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# 2020 ACC/AHA Clinical Performance and Quality Measures for Adults With Heart Failure:

A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures

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Developed in Collaboration With the Heart Failure Society of America

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# Keywords

ACC/AHA Performance Measures; heart failure; performance measures; quality indicators; quality measures

# TOP 10 TAKE-HOME MESSAGES FOR ADULTS WITH HEART FAILURE

1. This document describes performance measures for heart failure that are appropriate for public reporting or pay-for-performance programs.

- 2. The performance measures are from the 2017 American College of Cardiology/ American Heart Association/Heart Failure Society of America heart failure guideline update and are selected from the strongest recommendations (Class 1 or 3).
- Quality measures are also provided that are not yet ready for public reporting or pay for performance but might be useful for clinicians and healthcare organizations for quality improvement.
- **4.** A new safety measure (laboratory monitoring for patients treated with mineralocorticoid receptor antagonists) is paired with a new treatment measure (mineralocorticoid receptor antagonists in patients with heart failure with reduced left ventricular ejection fraction).
- **5.** Other additions to the performance measures include the new medication sacubitril/valsartan and use of cardiac resynchronization therapy.
- 6. To address frequent lack of titration of heart failure medications, 2 new performance measures are included based on dose, either reaching 50% of the recommended dose (e.g., beta blocker or angiotensin-converting enzyme inhibitor/angiotensin receptor antagonist/angiotensin receptor neprilysin inhibitor) or documenting that such a dose was not tolerated or otherwise inappropriate.
- 7. For all measures, if the clinician determines the care is inappropriate for the patient, that patient is excluded from the measure.
- **8.** For all measures, patients who decline treatment or care are excluded.
- **9.** A patient-centered discussion of the benefits and risks of implantable cardioverter-defibrillator treatment remains a performance measure.
- 10. To reflect the increasing importance of patient-reported outcome measures, 2 patient-reported outcomes quality measures were added that use heart failure patient-reported outcomes questionnaires currently accepted by the U.S. Food and Drug Administration.

# **PREAMBLE**

The American College of Cardiology (ACC)/American Heart Association (AHA) performance measurement sets serve as vehicles to accelerate translation of scientific evidence into clinical practice. Measure sets developed by the ACC/AHA are intended to provide practitioners and institutions that deliver cardiovascular services with tools to measure the quality of care provided and identify opportunities for improvement.

Writing committees are instructed to consider the methodology of performance measure development (1,2) and to ensure that the measures developed are aligned with ACC/AHA clinical practice guidelines. The writing committees also are charged with constructing measures that maximally capture important aspects of care quality, including timeliness, safety, effectiveness, efficiency, equity, and patient-centeredness, while minimizing, when possible, the reporting burden imposed on hospitals, practices, and practitioners.

Potential challenges from measure implementation may lead to unintended consequences. The manner in which challenges are addressed is dependent on several factors, including the measure design, data collection method, performance attribution, baseline performance rates, reporting methods, and incentives linked to these reports.

The ACC/AHA Task Force on Performance Measures (Task Force) distinguishes quality measures from performance measures. Quality measures are those metrics that *may* be useful for local quality improvement but are not yet appropriate for public reporting or pay for performance programs (uses of performance measures). New measures are initially evaluated for potential inclusion as performance measures. In some cases, a measure is insufficiently supported by the guidelines. In other instances, when the guidelines support a measure, the writing committee may feel it is necessary to have the measure tested to identify the consequences of measure implementation. Quality measures may then be promoted to the status of performance measures as supporting evidence becomes available.

P. Michael Ho, MD, PhD, FACC, FAHA Chair, ACC/AHA Task Force on Performance Measures

# 1. INTRODUCTION

In 2019, the Task Force convened the writing committee to begin the process of revising the existing performance measures set for heart failure that was released in 2011 (3). The writing committee also was charged with the task of developing new measures to evaluate the care of patients in accordance with the 2017 ACC/AHA/HFSA heart failure guideline update (4).

This updated performance measure set addresses in-hospital and continuing care in the outpatient setting. All Class 1 (strong) and 3 (no benefit or harmful, process to be avoided) guideline-recommended processes were considered for inclusion as performance measures. The current Class of Recommendation and Level of Evidence guideline classification scheme used by the ACC and AHA in their clinical guidelines is shown in Table 1. The value (benefit and cost) of a process of care was also considered. If high-quality, published,

cost-effectiveness studies indicate that a Class 1 guideline recommendation for a process of care is considered a poor value by ACC/AHA standards, then it was not included as a performance measure (5). There were no Class 1 recommended processes of care judged to be of poor value. All ACC/AHA clinical practice guideline recommendations (including Class 2) were considered as potential quality measures. Ultimately, we selected measures based on their importance for health, existing gaps in care, ease of implementation, potential duplication with other performance measure lists, and risk for unintended consequences.

The writing committee developed a comprehensive heart failure measure set that includes 18 measures: 13 performance measures, 4 quality measures, 1 structural measure, and 2 rehabilitation performance measures (from the 2018 ACC/AHA performance measures for cardiac rehabilitation (6)), as reflected in Table 2 and Appendix A. The performance measures for heart failure included in the measure set are summarized in Table 2, which provides information on the measure number, measure title, and care setting. The measure specifications (Appendix A) provide information included in Table 2 and more detailed information including, the measure description, numerator, denominator (i.e., denominator exclusions and exceptions), rationale for the measure, clinical practice guideline that supports the measure, measurement period, source of data, and attribution.

The writing committee recognized that the 2018 ACC/AHA performance measures for cardiac rehabilitation have been published that address heart failure (6). The cardiac rehabilitation measure set includes performance measures for exercise training referral for inpatients and outpatients with heart failure and reduced left ventricular ejection fraction (Table 2). These rehabilitation measures also should be considered heart failure—related ACC/AHA performance measures.

A comprehensive list of contraindications to care is not provided. Instead, it is expected that clinical judgment will be used to determine if a contraindication exists. For example, certain patients with heart failure and congenital heart disease would not qualify for certain treatment measures and should be excluded from the denominator if documented by the clinician.

Although the measures are published as a set, their implementation can be individualized. It is not expected that all measures will be adopted simultaneously. Although all the measures are considered valuable in improving care, we recognize that organizations may only be able to focus on a limited number of measures. When implementing any measure that involves patient input, it is important to consider the patient's health literacy and adapt data collection accordingly. Performance measures are a critical step in addressing disproportionately lower quality of care and potentially worse health status and outcomes among an underserved population.

# 1.1. Scope of the Problem

Heart failure is a major and growing public health problem in the United States with significant morbidity, mortality, and associated cost. A detailed discussion of the scope of the problem and opportunities to improve the quality of care that is provided to patients with

this condition is available in the ACCF/AHA 2013 heart failure clinical practice guideline (7) and 2017 ACC/AHA/HFSA heart failure guideline update (4).

# 1.2. Disclosure of Relationships With Industry and Other Entities

The Task Force makes every effort to avoid actual, potential, or perceived conflicts of interest that could arise as a result of relationships with industry or other entities (RWI). Information about the ACC/AHA policy on RWI can be found online. All members of the writing committee, as well as those selected to serve as peer reviewers of this document, were required to disclose all current relationships and those existing within the 12 months before the initiation of this writing effort. ACC/AHA policy also requires that the writing committee chair and at least 50% of the writing committee have no relevant RWI. Writing committee members are excluded from voting on sections to which their specific RWI may apply.

Any writing committee member who develops new RWI during his or her tenure on the writing committee is required to notify staff in writing. These statements are reviewed periodically by the Task Force and by members of the writing committee. Writing committee member and peer reviewer RWI, which are pertinent to the document, are included in the appendixes: Appendix B for relevant writing committee RWI and Appendix C for comprehensive peer reviewer RWI. Additionally, to ensure complete transparency, the writing committee members' comprehensive disclosure information, including RWI not relevant to the present document, is available online. Disclosure information for the Task Force is also available online.

The work of the writing committee was supported exclusively by the ACC and the AHA without commercial support. Members of the writing committee volunteered their time for this effort. Meetings of the writing committee were confidential and attended only by writing committee members and staff from the ACC, AHA, and the Heart Failure Society of America, which served as a collaborator on this project.

# 2. METHODOLOGY

# 2.1. Literature Review

In developing the updated heart failure measure set, the writing committee reviewed evidence-based guidelines and statements that would potentially impact the construct of the measures. The clinical practice guidelines and scientific statements that most directly contributed to the development of these measures are shown in Table 3.

#### 2.2. Definition and Selection of Measures

The writing committee considered a number of additional factors, which are listed in Table 4. The potential impact, appropriateness for public reporting and pay for performance, validity, reliability, and feasibility were considered. The writing committee examined available information on current gaps in care. The term "heart failure" refers to stage C or D heart failure unless otherwise stated (4).

# 3. ACC/AHA HEART FAILURE MEASURE SET

# 3.1. Discussion of Changes to 2011 Heart Failure Measure Set

After reviewing the existing clinical practice guidelines, and the 2011 ACCF/AHA/PCPI heart failure performance measurement set (3), the writing committee discussed which measures required revision to reflect updated science related to heart failure and identified which guideline recommendations could serve as the basis for new performance or quality measures. The writing committee also reviewed existing publicly available measure sets.

These subsections serve as a synopsis of the revisions that were made to previous measures and a description of why the new measures were created for both the inpatient and outpatient setting.

- **3.1.1. Retired Measures**—The writing committee decided to retire the left ventricular ejection fraction assessment measure used in the inpatient setting due to >97% of use (12) (Table 5). Left ventricular ejection fraction assessment in the outpatient setting was retained.
- **3.1.2. Revised Measures**—The writing committee reviewed and made changes to the patient self-care education, angiotensin-converting enzyme inhibitor or angiotensin receptor blocker therapy for left ventricular systolic dysfunction, and postdischarge appointment measures, as summarized in Table 6. Table 6 provides information on the updated measures including the care setting, title, and a brief rationale for revisions made to the measures.
- **3.1.3. New Measures**—The writing committee created 7 new performance measures (PM 6–11, 13), 2 quality measures (QM 2, 3), and 1 structural measure (SM-1) (Table 7). Six of the new performance measures were based on Class 1 guideline recommendations for therapies known to prolong survival. An additional performance measure (PM-10, measurement of potassium after a mineralocorticoid receptor antagonist prescription) is also guideline recommended and included as a safety measure to accompany prescription for mineralocorticoid receptor antagonist (PM-9). Two new measures based on dose were created (PM-7 and PM-8). These were chosen because of the gap between doses used in practice and those shown to provide survival benefit in clinical trials. They were designed to apply only to those patients without demonstrated intolerance at higher doses.

For more detailed information on each measure's construct, refer to the specifications in Appendix A.

# 4. AREAS FOR FURTHER RESEARCH

There are multiple ways that cardiac rehabilitation and exercise prescriptions can be implemented (13). Further studies are needed to determine if there are differences in the magnitude of outcome improvements by approach. Similarly, although patient-reported outcomes are considered an important metric, the best way to measure these needs additional research. Two surveys are well validated: The Kansas City Cardiomyopathy Questionnaire (14) and the Minnesota Living with Heart Failure Questionnaire (15). However, risk-adjustment is required to fairly compare groups for use as an outcome

measure. The collection of the measure (process of care) does not require risk-adjustment but will benefit from additional research to understand optimal timing of collection of patient-reported outcomes, including frequency and relation to the clinic visit. Finally, data supporting sodium-glucose cotransporter-2 inhibitors are emerging for heart failure treatment; however, with additional trials ongoing and having not been integrated into guideline recommendations at the time of generation of the measure set, the writing committee was unable to include them in the measure set.

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# APPENDIX A.: HEART FAILURE MEASURE SET

# **Performance Measures for Heart Failure**

SHORT TITLE: PM-1 Left Ventricular Ejection Fraction Assessment (Outpatient Setting)

PM-1: Left Ventricular Ejection Fraction Assessment (Outpatient Setting)

Measure Description: Percentage of patients age 18 y with a diagnosis of heart failure for whom the quantitative result of prior (any time in the past) LVEF assessment, using any imaging modality, is available in the medical record		
Numerator	Patients for whom the quantitative* results of prior (any time in the past) LVEF assessment, using any imaging modality, is available in the medical record (includes note documentation) *Single value or numerical range	
Denominator	All patients age 18 y with a diagnosis of heart failure	
<b>Denominator Exclusions</b>	Heart transplant LVAD	
Denominator Exceptions	Documentation of medical reason(s) for not evaluating LVEF (e.g., comfort care only) Documentation of patient reason(s) for not evaluating LVEF (e.g., patient refusal)	
Measurement Period	12 mo	
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims)	

	Rationale
Care Setting	Outpatient
Attribution	Individual practitioner Facility
	Administrative data/claims expanded (multiple sources) Paper medical record

Evaluation of LVEF in patients with heart failure provides important information that is required to appropriately direct treatment. Several pharmacological therapies have demonstrated efficacy in slowing disease progression and improving survival in patients with left ventricular systolic dysfunction (3).

Although most patients have an LVEF recorded, this remains a performance measure because knowledge of LVEF is required to determine eligibility for appropriate heart failure care.

Patients post-heart transplant or with an LVAD are excluded, because these patients were excluded from clinical treatment trials for low LVEF heart failure.

#### Clinical Recommendation(s)

#### 2013 ACCF/AHA heart failure clinical practice guideline (7)

- A 2-dimensional echocardiogram with Doppler should be performed during initial evaluation of patients presenting
  with HF to assess ventricular function, size, wall thickness, wall motion, and valve function. (Class 1, Level of
  Evidence: C)
- 2. Repeat measurement of EF and measurement of the severity of structural remodeling are useful to provide information in patients with HF who have had a significant change in clinical status; who have experienced or recovered from a clinical event; or who have received treatment, including GDMT, that might have had a significant effect on cardiac function; or who may be candidates for device therapy. (Class 1, Level of Evidence: C)
- 3. Radionuclide ventriculography or magnetic resonance imaging can be useful to assess LVEF and volume when echocardiography is inadequate. (Class 2a, Level of Evidence: C)

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; EF, ejection fraction; EHR, electronic health record; GDMT, guideline-directed medical therapy; HF, heart failure; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; and PM, performance measure.

SHORT TITLE: PM-2 Symptom and Activity Assessment (Outpatient Setting)

PM-2: Symptom and Activity Assessment (Outpatient Setting)

Measure Description: Percentage of patient visits for those patients age 18 y with a diagnosis of heart failure with quantitative results of an evaluation of both current level of activity and clinical symptoms documented

# Numerator

Patient visits with quantitative results of an evaluation of both current level of activity and clinical symptoms documented\*

- \*Evaluation and quantitative results documented can include:
  - Documentation of NYHA class or
  - Documentation of completion of a valid, reliable, diseasespecific instrument (e.g., KCCQ or MLHFQ)

#### **Numerator Definitions/Instructions:**

The NYHA functional classification reflects a subjective assessment by a healthcare provider of the severity of a patient's symptoms. Patients are assigned to one of the following classes:

- Class I: Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
- Class II: Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
- Class III: Patients with marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
- Class IV: Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort.
   Symptoms of heart failure or of the anginal syndrome may

be present even at rest. If any physical activity is undertaken, discomfort is increased.

Patient-reported health status as assessed by a structured survey/ questionnaire instrument offers another, more patient-centric approach to assessing and summarizing the patient's overall heart failure symptom burden. These instruments serve as important constructs for delivering and evaluating heart failure care. Denominator All patient visits for those patients age 18 y with a diagnosis of heart Denominator Exclusions Heart transplant LVAD **Denominator Exceptions** Documentation of medical reason(s) for not evaluating both current level of activity and clinical symptoms (e.g., severe cognitive or functional impairment) Documentation of patient reason(s) for not evaluating both current level of activity and clinical symptoms Measurement Period 12 mo EHR data Sources of Data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record Attribution Individual practitioner Facility Care Setting Outpatient

Initial and ongoing evaluations of patients with heart failure should include an assessment of symptoms and their functional consequences. These assessments serve as the basis for making treatment decisions, monitoring the effects of treatment, and modifying treatment as appropriate. Decreasing symptoms and improving function are 2 of the primary goals of heart failure treatment and represent important patient-centric outcomes for heart failure care. The ACC/AHA have not addressed PRO tool selection. However, the FDA has provided guidelines for an appropriate PRO tool (16) and, currently, 2 heart failure survey tools—the MLHFQ (15) and the KCCQ (14)—are considered qualified tools for FDA device use in heart failure (17).

