Practical Implementation and Optimization of A Closed Loop System

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  – 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

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Objectives

– Name the features of a Hybrid Closed Loop (HCL) System
– Set Patient Expectations for HCL use
– Facilitate continued patient success using HCL

What is a Hybrid Closed Loop (HCL) System

A system where the insulin pump delivers insulin based on sensor readings and an algorithm

SAP VS HCL

Sensor Augmented Pump (SAP):
- Sensor data is read on the pump
- Pump may make some insulin shut off decisions based on sensor data
  - Insulin is suspended for set amount of time once low threshold is reached
  - Predictive low glucose suspend
    - Insulin is suspended 30 minutes before sensor glucose is predicted to drop below 80 mg/dL and resumes once glucose has risen above 80 mg/dL (1/2 HCL)

Hybrid Closed Loop (HCL):
- Medtronic 670G - Only FDA Approved HCL System
- Approved Sept 2016 (Children 7-13 June 2018)
  - Pump makes insulin delivery decisions based on sensor glucose and algorithm (able to give more insulin and suspend insulin based on sensor glucose)
A Closer Look at Medtronic 670G

Auto Mode (Closed Loop)

- 670G terminology for hybrid closed-loop mode
- System replaces programmed basal rates with auto-basal delivered every 5 minutes based on sensor glucose level
- Algorithm calculates auto-basal from total daily dose over the past 2-6 days
- Requires ≥ 8 units and ≤ 250 units per day
- Target 120 mg/dL

Auto Mode Continued

- Patient must bolus for all carbs consumed (Hybrid Closed Loop)
  - Bolus calculator accepts carbs and BG only
  - Bolus is calculated from programmed carb ratio and active insulin time
    - Only 2 modifiable settings in auto-mode
  - Cannot override bolus recommendation
- Correction bolus is offered if entered BG > 150 mg/dL
  - Target of 150 mg/dL for corrections
  - Sensitivity factor calculated by system using 1500 rule
Patient Expectations

Set Realistic Initial EXPECTATIONS
1-2 month learning curve:
- More alerts
- Less than optimal BG control while optimizing dose settings

Work load:
- 3-4 calibrations/day
- Entering and exiting Auto Mode (potential additional BG requests)
- Still need to bolus for meals
- Need for close Follow Up (Remote or Face to Face)

REALISTIC EXPECTATIONS

Accuracy
- Guardian™ Sensor 3 more accurate than past Medtronic iterations (9-10% MARD)

Glucose control
- In clinical trials, HbA1c decreased 0.5% in 3 months
- A1c may go up if patient has significant hypoglycemia
- Most noticeable improvement overnight/fasting in clinical trials
- Increased time in range 70-180 mg/dL and less hypoglycemia
- Will still have some hyperglycemia and some hypoglycemia

What patient might be more successful on HCL?

- Comfortable wearing pump and sensor
- Test BG ~4 times/day
- Gives most meal boluses
- Not obsessive/controlling of diabetes
- Understanding the system will aid in diabetes care but will not control diabetes for them
- Willing to give control over to a system
- Willing to give it 1-2 months to optimize settings
Who is not ideal? Type As and Zs

**BASED ON EXPERIENCE**

- Difficulty wearing CGM (tape sensitivity)
- **Type As**
  - Anxious-obsessive tendencies with diabetes care
  - Expecting perfect diabetes control
  - Patient's with low A1c (6.3% or less)
- **Type Zs**
  - Does not test BG enough to keep CGM calibrated
  - Misses many insulin doses

Keys to Success: Three C's

- **Carbs**
- **Calibrations**
- **Corrections**

Goal: To Stay in Auto Mode as much as possible
Increased Time In Auto Mode = Increased Time In Range

