

HEART FAILURE TOPIC BRIEF: OPTIMIZING HFrEF THERAPIES

Overview

When it comes to treatment of heart failure with reduced left ventricular ejection fraction (HFrEF), there have been two exciting advances added to the existing medical options. These were outlined in the *2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure*.

Optimizing heart failure therapy is critically important—whether it’s integrating expanding practice guidelines or looking for ways to maximize current treatment plans. Of course, gauging patient preferences and the impact the diagnoses and treatments have on their quality of life also need to be part of the picture; as does providing them with basic education about medication adherence and managing comorbid conditions. Data reveal up to 30 percent of HFrEF patients prescribed beta blockers and ACE inhibitors do not take them as they should. There remain important gaps in care.

“It’s hard work to get patients on the right medications – it takes time, and we need to counsel patients and monitor side effects. But doing this hard work can have big benefits for patients, and that’s why we should want to take the time.”

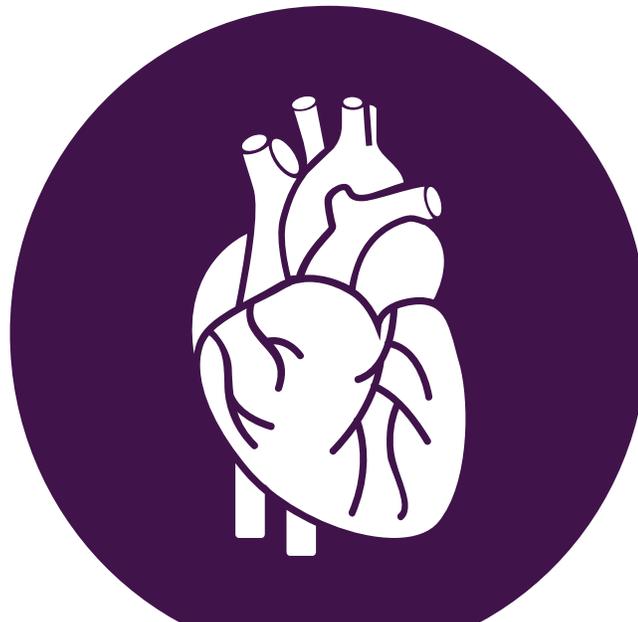
– **Larry Allen, MD**, Medical Director, Advanced Heart Failure at the University of Colorado Denver

The following resource is **intended to help guide your discussions about heart failure treatments** with your patients to help optimize outcomes. The need for a practice-based discussion guide around this topic arose from the American College of Cardiology’s *Emerging Strategies for Heart Failure Roundtable* that brought together some of the nation’s leading cardiologists, advanced care practitioners and patients.



What's Included in this Resource

- STEPS TO OPTIMIZE HFrEF MEDICATIONS
- TALKING WITH YOUR PATIENTS ABOUT OPTIMIZING THEIR HFrEF TREATMENT
 - Patient Goals: Getting to the Heart of the Matter
 - Things to Consider Before Starting Newer HFrEF Medications
 - Common Questions Patients Have about HFrEF Medications
- EXPLORING CO-MORBIDITIES AS BARRIERS TO HFrEF CARE AND TREATMENT
- ENCOURAGING MEDICATION ADHERENCE
- HELPFUL RESOURCES TO SHARE WITH YOUR PATIENTS
- AT-A-GLANCE: KEY CONSIDERATIONS FOR DISCUSSING TREATMENT INTENSIFICATION AND NEW THERAPIES FOR CERTAIN HEART FAILURE PATIENTS





STEPS TO OPTIMIZE HF_rEF MEDICATIONS

Is the patient:

- ✓ On optimal beta blocker and ACE-I (or ARB) therapy?
- ✓ Already on ACE-I (or ARB) therapy?
- ✓ Eligible for an angiotensin receptor/neprilysin inhibitor (ARNI), either as a first/initial therapy or to replace a current ACE-I (or ARB)?

