



PERSONAL CONTINUOUS GLUCOSE MONITORING IMPLEMENTATION PLAYBOOK





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The ADCES and APhA/APhA Foundation Personal CGM Implementation Playbook represents information believed to be current best practices, but it is not intended as legal, financial, medical or consulting advice.

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Table of Contents

PART ONE:	Overview and Introduction to Personal Continuous Glucose Monitoring (CGM)	4
	Introduction to the Personal CGM Implementation Playbook	4
	Introduction to Continuous Glucose Monitoring (CGM).	5
	Personal CGM vs. Professional CGM.	5
	Timeline of Personal CGM	7
	Comparison of Personal CGM Devices Currently Available	8
	Effectiveness of Continuous Glucose Monitoring	9
	Guidelines/Position Statements Pertaining to Continuous Glucose Monitoring	14
	Potential Advantages/Disadvantages of Personal CGM for the Person with Diabetes.	15
	Benefits of Personal CGM to the Healthcare Team	15
	Candidate Selection Characteristics for Personal Continuous Glucose Monitoring	16
	Payor Considerations.	16
	Cost Implications of CGM Use in Type 2 Diabetes	16
	Patient Readiness for Use of Continuous Glucose Monitoring	17
	Personal CGM Case Studies	17
	Personal Stories of CGM Use	20
	Clinician Readiness to Promote Continuous Glucose Monitoring	23
	Overcoming Therapeutic Inertia	23
	Usability and the Human Interface	24
	Interpretation of CGM Data and Reports.	25
	Practice Spotlights	30

PART TWO:	Getting Started - Steps to Develop a Personal CGM Program	33
	Step 1: Identify the Demand for a Personal CGM Program	34
	Step 2: Establish the Clinical Team and Define Roles	35
	Step 3: Design the Workflow	36
	Step 4: Define Personal CGM Coverage/Reimbursement Issues.	36
	Step 5: Define Clinic Documentation and Billing Process for Personal CGM Encounter	37
	Step 6: Train the Staff on the Personal CGM Program	38
	Step 7: Prepare the Practice/Team	38
	Step 8: Prepare the Person with Diabetes.	39
	Step 9: Implement the Program.	39
	Step 10: Evaluate the Program	40
	Step 11: Follow up/Plan for Future.	41

PART THREE:	Worksheet Resources	42
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PART FOUR:	Resources for CGM Device Report Examples	57
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PART FIVE:	Resources	58
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PART SIX:	References	60
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PART ONE:

Overview and Introduction to Personal Continuous Glucose Monitoring (CGM)

Before you begin your journey to incorporate Personal Continuous Glucose Monitoring (Personal CGM) into your practice, it is important to have a thorough understanding of this technology. The following pages describe Personal CGM and introduce this Playbook.

Introduction to the Personal CGM Implementation Playbook

Personal continuous glucose monitoring is a tool that can help to optimize diabetes management. Personal CGM can be a gamechanger for the person living with diabetes and can lead to improved diabetes self-management. With the right guidance, providers in any practice, large or small, specialized or general, can incorporate Personal CGM into their practice and offer this potentially game-changing tool for persons living with diabetes.

This Playbook brings together information available from multiple sources to provide an inclusive and unbiased approach to implementation of Personal CGM into your practice. It includes a step-by-step approach to implementation, additional resources and the latest research.

WHO IS THIS PLAYBOOK WRITTEN FOR?

This Playbook is for primary care providers, pharmacists and diabetes care and education specialists who have an interest in implementing Personal CGM in their practices.

HOW WILL THIS PLAYBOOK BENEFIT ME?

Implementation of an efficient and effective Personal CGM Program can initially feel complicated and confusing. The Playbook is designed to help you successfully implement Personal CGM into your practice.

HOW DO I UTILIZE THIS PLAYBOOK?

The Playbook is organized into six sections that will assist you in your journey to implement Personal CGM into your practice.

WILL THE INFORMATION IN THIS PLAYBOOK BECOME OUTDATED?

Because of rapid changes in technology and practice recommendations, this Playbook is intended to be a living document and will be reviewed and updated annually, at a minimum, to reflect new information and replace outdated information. Look for the Last Updated date on the second page of the manual to ensure you have the most updated version.

Introduction to Continuous Glucose Monitoring (CGM)

The HbA1c has been the gold standard for assessing level of glucose control for years. However, the HbA1c does not reveal anything about glycemic variability or incidence of hypoglycemia. HbA1c values can be affected by red blood cell (RBC) turnover, anemia, iron deficiency, genetic factors, liver disease and race¹. The HbA1c value only offers an average blood glucose measurement over 2-3 months, which gives the healthcare provider limited information as to how to adjust the diabetes medications to best serve the person with diabetes.

To thoroughly assess glycemic patterns and make treatment decisions, it is important to know and understand glycemic variability. Glycemic variability is a measure of the extremes in glucose values over time. A larger amount of glycemic variability is associated with more frequent and severe hypoglycemia and may lead to both microvascular and macrovascular diabetes complications.^{2,3}

To better assess glycemic variability and patterns, Continuous Glucose Monitoring has become more widely adopted and utilized in recent years. Continuous glucose monitors measure interstitial fluid glucose levels and display numerical and graphic data regarding current glucose status, along with current and projected trends in the glucose. The projected future glucose trend is depicted by directional arrows. This allows users to proactively respond to glucose data rather than waiting for hyper- or hypoglycemia to develop, therefore offering the ability to take preventive action to avoid hyper- or hypoglycemia.^{4,5}

Although not a new technology, CGM devices are constantly evolving and improving. Devices continue to improve in accuracy, reliability and convenience and insurance coverage is more widespread. Continuous glucose monitoring is considered a standard of care for people treated with intensive insulin programs.

Abbott's FreeStyle Libre 2 system used for illustration purposes only

Personal CGM vs. Professional CGM

Continuous glucose monitoring devices are either owned by the user for personal use or owned by the healthcare center for professional use. Some continuous glucose monitors link to other compatible devices, such as insulin pumps, blood glucose meters, smartphones, automated insulin-dosing systems and smart pens. Most CGM devices may be used as stand-alone devices.

Consumers who own personal CGM devices utilize the data in real time to make decisions about their diabetes management. The devices display trend arrows, indicating whether there is a pattern of rising or falling glucose to assist them in problem solving and self-management. Clinicians who offer Personal or Professional CGM analyze retrospective data, sometimes combined with a user diary, log or mobile app information to gain insights into glycemic patterns.

Learn more about Professional CGM implementation in the [ADCES/AANP Professional CGM Implementation Playbook](#).



Abbott's FreeStyle Libre 2 system used for illustration purposes only

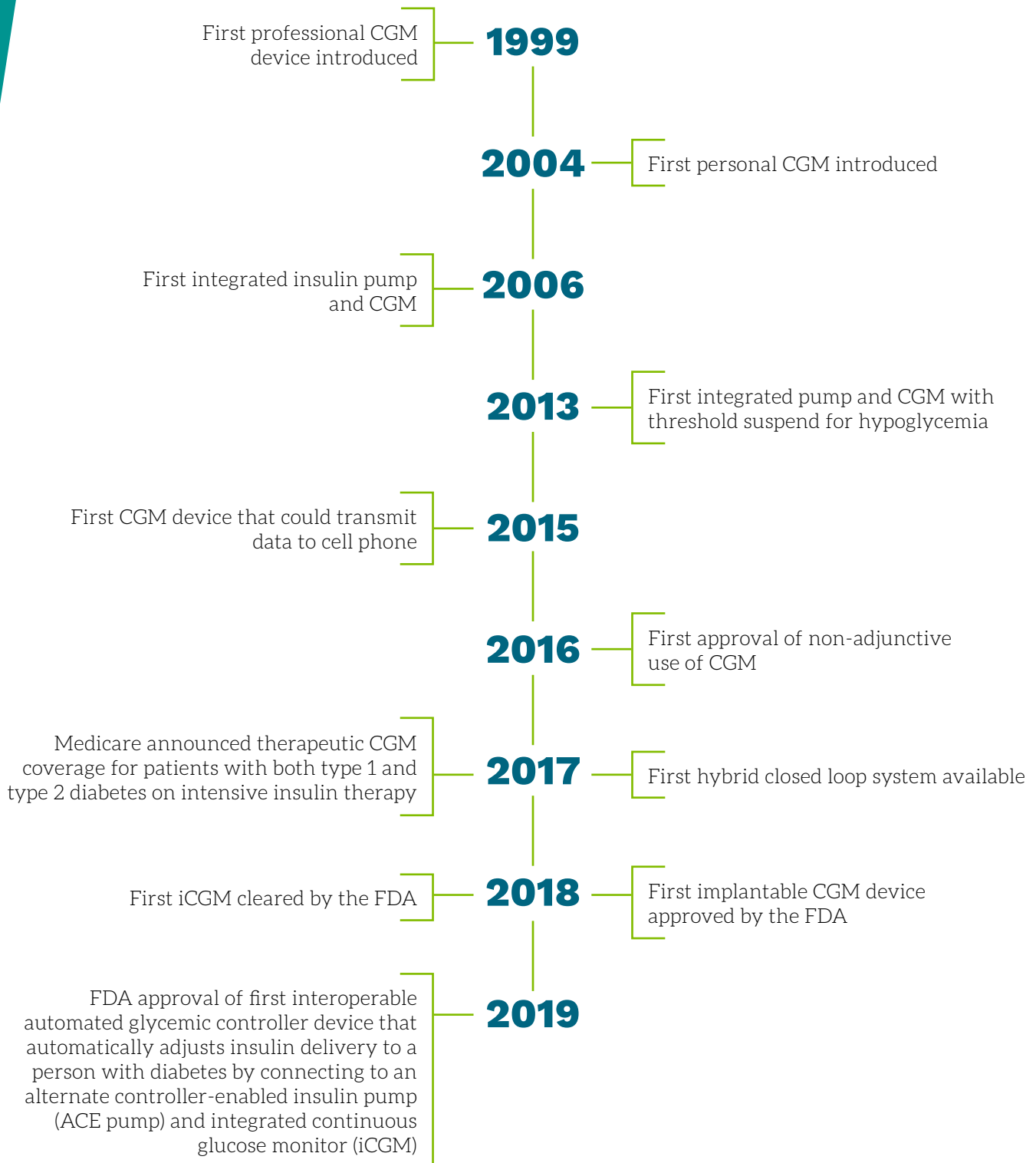


Terms to Know

- **Sensor** – A glucose sensor is the part of a continuous glucose monitoring (CGM) system that is inserted under the skin and measures your interstitial glucose levels.
- **Interstitial glucose level** - The glucose found in the fluid surrounding the cells in the tissue.
- **Transmitter** – A small, reusable or disposable transmitter connected to the sensor allows the system to send real-time glucose readings wirelessly to another device that displays your glucose data.
- **Receiver or reader** – The receiver (reader) or compatible smart device receives glucose data from the transmitter and displays current levels, historical trends in levels, and arrows to show direction that glucose is heading.
- **Real-time CGM** – This device automatically transmits glucose data to the receiver/smartphone.
- **Intermittently-scanned CGM** – This device requires the wearer to swipe the receiver/reader/smartphone over the sensor to obtain glucose data.
- **Trend arrows** – Trend arrows indicate the direction the glucose is heading and allows anticipatory changes to be made to prevent hyper/hypoglycemia.
- **Calibration** – Some CGM systems require fingerstick blood glucose (BG) meter readings in order to generate accurate sensor interstitial glucose readings. These BG meter readings are entered into the device and are used for scheduled calibrations or as needed. Calibrations with blood glucose readings are used to ensure that the glucose sensor maintains its accuracy over time. When systems are factory calibrated, fingerstick calibration is not recommended.
- **Warm-up time** – The amount of time it takes for the sensor to calibrate after it is placed under the skin, before the data is considered to be accurate. The warm-up time varies for different devices. During the warm-up time, the person with diabetes must check a fingerstick blood glucose for treatment decisions.
- **Lag time** – This refers to CGM sensor interstitial glucose readings lagging behind fingerstick blood glucose readings. This occurs because the interstitial fluid glucose that the CGM sensor measures tends to lag behind the fingerstick glucose that the blood glucose meter reads, especially when the glucose level is changing rapidly. The lag time can be up to 15 minutes but is typically less than that in current CGM systems due to algorithm adjustments.
- **Adjunctive indication** – A CGM that cannot be used to make treatment decisions. A stand-alone home blood glucose monitor result should be used to make treatment decisions in this case.
- **Non-adjunctive indication** – A CGM that can be used to make treatment decisions without the need for a stand-alone home blood glucose monitor to confirm blood glucose results.
- **Standalone device** – A CGM that does not require integration with an insulin pump.
- **iCGM** – Per the U.S. FDA, “An integrated continuous glucose monitoring system (iCGM) is intended to automatically measure glucose in bodily fluids continuously or frequently for a specified period of time. iCGM systems are designed to reliably and securely transmit glucose measurement data to digitally connected devices, including automated insulin dosing systems, and are intended to be used alone or in conjunction with these digitally connected medical devices for the purpose of managing a disease or condition related to glycemic control.”

[Product Classification \(fda.gov\)](https://www.fda.gov)

Timeline of Personal CGM



Comparison of Personal CGM Devices Currently Available

					
	Abbott FreeStyle Libre 14 day system	Abbott FreeStyle Libre 2 system	Dexcom G6	Medtronic Guardian Connect and Guardian 3	Senseonics Eversense
Calibrations	None	None	None, optional	At least twice daily	At least twice daily
Sensor Wear	14 days	14 days	10 days	7 days	90 days
FDA Approved for Insulin Dosing	Yes	Yes	Yes	No	Yes
Warm Up Period	One hour	One hour	2 hours	Up to 2 hours	24 hours
Approved Sites	Arm-Subcutaneous	Arm-Subcutaneous	Abdomen, Buttocks (pediatric)-Subcutaneous	Abdomen, Arm-Subcutaneous	Implanted in arm by approved health care professional
MARD (Accuracy-lower is better)	9.4%	9.2%	9.0% overall	8.7-10.6%, lower MARD with more calibrations and wearing on arm	8.5%
Insulin Pump Integration	No	Not available yet	Yes. Tandem t:slim X2	Yes. Minimed 630G, 670G, and 770G	No
Share Data in Real Time Remotely	Yes	Not available yet	Yes	Yes	Yes
Apps	FreeStyle LibreLink, LibreLinkUp	FDA approval applied for and pending	Dexcom G6 Mobile, Follow, CLARITY	Guardian Connect App, Sugar.IQ App	Eversense App
Software	LibreView, Tidepool	LibreView, Tidepool	Dexcom CLARITY, Glooko, Tidepool	Carelink, Tidepool	Eversense DMS, Glooko
Compatibility with Mobile Devices	Reader, Apple and Android smartphone	Reader	Receiver, Android and Apple smartphones, smartwatches	Guardian Connect app on Apple and Android	Android and Apple iOS smartphones, smartwatches and other devices
Available Frequency of Glucose Measurement	Every minute	Every minute	Every 5 minutes	Every 5 minutes	Every 5 minutes
Predictive Low Glucose Alert	No	No	Yes	Yes	Yes
Real-time Alarms	No	Yes	Yes	Yes	Yes
Alarm Detection	No	Available every minute	Every 5 minutes	Every 5 minutes	Every 5 minutes
Interfering Substances	Vitamin C, Salicylic Acid	Vitamin C	Hydroxyurea	Acetaminophen	Tetracycline, Mannitol
Age Approved For	Adults ages 18 and up	Adults and children age 4 and up	Adults and children age 2 and up	Ages 14-75	Adults ages 18 and up
Concerns with Data Loss	None, if scanned every 8 hours	None, if scanned every 8 hours	None, as long as the transmitter and smart phone/receiver are no more than 20 feet apart	None, as long as the transmitter and smart phone/receiver are no more than 20 feet apart	None while wearing transmitter

Information subject to change based on market availability.

Effectiveness of Continuous Glucose Monitoring

Multiple research studies confirm the effectiveness of continuous glucose monitoring.

