THE OTHER 50% OF TDD: PRANDIAL INSULIN

Alison Evert, MS, RD, CDE
NUTRITION THERAPY & INSULIN REQUIRING DIABETES
Participant will be able to:

- List two formulas or “Rules” used to determine the prandial insulin dose.
- Describe two eating pattern or food habits that may evolve over time after following long-term adherence to the carbohydrate counting meal-planning approach.
REFERENCES

- Refer to Handout
- June 2012 – American Diabetes Association’s – *Guide to Nutrition Therapy for Diabetes*
It is true – nutrition therapy recommendations change over time based on new research and evidence-based recommendations.

As time goes by – new recommendations may contradict previous recommendations.

Many of our colleagues may not understand the principles of diabetes nutrition therapy or emphasize its importance.
In our society – food has many purposes in addition to meeting biological needs.

When we ask our patients initiate basal-bolus insulin therapy, we are asking them to literally learn how to “think like a pancreas.”

Long-term application of basal-bolus insulin therapy is a lot of work.

Adherence over time is difficult.
HEALTHY EATING PATTERNS
KEY ELEMENT IN DIABETES MANAGEMENT - GOALS

• To establish optimal glucose and lipid control
• To help prevent complications such as CVD
• To address individual needs, taking into account, taking into account personal and cultural preferences and willingness to change.
• To maintain the pleasure of eating by only limiting food choices when indicated by scientific evidence

American Diabetes Association. Diabetes Care. 31(Suppl 1):S61-S78,
• Diabetes medications can lower A1C.
• Diabetes nutrition therapy can lower A1C, too.
• Nutrition therapy trials and outcome studies:
  ✧ Type 1 diabetes: 1% reduction in A1C
  ✧ Type 2 diabetes: 1-2% reduction in A1C

Without a strong nutrition component, most treatment plans will fall short

John Bantle, MD
• What guides your practice?
Carbohydrate intake and available insulin are the primary determinants of postprandial glucose levels.

Management of carbohydrate intake is the primary strategy for achieving glycemic control.

• Adjusting prandial insulin doses to match desired carbohydrate intake (using a meal-planning approach such as carbohydrate counting) in people with type 1 diabetes results in improved glycemic control.

• For individuals using fixed daily insulin doses, carbohydrate intake on a day-to-day basis should be kept consistent with respect to time and amount.

CARBOHYDRATE COUNTING

- One of the more popular diabetes meal planning approaches
- Used in the landmark Diabetes Control and Complications Trial in type 1 diabetes
- Used outside the United States; the Dose Adjustment for Normal Eating (DAFNE) randomized, controlled trial using Flexible Intensive Insulin Therapy or “FIIT”

Teach:

- What “IS” a carbohydrate food
- Glycemic Impact of Macronutrients: Carbs, Protein & Fat
- Carbs - most dramatic impact on BG in 1-2 hours the form of the carb - liquid vs. whole food
DIABETES NUTRITION – BASICS

• Protein - doesn’t impact blood glucose too much - although protein is a potent stimulant of insulin secretion
• Fats - delay the emptying of the stomach for several hours
GOAL – TEACH SOME TYPE OF METHOD FOR MEAL PLANNING

- AKA - “Carbohydrate Awareness”
- Carbohydrate Counting
- Exchange System
- Glycemic Index
- WAG Method
- Small, Medium, Large Approach
Patients must also understand how their insulin works.

Need to understand integration of food and prandial insulin!

- Onset: 10-15 minutes
- Peak: 1-2 hours
- Duration: 4-5 hours
PUTTING IT TOGETHER - match amount of carb to action of insulin

- Peak postprandial glycemic excursion – 1 to 2 hours
- Rapid-acting insulin in peaking in – 1 to 2 hours
MATCH YOUR INSULIN TO YOUR CARBS
For people with type 1 diabetes or insulin-requiring type 2 diabetes when using flexible intensive insulin therapy: recommend dosing algorithms

- Prandial dosing: Insulin-to-carbohydrate ratio (ICR)
- Blood glucose correction: insulin sensitivity factor (ISF)

PRANDIAL DOSING ALGORITHMS

- Prandial and blood glucose correction algorithms: rules and formulas
- Dusseldorf model in the 1970s: basis of the DAFNE program in the 1980s, flexible intensive insulin dosing
- WHERE DO THE COMMONLY USED DOSING ALGORITHMS COME FROM IN THE US???

