Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to sub criterion 1b).

Brief Measure Information

NQF #: 2377

Corresponding Measures:

Measure Title: Overall Defect Free Care for AMI

Measure Steward: American College of Cardiology

sp.02. Brief Description of Measure: The proportion of acute MI patients >= 18 years of age that receive "perfect care" based upon their eligibility for each performance measures

1b.01. Developer Rationale: This composite measure is vital as it shows that the patient received all of the treatments for care of AMI that are strongly recommended in national guidelines. While performance may be higher for some individual measures the data has shown that performance on total care of the MI patient can be greatly improved.

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sp.12. Numerator Statement: Count of patients with ALL care opportunities met for which they were eligible.

sp.14. Denominator Statement: Count of patients with at least one eligible care opportunity

sp.16. Denominator Exclusions: The exclusions for this measure were minimal and comprised: patients <18 years of age, hospital submissions that did not pass the NCDR quality check, and patients who were ineligible for defect free care measure (e.g., contraindications, clinical studies).

Measure Type: Composite

sp.29. Data Source:

Registry Data

Other

sp.07. Level of Analysis:

Facility

IF Endorsement Maintenance – Original Endorsement Date: 2014-09-08 03:07 PM

Most Recent Endorsement Date: 6/10/2019 11:30:21 AM

IF this measure is included in a composite, NQF Composite#/title: Overall defect free care for AMI

#2377 - Overall Defect Free Care for AMI

IF this measure is paired/grouped, NQF#/title:

sp.03. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?:

1. Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.

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.

[Response Begins]

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

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.

[Response Begins]

Clinical Practice Guideline recommendation (with evidence review)

[Response Ends]

Attachment: 2377_2377_Evidence addendum 2377 Spring 2022-508.docx

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.

Evidence - Systematic Reviews Table (Repeatable)

Group 1 - Evidence - Systematic Reviews Table

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

[Response Begins]

Amsterdam EA, Wenger NK, Brindis RG et al. 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-e228.

Gulati H, Levy P, Mukhergee D, et al., 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2021 Nov, 78 (22) e187–e285

Jneid H, Addison D, Bhatt DL, et al. 2017 AHA/ACC clinical performance and quality measures for adults with ST-elevation and non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol. 2017;70:2048–90.

Lawton J, Tamis-Holland J, et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization. J Am Coll Cardiol. 2022 Jan, 79 (2) e21–e129. https://doi.org/10.1016/j.jacc.2021.09.006 @ @

O'Gara PT, Kushner FG, Ascheim DD et al. 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.

[Response Ends]

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.

[Response Begins]

Beta blocker prescribed at discharge for AMI patients

- 2013 ACCF/AHA Guideline for the Management of Patients With 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 (49,50). (Class I, Level of Evidence: B)

- 2014 AHA/ACC Guideline for the Management of Patients With Non—¬ST-Elevation Acute Coronary Syndromes (p. e159)

  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)

[Response Ends]

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

[Response Begins]

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."

[Response Ends]

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

[Response Begins]

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

[Response Ends]

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

[Response Begins]

The recommendations included have been assigned a Class I recommendation. 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."

[Response Ends]

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

[Response Begins]

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 e 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.

Table 1. 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

This table provides additional detail regarding the classification of recommendation and level of evidence. The class of recommendation includes 3 categories. Class 1 (strong), class 2a (moderate), class 2b (weak), and class 3 (moderate evidence suggesting no benefit) and class 3 (strong evidence suggesting harm). This tables also defines the quality of evidence. Level A suggests high quality evidence from a randomized control trial, level B-R suggests moderate quality evidence from a randomized control trial, level B-NR is moderate quality evidence from non-randomized control

study, level C-LD is evidence from an observational or registry studies, level C-EO is consensus expert opinion.

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

This table provides additional detail regarding the classification of recommendation and level of evidence. The class of recommendation includes 3 categories. Class 1 (strong), class 2a (moderate), class 2b (weak), and class 3 (moderate evidence suggesting no benefit) and class 3 (strong evidence suggesting harm). This tables also defines the quality of evidence. Level A suggests high quality evidence from a randomized control trial, level B-R suggests moderate quality evidence from a randomized control trial, level B-NR is moderate quality evidence from non-randomized control study, level C-LD is evidence from an observational or registry studies, level C-EO is consensus expert opinion.

CORand LOEare determined independently (any COR maybe paired with anyLOE).

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 clinicalconsensus that a particular test or therapyis useful or effective.

* The outcome or result of the intervention should be specified(an improved clinicaloutcome or increased diagnosticaccuracy 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 qualityis evolving, including the application of stan- dardized, widely-used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an EvidenceReview 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.

[Response Ends]

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

[Response Begins]

All but one 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, the cited guidelines discuss the evidence supporting the use of beta blockers at discharge in this population, which is provided below.

[Response Ends]

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

[Response Begins]

Estimates of the benefits of beta blockers at discharge across the body of evidence are not reported.

[Response Ends]

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

[Response Begins]

N/A

[Response Ends]

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

[Response Begins]

2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization

> In patients who have undergone revascularization, the risks and benefits of beta blockers should be considered before the initiation of therapy. The benefit of beta blockers for secondary prevention after acute infarction or for those with left ventricular dysfunction has been clearly reported in clinical trials examining these subgroups, and recommendations based on this evidence are outlined in previous guidelines (7,8). (p. e84)

[Response Ends]

Group 2 - Evidence - Systematic Reviews Table

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

[Response Begins]

Evaluation of LV systolic function

> O'Gara PT, Kushner FG, Ascheim DD et al. 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.
>
> Amsterdam EA, Wenger NK, Brindis RG et al. 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-e228.

Jneid H, Addison D, Bhatt DL, Fonarow GC, Gokak S, Grady KL, Green LA, Heidenreich PA, Ho PM, Jurgens CY, King ML, Kumbhani DJ, Pancholy S. 2017 AHA/ACC clinical performance and quality measures for adults with ST-elevation and non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol. 2017;70:2048–90.

[Response Ends]

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.

[Response Begins]

2013 ACCF/AHA Guideline for the Management of Patients With ST-Elevation Myocardial Infarction (p. e114)

1. LVEF should be measured in all patients with STEMI. (Class I, Level of Evidence: C)

   2014 AHA/ACC Guideline for the Management of Patients With Non–¬ST-Elevation Acute Coronary Syndromes (p. e170)

2. A noninvasive imaging test is recommended to evaluate LV function in patients with definite ACS (56-60). (Class I, Level of Evidence: C)

[Response Ends]

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

[Response Begins]

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.”

[Response Ends]

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

[Response Begins]

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

[Response Ends]

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

[Response Begins]

The recommendations included have been assigned a Class I recommendation. 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.”

[Response Ends]

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

[Response Begins]

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 e 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.

[Response Ends]

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

[Response Begins]

All of the recommendations for this process are rated as Level of Evidence C, meaning that very limited populations were evaluated and the recommendations are based on only consensus opinion of experts, case studies, or standard of care. Neither guideline discusses the evidence to support LV systolic function evaluation in this population.

[Response Ends]

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

[Response Begins]

Estimates of the benefit of LV systolic function evaluation across the body of evidence are not reported.

[Response Ends]

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

[Response Begins]

N/A

[Response Ends]

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

[Response Begins]

Updated guidelines continue to support this measure.

[Response Ends]

Group 3 - Evidence - Systematic Reviews Table

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

[Response Begins]

ACE-I or ARB for LVSD prescribed at discharge for AMI patients

O'Gara PT, Kushner FG, Ascheim DD et al. 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.

Amsterdam EA, Wenger NK, Brindis RG et al. 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-e228.

Jneid H, Addison D, Bhatt DL, Fonarow GC, Gokak S, Grady KL, Green LA, Heidenreich PA, Ho PM, Jurgens CY, King ML, Kumbhani DJ, Pancholy S. 2017 AHA/ACC clinical performance and quality measures for adults with ST-elevation and non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol. 2017;70:2048–90.

[Response Ends]

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.

[Response Begins]

2013 ACCF/AHA Guideline for the Management of Patients With ST-Elevation Myocardial Infarction (p. e104)

1. An angiotensin-converting enzyme inhibitor (ACE) should be administered within the first 24 hours to all patients with STEMI with anterior location, HF, or ejection fraction (EF) less than or equal to 0.40, unless contraindicated (61,65-67). (Class I, Level of Evidence: A)
2. An angiotensin receptor blocker (ARB) should be given to patients with STEMI who have indications for but are intolerant of ACE inhibitors (64,68). (Class I, Level of Evidence: B)

2014 AHA/ACC Guideline for the Management of Patients With Non—¬ST-Elevation Acute Coronary Syndromes (p. e161)

1. ACE inhibitors should be started and continued indefinitely in all patients with LVEF <0.40 and in those with hypertension, diabetes mellitus, or stable chronic kidney disease (CKD), unless contraindicated (69,70). (Class I, Level of Evidence: A)
2. ARBs are recommended in patients with HF or MI with LVEF less than 0.40 who are ACE inhibitor intolerant (64,71). (Class I, Level of Evidence: A)

[Response Ends]

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

[Response Begins]

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."

[Response Ends]

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

[Response Begins]

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

[Response Ends]

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

[Response Begins]

The recommendations included have been assigned a Class I recommendation. 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."

[Response Ends]

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

[Response Begins]

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 e 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

[Response Ends]

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

[Response Begins]

All but one 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, the cited guidelines discuss the evidence supporting the use of ACE-I or ARB therapy at discharge in this population, which is provided below.

> 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction (p. e105)
>
> Oral ACE inhibitors reduce fatal and nonfatal major cardiovascular events in patients with STEMI (360,361,420,422,428–430). Their protective effects have been demonstrated independent of the use of other pharmacotherapies (i.e., fibrinolytics, aspirin, and beta blockers). The magnitude of clinical benefit is greatest in high-risk patient subgroups (i.e., anterior MI, EF ≤0.40, HF, prior MI, and tachycardia) (431). Demonstration of an early benefit (within the first 24 hours) supports the prompt use of these agents in patients without existing contraindications (hypotension, shock, bilateral renal artery stenosis or history of worsening of renal function with ACE inhibitor/ARB exposure, renal failure, or drug allergy). The role of routine long-term ACE inhibitor therapy in low-risk patients after STEMI who have been revascularized and treated with aggressive lipid-lowering therapies is less certain (432). ARBs are indicated for ACE inhibitor–intolerant patients. Specifically, valsartan was found to be noninferior to captopril in the VALIANT (Valsartan in Acute Myocardial Infarction) trial (424).
>
> 2014 AHA/ACC guideline for the management of patients with non–ST-elevation acute coronary syndromes (p. e161)
>
> ACE inhibitors reduce mortality in patients with recent MI, primarily those with LV dysfunction (LVEF <0.40) with or without pulmonary congestion (283–285). In patients with normal LV function (including patients with diabetes mellitus), total mortality and MACE (including HF) are reduced. It has been found that approximately 15% of patients with NSTEMI develop HF during hospitalization, with the rate increasing to 24% of patients 1 year later (286). A meta- analysis demonstrated a small but significant (0.48%) ab- solute benefit of early initiation of an ACE inhibitor on survival at 30 days, with benefit seen as early as 24 hours after admission for AMI (283). An ACE inhibitor should be used cautiously in the first 24 hours of AMI, because it may result in hypotension or renal dysfunction (283). It may be prudent to initially use a short-acting ACE inhibitor, such as captopril or enalapril, in patients at increased risk of these adverse events. In patients with significant renal dysfunction, it is sensible to stabilize renal function before initiating an ACE inhibitor or an ARB, with re-evaluation of creatinine levels after drug initiation. An ARB may be substituted for an ACE inhibitor with similar benefits on survival (277,278). Combining an ACE inhibitor and an ARB may result in an increase in adverse events (277,278). In a study in which patients with AMI with LV dysfunction (LVEF <0.40) Estimates of the benefit of ACE-I or ARB therapy at discharge across the body of evidence are not reported.with or without HF were randomized 3 to 14 days after AMI to receive eplerenone (a selective aldosterone blocker), eplerenone was efficacious as an adjunct to ACE inhibitors and beta blockers in decreasing long-term mortality (279,287). In a study of patients with HF, >50% of whom had an ischemic etiology, spironolactone (a nonselective aldosterone inhibitor) was beneficial (279); however, RCT data on MI are not available.

[Response Ends]

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

[Response Begins]

Estimates of the benefit of ACE-I or ARB therapy at discharge across the body of evidence are not reported.

[Response Ends]

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

[Response Begins]

N/A

[Response Ends]

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

[Response Begins]

Updated guidelines continue to support this measure.

[Response Ends]

Group 4 - Evidence - Systematic Reviews Table

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

[Response Begins]

Cardiac rehabilitation referral from an inpatient setting for AMI patients

O'Gara PT, Kushner FG, Ascheim DD et al. 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.

Amsterdam EA, Wenger NK, Brindis RG et al. 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-e228.

Jneid H, Addison D, Bhatt DL, Fonarow GC, Gokak S, Grady KL, Green LA, Heidenreich PA, Ho PM, Jurgens CY, King ML, Kumbhani DJ, Pancholy S. 2017 AHA/ACC clinical performance and quality measures for adults with ST-elevation and non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol. 2017;70:2048–90.

Thomas RJ, Balady G, Banka G, Beckie TM, Chiu J, Gokak S, Ho PM, Keteyian SJ, King M, Lui K, Pack Q, Sanderson BK, Wang TY. 2018 ACC/AHA clinical performance and quality measures for cardiac rehabilitation: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol 2018;71:1814–37.

[Response Ends]

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.

[Response Begins]

2013 ACCF/AHA Guideline for the Management of Patients With ST-Elevation Myocardial Infarction (p. e114)

1. Exercise-based cardiac rehabilitation/secondary prevention programs are recommended for patients with STEMI (44,46–48). (Class I, Level of Evidence: B)

2014 AHA/ACC Guideline for the Management of Patients With Non—¬ST-Elevation Acute Coronary Syndromes (p. e179)

2. All eligible patients with NSTE-ACS should be referred to a comprehensive cardiovascular rehabilitation program either before hospital discharge or during the first outpatient visit (38,43–45). (Class I, Level of Evidence: B)

[Response Ends]

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

[Response Begins]

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."

[Response Ends]

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

[Response Begins]

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

[Response Ends]

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

[Response Begins]

The recommendations included have been assigned a Class I recommendation. 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."

[Response Ends]

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

[Response Begins]

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 e 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

[Response Ends]

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

[Response Begins]

All of the recommendations for this process are rated as Level of Evidence B, meaning that the data was derived from a single RCTs or nonrandomized studies. Additional information on the overall quality of evidence across the RCTs and studies is not provided; although, the cited guidelines discuss the evidence supporting cardiac rehabilitation after discharge in this population, which is provided below.

> 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction (p. e116)
>
> Among 601,099 U.S. Medicare beneficiaries who were hospitalized for coronary conditions or revascularization procedures, mortality rates were 21% to 34% lower among participants in cardiac rehabilitation programs than among nonparticipants (599). It has been suggested that contemporary reperfusion and cardioprotective drug therapies may diminish the impact of adjunctive exercise-based cardiac rehabilitation programs on post-MI survival rate. Taylor et al. (600) conducted a systematic review and meta-analysis of RCTs of cardiac rehabilitation with ?6 months of follow-up. The study population included 8,940 patients, a greater number were women (20% of the cohort), patients ?65 years of age, and individuals who had undergone revascularization procedures. Compared with usual care, cardiac rehabilitation was associated with a reduction in total and cardiac mortality rates of 20% and 26%, respectively. Subgroup analyses showed that the decreased mortality rates did not differ across several patient subsets, between programs limited to exercise and those providing more comprehensive secondary interventions, or between pre- and post-1995 studies, which suggests that the mortality benefits of cardiac rehabilitation persist in the modern era. However, despite these impressive outcomes, cardiac rehabilitation services remain vastly underutilized (582,615).
>
> 2014 AHA/ACC guideline for the management of patients with non–ST-elevation acute coronary syndromes (p. e179)
>
> The U.S. Public Health Service emphasizes comprehensive cardiac rehabilitation programs (449), and the 2011 secondary prevention CPG underscores referral to cardiac rehabilitation for survivors of ACS (27). Since 2007, referral to these programs has been designated a quality performance measure (453–455). Barriers to referral can be obviated by discussion with the patient and referral by the patient's primary care clinician and/or cardiovascular care- giver. These comprehensive programs provide patient education, enhance regular exercise, monitor risk factors, and address lifestyle modification (456). Aerobic exercise training can generally begin 1 to 2 weeks after discharge in patients treated with PCI or CABG (457). Mild-to-moderate resistance training can be considered and started 2 to 4 weeks after aerobic training (458). Unsupervised exercise may target a heart rate range of 60% to 75% of maximum age-predicted heart rate based on the patient's exercise stress test. Supervised training may target a higher heart rate (70% to 85% of age-predicted maximum) (457). Additional restrictions apply when residual ischemia is present.
>
> Daily walking can be encouraged soon after discharge for most patients. Resource publications on exercise prescription in cardiovascular patients are available (456,457). Regular physical activity reduces symptoms in patients with cardiovascular disease, enhances functional capacity, im- proves other risk factors such as insulin resistance and glucose control, and is important in weight control (456). Questionnaires and nomograms for cardiac patients have been developed to guide exercise prescription if an exercise test is unavailable (459–462).

