

# Go for the GOLD: 2021 Chronic Obstructive Pulmonary Disease (COPD) Updates

A presentation for HealthTrust Members  
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# Objectives

1.

Recall guideline updates to recommendations and current trends in COPD treatment

2.

Identify recently published outcomes and studies regarding COPD management

3.

Recognize appropriate recommendations for pharmacologic therapy in COPD patients based on new clinical evidence

# Definitions

## Diagnosis, Spirometry, Assessment

**COPD: Chronic Obstructive Pulmonary Disease**

**FVC: forced vital capacity**

**FEV1: forced expiratory volume in 1 second**

**mMRC: Modified Medical Research Council**

**CAT: COPD Assessment Test**

## Treatment

**LABA: long-acting beta agonist**

**LAMA: long-acting muscarinic antagonist**

**ICS: inhaled corticosteroid**

## Other

**Eos: eosinophils**

**cAMP: cyclic adenosine monophosphate**

**ATP: adenosine triphosphate**

**RCT: randomized controlled trial**

# Overview

Background

Prevention  
Updates

Treatment  
Updates

COPD  
during  
COVID19

# Knowledge Check 1

Which of the following was NOT a finding of a recently published study on COPD treatments?

- A. E-cigarettes were found to be a safe and effective method to help patients quit smoking
- B. LABA/LAMA improved symptoms compared to long acting bronchodilator monotherapy in patients with low exacerbation risk not on ICS
- C. LABA/LAMA/ICS therapy reduced risk of death in symptomatic patients at risk for exacerbation compared to LABA/LAMA or ICS/LABA
- D. Lower-dose inhaled glucocorticoid triple-therapy regimen showed greater efficacy than higher dose glucocorticoid-LABA regimen, with greater reductions in symptoms

# Knowledge Check 1- Correct Response

Which of the following was NOT a finding of a recently published study on COPD treatments?

7

- A. E-cigarettes were found to be a safe and effective method to help patients quit smoking
- B. LABA/LAMA improved symptoms compared to long acting bronchodilator monotherapy in patients with low exacerbation risk not on ICS
- C. LABA/LAMA/ICS therapy reduced risk of death in symptomatic patients at risk for exacerbation compared to LABA/LAMA or ICS/LABA
- D. Lower-dose inhaled glucocorticoid triple-therapy regimen showed greater efficacy than higher dose glucocorticoid-LABA regimen, with greater reductions in symptoms

# Background

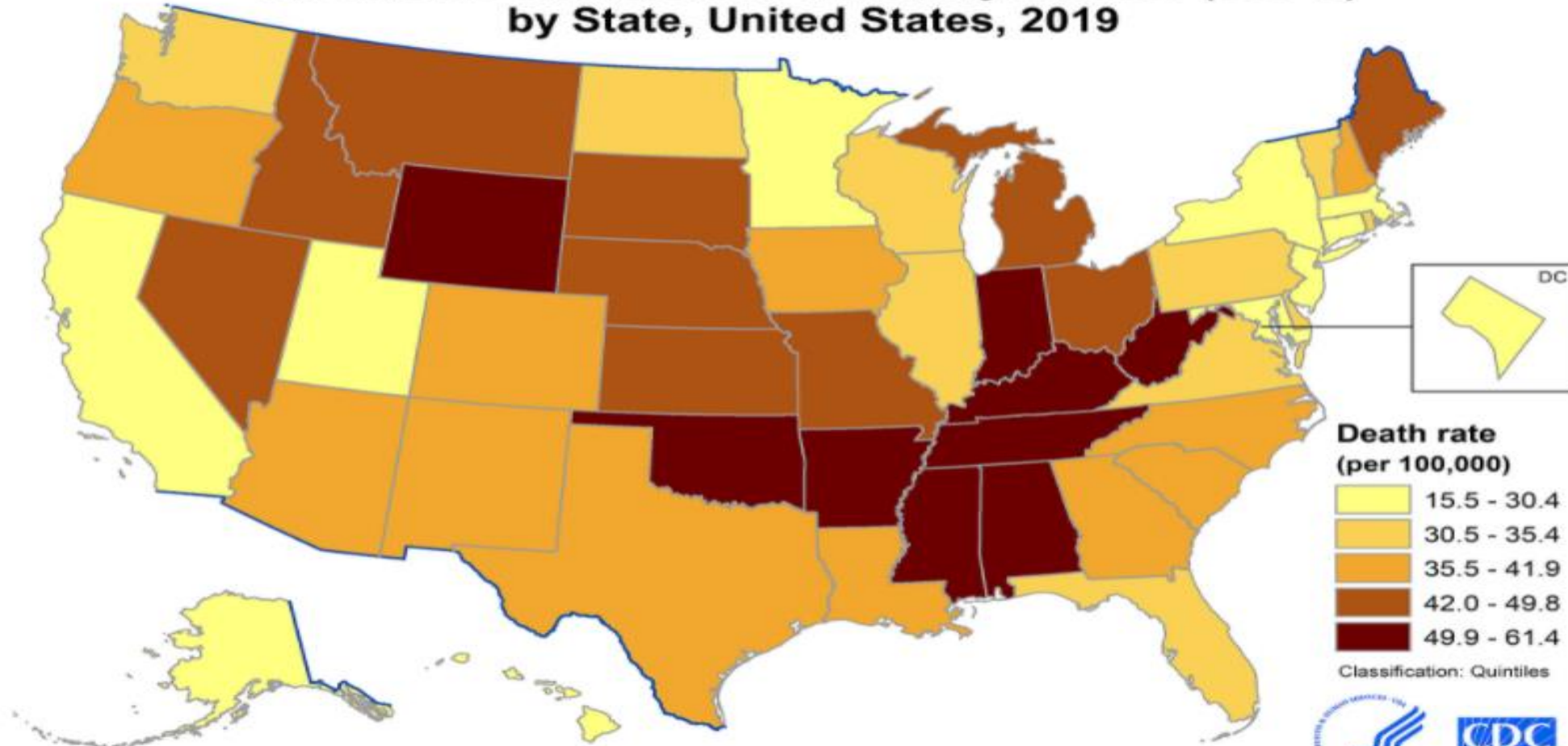


# What is COPD?

- ▶ COPD is common, preventable and treatable
- ▶ COPD is characterized by:
  - ▶ Persistent respiratory symptoms
  - ▶ Airway and/or alveolar abnormalities



**Age-Standardized Death Rate (Per 100,000 US Population)  
for Chronic Obstructive Pulmonary Disease (COPD)  
by State, United States, 2019**



Data source: CDC National Vital Statistics System data obtained from <http://wonder.cdc.gov>.  
COPD as underlying cause of death was defined by ICD-10 codes J40-J44.  
Death rates (per 100,000 US population) were age-adjusted to the 2000 US standard population.



