HOSPITAL & INTERNAL MEDICINE FORUM

Optimizing the Management of Heart Failure from Hospital to Home: Translating the Latest Evidence into Practice

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Faculty Disclosures

- Dr. Morris has no real or apparent conflicts of interest to report.

Learning Objectives

- Assess the type, stage, and functional classification of heart failure in hospitalized patients
- Develop a patient-centered, guideline-directed, evidence-based management plan for patients hospitalized with heart failure with reduced ejection fraction (HFrEF)
- Integrate data on newer agents approved for HFrEF to ensure safe and appropriate administration in patients shortly after an acute episode
- Summarize the FDA recall of common heart failure medications and which agents have and have not been recalled
- Apply effective transitions of care strategies for the management of patients with HF

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Introduction

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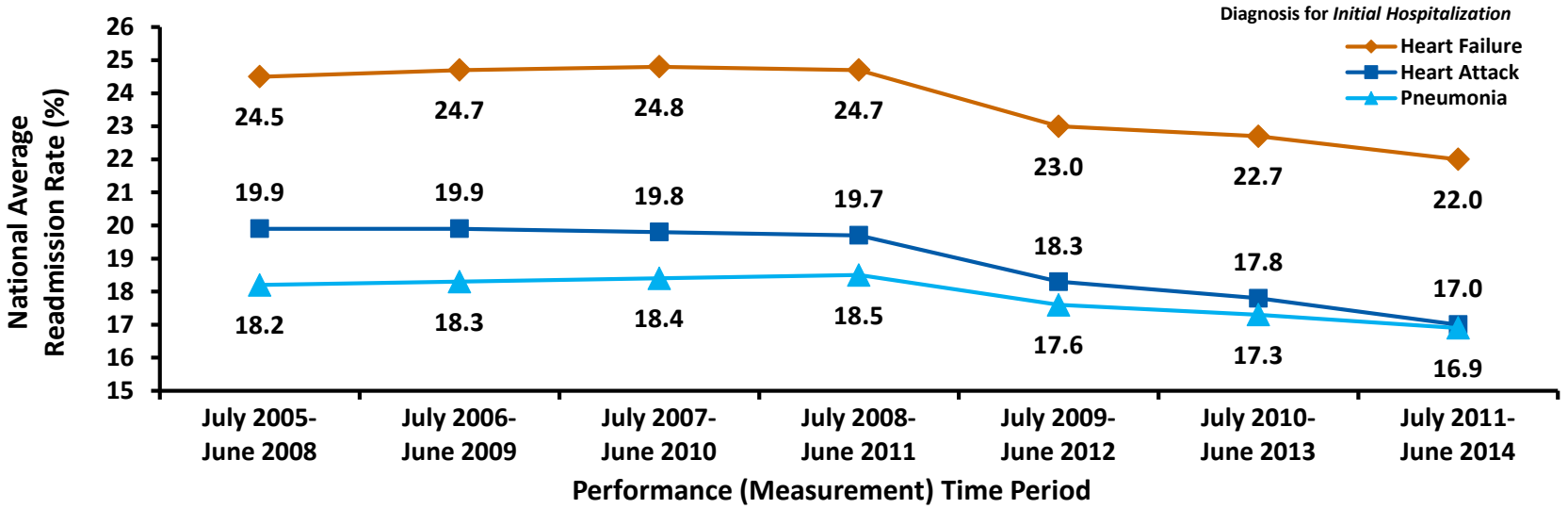
Medicare Readmission Rates Among Patients Hospitalized for Heart Failure



Despite recent decreases, a significant percentage (22%) of patients hospitalized with heart failure are readmitted within 30 days.

Boccuti C. and Casillas G. Aiming for Fewer Hospital U-turns. Issue Brief. March 2017.

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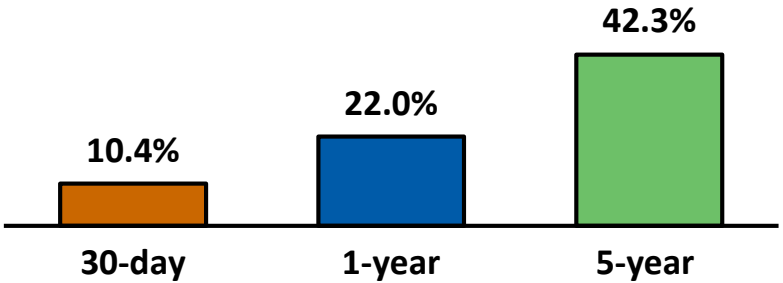
Mortality of Heart Failure

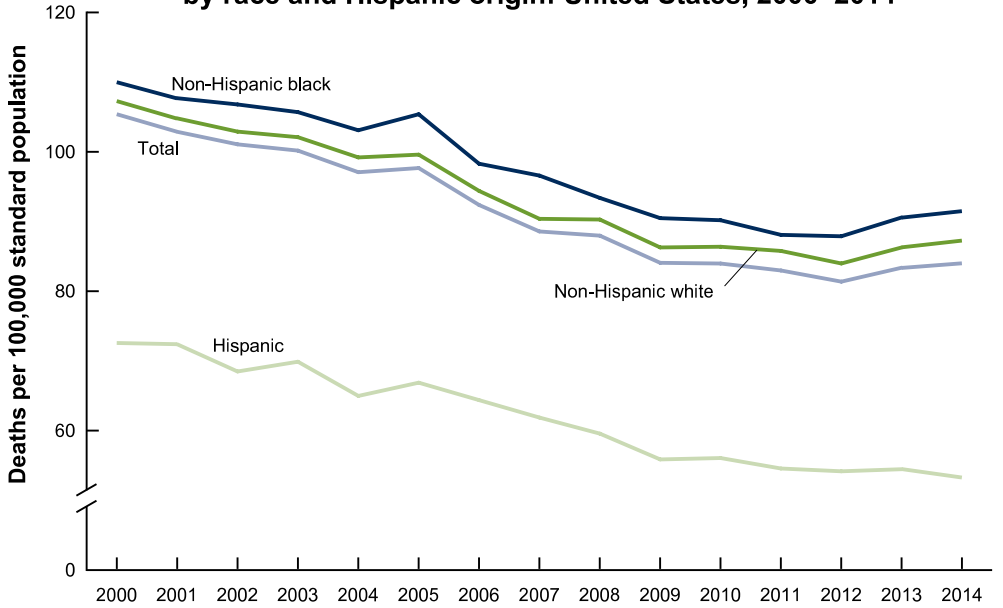
*Every **1 in 8 deaths** has heart failure mentioned on the death certificate.*

Survival has improved due to evidence-based approaches to treat risk factors and appropriate medical therapy. However, **mortality remains high.**

Case Fatality Rates After Hospitalization for Heart Failure



Age-adjusted rate for heart failure-related deaths, by race and Hispanic origin: United States, 2000–2014



Benjamin EJ, et al. *Circulation*. 2018;137:e67–e492.
Ni H, Xu J. NCHS 2015. Ni H and Xu J. NCHS Data Brief. No. 231. December 2015

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Best Practices for Diagnosis, Assessment, and Monitoring of HF in the Hospital Setting

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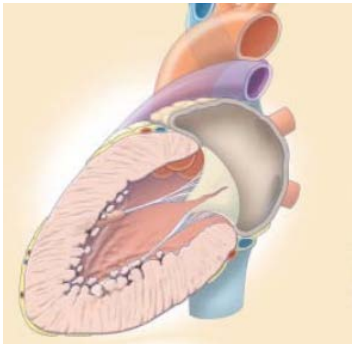
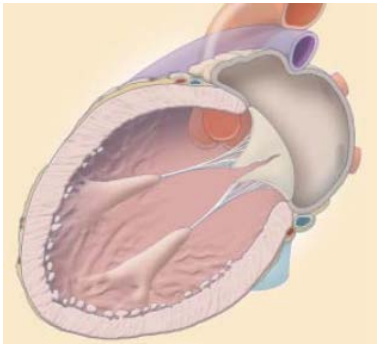
Definition of HF

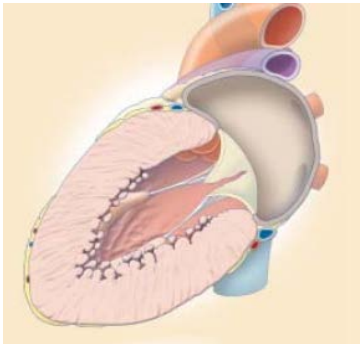
A clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection of blood



Normal Heart



HF with Reduced Ejection Fraction (HF*r*EF)



HF with Preserved Ejection Fraction (HF*p*EF)

Major clinical manifestations: dyspnea, fatigue, and fluid retention*

*Patient presentation varies

Jessup M and Brozena SA. *New Engl J Med.* 2003; 348:2007-2018. Yancy CW, et al. *Circulation.* 2013;128:e240-e327.

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Classification of HF

Classification	EF (%)	Description
HF*r*EF	**≤40**	Also referred to as **systolic HF**. RCTs have mainly enrolled patients with HF*r*EF; to date, only in these patients have effective therapies been demonstrated.
HF*mr*EF	**41-49**	HF with **mid-range ejection fraction**. New category with overlapping characteristics of HFrEF and HFpEF. Clinical course and mortality are more like HFrEF than HFpEF.
HF*p*EF	**≥50**	Also referred to as **diastolic HF**. Several different criteria have been used to further define HF*p*EF. Diagnosis of HF*p*EF is challenging because it largely involves excluding other potential noncardiac causes of symptoms suggestive of HF. To date, no effective therapies have been identified.

RCTs, randomized control trials.

Yancy CW, et al. *Circulation*. 2013;128:e240-e327. Bhambhani V, et al. *Eur J Heart Fail.* 2018 April ; 20(4): 651–659.

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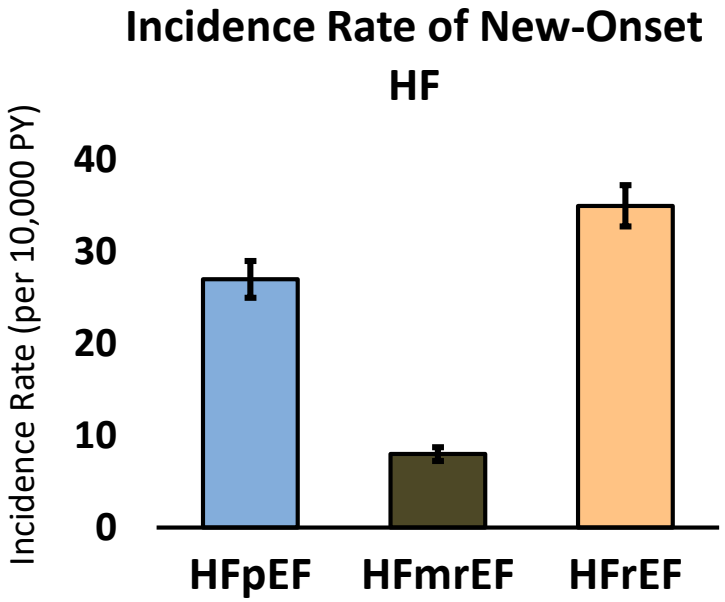
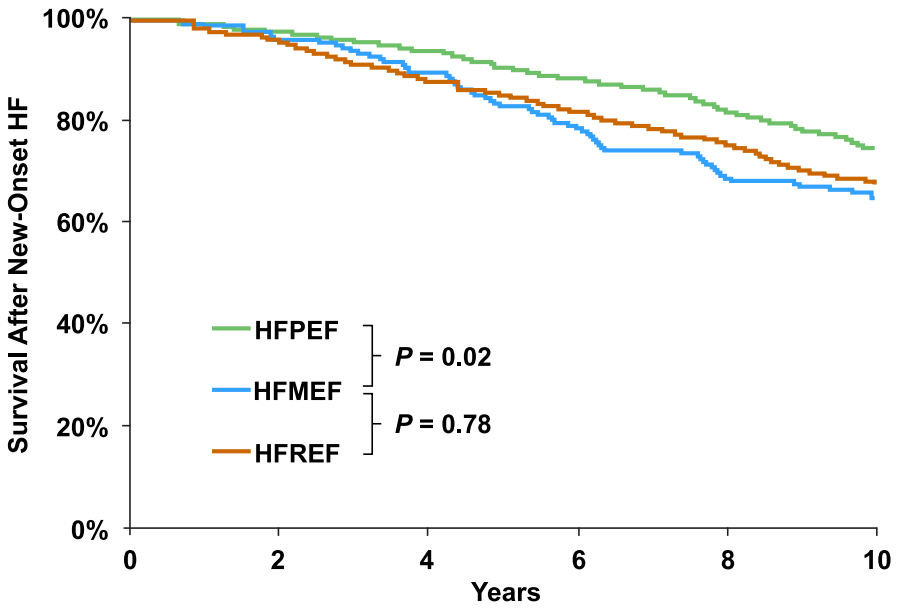
HF Incidence and Mortality by LVEF

