2016 Diabetes Update

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Disclosure Statement

- I have nothing to disclose

Objectives

- Summarize the 2016 revisions to the American Diabetes Association (ADA) Standards of Medical Care in Diabetes and other guidelines.
- Summarize vaccine recommendations for individuals with diabetes.
- Summarize and evaluate new products and medications to improve diabetes control.

Question 1

- JC is a 66 yo male with type 2 diabetes. He presents to the pharmacy counter asking about vaccinations. He claims that he received a pneumonia shot (Pneumovax) 3 years ago at his doctors office. Which recommended vaccines would JC be eligible to receive today?

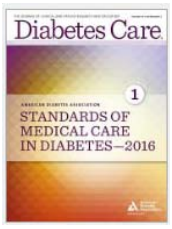
Question 2

- Which of the following statements is false regarding Adlyxin (lixisenatide)

a. Adlyxin is a GLP-1 Agonist
b. Adverse effects include Nausea and general GI upset
c. Adlyxin is administered via SC injection
d. Once activated Adlyxin pens are stable for 28 days

ADA Standards of Care

- Updated in January 2016
- Found on www.diabetes.com



2016 Revisions to ADA Standards of Care

2016 Revisions

- **General Changes**
  - Individuals with diabetes shall no longer be referred to as "Diabetic"
- **Section 1: Strategies for Improving Care**
  - Tailor treatment to specific vulnerable populations with Diabetes
    - Food Insecurity, mental illness, cognitive dysfunction, and HIV
  - Discusses disparities
    - Ethnicity, culture, sex, socioeconomic, etc.

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

2016 Revisions

- **Section 2: Classification and Diagnosis of Diabetes**
  - Type of Test
    - No single test is preferred when diagnosing
    - A1C, OGTT, Fasting BG are all equally acceptable
  - Who should be tested?
    - All Adults >45 years old regardless of weight and health history
    - All adults <45 overweight/obese with additional risk factors
  - Updates in testing for gestational DM and monogenic DM

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

2016 Revisions

- **Section 3: Foundations of Care and Comprehensive Medical Evaluation**
  - Combines Sections 3 and 4 from previous editions
  - Nutrition and Vaccination recommendations are streamlined
    - Nutrition
      - Promotes and supports healthy eating
      - Individualized nutrition approach
      - Provides practical tools for developing healthy eating habits

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

2016 Revisions

Section 3 *continued*

- Vaccination Recommendations
  - Routine Adult vaccinations according to Age
    - Follow CDC age appropriate guidelines
  - Influenza
    - Should receive each year
  - Hepatitis B
    - 3 part series at month 0, 1, and 6
  - Pneumococcal Pneumonia
    - *See next slide*

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

Pneumococcal Pneumonia Vaccines

- Age 2-64 with Diabetes
  - Administer 1 dose of PPSV23 (Pneumovax)
- Age >65 with diabetes
  - Administer 1 dose of PCV13 (Prevnar13)
  - After 12 months- Administer 1 dose of PPSV23

*****Make sure that there is at least 5 years in between doses of PPSV23*****

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

2016 Revisions

- **Section 4: Prevention or Delay of Type 2 Diabetes**
  - Strongly encourages the use of new technology
    - MyFitnessPal, Fit bits, and other apps
- **Section 5: Glycemic Targets**
  - Individuals that utilize insulin pumps or continuous glucose monitoring systems should have continued access after they turn 65 years of age

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

2016 Revisions

- **Section 6: Obesity Management for the Treatment of Type 2 Diabetes**
  - New Section
    - Previously Bariatric Surgery
    - New recommendations related to assessment of weight and behavioral modifications
    - Table of current FDA approved medications for long-term treatment was included

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

Weight Loss Interventions: ADA 2016 Recommendations

Table 6.1—Treatment for overweight and obesity in type 2 diabetes

	BMI category (kg/m^2)				
Treatment	23.0* or 25.0–26.9	27.0–29.9	30.0–34.9	35.0–39.9	≥40
Diet, physical activity, and behavioral therapy	†	†	†	†	†
Pharmacotherapy		†	†	†	†
Bariatric surgery				†	†

†Treatment may be indicated for selected motivated patients.
*Cutoff points for Asian American individuals.

