Navigating Insulin Pumps and Continuous Glucose Monitors for Improved Diabetes Management

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Nothing to disclose

Objectives

- Examine advanced technologies to assist the clinician in hyperglycemia and hypoglycemia treatment
- Evaluate the evidence and indications for continuous glucose monitors and insulin pumps use
- Integrate practical application of advance technologies for improved diabetes management

IHS Division of Diabetes Treatment and Prevention Resources for Glucose Management with Insulin

• Webinars

- Insulin Management. Richard Arakaki, 4/20/22
- Simple to Advanced Approaches to Carbohydrate Counting.
 Kibbe Brown and Wendy Castle, 3/8/23
- Algorithm
 - Insulin Therapy in Type 2 Diabetes
 - Insulin Concentration

IHS Division of Diabetes Treatment and Prevention. https://www.ihs.gov/diabetes/

Case study- Scenario 1

- 51 yo patient with T1DM on basal insulin 20 units at bedtime and rapid-acting insulin 8-7-8 units, TID ac (ICR is 1:15 and ISF is 1:40 mg/dL over 140 mg/dL).
- Prelunch BGM value was 120 mg/dL and he took is 7 units had soup and sandwich meal with water. He had a snack at 4 PM, following his afternoon walk as he felt a little "woozy" (didn't check BG).

Case study- Scenario 1

- 51 yo patient with T1DM on basal insulin 20 units at bedtime and rapid-acting insulin 8-7-8 units, TID ac (ICR is 1:15 and ISF is 1:40 mg/dL over 140 mg/dL).
- Prelunch BGM value was 120 mg/dL and he took is 7 units had soup and sandwich meal with water. He had a snack at 4 PM, following his afternoon walk as he felt a little "woozy" (didn't check BG).

5:30 PM AC dinner What do you make of his BGM reading of 141 before dinner (not at goal of <130 mg/dL)? What should his dinner insulin dose be? Should he take more or less than the 8 units?

Case study- Scenario 1 (con't)

- He took 8 units at 6 PM just before his dinner, and he had a snack at at 7:30 PM. He was feeling quite well.
- His bedtime BGM read 110 mg/dL and he is scheduled to take his long-acting insulin soon.

What do you make of his bedtime BGM reading (BS decreased from 141 to 110 after dinner)? Adequate or too much dinner dose? He is scheduled for 20 units of basal insulin? Should he take more or less insulin; 10 or 20 % increase or decrease?

Case study- Scenario 1 (con't)

- He took 8 units at 6 PM just before his dinner, and he had a snack at at 7:30 PM. He was feeling quite well.
- His bedtime BGM read 110 mg/dL and he is scheduled to take his long-acting insulin soon.

What do you make of his bedtime BGM reading (BS decreased from 141 to 110 after dinner)? Adequate or too much dinner dose? He is scheduled for 20 units of basal insulin? Should he take more or less insulin; 10 or 20 % increase or decrease?

 He took his usual dose of 20 units and had a bedtime snack. At 3 AM, he woke up feeling "funny" and a little sweaty. His BGM showed a glucose value of 58 mg/dL.

Case Study- Scenario 1A

- 51 yo patient with T1DM on basal insulin 20 units at bedtime and rapid-acting insulin 8-7-8 units, TID ac (ICR is 1:15 and ISF is 1:40 mg/dL over 140 mg/dL).
- Prelunch CGM value was 120 mg/dL and he took is 7 units had soup and sandwich meal with water. He had a snack at 4 PM, following his afternoon walk as he felt a little "woozy" (his CGM showed glucose values of 70-80 mg/dl).

Case Study- Scenario 1A

- 51 yo patient with T1DM on basal insulin 20 units at bedtime and rapid-acting insulin 8-7-8 units, TID ac (ICR is 1:15 and ISF is 1:40 mg/dL over 140 mg/dL).
- Prelunch CGM value was 120 mg/dL and he took is 7 units had soup and sandwich meal with water. He had a snack at 4 PM, following his afternoon walk as he felt a little "woozy" (his CGM showed glucose values of 70-80 mg/dl).



What do you make of his CGM reading of 141 and the diagonal falling arrow before dinner? What should the patient do? Lower his meal dose (<8 units)? Give usual dose, delay his meal 30 minutes? Recommend increase his meal CHO? No change in treatment

Addressing Rate of Change (ROC): What does the arrows mean?