Randomized controlled trials have demonstrated:

- Decreased HbA1C
- Decreased glycemic variability
- Increased time in range
- Decreased time in hypoglycemia
- Reduction in hypoglycemic events

Results from the three-year follow-up to the COMISAIR Study, which were published in *Diabetes Care* in January 2020⁶, demonstrated that CGM is superior to self-monitoring of fingerstick glucose in reduction of HbA1c, hypoglycemia and other end points in people with type 1 diabetes regardless of their insulin delivery method. They went on to say that CGM plus multiple daily insulin injections can be considered an equivalent but lower-cost alternative to sensor-augmented insulin pump therapy and superior to treatment with self-monitoring of fingerstick glucose plus multiple daily insulin injections or self-monitoring of fingerstick glucose plus continuous subcutaneous insulin infusion therapy.

Published in *Diabetes Technology & Therapeutics* in 2019, Mulinacci et al⁷ investigated the efficacy and safety of CGM initiation within one year of type 1 diabetes diagnosis among all age groups. They concluded that “Irrespective of insulin delivery system, early initiation of CGM within one year from T1D diagnosis was associated with better glucose control and fewer diabetes-related emergency visits.”

Many studies have been performed with multiple populations and different device types: people with type 1 and type 2 diabetes, adults and children, personal and professional CGM. Dr. Anne Peters, Endocrinologist at the Keck School of Medicine at University of Southern California, provided a detailed review of CGM studies and outcomes in the [Role of Continuous Glucose Monitoring in Diabetes Treatment](#) supplement published by the American Diabetes Association (Chart used by permission, American Diabetes Association, 2018)⁸.

Study	Design	Primary Outcome/ Type of CGM	A1C Outcome	Hypoglycemia Change/Other
ADULTS WITH T1D: A1C PRIMARY OUTCOME				
Beck et al. (1,2)	<ul style="list-style-type: none"> • Adults with T1D on MDI • n = 158 • Baseline A1C: ~8.6% • Parallel arms, 24 weeks 	A1C reduction / Dexcom G4 Platinum	-0.6%, P<0.001	<ul style="list-style-type: none"> • Time <70 mg/dL was 43 vs. 80 min/day, P = 0.002 • No difference in severe lows
Lind et al. (3)	<ul style="list-style-type: none"> • Adults with T1D on MDI • n=161 • Baseline A1C: 8.6% • Crossover, 26-week arms 	A1C reduction / Dexcom G4 Platinum	-0.43, P<0.001	<ul style="list-style-type: none"> • Numerically less time in a hypoglycemic range with CGM
Sequeira et al. (4)	<ul style="list-style-type: none"> • Underserved adults with T1D MDI • n = 25 • Baseline A1C: 8.5% • Crossover, 28-week arms 	A1C reduction / Dexcom SEVEN	No significant difference between groups	<ul style="list-style-type: none"> • No change in rates of hypoglycemia
Tumminia et al. (5)	<ul style="list-style-type: none"> • Adults with T1D on MDI or CSII • n = 20 • Baseline A1C: ~8.65% • Crossover, 24-week arms 	A1C reduction / Medtronic Guardian REAL-Time	Only analyzed 14 patients who used CGM ≥40% of the time; in these patients, there was a significant reduction in A1C (P<0.05)	<ul style="list-style-type: none"> • Risk for hypoglycemia was reduced (time sent<70 mg/dL/day), P<0.05

ADULTS WITH T1D: HYPOGLYCEMIA PRIMARY OUTCOME				
Bolinder et al. (6)	<ul style="list-style-type: none"> Adults with T1D on MDI or CSII n = 241 Baseline A1C: 6.7% Parallel arms, 6 months 	Change in time in hypoglycemic range (<70 mg/dL) / Abbott FreeStyle Libre	NS	<ul style="list-style-type: none"> Overall, 38% reduction in time in hypoglycemia (–1.24 hours/day, P <0.0001) Time in range (3.9–10.0 mmol/L [70–180 mg/dL]; mean difference) improved by 1.0 ± 0.30 hour, P = 0.0006
Hermanns et al. (7)	<ul style="list-style-type: none"> Adults with T1D, most on MDI n = 41 Baseline A1C: 8.2% Crossover design, 5-day arms; patients were free-living within inpatient research setting 	Proportion of time spent hypoglycemic / Dexcom SEVEN PLUS	N/A	Reduction in time in hypoglycemic range: 125 ± 89 vs. 181 ± 125 min/day, P = 0.005
van Beers et al. (8)	<ul style="list-style-type: none"> Adults with T1D on MDI or CSII with a Gold score ≥4 n = 52 Baseline A1C: 7.5% Crossover, 16-week arms 	Mean difference in time in range (4–10 mmol/L [72–180 mg/dL]) / Medtronic Enlite with a MiniMed Paradigm Veo system (used as a monitor)	NS	<ul style="list-style-type: none"> Reductions in hypoglycemia (≤3.9 mmol/L [70.2 mg/dL]) –4.7%, P <0.0001 Severe hypoglycemia: 14 events with CGM vs. 34 events with SMBG, P = 0.033 Time in range (mean difference) improved by 9.6%, P = 0.0001
ADULTS AND CHILDREN WITH T1D: A1C/TIME IN RANGE PRIMARY OUTCOME				
Battelino et al. (9)	<ul style="list-style-type: none"> Adults and children with T1D on CSII n = 153 Baseline A1C: 8.1% for adults, 8.6% for children Crossover, 6-month arms 	A1C reduction / Medtronic Guardian REAL-Time	A1C difference –0.43% in favor of sensor on, P <0.001	<ul style="list-style-type: none"> Time spent <3.9 mmol/L (70.2 mg/dL) was 19 vs. 31 min/day, P = 0.009 Four severe hypoglycemic episodes in sensor on mode, two in sensor off mode
Deiss et al. (10)	<ul style="list-style-type: none"> Adults and children with T1D on MDI or CSII n = 156 Baseline A1C: 9.5% in arm 1, 9.7% in arm 2 Three parallel arms: continuous CGM (arm 1) vs. biweekly 3-day CGM (arm 2) vs. control for 3 months 	A1C reduction / Medtronic Guardian REAL-Time	Arm 1: –0.6%, P = 0.003; Arm 2: no difference in A1C	One episode of severe hypoglycemia in each arm
JDRF CGM Study Group (11)	<ul style="list-style-type: none"> Adults and children with T1D on MDI or CSII n = 322 Three age-groups: ≥25 years (n = 98), 15–24 years (n = 110), and 8–14 years (n = 98) Baseline A1C: ≥25 years, 7.6%; 15–24 years, 7.9–8.0%; and 8–14 years, 7.9–8.0% Parallel arms, 26 weeks 	A1C reduction / DexCom SEVEN, Medtronic MiniMed Paradigm REAL-Time insulin pump and CGMS, and Abbott FreeStyle Navigator	<ul style="list-style-type: none"> A1C difference: in those ≥25 years of age, –0.53%, P <0.001; in those <25 years of age, no difference A1C response related to use of CGM 	No difference in time spent in a hypoglycemic range or in number of severe hypoglycemic episodes
O'Connell et al. (12)	<ul style="list-style-type: none"> Adults and adolescents with T1D on CSII n = 55 Baseline A1C 7.3% for intervention group, 7.5% for control group Parallel arms, 3 months 	Time in range during the 3-month study period / Medtronic MiniMed Paradigm REAL-Time insulin pump and CGMS	<ul style="list-style-type: none"> No difference in primary outcome A1C was –0.43% lower in the CGM group, P = 0.009 Greater reduction in group with more use 	No difference in time in range, variability, or hypoglycemia

ADULTS AND CHILDREN WITH T1D: HYPOGLYCEMIA PRIMARY OUTCOME				
JDRF CGM Study Group (13)	<ul style="list-style-type: none"> Adults and children with T1D on MDI or CSII n = 129 Baseline A1C: 6.4% for CGM group, 6.5% for control group Parallel arms, 26 weeks 	Change in time ≤70 mg/dL / DexCom SEVEN, MiniMed Paradigm REAL-Time insulin pump and CGMS, and Abbott FreeStyle Navigator	A1C treatment difference favoring CGM, P <0.001	<ul style="list-style-type: none"> Time ≤70 mg/dL numerically less frequent (54 vs. 91 min/ day) but not significant, P = 0.16 Median time with blood glucose ≤60 mg/dL was 18 vs. 35 min/day, P = 0.05 Severe hypoglycemia 10 and 11% for CGM and control groups, respectively, P = 1.0
Battelino et al. (14)	<ul style="list-style-type: none"> Adults and children with T1D on MDI or CSII n = 120 Baseline A1C: 6.9% Parallel arms, 26 weeks 	Time spent in hypoglycemic range / Abbott FreeStyle Navigator	A1C treatment difference favoring CGM: -0.27%, P = 0.008	<ul style="list-style-type: none"> Time spent <63 mg/dL shorter in CGM group; ratio of means 0.49, P = 0.03 No severe hypoglycemia
Heinemann et al. (15)	<ul style="list-style-type: none"> Adults and children with T1D on MDI with a history of impaired hypoglycemia awareness or severe hypoglycemia n = 149 Baseline A1C: 7.3% for control group, 7.6% for CGM group Parallel arms, 26 weeks 	Baseline-adjusted hypoglycemia events (glucose ≤3.0 mmol/L [54 mg/dL] for ≥20 minutes) / Dexcom G5 Mobile	No difference in A1C	Adjusted between-group difference in low glucose events: 0.28, P <0.0001
CHILDREN WITH T1D				
Ludvigsson et al. (16)	<ul style="list-style-type: none"> Children with T1D on MDI or CSII n = 27 Baseline A1C: ~7.7% Cross-over, 12-week arms; wore CGM for 3 days every 2 weeks 	A1C reduction/ Medtronic CGMS	A1C difference at 12 weeks during open vs. blind CGM: ~-0.39%, P = 0.011	No significant differences in hypoglycemia
Chase et al. (17)	<ul style="list-style-type: none"> Children with T1D n = 200 Baseline A1C: 8.0% Parallel arms, 6 months 	A1C reduction / GlucoWatch G2 Biographer	No significant change in A1C	Sensor use declined from 2.1 to 1.5 times/week because of skin irritation and other issues
ADULTS WITH T2D				
Beck et al. (18)	<ul style="list-style-type: none"> Adults with T2D on MDI n = 158 Baseline A1C: 8.5% Parallel arms, 24 weeks 	A1C reduction / Dexcom G4 Platinum with an enhanced algorithm	Adjusted mean A1C difference: -0.3%, P = 0.022	No change in hypoglycemia
Ehrhardt et al. (19)	<ul style="list-style-type: none"> Adults with T2D not on prandial insulin (half on oral medication alone) n = 100 Baseline A1C: 8.2% for SMBG group, 8.4% for CGM group Parallel arms, 2 weeks on/1 week off, 4 cycles over 12 weeks 	A1C reduction / Dexcom SEVEN	Difference in A1C: -0.6%, P = 0.002	<ul style="list-style-type: none"> Hypoglycemia data NA Most improvement in people who used CGM per protocol
Haak et al. (20)	<ul style="list-style-type: none"> Adults with T2D on prandial-only insulin on MDI or CSII n = 224 Baseline A1C: 8.74% in intervention group, 8.88% in control group Parallel arms, 2:1 randomization, 6 months 	A1C reduction / Abbott FreeStyle Libre	No difference in A1C overall; difference in A1C if <65 years of age, P = 0.03	Time in hypoglycemia (<70 mg/dL) was reduced by 43%, P = 0.000
Yoo et al. (21)	<ul style="list-style-type: none"> Adults with T2D on oral agents or insulin n = 65 Baseline A1C: 8.7% in SMBG group, 9.1% in CGM group Parallel arms, real-time CGM for 3 days once per month for 12 weeks 	A1C reduction / Medtronic Guardian REAL-Time	Improvement in A1C greater in CGM group, ~0.5%, P = 0.004 (CGM: from 9.1 ± 1.0 to 8.0 ± 1.2%, P <0.001; SMBG: from 8.7 ± 0.7 to 8.3 ± 1.1%, P = 0.01)	<ul style="list-style-type: none"> No significant changes in hypoglycemia In real-time CGM, reduced caloric intake, weight, BMI, and postprandial glucose level; increased physical activity

ADULTS WITH T1D OR T2D				
Garg et al. (22)	<ul style="list-style-type: none"> Adults with T1D or T2D on insulin n = 91 Baseline A1C: 7.6% in control group, 8.0% in CGM group Parallel arms, 3-day CGM for three consecutive 72-hour periods 	Time spent in high, low, and target glucose zones / Dexcom STS sensor	<ul style="list-style-type: none"> 23% less time in hyperglycemia (≥ 240 mg/dL) 26% increase in time in range (81–140 mg/dL) P < 0.001 for each comparison 	CGM group spent 21% less time in hypoglycemia (<55 mg/dL), P < 0.0001
New et al. (23)	<ul style="list-style-type: none"> Adults with T1D or T2D on MDI or CSII n = 160 Baseline A1C: 8.2% Parallel arms, 100 days 	Time spent outside of target range / Abbott FreeStyle Navigator; 1/3 CGM with no alarm, 1/3 CGM with alarm, 1/3 SMBG	No difference in A1C or time spent outside of target range	Less time in hypoglycemia range in group with alarms compared to SMBG group, P = 0.03
Cooke et al. (24)	<ul style="list-style-type: none"> Adults with T1D or T2D treated with at least twice-daily insulin injections n = 404 Baseline A1C: 9.1% Parallel arms, 18 months; GlucoWatch group wore device at least four times in the first 3 months and then as needed; Medtronic group wore device for 72 hours three times during first 3 months and on three more occasions thereafter 	A1C reduction / GlucoWatch G2 Biographer vs. Medtronic MiniMed CGMS (blinded)	No significant difference in A1C reduction	No reduction in hypoglycemia; possibly an increase
PREGNANT PATIENTS WITH T1D, T2D, OR GDM				
Feig et al. (25)	<ul style="list-style-type: none"> Adult women with T1D on MDI or CSII who were pregnant or planning pregnancy n = 325 (215 pregnant, 110 planning pregnancy) Baseline A1C: 6.83% in CGM group and 6.95% in control group (pregnant) and 7.57% in both CGM and control group (planning pregnancy) Parallel arms, to 34 weeks in pregnant women; for 24 weeks in those planning pregnancy 	A1C reduction / Medtronic Guardian REAL-Time or MiniMed MiniLink	A1C difference -0.19%, P = 0.0207 in pregnant women; no A1C difference in women planning pregnancy	<ul style="list-style-type: none"> Comparable severe hypoglycemia events (18 vs. 21) and time spent hypoglycemic (3 vs. 4%) Neonatal health outcomes: fewer LGA babies, fewer neonatal ICU stays for >24 hours, and fewer neonatal hypoglycemia events
Secher et al. (26)	<ul style="list-style-type: none"> Adult women with T1D or T2D who were pregnant n = 154 Baseline A1C: 6.6% in CGM group, 6.8% in control group Parallel arms, 6 days of CGM at 8, 12, 21, 27, and 33 weeks vs. routine care 	LGA babies / Medtronic Guardian REAL-time CGM with Sof-Sensor	No difference in A1C	<ul style="list-style-type: none"> No difference in number of LGA babies No difference in hypoglycemia
Wei et al. (27)	<ul style="list-style-type: none"> Adult women with GDM at 24–28 weeks of pregnancy n = 106 Baseline A1C: 5.8% in SMBG group, 5.7% in CGM group Parallel arms; women were asked to wear CGM intermittently early (second trimester) or late (third trimester) or perform SMBG 	Prenatal or obstetrical outcomes / Medtronic Gold CGMS	No significant reduction in A1C	<ul style="list-style-type: none"> No difference in obstetrical outcomes Some reduction in maternal weight gain

JDRF, Juvenile Diabetes Research Foundation; LGA, large-for-gestational-age; NA, no applicable; NS, non-significant; T1D, type 1 diabetes; T2D, type 2 diabetes.