Sacubitril/valsartan is first in a new class of drugs called ARNIs that has been shown to significantly reduce the rates of death, hospitalization and heart failure symptoms when used instead of ACE-I inhibitor.

- ✓ Eligible for spironolactone (or eplerenone), which is often underutilized.

Three large, randomized, controlled trials (RALES, EPHEBUS, EMPHASUS) found a 25-30 percent risk reduction in HF_rEF populations when taking this medication. Other considerations: rates of hyperkalemia are relatively low with appropriate monitoring, and spironolactone is low cost.

- ✓ Eligible for ivabradine?

This drug has been shown to help reduce HF hospitalizations.

Would he/she be a candidate for one or both of the newer therapies based on the 2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure?

Sacubitril/Valsartan

2016 Guideline Recommendation:

The clinical strategy of inhibition of the renin-angiotensin system with ACE inhibitors (Level of Evidence: A) (9-14), OR ARBs (Level of Evidence: A) (15-18), OR ARNI (Level of Evidence: B-R) (19) in conjunction with evidence-based beta blockers (20-22), and aldosterone antagonists in selected patients (23, 24), is recommended for patients with chronic HF_rEF to reduce morbidity and mortality.

*Class of Recommendation: I
Level of Evidence: B-R*

Patients with chronic symptomatic HF_rEF NYHA class II/III who tolerate an ACE-I or ARB, replacement by ARNI is recommended in patients with adequate blood pressure to further reduce morbidity and mortality

*Class of Recommendation: I
Level of Evidence: B-R*

Key considerations:

- Patients need to be off an ACE-I for 36 hours before starting new therapy
- Approved ARNI is available in three doses
- The most common side effect is hypotension, followed by high blood potassium levels and renal impairment, although all at rates relatively similar to ACE-I
- This therapy should not be administered to patients with a history of angioedema or who are pregnant or might become pregnant

Early clinical experience suggests that most patients are being switched from a stable HF_rEF regimen in an ambulatory setting.

Ivabradine

2016 Guideline Recommendation:

Symptomatic (NYHA class II-III) stable chronic HF_rEF (LVEF ≤35%) who are:

- Receiving optimal guideline-directed evaluation and management, including taking a beta blocker at the maximum tolerated dose and
- In sinus rhythm with a heart rate of 70 beats per minute or greater at rest (patients with highest heart rates seemed to do best)

*Class of Recommendation: Class IIa
Level of Evidence: B-R*

Key considerations:

- Patients should be on an optimal dose of a beta blocker *before* assessing resting heart rate; most patients in the trial were stable for a month prior to starting ivabradine
- Patients who had a heart attack within the preceding two months were excluded

Clinical judgement should drive decisions to switch therapies, which may not always be approached in a stepwise or linear manner.



