

Ask the Experts: Building a Toolkit for Managing Heart Failure

Presented as a Live Webinar

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FACULTY



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Ask the Experts

Building a Toolkit for Managing Heart Failure



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1 hr.

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Learning Objectives

- Identify clinical controversies & barriers leading to suboptimal use of guideline-directed medical therapy (GDMT) regimens for patients with heart failure with reduced ejection fraction (HFrEF).
- Develop plans to optimize GDMT regimens for patients with HFrEF.
- Adopt strategies to overcome barriers to implementing successful transitions of care programs for patients with HFrEF hospitalized for acute heart failure.

Abbreviations

- ACEI=angiotensin converting-enzyme inhibitor
- ADEs=adverse drug events
- ARB=angiotensin receptor blocker
- ARNI=angiotensin receptor-neprilysin inhibitor
- BID=twice daily
- BP=blood pressure
- BUN=blood urea nitrogen
- CI=confidence interval
- COR=class of recommendation
- CrCl=creatinine clearance
- CV=cardiovascular
- Non-DHP CCB=non-dihydropyridine calcium channel blocker
- ED=emergency department
- eGFR=estimated glomerular filtration rate
- EMR=electronic medical record
- GDMT=guideline-directed medical therapy

- HF=heart failure
- HFrEF=heart failure with reduced ejection fraction
- HYD=hydralazine
- HR=heart rate
- ISDN=isosorbide dinitrate
- LOE=level of evidence
- LVEF=left ventricular ejection fraction
- MTM=medication therapy management
- MRA=mineralocorticoid receptor antagonist
- NSAIDs=non-steroidal anti-inflammatory drugs
- NSR=normal sinus rhvthm
- NYHA=New York Heart Association
- OACs=oral anticoagulants
- PCPs=primary care providers
- RR=respiratory rate
- TOC=transitions of care

Clinical Barriers and Controversies in Heart Failure

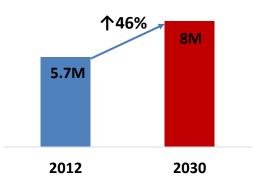
Tien M.H. Ng, Pharm.D., BCPS AQ Cardiology, FACC, FCCP, FHFSA

Associate Professor of Clinical Pharmacy and Medicine
Director, PGY2 Residency in Cardiology
Vice Chair, Titus Family Department of Clinical Pharmacy
School of Pharmacy and Keck School of Medicine
University of Southern California, Los Angeles, California

HF in 2019

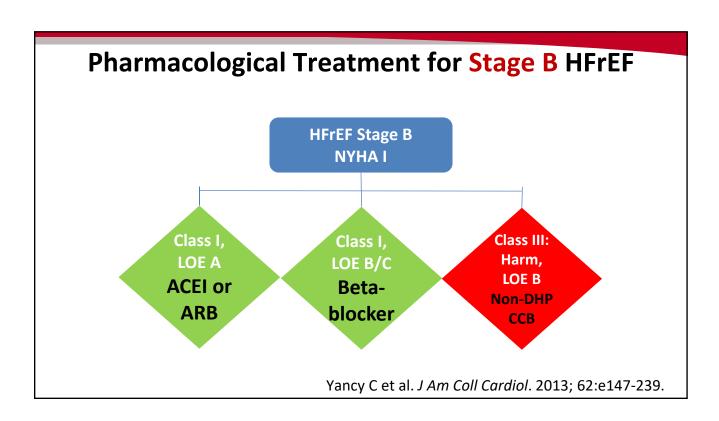
- #big problem, #long way to go
- Prevalence: 5.7 million (U.S.)
- Annual mortality: 75,251
- Lifetime risk @ age 45 years:
 1 in 2-5

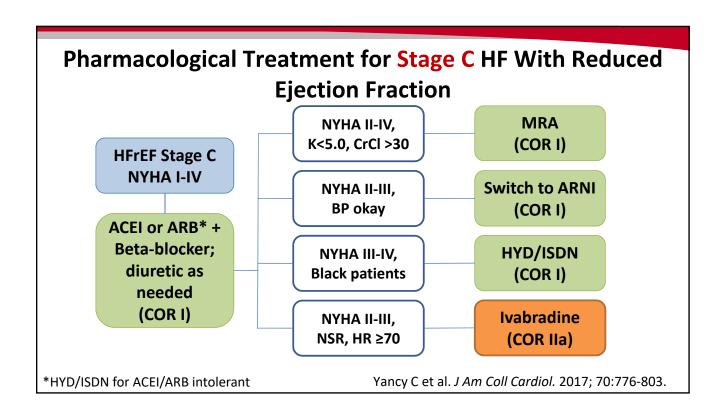
Estimated HF Prevalence



Benjamin EJ et al. Circulation. 2018; 137:e67-492.

