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GOLD 2024 update:

implications for clinical practice

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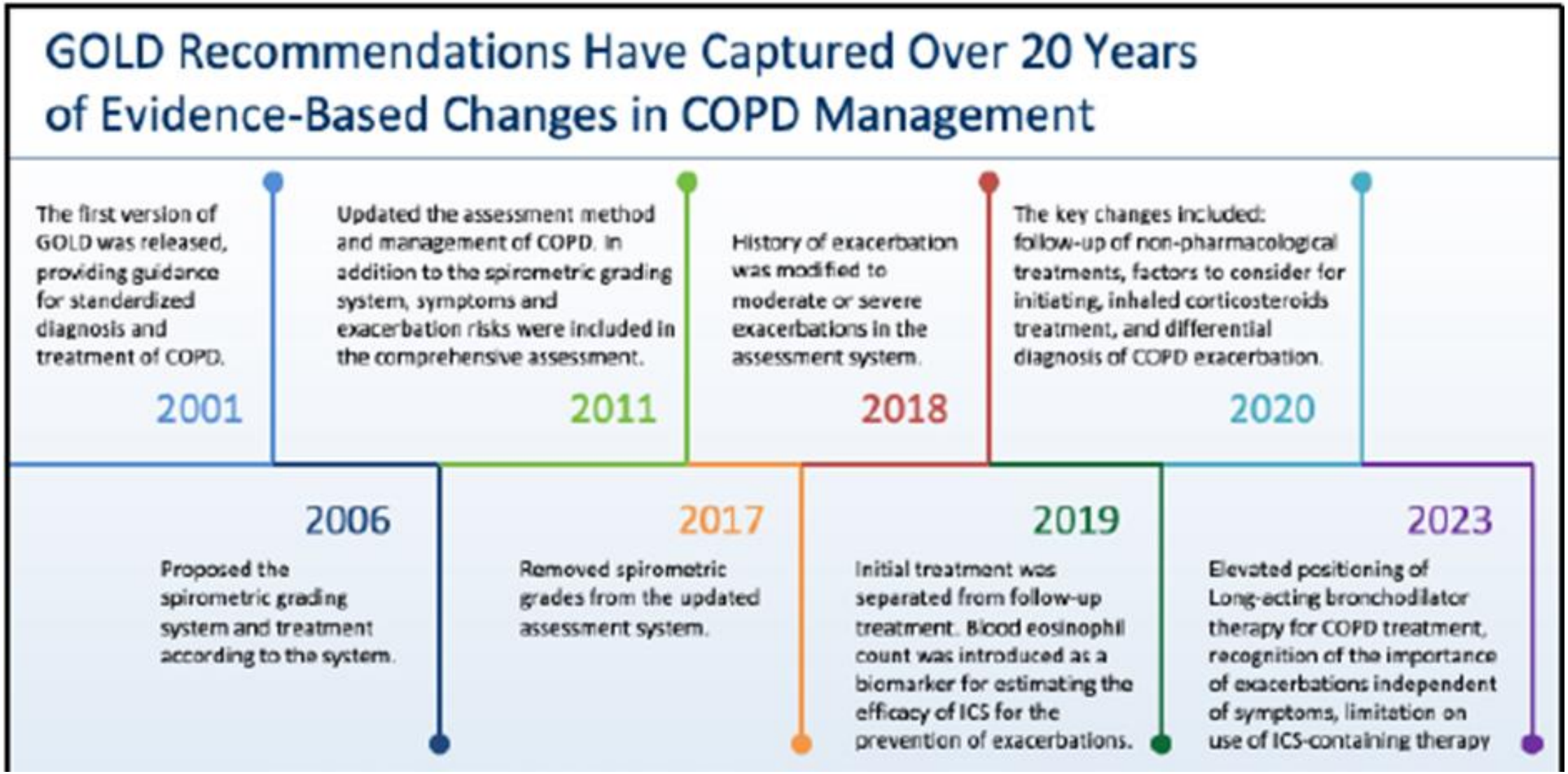
Professor of Medicine

What is GOLD?

- Initiated in 1998 – first report 2001
- International committee of experts in COPD
- Goal: produce recommendations for COPD management
- GOLD Science Committee established in 2002 to review literature and update the report annually
- 5 major revisions of the report; the last was 2023

GOLD Recommendations Have Captured Over 20 Years of Evidence-Based Changes in COPD Management



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GOLD 2023 revision

New definition of COPD

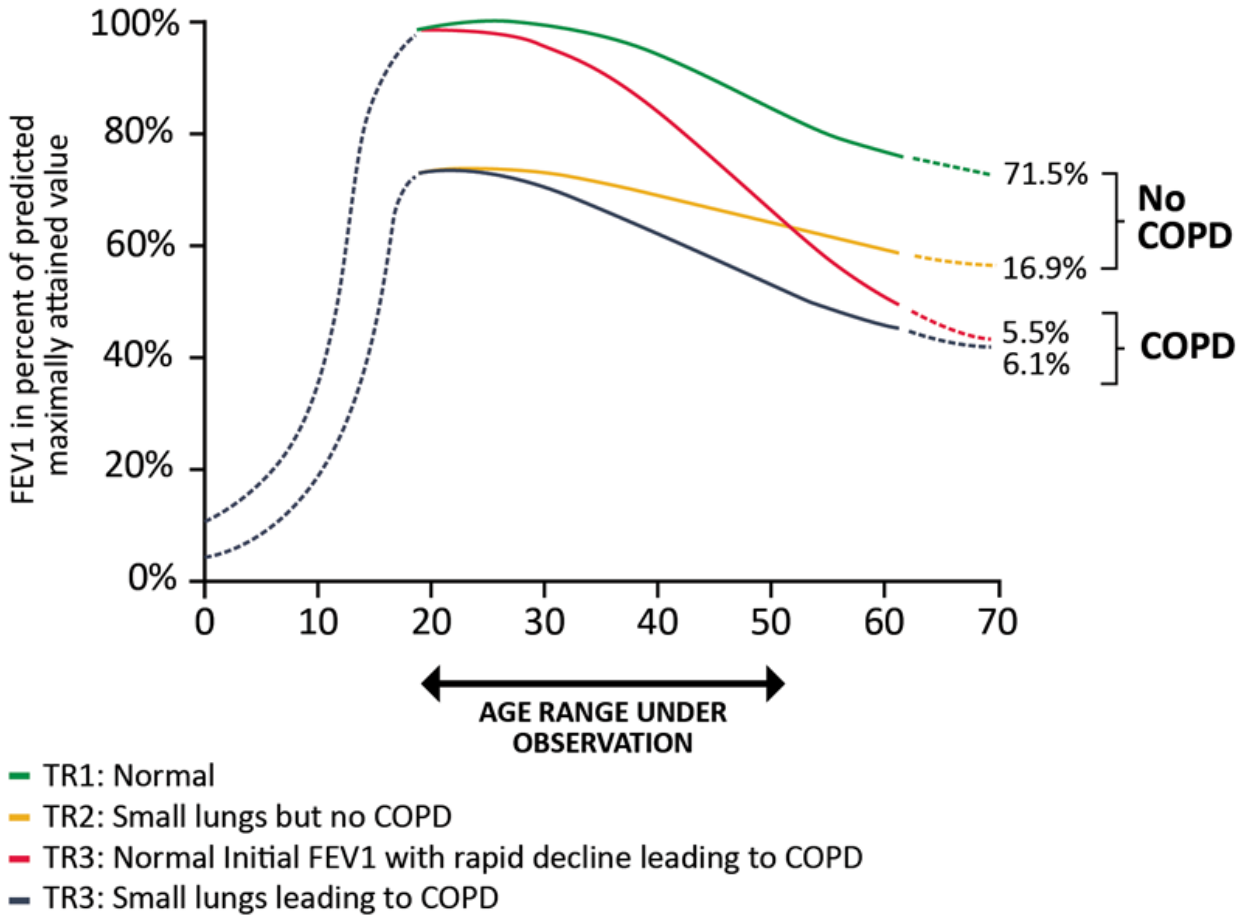
New definition

Chronic Obstructive Pulmonary Disease (COPD) is a heterogeneous lung condition characterized by chronic respiratory symptoms (dyspnea, cough, sputum production) due to abnormalities of the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that cause persistent, often progressive, airflow obstruction.[1]

Old definition

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 and influenced by host factors including abnormal lung development. Significant comorbidities may have an impact on morbidity and mortality.

Terminology and taxonomy- FEV1 trajectories



Terminology

- **Mild COPD**: Some studies have used “mild” airflow obstruction as a surrogate for early disease. This is incorrect because not all patients start their journey from a normal peak lung function in early adulthood, so some of them may never suffer “mild” disease in terms of severity of airflow obstruction. Further, “mild” disease can occur at any age and may progress or not over time. Therefore “mild” should be used only to describe the severity of airflow obstruction measured spirometrically.

