean glucose (36). Numerous studies have shown that there is a wide range of possible mean glucose levels for a given A1C level, meaning that for some people with diabetes, the laboratory-measured A1C may be an underestimate of mean glucose, and for others, it may be an overestimate. It is presumed that the discordance is often the result of red blood cell life span or other nonglycemic factors. The discordance is reflected in the correlation between mean glucose (or TIR) being only about 0.70 (7). Although this correlation may seem high, we would expect the correlation to be substantially higher if A1C was solely reflective of the level of glucose control.

Fabris et al. (37) demonstrated that, when hemoglobin glycation was modeled by a first-order differential equation driven by TIR, the A1C level estimated from TIR tracked closely with the laboratory-measured A1C, with the correlation between TIR and A1C increasing from about 0.70 to >0.90 (37). This analysis is important in terms of being able to extrapolate the strong association between A1C and vascular complications to also apply to CGM metrics of TIR and mean glucose.

An argument for continuing to rely on A1C for diabetes management has been that the level of A1C is associated with the risk for development of chronic diabetes complications. However, as CGM use has become more widespread, there are increasing data demonstrating an association between TIR and vascular complications. These studies primarily have been cross-sectional (38–44), although a recent study demonstrated the association of TIR and subsequent all-cause and cardiovascular disease mortality during median follow-up of 6.9 years (41). Additionally, the aforementioned analysis of DCCT data demonstrated a strong association between TIR and the development of microvascular complications (35).

In certain respects, A1C is a surrogate measure for mean glucose. Its availability had a transformative impact on diabetes management more than 25 years ago, long before CGM was available, and it became the gold standard for assessing hyperglycemia exposure over a 3-month period. Measurement of A1C to assess glucose control is particularly valuable for people with diabetes who are not using CGM. However, for those using CGM, the value of A1C, when the actual glucose concentrations can be continuously measured, must be questioned. Eventually, as CGM use becomes more readily available, particularly for people with type 2 diabetes, reliance on A1C may lessen. Until then, when CGM is available, there may be value in estimating A1C from CGM. This estimate of A1C from mean glucose is now known as the glucose management indicator (GMI) (45). This point was emphasized in a recent commentary by Battelino and Bergenstal (46) stating that, as we move from the A1C management era to the CGM management era, the GMI can be considered a bridge between A1C and TIR for clinical management.

Visualization of CGM Data

In using CGM to optimize diabetes management, the information available from CGM goes well beyond the metrics representing the amount of time in the different ranges. Viewing the pattern of glucose levels over a 24-hour day provides insights into when hyperglycemia and hypoglycemia tend to occur that are extremely valuable for adjusting basal and bolus insulin regimens. For many years, there was no standardized format for displaying CGM data irrespective of the CGM device, which likely in part stifled adoption of CGM by clinicians (47). Establishing common reporting metrics has helped substantially, and a standard format for displaying CGM data aggregated over a number of days has emerged as the ambulatory glucose profile (AGP) (46). The AGP was developed by Mazze et al. (48) in 1987 for use with self-monitoring of blood glucose data from glucose meters and was later refined for CGM data when Mazze joined the International Diabetes Center in Minneapolis, MN. The AGP gained traction in 2012, when Bergenstal et al. (49) of the International Diabetes Center held and then reported on the first CGM metrics and visualization expert panel (supported by the Leona M. and Harry B. Helmsley Charitable Trust), at which there was strong support to move to a standardized approach to the presentation of CGM data. Clinicians and researchers refined the AGP report with input from panel members, as well as industry and U.S. Food and Drug Administration regulatory observers. The expert panel consensus was presented to CGM manufacturing company representatives who, in subsequent years, began to incorporate the AGP into their CGM systems' reports.

The AGP has continued to evolve as there has been a coalescence of many different groups into an international consensus on refining CGM metrics and nomenclature. The core features of the AGP report (Figures 1 and 2) include a stacked bar showing the percentages of time in the different ranges specified in Table 1, the GMI, and a graphical display showing the distribution of glucose concentrations over each hour of the day. The distribution is depicted with a median line and the interquartile range (25th and 75th percentiles), which provides at a glance a sense of the patient's glycemic control and variability throughout the day, plus outlier cloud lines representing the 5th and 95th percentiles. The CGM metrics are useful as an overall summary of glucose levels and facilitate a quick assessment of the clinically important balance between TIR and time below range, while the graphical display is useful for identifying times of the day in which hypoglycemia or hyperglycemia tends to occur to target changes in diabetes management.