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Guidelines/Position Statements Pertaining to CGM

<p><u>ADCES 2019 Practice Paper</u>⁹</p>	<p>Diabetes care and education specialists who are well versed in professional and personal CGM devices are in a key position to promote and support this option for people with type 1 and type 2 diabetes. The diabetes care and education specialist can help identify those who would benefit from professional or personal CGM, collaborate with their provider to facilitate obtaining an appropriate device, educate them on the utilization, and download the results to evaluate in order to maximize diabetes management outcomes. Diabetes care and education specialists provide the coaching needed to help PWD reap the benefits of the technology by utilizing the information to make smarter diabetes management decisions, reduce risk of hypoglycemia and hyperglycemia and thereby improve quality of life.</p>
<p><u>ADA 2020</u>¹⁰</p>	<p>CGMs, in conjunction with insulin therapy, are a useful tool to lower HbA1C levels and/or reduce hypoglycemia in adults with type 1 diabetes who are not meeting glycemic targets, have hypoglycemia unawareness and/or have episodes of hypoglycemia.</p> <p>CGM should be considered in all children and adolescents with type 1 diabetes, whether using injections or continuous subcutaneous insulin infusion, as an additional tool to help improve glucose control.</p> <p>CGMs in conjunction with insulin therapy are useful tools to lower A1C and/or reduce hypoglycemia in adults with type 2 diabetes who are not meeting glycemic targets.</p> <p>Real-time CGM may be used effectively to improve A1C levels, time in range and neonatal outcomes in pregnant women with type 1 diabetes.</p> <p>Real-time CGM devices should be used as close to daily as possible for maximal benefit. Intermittently scanned CGM devices should be scanned frequently, at a minimum once every 8 hours.</p>
<p><u>Endocrine Society 2016</u>¹¹</p>	<p>Real-time CGM is recommended for adults with type 1 diabetes who are willing and able to use device on a nearly daily basis.</p> <p>Short-term, intermittent, real-time CGM is recommended for adult patients with type 2 diabetes (not on prandial insulin) who have HbA1C greater than or equal to 7.0%.</p>
<p><u>AACE/ACE 2020</u>¹²</p>	<p>CGM is preferred over SMBG.</p> <p>Use of personal CGM devices (i.e., those owned by the patient) should be considered for those patients who are on intensive insulin therapy (3 to 4 injections/day or on insulin pump), for those with history of hypoglycemia unawareness, or those with recurrent hypoglycemia. While these devices could be used intermittently in those who appear stable on their therapy, most patients meeting these criteria will need to use this technology on a continual basis.</p> <p>As experience with CGM in T2D grows, we anticipate more frequent use of both professional and personal devices, which may increasingly replace SMBG.</p>
<p><u>International Consensus 2017</u>¹³</p>	<p>CGM should be considered in conjunction with HbA1C monitoring for glycemic status assessment and therapy adjustment for all patients with type 1 diabetes and patients with type 2 diabetes treated with intensive insulin therapy who are not achieving glucose targets, especially if the patient is experiencing problematic hypoglycemia. See update in 2019 here for further details about glycemic goals and use of AGP data: Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range</p>



Abbott's FreeStyle Libre 2 system used for illustration purposes only

Potential Advantages/Disadvantages of Personal CGM for the Person with Diabetes

ADVANTAGES:

- Shows a more accurate picture of glucose levels through the day
- Shows current glucose level and predicts direction that glucose is heading and rate of change
- Allows patient to assess glycemic patterns and glycemic variability
- Can potentially prevent hypoglycemia and hyperglycemia
- Provides alerts when glucose level is too low or too high
- Shows how lifestyle choices and other factors affect glucose
- Ability to share glucose levels with a family member and/or healthcare team
- Provides information about what is happening with glucose levels overnight
- Ability to adjust insulin dosing based on numbers and trend arrows
- If integrated with an insulin pump, may be able to pause or adjust insulin delivery in response to changes in glucose levels

DISADVANTAGES:^{14,15}

- Cost
- Insurance coverage or qualifications for coverage may be an issue
- May require calibration with fingerstick glucose
- Need to remember to scan an intermittently-scanned device
- Can be complicated to learn, up front learning curve
- Information overload
- Alarm fatigue – the condition in which device users are repeatedly bothered by frequent and/or false alarms
- Constant presence of sensor on/in the body
- Skin irritation



The Dexcom G6 RT-CGM sensor and transmitter is shown above

Benefits of Personal CGM to the Healthcare Team

- Offers detailed glucose metrics including time in range, time above/below range, and glycemic variability
- Shows 24-hour-a-day glucose values, including times when the patient may not have checked, such as while sleeping, post-prandial, etc.
- Data can be viewed remotely which allows for therapy changes between traditional clinic visits
- Allows for intensification in treatment program based on real-time glucose results
- Reduction in hypoglycemia events
- Potentially avoid hospitalizations via reduction in extremes of glucose levels
- Potentially decrease long-term complications of diabetes via improved glucose control



Candidate Selection Characteristics for Personal Continuous Glucose Monitoring

- Any of the following may be an indication for Personal CGM: Type 1 or Type 2 Diabetes
 - Taking multiple daily injections of insulin
 - Using an insulin pump
 - Frequent hypoglycemia
 - Hypoglycemia unawareness
 - High degree of glycemic variability
 - Not achieving glucose targets

The American Diabetes Association makes the following recommendation in its 2020 Standards of Medical Care in Diabetes¹⁶: “Use of technology should be individualized based on a patient’s needs, desires, skill level, and availability of devices.” By offering a personal CGM program, providers can assess a patient’s needs, desires, and skill level and help them identify a CGM device that will work for them.

The American Diabetes Association goes on to say that “Nonprofit websites can offer advice for providers and patients to determine the suitability of various options.” An example of a valuable not-for-profit website that can help both providers and people with diabetes make decisions as to the initial choice of device is [DiabetesWise from Stanford University](https://diabeteswise.org), funded by The Leona M. and Harry B. Helmsley Charitable Trust.

DiabetesWise.org

Payor Considerations

The four criteria set down by CMS¹⁷, all of which must be met for coverage, include that the patient must:

- Have a diagnosis of diabetes, either type 1 or type 2
- Use a home blood glucose monitor (BGM) and conduct four or more daily BGM tests
- Be treated with insulin with multiple daily injections or a constant subcutaneous infusion (CSI) pump
- Require frequent adjustments of the insulin treatment regimen, based on therapeutic CGM test results

To meet the criteria, the system must be classified as a therapeutic CGM. That means users can make treatment decisions using the device.

Most commercial payors have coverage for CGM. Eligibility may vary and providers can assist patients in identifying the criteria and help them navigate approval processes.

Cost Implications of CGM Use in Type 2 Diabetes

In the American Journal of Managed Care’s Evidence Based Diabetes Management, 2019¹⁸, Kompala and Neinstein discuss that one study looked at long-term cost-effectiveness for CGM use in people with type 2 diabetes based on HbA1c reduction, projecting decreased rates of diabetes-associated complications.

“Although we anticipate that HbA1c reduction through lifestyle changes by CGM users could prevent the addition of costly new medications or dose intensification of existing treatments, more study is needed to test this. This matters: Studies looking at HbA1c compared with healthcare costs have found significant impacts. In one case, a 1% decrease in A1C was associated with \$685 to \$950 per year lower total healthcare costs, and in another, a 1% increase in HbA1c was associated with a 7% increase in healthcare costs over the next 3 years.”

Patient Readiness for Use of Continuous Glucose Monitoring

Is your patient with diabetes ready to utilize continuous glucose monitoring technology?

Welsh notes, in his June 2018 Diabetes Technology & Therapeutics¹⁹ article, “Role of Continuous Glucose Monitoring in Insulin-Requiring Patients with Diabetes,” that it is important to set realistic expectations of CGM use to help avoid frustrations and disappointment. “CGM use should not be imposed on those who are unwilling to use it consistently or incapable of using it beneficially.” Comprehensive training on the device is important, both initially and ongoing, and will lead to the long-term success of the individual with the CGM²⁰. One strategy to assist the person with diabetes who is feeling uncertain if personal CGM is right for them would be to offer a short-term trial with professional CGM²¹.

Personal CGM Case Studies

PERSONAL CGM CASE STUDY #1



The Dexcom G6 RT-CGM sensor and transmitter is shown above

John B. is a 63-year-old gentleman who has been living with type 2 diabetes for 20 years. BMI is 33 kg/m². Medications include basal insulin 30 units daily, mealtime insulin analog 8 units before each meal plus a correction scale, a statin, low dose aspirin, ace inhibitor and a once weekly GLP-1 receptor agonist. John has the following comorbidities: Hyperlipidemia, hypertension, obesity, osteoarthritis and chronic renal insufficiency. Recent A1C 8.1%.

He was maintained on oral diabetes medications for over 15 years and then transitioned to insulin therapy five years ago. He started to experience more glycemic variability as time went by. He checks his fingerstick blood glucose level four times daily and results are as follows:

Before breakfast: 52-305 mg/dl

Before lunch: 121-298 mg/dl

Before dinner: 58-233 mg/dl

Before bed: 67-402 mg/dl

John feels that he eats relatively carbohydrate-consistent meals and can't identify reasons for his blood glucose fluctuations.

His primary care provider recommends a personal CGM for him with training and follow up with the diabetes care and education specialist (DCES). After meeting with the DCES, John chose a CGM device. He learned to keep food logs and to aim for 45-60 grams of carbohydrates at meals

and to not skip meals, which he had been doing at times. He was instructed to start logging his activity along with his food.

Four weeks later, John followed up with his primary care provider. His CGM device was downloaded and available for review by the PCP. The Ambulatory Glucose Profile (AGP) report showed that John has an average glucose of 164 mg/dl and his time in range is 60%. However, 6% of the time he is in Low Time Below Range, 30% of the time he is in High Time Above Range and 4% of the time he is in Very High Time Above Range. Glucose trends include a pattern of falling overnight and running high post-prandially after the noon and evening meals. John is sometimes running low before the noon meal.

The following adjustments were made to John's insulin plan: Basal insulin was reduced to 26 units per day. Mealtime insulin was adjusted to 6 units at breakfast meal, 10 units at noon and evening meal.

He returned to the PCP six weeks later. A1C 6.9%. Time in range now 72% and no time spent in low or very low range. 28% of values are in High Time Above Range. John continues to work with the DCES to learn more about diabetes self-management.

PERSONAL CGM CASE STUDY #2



Abbott's FreeStyle Libre 14 day system used for illustration purposes only.

Jean C. is a 42-year-old female with type 2 diabetes. Due to HbA1C of 10.4%, she has recently been started on a multiple daily insulin injection program by her primary care provider, which includes one injection of 30 units of basal insulin every evening and 10 units of rapid-acting insulin before each meal. She started personal CGM about two weeks ago and is using an intermittently-scanned device. She is following a carbohydrate-consistent diet and states “pretty good success” with it.

Jean visits her pharmacist due to complaints about her personal CGM “alarming all day long, especially in the afternoon and evening. I’m ready to toss it out the window.” Jean’s pharmacist asks her about her recent glycemic management and requests to download her glucose data. Fasting glucose values are mostly around 110 mg/dl. Results throughout the day are mostly in the 160-280 mg/dl range, with higher values in the afternoon and evening. There are many gaps where there is missing data on the ambulatory glucose profile (AGP). AGP report shows no hypoglycemia, 35% of readings are in target range and 65% of readings are high or very high.

Jean’s pharmacist offers positive feedback that Jean has persisted with the CGM, despite experiencing some issues with it, and advises that she did the right thing by coming in to discuss the situation versus quitting due to frustration.

Jean’s pharmacist completes the following actions:

- First, the pharmacist discusses the missing CGM data. “Did you know that in order to have complete glucose data every day you need to scan at least every 8 hours? Try to scan at least before each meal and before bed.” Jean did not know this but says she will be sure to do this going forward.
- Next, the pharmacist checks the CGM settings. The high alert is set at 180 mg/dl, meaning that it is alarming every time her glucose goes above that level. The pharmacist knows that with Jean’s recent HbA1C of 10.4% and adjustment to a new insulin and CGM program that the high alert should not be set so ambitiously. She adjusts the high alert setting to 240 mg/dl.
- Knowing that medication adherence can sometimes be a barrier to achieving optimal glycemic control, the pharmacist asks Jean if she is always taking all four insulin injections every day as prescribed. Jean confides that she often misses the pre-lunch injection because she is busy making lunch for her kids and she goes ahead and eats and forgets to take the injection. Together, they did some brainstorming to help Jean remember to take her lunch dose, and the decision was made for her to keep her in-use rapid-acting insulin pen at the kitchen table since she eats lunch there every single day.
- Jean and the pharmacist determine a follow-up plan in one week that is mutually agreed upon.

PERSONAL CGM CASE STUDY #3



Abbott's FreeStyle Libre 14 day system used for illustration purposes only.

Frank O. is a 72-year-old male who was diagnosed with type 2 diabetes five years ago. Diabetes medications include Glimepiride 2 mg every morning, Metformin 500 mg twice daily, and basal insulin 12 units every evening. Cost of medications is a concern for Frank and he has had difficulties affording other newer, more costly, diabetes medications in the past. The regimen that he is currently on is affordable to him due to availability of generics. Frank has not been testing his fingerstick blood glucose consistently due to complaints of pain in his fingertips.

Frank's HbA1C has been steadily creeping up, despite following a relatively low carbohydrate diet and maintaining a daily walking program. HbA1C is currently 8.4% and his primary care provider decides to refer Frank to a diabetes care and education specialist (DCES) to begin use of a CGM. The DCES shows Frank the CGM choices and he opts for the lowest cost CGM and does have some coverage for this therapy with his healthcare plan. He gets started on it at the visit.

Frank returns to see his primary care provider (PCP) four weeks later. His CGM device is downloaded and reviewed by his PCP. He has been scanning before each meal and at bedtime and therefore has consistent data to review. His Ambulatory Glucose Profile shows that average glucose is 194 mg/dl and time in range is 52%. Time below range is 0% and time above range is 48%. Glucose trends show elevated fasting readings and elevated pre-evening meal and bedtime readings.

Frank's PCP decides to increase the basal insulin to 16 units every evening and to increase his Glimepiride to 4 mg every morning. They follow up by telephone one week later and at that time most of Frank's glucose results are in desired target range and there has been no hypoglycemia. Frank states that he "loves his CGM" and never wants to return to poking his fingers.

“Nothing is impossible, the word itself says ‘I’m possible!’”

—Audrey Hepburn



PERSONAL STORIES OF CGM USE

Story 1: Christel O.

Christel O. is a 41-year-old female who has lived with type 1 diabetes since 1997. Her insulin plan includes Detemir and Lispro. Christel considered getting a CGM for several years and has now used one for about five years. She researched her possibilities before getting it and her endocrinologist ordered it for her. She did not encounter any difficulties with obtaining insurance approval for the device or for the ongoing supplies.

Christel shares that she felt that she had a lot of initial training on the technical part of CGM use but not much on the emotional part of the use of CGM. She found the technology easy to use but felt that she “overreacted to the information initially and ended up chasing my BG.” She states that ongoing CGM training and support has been “limited.”

She does use the CGM results and trend arrows to help determine how much mealtime and correction insulin to take. Christel shares that one thing she really likes about the CGM is that she “hardly ever has a bad low while wearing the CGM since it alerts me before things go wrong. It can help me troubleshoot and make adjustments to my diabetes care more frequently.” She also shares the following CGM dislikes: “It can be stressful to constantly see your BG and the inaccuracy or when it doesn’t work is frustrating. Lastly, it’s costing me a lot of money.”

Christel says she plans to continue with her CGM. “I think it’s a complete gamechanger. It not only helps with the daily management but can also help fear of lows.” **She offers the following advice to healthcare professionals:** “Don’t just focus on the mechanical part of using a CGM, that’s the easy part. Focus more on how to use CGM in a mentally safe way. I try to tell myself to only check it when I want to make a management decision and don’t chase my BG but rely on my Smart Insulin Pen calculator (could just as well be a pump calculator or an app).”

CASE INSIGHTS:

Christel’s healthcare team could have taken the following actions to help increase her comfort level and satisfaction with personal CGM:

- Discuss emotional/human factors involved with device use, at device initiation and ongoing
- Provide ongoing support and education about her personal CGM, at device initiation and ongoing
- Discuss the potential disadvantages of wearing the device, starting at device initiation, and explore solutions together



PERSONAL STORIES OF CGM USE

Story 2: Nikki P.

