GLUCOSE CONTROL WITH TODAY’S INSULIN PUMPS & CGMS

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Sanofi

John Walsh, PA, CDTC
Advanced Metabolic Care and Research
Escondido, CA

Know The Bolus Calculator Settings

<table>
<thead>
<tr>
<th>Setting</th>
<th>Helps</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDD (total daily dose of insulin)</td>
<td>Best guide to initial pump settings – controls A1c, avg glucose, frequency of lows</td>
</tr>
<tr>
<td>Basal rates</td>
<td>For sound sleep and skipping meals</td>
</tr>
<tr>
<td>CarbF (E:C ratio)</td>
<td>Cover carbs well</td>
</tr>
<tr>
<td>CorrF (ISF)</td>
<td>Lower highs safely</td>
</tr>
<tr>
<td>Target glucose</td>
<td>BG goal 4-5 hrs after bolus</td>
</tr>
<tr>
<td>DIA</td>
<td>Minimize insulin stacking from BOB</td>
</tr>
</tbody>
</table>

Advantages of an Insulin Pump

- Avg. A1c reduction = 0.2%1,2
- Convenience = compliance
- Software calculates dose recommendations and tracks BOB
- Reduces insulin stacking, severe hypoglycemia, and BG variability3,4
- Plus a freer and more varied lifestyle
- And better data (clinicians, pumpers, and parents)

4 Hirose M, Kawamura T, Hashimoto T, et al. J Japan Diab Soc. 2009 52(9), 767-775

21st Century Line Pumps

- Accu-Chek Aviva Combo
- Animas Ping or Vibe
- Medtronic Revel
- Asante Snap
- Animas Ping or Vibe
- Medtronic Revel, 530G, 640G
- Animas Ping or Vibe
- Medtronic Revel, 530G, 640G

21st Century Patch Pumps

- Animas Ping or Vibe
- Medtronic Revel
- Asante Snap
- Animas Ping or Vibe
- Medtronic Revel
- Asante Snap
Advantages of a CGM

- Average A1c reduction = 0.3%\(^1\)
- Reads glucose every 5 min
- Alarms for lows and highs
- Security for wearer and family
- Trend line and arrows improve bolus doses
- Better data (clinicians, pumpers, parents)


21st Century CGM’s

- Better BG meters have a mean average relative difference (MARD or error) of 5-6%\(^2\)


APP Study – What Impacts the Glucose?

<table>
<thead>
<tr>
<th>Glucose, Insulin and Carb Data</th>
<th>132 people in each tertile with the lowest and highest glucose levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>Low BG Tertile</td>
</tr>
<tr>
<td>Avg. Meter BG</td>
<td>144 mg/dL</td>
</tr>
<tr>
<td>BG Tests/Day</td>
<td>4.73</td>
</tr>
<tr>
<td>TDD u/d</td>
<td>47.9 u</td>
</tr>
<tr>
<td>Basal %</td>
<td>47.6%</td>
</tr>
<tr>
<td>CarbBolus u/d</td>
<td>20.9 u</td>
</tr>
<tr>
<td>CarbBoluses/Day</td>
<td>4.07</td>
</tr>
<tr>
<td>CarbGrams/Day</td>
<td>185.2</td>
</tr>
</tbody>
</table>


Find the Optimal TDD First

- Most people do not get enough insulin
- A few get too much
- An accurate TDD is the best guide to correct pump settings
- Pattern management is simpler once TDD and settings are optimized

The TDD controls the frequency of lows, A1c, & avg BG

Improve Insulin Doses In Sequence

1. Stop frequent lows first
2. Then correct high A1c/avg BG
3. Set & test basal rates
4. Set & test CarbF for normal pre and post meal readings
5. Set & test CorrF to lower high BGs safely
6. Enjoy good control or return to #1

Brittle diabetes or frequent highs? Usually = wrong pump settings

Get an Optimal TDD – Stop Frequent Lows First

You cannot tell how much excess insulin there is!

1. Start with a 5% or 10% reduction in TDD
2. Or multiply weight (kgs) by 0.55 for “ideal” TDD of someone with an average sensitivity to insulin\(^1,2\)
3. Example: Someone who weighs 73 kg (160 lbs) would be expected to have a TDD of 40 units (73 x 0.55 = 40).

Insulin Pumps Reduce Severe Hypoglycemia in Japan

In a 2009 report on 121 patients with Type 1 diabetes followed for 12 months:

- A1c levels were reduced from 8.7% +/- 2.0 to 7.9% +/- 1.5
- Severe hypoglycemia decreased from 26.7 to 2.7 per 100 person-years
- Ketoacidosis events were more frequent at the start of therapy (ie, infusion set failures)

Hirose M, Kawamura T, Hashimoto T, et al. J. Japan Diab Soc. 2009 52(9), 767-775

For Low BGs, Optimize the TDD!

