COPD 2024 GOLD Guideline Update AAPA 2024 – Houston, Texas

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Disclosures

INDUSTRY AFFILIATIONS Grifols Pharmaceutical - speaker, consultant AstraZeneca – advisory board Regeneron – advisory board

CLINICAL RESEARCH 2017 – Sub-I, Genetech Zenyatta Severe Asthma Study 2016 – Sub-I, Biota Human Rhinovirus Study 2015 – Sub-I, Sanofi Traverse Severe Asthma Study 2015 – Sub-I, Sanofi Liberty Severe Asthma Study 2013 – Study Coordinator: MediVector Influenza Study

Brian Bizik does not intend to discuss the use of any off-label use/unapproved use of drugs or devices with the exception of NON-APPROVED inhaler recommendations that are Guideline based but not yet FDA approved (asthma only).

- Review medication classes for COPD and new inhalers
- Talk over the guidelines, focus on the changes that you must know
- Some tips for personalized respiratory care/exacerbations and smoking cessation



Plan For Today

Nearly all PAs/NPs must treat COPD



Asthma and COPD

 Asthma – bronchoconstriction, airway inflammation, mucous production

 COPD – Tissue destruction, chronic cough, due to exposure

COPD – Chronic (long term, you get this over time), Obstructive (elasticity is gone, things get floppy and weak, alveoli break down)



COPD – Big, floppy lungs. Flattened diaphragm. Harder to inhaler but MUCH hard to exhale, air is trapped, stale.



Normal Lungs

Hyperinflated Lungs



Respiratory medications: We have three categories of medications



Medication Categories

Albuterol – short acting bronchodilator, relaxes smooth muscle. Binds to beta receptors on smooth muscle, causing about a billion things to happen that drop the calcium in the cell and it relaxes.

Salmeterol/formoterol/vilanterol – Same thing as above but lasts 12 or 24 hours

Code for English Inhalers



Code for Spanish Inhalers





Respiratory medications: We have three categories of medications



Medication Categories: Steroids

- Corticosteroids bind to the glucocorticoid receptor and mediate changes in gene expression that lead to multiple downstream effects over hours to days.
- Almost every inflammation mediator is reduced
- Many actions, all with a central goal of reducing inflammation at the source
- Most aspects of inflammation are affected



Respiratory medications: We have three categories of medications

SAMA/LAMA

Short – SAMA Long – LAMA

Anticholinergic and constriction prevention

Medication Categories: SAMA/LAMA

 Ipratropium bromide is our only short acting muscarinic, and there are several long acting

 These are anti-cholinergic medications that dry up secretions and help prevent constriction



Respiratory medications: We have three categories of medications



FOR REFERENCE

RESPTREC® & EDUCATOR COURSE COPD MEDICATIONS

www.resptrec.org www.lungsask.ca





GLOBAL INITIATIVE FOR CHRONIC OBSTRUCTIVE LUNG DISEASE (GOLD):



www.goldcopd.org

Global Initiative for Chronic Obstructive Lung Disease 2024 REPORT



https://goldcopd.org/wp-content/uploads/2023/12/GOLD-2024_v1.1-1Dec2023_WMV.pdf

COPD Defined

'A common preventable and treatable disease, is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. Exacerbations and comorbidities contribute to the overall severity in individual patients.'

COPD is Underdiagnosed



COPD Diagnosis Considerations

Consider COPD and perform spirometry if any of these indicators are present in a patient over 40 years of age:

Symptom	Detail
Dyspnea that is:	 Progressive over time Characteristically worse with exercise Persistent
Chronic cough	May be intermittent and unproductiveRecurrent wheeze
Chronic sputum production	 Any pattern of chronic sputum production may indicate COPD
Recurrent LRTIs	
History of risk factors	 Host factors (eg, genetic factors, congenital/developmental abnormalities) Tobacco smoke Smoke from home cooking and heating fuels Occupational dusts, vapors, fumes, gases and other chemicals
Family history of COPD and/or childhood factors	 Examples include: low birthweight, childhood respiratory infections, Hx of Alpha-1 Antitrypsin Deficiency or unexplained pulmonary disease

These indicators are not diagnostic themselves, but the presence of multiple key indicators increases the probability of a diagnosis of COPD. COPD, chronic obstructive pulmonary disease; GOLD, Global Initiative for Chronic Obstructive Lung Disease; LRTI, lower respiratory tract infection. 2023 GOLD Report. https://goldcopd.org/2023-gold-report-2/.

