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CONTINUOUS GLUCOSE MONITORING IN CLINICAL PRACTICE

Assessment of Blood Glucose Levels

Assessments of glycated hemoglobin (HbA1c), postprandial glucose (PPG), and fasting plasma glucose (FPG) are used in the diagnosis and management of diabetes.^{1,2}

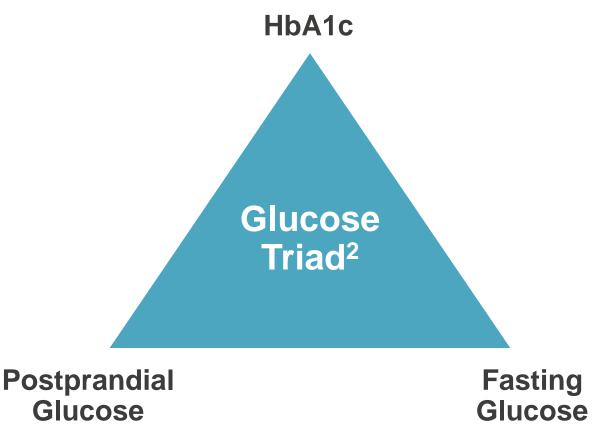


Figure adapted from Monnier L, Colette C. Diabetes Care, 2009.²

FPG = fasting plasma glucose; HbA1c = glycated hemoglobin; PPG = postprandial glucose

Both PPG and FPG contribute to

1. American Diabetes Association [web annotation]. Diabetes Care. 2020;43(suppl 1):S1-212. 2. Monnier L, Colette C. Diabetes Care. 2009;32 (suppl 2):S199-204.

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measured HbA1c³

Need for Metrics Beyond HbA1c



HbA1c levels >7.0% are associated with significantly increased risk of developing micro- and macrovascular complications.¹

HbA1c is a useful and validated metric but does not capture the full picture of blood glucose management.²

- HbA1c limitations³:
 - Fails to identify daily variations in glucose
 - Certain conditions can confound measurements
 - Lack of information about acute glycemic excursions

FPG = fasting plasma glucose; HbA1c = glycated hemoglobin; PPG = postprandial glucose.

1. Imran SA, et al. Targets for Glycemic Control. In: Diabetes Canada Clinical Guidelines Expert Committee. Can J Diabetes. 2018;42(Suppl 1):S1-S325. 2. Runge A, et al. Clinical Diabetes. 2018;36(2):112-119. 3. Battelino T, et al. Diabetes Care. 2019;42(8):1593-1603.

Why Use CGM?

Self-monitoring of blood glucose (SMBG) and/or continuous glucose monitoring (CGM) is an important part of effective therapy for individuals being treated with insulin^{1,2}



- CGM allows:
 - observation of daily profiles and glycemic excursions.³
 - deduction of patterns over time³
 - to inform immediate therapy decisions and/or modification of lifestyle³
- Consistently well-managed blood glucose greatly assists those with diabetes in preventing development of complications⁴

CGM = continuous glucose monitoring; SMBG = self-monitoring of blood glucose.

1. American Diabetes Association [web annotation]. Diabetes Care. 2020;43(suppl 1):S1-212. 2. Danne T, et al. Diabetes Care. 2017;40(12):1631-1640. 3. Battelino T, et al. Diabetes Care. 2019;42(8):1593-1603.

4. NIDDK. NIH. https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/continuous-glucose-monitoring. Updated 2017. Accessed February 19, 2020.

CGM in Clinical Practice

Integrating CGM-derived metrics into diabetes management can be a useful tool to help guide treatment.¹

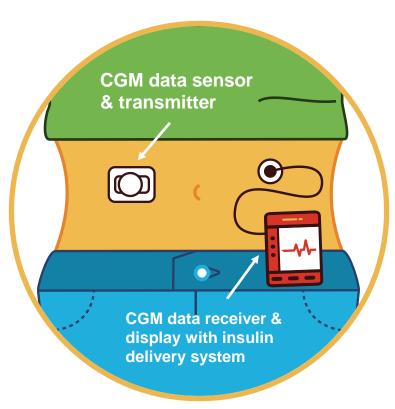
ROUTINE USE OF CGM DATA IN CLINICAL PRACTICE IS GROWING RAPIDLY²



CGM = continuous glucose monitoring.

