HOSPITAL & INTERNAL MEDICINE FORUM

Achieving Optimal COPD Management through Individualized Treatment and Device Selection

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Faculty Disclosures

- Consultant: AstraZeneca, GlaxoSmithKline, Sunovion
- Speakers' Bureaus: GlaxoSmithKline

Learning Objectives

- Describe an approach to chronic obstructive pulmonary disease (COPD) treatment that is consistent with current evidence-based guideline recommendations
- Review the efficacy, safety, and utility of available therapies for the long-term management of COPD
- Match patients with appropriate COPD medication delivery devices

COPD in the Hospital Setting

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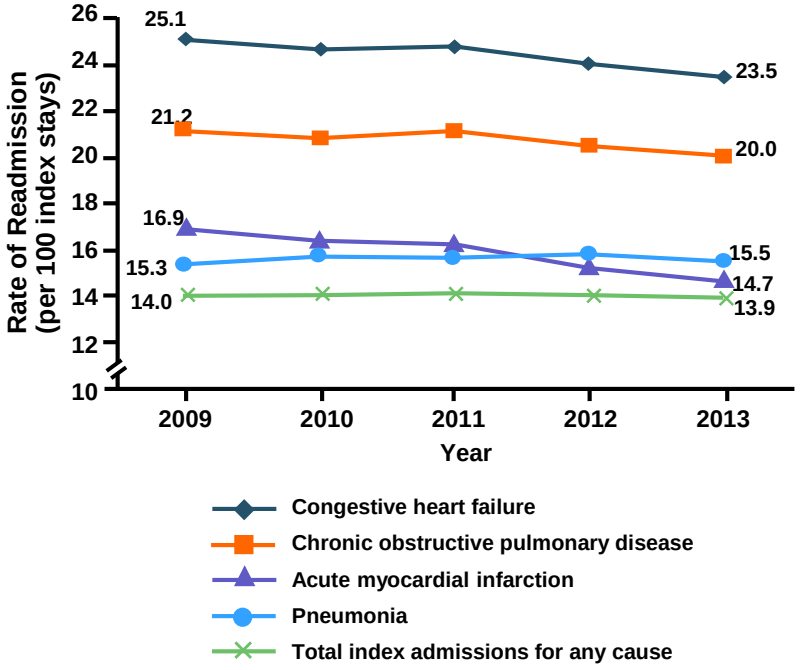
In-hospital Burden of COPD

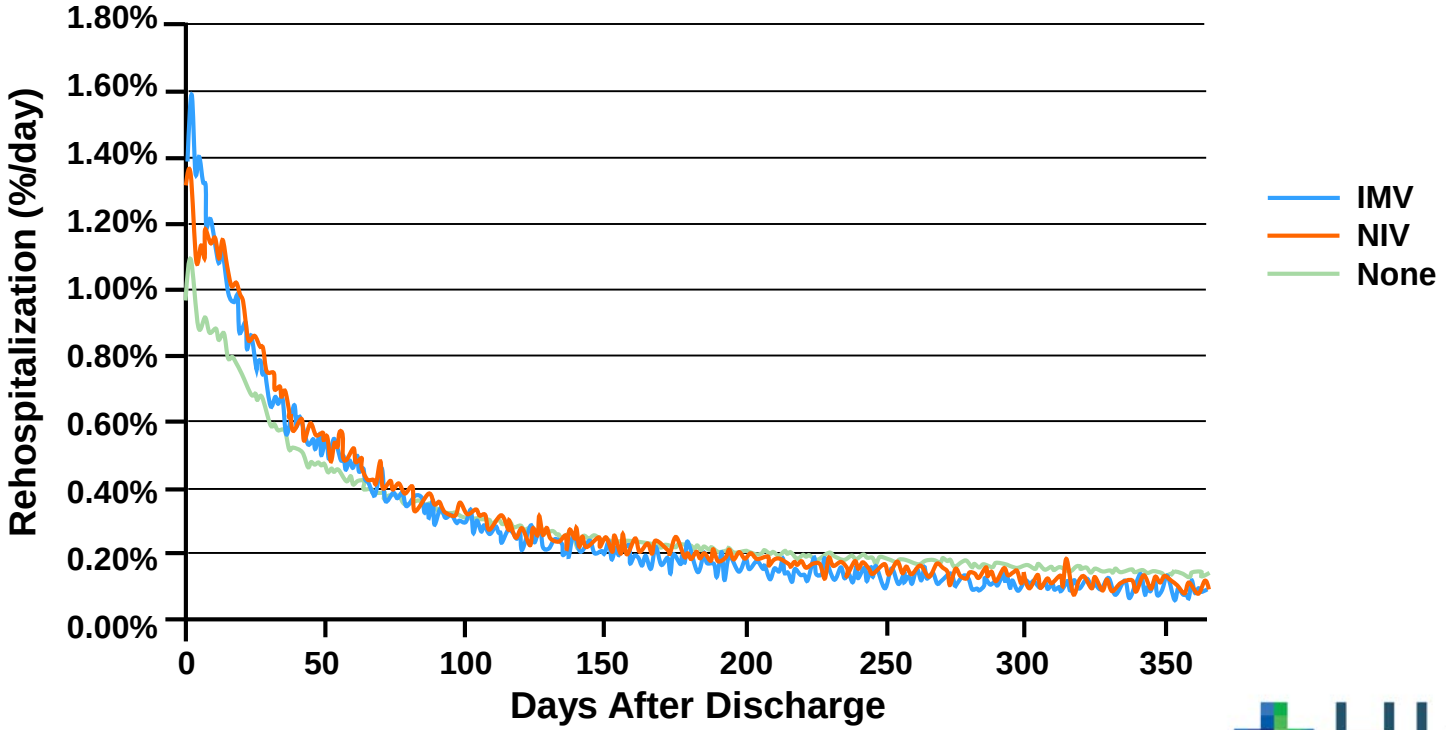
- 1.1 million COPD-related ED visits
- 660,000 discharges with a primary diagnosis of COPD
- 20% all-cause 30-day readmission rate among patients with an index hospitalization for COPD
- In-hospital mortality:
  - 2.5% for exacerbation-related admissions
  - Up to 28% for patients requiring mechanical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



ED, emergency department.

Singh JA, Yu S. *Respir Res*. 2016;17:1; Ford ES. *Chest*. 2015;147(4):989-998;
Fingar K, et al. HCUP Stat Briefs. 2015;196; Perera PN, et al. *J COPD*. 2012;9:131-141.

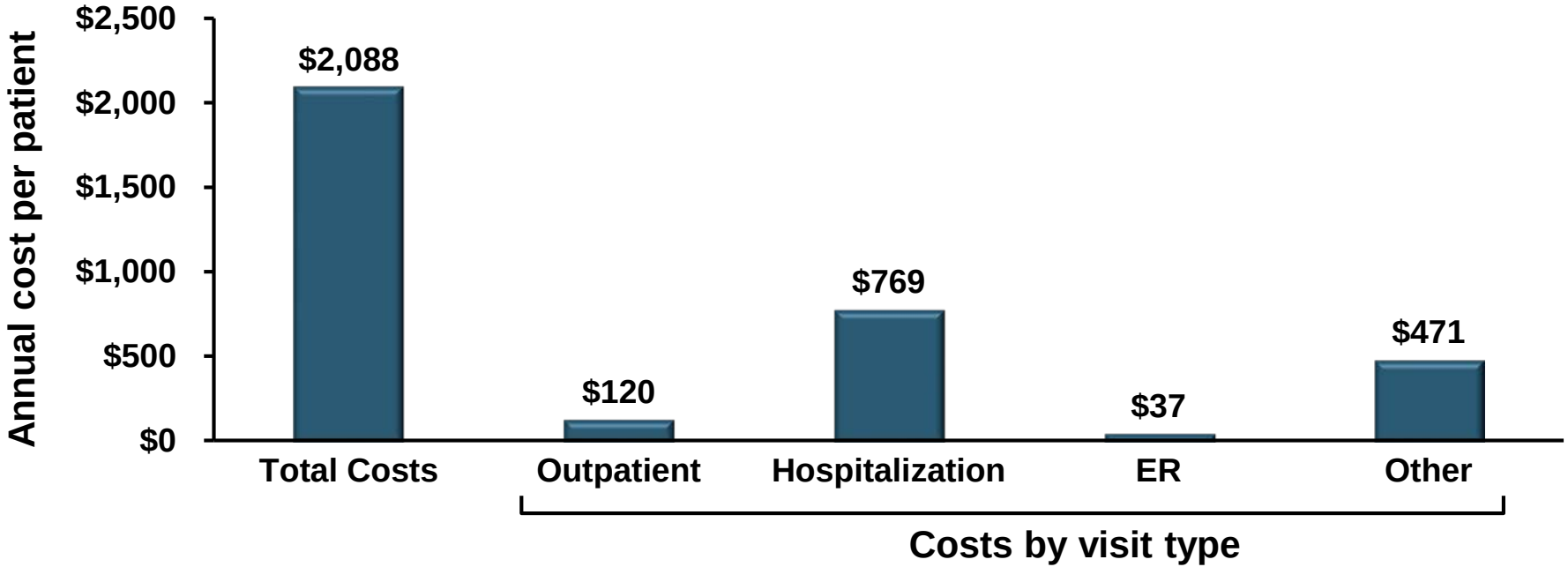
Prolonged Risk for Readmission Following Hospitalization for COPD



IMV, invasive mechanical ventilation; NIV, noninvasive mechanical ventilation.

