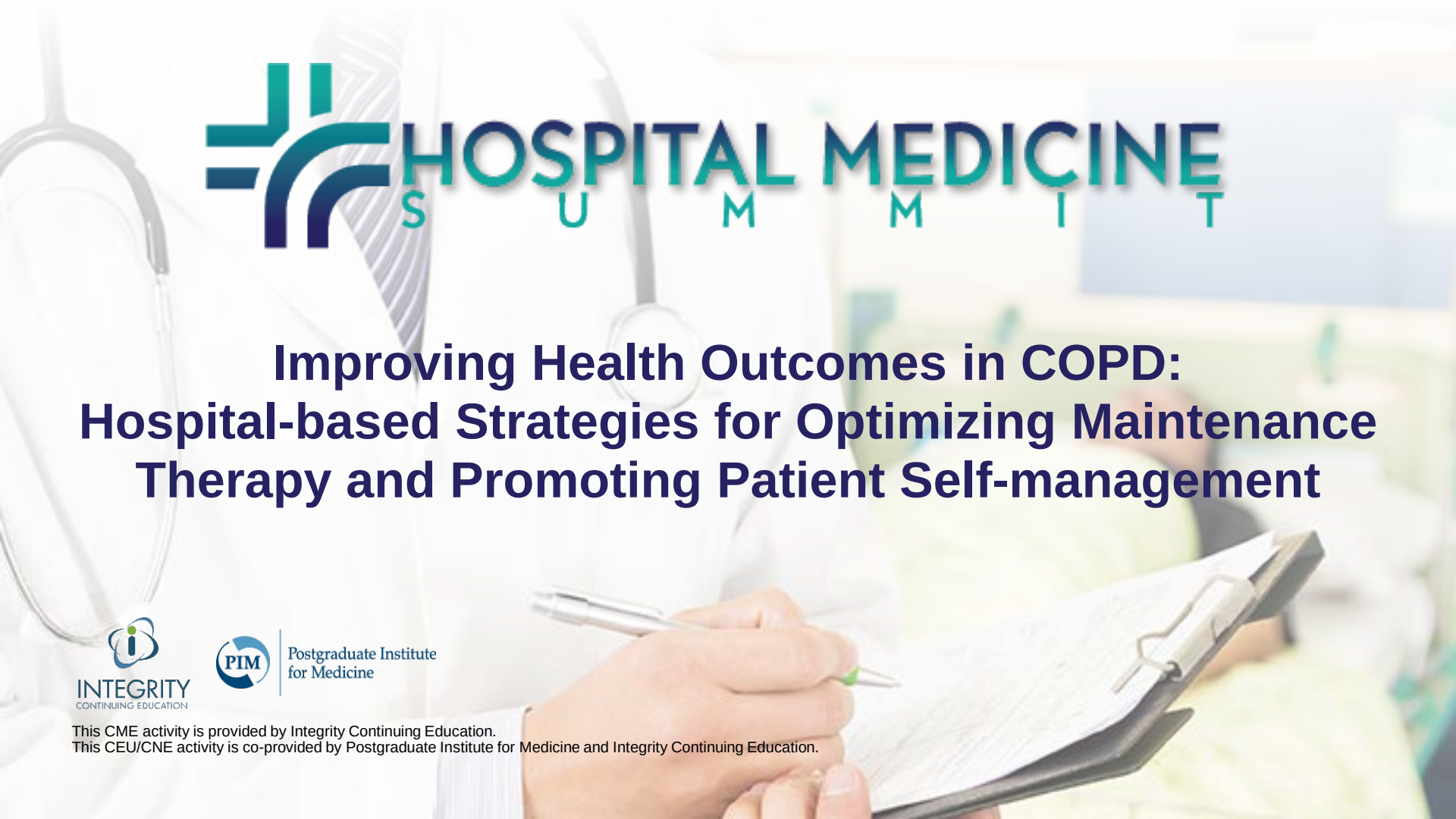
HOSPITAL MEDICINE SUMMIT

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



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Faculty Disclosures

- Consultant: AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Theravance, Sunovion Pharmaceuticals
- Research: Sunovion Pharmaceuticals

