Emerging Challenges in Primary Care: 2017

The Evolving Landscape of COPD: Strategies to Optimize Care and Improve Outcomes
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Disclosures

- **Fernando Martinez, MD, MS** serves on the steering committee for Afferent, AstraZeneca, Bayer, Boehringer-Ingelheim, Gilead, GSK, and Veracytes. Dr. Martinez also serves on the advisory board for Adept, AZ, BI, ProTerrix Bio, Concert, Genentech, GSK, Novartis, Patara, Pearl, and Theravance. Dr. Martinez has done CME Presentations and served as a speaker for AZ, BI, Columbia University, GSK, Integritas, Methodist Hospital, Mitler, NYU, NACE, Peer View, Potomac, Prime, and the Puerto Rican Respiratory Society. Additionally, Dr. Martinez has served on the DSMB for Chiesi, UpToDate, WebMD, Biogen, and GSK.

- **Franck Rahaghi, MD, MHS, FCCP** serves as a consultant/speaker for Shire, CSL Behring, and Grifols.

- **Sandra G. Adams, MD, MS** serves as an investigator/grants/research and Continuing Education for the National Institute of Health, Veterans Affairs, University of Texas System (Patient Safety Education Grant), Chest Foundation (GSK Distinguished Scholar Award), AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals, Inc, Daiichi Sankyo, GlaxoSmithKline, Novartis Pharmaceuticals, Sunovion Pharmaceuticals, Inc. Dr. Adams serves as a President for WipeDiseases Foundation.

- **Diego J. Maselli, MD FCCP** serves on the advisory board for Sanofi, and GSK.

- **Arunabh Talwar, MD, FCCP** serves as a consultant for Boehringer Ingleheim.
Learning Objectives

- Describe strategies of care in COPD to improve diagnosis and ongoing symptom assessment
- Tailor COPD pharmacotherapy according to current guidelines while incorporating unique patient needs and characteristics
- Discuss the appropriate use of inhaled therapies for COPD, including the importance of proper inhaler technique
- Collaborate with members of interprofessional health care team for effective chronic disease management
PRE-TEST QUESTIONS
Pre-test ARS Question 1

How confident are you in your ability to select appropriate inhaled therapies for patients with COPD, based on disease severity and patient characteristics?

1. Not at all confident
2. Slightly confident
3. Moderately confident
4. Pretty much confident
5. Very confident
Pre-test ARS Question 2

How often do you perform spirometry as part of your evaluation for a patient with chronic cough and progressive dyspnea?

1. Never
2. Rarely
3. Sometimes
4. Frequently
5. Always
Chronic Obstructive Pulmonary Disease (COPD) is a common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases.

Exacerbations and comorbidities contribute to the overall severity in individual patients.
Risk factors for COPD

Smoking accounts for 80% of all COPD diagnosis

Other etiologies:
- Second hand smoke
- Environmental Exposures
  - Cooking or heating with wood, peat, dung
- Occupational Exposures
- Undertreated asthma
- Genetics
COPD SYMPTOMS

- **Chronic cough**
  - usually the first symptom that occurs in COPD
  - initially intermittent

- **Chronic expectoration**

- **Dyspnea**
  - Symptom for which patients with COPD seek medical advice.
  - Persistent, daily, progressive over time, exacerbated by exercise and respiratory infections.
Burden of COPD in the US

- Total costs from hospitalization and absenteeism estimated at $36 Billion
- COPD exacerbations account for >70% of total costs
- ≈13 million office visits/year due to exacerbations
- Disproportionately affects individuals of lower socioeconomic status

COPD is Underdiagnosed

- Roughly half of those in the US with COPD are undiagnosed (~15 million Americans)

Barriers to Diagnosis of COPD in Primary Care

**Care Providers**
- Time Limitations
- Failure to probe at-risk patients about symptoms and activity levels and lack of good case-finding methods
- Limited spirometry availability and expertise to interpret

**Patients**
- Under-recognized symptoms leading to delayed presentation
- Poor awareness of COPD
- Lack of knowledge regarding COPD risk factors and appropriate diagnostic testing

COPD Diagnosis Requires Spirometry

SYMPTOMS
- cough
- sputum
- dyspnea

EXPOSURE TO RISK FACTORS
- tobacco (10-20 pack/years)
- occupation
- indoor/outdoor pollution

