Troubleshooting Common Control Issues

John Walsh, PA, CDTC  Saturday, March 7, 2015
Disclosure

- Book sales – all pump companies
- Advisory Boards – Companion Diabetes, Convatec, PicoLife Technologies
- Consultant – Bayer, Roche, BD, Abbott, Tandem Diabetes, Acon Laboratories, Companion Diabetes
- Speakers Bureau – Tandem Diabetes, Animas
- Sub-Investigator – Glaxo Smith Kline, Animas, Lilly, Sanofi-Aventis, Bayer, Medtronic, Biodel, Dexcom, Novo Nordisk, Halozyrne
- Pump Trainer – Accu-Chek, Animas, Medtronic, Omnipod, Tandem
- Web Advertising – Sanofi-Aventis, Sooil, Tandem Diabetes Medtronic, Animas, Accu-Chek, Abbott, etc.
Outline

- How to use CGM to troubleshoot control problems
- Troubleshooting the infusion set
- The Future
  - Better connectivity and analysis
  - Replace fingersticks
  - Control via the closed loop (or variations of)
In early 2014, we surveyed 502 US pumpers – 79% had experience (short or long) with a CGM and 59% currently wore one.
CGM Calibration Tips

- Use an accurate meter
- Use good technique – clean fingers, no expired strips, enter reading right away
- Calibrate when CGM requests this and anytime that fingerstick varies from CGM reading (and consider whether to retest fingerstick)
- Do more calibrations on first day of use
- Calibrate at the extremes (when low and when high)
CGM Screen Information

- **Glucose value** – updated every 5 min
- **Trend line** – direction of glucose change
- **Trend arrow** – rate of change (ROC)
- **Alerts**
  - High and low threshold
  - Predictive
  - Rate-of-change
# Trends Arrows (mg/dL/hour)

<table>
<thead>
<tr>
<th>Arrow</th>
<th>Dexcom</th>
<th>Medtronic</th>
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</thead>
<tbody>
<tr>
<td><img src="orientation" alt="upward-arrow" /></td>
<td>Rise &gt; 180 mg/dl/hour</td>
<td>Rise &gt; 120 mg/dl/hour</td>
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<tr>
<td><img src="orientation" alt="upward-arrow" /></td>
<td>Rise = 120 to 180</td>
<td>Rise = 60 to 120</td>
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<tr>
<td><img src="orientation" alt="upward-arrow" /></td>
<td>Rise = 60 to 120</td>
<td>(n/a)</td>
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<tr>
<td><img src="orientation" alt="horizontal-arrow" /></td>
<td>&lt; 60 rise or fall (stable)</td>
<td>(n/a)</td>
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<tr>
<td><img src="orientation" alt="downward-arrow" /></td>
<td>Fall = 60 to 120</td>
<td>(n/a)</td>
</tr>
<tr>
<td><img src="orientation" alt="downward-arrow" /></td>
<td>Fall = 120 to 180</td>
<td>Fall = 60 to 120</td>
</tr>
<tr>
<td><img src="orientation" alt="downward-upward-arrow" /></td>
<td>Fall &gt; 180</td>
<td>Fall &gt; 120</td>
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</tbody>
</table>
Where To Set Alerts

LOW: 80 mg/dl to start
Higher for young children and high risk jobs

HIGH: 200 mg/dL based on current BGs
Gradually lower to 160 or 140 as control improves
The lower the high alert is, the earlier the wearer knows their BG is rising

Adjust Insulin for BG, Trend, & BOB*

- BG Stable: Usual Dose
- BG Rising Gradually:
  \(\uparrow\) bolus 10%
- BG Rising Sharply:
  \(\uparrow\uparrow\uparrow\) bolus 20% (140%)
- BG Dropping Gradually:
  \(\downarrow\) bolus 10%
- BG Dropping Sharply:
  \(\downarrow\downarrow\downarrow\) bolus 20%

*BOB = bolus [insulin] on board
CGM Tips

- **Wear** the CGM at least 90% of the time and **look at the monitor** 10-20 times per day

- Look at trend lines not just individual BGs!