[Response Ends]

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

[Response Begins]

Estimates of the benefit of cardiac rehabilitation after discharge across the body of evidence are not reported.

[Response Ends]

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

[Response Begins]

N/A

[Response Ends]

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

[Response Begins]

Updated guidelines continue to support this measure.

[Response Ends]

Group 5 - Evidence - Systematic Reviews Table

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

[Response Begins]

Aspirin prescribed at arrival for AMI patients

O'Gara PT, Kushner FG, Ascheim DD et al. 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.

Amsterdam EA, Wenger NK, Brindis RG et al. 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-e228.

Jneid H, Addison D, Bhatt DL, Fonarow GC, Gokak S, Grady KL, Green LA, Heidenreich PA, Ho PM, Jurgens CY, King ML, Kumbhani DJ, Pancholy S. 2017 AHA/ACC clinical performance and quality measures for adults with ST-elevation and non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol. 2017;70:2048–90.

[Response Ends]

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.

[Response Begins]

2013 ACCF/AHA Guideline for the Management of Patients With ST-Elevation Myocardial Infarction (p. e91-e96)

1. Aspirin 162 to 325 mg should be given before primary PCI (34,36,37). (Class I, Level of Evidence: B)

2. Aspirin (162- to 325-mg loading dose) and clopidogrel (300-mg loading dose for patients <75 years of age, 75-mg dose for patients >75 years of age) should be administered to patients with STEMI who receive fibrinolytic therapy (31,38,39). (Class I, Level of Evidence: A)

   2014 AHA/ACC Guideline for the Management of Patients With Non–¬ST-Elevation Acute Coronary Syndromes (p. e161, e171) p. e161
3. Non–enteric-coated, chewable aspirin (162 mg to 325 mg) should be given to all patients with NSTE-ACS without contraindications as soon as possible after presentation, and a maintenance dose of aspirin (81 mg/d to 162 mg/d) should be continued indefinitely (7,40-43). (Class I, Level of Evidence: A)
4. In patients with NSTE-ACS who are unable to take aspirin because of hypersensitivity or major gastrointestinal intolerance, a loading dose of clopidogrel followed by a daily maintenance dose should be administered (46). (Class I, Level of Evidence: B) p. e171:
5. Patients not on aspirin therapy should be given non−enteric-coated aspirin (325 mg) as soon as possible before PCI (36,37,44,45). (Class I, Level of Evidence: B)

[Response Ends]

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

[Response Begins]

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.”

[Response Ends]

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

[Response Begins]

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

[Response Ends]

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

[Response Begins]

The recommendations included have been assigned a Class I recommendation. 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.”

[Response Ends]

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

[Response Begins]

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 e 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

[Response Ends]

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

[Response Begins]

All but one 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, the cited guidelines discuss the evidence supporting the use of aspirin at arrival in this population, which is provided below.

2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction (p. e93-e96)

Although the minimum effective aspirin dose in the setting of PCI for STEMI has not been established prospectively, the writing committee recommends that an empiric dose of 325 mg be given as early as possible before PCI and a maintenance dose continued indefinitely thereafter. It is the consensus of the writing committee that the 81-mg maintenance dose is preferred even among patients who receive a stent during primary PCI. This recommendation is based on evidence of an increased risk of bleeding in most studies comparing higher- with lower-dose aspirin (253,254,263,264), as well as the absence of data from RCTs demonstrating superior efficacy of higher aspirin doses in this setting. However, because the CURRENT-OASIS 7 (Clopidogrel Optimal Loading Dose Usage to Reduce Recurrent Events–Organization to Assess Strategies in Ischemic Syndromes) trial did not report differences in either efficacy or safety in patients with STEMI randomized to 81 mg versus 325 mg of aspirin, the committee did not think that the evidence favoring 81 mg over higher dosages was sufficiently conclusive to merit a Class I recommendation (253).

The beneficial effects of aspirin and clopidogrel with fibrinolytic therapy are well established (254,257,263,264). These agents should be given before or with the fibrinolytic (330).

2014 AHA/ACC guideline for the management of patients with non–ST-elevation acute coronary syndromes (p. e163, e172) p. e163:

Aspirin is the established first-line therapy in patients with NSTE-ACS and reduces the incidence of recurrent MI and death (288,289). A loading dose of non–enteric- coated aspirin 162 mg to 325 mg is the initial antiplatelet therapy. The subsequent maintenance dose is 81 mg per day to 162 mg per day; in special circumstances, a higher maintenance dose up to 325 mg daily has been used (391). The lower dose is favored and all patients treated with ticagrelor should receive only 81 mg per day (290). In other countries, available low-dose aspirin formations may include 75 mg and 100 mg. High-dose ($160 mg) versus low-dose (<160 mg) aspirin is associated with increased bleeding risk in the absence of improved

outcomes (298). Most NSAIDs reversibly bind to COX-1, preventing inhibition by aspirin and by COX-2 and may cause prothrombotic effects. Enteric-coated aspirin should be avoided initially because of its delayed and reduced absorption (299). p. e172:

Aspirin reduces the frequency of ischemic complications after PCI and is ideally administered at least 2 hours, and preferably 24 hours, before PCI (26,368,369).

[Response Ends]

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

[Response Begins]

Estimates of the benefit of aspirin at arrival across the body of evidence are not reported.

[Response Ends]

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

[Response Begins]

N/A

[Response Ends]

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

[Response Begins]

Updated guidelines continue to support this measure.

[Response Ends]

Group 6 - Evidence - Systematic Reviews Table

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

[Response Begins]

Aspirin prescribed at discharge for AMI patients

O'Gara PT, Kushner FG, Ascheim DD et al. 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.

Amsterdam EA, Wenger NK, Brindis RG et al. 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-e228.

Jneid H, Addison D, Bhatt DL, Fonarow GC, Gokak S, Grady KL, Green LA, Heidenreich PA, Ho PM, Jurgens CY, King ML, Kumbhani DJ, Pancholy S. 2017 AHA/ACC clinical performance and quality measures for adults with ST-elevation and non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol. 2017;70:2048–90.

[Response Ends]

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.

[Response Begins]

2013 ACCF/AHA Guideline for the Management of Patients With ST-Elevation Myocardial Infarction (p. e91-e96)

1. After PCI, aspirin should be continued indefinitely (13,33,48). (Class I, Level of Evidence: A)
2. Aspirin should be continued indefinitely (31,38,39) (Class I, Level of Evidence: A), and clopidogrel (75 mg daily) should be continued for at least 14 days (38,39) (Class I, Level of Evidence: A) and up to 1 year (Class I, Level of Evidence: C) in patients with STEMI who receive fibrinolytic therapy.

2014 AHA/ACC Guideline for the Management of Patients With Non—¬ST-Elevation Acute Coronary Syndromes (p. e171)

1. After PCI, aspirin should be continued indefinitely at a dose of 81 mg to 325 mg daily (13,40,48). (Class I, Level of Evidence: B).
2. Aspirin should be continued indefinitely. The maintenance dose should be 81 mg daily in patients treated with ticagrelor and 81 mg to 325 mg daily in all other patients (40,41,43). (Class I, Level of Evidence: A).

[Response Ends]

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

[Response Begins]

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.”

[Response Ends]

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

[Response Begins]

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

[Response Ends]

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

[Response Begins]

The recommendations included have been assigned a Class I recommendation. 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.”

[Response Ends]

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

[Response Begins]

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 e 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

[Response Ends]

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

[Response Begins]

The recommendations for this process are rated as Level of Evidence A, B, or C meaning that the data was derived from one or more RCTs or meta-analyses through consensus opinions 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 guidelines discuss the evidence supporting the use of aspirin at discharge in this population, which is provided below.

2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction (p. e93-e96)

Although the minimum effective aspirin dose in the setting of PCI for STEMI has not been established prospectively, the writing committee recommends that an empiric dose of 325 mg be given as early as possible before PCI and a maintenance dose continued indefinitely thereafter. It is the consensus of the writing committee that the 81-mg maintenance dose is preferred even among patients who receive a stent during primary PCI. This recommendation is based on evidence of an increased risk of bleeding in most studies comparing higher- with lower-dose aspirin (253,254,263,264), as well as the absence of data from RCTs demonstrating superior efficacy of higher aspirin doses in this setting. However, because the CURRENT-OASIS 7 (Clopidogrel Optimal Loading Dose Usage to Reduce Recurrent Events–Organization to Assess Strategies in Ischemic Syndromes) trial did not report differences in either efficacy or safety in patients with STEMI randomized to 81 mg versus 325 mg of aspirin, the committee did not think that the evidence favoring 81 mg over higher dosages was sufficiently conclusive to merit a Class I recommendation (253).

The beneficial effects of aspirin and clopidogrel with fibrinolytic therapy are well established (254,257,263,264). These agents should be given before or with the fibrinolytic (330).

2014 AHA/ACC guideline for the management of patients with non–ST-elevation acute coronary syndromes (p. e172)

Aspirin reduces the frequency of ischemic complications after PCI and is ideally administered at least 2 hours, and preferably 24 hours, before PCI (26,368,369).

[Response Ends]

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

[Response Begins]

Estimates of the benefit of aspirin at discharge across the body of evidence are not reported.

[Response Ends]

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

[Response Begins]

[Response Ends]

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

[Response Begins]

Updated guidelines continue to support this measure.

[Response Ends]

Group 7 - Evidence - Systematic Reviews Table

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

[Response Begins]

High-intensity statin prescribed at discharge for AMI patients

O'Gara PT, Kushner FG, Ascheim DD et al. 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.

Amsterdam EA, Wenger NK, Brindis RG et al. 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-e228.

Grundy SM, Stone NJ, Bailey AL, Beam C, Birtcher KK, Blumenthal RS, Braun LT, de Ferranti S, Faiella-Tommasino J, Forman DE, Goldberg R, Heidenreich PA, Hlatky MA, Jones DW, Lloyd-Jones D, Lopez-Pajares N, Ndumele CE, Orringer CE, Peralta CA, Saseen JJ, Smith SC Jr, Sperling L, Virani SS, Yeboah J. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019;73:e285–350.

Jneid H, Addison D, Bhatt DL, Fonarow GC, Gokak S, Grady KL, Green LA, Heidenreich PA, Ho PM, Jurgens CY, King ML, Kumbhani DJ, Pancholy S. 2017 AHA/ACC clinical performance and quality measures for adults with ST-elevation and non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol. 2017;70:2048–90.

[Response Ends]

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.

[Response Begins]

2013 ACCF/AHA Guideline for the Management of Patients With ST-Elevation Myocardial Infarction (p. e106)

1. High-intensity statin therapy should be initiated or continued in all patients with STEMI and no contraindications to its use (434–436). (Class I, Level of Evidence: B)

2014 AHA/ACC Guideline for the Management of Patients With Non–¬ST-Elevation Acute Coronary Syndromes (p. e160)

1. High-intensity statin therapy should be initiated or continued in all patients with NSTE-ACS and no contraindications to its use (269–273). (Class I, Level of Evidence: A)

2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol (p. e295)

1. In patients who are 75 years of age or younger with clinical ASCVD,* high-intensity statin therapy should be initiated or continued with the aim of achieving a 50% or greater reduction in LDL-C levels (S4.1-1—S4.1-5). (Class I, Level of Evidence: A)

[Response Ends]

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

[Response Begins]

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.

[Response Ends]

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

[Response Begins]

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

[Response Ends]

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

[Response Begins]

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."

[Response Ends]

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

[Response Begins]

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 e 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

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.

[Response Ends]

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

[Response Begins]

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, the cited guidelines discuss the evidence supporting the use of high-intensity statins at discharge in this population, which is provided below.

2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction (p. e106)

Treatment with statins in patients stabilized after an ACS, including STEMI, lowers the risk of coronary heart disease death, recurrent MI, stroke, and the need for coronary revascularization (437,438). More intensive statin therapy, compared with less intensive therapy, appears to be associated with an additional lowering of nonfatal clinical end- points (434,436,439). Among currently available statins, only high-dose atorvastatin (80 mg daily) has been shown to reduce death and ischemic events among patients with ACS (436,440). Approximately one third of patients in the PROVE-IT TIMI 22 (Pravastatin or Atorvastatin Evaluation and Infection Therapy—Thrombolysis in Myocardial Infarction 22) trial had STEMI (436). Cardiovascular event rates were not significantly reduced with a tiered strategy of simvastatin (40-mg daily for 1 month followed by 80 mg daily) in the A to Z Trial (Aggrastat to Zocor) (439), and concerns have been raised recently about the safety of high-dose simvastatin (i.e., 80 mg daily) (441). Although the benefit of high-intensity statins declines among statin-naïve patients with ACS as a function of decreasing low-density lipoprotein levels (442), the writing committee recommends the use of statins in all patients with STEMI (435). Statin therapy after ACS is beneficial even in patients with baseline low-density lipoprotein cholesterol levels 70 mg/dL (443). Trials of statin therapy in patients with ACS and stable ischemic heart disease have been designed to compare either more intensive versus less intensive statin treatment or active statin versus placebo (434 – 440). They have not been de- signed to compare clinical outcomes as a function of the specific low-density lipoprotein cholesterol level achieved with treatment. Improved compliance with therapy is a strong rationale for timing the initiation of lipid-lowering drug therapy before discharge after STEMI. Longer-term lipid management after STEMI, including indications for targeting triglycerides and non– high-density lipoprotein cholesterol, are addressed in the "AHA/ACC Secondary Prevention and Risk Reduction Therapy for Patients With Coronary and Other Vascular Disease: 2011 Update" (257).

2014 AHA/ACC guideline for the management of patients with non–ST-elevation acute coronary syndromes (p. e160-e161)

Therapy with statins in patients with NSTE-ACS reduces the rate of recurrent MI, coronary heart disease mortality, need for myocardial revascularization, and stroke. High-risk patients, such as those with NSTE-ACS, derive more benefit in reducing these events from high-intensity statins, such as atorvastatin which lower low-density lipoprotein cholesterol levels by $50% as in the PROVE IT-TIMI 22 (Pravastatin or Atorvastatin Evaluation and Infection Therapy-Thrombolysis In Myocardial Infarction) and MIRACL (Myocardial Ischemia Reduction With Acute Cholesterol Lowering) trials (273,274), than from moderate- or low-intensity statins (18,272). These findings provide the basis for high-intensity statin therapy after stabilization of patients with NSTE-ACS. In addition, early introduction of this approach can promote improved compliance with this regimen.

2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol (p. e296-e297)

CTT meta-analysis (S4.1-3, S4.1-4) showed that LDL-C lowering with statins reduces major ASCVD events. Patients with stroke (S4.1-1) or peripheral artery disease (S4.1-5) also derive these benefits. In a meta-analysis of 5 RCTs (S4.1-3), high-intensity statins compared with moderate-intensity statin therapy, significantly reduced major vascular events by 15% with no significant reduction in coronary deaths. Large absolute LDL-C reduction was associated with a larger proportional reduction in major vascular events (S4.1-4). High-intensity statin therapy generally reduces LDL-C levels by 50%. This percentage can be used to judge clinical efficacy. Absolute benefit from statin therapy depends on baseline LDL-C levels; the greatest absolute benefit accrues to patients with the highest baseline LDL-C levels. Percentage reduction of LDL-C levels is the most efficient means to estimate expected efficacy. An alternative to evaluating the adequacy of therapy is to examine LDL-C on maximum- intensity statins. In a patient with ASCVD, if LDL-C level is 70 mg/dL (1.8 mmol/L), adding ezetimibe may be reasonable.