But…spirometry is underused

- Survey of 29 primary care offices
  - 2/3 of offices owned a spirometer
  - Spirometry performed on 50% of patients with COPD, asthma, or respiratory symptoms

<table>
<thead>
<tr>
<th>Main Reasons Cited for Not Performing Spirometry</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsure of impact on care</td>
<td>41%</td>
</tr>
<tr>
<td>Unfamiliar with test</td>
<td>38%</td>
</tr>
<tr>
<td>Lack of training</td>
<td>34%</td>
</tr>
<tr>
<td>Concern about reimbursement</td>
<td>28%</td>
</tr>
<tr>
<td>Equipment too costly</td>
<td>28%</td>
</tr>
<tr>
<td>Concern about quality control</td>
<td>28%</td>
</tr>
</tbody>
</table>

Spirometry Equipment

- Cost – equipment costs $500-$1,000
  Mouthpiece & nose clip – $0-$1.50 per test

Spirometers: www.nlhep.org
Spirometry Testing

- Maximal, forced exhalation after a maximal inhalation into a spirometer
- Need 2 *reproducible* efforts to assure maximum values are obtained
- Patient may be seated (preferred) or standing, but use the same position on subsequent tests
- Nose clip is preferred

### Spirometry Reimbursement

- Billing codes and reimbursement for spirometry vary by state

<table>
<thead>
<tr>
<th>Procedure</th>
<th>CPT Code</th>
<th>2016 National Medicare Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiratory spirometry only</td>
<td>94010</td>
<td>$36</td>
</tr>
<tr>
<td>Pre- and post-bronchodilator</td>
<td>94060</td>
<td>$62</td>
</tr>
<tr>
<td>Spirometry with flow volume loop</td>
<td>94375</td>
<td>$40</td>
</tr>
<tr>
<td>Vital capacity</td>
<td>94150</td>
<td>$26</td>
</tr>
<tr>
<td>Maximum breathing capacity and maximum voluntary ventilation</td>
<td>94200</td>
<td>$26</td>
</tr>
</tbody>
</table>

Spirometry: Obstructive Disease

- FEV\textsubscript{1} = 1.7L
- FVC = 3.3L
- FEV\textsubscript{1}/FVC = 0.51
Classification of Airflow Limitation Severity Grade in COPD based on Post Bronchodilator FEV₁

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>I: Mild</td>
<td>FEV₁ ≥ 80% predicted</td>
<td>At this stage, the patient may not be aware that their lung function is abnormal.</td>
</tr>
<tr>
<td>II: Moderate</td>
<td>50% ≤ FEV₁ &lt; 80% predicted</td>
<td>Symptoms usually progress at this stage, with shortness of breath typically developing on exertion.</td>
</tr>
<tr>
<td>III: Severe</td>
<td>30% ≤ FEV₁ &lt; 50% predicted</td>
<td>Shortness of breath typically worsens at this stage and often limits patients’ daily activities.</td>
</tr>
<tr>
<td>IV: Very Severe</td>
<td>FEV₁ &lt; 30% predicted <em>or</em> FEV₁ &lt; 50% predicted plus chronic respiratory failure</td>
<td>At this stage, quality of life is very appreciably impaired and exacerbations may be life-threatening.</td>
</tr>
</tbody>
</table>

All Grades Require FEV₁ / FVC < 0.7
Screening for Chronic Obstructive Pulmonary Disease
US Preventive Services Task Force Recommendation Statement

FINDINGS  Similar to 2008, the USPSTF did not find evidence that screening for COPD in asymptomatic persons improves health-related quality of life, morbidity, or mortality. The USPSTF determined that early detection of COPD, before the development of symptoms, does not alter the course of the disease or improve patient outcomes. The USPSTF concludes with moderate certainty that screening for COPD in asymptomatic persons has no net benefit.
Screening vs. Case Finding

- Many individuals at increased risk for COPD self restrict activity to minimize symptoms.

- USPSTF recommendation is based on lack of evidence, not negative evidence.

- GOLD recommends case-finding in symptomatic patients but does not recommend screening in asymptomatic populations.

- Future trials are needed to better assess the effects of screening and treatment of at risk individuals in primary care on long-term health outcomes.