Spirometry or PFTs are Required



<u>ل</u>

COPD, chronic obstructive pulmonary disease; GOLD, Global Initiative for Chronic Obstructive Lung Disease; FEV₁, forced expiratory volume in one second; FVC, forced vital capacity. 2023 GOLD Report. https://goldcopd.org/2023-gold-report-2/.

COPD Diagnosis Considerations

CLASSIFICATION OF AIRFLOW LIMITATION SEVERITY IN COPD (BASED ON POST-BRONCHODILATOR FEV₁)

In patients with FEV1/FVC < 0.70:

GOLD 1:	Mild	$FEV_1 \ge 80\%$ predicted	
GOLD 2:	Moderate	$50\% \leq FEV_1 < 80\%$ predicted	
GOLD 3:	Severe	$30\% \le FEV_1 < 50\%$ predicted	
GOLD 4:	Very Severe	$FEV_1 < 30\%$ predicted	

In patients with FEV1/FVC < 0.70:

This is comparing the patient to themselves

CLASSIFICATION OF AIRFLOW LIMITATION SEVERITY IN COPD (BASED ON POST-BRONCHODILATOR FEV₁)

In patients with FEV1/FVC < 0.70:

GOLD 1:	Mild	FEV₁ ≥ 80% predicted
GOLD 2:	Moderate	$50\% \le FEV_1 < 80\%$ predicted
GOLD 3:	Severe	$30\% \leq FEV_1 < 50\%$ predicted
GOLD 4:	Very Severe	FEV ₁ < 30% predicted

This is comparing the patient to a peer based on height, weight, age, gender and ethnicity.

COPD Diagnosis and Treatment



So do this once, then, the good news . . .

COPD Diagnosis and Treatment



COPD Diagnosis and Treatment



Set this aside and ask them how they are doing

CLASSIFICATION OF AIRFLOW LIMITATION SEVERITY IN COPD (BASED ON POST-BRONCHODILATOR FEV₁)

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GOLD 3:	Severe	$30\% \leq FEV_1 < 50\%$ predicted
GOLD 4:	Very Severe	FEV ₁ < 30% predicted



Just like with asthma, every visit needs to start with an assessment of symptoms, exacerbations and overall condition

CAT™ ASSESSMENT

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 never cough (0) (1) (2) (3) (4) (5) I cough all the time I have no phlegm (mucus) (0) (1) (2) (3) (4) (5) My chest is completely full of phlegm (mucus) My chest at all (0) (1) (2) (3) (4) (5) My chest feels very tight 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	EXAMPLE: I am very happy	0 2 3 4 5	I am very sad	SCORE
I have no phlegm (mucus) (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 despite 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	l never cough	012345	I cough all the time	
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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	I am confident leaving my home despite my lung condition	012345	I am not at all confident leaving my home because of my lung condition	
I have lots of energy 0 1 2 3 4 5 I have no energy at all	I sleep soundly	012345	I don't sleep soundly because of my lung condition	
	I have lots of energy	012345	I have no energy at all	
Beference: Jones et al. EBJ 2009: 34 (3): 648-54				

Quick Review

- **COPD** is widespread and largely underdiagnosed
- Most are tobacco related but there are others
- Consider this in patients with chronic issues
- You need spirometry to get the diagnosis and stage of COPD
- But the stage DOES NOT equal quality of life, life expectancy and does not effect treatment decisions
- Once this is done, you don't need to repeat it, now we just want to know
 - How are you?
 - How often are you sick?





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

GROUP A A bronchodilator

mMRC 0-1, CAT < 10



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

GROUP B

LABA + LAMA*

mMRC \geq 2, CAT \geq 10



GROUP E

LABA + LAMA*

consider LABA+LAMA+ICS* if blood $eos \ge 300$

mMRC 0-1, CAT < 10

mMRC \geq 2, CAT \geq 10



Inhaled Steroids (ICS)

If not needed don't use them!

