Inpatient Pediatric Diabetes Technology Use

Erin Cobry, MD
Erin.Cobry@cuanschutz.edu
Assistant Professor
Barbara Davis Center
University of Colorado
06/2024

Disclosures

- Research: Medtronic, Dexcom, Abbott, Tandem, Insulet, Beta Bionics, Luna Health, and Lilly

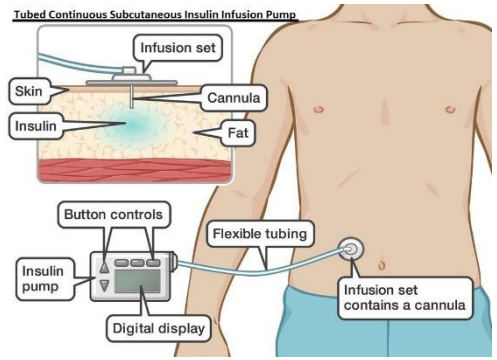
- Speaking, Ad Board: Dexcom, Insulet

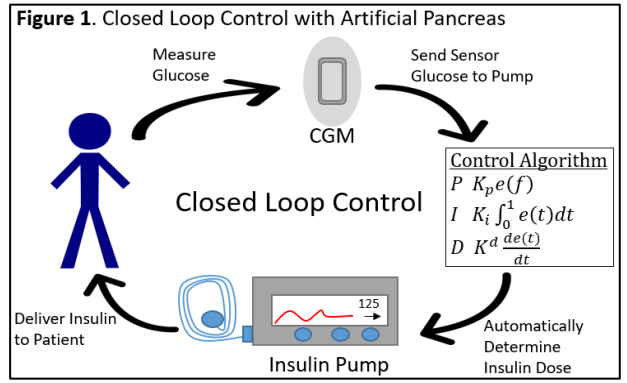
Learning Objectives

- Understand the diabetes technologies that are currently available
- Understand the current literature on inpatient technology use
- Review current guidelines for inpatient diabetes management in relation to technologies
- Discuss special considerations for inpatient technology use

Diabetes Devices Currently Available

- Continuous subcutaneous insulin infusion (CSII)/Insulin Pump
  - Rapid acting insulin only
  - Basal/bolus therapy
- Continuous Glucose Monitors (CGM)
  - Flash and Real-time
  - Subcutaneous glucose
- Automated Insulin Delivery (AID) Systems
  - Hybrid Closed Loop
  - Fully Closed Loop





Diabetes Control by Device

State of Type 1 Diabetes Management and Outcomes from the T1D Exchange in 2016–2018

Nicole C. Foster, MS,[1] Roy W. Beck, MD, PhD,[1] Kellee M. Miller, PhD,[1] Mark A. Clements, MD,[2] Michael R. Rickels, MD, MS,[3] Linda A. DiMeglio, MD, MPH,[4] David M. Maahs, MD, PhD,[5] William V. Tamborlane, MD,[6] Richard Bergenstal, MD,[7] Elizabeth Smith, BS,[1] Beth A. Olson, BAN, RN, CDE,[7] and Satish K. Garg, MD[8]; for the T1D Exchange Clinic Network