Lindenauer PK, et al. *Am J Respir Crit Care Med*. 2017.

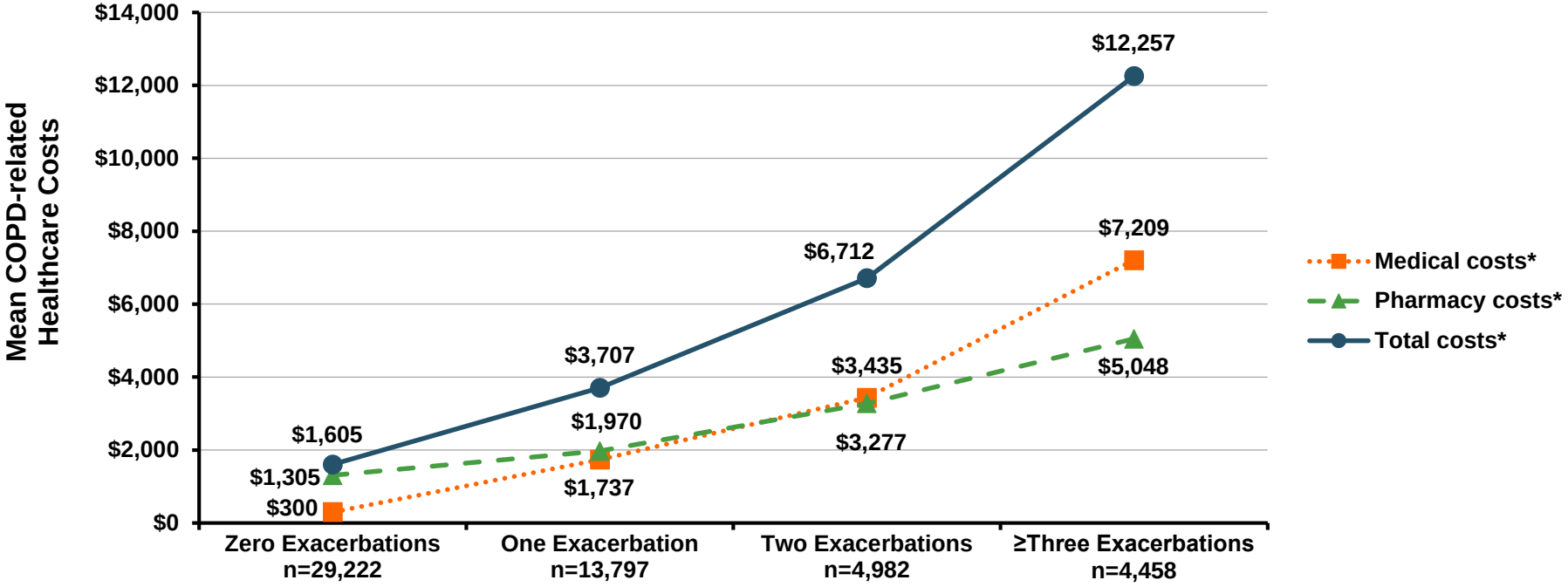
COPD-related Healthcare Costs



ER, emergency room.

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;10:2609-2618.

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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 conditions, 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.

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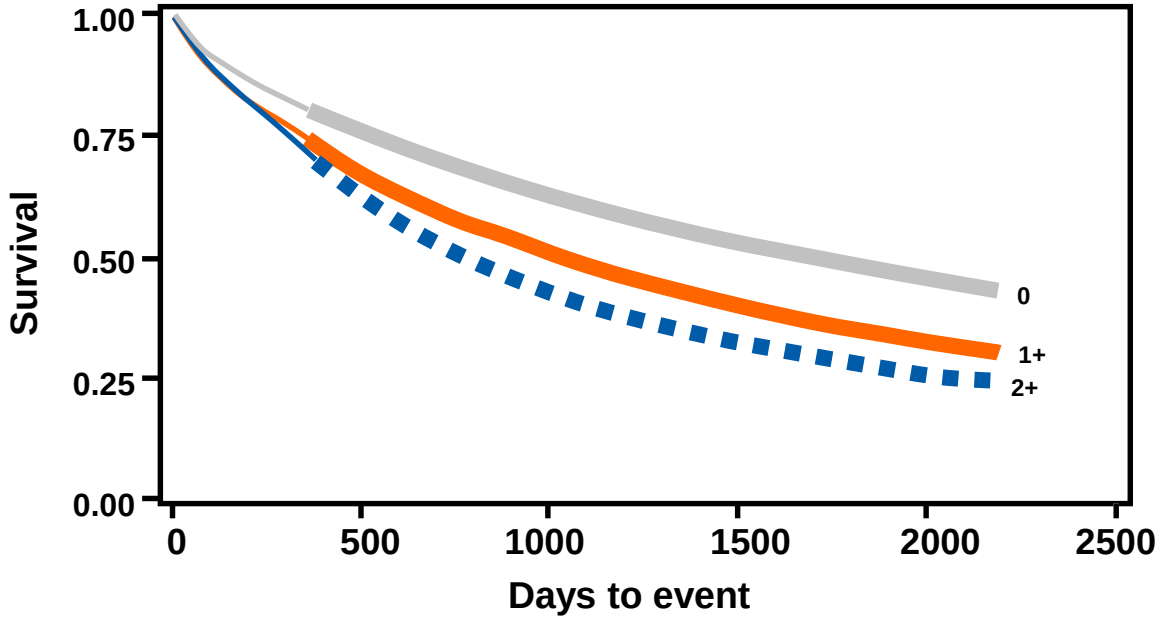
Mortality After Hospitalization In COPD



51,353 VA patients in the USA.

Increasing mortality with additional hospitalizations.

McGhan R, et al. *CHEST.* 2007;132:1748-1755.

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Management of an Acute Exacerbation

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Assessment of an Exacerbation

- Assess severity of symptoms
- Chest radiograph
- Blood gases and/or O_2 saturation

Vestbo J, et al. GOLD 2019 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
- Oxygen therapy
- Noninvasive ventilation/Invasive mechanical ventilation

SABA, short-acting beta2-agonist.

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

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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 2019 Update. Available at http://goldcopd.org.

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Assessment of COPD Severity and Exacerbation Risk

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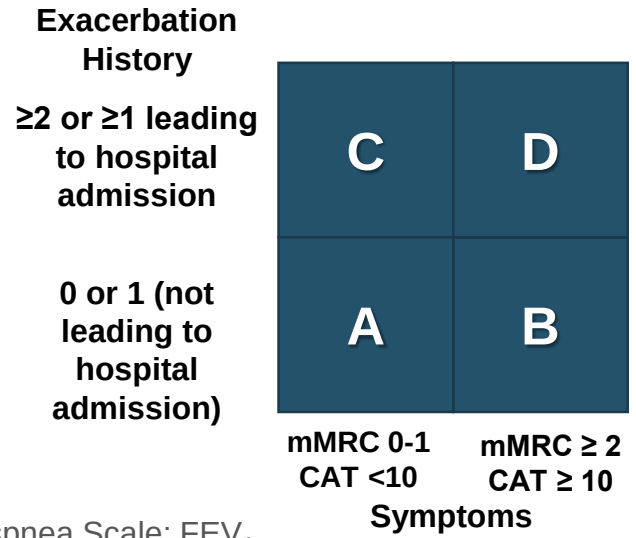
The Redefined ABCD Assessment Tool

Spirometrically confirmed COPD → **Assessment of airflow limitation** → **Assessment of symptoms/ risk of exacerbations**

Post-bronchodilator $FEV_1/FVC < 0.7$

GOLD	FEV_1 (% predicted)
1	≥80
2	50-79
3	30-49
4	<30



CAT, COPD Assessment Test; mMRC, modified Medical Research Council Dyspnea Scale; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; GOLD, Global Initiative for Chronic Obstructive Lung Disease.

