

## PEDIATRIC TRACK

### DIABETES TECHNOLOGIES



R. Paul Wadwa, MD  
Associate Professor of Pediatrics  
Barbara Davis Center for Diabetes  
University of Colorado Anschutz Medical Campus  
Aurora, Colorado



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**EMPOWERING PATIENTS**  
**FOR**  
**INDIVIDUALIZED CARE**

The Barbara Davis Center for Diabetes logo, featuring a silhouette of a person riding a horse, with the text "Barbara Davis Center for Diabetes" and "Children's Diabetes Foundation" around it.

## DISCLOSURES

### Research Support

National Institutes for Health (NIH)

Abbott, Dexcom, Insulet, Medtronic, Tandem, Eli Lilly & Co,  
Mannkind

### Honorarium/ Consulting Fees

Dexcom

Eli Lilly & Co

Medtronic



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## OUTLINE

- Background
- Currently available technology
  - Glucose Monitoring
  - Insulin Delivery
- Future Developments
  - Glucose Monitoring
  - Insulin Delivery
- Summary
- Questions & Answers

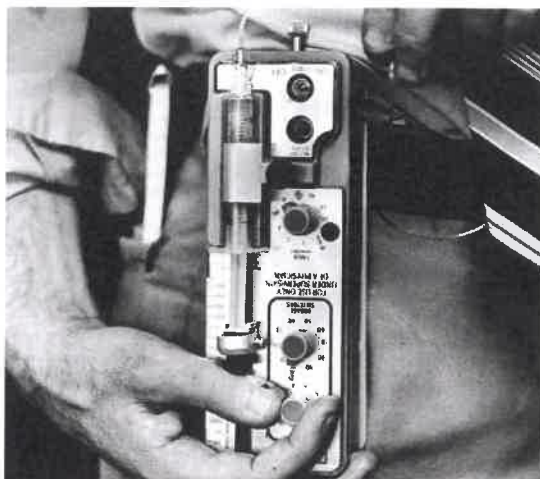


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## BACKGROUND

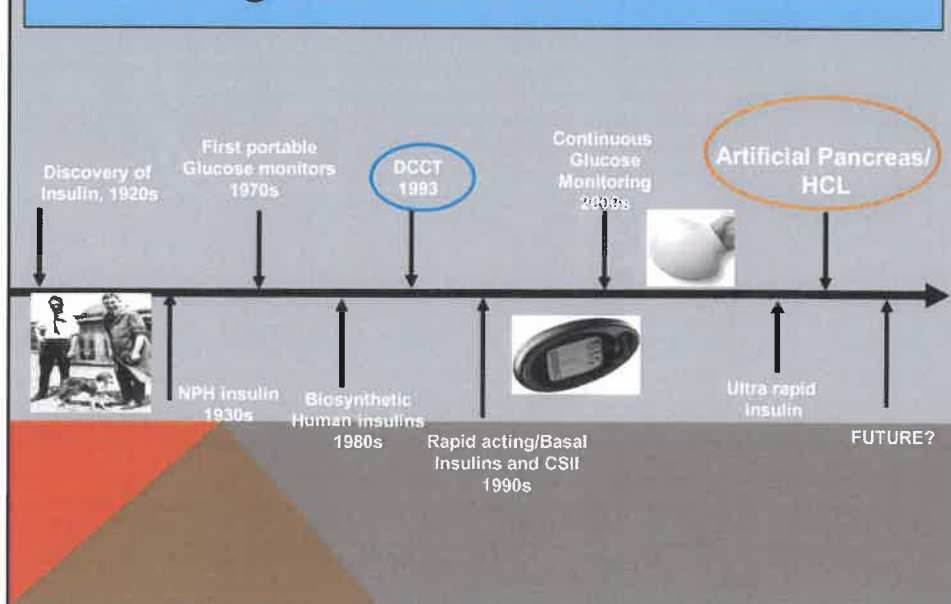


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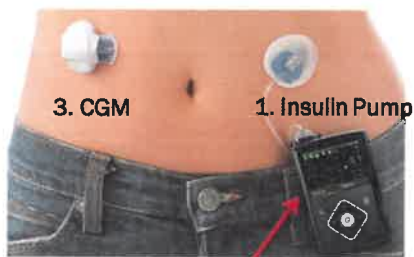


## Progress in Diabetes Care



## ARTIFICIAL PANCREAS

What is an “artificial pancreas?”

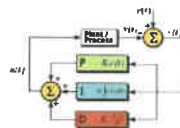


3. CGM

1. Insulin Pump

2. Rapid Acting Insulin  
± Glucagon

### 4. Insulin Dosing Algorithm(s)



### 5. ± Communication Device



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# Why do we need the artificial pancreas?



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## CURRENT T1D CONTROL IN THE UNITED STATES

Despite >20 years of knowledge of the importance of tight control, patients are still poorly controlled.

- Evidence from the Type 1 Diabetes Exchange Registry from 2015 (Miller, *Diabetes Care*).
- Average A1c by age group is too high everywhere and much too high in adolescents.