Siu, et al. JAMA 2016;315:1372-7
Case Finding: A New Approach

- Joint partnership between NHLBI and COPD Foundation
- 5 item questionnaire plus Peak Expiratory Flow
- Designed to identify individuals who are symptomatic or have history of exacerbations
- In a case control study, CAPTURE exhibited an sensitivity of 95.7% and an specificity of 67.8% for differentiating cases from no-COPD control subjects.

Martinez FJ et al, AJRCCM 2017; 195: 748-56
Case: June

- June is a 54 year old woman with a past cigarette smoking history. You have confirmed a diagnosis of COPD (FEV₁ 60% predicted)
- She reports breathlessness, with COPD assessment test (CAT) score of 20 and a modified Medical Research Council (mMRC) dyspnea score of 3
- Mild chronic sputum production (clear) daily
- No bronchitis over the past year
- PMH: Hypertension, osteoporosis
- Medications: amlodipine, metoprolol succinate, vitamin D, SABA prn
- PE: BMI 28 kg/m², decreased BS, no wheezing
What is this patient’s GOLD grade?

1. GOLD A
2. GOLD B
3. GOLD C
4. GOLD D
GOLD 2017 Strategy recommends multidimensional assessment of COPD

**First Step:**
- Assess Risk: Ask about Exacerbation
  - Exacerbation ≥2/ One or more Hospitalizations
  - Exacerbation <2

**Second Step:**
- Ask about Symptoms Use Scales
  - mMRC 0-1/CAT <10
    - Less Symptoms
    - C
  - mMRC 2-4/CAT ≥ 10
    - More Symptoms
    - D

## Modified Medical Research Council (mMRC) Dyspnea Scale

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description of Breathlessness</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Not troubled by breathlessness except on strenuous exercise</td>
</tr>
<tr>
<td>1</td>
<td>Shortness of breath when hurrying on level ground or walking up a slight hill</td>
</tr>
<tr>
<td>2</td>
<td>Walks slower than people of the same age on level ground because of breathlessness or has to stop for breath when walking at own pace on level ground</td>
</tr>
<tr>
<td>3</td>
<td>Stops for breath after walking about 100 meters or after a few minutes on level ground</td>
</tr>
<tr>
<td>4</td>
<td>Too breathless to leave the house or breathless when dressing or undressing</td>
</tr>
</tbody>
</table>

**COPD Assessment Test**

<table>
<thead>
<tr>
<th>Question</th>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I never cough</td>
<td>0</td>
<td>I cough all the time</td>
</tr>
<tr>
<td>I have no phlegm in my chest at all</td>
<td>0</td>
<td>My chest is completely full of phlegm</td>
</tr>
<tr>
<td>My chest does not feel tight at all</td>
<td>0</td>
<td>My chest feels very tight</td>
</tr>
<tr>
<td>When I walk up a hill or flight of stairs I am not breathless</td>
<td>0</td>
<td>When I walk up a hill or stairs I am very breathless</td>
</tr>
<tr>
<td>I am not limited doing any activities at home</td>
<td>0</td>
<td>I am very limited doing activities at home</td>
</tr>
<tr>
<td>I am confident leaving my home despite my lung condition</td>
<td>0</td>
<td>I am not at all confident leaving my home because of my lung condition</td>
</tr>
<tr>
<td>I sleep soundly</td>
<td>0</td>
<td>I don’t sleep soundly because of my lung condition</td>
</tr>
<tr>
<td>I have lots of energy</td>
<td>0</td>
<td>I have no energy at all</td>
</tr>
</tbody>
</table>

*Score ≥10 represents significant symptoms*


Total Score: **20**
Pharmacologic Treatment Options

**Bronchodilators**

- **Short-acting**
  - β₂-agonists
    - Albuterol
    - Levalbuterol
  - Muscarinic antagonist
    - Ipratropium
  - Combination
    - Albuterol + Ipratropium

- **Long-acting**
  - β₂-agonists
    - Arformoterol
    - Formoterol
    - Indacaterol
    - Olodaterol
    - Salmeterol
  - Muscarinic antagonist
    - Tiotropium
    - Aclidinium
    - Umeclidinium
    - Glycopyrrolate
  - Combination
    - Vilanterol + Umeclidinium
    - Indacaterol + Glycopyrronium
    - Tiotropium + Olodaterol
    - Formoterol + Glycopyrrolate
    - Theophylline

