Diabetes Technology

-The Bionic Person With Diabetes-

Definitions

• Diabetes technology
  • Hardware, devices and software used by people with diabetes
  • Help manage blood glucose levels
  • Stave off diabetes complications
  • Reduce the burden of living with DM
  • Improve quality of life
  • When applied appropriately can improve the lives and health of PWD

Definitions

• Internet of things (IoT)
  • Interconnection via the internet of computing devices embedded in everyday objects, enabling them to send and receive data
IoT-based Glucose Monitoring

- Connected devices collect/store data and make tx decisions
- Glucose meters are connected to smartphones and are recording glucose measurement to track daily trends
- Large growth in apps used for glucose monitoring
- Connected devices ensure glucose monitoring, insulin delivery and prevention of severe hypo and hyperglycemia

Case Study – Surprise .. new tech in the office!

Mrs. Sanchez is 63 years old. She currently takes metformin and glyburide for her T2D. She arrives at her doctor's office with a Freestyle Libre system which was given to her by her sister who “doesn’t like tech attached to her body.” She wants to start using the new meter because the commercial she saw said she wouldn’t have to poke her finger to check her blood sugar, which she is tired of doing every morning. Her doctor tells her the following:

A. These meters require a lot of work and are unreliable. You cannot believe what you see on commercials.
B. These meters are only good for people with uncontrolled diabetes.
C. Just walk in to the endo clinic upstairs and ask for one of the clinic MAs to put the sensor on for you. They’ll be happy to do it for you.
D. I’m excited you want to use this technology. While I’m not familiar with this meter, I can make a referral to the endo center upstairs for diabetes education and a visit with a CDE. They will be able to work with you and make sure this is the right tool to help you.
Challenges of Technology

• Complexity and the rapidly changing DM tech can be a barrier to implementation for both the PWD & the provider
• Insurance coverage of glucose strips, sensors and technology
• HIPAA compliance

And more challenges and more tech is coming . . .

• Software as a medical device
• Privacy issues
• Security
• Cost
• Technology-enabled diabetes education and support
• Telemedicine

Diabetes Management Technology Categories

1. Insulin administration
   • By syringe, pen or pump
2. Glucose monitoring
   • As assessed by meter or CGM
3. Hybrid devices
   • Monitor both glucose and deliver insulin, some automatically
   • Software which services as a medical device, providing DM self-management support
Diabetes & Endocrine Center
Salinas Valley Medical Clinic

Markets

• Mature
  • Blood glucose/β-ketone test strips
  • Traditional insulin pens
• Growing
  • Insulin pumps
  • Continuous glucose monitors
  • Flash glucose monitors
  • Closed loop insulin delivery system
• Emerging
  • Non-invasion glucose monitoring
  • Glucose monitoring based on non-blood fluids
  • Wearable technology for side effect monitoring
  • Advanced diagnostic techniques

Smart Pens

“I never miss my insulin.”

InPen

• Reusable pen which uses Bluetooth to deliver data to a smartphone app (iOS 10+/Android OS 6.0+), available by rx for those 12 and older
• Uses a non-rechargeable battery (1 yr use) and works with Humalog/Novalog insulin cartridges
• Most major insurers (UHC, Aetna, Humana, and Cigna) cover the InPen
• Co-pays ~$50-60 (insurance dependent) and a discounted cash price of $549
**InPen**

- Tracks insulin doses (including priming) and automatically sends data to a user’s phone if the app is running in the background.
- Calculates and recommends optimal doses, tracks dose history and timing, monitors insulin temperature, allows insulin data to be shared, gives dosing reminders, and comes in 3 colors, a benefit when keeping different insulins separate is a need.
- App allows glucose integration from BGMs & CGM via Apple Health.
- Plans to integrate other established data management systems.

