Updates Primary Care

Erica Tate, MD
Assistant Professor of Medicine, Tulane School of Medicine
Disclosures

- No Disclosures
Asthma
FDA approves drug combination treatment for adults with asthma

- Airsupra (albuterol and budesonide) inhalation aerosol
  - for the as-needed treatment or prevention of bronchoconstriction
  - reduce the risk of asthma attacks in patients with asthma 18 years of age and older
- first combination of an inhaled corticosteroid (ICS) and a short-acting beta-agonist to be approved in the U.S.
- first product containing an ICS to be approved in the U.S. as a reliever treatment (rather than as a controller) for asthma

MANDALA Study

- Reduce the risk of severe asthma attacks in patients with moderate to severe asthma
- Randomized, double-blind, multinational, multicenter study
- Airsupra 180 mcg/160 mcg or albuterol 180 mcg and instructed to take as needed for asthma symptoms
- Treated for at least 24 weeks
- Primary Endpoint: time to first severe asthma attack (defined as worsening or onset of asthma symptoms that required systemic corticosteroids for at least three days or an emergency room visit that led to the use of systemic corticosteroids for at least three days or a hospitalization for at least 24 hours due to asthma)
- 28% reduction in the risk of a severe asthma attack as assessed by the time to first severe asthma attack

### First Severe Asthma Exacerbation

**Minimum Follow-up, 24 Wk**

<table>
<thead>
<tr>
<th>Combination</th>
<th>Probability</th>
<th>Weeks since Randomization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Higher-dose combination</td>
<td>0.92</td>
<td>0  \to  24  \to  48  \to  72  \to  96  \to  112</td>
</tr>
<tr>
<td>Lower-dose combination</td>
<td>0.90</td>
<td>0  \to  24  \to  48  \to  72  \to  96  \to  112</td>
</tr>
<tr>
<td>Albuterol alone</td>
<td>0.85</td>
<td>0  \to  24  \to  48  \to  72  \to  96  \to  112</td>
</tr>
</tbody>
</table>

**Higher-dose combination vs. albuterol alone:**
- HR, 0.74 (95% CI, 0.62–0.89); P=0.001

**Lower-dose combination vs. albuterol alone:**
- HR, 0.84 (95% CI, 0.71–1.00)

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COPD
GOLD ABE Assessment Tool

1. Spirometrically confirmed diagnosis
2. Assessment of airflow obstruction
3. Assessment of symptoms/risk of exacerbations

Post-bronchodilator FEV1/FVC < 0.7

<table>
<thead>
<tr>
<th>GRADE</th>
<th>FEV1 (% predicted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOLD 1</td>
<td>≥ 80</td>
</tr>
<tr>
<td>GOLD 2</td>
<td>50-79</td>
</tr>
<tr>
<td>GOLD 3</td>
<td>30-49</td>
</tr>
<tr>
<td>GOLD 4</td>
<td>&lt; 30</td>
</tr>
</tbody>
</table>

EXACERBATION HISTORY

E
- ≥ 2 moderate exacerbations or ≥ 1 leading to hospitalization
- 0 or 1 moderate exacerbations (not leading to hospitalization)

A
- mMRC 0-1
- CAT < 10

B
- mMRC ≥ 2
- CAT ≥ 10

SYMPTOMS

© 2022, 2023 Global Initiative for Chronic Obstructive Lung Disease
## Modified MRC Dyspnea Scale

<table>
<thead>
<tr>
<th>mMRC Grade 0</th>
<th>mMRC Grade 1</th>
<th>mMRC Grade 2</th>
<th>mMRC Grade 3</th>
<th>mMRC Grade 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>I only get breathless with strenuous exercise</td>
<td>I get short of breath when hurrying on the level or walking up a slight hill</td>
<td>I walk slower than people of the same age on the level because of breathlessness, or I have to stop for breath when walking on my own pace on the level</td>
<td>I stop for breath after walking about 100 meters or after a few minutes on the level</td>
<td>I am too breathless to leave the house or I am breathless when dressing or undressing</td>
</tr>
</tbody>
</table>

## CAT™ Assessment

For each item below, place a mark (x) in the box that best describes you currently. Be sure to only select one response for each question.