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 21, Number 2, 2019

DOI: 10.1089/dia.2018.0384

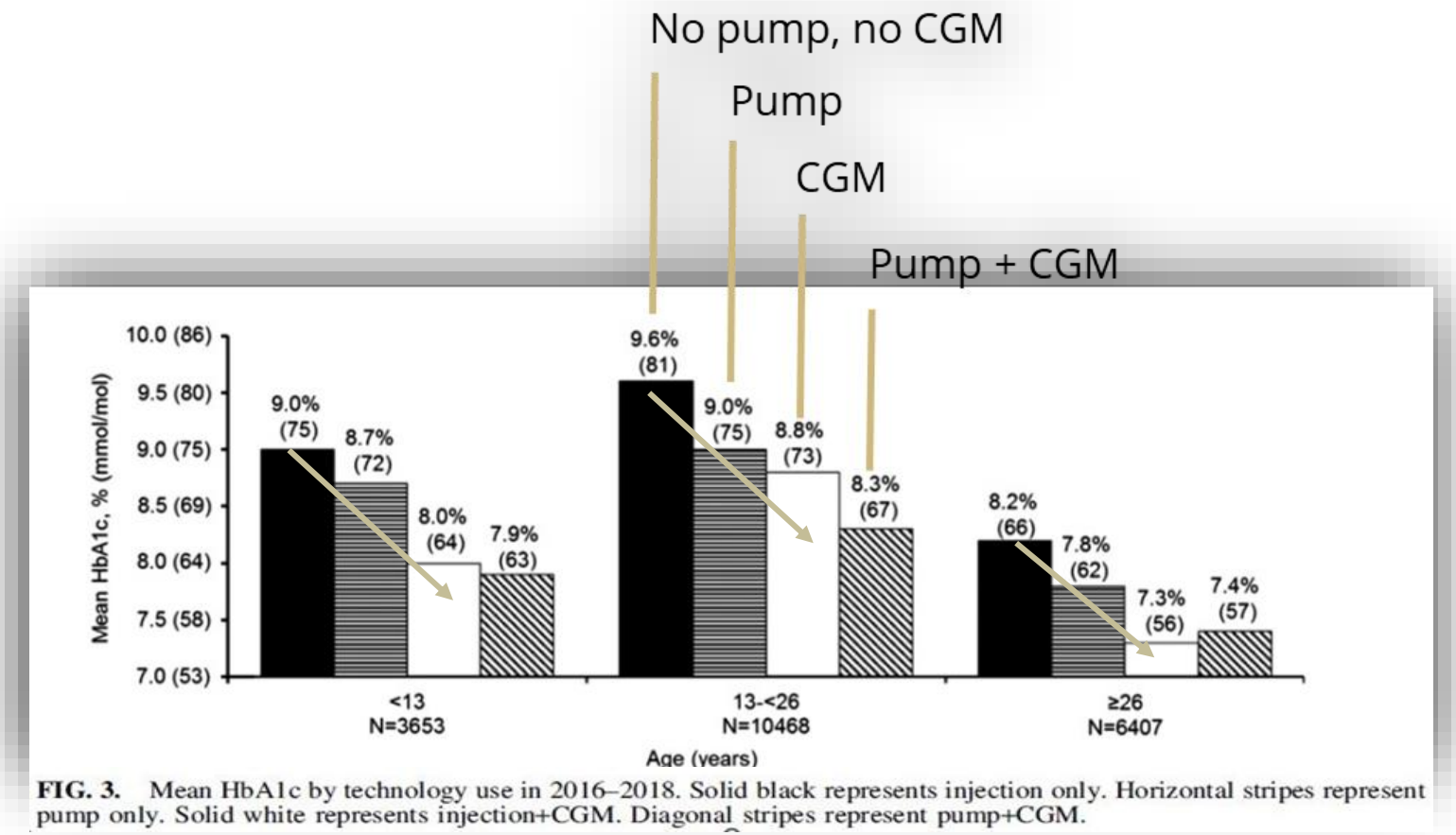


FIG. 3. Mean HbA1c by technology use in 2016–2018. Solid black represents injection only. Horizontal stripes represent pump only. Solid white represents injection+CGM. Diagonal stripes represent pump+CGM.