TALKING WITH YOUR PATIENTS ABOUT OPTIMIZING THEIR HF_rEF TREATMENT

Promoting Discussion and Engaging Your Patients With Heart Failure

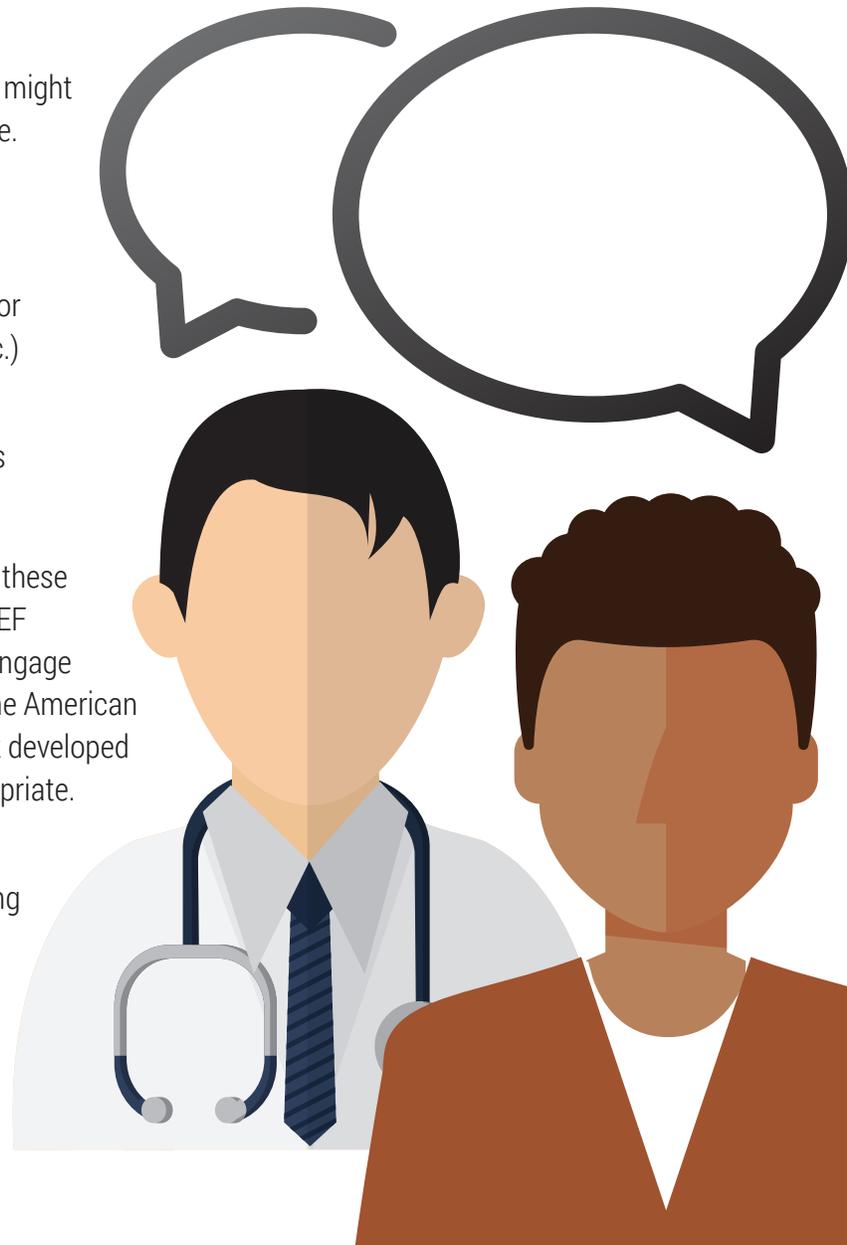
Below are some practical tips around topics you might want to talk about with patients with heart failure.

Of course, the types of conversations you have will depend on:

- Where the patient is in the course of his or her disease (newly diagnosed, stable, etc.)
- Previous treatments attempted
- Co-existing condition management plans
- Patient goals, concerns and preferences

You are most likely already addressing many of these issues, but amid new treatment options for HF_rEF patients, in particular, and an ongoing need to engage these patients to stay motivated in their care, the American College of Cardiology's collaborative Think Tank developed this resource to help guide discussion, as appropriate.

Included as part of this resource are sample conversation tracks that may be useful in helping advanced care practitioners talk with patients at different stages of heart failure treatment.





Patient Goals: Getting to the Heart of the Matter

One of the best ways to help patients engage in their care is to understand and frame treatment plans around their specific goals for managing heart failure.

You might ask:

- When it comes to heart failure treatment, **what matters most** to you?

If you need help moving the conversation along, you might ask “Are your main goals to: live longer, feel better, assure heart failure doesn’t limit your ability to perform certain tasks or miss out on certain aspects of life, maintain a good quality of life overall and continue certain hobbies, travel or recreational activities?” Help the patient understand that these goals are more likely to be achieved by maximizing medical therapies and taking necessary steps to adhere to their medications.

- Are there things about your current treatment plan that concern you or that you are having a hard time with? Are there constraints on your life—caring for others, work, how you have been feeling, etc.—that make managing your condition more difficult?

For example, you might ask “Are you having trouble getting or paying for your medications?”
“Do you think any of your medications make you feel worse, not better?”
“Are you having more difficulty meeting daily tasks or exercising?” Reinforce how important it is that they are prepared to share their health status at each visit and in between.