AIM FORMULAS

- Davidson and Bode in the 1980s: large endocrine practice, type 1 diabetes, using pumps
- Accurate Insulin Management formulas based on total daily dose (TDD) of insulin
- Mathematical models statistically correlated based on data from large endocrine practice (2 groups analyzed: well-controlled test group [n=167], A1C ≤ 7%, on pump >180 days and control group [n=209], A1C > 7%, on pump <180 days)

CIR = 2.8 \times \text{BWlb/TDD} \\
(\text{BWlb} = \text{body weight in pounds})

For example: if TDD = 50 units

\[2.8 \times \frac{180 \text{ lbs}}{50} = 10\]

CIR = 1:10

1 unit of rapid-acting insulin will “match” 10 grams carbohydrate

AIM FORMULAS
BG CORRECTION INSULIN

CF = 1700/TDD

For example: if the TDD = 34 units
1700/34 = 50 mg/dL
CF = 1:50

1 unit of rapid-acting insulin will “lower” blood glucose 50 mg/dL

TDD = 0.24 x BWlb

Basal Units/day = 0.47 x TDD

500 Rule and 1800 Rule - Using rapid-acting insulin
(Walsh 2003)

450 Rule and 1500 Rule – Using regular insulin
(Walsh 1994)

If using the 500 Rule: 500/TDD

For example: if the TDD = 50 units
500/50 = 10
CarbF = 1:10

1 unit of rapid-acting insulin will “match” 10 grams carbohydrate

If using the 1800 Rule
1800/TDD – rapid-acting insulin

For example: if the TDD = 36 units
1800/36 = 50 mg/dL
CorrF = 1:50

1 unit of rapid-acting insulin will “lower” blood glucose 50 mg/dL

TDD – based on five step process – dose based on process of SMBG, varies based on weight, levels of fitness and stress, and special conditions.

Basal Dose/day = 0.50 x TDD

Howorka Algorithms for Flexible Insulin Therapy

(adapted for 20 gram carbohydrate portions at mealtime)

NOTE: blood glucose units are in mmol/L to convert to mg/dL multiply mmol/L x 18

Insulin sensitivity coefficient $K = \frac{\text{current total insulin requirement}}{\text{theoretical (prandial + basal) insulin}}$

Theoretical basal insulin requirement = $0.35\text{U/kg (body weight)}$

Theoretical prandial insulin requirement = $\left[\frac{\text{average daily carbohydrate (g)}}{20}\right] \times 2.2$

Prandial insulin and correction of abnormal blood glucose (BG) values
Insulin requirement for one 20 g carbohydrate portion = $2.2 \times K$

One unit extra short-acting-insulin BG-lowering effect: $\Delta BG \text{ (mmol/L)} = -1.94 \times \frac{1}{K} \times 60/\text{kg}$

BG increase induced by one 20g carbohydrate portion: $\Delta BG \text{ (mmol/L)} = 4.44 \times 60/\text{kg}$

Basal insulin requirement = $0.35\text{U/kg} \times K$

An additional algorithm for protein/fat was proposed by Howorka (1990) for meals low in carbohydrate: $0.45\text{U/100kcal protein or fat} \times K$. 
HOW DO WE CONFIRM PRANDIAL AND CORRECTION INSULIN ALGORITHMS AT THE UWMC DIABETES CARE CENTER?

- START WITH ALGORITHMS
- Record keeping to confirm!
- Food intake (Carb = grams)
- Self-monitoring of blood glucose (SMBG) records
- Insulin doses
- 3-4 days at a time
IC Ratios

1 unit of rapid-acting insulin will “match” a certain number of grams of carbohydrate

Clinical Experience:

- Toddlers—1:30 to 1:40
- Children—1:15 to 1:20
- Teenagers—1:8 to 1:10
- Adults—1:10
- Obese—1:1 to 1:5
PRANDIAL INSULIN: DOSE DEPENDS ON THE INDIVIDUAL

ISF Ratios

How much does 1 unit rapid-acting insulin drop BG mg/dL.