- Don’t over-react – avoid frequent corrections until pattern is clear

- A rapid rise usually means more insulin needed, BUT check BOB first!

- Lag times (usually 5-8 min) are longest after you treat a low glucose
Glucose Profile – No Diabetes

Avg BG 97, SD 24, %CV 23%, IQR 29

Avg BG 97, SD 24, CV 23%, IQR 29
Glucose Profile – Poor Control

Comes in many variations!
Downloads Help Your Health Care Provider – So Bring Meaningful Data

“Pumping gas and brakes”

- Look for repeat patterns – correct patterns rather than reacting and making same mistake over and over again
Why People Don’t Download

Takes 30 min or more to download data for doctor visit.

Thanks to Laddie at http://testguessandgo.com/tag/dexcom/
Jackson Pollack’s CGM Tracing

Price: $3,000,000
What CGM Information is Used?

Of 222 survey respondents with Type 1 diabetes:

- 51% rated trend line/trend arrow as most important
- 30% rated low and high glucose alerts as most important
- 15% thought real-time and download information were important
- **Only 3.6% reported that finding patterns from downloads was helpful**

40% never download and 17% report doing so only rarely

CGM Data – Trends vs Downloads

RT Trendlines show:
- Last 1-24 hrs readings
- One night’s basal profile
- Profile of one meal
- A limited picture

Downloaded data shows:
- Multiple days’ readings
- Frequent highs
- Frequent lows
- Roller-coaster readings
- Post-meal spiking
- A complete picture
Adjust from Trendlines
First 2 Days (Download)
Type 1 Chef (DM x 13 yr, c-peptide <0.5)

Cgm as a Behavior Modification Tool
Adjust from Trendlines
CGM Tracing – Following 2 Days

CGM as a Behavior Modification Tool
Honesty Improves Downloaded Data

Overeating in the evening comes to haunt me at 3:00AM.

With the extreme dryness in AZ this winter, I’ve lost readings as a result of static.

Infusion Set Failure
(Meter readings were closer to 400)

5hrs

Not My Best Dexcom Tracing....

Thanks to Laddie at http://testguessandgo.com/tag/dexcom/
Woman on Pump – 1st Visit

Glucose Trend

Avg BG 205, SD 118, CV 58%, IQR 204
Woman on Pump – 1\textsuperscript{st} Visit
Woman on Pump – 2nd Visit

Avg BG 176, SD 89, %CV 51%, IQR 125
How To Optimize Insulin
Optimize Insulin Doses In Sequence

1. Correct frequent lows first
2. Then correct high A1c/avg BG
3. Set & test basals from iTDD  Keep overnight readings level
4. Set & test CarbF from iTDD  Fine-tune premeal BGs
5. Lower post meal BG’s      Bolus early, low GI foods,  
                              add Symlin, GLP-1 agonist, etc
6. Set & test CorrF from iTDD  Brings highs down safely
7. Enjoy good control or return to #1

Brittle diabetes or frequent highs?  
Usually = the wrong pump settings
Incidence Rate* of SH at various ages

* the rate of seizure/coma in the DCCT was 26.7 /100 patient year.
Hidden Hypoglycemia

He/She ate when low but never tested with a meter. *Only a CGM sees this!*
Nocturnal Hypoglycemic Seizures

Buckingham B. Diabetes Care 2008. 31:2110–2112
Stop Frequent Lows First

- You cannot tell how much excess insulin there is!
- Start with a 5% or 10% reduction in TDD
- Compare the current TDD to an “ideal” TDD for weight.
- Divide weight(lbs) by 4 to see what TDD would be used with an average sensitivity to insulin

Example: Someone who weighs 160 lbs would be expected to have a TDD of 40 units (160/4 = 40).
Example 1 – Frequent Lows on Meter

