

Advancements in Type 1 (and type 2) Diabetes Management



- Associate Clinician Lurie Children's
- Assistant Professor of Pediatrics, Northwestern Feinberg School of Medicine
- Medical advisor for JDRF
- Volunteer physician leader for Diabetes Training Camp (diabetestrainingcamp.com)
- Volunteer educator for Chicago Public Schools

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Objectives

- Discover new pumps and sensors on the market
- Learn about potential future therapies for management of diabetes
- Learn how time in range is a more meaningful value than hemoglobin A1c
- Learn about the new glucagon options

99 years of progress...

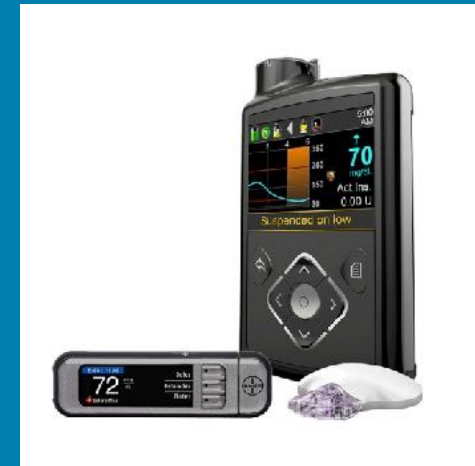
1921: insulin
1922: first human tx

1930s: NPH
1960s: Lente
1961: Glucagon
1970: first glucose meter

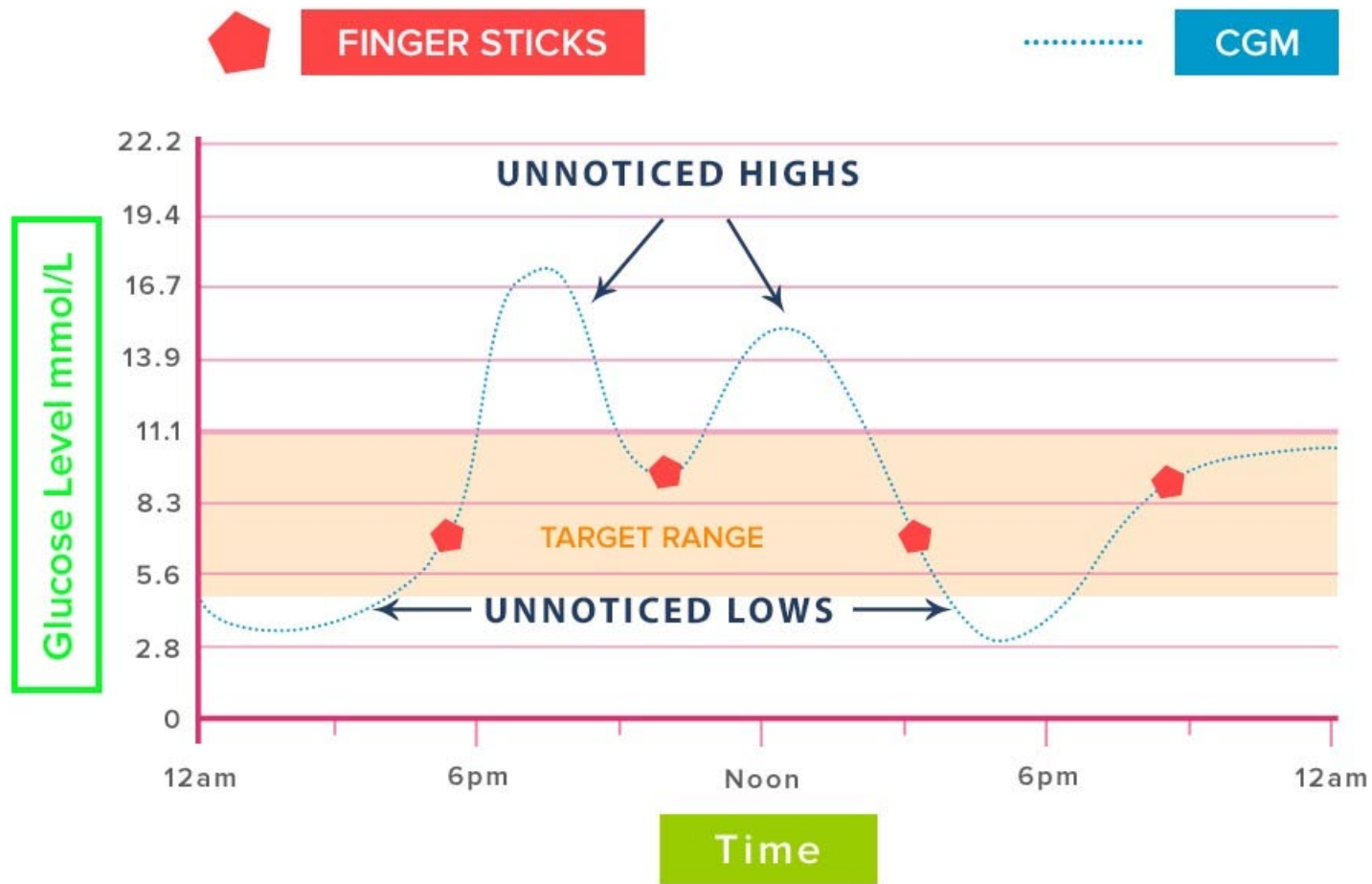
1970s: insulin pump conceptualized
1980s: commercialization of first pump

1990s: Analogue insulin
2003: Glargine
2005: Detemir

2009: first semi-closed loop system Europe
2013: Medtronic low glucose suspend in US
2014: shared data system for CGM
2016-7: Freestyle Libre
2018 - 2020 Dexcom G6, Tandem integration, Omnipod Dash system, Medtronic 780G, InPen