Nikki P. is a 48-year-old female who has lived with type 1 diabetes for five and a half years. She uses an insulin pump to manage her diabetes. Nikki thought about getting a CGM for about six weeks before deciding to get one. She has used a CGM for about five years. She did some research online and asked questions in Facebook Diabetes groups to help her with her decision about CGM. Her endocrinologist ordered it for her, and she initially encountered some difficulties with getting it approved by the insurance company, but with use of an appeal process was able to obtain it.

Nikki shares that she received no training on the use of her CGM and watched a video on her own which helped her to learn about it. She did not have any difficulty learning how to use the CGM device. She has not received any ongoing training but will sometimes reach out to the Facebook community to ask questions from others.

She does use the CGM to make treatment decisions. Nikki shares that one thing she really likes about the CGM is that it “gives me a freedom and peace of mind that I don’t have otherwise. I can go about my life, particularly runs or bike rides, without worrying about what my glucose is.” She adds, “Knowing that I will be alerted when I’m out of range makes managing diabetes feel manageable.” She dislikes that her current CGM device requires 2x daily fingerstick glucose readings to calibrate it.

Nikki shares that her overall CGM experience has been positive and that she plans to always have one. “It is a complete gamechanger that makes exercise and sleep possible (if not perfect).” For ongoing support, she is a member of the Diabetes Sisters virtual pod and several other Facebook groups.

Nikki offers the following advice to healthcare professionals: “I think an emphasis on having the data to make decisions and regain control might appeal to a hesitant user. I also know that the fear of being judged by healthcare providers exists so again, an emphasis on it just being data being reviewed for trends, not judgment.” She advises to recommend that people with diabetes who are new to CGM “stick with it for at least a month. It might be hard to adjust to having something attached.” She recommends that the healthcare professional “Set alerts wide at first and narrow as results improve” (meaning that the low alert should not be set at too high a level and the high alert should not be set at too low of a level initially). Nikki recommends Facebook groups and others in the diabetes community as good sources of support for answering questions about the real-life challenges of CGM use.

CASE INSIGHTS:

Nikki’s healthcare team could have taken the following actions to help increase her comfort level and satisfaction with personal CGM:

- Enlist the pharmacist on the team to assist with checking insurance benefits
- Discuss pros and cons of all CGM devices with her before she obtains one so she can choose, although her choice of device may be limited to those covered by her health plan
- Provide ongoing support and education about her personal CGM, at device initiation and ongoing
- Discuss potential disadvantages of wearing the device, starting at device initiation, and explore solutions together



PERSONAL STORIES OF CGM USE

Story 3: Keena B.

Keena B. is a 47-year-old female who has lived with type 1 diabetes since 1974. She uses an insulin pump to manage her diabetes. Keena considered getting a CGM for less than a year and has now used one since 2011. Her endocrinologist prescribed it for her, and she did not experience any difficulties getting it approved by the insurance company.

Keena shares that her initial CGM training was “limited, but adequate.” The training was provided by a diabetes educator and company representative. Her ongoing training and support have been “limited but adequate” and she has “switched CGM providers and asked questions.”

She does use the CGM results and trend arrows to make treatment decisions and says, “This is one of the primary drivers for me ever trying a CGM. I wanted more convenience in managing my diabetes.” Keena shares that one thing she really likes about CGM is “the convenience it provides for making treatment decisions and peace of mind knowing blood sugar readings and trends, especially when I’m alone, traveling, and in the company of friends/family who may not be as aware or knowledgeable about my condition in terms of what CGM or blood sugar readings/trends mean to my treatment and overall health.” She also shares some dislikes regarding CGM: 1. Aesthetic qualities, “I don’t know many people who would or do find machinery attached to my body to be particularly flattering to my body type or attire.” 2. “Constant reminder of diabetes, especially on days when my diabetes is more frustrating to treat.” 3. “Not having customization of alarms on my receiver or the iPhone app to the degree I would prefer. Consequently, I am one of the few people I know who prefers to use the CGM receiver over an iPhone app for readings because I feel like I can control the (sometimes) barrage of alarms at inconvenient times, especially when coupled with the (sometimes) barrage of alarms from my pump.”

Keena does plan to continue using a CGM. With her current busy schedule, “I cannot risk a low blood sugar, so I depend on my CGM, all the time!” She “believes that my CGM has eased my diabetes burden as I pursue my goal. I miss it when it is not with me.”

She offers the following advice to healthcare professionals: “Obviously, HIPAA prevents healthcare professionals from sharing patient references; however, if they could build a data bank of patients who are willing to speak to other patients about their experience, I think that could be really helpful. Speaking to someone who is already on a particular system provides real-world experience a potential user can rely on.”

CASE INSIGHTS:

Keena’s healthcare team could have taken the following actions to help increase her comfort level and satisfaction with personal CGM:

- Provide ongoing support and education about her personal CGM, at device initiation and ongoing
- Discuss emotional/human factors involved with device use, at device initiation and ongoing
- Discuss and provide a resource listing of social support/networks for Keena to connect with

Clinician Readiness to Promote Continuous Glucose Monitoring

How ready are you and your staff to promote Personal CGM in your practice?

Tanenbaum et al., in 2018²², surveyed 209 diabetes care providers who treat people with type 1 diabetes. Three clinician personas emerged regarding readiness to promote continuous glucose monitoring.

- **Ready clinicians** (20% of sample; 24% physicians, 38% certified diabetes educators – CDEs) had positive technology attitudes, had clinic time to work with people using CGM and found it easy to keep up with technology advances.
- **Cautious clinicians** (41% of sample; 17% physicians, 53% CDEs) perceived that their patients had many barriers to adopting CGM and had less time than the ready group to work with people using CGM data.
- **Not yet ready clinicians** (40% of sample; 9% physicians, 79% CDEs) had negative technology attitudes and the least clinic time to work with CGM data. They found it difficult to keep up with technology advances.

Overcoming Therapeutic Inertia

Therapeutic inertia is a well-known problem in the management of diabetes. Treatment intensification may be delayed for a prolonged period due to several reasons. Kamlesh Khunti, FMedSci, FRCGP, FRCP, MD, PhD, presented an overview of the scope and impact of therapeutic inertia as well as clinician barriers related to therapy intensification reported in the American Diabetes Association's publication, Summary of the Proceedings of the American Diabetes Association Summit - Overcoming Therapeutic Inertia: Accelerating Diabetes Care For Life²³.

These barriers include the following:

- lack of time
- lack of resources
- lack of training and education
- suboptimal patient medication-taking behavior
- perceptions about patients' ability and willingness to follow treatment protocols
- hypoglycemia concerns and management of comorbidities.

In this same publication, session participants were asked to share their ideas of the causes and impact of therapeutic inertia and to summarize that in one word. Words identified to describe the top contributors to therapeutic inertia were "time," "cost," "fear," "apathy" and "overwhelmed." Words identified to describe the solutions to address therapeutic inertia were "education" and "time."

Results of a nationally representative, serial cross-sectional study of adults with diabetes were reported in JAMA in 2019's "Evaluation of the Cascade of Diabetes Care in the United States, 2005-2016"²⁴. The conclusion was that there was no significant improvement in diabetes care in the US between 2005 and 2016. Certainly, therapeutic inertia comes into play here.

A Personal CGM program can address therapeutic inertia by identifying glycemic patterns and changing the treatment plan to address problem areas that are uncovered. Changing the treatment plan does not only entail making medication related interventions, but also, very importantly, includes an analysis of lifestyle factors and behavioral issues and a plan to overcome these obstacles. A diabetes care and education specialist is a great person to have on your team to address these topics with people with diabetes, as they are skilled at coaching persons with diabetes in all aspects of self-management of their condition using an evidence-based framework, the [AADE7 Self-Care Behaviors®](#). The pharmacist is another important person to have on your team to provide their expertise related to medication management and medication related interventions, and for helping adjust medications based on results from personal CGM.



Usability and the Human Interface

David Rodbard, in his article, “Continuous Glucose Monitoring: A Review of Successes, Challenges and Opportunities”²⁵, identifies the critical role of usability and the human interface as a potential barrier to clinical implementation of CGM. He points out the need for more research into questions such as:

- How much time and training are required for the healthcare provider to learn and then teach the patient the basics of operation and a systematic approach to use CGM data?
- How much time and training are required by the patient to become familiar with the use of the device, insertion and removal of the sensor, routine daily use, and transmission of the data to a computer and the internet?
- How much time and training are required for the healthcare provider and/or patient (individually or jointly) to perform and interpret retrospective data analysis?
- How reliably, consistently and effectively do healthcare providers and patients interpret and apply the results?
- How well does information obtained from CGM get translated into actions and behaviors that improve measurable clinical outcomes, including quality of glycemic control and glycemic variability, treatment satisfaction and quality of life?

Smith, Albanese-O'Neill, et al., in their article, “Human Factors Associated with Continuous Glucose Monitor Use in Patients with Diabetes: A Systematic Review”²⁶, point out that “understanding the disparity in CGM use should be approached as a two-fold issue; 1. Why is initial uptake of CGM low and, 2. Among CGM users, why are the systems not worn with consistency?”

They identify that the “perceived benefits and hassles of CGM use is an informative measure that is associated with consistent use and generates evidence to support future clinical interventions.” They also note, “given that the first month of CGM use has been shown to predict future adherence, emphasis should be placed on improving the initial patient engagement and perceptions related to CGM.”

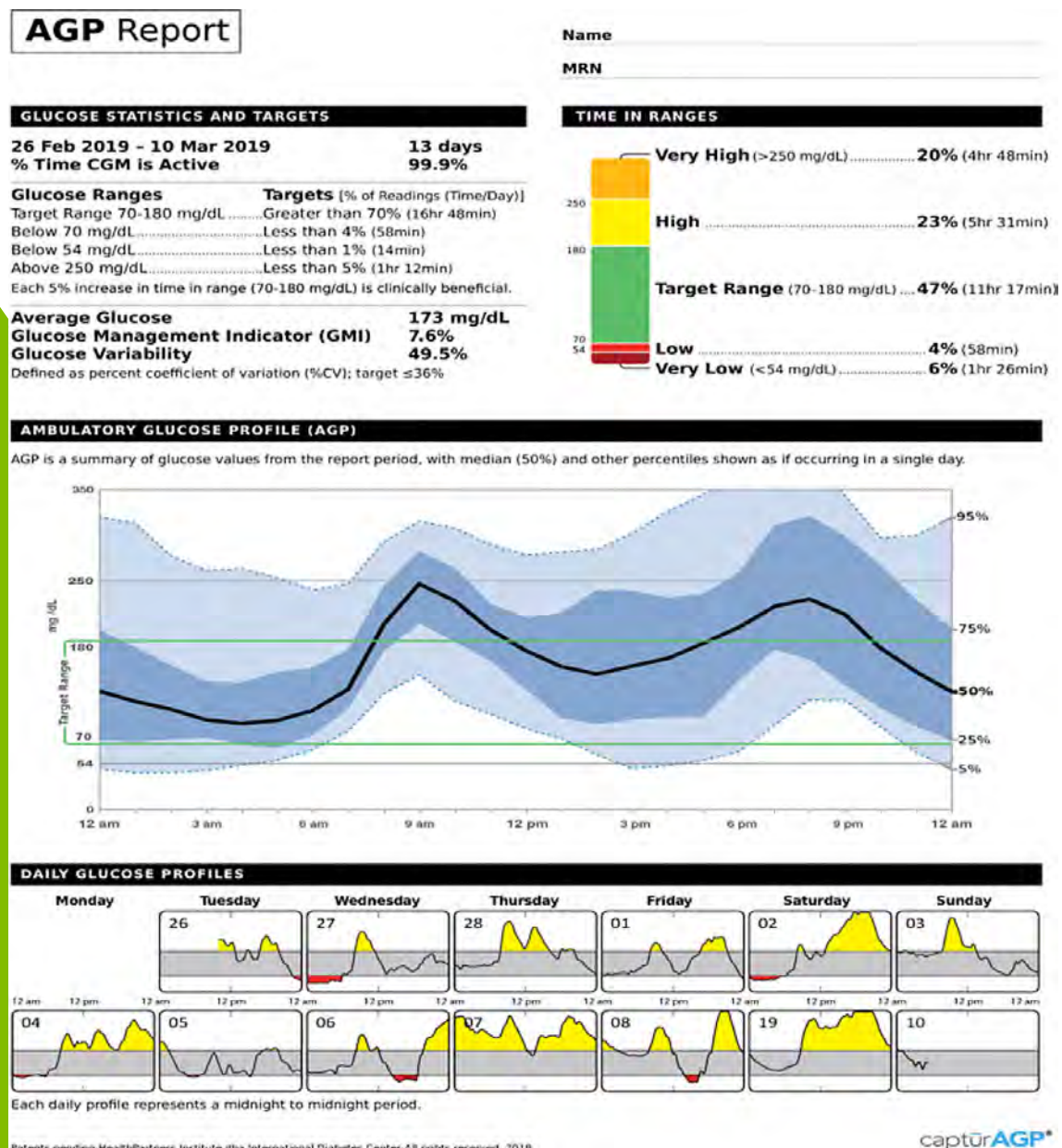
Smith, Albanese-O'Neill, et al., advise further that, “interventions should focus on improving patient satisfaction by reducing hassles, addressing barriers to use, lessening implementation burden, setting realistic expectations, and enhancing the perceived benefits of use.”

Interpretation of CGM Data and Reports

The health care professional interprets the personal CGM reports retrospectively and evaluates for glycemic excursions above/below target range, seeking to identify patterns and potential causes for these excursions with the person with diabetes.

Device download reports vary by manufacturer and include differing data presentations; however, there has been a recent push to focus on use of the Ambulatory Glucose Profile (AGP) report, which was developed by the Park Nicollet International Diabetes Center (IDC) in Minneapolis, Minnesota²⁷. The use of one report would aid in standardization of care and would help to make interpretation more accurate and efficient. The AGP report includes summary statistics, a glucose profile graph and an insulin profile graph or glucose daily calendar graphs.

EXAMPLE OF AGP REPORT



The 2017 International Consensus on Use of Continuous Glucose Monitoring report published in Diabetes Care provides a detailed description of the 14 key metrics that can be analyzed when reviewing retrospective data²⁸.

More recently, the International Consensus on Time in Range identified standardized clinical targets for CGM data interpretation, as follows²⁹:

Number of days CGM is worn

14 days is recommended

Percentage of time CGM is active

70% of data from 14 days is recommended

Mean glucose**Glucose Management Indicator (GMI)**

This used to be called the estimated A1C (eA1C) but now uses an updated formula for converting CGM-derived mean glucose to an estimate of current A1C level.

Coefficient of Variation (CV)

This is a measure of glycemic variability. A CV of less than or equal to 36% is considered acceptable, >36% is considered unstable and intervention is needed.

Very High Time Above Range (TAR)

% of readings and time >250 mg/dl

High Time Above Range (TAR)

% of readings and time 181-250 mg/dl

Time In Range (TIR)

% of readings and time 70-180 mg/dl

Low Time Below Range (TBR)

% of readings and time 54-69 mg/dl

Very Low Time Below Range (TBR)

% of readings and time <54 mg/dl

The first priority is to reduce the time spent below range (work to eliminate hypoglycemia) and then focus on decreasing time above range or increasing time in range.

Glucose time in target range (TIR) is another important measure and Dr. Richard Bergenstal, in 2018³⁰, identified correlations of TIR and HbA1C as follows:

CONTINUOUS GLUCOSE MONITORING (CGM) DATA INTERPRETATION USING THE AMBULATORY GLUCOSE PROFILE (AGP)³

TIME IN RANGE % (TIR%)	AVERAGE HBA1C
40%	8.1%
50%	7.7%
60%	7.3%
70%	6.9%
80%	6.5%

Step 1 Confirm that adequate data are available. For Current CGM users, a minimum of 70% of 2 weeks of data is recommended.³⁴ Fewer days are needed when professional CGM systems are used.