Glycemic Control in Relation to Technology Use in a Single-Center Cohort of Children with Type 1 Diabetes

Alexandra Sawyer, MD, MPH,[1] Marisa Sobczak, BA,[2]
Gregory P. Forlenza, MD,[3] and Guy Todd Alonso, MD[3]

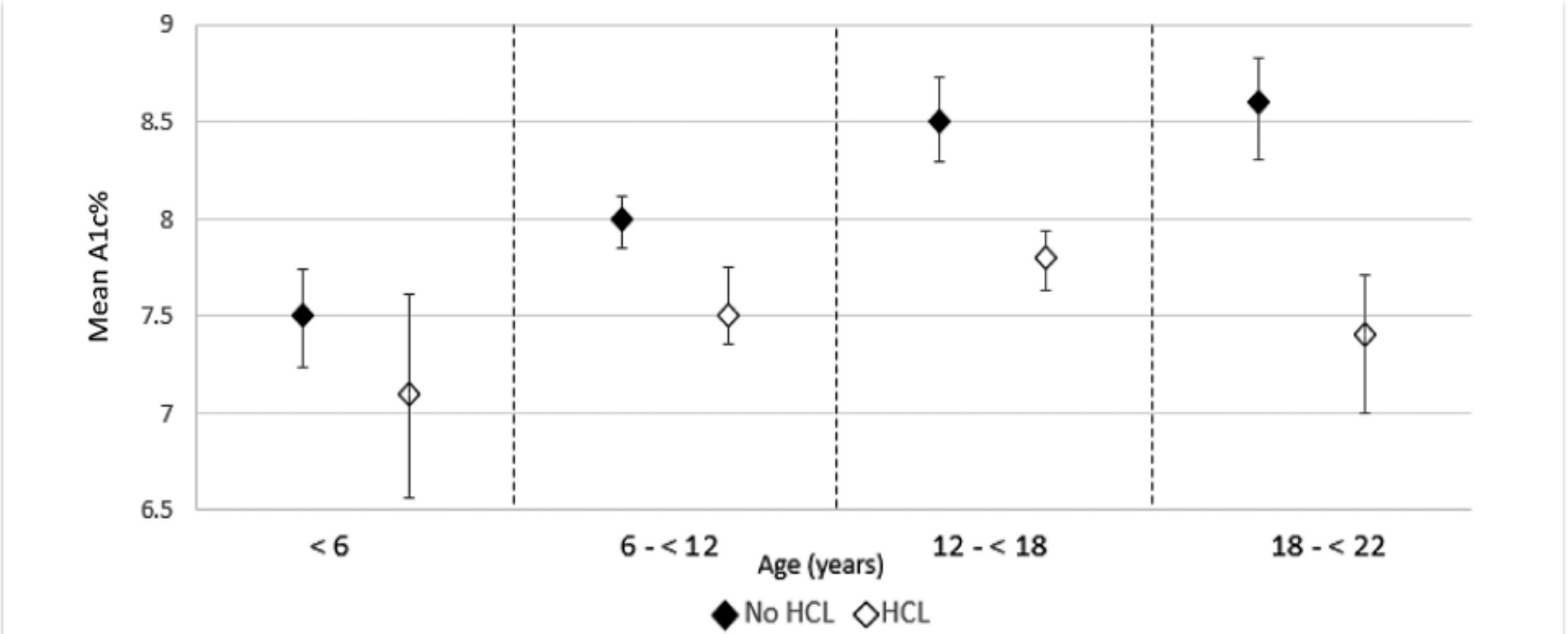
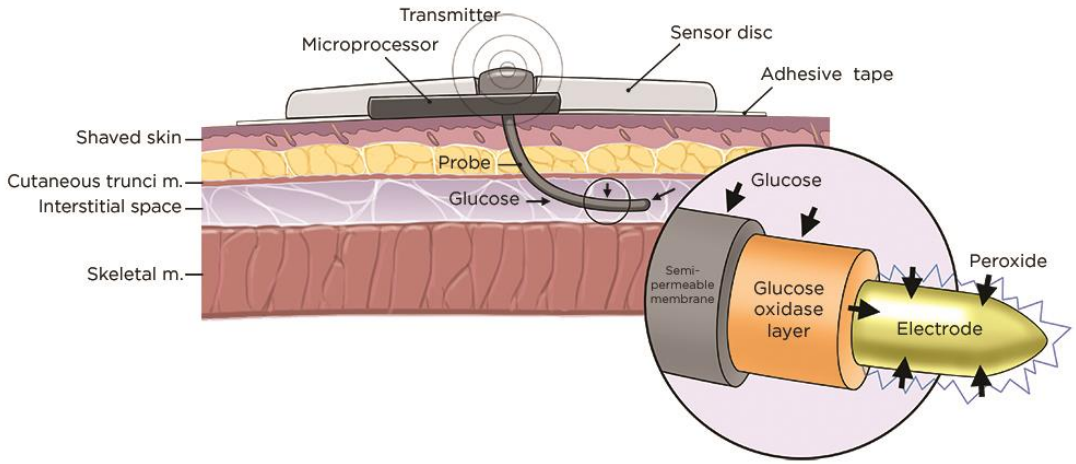
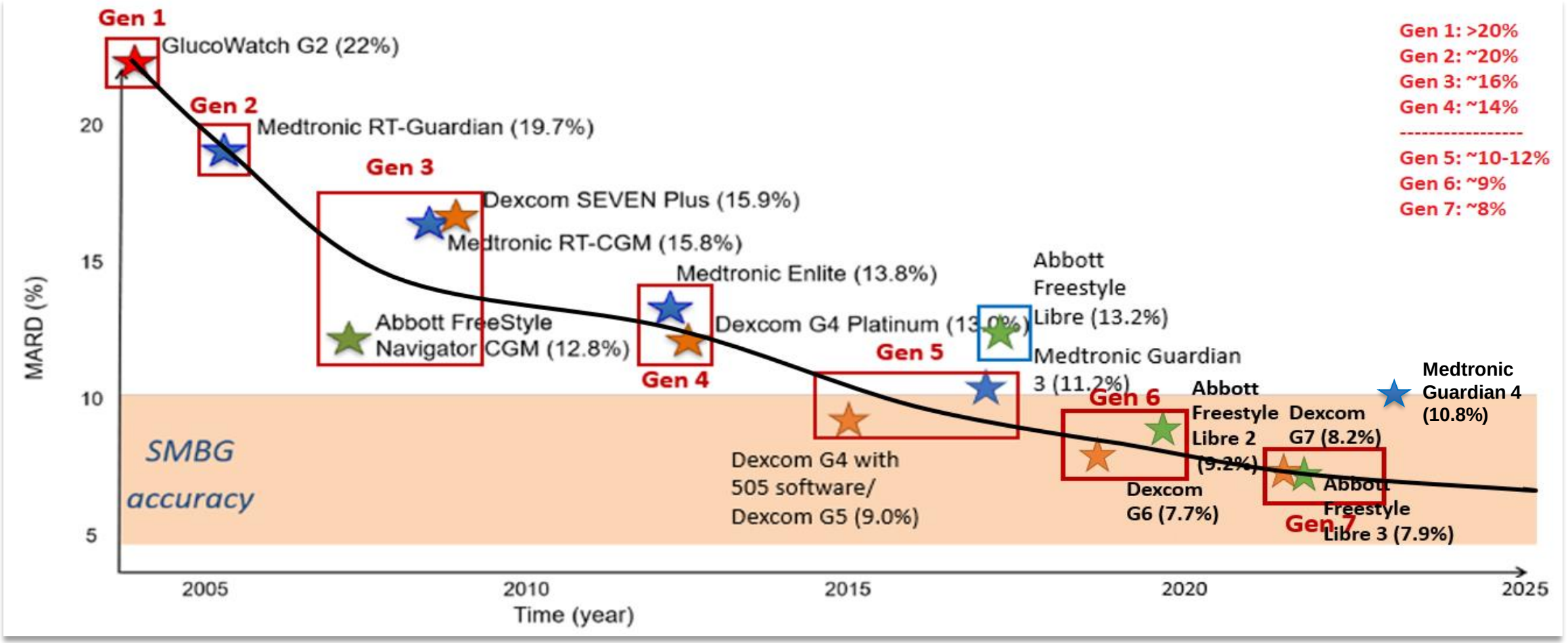


