Updates on Diabetes
Pharmacotherapy: What is new?

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• I have no financial disclosures
• I have no conflict of interests
Objectives

1. Describe the therapeutic actions of the newer diabetes agents.

2. Discuss the available insulin products and their role in patient management.

3. Select appropriate diabetes agents based on current diabetes guidelines.
• Which of the following diabetes agents have received FDA indication for cardiovascular mortality reduction in adult patients with Type 2 diabetes and CVD?

A. Exenatide and Soliqua
B. Liraglutide and Dapagliflozin
C. Liraglutide and Empagliflozin
D. Exenatide and Canagliflozin
• Which of the following diabetes agents have received FDA indication for cardiovascular mortality reduction in adult patients with Type 2 diabetes and CVD?

A. Exenatide and Soliqua

B. Liraglutide and Dapagliflozin

C. Liraglutide and Empagliflozin

D. Exenatide and Canagliflozin
Which of the following is true about Humulin R U-500?

A. Available in pen and vial

B. May be used in patients requiring more than 200 units of insulin per day

C. Maximum units of insulin per injection with pen delivery is 300 units

D. All of the above
Which of the following is true about Humulin R U-500?

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B. May be used in patients requiring more than 200 units of insulin per day

C. Maximum units of insulin per injection with pen delivery is 300 units

D. All of the above
Diabetes burden in US

**Diabetes is the 7th leading cause of death in US**

Morbidity associated with diabetes
Older diabetes medications

- **Sulfonylureas/Meglitinides**
  - glyburide, glipizide, glimepiride
- **Meglitinides**
  - repaglinide, nateglinide
- **Biguanides**
  - metformin
- **Thiazolidinediones**
  - Rosiglitazone, pioglitazone
  - Regular, NPH, Mix
- **Insulin**
  - U100, U500
  - Rapid, Long acting

*Meglitinides: repaglinide, nateglinide*
Infrequently used diabetes medications

- Alpha-glucosidase inhibitors: acarbose, miglitol
- Bile acid sequestrant: colesevelam
- Dopamine agonist: bromocriptine
- Amylinomimetic: pramlintide
Newer diabetes medications

- **Glucagon-like peptide 1 receptor agonist (GLP-1 RA)**
  - exenatide
  - liraglutide
  - albiglutide
  - dulaglutide
  - lixisenatide

- **Dipeptidyl peptidase 4-inhibitor (DPP4-I)**
  - sitagliptin
  - saxagliptin
  - linagliptin
  - alogliptin

- **Sodium glucose co-transporter 2 inhibitor (SGLT2-I)**
  - canagliflozin
  - dapagliflozin
  - empagliflozin
Newer Insulin formulations

Bolus insulin

Inhaled insulin (Afrezza)

Insulin lispro 200 units/ml (Humalog U200 KwikPen)

Bolus insulin
Newer Insulin formulations, cont’d

Insulin glargine (Basaglar)

Insulin glargine 300 units/ml (Toujeo)
Newer Insulin formulations, cont’d

- Insulin degludec (Tresiba)
  - Basal insulin

- Insulin degludec with aspart (Ryzodeg)
  - Bolus-Basal insulin
Newer Insulin formulations, cont’d

- Insulin glargine with lixisenatide (Soliqua)
- Insulin degludec with liraglutide (Xultophy)