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**Diabnext App & Clipsulin**

- Insulin pen dose recorder
- Bluetooth-enabled diabetes log book
- Store and track dosage, date and time of injection

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**Diabnext/Clipsulin**

- Attaches on the main insulin pens on the market whether they are reusable or disposable (excluding ½-dose pens)
- Sanofi Solostar pens
- Lilly KwikPen pens
- Novo Nordisk FlexPen/FlexTouch pens
**Connected Insulin Pens**

- NovoPen 6 and NovoPen Echo Plus
- Estimated to launch in Q1-Q2 2019
- Insulin dose data from the pens links directly into digital health tools compatible with the FreeStyle Libre system
- Pens will also connect to the Dexcom G6 the DM management platform Glooko and record how much insulin is injected and IOB
- 800-injection dose memory and a 5 yr battery life

**Continuous Glucose Monitoring (CGM)**

Revolutionizing Glucose Control and Management
Powerful Tool – for provider AND patient

- SMBG vs CGM – the difference between 0-10 finger sticks/day and 288 sensor glucose data points/day
- It "turns on the lights" regarding glucose peaks and valleys
- Using the right graphs/format, it improves the conversation between the person with diabetes and the healthcare provider, especially when combining insulin data with glucose data

Ideal CSM Candidate

- Anyone with T1D
- Anyone with T2D on intensive insulin management
- Everyone else with A1C > goal
- Medicare limits CGM to devices with dosing approval only (currently 2 options) and to PWM who test 4 times per day and use intensive insulin management

CGMS DOES . . .

- Less BG variability – more time in range
- Less apprehension at work, at school, while sleeping, or driving
- Give great data a majority of the time
- Glucose value every 5 minutes
- Eliminate SMBG (for some systems) most of the time
CGMS DOES NOT: . . .

• Completely eliminate the need for SMBG (for some systems)
• ‘Take over’ all diabetes control (getting closer)
• Give 100% data all of the time

Sensor Glucose ≠ Blood Glucose

• **Sensor** measures glucose in the **interstitial fluid**
• **BG meter** measures glucose in the **blood**

Sensor Glucose ≠ Blood Glucose
CGM Systems

• Some offer alarms for glucose highs and lows
• Ability to download data and track trends over time and share data
• Offers ability to easily observe how any given food, exercise or insulin dose affects control over the course of a few hours
• Allows immediate feedback - pts able to modify behaviors to gain better control

CGM Systems

• Identify post-prandial glucose excursions
• Identify undetected nocturnal hypo
• Visual patient teaching tool
• Stop insulin delivery when BG < set value (integrated systems only)
• Allow patient to improve dosing (based on arrows)

Use of CGM

• Improvements in DM management
  • Decreased variability
  • Decreased hypoglycemia
  • Decreased A1C
  • FOCUS on increasing Time In Range
• Improvements in lifestyle
• Reinforces education
• Increased understanding of self-management choices
**Alarm Fatigue**

- Patient will say to you:
  
  “These alarms are going off ALL THE TIME!”
  
  “I hate this sensor!”

- Issues:
  
  1) **Too many** alarms turned on
  
  2) **MOST likely due to** . . .
      
      Insulin/activity/food behaviors
      
      Actions, delivery, rates and/or ratios are what need to be changed

**CGM Systems**

- Directional arrows available
- Key aid to control
- Blood glucose levels in a state of flux
- Info regarding direction of glucose
- Predictive alarms based on rate of change
- **Allows for adjustments in insulin dosing**

<table>
<thead>
<tr>
<th>Glucose not rising or falling &gt;1mg/dL/minute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose rising 1-2 mg/dL per minute**</td>
</tr>
<tr>
<td>Glucose rising 1-2 or 2-3 mg/dL per minute*</td>
</tr>
<tr>
<td>Glucose rising 2-3 or &gt;3 mg/dL per minute*</td>
</tr>
<tr>
<td>Glucose rising 3 or more mg/dL per minute**</td>
</tr>
<tr>
<td>Glucose falling 1-2 mg/dL per minute**</td>
</tr>
<tr>
<td>Glucose falling 1-2 or 2-3 mg/dL per minute*</td>
</tr>
<tr>
<td>Glucose falling 2-3 or &gt;3 mg/dL per minute*</td>
</tr>
<tr>
<td>Glucose falling 3 or more mg/dL per minute**</td>
</tr>
</tbody>
</table>

