YOUR ANNUAL DIABETES UPDATE

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Disclosures

• Dr. Hinson declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program.

• Dr. Smith declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program.
CPE Information

• Target Audience: Pharmacists
• ACPE#: 0202-0000-19-035-L01-P
• Activity Type: Knowledge-based
Supporter

This activity is supported by an independent educational grant from Boehringer Ingelheim Pharmaceuticals, Inc. and Lilly USA, LLC and Merck Sharp & Dohme Corp.
At the completion of this knowledge-based activity, participants will be able to:

• Summarize important recent changes to the American Diabetes Association (ADA) Standards of Medical Care in Diabetes and other authoritative guidelines.

• Describe evidence regarding new and emerging trends in management of patients with diabetes.

• Identify noteworthy findings from recent clinical trials that have the potential to influence diabetes care.

• Discuss the application of emerging trends in the care of patients with diabetes.
Which of the following is a studied benefit of utilizing a closed-loop insulin delivery system that combines CGM, insulin delivery, and insulin dosing algorithms?

A. Reduces the risk of hypoglycemia
B. Eliminates the need for bolus dosing
C. Improves % time in glucose target range
D. Reduces the risk of ketoacidosis
According to the ADA Standards of Medical Care in Diabetes-2019, which of the following is the most preferred agent for a patient with existing ASCVD?

A. Dapagliflozin
B. Canagliflozin
C. Dulaglutide
D. Lixisenatide
According to the 2019 Standards of Medical Care in Diabetes, how often should a patient with no diabetes complications have their feet inspected?

A. Every visit
B. Every 3 months
C. Every 6 months
D. Annually
Assessment Question #4

Fournier’s gangrene has been associated with:

A. GLP-1 receptor agonists
B. Thiazolidinediones
C. SGLT-2 inhibitors
D. DPP-4 inhibitors
2019 Recommendations In Diabetes Care
Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)¹

The American Diabetes Association (ADA) Standards of Medical Care in Diabetes - 2019²

2. Introduction: Standards of Medical Care in Diabetes-2019, ADA. S1-S2.
Consistency of Care

- Reinforces patient centered care
- Endorses the chronic care model
- Supports telemedicine efforts
- Awareness of social determinants of health
- Guidance on patient friendly language

1. Section 1: Improving Care and Promoting Health in Populations. Standards of Medical Care in Diabetes-2019, ADA. S7-S12.
2. Section 4: Comprehensive Medical Evaluation and Assessment. Standards of Medical Care in Diabetes-2019, ADA. S34-S45.
Diabetes self-management education and support (DSMES)

- Emphasizes patient centered care
- Rejects “one size fits all” approach

Section 5: Lifestyle Management. Standards of Medical Care in Diabetes-2019, ADA. S46-S60.
Diagnostic Criteria Update

Two different samples

Different tests from same sample

Two abnormal tests

Section 2: Classification and Diagnosis of Diabetes. Standards of Medical Care in Diabetes-2019, ADA. S15-16.
### Diagnostic Criteria Overview

<table>
<thead>
<tr>
<th>Test</th>
<th>Pre-Diabetes</th>
<th>Type 2 Diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting Plasma Glucose</td>
<td>100 - 125 mg/dL</td>
<td>≥ 126 mg/dL</td>
</tr>
<tr>
<td>2-hour Plasma Glucose</td>
<td>140 - 199 mg/dL</td>
<td>≥ 200 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin A1c (HbA1c)</td>
<td>5.7 - 6.4%</td>
<td>≥ 6.5%</td>
</tr>
</tbody>
</table>

*Section 2. Classification and Diagnosis of Diabetes. Standards of Medical Care in Diabetes-2019, ADA. S15-S17.*
Hemoglobin variants interfere with HbA1C measurements

