Background Information

Epidemiology and Risk Factors
Diabetes – Its Definition and Its Impact

• “A metabolic disorder characterized by chronic hyperglycemia with disturbances in carbohydrate, fat and protein metabolism caused by defects in insulin secretion, insulin action, or both.” [WHO definition]
• 7th leading cause of death in the United States
• Estimates of prevalence in nursing homes ranges from 23.4-32.1%
  — greater prevalence in non-Caucasian residents (up to 35.6%)
• Diabetic nursing home residents were more likely to:
  — be admitted from acute care hospitals (42.5% v 35.3%)
  — take more medications (10.3 v. 8.4)
  — have an emergency department visit in the previous 90 days (10% v. 7.4%)
  — have a pressure ulcer (14% v. 9.4%)

Diabetes Facts

- 25.8 million people (8.3%) in the U.S. have diabetes
  - 18.8 million diagnosed and 7 million undiagnosed
  - 10.9 million Americans (26.9%) 65 years or older have diabetes
- Overall seventh leading cause of death in U.S. in 2007 and the sixth leading cause of death in Americans 65 years and older
- Estimates of prevalence in nursing homes ranges from 23.4-32.1%
  - greater prevalence in non-Caucasian residents (up to 35.6%)
- Diabetic nursing home residents were more likely to:
  - be admitted from acute care hospitals (42.5% v 35.3%)
  - take more medications (10.3 v. 8.4)
  - have an emergency department visit in the previous 90 days (10% v. 7.4%)
  - have a pressure ulcer (14% v. 9.4%)
- Compared to non-diabetics, diabetics in nursing homes have:
  - a significantly higher rate of cardiovascular disease (male, 74.1% v. 67.8%; female, 78.9% v. 68.3%)
  - a higher prevalence of renal disease (male, 19.1% v. 13.7%; female, 14.7% v. 10.3%)

Therapies for Type 2 Diabetes

Tier 1: Well-validated core therapies

- At diagnosis: Lifestyle + Metformin
  - Lifestyle + Metformin + Basal insulin
  - Lifestyle + Metformin + Sulfonylurea
  - Lifestyle + Metformin + Pioglitazone + Sulfonylurea
  - Lifestyle + Metformin + Intensive Insulin

Tier 2: Less well-validated therapies

- Lifestyle + Metformin + Pioglitazone
  - Lifestyle + Metformin + GLP-1 agonist

- Lifestyle + Metformin + Basal insulin

# Insulin Preparations*

<table>
<thead>
<tr>
<th></th>
<th>Onset</th>
<th>Peak</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rapid</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspart (Novolog®)</td>
<td>&lt;20 min</td>
<td>0.5-1.5 hrs</td>
<td>3-5 hrs</td>
</tr>
<tr>
<td>Glulisine (Apidra®)</td>
<td>&lt;30 min</td>
<td>0.5-1.5 hrs</td>
<td>3-5 hrs</td>
</tr>
<tr>
<td>Lispro (Humalog®)</td>
<td>&lt;30 min</td>
<td>0.5-2.5 hrs</td>
<td>3-6.5 hrs</td>
</tr>
<tr>
<td><strong>Short</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular (Novolin® R, Humulin® R)</td>
<td>0.5 – 1 hr</td>
<td>1-5 hrs</td>
<td>5-10 hrs</td>
</tr>
<tr>
<td><strong>Intermediate</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NPH (Novolin N®, Humulin N®)</td>
<td>1-4 hrs</td>
<td>Dual</td>
<td>12-18 hrs</td>
</tr>
<tr>
<td><strong>Long</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glargine (Lantus®)</td>
<td>1-2 hrs</td>
<td>None</td>
<td>Up to 24 hrs</td>
</tr>
<tr>
<td>Detemir (Levemir®)</td>
<td>0.8-2 hrs</td>
<td>None</td>
<td>6-23 hrs</td>
</tr>
</tbody>
</table>

*Some variability exists depending upon which reference source is consulted.*
3 Main Types of Insulin Regimens

• Basal insulin: inhibits liver glucose production overnight and between meals
• Bolus insulin (aka prandial or meal-time): promotes glucose disposal into muscles from food consumption
• Sliding Scale insulin (SSI): PRN insulin, based on bedside capillary glucose measurement (often before meals and at bedtime)
Activity Profiles of Insulin Analogues Compared with Human Type

Aspart, Glulisine, Lispro 3–6 hours

Regular 5-10 hours

NPH 12-18 hours

Detemir 6-23 hours

Glargine up to 24 hours

Plasma insulin levels

Hours
Optimizing Insulin Therapy and Eliminating Sliding Scale Insulin
When Should Insulin Be Added?