FIG. 2. Mean HbA1c compared between pump/CGM users without HCL and pump/CGM users with HCL using ANCOVA and controlling for diabetes duration, race, and insurance (Medicaid/not). *P*-value is <0.0001 for comparisons within the 6 to <12, 12 to <18, and 18 to <22 years groups, but >0.05 in the <6-year age group. Error bars represent 95% CI. HCL, hybrid closed-loop.

Continuous Glucose Monitors



CGM Accuracy



Adapted from Facchinetti, Sensors 2016 and various publications.

Currently available CGMs

- **Dexcom**
  - G6 and G7
    - 2yo+, 10-day wear, factory calibrated, non-adjunctive, remote share, all-in-one G7.
- **Abbott Freestyle Libre**
  - Libre 2 (2 Plus) and 3
    - 2yo+, 14-day wear, factory calibrated, non-adjunctive, all-in-one, remote share with Libre 3
- **Medtronic**
  - Guardian 4
    - 7yo+, 1 cal/week, non-adjunctive, no standalone, remote share
  - Simplera/Instinct
    - Pending approval, all-in-one, factory calibrated, non-adjunctive, remote share
- (Eversense – approval for 18yo+)



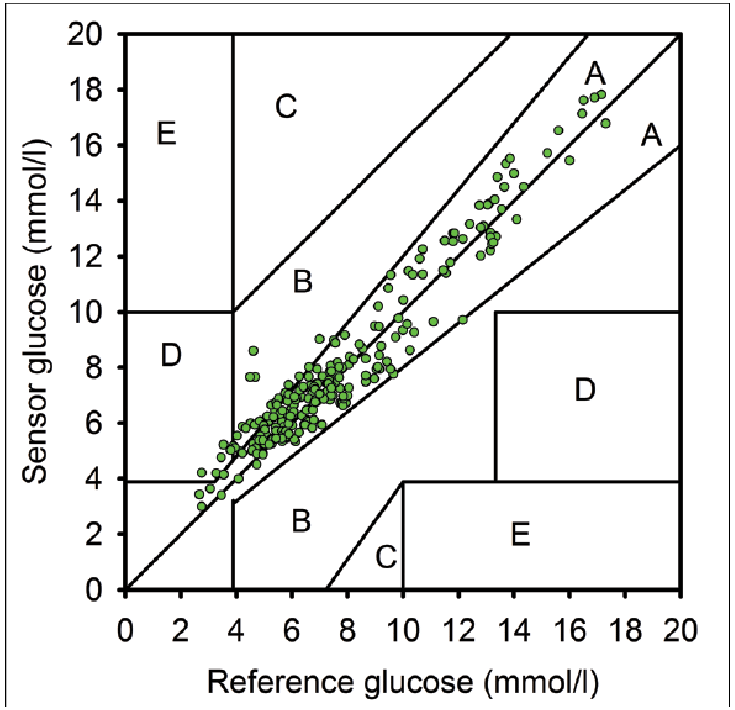


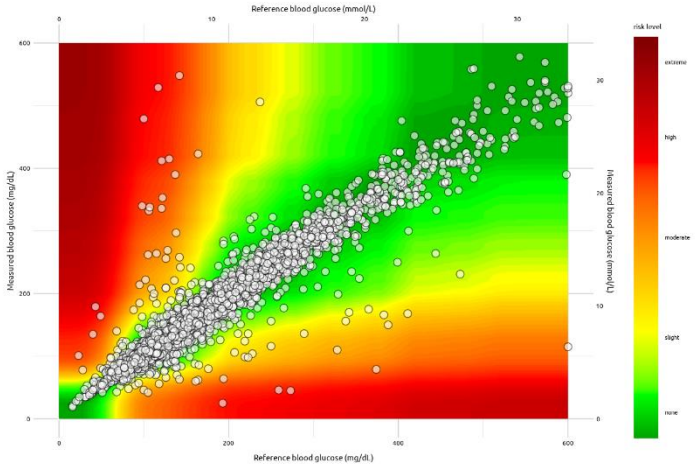
Accuracy Statistics

- **Mean Absolute Relative Difference (MARD)**
  - Average difference between device and reference results.

- **Error Grids**
  - Clarke Error Grid [CEG] uses Zones (A-E)
  - Surveillance Error Grid uses risk levels

- **15/15, 20/20, 30/30**
  - 15/20/30 mg/dL when reference glucose is <= 100 mg/dL AND 15/20/30% when reference glucose is >100mg/dL





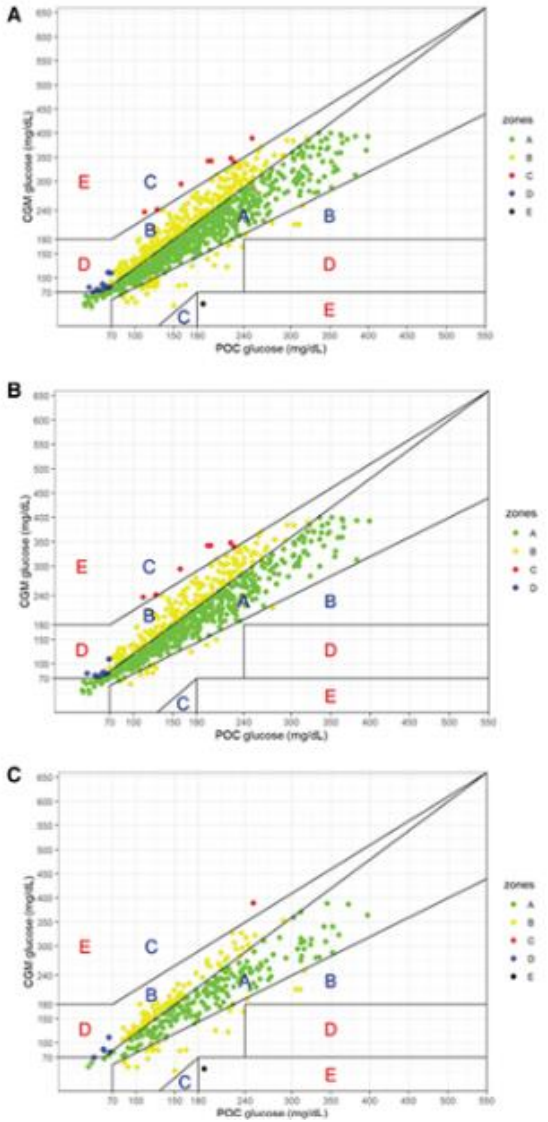
Inpatient CGM Accuracy Studies

- Since COVID, significant number of studies on inpatient CGM have come out.
- Vast majority are adult studies, as CGMs were more commonly used inpatient during the pandemic in adult hospitals.

ADULT STUDIES	Patient Population	Number of Matched Pairs	Overall MARD	Additional MARD Calculations	Percent Within A and B Zones	15/15; 20/20; 30/30
Boeder et al[1]	Critically ill COVID patients	N = 2194	14.8%	N/A	99.5%	N/A
Logo et al[2]	General floor vs ICU	N = 808	13.2%	POC glucose: 13.9% Lab glucose: 10.9% Floor: 14% ICU: 12.1%	N/A	N/A
Villard et al[3]	Hemodialysis patients	N = 1308	N/A	Lab glucose: 14.4% POC glucose: 13.8%	Lab: 100% POC: 98.7%	N/A
Davis et al[4]	Non-critically ill patients	N = 4067	12.8%	N/A	98.7%	68.7%; 81.7%; 93.8%

[1]Boeder et al. JDST. 2023
[2]Longo et al. JDST. 2021
[3]Villard et al. Diabetes Care. 2022
[4]Davis et al. Diabetes Care. 2021