Rationale

#### Clinical Recommendation(s)

### 2013 ACCF/AHA heart failure clinical practice guideline (7)

- 1. A thorough history and physical examination should be obtained/performed in patients presenting with HF to identify cardiac and noncardiac disorders or behaviors that might cause or accelerate the development or progression of HF. (Class 1, Level of Evidence: C)
- 2. The NYHA functional classification gauges the severity of symptoms in those with structural heart disease. Although reproducibility and validity may be problematic (18), the NYHA functional classification is an independent predictor of mortality (19). It is widely used in clinical practice and research and for determining the eligibility of patients for certain healthcare services (7). However, NYHA functional class assessment is not reported in a significant number of patients in contemporary HF practices in the United States (20).
- 3. Evaluate general health status (see Figure 2, 2013 ACCF/AHA guideline) (7).

Although no specific 2013 ACCF/AHA guideline recommendation is made regarding collection of NYHA or other quantitative result, knowledge of symptom status is needed to determine candidacy for appropriate HF treatments (7).

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; AHA, American Heart Association; EHR, electronic health record; FDA, U.S. Food and Drug Administration; HF, heart failure; KCCQ, Kansas City Cardiomyopathy Questionnaire; LVAD, left ventricular assist device; MLHFQ, Minnesota Living with Heart Failure Questionnaire; NYHA, New York Heart Association; PM, performance measure; and PRO, patient-reported outcome

SHORT TITLE: PM-3 Symptom Management (Outpatient Setting)

PM-3: Symptom Management (Outpatient Setting)

Measure Description: Percentage of patient visits for those patients age 18 y with a diagnosis of heart failure and with quantitative results of an evaluation of both level of activity and clinical symptoms documented in

# which patient symptoms have improved or remained consistent with treatment goals, or patient symptoms have worsened since last assessment and have a documented plan of care

#### Numerator

Patient visits in which patient symptoms have improved or remained consistent with treatment goals since last assessment,\* or patient symptoms have worsened since last assessment\* and have a documented plan of care† \*Examples of quantitative assessment:

- NYHA class or
- A valid, reliable, disease-specific instrument (e.g., KCCQ [clinically important deterioration can be classified as a 5point reduction in the overall summary score] or MLHFQ [clinically important deterioration can be classified as a 10point increase in the total score])
- 6-Minute Walk Test
- Peak oxygen consumption (VO<sub>2</sub>) or the slope of minute ventilation to carbon dioxide production (VE/VCO<sub>2</sub> slope)

†A documented plan of care may include 1 of the following: reevaluation of medical therapy including up-titration of medication doses, consideration of electrical device therapy, recommended lifestyle modifications (e.g., salt restriction, exercise training), initiation of palliative care, referral for more advanced therapies (e.g., cardiac transplant, ventricular assist device), or referral to disease management programs.

Denominator	All patient visits for those patients age 18 y with a diagnosis of heart failure and with quantitative results of an evaluation of both level of activity and clinical symptoms documented at the time of the encounter and at a prior time point 1 to 12 mo previously.
<b>Denominator Exclusions</b>	Heart transplant LVAD
<b>Denominator Exceptions</b>	None
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record
Attribution	Individual practitioner Facility
Care Setting	Outpatient

#### Rationale

Heart failure significantly decreases HRQOL, especially in the areas of physical functioning and vitality (21,22). Lack of improvement in HRQOL after discharge from the hospital is a powerful predictor of rehospitalization and mortality (23,24). Women with heart failure have consistently been found to have worse HRQOL than men (22,25). Ethnic differences also have been found, with Mexican Hispanics reporting better HRQOL than other ethnic groups in the United States (26). Other determinants of poor HRQOL include depression, younger age, higher BMI, greater symptom burden, lower systolic blood pressure, sleep apnea, low perceived control, and uncertainty about prognosis (25,27–31). Objective data on symptoms and functional status from at least 2 time points are needed to decide if patients are benefitting from therapy.

#### Clinical Recommendation(s)

# 2013 ACCF/AHA heart failure clinical practice guideline (7)

1. Goals of treatment in heart failure are to improve health-related quality of life and symptoms (see Figure 3, 2013 ACCF/AHA guideline) (7).

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; BMI, body mass index; EHR, electronic health record; ICC, intraclass correlation coefficient; HRQOL, health-related quality of life; KCCQ, Kansas City Cardiomyopathy Questionnaire; LVAD, left ventricular assist device; MLHFQ, Minnesota Living with Heart Failure Questionnaire; NYHA, New York Heart Association; PM, performance measure; PRO, patient-reported outcome; VE/VCO2, ventilation and carbon dioxide; and VO2, oxygen consumption.

SHORT TITLE: PM-4 Beta-Blocker Therapy for Heart Failure With Reduced Ejection Fraction (Outpatient and Inpatient Setting)

PM-4: Beta-Blocker Therapy for Heart Failure With Reduced Ejection Fraction (Outpatient and Inpatient Setting)

Measure Description: Percentage of patients age 18 y with a diagnosis of heart failure with a current or prior
LVEF 40% who were prescribed beta-blocker therapy either within a 12-mo period when seen in the outpatient
setting or at hospital discharge

Numerator	Patients who were prescribed* beta-blocker therapy† either within a 12-mo period when seen in the outpatient setting or at hospital discharge *Prescribed may include:		
	<ul> <li>Outpatient setting: Prescription for beta blocker given to the patient for beta-blocker therapy at 1 visits in the 12- mo measurement period or patient already taking beta- blocker therapy as documented in current medication list.</li> </ul>		
	<ul> <li>Inpatient setting: Prescription given to the patient for beta- blocker therapy at discharge or beta-blocker therapy to be continued after discharge as documented in the discharge medication list.</li> </ul>		
	†Beta-blocker therapy should include bisoprolol, carvedilol, or sustained-release metoprolol succinate (see technical specifications for additional information on medications).		
Denominator	All patients age 18 y with a diagnosis of heart failure with a current or prior LVEF 40%		
<b>Denominator Exclusions</b>	Heart transplant LVAD		
<b>Denominator Exceptions</b>	Documentation of medical reason(s) for not prescribing beta-blocker therapy (e.g., intolerance)  Documentation of patient reason(s) for not prescribing beta-blocker therapy (e.g., patient refusal)		
Measurement Period	12 mo		
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record		
Attribution	Individual practitioner Facility		
Care Setting	Outpatient Inpatient		

Beta blockers improve survival and reduce hospitalization for patients with stable heart failure and reduced LVEF (HFrEF) (7). Treatment should be initiated as soon as a patient is diagnosed with reduced LVEF and does not have prohibitively low systemic blood pressure, fluid overload, or recent treatment with an intravenous positive inotropic agent. Beta blockers have also been shown to lessen the symptoms of heart failure, improve the clinical status of patients, and reduce future clinical deterioration. Despite these benefits, use of beta blockers in eligible patients remains suboptimal (20).

### Clinical Recommendation(s)

# 2013 ACCF/AHA heart failure clinical practice guideline (7)

- 1. Use of 1 of the 3 beta blockers proven to reduce mortality (e.g., bisoprolol, carvedilol, and sustained-release metoprolol succinate) is recommended for all patients with current or prior symptoms of HFrEF, unless contraindicated, to reduce morbidity and mortality (32–37). (Class 1, Level of Evidence: A)
- 2. Initiation of beta-blocker therapy is recommended after optimization of volume status and successful discontinuation of intravenous diuretics, vasodilators, and inotropic agents. Beta-blocker therapy should be initiated at a low dose and only in stable patients. Caution should be used when initiating beta blockers in patients who have required inotropes during their hospital course (38–40). (Class 1, Level of Evidence: B)

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; EHR, electronic health record; HFrEF, heart failure reduced ejection fraction; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; and PM performance measure.

SHORT TITLE: PM-5 Angiotensin-Converting Enzyme Inhibitor or Angiotensin Receptor Blocker or Angiotensin Receptor-Neprilysin Inhibitor Therapy for Heart Failure With Reduced Ejection Fraction (Outpatient and Inpatient Setting)

PM-5: Angiotensin-Converting Enzyme Inhibitor or Angiotensin Receptor Blocker or Angiotensin Receptor-Neprilysin Inhibitor Therapy for Heart Failure With Reduced Ejection Fraction (Outpatient and Inpatient Setting)

Measure Description: Percentage of patients age	18 y with a diagnosis of heart failure with a current or prior
LVEF 40% who were prescribed ACE inhibitor,	ARB, or ARNI either within a 12-mo period when seen in the
outpatient setting or at hospital discharge	

Numerator	Patients who were prescribed* ACE inhibitor, ARB, or ARNI either within a 12-mo period when seen in the outpatient setting or at hospital discharge *Prescribed may include:		
	<ul> <li>Outpatient setting: Prescription given to the patient for ACE inhibitor, ARB, or ARNI at 1 visits in the 12-mo measurement period or patient already taking ACE inhibitor, ARB, or ARNI as documented in current medication list.</li> </ul>		
	<ul> <li>Inpatient setting: Prescription given to the patient for ACE inhibitor, ARB, or ARNI at discharge or ACE inhibitor, ARB, or ARNI to be continued after discharge as documented in the discharge medication list.</li> </ul>		
Denominator	All patients age $$ 18 y with a diagnosis of heart failure with a current or prior LVEF $$ 40%		
<b>Denominator Exclusions</b>	Heart transplant LVAD		
<b>Denominator Exceptions</b>	Documentation of medical reason(s) for not prescribing ACE inhibitor, ARB, or ARNI (e.g., intolerance) Documentation of patient reason(s) for not prescribing ACE inhibitor, ARB, or ARNI (e.g., patient refusal)		
Measurement Period	ACE inhibitor, ARB, or ARNI therapy initiated within a 12-mo period of being seen in the outpatient setting or from hospital discharge		
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record		
Attribution	Individual practitioner Facility		
Care Setting	Outpatient Inpatient		

#### Rationale

Use of ACE inhibitor, ARB, or ARNI therapy has been associated with improved outcomes in patients with reduced LVEF (7).

Long-term therapy with ARBs has also been shown to reduce morbidity and mortality, especially in ACE inhibitor-intolerant patients (41–44). More recently, ARNI therapy has also been shown to more significantly improve outcomes (45), such that the newest guidelines recommend replacement of ACE inhibitors or ARBs with ARNI therapy in eligible patients (4). However, despite the benefits of these drugs, use of ACE inhibitor, ARB, or ARNI remains suboptimal (20)

# $Clinical\ Recommendation (s)$

# 2017 ACC/AHA/HFSA heart failure guideline update (4)

1. The clinical strategy of inhibition of the renin-angiotensin system with ACE inhibitors (Class 1, Level of Evidence: A) (46–51), OR ARBs (Class 1, Level of Evidence: A) (41–44), OR ARNI (Class 1, Level of Evidence: B-R) (45) in conjunction with evidence-based beta blockers (7,33,52), and aldosterone antagonists in selected patients (53,54), is recommended for patients with chronic HFrEF to reduce morbidity and mortality.

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; ACE, angiotensin-converting enzyme; AHA, American Heart Association; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor—

> neprilysin inhibitor; EHR, electronic health record; HFrEF, heart failure reduced ejection fraction; HFSA, Heart Failure Society of America; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; and PM, performance

SHORT TITLE: PM-6 Angiotensin Receptor-Neprilysin Inhibitor Therapy for Heart Failure With Reduced Ejection Fraction (Outpatient and Inpatient Setting)

PM-6: Angiotensin Receptor-Neprilysin Inhibitor Therapy for Heart Failure With Reduced Ejection Fraction (Outpatient and Inpatient Setting)

Measure Description: Percentage of patients age 18 y with a diagnosis of heart failure with a current or prior LVEF 40% who remained symptomatic at NYHA functional class II or class III despite ACE inhibitor or ARB

Numerator	Patients who were prescribed* ARNI therapy either within a 12-mo period when seen in the outpatient setting or at hospital discharge *Prescribed may include:	
	<ul> <li>Outpatient setting: Prescription given to the patient for ARNI therapy at 1 visits in the measurement period or patient already taking ARNI therapy as documented in current medication list.</li> </ul>	
	<ul> <li>Inpatient setting: Prescription given to the patient for ARNI at discharge or ARNI therapy to be continued after discharge as documented in the discharge medication list.</li> </ul>	
Denominator	All patients age 18 y with a diagnosis of heart failure with a current or prior LVEF 40% after 3 mo of ACE inhibitor or ARB therapy	
<b>Denominator Exclusions</b>	Heart transplant LVAD NYHA class I and class IV	
<b>Denominator Exceptions</b>	Documentation of medical reason(s) for not prescribing ARNI therapy (e.g., intolerant) Documentation of patient reason(s) for not prescribing ARNI therapy (e.g., patient refusal, cost) Documentation of system reason(s) for not prescribing ARNI therapy	
Measurement Period	ARNI therapy initiated within a 12-mo period of being seen in the outpatient setting or from hospital discharge	
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record	
Attribution	Individual practitioner Facility	
Care Setting	Outpatient Inpatient	

In a large randomized clinical trial, an ARNI (valsartan/sacubitril) was compared with an ACE inhibitor (enalapril) in symptomatic patients with HFrEF. The ARNI reduced the composite endpoint of cardiovascular death or heart failure hospitalization significantly, by 20% (45). The benefit was seen to a similar extent for both death and heart failure hospitalization and was consistent across subgroups. Since the initial large randomized clinical trial with ARNI, there has been additional clinical trial evidence (55,56), meta-analyses (57), and observational clinical effectiveness studies (58), which further support the use of valsartan/sacubitril in replacement of ACE inhibitor or ARB therapy to reduce mortality and morbidity.

# Clinical Recommendation(s)

# 2017 ACC/AHA/HFSA heart failure guideline update (4)

1. 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 (45). (Class 1, Level of Evidence: ARNI: B-R)

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; ACE, angiotensin-converting enzyme; AHA, American Heart Association; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor-neprilysin inhibitor; EHR, electronic health record; HFrEF, heart failure reduced ejection fraction; HFSA, Heart Failure Society of America; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; and PM, performance measure.

SHORT TITLE: PM-7 Dose of Beta-Blocker Therapy for Heart Failure With Reduced Ejection Fraction (Outpatient Setting)

PM-7: Dose of Beta-Blocker Therapy for Heart Failure With Reduced Ejection Fraction (Outpatient Setting)

Measure Description: Percentage of patients age 18 y with a diagnosis of heart failure with a current or prior LVEF 40% who were prescribed a guideline-recommended beta blocker (e.g., bisoprolol, carvedilol, or sustained-release metoprolol succinate) at a dose that is at least 50% of the target dose (see Table A for target doses)

doses)		
Numerator	Patients who were prescribed a guideline-recommended beta blocker at a dose that is at least 50% of the target dose (see Table A for target doses)	
Denominator	All patients age 18 y with a diagnosis of heart failure with a current or prior LVEF 40% who were prescribed a recommended beta blocker	
<b>Denominator Exclusions</b>	Heart transplant LVAD	
Denominator Exceptions	Documentation of intolerance of higher dose or medical reason(s) for not prescribing higher dose of beta blocker Documentation of patient reason(s) for not prescribing higher dose of beta blocker Documentation of system reason(s) for not prescribing higher dose of beta blocker	
Measurement Period	Annually	
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record	
Attribution	Individual practitioner Facility	
Care Setting	Outpatient	
	Rationale	

Use of guideline-recommended beta blockers has been proven to reduce morbidity and mortality in patients with HFrEF, and studies have supported a dose-response relationship of beta blockers with improved outcomes (59–64). These findings suggest that, among HFrEF patients in whom target doses might be well tolerated, treating at less than the target dose may result in worse clinical outcomes. Despite guideline recommendations for clinicians to achieve target doses of beta blockers shown to be effective in major clinical trials, the percentage of patients achieving these doses is low and remains low over time (20.65.66).

Treatment with a beta blocker should be initiated at very low doses, followed by gradual incremental increases in dose if lower doses have been well tolerated. Clinicians should make every effort to achieve the target doses of the beta blockers shown to be effective in major clinical trials (7).