* Varies based on system  **Not available on all systems
Dexcom G5 & G6 / Abbott Freestyle Libre Approved for Dosing Off CGM Values

- **Use Caution:**
  - First 24 hours
  - Last 24 hours
  - Higher-carb meals
  - Stressful situations
  - Lows and rebound highs

### Freestyle Libre

**Pros**
- No calibration needed
- 14 day sensor use
- Low cost
- Medicare approved
- Easy insertion
- Glucometer/Reader as one device
- Stores up to 8 hours of data
- Data upload software available

**Cons**
- No alerts
- Must scan every 8 hrs to prevent dropped data
- No calibration to improve accuracy
- Increase in inaccuracy in low range
- Must enter events at time of occurrence (no back dating)
- No data sharing
- No integration with any CSII systems

### Dexcom

**Pros**
- No calibration (G6) needed, but can be done to improve accuracy
- 10 day sensor use (can be reused)
- High, low, predictive urgent low alerts
- Easy insertion
- Shareable data
- Medicare approved
- Data to phone app, receiver or pump
- Clarity app auto uploads data
- Integrates with Tandem CSII

**Cons**
- Costly sensors and transmitters
- Transmitter replaced every 3 months
- Lots of medical waste with sensor inserters
- Some product order and tech support delays
- No financial assistance
Guardian Connect

- No receiver
- Bluetooth connection via Guardian Connect App to Smartphone
- Data-sharing
- Currently iOS only – Android pending
- Sugar IQ App – IBM Watson analytics to find patterns and offers real-time, actionable and personalized insights

Sugar IQ and IBM Watson

Conquer challenging foods with Glycemic Assist

Check your trends with My Data

You have the power to shape your days like never before.

My Data lets you easily see a daily summary of your glucose* trends, so you know how you’re doing in the moment and overall.

Guardian Connect

Pros
- 7 day sensor use (can be reused)
- High, low, predictive urgent low alerts
- Easy insertion
- Phone is receiver (via Connect app)
- Shareable data
- Sugar IQ app indicates patterns and trends
- Financial assistance available
- App auto uploads data to CareLink software

Cons
- Costly sensors and transmitters
- Complicated taping process
- Calibration q 2x/day minimum
- Not on available on android devices
- Impacted by acetaminophen use
Diabetes & Endocrine Center
Salinas Valley Medical Clinic

Dana Armstrong, RD, CDE

Costs

• Systems
  • $360 to $1,400 for the hardware
  • $3000 when initially introduced

• Sensors
  • Costs vary from $100-300 per month ($3.60-10/day) for continuous use
  • Does not include the cost of the test strips needed for calibration and BG confirmations (if needed)

MARD – Mean Absolute Relative Difference
(average difference between sensor values and lab values)

MARD – Glucose Sensors

<table>
<thead>
<tr>
<th>SYSTEM</th>
<th>MARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexcom G5</td>
<td>9.0%</td>
</tr>
<tr>
<td>Dexcom G6</td>
<td>9.0%</td>
</tr>
<tr>
<td>Freestyle Libre</td>
<td>9.7%</td>
</tr>
<tr>
<td>Medtronic Guardian 3</td>
<td>8.7%</td>
</tr>
</tbody>
</table>
2018 BG Monitoring System Surveillance Program