- Predicting glucose levels based on preceding values
 - Targets glucose levels over 30 minutes
 - Based on previous 10-minute values

Trend Arrow	Glucose change rates:	Patient intervention:
††	Rapidly rising > 3 mg/min	-Patient with 141 mg/dl and
1	Rising > 2-3 mg/min	diagonal falling arrow.
/	Slowly rising > 1-2 mg/min	-Expect to have glucose between
	Steady, not increasing or decreasing > 1 mg/min	111 to 81 mg/dL in 30 minutes
	Slowly falling > 1-2 mg/min	-ISF: 1:40 over 140 mg/dL
Ļ	Falling > 2-3 mg/min	What should he do with is
↓↓	Rapidly Falling > 3 mg/min	mealtime insulin dose?

Addressing Rate of Change (ROC): What should patients do with the arrows

TABLE 1 Published Trend Arrow Methods for Insulin Dose Adjustment

Trend Arrow	DirecNet (43)	Scheiner (44)	Pettus and Edelman (45)	Klonoff and Kerr (46)	Endocrine Society (Dexcom G5 only) (47)
††	20% increase	+60 mg/dL	+100 mg/dL	+2 units	+1.5–4.5 based on correction factor
1	20% increase	+30 mg/dL	+75 mg/dL	+1.5 units	+1–3.5 based on correction factor
-	10% increase	0	+50 mg/dL	+1 units	+0.5–2.5 based on correction factor
+	No changes	No changes	No changes	No changes	No changes
×	10% decrease	0	−50 mg/dL	–1 units	-0.5–2.5 based on correction factor
↓ _	20% decrease	-30 mg/dL	-75 mg/dL	-1.5 units	-1–3.5 based on correction factor
ţţ	20% decrease	-60 mg/dL	-100 mg/dL	-2 units	-1.5-4.5 based on correction factor

Note: Intermittent corrections for persistent trends 2 hours after previous bolus

Trend Arrow	FreeStyle Libre Trend Definition	Correction Factor (mg/dL)*	Insulin Dose Adjustment (Units)⁺
1	Glucose is rising quickly (>2 mg/dL per minute)	<25 25–50 50–75 >75	+4 +3 +2 +1
*	Glucose is rising (1–2 mg/dL per minute)	<25 25–50 50–75 >75	+3 +2 +1 No changes
-	Glucose is changing slowly (<1 mg/dL per minute)	<25 25–50 50–75 >75	No changes No changes No changes No changes
	Glucose is falling (1–2 mg/dL per minute)	<25 25–50 50–75 >75	−3 −2 −1 No changes
ł	Glucose is falling quickly (>2 mg/dL per minute)	<25 25–50 50–75 >75	-4‡ -3‡ -1‡§ No changes‡§

Patient intervention:

-Patient with 141 mg/dl and diagonal falling arrow.

-Expect to have glucose between 111 to 81 mg/dL in 30 minutes

-ISF: 1:40

What should he do with is mealtime insulin?

Case Study- Scenario 1A con't

- 51 yo patient with T1DM on basal insulin 20 units at bedtime and rapid-acting insulin 8-7-8 units, TID ac (ICR is 1:15 and ISF is 1:40 mg/dL over 140 mg/dL).
- Prelunch CGM value was 120 mg/dL and he took is 7 units had soup and sandwich meal with water. He had a snack at 4 PM, following his afternoon walk as he felt a little "woozy" (his CGM showed glucose values of 70-80 mg/dl).



The patient lowered his meal dose to 6 units (25% reduction).

He took is usual dose of basal insulin, 20 units at bedtime as his glucose reading was 135 mg/dl at bedtime with a horizontal arrow. He took no snacks. He woke the next morning with BS level of 102 mg/dL.

Should he change his basal insulin dose?

Recommendation for BGM and CGM

Blood Glucose Monitoring (BGM)

 Most patients using intensive insulin regimens (MDI or pump) should assess glucose levels using BGM prior to meals and snacks, at bedtime, occasionally postprandially, prior to exercise when they suspect low blood glucose, and prior to critical tasks such as driving.

Continuous Glucose Monitoring (CGM)

- When used properly, real-time continuous glucose monitoring in conjunction with intensive insulin regimens is a useful tool to lower A1c in adults with type 1 diabetes not meeting glycemic targets.
- Real-time continuous glucose monitoring may be a useful tool in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes.
- Real-time continuous glucose monitoring may be used effectively to improve A1C levels and neonatal outcomes in pregnant women with type 1 diabetes.

Note: Prescribe as part of a broad educational program, training, and support for BGM and CGM.