Inpatient Pediatric CGM Data



DIABETES TECHNOLOGY & THERAPEUTICS
Volume 26, Number 2, 2024

https://doi.org/10.1089/dia.2023.0375

ORIGINAL ARTICLE

Accuracy of a Continuous Glucose Monitor During Pediatric Type 1 Diabetes Inpatient Admissions

Erin C. Cobry, MD [1], Laura Pyle, PhD [1,2], Lauren A. Waterman, MD [1], Gregory P. Forlenza, MD [1], Lindsey Towers, BS [1], Angela J. Karami, BS [1], Emily Jost, RD [1], Cari Berget, RN [1], and R. Paul Wadwa, MD [1]

Table 3. Accuracy Statistics (Table view)

	MARD (%)	*% Within A and B zones*[a]	*% 15/15 (%)*	*% 20/20 (%)*	*% 30/30 (%)*
Point-of-care glucose values					
Overall ($N = 1120$)	11.8	98.0	56.4	70.0	85.8
Medical floor ($N = 777$)	13.5	98.1	57.9	71.6	86.1
ICU ($N = 343$)	7.9	98.0	49.4	63.2	83.5
Hypoglycemia (40–70 mg/dL) ($N = 42$)[b]	28.2	69	61.5	74.4	92.3
Hyperglycemia (250–400 mg/dL) ($N = 171$)[b]	5.6	100	66.7	83.3	94.9
Laboratory glucose values					
Overall ($N = 288$)	6.5	98	64.0	75.5	91.7

[a]Zones refer to Clarke Error Grids.
[b]Values include both medical floor and ICU.
ICU, intensive care unit; MARD, mean absolute relative difference.

DIABETES TECHNOLOGY & THERAPEUTICS
Vol 0 Iss 0, March 20, 2024

https://doi.org/10.1089/dia.2023.0542

ORIGINAL ARTICLE

Accuracy of a Real-Time Continuous Glucose Monitor in Pediatric Diabetic Ketoacidosis Admissions*

Lauren A. Waterman, MD [1], Laura Pyle, PhD[1,2], Gregory P. Forlenza, MD [1], Lindsey Towers, BS[1], Angela J. Karami, BS[1], Emily Jost, RD[1], Cari Berget, RN[1], R. Paul Wadwa, MD [1], and Erin C. Cobry, MD [1]

Table 2. Accuracy Statistics for Diabetic Ketoacidosis Versus Nondiabetic Ketoacidosis Admissions (Table view)

	MARD	*% within A and B Zones*	*% 15/15*	*% 20/20*	*% 30/30*
DKA ($N = 612$)	11.8%	97.6%	53.0%	67.0%	83.6%
Non-DKA ($N = 503$)	11.7%*	98.6%	60.4%	73.6%	88.3%
Severe DKA ($N = 288$)	8.9%	98.3%	50.4%	66.5%	85.3%
Nonsevere DKA ($N = 324$)	14.3%**	96.9%	55.3%	67.3%	82.0%
IV insulin ($N = 266$)	13.4%	98.1%	50.6%	66.4%	85.0%
Subcutaneous insulin ($N = 346$)	10.5%	97.1%	54.9%	67.4%	82.4%

*P-value 0.95 (DKA vs. non-DKA).
**P-value 0.004 (severe DKA vs. nonsevere DKA).
IV, intravenous; MARD, mean absolute relative difference.

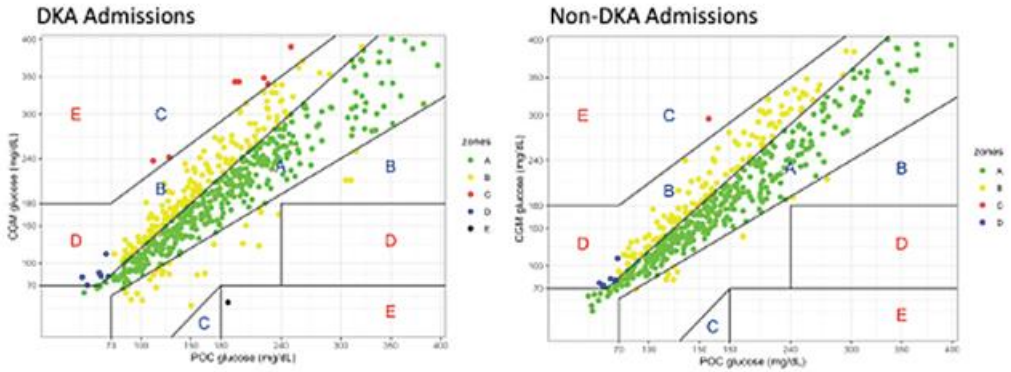


FIG. 1. Clarke error grids for DKA versus non-DKA admissions. DKA, diabetic ketoacidosis.

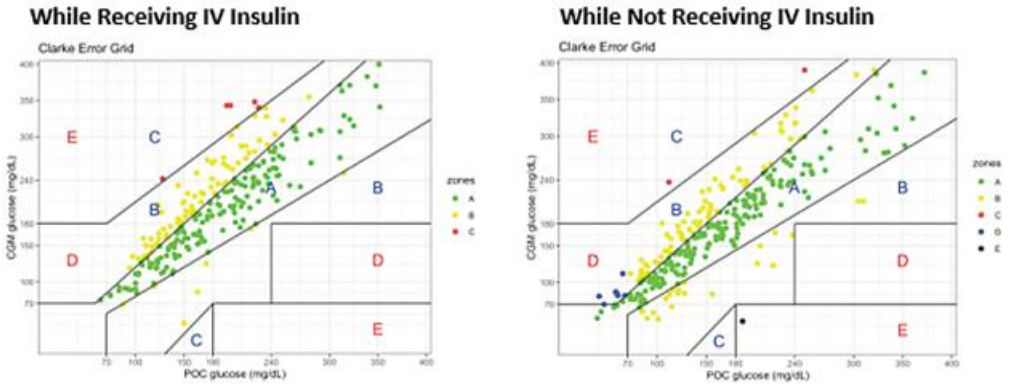


FIG. 2. Clarke error grids for pediatric patients admitted for DKA, while on and off IV insulin. IV, intravenous.