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

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The Redefined ABCD Assessment Tool

Assess
1 – symptoms
and
2 – risk of exacerbations

Exacerbation History	mMRC 0-1 CAT <10	mMRC ≥ 2 CAT ≥ 10
≥2 or ≥1 leading to hospital admission	C	D
0 or 1 (not leading to hospital admission)	A	B

Symptoms

CAT, COPD Assessment Test; mMRC, modified Medical Research Council Dyspnea Scale; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity.

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

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mMRC Questionnaire

PLEASE TICK THE BOX THAT APPLIES TO YOU

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.**	☐

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

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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	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 condition		0	1	2	3	4	5	I don't sleep soundly because of my lung	
I have lots of energy		0	1	2	3	4	5	I have no energy at all	
								TOTAL SCORE	

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

Medication Selection

Long-term Maintenance Therapy

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Approved Long-acting Bronchodilator Monotherapies

Class	Agent	Brand	Delivery
LABA	Arformoterol	Brovana®	Nebulizer
	Formoterol	Perforomist®	Nebulizer
		Foradil® Aerolizer	DPI
	Indacaterol	Arcapta® Neohaler®	DPI
	Olodaterol	Striverdi® Respimat®	SMI
	Salmeterol	Serevent® Diskus®	DPI
LAMA	Aclidinium	Tudorza® Pressair®	DPI
	Tiotropium	Spiriva® Respimat®	DPI IS
		Spiriva® Handihaler®	IS
	Umeclidinium	Incruse® Ellipta®	DPI
	Glycopyrronium	Seebri® Neohaler®	DPI
		Lonhala® Magnair®	Nebulizer
	Revefenacin	Yupelri®	Nebulizer

IS, inhalation spray; SMI, slow mist inhaler.

GOLD. Global Strategy for the diagnosis, management, and prevention of COPD. 2019 Report. Available at: https://www.goldcopd.org.

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Approved Fixed-dose Combination Therapies

Combination	Agent	Brand	Delivery
LABA/LAMA	Vilanterol + umeclidinium	Anoro® Ellipta®	DPI
	Olodaterol + tiotropium	Stiolto® Respimat®	SMI
	Indacaterol + glycopyrrolate	Utibron® Neohaler®	DPI
	Formoterol + glycopyrrolate	Bevespi® Aerosphere®	MDI
LABA/ICS	Formoterol + budesonide	Symbicort®	MDI
	Salmeterol + fluticasone	Advair® Diskus®	DPI
	Vilanterol + fluticasone	Breo® Ellipta®	DPI
	Formoterol + mometasone*	Dulera®	MDI
LABA/LAMA/ICS	Fluticasone furoate + vilanterol + umeclidinium	Trelegy® Ellipta®	DPI

*Off-label use. Not indicated for the treatment of patients with COPD.
MDI, metered dose inhaler.
GOLD. Global Strategy for the diagnosis, management, and prevention of COPD. 2019 Report. Available at: https://www.goldcopd.org.

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Emerging Therapies

Type	Agent	Delivery
LABA/LAMA	Aclidinium + formoterol	DPI
LABA/LAMA/ICS	Glycopyrronium + formoterol + budesonide	MDI
	Glycopyrronium + formoterol + beclomethasone	MDI

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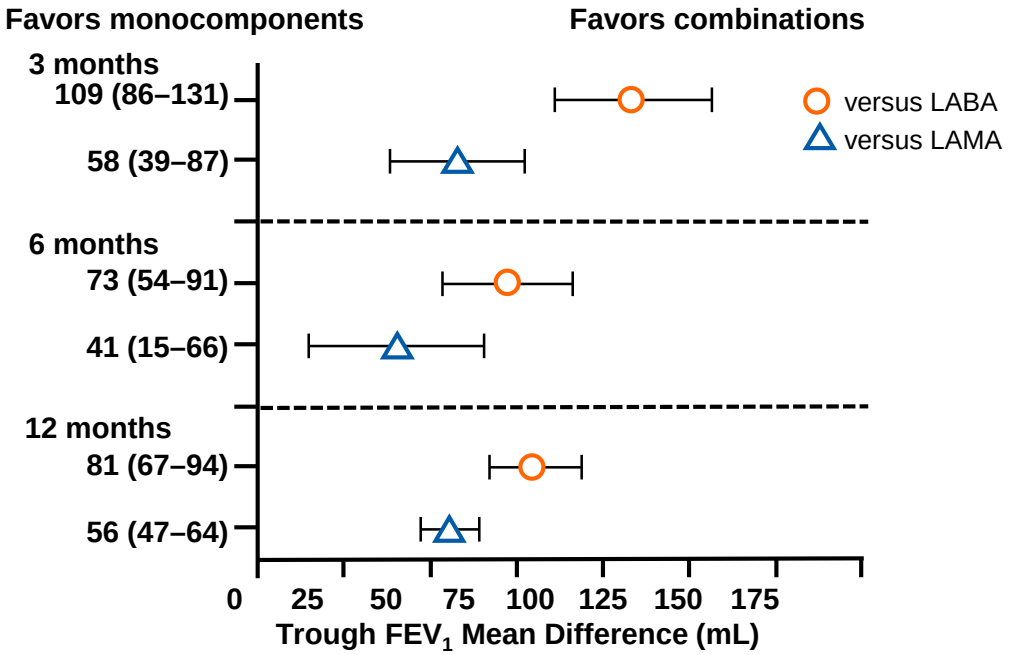
LABA/LAMA Combined Bronchodilator Therapy vs Monotherapy

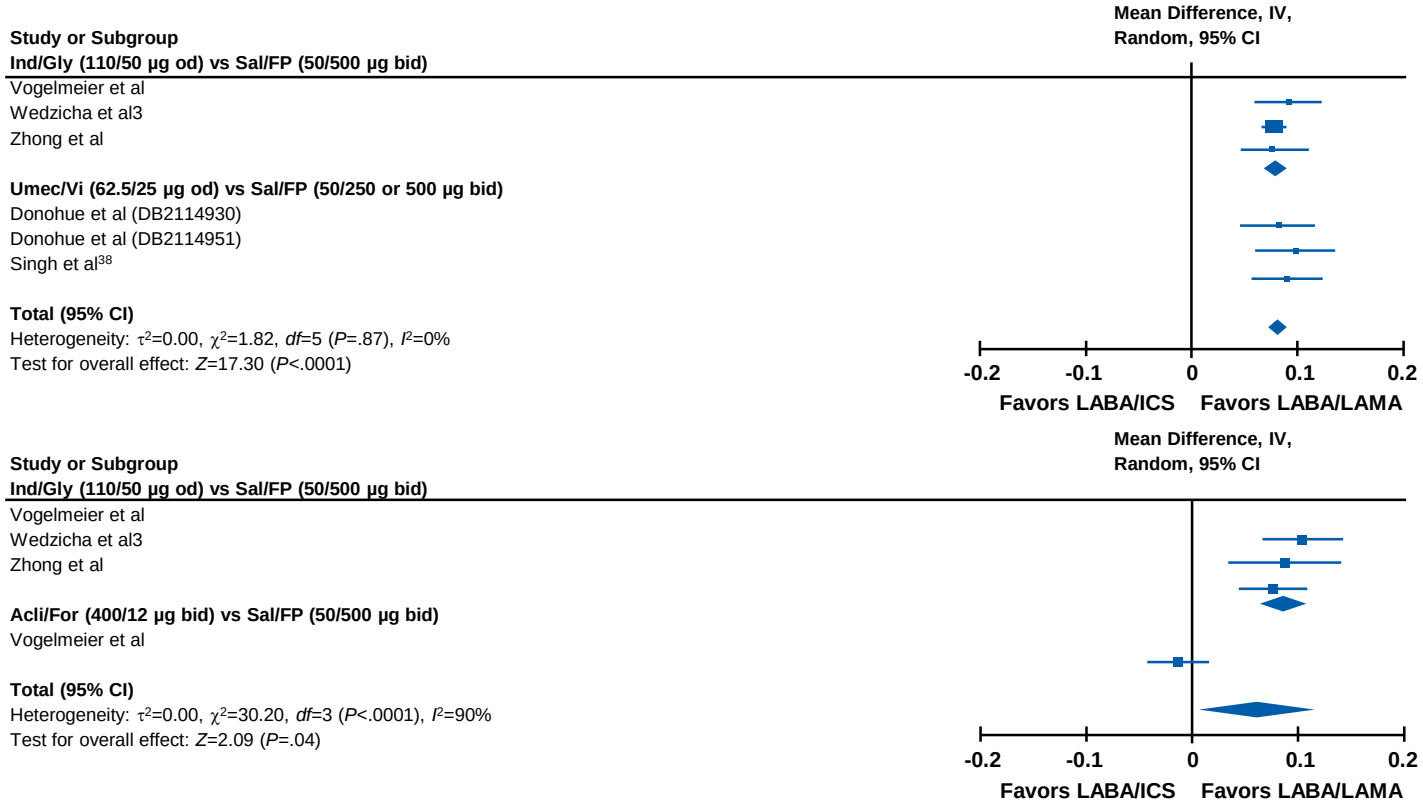


- Meta analysis of 14 studies
- N=20,329 patients
- LABA/LAMA combinations were more effective vs monocomponents at 3, 6, and 12 months of treatment
  - Improvements in trough FEV_1
  - Transition dyspnea index
  - SGRQ scores

SGRQ, St George's Respiratory Questionnaire.