[Response Ends]

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

[Response Begins]

Estimates of the benefit of high-intensity statins at discharge across the body of evidence are not reported.

[Response Ends]

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

[Response Begins]

N/A

[Response Ends]

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

[Response Begins]

Updated guidelines continue to support this measure.

[Response Ends]

Group 8 - Evidence - Systematic Reviews Table

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

[Response Begins]

P2Y12 inhibitor prescribed at discharge for AMI patients

O'Gara PT, Kushner FG, Ascheim DD et al. 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.

Amsterdam EA, Wenger NK, Brindis RG et al. 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-e228.

Jneid H, Addison D, Bhatt DL, Fonarow GC, Gokak S, Grady KL, Green LA, Heidenreich PA, Ho PM, Jurgens CY, King ML, Kumbhani DJ, Pancholy S. 2017 AHA/ACC clinical performance and quality measures for adults with ST-elevation and non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol. 2017;70:2048–90.

[Response Ends]

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.

[Response Begins]

2013 ACCF/AHA Guideline for the Management of Patients With ST-Elevation Myocardial Infarction (p. e91-e93)

1. P2Y12 inhibitor therapy should be given for 1 year to patients with STEMI who receive a stent (bare-metal or drug-eluting) during primary PCI using the following maintenance doses:

a. Clopidogrel 75 mg daily (115,116) (Class I, Level of Evidence: B); or

b. Prasugrel 10 mg daily (115) (Class I, Level of Evidence: B); or

c. Ticagrelor 90 mg twice a day* (117) (Class I, Level of Evidence: B)

*The recommended maintenance dose of aspirin to be used with ticagrelor is 81 mg daily.

2. Prasugrel should not be administered to patients with a history of prior stroke or transient ischemic attack (116). (Class III, Level of Evidence: B)

2014 AHA/ACC Guideline for the Management of Patients With Non–¬ST-Elevation Acute Coronary Syndromes (p. e 161, e172, e175)

p.e161:

1. A P2Y12 inhibitor (either clopidogrel or ticagrelor) in addition to aspirin should be administered for up to 12 months to all patients with NSTE-ACS without contraindications who are treated with either an early invasive or ischemia-guided strategy. Options include:

a. Clopidogrel: 300-mg or 600-mg loading dose, then 75 mg daily (289,292) (Class I, Level of Evidence: B)

b. Ticagrelor: 180-mg loading dose, then 90 mg twice daily (293,294) (Class I, Level of Evidence: B)

p. e172:

2. In patients receiving a stent (bare-metal stent or drug- eluting stent [DES]) during PCI for NSTE-ACS, P2Y12 inhibitor therapy should be given for at least 12 months (330). Options include:

a. Clopidogrel: 75 mg daily (296,331) (Class I, Level of Evidence: B); or

b. Prasugrel: 10 mg daily (302) (Class I, Level of Evidence: B); or

c. Ticagrelor: 90 mg twice daily (293) (Class I, Level of Evidence: B)

p. e175:

3. In addition to aspirin, a P2Y12 inhibitor (either clopidogrel or ticagrelor) should be continued for up to 12 months in all patients with NSTE-ACS without contraindications who are treated with an ischemia-guided strategy. Options include:

a. Clopidogrel: 75 mg daily (289,292) (Class I, Level of Evidence: B)

b. Ticagrelor: 90 mg twice daily (293,294) (Class I, Level of Evidence: B)

[Response Ends]

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

[Response Begins]

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.”

[Response Ends]

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

[Response Begins]

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

[Response Ends]

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

[Response Begins]

The recommendations included have been assigned a Class I recommendation. 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."

[Response Ends]

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

[Response Begins]

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 e 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

[Response Ends]

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

[Response Begins]

All of the recommendations for this process are rated as Level of Evidence B, meaning that the data was derived from one RCTs or nonrandomized studies. Additional information on the overall quality of evidence across the RCTs and studies is not provided; although, the cited guidelines discuss the evidence supporting the use of high-intensity statin at discharge in this population, which is provided below.

2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction (p. e93-e94)

Loading doses of P2Y12 inhibitors are provided before or at the time of primary PCI. These agents are continued in a maintenance dose for 1 year after PCI with a stent (BMS or DES) in the absence of bleeding. A 600-mg loading dose of clopidogrel is preferred to a 300-mg loading dose, given the more extensive and rapid platelet inhibition achieved with the higher dose, as well as the beneficial effects reported in a CURRENT-OASIS 7 subgroup analysis (259). The under- powered ARMYDA-6 MI (Antiplatelet Therapy for Reduction of Myocardial Damage During Angioplasty–Myocardial Infarction) study also reported beneficial surrogate outcomes with the higher clopidogrel loading dose (258).

The antiplatelet response to clopidogrel may vary as a function of patient phenotype (obesity, diabetes mellitus), enteric ABCB 1 polymorphisms, hepatic CYP450 enzyme system polymorphisms (predominantly CYP 2C19*2), and medications that interfere with clopidogrel biotransformation. Approximately 25% to 30% of patients may harbor a reduced-function CYP2C19 allele. In TRITON-TIMI 38 (Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel—Thrombolysis In Myocardial Infarction) (285) and 3 cohort studies (286–288), patients who were carriers of the reduced-function CYP2C19*2 allele had significantly lower levels of the active metabolite of clopidogrel, diminished platelet inhibition, and increased rates of major adverse cardiovascular events and stent thrombosis (285). The U.S. Food and Drug Administration has changed clopidogrel's prescribing information to highlight the potential impact of CYP2C19 genotype on clopidogrel pharmacokinetics and clinical response (289). Nevertheless, other studies have not confirmed associations between CYP2C19 polymorphisms and adverse outcomes in clopidogrel-treated patients (290). Future studies are needed to further clarify the risk associated with these genetic polymorphisms and to develop effective therapeutic strategies for carriers of allelic variants of responsible enzyme systems. Proton-pump inhibitors, most prominently omeprazole, can interfere with clopidogrel metabolism and result in diminished in vitro antiplatelet effect (291), but it does not appear that this pharmacokinetic effect translates into worse clinical outcomes (291,292).

Prasugrel, an alternative thienopyridine, achieves greater inhibition of platelet aggregation than clopidogrel. In the TRITON-TIMI 38 trial(260) of prasugrel versus clopidogrel in patients with ACS for whom an invasive strategy was planned, patients with STEMI who were assigned to prasugrel had a lower 30-day rate of the composite primary outcome. This difference persisted to 15 months. In addition, the rate of stent thrombosis reported at 30 days was significantly lower with prasugrel (260,262). The loading dose of clopidogrel in TRITON-TIMI 38, which rarely was administered before coronary angiography and was limited to 300 mg, may have contributed to differences in efficacy and safety between treatment groups (262).

The benefits of prasugrel relative to clopidogrel in STEMI must be weighed against the increase in the risk of bleeding associated with its use. Prasugrel should not be administered to patients with a history of stroke or transient ischemic attack and was not shown to be beneficial in patients =>75 years of age or patients who weigh <60 kg (260). In TRITON-TIMI 38, interaction testing for efficacy and safety showed no significant difference in bleeding risk across the spectrum of ACS. Prasugrel may be best suited for younger patients with diabetes mellitus or large areas of myocardium at risk, who are also at low bleeding risk, have the ability to continue a regimen of DAPT, and have no anticipation of surgery over the subsequent year. The package insert for prasugrel suggests that a lower maintenance dose of 5 mg daily might be considered for patients at high risk of bleeding, though this dose has not been prospectively studied (293).

Ticagrelor is a reversible, nonthienopyridine P2Y12 receptor antagonist that does not require metabolic conversion to active drug. The PLATO (Platelet Inhibition and Patient Outcomes) study compared ticagrelor (180-mg loading dose, 90 mg twice daily thereafter) with clopidogrel (300- or 600-mg loading dose, 75 mg daily thereafter) for the prevention of cardiovascular events in 18,624 patients with ACS, of whom 35% had STEMI (294). Among the 7544 patients enrolled with ST elevation or LBBB who underwent primary PCI, findings were consistent with the overall trial results. Significant reductions favoring ticagrelor were seen in the primary PCI subgroup for stent thrombosis and total deaths, though there were more strokes and episodes of ICH with ticagrelor (261). A prespecified subgroup analysis in the PLATO trial showed a significant interaction between treatment effect and geographic region, with an apparently smaller ticagrelor effect in North America than in other areas. Although this interaction could have been due to chance alone (295), a contribution from higher aspirin doses, as more commonly used in the United States, cannot be excluded. When provided long term with ticagrelor as a component of DAPT, the dose of aspirin should not exceed 100 mg (293).

Although 1 year of DAPT is recommended after stent implantation during primary PCI for STEMI, earlier discontinuation of a P2Y12 inhibitor may be necessary if the risk of morbidity from bleeding outweighs the anticipated benefit of DAPT. Clinical judgment is required, and discussion with the interventional cardiologist is recommended.

DAPT with aspirin and either clopidogrel or prasugrel has increased the risk of ICH in several clinical trials and patient populations (especially in those with prior stroke) (260,296– 298). In PLATO, the number of patients with prior stroke was small, limiting the power to detect treatment differences in intracranial bleeding in this subgroup

(299). Until further data become available, it would seem prudent to weigh the possible increased risk of intracranial bleeding when the addition of ticagrelor to aspirin is considered in patients with prior stroke or transient ischemic attack (300).

2014 AHA/ACC guideline for the management of patients with non–ST-elevation acute coronary syndromes (p. e 161, e172, e178)

p.e161:

Despite the large number of new antiplatelet and antithrombotic agents, aspirin, which targets COX and subsequent thromboxane A2 inhibition, is the mainstay of antiplatelet therapy. Multiple other pathways of platelet activation can be targeted by agents that inhibit the platelet P2Y12 receptor, including thienopyridine prodrug agents, such as clopidogrel and prasugrel, which require conversion into molecules that bind irreversibly to the P2Y12 receptor. Additional pyrimidine derivatives, including ticagrelor, do not require biotransformation and bind reversibly to the P2Y12 receptor, antagonizing adenosine diphosphate platelet activation. In addition to these oral agents, intravenous GP IIb/IIIa receptor inhibitors, including abciximab, eptifibatide, and tirofiban, target the final common pathway of platelet aggregation. In the EARLY ACS (Early Glycoprotein IIb/IIIa Inhibition in Patients With Non–ST- Segment Elevation Acute Coronary Syndrome) trial, patients were randomly assigned to either early, pre–PCI double-bolus eptifibatide or delayed, provisional eptifibatide. Seventy-five percent of the patients received upstream, preprocedure clopidogrel. The risk of TIMI major bleeding in the early eptifibatide group was 2.6% compared with 1.8% (p1⁄40.02) in the delayed provisional group (295). In the GUSTO IV-ACS (Global Use of Strategies To Open Occluded Coronary Arteries IV- Acute Coronary Syndromes) trial, there was no clinical benefit of abciximab in this population; in troponin-negative patients, mortality was 8.5% compared with 5.8% in controls (p1⁄40.002) (288,289,296,297).

Clopidogrel

Administration of clopidogrel with aspirin was superior to administration of aspirin alone in reducing the incidence of cardiovascular death and nonfatal MI or stroke both acutely and over the following 11 months (289,296). There was a slight increase in major bleeding events with clopidogrel, including a nonsignificant increase in life-threatening bleeding and fatal bleeding (289). An initial loading dose of 300 mg to 600 mg is recommended (289,296,300). A 600-mg loading dose results in a greater, more rapid, and more reliable platelet inhibition compared with a 300-mg loading dose (301). Use of clopidogrel for patients with NSTE-ACS who are aspirin intolerant is based on a study in patients with stable ischemic heart disease (291). When possible, discontinue clopidogrel at least 5 days before surgery (301).

Prasugrel

The metabolic conversion pathways of prasugrel produce more rapid and consistent platelet inhibition than clopidogrel (300). In patients with NSTE-ACS and defined coronary anatomy undergoing planned PCI, a 60-mg loading dose of prasugrel followed by 10 mg daily was compared with a 300-mg loading dose and 75 mg daily of clopidogrel. The composite primary endpoint (cardiovascular death, nonfatal MI, and stroke) was reduced in patients treated with prasugrel (hazard ratio [HR]: 0.81; p1⁄40.001). This was driven by a risk reduction for MI and stent thrombosis with no difference in mortality (302). Counterbalancing the salutary effects of prasugrel was a significant increase in spontaneous bleeding, life- threatening bleeding, and fatal bleeding in the patients treated with prasugrel compared with patients treated with clopidogrel. There was net harm in patients with a history of cerebrovascular events and no clinical benefit in patients >75 years of age or those with low body weight (<60 kg) (302). In patients with NSTE-ACS treated with an ischemia-guided strategy, 1 RCT comparing aspirin and either clopidogrel or prasugrel evaluated the primary endpoint of death from cardiovascular causes, MI, or stroke for up to 30 months; there were similar bleeding rates and no benefit of treatment with prasugrel when compared with treatment with clopidogrel (303). The ACCOAST (A Comparison of Prasugrel at the Time of Percutaneous Coronary Intervention or as Pretreatment at the Time of Diagnosis in Patients With Non–ST-Elevation Myocardial Infarction) RCT of high-risk patients with NSTE-ACS scheduled to undergo early coronary angiography found that a strategy of administration of prasugrel at the time of randomization before angiography did not lead to a reduction in the composite primary endpoint when compared with a strategy of administration of prasugrel only at the time of PCI; however, it did lead to an increase in bleeding complications (304). On the basis of TRITON (Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel) study design and the

results of TRILOGY ACS (Targeted Platelet Inhibition to Clarify the Optimal Strategy to Medically Manage Acute Coronary Syndromes) and ACCOAST, prasugrel is not recommended for "upfront" therapy in patients with NSTE-ACS. The use of prasugrel in patients undergoing PCI is addressed in Section 5.

Ticagrelor

Ticagrelor is an oral, reversibly binding P2Y12 inhibitor with a relatively short plasma half-life (12 hours). Compared with clopidogrel, ticagrelor has a more rapid and consistent onset of action and, because it is reversible, it has a faster recovery of platelet function. The loading dose of ticagrelor for patients treated either invasively or with an ischemia-guided strategy is 180 mg followed by a maintenance dose of 90 mg twice daily (293,294). In patients with NSTE-ACS treated with ticagrelor compared with clopidogrel, there was a reduction in the composite outcome of death from vascular causes, MI, or stroke (reduction: 11.7% to 9.8%; HR: 0.84; p<0.001) (293). The mortality rate was also lower in those patients treated with ticagrelor. Although overall major bleeding was not increased with ticagrelor, a modest increase in major bleeding and non–procedure-related bleeding occurred in the subgroup of patients who did not undergo CABG (major bleeding: 4.5% versus 3.8%; p1⁄40.02; non- procedure major bleeding: 3.1% versus 2.3%; p1⁄40.05); however, there was no difference in blood transfusion or fatal bleeding (305). Side effects unique to ticagrelor include dyspnea (which occurs in up to 15% of patients within the first week of treatment but is rarely severe enough to cause discontinuation of treatment) (293) and bradycardia. The benefit of ticagrelor over clopidogrel was limited to patients taking 75 mg to 100 mg of aspirin (290). The short half-life requires twice-daily administration, which could potentially result in adverse events in non- compliant patients, particularly after stent implantation. When possible, ticagrelor should be discontinued at least 5 days before surgery (306). Although ticagrelor has not been studied in the absence of aspirin, its use in aspirin-intolerant patients is a reasonable alternative.

p. e172:

Comprehensive recommendations on the use of antiplatelet and anticoagulant therapy in patients with NSTE-ACS under-going PCI are given in the 2011 PCI CPG (26). Aspirin reduces the frequency of ischemic complications after PCI and is ideally administered at least 2 hours, and preferably 24 hours, before PCI (26,368,369). DAPT, consisting of aspirin and a P2Y12 inhibitor, in patients treated with coronary stents reduces the risk of stent thrombosis and composite ischemic events (296,331,372–375,389,390). Compared with a loading dose of 300 mg of clopidogrel, a loading dose of 600 mg of clopidogrel in patients undergoing PCI achieves greater platelet inhibition with fewer low responders and decreases the incidence of MACE (376–378). In patients with ACS who have undergone coronary stenting, treatment with prasugrel or ticagrelor, compared with treatment with clopidogrel, results in a greater reduction in composite ischemic events and the incidence of stent thrombosis, although at a risk of increased non–CABG bleeding (293,302). The optimal duration of DAPT therapy in patients treated with DES is not well established (26). However, aspirin is continued indefinitely in all patients managed with a bare-metal stent or DES, and DAPT is an option for >12 months in patients who have received a DES. This determination should balance the risks of stent thrombosis and ischemic complications versus bleeding and should be jointly made by the clinician and the patient.