Basal insulin:GLP-1RA

Basal insulin:GLP-1RA
Newer type 2 diabetes medications
<table>
<thead>
<tr>
<th>Drug</th>
<th>Generic</th>
<th>Dosing Schedule</th>
<th>Mixing Required</th>
<th>Pre-injection waiting time</th>
<th>Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Byetta</td>
<td>Exenatide IR</td>
<td>BID</td>
<td>No</td>
<td>None</td>
<td>5mcg, 10 mcg</td>
</tr>
<tr>
<td>Bydureon</td>
<td>Exenatide ER</td>
<td>QW</td>
<td>Yes</td>
<td>None</td>
<td>2mg</td>
</tr>
<tr>
<td>Tanzeum</td>
<td>Albiglutide</td>
<td>QW</td>
<td>Yes</td>
<td>Yes: 15-30 minutes</td>
<td>30mg, 50mg</td>
</tr>
<tr>
<td>Trulicity</td>
<td>Dulaglutide</td>
<td>QW</td>
<td>No</td>
<td>None</td>
<td>0.75mg, 1.5mg</td>
</tr>
<tr>
<td>Victoza</td>
<td>Liraglutide</td>
<td>QD</td>
<td>No</td>
<td>None</td>
<td>0.6mg, 1.2mg, 1.8mg</td>
</tr>
<tr>
<td>Adlyxin</td>
<td>Lixisenatide</td>
<td>QD</td>
<td>No</td>
<td>None</td>
<td>10mcg, 20mcg</td>
</tr>
</tbody>
</table>
# GLP-1RA: glycemic efficacy, safety profile

<table>
<thead>
<tr>
<th>Generic</th>
<th>A1C Lowering</th>
<th>Safety concern</th>
<th>Weight effect</th>
<th>Hypoglycemia</th>
<th>Cardiovascular effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exenatide IR</td>
<td>1%</td>
<td>Pancreatitis?</td>
<td>2kg</td>
<td>---</td>
<td>Possible CV benefit?</td>
</tr>
<tr>
<td>Exenatide ER</td>
<td>1.5%</td>
<td>Thyroid cancer?</td>
<td>2.5kg</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Albiglutide</td>
<td>1%</td>
<td>Thyroid cancer? Pancreatitis?</td>
<td>-1kg</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Dulaglutide</td>
<td>1.5%</td>
<td>Thyroid cancer?</td>
<td>2.5kg</td>
<td>---</td>
<td>CV death, MI, stroke</td>
</tr>
<tr>
<td>Liraglutide</td>
<td>1.5%</td>
<td>Thyroid cancer?</td>
<td>2.5kg</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Lixisenatide</td>
<td>0.7-1.0%</td>
<td>Pancreatitis?</td>
<td>2kg</td>
<td>---</td>
<td>Possible CV benefit?</td>
</tr>
</tbody>
</table>
LEADER Trial

- Randomized, double-blind, placebo-controlled trial in patients with type 2 diabetes with high CVD risk (81.3% had established CVD)

- Liraglutide vs. placebo on CV effect
  - MI, Stroke, CV death

- Outcome
  - 13% of composite outcome (95% CI, 0.78 to 0.97); P<0.001 for noninferiority; P=0.01 for superiority
  - 22% of CV death (95% CI, 0.66 to 0.93); P=0.007
  - Lower MI, Stroke with liraglutide (not significant)
  - FDA label change on indication
Newer type 2 diabetes medications
# Gliptins Comparison Chart

<table>
<thead>
<tr>
<th></th>
<th>Saxagliptin (Onglyza)</th>
<th>Sitagliptin (Januvia)</th>
<th>Linagliptin (Tradjenta)</th>
<th>Alogliptin (Nesina)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration</td>
<td>Oral, Once Daily</td>
<td>Oral, Once Daily</td>
<td>Oral, Once Daily</td>
<td>Oral, Once Daily</td>
</tr>
<tr>
<td>A1C</td>
<td>0.4-0.7%</td>
<td>0.6-0.79%</td>
<td>0.5-0.7%</td>
<td>0.4-0.6%</td>
</tr>
<tr>
<td>Dose</td>
<td>2.5-5mg PO QD</td>
<td>100mg PO QD</td>
<td>5mg PO QD</td>
<td>25mg PO QD</td>
</tr>
<tr>
<td>Renal Dosing Adjustment</td>
<td>2.5mg:CrCl ≤ 50ml/min</td>
<td>25mg: CrCl &lt; 30ml/min</td>
<td>None</td>
<td>6.25mg: CrCl &lt; 30ml/min</td>
</tr>
<tr>
<td></td>
<td>5mg:CrCl &gt; 50ml/min</td>
<td>50mg: CrCl 30-50ml/min</td>
<td></td>
<td>12.5mg: CrCl 30-60ml/min</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100mg: CrCl &gt; 50ml/min</td>
<td></td>
<td>25mg: CrCl &gt; 60ml/min</td>
</tr>
<tr>
<td>Drug Interaction</td>
<td>CYP450 3A4/5 Inhibitors</td>
<td>CYP450 3A4/P-glyp Inducers</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Gliptins: glycemic efficacy, safety profile