Date: 3/30/2021

# Risk Factors



Tobacco  
smoke



Indoor air  
pollution



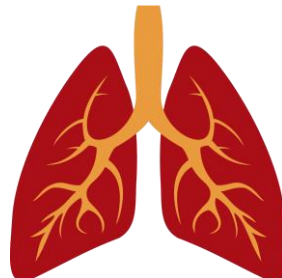
Occupational  
exposures



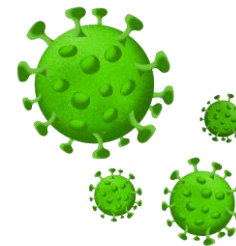
Outdoor air  
pollution



Age and sex



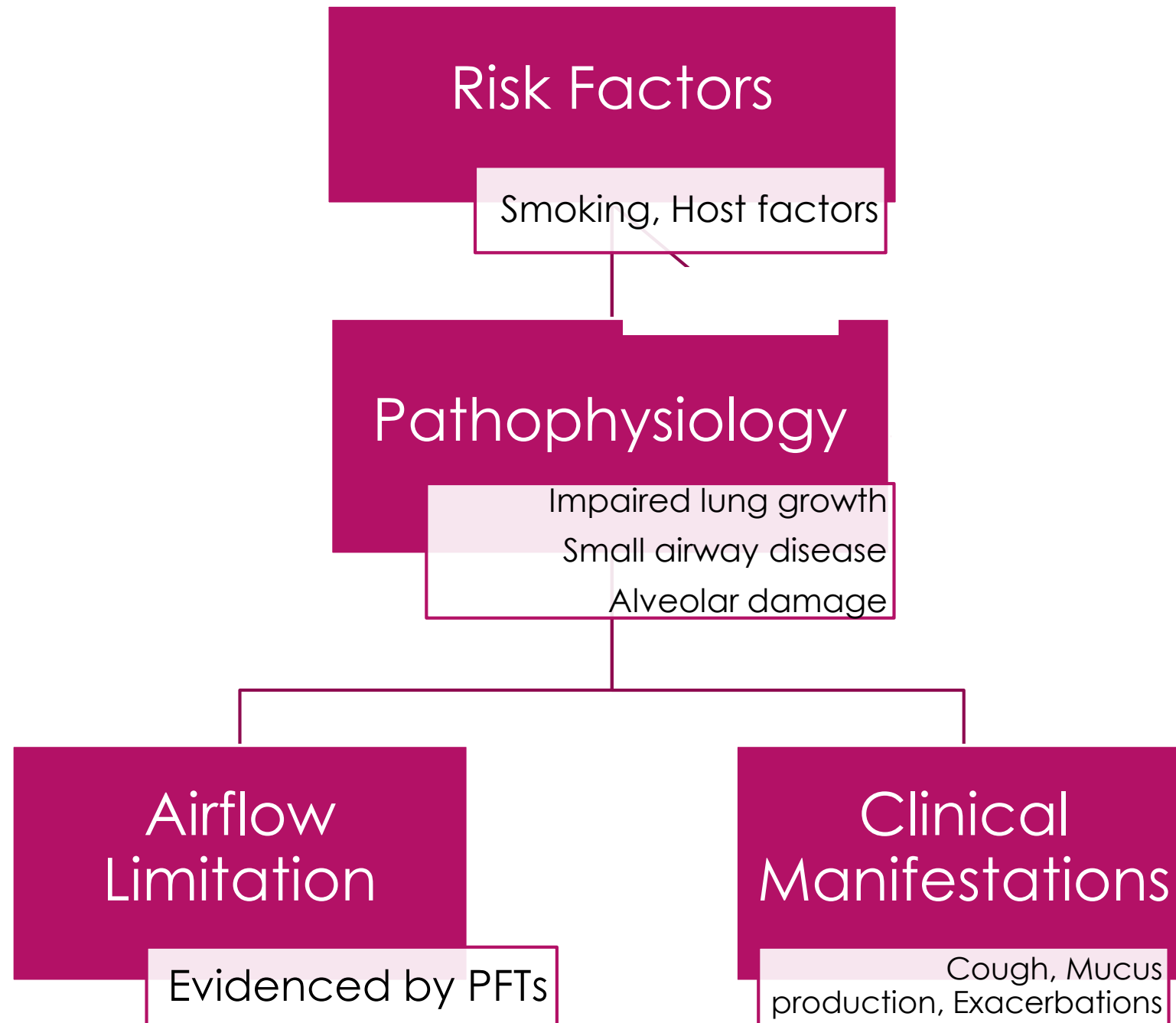
Lung growth and  
development/asthma

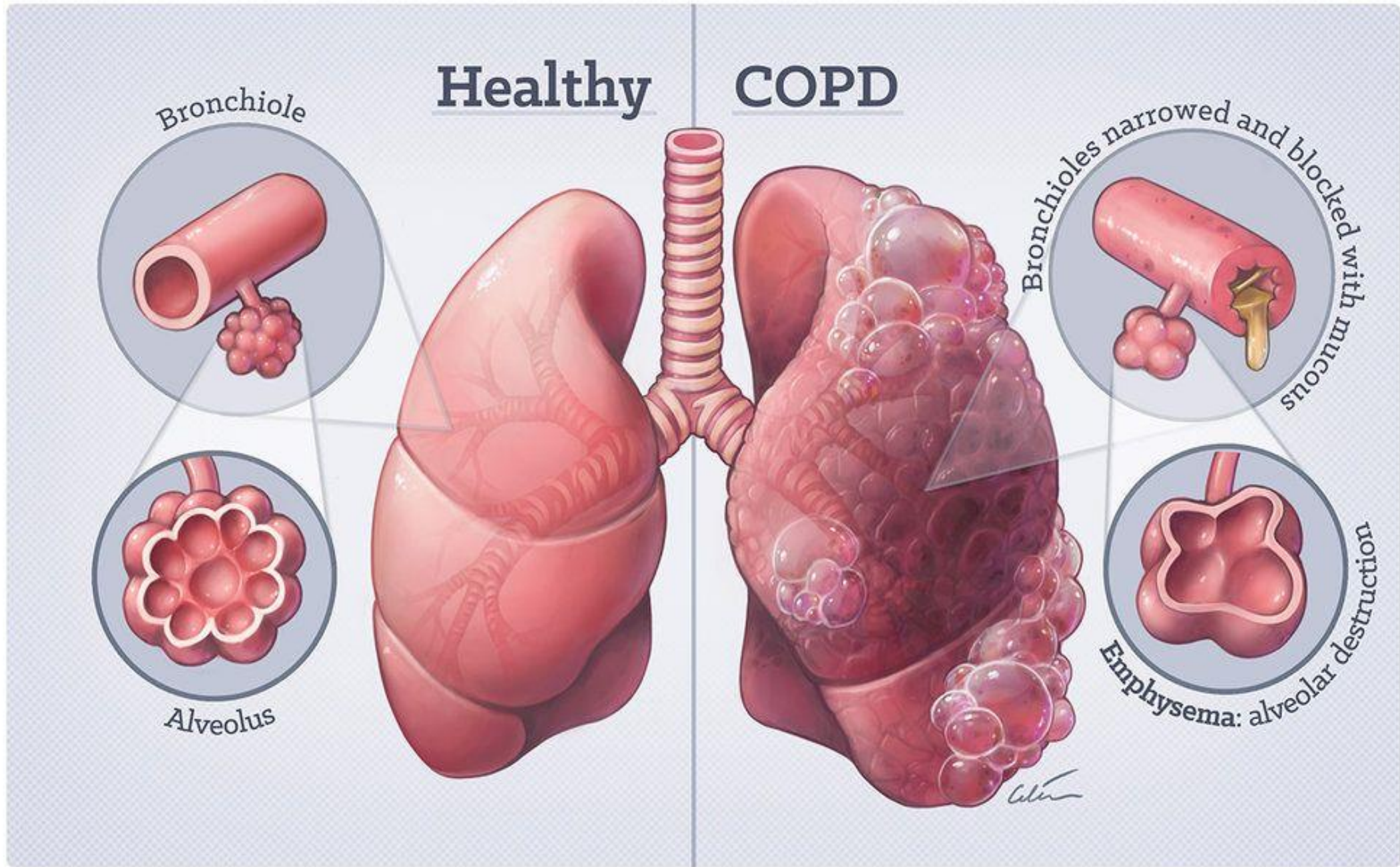


Infections/chronic  
bronchitis



Genetic factors





# Diagnosis

- ▶ COPD is NOT a clinical diagnosis
  - ▶ Spirometry required to confirm diagnosis