#### Clinical Recommendation(s)

## 2013 ACCF/AHA heart failure clinical practice guideline (7)

1. Use of 1 of the 3 beta blockers proven to reduce mortality (e.g., bisoprolol, carvedilol, and sustained-release metoprolol succinate) is recommended for all patients with current or prior symptoms of HFrEF, unless contraindicated, to reduce morbidity and mortality (32–37). (Class 1, Level of Evidence: A)

# $\textbf{2017 ACC expert consensus decision pathway for optimization of heart failure treatment} \ (10)$

- 1. After a diagnosis of heart failure is made, GDMT should be initiated and therapies should be adjusted no more frequently than every 2 weeks to target doses (or maximally tolerated doses).
- 2. To achieve the maximal benefits of GDMT in patients with chronic HFrEF, therapies must be initiated and titrated to maximally tolerated doses (33,45,60,67).

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; AHA, American Heart Association; EHR, electronic health record; GDMT, guideline-directed medical therapy; HFrEF, heart failure reduced ejection fraction; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; and PM, performance measure.

**TABLE A**Target Doses of Guideline-Directed Medical Therapies

ACE Inhibitors	Target Dose	<b>Total Daily Target Dose</b>	50% of Total Daily Target Dose
Captopril	50 mg, three times daily	150 mg	75 mg
Enalapril	10 mg, twice daily	20 mg	10 mg
Lisinopril	20 mg, once daily	20 mg	10 mg
Ramipril	10 mg, once daily	10 mg	5 mg
Perindopril	8 mg, once daily	8 mg	4 mg
Trandolapril	4 mg, once daily	4 mg	2 mg
Benazepril	40 mg, once daily	40 mg	20 mg
Fosinopril	40 mg, once daily	40 mg	20 mg
Quinapril	20 mg, twice daily	40 mg	20 mg
ARB			
Candesartan	32 mg, once daily	32 mg	16 mg
Losartan	100 mg, once daily *	100 mg	50 mg
Valsartan	160 mg, twice daily	320 mg	160 mg
Irbesartan	300 mg, once daily	300 mg	150 mg
Telmisartan	80 mg, once daily	80 mg	40 mg
Olmesartan	40 mg, once daily	40 mg	20 mg
Azilsartan	80 mg, once daily	80 mg	40 mg
ARNI	,		
Sacubitril/valsartan	97/103 mg, twice daily	194/206 mg	98/102 mg <sup>†</sup>
Evidence-Based Beta-Blockers			
Bisoprolol	10 mg, once daily	10 mg	5 mg
Carvedilol	25 mg, twice daily	50 mg	25 mg
Carvedilol extended release	80 mg, once daily	80 mg	40 mg
Metoprolol succinate sustained release	200 mg, once daily	200 mg	100 mg

Sources for target doses include: 2013 ACCF/AHA heart failure clinical practice guideline (7), 2017 ACC/AHA/HFSA heart failure guideline update (4), 2017 ACC expert consensus decision pathway for optimization of heart failure treatment (10), and FDA-approved labels (68).

ACE indicates angiotensin-converting enzyme; ARB, angiotensin II receptor blocker; and ARNI, angiotensin receptor-neprilysin inhibitor.

SHORT TITLE: PM-8 Dose of Angiotensin-Converting Enzyme Inhibitor, Angiotensin Receptor Blocker, or Angiotensin Receptor-Neprilysin Inhibitor Therapy for Heart Failure With Reduced Ejection Fraction (Outpatient Setting)

<sup>\*</sup>ACC/AHA Guidelines recommend losartan 150 mg as target dose. However, because current FDA-approved labeling has 100 mg as the maximal dose, the 100-mg dose is used in the performance measure.

 $<sup>^{7}</sup>$ The sacubitril 98 mg and valsartan 102 mg total daily dosing (49/51 mg twice daily) is considered fulfilling the 50% of target dosing criteria.

PM-8: Dose of Angiotensin-Converting Enzyme Inhibitor, Angiotensin Receptor Blocker, or Angiotensin Receptor-Neprilysin Inhibitor Therapy for Heart Failure With Reduced Ejection Fraction (Outpatient Setting)

Measure Description: Percentage of patients age 18 y with a diagnosis of heart failure with a current or prior LVEF 40% who were prescribed an ACE inhibitor, ARB, or ARNI at a dose that is at least 50% of the target dose (see Table A for target doses)	
Numerator	Patients who were prescribed an ACE inhibitor, ARB, or ARNI at a dose that is at least 50% of the target dose (see Table A for target doses)
Denominator	All patients age 18 y with a diagnosis of heart failure with a current or prior LVEF 40% who were prescribed an ACE inhibitor, ARB, or ARNI
<b>Denominator Exclusions</b>	Heart transplant LVAD
<b>Denominator Exceptions</b>	Documentation of intolerance of higher dose or medical reason(s) for not prescribing higher dose of ACE inhibitor, ARB or ARNI  Documentation of patient reason(s) for not prescribing higher dose of ACE inhibitor, ARB, or ARNI  Documentation of system reason(s) for not prescribing higher dose of ACE inhibitor, ARB, or ARNI
Measurement Period	Annually
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record
Attribution	Individual practitioner Facility
Care Setting	Outpatient
	Rationale

Inhibition of the renin-angiotensin system with ACE inhibitor, ARB, or ARNI therapy has been proven to reduce morbidity and mortality in patients with HFrEF, and studies have supported a dose-response relationship of these therapies with improved outcomes (42,50,69,70). These findings suggest that, among HFrEF patients in whom target doses might be well tolerated, treating at less than the target dose may result in worse clinical outcomes. Despite guideline recommendations for clinicians to achieve target doses of ACE inhibitors, ARBs, or ARNIs, the number of patients achieving these doses is low and remains low over time (20,65,66).

#### Clinical Recommendation(s)

#### 2017 ACC/AHA/HFSA heart failure guideline update (4)

- 1. The clinical strategy of inhibition of the renin-angiotensin system with ACE inhibitors (Class 1, Level of Evidence: A) (46–51), OR ARBs (Class 1, Level of Evidence: A) (41–44), OR ARNI (Class 1, Level of Evidence: B-R) (45) in conjunction with evidence-based beta blockers (7,33,52), and aldosterone antagonists in selected patients (53,54), is recommended for patients with chronic HFrEF to reduce morbidity and mortality.
- ACE inhibitors should be started at low doses and titrated upward to doses shown to reduce the risk of cardiovascular events in clinical trials.
- ARBs should be started at low doses and titrated upward, with an attempt to use doses shown to reduce the risk of cardiovascular events in clinical trials.

# $\textbf{2017 ACC expert consensus decision pathway for optimization of heart failure treatment} \ (10)$

- 1. After a diagnosis of heart failure is made, GDMT should be initiated and therapies should be adjusted no more frequently than every 2 weeks to target doses (or maximally tolerated doses).
- 2. To achieve the maximal benefits of GDMT in patients with chronic HFrEF, therapies must be initiated and titrated to maximally tolerated doses (33,45,60,67).

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; ACE, angiotensin-converting enzyme; AHA, American Heart Association; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor-neprilysin inhibitor; EHR, electronic health record; GDMT, guideline-directed medical therapy; HFrEF, heart failure reduced ejection fraction; HFSA, Heart Failure Society of America; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; and PM, performance measure.

SHORT TITLE: PM-9 Mineralocorticoid Receptor Antagonist Therapy for Heart Failure With Reduced Ejection Fraction (Outpatient and Inpatient Setting)

PM-9: Mineralocorticoid Receptor Antagonist Therapy for Heart Failure With Reduced Ejection Fraction (Outpatient and Inpatient Setting)

Measure Description: Percentage of patients age 18 y with a diagnosis of heart failure with a current or prior LVEF 35% who are NYHA class II through class IV despite attempts at treatment with beta blockers and ACE inhibitors, ARB, or ARNI		
Numerator	Patients who were prescribed* MRA either within a 12-mo period when seen in the outpatient setting or at hospital discharge *Prescribed may include:	
	<ul> <li>Outpatient setting: Prescription given to the patient for MRA therapy at 1 visits in the measurement period or patient already taking MRA therapy as documented in current medication list.</li> </ul>	
	Inpatient setting: Prescription given to the patient for MRA therapy at discharge or MRA therapy to be continued after discharge as documented in the discharge medication list.	
Denominator	All patients age 18 y with a diagnosis of heart failure with a current or prior LVEF 35% who are NYHA class II-IV despite attempts at treatment with beta blockers and ACE inhibitors, ARB, or ARNI, and have Cr 2.5 mg/dL for men and 2.0 mg/dL for women (or estimated glomerular filtration rate >30 mL/min/1.73 m²) and K <5.0 mEq/L	
<b>Denominator Exclusions</b>	Heart transplant LVAD	
<b>Denominator Exceptions</b>	Documentation of medical reason(s) for not prescribing MRA therapy Documentation of patient reason(s) for not prescribing MRA therapy	
Measurement Period	12 mo	
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record	
Attribution	Individual practitioner Facility	
Care Setting	Outpatient Inpatient	
Rationale		

MRA therapy improves outcome in patients with heart failure and reduced LVEF (7). Use of MRA therapy in those without contraindications was 33% among 150 primary care and cardiology practices in the CHAMP-HF registry demonstrating a moderate to large treatment gap (20).

# $Clinical\ Recommendation (s)$

# 2013 ACCF/AHA heart failure clinical practice guideline (7)

1. Aldosterone receptor antagonists (or mineralocorticoid receptor antagonists) are recommended in patients with NYHA class II-IV HF and who have LVEF of 35% or less, unless contraindicated, to reduce morbidity and mortality. Patients with NYHA class II HF should have a history of prior cardiovascular hospitalization or elevated plasma natriuretic peptide levels to be considered for aldosterone receptor antagonists. Creatinine should be 2.5 mg/dL or less in men or 2.0 mg/dL or less in women (or estimated glomerular filtration rate >30 mL/min/1.73 m²), and potassium should be less than 5.0 mEq/L. Careful monitoring of potassium, renal function, and diuretic dosing should be performed at initiation and closely followed thereafter to minimize risk of hyperkalemia and renal insufficiency (54,71,72). (Class 1, Level of Evidence: A)

2. Aldosterone receptor antagonists are recommended to reduce morbidity and mortality following an acute MI in patients who have LVEF of 40% or less who develop symptoms of HF or who have a history of diabetes mellitus, unless contraindicated (73). (Class 1, Level of Evidence: B)

ACCF indicates American College of Cardiology Foundation; ACE, angiotensin-converting enzyme; AHA, American Heart Association; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor-neprilysin inhibitor; CHAMP-HF, CHAnge the Management of Patients with Heart Failure; Cr, creatinine; EHR, electronic health record; HF, heart failure;

LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; MI, myocardial infarction; MRA, mineralocorticoid receptor antagonist; NYHA, New York Heart Association; and PM, performance measure.

SHORT TITLE: PM-10 Laboratory Monitoring in New Mineralocorticoid Receptor Antagonist Therapy (Outpatient and Inpatient Setting)

PM-10: Laboratory Monitoring in New Mineralocorticoid Receptor Antagonist Therapy (Outpatient and Inpatient Setting)

Measure Description: Percentage of patients age 18 y with a diagnosis of heart failure who were started on MRA therapy and had potassium and renal function checked within 1 wk of the patient initiation of the MRA prescription	
Numerator	Patients who had potassium and renal function checked within 1 wk of the patient initiation of the MRA prescription
Denominator	All patients age 18 y with a diagnosis of heart failure who filled a new prescription for MRA therapy
<b>Denominator Exclusions</b>	Heart transplant LVAD
<b>Denominator Exceptions</b>	None
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record
Attribution	Individual practitioner Facility
Care Setting	Outpatient Inpatient

The major risk associated with use of aldosterone receptor antagonists is hyperkalemia attributable to inhibition of potassium excretion, ranging from 2% to 5% in trials (54,72,73) to 24% to 36% in population-based registries (74,75). The development of potassium levels >5.5 mEq/L (approximately 12% in EMPHASIS-HF (72)) should trigger discontinuation or dose reduction of the aldosterone receptor antagonist unless other causes are identified. The development of worsening renal function should lead to careful evaluation of the entire medical regimen and consideration for stopping the aldosterone receptor antagonist (7). Close monitoring of serum potassium is required; potassium levels and renal function are most typically checked in 3 d and at 1 wk after initiating therapy and at least monthly for the first 3 mo (Table 17, 2013 ACCF/AHA guideline (7)).

Rationale

Despite the known risk of hyperkalemia with MRA initiation, the rate of measurement of potassium levels within 2 wk of initiation is low (76).

Although the clinical guideline suggests checking in 3 d, this is not a formal recommendation. Thus, the writing committee chose a more conservative 7-d time period to allow patient and provider flexibility and acknowledge challenges with weekend and holiday laboratory assessments.

#### Clinical Recommendation(s)

# 2013 ACCF/AHA heart failure clinical practice guideline (7)

1. Aldosterone receptor antagonists (or mineralocorticoid receptor antagonists) are recommended in patients with NYHA class II-IV HF and who have LVEF of 35% or less, unless contraindicated, to reduce morbidity and mortality. Patients with NYHA class II HF should have a history of prior cardiovascular hospitalization or elevated plasma natriuretic peptide levels to be considered for aldosterone receptor antagonists. Creatinine should be 2.5 mg/dL or less in men or 2.0 mg/dL or less in women (or estimated glomerular filtration rate >30 mL/min/1.73 m²), and potassium should be less than 5.0 mEq/L. Careful monitoring of potassium, renal function, and diuretic dosing should be performed at initiation and closely followed thereafter to minimize risk of hyperkalemia and renal insufficiency (54,71,72). (Class 1, Level of Evidence: A)

2. Inappropriate use of aldosterone receptor antagonists is potentially harmful because of life-threatening hyperkalemia or renal insufficiency when serum creatinine is greater than 2.5 mg/dL in men or greater than 2.0 mg/dL in women (or estimated glomerular filtration rate <30 mL/min/1.73 m²), and/or potassium greater than 5.0 mEq/L (74,75). (Class 3, Harm, Level of Evidence: B)

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; EHR, electronic health record; EMPHASIS-HF, Eplerenone in Mild Patients Hospitalization And SurvIval Study in Heart Failure; HF, heart

failure; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; MRA, mineralocorticoid receptor antagonist; NYHA, New York Heart Association; and PM, performance measure.

SHORT TITLE: PM-11 Hydralazine/Isosorbide Dinitrate Therapy for Heart Failure With Reduced Ejection Fraction in Those Self-Identified as Black or African American (Outpatient and Inpatient Setting)

PM-11: Hydralazine/Isosorbide Dinitrate Therapy for Heart Failure With Reduced Ejection Fraction in Those Self-Identified as Black or African American (Outpatient and Inpatient Setting)

Numerator	Patients who were prescribed* hydralazine and isosorbide dinitrate or fixed dose combination of hydralazine/isosorbide dinitrate within a 12-mo period when seen in the outpatient setting or at hospital discharge *Prescribed may include:	
	<ul> <li>Outpatient setting: Prescription given to the patient for hydralazine/isosorbide dinitrate therapy at 1 visits in the measurement period or patient already taking hydralazine/ isosorbide dinitrate therapy as documented in current medication list.</li> </ul>	
	<ul> <li>Inpatient setting: Prescription given to the patient for hydralazine/isosorbide dinitrate therapy at discharge or hydralazine/isosorbide dinitrate therapy to be continued after discharge as documented in the discharge medication list.</li> </ul>	
	Use of formulations of nitrates other than isosorbide dinitrate do not meet the numerator requirements.	
Denominator	All patients age 18 y with a diagnosis of heart failure (NYHA class III or class IV) with a current or prior LVEF 40% who are self-identified as Black or African American and receiving ACEI, ARB, or ARNI, and beta-blocker therapy	
<b>Denominator Exclusions</b>	Heart transplant LVAD	
Denominator Exceptions	Documentation of medical reason(s) for not prescribing hydralazine/isosorbide dinitrate therapy  Documentation of patient reason(s) for not prescribing hydralazine/isosorbide dinitrate therapy	
Measurement Period	Hydralazine/isosorbide dinitrate therapy initiated within a 12-mo period of being seen in the outpatient setting or from hospital discharge	
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record	
Attribution	Individual practitioner Facility	
Care Setting	Outpatient Inpatient	

The combination of hydralazine and isosorbide dinitrate is recommended to improve outcomes for patients self-identified as African American or Black, who have moderate-to-severe symptoms on optimal medical therapy (7). Use of hydralazine and isosorbide dinitrate in self-identified African American or Black candidates for therapy has been suboptimal (77).

