Preventing Adverse Drug Events
Individualizing Glycemic Targets Using Health Literacy Strategies

Introduction

Welcome

Introduction
(This information on this slide applies mainly to the interactive version of the course)

This course will take approximately 1 hour to complete.

It includes several video and audio clips, so be sure to have your speakers or headphones ready before proceeding.

Use the “Next” and “Previous” buttons to navigate through the course. To return to sections already reviewed, use the menu on the left-hand side or use the keyboard shortcuts.

When the course links to resources on non-federal websites, links will include this symbol: 🌐. You can read the exit disclaimer here (http://health.gov/communication/exitdisclaimer.asp#external).

Introduction Video

Medical science is always evolving. When it comes to treating diabetes, we’ve been taught - and continue to practice - that everyone should set their glycemic target - or A1C - at less than 7.

There is now a convincing body of evidence that for some patients a target of less than 7 isn’t always the safest or most beneficial.

Hypoglycemia is one of our biggest safety concerns for patients who have tighter control. In 2010, more than 25 million adults in the United States had diagnosed or undiagnosed diabetes mellitus.
Among patients 65 and older, 2 of the most common medication classes associated with emergency department visits were hypoglycemic agents. Yet, nearly all cases of hypoglycemia are considered preventable.

We can make care safer by individualizing care and improving communication between patients and health care providers.

How can we prevent hypoglycemia? What role does individual care play? And how can you implement these strategies with your patients? I invite you to join me to learn more about the answers to these questions.

Hi, I'm Dr. Justin Mills. For the next hour, I'll be walking you through some of the main themes you'll learn in each lesson.

**Course Overview**

**Course Purpose**
The purpose of this course is to train health care providers to reduce hypoglycemic adverse drug events (ADEs) in older adults.

You will learn how to apply current evidence-based guidelines for individualized glycemic target goals and how to use health literacy strategies.

**Course Learning Objectives**
**By the end of this course, you will be able to:**

- Describe the national burden of adverse drug events (ADEs).
- Define hypoglycemia.
- Identify the individual risk factors, hypoglycemic agents, and medication interactions that place individuals with diabetes at higher risk for hypoglycemic ADEs.
- Describe the importance of setting target glycemic goals based on individual factors.
- Apply evidence-based guidelines for diabetes management, focusing on setting individualized glycemic targets with patients to reduce the risk of hypoglycemic episodes.
- Apply health literacy strategies to help patients understand and act on information to prevent ADEs.
How to Obtain Continuing Education

Continuing Education
The Centers for Disease Control and Prevention (CDC) Training and Continuing Education Online system offers continuing education, free of charge, to participants who complete the course.

1.5 Continuing Medical Education (CME) Activities with Joint Sponsors
This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the Centers for Disease Control and Prevention and the Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary, USDHHS.

The Centers for Disease Control and Prevention is accredited by the ACCME® to provide medical education for physicians. The Centers for Disease Control and Prevention designates this enduring educational activity for a maximum of 1.5 AMA PRA Category 1 Credits™.

1.3 Continuing Nursing Education (CNE) Contact Hours
The Centers for Disease Control and Prevention is accredited as a provider of Continuing Nursing Education by the American Nurses Credentialing Center’s Commission on Accreditation. This activity provides 1.3 contact hours.

0.1 IACET Continuing Education Units (CEU)
The CDC has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102.

The CDC is authorized by IACET to offer 0.1 ANSI/IACET Continuing Education Units for this program.

0.1 Continuing Pharmacy Education (CPE)
The CDC is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

This program is a designated event for pharmacists to receive 0.1 Contact Hours in pharmacy education. The Universal Activity Number is 0387-****.**-***.***-P.

Category: This activity has been designated as Knowledge-Based.

Continuing Education (Continued)
After the course, you will be directed to the CDC Training and Continuing Education Online system to complete an online post-test.
Chapter 1

Chapter 1 Overview

By the end of this chapter, you will be able to:

- Describe the national burden of adverse drug events (ADEs).

National Rates of ADEs

Adverse Drug Events: A National Public Health Issue

These harms include, but are not limited to:

- Medication errors
  - Errors made during the prescribing, transcribing, dispensing, administering, adherence, or monitoring of a drug.
- Adverse drug reactions

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• Harms directly caused by a drug at normal doses.
  • Allergic reactions
  • Overdoses

Description of image: The majority of Adverse Drug Events are adverse drug reactions caused at normal doses. A smaller number of Adverse Drug Events are caused by medication errors.

**National Rates of ADEs**

In **inpatient settings**, research indicates that ADEs are the single largest contributor to hospital-related complications.³

In **outpatient settings**, nationally representative surveillance data indicate that each year ADEs account for:

- Over **3.5 million** physician office visits⁴
- An estimated **1 million** emergency department (ED) visits⁵
- Approximately **125,000** hospital admissions⁵

**ADEs and Older Adults**

Age is a principal underlying risk factor for ADEs, and older adults (age 65 and older) are particularly vulnerable.

**ADEs Treated in U.S. Emergency Departments (2004 - 2005)⁵**

Graph Description: Annual rates of ADEs in older adults are nearly twice that of people age 45 to 64 and nearly three times that of people ages 25 to 44.

**ADEs and Older Adults (Continued)**

National surveillance data indicate that older adults are 2 to 3 times more likely than younger people to have an ADE requiring a physician office or ED visit.

Older adults are also 7 times more likely to have an ADE requiring hospital admission.⁵

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Many adverse drug events are not reported or measured. These numbers are likely an underestimate of the true numbers.

Other Vulnerable Populations
These patient populations may also be especially vulnerable to ADEs:\(^2\)

- Very young children
- People with low socioeconomic status
- People with limited health literacy
- People who have limited access to health care services
- Certain minority racial or ethnic groups

The Cost of ADEs
ADEs place a huge financial burden on annual health care expenditures, costing up to $5.6 million per hospital.\(^6\)

National estimates suggest that ADEs contribute $3.5 billion annually to U.S. health care costs.\(^7\)

ADE Action Plan

Chapter 1
5% of course complete

Adverse Drug Events: A National Public Health Issue

- National Rates of ADEs
- ADE Action Plan
- Key Points and Knowledge Check

National Action Plan for ADE Prevention
Since ADEs contribute significantly to health care-related harms and costs, the Office of the Assistant Secretary for Health (OASH) formed the Federal Interagency Steering Committee to develop the National Action Plan for ADE Prevention.

The Action Plan identifies common, clinically significant, preventable, and measurable ADEs and suggests a 4-pronged approach to reduce these ADEs.


Action Plan Approach

- **Surveillance:** Coordinate existing federal surveillance resources and data to assess the health burden and rates of ADEs.
- **Prevention:** Share existing evidence-based prevention tools across federal agencies and with non-federal health care providers and patients.
- **Incentives and Oversight:** Explore opportunities, including financial incentives and oversight authorities, to promote ADE prevention.
- **Research:** Identify current knowledge gaps and future research needs (unanswered questions) for ADE prevention.

Action Plan Criteria
Given the breadth and depth of ADEs in the United States and the complexity of addressing the full scope of medication-related harms, the Action Plan focuses on those ADEs that:

- Account for the greatest number of measurable harms
- Can be effectively measured
- Are considered largely preventable

The 3 drug classes addressed in the Action Plan are anticoagulants, diabetes agents, and opioids.

Course Context
This course is part of a larger effort to implement the National Action Plan for ADE Prevention and the National Action Plan to Improve Health Literacy.


Key Points and Knowledge Check

**Chapter 1**
9% of course complete

Adverse Drug Events: A National Public Health Issue

- National Rates of ADEs
• ADE Action Plan
• Key Points and Knowledge Check

Chapter 1 Key Points
• The potential for harms from ADEs is a critical patient safety and public health challenge.
• Older adults are more likely than younger people to have an ADE requiring a physician office or ED visit.
• The National Action Plan for ADE Prevention presents strategies and resources for preventing ADEs locally and nationally.

Knowledge Check Question 1
Nationally representative surveillance data indicate that ADEs account for how many emergency department visits per year?

☐ Approximately 125,000
☐ Approximately 1 million
☐ Approximately 3.5 million

Question Feedback 1
In the U.S., ADEs account for an estimated 1 million emergency department visits per year.

• ADEs account for over 3.5 million physician office visits and approximately 125,000 hospital admissions each year.
• In inpatient settings, ADEs affect approximately 2 million hospital stays annually, and prolong the length of hospital stays by approximately 1.7 to 4.6 days.

Knowledge Check Question 2
Older adults (age 65 and older) are how many times more likely than younger people to have an ADE requiring hospital admission?

☐ 2 to 3 times more likely
☐ 5 times more likely
☐ 7 times more likely
☐ 10 times more likely

Question Feedback 2
Older adults are 7 times more likely to have an ADE requiring hospital admission.

• Older adults are 2 to 3 times more likely to have an ADE requiring a visit to a physician’s office or emergency department.
• Age is a principal underlying risk factor for ADEs and is likely secondary to altered pharmacokinetics, polypharmacy, or cognitive decline.
• Older adults age 65 or older, comprise approximately 35% of all inpatient stays, but contribute to approximately 53% of inpatient stays complicated by ADEs.

Chapter 2

Chapter 2 Overview

Chapter 2 Introduction Video
Chapter 2 will look at medications that are commonly associated with outpatient ADEs.

We’ll also go over how evidence-based health literacy and patient engagement processes can help improve diabetes management and prevent hypoglycemia in the outpatient setting.

This chapter includes a brief video scenario that will walk you through the steps of the teach-back method, a tool you can use to confirm a patient’s understanding.

Chapter 2
Key Determinants and a Patient-Centered Approach to Risk Reduction

By the end of this chapter, you will be able to:

• Define hypoglycemia.
• Identify the individual risk factors, hypoglycemic agents, and medication interactions that place individuals with diabetes at higher risk for hypoglycemic ADEs.

Diabetes Agents and ADEs

Chapter 2
13% of course complete

Key Determinants and a Patient-Centered Approach to Risk Reduction

• Diabetes Agents and ADEs
• Hypoglycemia
• Individual Risk Factors
• Health Literacy and ADE Reduction
• Health Literacy Strategy: Teach-Back
• Key Points and Knowledge Check

**Hypoglycemic ADEs**

Intensive treatment and misunderstandings or errors related to the administration of diabetes agents commonly contribute to ADEs in both inpatient and outpatient settings.

Insulin and oral diabetes agents (especially the sulfonylurea drugs) are some of the most common medications associated with emergency department visits for ADEs among individuals age 65 and older.\(^8\)

**Hypoglycemic ADEs and Older Adults**

From 1999 to 2010, rates of hospital admissions for hypoglycemia among Medicare beneficiaries increased by 22.3%.\(^8\)

However, these data may underestimate the magnitude of the problem, since many hypoglycemic episodes are treated in the ambulatory care setting.

**Engaging Patients in Their Care**

Self-efficacy and health literacy have been found to be important predictors of self-care behaviors in patients with type 2 diabetes.\(^9\)

Effective diabetes management requires active participation and informed decision making on the part of patients and caregivers, as well as collaboration between patients and providers. Patient engagement is critical to this effort.

*Patient engagement* is defined as “actions individuals must take to obtain the greatest benefit from the health care services available to them.”\(^10\)

**The Importance of Patient Education**

To help prevent hypoglycemic ADEs, patients and caregivers need to recognize the signs and symptoms of hypoglycemia and also understand issues that may affect medication adherence or increase side effects, such as:

- Comorbid conditions

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Health Literacy and Hypoglycemia

Health literacy plays an important role in patients’ ability to recognize symptoms of hypoglycemia. This course covers strategies to improve health literacy later in the chapter.

