COMPOSITE MEASURE SUBMISSION FORM

Version: 1.0; Generated: 13 April 2023

Introduction

Thank you for your interest in submitting a measure to Battelle for possible endorsement.

What criteria are used to evaluate measures? Measures are evaluated on standardized criteria: importance to measure and report, scientific acceptability of measure properties, feasibility, usability and use, and related and competing measures. For your measure to be evaluated against these measure evaluation criteria, you must complete the measure submission form.

Why do I have to complete a form? Due to the volume and/or complexity of proposed measures, Battelle provides measure information to committee reviewers in a standardized format to facilitate their evaluation of whether the measure meets the measure evaluation criteria. This form allows the measure steward to present information demonstrating that the proposed measure meets endorsement criteria.

What is on the form? The information requested in this form is directly related to the measure evaluation criteria.

Can't I just submit our files for consideration? No. Measures must be submitted through the online form to be considered for the Spring 2023 cycle. Requested information should be entered directly into this form and as well as any necessary or required attachments.

Can I submit additional details and materials? Additional materials will be considered only as supplemental. Do NOT rely on material provided in an appendix to provide measure specifications or to demonstrate meeting the criteria. The core information needed to evaluate the measure should be provided in the appropriate submission form fields and required attachments. Please contact PQMsupport@battelle.org regarding questions about submitting supplemental materials.

What do I do first? If you have started a new submission by answering five qualifying questions, you may proceed to the “Previous Submission Information" tab to continue with your submission. The “Conditions” tab will list the conditions that must be met before your proposed measures may be considered and evaluated for suitability as endorsed voluntary consensus standards. You are asked to acknowledge reading and

accepting the conditions.

Can I make changes to a form once I have submitted it? No. Once you submit your measure, you will NOT be able to return to this submission form to make further revisions. You will need to contact project staff.

What if I need additional help? Please contact the project staff at PQMsupport@battelle.org if you have questions regarding the information requested or submitting supplemental materials.

NOTE: All measure submissions should be 508-compliant. Refer to the Checklist for Developer 508 Guidelines (PDF) to ensure all guidelines apply to all parts of your submission, including all fields and attachments used within the measure submission form.

Please email us at PQMsupport@battelle.org if you experience technical difficulties using the online submission form.

Thank you for your interest in submitting measures to Battelle.

Previous Submission Information (1 - 4)

1) Select whether this measure was previously submitted to the prior consensus-based entity (the National Quality Forum [NQF]) and given an identifying number

☐ Previously submitted to NQF
☒ New measure, never submitted.

2) Provide the measure number of the previously submitted measure.

3) If the measure has an electronic clinical quality measure (eCQM) version, provide the measure number of the previously submitted measure.
N/A

4) If this eCQM has a registry version, provide the measure numbers of the previously submitted measure.

N/A

Conditions (1 - 2)

Several conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards. If any of the conditions are not met, the measure will not be accepted for consideration.

A. A Measure Steward Agreement is signed or the steward is a government organization. (All non-government organizations must sign a Measure Steward Agreement.) For more information about completing a Measure Steward Agreement, please go to: Endorsement | Partnership for Quality Measurement (p4qm.org) and follow the instructions.

B. The measure owner/steward verifies there is an identified responsible entity and a process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every three years.

C. The intended use of the measure includes both accountability applications (including public reporting) and performance improvement to achieve high-quality, efficient healthcare.

D. The measure is fully specified and tested for reliability and validity.

E. The measure developer/steward attests that harmonization with related measures and issues with competing measures have been considered and addressed, as appropriate.

F. The requested measure submission information is complete and responsive to the questions so that all the information needed to evaluate all criteria is provided.

1) Check if either of the following apply.

☐ Proprietary measure or components (e.g., risk model, codes)

☒ Proprietary measure or components with fees

☐ None of the above

2) Check the box below to agree to the conditions listed above.

☒ I have read and accept the conditions as specified above

Specifications: Maintenance Update (spma.01 - spma.02)

spma.01) Indicate whether there are changes to the specifications since the last updates/submission. If yes, update the specifications in the Measure Specifications section of the Measure Submission Form, and explain your reasoning for the changes below.

☒ No

☐ Yes

spma.02) Briefly describe any important changes to the measure specifications since the last measure update and provide a rationale.

For annual updates, please explain how the change in specifications affects the measure results. If a material change in specification is identified, data from re-testing of the measure with the new specifications is required for early maintenance review.

For example, specifications may have been updated based on suggestions from a previous measure endorsement review.

N/A. This is a new measure.

Measure Specifications (sp.01 - sp.32)

sp.01) Provide the measure title.

Measure titles should be concise yet convey who and what is being measured.

Quality of Care Composite for Implantable Cardioverter-Defibrillator (ICD)/Cardiac Resynchronization Therapy Defibrillator (CRT-D)

sp.02) Provide a brief description of the measure.

Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).

This measure is an all-or-none composite of the number of patients following an ICD/CRT-D implant procedure who received prescriptions for all medications (Angiotensin-converting enzyme inhibitors (ACE-I)/ Angiotensin receptor blockers (ARB)/ Angiotensin receptor-neprilysin inhibitors (ARNI) and beta blockers) for which they are eligible at discharge and those patients with procedures that fulfill class I, IIa, or IIb guideline indication for device implantation.

sp.03) Provide a rationale for why this measure must be reported with other measures to appropriately interpret results.

This composite measure is intended to assess the extent to which eligible patients receive evidence-based medications that are indicated at hospital discharge following ICD placement and to assess the proportion of eligible patients that meet class I, IIa or IIb guideline indications. By providing a composite score, this measure will allow hospitals to interpret their quality performance score more easily. This single score can be used in the NCDR voluntary hospital public reporting program which monitors the quality of cardiovascular care using high quality data that provides actionable insights.

sp.04) Check all the clinical condition/topic areas that apply to your measure, below.

☒ Cardiovascular
☒ Cardiovascular: Arrythmia

sp.05) Check all the non-condition specific measure domain areas that apply to your measure, below.

☐ Access to Care
☒ Care Coordination

☐ Care Coordination: Readmissions
☐ Care Coordination: Transitions of Care
☐ Disparities Sensitive
☐ Health and Functional Status
☐ Health and Functional Status: Change
☐ Health and Functional Status: Nutrition
☐ Health and Functional Status: Obesity
☐ Health and Functional Status: Physical Activity
☐ Health and Functional Status: Quality of Life
☐ Health and Functional Status: Total Health
☐ Immunization
☐ Other (please specify here:)
☐ Person-and Family-Centered Care: Person-and Family-Centered Care
☐ Person-and Family-Centered Care: Workforce
☐ Primary Prevention
☐ Primary Prevention: Nutrition
☐ Primary Prevention: Tobacco Use
☒ Safety
☐ Safety: Complications
☐ Safety: Healthcare Associated Infections
☐ Safety: Medication
☐ Safety: Overuse
☐ Screening

sp.06) Select one or more target population categories.

Select only those target populations which can be stratified in the reporting of the measure's result.

☒ Adults (Age >= 18)
☐ Children (Age < 18)
☐ Elderly (Age >= 65)
☐ Populations at Risk: Dual eligible beneficiaries of Medicare and Medicaid
☐ Populations at Risk: Individuals with multiple chronic conditions
☐ Populations at Risk: Veterans
☐ Women

sp.07) Select the levels of analysis that apply to your measure.

Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.

☐ Accountable Care Organization
☐ Clinician: Group/Practice
☐ Clinician: Individual
☒ Facility
☐ Health Plan
☐ Integrated Delivery System
☐ Other (please specify here:)
☐ Population: Community, County or City
☐ Population: Regional and State

sp.08) Indicate the care settings that apply to your measure.

Check ONLY the settings for which the measure is SPECIFIED and TESTED.

☐ Ambulatory Care
☐ Behavioral Health
☐ Home Care
☒ Inpatient/Hospital
☐ Other (please specify here:)
☐ Outpatient Services
☐ Post-Acute Care

sp.09) Provide a Uniform Resource Locator (URL) link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials.

Do not enter a URL linking to a home page or to general information. If no URL is available, indicate "none available".

None available. A measure companion guide is provided for all facilities participating in the Electrophysiology Device Implant (EPDI) Registry.

sp.10) Indicate whether Health Quality Measure Format (HQMF) specifications are attached.

Attach the zipped output from the measure authoring tool (MAT) for eCQMs - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications). HQMF specifications are attached.

☒ HQMF specifications are NOT attached (Please explain). This is not an eCQM

sp.11) Attach the simulated testing attachment.

All eCQMs require a simulated testing attachment to confirm that the HTML output from Bonnie testing (or testing of some other simulated data set) includes 100% coverage of measured patient population testing, with pass/fail test cases for each sub-population. This can be submitted in the form of a screenshot.

☐ Testing is attached
☒ Testing is NOT attached (please explain)
This is not an eCQM

sp.12) Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.

Attach an excel or csv file; if this poses an issue, contact staff at PQMsupport@battelle.org. Provide descriptors for any codes. Use one file with multiple worksheets, if needed.

☐ Available in attached Excel or csv file
☒ No data dictionary/code table – all information provided in the submission form

Please respond to the following questions about the numerator, denominator, and exclusions to describe the composite measure, as opposed to the individual component measures.

sp.13) State the numerator.

Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome).

DO NOT include the rationale for the measure.

Generator patients:

- Who receive all medications for which they are eligible:
    - ACE/ARB/ARNI prescribed at discharge (if eligible for ACE/ARB/ARNI as described in denominator) **AND**
    - Beta blockers prescribed at discharge (if eligible for beta blockers as described in denominator)

AND

- Whose procedures fulfill class I, IIa, or IIb guideline indications

sp.14) Provide details needed to calculate the numerator.

All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

For generator patients who receive all medications for which they are eligible:

ACE/ARB/ARNI

1. If eligible for ACE/ARB/ARNI and given, then code “Yes”
2. If eligible for ACE/ARB/ARNI but contraindicated, then code “No – medical reason” or "No – patient reason”
3. If eligible for ACE/ARB/ARNI and not given, then code “No, no reason”
4. If any “No, no reason” present, then the performance is not met. Otherwise, the performance is met.

Beta Blocker

1. If eligible for beta blocker and given, then code “Yes”
2. If eligible for beta blocker but contraindicated, then code “No – medical reason” or "No – patient reason”
3. If eligible for beta blocker and not given, then code “No, no reason”.
4. If any “No, no reason” present, then the performance is not met. Otherwise, the performance is met.

Note: Contraindicated and those participating in blinded studies are considered performance met. There are technically no exclusions or exceptions that would remove patients from the denominator.

AND

For generator patients whose procedures fulfill class I, IIa, or IIb guideline indications.

Guideline indications:

The 2008 ACC/AHA/HRS Guidelines and 2012 ACCF/AHA/HRS Focused Update for device-based therapy of cardiac rhythm abnormalities provides recommendations for ICD therapy for secondary prevention of sudden cardiac death, for primary prevention of sudden cardiac death, and for children, adolescents, and patients with congenital heart disease.

Class I guidelines indicate that the estimated size of treatment effect is significantly higher than the estimated risk of the therapy, and the treatment "should be administered". The weight of the evidence identified to support these recommendations is ranked as either Level A (multiple supporting randomized trials or meta-analyses) or Level B (evidence from single randomized trial or nonrandomized studies).

Class IIa guidelines indicate that the estimated benefit of therapy is greater than the estimated risk of therapy and that it is "reasonable to perform procedure/administer treatment" but additional studies with focused objectives are needed. The weight of the evidence identified to support these recommendations is ranked as either Level of Evidence: B (evidence from single randomized trial or nonrandomized studies) or Level of Evidence: C (only expert opinion, case studies, or standard of care to support the recommendation).

Class IIb guidelines indicate that the estimated benefit of the therapy is greater than or equal to the estimated risk of the therapy, and that the "procedure/treatment may be considered", but additional studies with broad objectives are needed. The weight of the evidence identified to support these recommendations is ranked as either Level of Evidence: B (evidence from single randomized trial or nonrandomized studies) or Level of Evidence: C (only expert opinion, case studies, or standard of care to support the recommendation).

- Tracy CM, Epstein AE, Darbar D, et al. 2012 ACCF/AHA/HRS focused update of the 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2012;60:1297– 131

Note: Patients participating in blinded studies are considered performance met. There are technically no exclusions or exceptions that would remove patients from the denominator.

sp.15) State the denominator.

Brief, narrative description of the target population being measured.

All generator patients who survived to discharge and meet the criteria for the individual metrics in the composite.

sp.16) Provide details needed to calculate the denominator.

All information required to identify and calculate the target population/denominator such

as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

All generator patients surviving hospitalization

To be included in the medication metric, patients must be eligible to receive any one of the two medication classes:

1. ACE-I/ARB/ARNI: Patients who have an ejection fraction (EF) of <40% OR
2. Beta blockers: EF<40% AND/OR Previous myocardial infarction

sp.17) Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

None

sp.18) Provide details needed to calculate the denominator exclusions.

All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

N/A

sp.19) Provide all information required to stratify the measure results, if necessary.

Include the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate. Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format in the Data Dictionary field.

N/A

sp.20) Is this measure adjusted for socioeconomic status (SES)?

☐ Yes

☒ No

sp.21) Select the risk adjustment type.

Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section.

☒ No risk adjustment or risk stratification
☐ Statistical risk model
☐ Stratification by risk category/subgroup (specify number of risk factors)
☐ Other approach to address risk factors (please specify here:)

sp.22) Select the most relevant type of score.

Attachment: If available, please provide a sample report.

☐ Categorical, e.g., yes/no
☐ Continuous variable, e.g. average
☐ Count
☐ Frequency Distribution
☐ Non-weighted score/composite/scale
☐ Other (please specify here:)
☒ Rate/proportion
☐ Ratio
☐ Weighted score/composite scale

sp.23) Select the appropriate interpretation of the measure score.

Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score

☒ Better quality = Higher score
☐ Better quality = Lower score
☐ Better quality = Score within a defined interval
☐ Passing score defines better quality

sp.24) Diagram or describe the calculation of the measure score as an ordered sequence of steps.

Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.

The EPDI Quality Composite is comprised of two equally weighted process measures, which contribute to the overall hospital quality composite score. The composite score ranges from 0-100, with a higher score indicative of better quality. These measures are:

EPDI Registry metric 14: Discharge Medication (ACE/ARB/ARNI/Beta Blockers) in eligible ICD/CRT-D Implant patients. NQF endorsed # 0965

EPDI Registry metric 25: Proportion of ICD/CRT-D patients that fulfill class I, IIa or IIb guideline indications.

Target population: ICD/CRT-D implant patients

Time period of data: Both are derived from facility-level metric performance rates and are reported as a rolling four quarter value.

Eligibility criteria: To report a composite, sites must contribute to both metrics. Additionally, if there are no eligible cases within a metric, the hospital is not eligible to be included in the composite metric. The minimum number of cases to be eligible for this measure is n=11. A sample size of 11 is the standard volume exclusion used in the EPDI registry measures and metrics. In analysis of 2019 data, only 6.0% sites were excluded (n=52).

Diagram 1: Measure score calculation

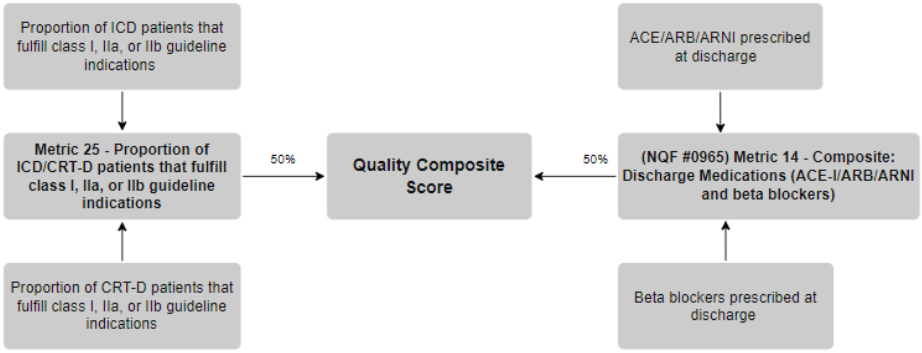


Diagram description: This diagram depicts how each component measure feeds into the quality composite score.

sp.25) Indicate the responder for your instrument.

☐ Patient
☐ Family or other caregiver
☒ Clinician
☐ Other (specify)

sp.26) Attach a copy of the instrument (e.g. survey, tool, questionnaire, scale) used as a data source for your measure, if available.

☒ Copy of instrument is attached.
☐ Copy of instrument is NOT attached (please explain).

sp.27) If measure testing is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.

Examples of samples used for testing:

- *Testing may be conducted on a sample of the accountable entities (e.g., hospital, physician). The analytic unit specified for the particular measure (e.g., physician, hospital, home health agency) determines the sampling strategy for scientific acceptability testing.*

- *The sample should represent the variety of entities whose performance will be measured. The samples used for reliability and validity testing often have limited generalizability because measured entities volunteer to participate. Ideally, however, all types of entities whose performance will be measured should be included in reliability and validity testing.*

- *The sample should include adequate numbers of units of measurement and adequate numbers of patients to answer the specific reliability or validity question with the chosen statistical method.*

- *When possible, units of measurement and patients within units should be randomly selected.*

N/A

Sp.28) Identify whether and how proxy responses are allowed.

N/A

Sp.29) Survey/Patient-reported data.

Provide instructions for data collection and guidance on minimum response rate. Specify calculation of response rates to be reported with performance measure results.

N/A

Sp.30) Provide the data collection instrument.

☒ Available at measure-specific web page URL identified in sp.09
☒ Available in attached appendix in Question 1 of the Additional Section
☐ No data collection instrument provided

sp.31) Select only the data sources for which the measure is specified.

☒ Registry Data

sp.32) Describe the component measures and composite construction.

Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.

Component measures:

1. EPDI Registry Metric # 14: (NQF #0965) Discharge Medications (ACE/ARB/ARNI and beta blockers) in Eligible ICD/CRT-D Implant Patients

2. EPDI Registry Metric # 25: Proportion of ICD/CRT-D patients that fulfill class I, IIa or IIb guideline indications

Aggregation rules and weighting rules:

Each measure is weighted equally within the composite measure. Data is aggregated on a rolling four quarter basis with results returned to participating sites on their facility NCDR dashboard as quarterly rates, hospital rates and a national rate. The participants' dashboards aggregate weekly to allow data to be reviewed for accuracy prior to the formal quarterly aggregation that establishes the national benchmark. The report allows participating sites to see improvement or decline in their level of care and allows for comparison against a national aggregate that includes all participating sites.

Handling of missing data:

The Data Quality Report (DQR) consists of registry-specific algorithms that require predetermined levels of completeness and consistency for submitted data fields. Before entering the Enterprise Data Warehouse (EDW), all submissions are scored for file integrity and data completeness, receiving 1 of 3 scores that are transmitted back to facilities using a color-coded scheme. A "red light" means that a submission has failed because of file integrity problems such as excessive missing data and internally inconsistent data. Such data are not processed or loaded into the EDW. A "yellow light" status means that a submission has passed the integrity checks but failed in completeness according to predetermined thresholds. Such data are processed and loaded into the EDW but are not included in any registry aggregate computations until corrected. Facilities are notified about data submission problems and are provided with an opportunity to resubmit data. Finally, a "green light" means that a submission

has passed all integrity and quality checks. Such submissions are loaded to the EDW. After passing the DQR, data are loaded into a common EDW that houses data from all registries and included for all registry aggregate computations. In a secondary transaction process, data are loaded into registry-specific, dimensionally modeled data mart.

The predetermined data element thresholds for data elements specific to the Performance Measures is established at 95 % to 100%. Data completeness is required to pass the NCDR Data Quality Report and have their data accepted into the registry wide aggregation. Thus, missing data relevant to these performance measures is not acceptable in the majority of scenarios. In the rare scenario of a missing data point, the concept will be documented as “No” or “not meeting numerator” and “performance not met”.

Standardizing scales across component measures:

There are no scales or outcome measures within the composite. The component parts are all process measures with equal weights associated.

Required sample sizes:

The minimum sample size to be eligible for the composite measure is 11 patients. There is no sampling of patient data allowed within the Electrophysiology Device Implant Registry.

Importance to Measure and Report: Maintenance of Endorsement (1ma.01)

1ma.01) Indicate whether there is new evidence about the measure since the most recent maintenance evaluation. If yes, please briefly summarize the new evidence, and ensure you have updated entries in the Evidence section as needed.

☒ Yes
☐ No

Importance to Measure and Report: Evidence (1a.01 - 1a.18)

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Measure and Report: Evidence section. For example:

Current Submission:

Updated evidence information here.

Previous (Year) Submission:

Evidence from the previous submission here.

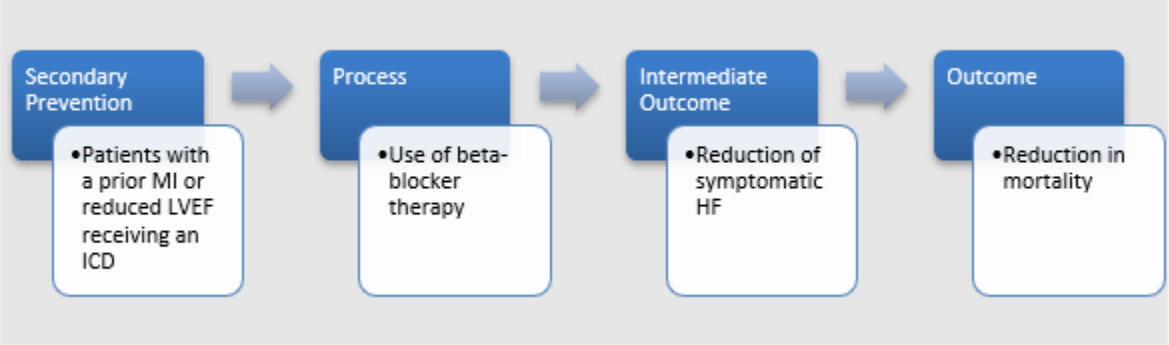
Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All sub-criteria must be met to pass this criterion.

Please include individual entries for each component measure, unless several components were studied together. If a component measure is submitted as an individual performance measure, complete the evidence section as part of that individual measure submission.

1a.01) Provide a logic model.

Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Diagram 2: Logic model – beta blockers



Beta-blockers reduce morbidity, mortality, and hospitalizations in patients who had a prior myocardial infarction (MI).

1a.02) If this measure is derived from patient report, provide evidence that the target population values the measured outcome, process, or structure and finds it meaningful. Otherwise, enter "N/A."

Describe how and from whom input was obtained.
N/A

1a.03) If this measure is derived from intermediate outcome, process, or structure performance measures, including those that are instrument-based, select the type of source for the systematic review of the body of evidence that supports the performance measure. Otherwise, select "N/A."

A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data.

☒ Clinical Practice Guideline recommendation (with evidence review)
☐ US Preventive Services Task Force Recommendation
☐ Other systematic review and grading of the body of evidence (e.g., Cochrane Collaboration, AHRQ Evidence Practice Center)
☐ Other (please specify here:)
☐ N/A

If the evidence is not based on a systematic review, skip to the end of the section and do not complete the repeatable question group below. If you wish to include more than one systematic review, you may add additional tables to the relevant sections. Please follow the 508 Checklist for tables.

Evidence - Systematic Reviews Table (Repeatable)

1a.04) Provide the title, author, date, citation (including page number) and URL for the systematic review.

Heidenreich PA, Bozkurt B, Aguilar D, Allen LA, Byun JJ, Colvin MM, Deswal A, Drazner MH, Dunlay SM, Evers LR, Fang JC, Fedson SE, Fonarow GC, Hayek SS, Hernandez AF, Khazanie P, Kittleson MM, Lee CS, Link MS, Milano CA, Nnacheta LC, Sandhu AT, Stevenson LW, Vardeny O, Vest AR, Yancy CW. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of

Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2022;79:e263–e421.

https://doi.org/10.1016/j.jacc.2021.12.012

Al-Khatib SM, Stevenson WG, Ackerman MJ, Bryant WJ, Callans DJ, Curtis AB, Deal BJ, Dickfeld T, Field ME, Fonarow GC, Gillis AM, Granger CB, Hammill SC, Hlatky MA, Joglar JA, Kay GN, Matlock DD, Myerburg RJ, Page RL. 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 Foundation/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol 2018;72:e91–220.
http://www.onlinejacc.org/content/accj/72/14/e91.full.pdf?_ga=2.238225088.1385433901.1570125164-1634948755.1534437338

Amsterdam EA, Wenger NK, Brindis RG, Casey DE Jr, Ganiats TG, Holmes DR Jr, Jaffe AS, Jneid H, Kelly RF, Kontos MC, Levine GN, Liebson PR, Mukherjee D, Peterson ED, Sabatine MS, Smalling RW, Zieman SJ. 2014 AHA/ACC guideline for the management of patients with non–ST-elevation acute coronary syndromes: a report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2014;64:e139–228.
http://content.onlinejacc.org/article.aspx?articleid=1910086

O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2013;61:e78–140, doi:10.1016/j.jacc.2012.11.019.
http://content.onlinejacc.org/article.aspx?articleid=1486115

Fihn SD, Gardin JM, Abrams J, Berra K, Blankenship JC, Dallas AP, Douglas PS, Foody JM, Gerber TC, Hinderliter AL, King SB III, Kligfield PD, Krumholz HM, Kwong RYK, Lim MJ, Linderbaum JA, Mack MJ, Munger MA, Prager RL, Sabik JF, Shaw LJ, Sikkema JD, Smith CR Jr, Smith SC Jr, Spertus JA, Williams SV. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. J Am Coll Cardiol 2012;60:e44–164.
http://content.onlinejacc.org/article.aspx?articleid=1391404

Smith SC Jr., Benjamin EJ, Bonow RO, Braun LT, Creager MA, Franklin BA, Gibbons RJ, Grundy SM, Hiratzka LF, Jones DW, Lloyd-Jones DM, Minissian M, Mosca L, Peterson ED, Sacco RL, Spertus J, Stein JH, Taubert KA. AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update: a guideline from the American Heart

Association and American College of Cardiology Foundation. Circulation. 2011: published online before print November 3, 2011, 10.1161/CIR.0b013e318235eb4d. http://content.onlinejacc.org/article.aspx?articleid=1147807

1a.05) Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines (p. e295, e305)

- In patients with a recent or remote history of MI or acute coronary syndrome (ACS) and LVEF <=40%, evidence-based beta blockers should be used to reduce mortality. **Class: 1 Level of Evidence: B-R**

- In patients with HFrEF, with current or previous symptoms, use of 1 of the 3 beta blockers proven to reduce mortality (e.g., bisoprolol, carvedilol, sustained-release metoprolol succinate) is recommended to reduce mortality and hospitalizations. **Class: 1 Level of Evidence: A**

2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death (p. e116)

- In patients with HFrEF (LVEF ≤40%), treatment with a beta blocker, a mineralocorticoid receptor antagonist and either an angiotensin-converting enzyme inhibitor, an angiotensin-receptor blocker, or an angiotensin receptor-neprilysin inhibitor is recommended to reduce SCD and all-cause mortality. **Class I: Level of Evidence: A**

2014 AHA/ACC guideline for the management of patients with non–ST-elevation acute coronary syndromes (p. e 159)

- In patients with concomitant NSTE-ACS, stabilized HF, and reduced systolic function, it is recommended to continue beta-blocker therapy with 1 of the 3 drugs proven to reduce mortality in patients with HF: sustained-release metoprolol succinate, carvedilol, or bisoprolol. **Class I: Level of Evidence: C**

2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction (p. e104)

- Beta blockers should be continued during and after hospitalization for all patients with STEMI and with no contraindications to their use. **Class I: Level of Evidence: B**

2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease (p. e96)

- Beta-blocker therapy should be started and continued for 3 years in all patients with normal LV function after MI or ACS. **Class I: Level of Evidence: B**

- Beta-blocker therapy should be used in all patients with LV systolic dysfunction (EF <40%) with heart failure or prior MI, unless contraindicated. (Use should be limited to carvedilol, metoprolol succinate, or bisoprolol, which have been shown to reduce risk of death.). **Class I: Level of Evidence: A**

AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update (p. e2435)

- Beta-blocker therapy should be used in all patients with left ventricular systolic dysfunction (ejection fraction <40%) with heart failure or prior myocardial infarction, unless contraindicated. (Use should be limited to carvedilol, metoprolol succinate, or bisoprolol, which have been shown to reduce mortality.) **Class I: Level of Evidence: A**
- Beta-blocker therapy should be started and continued for 3 years in all patients with normal left ventricular function who have had myocardial infarction or ACS. **Class I: Level of Evidence: B**

1a.06) Provide the grade assigned to the evidence associated with the recommendation and include the definition of the grade.