### Example: I am very happy

<table>
<thead>
<tr>
<th>Item</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>I never cough</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>I have no phlegm (mucus) in my chest at all</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>My chest does not feel tight at all</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>When I walk up a hill or one flight of stairs I am not breathless</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>I am not limited doing any activities at home</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>I am confident leaving my home despite my lung condition</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>I sleep soundly</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>I have lots of energy</td>
<td>0 1 2 3 4 5</td>
</tr>
</tbody>
</table>

### I am very sad

<table>
<thead>
<tr>
<th>Item</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>I cough all the time</td>
<td></td>
</tr>
<tr>
<td>My chest is completely full of phlegm (mucus)</td>
<td></td>
</tr>
<tr>
<td>My chest feels very tight</td>
<td></td>
</tr>
<tr>
<td>When I walk up a hill or one flight of stairs I am very breathless</td>
<td></td>
</tr>
<tr>
<td>I am very limited doing activities at home</td>
<td></td>
</tr>
<tr>
<td>I am not at all confident leaving my home because of my lung condition</td>
<td></td>
</tr>
<tr>
<td>I don’t sleep soundly because of my lung condition</td>
<td></td>
</tr>
<tr>
<td>I have no energy at all</td>
<td></td>
</tr>
</tbody>
</table>

### Score

**TOTAL SCORE:**

Reference: Jones et al. ERJ 2009; 34 (3); 648-54.
Initial Pharmacological Treatment

**GROUP E**

LABA + LAMA*

consider LABA+LAMA+ICS* if blood eos ≥ 300

**GROUP A**

A bronchodilator

mMRC 0-1, CAT < 10

**GROUP B**

LABA + LAMA*

mMRC ≥ 2, CAT ≥ 10

*single inhaler therapy may be more convenient and effective than multiple inhalers
Vaccination for Stable COPD

- Influenza vaccination is recommended in people with COPD (Evidence B)
- The WHO and CDC recommends SARS-CoV-2 (COVID-19) vaccination for people with COPD (Evidence B)
- The CDC recommends one dose of 20-valent pneumococcal conjugate vaccine (PCV20); or one dose of 15-valent pneumococcal conjugate vaccine (PCV15) followed by 23-valent pneumococcal polysaccharide vaccine (PPSV23) in people with COPD (Evidence B)
- Pneumococcal vaccination has been shown to reduce the incidence of community-acquired pneumonia and exacerbations in people with COPD (Evidence B)
- The CDC recommends Tdap (dTaP/dTPa) vaccination to protect against pertussis (whooping cough) for people with COPD that were not vaccinated in adolescence (Evidence B), and Zoster vaccine to protect against shingles for people with COPD over 50 years (Evidence B)
Vaccines
Pneumococcal Vaccine Recommendations

- Use of PCV20 alone or PCV15 in series with PPSV23
  - To reduce pneumococcal disease incidence in adults aged ≥65 years and in those aged 19–64 years with certain underlying conditions.
  - Immunogenicity and safety, comparable to PCV13 alone or PCV13 in series with PPSV23
  - Cost-effectiveness studies demonstrated was cost-saving
  - Simplifies adult pneumococcal vaccine recommendations

Pneumococcal Vaccine Timing for Adults

Make sure your patients are up to date with pneumococcal vaccination.