# ${\bf Clinical\ Recommendation}(s)$

#### 2013 ACCF/AHA heart failure clinical practice guideline (7)

**Denominator Exclusions** 

Care Setting

1. The combination of hydralazine and isosorbide dinitrate is recommended to reduce morbidity and mortality for patients self-described as African Americans with NYHA class III-IV HFrEF receiving optimal therapy with ACE inhibitors and beta blockers, unless contraindicated (78,79). (Class 1, Level of Evidence: A)

ACCF indicates American College of Cardiology Foundation; ACE, angiotensin–converting enzyme; AHA, American Heart Association; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor–neprilysin inhibitor; EHR, electronic health record; HFrEF, heart failure reduced ejection fraction; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; and PM, performance measure.

SHORT TITLE: PM-12 Counseling Regarding Implantable Cardioverter-Defibrillator Implantation for Patients With Heart Failure With Reduced Ejection Fraction on Guideline-Directed Medical Therapy (Outpatient Setting)

PM-12: Counseling Regarding Implantable Cardioverter-Defibrillator Implantation for Patients With Heart Failure With Reduced Ejection Fraction on Guideline-Directed Medical Therapy (Outpatient Setting)

Measure Description: Percentage of patients age 18 y with a diagnosis of heart failure with current LVEF 35% despite ACE inhibitor, ARB, or ARNI and beta-blocker therapy for at least 3 mo who were counseled regarding ICD implantation as a treatment option for the prophylaxis of sudden death		
Numerator	Patients who were counseled* regarding ICD implantation as a treatment option for the prophylaxis of sudden death *Counseling should be specific to each individual patient and include documentation of a discussion regarding the risk of sudden and non-sudden death and the efficacy, safety, and risks of an ICD.	

ICD implantation and better able to make decisions based on the valuation of sudden cardiac death versus other risks.

Denominator

All patients age 18 y with a diagnosis of heart failure with current LVEF 35% despite ACE inhibitor, ARB, or ARNI and betablocker therapy for at least 3 mo

Functional ICD in situ Heart transplant

This will allow patients to be informed of the risks and benefits of

Denominator Exceptions

Documentation of medical reason(s) for not providing counseling regarding ICD implantation as a treatment option for the prophylaxis of sudden death (e.g., significant comorbidities, limited life expectancy, up titration of medical therapy is ongoing with anticipated LVEF improvement)

Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record
Attribution	Individual practitioner Facility

# Outpatient Rationale

ICDs prevent sudden death due to ventricular tachyarrhythmias in select patients with HFrEF (7). However, frequent or inappropriate shocks from an ICD can lead to reduced quality of life. Patients may differ in the willingness to have an ICD implanted based on their preferences for quality and length of life. Given the significant risks and benefits of ICD implantation, eligible patients should be fully informed of this treatment option (7).

Among 21,059 patients from 236 sites in the GWTG Registry, 23% received predischarge ICD counseling. Women were counseled less frequently than men, and racial and ethnic minorities were less likely to receive counseling than White patients (80).

#### Clinical Recommendation(s)

#### 2013 ACCF/AHA heart failure clinical practice guideline (7)

1. ICD therapy is recommended for primary prevention of SCD to reduce total mortality in selected patients with nonischemic DCM or ischemic heart disease at least 40 days post-MI with LVEF of 35% or less and NYHA class II or III symptoms on chronic GDMT, who have reasonable expectation of meaningful survival for more than 1 year (81,82).† (Class 1, Level of Evidence: A)

†Counseling should be specific to each individual patient and should include documentation of a discussion about the potential for sudden death and non-sudden death from HF or noncardiac conditions. Information should be provided about the efficacy, safety, and potential complications of an ICD and the potential for defibrillation to be inactivated if desired in the future, notably when a patient is approaching end of life. This will facilitate shared decision-making among patients, families, and the medical care team about ICDs (83).

2017 AHA/ACC/HRS ventricular arrhythmias and prevention of sudden cardiac death guideline (9)

1. Patients considering implantation of a new ICD or replacement of an existing ICD for a low battery should be informed of their individual risk of SCD and non-sudden death from HF or noncardiac conditions and the effectiveness, safety, and potential complications of the ICD in light of their health goals, preferences, and values (84–88). (Class 1, Level of Evidence: B-NR)

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; ACE, angiotensin-converting enzyme; AHA, American Heart Association; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor-neprilysin inhibitor; DCM, dilated cardiomyopathy; EHR, electronic health record; GWTG, Get With The Guidelines; GDMT, guideline-directed medical therapy; HF, heart failure; HFrEF, heart failure reduced ejection fraction; HRS, Heart Rhythm Society; ICD, implantable cardioverter-defibrillator; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; PM, performance measure; and SCD, sudden cardiac death.

SHORT TITLE: PM-13 Cardiac Resynchronization Therapy Implantation for Patients With Heart Failure With Reduced Ejection Fraction on Guideline-Directed Medical Therapy (Outpatient Setting)

PM-13: Cardiac Resynchronization Therapy Implantation for Patients With Heart Failure With Reduced Ejection Fraction on Guideline-Directed Medical Therapy (Outpatient Setting)

Measure Description: Percentage of patients age 18 y with a diagnosis of heart failure with current LVEF 35%, LBBB, QRS duration 150 ms, NYHA class II,III, and IV, despite ACE inhibitor, ARB, or ARNI and beta-blocker therapy for at least 3 mo who have undergone CRT implantation		
Numerator	Patients (meeting denominator criteria) who have undergone CRT implantation	
Denominator	All patients age 18 y with a diagnosis of heart failure with current LVEF 35%, LBBB, QRS duration 150 ms, NYHA class II, III, and IV, despite ACE inhibitor, ARB, or ARNI and beta-blocker therapy for at least 3 mo	
<b>Denominator Exclusions</b>	Heart transplant LVAD	
<b>Denominator Exceptions</b>	Documentation of medical reason(s) for not undergoing CRT implantation (e.g., multiple or significant comorbidities, limited life expectancy)  Documentation of patient reason(s) for not undergoing CRT implantation (e.g., refusal)	
Measurement Period	12 mo	
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record	
Attribution	Individual practitioner Facility	
Care Setting	Outpatient	

#### Rationale

CRT has been shown to improve survival and symptoms among symptomatic patients with heart failure and LVEF 35%, LBBB, and QRS duration 150 ms (7). CRT implantation (not just counseling) is recommended as CRT improves both quantity and quality of life, unlike ICDs, where there is no symptomatic benefit. In the GWTG database from 2014, 26% of eligible patients had CRT in place, implanted, or prescribed (89). Women were less likely to receive CRT, and this disparity increased over time. Black patients were less likely than White patients to have CRT.

#### Clinical Recommendation(s)

#### 2013 ACCF/AHA heart failure clinical practice guideline (7)

1. CRT is indicated for patients who have LVEF of 35% or less, sinus rhythm, LBBB with a QRS duration of 150 ms or greater, and NYHA class II, III, or ambulatory IV symptoms on GDMT. (Class 1, Level of Evidence: A for NYHA class III/IV (90–93); Level of Evidence: B for NYHA class II (94,95))

ACCF indicates American College of Cardiology Foundation; ACE, angiotensin-converting enzyme; AHA, American Heart Association; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor-neprilysin inhibitor; CRT, cardiac resynchronization therapy; EHR, electronic health record; GWTG, Get With The Guidelines; GDMT, guideline-directed medical therapy; ICD, implantable cardioverter-defibrillator; LBBB, left bundle branch block; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; and PM, performance measure.

# **Quality Measures for Heart Failure**

SHORT TITLE: QM-1 Patient Self-Care Education (Outpatient Setting)

QM-1: Patient Self-Care Education (Outpatient Setting)

Measure Description: Percentage of patients age 18 y with a diagnosis of heart failure who were provided with self-care education during 1 visits within a 12-mo period	
Numerator	Patients who were provided with self-care education* during \$1 visits within a 12-mo period *Self-care education may include the following: Definition of heart failure (linking disease, symptoms, and treatment) and cause of patient's heart failure; recognition of escalating symptoms and concrete plan for response to particular symptoms; indications and use of each medication; recommendations for modification of risks for heart failure progression; specific diet recommendations; individualized low-sodium diet; recommendation for alcohol intake; specific activity/exercise recommendations; importance of treatment adherence and behavioral strategies to promote treatment adherence; importance of monitoring weight daily at home.
Denominator	All patients age 18 y with a diagnosis of heart failure who were seen at least once for any visit within a 12-mo period
<b>Denominator Exclusions</b>	Heart transplant LVAD
Denominator Exceptions	Documentation of medical reason(s) for not providing self-care education (e.g., comfort care only, dementia, or cognitive impairment) Documentation of patient reason(s) for not providing self-care education (e.g., patient refusal)
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record
Attribution	Individual practitioner Facility
Care Setting	Outpatient

#### Rationale

Patient self-care education is a useful nonpharmacological component to heart failure care. It may reduce the likelihood of nonadherence with recommended therapeutic strategies and lead to early identification of worsening clinical status and subsequent treatment. Heart failure disease management programs, in which patient education is an integral component, have been shown to be effective in improving self-care and reducing readmissions (96). This measure is intended to highlight the importance of providing appropriate self-care education to patients with heart failure. The form and manner of education (e.g., counseling, information in the form of pamphlets or booklets) is at the discretion of the individual clinician and should be specific to the needs of the patient.

Data from the IMPROVE-HF registry indicate that only 61% of outpatients with heart failure were provided with education (including discussion of salt-restricted diet, monitoring of daily weight, warning signs of worsened heart failure, and activity recommendations), with rates of adherence ranging from 0% to 100% among practices (97). A number of consensus groups/patient advocacy organizations have developed educational materials that are recommended to aid implementation of the measure. These materials/tools include, but are not limited to:

- AHA's Health Topics on Heart Failure. Available at: https://www.heart.org/en/health-topics/heart-failure (98)
- ACC's CardioSmart. Available at: https://www.cardiosmart.org/Heart-Conditions/Heart-Failure (99)
- HFSA Education Modules on Heart Failure. Available at: https://learningcenter.hfsa.org/Public/Catalog/ Home.aspx?Search=heart+failure&Criteria=18&tab=2 (100)
- National Heart, Lung, and Blood Institute Heart Failure Information. Available at: https://www.nhlbi.nih.gov/health-topics/heart-failure (101)
- Heart Failure Association of the European Society of Cardiology. Available at: https://www.heartfailurematters.org/en\_GB (102)

# Clinical Recommendation(s)

2013 ACCF/AHA heart failure clinical practice guideline (7)

1. Patients with HF should receive specific education to facilitate HF self-care (103–108). (Class 1, Level of Evidence: B)

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; AHA, American Heart Association; EHR, electronic health record; HF, heart failure; HFSA, Heart Failure Society of America; IMPROVE-HF, Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting; LVAD, left ventricular assist device; and QM, quality measure.

SHORT TITLE: QM-2 Measurement of Patient-Reported Outcome-Health Status (Outpatient Setting)

QM-2: Measurement of Patient-Reported Outcome-Health Status (Outpatient Setting)

Measure description: Percentage of outpatients age 18 y with a diagnosis of heart failure who have a disease- specific patient-reported health status measurement recorded within each 6-mo period	
Numerator	Patients with a disease-specific PRO reported in the medical record during a 6-mo period
Denominator	All patients age 18 y with a diagnosis of heart failure
<b>Denominator Exclusions</b>	Heart transplant LVAD
Denominator Exceptions	Documentation of medical reason(s) for not reporting a disease- specific, patient-reported health status measurement (e.g., severe cognitive or functional impairment) Documentation of patient reason(s) for not reporting a disease- specific, patient-reported health status measurement
Measurement Period	12 mo with at least 1 PRO reported in each 6 mo of the reporting cycle
Sources of Data	EHR data Clinical registry
Attribution	Individual practitioner Facility

Care Setting Outpatient

#### Rationale

A fundamental goal of treating patients with heart failure is to improve symptoms, which is most accurately quantified by directly asking them. Disease-specific PROs (e.g., MLHFQ or KCCQ) are recommended as they are more sensitive to clinical change in heart failure than general health status measures. PROs are also predictive of other outcomes such as mortality, hospitalization, and costs (109–111) and often vary by sex, race/ethnicity, and socioeconomic status (112,113). Knowledge of a patient's reported health status may prompt changes in medications that will further improve care (114).

There are multiple disease-specific tools that have been developed to capture PROs in heart failure. The ACC/AHA have not addressed PRO tool selection. However, the FDA has provided guidelines for an appropriate PRO tool (16) and, currently, 2 heart failure survey tools—the MLHFQ (15) and the KCCQ (14)—are considered qualified tools for FDA device use in heart failure (17).

As a process measure for capturing a clinically important outcome, no risk-adjustment methods are required. It is required as a foundation for outcomes-based performance measure and is paired with QM-3.

#### Clinical Recommendation(s)

#### 2013 ACCF/AHA heart failure clinical practice guideline (7)

1. The ACC/AHA heart failure guideline modifies several recommendations based on the health status of the patient, usually quantified by the NYHA classification (7).

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; AHA, American Heart Association; EHR, electronic health record; FDA, U. S. Food and Drug Administration; KCCQ, Kansas City Cardiomyopathy Questionnaire; LVAD, left ventricular assist device; MLHFQ, Minnesota Living with Heart Failure Questionnaire; NYHA, New York Heart Association; PRO, patient-reported outcome; and QM, quality measure.

SHORT TITLE: QM-3 Sustained or Improved Health Status in Heart Failure (Outcome)

QM-3: Sustained or Improved Health Status (Patient-Reported Symptoms, Function, and Quality of Life) During the Reporting Period for All Patients With Heart Failure

Measure Description: Percentage of patients age 18 y with heart failure whose patient-reported outcome score does not decline significantly (a decrease in scores of 5 points for the KCCQ or an increase of 7 points for the MLHFQ*) during a 12-mo period		
Numerator	Patients whose last score within the past 6 mo of the reporting period is not significantly worse (did not decrease by 5 points for the KCCQ or did not increase by 7 points for the MLHFQ*) than the first score in the first 6 mo of the reporting period *A clinically significant change in PROMIS-PLUS-HF is not established at the time of this writing.	
Denominator	Heart failure patients age 18 y with at least 1 patient-reported outcome measurement in both the first and past 6 mo of the measurement period (12 mo)	
<b>Denominator Exclusions</b>	Heart transplant LVAD	
<b>Denominator Exceptions</b>	None	
Measurement Period	12 mo	
Sources of Data	Qualified EHR, QCDR, electronically or telephonically transmitted PROs	
Attribution	Individual practitioner Facility	
Care Setting	Outpatient	
Rationale		

Unlike the other measures in this measure set, this is an outcome comparable to mortality. Although using each patient as their own control minimizes some of the need for risk adjustment, this measure has been designated as a quality metric because development of adequate risk-adjustment is needed prior to use as a performance measure (accountability). Two of the disease-specific PROs (KCCQ and MLHFQ) have published thresholds for change that are considered clinically meaningful (115,116). This outcome-based measure will enable comparison of the proportion of

patients in each reporting unit that are not clinically worse over a year of treatment. Given that patients are expected to decline over time, this measure is not expected to be near 100%.

#### Clinical Recommendation(s)

# 2013 ACCF/AHA heart failure clinical practice guideline (7)

1. Goals of treatment of heart failure preserved ejection fraction and heart failure reduced ejection fraction are to improve health-related quality of life and symptoms (Figure 3, 2013 ACCF/AHA guideline) (7).

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; EHR, electronic health record; KCCQ, Kansas City Cardiomyopathy Questionnaire; LVAD, left ventricular assist device; MLHFQ, Minnesota Living with Heart Failure Questionnaire; PRO, patient-reported outcome; PROMIS-PLUS-HF, Patient-Reported Outcomes Measurement Information System-Plus-Heart Failure; QCDR, Qualified Clinical Data Registry; and QM, quality measure.