Journal of Diabetes Science and Technology
OnlineFirst

https://doi.org/10.1177/19322968221140430

Sage Journals

Original Article

Continuous Glucose Monitoring in Pediatric Diabetic Ketoacidosis

Thomas Pott, MD [1,2,3], Jose Jimenez-Vega, MD [2,4], Jessica Parker, PhD [5], and Robert Fitzgerald, MD [1,2]

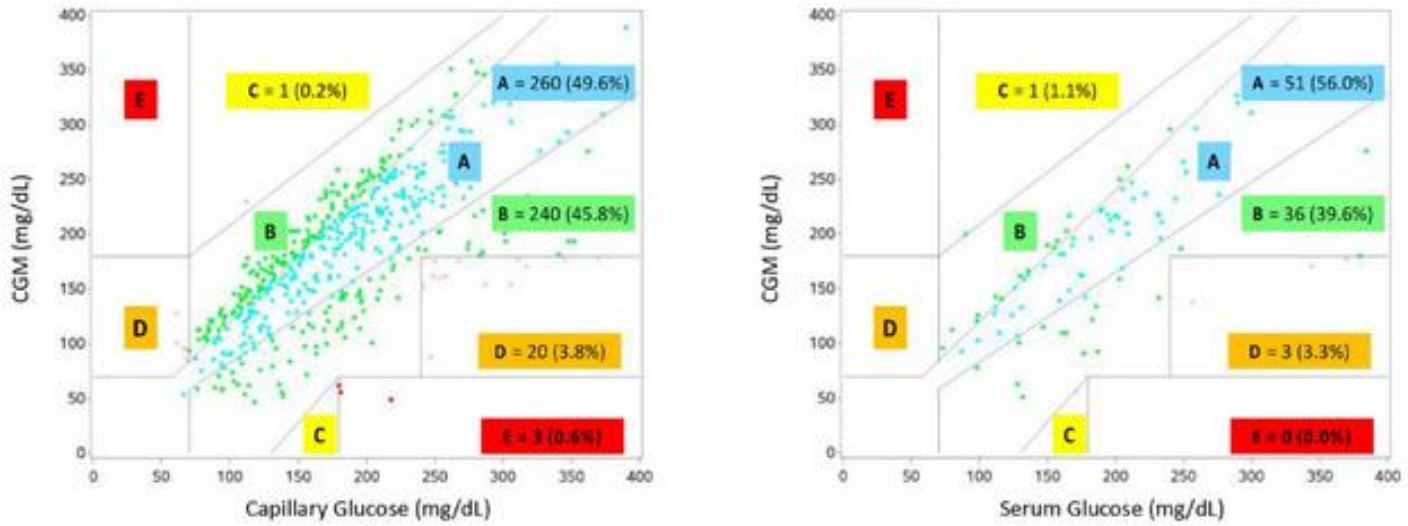


Figure 1. Clarke Error Grid analysis for rtCGM versus capillary and serum glucose. Abbreviation: rtCGM, real-time continuous glucose monitoring.

Within zones A and B
- Capillary: 95.4%
- Serum: 95.6%

No impact of bicarb on CGM

Benefits of Inpatient CGM Use

- Frequent glucose values and trends
    - Improve glucose management
- Alerts for hypo and hyperglycemia
    - Avoid acute glycemic complications
- Decrease frequency of blood glucose testing
    - Decrease nursing workload
    - Decrease patient discomfort/burden
    - Increase patient satisfaction

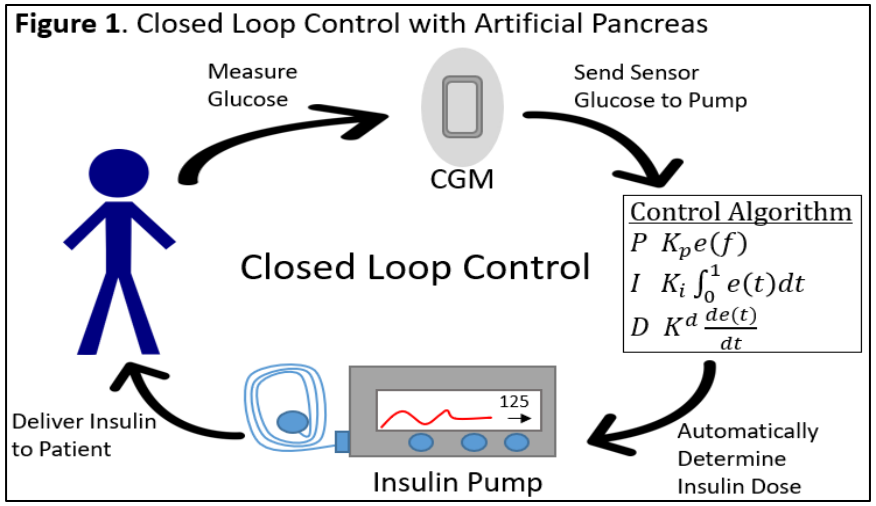
- Yeh et al. 2021. Curr Diabetes Reports
- Avari et al. 2022. J Diabetes Sci Technol
- El Sayed et al. 2023. Diabetes Care

Guidelines for Inpatient CGM Use

- Many professional societies recommend continued use of CGM in the hospital “if appropriate.”