- 3 clinical sites - 1035 subjects
- Evaluated 18 blood glucose meters
- Tests required to be within 15% for a reference plasma value for a BG >100
- Tests required to be within 15 mg/dL for a BG <100

https://www.diabetestechnology.org/surveillance.shtml

Study Seal of Approval in GREEN

<table>
<thead>
<tr>
<th>Brand</th>
<th>Meter</th>
<th>% Compliant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bayer</td>
<td>Contour Next</td>
<td>100%</td>
</tr>
<tr>
<td>Roche</td>
<td>Aviva Plus</td>
<td>98%</td>
</tr>
<tr>
<td>Walmart</td>
<td>ReliOn Confirm</td>
<td>95%</td>
</tr>
<tr>
<td>CVS</td>
<td>Advanced</td>
<td>97%</td>
</tr>
<tr>
<td>Abbott</td>
<td>Freestyle Lite</td>
<td>96%</td>
</tr>
<tr>
<td>Roche</td>
<td>Smart View</td>
<td>95%</td>
</tr>
<tr>
<td>Walmart</td>
<td>ReliOn Prime</td>
<td>92%</td>
</tr>
<tr>
<td>Lifescan</td>
<td>OT Verio</td>
<td>92%</td>
</tr>
<tr>
<td>Prodigy</td>
<td>Auto Code</td>
<td>90%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Brand</th>
<th>Meter</th>
<th>% Compliant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lifescan</td>
<td>OT Ultra 2</td>
<td>90%</td>
</tr>
<tr>
<td>Walmart</td>
<td>ReliOn Ultima</td>
<td>89%</td>
</tr>
<tr>
<td>Bayer</td>
<td>Contour Classic</td>
<td>89%</td>
</tr>
<tr>
<td>Omnis</td>
<td>Embrace</td>
<td>88%</td>
</tr>
<tr>
<td>Nipro</td>
<td>True Result</td>
<td>88%</td>
</tr>
<tr>
<td>Nipro</td>
<td>True Track</td>
<td>81%</td>
</tr>
<tr>
<td>Biosense</td>
<td>SolusV2</td>
<td>76%</td>
</tr>
<tr>
<td>Suncoast</td>
<td>Redi-Code+</td>
<td>76%</td>
</tr>
<tr>
<td>Philosys</td>
<td>Gmate Smart</td>
<td>71%</td>
</tr>
</tbody>
</table>

Blood Glucose Meter Accuracy

Ekhaspour et al, JDST 2017

17 meters: MARD<5.6%; 9 with MARD >10%
NO Fingersticks and NO Calibrations Required

• Abbott Freestyle Libre
  • Covered by Medicare BUT requires SMBG 4x/day prior to submission
  • Fairly “low tech”
• Dexcom G6
  • Covered by Medicare BUT requires SMBG 4x/day prior to submission
  • More technology options

<table>
<thead>
<tr>
<th>SOURCE</th>
<th>FREESTYLE LIBRE</th>
<th>DEXCOM G6</th>
<th>MEDTRONIC GUARDIAN 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company Purchase</td>
<td>$75.00 voucher</td>
<td>$318.00</td>
<td>$345.00</td>
</tr>
<tr>
<td>Costco*</td>
<td>$116.18</td>
<td>$353.87</td>
<td>N/A</td>
</tr>
<tr>
<td>Walmart*</td>
<td>$116.31</td>
<td>$369.12</td>
<td>N/A</td>
</tr>
<tr>
<td>Ralphs*</td>
<td>$117.96</td>
<td>$365.33</td>
<td>N/A</td>
</tr>
<tr>
<td>Rite Aide*</td>
<td>$121.35</td>
<td>$369.12</td>
<td>N/A</td>
</tr>
<tr>
<td>Albertsons*</td>
<td>$121.60</td>
<td>$366.78</td>
<td>N/A</td>
</tr>
<tr>
<td>Safeway*</td>
<td>$121.60</td>
<td>$366.78</td>
<td>N/A</td>
</tr>
</tbody>
</table>

* GoodRx pricing as of April 1, 2019, with coupon

Case Study – Mrs. Sanchez

Mrs. Sanchez is 63 years old. She currently takes metformin and glyburide for her T2D. You are seeing her today following a referral from her PCP for diabetes education and help with a Freestyle Libre system which was given to her by her sister who “doesn’t like tech attached to her body.” She wants to start using the new meter because the commercial she saw said she wouldn’t have to poke her finger to check her blood sugar, which she is tired of doing every morning.
**Case Study – Mrs. Sanchez**

- A1C 11.9%
- RBG 327 mg/dL, fasting
- Ht/Wt: 5’6”/135 lb
- SMBG 0-1 times per day
- Meter BG avg 298 mg/dL, generally fasting
- 67 year old sister with T1D diagnosed 10 years ago
- Metformin 500 mg, 2 bid
- Glyburide 10 mg, 1 bid
- No hx DSMT

**Case Study – Mrs. Sanchez**

- Discuss as a team
- Where do you go from here?
- Is she a candidate for any type of technology? If so, what do you recommend?
- What will be the educational and tech hurdles for you and for Mrs. Sanchez?