The Sensational Sensor

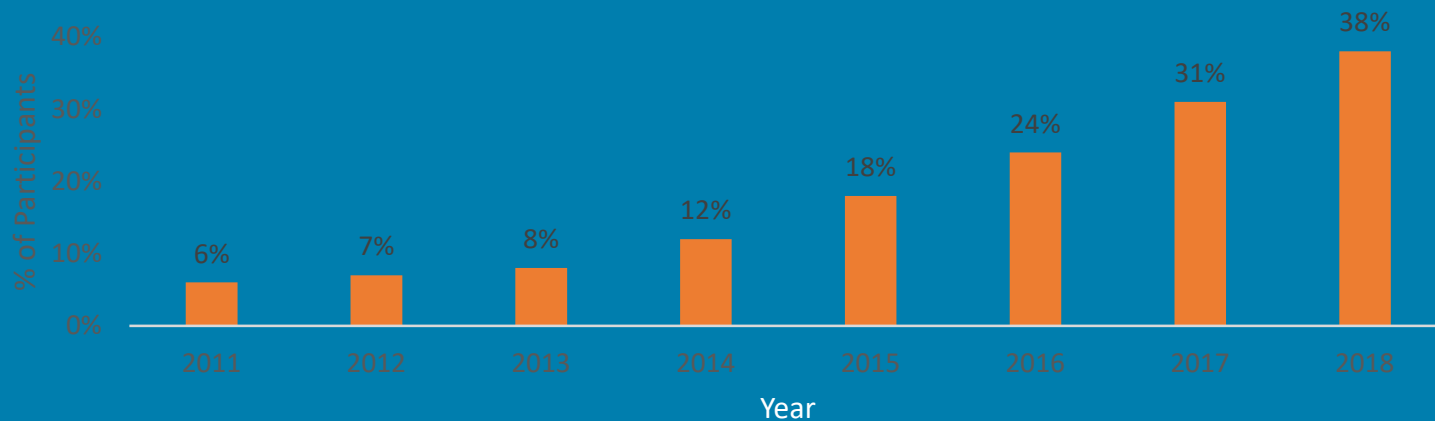


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2016-2018

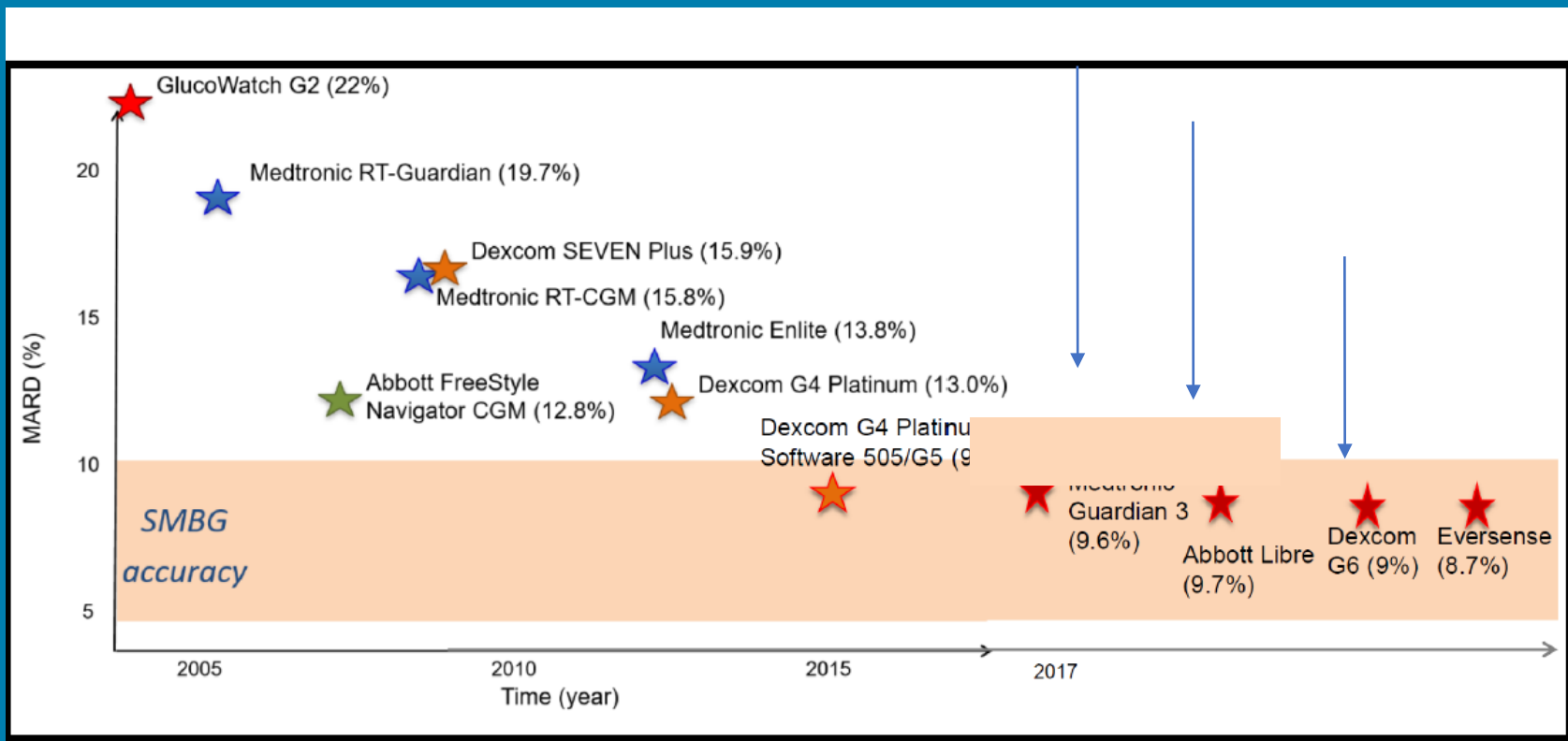
T1D Exchange Registry Data

rtCGM use over time



Foster et al. *Diabetes Technol Ther.* 2019 Jan 18.

CGM accuracy: same as finger-stick?



DiaMonD (T1D)

Dexcom CGM vs fingerstick glucose

Design

- Randomized, controlled 24-week trial in 158 adults (>25 y) with T1D (mean baseline A1c 8.6%)
- Primary endpoint: change in A1c from baseline to week 24



A1c Reduction

After 24 weeks, CGM users had a mean 1.0% A1c reduction from baseline (0.6% lower than SMBG; $P < .001$). 52% of patients had $\geq 1\%$ A1c reduction.

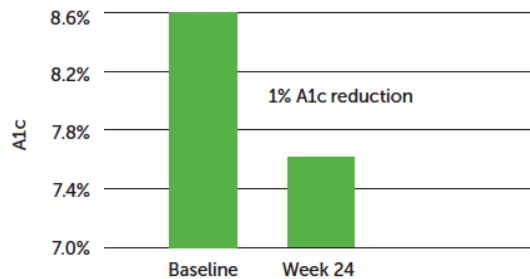


Reduced Time in Nighttime Hypoglycemia (<60mg/dL)

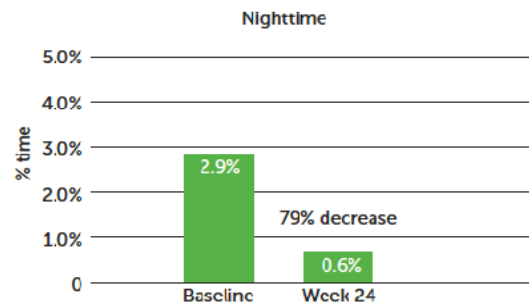
CGM group had 79% reduction in the median time spent in hypoglycemia at night.

At week 24, CGM users spent significantly less time in hypoglycemia vs SMBG users (0.6% vs 2.4%; $P < .005$).