41 yo 69 kg female with A1c = 6.9%
TDD = 50.5 u/d
69 kg x 0.55 = 38.0 u/d
Reset pump settings from a TTD of 41 units

Low BGs with a Pattern

Excess TDD in a 72 yo Type 1 with an A1c of 6.1% who gives boluses after meals and then overcorrects highs

Get an Optimal TDD – Stop Frequent Highs Next

Raise the TDD with the 5 and 6 Rules:
Raise the TDD by 5% to lower an A1c by 1%
Or by 1% to lower average BG by 6 mg/dL
Current BG – Target BG = % rise in TDD

Example: Amy’s avg TDD is 40 u/day, avg BG 200 mg/dL (few lows, goal = 140 mg/dL):
200 mg/dL − 140 mg/dL = 60 mg/dL
60 mg/dL ÷ 6 = 10% rise in TDD
40 units x 1.10 = 44 units a day

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For High BGs, Optimize the TDD!

From the 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 – They can help you interpret them!
For High BGs, Optimize the TDD

From an avg BG:
53 yo female
TDD = 36 u
Avg BG = 190

190 – 140 = 50
= 8.3%

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

TDD = 39 u
an 8.3% increase

Derive Pump Settings from an Optimal TDD

Basal insulin = ~ Half of the TDD (Lower in Japan?)

CarbF = \( \frac{5.7 \times \text{Wt(kgs)}}{\text{TDD}} \) or \( \frac{2.6 \times \text{Wt(lbs)}}{\text{TDD}} \)

CorrF = \( \frac{1960}{\text{TDD}} \)

CorrF is inversely related to TDD and to avg. BG
A smaller CorrF is required for someone in poor control


Use Decision Support Software to Select Pump Settings

JD is a 20 yo DM1 college student referred to clinic.
Wt 84 kg (180 lb), TDD = 80 u (78-83 u/day), avg BG = 194 mg/dL.

- Basal rate: 1.8 u/hr
- CarbF 10
- CorrF 45
- DIA 4 hrs
- A1c 8.4%

Don’t use “magic” numbers!

Improved Outcome From Decision Support Suggestions

JD’s Pump Settings:

<table>
<thead>
<tr>
<th>Original</th>
<th>New</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDD</td>
<td>80 u</td>
</tr>
<tr>
<td>Basal rate</td>
<td>1.8 u/hr</td>
</tr>
<tr>
<td>CarbF</td>
<td>10</td>
</tr>
<tr>
<td>CorrF</td>
<td>45</td>
</tr>
<tr>
<td>DIA</td>
<td>4 hrs</td>
</tr>
<tr>
<td>A1c</td>
<td>8.4%</td>
</tr>
</tbody>
</table>


Select & Improve Pump Settings with Decision Support Software

Enter Your Information:

Settings For Target BG

- Units: English
  - Weight: 180 lbs
  - Avg TDD: 80 u/day
  - Current Avg BG: 164 mg/dL
  - Target Avg BG: 140 mg/dL

Submit

www.opensourcediabetes.org

APP Study – Pump Settings Often Wrong

Only 40% of CarbFs have expected value
People prefer “magic” numbers – 5, 10, 15, and 20 g/unit.
Formulas provide accurate settings – > far better than WAG!

Carb Factors Found In 405 Pumps

R^2 = 0.403

<table>
<thead>
<tr>
<th>Carb settings</th>
<th>found in pumps</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>20</td>
<td>25</td>
</tr>
</tbody>
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Submit

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**Which Way Do You Adjust Settings?**

<table>
<thead>
<tr>
<th>13.4 Which Way Do You Change Your Pump Settings?</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you are having</td>
</tr>
<tr>
<td>Frequent lows</td>
</tr>
<tr>
<td>Frequent highs</td>
</tr>
</tbody>
</table>

Smaller factors = larger boluses

**APP Study – Doses that Successful Pumpers Use**

<table>
<thead>
<tr>
<th>Insulin Source</th>
<th>% of TDD</th>
<th>Interquartile Range (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal</td>
<td>47.8%</td>
<td>39.6% to 54.9%</td>
</tr>
<tr>
<td>Carb Boluses</td>
<td>43.1%</td>
<td>35.6% to 51.2%</td>
</tr>
<tr>
<td>Corr Boluses</td>
<td>9.0%</td>
<td>6.2% to 11.3%</td>
</tr>
</tbody>
</table>

Corr: Rule Number* = (160 mg/dl per u) (IQR = 141.3 to 215.1)

* Corr Rule Number = Avg Carb x Avg TDD


**Does Basal Percentage Differ in Japan?**

- Average basal percentage of the TDD in most US/European studies is 48 to 52%, although individuals vary.
- In a hospital-based study of 35 Japanese Type 1 patients with an average age of 40, Dr. Kuroda et al found an average basal need of 27.7% +/- 6.9% (16.6% to 43.9%).
- In a younger Japanese population with an average age of 16, Dr. Hashimoto found an average basal need of 35% with a strong association between basal requirements and dietary fat intake

(p < 0.001, R^2 = 0.22).


