HOSPITAL MEDICINE

Improving Health Outcomes in COPD: Hospital-based Strategies for Optimizing Maintenance Therapy and Promoting Patient Self-management



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Faculty Disclosures

- Consultant: Amirall, AstraZeneca, Avisa, Boehringer Ingelheim, Broncus, CSA Medical, GlaxoSmithKline, Holaira, Lungpacer, Mereo, Pearl, PneumRX, Pulmonx, Third Pole
- Research: Department of Defense, National Institutes of Health
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Learning Objectives

- Utilize long-term treatment strategies to reduce hospital readmissions for COPD exacerbations
- Review the clinical evidence regarding the efficacy and safety of long-acting maintenance regimens for COPD
- Select medication delivery devices for patients with COPD based upon individual physical and cognitive characteristics
- Outline a transitional care plan that promotes patient self-management to reduce the risk for future exacerbations and hospital readmissions



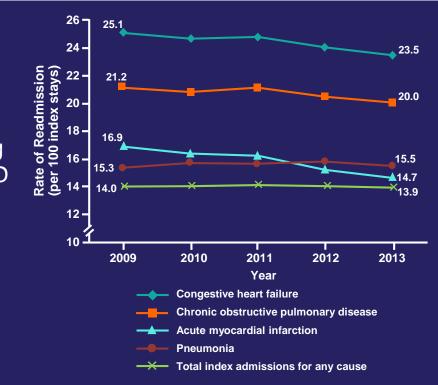


In-hospital Burden of COPD

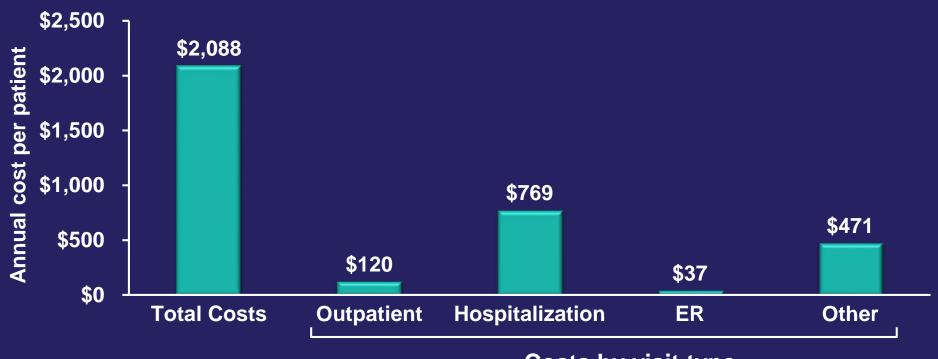
- 1.1 million COPD-related ED visits
- 660,000 discharges with a primary diagnosis of COPD
- 20% all-cause 30-day readmission rate among patients with an index hospitalization for COPD
- In-hospital mortality:
 - 2.5% for exacerbation-related admissions
 - Up to 28% for patients requiring mechanical ventilation

ED, emergency department.





COPD-related Healthcare Costs



ER, emergency room.

Costs by visit type

Schwab P. Int J COPD. 2017;12:735-744.

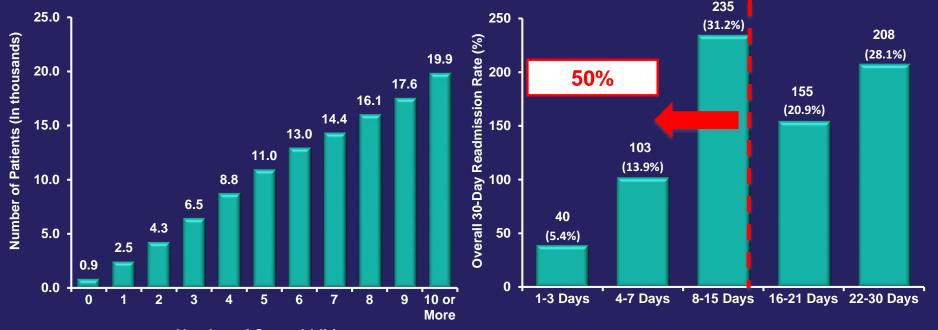
COPD-related Healthcare Costs Increase with Greater Exacerbation Frequency



^{*}Statistically significant (*P*<.001) trend.