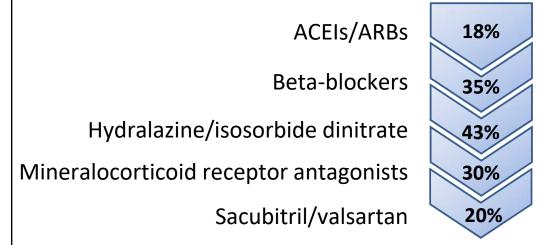
	Heart Fail	ure Stages	
А	В	С	D
High risk for HF but without structural heart disease or symptoms of HF	Structural heart disease but without signs or symptoms of HF	Structural heart disease with prior or current symptoms of HF	Refractory HF requiring specialized interventions
ACEI or ARB in appropriate patients for vascular disease/diabetes mellitus	ACEI or ARB Beta-blocker	Diuretic ACEI or ARB (or ARNI) Beta-blocker MRA	Advanced measures Heart transplantation Chronic inotropes Mechanical Circulatory Support
Statins as appropriate		Selected patients: HYD/ISDN Digitalis Ivabradine	Palliative care





Generally, consider titrating do	Titrating GDMT oses of GDMT every 2 weeks	
	Starting Dose	Target Dose
Bisoprolol Carvedilol Metoprolol succinate	1.25 mg daily 3.125 mg twice daily 12.5-25 mg daily	10 mg daily 25-50 mg twice daily 200 mg daily
Sacubitril/valsartan	24/26-49/51 mg twice daily	97/103 mg twice daily
Captopril Enalapril Lisinopril	6.25 mg three times daily 2.5 mg twice daily 2.5-5 mg daily	50 mg three times daily 10-20 mg twice daily 20-40 mg daily
Candesartan Losartan Valsartan	4-8 mg daily 25-50 mg daily 40 mg twice daily	32 mg daily 150 mg daily 160 mg twice daily
Spironolactone Eplerenone	12.5-25 mg daily 25 mg daily	25-50 mg daily 50 mg daily
Hydralazine/isosorbide dinitrate	25/20 mg three times daily Yancy CW et al.	75/40 mg three times daily <i>J Am Coll Cardiol</i> . 2018; 71:201-30.

Mortality Reduction in HFrEF



Yancy CW et al. J Am Coll Cardiol. 2018; 71:201-30.

Clinical Controversies and Barriers to Medication Optimization

- HP is a 67-year-old female with a history of HFrEF (LVEF 18%) being seen for the first time in clinic after a recent hospitalization. She remains in NYHA functional class III.
- Current medications: enalapril 10 mg once daily, metoprolol tartrate 25 mg twice daily, furosemide 20 mg once daily
- Vitals: BP 89/67 mm Hg, HR 84 bpm, RR 18 breaths/min
- Pertinent labs:
 - Sodium 136 mEq/L, potassium 4.8 mEq/L, creatinine 1.22 mg/dL, BUN 23 mg/dL, eGFR 46 mL/min/m²
 - NT-proBNP 4,300 pg/mL
 - HOW DO WE FURTHER OPTIMIZE CARE FOR THIS PATIENT?

Which Beta-blocker?

Beta-blocker Pharmacology Comparison

	Carvedilol	Metoprolol succinate	Metoprolol tartrate	Bisoprolol
Pharmacology	β1, β2, α1	β1	β1	β1
Half-life (hours)	7-10	3-7	3-4	9-12
Duration of action (hours)	12	24	8-12	24
Others	Antioxidant, ↓Insulin resistance			

Hemodynamics, degree of neurohormonal blockade, cardioprotection?

Talbert RL. Heart Fail Rev. 2004; 9:131-7. Leopold G. J Cardiovasc Pharmacol. 1986; 8 suppl 11:S16-20.

Carvedilol Or Metoprolol European Trial (COMET)

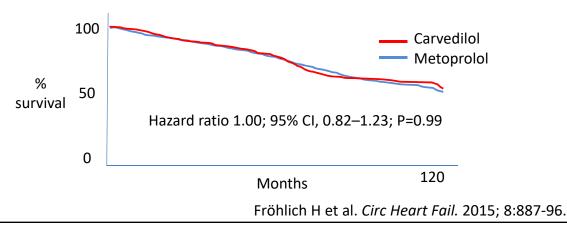
- N=1511 HFrEF, NYHA II-IV
- Carvedilol 25 mg twice daily (41.8 mg/day) vs.
 metoprolol tartrate 50 mg twice daily (85 mg/day)

%	Carvedilol	Metoprolol	Hazard Ratio (95% confidence interval)
All-cause mortality	34	40	0·83 (0·74–0·93)
CV death	29	35	0·80 (0·70–0·90)
Death or hospital admission	74	76	0.94 (0.86–1.02)

Poole-Wilson PA. Lancet. 2003; 362:7-13.