Health literacy
The ability to obtain, communicate, process, and understand health information and services in order to make appropriate health decisions.

Only 50% of patients with diabetes who have low health literacy know the symptoms of hypoglycemia.

In contrast, 94% of patients with diabetes who have functional health literacy know the symptoms of hypoglycemia.11

Hypoglycemia

Chapter 2
19% of course complete

Key Determinants and a Patient-Centered Approach to Risk Reduction

- Diabetes Agents and ADEs
- **Hypoglycemia**
- Individual Risk Factors
- Health Literacy and ADE Reduction
- Health Literacy Strategy: Teach-Back
- Key Points and Knowledge Check

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Definitions of Hypoglycemia

Definitions for hypoglycemia are variable, which complicates both the study and tracking of hypoglycemic events.

Rather than refer to a specific blood glucose concentration for all individuals, hypoglycemia in patients with diabetes can be defined as:

**An abnormally low plasma glucose concentration that exposes the individual to potential or actual harm.**\(^2\)

Using an “Alert” Value

While it’s not possible to define a single threshold glucose value that defines hypoglycemia in all individuals, a glucose value of \(\leq 70\) mg/dL is commonly recommended for generating concern (an “alert”).

An “alert” value may give patients and caregivers time to prevent a serious clinical hypoglycemic episode. It also accounts for the limited accuracy of some monitoring devices.

- Glucose measurements generally vary depending on the sample source (e.g., capillary blood from fingerstick, venous blood draw), sample type (e.g., plasma, whole blood), and method of measurement. These variables may change the glucose alert thresholds.

The A1c Test\(^{12}\)

The A1c test provides information about a person’s average blood glucose levels in the past 3 months. An A1c test result can be up to 0.5% higher or lower than the actual percentage. This means an A1c measured as 7.0% could indicate a true A1c between 6.5% and 7.5%.

In contrast, Fasting Plasma Glucose (FPG) tests are less accurate than A1c tests. An FPG test result can be up to 16 mg/dl higher or lower than the actual level. This means an FPG measured as 126 mg/dl could indicate a true FPG between 110 mg/dl and 142 mg/dl.

Symptoms of Hypoglycemia

Signs and symptoms of hypoglycemia include, but are not limited to:

- Hunger
- Shakiness
- Nervousness

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• Sweating
• Dizziness or light-headedness
• Sleepiness
• Confusion
• Difficulty speaking
• Anxiety
• Weakness

Some patients, especially those with longstanding diabetes, may not have typical early warning signs of hypoglycemia.

Get a patient handout on symptoms of hypoglycemia [PDF - 1.2 MB]. (http://learningaboutdiabetes.org/downloads/LowBloodSugarEN.pdf)

**Potential Harms of Hypoglycemic Episodes**
Hypoglycemia puts patients at risk for injury and death. For some patients, even infrequent hypoglycemia can be devastating.

Hypoglycemia may lead to:

• Cardiac dysrhythmias
• Accidents and falls
• Dizziness
• Confusion
• Infections (such as aspiration pneumonia from impaired awareness)
• Serious, permanent neurological deficits
• Death

**Hypoglycemia Unawareness**
Another potential harm of frequent hypoglycemic episodes is hypoglycemia unawareness.

This is a condition in which patients stop sensing the early warning signs of hypoglycemia.

**Example from the Field**
Hypoglycemia Unawareness

“I recently explained to a patient with type 1 diabetes mellitus why he needs to watch out for hypoglycemia even when he has no symptoms. For this patient, I thought an ‘alert value’ for hypoglycemia should actually be 80 mg/dl. At that level, he needs to treat himself as if he’s low because if he doesn’t act then, he’ll continue to trend lower and have difficulty recovering.”
We also talked about re-evaluating his insulin regimen to help him avoid hypoglycemia in the first place. Once he understood that he had options for preventing hypoglycemia, he became more engaged in managing his blood sugar.”

**Types of Hypoglycemia**
Hypoglycemia can be either symptomatic or asymptomatic.

This section of the lesson will discuss:

1. Symptomatic hypoglycemia
2. Asymptomatic hypoglycemia
3. Severe hypoglycemia
4. Nocturnal hypoglycemia
5. Pseudo-hypoglycemia

**Symptomatic Hypoglycemia**
Symptomatic hypoglycemia can present in 2 ways:

- Confirmed (with a measured plasma glucose concentration <=70 mg/dL)
- Probable (without a measure of blood glucose but with typical symptoms)

**Asymptomatic Hypoglycemia**
Asymptomatic hypoglycemia is an event not accompanied by typical symptoms of hypoglycemia, but with a measured plasma glucose concentration <=70 mg/dL (<=3.9 mmol/L).

Although patients may not have clinical symptoms, asymptomatic hypoglycemia can nonetheless be dangerous.

It’s important to assess the risk of hypoglycemia at every visit with patients treated with insulin or sulfonylureas.

**Strategies for Assessing the Risk of Hypoglycemia**
Ask questions to find out how often patients experience symptomatic and asymptomatic hypoglycemia, and what they do to treat it.

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• “How do you know when you have low blood sugar?”
• “When your blood glucose goes below 70, what is the usual cause?”
• “How often do you feel badly because of low blood sugar, while still being able to stop and treat yourself?”

Review patients’ glucose logs. Make note of:

• The date, approximate time, and circumstances surrounding recent episodes of hypoglycemia
• Information about patients’ awareness of the warning symptoms of hypoglycemia
• Description of image: Sample patient glucose log showing time of day and blood sugar level before and after breakfast, lunch, and dinner, and at bedtime.

Severe Hypoglycemia
Severe hypoglycemia is an event requiring the assistance of another person to actively administer carbohydrates or glucagon, or take other corrective actions.

Profound and prolonged hypoglycemia can cause brain injury, ventricular arrhythmias, and fatal events.

Nocturnal Hypoglycemia
Almost 50% of all hypoglycemic episodes occur during nighttime sleep. These episodes can have a significant impact on quality-of-life measures in patients with both type 1 and type 2 diabetes.

Nocturnal hypoglycemia in particular can affect patients’ sense of well-being because of its impact on sleep quantity and quality.

Potential warning signs of nocturnal hypoglycemia include:

• Sweating overnight
• Waking up with a headache
• Having nightmares

However, nocturnal hypoglycemia in patients with type 1 diabetes is usually asymptomatic.

Using a basal-bolus regimen (with short- and long-acting insulin analogues) that mimics normal physiology may decrease the risk of nocturnal hypoglycemia among patients with type 1 diabetes mellitus.\textsuperscript{17}

Regular blood glucose monitoring and appropriate bedtime snacks can also help prevent or minimize nocturnal hypoglycemia.

\textbf{Pseudo-hypoglycemia}

Pseudo-hypoglycemia is an event during which a person with diabetes reports typical symptoms of hypoglycemia with a measured plasma glucose concentration >70 mg/dl (but possibly close to that level), or during times when the glucose levels are dropping quickly.

\textbf{Example from the Field}

\textbf{Pseudo-hypoglycemia}

“One of my patients is a 62-year-old male with type 2 diabetes. Previously, his average blood glucose value was 230 mg/dl. After he was initiated on insulin, he had mild symptoms of hypoglycemia when his meter reading was 130 mg/dl.

Our diabetes educator worked with this patient to help him to not over-treat the symptoms of hypoglycemia when his glucose meter did not confirm low blood glucose.”

\textbf{Causative Agents}

The diabetes agents cited in the \textit{National Action Plan for Adverse Drug Event Prevention} as having been most commonly reported to cause hypoglycemic ADEs fall into these categories:

\textbf{Insulin}

\textbf{Rapid-acting insulin}

- Insulin lispro
- Insulin aspart
- Insulin glulisine

\textbf{Short-acting insulin}

\textbf{Intermediate-acting insulin}

\textbf{Long-acting insulin}

• Insulin glargine
• Insulin detemir

**Premixed**

• Insulin lispro protamine/insulin lispro
• Insulin aspart protamine/insulin aspart
• NPH insulin/regular insulin

**Sulfonylureas**

• Chlorpropamide
• Glimepiride
• Glipizide
• Glyburide
• Tolazamide
• Tolbutamide

For patients on these drugs, it’s essential to maintain a heightened sense of awareness of this potential adverse outcome and mitigate risk with ongoing assessment and interventions when appropriate.

**Diabetes Agents**

Explore the classes of diabetes agents by selecting each one.

### SGLT2 Inhibitors

<table>
<thead>
<tr>
<th>Compound</th>
<th>Canagliflozin</th>
<th>Dapagliflozin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellular mechanism</td>
<td>Sodium-glucose co-transporter 2 inhibitor</td>
<td></td>
</tr>
</tbody>
</table>
| Primary physiological action | • Increases urinary glucose excretion  
• Lowers the renal threshold for glucose  
• Reduces reabsorption of filtered glucose |
| Advantages             | • Minimal risk of hypoglycemia  
• Slight reduction in BP |
<table>
<thead>
<tr>
<th>Disadvantages</th>
<th>Weight reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genital fungal infections, UTIs</td>
<td></td>
</tr>
<tr>
<td>Increased urination</td>
<td></td>
</tr>
<tr>
<td>Hypotension</td>
<td></td>
</tr>
<tr>
<td>? stroke risk (canagliflozin)</td>
<td></td>
</tr>
<tr>
<td>? bladder cancer (dapagliflozin)</td>
<td></td>
</tr>
</tbody>
</table>

**Cost**

|        | High |

**Insulins**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Human NPH</th>
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<tbody>
<tr>
<td></td>
<td>Human Regular</td>
</tr>
<tr>
<td></td>
<td>Lispro</td>
</tr>
<tr>
<td></td>
<td>Aspart</td>
</tr>
<tr>
<td></td>
<td>Glulisine</td>
</tr>
<tr>
<td></td>
<td>Glargine</td>
</tr>
<tr>
<td></td>
<td>Detemir</td>
</tr>
<tr>
<td></td>
<td>Premixed (several types)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cellular mechanism</th>
<th>Activates insulin receptors</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Primary physiological action</th>
<th>Increase Glucose disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Decrease Hepatic glucose production</td>
</tr>
</tbody>
</table>

**Advantages**

<table>
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<tr>
<th>Universally effective</th>
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<tbody>
<tr>
<td>Theoretically unlimited efficacy</td>
</tr>
<tr>
<td>Decrease Microvascular risk (UKPDS)</td>
</tr>
</tbody>
</table>

**Disadvantages**

<table>
<thead>
<tr>
<th>Hypoglycemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight gain</td>
</tr>
<tr>
<td>? Mitogenic effects</td>
</tr>
<tr>
<td>Injectable</td>
</tr>
<tr>
<td>Training requirements</td>
</tr>
<tr>
<td>“Stigma” (for patients)</td>
</tr>
</tbody>
</table>

**Cost**

Cost of insulin depends on type (analogs > human insulins) and dosage.)
### Amylin mimetics