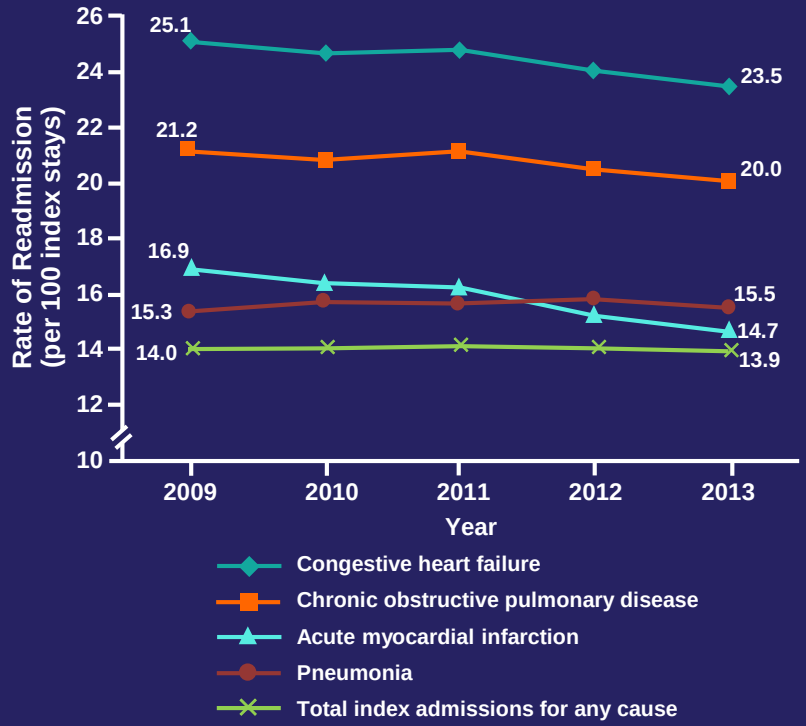
Learning Objectives

- 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

COPD in the Hospital Setting

In-hospital Burden of COPD

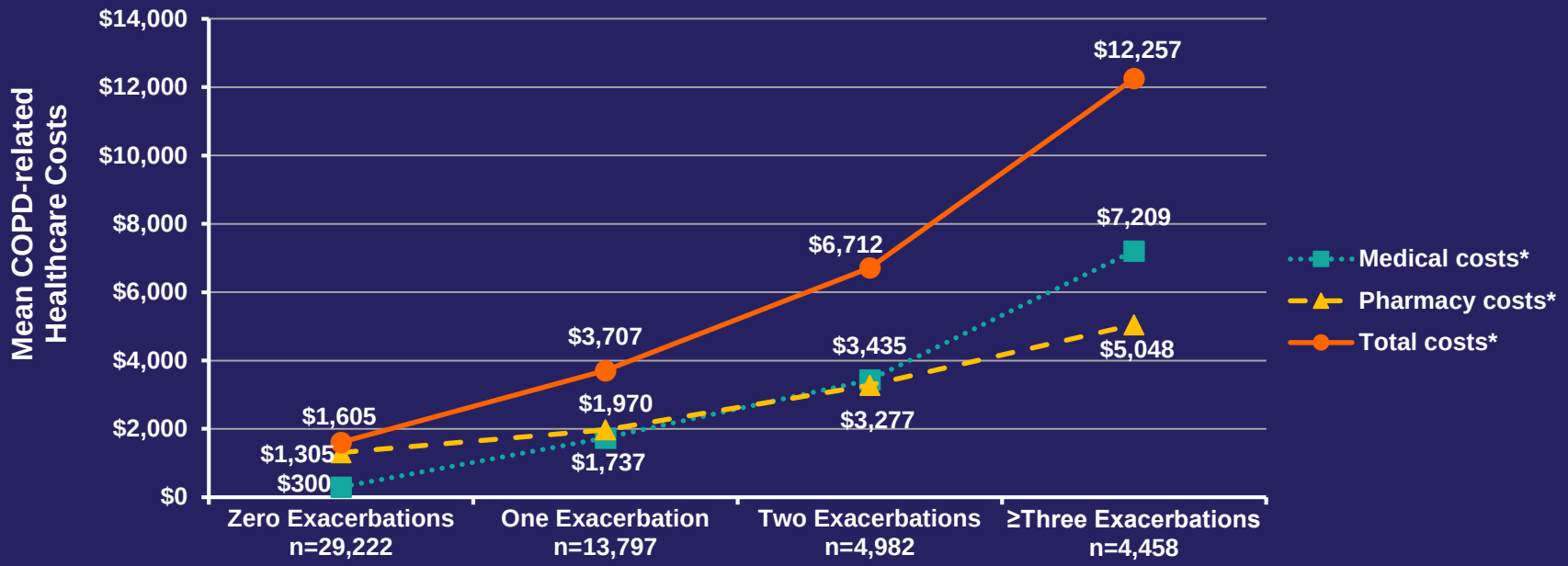
- 1.1 million COPD-related ED visits
- 660,000 discharges with a primary diagnosis of COPD
- 20% all-cause 30-day readmission rate among patients with an index hospitalization for COPD
- In-hospital mortality:
  - 2.5% for exacerbation-related admissions
  - Up to 28% for patients requiring mechanical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



ED, emergency department.

Singh JA, et al. *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.

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.

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

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
- O_2 therapy
- NIV/IMV

IMV, invasive mechanical ventilation; NIV, noninvasive ventilation; SABA, short-acting beta$_2$-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.

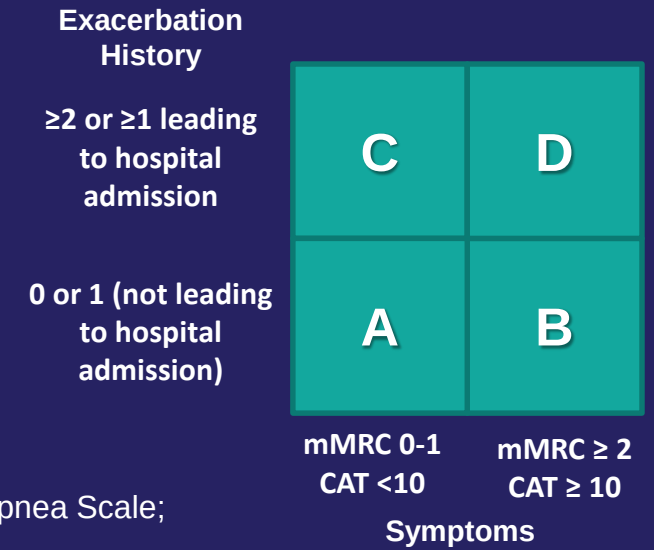
Assessment of COPD Severity and Exacerbation Risk

The Redefined ABCD Assessment Tool

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.

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.

*N=668 patients with spirometry results that could be rated for severity. Multi-center, cross-sectional, observational study conducted in 83 primary care clinics in the US.

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.**	☐

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

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

Long-term Maintenance Therapy

Medication Selection

Approved Long-acting Bronchodilator Monotherapies

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

LABA, long-acting beta$_2$-agonist; LAMA, long-acting muscarinic antagonist; DPI, dry powder inhaler; IS, inhalation spray; SMI, slow mist inhaler.