Significant A1c Reduction in MDI Patients with Dexcom CGM System



Dexcom CGM System Reduced Time Spent in Hypoglycemia (<60 mg/dL)



RESULTS



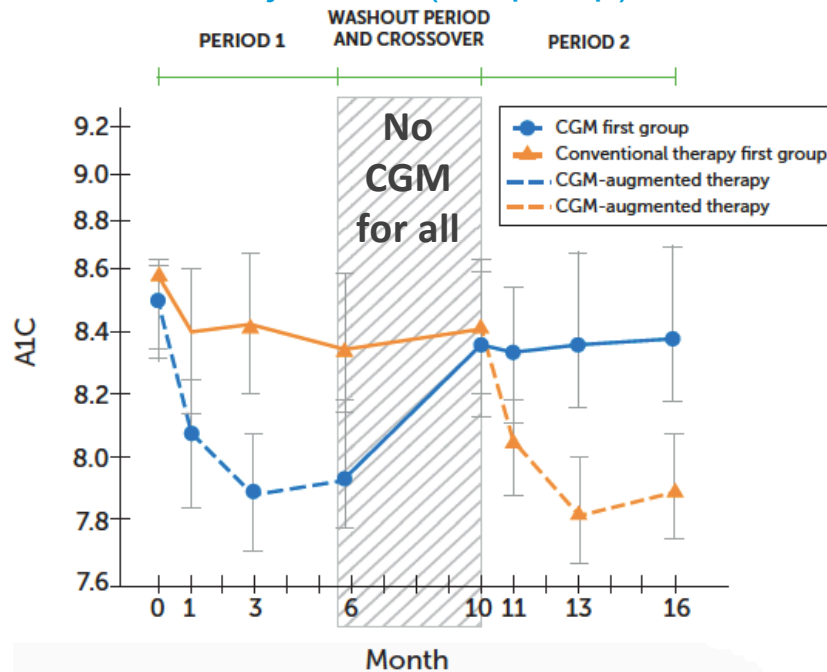
SIGNIFICANT A1c REDUCTIONS regardless of patients' education level, math ability, and age



HIGH RATE OF ADHERENCE at week 24, 93% of patients were still using the Dexcom CGM System ≥ 6 days/week.

2017 GOLD Study

- Randomized cross-over CGM Dexcom G5 vs. fingerstick (SMBG)
- 161 T1 adults on injections (not pump)



Lind M, et al JAMA. 2017;317(4):363-364.

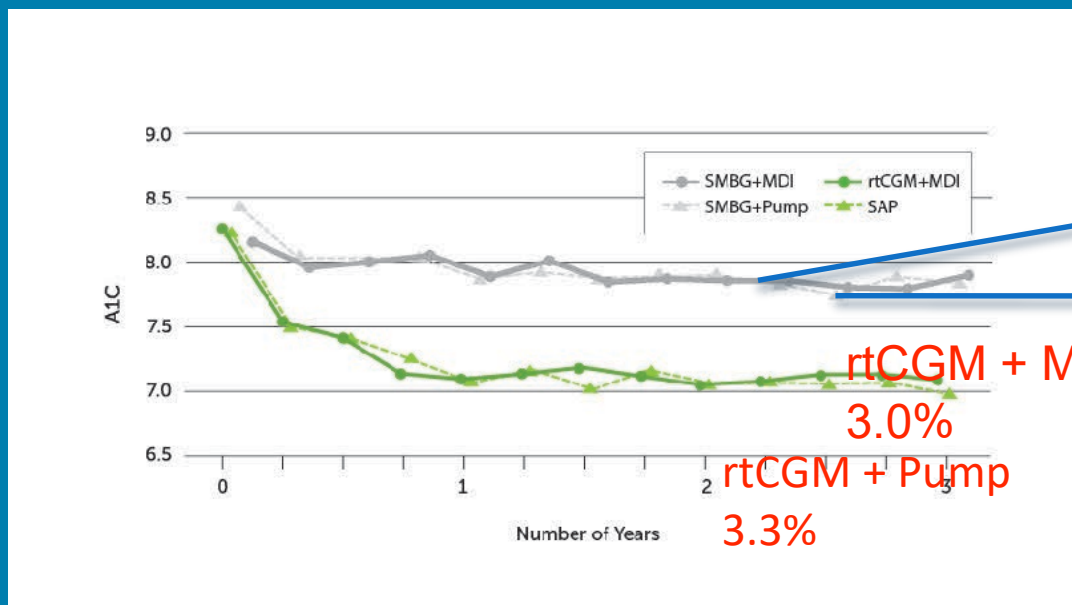
- 0.8 % A1C drop vs. baseline

- Time in hypo reduced

- 12 severe hypo. Events in the SMBG group vs 1 in the rtCGM group

- Included only patients on MDI so rtCGM works

2019 COMISAIR – 3 Year Data



Change in A1C

SMBG + MDI
0.7%

SMBG + Pump
1.2%

rtCGM + MDI
3.0%

rtCGM + Pump
3.3%

A1C decreases with CGM regardless of insulin delivery method



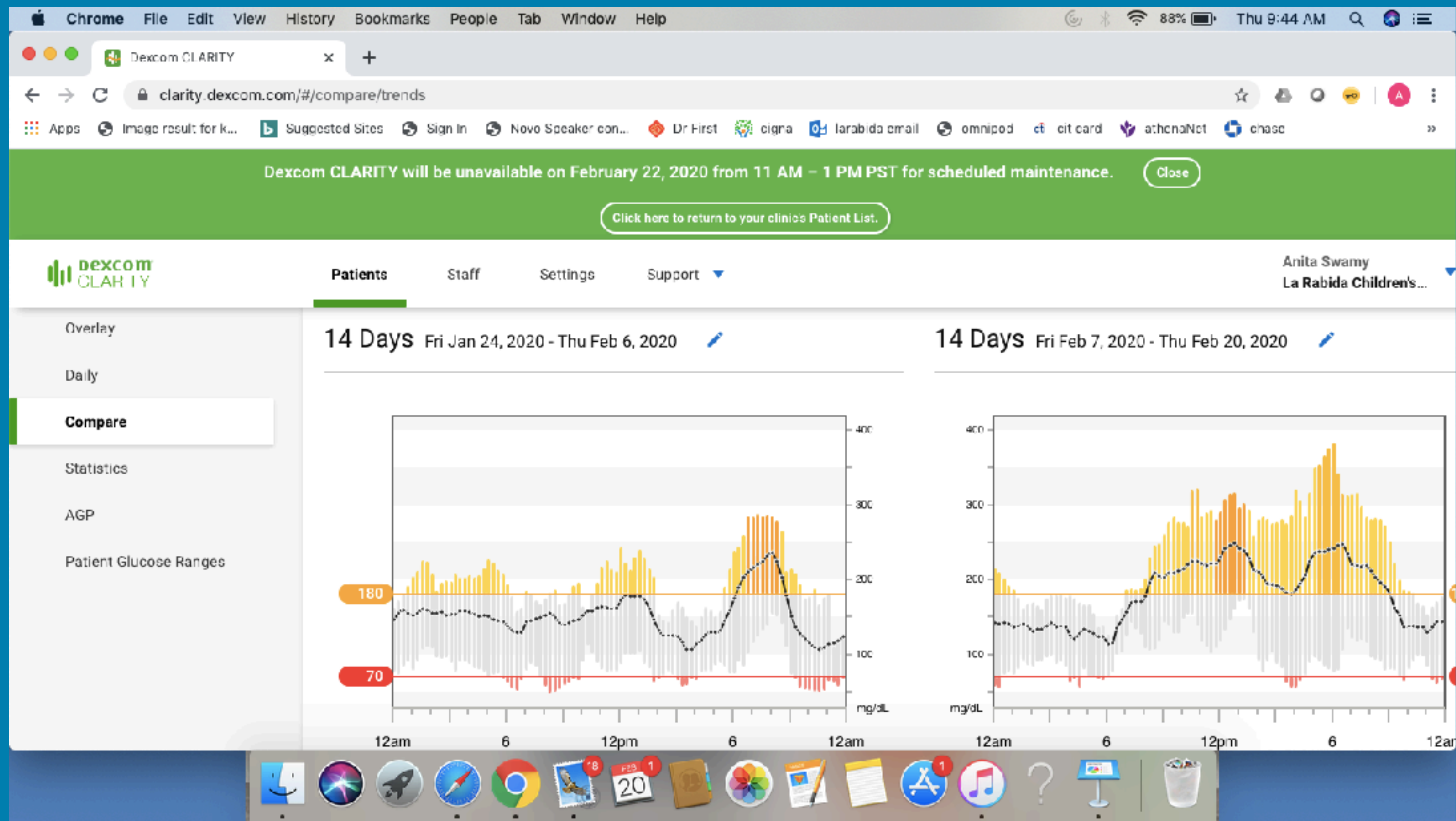
Šoupal J, Petruželková J, Grunberger G, et al. Diabetes Care 2019