<table>
<thead>
<tr>
<th>Compound</th>
<th>Pramlintide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellular mechanism</td>
<td>Activates amylin receptors</td>
</tr>
</tbody>
</table>
| Primary physiological action | • Decrease Glucagon secretion  
• Slows gastric emptying  
• Increase Satiety |
| Advantages | • Decrease Postprandial glucose excursions  
• Weight reduction |
| Disadvantages | • Generally modest HbA1c efficacy  
• Gastrointestinal side effects (nausea/vomiting)  
• **Hypoglycemia unless insulin dose is simultaneously reduced**  
• Injectable  
• Frequent dosing schedule |
| Cost | High |

### GLP-1 receptor agonists

| Compound | • Exenatide (and Exenatide extended release)  
• Liraglutide  
• Albiglutide |
| Cellular mechanism | Activates GLP-1 receptors |
| Primary physiological action | • Increase Insulin secretion (glucose-dependent)  
• Decrease Glucagon secretion (glucose-dependent)  
• Slows gastric emptying  
• Increase Satiety |
| Advantages | • Low risk of hypoglycemia  
• Weight reduction  
• ? Potential for improved β-cell mass/function |
### Dopamine-2 agonists

<table>
<thead>
<tr>
<th>Compound</th>
<th>Bromocriptine (quick release)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellular mechanism</td>
<td>Activates dopaminergic receptors</td>
</tr>
</tbody>
</table>
| Primary physiological action | • Modulates hypothalamic regulation of metabolism  
|                           | • Increase Insulin sensitivity |
| Advantages                | • No hypoglycemia  
|                           | • ? Decrease CVD events (Cycloset Safety Trial) |
| Disadvantages             | • Generally modest HbA1c efficacy  
|                           | • Constipation  
|                           | • Increase Triglycerides  
|                           | • May decrease absorption of other medications |
| Cost                      | High                          |

### Bile acid sequestrants

<table>
<thead>
<tr>
<th>Compound</th>
<th>Colesevelam</th>
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<tbody>
<tr>
<td>Cellular mechanism</td>
<td>Binds bile acids in intestinal tract, increasing hepatic bile acid production; ? activation of</td>
</tr>
<tr>
<td>farnesoid X receptor (FXR) in liver</td>
<td></td>
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<td>-----------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Primary physiological action</strong></td>
<td></td>
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<tr>
<td>• Unknown</td>
<td></td>
</tr>
<tr>
<td>• ? Decrease Hepatic glucose production</td>
<td></td>
</tr>
<tr>
<td>• ? Increase Incretin levels</td>
<td></td>
</tr>
<tr>
<td><strong>Advantages</strong></td>
<td></td>
</tr>
<tr>
<td>• No hypoglycemia</td>
<td></td>
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<tr>
<td>• Decrease LDL-C</td>
<td></td>
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<tr>
<td><strong>Disadvantages</strong></td>
<td></td>
</tr>
<tr>
<td>• Generally modest HbA1c efficacy</td>
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<tr>
<td>• Constipation</td>
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<tr>
<td>• Increase Triglycerides</td>
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<tr>
<td>• May decrease absorption of other medications</td>
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<tr>
<td><strong>Cost</strong></td>
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<td>High</td>
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**DPP-4 inhibitors**

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<tr>
<th>Compound</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sitagliptin</td>
</tr>
<tr>
<td>• Vildagliptin</td>
</tr>
<tr>
<td>• Saxagliptin</td>
</tr>
<tr>
<td>• Linagliptin</td>
</tr>
<tr>
<td>• Alogliptin</td>
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<table>
<thead>
<tr>
<th>Cellular mechanism</th>
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</thead>
<tbody>
<tr>
<td>Inhibits DPP-4 activity, increasing postprandial active incretin (GLP-, GIP) concentrations</td>
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</table>

<table>
<thead>
<tr>
<th>Primary physiological action</th>
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</thead>
<tbody>
<tr>
<td>• Increase Insulin secretion (glucose-dependent)</td>
</tr>
<tr>
<td>• Decrease Glucagon secretion (glucose-dependent)</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Advantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No hypoglycemia</td>
</tr>
<tr>
<td>• Well tolerated</td>
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<table>
<thead>
<tr>
<th>Disadvantages</th>
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<tbody>
<tr>
<td>• Generally modest HbA1c efficacy</td>
</tr>
<tr>
<td>• Urticaria/angioedema</td>
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<tr>
<td>• ? Pancreatitis</td>
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<table>
<thead>
<tr>
<th>Cost</th>
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<tbody>
<tr>
<td>High</td>
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</tbody>
</table>
### α-Glucosidase inhibitors

| Compound      | • Acarbose  
|              | • Miglitol  
|              | • Voglibose |
| Cellular mechanism | Inhibits intestinal α-glucosidase |
| Primary physiological action | • Slows intestinal carbohydrate digestion/absorption |
| Advantages | • No hypoglycemia  
|            | • Decrease Postprandial glucose excursions  
|            | • ? Decrease CVD events (STOP-NIDDM)  
|            | • Nonsystemic  |
| Disadvantages | • Generally modest HbA1c efficacy  
|              | • Gastrointestinal side effects (flatulence, diarrhea)  
|              | • Frequent dosing schedule  |
| Cost | Moderate |

### Thiazolidinediones

| Compound      | • Pioglitazone  
|              | • Rosiglitazone |
| Cellular mechanism | Activate the nuclear transcription factor PPAR-γ |
| Primary physiological action | Increase Insulin sensitivity |
| Advantages | • No hypoglycemia  
|            | • Durability  
|            | • Increase HDL-C  
|            | • Decrease Triglycerides (pioglitazone)  
|            | • ? Decrease CVD events (ProACTIVE, pioglitazone)  |
### Meglitinides (glinides)

<table>
<thead>
<tr>
<th>Compound</th>
<th>Repaglinide</th>
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<td>Nateglinide</td>
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<tr>
<th>Cellular mechanism</th>
<th>Closes KATP channels on β-cell plasma membranes</th>
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<tr>
<th>Primary physiological action</th>
<th>Increase Insulin secretion</th>
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<th>Advantages</th>
<th>Decrease Postprandial glucose excursions</th>
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<td></td>
<td>Dosing flexibility</td>
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<tr>
<th>Disadvantages</th>
<th>Hypoglycemia</th>
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<tr>
<td></td>
<td>Weight gain</td>
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<tr>
<td></td>
<td>? Blunts myocardial ischemic preconditioning</td>
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<td>Frequent dosing schedule</td>
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<th>Cost</th>
<th>High</th>
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### Sulfonylureas

<table>
<thead>
<tr>
<th>Compound</th>
<th>Glyburide/glibenclamide</th>
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<tbody>
<tr>
<td></td>
<td>Glipizide</td>
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<td>Glimepiride</td>
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<td>Chlorpropamide</td>
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<td>Tolazamide</td>
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<th>Cost</th>
<th>High</th>
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<tbody>
<tr>
<td></td>
<td>Tolbutamide</td>
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</tr>
<tr>
<td><strong>Cellular mechanism</strong></td>
<td>Closes KATP channels on β-cell plasma membranes</td>
</tr>
<tr>
<td><strong>Primary physiological action</strong></td>
<td>Increase Insulin secretion</td>
</tr>
</tbody>
</table>
| **Advantages** | • Extensive secretion  
|                  | • Decrease Microvascular risk (UKPDS) |
| **Disadvantages** | • Hypoglycemia  
|                  | • Weight gain  
|                  | • ? Blunts myocardial ischemic preconditioning  
|                  | • Low durability |
| **Cost** | Low |

### Biguanides

<table>
<thead>
<tr>
<th><strong>Compound</strong></th>
<th>Metformin</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cellular mechanism</strong></td>
<td>Activates AMP-kinase</td>
</tr>
<tr>
<td><strong>Primary physiological action</strong></td>
<td>Decrease Hepatic glucose production</td>
</tr>
</tbody>
</table>
| **Advantages** | • Extensive experience  
|                  | • No weight gain  
|                  | • No hypoglycemia  
|                  | • Likely decrease CVD events (UKPDS) |
| **Disadvantages** | • Gastrointestinal side effects (diarrhea, abdominal cramping)  
|                  | • Lactic acidosis risk (rare)  
|                  | • Vitamin B12 deficiency  
|                  | • Multiple contraindications: Acidosis, hypoxia, dehydration, etc. |
| **Cost** | Low |
Matching Activity Introduction

Now that you have read about the types of hypoglycemia, use the following activity to review what you have learned.

This matching activity features 5 questions, each with a definition and a word bank of hypoglycemia types.

**Question 1 of 5**
This hypoglycemic event is not accompanied by typical hypoglycemia symptoms, although the patient’s measured plasma glucose concentration is <=70 mg/dL (<=3.9 mmol/L).

- [ ] Symptomatic hypoglycemia
- [ ] Asymptomatic hypoglycemia
- [ ] Severe hypoglycemia
- [ ] Pseudo-hypoglycemia
- [ ] Nocturnal hypoglycemia

**Question 1 Feedback**
Asymptomatic hypoglycemia is an event not accompanied by typical hypoglycemia symptoms but with a measured plasma glucose concentration <=70 mg/dl (<=3.9 mmol/L).

- Although patients do not experience clinical symptoms, asymptomatic hypoglycemia can nonetheless be dangerous.
- It’s important to assess the risk of hypoglycemia at every visit for patients treated with insulin or sulfonylureas.

**Question 2 of 5**
In order for a patient to recover from this hypoglycemic event, another person must administer carbohydrates or glucagon, or take other corrective actions.

- [ ] Symptomatic hypoglycemia
- [ ] Asymptomatic hypoglycemia
- [ ] Severe hypoglycemia
- [ ] Pseudo-hypoglycemia
- [ ] Nocturnal hypoglycemia

**Question 2 Feedback**
In order for a patient to recover from severe hypoglycemia, another person must administer carbohydrates or glucagon, or take other corrective actions.
• Profound and prolonged hypoglycemia can cause brain injury, ventricular arrhythmias, and fatal events.
• Severe but non-fatal hypoglycemic episodes can lead to a lack of confidence in self-management and increased stress for family members and caregivers.
• Almost 50% of all severe hypoglycemic episodes occur during nighttime sleep. These episodes can have a significant impact on quality-of-life measures in patients with both type 1 and type 2 diabetes.

Question 3 of 5
Potential warning signs of this hypoglycemic event include sweating overnight, waking up with a headache, and having nightmares.

☐ Symptomatic hypoglycemia
☐ Asymptomatic hypoglycemia
☐ Severe hypoglycemia
☐ Pseudo-hypoglycemia
☐ Nocturnal hypoglycemia

Question 3 Feedback
Potential warning signs of nocturnal hypoglycemia include sweating overnight, waking up with a headache, and having nightmares.

• Nocturnal hypoglycemia can affect sleep quantity and quality.
• Although this event is symptomatic among many patients, it is usually asymptomatic in patients with type 1 diabetes.
• Using short- and long-acting insulin analogues can prevent or minimize this event, as can regular blood glucose monitoring and appropriate bedtime snacks.

Question 4 of 5
This type of hypoglycemia can be either documented (with a measured plasma glucose concentration <=70 mg/dl) or probable (without a measure of blood glucose but with typical symptoms).

☐ Symptomatic hypoglycemia
☐ Asymptomatic hypoglycemia
☐ Severe hypoglycemia
☐ Pseudo-hypoglycemia
☐ Nocturnal hypoglycemia
**Question 4 Feedback**
Symptomatic hypoglycemia can be either documented or probable.