41 yo female with A1c = 6.9%

TDD = 50.5 u/d

152 lb/4 = 38.0 u/d
Example 2 – Frequent Lows on CGM

28 yo female – Wt: 120 lbs

Current TDD = 43.6 u/day
Wt/4 (120/4) = 30.0 u/day
Then Stop Frequent Highs

Raise TDD:

- by 1% to lower average BG by 6 mg/dL
- or by 5% to lower A1c by 1%

\[
\text{Current BG} - \text{Target BG} = \frac{\% \text{ rise in TDD}}{6}
\]

**Example:** Amy’s avg TDD is 40 u/day, avg BG 200 mg/dL (few lows), and BG goal 140 mg/dL:

\[
200 \text{ mg/dL} - 140 \text{ mg/dL} = 60 \text{ mg/dL}
\]

\[
60 \text{ mg/dL} \div 6 = 10\% \text{ rise in TDD}
\]

\[
40 \text{ units} \times 1.10 = 44 \text{ units a day}
\]
Example 1 – Lower Highs from A1c

27 yo male, A1c = 8.6%, TDD = 50 u/day

8.6% - 7.0% = 1.6% x 5 = an 8% increase in TDD

50u x 1.08 = 54u

Bring downloads to your HCP so they can help you interpret them yourself!
Example 2 – Lower Highs from Avg BG

53 yo female
TDD = 36 u
Avg BG = 191

- Raise basal by 0.05 u/hr all day (+1.2 u/day)
- Lower CarbF from 1u/13g to 1u/12g (+1.8 u/day)

TDD = 39 u
8.3% increase
T1 DM on the “Rollercoaster”
Type 1 Initial Visit – What’s the Problem?

Type I DM  A1C 9.0%  -  Avg BG = 176 (SD=66)
Type 1 After Pramlintide (Symlin)

Type I DM  A1C 7.4%  -  Avg BG =176 (SD=66)
Recurrent DKA (A1c 9.5%)
Recurrent DKA – Reactive Bolusing

<table>
<thead>
<tr>
<th>Total Insulin</th>
<th>19.55</th>
<th>32.10</th>
<th>28.10</th>
<th>25.30</th>
<th>19.85</th>
<th>35.25</th>
<th>24.70</th>
<th>26.15</th>
<th>20.90</th>
<th>22.75</th>
<th>26.20</th>
<th>25.10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal (U)</td>
<td>35%</td>
<td>6.90</td>
<td>44%</td>
<td>14.15</td>
<td>50%</td>
<td>14.15</td>
<td>56%</td>
<td>14.10</td>
<td>65%</td>
<td>12.90</td>
<td>32%</td>
<td>11.15</td>
</tr>
<tr>
<td>Bolus (U)</td>
<td>65%</td>
<td>12.65</td>
<td>56%</td>
<td>17.95</td>
<td>50%</td>
<td>13.95</td>
<td>44%</td>
<td>11.20</td>
<td>35%</td>
<td>6.95</td>
<td>68%</td>
<td>24.10</td>
</tr>
<tr>
<td># of Boluses</td>
<td>5</td>
<td>9</td>
<td>8</td>
<td>6</td>
<td>3</td>
<td>7</td>
<td>4</td>
<td>4</td>
<td>5</td>
<td>7</td>
<td>11</td>
<td>6</td>
</tr>
<tr>
<td>Avg. Bolus (U)</td>
<td>2.53</td>
<td>1.90</td>
<td>1.74</td>
<td>1.87</td>
<td>2.32</td>
<td>3.44</td>
<td>3.58</td>
<td>3.28</td>
<td>1.40</td>
<td>1.76</td>
<td>1.12</td>
<td>2.23</td>
</tr>
<tr>
<td># Corr. Bolus</td>
<td>100%</td>
<td>5%</td>
<td>78%</td>
<td>7%</td>
<td>75%</td>
<td>6%</td>
<td>83%</td>
<td>5%</td>
<td>100%</td>
<td>3%</td>
<td>86%</td>
<td>6%</td>
</tr>
</tbody>
</table>

