Pumps and Sensors

-The Bionic Patient-

Subcutaneous Continuous Insulin Infusion (CSII)

Computerized Basal/Bolus Insulin Delivery

Where We Stand

- 30% of pts with T1DM and 1-2% of pts with T2DM use CSII
- 2016: estimated 500,000 pts using CSII in the U.S.
- 2017/2018: 50,000 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

Insulin Delivery **(not all options available on all pumps)**	• Small bolus increments: 0.05-0.10 units • Extended boluses for delayed digestion or grazing • Multiple insulin-to-carbohydrate ratios, sensitivity factors, BG targets • Bolus calculators (based on BG level and carbohydrate quantity) • Low basal rates: 0.025-0.05 units/h • Multiple basal rates • Temporary basal rates and suspension mode • Automated delivery based on CGM data

Technological Features of CSII

Safety Features **(not all options available on all pumps)**	• Alarms for occlusion and low insulin reservoir • Active insulin to prevent insulin stacking • Keypad lock • Waterproof or watertight • Auto-suspends insulin delivery when a CGM value reaches or falls below a pre-set threshold • Auto-suspends insulin delivery when a CGM value is predicted to fall below a pre-set threshold

Technological Features of CSII

Miscellaneous **(not all options available on all pumps)**	• Electronic logbook software (insulin doses, BG levels, carbohydrates) • Integrated food databases with customization • Reminder alarms for BG checks, bolus doses • Wireless communication with remote glucose meter • Integration with continuous glucose monitoring technology

Pumps DO NOT . . .

- Take over care of patient's diabetes (yet)
- Make diabetes perfect
- Lessen the work of diabetes (it's just different)

Patient Selection for CSII

~ Ideal Candidates ~

~ Patient Selection ~

Ideal CSII Candidate

- Pt with T1DM or intensively managed insulin-dependent T2DM
- 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

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)

Patient Selection Criteria

- Self-motivated
- Acceptance of diabetes
- Ability to problem solve
- Financial resources

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???

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

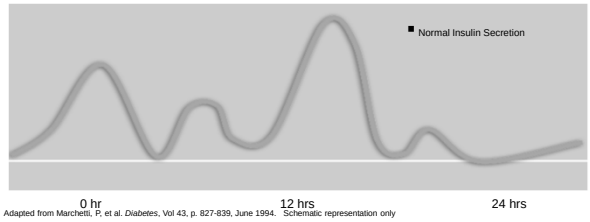
Programming the Pump

~ Basal Rates ~

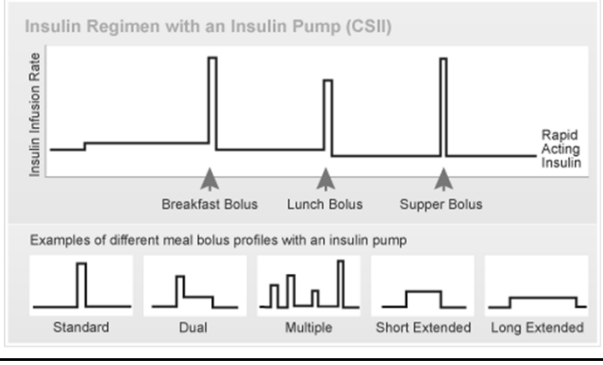
~ Bolus Rates ~

~ Active Insulin/Insulin on Board ~

Normal Insulin Production



Adapted from Marchetti, P. et al. *Diabetes*, Vol 43, p. 827-839, June 1994. Schematic representation only



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

- Start with 1 basal rate, adjust according to glucose trends over 2-3 days
- Adjust to maintain stability in fasting state (between meals & sleep)
- Add additional basals according to diurnal variation (dawn phenomenon)

CARB RATIO

450 / Pump TDD

- Adjust based on low-fat meals with known carbohydrate content
- Acceptable 2-h post-prandial rise is ~60mg/dL above pre-prandial BG
- Adjust carb ratio in 10%-20% increments based on post-prandial BG

CORRECTION RATIO

1700 / Pump TDD

- Sensitivity Factor is correct if BG is within 30 mg/dL of target range within 2 hours after correction
- Make adjustments in 10%-20% increments if 2-hr post-correction BGs are consistently above or below target

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 patients using the 670G auto mode

Continuous Glucose Monitoring (CGM)

Revolutionizing Glucose Control and Management

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) and to people with DM who test 4 times per day and use intensive insulin management

CGMS DOES . . .

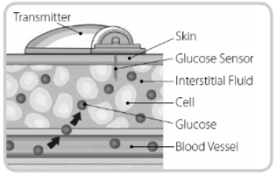
- Less BG variability – more time in range
- Less apprehension at work, at school, while sleeping, or driving
- Give great data a majority of the time
- Glucose value every 5 minutes
- Eliminate SMBG (for some systems) most of the time

CGMS DOES NOT. . .