Signs and symptoms of symptomatic hypoglycemia include, but are not limited to:

- Hunger
- Shakiness
- Nervousness
- Sweating
- Dizziness or light-headedness
- Sleepiness
- Confusion
- Difficulty speaking
- Anxiety
- Weakness

**Question 5 of 5**
This hypoglycemic event occurs when a person with diabetes has typical symptoms of hypoglycemia with a measured plasma glucose concentration >70 mg/dl.

- [ ] Symptomatic hypoglycemia
- [ ] Asymptomatic hypoglycemia
- [ ] Severe hypoglycemia
- [ ] Pseudo-hypoglycemia
- [ ] Nocturnal hypoglycemia

**Question 5 Feedback**
Pseudo-hypoglycemia occurs when a person with diabetes has typical symptoms of hypoglycemia with a measured plasma glucose concentration of >70 mg/dL.

Pseudo-hypoglycemia can also occur when glucose levels are dropping quickly.

**Individual Risk Factors**

**Chapter 2**
35% of course complete

**Key Determinants and a Patient-Centered Approach to Risk Reduction**

- Diabetes Agents and ADEs
- Hypoglycemia
- **Individual Risk Factors**
- Health Literacy and ADE Reduction
- Health Literacy Strategy: Teach-Back
- Key Points and Knowledge Check

**Individual Risk Factors: Age**
Tight glucose control has been consistently shown to produce higher rates of hypoglycemia in older adults.\(^\text{18}\)

People age 65 and older are also more likely to be injured or harmed due to hypoglycemia.

For example:

- Unsteadiness may result in falls and fractures.
- A tenuous cardiac status can deteriorate into a catastrophic event.

**Individual Risk Factors: Comorbid Conditions**
Certain comorbid conditions are risk factors for ADEs, regardless of a patient’s age. These include, but are not limited to:

- Depression
- Cognitive impairment
- Epilepsy
- Cardiovascular disease
- Advanced diabetes complications, such as hypoglycemia unawareness and impaired renal function

**Example from the Field**

**Cardiovascular Disease and Hypoglycemia Risk**

Audio Clip Transcript (*Audio examples have been collected from evidence-based research and stories from real providers working with patients with diabetes.*): Well, I'd like to discuss an 88 year-old male who came to see me with end-stage heart failure from valvular heart failure and aortic stenosis. He was not a surgical candidate, and he had accepted that quite well. And it took a while to sort out what medications he was taking, but with his wife's help, we determined he was taking Metoprolol 50 milligrams twice a day, an aspirin daily, Simvastatin 20

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milligrams daily, and Glipizide 2 and a half milligrams twice daily. His blood pressure was 108 over 60, a heart rate of 56, and a total cholesterol of 81. And he had an A1c of 6.4%. So our electronic health record alerted me to the fact that he may be at risk of hypoglycemia due to specific factors, in his, case his age, an A1c of less than 7, and having an active prescription for a sulfonylurea. In speaking with him and doing simple screening revealed he'd been having mid-morning symptoms of hypoglycemia at least once a week, resolved when his wife would give him orange juice. And fortunately, none of the episodes had yet resulted in a hospitalization or third-party rescue. As we discussed what seemed to be mid-morning hypoglycemia, and the fact that his A1c was very low, he and his wife were very glad to be allowed to stop Glipizide and allow his sugars to rise passively, assuring him that we would watch for any kind of problematic hyperglycemia, but that that was distinctly unlikely. And this is an example of trying to intervene and reduce medications when we're getting a warning in a high-risk patient before there was a serious adverse event.

Other Risk Factors
The risk of hypoglycemia is also increased by:

- Changes in diet or physical activity level
- Medication interactions and polypharmacy

Example from the Field
Changes in Diet Due to Low Income

“One of my patients with diabetes mellitus got laid off from his job and was struggling financially. Toward the end of the month, he was taken to the hospital and admitted with severe hypoglycemia. Eventually, we realized that the cause of the hypoglycemic episode was the patient’s lack of money for food at the end of the month, since his unemployment check did not cover all his expenses.

This patient was unable to eat 3 meals a day, but he continued to take the same doses of his diabetes medications, which resulted in seriously low blood sugar. Our diabetes educator worked with him to adjust his medications based on how much he was eating - and she also referred him to a food pantry where he could go if needed in the future.”

Common Medication Interactions
Select each drug type to learn more.

Anti-infective

- Antibiotics (e.g., fluoroquinolones)
May interact with: Oral antidiabetes agent
Potential result: Potential for interference with antihyperglycemic actions

- Antifungals (e.g., ketoconazole)
  - May interact with: Sulfonylureas
  - Potential result: Potential hypoglycemia

Anti-hypertensive

- ACE inhibitors
  - May interact with: Thiazides
  - Potential result: Potential hyperglycemia, potential hypotension
- β-blockers
  - May interact with: Inducers of CYP3A4 - e.g., phenobarbital
  - Potential result: May mask tachycardia of insulin-induced hypoglycemia
- Diuretics: loop, thiazides
  - May interact with: Captopril
  - Potential result: Significant hypotension and hyperglycemia when combined with thiazides

Medication Adherence
Taking medication as prescribed is an important aspect of what patients do to self-manage their diabetes.

Diabetes treatment regimens are very complex, and this complexity can have an impact on medication adherence.

Example from the Field
Depression’s Effect on Medication Adherence

“A patient of mine who has insulin-dependent diabetes mellitus and a history of depression recently suffered from a recurrence of her depression. In the past, this patient was able to effectively self-manage her diabetes.

Now, she’s having trouble eating regular meals and checking her blood glucose levels at home. Subsequently, this patient has had several episodes of severe hypoglycemia.”

Other factors that can affect medication adherence include:

- Not being able to afford medication
- Distrust of provider or treatment plan
• Longer duration of disease
• Personal challenges such as depression or stress

For more information, see Adherence to Long-Term Therapies: Evidence for Action [PDF - 1.6 MB]. (http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf)

Tips for Discussing Medication Adherence with Patients

Ask open-ended questions.

“How often do you miss taking your medicine?”
“What’s been going on with you since we last met?”

Speak in a sympathetic way.

“You seem to be feeling ____ . Tell me about that.”
“It sounds like you are saying ____ . Did I get that right?”

Set a positive tone.

“It sounds like you are really trying to ____ .”
“You’ve been doing a great job with ____ .”

Health Literacy and ADE Reduction

Chapter 2
41% of course complete

Key Determinants and a Patient-Centered Approach to Risk Reduction

• Diabetes Agents and ADEs
• Hypoglycemia
• Individual Risk Factors
• Health Literacy and ADE Reduction
• Health Literacy Strategy: Teach-Back

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• Key Points and Knowledge Check

Health Literacy Definition
Health literacy is the ability to “obtain, communicate, process, and understand health information and services in order to make appropriate health decisions.”20

Health Literate Care
Health literacy is determined not only by individual factors, but also by the skills, preferences, and expectations of care providers, health educators, and health care organizations. (source: U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion.21

Using patient-centered communication techniques can greatly increase health literacy and patient engagement.

To learn more, visit the Health Literate Care Model: A Universal Precautions Approach (http://health.gov/communication/interactiveHLCM/#overview) interactive learning tool.

Taking a Patient-Centered Approach
Be sure to consider each patient’s values and preferences when setting treatment goals. Part of your role is to support patients and caregivers as they make complex decisions regarding lifestyle choices and pharmaceutical interventions.

Example from the Field
Patient Values and Preferences

“One of my patients with diabetes mellitus shared with me that she loved to go hiking in the fall, but her children and grandchildren didn’t want her to hike alone anymore.

She had recently been taken to the emergency room with severe hypoglycemia, and they were fearful she would have another episode when she was alone in the woods. Now the patient and I are working to adjust her insulin and snack regimen, especially when she is more physically active.”

In addition, providing balanced information in plain language can help improve patient understanding.


Health Literacy and Prevention of Hypoglycemia

The 2003 National Assessment of Adult Literacy measured how many Americans have proficient, intermediate, basic, or below basic health literacy. Only 12 percent of adults were found to be proficient.  

When you explain diabetes management to your patients in plain language (and confirm their understanding of what you said), they will be better equipped to recognize precipitating factors and avoid hypoglycemic events.

Read more about health literacy levels in *The Health Literacy of America’s Adults* [PDF - 1.2 MB].

“Universal Precautions” for Patient Education

Research suggests that taking a “universal precautions” approach to patient education will improve care for all patients, regardless of their level of health literacy.

It’s appropriate to assume initially that everyone may have some trouble understanding health care information.

See how to apply Universal Precautions in your practice.

- By using the *Universal Precautions Toolkit* [PDF - 5.6 MB](http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/index.html), you can make your practice more health literate for all patients.
- This toolkit offers 20 easy-to-use tools to address health literacy ranging from how to welcome and communicate with patients to how to improve medication adherence and accuracy.

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Strategies to Improve Health Literacy
In this course, we review the following 2 strategies for providers to decrease the risk of ADEs by improving patients’ health literacy and engaging them in care management:

- Shared decision making
- The teach-back method

Shared Decision Making

**Shared decision making** engages patients in collaborative goal setting and problem solving, resulting in shared care management. It’s a key element of setting individualized glycemic goals. 24

You will go through a scenario demonstrating shared decision making in chapter 4 of this course.

If providers advocate for an A1c goal of less than 7% for all patients, many patients for whom that goal is not indicated are almost certain to be **overtreated**.

Health Literacy Teach Strategy: Teach-Back

Chapter 2

46% of course complete

Key Determinants and a Patient-Centered Approach to Risk Reduction

- Diabetes Agents and ADEs
- Hypoglycemia
- Individual Risk Factors
- Health Literacy and ADE Reduction
- **Health Literacy Strategy: Teach-Back**
- Key Points and Knowledge Check

The Teach-Back Method 24

The teach-back method is a way to confirm that you have explained what patients need to know in a manner they understand so they are able to self-manage diabetes with confidence.

Prompted by your questions, the patient repeats or explains the information back to you in his or her own words.

If the patient can’t restate or demonstrate what you just said, that signals you to either say it again or try explaining it differently.

Description of image: A smiling health care provider and an older female patient review a list of instructions.

Read sample teach-back questions.

- “I want to be sure that I explained everything correctly, so please tell me: How are you going to take this medicine?”
- “We covered a lot today, and I want to make sure that I explained things clearly. Let’s review what we discussed. What are you going to do to keep from having low blood sugar?”

**Practical Application**
The video on the next slide shows an example of provider-patient interaction, and how using the teach-back method checks for patient understanding and leads to a productive interaction.

In this scenario, a diabetes nurse educator is meeting with a patient who has complained of mild hypoglycemia symptoms.

**Teach-Back Scenario Video**

**Voice-over:** Prompted by his son, Harold has come in for a visit to discuss the new medication he started. His hemoglobin A1c goal is less than 7%, a decision he made with his physician due to his age, short duration of diabetes mellitus, and minimal disease complications. To reach that goal, he started taking a sulfonylurea medication, but since then, he started to feel shaky and sweaty. You just talk with him about how to be aware of and prevent hypoglycemia, and now you want to use teach back to ensure he understands.

**Nurse:** We talked about a lot of things today, and I want to make sure that I explain things clearly. Would you explain, in your own words, what signs or symptoms might let you know that your blood sugar is low?

**Harold:** Well it might be low if I'm feeling shaky or jittery. I think it might be low if I start to feel groggy?

**Nurse:** Great. Is there anything else that you or your son might notice?
Harold: You said some other things, but I just don't remember.