For guidelines released prior to 2015:
The weight of the evidence in support of most of the recommendations included are rated as Level A, Level B and Level C, as noted following each statement. Level A evidence refers to "Data derived from multiple randomized clinical trials or meta-analyses." The weight of the evidence in support of additional recommendations is rated as Level B and C. Level B evidence refers to "Data derived from a single randomized trial, or nonrandomized studies" while Level C evidence refers to "Only consensus opinion of experts, case studies, or standard-of-care."

For guidelines released from 2015 forward:
The weight of the evidence in support of most of the recommendations included are rated as Level A, Level B-R, Level B-NR, Level C-LD and Level C-EO, as noted following each statement. Level A evidence refers to high quality evidence from more than one randomized control trial (RCT), meta analyses of high-quality RCTs, and/or one or more RCTs corroborated by high-quality registry studies. Level B-R evidence refers to moderate-quality evidence from one or more RCTs and/or meta-analyses of moderate-quality RCTs and Level B-NR evidence includes moderate quality evidence from one or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies and/or meta-analyses of such studies. Level C-LD refers to randomized or nonrandomized observational or registry studies with limitation of design or execution, meta-analyses of such studies, and/or physiological or mechanistic studies in human subjects. Level C-EO refers to consensus of expert opinion based on clinical experience.

1a.07) Provide all other grades and definitions from the evidence grading system.

See question above and next two questions below for more information.

1a.08) Provide the grade assigned to the recommendation, with definition of the grade.

The recommendations included have been assigned a Class I recommendation.

For guidelines released prior to 2015:
Class I recommendations refer to “Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.”

For guidelines released from 2015 forward:
Class I recommendations are “strong and indicate that the treatment, procedure, or intervention is useful and effective and should be performed or administered for most patients under most circumstances.”

1a.09) Provide all other grades and definitions from the recommendation grading system.

For guidelines released prior to 2015:
ACCF/AHA guideline methodology categorizes indications as class I, II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows and noted in the table below:

Classification Types:
Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.
Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

- IIa: Weight of evidence/opinion is in favor of usefulness/efficacy
- IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.

- No Benefit- Procedure/Test not helpful or Treatment w/o established proven benefit
- Harm- Procedure/Test leads to excess cost w/o benefit or is harmful, and or Treatment is harmful

Additional detail regarding the classification of recommendation and level of evidence is

provided in the following figure.

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

CLASS (STRENGTH) OF RECOMMENDATION	
CLASS 1 (STRONG)	**Benefit >>> Risk**
Suggested phrases for writing recommendations: • Is recommended • Is indicated/useful/effective/beneficial • Should 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	
CLASS 2a (MODERATE)	**Benefit >> Risk**
Suggested phrases for writing recommendations: • Is reasonable • Can be useful/effective/beneficial • Comparative-Effectiveness Phrases†: - Treatment/strategy A is probably recommended/indicated in preference to treatment B - It is reasonable to choose treatment A over treatment B	
CLASS 2b (WEAK)	**Benefit ≥ Risk**
Suggested phrases for writing recommendations: • May/might be reasonable • May/might be considered • Usefulness/effectiveness is unknown/unclear/uncertain or not well- established	
CLASS 3: No Benefit (MODERATE) (Generally, LOE A or B use only)	**Benefit = Risk**
Suggested phrases for writing recommendations: • Is not recommended • Is not indicated/useful/effective/beneficial • Should not be performed/administered/other	
CLASS 3: Harm (STRONG)	**Risk > Benefit**
Suggested phrases for writing recommendations: • Potentially harmful • Causes harm • Associated with excess morbidity/mortality • Should not be performed/administered/other	

LEVEL (QUALITY) OF EVIDENCE‡	
LEVEL A	
• High-quality evidence‡ from more than 1 RCT • Meta-analyses of high-quality RCTs • One or more RCTs corroborated by high-quality registry studies	
LEVEL B-R	**(Randomized)**
• Moderate-quality evidence‡ from 1 or more RCTs • Meta-analyses of moderate-quality RCTs	
LEVEL B-NR	**(Nonrandomized)**
• Moderate-quality evidence‡ from 1 or more well-designed, well- executed nonrandomized studies, observational studies, or registry studies • Meta-analyses of such studies	
LEVEL C-LD	**(Limited Data)**
• Randomized or nonrandomized observational or registry studies with limitations of design or execution • Meta-analyses of such studies • Physiological or mechanistic studies in human subjects	
LEVEL C-EO	**(Expert Opinion)**
• Consensus of expert opinion based on clinical experience	

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

† 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 of the treatments or strategies being evaluated.

‡ The method of assessing quality is evolving, including the application of standardized, widely-used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

For guidelines released from 2015 forward:

In 2015, the ACC and AHA updated Classes of Recommendation (COR) and Levels of Evidence (LOE) in an effort to align patient care with scientific evidence.

The COR reflects the magnitude of benefit over risk and corresponds to the strength of the recommendation. Class I recommendations are strong and indicate that the treatment, procedure, or intervention is useful and effective and should be performed or administered for most patients under most circumstances. Class II recommendations are weaker, denoting a lower degree of benefit in proportion to risk. Benefit is generally greater for Class IIa (moderate) recommendations and smaller for Class IIb (weak) recommendations, for which benefit only

marginally exceeds risk. A COR of IIb suggests that implementation should be selective and based on careful consideration of individual patient factors and, for invasive procedures, available expertise. Class III is assigned when actions are specifically not recommended, either because studies have found no evidence of benefit or because the intervention causes harm.

1a.10) Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

All but one of the recommendations for this process is rated as Level of Evidence A or B, meaning that the data was derived from one or more RCTs or meta-analyses. Additional information on the overall quality of evidence across the RCTs is not provided; although, two of the cited guidelines discuss the evidence supporting the use of beta blockers in this population, which is provided below.

2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines (p. e296, e305-306)

p. e296:

Current evidence supports the use of beta blockers to improve adverse cardiac remodeling and outcomes in patients with asymptomatic reduced LVEF after MI. Among patients with a recent MI and reduced LVEF, carvedilol reduced maladaptive remodeling and reduced mortality compared with placebo. Among patients with asymptomatic LV systolic dysfunction in the SOLVD prevention trial (which included 80% with previous MI) and the SAVE (Survival and Ventricular Enlargement) trial, secondary analyses showed that the administration of beta blockers in addition to ACE-I reduced mortality and hospitalization.

p. e305-306:

Three beta blockers have been shown to be effective in reducing the risk of death in patients with HFrEF: bisoprolol, sustained-release metoprolol (succinate), and carvedilol. The favorable findings with these 3 agents, however, should not be considered a beta-blocker class effect in HFrEF. Other beta blockers are not included in this recommendation for use. Even when asymptomatic, or when symptoms are mild or improve with other therapies, beta-blocker therapy is important and should not be delayed until symptoms return or disease progression is documented. Data show that beta blockers can be safely initiated before hospital discharge, provided patients are clinically stabilized and do not require intravenous inotropic therapy for HF. If a contraindication or intolerance are noted, they should be documented, and the patient restarted on beta-blocker therapy in the future, so long as an absolute contraindication is not present. Even if symptoms or LVEF improve, long-term treatment with beta blockers and use of target doses should be maintained to reduce the risk of progression in LV dysfunction or major cardiovascular events. Abrupt withdrawal of beta-blocker therapy can lead to clinical deterioration and should be avoided unless indicated.

Multiple analyses have shown the high value of beta-blocker therapy among HF patients. A model-based analysis, using generic beta-blocker costs, found beta-blocker therapy was high value. These results were consistent with earlier model-based cost-effectiveness analyses and a trial-based economic analysis of the U.S. Carvedilol Heart Failure (CHF) Trials Program. Each of these studies also found treatment with a beta blocker was high value despite using previously higher beta-blocker costs.

2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death (p. e116):

RCTs in patients with HFrEF have consistently demonstrated that chronic therapy with beta blockers reduces all-cause mortality, VA, and SCD (S5.2-2,S5.2-4, S5.2-5,S5.2-9). Three beta blockers (i.e., bisoprolol, carvedilol, sustained-release metoprolol succinate) have been proven to reduce mortality in patients with current or prior symptoms of HFrEF without beta-blocker contraindications.

2013 ACCF/AHA Guideline for the Management of Heart Failure (p. e169-170, 176, 195)
The body of evidence supporting the recommendations on beta-blocker therapy for patients with LVSD in this guideline includes 7 randomized controlled trials.

p. e170:
CAD is a major risk factor for the development of HF and a key target for prevention of HF. The 5-year risk of developing HF after acute MI is 7% and 12% for men and women, respectively; for men and women between the ages of 40 and 69 and those >70 years of age, the risk is 22% and 25%, respectively (51). Current evidence supports the use of ACE inhibitors and (to a lower level of evidence) beta-blocker therapy to impede maladaptive LV remodeling in patients with stage B HF and low LVEF to improve mortality and morbidity (344).

In 1 study, losartan reduced adverse outcomes in a population with hypertension (357), and in another study of patients post-MI with low LVEF, valsartan was equivalent to captopril (345). Data with beta blockers are less convincing in a population with known CAD, although in 1 trial (346) carvedilol therapy in patients with stage B and low LVEF was associated with a 31% relative risk reduction in adverse long-term outcomes. In patients with previously established structural heart disease, the administration of agents known to have negative inotropic properties such as non-dihydropyridine calcium channel blockers and certain antiarrhythmics should be avoided.

p. e176:

Three beta blockers have been shown to be effective in reducing the risk of death in patients with chronic HFrEF: bisoprolol and sustained-release metoprolol (succinate), which selectively block beta-1–receptors; and carvedilol, which blocks alpha-1–, beta-1–, and beta-2–receptors. Positive findings with these 3 agents, however, should not be considered a beta-blocker class effect. Bucindolol lacked uniform effectiveness across different populations, and short-acting metoprolol tartrate was less effective in HF clinical trials. Beta-1 selective blocker nebivolol demonstrated a modest reduction in the primary endpoint of all-cause mortality or cardiovascular hospitalization but did not

affect mortality alone in an elderly population that included patients with HFpEF (472).

1a.11) Provide the estimates of benefit, and consistency across studies.

Estimates of the benefit of beta blocker therapy across the body of evidence are not reported.

1a.12) Indicate what, if any, harms were identified in the study.

N/A

1a.13) Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

Updated guidelines continue to support this measure.

Component # 2 ACE-I/ARB/ARNI Therapy

Evidence

Group 1 - Evidence

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Measure and Report: Evidence section. For example:

Current Submission:

Updated evidence information here.

Previous (Year) Submission:

Evidence from the previous submission here.

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All sub-criteria must be met to pass this criterion. See guidance on evidence.

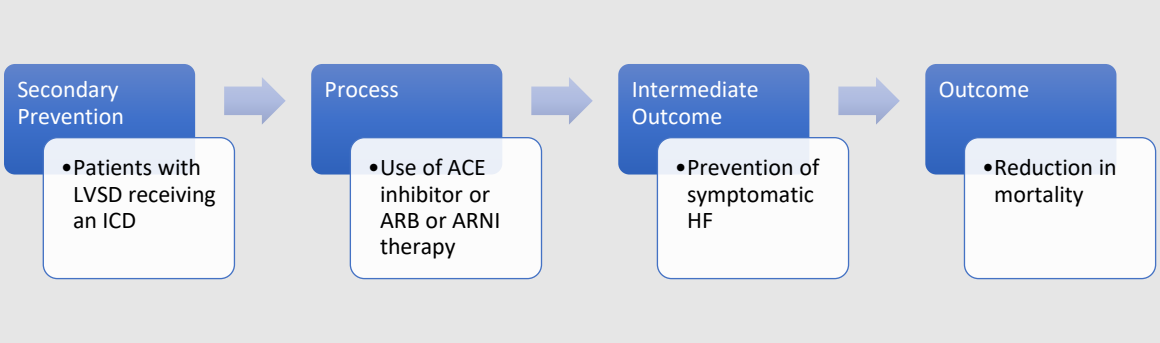
Please include individual entries for each component measure, unless several components were studied together. If a component measure is submitted as an individual performance measure, complete the evidence section as part of that individual measure submission.

1a.01) Provide a logic model.

Briefly describe the steps between the healthcare structures and processes (e.g.,

interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Diagram 3: Logic Model – Use of ARB or ARNI



Angiotensin-converting enzyme (ACE) inhibitors, angiotensin-receptor antagonists/blockers (ARBs), or angiotensin-receptor-neprilysin inhibitory (ARNI) reduce morbidity, mortality, and hospitalizations for patients with heart failure and left ventricular systolic dysfunction.

1a.02) If this measure is derived from patient report, provide evidence that the target population values the measured outcome, process, or structure and finds it meaningful. Otherwise, enter "N/A."

Describe how and from whom input was obtained.

1a.03) If this measure is derived from intermediate outcome, process, or structure performance measures, including those that are instrument-based, select the type of source for the systematic review of the body of evidence that supports the performance measure. Otherwise, select "N/A."

A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data.

☒ Clinical Practice Guideline recommendation (with evidence review)
☐ US Preventive Services Task Force Recommendation
☐ Other systematic review and grading of the body of evidence (e.g., Cochrane Collaboration, AHRQ Evidence Practice Center)
☐ Other (please specify here:)
☐ N/A

If the evidence is not based on a systematic review, skip to the end of the section and do not complete the repeatable question group below. If you wish to include more than

one systematic review, add additional tables by clicking “Add” after the final question in the group.

Group 1 - Evidence - Systematic Reviews Table

1a.04) Provide the title, author, date, citation (including page number) and URL for the systematic review.

Heidenreich PA, Bozkurt B, Aguilar D, Allen LA, Byun JJ, Colvin MM, Deswal A, Drazner MH, Dunlay SM, Evers LR, Fang JC, Fedson SE, Fonarow GC, Hayek SS, Hernandez AF, Khazanie P, Kittleson MM, Lee CS, Link MS, Milano CA, Nnacheta LC, Sandhu AT, Stevenson LW, Vardeny O, Vest AR, Yancy CW. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2022;79:e263–e421.

https://doi.org/10.1016/j.jacc.2021.12.012

Al-Khatib SM, Stevenson WG, Ackerman MJ, Bryant WJ, Callans DJ, Curtis AB, Deal BJ, Dickfeld T, Field ME, Fonarow GC, Gillis AM, Granger CB, Hammill SC, Hlatky MA, Joglar JA, Kay GN, Matlock DD, Myerburg RJ, Page RL. 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 Foundation/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol 2018;72:e91–220.
http://www.onlinejacc.org/content/accj/72/14/e91.full.pdf?_ga=2.238225088.1385433901.1570125164-1634948755.1534437338

Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Colvin MM, Drazner MH, Filippatos GS, Fonarow GC, Givertz MM, Hollenberg SM, Lindenfeld J, Masoudi FA, McBride PE, Peterson PN, Stevenson LW, Westlake C. 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.
http://www.onlinejacc.org/content/accj/72/14/e91.full.pdf?_ga=2.238225088.1385433901.1570125164-1634948755.1534437338

Amsterdam EA, Wenger NK, Brindis RG, Casey DE Jr, Ganiats TG, Holmes DR Jr, Jaffe AS, Jneid H, Kelly RF, Kontos MC, Levine GN, Liebson PR, Mukherjee D, Peterson ED, Sabatine MS, Smalling RW, Zieman SJ. 2014 AHA/ACC guideline for the management of patients with non–ST-elevation acute coronary syndromes: a report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2014;64:e139–228.
http://content.onlinejacc.org/article.aspx?articleid=1910086

O’Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA,

Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2013;61:e78–140, doi:10.1016/j.jacc.2012.11.019.
http://content.onlinejacc.org/article.aspx?articleid=1486115

Fihn SD, Gardin JM, Abrams J, Berra K, Blankenship JC, Dallas AP, Douglas PS, Foody JM, Gerber TC, Hinderliter AL, King SB III, Kligfield PD, Krumholz HM, Kwong RYK, Lim MJ, Linderbaum JA, Mack MJ, Munger MA, Prager RL, Sabik JF, Shaw LJ, Sikkema JD, Smith CR Jr, Smith SC Jr, Spertus JA, Williams SV. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. J Am Coll Cardiol 2012;60:e44–164.
http://content.onlinejacc.org/article.aspx?articleid=1391404

Smith SC Jr., Benjamin EJ, Bonow RO, Braun LT, Creager MA, Franklin BA, Gibbons RJ, Grundy SM, Hiratzka LF, Jones DW, Lloyd-Jones DM, Minissian M, Mosca L, Peterson ED, Sacco RL, Spertus J, Stein JH, Taubert KA. AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update: a guideline from the American Heart Association and American College of Cardiology Foundation. Circulation. 2011: published online before print November 3, 2011, 10.1161/CIR.0b013e318235eb4d.
http://content.onlinejacc.org/article.aspx?articleid=1147807

1a.05) Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines (p. e295, e305)

- In patients with HFrEF and NYHA class II to III symptoms, the use of ARNI is recommended to reduce morbidity and mortality. **Class: 1 Level of Evidence: A**
- In patients with previous or current symptoms of chronic HFrEF, the use of ACEi is beneficial to reduce morbidity and mortality when the use of ARNi is not feasible. **Class: 1 Level of Evidence: A**
- In patients with previous or current symptoms of chronic HFrEF who are intolerant to ACEi because of cough or angioedema and when the use of ARNi is not feasible, the use of ARB is recommended to reduce morbidity and mortality. **Class: 1 Level of Evidence: A**
- In patients with chronic symptomatic HFrEF NYHA class II or III who tolerate an ACEi or ARB, replacement by an ARNi is recommended to further reduce morbidity and mortality. **Class: 1 Level of Evidence: B-R**

2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death (p. e116)

- In patients with HFrEF (LVEF ≤40%), treatment with a beta blocker, a mineralocorticoid receptor antagonist and either an angiotensin-converting enzyme inhibitor, an angiotensin-receptor blocker, or an angiotensin receptor-neprilysin inhibitor is recommended to reduce SCD and all-cause mortality. **Class I: Level of Evidence: A**

2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure (p. e784):

- The clinical strategy of inhibition of the renin-angiotensin system with ACE inhibitors (128–133), OR ARBs (134–137), OR ARNI (138) in conjunction with evidence-based beta blockers (9,139,140), and aldosterone antagonists in selected patients (141,142), is recommended for patients with chronic HFrEF to reduce morbidity and mortality. **Class I; ACE inhibitor: Level of Evidence: A, ARBs: Level of Evidence: A or ARNI: Level of Evidence: B-R**
- The use of ACE inhibitors is beneficial for patients with prior or current symptoms of chronic HFrEF to reduce morbidity and mortality. **Class I; Level of Evidence: A**
- The use of ARBs to reduce morbidity and mortality is recommended in patients with prior or current symptoms of chronic HFrEF who are intolerant to ACE inhibitors because of cough or angioedema. **Class I; Level of Evidence: A**
- 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 (138). **Class I; Level of Evidence: B-R**

2014 AHA/ACC guideline for the management of patients with non–ST-elevation acute coronary syndromes (p. e 161)

- ACE inhibitors should be started and continued indefinitely in all patients with LVEF less than 0.40 and in those with hypertension, diabetes mellitus, or stable CKD, unless contraindicated. **Class I: Level of Evidence: A**

- ARBs are recommended in patients with HF or MI with LVEF less than 0.40 who are ACE inhibitor intolerant. **Class I: Level of Evidence: A**

2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction (e169-170, 174-175, 195)

Stages of Heart Failure:

- Stage A: At high risk for HF, but without structural heart disease or symptoms of Failure
- Stage B: Structural heart disease, but without signs or symptoms of HF
- Stage C: Structural heart disease with prior or current symptoms of HF
- Stage D: Refractory HF requiring specialized interventions

Stage B recommendations (e169-170):

- In all patients with a recent or remote history of MI or ACS and reduced EF, ACE inhibitors should be used to prevent symptomatic HF and reduce mortality. In patients intolerant of ACE inhibitors, ARBs are appropriate unless contraindicated. **Class I; Level of Evidence: A**
- ACE inhibitors should be used in all patients with a reduced EF to prevent symptomatic HF, even if they do not have a history of MI. **Class I; Level of Evidence: A**

2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease (p. e97)

- ACE inhibitors should be prescribed in all patients with SIHD who also have hypertension, diabetes mellitus, LVEF 40% or less, or CKD, unless contraindicated. **Class I: Level of Evidence: A**
- ARBs are recommended for patients with SIHD who have hypertension, diabetes mellitus, LV systolic dysfunction, or CKD and have indications for, but are intolerant of, ACE inhibitors. **Class I: Level of Evidence: A**

AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update (p. e2435)

- ACE inhibitors should be started and continued indefinitely in all patients with left ventricular ejection fraction <40% and in those with hypertension, diabetes, or chronic kidney disease, unless contraindicated. **Class I; Level of Evidence: A**
- The use of ARBs is recommended in patients who have heart failure or who have had a myocardial infarction with left ventricular ejection fraction <40% and who are ACE-inhibitor intolerant. **Class I; Level of Evidence: A**

1a.06) Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

For guidelines released prior to 2015:
The weight of the evidence in support of most of the recommendations included are rated as Level A, Level B and Level C, as noted following each statement. Level A evidence refers to “Data derived from multiple randomized clinical trials or meta-analyses.” The weight of the evidence in support of additional recommendations is rated as Level B and C. Level B evidence refers to “Data derived from a single randomized trial, or nonrandomized studies” while Level C evidence refers to “Only consensus opinion of experts, case studies, or standard-of-care.”

For guidelines released from 2015 forward:
The weight of the evidence in support of most of the recommendations included are rated as Level A, Level B-R, Level B-NR, Level C-LD and Level C-EO, as noted following each statement. Level A evidence refers to high quality evidence from more than one randomized control trial (RCT), meta analyses of high-quality RCTs, and/or

one or more RCTs corroborated by high-quality registry studies. Level B-R evidence refers to moderate-quality evidence from one or more RCTs and/or meta-analyses of moderate-quality RCTs and Level B-NR evidence includes moderate quality evidence from one or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies and/or meta-analyses of such studies. Level C-LD refers to randomized or nonrandomized observational or registry studies with limitation of design or execution, meta-analyses of such studies, and/or physiological or mechanistic studies in human subjects. Level C-EO refers to consensus of expert opinion based on clinical experience.

1a.07) Provide all other grades and definitions from the evidence grading system.

See question above and next two questions below for more information.

1a.08) Provide the grade assigned to the recommendation, with definition of the grade.

The recommendations included have been assigned a Class I recommendation.

For guidelines released prior to 2015:
Class I recommendations refer to “Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.”

For guidelines released from 2015 forward:
Class I recommendations are “strong and indicate that the treatment, procedure, or intervention is useful and effective and should be performed or administered for most patients under most circumstances.”

1a.09) Provide all other grades and definitions from the recommendation grading system.

For guidelines released prior to 2015:
ACCF/AHA guideline methodology categorizes indications as class I,II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows and noted in the table below:
Classification Types:
Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.
Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

- IIa: Weight of evidence/opinion is in favor of usefulness/efficacy
- IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.

- No Benefit- Procedure/Test not helpful or Treatment w/o established proven benefit

- Harm- Procedure/Test leads to excess cost w/o benefit or is harmful, and or Treatment is harmful

Additional detail regarding the classification of recommendation and level of evidence is provided in the following table.

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

CLASS (STRENGTH) OF RECOMMENDATION	
CLASS 1 (STRONG)	**Benefit >>> Risk**
Suggested phrases for writing recommendations: • Is recommended • Is indicated/useful/effective/beneficial • Should 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	
CLASS 2a (MODERATE)	**Benefit >> Risk**
Suggested phrases for writing recommendations: • Is reasonable • Can be useful/effective/beneficial • Comparative-Effectiveness Phrases†: - Treatment/strategy A is probably recommended/indicated in preference to treatment B - It is reasonable to choose treatment A over treatment B	
CLASS 2b (WEAK)	**Benefit ≥ Risk**
Suggested phrases for writing recommendations: • May/might be reasonable • May/might be considered • Usefulness/effectiveness is unknown/unclear/uncertain or not well- established	
CLASS 3: No Benefit (MODERATE) (Generally, LOE A or B use only)	**Benefit = Risk**
Suggested phrases for writing recommendations: • Is not recommended • Is not indicated/useful/effective/beneficial • Should not be performed/administered/other	
CLASS 3: Harm (STRONG)	**Risk > Benefit**
Suggested phrases for writing recommendations: • Potentially harmful • Causes harm • Associated with excess morbidity/mortality • Should not be performed/administered/other	

LEVEL (QUALITY) OF EVIDENCE‡	
LEVEL A	
• High-quality evidence‡ from more than 1 RCT • Meta-analyses of high-quality RCTs • One or more RCTs corroborated by high-quality registry studies	
LEVEL B-R	**(Randomized)**
• Moderate-quality evidence‡ from 1 or more RCTs • Meta-analyses of moderate-quality RCTs	
LEVEL B-NR	**(Nonrandomized)**
• Moderate-quality evidence‡ from 1 or more well-designed, well- executed nonrandomized studies, observational studies, or registry studies • Meta-analyses of such studies	
LEVEL C-LD	**(Limited Data)**
• Randomized or nonrandomized observational or registry studies with limitations of design or execution • Meta-analyses of such studies • Physiological or mechanistic studies in human subjects	
LEVEL C-EO	**(Expert Opinion)**
• Consensus of expert opinion based on clinical experience	

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

† 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 of the treatments or strategies being evaluated.