## SYMPTOMS

- Shortness of Breath
- Chronic Cough
- Sputum



## SPIROMETRY

- FVC
- FEV1
- FEV1/FVC < 70%

# Assessment Scales

## Moderate or Severe Exacerbation History

≥2 or  
≥ 1 leading  
to hospital  
admission

0 or 1  
(not leading  
to hospital  
admission)

<b>C</b>	<b>D</b>
<b>A</b>	<b>B</b>

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

# Assessment Scales

## ▶ MODIFIED MRC DYSPNEA SCALE<sup>a</sup>

PLEASE TICK IN THE BOX THAT APPLIES TO YOU | ONE BOX ONLY | Grades 0 - 4

mMRC Grade 0.	I only get breathless with strenuous exercise.	<input type="checkbox"/>
mMRC Grade 1.	I get short of breath when hurrying on the level or walking up a slight hill.	<input type="checkbox"/>
mMRC Grade 2.	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.	<input type="checkbox"/>
mMRC Grade 3.	I stop for breath after walking about 100 meters or after a few minutes on the level.	<input type="checkbox"/>
mMRC Grade 4.	I am too breathless to leave the house or I am breathless when dressing or undressing.	<input type="checkbox"/>

<sup>a</sup> Fletcher CM. BMJ 1960; 2: 1662.



# Assessment Scales

Cutoff at 10

▶ CAT™ ASSESSMENT			
<i>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.</i>			
EXAMPLE: I am very happy	<input type="radio"/> 0 <input checked="" type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	I am very sad	SCORE
I never cough	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	I cough all the time	
I have no phlegm (mucus) in my chest at all	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	My chest is completely full of phlegm (mucus)	
My chest does not feel tight at all	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	My chest feels very tight	
When I walk up a hill or one flight of stairs I am not breathless	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	When I walk up a hill or one flight of stairs I am very breathless	
I am not limited doing any activities at home	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	I am very limited doing activities at home	
I am confident leaving my home despite my lung condition	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	I am not at all confident leaving my home because of my lung condition	
I sleep soundly	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	I don't sleep soundly because of my lung condition	
I have lots of energy	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	I have no energy at all	
Reference: Jones et al. ERJ 2009; 34 (3); 648-54.			TOTAL SCORE: <input type="text"/>

# Treatment and Updates



# Vaccination for Stable COPD

## Influenza

- Reduces serious illness and death in COPD patients

## Pneumovax 23® (PPSV23)

- COPD patients < 65 yo with FEV<sub>1</sub> < 40% predicted and those with comorbidities to reduce community acquired pneumonia

## Prevnar 13® (PCV13)

- COPD patients greater than or equal to 65 to reduce bacteremia and pneumococcal disease

## Tetanus, Diphtheria, Pertussis (Tdap)

- COPD patients who were not vaccinated in adolescence to protect against pertussis (whooping cough)



# Knowledge Check 2

E-cigarettes contain all of the following ingredients EXCEPT:

- A. Nicotine
- B. Reactive oxygen species
- C. Volatile carbonyls
- D. All of the above can be contained in e-cigarettes
- E. Only A and B

# Knowledge Check 2 – Correct Response

E-cigarettes contain all of the following ingredients EXCEPT:

- A. Nicotine
- B. Reactive oxygen species
- C. Volatile carbonyls
- D. All of the above can be contained in e-cigarettes
- E. Only A and B

# Smoking Cessation

Smoking  
cessation

The diagram consists of two large magenta circles. The left circle contains the text 'Smoking cessation'. To its right is an equals sign, represented by two horizontal magenta bars. To the right of the equals sign is another large magenta circle containing the text 'Slowed disease progression'.

Slowed  
disease  
progression

# Smoking Cessation ★

- ▶ E-cigarettes and vaping
  - ▶ Contain nicotine, propylene glycol, volatile carbonyls, diacetyl, reactive oxygen species, furones, and metals
  - ▶ Case reports of severe acute lung injury, eosinophilic pneumonia, alveolar hemorrhage, respiratory bronchitis, and sometimes death
- ▶ E-cigarette or vaping associated lung injury (EVALI) outbreak was investigated by FDA and CDC
  - ▶ Vitamin E acetate was found to be linked to EVALI and cases have decreased since
  - ▶ Airway inflammation and irritability, ciliary paresis, and mucus hypersecretion seen in animal and in vitro human models



# Initial Management

≥ 2 moderate exacerbations or ≥ 1 leading to hospitalization

## Group C

LAMA

Group D LAMA or  
LAMA + LABA\* or  
ICS + LABA\*\*

\*Consider if highly symptomatic (e.g. CAT > 20)  
\*\*Consider if eos ≥ 300

0 or 1 moderate exacerbations (not leading to hospital admission)

## Group A

A Bronchodilator

## Group B

A Long Acting Bronchodilator (LABA or LAMA)

mMRC 0-1, CAT < 10

mMRC ≥ 2, CAT ≥ 10



# Bronchodilator Therapy

- ▶ Increase FEV<sub>1</sub> and/or change other spirometric variables
- ▶ Most often given on a regular basis to prevent or reduce symptoms