1. American Diabetes Association [web annotation]. Diabetes Care. 2020;43(suppl 1):S1-212. 2. Battelino T, et al. Diabetes Care. 2019;42(8):1593-1603.

Components of CGM



Special features for your patients¹:

- Alarm can indicate blood glucose levels that are out of range
- Meals, insulin doses, and physical activity can be noted by patient in a CGM device
- Data can be downloaded to a computer or smart device to facilitate understanding of glucose patterns
- Some devices allow for download to a caregiver's or HCP's device

Image adapted from NIH NIDDK, Continuous Glucose Monitoring, 2017.

CGM = continuous glucose monitoring; HCP = healthcare provider

1. NIDDK. NIH. https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/continuous-glucose-monitoring. Updated 2017. Accessed February 19, 2020.

Reflection Question



What benefits of CGM have you observed in your practice?

Module Outline

CGM IN CLINICAL PRACTICE



CGM = continuous glucose monitoring; PPG = postprandial glucose; TIRs = time in ranges.

1. NIDDK. NIH. https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/continuous-glucose-monitoring. Updated 2017. Accessed February 19, 2020.



Meet Fran

Medical History

- 7 months pregnant with gestational Diabetes Mellitus (GDM)
- On multiple daily injections of insulin
- Started using CGM 3 months ago
- Having difficulty keeping blood glucose levels within target range
- Analysis of CGM shows she often has high PPG levels after meals

Lifestyle Factors

- 36-year-old woman, married
- Works full-time with two kids, ages 3 and 11
- Husband works 2 jobs and has limited time to help her
- She wants to exercise more and eat healthier, but finds it difficult to have the time to do so

Disclaimer: This scenario is based on a hypothetical patient.

CGM = continuous glucose monitoring; GDM = gestational diabetes mellitus; PPG = postprandial glucose.



Meet Tom

Medical History

- Type 2 Diabetes (T2D)
- Started using CGM 2 years ago
- On multiple daily injections of insulin for the past 15 years
- Frequent CGM hypoglycemia alarms

Lifestyle Factors

- 82-year-old man, lives in a retirement residence
- Wife passed away several years ago
- Frustrated by frequent hypoglycemia alarms
- Is overwhelmed by all the information in the CGM report

Importance of PPG and TIRs



PPG = postprandial glucose; TIRs = time in ranges. VV-HE-US-DEL-0736. © 2020 Lilly USA, LLC. ALL RIGHTS RESERVED.

Why is Postprandial Glucose (PPG) Important?



PPG¹: Blood glucose after eating a meal. In people without diabetes:

- peaks approximately 1 hour after the start of a meal
- returns to pre-meal levels within 2-3 hours

Elevated PPG values have been linked to a higher risk of developing complications²

PPG = postprandial glucose.

1. American Diabetes Association. Diabetes Care. 2001;24(4):775-778. 2. American Diabetes Association [web annotation]. Diabetes Care. 2020;43(suppl 1):S1-212.

Postprandial Glucose (PPG) Recommendations¹

- Postprandial testing for those with premeal glucose levels within target range, but with HbA1c levels above target
- Recommended measurement 1-2 hours after the start of a meal
- Using treatments aimed at reducing PPG values to <180mg/dL (10.0mmol/L) may help lower HbA1c

HbA1c = glycated hemoglobin; PPG = postprandial glucose

1. American Diabetes Association [web annotation]. Diabetes Care. 2020;43(suppl 1):S1-212.

PPG Recommendations by Subpopulation¹



- Nonpregnant adults with diabetes:
 - should be <10.0mmol/L (180mg/dL)[¶]
- Children and adolescents:
 - PPG should be measured to assess preprandial insulin doses in those on basal-bolus or pump regimens
- Gestational diabetes mellitus (GDM) and pre-existing diabetes in pregnancy:
 - FPG and PPG self-monitoring recommended
 - Preprandial testing may be required for some women with pre-existing diabetes

*, [¶] See speaker notes for more information.

