

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (if previously endorsed): 0079

Measure Title: [Heart Failure: Left Ventricular Ejection Fraction \(LVEF\) Assessment \(Outpatient Setting\)](#)

IF the measure is a component in a composite performance measure, provide the title of the

Composite Measure here: [Click here to enter composite measure #/ title](#)

Date of Submission: [6/23/2015](#)

Instructions

- For composite performance measures:
 - A separate evidence form is required for each component measure unless several components were studied together.
 - If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.
- Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of supplemental materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Maximum of 10 pages (*includes questions/instructions*; minimum font size 11 pt; do not change margins).
Contact NQF staff if more pages are needed.
- Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](#).

Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF's evaluation criteria.

1a. Evidence to Support the Measure Focus

The measure focus is evidence-based, demonstrated as follows:

- **Health outcome:** ³ a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior.
- **Intermediate clinical outcome:** a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured intermediate clinical outcome leads to a desired health outcome.
- **Process:** ⁵ a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured process leads to a desired health outcome.
- **Structure:** a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured structure leads to a desired health outcome.
- **Efficiency:** ⁶ evidence not required for the resource use component.

Notes

3. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.

4. The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](#) and [methods](#), or Grading of Recommendations, Assessment, Development and Evaluation ([GRADE](#)) [guidelines](#).

5. Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

6. Measures of efficiency combine the concepts of resource use and quality (see NQF's [Measurement Framework: Evaluating Efficiency Across Episodes of Care](#); [AQA Principles of Efficiency Measures](#)).

1a.1. This is a measure of: (should be consistent with type of measure entered in De.1)

Outcome

- ☐ Health outcome: Click here to name the health outcome
- ☐ Patient-reported outcome (PRO): Click here to name the PRO
PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors
- ☐ Intermediate clinical outcome (e.g., lab value): Click here to name the intermediate outcome
- ☒ Process: [Assessment of left ventricular ejection fraction](#)
- ☐ Structure: Click here to name the structure
- ☐ Other: Click here to name what is being measured

HEALTH OUTCOME/PRO PERFORMANCE MEASURE *If not a health outcome or PRO, skip to 1a.3*

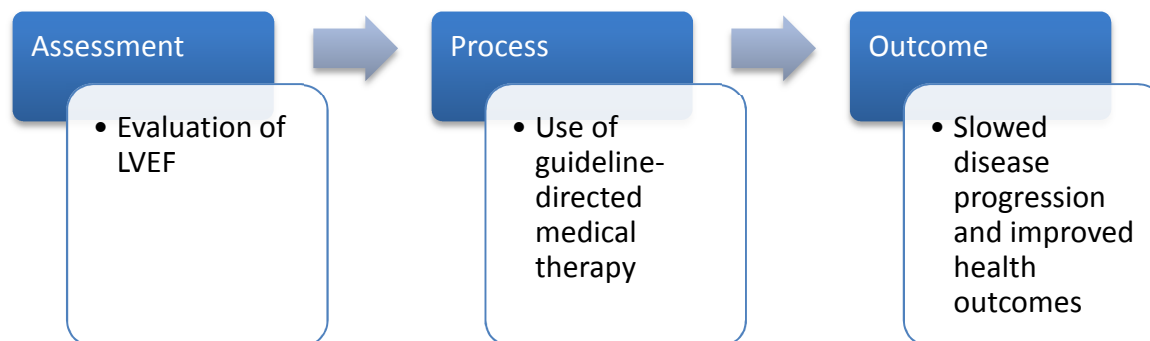
1a.2. Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.

1a.2.1. State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (i.e., influence on outcome/PRO).

Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.

INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURE

1a.3. Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes. Include all the steps between the measure focus and the health outcome.



Evaluation of LVEF in patients with heart failure provides important information that is required to appropriately direct treatment. Several pharmacologic therapies have demonstrated efficacy in slowing disease progression and improving outcomes in patients with left ventricular systolic dysfunction. LVEF assessed during the initial evaluation of patients presenting with heart failure can be considered valid unless the patient has demonstrated a major change in clinical status, experienced or recovered from a clinical event, or received therapy that might have a significant effect on cardiac function.