- If glycemic control cannot be obtained using therapeutic lifestyle modification + metformin
- If diet, exercise, and oral medication combinations have failed to adequately control blood glucose
- If oral medications or incretin-based therapies (e.g., Victoza®, Byetta®) are not feasible, are unsuccessful or are contraindicated
- If fasting blood glucose is consistently > 180 mg/dL even after two or more non-insulin antidiabetic agents have been optimized
- If the patient is medically unstable

Table 14 - American Medical Directors Association. Diabetes Management in the Long-Term Care Setting Clinical Practice Guideline. 2008.
Why Basal Insulin?

- Research in elderly patients has shown that once-daily glargine + oral antidiabetic agents restored glycemic control more effectively and with less hypoglycemia (3.68 episodes/pt year v. 9.09 episodes/pt year) than twice daily insulin 70/30.

- The Treat-to-Target Trial showed that once daily glargine + OADs and once daily NPH + OADs result in similar glycemic control but glargine + OAD results in less symptomatic hypoglycemia.

- The 4-T Study showed basal insulin and prandial insulin superior to biphasic insulin regimens but basal insulin produces the least weight gain and fewest hypoglycemic episodes.


Riddle MC et al. The Treat-to-Target trial. Diab Care 2003; 26:3080-3086.

Basal Insulin

• Specifically targets morning fasting blood glucose
• Once daily Levemir (detemir) should be generally administered with the evening meal or at bedtime
• Once daily Lantus (glargine) may be administered at any time of day but consistently at the same time, but may be best given at bedtime
• Total daily basal insulin requirements greater than 50 units may need to be given in divided doses
  – *For patients who require twice-daily dosing of Levemir, the evening dose can be administered either with the evening meal, at bedtime, or 12 hours after the morning dose*
• Research has demonstrated that basal insulin is associated with:
  – The least amount of weight gain (compared to bolus or mixed insulins)
  – Less hypoglycemia when compared to mixed insulins or NPH insulin
  – Superior glycemic control compared to mixed insulins or Sliding Scale Coverage

Riddle MC et al. The Treat-to-Target trial. Diab Care 2003; 26:3080-3086.
Sliding Scale Insulin

- First described by Elliot Joslin in 1934
- Was used for decades based on fractional urine glucose testing until about 1980 when capillary blood glucose monitoring was introduced
- Numerous variations exist including “conservative” and “aggressive” sliding scales
- Still believed to be the most prescribed insulin regimen
- Is considered convenient and straightforward to administer
- May be appropriately used in the hospital setting during short-term acute illness

BUT….

Concerns Associated with Chronic Sliding Scale Insulin

- Reactive approach instead of preventative approach (non-physiologic)
- Can lead to rapid changes in blood glucose exacerbating both hyperglycemia and hypoglycemia
- Wrongly assumes all patients have similar insulin sensitivities or no change in insulin sensitivity during different stages of acute illness
- Promotes misconception that mild elevations in glucose (i.e. less than 200 mg/dl) are not deleterious
- Usually does not provide or provides only minimal amounts of insulin coverage for the meal itself, which subsequently results in continued hyperglycemia
- Orders are less likely to be changed and are therefore not individualized to patient’s needs

What Does AMDA Say About Sliding Scale Insulin

- May be useful in newly recognized diabetes, when insulin requirements are unknown
- May be useful when new therapies such as enteral and parenteral nutrition or treatment with glucocorticoids is initiated
- “Routine and prolonged use is generally **not** recommended”
- “SSI regimens are not considered optimal physiologic insulin strategies because of a lack of evidence and efficacy.”
- Widespread use of SSI results in:
  - Greater patient discomfort
  - Increased nursing time due to increased monitoring
  - Increased nursing time due to the increased number of injections administered
- Typical notification only when blood glucose is less than 60 mg/dL or greater than 400 mg/dL may result in sustained periods of hypoglycemia or hyperglycemia without adjustments in therapy
Table 1 - MEDICATION ISSUES OF PARTICULAR RELEVANCE

NOTE: Continued or long-term need for sliding scale insulin for non-emergency coverage may indicate inadequate blood sugar control

CFR 483.25(I), Unnecessary Drugs
AMDA’s Approach to Minimizing the Use of Sliding Scale Insulin

- Any patient on SSI should be re-evaluated within 1 week and converted to fixed daily insulin doses that minimize the need for correction doses
- “It has been shown in LTC facilities that blood glucose control can be achieved with single or multiple daily insulin injections, with few episodes of hypoglycemia.”

