“A Breath of Fresh Air”
An Update on COPD Classification and Management

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University of Maryland Eastern Shore/Apple Discount Drugs
Objectives

- Review the foundational concepts of chronic-obstructive pulmonary disease (COPD).
- Discuss key updates in the assessment and management of COPD.
- Recommend appropriate evidence-based treatment options for patients with COPD.
- Identify key technique and counseling points for specific inhalers.
- Determine individual factors to optimize outcomes for patients with COPD.
Disclosure

• The presenter has nothing to disclose.
Chronic Obstructive Pulmonary Disease (COPD) is:

• A common, preventable and treatable disease

• Characterized by persistent respiratory symptom and airflow limitation due to airway and/or alveolar abnormalities

• Usually caused by significant exposure to noxious particles or gases

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Epidemiology

• 4th leading cause of death in the world

• 3 million people died from COPD in 2010
  – Estimated 4.5 million deaths annually by 2030

• < 6% of the adult population have been told that they have COPD

• Increased prevalence of smoking in developing countries and in the aging populations in high-income countries

• COPD exacerbations count for the greatest portion of total healthcare costs
  – Direct cost of $32 billion and $20.4 billion in indirect cost

• 2nd leading cause of disability adjusted life years in the United States

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
State of Maryland

- 11,189 Eligible COPD Discharges
- 2,081 Readmissions
Etiology

Smoking

• Prevalence of COPD directly related to prevalence of tobacco smoking
• Responsible for 85-90% of cases

Environmental Factors

• Organic and inorganic dusts
• Chemical agents
• Air pollution
Host Factors

• Genetics
  – Deficiency of alpha-1 antitrypsin (AATD)
• Airway hyper-responsiveness
• Impaired lung growth
• Gender
• Age
Presentation

• Dyspnea
  – Progressive, persistent, worsens with exercise

• Chronic cough
  – Recurrent wheezing and possible productive cough

• Sputum production

*Significant airflow limitation may present WITHOUT chronic dyspnea and/or cough and sputum production*
Progression of COPD

- Chronic respiratory symptoms may precede the development of airflow limitation and may be associated with the development of acute respiratory events.

- Respiratory symptoms are seen in patients with normal spirometry.

- Smokers may not have airway limitation but show structural evidence of lung disease:
  - Varying presence of emphysema, airway wall thickening and gas trapping.

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
COPD

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
2017 Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines
Key Updates

• Role of FEV$_1$ on breathlessness, exercise limitation and health status impairment
  – Airflow limitation correlates less well with functional limitations and quality of life than patient reported symptoms and history of exacerbations

• Updates in the ABCD assessment tool to consider symptoms along with exacerbation frequency and severity

• Re-emphasize the importance of inhaler technique

• Individualized treatment through interprofessional integrated care

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Limitations of Spirometry

- FEV₁ lacks sufficient precision as a predictor for exacerbation or mortality in patients with COPD

- Weak correlation between FEV₁, symptoms and impairment of health status

- Lack of data indicating that screening spirometry is effective in direct decisions or in approving COPD outcomes in patients who are identified before the development of significant symptoms

- Cannot be used alone to determine therapeutic options

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
The Role of Spirometry

• Spirometry is still **required** for diagnosis
  – Post-bronchodilator FEV₁/FVC < 0.70 confirms consistent airflow limitation
  – Lacks specificity and should not be used as the only diagnostic test

• Prognosis—assessment of severity of airflow obstruction

• Follow-up assessment

• Therapeutic decisions
  – Discrepancy between spirometry and level of symptoms
  – Alternative diagnosis when symptoms are disproportionate to degree of airflow obstruction
  – Non-pharmacological such as interventional procedures (lung transplant, lung volume reduction, or bullèctomy)

• Identifier of rapid decline

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
ABCD groups will be derived exclusively from patient symptoms and history of exacerbations

ASSESSMENT OF COPD
Modified British Medical Research Council (mMRC) Questionnaire

• Measures breathlessness

• Good indicator of symptoms, health status, and predicts mortality risk

Grade 0
• I only get breathless with strenuous exercise

Grade 1
• I get short of breath when hurrying on the level or walking up a slight hill

Grade 2
• I walk slower than people of the same age on the level because of breathlessness, or have to stop for breath when walking on my own pace on the level