Step 2 Print out the AGP and ask patients to describe their daily self-management. When are they taking their insulin and how much? When do they wake? When do they eat? Do they exercise and, if so, what type of exercise and when are they doing it? Document this information on the AGP printout.

Step 3 Ask the patients what they see in the AGP and why they think it may be important. Then listen. Interactive discussion with patients allows them to better understand how their insulin, food and other factors affect their glucose levels and also helps clinicians identify knowledge deficits or behaviors that may not support glycemic goals.

Step 4 Look for problematic glycemic patterns in the following order of priority:

1) Hypoglycemia, 2) Hyperglycemia, 3) Wide glycemic variability. Review the overall glucose profile (initial view) to determine the time of day when patterns are occurring, then review the daily graphs to double-check patterns to see if they are clustered on certain days.

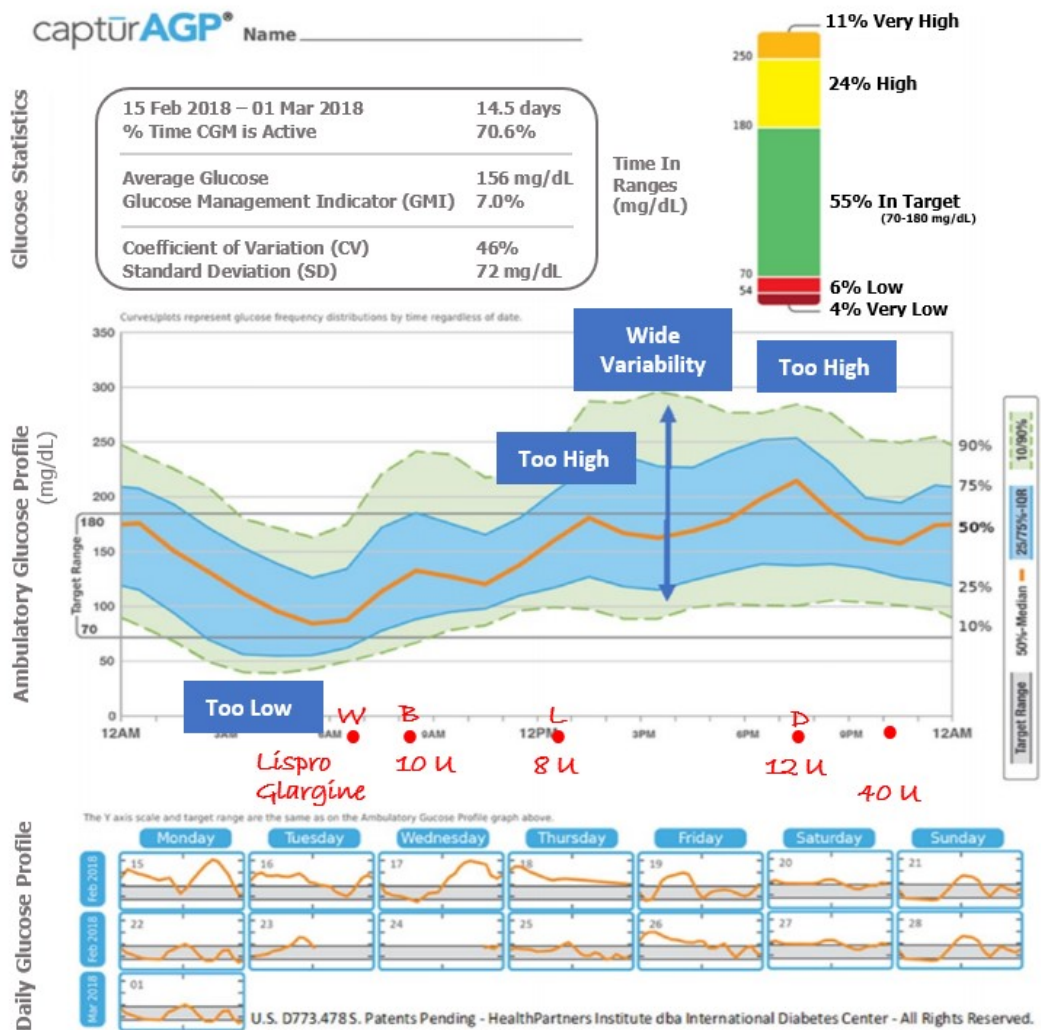
Step 5 Encourage patients to reflect on what they think may be causing the problem and discuss potential solutions.

Step 6 Collaboratively develop an action plan. Make sure patients fully understand the changes they will be making and that they have the knowledge/skills to implement the plan.

Step 7 Make a copy of the marked up AGP printout for the patient and enter the original into the electronic medical record (EMR). If electronic entry is not possible, copy and paste the AGP into the EMR as a progress note.

³An expanded teaching tool is available at <https://www.idcpublishing.com/>.

Used with permission. Sage Publications. *Reference Guide for Integrating Continuous Glucose Monitoring Into Clinical Practice*³¹.



History:

- Robert is 27-year-old male who has had T1DM for 8 years, treated with multiple daily insulin injection (MDI) therapy-aspart at meals.
- His self-reported insulin regimen is 8-12U aspart at meals, 40U glargine at bedtime.
- His current A1C (7.0%) is at target; however, Robert complains of occasional headaches when he wakes in the morning.

Interpretation:

- AGP indicates an adequate number of days (14) for assessment.
- Extremely low glucose for several hours in the early morning.
- High glucose post-supper appears to be driven by post-lunch excursions.
- Glycemic variability indicates instability.
- Daily Graphs suggest that Sunday mornings are problematic for lows; however glycemic patterns vary from day to day.
- Wide glycemic variability prompts discussion about meals/snacks and insulin dosing. Robert explains that he does snack throughout the day but is uncomfortable about calculating insulin doses; he avoids taking correction insulin even when glucose is high.

Action:

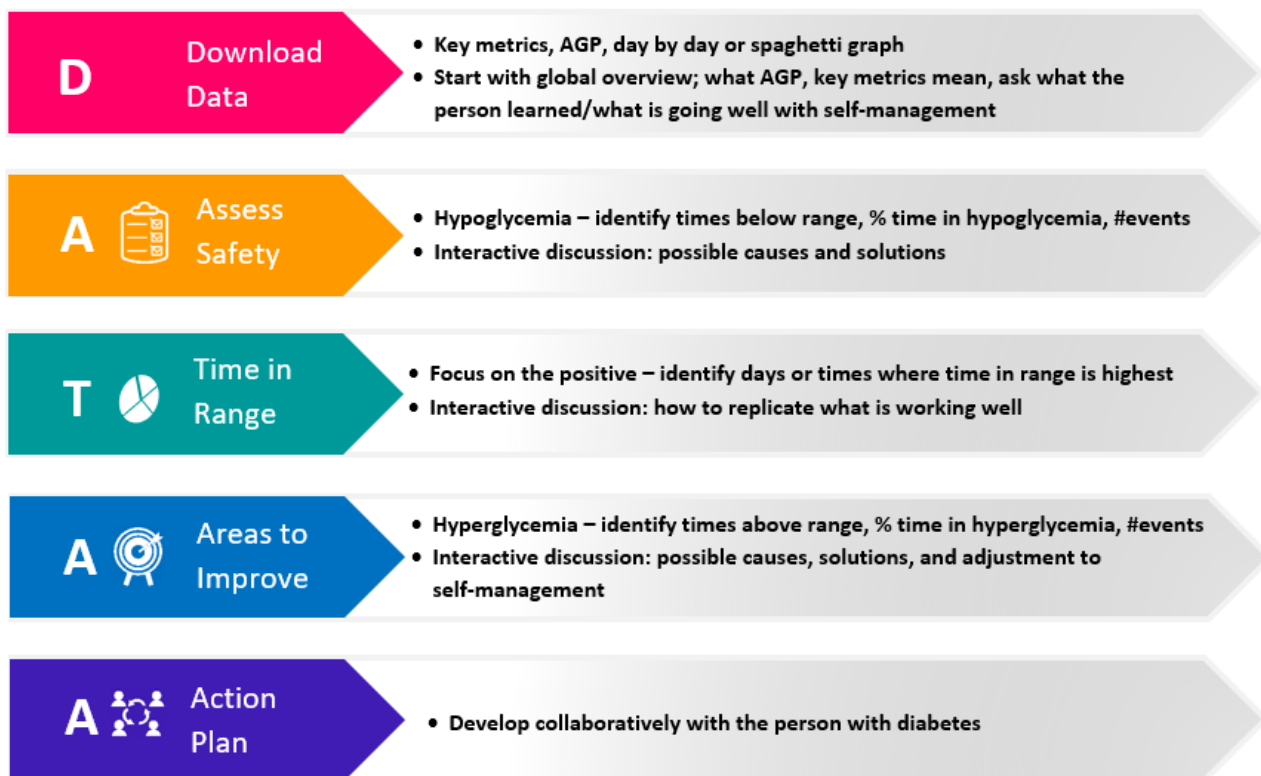
- Reduce the glargine dose at bedtime to address the low glucose. Another option is to switch the patient to glargine U-300 or degludec. This would avoid possibility of elevated afternoon glucose.
- Provide/schedule education in CHO counting, insulin dose calculation and use of correction insulin.
- Review CGM data again at 2 weeks - if overnight glucose is stabilized, increase the aspart insulin at lunch and supper to address the postprandial glucose.

Used with permission. Sage Publications. Reference Guide for Integrating Continuous Glucose Monitoring Into Clinical Practice.



Additionally, ADCES recommends the use of the DATAA Model for reviewing CGM data, as described by Isaacs et al in the August 2020 issue of “The Diabetes Educator”³²:

Review of CGM - DATAA



*****At each step, express that this is information, not good or bad*****



Practice Spotlight

Dr. Jeff Unger, MD, FAAFP, FACE, directs his own primary care practice in Rancho Cucamonga, California. Dr. Unger operates a personal and professional CGM program and states that he doesn't think he would be able to provide the best care to his patients who have diabetes without it.

Most people with diabetes that he treats will receive a CGM, whether they have type 1 or type 2 diabetes. "If they have the risk of hypoglycemia, they will benefit from a CGM." He states that healthcare providers benefit from their patients who have diabetes having a CGM by being able to see all the glucose data, 24 hours a day. This allows for being able to change treatment plans knowledgeably and safely. The people who have diabetes benefit from a CGM by being able to respond to trend arrows and often to avoid major glucose excursions.

Dr. Unger feels that he can train a person on a CGM pretty quickly and that their glycemic control will start to improve within two weeks of initiation. From his experience, people love the CGM and most people wear it 99% of the time. If a person with diabetes is thinking about going on an insulin pump soon, he takes that into consideration, and will help them choose a CGM that will integrate with the insulin pump that they are leaning toward. There are many choices of available CGM devices and Dr. Unger matches the patient's need to the particular device.

Dr. Unger states that it is very important to do proper coding of the visit with the patient with diabetes. The diagnosis code for hypoglycemia is important to list, if applicable, and is a code that is sometimes overlooked. He takes an orderly approach to CGM interpretation and follows these steps:

1. Identify and correct hypoglycemia, aiming for a target of less than 4%.
2. Identify and correct post-prandial spikes in glucose.
3. Identify and correct glycemic variability, aiming for glucose time in range target of 70-180 mg/dl at least 70% of the time.

It takes him less than five minutes to complete the CGM interpretation and he will often compare it to the past office visit CGM data and use that as a teaching point to show the patient what sort of progress they have made.

Lastly, Dr. Unger strongly believes that it would be a disservice to the person with diabetes to not utilize personal CGM in the appropriate person. CGM gives you the benefit of being able to successfully treat your patients who have diabetes. CGM gives the provider a reason to praise the patient with diabetes, which Dr. Unger feels will help the patient do their best to remain adherent to their medication regimen. "Diabetes management is time-consuming and difficult for many patients." CGM is a tool that can increase success with diabetes management and one that should be used much more often.

Dr. Unger feels that he can train a person on a CGM pretty quickly and that their glycemic control will start to improve within two weeks of initiation.



Practice Spotlight

Dr. Anastasia Albanese-O'Neill, PhD, ARNP, CDCES, is the Director of Diabetes Education and Clinic Operations in the Division of Pediatric Endocrinology at the University of Florida in Gainesville. In 2015, UF Health pediatrics implemented a professional continuous glucose monitoring program. This gave patients the opportunity to experience a real-time CGM device and allowed the diabetes care team to review and interpret CGM data to inform patient care.

In 2016, she launched the clinic's personal RT-CGM training and education program. This structured program gave children served by the UF Health clinic the training and support required to use the RT-CGM device prescribed by their diabetes healthcare provider.

One of the first things that Dr. Albanese-O'Neill implemented was a "Wear and Share" program so that clinic staff and providers could wear the device. This gave them the opportunity to interact directly with the CGM, feel what it was like to insert it, experience alarms overnight, and set up the receiver and related Apps. This first-hand experience allowed providers, educators and staff to talk more confidently about the device with families.

A half day each week was designated for CGM training for people with diabetes and their family caregivers. Appointments were scheduled as a "CGM Start" with a nurse practitioner and Certified Diabetes Care and Education Specialist (CDCES). A suite of CGM-related resources were created in the electronic medical record (EPIC), including a Letter of Medical Necessity for CGM, a Referral to CGM clinic, and Assignment of Benefits form (so patient would know what the cost would be for the device and ongoing supplies). CGM documentation templates and visit summary templates with instructions were also created and available in EPIC. For the first year, devices were shipped directly to the clinic rather than the patient, due to problems in the past with patients forgetting to bring all components of the device or supplies with them to clinic on CGM start day.

During the training visit, comprehensive training for RT-CGM was provided. In addition, families were guided through setting up all related apps and linked to the clinic's data sharing accounts. Written instructions were provided so families knew how to upload data to the clinic for review between clinic visits.

The workflow utilized a team approach for return visits. The clinic MAs checked the patient in, uploaded the patient's device, and entered key variables into flowsheet in EPIC. The MAs also clipped the Ambulatory Glucose Profile and other glucose data into the visit template from Glooko or CLARITY. These data were readily available to clinicians during the visit to utilize for teaching, review with the family, and inform the diabetes care plan. The AGP was also pasted into the patient visit summary for goal setting.

An Advanced CGM course was offered that is co-taught by a nurse practitioner and CDCES. This class includes content on international guidelines for time in range (TIR), use of trend arrows, and factors impacting glucose levels.

All clinic visit types had a written Standard Operating Procedure (SOP) that outlined the role of clinic staff and included a list of relevant EPIC templates, required referrals and related educational materials.

The billing process had been variable since program inception, but it has been revenue positive since 2018. The initial CGM placement for personal CGM was billed as CPT Code 95249. Review and interpretation of CGM data was billed with CPT Code 95251 following the placement and then at subsequent clinic visits when CGM data was interpreted during the clinic visit.

Ongoing resources for clinic staff included a weekly Diabetes Education and Clinic Operations meeting. The weekly meeting was attended by staff, fellows and providers and served as a forum to discuss metrics and opportunities to improve clinical outcomes using quality improvement principles. Educational in-services were also provided during this scheduled weekly meeting.

Dr. Albanese-O'Neill believes that every clinic that wants to initiate a personal CGM program needs a champion to get the program up and running and to continue to nurture and grow the program.

She identifies challenges of personal CGM for the person with diabetes to be: initial cost, difficulty obtaining ongoing supplies, embarrassment with wearing a device, alarm fatigue, usability issues and data overload. She believes that these challenges can be overcome on an individualized basis and that the benefit of personal CGM outweighs the drawbacks.



Practice Spotlight

Sara (Mandy) Reece, PharmD, CDCES, BC-ADM, BCACP, FADCES, is embedded within a family medicine clinic that is part of the Family Medicine Graduate Medical Education Program with Northeast Georgia Medical Center in Gainesville, GA, and she understands the value of offering both a professional and personal CGM program. Mandy performs team visits along with a physician or NP and is known as the “diabetes specialist” in her practice. She provides education for the other providers and residents about the CGM process; including how to interpret the Ambulatory Glucose Profile (AGP), how to prescribe CGM and understanding of the Medicare CGM requirements. Her next goal is to develop a CGM training program for the practice’s support staff so they know about the ins and outs of CGM and will be able to identify people with diabetes who might benefit from CGM.