Dhamane AD, et al. Int J COPD. 2015;10:2609-18.

Impact of Comorbidities and Outpatient Follow-up on Readmission Risk



Number of Comorbidities

Zhang X, et al. Available at: https://www.ispor.org/research_pdfs/52/pdffiles/PRS6.pdf; Sharif R et al. *Annals Am Thoracic Soc.* 2014;11(5):685-694.

Factors Associated With Increased Risk of Early Readmission After an Acute Exacerbation

- Black race
- Comorbidities
 - Congestive heart failure
 - Frailty
 - Other medical conditions (eg, chronic renal insufficiency, diabetes)
 - Psychiatric, including depression, anxiety, psychosis, alcohol and drug use
 - Risk of readmission is increased with increasing number of comorbidities
- Discharge to post-acute care
- Dual eligibility for Medicare and Medicaid
- Elevated serum arterial blood carbon dioxide level
- Low body mass index
- Longer length of stay
- Male sex

Shah T, et al. Chest. 2016;150(4):916-926.

Management of an Acute Exacerbation



Assessment of an Exacerbation

- Assess severity of symptoms
- Chest radiograph
- Blood gases and/or O₂ saturation

Vestbo J, et al. GOLD 2018 Update. Available at http://goldcopd.org.

Initial Treatment of an Acute Exacerbation

Bronchodilator therapy

- Increase doses/frequency of SABA therapy
- Combine SABAs with anticholinergics
- Use spacers or air-driven nebulizers
- Corticosteroids
- Antibiotics
- O₂ therapy
- Adjunctive therapies
- NIV/IMV

IMV, invasive mechanical ventilation; NIV, noninvasive ventilation; SABA, short-acting beta₂-agonist. Vesto J, et al. GOLD 2018 Update. Available at http://goldcopd.org.

Criteria for Hospital Admission

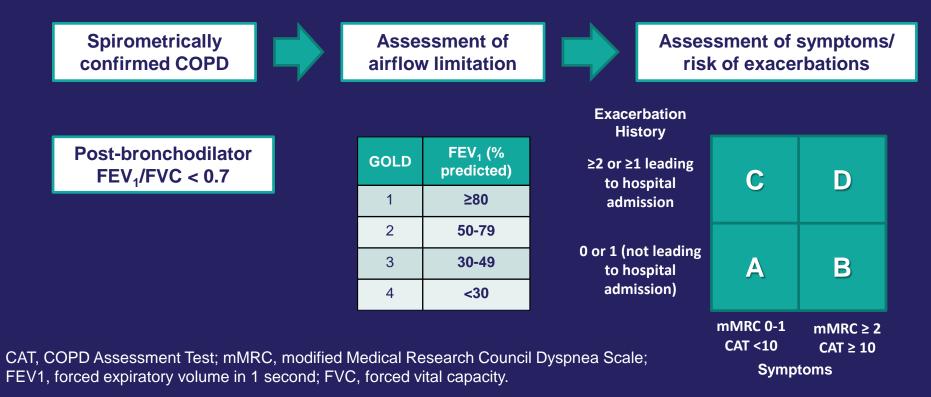
- Clinical assessment
 - Symptoms
 - Severity (as determined by spirometry)
 - Risk of exacerbations
 - Comorbidities
- Response to therapy
- Post-discharge environment

Vestbo J, et al. GOLD 2018 Update. Available at http://goldcopd.org.

Assessment of COPD Severity and Exacerbation Risk



The Redefined ABCD Assessment Tool



Vestbo J, et al. GOLD 2018 Update. Available at http://goldcopd.org.

