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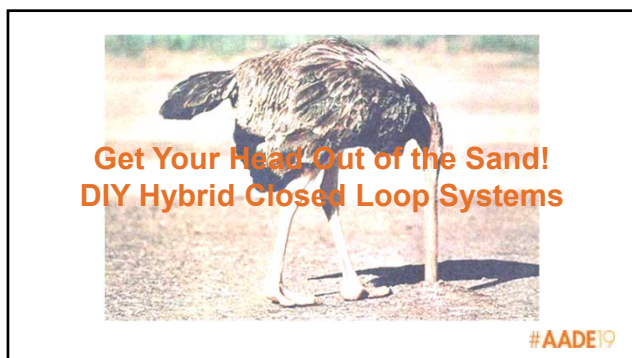
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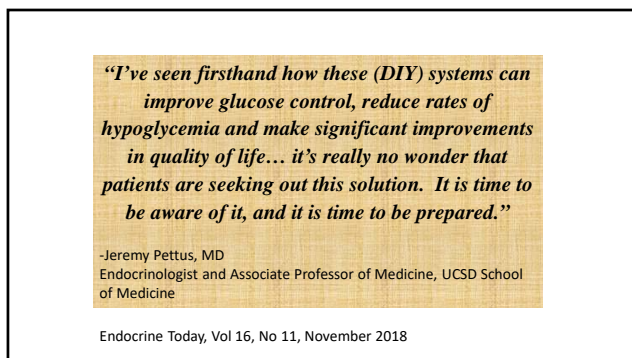
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**Gary Scheiner**  
MS, CDE  
Owner/Clinical Director,  
Integrated Diabetes Services LLC

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**Jennifer Smith**  
RD, LD, CDE  
Director of Lifestyle and Nutrition  
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Philadelphia, PA

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**Disclosure to Participants**

- **Notice of Requirements For Successful Completion**
  - Please refer to learning goals and objectives
  - Learners must attend the full activity and complete the evaluation in order to claim continuing education credit/hours
- **Conflict of Interest (COI) and Financial Relationship Disclosures:**
  - Gary Scheiner MS, CDE – Speaker: Ascensia Diabetes Care US, Dexcom, JDRF, Senseonics, Tandem; Advisory Board: Biopollary, Companion Medical, Clooko, Eli Lilly;
  - Jennifer Smith, RD, LD, CDE – No COI/Financial Relationship to disclose
- **Non-Endorsement of Products:**
  - Accredited status does not imply endorsement by AADE, ANCC, ACPE or CDR of any commercial products displayed in conjunction with this educational activity
- **Off-Label Use:**
  - Participants will be notified by speakers to any product used for a purpose other than for which it was approved by the Food and Drug Administration.

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### Learning Objectives

- Explain the pros and cons of utilizing a DIY hybrid closed-loop system
- Differentiate between the various DIY hybrid closed loop systems
- Assess patient safety and outcomes when a DIY hybrid closed loop system is utilized
- Detail strategies for teaching patients to maximize safety and outcomes with DIY hybrid closed-loop systems

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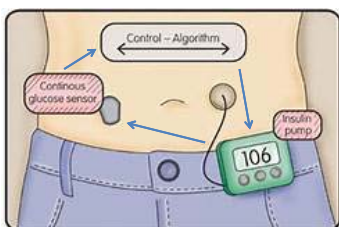
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### What Is a Hybrid Closed Loop (HCL)?



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### What HCL Can Do:

- Regulated/adjust basal insulin delivery automatically
- Compensate for bolus inequities
- Prevent/minimize hypoglycemia
- Fix/minimize hyperglycemia