Sensor advancements

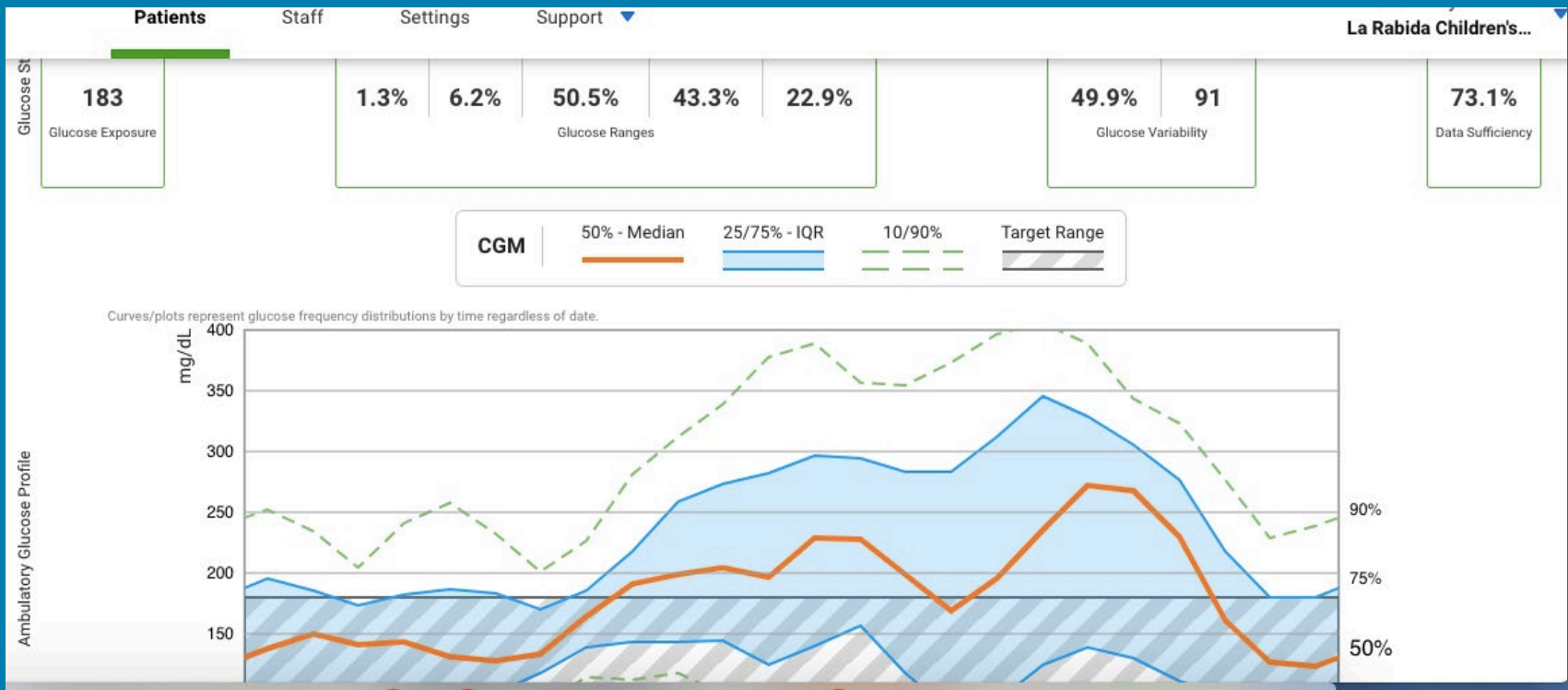
- Medtronic guardian connect 3 now used alone with bluetooth and has auto uploads
 - with 780G single calibration day 1, bluetooth
- Libre: pediatric indication?
- Dexcom G7 - much smaller, less plastic and looking at 10-15 day wear possibly - release in 2020?



A Little Clarity on CLARITY



A little clarity on CLARITY



**we go together like shoobie-da-
wop...sensor integrated systems**

InPen is "in"



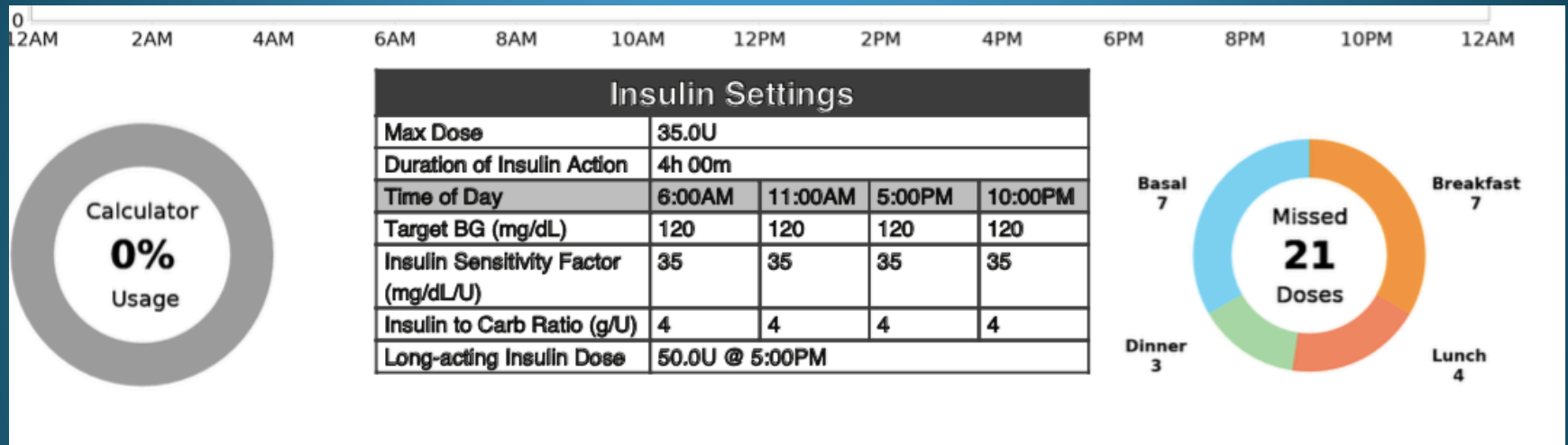
InPen

- smart pen
- houses rapid-acting insulins only (those that come in cartridges)
 - Humalog, Novolog, Fiasp
- calculates doses like a pump
- we program therapy settings: targets, IC, corrections
- soon will have preset doses as well
- it calculates and records doses
- reminders for long-acting basal and meals