Calzetta L, Rogliani P, Ora J, et al. *Eur Respir Rev*.2017;26(143).

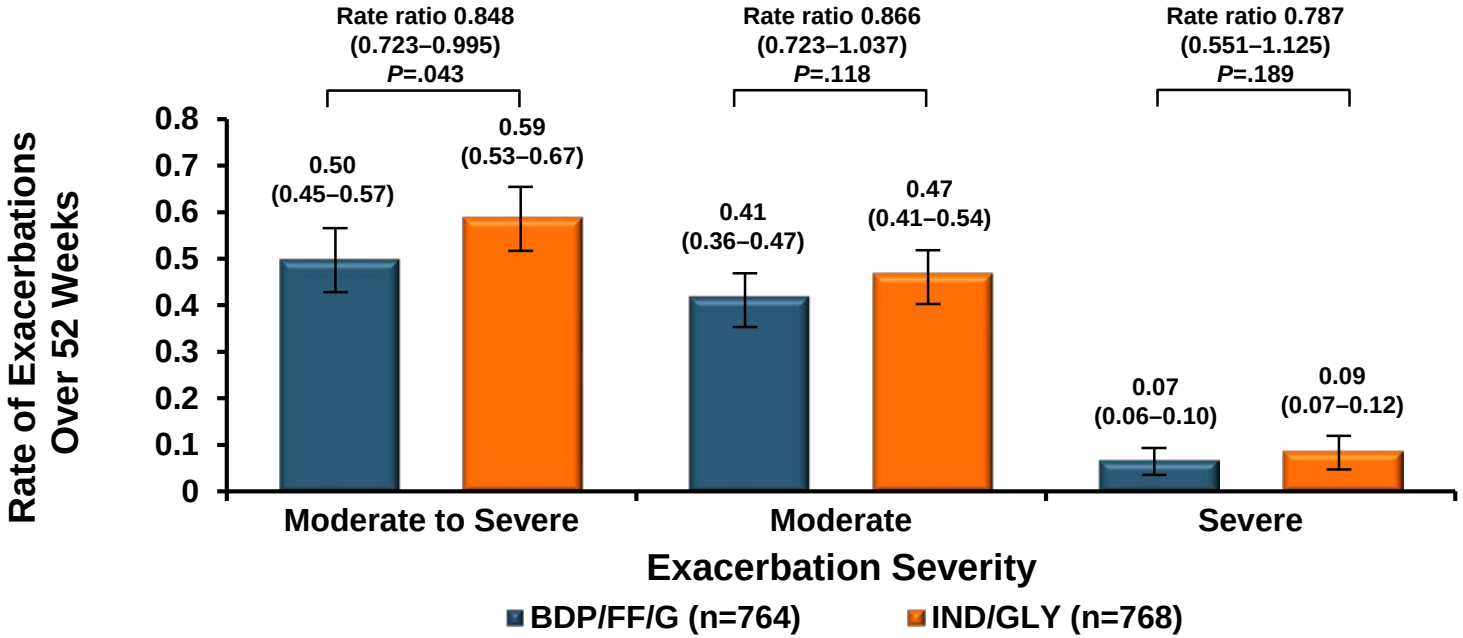
Effect of Combined Therapy with LABA/LAMA vs LABA/ICS on Lung Function



Ind, indacaterol;
Gly, glycopyrronium;
Sal, salmeterol;
FP, fluticasone propionate;
bid, twice daily;
Umec, umeclidinium;
Vi, vilanterol;
Acli, aclidinium;
Od, once daily
For, formoterol.

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

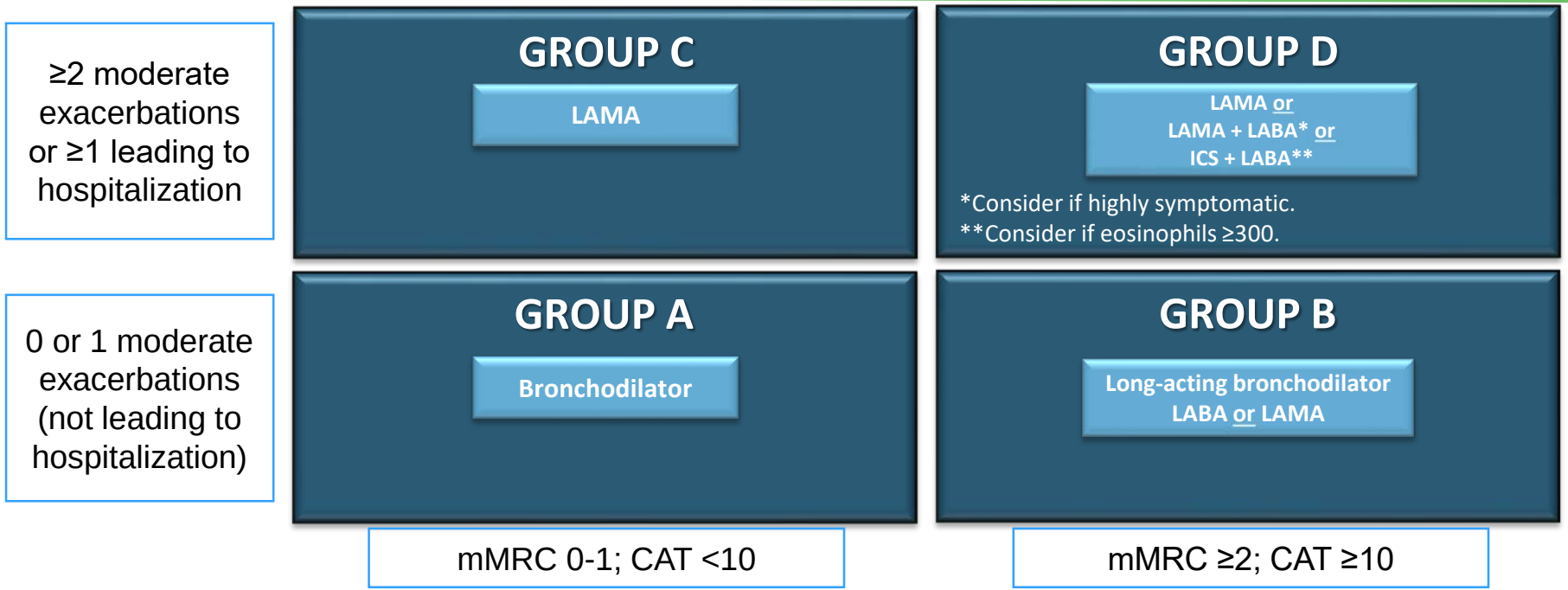
Extrafine Inhaled Triple Therapy Reduces Exacerbations vs Dual Bronchodilator Therapy



BDP/FF/G, beclometasone dipropionate, formoterol fumarate, and glycopyrronium; IND/GLY, indacaterol plus glycopyrronium.

Papi A, et al. *Lancet*. 2018;391:1076-1084.

Initial Treatment Recommendations by GOLD Grade



ICS, inhaled corticosteroid.

GOLD. Global Strategy for the diagnosis, management, and prevention of COPD. 2019 Report. Available at: https://www.goldcopd.org.