Nurse: Let's go over them together. So, feeling hungry, sweating a lot, having headaches, or feeling confused or weak, are all signs that you have low blood sugar.

Harold: Got it. Hungry, sweating, and headache. But I'm a young man, I'm not going to get confused.

Nurse: (laughter) And Chris, you can be on the lookout for these signs also.

Chris: Okay.

Nurse: So, Harold, when you have any of these signs or symptoms, what will you do?

Harold: I should write them down.

Nurse: Okay. And what else would it be good for you to write down when you feel like you're having low blood sugar?

Harold: If my glucose level is low, I should write down what I was doing, last time I ate something, and my finger stick reading.

Nurse: Right. And it's a lot to remember though, so I'm going to give you this pamphlet that you can read to remind yourself what we talked about today. And Chris, you can have one also. I know this can be overwhelming; diabetes is a very complicated disease. I saw in your chart that you've had depression in the past. Have you been feeling depressed lately?

Harold: No.

Nurse: I'm glad to hear that. And you know, a lot of people with diabetes have trouble remembering to take their medicine all the time. Do you ever miss taking your medicines?

Harold: In the beginning I did, but not so much anymore. Plus, Chris here reminds me to take them, he's always nagging me to take better care of myself.

Chris: You gotta take care of yourself, Dad.

Harold: I know.

Voice-over: You think Harold understands the signs and symptoms of hypoglycemia, but you also want to make sure he knows what to do when his blood sugar is getting low.

Nurse: Okay, so you know the signs and symptoms of low blood sugar. Can you tell me, in your own words, how you'll get your blood sugar back up if it's too low?

Harold: If my glucose level is below 100, I should eat something.

Nurse: Actually if it's below 70, you should definitely eat something. 100 isn't considered too low.

Harold: Well okay, if it's below 70 I should eat something.

Nurse: Yes. And then what would you do?

Harold: Check again in 15 minutes.

Nurse: Mm hm. And if your blood sugar is below 70, what's good to eat?

Harold: I should probably eat hard candy, orange juice, honey, or sugar. But I don't think I want to eat a spoonful of honey, though, yuck.

Nurse: (laughter). Well, be sure to keep some hard candy around the house then, and Chris can
you help make sure your dad always has candy on hand just in case?

Chris: Sure.

Nurse: Great. So Harold, I'm glad you know what to do if your blood sugar gets too low. What can you do to prevent having low blood sugar in the first place?

Harold: I can eat three meals a day: breakfast, lunch, and dinner. I'm gonna buy a box of protein bars to have in the truck so I can have it for lunch in case I'm having to drive around town all day.

Nurse: That is a great idea. So one more question: when should you call Dr. Brown about your blood sugar?

Harold: I should call Dr. Brown if my blood sugar is below 100. No, below 70. More than once or twice.

Nurse: Good. Now, there's also information about these things in the pamphlets I gave you in case you're ever in doubt. If the changes in your diet don't work, Dr. Brown may want to change your Glipizide to another medication. But let's try this for now, alright?

Harold: Sounds good to me.

Voice-over: The visit ends with you asking Harold to show you how to use a blood glucometer, and arranging for a follow-up visit. You also provide him with community resources for people with diabetes.

Key Points and Knowledge Check

Chapter 2

49% of course complete

Key Determinants and a Patient-Centered Approach to Risk Reduction

- Diabetes Agents and ADEs
- Hypoglycemia
- Individual Risk Factors
- Health Literacy and ADE Reduction
- Health Literacy Strategy: Teach-Back
- Key Points and Knowledge Check

Chapter 2 Key Points

- Sulfonylureas and insulin are frequently associated with hypoglycemic ADEs, but virtually any diabetes treatment is capable of causing an adverse drug event.
- Assess the risk of hypoglycemia at every visit with patients treated with insulin and sulfonylureas.
- Hypoglycemia puts patients at risk for injury and death.
• Nearly all cases of hypoglycemic ADEs are preventable.
• It’s important to identify the cause of a hypoglycemic episode, so that it can be prevented from happening again.
• Nearly 9 out of 10 adults have difficulty understanding and using health information.
• It’s appropriate to assume that everyone may have some trouble understanding health care information.
• Methods that increase health literacy, such as teach-back and shared decision making, can help you to ensure patient understanding and increase patient engagement.
• Patient education has been shown to improve outcomes in individuals with diabetes.

Knowledge Check Question 1
People age 65 and older are more likely to be injured or harmed due to hypoglycemia because:

☐ A) A tenuous cardiac status can deteriorate into a catastrophic event
☐ B) Unsteadiness may result in falls and fractures
☐ C) Both A and B
☐ D) Neither A nor B

Question 1 Feedback
People age 65 and older are more likely to be injured or harmed due to hypoglycemia because a tenuous cardiac status can deteriorate into a catastrophic event and unsteadiness may result in falls and fractures.

• Hypoglycemia can lead to multiple harms for patients of all ages, but it is more dangerous among the elderly, who are more vulnerable to adverse events.
• Hypoglycemia can cause dizziness, falls, confusion, and dysrhythmias.
• Repeated episodes of hypoglycemia may increase the risk of brain dysfunction later in life.

Knowledge Check Question 2
Which of the following are considered to increase a patient’s risk of having a hypoglycemic ADE?

☐ Depression
☐ Progressive renal dysfunction
☐ Low health literacy
☐ All of the above
☐ None of the above
Question 2 Feedback
Depression, progressive renal dysfunction, and low health literacy all increase a patient’s risk of having a hypoglycemic ADE.

- Patients with diabetes mellitus and depression have been found to be at increased risk for a severe hypoglycemic episode and a greater number of hypoglycemic episodes when compared to non-depressed patients with diabetes.
- Progressive renal dysfunction increases the risk of hypoglycemia through multiple factors, such as slower elimination of insulin, incretin hormones, and diabetes agents.
- Patients with diabetes who report limited health literacy are more likely to have a significant hypoglycemic event; those who report difficulty with reading, problems with learning, and lack of confidence with forms have increased odds of severe hypoglycemia.

Knowledge Check Question 3
Which of the following drugs can increase the risk of hypoglycemia in monotherapy?

- Pioglitazone
- Glyburide
- Pramlintide
- Exenatide
- Sitagliptin

Question 3 Feedback
Glyburide can increase the risk of hypoglycemia in monotherapy.

- Glyburide is a sulfonylurea that increases insulin secretion, which can result in hypoglycemia. Pramlintide, exenatide, and sitagliptin can result in hypoglycemia if combined with certain other diabetes agents.
- Pramlintide is an amylin mimetic that is used with insulin. Pramlintide activates amylin receptors resulting in decreased glucagon secretion, slowed gastric emptying, and increased satiety. Hypoglycemia occurs when the insulin dose is not reduced with the start of pramlintide.
- Exenatide is a GLP-1 receptor agonist that slows gastric emptying, increases satiety, and increases insulin secretion and decreases glucagon secretion when glucose is present. Exenatide can cause hypoglycemia when used in combination with sulfonylureas and hypoglycemia risk could increase with use of meglitinides.
• Sitagliptin is a DPP-4 inhibitor that, when glucose is present, increases insulin secretion and decreases glucagon secretion. Sitagliptin increases the risk of hypoglycemia when used in combination with a sulfonylurea or insulin.

Knowledge Check Question 4
Which of the following medications may increase the risk for both hyperglycemia and hypoglycemia?

☐ Levofloxacin
☐ Gemfibrozil
☐ Varenicline
☐ Propranolol

Question 4 Feedback
Levofloxacin may increase the risk for both hyperglycemia and hypoglycemia.

• Fluoroquinolones such as levofloxacin have been reported to cause both hyper- and hypoglycemia. These symptoms usually occur in patients with diabetes who are taking either sulfonylureas or insulin.
• Gemfibrozil is contraindicated with repaglinide, as gemfibrozil increases repaglinide concentration, thereby increasing the risk of severe hypoglycemia.
• Hypoglycemia has rarely been reported in patients with diabetes who are taking varenicline.
• Beta-adrenergic blockade with propranolol may cause patients with diabetes to not experience symptoms associated with hypoglycemia.

Knowledge Check Question 5
The teach-back method is a health literacy strategy that providers can use to:

☐ Persuade patients to make a health care decision
☐ Help patients memorize how to take their medications
☐ Confirm a patient’s understanding of health information
☐ Test patients’ knowledge of their health care options

Question 5 Feedback
The teach-back method is a health literacy strategy that providers can use to confirm a patient’s understanding of health information.
Chapter 3

Chapter 3 Overview

Chapter 3 Introduction Video
In Chapter 3, we’ll review current guidelines for diabetes medication management, while answering these questions: Why is it important to individualize target glycemic goals in each person with diabetes?; what clinical criteria should be considered when setting individualized glycemic targets?; and how can health care providers make sure that patient values are part of the treatment decision-making process?

Chapter 3
Applying Current Guidelines for Individualized Care of People with Diabetes

By the end of this chapter, you will be able to:

• Describe the importance of setting target glycemic goals based on individual factors.
• Apply evidence-based guidelines for diabetes management, focusing on setting individualized glycemic targets with patients to reduce the risk of hypoglycemic episodes.

Guidelines for Individualized Glycemic Goals

Chapter 3
56% of course complete

Applying Current Guidelines for Individualized Care of People with Diabetes

• Guidelines for Individualized Glycemic Goals
• Clinical Application Activity
• Key Points and Knowledge Check

Guidelines for Individual Glycemic Goals

The most recent private sector and federal guidelines recommend individualized target HbA1c values for all individuals with diabetes.

The American Diabetes Association (ADA) and American Geriatrics Society (AGS), as well as the Department of Veterans Affairs (VA) and the Department of Defense (DoD), recommend individualizing target glycemic goals based on the following:

- Life expectancy
- Comorbid conditions
- Microvascular complications
- Patient preferences

**Guidelines for Individual Glycemic Goals**

Implementing these guidelines requires careful integration of current evidence and patient-specific factors.

This chapter includes helpful charts and stories from the field to give you the resources necessary to make these complex decisions with your patients.

**Recent Findings**

Recent studies have found that setting glycemic targets too low ("intensive glucose therapy") increases the risk of hypoglycemia and mortality in individuals with certain risk factors.

Less intensive control may be appropriate in people with:

- Advanced age (65 years or older) ²⁵
- Cognitive impairment ²⁵
- Chronic kidney disease ²⁵
- Epilepsy ²⁷
- Advanced diabetes complications ²⁷
- Longstanding diabetes ²⁷
- Cardiovascular disease ²⁵²⁷
- Other risk factors of severe hypoglycemia ²⁷

**A1c Target Recommendations, %**

Description of table: An A1c target of less than 7 percent is recommended for patients with absent or mild microvascular complications, no major comorbidity, and more than 10 years life

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expectancy. An A1c target of less than 8 percent is recommended for patients with moderate microvascular complications, manageable comorbid conditions, and 5 to 10 years life expectancy. An A1c target of 8 to 9 percent is recommended for patients with advanced microvascular complications, significantly challenging or end-stage comorbid conditions, and less than 5 years life expectancy. For a recommended target of 8 to 9 percent, further reductions may be appropriate to balance safety and tolerability of therapy. Definitions: "Major comorbidity": Major comorbidity includes, but is not limited to, any or several of the following active conditions: significant cardiovascular disease, severe chronic liver disease, recent stroke, and life threatening malignancy. "Absent or mild microvascular complications": Mild microvascular disease is defined by early background retinopathy, microalbuminuria, and/or mild neuropathy. "Moderate microvascular complications": Moderate microvascular disease is defined by: preproliferative (without severe hemorrhage, intraretinal microvascular anomalies [IRMA] or venous bleeding) retinopathy; and/or persistent, fixed proteinuria (macroalbuminuria); and/or demonstrable peripheral neuropathy (sensory loss). "Advanced microvascular complications": Advanced microvascular disease is defined by: severe nonproliferative (with severe hemorrhage, IRMA or venous bleeding) or proliferative retinopathy; and/or renal insufficiency (serum creatinine level, >2 mg/dL); and/or insensate extremities or autonomic neuropathy (for example, gastroparesis, impaired sweating or orthostatic hypotension).