**Basal Tips – Avoid Over-Steering**

- Basal rates usually remain similar through the day, such as between 0.75 to 1.0 u/hr
- Adjust basal rates early
  - by 0.025 to 0.1 u/hr 2 hours before the glucose starts to rise or fall,
  - or 5-8 hours before high or low readings happen

**Clever Pump Trick – Bolus Early To Stop Meal Spikes**

- Figure shows Regular insulin injected 0, 30, or 60 min before a meal
- Normal glucose profile shown in shaded area
- Best glucose occurred with 60 minute bolus – but too risky!!!
- Bolus 15-30 min before meals – the best-kept secret for better control


**Clever Pump Trick – Get the Right Number of Carbs for a Low**

1. **No BOB:** 1 gram for each 4.5 kg (~10 lbs) of weight
2. **With BOB:** Add grams = BOB* x CarbF

**Example:** Amy’s BG = 52 mg/dL with 2u of BOB (CarbF = 10 g/u)
- At 45 kgs (100 lbs), she needs 10 grams for the low glucose
- **Plus** 2u BOB x 8 gram/u = 16 grams to offset BOB
- Amy needs 10 g + 16 g = 26 grams for this low

* DIA time must be accurate
Bolus on Board / Insulin Stacking

Bedtime BG = 180 mg/dL – is there an insulin or a carb deficit?

Duration Of Insulin Action in the Body
Accurate boluses require an accurate DIA

Bedtime BG = 180 mg/dL

Insulin Action Time ≠ Duration of Insulin Action

Fig. 1  Insulin Action Time

Glucose Infusion (mg/kg/min)
Basal Delivery Suppressed

Fig. 2  Duration of Insulin Action

Glucose Infusion (mg/kg/min)
Basal Delivery Maintained

Insulin Stacking Is Common

Of 201,538 boluses, 65% were given within 4.5 hrs of a previous bolus. Some BOB remains in at least 65% of all boluses.

A Short DIA Hides BOB & Causes Unexplained Hypoglycemia

This is how much BOB a pump thinks is left 3 hrs after a 16-unit bolus using these DIA times:

When DIA is set to:

<table>
<thead>
<tr>
<th>3 hr</th>
<th>4.5 hr</th>
<th>5.0 hr</th>
<th>5.5 hr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pump’s estimate of Insulin On Board</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated BOB is:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 u</td>
<td>2.5 u</td>
<td>3.4 u</td>
<td>4.0 u</td>
</tr>
</tbody>
</table>

39 yo woman has 2 lows on Friday and another on Saturday from hidden insulin stacking caused by her short DIA time of 3 hours.
Avoid Excess Bolus Recommendations

4.35 u of BOB remain from a bolus given 3 hrs earlier – is 2.9 more units really needed for a bedtime snack?

Infusion Set/Cannula Options

<table>
<thead>
<tr>
<th>Type</th>
<th>Recommended use</th>
<th>Time of use in US</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slanted Teflon</td>
<td>3 days</td>
<td>3.4 days*</td>
</tr>
<tr>
<td>Straight-In Teflon</td>
<td>2 days</td>
<td></td>
</tr>
<tr>
<td>Straight-In Metal</td>
<td>3.7 days*</td>
<td></td>
</tr>
</tbody>
</table>


Infusion Set Failure Is Common

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

Auto-Inserters

- Inset/Mio
- Accu-Chek Link Assist
- Inset/Sure-T
- Quick-Serter
- Cleo
- Omnipod

Low Failure Infusion Setups

- Contact Detach/Sure-T
- Comfort/Silhouette
- Contact Detach/Sure-S

Ideal for small child, pregnancy, decreased dexterity, and normal people:
- Place clear adhesive (IV3000, Tegaderm) on top of Sure-T/Contact Detach infusion sets
- Place 1" tape (Transpore, Durapore, etc) on infusion line of a Teflon set to reduce site irritation and line tugs that cause leaks

Clever Pump Trick – Super Bolus to Stop Meal Spikes

Super Bolus – use temp basal reduction to shift part of the next 2 to 3.5 hrs of basal insulin into a bolus

Less spiking + less risk of a low later

1. Done by user, not the pump

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