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

Approved Fixed-dose Combination Therapies

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

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

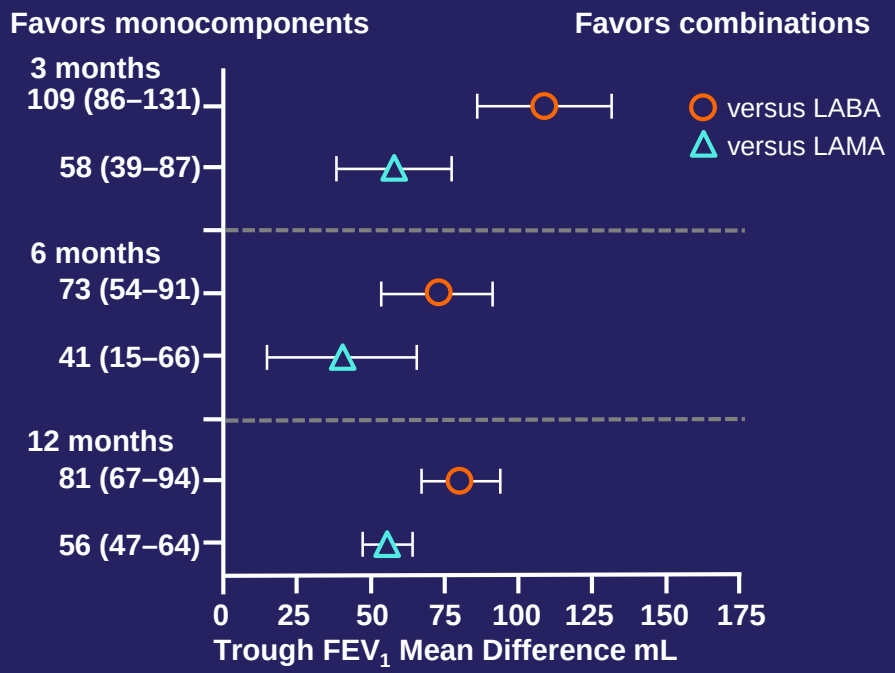
ICS, inhaled corticosteroid; MDI, metered dose inhaler.

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

Emerging Therapies

Type	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

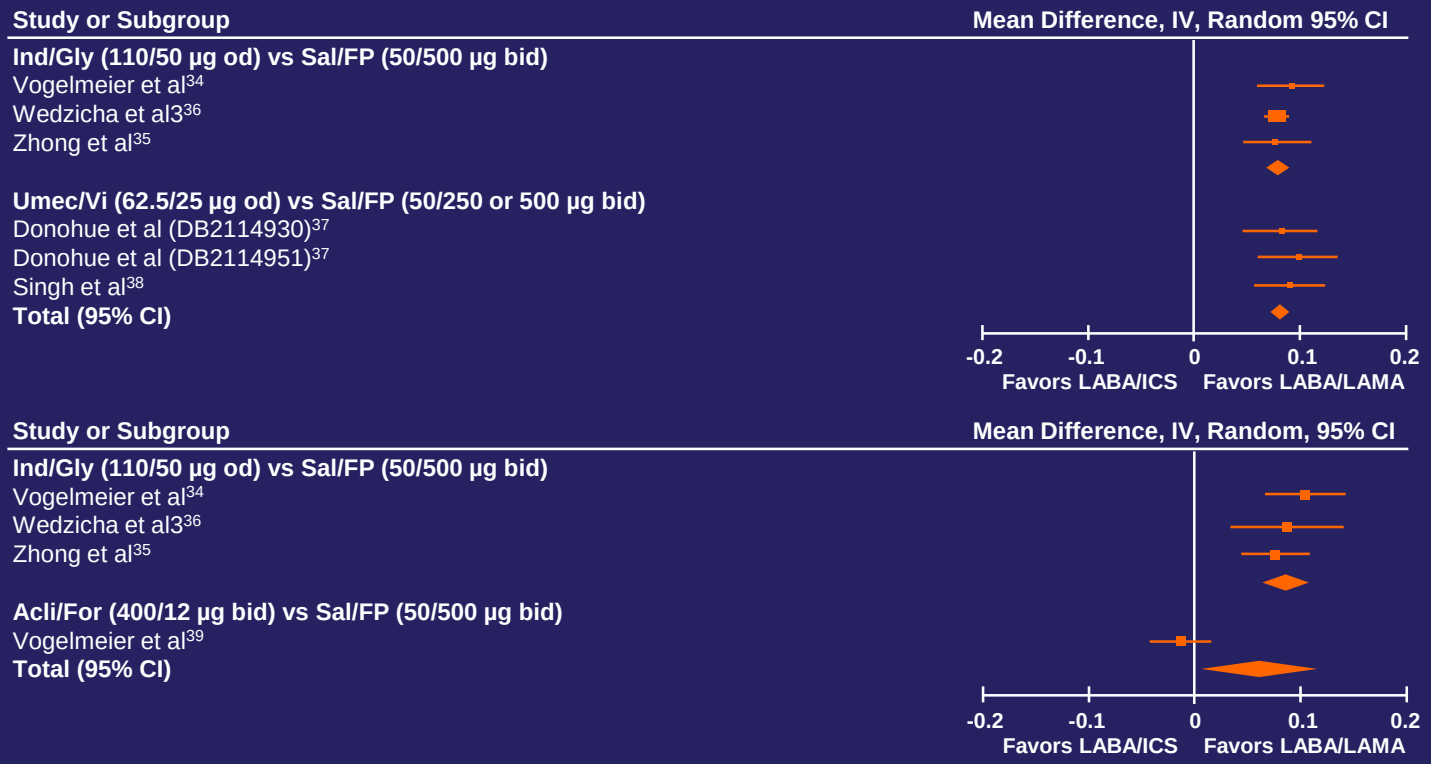


- Meta analysis of 14 studies
- N=20,329 patients
- LABA/LAMA combinations were more effective vs monocomponents at 3, 6, and 12 months of treatment
  - Improvements in trough FEV_1
  - Transition dyspnea index
  - SGRQ scores

SGRQ, St George's Respiratory Questionnaire.