Beta2 agonists

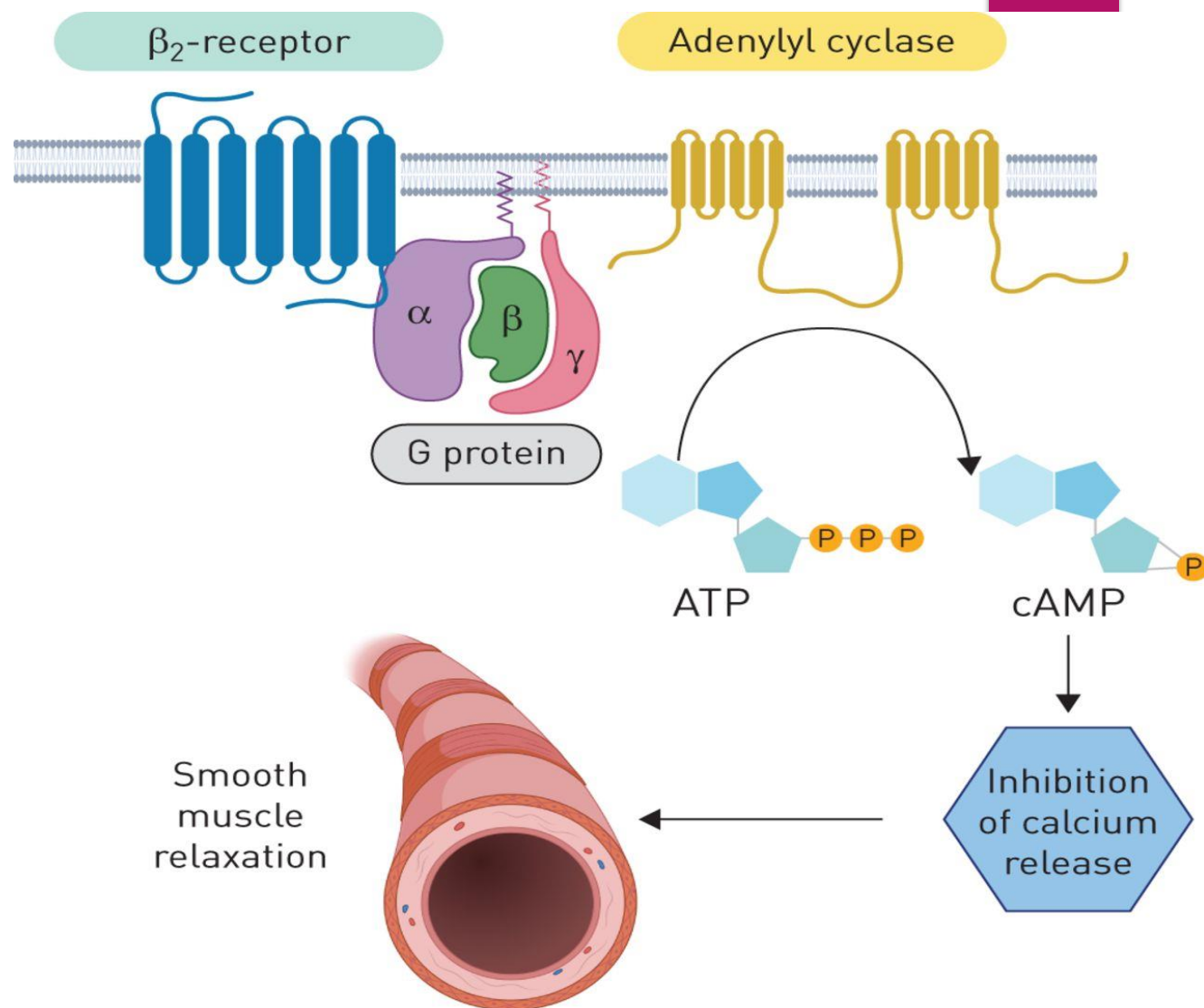
Antimuscarinic  
drugs

Methylxanthines

Combination  
therapy

# Beta2 Agonists

- Primary action is to relax airway smooth muscle
- Adverse effects:
  - Nervousness
  - Tachycardia
  - Cough
  - Hyperglycemia
  - Decreased potassium



### Short-Acting B<sub>2</sub> Agonists (SABA)

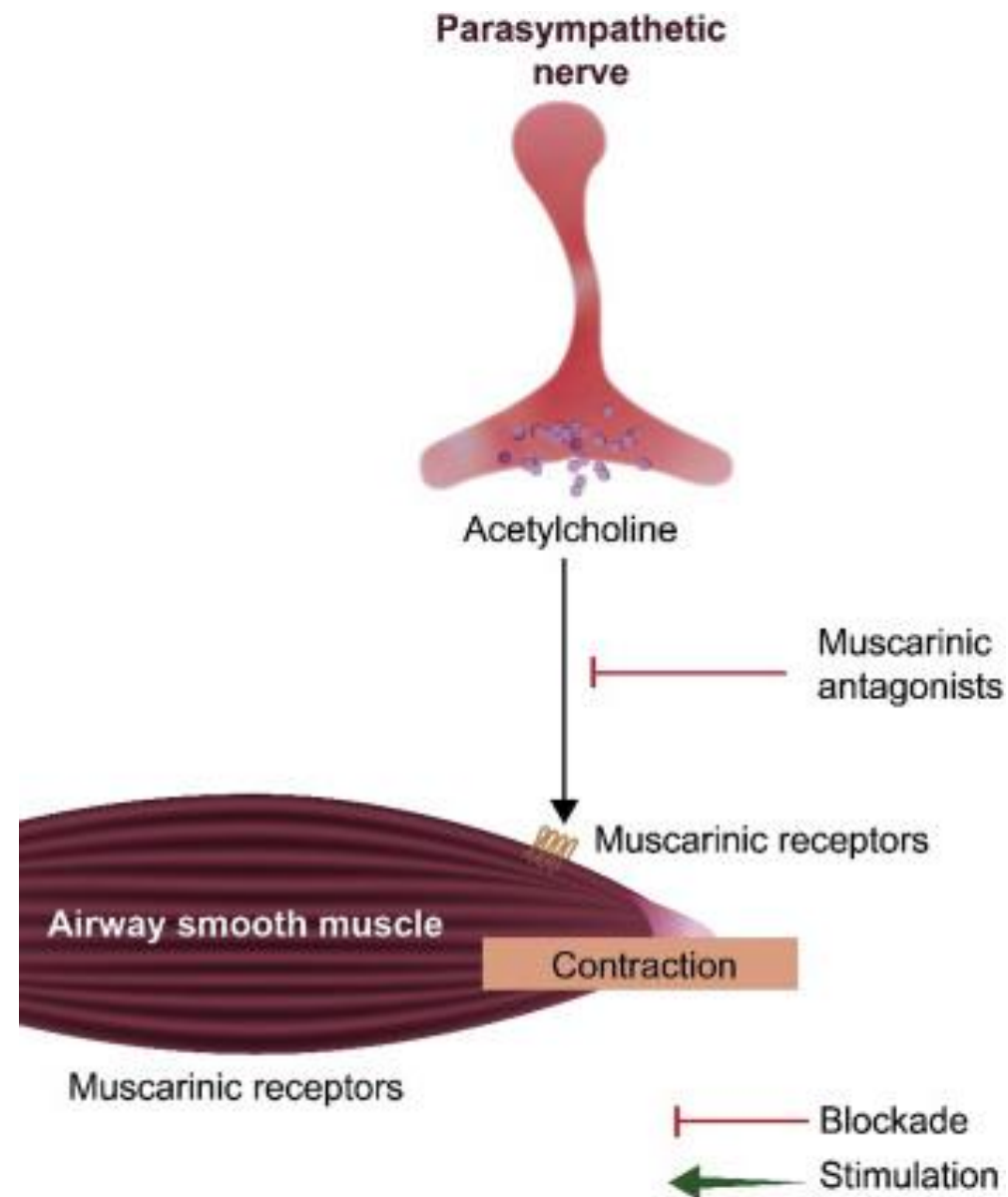
Medication	Inhaler Type	Nebulizer Solution Available?	Duration of Action
Levalbuterol (Xopenex®)	Metered dose inhaler (MDI)	Yes	6-8 hours
Albuterol (ProAir®, Ventolin®, Proventil®)	Metered dose inhaler (MDI) Dry powder inhaler (DPI)	Yes	4-6 hours

### Long-Acting B<sub>2</sub> Agonists (LABA)

Medication	Inhaler Type	Nebulizer Solution Available?	Duration of Action
Formoterol (Foradil®)	Dry powder inhaler (DPI)	Yes	12 hours
Indacaterol (Arcapta®)	Dry powder inhaler (DPI)	No	12 hours
Olodaterol (Striverdi Respimat®)	Soft mist inhaler (SMI)	No	24 hours
Salmeterol (Serevent®)	Metered dose inhaler (MDI) Dry powder inhaler (DPI)	No	12 hours

# Muscarinic Antagonists

- Block bronchoconstrictor effects of acetylcholine at M3 muscarinic receptors expressed in airway smooth muscle
- Adverse effects:
  - Dry mouth
  - Bitter taste
  - Upper respiratory tract infections



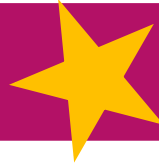
### Short-Acting Muscarinic Antagonists (SAMA)

Medication	Inhaler Type	Nebulizer Solution Available?	Duration of Action
Ipratropium bromide (Atrovent®)	Metered dose inhaler (MDI)	Yes	6-8 hours