‡ The method of assessing quality is evolving, including the application of standardized, widely-used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

For guidelines released from 2015 forward:

In 2015, the ACC and AHA updated Classes of Recommendation (COR) and Levels of Evidence (LOE) in an effort to align patient care with scientific evidence.

The COR reflects the magnitude of benefit over risk and corresponds to the strength of the recommendation. Class I recommendations are strong and indicate that the treatment, procedure, or intervention is useful and effective and should be performed or administered for most patients under most circumstances. Class II recommendations are weaker, denoting a lower degree of benefit in proportion to risk. Benefit is generally greater for Class IIa (moderate) recommendations and smaller for Class IIb (weak) recommendations, for which benefit only marginally exceeds risk. A COR of IIb suggests that implementation should be selective and based on careful consideration of individual patient factors and, for invasive procedures, available expertise. Class III is assigned when actions are specifically not recommended, either because studies have found no evidence of benefit or because the intervention causes harm.

1a.10) Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

All of the recommendations for this process are rated as Level of Evidence A or B, meaning that the data was derived from one or more RCTs or meta-analyses. Additional information on the overall quality of evidence across the RCTs is not provided; although, two of the cited guidelines discuss the evidence supporting the use of beta blockers in this population, which is provided below.

2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

p. e303-304:

An ARNi is composed of an ARB and an inhibitor of neprilysin, an enzyme that degrades natriuretic peptides, bradykinin, adrenomedullin, and other vasoactive peptides. In PARADIGM-HF (Prospective Comparison of ARNi with ACEi to Determine Impact on Global Mortality and Morbidity in Heart Failure), an RCT that compared the first approved ARNi, sacubitril-valsartan, with enalapril in symptomatic patients with HFrEF tolerating an adequate dose of either ACEi or ARB, sacubitril-valsartan significantly reduced the composite endpoint of cardiovascular death or HF hospitalization by 20% relative to enalapril. The benefit was observed to a similar extent for death and HF hospitalization and was consistent across prespecified subgroups. Use of an ARNi is more frequently associated with symptomatic hypotension and a comparable incidence of angioedema when compared with enalapril. Sacubitril-valsartan has been approved for patients with symptomatic HF. HF effects and potential off-target effects may be complex with inhibition of the neprilysin enzyme, which has multiple biological targets. Trial data have included ACEi/ARB-naïve patients before ARNi initiation (53% in the PIONEER-HF [Comparison of Sacubitril-Valsartan versus Enalapril on Effect on NT-proBNP in Patients Stabilized from an Acute Heart Failure Episode] trial and 24% in the TRANSITION [Comparison of Pre- and Post-discharge Initiation of Sacubitril/Valsartan Therapy in HFrEF Patients After an Acute Decompensation Event] trial) and have shown similar efficacy and safety in treatment-naïve patients. The PIONEER-HF trial showed that ARNi reduced NT-proBNP levels in

patients hospitalized for acute decompensated HF without increased rates of adverse events (worsening renal function, hyperkalemia, symptomatic hypotension, angioedema) when compared with enalapril. Additional outcome analyses suggested reduction in all-cause mortality and rehospitalization for HF but were only hypothesis-generating as exploratory study endpoints. In the open-label TRANSITION trial, patients with HFrEF hospitalized with worsening HF were randomized to start ARNi either before or after discharge. Safety outcomes were similar for both arms, suggesting that early initiation may simplify management (rather than initiating and uptitrating ACEi first and then switching to ARNi). ARNi should be initiated de novo in patients hospitalized with acute HFrEF before discharge in the absence of contraindications. ARNi may be initiated de novo in patients with chronic symptomatic HFrEF to simplify management, although data are limited. The PARADISE-MI (Prospective ARNi vs ACE Inhibitor Trial to Determine Superiority in Reducing Heart Failure Events After MI) trial will provide information on whether sacubitril-valsartan will significantly reduce the rate of cardiovascular death, HF hospitalization or outpatient HF requiring treatment in patients after acute MI, with LVEF #40% and/or pulmonary congestion, and 1 of 8 additional risk-enhancing factors like AF, previous MI, diabetes, compared with the ACEi ramipril; and whether the safety and tolerability of sacubitril-valsartan was comparable to that of ramipril. Thus, at the present time, the efficacy of ARNi in patients with LV dysfunction, and HF in the early post-MI period, remains uncertain.

ACEi reduce morbidity and mortality in HFrEF. RCTs clearly establish the benefits of ACE inhibition in patients with mild, moderate, or severe symptoms of HF and in patients with or without CAD. Data suggest that there are no differences among available ACEi in their effects on symptoms or survival. ACEi should be started at low doses and titrated upward to doses shown to reduce the risk of cardiovascular events in clinical trials. ACEi can produce angioedema and should be given with caution to patients with low systemic blood pressures, renal insufficiency, or elevated serum potassium (>5.0 mEq/L). If maximal doses are not tolerated, intermediate doses should be tried; abrupt withdrawal of ACE inhibition can lead to clinical deterioration and should be avoided. Although the use of an ARNi in lieu of an ACEi for HFrEF has been found to be superior, for those patients for whom ARNi is inappropriate, continued use of an ACEi for all classes of HFrEF remains strongly advised.

ARB have been shown to reduce mortality and HF hospitalizations in patients with HFrEF in large RCTs. Long-term treatment with ARB in patients with HFrEF produces hemodynamic, neurohormonal, and clinical effects consistent with those expected after interference with the renin-angiotensin system. Unlike ACEi, ARB do not inhibit kininase and are associated with a much lower incidence of cough and angioedema, although kininase inhibition by ACEi may produce beneficial vasodilatory effects. Patients who are intolerant to ACEi because of cough or angioedema should be started on an ARB. ARB 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. ARB should be given with caution to patients with low systemic blood pressure, renal insufficiency, or elevated serum potassium (>5.0 mEq/L). Although ARB are alternatives for patients with ACEi-induced angioedema, caution is advised because some patients have also developed angioedema with ARB. For those patients for whom an ACEi or ARNi is inappropriate, use of an ARB remains advised.

Several cost-effectiveness analyses consistently found that ACEi therapy provides high value for patients with chronic HF. A model-based analysis, using generic ACEi costs, found ACEi therapy was high value. Previous analyses also found ACEi therapy was high value despite previously higher ACEi costs. This includes a trial-based analysis of SOLVD (Studies of Left Ventricular Dysfunction) that modeled long-term outcomes. Previous analyses included a range of clinical scenarios including asymptomatic LV dysfunction and LV dysfunction after MI, with ACEi therapy providing high value in each. There are limited data on the cost-effectiveness of ARBs from 2 clinical trials—a within-trial analysis of Val-HeFT (Valsartan Heart Failure Trial) and an analysis of the ELITE (Evaluation of Losartan in the Elderly) study —which both suggested ARB therapy is high value. The high value of ARB therapy is also supported by its similar efficacy as ACEi therapy and the low-cost generic availability for both medication classes.

Patients with chronic stable HFrEF who tolerate ACEi and ARB should be switched to ARNi. In patients with mild-to-moderate HF who were able to tolerate both a target dose of enalapril (10 mg twice daily) and then subsequently an ARNi (sacubitril-valsartan; 200 mg twice daily, with the ARB component equivalent to valsartan 160 mg), hospitalizations and mortality were significantly decreased with the valsartan-sacubitril compound compared with enalapril. Another RCT and meta-analysis showed improvement in LV remodeling parameters with ARNi compared with enalapril.

2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure (p. e784):

Angiotensin-converting enzyme (ACE) inhibitors reduce morbidity and mortality in heart failure with reduced ejection fraction (HFrEF). Randomized controlled trials (RCTs) clearly establish the benefits of ACE inhibition in patients with mild, moderate, or severe symptoms of HF and in patients with or without coronary artery disease (128–133). ACE inhibitors can produce angioedema and should be given with caution to patients with low systemic blood pressures, renal insufficiency, or elevated serum potassium. ACE inhibitors also inhibit kininase and increase levels of bradykinin, which can induce cough but also may contribute to their beneficial effect through vasodilation.

Angiotensin receptor blockers (ARBs) were developed with the rationale that angiotensin II production continues in the presence of ACE inhibition, driven through alternative enzyme pathways. ARBs do not inhibit kininase and are associated with a much lower incidence of cough and angioedema than ACE inhibitors; but like ACE inhibitors, ARBs should be given with caution to patients with low systemic blood pressure, renal insufficiency, or elevated serum potassium. Long-term therapy with ARBs produces hemodynamic, neurohormonal, and clinical effects consistent with those expected after interference with the renin-angiotensin system and have been shown in RCTs (134–137) to reduce morbidity and mortality, especially in ACE inhibitor–intolerant patients.

Benefits of ACE inhibitors with regard to decreasing HF progression, hospitalizations, and mortality rate have been shown consistently for patients across the clinical

spectrum, from asymptomatic to severely symptomatic HF. Similar benefits have been shown for ARBs in populations with mild-to-moderate HF who are unable to tolerate ACE inhibitors. In patients with mild-to-moderate HF (characterized by either 1) mildly elevated natriuretic peptide levels, BNP [B-type natriuretic peptide]≥150 pg/mL or NT-proBNP [N-terminal pro-B-type natriuretic peptide] >600 pg/mL; or 2) BNP≥100 pg/mL or NT-proBNP≥400 pg/mL with a prior hospitalization in the preceding 12 months) who were able to tolerate both a target dose of enalapril (10 mg twice daily) and then subsequently an ARNI (valsartan/sacubitril; 200 mg twice daily, with the ARB component equivalent to valsartan160 mg), hospitalizations and mortality were significantly decreased with the valsartan/sacubitril compound compared with enalapril. The target dose of the ACE inhibitor was consistent with that known to improve outcomes in previous landmark clinical trials(129). This ARNI has been approved for patients with symptomatic HFrEF and is intended to be substituted for ACE inhibitors or ARBs. HF effects and potential off-target effects maybe complex with inhibition of the neprilysin enzyme, which has multiple biological targets. Use of an ARNI is associated with hypotension and a low-frequency incidence of angioedema.

2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death (p. e116):

Angiotensin-converting enzyme inhibition also reduces mortality and SCD (S5.2-3). Angiotensin-receptor blockers added to angiotensin-converting enzyme inhibitor showed additional benefit to angiotensin-converting enzyme inhibitors in some (S5.2-10) but not other RCTs (S5.2-8,S5.2-11). Therapy with the mineralocorticoid-receptor antagonists, spironolactone and eplerenone, have also demonstrated reductions in both all-cause mortality and SCD (S5.2-6,S5.2-12,S5.2-13). Recent studies of the angiotensin receptor-neprilysin inhibitor (sacubitril/valsartan) versus angiotensin-converting enzyme inhibitor demonstrated a reduction in SCD and cardiac mortality (S5.2-14).

2013 ACCF/AHA Guideline for the Management of Heart Failure (p. e170)

The body of evidence supporting the recommendations on ACE/ARB therapy in this guideline includes 15 randomized controlled trials.

CAD is a major risk factor for the development of HF and a key target for prevention of HF. The 5-year risk of developing HF after acute MI is 7% and 12% for men and women, respectively; for men and women between the ages of 40 and 69 and those >70 years of age, the risk is 22% and 25%, respectively (51). Current evidence supports the use of ACE inhibitors and (to a lower level of evidence) beta-blocker therapy to impede maladaptive LV remodeling in patients with stage B HF and low LVEF to improve mortality and morbidity (344). At 3-year follow-up, those patients treated with ACE inhibitors demonstrated combined endpoints of reduced hospitalization or death, a benefit that extended up to a 12-year follow-up (65). ARBs are reasonable alternatives to ACE inhibitors.

1a.11) Provide the estimates of benefit, and consistency across studies.

Estimates of the benefit of ACE/ARB/ARNI therapy across the body of evidence are not

reported.

1a.12) Indicate what, if any, harms were identified in the study.

N/A

1a.13) Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

Updated guidelines continue to support this measure.

Component # 3 Fulfillment of Class I, IIa, or IIb guideline indications

Evidence

Group 1 - Evidence

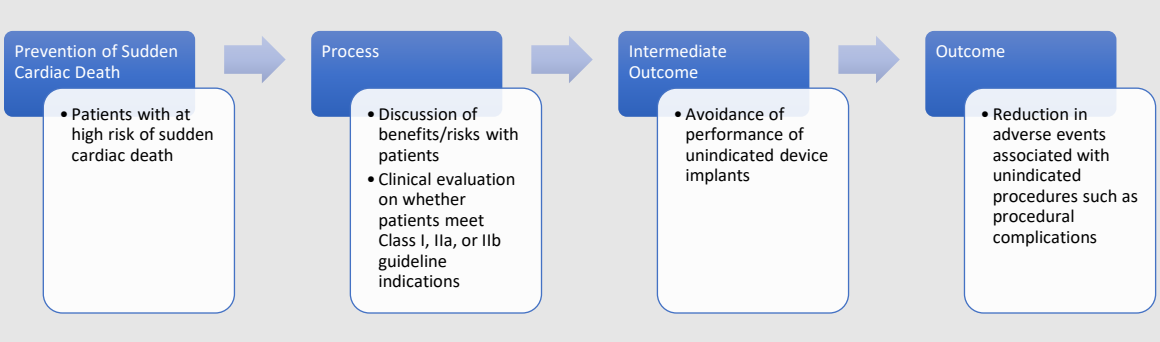
Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All sub-criteria must be met to pass this criterion. See guidance on evidence.

Please include individual entries for each component measure, unless several components were studied together. If a component measure is submitted as an individual performance measure, complete the evidence section as part of that individual measure submission.

1a.01) Provide a logic model.

Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Diagram 4: Logic model – guideline indications



ICD therapy can provide primary and secondary prevention of sudden cardiac death but should only be considered in those individuals who meet Class I, IIa, or IIb guideline indications; along with a patient discussion about whether the anticipated benefits

outweigh the risks of device therapy.

1a.02) If this measure is derived from patient report, provide evidence that the target population values the measured outcome, process, or structure and finds it meaningful. Otherwise, enter "N/A."

Describe how and from whom input was obtained.

1a.03) If this measure is derived from intermediate outcome, process, or structure performance measures, including those that are instrument-based, select the type of source for the systematic review of the body of evidence that supports the performance measure. Otherwise, select "N/A."

A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data.

☒ Clinical Practice Guideline recommendation (with evidence review)
☐ US Preventive Services Task Force Recommendation
☐ Other systematic review and grading of the body of evidence (e.g., Cochrane Collaboration, AHRQ Evidence Practice Center)
☐ Other (please specify here:)
☐ N/A

If the evidence is not based on a systematic review, skip to the end of the section and do not complete the repeatable question group below. If you wish to include more than one systematic review, add additional tables by clicking “Add” after the final question in the group.

Group 1 - Evidence - Systematic Reviews Table

1a.04) Provide the title, author, date, citation (including page number) and URL for the systematic review.

Epstein AE, DiMarco JP, Ellenbogen KA, Estes NAM III, Freedman RA, Gettes LS, Gillinov AM, Gregoratos G, Hammill SC, Hayes DL, Hlatky MA, Newby LK, Page RL, Schoenfeld MH, Silka MJ, Stevenson LW, Sweeney MO 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol 2013;61:e6–75. doi/10.1016/j.jacc.2012.11.007

1a.05) Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities (p. e26, 43-44)

- ICD therapy is indicated in patients who are survivors of cardiac arrest due to VF or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes. **Class: I Level of Evidence: A**
- ICD therapy is indicated in patients with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable. **Class: I Level of Evidence: B**
- ICD therapy is indicated in patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study. **Class: I Level of Evidence: B**
- ICD therapy is indicated in patients with LVEF less than or equal to 35% due to prior MI who are at least 40 days post-MI and are in NYHA functional Class II or III. **Class: I Level of Evidence: A**
- ICD Therapy is indicated in patients with nonischemic DCM who have an LVEF less than or equal to 35% and who are in NYHA functional class II or III. **Class: I Level of Evidence: B**
- ICD therapy is indicated in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than or equal to 30%, and are in NYHA functional class I. **Class: I Level of Evidence: A** ICD therapy is indicated in patients with non-sustained VT due to prior MI, LVEF less than or equal to 40%, and inducible VF or sustained VT at electrophysiological study. **Class: I Level of Evidence: B**
- ICD implantation is reasonable for patients with unexplained syncope, significant LV dysfunction, and nonischemic DCM. **Class: IIa Level of Evidence: C**
- ICD implantation is reasonable for patients with sustained VT and normal or near-normal ventricular function. **Class: IIa Level of Evidence: C**
- ICD implantation is reasonable for patients with HCM who have 1 or more major risk factors for SCD. **Class: IIa Level of Evidence: C**
- ICD implantation is reasonable for the prevention of SCD in patients with ARVD/C who have 1 or more risk factors for SCD. **Class: IIa Level of Evidence: C**
- ICD implantation is reasonable to reduce SCD in patients with long-QT syndrome who are experiencing syncope and/or VT while receiving beta blockers. **Class: IIa Level of Evidence: B**
- ICD implantation is reasonable for non-hospitalized patients awaiting transplantation. **Class: IIa Level of Evidence: C**
- ICD implantation is reasonable for patients with Brugada syndrome who have had syncope. **Class: IIa Level of Evidence: C**
- ICD implantation is reasonable for patients with Brugada syndrome who have documented VT that has not resulted in cardiac arrest. **Class: IIa Level of Evidence: C**
- ICD implantation is reasonable for patients with catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta blockers. **Class: IIa Level of Evidence: C**

- ICD implantation is reasonable for patients with cardiac sarcoidosis, giant cell myocarditis, or Chagas disease. **Class: IIa Level of Evidence: C**
- ICD therapy may be considered in patients with nonischemic heart disease who have an LVEF of less than or equal to 35% and who are in NYHA functional Class I. **Class: IIb Level of Evidence: C**
- ICD therapy may be considered for patients with long-QT syndrome and risk factors for SCD. **Class: IIb Level of Evidence: B**
- ICD therapy may be considered in patients with syncope and advanced structural heart disease in whom thorough invasive and noninvasive investigations have failed to define a cause. **Class: IIb Level of Evidence: C**
- ICD therapy may be considered in patients with a familial cardiomyopathy associated with sudden death. **Class: IIb Level of Evidence: C**
- ICD therapy may be considered in patients with LV noncompaction. **Class: IIb Level of Evidence: C**
- CRT is indicated for patients who have LVEF less than or equal to 35%, sinus rhythm, LBBB with a QRS duration greater than or equal to 150 ms, and NYHA class II, III, or ambulatory IV symptoms on GDMT. **Class: I Level of Evidence: A for NYHA class III/IV; Level of Evidence: B for NYHA class II**
- CRT can be useful for patients who have LVEF less than or equal to 35%, sinus rhythm, LBBB with a QRS duration 120 to 149 ms, and NYHA class II, III, or ambulatory IV symptoms on GDMT. **Class: IIa Level of Evidence: B**
- CRT can be useful for patients who have LVEF less than or equal to 35%, sinus rhythm, a non-LBBB pattern with a QRS duration greater than or equal to 150 ms, and NYHA class III/ambulatory class IV symptoms on GDMT. CRT can be useful for patients who have LVEF less than or equal to 35%, sinus rhythm, LBBB with a QRS duration 120 to 149 ms, and NYHA class II, III, or ambulatory IV symptoms on GDMT. **Class: IIa Level of Evidence: A**
- CRT can be useful in patients with atrial fibrillation and LVEF less than or equal to 35% on GDMT if a) the patient requires ventricular pacing or otherwise meets CRT criteria and b) AV nodal ablation or pharmacologic rate control will allow near 100% ventricular pacing with CRT. **Class: IIa Level of Evidence: B**
- CRT can be useful for patients on GDMT who have LVEF less than or equal to 35% and are undergoing new or replacement device placement with anticipated requirement for significant (>40%) ventricular pacing. **Class: IIa Level of Evidence: C**
- CRT may be considered for patients who have LVEF less than or equal to 30%, ischemic etiology of heart failure, sinus rhythm, LBBB with a QRS duration of greater than or equal to 150 ms, and NYHA class I symptoms on GDMT. **Class: IIb Level of Evidence: C**
- CRT may be considered for patients who have LVEF less than or equal to 35%, sinus rhythm, a non-LBBB pattern with QRS duration 120 to 149 ms, and NYHA class III/ambulatory class IV on GDMT **Class: IIb Level of Evidence: B**
- CRT may be considered for patients who have LVEF less than or equal to 35%, sinus rhythm, a non-LBBB pattern with a QRS duration greater than or equal to 150 ms, and NYHA class II symptoms on GDMT, **Class: IIb Level of Evidence: B**

1a.06) Provide the grade assigned to the evidence associated with the

recommendation, and include the definition of the grade.

For guidelines released prior to 2015:
The weight of the evidence in support of most of the recommendations included are rated as Level A, Level B and Level C, as noted following each statement. Level A evidence refers to “Data derived from multiple randomized clinical trials or meta-analyses.” The weight of the evidence in support of additional recommendations is rated as Level B and C. Level B evidence refers to “Data derived from a single randomized trial, or nonrandomized studies” while Level C evidence refers to “Only consensus opinion of experts, case studies, or standard-of-care.”

1a.07) Provide all other grades and definitions from the evidence grading system.

See question above and next two questions below for more information.

1a.08) Provide the grade assigned to the recommendation, with definition of the grade.

The recommendations included have been assigned a Class I, IIa, or IIb recommendation.

For guidelines released prior to 2015:
Class I recommendations refer to “Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.”

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
- IIa: Weight of evidence/opinion is in favor of usefulness/efficacy
- IIb: Usefulness/efficacy is less well established by evidence/opinion.

1a.09) Provide all other grades and definitions from the recommendation grading system.

For guidelines released prior to 2015:
ACCF/AHA guideline methodology categorizes indications as class I, II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows and noted in the table below:
Classification Types:
Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.
Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
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Additional detail regarding the classification of recommendation and level of evidence is provided in the following table.

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Suggested phrases for writing recommendations: • Is recommended • Is indicated/useful/effective/beneficial • Should 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	
CLASS 2a (MODERATE)	**Benefit >> Risk**
Suggested phrases for writing recommendations: • Is reasonable • Can be useful/effective/beneficial • Comparative-Effectiveness Phrases†: - Treatment/strategy A is probably recommended/indicated in preference to treatment B - It is reasonable to choose treatment A over treatment B	
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LEVEL (QUALITY) OF EVIDENCE‡	
LEVEL A	
• High-quality evidence‡ from more than 1 RCT • Meta-analyses of high-quality RCTs • One or more RCTs corroborated by high-quality registry studies	
LEVEL B-R	**(Randomized)**
• Moderate-quality evidence‡ from 1 or more RCTs • Meta-analyses of moderate-quality RCTs	
LEVEL B-NR	**(Nonrandomized)**
• Moderate-quality evidence‡ from 1 or more well-designed, well- executed nonrandomized studies, observational studies, or registry studies • Meta-analyses of such studies	
LEVEL C-LD	**(Limited Data)**
• Randomized or nonrandomized observational or registry studies with limitations of design or execution • Meta-analyses of such studies • Physiological or mechanistic studies in human subjects	
LEVEL C-EO	**(Expert Opinion)**
• Consensus of expert opinion based on clinical experience	

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

† 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 of the treatments or strategies being evaluated.

‡ The method of assessing quality is evolving, including the application of standardized, widely-used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

1a.10) Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

Recommendations for this process are rated as Level of Evidence A, B, or C meaning that the data was derived from either one or more RCTs or meta-analyses or consensus opinion of experts, case studies, or standard-of-care. Additional information on the overall quality of evidence across the RCTs is not provided; although, the cited guideline discusses the evidence supporting the indications for device therapy, which is provided below.

p. e38-43:

Primary prevention of SCD refers to the use of ICDs in individuals who are at risk for but have not yet had an episode of sustained VT, VF, or resuscitated cardiac arrest. Clinical trials have evaluated the risks and benefits of the ICD in prevention of sudden death and have improved survival in multiple patient populations, including those with prior MI and heart failure due to either coronary artery disease or nonischemic DCM. Prospective registry data are less robust but still useful for risk stratification and recommendations for ICD implantation in selected other patient populations, such as those with HCM, ARVD/C, and the long-QT syndrome. In less common conditions (e.g., Brugada syndrome, catecholaminergic polymorphic VT, cardiac sarcoidosis, and LV noncompaction), clinical reports and retrospectively analyzed series provide less rigorous evidence in support of current recommendations for ICD use, but this constitutes the best available evidence for these conditions.

3.2.1. Coronary Artery Disease

There now exists a substantial body of clinical trial data that support the use of ICDs in patients with chronic ischemic heart disease. A variety of risk factors have been used to identify a high-risk population for these studies. MADIT I and MUSTT required a history of MI, spontaneous non-sustained VT, inducible VT at electrophysiological study, and a depressed LVEF (less than or equal to 35% or less than or equal to 40%, respectively) to enter the study. MADIT I showed a major relative risk reduction of 54% with the ICD. MUSTT was not specifically a trial of ICD therapy, because it compared no therapy with electrophysiologically guided therapy, but in the group randomized to electrophysiologically guided therapy, benefit was seen only among those who received an ICD.

MADIT II enrolled 1,232 patients with ischemic cardiomyopathy and an LVEF less than or equal to 30%. No spontaneous or induced arrhythmia was required for enrollment. All-cause mortality was 20% in the control group and 14.2% in the ICD group (relative risk 31%; p0.016). SCD-HeFT included patients with both ischemic and non-ischemic cardiomyopathies, an LVEF less than or equal to 35%, and NYHA Class II or III congestive heart failure. Among the 1,486 patients with ischemic heart disease randomized to either placebo or ICD therapy, the 5-year event rates were 0.432 and 0.359, respectively (HR 0.79; p0.05). Two recent meta-analyses of these trials have supported the overall conclusion that ICD therapy in high-risk individuals with coronary artery disease results in a net risk reduction for total mortality of between 20% and 30%.