Carvedilol or Metoprolol Evaluation Study

- N=14,016 Norwegian HF and German HF registries
- Selecting 740 propensity-score matched pairs, comparing carvedilol vs. metoprolol succinate (at equivalent doses)

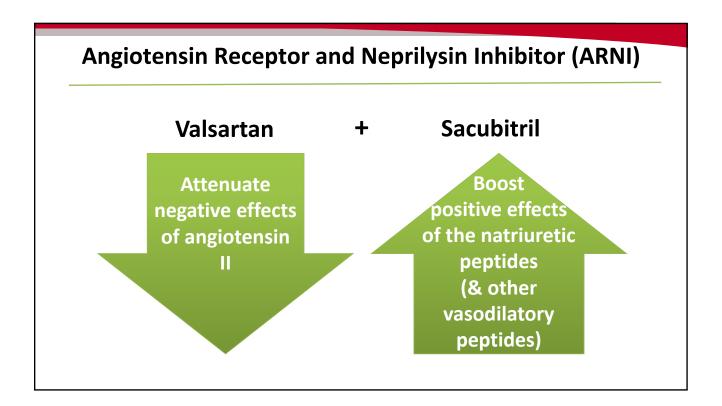


Approach to Beta-blocker Selection

	Carvedilol immediate release	Metoprolol succinate	Bisoprolol
Adherence	Controlled release	+	+
Low BP		+	+
High BP	+		
Diabetes	+		
Evidence-based	+	+	+
Target doses	25-50 mg twice daily	200 mg once daily	10 mg once daily

If you must use metoprolol tartrate, use at least 75 mg twice daily

ARNI or not to ARNI?



PARADIGM-HF - Study Design

Single-blind Active Run-in Period Double-blind Treatment Period

Enalapril Sac/Val Sac/Val
10 mg BID 100 mg BID 200 mg BID
Run-in Run-in

Sac/Val 200 mg BID

Enalapril 10 mg BID

2 weeks 1-2 weeks 1-2 weeks

Sac/Val = sacubitril/valsartan

McMurray JJ et al. Eur J Heart Fail. 2013; 15:1062-73.

PARADIGM-HF - Results

%	Sac/Val (n=4187)	Enalapril (n=4212)	Hazard Ratio (95% CI)	P Value
Primary endpoint	21.8	26.5	0.80 (0.73-0.87)	<0.001
Cardiovascular death	13.3	16.5	0.80 (0.71-0.89)	<0.001
Hospitalization for HF	12.8	15.6	0.79 (0.71- 0.89)	<0.001
Symptomatic Hypotension	14.0	9.2		<0.001

McMurray JJ et al. N Engl J Med. 2014; 371:993-1004.

Perceived Barriers to ARNI

- Cost, access
 - Patient assistance program:
 - Be a U.S. resident
 - Meet income requirements
 - Have limited or no private or public prescription coverage
 - https://www.pharma.us.novartis.com/our-products/patient-assistance/patient-assistance-foundation-enrollment
- Clinical
 - Risk of hypotension
 - Twice daily regimen
 - Risk of angioedema
 - Risk of renal dysfunction

PARADIGM-HF Stratified

- Systolic blood pressure (Eur Heart J. 2017; 38:1132–43.)
 - Low systolic BP (<110 mm Hg) was associated with increased risk for primary endpoint and all-cause mortality
 - Similar tolerability and benefit compared to enalapril
- LVEF (Circ Heart Fail. 2016; 9:e002744.)
 - Lower LVEF was associated with increased risk of primary endpoint and all-cause mortality
 - Similar benefit compared to enalapril regardless of LVEF

PARADIGM-HF and Hypotension

Single-blind Active Run-in Period Double-blind Treatment Period

Enalapril Sac/Val Sac/Val
10 mg BID 100 mg BID 200 mg BID
Run-in Run-in Run-in

Sac/Val 200 mg BID

Enalapril 10 mg BID

2 weeks 1-2 weeks 1-2 weeks

136 (1.3%)
$$\rightarrow$$
 43 \rightarrow 6 (14%)
10513 \longrightarrow 8442 \rightarrow 976 (11.6%) 588 (14.0%) Sac/Val
10377 \longrightarrow 9419 \rightarrow 228 (2.4%) 588 (9.2%) Enalapril

Vardeny O et al. Circ Heart Fail. 2018; 11:e004745.

PARADIGM-HF and Hypotension

Older +

more

severe HF

- Predictors:
 - Lower systolic BP
 - Older age
 - ICD implanted
 - Higher creatinine
 - Atrial fibrillation history
 - North America
 - Diabetes

- Outcomes:
 - Study drug did not affect predictors of hypotension (except diabetes – higher risk in enalapril arm)
 - Similar benefit compared to enalapril in those that experienced hypotension

Vardeny O et al. Circ Heart Fail. 2018; 11:e004745.