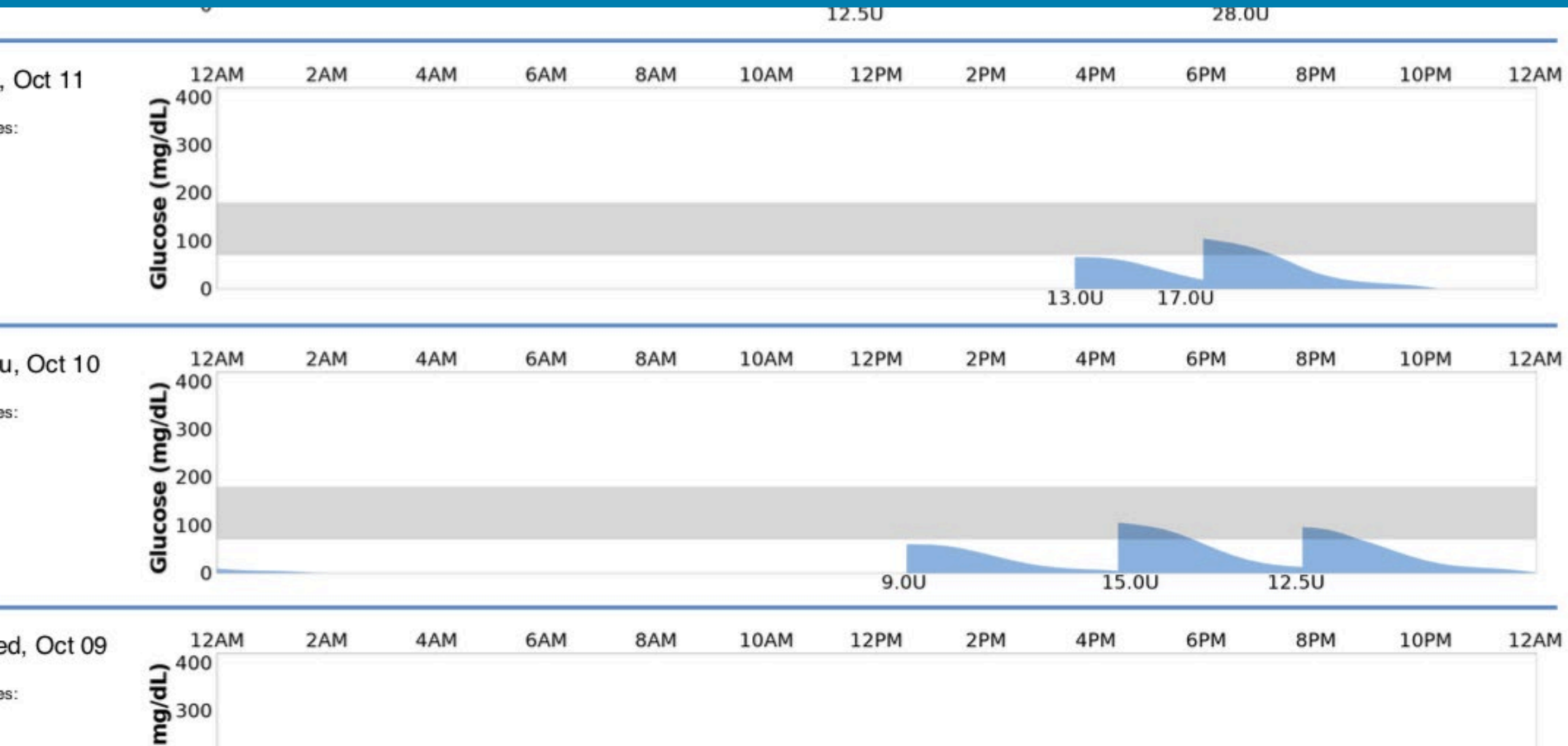
InPen

- insurance sometimes covers 2
- not yet medicaid covered, cash cost \$35
- downloads data from pen to app up to 1 year back
- integrated with dexcom G6 sensor

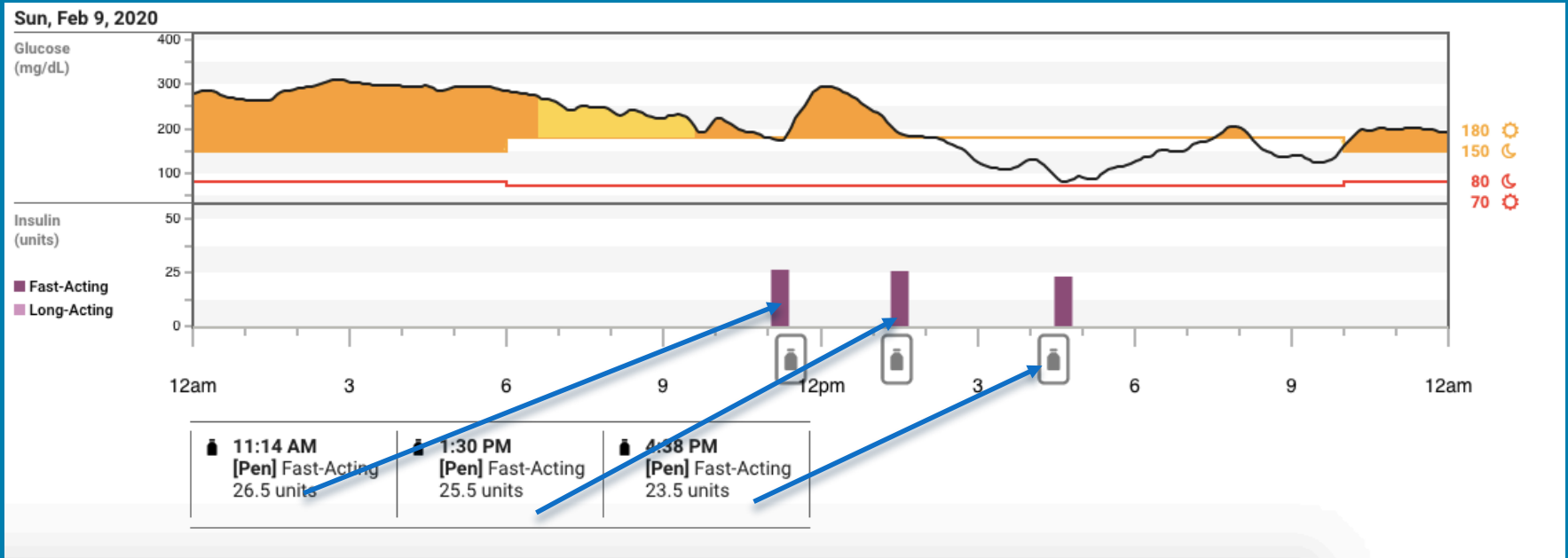
inpen report showing settings, missed doses