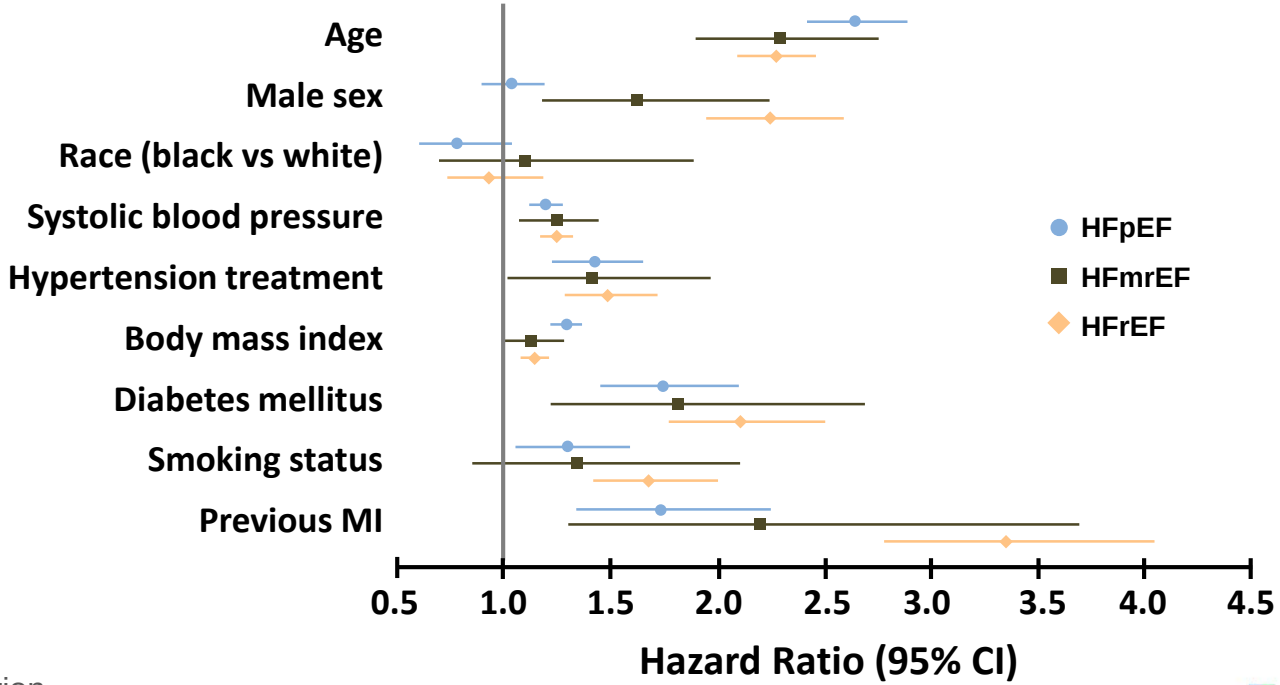




LVEF, left ventricular ejection fraction; PY, person-year.

Bhambhani V, et al. *Eur J Heart Fail.* 2018 April;20(4): 651–659.

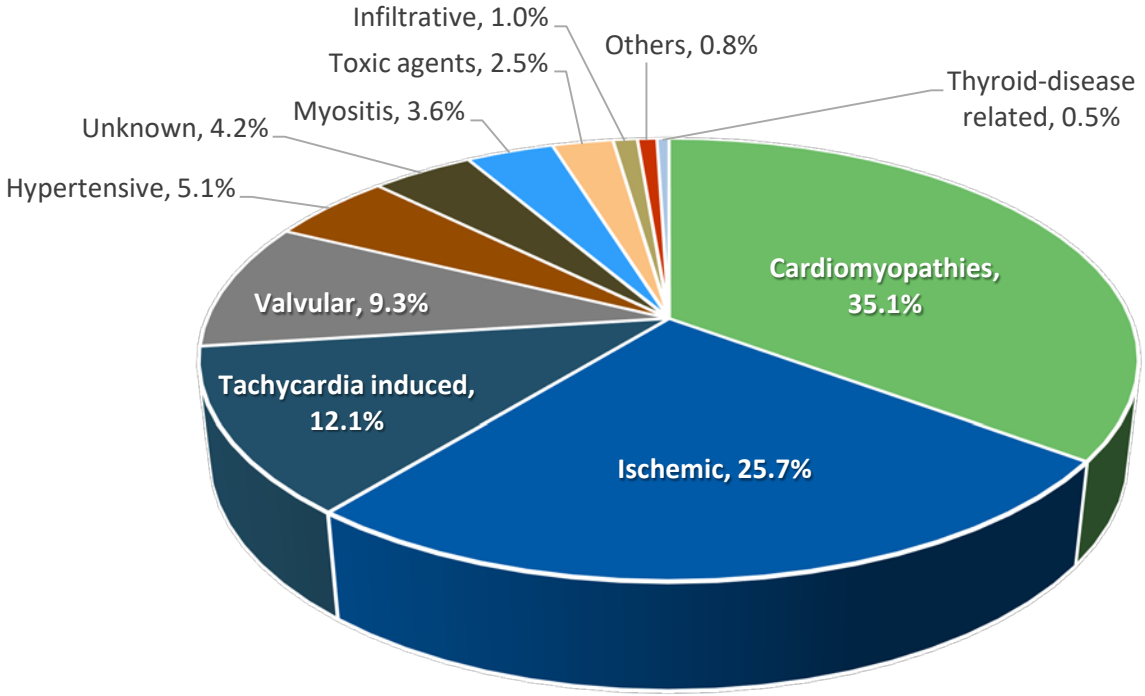
Predictors of HF by LVEF



MI, myocardial infarction.

Bhambhani V, et al. *Eur J Heart Fail.* 2018 April;20(4): 651–659.

Etiology of HF



Park CS, et al. *J Am Heart Assoc.* 2019 Mar 19;8(6): e011077.

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Staging and Functional Classifications of HF

ACCF/AHA Stage	Description of Stage	NYHA Class	Description of Class
A	At high risk of HF but without structural heart disease or symptoms	None	NA
B	Structural heart disease but without signs or symptoms	I	No limitation of physical activity
C	Structural heart disease with prior or current symptoms	I	No limitation of physical activity
		II	Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in symptoms of HF
		III	Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes symptoms of HF
		IV	Unable to carry on with any physical activity without symptoms of HF, or symptoms of HF at rest
D	Refractory heart failure requiring specialized interventions	IV	Unable to carry on with any physical activity without symptoms of HF, or symptoms of HF at rest

emphasizes the development and progression of disease

underscores exercise capacity and symptom status

ACCF, American College of Cardiology Foundation; AHA, American Heart Association; NYHA, New York Heart Association.

Yancy CW, et al. *Circulation*. 2013;128:e240-e327.

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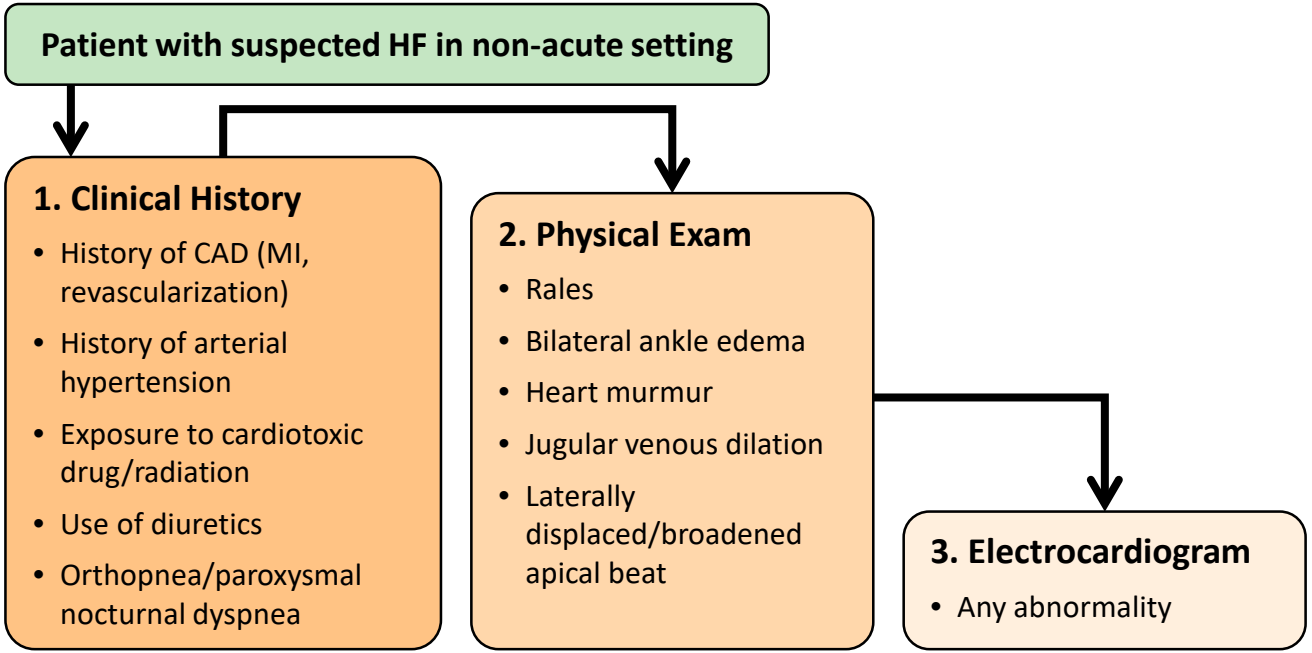
Signs and Symptoms of HF

Symptoms			
Typical	• Breathlessness • Orthopnea • Paroxysmal nocturnal dyspnea	• Reduced exercise tolerance • Fatigue, tiredness, and increased time to recover after exercise • Ankle swelling	
Less Typical	• Nocturnal cough • Wheezing • Bloated feeling • Loss of appetite • Confusion (esp. the elderly)	• Depression • Palpitations • Dizziness • Syncope • Bendopnea	
Signs			
Specific	• Elevated jugular venous pressure	• Hepatojugular reflux • Third heart sound (gallop rhythm)	• Laterally displaced apical impulse
Less Specific	• Weight gain (>2kg/week) • Weight loss • Cachexia • Cardiac murmur • Narrow pulse pressure	• Peripheral edema • Pulmonary crepitations • Pleural effusion • Tachycardia • Irregular pulse • Oliguria	• Tachypnea • Cheyne Stokes respiration • Hepatomegaly • Ascites • Cold extremities

Ponikowski P, et al. *Eur J Heart Fail*. 2016 Aug;18(8):891-975.

Assessment of HF Probability



CAD, coronary artery disease.

Ponikowski P, et al. *Eur J Heart Fail*. 2016 Aug;18(8):891-975.