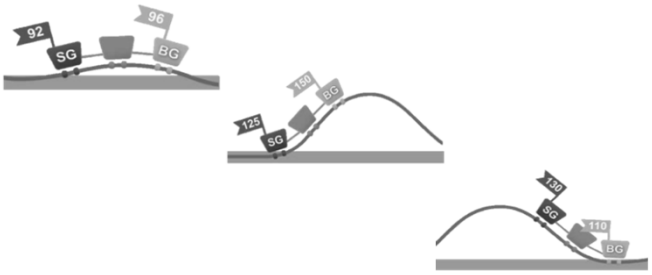
- Completely eliminate the need for SMBG (for some systems)
- 'Take over' all diabetes control (getting closer)
- Give 100% data all of the time

Sensor Glucose ≠ Blood Glucose

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



Sensor Glucose ≠ Blood Glucose



CGM Systems

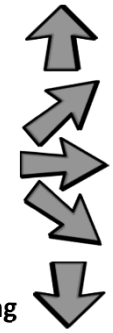
- Offer alarms for glucose highs and lows
- Ability to download data and track trends over time and share data
- Offers ability to easily observe how any given food, exercise or insulin dose affects control over the course of a few hours
- Allows immediate feedback - pts able to modify behaviors to gain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

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**



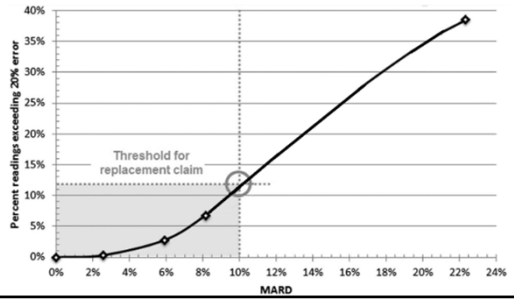
	Glucose not rising or falling >1mg/dL/minute
	Glucose rising 1-2 mg/dL per minute**
	Glucose rising 1-2 or 2-3 mg/dL per minute*
	Glucose rising 2-3 or >3 mg/dL per minute*
	Glucose rising 3 or more mg/dL per minute**
	Glucose falling 1-2 mg/dL per minute**
	Glucose falling 1-2 or 2-3 mg/dL per minute*
	Glucose falling 2-3 or >3 mg/dL per minute*
	Glucose falling 3 or more mg/dL per minute**

*** 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

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



MARD – Glucose Sensors

SYSTEM	MARD
Dexcom G5	9.0%
Dexcom G6	9.0%
Freestyle Libre	9.7%
Medtronic Guardian 3	8.7%

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

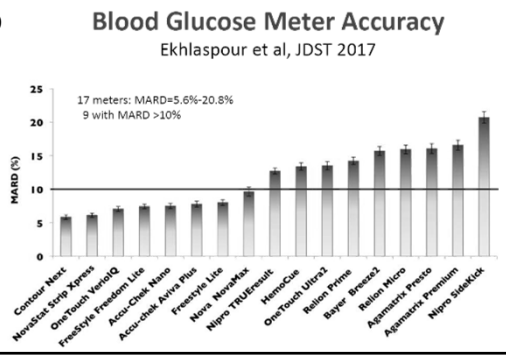
https://www.diabetestechnology.org/surveillance.shtml

Study Seal of Approval in GREEN

Brand	Meter	% Compliant
Bayer	Contour Next	100%
Roche	Aviva Plus	98%
Walmart	ReliOn Confirm	95%
CVS	Advanced	97%
Abbott	Freestyle Lite	96%
Roche	Smart View	95%
Walmart	ReliOn Prime	92%
Lifescan	OT Verio	92%
Prodigy	Auto Code	90%

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

MARD



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
  - Not yet covered by Medicare
  - More technology options

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

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

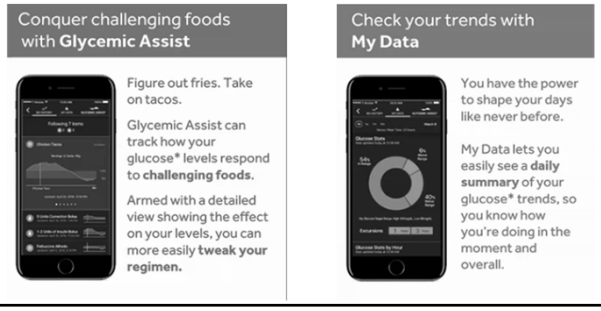
Tandem T:Slim X2 Pump and Dexcom G6 CGM

- Basal–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

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



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)

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

Future Systems and Sensors