**Anti-inflammatory**

- **Corticosteroids**
  - Combination
    - Formoterol + Budesonide
    - Salmeterol + Fluticasone propionate
    - Vilanterol + Fluticasone furoate

- **Other oral agents**
  - Combination
    - Roflumilast
  - Macrolide
    - Azithromycin

*Formoterol/Mometasone is another combination agent available in the US, but is not FDA-approved for COPD

PDE-4 = phosphodiesterase 4

https://wipediseases.org/dev3/inhalers/
<table>
<thead>
<tr>
<th></th>
<th>Agonists(^1,2)</th>
<th>Anticholinergics(^3,4)</th>
<th>Inhaled Glucocorticoids(^5)</th>
<th>Roflumilast(^6)</th>
<th>Azithromycin(^7,8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tremors</td>
<td>Dry Mouth</td>
<td>Dysphonia</td>
<td>Diarrhea</td>
<td></td>
<td>Antimicrobial resistance</td>
</tr>
<tr>
<td>Palpitations</td>
<td>Urinary retention</td>
<td>Thrush</td>
<td>Weight decrease</td>
<td></td>
<td>Hearing decrease</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>Glaucoma</td>
<td>Systemic Effects: bruising, bone density, cataract</td>
<td>Nausea</td>
<td>Arrhythmia</td>
<td></td>
</tr>
<tr>
<td>Arrhythmias</td>
<td>Arrhythmias</td>
<td>Pneumonia</td>
<td>Headache</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Depression</td>
</tr>
</tbody>
</table>

“Each pharmacologic treatment regimen should be individualized and guided by the severity of symptoms, risk of exacerbations, side-effects, comorbidities, drug availability and costs, and the patient’s response, preference and ability to use various drug delivery devices.”

GOLD, Global Initiative for Chronic Obstructive Lung Disease.
June is a 54 y/o with a past smoking history, confirmed COPD, a CAT score of 20, mMRC score of 3, minimal chronic sputum production and no bronchitis over the past year (GOLD group B). Current COPD medications include short-acting beta-agonist prn.

What therapeutic option would you recommend for June?

1. Add a SAMA
2. Add a LAMA/LABA
3. Add an ICS/LABA
4. Add roflumilast

CAT = COPD Assessment Test
mMRC = modified Medical Research Council
SAMA = short-acting muscarinic antagonist
LAMA = long-acting muscarinic antagonist
LABA = long-acting beta-agonist
ICS = inhaled corticosteroid
GOLD therapeutic recommendations

Group A
- Continue, stop or try alternative class of bronchodilator
- Evaluate effect
- A bronchodilator

Group B
- A long-acting bronchodilator (LABA or LAMA)
- Persistent symptoms

Group C
- LAMA + LABA
- LABA + ICS
- Further Exacerbation(s)

Group D
- Consider roflumilast if FEV1 < 50% pred and patient has chronic bronchitis
- Consider macrolide
- Further Exacerbation(s)
- Persistent symptoms/further exacerbations

Further Exacerbation(s)
- LAMA + LABA + ICS
- LAMA + LABA
- LABA + ICS

Symptomatic response to dual bronchodilators is dependent on baseline symptom burden

- Least squared mean difference (95% CI) in change in baseline in SGRQ at Week 24. Pooled data from PINNACLE-1 and -2. The primary endpoint was change from baseline in morning pre-dose trough FEV₁.

- FF, formoterol fumarate; GFF, glycopyrrolate/formoterol fumarate; GP, glycopyrrolate; T, tiotropium.

Symptomatic response to dual bronchodilators is dependent on baseline symptom burden

- **Bottom Line:**
  - LAMA or LABA alone is effective in patients with milder COPD symptoms
  - Combination therapy with LABA + LAMA should be prescribed in patients with more severe COPD symptoms

Case: James

- James is a 63 y/o with a past cigarette smoking history and confirmed severe COPD (FEV\textsubscript{1} 40% predicted).

- He has chronic exertional symptoms, with a CAT score of 20 with mMRC score of 3, and no significant sputum production.

- He has had 2 episodes of bronchitis in the last year that required oral antibiotics and oral prednisone and 1 episode of pneumonia that required a brief hospitalization.