<table>
<thead>
<tr>
<th>Conditions Known to Impact HbA1c Test Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sickle cell disease</td>
</tr>
<tr>
<td>Pregnancy (2\textsuperscript{nd} &amp; 3\textsuperscript{rd} trimester)</td>
</tr>
<tr>
<td>Post partum period</td>
</tr>
<tr>
<td>Glucose-6-phosphate dehydrogenase deficiency</td>
</tr>
<tr>
<td>Human immunodeficiency virus (HIV)</td>
</tr>
<tr>
<td>Hemodialysis</td>
</tr>
<tr>
<td>Recent blood loss</td>
</tr>
<tr>
<td>Recent blood transfusion</td>
</tr>
</tbody>
</table>

Section 2: Classification and Diagnosis of Diabetes. Standards of Medical Care in Diabetes-2019, ADA. S15.
Automated Hybrid closed-loop system

- Insulin Pump
- Continuous Glucose Sensor
- Algorithm determining insulin delivery

Combines previous technology

Section 7: Diabetes Technology. Standards of Medical Care in Diabetes-2019, ADA. S77.
## Hybrid System Considerations

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>↓ Risk exercise related hypoglycemia</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; generation technology</td>
</tr>
<tr>
<td>Potential psychosocial benefits</td>
<td>Not truly automated</td>
</tr>
<tr>
<td>Approved for children young as age 7</td>
<td>Manually adjust for meals/snacks</td>
</tr>
</tbody>
</table>

*Section 7: Diabetes Technology. Standards of Medical Care in Diabetes-2019, ADA. S77.*
• Open-label, multicenter, multinational, parallel randomized control trial
  • Longest duration insulin hybrid-system study (12-week)
  • Largest study population (86 participants)
  • Included children ≤ 6 years

Closed-Loop Insulin Delivery

## Closed-Loop Insulin Delivery

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th></th>
<th>12-Weeks</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Closed-loop</td>
<td>Control</td>
<td>Closed-loop</td>
<td>Control</td>
</tr>
<tr>
<td>% time w/ target glucose*</td>
<td>52%</td>
<td>52%</td>
<td>65%</td>
<td>54%</td>
</tr>
<tr>
<td>% time w/ target night glucose*</td>
<td>54%</td>
<td>53%</td>
<td>77%</td>
<td>56%</td>
</tr>
<tr>
<td>HbA1c*</td>
<td>8%</td>
<td>7.8%</td>
<td>7.4%</td>
<td>7.7%</td>
</tr>
<tr>
<td>% time hyperglycemic*</td>
<td>49.5%</td>
<td>48.9%</td>
<td>35.5%</td>
<td>46.4%</td>
</tr>
</tbody>
</table>

*Statistical significance: p < 0.001 & confidence interval (CI) does not cross 1

Future of Technology

- Ongoing clinical trials on hybrid devices
  - Some with dual hormonal function
    - Insulin and glucagon
    - Insulin and pramlintide

- Do it yourself instructions on the internet
  - Not FDA approved
  - Not recommended for use
Greater patient-centered focus

Incorporated new data on GLP-1 and SGLT2

Reinforces ADA/EASD consensus report

Section 9: Pharmacologic Approaches to Glycemic Treatment. Standards of Medical Care in Diabetes-2019, ADA. S90-102.
ASCVD

GLP-1 RA
OR
SGLT2i

Combination Therapy

Section 9: Pharmacologic Approaches to Glycemic Treatment. Standards of Medical Care in Diabetes-2019, ADA. S90-102.
Preferred Agents ASCVD

GLP-1 RA
- Liraglutide
- Semaglutide
- Exenatide ER

SGLT2i
- Empagliflozin
- Canagliflozin

Section 9: Pharmacologic Approaches to Glycemic Treatment. Standards of Medical Care in Diabetes-2019, ADA. S90-102.
HF and/or CKD

SGLT2

if not tolerated

GLP-RA

Combination Therapy

Section 9: Pharmacologic Approaches to Glycemic Treatment. Standards of Medical Care in Diabetes-2019, ADA. S90-102.
Preferred Agents HF/CKD