**Reasonable Range of Glycemic Targets**

When setting the initial target range for discussion with a patient, consider the following: 24

**An HbA1c target of <7% is reasonable (if it can be achieved without risk) for patients who:**

- Have either no or very mild microvascular complications of diabetes
- Are free of major comorbid conditions
- Have a life expectancy of at least 10-15 years

Patients should have an **HbA1c target of <8%** if they:

- Have longer duration diabetes (more than 10 years)
- Have comorbid conditions
- Require a combination medication regimen including insulin

Patients are unlikely to benefit from aggressive glucose management and should have an **HbA1c target of 8-9%** if they have:

- Advanced microvascular complications
- Major comorbid illness
• A life expectancy of less than 5 years

Summary Chart for Individualized Glycemic Goals

Description of Chart: Factors to consider when setting individualized glycemic goals are: psychosocioeconomic considerations (such as motivation, knowledge, and social support), hypoglycemia risk, patient age, disease duration, comorbid conditions, cardiovascular disease, and microvascular complications. If these factors are low or few, more intensive glucose control is recommended. If these factors are high or many, less intensive glucose control is recommended. A list of psychosocioeconomic considerations that are low or few: highly motivated, adherent, knowledgeable, excellent self-care capacities, and comprehensive support system. A list of psychosocioeconomic considerations that are high or many: less motivated, nonadherent, limited insight, poor self-care capacities, and weak support systems.

Risk Factors and Glycemic Goals
For each patient, there are multiple factors to consider when determining a reasonable glycemic target range.

Example from the Field (1 of 2)
Age, Individual Risk Factors, and Hypoglycemia Risk

Audio Clip Transcript: So an 83-year-old, chronically ill woman came in for consultation because she had received a letter from her primary care provider stating that her fasting glucose was 128, and her A1c was 7.1%. And that over the past few years she had gone from a condition of pre-diabetes to frank diabetes. In discussing what this would mean for her, we advised against initiating pharmacologic treatment for glycemia and instead focused the discussion on optimizing her function and safety and reasonable monitoring of glucose to ensure that this would not turn into symptomatic hyperglycemia. Much of this centered around reassuring her and letting her know that we could not honestly promise her any long-term benefits from taking medications to lower her sugars, which were in a range that the Choosing Wisely campaign would suggest we not add medications, which is an A1c of 7.5 or less.

Example from the Field (2 of 2)
Cognitive Impairment and Hypoglycemia Risk

Audio Clip Transcript: An 80-year-old woman with longstanding diabetes and moderate cognitive impairment was sent by a specialist, suggesting that she should have her blood sugar better controlled. Currently, she was taking Galantamine for memory, Glyburide, Simvastatin, and a once-daily NPH insulin injection. Her blood pressure was 138 over 70, and her A1c, over the past 2 years, had decreased from 11.6 to 7.3 with the treatment of her diabetes listed above. So at this point we advised her that research informs us that she would not benefit from lower sugars than she already has and that in fact, she’s on insulin and a sulfonylurea, and with cognitive impairment, our main concern is that she is at very high risk of serious hypoglycemia. And we suggested, and she agreed to a plan, of a careful reduction in her medications to try to allow her some permissive hyperglycemia without adding the risks that the NPH, the Glyburide, and the cognitive impairment would give to her given her age.

Links to More Information
A review of the evidence behind these recommendations can be found in the following resources:

Clinical Guidelines
- American Geriatrics Society
  o Guidelines for Improving the Care of Older Adults with Diabetes Mellitus: 2013 Update [PDF - 78 KB] (http://health.gov/hai/trainings/preventhypoglycemicades/Concl-Summary/story_content/external_files/AGS%20Guidelines.pdf)
- VA/DoD

Evidence-Based Education Resources for Professionals
- AGS Education & Clinical Resources on Diabetes (http://www.americangeriatrics.org/health_care_professionals/clinical_practice/clinical_guidelines_recommendations/)
Evidence-Based Education Resources for Consumers

- Medicines for Type 2 Diabetes: A Review of the Research for Adults (http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=721&PC=db)

Related Research Literature

Summary article

- AGS Management of Hyperglycemia in Type 2 Diabetes: A Patient-Centered Approach [PDF - 1.2 MB] (http://care.diabetesjournals.org/content/early/2012/04/17/dc12-0413.full.pdf+html)

Clinical trials


Clinical Application Activity

Chapter 3
64% of course complete

Applying Current Guidelines for Individualized Care of People with Diabetes

- Guidelines for Individualized Glycemic Goals
- Clinical Application Activity
- Key Points and Knowledge Check

Clinical Application Activity

Now that you have read the clinical guidelines for setting individualized glycemic (A1c) goals, answer the following series of questions to review what you have learned.
This clinical application activity features 4 slides, each with a clinical scenario and a multiple choice question. On each screen, read the scenario and select the optimal A1c goal.

**Clinical Activity Question 1**
- A 68-year-old female was diagnosed with type 2 diabetes mellitus approximately 15 years ago.
- She dislikes doing frequent fingerstick blood sugar tests but she is able to adjust her insulin accordingly.
- She was recently diagnosed with hyperlipidemia, she has peripheral neuropathy, and her last eye exam showed pre-proliferative retinopathy.

**What is her optimal hemoglobin A1c goal?**
- □ <7
- □ 7 to 8
- □ 8 to 9

**Question 1 Feedback**
In this case, the optimal hemoglobin A1c goal is 7 to 8, due to:
- The patient’s age
- 15-year duration of disease
- Preference to do less fingerstick blood sugar checks
- Few other comorbid conditions
- Moderate microvascular disease (pre-proliferative retinopathy and peripheral neuropathy)

**Clinical Activity Question 2**
- A 46-year-old male was diagnosed with type 2 diabetes mellitus approximately 5 years ago.
- He has attended multiple community-organized diabetes education classes and has no significant comorbidities or vascular complications.

**What is his optimal hemoglobin A1c goal?**
- □ <7
- □ 7 to 8
- □ 8 to 9
Question 2 Feedback
His optimal hemoglobin A1c goal is <7, due to:

- The patient’s age
- Short duration of disease
- Motivation
- Lack of significant comorbidities and vascular complications

Clinical Activity Question 3
- A 72-year-old male was diagnosed with type 2 diabetes mellitus approximately 15 years ago and was recently hospitalized with acute myocardial infarction.
- He has chronic renal insufficiency (creatinine 2.3) and congestive heart failure.

What is his optimal hemoglobin A1c goal?

☐ <7
☐ 7 to 8
☐ 8 to 9

Question 3 Feedback
His optimal hemoglobin A1c goal is 8 to 9, due to:

- The patient’s age
- Longer duration of disease
- Major comorbidity
- Advanced microvascular disease

Clinical Activity Question 4
- A 55-year-old female was diagnosed with type 2 diabetes mellitus approximately 10 years ago.
- She works out daily and has supportive family members who help her to follow a diabetic diet.
- She has early retinopathy, microalbuminuria, and hypertension, but no other significant cardiovascular disease.

What is her optimal hemoglobin A1c goal?

☐ <7
☐ 7 to 8
☐ 8 to 9
**Question 4 Feedback**
Her optimal hemoglobin A1c goal is <7, due to:

- Mild microvascular disease (early retinopathy, microalbuminuria)
- Absence of significant comorbidities
- High motivation
- Support systems

**Key Points and Knowledge Check**

**Chapter 3**  
*68% of course complete*

**Applying Current Guidelines for Individualized Care of People with Diabetes**

- Guidelines for Individualized Glycemic Goals
- Clinical Application Activity
- Key Points and Knowledge Check

**Chapter 3 Key Points**

- Intensive therapy is not appropriate for all patients with diabetes.
- It is important to individualize target glycemic goals based upon life expectancy, comorbid conditions, microvascular complications, and the patient’s personal preference.
- Refer to the reasonable range of glycemic targets to set an initial glycemic target for discussion with patients.

**Knowledge Check Question 1**
In patients with long-standing type 2 diabetes mellitus, intensive treatment has been found to decrease which of the following vascular complications?

- [ ] Microvascular only
- [ ] Macrovascular only
- [ ] Both (microvascular and macrovascular)
- [ ] Neither

**Question 1 Feedback**
In patients with long-standing type 2 diabetes mellitus, intensive treatment has been found to decrease microvascular complications.
• Intensive treatment of type 2 diabetes has not been found to improve macrovascular disease outcomes in patients with long-standing disease.
• The United Kingdom Prospective Diabetes Study (UKPDS) found that intensive therapy did not reduce the risk of myocardial infarction in type 2 diabetes.
• The Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial in patients with long-standing type 2 diabetes showed no decrease in the risk of macrovascular disease, but did show an increased all-cause mortality and cardiovascular-related mortality for those in the intensive treatment arm of the study.
• Neither the Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified-Release Control Evaluation (ADVANCE) trial nor the Veterans Affairs Diabetes (VADT) trial found reduction in macrovascular disease complications in patients with intensive treatment for type 2 diabetes.
• UKPDS, ACCORD, ADVANCE, and VADT all found improved microvascular outcomes for patients with intensive treatment for type 2 diabetes.

Knowledge Question 2
True or false? A recent study found that intensive glucose therapy decreases the risk of mortality in individuals with long-standing type 2 diabetes mellitus.

☐ True
☐ False

Question 2 Feedback
A recent study did not find that intensive glucose therapy decreases the risk of mortality in individuals with long-standing type 2 diabetes mellitus.

The Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial in patients with long-standing type 2 diabetes actually showed increased all-cause mortality and cardiovascular-related mortality for those in the intensive treatment arm of the study.

Knowledge Question 3
Along with major comorbidities, the other major factor(s) to consider in setting individualized glycemic targets are:

☐ Life expectancy
☐ Life expectancy and microvascular complications
☐ Life expectancy, microvascular complications, and patient preference
☐ Microvascular complications
☐ Patient preference and microvascular complications
Question 3 Feedback
Life expectancy, microvascular complications, and patient preference are all important factors to consider when setting individualized glycemic targets.

Chapter 4

Chapter 4 Overview

Chapter 4 Introduction Video
This next chapter turns to the health literacy process of shared decision-making, and how it can be used to set hypoglycemic goals. How can health care providers use shared decision-making to increase patient engagement and prevent hypoglycemia? In this chapter, you will watch a video scenario showing shared decision-making in action.

Chapter 4
Shared Decision Making for Individualized Glycemic Goals

By the end of this chapter, you will be able to:

• Apply health literacy strategies to help patients understand and act on information to prevent ADEs.

