THE ACCURATE INSULIN DECISIONS (AID) PROGRAM
TOOLS TO PROMOTE SHARED DECISION MAKING FOR MEALTIME INSULIN

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disclosures

Member of the A.I.M. committee
Washington D.C. 2012
Disclaimer/Limitations

- Not about Science but based on review of the evidence
- Not “stump the expert” cases
- Not a “one sizes fits all”
- Is a “good tool with great potential”

About Care Delivery
(“the vehicle by which technical care is implemented”)

- PCP cases (showcase the tools and ways to use)
- Missing evidence or Clinical considerations (individualization of glycemic targets)
Supporters: Lilly, Novo Nordisk, Sanofi Aventis

Specific Target for Mealtime Insulin Initiation

Premise: The current recommendations were not working

Proposal: PCP-Centered/ Patient-Centered approach

The tools and the process of developing them was:

An exercise in Collaborating and Contextualizing

Results: A simple unified approach to the limitations of basal insulin and initiation and titration of analog insulin
Participating Organizations

The Endocrine Society
- Carol Greenlee, MD (Chair)
- Robert Gabbay, MD, PhD
- James Rosenzweig, MD
- Meredith Dyer

Hormone Health Network
- Margaret Eckert-Norton, NP

American College of Physicians
- Dave O’Dell, MD
- Daisy Smith, MD

American Osteopathic Association
- Jay Shubrook, DO

American Diabetes Association
- Neil Skolnik, MD, Charles Rattner MD

American Association of Diabetes Educators
- Carol Manchester, MSN,

American Pharmacists Association
- Magaly Rodriguez de Bittner, PharmD, CDE

Diabetes Nation
- Richard Aguilar, MD, Eden Miller, DO
- Kevin Miller, DO
A.I.M. (Advancing Insulin Management)

Committee was formed to answer the questions

- What is the scope and limitations of basal insulin
- When should analog insulin be added to a patient treatment plan
- What are the options to adding analog insulin
- How can titration and advancing insulin be best communicated to patients and providers
The Paradigm of Diminishing Returns

- **Endocrinologist/ Expert/ or self taught PCP**
  - Complexity
  - Time/ Staff/ Safety
  - Perceived barriers patients/ insurance/ societal

- **PCP Communicates to the Patient**
  - Complexity
  - Time
  - Confusion/ Misperceptions
  - Safety/ Fear

- **Patient successfully manages diabetes with Insulin**

  How diluted is the message by now?
Current T2DM Care Paradigm

90% of patients with T2DM cared for in Primary care setting

- <25% referred to specialists
  - Major reason for referral: complications of diabetes (gastroparesis, etc), difficulty with insulin therapy
- PCP serves as primary provider of diabetes education
  - Low use of CDE resources
    - <25% of patients counseled by CDE annually
    - 24% have no access to CDE in geographic region

Major obstacles to optimal diabetes care cited by PCPs
- Patient non-adherence “Non-compliant”
- Insufficient time / Insufficient staff

Endocrine Practice Dec 2011; Beaser et al
Who and Where is Insulin Started?

- Who is more apprehensive about starting insulin? **Providers**

- What is the mostly common insulin initiated? **BASAL**

- What Specialty Initiates Insulin the most? **Primary Care**

- Where do patients often get their first ever injection of insulin? **Hospital**
Obligation to be a “good” patient. Fear of being labeled a difficult patient. Threat of being expelled if fail to comply (“If you don’t ----, I can’t take care of you any more”)
Another viewpoint.

“Non-adherence may be the means by which a patient may express their preferences when their values, goals and preferences are not incorporated into the treatment decisions during the encounter.” Shah et al, Med Care 2010;48

It can also represent frustration, lack of understanding, negativism surrounding the disease, or down right depression — Eden Miller
Almost all decisions related to diabetes are, in fact, made by the patients themselves!
Patient Centered Care

“...care that is respectful of and responsive to individual patient preferences, needs and values and ensuring that patient values guide all clinical decisions.” Institute of Medicine 2001

“My goal as a provider is to turn patients into experts on their own disease ~Eden Miller “

Treat others how you want to be treated, and give them a personalized prescription for care.
Clinician as a Coady Cheerleader!
“Psychological Insulin Resistance”

ONE THIRD of patients prescribed insulin either did not fill the first prescription or had zero refills (“non-adherence”)

- Planned to change health behaviors instead / did not believe insulin needed
- Injection phobia / pain
- Negative impact on work / social life
- Inconvenience
- Belief that people who needed insulin had not taken care of themselves
- Fear that taking insulin could cause blindness, renal failure, amputations
- Fear of hypoglycemia
- Inability to understand materials or how to adjust insulin (literacy, numeracy)
- Lack of insulin self management training

“Primary adherence for insulin may be improved through better provider communication, shared decision making and insulin self-management training.” Karter et al; Diabetes Care 33: 733-735
Our new trick: Balancing Care Delivery

Efficient yet Effective

Standardized yet Individualized

Accountability yet Patient-Centered
Reconciling...

“Evidence Based” medicine

“Preference Based” Medicine

Bridge By Shared Decision Making

- Asking focused questions
- Finding the evidence
- Performing critical appraisal
- Making a decision
- Evaluating performance

Quill & Holloway, NEJM 2012

- Proper setup and introduction
- Eliciting values and preference and learning about goals
- De-biasing strategies and responding to emotions
- Making recommendations and seeking consensus
- Assuring nonabdonment and follow up
Contextualizing Care

Shared Decision Making

Patient-Centered Decision Making

‘The process of adapting best evidence to the care of the individual patient’

Having a conversation, coming to agreement
Ultimate Goal

Can we develop tools specifically for Mealtime Insulin that:

- Help bridge the practical knowledge gap and practice barriers (complexity, time) for clinicians?
- Provide decision aids that translate into Action plans for patients?
- Help "focus" the conversation regarding insulin, specifically mealtime insulin, for more effective time spent in shared decision making?