SGLT2i therapy with evidence of benefit in HF and CKD

Empagliflozin

Canagliflozin

Section 9: Pharmacologic Approaches to Glycemic Treatment. Standards of Medical Care in Diabetes-2019, ADA. S90-102.
• DECLARE-TIMI 58
• Randomized, double-blind, multinational, placebo-controlled trial
  • Type 2 diabetes
  • ASCVD or multiple risk factors for ASCVD

DECLARE-TIMI 58

25,698 enrolled

17,160 completed run-in

17,143 randomized

8574 dapagliflozin

1811 discontinued early

6763 completed

8569 placebo

2151 discontinued early

6418 completed

Wiviott SD, et al. Dapagliflozin and Cardiovascular Outcomes in Type 2 Diabetes. p 347-357.
### DECLARE-TIMI 58

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Dapagliflozin</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>CV death/HF hospitalization*</td>
<td>4.9%</td>
<td>5.8%</td>
</tr>
<tr>
<td>MACE</td>
<td>8.8%</td>
<td>9.4%</td>
</tr>
<tr>
<td>≥ 40% decrease in GFR</td>
<td>1.5%</td>
<td>2.8%</td>
</tr>
</tbody>
</table>

*Statistical significance: \( p = 0.005 \)

Wiviott SD, et al. *Dapagliflozin and Cardiovascular Outcomes in Type 2 Diabetes.* p 347-357.
• Multicenter, open label, international study
  • Type 2 diabetes
  • Moderate to severe CKD (stages 3 & 4)
  • HbA1c 7.5% - 10.5%
  • Therapy w/insulin and/or oral anti-hyperglycemic medication

<table>
<thead>
<tr>
<th>eGFR @ 52 weeks</th>
<th>Dulaglutide 1.5 mg</th>
<th>Dulaglutide 0.75 mg</th>
<th>Insulin glargine</th>
</tr>
</thead>
<tbody>
<tr>
<td>mL/min per 1.73m² (cystatin C equation)</td>
<td>-0.7 ( p=0.0372 )</td>
<td>-0.7 ( p=0.0324 )</td>
<td>-3.3</td>
</tr>
<tr>
<td>mL/min per 1.73m² (creatinine equation)</td>
<td>-1.1</td>
<td>-1.5</td>
<td>-2.9</td>
</tr>
</tbody>
</table>

* p values when compared to insulin data
* p values not provided for data using CrCl equation

CAUTION: insulin and SU

DPP-4i, GLP-1 RA, SGLT2i, TZD

add agents for combo therapy:
Preference for SGLT2i and TZD

Section 9: Pharmacologic Approaches to Glycemic Treatment. Standards of Medical Care in Diabetes-2019, ADA. S90-102.
Weight Concerns

CAUTION: SU, TZD, Insulin

GLP-1 RA
OR
SGLT2i

Combination Therapy

add
DPP-4i

Section 9: Pharmacologic Approaches to Glycemic Treatment. Standards of Medical Care in Diabetes-2019, ADA. S90-102.
GLP-1 RA & Weight Loss

GLP-1 RA therapy preferred for patients with weight concerns

Section 9: Pharmacologic Approaches to Glycemic Treatment. Standards of Medical Care in Diabetes-2019, ADA. S90-102.
Affordability

SU
OR
TZD

Lowest Acquisition Cost:
DPP-4i, SGLT2i, insulin

Section 9: Pharmacologic Approaches to Glycemic Treatment. Standards of Medical Care in Diabetes-2019, ADA. S90-102.
If no co-morbidities

- Any 1st line therapy option
- Patient preferences
- Long disease duration often requires injectable therapy

- SU
- TZD
- SGLT2i
- GLP-1 RA
- DPP-4
- Basal Insulin

Section 9: Pharmacologic Approaches to Glycemic Treatment. Standards of Medical Care in Diabetes-2019, ADA. S90-102.
Injectable Therapy