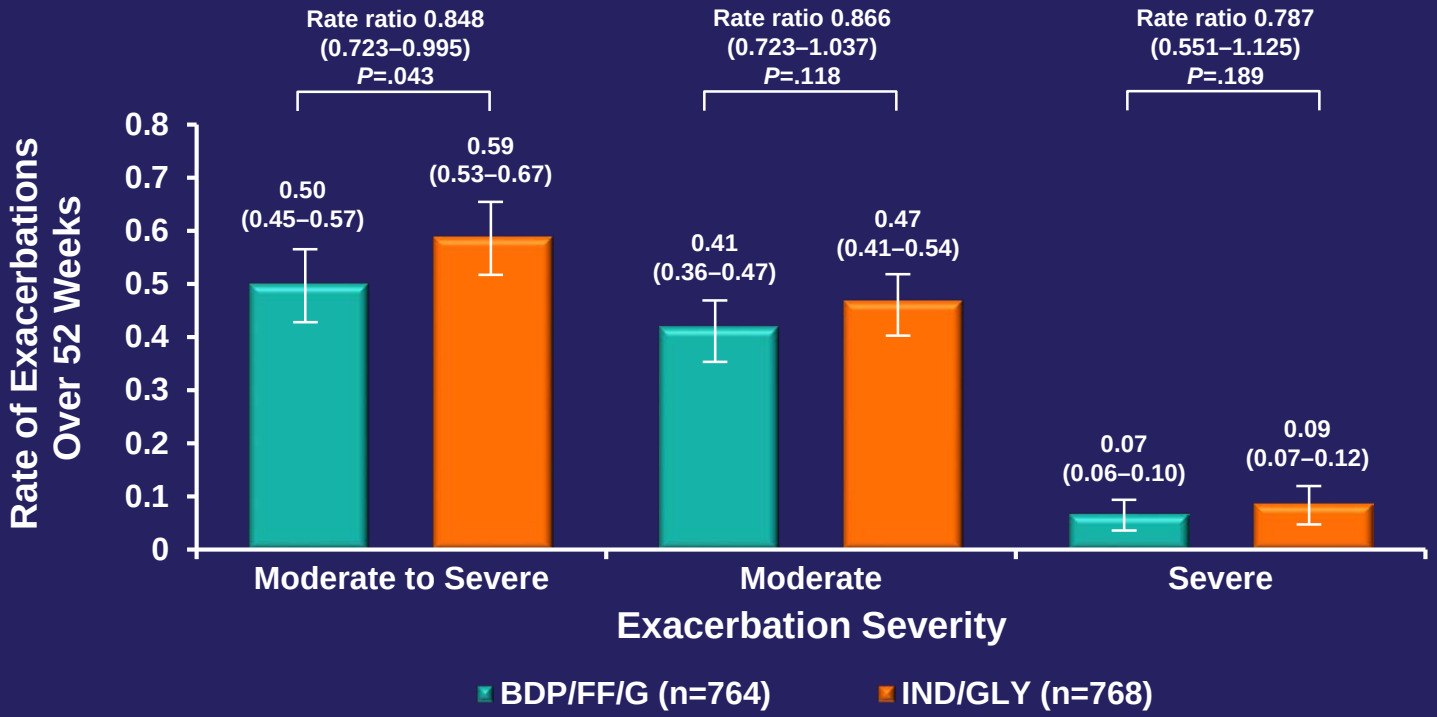
Calzetta L, Rogliani P, Ora J, et al. *Eur Respir Rev.*2017;26:160043.

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



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

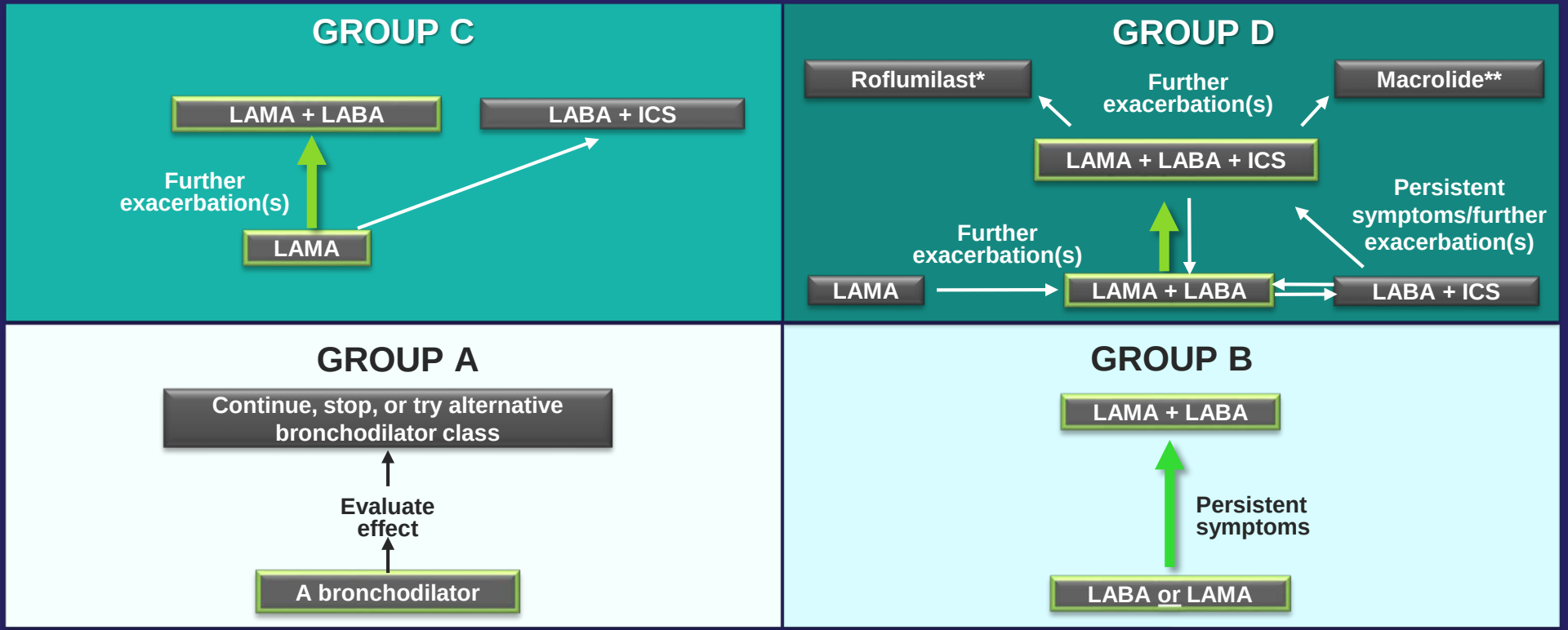
Extrafine Inhaled Triple Therapy Reduces Exacerbations vs Dual Bronchodilator Therapy