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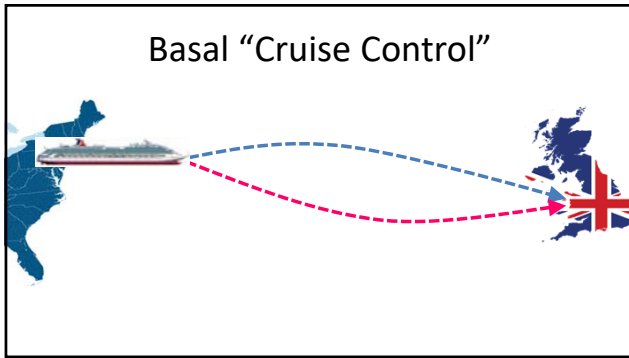
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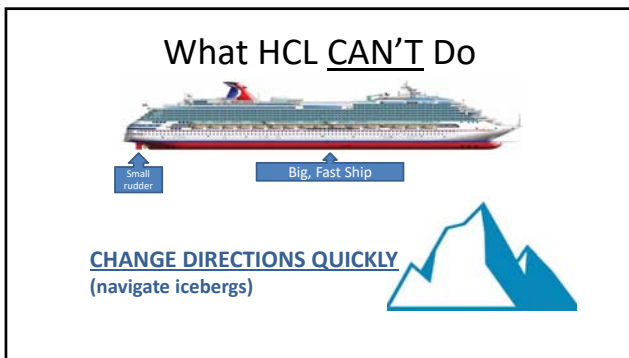
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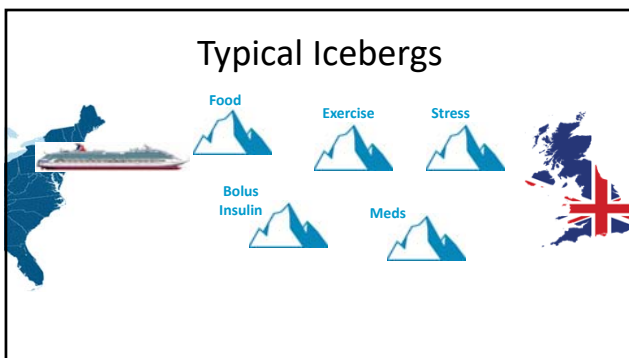
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### **CURRENT HCL SYSTEMS**

- Medtronic 630G, 670G
- Tandem X2 with Basal IQ
- Pending:
  - OmniPod Horizon
  - Tandem Control IQ
  - Bigfoot Biomedical
  - Beta Bionics iLet



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### **WHY are people with diabetes going “off the grid”?**



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### **The “Regulatory” Process Imposes Limits.**

- Higher production costs
- Delayed market entry
- Conservative algorithms
- Lack of individualization
- Very slow product adaption
- Sales before functionality

*“The systems developed by companies are often developed by engineers at a desktop. This (DIY) is designed by the people wearing it.”*  
- Bruce Buckingham, MD

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### Additional Factors Driving Use of DIY

- ✓ Technology is changing fast – systems need to keep up
- ✓ **#WeAreNotWaiting** movement sparked interest as of 2013
- ✓ People with diabetes WANT and NEED customization
- ✓ Desire for interoperability
- ✓ Support in the DOC

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### The Value Proposition




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### DIY HCL: Unique Benefits

- Ability to set personal parameters
- Large online community for support / troubleshooting
- Frequent updates to system algorithm / features
- No need to wait for new pump in the mail or warranty to expire
- Utilize preferred CGM system, user's own phone
- Superior outcomes

*"I can't tell you why the math is better, but the algorithms for adjusting insulin dosing with DIY seem less constrained."*  
- Ann Peters, MD

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### DIY HCL: Outcomes

- Retrospective crossover study @ Johns Hopkins Diabetes Center
- Data collected 4-6 weeks prior to and 4-6 weeks after initiating Open APS

	Pre-DIY	Post-DIY
Mean Glucose	136 mg/dl	128 mg/dl
Time In-Range	76%	82%
Time below 70	6.4%	4.2%
Time below 50	2.3%	1.0%

Lewis, et al. Diabetes, June 2018.



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### DIY HCL: Potential Drawbacks

- Require older pumps, no warranty
- Need access to disposables
- Requires significant computer/tech skills to set up (especially w/Mac systems)
- No “customer support” line for help Must reach out to online community)
- Must carry signal converter, charge daily
- Learning curve for insulin action and carb/food impact



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### How do the systems work?



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## Components for setup of DIY systems

### Loop

- Compatible insulin pump
  - Medtronic (X22 or X23 w/firmware  $\leq$  2.4)
  - Omnipod (radio; non-DASH)
- Compatible CGM (Dexcom G5/G6)
- RileyLink
- Compatible iPhone/iPod Touch
- Apple computer running High Sierra/Mojave macOS 10.13.6/10.14 or later
- Xcode (a free Apple application)
- Apple Developer Membership



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## Components for setup of DIY systems