Increased risk of all URIs and increased risk of pneumonia and exacerbations

Fluticasone is the worst

GROUP E

LABA + LAMA*

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

Meta-Analysis> Int Immunopharmacol. 2019 Dec;77:105950. doi: 10.1016/j.intimp.2019.105950.Epub 2019 Oct 17.

Inhaled corticosteroids and risk of pneumonia in patients with chronic obstructive pulmonary disease: A meta-analysis of randomized controlled trials

Mingjin Yang ¹, Yuejun Du ¹, Hong Chen ¹, Depeng Jiang ², Zhibo Xu ³ Affiliations **+** expand PMID: 31629940 DOI: 10.1016/j.intimp.2019.105950

Abstract

Objective: Inhaled corticosteroids (ICS) are generally used to treat patients with chronic obstructive pulmonary disease (COPD) who suffer from repeated exacerbations. Recently, it was reported that ICS treatment increased the risk of pneumonia in COPD patients. But it is controversial. The objective of this paper is to clarify the associations between ICS treatment and the risk of pneumonia in COPD patients.

Methods: PubMed, Cochrane Library, Clinical Trials.gov, and Embase were searched from February 2019 to June 2019. Randomized clinical trials (RCTs) were incorporated that compared ICS with non-ICS treatment on the risk of pneumonia in COPD patients. Meta-analyses were conducted by the Peto and Mantel-Haenszel approaches with corresponding 95% Cls.

Results: Twenty-five trials (N = 49,982 subjects) were included. Pooled results demonstrated a significantly increased risk of pneumonia with ICS use in COPD patients (RR, 1.59, 95% CI, 1.33-1.90; I² = 51%). ICS treatment also increased the risk of severe pneumonia (RR, 2.17, 95% CI, 1.47-3.22; I² = 29%). The results of subgroup analysis based on doses of ICS were consistent with the above. However, subgroup analyses based on types of ICS revealed that fluticasone therapy was associated with an increased risk of pneumonia but not budesonide. In addition, medium- and low-doses of budesonide treatment also did not increase the risk of pneumonia.

Conclusions: Use of ICS increases the risk of pneumonia in patients with COPD. The above is prominent for fluticasone-containing ICSs but not for budesonide-containing ICSs.

Factors to consider when adding ICS to long-acting bronchodilators:

(note the scenario is different when considering ICS withdrawal)

STRONGLY FAVORS USE	History of hospitalization(s) for exacerbations of COPD [#] ≥ 2 moderate exacerbations of COPD per year [#] Blood eosinophils ≥ 300 cells/µL History of, or concomitant asthma
FAVORS USE	1 moderate exacerbation of COPD per year [#] Blood eosinophils 100 to < 300 cells/μL
AGAINST USE	Repeated pneumonia events Blood eosinophils < 100 cells/μL History of mycobacterial infection

[#]despite appropriate long-acting bronchodilator maintenance therapy (see Table 3.4 and Figure 4.3 for recommendations); *note that blood eosinophils should be seen as a continuum; quoted values represent approximate cut-points; eosinophil counts are likely to fluctuate.

Adapted from & reproduced with permission of the © ERS 2019: *European Respiratory Journal 52 (6) 1801219; DOI:* 10.1183/13993003.01219-2018 Published 13 December 2018

Three Keys to COPD care/future focus

- . Diagnose
- How are you? How often are you sick?
- Decide on what inhaler(s) to use (hint: not a steroid)
- Then become a superstar!



Three Keys to COPD care/future focus Key #1 - Exacerbations

 Exacerbations are not "bumps" in the road like they are for asthma

 Moderate to severe exacerbations are life altering, patients never recover fully.

 An exacerbation is an acute change in a patient's baseline dyspnea, cough, or sputum that is beyond normal variability, and that is sufficient to warrant a change in therapy.

> 1.Cazzola M, MacNee W, Martinez FJ, et al.; for the American Thoracic Society, European Respiratory Society Task Force on Outcomes of COPD. Outcomes for COPD pharmacological trials: from lung function to bio-markers. *Eur Respir J*. 2008;31(2):416-469.