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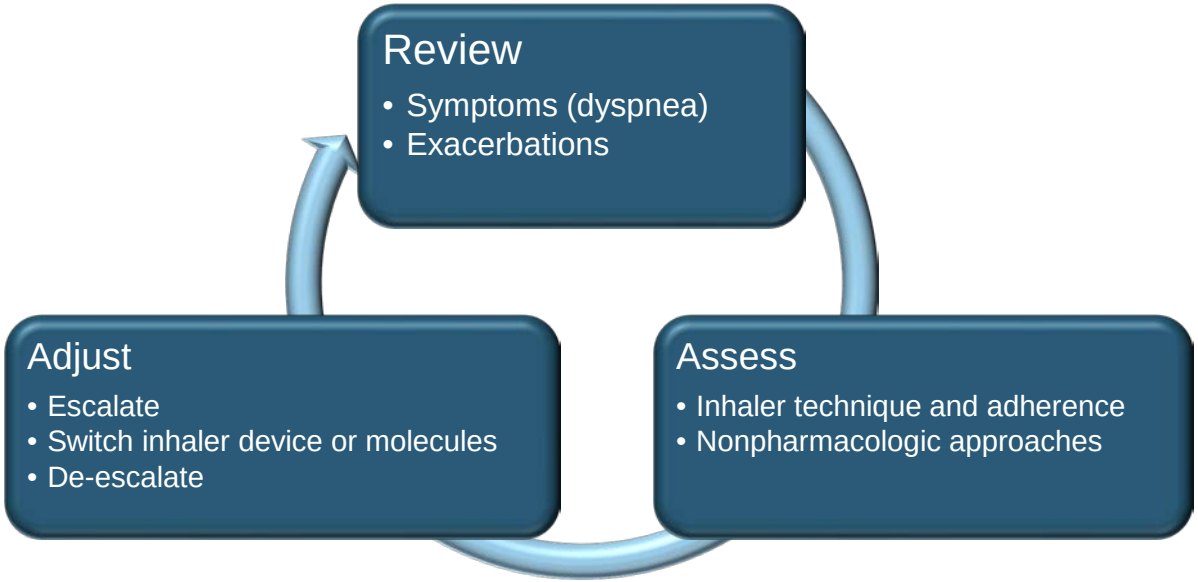
COPD Management Cycle

Following Implementation of Therapy:



GOLD. Global Strategy for the diagnosis, management, and prevention of COPD. 2019 Report. Available at: https://www.goldcopd.org.

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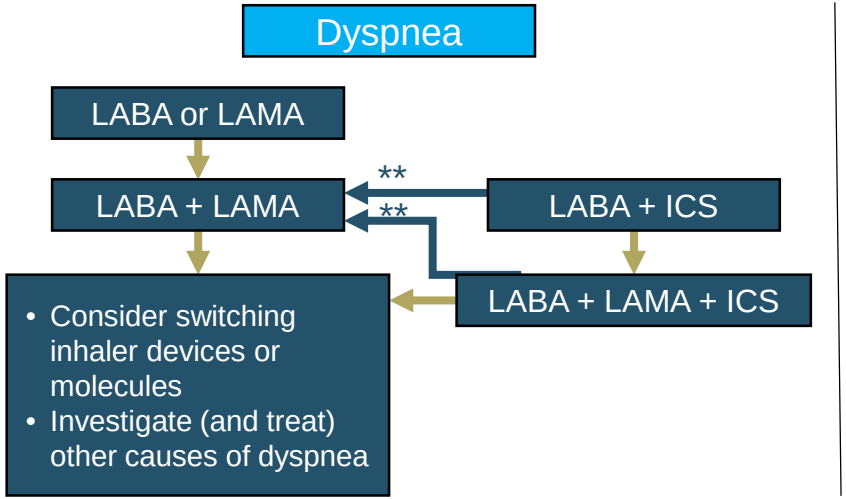
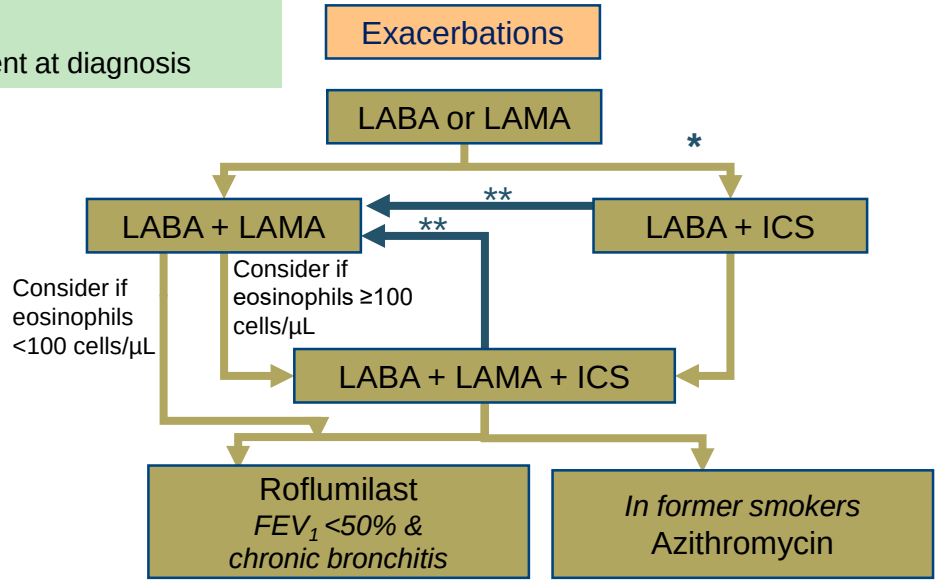
Follow-up Pharmacologic Treatment

If response to initial treatment is appropriate, maintain it.
If not:

- Consider predominant treatable trait to target
- These recommendations do not depend on the ABCD assessment at diagnosis





*Consider if eosinophils ≥300 cells/µL or eosinophils ≥100 cells/µL and ≥2 moderate exacerbations/hospitalizations.
**Consider de-escalation of ICS if pneumonia, inappropriate original indication, or lack of response.

GOLD. Global Strategy for the diagnosis, management, and prevention of COPD. 2019 Report. Available at: https://www.goldcopd.org.

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Appropriate Delivery Device Selection

Long-term Maintenance Therapy

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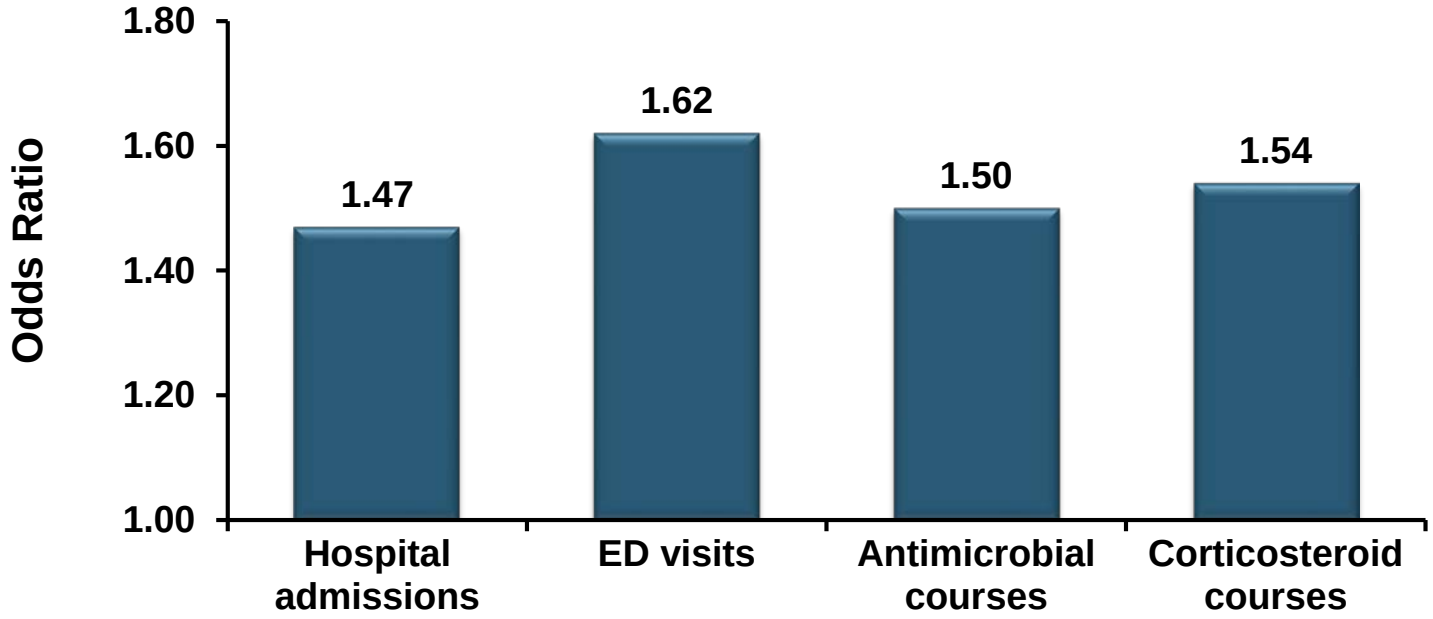
Association between Critical Inhaler Errors* and Healthcare Utilization



*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.