Grade 3
• I stop for breath after walking about 100 meters or after a few minutes on the level

Grade 4
• I am too breathless to leave the house or I am breathless when dressing or undressing

COPD Assessment Test (CAT)

Score ranges from 0-40

http://www.catestonline.org/english/indexEN.htm
St. George's Respiratory Questionnaire (SGRQ)

• 50 item questionnaire
• Scored based on:
  – Symptoms, activity, and impact
• Scores ≥ 25 common in COPD patients
• Changes in score by 4 units is clinically relevant
• Not used often due to complexity

New Assessment Tool

1. Confirmed diagnosis by spirometry
2. Assess Airflow Limitation
3. Assess symptoms & risk of exacerbations

Post-bronchodiolarator

FEV1/FVC < 0.7

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From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Treatment Goals

Reduce Symptoms
• Relieve symptoms (SOB, sputum)
• Improve exercise tolerance
• Improve health status

Reduce Risk
• Prevent disease progression
• Prevent and treat exacerbations
• Reduce mortality

The main treatment goals are reduction of symptoms and future risk of exacerbations.

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Mr. McHenry

40 y.o. WM diagnosed with COPD.
  – FEV$_1$ = 45%
  – 1 exacerbation without hospitalization
  – CAT score = 6

How would you assess Mr. McHenry’s COPD?
New Assessment Tool

1. Confirmed diagnosis by spirometry

2. Assess Airflow Limitation

3. Assess symptoms & risk of exacerbations

Post-bronchodilator FEV$_1$/FVC < 0.7

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>2 or >1 leading to admission

C

0 or 1 (not leading to admission)

A

Exacerbation History

mMRC 0-1 CAT <10

mMRC >2 CAT ≥10

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
## OLD GUIDELINES

<table>
<thead>
<tr>
<th>Patient</th>
<th>Characteristic</th>
<th>Spirometric Classification</th>
<th>Exacerbations Per Year</th>
<th>CAT</th>
<th>mMRC</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Low Risk Low Symptoms</td>
<td>GOLD 1-2</td>
<td>≤ 1</td>
<td>&lt;10</td>
<td>0-1</td>
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<tr>
<td>B</td>
<td>Low Risk More Symptoms</td>
<td>GOLD 1-2</td>
<td>≤ 1</td>
<td>&gt;10</td>
<td>&gt;2</td>
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<tr>
<td>C</td>
<td>High Risk Less Symptoms</td>
<td>GOLD 3-4</td>
<td>≥ 2</td>
<td>&lt;10</td>
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<tr>
<td>D</td>
<td>High Risk Mores Symptoms</td>
<td>GOLD 3-4</td>
<td>≥ 2</td>
<td>≥10</td>
<td>&gt;2</td>
</tr>
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</table>
2017 TREATMENT ALGORITHM
Non-Pharmacological treatment

• Smoking Cessation
  – Counseling
  – Nicotine replacement therapy

• Preventive Care
  – Minimize second hand smoke and occupational fumes
  – Monitor pollution index and stay indoors when pollution is high

• Vaccinations
  – Influenza
  – Pneumococcal

• Supportive Care
  – Regular physical activity
  – Oxygen
  – Education and self-management
  – Pulmonary rehabilitation

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Pharmacological Treatments

Bronchodilators
- Short-acting beta agonists (SABA)
- Long-acting beta agonists (LABA)
- Short-acting antimuscarinic (SAMA)
- Long-acting antimuscarinic (LAMA)
- Methylxanthines

Anti-Inflammatory Therapy
- Inhaled Corticosteroids (ICS)
- Oral glucocorticoids
- Phosphodiesterase-4 inhibitors
- Antibiotics
- Mucolytics

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Bronchodilators

LABAs
Target B2 receptors, throughout the lungs and distal airways

LAMAs
Target M3 receptors, more concentrated in proximal airways

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Group A

- mMRC 0-1 or CAT <10 with 0-1 exacerbations not leading to hospital admission

- LABAs and LAMAs are preferred over short acting agents (Evidence A)

A bronchodilator
(Short or Long Acting)

Evaluate Efficacy

Continue, stop, or try alternate class of bronchodilator

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Group B

- mMRC >2 or CAT score >10 with 0-1 exacerbations that do not lead to hospital admission
- Monitor development of comorbidities