Importance and Confidence

Take best evidence and contextualize it through collaboration
THE ACCURATE INSULIN DECISIONS (AID) PROGRAM
“Insulin is not the enemy it is the misuse of insulin that is the enemy.”
Richard Aguilar
Over View of A.I.D.

http://www.accurateinsulin.org/
Helping patients and their doctors manage diabetes together

Starting and Adjusting Mealtime Insulin

For Patients
- Is Mealtime Insulin Right for Me?
- Settings Goals & Keeping Your Body Healthy
- Starting Premixed Analog Insulin
- Starting Mealtime Insulin

For Doctors
- Deciding Whether to Transition Your Patient to Mealtime Insulin
- Starting Premixed Analog Insulin
- Starting Mealtime Insulin
- Is the Mealtime Insulin Approach Working?

About This Website
- About This Website
STEP ONE: IS THE GOAL APPROPRIATE FOR THE PATIENT?

If your patient continues to have trouble controlling their blood sugar, first evaluate whether the blood sugar and A1c goals are appropriate.
Determining whether your patient could benefit from mealtime insulin can be difficult. While there are a number of indicators that may signal that it’s time for your patient to move beyond basal insulin, there are many factors to consider when deciding to make this transition. The following decision support tool will help you think through whether this treatment approach would help your patient.
IS THE GOAL APPROPRIATE FOR THE PATIENT?

If your patient continues to have trouble controlling their blood sugar, first evaluate whether the blood sugar and A1c goals are appropriate.

Physicians should individualize goals with the patient for those with medium risk for hypoglycemia using clinical judgment and patient agreement. Patients with end-stage or terminal co-morbid conditions should be maintained at glucose levels that prevent catabolism and symptoms, such as an A1C >8% which corresponds with an estimated average daily blood sugar of 183mg/dL.

A number of factors should also be considered when setting an appropriate A1c goal for someone with type 2 diabetes. It should also be noted that A1C is not a perfect indicator as it does not reveal glycemic variability or other factors that may impact risk for complications. The graph below can help you to determine whether your patient’s goal is appropriate based on risks for hypoglycemic events, age, comorbidities, and other lifestyle factors. A more in-depth examination of recommended A1c targets based on clinical characteristics can be found in the following graph.

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### Goals for Patients at Low Risk for Hypoglycemia

<table>
<thead>
<tr>
<th>Pre-Meal</th>
<th>Post-Meal</th>
<th>Bedtime</th>
<th>A1C</th>
</tr>
</thead>
<tbody>
<tr>
<td>70-130</td>
<td>&lt;180</td>
<td>&lt;180</td>
<td>6.5%-7.0%</td>
</tr>
</tbody>
</table>

### Goals for Patients at High Risk for Hypoglycemia

<table>
<thead>
<tr>
<th>Pre-Meal</th>
<th>Post-Meal</th>
<th>Bedtime</th>
<th>A1C</th>
</tr>
</thead>
<tbody>
<tr>
<td>100-180</td>
<td>&lt;250</td>
<td>&lt;250</td>
<td>7.0%-8.0%</td>
</tr>
</tbody>
</table>

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**Most Intensive**

- 6.0%

**Least Intensive**

- 8.0%

**Psychosociocconomic Considerations**

- **Most Intensive**: Highly motivated, adherent, knowledgeable, excellent self-care capabilities, and comprehensive support system
- **Moderate**: Less motivated, nonadherent, limited insight, poor self-care capacities, and weak support systems
- **Least Intensive**:

**Hypoglycemia Risk**

- Low
- Moderate
- High

**Patient Age, y**

- 40
- 45
- 50
- 55
- 60
- 65
- 70
- 75

**Disease Duration, y**

- 5
- 10
- 15
- 20

**Established Vascular Complications**

- None
- Early microvascular
- Cardiovascular disease
- Advanced microvascular

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*Note: These goals are not evidence-based but are consensus opinion. Goals for any patient should be individualized further based on patient preference and clinical judgment.*

*Pre-meal goals for patients with a high risk for hypoglycemia may vary and should be individualized.*
**Step 2: Is Mealtime Insulin an Appropriate Approach?**

Use the following checklist to determine if your patient may benefit from mealtime insulin.

1. Is the patient’s A1C above their individualized goal? □ Yes □ No
2. Is the patient’s basal insulin dose at or above 0.5 U/kg? □ Yes □ No
3. Is the patient’s fasting blood sugar at goal, but A1C still high? □ Yes □ No
4. Is the patient’s post-meal blood sugar >180 for low risk patients or >250 for high risk? □ Yes □ No

The more yes responses, the more likely it is that your patient would benefit from mealtime insulin. However, before you make this transition, consider whether the basal insulin dose is adequate and whether there may be problems with adherence to the treatment plan.

**Step 3: Is the Basal Insulin Dose Adequate?**

- Before deciding to move your patient to mealtime insulin, it is recommended that the patient first be on basal insulin.
- If the basal insulin dose is not yet 0.5-1.0U/kg, further titration of the basal insulin may be helpful before transitioning a patient to mealtime insulin.
- A simple approach is to have patients increase their basal dose by 1 unit each day until their fasting blood glucose is at goal.

**Step 4: Is the Patient Adhering to Their Treatment Plan?**

A few questions to consider asking your patient or assessing to determine if adherence is a problem.