Loading and short-term maintenance doses of clopidogrel were studied in CURRENT–OASIS (Clopidogrel Optimal Loading Dose Usage to Reduce Recurrent Events– Organization to Assess Strategies in Ischemic Syndromes) 7, which demonstrated a potential benefit of higher-dose clopidogrel (600-mg loading dose, 150 mg daily for 6 days, 75 mg daily thereafter) in patients with NSTE-ACS undergoing an invasive management strategy (292,391). Although the overall trial (292) failed to demonstrate a significant difference in the primary endpoint between the clopidogrel and aspirin groups (4.2% versus 4.4%), the PCI subset (n1⁄417,263) showed significant differences in the clopidogrel arm (391). Notably, the higher-dose clopidogrel therapy increased major bleeding in the entire group (2.5% versus 2.0%; p1⁄40.012) and the PCI subgroup (1.1% versus 0.7%; p1⁄40.008). In addition, during the period of several hours required for conversion of clopidogrel to its active metabolite, there is reduced effectiveness. However, efficacy is restored following conversion.

Patients undergoing PCI who have previously received a loading dose of 300 mg of clopidogrel and are on a 75-mg daily maintenance dose should receive another 300-mg loading dose (315). There are no data appropriate for prasugrel because this drug is administered before PCI. For ticagrelor, there are no data on additional loading.

p.e178:

The combination of oral antiplatelet therapy and oral anticoagulant therapy significantly increases the risk of bleeding. This risk varies widely, but on average, the addition of a single antiplatelet agent increased the risk of bleeding from a range of 2% to 3% to a range of 4% to 6%, whereas the addition of DAPT to oral anticoagulant therapy ("triple therapy") increased the risk of bleeding from a range of 4% to 6% to a range of 10% to 14% (432–435). This risk was also related to the duration of triple therapy.

In patients with NSTE-ACS in whom there are indications for triple therapy, the benefit of such therapy in terms of prevention of stent thrombosis, thrombo- embolic events, and recurrent MI must be weighed against the risk of bleeding complications. Similarly, DAPT, in addition to anticoagulant therapy, requires consideration of the increased risk of bleeding. It is essential that therapeutic decision making in this critical area include discussion with the patient about the options, advantages, and limitations of available approaches.

Recommendations about the management of patients treated with triple therapy have been published in ACC/AHA CPGs and by other organizations (17,26,430,433,436). Although some organizations have recommended a target INR of 2.0 to 2.5 in patients with atrial fibrillation (AF) who require triple therapy (437), others continue to recommend a target INR of 2.0 to 3.0 (12,436). The HAS-BLED (Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly) score has relevance in these deliberations (439). No prospective study to date has demonstrated that a target INR of 2.0 to 2.5 reduces bleeding complications.

Whenever possible, shorter durations of triple therapy are favored in preference to longer durations of triple therapy. In patients with NSTE-ACS who require oral anticoagulation for AF, mechanical heart valve, deep venous thrombosis, or other conditions, a bare- metal stent may offer the advantages of lower bleeding risk over a DES because of the potentially shorter duration of triple antithrombotic therapy. The WOEST (What is the Optimal Antiplatelet and Anticoagulant Therapy in Patients With Oral Anticoagulation and Coronary Stenting) trial is the first published study to address the question of optimal antiplatelet therapy in patients taking oral anticoagulant medication (440). WOEST was a randomized, open-label trial of 563 patients (approximately 25% of whom had NSTE- ACS) receiving oral anticoagulant therapy and under- going coronary stenting. Patients randomized to single antiplatelet treatment with clopidogrel had significantly fewer bleeding complications and no increase in thrombotic events compared with those randomized to DAPT with aspirin and clopidogrel. Larger clinical trials are needed to compare double versus triple therapy in the setting of coronary stenting and NSTE-ACS. One such study that has been initiated is PIONEER AF-PCI (an Open-Label, Randomized, Controlled, Multicenter Study Exploring two Treatment Strategies of Rivaroxaban and a Dose-Adjusted Oral Vitamin K Antagonist Treatment Strategy in Subjects With Atrial Fibrillation who Undergo Percutaneous Coronary Intervention).

Although there are some data on therapy with aspirin, clopidogrel, and warfarin, there is sparse information on the use of newer P2Y12 inhibitors (prasugrel, ticagrelor), direct thrombin inhibitor (dabigatran), or factor-Xa inhibitors (rivaroxaban, apixaban) in patients receiving triple therapy. Prasugrel (302) and ticagrelor (412) pro- duce a greater degree of platelet inhibition than clopidogrel and are associated with greater rates of bleeding (300,302,412,441). These are important potential disadvantages in patients requiring triple therapy, a group in which the inherent risks of bleeding are significantly increased. (Overall bleeding risk was not increased with ticagrelor, although there was increased bleeding in certain subgroups on this drug (412)). Because there are no well-established therapies to reverse the anticoagulant effects of the newer oral antiplatelet agents, caution is required when considering the use of these agents in patients who require triple therapy and are at significantly increased risk of bleeding. This admonition is especially important in elderly patients, a group in which bleeding risk is inherently increased (Section 7.1).

[Response Ends]

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

[Response Begins]

Estimates of the benefit of high-intensity statin at discharge across the body of evidence are not reported.

[Response Ends]

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

[Response Begins]

N/A

[Response Ends]

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

[Response Begins]

Updated guidelines continue to support this measure.

[Response Ends]

Group 9 - Evidence - Systematic Reviews Table

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

[Response Begins]

Reperfusion therapy for STEMI patients

O'Gara PT, Kushner FG, Ascheim DD et al. 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.

Jneid H, Addison D, Bhatt DL, Fonarow GC, Gokak S, Grady KL, Green LA, Heidenreich PA, Ho PM, Jurgens CY, King ML, Kumbhani DJ, Pancholy S. 2017 AHA/ACC clinical performance and quality measures for adults with ST-elevation and non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol. 2017;70:2048–90.

[Response Ends]

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.

[Response Begins]

2013 ACCF/AHA Guideline for the Management of Patients With ST-Elevation Myocardial Infarction (p. e86, e90, e94-e95)

p. e86:

1. Reperfusion therapy should be administered to all eligible patients with STEMI with symptom onset within the prior 12 hours (72,94). (Class I, Level of Evidence: A)
2. Primary PCI is the recommended method of reperfusion when it can be performed in a timely fashion by experienced operators (94-96) . (Class I, Level of Evidence: A)
3. EMS transport directly to a PCI-capable hospital for primary PCI is the recommended triage strategy for patients with STEMI, with an ideal FMC-to-device time system goal of 90 minutes or less* (97-99). (Class I, Level of Evidence: B)
4. Immediate transfer to a PCI-capable hospital for primary PCI is the recommended triage strategy for patients with STEMI who initially arrive at or are transported to a non–PCI-capable hospital, with an FMC-to-device time system goal of 120 minutes or less* (95,96,100,101). (Class I, Level of Evidence: B)

5. In the absence of contraindications, fibrinolytic therapy should be administered to patients with STEMI at non–PCI-capable hospitals when the anticipated FMC-to-device time at a PCI-capable hospital exceeds 120 minutes because of unavoidable delays (72,76,77). (Class I, Level of Evidence: B)

   p. e90:

6. 6Primary PCI should be performed in patients with STEMI and ischemic symptoms of less than 12 hours' duration (92-94). (Class I, Level of Evidence: A)
7. Primary PCI should be performed in patients with STEMI and ischemic symptoms of less than 12 hours' duration who have contraindications to fibrinolytic therapy, irrespective of the time delay from FMC (102,103). (Class I, Level of Evidence: B)
8. Primary PCI should be performed in patients with STEMI and cardiogenic shock or acute severe HF, irrespective of time delay from MI onset (104-107). (Class I, Level of Evidence: B)

   p. e94-e95:

9. In the absence of contraindications, fibrinolytic therapy should be given to patients with STEMI and onset of ischemic symptoms within the previous 12 hours when it is anticipated that primary PCI cannot be performed within 120 minutes of FMC (31,72,81-85). (Class I, Level of Evidence: A)

*The proposed time windows are system goals. For any individual patient, every effort should be made to provide reperfusion therapy as rapidly as possible.

[Response Ends]

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

[Response Begins]

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."

[Response Ends]

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

[Response Begins]

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

[Response Ends]

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

[Response Begins]

The recommendations included have been assigned a Class I recommendation. 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."

[Response Ends]

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

[Response Begins]

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 e 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

[Response Ends]

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

[Response Begins]

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 and studies is not provided; although, the cited guideline discusses the evidence supporting reperfusion therapy for STEMI patients in this population, which is provided below.

2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction (p. e86-e87, e90-e91, e95-e96)

p.e86-87:

Any regional medical system must seek to enable rapid recognition and timely reperfusion of patients with STEMI. System delays to reperfusion are correlated with higher rates of mortality and morbidity (96–100). Although attention to certain performance metrics, such as D2B, door-to-needle, and door-in–door-out times, have catalyzed important institutional quality improvement efforts, broader initiatives at a systems level are required to reduce total ischemic time, the principal determinant of outcome (101,102). Questions have been raised about the overreliance on primary PCI for reperfusion, especially in the United States, and the unintended consequences that have evolved as familiarity with fibrinolysis has waned (101). The writing committee reiterates the principle highlighted in the 2004 ACC/AHA STEMI guideline, namely that “the appropriate and timely use of some form of reperfusion therapy is likely more important than the choice of therapy” (4). Greatest emphasis is to be placed on the delivery of reperfusion therapy to the individual patient as rapidly as possible.

Only a minority of U.S. hospitals are capable of performing primary PCI (103), and any delay in time to reperfusion (D2B) after hospital arrival is associated with a higher adjusted risk of in-hospital mortality in a continuous, nonlinear fashion (96). Strict time goals for reperfusion may not always be relevant or possible for patients who have an appropriate reason for delay, including initial uncertainty about diagnosis, the need for evaluation and treatment of other life-threatening conditions (e.g., acute respiratory failure, cardiac arrest), delays involving informed consent, and long transport times due to geographic distance or adverse weather. To reduce hospital treatment delays, the ACC initiated the D2B Alliance in 2006 to improve door-to-device times in patients with

STEMI (104). The D2B Alliance goal was for participating PCI-capable hospitals to achieve a D2B time of =<90 minutes for at least 75% of nontransferred patients with STEMI. The Alliance met this goal by 2008 (105). A longitudinal study of hospitals participating in the NCDR Cath-PCI Registry demonstrated that patients treated in hospitals that had been enrolled in the D2B Alliance for =>3 months were significantly more likely to have D2B times of =<90 minutes than patients treated in nonenrolled hospitals (105).

In a similar manner, the AHA launched "Mission: Lifeline" in 2007 to improve health system readiness and response to STEMI (106,107), with a focus on the continuum of care from EMS activation to primary PCI. Patients may present directly by private transport to a PCI-capable hospital, in which case all medical care occurs in a single center responsible for optimizing door-to-device times. For patients who call 9-1-1, direct care begins with FMC, defined as the time at which the EMS provider arrives at the patient's side. EMS personnel should be accountable for obtaining a pre- hospital ECG, making the diagnosis, activating the system, and deciding whether to transport the patient to a PCI-capable or non–PCI-capable hospital. Consideration should be given to the development of local protocols that allow preregistration and direct transport to the catheterization laboratory of a PCI-capable hospital (bypassing the ED) for patients who do not require emergent stabilization upon arrival. Although "false positives" are a concern when EMS personnel and/or emergency physicians are allowed to activate the cardiac catheterization laboratory, the rate of false activations is relatively low (approximately 15%) and is more than balanced by earlier treatment times for the majority of patients for whom notification is appropriate (108–114). The concept of what constitutes false activation is evolving (115,116). For patients who arrive at or are transported by EMS to a non–PCI-capable hospital, a decision about whether to trans- fer immediately to a PCI-capable hospital or to administer fibrinolytic therapy must be made. Each of these scenarios involves coordination of different elements of the system. On the basis of model systems of STEMI care in the United States and Europe, (77,78,117–121) Mission: Lifeline recommends a multifaceted community-wide approach that involves patient education, improvements in EMS and ED care, establishment of networks of STEMI-referral (non–PCI-capable) and STEMI-receiving (PCI-capable) hospitals, and coordinated advocacy efforts to work with payers and policy makers to implement healthcare system redesign. Detailed information about this program can be found on the AHA website (122).

Several factors should be considered in selecting the type of reperfusion therapy (Figure 2). For patients with STEMI presenting to a PCI-capable hospital, primary PCI should be accomplished within 90 minutes. For patients presenting to a non–PCI-capable hospital, rapid assessment of 1) the time from onset of symptoms, 2) the risk of complications related to STEMI, 3) the risk of bleeding with fibrinolysis, 4) the presence of shock or severe HF, and 5) the time required for transfer to a PCI-capable hospital must be made and a decision about administration of fibrinolytic therapy reached. Even when interhospital transfer times are short, there may be relative advantages to a strategy of immediate fibrinolytic therapy versus any delay to primary PCI for eligible patients who present within the first 1 to 2 hours after symptom onset (89,101,123,124).

Several trials have suggested a benefit of transferring patients with STEMI from a non–PCI-capable hospital to a PCI-capable hospital for primary PCI (83,125), but in many instances, transfer times are prolonged and delays may be unavoidable. In the NCDR (126,127), only 10% of transferred patients were treated within 90 minutes of initial presentation, with a median first door-to-device time of 149 minutes. In many communities, a significant percentage of patients with STEMI who present initially to a non–PCI- capable hospital cannot physically be transferred to a PCI-capable hospital and achieve an FMC-to-device time treatment goal of =<90 minutes. DANAMI-2 (Danish Multicenter Randomized Study on Thrombolytic Therapy Versus Acute Coronary Angioplasty in Acute Myocardial Infarction) showed that a reperfusion strategy involving the transfer of patients with STEMI from a non–PCI-capable hospital to a PCI-capable hospital for primary PCI was superior to the use of fibrinolysis at the referring hospital, driven primarily by a reduction in the rate of reinfarction in the primary PCI–treated group (83,85). In this study, the average first door-to- device time delay was approximately 110 minutes (85). Shorter system delays were associated with a reduced mortality rate for both fibrinolysis- and primary PCI–treated patients. In an analysis of approximately 19,000 propensity score–matched patients with STEMI from NRMI-2, -3, -4, and -5, when delays related to transfer for primary PCI exceeded 120 minutes from FMC, the survival advantage of primary PCI over fibrinolysis was negated. Delays beyond 120 minutes occurred in nearly half the patients in the analysis (100). Thus, interhospital transfer to a PCI-capable hospital is the recommended triage strategy if primary PCI consistently can be performed within 120 minutes of FMC. Fibrinolytic therapy, in the absence of contraindications to its use, should be administered within 30 minutes of first door arrival when this 120-minute

time goal cannot be met. Transfer delays can occur at multiple levels and for varied reasons (128). Efforts are needed to reduce the time delay between arrival to and transfer from a non–PCI-capable hospital (i.e., door-in–door-out). Among a subset of 14,821 patients in the NCDR ACTION–GWTG registry, the median door-in–door-out time was 68 minutes (interquartile range, 43 to 120 minutes). A door-in–door-out time =<30 minutes, achieved in only 11% of patients, was associated with shorter delays to reperfusion and a lower in-hospital mortality rate (129). Because estimation of treatment times for patients can be inaccurate, the decision to transfer for primary PCI should be based on actual, historical times achieved within the regional system, with quality assurance programs to ensure that such goals are consistently met. A reasonable goal would be that 90% of patients should meet the 120-minute time-to- treatment standard to achieve performance standards.