Two trials, however, have failed to show improved survival with ICD therapy in patients either at the time of surgical revascularization or within 40 days of an acute MI. In the CABG-Patch (Coronary Artery Bypass Graft-Patch) trial, routine ICD insertion did not improve survival in patients with coronary artery disease undergoing bypass surgery who were believed to be at high risk of sudden death on the basis of an abnormal signal-averaged ECG and severe LV dysfunction (LVEF less than or equal to 35%). Similar data about the effects of percutaneous revascularization are not available. In DINAMIT (Defibrillator in Acute Myocardial Infarction Trial), 674 patients with a recent MI (within 6 to 40 days), reduced LV function (LVEF less than or equal to 35%), and impaired cardiac autonomic function (depressed heart rate variability or elevated average heart rate) were randomized to either ICD therapy or no ICD therapy. Although arrhythmic death was reduced in the ICD group, there was no difference in total mortality (18.7% versus 17.0%; HR for death in the ICD group 1.08; p0.66). See Table 5 for further information.

3.2.2. Nonischemic Dilated Cardiomyopathy

Multiple randomized prospective trials now supplement the available observational studies that have reported on the role of the ICD in primary prevention of SCD in patients with nonischemic DCM Observational studies suggest that up to 30% of deaths in patients with DCM are sudden. Mortality in medically treated patients with DCM and a prior history of syncope may exceed 30% at 2 years, whereas those treated with an ICD experience a high frequency of appropriate ICD therapy.

CAT (Cardiomyopathy Trial) enrolled patients with recently diagnosed DCM with randomization to medical therapy versus medical therapy with an ICD. The study was terminated before the primary end point was reached because of a lower-than-expected incidence of all-cause mortality. There was no statistical probability of finding a significant survival advantage with either strategy. With 50 patients in the ICD arm and 54 in the control group, the study was underpowered to find a difference in survival with ICD therapy. At the time of 5-year follow-up, there were fewer deaths in the ICD group than in the control group (13 versus 17, respectively).

Another inconclusive trial was the AMIOVIRT (Amiodarone Versus Implantable Defibrillator in Patients with Non-ischemic Cardiomyopathy and Asymptomatic Non-sustained Ventricular Tachycardia) study. The trial randomized 103 patients with DCM, LVEF less than or equal to 35%, and non-sustained VT to amiodarone or ICD. The study was stopped prematurely due to statistical futility in reaching the primary end point of reduced total mortality. The DEFINITE (Defibrillators in Nonischemic Cardiomyopathy Treatment Evaluation) trial randomized 458 patients with nonischemic cardiomyopathy, NYHA Class I to III heart failure, LVEF less than or equal to 35%, and more than 10 premature ventricular complexes per hour or non-sustained VT to optimal medical therapy with or without an ICD. With a primary end point of all-cause mortality, statistical significance was not reached, but there was a strong trend toward reduction of mortality with ICD therapy (p0.08). After 2 years, mortality was 14.1% in the standard therapy group versus 7.9% among those receiving an ICD, which resulted in a 6.2% absolute reduction and a 35% relative risk reduction with ICD implantation. The results were consistent and comparable to those of other similar trials.

SCD-HeFT compared amiodarone, ICD, and optimal medical therapy in 2,521 patients with coronary artery disease or nonischemic cardiomyopathy with NYHA functional Class II or III heart failure and LVEF less than or equal to 35%. The amiodarone treatment group received the drug by way of a double-blinded, placebo-controlled design. The median follow-up was 45.5 months. The absolute mortality decrease in the medical group was 7.2% after 5 years in the overall population. The ICD group experienced a decreased risk of death of 23% compared with the placebo group (HR 0.77, 97.5% CI 0.62 to 0.96), and total mortality in the medical group was 7.2% per year, with a risk reduction of 23% in the ICD group versus placebo (95% CI 0.62 to 0.96; p0.007). Relative risk reduction was comparable for the group with LV dysfunction due to prior MI and the nonischemic group, but absolute mortality was lower in the nonischemic group. This resulted in a greater number needed to treat per life saved among ischemic patients. There was no mortality difference between the amiodarone and placebo groups. Further risk stratification may decrease the number of individuals needed to undergo ICD implantation to save a life in this population.

With the exception of DEFINITE (25% in the ICD arm), trials assessing ICD therapy in primary prophylaxis of DCM have not generally included asymptomatic patients in NYHA functional Class I; therefore, the efficacy of ICDs in this population is not fully known. Because mortality may be low in this subgroup, the benefit of ICD therapy is moderate at best.

The COMPANION trial randomized patients with Class III or IV heart failure, ischemic or nonischemic DCM, and QRS duration greater than 120 milliseconds in a 1:2:2 ratio to receive optimal pharmacological therapy alone or in combination with CRT with either a pacemaker or a pacemaker-defibrillator. Of the 1,520 patients randomized in the trial, 903 were allocated to either the medical therapy or defibrillator arms; of this subset, 397 (44%) had DCM. Cardiac resynchronization with an ICD significantly reduced all-cause mortality compared with pharmacological therapy alone in patients with DCM (HR for all-cause death 0.50, 95% CI 0.29 to 0.88; p0.015).

Two studies have evaluated the time dependence of risk for sudden death relative to the time of diagnosis of nonischemic DCM. An analysis of the DEFINITE study demonstrated that those who have a recent cardiomyopathy diagnosis do not benefit less from use of an ICD than those with a remote diagnosis. On the basis of these data, ICD therapy should be considered in such patients provided that a reversible cause of transient LV function has been excluded and their response to optimal medical therapy has been assessed. The optimal time required for this assessment is uncertain; however, another analysis determined that patients with nonischemic DCM experienced equivalent occurrences of treated and potentially lethal arrhythmias irrespective of diagnosis duration. These findings suggest that use of a time qualifier relative to the time since diagnosis of a nonischemic DCM may not reliably discriminate patients at high risk for SCD in this selected population. Given these considerations, physicians should consider the timing of defibrillator implantation carefully.

3.2.3. Long-QT Syndrome

The long-QT syndromes represent a complex spectrum of electrophysiological disorders characterized by a propensity for development of malignant ventricular arrhythmias, especially polymorphic VT. Because this is a primary electrical disorder, with most patients having no evidence of structural heart disease or LV dysfunction, the long-term prognosis is excellent if arrhythmia is controlled. Long-term treatment with beta blockers, permanent pacing, or left cervicothoracic sympathectomy may be helpful. ICD implantation is recommended for selected patients with recurrent syncope despite drug therapy, sustained ventricular arrhythmias, or sudden cardiac arrest. Furthermore, use of the ICD for primary prevention of SCD may be considered when there is a strong family history of SCD or when compliance or intolerance to drugs is a concern.

The clinical manifestations of a long-QT mutation may be influenced by the specific gene involved and the functional consequences of the mutation in that gene. Risk stratification of patients with long-QT syndrome continues to evolve, with data from genetic analysis becoming increasingly useful for clinical decision making.

3.2.4. Hypertrophic Cardiomyopathy

Most individuals with HCM are asymptomatic, and the first manifestation of the condition may be SCD. SCD in patients with HCM is generally related to ventricular arrhythmia thought to be triggered by factors such as ischemia, outflow obstruction, or AF. SCD is less frequently due to bradycardia. Among selected high-risk patients, the annual mortality from HCM has been estimated to be as high as 6% in reports from tertiary centers. However, community-based studies suggest a more benign disease in the majority of individuals, with an annual mortality rate in the range of 1% or less.

Risk factors for SCD have been derived from multiple observational studies and registries. A consensus document on HCM from the ACC and the European Society of Cardiology categorized known risk factors for SCD as “major” and “possible” in individual patients. The major risk factors include prior cardiac arrest, spontaneous sustained VT, spontaneous non-sustained VT, family history of SCD, syncope, LV thickness greater than or equal to 30 mm, and an abnormal blood pressure response to exercise. This consensus document also noted possible risk factors, which included AF, myocardial ischemia, LV outflow obstruction, high-risk mutations, and intense (competitive) physical exertion. The severity of other symptoms, such as dyspnea, chest pain, and effort intolerance, has not been correlated with increased risk of SCD. A flat or hypotensive response to upright or supine exercise testing in patients younger than 40 years old has been shown to be a risk factor for SCD, although the positive predictive value of this finding is low. A normal blood pressure response identifies a low-risk group. The presence of non-sustained VT on Holter monitoring has been associated with a higher risk of SCD, although the positive predictive accuracy is relatively low. Recent analyses indicate that in a high-risk HCM cohort, ICD interventions were frequent and were highly effective in restoring normal sinus rhythm. However, an important proportion of ICD discharges occur in primary prevention patients who undergo implantation of the ICD for a single risk factor. Therefore, a single risk marker of high risk for sudden cardiac arrest may be sufficient to justify consideration for prophylactic ICD implantation in selected patients.

Although no randomized studies are available, the ICD has been used in patients with cardiac arrest, sustained VT, or VF, with a high percentage of patients receiving appropriate ICD discharge during follow-up at a rate of 11% per year. In a nonrandomized study of ICD implantation in HCM, ICD implantation in a subgroup of patients for primary prophylaxis on the basis of perceived high risk for SCD (syncope, family history of SCD, non-sustained VT, inducible VT, or septal thickness greater than or equal to 30 mm) resulted in a lower rate of appropriate discharge of 5% per year. The ICD is not indicated in the majority of asymptomatic patients with HCM, who will have a relatively benign course. Its role is individualized in the patient considered to be at high risk for SCD. Although precise risk stratification has not been validated, patients with multiple risk factors (especially severe septal hypertrophy, greater than or equal to 30 mm) and those with SCD (especially multiple SCDs) in close relatives appear to be at sufficiently high risk to merit consideration of ICD therapy.

3.2.5. Arrhythmogenic Right Ventricular Dysplasia/ Cardiomyopathy

Selected patients with ARVD/C may be at risk for SCD. Because clinical series have reported favorable outcomes with this therapy for primary prevention of SCD in ARVD/C, the ICD has assumed a larger role in therapy. On the basis of the available clinical data from observational studies, it is reasonable to conclude that ICD is a reasonable therapy for secondary prevention of sudden cardiac arrest in patients with ARVD/C.

When an ICD is being considered for primary prevention, it should be kept in mind that predictive markers of SCD in patients with ARVD/C have not yet been defined in large prospective studies focusing on survival. Risk factors that have clinical utility in identifying patients with ARVD/C who are at risk for life-threatening ventricular arrhythmias include induction of VT during electrophysiological testing, detection of non-sustained VT on noninvasive monitoring, male gender, severe RV dilation, and extensive RV involvement. Young age at presentation (less than 5 years), LV involvement, prior cardiac arrest, and unexplained syncope serve as markers of risk. Patients with genotypes of ARVD/C associated with a high risk for SCD should be considered for ICD therapy.

Although the role of ICD therapy for primary prevention of sudden death in patients with ischemic heart disease and dilated, nonischemic cardiomyopathy is well established on the basis of multiple clinical trials with a consistent finding of benefit, the data supporting ICD use in patients with ARVD/C are less extensive. Some authorities have proposed that an ICD should be implanted in patients with ARVD/C and an increased risk for SCD based on the presence of a previous cardiac arrest, syncope due to VT, evidence of extensive RV disease, LV involvement, or presentation with polymorphic VT and RVA aneurysm, which is associated with a genetic locus on chromosome 1q42–43.

It is evident that there is not yet clear consensus on the specific risk factors that identify those patients with ARVD/C in whom the probability of SCD is sufficiently high to warrant an ICD for primary prevention. In the future, the results of large prospective registries with rigorous enrollment criteria for patients with ARVD/C in whom ICDs have

been placed for primary prevention will give insights into the optimal risk stratification techniques for primary prevention. In the meantime, individualized decisions for primary prevention of SCD must be based on experience, judgment, and the available data. In considering this decision, the clinician should be mindful that in patients with ARVD/C, the ICD has proved safe and reliable in sensing and terminating sustained ventricular arrhythmias. Sudden death is rare in the available clinical series, whereas appropriate ICD shocks are common.

3.2.6. Noncompaction of the Left Ventricle

Noncompaction of the LV is a rare congenital cardiomyopathy characterized anatomically by excessive prominent trabeculae and deep intertrabecular recesses in the LV without other major congenital cardiac malfunction. The origin of the anatomic abnormalities is likely due to an arrest of normal embryogenesis of the endocardium and epicardium of the ventricle during development. This leads to suspension of the normal compaction process of the loose myocardial meshwork. Diagnosis is difficult and is frequently missed or delayed owing to lack of knowledge about this uncommon disease. Echocardiography is considered by many to be the diagnostic procedure of choice, but some cases are detected by computed tomography or magnetic resonance imaging. Abnormalities in the resting ECG, including bundle-branch block or ST-segment depression, are found in most patients, but the findings do not have a high degree of sensitivity or specificity.

Ventricular arrhythmias and sudden death are among the major complications of this disorder. Sudden death can occur at any age, and there are currently no techniques clinically useful for risk stratification for life-threatening ventricular arrhythmias with noncompaction. Although there is no impairment of systolic function, ventricular arrhythmias are frequent in noncompaction. Approximately 40% of children with noncompaction demonstrate complex ventricular arrhythmias. Available clinical data indicate that sudden death is the most common cause of mortality. Although there are no prospective trials or registry data, there are sufficient observational data to indicate that placement of an ICD as a strategy to reduce the risk of sudden death is a reasonable clinical strategy.

3.2.7. Primary Electrical Disease (Idiopathic Ventricular Fibrillation, Short-QT Syndrome, Brugada Syndrome, and Catecholaminergic Polymorphic Ventricular Tachycardia)

The Brugada syndrome is characterized by ST-segment elevation across the right precordial leads in association with a high risk of SCD. Although the Brugada-pattern ECG most commonly shows J-point segment elevation in leads V1 to V3 and right bundle-branch block, the ECG pattern can be intermittent. Less commonly, the J-point elevation occurs in the inferior leads. Patients with the Brugada syndrome have a structurally normal heart with a primary channelopathy. This is transmitted with an autosomal dominant pattern of inheritance, and more than 90% of those affected are male. The genetic basis for the Brugada syndrome involves the cardiac sodium channel gene (SCN5A).

Cardiac events such as syncope or cardiac arrest occur predominantly in the third and fourth decades of life, although presentation with cardiac arrest in neonates or children has been reported. Fever can acutely predispose to cardiac arrest in the Brugada syndrome.

Risk stratification for SCD in patients with the Brugada syndrome is of clinical importance, because implantation of an ICD is the only prophylactic measure able to prevent SCD. As with long-QT syndrome, there are no data showing that family history predicts cardiac events among family members with the Brugada syndrome. Accordingly, asymptomatic individuals with the characteristic ECG but with no family history are not necessarily at low risk (16). Additionally, family members of an individual with SCD due to Brugada syndrome should not be assumed to be at increased risk of SCD (16). Patients with a spontaneous Brugada pattern have a worse prognosis than individuals in whom the typical ECG is observed only after pharmacological drug challenge. Patients with syncope and the ECG pattern of spontaneous ST-segment elevation have a 6-fold higher risk of cardiac arrest than patients without syncope and the spontaneous ECG pattern.

The role of electrophysiological testing remains controversial in the Brugada syndrome. Although some investigators suggest that electrophysiological testing has a useful role in risk stratification, others have not confirmed this observation. Electrophysiological testing had a low positive predictive value (23%), but over a 3-year follow-up, it had a very high negative predictive value (93%). By contrast, Priori et al. reported that electrophysiological testing has a low accuracy in predicting individuals who will experience cardiac arrest. Priori et al. have proposed that noninvasive risk stratification based on the ECG and symptoms provides an accurate alternative for risk stratification.

Because only a single gene has been linked to the Brugada syndrome, there is still insufficient information about the contribution of genetic defects in predicting clinical outcome. Specific mutations in the SCN5A gene do not identify a subset of patients at higher risk of cardiac events. SCD is caused by rapid polymorphic VT or VF that frequently occurs at rest or during sleep. Patients with Brugada syndrome usually do not have ventricular extrasystoles or non-sustained runs of VT at Holter recording. Therefore, the therapeutic approach for these patients is centered on the prevention of cardiac arrest.

Catecholaminergic polymorphic VT is characterized by ventricular tachyarrhythmias that develop in relation to physical or emotional stress in the presence of a resting ECG that shows no diagnostic abnormalities at rest. The initial symptoms often manifest during childhood, although late-onset cases have been described. Catecholaminergic polymorphic VT is transmitted by either an autosomal dominant or recessive inheritance pattern. Approximately one-half of the autosomal dominant cases are caused by mutations in the gene encoding the cardiac ryanodine receptor (RyR2). This receptor is responsible for calcium release from the stores of the sarcoplasmic reticulum. Mutations in the gene that encodes calsequestrin (CASQ2), a calcium buffering protein in the sarcoplasmic reticulum, have been associated with the recessive form of catecholaminergic polymorphic VT.

Risk stratification for SCD in catecholaminergic polymorphic VT is not possible given the relatively small number of patients reported. Most clinical reports indicate that beta blockers appear to be an effective treatment. Patients who have had an episode of VF are considered at higher risk and are usually treated with an ICD in addition to beta-blocker therapy. The recurrence of sustained VT, hemodynamically untolerated VT, or syncope for which causes other than VT are excluded while the patient is receiving a beta blocker are similarly considered markers of higher risk. In such patients, an ICD is a commonly used and reasonable approach. Furthermore, electrophysiological testing is not useful in the management of patients with catecholaminergic polymorphic VT since the arrhythmia is usually not inducible with programmed ventricular stimulation. Both supraventricular and ventricular arrhythmias are usually reproducibly induced by exercise stress test. Isolated premature ventricular complexes generally precede runs of non-sustained VT.

With continued exercise, the runs of VT typically increase in duration, and VT may become sustained. A beat-to-beat alternating QRS axis that changes by 180° ("bidirectional VT") is a typical pattern of catecholaminergic polymorphic VT-related arrhythmias. Catecholaminergic polymorphic VT patients can also present with irregular polymorphic VT or VF. Beta blockers are generally effective in preventing recurrences of syncope even when arrhythmias can still be elicited during an exercise stress test. If syncope occurs in a patient taking a beta blocker, implantation of an ICD is recommended.

VF has been reported in patients with abnormal repolarization due to ion channel mutations that result in a markedly shortened QT interval. Only a few small series of such patients have been described, and at present, evidence-based recommendations about management of asymptomatic individuals with a short QT interval cannot be made. Some patients who survive a clinical episode of VF have no identifiable structural heart disease, no documented transient cause for arrhythmia, and no known ion channel defect. In such patients, VF is termed "idiopathic." ICD therapy is appropriate for secondary prevention in patients with the short-QT syndrome and idiopathic VF.

3.2.8. Idiopathic Ventricular Tachycardias

Monomorphic VT may be seen in individuals with structurally normal hearts who have no known ion channelopathies. The most common sites of origin are the RV outflow tract, the fascicular region of the LV, structures in the LV outflow tract, and the mitral annular region. The risk for sudden death related to these arrhythmias is low.

3.2.9. Advanced Heart Failure and Cardiac Transplantation

Patients with moderate to severe heart failure face the twin risks of terminal heart failure decompensation and death due to unanticipated ventricular tachyarrhythmias. When ICD or CRT-D implantation is discussed with these patients, the likelihood of both life-saving and inappropriate shocks should be placed in the context of the overall anticipated mortality with heart failure, the expected duration of life prolongation after effective therapies, and the likely evolution to limiting symptoms and ultimately death due to pump failure. The relative contribution of preventable sudden death to mortality

decreases with repeated hospitalizations and multiple comorbidities, particularly in the setting of kidney dysfunction or advanced age. These factors, whether cardiac or noncardiac, also influence the value that patients place on quality versus length of life remaining. However, individual preferences cannot be assumed and should be explored with each patient.

Candidates for transplantation constitute a special case of severe heart failure because of the likelihood of prolonged survival after transplantation, with 50% of patients currently surviving at 10 years after transplantation. The high rate of sudden death on the transplant waiting list merits ICD implantation in most candidates with heart failure who are awaiting transplantation out of the hospital. The ICD has been highly effective as a bridge to transplantation for these individuals both with and without a prior history of life-threatening arrhythmias.

Class IV status itself is a heterogenous and dynamic state in which the absolute incidence of sudden death increases but the proportion of sudden deaths prevented by ICDs declines, and heart failure deaths account for a greater proportion of overall mortality. Once patients have persistent or frequently recurrent Class IV symptoms despite optimal management, life expectancy is less than 12 months, and ICD implantation is not indicated, regardless of patient and family preferences. Occasionally, patients cannot be weaned from intravenous inotropic infusions and are discharged with chronic inotropic infusion therapy for symptom palliation, with the expectation that death due to heart failure will likely occur within the next 6 months. Despite the proarrhythmic potential of inotropic agents, these patients receiving chronic infusions should not be given an ICD (unless awaiting transplantation or other definitive therapy).

Often, patients hospitalized with Class IV symptoms will undergo substantial improvement and can be discharged on oral therapy with minimal or no symptoms at rest. For these patients who can remain stable at 1 month after discharge, without evidence of recurrent congestion or worsening renal function, survival is similar to that of other Class III patients who have not been recently hospitalized. In this situation, ICD implantation can be discussed and may be expected to improve survival.

Patients with Class IV symptoms of heart failure with prolonged QRS duration and optimal lead placement may return to Class III status or better for both function and survival, at which point prevention of sudden death again becomes a relevant goal. Information on this group is limited because only 10% of the almost 4,000 patients in resynchronization trials have had Class IV symptoms. In the COMPANION trial, there were Class IV patients for whom resynchronization improved QOL and reduced rehospitalization and mortality; however, these patients had been stable at home before study entry and may not represent typical Class IV patients. Even in this selected group, there was no difference in 2-year survival between CRT patients with and without the defibrillator feature. In patients with Class IV symptoms in whom resynchronization is inadequate to restore clinical stability, the presence of a defibrillator often complicates the impending transition to end-of-life care.

Recommendations for Implantable Cardioverter Defibrillators

Secondary prevention refers to the prevention of SCD in those patients who have survived a prior cardiac arrest or sustained VT. Primary prevention refers to the prevention of SCD in individuals without a history of cardiac arrest or sustained VT. Patients with cardiac conditions associated with a high risk of sudden death who have unexplained syncope that is likely to be due to ventricular arrhythmias are considered to have a secondary indication.

Recommendations for consideration of ICD therapy, particularly those for primary prevention, apply only to patients who are receiving optimal medical therapy and have a reasonable expectation of survival with a good functional status for more than 1 year. It is difficult to estimate survival with heart failure in the general population, for whom comorbidities and age differ from those in trial populations from which the predictive models have been derived. Patients with repeated heart failure hospitalizations, particularly in the presence of reduced renal function, are at high risk for early death due to heart failure. See above for discussion regarding the use of LVEFs based on trial inclusion criteria.

We acknowledge that the “ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death” used the LVEF of less than 40% as a critical point to justify ICD implantation for primary prevention of SCD. The LVEF used in clinical trials assessing the ICD for primary prevention of SCD ranged from less than or equal to 40% in MUSTT to less than or equal to 30% in MADIT II. Two trials, MADIT I and SCD-HeFT used LVEFs of less than or equal to 35% as entry criteria for the trial. This writing committee reached consensus that it would be best to have ICDs offered to patients with clinical profiles as similar to those included in the trials as possible. Having given careful consideration to the issues related to LVEF for these updated ICD guidelines, we have written these indications for ICDs on the basis of the specific inclusion criteria for LVEF in the trials. Because of this, there may be some variation from previously published guidelines.

We also acknowledge that the determination of LVEF lacks a “gold standard” and that there may be variation among the commonly used clinical techniques of LVEF determination. All clinical methods of LVEF determination lack precision and the accuracy of techniques varies amongst laboratories and institutions. Based on these considerations, this writing committee recommends that the clinician use the LVEF determination that they feel is the most clinically accurate and appropriate in their institution.

p. e22-26:

Progression of LV systolic dysfunction to clinical HF is frequently accompanied by impaired electromechanical coupling, which may further diminish effective ventricular contractility. The most common disruptions are prolonged atrioventricular conduction (first-degree atrioventricular block) and prolonged interventricular conduction, most commonly LBBB. Prolonged interventricular and intraventricular conduction causes regional mechanical delay within the left ventricle that can result in reduced ventricular systolic function, altered myocardial metabolism, functional mitral regurgitation, and adverse remodeling with ventricular dilatation. Prolongation of the QRS duration occurs

in approximately one third of patients with advanced HF and has been associated with ventricular electromechanical delay ("dyssynchrony"), as identified by multiple sophisticated echocardiographic indices. QRS duration and dyssynchrony both have been identified as predictors of worsening HF, sudden cardiac death, and total death.

Modification of ventricular electromechanical delay with multisite ventricular pacing (commonly called "biventricular pacing" or CRT) can improve ventricular systolic function, reduce metabolic costs, ameliorate functional mitral regurgitation, and, in some patients, induce favorable remodeling with reduction of cardiac chamber dimensions. Functional improvement has been demonstrated for exercise capacity, with peak oxygen consumption in the range of 1 to 2 mL/kg/min and a 50- to 70-meter increase in 6-minute walking distance, as well as a 10-point or greater reduction of HF symptoms on the 105-point Minnesota Living with Heart Failure scale.

Meta-analyses of initial clinical experiences and larger subsequent trials of CRT confirmed an approximately 30% decrease in hospitalizations and a mortality rate benefit of 24% to 36%. In the COMPANION (Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure) trial (NYHA class III/IV HF, QRS duration 120 ms, and LVEF 35% on GDMT), GDMT was compared to CRT pacing therapy without backup defibrillation (CRT-Pacemaker) and to CRT therapy with defibrillation backup (CRT-D). Both CRT-Pacemaker and CRT-D reduced the risk of the primary composite endpoint by approximately 20% as compared with GDMT alone. CRT-D reduced the mortality rate by 36% compared with medical therapy, but there was insufficient evidence to conclude that CRT-Pacemaker was inferior to CRT-D. The CARE-HF (Cardiac Resynchronization in Heart Failure) trial limited subjects to a QRS duration 150 ms (89% of patients) or QRS duration 120 to 150 ms with echocardiographic evidence of dyssynchrony (11% of patients). It was the first study to show a significant (36%) reduction in death rate for resynchronization therapy unaccompanied by backup defibrillation compared with GDMT.