Clinical Experience:

- Toddlers—1:75 to 1:100 mg/dL
- Children—1:50 to 1:75
- Teenagers—1:25 to 1:50
- Adults—1:30 to 1:50
- Overweight/Obese—1:10 to 1:30
The American Diabetes Association’s 2011 Standards of Care noted that “some surrogate measures of vascular pathology, such as endothelial dysfunction, are negatively affected by postprandial hyperglycemia.”

Postprandial hyperglycemia may be related to the production of free radicals, which in turn can induce endothelial dysfunction and inflammation.

Dysglycemia of patients with diabetes is the sum of the two following disorders:

- Sustained chronic elevations of glucose
- Glycemic variability with postprandial excursions and downward changes
- Glucose variability is also associated with activation of oxidative stress, one of the main mechanisms leading to complications

Postprandial hyperglycemia can be caused by a mismatch between prandial insulin and carbohydrate intake.

Our patients using continuous glucose monitoring see this happening in real time.

Treatment strategies:

- Nutrition therapy: patients need to know how many carbohydrates will be consumed to correctly “match” their prandial insulin dose
- Adjusting the timing of prandial insulin doses
• DeWitt and Hirsch described the term “lag time” in their scientific review of outpatient insulin therapy for type 1 and type 2 diabetes.
• It’s on the package insert.
• Three recent small studies recommend injecting prandial insulin 15-20 minutes before the start of the meal.

### LAG TIMES BASED ON DEGREE OF PREPRANDIAL HYPERGLYCEMIA

<table>
<thead>
<tr>
<th>Pre-Meal Blood Glucose (mg/dL)</th>
<th>Lag Time (minutes)</th>
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<tbody>
<tr>
<td>80-99</td>
<td>0</td>
</tr>
<tr>
<td>100-199</td>
<td>10-20</td>
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<tr>
<td>200-299</td>
<td>20-30</td>
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<td>≥300</td>
<td>30-40</td>
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• 3 studies exploring food and eating practices of PWD – type 1 over time
• UK/Australia – Flexible Intensive Insulin Therapy (FIIT) – as a part of the DAFNE course
• Lawton, Rankin, Casey – 2011

TIPS FOR KEEPING OUR LONG-LIVED PATIENTS ENGAGED

- Lawton collected information after 12 months
- Greater rigidity in food choices over time
- Simplify/limit food choices to make carb estimation easier
- Reliance on packaged foods vs fresh food
- Leading to: Increased intake of saturated fat and sodium
- Increased consumption of low carb/no carb foods to reduce/eliminate prandial dose
- Despite education – fear of hypo and anxiety about miscalculation of prandial dose

Rankin collected information after 12 months. Participants generally preferred FIIT over “fixed” insulin dosing. Many made adjustments in their lives in order to sustain this method.

- Adjusted food intake by creating food habit routines or maintained fixed schedule.

Researchers suggest need to include interventions and strategies that can help PWD over time to follow FIIT long-term.

TIPS FOR KEEPING OUR LONG-LIVED PATIENTS ENGAGED

- Casey – collected information at 6 weeks, 6 and 12 months
- Participants at 6 weeks felt support from other participants such as sharing experiences was important helpful
- After 6 months – began to value support from HCP that focused on collaborative decision making
- 6 months – important timeframe, motivation at this point was lowest for many

TIPS FOR KEEPING OUR LONG-LIVED PATIENTS ENGAGED

- Gross - bolus calculator study with Medtronic Pump. Study findings:
  - Most diligently perform calculations when beginning FIIT
  - Adherence may become relaxed over time
  - Tendency to approximate carb content by using “standard” or “usual” pre-meal doses
  - Many were actually hesitant to take responsibility for increasing/decreasing prandial doses

DIABETES NUTRITION THERAPY & PUMPS
TRANSITIONING TO INSULIN PUMP THERAPY

• PWD that wants to transition to pump
• Learn to count or quantify carbs
• Check BGs over 4-6x/day
• Encourage use of bolus calculators
• After the basal rates are confirmed – evaluate ICR and ISF
• May need different ICR for different time periods.
OPTIMIZING USE OF INSULIN PUMP