1/6 1/7 1/8 1/9 1/10 1/11 1/12 1/13 1/14 1/15 1/16 1/17
72 yo Type 1 with A1c = 6.1%

Post-meal boluses and overcorrections
Connectivity – the Next Big Wave

- Bluetooth LE allows connecting:
  - Pumps or smart insulin pens
  - Meters and CGMs
  - Cell phones
  - Activity monitors – FitBit, JawBone, MotoActv, BodyMedia
- Integrate data from different device manufacturers
  - Tidepool, DiaSend, Share
- FDA is on board!
The Near Future

- Connectivity
  - Interoperability
  - Standard Display formats
- CGMs Replace Fingersticks
- Control
  - Assisted
  - Fully-closed loop
Dexcom BLE Share System

Caregiver’s Phone with Follow App

Dexcom Share

Wi-Fi or Cellular

Wi-Fi or Cellular

Bluetooth®
Next Step: Replace Fingersticks
Sensors vs SMBG

89% of the CGM readings are ± 20% of YSI (or ±20 mg/dL for YSI ≤ 100 mg/dL)

Factory Calibration

- First step to fingerstick replacement
- Available today in E.U. without a prescription
  - Abbott Freestyle Libre (MARD 11.5%)
Troubleshooting the Infusion Set
Infusion Set Failure Is Common

- Most of the 16,849 adverse pump events reported to the FDA between 2006-2009\(^1\) involved infusion sets\(^1\)
- A 2006 review of pumps in France likewise found that most serious adverse events involved infusion sets\(^2\)
- Auto-insertion devices have a high failure rate of 8.9\%\(^3\)

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1 www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralHospitalandPersonalUseDevicesPanel/UCM202779.pdf
Infusion Sets – The Achilles Heel Of Pumps

Survey of 1142 pumpers in 40 German diabetes clinics

- 54% reported an increase in glycemia for unknown reasons until their infusion set is changed
- 19% reported kinking, 12% had leakage, 12% air bubbles, and 33% had other issues
- 36% used auto-insertion devices – 72% of them reported that the device failed to work ~10% of the time

Infusion Sets

- Subcutaneous indwelling catheters
- Teflon cannula or steel needle
- Change Teflon every 3 days (3.4 d*) and steel every 2 days (3.7 d*)
- Pump and tubing may be disconnected without removing insertion site

* >500 self-reports of length of use in U.S.
Cannula Options

- **Straight**
  - Teflon
  - Metal
  - Sizes: 6, 9 mm

- **Slanted**
  - Teflon
  - Sizes: 13, 17 mm

Sizes: 4, 5, 6, 9 mm
Line Disconnect Mechanisms

Motion and degree of manual dexterity required

- Pinch & pull easiest
- Twist & pull easiest
- Pinch, twist, & lift hardest
- Pinch & lift harder

Tubing lengths: 24”, 32”, and 43” for most sets
Auto-Inserters

Inset 30

Accu-Chek Link Assist

Inset/Mio

Quick-Serter

Cleo

Omnipod
Is The Infusion Set The Problem?

- Sites often “go bad”?
- Have “scarring” or “poor absorption”?
- Often have 2 or more unexplained highs in a row?
- Do correction boluses sometimes not work?
- High BGs until the set is changed?
Infusion Set Failure On CGM

Alert for rising BG. Took 1st “bolus”

2nd rising BG, confirmed with BG test. Infusion set was detached. A “2nd” corr. bolus taken after set replaced.

DIA = 5 hrs or more
Set problem started on afternoon of May 1\textsuperscript{st} and lasted until late in the day on the 2\textsuperscript{nd} when the infusion set was changed.
How Infusion Sets Fail

- Complete pullout
- Insulin leak along Teflon to skin
- Hematoma under the skin
- Autoinsserter
- Occlusion
- Loose hub
- Punctured line

Goal: Less than one failure a year!
Stop Infusion Set Problems!!