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

Pharmacotherapy

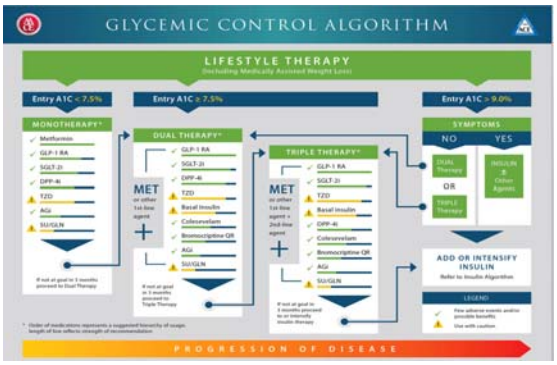
- Phentermine/topiramate (Qsymia)
  - All strengths
- Orlistat (Alli or Xenical)
  - 60 mg or 120 mg capsules
- Lorcaserin (Belviq)
  - 10 mg tabs
- Naltrexone/bupropion (Contrave)
  - 8 mg/90 mg tabs
- Liraglutide (Saxenda)
  - 6 mg/mL prefilled pen
  - Note that a 3mg dose is indicated for obesity (1.8mg dose of Victoza for diabetes)

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

2016 Revisions

- **Section 7: Approaches to Glycemic Treatment**
  - Bariatric surgery recommendations were removed and added to section 6
  - No changes in treatment algorithm

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.



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2016 Revisions

- **Section 8: Cardiovascular Disease and Risk Management**
  - ASCVD replaces CVD as the preferred descriptive term
  - Antiplatelet Therapy:
    - Women who are >50 years should consider Aspirin therapy
    - Consideration in all patients <50 with multiple risk factors
  - Recommends against targeting a BP <130/70
  - Ezetimibe should be considered in select patients

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

ADA 2016 Statin Recommendations

Age	Risk factors	Recommended statin dose*	Monitoring with lipid panel
<40 years	None CVD risk factor(s)** Overt CVD***	None Moderate or high High	Annually or as needed to monitor for adherence
40–75 years	None CVD risk factors Overt CVD	Moderate High High	As needed to monitor adherence
>75 years	None CVD risk factors Overt CVD	Moderate Moderate or high High	As needed to monitor adherence

*In addition to lifestyle therapy.
**CVD risk factors include LDL cholesterol ≥100 mg/dL (2.6 mmol/L), high blood pressure, smoking, and overweight and obesity.
***Overt CVD includes those with previous cardiovascular events or acute coronary syndromes.

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

2016 Revisions

- **Section 9: Microvascular Complications and Foot Care**
  - "Diabetic Kidney Disease" is now preferred over "Nephropathy"
  - New recommendations on when to refer patients for renal replacement therapy (RRT) or to a specialist
    - RRT referral when GFR <30mL/min/1.73m2
    - Specialist referral for uncertainty about the etiology of kidney disease, difficultly managing, and rapid progression.
  - Guidance was added on the use of intravitreal anti-VEGF agents in Diabetic Retinopathy
    - Proved to be more effective than other therapies

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

2016 Revisions

- **Section 10: Older Adults**
  - Focus on providing comprehensive, individualized care for the aging population
- **Section 11: Children and Adolescents**
  - New recommendations addressing diabetes self-management education and support, psychosocial issues, and treatment guidelines for type 2 diabetes in youth.
  - Obtain a fasting lipid profile in children starting at age 10
    - Prior age was 2 years old

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

2016 Revisions

- **Section 12: Management of Diabetes in Pregnancy**
  - A1C target for pregnant women with diabetes is now 6-6.5%
    - Prior A1C Target was <6%
  - If patient has elevated blood sugar, family planning should be discussed with patient until she is in the target A1C range
  - Treatment of gestational DM
    - Lifestyle modification, insulin, and metformin
    - The use of glyburide was deemphasized because new data suggests that it may be inferior to insulin and metformin.