A Lack of Spirometry is Associated with Inaccurate Estimation of COPD Severity

Assessment of Severity	Patients (%)
Physician < Spirometry	41
Physician = Spirometry	30
Physician > Spirometry	29

Spirometry resulted in a change in treatment in ~33% of patients.

Mapel DW, et al. Am J Med. 2015;128(6):629-637.

mMRC Questionnaire

PLEASE TICK THE BOX THAT APPLIES TO YOU (ONE BOX ONLY)

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

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.

Example: I am very happy	0 🚺 2 3 4 5	I am very sad	SCORE
l 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	
l 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	
		TOTAL	

SCORE

Jones et al. *Eur Respir J*. 2009;34(3):648-654.

Long-term Maintenance Therapy Medication Selection



Approved Long-acting Bronchodilator Monotherapies

Agent		Delivery	
	Arformoterol	Nebulizer	
	Formatoral	Nebulizer	
	Formoterol DPI		
LABA	Indacaterol	DPI	
	Olodaterol	SMI	
	Salmeterol	DPI	
	Aclidinium	DPI	
LAMA	Tiotropium	DPI, IS	
	Umeclidinium	DPI	
	Glycopyrronium	DPI, Nebulizer	

LABA, long-acting beta-agonist; LAMA, long-acting muscarinic antagonist; DPI, dry powder inhaler; IS, inhalation spray; SMI, soft mist inhaler. Vestbo J, et al. GOLD 2018 Update. Available at http://goldcopd.org.

Approved Fixed-dose Combination Therapies

Combination	Agent	Delivery
	Vilanterol + umeclidinium	DPI
	Olodaterol + tiotropium	SMI
LABA/LAMA	Indacaterol + glycopyrrolate	DPI
	Formoterol + glycopyrrolate	MDI
LABA/ICS	Formoterol + budesonide	MDI
	Salmeterol + fluticasone	DPI
	Vilanterol + fluticasone	DPI
	Formoterol + mometasone*	MDI
LABA/LAMA/ICS	A/LAMA/ICS Fluticasone furoate + vilanterol + umeclidinium	

*Off-label use. Not indicated for the treatment of patients with COPD.

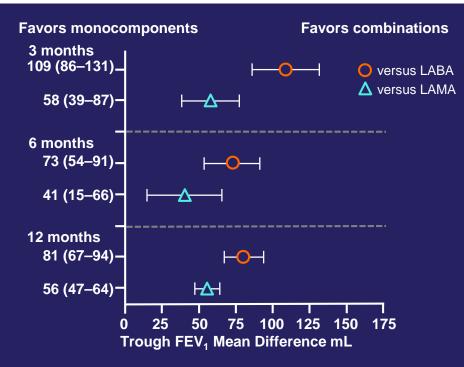
ICS, inhaled corticosteroid; MDI, metered dose inhaler.

Vestbo J, et al. GOLD 2018 Update. Available at http://goldcopd.org.

Emerging Therapies

Туре	Agent	Delivery
LAMA	Revefenacin	Nebulizer
LABA/LAMA	Aclidinium + formoterol	DPI
LABA/LAMA/ICS	Glycopyrronium + formoterol + budesonide	MDI
	Glycopyrronium + formoterol + beclomethasone	MDI

LABA/LAMA Combined Bronchodilator Therapy vs Monotherapy



Meta analysis of 14 studies

- N=20,329 patients
- LABA/LAMA combinations were more effective vs monocomponents at 3, 6, and 12 months of treatment
 - Improvements in trough FEV₁
 - Transition dyspnea index
 - SGRQ scores