GOLD Grades and Severity of Airflow Obstruction in COPD (based on post-bronchodilator FEV1) Table 2.6

In COPD patients (FEV1/FVC < 0.7):

GOLD 1:	Mild	FEV1 ≥ 80% predicted
GOLD 2:	Moderate	50% ≤ FEV1 < 80% predicted
GOLD 3:	Severe	30% ≤ FEV1 < 50% predicted
GOLD 4:	Very Severe	FEV1 < 30% predicted

Terminology

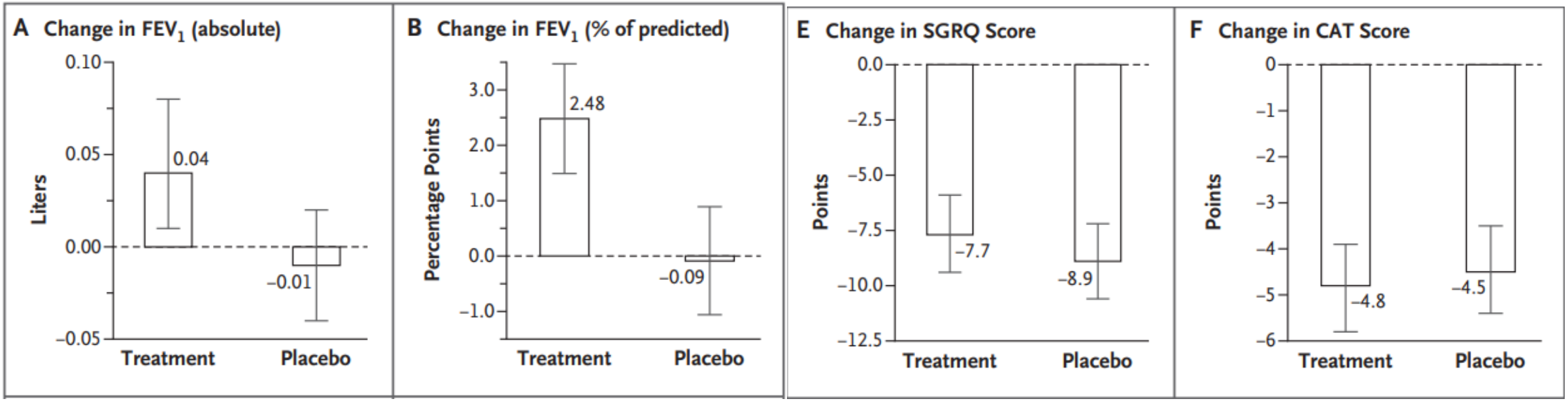
- **Young COPD:** Directly relates to the chronologic age of the patient. Since lung function peaks at 20 to 25 years young COPD patient's are aged 20 to 50 years. Can include patients who never achieved normal peak lung function in early adulthood and or those with early lung function decline. Often associated with a history of early life events such as hospitalizations before the age of 5 years or a family history of respiratory diseases.

- **Pre-COPD**: Identifies individuals of any age who have respiratory symptoms and or other detectable structural and or functional abnormalities in the absence of airflow obstruction on forced spirometry. These individuals may or may not develop persistent airflow obstruction over time.

- **PRISm:** Post BD preserved ratio (FEV1/FVC $\geq$ 0.7) but impaired spirometry (FEV1 and or FVC <80%) prevalence 7.1 to 20.3%. May transition to normal or obstruction over time.

Implications

Symptomatic smokers with preserved lung function



This is why we need spirometry for a COPD diagnosis

Han MK. N Engl J Med. 2022 Sep 29;387(13):1173-1184.

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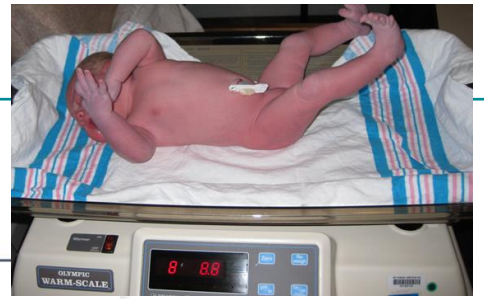
Taxonomy



Classification	Description
Genetically determined COPD (COPD-G)	Alpha-1 antitrypsin deficiency (AATD) Other genetic variants with smaller effects acting in combination
COPD due to abnormal lung development (COPD-D)	Early life events, including premature birth and low birthweight, among others
Environmental COPD	
Cigarette smoking COPD (COPD-C)	• Exposure to tobacco smoke, including *in utero* or via passive smoking • Vaping or e-cigarette use • Cannabis
Biomass and pollution exposure COPD (COPD-P)	Exposure to household pollution, ambient air pollution, wildfire smoke, occupational hazards
COPD due to infections (COPD-I)	Childhood infections, tuberculosis-associated COPD, HIV-associated COPD
COPD & asthma (COPD-A)	Particularly childhood asthma
COPD of unknown cause (COPD-U)	

Screening and case finding

GOLD advocates active case finding

- Use of spirometry in patients with risks (cigarette smoking, asthma, exposure to biomass fuels, prematurity, low birth weight, H/O frequent URIs)
- Sx are often not reported – use of Sx assessment tools (CAT)

CAT™ Assessment Figure 2.2

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	0 X 2 3 4 5	I am very sad	Score
I never cough	0 1 2 3 4 5	I cough all the time	
I have no phlegm (mucus) in my chest at all	0 1 2 3 4 5	My chest is completely full of phlegm (mucus)	
My chest does not feel tight at all	0 1 2 3 4 5	My chest feels very tight	
When I walk up a hill or one flight of stairs I am not breathless	0 1 2 3 4 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	0 1 2 3 4 5	I am very limited doing activities at home	
I am confident leaving my home despite my lung condition	0 1 2 3 4 5	I am not at all confident leaving my home because of my lung condition	
I sleep soundly	0 1 2 3 4 5	I don't sleep soundly because of my lung condition	
I have lots of energy	0 1 2 3 4 5	I have no energy at all	

Jones P. ERJ 2009 34(3) p648

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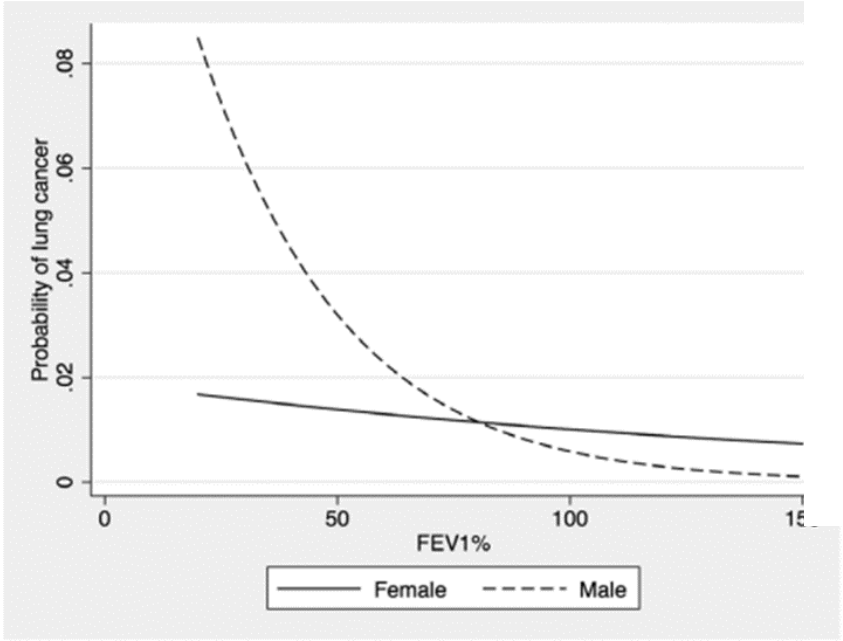
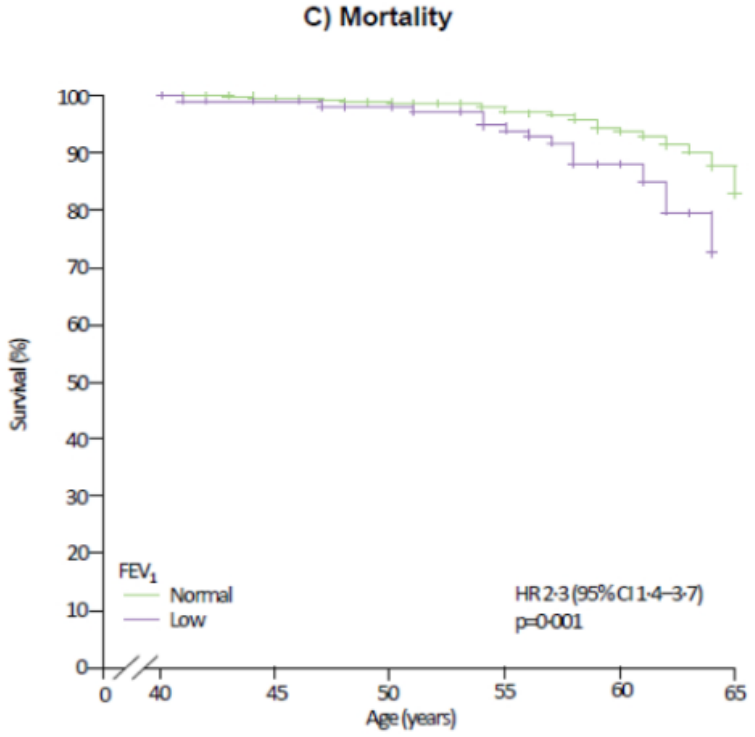
Screening and case finding

Screening spirometry is not indicated for aSx individuals without risks however..

FEV1 & FVC predict all cause mortality & lung cancer risk





Agustí A. Lancet Respir Med 2017;5:935–45Tammemagi MC. Cancer Prev Res (Phila) (2011) 4 (4): 552–561

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Initial pharmacologic therapy