Real World vs. Clinical Trial

- PARADIGM-HF exclusion criteria:
 - eGFR ≤30 mL/min/m²
 - Systolic BP ≤100 mm Hg
 - Potassium ≥5.2 mmol/L
 - Not on ACEI (enalapril 10 mg/day or equivalent)

- Cleveland Clinic analysis
 - Met FDA criteria: 71%
 - Met PARADIGM-HF criteria: 26%

Perez AL et al. JACC Heart Fail. 2017; 5:460-3.

PIONEER-HF

- Assess safety and efficacy of sacubitril/valsartan initiation among patients hospitalized for acute heart failure after hemodynamic stabilization
- Sacubitril—valsartan target dose 200 mg twice daily vs. enalapril target dose 10 mg twice daily

↓ NT-proBNP @ 4 and 8 weeks with sacubitril/valsartan

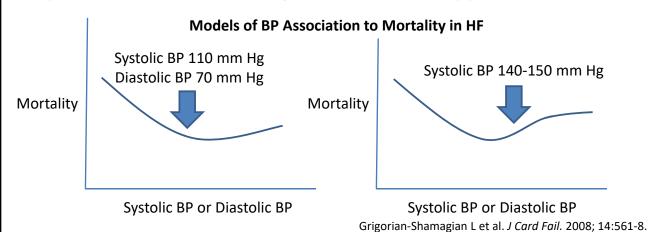
No significant differences: worsening renal function, hyperkalemia, symptomatic hypotension, angioedema, or clinical events

Velazquez EJ et al. N Engl J Med. 2019; 380:539-48.

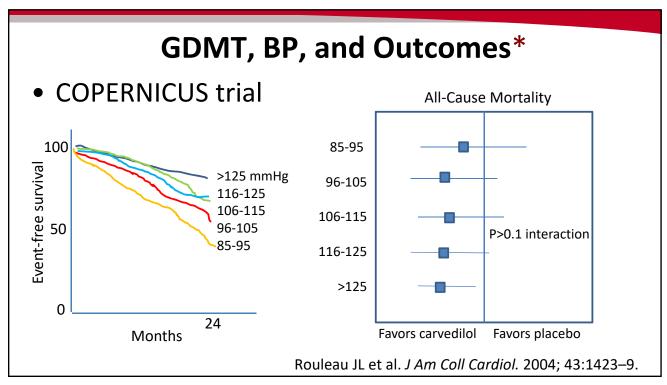
Low Blood Pressure?

BP and HF Outcomes

 Low BP has been associated with lower survival in ambulatory patients with HF, but changes in BP with therapy have not



Lee DS et al. Circ Heart Fail. 2009; 2:616-23. Ather S et al. Am Heart J. 2011; 161:567-73.



*slide contains corrected data

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Potential Benefits of Lower Blood Pressure in HF

Reduced afterload Reduced ventricular wall tension Improved vascular vasoreactivity



Improved diastolic function
Increased stroke volume
Reduced myocardial oxygen consumption

Approach to Assessment of Low BP

- Symptomatic?
- Perfusing?
- Volume status?
- Separate dose administration times?
- Unnecessary polypharmacy?

Circling Back on Loops

Loop Diuretic Comparison

	Furosemide	Bumetanide	Torsemide	Ethacrynic Acid
Relative Potency	40	0.5-1	20	50
Bioavailability (%)	≈50 (10-90)	>90	>90	100
Half-life (hours)	2-3	1-1.5	3-6	0.25-2
Duration of Action (hours)	6-8	4-6	18-24	2-4
Notes	Absorption reduced by meals		Absorption not reduced in HF; antifibrotic	No sulfur group

DiNicolantonio JJ. *Future Cardiol*. 2012; 8:707-28. Brater DC et al. *Kidney Int*. 1984; 26:183-9. Vargo DL et al. *Clin Pharm Ther*. 1995; 57:601-9. Molnar J, Somberg JC. *Am J Ther*. 2009; 16:86-92.

Torsemide vs. Furosemide in HF: Meta-Analysis of RCTs

HF READMISSIONS	Sample Size	OR
Mueller et al. (2003)	237	0.62 (0.10, 3.79)
Murray et al. (2001)	234	0.25 (0.14, 0.45)
Stroupe et al. (2000)	193	0.43 (0.22, 0.85)
Overall	664	0.33 (0.22, 0.50)

MORTALITY	Sample Size	OR
Mueller et al. (2003)	237	1.27 (0.43, 3.79)
Murray et al. (2001)	234	0.73 (0.37, 1.42)
Stroupe et al. (2000)	193	0.77 (0.37, 1.61)
Overall	664	0.82 (0.52, 1.28)

Shah P et al. *Eur J Heart Fail*. 2018; 57:e38-e40.

Torsemide vs. Furosemide in HF: Duke Experience

 N=4,580 admitted with HF to Duke Hospital (2000–2010), then discharged on either torsemide (14%) or furosemide (86%)

Adjusted Model	Odds Ratio or Hazard Ratio	P-value
30-day mortality or hospitalization	1.22	0.1789
30-day hospitalization	1.29	0.1607
5-year mortality	1.09	0.2279

Mentz RJ et al. J Cardiovasc Pharmacol. 2015; 65:438-43.