1a.3.1. What is the source of the systematic review of the body of evidence that supports the performance measure?

- ☒ Clinical Practice Guideline recommendation – *complete sections 1a.4, and 1a.7*
- ☐ US Preventive Services Task Force Recommendation – *complete sections 1a.5 and 1a.7*

- ☐ Other systematic review and grading of the body of evidence (e.g., *Cochrane Collaboration*, *AHRQ Evidence Practice Center*) – **complete sections 1a.6 and 1a.7**
- ☐ Other – **complete section 1a.8**

Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (including date) and **URL for guideline** (if available online):

Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Drazner MH, Fonarow GC, Geraci SA, Horwich T, Januzzi JL, Johnson MR, Kasper EK, Levy WC, Masoudi FA, McBride PE, McMurray JJV, Mitchell JE, Peterson PN, Riegel B, Sam F, Stevenson LW, Tang WHW, Tsai EJ, Wilkoff BL. 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. *J Am Coll Cardiol* 2013;62:e147–239.

<http://content.onlinejacc.org/article.aspx?articleid=1695825>

1a.4.2. Identify guideline recommendation number and/or page number and quote verbatim, the specific guideline recommendation.

2013 ACCF/AHA guideline for the management of heart failure (p. e165-166)

1. 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 I: 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 I: Level of Evidence: C**

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:

Guideline Statement # (see 1a.4.2 above)	Class of Recommendation/Level of Evidence (for definitions see 1a.4.4 below)
1	Class Ic
2	Class Ic

1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system. (Note: If separate grades for the strength of the evidence, report them in section 1a.7.)

Class of Recommendation (COR) is an estimate of the size of the treatment effect considering risks versus benefits in addition to evidence and/or agreement that a given treatment or procedure is or is not useful/effective or in some situations may cause harm.

Class I: Procedure/Treatment should be performed/administered
Class IIa: It is reasonable to perform procedure/administer treatment
Class IIb: Procedure/Treatment may be considered
Class III: No benefit (Not helpful or No proven benefit)
Class III: Harm (Excess cost w/o benefit or Harmful to patients)

Specific COR definitions are included in Table 1 below.

Table 1. Applying Classification of Recommendation and Level of Evidence

		SIZE OF TREATMENT EFFECT												
		CLASS I <i>Benefit >>> Risk</i> Procedure/Treatment SHOULD be performed/ administered	CLASS IIa <i>Benefit >> Risk</i> <i>Additional studies with focused objectives needed</i> IT IS REASONABLE to per- form procedure/administer treatment	CLASS IIb <i>Benefit ≥ Risk</i> <i>Additional studies with broad objectives needed; additional registry data would be helpful</i> Procedure/Treatment MAY BE CONSIDERED	CLASS III <i>No Benefit or CLASS III Harm</i> <table><tr><th colspan="2">Procedure/ Test</th><th>Treatment</th></tr><tr><td>COR III: No benefit</td><td>Not Helpful</td><td>No Proven Benefit</td></tr><tr><td>COR III: Harm</td><td>Excess Cost w/o Benefit or Harmful</td><td>Harmful to Patients</td></tr></table>	Procedure/ Test		Treatment	COR III: No benefit	Not Helpful	No Proven Benefit	COR III: Harm	Excess Cost w/o Benefit or Harmful	Harmful to Patients
Procedure/ Test		Treatment												
COR III: No benefit	Not Helpful	No Proven Benefit												
COR III: Harm	Excess Cost w/o Benefit or Harmful	Harmful to Patients												
ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses									
	LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies									
	LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care									
Suggested phrases for writing recommendations		should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit is not recommended is not indicated should not be performed/ administered/ other is not useful/ beneficial/ effective	COR III: Harm potentially harmful causes harm associated with excess morbidity/mortality should not be performed/ administered/ other								
Comparative effectiveness phrases†		treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B											

Note: A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective. *Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use. †For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

1a.4.5. Citation and URL for methodology for grading recommendations (if different from 1a.4.1):

ACCF/AHA Task Force on Practice Guidelines. Methodology Manual and Policies From the ACCF/AHA Task Force on Practice Guidelines. American College of Cardiology Foundation and American Heart Association, Inc. Cardiosource.com. 2010. Available at:
http://assets.cardiosource.com/Methodology_Manual_for_ACC_AHA_Writing_Committees.pdf and
http://my.americanheart.org/idc/groups/ahamah-public/@wcm/@sop/documents/downloadable/ucm_319826.pdf

1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?