Comprehensive Guidance

GLP-1 preferred over Insulin

Section 9: Pharmacologic Approaches to Glycemic Treatment. Standards of Medical Care in Diabetes-2019, ADA. S90-102.
### CV Disease and Risk Management

**Blood Pressure**

<table>
<thead>
<tr>
<th>High ASCVD Risk</th>
<th>Lower Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>130/80 mmHg</td>
<td>140/90 mmHg</td>
</tr>
</tbody>
</table>

10-year ASCVD risk score calculation as part of routine care

*Section 10: Cardiovascular Disease and Risk Management. Standards of Medical Care in Diabetes-2019, ADA. S104.*
## CV Disease and Risk Management

**Hyperlipidemia**

<table>
<thead>
<tr>
<th>High intensity statin</th>
<th>Moderate intensity statin</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of ASCVD</td>
<td>&lt; age 40 with other ASCVD risk factors</td>
</tr>
<tr>
<td>10-year risk &gt; 20%</td>
<td>&gt; age 40 w/o ASCVD</td>
</tr>
<tr>
<td>Multiple risk factors</td>
<td>Do not tolerate high-intensity statins</td>
</tr>
</tbody>
</table>

*Section 10: Cardiovascular Disease and Risk Management. Standards of Medical Care in Diabetes-2019, ADA. S109-S110.*
All patients with diabetes should have their feet inspected at every visit.

Patients with evidence of sensory loss or prior ulceration or amputation should have their feet inspected at every visit.

Cost of Care
Diabetes is Expensive...

2.3 times higher expenditures if diabetes is present

Average medical expenditure per year
∼$16,750

Directly attributed to diabetes: $9,600

Cost of Insulin

The prices for life-saving diabetes medications have increased again.

Diabetes Patients at Risk From Rising Insulin Prices

The rising cost of insulin: "Horror stories every day"

Soaring insulin prices have patients terrified and pharmacists scrambling.

What’s behind skyrocketing insulin prices?

Spiking Insulin Costs Put Patients in Brutal Bind

The Rising Cost of Insulin

Why the price of this lifesaving drug is reaching new heights.

Insulin Prices Have More Than Doubled in the Last 6 Years — and Now People Are Dying Because They Can’t Afford the Drug.
Insulin Supply Chain

Rising Insulin Costs

**List Price:** medication price set by manufacturer

**Net Price:** price manufacturer receives after rebates, discounts, & fees

Insulin Costs

Awareness
- ADA insulin access and affordability working group

Advocacy
- ADA petition for insulin transparency, affordability and access (https://makeinsulinaffordable.org/)

Action
- FDA has included insulin in priority medicines with the aim of lowering cost

https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm564725.htm
Follow-on Biologic Insulin

- Basaglar
  - Insulin Glargine
- Lusduna
  - Insulin Glargine
- Nexvue
  - Insulin Glargine
- Admelog
  - Insulin Lispro
Melvin

70 years of age

PMH: T2DM, HTN, hypothyroidism

Current diabetes regimen:
metformin 1000 mg BID, glargine U-300
20 units daily, glipizide 10 mg BID, &
dulaglutide 0.75 mg weekly

A1C 10.1%; Scr 1.3; eGFR 51; BP 128/70;
weight 240 lbs
## Cost of Regimen

<table>
<thead>
<tr>
<th>Agent</th>
<th>Cost (30 day supply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-acting basal insulin</td>
<td>451.00</td>
</tr>
<tr>
<td>Metformin</td>
<td>27.00</td>
</tr>
<tr>
<td>Sulfonylurea</td>
<td>20.00</td>
</tr>
<tr>
<td>GLP-1 RA</td>
<td>887.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$1,385.00</strong></td>
</tr>
<tr>
<td>ACE-I</td>
<td>12.00</td>
</tr>
<tr>
<td>Statin</td>
<td>114.00</td>
</tr>
<tr>
<td>Aspirin 81 mg</td>
<td>3.00</td>
</tr>
<tr>
<td>Levothyroxine 100 mcg</td>
<td>20.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$1,534.00</strong></td>
</tr>
</tbody>
</table>