NEW

≥ 2 moderate exacerbations or ≥ 1 leading to hospitalization

GROUP E

LABA + LAMA*

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

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

GROUP A

A bronchodilator

mMRC 0-1, CAT < 10

GROUP B

LABA + LAMA*

mMRC ≥ 2, CAT ≥ 10

OLD

INITIAL PHARMACOLOGICAL TREATMENT

≥ 2 moderate exacerbations or ≥ 1 leading to hospitalization

Group C

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

mMRC 0-1 CAT < 10

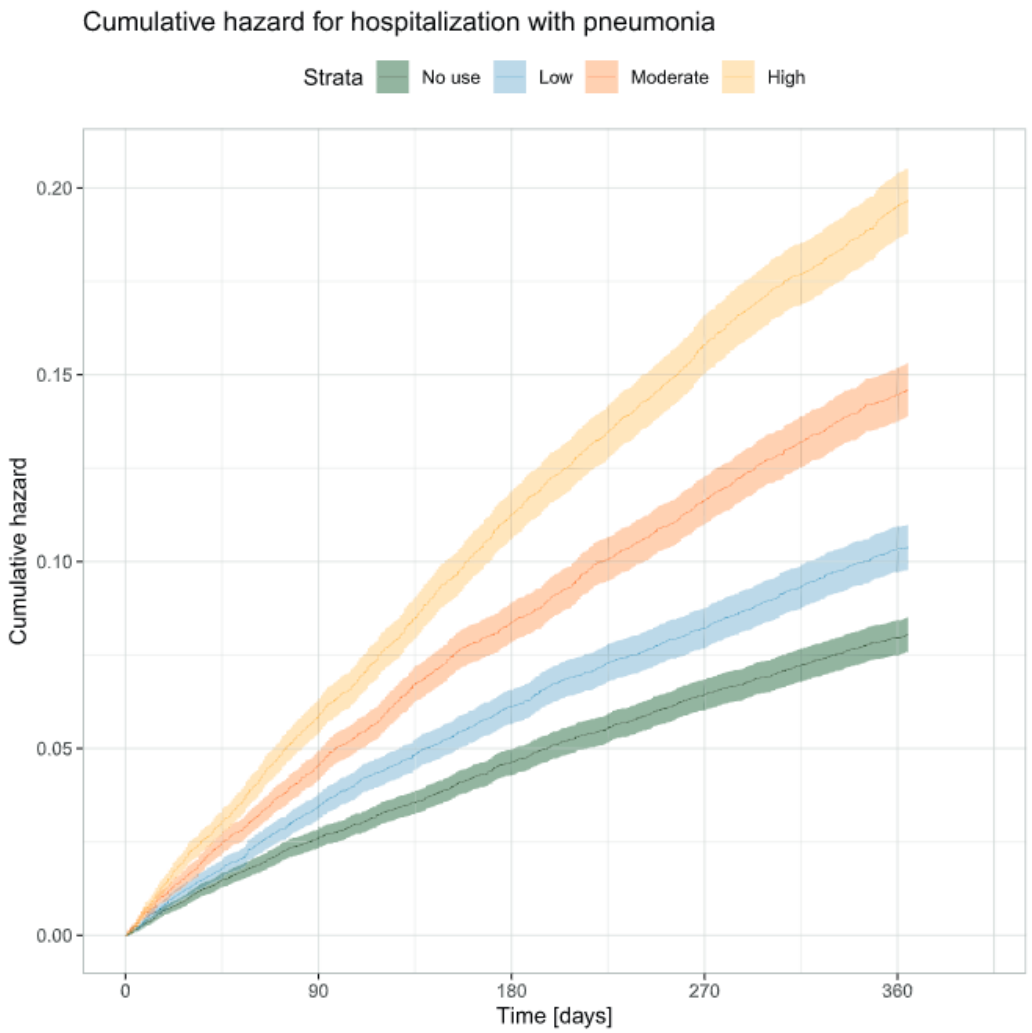
Group B

A Long Acting Bronchodilator (LABA or LAMA)

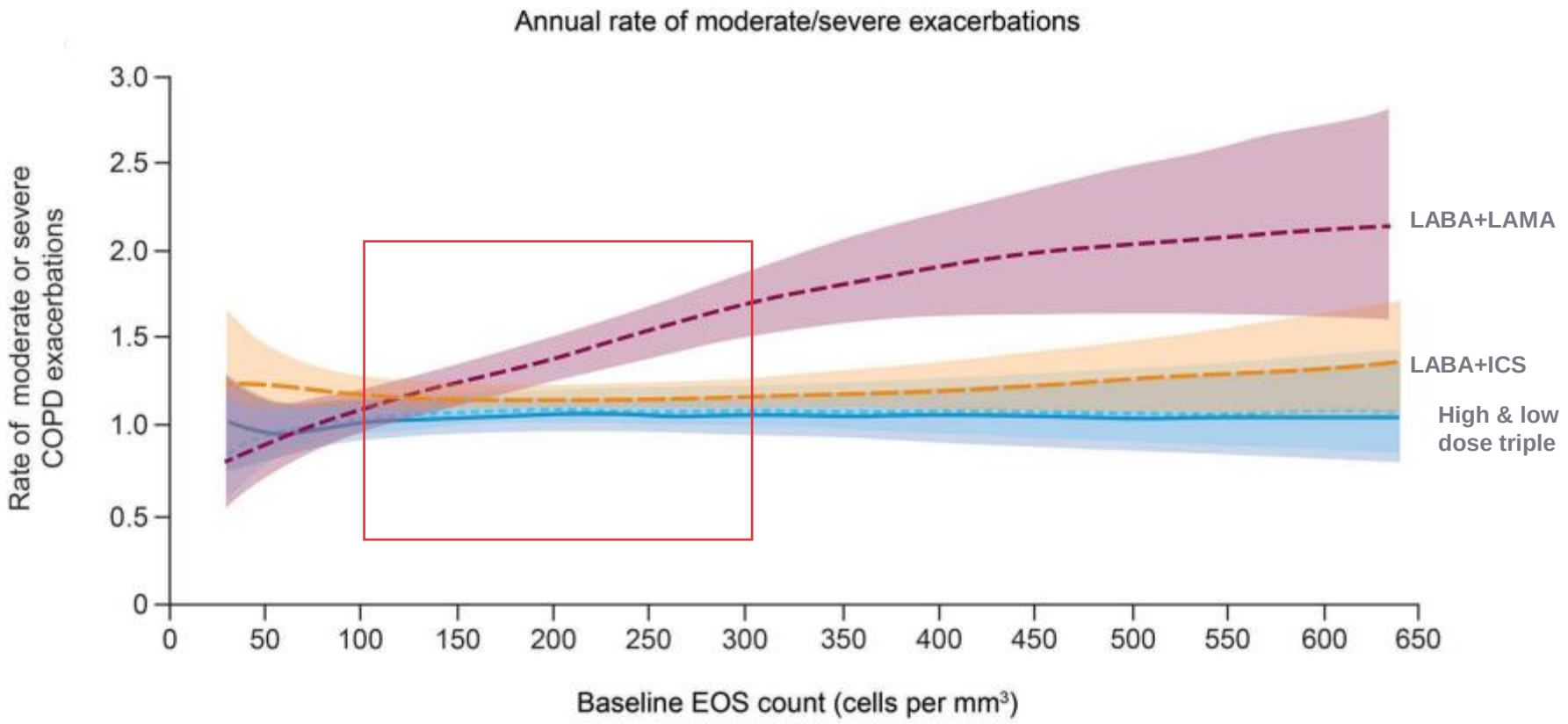
mMRC ≥ 2 CAT ≥ 10

*single inhaler therapy may be more convenient and effective than multiple inhalers
Exacerbations refers to the number of exacerbations per year

Implications – ICS associated PNA risk



Implications – ICS reduce AECOPD



Bafadhel M. Int J COPD 2022:17 3061

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Implications – eos guide risk vs benefit

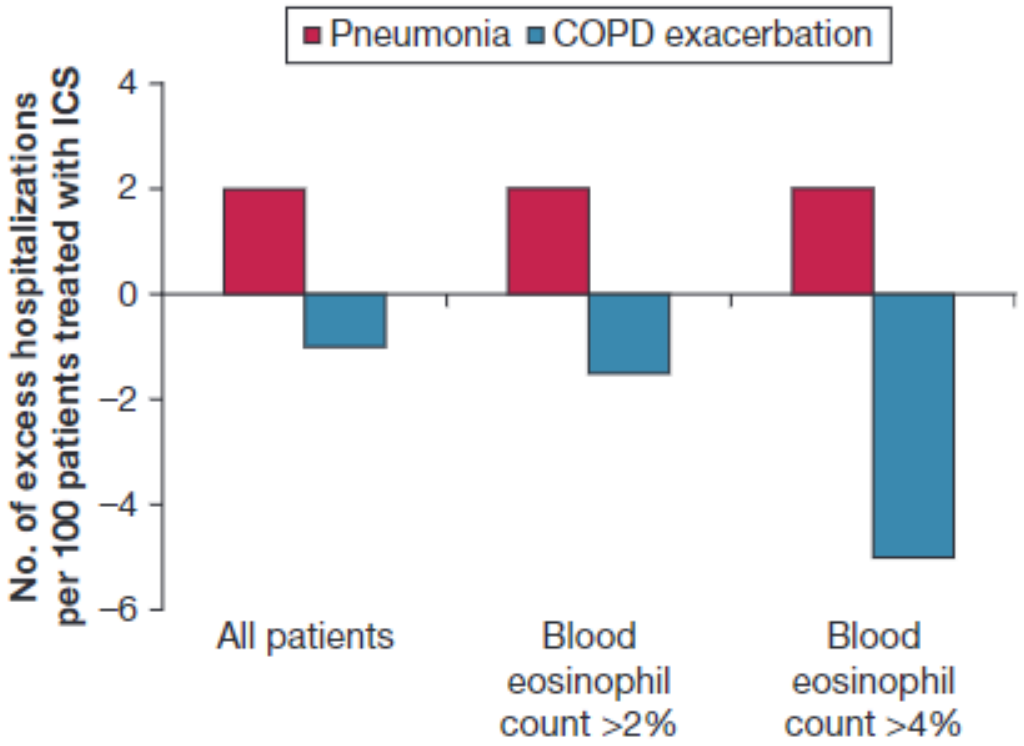
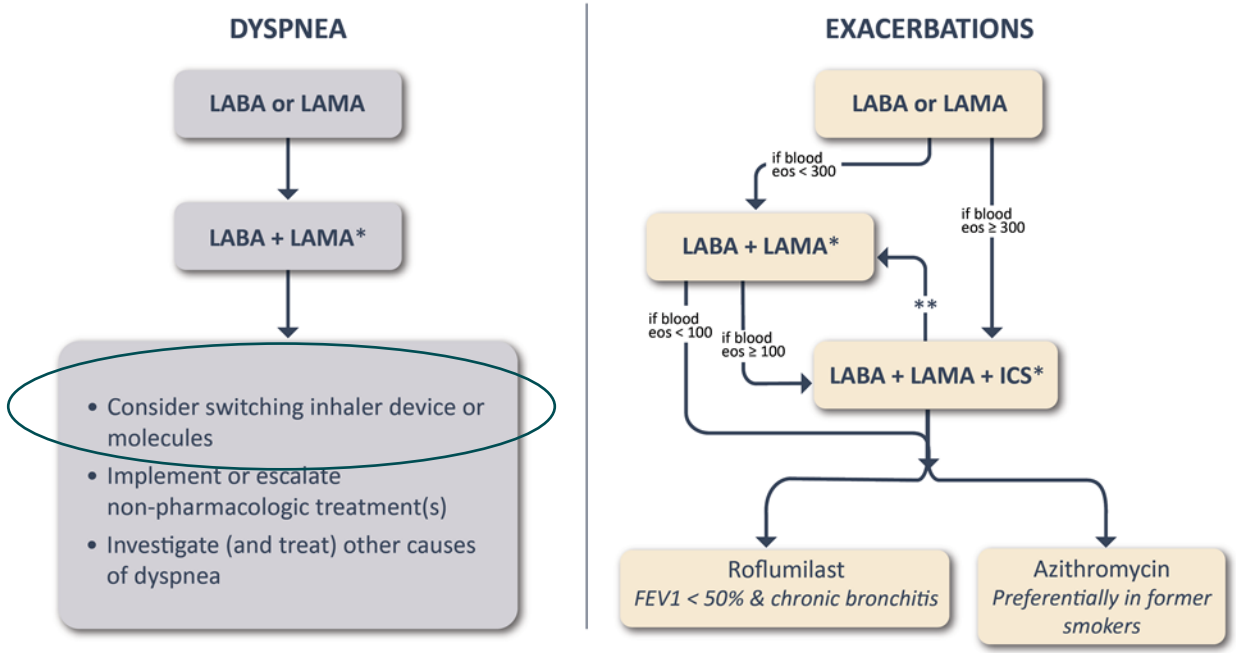