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 FEV_1 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

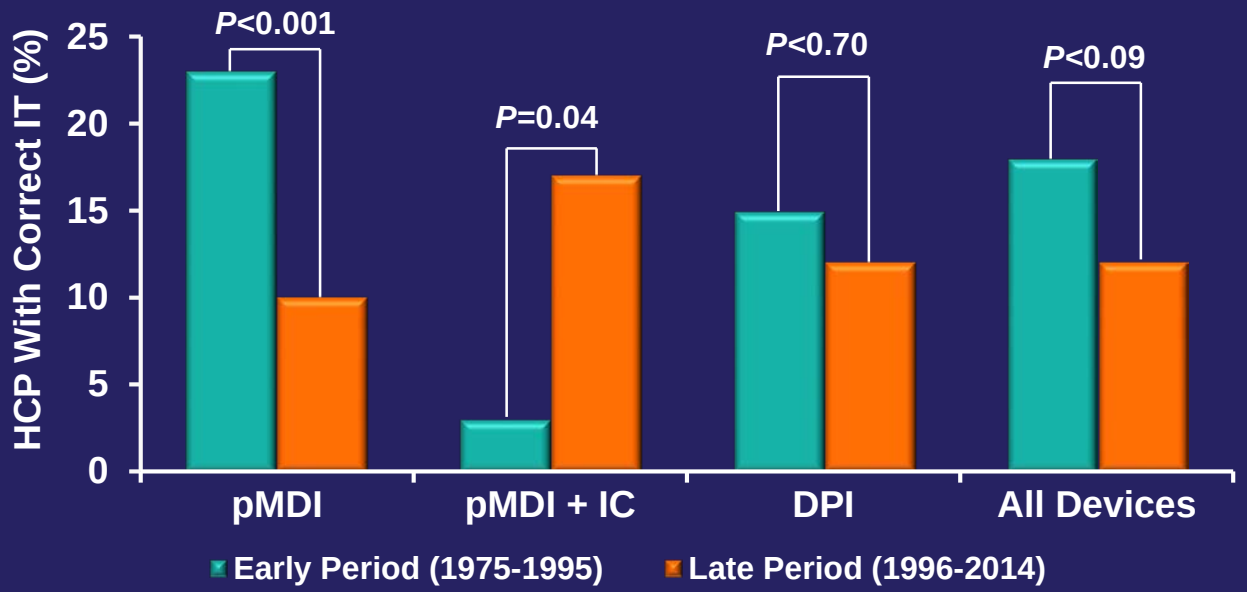
Appropriate Delivery Device Selection

Knowledge of Inhaler Technique Is Important

1. Guidelines recommend all patients should be trained in proper inhaler technique
2. They recommend regular assessment of patient's technique
3. Inadequate technique is common & associated with poor disease control, exacerbations, hospitalizations, additional therapies

Plaza VJ. *Allergy Clin Immunol Pract*. 2018;6(3):987-995.

HCPs Rarely Demonstrate Correct Technique



Percentage of the correct inhalation technique of the health care professionals over time for all devices separately and as a group. For a dry powder inhaler, the early period was from 1990 to 2002 and the late period was from 2003 to 2014.

Only 15.5% of HCP showed correct IT

HCP IT has decayed over time

DPIs associated with highest error rate

No significant difference among HCP type

Plaza VJ. *Allergy Clin Immunol Pract*. 2018;6(3):987-995.

Poor Technique is Associated with Hospital Readmission after AECOPD

Readmission rates and days to readmission for all patients and for subgroups with suboptimal and optimal peak inspiratory flor

	All Patients	sPIF	oPIF	*P* Value
All-cause readmittance <30 days	15/125 (12.2%)	11/64 (17.2%)	4/49 (6.8%)	.078
COPD readmittance <30 days	9/123 (7.3%)	7/64 (10.9%)	2/59 (3.4%)	.11
All-cause readmittance <90 days	40/123 (32.5%)	25/64 (39.1%)	15/59 (25%)	.11
COPD readmittance <90 days	26/123 (21.1%)	18/64 (28.1%)	8/59 (13.6%)	**.048**
Days to all-cause readmittance	80 (42-142) (N=69)	65.5 (24.3-107.3) (N=36)	101 (54.5-205.5) (N=33)	**.000**
Days to COPD readmittance	83 (45-159) (N=47)	63.5 (21-89.8) (N=24)	144 (66-218) (N=23)	**.002**

Loh C, et al. *Ann Am Thorac Soc*. 2017;14(8):1305-1311.

There is no perfect inhaler device…each is outstanding in it's own right

Inhaler	Advantages	Dis
pMDI	(i) Portable and compact; (ii) Multidose device; (iii) Metered dose; (iv) Established/familiar; (v) Available for most inhaled meds	(i) Require coordination; (ii) High deposition in mouth and oropharynx; (iii) "Cold Freon" effect; (iv) Contain propellants
pMDI + spacer	(i) Lower dependence on inspiratory effect; (ii) Easier to coordinate; (iii) Higher lung deposition than pMDI; (iv) Reduced mouth and oropharynx deposition	(i) Less portable; (ii) Certain spacers require electrostatic charge; (iii) Additional cost to pMDI; (iv) Requires a moderate inspiratory effect
BA-MDI	(i) Portable and compact; (i) Multidose device; (ii) Breath-actuated	(i) Contain propellants; (ii) "Cold Freon" effect; (iii) Requires a moderate inspiratory effect
DPI	(i) Portable and compact; (ii) Breath-actuated; (iii) Does not contain propellants; (iv) Multi-dose devices available	(i) Requires a minimum inspiratory effect; (ii) May not be appropriate for emergency situations; (iii) Multiple designs; (iv) May be complicated to load
SMI	(i) Portable and compact; (ii) Multidose device; (iii) Lower dependency on inspiratory effect; (iv) High fine-particle fraction: (v) High lung deposition, low mouth and oropharynx deposition; (vi) Does not contain propellants	(i) Not breath actuated; (ii) Only one device currently available
Nebulizer	(i) Can be used at any age; (ii) Can be used by acutely ill; (iii) No specific inhalation technique required; (iv) Can be used to dispense drugs not available as pMDI or DPI	(i) Most lack portability; (ii) Some require an outside energy source; (iii) Noise); (iv) Can result in longer treatment times; (v) Can be expensive