• Is your patient using bolus calculator?
• Are they using it correctly?
• How can you tell?
• Download reports give us information that MDI can’t!
• Look at BG records.
### Blood Glucose Test Results

<table>
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<tr>
<th>DATE</th>
<th>Breakfast</th>
<th>Lunch</th>
<th>Dinner</th>
<th>Bed-Time</th>
<th>Overnight</th>
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<td>Before</td>
<td>After</td>
<td>Before</td>
<td>After</td>
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Odegard P S, Beach J R *Diabetes Spectr.* 21:100-111, 2008
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<th>Breakfast 05:00-09:00</th>
<th>MID-AM 09:00-11:00</th>
<th>Lunch 11:00-14:00</th>
<th>MID-AFTERN 14:00-17:00</th>
<th>Dinner 17:00-20:00</th>
<th>MID-EVENIN 20:00-22:00</th>
<th>BEDI 22:00-00:00</th>
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<td>43 %</td>
<td>12 %</td>
<td>9 %</td>
<td>11 %</td>
<td>14 %</td>
<td>2 %</td>
<td>26 %</td>
<td>1 %</td>
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<td><strong>Maximum</strong></td>
<td>207</td>
<td>171</td>
<td>196</td>
<td>220</td>
<td>136</td>
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<td>170.50</td>
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<td>103</td>
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<td>1</td>
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<td><strong>Above Target</strong></td>
<td>19 %</td>
<td>8.20 %</td>
<td>3.45 %</td>
<td>5.53 %</td>
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<td>2.0 %</td>
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<td><strong>On Target</strong></td>
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<td>33.67 %</td>
<td>10.45 %</td>
<td>5.41 %</td>
<td>7.100 %</td>
<td>2.44 %</td>
<td>14.100 %</td>
<td>1.60 %</td>
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<td><strong>Below Target</strong></td>
<td>5 %</td>
<td>2.13 %</td>
<td>2.9 %</td>
<td>1.6 %</td>
<td>1.0 %</td>
<td>0.50 %</td>
<td>16.0 %</td>
<td>0.18 %</td>
<td>22</td>
</tr>
</tbody>
</table>

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CGM TECHNOLOGY

Slide courtesy of DexCom
Hourly Statistics from 1/3/2008 12:00 AM to 1/17/2008 12:00 AM. ## With all days of the week. ## With all times of the day. ## With all glucose values.
ESTIMATION OF CARB INTAKE

• If your patient can’t count carbs, the bolus calculation won’t be correct.
• We do know that estimations can work, but they need to be fairly accurate.
• Smart (2009) – ranges
• Sharpria (2010) – Mean % error greater with larger loads carb

“INSULIN ON BOARD”
TIPS TO OPTIMIZE CONTROL

• Insulin On Board – key concept for our patients to understand.
• Give specific guidelines about how often your patient can administer a correction bolus.
• Remind your patient that 40-50% bolus still active after 2 hours.
• Discuss bolus coverage for extra food eaten between meals.
• If continually over-riding bolus estimate – may need to adjust settings.
ART & SCIENCE OF PRANDIAL DOSING

• Bolus insulin adjustments based on experience, more of an “art” than science-based!
• Not a lot of evidence available to guide practice
• Based on information from SMBG and CGM data meals with larger and varying amounts of protein and fat are found to prolong PP BG up to several hours
• Suggesting – delayed in absorption of glucose and additional prandial insulin may be needed
Pump manufacturers developed ability to deliver prandial bolus in an attempt to “match” the circulating insulin levels to the rate of glucose absorption from the gut in order to minimize PP BGs.

Variable Bolus Features:
- Normal
- Extended or Square-Wave
- Combination or Dual-Wave
Skills necessary to use variable bolus features:

Does PWD understand how macronutrients and action of insulin impact blood glucose control?

Besides being able to “count carbs”, do they know what foods are high in fat/protein, where to find this information?

Does your patient know the feature(s) works?