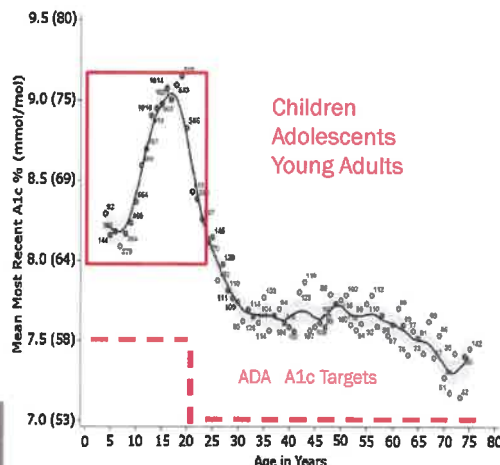
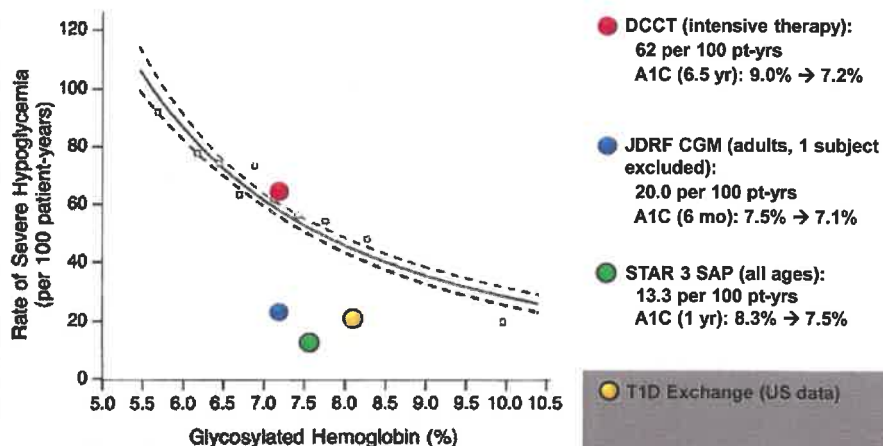


Figure 1—Mean  $HbA_{1c}$  by age. Average  $HbA_{1c}$  for each year of age was plotted using the most recent  $HbA_{1c}$  value available for each of the 16,057 participants with a recent update. The line was estimated using local regression scatter plot smoothing (LOESS), which is a nonparametric method for estimating the regression equation that fits a smoothing parameter. Circles represent the mean  $HbA_{1c}$  for each year of age. Participants <4 years were lumped as age 4 and participants ≥75 years were lumped as age 75. Gray shaded area represents the 95% CI around the smoothed LOESS line. Numbers next to circles are the n for each year of age.

## SEVERE HYPOGLYCEMIA AND A1C

DCCT (1993), JDRF (2008), STAR 3 (2010) AND T1D EXCHANGE (2012) STUDIES



● DCCT (intensive therapy):  
62 per 100 pt-yrs  
A1C (6.5 yr): 9.0% → 7.2%

● JDRF CGM (adults, 1 subject excluded):  
20.0 per 100 pt-yrs  
A1C (6 mo): 7.5% → 7.1%

● STAR 3 SAP (all ages):  
13.3 per 100 pt-yrs  
A1C (1 yr): 8.3% → 7.5%

● T1D Exchange (US data)

Adapted from Figure 5B of: DCCT. *NEJM*. 1993;329:977-986.  
JDRF CGM Study Group. *NEJM*. 2008;359:1465-1476.  
Bergstralh RM, Tamborlane WV, Akerman A, et al. *NEJM*. 2010;363:311-320.  
Garg et al. *ATTD: Barcelona* 2012.

# BURDEN V BENEFIT

**Burden**

**Benefit**

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## CURRENTLY AVAILABLE TECHNOLOGY

- Glucose Monitoring
- Insulin Delivery/ Artificial Pancreas

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## CURRENTLY AVAILABLE TECHNOLOGY

- Glucose Monitoring



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## GLUCOSE MONITORING

### Progress over the last 50 years

- Urine glucose
- Fingertstick blood glucose
  - Improvements in accuracy and technique
  - Limitations: fingersticks, frequency, rate of change
- Interstitial fluid monitoring
  - Continuous glucose monitoring (CGM)
  - Flash glucose

## CONTINUOUS GLUCOSE MONITORS

- Continuous Glucose Monitors provide increasingly accurate real-time glucose values to assist with diabetes decision making
- Sample interstitial fluid glucose and give filtered blood glucose value which is generally within 8-12% of the serum glucose with an 4-10 minute lag-time



## CONTINUOUS GLUCOSE MONITORS

- Studies show CGM use lowers HbA1c by 0.5% with decreased hypoglycemia.
- Greater benefit seen in people who wear the sensor 6 or more days per week.
- Early CGM Studies showed overall use is only about 10% of pediatric patients with high rates of discontinuation (~40% within 1 year).
- More recent (2017) evidence shows rates of use at 50% among younger children and older adults with rates around 20% among adolescents.