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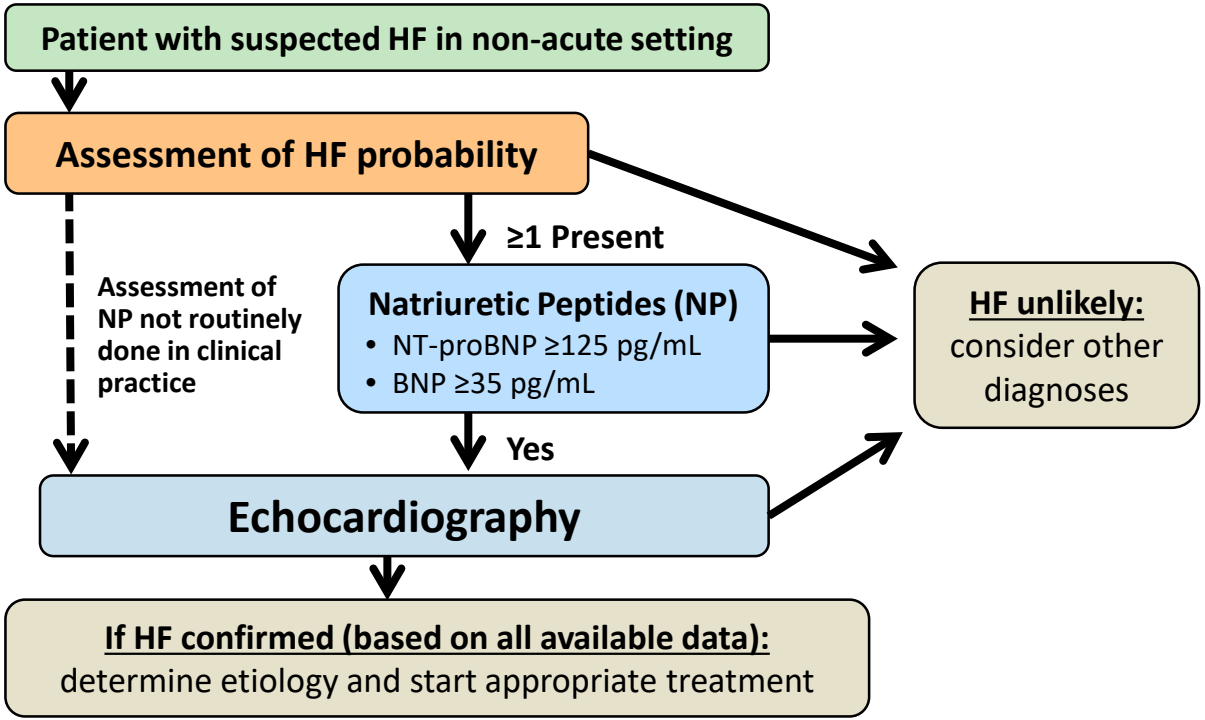
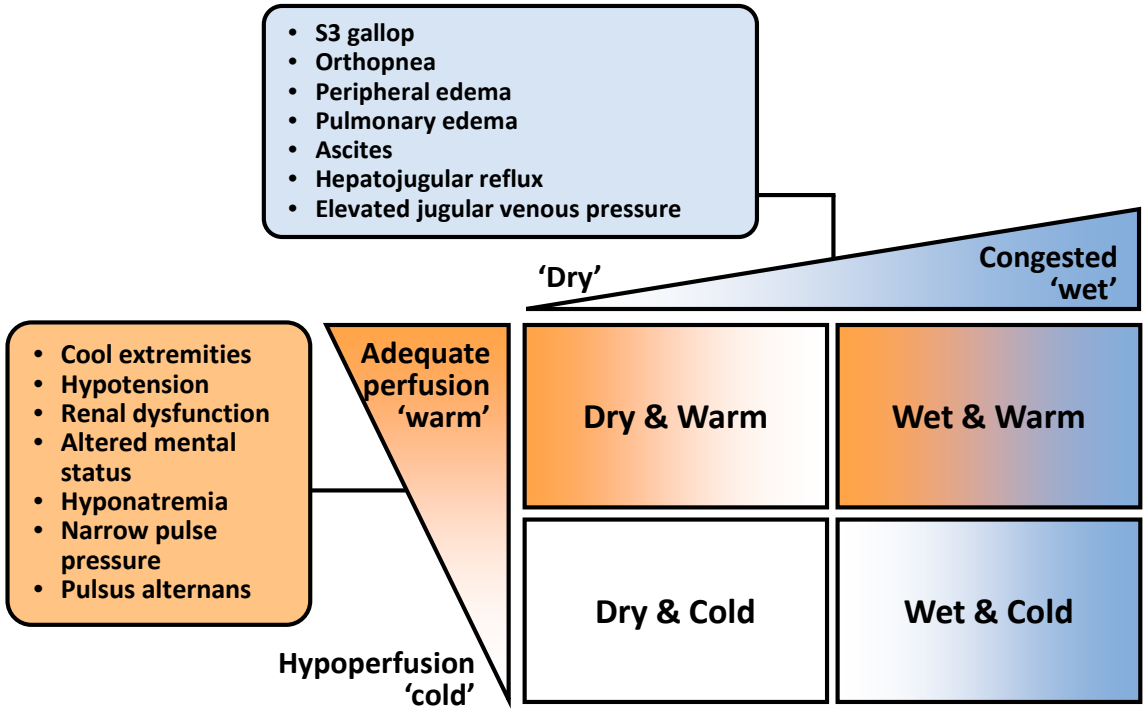
Diagnosis of HF



Ponikowski P, et al. *Eur J Heart Fail*. 2016 Aug;18(8):891-975.

Bedside Assessment: Congestion and Perfusion



Bloom MW, et al. *Nat Rev Dis Prim.* 2017;3:17058

Nohria A, Stevenson LW, et al. JAMA 2002;287:628.

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Get with the Guidelines: Implementing Guideline-Recommended Therapies in HF

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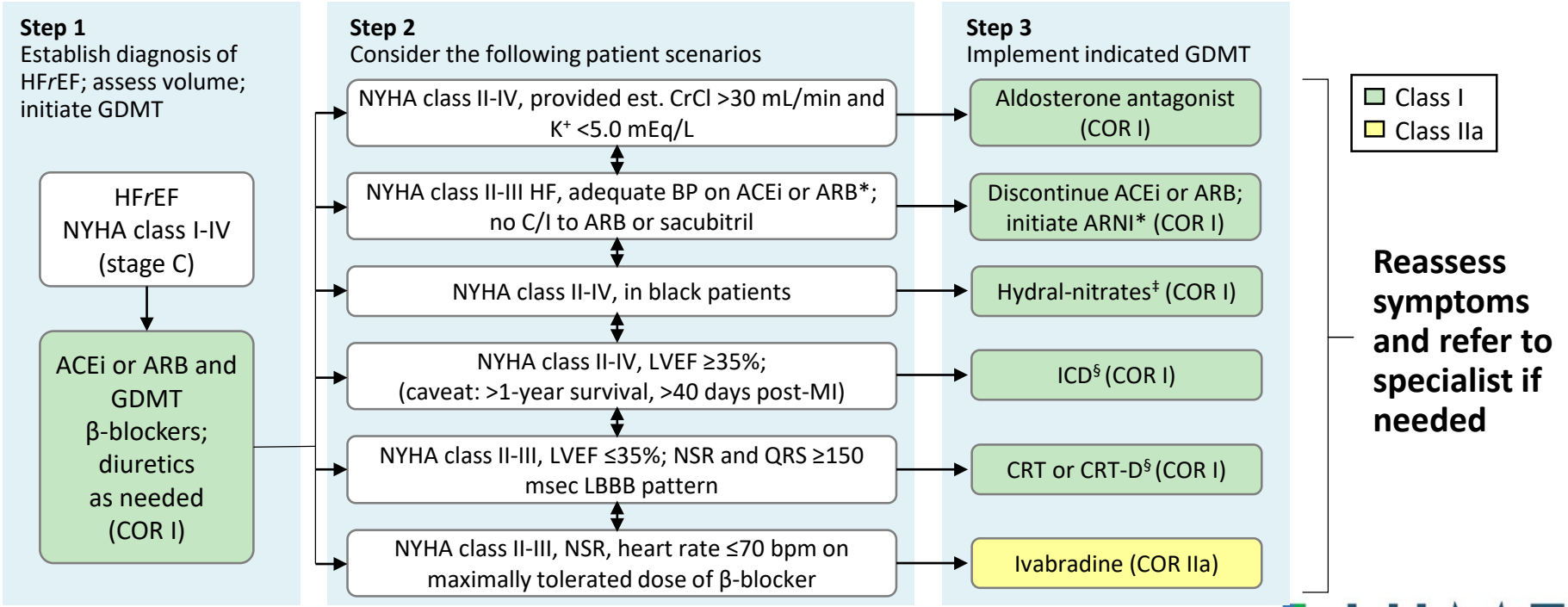
Treatment of Stage C-D HFrEF



C/I, contraindication; CrCl, creatinine clearance; CRT, cardiac resynchronization therapy; CRT-D, cardiac resynchronization therapy-device; ICD, implantable cardioverter-defibrillator; LBBB, left bundle-branch block; NSR, normal sinus rhythm.

Yancy CW, et al. *Circulation.* 2017 Aug 8;136(6):e137-e161. Bloom MW, et al. *Nat Rev Dis Primers*. 2017 Aug 24;3:17058.

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Medications for HFrEF

Class	Mechanism of Action	Drug	Initial Daily Dose(s)	Max Dose(s)	Mean RCT Dose
ACE Inhibitors	Inhibit the conversion of angiotensin I to angiotensin II, and upregulate bradykinin, thereby counteracting the overactivation of the RMS system and the effects of adverse cardiac remodeling	Captopril	6.25mg TID	50mg TID	122.7mg QD
		Enalapril	2.5mg BID	10–20mg BID	16.6mg QD
		Fosinopril	5–10mg QD	40mg QD	NA
		Lisinopril	2.5–5mg QD	20–40mg QD	32.5–35.0mg QD
		Perindopril	2mg QD	8–16mg QD	NA
		Quinapril	5mg BID	20mg BID	NA
		Ramipril	1.25–2.5mg QD	10mg QD	NA
		Trandolapril	1mg QD	4mg QD	NA
ARBs	Inhibits angiotensin II AT1 receptors, thereby counteracting the overactivation of the RAAS system and counteracting the effects of adverse cardiac remodeling	Candesartan	4–8mg QD	32mg QD	24mg QD
		Losartan	25–50mg QD	50–150mg QD	129mg QD
		Valsartan	20–40mg BID	160mg BID	254mg QD
ARNI	Inhibits neprilysin and blocks angiotensin II receptor; inhibition of neprilysin leads to increased circulating levels of natriuretic peptides, vasodilation and natriuresis	Sacubitril/ valsartan	49/51mg BID Therapy may be initiated at 24/26mg BID	97/103mg BID	375mg QD; target dose: 24/26mg, 49/51mg OR 97/103mg BID

ACE, angiotensin-converting enzyme; ARB, angiotensin II receptor blockers; ARNI, angiotensin II receptor-neprilysin inhibitor; AT1, angiotensin II receptor type 1; BID, twice daily; QD, daily; TID, three times daily; RAAS, renin-angiotensin-aldosterone system; RMS, records management system.

Yancy CW, et al. *Circulation.* 2017 Aug 8;136(6):e137-e161.