FPG = fasting plasma glucose; GDM = gestational diabetes; HbA1c = glycated hemoglobin; PPG = postprandial glucose.

1. American Diabetes Association [web annotation]. Diabetes Care. 2020;43(suppl 1):S1-212.

Why are Time in Ranges (TIRs) Important?



TIRs: time spent in an individual's target glucose range, hypoglycemic range, or hyperglycemic range¹

- CGM allows for the monitoring of TIRs²
- TIRs provide more practical insights to glycemic control data than HbA1c alone^{1,3}
- Less time in target range has been associated with an increased risk of microvascular complications⁴

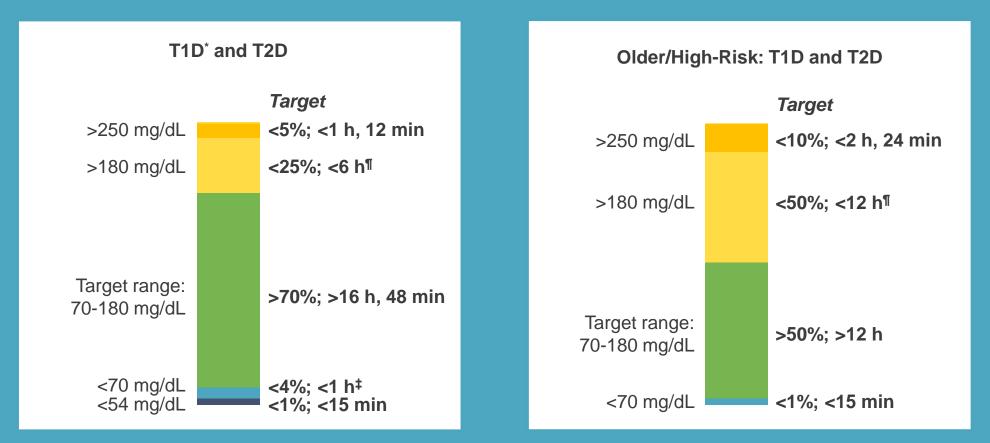
CGM = continuous glucose monitoring; HbA1c = glycated hemoglobin; TIR = time in range.

1. Battelino T, et al. Diabetes Care. 2019;42(8):1593-1603. 2. American Diabetes Association [web annotation]. Diabetes Care. 2020;43(suppl 1):S1-212. 3. Danne T, et al. Diabetes Care. 2017;40(12):1631-1640.

^{4.} Beck RW, et al. Diabetes Care. 2019;42(3):400-405.

CGM-Derived Glycemic Targets are Now Available¹

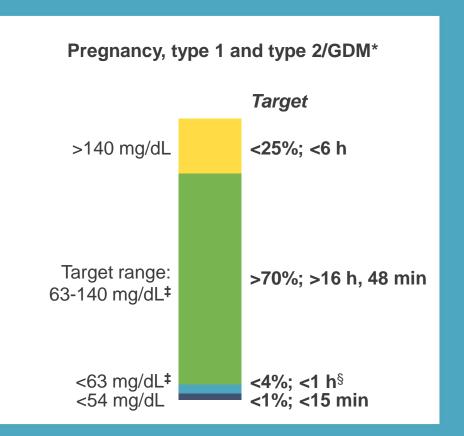
Guidance for setting glycemic targets for adults with type 1 or 2 diabetes and older/high risk individuals



*For age <25 years, if the HbA1c goal is 7.5%, then set TIR target to approximately 60%; ¶Includes percentages of values >250 mg/dL; ‡Includes percentages of values <54 mg/dL. CGM = continuous glucose monitoring; HbA1c = glycated hemoglobin; T1D = type 1 diabetes; T2D = type 2 diabetes; TIR = time in range. 1. Battelino T, et al. *Diabetes Care*. 2019;42(8):1593-1603. Images adapted from Battelino T, et al. *Diabetes Care*. 2019;42(8):1593-1603.

CGM-Derived Glycemic Targets are Now Available¹

Guidance for setting glycemic targets during pregnancy



Each incremental 5% increase in TIR is associated with clinically significant benefits for individuals with type 1 or type 2 diabetes.