Things to Consider Before Starting Newer HFrEF Medications

Many patients may be curious about new medications to manage heart failure and if they might be options for them. But before talking about adding newer agents, it's important to first make sure to review the basics together. For example:

✓ **Review their current treatment plan and the primary goals for treatment:**

- Easing symptoms
- Improving function/daily living
- Reducing hospitalizations
- Helping them live a long life
- Focusing on other goals that are important to them

✓ **Is their volume status ideally controlled?**

- It is difficult to intensify beta blockers and ACE-I ARB, or ARNI if patients are congested or overdiuresed
- Are they doing daily weights and keeping sodium and fluid intake consistent?

✓ **How are they doing with the basics? Are they able to take their medications as prescribed?**

- In any given month, how many times do they miss a dose?
- How are they feeling?
- If they are unable to adhere, why?
- Is there an opportunity to intensify dosing? (usually at 2-week intervals)
- What side effects do they need to be concerned about?
- How often should they communicate with the provider when dose is being increased?





Things to Consider Before Starting Newer HFrEF Medications (continued from previous page)

✓ **Are they taking spironolactone?**

- This tends to be underused, yet there is robust data that it can improve outcomes

✓ **Consider newer agents**

- Explain new medications and/or other steps to help optimize treatment if appropriate
- Sacubitril/valsartanas an alternative to ACE-I (or ARB)
- Ivabradine if sinus rhythm, heart rate >70 bpm at rest, and beta blocker maximally intensified
- Call the patient’s pharmacy or use online information to check out-of-pocket costs

✓ **Talk about potential benefits, risks, and burdens of these medications**

Common Questions Patients Have About HFrEF Medications

When presenting new drug options, here are some of the questions patients and their caregivers often ask about to help them be able to understand the medication and make a shared and informed decision.

- Specific drug name (spell it out for patients)
- When it might be used or considered?
- How does it work for heart failure?
- How might it help me feel better or be a better option?
- What side effects should I be aware of?
- How I should take it? (How often? At what time of day? With/without food? What to do if I miss a dose?)
- Does it interact with other medications or food?
- How quickly will it work?
- How will we monitor how I’m doing on this and the other medication(s) I take?
- How much will it cost me?