American Diabetes Association. 7. Diabetes Technology: *Standards of Care in Diabetes-2023. Diabetes Care* 2023;46(Suppl. 1):S111-S127. <u>https://doi.org/10.2337/dc23-S007</u>.

Effectiveness of Glucose Monitoring

Blood Glucose Monitoring

- A1C reduction is associated with more frequent use
- Limited value in people not using insulin
- No impact on hypoglycemic rates
- Realtime Continuous Glucose Monitoring (rtCGM)
 - Glycemic benefits in all adults and teens with type 1 and adults with type 2 diabetes (basal and MDI treatments)
 - Benefits in children unclear
 - Decrease hypoglycemic rates in patients with type 1 diabetes treatment but not in patients with type 2 diabetes



CGM Components

Sensor: Checks glucose levels every 5 minutes. Can be worn on the abdomen, arm, or buttock depends on on age. Water resistant tape to secure sensor on the skin.

Transmitter: Connects to sensor and sends glucose information to reader or smartphone (via Bluetooth)



Reader: Provided by the company Must have on hand; personal use for management; transfer data to PC via USB port

Smartphone (via cloud):

Personal use for management; Apps available to transfer data into central repository (company-based)- allow others to view realtime data; allow provider to view AGP



Table 7.3–Continuous glucose monitoring devices

Type of CGM	Description
rtCGM	CGM systems that measure and store glucose levels continuously and without prompting
isCGM with and without alarms	CGM systems that measure glucose levels continuously but require scanning for storage of glucose values
Professional CGM	CGM devices that are placed on the patient in the provider's office (or with remote instruction) and worn for a discrete period of time (generally 7–14 days). Data may be blinded or visible to the person wearing the device. The data are used to assess glycemic patterns and trends. These devices are not fully owned by the patient—they are clinic-based devices, as opposed to the patient-owned rtCGM/isCGM devices.

CGM, continuous glucose monitoring; isCGM, intermittently scanned CGM; rtCGM, real-time CGM.

American Diabetes Association. 7. Diabetes Technology: *Standards of Medical Care in Diabetes-2022. Diabetes Care* 2022;45(Suppl. 1):S97-S112. <u>https://doi.org/10.2337/dc22-S007</u>.

A Patient with CGM: Reviewing the Data

AMBULATORY GLUCOSE PROFILE (AGP)

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



A Patient with CGM: Reviewing the Data



Another Patient with CGM: Reviewing the Data



AGP Report: Continuous Glucose Monitoring



American Diabetes Association. 4. Comprehensive Medical Evaluation and Assessment of Comorbidities: *Standards of Care in Diabetes-2023*. *Diabetes Care* 2023;46(Suppl 1):S49-S67. <u>https://doi.org/10.2337/dc23-S004</u>.

Ambulatory Glucose Profile Example



TABLE 1 Correlations of TIR and A1C Achieved from an Analysis of Several Hundred People with Type 1 or Type 2 diabetes (4)

Measured TIR (70–180 mg/dL)	A1C	95% CI
40%	8.1%	7.1–9.1%
50%	7.7%	6.7–8.7%
60%	7.3%	6.3-8.3%
70%	6.9%	5.9–7.9%
80%	6.5%	5.5–7.5%

Recommendations for Continuous Subcutaneous Insulin Infusion (CSII) Therapy

- 7.25 Insulin pump therapy alone with or without sensor-augmented pump low glucose suspend feature and/or automated insulin delivery systems should be offered for diabetes management to youth and adults on multiple daily injections with type 1 diabetes A or other types of insulin-deficient diabetes E who are capable of using the device safely (either by themselves or with a caregiver) and are not able to use or do not choose an automated insulin delivery system. The choice of device should be made based on the individual's circumstances, preferences, and needs. A
- 7.26 Insulin pump therapy can be offered for diabetes management to youth and adults on multiple daily injections with type 2 diabetes who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs. A

American Diabetes Association. 7. Diabetes Technology: *Standards of Care in Diabetes-2023. Diabetes Care* 2023;46(Suppl. 1):S111-S127. <u>https://doi.org/10.2337/dc23-S007</u>.