**Adults ≥65 years old**

**Complete pneumococcal vaccine schedules**

<table>
<thead>
<tr>
<th>Prior vaccines</th>
<th>Option A</th>
<th>Option B</th>
</tr>
</thead>
<tbody>
<tr>
<td>None*</td>
<td>PCV20</td>
<td>PCV15 ≥1 year</td>
</tr>
<tr>
<td>PPSV23 only at any age</td>
<td>≥1 year</td>
<td>PCV15</td>
</tr>
<tr>
<td>PCV13 only at any age</td>
<td>≥1 year</td>
<td>PCV15 ≥1 year</td>
</tr>
<tr>
<td>PCV13 at any age &amp; PPSV23 at &lt;65 yrs</td>
<td>≥5 years</td>
<td>PCV20 ≥5 years ≥1 year PPSV23</td>
</tr>
</tbody>
</table>

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines

1. Consider minimum interval (≥8 weeks) for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak (CSF) leak

3. For adults with an immunocompromising condition, cochlear implant, or CSF leak, the minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose; for others, the minimum interval for PPSV23 is ≥1 year since last PCV13 dose and ≥5 years since last PPSV23 dose

**Shared clinical decision-making for those who already completed the series with PCV13 and PPSV23**

<table>
<thead>
<tr>
<th>Prior vaccines</th>
<th>Shared clinical decision-making option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete series: PCV13 at any age &amp; PPSV23 at ≥65 yrs</td>
<td>PCV20 Together, with the patient, vaccine providers may choose to administer PCV20 to adults ≥65 years old who have already received PCV13 (but not PCV15 or PCV20) at any age and PPSV23 at or after the age of 65 years old.</td>
</tr>
</tbody>
</table>

### Adults 19–64 years old with specified immunocompromising conditions

#### Complete pneumococcal vaccine schedules

<table>
<thead>
<tr>
<th>Prior vaccines</th>
<th>Option A</th>
<th>Option B</th>
</tr>
</thead>
<tbody>
<tr>
<td>None*</td>
<td>PCV20</td>
<td>PCV15, ≥8 weeks → PPSV23</td>
</tr>
<tr>
<td>PPSV23 only</td>
<td>PCV20, ≥1 year</td>
<td>PCV15, ≥1 year</td>
</tr>
<tr>
<td>PCV13 only</td>
<td>PCV20, ≥1 year</td>
<td>PPSV23, ≥8 weeks → PPSV23, ≥5 years</td>
</tr>
<tr>
<td>PCV13 and 1 dose of PPSV23</td>
<td>PCV20, ≥5 years</td>
<td>PPSV23, ≥5 years</td>
</tr>
<tr>
<td>PCV13 and 2 doses of PPSV23</td>
<td>PCV20, ≥5 years</td>
<td>No vaccines recommended at this time.</td>
</tr>
</tbody>
</table>

#### Immunocompromising conditions

- Chronic renal failure
- Congenital or acquired asplenia
- Congenital or acquired immunodeficiency
- Generalized malignancy
- HIV infection
- Hodgkin disease
- Iatrogenic immunosuppression
- Leukemia
- Lymphoma
- Multiple myeloma
- Nephrotic syndrome
- Sickle cell disease/other hemoglobinopathies
- Solid organ transplant

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines

† The minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose

‡ Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease)

† Includes diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy

### Adults 19–64 years old with a cochlear implant or cerebrospinal fluid leak

**Complete pneumococcal vaccine schedules**

<table>
<thead>
<tr>
<th>Prior vaccines</th>
<th>Option A</th>
<th>Option B</th>
</tr>
</thead>
<tbody>
<tr>
<td>None*</td>
<td>PCV20</td>
<td>PCV15   ≥8 weeks PPSV23</td>
</tr>
<tr>
<td>PPSV23 only</td>
<td>≥1 year PCV20</td>
<td>≥1 year PCV15</td>
</tr>
<tr>
<td>PCV13 only</td>
<td>≥1 year PCV20</td>
<td>≥8 weeks PPSV23</td>
</tr>
<tr>
<td>PCV13 and 1 dose of PPSV23</td>
<td>≥5 years PCV20</td>
<td><strong>No vaccines</strong> recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 65 years old.</td>
</tr>
</tbody>
</table>

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines

The PneumoRecs VaxAdvisor Mobile App was updated on February 9, 2023, to reflect CDC’s new adult pneumococcal vaccination recommendations including for those who previously received PCV13.