- What insulin are you taking and when do you take it?
- Where do you take your shots and how do you rotate the sites?
- How often do you miss a shot?
- What went well? What were the problems?
- Have you had any problems with your diet and exercise plan?
- When did you last attend a diabetes education class and what did you find to be helpful?

If your patient is still not able to control their blood sugars after you have determined that their A1C goal and their basal dose are appropriate, evaluate whether the patient is adhering to the treatment plan. Review the patient’s blood glucose logs if available to assess fasting and post-prandial blood sugars and patterns that may indicate non-adherence.

Also assess if there are any superimposed factors (added glucocorticoids, etc.). If there are issues in these areas, it is recommended that you address them before moving beyond basal insulin.

For more information, visit www.AccurateInsulin.org
5 WHAT MEALTIME INSULIN OPTION WOULD BE BEST?

Once you determine that mealtime insulin is the appropriate approach, discuss with your patient whether basal/bolus therapy or pre-mixed insulin would be a better treatment option. Below are descriptions, along with the pros and cons, to help you and your patient think through what approach may be best.

### Basal + Bolus Insulin Therapy

- To start on basal (background) + bolus (mealtimes) insulin therapy, add rapid-acting insulin to the background insulin, starting with one dose at the largest meal.
- Background + rapid-acting insulin therapy is often the best choice for mealtime insulin in patients who have unpredictable schedules or who do not eat meals at the same time every day.

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background + rapid-acting insulin allows for greater flexibility. You can adjust your insulin intake to fit less regular schedules and to more/less carb intake.</td>
<td>Patients may need to take 2-5 injections each day depending on how many meals need mealtime insulin. Some people also split the long-acting insulin into morning and evening shots.</td>
</tr>
<tr>
<td>Studies have shown that adding just one mealtime dose of rapid acting insulin per day, given before the largest meal, improves glycemic control nearly as much as adding 2-3 doses per day*1.</td>
<td>When rapid-acting insulin is added at dinner time, this may result in lower bedtime blood glucose and this may necessitate a lower dose of background insulin.</td>
</tr>
<tr>
<td>It’s an easier transition for many patients because they are already on background insulin and they understand how insulin works.</td>
<td>There are two copays for basal/bolus insulin. One copay is for the background insulin and one copay is for the mealtime insulin. Patients will need to carry the insulin with them but the availability of pens has helped somewhat alleviate this concern.</td>
</tr>
</tbody>
</table>

### Premixed Insulin Therapy

- Premixed insulin is a combination of rapid or short-acting insulin with intermediate (NPH) insulin mixed into one bottle (vial).
- This combination can control blood glucose levels both after and between meals.
- It can be administered as 1 (before largest meal) shot per day but most commonly given as 2-3 injections per day (one dose before breakfast and one before dinner).
- It is often most effective to start premixed insulin with the patient’s largest meal.

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premixed insulin has only one copay and is best suited for a patient with a fairly predictable schedule with regular meals and with a lower risk of hypoglycemia.</td>
<td>Patients must eat regular meals or they will be at a greater risk for hypoglycemia.</td>
</tr>
<tr>
<td>Patients often need fewer shots (1-2 per day) than basal/bolus therapy.</td>
<td>Nocturnal hypoglycemia may be a greater concern with pre-mixed insulin.</td>
</tr>
<tr>
<td>Premixed R &amp; N has the lowest cost.</td>
<td>Premixed Regular &amp; NPH has a greater risk for hypoglycemia.</td>
</tr>
<tr>
<td>Premixed Humalog 50/50 is an option for patients who need larger doses of the rapid acting component because of high carbohydrate meals.</td>
<td>There is an increased need for between meal snacks.</td>
</tr>
</tbody>
</table>

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This program was supported by educational grants from Lilly USA, LLC, Novo Nordisk Inc., and sanofi-aventis U.S.
**HOW TO START MEALTIME (BOLUS) INSULIN**

Add 4 units of mealtime insulin to the basal dose before the largest meal or the meal that is agreed upon.

**HOW TO ADJUST YOUR BOLUS INSULIN**

<table>
<thead>
<tr>
<th>When Mealtime Insulin Is Taken</th>
<th>When To Test Blood Sugar</th>
<th>If The Blood Sugar Results Are</th>
<th>Then You Should</th>
<th>When:</th>
</tr>
</thead>
<tbody>
<tr>
<td>At Breakfast</td>
<td>Before Lunch</td>
<td>Under 80</td>
<td>Subtract 2 Units From the Mealtime Dose</td>
<td>Before Breakfast the Next Day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80–130</td>
<td>Do Not Adjust Mealtime Insulin Dose</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Over 130</td>
<td>Add 2 Units to Your Mealtime Dose</td>
<td></td>
</tr>
<tr>
<td>At Lunch</td>
<td>Before Dinner</td>
<td>Under 80</td>
<td>Subtract 2 Units From Mealtime Dose</td>
<td>Before Lunch the Next Day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80–130</td>
<td>Do Not Adjust Mealtime Insulin Dose</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Over 130</td>
<td>Add 2 Units to Mealtime Dose</td>
<td></td>
</tr>
<tr>
<td>At Dinner</td>
<td>Before Bed</td>
<td>Under 125</td>
<td>Subtract 2 Units From Mealtime Dose</td>
<td>Before Dinner the Next Day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>125–150</td>
<td>Do Not Adjust Mealtime Insulin Dose</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Over 150</td>
<td>Add 2 Units to Your Mealtime Dose</td>
<td></td>
</tr>
</tbody>
</table>

If blood sugar is under 70, drink 1/2 cup of juice or soda or eat something that contains sugar. You can also take glucose tablets to bring your blood sugar into normal range. Let your physician/care team know that you had low blood sugar.
## Starting Premixed Analog Insulin: When To Test and How To Adjust Your Dose

(Using Humalog Mix 75/25%* OR Novolog Mix 70/30%* | For Patients Who Are Not On Basal Insulin)

### How To Start Premixed Insulin

The first dose should be 10% of the patient's weight in pounds (i.e. 220 lbs = 22 units) taken once daily at the largest meal.