Insulin Pump Systems

- Patch pumps
 - V-GO: disposable preset pumps for patients with type 2 diabetes; provides basal rate with occasional correction bolus. 20, 30, 40 units basal/24hrs. 36 units max bolus in 2 unit increments
- Sensor-augmented pump therapy with or without low-glucose suspend (basal-bolus rates are managed by the patient)
- Hybrid closed-loop system (automated insulin delivery systems) requires CGM (basal rates controlled by pump with sophisticated algorithm and bolus doses requires CHO input by patient)
- Closed-loop insulin delivery (Artificial Pancreas) is the future; a combination of CSII and CGM system providing insulin delivery without input from the user.

American Diabetes Association. 7. Diabetes Technology: *Standards of Care in Diabetes-2023. Diabetes Care* 2023;46(Suppl. 1):S111-S127. <u>https://doi.org/10.2337/dc23-S007</u>.

Insulin Pump Systems Efficacy and Limitations

- Benefits (primarily in type 1 diabetes)
 - Trend to decrease A1C level
 - Decrease rate of hypoglycemia
 - Improve Quality of Life
 - Requires CGM to improve and sustain glycemic effect
- Limitations
 - Wearability and skin reactions
 - Dependent on manufacturer's products and software updates
 - DKA occurrence due to loss of insulin infusion

Diaz-Balzac CA, Pillinger D, Wittlin SD. *Continuous Subcutaneous Insulin Infusions: Closing the Loop. J Clin Endo Metab* 2023;108:1019-1033. <u>https://doi.org/10.1210/clinem/dgac746</u>.

Insulin Pump Systems: Components



Insulin Pump Systems: Additional Considerations

- U-100 Insulins for the reservoir
 - Aspart (Novolog) and Faster Aspart (Fiasp)
 - Lispro (Humalog) and Lispro_{aabc} (Lyumjev)
- Pump and Reservoir
 - MiniMed- 5x10x2 cm with 300 unit capacity, requires tubing
 - T:slim- 8x5x1.5 cm with 300 unit capacity, requires tubin
 - Omnipod- 4x5x1.4 with 200 unit capacity, no tubing and disposable
- CGM coupling
 - MiniMed 770G/780G has internal CGM (Guardian 4 sensor)
 - T:slim X2 and Omnipod uses DEXCOM CGM

Diaz-Balzac CA, Pillinger D, Wittlin SD. *Continuous Subcutaneous Insulin Infusions: Closing the Loop. J Clin Endo Metab* 2023;108:1019-1033. <u>https://doi.org/10.1210/clinem/dgac746</u>.







	MINIMED [™] 780G	OMNIPOD 5	T:SLIM X2 control IQ
Auto correction bolus	Every 5 mins 100% correction bolus	Every 5 mins—	Every 60 mins 60% correction bolus
Meal detection technology	Boluses every 5 minutes during meal based on glucose pattern /algorithm	No	No
Automated basal delivery every 5 minutes	Yes	Yes	Yes
Infusion/cannula set duration	7 days Infusion set	3 days Pods, tubeless	3 days Infusion set
Glucose targets	100 mg/dL	110 mg/dL	112 mg/dL
CGM and transmitter lifespan	Guardian 4 1 year lifespan	DEXCOM 6 3 months	DEXCOM 6 3 months

Case study: CGM with MDI

Time in	Ranges Goals for Typ	pe 1 and Type 2 Diabetes	Glucose Metrics	
Each 5% increa Each 1% tirne is	ase in the Target Range is clinically in range = about 15 minutes per da	beneficial. Y	Average Glucose Goal: <154 mg/dL	185 mg/dL
1	17% Very High iosi: <5% 84% High	51% Goat +25%	GM1 Goal: <7%	7.7%
G	48% In Range		Coefficient of Variation	37.7%
1	1% Low 1% Very Low	1% Goal: <4%	Goal: <36%	
Target Range:	70-180 mg/di. Very High: Above		Time CGM Active	94.7%

Ambulatory Glucose Profile (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if they occurred in a single day.



Daily Glucose Profile

Each daily profile represents a midnight-to-midnight period.



Case study: Hybrid Closed-Loop System

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CGM Data by Dexcom

Case study: Hybrid Closed-Loop System

Boluses

Bolus Table only shows the first 10 bolus events for the day.