Several triage and transfer strategies have been tested and are discussed further in Section 5.3. The term facilitated PCI was used previously to describe a strategy of full- or half-dose fibrinolysis, with or without administration of a glycoprotein (GP) IIb/IIIa receptor antagonist, with immediate transfer for planned PCI within 90 to 120 minutes. Two large studies failed to show a net clinical benefit with this strategy (130,131). The term rescue PCI refers to the transfer for PCI of patients who demonstrate findings of failed reperfusion with fibrinolysis (103,130). The term pharmacoinvasive strategy refers to the administration of fibrinolytic therapy either in the prehospital setting or at a non–PCI-capable hospital, followed by immediate transfer to a PCI-capable hospital for early coronary angiography and PCI when appropriate. Patients with STEMI who are best suited for immediate interhospital transfer for primary PCI without fibrinolysis are those patients who present with shock or other high-risk features, those with high bleeding risk with fibrinolytic therapy, and those who present >3 to 4 hours after symptom onset and who have short transfer times. Patients best suited for initial fibrinolytic therapy are those with low bleeding risk who present very early after symptom onset (<2 to 3 hours) to a non–PCI-capable hospital and who have longer delay to PCI.

p. e90-e91:

Primary PCI of the infarct artery is preferred to fibrinolytic therapy when time-to-treatment delays are short and the patient presents to a high-volume, well-equipped center with experienced interventional cardiologists and skilled support staff. Compared with fibrinolytic therapy, primary PCI produces higher rates of infarct artery patency, TIMI 3 flow, and access site bleeding and lower rates of recurrent ischemia, reinfarction, emergency repeat revascularization procedures, intracranial hemorrhage (ICH), and death (82). Early, successful PCI also greatly decreases the complications of STEMI that result from longer ischemic times or unsuccessful fibrinolytic therapy, allowing earlier hospital discharge and resumption of daily activities. Primary PCI has its greatest survival benefit in high-risk patients. PCI outcomes have been shown to be worse with delays to treatment and with low-volume hospitals and opera- tors. Quality metrics for both laboratory and operator performance and considerations with regard to primary PCI at hospitals without on-site cardiac surgery are reviewed in the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, Section 7 (219).

Potential complications of primary PCI include problems with the arterial access site; adverse reactions to volume loading, contrast medium, and antithrombotic medications; technical complications; and reperfusion events. The “no- reflow” phenomenon refers to suboptimal myocardial perfusion despite restoration of epicardial flow in the infarct artery and has been attributed to the combined effects of inflammation, endothelial injury, edema, atheroembolization, vasospasm, and myocyte reperfusion injury (220). No-reflow is associated with a reduced survival rate. Treatment and prevention strategies have included use of the GP IIb/IIIa antagonist abciximab, vasodilators (nitroprusside, verapamil, adenosine), and inhibitors of various metabolic pathways (nicorandil, pexelizumab), albeit without consistent effect. Manual thrombus aspiration at the time of primary PCI results in improved tissue perfusion and more complete ST resolution (221,222) (Section 4.2), though not all studies have shown positive results (223).

PCI of a noninfarct artery with TIMI 3 flow at the time of primary PCI in hemodynamically stable patients has been associated with worse clinical outcomes in several studies, (216–218,224) though others have suggested that it may be performed safely (225–229). Noninfarct artery PCI is not recommended in this context unless multiple complex lesions are seen on angiography and ECG localization of the infarct is ambiguous (230,231). Clinical stability may be defined broadly as the absence of low output, hypotension, persistent tachycardia, apparent shock, high-grade ventricular or symptomatic supraventricular tachyarrhythmias, and spontaneous recurrent ischemia. In patients with cardiogenic shock due to pump failure, PCI of a severe stenosis in a large noninfarct

artery might improve hemodynamic stability and should be considered during the primary procedure (Section 9.1.1). In the majority of patients, delayed PCI can be performed in a noninfarct artery at a later time if indicated by clinical events or the results of noninvasive testing (218,232,233).

p. e95-e96:

The benefits of fibrinolytic therapy in patients with ST elevation or bundle-branch block MI are well established, with a time-dependent reduction in both mortality and morbidity rates during the initial 12 hours after symptom onset (81,306 –311,314 –320). As noted in Section 3.2, even when interhospital transport times are short, there may be advantages to the immediate delivery of fibrinolytic therapy versus any delay to primary PCI for patients with STEMI and low bleeding risk who present within the first 1 to 2 hours of symptom onset (123,321). Benefit from fibrinolytic therapy in patients who present >12 hours after symptom onset has not been established (81,307,309,322,323), although there remains consensus that consideration should be given to administering a fibrinolytic agent in symptomatic patients presenting >12 hours after symptom onset with STEMI and a large area of myocardium at risk or hemodynamic instability if PCI is unavailable (4,48).

Absolute and relative contraindications to fibrinolytic therapy are listed in Table 6. The decision to use fibrinolytic therapy for patients with STEMI is predicated on a risk–benefit analysis that integrates time from onset of symptoms, the clinical and hemodynamic features at presentation, patient comorbidities, risk of bleeding, presence of contraindications, and time delay to PCI (Section 3.2).

Table 6. Contraindications and Cautions for Fibrinolytic Therapy in STEMI*

Absolute contraindications

- Any prior ICH
- Known structural cerebral vascular lesion (e.g., arteriovenous malformation)
- Known malignant intracranial neoplasm (primary or metastatic)
- lschemic stroke within 3 mo
- EXCEPT acute ischemic stroke within 4.5 h
- Suspected aortic dissection
- Active bleeding or bleeding diathesis (excluding menses)
- • Significant closed-head or facial trauma within 3 mo
- lntracranial or intraspinal surgery within 2 mo
- Severe uncontrolled hypertension (unresponsive to emergency therapy)
- For streptokinase, prior treatment within the previous 6 mo

Relative contraindications

- History of chronic, severe, poorly controlled hypertension
- Significant hypertension on presentation (SBP > 180 mm Hg or DBP >110 mm Hg)
- History of prior ischemic stroke >3 mo
- Dementia
- Known intracranial pathology not covered in absolute contraindications
- Traumatic or prolonged (> 1 0 min) CPR
- Major surgery (<3 wk)
- Recent (within 2 to 4 wk) internal bleeding
- Noncompressible vascular punctures
- Pregnancy
- Active peptic ulcer

- Oral anticoagulant therapy

* Viewed as advisory for clinical decision making and may not be all-inclusive or definitive.

CPR indicates cardiopulmonary resuscitation; DBP; diastolic blood pressure; ICH, intracranial hemorrhage; SBP, systolic blood pressure; and STEMI,

ST-elevation myocardial infarction.

[Response Ends]

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

[Response Begins]

Estimates of the benefit of reperfusion therapy for STEMI patients across the body of evidence are not reported.

[Response Ends]

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

[Response Begins]

N/A

[Response Ends]

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

[Response Begins]

Updated guidelines continue to support this measure.

[Response Ends]

Group 10 - Evidence - Systematic Reviews Table

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

[Response Begins]

Door-to-needle time for STEMI patients

O'Gara PT, Kushner FG, Ascheim DD et al. 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.

Jneid H, Addison D, Bhatt DL, Fonarow GC, Gokak S, Grady KL, Green LA, Heidenreich PA, Ho PM, Jurgens CY, King ML, Kumbhani DJ, Pancholy S. 2017 AHA/ACC clinical performance and quality measures for adults with ST-elevation and non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol. 2017;70:2048–90.

[Response Ends]

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.

[Response Begins]

2013 ACCF/AHA Guideline for the Management of Patients With ST-Elevation Myocardial Infarction (p. e86, e94-e95, e107)

p. e86:

1. In the absence of contraindications, fibrinolytic therapy should be administered to patients with STEMI at non–PCI-capable hospitals when the anticipated FMC-to-device time at a PCI-capable hospital exceeds 120 minutes because of unavoidable delays (72,76,77). (Class I, Level of Evidence: B)
2. When fibrinolytic therapy is indicated or chosen as the primary reperfusion strategy, it should be administered within 30 minutes of hospital arrival* (73,75,78-80). (Class I, Level of Evidence: B)

   p. e94-e95:

3. In the absence of contraindications, fibrinolytic therapy should be given to patients with STEMI and onset of ischemic symptoms within the previous 12 hours when it is anticipated that primary PCI cannot be performed within 120 minutes of FMC (31,72,81-85). (Class I, Level of Evidence: A)
4. Fibrinolytic therapy should not be administered to patients with ST depression except when a true posterior (inferobasal) MI is suspected or when associated with ST elevation in lead aVR (72,86-89). (Class III, Level of Evidence: B)

   p. e107:

5. In the absence of contraindications, fibrinolytic therapy should be administered to patients with STEMI and cardiogenic shock who are unsuitable candidates for either PCI or CABG (72,90,91). (Class I, Level of Evidence: B)

*The proposed time windows are system goals. For any individual patient, every effort should be made to provide reperfusion therapy as rapidly as possible.

[Response Ends]

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

[Response Begins]

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.”

[Response Ends]

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

[Response Begins]

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

[Response Ends]

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

[Response Begins]

The recommendations included have been assigned a Class I or III recommendation. 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 III recommendations refer to "Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective e and in some cases may be harmful."

[Response Ends]

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

[Response Begins]

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 e 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

[Response Ends]

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

[Response Begins]

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 and studies is not provided; although, the cited guideline discusses the evidence supporting door-to-needle time for STEMI patients in this population, which is provided below.

2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction (p. e86-e87, e95-e96, e107)

p.e86-87:

Any regional medical system must seek to enable rapid recognition and timely reperfusion of patients with STEMI. System delays to reperfusion are correlated with higher rates of mortality and morbidity (96–100). Although attention to certain performance metrics, such as D2B, door-to-needle, and door-in–door-out times, have catalyzed important institutional quality improvement efforts, broader initiatives at a systems level are required to reduce total ischemic time, the principal determinant of outcome (101,102). Questions have been raised about the overreliance on primary PCI for reperfusion, especially in the United States, and the unintended consequences that have evolved as familiarity with fibrinolysis has waned (101). The writing committee reiterates the principle highlighted in the 2004 ACC/AHA STEMI guideline, namely that "the appropriate and timely use of some form of reperfusion therapy is likely

more important than the choice of therapy" (4). Greatest emphasis is to be placed on the delivery of reperfusion therapy to the individual patient as rapidly as possible.

Only a minority of U.S. hospitals are capable of performing primary PCI (103), and any delay in time to reperfusion (D2B) after hospital arrival is associated with a higher adjusted risk of in-hospital mortality in a continuous, nonlinear fashion (96). Strict time goals for reperfusion may not always be relevant or possible for patients who have an appropriate reason for delay, including initial uncertainty about diagnosis, the need for evaluation and treatment of other life-threatening conditions (e.g., acute respiratory failure, cardiac arrest), delays involving informed consent, and long transport times due to geographic distance or adverse weather. To reduce hospital treatment delays, the ACC initiated the D2B Alliance in 2006 to improve door-to-device times in patients with STEMI (104). The D2B Alliance goal was for participating PCI-capable hospitals to achieve a D2B time of =<90 minutes for at least 75% of nontransferred patients with STEMI. The Alliance met this goal by 2008 (105). A longitudinal study of hospitals participating in the NCDR Cath-PCI Registry demonstrated that patients treated in hospitals that had been enrolled in the D2B Alliance for =>3 months were significantly more likely to have D2B times of =<90 minutes than patients treated in nonenrolled hospitals (105).

In a similar manner, the AHA launched "Mission: Lifeline" in 2007 to improve health system readiness and response to STEMI (106,107), with a focus on the continuum of care from EMS activation to primary PCI. Patients may present directly by private transport to a PCI-capable hospital, in which case all medical care occurs in a single center responsible for optimizing door-to-device times. For patients who call 9-1-1, direct care begins with FMC, defined as the time at which the EMS provider arrives at the patient's side. EMS personnel should be accountable for obtaining a pre- hospital ECG, making the diagnosis, activating the system, and deciding whether to transport the patient to a PCI-capable or non–PCI-capable hospital. Consideration should be given to the development of local protocols that allow preregistration and direct transport to the catheterization laboratory of a PCI-capable hospital (bypassing the ED) for patients who do not require emergent stabilization upon arrival. Although "false positives" are a concern when EMS personnel and/or emergency physicians are allowed to activate the cardiac catheterization laboratory, the rate of false activations is relatively low (approximately 15%) and is more than balanced by earlier treatment times for the majority of patients for whom notification is appropriate (108–114). The concept of what constitutes false activation is evolving (115,116). For patients who arrive at or are transported by EMS to a non–PCI-capable hospital, a decision about whether to trans- fer immediately to a PCI-capable hospital or to administer fibrinolytic therapy must be made. Each of these scenarios involves coordination of different elements of the system. On the basis of model systems of STEMI care in the United States and Europe, (77,78,117–121) Mission: Lifeline recommends a multifaceted community-wide approach that involves patient education, improvements in EMS and ED care, establishment of networks of STEMI-referral (non–PCI-capable) and STEMI-receiving (PCI-capable) hospitals, and coordinated advocacy efforts to work with payers and policy makers to implement healthcare system redesign. Detailed information about this program can be found on the AHA website (122).

Several factors should be considered in selecting the type of reperfusion therapy (Figure 2). For patients with STEMI presenting to a PCI-capable hospital, primary PCI should be accomplished within 90 minutes. For patients presenting to a non–PCI-capable hospital, rapid assessment of 1) the time from onset of symptoms, 2) the risk of complications related to STEMI, 3) the risk of bleeding with fibrinolysis, 4) the presence of shock or severe HF, and 5) the time required for transfer to a PCI-capable hospital must be made and a decision about administration of fibrinolytic therapy reached. Even when interhospital transfer times are short, there may be relative advantages to a strategy of immediate fibrinolytic therapy versus any delay to primary PCI for eligible patients who present within the first 1 to 2 hours after symptom onset (89,101,123,124).

Several trials have suggested a benefit of transferring patients with STEMI from a non–PCI-capable hospital to a PCI-capable hospital for primary PCI (83,125), but in many instances, transfer times are prolonged and delays may be unavoidable. In the NCDR (126,127), only 10% of transferred patients were treated within 90 minutes of initial presentation, with a median first door-to-device time of 149 minutes.

In many communities, a significant percentage of patients with STEMI who present initially to a non–PCI-capable hospital cannot physically be transferred to a PCI-capable hospital and achieve an FMC-to-device time treatment goal of =<90 minutes. DANAMI-2 (Danish Multicenter Randomized Study on Thrombolytic Therapy Versus Acute Coronary Angioplasty in Acute Myocardial Infarction) showed that a reperfusion strategy involving the transfer of patients with STEMI from a non–PCI-capable hospital to a PCI-capable hospital for primary PCI was superior to the use of fibrinolysis at the referring hospital, driven primarily by a reduction in the rate of reinfarction in the primary PCI–treated group (83,85). In this study, the average first door-to- device time delay was approximately 110 minutes (85). Shorter system delays were associated with a reduced mortality rate for both fibrinolysis- and primary PCI–treated patients. In an analysis of approximately 19,000 propensity score–matched patients with STEMI from NRMI-2, -3, -4, and -5, when delays related to transfer for primary PCI exceeded 120 minutes from FMC, the survival advantage of primary PCI over fibrinolysis was negated. Delays beyond 120 minutes occurred in nearly half the patients in the analysis (100). Thus, interhospital transfer to a PCI-capable hospital is the recommended triage strategy if primary PCI consistently can be performed within 120 minutes of FMC. Fibrinolytic therapy, in the absence of contraindications to its use, should be administered within 30 minutes of first door arrival when this 120-minute time goal cannot be met. Transfer delays can occur at multiple levels and for varied reasons (128). Efforts are needed to reduce the time delay between arrival to and transfer from a non–PCI-capable hospital (i.e., door-in–door-out). Among a subset of 14,821 patients in the NCDR ACTION–GWTG registry, the median door-in–door-out time was 68 minutes (interquartile range, 43 to 120 minutes). A door-in–door-out time =<30 minutes, achieved in only 11% of patients, was associated with shorter delays to reperfusion and a lower in-hospital mortality rate (129). Because estimation of treatment times for patients can be inaccurate, the decision to transfer for primary PCI should be based on actual, historical times achieved within the regional system, with quality assurance programs to ensure that such goals are consistently met. A reasonable goal would be that 90% of patients should meet the 120-minute time-to- treatment standard to achieve performance standards.