### Long-Acting Muscarinic Antagonists (LAMA)

Medication	Inhaler Type	Nebulizer Solution Available?	Duration of Action
Aclidinium bromide (Tudorza Pressair®)	Metered dose inhaler (MDI), Dry powder inhaler (DPI)	No	12 hours
Tiotropium (Spiriva Handihaler®, Spiriva Respimat®)	Metered dose inhaler (MDI) Dry powder inhaler (DPI) Soft mist inhaler (SMI)	No	24 hours
Umeclidinium (Incruse Ellipta®)	Dry powder inhaler (DPI)	No	24 hours
Glycopyrronium bromide (Seebri Breezhaler®)	Dry powder inhaler (DPI)	Yes	12 hours

# EMAX Trial



30

Randomized patients at low risk for exacerbation to receive umeclidinium/vilanterol, umeclidinium monotherapy, or salmeterol monotherapy

Results: change from baseline of FEV1 at week 24

LABA/LAMA versus LAMA monotherapy:  
66 mL greater ( $p < 0.001$ )

LABA/LAMA versus LABA monotherapy:  
141 mL greater ( $p < 0.001$ )

Conclusion: LABA/LAMA combination inhaler improved lung function and symptoms versus long-acting bronchodilator monotherapy in symptomatic patients with low exacerbation risk not receiving inhaled corticosteroids

# Combination Bronchodilator Inhalers

## SABA/SAMA Inhalers

- Albuterol/ipratropium (Combivent Respimat®, DuoNeb®)

## LABA/LAMA Inhalers

- Formoterol/acclidinium (Duaklir Pressair®)
- Formoterol/glycopyrronium (Bevespi Aerosphere®)
- Vilanterol/umeclidinium (Anoro Ellipta®)
- Olodaterol/tiotropium (Stiolto Respimat®)

# Methylxanthines

Not recommended unless other bronchodilators not an option

- Contradictory evidence with low-dose therapy

Dose-related toxicity

- Small therapeutic range
- Nausea, repetitive vomiting

Adverse Effects

- Arrhythmias
- Grand mal seizures
- Headaches
- Insomnia

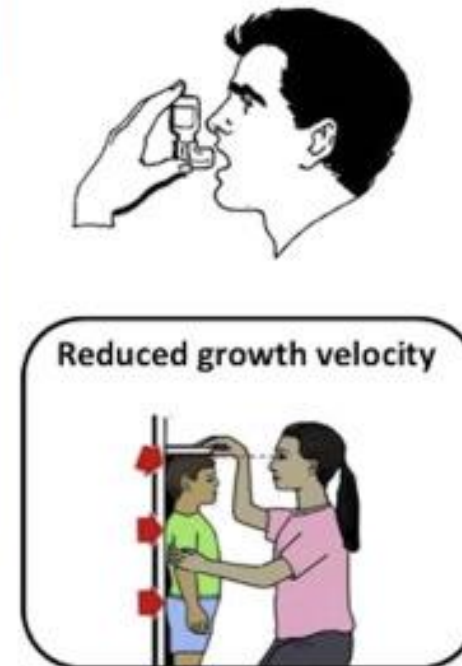
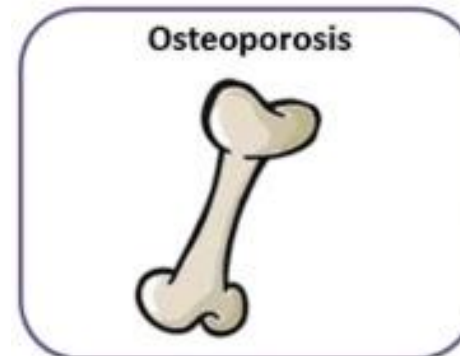
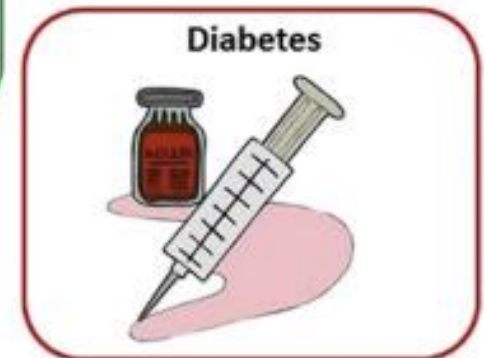
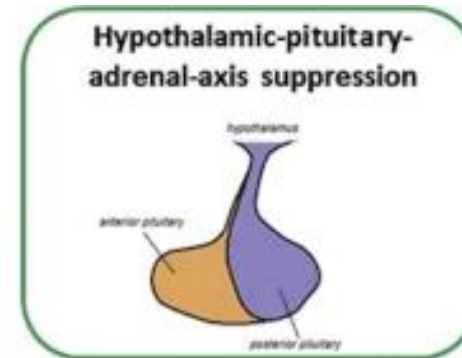
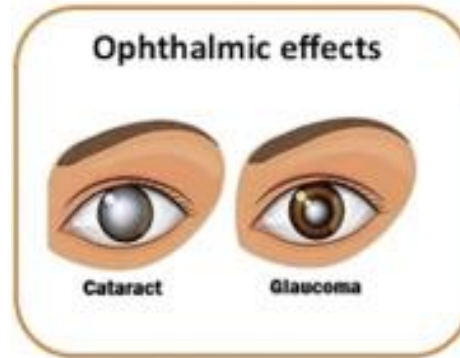


Significant interactions with commonly prescribed medications



# Inhaled Corticosteroids (ICS)

- ▶ Reduce lung inflammation by inhibiting synthesis of pro-inflammatory mediators



# Combination ICS Inhalers

## LABA/ICS Inhalers

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

# ICS Takeaways and Updates

- ▶ ICS/LABA combination more effective than individual components in improving lung function and reducing exacerbations
- ▶ Regular treatment with ICS increases pneumonia risk, especially in those with severe disease
- ▶ Both current and former smokers benefit from ICS use
  - ★ ▶ Magnitude of effect is lower in heavy or current smokers
- ★ ▶ Studies investigating ICS treatment and risk of lung cancer had conflicting results