Medications for HFrEF (cont'd)

Class	Mechanism of Action	Drug	Initial Daily Dose(s)	Max Dose(s)	Mean RCT Dose
I_f Channel Inhibitor	Inhibits the I_f node, which slows the sinus nodal rate in patients who are in sinus rhythm	Ivabradine	5mg BID	7.5mg BID	6.4mg BID (at 28 days) 6.5mg BID (at 1 year)
Aldosterone antagonists (a.k.a. MRAs)	Competitively bind to the aldosterone receptor, which increases the secretion of water and sodium in the distal tubule, and decreases the secretion of potassium	Spironolactone	12.5-25 mg QD	50-100 mg QD	24mg QD
		Eplerenone	25–50mg QD	50–150mg QD	129mg QD
Beta blockers	Inhibits neprilysin and blocks angiotensin II receptor; inhibition of neprilysin leads to increased circulating levels of natriuretic peptides, vasodilation and natriuresis	Bisoprolol	1.25mg QD	10mg QD	8.6mg QD
		Carvedilol	3.125mg BID	50mg BID	37mg QD
		Carvedilol CR	10mg QD	80mg QD	NA
		Metoprolol CR/XL	12.5–25mg QD	200mg QD	159mg QD
Isosorbide dinitrate (ID) and hydralazine (HYD)	Arterial and venous vasodilation and a nitric oxide donor (isosorbide)	Fixed-dose combination	20mg ID/37.5mg HYD TID	40mg ID/75mg HYD TID	90mg ID/~175mg HYD QD
		ID and HYD	20-30 mg ID/25-50 HYD TID or QD	40mg ID TID with 100mg HYD TID	N/A

Yancy CW, et al. *Circulation.* 2017 Aug 8;136(6):e137-e161.

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Diuretics Commonly Used in HF

Class	Mechanism of Action	Drug	Initial Dose	Usual Daily Dose
Loop diuretics	Inhibits primarily the absorption of sodium and chloride not only in the proximal and distal tubules but also in the loop of Henle.	Furosemide	20-40 mg	40-240 mg
		Bumetanide	0.5-1.0 mg	1-5 mg
		Torsemide	20-40 mg	20-100 mg
Thiazides	Inhibits sodium chloride transport in the distal convoluted tubule. More sodium is then excreted in the kidney with accompanying fluid.	Bendroflumethiazide	2.5 mg	2.5-10 mg
		Hydrochlorothiazide	25 mg	12.5-100 mg
		Metolazone	2.5 mg	2.5-10 mg
		Indapamide	2.5 mg	2.5-5 mg

Potassium-sparing diuretics	Initial Dose	Usual Daily Dose
Spironolactone/eplerenone	**+ ACE-I/ARB**: 12.5-25 mg **- ACE-I/ARB**: 50 mg	**+ ACE-I/ARB**: 50 mg **- ACE-I/ARB**: 100-200 mg
Amiloride	**+ ACE-I/ARB**: 2.5 mg **- ACE-I/ARB**: 5 mg	**+ ACE-I/ARB**: 5-10 mg **- ACE-I/ARB**: 10-20 mg
Triamterene	**+ ACE-I/ARB**: 25 mg **- ACE-I/ARB**: 50 mg	**+ ACE-I/ARB**: 100 mg **- ACE-I/ARB**: 200 mg

Ponikowski P, et al. *Eur J Heart Fail*. 2016 Aug;18(8):891-975. Herman LL, Bashir K. Hydrochlorothiazide. In: StatPearls [Internet]. Treasure Island, FL: StatPearls Publishing; 2019.

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2017 Focused Update of the 2013 Guideline for the Management of HF

Class (Strength) of Recommendation		Level (Quality) of Evidence	
I (Strong)	Benefit >>> Risk	A	High quality
IIa (Moderate)	Benefit >> Risk	B-R	Moderate quality, randomized
IIb (Weak)	Benefit ≥ Risk	B-NR	Moderate quality, non-randomized
III: No Benefit (Moderate)	Benefit = Risk	C-LD	Limited data
III: Harm (Strong)	Risk > Benefit	C-EO	Expert opinion

Yancy CW, et al. *Circulation.* 2017 Aug 8;136(6):e137-e161.

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Treatment of Stage C HFrEF

	COR	LOE	Recommendation
NEW	I	ACE-I: A ARB: A ARNI: B-R	The clinical strategy of **inhibition of the renin-angiotensin system with ACE inhibitors, or ARBs, or ARNI in conjunction with evidence-based beta blockers and aldosterone antagonists in selected patients is recommended for patients with chronic HFrEF** to reduce morbidity and mortality.
	I	ACE-I: A	The **use of ACE inhibitors is beneficial for patients with prior or current symptoms of chronic HFrEF** to reduce morbidity and mortality.
	I	ARB: A	The use of **ARBs to reduce morbidity and mortality is recommended in patients** with prior or current symptoms of chronic HFrEF **who are intolerant to ACE inhibitors** because of cough or angioedema.
NEW	I	ARNI: B-R	In patients with chronic symptomatic HFrEF NYHA class II or III who tolerate an ACE inhibitor or ARB, **replacement by an ARNI is recommended to further reduce morbidity and mortality**.
NEW	III: Harm	B-R	**ARNI should not be administered concomitantly with ACE inhibitors** or within 36 hours of the last dose of an ACE inhibitor.
NEW	III: Harm	C-EO	**ARNI should not be administered to patients with a history of angioedema**.
NEW	IIa	Iva: B-R	**Ivabradine can be beneficial to reduce HF hospitalization for patients with symptomatic (NYHA class II-III) stable chronic HFrEF (LVEF ≤35%) who are receiving GDMT**, including a beta blocker at maximum tolerated dose, and who are in sinus rhythm with a heart rate of 70 bpm or greater at rest.

COR, class of recommendation; GDMT, guideline-directed medical therapy; LOE, level of evidence.

Yancy CW, et al. *Circulation.* 2017 Aug 8;136(6):e137-e161.

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Treatment of Stage C HFpEF

	COR	LOE	Recommendation
	I	B	**Systolic and diastolic blood pressure should be controlled** in patients with HFpEF in accordance with published clinical practice guidelines to prevent morbidity.
	I	C	**Diuretics should be used for relief of symptoms due to volume overload** in patients with HFpEF.
	IIa	C	Coronary revascularization is reasonable in patients with CAD in whom symptoms (angina) or demonstrable myocardial ischemia is judged to be having an adverse effect on symptomatic HFpEF despite GDMT.
	IIa	C	Management of AF according to published clinical practice guidelines in patients with HFpEF is reasonable to improve symptomatic HF.
	IIa	C	The **use of beta-blocking agents, ACE inhibitors, and ARBs in patients with hypertension is reasonable** to control blood pressure in patients with HFpEF.
NEW	IIb	B-R	In appropriately selected patients with HFpEF, **aldosterone receptor antagonists might be considered to decrease hospitalizations**.
	IIb	B	The use of **ARBs might be considered to decrease hospitalizations** for patients with HFpEF.
NEW	III: No Benefit	B-R	**Routine use of nitrates or phosphodiesterase-5 inhibitors to increase activity or QoL** in patients with HFpEF is **ineffective**.
	III: No Benefit	C	Routine **use of nutritional supplements is not recommended** for patients with HFpEF.

AF, atrial fibrillation; QoL, quality of life.

Yancy CW, et al. *Circulation.* 2017 Aug 8;136(6):e137-e161.

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Recommendations for Hypertension

	COR	LOE	Recommendation
NEW	I	B-R	In patients at increased risk, stage A HF, the optimal blood pressure in those with hypertension should be **<130/80 mmHg**.
NEW	I	C-EO	Patients with HFrEF (stage C) and hypertension should be prescribed GDMT titrated to **attain systolic blood pressure <130 mmHg**.
NEW	I	C-LD	Patients with HFpEF and persistent hypertension after management of volume overload should be **prescribed GDMT titrated to attain systolic blood pressure <130 mmHg.**

Yancy CW, et al. *Circulation.* 2017 Aug 8;136(6):e137-e161.

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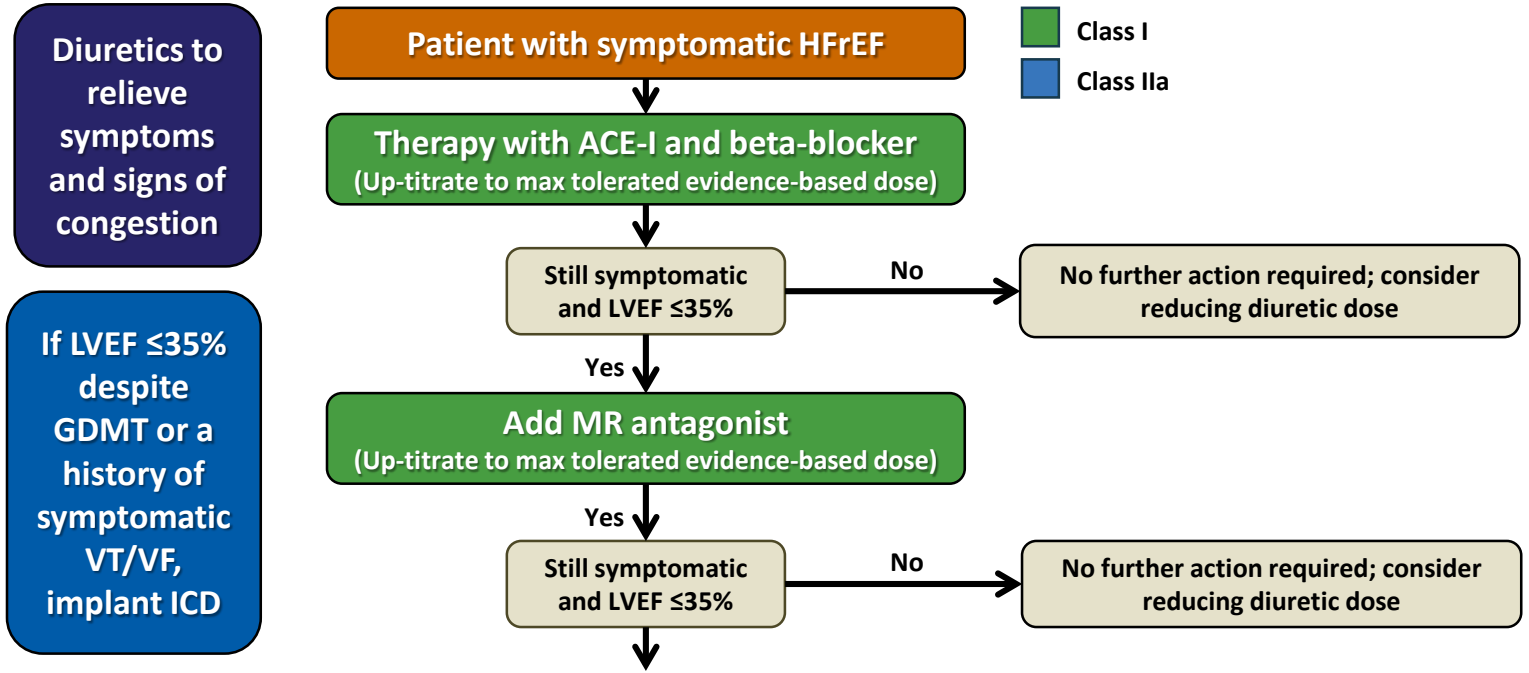
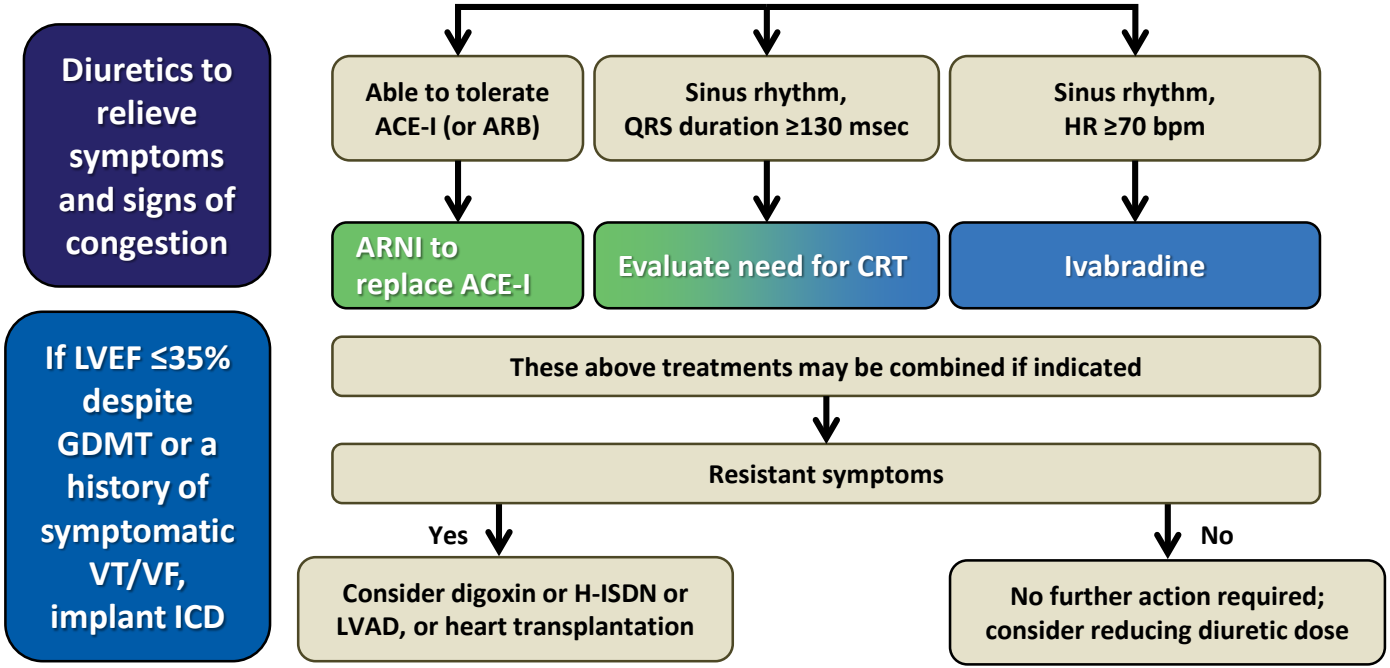
2016 ESC Guidelines for the Diagnosis and Treatment of Acute and Chronic HF