Several triage and transfer strategies have been tested and are discussed further in Section 5.3. The term facilitated PCI was used previously to describe a strategy of full- or half-dose fibrinolysis, with or without administration of a glycoprotein (GP) IIb/IIIa receptor antagonist, with immediate transfer for planned PCI within 90 to 120 minutes. Two large studies failed to show a net clinical benefit with this strategy (130,131). The term rescue PCI refers to the transfer for PCI of patients who demonstrate findings of failed reperfusion with fibrinolysis (103,130). The term pharmacoinvasive strategy refers to the administration of fibrinolytic therapy either in the prehospital setting or at a non–PCI-capable hospital, followed by immediate transfer to a PCI-capable hospital for early coronary angiography and PCI when appropriate. Patients with STEMI who are best suited for immediate interhospital transfer for primary PCI without fibrinolysis are those patients who present with shock or other high-risk features, those with high bleeding risk with fibrinolytic therapy, and those who present >3 to 4 hours after symptom onset and who have short transfer times. Patients best suited for initial fibrinolytic therapy are those with low bleeding risk who present very early after symptom onset (<2 to 3 hours) to a non–PCI-capable hospital and who have longer delay to PCI.

p. e95-e96:

The benefits of fibrinolytic therapy in patients with ST elevation or bundle-branch block MI are well established, with a time-dependent reduction in both mortality and morbidity rates during the initial 12 hours after symptom onset (81,306 –311,314 –320). As noted in Section 3.2, even when interhospital transport times are short, there may be advantages to the immediate delivery of fibrinolytic therapy versus any delay to primary PCI for patients with STEMI and low bleeding risk who present within the first 1 to 2 hours of symptom onset (123,321). Benefit from fibrinolytic therapy in patients who present >12 hours after symptom onset has not been established (81,307,309,322,323), although there remains consensus that consideration should be given to administering a fibrinolytic agent in symptomatic patients presenting >12 hours after symptom onset with STEMI and a large area of myocardium at risk or hemodynamic instability if PCI is unavailable (4,48).

Absolute and relative contraindications to fibrinolytic therapy are listed in Table 6. The decision to use fibrinolytic therapy for patients with STEMI is predicated on a risk–benefit analysis that integrates time from onset of

symptoms, the clinical and hemodynamic features at presentation, patient comorbidities, risk of bleeding, presence of contraindications, and time delay to PCI (Section 3.2).

Table 6. Contraindications and Cautions for Fibrinolytic Therapy in STEMI*

Absolute contraindications

- Any prior ICH
- Known structural cerebral vascular lesion (e.g., arteriovenous malformation)
- Known malignant intracranial neoplasm (primary or metastatic)
- lschemic stroke within 3 mo
- EXCEPT acute ischemic stroke within 4.5 h
- Suspected aortic dissection
- Active bleeding or bleeding diathesis (excluding menses)
- • Significant closed-head or facial trauma within 3 mo
- lntracranial or intraspinal surgery within 2 mo
- Severe uncontrolled hypertension (unresponsive to emergency therapy)
- For streptokinase, prior treatment within the previous 6 mo

Relative contraindications

- History of chronic, severe, poorly controlled hypertension
- Significant hypertension on presentation (SBP > 180 mm Hg or DBP >110 mm Hg)
- History of prior ischemic stroke >3 mo
- Dementia
- Known intracranial pathology not covered in absolute contraindications
- Traumatic or prolonged (> 1 0 min) CPR
- Major surgery (<3 wk)
- Recent (within 2 to 4 wk) internal bleeding
- Noncompressible vascular punctures
- Pregnancy
- Active peptic ulcer
- Oral anticoagulant therapy

* Viewed as advisory for clinical decision making and may not be all-inclusive or definitive.

CPR indicates cardiopulmonary resuscitation; DBP; diastolic blood pressure; ICH, intracranial hemorrhage; SBP, systolic blood pressure; and STEMI,

ST-elevation myocardial infarction.

p. e107:

For those with pump failure, 15% of cases occur at time of presentation, and 85% develop during hospitalization. Revascularization with timely PCI or CABG is the preferred reperfusion strategy for patients with STEMI and shock due to pump failure, irrespective of the time delay. Shock or severe HF is perhaps the only clinical scenario in which acute revascularization of significant stenoses in noninfarct arteries can be justified. In the SHOCK trial, mortality rates at 6 and 12 months were significantly lower in patients allocated to emergency revascularization than in patients who received immediate medical stabilization (212,354). Nearly two thirds of the patients in the medical stabilization group received fibrinolytic therapy, and 25% underwent delayed revascularization. IABP support was used in 86% of both groups. Although the trial did not show benefit with emergency revascularization

for the prespecified age group ≥75 years, the small number of patients in the trial did not allow for firm conclusions to be drawn about management. Elderly patients offered emergency revascularization in the nonrandomized SHOCK registry had a substantial adjusted survival benefit with emergency revascularization compared with delayed or no revascularization (460). Similar findings in favor of early revascularization for selected elderly patients were reported from 2 additional registries (461,462). Although age alone is not a contraindication to emergency revascularization in this setting, individual judgment based on comorbidities, functional status, and patient directives is necessary in the elderly. Triage and immediate transfer to a PCI-capable facility with on-site cardiac surgical backup are indicated for patients with STEMI complicated by shock. Fibrinolytic therapy is re- served for patients without contraindications within 24 hours of MI for whom revascularization is considered not feasible for technical, anatomic, or patient-related issues. The need for hemodynamic support with inotropic therapy, IABP, or both should be assessed on an individual basis. Observational data on the usefulness of IABP in this setting are conflicting. A meta-analysis supports IABP therapy as an adjunct to fibrinolysis but not to primary PCI (458). Compared with IABP, LV assist devices may provide superior hemodynamic support and serve as more effective bridges to recovery or transplantation, though experience with their use in this setting is limited (463,464). Medical support with inotropes and vasopressor agents should be individualized and guided by invasive hemodynamic monitoring. Use of dopamine in this setting may be associated with excess hazard (465).

[Response Ends]

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

[Response Begins]

Estimates of the benefit of door-to-needle time for STEMI patients across the body of evidence are not reported.

[Response Ends]

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

[Response Begins]

NA

[Response Ends]

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

[Response Begins]

Updated guidelines continue to support this measure.

[Response Ends]

1a.14. Provide empirical data demonstrating the relationship between the outcome (or PRO) and at least one healthcare structure, process, intervention, or service.

[Response Begins]

This information has been addressed in the repeatable question group and in the appendix

[Response Ends]

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.

[Response Begins]

This information has been addressed in the repeatable question group and in the appendix

[Response Ends]

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

[Response Begins]

This information has been addressed in the repeatable question group and in the appendix

[Response Ends]

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

[Response Begins]

This information is based on clinical guidelines.

[Response Ends]

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

[Response Begins]

This information has been addressed in the repeatable question group and in the appendix

[Response Ends]

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.

[Response Begins]

This composite measure is vital as it shows that the patient received all of the treatments for care of AMI that are strongly recommended in national guidelines. While performance may be higher for some individual measures the data has shown that performance on total care of the MI patient can be greatly improved.

[Response Ends]

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.

[Response Begins]

The table below displays the mean, std dev, min, max, interquartile range and scores by decile. The data source was the NCDR Chest Pain-MI registry, years 2019Q1-2019Q4. The performance scores are from 764 hospitals.

The median rate of performance for defect free care across all hospitals was 72.32%.

The distribution was right-skewed such that most hospitals were, between 56% to 100%, providing defect free care as displayed in the histogram below.

Distribution of Performance of DFC (N=764) 2019Q1-2019Q4

LPS= Lowest Performing Sites

HPS= Highest Performing Sites

*	*	LPS	LPS	LPS	LPS	*	*	*	HPS	HPS	HPS
Description	**DFC Total**	**0 - 9%**	**10 - 19%**	**20 - 29%**	**30 - 39%**	**40 - 49%**	**50 - 59%**	**60 - 69%**	**70 - 79%**	**80 - 89%**	**90 - 100%**
N	764	15	29	46	63	85	112	156	142	90	26
Mean	58.47	4.27	15.39	24.96	35.22	44.93	55.04	65.06	75.04	84.18	93.56
Std Deviation	21.24	3.86	2.90	3.05	3.12	2.98	2.93	2.93	2.83	2.88	2.57
100% Max	99.12	9.73	19.61	29.87	39.78	49.63	59.70	69.98	79.71	89.88	99.12
99%	94.89	9.66	19.58	29.76	39.71	49.62	59.58	69.88	79.55	89.69	98.71
95%	87.73	9.36	19.40	29.39	39.64	49.38	59.11	69.44	79.33	89.09	97.34
90%	83.08	8.95	19.07	28.90	39.35	49.07	58.48	68.96	78.83	88.08	96.74
75% Q3	74.72	7.33	17.42	27.36	38.01	47.46	57.51	67.38	77.52	86.45	95.80
50% Median	62.32	5.48	16.11	25.00	35.40	45.11	55.23	65.10	74.96	83.66	93.03
25% Q1	44.35	0.00	12.76	22.66	32.39	42.14	52.67	62.63	72.66	81.64	91.54
10%	27.12	0.00	11.35	20.34	30.96	40.90	50.66	60.99	71.04	80.55	90.51
5%	17.98	0.00	10.73	20.03	30.89	40.48	50.00	60.19	70.50	80.14	90.37
1%	5.78	0.00	10.48	20.00	30.57	40.05	50.00	60.00	70.00	80.00	90.32
0% Min	0.00	0.00	10.46	20.00	30.47	40.00	50.00	60.00	70.00	80.00	90.31

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Histogram of Performance of Overall Free Defect Care Measure 2019Q1-2019Q4

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

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.

[Response Begins]

We attributed social risk factors at the hospital-level for the purposes of this analysis. We used Medicaid insurance status as an economic indicator of social risk. We also examined race/ethnicity, age, and gender to determine if there were differences in these demographic indicators of social risk.

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.

For all the descriptive statistics, we used data collected by the Chest Pain-MI Registry between January 2019 and December 2019. Descriptive statistics about the patients included in this dataset are provided below (Table 2):

Table 2. Patient Characteristics

*	Total	Total
Description	#	%
ALL	130279	100.00
Age ≥ 65	*	*
No	62559	48.02
Yes	67720	51.98
Sex	*	*
Male	86768	66.60
Female	43511	33.40
Race	*	*
Hispanic	10034	7.70
White non-hispanic	100794	77.37
Black non-Hispanic	14302	10.98
Other	5149	3.95
Insurance	*	*
Medicare	66581	51.11
Medicaid	9131	7.01
Private	39690	30.47

*	Total	Total
Other	14877	11.42

Table 2. Patient Characteristics

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Race/Ethnicity

The distribution of hospital performance was examined among White (non-Hispanic), Black (non-Hispanic), Hispanic and Other race patients. There was significant overlap in hospital performance with median performance ranging from 55.88% for patients who identify as Black non-Hispanic to 66.67% for Other race. Those who identify as White non-Hispanic and Hispanic had median performances of 61.43% and 59.09%, respectively (Table 7 and Figure 3).

Table 7. Distribution of the Performance of the Defect Free Care Measure Stratified by Race at the Hospital-Level (N=695)

Description	Hispanic	White non-hispanic	Black non-hispanic	Other
Mean	57.55%	57.97%	54.99%	59.36%
Std Deviation	31.44%	21.11%	30.01%	34.17%
*	*	*	*	*
100% Max	100.00%	100.00%	100.00%	100.00%
99%	100.00%	96.43%	100.00%	100.00%
95%	100.00%	87.61%	100.00%	100.00%
90%	100.00%	83.13%	100.00%	100.00%
75% Q3	81.82%	74.17%	77.78%	90.63%
50% Median	59.09%	61.43%	55.88%	66.67%
25% Q1	35.00%	43.36%	33.33%	33.33%
10%	0.00%	28.13%	11.11%	0.00%
5%	0.00%	18.10%	0.00%	0.00%
1%	0.00%	2.80%	0.00%	0.00%
0% Min	0.00%	0.00%	0.00%	0.00%

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Figure 3. Distribution of the Performance Rates of the Defect Free Care Measure Stratified by Race/Ethnicity at the Hospital-Level

Figure 3. Distribution of the Performance Rates of the Defect Free Care Measure Stratified by Race/Ethnicity at the Hospital-Level Proportion of Non-White Patients

Hospitals (n=695) were stratified into quartiles by their proportion of non-White patients (median: 12.1%, IQR: 4.93% to 23.28%). Hospital performance across quartiles was similar regardless of the percent of non-White patients hospitals treated, with median performance ranging from 62.6% to 59.1% (Table 8; Figure 4).

Table 8. Distribution of Performance Rates for the Defect Free Care Measure Stratified by Hospital Quartiles of Non-White Patients (N=695)

Description	Non White (%)	Non White (%)	Non White (%)	Non White (%)
*	**Q1**	**Q2**	**Q3**	**Q4**
N	173	174	174	174
Mean	58.33%	58.98%	55.31%	55.69%
Std Deviation	21.66%	20.78%	20.25%	21.92%
*	*	*	*	*
100% Max	100.00%	94.04%	94.81%	98.34%
99%	97.78%	93.28%	93.10%	96.88%
95%	87.50%	89.03%	86.05%	85.29%
90%	82.47%	85.63%	80.73%	81.48%
75% Q3	74.83%	74.76%	71.30%	70.94%
50% Median	62.63%	60.88%	57.14%	59.09%
25% Q1	45.45%	43.79%	39.66%	40.52%
10%	25.00%	30.92%	26.87%	25.00%
5%	18.71%	19.88%	20.19%	12.50%
1%	0.00%	7.32%	12.12%	0.00%
0% Min	0.00%	5.95%	7.34%	0.00%

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Figure 4. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Quartiles of Non-White Patients at the Hospital-Level

Figure 4. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Quartiles of Non-White Patients at the Hospital-Level

Gender

The median hospital performance among female patients was 56.8% (IQR: 38.9% to 71.43%) while among male patients it was slightly higher at 62.2% (IQR: 44.3% to 75.1%) (Table 9 and Figure 5)

Table 9. Distribution of the Performance Rates for the Defect Free Care Measure Stratified by Gender at the Hospital-Level (N=695)

Description	Female	Male
*	*	*
Mean	54.68%	58.56%
Std Deviation	22.40%	21.36%
*	*	*
100% Max	100.00%	100.00%
99%	100.00%	94.23%
95%	87.50%	87.72%
90%	82.76%	83.81%
75% Q3	71.43%	75.15%
50% Median	56.83%	62.16%
25% Q1	38.93%	44.26%

Description	Female	Male
10%	21.43%	28.13%
5%	16.67%	18.99%
1%	0.00%	1.33%
0% Min	0.00%	0.00%
*	*	*

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Figure 5. Distribution of the Performance Rates of the Defect Free Care Measure Stratified by Gender at the Hospital-Level

Figure 5. Distribution of the Performance Rates of the Defect Free Care Measure Stratified by Gender at the Hospital-Level

Age

The median hospital performance in delivering Defect Free Care among patients aged less than 65 years was 62.35% (IQR: 45.58% to 75.25%) while that among patients aged 65 years or greater was 57.58% (IQR: 39.39% to 72.41%) (Table 10 and Figure 6).

Table 10. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Age at the Hospital-level (N=695)

Age ≥ 65	*	*
Description	**Yes**	**No**
*	*	*
Mean	55.69%	59.09%
Std Deviation	21.71%	22.07%
*	*	*
100% Max	100.00%	100.00%
99%	99.07%	97.18%
95%	87.25%	89.92%

Age ≥ 65	*	*
90%	83.20%	84.68%
75% Q3	72.41%	75.25%
50% Median	57.58%	62.35%
25% Q1	39.39%	45.58%
10%	25.00%	25.81%
5%	18.86%	15.79%
1%	0.00%	0.00%
0% Min	0.00%	0.00%
*	*	*

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Figure 6. Distribution of the Performance Rates of the Defect Free Care Measure Stratified by Age Group at the Hospital-Level

Figure 6.
Distribution of the Performance Rates of the Defect Free Care Measure Stratified by Age Group at the Hospital-Level

Insurance

Hospitals (n=695) were stratified into quartiles by their proportion of patients with Medicaid as the primary insurance (median: 10.37%, IQR: 6.0% to 15.92%). Hospital performance was similar across hospitals stratified into quartile by the proportion of patients they care for who have Medicaid insurance coverage. Median hospital performance ranged from 56.39% (Quartile 4) to 64.73% (Quartile 3) (Table 11 and Figure 7).