SHORT TITLE: QM-4 Postdischarge Appointment for Patients With Heart Failure (Inpatient Setting)

QM-4: Postdischarge Appointment for Patients With Heart Failure (Inpatient Setting)

Measure Description: Percentage of patients age 18 y discharged from an inpatient facility to ambulatory care or home health care with a principal discharge diagnosis of heart failure for whom a follow-up appointment was scheduled within 7 d and documented before discharge (as specified)	
Numerator	Patients for whom a follow-up appointment was scheduled within 7 d and documented before discharge including either:
	<ul> <li>An office visit (including location, date, and time) for management of heart failure</li> </ul>
	<ul> <li>A home health visit (including location and date) for management of heart failure</li> </ul>

A telehealth visit (including location and date) for

management of heart failure

	Because of the nature of scheduling home health visits, the location and date of the follow-up appointment is sufficient for meeting the measure.
Denominator	All patients age 18 y discharged from an inpatient facility (e.g., hospital inpatient or observation) to ambulatory care (home or self-care) or home health care with a principal discharge diagnosis of heart failure
<b>Denominator Exclusions</b>	Heart transplant LVAD
<b>Denominator Exceptions</b>	Documentation of medical reason(s) for not documenting that a follow-up appointment was scheduled (e.g., patients transferring to another facility) Documentation of patient reason(s) for not documenting that a follow-up appointment was scheduled (e.g., patients who left against medical advice or discontinued or transferred care)
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record
Attribution	Individual practitioner Facility
Care Setting	Inpatient

# Rationale

An observational study found that early outpatient follow-up (within 7 d) after discharge from a heart failure hospitalization is associated with a lower risk of 30-d readmission (117), although this has been an inconsistent finding (118). The writing committee agreed that more evidence is needed to support a short time period (<7 d) for the postdischarge appointment before this metric becomes a performance measure.

#### Clinical Recommendation(s)

#### 2013 ACCF/AHA heart failure clinical practice guideline (7)

1. Scheduling an early follow-up visit (within 7 to 14 days) and early telephone follow-up (within 3 days) of hospital discharge are reasonable (117,119). (Class 2a, Level of Evidence: B)

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; EHR, electronic health record; LVAD, left ventricular assist device; and QM, quality measure.

# Structural Measure for Heart Failure

SHORT TITLE: SM-1 Heart Failure Registry Participation

SM-1: Participation in 1 Regional or National Registries That Include Patients With Heart Failure

Measure Description: Participation in a national or regional heart failure registry that provides regular performance reports based on benchmarked data	
Numerator	Does the facility participate in a national or regional heart failure registry* that provides regular performance reports based on benchmarked data? (yes/no)  *Examples of such registries include the GWTG-HF, GWTG-360, PINNACLE Registry, and PINNACLE Registry Research Alliance.
Denominator	Not applicable
Denominator Exclusions	None
Denominator Exceptions	None
Measurement Period	Not applicable
Sources of Data	Facility attestation
Attribution	Measure reportable at the facility level only
Care Setting	Outpatient Inpatient
	Rationale

Participation in a registry allows measurement of performance for heart failure care, including benchmarking against other facilities.

# Clinical Recommendation(s)

#### 2013 ACCF/AHA heart failure clinical practice guideline (7)

1. Participation in quality improvement programs and patient registries based on nationally endorsed, clinical practice guideline-based quality and performance measures can be beneficial in improving the quality of HF care (120,121). (Class 2a, Level of Evidence: B)

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; GWTG, Get With The Guidelines; HF, heart failure; PINNACLE, Practice Innovation And Clinical Excellence; and SM, structural measure.

# Rehabilitation Performance Measures Related to Heart Failure

(From the 2018 ACC/AHA performance measures for cardiac rehabilitation (6))

SHORT TITLE: PM-2 Exercise Training Referral for HFrEF From Inpatient Setting

PM-2: Exercise Training Referral for HFrEF From an Inpatient Setting

Measure Description: Percentage of patients, age 18 y, hospitalized with a primary diagnosis of HFrEF in the previous 12 mo, who are referred for outpatient exercise training (or regular physical activity), typically delivered in the setting of an outpatient CR program

Numerator	Patients hospitalized with primary diagnosis of HFrEF who have been referred to an outpatient CR program before hospital discharge Referral is defined as:  1. Documented communication* between the healthcare provider and the patient to recommend an outpatient CR program AND  2A. Official referral order† is sent to outpatient CR program OR  2B. Documentation of patient refusal to justify why patient information was not sent to the CR program.  Note: Performance is met if steps 1 AND either 2A (official referral order transmitted) OR 2B (patient refusal documented in the patient's medical record) are completed and documented.  *All communications must maintain appropriate confidentiality as outlined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).  †All patient information required for enrollment should be transmitted to the CR program. Necessary patient information may be found in the hospital discharge summary.  ‡Patients who refuse a CR referral should not have their data transmitted to the receiving CR program against their will.
Denominator	All patients who have had HFrEF during the previous 12 mo, who are discharged from the hospital during the reporting period
<b>Denominator Exclusions</b>	Patients age <18 y Patients who leave during hospitalization against medical advice Patients who die during hospitalization Patients who are transferred to another hospital for inpatient care Patients who are already participating in a CR program before hospitalization
Denominator Exceptions	Documentation of a patient-oriented reason that precludes referral to CR (e.g., no traditional CR program available to the patient, within 60 min [travel time] from the patient's home, or patient does not have access to an alternative model of CR delivery that meets all criteria for a CR program)  Documentation of a medical reason that precludes referral to CR (e.g., patient deemed by a medical provider to have a medically unstable, life-threatening condition, or has other cognitive or physical impairments that preclude CR participation)  Documentation of a healthcare system reason that precludes referral to CR (e.g., patient is discharged to a nursing care or long-term care facility, or patient lacks medical coverage for CR)
Measurement Period	Encounter
Sources of Data	Medical record or other database (e.g., administrative, clinical, registry)
Attribution	Measure reportable at facility level
Care Setting	Inpatient
	Rationale

Exercise training services have been shown to improve functional status and may help reduce morbidity and mortality in persons with stable chronic heart failure with reduced HFrEF. However, these services are used in a minority of eligible patients (122,123).

A key component to outpatient exercise training (typically carried out in a CR program) is the appropriate and timely referral of patients. Generally, the most important time for this referral to take place is while the patient is hospitalized for a HFrEF.

This performance measure has been developed to help healthcare systems implement effective steps in their systems of care that will optimize the appropriate referral of a patient to an outpatient exercise training program.

This measure is designed to serve as a stand-alone measure or, preferably, to be included within other performance measurement sets that involve patients with HFrEF.

This performance measure is provided in a format that allows for easy and flexible inclusion into such performance measurement sets.

Effective referral of appropriate inpatients to an outpatient exercise training program is the responsibility of the healthcare team within a healthcare system that is primarily responsible for providing cardiovascular care to the patient with HFrEF during hospitalization.

Published evidence suggests that automatic referral systems, accompanied by strong and supportive advice and guidance

from a healthcare professional, can significantly help improve CR referral and enrollment, where exercise training typically takes place for patients with HFrEF.

#### Clinical Recommendation(s)

# 2013 ACCF/AHA heart failure clinical practice guideline (7)

1. Exercise training (or regular physical activity) is recommended as safe and effective for patients with HF who are able to participate to improve functional status (124–130). (Class 1, Level of Evidence: A)

# 2011 AHA prevention of cardiovascular disease in women guideline update (131)

1. A comprehensive CVD risk-reduction regimen such as cardiovascular or stroke rehabilitation or a physician-guided home- or community-based exercise training program should be recommended to women with a recent acute coronary syndrome or coronary revascularization, new-onset or chronic angina, recent cerebrovascular event, peripheral arterial disease (Class 1; Level of Evidence A) or current/prior symptoms of heart failure, and an LVEF 35%. (Class 1; Level of Evidence B)

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; CR, cardiac rehabilitation; CVD, cardiovascular disease; HF, heart failure; HFrEF, heart failure with reduced ejection fraction; LVEF, left ventricular ejection fraction; and PM, performance measure.

SHORT TITLE: PM-4 Exercise Training Referral for HFrEF From Outpatient Setting

Measure Description: Percentage of patients, age 18 y, evaluated in an outpatient setting who, within the

PM-4: Exercise Training Referral for HFrEF From an Outpatient Setting

previous 12 mo, have had a new HFrEF event or exacerbation and have not participated in an exercise training program, such as provided in CR programs, for the qualifying event/diagnosis, are to be referred for exercise training. Numerator Patients in an outpatient clinical practice who have had a new HFrEF event or exacerbation and have not participated in a supervised exercise training program (e.g., as a CR program) during the previous 12 mo, who have been referred to an outpatient CR program Referral is defined 1. Documented communication\* between the healthcare provider and the patient to recommend an outpatient CR program ÂND 2A. Official referral order† is sent to outpatient CR program OR 2B. Documentation of patient refusal to justify why patient information was not sent to the CR program; Note: Performance is met if steps 1 AND either 2A (official referral order transmitted) OR 2B (patient refusal documented in the patient's medical record) are completed and documented. \*All communications must maintain appropriate confidentiality as outlined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). †All patient information required for enrollment should be transmitted to the CR program. Necessary patient information may be found in the hospital discharge summary. ‡Patients who refuse a CR referral should not have their data transmitted to the receiving CR program against their will. Denominator All patients in an outpatient clinical practice who have had HFrEF during the previous 12 mo **Denominator Exclusions** Patients age <18 y Patients who leave clinic visit against medical advice Patients have already participated in or had already completed a CR program prior to clinic visit **Denominator Exceptions** Documentation of a patient-oriented reason that precludes referral to CR (e.g., no traditional CR program available to the patient, within 60 min [travel time] from the patient's home, or patient does not have access to an alternative model of CR delivery that meets all criteria for a CR program) Documentation of a medical reason that precludes referral to CR (e.g., patient deemed by a medical provider to have a medically unstable, lifethreatening condition, or has other cognitive or physical impairments that preclude CR participation) Documentation of a healthcare system reason that precludes referral to

CR (e.g., patient resides in a nursing care o	or long-term care facility, or
patient lacks medical coverage for CR)	

Measurement Period	Encounter
Sources of Data	Medical record or other database (e.g., administrative, clinical, registry)
Attribution	Measure reportable at provider and facility level
Care Setting	Outpatient

#### Rationale

CR services have been shown to help improve functional status and may help reduce morbidity and mortality in persons with stable chronic heart failure with reduced HFrEF. However, these services are used in a minority of eligible patients (122,123).

A key component to outpatient CR program utilization is the appropriate and timely referral of patients. Generally, the most important time for this referral to take place is while the patient is hospitalized for a HFrEF.

This performance measure has been developed to help healthcare systems implement effective steps in their systems of care that will optimize the appropriate referral of a patient to an outpatient CR program.

This measure is designed to serve as a stand-alone measure or, preferably, to be included within other performance measurement sets that involve patients with HFrEF.

This performance measure is provided in a format that allows for easy and flexible inclusion into such performance measurement sets.

Effective referral of appropriate inpatients to an outpatient CR program is the responsibility of the healthcare team within a healthcare system that is primarily responsible for providing cardiovascular care to the patient with HFrEF during hospitalization.

Published evidence suggests that automatic referral systems accompanied by strong and supportive advice and guidance from a healthcare professional can significantly help improve CR referral and enrollment.

# Clinical Recommendation(s)

#### 2013 ACCF/AHA heart failure clinical practice guideline (7)

1. Exercise training (or regular physical activity) is recommended as safe and effective for patients with HF who are able to participate to improve functional status (124–130). (Class 1, Level of Evidence: A)

2011 AHA prevention of cardiovascular disease in women guideline update (131)

1. A comprehensive CVD risk-reduction regimen such as cardiovascular or stroke rehabilitation or a physician-guided home- or community-based exercise training program should be recommended to women with a recent acute coronary syndrome or coronary revascularization, new-onset or chronic angina, recent cerebrovascular event, peripheral arterial disease (Class 1; Level of Evidence A) or current/prior symptoms of heart failure and an LVEF 35%. (Class 1; Level of Evidence B)

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; CR, cardiac rehabilitation; CVD, cardiovascular disease; HF, heart failure; HFrEF, heart failure with reduced ejection fraction; LVEF, left ventricular ejection fraction; and PM, performance measure.

**CHF Solutions** 

# APPENDIX B.: AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)-2020 ACC/AHA CLINICAL PERFORMANCE AND QUALITY MEASURES FOR HEART FAILURE

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Ot Financial Benefit
Paul A. Heidenreich ( <i>Chair</i> )	Stanford VA Palo Alto Health Care System— Professor of Medicine	None	None	None	None	None
Gregg C.* Fonarow* ( <i>Vice</i> <i>Chair</i> )	UCLA Medical Center– Professor of Medicine	<ul> <li>Abbott †</li> <li>Amgen</li> <li>Astra Zeneca</li> </ul>	None	None	<ul> <li>Medtronic</li> <li>Novartis †</li> </ul>	Boston Scientific

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or O Financial Benefit
		<ul> <li>Janssen         Pharmaceuticals</li> <li>Medtronic</li> <li>Merck</li> <li>Novartis †</li> </ul>		•		
Khadijah Breathett‡	UA College of Medicine, Tucson– Assistant Professor of Medicine	None	None	None	None	None
Corrine Y. Jurgens	Boston College, School of Nursing– Associate Professor	None	None	None	None	None
Barbara A. Pisani *	Wake Forest Baptist Medical Center-Medical Director, Heart Failure, Heart Transplant, Mechanical Circulatory Support	None	None	None	None	Abbotts     Amgen-GALAC     HF Tria     (PI)     Medtror     Novartis     PIONEI     Trial (P)     Sanofi-Aventis- SOLOIS Study (I)
Bunny J. Pozehl	University of Nebraska Medical Center, Omaha Division— Professor College of Nursing	None	None	None	None	None
John A. Spertus*	Saint Luke's Mid America Heart Institute— Director, Health Outcomes Research; University of Missouri- Kansas City— Professor	<ul> <li>Amgen</li> <li>AstraZeneca<sup>†</sup></li> <li>Bayer</li> <li>Boehringer Ingelheim<sup>†</sup></li> <li>Janssen Pharmaceuticals<sup>†</sup></li> <li>KCCQ<sup>†</sup></li> <li>Merck<sup>†</sup></li> <li>Novartis<sup>†</sup></li> </ul>	None	None	None	Abbott     AstraZe     UK Lim     Outcom     Instrum     Medtror     Novartis
Kenneth G. Taylor	Piedmont Heart Institute–Heart Failure and Interventional Cardiologist	None	None	None	None	None

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Ot Financial Benefit
Jennifer T. Thibodeau*	University of Texas Southwestern Medical Center— Associate Professor; Director, Heart Failure; Interim Section Chief, Heart Failure, Cardiac Transplantation, Ventricular Assist Devices	None	None	None	• Novartis	None
Clyde W. Yancy	Northwestern University, Feinberg School of Medicine— Magerstadt Professor of Medicine; Division of Cardiology— Chief	None	None	None	None	• Abbott§
Boback Ziaeian	UCLA David Geffen School of Medicine— Assistant Professor; VA Greater Los Angeles Healthcare System— Director of Telecardiology	None	None	None	None	None

This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% of the voting stock or share of the business entity, or ownership of \$5,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. According to the ACC/AHA, a person has a relevant relationship IF: a) the relationship or interest relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the document; or b) the company/entity (with whom the relationship exists) makes a drug, drug class, or device addressed in the document or makes a competing drug or device addressed in the document; or c) the person, or a member of the person's household, has a reasonable potential for financial, professional, or other personal gain or loss as a result of the issues/content addressed in the document.

Writing committee members were excluded from voting on sections to which their specific relationships with industry and other entities may apply. Dr. Fonarow was excluded from voting on PM-4, PM-5, PM-6, PM-7, PM-8, PM-9, PM-10, PM-12, PM-13, and SM-1. Dr. Pisani was excluded from voting on PM-5, PM-6, PM-8, PM-12, and PM-13. Dr. Spertus was excluded from voting on PM-2, PM-3, PM-4, PM-5, PM-6, PM-7, PM-8, PM-9, PM-10, PM-12, PM-13, QM-2, QM-3, and SM-1. Dr. Thibodeau was excluded from voting on PM-5, PM-6, and PM-8.

Significant relationship.

<sup>&</sup>lt;sup>7</sup>CMS reported payments to Dr. Breathett in 2019 related to food, beverage, travel, and lodging for Abbott; however, she disagrees with this report. Dr. Breathett was not the lead author on any measures.

No financial benefit.

CMS reported a food and beverage payment from Novartis to Dr. Taylor in 2019, however, he disagrees with this report. Novartis has marked the food and beverage entry for deletion. Dr. Taylor was not the lead author on any measures.