- Consider discontinuation of CGM in the setting of:
  - DKA (? Data now showing accuracy may be maintained)
  - Rapidly changing glucose levels and fluid/electrolyte shifts (? Often temporary, trends may be beneficial)
  - Skin infections or edema at or near the sensor site (? Place elsewhere?)
  - Treatment with vasoactive agents or with poor tissue perfusion (? More data needed, use for guidance, not medical decision making?)
  - Imaging (MRI, CT, diathermy) (Replace CGM when completed, Libre 3 ok with MRI)

Insulin Pumps and Automated Insulin Delivery



Existing Commercial Automated Insulin Delivery Systems

- **Medtronic MiniMed 780G AHCL**:
  - Approved April 2023 (7+ y/o)
  - Trials for 2-6 y/o not yet started

- **Tandem t:slim X2 with Control IQ**:
  - Approved 14+ y/o in December 2019
  - Approved 6-13 y/o in June 2020
  - Trial for 2-5 y/o completed in 2022
    - **Tandem Mobi**: Approved July 2023 (6+ y/o with CIQ)

- **Insulet Omnipod 5**:
  - Approved January 2022 (6+ y/o)
  - Approved for 2-5 y/o in August 2022

- **Beta Bionics iLet**:
  - Approved May 2023 (6+ y/o)
  - Trial for 2-5 y/o not yet announced

MiniMed™ 780G

Tandem® t:slim X2™ and Mobi

iLet Bionic Pancreas™

Omnipod 5™

Summary of Outpatient Pivotal Device Trials

Table 1. Select Metrics from Device Pivotal Trials

Device	Adults or Adults/Adolescents									Children								
	Source	TIR 70-180 mg/dL (%)	Change in TIR (%)	Mean SG (mg/dL)	HbA1c (%)	TAR >250 mg/dL (%)	TBR <70 mg/dL (%)	TBR <54 mg/dL (%)	%CV	Source	TIR 70-180 mg/dL (%)	Change in TIR (%)	Mean SG (mg/dL)	HbA1c (%)	TAR >250 mg/dL (%)	TBR <70 mg/dL (%)	TBR <54 mg/dL (%)	% CV
Medtronic 670G	Garg - DTT - 2017*	68.8 / 67.2	+5.0 / +6.8	148.3 / 158.5	6.8 / 7.1	1.3 / 2.8 *	3.4 / 2.8	0.6 / 0.5 *	30.3 / 32.2	Forlenza - DTT - 2018	65	+8.8	162	7.5	10.3	3	0.8	33.7
Medtronic 780G	Carlson - DTT - 2021	75.1 / 72.7	+4.2 / +10.3	147 / 150	7.0 / 7.1	4.3 / 5.6	2.3 / 2.4	0.5 / 0.6	33.7 / 35.7	Pivotal Data Not Yet Published								
Tandem Control IQ	Brown - NEJM - 2019	71	+11	156	7.06	5.2	1.58	0.29	34	Breton - NEJM - 2020	67	+11	162	7	7.8	1.6	0.2	38
Insulet OP5	Brown - DC - 2021	73.9	+9.3	154	6.78	5.8	1.32	0.23	31.7	Brown - DC - 2021	68	+15.6	160	6.99	9.6	1.78	0.32	37
Beta Bionics iLet	Russell - NEJM - 2022	65	+11	164	7.3	8.5	1.8	0.3	36	Included in the adult/adolescent data								

* The Garg 670G trial reported TBR <50 mg/dL instead of <54 mg/dL and TAR >300 mg/dL instead of >250 mg/dL

Inpatient Insulin Pump Literature

- Limited data on pump use in the hospital setting, especially in children
  - Adults:
    - Inpatient pump use with education vs pumps without education vs switch to MDI (if deemed not appropriate for pump). (1)
      - 50 pts, mean 5.6 days.
      - Mean glucose and frequency of hyperglycemia and hypoglycemia not statistically different between all 3 groups.
      - No DKA while on pump.
    - Pump continued vs discontinued. (2)
      - 136 patients with 253 hospitalizations. Pump continued in 164 hospitalizations.
      - Mean glucose not different between pump vs no pump.
      - Severe hypoglycemia (<40) and hyperglycemia (>300) were significantly less common in pump users. No pump site infections, pump failures, or DKA.
  - Children:
    - Retrospective review of children 6 months to 25 years using a hospital pump, home pump (both manual mode) or MDI. (4)
      - 2738 patients with 18,096 days.
      - Injection users had significantly higher number of days with hyperglycemia and slightly more with hypoglycemia.
      - No difference in severe hypoglycemia. Two injection users developed DKA, no pump users had DKA.

Inpatient AID Literature

- Adults:

Study	Device	Study Design and Population	Glycemic Outcomes	Adverse Events	Comments
Pelkey et al, Ednocr Pract, 2023	HCL vs Manual Mode, vs Injection	71 patients		No adverse events reported	
Medina et al, Diabetes Res Clin Pract 2023	670G vs 780G	24 pts with T1D. Observational design	Overall: TIR 75.5% (71% achieved TIR > 70%) TBR 2.1% TIR 780G 79% vs 670G 76%	No device-related serious adverse events	
Davis et al, Diabetes Technol Ther, 2023	Pilot feasibility with OP5	22 pts w insulin requiring diabetes. Not in intensive care unit. Mean 5.3 days/pt.	Time in automation 95%. TIR 68%. TBR <70 0.17%, <54 0.06%. Sensor mean glucose 167mg/dL.	No DKA or severe hypoglycemic events	Participants reported satisfaction.
Boughton et al, Diabet Med, 2023	CamAPs system	32 pts w T1D. Median 14 days/pt.	TIR 53.3% TAR 46% TBR 0.4%	No DKA or severe hypoglycemia	
Krutkyte et al, Diabetes Technol Ther, 2023	CamAPS system vs usual care	Pts undergoing pancreatic surgery.	CamAPS TIR 77.7% vs usual care 41.1%. TAR 15.8% vs 49.5%.		
Bally et al, N Engl J Med, 2018	Fully closed loop algorithm vs usual care	136 pts with T2D.	TIR 65.8% vs 41.5%. TAR 23.6% vs 49.5%. Mean glucose 154 mg/dL vs 188 mg/dL.	No severe hypoglycemia or significant hyperglycemia or ketonemia	