Carbohydrates

- Patients should bolus for all carbs consumed, patients may need to bolus for coffee/caffeine
- Accurate carb counting helps
- Pre-bolusing helps
- Most patients need to strengthen carb ratio by ~20% (15–12, 12–10), however can be too aggressive and cause auto-basal to shut down too long after meals
- Consuming large carb meals can make staying in Auto Mode more difficult
- Avoid entering carbs not actually consumed to get corrections, over estimating carbs or entering more carbs than consumed can cause auto-basal shut off and rebound hyperglycemia
Calibrations

Calibrations = Sensor accuracy

- System requires at least 1 calibration every 12 hours, may request additional calibrations
- Good practice to calibrate before bed to avoid calibration request while sleeping
- Use good finger stick technique for calibrations (no alternate site, wash hands)
- No need to over calibrate, no more than 2-3 per day
- If repeated calibration requests, STOP and try again 30 min -1 hour later
- Best to calibrate when glucose is not changing rapidly (no or only 1 arrow)
- If not a good time to calibrate, set snooze and revisit later

Corrections

- Corrections are helpful and often necessary to stay in Auto Mode
- Most patients need a more aggressive Active Insulin Time (usually 2.5 – 3 hours)
- Correcting after dinner and/or before bed can avoid unnecessary auto-mode exits
- BG must be entered for the system to offer a correction
- Over time, corrections add to the TDD and increase auto-basal delivery if needed
- Avoid over correcting lows which can cause a rebound hyperglycemia
- Look at sensor graph, if no pink dots then treat cautiously (5 grams of carbs)

Increased Time in Auto Mode = Increased Time Range

Goal: Auto Mode
80% of the time
Time In Range – What is the goal?

- Must be individualized for each patient with goal to improve over time
- 0% Time ≤ 50
- 1-5% 51-70
- 60-70% 71-180

Real World Frustrations and How can you help?

- Too many BG requests
- Too many calibration requests
- Auto-Mode exits

- Make sure patient has most updated version of transmitter (2.2A)
- Try to calibrate only 2-3 times per day, before breakfast, lunch or dinner, and bedtime
- Determine reason for Auto-Mode exit (high sensor BG, safe basal time-out, missed calibrations)
- Sometimes it's patient behavior and not settings that need to change

What causes Auto-mode Exits?

**Most common reasons:**
- High SG: 300 mg/dL for 1 hour
- High SG: 250 mg/dL for 3 hours
- Missed calibration
- Min (2.5 hr)/Max (4 hrs) delivery
- Ignoring BG required alert leading to safe basal time out

**Potential Solution:**
- Pre-Bolus for meal or check carb counting
- Tighten carb ratio
- Carb counting instruction
- After meal correction if needed
- Adjust Active Insulin time
- Respond to BG required (not calibrations) to avoid safe basal time out
Successful Implementation of HCL

- Help patients choose the best system
- Set patient expectations
- Training and follow up is the key to success
- New to pump and CGM patients may take 1-2 months to get into auto-mode

New to Pump and CGM: 1-2 months

1. Initial Pump and CGM training (can do together if tech savvy patient).
2. Possibly 2 separate trainings, maybe CGM first to help in fine tuning manual mode settings.
3. Manual mode (programmed basal rate) for 2 weeks to 1 month depending on patient and follow up.
4. Follow up every few days to weekly to fine tune basal rates and bolus settings (Carelink).
5. Auto-mode training: face to face or remote?
6. Follow up: weekly by Carelink and 1 month clinic visit

Pump upgrade: 1-2 weeks

- Pump and CGM training together
- Auto-mode training: face-to-face or remote
- Patient can turn on Auto-Mode 48 hr after pump start but we recommend 5-6 days later
- Remote follow after 1 week in Auto-Mode (Carelink) and in clinic follow up 1 month after starting auto-mode
With Education and Support patients have great success on HCL

33 year old female
3/22/17 A1c 9.7%
Started on 670G in Auto-Mode 5/27/2017
A1c 8/21/18 7.7%

Orange period B
pre-auto-mode
Blue period A is 3 months after
starting Auto-Mode
8/11/17-8/24/17