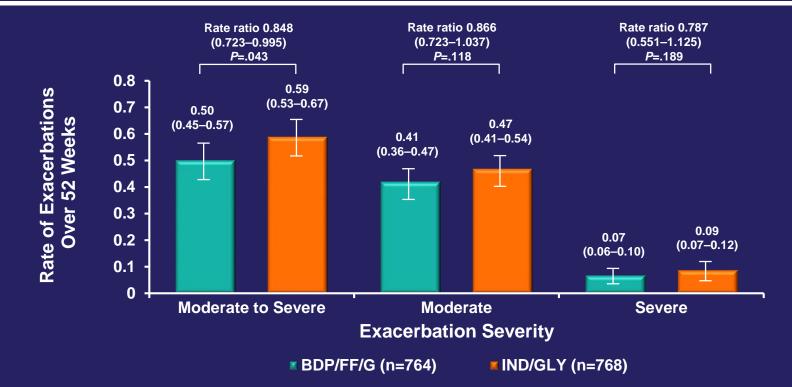
SGRQ, St George's Respiratory Questionnaire. Calzetta L, Rogliani P, Ora J, et al. *Eur Respir Rev.*2017;26:160043.

Effect of Combined Therapy with LABA/LAMA vs LABA/ICS on Lung Function

Α	
	Mean Difference, IV,
Study or Subgroup	Random, 95% Cl
Ind/Gly (110/50 μg od) vs Sal/FP (50/500 μg bid)	
Vogelmeier et al ³⁴	
Wedzicha et al3 ³⁶	
Zhong et al ³⁵	
Umec/Vi (62.5/25 µg od) vs Sal/FP (50/250 or 500 µg bid)	
Donohue et al (DB2114930) ³⁷	
Donohue et al (DB2114951) ³⁷	
Singh et al ³⁸	
Total (95% CI)	
Heterogeneity: τ ² =0.00, χ ² =1.82, <i>df</i> =5 (<i>P</i> =.87), <i>P</i> =0%	
Test for overall effect: Z=17.30 (P<.0001)	-0.2 -0.1 0 0.1 0.2
	Favors LABA/ICS Favors LABA/LAMA
В	
	Mean Difference, IV, Ind, indacaterol;
Study or Subgroup	Random, 95% CI Gly, glycopyrronium;
Ind/Gly (110/50 μg od) vs Sal/FP (50/500 μg bid)	Sal, salmeterol;
Vogelmeier et al ³⁴	FP, fluticasone propionate:
Wedzicha et al3 ³⁶	bid, bidaily;
Zhong et al ³⁵	Umec, umeclindinium;
	Vi, vilanterol;
Acli/For (400/12 μg bid) vs Sal/FP (50/500 μg bid)	
Vogelmeier et al ³⁹	Acli, aclidinium;
	For, formoterol.
Total (95% CI)	
Heterogeneity: τ²=0.00, χ²=30.20, <i>df</i> =3 (<i>P</i> <.0001), <i>P</i> =90%	
Test for overall effect: Z=2.09 (P=.04)	-0.2 -0.1 0 0.1 0.2
	Favors LABA/ICS Favors LABA/LAMA

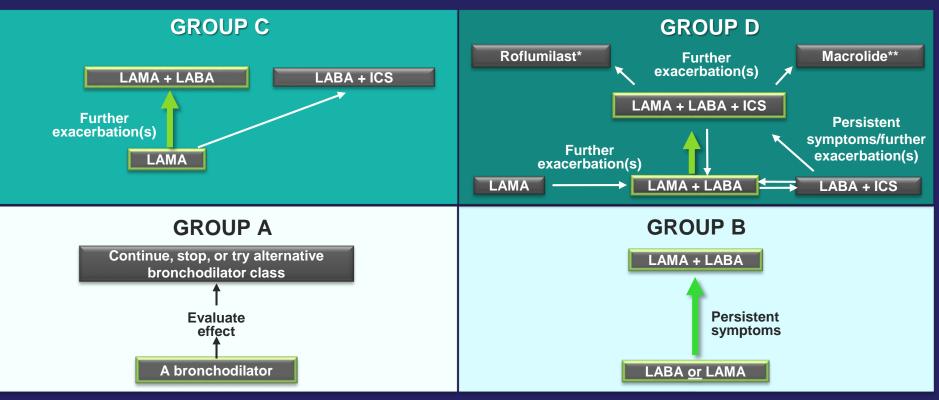
Rodrigo GJ, et al. Int J Chron Obstruct Pulmon Dis. 2017;12:907-922.