Approach to Selection of Loop in HFrEF

	Furosemide	Bumetanide	Torsemide
Dosing for persistent volume overload	Twice daily	Two to three times daily	Once daily
Absorption issues		+	++
Adherence issues			++
Higher doses needed		++	

Ethacrynic Acid for true sulfonamide intolerance

Tools to Address Barriers for Optimizing Heart Failure Transitions of Care

Robert J. DiDomenico, Pharm.D., BCPS AQ Cardiology, FACC, FCCP, FHFSA

Associate Professor

Director, PGY2 Residency in Cardiology

University of Illinois at Chicago College of Pharmacy

Chicago, Illinois

How Do We Further Optimize Care for This Patient Prior to Discharge?

- HP is a 67-year-old African-American female with HFrEF (LVEF 18%)
 hospitalized for the first time for acute heart failure. Poor historian, lives
 with her daughter who assists with her care
- Current medications: enalapril 10 mg once daily, metoprolol tartrate 25 mg twice daily, furosemide 20 mg once daily, metformin 500 mg twice daily, atorvastatin 40 mg daily, levothyroxine 0.1 mg daily, enteric-coated aspirin 81 mg daily
- Vitals: BP 109/67 mm Hg, HR 84 bpm, RR 18 breaths/min
- Pertinent labs:
 - Sodium 136 mEq/L, potassium 4.8 mEq/L, creatinine 1.22 mg/dl, BUN 23 mg/dl, eGFR 46 mL/min/m²

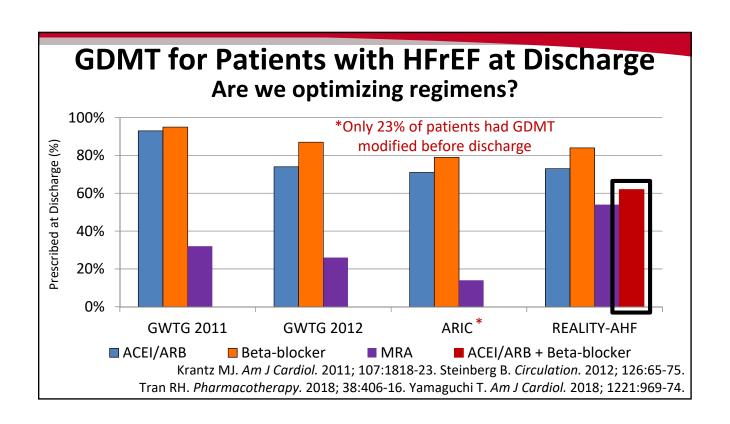
Clinical Predictors of HF Readmission Opportunities for Improvement?

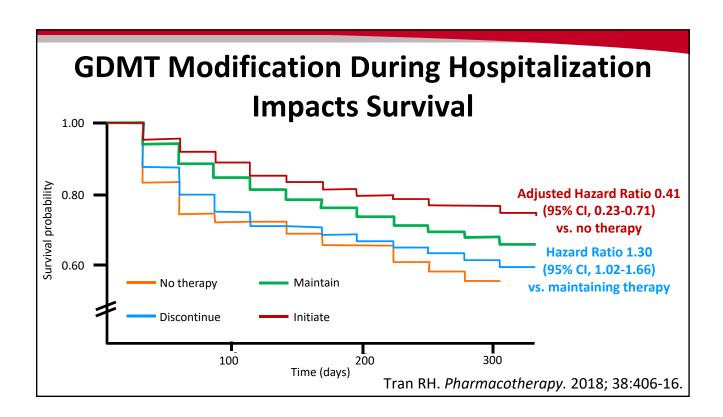
- Acute coronary syndrome, ischemia
- Increasing age
- Anemia
- Arrhythmia
- Depression
- Hyponatremia
- Low LVEF

- NYHA class IV symptoms
- Pneumonia/respiratory pathology
- Suboptimal HF medication regimen
- Uncontrolled hypertension
- Worsening renal function

Fonarow G. Arch Intern Med. 2008; 168:847-54.

Murray M. Clin Pharmacol Ther. 2009; 85:651-8. Annema C. Heart Lung. 2009; 38:427-34.





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Consider Additional GDMT for HFrEF ✓ ACEI or ARB ✓ Beta-blocker ✓ Diuretic □ Aldosterone antagonist

□ Aldosterone antagonis
☐ Hydralazine/nitrate
☐ Sacubitril/valsartan
□Ivabradine
□ Digoxin



Hospitalization = Opportunity to Titrate Dose!