inpen report showing each dose taken by day



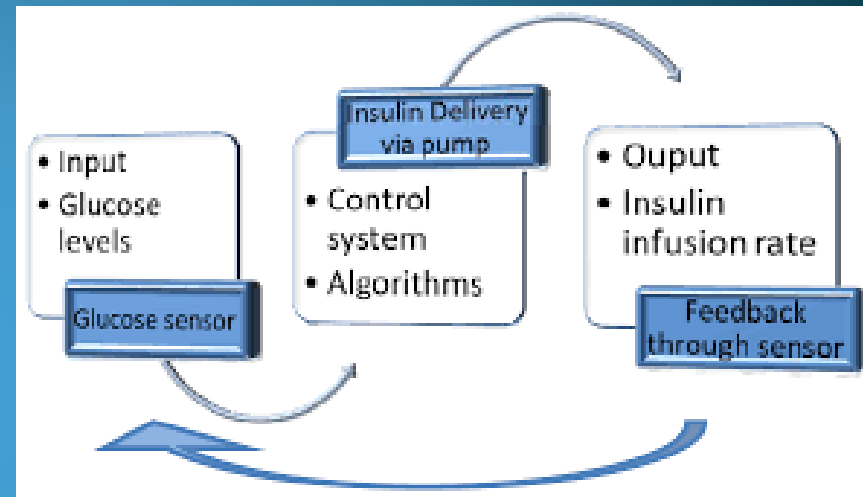
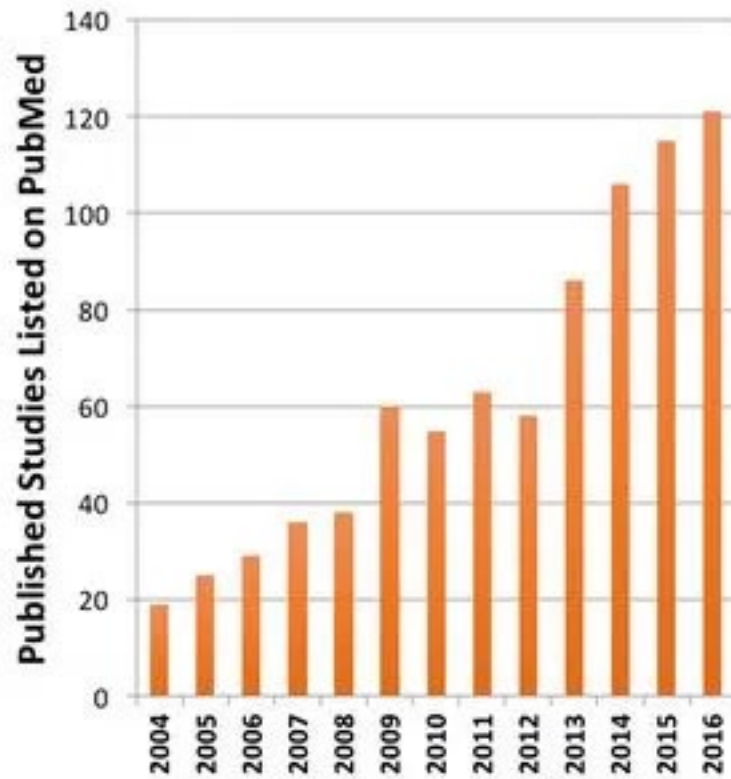
Integrated inpen data into clarity report



The Great Race! to automated insulin delivery



Automated Insulin Delivery Research Has Accelerated!



Pump updates: Medtronic

- 780 G system:
 - TIR goal is over 80% with over 90% in auto mode
 - auto correction bolus every 5 minute
 - can adjust target down to 100
 - day 1 calibration ONLY



Medtronic 780G pump

- extended wear infusion set
- bluetooth
- remote monitoring
- trials underway now regarding this pump, will be presented in June at ADA (in Chicago this year!)
 - in home trial of 350 type 1 kids and adults over 3 months
 - second trial of guardian connect sensor
 - calibration only on day 1
 - 7 day trial
 - completed Feb 2020

Medtronic 780G

- software upgrades (upgrades you can download versus having to buy new pump) and special upgrade pathways
- mid-2020 release?
- future: single transmitter and sensor in 1, and then single site for both infusion and sensor is goal

DIABETES: MEANINGFUL TECHNOLOGY LAUNCHES

LAUNCHING



MiniMed™ 670G Hybrid Closed-Loop System

- Over 135K U.S. patients currently trained on the 670G
- Ongoing international rollout



Guardian™ Connect CGM

- Only CGM with IQcast, predicting potential lows, up to 4 hours in advance
- Strong interest outside traditional sales channels in U.S.

FY20

Advanced Hybrid Closed- Loop System with Bluetooth

(MiniMed™ 780G)

- Bluetooth connectivity allowing sharing and software upgrades
- Auto correction bolusing for simplified meal management and hyperglycemia protection
- Data from 3 feasibility studies indicating time-in-range (TIR) of approximately 80%



Non-Adjunctive iCGM Designation

- Non-adjunctive sensor to allow dosing and CMS reimbursement



Sugar.IQ™ Gen 2

- Meal handling + carb counting with Nutrino
- Extend predictive insights beyond 60 mins

BEYOND

Personalized Closed- Loop System

(MiniMed™ 890G)

- Real-time personalized therapy
- Advanced adaptation
- >85% TIR goal



Synergy Sensor

- 50% smaller than GS3
- Day 1 calibrations
- Easy 3 step application



Unity Sensor

- No calibrations
- 10-14 days of wear



Sugar.IQ™ Gen 3

- Behavioral feedback
- Overnight glucose prediction



Sugar.IQ™ Gen 4

- Meal prediction w/ dosing
- Advanced glucose prediction

Tandem Control IQ



X2 Insulin Pump With Control-IQ Tech. In The U.S.

Published on January 16, 2020

By: DLife Editors

Print This Page 

Tandem Diabetes Care, Inc. today announced the commercial launch of the t:slim X2™ insulin pump with Control-IQ™ technology, an advanced hybrid-closed loop feature designed to help increase time in range (70-180 mg/dL).

It is the first and only system cleared to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar.

The system integrates with Dexcom G6 continuous glucose monitoring (CGM), which

Pump Update: Tandem

- Control IQ just released
- patients on previous tandem pumps need only a software update
- first system which provides correction boluses for high glucose
- approved for age 14* up
- min 55 lbs and 10 units daily
- mobile app soon to come =
 - auto upload



Initial study results

Want to know more about the trial? The trial had 168 participants ages 14-71 and followed them for six months. Comparing the Control-IQ hybrid closed loop vs. the same pump and CGM with no automatic correction boluses:

- Time-in-range (TIR) was 2.6 hours per day better with Control-IQ (70% vs. 59%), with most of the benefit from users spending 2.4 fewer hours per day above 180 mg/dl
- A1C was 0.3% lower with Control-IQ (7.1% vs. 7.4%)
- Average blood glucose was 14 mg/dl lower with Control-IQ (156 mg/dl vs. 170 mg/dl)
- Time below 70 mg/dl was low (less than 2%) in both groups, though Control-IQ did slightly better at reducing time below 70 mg/dl by 13 minutes. That may not sound like so much to everyone but it's six and a half hours a month less time that participants were hypoglycemic!