Mandy began her CGM practice with professional CGM and now has integrated a personal CGM program into that. Both practices have been expanding rapidly. She also teaches personal CGM to eligible people with diabetes in the employee clinic. When asked how she learned about CGM and prepared to add this to her practice, Mandy explained that the ADCES [CGM Certificate Program \(danatech.org\)](https://danatech.org) was invaluable to her and this is where a lot of her knowledge came from.

She has encountered some barriers in obtaining personal CGM devices for all that would benefit from them. One barrier that she has come across is that the state Medicaid program does not cover CGM for people with type 2 diabetes and has only limited coverage for people with type 1 diabetes. One way she has been able to still provide some CGM benefit for people without coverage for personal CGM is through offering professional CGM.

As a pharmacist, Mandy brings many important skills to the CGM process in her practice. She assists the person with diabetes with device selection, checks insurance benefits, directs person where to go to obtain their CGM, provides training about the CGM, provides individualized CGM settings, troubleshoots any problems that the person is experiencing related to their CGM and downloads and interprets data.

Mandy advises to be cautious with setting CGM alerts in the beginning of device wear. This will minimize early frustrations due to alarms. These alerts can be adjusted as you go along. She also states the importance of starting a CGM with realistic expectations. Mandy tells people who are new to CGM that “it is a tool to help you better understand your diabetes, not a cure all.” Common concerns that she addresses with people who have been using their CGM for a while include the device getting knocked off their arm, sweating too much and it falls off and worries about the fingerstick blood glucose value and the CGM interstitial glucose value not matching up.

Mandy shares two recommendations related to CGM:

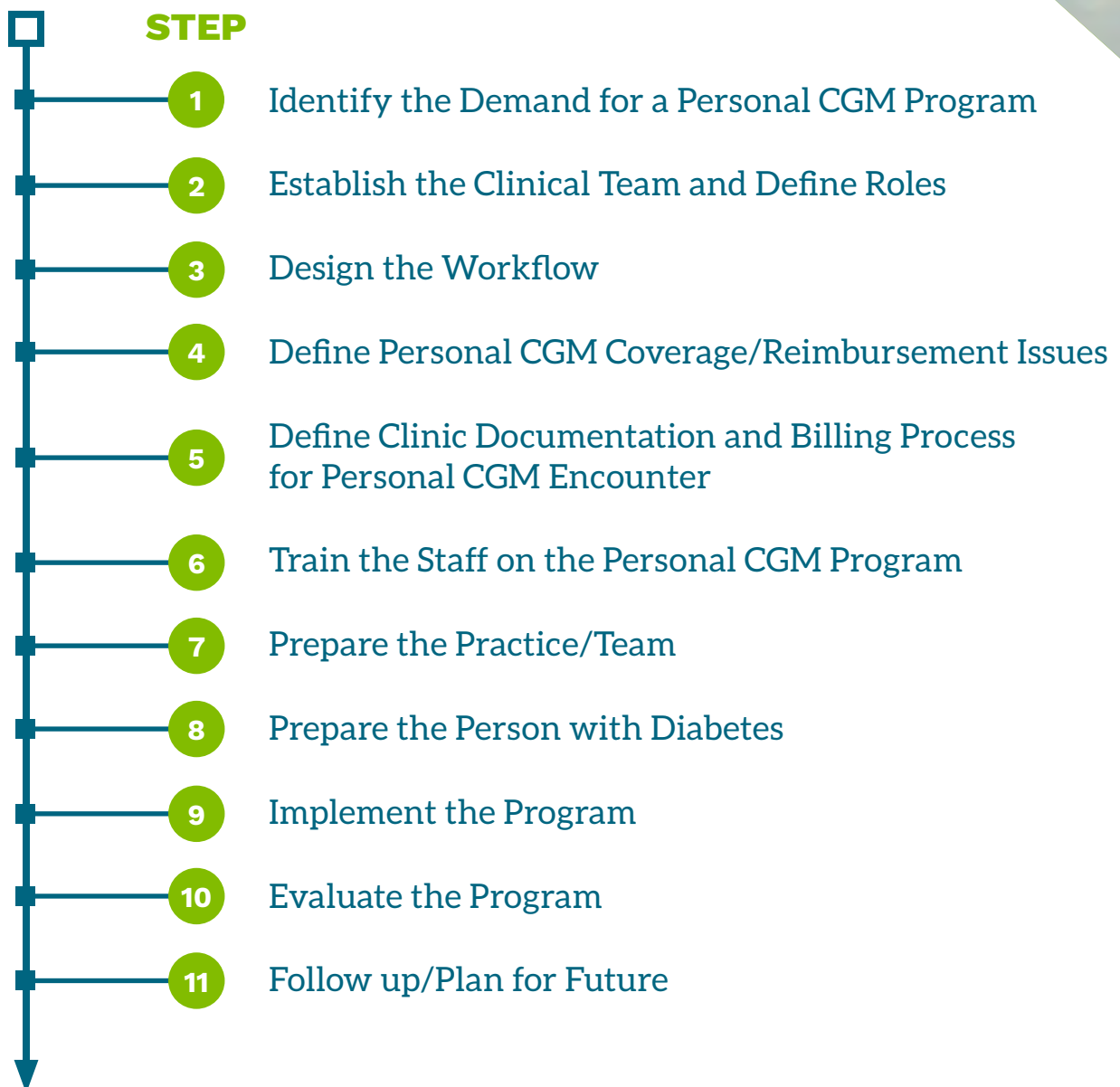
1. Sign up for the ADCES CGM Certificate Program
2. Look for practice opportunities for both personal and professional CGM.

CGM will help make the picture clear as to why someone’s diabetes is not well managed. Her advice to practices that have not started a CGM program yet is that if you are measured by quality measures, CGM will improve your quality metrics. Secondly, CGM will empower your patients and increase their satisfaction with you as their provider. It truly is a win-win.

When asked how she learned about CGM and prepared to add this to her practice, Mandy explained that the ADCES CGM Certificate Program was invaluable to her and this is where a lot of her knowledge came from.

PART TWO:

Getting Started - Steps to Develop a Personal CGM Program



STEP 1:

Identify the Demand for a Personal CGM Program

Identify feasibility of the program through evaluation of your population and of support structures within your practice setting.

Begin by outlining benefits to the people with diabetes, providers and practice.

- Are you doing all you can to optimize your patients' diabetes management?
- How could personal CGM benefit your patient population?
- Would your patient population be amenable to personal CGM?
- Are the providers in your practice resourced appropriately to support a personal CGM program?
- What does your practice hope to gain by implementing this program?
- How could a personal CGM program add value to your patients, providers and practice?
- Could it help improve the diabetes care provided in your practice?
- Could it help to improve the diabetes metrics in your practice?

Once this genuine need is clearly identified, you will know that you are headed in the right direction.

CHECKLIST OF ITEMS TO ACCOMPLISH DURING THIS PHASE

- ☐ Categorize your diabetes population by types of diabetes therapies that they utilize.
 - What percent uses multiple daily insulin injections or insulin pumps?
 - What percent uses basal insulin plus orals or other injectables?
 - What percent uses oral agents that may cause hypoglycemia, such as sulfonylureas, etc.?
 - How many are currently utilizing personal CGM devices?
- ☐ Meet with the members of your healthcare team to identify pros and cons of using personal CGM to manage people with diabetes in your practice [See Worksheet 1](#)
- ☐ Meet with all important stakeholders (e.g., leadership team, support staff) to identify any concerns they have and obtain their buy-in
- ☐ Identify outcomes of a successful Personal CGM Program, to people with diabetes, the providers and to the practice [See Worksheet 2](#)

QUICK TIP

Reach out to colleagues at other practices with an already established Personal CGM Program and network with them about what worked – and what did not go as smoothly as hoped – when getting the program off the ground. Continue to call on them as a resource as you create and implement your program. The experience and advice of these key people will be invaluable to you as you move forward.

QUICK TIP

Professional CGM implementation can be an important steppingstone for preparation of personal CGM implementation. [See Professional CGM Implementation Playbook](#) for more information.

STEP 2:

Establish the Clinical Team and Define Roles

Finding the right composition of the team is vital, and depending on your practice, you will need to decide who should be included on the team.

Enthusiastic and well-qualified team members will ensure a successful launch of the program. In this phase you will need to identify who will be on the team and what their roles will be.

- A diabetes care and education specialist (DCES) is valuable to the team if you have one on your staff. The diabetes care and education specialist can help the individual understand how various lifestyle factors and self-care behaviors affect their diabetes management and possess the knowledge base to offer thorough training on the CGM device to the person with diabetes.
- A pharmacist can provide medication-related expertise, which can add value to a personal CGM program because they can work with the patient and the physician to make adjustments to the treatment plan based on CGM results.
- A person that is knowledgeable in downloading CGM devices will be vital to the team.
- The CGM device company representative may be part of your team to assist with device training and follow-up.

CHECKLIST OF ITEMS TO ACCOMPLISH DURING THIS PHASE

- ☐ Identify the members of your team [See Worksheet 3](#)
- ☐ Define roles and responsibilities of each team member [See Worksheet 4](#) & [Worksheet 5](#)
- ☐ Meet as a team regularly
- ☐ Seek ongoing feedback from all involved parties

QUICK TIP

Pay attention to the climate of the team. Seek ongoing ideas from all and don't be averse to changing direction if warranted.

***“The future depends
on what you do today.”***

—Mahatma Gandhi

STEP 3:

Design the Workflow

Adding a Personal CGM Program to your practice will require changes to your current workflow. You have already identified the roles of your team members, so you are aware of what new responsibilities they will be taking on. It is helpful to define the Personal CGM process from start to finish so you have a clear understanding of all steps.

[See Worksheet 6](#)

CHECKLIST OF ITEMS TO ACCOMPLISH DURING THIS PHASE

- ☐ Seek input from all team members regarding the design of the workflow
- ☐ Define the workflow of an in-person visit from beginning to end
 - Include specifics about patient selection, use of the device, providing education to patient, diagnosis/coding/billing, documentation, downloading and interpreting results
 - The ADCES Identify-Configure-Collaborate framework provides a standardized 3-step process for integrating diabetes technology into your practice³³. [See Worksheet 7](#)
- ☐ Define the workflow of a remote monitoring visit from beginning to end
- ☐ Update existing protocols or create new ones to accommodate this new workflow in daily practice
- ☐ Plan for enhanced staffing levels as you roll out the new program
- ☐ Identify necessary resources that will support the new workflow
- ☐ Solicit staff feedback every step of the way
- ☐ Plan for ongoing scheduled evaluation of workflow and adjust as needed
- ☐ Determine what data you will want to collect ongoing

QUICK TIP

Actively seek to minimize disruption to the current workflow. Anticipate barriers and be prepared to address them. It is important to consider all perspectives when designing the workflow, including that of the person with diabetes, the support staff and the providers. You may want to appoint a patient representative to assist with design, implementation and evaluation of the workflow to ensure that you fully understand their perspective. As you learn and grow, your program will continue to adjust its workflow.

STEP 4:

Define Personal CGM Coverage/ Reimbursement Issues

Commercial insurance and Medicaid plans vary in regard to amount of coverage for personal CGM devices and their ongoing supplies.

Medicare will cover personal CGM if the following criteria are met:

- Have a diagnosis of diabetes, either type 1 or type 2
- Use a home blood glucose monitor (BGM) and conduct four or more daily BGM tests
- Treated with insulin with multiple daily injections or a continuous subcutaneous insulin infusion (CSII) pump.
- Require frequent adjustments of the insulin treatment regimen, based on therapeutic CGM test results.

CHECKLIST OF ITEMS TO ACCOMPLISH DURING THIS PHASE

- ☐ Seek input from all team members regarding the design of the workflow
- ☐ Define the workflow of an in-person visit from beginning to end

QUICK TIP

You may be requested to do a peer-to-peer review to further determine medical necessity for the personal CGM. It may be helpful to have a template prepared that includes details that you want to include in a review.

STEP 5:

Define Clinic Documentation and Billing Process for Personal CGM Encounter

Defining the documentation and billing process before you begin will help ensure that all potential roadblocks are anticipated, identified and addressed. Educate staff on the billing codes to utilize for Personal CGM. [See Worksheet 8](#)

CHECKLIST OF ITEMS TO ACCOMPLISH DURING THIS PHASE

- ☐ Identify the team member to be accountable for coordination of insurance benefits and requirements
- ☐ Provide an in-service for staff on coding, billing and documentation requirements for Personal CGM
- ☐ Provide an in-service for staff about CGM remote monitoring visits that includes documentation and billing requirements
- ☐ Identify team member(s) to perform ongoing documentation, coding and billing audits of individuals in the program

QUICK TIP

Mapping out the documentation and billing process *before* you begin will help ensure that all involved staff understands the necessary codes to bill when there is a patient visit with a personal CGM to be evaluated.

STEP 6:

Train the Staff on the Personal CGM Program

Staff will need to be trained on the personal CGM program being offered in your practice. Training should cover an overview of the workflow, including patient selection, use of the device, providing education to patient, diagnosis/coding/billing, documentation³⁴, download and interpretation of results.

CHECKLIST OF ITEMS TO ACCOMPLISH DURING THIS PHASE

- ☐ Develop protocol that identifies characteristics of individuals that would most likely benefit from Personal CGM
[See Worksheet 9](#)
- ☐ Set up vendor training sessions for all involved staff to learn about the different personal CGM devices and how to download information
- ☐ Provide resources for staff about the different routes to obtain Personal CGM (how to pick up the product at pharmacy or obtain from DME supplier) [See Worksheet 10](#)
- ☐ Develop staff competencies that are role specific and identify a process to review and document their skills on an ongoing basis
- ☐ Set up provider training on program workflow and protocols, diagnosis/coding/billing, interpretation and documentation of downloaded information
- ☐ Plan for annual training refresher

QUICK TIP

Providing thorough pre-implementation training will help ensure a smooth start to the program. Solicit staff feedback frequently during and after the training sessions. Consider recording the training sessions so that new staff joining the program in the future will have access to it.

“Individually, we are one drop. Together, we are an ocean.”

—Ryunosuke Satoro

STEP 7:

Prepare the Practice/Team

Ensure that all team members are aware of their roles and responsibilities. Proper staff preparation will make sure that the team is on board with the program and motivated to put in their best effort to help make it a success. Remember to start process evaluation as soon as the implementation stage kicks off.

CHECKLIST OF ITEMS TO ACCOMPLISH DURING THIS PHASE

- ☐ Host a program launch kick-off event to review roles/responsibilities and provide a program overview
- ☐ Identify staff “superusers” who can serve as resources to others
- ☐ Have vendor and IT available during implementation
- ☐ Make device procedure reference materials and troubleshooting guides widely available
- ☐ Provide a forum for staff to provide feedback and suggestions

QUICK TIP

Keep an open communication line with the team members and involved staff. It is important that the team feels that this is a collective effort and that everyone's feedback is equally important.

QUICK TIP

You may want to try the program out with just a few people with personal CGM devices at first, as a test pilot. This will help to identify any process issues.

STEP 8:

Prepare the Person with Diabetes

The Personal CGM Program will anticipate an upfront learning curve for the person with diabetes. It is vitally important to provide initial and ongoing education about their personal CGM device.

CHECKLIST OF ITEMS TO ACCOMPLISH DURING THIS PHASE

- ☐ Develop a handout for the person with diabetes that discusses how to get the most out of their Personal CGM. The power of data can help the person feel more in control of their diabetes and can facilitate a more collaborative approach with the healthcare team. [See Worksheet 11](#)
- ☐ Provide initial training including a detailed education plan for the patient about their personal CGM device and ongoing training to help them maximize the use of their device. [See Worksheet 12](#)
- ☐ Identify procedure to provide ongoing support for person using personal CGM

QUICK TIP

Make the person with diabetes the centerpiece of the program. Spend time up front on education and support to ensure their understanding of the device use and personal goals. Provide ongoing support as they continue their personal CGM journey.