Future Directions

The AGP has undergone numerous enhancements during the past several years, but these are just a starting point for expanding this approach more broadly into diabetes management. In the next several years, we can expect the integration of insulin data from pumps and smart pens, as well as meal and exercise information (50). These additional

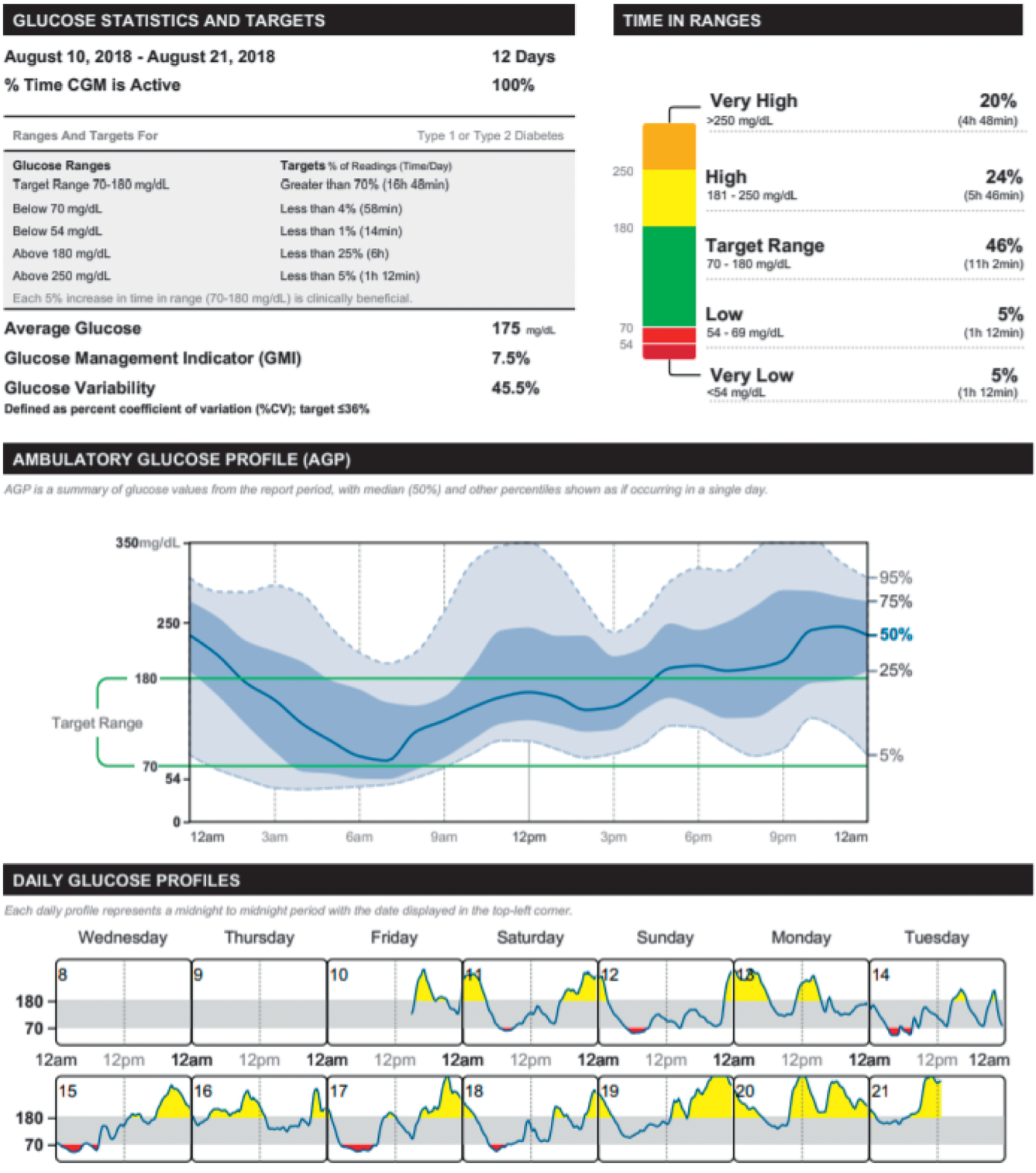

FIGURE 1 Case 1 AGP report interpretation. **Patient history:** Type 2 diabetes on metformin 1,000 mg twice daily, once-weekly glucagon-like peptide 1 receptor agonist, and 80 units insulin glargine at night. **Quick analysis:** *Panel 1*. Ask: Is action needed? Answer: Yes, both TIR and time below range (TBR) are not at target. TIR = 46% (target >70%); TBR (Low + Very Low) = 10% (target <4%); and TBR (Very Low) = 5% (target <1%). *Panel 2*. Ask: Where is action needed? Address hypoglycemia first. Note that from 4:00 to 8:00 a.m., 25% of values are <70 mg/dL, and from 3:00 to 6:00 a.m., 5% of values are <54 mg/dL. Note the classic "stair-step" pattern of postmeal elevations associated with overbasalization (continued titration of basal insulin without attaining glycemic targets). *Panel 3*. This graphic representation of data confirms low and high glucose occurring on both weekends and weekdays. **Plan:** Reduce basal insulin (we went to 36 units of glargine) and add premeal rapid-acting insulin (14 units at breakfast, 10 units at lunch, and 12 units at dinner). Also, work on consistency of food intake and exercise to address the considerable glucose variability.