Algorithm for Residents with Orders for Sliding Scale Insulin

1. Obtain A1c and FBS* goals, if possible
2. Is SSI being administered?
   - No
     - Recommend SSI discontinuation
   - Yes
     - Are all or most FBS* values ≤ 180 mg/dL?
       - Yes
         - Recommend discontinuation of SSI
       - No
         - SSI used most days of the week?
           - Yes
             - Doses of antidiabetic medications optimized?
               - Yes
                 - Recommend increase in dose of at least 1 current antidiabetic medication.
                 - FBS* should be monitored regularly over next month.
                 - Review FBS* values and SSI use at next monthly visit.
                 - Recommend D/C of SSI if most FBS* are ≤ 180 mg/dL or if SSI use has decreased significantly.
               - No
                 - Resident receiving 2 or more non-insulin antidiabetic agents?
                   - Yes
                     - Recommend addition of basal insulin 10 units at bedtime.
                     - Monitor FBS* over next month.
                     - Review FBS* values and SSI use at next monthly visit.
                     - Recommend D/C of SSI if most FBS* are ≤ 180 mg/dL or if SSI use has decreased significantly.
                   - No
                     - Recommend addition of oral antidiabetic agent.
                     - Monitor FBS* over next month.
3. FBS* should be monitored regularly over next month.
4. Review FBS* values and SSI use at next monthly visit.
5. Recommend D/C of SSI if most FBS* are ≤ 180 mg/dL or if SSI use has decreased significantly.

* FBS refers to the first morning fasting blood sugar only
Optimizing Basal Insulin

- After initiation of basal insulin, add an additional 8 units of basal insulin every month if FBS >180 mg/dL and re-evaluate
- If hypoglycemia occurs (FBS < 70 mg/dL), reduce basal dose by ≥ 5 units, or reduce doses of other antidiabetic medications being used
- If fasting blood glucose is at goal, but postprandial blood glucose is still elevated, consider bolus of rapid-acting insulin prior to the largest meal of the day
- Once daily detemir should be generally administered with the evening meal or at bedtime
- Once daily glargine may be administered at any time of day but consistently at the same time
- Total daily basal insulin requirements greater than 50 units may need to be given in divided doses
  - For patients who require twice-daily dosing of detemir insulin, the evening dose can be administered either with the evening meal, at bedtime, or 12 hours after the morning dose
## Adjusting Insulin Therapy – Basal Bolus Model

<table>
<thead>
<tr>
<th>Average Blood Glucose</th>
<th>Basal</th>
<th>Rapid Acting Analog</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Breakfast</td>
</tr>
<tr>
<td><strong>Fasting</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>↓</td>
<td></td>
</tr>
<tr>
<td>HIGH</td>
<td>↑</td>
<td></td>
</tr>
<tr>
<td><strong>Before Lunch</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>↓</td>
<td></td>
</tr>
<tr>
<td>HIGH</td>
<td>↑</td>
<td></td>
</tr>
<tr>
<td><strong>Before Supper</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td></td>
<td>↓</td>
</tr>
<tr>
<td>HIGH</td>
<td></td>
<td>↑</td>
</tr>
<tr>
<td><strong>Bedtime</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIGH</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 17 - American Medical Directors Association. Diabetes Management in the Long-Term Care Setting Clinical Practice Guideline. 2008.
Insulin Pens
# Insulin Available in Pen Devices

## RAPID ACTING
- Humalog KwikPen (lispro)
- HumaPen MEMOIR (lispro)
- HumaPen LUXURA HD (lispro)
- Novolog FlexPen (aspart)
- Apidra SoloSTAR Pen (glulisine)

## INTERMEDIATE ACTING
- Humulin N Pen

## INTERMEDIATE/RAPID MIXES
- Humalog KwikPen Mix 50/50
- Humalog KwikPen Mix 75/25
- Humulin 70/30 Pen
- Novolog Mix 70/30 FlexPen

## BASAL
- Levemir FlexPen (detemir)
- Lantus SoloSTAR Pen (glargine)
- Lantus OptiClik* Pen (glargine)

* Will be discontinued as of 3/31/11
Insulin Pens

- **Potential benefits**
  - Less waste due to decreased volume (3 mL versus 10 mL)
  - Portable and discrete
  - More accurate dosing mechanisms
  - Faster and easier than conventional syringes
    - Estimated decreased staff time (2 minutes v. 8-10 minutes)
  - Improved patient attitude and compliance