Table 11. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Quartile of Hospital Percent Medicaid (N=695)

%Medicaid	*	*	*	*
Description	**Q1**	**Q2**	**Q3**	**Q4**
N	174	173	174	174
Mean	54.75%	58.88%	59.95%	54.74%

%Medicaid	*	*	*	*
Std Deviation	21.12%	20.35%	21.11%	21.74%
*	*	*	*	*
100% Max	100.00%	93.10%	98.34%	96.88%
99%	97.50%	92.62%	97.78%	94.81%
95%	83.33%	88.89%	86.92%	85.00%
90%	78.70%	85.63%	83.53%	80.53%
75% Q3	71.11%	75.89%	75.22%	71.66%
50% Median	59.23%	60.00%	64.73%	56.39%
25% Q1	39.43%	44.26%	45.45%	41.86%
10%	25.15%	30.77%	29.09%	20.13%
5%	16.22%	23.02%	16.84%	14.81%
1%	0.00%	13.84%	5.95%	0.00%
0% Min	0.00%	0.00%	2.73%	0.00%
*	*	*	*	*

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Figure 7. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Quartile of Hospital Percent Medicaid

Figure 7. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Quartile of Hospital Percent Medicaid

Figure 7. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Quartile of Hospital Percent Medicaid

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.

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

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 NQF 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)*

[Response Begins]

two or more individual component measures assessed separately for each patient and then aggregated into one score

[Response Ends]

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).

[Response Begins]

Please refer to Sp.30. Empirical validity was tested and evaluated by assessing the correlation of the Defect Free Care measure with its components. The correlation coefficients between the overall defect free care measure and its components is listed in the testing section below.

[Response Ends]

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.

[Response Begins]

Each individual measure characterizes individual guideline-recommended processes of care for AMI. However, the construction of a composite measure encompassing all of the scientifically validated best practices allows for a holistic assessment of evidence-based AMI care.

Composite performance measures have a variety of uses:

Data reduction

A large and growing array of individual indicators makes it possible for users to become overloaded with data. 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 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 an NQF-endorsed composite measure to reflect the comprehensive care provided for AMI.

[Response Ends]

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

[Response Begins]

This is an all-or-none composite, thus no empirical analyses pertinent to aggregations or weighting were conducted. The components mentioned throughout the application are part of the composite measure indicator definition, not the composite of different measures.

[Response Ends]

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.

[Response Begins]

Yes

[Yes Please Explain]

This measure, and the composites, all are based on Class IA or B recommendations and represent optimal clinical care for patients admitted for STEMI or NSTEMI treatment. The measures were developed based on clinical guidelines and are routinely evaluated to ensure they are still in alignment with these guidelines. The evidence base is described in great detail in the evidence portion and in the appendix.

[Response Ends]

2. Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.

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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.

[Response Begins]

Yes

[Yes Please Explain]

The performance measures that comprise the Overall Defect Free Care for AMI composite have undergone changes to align with the updates included in the 2017 AHA/ACC Clinical Performance and Quality Measures for Adults With ST-Elevation and Non–ST-Elevation Myocardial Infarction (Jneid et al., 2017). To accommodate the modifications within the 2017 AMI Performance Measure set, NCDR's Chest Pain-MI registry underwent a version upgrade from version 2.4 to version 3.0. This version update included new data elements (see attached data dictionary) and the version went live to participating hospitals in early 2019. The respective measures were available to participants in early 2020.

[Response Ends]

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 NQF CDP review.

[Response Begins]

The Chest Pain-MI (CPMI) Registry, formerly known as the ACTION registry of the National Cardiovascular Registry (NCDR) captures data on the population of patients diagnosed with acute myocardial infarction (AMI). The population is further divided clinically into ST Elevation Myocardial Infarction (STEMI) and Non-ST Elevation Myocardial Infarction (NSTEMI). The registry collects data on and reports performance to participating sites on guideline-based measures for AMI endorsed by the American College of Cardiology (ACC) and the American Heart Association (AHA).).

The **measures included within the composite have changed** since the last Endorsement in 2018.

How the measures are calculated has not changed. All of the care opportunities for which the patient is eligible must be fulfilled in order to satisfy the composite.

For this 2022 Endorsement cycle, the STEMI component of the composite includes 14 measures:

- Aspirin at Arrival
- Aspirin prescribed at Discharge
- Beta-Blocker Prescribed at Discharge
- High Intensity Statin at Discharge (new)
- P2Y12 Inhibitor at Discharge (new)

- Evaluation of LV Systolic Function
- ACEI or ARB for LVSD at Discharge
- Cardiac Rehabilitation Patient Referral From an Inpatient Setting
- Reperfusion Therapy
- Door-to-needle Time (name change from Time to Fibrinolytic Therapy)
- First Medical Contact-Device Time
- Immediate Angiography After Cardiac Arrest
- Door-in Door-out Time
- Time to Primary PCI transferred STEMI

In alignment with the 2017 STEMI Performance measures publication, the three old measures from the 2018 STEMI composite that were removed are:

- Statin Prescribed at Discharge
- Time to Primary PCI
- Adult Smoking Cessation Advice Counseling

There were "topped-out" measures.

New measures added to the STEMI composite include:

- High Intensity Statin at Discharge
- P2Y12 Inhibitor at Discharge
- First Medical Contact-Device Time
- Immediate Angiography After Cardiac Arrest
- Door-in Door-out Time
- Time to Primary PCI transferred STEMI

For this 2022 Endorsement cycle, the NSTEMI component of the composite includes 9 measures:

- Aspirin at Arrival
- Aspirin prescribed at Discharge
- Beta-Blocker Prescribed at Discharge
- High Intensity Statin at Discharge
- P2Y12 Inhibitor at Discharge
- Evaluation of LV Systolic Function
- ACEI or ARB for LVSD at Discharge
- Cardiac Rehabilitation Patient Referral From an Inpatient Setting
- Early troponin measurement after NSTEMI

In alignment with the 2017 STEMI Performance measures publication, the two old measures from the 2018 NSTEMI composite that were removed are:

- Statin Prescribed at Discharge
- Adult Smoking Cessation Advice Counseling

There were "topped-out" measures.

New measures added to the NSTEMI composite include:

- High Intensity Statin at Discharge
- P2Y12 Inhibitor at Discharge
- Early troponin measurement after NSTEMI

Population	2018 measure components	2022 measure components	Removed for 2022	New for 2022

Population	2018 measure components	2022 measure components	Removed for 2022	New for 2022
STEMI	1. Aspirin at Arrival 2. Aspirin prescribed at Discharge 3. Beta-Blocker Prescribed at Discharge 4. Statin Prescribed at Discharge 5. Evaluation of LV Systolic Function 6. ACEI or ARB for LVSD at Discharge 7. Time to Fibrinolytic Therapy 8. Time to Primary PCI 9. Reperfusion Therapy 10. Adult Smoking Cessation Advice Counseling 11. Cardiac Rehabilitation Patient Referral From an Inpatient Setting	1. Aspirin at Arrival 2. Aspirin prescribed at Discharge 3. Beta-Blocker Prescribed at Discharge 4. High Intensity Statin at Discharge 5. P2Y12 Inhibitor at Discharge 6. Evaluation of LV Systolic Function 7. ACEI or ARB for LVSD at Discharge 8. Cardiac Rehabilitation Patient Referral From an Inpatient Setting 9. Reperfusion Therapy 10. Door-to-needle Time (name change from Time to Fibrinolytic Therapy) 11. First Medical Contact-Device Time 12. Immediate Angiography After Cardiac Arrest 13. Door-in Door-out Time 14. Time to Primary PCI	• Statin Prescribed at Discharge • Time to Primary PCI • Adult Smoking Cessation Advice Counseling	• High Intensity Statin at Discharge • P2Y12 Inhibitor at Discharge • First Medical Contact-Device Time • Immediate Angiography After Cardiac Arrest • Door-in Door-out Time • Time to Primary PCI transferred STEMI

Population	2018 measure components	2022 measure components	Removed for 2022	New for 2022
		transferred STEMI		
NSTEMI	1. Aspirin at Arrival 2. Aspirin prescribed at Discharge 3. Beta-Blocker Prescribed at Discharge 4. Statin Prescribed at Discharge 5. Evaluation of LV Systolic Function 6. ACEI or ARB for LVSD at Discharge 7. Adult Smoking Cessation Advice Counseling 8. Cardiac Rehabilitation Patient Referral From an Inpatient Setting	1. Aspirin at Arrival 2. Aspirin prescribed at Discharge 3. Beta-Blocker Prescribed at Discharge 4. High Intensity Statin at Discharge 5. P2Y12 Inhibitor at Discharge 6. Evaluation of LV Systolic Function 7. ACEI or ARB for LVSD at Discharge 8. Cardiac Rehabilitation Patient Referral From an Inpatient Setting 9. Early troponin measurement after NSTEMI	• Statin Prescribed at Discharge • Adult Smoking Cessation Advice Counseling	• High Intensity Statin at Discharge • P2Y12 Inhibitor at Discharge • Early troponin measurement after NSTEMI

This table summarizes the changes in composite makeup since the previous endorsement cycle

[Response Ends]

sp.01. Provide the measure title.

Measure titles should be concise yet convey who and what is being measured (see [What Good Looks Like](#)).

[Response Begins]

Overall Defect Free Care for AMI

[Response Ends]

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).

[Response Begins]

The proportion of acute MI patients >= 18 years of age that receive "perfect care" based upon their eligibility for each performance measures

[Response Ends]

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

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Surgery: General*

[Response Begins]

Cardiovascular: Coronary Artery Disease

Cardiovascular: Coronary Artery Disease (PCI)

[Response Ends]

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

[Response Begins]

Care Coordination

[Response Ends]

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.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Populations at Risk: Populations at Risk*

[Response Begins]

Adults (Age >= 18)

Populations at Risk: Populations at Risk

[Response Ends]

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.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]

Facility

[Response Ends]

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

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

[Response Begins]

Inpatient/Hospital

[Response Ends]

sp.09. Provide a 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".

[Response Begins]

ACC does not have a measure specific webpage. However more information about the clinical registry that the measure is included in can be found at: https://cvquality.acc.org/NCDR-Home/registries/hospital-registries/chest-pain-mi-registry

A measure companion guide, data collection form and data dictionary are available to all participants in password protected pages of the website that contains measure specifications. These artifacts are only available to registry participants.

[Response Ends]

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. Provide descriptors for any codes. Use one file with multiple worksheets, if needed.

[Response Begins]

No data dictionary/code table – all information provided in the submission form

[Response Ends]

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.

[Response Begins]

Count of patients with ALL care opportunities met for which they were eligible.

[Response Ends]

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.

[Response Begins]

All eligible care opportunities must be met in order for the composite measure to be achieved. There are 14 potential opportunities for the ST Elevation Myocaridal Infarction (STEMI) population and 9 potential opportunities for the NSTEMI (Non ST Elevation Myocardial Infarction) population.

[Response Ends]

sp.15. State the denominator.

Brief, narrative description of the target population being measured.

[Response Begins]

Count of patients with at least one eligible care opportunity

[Response Ends]

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.

[Response Begins]

The denominator includes two populations, those who have had either a STEMI or NSTEMI.

- Patient type = pre-admit STEMI and NSTEMI

[Response Ends]

sp.17. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

[Response Begins]

The exclusions for this measure were minimal and comprised: patients <18 years of age, hospital submissions that did not pass the NCDR quality check, and patients who were ineligible for defect free care measure (e.g., contraindications, clinical studies).

[Response Ends]

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.

[Response Begins]

Denominator Exclusions are:

1. patients <18 years of age;
2. hospital submissions that did not pass the NCDR quality check;
3. Patients who were ineligible for defect free care measure (e.g., contraindications, clinical studies).

Denominator exclusions associated with the process measures for medications at discharge include:

Patient with any of the following:

1. Left against medical advice
2. Deceased during hospitalization
3. Comfort measures only
4. Hospice care initiated
5. Transferred to other acute care hospital

[Response Ends]

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.

[Response Begins]

There is no stratification.

[Response Ends]

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

[Response Begins]

No

[Response Ends]

sp.21. Select the risk adjustment type.

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

[Response Begins]

No risk adjustment or risk stratification

[Response Ends]

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

Attachment: If available, please provide a sample report.

[Response Begins]

Rate/proportion

[Response Ends]

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

[Response Begins]

Better quality = Higher score

[Response Ends]

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.

[Response Begins]

- For each individual measure if the denominator is met (patient eligible for care) and the numerator is met (the appropriate care is received) then increase the denominator opportunity and numerator care received each by 1.
- If the denominator is met but the care received is NOT met then only increase the denominator (eligibility).
- This logic is followed for 14 individual measures for STEMI and 9 individual measures for NSTEMI.
- Then if the care opportunities are equal to the number of times care is received then the numerator of the composite measure is increased by one.
- If the numerator and denominator are not equal the numerator is not increased.

Numerator = # of defect free care STEMI patients + # defect free care NSTEMI patient

Denominator = # STEMI eligible patient + # NSTEMI eligible patients

DefectFreeCareCounter = 0

PMCareOpportunity = 0

PMTherapy = 0

CASE Population ID = 41 (STEMI)

1. IF(ASAArrivalPMInd denominator = 1 AND ASAArrivalPMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(ASAArrivalPMInd denominator = 1 AND ASAArrivalPMInd numerator = 0) increment PMCareOpportunity by 1
2. IF(ImmAngiCAPMInd denominator = 1 AND ImmAngiCAPMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(ImmAngiCAPMInd denominator = 1 AND ImmAngiCAPMInd numerator = 0) increment PMCareOpportunity by 1
3. IF(D2NPMLessThan30Ind denominator = 1 AND D2NPMLessThan30Ind numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(D2NPMLessThan30Ind denominator = 1 AND D2NPMLessThan30Ind numerator = 0) increment PMCareOpportunity by 1
4. IF(FMC2BLessThan90Ind = denominator 1 AND FMC2BLessThan90Ind numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(FMC2BLessThan90Ind denominator = 1 AND FMC2BLessThan90Ind numerator = 0) increment PMCareOpportunity by 1
5. IF(DIDOTPPMInd denominator = 1 AND DIDOTPPMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(DIDOTPPMInd denominator = 1 AND DIDOTPPMInd numerator = 0) increment PMCareOpportunity by 1
6. IF(D2BTPPMLessThan90Ind denominator = 1 AND D2BTPPMLessThan90Ind numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(D2BTPPMLessThan90Ind denominator = 1 AND D2BTPPMLessThan90Ind numerator = 0) increment PMCareOpportunity by 1
7. IF(ReperfusionPMInd denominator = 1 AND ReperfusionPMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(ReperfusionPMInd denominator = 1 AND ReperfusionPMInd numerator = 0) increment PMCareOpportunity by 1
8. IF(EvalLVSysFuncPMInd denominator = 1 AND EvalLVSysFuncPMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(EvalLVSysFuncPMInd denominator = 1 AND EvalLVSysFuncPMInd numerator = 0) increment PMCareOpportunity by 1
9. IF(ACEARBDischargePMInd denominator = 1 AND ACEARBDischargePMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(ACEARBDischargePMInd denominator = 1 AND ACEARBDischargePMInd numerator = 0) increment PMCareOpportunity by 1
10. IF(ASADischargePMInd denominator = 1 AND ASADischargePMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

    IF(ASADischargePMInd denominator = 1 AND ASADischargePMInd numerator = 0) increment PMCareOpportunity by 1
11. IF(BBDischargePMInd denominator = 1 AND BBDischargePMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

    IF(BBDischargePMInd denominator = 1 AND BBDischargePMInd numerator = 0) increment PMCareOpportunity by 1

12. IF(HighIntensityStatinTherapyInd denominator = 1 AND HighIntensityStatinTherapyInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

    IF(HighIntensityStatinTherapyInd denominator = 1 AND HighIntensityStatinTherapyInd numerator = 0) increment PMCareOpportunity by 1
13. IF(P2Y12IndDisPMInd denominator = 1 AND P2Y12IndDisPMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

    IF(P2Y12IndDisPMInd denominator = 1 AND P2Y12IndDisPMInd numerator = 0) increment PMCareOpportunity by 1
14. IF(CardRehabPMInd denominator = 1 AND CardRehabPMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

    IF(CardRehabPMInd denominator = 1 AND CardRehabPMInd numerator = 0) increment PMCareOpportunity by 1

    IF PMCareOpportunity = PMTherapy THEN increment DefectFreeCareCounter by 1

CASE Population ID = 42 (NSTEMI)

1. IF(ASAArrivalPMInd denominator = 1 AND ASAArrivalPMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(ASAArrivalPMInd denominator = 1 AND ASAArrivalPMInd numerator = 0) increment PMCareOpportunity by 1
2. IF(ETropMeasSTEMIPMInd denominator = 1 AND ETropMeasSTEMIPMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(ETropMeasSTEMIPMInd denominator = 1 AND ETropMeasSTEMIPMInd numerator = 0) increment PMCareOpportunity by 1
3. IF(EvalLVSysFuncPMInd denominator = 1 AND EvalLVSysFuncPMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(EvalLVSysFuncPMInd denominator = 1 AND EvalLVSysFuncPMInd numerator = 0) increment PMCareOpportunity by 1
4. IF(ACEARBDischargePMInd denominator = 1 AND ACEARBDischargePMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(ACEARBDischargePMInd denominator = 1 AND ACEARBDischargePMInd numerator = 0) increment PMCareOpportunity by 1
5. IF(ASADischargePMInd denominator = 1 AND ASADischargePMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(ASADischargePMInd denominator = 1 AND ASADischargePMInd numerator = 0) increment PMCareOpportunity by 1
6. IF(BBDischargePMInd denominator = 1 AND BBDischargePMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(BBDischargePMInd denominator = 1 AND BBDischargePMInd numerator = 0) increment PMCareOpportunity by 1
7. IF(HighIntensityStatinTherapyInd denominator = 1 AND HighIntensityStatinTherapyInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(HighIntensityStatinTherapyInd denominator = 1 AND HighIntensityStatinTherapyInd numerator = 0) increment PMCareOpportunity by 1
8. IF(P2Y12IndDisPMInd denominator = 1 AND P2Y12IndDisPMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

IF(P2Y12IndDisPMInd denominator = 1 AND P2Y12IndDisPMInd numerator = 0) increment PMCareOpportunity by 1

9. IF(CardRehabPMInd denominator = 1AND CardRehabPMInd numerator = 1) increment PMCareOpportunity by 1, increment PMTherapy by 1

   IF(CardRehabPMInd denominator = 1 AND CardRehabPMInd numerator = 0) increment PMCareOpportunity by 1

   IF PMCareOpportunity = PMTherapy THEN increment DefectFreeCareCounter by 1)

[Response Ends]

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 2010 Measure Testing Task Force recognized that 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.