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<th>Cardiovascular effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saxagliptin</td>
<td>0.4-0.7%</td>
<td>CHF? Arthralgia, Pancreatitis?</td>
<td>---</td>
<td>---</td>
<td>----</td>
</tr>
<tr>
<td>Sitagliptin</td>
<td>0.6-0.79%</td>
<td>Pancreatitis? Arthralgia</td>
<td>---</td>
<td>---</td>
<td>----</td>
</tr>
<tr>
<td>Linagliptin</td>
<td>0.5-0.7%</td>
<td>Pancreatitis? Arthralgia</td>
<td>---</td>
<td>---</td>
<td>----</td>
</tr>
<tr>
<td>Alogliptin</td>
<td>0.4-0.6%</td>
<td>CHF? Pancreatitis? Arthralgia</td>
<td>----</td>
<td>---</td>
<td>----</td>
</tr>
</tbody>
</table>
Newer type 2 diabetes medications
# SGLT2-Comparison Chart

<table>
<thead>
<tr>
<th></th>
<th>Canagliflozin (Invokana)</th>
<th>Dapagliflozin (Farxiga)</th>
<th>Empagliflozin (Jardiance)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Administration</strong></td>
<td>Take prior to first meal of the day</td>
<td>Take in the morning with or without food</td>
<td>Take in the morning with or without food</td>
</tr>
<tr>
<td><strong>Normal Dose</strong></td>
<td>Start: 100 mg po qd Max: 300 mg po qd</td>
<td>5 mg po qd 10 mg po qd</td>
<td>Start: 10 mg po qd Max: 25 mg qd</td>
</tr>
<tr>
<td><strong>Dose Adjustment</strong></td>
<td>eGFR: 45-59ml/min max. 100 mg qd, &lt; 45 ml/min, not recommended, &lt; 30ml/min, CI. Hepatic: use not recommended in severe (Child-Pugh class C)</td>
<td>eGFR: 30-59ml/min, not recommended, &lt; 30ml/min, CI. Hepatic impairment: No adjustment necessary</td>
<td>eGFR: &lt; 45ml/min, don’t initiate, &lt;30ml/min, CI Hepatic: No dose adjustment required</td>
</tr>
<tr>
<td><strong>Drug Interaction</strong></td>
<td>UGT enzyme inducer, Diuretics, ACEI</td>
<td>Diuretic-volume depletion, ACEI</td>
<td>Diuretics-volume depletion, ACEI</td>
</tr>
</tbody>
</table>
## SGLT2-Is: glycemic efficacy, safety profile

<table>
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<tr>
<th>Generic</th>
<th>A1C Lowering</th>
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<th>Hypoglycemia</th>
<th>Cardiovascular effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canagliflozin</td>
<td>0.7-1.0%</td>
<td>DKA, bone fx, genital infections</td>
<td></td>
<td>---</td>
<td>Possible benefit?</td>
</tr>
<tr>
<td>Dapagliflozin</td>
<td>0.7-1.0%</td>
<td>DKA, genital infections</td>
<td></td>
<td>---</td>
<td>Possible benefit?</td>
</tr>
<tr>
<td>Empagliflozin</td>
<td>0.7-1.0%</td>
<td>DKA, genital infections</td>
<td></td>
<td>---</td>
<td>CV death</td>
</tr>
</tbody>
</table>
EMPA-REG Outcome Trial

- Randomized, double-blind, placebo-controlled trial in patients with type 2 diabetes with established CVD
- Empagliflozin v. placebo on CV effect
  - MI, Stroke, CV death
- Outcome
  - 38% of CV death (95% CI, 0.49 to 0.77; P<0.001)
  - 14% of composite outcome (95.02% CI, 0.74 to 0.99); P<0.001 for noninferiority and P=0.04 for superiority
  - FDA label change on indication
Question #1