### OpenAPS and AndroidAPS

- **Compatible Insulin Pump**
- Android APS can work with Accu-chek Combo pump, Dana RS pump (phone app)
- Leverages OpenAPS's oref0 algorithm but allows you to interface using an Android phone and Bluetooth to communicate directly with the alternate pump
- **Communication:** small computer – (intel Edison, or Raspberry Pi) circuit board – Explorer Board for Edison or Explorer HAT for Pi
- **Compatible CGM** – Dexcom (G4/G5/G6), Enlite, Libre
- **Internet Connection** – Smart phone, Smart watch, PiHAT
- **Battery**



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## Algorithmic Features

- OpenAPS
  - See data and description: <https://openaps.org/>
- Loop
  - See data and description: <https://loopkit.github.io/loopdocs/operation/algorithm/prediction/>

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## Counseling People with Diabetes on DIY Systems

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### CDE's Role

- **Practicality of use**
- Consider QOL factors for the person with diabetes
  - Schedule – variable vs stable
  - Work
  - Activity level
  - Time in life (Menopause, pregnancy, illness)
- Evaluate the PWD and ability to manage – how are they currently handling the technology they use
- Evaluate with PWD which system is best for their lifestyle
- Is DIY system for someone who is entirely NEW to pumping and CGM use?
- Consider age and ability – don't discriminate

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### CDE's Role

#### Legal issues?

- Professional liability
- Consider Legal Verbiage
- Educate on all pump systems - including the DIY products
  - Better to inform than hide the option
- ? Competence of use
- Document all discussions/recommendations
- Training is biggest legal issue
- Beyond CDE use and programming recommendations - the legal responsibility is **the same** as any other pump system.
- **DOCUMENT, DOCUMENT, DOCUMENT**

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**As clinicians we are not responsible for HOW the PWD uses/programs the pump, only for the clinical veracity of our recommendations based on our knowledge and licensure.**

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**To DIY or NOT to DIY?**

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**Who is using a DIY system?**

- Mostly those with type 1 diabetes
- Parents of kids with T1D, college students, Endos, RNs, RDs, CDEs, many software developers as well as retired persons, and most are not "tech" gurus
- All ages – 1year to 75+
- World wide use (As of April 2019 - 2300 just on Medtronic Loop with RileyLink – 1400+ from the USA, followed by CA, AU and DE with >120 each)
- Increase in use post Omnipod Loop release mid-April 2019
  - More access, product in warranty, no old pump

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### Assisting with Navigation of Choices

- Advise all PWD to read documents for systems to prepare
- Computer/programming skills NOT required – willingness to ask questions is necessary
- Explain **NO systems are “Closed”** – all require engaged attention
- MOST IMPORTANT – regardless of system – have a strong understanding of insulin action and glucose response

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### Resources/Tools

#### Person with Diabetes

- Computer – Mac or PC
  - Depends on DIY system
  - Understanding of upgrades
- Supportive Careteam
- Connection to online community
  - FB groups
  - Blogs
- Small initial/yearly monetary commitment
- Nightscout setup – CGM and system Data analysis/following data
- Tidepool account – Loop and CGM data analysis



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### Resources/Tools

#### Diabetes Educators

- Read Loopdocs and Openaps.readthedocs
  - Learn difference between systems
  - Learn HOW the algorithms work
  - Learn how to help PWD navigate adjustment
- Understand Tools needed for PWD
- Connect with CDEs who are looping
- Understand DIY adjustments – system uses data just as a conventional pumper – algorithm interacts more frequently without distractions of life such as the PWD has when making decisions on adjustment

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## Choosing the RIGHT system



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## Points to Compare

- Cost (Similar for all systems)
- Size
- Durability (Potential advantage - Loop)
- Ease of build/maintenance (Advantage – Loop – Apple interface vs OpenAPS – Linux)
- Ease of use for all (PWD, caregivers – parents/school nurses)
- Reliability – (Loop advantage – no need for wifi/internet)
- Troubleshooting issues – factors to consider system to system
- Ease of use (Potential Loop advantage)
- Age appropriate features (both systems advantageous)
- Comparison of systems:  
 - <http://seemycgm.com/2017/09/02/loop-vs-openaps-update/>

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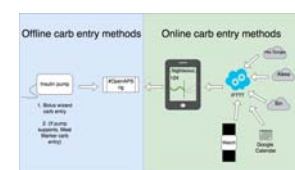
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## Comparative features

### OpenAPS

- SMB – SuperMicroBolus
- Offline looping for Medtronic CGM users
- Offline looping for Dexcom users via plug-in receiver or xDrip+ for Android users