Are they willing to perform pre/post BG?
VARIABLE BOLUS FEATURES

RESEARCH

• Literature Review: PubMEDLINE
• Search criteria: studies after 1999, human, English language
• 7 articles, 1 abstract - 4 youth/4 adult
• Excellent Review Article – Heinemann
• Limitations: small sample size, pre-meal BGs varied, only 2 confirmed basal rates prior to study, only 1 evaluated c-peptide levels, 2 did not specify type of insulin, 1 used Regular

Heinemann L: J Diabetes Sci Technol. 3:1490-1500, 2009
Chase/Lee/Jones – evaluated different bolus delivery methods [NL bolus vs. DW bolus] with pizza meals (> 36% fat) to reduce PP BG

Chase: n=9 youth with type 1 used CSII
Lee: n=10 adults with type 1, used CSII + CGM
Jones: n=24 adults with type 1, used CSII + CGM

Lee SW et al: *Diabetes Nutr Metab.* 17:211-216, 2004
Findings:

- Using DW bolus – helped to reduce postprandial BG excursion
- % SW/extended bolus varied from 2 to 8 hours
- Amount given as “normal” bolus at beginning of the meal varied from 30 to 70 %
• O’Connell - randomized crossover trial
• Findings:
• DW bolus before low GI meal reduced PP AUC by up to 47% when compared to NL bolus

VARIABLE BOLUS FEATURES

RESEARCH – NOVEL PRANDIAL BOLUS

- Pankowska 2009/2011 – cross-sectional clinical trial & randomized control trial
- Evaluated use of DW or SW bolus on metabolic control
- 2009, n=499, youth with type 1, used CSII, insulin type?
- Uncontrolled evaluation of data collected in OP clinic during routine office visit
- 2011, n=24, youth with type 1 on CSII.

NOVEL ALGORITHM FOR PRANDIAL BOLUS

• 10 gm carb = 1 carbohydrate unit = 1 CU
• Carb content of meal is determined by dividing gm carb by 10, use NL bolus to deliver
• Fat-protein unit (FPU) is added to prandial dose
• FPU = 100 calories of fat and/or protein that is covered by 1 unit of RA analog
• Grams fat and/or protein consumed converted to calories (1 g fat=9kcal, 1 g pro=4kcal)

NOVEL ALGORITHM FOR PRANDIAL BOLUS

- FPU is administered using SW bolus which is extended based on number of FPUs
  - 1 FPU = SW bolus extend over 3 hr (100 kcal)
  - 2 FPU = SW bolus extend over 4 hr (200 kcal)
  - 3 FPU = SW bolus extend over 5 hr (300 kcal)
  - > 3 FPU = SW bolus extend over 8 hr (> 300 kcal)
- Due to lengthy calculations developed on-line software program – includes bolus calculator and nutrition database

Pankowska/Blazik Findings:
Use of FPU results in significantly lower PP BGs after “main” meals were observed
DO NOT use Diabetics software in conjunction with pump bolus calculator
Research group in final research stage of safety analysis of software program
Diabetics software DOES NOT take into account current BG, target BG, IOB
? Applicability of nutrition database with US foods

WHEN TO USE COMBINATION BOLUS?

CLINICAL PRACTICE RECOMMENDATIONS

• Consider meal composition:
  * Creamy, cheesy, gooey or deep-fat fried
• Almost any meal consumed away from home
• Over 25 to 30 grams of fat if nutrition info available
• Protein serving larger than your palm
• Thanksgiving or other type of holiday meal
• People who use a lot of oil or fat in meal preparation
VARIABLE BOLUS FEATURES

CLINICAL PRACTICE RECOMMENDATIONS SINCE 2002

• Start with:
  • 50% as “normal” bolus
  • 50% extended using over time (SW)
  • Start with 1½ to 2 hours to extend bolus
  • The fattier the meal, the longer you need to extend bolus, may be 3 or more hours.
  • If BG higher at start of meal, give correction and carb as “normal” bolus
  • May need a unit or two more more for higher fat and/or protein meal and add this to extended bolus
IN CONCLUSION

- Few RCT comparing pump to MDI
- Little research to about how to best teach and utilize CSII to optimize glycemic control
- Future – hopefully well-powered meal related studies conducted using CSII and CGM
- Until then prandial dosing remains an “Art”
- AADE 2009 – Insulin pump guidelines of successful outcomes
- Hirsch 2010 – practical pearls

THANK YOU!

“Our food should be our medicine, and our medicine should be our food.”

*Hippocrates, 400 BC*