<table>
<thead>
<tr>
<th>When Premixed Insulin Is Taken:</th>
<th>When To Test Blood Sugar:</th>
<th>If The Blood Sugar Results Are:</th>
<th>Then You Should:</th>
</tr>
</thead>
<tbody>
<tr>
<td>At Breakfast</td>
<td>Before Dinner</td>
<td>Under 80</td>
<td>Subtract 2 Units Every 3-5 Days Until Blood Sugar is 80–130 Before Dinner</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80–130</td>
<td>Do Not Adjust</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Over 130</td>
<td>Add 2 Units Every 3-5 Days Until Blood Sugar is 80–130 Before Dinner</td>
</tr>
<tr>
<td>Before Bed</td>
<td>Before Breakfast</td>
<td>80–130</td>
<td>Eat a Small Snack</td>
</tr>
<tr>
<td></td>
<td></td>
<td>130–180</td>
<td>For Most People on Premixed Insulin, This is a Good Blood Sugar Goal to Have in Order to Avoid Hypoglycemia During the Night.</td>
</tr>
<tr>
<td>At Dinner</td>
<td>Before Breakfast</td>
<td>Under 80</td>
<td>Subtract 2 Units Every 3-5 Days Until Blood Sugar is 80–130 Before Breakfast</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80–130</td>
<td>Do Not Adjust Dose</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Over 130</td>
<td>Add 2 Units Every 3-5 Days Until Blood Sugar is 80–130 Before Breakfast</td>
</tr>
</tbody>
</table>

If blood sugar is under 70, drink 1/2 cup of juice or soda or eat something that contains sugar. You can also take glucose tablets to bring your blood sugar into normal range. Let your physician/care team know that you had low blood sugar.
Patient Section

- Online tool goes straight to patient portion

- All resources usable online or downloadable in PDF
Deciding what hemoglobin A1C (A1C) and blood sugar goals are right for you depends on many factors. Talk to your doctor to decide what goals will work best for you.

**BLOOD SUGAR RANGES & DIABETES**

Diabetes occurs when the body can no longer control the sugar levels in the blood. As a result, blood sugar levels in people with diabetes are higher than normal. This is called hyperglycemia, or high blood sugar. It can lead to problems like blindness, kidney failure, amputation, and heart problems.

Low blood sugar (below 70) can sometimes happen, especially with insulin and some diabetes pills.

<table>
<thead>
<tr>
<th>Blood Sugar is Normal When:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before breakfast</td>
</tr>
<tr>
<td>After eating</td>
</tr>
<tr>
<td>A1C results</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diabetes is Diagnosed When:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before breakfast</td>
</tr>
<tr>
<td>After eating</td>
</tr>
<tr>
<td>A1C results</td>
</tr>
</tbody>
</table>

**WHAT BLOOD SUGAR GOAL IS RIGHT FOR ME?**

Because people with diabetes are different in their risk for low blood sugar, are in different stages of the disease, and have different complications, blood sugar and A1C goals should be matched to each person. The chart below shows you what blood sugar ranges are recommended based on individual factors. You and your doctor should decide together what the best goal would be for you.

**Recommended Blood Sugar Goals for People with Diabetes Based on Individual Factors**

<table>
<thead>
<tr>
<th>About You</th>
<th>If You:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Are newly diagnosed</td>
</tr>
<tr>
<td></td>
<td>• Are under 65 years old</td>
</tr>
<tr>
<td></td>
<td>• Are less likely to have low blood sugar</td>
</tr>
<tr>
<td></td>
<td>• Have no or minor complications</td>
</tr>
<tr>
<td></td>
<td>If You:</td>
</tr>
<tr>
<td></td>
<td>• Are over 65 years old</td>
</tr>
<tr>
<td></td>
<td>• Have kidney failure, heart disease, or other serious complications</td>
</tr>
<tr>
<td></td>
<td>• Have been diagnosed with other serious health problems</td>
</tr>
<tr>
<td></td>
<td>• Have frequent low blood sugar</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Goal Before Breakfast</th>
<th>80-130^v</th>
<th>100 -180^v</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal After a Meal</td>
<td>Under 180^vi</td>
<td>Under 250</td>
</tr>
<tr>
<td>Goal at Bedtime</td>
<td>Under 180</td>
<td>Under 250</td>
</tr>
</tbody>
</table>

Some patients may want to get even closer to the normal range of 70-99 before a meal and below 140 after a meal.

You and your doctor should talk about what the right goal is for you based on your individual factors. If you are prone to low blood sugar or are dealing with a major illness, having a goal that is a bit higher can be better for you.
**HOW CAN I MONITOR MY BLOOD SUGAR & KEEP MY BODY HEALTHY?**

Home glucose meters show what your blood sugar level is at that moment. Measuring your blood sugar level at the same times each day can show you if there is a pattern when your blood sugars are out of range. It will also tell you how food, exercise, and medication affect your blood sugar levels. For instance, some people have higher blood sugars when they wake up in the morning and some have higher levels after certain meals.

A1c blood tests show what your average blood sugar levels have been over the last three months. It is a simple blood test that is done at the doctor’s office or at the lab every 3 to 6 months.

The normal A1c range is 4.5 to 5.6%. The A1c level goes up or down as the average blood sugar level goes up or down, but the A1c test cannot tell how much your blood sugars are fluctuating throughout the day.