Three Keys to COPD care/future focus Key #1 - Exacerbations

Causes – viral make up about 80% of flares in a standard COPD population.

 Bacterial infections, wildfire smoke, cooking fuels or toxin exposure

Ran out of meds/noncompliance

Three Keys to COPD care/future focus Key #1 - Exacerbations

- Generally, PO steroids are used:
- Consider shorter and lower
- 40 mg for 3 days and 20 mg for 3 days (Medrol dose packs are \$\$)
- Patient controlled taper 40 mg till they are 50% better then 20 mg till they are close to normal
- Macrolides (or doxycycline) should be used for most flares, may use without prednisone in the right patient. Consider a longer duration.
- Have them do their rescue medication Q4H or Q6H for a couple days then move back to PRN.
- OK to help them control cough (anyone know what benzonatate does?)

Three Keys to COPD care/future focus Key #2 – Switch to nebulized therapy



Review article

Check for updates

The role of inspiratory flow in selection and use of inhaled therapy for patients with chronic obstructive pulmonary disease

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ARTICLE INFO

ABSTRACT

Keywords: Chronic obstructive pulmonary disease Hand-held inhalers Inhalation technique Inspiratory flow Peak inspiratory flow Inhalation therapy is the mainstay of chronic obstructive pulmonary disease management, and inhaler selection can have a profound impact on drug delivery and medication adherence, as well as on treatment outcomes. Although multiple delivery systems, such as pressurized metered-dose inhalers, dry powder inhalers, slow-mist inhalers, and nebulizers, are available, clinical benefits achieved by patients rely on effective delivery of the inhaled medication to the airways. Among several factors influencing drug deposition, inspiratory flow is one of the most important. Inspiratory flow impacts drug delivery and subsequent clinical efficacy, making it necessary to adequately train patients to ensure correct inhaler use. Peak inspiratory flow is the maximal airflow generated during a forced inspiratory maneuver. Health care professionals need to select the appropriate delivery system after carefully considering patient characteristics, including lung function, optimal inspiratory flow, manual dexterity, and cognitive function. Herein, the role of inspiratory flow in the selection and use of inhaled therapy in patients with COPD is reviewed.

Three Keys to COPD care/future focus Key #2 – Switch to nebulized therapy



Three Keys to COPD care/future focus Key #2 – Switch to nebulized therapy

- Measure this with an In-Check
 Device
- Can also see if they can "make noise" with their inhaler



- Can they hold a Post-it note to their lips?
- Do they feel nebulized medication is sig better?