☒ Yes → **complete section 1a.7**

☐ No → **report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7**

1a.5. UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

1a.5.1. Recommendation citation (including date) and URL for recommendation (if available online):

1a.5.2. Identify recommendation number and/or page number and quote verbatim, the specific recommendation.

1a.5.3. Grade assigned to the quoted recommendation with definition of the grade:

1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system. (Note: the grading system for the evidence should be reported in section 1a.7.)

1a.5.5. Citation and URL for methodology for grading recommendations (if different from 1a.5.1):

Complete section 1a.7

1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE

1a.6.1. Citation (including date) and URL (if available online):

1a.6.2. Citation and URL for methodology for evidence review and grading (if different from 1a.6.1):

Complete section 1a.7

1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE

If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.

1a.7.1. What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?

2013 ACCF/AHA Guideline for the Management of Heart Failure

This guideline covers multiple evaluation and management issues for the adult patient with Heart Failure (HF) including the assessment of left ventricular ejection fraction to enable appropriate treatment.

1a.7.2. Grade assigned for the quality of the quoted evidence with definition of the grade:

An overall grade for the quality of evidence was not assigned. Rather, the quality of a study (or set of studies) supporting a recommendation was graded on an estimate of the certainty or precision of the treatment effect (see 1a.4.3).

Recommendations used to support this measure have a Level of Evidence C: Consensus opinion of experts, case studies, or standard of care.

1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.

Level of Evidence (LOE) is an estimate of the certainty or precision of the treatment effect.

Level of Evidence A: Data derived from multiple randomized clinical trials or meta- analyses. References used to determine level of evidence must be provided and cited with the recommendation.

Level of Evidence B: Data derived from a single randomized trial, or nonrandomized studies. References used to determine level of evidence must be provided and cited with the recommendation.

Level of Evidence C: Consensus opinion of experts, case studies, or standard of care.

Specific LOE definitions are included in Table 1 in 1a.4.4.

1a.7.4. What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). **Date range: An extensive evidence review was conducted through October 2011 and includes selected other references through April 2013.**

QUANTITY AND QUALITY OF BODY OF EVIDENCE

1a.7.5. How many and what type of study designs are included in the body of evidence? (*e.g., 3 randomized controlled trials and 1 observational study*)

2013 ACCF/AHA Guideline for the Management of Heart Failure

The body of evidence supporting the recommendations on ACE/ARB therapy includes:

- 4 observational
- 1 meta-analysis
- 1 prospective multicenter cohort
- 1 retrospective cohort
- 1 review paper

1a.7.6. What is the overall quality of evidence across studies in the body of evidence? *(discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)*

2013 ACCF/AHA Guideline for the Management of Heart Failure

The recommendations for this process are rated as Level of Evidence C, meaning consensus opinion of experts, case studies, or standard of care. Additional information on the overall quality of evidence is not provided.

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1a.7.7. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? *(e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance)*

2013 ACCF/AHA Guideline for the Management of Heart Failure (p. e165)

Although a complete history and physical examination are important first steps, the most useful diagnostic test in the evaluation of patients with or at risk for HF (e.g., postacute MI) is a comprehensive 2-dimensional echocardiogram; coupled with Doppler flow studies, the transthoracic echocardiogram can identify abnormalities of myocardium, heart valves, and pericardium. Echocardiography can reveal subclinical HF and predict risk of subsequent events. Use of echocardiograms in patients with suspected HF improves disease identification and provision of appropriate medical care.

1a.7.8. What harms were studied and how do they affect the net benefit (benefits over harms)?

No harms have been identified related to the evaluation of patients with or at risk for HF. Rather, the 2013 ACCF/AHA Guideline for the Management of Heart Failure discusses whether certain testing modalities are superior to others with echocardiography being preferred “due to its widespread availability and lack of ionizing radiation” (p. e165).

UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1a.7.9. If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

One prospective study and one retrospective analysis were published after the publication of the 2013 ACCF/AHA Guideline for the Management of Heart Failure.

Note: Text below for description and results is verbatim from the article abstract.

Abbasi SA, Ertel A, Shah RV, Dandekar V, Chung J, Bhat G, Desai AA, Kwong RY, Farzaneh-Far A. Impact of cardiovascular magnetic resonance on management and clinical decision-making in heart failure patients. J Cardiovasc Magn Reson. 2013;15:89.

Description: We prospectively studied 150 consecutive patients with heart failure and an ejection fraction $\leq 50\%$ referred for CMR [Cardiovascular magnetic resonance]. Definitions for “significant clinical

impact" of CMR were pre-defined and collected directly from medical records and/or from patients. Categories of significant clinical impact included: new diagnosis, medication change, hospital admission/discharge, as well as performance or avoidance of invasive procedures (angiography, revascularization, device therapy or biopsy).

Results: Overall, CMR had a significant clinical impact in 65% of patients. This included an entirely new diagnosis in 30% of cases and a change in management in 52%. CMR results directly led to angiography in 9% and to the performance of percutaneous coronary intervention in 7%. In a multivariable model that included clinical and imaging parameters, presence of late gadolinium enhancement (LGE) was the only independent predictor of "significant clinical impact" (OR 6.72, 95% CI 2.56-17.60, $p=0.0001$).

Conclusion: CMR made a significant additive clinical impact on management, decision-making and diagnosis in 65% of heart failure patients. This additive impact was seen despite universal use of prior echocardiography in this patient group. The presence of LGE was the best independent predictor of significant clinical impact following CMR.

Liosis S, Bauer T, Schiele R, Gohlke H, Gottwik M, Katus H, Sabin G, Zahn R, Schneider S, Rauch B, Senges J, Zeymer U. Predictors of 1-year mortality in patients with contemporary guideline-adherent therapy after acute myocardial infarction: results from the OMEGA study. *Clin Res Cardiol.* 2013;102:671-7.

Description and Results: We performed a retrospective analysis of 3,782 patients surviving acute ST-elevation and non ST-elevation myocardial infarction who were enrolled in the prospective, randomized, double-blind, controlled OMEGA trial with 104 German centers. The primary objective of the OMEGA study was to determine the effect of highly purified omega-3 fatty acid ethyl esters-90 on the rate of sudden cardiac death in patients surviving AMI and receiving current guideline-adherent treatment within the 1-year of follow-up. 80.8 % of the patients received early revascularization therapy. At discharge, 94.2 % of the patients received beta-blocker, 90.4 % ACE inhibitor/angiotensin receptor blocker, 94.3 % statin, 95.4 % aspirin and 88.4 % clopidogrel. During the 1-year follow-up 139 patients (3.7 %) died. Multivariate logistic regression analysis revealed the following independent predictors of 1-year mortality in decreasing order of importance: ejection fraction <45 % [odds ratio (OR) 2.28, 95 % confidence interval (CI) 1.53-3.41], age ≥ 70 years (OR 2.17, 95 % CI 1.42-3.32), no acute revascularization (OR 2.02, 95 % CI 1.33-3.08), prior stroke/transient ischemic attack (OR 1.90, 95 % CI 1.09-3.30), peripheral arterial disease (OR 1.86, 95 % CI 1.12-3.10), heart rate >85 /min (OR 1.82, 95 % CI 1.23-2.71), chronic obstructive lung disease (OR 1.77, 95 % CI 1.01-3.10) and HDL cholesterol <40 mg/dl (OR 1.75, 95 % CI 1.15-2.67).

Conclusion: In patients surviving AMI and treated with contemporary guideline-adherent therapy, 1-year mortality was low. Nevertheless, traditional risk factors such as ejection fraction <45 %, older age, no acute revascularization and comorbidities were the strongest predictors of long-term mortality supporting the findings from previous studies.

Impact on conclusions of systematic review: Both articles further support the assessment of ejection fraction to enable appropriate guideline-directed medical treatment.

1a.8 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.8.1 What process was used to identify the evidence?

1a.8.2. Provide the citation and summary for each piece of evidence.