- **Potential advantages of newer insulin pens**
  - Dosage settings change quickly and easily
  - Safety button automatically resets after drug delivery
  - LCD display to show dosage setting or audible clicks

Final Reminders About Insulin Pens

- FDA Reminder (3/19/09) - insulin pens and cartridges are never to be shared among patients due to risk of HIV, Hepatitis and other blood-borne pathogens
  - A military hospital had been sharing for about 2 years in over 2,000 patients and in one other smaller hospital
- Needles are only to be used once
  - Bent needles, increased air in injection resulting in underdosing
  - Safety needles are best
- Most pens have a limitation to the number of units you can give per dose
  - Maximum of 60 units per injection for Novolog (aspart), Levemir (detemir), and Humalog (lispro)
  - Maximum of 80 units per injection for Apidra (glulisine) and Lantus (glargine)
- A safety test using 2 units of insulin must be released PRIOR TO EACH injection
- Keep the needle in the injection site for 5-10 seconds
Storage of Insulin

- Insulin products should **never** be used if they were frozen.
- All unused insulin products are best stored in the refrigerator before opening.
- All insulin vials are best stored at room temperature after opening.
- All insulin pens must be stored at room temperature after opening.
- Insulin vials and pens have varying expiration dates upon opening.

Refer to Omnicare’ Insulin Storage Recommendation document

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### INSULIN STORAGE RECOMMENDATIONS

<table>
<thead>
<tr>
<th>VIALS</th>
<th>Unopened</th>
<th>Opened</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Refrigerated (36°F to 46°F)</td>
<td>Room Temperature (59°F to 86°F)</td>
</tr>
<tr>
<td>Apidra</td>
<td>Until expiration date</td>
<td>28 days</td>
</tr>
<tr>
<td>Humalog</td>
<td>Until expiration date</td>
<td>28 days</td>
</tr>
<tr>
<td>Lantus</td>
<td>Until expiration date</td>
<td>28 days</td>
</tr>
<tr>
<td>Levemir</td>
<td>Until expiration date</td>
<td>42 days</td>
</tr>
<tr>
<td>Novolin (R, N, 70/30)</td>
<td>Until expiration date</td>
<td>42 days (up to 77°F)</td>
</tr>
<tr>
<td>Novolog</td>
<td>Until expiration date</td>
<td>28 days</td>
</tr>
</tbody>
</table>

***Do Not Use any Insulin products that have been frozen***

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### CARTRIDGES / PENS

<table>
<thead>
<tr>
<th>PREFILLED SYRINGE</th>
<th>Unopened</th>
<th>Opened</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Refrigerated (36°F to 46°F)</td>
<td>Room Temperature (59°F to 86°F)</td>
</tr>
<tr>
<td>Apidra pen</td>
<td>Until expiration date</td>
<td>28 days</td>
</tr>
<tr>
<td>Humalog cartridge or pen</td>
<td>Until expiration date</td>
<td>28 days</td>
</tr>
<tr>
<td>Humalog Mix 5050 pen</td>
<td>Until expiration date</td>
<td>Must Keep Refrigerated</td>
</tr>
<tr>
<td>Humalog Mix 75/25 pen</td>
<td>Until expiration date</td>
<td>Must Keep Refrigerated</td>
</tr>
<tr>
<td>Humulin N pen</td>
<td>Until expiration date</td>
<td>Must Keep Refrigerated</td>
</tr>
<tr>
<td>Humulin 70/30 pen</td>
<td>Until expiration date</td>
<td>Must Keep Refrigerated</td>
</tr>
<tr>
<td>Lantus pen</td>
<td>Until expiration date</td>
<td>28 days</td>
</tr>
<tr>
<td>Levemir pen</td>
<td>Until expiration date</td>
<td>Must Keep Refrigerated</td>
</tr>
<tr>
<td>Novolog cartridge or pen</td>
<td>Until expiration date</td>
<td>Must Keep Refrigerated</td>
</tr>
<tr>
<td>Novolog Mix 70/30 pen</td>
<td>Until expiration date</td>
<td>Must Keep Refrigerated</td>
</tr>
</tbody>
</table>

***Do Not Use any Insulin products that have been frozen***
Questions
??????