The overall goal of treating diabetes is to prevent damage to the body and to keep people with diabetes healthy and feeling good. Wide swings in blood sugar levels can make you feel bad and may cause more harm to the body.

### WHAT A1C GOAL IS RIGHT FOR ME?

Please circle the answers to the following questions to help you and your doctor talk about what the right blood sugar and A1c goals are for you. It can be helpful to aim for a range instead of a fixed goal.

<table>
<thead>
<tr>
<th>How long have you had diabetes?</th>
<th>Almost never</th>
<th>Sometimes</th>
<th>Often a problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you ever have low blood sugars?</td>
<td>Yes</td>
<td>Sometimes</td>
<td>No</td>
</tr>
<tr>
<td>Can you tell when your blood sugar is low?</td>
<td>No</td>
<td>Some</td>
<td>Yes, I have problems with my vision</td>
</tr>
<tr>
<td>Have you had any vision changes?</td>
<td>No</td>
<td>Some</td>
<td>Yes, I can’t feel my feet and/or my fingers</td>
</tr>
<tr>
<td>Do you have neuropathy or nerve pain?</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Have you had a heart attack, stroke or bypass surgery?</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Have you had a heart stent or angioplasty?</td>
<td>No</td>
<td>Unsure</td>
<td>Yes</td>
</tr>
<tr>
<td>Do you have kidney or liver problems?</td>
<td>No</td>
<td>Some help</td>
<td>No</td>
</tr>
<tr>
<td>Do you have good support at home?</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Do you have other major health problems?</td>
<td>I have a good understanding</td>
<td>I want to learn</td>
<td>I don’t understand diabetes</td>
</tr>
<tr>
<td>How much do you know about diabetes?</td>
<td>Whatever it takes</td>
<td>Some</td>
<td>I don’t have much time in my schedule for this</td>
</tr>
<tr>
<td>How much time and effort can you devote to managing your diabetes?</td>
<td>No</td>
<td>Sometimes</td>
<td>Once or twice</td>
</tr>
<tr>
<td>Are you concerned about your blood sugar while at work?</td>
<td>As many times as needed</td>
<td>More than two times</td>
<td></td>
</tr>
</tbody>
</table>

**Suggested A1c Goal**

**A1c:**
- 12%: 298
- 11%: 269
- 10%: 240
- 9%: 212
- 8%: 183
- 7.5%: 169
- 7.0%: 154
- 6.5%: 140
- 6.0%: 126
- 5.0%: 97

It is important that you discuss this with your doctor as your answers may fall across a spectrum.
WHAT IS HYPOGLYCEMIA & WHY SHOULD I AVOID IT?

Hypoglycemia happens when your blood sugar falls below 70. Because some people are more likely to have problems with low blood sugar, they may need to set their goal a bit higher to prevent their blood sugar from falling too low.

Just as having blood sugar levels that are high can cause problems, having blood sugar levels that are too low can also cause problems.

Hypoglycemia is more likely with certain diabetes medications, including insulin.

The overall goal of treating diabetes is to prevent damage to the body and to keep people with diabetes healthy and feeling good. Wide swings in blood sugar levels can make you feel bad and may cause more harm to the body.

<table>
<thead>
<tr>
<th>Medications That May Cause Hypoglycemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glyburide (Micronase)</td>
</tr>
<tr>
<td>Glimperide (Amaryl)</td>
</tr>
<tr>
<td>Repaglinide (Prandin)</td>
</tr>
<tr>
<td>Nateglinide (Starlix)</td>
</tr>
<tr>
<td>Any type of Insulin</td>
</tr>
<tr>
<td>Glipizide (Glucotrol)</td>
</tr>
</tbody>
</table>

Exercise, skipping meals, and big changes in what you eat at meals can also cause low blood sugar. If blood sugar falls too low, it can damage your body, just as high blood sugar can. It is best to try to avoid low blood sugar as much as possible.

FACTORS THAT MAY MAKE LOW BLOOD SUGAR MORE DANGEROUS

- Having a heart condition
- Living alone with no one to assist if you have a low blood sugar attack
- Using heavy equipment, mining, law enforcement, working with chemicals, or working in isolated situations can make having a low blood sugar attack more dangerous.

For more information, visit www.AccurateInsulin.org

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DIABETES & INSULIN

In diabetes, your body does not make enough insulin or use it properly. This causes your blood sugar to go too high. Oral medications, like metformin, may help your body to use insulin more efficiently. Other oral medications can help your body make more insulin. However, these medicines often work for only a few years.

When the oral medications stop working, you will need to give yourself background and/or mealtime insulin shots to help control your blood sugar. If you need insulin, it does not mean that you have failed. It is just a part of diabetes.

Background insulin can help control your blood sugar when you are not eating. However, it does not cover the carbs that you eat at meals.

If the dose of background insulin is raised to cover spikes in blood sugars that happen after you eat, your body will have too much insulin in between your meals and while you sleep. This can cause your blood sugar to go too low. This is called hypoglycemia.

If you have high blood sugars after meals, this can cause tiredness, irritability, blurry vision, more frequent urination and thirst. Over time, high blood sugars can damage your feet, hands, and eyes.

By adding mealtime insulin you can better match the insulin to what your body would produce if you did not have diabetes. This will help prevent both low and high blood sugars so that you feel better and get less damage from the diabetes.

What is Insulin?

- Natural insulin is made from the pancreas to match what the body needs so your blood sugar stays in a normal range.
- The pancreas makes some amount of insulin all the time, called background or basal insulin.
- Background insulin helps to supply fuel to your muscles and controls the glucose that is released from your liver.
- Every time you eat, the pancreas releases a spike of insulin to match the amount of carbohydrates (carbs) you eat.
- Insulin helps process sugar that comes from the carbs and keeps the blood sugar from going too high.