In the present document, we give a Class I recommendation for CRT in patients with QRS duration 150 ms. The differential classification seen in this document related to QRS duration is based on the results of multiple analyses of CRT benefit. The prevalence of mechanical dyssynchrony has been documented in 40% of patients with dilated cardiomyopathy and QRS duration 120 ms, and is as high as 70% among patients with QRS duration 150 ms and intraventricular mechanical delay, as identified by several echocardiographic techniques. However, the aggregate clinical experience has consistently demonstrated that a significant clinical benefit from CRT is greatest among patients with QRS duration 150 ms. In a meta- analysis of 5 trials involving 6501 patients, CRT significantly decreased the primary endpoint of death or hospitalization for HF in patients with QRS duration 150 ms (HR: 0.58; 95% CI: 0.50 to 0.68; p=0.00001) but not in patients with QRS duration 150 ms (HR: 0.95; 95% CI: 0.83 to 1.10; p=0.51). In addition, subgroup analyses from several studies have suggested that a QRS duration of 150 ms is a risk factor for failure to respond to CRT therapy. The observed differential benefit of CRT was seen across patients in NYHA classes I through IV. It has not been possible to reliably identify those with shorter QRS durations who may benefit. Patients with shorter QRS durations who otherwise qualify for CRT are afforded Class II recommendations in these guidelines.

An additional difference in the present document compared with the 2008 DBT guideline (1d) is the limitation of the recommendation for Class I indication to patients with LBBB pattern as compared to those with non-LBBB. For patients with QRS duration 120 ms who do not have a complete LBBB (non-LBBB patterns), evidence for benefit with CRT is less compelling than in the presence of LBBB. The impact of the specific QRS morphology on clinical event reduction with CRT was evaluated in a meta-analysis of 4 clinical trials including 5,356 patients. In those with LBBB, CRT significantly reduced composite adverse clinical events (RR: 0.64; 95% CI: 0.52 to 0.77; p=0.00001). No benefit was observed for patients with non-LBBB conduction abnormalities (RR: 0.97; 95% CI: 0.82 to 1.15; p=0.75). Specifically, there was no benefit in patients with right bundle-branch block (RR: 0.91; 95% CI: 0.69 to 1.20; p=0.49) or nonspecific intraventricular conduction delay (RR: 1.19; 95% CI: 0.87 to 1.63; p0.28). Overall, the difference in effect of CRT between LBBB versus non-LBBB patients was highly statistically significant (p=0.0001). Nevertheless, other studies have shown that CRT is more likely to be effective in patients with advanced HF and non-LBBB morphologies if they have a markedly prolonged QRS duration (see RAFT [Resynchronization-Defibrillation for Ambulatory Heart Failure Trial] discussion below). Furthermore, patients with QRS prolongation due to frequent right ventricular apical pacing may benefit from CRT when other criteria for CRT are met. No large trial has yet demonstrated clinical benefit among patients without QRS prolongation, even when they have been selected with echocardiographic measures of dyssynchrony.

The observed heterogeneity of response even among those who would appear to be excellent candidates for CRT also may result from factors such as suboptimal lead location and the location of conduction block from fibrosis in relation to the pacing site. Several recent studies have emphasized the importance of LV lead placement. For example, wider LV-right ventricular lead separation has been shown to provide better results. A sub analysis of MADIT-CRT (Multi-center Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy) showed that an apical LV lead position, as compared with a basal or midventricular position, resulted in a significant increased risk for HF or death.

Clinical trials of resynchronization included mainly patients in sinus rhythm. However, prospective experience among patients with permanent atrial fibrillation and with decreased LV systolic function suggests that benefit may result from biventricular pacing when the QRS duration is 120 ms, although it may be most evident in patients in whom atrioventricular nodal ablation has been performed, such that right ventricular pacing is obligate. The benefit of CRT in patients with atrial fibrillation is more pronounced in those with depressed ejection fraction. Similarly, patients receiving prophylactic ICDs often evolve progressively to dominant ventricular pacing, which may reflect both intrinsic chronotropic incompetence and aggressive up-titration of beta-adrenergic-blocking agents.

When device implantation or reimplantation is being considered for patients who require ventricular pacing, it is prudent to recall the results of the DAVID (Dual Chamber and VVI Implantable Defibrillator) trial. In this trial, dual-chamber rate-responsive pacing increased HF admissions and mortality rate as compared to sinus rhythm. A cutoff of approximately 40% right ventricular pacing was seen as deleterious. Similarly, in a sub study from MADIT-II (Multicenter Automatic Defibrillator Implantation Trial II), patients

who were right ventricular paced 50% of the time had a higher rate of new or worsened HF than those right ventricular paced 50% of the time.

The major experience with resynchronization derives from patients with NYHA class III symptoms of HF and LVEF 35%. Patients with NYHA class IV symptoms of HF have accounted for only 10% of all patients in clinical trials of resynchronization therapy. These patients were highly selected ambulatory outpatients who were taking oral medications and had no history of recent hospitalization. Although a benefit has occasionally been described in patients with more severe acute decompensation that required brief positive intravenous inotropic therapy to aid diuresis, CRT is not generally used as a “rescue therapy” for such patients. Patients with dependence on intravenous inotropic therapy, refractory fluid retention, or advanced chronic kidney disease represent the highest-risk population for complications of any procedure and for early death after hospital discharge, and they are also unlikely to receive a meaningful mortality risk benefit from concomitant defibrillator therapy.

Patients with NYHA class IV HF symptoms who derive functional benefit from resynchronization therapy may return to a better functional status, in which prevention of sudden death becomes a relevant goal. Even among the selected NYHA class IV patients identified within the COMPANION trial, there was no difference in 2-year survival rate between the CRT patients with and without backup defibrillation, although more of the deaths in the CRT-Pacemaker group were classified as sudden deaths.

Perhaps the most significant changes in the present document compared to the 2008 DBT Guideline 1d are the expansion of the Class I recommendation for CRT to include patients with LBBB, QRS duration 150 ms, and NYHA class II and the addition of a Class IIb recommendation for patients who have LVEF 30%, ischemic etiology of HF, sinus rhythm, LBBB with a QRS duration of 150 ms, and NYHA class I symptoms. These recommendations are based on 4 studies in which CRT was evaluated in patients with minimal or mild symptoms of HF in the setting of low LVEF. These include MADIT-CRT, RAFT, REVERSE (Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction), and MIRACLE ICD II (Multicenter InSync ICD Randomized Clinical Evaluation II), all of which are discussed in the following paragraphs, randomized patients with NYHA class I or II ischemic and NYHA class II nonischemic cardiomyopathy, LVEF 30%, and QRS duration 130 ms on GDMT to CRT-D or ICD alone. Of note, only 15% of the total cohort of patients were NYHA class I. The primary endpoint, a composite of death or HF event, was reduced by 34% by CRT-D (HR: 0.66), with comparable benefit for both ischemic and nonischemic etiology of HF. HF events were reduced by 41%, without significant reduction in mortality rate. CRT-D therapy was demonstrated to be of more benefit in women than in men (HR: 0.37 and 0.76, respectively) and in patients with QRS duration 150 ms than in patients with QRS duration 150 ms (HR: 0.48 and 1.06, respectively). Patients with LBBB had a significant reduction in ventricular tachycardia, ventricular fibrillation, and death compared to non-LBBB patients, who derived no benefit (HR: 0.47 and 1.24, respectively).

RAFT reported the use of CRT-D in patients with NYHA class II or class III ischemic or nonischemic cardiomyopathy, LVEF 30%, and QRS duration 120 ms, as compared to those treated with an ICD alone. The primary outcome of death or hospitalization for HF

occurred in 33% of patients receiving CRT-D and in 40% of patients receiving ICD only. RAFT not only showed a significant reduction in hospitalization for HF (HR: 0.68; 95% CI: 0.56 to 0.83; p=0.001) but also was the first study to show a statistically significant reduction in death (HR: 0.75; 95% CI: 0.62 to 0.91; p=0.003) in mildly symptomatic patients with NYHA class II symptoms. However, CRT-D was associated with a higher risk of adverse device-or implantation-related complications at 30 days after implantation (p0.001) compared with an ICD and no CRT. Patients with LBBB had a better outcome than did non-LBBB patients, but the statistical interaction between benefit and QRS morphology was weak in this trial (p0.046). CRT-D therapy was effective in patients with QRS duration 150 ms but of no benefit in patients with QRS duration 150 ms (HR for QRS duration 150 ms: 0.59; 95% CI: 0.48 to 0.73; HR for QRS duration 150 ms: 0.99; 95% CI: 0.77 to 1.27; p0.002 for interaction). Thus, both MADIT-CRT and RAFT showed benefit in NYHA class II patients treated with CRT-D and demonstrated that the benefit was primarily achieved in patients with QRS duration 150 ms and LBBB.

The REVERSE trial consisted of 610 patients. This study assessed CRT-D therapy in patients with NYHA class I or II HF symptoms on maximum medical therapy, LVEF 40%, and QRS duration 120 ms followed for 12 months and showed that 16% of patients receiving CRT and 21% without CRT worsened (p0.10). The time to first HF hospitalization was delayed in patients receiving CRT therapy (HR: 0.47). The primary echocardiographic endpoint of ventricular re-modeling assessed by LV end-systolic volume index was significantly improved (reduction in end-systolic volume index) in patients treated with CRT therapy (p0.0001). REVERSE did not report a mortality rate benefit of CRT-D therapy. The lack of reported mortality rate benefit may be related to the higher ejection fraction enrollment criterion (LVEF 40%) and the relatively short-term follow-up (12 months).

MIRACLE ICD II included patients with NYHA class II HF on GDMT with LVEF 35% and QRS duration 130 ms who were undergoing implantation of an otherwise indicated ICD. In these patients, CRT did not alter exercise capacity but did result in significant improvement in cardiac structure and function and composite clinical response over 6 months.

Analysis of the multiple clinical trials of CRT is complicated because trials encompass a range of LVEFs in their entry criteria, as well as a range of measured outcomes. For mortality rate, the trials showing benefit in NYHA class III and IV patients typically included those with LVEF 35%. For patients with NYHA class II, trials showing mortality rate benefit included those with LVEF 30%. A mortality rate benefit with CRT has not been shown for patients who are NYHA class I. In terms of demonstrating improvement in cardiac function (e.g., significant reduction in LV size and improvement in ejection fraction), trials have included patients with LVEF 35% who are NYHA class III and IV. Similarly, for patients with LVEF 40%, trials demonstrating improvement in function have included those who are NYHA class I and II (548). The congruence of results from the totality of CRT trials with regard to remodeling and HF events provides evidence supporting a common threshold of 35% for benefit from CRT in patients with NYHA class II through IV HF symptoms. Although there is evidence for benefit in both CRT-D and CRT-Pacemaker patients with NYHA class III and IV symptoms, for NYHA class I

and II HF, all of the trials tested only CRT-D and not CRT-Pacemaker, and as such, recommendations for these classes of patients can be made only for CRT-D.

Taken together, the evidence from the randomized trials of CRT-D in patients with reduced LVEF and NYHA class I or II shows that CRT can provide functional improvement and decrease the risk of HF events and composite outcomes. Still, CRT-D also has been shown to decrease the mortality rate for patients with NYHA class II but not for those who have NYHA class I HF. As a result, the data support a Class I recommendation for CRT implantation in patients with LBBB and QRS duration 150 ms and NYHA class II. Because of the lack of mortality rate benefit and smaller sample size, we believe CRT may be considered for patients who have LVEF 30%, ischemic etiology of HF, sinus rhythm, LBBB with a QRS duration 150 ms, and NYHA class I symptoms on GDMT (*Class IIb; LOE: B*).

For all patients, optimal outcomes with CRT require effective placement of ventricular leads, ongoing HF management with neurohormonal antagonists and diuretic therapy, and in some cases, later optimization of device programming, especially atrioventricular (A-V) and interventricular (V-V) intervals.

Consistent with entry criteria for studies upon which these recommendations are based, CRT implantation should be performed only when the LVEF meets guideline criteria for patients with nonischemic cardiomyopathy who have received 3 months of GDMT, or for patients with ischemic cardiomyopathy 40 days after myocardial infarction receiving GDMT when there was no intervening revascularization, or 3 months if revascularization was performed. It is assumed that the final decision to recommend CRT will be based on an assessment of LVEF made after any appropriate waiting period has concluded, during which GDMT has been applied. Finally, the pivotal trials demonstrating the efficacy of CRT took place in centers that provided expertise in device and HF therapy both at implantation and during long-term follow-up.

Two other organizational guidelines by the Heart Failure Society of America and the European Society of Cardiology have ~~recently~~ been published that address indications for CRT. For the patient categories in common between the Heart Failure Society of America document and the present focused update, there was a good deal of concordance. Although there are many areas of agreement, some differences exist between the present guideline and the European Society of Cardiology document. One difference is that in the present guideline, CRT is recommended in NYHA class I patients who have LVEF 30%, have ischemic heart disease, are in sinus rhythm, and have a LBBB with a QRS duration 150 ms (*Class IIb; LOE: C*). There is no similar recommendation in the European Society of Cardiology document. The European Society of Cardiology recommendations include patients with QRS duration 120 ms. We have not recommended CRT for any functional class or ejection fraction with QRS durations 120 ms. We also have elected to consider the presence of LBBB versus non-LBBB in the class of recommendations, on the basis of perceived differential benefit by functional class, QRS morphology, and QRS duration.

1a.11) Provide the estimates of benefit, and consistency across studies.

Estimates of the benefit of patients receiving device therapy based on Class I, IIa, or IIb

guideline indications across the body of evidence are not reported.

1a.12) Indicate what, if any, harms were identified in the study.

N/A

1a.13) Identify any new studies conducted since the systematic review and indicate whether the new studies change the conclusions from the systematic review.

Updated guidelines continue to support this measure.

Evidence

1a.14) Provide empirical data demonstrating the relationship between the outcome (or PRO) and at least one healthcare structure, process, intervention, or service.
N/A evidence has been provided above
1a.15) If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, describe the evidence on which you are basing the performance measure.

N/A evidence has been provided above

1a.16) Briefly synthesize the evidence that supports the measure.

N/A evidence has been provided above

1a.17) Detail the process used to identify the evidence.

N/A evidence has been provided above

1a.18) Provide the citation(s) for the evidence.

N/A evidence has been provided above

Importance to Measure and Report: Gap in Care/Disparities (1b.01 - 1b.05)

1b.01) Briefly explain the rationale for this measure.

Explain how the measure will improve the quality of care and list the benefits or improvements in quality envisioned by use of this measure.

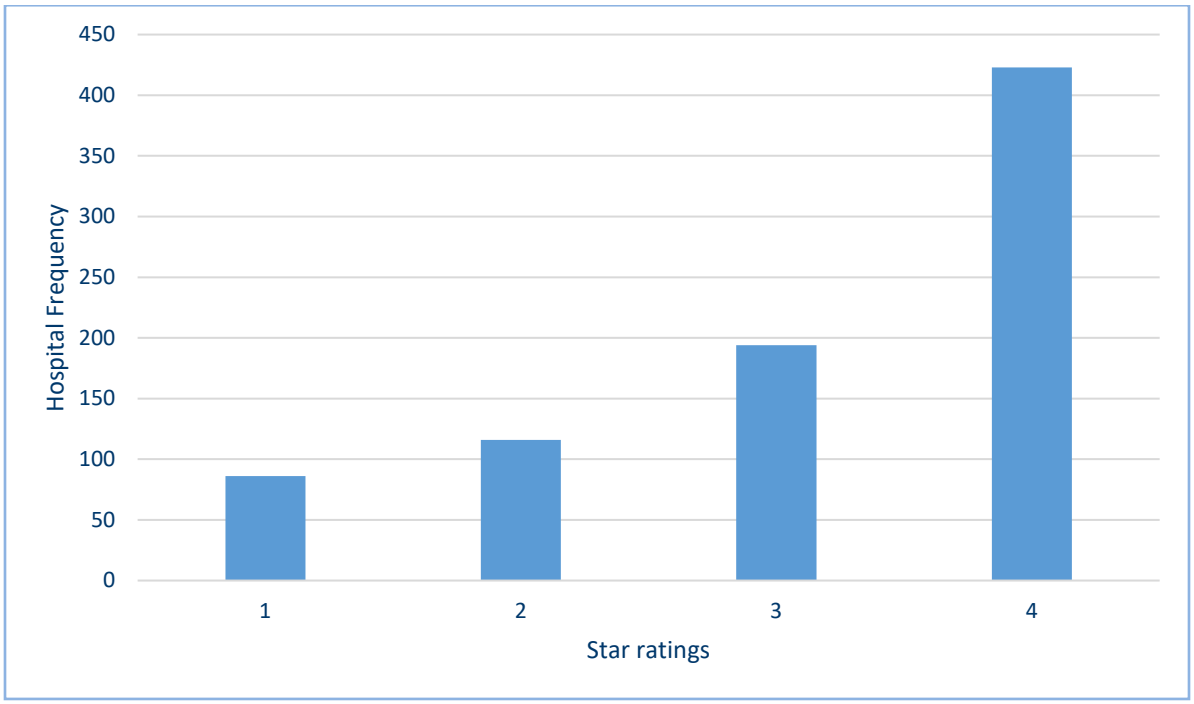
This composite measure is intended to assess the extent to which eligible patients receive evidence-based medications that are indicated at hospital discharge following ICD placement and to assess the proportion of eligible patients that meet class I, IIa or IIb guideline indications. By providing a composite score, this measure will allow hospitals to interpret their quality performance score more easily. This single score can be used in the NCDR voluntary hospital public reporting program which monitors the quality of cardiovascular care using high quality data that provides actionable insights.

1b.02) Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Include mean, std dev, min, max, interquartile range, and scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

To more easily interpret the quality performance score, hospitals are grouped into four-star categories. These star categories are set based on the recommended performance (P score) that all hospitals should achieve in their care of patients. Star cutoff values are the same for all metrics. These values are below:

Star rating	Thresholds (P score)	Frequency
One star	0 – 69.99	86
Two star	70 – 79.99	116
Three star	80 - 89.99	194
Four star	90 - 100	423



Performance scores for EPDI registry metric #14 (NQF # 0965) Discharge Medication (ACE/ARB/ARNI/Beta Blockers) in eligible ICD/CRT-D Implant

Distribution of Performance (N=1085) 2019Q1-2019Q4 EPDI Measure 14:

*	*	*Lowest Performing Sites*	*Lowest Performing Sites*	*Lowest Performing Sites*	*	*	*	*	*Highest Performing Sites*	*Highest Performing Sites*	*Highest Performing Sites*
Description	Total	**0-9%**	**10-19%**	**20-29%**	**30-39 %**	**40-49 %**	**50-59 %**	**60-69 %**	**70-79%**	**80-89%**	**90-100%**
*	*	*	*	*	*	*	*	*	*	*	*
N	1085	14	3	9	10	16	28	69	131	212	593
Mean	85.67	0.94	13.25	24.12	34.22	43.84	54.95	65.19	74.85	85.07	97.41
Std Deviation	18.40	2.58	2.59	2.45	2.91	2.76	3.64	3.06	2.93	2.92	2.99
*	*	*	*	*	*	*	*	*	*	*	*

100% Max	100.00	9.09	16.13	28.07	38.46	48.28	59.77	69.77	79.84	89.95	100.00
99%	100.00	8.43	16.06	27.82	38.45	48.26	59.66	69.72	79.49	89.89	100.00
95%	100.00	5.78	15.77	26.84	38.40	48.18	59.28	69.23	79.26	89.45	100.00
90%	100.00	2.80	15.40	25.61	38.35	47.88	58.95	69.15	78.79	88.89	100.00
75% Q3	99.06	0.00	14.31	25.00	36.46	45.68	58.38	67.59	77.59	87.50	100.00
50% Median	92.31	0.00	12.50	25.00	33.33	43.65	55.85	66.00	75.00	85.24	98.64
25% Q1	79.17	0.00	11.81	23.08	33.33	41.54	50.00	62.50	72.50	82.85	95.04
10%	65.09	0.00	11.39	20.72	31.16	40.86	50.00	60.00	70.59	80.89	92.64
5%	50.00	0.00	11.25	20.36	30.58	40.61	50.00	60.00	70.09	80.00	91.34
1%	0.00	0.00	11.14	20.07	30.12	40.12	50.00	60.00	70.00	80.00	90.46
0% Min	0.00	0.00	11.11	20.00	30.00	40.00	50.00	60.00	70.00	80.00	90.00

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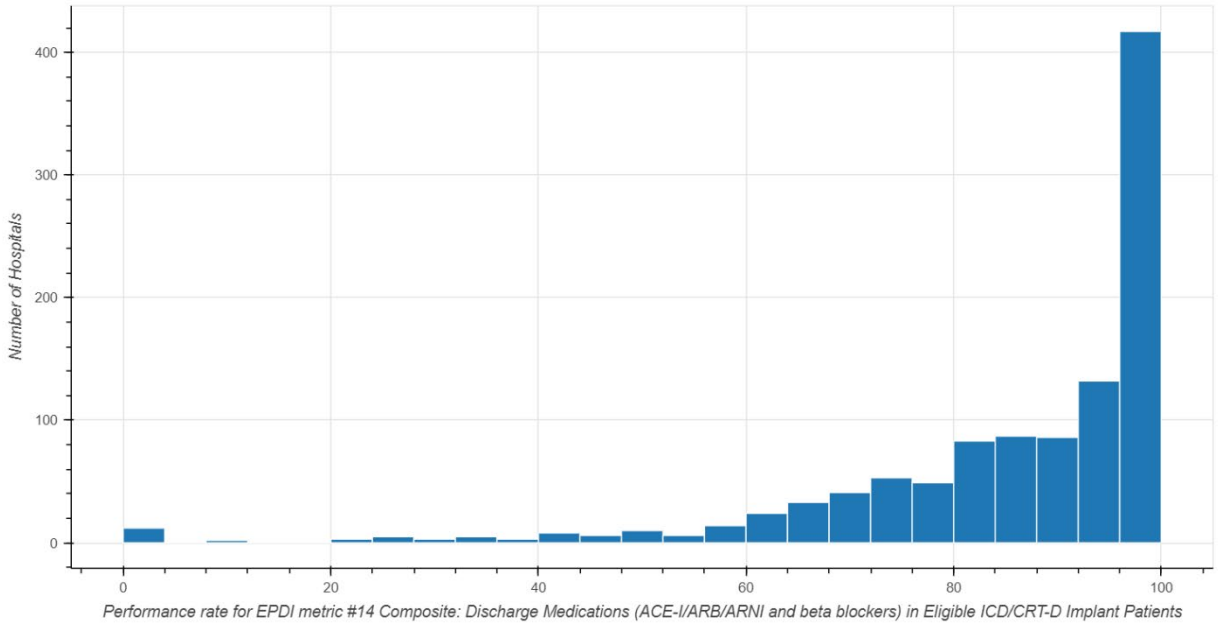
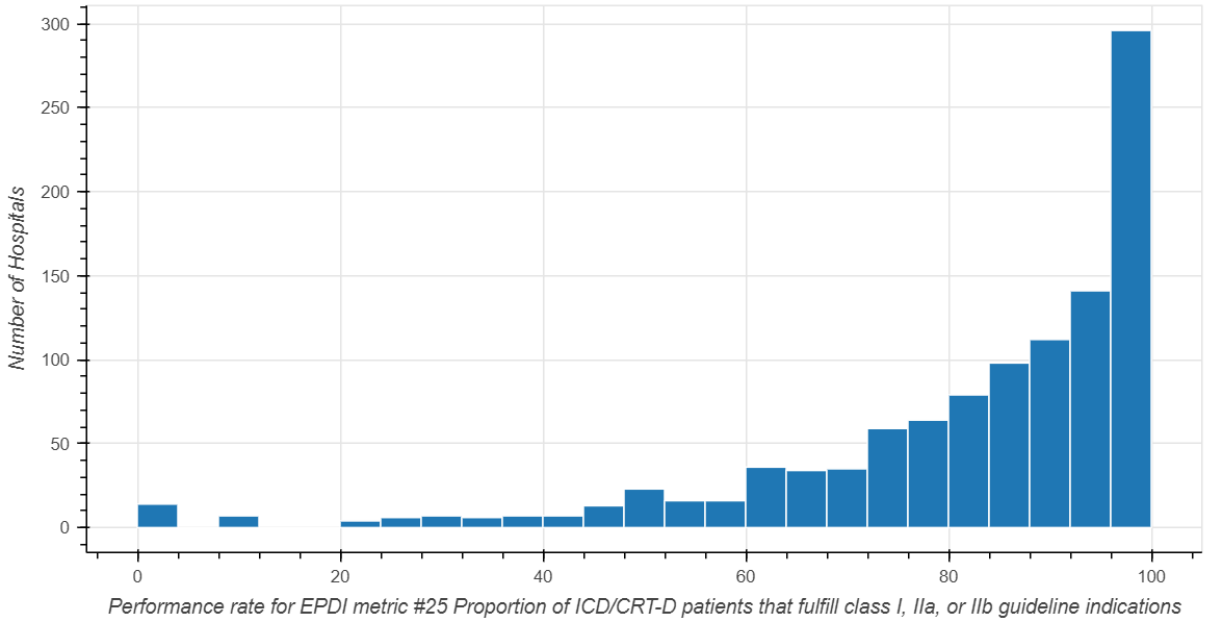
Histogram of Performance of EPDI measure 14 (ACE-I, ARB/ARNI and Beta Blockers) Measure 2019Q1-2019Q4



Performance scores for EPDI Registry metric #25: Proportion of ICD/CRT-D patients that fulfill class I, IIa or IIb guideline indications.

		Lowest Performing Sites							Highest Performing Sites		
Description	**Total**	**0-9%**	**10-19%**	**20-29%**	**30-39%**	**40-49%**	**50-59%**	**60-69%**	**70-79%**	**80-89%**	**90-100%**
N	1080	17	4	13	17	20	55	85	143	229	497
Mean	82.05	1.50	10.90	24.81	35.05	44.32	53.51	64.79	75.34	85.25	96.57
Std Deviation	20.03	3.33	0.74	2.79	3.09	2.51	3.48	2.93	2.74	2.91	3.22
100% Max	100.00	8.77	11.76	28.57	39.58	47.62	59.38	69.88	79.80	89.94	100.00
99%	100.00	8.70	11.75	28.57	39.44	47.51	59.31	69.73	79.76	89.83	100.00
95%	100.00	8.42	11.67	28.57	38.88	47.09	58.90	69.31	79.56	89.47	100.00
90%	100.00	8.33	11.57	28.57	38.56	46.95	58.63	68.50	78.91	88.89	100.00
75% Q3	96.67	0.00	11.27	26.15	37.50	46.22	56.90	66.67	77.78	87.68	100.00
50% Median	88.35	0.00	10.91	25.00	35.59	45.45	53.13	65.49	75.00	85.45	97.06
25% Q1	75.00	0.00	10.54	22.22	33.33	42.29	50.00	62.50	73.02	83.02	94.12
10%	55.53	0.00	10.21	21.54	31.07	40.00	50.00	60.75	71.43	80.94	91.64
5%	41.58	0.00	10.11	20.86	30.24	40.00	50.00	60.00	70.97	80.00	90.91
1%	0.00	0.00	10.02	20.17	30.05	40.00	50.00	60.00	70.25	80.00	90.00
0% Min	0.00	0.00	10.00	20.00	30.00	40.00	50.00	60.00	70.00	80.00	90.00

Histogram of Performance of Proportion of ICD/CRT-D patients that fulfill class I, IIa or IIb guideline indications 2019Q1-2019Q4



1b.03) If no or limited performance data on the measure as specified is reported above, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement. Include citations.