Figure 1 – *Expected excess incidence of hospitalization for COPD exacerbation and for pneumonia per 100 patients with COPD treated with ICS for 1 year, overall, and stratified according to two cutoff values of blood eosinophil count. ICS = inhaled corticosteroids.*

Suissa S. Chest 2017 p227

Follow-up pharmacologic therapy

1. **IF RESPONSE TO INITIAL TREATMENT IS APPROPRIATE, MAINTAIN IT.**
2. **IF NOT:**
   - Check adherence, inhaler technique and possible interfering comorbidities
   - 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 ABE assessment at diagnosis



*Single inhaler therapy may be more convenient and effective than multiple inhalers

**Consider de-escalation of ICS if pneumonia or other considerable side-effects. In case of blood eos ≥ 300 cells/µl de-escalation is more likely to be associated with the development of exacerbations

Exacerbations refers to the number of exacerbations per year

Mortality as a therapeutic endpoint

Therapy	RCT*	Treatment effect on mortality	Patient characteristics
Pharmacotherapy			
LABA+LAMA+ICS[1]	Yes	Single inhaler triple therapy compared to dual LABD therapy relative risk reduction: IMPACT: HR 0.72 (95% CI: 0.53, 0.99)[1a] ETHOS: HR 0.51 (95% CI: 0.33, 0.80)[1b]	Symptomatic people with a history of frequent and/or severe exacerbations
Non-pharmacological Therapy			
Smoking cessation[2]	Yes	HR for usual care group compared to intervention group (smoking cessation) HR 1.18 (95% CI: 1.02, 1.37)[2]	Asymptomatic or mildly symptomatic
Pulmonary rehabilitation[3#]	Yes	Old trials: RR 0.28 (95% CI 0.10, 0.84)[3a] New trials: RR 0.68 (95% CI 0.28, 1.67)[3b]	Hospitalized for exacerbations of COPD (during or ≤ 4 weeks after discharge)
Long-term oxygen therapy[4]	Yes	NOTT: ≥ 19 hours of continuous oxygen vs ≤ 13 hours: 50% reduction[4a] MRC: ≥ 15 hours vs no oxygen: 50% reduction[4b]	PaO_2 ≤ 55 mmHg or < 60 mmHg with *cor pulmonale* or secondary polycythemia
Noninvasive positive pressure ventilation[5]	Yes	12% in NPPV (high IPAP level) and 33% in control HR 0.24 (95% CI 0.11, 0.49)[5]	Stable COPD with marked hypercapnia
Lung volume reduction surgery[6]	Yes	0.07 deaths/person-year (LVRS) vs 0.15 deaths/person-year (UC) RR for death 0.47 (p = 0.005)[6]	Upper lobe emphysema and low exercise capacity

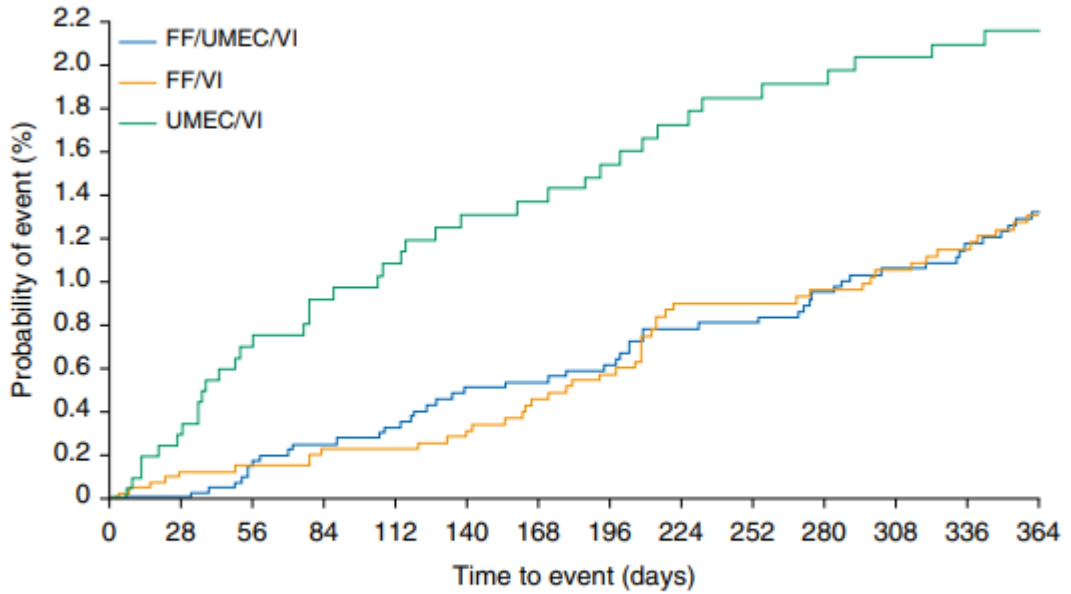
*RCT with pre-specified analysis of the mortality outcome (primary or secondary outcome); #Inconclusive results likely due to differences in pulmonary rehabilitation across a wide range of participants and settings.

1. a) IMPACT trial (Lipson et al. 2020) and b) ETHOS trials (Martinez et al. 2021); 2.Lung Health Study (Anthonisen et al. 2005); 3. a) Puhan et al. (2011) and b) Puhan et al. 2016; 4. a) NOTT (NOTT, 1980) and b) MRC (MRC, 1981); 5. Kohlein trial (Kohlein et al. 2014); 6. NETT trial (Fishman et al. 2003)

ICS: inhaled corticosteroid; IPAP: inspiratory positive airway pressure; LABA: long-acting beta$_2$-agonist; LABD: long-acting bronchodilator; LAMA: long-acting anti-muscarinic; LTOT: long-term oxygen therapy; NPPV: noninvasive positive pressure ventilation; LVRS: lung volume reduction surgery; UC: usual treatment control group.

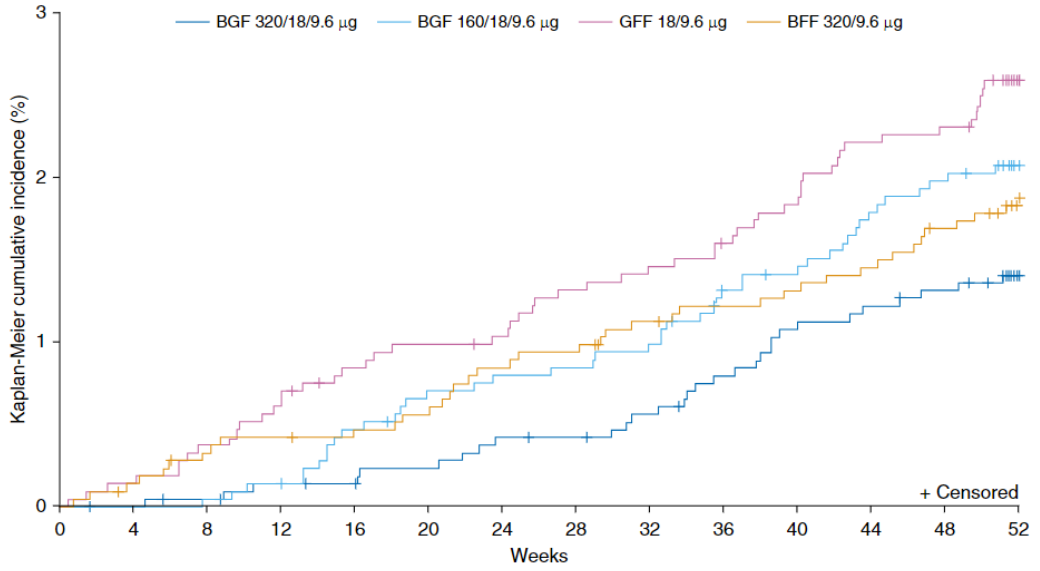
Implications – mortality

A



FF/UMEC/VI	4,151	4,082	3,968	3,898	3,838	3,752	3,714	3,690	3,613	3,581	3,545	3,486	3,454	3,346
FF/VI	4,134	3,984	3,798	3,694	3,619	3,496	3,443	3,391	3,291	3,258	3,230	3,182	3,152	3,044
UMEC/VI	2,070	1,993	1,880	1,820	1,769	1,713	1,685	1,656	1,612	1,595	1,578	1,548	1,531	1,485

Figure 1. Kaplan-Meier plots of time to all-cause mortality for (*A*) on-treatment deaths and (*B*) on/off-treatment deaths. FF = fluticasone furoate; UMEC = umeclidinium; VI = vilanterol.