With Control-IQ, the time-in-range benefits existed for every level of starting A1C – a positive sign that Control-IQ can help those already at a low A1C *and* those with an A1C above 8%. Remarkably, *all* 168 participants completed the study, and Control-IQ users spent 92% of the six months with closed loop active.

what is TIR?

Key features of control IQ

- sleep activity
- exercise activity just turns on and off - like temp basal but no duration
- basal increase
- auto correction bolus
 - if glucose predicted to be over 180 in next 30 minute
 - gives insulin to target of 110 at 60% dose
 - an auto correction can occur hourly

Tandem: Control IQ

180	  Delivers	Delivers an automatic correction bolus if sensor glucose is predicted to be above 180 mg/dL
160	  Increases	Increases basal insulin delivery if sensor glucose is predicted to be above 160 mg/dL
112.5	  Maintains	Maintains active Personal Profile settings
70	  Decreases	Decreases basal insulin delivery if sensor glucose is predicted to be below 112.5 mg/dL
70 mg/dL	  Stops	Stops basal insulin delivery if sensor glucose is predicted to be below 70 mg/dL

Omnipod DASH and Horizon (and looping;)



DASH

- touch screen, android phone
- the basis for the horizon system to come
- integrated calorie king
- 0 basal rate
- English and Spanish



DASH

- view and display apps: yes, you can now watch what the wearer is doing remotely = stalking? :)
- auto upload soon available! - no wasted clinic time and we can monitor activity remotely as needed
- pharmacy benefit - no 4 year commitment, less out of pocket cost

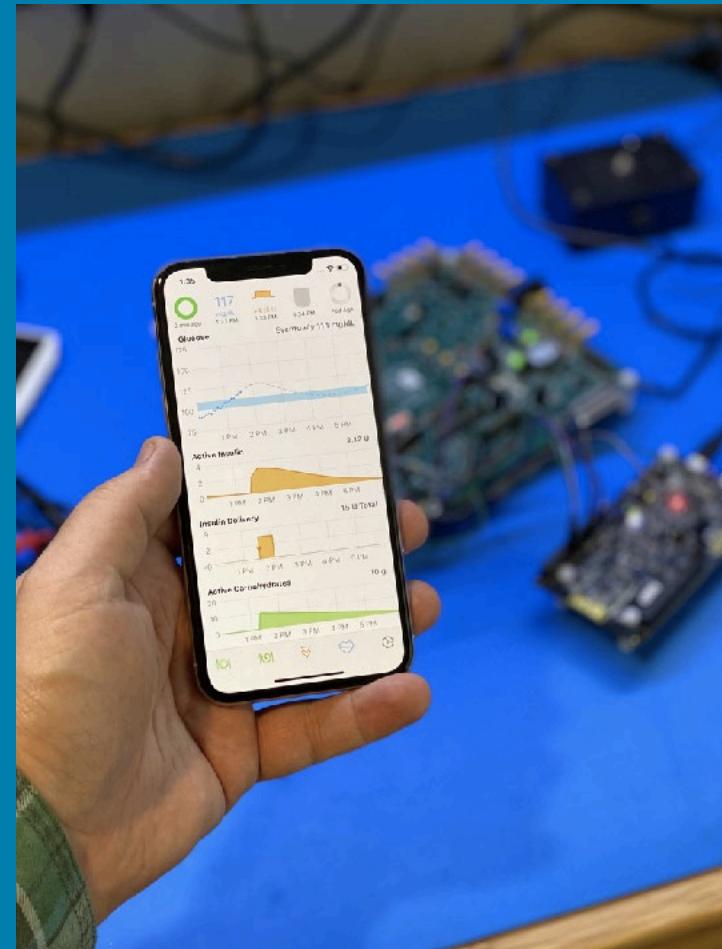


Omnipod: Horizon

- Omnipod DASH + sensor* + smart phone and algorithm controlling pump based on sensor input
- Insulet just announced 2/18 that they will partner with BOTH Freestyle Libre AND DEXCOM
 - Libre does not yet have iCGM approval but hopes to
- Pediatric study age 2-6 presented June 2019
 - safe
 - 73% TIR, 85% overnight
 - hypo under 2% overnight

Tidepool Loop

- initially the loop concept worked with old medtronic pumps and with old omnipod Eros pumps
- now tide pool is working to enable the pump to work with sensor directly via phone app



Tidepool Loop, one year in: A development update



Christopher Snider

It's been a little over a year since we [publicly announced](#) our intention to develop Tidepool Loop, a fully supported and FDA-cleared iPhone app that brings together an insulin pump, CGM, and automated insulin dosing algorithm that adjusts your basal rates as often as every five minutes and allows you to bolus from your phone. [Thanks to support from JDRF and the Helmsley Charitable Trust](#), we've been able to grow our team significantly and make tremendous progress on this ambitious goal.

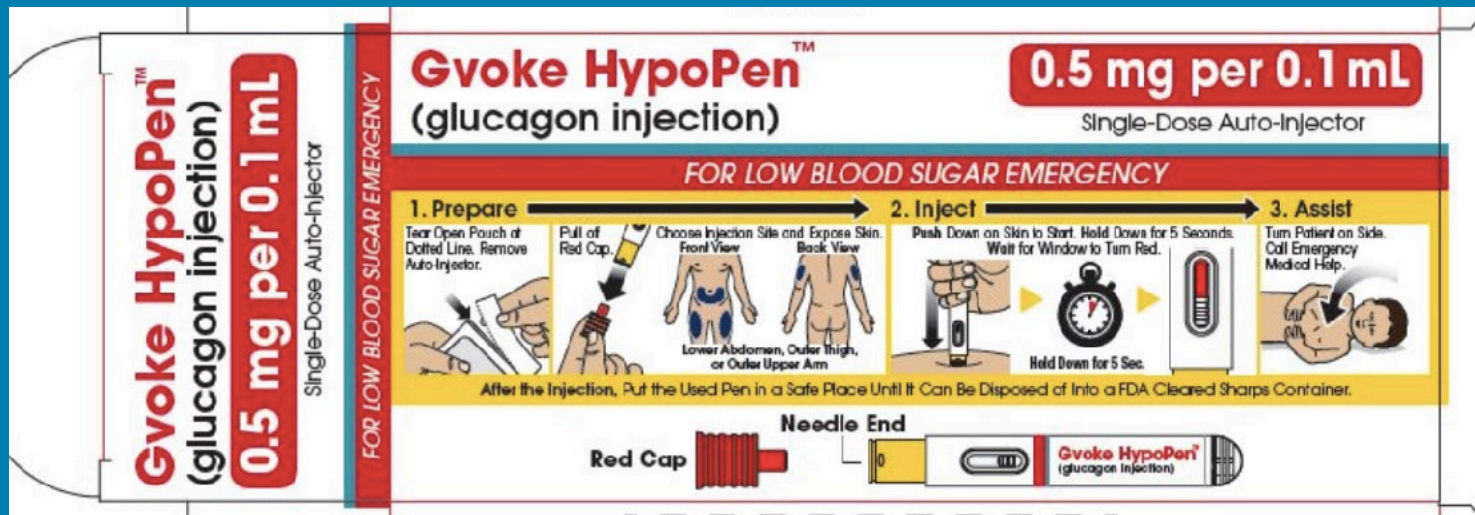
This post will cover everything about Tidepool Loop that we can cover, and there's a lot.