## Cost of Regimen

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<td><strong>$1,385.00</strong></td>
</tr>
<tr>
<td>Metformin</td>
<td>27.00</td>
</tr>
<tr>
<td>NPH</td>
<td>143.00</td>
</tr>
<tr>
<td>(Discounted NPH)*</td>
<td>26.07</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$53.07 — 170.00</strong></td>
</tr>
</tbody>
</table>


* Sold in select locations
Geriatric and Pediatric Diabetes
### Older Adult

<table>
<thead>
<tr>
<th>Healthy</th>
<th>Complex</th>
<th>Very complex</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1C goal &lt; 7.5%</td>
<td>A1C goal &lt; 8.0%</td>
<td>Long-term care or end-stage chronic illnesses or moderate-to-severe cognitive impairment or 2+ ADL dependencies</td>
</tr>
<tr>
<td>Fasting: 90–130 mg/dL</td>
<td>A1C goal &lt; 8.0%</td>
<td>A1C goal &lt; 8.5%</td>
</tr>
<tr>
<td>Bedtime: 90–150 mg/dL</td>
<td>Fasting: 90–150 mg/dL</td>
<td>Fasting: 100–180 mg/dL</td>
</tr>
<tr>
<td></td>
<td>Bedtime: 100–180 mg/dL</td>
<td>Bedtime: 110–200 mg/dL</td>
</tr>
</tbody>
</table>

Older Adult

Simplify:
Decrease complexity of regimen:
• ↓ frequency of administration
• Change from calculated doses to standard meal doses

Deintensify:
Make regimen less intense:
• ↓ dose or frequency of administration
• Discontinue treatment, particularly if no clear benefit

Severe/recurrent hypoglycemia on insulin, unable to manage complexity of insulin regimen, significant change in social circumstances

Severe/recurrent hypoglycemia on insulin, wide glucose fluctuations, polypharmacy, or taking medications without clear benefit

Simplify Complex Regimen

Adjust Basal

- Change to morning dosing
- 50%+ fasting > goal: ↑ 2 units
- >2 fastings/week <80: ↓ 2 units

*If pre-mixed, give 70% as morning basal

Change Bolus

- Bolus >10 units/dose: ↓ by 50%
- Bolus <10 units/dose: Discontinue
- Add non-insulin agent

*Aim to discontinue bolus


Pediatric Diabetes

A1C < 8.5%:
Metformin BID; titrate to 2,000 mg/day as tolerated

A1C > 8.5%:
Basal insulin at 0.5 units/kg/day; titrate every 2-3 days
+ Metformin BID

Acidosis: Manage with IV insulin first

Metformin 500 mg BID, titrated to 1000 mg BID

Prandial insulin or “other drug therapy”

Basal insulin, titrated to maximum 1.5 units/kg/day

New and Emerging Information, Agents, & Devices
Fournier’s Gangrene

10:1 males versus females
1.6 out of 100,000 US males per year
Males 50-79 years

Risk Factors

Diabetes, malignancy, advanced age, cirrhosis, renal failure, obesity, chronic alcoholism, vasculopathy, steroid use

Prodromal: genital discomfort, pruritus
Common: scrotal swelling, fever, pain

https://www.fda.gov/Drugs/DrugSafety/ucm617360.htm

SGLT2 Inhibitors

12 hospitalizations requiring surgery: 1 death

Careful patient selection for use
Counsel: risks & importance of good hygiene

https://www.fda.gov/Drugs/DrugSafety/ucm617360.htm
Legislature Change

- Individuals with T1DM can operate commercial motor vehicles if:
  - stable insulin regimen
  - well-controlled insulin-treated diabetes mellitus