ICD, implantable cardioverter defibrillators; MR, mineralocorticoid receptor; VT/VF, ventricular tachycardia/ventricular fibrillation.

Ponikowski P, et al. *Eur J Heart Fail*. 2016 Aug;18(8):891-975.

2016 ESC Guidelines (cont'd)



VT/VF, ventricular tachycardia/ventribular fibrillation; CRT, cardiac resynchronization therapy; LVAD, left ventricular assist device; H-ISDN, hydralazine-isosorbide dinitrate.

Ponikowski P, et al. *Eur J Heart Fail*. 2016 Aug;18(8):891-975.

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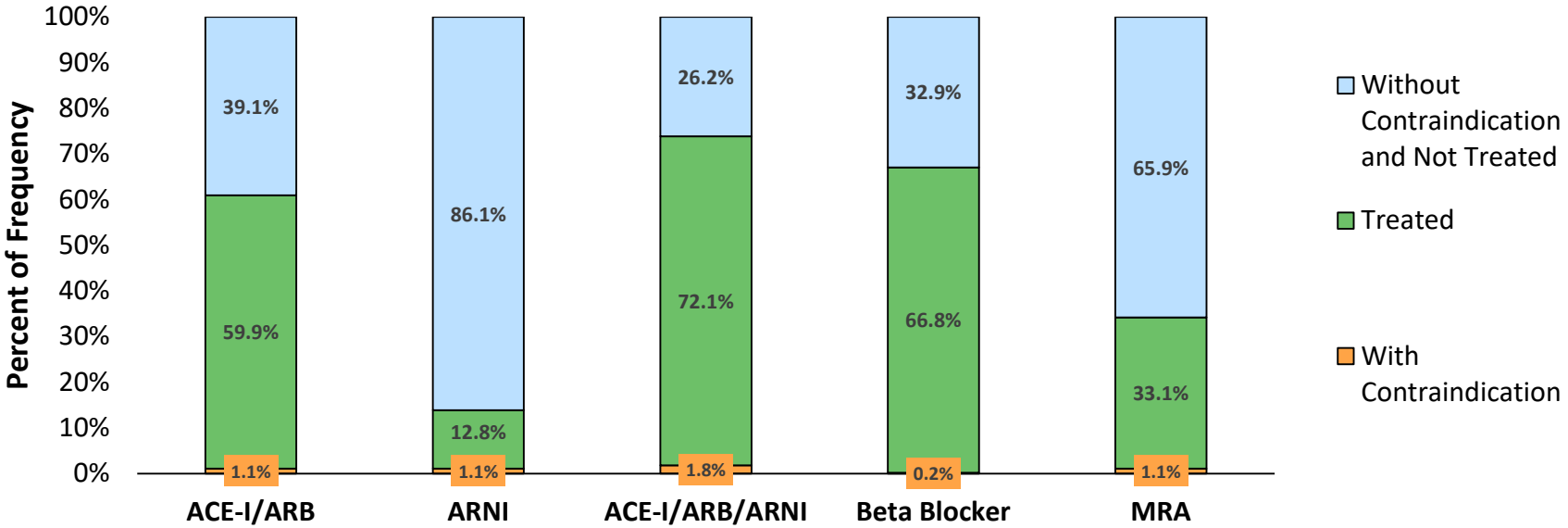
Real-World Utilization of Medical Therapy for HFrEF



VT/VF, ventricular tachycardia/ventribular fibrillation; CRT, cardiac resynchronization therapy; LVAD, left ventricular assist device; H-ISDN, hydralazine-isosorbide dinitrate.

Greene SJ, et al. *JACC*. 2018;72:351-366.

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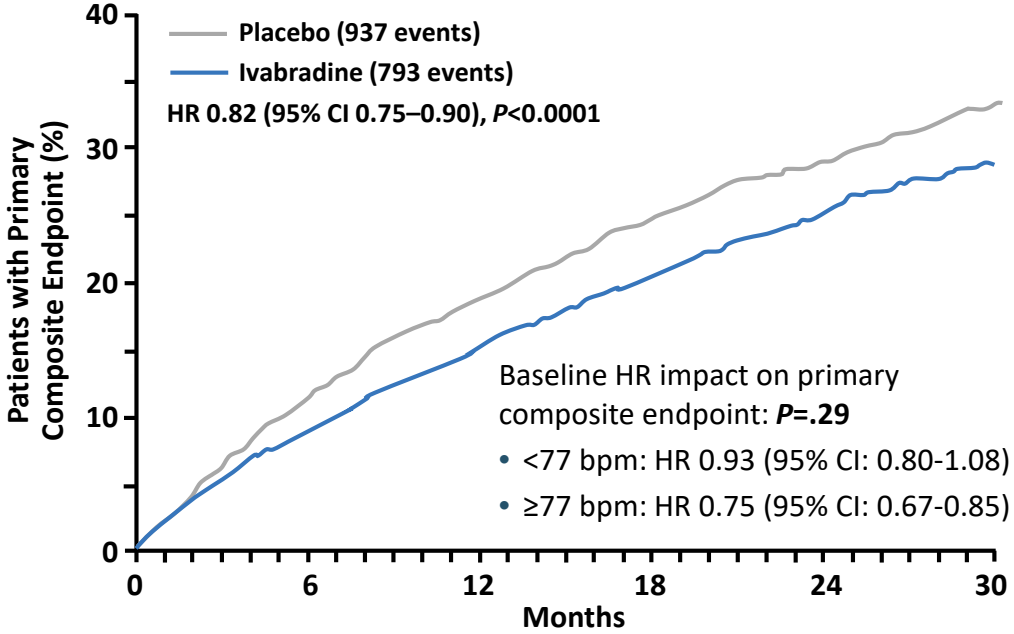
Use of Newer Agents Following an Acute Event

- Ivabradine
  - SHIFT Trial
- Sacubitril/valsartan
  - PARADIGM-HF Trial
  - PIONEER HF Trial
  - TRANSITION Trial

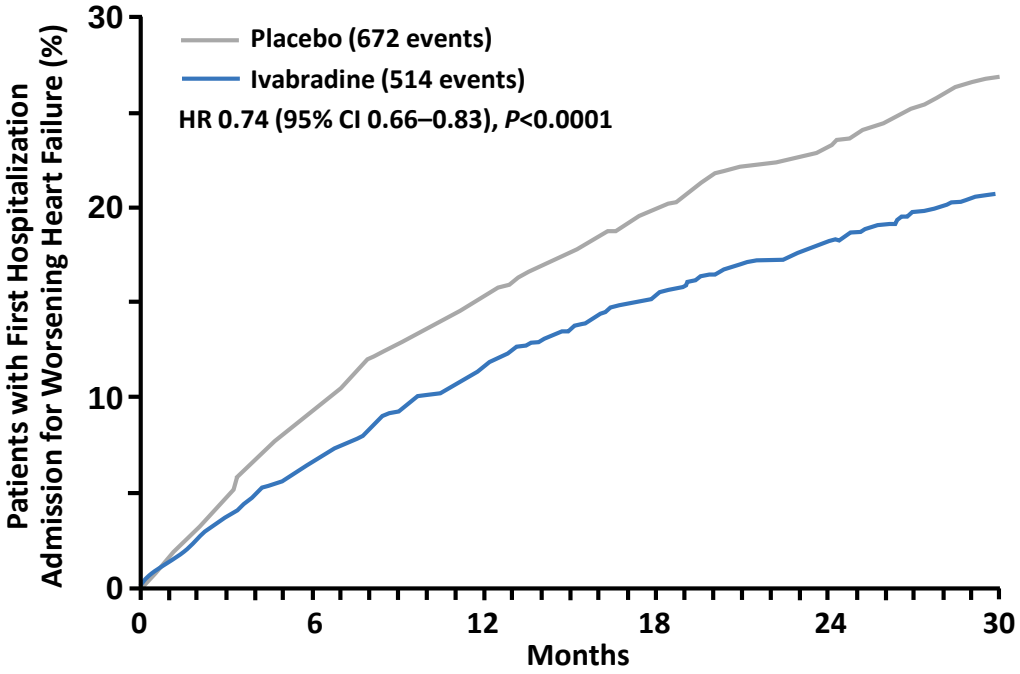
SHIFT Trial: Ivabradine vs. placebo in 6558 Patients with HFrEF

- Primary endpoint: composite of cardiovascular death or hospitalization for worsening HF
- Results
  - Primary endpoint: HR 0.82 (95% CI 0.75-0.90), p<.0001
  - Cardiovascular death: HR 0.91 (95% CI 0.80-1.03), p=.128
  - Hospitalization for worsening HF: HR 0·74 (95% CI 0.66–0.83, p<.0001



Swedberg K, et al. *Lancet.* 2010 Sep 11;376(9744):875-85.

SHIFT Trial: Ivabradine vs. placebo in 6558 Patients with HFrEF (cont'd)



Swedberg K, et al. *Lancet.* 2010 Sep 11;376(9744):875-85.