**Freestyle Libre – 14 Days**

<table>
<thead>
<tr>
<th>Average Glucose</th>
<th>Confidence Interval</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>197 mg/dL</td>
<td>33.4 mg/dL</td>
<td>65.7 mg/dL</td>
</tr>
</tbody>
</table>

*Ambulatory Glucose Profile*

Curves/polygons represent glucose frequency distributions by time regardless of date.
Subcutaneous Continuous Insulin Infusion (CSII)

Computerized Basal/Bolus Insulin Delivery

Where We Stand

- 30-40% of pts with T1DM and 2-5% of pts with T2DM use CSII
- 2016: estimated 500,000 pts using CSII in the U.S.
- Up through 2018: 150,000 670G pumps shipped
- From 2009-2016 CGM users have increased 35%
- Annual revenue from CGM devices will overtake test strip and meter revenue by 2020
- 2050: Up to 1/3 of US residents may have T2DM; many will be insulin-requiring

Clinicians must have a comprehensive understanding of CSII/CGM

Technological Features of CSII

<table>
<thead>
<tr>
<th>Insulin Delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>(not all options available on all pumps)</td>
</tr>
<tr>
<td>• Small bolus increments: 0.05-0.10 units</td>
</tr>
<tr>
<td>• Extended boluses for delayed digestion or grazing</td>
</tr>
<tr>
<td>• Multiple insulin-to-carbohydrate ratios, sensitivity factors, BG targets</td>
</tr>
<tr>
<td>• Bolus calculators (based on BG level and carbohydrate quantity)</td>
</tr>
<tr>
<td>• Low basal rates: 0.025-0.05 units/h</td>
</tr>
<tr>
<td>• Multiple basal rates</td>
</tr>
<tr>
<td>• Temporary basal rates and suspension mode</td>
</tr>
<tr>
<td>• Automated delivery based on CGM data</td>
</tr>
<tr>
<td>Safety Features (not all options available on all pumps)</td>
</tr>
<tr>
<td>---------------------------------------------------------</td>
</tr>
<tr>
<td>- Alarms for occlusion and low insulin reservoir</td>
</tr>
<tr>
<td>- Active insulin to prevent insulin stacking</td>
</tr>
<tr>
<td>- Keypad lock</td>
</tr>
<tr>
<td>- Waterproof or watertight</td>
</tr>
<tr>
<td>- Auto-suspends insulin delivery when a CGM value reaches or falls below a pre-set threshold</td>
</tr>
<tr>
<td>- Auto-suspends insulin delivery when a CGM value predicted to fall below a pre-set threshold</td>
</tr>
</tbody>
</table>

### Technological Features of CSII

<table>
<thead>
<tr>
<th>Miscellaneous (not all options available on all pumps)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Electronic logbook software (insulin doses, BG levels, carbohydrates)</td>
</tr>
<tr>
<td>- Integrated food databases with customization</td>
</tr>
<tr>
<td>- Reminder alarms for BG checks, bolus doses</td>
</tr>
<tr>
<td>- Wireless communication with remote glucose meter</td>
</tr>
<tr>
<td>- Integration with continuous glucose monitoring technology</td>
</tr>
</tbody>
</table>

### Technological Features of CSII

- Pumps DO NOT . . .
  - Take over care of a person’s diabetes (yet)
  - Make diabetes perfect
  - Lessen the work of diabetes (it’s just different)
CSII Selection