Extrafine Inhaled Triple Therapy Reduces Exacerbations vs Dual Bronchodilator Therapy



BDP/FF/G, beclometasone dipropionate, formoterol fumarate, and glycopyrronium; IND/GLY, indacaterol plus glycopyrronium. Papi A, et al. *Lancet*. 2018;391:1076-1084.

Treatment Recommendations by GOLD Grade



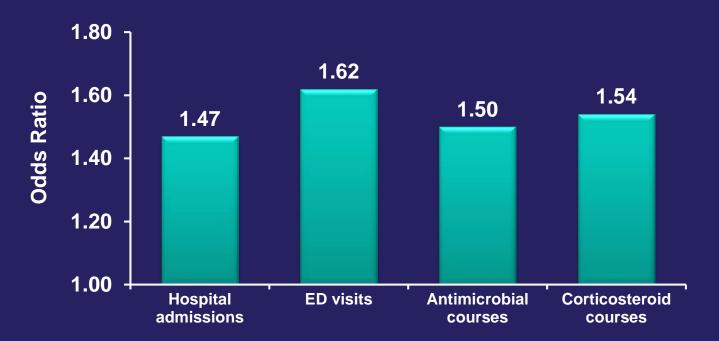
*Consider if FEV₁ is <50% predicted and patient has chronic bronchitis; **Consider for former smokers. Vestbo J, et al. GOLD 2018 Update. Available at http://goldcopd.org.

Long-term Maintenance Therapy

Appropriate Delivery Device Selection



Association Between Critical Inhaler Errors* and Healthcare Utilization



*Data includes asthma and COPD patient populations.

Dekhuijzen PNR, et al. Patient Prefer Adherence. 2016;10:1561-1572; Melani AS, et al. Respir Med. 2011;105(6):930-938.

Assessments to Aid in Device Selection

Cognitive

- Any test for higher level cognitive function
 - Failure indicates MDI or DPI may be inappropriate

Physical

- Validated teach-back methods for specific devices
- Check for inspiratory flow (eg, In-Check DIAL)



Available at: http://www.alliancetechmedical.com/products/check-dial-training-device/

Overcoming Cognitive and Physical Limitations

	Limitation	Potential Strategy
	Unable to generate adequate PIFR	SMI, nebulizer
Physical	 Impaired manual dexterity (eg, arthritis, Parkinsonism, or stroke) 	Nebulizer
	 Pain or weakness from neuromuscular disease (eg, multiple sclerosis) 	Nebulizer
Cognitive	 Unable to coordinate breathing with device requirements 	Spacer, SMI, nebulizer
	Unable to remember instructions for device actuation (eg, Alzheimer's disease, altered consciousness)	Device with fewer steps, nebulizer
	Unable to keep track of doses	Device with a dose counter

PIFR; peak inspiratory flow rate.

Wise RA, et al. Chronic Obstr Pulm Dis. 2017;4(1):13. Dhand R, et al. COPD. 2012;9(1):58-72; Nobles J, et al. Consult Pharm. 2014;29(11):753-756.

Opportunities to Improve Long-term COPD

CareConsideration of Comorbidities



Prevalence of Comorbidities Among Patients with COPD

Patients (%) (N=52,643) 0 20 40 60 80 100 47.8 43.8 40.9 27.6 27.3 26.9 25.8 23.3 20.1 19.65 16.6 92.34

Coronary artery disease Osteoarthritis Type 2 diabetes mellitus **Congestive heart failure** Cerebrovascular disease **Depressive disorders** Chronic kidney disease Anxiety disorders Osteoporosis Obesity Sleep apnea Any of the 11 comorbidities

Cardiovascular Disease in COPD

- Patients with COPD are at increased risk for CVD
- Approximately one-third of all deaths in those with COPD are due to CVD causes
- Prognosis following a MI is substantively worse in those with concomitant COPD
- Optimal management of patients diagnosed with both conditions remains a topic of debate

CVD, cardiovascular disease; MI, myocardial infarction.