Commonly Used Maintenance Medications in $\ensuremath{\mathsf{COPD}}^*$

			DELIVERY OPTIONS		
Generic Drug Name	Inhaler Type	Nebulizer	Oral	Injection	Duration of Action
BETA ₂ -Agonists					
Short-acting (SABA)					
Fenoterol	MDI	1	pill, syrup		4-6 hours
Levalbuterol	MDI	1			6-8 hours
Salbutamol (albuterol)	MDI & DPI	1	pill, syrup, extended	1	4-6 hours
			release tablet		12 hours (ext. release)
Terbutaline	DPI		pill	1	4-6 hours
Long-acting (LABA)					
Arformoterol		1			12 hours
Formoterol	DPI	1			12 hours
Indacaterol	DPI				24 hours
Olodaterol	SMI				24 hours
Salmeterol	MDI & DPI				12 hours
Anticholinergics					
Short-acting (SAMA)					
Ipratropium bromide	MDI	1			6-8 hours
Oxitropium bromide	MDI				7-9 hours
Long-acting (LAMA)					
Aclidinium bromide	DPI.				MDI 12 hours
Glycopyrronium bromide	DPI		solution	1	12-24 hours
Tiotropium	DPL SML MDI				24 hours
Umeclidinium	DPI				24 hours
Glycopyrrolate		1			12 hours
Revefenacin					24 hours
Combination Short-Acting Beta-Agonist	Plus Anticholiner	ric in One De	vice (SABA+SAMA)		24110015
Fenoterol/inratronium	SMI				6-8 hours
Salbutamol/ipratropium	SML MDI	1			6-8 hours
Combination Long-Acting Beta ₂ -Agonist P	lus Anticholinerg	ic in One De	vice (LABA+LAMA)		o o nouro
Formoterol/aclidinium	DPI				12 hours
Formoterol/glycopyrronium	MDI				12 hours
Indacaterol/glycopyrronium					12-24 hours
Vilanterol/umeclidinium					24 hours
Olodaterol/tiotropium	SMI				24 hours
Mothylyanthings	51411				24 110013
Aminonhulling			solution	1	Variable up to 24 bours
Aminophylline			solution	· ·	Variable, up to 24 hours
Theophylline (SR)			pili	~	variable, up to 24 hours
Combination of Long-Acting Beta ₂ -Agonis	t Plus Corticoster	oid in One D	evice (LABA+ICS)		
Formoterol/beclometasone	MDI, DPI				12 hours
Formoterol/budesonide	MDI, DPI				12 hours
Formoterol/mometasone	MDI				12 hours
Salmeterol/fluticasone propionate	MDI, DPI				12 hours
Vilanterol/fluticasone furoate	DPI				24 hours
Triple Combination in One Device (LABA+	LAMA+ICS)				
Fluticasone/umeclidinium/vilanterol	DPI				24 hours
Beclometasone/formoterol/glycopyrronium	MDI, DPI				12 hours
Budesonide/formoterol/glycopyrrolate	MDI				12 hours
Phosphodiesterase-4 Inhibitors					
D = floore the et			llin		24 hours
Roflumilast			pin		24110013
Mucolytic Agents			pii		24 110013
Mucolytic Agents Erdosteine			pill		12 hours
Mucolytic Agents Erdosteine Carbocysteine†			pill pill		12 hours

*Not all formulations are available in all countries. In some countries other formulations and dosages may be available. †Dosing regimens are under discussion. MDI = metered dose inhaler; DPI = dry powder inhaler; SMI = soft mist inhaler. Note that glycopyrrolate & glycopyrronium are the same compound.

Three Keys to COPD care/future focus Key #3 – Smoking Cessation

- •Motivational interviewing is great, stages of change is great...
- When this is ineffective I scare them
- Show them their chest xray
- •Shot them their CBC if it's off elevated RBC or HCT is a LATE sign



Three Keys to COPD care/future focus Key #3 – Smoking Cessation

•Tell them their lung "age"

MEN

Lung age = (2.87 × height [inches]) – (31.25 × observed FEV, [liters]) – 39.375 WOMEN Lung age = (3.56 × height [inches]) – (40 × observed FEV, [liters]) – 77.28

•This works! You can estimate: Age + $\frac{1}{2}$ their pack years.

•50 year old who has 40 pack year history has a lung age of 70.

•"Well Mr. Jones, most will need oxygen around (pick an age about 3-5 years older than the lung age)" Visit the Journal of Family Practic www.ifponline.com



J Fam Pract. 2008 Sep; 57(9): 584-586.

Help smokers quit: Tell them their "lung age"

John Hickner, MD, MSc, PURLS Editor John Hickner, Department of Family Medicine, The University of Chicago

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Three Keys to COPD care/future focus Key #3 – Smoking Cessation

•Then the payoff – "Mr. Jones do you think you would prefer the kind of oxygen tank you carry or one that you pull? We could start looking at tank set ups now if you'd like?"





Am Fam Physician. 2021 Mar 15;103(6):380-381.

Author disclosure: No relevant financial affiliations.

Key Points for Practice

- Varenicline is more effective than nicotine patches and bupropion with similar or fewer adverse events, even with comorbid psychiatric or substance abuse conditions.
- Combining varenicline with nicotine patches appears to be more effective than using varenicline alone based on limited evidence.
- For people who smoke and are not ready to quit, prescribing varenicline increases six-month abstinence with an NNT of 6 compared with waiting for readiness.
- Extending treatment beyond 12 weeks increases abstinence, with an NNT of 19 compared with shorter treatment durations.

From the AFP Editors

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