The PneumoRecs VaxAdvisor mobile app helps vaccination providers quickly and easily determine which pneumococcal vaccines a patient needs and when. The app incorporates recommendations for all ages so internists, family physicians, pediatricians, and pharmacists alike will find the tool beneficial.

Users simply:

- Enter a patient’s age.
- Note if the patient has specific underlying medical conditions.
- Answer questions about the patient’s pneumococcal vaccination history.

Then the app provides patient-specific guidance consistent with the immunization schedule recommended by the U.S. Advisory Committee on Immunization Practices (ACIP).

Download the mobile app or use the web version

Download “PneumoRecs VaxAdvisor” free for iOS and Android devices.

https://www.cdc.gov/vaccines/vpd/pneumo/hcp/pneumoapp.html
Pneumococcal Vaccine Recommendations

PneumoRecs
VaxAdvisor

Tool to help determine which pneumococcal vaccines children and adults need.

Get Started

Enter a patient's age, pneumococcal vaccination history, and underlying medical conditions. Move through this tool to create customized pneumococcal vaccination recommendations.

- https://www2a.cdc.gov/vaccines/m/pneumo/pneumo.html
CDC recommends universal Hep B Vaccination 19-59

Vaccination with hepatitis B (HepB) vaccines shows well-established safety and efficacy. However, because of risk factor-based approaches of previous vaccination recommendations, coverage among adults has been suboptimal.

Universal adult HepB vaccination through age 59 years removes the need for risk factor screening and disclosure and could increase vaccination coverage and decrease hepatitis B cases.

- Heplisav-B and PreHevbridge data is currently insufficient to inform vaccine-associated risks in pregnancy.
- Vaccinate pregnant women needing HepB vaccination with Engerix-B, Recombivax HB, or Twinrix.

https://www.cdc.gov/mmwr/volumes/71/wr/mm7113a1.htm?s_cid=mm7113a1_w
Updates in Primary Care

By Vy Anh Mai, MD, MSc
Assistant Professor of Medicine
Tulane School of Medicine
Disclosure of Interest

Nothing to disclose
Topics

- Type 2 Diabetes
- Weight Loss Management
- Buprenorphine Prescribing
Learning Objectives for Type 2 Diabetes Mellitus

1. Acknowledge provider-related barriers leading to poor diabetes control
2. Review new screening guidelines
3. Review algorithms and medication profiles per American Diabetes Association (ADA) and American Association of Clinical Endocrinology (AACE)
4. Review updates in insulin affordability
Type 2 diabetes trends in the United States, 2006–2013. Advances in health technologies, drug therapies, and public policy have not translated to improvements in diabetes care quality. ACO, accountable care organization; DPP-4i, dipeptidyl peptidase 4 inhibitor; GLP-1RA, glucagon-like peptide 1 receptor agonist; HITECH, Health Information Technology for Economic and Clinical Health; PCMH, patient-centered medical home; SGLT2i, sodium–glucose cotransporter 2 inhibitor. Adapted from ref. 24.
Barrier to Care – Clinical Inertia

• Most often time we focus a lot on medical nonadherence and blame poor control due to limitations of our patients.

• It's also important to recognize our role in poor control of diabetes as well.

• Failure of healthcare providers to initiate or intensify therapy can be due to lack of education, training or having programs or clinical practices aimed at achieving therapeutic goals (Gabbay, 2020).

• Therapeutic inertia is common – affecting as many as 50% of patients with type 2 diabetes (McCoy, 2021).
  • Driven by wide range of barriers (Rattelman, 2021).
    • Clinician
    • Patient
    • Health system levels
UKPDS 35: any 1% decrease in HbA1c was associated with risk reduction (p<0.05 for all)

-21%  
-21%  
-37%  
-14%

Any reduction in HbA1c is likely to reduce the risk of complications

American Diabetes Association.