Ideal CSII Candidate
• Pt with T1D or intensively managed insulin-dependent T2D
• Currently performing ≥4 insulin injections and ≥4 SMBG measurements daily
• Willing and intellectually able to undergo the rigors of insulin pump therapy initiation and maintenance
• Willing to maintain frequent contact with their health care team

Practice Selection Criteria
• Self-motivated
• Acceptance of diabetes
• Ability to problem solve
• Financial resources
CSII Candidates of Concern

• Unable/unwilling to perform MDI injections, frequent SMBG and to carb count
• Lack of motivation to achieve tighter glucose control
• Hx of serious psychological or psychiatric condition(s) (e.g., psychosis, severe anxiety, or depression)

CSII Candidates of Concern

• Substantial reservations about pump usage interfering with lifestyle
• Unrealistic expectations of pump therapy (e.g., belief that it eliminates the need to be responsible for diabetes management)

Finances

• More expensive than multiple daily injections
• Initial expense
  • Pump: ~$7,000
  • Start-up: $1,500 - $10,000
• Ongoing expense
  • Supplies: $3,600/year
• Financial assistance???
Diabetes & Endocrine Center
Salinas Valley Medical Clinic

Dana Armstrong, RD, CDE

Practical Aspects
- Assessment of the PWD and family readiness
- Selection of pump type
- PWD/family education of potential pump complications
  - DKA with infusion set failure
  - Lipohypertrophy
  - Site infections
- Initial pump settings
- Transition from MDI
- Introduction of advanced pump setting
  - Temp basal rates
  - Extended, square and dual wave bolusing

Medicare Requirements
On CSII BEFORE Enrollment
- Has documented SMBG ≥4 times per day during the month before enrollment
- Fasting C-peptide ≤110% lower limit of normal or ≤200% lower limit of normal if CrCl ≤50 ml/min with concurrent FPG ≤225 mg/dL; OR beta-cell autoantibody positive (+ICA or GAD antibodies)

Medicare Requirements
Qualifications if CSII AFTER Enrollment
- Has completed a comprehensive DM ed program
- On MDI with self-adjustments for at least 6 months
- Documented SMBG ≥4x/d during the previous 2 mo
- Meets ≥1 of the following criteria:
  - HbA1c >7.0%
  - Hx recurrent hypoglycemia
  - Fluctuating BGs before meals
  - Dawn phenomenon
Programming the Pump

~ Basal Rates ~
~ Bolus Rates ~
~ Active Insulin/Insulin on Board ~

Normal Insulin Production

Initial Calculations for CSII

TDD: total daily dose

**METHOD 1**
Pre-pump TDD

- Pre-Pump TDD x 0.75

**METHOD 2**
Patient Weight

- Wt (kg) x 0.50

**STARTING Pump TDD**
Average method 1 & 2

- **BASAL RATE**
  Pump TDD x 0.5 / 24

- **CARB RATIO**
  450 / Pump TDD

- **CORRECTION RATIO**
  1700 / Pump TDD

- **Hypoglycemia patients** – start at lower value of method 1 & 2
- **Hyperglycemic, elevated A1C or pregnant** – start at higher value of method 1 & 2

- **Consensus Statement by AACE/ACE insulin pump management task force.** Endocr Pract. 2014 May; 20(5):463-89.
Initial Calculations for CSII

- **Active Insulin (IOB)**
  - Generally set from 3-4 hours (shorter in 670G)

- **Auto Mode of 670G**
  - Carb ratio and IOB **ONLY VALUES** set by provider
  - Carb ratio calculation closer to 300/TDD
  - Basal 40% and Bolus 60%

- **IMPORTANT** to assess the manual mode settings for individuals using the 670G auto mode

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### Changes to Pump Therapy With Imaging Studies

