

# ACHIEVING OPTIMAL COPD MANAGEMENT THROUGH INDIVIDUALIZED TREATMENT AND DEVICE SELECTION



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# Faculty Disclosures

• Dr. Sharafkhaneh has no real or apparent conflicts of interest to report.



# 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

HIN.

 Match patients with appropriate COPD medication delivery devices

# **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, 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



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

# **COPD-related Healthcare Costs**



+HIN

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.

### 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.



# Mortality After Hospitalization In COPD



- **HIMF** 

51,353 VA patients in the USA.

Increasing mortality with additional hospitalizations.

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

# MANAGEMENT OF AN ACUTE EXACERBATION

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# Assessment of an Exacerbation

- Assess severity of symptoms
- Chest radiograph
- Blood gases and/or O<sub>2</sub> 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.



# 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.

# ASSESSMENT OF COPD SEVERITY AND EXACERBATION RISK

# The Redefined ABCD Assessment Tool



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.

# The Redefined ABCD Assessment Tool

#### **Exacerbation History**

Assess 1 – symptoms	≥2 or ≥1 leading to hospital admission	C	D
and 2 – risk of exacerbations	0 or 1 (not leading to hospital admission)	Α	B
		mMRC 0-1 CAT <10 Symj	mMRC ≥ 2 CAT ≥ 10 otoms

**HIMF** 

CAT, COPD Assessment Test; mMRC, modified Medical Research Council Dyspnea Scale; FEV<sub>1</sub>, forced expiratory volume in 1 second; FVC, forced vital capacity. Vestbo J, et al. GOLD 2018 Update. Available at http://goldcopd.org.

### 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.	

**HIMF** 

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

### CAT Assessment

For each item below, place a mark ( $\chi$ ) in the box that best describes you currently. Be sure to only select one response for each question.

Example:	l am very happy	0 💔	2	3	4	5	I am very sad	SCORE
I never cough		01	2	3	4	5	I cough all the time	
I have no phlegm (r	nucus) in my chest at all	01	2	3	4	5	My chest is completely full of phlegm (mucus)	
My chest does not	feel tight at all	01	2	3	4	5	My chest feels very tight	
When I walk up a hi I am not breathless	ill or one flight of stairs,	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 doi	ng any activities at home	01	2	3	4	5	I am very limited doing activities at home	
I am confident leav my lung condition	ing my home despite	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 energ	у	0 1	2	3	4	5	I have no energy at all	
							ΤΟΤΑΙ	

SCORE

# **MEDICATION SELECTION**

Long-term Maintenance Therapy

### Approved Long-acting Bronchodilator Monotherapies

Class	Agent	Brand	Delivery	
	Arformoterol	Brovana®	Nebulizer	
	Formatoral	Perforomist <sup>®</sup>	Nebulizer	
	Formoteror	Foradil <sup>®</sup> Aerolizer	DPI	
LADA	Indacaterol	Arcapta <sup>®</sup> Neohaler <sup>®</sup>	DPI	
	Olodaterol	Striverdi <sup>®</sup> Respimat <sup>®</sup>	SMI	
	Salmeterol	Serevent <sup>®</sup> Diskus <sup>®</sup>	DPI	
LAMA	Aclidinium	Tudorza <sup>®</sup> Pressair <sup>®</sup>	DPI	
	Tietropium	Spiriva <sup>®</sup> Respimat <sup>®</sup>	DPI IS	
	notopium	Spiriva <sup>®</sup> Handihaler <sup>®</sup>	IS	
	Umeclidinium	Incruse <sup>®</sup> Ellipta <sup>®</sup>	DPI	
	Chronnium	Seebri <sup>®</sup> Neohaler <sup>®</sup>	DPI	
	Giycopyrronium	Lonhala <sup>®</sup> Magnair <sup>®</sup>	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.



## Approved Fixed-dose Combination Therapies

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



# Emerging Therapies

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



### LABA/LAMA Combined Bronchodilator Therapy vs Monotherapy



SGRQ, St George's Respiratory Questionnaire. Calzetta L, Rogliani P, Ora J, et al. *Eur Respir Rev*.2017;26(143).