N/A

1b.04) Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

In order to explore the disparities data relevant to this composite measure over time, we examined the mean and median score of each disparity group and compared 2018 (n=1141) vs. 2019 (n=819) hospital to ascertain if there was an observed difference over time.

	Proportion of Non-White Patients	P-score by Quartile of Non-White Patients			
		Q1	Q2	Q3	Q4

2018					
Mean	0.2631	0.8517	0.8464	0.8312	0.8089
Std Deviation	0.2190	0.1399	0.1336	0.1399	0.1482
2019					
Mean	0.2643	0.8725	0.8795	0.8610	0.8473
Std Deviation	0.2206	0.1440	0.1301	0.1286	0.1274
	Proportion of Female Patients	**P-score by Quartile of Female Patients**			
		Q1	**Q2**	**Q3**	**Q4**
2018					
Mean	0.2878	0.8274	0.8242	0.8546	0.8325
Std Deviation	0.0667	0.1314	0.1591	0.1272	0.1436
2019					
Mean	0.2948	0.8439	0.8689	0.8833	0.8630
Std Deviation	0.0699	0.1388	0.1357	0.1213	0.1342
	Proportion of Patients Aged 65+	**P-score by Quartile of Patients Aged 65+ Years**			
		Q1	**Q2**	**Q3**	**Q4**
2018					
Mean	0.6120	0.8268	0.8408	0.8496	0.8212
Std Deviation	0.1089	0.1436	0.1457	0.1322	0.1422
2019					
Mean	0.6083	0.8441	0.8828	0.8890	0.8449
Std Deviation	0.1061	0.1502	0.1122	0.1208	0.1394
	Proportion of Medicaid Patients	**P-score by Quartile of Medicaid Patients**			
		Q1	**Q2**	**Q3**	**Q4**
2018					
Mean	0.0773	0.8318	0.8354	0.8567	0.8145
Std Deviation	0.0733	0.1360	0.1495	0.1286	0.1476
2019					
Mean	0.0802	0.8583	0.8678	0.8793	0.8548
Std Deviation	0.0730	0.1399	0.1430	0.1208	0.1268

	Overall Composite P-score				
2018					
Mean	0.8347				
Std Deviation	0.1413				
2019					
Mean	0.8651				
Std Deviation	0.1330				

1b.05) If no or limited data on disparities from the measure as specified is reported above, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in above.

N/A

Importance to Measure and Report: Composite Quality Construct and Rationale (1c.01 - 1c.04)

1c.01) Select the method of composite measure construction.

A composite performance measure is a combination of two or more component measures, each of which individually reflect quality of care, into a single performance measure with a single score. For purposes of Battelle measure submission, evaluation, and endorsement, the following will be considered composites:

- Measures with two or more individual performance measure scores combined into one score for an accountable entity.
- Measures with two or more individual component measures assessed separately for each patient and then aggregated into one score for an accountable entity.
    - all-or-none measures (e.g., all essential care processes received, or outcomes experienced, by each patient)

☐ two or more individual performance measure scores combined into one score
☒ two or more individual component measures assessed separately for each patient and then aggregated into one score

1c.02) Describe the quality construct.

Describe the area of quality measured, component measures, and the relationship of the component measures to the overall composite and to each other (whether reflective or formative model was used to develop this measure, and whether components are correlated).

Area of quality measured: This measure focuses on processes that are recommended for optimal care for patients following ICD/CRT-D implantation. Each component of the measure has been shown in randomized clinical trials to impact clinical outcomes and represents a Class 1 guideline indication for the care of patients with left ventricular systolic dysfunction or prior myocardial infarction. Combining the individual process measures into a single composite provides patients, physicians, and hospitals with a perspective of the overall quality of medical therapy provided to patients undergoing ICD/CRT-D implantation. Hospitals with a gap in performance can investigate the individual components of the measure to identify specific opportunities for improvement. The content validity of this measure has been achieved by virtue of its consistency with strong guideline recommendations and the expertise of the individuals who developed this measure.

Component measures: EPDI Registry metric 14: NQF # 0965 Discharge Medication (ACE/ARB/ARNI/Beta Blockers) in eligible ICD/CRT-D Implant patients and EPDI Registry metric 25: Proportion of ICD/CRT-D patients that fulfill class I, IIa or IIb guideline indications.

Relationship of component measures to overall composite: The EPDI Quality Composite comprises two equally weighted process measures, which contribute equally to the overall hospital quality composite score. The composite score ranges from 0-100, with a higher score indicative of better quality

1c.03) Describe the rationale for constructing a composite measure, including how the composite provides a distinctive or additive value over the component measures individually.

Rationale: This measure is intended to assess the extent to which eligible patients receive evidence-based care and provides several benefits to our participating hospitals. A composite measure has several benefits that improves quality.

Data reduction - A composite measure reduces the information burden by distilling the available indicators into a simple summary.

Scope expansion - The information in a composite measure is highly condensed, making it feasible to track a broader range of metrics than would be possible otherwise. Composite measures have been described as a tool for making provider assessments more comprehensive.

Provider performance valuation - Performance indicators are used for various decisions about providers, including the allocation of pay-for-performance incentives, designation of preferred provider status, and assignment of letter grades and star rating categories. If a decision is to be based on multiple indicators instead of a single indicator, a method of translating several variables into a single decision is needed. Composite measures serve this function by assigning providers to 1 position on a scale of better-to-worse performance.

Given all these uses, NCDR believes that while we will continue to report these measures at the individual level there is a distinctive value of having a composite measure endorsed by NQF.

1c.04) Describe how the aggregation and weighting of the component measures are consistent with the stated quality construct and rationale.

The EPDI Quality Composite comprises two equally weighted process measures, which contribute equally to the overall hospital quality composite score. Combining the individual process measures into a single composite provides patients, physicians, and hospitals with a perspective of the overall quality of medical therapy provided to patients undergoing ICD/CRT-D implantation.

Scientific Acceptability: Maintenance (2ma.01 - 2ma.04)

2ma.01) Indicate whether additional empirical reliability testing at the accountable entity level has been conducted. If yes, please provide results in the following section, Scientific Acceptability: Reliability - Testing. Include information on all testing conducted (prior testing as well as any new testing).

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission:

Updated testing information here.

Previous Submission:

Testing from the previous submission here.

☒ Yes
☐ No

2ma.02) Indicate whether additional empirical validity testing at the accountable entity level has been conducted. If yes, please provide results in the following section, Scientific Acceptability: Validity - Testing. Include information on all testing conducted (prior testing as well as any new testing).

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission:

Updated testing information here.

Previous Submission:

Testing from the previous submission here.

☒ Yes
☐ No

2ma.03) For maintenance measures in which risk adjustment/stratification has been performed, indicate whether additional risk adjustment testing has been conducted since the most recent maintenance evaluation. This may include updates to the risk adjustment analysis with additional clinical, demographic, and social risk factors.

Please update the Scientific Acceptability: Validity - Other Threats to Validity section.

Note: This section must be updated even if social risk factors are not included in the risk adjustment strategy.

☐ Yes - Additional risk adjustment analysis is included
☒ No additional risk adjustment analysis included

Scientific Acceptability: Reliability - Testing (2a.01 - 2a.12)

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing must be conducted at the composite score level.

If a component measure is submitted as an individual performance measure, the Scientific Acceptability sections must be completed and submitted as part of the individual measure's submission.

- Measures must be tested for all the data sources and levels of analyses that are specified. If there is more than one set of data specifications or more than one level of analysis, contact Battelle staff at PQMsupport@battelle.org about how to present all the testing information in one form.
- All required sections must be completed.
- For composites with outcome and resource use measures, Questions 2b.23-2b.37 (Risk Adjustment) also must be completed.
- If specified for multiple data sources/sets of specifications (e.g., claims and EHRs), Questions 2b.11-2b.13 also must be completed.
- An appendix for supplemental materials may be submitted (see Question 1 in the Additional section), but there is no guarantee it will be reviewed.
- Contact Battelle staff at PQMsupport@battelle.org with any questions.
- For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for the 2021 Measure Evaluation Criteria and Guidance.

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet the evaluation criteria for testing.

2a. Reliability testing demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.

2b1. Validity testing demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument-based measures (including-PRO-PMs) and

composite performance measures, validity should be demonstrated for the computed performance score.

2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure;

AND

If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

2b3. For outcome measures and other measures when indicated (e.g., resource use):

- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; and has demonstrated adequate discrimination and calibration

OR

- rationale/data support no risk adjustment/ stratification.

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance;

OR

there is evidence of overall less-than-optimal performance.

2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results.

2b6. Analyses identify the extent and distribution of missing data (or nonresponse), demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders), and how the specified handling of missing data minimizes bias.

2c. For composite performance measures, empirical analyses support the composite construction approach and demonstrate that:

2c1. the component measures fit the quality construct and add value to the overall

composite while achieving the related objective of parsimony to the extent possible; and

2c2. the aggregation and weighting rules are consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible.

(if not conducted or results not adequate, justification must be submitted and accepted)

Definitions

Reliability testing applies to the computed measure score. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

Validity testing applies to the computed measure score. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, (e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method); correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.

Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.

Patient preference: Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

Risk factors that influence outcomes should not be specified as exclusions.

Meaningful differences: With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v.$5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers.

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing (e.g., reliability vs. validity), be sure to indicate the specific differences below.

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission:

Updated testing information here.

Previous (Year) Submission:

Testing from the previous submission here.

2a.01) Select only the data sources for which the measure is tested.

☐ Assessment Data
☐ Claims
☐ Electronic Health Data
☐ Electronic Health Records
☐ Instrument-Based Data
☐ Management Data
☐ Other (please specify here:)
☐ Paper Medical Records
☒ Registry Data

2a.02) If an existing dataset was used, identify the specific dataset.

The dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).

We used data from the Electrophysiology Device Implant Registry, formerly known as the ICD registry. This is one of the suite of ACC's cardiovascular data registries that make up the National Cardiovascular Data Registry (NCDR®). This national quality improvement registry helps hospitals and private practices measure and improve the quality of care they provide. Rigorous quality standards are applied to the data and both quarterly and ad hoc performance reports are generated for participating centers to track and improve their performance.

2a.03) Provide the dates of the data used in testing.

Use the following format: "MM-DD-YYYY - MM-DD-YYYY"

01-01-2019 - 12-31-2019

2a.04) Select the levels of analysis for which the measure is tested.

Testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan.

☐ Accountable Care Organization
☐ Clinician: Group/Practice
☐ Clinician: Individual
☒ Facility
☐ Health Plan
☐ Integrated Delivery System
☐ Other (please specify here:)
☐ Population: Community, County or City
☐ Population: Regional and State

2a.05) List the measured entities included in the testing and analysis (by level of analysis and data source).

Identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample.

The final cohort included cases from 819 facilities who reported data to the NCDR. Measure development and testing was based on EPDI Registry data from patients undergoing ICD implantation who were discharged between January 1, 2019 - December 31, 2019. Only facilities with a minimum of eleven (11) ICD cases were eligible for participating in the quality composite. This ensured a reasonable degree of confidence that the score given is truly representative for the performance at the facility. We excluded sites unable to contribute to both ICD-Metric 14: Composite: Discharge medications (ACE/ARB and Beta Blockers) in eligible ICD patients and ICD-Metric 25: Proportion of ICD/CRT-D patients that fulfill class I, IIa, or IIb guideline indications.

Table 1. Facility Level Metric Distribution

Exclusions	Number of Hospitals
Initial Sample	1281
ICD cases <11 or no data reported	410
Remaining	871
Missing metric 14 or 25	52
Final cohort	819

2a.06) Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis), separated by level of analysis and data source; if a sample was used, describe how patients were selected for inclusion in the sample.

If there is a minimum case count used for testing, that minimum must be reflected in the specifications.

Please refer to the table below, illustrating patient demographics, medical history, diagnostic studies, procedural factors, discharge medications and hospital factors.

Table 2. Patient characteristics

Cells with * are intentionally left blank

** indicates the variable category is mutually exclusive variable

Description	Total	
	#	%
All	93784	100
Demographics	*	*
Age, years	66.39	13.15
Gender: Female **	27486	29.31
Race		
White (non-Hispanic)	69594	74.21

Description	Total	
Black (non-Hispanic)	14886	15.87
Hispanic	6404	6.83
Other	2900	3.09
Insurance Payors **	*	*
Medicare	57487	61.3
Medicaid	7135	7.61
Private Health Insurance	24832	26.48
Other	4330	4.62
Hospital Reason	*	*
Admitted for this Procedure	69722	74.34
Admitted for Heart Failure	5561	5.93
Other Reason	18299	19.51
Missing or Unknown	202	0.22
Medical History	*	*
Heart Failure	80667	86.01
NYHA Functional Classification	*	*
Missing	14001	14.93
Class I	6390	6.81
Class II	33911	36.16
Class III	37516	40
Class IV	1966	2.1
Non-Ischemic Dilated Cardiomyopathy	41033	43.75
Syncope	16767	17.88

Description	Total	
Family History of Sudden Death	2059	2.2
Atrial Fibrillation/Flutter	35827	38.2
Ventricular Tachycardia	37095	39.55
Hemodynamic Instability	17416	18.57
History of a Cardiac Arrest	12325	13.14
Syndromes with risk sudden death	5591	5.96
Previous ICD	48333	51.54
Permanent Pacemaker	47617	50.77
Ischemic Heart Disease	53171	56.7
Prior MI	38816	41.39
Prior PCI	30712	32.75
Prior CABG	21066	22.46
Primary Valvular Heart Disease	11128	11.87
Other Structural Abnormalities	7023	7.49
Cerebrovascular disease	14471	15.43
Lung disease	17923	19.11
Diabetes mellitus	35974	38.36
Current on dialysis	2665	2.84
Diagnostic Studies	*	*
Electrophysiology Study **	14335	15.29
QRS Duration (Non-VT Paced Complex): Mean (SD)	123.84	31.7
Ventricular Paced QRS Duration: Mean (SD)	161.86	31.84

Description	Total	
Abnormal Intraventricular Conduction **	43261	46.13
Abnormal Intraventricular Conduction: Type	*	*
Left Bundle Branch Block	24237	25.84
Delay, Nonspecific	12517	13.35
Right Bundle Branch Block	8802	9.39
Ventricular Paced Rhythm	19555	20.85
Cardiac Rhythm: Type	*	*
AFib/Flutter	13837	14.75
Paced	9298	9.91
Sinus Rhythm	64827	69.12
BUN: Mean (SD)	23.46	13.14
Hemoglobin: Mean (SD)	12.99	2.08
Sodium: Mean (SD)	138.86	4.54
Procedural Factors	*	*
Procedure Type **	*	*
Initial Generator Implant	57148	60.94
Generator change	31361	33.44
Lead only	2902	3.09
ICD Generator Explanted	2373	2.53
ICD Indication **	*	*
Missing	3059	3.26
Primary prevention	66553	70.96
Secondary prevention	24172	25.77

Description	Total	
Final device type **	*	*
Missing	5294	5.64
Single chamber	18887	20.14
Dual chamber	29198	31.13
CRT-D	37207	39.67
S-ICD (Sub Q)	3198	3.41
Discharge Medication	*	*
ACE Inhibitor (Any)	33744	35.98
ARB (Any)	34390	36.67
Aspirin (any)	57311	61.11
Beta Blocker (Any)	83761	89.31
Warfarin (Coumadin)	12399	13.22
Hospital Characteristics	*	*
US Census Region **	*	*
Midwest Region	23760	25.33
Northeast Region	18557	19.79
South Region	39576	42.2
West Region	11240	11.98
Hospital Location **	*	*
Rural	10231	10.91
Suburban	28195	30.06
Urban	55358	59.03
Participant Type **	*	*

Description	Total	
Government	2280	2.43
Private/Community	76425	81.49
University	15079	16.08
# of Certified Beds: Mean (SD)	490	2859
Public Hospital **	*	*
No	46606	49.7
Yes	47178	50.3
Teaching Hospital **	*	*
No	39436	42.05
Yes	54348	57.95
Hospital Volume: Mean (SD)	212	1565

2a.07) If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing.

We used the same data described above for all aspects of this measure testing supplement.

2a.08) List the social risk factors that were available and analyzed.

For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

Note: Current guidance for composite measure evaluation states that reliability must be demonstrated for the composite performance measure score.

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.09 check patient or

encounter-level data; in 2a.010 enter "see validity testing section of data elements"; and enter "N/A" for 2a.11 and 2a.12.

Social risk factors were attributed at the hospital level for the purposes of this analysis. Medicaid insurance status was used as an economic indicator of social risk. We examine patient demographic data (age, sex, race/ethnicity) to determine if there were differences in these demographic indicators of social risk. All analyses were conducted at the hospital-level, as the EPDI quality composite is a hospital-level measure.

2a.09) Select the level of reliability testing conducted.

Choose one or both levels.
☒ Patient or Encounter-Level (e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements)

☒ Accountable Entity Level (e.g., signal-to-noise analysis)

2a.10) For each level of reliability testing checked above, describe the method of reliability testing and what it tests.

Describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used.

Assessment of test-retest reliability

To assess reliability of the composite, we examined the extent to which one time period of evaluation (2018) compared to a different time period of evaluation (2019). That is, we took a 'test-retest' approach in which hospital performance is measured using 2018 data, then again measured using 2019 data, and calculated the agreement of the two resulting performance measures across hospitals. As a metric of agreement, we calculated the intra-class correlation coefficient.

We are unable to perform a split sample methodology or signal-to-noise analysis due to our measure being reported strictly at the hospital-level. As opposed to most ACC measures, including the NQF endorsed component measure #0965, where facility-level data are rolled up from the individual to the facility-level, the metrics used to calculate this measure are only at the hospital-level. Thus, it is not advisable to conduct either the split sample methodology or signal-to-noise analysis in a meaningful way with a sample size that equates to 819 sites.

Inter-rater reliability

Data is entered into NCDR via chart abstraction. ACC audited abstraction from July 2021 through September 2021 on data submitted to the EPDI (formerly ICD) registry in 2020. The audit consisted of abstracting selected data elements from a sample of ICD records of patients whose treatment was previously reported to the Registry. Nurses with

specialized training and expertise used an electronic audit tool to collect data for comparison with registry data entered at the time of the patient's arrival. The data elements included in the audit are reviewed annually and are determined based upon prior year audit results and feedback from the individual registry steering committees as well as the NCDR Science and Quality Oversight Committee.

ACC randomly selected one hospital from the pool of hospitals assigned to ten nurses for inter-rater reliability assessment (IRRA). IRRA is a measure of how consistently different raters score the same individuals. Ten records from each of the selected facilities (for a total of 100 records) were evaluated.

Inter-rater Reliability Assessment	
Number of Participants selected from audit sample	10
Number of records re-abstracted	100

2a.11) For each level of reliability testing checked above, what were the statistical results from reliability testing?

For example, provide the percent agreement and kappa for the critical data elements, or distribution of reliability statistics from a signal-to-noise analysis. For score-level reliability testing, when using a signal-to-noise analysis, more than just one overall statistic should be reported (i.e., to demonstrate variation in reliability across providers). If a particular method yields only one statistic, this should be explained. In addition, reporting of results stratified by sample size is preferred (pg. 18, Measure Evaluation Criteria).

Measure Score Reliability

We calculated the correlation of the composite overall score from our final model in two different samples.

Reliability Testing (ICC)				
N1 (2019)	**N2 (2018)**	**ICC**	**ICC LCI**	**ICC UCI**
819	1142	0.77716	0.76174	0.80549

Inter rater reliability:

Inter-Rater Reliability	Data Points	Score	10th	90th Percentile
Overall Accuracy	8,700	93.7	83.0	100.0
PABAK	8,000	0.955	0.746	1.000
Pearson	700	0.934	0.778	1.000

2a.12) Interpret the results, in terms of how they demonstrate reliability.

(In other words, what do the results mean and what are the norms for the test conducted?)

The reliability of a measurement is the degree to which repeated measurements of the same entity agree with one another. For measures of hospital performance, the measured entity is the hospital, and the reliability is conceptualized as the extent to which repeated measurements of the same hospital give similar results. Accordingly, our approach to assessing reliability is to consider the extent to which assessments of a hospital using different time periods of data produce similar measures of hospital performance. As measured by intraclass correlation coefficient (ICC), the agreement between the 2018 time period and the 2019 time period for each hospital was 0.777, which is indicative of "good reliability" (Koo et al., 2016). The lower and upper confidence intervals were 0.762 and 0.805, respectively. There is moderately high correlation with minimal variation between the two periods of evaluation.

NQF # 0965 is a component measure and has been previously endorsed and therefore, shown to be a reliable measure.

References:

Koo TK, Li MY. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. J Chiropr Med. 2016 Jun;15(2):155-63. doi: 10.1016/j.jcm.2016.02.012. Epub 2016 Mar 31.

Inter-rater reliability

Overall, rates were high on item-specific IRRA agreement rates. The range of item specific agreement was 77.8% -100.0%. The 10th percentile was 83%, the median was 96%, and the 90th percentile was 100.0%. The overall aggregate score was 93.4%. The calculated PABAK statistics covered a wide range but generally indicated a high agreement beyond what one would expect to find by chance alone. The 10thpercentile was 0.746, while the median was 0.955, and the 90th percentile
reliability statistic was 1.000. Correlation coefficients for continuous variables were high with a p-value of less than 0.001 for all items.

For reference: Categories of PABAK (Adjusted KAPPA) Scores: Prevalence-AdjustedBias-Adjusted Kappa (PABAK)is a statistical measure of interrater agreement statistic and corrects agreement rates for the possibility of agreement by chance. PABAK is an alternative to KAPPA to reduce or eliminate interference due to skewed data.

PABAK	Interpretation
0.81-1.00	Almost perfect agreement
0.61-0.80	Substantial agreement
0.41-0.60	Moderate agreement
0.21-0.40	Fair agreement
0.01-0.20	Slight agreement
0.00	Poor agreement

Pearson Correlation Coefficient: The Pearson correlation coefficient is a statistic indicating the strength of a linear relationship existing
between two values from the registry data and the auditors for a given data element.

Pearson Correlation Coefficient	Interpretation
0.70 - 1.0	Strong linear relationship
0.50 - 0.70	Moderate linear relationship
0.30 - .50	Fair linear relationship
< 0.30	Poor linear relationship

Scientific Acceptability: Validity Testing (2b.01 - 2b.04)

2b.01) Select the level of validity testing that was conducted.

☐ Patient or Encounter-Level (data element validity must address ALL critical data elements)

☐ Accountable Entity Level (e.g., hospitals, clinicians)

☒ Empirical Validity Testing of the Composite (Measure Score)

☒ Systematic assessment of face validity of performance measure score as an indicator of quality or resource use (i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance)

☒ Validity testing for component measures (check all that apply) Note: applies to ALL component measures, unless already endorsed or are being submitted for individual endorsement.

☐ Endorsed (or submitted) as individual performance measures

☐ Patient or Encounter-Level (data element validity must address ALL critical data elements)

☐ Empirical validity testing of the component accountable entity-level (measure score(s))

☐ Systematic assessment of face validity of component measure score(s) as an indicator of quality or resource use (i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance)

2b.02) For each level of testing checked above, describe the method of validity testing and what it tests.

Describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used.

Face Validity: Each measure submitted to the National Quality Forum by ACC undergoes extensive discussion and review. This composite measure was created by NCDR Measure and Reporting Methodology (MRM) committee (see below for full description of committee) using two current EPDI registry measures. As part of the development process the MRM reviewed the specific weighting for the component measures and reviewed results on P score thresholds would affect the overall star scoring. These star rating distributions were discussed by the MRM until the final proposed measure received unanimous approval. After voting, the measure goes through a 30-day public comment period, which resulted in 13 responses specific to this measure. The verbatim comments have been added as an appendix. Once the public comment period is completed, any comments are discussed by MRM and voted on once again. If the committee passes the measure, it is recommended for review by the Clinical Science and Quality Committee (CSQC) (see below for full description). The CSQC voted to approve this measure for implementation in the registry as a test metric to be reviewed after 1 year of implementation. Throughout the process, the EPDI Registry Steering Committee provided strategic direction for the EPDI Registry and ensuring that this measure submitted to NQF meets key criterion such as reliability, feasibility, and that there is compelling evidence base behind the development and implementation of this measure. A summary of this process is

below.

- EPDI (formerly ICD) registry steering committee provides strategic direction for future registry measures based on current evidence.
- NCDR Measures and Reporting Methodology committee creates a measure development plan.
- Yale Center for Outcomes Research conducts analysis using past NCDR data.
- MRM reviews the results of the analysis and votes to approve or to run further analysis.
- 30-day public comment period is opened after MRM approval.
- Comments are reviewed by the MRM and, if necessary, the measure is changed in response to feedback. If no changes, this measure is considered approved by the MRM.
- The NCDR CSQC provides final review of the measure. The committee voted to approve this measure for implementation as a test metric for 1 year and then review the data.

In summary, face validity testing was accomplished by expert consensus, measure development that is led by those that will be measured (cardiologists), extensive committee review and comments from the public.

MRM: The Measure, Reporting and Methodology committee is a designated set of experts that oversees this NQF application. Prior to submission, it ensures there is variation in care, disparities data, and that the measure is a true reflection of quality care at a particular site and can also be used to improve quality. This committee is chaired by Dr. Jason Wasfy. This committee made up of a physicians with a background in measure development and statistics and, most importantly, made up of those that will directly be measured. These members are Drs. Matthew Cavender, Ann Connors, Jonathan Hsu, Dhaval Kolte, Tom Ryan, Amneet Sanhu, Sreekanth Vemulapalli and Omari Yousuf.

CSQC: NCDR Clinical Science and Quality is an ACC leadership committee that serves as the primary resource for crosscutting scientific and quality of care methodological issues. This committee ensures the metrics are consistent across registries. They also reviewed and approved the methodology and results of this measure. These members include Dr. Amit Amin (chair) and Drs David Cox, Emily Zeitler, Fred Kusumoto, Joaquin Cigarroa, John Carroll, Michael Kontos, Nihar Desai, Pamela Peterson, Stacie Daugherty, and Tarek Alsaied.

Lastly, the 16 member NCDR Management Board and 31 member ACCF Board of Trustees approved these measures for submission to NQF.