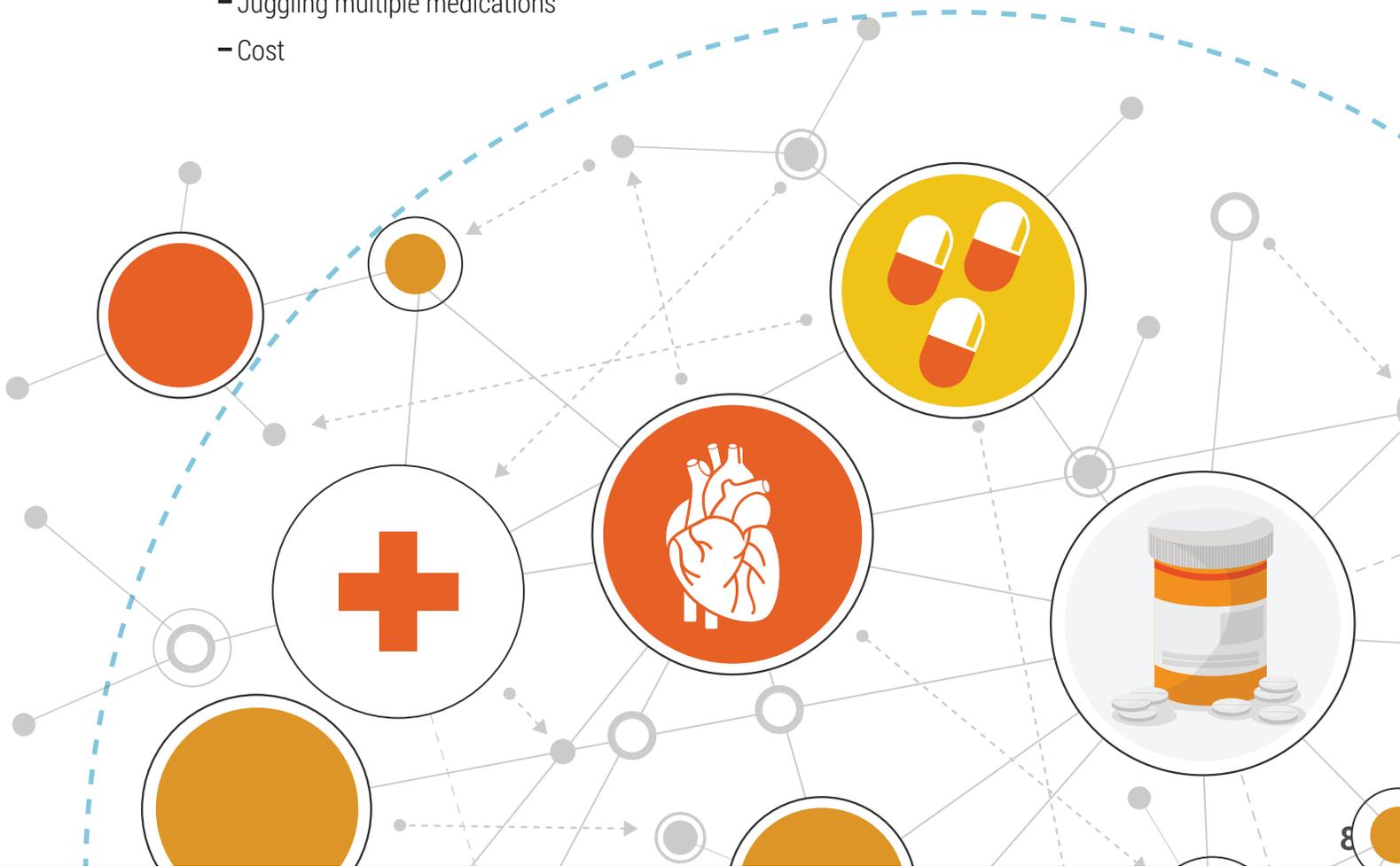




EXPLORING CO-MORBIDITIES AS BARRIERS TO HF_rEF CARE AND TREATMENT

Many patients with heart failure have other medical problems that also need to be managed. It's a good idea to review these health issues at each visit and explain why.

- What other health conditions do you have?
 - What are the treatments?
 - Which doctors are helping you manage these?
- Remember that you're not alone. Half of people with heart failure have 5 or more co-occurring conditions.
- It can make managing heart failure more difficult, so encourage patients to talk openly about challenges especially related to:
 - Taking all these medications as prescribed, every day, on time
 - Juggling multiple medications
 - Cost





ENCOURAGING MEDICATION ADHERENCE

This is an ongoing challenge. Patients describe this as “hard work.” Often, patients don’t understand why they are taking a specific medication or, more importantly, the dangers of NOT taking them. There may be other reasons too: unpleasant side effects, costs concerns, difficulty managing complex dosing schedules or polypharmacy, not knowing how to take the medication correctly, not being able to get to the pharmacy or simply forgetting to refill or take their medications, among others.

Teach patients about:

- Why they need to take each medication
 - ✓ Usually most concordant with their long-term goals
 - ✓ Ask them to repeat this information back to you in their own words
- What being adherent means
 - ✓ Make sure they understand when and how to take their medications, and what to do if they miss a dose, how to handle refills or to prepare for travel
 - ✓ Side effects being a leading reason people might stop taking medications without talking with their health care team
 - ✓ Remind them adjustments can often be made to help manage or avoid side effects, so they need to report in
 - ✓ Some side effects can be difficult to distinguish from heart failure symptoms themselves (for example, in trials, reports of fatigue are similar among patients taking a beta blocker and those on a placebo, 23.6 and 22.4 percent, respectively)
- Drug interactions
 - ✓ Need to consistently review a complete list of prescriptions, over-the-counter and supplements, especially when beginning a new medication or making adjustments
 - ✓ Complex dosing schedules or how to manage multiple medications