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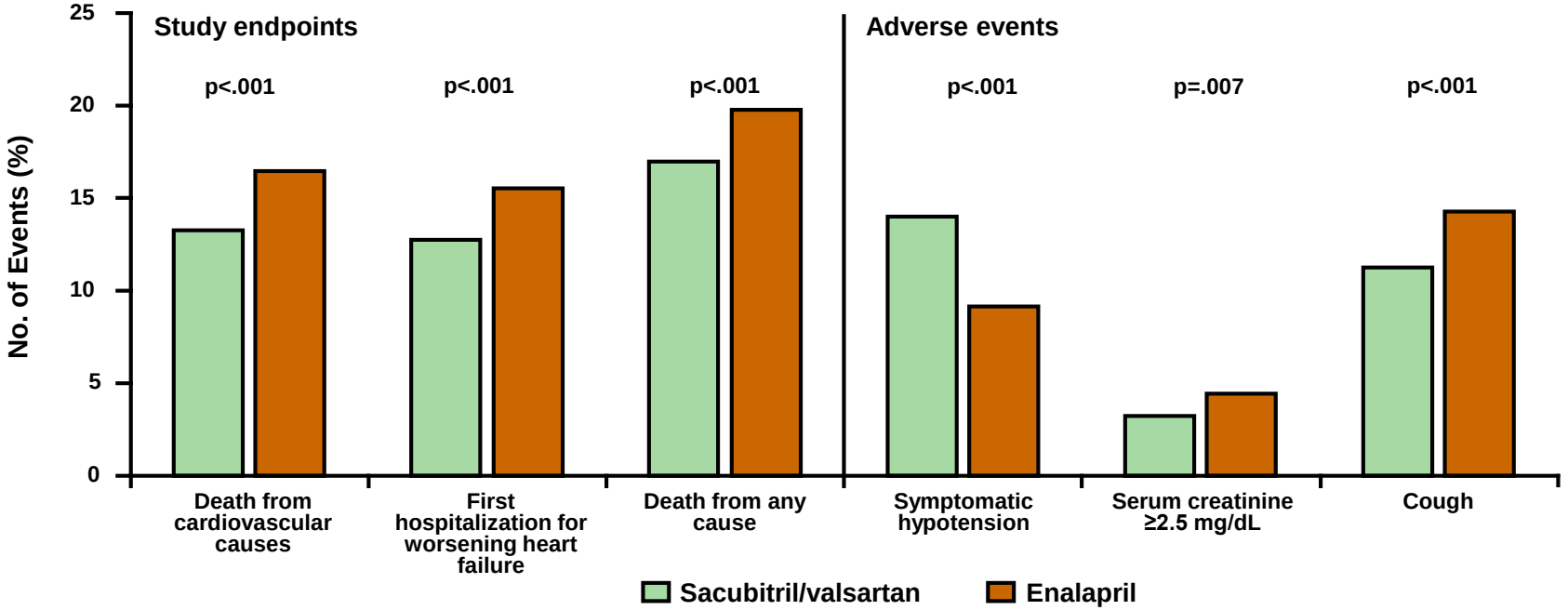
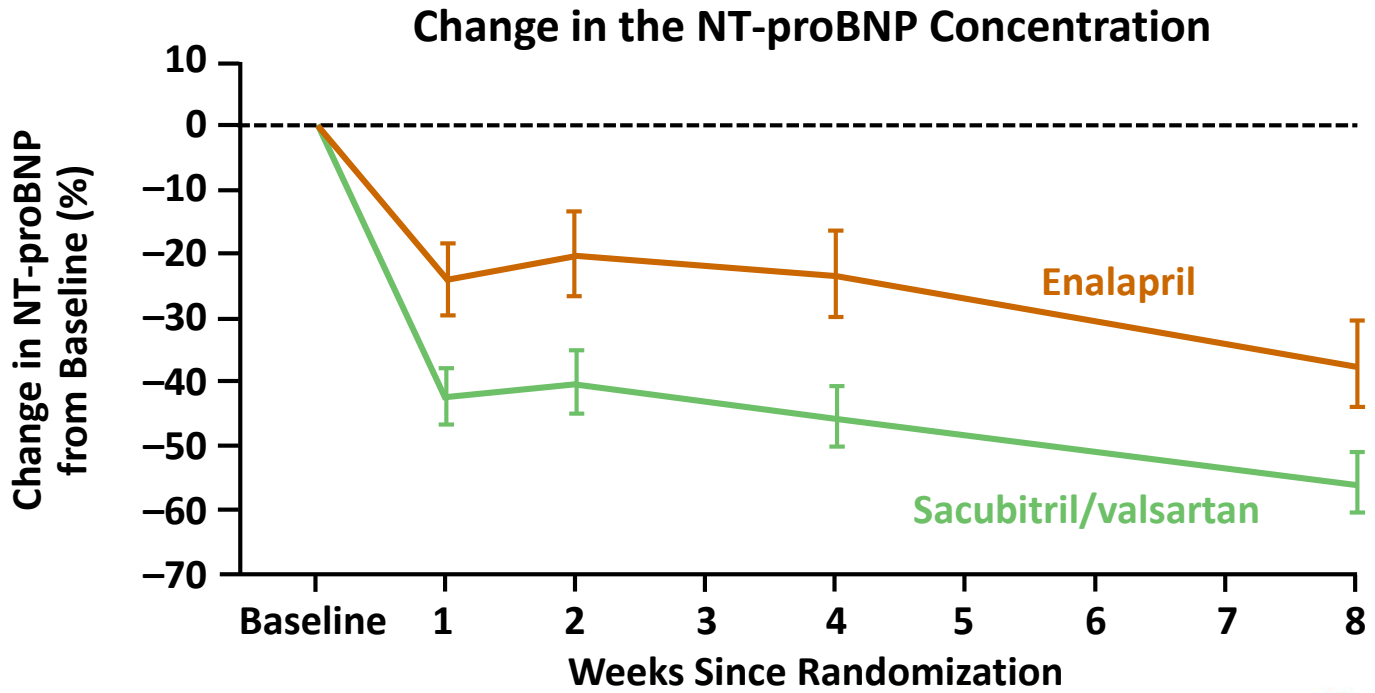
PARADIGM-HF Trial: Sacubitril/valsartan vs. enalapril in 8442 Patients with HFrEF



McMurray JJ, et al. *N Engl J Med* 2014;371:993-1004.
Berliner D and Bauersachs J. *Korean Circ J*. 2017 Sep;47(5):543-554.

PIONEER-HF Trial: Sacubitril/valsartan vs. enalapril in 881 Hospitalized Patients with HFrEF



NT-proBNP, N-terminal pro b-type natriuretic peptide.

Velazquez EJ, et al. *N Engl J Med.* 2019 Feb 7;380(6):539-548.

TRANSITION Trial: Sacubitril/valsartan Initiated Before Discharge vs. Outpatient Settings

- Primary endpoint: proportion of 1002 patients achieving target dose of sacubitril/valsartan 200 mg twice daily by 10 weeks
  - Two cohorts: pre-hospital discharge and post-hospital discharge patients with HFrEF
- Primary endpoint results
  - 45% of pre-discharge group
  - 50.4% of post-discharge group
  - No significant difference
    - RRR 0.893 (95% CI 0.783-1.019)
- Additional results
  - 62.5% of pre-discharge group and 68% of post-discharge group maintained dose of 100 or 200 mg for at least 2 weeks
  - 86.4% of pre-discharge group and 88.8% of post-discharge group maintained any dose for at least 2 weeks

*"It is **as safe and efficacious to start sacubitril/valsartan in the hospital as in the outpatient setting**, whether the patient is on a high dose or a medium dose of the drug. **You do not have to wait until discharge to start a patient on this therapy."***

- **Rolf Wachter, MD,** professor of medicine and senior cardiology consultant at University Hospital Leipzig, Germany

Helio.com. TRANSITION: Sacubitril/valsartan feasible as in-hospital HF treatment. Available at: https://www.healio.com/cardiology/hf-transplantation/news/online/%7Bb9a21824-5b27-47df-b9b2-bac58dcb78a6%7D/transition-sacubitrilvalsartan-feasible-as-in-hospital-hf-treatment

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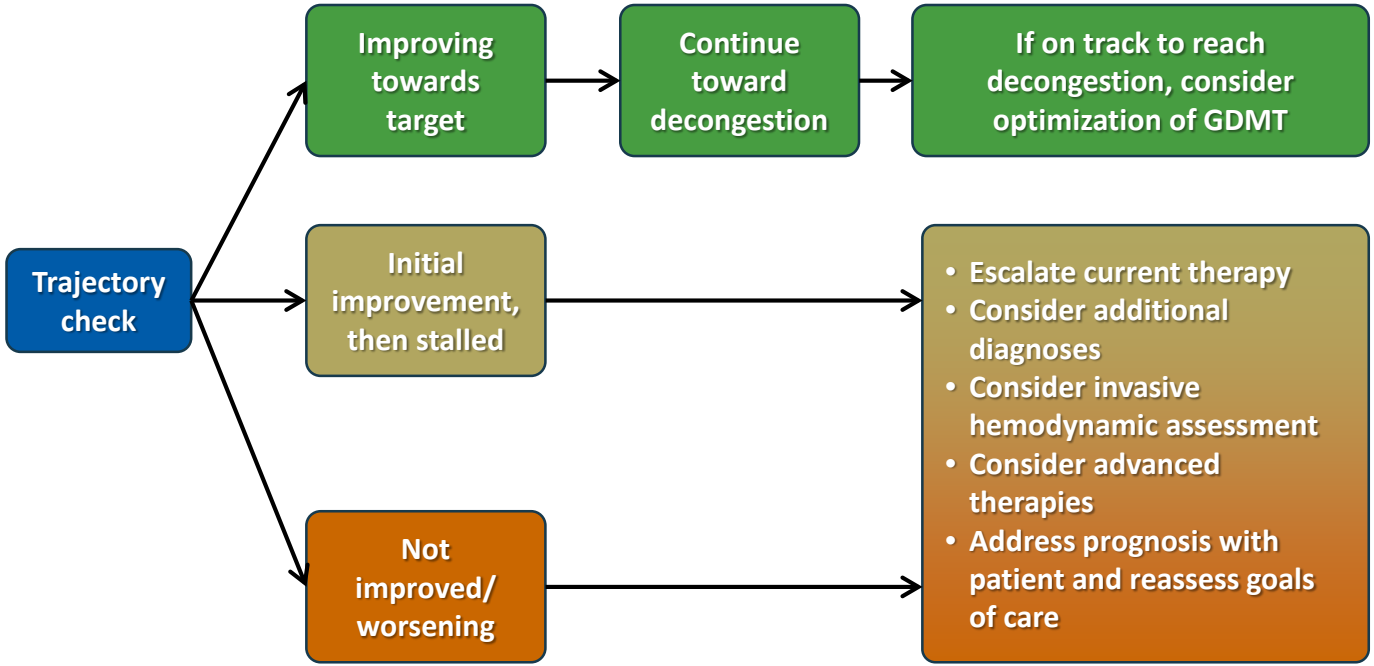
Clinical Trajectories and Their Implications for Therapy



Hollenberg SM, et al. *JACC*. 2019

The FDA Recall of Valsartan and Other HF Medications: What You and Your Patients Need to Know

HOSPITAL INTERNAL MEDICINE FORUM

FDA Investigation

FDA warns API manufacturer involved in valsartan recall, provides information for patients taking these medications

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For Immediate Release: December 11, 2018

The U.S. Food and Drug Administration today released a warning letter issued to Zhejiang Huahai Pharmaceutical Co. Ltd. (ZHP), in Linhai, Taizhou Zhejiang China, the manufacturer of the active pharmaceutical ingredient (API) found in valsartan that is the subject of an ongoing FDA investigation into probable cancer-causing impurities in certain commonly prescribed heart medicines. The letter outlines several manufacturing violations at ZHP's Chuannan facility, including impurity control, change control and cross contamination from one manufacturing process line to another. The warning letter is another step forward in the ongoing investigation. The agency is still looking into the root

FDA. FDA warns API manufacturer involved in valsartan recall, provides information for patients taking these medications. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628189.htm.

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Recall of Valsartan

- 10 formulations have currently been recalled
- Sacubitril/valsartan
  - ***Not recalled***

"This recall is due to an impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled products."

"However, not all products containing valsartan are being recalled."

"An indication of "**TBD**" means that one or more parts of our assessment remain incomplete and the ***product remains acceptable for distribution*** *and* ***for patient use***."