- Anchor the infusion line with 1” tape*
  - Stops tugs and pullouts, “unexplained highs” (insulin leaks), skin irritation and “pump bumps” No anchor!
- Insert set by hand
- Review site prep and insertion technique with clinician or trainer
- Switch to a reliable infusion set

* Transpore, Durapore, Hypafix, Micropore
Data Tools and Standardized Data
Use Data Tools

- “On-board” information
- Pump Download software
  - Use with sensor and bG downloads
- Decision Support software
Ambulatory Glucose Profile for CGM Data

- Time in range
- Shaded modal day with median, IQ range, and 10/90% range
- Dashboard

Bergenstal et al: DT&T 2013
# Freestyle Libre/Flash Glucose Patterns

## Glucose Pattern Insights
**13 September 2014 - 10 October 2014 (28 days)**

- Low-glucose allowance setting: Medium
- Median goal setting: 8.6 mmol/L (A1c: 7.0% or 53 mmol/mol)

**Estimated A1c 5.8% or 40 mmol/mol**

### Graphical Representation

- Glucose levels from 03:00 to 05:00 to 07:00 to 09:00 to 11:00 to 13:00 to 15:00 to 17:00 to 19:00 to 21:00 to 23:00 to 01:00 to 03:00

#### Glucose Pattern Insights:

<table>
<thead>
<tr>
<th>Time</th>
<th>Glucose Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>03:00</td>
<td>05:00</td>
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<td>11:00</td>
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<td>03:00</td>
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</tbody>
</table>

- **Low glucose**
- **Median glucose** (compared with goal)
- **Variability below median** (median to 10th percentile)

**Likelihood of low glucose**

<table>
<thead>
<tr>
<th>Time</th>
<th>Low Glucose</th>
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<tbody>
<tr>
<td>03:00</td>
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<td>05:00</td>
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**Median glucose**

- **OK** (comparing with goal)

**Variability below median**

<table>
<thead>
<tr>
<th>Time</th>
<th>Low</th>
<th>Moderate</th>
<th>High</th>
<th>Meal</th>
<th>Bedtime</th>
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<tbody>
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<td>03:00</td>
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**Type One Nation**

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Diabetes Management System

- Automated report
- Facilitates patient counseling
- Discloses educational deficits
- Recommends device settings
- Tracks glycemic outcomes
- Understands behaviors
- Informs health care provider
Review Data On The Device

- TDD = 35.19 u
- Basal % is low at 36%
- 2 grams of carb/day means Bolus Wizard is not being used
Connectivity

Get ready – the next big wave in diabetes devices and care!

Gadgets + Interfaces + Intelligence

Eventually, easier for everyone
Going Beyond Simple Pumps

- Show how a setting change affects the TDD (& BG)
- Temp basal PLUS bolus doses
- Super Bolus
- Meal-size boluses
- Alert for excess BOB (bolus without BG but BOB is ++)
- Low BG predictor (HypoManager)
- Exercise compensator (duration + intensity = gr of carb)
- Automated basal and bolus testing
Faster Insulins

- Diaport intraperitoneal delivery
- Faster insulin analogs
  - Novo Nordisk
  - Lilly
  - Biodel
  - MannKind Afrezza (inhaled)
- Micro-needles (1.5 mm)
- Oral insulin

Goal: fewer highs and fewer lows
Implanted CGMs

- Months to years of use
- No disposables
- Minor surgery
- Revenue model?

Sensionics

Dexcom G1 2004

Biorasis Glucowizzard

GlySens

JDRF type one nation
Artificial Pancreas Pathway

- Threshold Suspend
  - Reactive
  - Predictive
- Control to Range
- Control to Target
  - Insulin-only
  - Bi-hormonal

fda.gov/GuidanceDocuments/UCM259305.pdf
Life Is Better When You Know More!

PI5 on Kindle, i-Pad, and Nook – $16.99

Slides at www.diabetesnet.com/diabetes-resources/diabetes-presentations
Books at www.diabetesnet.com/dmall/ or 800-988-4772