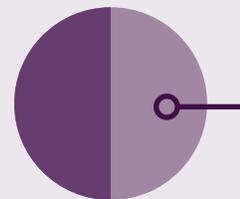
Medication Adherence Continues To Be A Big Problem



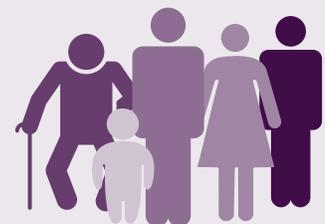
Medication prescriptions never filled: 20 to 30%



Patients not taking medications as prescribed: about 50%



Less than half of MI patients still take recommended medications a year later



Poor medication adherence takes the lives of 125,000 Americans annually



HELPFUL RESOURCES TO SHARE WITH YOUR PATIENTS

CardioSmart.org has a wealth of information and tools to help patients manage their condition. Be sure to check out the:

Med Reminder App

CardioSmart.org/Tools/Med-Reminder



Dealing with Healthcare Costs

The out-of-pocket costs for medications are often a barrier to adherence. If this is the case, talk to your patients about their options.

There are also resources to help, including at CardioSmart.org/Drugs-and-Treatments/Drug-Costs-Support.



Supported by
Novartis Pharmaceuticals Corporation



AT-A-GLANCE: KEY CONSIDERATIONS FOR DISCUSSING TREATMENT INTENSIFICATION AND NEW THERAPIES FOR CERTAIN HEART FAILURE PATIENTS

Potential Conversation Tracks Depending on the Stage of Treatment	Suggested Language to Consider When Engaging Patients
<p>When talking with a new patient about medication management</p>	<ul style="list-style-type: none"> • There are a number of medications available that can help a weak heart stay strong. • Most people with heart failure end up taking at least three of these, usually more. • One of the first things these medications do is lower blood pressure and slow heart rate. • It takes a while to get patients on the right dose (amount) of these medications; it's best to go slowly and gradually up the dose while we monitor you to see how you tolerate them.
<p>When talking with patients who could benefit from intensification of beta blockers</p>	<ul style="list-style-type: none"> • Beta blockers tell your heart to slow down. • Many people say they feel more sluggish and tired when they first take it, but over time (1-2 years based on studies) you are likely to feel better because you aren't wearing down the heart. • Getting you to the highest dose (amount) that you can tolerate is important. We will do this little by little based on any side effects or changes in how you feel.
<p>When talking with patients who aren't on spironolactone (or eplerenone)</p>	<ul style="list-style-type: none"> • Explain spironolactone and how it works, as well as how it is different to true diuretics. • It has been shown to be very effective and well-tolerated.
<p>When talking with patients who might be eligible to switch to sacubitril/valsartan</p>	<ul style="list-style-type: none"> • You've been on X drug for a long time and you are doing well. • There is now a drug that looks like it might be better. • It's been shown to reduce the rate of death, hospitalizations and heart failure symptoms. • Unlike many of your medications which are generic, this new drug is on patent and can be expensive; review costs, risks and benefits.
<p>When addressing whether ivabradine should be added once a patient has reached maximum doses of a beta blocker</p>	<ul style="list-style-type: none"> • This becomes an option once you are taking maximum doses of beta blockers, but still have a relatively fast heart rate. • It works to further stabilize heart function. • Unlike many of your medications which are generic, this new drug is on patent and can be expensive; review costs, risks and benefits.
<p>If you are worried about medication adherence</p>	<ul style="list-style-type: none"> • Taking medications the right way is important. • Set a medication schedule and stick to it. • Keep and share an updated list of your medications with ALL of your providers. • Share concerns over copays and out-of-pocket costs. • Read medication labels and call with any questions. • Consider using a pill box if you take multiple medications. • Changes to medications may be needed, but don't make changes without talking to your clinician/doctor.

