THE CHALLENGES OF COPD MANAGEMENT IN PRIMARY CARE
An Expert Roundtable

This activity is supported by an educational grant from Sunovion Pharmaceuticals Inc.
COPD in the United States

- Third leading cause of death
- Second leading cause of disability
- 15 million Americans diagnosed; 12 million more undiagnosed
- $50 billion per year in health-related costs
- Most COPD patients are still in the workforce
- Burden increasing with aging population

Key Messages From “COPD 360”

- COPD is a considerable cause of morbidity in the United States
  - Disproportionately affects individuals with low socioeconomic status
- Improvements needed in patient access to:
  - Disease-state education
  - Drug therapies
  - Nonpharmacologic interventions (eg, pulmonary rehabilitation)
- Insufficient disease-specific training for healthcare providers—mostly PCPs, who provide most COPD care

PCP = primary care provider.
Barriers to Diagnosis of COPD Relate to Both Patient- and Provider-Specific Factors

Barriers to diagnosis of COPD in primary care

- 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 results
- Underrecognition of symptoms, leading to delayed presentation
- Poor awareness of COPD
- Lack of knowledge regarding COPD risk factors and appropriate diagnostic testing

Figure adapted from Haroon S, et al. Int J Chron Obstruct Pulmon Dis. 2015;10:1711-1718.
Diagnosis of COPD

- Consider COPD in any patient with chronic cough, dyspnea, or sputum production
  - Cough: may be intermittent and nonproductive
  - Dyspnea: progressive, persistent, usually worse with exercise; patients describe “heaviness” or “air hunger”
  - Sputum production: any pattern
- History of exposure to risk factors
- Significant airflow limitation may occur without cough or sputum production

CAPTURE™ Screening Tool for Primary Care: 5 Questions

1. Have you ever lived or worked in a place with dirty or polluted air, smoke, secondhand smoke, or dust?
2. Does your breathing change with seasons, weather, or air quality?
3. Does your breathing make it difficult to do things such as carry heavy loads, shovel dirt or snow, jog, play tennis, or swim?
4. Compared with others your age, do you tire easily?
5. In the past 12 months, how many times did you miss work, school, or other activities due to a cold, bronchitis, or pneumonia?

CAPTURE = COPD Assessment in Primary Care to Identify Undiagnosed Respiratory Disease and Exacerbation Risk.
**CAPTURE™ Screening Tool**

<table>
<thead>
<tr>
<th></th>
<th>CAPTURE</th>
<th>PEF</th>
<th>CAPTURE + PEF (increase in sensitivity and specificity)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
<td>Specificity</td>
<td>Sensitivity</td>
</tr>
<tr>
<td>Differentiating cases from all controls</td>
<td>95.7%</td>
<td>44%</td>
<td>88%</td>
</tr>
<tr>
<td>Differentiating cases from controls with COPD</td>
<td>95.7%</td>
<td>67.8%</td>
<td>88%</td>
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</table>

- Combined approach performed better than either single approach alone (missed fewer cases and identified fewer false positives)
- CAPTURE with PEF can identify COPD patients who would benefit from currently available therapy and who require further diagnostic evaluation

**PEF** = peak expiratory flow.

Spirometry: Normal Versus Obstructive Disease

- Post-bronchodilator: FEV₁/FVC <0.70 confirms the presence of airflow limitation
- Irreversibility of airflow limitation is COPD hallmark
- Where possible, compare values with age-related normal values to avoid overdiagnosis in elderly

FEV₁ = forced expiratory volume in 1 second; FVC = forced vital capacity.

GOLD 2017: Refined ABCD Assessment Tool

Spirometrically confirmed diagnosis

Assessment of airflow limitation

Exacerbation history

Assessment of symptoms/risk of exacerbations

Post-bronchodilator FEV₁/FVC <0.7

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

0 or 1 (not leading to hospital admission)

C

D

A

B

Symptoms

CAT = COPD assessment test; mMRC = modified Medical Research Council.
Nonpharmacologic COPD Management

<table>
<thead>
<tr>
<th>GOLD Grade</th>
<th>Essential</th>
<th>Recommended</th>
<th>Per Local Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Smoking cessation(^a) (may include pharmacotherapy and nicotine replacement)(^b)</td>
<td>Physical activity</td>
<td>Flu and pneumococcal vaccinations</td>
</tr>
<tr>
<td>B, C, D</td>
<td>Smoking cessation (per above) Pulmonary rehabilitation</td>
<td>Physical activity</td>
<td>Flu and pneumococcal vaccinations</td>
</tr>
</tbody>
</table>

\(^a\)Clinician counseling as brief as 3 minutes results in smoking quit rates of 5%-10%.
\(^b\)Nicotine replacement therapy, varenicline, bupropion, and nortriptyline increase long-term quit rates.