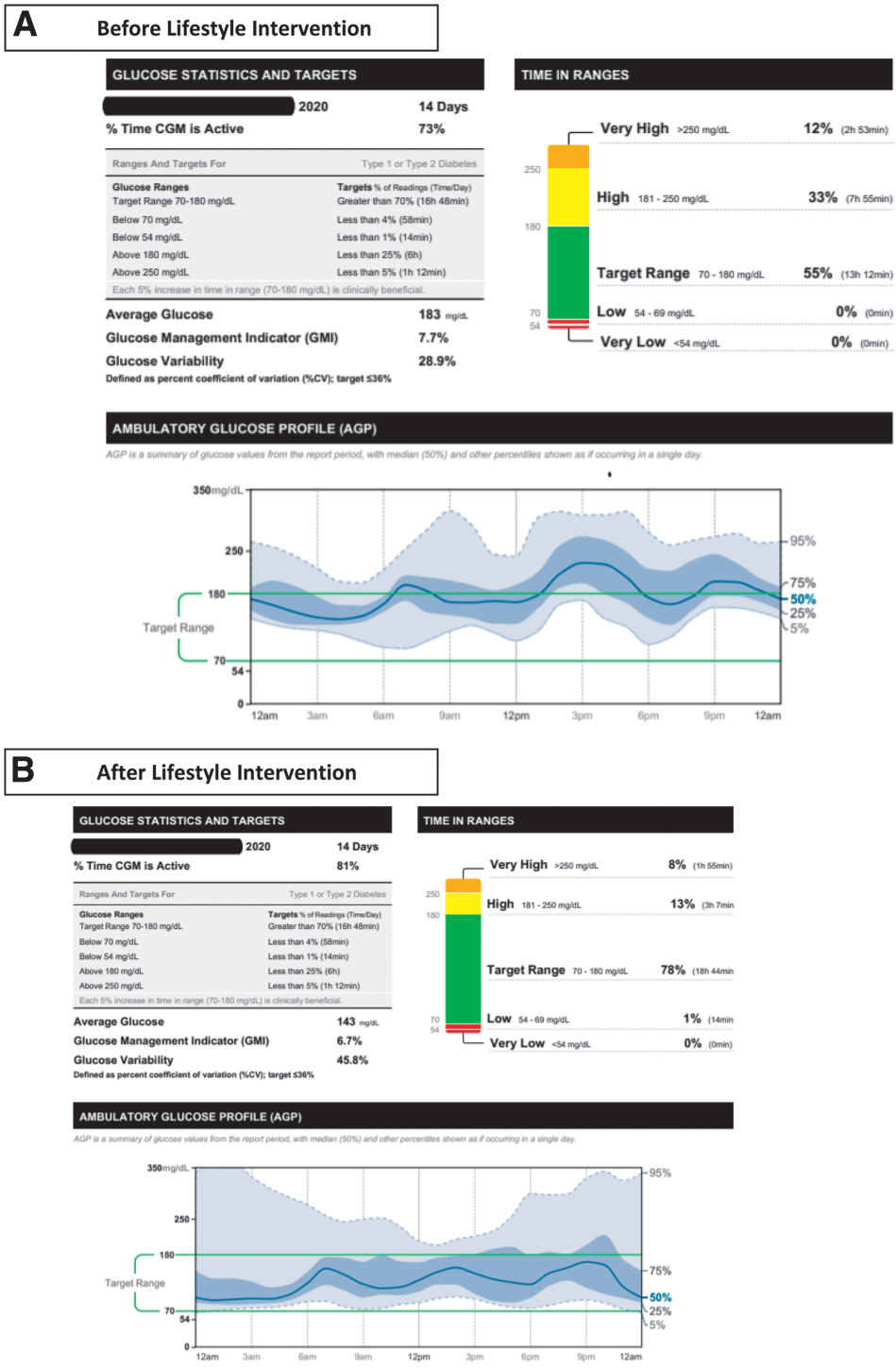

FIGURE 2 Case 2 AGP report interpretation before and after lifestyle intervention. **Patient history:** Type 2 diabetes with history of cardiovascular disease on metformin 1,000 mg twice daily and once-weekly glucagon-like peptide 1 receptor agonist. *A*) Initial AGP before lifestyle intervention. **Quick analysis:** *Panel 1*. Ask: Is action needed? Answer: Yes, TIR = 55% (target >70%), TBR = OK. *Panel 2*. Ask: Where is action needed? The entire glucose curve needs to shift down, and each postmeal excursion needs to be reduced, particularly after lunch. **Plan:** Initiation of a basal insulin was considered to shift the glucose curve down or the addition of a sodium–glucose cotransporter 2 inhibitor to minimize glucose excursions, but the patient wanted to try changing food intake. The patient was given the International Diabetes Center's CGM Lifestyle Choices guide (http://www.agpreport.org/agp/learning). *B*) Follow-up AGP after lifestyle intervention. Follow-up AGP was markedly improved. TIR increased from 55 to 78% with no hypoglycemia of concern. thepatient stated that he stopped drinking sugar-containing beverages (particularly at lunch), used the plate method of meal planning, and increased his daily walking, demonstrating that, with some guidance and support, CGM can facilitate helpful lifestyle changes.

enhancements will set the stage for incorporating decision-support tools using artificial intelligence to identify times of the day during which hyperglycemia or hypoglycemia tend to occur and provide additional guidance to patients and health care providers about how to optimally manage glucose levels.