- Which of the following newer diabetes agents has been associated with genitourinary infections, especially among women users?

  a. empagliflozin
  b. dulaglutide
  c. linagliptin
  d. inhaled insulin
Which of the following newer diabetes agents has been associated with genitourinary infections, especially among women users?

a. empagliflozin

b. dulaglutide

c. linagliptin

d. inhaled insulin
**Insulin Afrezza**

- It uses a palm-sized handheld breath-activated inhaler; available as single-use cartridges of 4 unit, 8 unit, 12 unit

- Technosphere particles are made of human regular insulin loaded into a diketopiperazine molecule. It dissolves quickly at physiological pH and allows for rapid insulin absorption from the lungs

- Technosphere® insulin works within 12 to 15 minutes, peaks in 30 minutes, and clears out by 180 minutes; mimicking physiological meal time insulin
### Glycemic control

<table>
<thead>
<tr>
<th>Type 1: non-inferior to insulin aspart (but less A1C reduction)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 2: more effective than placebo</td>
</tr>
</tbody>
</table>

### Safety concern

- Acute Bronchospasm
- Pulmonary function
- Lung cancer

**Role in management:** use as bolus insulin in patients type 1 or type 2 diabetes
Insulin human R U-500
Insulin Lispro 200 units/ml (Humalog 200)
Insulin glargine (Basaglar)

- Approved for type 1 and type 2 diabetes
- Follow-on product (biosimilar-like)
- Dosed once daily
- Comparable A1C lowering with Lantus
- Available as U100 KwikPen
- 1:1 dosing when switching from Lantus
Insulin Glargine 300 units/ml (Toujeo)
Insulin degludec (Tresiba)

- Approved for type 1 and type 2 diabetes
- Long acting insulin analog
- Dosed daily subcutaneously at any time of the day
- 42 hours duration of action
- Available in U100 and U200 FlexTouch Pen
- No dose conversion necessary
Insulin degludec with aspart (Ryzodeg 70/30)

- Approved for type 1 and type 2 diabetes
- Premixed combination: 70% insulin degludec; 30% insulin aspart
- Dosed once or twice daily with main meals
- Bolus insulin may be added to other meals
- Comparable A1C lowering with Novolog 70/30
- Available as U100 FlexTouch pen
Insulin glargine with lixisenatide (Soliqua 100/33)

Approved for type 2 diabetes

Premixed combination: 100 units of insulin glargine; 33mcg lixisenatide per ml

Dosed once daily within 1 hour prior to first meal

For patients uncontrolled with <60 units of basal insulin or lixisenatide

Available in 3ml pen

Available in January 2017
Insulin degludec with liraglutide (Xultophy 100/3.6)

Approved for type 2 diabetes

Premixed combination: 100 units of insulin degludec; 3.6 mg liraglutide per ml

Dosed once daily with or without food

For patients uncontrolled with <50 units of basal insulin or liraglutide

Available in 2017
• Which of the following newer insulin formulation may be used by patients with type 1 or type 2 diabetes?

• insulin lispro with lixisenatide
• insulin degludec with aspart
• Insulin glargine with lixisenatide
• Insulin degludec with liraglutide
Question #2

• Which of the following newer insulin formulation may be used by patients with type 1 or type 2 diabetes?

  • insulin lispro with lixisenatide
  • **insulin degludec with aspart**
  • Insulin glargine with lixisenatide
  • Insulin degludec with liraglutide
Diabetes management guideline update: ADA

Premeal blood glucose: 80-130 mg/dl

A1C: <7%*

2 hours postmeal blood glucose: <180 mg/dl

American Diabetes Association.
Standards of Medical Treatment 2017.
Diabetes management guideline update: AACE

A1C: ≤ 6.5%*

Fasting plasma glucose: < 110 mg/dl

2 hours Post-prandial glucose: < 140 mg/dl

American Association of Clinical Endocrinologists, Diabetes Guideline 2017
Approach to management of hyperglycemia:

Patient attitude and expected treatment efforts
- More stringent: Highly motivated, adherent, excellent self-care capacities
- Less stringent: Less motivated, non-adherent, poor self-care capacities

Risks potentially associated with hypoglycemia, other adverse events
- More stringent: Low
- Less stringent: High

Disease duration
- More stringent: Newly diagnosed
- Less stringent: Long-standing

Life expectancy
- More stringent: Long
- Less stringent: Short

Important comorbidities
- More stringent: Absent
- Less stringent: Few / mild, Severe

Established vascular complications
- More stringent: Absent
- Less stringent: Few / mild, Severe

Resources, support system
- More stringent: Readily available
- Less stringent: Limited
**Start With Monotherapy Unless:**

- HbA1c level is ≥9%, consider dual therapy.
- HbA1c level is ≥10%, blood glucose level is ≥300 mg/dL, or patient is markedly symptomatic, consider combination injectable therapy.

### Monotherapy

<table>
<thead>
<tr>
<th>Metformin</th>
<th>Lifestyle Management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EFFICACY</strong></td>
<td>High</td>
</tr>
<tr>
<td>HYPOGLYCEMIA RISK</td>
<td>Low risk</td>
</tr>
<tr>
<td>WEIGHT</td>
<td>Neutral/loss</td>
</tr>
<tr>
<td>SIDE EFFECTS</td>
<td>GI/lactic acidosis</td>
</tr>
<tr>
<td>COSTS*</td>
<td>Low</td>
</tr>
</tbody>
</table>

If HbA1c target not achieved after approximately 3 mo of monotherapy, proceed to 2-drug combination (order not meant to denote any specific preference; choice dependent on a variety of patient- and disease-specific factors):

### Dual Therapy

<table>
<thead>
<tr>
<th>Metformin +</th>
<th>Lifestyle Management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EFFICACY</strong></td>
<td>High</td>
</tr>
<tr>
<td>HYPOGLYCEMIA RISK</td>
<td>High</td>
</tr>
<tr>
<td>WEIGHT</td>
<td>Intermediate</td>
</tr>
<tr>
<td>SIDE EFFECTS</td>
<td>Low risk</td>
</tr>
<tr>
<td>COSTS*</td>
<td>Loss</td>
</tr>
</tbody>
</table>

If HbA1c target not achieved after approximately 3 mo of dual therapy, proceed to 3-drug combination (order not meant to denote any specific preference; choice dependent on a variety of patient- and disease-specific factors):

### Triple Therapy

<table>
<thead>
<tr>
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<th>Lifestyle Management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EFFICACY</strong></td>
<td>High</td>
</tr>
<tr>
<td>HYPOGLYCEMIA RISK</td>
<td>Moderate risk</td>
</tr>
<tr>
<td>WEIGHT</td>
<td>Gain</td>
</tr>
<tr>
<td>SIDE EFFECTS</td>
<td>Hypoglycemia</td>
</tr>
<tr>
<td>COSTS*</td>
<td>Gain</td>
</tr>
</tbody>
</table>

If HbA1c target not achieved after approximately 3 mo of triple therapy and patient on oral combination, move to basal insulin or GLP-1-RA; if the patient is on GLP-1-RA, add basal insulin; or if the patient is on optimally titrated basal insulin, add GLP-1-RA or mealtime insulin. Metformin therapy should be maintained, whereas other oral agents may be discontinued on an individual basis to avoid unnecessarily complex or costly regimens (i.e., adding a fourth antihyperglycemic agent).