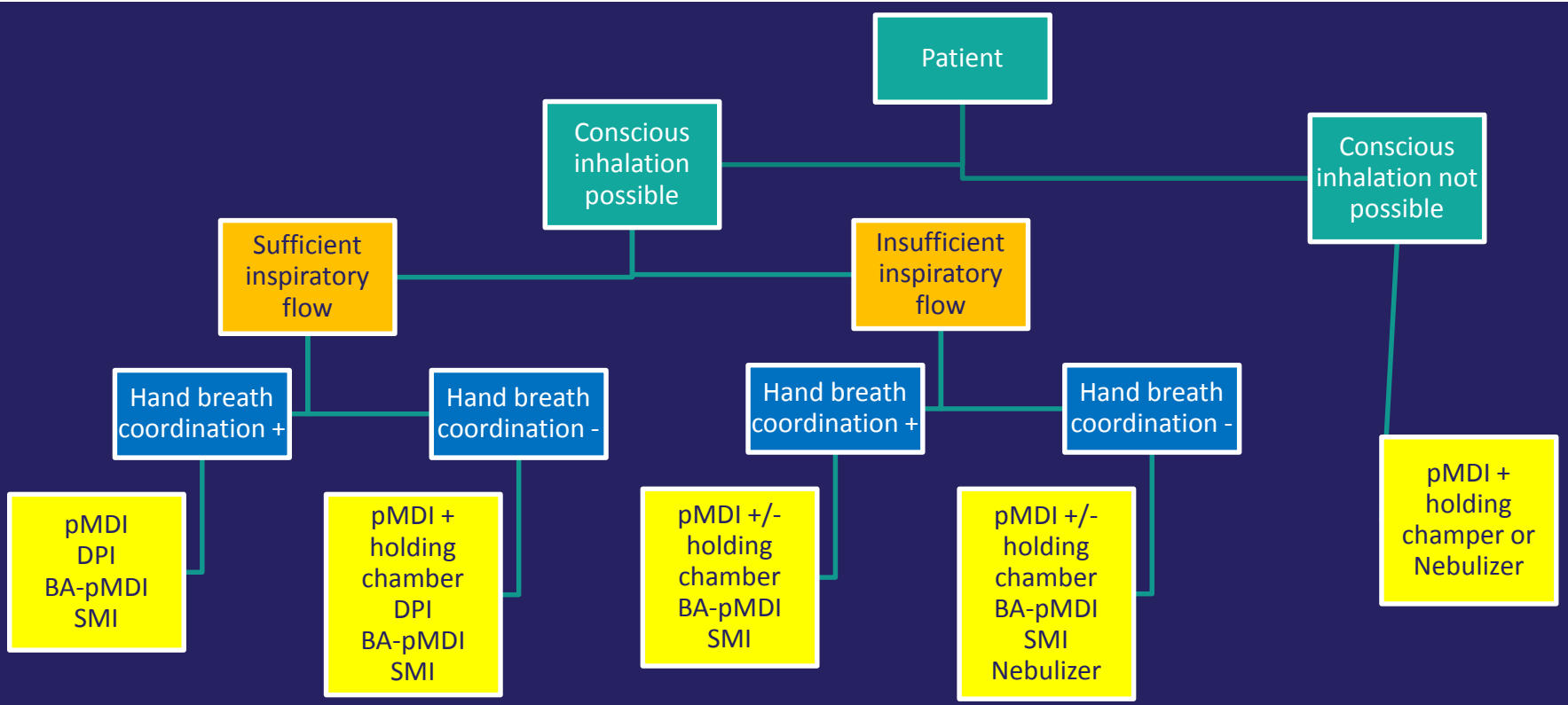
Kaplan A. *Can Respir J.* 2018;Article #9473051.

Matching the Device to the Patient

- Up to 100% of patients demonstrate at least one error
- Many factors affect patient's ability to use device correctly
  - Age
  - Dexterity
  - Coordination
  - PIFR
  - Cognitive ability
  - Co-morbid conditions (arthritis, blindness, deafness, neuromuscular)
  - Health literacy
  - Ethnicity
- Treatment success influenced by
  - Patient preferences
  - Patient perceptions

Kaplan A. *Can Respir J.* 2018;Article #9473051.

Matching the Device to the Patient



Kaplan A. *Can Respir J.* 2018;Article #9473051.

Overcoming Cognitive and Physical Limitations

Limitation		Potential Strategy
Physical	• Unable to generate adequate PIFR	SMI, nebulizer
	• 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