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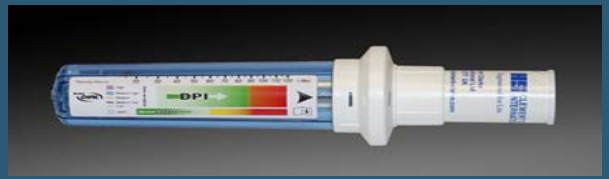
Assessments to Aid in Device Selection

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)



Alliance Tech Medical. In-Check DIAL G16. Available at: http://www.alliancetechmedical.com/products/check-dial-training-device/

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Key Characteristics of Different Device Types

Characteristics	pMDIs	DPIs	SMIs	Nebulizers
Ease of use	Requires coordination between actuation and inhalation (ease of use increased when used in conjunction with a spacer, or by using a breath-actuated pMDI)	Varies, they are generally breath-actuated and do not required coordination between actuation adn inhalation	Requires assembly and coordination between actuation and inhalation	No specific breathing techniques have to be taught for using nebulizers
Suitable for maintenance or reliever medication	Reliever and maintenance	Reliever and maintenance	Reliever and maintenance	Reliever and maintenance
Treatment time	Short	Short	Short	Longer than pMDIs/ DPIs (duration depends on nebulizer device type)
Portability	High	High	High	Depends on type
Multi-dose device	Yes	Some DPIs	Yes	No
Dose counter	Yes	Yes	Yes	No

DPIs, dry powder inhalers; pMDIs, pressurized metered-dose inhalers.

Dhand R, et al. *Cleve Clin J Med*. 2018;85(2 Suppl 1):S19-S27; Bonini M, Usmani OS. *COPD Res Pract*. 2015;1:9.; Lavorini F, et al. *Respiratio*n. 2014;88(1):3-15. Ibrahim M, et al. *Med Devices (Auckl)*. 2015;8:131-139.

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Pulmonary Rehabilitation

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Cochrane Review Conclusions

- Pulmonary rehabilitation following COPD exacerbations:
  - Exercise and health status improve; high quality evidence of benefit
  - Readmissions and mortality: heterogeneity of effect with both positive and negative studies
  - Pulmonary rehabilitation programs differ widely in components, duration

No serious adverse events reported!

McCarthy B, et al. Cochrane Database of Systematic Reviews 2015, Issue 2. Art. No.: CD003793. DOI: 10.1002/14651858.CD003793.pub3.

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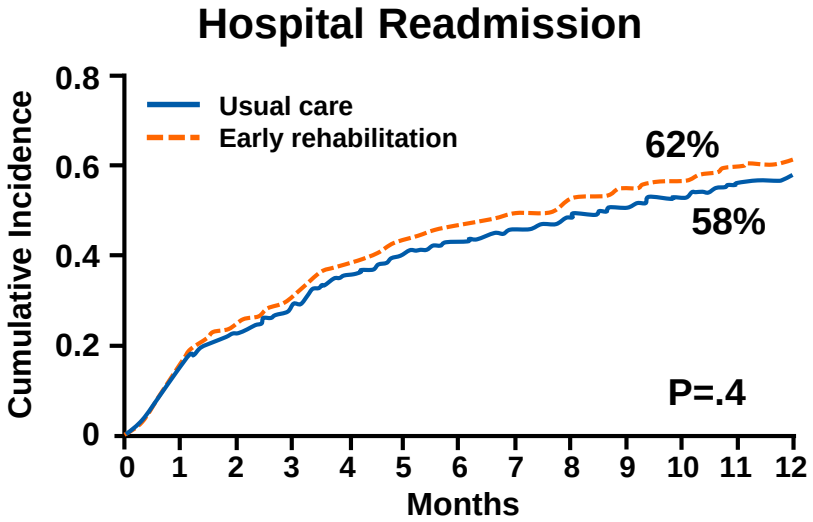
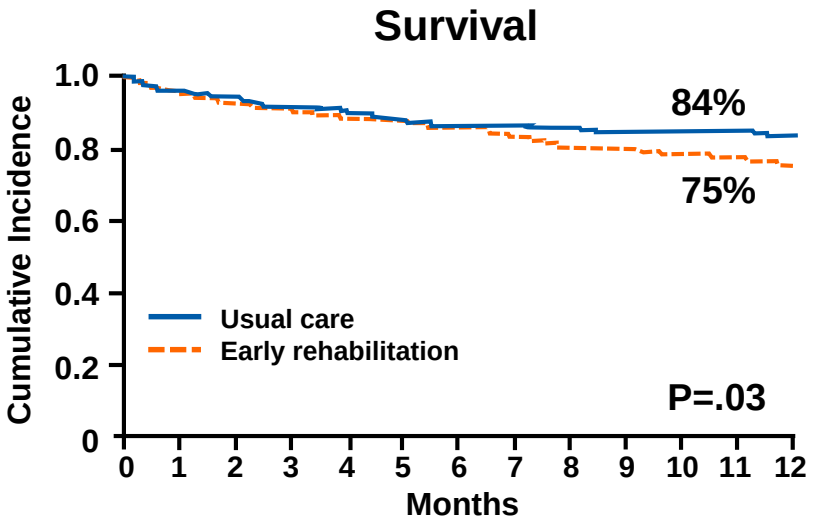
Effects of Early PR in COPD Exacerbation





RCT. N=389 subjects with exacerbation of CRD (not only COPD)

Inpatient (48h): aerobic, resistance and NMES training; self-management and education (median 5 days)

After discharge: unsupervised home-based programme supported by telephone consultations (motivational interview techniques). Total: 6 weeks

CRD, chronic respiratory disease; NMES, neuromuscular electrostimulation; PR, pulmonary rehabilitation; RCT, randomized control trial.

Greening NJ, et al. *BMJ*. 2014;349:g4315.

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Patient Resistance & Acceptance of PR

Why Do Patients Decline Pulmonary Rehabilitation?[1,2]

- Too sick; fear COPD/comorbidities would worsen
- Not sick enough, lack of relevance
- Other obligations, interruption of daily routine
- Lack of information/referral
- Transportation problems, location of PR
- Financial burden

Why Do Patients Accept Pulmonary Rehabilitation?[3,4]

- Build confidence, learn to live/cope with limitations
- Gain support and encouragement from professionals
- Gain tangible results
- 11-fold increased likelihood of uptake if patients have a spouse/resident caregiver[5]

1. Mathar H, et al. *Scand J Caring Sci*. 2016;30:432-441; 2. Mathar,H, et al. *Clin Rehabil*. 2017;31:1674-1683. 3. Guo. *Plos One*. 2014; 9:e110835; 4. Meis J, et al. *Respir Med*. 2014;108:500-10; 5. Chen Z, et al. *Ann Am Thorac Soc.* 2017;14:1419-1427.

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Consideration of Comorbidities