American Diabetes Association.
Standards of Medical Treatment 2017.
# AACE Glycemic Control Algorithm

## LIFESTYLE THERAPY

<table>
<thead>
<tr>
<th>Initial A1C &lt;7.5%</th>
<th>Initial A1C ≥7.5%</th>
<th>Initial A1C &gt;9.0%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Monotherapy</strong></td>
<td><strong>Dual Therapy</strong></td>
<td><strong>Triple Therapy</strong></td>
</tr>
<tr>
<td>Metformin</td>
<td>GLP-1 RA</td>
<td>GLP-1 RA</td>
</tr>
<tr>
<td>GLP-1 RA</td>
<td>SGLT-2i</td>
<td>SGLT-2i</td>
</tr>
<tr>
<td>SGLT-2i</td>
<td>DPP-4i</td>
<td>DPP-4i</td>
</tr>
<tr>
<td>DPP-4i</td>
<td>TZD</td>
<td>TZD</td>
</tr>
<tr>
<td>TZD</td>
<td>Basal insulin</td>
<td>Basal insulin</td>
</tr>
<tr>
<td>AGI</td>
<td>Colesevelam</td>
<td>Colesevelam</td>
</tr>
<tr>
<td>SU/GLN</td>
<td>Bromocriptine QR</td>
<td>Bromocriptine QR</td>
</tr>
<tr>
<td></td>
<td>AGI</td>
<td>AGI</td>
</tr>
<tr>
<td></td>
<td>SU/GLN</td>
<td>SU/GLN</td>
</tr>
</tbody>
</table>

**Absence of Symptoms:** Dual or Triple Therapy

**Presence of Symptoms:** Insulin ± Other medications

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American Association of Clinical Endocrinologists, Diabetes Guideline 2017
Case #1

• GB is a 50 year old black female with a 2 year history of type 2 diabetes. She has been controlled on metformin 1000mg XR bid until recently. Her current A1C is 7.8% and she is very motivated to do anything necessary to reach glycemic control. Even though she exercises 150 minutes weekly and has been counseled by a dietician, her current BMI is 32. She also has mild heart failure condition. Her kidney/liver labs are normal. Blood pressure and lipids values are
Case #1-Answer

- GB is a 50 year old black female with a 2 year history of type 2 diabetes. She has been controlled on metformin 1000mg XR bid until recently. Her current A1C is 7.8% and she is very motivated to do anything necessary to reach glycemic control. Even though she exercises 150 minutes weekly and has been counseled by a dietician, her current BMI is 32. She also has mild heart failure condition. Her kidney/liver labs are normal. Blood pressure and lipids values are
Case #1 Considerations
CK is a 60 year Hispanic male with a 15 year history of type 1 diabetes. He currently injects 34 units of Insulin Lispro U100 with each meal; 100 units of Glargine U100 at bedtime. His current A1C is 6.8%, BMI is 25; BP, Lipids, LFT/Renal within normal limits. His other meds include benazepril 40mg, rosuvastatin 5mg, and ASA 81. He is very concerned about having to inject his Glargine insulin twice to get a dose. Which of the following is the best treatment option for CK?

- A. Switch his Glargine U100 to U300 at same dose
- B. Switch his Glargine U100 to U300 at higher dose
- C. Switch his Glargine U100 to Degludec U100 at same dose
- D. Switch his Glargine U100 to Degludec U200 at higher dose
CK is a 60 year Hispanic male with a 15 year history of type 1 diabetes. He currently injects 34 units of Insulin Lispro U100 with each meal; 100 units of Glargine U100 at bedtime. His current A1C is 6.8%, BMI is 25; BP, Lipids, LFT/Renal within normal limits. His other meds include benazepril 40mg, rosuvastatin 5mg, and ASA 81. He is very concerned about having to inject his Glargine insulin twice to get a dose. Which of the following is the best treatment option for CK?

- A. Switch his Glargine U100 to U300 at same dose
- B. Switch his Glargine U100 to U300 at higher dose
- C. Switch his Glargine U100 to Degludec U100 at same dose
- D. Switch his Glargine U100 to Degludec U200 at higher dose
Case #2 Considerations
Summary

- The number of available diabetes agents have increased tremendously over the last decade.
- Pharmacists must ensure that optimal insulin concentration product is selected for patient use.
- The fast rate of diabetes drug approval and drug safety information demands that pharmacist stay abreast on diabetes pharmacotherapy.
- The pharmacist plays a vital role to ensure the proper selection of pharmacotherapy agents in order to optimize diabetes care.
References