Patients at risk														
BGF 320/18/9.6 µg	2,137	2,136	2,134	2,131	2,130	2,127	2,123	2,122	2,118	2,112	2,106	2,103	2,100	2,075
BGF 160/18/9.6 µg	2,121	2,121	2,120	2,118	2,110	2,104	2,102	2,101	2,098	2,087	2,084	2,076	2,072	2,062
GFF 18/9.6 µg	2,120	2,117	2,112	2,106	2,100	2,097	2,095	2,089	2,086	2,082	2,077	2,069	2,067	2,045
BFF 320/9.6 µg	2,131	2,127	2,122	2,120	2,118	2,116	2,110	2,108	2,102	2,099	2,097	2,094	2,088	2,075

Figure 2. Kaplan-Meier plot for time to all-cause death (final retrieved dataset; intent-to-treat population). BFF = budesonide/formoterol fumarate; BGF = budesonide/glycopyrrolate/formoterol fumarate; GFF = glycopyrrolate/formoterol fumarate.

Lipson DA . Am J Respir Crit Care Med 2020, pp 1508–1516 (IMPACT)
Martinez FJAm J Respir Crit Care Med 2021 (ETHOS)

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Implications – eos & mortality

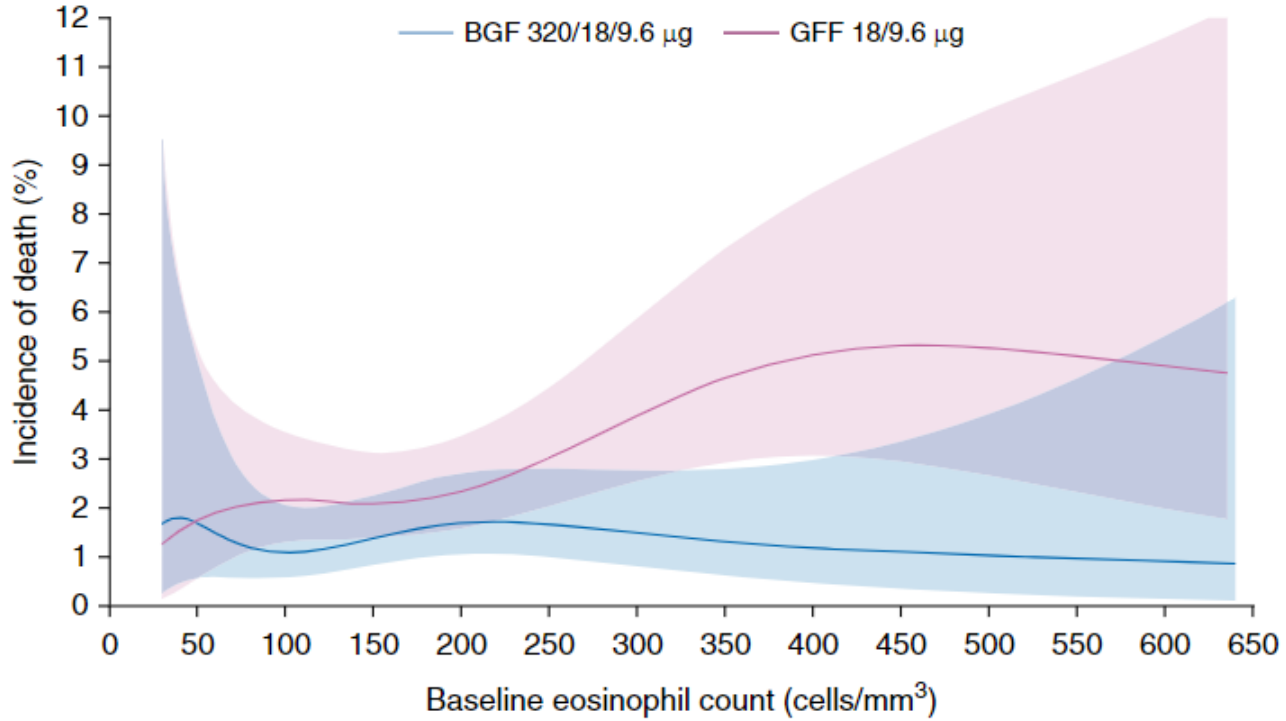

Figure 5. Incidence of death by baseline blood eosinophil count for 320/18/9.6 µg BGF versus GFF (final retrieved dataset; intent-to-treat population). Data are from a generalized additive model. Banded areas indicate 95% CIs that reflect the skewed distribution of eosinophil counts, (i.e., 17.3% of patients had counts <100 cells/mm^3, 67.9% had 100–300 cells/mm^3, and 14.7% had >300 cells/mm^3). BGF = budesonide/glycopyrrolate/formoterol fumarate; CI = confidence interval; GFF = glycopyrrolate/formoterol fumarate.

Martinez FJ Am J Respir Crit Care Med 2021 (ETHOS)

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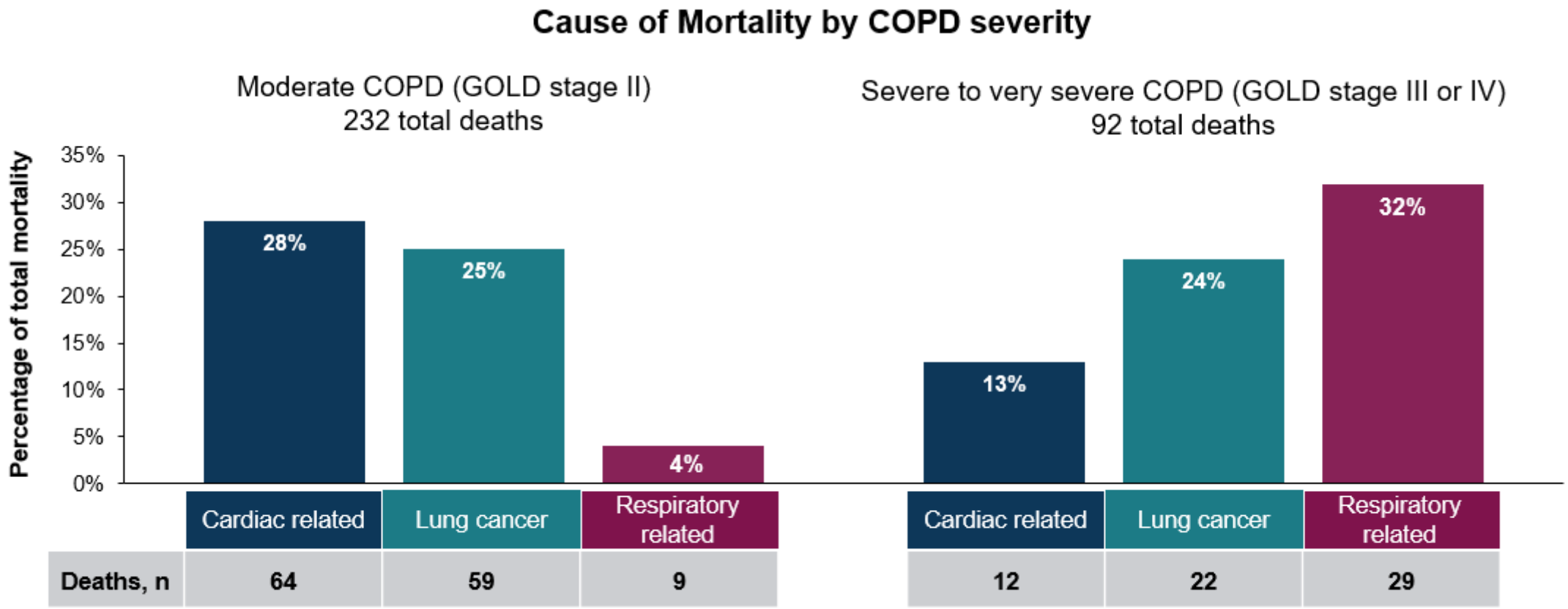
Implications – cause of death



Mannino DM. Respir Med 2006 100:115 (ARIC)

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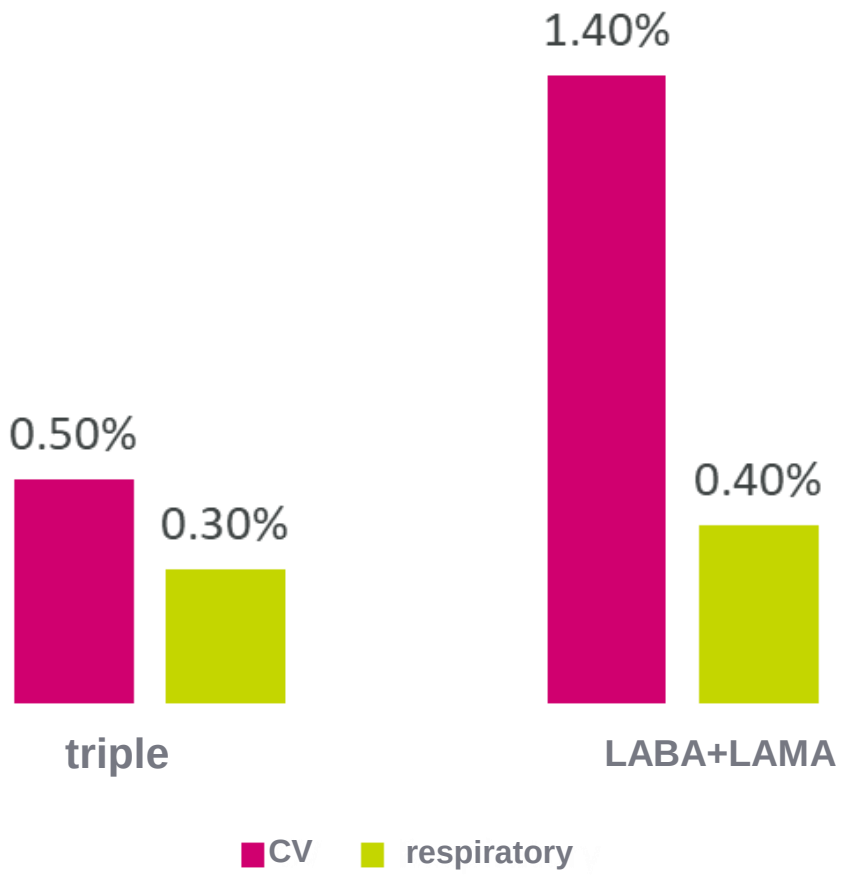
Implications – CV deaths