*Percentages of TIR are based on limited evidence. In addition, percentages of TIR apply only to pregnancy in T1D, since there is very limited evidence regarding percentages of TIR in gestational diabetes and pregnancy in T2D. More research is needed. ‡Glucose levels are physiologically lower during pregnancy. §Includes percentages of values <3.0 mmol/L. CGM = continuous glucose monitoring; GDM = gestational diabetes mellitus; T1D = type 1 diabetes; T2D = type 2 diabetes; TIR = time in range. 1. Battelino T, et al. *Diabetes Care*. 2019;42(8):1593-1603. Image adapted from Battelino T, et al. *Diabetes Care*. 2019;42(8):1593-1603.

Benefits of TIR¹



- TIR target points can be adapted to different diabetes populations (eg, high-risk or pregnancy)
- Facilitates therapeutic decision making within the established glycemic goal parameters

Reflection Question



What is your experience with TIR?

How frequently do you discuss PPG and TIR in your practice?

Interpreting CGM Data



CGM = continuous glucose monitoring. VV-HE-US-DEL-0736. © 2020 Lilly USA, LLC. ALL RIGHTS RESERVED.

Process for Sharing CGM Data



- CGM data can be downloaded
- Some devices allow data download by others (e.g. caregiver, partner, parent, HCP)¹
- The AGP report is a standardized representation of CGM data²
- AGP data is reported for a period of time (recommended 2 weeks per report)^{3,4}

AGP = ambulatory glucose profile; CGM = continuous glucose monitoring; HCP = healthcare provider.

1. NIDDK. NIH. https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/continuous-glucose-monitoring. Updated 2017. Accessed February 19, 2020. 2. Battelino T, et al. *Diabetes Care*. 2019;42(8):1593-1603. 3. American Diabetes Association [web annotation]. *Diabetes Care*. 2020;43(suppl 1):S1-212. 4. Johnson ML, et al. *Diabetes Technol Ther*. 2019;21(Suppl 2).

Example AGP Report¹

Glucose Statistics and Targets

26 September 2020-10 O Time CGM is active (%)	ctober 2020 15 days 99.8%
<70 mg/dL <54 mg/dL >180 mg/dL	
Each 5% increase in TIR (70-180	mg/dL) is clinically beneficial.

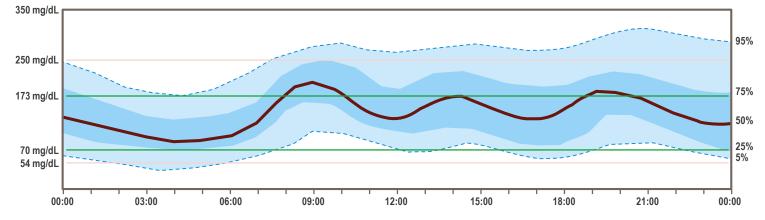
Average glucose	167 mg/dL
Glucose management indicator	9.2%
Glucose variability	52.8%
Defined as percentage coefficient of variation;	target ≤36%.

Time in Ranges

Very high >250 mg/dL	9% (2 h 10 min)
High 181-250 mg/dL	
Target range 70-180 mg/dL	

AGP

AGP is a summary of glucose values (left y-axis) from the report period, with median (50%) and other percentiles shown (right y-axis) as if occurring in a single day.



Low	
54-69 mg/dL	(43 min
ery low	
<54 mg/dL	(43min

 $\mathsf{AGP} = \mathsf{ambulatory} \ \mathsf{glucose} \ \mathsf{profile}; \ \mathsf{CGM} = \mathsf{continuous} \ \mathsf{glucose} \ \mathsf{monitoring}; \ \mathsf{TIR} = \mathsf{time} \ \mathsf{in} \ \mathsf{range}.$

1. Battelino T, et al. Diabetes Care. 2019;42(8):1593-1603. Images adapted from Battelino T, et al. Diabetes Care. 2019;42(8):1593-1603.