Favoring Use

Blood eosinophils  
>300 cells/microL

2 or more  
moderate COPD  
exacerbations per  
year

History of asthma

Blood eosinophils  
<100 cells/microL

History of  
mycobacterial  
infection

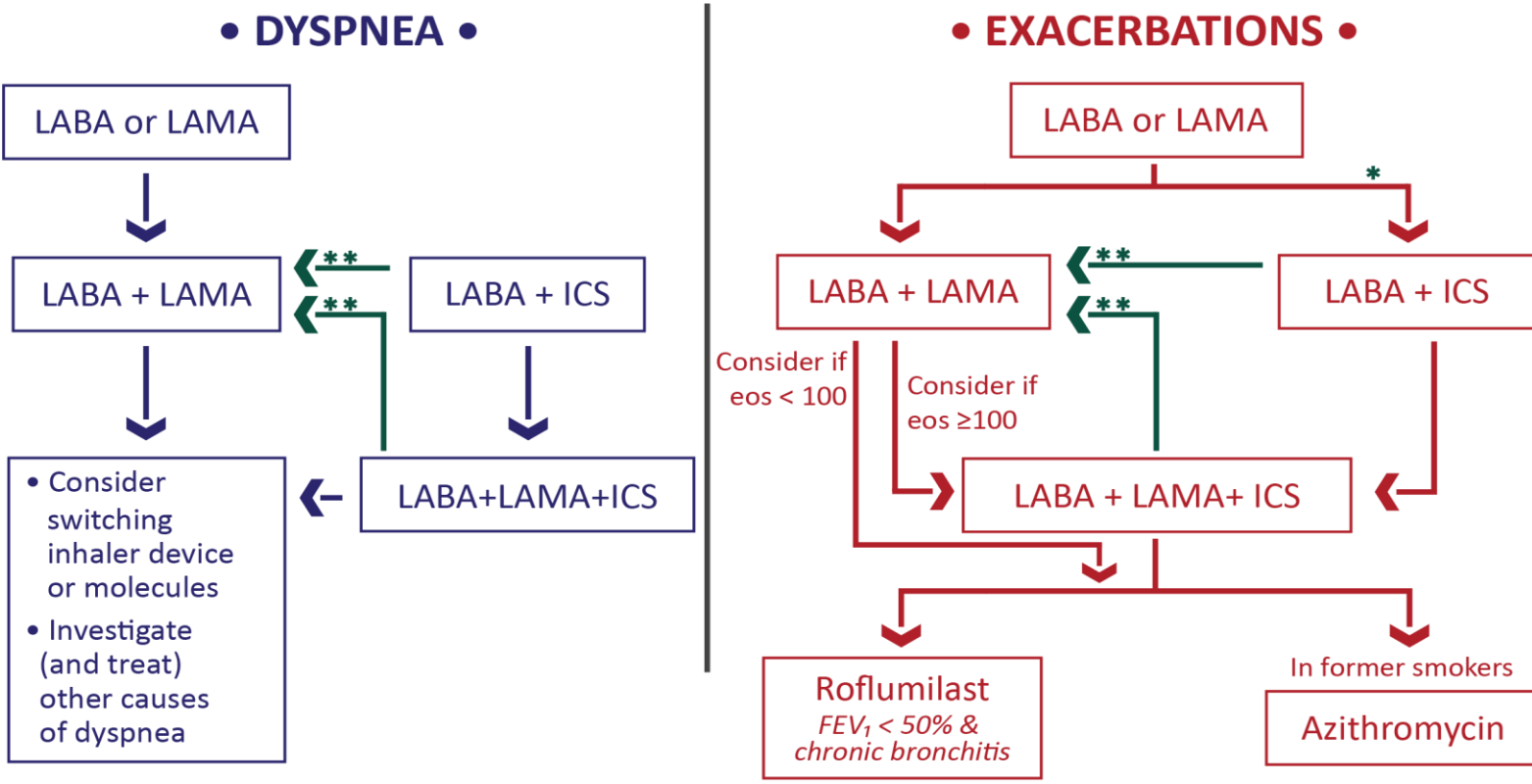
Repeated  
pneumonia events



Against Use

# FOLLOW-UP PHARMACOLOGICAL TREATMENT

1. IF RESPONSE TO INITIAL TREATMENT IS APPROPRIATE, MAINTAIN IT.
2. IF NOT:
  - ✓ Consider the predominant treatable trait to target (dyspnea or exacerbations)
  - Use exacerbation pathway if both exacerbations and dyspnea need to be targeted
  - ✓ Place patient in box corresponding to current treatment & follow indications
  - ✓ Assess response, adjust and review
  - ✓ These recommendations do not depend on the ABCD assessment at diagnosis



*eos = blood eosinophil count (cells/μL)*

\* Consider if eos ≥ 300 or eos ≥ 100 AND ≥2 moderate exacerbations / 1 hospitalization

\*\* Consider de-escalation of ICS or switch if pneumonia, inappropriate original indication or lack of response to ICS

FIGURE 4.4

Source: Vogelmeier C, Agustí A, Anzueto A, et al. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. 2021 report

# Knowledge Check 3

Which patient is the best candidate for triple therapy inhaler based on GOLD guideline recommendations?

- A. Patient on LABA/LAMA inhaler with eosinophils  $>100$  cells/microL, who continues to experience dyspnea and exasperations
- B. Patient on LAMA inhaler, who continues to have dyspnea
- C. Patient on LABA/ICS inhaler, who continues to have exacerbations
- D. Patient on LABA/LAMA inhaler with eosinophils  $<100$  cells/microL, who continues to have dyspnea and exacerbations
- E. A and C

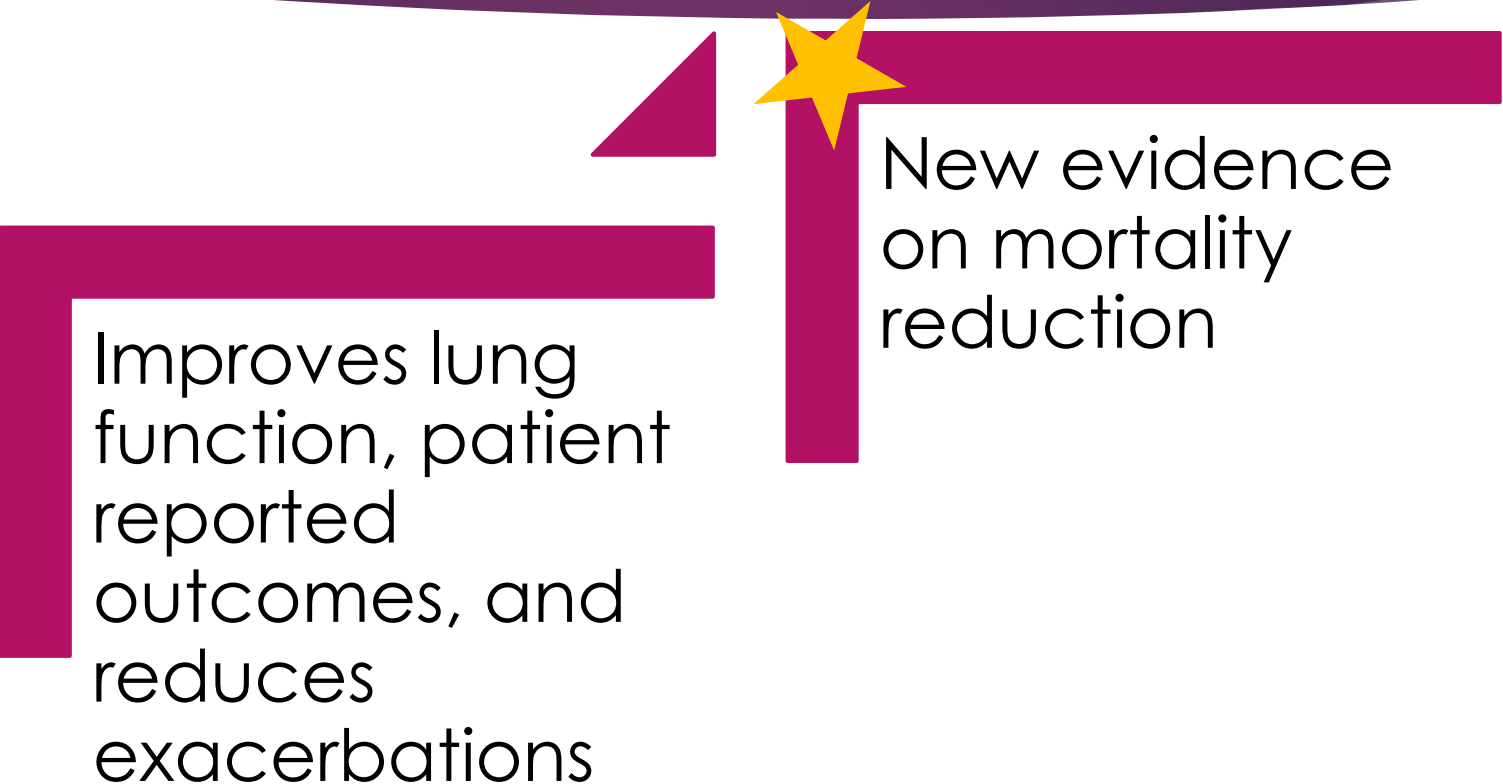
# Knowledge Check 3 – Correct Response

Which patient is the best candidate for triple therapy inhaler based on GOLD guideline recommendations?