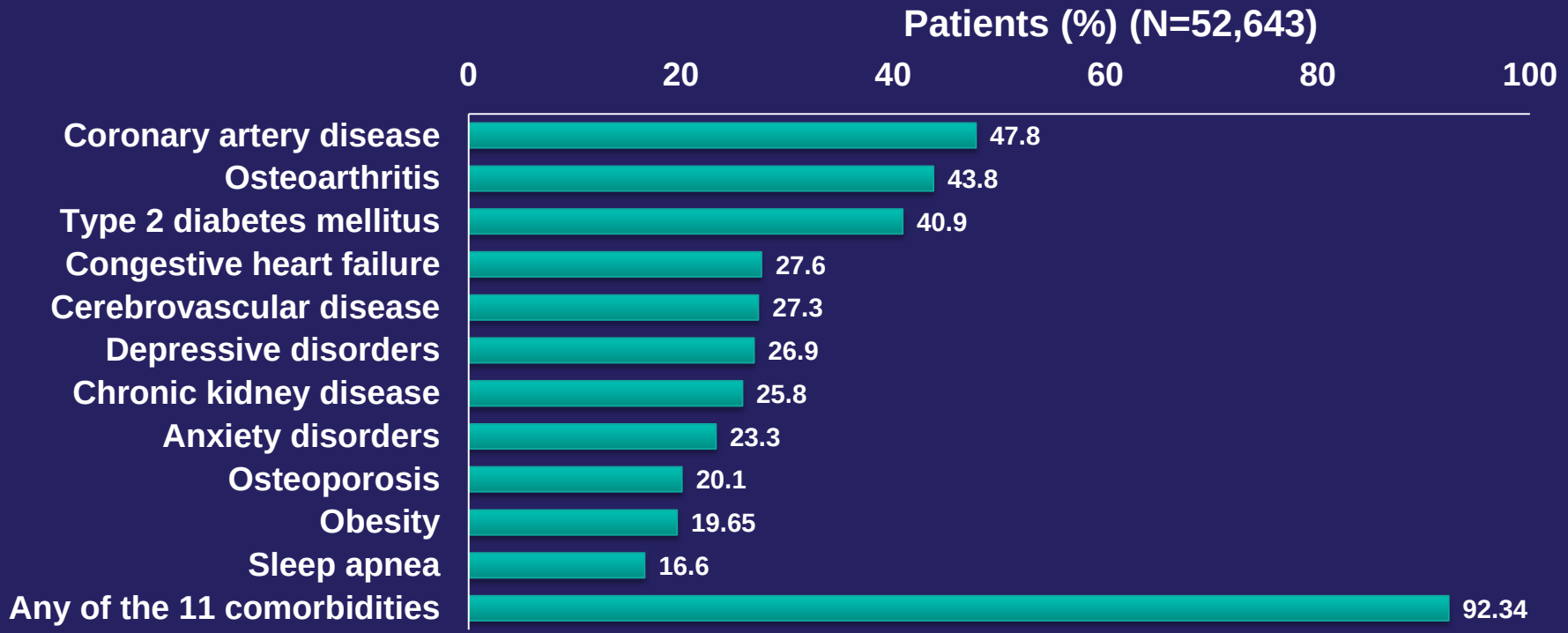
PIFR; peak inspiratory flow rate.

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 Care

Consideration of Comorbidities

Prevalence of Comorbidities Among Patients with COPD



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

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

Total Costs	COPD Patients (n=11,493) Event/1000 Person-Years	Matched Controls (n= 22,986) 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.

Opportunities to Improve Long-term COPD Care

Patient Discharge and Follow-up

HOSPITAL MEDICINE SUMMIT

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

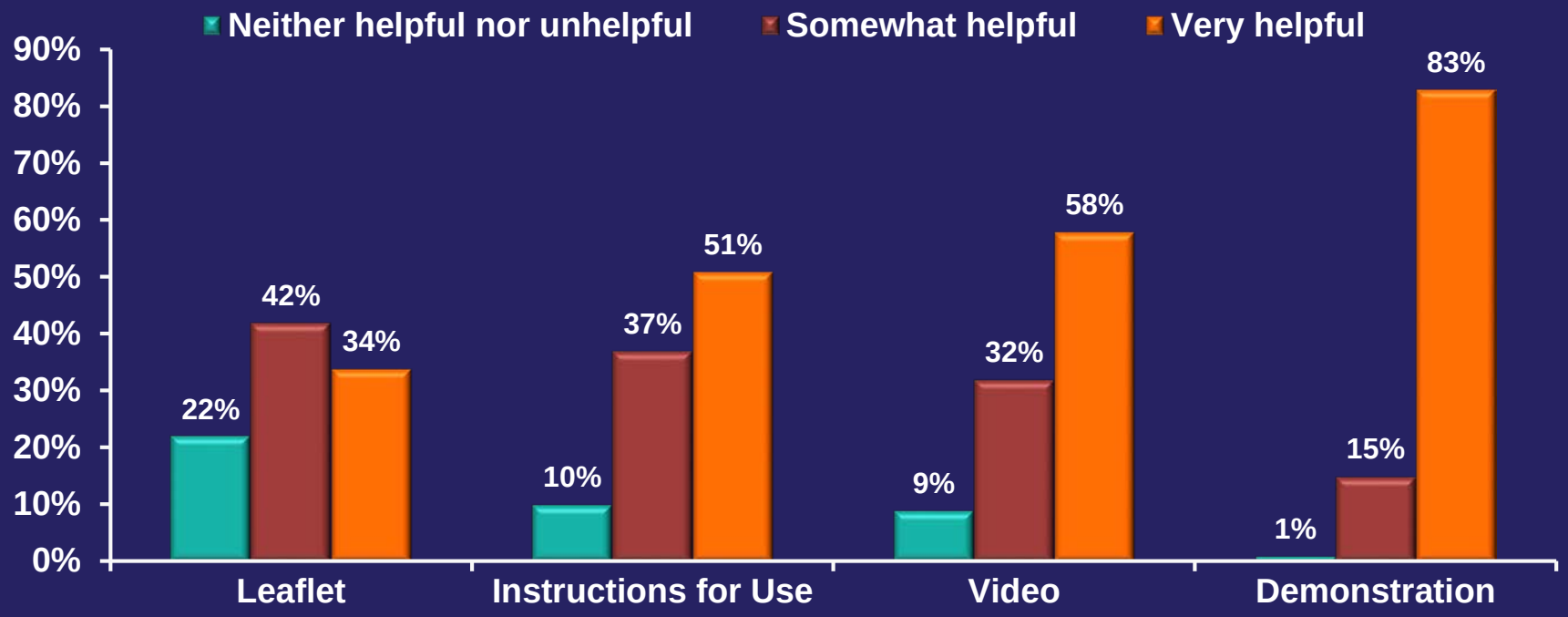
Referral & Follow-up

- 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.