AGP Report Metrics¹

TIR enables:

- identification of time spent above, below and within individual's target range
- improved personalization of therapy through shared decision making

AGP curve and daily glucose profiles (depict PPG):

- Shows potential discrepancies in glucose exposure
- Highlights patterns in CGM data

AGP = ambulatory glucose profile; CGM = continuous glucose monitoring; HbA1c = glycated hemoglobin; PPG = postprandial glucose; TIRs = time in ranges.

1. Battelino T, et al. Diabetes Care. 2019;42(8):1593-1603.

Reviewing AGP Reports with Patients is Important¹



Best practices for discussion:

- Explain any unfamiliar terms or concepts
- Empower the patient with information to support glucose management
- Use as Shared decision-making tool
- Set personalized goals (eg, SMART goal intervention)
- Communicating the amount of time, vs. the percent reduction of time, can improve patient understanding

AGP = ambulatory glucose profile; HCP = healthcare provider; SMART = Specific, Measurable, Achievable, Relevant, Time-bound.

1. Battelino T, et al. Diabetes Care. 2019;42(8):1593-1603.

Discussing AGP Reports in Practice

Disclaimer: This scenario is based on a hypothetical patient.

Tom, thank you for bringing your two-week AGP report with you. I understand that you are overwhelmed by the amount of information that is provided here. Let me highlight the most important information for you.

The individual data for the last two weeks is useful to see your extreme high and extreme low values. Average values are useful to see trends. For example, here we can see the time that your blood sugar stayed within target range, vs above or below this range. Overall, we can see that your blood sugar stayed within target range for more than 11 hours each day – this is great news! On the other hand you have about 4 hours of low blood sugar every day.

Based on your AGP report, I can see that your blood sugar is often below range in the afternoons. We should discuss some options and ideas for how to address this.

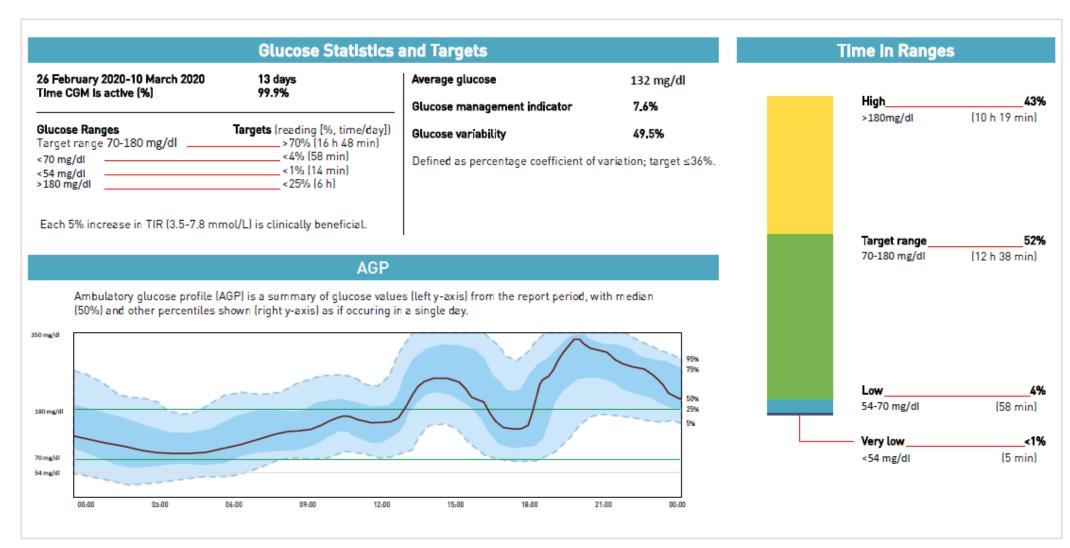


AGP = ambulatory glucose profile.