Difference versus LAMA/LABA driven by reduction in CV events (ETHOS causes of death)



Martinez FJ Am J Respir Crit Care Med 2021 (ETHOS)

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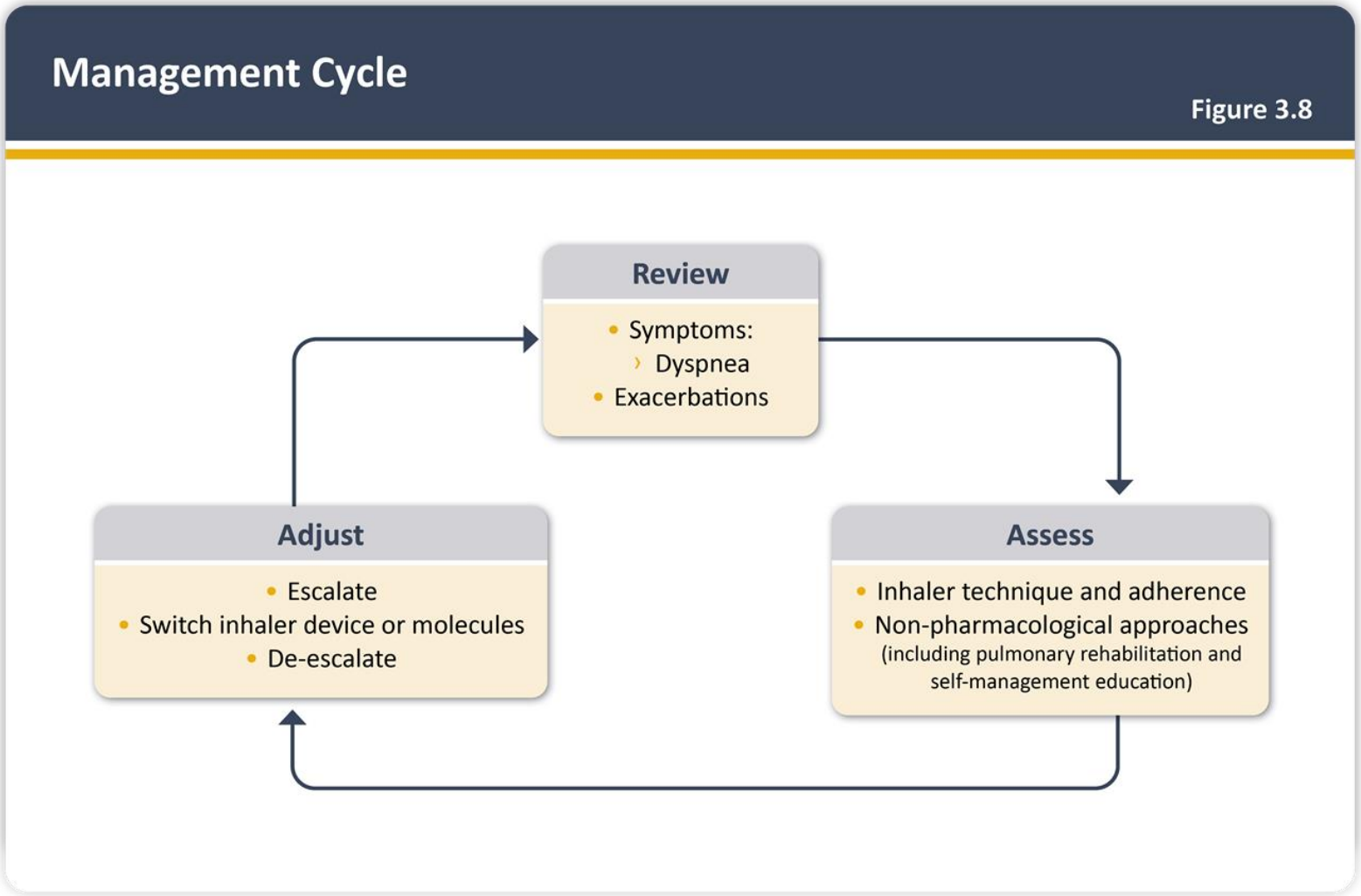
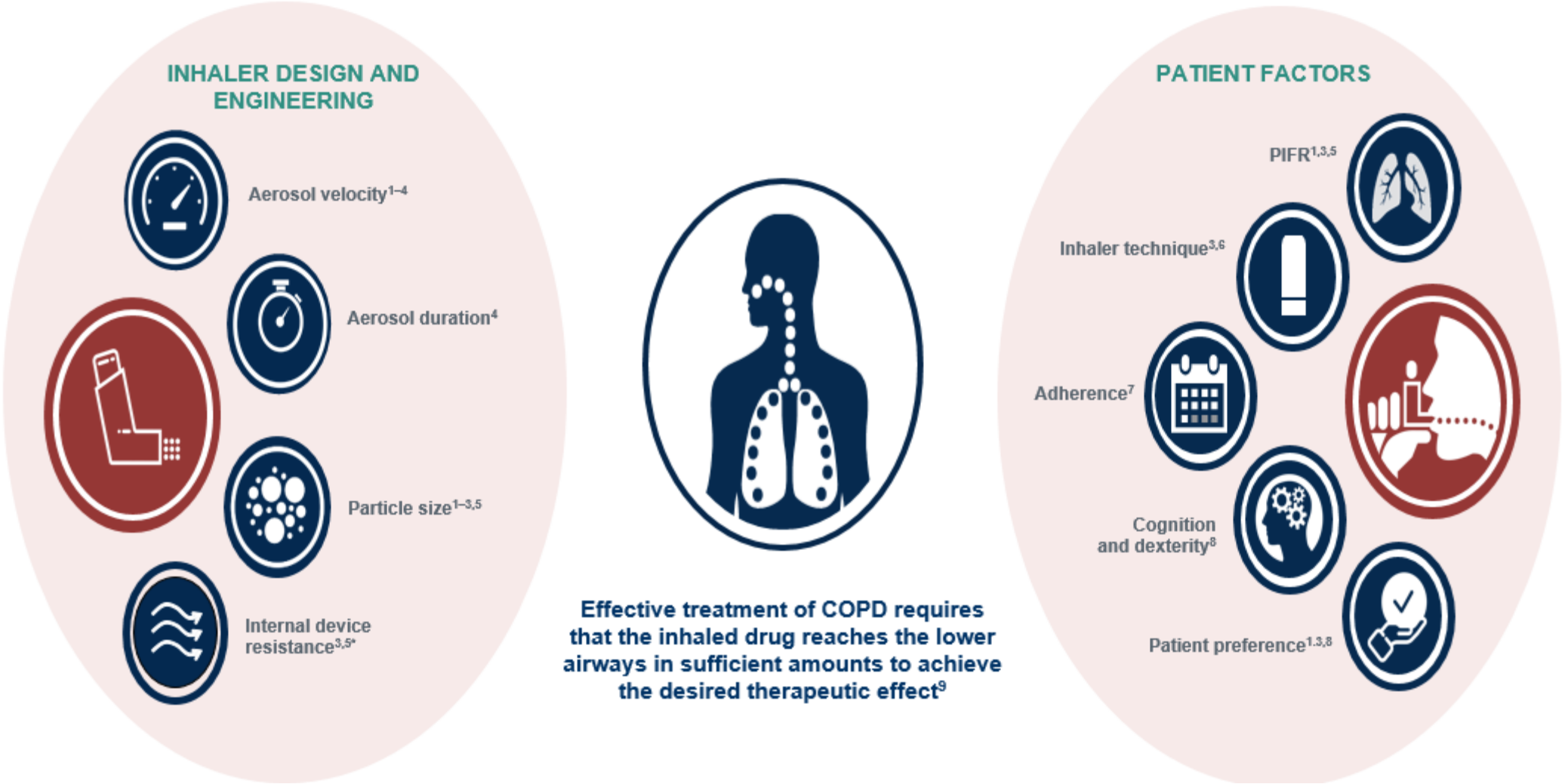
Management cycle