Data Element:

The NCDR Data Quality Program ensures that data submitted to the NCDR are complete and validly collected. The NCDR Data Quality Program consists of 3 main components: data completeness, consistency, and accuracy. Completeness focuses on the proportion of missing data within fields, whereas consistency determines the extent to which logically related fields contain values consistent with other fields. Accuracy characterizes the agreement between registry data and the contents of original charts from the hospitals submitting data. Before entering the Enterprise Data Warehouse (EDW), all submissions are scored for file integrity and

data completeness, receiving 1 of 3 scores that are transmitted back to facilities using a color-coding scheme. A “red light” means that a submission has failed because of file integrity problems such as excessive missing data and internally inconsistent data.

Such data are not processed or loaded into the EDW. A “yellow light” status means that a submission has passed the integrity checks but failed in completeness according to predetermined thresholds. Such data are processed and loaded into the EDW but are not included in any registry aggregate computations until corrected. Facilities are notified about data submission problems and provided an opportunity to resubmit data. Finally, a “green light” means that a submission has passed all integrity and quality checks. Such submissions are loaded to the EDW. After passing the DQR, data are loaded into a common EDW that houses data from all registries and included for all registry aggregate computations. In a secondary transaction process, data are loaded into registry-specific, dimensionally modeled data marts. A summary of the Program is noted under Table 5.

Table 5. Data Quality Program Overview

Methodology	• Nationwide program (i.e., all submitting participants in the United States) • Review of data submitted the previous year • Review of a subset of data elements that can rotate each year • Remote review of data combined with couple of onsite visit • Onsite visits are targeted based on the Data Outlier Program • Random selection of sites and records • Blinded data abstraction from medical charts • Inter-rater Reliability Assessment conducted to validate the audit • findings • Adjudication step for participant to refute audit findings
Scope	• Review of hospital's medical records for related episodes of care • Assessment of complete submission (Comparison of two lists : hospital list of cases with specific billing codes versus NCDR submitted records)
Criteria for selecting sites/records	Remote audit : • Sites passing their quarterly Data Quality Report for 2 quarters within audited year • Sites submitting at least the number of records/sites being reviewed Onsite audit • Sites identified with an outlier and not contacted with the data outlier program

Methodology	• Nationwide program (i.e., all submitting participants in the United States) • Review of data submitted the previous year • Review of a subset of data elements that can rotate each year • Remote review of data combined with couple of onsite visit • Onsite visits are targeted based on the Data Outlier Program • Random selection of sites and records • Blinded data abstraction from medical charts • Inter-rater Reliability Assessment conducted to validate the audit • findings • Adjudication step for participant to refute audit findings
Scoring	NCDR uses a grading system for identifying the amount of agreement or matching between the data captured during the medical record review and data submitted to the NCDR.

Empirical Validity:

Empirical validity testing was performed by comparing hospital performance on the EPDI Quality Composite to the EPDI Complications model. The testing focused on construct validation, which tested the hypothesis that the use of the composite process measures for EPDI hospitals led to better outcomes. To achieve this, we examined the distribution and correlation of the EPDI Quality composite score and the in-hospital risk-standardized complications rate for ICD placement. Complications were attributed to the hospital-level, where the lower score was indicative of better quality (the opposite of the EPDI quality composite). The variables in the complications model include sex, reason for hospitalization, NYHA class III and IV, previous CABG, abnormal conduction, sodium, hemoglobin, BUN, and ICD type (Dodson J, Reynolds M, Bao H, et al. Developing a Risk Model for In-Hospital Adverse Events Following Implantable Cardioverter-Defibrillator Implantation. *J Am Coll Cardiol.* 2014 Mar, 63 (8) 788–796). For this specific analysis, the study period included 01/01/2019 – 12/31/2019, the same period of performance for both the EPDI quality composite and the complications measure.

2b.03) Provide the statistical results from validity testing.

Examples may include correlations or t-test results.

Face Validity: Face validity was achieved through reaching expert consensus that the measure score had strong clinical evidence and was reliable. This was achieved through several years of discussion and voting on this measure. The voting results were:

Method and Reporting Methodology subcommittee: November 2020, seven members of the committee voted to approve the measure. Two voting members were absent, and no members voted to not approve. This measure was recommended to be presented to the Clinical Science and Quality Committee.

Clinical Science and Quality Committee: October of 2021, eight yes votes and zero no votes. One yes vote was received with a request for further details on the distribution of patients at the hospitals meeting each of the metric. A quorum was present during voting. The measure was recommended to be implemented into NCDR. The committee recommended that this measure be reevaluated after one years' worth of data to ensure it is performing as expected.

Voting members have the option to vote either "Yes, I vote to approve," "Yes, I vote to approve with the following comments" and "No, I do not vote to approve." In the future NCDR will be moving towards a Likert scale for voting.

Empirical Validity: Below are the results of the empirical validity testing (table 6):

Table 6. Distribution of Performance Rates for EPDI Quality Composite Measure and EPDI Complications Model in the time period 2019Q1 to 2019Q4 (N=819)

Description	Overall EPDI Quality Composite	Discharge Medications	Guideline Indications	EPDI Complication Measure Score
N	819	819	819	819
Mean	0.8651	0.8795	0.8507	0.5208
Std Deviation	0.133	0.1384	0.1559	0.3204
100% Max	1	1	1	1
99%	1	1	1	0.9926
95%	0.9942	1	1	0.9632
90%	0.9872	1	0.9919	0.9245
75% Q3	0.9688	0.9844	0.9625	0.8112

Description	Overall EPDI Quality Composite	Discharge Medications	Guideline Indications	EPDI Complication Measure Score
50% Median	0.9056	0.931	0.8981	0.6004
25% Q1	0.8033	0.8172	0.7931	0.2155
10%	0.694	0.6923	0.6486	0.0801
5%	0.5985	0.6071	0.5429	0.0378
1%	0.4005	0.4082	0.2857	0.0074
0% Min	0.1842	0.04	0	0

Table 7. Pearson Correlation coefficient between EPDI quality composite and its components and the EPDI complications model

*cell intentionally left blank

*	Composite	Discharge Medications	Guideline Indications
Pearson Correlation Coefficients	-0.03769	-0.03084	-0.03694
P Value	0.2813	0.3781	0.291

2b.04) Provide your interpretation of the results in terms of demonstrating validity. (i.e., what do the results mean and what are the norms for the test conducted?)

Face validity: The individual components of the composite measure have been associated with better outcomes and are accepted quality measures.

Empirical validity: The median score of the quality composite was 90.6, and the median complications score was 60.0. While the negative correlation coefficient was not significant, it was in the hypothesized direction, such that a higher group of patients receiving better overall quality was associated with a lower complications score. Yet, the correlation is relatively low (-0.038), which is not surprising when comparing a process of care measure to an outcome measure. The low correlation may be explained by the fact that there are a number of other unmeasured factors that could contribute to complications beyond a site's overall EPDI quality (as indicated by medications provided at discharge and class guideline indications).

Scientific Acceptability: Validity - Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data) (2b.05 - 2b.14)

Note: Applies to the composite performance measure.

2b.05) Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified.

Describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided in Importance to Measure and Report: Gap in Care/Disparities.

We examined variations in hospital performance for the composite measure based on overall performance and stratified by subgroups of race, sex, age and proportion of patients insured through Medicaid to identify if there were meaningful differences in categories of social risk.

2b.06) Describe the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities.

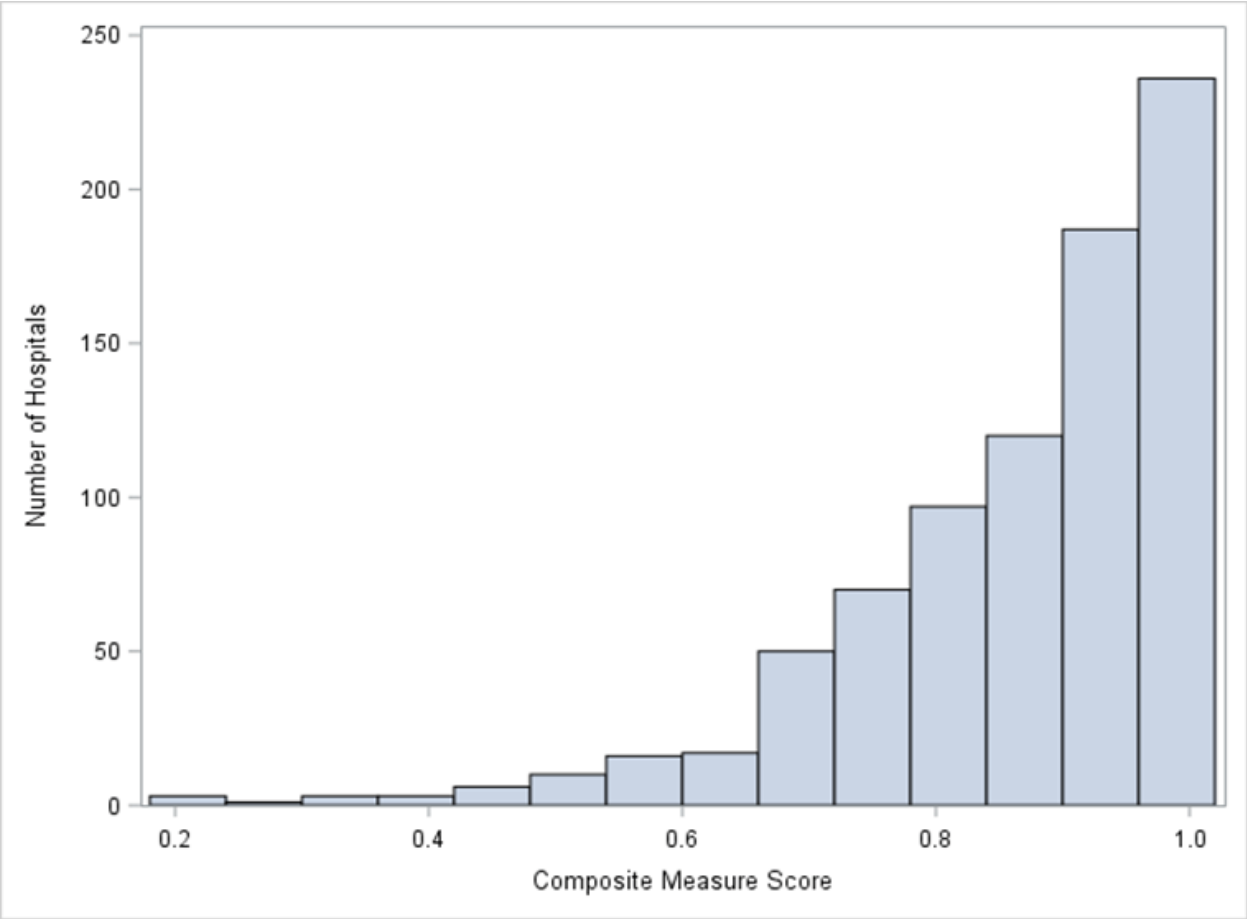
Examples may include number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined.

Overall: The median rate of performance for the EPDI composite measure score across all hospitals was 90.56. Composite measure score ranged from 80.33 to 96.88 for the first and third quartiles of hospitals, respectively (Table 8), and the distribution was left skewed such that the majority of hospitals were in the third and fourth quartiles.

Table 8. Distribution of Hospital Composite Measure Score	
Description	Composite Measure Score
N	819
Mean	0.8651
Std Deviation	0.133
100% Max	1

Table 8. Distribution of Hospital Composite Measure Score	
99%	1
95%	0.9942
90%	0.9872
75% Q3	0.9688
50% Median	0.9056
25% Q1	0.8033
10%	0.694
5%	0.5985
1%	0.4005
0% Min	0.1842

Figure 1. Histogram of Performance of EPDI Quality Composite Measure Score



Subgroup Analyses

Proportion of Non-White

Hospitals (N=819) were stratified into quartiles by their proportion of non-White patients. Hospital performance across quartiles was modestly different across the percent of non-White patients treated by the hospitals, with the median performance ranging from 87.83 in hospitals with the highest quartile non-white patients to 93.26 in hospitals with the second to lowest quartile of non-white patients (Table 9 and Figure 2).

Table 9. Distribution of The Hospital Composite Measure Score Stratified by Hospital Percent of Non-White Patients (N=819)

Description	%Non-White	Quartiles Non-White (%)	*	*	*
*		Q1	Q2	Q3	Q4
N	819	204	205	205	205
Mean	0.2643	0.8725	0.8795	0.861	0.8473

Description	%Non-White	Quartiles Non-White (%)	*	*	*
Std Deviation	0.2206	0.144	0.1301	0.1286	0.1274
100% Max	1	1	1	1	1
99%	0.9474	1	1	1	1
95%	0.75	0.9966	0.9929	0.9939	0.9938
90%	0.5727	0.9901	0.9861	0.9853	0.9818
75% Q3	0.3795	0.9783	0.9731	0.9614	0.95
50% Median	0.2025	0.9295	0.9326	0.8835	0.8783
25% Q1	0.0902	0.7937	0.8222	0.7999	0.7803
10%	0.04	0.7	0.7037	0.6869	0.6812
5%	0.0175	0.5918	0.661	0.6228	0.5687
1%	0	0.3488	0.353	0.495	0.469
0% Min	0	0.2308	0.2255	0.1842	0.4005

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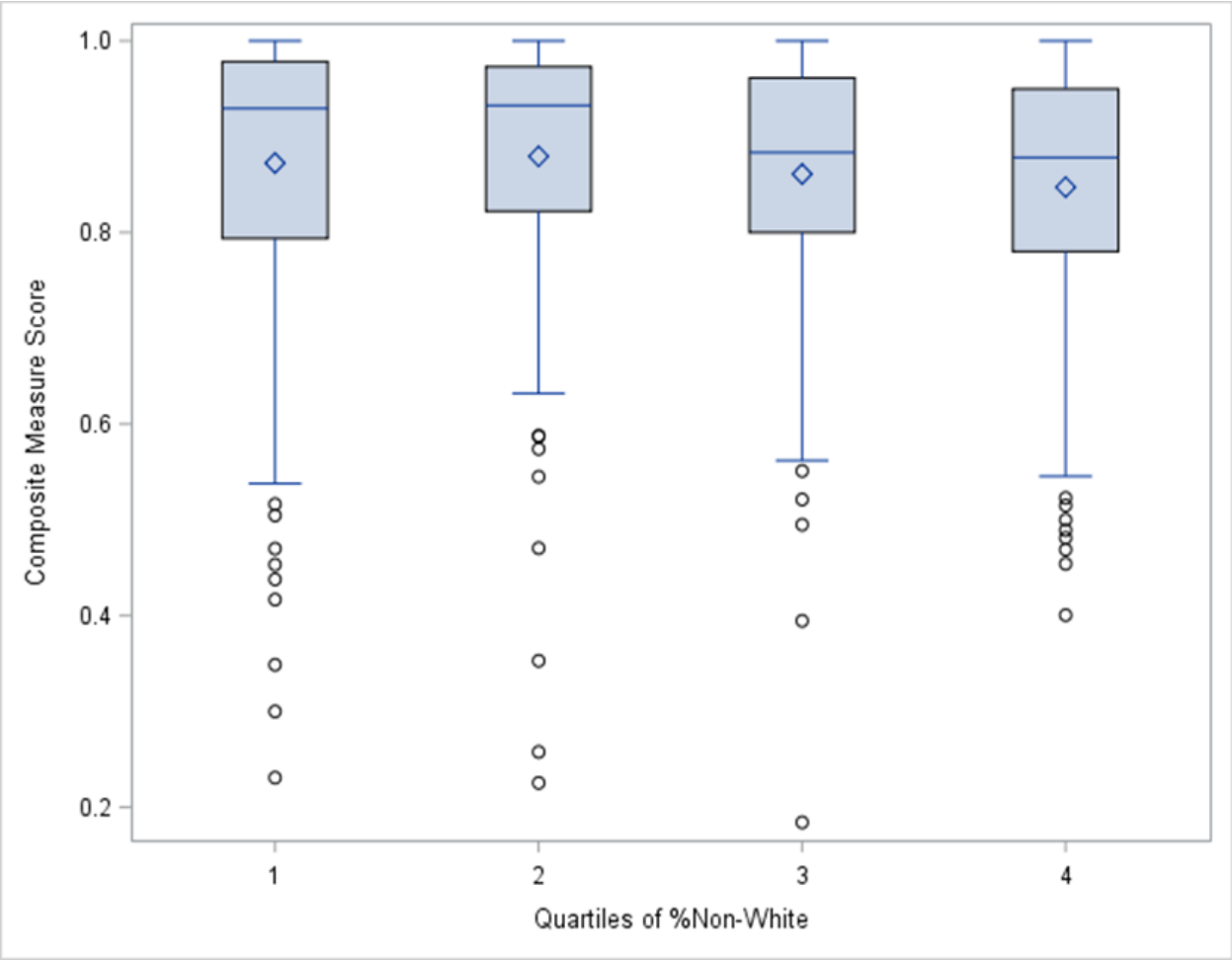
Figure 2. Distribution of Composite Measure Scores Stratified by Quartiles of Non-White Patients at the Hospital-Level



Gender

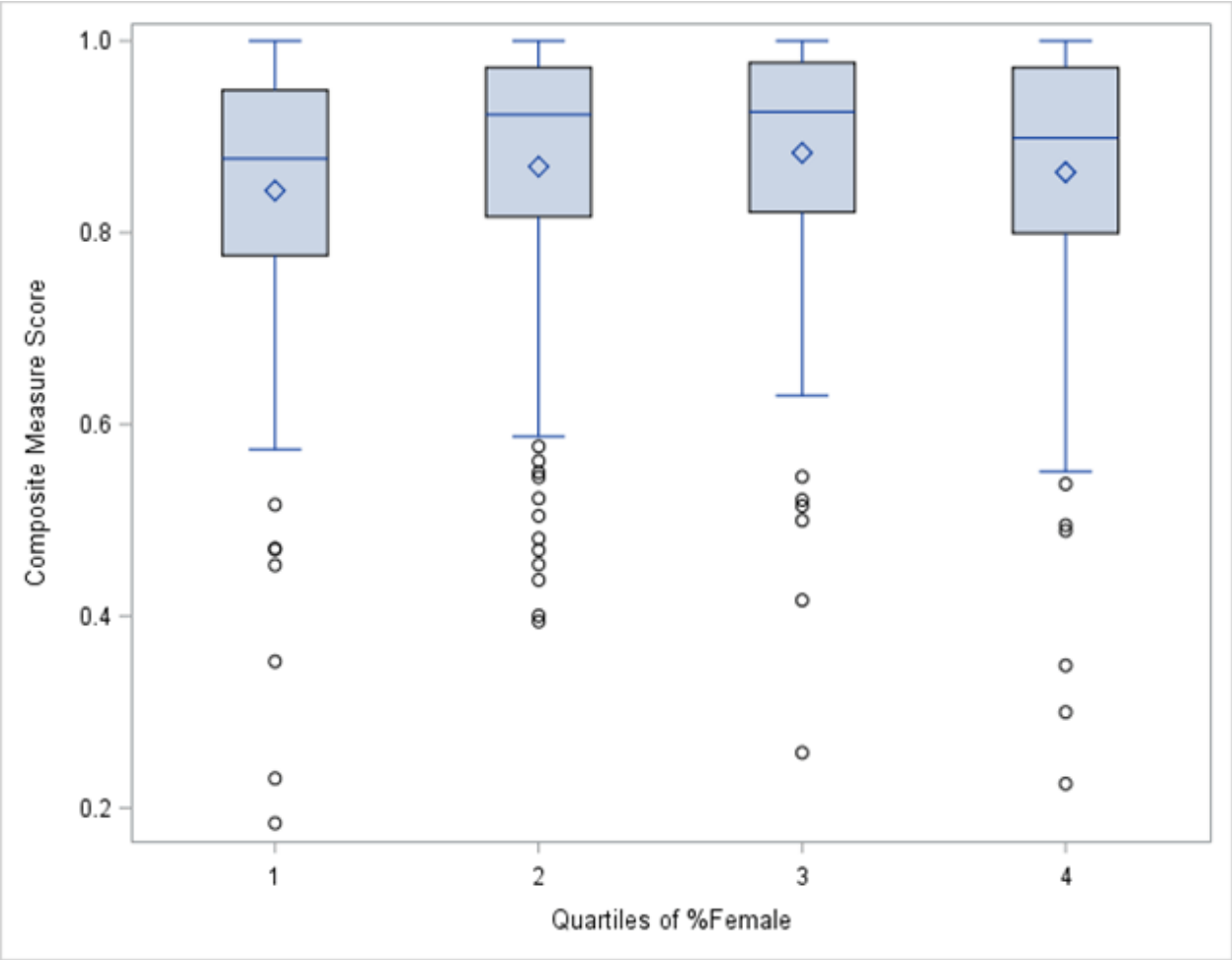
Hospitals (N=819) were stratified into quartiles by their proportion of female patients. Hospital performance across quartiles was modestly different across the percent of female patients treated by hospitals , with the median performance ranging from 87.73 in hospitals with the lowest quartile of female patients to 92.60 in hospitals with the second to highest quartile of female patients (Table 10 and Figure 3).

Table 10. Distribution of Composite Measure Scores Stratified by Gender at the Hospital Level (N=819)

Description	%Female	Quartiles, Female (%)			
		Q1	Q2	Q3	Q4
N	819	204	205	216	194
Mean	0.2948	0.8439	0.8689	0.8833	0.863

Description	%Female	Quartiles, Female (%)			
Std Deviation	0.0699	0.1388	0.1357	0.1213	0.1342
100% Max	0.65	1	1	1	1
99%	0.5	1	1	1	1
95%	0.4091	0.9891	0.9933	1	1
90%	0.375	0.9795	0.9875	0.9908	0.9872
75% Q3	0.3333	0.9486	0.9725	0.9774	0.9722
50% Median	0.2895	0.8773	0.9231	0.926	0.8988
25% Q1	0.2505	0.7763	0.8166	0.8213	0.7994
10%	0.2152	0.6667	0.6722	0.7193	0.694
5%	0.1887	0.5918	0.5619	0.6595	0.6258
1%	0.12	0.353	0.4379	0.5	0.3
0% Min	0.0556	0.1842	0.3946	0.2577	0.2255

Figure 3. Distribution of Composite Measure Scores by Gender at the Hospital Level



Age

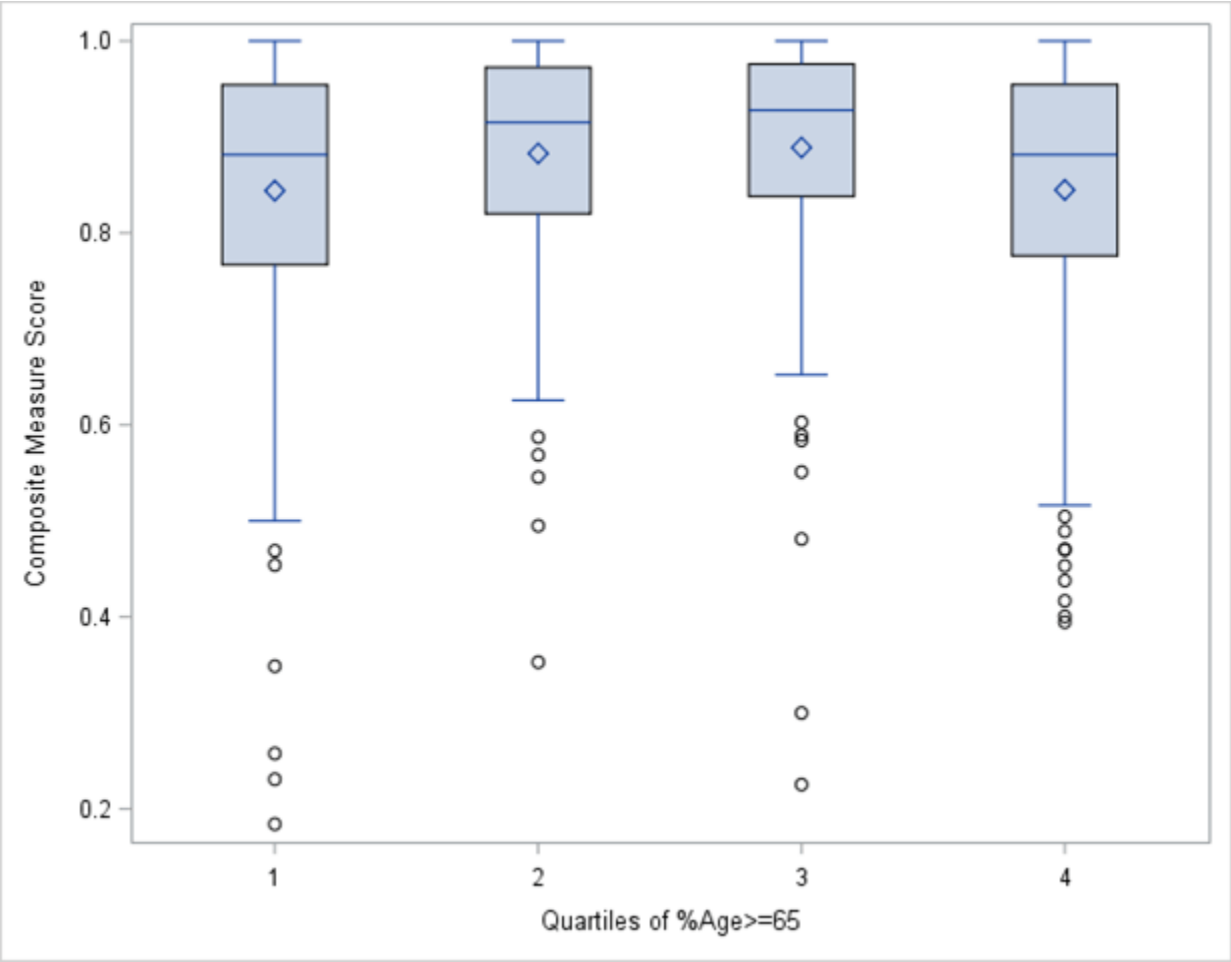
The median hospital performance in the quality composite among patients aged greater than 65 years was 61.5. (Table 11 and Figure 4) and ranged from 88.2 to 92.8.

