“I’ve seen firsthand how these (DIY) systems can improve glucose control, reduce rates of hypoglycemia and make significant improvements in quality of life... it’s really no wonder that patients are seeking out this solution. It is time to be aware of it, and it is time to be prepared.”

Jeremy Pettus, MD
Endocrinologist and Associate Professor of Medicine, UCSD School of Medicine

Endocrine Today, Vol 16, No 11, November 2018
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: Biocapillary, Companion Medical, Glooko, Eli Lilly; Consultant: Adocia, Byram Healthcare, MySugr
  - 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 the educational activity

- Off-Label Use:
  - Participants will be notified by speakers if any product used for a purpose other than for which it was approved by the Food and Drug Administration.
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

What Is a Hybrid Closed Loop (HCL)?

What HCL Can Do:

• Regulated/adjust basal insulin delivery automatically
• Compensate for bolus inequities
• Prevent/minimize hypoglycemia
• Fix/minimize hyperglycemia
Basal “Cruise Control”

What HCL CAN’T Do

CHANGE DIRECTIONS QUICKLY
(navigate icebergs)

Typical Icebergs

Food
Exercise
Stress
Bolus
Insulin
Meds
**Current HCL Systems**

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

---

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

> I don’t ask for much... just peace of mind.
> - Henry Ford

---

**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

---
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

The Value Proposition

- 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

DIY HCL: Unique Benefits

- 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
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

<table>
<thead>
<tr>
<th></th>
<th>Pre-DIY</th>
<th>Post-DIY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Glucose</td>
<td>136 mg/dl</td>
<td>128 mg/dl</td>
</tr>
<tr>
<td>Time In-Range</td>
<td>76%</td>
<td>82%</td>
</tr>
<tr>
<td>Time below 70</td>
<td>6.4%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Time below 50</td>
<td>2.3%</td>
<td>1.0%</td>
</tr>
</tbody>
</table>


DIY HCL: Potential Drawbacks
• Require older pumps, no warranty
• Need access to disposables
• Requires significant computer/tech skills to set up (especially with 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

How do the systems work?
Components for setup of DIY systems

**Loop**
- Compatible insulin pump
  - Medtronic (X22 or X23 w/firmware ≤ 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

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

Algorithmic Features

- **OpenAPS**
  - See data and description: https://openaps.org/
- **Loop**
  - See data and description: https://loopkit.github.io/loopdocs/operation/algorithm/prediction/
Counseling People with Diabetes on DIY Systems

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

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**
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.

To DIY or NOT to DIY?

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 – 1 year 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
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

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

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
Choosing the RIGHT system

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/
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

Ensuring Safe Use

Okay okay, So...
If my blood sugar is high...
and I eat 60 carbs...
And I’m going to go for a run...
And I feel a cold coming on.
How much insulin do I take right now?

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
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

Visibility at a Distance

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

Support for Performance

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

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)
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

Identifying Candidates for DIY

<table>
<thead>
<tr>
<th>Good</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Tight</td>
<td>BG Control Sought</td>
</tr>
<tr>
<td>Savvy</td>
<td>Technical Ability</td>
</tr>
<tr>
<td>Willing</td>
<td>Risk-Taking</td>
</tr>
<tr>
<td>Adept</td>
<td>Troubleshooting Skills</td>
</tr>
<tr>
<td>Easily Accessible</td>
<td>Equipment/Supplies</td>
</tr>
</tbody>
</table>

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
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

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

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
What is an educator's job?
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

Resources & References

• Documentation
  – Loop: loopkit.github.io
  – OpenAPS.org: https://openaps.readthedocs.io
• Gitter: https://gitter.im
• Github.com: LoopKit/Loop

Resources & References

• Social Media
  – Facebook groups: Looped, CGM in the Cloud, xDripG5, Nightscout, Looping and Pregnancy, AndroidAPS
  – Twitter: #WeAreNotWaiting
• Helpful Blogs
  – Dana Lewis: www.DIYP5.org
  – Tim Street: www.diabettech.com
  – Katie DiSimone: www.seemycgm.com
Resources and References

• Provenzano V, Guastamacchia E, Brancato D, et al. Closing the loop with OpenAPS in people with type 1 diabetes—experience from Italy. Diabetes. 2018;67(suppl 1). Available at: https://doi.org/10.2337/db18-993-P
• Choi SB, Hong ES, Noh YH. Open artificial pancreas system reduced hypoglycemia and improved glycemic control in patients with type 1 diabetes. Diabetes. 2018;67(suppl 1). Available at: https://doi.org/10.2337/db18-644-P
• Crozier H. Learning to close the loop. Diabetes. 2018;67(suppl 1). Available at: https://doi.org/10.2337/db18-580-P
• Crozier H. Learning to close the loop. Diabetes. 2018;67(suppl 1). Available at: https://doi.org/10.2337/db18-580-P
• Choi SB, Hong ES, Noh YH. Open artificial pancreas system reduced hypoglycemia and improved glycemic control in patients with type 1 diabetes. Diabetes. 2018;67(suppl 1). Available at: https://doi.org/10.2337/db18-644-P

Questions?

#AADE