Active Ingredient	Drug Product	Strength	Labeler Name	Overall Nitrosamine Determination	Date Updated
SACUBITRIL; VALSARTAN	ENTRESTO	24MG; 26MG, 49MG; 51MG, 97MG; 103MG	NOVARTIS PHARMACEUTICALS CORPORATION	TBD	2019/04/04

1. FDA. FDA's assessment of currently marketed ARB drug products. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fdas-assessment-currently-marketed-arb-drug-products. 2. FDA. Search list of recalled angiotensin II receptor blockers (ARBs) including valsartan, losartan and irbesartan. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and.

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Current Recalls of Valsartan (as of May 17, 2019)

Date of Recall	Manufacturer	Product
03/01/2019	Aurobindo Pharma	Valsartan/amlodipine and valsartan tablets
12/31/2018	Aurobindo Pharma	Amlodipine/valsartan tablets USP, valsartan/hydrochlorothiazide (HCTZ) tablets USP, valsartan tablets USP
12/04/2018	Mylan Pharmaceuticals	Valsartan-containing products
11/27/2018	Teva Pharmaceuticals	Amlodipine/valsartan combination tables and amlodipine/valsartan/HCTZ combination tablets
08/22/2018	Torrent Pharmaceuticals	Valsartan/amlodipine/HCTZ; valsartan/amlodipine; and valsartan tablets
08/17/2018	Torrent Pharmaceuticals	Valsartan/amlodipine/HCTZ tablets
08/07/2018	Camber Pharmaceuticals	Valsartan tablets, USP, 40mg, 80mg, 160mg and 320mg
07/17/2018	Teva Pharmaceuticals USA	Valsartan and valsartan/HCTZ tablets
07/16/2018	Prinston Pharmaceutical Inc. (dba Solco Healthcare LLC)	Valsartan tablets, 40 mg, 80mg, 160mg, and 320mg; and valsartan/HCTZ Tablets, 80mg/12.5mg, 160mg/12.5mg, 160mg/25mg, 320mg/12.5mg, and 320mg/25mg
07/13/2018	Major Pharmaceuticals	Valsartan tablets, 80mg USP and 160 mg USP

FDA. Drug recalls. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls

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Resources for Up-to-date Information

- https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan

FDA. FDA updates and press announcements on angiotensin II receptor blocker (ARB) recalls (valsartan, losartan, and irbesartan). Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

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Easing the Transition from Hospital to Home

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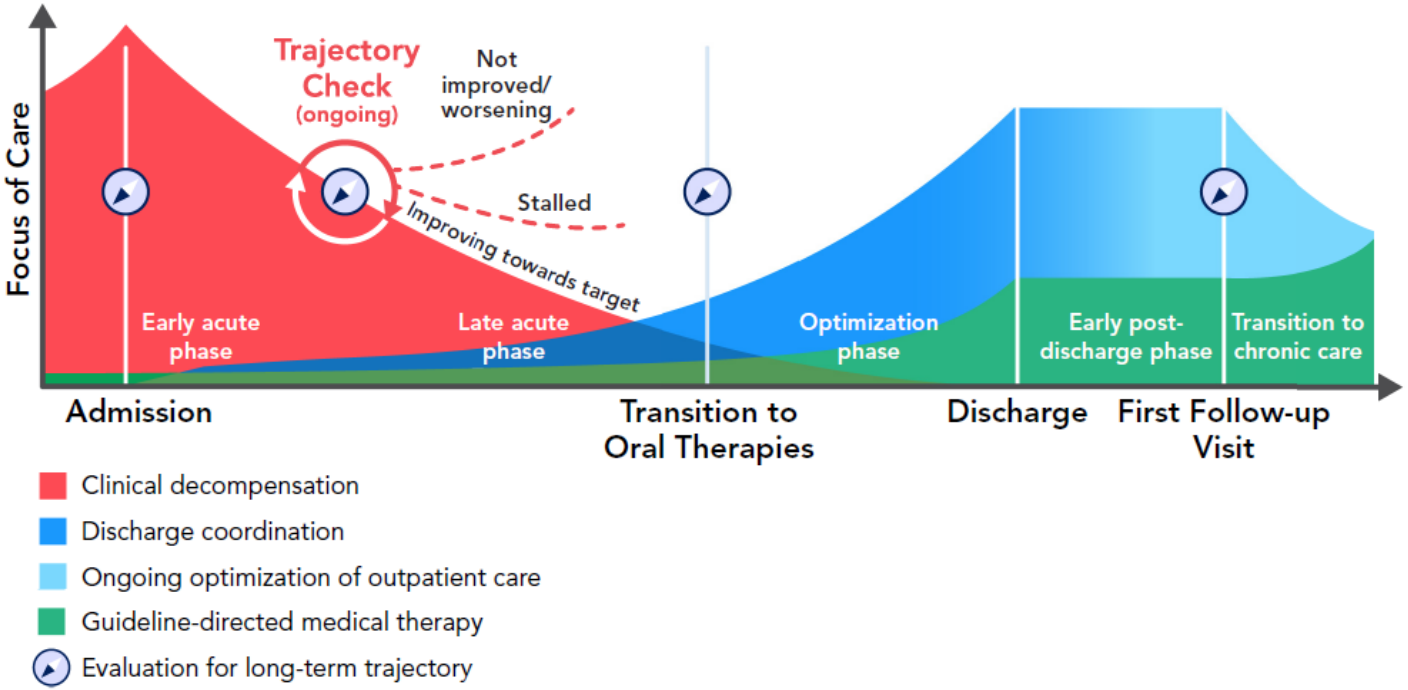
Clinical Course of Heart Failure



Hollenberg SM, et al. *JACC*. 2019

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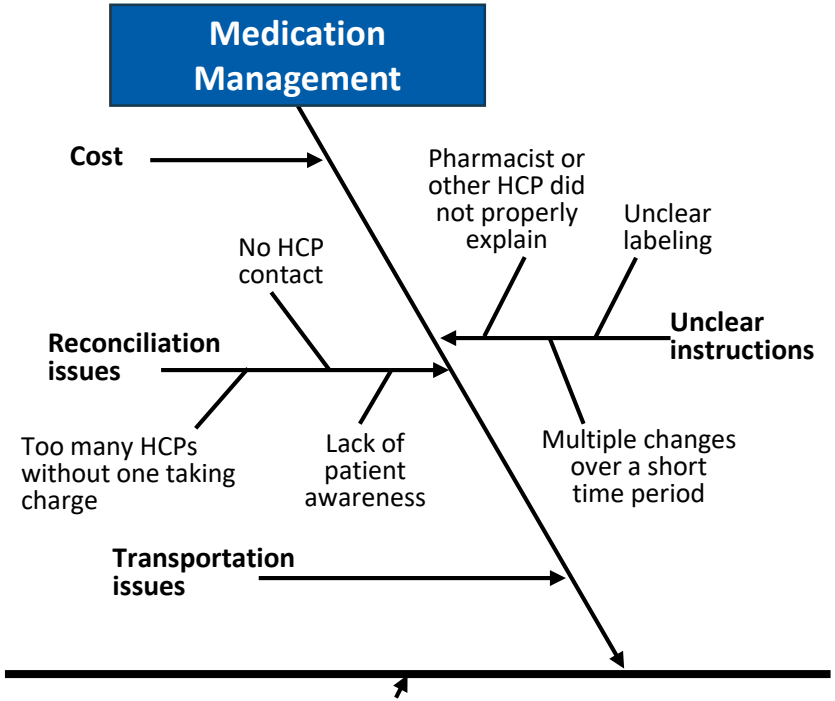
Barriers to Effective Transitions of Care



HCP, healthcare provider.

Albert NM, et al. *Circ Heart Fail.* 2015;8(2):384-409.

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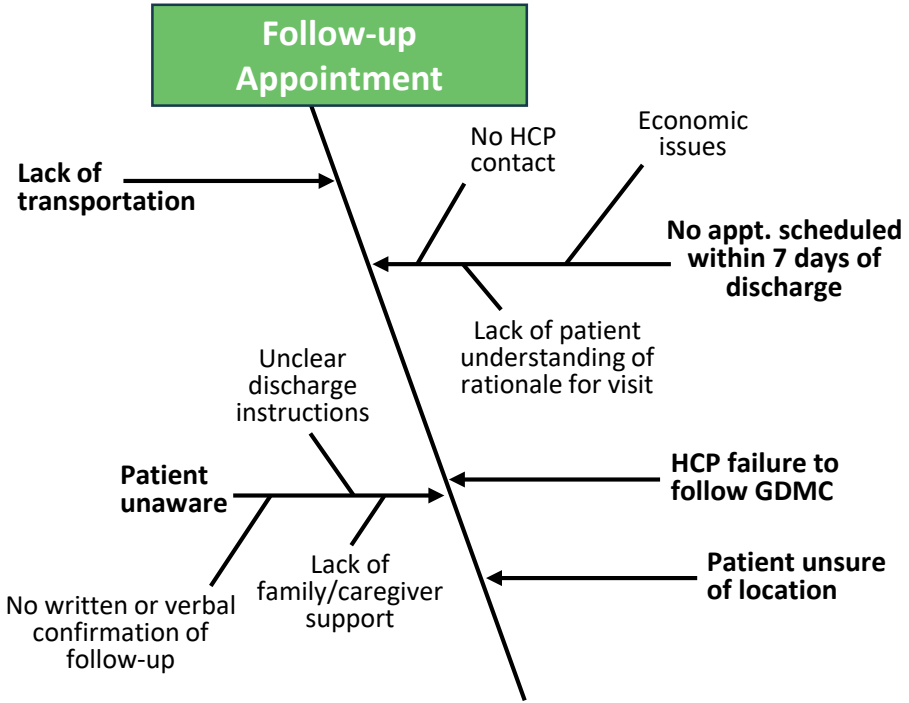
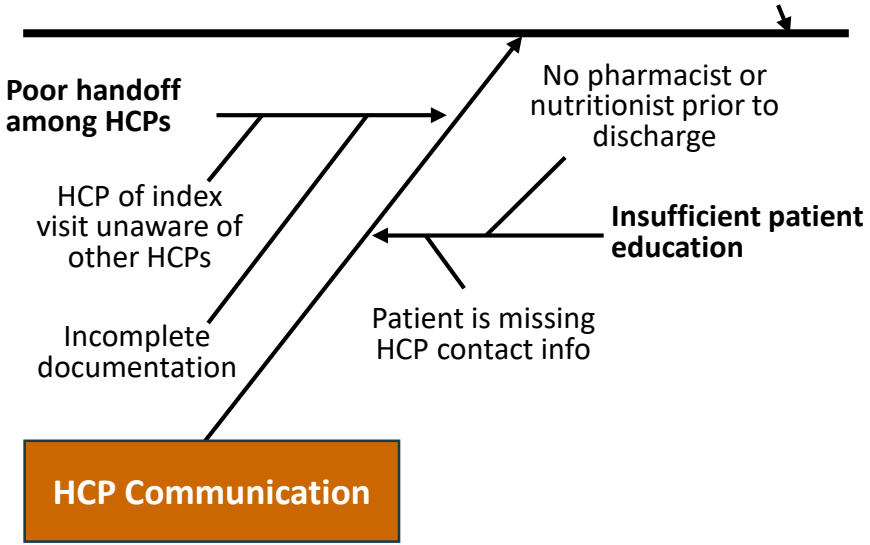
Barriers to Effective Transitions of Care (cont'd)