STEP 9:

Implement the Program

You are now ready to try out your new program! All the pieces should be in place. Solicit feedback and ideas from staff and patients throughout the implementation process. Start tracking success measures at program initiation.

CHECKLIST OF ITEMS TO ACCOMPLISH DURING THIS PHASE

- ☐ Walk through the process from start to finish
- ☐ Provide on-site technical and product support resources to staff during launch
- ☐ Perform frequent check-ins with staff at this beginning phase of the program implementation
- ☐ Schedule a weekly staff meeting to discuss how things are going
- ☐ Start collecting any clinical and financial data that you will want to analyze on an ongoing basis

QUICK TIP

If possible, try to have some cushion in your staffing during this time. This will enable staff to take the time necessary to fully learn and practice the new procedures and processes. Communicate frequently with your support staff to identify any challenges or obstacles to program success. Utilize vendor support and IT support to ensure a smooth implementation.

STEP 10:

Evaluate the Program

Program evaluation is an ongoing process. Be thoughtful and quickly responsive to suggestions/ideas/feedback. Continually refer to the metrics of program success that you have identified. Celebrate once you are meeting these success points. If you are not meeting them, determine what the obstacles and challenges are and how you can address or avoid these barriers moving forward. Practice continuous quality improvement.

CHECKLIST OF ITEMS TO ACCOMPLISH DURING THIS PHASE

- ☐ Gather staff feedback on a consistent basis
- ☐ Survey the persons with diabetes that are being served by this program regarding their satisfaction
- ☐ Analyze and evaluate the clinical and financial data that you have collected
- ☐ Compare diabetes outcomes post-Personal CGM Program to pre-program outcomes
- ☐ If you are not meeting success metrics, re-evaluate your program process and amend as necessary
- ☐ If you are meeting success metrics, disseminate the results widely
- ☐ Meet with the entire team to determine next steps. Is program the right size? Does it have the right composition of staff? Is there reasonable access to the program?

QUICK TIP

Establish a timeline for ongoing program evaluation. A program may not attain the expected measures of success in the first few rounds of evaluation. Staff will become more efficient with the program processes as time goes by. Ease of use will improve, and staff confidence and competence will show ongoing improvements as well.

STEP 11:

Follow up/Plan for Future

Planning for the future of your Personal CGM program is a crucial component of a successful program.

- What are the next steps for your program?
- Do you want to establish a satellite location?
- Do you want to start working with patients remotely?
- Do you want to offer a personal CGM support group or annual group education class geared to people who use personal CGM devices?
- Do you want to share your program experience and lessons learned with other care teams?

CHECKLIST OF ITEMS TO ACCOMPLISH DURING THIS PHASE

- ☐ Hold a meeting with the entire team to discuss future goals for the program
- ☐ Explore feasibility of goals
- ☐ Market the program to others that may wish to refer to your program

QUICK TIP

Remember to include administration when planning for the future of the program.

“Success is the sum of small efforts repeated day in and day out.”

—Robert Collier



PART THREE: Worksheet Resources

The following resources have been developed to enhance your program design, implementation and evaluation as detailed in the Playbook.

WORKSHEET 1:

Evaluate the Value (Pros) and Challenges (Cons)
of a Personal CGM Program

PROS	CONS

Some examples of pros: Improve self-care outcomes, improve diabetes metrics, create a revenue stream.

Some examples of cons: Increased workload to staff, pushback from providers, etc.

WORKSHEET 2:**Identify Outcomes of a Successful Personal CGM Program**

List the criteria for program success to the person with diabetes and to the practice. Examples may be improved self-care outcomes (be specific about your population), decreased hypoglycemia, improved diabetes care metrics, the creation of a new revenue source, etc.

1.

2.

3.

4.

5.

Place this list in a prominent location to allow for frequent review.

WORKSHEET 3: Form Your Team

How many teams do you need? Who should be on your team?

Diabetes Care and Education Specialist? Physician? Clinic Manager? Pharmacist? Nurse? Dietitian?

Often there will be several sub-teams: a Leadership Team that makes high-level decisions, a Management Team that is accountable for day-to-day operations and an Advisory Team that may be partly composed of people with diabetes.

List your team structure and team members below:



WORKSHEET 4:**Define Team Member Roles and Responsibilities**

The following lists include some examples of roles and responsibilities for team members. You should develop your own list of roles and responsibilities.

**LEADERSHIP TEAM**

- Identify need for the program
- Develop a business plan
- Provide administrative support for the program
- Identify key members of management team
- Market the program
- Define outcomes to measure and evaluate success

**MANAGEMENT TEAM**

- Responsible for day-to-day operations
- Identify team members and roles
- Implement program
- Provide ongoing support to team members
- Evaluate program continuously

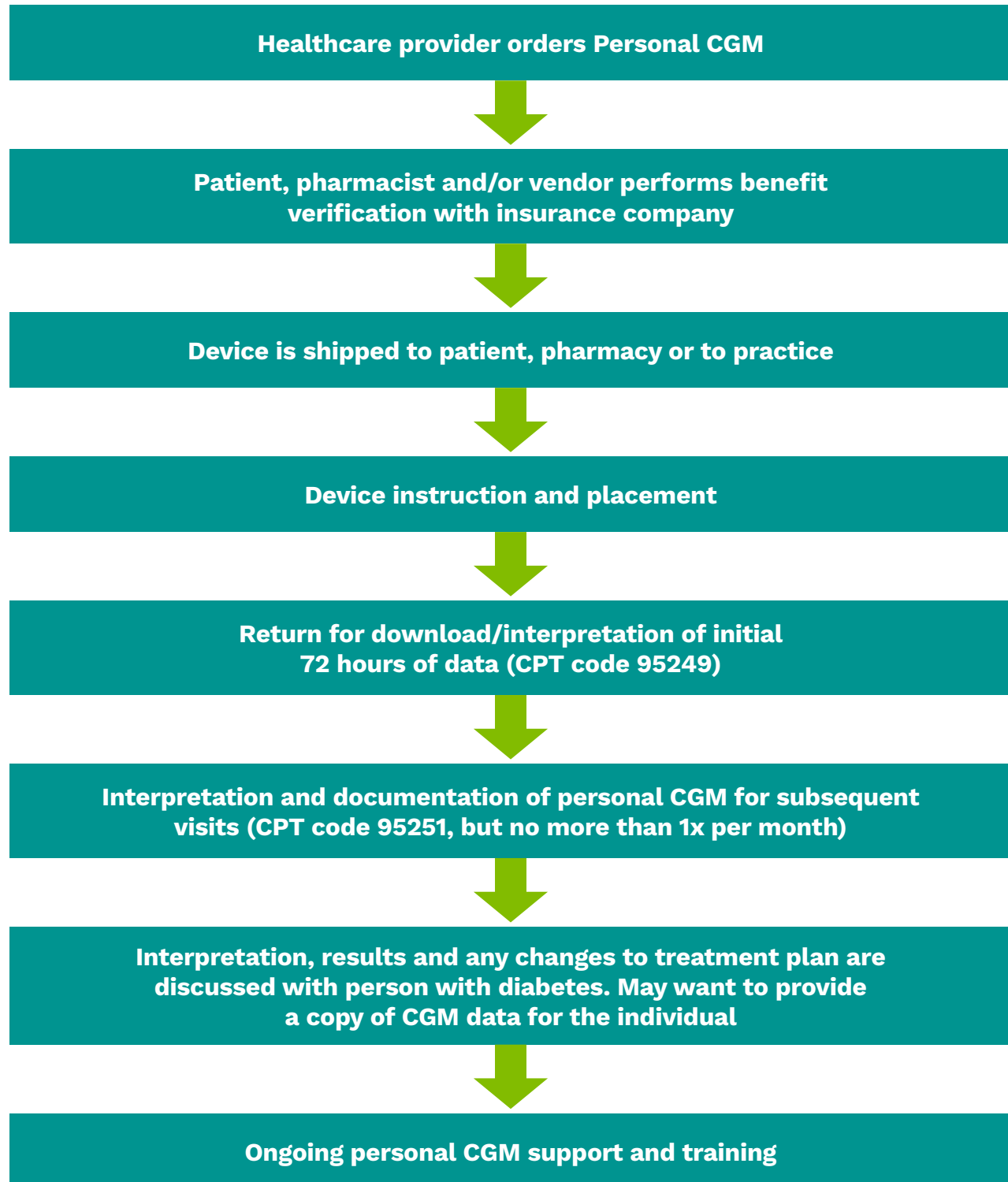
**ADVISORY TEAM**

- Identify need for the program
- Partner with the patient and evaluate patient satisfaction with program
- Support program implementation and evaluation

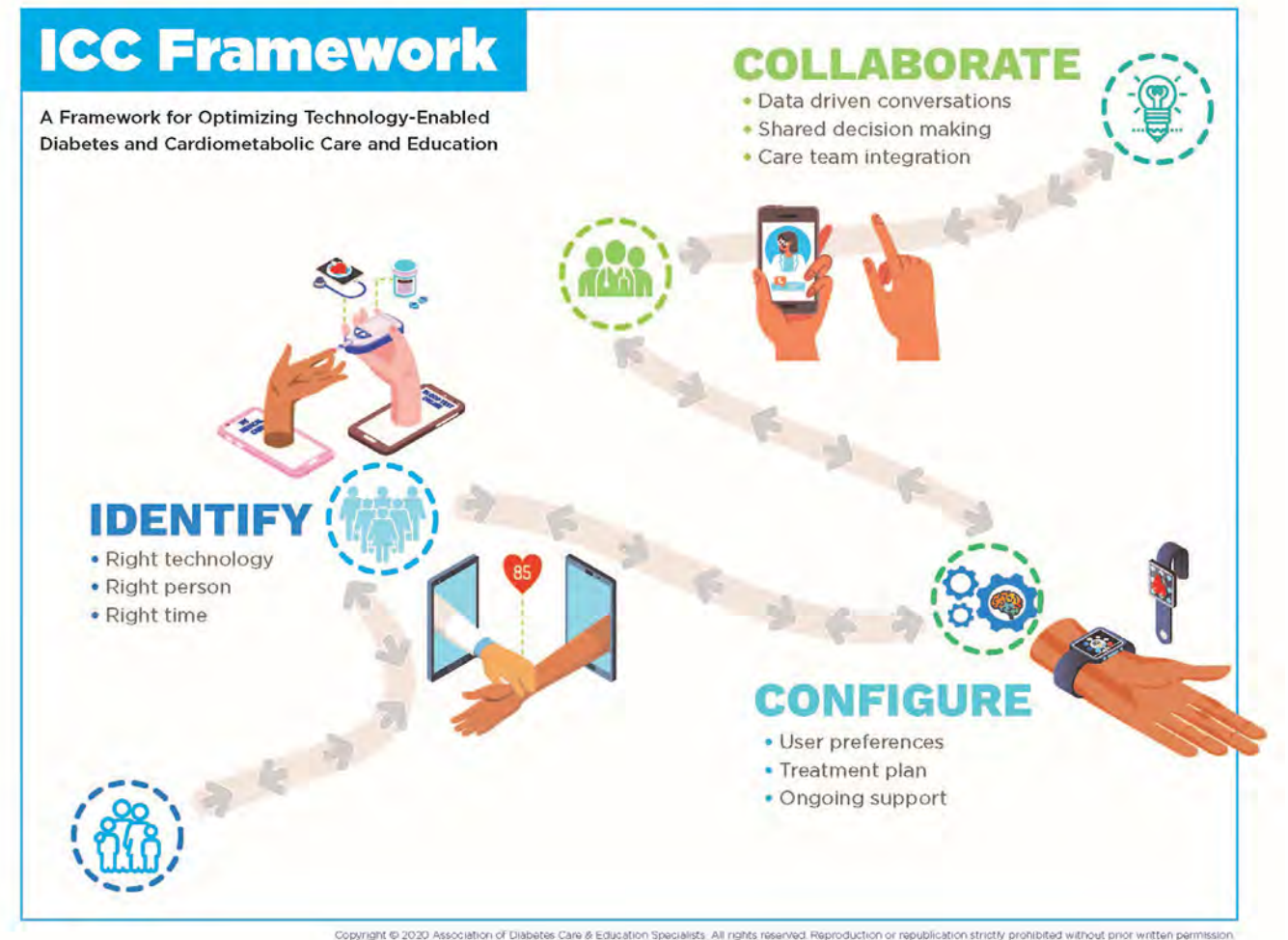
WORKSHEET 5:**Identify Program Processes and Assign Tasks to Team Members**

The following table includes some examples to consider. You should develop your own comprehensive list and assign team members to each task.

PROGRAM PROCESSES/TASKS	TEAM MEMBER ASSIGNED
Billing/Prior Authorization/ Pre-certification	
Patient Education and Support	
Download of Device Data or Establish Data Sharing	
Interpretation of Device Data	
Communication of Plan to Patient	
Analyze Clinical and Financial Outcomes Data	
Market the Program	

WORKSHEET 6:**Personal CGM Process Flow**

WORKSHEET 7: ICC Framework



SUGGESTIONS FOR USE:

When applying this framework:

1. **Identify** the right technology for the right person at the right time – for example, is this person a good candidate for personal CGM? Are they interested? What questions do they have? Have they done their own research?
2. **Configure** the settings, the alarms and alerts based on user preferences and the treatment plan and how people will engage with the technology and the support they will need to use the technology successfully.
3. **Collaborate** with the person with diabetes, using shared decision making with data-driven discussions from the CGM data reports.

WORKSHEET 8:**Billing and Coding for Personal CGM**

CPT Codes for Placement and Interpretation of Personal CGM		
CPT CODE	EXPLANATION OF CODE	WHO CAN PERFORM DUTY
95249	Ambulatory CGM of interstitial fluid via subcutaneous catheter for minimum of 72 hours with patient-provided equipment. Includes sensor placement, hook-up, calibration of monitor, patient training and print-out of recording. This code is used once for the lifetime of the personal CGM device.	Examples of staff who may perform this duty include: MD/DO, PharmD, NP/PA, DCES <i>*Other healthcare personnel may be able to perform this duty if within their scope of practice.</i>
95251	This code is used for interpretation of professional or personal CGM. Does not require face-to-face visit. Cannot be billed more than once per month.	Interpretation can be performed by MD/DO, or NP/PA. Pharmacists can do this in many states with a collaborative practice agreement and co-signature of MD/DO or NP/PA
Notes: An E/M Code (Evaluation and Management) can be billed on the same day of either of these codes as long as a distinct and separate E/M service was medically necessary and provided over and above the Personal CGM service. In this case, the modifier -25 must be attached to the E/M code.		

CHECKLIST FOR PAYORS:

- ☐ What is their formal policy for Personal CGM?
- ☐ Do they require prior authorization?
- ☐ How often do they allow Personal CGM interpretation to be performed on a particular patient?