British Medical Journal 2000; 321: 405-412

(Clore, 2019)
When to Screen

• New guidelines include screening adults without diabetes symptoms for both prediabetes and diabetes at the age of 35 (Kenney, 2022).
• Any individual who is overweight or obese (BMI ≥25 kg/m\(^2\) or ≥23 kg/m\(^2\) in Asian American individuals) who have one or more of the following risk factors:
  • 1st degree relative with diabetes
  • High risk race/ethnicity
  • History of CVD
  • HTN (≥130/80 mmHg or on therapy for hypertension)
  • HDL cholesterol level <35 mg/dL (0.90 mmol/L) and/or a triglyceride level >250 mg/dL (2.82 mmol/L)
  • Individuals with polycystic ovary syndrome
  • Physical inactivity
  • Other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans)
• Individuals with HIV
• People with prediabetes should be tested yearly
• People diagnosed with gestational diabetes should have lifelong testing every 3 years
• If results are normal, testing should be repeated at minimum of 3-year intervals with consideration to the patients’ risk factors and exam findings
REDUCTION IN DIABETES COMPLICATIONS

LIFESTYLE MODIFICATION AND DIABETES EDUCATION

Glycemic Management
Blood Pressure Management
Lipid Management
Agents with Cardiovascular and Kidney Benefit*

Foundations of Diabetes Therapy

- Healthy Diet and Exercise
- Metformin is usually still the initial therapy for patients with type 2 diabetes.
  - Recommended dose is 1000 mg twice daily if tolerated
  - Titrate slowly over 1-2 weeks in 500 mg increments
  - Extended-release formulation is highly recommended
  - Medication must be renally dosed and should not be used if GFR less than 30 cc/min (Clore, 2019)
- New guidelines are now recommending an individualized approach at the time of diagnosis.
- From the Chief Science and Medical Officer of American Diabetes Association – Robert A. Gabbay, MD, PhD:
  - “We know now that many of these medications that lower cardiovascular [heart] and renal [kidney] disease can be quite effective, often literally life-saving,” said Gabbay. “Metformin is still a good drug, but it should not be a deterrent to work quickly and start medications we know will be effective” (Kenney, 2022).
Use of glucose-lowering medications in the management of type 2 diabetes. ACEi, ACE inhibitor; ACR, albumin-to-creatinine ratio; CVOT, cardiovascular outcomes trial; DPP-4i, dipeptidyl peptidase 4 inhibitor; GLP-1 RA, glucagon-like peptide 1 receptor agonist; HHF, hospitalization for heart failure; SGLT2i, sodium-glucose cotransporter 2 inhibitor; T2D, type 2 diabetes. Adapted from Davies MJ, Aroda VR, Collins BS, et al. Diabetes Care 2022;45:2753–2786.

Figure Legend:
Figure Legend:

• Eli Lilly announced on March 1, 2023 that it plans on reducing cost of insulin by 70%
• Automatic cap on out-of-pocket costs of $35 or less for those with private insurance and use of participating pharmacies
• People who don't have insurance can continue to go to InsulinAffordability.com and immediately download the Lilly Insulin Value Program savings card to receive Lilly insulins for $35 per month.

(Christensen, 2023)
Steps Towards Insulin Cost Reductions

• Cutting the list price of its non-branded insulin, Insulin Lispro Injection 100 units/mL, to $25 a vial. Effective May 1, 2023, it will be the lowest list-priced mealtime insulin available, and less than the price of a Humalog® vial in 1999.

• Cutting the list price of Humalog® (insulin lispro injection) 100 units/mL, Lilly's most commonly prescribed insulin, and Humulin® (insulin human) injection 100 units/mL by 70%, effective in Q4 2023.