- Children:
  - None
  - Retrospective chart review currently underway

Benefits of Insulin Pumps and AID Systems in the Hospital

- Improved diabetes management
  - More accurate and precise insulin dosing
  - Ability to repeat insulin dosing more frequently
  - Insulin on board feature
  - Algorithms respond to glucose fluctuations faster than can be done with injections

- Improved patient/staff satisfaction
  - Decrease nursing staff burden (ordering, calculating, drawing up insulin)
  - Fewer injections
  - Decreased interruptions to dose insulin
    - Automation reduces hyperglycemia without bolusing
    - Dosing can be done remotely in some cases and while child is sleeping

- Avari et al. 2023. J Diabetes Sci Technol
- El Sayed et al. 2023. Diabetes Care
- Yeh et al. 2021. Curr Diabetes Reports

Guidelines for Inpatient Use: Insulin Pumps

- Major professional societies encourage continued insulin pump use in the hospital if it “can be done safely.”
  - May reduce the risk of insulin administration errors, provide more patient autonomy for self-management of their diabetes/insulin, and increased satisfaction.

- On admission, must determine if safe to continue pump therapy.
  - Medically stable, willing and capable of managing their pump, care team comfortable with insulin dosing through the pump (admitting team and consulting teams).

- Reassess ability to manage insulin pump throughout the admission.
  - Consider temporary or permanent discontinuation if status acutely worsens, hyperglycemia is persistent, undergoing imaging or surgery.

- Follow local hospital policies for insulin pump use and management.

- Avari et al. 2023. J Diabetes Sci Technol
- El Sayed et al. 2023. Diabetes Care
- Yeh et al. 2021. Curr Diabetes Reports

Guidelines for Inpatient Use: AID Systems

- Same guidelines as for insulin pump.
- Minimal data currently available to determine glycemic or adverse outcomes.
- If well and expected hospital duration is short, AID may be appropriate to continue. (Some patients with prolonged hospitalization but overall stable may still benefit)
- If unwell/critical, recommendation is to discontinue automation due to:
  - Potential for rapid glucose fluctuations (?temporary vs critical?)
  - Insulin resistance with stress and high doses of medications (ie steroids) that are not well or rapidly adjusted for with automated algorithms (consider immediate setting changes or manual mode settings that take these increased needs in to account)
  - Inability of the automation to accurately dose in acute critical conditions
  - Dependent on CGM accuracy which can be altered by critical illness and/or medications.
    - May consider still utilizing the pump in manual mode with ability to make frequent dose adjustments.

Special Considerations for CGM and Pump/AID Use

- Imaging that requires removal of metal devices.
  - Consider replacement after imaging

- Sensor and infusion site location
  - Compression risk (CGM), consider different location
  - If a DKA admission, infusion set needs replaced before relying on pump for accurate dosing
  - Infusion sites need changed q 3 days, sensors q7-14 days

- Acute and Critical Illness
  - Insulin settings (ie carb ratios and correction factors) may not be accurate in the setting of acute illness
  - Physiologic changes during critical illness may interfere with CGM accuracy (critical hypotension or ECMO).
  - High medication doses affect CGM accuracy, more research is needed.
  - Fluid shifts and edema may impact subcutaneous perfusion (CGM accuracy and insulin infusion).
  - AID is dependent on CGM accuracy.

Special Considerations

- Surgery
  - Run AID while NPO due to automated adjustments to insulin delivery.
  - Consider exercise/activity mode if tends to drop overnight.
  - Consider not using manual mode pre-op as programmed settings may not be accurate/up to date.
  - Manual mode recommended in the OR due to questions around CGM accuracy under anesthesia.

- Hospital policies are important to determine appropriate use of devices.
  - CGM accuracy protocols on admission and throughout.
  - Who will manage the devices, who will monitor the glucose output?
  - Many nursing staff not comfortable operating devices.
    - Training sessions to increase familiarity and comfort.
    - Ensure patients/families are capable of managing the system, including troubleshooting

- Difficult to document insulin administration in the hospital
  - Concerns around documenting medical management throughout hospitalization.
  - Integration into the EMR could help with this.

- Need to establish remote monitoring capabilities for endocrine service and nursing.

Final Thoughts

- For determining CGM accuracy in the hospital, what MARD is going to be considered “accurate enough”, or other measure of accuracy?
- Inpatient protocols for CGM, pump, and AID use will be necessary.
  - Develop national/international guidelines/protocols that can be adapted to each hospital.
- Need infrastructure for monitoring, assessing, and intervening on data.
  - Includes both CGM data as well as pump/AID data for feasible use and accurate documentation.
- Need supplies available at hospitals.
- Consider temporary implementation of devices (CGMs or pumps) for patients who may not be on them outpatient
  - T2D patients, steroid induced hyperglycemia, cystic fibrosis related diabetes, etc.

Our Center

- CGMs
  - Allow CGM wear, but all interventions based on POC glucose.
  - All data goes to the patient/family, not to hospital staff.

- Pumps
  - Allow pump wear, but patient/family must be responsible/at the bedside.
  - Nursing oversees doses and documents insulin dosing, but don’t administer.

- AID systems
  - No protocols in place currently.
  - Hospital staff in general are nervous about AID.
  - Use is variable, case by case, and typically Endo is open for it.
  - Depending on hospital staff with the patient, may be blocked or allowed.

Thank You!

- **The BDC AP Research Team**
  - Gregory Forlenza, MD
  - Paul Wadwa, MD
  - Cari Berget, RN, CDCES
  - Samantha Lange, NP, CDCES
  - Angela Karami
  - Emily Fivekiller
  - Lindsey Towers
  - Estella Escobar
  - Kasserine Taylor
  - Luke Geiser

- **Our patients and families**

Coming soon….. CGM/Technologies in the Hospital resources on the Panther website!