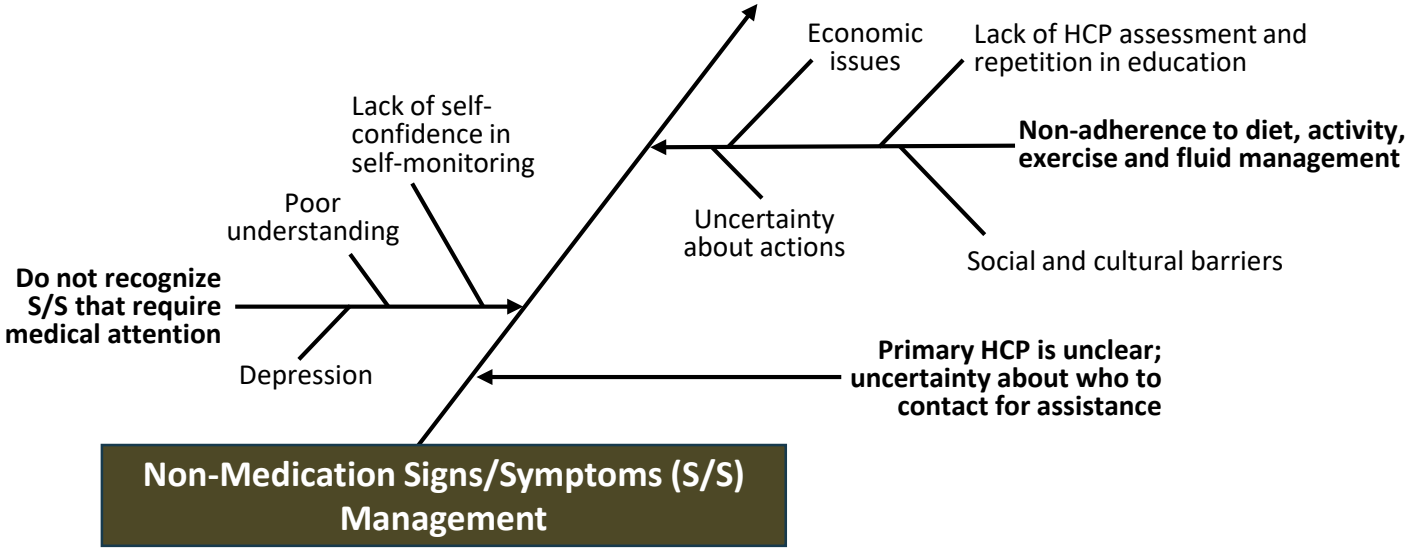
Albert NM, et al. *Circ Heart Fail.* 2015;8(2):384-409.

Barriers to Effective Transitions of Care (cont'd)



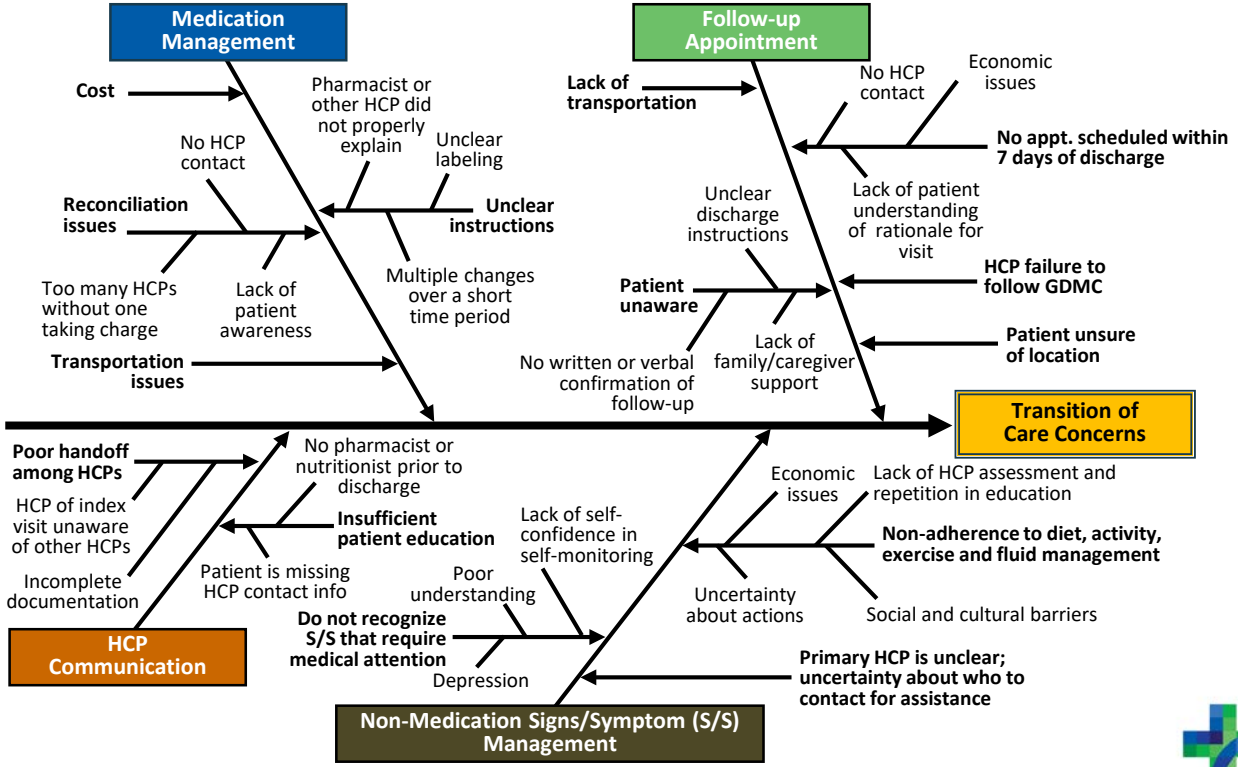
Albert NM, et al. *Circ Heart Fail.* 2015;8(2):384-409.

Barriers to Effective Transitions of Care (cont'd)



Albert NM, et al. *Circ Heart Fail.* 2015;8(2):384-409.

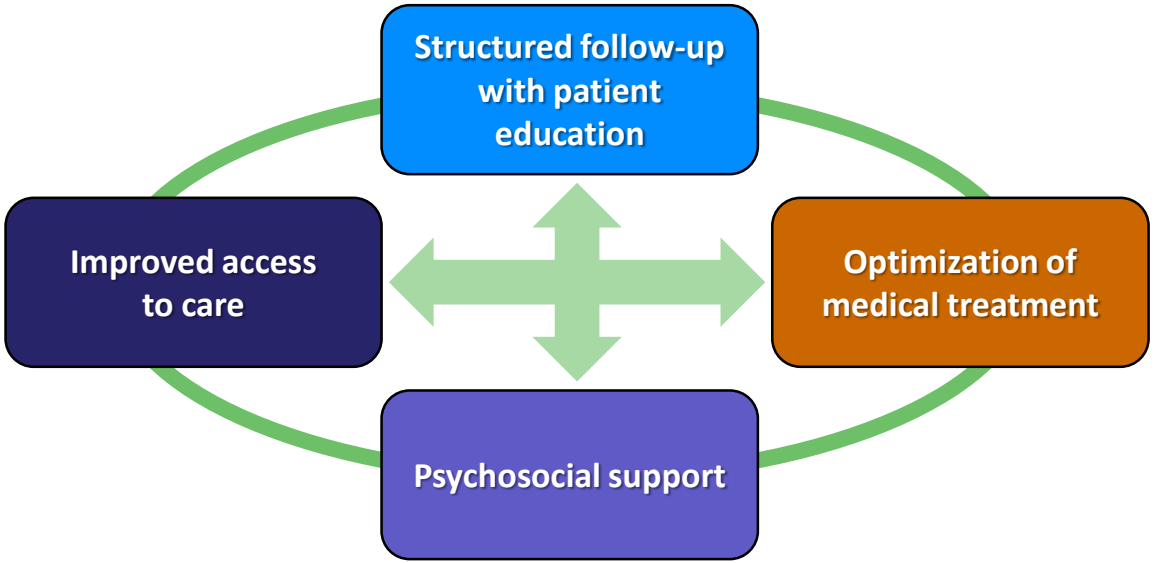
Barriers to Effective Transitions of Care (cont'd)



Albert NM, et al. *Circ Heart Fail.* 2015;8(2):384-409.

Effective Transitions of Care

- "*The goal of management of HF is to provide a 'seamless' system of care that embraces both the community and hospital throughout the health care journey.*"



Ponikowski P, et al. *Eur J Heart Fail*. 2016;18(8):891-975.

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Components of Effective Transition Programs

ESC Guideline Recommendations	
Characteristics	Should employ a **multidisciplinary approach** (cardiologists, primary care physicians, nurses, pharmacists, physiotherapists, dieticians, social workers, surgeons, psychologists, etc.).
	Should target high-risk symptomatic patients.
	Should include competent and professionally educated staff.

ESC, European Society of Cardiology.

Ponikowski P, et al. *Eur J Heart Fail*. 2016;18(8):891-975.

Components of Effective Transition Programs

ESC Guideline Recommendations	
Components	Optimized medical and device management.
	Adequate **patient education**, with special emphasis on adherence and self-care.
	Patient involvement in symptom monitoring and flexible diuretic use.
	Follow-up after discharge (regular clinic and/or home-based visits; possible telephone support or remote monitoring).
	Increased access to healthcare (through in-person follow-up and by telephone contact; possibly through remote monitoring).
	Facilitated access to care during episodes of decompensation.
	Assessment of (and appropriate intervention in response to) an unexplained change in weight, nutritional status, functional status, quality of life, or laboratory findings.
	Access to advanced treatment options.
	Provision of **psychosocial support** to patients and family and/or caregivers.

Ponikowski P, et al. *Eur J Heart Fail*. 2016;18(8):891-975.

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ESC Guideline Recommendations for Improving Shared Decision-Making

- Provide oral and written information that takes account of educational grade and health literacy
  - Dosing, beneficial effects, and adverse events
- Provide individualized information to support self-management
- Regularly communicate information on disease, treatment options, and self-management
- Involve family and caregivers in HF management and self-care

Ponikowski P, et al. *Eur J Heart Fail*. 2016;18(8):891-975.

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Strategies for Motivational Interviewing

1. **Open-ended questions**. Avoid asking questions that can be answered with a “yes” or “no.”
2. **Affirmations**. Never underestimate the power of expressing empathy during tough spots or in celebrating patients’ accomplishments.
3. **Reflective listening**. Patients often have the answers; the physician’s role is to help guide them.
    - Acknowledge the patient’s mood about what he or she is telling you
    - Reflecting patients’ statements and feelings back to them reinforces self-efficacy

Stewart EE and Fox C. *Fam Pract Manag*. 2011;18(3):21-25.

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Summary

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Summary

- HF will continue to grow and affect morbidity and mortality
  - Every 1 in 8 deaths has HF mentioned on death certificate
  - 22% of patients hospitalized with HF are readmitted within 30 days
- Appropriate diagnosis includes history, physical, electrocardiography, BNP, and echocardiography
- GDMT
  - ACE inhibitors, ARBs, beta blockers, and aldosterone antagonists
  - Sacubitril/valsartan (ARNI) provides significant morbidity and mortality benefits vs enalapril
- Hypertension
  - Prevention: target <130/80
  - Treatment in patient with HFrEF: target systolic <130

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Summary (cont'd)

- Valsartan recalls
  - 10 formulations have been recalled
  - Sacubitril/valsartan has ***not*** been recalled
- Transitions of care
  - Barriers occur at the levels of medication management, follow-up appointments, HCP communication, and non-medication management of signs/symptoms
  - Effective care should include:
    - Structured follow-up with patient education
    - Optimization of medical treatment
    - Psychosocial support
    - Improved access to care

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Clinical Pearls

- Echocardiography is key to the diagnosis of HF
- Therapy initially relies on the use of ACE inhibitors and beta blockers
- Patients with NYHA class II or III HF and on ACE inhibitors should be transitioned to ARNI
  - ARNI further reduces morbidity and mortality
  - Must have 36-hour washout period between ACE inhibitor and ARNI
  - ARNI combination containing valsartan has not been recalled by FDA
- Diuretics used to relieve symptoms and signs of congestion
- BP target in patients with hypertension + HF: 130/80 mmHg

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Thank You!

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