• Launching Rezvoglar™ (insulin glargine-aglr) injection, a basal insulin that is biosimilar to, and interchangeable with, Lantus® (insulin glargine) injection, for $92 per five pack of KwikPens®, a 78% discount to Lantus, effective April 1, 2023.

(Lilly, 2023)
Standards of Care in Diabetes—2023
# Profiles of AntiHyperglycemic Medications

<table>
<thead>
<tr>
<th></th>
<th>MET</th>
<th>GLP1-RA</th>
<th>SGLT2i</th>
<th>DPP4i</th>
<th>AGI</th>
<th>TZD (moderate dose)</th>
<th>SU</th>
<th>GLN</th>
<th>COLSVL</th>
<th>BCR-QR</th>
<th>INSULIN</th>
<th>PRAML</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYPO</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Moderate/Severe</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Moderate to Severe</td>
<td>Neutral</td>
</tr>
<tr>
<td>WEIGHT</td>
<td>Slight Loss</td>
<td>Loss</td>
<td>Loss</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Gain</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Gain</td>
<td>Loss</td>
</tr>
<tr>
<td>RENAL / GU</td>
<td>Contra-indicated if eGFR &lt;30 mL/min/1.73 m²</td>
<td>Exenatide Not Indicated CrCl &gt;30</td>
<td>Not Indicated for eGFR &lt;45 mL/min/1.73 m²</td>
<td>Dose Adjustment Necessary (Except Linagliptin)</td>
<td>Effective in Reducing Albuminuria</td>
<td>Neutral</td>
<td>Neutral</td>
<td>More Hypo Risk</td>
<td>Neutral</td>
<td>Neutral</td>
<td>More Hypo Risk</td>
<td>Neutral</td>
</tr>
<tr>
<td>GI Sx</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
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<td>Neutral</td>
<td>Neutral</td>
<td>Moderate</td>
</tr>
<tr>
<td>CHF</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Prevent HF Hospitalization Manage HFREF</td>
<td>See #4</td>
<td>Neutral</td>
<td>Moderate</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>CHF Risk</td>
<td>Neutral</td>
</tr>
<tr>
<td>CARDIAC</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Prevent HF Hospitalization Manage HFREF</td>
<td>See #4</td>
<td>Neutral</td>
<td>Moderate</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>CHF Risk</td>
<td>Neutral</td>
</tr>
<tr>
<td>ASCVD</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Prevent HF Hospitalization Manage HFREF</td>
<td>See #4</td>
<td>Neutral</td>
<td>Moderate</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>CHF Risk</td>
<td>Neutral</td>
</tr>
<tr>
<td>BONE</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Moderate Fracture Risk</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
<tr>
<td>KETOACIDOSIS</td>
<td>Neutral</td>
<td>Neutral</td>
<td>DKA Can Occur in Various Stress Settings</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
</tbody>
</table>

### Adverse Events and Usage Guidelines
1. Canagliflozin indicated for eGFR ≥30 mL/min/1.73 m² in patients with CKD 3a albuminuria.
2. Dapagliflozin—potential primary prevention of HF hospitalization & demonstrated efficacy in HFREF.
3. Empagliflozin—FDA approved to reduce CV mortality. Canagliflozin—FDA approved to reduce MACE events.
4. Possible increased hospitalizations for heart failure with alogliptin and saxagliptin.

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Weight Loss
Learning Objectives for Obesity Medicine

- Review data supporting more intense behavioral interventions for weight loss
- Discuss available weight loss medications that are FDA approved
Clinical Trials

PROPEL (Promoting Successful Weight Loss in Primary Care in Louisiana)

• 18 primary care clinics from 5 health systems in Louisiana that served a large percentage of low-income and underserved patient

REPOWER (Rural Engagement in Primary Care for Optimizing Weight Reduction)

• 36 primary care practices from the Midwestern US that predominantly or solely served rural patients