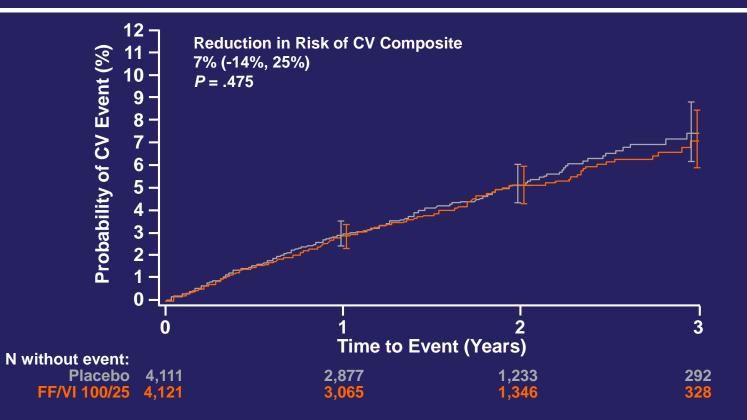
Morgan AD, et al. Ther Adv Respir Dis. 2018;12:1-16; Brook RD, et al. Heart. 2017;103:1536-1542.

Risk for Hospitalization and Mortality Due to Cardiovascular Causes in COPD

	COPD Patients (n=11,493)	Matched Controls (n= 22,986)
Total Costs	Event/1000 Person-Years	Event/1000 Person-Years
Cause of hospitalization		
Arrhythmia	16.44	8.18
Angina	6.02	2.34
Acute myocardial infarction	10.86	6.56
Congestive heart failure	31.96	6.10
Stroke	12.44	9.77
Pulmonary embolism	1.72	0.31
Any cardiovascular hospitalization	109.50	44.66
Any hospitalization	598.36	221.23
Underlying case of death		
Arrhythmia	1.94	0.69
Acute myocardial infarction	5.89	3.90
Congestive heart failure	4.10	1.00
Stroke	4.17	3.37
Pulmonary embolism	0.33	0.15
Any cardiovascular mortality	31.89	15.39
Any mortality	106.58	37.79

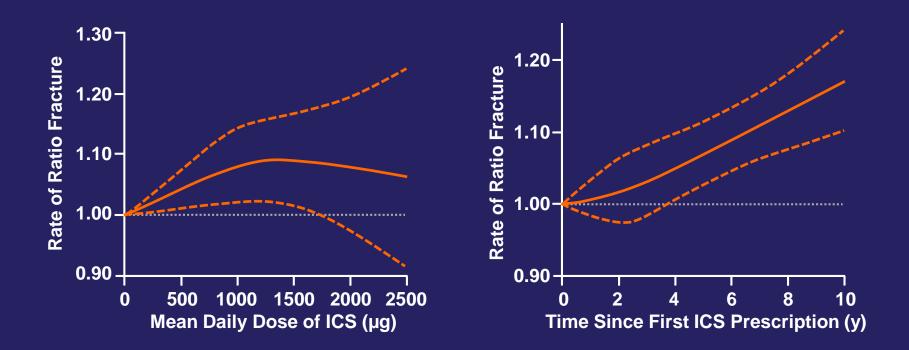
Curkendall SM, et al. Ann Epidemiology. 2006;16(1):63-70.