A Few Common Carbs

- Breads
- Cakes
- Cookies
- Soda
- Pasta
- Rice
- Crackers
- Potatoes
- Candy
- Fruit

Insulin Spikes When You Eat. Graph from adapted from Eli Lilly
**WHAT TYPES OF INSULIN ARE THERE?**

Different types of insulin are classified by how fast they work and how long they continue to work in the body. Many different types of insulin can be used to replace the insulin your body cannot make.

### Background (Basal) Insulin

<table>
<thead>
<tr>
<th>Long-acting Insulin</th>
<th>Intermediate-acting Insulin (NPH)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Lasts about 24 hours</td>
<td></td>
</tr>
<tr>
<td>• Absorbed slowly</td>
<td></td>
</tr>
<tr>
<td>• Given once a day, sometimes twice</td>
<td></td>
</tr>
<tr>
<td>• Lasts for 8-12 hours</td>
<td></td>
</tr>
<tr>
<td>• Usually given twice a day</td>
<td></td>
</tr>
<tr>
<td>• Appears cloudy and needs to be mixed by rolling vial/pen</td>
<td></td>
</tr>
<tr>
<td>• Some people may be more prone to low blood sugar reactions than with long-acting insulin</td>
<td></td>
</tr>
</tbody>
</table>

**Names:**
- Insulin glargine (Lantus)
- Insulin detemir (Levemir)

**Names:**
- Humulin N
- Novolin N
- Relion N

### Mealtime (Bolus) Insulin

<table>
<thead>
<tr>
<th>Short-acting (Regular) Insulin</th>
<th>Rapid-acting Insulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Lasts 6 hours or longer</td>
<td></td>
</tr>
<tr>
<td>• Takes 30 minutes to start working</td>
<td></td>
</tr>
<tr>
<td>• Tends to last longer than needed to cover a meal so some people are more likely to get low blood sugar</td>
<td></td>
</tr>
<tr>
<td>• Absorbed quickly and last only for a few hours</td>
<td></td>
</tr>
<tr>
<td>• Works faster than regular insulin and is used at mealtime to keep down the spike in blood sugar after you eat</td>
<td></td>
</tr>
</tbody>
</table>

**Names:**
- Humulin R
- Novolin R
- Relion R

**Names:**
- Insulin Lispro (Humalog)
- Insulin Aspart (Novolog)
- Insulin Glulisin (Apidra)

### Premixed Insulin

<table>
<thead>
<tr>
<th>Rapid-Acting &amp; NPH</th>
<th>Regular &amp; NPH</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Used twice daily—before breakfast and dinner—and is cloudy</td>
<td></td>
</tr>
<tr>
<td>• A mix of two types of insulin, either: rapid-acting &amp; NPH or regular &amp; NPH</td>
<td></td>
</tr>
</tbody>
</table>

**Rapid-Acting & NPH**
- Humalog Mix 75/25
- Humalog Mix 50/50
- Novolog Mix 70/30

**Regular & NPH**
- Humulin 70/30
- Novolin 70/30
- Relion 70/30
WHAT ARE MY CHOICES FOR MEALTIME INSULIN?

ADDING RAPID-ACTING INSULIN TO BACKGROUND INSULIN

- Adding rapid-acting insulin to the long-acting background insulin that you are already taking is a good way to make sure your blood sugar doesn’t go too high after eating.
- You can start by adding a shot right before your largest meal, or the meal that causes the blood sugar to go the highest.
- Some people get their diabetes back into control with just this one extra shot.
- Others may need to add another shot before their second largest meal and third meal.

**PROS**

- You can adjust your insulin intake to fit less regular schedules and to more/less carb intake.
- It’s an easier transition for many patients because they are already on basal insulin and they understand how insulin works.
- It can be used alone or with oral medicines.

**CONS**

- You need to carry the mealtime insulin with you.
- You may need to take 2-5 injections each day depending on how many meals need mealtime insulin.
- There are two co-pays. One co-pay is for the background insulin and one is for the mealtime insulin.

USING PREMIXED INSULIN

- Premixed insulin contains two different types of insulin in one shot: a rapid acting and intermediate acting insulin.
- Premixed insulin can control blood sugar levels after and between meals and works best if meals are on a regular schedule and fairly consistent in amount.
- It is usually used twice daily—before breakfast and before dinner.
- If injected before breakfast, the rapid acting part covers breakfast and the intermediate part covers lunch and between meals.
- If injected before supper, the rapid acting part covers suppertime meal and the intermediate covers overnight.

**PROS**

- There’s only one co-pay.
- You can take fewer shots (1-2 per day).
- It can be used alone or with oral medicines.

**CONS**

- You need to eat regular meals or you will get low blood sugar.
- There’s a greater chance of low blood sugar at night.
- You cannot adjust one insulin without adjusting the other.

For more information, visit www.AccurateInsulin.org
Patient #1 Rudi

- 72 year old Caucasian male
  - T2DM dx +/- 20 years ago
  - Cr 1.8
  - Peripheral paresthesias
  - S/P acute MI 2005 with stents
  - BMI 32
  - Had Metformin & glyburide stopped a year ago, replaced with bedtime dose of insulin glargine
  - His last A1c was 7.7% and he was told to increase glargine dose from 48 units to 60 units
  - POC (rapid) A1c now 6.9%
- His wife is here with him concerned about low BGs around 4 AM and also when out doing gardening and yard work
Together decide that his goal should be 7.5-8.0% range rather than <7%

Based on low BGs and A1c lower than appropriate goal, basal insulin lowered back to 48 units

Monitoring post prandial blood sugar and Q3 mos A1c to keep him in this range.