• Generally, consider titrating doses of GDMT every 2 weeks

	Starting Dose	Target Dose
Bisoprolol Carvedilol Metoprolol succinate	1.25 mg daily 3.125 mg twice daily 12.5-25 mg daily	10 mg daily 25-50 mg twice daily 200 mg daily
Sacubitril/valsartan	24/26-49/51 mg twice daily	97/103 mg twice daily
Captopril Enalapril Lisinopril	6.25 mg three times daily 2.5 mg twice daily 2.5-5 mg daily	50 mg three times daily 10-20 mg twice daily 20-40 mg daily
Candesartan Losartan Valsartan	4-8 mg daily 25-50 mg daily 40 mg twice daily	32 mg daily 150 mg daily 160 mg twice daily
Spironolactone Eplerenone	12.5-25 mg daily 25 mg daily	25-50 mg daily 50 mg daily
Hydralazine/isosorbide dinitrate	25/20 mg three times daily	75/40 mg three times daily
	Yancy CW et al.	I Am Coll Cardiol. 2018; 71:201-30

GDMT Dose Matters!Dose-dependent Effect on Left Ventricle

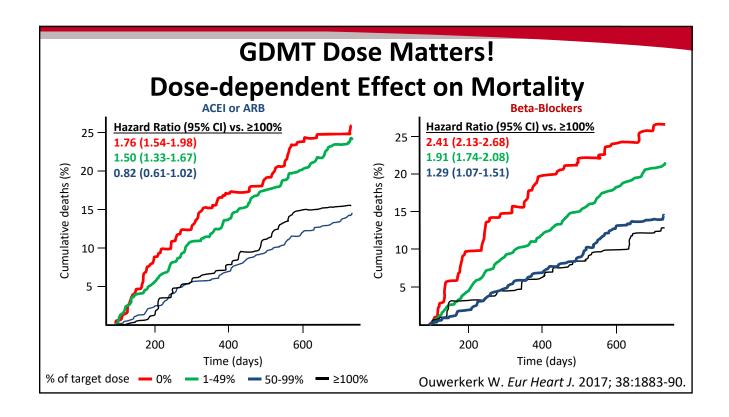
- MOCHA
 - Dose-related increaseDose-dependentin LVEF with carvedilolimprovement in
- REVERT
 - Dose-dependent improvement in left ventricular remodeling

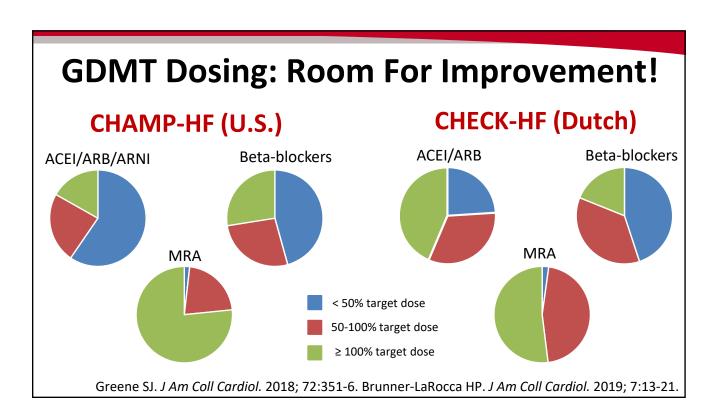
Bristow MR. Circulation. 1996; 94:2807-16. Colucci WS. Circulation. 2007; 116:49-56.

GDMT Dose-dependent Effect on Outcomes

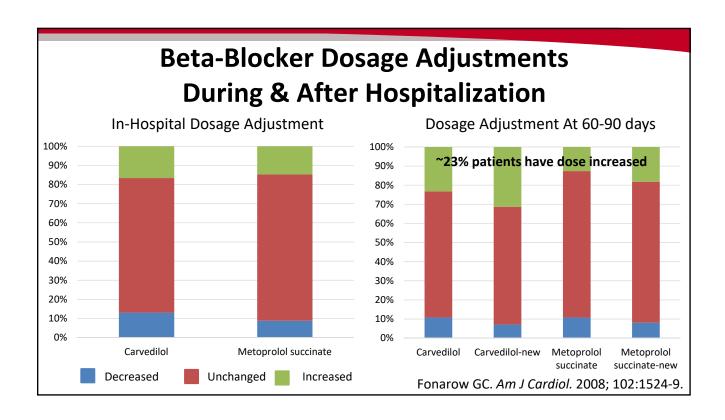
Trial	Hazard Ratio for death or HF hospitalization	95% Confidence Interval	
ACEI or ARBs			
ATLAS (lisinopril)	0.85	0.78-0.93	
HEAAL (losartan)	0.90	0.82-0.99	
Egiziano et al.	ACEI: 0.91 ARB: 0.85	0.87-0.95 0.77-0.95	
Beta-blockers			
HF-ACTION	0.96 per 10-mg dose increase	0.93-0.99	
McAlister et al.	No dose-response relationship		