Statistics

********	1 1	2	3	4	5	6	7	8	9	10	2
	5:24 a	8:30 a	2:05 p	8:22 p						****	
Bolus Delivered	0.75	1.8	2.2	1.5	-	-	-	-	-	-	
Suggested	0.75	1.8	2.2	1.5	-	-	-	-	-	-	
MEAL	0.25	2	1.87	1.62	-	-	-	-	-	-	
Correction	0.55	0	0.35	0	-	-	-	-	-	-	
Insulin On Board	0.7	0.75	0.15	0.5	-	-	-	-	-	-	
Initial	-	-	-	-	-	-	-	-	-	-	
Extended	-	-	-	-	-	-	-	-	-	-	
Duration	-	-	-	-	-	-	-	-	-	-	
System (Omnipod® 5)	GIL	Icose			Insulin Do	se	Basal				
🎉 Automated Mode	Lonk Go	 Before I 	Meal Uppe	٢	🏶 Overr	ide	A P	ump Alert			

- Automated Mode - 學-
- Automated: Activity
- Automated: Limited 温泉
- 🐲 Manual
- Types of Readings
- Below Target
- In Range
- Above Target 徽
- *** *** *** CGM Readings
- Estimated readings from the CGM device
- O Pump Meter
- 🌰 Above 400
- 🏠 Pump BG Above 400

- Before Meal Upper Limit: 130
- ***** After Meal Upper Limit: 180
- www Normal Glucose; 70
- Target Range: 70 180
- Interrupted
- Undelivered
- The basal segment in progress at the time of download is not. displayed

- 🌨 Override Extended Bolus
- 83 Combo Bolus
- **Bolus Delivered**
- Basal Premixed
- Custom
- Carbs
- 20×2 Temp Basal Set and/or Site Change cc Suspend 貜 LGS/PLGS

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Basal Delivery - Omnipod® 5

Advisory Alert

Reservoir Fill

Basal Rate

- Automated Delivery
- Automated Max Delivery
- Automated Pause

	1	1
Avg. BG	0	194
Median BG	0	201
BG Readings	0	3
Avg. CGM	175	1.98
Median CGM	174	188
% CGM Very High	0%	13%
% CGM High	34%	45%
% CGM Target Range	66%	42%
% CGM Low	0%	0%
% CGM Very Low	0%	0%
Total Daily Bolus	6.3 u	13.5 u
Total Daily Basal	21.6 u	23.7 u
Total Daily insulin	27.8 u	37.3 u
# of Boluses	4	3.8
Avg. Bolus	1.6 u	3.6 u
# Corr. Bolus	50% (2)	79% (3)

System Details

Automated Mode	100%	100%
Automated: Activity	0%	0%
Automated: Limited	0%	11%
Manual	0%	0%

CGM Data by Dexcom

Case study: Hybrid Closed-Loop System

Glud	cose - Time In Range	Summary
100000 au	6% Very High > 250 mg/dL	GMI
	45% High 181-250 mg/dL	7.7% (60.5 mmol/mo
New Market	149% Target Range 70-180 mg/dL	183 mg/dL
6	10% Low 54-69 mg/dL	% Time CGM Active
	10% Very Low < 54 mg/dL	95.5% (13.4 days)

Ambulatory Glucose Profile (AGP)

	SD43 mg/dL
))	CV23.3%
	Median Markan
	Highest 324 mg/dL
	Lowest 56 mg/dL



Insulin



System Details

Insulet Omnipod® 5 (229d 2h)

Automated Mode 100% (229d 1h)
Automated: Limited ——————— 2% (3d 23h)
W Automated: Activity are and and an an an are an one of 0%
Manual Mode (14) 10 10 10 10 10 10 10 10 10 10 10 10 10

Diet

Fitness

No fitness tracker connected

Comments

Another case study: Hybrid Closed-Loop System

Time in Ranges Glucose Metrics Goals for Type 1 and Type 2 Diabetes Each 5% increase in the Target Range is clinically beneficial. Average Glucose 151 mg/dL Each 1% time in range = about 15 minutes per day Goal: <154 mg/dL 5% Very High 21% Coal: <5% GMI Goal: <25% 6.9% 16% High Goal: <7% 78% In Range Goal: >70% Coefficient of Variation 37.9% Goal: <36% 1% Low 1% <1% Very Low Goat: <4% Goal: <1% Time CGM Active 70.4% Target Range: 70-180 mg/dL Very High: Above 250 mg/dL Very Low: Below 54 mg/dL

Ambulatory Glucose Profile (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if they occurred in a single day.



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Each daily profile represents a midnight-to-midnight period.



Insulin Pump Systems: Future Considerations

- Automated pump (hybrid closed-loop) with glucagon or pramlintide
- Use with concentrated insulin to accommodate T2DM patients requiring high doses
 - U-500 Regular insulin
 - U-200 Humalog
- Working toward the artificial pancreas

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Any Questions or Comments?