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray/CT</td>
<td>Pump should be covered by lead apron</td>
</tr>
<tr>
<td>MRI</td>
<td>Pump and metal infusion set should be removed</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>No need to remove pump but transducer should not be pointed directly at the pump</td>
</tr>
<tr>
<td>Cardiac catheterization</td>
<td>Pump should be covered by lead apron</td>
</tr>
<tr>
<td>Pacemaker/automatic implantable cardioverter defibrillator (AICD)</td>
<td>Pump should be covered by lead apron</td>
</tr>
<tr>
<td>Colonoscopy/EGD</td>
<td>Pump can remain in place</td>
</tr>
<tr>
<td>Laser surgery</td>
<td>Pump can remain in place</td>
</tr>
</tbody>
</table>
CURRENT CSII SYSTEMS

Pumps Today: Tandem, OmniPod, & Medtronic

Pump & CGM Combo
• Medtronic and Tandem have combination pump/CGM systems
• The sensor is a separate site on the skin from the pump
  • The sensor’s glucose information is visible on the pump screen
• Life-changing future pump technology relies heavily on CGM technology
Tandem

**Pros**
- Touch screen
- Basal–IQ (pending Control IQ)
- Predictive low glucose suspend (PLGS)
- Stops insulin 30 minutes before set low limit and restart once glucose levels begin to rise
- Does not work with Dexcom G5
- Free upgrade to pump users in warranty

**Cons**
- No hybrid closed loop (pending)
- Small buttons
- No clip
- Weak vibration alert
- No meter link
- Requires charging 1-2x/week
- Company viability uncertain (pump is only product)

Omnipod

- Touch screen
- Calorie King food library
- Pending integration of Omnipod Horizon system and Tidepool Loop (hybrid closed loop)
- Medicare Part D pharmacy benefit (coverage T1D & T2D)
OmniPod

**Pros**
- Lower upfront costs
- Small size
- No tubing
- No disconnecting/reconnecting
- Simple insertion (less human error)
- Forced pod changes (decreases lipohypertropy & absorption issues)
- Meter built into PDM (non-DASH)
- DASH – android-based PDM (no meter)

**Cons**
- No CGM integration (in development)
- Non-DASH – bulky PDM
- DASH PDM – locked down Samsung
- Need PDM to bolus/make changes in settings – DON’T LOSE IT!
- One cannula length
- Max reservoir – 200 units
- 72 hour pod life
- Must suspend if making PDM changes
- Infusion issue – requires new pod

670G Hybrid Insulin Pump

- Suspend before low – stops insulin 30 minutes before set low limit and restarts when level recovers
- Auto Mode
  - Adjusts basal insulin based on BG to keep glucose at 120 mg/dL
  - Adjusts correction based on learned history
**Medtronic**

**Pros**
- Established company/R&D leader
- CGM data displayed on-screen
- Auto basal shutoff when low detected
- Hybrid closed loop basal based on CGM and predictive algorithms
- High-contrast full-color screen
- Integrated meter
- Boluses & temp basal “presets”
- Slow or fast bolus delivery
- Insulin/carb/BG statistics reports
- Financial assistance available

**Cons**
- Maintaining Automode requires increased interaction with the pump.
- Automode system alerts may become intrusive (significantly less with new transmitter)
- Max bolus 25 units
- Screen and text are relatively small
- Multiple menus and programming can be complex to master
- Company’s marketing can be overly aggressive

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**Let’s Talk Reports!**

So many options, so many numbers, so many pages, just so many . . .

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**Ambulatory Glucose Profile (AGP)**
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- February 2017, the Advanced Technology and Treatment for Diabetes Congress concluded recommended AGP as the standard for visualization of CGM data and recommended as a universal software report to standardize summary metrics among devices and manufacturers.
- Is now recognized as an international standard report for glucose patterns.
- Reports now available for self monitoring blood glucose and continuous glucose monitoring devices as well as insulin pumps (tradition and closed loop) and downloadable insulin pens.