A long acting beta agonist (LABA) or long acting anti-muscarinic (LAMA)

Persistent symptoms

LAMA + LABA

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
• mMRC 0-1 or CAT <10 with ≥2 or >1 exacerbation leading to admission

• LAMAs have a greater effect on exacerbation reduction compared to LABAs (Evidence A) and decrease hospitalizations (Evidence B)

• Progression to a combination with a LABA is preferred due to the increased risk of pneumonia

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
LAMA vs. LABA

- Vogelmeier et al. showed that long acting muscarinic antagonist (tiotropium) was more effective in preventing exacerbations compared to long acting beta agonist (salmeterol)

- A Study in 2013 showed similar results in a once daily beta agonist (indacaterol) compared to (tiotropium)
Corticosteroids

• Monotherapy
  – ICS alone do not modify the long-term decline of FEV$_1$ nor mortality in COPD patients

• ICS with long acting bronchodilator
  – In patients with moderate to severe COPD and exacerbations ICS and LABA are more effective than alone

• Long term monotherapy of inhaled or systemic corticosteroids is NOT recommended (Evidence A)

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Blood Eosinophil Count

• Biomarker of exacerbation risk in patients with a history of exacerbations
  – Higher levels are associated with increased exacerbation frequency
  – ICS may be beneficial in preventing exacerbations

• Post-hoc analysis of the FORWARD trial showed a greater reduction in exacerbation risk in patients with high eosinophil counts treated with an ICS

• Therefore, patients with high eosinophil counts >2%, a combination of ICS+ LABA may be beneficial in preventing exacerbations

mMRC >2 or CAT > 10 with >2 or >1 exacerbation leading to admission

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Triple Therapy

• Triple therapy of ICS/LABA/LAMA improves lung function, symptoms and health status *(Evidence A)* and reduces exacerbations *(Evidence B)* compared to ICS/LABA or LAMA monotherapy
  – Highly effective therapy to control symptoms and exacerbations

• Mostly seen by adding a LAMA to a LABA + ICS inhaler

• Area for increase research and potential combined inhaler devices

Frith PA, et al. Thorax 2015;0:1–9
From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Roflumilast (Daliresp®)

Phosphodiesterase-4 Inhibitor

- Recommended for add-on therapy in patients with a history of exacerbations despite LABA/ICS or LABA/LAMA/ICS with FEV$_1$<50% predicted and persistent chronic bronchitis (Evidence B)

- MOA
  - Reduces pulmonary inflammation through decreasing prolyl endopeptidase activity

- Dose: 500 mcg by mouth daily

- Adverse Events
  - Weight loss
  - Sleep disturbances
  - Monitor in patients with depression

Am J Respir Crit Care Med. 2015;192(8):934-42.
Antibiotics

• Clinical controversies over the effectiveness of chronic antibiotics use in severe COPD patients

• Can be considered in former smokers with exacerbations despite appropriate therapy (Evidence B)

• Macrolides are often used for up to a year to reduce exacerbations
  – Azithromycin is the most commonly used agent
    • Concern with bacterial resistance and impaired hearing

Additional Therapies

• Alpha-1 antitrypsin augmentation therapy (Evidence B)
  – IV augmentation used to slow the progression of emphysema
  – Indicated for patients with AATD and FEV$_1$<65% predicted
    • Most effective in patients FEV1 35-49% predicted value
    • Utilized in patients with continued progression followed by smoking cessation

• Antitussives (Evidence C)
  – Lack of evidence

• Vasodilators (Evidence B)
  – Avoid as they can worsen oxygenation and do not improve outcomes
  – Inhaled nitric oxide can worsen gas exchange

• Pharmacotherapy indicated for primary pulmonary hypertension are NOT recommended for patients with pulmonary hypertension secondary to COPD (Evidence B)

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Additional Treatment Options

• Statins
  – Not recommended for prevention of exacerbations (Evidence A)

• Antioxidant agents
  – Mucolytics
    • Carbocysteine and N-acetylcysteine
    • Recommended in specific patients (Evidence A)

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Inhalers

LABA
• Salmeterol (Serevent Diskus®)
• Formoterol (Foradil Aerolizer®)
• Arformoterol (Brovana®)
• Indacaterol (Arcapta Neohaler®)
• Olodaterol (Striverdi Respimat®)