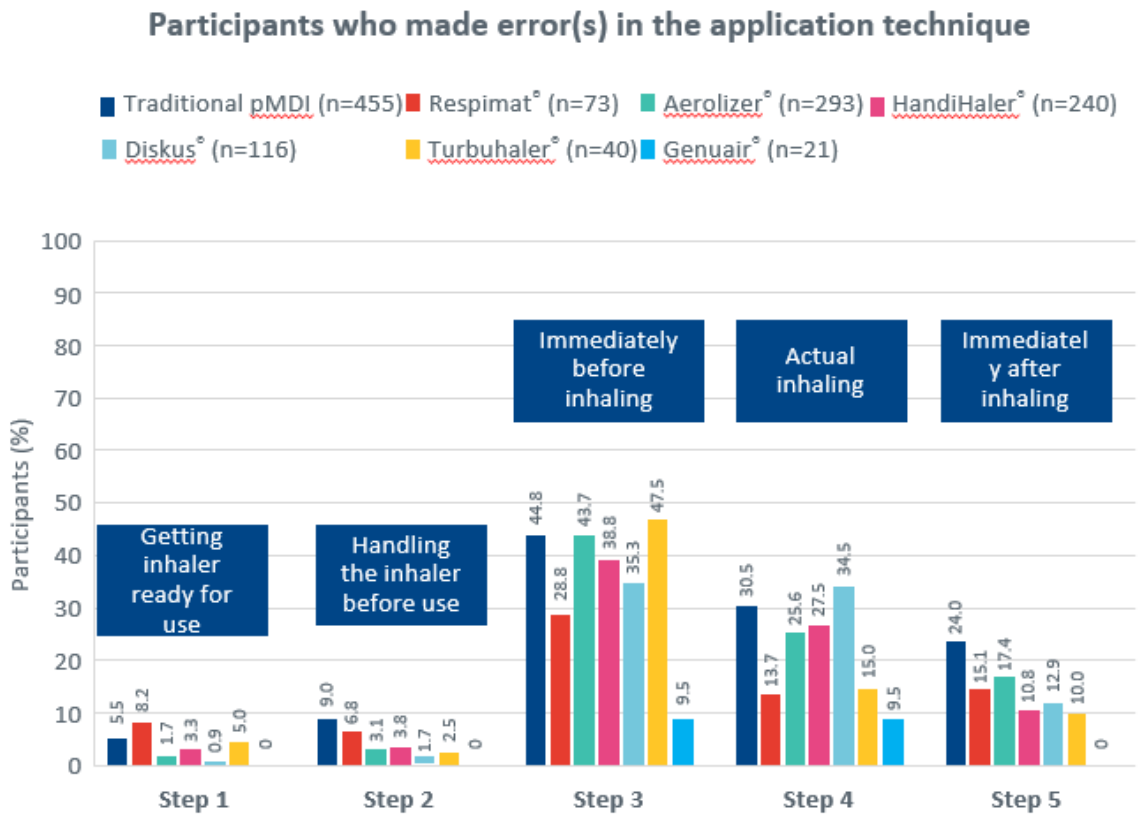


Inhaler delivery-appropriate device choice



1. Usmani OS, et al. Ther Clin Risk Manag 2019 461–472; 2. Dalby RN, et al. Med Devices (Auckl) 2011; 4: 145–155; 3. Capstick TG, Clifton IJ. Expert Rev Respir Med 2012; 6: 91–103; 4. Hochrainer D, et al. J Aerosol Med 2005; 18: 273–282; 5. Virchow JC, et al. Respir Med 2008; 102: 10–19; 6. Newman SP. Eur Respir Rev 2005; 14: 102–108; 7. Darba J, et al. Int J Chron Obstruct Pulmon Dis 2015; 10: 2335–2345; 8. Rogliani P, et al. Respir Med 2017; 124: 6–14; 9. Ganderton D. J Aerosol Med 1999; 12 Suppl 1: S3–S8.

Inhaler delivery - errors



The most problematic steps were **breathing out completely in one breath** before inhalation (Step 3) and the **actual inhalation maneuver** (Step 4)

Inhaler delivery - errors

Patients often report they use good techniques even when error rates are high[2]
Patients may not realize they are committing technique errors[3]

pMDI		DPI	
Correct technique	Most common error	Correct technique	Most common error
Breathe out before actuating	No exhalation before actuation	Inhale quickly and deeply	Stop inhaling prematurely (not inhaling to total lung capacity)
Actuate while breathing in deeply and slowly, and continue until total lung capacity	Forceful inhalation	Forceful and deep inhalation	Slow and not forceful inhalation
Hold breath	No, or short, breath-holding after inhalation	Hold breath	No breath-holding after inhalation

Occurred in >20% of users. Observational study, N=1664.[1]

1. Melani AS. Respir Med. 2011p930. 2. Souza MLM. J Bras Pneumol. 2009p824. 3. Jahedi L. J Aerosol Med Pulm Drug Deliv. 2017p42.

Non-pharmacologic therapy

Non-Pharmacologic Management of COPD*

Table 4.9

Patient Group	Essential	Recommended	Depending on Local Guidelines
A	Smoking Cessation (can include pharmacological treatment)	Physical Activity	Flu Vaccination Pneumococcal Vaccination* Pertussis Vaccination COVID-19 Vaccinations Shingles Vaccination
B and E	Smoking Cessation (can include pharmacological treatment) Pulmonary Rehabilitation	Physical Activity	Flu Vaccination Pneumococcal Vaccination* Pertussis Vaccination COVID-19 Vaccinations Shingles Vaccination

*Can include pharmacologic treatment

*one dose of 20-valent (PCV20) or one dose of 15-valent followed by 23-valent (PPSV23)

Interventions that Reduce the Frequency of COPD Exacerbations

Figure 4.11

Intervention Class	Intervention
Bronchodilators	LABAs LAMAs LABA + LAMA
Corticosteroid-containing regimens	LABA + ICS LABA + LAMA + ICS
Anti-inflammatory (non-steroid)	Roflumilast
Anti-infectives	Vaccines Long Term Macrolides
Mucoregulators	N-acetylcysteine Carbocysteine Erdosteine
Various others	Smoking Cessation Rehabilitation Lung Volume Reduction Vitamin D Shielding measures (e.g., mask wearing, minimizing social contact, frequent hand washing)

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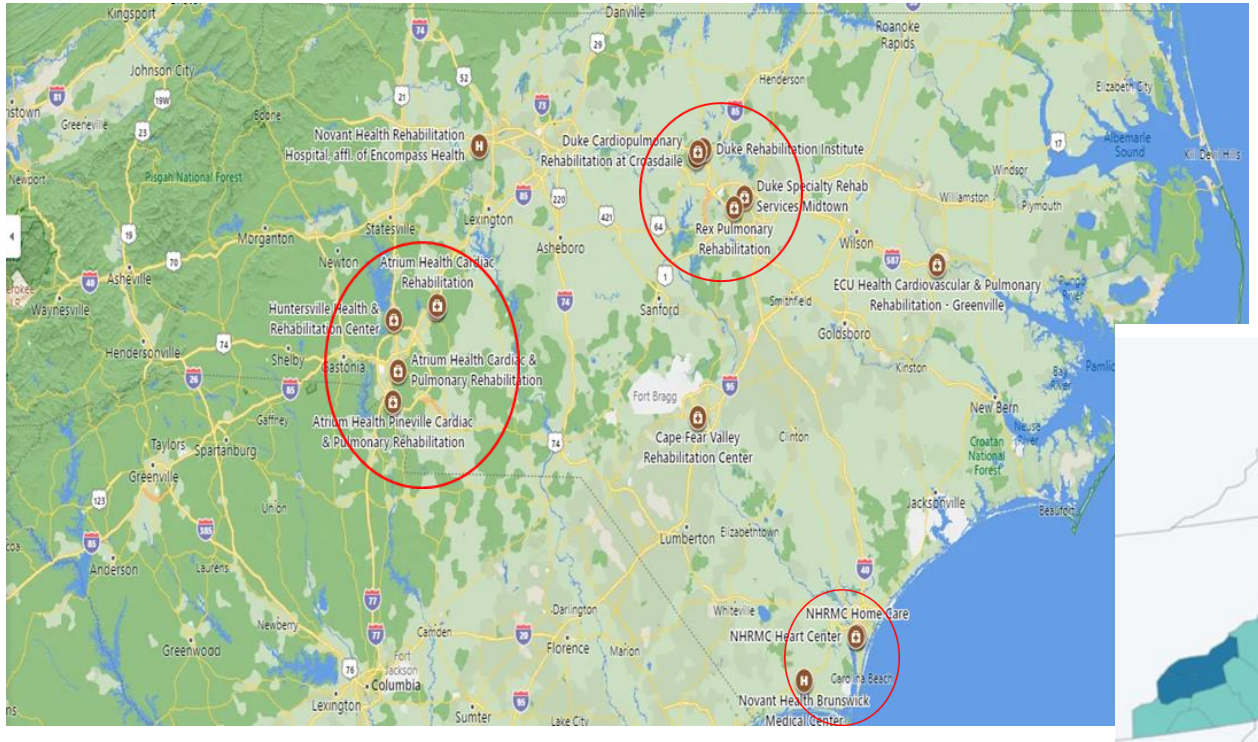
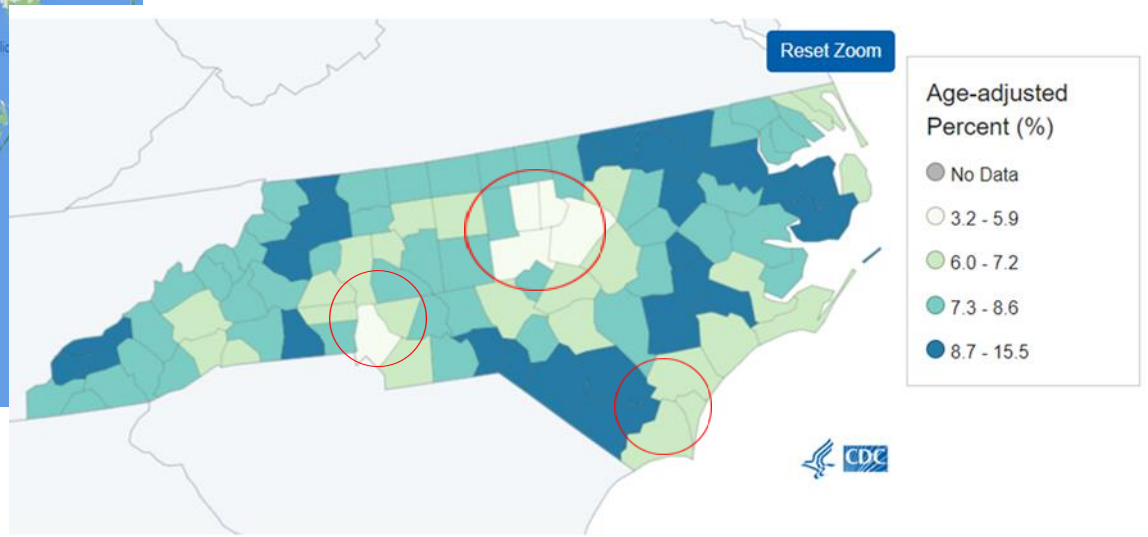
Pulmonary rehabilitation reduces mortality



BUT……**PR programs cluster in population centers away from high burden of disease**



Data sources: The model-based estimates were generated using data from BRFSS 2019 and ACS 2015-2019, and 2019 Census county population estimates.

Download Data (CSV)

Tele-rehabilitation – the 97% soln.