(Katzmarzyk et al., 2021)
PROPEL – In Clinic/Phone

• Received weekly counseling sessions (16 in-person and 6 telephone) in the first 6 months followed by monthly sessions (alternating in person visits and telephone calls) for the remaining 18 months.
• Mostly individual sessions but also could be done in small groups (2-3 patients)
  • In person individual sessions were 30 minutes
  • In person group sessions were 1 hour
  • Phone sessions were 15 – 20 minutes
• All sessions were done by study-employed health coaches embedded in primary care clinics
• Received counseling on how to set goals and develop individual action plans for diet and exercise with goal to achieve 10% weight loss in 6 months
• Primary care physicians had access to an online obesity science education program that provided education on obesity management, management of co-existing conditions such as Type 2 diabetes and hypertension, minimizing bias and stigma related to obesity, and principles of health literacy

PROPEL – Usual Care

• Routine care with primary care team – training included a presentation and brochure on obesity management guidelines and CMS reimbursement.
• Received 6 newsletters covering topics related to sitting and health, goal setting, staying safe in the heat, memory health, self-care, sleepy hygiene and smoking cessation

(Katzmarzyk et al., 2021)
REPOWER-clinic-individual

• 15-minute face-to-face individual counseling visits from practice-employed clinicians that occurred weekly for 1 month, every other week for months 2 to 6, and monthly thereafter.
• Each practice selected 1 to 2 counselors, most commonly were clinic-employed nurses
• The counselors participated in a single, 3-hour training session focused on dietary and physical activity recommendations, behavioral strategies, and motivational interviewing.

REPOWER-clinic-group

• Led by practice-employed clinicians
• Visits were 60 minutes and occurred weekly for the first 3 months and every other week for months 4-6 and monthly thereafter.
• First 14 sessions were face to face. Afterwards – practices had the option to switch to group telephone conference calls
  • All but one practice opted to continue face to face visits.
• Each clinic selected between 1 and 3 counselors (predominantly nurses) to deliver intervention.

(Katzmarzyk et al., 2021)
• Received same group-based intervention as REPOWER clinic-group but sessions were delivered via telephone conference calls by centralized study staff

• Staff employed by research team with graduate degrees in relevant fields (ex: psychology, nutrition, exercise science).

(Katzmarzyk et al., 2021)
Weight loss in primary care: A pooled analysis of two pragmatic cluster-randomized trials

PROPEL: 18 clinics randomized
- 9 clinics allocated to UC
- 888 patients screened for eligibility
- 351 patients enrolled
- 340 patients had weight measured at 6 months
- 326 patients had weight measured at 18 months
- 316 patients had weight measured at 24 months
- 9 clinics & 351 patients included in analysis

REPOWER: 36 clinics randomized
- 9 clinics allocated to clinic/phone
- 1070 patients screened for eligibility
- 452 patients enrolled
- 386 patients had weight measured at 6 months
- 365 patients had weight measured at 18 months
- 357 patients had weight measured at 24 months
- 9 clinics & 452 patients included in analysis

- 12 clinics allocated to clinic-individual
- 615 patients screened for eligibility
- 478 patients enrolled
- 436 patients had weight measured at 6 months
- 396 patients had weight measured at 18 months
- 410 patients had weight measured at 24 months
- 12 clinics & 473 patients included in analysis

- 12 clinics allocated to clinic-group
- 650 patients screened for eligibility
- 479 patients enrolled
- 429 patients had weight measured at 6 months
- 406 patients had weight measured at 18 months
- 410 patients had weight measured at 24 months
- 12 clinics & 468 patients included in analysis

- 12 clinics allocated to phone-group
- 666 patients screened for eligibility
- 475 patients enrolled
- 425 patients had weight measured at 6 months
- 388 patients had weight measured at 18 months
- 400 patients had weight measured at 24 months
- 12 clinics & 466 patients included in analysis

8 patients removed a priori; 473 patients remained eligible
11 patients removed a priori; 468 patients remained eligible
9 patients removed a priori; 466 patients remained eligible