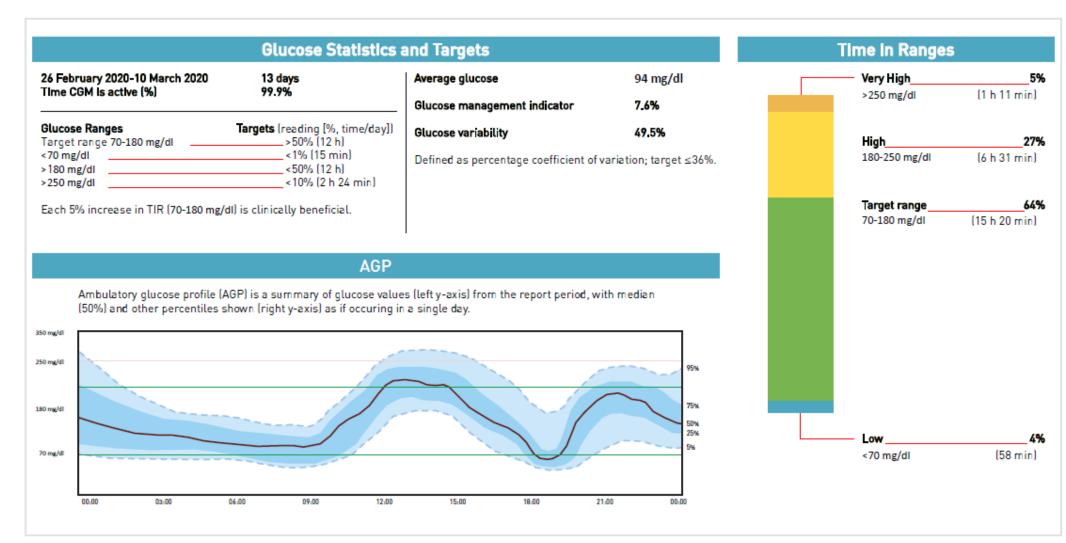
Reflection Question



What options and ideas would you discuss with Fran or Tom based on the sample AGP in the next slides? Fran's AGP Report¹



This scenario is based on a hypothetical patient.



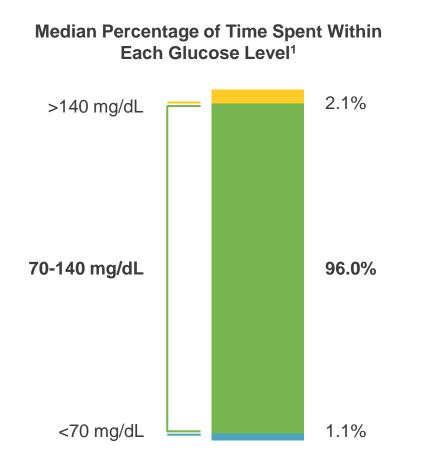
This scenario is based on a hypothetical patient.

Applying CGM Data



CGM = continuous glucose monitoring. VV-HE-US-DEL-0736. © 2020 Lilly USA, LLC. ALL RIGHTS RESER

Using CGM to Establish a Normative Glycemic Benchmark¹





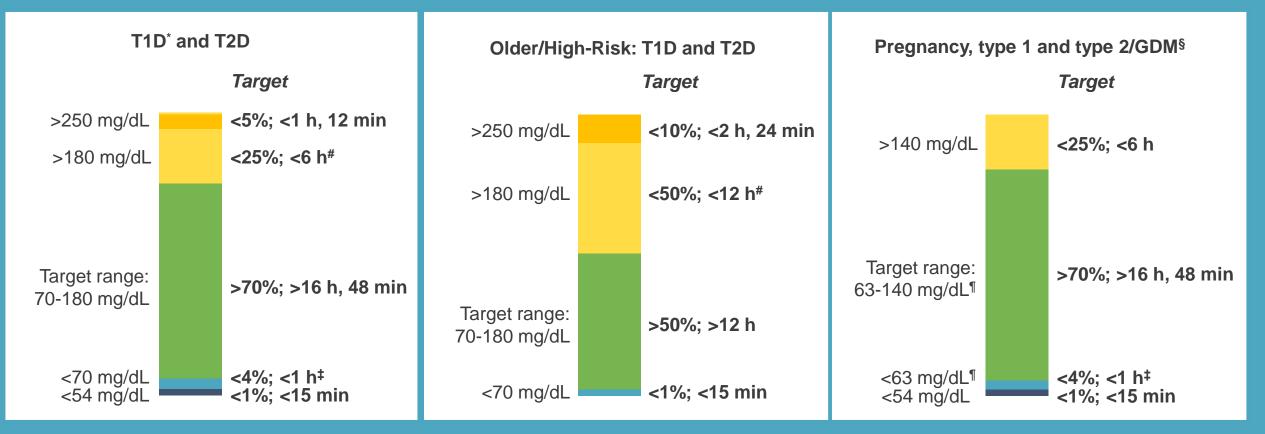
Assessment of CGM data over a 24-hour period from a healthy population without diabetes¹:

- 153 participants
- 7-80 years of age
- Mean glucose was 99±7 mg/dL

CGM = continuous glucose monitoring.