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

2016 Revisions

- **Section 13. Diabetes Care in the Hospital**
  - Perform A1C for all patients with diabetes or hyperglycemia who have not had one in 3 months
  - Initiate insulin if BG is consistently >180 mg/dL
    - Target BG between 140-180 mg/dL
    - Critically ill: May target 110-140 mg/dL as long as hypoglycemia is avoided
  - Basal + bolus regimen is preferred for non-critically ill patients
  - The sole use of sliding scale insulin is STRONGLY DISCOURAGED
- **Section 14. Diabetes Advocacy**
  - Position statement for diabetes care in the school setting was revised

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.

New Drug Products

Tresiba (Insulin degludec; Novo Nordisk)

- New long-acting insulin analog
  - $T_{1/2}$= 25 hours,
  - Duration of action up to 42 hours
- Dosed once daily
  - May administer at any time of the day as long as there is at least 8 hours between doses
- Flat, steady state dose reached after 3-4 days
- Stability: 56 days after opening at room temperature

Tresiba (insulin degludec) [prescribing information]. Princeton, NJ: Novo Nordisk; September 2015.

Ryzodeg 70-30 (Insulin degludec and insulin aspart; Novo Nordisk)

- New insulin analog
  - Combination of:
    - Long acting (insulin degludec, 70%)
    - Ultra-fast acting (insulin aspart, 30%)
- Available in 3 ml flex-pen device
- May be given once or twice daily with largest meal
  - Dose can given at any point during the day
- Adjust the dose according to fasting BG reading

American Diabetes Association (ADA). Standards of medical care in diabetes, 2016.
Ryzodeg (insulin degludec and insulin aspart) [prescribing information]. Plainsboro, NJ: Novo Nordisk; September 2015.

Basaglar (Insulin glargine U100; Eli Lilly)

- Approved December 2015
  - 3ml Prefilled Basaglar KwikPen
  - Will be available for sale on 12/15/16
- First FDA-approved "follow-on" insulin glargine
- Proved to be biosimilar to Lantus

Basaglar (Insulin glargine) Eli Lilly; December 2015

Synjardy (empagliflozin/metformin, Eli Lilly)

- Combination of a SGLT2 inhibitor and biguanide for Type 2 Diabetes Mellitus
- Recommended dose:
  - Titrate to 12.5/1000 mg BID
    - Gradual dose escalation to avoid GI AEs with metformin
- Adverse Effects
  - Genital mycotic infections and UTI's
  - N/V/D
- CI in patients with serum creatinine >1.4 in women and >1.5 in men

Synjardy (empagliflozin/metformin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; December 2015.

Adlyxin (lixisenatide; Sanofi)

- Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist
- Approved July 2016
- Once daily subcutaneous injection
- AE's:
  - Mild/Moderate GI upset, Nausea, Headache
- Stability: 14 days after pen is activated

Adlyxin (lixisenatide) Safofi; July 2016

Question 1

- JC is a 66 yo male with type 2 diabetes. He presents at the pharmacy counter asking about vaccinations. He claims that he received a pneumonia shot (Pneumovax) 3 years ago at his doctors office. Which recommended vaccines would JC be eligible to receive today?

Question 1 Answer

- JC is a 66 yo male with type 2 diabetes. He presents at the pharmacy counter asking about vaccinations. He claims that he received a pneumonia shot (Pneumovax) 3 years ago at his doctors office. Which recommended vaccines would JC be eligible to receive today?

1. **Prevnar today, Pneumovax in 2 more years**
2. **Flu HD**
3. **Hepatitis**
4. **TDaP if eligible**
5. **Zostavax**

Question 2 Answer

- Which of the following statements is false regarding Adlyxin (lixisenatide)

a. Adlyxin is a GLP-1 Agonist
b. Adverse effects include Nausea and general GI upset
c. Adlyxin is administered via SC injection
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Question 2 Answer

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