- A. Patient on LABA/LAMA inhaler with eosinophils  $>100$  cells/microL, who continues to experience dyspnea and exasperations
- B. Patient on LAMA inhaler, who continues to have dyspnea
- C. Patient on LABA/ICS inhaler, who continues to have exacerbations
- D. Patient on LABA/LAMA inhaler with eosinophils  $<100$  cells/microL, who continues to have dyspnea and exacerbations

E. A and C

# Triple Therapy Inhaler (LABA/LAMA/ICS)



Improves lung function, patient reported outcomes, and reduces exacerbations

New evidence on mortality reduction



## Reduction in All-Cause Mortality with Fluticasone Furoate/Umeclidinium/Vilanterol in Patients with Chronic Obstructive Pulmonary Disease

FF: fluticasone furoate  
UMEC: umeclidinium  
VI: vilanterol

### IMPACT Study

Intervention: randomized 2:2:1 to receive FF/UMEC/VI, FF/VI, or UMEC/VI

Patient population: 10,355 COPD patients with either

- 1. FEV<sub>1</sub> <50% and ≥ 1 moderate or severe exacerbation OR
- 2. FEV<sub>1</sub> 50% - <80% and ≥ 2 moderate or 1 severe exacerbation

# IMPACT Results

## Results:

FF/UMEC/VI:  
98 deaths  
(2.36%)

FF/VI: 109  
deaths (2.64%)  
• HR=0.89 (0.67-  
1.16)

UMEC/VI: 66  
deaths (3.19%)  
• HR=0.72 (0.53-  
0.99)

Conclusion: once-daily FF/UMEC/VI inhaler reduced all-cause mortality versus UMEC/VI in patients with symptomatic COPD and a history of exacerbations

**FF: fluticasone furoate**  
**UMEC: umeclidinium**  
**VI: vilanterol**

# Triple Inhaled Therapy at Two Glucocorticoid Doses in Moderate-to-Very-Severe COPD

BD: budesonide  
GP: glycopyrronium bromide  
FM: formoterol

## ETHOS Study

Intervention: randomized 1:1:1 to receive BD/GP/FM, BD/FM, or GP/FM

Patient population: 8,509 symptomatic COPD patients (CAT  $\geq 10$ ) on at least 2 maintenance therapies, postbronchodilator FEV<sub>1</sub> 25% - 65%, smoking history of at least 10 pack years, and either

- 1.  $\geq 1$  moderate or severe exacerbation if FEV<sub>1</sub>  $< 50\%$  OR
- 2.  $\geq 2$  moderate, or 1 severe, exacerbation if FEV<sub>1</sub>  $\geq 50\%$

# ETHOS Results

**LABA/ICS**

- **Exacerbation Rate= 1.24 (2131 patients)**

**LABA/LAMA**

- **Exacerbation Rate= 1.42 (2120 patients)**

**Triple therapy  
(320mcg):**

- **Exacerbation Rate= 1.08 (2137 patients)**
- 13% lower rate than LABA/ICS (P=0.003)
- 24% lower rate than LABA/LAMA (P<0.001)

**Triple therapy  
(160mcg):**

- **rate = 1.07 (2121 pts)**
- 14% lower rate than LABA/ICS (P=0.002)
- 25% lower rate than LABA/LAMA (P<0.001)

## Ethos Conclusion

Triple therapy with twice-daily glycopyrronium bromide, budesonide, and formoterol resulted in a lower rate of moderate or severe COPD exacerbations than budesonide/formoterol or glycopyrronium bromide/formoterol therapy

# New Evidence on other Pharmacologic Therapy

- ▶ Erdosteine may have significant effect on mild exacerbations
- ▶ RCT looking at metoprolol in COPD patients without established indication for beta-blocker use showed it did not delay the time until first exacerbation, and hospitalization for exacerbation was more common in metoprolol group
- ▶ Pharmacist-led interventions and lay health coaching can improve inhalation technique and adherence in COPD patients
- ▶ Procalcitonin-guided antibiotic treatment regimens have been studied for management of COPD exacerbation with controversial results

# COPD and COVID-19

# Risk

## Unknown if COPD increases risk of COVID-19 infection

- One population survey with random sampling found no increased risk of COVID-19 infection
- Most studies of people in the community tested for SARS-CoV-2 have not shown COPD as an independent risk factor
- Many studies reporting comorbidities of patients hospitalized with COVID-19 have shown lower COPD prevalence than expected
- A large study with comprehensive data on comorbidities showed a high prevalence of COPD among those admitted (19%)
- A further study showed COPD as an independent risk factor for hospital admission

**Takeaway: increased risk of hospitalization and severe disease**



# When to Get Tested

- ▶ Patients with COPD presenting with
  - ▶ Respiratory symptoms
  - ▶ Fever
  - ▶ Other symptoms suggestive of COVID-19 infection