<table>
<thead>
<tr>
<th><a href="http://www.agpreport.org/agp/agpreports">http://www.agpreport.org/agp/agpreports</a></th>
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<tr>
<td><strong>Glucose Statistics:</strong></td>
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<td>- Dates &amp; number of days in report</td>
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<td>- Avg Tests/Day: Number of finger sticks, divided by days in report</td>
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<tr>
<td>- Avg. Glucose: All glucose values added together, divided by no. of readings</td>
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<td>- GMI (glucose management indicator): Calculated from average glucose; estimates your future lab A1c</td>
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Diabetes & Endocrine Center
Salinas Valley Medical Clinic

Ambulatory Glucose Profile (AGP)

- Time in Ranges:
  - Time in Target: Ideally, glucose values are in target range
  - Low/Very Low: Goal - few very low or low values; reducing lows reduces risks
  - High/Very High: Goal - few very high or high values; reducing highs lowers A1c

Ambulatory Glucose Profile (AGP)

- Glucose Profile: Daily glucose profiles are combined to make a one day (24-hour) picture. Ideally, lines stay within the grey shaded area (target range)
- Orange: median (middle) line where half of the glucose values are above and half are below; ideally, the orange line is mostly flat and inside the grey shaded area
- Blue: area between blue lines shows 50% of the glucose values; ideally, space between is narrow
- Green: 10% of values are above (90% top line) and 10% are below (10% bottom line); ideally, the closer the green lines are to the grey shaded area, the better

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<th>% Time CGM is Active</th>
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Case Study – Mrs. Sanchez

On your recommendation, Mrs. Sanchez’s PCP checked her c-peptide (0.6) and GAD antibodies (positive). She was then referred to the clinic endo, who diagnosed her with T1D and started her on MDI. She has completed your DSMT program, uses a carb ratio and correction for her meals (but not for her snacks) and now wears a Dexcom G5 CGM as part of her management. The endo believes she would do well on CSII given her glucose variability and her highs after dinner and during the night. She is now following up with you after her endo apt.

Case Study – Mrs. Sanchez

• A1C 7.9%
• RBG 272 mg/dL, 3 hr pp
• Ht: 5’6”
• Wt: 154 lb
• SMBG 1-2 times per day

• Novolog: ICR 15 / ISR 40
• Basaglar: 20 units q 8 pm
• TDD = average 40 units/day

TDD = average 40 units/day
Case Study – Mrs. Sanchez

• Discuss as a team
• Where do you go from here?
• Is she a good CSII candidate? If so, what do you recommend?
• If she decides to pursue CSII, what would be her starting basal rate and ratios?

Pump Rates/Ratios

Method 1 - TDD
• ____________________
• ____________________

Starting Pump TDD
• ____________________

Method 2 - Weight
• ____________________
• ____________________

Starting Rates/Ratios
• basal
• ICR
• ISR

• A1C 6.5%
• 134 lb
• ICR 10
• IOB 3.0 hrs
Future Systems and Sensors

#WeAreNotWaiting and #OpenAPS

• Group frustrated with regulatory controls has released information on building an AP using an insulin pump and CGM
• As the information is freely available and the device is not being sold, medical regulation does not apply
• Building instructions and all codes are freely available on the internet

Resources – Endocrine Society

• Technology Guidelines
• Clinical Education talk
• Educational Slide Deck
• Guidelines Pocket Card
• Patient Resources
• App and point of care tools
Resources - Diabetes Advanced Network Access

- Product clearinghouse: 200+ reviews for CGMs, BG monitors, CSII, med delivery devices
- Education: On-demand, live courses, webinars Innovation and up-to-date technology news, focus groups and polls
- Resources: Publications, guidelines and practical tools
- App Review: Info on mobile apps, with a focus on DM mgt
- www.danatech.org

Resources - Diabetes Technology & Therapeutics

- Devices, drugs, drug delivery systems, software
- Detection/prevention of long-term complications
- Breakthrough technologies and new therapeutic drug classes
- Behavioral aspects and approaches to diabetes care
- Advancement/applications of new/emerging tech
  - Alternate insulin delivery methods
  - Continuous glucose monitoring
  - Artificial pancreas
  - Computerized case management/telemedicine
  - New insulins with ultra-rapid onset of action
  - Detection and prevention of hypoglycemia

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Dana Armstrong, RD, CDE