ACC indicates American College of Cardiology; AHA, American Heart Association; HF, heart failure; KCCQ, Kansas City Cardiomyopathy Questionnaire; PI, principal investigator; UA, University of Arizona; UCLA, University of California, Los Angeles; UK, United Kingdom; and VA, Veterans Affairs.

# APPENDIX C.: REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (COMPREHENSIVE)-2020 ACC/AHA CLINICAL PERFORMANCE AND QUALITY MEASURES FOR HEART FAILURE

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal l
Siqin Kye Ye	ACC/AHA TFPM Lead Reviewer	Center for Behavioral Cardiovascular Health-Assistant Professor of Medicine; Cardiology Inpatient Consultation Service-Director; Columbia Doctors- Associate Chief Medical Officer	None	None	None	Noi
John L. Jefferies	Official ACC	University of Tennessee Health Science Center— Jay M. Sullivan Distinguished Chair in Cardiovascular Medicine, Chief of Cardiology	<ul> <li>Abbott*</li> <li>Amicus</li> <li>AstraZeneca</li> <li>Bayer*</li> <li>CHF Solutions*</li> <li>Medtronic*</li> <li>Myokardia</li> <li>Protalix</li> <li>Sanofi Genzyme*</li> <li>Stealth Biotherapeutic</li> </ul>	<ul> <li>Ambry Genetics</li> <li>Pfizer</li> <li>Sanofi Genzyme *</li> </ul>	None	No
Pam Peterson	Official ACC	University of Colorado Anschutz Medical Campus– Professor of Medicine, Denver Health Medical Center	• AHA*	None	None	• NF
Howard J. Eisen	Official AHA	Penn State College of Medicine—Chief, Division of Cardiology	None	None	None	Noi
Janet N. Scheel	Official AHA	Washington University School of Medicine/St. Louis Children's Hospital- Professor of Pediatrics and	None	None	None	No

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal
		Pediatric Cardiologist				
Robert John Mentz	Official HFSA	Duke University School of Medicine— Associate Professor of Medicine, Associate Professor in Population Health Sciences, Member in the Duke Clinical Research Institute	<ul> <li>Abbott</li> <li>Akros</li> <li>Amgen *</li> <li>Bayer *</li> <li>Boehringer Ingelheim *</li> <li>HeartWare</li> <li>Janssen</li> <li>Luitpold Pharmaceutical</li> <li>Merck *</li> <li>Novartis *</li> <li>Sanofi-Aventis</li> <li>Thoratec</li> </ul>	None	None	• Ar • Ar • Ar • Ar • Br • Sq • Gi • Gl • Lu Ph • M • M • No • Ot Ph Co • Re • Vi
Mary Norine Walsh	Content ACC	St. Vincent Heart Center of Indiana—Medical Director Heart Failure and Cardiac Transplantation	None	None	None	No
Eldrin F. Lewis	Content AHA	Brigham and Women's Hospital— Associate Physician; Harvard Medical School—Associate Professor of Medicine	<ul> <li>Amgen<sup>†</sup></li> <li>DalCor<sup>*</sup></li> <li>Novartis<sup>*</sup></li> </ul>	None	None	• Ai • M • NI
Nancy M. Albert	Content ACC/AHA	Research and Innovation, Cleveland Clinic Health System & CNS/Kaufman Center for Heart Failure, Heart, Vascular & Thoracic Institute— Associate Chief Nursing Officer	<ul> <li>AstraZeneca</li> <li>Boston Scientific †</li> <li>Novartis</li> </ul>	• Novartis	None	• No

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal
Sana M. Al-Khatib	Content ACC/AHA	Duke University School of Medicine— Professor of Medicine, Member in the Duke Clinical Research Institute	Medtronic     Milestone     Pharmaceuticals	None	None	• A • Fi • M • N • P
Anita Deswal	Content ACC/AHA	Baylor College of Medicine-Chief, Medicine- Cardiology, Michael E. DeBakey VA Medical Center & Baylor College of Medicine; Professor, Medicine- Cardiology, Winters Center for Heart Failure Research	None	None	None	• N
Mona Fiuzat	Content ACC/AHA	Duke University School of Medicine— Adjunct Associate Professor, Department of Medicine	None	None	None	• Re
Adrian F. Hernandez	Content ACC/AHA	Duke University School of Medicine–Vice Dean for Clinical Research	<ul> <li>Amgen</li> <li>AstraZeneca</li> <li>Bayer</li> <li>BioFourmis</li> <li>Boehringer Ingelheim</li> <li>Boston Scientific *</li> <li>Merck</li> <li>Novartis *</li> <li>Pfizer</li> <li>Relypsa</li> <li>Sanofi-Aventis</li> <li>Xogenex</li> </ul>	None	None	• A • A • D • Ei • G • G • L • P • N • M • N • V • V • V • V • V • V • V • V • V • V

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal 1
J. Herb Patterson	Content ACC/AHA	UNC Eshelman School of Pharmacy— Interim Chair, Division of Pharmacotherapy and Experimental Therapeutics, Professor of Pharmacy, Research Professor of Medicine	• Novartis*	None	None	Ar Be Ing Me No
Andrea Russo	Content ACC/AHA	Cooper Medical School of Rowan University— Professor of Medicine and Director; Cardiac Electrophysiology and Arrhythmia Services— Director; Cardiovascular Research Cooper University Hospital Dorrance #393— Program Director, Clinical Cardiac Electrophysiology Fellowship	None	None	None	No
Paul Varosy	Content ACC/AHA	VA Eastern Colorado Health Care System– Director of Cardiac Electrophysiology	None	None	None	• Re Fu Ca De Av Im Mc Gr

This table represents all relationships of reviewers with industry and other entities that were reported at the time of peer review, including those not deemed to be relevant to this document, at the time this document was under review. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% of the voting stock or share of the business entity, or ownership of \$5,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review. Please refer to <a href="http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy">http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy</a> for definitions of disclosure categories or additional information about the ACC/AHA Disclosure Policy for Writing Committees.

ACC indicates American College of Cardiology; AHA, American Heart Association; CNS, Clinical Nurse Specialist; DSMB, Data Safety and Monitoring Board; FDA, U. S. Food and Drug Administration; HFSA, Heart Failure Society of America; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Institutes of Health; PCORI, Patient-Centered Outcomes Research Institute; PI, principal investigator; SCD, sudden cardiac death; TFPM, Task Force on Performance Measures; UNC, University of North Carolina; VA, Veterans Administration; and VT, ventricular tachycardia.

Significant (greater than \$5,000) relationship.

<sup>&</sup>lt;sup>†</sup>No financial relationship.

This disclosure was entered under the Clinical Trial Enroller category in the ACC's disclosure system.

## **REFERENCES**

 Spertus JA, Bonow RO, Chan P, et al. ACCF/AHA new insights into the methodology of performance measurement: a report of the American College of Cardiology Foundation/American Heart Association Task Force on performance measures. J Am Coll Cardiol. 2010;56:1767–82.
 [PubMed: 21070935]

- Spertus JA, Eagle KA, Krumholz HM, et al. American College of Cardiology and American Heart Association methodology for the selection and creation of performance measures for quantifying the quality of cardiovascular care. J Am Coll Cardiol. 2005;45:1147–56. [PubMed: 15808779]
- 3. Bonow RO, Ganiats TG, Beam CT, et al. ACCF/AHA/AMA-PCPI 2011 performance measures for adults with heart failure. J Am Coll Cardiol. 2012;59:1812–32. [PubMed: 22534627]
- 4. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. J Am Coll Cardiol. 2017;70:776–803. [PubMed: 28461007]
- Anderson JL, Heidenreich PA, Barnett PG, et al. ACC/AHA statement on cost/value methodology in clinical practice guidelines and performance measures: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines. J Am Coll Cardiol. 2014;63:2304–22. [PubMed: 24681044]
- 6. Thomas RJ, Balady G, Banka G, et al. 2018 ACC/AHA clinical performance and quality measures for cardiac rehabilitation: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol. 2018;71:1814–37. [PubMed: 29606402]
- 7. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Developed in collaboration with the American College of Chest Physicians, Heart Rhythm Society and International Society for Heart and Lung Transplantation. J Am Coll Cardiol. 2013;62:e147–239. [PubMed: 23747642]
- 8. Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure: the Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC). Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. Eur Heart J. 2016;37:2129–200. [PubMed: 27206819]
- Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2018;72:e91–220. [PubMed: 29097296]
- 10. Yancy CW, Januzzi JL, Allen LA, et al. 2017 ACC expert consensus decision pathway for optimization of heart failure treatment: answers to 10 pivotal issues about heart failure with reduced ejection fraction: a report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways. J Am Coll Cardiol. 2018;71:201–30. [PubMed: 29277252]
- 11. Normand SL, McNeil BJ, Peterson LE, et al. Eliciting expert opinion using the Delphi technique: identifying performance indicators for cardiovascular disease. Int J Qual Health Care. 1998;10:247–60. [PubMed: 9661064]
- 12. Patel DB, Shah RM, Bhatt DL, et al. Guideline-appropriate care and in-hospital outcomes in patients with heart failure in teaching and nonteaching hospitals: findings from Get With The Guidelines-Heart Failure. Circ Cardiovasc Qual Outcomes. 2016;9:757–66. [PubMed: 27780849]
- Taylor RS, Long L, Mordi IR, et al. Exercise-based rehabilitation for heart failure: Cochrane systematic review, meta-analysis, and trial sequential analysis. J Am Coll Cardiol HF. 2019;7:691– 705
- 14. Green CP, Porter CB, Bresnahan DR, et al. Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: a new health status measure for heart failure. J Am Coll Cardiol. 2000;35:1245–55. [PubMed: 10758967]

15. Rector TS, Kubo SH, Cohn JN. Patients' self-assessment of their congestive heart failure. Part 2: content, reliability and validity of a new measure, the Minnesota Living with Heart Failure Questionnaire. Heart Failure. 1987;Oct/Nov:198–209.

- 16. U.S. Food and Drug Administration. Guidance for industry patient-reported outcome measures: use in medical product development to support labeling claims. Available at: https://www.fda.gov/ regulatory-information/search-fda-guidance-documents/patient-reported-outcome-measures-usemedical-product-development-support-labeling-claims. Accessed June 24, 2020.
- 17. U.S. Food and Drug Administration. Medical device development tools (MDDT). Available at: https://www.fda.gov/medical-devices/science-and-research-medical-devices/medical-device-development-tools-mddt#Qualified\_Tools. Accessed June 24, 2020.
- Goldman L, Hashimoto B, Cook EF, et al. Comparative reproducibility and validity of systems for assessing cardiovascular functional class: advantages of a new specific activity scale. Circulation. 1981;64:1227–34. [PubMed: 7296795]
- 19. Madsen BK, Hansen JF, Stokholm KH, et al. Chrome congestive heart failure: description and survival of 190 consecutive patients with a diagnosis of chronic congestive heart failure based on clinical signs and symptoms. Eur Heart J. 1994;15:303–10. [PubMed: 8013501]
- 20. Greene SJ, Butler J, Albert NM, et al. Medical therapy for heart failure with reduced ejection fraction: the CHAMP-HF registry. J Am Coll Cardiol. 2018;72:351–66. [PubMed: 30025570]
- 21. Heo S, Doering LV, Widener J, et al. Predictors and effect of physical symptom status on health-related quality of life in patients with heart failure. Am J Crit Care. 2008;17:124–32. [PubMed: 18310649]
- 22. Lesman-Leegte I, Jaarsma T, Coyne JC, et al. Quality of life and depressive symptoms in the elderly: a comparison between patients with heart failure and age- and gender-matched community controls. J Card Fail. 2009;15:17–23. [PubMed: 19181289]
- 23. Moser DK, Yamokoski L, Sun JL, et al. Improvement in health-related quality of life after hospitalization predicts event-free survival in patients with advanced heart failure. J Card Fail. 2009;15:763–9. [PubMed: 19879462]
- 24. Rodríguez-Artalejo F, Guallar-Castillón P, Pascual CR, et al. Health-related quality of life as a predictor of hospital readmission and death among patients with heart failure. Arch Intern Med. 2005;165:1274–9. [PubMed: 15956007]
- 25. Heo S, Moser DK, Widener J. Gender differences in the effects of physical and emotional symptoms on health-related quality of life in patients with heart failure. Eur J Cardiovasc Nurs. 2007;6:146–52. [PubMed: 16919502]
- 26. Riegel B, Moser DK, Rayens MK, et al. Ethnic differences in quality of life in persons with heart failure. J Card Fail. 2008;14:41–7. [PubMed: 18226772]
- Bosworth HB, Steinhauser KE, Orr M, et al. Congestive heart failure patients' perceptions of quality of life: the integration of physical and psychosocial factors. Aging Ment Health. 2004;8:83–91. [PubMed: 14690872]
- 28. Carmona-Bernal C, Ruiz-García A, Villa-Gil M, et al. Quality of life in patients with congestive heart failure and central sleep apnea. Sleep Med. 2008;9:646–51. [PubMed: 18203661]
- 29. Lewis EF, Lamas GA, O'Meara E, et al. Characterization of health-related quality of life in heart failure patients with preserved versus low ejection fraction in CHARM. Eur J Heart Fail. 2007;9:83–91. [PubMed: 17188020]
- 30. Masoudi FA, Rumsfeld JS, Havranek EP, et al. Age, functional capacity, and health-related quality of life in patients with heart failure. J Card Fail. 2004;10:368–73. [PubMed: 15470645]
- 31. Pressler SJ, Subramanian U, Kareken D, et al. Cognitive deficits and health-related quality of life in chronic heart failure. J Cardiovasc Nurs. 2010;25:189–98. [PubMed: 20357665]
- 32. Xamoterol in severe heart failure. The Xamoterol in Severe Heart Failure Study Group. Lancet. 1990;336:1–6. [PubMed: 1694945]
- Merit-HF Study Group. Effect of metoprolol CR/XL in chronic heart failure: Metoprolol CR/XL Randomised Intervention Trial in-Congestive Heart Failure (MERIT-HF). Lancet. 1999;353:2001–7. [PubMed: 10376614]

34. Australia-New Zealand Heart Failure Research Collaborative Group. Effects of carvedilol, a vasodilator-beta-blocker, in patients with congestive heart failure due to ischemic heart disease. Circulation. 1995;92:212–8. [PubMed: 7600653]