Shared Decision Making with Patients

Chapter 4
72% of course complete

Shared Decision Making for Individualized Glycemic Goals

• Shared Decision Making with Patients
• Applying Shared Decision Making
• Key Points and Knowledge Check

Shared Decision Making
Shared decision making is a patient-centered communication strategy that engages patients in their ongoing care.

Shared decision making helps patients participate in decisions related to their illness in the context of their values and preferences, and improves a provider’s understanding of the patient’s priorities.
Shared Decision Making (Continued)

In order to lower the risk of hypoglycemic ADEs, patients need to be both informed and engaged. Clear communication between providers, patients, and caregivers is what makes this work.

For shared decision making to be effective, patients need to clearly understand the relevant health information, including the benefits and risks of treatment.

Example from the Field

Shared Decision Making (Example 1)

Audio Clip Transcript: An 80-year-old male, with Type 2 Diabetes for over 10 years, came to see me. He was taking Metformin, Metoprolol, Losartan, Simvastatin, and aspirin. Regular dilated funduscopic exams had been done, showing moderate background retinopathy. And he stated, in talking to him and just trying to pursue his values and goals, the big things he wanted to do were to prevent blindness, heart attack, or stroke. His blood pressure was 128 over 68, His A1c was 7.7%, and his specialist had recommended that he come in to initiate Pioglitazone or Glargine insulin in order to get his blood sugar under control. So we discussed this with he and his wife about the fact that macrovascular disease, one of the things he was concerned about, was being dealt with very nicely by the fact that he doesn't smoke, was using Losartan and Simvastatin and aspirin, and that we do not have proof that, for him, lowering his sugar from where he is will prevent microvascular disease or more of the retinopathy, but it certainly would increase his risk of hypoglycemia. And at that point, he chose not to add more medication.

Example from the Field

Shared Decision Making (Example 2)

“I have found that when a patient is able to participate in shared decision making, the treatment plan can reflect the patient’s values and preferences. One patient in particular likes to make a chart with pros and cons for each choice before making a decision. This allows him to thoughtfully consider his values and how they impact each choice.

This man’s favorite hobby is to perform as part of a cultural dance group, so his greatest goal is to prevent diabetic complications that would affect the nerves in his feet and his sense of balance. Taking this into consideration along with many other factors, we formulated a treatment plan with tight control for his diabetes to help minimize the risk of developing neuropathy.”
8 Key Elements of Shared Decision Making

1. Ask: Identify the issues by asking patient-centered questions.
2. Prioritize: Explore patients’ needs and help them prioritize their needs and expectations.
3. Assess: Identify any barrier to shared decision making on the part of both patient and provider. Assess the patient’s capacity to be part of the decision-making process.
5. Acknowledge: Learn what's important to the patient and acknowledge the criteria that patients use to make decisions so you can both share values, power, and expectations.
6. Assist: Provide tools to help patients weigh their options. Invite input from others, such as spouses and caregivers.
7. Make the Decision: When the patient is ready, agree upon the glycemic target.
8. Evaluate: Follow up with patients to learn about their expectations of satisfaction with the decision-making process. Revisit the process if you or the patient have concerns.

Applying Shared Decision Making

Chapter 4

75% of course complete

Shared Decision Making for Individualized Glycemic Goals

- Shared Decision Making with Patients
- Applying Shared Decision Making
- Key Points and Knowledge Check

Practical Application

Applying Shared Decision Making to Set a Patient’s Glycemic Goal

You are about to meet with Linda, a patient of yours living with type 2 diabetes.

In this case study, you will talk with Linda about the risks and benefits of more intense or less intense glycemic control given her age, comorbid conditions, and risk for hypoglycemia.

Patient Profile

Medical History

- Diabetes mellitus type 2, diagnosed approximately 25 years ago
- Diabetes mellitus-related complications
  - Pre-proliferative retinopathy (eye exam done 9 months ago)
Mild peripheral neuropathy
- Macroalbuminuria
- Hypertension
- Hyperlipidemia
- Osteoarthritis

Social History/Lifestyle
- Linda is a 67-year-old Mexican-American woman who was diagnosed with type 2 diabetes when she was 40.
- She lives alone and works on the assembly line of a plastics manufacturing company.
- One of her 2 adult children lives nearby and brings Linda’s 3 young grandchildren to visit her once a week.
- Linda does not drink or smoke.

Active Medications
- Aspart insulin  5 units subcut with each meal
- Aspirin  81 mg po qday
- Gabapentin  300 mg po qhs
- Glargine insulin  20 units subcut nightly
- Glyburide  10 mg po bid
- Lisinopril  40 mg po qday
- Metoprolol XL  25 mg po qday
- Simvastatin  20 mg po qhs
- Acetaminophen  325 mg, 1 to 2 tabs as needed every 6 hours

Vitals
- BMI  8 kg/m^2
- Height  5 feet 4 inches
- Weight  165 pounds
- Blood pressure  130/78 mm/Hg
- Heart rate  72
- Respiratory rate  12
- Temperature  98.2

Labs (Fasting)

<table>
<thead>
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<th>Basic metabolic panel</th>
<th>Normal ranges</th>
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<tr>
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<td>136 - 145 mEq/L</td>
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<tr>
<td>Test</td>
<td>Result</td>
</tr>
<tr>
<td>-------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Potassium</td>
<td>4.0 mEq/L</td>
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<tr>
<td>Chloride</td>
<td>106 mEq/L</td>
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<tr>
<td>Carbon dioxide</td>
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<tr>
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<td>Glucose</td>
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<tr>
<td>HbA1c</td>
<td>6.5%</td>
</tr>
<tr>
<td>Creatinine clearance</td>
<td>40 mL/min</td>
</tr>
<tr>
<td>Proteinuria</td>
<td>&gt;300 mg/24 hour</td>
</tr>
</tbody>
</table>

**Doctor’s Notes on Linda**

**Patient-provider relationship:**

Linda has been seeing you for several years. She often seems reserved and rarely asks questions, usually just nodding or giving brief answers to questions.

**Linda’s approach to her diabetes:**

Linda struggles with health literacy but seems committed to good self-care. She lives alone but is in close contact with her daughter, who also has diabetes.

**Prepare to Meet with Linda**

Review resources to identify Linda’s new likely glycemic target.
Summary Chart for Individualized Glycemic Goals
Description of chart: Factors to consider when setting individualized glycemic goals are: psychosocioeconomic considerations (such as motivation, knowledge, and social support), hypoglycemia risk, patient age, disease duration, comorbid conditions, cardiovascular disease, and microvascular complications. If these factors are low or few, more intensive glucose control is recommended. If these factors are high or many, less intensive glucose control is recommended. A list of psychosocioeconomic considerations that are low or few: highly motivated, adherent, knowledgeable, excellent self-care capacities, and comprehensive support system. A list of psychosocioeconomic considerations that are high or many: less motivated, nonadherent, limited insight, poor self-care capacities, and weak support systems.

Table of A1c Recommendations
Description of table: An A1c target of less than 7 percent is recommended for patients with absent or mild microvascular complications, no major comorbidity, and more than 10 years life expectancy. An A1c target of less than 8 percent is recommended for patients with moderate microvascular complications, manageable comorbid conditions, and 5 to 10 years life expectancy. An A1c target of 8 to 9 percent is recommended for patients with advanced microvascular complications, significantly challenging or end-stage comorbid conditions, and less than 5 years life expectancy. For a recommended target of 8 to 9 percent, further reductions may be appropriate to balance safety and tolerability of therapy. Definitions: "Major comorbidity": Major comorbidity includes, but is not limited to, any or several of the following active conditions: significant cardiovascular disease, severe chronic liver disease, recent stroke, and life threatening malignancy. "Absent or mild microvascular complications": Mild microvascular disease is defined by early background retinopathy, microalbuminuria, and/or mild neuropathy. "Moderate microvascular complications": Moderate microvascular disease is defined by: preproliferative (without severe hemorrhage, intraretinal microvascular anomalies [IRMA] or venous bleeding) retinopathy; and/or persistent, fixed proteinuria (macroalbuminuria); and/or demonstrable peripheral neuropathy (sensory loss). "Advanced microvascular complications": Advanced microvascular disease is defined by: severe nonproliferative (with severe hemorrhage, IRMA or venous bleeding) or proliferative retinopathy; and/or renal insufficiency (serum creatinine level, >2 mg/dL); and/or insensate extremities or autonomic neuropathy (for example, gastroparesis, impaired sweating or orthostatic hypotension).

Practical Application Question
Given Linda’s diabetes-related complications, her age, and her 27-year history with diabetes, what would you recommend for her optimal hemoglobin A1c goal?

☐ <7
Question Feedback

- Linda’s optimal hemoglobin A1c goal is 7 to 8, due to:
  - Linda’s diabetes-related complications
  - Her age
  - Her 27-year duration of disease

Shared Decision Making Scenario Video (Part 1)

**Video Text:** Ask. Identify the Issues.

**Doctor:** Good morning, Linda. What brings you in today?

**Linda:** Well, I've been getting headaches and I feel extra tired after work, more than usual, so I wanted to come in and see if there is something going on.

**Voice-Over:** After you ask more about the headaches and fatigue, review her lab results, and rule out other common potential causes of fatigue, you begin to think Linda's symptoms may be caused by hypoglycemia, so you ask about her diabetes.

**Doctor:** and how do you feel you've been doing with the insulin and your other diabetic medicines?

**Linda:** Sometimes on Saturdays I forget my pills, and if I skip a meal I also skip my insulin. But I'm usually pretty good about it.

**Doctor:** And what about your blood sugar? How do you feel you've been doing with that?

**Linda:** I think I've been doing great job keeping my blood sugar down, and well, sometimes it gets so low, and I kinda get shaky, and especially if I've missed a meal, but when that happens I just eat some candy, and get it back up.

**Doctor:** Besides getting shaky sometimes, how do you know you're keeping your blood sugar down?

**Linda:** Well, I check it a couple of times a day, like the nurse taught me to.

**Doctor:** Huh. And what are your finger stick blood sugar values when you get headaches or feel extra tired?

**Linda:** I'll check it sometimes when I feel tired, and it's usually 60 or 55.
Doctor: Why don't we take a look at your finger stick values and your hemoglobin A1c? I see that your blood test shows your A1c is now 6.5?

Linda: That's good, right?

Linda: You said to not get it higher than seven?

Doctor: That is what we discussed, but you know, our understanding of diabetes is always changing. Recent studies now show that tight control 7 is too low for some people, so what I want to do is work with you to find out what numbers right for you.

Linda: Good.

Voice-over: You give Linda an easy-to-read handout on hypoglycemia that she can take home. You also offer to send her a text with a link to the handout online, if she prefers.

[Video Text: Step 2: Prioritize. Focus on the patient’s needs.]

Voice-over: You're beginning to think that Linda may benefit from a higher A1c target, but you want to learn more about her needs and goals before making a treatment decision.

Doctor: What's most important to you to keep your diabetes from causing you other problems?

Linda: I'm scared to get other problems from my diabetes. And because I live alone, I'm afraid something serious could happen to me.

Doctor: It sounds like you would like to have fewer headaches, you would like to take less medicine, and you would like to feel safe. It is totally understandable that you are worried about your diabetes causing you other problems. But on the other hand, if your blood sugar is very low, that can be risky too.

[Video Text: Step 3: Assess. Identify barriers to shared decision-making.]

Voice-over: Normally, you would assess a patient’s cognitive ability related to making treatment decisions, but you know Linda and have seen her recently. However, you do need to assess her beliefs and values, and any knowledge gaps.