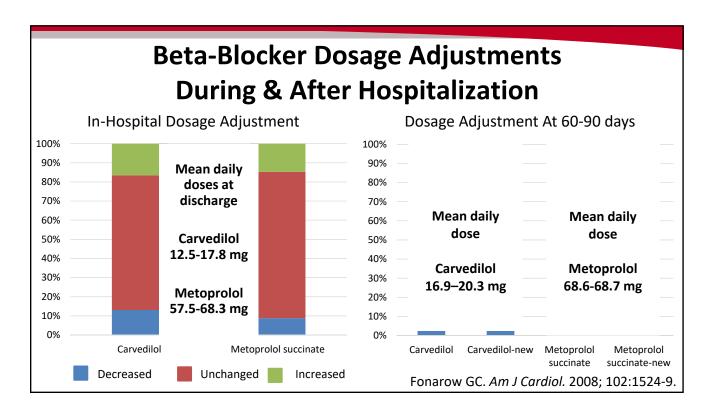
Packer M. Circulation. 1999; 100:2312-8. Konstam MA. Lancet. 2009; 374:1840-8. Egiziano G. Arch Intern Med. 2012; 172:1263-5. Fiuzat M. J Am Coll Cardiol. 2012; 60:208-15. McAlister FA. Ann Intern Med. 2009; 150:784-94.





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Effective Care Transitions to Optimize Post-Discharge Outcomes

Patient Education & Discharge Counseling Heart Failure and Post-Myocardial Infarction

- Address barriers
- Perform thorough review of medications
- Use inpatient and outpatient settings
- Assess readiness to learn
- Vary teaching methods
- Engage caregivers
- Engage other team members

- Optimize written materials
- Emphasize self-care
- Employ teach-back method
- Assess patient resources
- Refer to disease management programs
- Focus on smooth care transitions

Wiggins B. Pharmacotherapy. 2013; 33:558-80.

Inpatient Medication Histories & Reconciliation Clinical & Economic Outcomes

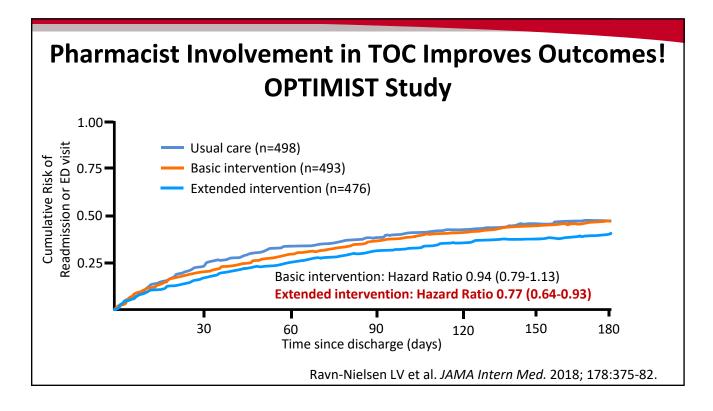
Medication Histories

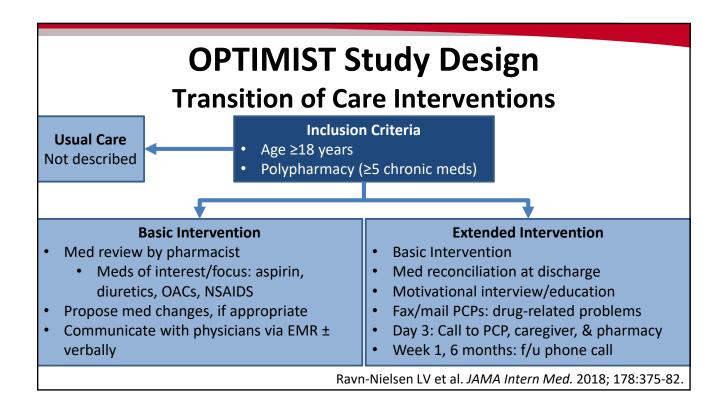
- ↓ Adverse drug events (ADEs)
- ↓ Drug costs
- ↓ Total costs
- ullet Inpatient mortality

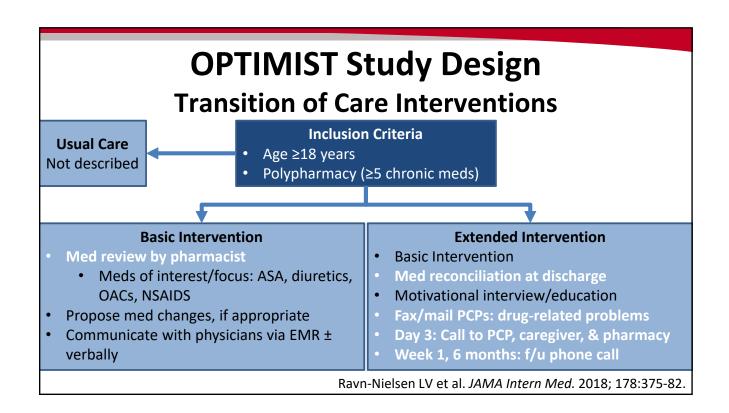
Medication Reconciliation

- ↓ Medication discrepancies
- ↓ Potential ADEs
- ↓ Preventable ADEs
- ↓ Health care resource use

Bond CA et al. *Pharmacotherapy*. 1999; 19:1354-62. Bond CA et al. *Pharmacotherapy*. 2000; 20:609-21. Bond CA et al. *Pharmacotherapy*. 2004; 24:427-40. Bond CA et al. *Pharmacotherapy*. 2006; 26:735-47. Bond CA et al. *Pharmacotherapy*. 2007; 27:481-93. Mueller S. *Arch Intern Med*. 2012; 172:1057-69.