- PMH: Hypertension, coronary artery disease (SP stent last year)

- Medications: amlodipine, metoprolol succinate, aspirin, SABA prn, LAMA

- PE: BMI 18 kg/m\textsuperscript{2}, O\textsubscript{2} sat at rest with RA 91%, decreased BS
James is a 63 y/o with a severe COPD (FEV₁ 40% predicted). CAT score of 20, mMRC score of 3, and no chronic sputum production. He’s had 2 episodes of bronchitis last year and 1 hospitalization for pneumonia. He also has CAD (s/p PCI last year). Medications: amlodipine, metoprolol succinate, aspirin, SABA prn, LAMA. Exam: BMI 18 kg/m², oxygen saturation at rest with RA 91%, decreased breath sounds

What therapeutic option would you recommend for James at this point?

1. Add a LABA (LABA/LAMA)
2. Add theophylline to his LAMA
3. Discontinue metoprolol
4. Discontinue the LAMA and change to an ICS

CAT = COPD Assessment Test, mMRC = modified Medical Research Council
SABA = short-acting beta-agonist, LAMA = long-acting muscarinic antagonist
LABA = long-acting beta-agonist, ICS = inhaled corticosteroid
BMI = body mass index, RA = room air
GOLD therapeutic recommendations

Group A
- Continue, stop or try alternative class of bronchodilator
- Evaluate effect
- A bronchodilator

Group B
- LAMA + LABA
- Persistent symptoms
- A long-acting bronchodilator (LABA or LAMA)

Group C
- LAMA + LABA
- LABA + ICS
- Further Exacerbation(s)
- LAMA

Group D
- Consider roflumilast if FEV1 < 50% pred and patient has chronic bronchitis
- LAMA + LABA + ICS
- Consider macrolide
- Further Exacerbation(s)
- Persistent symptoms/further exacerbations
- LAMA
- LAMA + LABA
- LABA + ICS

ICS/LABA vs. LABA/LAMA for exacerbations

ICS/LABA vs. LABA/LAMA for exacerbations

And the winner is…

LABA/LAMA
(in this study)

ICS/LABA decreased exacerbations compared with ‘usual care’

**A**

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Percent Change (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary effectiveness analysis population</td>
<td>-8.4 (-15.2 to -1.1)</td>
</tr>
<tr>
<td>Entire trial population</td>
<td>-8.4 (-14.9 to -1.4)</td>
</tr>
</tbody>
</table>

**B**

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Percent Change (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LABA, LAMA, or LABA+LAMA</td>
<td>-11.6 (-31.2 to 13.6)</td>
</tr>
<tr>
<td>ICS, ICS+LABA, or ICS+LAMA</td>
<td>-15.7 (-26.3 to -3.4)</td>
</tr>
<tr>
<td>ICS+LABA+LAMA</td>
<td>-3.6 (-12.8 to 6.5)</td>
</tr>
</tbody>
</table>

ICS/LABA vs. LABA/LAMA for exacerbation prevention

And the winner is…

ICS/LABA
(in this study)

Risk Factors Associated With CXR Confirmed Pneumonia in Patients With COPD Treated With ICS\textsuperscript{1,2}

- Older age ($\geq 65$ years old)
- Low body mass index (BMI < 25 kg/m\textsuperscript{2})
- Very severe COPD (FEV\textsubscript{1} < 30\% predicted)

Given James’ level of breathlessness, recurrent exacerbations and recent pneumonia, you begin therapy with a combination of LABA/LAMA.

The combination helped his breathless, but…

Over the past 6 months he had another episode of bronchitis treated at an urgent care center with antibiotics.

He does not have chronic sputum production.
James was prescribed therapy with a combination agent, LABA/LAMA. Over the past 6 months he had another episode of bronchitis treated at an urgent care center with antibiotics. He does not have chronic sputum production.

What therapeutic option would you recommend for him at this point?