GOLD 2017 model for the initiation and subsequent escalation and/or de-escalation of pharmacologic management of COPD according to individualized assessment of symptoms and exacerbation risk.

**Pharmacologic Treatment Algorithms by GOLD Grade**

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

**Group B**
- LAMA + LABA
- Persistent symptoms
- Long-acting bronchodilator (LABA or LAMA)

**Group C**
- LAMA + LABA
- LABA + ICS
- Further exacerbation(s)
- LAMA

**Group D**
- Group A
- Group B
- Consider roflumilast if FEV$_1$ <50% predicted and patient has chronic bronchitis
- Consider macrolide (in former smokers)
- LAMA + LABA + ICS
- Further exacerbation(s)
- Persistent symptoms
- Further exacerbation(s)
- LABA + ICS
- LAMA
- LAMA + LABA

ICS = inhaled corticosteroid; LABA = long-acting beta agonist; LAMA = long-acting muscarinic antagonist.

Group C

- LAMA + LABA
- LABA + ICS

Further exacerbation(s)

LAMA

Group D

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

- Further exacerbation(s)

- Persistent symptoms/further exacerbation(s)

LAMA + LABA + ICS

Group A

- Continue, stop, or try alternative class of bronchodilator

- Evaluate effect

- Bronchodilator

Group B

- LAMA + LABA

- Persistent symptoms

- Long-acting bronchodilator (LABA or LAMA)
Differences Between Traditional Patient Education and Self-Management Education

**Patient Education**
- Driven by compliance
- Goals, problems, and challenges are identified by healthcare providers
- Information and advice given are specific to the disease
- In theory, behavior change is achieved through increased patient knowledge of the disease

**Self-Management Education**
- Driven by adherence
- Goals, problems, and challenges are identified by the patient
- Information and skills acquired are specific to the problem encountered by the patient
- In theory, behavior change is achieved by increased patient confidence in self-management

Education and Training: Inhaler Devices

- Choice of inhaler device should be individually tailored; depends on access, cost, prescriber, patient ability, preference
- Essential to provide instructions and demonstrate proper inhalation technique when prescribing device; recheck at each visit to ensure patients continue to use inhalers correctly
- Inhaler technique (and adherence to therapy) should be assessed before concluding that current therapy is insufficient

<table>
<thead>
<tr>
<th>Study</th>
<th>Patient Population/Age (Years)</th>
<th>% Inhaler Technique Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melani, 2011</td>
<td>1664 (52% with COPD); mean age: 62</td>
<td>12% with MDIs; 35%-44% with DPIs</td>
</tr>
<tr>
<td>Molimard, 2003</td>
<td>3811 (26% with COPD); mean age: 49</td>
<td>76% with MDIs; 49%-55% with DPIs</td>
</tr>
<tr>
<td>Souza, 2009</td>
<td>120 (50% with COPD); ages 47-91</td>
<td>94% with MDIs and DPIs</td>
</tr>
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DPI = dry powder inhaler; MDI = metered-dose inhaler.
Always Have Patients “Teach Back” Inhaler Use to Ensure Competence

Device Selection and Peak Inspiratory Flow Rate: Health Outcomes Research

Confidence in correct inhaler device technique and its association with health status and patient satisfaction: an analysis of real-world US COPD patients

- Data collected from survey of US physicians and their patients
- Low inhaler confidence and incorrect device technique may be associated with reduced patient satisfaction and poorer health status

Analysis of real-world treatment patterns among hospitalized COPD patients with PIF: interim findings from a prospective observational study

- 7 clinical sites: PIFR measured using the In-Check Dial\textsuperscript{®} device; data on treatment patterns collected from first 100 patients enrolled at discharge post therapy for a COPD exacerbation
- 1 in every 4 patients achieved PIF<60 L/min using resistance of the Diskus\textsuperscript{®} device; however, 70% with PIFR <60 L/min were receiving meds via DPIs
- Patients with COPD may not achieve optimal PIFR using commonly used devices

DPI = dry powder inhaler; PIFR = peak inspiratory flow rate.
Patient Case: Gayle

- Gayle is a 65-year-old chronic smoker
- Several years of progressive shortness of breath
- Denies chronic cough or bronchitis exacerbations
- Recently diagnosed with severe COPD
- O₂ saturation is 95% at rest; 93% with activity
- Minimal improvement with a short-acting bronchodilator
- Impaired dexterity due to rheumatoid arthritis
Patient Case: Gayle (cont’d)

• What should be the next therapeutic option(s)?
  – Inhaled corticosteroids
  – Chronic low-dose prednisone
  – One or more inhaled long-acting bronchodilators (LAMA +/- LABA)
  – Oxygen with activity
  – Triple therapy (LAMA + ICS/LABA)
  – One or more inhaled long-acting bronchodilators + pulmonary rehab
  – Triple therapy + pulmonary rehab
  – Add roflumilast or azithromycin