Opportunities to Improve Long-term COPD Care

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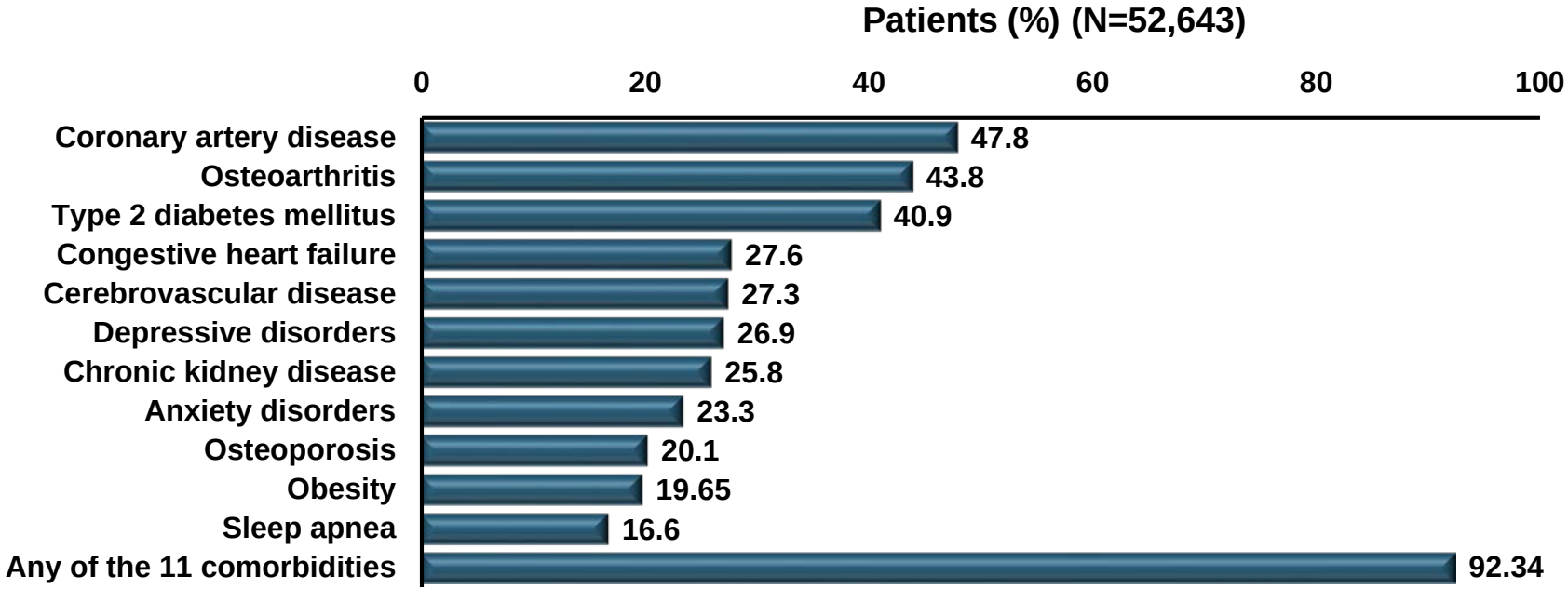
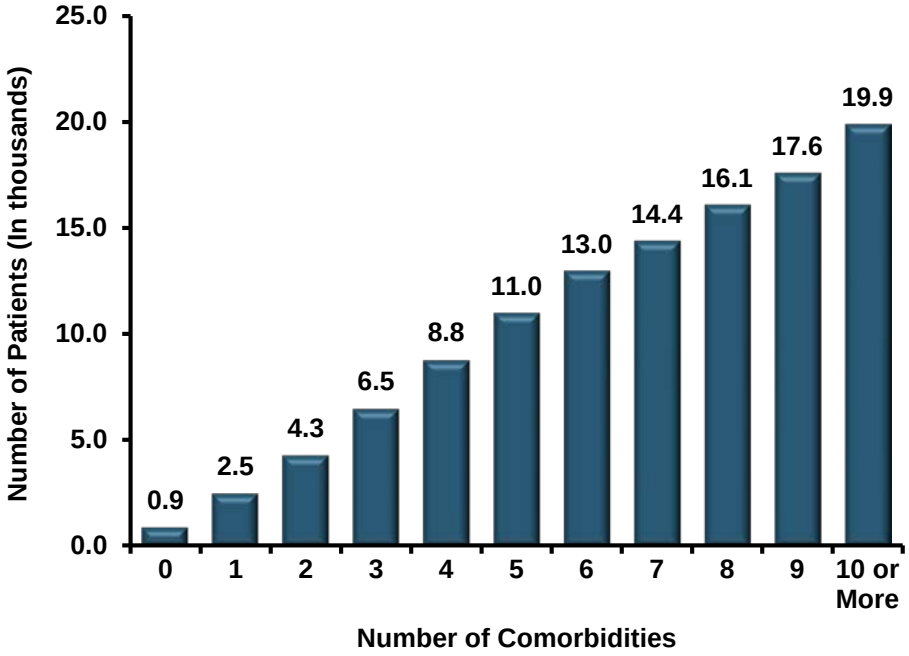
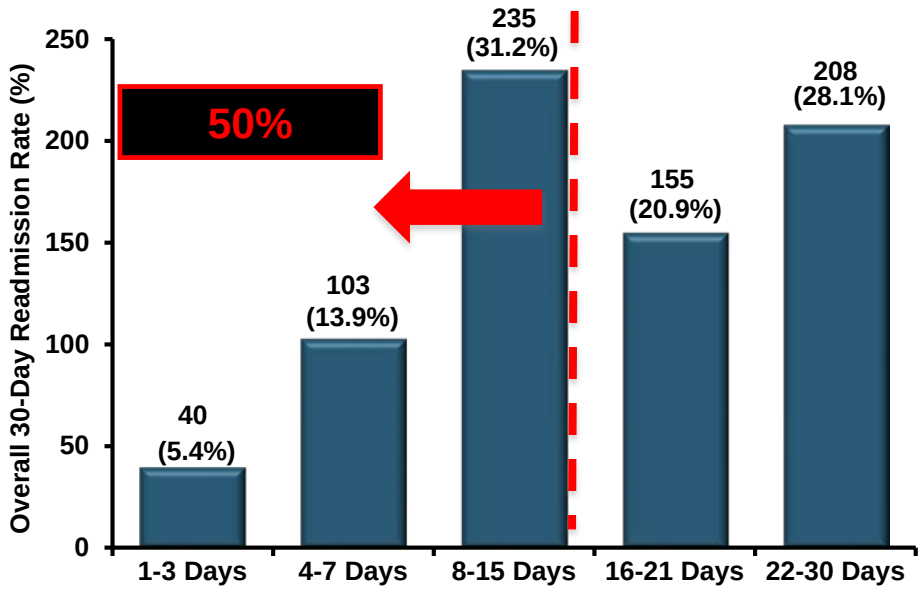
Prevalence of Comorbidities Among Patients with COPD



Schwab P, et al. *Int J Chron Obstruct Pulmon Dis*. 2017;12:735-744.

Impact of Comorbidities and Outpatient Follow-up on Readmission Risk





Du F, et al. *Value in Health*. 2014;17(3):A173.

Patient Discharge and Follow-up

Opportunities to Improve Long-term COPD Care

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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.

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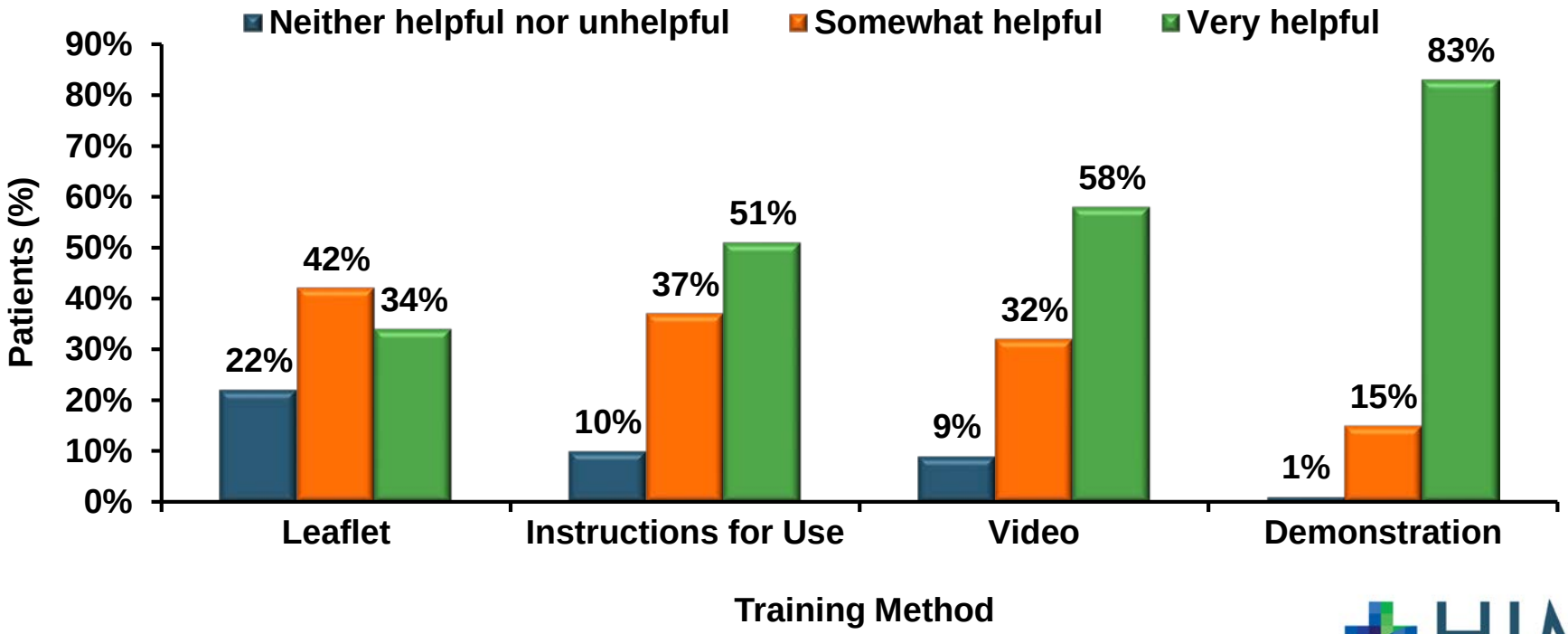
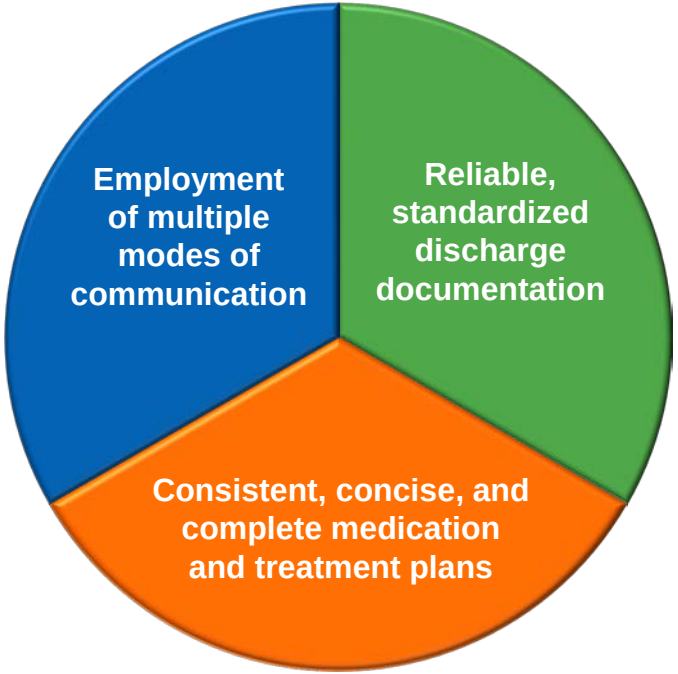
Patient Preferences for Using Different Training Methods