1. Review inhaler technique
2. Add an ICS (LAMA + LABA/ICS)
3. Add theophylline
4. #1 and #2 only
5. #1 and #2 and #3

LAMA = long-acting muscarinic antagonist
LABA = long-acting beta-agonist
ICS = inhaled corticosteroid
Group D

Consider roflumilast if FEV1 < 50% pred and patient has chronic bronchitis

Further Exacerbation(s)

Consider macrolide

LAMA + LABA + ICS

Persistent symptoms/further exacerbations

LAMA

LAMA + LABA

LABA + ICS

Triple therapy for exacerbations

Additional effect of a LAMA added to an ICS/LABA

Singh et al., Lancet 2016; 388: 963-73
Triple therapy for exacerbations: LABA/LAMA/ICS (single inhaler)

Higher FEV$_1$

E-RS (Improved respiratory symptoms)

E-RS = Exact Respiratory Symptoms

Lipson DA et al., AJRCCM (Published on 04-April-2017 as 10.1164/rccm.201703-0449OC)
ARS Question #7

James calls you because his insurance plan changed its formulary & switched him to a new ICS/LABA DPI.

Since the switch, he has felt more breathlessness and experienced another mild bronchitis flare. Changing back to his prior ICS/LABA MDI will cost him an extra $100 per month. What should you do at this point?

1. Ask him to demonstrate his new inhaler technique
2. Change him to nebulized ICS and nebulized LABA
3. Add oral corticosteroids (prednisone) daily
4. Increase the ICS dose

ICS = inhaled corticosteroid
LABA = long-acting beta-agonist
DPI = dry powder inhaler
MDI = metered dose inhaler
Numerous inhaler devices can be a challenge

Metered Dose Inhaler  Soft Mist Inhaler  Nebulizer

Metered Dose Inhaler with Valved Holding Chamber

3. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease
Inhaler devices (continued)

Single Dose Dry Powder Inhalers

Multi-dose Dry Powder Inhalers
Numerous inhaler devices can be a challenge

- No single inhaler will satisfy the needs of all patients
  - 28-68% of patients do not use inhalers correctly
  - A sub-optimal technique can result in decreased lung delivery and potentially reduced efficacy

- The proliferation of inhalation devices in the market can result in confusion for clinicians, nurses, respiratory therapists and patients
  - Each available device require specific inhalation techniques

- Studies have demonstrated lack of knowledge in the use of devices by healthcare professionals
  - 39-67% of HCPs are unable to adequately perform or describe inhalation techniques

- Physicians need to select the right inhaler for each patient
  - knowing each product’s characteristics is key

1. Anna Murphy, SIMPLE 2013
Factors That Determine Selection of an Inhaler Delivery System

### Clinician Factors
- Deliver wide range of therapies\(^1,2\)
- Clinical efficacy/safety\(^3\)
- Type of prescribed medications (ICS vs bronchodilator)
- Patient’s disease severity/ inspiratory flow\(^4\)
- Ease of use/liked by patients\(^1,2\)
- Cost/reimbursement insurance coverage\(^1,2\)

### Patient Factors
- Lifestyle/preference\(^2\)
- Disease severity\(^4\)
- Cost/reimbursement
- Clinical setting/ caregiver\(^1,2\)
- Physical ability/ dexterity\(^2\)
- Cognitive ability\(^5\)

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4. Rau JL. *Respir Care.* 2006;51(2)158-172.
Adherence to inhaled medications is poor among COPD patients

- Prospective study of 244 COPD patients (160 post exacerbation)
- Electronic monitoring of compliance with diskus device:
  - Mean adherence was 22.6%
  - Adherence > 80 in only 6%

Adherence decreases and inhaler misuse increases with time

ARS Question #8

According to GOLD recommendations, how often should healthcare professionals assess inhaler technique in a patient with COPD?

1. Every visit
2. Every other visit
3. Twice a year
4. Once every year
The choice of inhaler device has to be individually tailored and will depend on access, cost, prescriber and most importantly, patient’s ability and preference.

It is essential to provide instructions and to demonstrate the proper inhalation technique when prescribing a device, to ensure that inhaler technique is adequate and re-check at each visit that patients continue to use their inhaler correctly.

Inhaler technique (and adherence to therapy) should be assessed before concluding that the current therapy requires modification.
What Should Healthcare Professionals Know About Inhalers?