1. Shah VN, et al. J Clin Endocrinol Metab. 2019;104(10):4356-4364.

CGM-Derived Glycemic Targets for People with Diabetes¹ ATTD Guidelines



*For age <25 years, if the HbA1c goal is 7.5%, then set TIR target to approximately 60%; #Includes percentages of values >250 mg/dL; ‡Includes percentages of values <54 mg/dL. \$Percentages of TIR are based on limited evidence. More research is needed. Glucose levels are physiologically lower during pregnancy.

ATTD = Advanced Technologies and Treatments for Diabetes; CGM = continuous glucose monitoring; GDM = gestational diabetes mellitus; HbA1c = glycated hemoglobin; TIR = time in range; T1D = type 1 diabetes; T2D = type 2 diabetes. 1. Battelino T, et al. *Diabetes Care*. 2019;42(8):1593-1603. Image adapted from Battelino T, et al. *Diabetes Care*. 2019;42(8):1593-1603.

Considerations in Setting Blood Glucose Targets



- Depending on the individual patient, more flexible or stringent glycemic goals may be appropriate^{1,2}
- Goals should be personalized based on¹:
 - Age/life expectancy
 - Diabetes duration
 - Presence of comorbid conditions
 - CVD or microvascular complications
 - Hypoglycemia unawareness
 - Individual patient considerations
- Individualized goals are especially important for pediatric, young adult, and pregnant women populations²

CVD = cardiovascular disease.

1. American Diabetes Association [web annotation]. Diabetes Care. 2020;43(suppl 1):S1-212. 2. Battelino T, et al. Diabetes Care. 2019;42(8):1593-1603.

Setting Individualized Blood Glucose Targets in Gestational Diabetes (GDM)

How have you been doing with monitoring your CGM data? Have you been keeping an eye on your PPG and TIR data as we'd discussed?

I've been watching my PPG readings, but they are still high a lot of the time. It is so difficult to calculate the right insulin dose based on the carbohydrates in my food.

It is great that you watch out for your PPG. It sounds like you tend to dose lower with insulin rather than higher. Have you seen any patterns? Does eating something specific result in high PPG?

It is usually really high after I have pizza.

Pizza is a tricky meal because it is high in both fat and carbohydrates. I'm going to refer you to a dietician who will help you develop a nutritional plan, and help you figure out the best way to adjust your dose. We will revisit how you are doing at your next appointment.

Disclaimer: This scenario is based on a hypothetical patient.

CGM = continuous glucose monitoring; GDM = gestational diabetes; PPG = postprandial glucose; TIR = time in range.

Setting Individualized Blood Glucose Targets in Practice

How have you been doing with monitoring your CGM data? Have you been keeping an eye on your PPG and TIR data as we'd discussed?

I've been trying, but the alarm keeps going off. It makes me feel like I'm doing something wrong. Managing my diabetes was easier before.

Have you seen any patterns in when the alarm goes off?

I go to a morning exercise class and it often goes off near the end. I don't like the alarm, so I silence it quickly.

> I'm very happy to hear you're going to exercise classes! The alarms can be important so let's work together to figure out a positive way to use them. I'm going to suggest that you eat a breakfast with long-lasting carbohydrates, then check your CGM before exercise. If your blood glucose is low, you could eat a snack or drink some juice before starting. How does that sound?

Disclaimer: This scenario is based on a hypothetical patient. CGM = continuous glucose monitoring; PPG = postprandial glucose; TIR = time in range. VV-HE-US-DEL-0736. © 2020 Lilly USA, LLC. ALL RIGHTS RESERVED.