- 35. Dargie H Effect of carvedilol on outcome after myocardial infarction in patients with left-ventricular dysfunction: the CAPRICORN randomised trial. Lancet. 2001;357:1385–90. [PubMed: 11356434]
- 36. Poole-Wilson PA, Swedberg K, Cleland JGF, et al. Comparison of carvedilol and metoprolol on clinical outcomes in patients with chronic heart failure in the Carvedilol Or Metoprolol European Trial (COMET): randomised controlled trial. Lancet. 2003;362:7–13. [PubMed: 12853193]
- 37. The Beta-Blocker Evaluation of Survival Trial Investigators. A trial of the beta-blocker bucindolol in patients with advanced chronic heart failure. N Engl J Med. 2001;344:1659–67. [PubMed: 11386264]
- 38. Butler J, Young JB, Abraham WT, et al. Beta-blocker use and outcomes among hospitalized heart failure patients. J Am Coll Cardiol. 2006;47:2462–9. [PubMed: 16781374]
- Fonarow GC, Abraham WT, Albert NM, et al. Influence of beta-blocker continuation or withdrawal on outcomes in patients hospitalized with heart failure: findings from the OPTIMIZE-HF program. J Am Coll Cardiol. 2008;52:190–9. [PubMed: 18617067]
- 40. Metra M, Torp-Pedersen C, Cleland JGF, et al. Should beta-blocker therapy be reduced or withdrawn after an episode of decompensated heart failure? Results from COMET. Eur J Heart Fail. 2007;9:901–9. [PubMed: 17581778]
- 41. Cohn JN, Tognoni G. A randomized trial of the angiotensin-receptor blocker valsartan in chronic heart failure. N Engl J Med. 2001;345:1667–75. [PubMed: 11759645]
- 42. Konstam MA, Neaton JD, Dickstein K, et al. Effects of high-dose versus low-dose losartan on clinical outcomes in patients with heart failure (HEAAL study): a randomised, double-blind trial. Lancet. 2009;374:1840–8. [PubMed: 19922995]
- 43. Pfeffer MA, McMurray JJV, Velazquez EJ, et al. Valsartan, captopril, or both in myocardial infarction complicated by heart failure, left ventricular dysfunction, or both. N Engl J Med. 2003;349:1893–906. [PubMed: 14610160]
- 44. Pfeffer MA, Swedberg K, Granger CB, et al. Effects of candesartan on mortality and morbidity in patients with chronic heart failure: the CHARM-Overall programme. Lancet. 2003;362:759–66. [PubMed: 13678868]
- 45. McMurray JJV, Packer M, Desai AS, et al. Angiotensin–neprilysin inhibition versus enalapril in heart failure. N Engl J Med. 2014;371:993–1004. [PubMed: 25176015]
- Group CTS. Effects of enalapril on mortality in severe congestive heart failure. Results of the Cooperative North Scandinavian Enalapril Survival Study (CONSENSUS). N Engl J Med. 1987;316:1429–35. [PubMed: 2883575]
- 47. Yusuf S, Pitt B, Davis CE, et al. Effect of enalapril on survival in patients with reduced left ventricular ejection fractions and congestive heart failure. The SOLVD Investigators. N Engl J Med. 1991;325:293–302. [PubMed: 2057034]
- 48. Effect of ramipril on mortality and morbidity of survivors of acute myocardial infarction with clinical evidence of heart failure. The Acute Infarction Ramipril Efficacy (AIRE) Study Investigators. Lancet. 1993;342:821–8. [PubMed: 8104270]
- 49. Køber L, Torp-Pedersen C, Carlsen JE, et al. A clinical trial of the angiotensin-converting–enzyme inhibitor trandolapril in patients with left ventricular dysfunction after myocardial infarction. Trandolapril Cardiac Evaluation (TRACE) Study Group. N Engl J Med. 1995;333:1670–6. [PubMed: 7477219]
- 50. Packer M, Poole-Wilson P, Armstrong P, et al. Comparative effects of low and high doses of the angiotensin-converting enzyme inhibitor, lisinopril, on morbidity and mortality in chronic heart failure. ATLAS Study Group. Circulation. 1999;100:2312–8. [PubMed: 10587334]
- 51. Pfeffer MA, Braunwald E, Moyé LA, et al. Effect of captopril on mortality and morbidity in patients with left ventricular dysfunction after myocardial infarction: results of the Survival and Ventricular Enlargement Trial. The SAVE Investigators. N Engl J Med. 1992;327:669–77. [PubMed: 1386652]

52. Packer M, Fowler MB, Roecker EB, et al. Effect of carvedilol on the morbidity of patients with severe chronic heart failure: results of the carvedilol prospective randomized cumulative survival (COPERNICUS) study. Circulation. 2002;106:2194–9. [PubMed: 12390947]

- 53. Eschalier R, McMurray JJ, Swedberg K, et al. Safety and efficacy of eplerenone in patients at high risk for hyperkalemia and/or worsening renal function: analyses of the EMPHASIS-HF study subgroups (Eplerenone in Mild Patients Hospitalization And SurvIval Study in Heart Failure). J Am Coll Cardiol. 2013;62:1585–93. [PubMed: 23810881]
- 54. Pitt B, Zannad F, Remme WJ, et al. The effect of spironolactone on morbidity and mortality in patients with severe heart failure. Randomized Aldactone Evaluation Study Investigators. N Engl J Med. 1999;341:709–17. [PubMed: 10471456]
- 55. Morrow DA, Velazquez EJ, DeVore AD, et al. Clinical outcomes in patients with acute decompensated heart failure randomly assigned to sacubitril/valsartan or enalapril in the PIONEER-HF Trial. Circulation. 2019;139:2285–8. [PubMed: 30955360]
- Velazquez EJ, Morrow DA, DeVore AD, et al. Angiotensin-neprilysin inhibition in acute decompensated heart failure. N Engl J Med. 2019;380:539–48. [PubMed: 30415601]
- 57. Solomon SD, Claggett B, McMurray JJ, et al. Combined neprilysin and renin-angiotensin system inhibition in heart failure with reduced ejection fraction: a meta-analysis. Eur J Heart Fail. 2016;18:1238–43. [PubMed: 27364182]
- 58. Tan NY, Sangaralingham LR, Sangaralingham SJ, et al. Comparative effectiveness of sacubitril-valsartan versus ACE/ARB therapy in heart failure with reduced ejection fraction. J Am Coll Cardiol HF. 2020;8:43–54.
- Campodonico J, Piepoli M, Clemenza F, et al. Dose-dependent efficacy of beta-blocker in patients with chronic heart failure and atrial fibrillation. Int J Cardiol. 2018;273:141–6. [PubMed: 30098827]
- 60. CIBIS-II Investigators Committee. The Cardiac Insufficiency Bisoprolol Study II (CIBIS-II): a randomised trial. Lancet. 1999;353:9–13. [PubMed: 10023943]
- 61. Paolillo S, Mapelli M, Bonomi A, et al. Prognostic role of beta-blocker selectivity and dosage regimens in heart failure patients. Insights from the MECKI score database. Eur J Heart Fail. 2017;19:904–14. [PubMed: 28233458]
- 62. Bristow MR, Gilbert EM, Abraham WT, et al. Carvedilol produces dose-related improvements in left ventricular function and survival in subjects with chronic heart failure. MOCHA Investigators. Circulation. 1996;94:2807–16. [PubMed: 8941106]
- 63. Fiuzat M, Wojdyla D, Kitzman D, et al. Relationship of beta-blocker dose with outcomes in ambulatory heart failure patients with systolic dysfunction: results from the HF-ACTION (Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training) trial. J Am Coll Cardiol. 2012;60:208–15. [PubMed: 22560018]
- 64. Fiuzat M, Wojdyla D, Pina I, et al. Heart rate or beta-blocker dose? Association with outcomes in ambulatory heart failure patients with systolic dysfunction: results from the HF-ACTION trial. J Am Coll Cardiol HF. 2016;4:109–15.
- 65. Gheorghiade M, Albert NM, Curtis AB, et al. Medication dosing in outpatients with heart failure after implementation of a practice-based performance improvement intervention: findings from IMPROVE HF. Congest Heart Fail. 2012;18:9–17. [PubMed: 22277172]
- 66. Greene SJ, Fonarow GC, DeVore AD, et al. Titration of medical therapy for heart failure with reduced ejection fraction. J Am Coll Cardiol. 2019;73:2365–83. [PubMed: 30844480]
- 67. Packer M, Bristow MR, Cohn JN, et al. The effect of carvedilol on morbidity and mortality in patients with chronic heart failure. U.S. Carvedilol Heart Failure Study Group. N Engl J Med. 1996;334:1349–55. [PubMed: 8614419]
- 68. U.S. National Library of Medicine. DailyMed. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed June 24, 2020.
- 69. Khan MS, Fonarow GC, Ahmed A, et al. Dose of angiotensin-converting enzyme inhibitors and angiotensin receptor blockers and outcomes in heart failure: a meta-analysis. Circ Heart Fail. 2017;10:e003956. [PubMed: 28790052]

70. Vardeny O, Claggett B, Packer M, et al. Efficacy of sacubitril/valsartan vs. enalapril at lower than target doses in heart failure with reduced ejection fraction: the PARADIGM-HF trial. Eur J Heart Fail. 2016;18:1228–34. [PubMed: 27283779]

- 71. Vizzardi E, D'Aloia A, Giubbini R, et al. Effect of spironolactone on left ventricular ejection fraction and volumes in patients with class I or II heart failure. Am J Cardiol. 2010;106:1292–6. [PubMed: 21029826]
- 72. Zannad F, McMurray JJ, Krum H, et al. Eplerenone in patients with systolic heart failure and mild symptoms. N Engl J Med. 2011;364:11–21. [PubMed: 21073363]
- 73. Pitt B, Remme W, Zannad F, et al. Eplerenone, a selective aldosterone blocker, in patients with left ventricular dysfunction after myocardial infarction. N Engl J Med. 2003;348:1309–21. [PubMed: 12668699]
- Bozkurt B, Agoston I, Knowlton AA. Complications of inappropriate use of spironolactone in heart failure: when an old medicine spirals out of new guidelines. J Am Coll Cardiol. 2003;41:211–4. [PubMed: 12535810]
- 75. Juurlink DN, Mamdani MM, Lee DS, et al. Rates of hyperkalemia after publication of the Randomized Aldactone Evaluation Study. N Engl J Med. 2004;351:543–51. [PubMed: 15295047]
- 76. Chauhan V, Dev S, Pham M, et al. Facility variation and predictors of serum potassium monitoring after initiation of a mineralocorticoid receptor antagonist in patients with heart failure. Am Heart J. 2015;170:543–9. [PubMed: 26385038]
- 77. Ziaeian B, Fonarow GC, Heidenreich PA. Clinical effectiveness of hydralazine-isosorbide dinitrate in African-American patients with heart failure. J Am Coll Cardiol HF. 2017;5:632–9.
- 78. Carson P, Ziesche S, Johnson G, et al. Racial differences in response to therapy for heart failure: analysis of the vasodilator-heart failure trials. Vasodilator-Heart Failure Trial Study Group. J Card Fail. 1999;5:178–87. [PubMed: 10496190]
- 79. Taylor AL, Ziesche S, Yancy C, et al. Combination of isosorbide dinitrate and hydralazine in blacks with heart failure. N Engl J Med. 2004;351:2049–57. [PubMed: 15533851]
- 80. Hess PL, Hernandez AF, Bhatt DL, et al. Sex and race/ethnicity differences in implantable cardioverter-defibrillator counseling and use among patients hospitalized with heart failure: findings from the Get With The Guidelines-Heart Failure Program. Circulation. 2016;134:517–26. [PubMed: 27492903]
- 81. Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med. 2005;352:225–37. [PubMed: 15659722]
- 82. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med. 2002;346:877–83. [PubMed: 11907286]
- Allen LA, Stevenson LW, Grady KL, et al. Decision making in advanced heart failure: a scientific statement from the American Heart Association. Circulation. 2012;125:1928–52. [PubMed: 22392529]
- 84. Hauptman PJ, Chibnall JT, Guild C, et al. Patient perceptions, physician communication, and the implantable cardioverter-defibrillator. JAMA Intern Med. 2013;173:571–7. [PubMed: 23420455]
- 85. Lewis KB, Stacey D, Matlock DD. Making decisions about implantable cardioverter-defibrillators from implantation to end of life: an integrative review of patients' perspectives. Patient. 2014;7:243–60. [PubMed: 24668214]
- 86. Ottenberg AL, Mueller PS, Topazian RJ. "It's not broke, so let's not try to fix it": why patients decline a cardiovascular implantable electronic device. Pacing Clin Electrophysiol. 2014;37:1306–14. [PubMed: 24889010]
- 87. Stewart GC, Weintraub JR, Pratibhu PP, et al. Patient expectations from implantable defibrillators to prevent death in heart failure. J Card Fail. 2010;16:106–13. [PubMed: 20142021]
- 88. Yuhas J, Mattocks K, Gravelin L, et al. Patients' attitudes and perceptions of implantable cardioverter-defibrillators: potential barriers to appropriate primary prophylaxis. Pacing Clin Electrophysiol. 2012;35:1179–87. [PubMed: 22897624]
- 89. Randolph TC, Hellkamp AS, Zeitler EP, et al. Utilization of cardiac resynchronization therapy in eligible patients hospitalized for heart failure and its association with patient outcomes. Am Heart J. 2017;189:48–58. [PubMed: 28625381]

 Abraham WT, Fisher WG, Smith AL, et al. Cardiac resynchronization in chronic heart failure. N Engl J Med. 2002;346:1845–53. [PubMed: 12063368]

- 91. Bristow MR, Saxon LA, Boehmer J, et al. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. N Engl J Med. 2004;350:2140–50. [PubMed: 15152059]
- 92. Cleland JG, Daubert JC, Erdmann E, et al. The effect of cardiac resynchronization on morbidity and mortality in heart failure. N Engl J Med. 2005;352:1539–49. [PubMed: 15753115]
- 93. Hunt SA, Abraham WT, Chin MH, et al. 2009 Focused update incorporated into the ACC/AHA 2005 guidelines for the diagnosis and management of heart failure in adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Developed in collaboration with the International Society for Heart and Lung Transplantation. J Am Coll Cardiol. 2009;53:e1–90. [PubMed: 19358937]
- 94. Moss AJ, Hall WJ, Cannom DS, et al. Cardiac-resynchronization therapy for the prevention of heart-failure events. N Engl J Med. 2009;361:1329–38. [PubMed: 19723701]
- 95. Tang AS, Wells GA, Talajic M, et al. Cardiac-resynchronization therapy for mild-to-moderate heart failure. N Engl J Med. 2010;363:2385–95. [PubMed: 21073365]
- 96. Stromberg A The crucial role of patient education in heart failure. Eur J Heart Fail. 2005;7:363–9. [PubMed: 15718176]
- 97. Fonarow GC, Yancy CW, Heywood JT. Adherence to heart failure quality-of-care indicators in US hospitals: analysis of the ADHERE registry. Arch Intern Med. 2005;165:1469–77. [PubMed: 16009861]
- 98. American Heart Association. Health topics heart failure. Available at: https://www.heart.org/en/health-topics/heart-failure. Accessed June 24, 2020.
- American College of Cardiology. CardioSmart heart failure. Available at: https:// www.cardiosmart.org/Heart-Conditions/Heart-Failure. Accessed June 24, 2020.
- 100. HFSA Learning Center. Patient education heart failure. Available at: https:// learningcenter.hfsa.org/Public/Catalog/Home.aspx?Search=heartpfailure&Criteria=18&tab=2. Accessed June 24, 2020.
- 101. NIH National Heart, Lung, and Blood Institute. Health topics heart failure. Available at: https://www.nhlbi.nih.gov/health-topics/heart-failure. Accessed June 24, 2020.
- 102. European Society of Cardiology. Heart failure matters: practical information for patients, families and caregivers. Available at: https://www.heartfailurematters.org/en\_GB. Accessed June 24, 2020.
- 103. Aguado O, Morcillo C, Delas J, et al. Long-term implications of a single home-based educational intervention in patients with heart failure. Heart Lung. 2010;39:S14–22. [PubMed: 20598745]
- 104. Boren SA, Wakefield BJ, Gunlock TL, et al. Heart failure self-management education: a systematic review of the evidence. Int J Evid Based Healthc. 2009;7:159–68. [PubMed: 21631856]
- 105. Gwadry-Sridhar FH, Arnold JM, Zhang Y, et al. Pilot study to determine the impact of a multidisciplinary educational intervention in patients hospitalized with heart failure. Am Heart J. 2005;150:982. [PubMed: 16290975]
- 106. Koelling TM, Johnson ML, Cody RJ, et al. Discharge education improves clinical outcomes in patients with chronic heart failure. Circulation. 2005;111:179–85. [PubMed: 15642765]
- 107. Riegel B, Moser DK, Anker SD, et al. State of the science: promoting self-care in persons with heart failure: a scientific statement from the American Heart Association. Circulation. 2009;120:1141–63. [PubMed: 19720935]
- 108. VanSuch M, Naessens JM, Stroebel RJ, et al. Effect of discharge instructions on readmission of hospitalised patients with heart failure: do all of the Joint Commission on Accreditation of Healthcare Organizations heart failure core measures reflect better care? Qual Saf Health Care. 2006;15:414–7. [PubMed: 17142589]
- 109. Chan PS, Soto G, Jones PG, et al. Patient health status and costs in heart failure: insights from the eplerenone post-acute myocardial infarction heart failure efficacy and survival study (EPHESUS). Circulation. 2009;119:398–407. [PubMed: 19139382]

110. Heidenreich PA, Spertus JA, Jones PG, et al. Health status identifies heart failure outpatients at risk for hospitalization or death. J Am Coll Cardiol. 2006;47:752–6. [PubMed: 16487840]