To answer the biggest question upfront: we do not have a release date for Tidepool Loop to share at this time.



Gvoke

- first ready to use liquid stable glucagon approved for ages ≥ 2 yrs
- subcutaneous (smaller needle) not intramuscular



Baqsimi

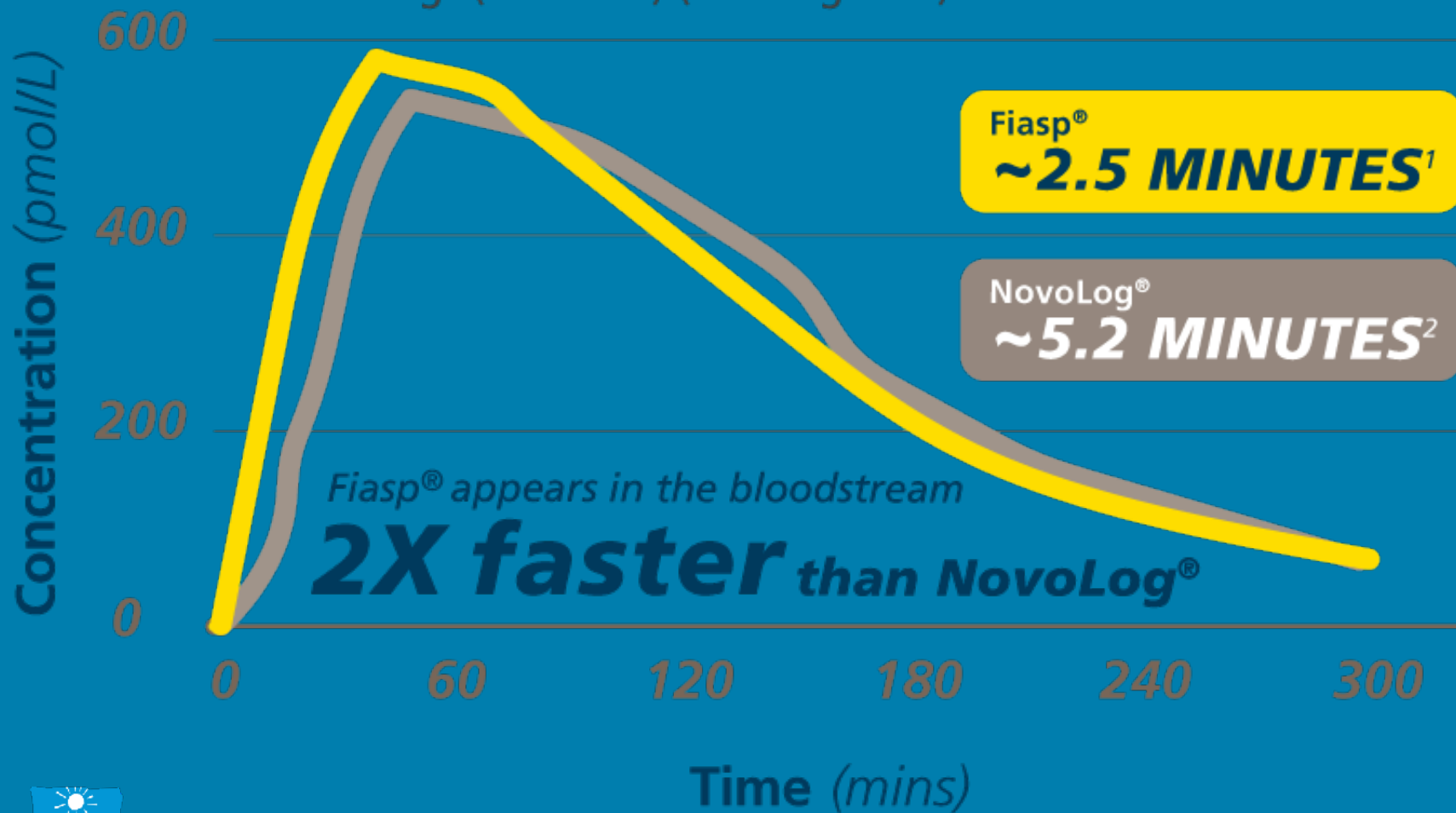
➤ inhaled nasal glucagon, not yet Medicaid covered



Fiasp

- “faster-acting aspart (novolog)”
- gets into circulation in 2.5 minutes, which is 50% faster than current rapid-acting insulins
- available in vial, pen and inpen cartridge
- recently approved down to age 2 and in the pump
 - anecdotal reports of more occlusions in certain pumps

- Fiasp® (mealtime) (0.2 U/kg dose)
- NovoLog® (mealtime) (0.2 U/kg dose)



BIOD-123 Data is Comparable to Novo Nordisk's FIAsp (*faster-acting insulin aspart*) in Meal Study

R&D UPDATE

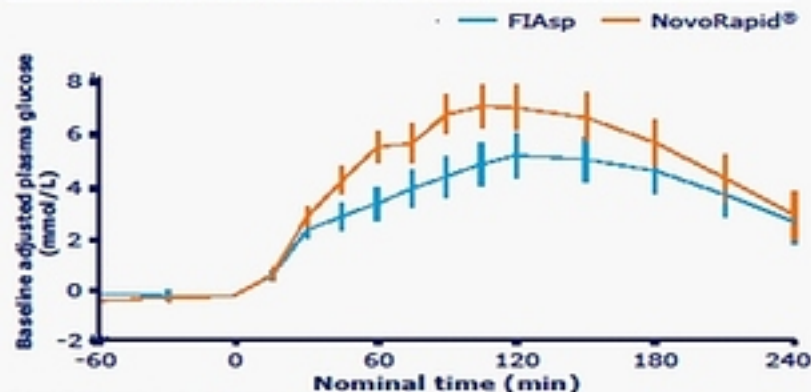
Investor Presentation

First six months of 2013

Slide 17

FIAsp completes phase 1 pump study in people with type 1 diabetes

Incremental Meal-test Glucose Profiles



FIAsp: Faster-acting Insulin Aspart
Error bars show 1 x standard error of the mean (SEM)
Source: Data on file

changing
diabetes

Key results of NN1218-3930 phase 1 trial in 42 people with type 1 diabetes

- Exploratory double blinded cross over trial evaluating short term efficacy, safety and pump compatibility during 14 days
- People treated with FIAsp experienced statistically significantly better glucose control during the first two hours after the meal
- Both FIAsp and NovoRapid® appeared to be safe and well-tolerated

Update on phase 3 program: Onset™

- Expected to include around 3,000 people with type 1 and type 2 diabetes
- Expected to start during the third quarter of 2013



Summary

- **Type 1 Diabetes is challenging; thankfully the technology is changing RAPIDLY**
- **There is a RACE to the closed-loop Payors are changing coverage for the better (albeit slowly)**
 - **CGM approved in nearly 30/50 states now**
- **There is NO DENYING the overwhelming evidence in support of CGM and integrated devices**
- **The finger-stick will soon be dead (thank goodness) and the push-button pump will be on display at the Smithsonian ;)**
- **In the words of the 80s group Timbuk3....**

The future's so bright...I gotta wear shades!



Questions