## CURRENTLY AVAILABLE TECHNOLOGY

- Medtronic Guardian Connect
  - Approved for age 14 years and over
  - Requires Apple device (iPhone)
  - Sensor: 7-day use, calibration 2/day
  - Allows sharing
  - Sugar IQ app – identifies trends



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## CURRENTLY AVAILABLE TECHNOLOGY

- Dexcom G6
  - FDA approved for pediatric & adult use in 2018
  - Factory calibration
  - 10-day use
  - Receiver or phone/ watch display
  - Share/follow apps
  - Integration with Tandem pump



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## CURRENTLY AVAILABLE TECHNOLOGY

- Abbott Freestyle Libre
  - “flash” glucose monitoring
  - No calibration
  - Up to 14-day use
  - No high/ low

**NOT APPROVED FOR PEDIATRIC USE (under age 18 yrs)**



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## CURRENTLY AVAILABLE TECHNOLOGY

**NOT APPROVED FOR PEDIATRIC USE (under age 18 yrs)**

- Senseonics Eversence
  - Requires in office procedure to implant sensor
  - 3-month sensor
  - Requires calibration (2/day)
  - High/low alarms on phone, vibration of sensor
  - Removable transmitter



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## CURRENTLY AVAILABLE TECHNOLOGY

- Insulin Delivery



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## INSULIN DELIVERY

**MiniMed™ 670G insulin pump with SmartGuard™ technology.**

**Guardian™ Sensor 3 glucose sensor and Guardian™ Link 3 transmitter.**

**CONTOUR®NEXT LINK blood glucose meter for calibrations.**



The MiniMed™ 670G system is currently approved for use in the US for type 1 diabetes ages 13 years.

1. Safety Evaluation of the Hybrid Closed-Loop (HCL) System in Pediatric Subjects With Type 1 Diabetes. ClinicalTrials.gov identifier: NCT02660927

## MEDTRONIC 670G: MODES

manual mode

Pump mode

Sensor Augmented Pump

Hybrid Closed Loop/ Auto mode

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## INSULIN DELIVERY

- Tandem t:slim X2 with BASAL IQ
  - Use with Dexcom G6 CGM
  - Predicted low glucose suspend
  - Decreases risk for hypoglycemia

1 Predicts glucose 30 minutes ahead

2 Suspends insulin to help avoid the low

3 Resumes insulin once glucose rises

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## INSULIN DELIVERY

- Omnipod (Insulet)
  - DASH rolling out in 2019
    - (selected areas/ insurance coverage)
  - Bluetooth enabled, wifi-compatible
  - Calorie King database
  - Display/ View apps to share info
  - iPhone widget allows CGM and pump views



Omnipod system



Omnipod DASH



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## INSULIN DELIVERY

- InPen (Companion Medical)
  - Bluetooth enabled pen
  - Phone app with “smart diabetes management tool”
  - Dose calculator for injections
  - Reports with data not found in meter alone



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## Future Developments

- Glucose Monitoring
- Insulin Delivery
  
- **WARNING! NOT FDA APPROVED FOR USE**
  
- **ALL INFORMATION PRESENTED IS PUBLICLY AVAILABLE**



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## Future Developments

- Glucose Monitoring
  - Studies in progress for pediatric use of Freestyle Libre
  - Next generation CGM from Dexcom, Medtronic
  - Increased interaction with "apps"



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## Future Developments

- Control IQ
  - Tandem X2, Dexcom G6
  - U Virginia/Kovatchev algorithm
  - Trials at 7 sites completed spring 2019 (including BDC)



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## Future Developments

- Medtronic
  - Bluetooth
  - 670G for age 2-6 yrs submitted for FDA review
  - Advanced Hybrid Closed Loop (integrate new algorithm)



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## Future Developments

- Omnipod Horizon
  - Trials in progress for hybrid closed loop
  - MPC algorithm



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## Future Developments

- Bionic Pancreas bihormonal systems
  - Trials in progress
    - Pilot at BDC in summer 2018 - insulin only Gen 3 iLet
    - Plans for future insulin only, bihormonal (insulin/ glucagon) trials



3<sup>rd</sup> gen.



4<sup>th</sup> gen. prototype

<https://www.betabionics.com/>

Not FDA Approved - Investigational Device Only



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## Future Developments

- Tidepool Loop
  - Loop algorithm
  - Partnership with Tidepool, Insulet
  - Under development



Tidepool Loop, included support for Omnipod DASH™, is currently under development. Tidepool Loop is not currently being marketed or sold.



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## Future Developments

- Other Systems
  - Several academic groups working on algorithms
    - Insulin only
    - bihormonal systems



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## SUMMARY

Diabetes control in general remains suboptimal for most pediatric and adult patients

New diabetes technology offers hope!

More developments coming

- With research, better tools are on the way!
- Future technology will reduce burden and increase benefit



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## ACKNOWLEDGEMENTS

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- G. Todd Alonso, MD
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- Laurel Messer, RN, CDE, MPH

### Research Team

- Cari Berget, RN, CDE
- Emily Jost, RD, CDE, MPH
- Samantha Lange, RN, CDE
- Maria Alex Rossick-Solis
- Emily Boranian, RN
- Lindsey Towers
- Alex Coakley
- Estella Escobar



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# QUESTIONS



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