Obesity, Volume: 29, Issue: 12, Pages: 2044-2054, First published: 29 October 2021, DOI: (10.1002/oby.23292)

(Katzmarzyk et al., 2021)
Conclusion

High-Intensity behavioral counseling in primary care settings when delivered in person, by phone or electronically produce clinical significant weight loss (4-7 kg) compared to low and moderate intensity counseling which only produces modest weight loss (1-2 kg)  

(Katzmarzyk et al., 2021)
Ozempic Shortage


https://www.tiktok.com/
Weight Loss – FDA approved

GLP-1s

- Semaglutide (Wegovy) and Liraglutide (Saxenda)

Other weight loss medications for long term use:

- Bupropion-naltrexone (Contrave)
- Orlistat (Xenical, Alli)
- Phentermine-topiramate (Qsymia)
- Setmelanotide (Imcivree)

Tirzepatide (Mounjaro)

- Glucose dependent insulinotropic polypeptide and glucagon like peptide-1 receptor agonist
- Only approved for adults with type 2 diabetes
- First and only FDA approved GIP and GLP-1 receptor agonist

(Mayo Clinic Staff, 2022)
Tirzepatide Once Weekly for the Treatment of Obesity

Jastreboff AM et al. DOI: 10.1056/NEJMc2206038

CLINICAL PROBLEM
Several clinical guidelines recommend pharmacotherapy for obesity. Tirzepatide — a dual glucose-dependent insulinotropic polypeptide and glucagon-like peptide-1 receptor agonist recently approved in the United States to treat type 2 diabetes — induces clinically relevant weight reduction in phase 2 studies of people with diabetes. However, its efficacy for weight reduction in these without diabetes is unknown.

CLINICAL TRIAL
Design: An international, phase 3, double-blinded, randomized, placebo-controlled trial examined the efficacy and safety of tirzepatide in adults with obesity or overweight who did not have diabetes.

Intervention: 2599 adults with a body-mass index of 30 or higher, or 27 or higher with at least one weight-related complication, were assigned to once-weekly subcutaneous tirzepatide at one of three doses (5 mg, 10 mg, or 15 mg) or placebo. In addition to lifestyle interventions, Treatment included a calorie-restriction phase and lasted for 72 weeks.

RESULTS
Efficacy: Both the percentage change in weight and the percentage of participants with at least 5% weight reduction were significantly greater with all three doses of tirzepatide than with placebo.

Safety: Gastrointestinal events, including nausea, diarrhea, and constipation, were the most common adverse events seen with tirzepatide; the majority of events were transient and mild to moderate in severity.

LIMITATIONS AND REMAINING QUESTIONS
- Enrolled participants may have been more committed to weight management than many people with obesity.
- Cardiovascular variables (e.g., blood pressure and lipid levels) were relatively normal at baseline, so the ability to show a potential improvement within the time frame of this study was limited.
- The number of participants with overweight plus at least one weight-related complication was small (840 of the 2599 participants: 5.9%) which prevented definitive conclusions in this subgroup.

CONCLUSIONS
All three doses of once-weekly subcutaneous tirzepatide led to clinically meaningful and sustained weight reduction in obese adults who did not have diabetes.
Buprenorphine
Subscribing Update
Drug overdose deaths have risen fivefold over the past 2 decades
According to the CDC - more than 107,000 Americans died from drug overdoses in 2021, an increase of more than 15 percent from 2020

(SAMHSA, 2022)
DEA Update

• DATA-Waiver for Buprenorphine Eliminated when the Consolidated Appropriations Act (the Act) of 2023 was signed on December 29, 2022
• All prescriptions for buprenorphine only require a standard DEA registration number
• There are no longer any limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine
• The Act doesn’t impact existing state laws or regulations that may be applicable

(Milgram, 2023)
Reference List


Reference List


Questions?

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