More work is needed to fill the pressing need to standardize the incorporation of the AGP into electronic health records for ready access by providers at the time of a clinic visit, whether in person or virtual. The coronavirus disease 2019 pandemic has demonstrated the value of virtual telemedicine visits and has underscored the importance of ready access to CGM glucose data presented in a standardized format for review by health care providers and patients during virtual visits. Finally, striking a balance between comprehensive analysis with decision support and the need for a clear, simple understanding of the next steps to take to best address the needs of each person with diabetes is paramount.

Summary

Great advances have been made in CGM technology. CGM should be considered an integral part of diabetes management for all patients with type 1 diabetes and for many with type 2 diabetes. Metrics for summarizing CGM glucose data have been standardized, with TIR of 70–180 mg/dL and time <54 mg/dL recognized as the key metrics of focus for diabetes management. The AGP has emerged as the standard for visualization of CGM data. Future work is needed to seamlessly integrate the AGP report into electronic health records and to combine it with decision-support tools to guide changes in diabetes management.

DUALITY OF INTEREST

R.W.B.'s employer has received consulting fees, paid to his institution, from Bigfoot Biomedical, Eli Lilly, Insulet, and vTv Therapeutics; grant support and supplies from Dexcom and Tandem; and supplies from Ascenia and Roche. R.M.B.'s employer has received funds on his behalf for research support, consulting, or serving on the scientific advisory boards for Abbott Diabetes Care, Dexcom, Hygieia, Johnson & Johnson, Lilly, Medtronic, Novo Nordisk, Onduo, Roche, Sanofi, and UnitedHealthCare. No other potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

R.W.B. and R.M.B. contributed equally to the writing of this article. Both authors are the guarantors of this work, and, as such, take responsibility for its content.

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