1) Know the types of devices that are available to deliver specific drugs and classes of drugs

2) Appreciate the advantages and disadvantages of each device

3) Choose devices that the patient can and will use effectively

4) Train patients about the correct inhalation maneuver that is appropriate for the device being prescribed

5) Check the patient’s inhaler technique regularly

6) Review the patient’s adherence to treatment at each visit

7) Do not switch to a new device without the patient’s involvement and without follow-up education on how to use the device properly

Laube BL et al; Eur Respir J 2011; 37: 1308–1331
James confirms adherence with ICS/LABA + LAMA inhalers and asks if there is anything else that can be done to improve his breathlessness. His $O_2$ sat at rest with room air is 91% and decreases transiently to 86% while walking for 6 minutes in your office.

Which of the following is most likely to improve his breathlessness?

1. Continuous long term oxygen therapy
2. Long-term oxygen therapy during ambulation
3. Nighttime oxygen therapy
4. Referral to pulmonary rehabilitation
Non-pharmacological therapy of stable COPD:

<table>
<thead>
<tr>
<th>Patient</th>
<th>Essential</th>
<th>Recommended</th>
<th>Local guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Smoking cessation</td>
<td>Physical activity</td>
<td>Flu and pneumococcal vaccination</td>
</tr>
<tr>
<td>B, C, D</td>
<td>Smoking cessation</td>
<td>Physical activity</td>
<td>Flu and pneumococcal vaccination</td>
</tr>
<tr>
<td></td>
<td>Pulmonary rehabilitation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

![Risk Diagram](image_url)
NON-PHARMACOLOGIC TREATMENT

Prescription of supplemental oxygen to COPD patients

Arterial Hypoxemia defined as:
PaO₂ < 55mmHg (8kPa) or SaO₂ < 88%

or

PaO₂ > 55 but < 60mmHg (> 8 but < 8.5 kPa) with right heart failure or erythrocytosis

Prescribe supplemental oxygen and titrate to keep SaO₂ ≥ 90%

Recheck in 60 to 90 days to assess:
If oxygen is still indicated If prescribed supplemental oxygen is effective

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Long term oxygen does not prolong time to death or 1\textsuperscript{st} Hospitalization or improve quality of life in COPD patients with moderate hypoxemia

- Prospective study in 738 COPD patients with moderate hypoxemia/desaturation
- Resting saturation 89-93\% or desaturation $\geq 80\%$ but $< 90\%$ during six minute walk
- Randomized to Oxygen or no Oxygen

CI = confidence interval; HR = hazard ratio; LTOT = long-term oxygen therapy; no. = number.
Pulmonary rehabilitation improves dyspnea

<table>
<thead>
<tr>
<th>Study</th>
<th>Mean Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behnke 200a</td>
<td>2.26 (1.34, 3.18)</td>
</tr>
<tr>
<td>Cambach 1997</td>
<td>1.20 (0.36, 2.04)</td>
</tr>
<tr>
<td>Goldstein 1994</td>
<td>0.66 (0.12, 1.20)</td>
</tr>
<tr>
<td>Gosselink 2000</td>
<td>0.82 (0.17, 1.47)</td>
</tr>
<tr>
<td>Griffiths 2000</td>
<td>1.18 (0.85, 1.51)</td>
</tr>
<tr>
<td>Gell 1995</td>
<td>1.30 (0.64, 1.96)</td>
</tr>
<tr>
<td>Gell 1998</td>
<td>1.00 (0.20, 1.80)</td>
</tr>
<tr>
<td>Hernandez 2000</td>
<td>0.78 (0.02, 1.54)</td>
</tr>
<tr>
<td>Simpson 1992</td>
<td>1.20 (0.37, 2.03)</td>
</tr>
<tr>
<td>Singh 2003</td>
<td>0.88 (0.35, 1.41)</td>
</tr>
<tr>
<td>Wijkstra 1994</td>
<td>0.90 (0.13, 1.67)</td>
</tr>
<tr>
<td>Total</td>
<td>1.06 (0.85, 1.26)</td>
</tr>
</tbody>
</table>

Lacasse et al, Cochrane Database of Systematic Reviews 2006; Issue 4; Art. No.: CD003793
Adherence to COPD Medications is Poor

• More than half of patients with COPD will stop new prescriptions after the first month\(^1\)
• Sustained adherence continues to decay over time\(^1,2\)

Persistence with any inhaler was 36%, 23%, and 17% at years 1, 2, and 3, respectively

2. Cecere LM et al. COPD. 2012;9:251-258
Multiple Factors Affect Adherence to Therapy

Horne R. Chest. 2006;130:65S-72S.
Recent Studies Support Several Strategies to Improve Adherence

- Use of individualized action plans
- Simplify treatment regimen
  - Plans that are clinically effective and user-friendly
  - Fewer doses per day
  - Oral versus inhaled medications
  - Vehicles that deliver two drugs at once
- Use of home visits by healthcare staff to reinforce adherence
- Use of self-monitoring, goal-setting, and other self-management techniques
Self-management education and coaching by healthcare professionals should be a major component of the “Chronic Care Model” within the context of the healthcare delivery system.