Outcome	Improved [a]	Inferior [b]	Not Different [c]	Not Inferior [d]
6MWT	Rutkowski et al. [17], Bernocchi et al. [18]		Hansen et al. [16], Paneroni et al. [23]	Bourne et al. [21]
CRQ dyspnea		Horton et al. [19]	Chaplin et al. [22]	
ESWT			Chaplin et al. [22]	
mMRC	Tabak et al. [24]		Paneroni et al. [23]	
SGRQ	Stickland et al. [25] —so did traditional		Paneroni et al. [23]	
CAT				Bourne et al. [21]
Arm Curl	Rutkowski et al. [17]			
Chair Stand	Rutkowski et al. [17]			
Up and Go	Rutkowski et al. [17]			
Physical Activity (steps per day)	Paneroni et al. [23]			

CRQ: Chronic Respiratory Disease; ESWT: Endurance Shuttle Walk Test; CAT: COPD Assessment Test; HADS: Hospital Anxiety and Depression Scale; mMRC: Modified Medical Research Council; SGRQ: St. George's Respiratory Questionnaire; 6MWT: 6 Minute Walk Test. [a] Statistically significant improvement found in both groups. [b] In this non-inferiority study tele-rehab was found to be inferior to conventional PR. [c] No statistical difference in outcomes between intervention and control group. [d] Non inferiority threshold reached in the non-inferiority RCT.

Rawal, H.; Cornelison, S.D.;Flynn, S.M.; Ohar, J.A. Life2021, 11, 1270. https://doi.org/10.3390/life11111270

GOLD 2024 update:

implications for clinical practice

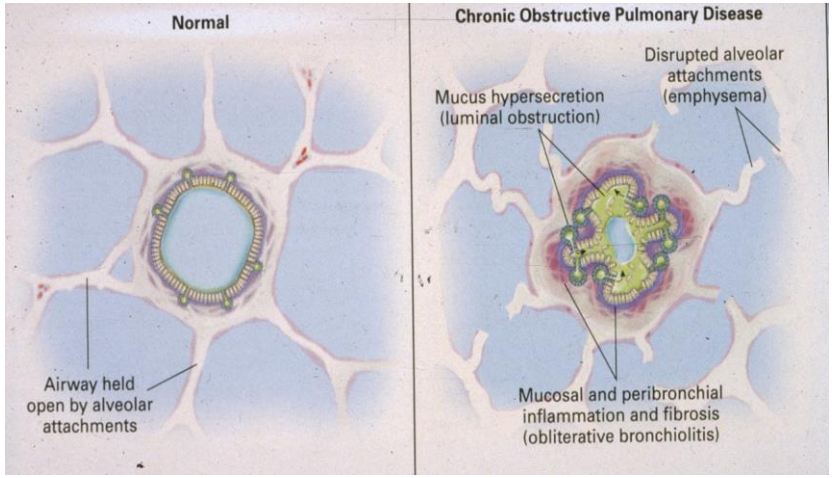
Atrium Health
Wake Forest Baptist

PRISM

- Post BD preserved ratio (FEV1/FVC > 0.7) but impaired spirometry (FEV1 and or FVC <80%) prevalence 7.1 to 20.3%. May transition to normal or obstruction over time.
- Prevalence: 7.1-11% in cohort studies; higher in current of former smokers (10.4-11.3%)
- Associated with: high and low BMI, obesity, female gender and multimorbidity
- Not a stable phenotype: may transition to normal or COPD (20-30%)
- Predictors for transition to COPD: age, current smoking, female, lower BL FEV1% predicted and FEV1/FVC

Hyperinflation

- Occurs when gas volume in the lungs is increased compared to normal at the end of a spontaneous exhalation - may reduce FVC
- Contributes to dyspnea, impaired exercise tolerance, hospitalization, development of respiratory failure and mortality
- May be improved with bronchodilators, heliox, pulmonary rehabilitation, pursed lip breathing, lung reduction therapies
- Due to loss of elastic recoil and airflow obstruction
- Can be static or dynamic

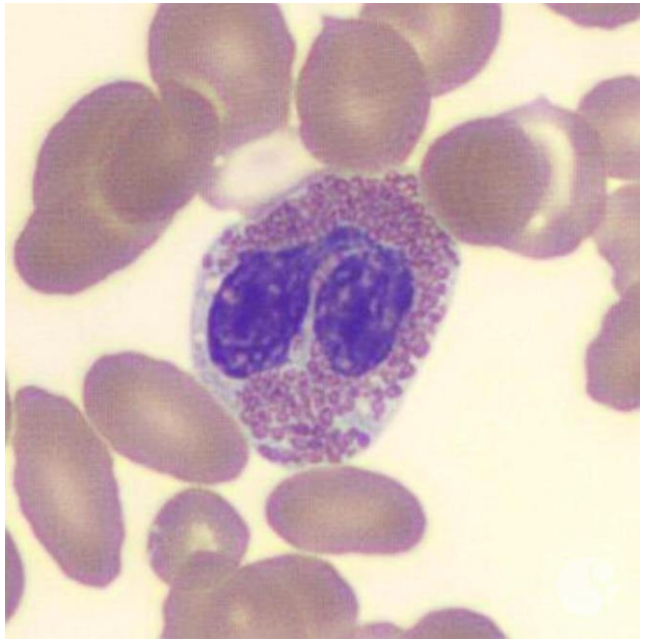


Screening for COPD

- USPSTF recommends against screening in normal aSx populations
- Does recommend lung cancer screening in patients 50-80 years, with a 20 pack-year smoking history
- GOLD recommends spirometry in patients undergoing lung CT for lung cancer surveillance or when incidental lung abnormalities are found that are c/w COPD (a/w thickening, emphysema, mucus plugging, air trapping)
- Air flow obstruction present is 34-57% of spirograms performed at screening CT
- Emphysema present in 68-73%, with 67% no prior Dx in either group (in some studies up to 90% prevalence without prior Dx)

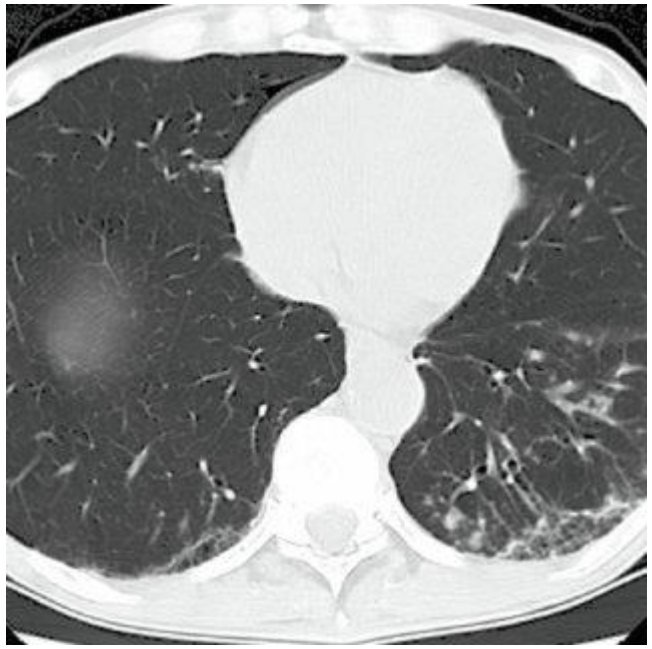
Blood eosinophil count

- Predict response to addition of ICS to bronchodilators
- Studies variable regarding eosinophil count's ability to predict future AECOPD
- Higher eosinophil counts are associated with greater annual decline in FEV1 in populations with low ICS use



Interstitial lung abnormalities

- Found in 4-9% of adults>60 years
- Affects Sx and mortality
- ½ of these in COPDGene met criteria for ILD defined as one of the following:
  - Definite fibrosis on CT defined as :
    - Traction bronchiectasis
    - Architectural distortion
    - honeycombing
  - FVC <80%
  - DLCO <70%



Smoking cessation

- 40% of COPD patients still smoke
- Assessment of nicotine dependence should be made
  - Within 30 min of awakening
  - Smoking at night
  - >20 cigarettes/day
  - Score of 7-10 on Fagerstrom
  - 5-6 on the Heaviness of Smoking Index
- PharmacoRx
  - Controller Rx
  - Rescue Rx
  - Efficacy of vaping is controversial

- Rescue

Vaccination recommendations

Vaccination for Stable COPD

Figure 3.6

- Influenza vaccination is recommended for 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) for people with COPD **(Evidence B)**
- Pneumococcal vaccination has been shown to reduce the incidence of community-acquired pneumonia and exacerbations for people with COPD **(Evidence B)**
- The CDC recommends the new respiratory syncytial virus (RSV) vaccine for individuals over 60 years and/or with chronic heart or lung disease **(Evidence A)**
- 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)**

Managing Inhaled therapies

Basic Principles for Appropriate Inhalation Device Choice

Figure 3.11

- Availability of the drug in the device
- Patients' beliefs, satisfaction with current and previous devices and preferences need to be assessed and considered
- The number of different device types should be minimized for each patient. Ideally, only one device type should be used
- Device type should not be switched in the absence of clinical justification nor without proper information, education and medical follow-up
- Shared decision-making is the most appropriate strategy for inhalation device choice
- Patient's cognition, dexterity and strength must be taken into account
- Patient's ability to perform the correct specific inhalation maneuver for the device must be assessed:
  - Dry powder inhalers are appropriate only if the patient can make a forceful and deep inhalation. Check visually that the patient can inhale forcefully through the device - if there is doubt assess objectively or choose alternative device
  - Metered-dose inhalers and, to a lesser extent, soft mist inhalers require coordination between device triggering and inhalation and patients need to be able to perform a slow and deep inhalation. Check visually that the patient can inhale slowly and deeply from the device - if there is doubt consider adding a spacer/VHC or choose an alternative device
  - For patients unable to use an MDI (with or without spacer/VHC), SMI or DPI a nebulizer should be considered
- Other factors to consider include size, portability, cost
- Smart inhalers may be useful if there are issues with adherence/persistence or inhalation technique (for devices that can check it)
- Physicians should prescribe only devices they (and the other members of the caring team) know how to use

Summary

- New definition – introduces structure as important in phenotyping
- FEV1 trajectories and their impact on terminology
  - mild COPD
  - young COPD
  - pre-COPD
  - PRISm
- Rethinc trial
- Taxonomy – not just cigarettes anymore
- Active case finding
- Group E – E is for elephant in the room
  - EOS
  - AECOPD
  - ICS
- Mortality as an endpoint
- Inhaler device choice
- Pulmonary rehabilitation