Support in Achieving Goals

- Use a non-judgmental approach and emphasize that achieving small, attainable goals can significantly improve blood sugar control^{1,2}
 - SMART goals with a management plan
- Many individuals require ongoing support from healthcare team¹
 - Education on problem solving skills for all components of diabetes management²
 - Emotional wellbeing²
 - Monitor glycemic status²
 - Check medication tolerability²
 - Biofeedback (SMBG, CGM, weight, step count, HbA1c, blood pressure, lipids)²
- Caregiver's support varies depending on needs of individual with diabetes

HbA1c = glycated hemoglobin; SMART = Specific, Measurable, Achievable, Relevant, Time-bound; SMBG = self-monitoring of blood glucose.

^{1.} Battelino T, et al. Diabetes Care. 2019;42(8):1593-1603. 2. American Diabetes Association [web annotation]. Diabetes Care. 2020;43(suppl 1):S1-212.

Incorporating CGM Into Every Visit



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Incorporating CGM Into Every Visit





Probe for understanding and barriers Reinforce goals and positive habits

CGM = continuous glucose monitoring; TIR = time in range. VV-HE-US-DEL-0736. © 2020 Lilly USA, LLC. ALL RIGHTS RESERVED.

Make CGM and TIR Part of the Visit Agenda



Prior to each visit, HCPs should:

- Set PPG and TIR data as a priority for the visit
- Proactively think about how to incorporate CGM and TIR into the agenda
- Review documentation of previous data trends
- Review patient history
- Tailor questions and the conversation to the patient and their situation

Probe for Understanding and Barriers

- Assess patient understanding and comfort with using CGM and identify any barriers¹
- Avoid making assumptions or being judgmental of patient who is having difficulty with self-management¹
 - Avoid thinking of patients as "noncompliant" or "nonadherent"¹
- Encourage a collaborative relationship¹
 - Try using person-centered and strength-based language
 - Empathize and use active listening techniques
- Encourage patient to ask questions
- Identify patient's sources of motivation for improving their health

CGM = continuous glucose monitoring.

1. American Diabetes Association [web annotation]. *Diabetes Care*. 2020;43(suppl 1):S1-212.

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Reflection Questions



How do you encourage a collaborative relationship with your patients?

What are good examples of person-centered and strengthbased language that you use?

Example for assessing patient understanding and comfort with using CGM and identify any barriers



My daily TIR decreased last week because I was busy with work and had to eat on the go. I wasn't able to make the best choices.

Sample Questions

- Tell me about how you've been managing your blood sugar since your last visit.
- Tell me about your week—what happened to reduce your TIR periods?
- Did anything change regarding your eating habits last week?

Remember:

Use non-judgmental language and tone when asking patients questions.

Reinforcing Goals and Positive Habits



- Goals should be revisited at each visit
- Offer positive reinforcement for goals achieved and encourage positive behavior changes

Conclusion



You Have Now Completed the Following:

CGM IN CLINICAL PRACTICE



CGM = continuous glucose monitoring; PPG = postprandial glucose; TIR = time in range. VV-HE-US-DEL-0736. © 2020 Lilly USA, LLC. ALL RIGHTS RESERVED.



Key Takeaways

- HbA1c fails to show the full picture¹
- CGM enables daily management of blood glucose levels²
- Data can be discussed in the form of an AGP report²
- TIRs provide guidance for the percentage of time blood glucose should remain within target ranges^{1,2}
- TIRs provide more actionable insights than HbA1c data alone^{1,2}
- Glycemic targets should be personalized to meet needs of patient²
- Small attainable goals and continued support can help individuals improve diabetes outcomes^{2,3}
- Include PPG and TIR on the agenda during visits, assess barriers to self-management for patients and reinforce goals and positive habits³

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AGP = ambulatory glucose profile; CGM = continuous glucose monitoring; HbA1c = glycated hemoglobin; PPG = postprandial glucose; TIRs = time in ranges

^{1.} Danne T, et al. Diabetes Care. 2017;40(12):1631-1640. 2. Battelino T, et al. Diabetes Care. 2019;42(8):1593-1603. 3. American Diabetes Association [web annotation]. Diabetes Care. 2020;43(suppl 1):S1-212.





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