Consideration to add non-hypoglycemic agents if A1c not at target range (not a part of AID)
Patient with a different A1C target

- Brittany a 34 year old Hispanic female
  - T2DM dx age 30; history of PCOS
  - Weight 176#/80 kg, Height 5’, BMI 34.4
  - Taking combo sitagliptin 50 mg/ metformin 1000 mg bid
  - Unable to tolerate TZD or GLP-1RA and allergic rash with SU
  - FBS 100-150 range with A1c 7.5%
  - Agree on Goal A1c of 6.5 to 7.0%
Homework assignment

- Dr P tells Brittany that he would like her input on what she thinks would work for her and her lifestyle and schedule.

- Asks her to go through the Patient decision AID and then schedule a f/u appointment so they can go over her thoughts and concern and work out what will be her best option to try.
Self Reflection Results

 Brittany decides to check her BG after some meals:
§ 140-170 range after breakfast and lunch but
§ often >180 and even >200 after her evening meal

From the questionnaire
§ Biggest concern would be extra copay for a second type of insulin;
§ Her schedule is usually predictable
§ She has never had low BG
Follow up appointment

- Dr PCP and Brittany review her questionnaire and concerns and questions

- Together they agree to try premixed insulin

- Based on her formulary they select insulin aspart 70/30 before supper beginning with 17 units

- She meets with MA to review the use of the insulin pen and the Action Plan and instructions, patient titration handout was given and CBG testing reviewed
Louise Case #2

- 66yr old AA female, now retired followed by a PCMH (primary care medical home)
- Her care team does pre-visit planning (log book, questions prior to appointment)
- A1c is still 9.2% despite having increased her insulin glargine dose to 40 units bid at her last appt.
- Her weight is 80 kg (1.0u/ kg basal insulin dose)

GOAL SETTING TOOL
(also testing of pre-meal blood sugars over the next couple weeks)
Patient 3: Louise continued

- Patient indicates that she would like A1C <7% but is very afraid of low BGs in the night and is eating a lot at bedtime.
- Sometimes reduces bedtime glargine to 30 units to ensure no low BG.
- Current FBS 130-280.
- Meets her PCP- they decide that she might feel safer aiming for a FBS of 100-140 rather than 70-130.
  - Continue glargine insulin 40 units bid but stop eating so much at bedtime.
  - Record Pre-Lunch and Pre-Dinner Blood sugars for 1-2 weeks.
- Provider or care team member discusses with patient if there are any problems with the insulin administration or other barriers.
Patient 3: Louise continued

- She meets with the health coach in 2 weeks and her FBS is now in desired range.
- The health coach reviews with her the “Is Mealtime Insulin Right for Me tool” and learns that the patient and her husband eat their largest meal at noon and that she would be “too afraid” to take any insulin at dinnertime;
- Her appointment happens to be about 1½ after lunch with BG at 296. Patient agrees to start mealtime insulin with lunch.
- She meets with RN to start the standing order utilizing the ACTION PLAN.
Patient 3: Louise continued

- She meets with the health coach/ reports to HCP in 2 weeks that her FBS is now in desired range, but her Pre-Lunch Blood sugars are all greater than 200.
- PCP uses Decision Support tool [step 2]- **Need mealtime insulin.**
- PCP adds Rapid acting analog insulin to breakfast of 2 units to treat the pre-lunch elevated blood sugars.
- Patient is instructed to continue monitoring Pre-lunch and Pre-Dinner CBG.
The TNEG (the New Economy Group) has joined a start up ACO, composed of primary care providers, specialists, and affiliated hospitals.

The ACO leadership came to the group with data showing that:

- 17% of their patient population has diabetes and 30% have A1c >9%.
- There is also a high rate of ED utilization for high BG and higher than average rate of diabetes-related amputations.
- A subgroup of patients with poorly-controlled diabetes is responsible for a high percentage repeat hospitalizations, missed appointments, and unfilled prescriptions.

The ACI offer to pay TNEG $$ to help work with other clinicians and departments to improve the ACO’s quality data and try to reduce the preventable events:

- (ED visits, repeat hospitalizations, DKA, severe hypoglycemia, falls and amputations).

If these numbers improve the TNEG and the PCP’s will receive a $$ bonus and X% of the savings from the prevented events.
Roll Out of the Program

- TNEG physicians meet with PCP groups in the ACO to plan a strategy.
- PCP’s indicate they comfortable starting basal insulin but tend to have poor patient “buy in.”
  - They lack the support in titrate it.
  - Many patients on basal insulin alone have suboptimal control.
  - The PCP’s are unsure about adding mealtime insulin. These practices are now all PCMH practices.
- TNEG utilizes the AID tools for their ACO.
  - They educate the ACO CDEs and designated case managers, patient navigators, and health coaches on motivational interviewing techniques and how to use the patient decision support tools.
  - PCP Clinicians are trained to use the provider support tools, Steps 1 through 5.
- The ACO and TNEG use the patient registries to identify all patients with A1c >9%, and potentially requiring insulin.
- Care managers arrange visits and pre-visit prep for those patients.
Results of Implementation

- Using the “Goal Setting Tool” health care providers AND patients can determine which patients are truly above goal.
- The patients facilitate the use of the patient questionnaires and decision support materials.
- They work with each patient and “care team” if available determine the right ACTION PLAN for that patient.
- If the patient is on background insulin, the dose is adjusted per the tool recommendations.
- If the patient is still not at goal; the physician/care team and patient use the “Mealtime Insulin” tools, to determine if the patient is a candidate for mealtime insulin and the care team helps with the patient education, uses standing orders for mealtime insulin initiation and Action Plan for dose titration.
- If the patient still is not at goal after 6-9 months, or there are problems such as severe hypoglycemia, gastroparesis, unusual responses to insulin or complicating comorbid conditions then the patient is referred to TNEG for endocrinology consultation or co-management.
- After the first year the A1c data improved dramatically and the ED visits for high BG dropped by 42%.
A few questions to consider asking your patient or assessing to determine if adherence is a problem:

- What insulin are you taking and when do you take it?
- Where do you take your shots and how do you rotate the sites?
- How often do you miss a shot?
- What went well? What were the problems?
- Have you had any problems with your diet and exercise plan?
- When did you last attend a diabetes education class and what did you find to be helpful?
CLOSING THE LOOP: IS THE MEALTIME INSULIN APPROACH WORKING?
THINGS TO THINK ABOUT AND POINTS TO MAKE

ASSESSING PATIENT ADHERENCE

It is recommended that physicians evaluate patient adherence utilizing the principles of motivational interviewing in order to better understand barriers to adherence. These principles include using open-ended questions, reflecting patient answers, and summarizing your discussion to clarify any miscommunication. Specific examples of motivational interviewing questions can be found below.

- Use open-ended questions (see educational video on motivational interviewing).
  - What insulin are you taking and when do you take it?
  - How often do you miss a shot?
  - How did the extra insulin shots work out?
  - What were the problems for now?
  - What is your plan for when you have hypoglycemia?
  - What went well?
  - What are your concerns about this plan?
  - Which shots are you having the most difficulty remembering to give?

- Reflect what the patient is telling you when following up on their answers. Start sentences with phrases like:
  - It sounds like you...
  - You mean that...
  - You’re wondering if...
  - So you feel...

- Summarize what you heard the patient tell you.
  - Demonstrates attentiveness
  - Allows patients to clarify their statements
  - Provides direction and saves time

- Reiterate why the approach that you’re recommending would benefit the patient or adjust the plan based on what you’ve heard the patient tell you.

EVALUATING BLOOD GLUCOSE LOGS

Review the blood glucose logs with the patient and assess if a dose adjustment is needed based on the following patterns:

<table>
<thead>
<tr>
<th>Recommended Adjustments Based on Blood Glucose Patterns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>If improved as expected</strong></td>
</tr>
<tr>
<td>- Continue current action plan</td>
</tr>
<tr>
<td><strong>If fasting blood sugar is above range</strong></td>
</tr>
<tr>
<td>- Increase basal insulin dose</td>
</tr>
<tr>
<td>- Consider getting a 3AM blood sugar</td>
</tr>
<tr>
<td><strong>If fasting blood sugar is below range or nocturnal hypoglycemia</strong></td>
</tr>
<tr>
<td>- Decrease basal insulin dose</td>
</tr>
<tr>
<td><strong>If both bedtime blood sugars and fasting blood sugars above range</strong></td>
</tr>
<tr>
<td>- Increase pre-dinner insulin dose</td>
</tr>
<tr>
<td><strong>If fasting blood sugar varies or erratic pattern</strong></td>
</tr>
<tr>
<td>- Indicates issue with diet/carb intake, injection technique/timing, or missed insulin doses. Suggest referral to CDE or specialist.</td>
</tr>
</tbody>
</table>

While evaluating the logs, ask the patient what they see. A long-term goal should be for patients to be able to identify glucose patterns and what they mean.

- If the patient sees a pattern, use it to reinforce suggested changes.
- If the patient does not see a pattern, show them what you see and ask what they think they can do to improve things further.
<table>
<thead>
<tr>
<th>CERTIFIED DIABETES EDUCATOR</th>
<th>ENDOCRINOLOGIST/DIABETOLOGIST</th>
</tr>
</thead>
<tbody>
<tr>
<td>• If possible, it is recommended that all patients see a dietician or diabetes educator when first starting mealtime insulin.</td>
<td>• The patient is not at goal after 6 months (e.g. consistent A1c of 9% or greater)</td>
</tr>
<tr>
<td>• If the patient continues to have difficulty adhering to their treatment plan, a subsequent visit is recommended.</td>
<td>• Difficulty breaking hyperglycemia</td>
</tr>
<tr>
<td>• A diabetes educator is also recommended if there are significant:</td>
<td>• Severe or recurrent hypoglycemia despite cautious insulin therapy</td>
</tr>
<tr>
<td>• Patient apprehension</td>
<td>• Complications arise (e.g. gastroparesis)</td>
</tr>
<tr>
<td>• Learning barriers (e.g. matching food and insulin)</td>
<td>• Confusing or erratic patterns</td>
</tr>
<tr>
<td>• Skill barriers (e.g. injection technique)</td>
<td>• Suspect type 1 diabetes</td>
</tr>
<tr>
<td></td>
<td>• Suggest first checking anti-GAD and anti-islet cell antibodies</td>
</tr>
<tr>
<td></td>
<td>• Also ask patient about carb avoidance which often delays diagnosis of latent autoimmune diabetes or slowly progressive type 1 diabetes</td>
</tr>
</tbody>
</table>

For more information, visit www.AccurateInsulin.org
Summary

- For optimal diabetes self-management, the patient must be an active participant in the decision making process, and at the center of care.
- A collaborative approach should be fostered between patient, provider and the care team.
- Pre-meal insulin initiation and titration present specific barriers in the primary care setting, where there are lack of resources, time, and appropriate communication.
- We have developed specialized resources to facilitate shared decision making for patients and PCP’s to overcome these barriers:
  - They accomplish focused communication on issues currently difficult or challenging for the patient.
  - They strive to promote self-insight, which is needed for a change in self-management.
- These tools can be used in a customized manner to suit different practice situations.
- They can also be used for population disease management and quality improvement.
THANK YOU