LABA/ LAMA
• Vilanterol/Umeclidinium (Anoro Ellipta®)
• Indacaterol/Glycopyrrolate (Utibron Neohaler®)
• Olodaterol/Tiotropium (Stioltto Respimat®)
• Formoterol/Glycopyrrolate (Bevespi Aerosphere®)

LAMA
• Tiotropium (Spiriva Handihaler® & Respimat®)
• Aclidinium (Tudorza Pressair®)
• Umeclidinium (Incruse Ellipta®)
• Glycopyrrolate (Seebri Neohaler®)

ICS/ LABA
• Fluticasone/salmeterol (Advair Diskus®)
• Budesonide/formoterol (Symbicort®)
• Mometasone/formoterol (Dulera®)
• Fluticasone/vilanterol (Breo Ellipta®)
Long Acting Muscarinic Antagonist

- aclidinium (Tudorza Pressair®)
- tiotropium (Spiriva Handihaler® & Respimat®)
- umeclidinium (Incruse Ellipta®)
- glycopyrrolate (Seebr Neohaler®)

https://www.tudorza.com/copd-treatment.html
https://www.spiriva.com/copd
http://www.incruse.com/
https://www.pharma.us.novartis.com/seebr-neohaler
Long Acting Beta Agonist + Inhaled Corticosteroid

- fluticasone/vilanterol (Breo Ellipta®)
- Mometasone/formoterol (Dulera®)
- Budesonide/formoterol (Symbicort®)
- Fluticasone/salmeterol (Advair Diskus®)

https://www.advair.com/
https://www.merckconnect.com/dulera/molecule.html
Long Acting Beta Agonist + Long Acting Muscarinic Antagonist

Olodaterol/Tiotropium (Stiolto Respimat®)

Formoterol/Glycopyrrolate (Bevespi Aerosphere®)

Vilanterol/Umeclidinium (Anoro Ellipta®)

Indacaterol/Glycopyrrolate (Utibron Neohaler®)

https://www.stiolto.com/what-is-stiolto-respimat
https://www.bevespi.com/
https://www.pharma.us.novartis.com/utibron-neohaler
Respimat Inhalers

• Dispenses medication as a fine mist
  – 75% of particles are absorbed

• Allows for inhalation at a normal breath speed

• Hard coordination and lacks ease of use

https://hcp.stiolto.com/respimat-inhaler
Bevespi Aerosphere®

- Pressurized metered dose inhaler (pMDI)

- Co-Suspension™ has phospholipids which dissolve in the airway releasing drug crystals
  - Prevents interaction of drug crystals

- Use similar to MDI, which requires hand to breath coordination

- Does not require a spacer
Ellipta Inhalers

• Daily single one step dosing

• Does not require hand to breath coordination

• Opening and closing cover will result in lost dose
  – Counter counts down by 1 each time cover is opened

NeoHaler

- Multistep process which requires dexterity
- Breath-actuated device
- Do NOT swallow capsules
LABA + LAMA Combination Therapies

- Improved adherence
- Lower ADRs
- Improved symptoms and decreased risk of exacerbations
- Decrease cost and complexity

<table>
<thead>
<tr>
<th>Device/Delivery</th>
<th>Stiolto Respimat</th>
<th>Bevespi Aerosphere</th>
<th>Anoro Ellipta</th>
<th>Utibron Neohaler</th>
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<tr>
<td>Improved drug delivery with Respimat</td>
<td>Improved drug delivery</td>
<td>Ease of use with Ellipta device</td>
<td>Complex delivery</td>
<td></td>
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<table>
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<tr>
<th>Dosing</th>
<th>2 inhalations once daily</th>
<th>2 inhalations Twice daily</th>
<th>1 inhalation once daily</th>
<th>1 inhalation Twice daily</th>
</tr>
</thead>
</table>
Case 2

• DT is a 45 year old man with COPD who smokes a pack per day since he was 20 years old. Despite several attempts of smoking cessation, he continues to smoke a pack per day.
  – FEV1/FVC < 0.60
  – FEV1: 46%
  – mMRC score: 3
  – No history of exacerbations
  – Private insurance

• Based on the provided information, which is the best initial treatment option for DT based upon the new 2017 GOLD guidelines?
What is DT’s Gold Grade and Group?