### OpenAPS carb entry



[https://openaps.readthedocs.io/en/master/docs/What%20you%20will%20for%20get/entering\\_carb\\_bolus.html](https://openaps.readthedocs.io/en/master/docs/What%20you%20will%20for%20get/entering_carb_bolus.html)

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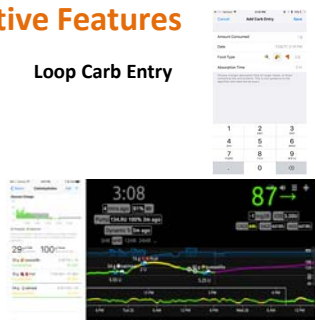
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## Comparative Features

### Loop

- Carb absorption – specific to food (GI based)
  - Based on *Glucodyn* model
- Time stamped carb entry – ability to adjust
- Bolus from phone app or Apple watch

### Loop Carb Entry




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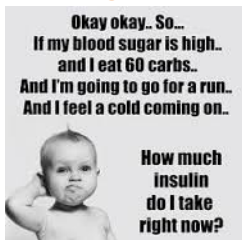
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## Ensuring Safe Use




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## System Safety features

- **Time limits:**
  - Temp basal – max 30 min
  - Temp targets – max 60 min
- Safety alarms: communication loss, low/high glucose (CGM alerts remain), battery low, insulin reservoir low, rig charge
- Ability to set custom alerts using Nightscout/Shortcuts/IFTTT




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## System Safety Features

- **System settings:**
  - Max basal
  - Max bolus
  - Suspend thresholds
  - Correction range customization
  - DIA – longer than conventional pumps
- **Visibility in operation:**
  - Loop app – iPhone
  - PiHAT – OpenAPS rig
  - Nightscout – DIY web URL

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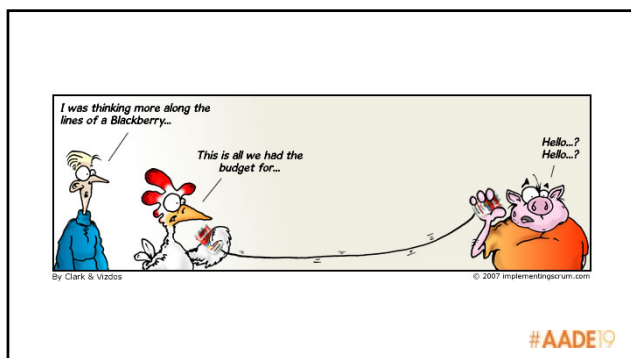
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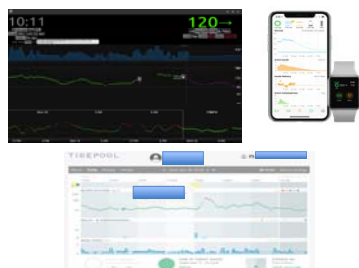
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## Visibility at a Distance

- Dexcom Follow
- Nightscout
- Tidepool
- SugarMate
- Spike
- Smart Watches



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### Enhancing Education and Interaction

- Be informed
- Understand how you feel about discussing DIY systems – do YOU need more information?
- Listen to the PWD
  - Why do they want to try DIY?
  - What are their expectations?
- Assist with resources for procuring supplies (pump/sets/sensors, etc)
- Be a partner in management

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### Support for Performance

- Discuss safe DIY preparation
- Eval if PWD has all necessary support tools
- Discuss safety backups

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### Support for Optimization

- Ensure optimized settings prior to set up and “closing Loop” (basal test, ratio settings for carb/sensitivity)
- Learn tools to teach PWD how to fine tune settings in DIY systems
- Learn use of smart features of DIY system (temp targets, pre-meal, SMB, unannounced meal, development branch options)

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### Evaluation Tools

**OpenAPS**

- AutoSens – an "on-the-go" ISF adjustment
  - Compares ISF to actual insulin used to achieve glucose target in 24 hr time
- Autotune: Calculation for basal, ISF, IC ratio
  - Auto adjustment of ISF, IC, target – requires user permission
  - Run as single report or within algorithm q 24 hrs.