Combined LABA and ICS Therapy Pose No Excess CV Risk

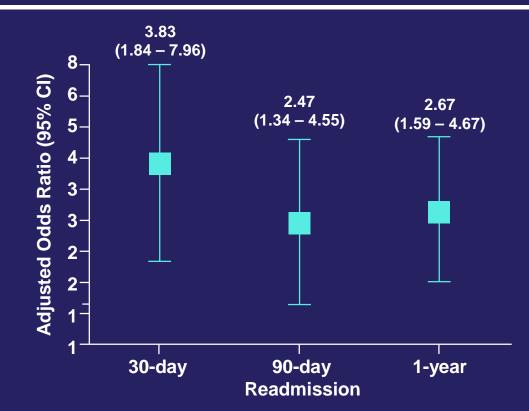


Brook RD, et al. *Heart.* 2017;103:1536-1542.

Impact of Long-term High-dose ICS Use on the Risk of Fractures in Patients with COPD



Depression Is Associated with Readmission for Acute Exacerbation



lyer et al. Ann Am Thorac Soc. 2016;13(2):197-203.

Opportunities to Improve Long-term COPD Care **Patient Discharge and Follow-up**



Crucial Issues to Address Prior to Discharge

Pharmacotherapy

- Individualized maintenance therapy
- Medication/device training

Patient/Caregiver Education

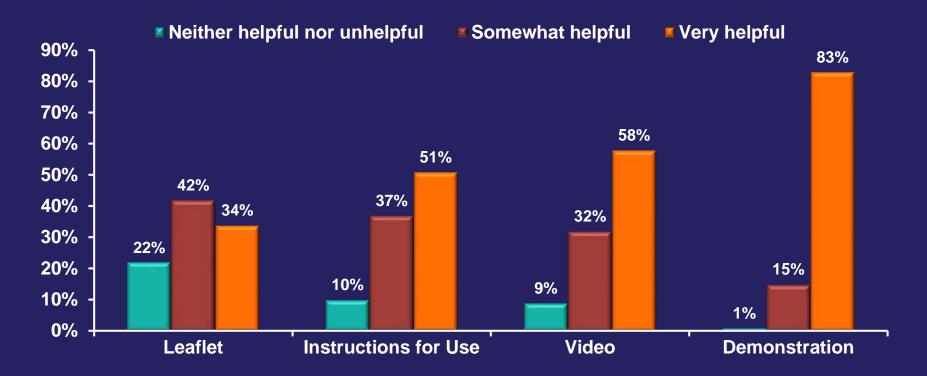
- Expectations
- Adherence
- Nonpharmacologic intervention
 - Smoking cessation
 - PR program
 - Vaccinations

Referral & Follow-up

- Schedule:
 - Home care visit and/or transition care team call
 - PCP appointment
- Ensure information transfer from ED to community HCPs

HCP, healthcare provider; PCP, primary care provider; PR, pulmonary rehabilitation. Vestbo J, et al. GOLD 2018 Update. Available at http://goldcopd.org.

Patient Preferences for Using Different Training Methods



Price et al. Int J COPD. 2018;13:695-702.

Improving Communication Between Inpatient and Outpatient HCPs

Reliable, Employment standardized discharge documentation

of multiple modes of communication

> Consistent, concise but complete medication and treatment plans

Rattray NA, et al. The Joint Commission Journal on Quality and Patient Safety. 2017;43(3):127-137.

Follow-up After Hospitalization for an Exacerbation Improves Patient Outcomes

- An outpatient visit within 1 month after admission resulted in fewer ED visits (14%) and 30-day readmissions (9%)¹
- Not attending primary care follow-up within 4 weeks was associated with a 10-fold greater likelihood of 30-day readmission²
- Not attending a follow-up visit within 30 days was associated with an increased risk of rehospitalization within 90 days of discharge³

1. Sharma G, et al. *Arch Intern Med.* 2010;170(18):1664-1670; 2. Misky GJ, et al. *J Hosp Med.* 2010;5(7):392-397; 3. Gavish R, et al. *Chest.* 2015;148(2):375-381.