- Maximum of 12 months

Implantable Sensor

Place Sensor
Placed by physician under skin of upper arm under local anesthesia

Wear 90 Days
Chemical produces light when exposed to glucose – transmits reading to device

Remove Sensor
Sensor removed by physician; new sensor in opposite arm

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611454.htm
https://www.eversensediabetes.com/hcp-clinical-studies/
Oral Semaglutide

- Contains sodium N-(8-[2-hydroxybenzoyl] amino) caprylate (SNAC)
  - Increases pH to prevent breakdown by DPP-4
  - Promotes absorption across gastric mucosa

- Pioneer Trials

1. Empagliflozin 25 mg
2. Sitagliptin 100 mg
3. Liraglutide 1.8 mg
4. CVOT: ↓ CV death
5. Dulaglutide 0.75 mg

Adverse Effects: mild/moderate nausea & constipation

Press Releases. Novo Nordisk Website: https://www.novonordisk.com
Oral Insulin

https://www.oramed.com/first-oral-insulin-for-diabetics-steps-towards-fda-approval/
https://clinicaltrials.gov/ct2/show/study/NCT02496000
Dual SGLT₁/SGLT₂ Inhibitor

- SGLT1 glucose and galactose transporter - intestines & kidney
- SGLT2 glucose transporter – kidneys


Efficacy (A1C < 7%)

- T1DM >1 year, 18 yo+
  - Sotagliflozin 400 mg
  - Placebo
  - Sotagliflozin 200/699 (28.6%)
  - Placebo 107/703 (15.2%)
  - P<0.001

Safety

- Hypoglycemia: 96.3%
- Diarrhea: 4.1%
- Genital infection: 6.4%
- Acidosis-related: 8.6%
- Hypoglycemia: 95.3%
- Diarrhea: 2.3%
- Genital infection: 2.1%
- Acidosis-related: 2.4%
Number of emergency room visits in adults with diabetes (2014):

- Hypoglycemia: 245,000
- Hyperglycemic crisis: 207,000

**Glucagon**

- **Emergency Kit**
  - Standard treatment
  - Reconstitution needed
  - IM Injection

- **Autoinjector**
  - Liquid-stable injection
  - No mixing needed
  - Room temp storage
  - Easy to use

- **Intranasal Glucagon**
  - Powder formulation
  - One-step nasal spray
  - Easy to use

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https://investors.xerispharma.com/node/6731/pdf
Closing remarks/conclusion

- The 2019 ADA guidelines focus on patient-centered, team-based care
- New closed-loop insulin delivery systems may offer patients better glycemic control
- Pharmacologic therapy is stratified by patient specific factors
- Be cognizant - diabetes can be a costly disease to manage
- As patients age, consideration may need to be given to simplification of the diabetes regimen
- Be on the lookout for new diabetes tools and treatments!
Which of the following is a studied benefit of utilizing a closed-loop insulin delivery system that combines CGM, insulin delivery, and insulin dosing algorithms?

A. Reduces the risk of hypoglycemia
B. Eliminates the need for bolus dosing
C. Improves % time in glucose target range
D. Reduces the risk of ketoacidosis
According to the ADA Standards of Medical Care in Diabetes-2019, which of the following is the most preferred agent for a patient with existing ASCVD?

A. Dapagliflozin  
B. Canagliflozin  
C. Dulaglutide  
D. Lixisenatide
Assessment Question #3

According to the 2019 Standards of Medical Care in Diabetes, how often should a patient with no diabetes complications have their feet inspected?

A. Every visit  
B. Every 3 months  
C. Every 6 months  
D. Annually
Fournier’s gangrene has been associated with:

A. GLP-1 receptor agonists
B. Thiazolidinediones
C. SGLT-2 inhibitors
D. DPP-4 inhibitors
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Ohio Northern University

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Clinical Pharmacy Specialist
US Department of Veterans Affairs