1. Confirmed diagnosis by spirometry

2. Assess Airflow Limitation

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3. Assess symptoms & risk of exacerbations

Exacerbation History

- ≥2 or >1 leading to admission: C
- 0 or 1 (not leading to admission): A

CAT
- mMRC 0-1: mMRC <10
- mMRC ≥2: mMRC ≥10

mMRC: Modified Medical Research Council
Which is the best initial treatment option for DT?

A. Spiriva®
B. ProAir®
C. Azithromycin
D. Advair®
Case 2 Continued

- Despite proper inhaler technique and medication adherence; DT continues to smoke and was admitted to the hospital for a COPD exacerbation.
  - FEV1/FVC <0.56
  - FEV1: 33%
  - mMRC score: 3
  - Private insurance
What is DT’s Gold Grade and Group?

1. Confirmed diagnosis by spirometry

2. Assess Airflow Limitation

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3. Assess symptoms & risk of exacerbations

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<th>0 or 1 (not leading to admission)</th>
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</tr>
<tr>
<td>mMRC ≥2 CAT ≥10</td>
<td>D</td>
<td>B</td>
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Which is the best initial treatment option for DT?

A. Spiriva®
B. Roflumilast®
C. Anoro Elipta®
D. Advair®
Inhaler Technique – A True Barrier in Optimizing Health Outcomes

• Retrospective systematic review of over 40 years reported direct observation inhaler technique to determine barriers and common improper inhaler technique

  – MDI: Coordination, and depth of inspiration, and lack of post-inhalation breath hold

  – DPI: incorrect preparation, lack of full expiration before inhalation, and no post-inhalation breath hold

• An average of 31% of participants had poor inhaler technique,

Inhaler Use

• Risk of Improper use
  – Older Age
  – Multiple Devices
  – Lack Of Education

• Implementing the “teach-back” approach

• Have placebo inhalers on hand to teach and assess proper technique

• At discharge and at the pharmacy assess patient adherence and technique
<table>
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<td><strong>Metered Dose Inhaler (MDI)</strong></td>
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<tr>
<td>• Breath/actuation coordination</td>
</tr>
<tr>
<td>• Force of breath and inhalation time</td>
</tr>
<tr>
<td>• Small dose counter</td>
</tr>
<tr>
<td><strong>Dry Powder Inhaler (DPI)</strong></td>
</tr>
<tr>
<td>• Breath force to aerosolize powder</td>
</tr>
<tr>
<td>• Require a minimum peak inspiratory flow</td>
</tr>
<tr>
<td>• Some devices require opening a blister pack to prepare dose</td>
</tr>
<tr>
<td><strong>Soft Mist Inhaler (SMI)</strong></td>
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<tr>
<td>• Breath force to aerosolize powder</td>
</tr>
<tr>
<td>• Inhalation time</td>
</tr>
<tr>
<td>• Loading cartridge into device</td>
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</table>
Identify Barriers to Therapy

• Monitor adherence
  – Delay or gaps in re-fill history

• Monitor therapy
  – Only fills prescriptions for albuterol and prednisone

• Monitor partial fills

• Poly-pharmacy
  – Frequently asking for transfers

• Requesting generics
Economic Burden

Problem
- Cost is the #1 factor for non-adherence
- Lack of generic options
- High tier medications

Solutions
- Pharmaceutical Assistance Programs
- Samples from Providers
- Medicare Part D Plans
  - State and federal subsidies for low-income patients
- Medicaid
  - Complete prior authorization and consider formulary changes
Hospital Discharge Recommendations

- Evaluate ability to cope in his/her usual environment
- Review understanding of treatment regimen
- Reassessment of inhaler technique
- Re-assess need for long-term oxygen
- Document the capacity to do physical activity and activities of daily living
- Document symptoms: CAT or mMRC
- Determine status of comorbidities

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017.
Summary

• Push for bronchodilators and combination inhaler therapy to alleviate symptoms and reduce the risk of exacerbations

• FEV$_1$ no longer used to assess ABCD categories but continues to play a vital role in COPD diagnosis

• Re-inforce proper inhaler technique through an interprofessional approach
Individualized Care

- Cost
- Prescriber
- Patient Preference
- Patient Ability