- 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<sub>1</sub>
  - Transition dyspnea index
  - SGRQ scores

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

	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	
Wedzicha et al3	
Zhong et al	
	•
Umec/Vi (62.5/25 µg od) vs Sal/FP (50/250 or 500 µg bid)	
Donohue et al (DB2114930)	
Donohue et al (DB2114951)	
Singh et al <sup>38</sup>	
Total (95% CI)	
Heterogeneity: $\tau^2$ =0.00, $\chi^2$ =1.82, df=5 (P=.87), P=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
	Mean Difference, IV.
Study or Subgroup	Random, 95% Cl
Ind/GIV (110/50 up od) vs Sal/EP (50/500 up bid)	Ind indeceteral:
Vocelmeier et al	Gly, glycopytronium:
Wedzicha et al3	Sal salmeterol:
Zhong et al	
	hid twice doily:
Acli/For (400/12 ug bid) vs Sal/FP (50/500 ug bid)	
Vonelier et al	
vogenneter et al	
Total (05% CI)	Acii, aciidinium;
Haterogenetic: $z^2 = 0.00$ , $z^2 = 20.20$ , $dz^2 = 2(P_z, 0.001)$ , $P_z = 0.00(z)$	Od, once daily
Therefore the provide the frequency $L = 0.00, L = 0.00, L = 0.000, L = 0.00$	For, formoterol.
1 = 31 101 0 = 1001. 2 = 2.03 (1 = .07)	-0.2 -0.1 0 0.1 0.2
	FAVOIS LADAVIUS FAVOIS LABAVLAMA

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

### Extrafine Inhaled Triple Therapy Reduces Exacerbations vs Dual Bronchodilator Therapy



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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

≥2 moderate exacerbations or ≥1 leading to hospitalization	GROUP C LAMA	GROUP D LAMA <u>or</u> LAMA + LABA* <u>or</u> ICS + LABA** *Consider if highly symptomatic. **Consider if eosinophils ≥300.		
0 or 1 moderate exacerbations (not leading to hospitalization)	GROUP A Bronchodilator	GROUP B Long-acting bronchodilator LABA <u>or</u> LAMA		
	mMRC 0-1; CAT <10	mMRC ≥2; CAT ≥10		

ICS, inhaled corticosteroid.

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

# **COPD** Management Cycle

#### Following Implementation of Therapy:



-HIMF

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# Follow-up Pharmacologic Treatment



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\*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.

# **APPROPRIATE DELIVERY DEVICE SELECTION**

Long-term Maintenance Therapy

#### Association between Critical Inhaler Errors\* and Healthcare Utilization



HIN/

\*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)



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

# ✤HIMF

# 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. *Respiration.* 2014;88(1):3-15. Ibrahim M, et al. *Med Devices (Auckl).* 2015;8:131-139.



# 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



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

# 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.

# Patient Resistance & Acceptance of PR

#### Why Do Patients Decline Pulmonary Rehabilitation?<sup>1,2</sup>

- 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?<sup>3,4</sup>

- 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<sup>5</sup>

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.



# **CONSIDERATION OF COMORBIDITIES**

Opportunities to Improve Long-term COPD Care

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# Prevalence of Comorbidities Among Patients with COPD



Patients (%) (N=52,643)

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

### Impact of Comorbidities and Outpatient Follow-up on Readmission Risk



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Number of Comorbidities

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.

### 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

Employment of multiple modes of communication

Reliable, standardized discharge documentation

➡ HIMF

Consistent, concise, and 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%)<sup>1</sup>
- <u>Not</u> attending primary care follow-up within 4 weeks was associated with a 10-fold greater likelihood of 30-day readmission<sup>2</sup>
- <u>Not</u> attending a follow-up visit within 30 days was associated with an increased risk of rehospitalization within 90 days of discharge<sup>3</sup>

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 & laboratory 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<sub>2</sub>
- Capacity for physical activity & ADLs
- Symptoms (CAT/mMRC)
- Comorbidities

#### 12 to 16 Weeks (Visit)

- Same as at 1 to 4 weeks
- Spirometry (FEV<sub>1</sub>)

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.

# **HIMF**

# **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<sub>1</sub>/FVC is .65 and his mMRC score is 2.





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





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

- A. Group A
- **B.** Group B
- C. Group C





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.



#### 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





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



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



- 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



- 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



# **THANK YOU!**