# Protective Strategies



Follow basic infection control measures



Wear a face covering



Consider shielding/sheltering in place

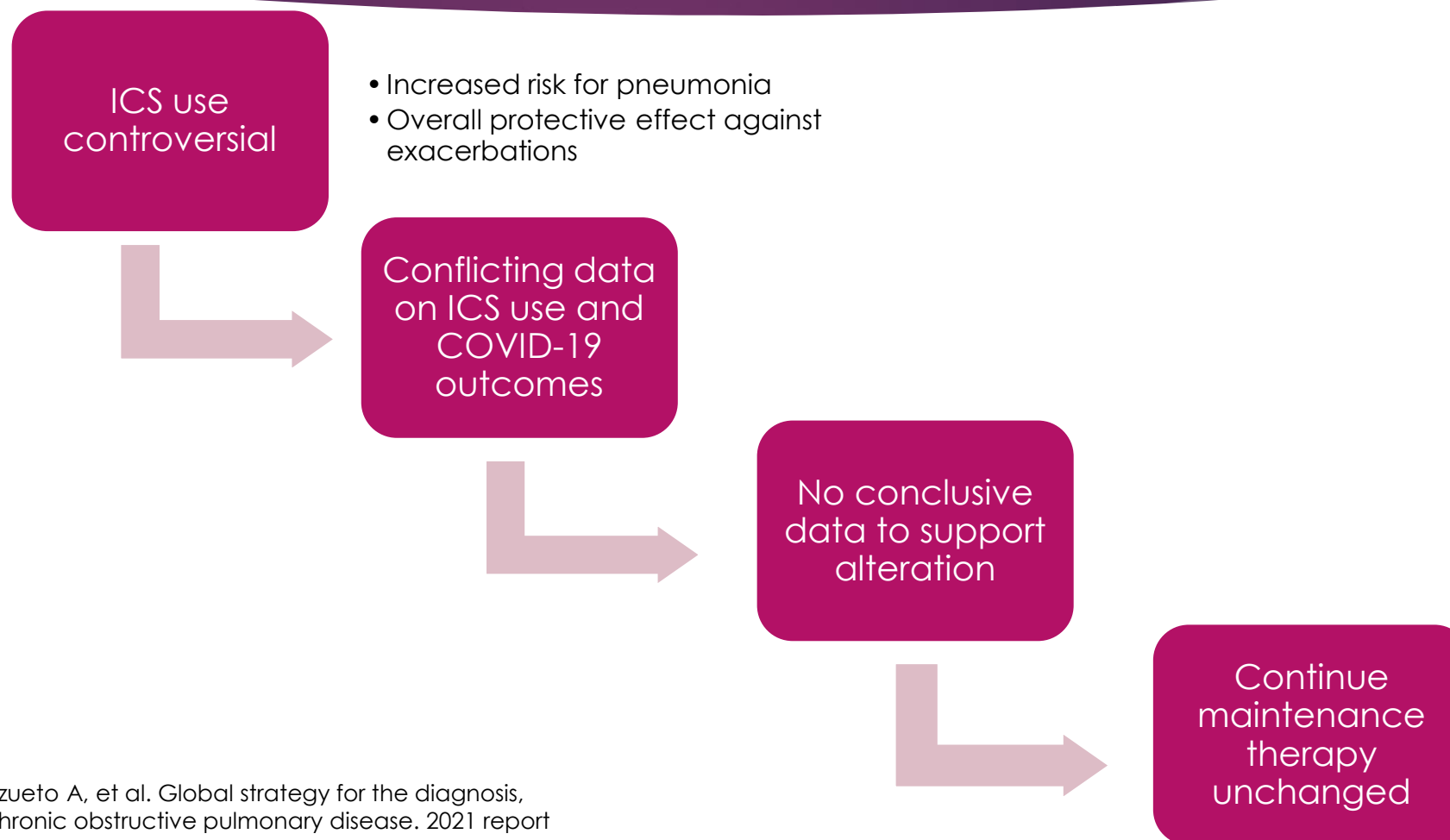


COVID-19 vaccination/annual influenza vaccination

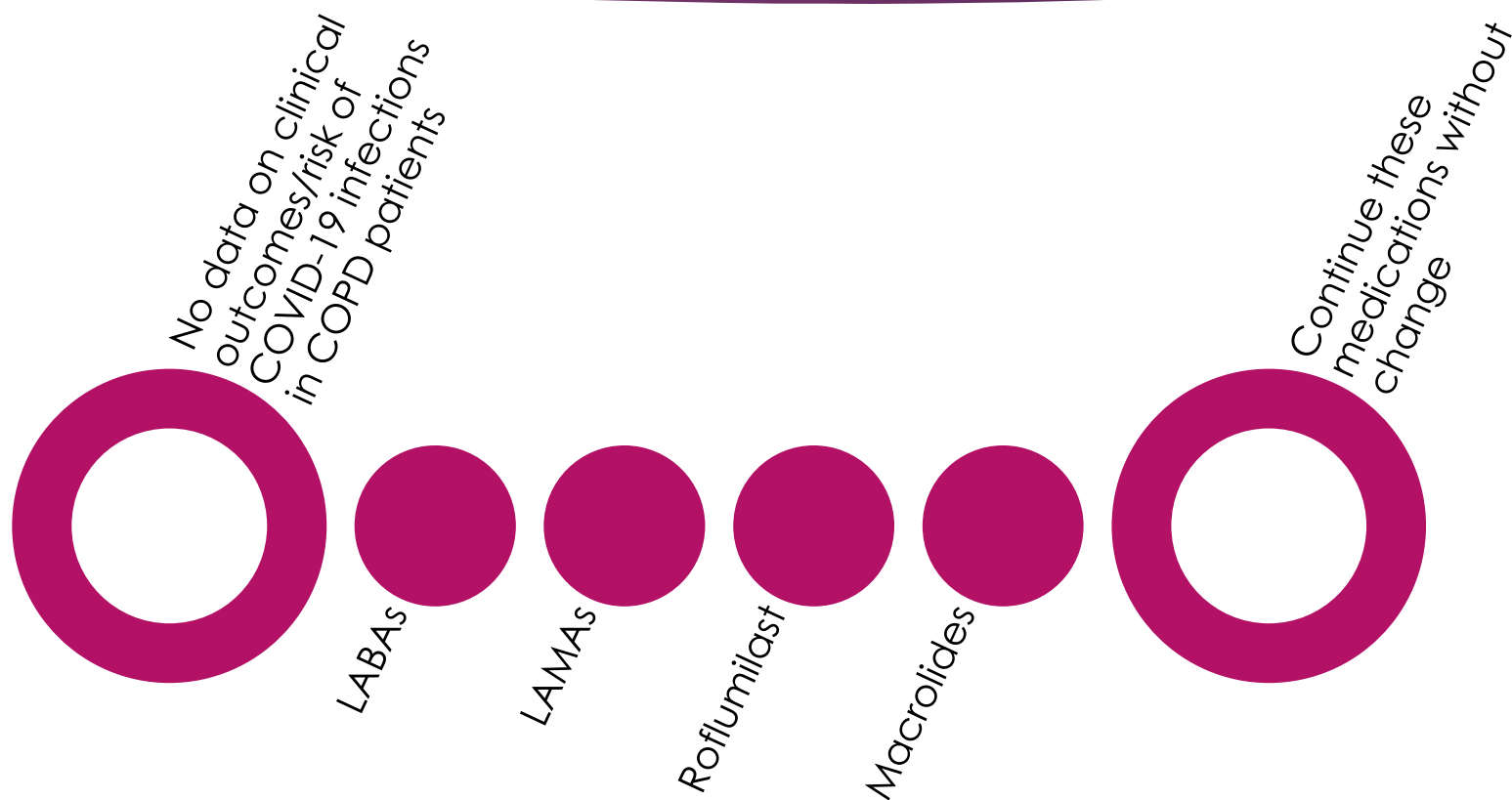


Only essential spirometry

# ICS Therapy during COVID-19 Pandemic



# Other Pharmacologic Treatment during COVID-19 Pandemic



# Treatment of COPD Exacerbations during COVID-19 Pandemic

Coronaviruses are among the respiratory viruses that trigger COPD exacerbations



To date MERS-CoV, SARS-CoV, and SARS-CoV-2 infections have not been reported in COPD exacerbations




Continue recommended treatments according to usual indications

Systemic corticosteroids

Antibiotics

# Treatment of COVID-19 Infection in COPD Patients

No recommendations to change management of COVID-19 in COPD patients



Continue usual course of therapy as indicated by patient parameters

# Knowledge Check 4

- ▶ What is the most appropriate recommendation based on the patient case?

LB is a 64 year old male with COPD currently on salmeterol/fluticasone (Advair Diskus®) inhaler. LB has persistent dyspnea despite his current regimen but has not had any exacerbations since starting treatment. He had a case of pneumonia less than a year ago. His labs show a blood eosinophil count of 67 cells/microL.

- A. Recommend starting LB on fluticasone furoate/umeclidinium/vilanterol (Trelegy Ellipta®)
- B. Recommend switching LB to formoterol/budesonide (Symbicort®)
- C. Recommend switching LB to vilanterol/ umeclidinium (Anoro Ellipta®)
- D. Recommend adding roflumilast (Daliresp®)

# Knowledge Check 4 – Correct Response

- ▶ What is the most appropriate recommendation based on the patient case?

LB is a 64 yo male with COPD currently on salmeterol/fluticasone (Advair Diskus®). LB has persistent dyspnea despite his current regimen but has not had any exacerbations since starting treatment. He had a case of pneumonia less than a year ago. His labs show an eosinophil count of 67.

- A. Recommend starting LB on fluticasone furoate/umeclidinium/vilanterol (Trelegy Ellipta®)
- B. Recommend switching from LB to formoterol/budesonide (Symbicort®)
- C. Recommend switching LB to vilanterol/ umeclidinium (Anoro Ellipta®)
- D. Recommend adding roflumilast (Daliresp®)



# Summary

## **New evidence has been added on**

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E-cigarettes and vaping

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LABA/LAMA combination therapy versus bronchodilator monotherapy

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Inhaled corticosteroid use in current or heavy smokers and in lung cancer

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Triple therapy benefits

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COPD treatment in context of COVID-19 pandemic

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# Thank you!

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