Follow-up Assessment Recommendations

72 Hours (Call)

- Health status
- Medications
- Clinician appointments
 & lab tests
- Home services
 coordination
- Action plan

1 to 4 Weeks (Visit)

- Ability to cope in usual environment
- Treatment regimen
- Inhaler technique
- Need for long-term O₂
- Capacity for physical activity & ADLs
- Symptoms (CAT/mMRC)
- Comorbidities

12 to 16 Weeks (Visit)

- Same as at 1 to 4 weeks
- Spirometry (FEV₁)

Re-Engineered Discharge (RED) Toolkit. Available at https://www.ahrq.gov/professionals/systems/hospital/red/toolkit/redtool5.html Vestbo J, et al. GOLD 2018 Update. Available at http://goldcopd.org.

Case Evaluations



Case Evaluation #1: Patient Description

A 74-year-old man with COPD (GOLD B) presents to the ED for an exacerbation. His current medications include a SABA (prn) and a LAMA maintenance therapy. He is short of breath, has a wet cough, trouble walking across the room, and chest tightness. Physical exam reveals wheezing and decreased breath sounds. Although he reports having "pretty good control" over his symptoms in general, his son believes that his father has had at least two mild exacerbations that he has managed on his own at home during the past 3 months.

Case Evaluation #1: Question 1

Which of the following validated clinical tools would you use to evaluate the patient's symptom burden?

- A. CAT
- B. mMRC
- C. SGRQ



Case Evaluation #1: Question 2

After confirming the patient's ability to use his inhaler device and adherence to treatment, what type of alteration to the patient's current regimen would you recommend?

- A. No alteration
- **B.** Addition of a LABA
- C. Addition of roflumilast



Case Evaluation #2: Patient Description

A 70-year-old woman with an established COPD diagnosis (GOLD C) is hospitalized for an acute exacerbation for the second time within two months. Since her initial diagnosis 7 years ago, the patient has typically exhibited good symptom control with treatment. She reports that she has recently been experiencing symptoms of memory loss, as well as poor vision and worsening osteoarthritis. She also relates a diminished ability to engage in her usual activities of late. Her current maintenance therapy regimen includes a LAMA, LABA, and SABA (prn).

Case Evaluation #2: Question 1

What is your next step in management once you have treated the exacerbation and the patient is stabilized?

- A. Addition of an ICS to her treatment regimen
- B. Evaluation of her device technique
- C. Evaluation of her home care environment



Case Evaluation #2 Cont'd

Further evaluation reveals that the patient has been having difficulty using her prescribed devices because of pain and stiffness in her hands. Additionally, she confides that she often has difficulty keeping track of whether she has taken all of her medications. You prescribe a fixed-dose combination therapy that is delivered with a device she appears able to use more easily.



What type of instruction would you offer to insure that the patient is able to use her device correctly?

- A. Instructional written materials
- B. Instructional video
- C. Physical demonstration





During what time frame would you recommend that the patient attend a follow-up visit?

- A. Within 3 days
- **B.** Within 4 weeks
- C. Within 8 weeks



Summary

- Exacerbations of COPD represent a significant health and economic burden in the hospital setting
- In-hospital care provides an important opportunity to assess COPD severity, symptom burden, and risk for exacerbations, as well as re-evaluate the efficacy of a patient's current treatment
- Individualized discharge plans and follow-up care that address behavioral, physical, and environmental barriers to effective COPD management are essential for preventing hospital readmissions



- Following an acute exacerbation, confirm the diagnosis of COPD and assess disease severity and risk for future exacerbations using clinical assessments and spirometry
- Reevaluate maintenance therapy regimens and make adjustments to insure that treatment is adequately individualized to meet the physiological and behavioral characteristics of the patient
- Provide patients with education that includes device training, and addresses therapeutic expectations, medication adherence, and nonpharmacologic interventions
- Schedule follow-up that consists of a home care visit or a call from the transition care team, and an appointment with a PCP

Thank You!