Table 11. Distribution of Composite Measure Score Stratified by Age at the Hospital Level (N=819)

Description	%Age>65	Quartiles of Age>=65 (%)			
		Q1	Q2	Q3	Q4
N	819	207	203	204	205
Mean	0.6083	0.8441	0.8828	0.889	0.8449
Std Deviation	0.1061	0.1502	0.1122	0.1208	0.1394

Description	%Age>65	Quartiles of Age>=65 (%)			
100% Max	0.8857	1	1	1	1
99%	0.8491	1	1	1	1
95%	0.7727	0.9941	0.9916	0.9944	0.9926
90%	0.7349	0.9885	0.9872	0.9887	0.982
75% Q3	0.6809	0.9545	0.9725	0.976	0.9546
50% Median	0.6154	0.8815	0.9151	0.9278	0.8816
25% Q1	0.5455	0.7669	0.8201	0.838	0.7762
10%	0.4688	0.6595	0.7265	0.7386	0.6667
5%	0.4286	0.5619	0.6721	0.6591	0.5212
1%	0.3333	0.2577	0.5455	0.4811	0.4167
0% Min	0.1935	0.1842	0.353	0.2255	0.3946

Figure 4. Distribution of Composite Measure Scores by Gender at the Hospital Level



Insurance

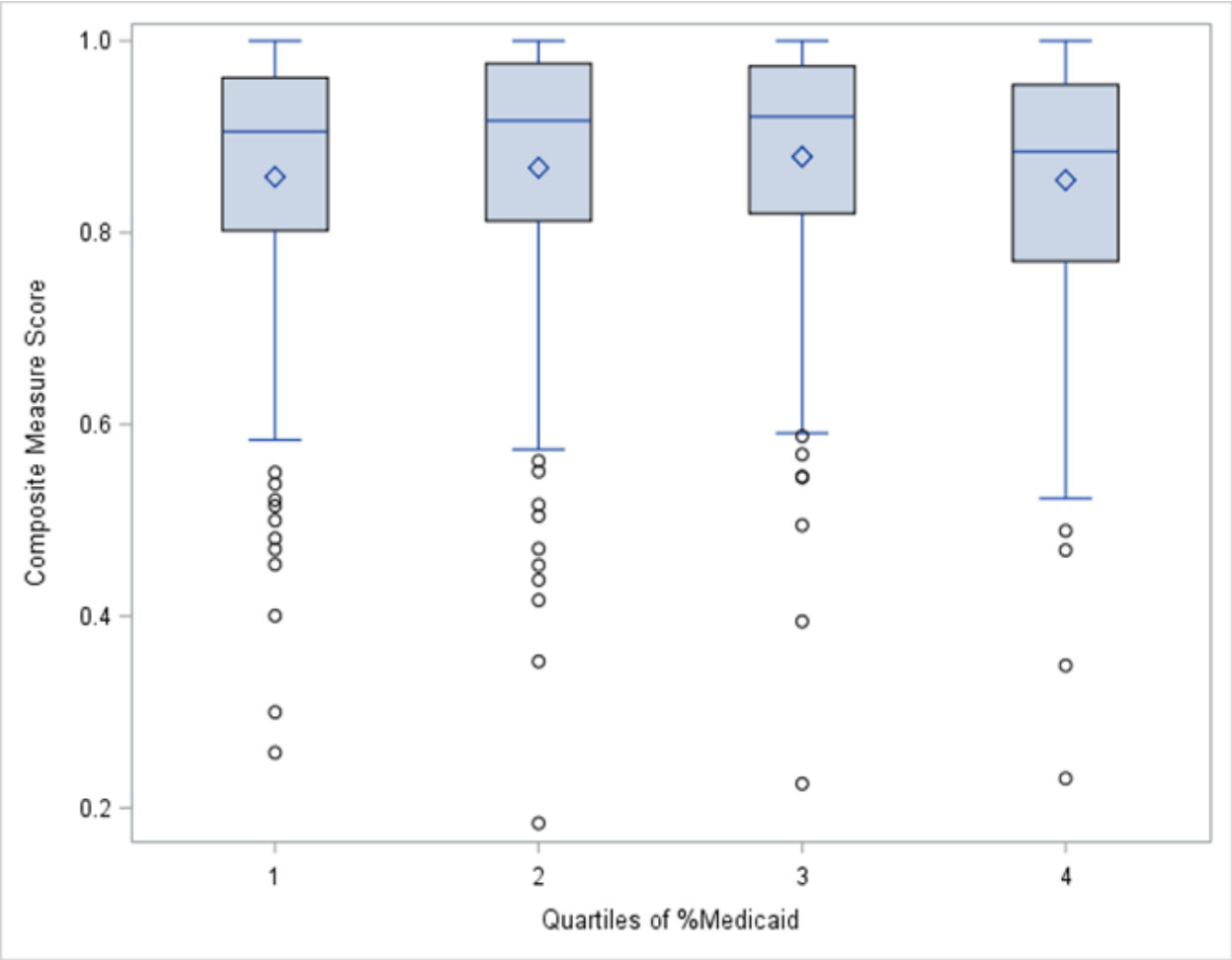
Hospitals were stratified into quartiles by their proportion of patients with Medicaid as the primary insurance (median: 11.0). Hospital performance was similar across hospitals stratified into quartile by the proportion of patients they treat who have Medicaid insurance coverage. Median hospital performance ranged from 88.5 (Quartile 4) to 90.6 (Quartile 3) (Table 12 and Figure 5).

Table 12. Distribution of Composite Measure Score Stratified by Percent Medicaid at the Hospital Level (N=819)

Description	%Medicaid	Quartiles of Medicaid (%)			
		Q1	Q2	Q3	Q4
N	819	204	203	207	205
Mean	0.0802	0.8583	0.8678	0.8793	0.8548

Description	%Medicaid	Quartiles of Medicaid (%)			
Std Deviation	0.073	0.1399	0.143	0.1208	0.1268
100% Max	0.5667	1	1	1	1
99%	0.3506	1	1	1	1
95%	0.2174	0.9913	1	0.9942	0.9914
90%	0.1676	0.9821	0.9914	0.9889	0.9844
75% Q3	0.1096	0.9616	0.9766	0.9737	0.9545
50% Median	0.0625	0.9055	0.9168	0.921	0.8847
25% Q1	0.0333	0.8022	0.8123	0.8201	0.7703
10%	0	0.6722	0.6727	0.7233	0.6934
5%	0	0.55	0.5741	0.6595	0.6387
1%	0	0.4005	0.4167	0.495	0.469
0% Min	0	0.2577	0.1842	0.2255	0.2308

Figure 5. Distribution of Composite Measure Score Stratified by Percent Medicaid at the Hospital Level



2b.07) Provide your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities.

In other words, what do the results mean in terms of statistical and meaningful differences?

Note: Applies to the overall composite measure.

The wide gap in performance rates, along with broad interquartile ranges, across various stratified populations demonstrates that this measure is necessary to improve the quality gap. This is illustrated in several ways. The median overall composite score was 90.56, with a relatively large interquartile range of 80.33 to 96.88, illustrating that many hospitals have room for improvement with only 25% of hospitals having a score over 96. Similar variation was observed in the social factor analysis, including median scores by the percent of hospitals with

non-white populations 92.95 (IQR 79.37-97.83), gender (female) 87.77 (IQR 77.63-94.86), age over 65 years 88.15 (IQR 76.69-95.45), and percent Medicaid insurance 90.55 (IQR 80.22-96.16).

2b.08) Provide the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data.

For example, provide results of sensitivity analysis of the effect of various rules for missing data/non-response. If no empirical sensitivity analysis was conducted, identify the approaches for handling missing data that were considered and benefits and drawbacks of each).

There were no missing data for this measure. Any hospitals with missing data were excluded from the measure as they would not have passed the NCDR data quality review.

2b.09) Describe the method of testing conducted to identify the extent and distribution of missing data (or non-response) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders). Include how the specified handling of missing data minimizes bias.

Describe the steps—do not just name a method; what statistical analysis was used.

There were no missing data for this measure. Any hospitals with missing data were excluded from the measure as they would not have passed the NCDR data quality review. The NCDR data quality review is described in detail in section 2b.02.

2b.10) Provide your interpretation of the results, in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders), and how the specified handling of missing data minimizes bias.

In other words, what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis was conducted, justify the selected approach for missing data.

Note: Applies to all component measures, unless already endorsed or are being submitted for individual endorsement.

Note: This item is directed to measures that are risk-adjusted (with or without social risk factors) OR to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record

abstraction and a different set of specifications for claims or eCQMs). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

N/A

2b.11) Indicate whether there is more than one set of specifications for this measure.

☐ Yes, there is more than one set of specifications for this measure
☒ No, there is only one set of specifications for this measure

2b.12) Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications.

Describe the steps—do not just name a method. Indicate what statistical analysis was used.

2b.13) Provide the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications.

Examples may include correlation, and/or rank order.

2b.14) Provide your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications.

In other words, what do the results mean and what are the norms for the test conducted.

Scientific Acceptability: Validity - Other Threats to Validity (Exclusions, Risk Adjustment) (2b.15 - 2b.32)

Applies to the composite performance measure, as well all component measures unless they are already endorsed or are being submitted for individual endorsement.

2b.15) Indicate whether the measure uses exclusions.

☐ N/A or no exclusions
☒ Yes, the measure uses exclusions.

2b.16) Describe the method of testing exclusions and what was tested.

Describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used?

The exclusions for this measure were minimal and comprised: facility-level data pertaining to discharge dates beyond the study period for this analysis (Jan 01, 2019 – Dec 31, 2019), hospitals unable to contribute to the component process metrics (i.e., discharge medications (ACE/ARB and Beta Blocker) in eligible ICD/CRT- D implant patients and the proportion of ICD/CRT-D patients that fulfill class I, IIa, or IIb guideline indications). Additionally, if there were no eligible cases within a metric, the hospital was not eligible to be included in the composite metric.

2b.17) Provide the statistical results from testing exclusions.

Include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores.

The table (13) below provides information about how the final sample was derived. “Not eligible for the composite measure” means those patients who are not eligible for any of the specific components/metrics of the composite. Ineligible reasons include contraindications, individuals enrolled in clinical trial studies, or data not reported by the site.

Table 13. Facility Level Metric Distribution

Exclusions	Patient Visits	Patient Stays	Patients	Facilities
Total	563,554	558,573	491,204	1,798

Discharge date not between 01/01/2019 and 12/31/2019	466,927	462,858	401,351	706
Remaining	96,627	95,715	89,853	1,092
Hospitals not in the composite measure	2,843	2,838	2,649	273
First Study Cohort	93,784	92,877	87,204	819

2b.18) Provide your interpretation of the results, in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results.

In other words, the value outweighs the burden of increased data collection and analysis. Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion.

Note: Applies to all outcome or resource use component measures, unless already endorsed or are being submitted for individual endorsement.

Exclusions only pertained to data quality thresholds and sites ineligible for individual components of the composite measure. These exclusions had minimal impact on the classification results of sites that met inclusion criteria and were necessary to derive a precise measure of quality. It would not be advisable to include information from hospitals that did not meet quality thresholds or include patients who are not eligible for individual components of the composite measure.

2b.19) Check all methods of controlling for differences in case mix that was used.

☐ Endorsed (or submitted) as individual performance measures
☒ No risk adjustment or stratification
☐ Statistical risk model with risk factors (specify number of risk factors)
☐ Stratification by risk category (enter number of risk categories)
☐ Other (please specify here:)

2b.20) If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.

N/A

2b.21) If an outcome or resource use measure is not risk-adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (i.e., case mix) is not needed to achieve fair comparisons across measured entities.
N/A

2b.22) Describe the conceptual and statistical methods and criteria used to test and select patient-level risk factors (e.g., clinical factors, social risk factors) used in the statistical risk model or for stratification by risk.

Please be sure to address the following: potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10 or other statistical tests; correlation of x or higher. Patient factors should be present at the start of care, if applicable. Also discuss any "ordering" of risk factor inclusion; note whether social risk factors are added after all clinical factors. Discuss any considerations regarding data sources (e.g., availability, specificity).

N/A

2b.23) Select all applicable resources and methods used to develop the conceptual model of how social risk impacts this outcome.

☐ Published literature
☐ Internal data analysis
☐ Other (please specify here:)

2b.24) Detail the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model/stratification.

2b.25) Describe the analyses and interpretation resulting in the decision to select or not select social risk factors.

Examples may include prevalence of the factor across measured entities, availability of the data source, empirical association with the outcome, contribution of unique variation in the outcome, or assessment of between-unit effects and within-unit effects. Also describe the impact of adjusting for risk (or making no adjustment) on providers at high or low extremes of risk.

2b.26) Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used). Provide the statistical results from testing the approach to control for differences in patient characteristics (i.e., case mix) below. If stratified ONLY, enter "N/A" for

questions about the statistical risk model discrimination and calibration statistics.

Validation testing should be conducted in a data set that is separate from the one used to develop the model.

2b.27) Provide risk model discrimination statistics.

For example, provide c-statistics or R-squared values.

2b.28) Provide the statistical risk model calibration statistics (e.g., Hosmer-Lemeshow statistic).

N/A

2b.29) Provide the risk decile plots or calibration curves used in calibrating the statistical risk model.

The preferred file format is .png, but most image formats are acceptable.

N/A

2b.30) Provide the results of the risk stratification analysis.

N/A

2b.31) Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix).

In other words, what do the results mean and what are the norms for the test conducted?

N/A

2b.32) Describe any additional testing conducted to justify the risk adjustment approach used in specifying the measure.

Not required but would provide additional support of adequacy of the risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed.

N/A

Empirical Analysis to Support Composite Construction Approach (2c.01 - 2c.08)

Note: If empirical analyses do not provide adequate results—or are not conducted—justification must be provided and accepted in order to meet the must-pass criterion of Scientific Acceptability of Measure Properties. Each of the following questions has instructions on what to provide if no empirical analysis was conducted.

2c.01) Provide empirical analysis demonstrating that the component measures fit the quality construct, add value to the overall composite, and achieve the object of parsimony to the extent possible.

We believe the face/content validity of this measure has been achieved by virtue of the noted expertise of those individuals who developed this measure. The individual components of the composite have already shown to impact clinical outcomes.

The empirical validity analysis demonstrated that the individual component measures fit the overall quality construct by assessing the correlation of the quality composite measure with its components.

2c.02) Describe the method used to support the composite construction.

Describe the steps—do not just name a method; indicate what statistical analysis was used; if no empirical analysis, provide a justification.

We computed hospital-level measures for the two measure components individually and then correlated the results with the hospital-level composite results using Pearson correlation.

2c.03) Provide the statistical results obtained from the analysis of the components.

Examples include correlations, contribution of each component to the composite score, etc.; if no empirical analysis, identify the components that were considered and the pros and cons of each.

The Pearson correlation coefficients between the EPDI quality composite measure and its components are available in Tables 14 and 15.

Table 14. Distribution of Overall Composite Measure Scores and its Components at the Hospital Level (N=819)

Description	Composite	Discharge Meds	Guideline Indications
N	819	819	819
Mean	0.8651	0.8795	0.8507
Std Deviation	0.133	0.1384	0.1559
100% Max	1	1	1
99%	1	1	1
95%	0.9942	1	1
90%	0.9872	1	0.9919
75% Q3	0.9688	0.9844	0.9625
50% Median	0.9056	0.931	0.8981
25% Q1	0.8033	0.8172	0.7931
10%	0.694	0.6923	0.6486
5%	0.5985	0.6071	0.5429
1%	0.4005	0.4082	0.2857
0% Min	0.1842	0.04	0

Table 15. Pearson Correlation Coefficient between EPDI Quality Composite and its Components			
Pearson Correlation Coefficients, N = 819			
	Composite	Discharge Meds	Guideline Indication
Composite	1	0.8911	0.9154
Discharge Meds	0.8911	1	0.6329
Guideline Indication	0.9154	0.6329	1

2c.04) Provide your interpretation of the results, in terms of demonstrating that the components included in the composite are consistent with the described quality construct and add value to the overall composite.

In other words, what do the results mean in terms of supporting inclusion of the components; if no empirical analysis, provide rationale for the components that were selected.

The results of the empirical validity testing demonstrate a correlation between all components of the measure and the overall performance of EPDI quality of care. Both metrics have a high correlation to the overall composite measure, namely r=0.89 with discharge medications and r=0.92 for guideline indications. Thus, we feel all components are important aspects in delivering high quality of care. The inclusion of all variables is also explained through achieving face validity.

2c.05) Provide an empirical analysis demonstrating that the aggregations and weighting rules are consistent with the quality construct and achieve the objective of simplicity to the extent possible.

This is an all-or-none composite, thus no empirical analyses pertinent to aggregations or weighting were conducted. This composite has each of the individual measure components weighed equally based on the strong clinical recommendations and studies demonstrating that patients who are prescribed each of these medications and receive the procedure based on evidence-based clinical indications will have better outcomes such as reduced readmission and mortality rate at six months. As a result, it would not be appropriate to apply different weighting where compliance with one component influences a facility's performance score more than the other.

2c.06) Describe the method used for composite aggregation.

Describe the steps—do not just name a method; what statistical analysis was used; if no empirical analysis, provide justification.

Please see 2c.05

2c.07) Provide the statistical results obtained from the analysis of the aggregation and weighting rules.

If no empirical analysis was conducted, identify the aggregation and weighting rules that were considered and the pros and cons of each.

N/A

2c.08) Provide your interpretation of the results, in terms of demonstrating the aggregation and weighting rules are consistent with the described quality construct.

In other words, what do the results mean in terms of supporting the selected rules for aggregation and weighting; if no empirical analysis, provide rationale for the selected rules for aggregation and weighting.
N/A

Feasibility (3.01 - 3.07)

3.01) Check all methods below that are used to generate the data elements needed to compute the measure score.

☐ Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

☐ Coded by someone other than person obtaining original information (e.g., DRG, ICD-10 codes on claims)

☒ Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

☐ Other (Please describe)

3.02) Detail to what extent the specified data elements are available electronically in defined fields.

In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields. ALL data elements are in defined fields in electronic health records (EHRs)

☐ ALL data elements are in defined fields in electronic claims

☒ ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)

☐ ALL data elements are in defined fields in a combination of electronic sources

☐ Some data elements are in defined fields in electronic sources

☐ No data elements are in defined fields in electronic sources

☐ Patient/family reported information (may be electronic or paper)

3.03) If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using data elements not from electronic sources.

N/A

3.04) Describe any efforts to develop an eCQM.
Currently we do not have plans to develop an eCQM version of this measure.

3.05) Complete and attach the eCQM-Feasibility-Scorecard.xls file.

3.06) Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

No difficulties have been identified.

3.07) Detail any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm),

Attach the fee schedule here, if applicable.

The ACCF's program the National Cardiovascular Data Registry (NCDR) provides evidence-based solutions for cardiologists and other medical professionals committed to excellence in cardiovascular care. NCDR hospital participants receive confidential benchmark reports that include access to measure macro specifications and micro specifications, the eligible patient population, exclusions, and model variables (when applicable). In addition to hospital sites, NCDR Analytic and Reporting Services provides consenting hospitals' aggregated data reports to interested federal and state regulatory agencies, multi-system provider groups, third-party payers, and other organizations that have an identified quality improvement initiative that supports NCDR-participating facilities. Lastly, the ACCF also allows for licensing of the measure specifications outside of the Registry.

Measures that are aggregated by ACCF and submitted to NQF are intended for public reporting and therefore there is no charge for a standard export package. However, on a case by case basis, requests for modifications to the standard export package will be available for a separate charge

Use (4a.01 - 4a.10)

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making.

Endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement, in addition to demonstrating performance improvement.

4a.01) Check all current uses. For each current use checked, please provide:

- Name of program and sponsor
- URL
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

☐ Public Reporting
☐ Public Health/Disease Surveillance
☐ Payment Program
☐ Regulatory and Accreditation Programs
☐ Professional Certification or Recognition Program
☐ Quality Improvement with Benchmarking (external benchmarking to multiple organizations)
☐ Quality Improvement (Internal to the specific organization)
☐ Not in use
☐ Use unknown
☒ Other (please specify here:) This is a new measure that is currently being implemented into NCDR, specifically the EPDI registry.

4a.02) Check all planned uses.

☒ Public reporting
☐ Public Health/Disease Surveillance
☐ Payment Program
☐ Regulatory and Accreditation Program

☐ Professional Certification or Recognition Program
☐ Quality Improvement with Benchmarking (external benchmarking to multiple organizations)
☐ Quality Improvement (internal to the specific organization)
☐ Measure Currently in Use
☐ Other (please specify here:)

4a.03) If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.

For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?

This is a new measure currently in the implementation phase of development which includes 1 year in the registry before being implemented in the public reporting program.

Voluntary Hospital Public Reporting Program: Hospitals may opt to publicly report their measure results based on data from the National Cardiovascular Data Registry (NCDR). Hospitals that choose to participate have their results displayed on ACC's CardioSmart. Currently Hospitals can report on the following NQF-endorsed measures:

NQF #0965: Use of all recommended medications (ACEI or ARB and beta-blocker) to improve heart function and blood pressure after ICD implant.

NQF # 0964: Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients (composite measure)

NQF# 2377: Overall Defect Free Care Composite (identified on website as "Complete Heart Attack Care")
NCDR ICD Registry:

National quality improvement registry intended to improve the quality of care provided to patients receiving ICD therapy since its inception in 2005. It provides a streamlined, consolidated method of collecting, monitoring and reporting clinically relevant cardiovascular data within a framework that ensures both hospital and patient confidentiality. This enables participants to better focus on ACC/AHA guideline-recommended care and to develop new ways for the registry to advance improvements in care and examine newer clinical questions.

4a.04) If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.

A credible plan includes the specific program, purpose, intended audience, and timeline

for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.

See 4a.03. This measure will be implemented in the public reporting program after a period of data collection in the EPDI registry.

4a.05) Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

Detail how many and which types of measured entities and/or others were included. If only a sample of measured entities were included, describe the full population and how the sample was selected.

Performance results are distributed to all ICD registry participants as part of quarterly benchmark reports, which provide a detailed analysis of an institution´s individual performance in comparison to the entire registry population from participating hospitals across the nation. Reports include an executive summary dashboard, at-a-glance assessments, and patient level drill-downs. Registry
participants also have access to an outcome report companion guide, which provides common definitions and detailed metric specifications to assist with interpretation of performance rates.

4a.06) Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

Results are provided as part of quarterly performance report, which includes a rolling 4 quarters of data.
Participating hospitals in the ICD registry report on the following: patient demographics; provider and facility characteristics; adverse event rates; ICD performance measures and select quality measures and outcomes and compliance with ACC/AHA clinical guideline recommendations.

The majority of the required data elements are routinely generated and acquired during the delivery of standard cardiac care to this patient population. Electronic extraction of data recorded as part of the procedure expedites data collection. This strategy offers point of care collection and minimizes time and cost. Institutions can manually report using a free web-based tool or automate the reporting by using certified software developed by third-party vendors. The data elements required for this measure are readily available within the patient's medical record or can be attained without undue burden within the hospital. Most data elements exist in a structured format within patient's electronic health record.
There are a number of methods used to educate and provide general support to registry participants.

This includes the following:
• Registry Site Manager Calls are available for all NCDR participants. RSM calls are provided as a source of communication between

NCDR and participants to provide a live chat Q and A session on a continuous basis.
• New User Calls are available for NCDR participants, and are intended for assisting new users with their questions.
• NCDR Annual Conference
The NCDR Annual Conference is a well-attended and energetic two-day program at which participants from across the country come together to hear about new NCDR and registry-specific updates. During informative general sessions, attendees can learn about topics such as transcatheter therapies, the NCDR dashboard, risk models, data quality and validation, and value-based purchasing.
Attendees also receive registry updates and participate in advanced case studies covering such topics as Appropriate Use Criteria and outcomes report interpretation.
• Release notes (for outcomes reports)
• Clinical Support
The NCDR Product Support and Clinical Quality Consultant Teams are available to assist participating sites with questions Monday through Friday, 9:00 a.m. - 5:00 p.m. ET.

4a.07) Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.
Feedback is typically obtained through monthly registry site manager monthly calls, ad hoc phone calls tracked with salesforce software, and during registry –specific break-out sessions at the NCDR's annual meeting. Registry Steering Committee members may also provide feedback during regularly scheduled calls.

4a.08) Summarize the feedback obtained from those being measured.
This measure was developed by the clinicians that will be measured. This ensures that the data elements are clear and are supported by the guidelines. Feedback will be obtained once this measure has been 'live' in the NCDR EPDI registry for several quarters.

4a.09) Summarize the feedback obtained from other users.
This is a new measure. Feedback will be shared when it is available.

4a.10) Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.
N/A. This is a new measure.

Usability (4b.01 - 4.03)

4b.01) You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included). If no improvement was demonstrated, provide an explanation. If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

While the mean rate of performance for the individual components measures across participating facilities was greater than 80%, opportunities for improvement across facilities continue to exist with some facilities demonstrating low performance scores (<50% in the 5th percentile).

4b.02) Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.

There have been no unexpected findings so far.

4b.03) Explain any unexpected benefits realized from implementation of this measure.

This is a new measure. Any unexpected benefits will be reported during the next measure cycle.

Related and Competing (5.01 - 5.06)

If you are updating a maintenance measure submission for the first time in MIMS, please note that the previous related and competing data appearing in question 5.03 may need to be entered in to 5.01 and 5.02, if the measures are endorsed. Please review and update questions 5.01, 5.02, and 5.03 accordingly.

5.01) Search and select all endorsed related measures (conceptually, either same measure focus or target population) by going to the PQM website.

(Can search and select measures.)
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5.02) Search and select all endorsed competing measures (conceptually, the measures have both the same measure focus or target population) by going to the PQM website.

(Can search and select measures.)
None

5.03) If there are related or competing measures to this measure, but they are not endorsed, please indicate the measure title and steward.
None known

5.04) If this measure conceptually addresses EITHER the same measure focus OR the same target population as endorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.

☒ Yes
☐ No

5.05) If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.
N/A

5.06) Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.

Provide analyses when possible.
The competing measure is a component measure. This composite uses that measure to gain a holistic view of quality care for ICD implants.

Additional (1 - 9)

1) Provide any supplemental materials, if needed, as an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be collated one file with a table of contents or bookmarks. If material pertains to a specific criterion, that should be indicated.

☒ Available in attached file
☐ No appendix
☐ Available at measure-specific web page URL identified in sp.09

2) List the workgroup/panel members' names and organizations.

Describe the members' role in measure development.
Please see 2b.02

3) Indicate the year the measure was first released. 2022

4) Indicate the month and year of the most recent revision.
This is a new measure, no revisions have been made

5) Indicate the frequency of review, or an update schedule, for this measure.
This will be reevaluated after 1 year of data collection to determine suitability for public reporting.

6) Indicate the next scheduled update or review of this measure.

7) Provide a copyright statement, if applicable. Otherwise, indicate "N/A".

8) State any disclaimers, if applicable. Otherwise, indicate "N/A".
ACC realizes the various NCDR endorsed measures are not readily available on their own main webpage. However, ACCF plans to update their main webpage (acc.org) to include the macro specifications of the NQF endorsed measures. Interested parties are always able to contact comment@acc.org to reach individuals at the ACC Quality Measurement Team.

9) Provide any additional information or comments, if applicable. Otherwise, indicate "N/A".
The ACCF thanks Battelle and CMS for the opportunity to submit this measure.