Price D, et al. *Int J Chron Obstruct Pulmon Dis*. 2018;13:695-702.

Improving Communication Between Inpatient and Outpatient HCPs



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

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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 readmission[2]
- Not attending a follow-up visit within 30 days was associated with an increased risk of rehospitalization within 90 days of discharge[3]

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.

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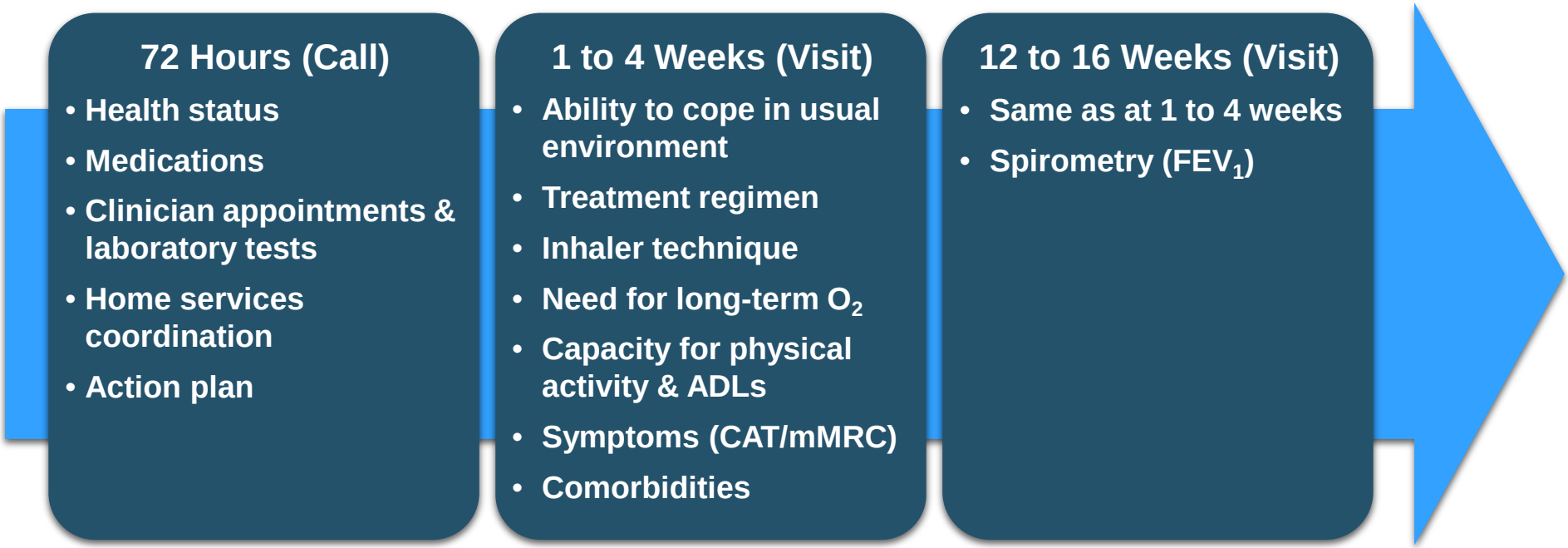
Follow-up Assessment Recommendations



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 https://www.goldcopd.org.

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Case Evaluations

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Case Evaluation #1: Patient Description

Jim is a 65-year-old male who presents to his internal medicine clinician with a complaint of shortness of breath while walking. He is a former smoker with a 35-pack-year history and was diagnosed with type 2 diabetes at age 56, which is managed with metformin. His physical exam is within normal limits. He reports no exacerbations in the past but describes multiple episodes of "having to take a break" while walking with his wife. He is referred for pulmonary function testing and his clinician administers an mMRC. His FEV_1/FVC is .65 and his mMRC score is 2.

Case Evaluation #1: Question 1

Based on the information presented, does Jim meet criteria for diagnosis of COPD?

A. **Yes**
B. No, additional testing is needed
C. No, he does not have COPD

Case Evaluation #1: Question 2

Which of the following is the appropriate GOLD grade for Jim?

A. Group A

B. Group B

C. Group C

Case Evaluation #1: Question 3

Jim is diagnosed with GOLD Group B COPD. Which of the following is the appropriate medication class?

A. A short-acting bronchodilator
B. LABA or LAMA
C. LABA + LAMA

Case Evaluation: 6 Months Later

Jim is managed with a LAMA monotherapy and responded well over the first 3 months. However, after 6 months he presents to the ED with a moderate exacerbation that requires hospitalization. He is treated and stabilized with oxygen therapy and repeated doses of nebulized SABA. On evaluation for discharge with the rounding physician, Jim states that he has not experienced increases in symptoms but he has reduced his activity levels. He says he frequently misses doses of his medication or does not remember if he took it and takes an extra dose. He has gained approximately 10 lbs in 6 months. His laboratory values are unremarkable and his blood eosinophil count is 150 cells/µL.

Case Evaluation #2: Question 1

What is your next step in management?

A. Discharge on current medications and instruction to follow-up with internist
B. Addition of a second long-acting bronchodilator to Jim's regimen and instruction to follow-up with internist
C. Evaluation of device technique
D. Evaluation of home care environment or environmental exposures

Case Evaluation #2: Question 2

If Jim exhibits correct inhaler technique, which of the following therapeutic strategies would you recommend on discharge?

A. Maintain current treatment regimen with a dose counter
B. LABA + LAMA with a dose counter
C. LABA + LAMA via nebulizer
D. LABA + ICS with a dose counter

Case Evaluation #2: Question 3

If Jim DOES NOT exhibit correct inhaler technique, which of the following therapeutic strategies would you recommend on discharge?

A. Retrain on technique and maintain current treatment regimen with a dose counter
B. Switch to LABA or LAMA via nebulizer
C. Switch to LABA + LAMA via nebulizer

Summary

- Exacerbations of COPD represent a significant health and economic burden in the hospital setting
- Diagnosis and COPD group stage is based on pulmonary function, symptoms, and exacerbations
- Newest GOLD Guidelines separate initial pharmacotherapy from step-up strategies on follow-up
- Individualized treatment and follow-up care that address behavioral, physical, and environmental barriers to effective COPD management are essential for preventing hospital readmissions

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Clinical Pearls

- Utilize an assessment of symptoms with mMRC or CAT and exacerbation history to establish GOLD Group and guide initial pharmacotherapy
- Evaluate symptoms and exacerbations at follow-up and make treatment modifications based on the predominant treatable trait
- 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

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Thank You!

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