The aim of self-management education is to motivate, engage and coach the patients to positively adapt their health behavior(s) and develop skills to better manage their disease.
In order to adjust therapy appropriately as the disease progresses, each follow-up visit should include a discussion of the current therapeutic regimen. Monitoring should focus on:

- Dosages of prescribed medications.
- Adherence to the regimen.
- Inhaler technique.
- Effectiveness of the current regime.
- Side effects.

*Treatment modifications should be recommended.*
POST-TEST QUESTIONS
After completing this activity, how confident are you now in your ability to select appropriate inhaled therapies for patients with COPD, based on disease severity and patient characteristics?

1. Not at all confident
2. Not very confident
3. Somewhat confident
4. Pretty much confident
5. Very confident
After completing this activity, how often do you intend to perform spirometry as part of the evaluation of a patient with chronic cough and progressive dyspnea?

1. Never
2. Rarely
3. Sometimes
4. Frequently
5. Always
A 54 y/o woman with past smoking history and confirmed COPD (FEV\textsubscript{1} 60% predicted) presents with breathlessness and a CAT score of 20, mMRC dyspnea score of 3. She has a daily cough with minimal chronic sputum production, but no episodes of bronchitis over the past year.

What is this patient’s GOLD grade?

1. GOLD A
2. GOLD B
3. GOLD C
4. GOLD D
June is a 54 y/o with a past smoking history, confirmed COPD, a CAT score of 20, mMRC score of 3, minimal chronic sputum production and no bronchitis over the past year (GOLD group B). Current COPD medications include short-acting beta-agonist prn.

What therapeutic option would you recommend for June?

1. Add a SAMA
2. Add a LAMA/LABA
3. Add an ICS/LABA
4. Add roflumilast

CAT = COPD Assessment Test  
mMRC = modified Medical Research Council  
SAMA = short-acting muscarinic antagonist  
LAMA = long-acting muscarinic antagonist  
LABA = long-acting beta-agonist  
ICS = inhaled corticosteroid
Post-test Question 5

James is a 63 y/o with a severe COPD (FEV₁ 40% predicted). CAT score of 20, mMRC score of 3, and no chronic sputum production. He’s had 2 episodes of bronchitis last year and 1 hospitalization for pneumonia. He also has CAD (s/p PCI last year). Medications: amlodipine, metoprolol succinate, aspirin, SABA prn, LAMA. Exam: BMI 18 kg/m², oxygen saturation at rest with RA 91%, decreased breath sounds

What therapeutic option would you recommend for James at this point?

1. Add a LABA (LABA/LAMA)
2. Add theophylline to his LAMA
3. Discontinue metoprolol
4. Discontinue the LAMA and change to an ICS

CAT = COPD Assessment Test, mMRC = modified Medical Research Council
SABA = short-acting beta-agonist, LAMA = long-acting muscarinic antagonist
LABA = long-acting beta-agonist, ICS = inhaled corticosteroid
BMI = body mass index, RA = room air
Post-test Question 6

According to GOLD recommendations, how often should healthcare professionals assess inhaler technique in a patient with COPD?

1. Every visit
2. Every other visit
3. Twice a year
4. Once every year
A 63 y/o man with severe COPD (FEV\(_1\) 40% predicted) confirms adherence with ICS/LABA + LAMA and asks if there is anything else that can be done to improve his breathlessness. His O\(_2\) sat at rest with room air is 91% and decreases transiently to 86% while walking for 6 minutes in your office.

Which of the following is most likely to improve his breathlessness?

1. Continuous long term oxygen therapy
2. Long-term oxygen therapy during ambulation
3. Nighttime oxygen therapy
4. Referral to pulmonary rehabilitation