ITEMS TO DOCUMENT IN THE INTERPRETATION NOTE – YOU CAN AMEND THIS NOTE CONTENT AS NEEDED BY YOUR PRACTICE:

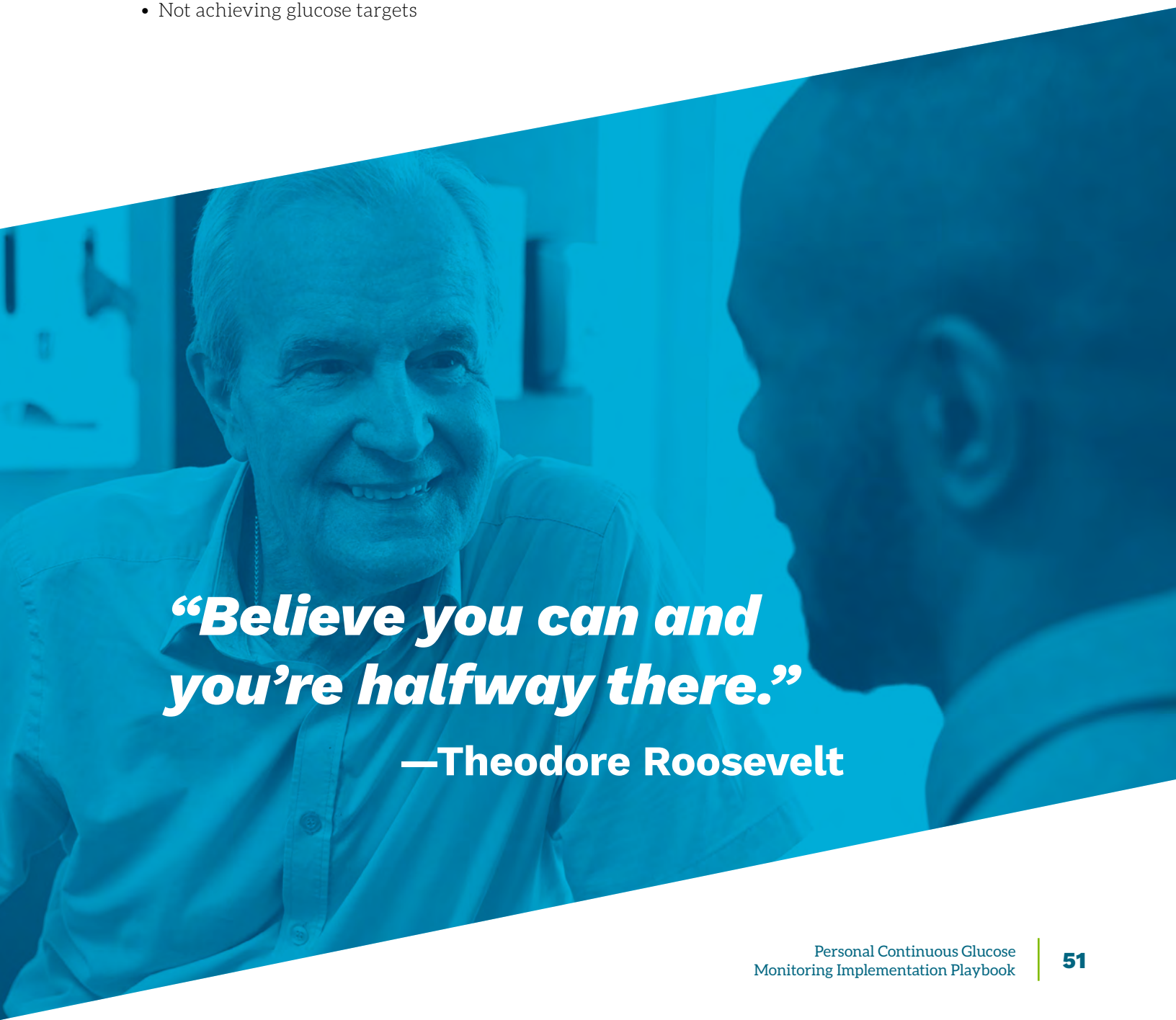
- Duration that the patient wore the Personal CGM device for initial start-up (needs to be >72 hours)
- Current diabetes treatment plan
- Current HbA1C
- Time in target range, time above and below target range
- Patterns of hypo/hyperglycemia
- Any changes recommended to treatment plan
- Any further actions, such as referral to diabetes care and education specialist
- Copy of the device download

WORKSHEET 9:**Characteristics of People Most Likely to Benefit from Personal CGM**

Consider personal CGM use in the following people with diabetes:

Type 1 or type 2 diabetes diagnosis who are:

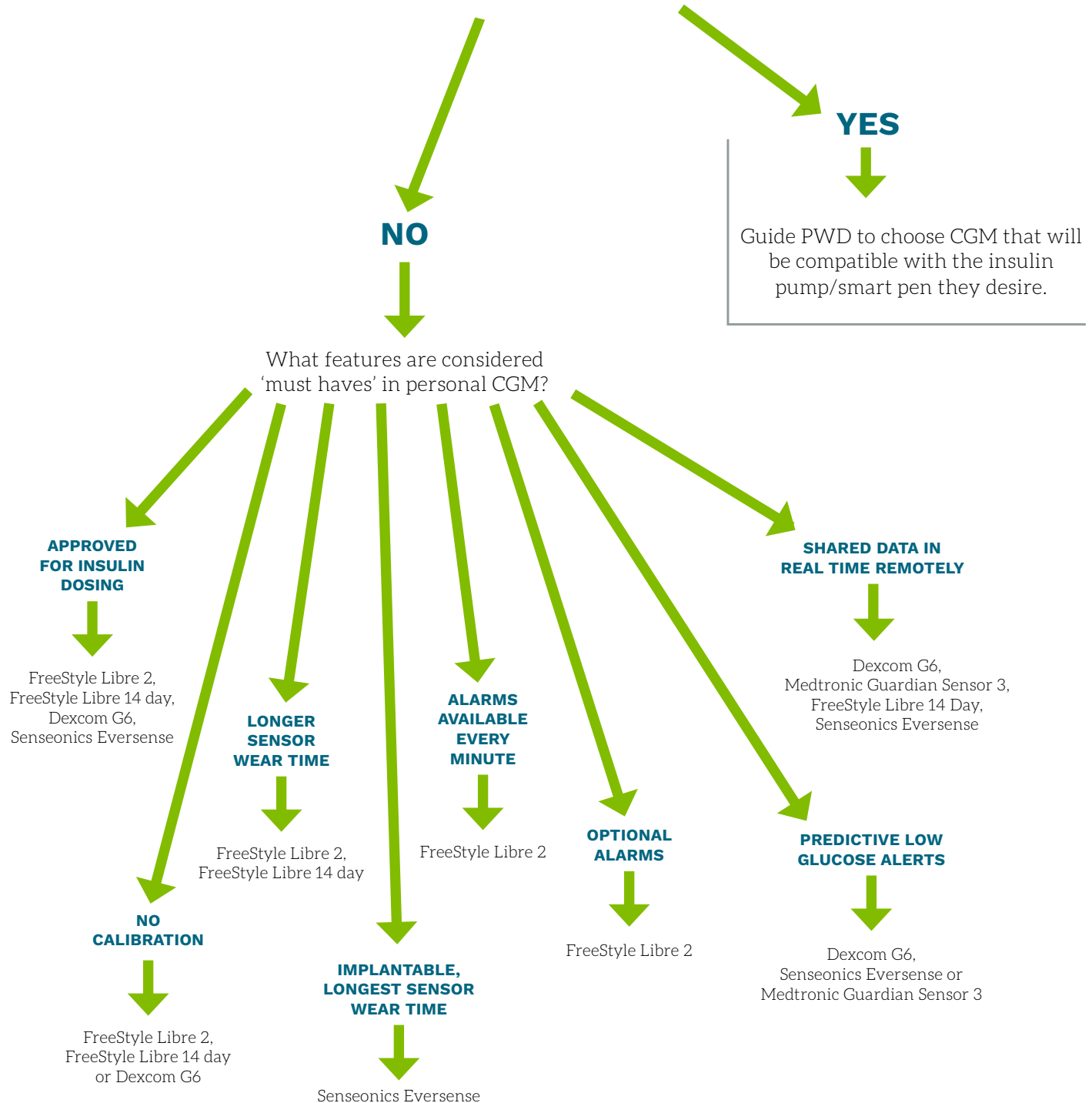
- Taking multiple daily injections of insulin
- Using an insulin pump or smart pen
- Experiencing frequent hypoglycemia
- Experiencing hypoglycemia unawareness
- Experiencing a high degree of glycemic variability
- Not achieving glucose targets



***“Believe you can and
you’re halfway there.”***
—Theodore Roosevelt

PWD meets criteria for personal CGM and would like to wear one:³⁵

Is person interested in an insulin pump/smart pen or do they already have an insulin pump/smart pen?



**The healthcare professional should always make a decision based on person-centered care including insurance coverage and the preferences of the person with diabetes.*

WORKSHEET 10:**Routes to Obtain Personal CGM Device and Ongoing Supplies**

CGM company representatives are one of your best sources of current information about this topic. Company website links for each of the CGM devices are listed below. The company website will provide you with the most up-to-date information, so when in doubt, always check there.

Abbott:

[14 Day - Medicare Prescribing Guide](#)

[Medicare Written Order and DME Suppliers](#)

[FreeStyle Libre 2 – Instructions to place order](#)

Dexcom:

[Dexcom G6 – Instructions to place order](#)

[Dexcom G6 Prescription Brochure](#)

[Prescribing Info | Dexcom Provider](#)

Medtronic:

[Ordering and billing information](#)

Senseonics:

[How to become an authorized provider](#)

[Eversense Bridge Program](#)

“A year from now you may wish you had started today.”

—Karen Lamb

This worksheet is an example only, and was created and published for people using a Dexcom device. A worksheet such as this can be modified to accommodate any CGM device.

WORKSHEET 11:

Sample Instructions for Personal CGM for the Person with Diabetes

Nine Tips to Improve Glucose Control Using CGM

by Katharine D. Barnard-Kelly and William H. Polonsky³⁶

#1: Wear your CGM as much as possible

The more you wear it and pay attention to it, the more you will be able to understand and control your glucose responses. Use your CGM to find out more about how foods and/or insulin dosing affect your glucose levels.

#2: Share your data in a way that works for you

If and when you decide to Share your CGM data, have a conversation ahead of time about boundaries and language that you prefer (e.g., supportive not bossy, helpful not intrusive).

#3: Make alerts and alarms your friends, not your foes

First, please don't ignore your alerts and alarms! And after responding to an alarm, take a few minutes to think about what may have caused it (e.g., you ate more or fewer carbs than usual, you were more or less active than usual, when did you last take any insulin?).

If you are getting too many alerts or alarms, you can adjust your settings so that they don't drive you crazy!

#4: Review your CGM results regularly

Regular review of your Dexcom Clarity reports can help you see if there are any patterns of highs or lows, helping you decide where—for example—you might want to adjust your insulin basal rates or doses in response.

#5: Know your personal glucose targets

If you're not achieving your targets as frequently as you like, please understand it may take awhile for things to improve. Be patient!

My pre-meal target is less than _____

My peak glucose target is less than _____

(after a meal)

My glucose is too low and requires action if it is less than _____

#6: Have a solid plan for preventing or responding to hypoglycemia

Try not to panic and overreact

Take 15–20g glucose and re-check in 15 Mins.

Repeat treatment if glucose level is not rising after 20 minutes

Depending on your own individual needs, a follow-up snack providing

15–20g carbohydrate may be necessary

If your CGM has predictive alerts, they can provide more time for you to take action to prevent lows

#7: Explore the big, bad world of food: Test out what really harms and helps your glucose control

A CGM is the perfect tool for discovering whether foods really raise your glucose or not. On occasion, try out your favorite snack, a new type of meal you've never tried before, or one of those nutritional "no-no's" and find out for yourself whether they are worth it

#8: Use the trend arrows to help you understand what is really going on

Whether it concerns something you have recently eaten, an insulin bolus you have just taken or some recent exercise, your CGM's trend arrows can help you understand the direction and speed of your glucose changes:

Constant: your glucose value is relatively stable

Rising: your glucose value is rising and could increase as much as 1.7mmol/l (30 mg/dl) in 15 minutes

Rising quickly: your glucose is rising and could increase as much as 2.5 mmol/l (45 mg/dl) in 15 minutes

Rising very quickly: your glucose value is rising quickly and could increase more than 2.5 mmol/l (45 mg/dl) in 15 minutes

Falling: your glucose is falling and could decrease as much as 1.7 mmol/l(30 mg/dl) in 15 minutes

Falling quickly: your glucose is falling and could fall as much as 2.5 mmol/l (45 mg/dl) in 15 minutes

Falling very quickly: your glucose is falling and could fall more than 2.5 mmol/l (45 mg/dl) in 15 minutes

#9: When diabetes is driving you crazy, remind yourself why you are bothering:

I am committed to keep using my CGM because I know it can help me to:

1. _____
2. _____
3. _____

Source:

Barnard-Kelly, KD, Polonsky, WH. Development of a Novel Tool to Support Engagement With Continuous Glucose Monitoring Systems and Optimize Outcomes. Journal of Diabetes Science and Technology, 2020;14(1), 151-154.
<https://doi.org/10.1177/1932296819848686>

WORKSHEET 12:**Basic and Advanced Personal CGM Training Needs*****Basic Training Needs:***

- Sensor site selection, rotation and sensor insertion
- Attachment of the transmitter to the sensor, if applicable
- Taping/securing of the sensor/transmitter, if applicable
- Connection of the transmitter to the receiver, if applicable
- Difference between interstitial glucose readings and blood glucose readings
- Understanding CGM data and trends
- Possible interference of products such as acetaminophen, salicylic acid, hydroxyurea, and high dose vitamin C
- Calibration including timing, frequency and importance of accurate meter/fingerstick technique, if applicable
- Education to prevent overcorrection of high glucose
- Treatment of hypoglycemia

Advanced Training Needs:

- Setting and managing alerts/alarms
- How to use trend arrows to adjust treatment decisions
- Problem solving for site adhesiveness and skin reactions
- Support with coping and problem solving
- Sharing of data

“The best interest of the patient is the only interest to be considered.”

—Dr. Will Mayo

PART FOUR:

Resources for CGM Device Report Examples



Abbott FreeStyle Libre 14 Day Flash Glucose Monitoring System

[Resources for Patients and Healthcare Professionals | FreeStyle Libre \(myfreestyle.com\)](#)

Abbott FreeStyle Libre 2

[Resources for Patients and Healthcare Professionals | FreeStyle Libre \(myfreestyle.com\)](#)

Dexcom G6

[Diabetes Management & Data | Dexcom Healthcare Provider](#)

[Dexcom CLARITY Reports](#)

Medtronic Guardian Sensor 3

[CareLink-Software-Report-Reference-Guide.pdf \(medtronicdiabetes.com\)](#)

Senseonics Eversense

[Long-term CGM System | Eversense Continuous Glucose Monitoring \(eversenseddiabetes.com\)](#)

PART FIVE:

Resources

Manufacturer Supplied Online Training/Tutorials

[Abbott Tutorials Support - Overview | The FreeStyle Libre System](#)

[Dexcom Tutorials](#)

[Medtronic Tutorials](#)

[Senseonics Tutorials](#)

Manufacturer Patient Training Checklists

[FreeStyle LibreLink App Quick Start Guide Support - Overview | The FreeStyle Libre System](#)

[Dexcom G6 Site Training Checklist \(Fillable PDF\)](#)

[Medtronic Guardian Connect Training Checklist](#)

[Long-term CGM System | Eversense Continuous Glucose Monitoring \(eversensediabete.com\)](#)

Danatech Product Specifications and Online Learning



ADCES Danatech: www.Danatech.org

Danatech includes access to CGM device information, including technical specifications and resources for healthcare professionals and people with diabetes. Free subscription access is available to ADCES, National Association of School Nurses (NASN) and American Society of Endocrine Physician Assistants (ASEPA) members.

A 14.5-hour CE-accredited [CGM Certificate Program \(danatech.org\)](#) with digital badge is available free to ADCES, NASN, and ASEPA members. Requires username and password.

Courses that are part of the CGM in Practice Certificate Program Include:

- Continuous Glucose Monitoring: Connecting the Dots (5 CE)
- Continuous Glucose Monitoring: Real World Case Studies in Pattern Management (4.5 CE)
- Webinar: CGM Data in Clinical Practice (1.5 CE)
- Webinar: The Ins and Outs of Starting a Continuous Glucose Monitoring Program (1.5 CE)
- Case Study Videos - Discussing CGM in Diabetes: The Diabetes Care and Education Specialist's Role (1.0 CE)
- CGM Certificate Post-Learning Assessment (1.0 CE)

Courses may also be taken individually for CE credit.



Educational handouts for the person with diabetes about CGM:

[ADCES Time in Range Tip Sheet](#)



APhA has the following ACPE accredited educational programs available:

[Updates and Advances in Diabetes Self-Management Technology](#)

[The Pharmacist's Role in Continuous Glucose Monitoring](#)

[Exciting Advancements in CGM Tech](#)

For more educational opportunities visit our [APhA website](#) and our [APhA Education Library](#).

“Success only comes to those who dare to attempt.”

—Mallika Tripathi

PART SIX:

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***“Success is best
when it’s shared.”***

—Howard Schultz



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supported by Abbott Diabetes Care and Dexcom**



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