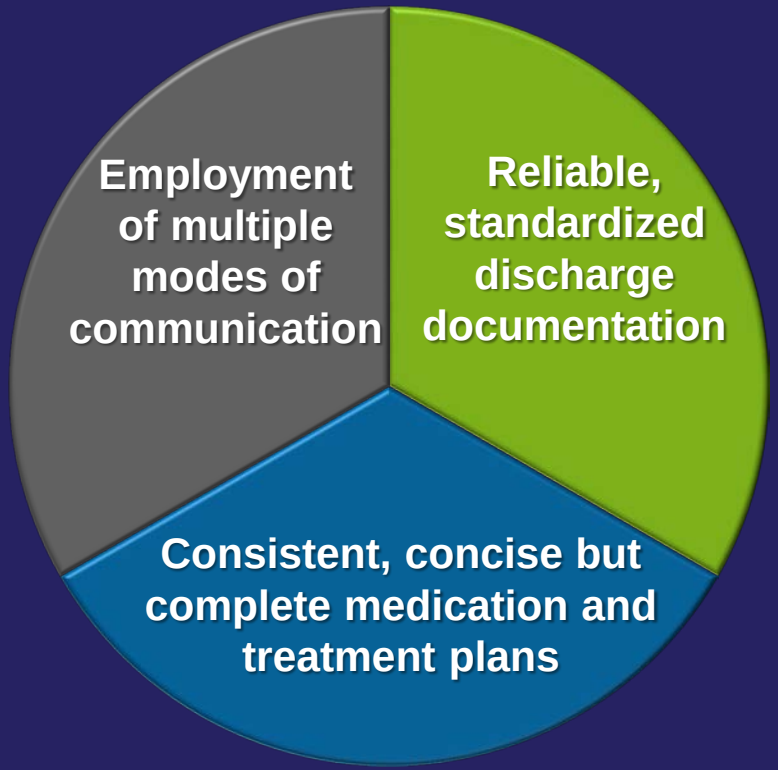
Vestbo J, et al. GOLD 2018 Update. Available at http://goldcopd.org.

Patient Preferences for Using Different Training Methods



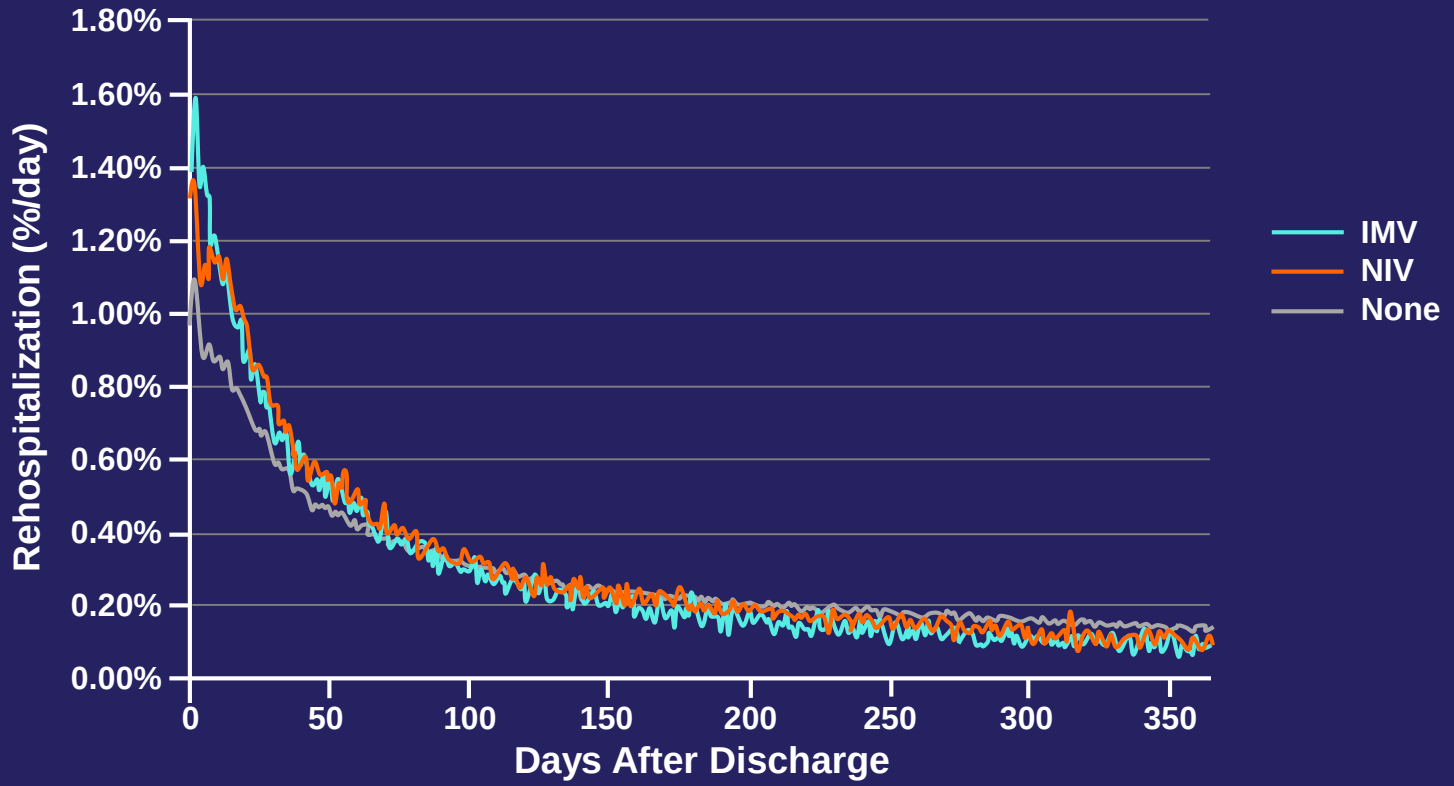
Price D, et al. *Int J COPD.* 2018;13:695-702.

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.

Prolonged Risk for Readmission Following Hospitalization for COPD



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

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.

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 O_2
- Capacity for physical activity & ADLs
- Symptoms (CAT/mMRC)
- Comorbidities

12 to 16 Weeks (Visit)

- Same as at 1 to 4 weeks
- Spirometry (FEV_1)

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.

Case Evaluation #2: Question 2

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

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

Case Evaluation #2: Question 3

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

Clinical Pearls

- 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!