Heart Failure Transitions of Care Programs Barriers & Potential Solutions

Barriers

- Lack of time/resources
- Patient out-of-pocket costs/insurance issues
- Lack of administration/ leadership support

Potential Solutions

- Utilize technicians ± students
- Focus intervention(s) on "high-risk" patients
- Partner with outpatient pharmacy
- Bill for MTM services?

Pharmacy Student Medication Reconciliation

Student-managed services

- Clinical interventions
- Post-discharge calls

RXCARES

Reconciliation

X-Drug Interaction

Coordination &

Communication

Access & Adherence

Risk reduction

Evidence-Based Medicine review / **E**limination of

meds

Savings

MoPhE

Mobile

Pharmacy

Education



Bursua A, Thambi M. University of Illinois Hospital.

Lubowski TJ. Am J Pharm Educ. 2007; 71:94. Walker PC. Am J Pharm Educ. 2010; 74:20. Lancaster JW. Am J Pharm Educ. 2014; 78:34.

Focus Efforts on "High-Risk" Patients

- Targeted patients (e.g., elderly, polypharmacy)
 - OPTIMIST: ≥5 meds
 - RXCARES
 - ≥10 meds
 - Age ≥65 AND ≥5 meds OR ≥2 admissions in last 1 year
- Targeted medications/disease states
 - MoPhE: anticoagulants, diabetes, inhaler technique
- Utilize EMR/Clinical Decision Support?

Reimbursement for Transitions of Care?

- Several inpatient clinical pharmacy services eligible under evaluation & management inpatient procedural codes
 - History-taking, physical exam, medical decision-making
 - Categorized by complexity
- Medicare/Medicaid ineligible

Steps to Consider

- 1. Review payer mix
- Review state laws governing MTM criteria
- 3. Establish billing values with finance department
- 4. Pharmacist must conduct face-toface visit & document
- 5. Establish reporting system

Traynor K. Am J Health-Syst Pharm. 2014; 71:774-6. Sanchez D. Pharmacy Purchasing & Products. 2014; 11:30.

Wild D. Pharmacy Practice News. http://www.pharmacypracticenews.com/Operations-Management/Article/02-15/An-Inside-Job-Hospital-Adds-1-6-Million-in-Billables-Via-MTM/29415/ses=ogst. (Accessed 2018 Oct 29.)

Optimizing GDMT for Patients with HFrEF What Should Be in Your Toolkit?

- Knowledge to identify & resolve clinical barriers for optimization of GDMT
- Skills for medication histories, reconciliation, & patient education for appropriate patients
- Post-discharge follow-up
- Human resource management
 - More efficient use of technicians ± students
- Reimbursement capabilities (MTM billing?)



Selected Resources

Guidelines & Consensus Statements

- Yancy C et al. 2013 ACCF/AHA guideline for management of heart failure. J Am Coll Cardiol. 2013; 62:e147-239.
- Yancy C et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. J Am Coll Cardiol. 2017; 70:776-803.
- Yancy CW et al. 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment. J Am Coll Cardiol. 2018; 71:201-30.

Other Selected Resources

- Tran RH et al. *Pharmacotherapy*. 2018; 38:406-16.
- Ouwerkerk W et al. Eur Heart J. 2017; 38:1883-90.
- Fonarow GC et al. Am J Cardiol. 2008; 102:1524-9.
- Ravn-Nielsen LV et al. JAMA Intern Med. 2018; 178:375-82.
- Traynor K. *Am J Health-Syst Pharm.* 2014; 71:774-6.
- Sanchez D et al. Pharmacy Purchasing & Products. 2014; 11:30. https://www.pppmag.com/article_print.php?id=1534.

Consider these practice changes. Which will you make?

- Read the 2017 ACC Expert Consensus Pathway.
- Compare my organization's protocols with the most up to date heart failure treatment guidelines.
- Evaluate my organization's utilization & escalation of GDMT for HFrEF prior to discharge.
- Assess my pharmacy department's participation in care transitions (e.g., frequency of medication histories upon admission & medication reconciliation upon discharge, participation in patient education).
- Engage both patients & caregivers in educational encounters.
- Determine the feasibility of post-discharge pharmacist involvement (e.g., post-discharge telephone contact, multidisciplinary clinic).