- 111. Soto GE, Jones P, Weintraub WS, et al. Prognostic value of health status in patients with heart failure after acute myocardial infarction. Circulation. 2004;110:546–51. [PubMed: 15262843]
- 112. Khariton Y, Hernandez AF, Fonarow GC, et al. Health status variation across practices in outpatients with heart failure: insights from the CHAMP-HF (Change the Management of Patients With Heart Failure) registry. Circ Cardiovasc Qual Outcomes. 2018;11:e004668. [PubMed: 29627798]
- 113. Khariton Y, Nassif ME, Thomas L, et al. Health status disparities by sex, race/ethnicity, and socioeconomic status in outpatients with heart failure. J Am Coll Cardiol HF. 2018;6:465–73.
- 114. Thomas M, Khariton Y, Fonarow GC, et al. Association of changes in heart failure treatment with patients' health status: real-world evidence from CHAMP-HF. J Am Coll Cardiol HF. 2019;7:615–25.
- 115. Dreyer RP, Jones PG, Kutty S, et al. Quantifying clinical change: discrepancies between patients' and providers' perspectives. Qual Life Res. 2016;25:2213–20. [PubMed: 26995561]
- 116. Nassif ME, Tang Y, Cleland JG, et al. Precision medicine for cardiac resynchronization: predicting quality of life benefits for individual patients-an analysis from 5 clinical trials. Circ Heart Fail. 2017;10:e004111. [PubMed: 29038172]
- 117. Hernandez AF, Greiner MA, Fonarow GC, et al. Relationship between early physician follow-up and 30-day readmission among Medicare beneficiaries hospitalized for heart failure. JAMA. 2010;303:1716–22. [PubMed: 20442387]
- 118. Grafft CA, McDonald FS, Ruud KL, et al. Effect of hospital follow-up appointment on clinical event outcomes and mortality. Arch Intern Med. 2010;170:955–60. [PubMed: 20548008]
- 119. Krumholz HM, Chen YT, Wang Y, et al. Predictors of readmission among elderly survivors of admission with heart failure. Am Heart J. 2000;139:72–7. [PubMed: 10618565]
- 120. Fonarow GC, Albert NM, Curtis AB, et al. Improving evidence-based care for heart failure in outpatient cardiology practices: primary results of the Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting (IMPROVE HF). Circulation. 2010;122:585–96. [PubMed: 20660805]
- 121. Fonarow GC, Heywood JT, Heidenreich PA, et al. Temporal trends in clinical characteristics, treatments, and outcomes for heart failure hospitalizations, 2002 to 2004: findings from Acute Decompensated Heart Failure National Registry (ADHERE). Am Heart J. 2007;153:1021–8. [PubMed: 17540205]
- 122. Cortes O, Arthur HM. Determinants of referral to cardiac rehabilitation programs in patients with coronary artery disease: a systematic review. Am Heart J. 2006;151:249–56. [PubMed: 16442885]
- 123. Park LG, Schopfer DW, Zhang N, et al. Participation in cardiac rehabilitation among patients with heart failure. J Card Fail. 2017;23:427–31. [PubMed: 28232047]
- 124. Austin J, Williams R, Ross L, et al. Randomised controlled trial of cardiac rehabilitation in elderly patients with heart failure. Eur J Heart Fail. 2005;7:411–7. [PubMed: 15718182]
- 125. Austin J, Williams WR, Ross L, et al. Five-year follow-up findings from a randomized controlled trial of cardiac rehabilitation for heart failure. Eur J Cardiovasc Prev Rehabil. 2008;15:162–7. [PubMed: 18391642]
- 126. Davies EJ, Moxham T, Rees K, et al. Exercise training for systolic heart failure: Cochrane systematic review and meta-analysis. Eur J Heart Fail. 2010;12:706–15. [PubMed: 20494922]
- 127. O'Connor CM, Whellan DJ, Lee KL, et al. Efficacy and safety of exercise training in patients with chronic heart failure: HF-ACTION randomized controlled trial. JAMA. 2009;301:1439–50. [PubMed: 19351941]
- 128. Piepoli MF, Davos C, Francis DP, et al. Exercise training meta-analysis of trials in patients with chronic heart failure (ExTraMATCH). BMJ. 2004;328:189. [PubMed: 14729656]
- 129. Pina IL, Apstein CS, Balady GJ, et al. Exercise and heart failure: a statement from the American Heart Association Committee on exercise, rehabilitation, and prevention. Circulation. 2003;107:1210–25. [PubMed: 12615804]

130. Smart N, Marwick TH. Exercise training for patients with heart failure: a systematic review of factors that improve mortality and morbidity. Am J Med. 2004;116:693–706. [PubMed: 15121496]

131. Mosca L, Benjamin EJ, Berra K, et al. Effectiveness-based guidelines for the prevention of cardiovascular disease in women–2011 update: a guideline from the American Heart Association. Circulation. 2011;123:1243–62. [PubMed: 21325087]

TABLE 1

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Applying Class of Recommendation and Level of Evidence to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care\* (Updated May 2019)

## COR indicates Class of Recommendation; E0, expert opinion; LD, limited data; LOE, Level For comparative-effectiveness recommendations (COR 1 and 2a; LOE A and B only) studies that support the use of comparator verbs should involve direct comparisons trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information). (Limited Data) (Randomized) (Nonrandomized) Expert Opinion) A recommendation with LOE C does not imply that the recommendation is weak. Many · Randomized or nonrandomized observational or registry studies with of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial. important clinical questions addressed in guidelines do not lend themselves to clinical dardized, widely-used, and preferably validated evidence grading tools; and for COR and LOE are determined independently (any COR may be paired with any LOE). executed nonrandomized studies, observational studies, or registry The method of assessing quality is evolving, including the application of stan- Moderate-quality evidence‡ from 1 or more well-designed, well-One or more RCTs corroborated by high-quality registry studies systematic reviews, the incorporation of an Evidence Review Committee Consensus of expert opinion based on clinical experience Physiological or mechanistic studies in human subjects Moderate-quality evidence‡ from 1 or more RCTs High-quality evidence‡ from more than 1 RCI · Meta-analyses of moderate-quality RCTs of the treatments or strategies being evaluated. Meta-analyses of high-quality RCTs particular test or therapy is useful or effective. limitations of design or execution Meta-analyses of such studies Meta-analyses of such studies LEVEL (QUALITY) OF EVIDENCE LEVEL B-NR LEVEL C-LD LEVEL C-EO EVEL B-R EVEL A Benefit >> Risk Benefit ≥ Risk Benefit = Risk Risk > Benefit Benefit >>> Risk Treatment/strategy A is recommended/indicated in preference to Usefulness/effectiveness is unknown/unclear/uncertain or not well-Treatment/strategy A is probably recommended/indicated in It is reasonable to choose treatment A over treatment B Freatment A should be chosen over treatment B Suggested phrases for writing recommendations: Should not be performed/administered/other Should not be performed/administered/other Associated with excess morbidity/mortality Is not indicated/useful/effective/beneficial CLASS (STRENGTH) OF RECOMMENDATION Should be performed/administered/other Is indicated/useful/effective/beneficia Comparative-Effectiveness Phrasest: Comparative-Effectiveness Phrases† Can be useful/effective/beneficial CLASS 3: No Benefit (MODERATE) (Generally, LOE A or B use only) preference to treatment B Mav/might be reasonable May/might be considered Class 3: Harm (STRONG) Is not recommended CLASS 2a (MODERATE) Potentially harmful CLASS 1 (STRONG) CLASS 2b (WEAK) Causes harm Is reasonable established

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**TABLE 2** 

ACC/AHA 2020 Heart Failure Clinical Performance, Quality and Structural Measures

	out outpost	Care Setting	Attribution	THE COMME	CONTROL
Performance Measures	Measures				
PM-1	LVEF assessment	Outpatient	Individual practitioner, Facility	Diagnostic	COR: 1, LOE: C; COR: 2a, LOE: C
PM-2	Symptom and activity assessment	Outpatient	Individual practitioner, Facility	Monitoring	COR: 1, LOE: C
PM-3	Symptom management	Outpatient	Individual practitioner, Facility	Treatment	See measure rationale in Appendix A for details
PM-4	Beta-blocker therapy for HFrEF	Outpatient, Inpatient	Individual practitioner, Facility	Treatment	COR: 1, LOE: A; COR: 1, LOE: B
PM-5	ACE inhibitor or ARB or ARNI therapy for HFrEF	Outpatient, Inpatient	Individual practitioner, Facility	Treatment	COR: 1, LOE: A; COR: 1, LOE: B-R
PM-6	ARNI therapy for HFrEF	Outpatient, Inpatient	Individual practitioner, Facility	Treatment	COR: 1, LOE: B-R
PM-7	Dose of beta-blocker therapy for HFrEF	Outpatient	Individual practitioner, Facility	Treatment	COR: 1, LOE: A
PM-8	Dose of ACE inhibitor, ARB, or ARNI therapy for HFrEF	Outpatient	Individual practitioner, Facility	Treatment	COR: 1, LOE: A; COR: 1, LOE: B-R
PM-9	MRA therapy for HFrEF	Outpatient, Inpatient	Individual practitioner, Facility	Treatment	COR: 1, LOE: A; COR: 1, LOE: B
PM-10	Laboratory monitoring in new MRA therapy	Outpatient, Inpatient	Individual practitioner, Facility	Monitoring	COR: 1, LOE: A
PM-11	Hydralazine/isosorbide dinitrate therapy for HFrEF in those self-identified as Black or African American	Outpatient, Inpatient	Individual practitioner, Facility	Treatment	COR: 1, LOE: A
PM-12	Counseling regarding ICD implantation for patients with HFrEF on guideline- directed medical therapy	Outpatient	Individual practitioner, Facility	Treatment	COR: 1, LOE: A
PM-13	CRT implantation for patients with HFrEF on guideline-directed medical therapy	Outpatient	Individual practitioner, Facility	Treatment	COR: 1, LOE: A; COR: 1, LOE: B
Quality Measures	ures				
QM-1	Patient self-care education	Outpatient	Individual practitioner, Facility	Self-Care	COR: 1, LOE: B
QM-2	Measurement of patient-reported outcome-health status	Outpatient	Individual practitioner, Facility	Monitoring	See measure rationale in Appendix A for details
QM-3	Sustained or improved health status in heart failure	Outpatient	Individual practitioner, Facility	Outcome	See measure rationale in Appendix A for details
QM-4	Postdischarge appointment for patients with heart failure	Inpatient	Individual practitioner, Facility	Treatment	COR: 2a, LOE: B
Structural Measure	easure				
SM-1	Heart failure registry participation	Outpatient, Inpatient	Facility	Structure	COR: 2a, LOE: B

COR/LOE	COR: 1, LOE: A	COR: 1, LOE: A
Measure Domain	Process	Process
Attribution	Facility	Individual practitioner, Facility Process
Care Setting	Inpatient	Outpatient
Measure Title	Rehab PM-2 Exercise training referral for HF from inpatient setting	Rehab PM-4 Exercise training referral for HF from outpatient setting
Measure No.	Rehab PM-2	Rehab PM-4

ACC indicates American College of Cardiology; ACE, angiotensin-converting enzyme; AHA, American Heart Association; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor-neprilysin inhibitor; COR, class of recommendation; CRT, cardiac resynchronization therapy; HF, heart failure; HFHEF, heart failure with reduced ejection fraction; ICD, implantable cardioverrer-defibrillator; LOE, level of evidence; LVEF, left ventricular ejection fraction; MRA, mineralocorticoid receptor antagonists; PM, performance measure; QM, quality measure; and SM, structural measure.

## TABLE 3

## Associated ACC/AHA Clinical Practice Guidelines and Other Clinical Guidance Documents

Clinical Practice Guide	elines
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2017 ACC/AHA/HFSA heart failure guideline update (4)

2016 ESC heart failure diagnosis and treatment guidelines (8)

2013 ACCF/AHA heart failure clinical practice guideline (7)

2017 AHA/ACC/HRS ventricular arrhythmias and prevention of sudden cardiac death guideline (9)

## Performance Measures

2011 ACCF/AHA/PCPI heart failure performance measurement set (3)

2018 ACC/AHA performance measures for cardiac rehabilitation (6)

2017 ACC expert consensus decision pathway for optimization of heart failure treatment (10)

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; AHA, American Heart Association; ESC, European Society of Cardiology; HFSA, Heart Failure Society of America; HRS, Heart Rhythm Society; and PCPI, Physician Consortium for Performance Improvement.

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## **TABLE 4**

ACC/AHA Task Force on Performance Measures: Attributes for Performance Measures (11)

1. Evidence Based	
High-impact area that is useful in improving patient outcomes	a) For structural measures, the structure should be closely linked to a meaningful process of care that, in turn, is linked to a meaningful patient outcome. b) For process measures, the scientific basis for the measure should be well established, and the process should be closely linked to a meaningful patient outcome. c) For outcome measures, the outcome should be clinically meaningful. If appropriate, performance measures based on outcomes should adjust for relevant clinical characteristics through the use of appropriate methodology and high-quality data sources.
2. Measure Selection	
Measure definition	a) The patient group to whom the measure applies (denominator) and the patient group for whom conformance is achieved (numerator) are clearly defined and clinically meaningful.
Measure exceptions and exclusions	b) Exceptions and exclusions are supported by evidence.
Reliability	c) The measure is reproducible across organizations and delivery settings.
Face validity	d) The measure appears to assess what it is intended to.
Content validity	e) The measure captures most meaningful aspects of care.
Construct validity	f) The measure correlates well with other measures of the same aspect of care.
3. Measure Feasibility	
Reasonable effort and cost	a) The data required for the measure can be obtained with reasonable effort and cost.
Reasonable time period	b) The data required for the measure can be obtained within the period allowed for data collection.
4. Accountability	
Actionable	a) Those held accountable can affect the care process or outcome.
Unintended consequences avoided	b) The likelihood of negative, unintended consequences with the measure is low.

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ACC indicates American College of Cardiology; and AHA, American Heart Association.

**TABLE 5** 

Retired Heart Failure Measures From the 2011 Set (3)

Measure No.	Care Setting	Measure Title	Rationale for Retiring the Measure
2	Inpatient	LVEF assessment	Inpatient documentation of LVEF is at >97% (12).

LVEF indicates left ventricular ejection fraction.

## **TABLE** 6

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Revised Heart Failure Measures

Measure No.	Measure Title	Description of Revision	Rationale for Revision
5	Patient self-care education	Moved from Performance Measure to Quality Measure	Concern regarding the accuracy of self-care education documentation; limited evidence of improved outcomes with better documentation.
7	ACE inhibitor or ARB therapy for Added LVSD	Added ARNI	2017 ACC/AHA/HFSA heart failure guideline update (4) made this revision to the recommendation.
6	Postdischarge appointment	Moved from Performance Measure to Quality Measure and included a time limit of 7 d	2013 ACCE/AHA heart failure clinical practice guideline (7) lists postdischarge appointment from 7–14 d as a Class 2a recommendation.

ACC indicates American College of Cardiology; ACE, angiotensin-converting enzyme; AHA, American Heart Association; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor-neprilysin inhibitor; HF, heart failure; and LVSD, left ventricular systolic dysfunction.

## **TABLE 7**

New Heart Failure Measures

Measure No.	Care Setting	Measure Title	Rationale for Creating New Measure	Kationale for Designating as a Quality Measure Versus a Performance Measure
PM-6	Outpatient, Inpatient	ARNI therapy for HFrEF	Important outcome benefit with large existing gap in care	N/A
PM-7	Outpatient	Dose of beta-blocker therapy for HFrEF	Important outcome benefit and large existing gap in care	N/A
PM-8	Outpatient	Dose of ACE inhibitor, ARB, or ARNI therapy for HFrEF	Important outcome benefit and large existing gap in care	N/A
PM-9	Outpatient, Inpatient	MRA therapy for HFrEF	Important outcome benefit and large existing gap in care	N/A
PM-10	Outpatient, Inpatient	Laboratory monitoring in new MRA therapy	Important outcome benefit and large existing gap in care	N/A
PM-11	Outpatient, Inpatient	Hydralazine/isosorbide dinitrate therapy for HFrEF in those self-identified as Black or African American	Important outcome benefit and large existing gap in care	N/A
PM-13	Outpatient	CRT implantation for patients with HFrEF on guideline-directed medical therapy	Important outcome benefit and large existing gap in care	N/A
QM-2	Outpatient	Measurement of patient-reported, outcome-health status	Important outcome that is rarely measured	Best method of implementation is unclear
QM-3	Outpatient	Sustained or improved health status in heart failure	Important outcome that is rarely measured	Needs validated risk-adjustment
SM-1	Outpatient, Inpatient	Heart failure registry participation	Registries are a useful structure for measuring performance	Additional data needed to determine the impact of registry participation on quality

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor-neprilysin inhibitor; CRT, cardiac resynchronization therapy; HFrEF, heart failure with reduced ejection fraction; MRA, mineralocorticoid receptor antagonists; N/A, not applicable; PM, performance measure; QM, quality measure; and SM, structural measure.