**Loop**

- Nightscout reports
- Autotune – run manually as a single report (not as robust for Loop)
- Tidepool



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### Identifying Candidates for DIY

<b>Good</b>		<b>Poor</b>
Very Tight	BG Control Sought	Conservative
Savvy	Technical Ability	Limited
Willing	Risk-Taking	Averse
Adept	Troubleshooting Skills	Challenged
Easily Accessible	Equipment/Supplies	Restricted

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### Case Study - Georgie

- 57 y.o. woman
- Party planner
- Insulin-requiring T2
- Uses OmniPod and Libre
- Relies heavily on diabetes team for troubleshooting advice
- A1c 8.2%, occasional mild lows



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### Case Study: Ally

- 12 y.o. student-athlete
- T1 x 9 years
- Very good parental support; mom is a software engineer
- Uses 670G, previously used Paradigm pump & dexcom
- A1c 7.5% (down from 8.3), wants to get below 7
- Hectic schedule, struggles with frequent peaks/valleys



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In 2016, we presented a self-reported outcomes study at #2016ADA, and also published the study.

**Letter to the Editor:**

Dana Lewis, Scott Leibrand, and #OpenAPS Community

**Real-World Use of Open Source Artificial Pancreas Systems**

J Diabetes Sci Technol 1932296816665635, first published on August 10, 2016 as doi:10.1177/1932296816665635

@DanaMLewis #2018ADA 📷✅

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#### In the 2016 self-reported study:

- 18 users self-reported their data and experiences.
- While using OpenAPS, **self-reported outcome measures showed median HbA1c dropped from 7.1% (SD 0.8%) to 6.2% (SD 0.5%), and median percent time in range (80-180 mg/dL) increased from 58% (SD 14%) to 81% (SD 8%).**

@DanaMLewis #2018ADA 📷✅

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**Results: Overall**  
*Self-crossover comparison of selected 14-day time segments +/- 4-6 weeks from OpenAPS initiation (n=20)*

	Control	OpenAPS	P-value
Mean BG	135.7 (22.3)	128.3 (18.9)	0.0084
Mean Estimated HbA1c	6.4 (0.78)	6.1 (0.66)	0.0084
Time (%) below 50	1.9 (2.3)	1.1 (1.5)	0.0399
Time (%) below 70	6.0 (4.3)	4.5 (3.9)	0.1248
Time (%) in range 70 to 180	75.8 (14.9)	82.2 (11.1)	0.0042
Time (%) above 180	18.3 (13.9)	13.3 (11.1)	0.0092
Time (%) above 250	5.0 (5.4)	2.5 (3.3)	0.0138
Time (%) above 300	1.7 (2.3)	0.35 (0.57)	0.0138

Mean [SD] **@DanaMLewis #2018ADA**   

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**Results: Overnight (11pm-7am)**  
*Self-crossover comparison of selected 14-day time segments +/- 4-6 weeks from OpenAPS initiation (n=20)*

	Control	OpenAPS	P-value
Mean BG	128.3 (19.2)	122.5 (18.4)	0.0869
Mean Estimated HbA1c	6.1 (0.67)	5.9 (0.64)	0.0869
Time (%) below 50	2.3 (3.2)	1.0 (2.7)	0.0265
Time (%) below 70	6.4 (4.8)	4.2 (5.2)	0.0616
Time (%) in range 70 to 180	80.4 (13.6)	86.2 (9.2)	0.0136
Time (%) above 180	13.2 (10.7)	9.6 (8.4)	0.0369
Time (%) above 250	3.1 (5.0)	1.4 (1.8)	0.1668
Time (%) above 300	1.0 (2.4)	0.17 (0.60)	0.1529

Mean [SD] **@DanaMLewis #2018ADA**   

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**What is an educator's job?**



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If it makes YOU feel better...



*"I, mostly, behave like a parent who sees his kids getting the life experience and observe them and sometimes guide them so as not to get harmed, but I don't stop them."*  
- Osama Handy, MD, PhD, FACE

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### Resources & References

- Documentation
  - Loop: [loopkit.github.io](http://loopkit.github.io)
  - OpenAPS.org: <https://openaps.readthedocs.io>
- Gitter: <https://gitter.im>
- Github.com: LoopKit/Loop

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### Resources & References

- Social Media
  - Facebook groups: Looped, CGM in the Cloud, xDripG5, Nightscout, Looping and Pregnancy, AndroidAPS
  - Twitter: #WeAreNotWaiting
- Helpful Blogs
  - Dana Lewis: [www.DIYPS.org](http://www.DIYPS.org)
  - Tim Street: [www.diabettech.com](http://www.diabettech.com)
  - Katie DiSimone: [www.seemycgm.com](http://www.seemycgm.com)

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## Questions?

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