Doctor: I think having a higher A1c will make you feel better and less tired, and we can still work toward lowering the chances that you'll have other problems with diabetes. So, are you willing to consider a higher A1c?
**Linda:** I think so, but my daughter also has diabetes, and this doctor that she sees said it's really important to keep her A1c below seven, and well, that's what I've been told in the past.

**Doctor:** That's a good point. But I think it's important to recognize that when you're managing diabetes, it's not one-size-fits-all, and that we're gonna work hard to find the number that's right for you... and that might be different from your daughter's.

**Voice-over:** You talk further with Linda to confirm that she understands the process of determining A1c goals.

**Patient Barriers**
Several patient factors may impede your ability to make shared decisions.

In the video you just viewed, Linda may be wondering whether, with less control, she will be at increased risk of diabetes-related complications.

For example, she might fear going blind or losing mobility. You would need to describe the benefits of less control and put the risks in context.

- Other potential patient-centered barriers to shared decision making may include:
  - Cognitive limitations
  - Feeling upset, or other emotional interference
  - Knowledge gaps

**Provider Barriers**
You may also face your own limitations in applying shared decision making to set glycemic goals with patients.

These provider-centered barriers may include:

- Lack of resources, such as decision-aid handouts
- Limited time with each patient
- Lack of comfort or inexperience with having two-way discussions with patients

**Addressing Challenges to Shared Decision Making**

**How can I share the decision-making process with patients who have cognitive challenges?**

Try these strategies:

- Use teach-back to confirm understanding
- Talk to family members if possible
• Write instructions down

**Shared decision making seems like it will take more time. What can I do about this?**

Try these strategies:

• Start out by trying shared decision-making with the last scheduled patient of the day
• Use a team-based approach to shared decision-making
• Use decision aids

**Shared Decision Making Scenario Video (Part 2)**

**Video Text:** Step 4: Advise. Discuss benefits and risks.

**Voice-over:** Based on what you know about the mechanisms of hypoglycemic agents, you decide to propose decreasing or stopping Linda's aspart insulin if you both agree on a higher A1c goal. Even if her A1c goal stays the same you know she will benefit from taking less insulin or discontinuing glyburide, since she's had multiple probable hypoglycemic episodes.

**Doctor:** Here are your choices. You can keep your A1c below 7, or you can change the number of your A1c to a number between 7 and 8. If you stay below 7, you may have more energy, you might not have the problems that come with having diabetes, such as damage to your nerves or eyes. But on the other hand, if you stay below 7, it's more likely that you would have low blood sugar, and you would need to take medicine, and you would need to come see me more often. I know it's a lot of information. I want to make sure that I explained it clearly. If you were to tell your daughter some of these changes that might come up, what would you tell her?

**Linda:** I could prevent damage to my nerves or eyes.

**Doctor:** ...And you might have more energy. Now what might happen if it stays below 7?

**Voice-over:** After confirming Linda's understanding, you hand her a simple decision aid to help her think about what less and more control means. You suggest she take it home, talk with her daughter, and think about her options.

**Doctor:** Either way, we need to watch your diabetes closely for a while to see how the changes work for you.

[**Video Text:** Step 5: Acknowledge criteria upon which the decision will be made.]

**Doctor:** As I already mentioned, the evidence tells us that an A1c of 7 or below is not best for all patients. We already know that you sometimes have low blood sugar, and that you have some
problems from diabetes. I understand that you want to take a less medicine, have fewer headaches, and feel safer now that you’re living alone… and that's important to you. Anything else we need to consider?

**Linda:** No, I think that's it.

**Doctor:** Okay.

[**Video Text:** Step 6: Assist. Present the options.]

**Doctor:** You have two choices at this point. You can stay where you are now, with your blood sugar below 7 but with more chances for low blood sugar, or you could try for the higher A1c number, with fewer chances for low blood sugar. If you try for the higher A1c number, you could try that for three months and see how you feel.

[**Video Text:** Step 7: Make the decision.]

**Doctor:** So how about we meet again in a couple weeks to give you time to think things through? Or, if you're ready to decide now…?

**Linda:** If you think the higher sugars are okay and not too dangerous for me, I'm - I'll try it.

**Doctor:** Okay. So let's try it for the next three months and see how you feel when you come back for your next check-up. In the meantime, we'll have a nurse from our office give you a call to check in on your finger stick blood sugar values.

**Voice-over:** You give Linda simple directions on how she should take her medications moving forward and ask her if she would like you to take them to her then you do a quick knowledge check using the teach-back method.

[**Video Text:** Step 8: Evaluate and follow up.]

**Doctor:** Alright, Linda. See you in three months. And be sure to make an appointment at the front desk before we leave. And I will be available if you need to call me with any questions or concerns before then, alright?

**Linda:** I will. Thank you.

**Doctor:** Sure.

**Tips for Discussing Glycemic Target Setting with Patients**

*Explain the risks and benefits of more intense or less intense glycemic control.*
Clarify short-term vs. long-term risks and benefits, and put them in the context of the patient’s overall health.

Description of image: A female health care provider helps an older woman create a list of pros and cons to adjusting her glycemic target.

**Ask about your patients’ values, abilities, and likes/dislikes.**

Learn what’s most important to your patients, and take into account factors such as occupation and the patient’s degree of social support.

Description of Image: A smiling health care provider chats with a patient while taking his blood pressure.

**Emphasize that treatment must work for the patient and fit in with the patient’s life.**

For example, if a patient strongly dislikes checking her fingerstick values on a regular basis, that may be a factor in the degree of glycemic control she’ll realistically be able to safely achieve.

Description of image: A doctor sits with a concerned patient and has a serious talk.

**Key Points and Knowledge Check**

**Chapter 4**

86% of course complete

**Shared Decision Making for Individualized Glycemic Goals**

- Shared Decision Making with Patients
- Applying Shared Decision Making
- Key Points and Knowledge Check

**Chapter 4 Key Points**

- Shared decision making lets patients participate in decisions related to their illness in the context of their values and preferences.
- Investing time in shared decision making can lead to increased patient engagement and fewer hypoglycemic ADEs.
In order for shared decision making to be effective, patients need to understand the risks and benefits of various treatment options.

**Knowledge Check Question 1**
Using shared decision making to improve health literacy requires:

- Effective communication between providers and patients
- Identification of patient preferences and values
- A and B
- All of the above

**Question 1 Feedback**
The shared-decision making approach requires:

- Effective communication between providers and patients
- Identification of patient preferences and values
- Addressing provider and patient barriers

**Knowledge Check Question 2**
Imagine that you have proposed a change in a patient’s glycemic target goal, and after listening to you explain the risks and benefits of this change, the patient chooses to maintain his or her current course of treatment.

**Is this an example of a shared decision-making step?**

- Yes
- No

**Question 2 Feedback**
This is an example of a shared decision-making step because you and the patient collaborated to set a glycemic target goal.

**Conclusion**

**Course Summary**

**Conclusion**
89% of course complete

- Course Summary
- Obtain Continuing Education
Revisiting the Learning Objectives

By now you should be able to:

- Describe the national burden of adverse drug events (ADEs).
- Define hypoglycemia.
- Identify the individual risk factors, hypoglycemic agents, and medication interactions that place individuals with diabetes at higher risk for hypoglycemic ADEs.
- Describe the importance of setting target glycemic goals based on individual factors.
- Apply evidence-based guidelines for diabetes management, focusing on setting individualized glycemic targets with patients to reduce the risk of hypoglycemic episodes.
- Apply health literacy strategies to help patients understand and act on information to prevent ADEs.

Course Review

Review key points from each chapter by clicking on the chapter title.

Adverse Drug Events: A National Public Health Issue

Chapter 1 Key Points

- The potential for harms from ADEs is a critical patient safety and public health challenge.
- Older adults are more likely than younger people to have an ADE requiring a physician office or ED visit.
- The National Action Plan for ADE Prevention presents strategies and resources for preventing ADEs locally and nationally.

Key Determinates and Patient-Centered Approach to Risk Reduction

Chapter 2 Key Points

- Sulfonylureas and insulin are frequently associated with hypoglycemic ADEs, but virtually any diabetes treatment is capable of causing an adverse drug event.
- Assess the risk of hypoglycemia at every visit with patients treated with insulin and sulfonylureas.
- Hypoglycemia puts patients at risk for injury and death.
- Nearly all cases of hypoglycemic ADEs are preventable.
• It’s important to identify the cause of a hypoglycemic episode so that it can be prevented from happening again.
• Nearly 9 out of 10 adults have difficulty understanding and using health information.
• It’s appropriate to assume that everyone may have some trouble understanding health care information.
• Methods that increase health literacy, such as teach-back and shared decision making, can help you to assure patient understanding and increase patient engagement.
• Patient education has been shown to improve outcomes in individuals with diabetes.

**Applying Current Guidelines for Individualized Care of People with Diabetes**

Chapter 3 Key Points

- Intensive therapy is not appropriate for all patients with diabetes.
- It is important to individualize target glycemic goals based upon life expectancy, comorbid conditions, microvascular complications, and the patient’s personal preference.
- Refer to the reasonable range of glycemic targets to set an initial glycemic target for discussion with patients.

**Shared Decision Making for Individualized Glycemic Goals**

Chapter 4 Key Points

- Shared decision making lets patients participate in decisions related to their illness in the context of their values and preferences.
- Investing time in shared decision making can lead to increased patient engagement and fewer hypoglycemic ADEs.
- In order for shared decision making to be effective, patients need to understand the risks and benefits of various treatment options.

**Course Conclusion Video**

The National Action Plan on Preventing Adverse Drug Events is an important step in galvanizing both U.S. government and other partners to prevent important adverse drug events such as hypoglycemia.

By breaking the inertia of setting every patient’s A1c target to 7, we as providers can help prevent hypoglycemia and provide safer and higher quality care to our patients.

As the Affordable Care Act focuses our health care system more on quality, equipping providers with tools that can improve care is very critical in meeting patient needs.
As we learn more about the advancements in current diabetes management, tools like shared decision making and teach back will help us improve communication with our patients so that they can improve their livelihood and have better health outcomes.

**Resources**

**Clinical Guidelines**


**Related Research Literature**

**Summary article**

- AGS: Management of Hyperglycemia in Type 2 Diabetes: A Patient-Centered Approach [PDF - 1.2 MB] (http://care.diabetesjournals.org/content/early/2012/04/17/dc12-0413.full.pdf+html)

**Clinical trials**


**Evidence-Based Resources for Providers**

- AGS Education & Clinical Resources on Diabetes (http://www.americangeriatrics.org/health_care_professionals/clinical_practice/clinical_guidelines_recommendations/)
Evidence-Based Consumer Education Materials

- Low Blood Sugar (Hypoglycemia) [PDF - 1.2 MB], LearningAboutDiabetes.org (http://learningaboutdiabetes.org/downloads/LowBloodSugarEN.pdf)
- Medicines for Type 2 Diabetes: A Review of the Research for Adults (http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=721&PC=db)

Health Literacy Tools

- Plain Language Thesaurus for Common Medical Terms (http://www.mmc.org/lrc_body.cfm?id=7631&fr=true)

Obtaining Continuing Education

Conclusion

92% of course complete

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**References**

**Conclusion**

*94% of course complete*

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**In-Text References**


**Additional References**


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Conclusion

100% of course complete

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Acknowledgments

We gratefully acknowledge the writers, editors, and reviewers who have produced this educational resource.
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