[Response Begins]

There is no sampling allowed within the Chest Pain MI registry for these patient populations

[Response Ends]

sp.28. Identify whether and how proxy responses are allowed.

[Response Begins]

N/A

[Response Ends]

sp.30. Provide the data collection instrument.

[Response Begins]

No data collection instrument provided

[Response Ends]

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

[Response Begins]

Registry Data

[Response Ends]

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.

[Response Begins]

Measure specifications are delineated in Sp.14 - Sp.17

Short Title: PM-1: Aspirin at Arrival

Short Title: PM-2: Aspirin at Discharge

Short Title: PM-3: Beta Blocker at Discharge

Short Title: PM-4: High-Intensity Statin at Discharge

Short Title: PM-5: Evaluation of LVEF

Short Title: PM-6: ACEI or ARB for LVSD

Short Title: PM-7: Door-to-Needle Time

Short Title: PM-8: First Medical Contact-Device Time

Short Title: PM-9: Reperfusion Therapy

Short Title: PM-10: Door-in-Door-Out Time

Short Title: PM-11: Time to Primary PCI Among Transferred Patients

Short Title: PM-12: Cardiac Rehabilitation Referral

Short Title: PM-13: P2Y12 Inhibitor at Discharge

Short Title: PM-14: Immediate Angiography After Cardiac Arrest

Short Title: PM-16: Early Troponin Measurement After NSTEMI

Aggregation rules and weighting rules:

Each measure is weighted equally within the composite measure. Data is aggregated on a rolling four quarter basis and returned back to participating sites with their 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 for 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 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.

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:

In the event that a hospital has a limited number of patients in any given quarter, identified as less than 20 AMI patients in one quarter, the NCDR has offered ‘low volume alerts’. The hospital data will continue to be included in the aggregate as long as they have at least one patient that meets the eligibility requirements.

There is no sampling of patient data allowed within the contractual terms of participation in the Chest Pain MI Registry. The registry is designed to include 100 percent of consecutive adult patients who have an acute MI at participating institutions.

Minimum sample size requirements for the component measures or the overall composite:

There is no minimum sample size. As long as there is one patient in the reporting quarter the hospital will be included in the measure as all AMI patient’s care should be evaluated for Defect Free care status.

[Response Ends]

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.

[Response Begins]

Yes

[Response Ends]

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.

[Response Begins]

Yes

[Response Ends]

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.

[Response Begins]

No additional risk adjustment analysis included

[Response Ends]

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 NQF staff 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 NQF staff with any questions. Check for resources at the Submitting Standards webpage.

• 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 NQF's 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.

[Response Begins]

Registry Data

[Response Ends]

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).

[Response Begins]

We use a clinical registry, namely the National Cardiovascular Data Registry for Chest Pain-MI Registry, formerly known as the ACTION Registry. This is a national quality improvement registry in which over 600 US hospitals participate. Some states and healthcare systems mandate participation. 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.

[Response Ends]

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

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

[Response Begins]

01/01/2019 -12/31/2019

[Response Ends]

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.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]

Facility

[Response Ends]

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.

[Response Begins]

The overall measure entities are as follows:

Table 1. Entities Evaluated by Level of Analysis

Level of Analysis	Variable	Data Source	Number
Patient	Patient Hospital Stay	NCDR Chest Pain-MI Registry	130,279
Hospital	Facilities	NCDR Chest Pain-MI Registry	695

Table 1. Entitites Evaluated by Level of Analysis. This analysis includes 130,279 patients from 695 hospitals.

Table 2. Hospital Characteristics

Table name: Hospital Characteristics	*	*
Description	**# Patient**	%
ALL	130279	100.00
Hospital Location	*	*
Rural	21077	16.18
Suburban	38023	29.19
Urban	71179	54.64
Participant Type	*	*
Government	2934	2.25
Private/Community	116365	89.32

Table name: Hospital Characteristics	*	*
University	10980	8.43
Certified Bed Number	*	*
Mean, SD	401.80	239.89
1%, 99%	53	1070.00
25%, 75%	222	536.00
Median, range	350	314.00
Teaching Hospital	*	*
No	71113	54.59
Yes	59166	45.41
Census Region	*	*
Midwest Region	32635	25.05
Northeast Region	11279	8.66
South Region	65097	49.97
West Region	21244	16.31
Public Hospital	*	*
No	65868	50.56
Yes	64411	49.44
Service Level	*	*
Diagnostic caths (only)	1143	0.88
Diagnostic caths and PCIs	23441	17.99
Diagnostic caths, PCIs, and cardiac surgeries	105411	80.91
No Cath Lab services	284	0.22

Table 2. Hospital Characteristics - describes the hospital type by region, type, bed number and number of diagnostic catheterizations performed.

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[Response Ends]

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.

[Response Begins]

For all the descriptive statistics, we used data collected by the Chest Pain-MI Registry between January 2019 and December 2019. Descriptive statistics about the patients included in this dataset are provided below (Table 2):

Table 2. Patient Characteristics

*	Total	Total
Description	#	%
ALL	130279	100.00
Age ≥ 65	*	*
No	62559	48.02
Yes	67720	51.98
Sex	*	*
Male	86768	66.60
Female	43511	33.40
Race	*	*
Hispanic	10034	7.70
White non-hispanic	100794	77.37
Black non-Hispanic	14302	10.98
Other	5149	3.95
Insurance	*	*
Medicare	66581	51.11
Medicaid	9131	7.01
Private	39690	30.47
Other	14877	11.42

Table 2. Patient Characteristics are described by age, sex, race, and insurance status

*Cell is intentionally left blank

[Response Ends]

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.

[Response Begins]

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

The datasets, dates, number of measured entities, and number of admissions for all forms of reliability and validity testing were from an uninterrupted 1-year period: 01/01/2019-12/31/2019

[Response Ends]

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.

[Response Begins]

We attributed social risk factors at the hospital-level for the purposes of this analysis. We used Medicaid insurance status as an economic indicator of social risk. We also examined race/ethnicity, age, and gender to determine if there were differences in these demographic indicators of social risk.

[Response Ends]

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.

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

Choose one or both levels.

[Response Begins]

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)

[Response Ends]

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.

[Response Begins]

Split Sample Methodology

For the performance rates and social risk data, raw rates were calculated and a Pearson correlation coefficient and Cronbach coefficient were computed. Methodology, scope, site and record selection criteria, and scoring is described below.

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 DQR 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

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. Below are a few definitions for computing these scores and others depending on the Registry:

- The accuracy score for each variable represents how often the NCDR data matches the auditors' data.
- The overall accuracy score is the total number of agreements divided by total number of possible agreements.
- Each measurement is summed up for each participant and an overall audit accuracy score is computed.
- An overall compliance score is calculated based on the number of matches across two lists.

Onsite and Overall accuracy Score

- A : Above 93%
- B : Between 80 and 93%
- C : Between 70 and 79%
- D : Between 60 and 69%
- E : Below 60%

[Response Ends]

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, NQF Measure Evaluation Criteria).

[Response Begins]

Split Sample Methodology

The split samples were calculated during the same timeframe to mitigate confounding factors based on time differences. The cohort was split into two random samples to compare measure scores. The distribution of hospital performance was similar in the two samples, and there was a strong correlation between hospital performance assessed in the two samples (Pearson correlation coefficient: 0.87685) (Table 3).

Table 3. Distribution of Performance for the Defect Free Care Measure Stratified by the Randomly Split Samples

*	Randomly split sample	Randomly split sample
Description	**First (RAND=1)**	**Second (RAND=0)**
Mean	0.5711	0.5729
Std Deviation	0.2164	0.2177
100% Max	1.0000	1.0000
99%	0.9565	0.9894
95%	0.8803	0.8889
90%	0.8278	0.8350
75% Q3	0.7363	0.7353
50% Median	0.6042	0.6051
25% Q1	0.2519	0.2458
10%	0.0455	0.0625
5%	0.0000	0.0000
1%	0.0000	0.0000
0% Min	0.0000	0.0000

Table 3. Distribution of Performance for the Defect Free Care Measure Stratified by the Randomly Split Samples - The split samples were calculated during the same timeframe to mitigate confounding factors based on time differences. The cohort was split into two random samples to compare measure scores. The distribution of hospital performance was similar in the two samples, and there was a strong correlation between hospital performance assessed in the two samples (Pearson correlation coefficient: 0.87685)

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Pearson correlation coefficient: 0.87685

Cronbach Coefficient 0.93438

Figure 1. Distribution of Performance for the Defect Free Care Measure Stratified by Randomly Split Samples (Top) and by Split Sample Correlation (Bottom)

Figure 2

Additional data and conclusions are available in the Validity Testing section.

The 2 split samples were calculated during the same timeframe to mitigate confounding factors based on time differences. Results of the split sample testing are provided below. The distribution of hospital performance was similar in the two samples (below), and there was a high correlation between hospital performances assessed in the two samples (r 0.87685).

[Response Ends]

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?)

[Response Begins]

The results of the split sample show a similar performance of the composite measure at discharge for both samples, which demonstrates this is a very reliable measure with a strong correlation between hospital performance assessed in the two samples (r = 0.87685).

Additional data and conclusions are available in the Validity Testing section.

The 2 split samples were calculated during the same timeframe to mitigate confounding factors based on time differences. Results of the split sample testing are provided below. The distribution of hospital performance was similar in the two samples (below), and there was a high correlation between hospital performances assessed in the two samples (r 0.87685).

[Response Ends]

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

[Response Begins]

Empirical Validity Testing of the Composite (Measure Score)

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.

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)

[Response Ends]

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.

[Response Begins]

Data Element Validity

The National Cardiovascular Data Registry® (NCDR®) Data Quality Program ensures that data submitted to the NCDR are 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 Data Quality Review, 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 above.

Face Validity: (Initial testing of this measure):

NCDR's Clinical Science and Quality Committee— an ACC leadership oversight committee that serves as the primary resource for crosscutting scientific and quality of care methodological issues – ensured the data dictionaries and metrics are consistent across registries. They also reviewed and approved the methodology and results of the outcome and model.

These members include John Messenger (chair), Frederick Masoudi, Joaquin Cigarroa, John Carroll, David Cox, Jeptha Curtis, Stace Daugherty, Deborah Diercks, Charles Henrikson, Jeffery Jacobs, Fred Kusumoto, Doff McElhinney, David Malenka, John Spertus, James Tcheng, Salim Virani, Tracy Wang

NCDR Registry Steering Committee provides strategic direction for the Registry and ensures the measures submitted to NQF met key criterion such as reliability, feasibility, and that there is compelling evidence base behind the development and implementation of this measure. These members includeMichael Kontos (Chair), Sanjay Gandhi, Leslie Davis, Deborah Diercks, Cian McCarthy, Simon Mahler, Diane Penzkowski, Julie Clary, Michael Levy, Suresh Mulukutla, Tracy Wang, Kirk Garratt, .

Lastly the NCDR Oversight Committeee and ACCF Board of Trustees approved these measures for submission to NQF. The face/content validity of this measure has been achieved by virtue of the noted expertise of those individuals who developed this measure.

Empirical Validity (Re-endorsement Testing):

For re-endorsement of this measure, additional empirical validity testing was completed. Empirical analysis was tested by determining if hospitals performed similarly on the defect free care measure and 30-day AMI mortality. The testing focused on construct validation which tested the hypothesis that use of defect free care processes for AMI patients may be associated with lower mortality rates. This was achieved by examining the distribution and correlation of the defect free care (DFC) composite score and the 30-day risk-standardized mortality rates (RSMR) for AMI from admission to 30-days. The variables in the model included age, heart rate, systolic blood pressure, troponin ratio, and creatinine level (*McNamara et al. Development of a hospital outcome measure intended for use with electronic health records: 30-day risk-standardized mortality after acute myocardial infarction. Med Care, 2015, vol. 53 (pg. 818-26*). Hospital data for the RSMR model comprised of the study period Q4 2013 to Q3 2014 as this was the latest NDI-CPMI linked data available. Thus, there is a smaller sample size as this analysis was conducted among eligible sites that reported data to both the 2019 DFC measure and the 2014 RSMR measure (n=526).

[Response Ends]

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

Examples may include correlations or t-test results.

[Response Begins]

Data Element Validity: CPMI Registry Audit V3.0 (data from 1/1/2019 – 12/31/2019

This audit assesses a random sample of CPMI Registry participating facilities (n=80) for data accuracy, facility abstractor's inter-rater reliability (as measured by agreement rates). Agreement rates from the individual data elements (n=194) is currently in review but will be added to this application once committee members have reviewed and releases a public summary report. Overall results are listed below.

Overall Scores

How are Participants performing?	# of Participants	Good	Poor	Score
Overall Agreement Rate	80	75	5	91.8%

Overall Agreement Rates among 80 participants were 91.8%

Data Accuracy Assessment	Data Points	Score	10th Percentile	90th Percentile
Agreement Rates	*	*	*	*
All Data	167,333	89.9	86.3	91.8
PABAK Categorical Data	93,748	0.939	0.761	0.995
Pearson Continuous Data	23,206	0.888	0754	0.943

Data Accuracy Assessment 90th percentiles for all data is 91.8, for PABAK categorical data 0.995, for Pearson Continous Data .0943

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Abstractors Inter-Rater Reliability	Data Points	Score	10th Percentile	90th Percentile
All data agreement	9,920	97.1	89.1	100.0
PABAK	8,139	0.971	0.829	1.000
Pearson	1,781	0.990	0.802	1.000

Abstractors inter rater reliability was 100% at the 90th percentile for all data agreement, PABAK and Pearson

Note: For confidentiality reasons individual data element results are not available at this time.

Performance refers to accurate the data submitted to NCDR is upon audit

Prevalence-adjusted and bias-adjusted kappa (PABAK) is used to assess the agreement between hospital data and chart review data conditions.

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Face Validity

Face validity was achieved through reaching consensus that the measure had strong clinical evidence and was reliable.

Empirical Validity

Below are the results achieved from the empirical validity testing (Table 4):

Table 4. Distribution of Performance Rates for DFC and RSMR in the Time Period 2013Q4 to 2014Q3 (n=526)

*	Performance rate (%)	Performance rate (%)
Description	**DFC***	**RSMR****
Mean	59.8%	6.3%
Std Deviation	19.6%	1.1%

*	Performance rate (%)	Performance rate (%)
*	*	*
100% Max	97.8%	11.5%
99%	93.6%	9.3%
95%	86.5%	8.3%
90%	83.0%	7.9%
75% Q3	74.8%	6.9%
50% Median	62.4%	6.2%
25% Q1	47.5%	5.5%
10%	31.0%	4.9%
5%	21.4%	4.6%
1%	10.9%	4.0%
0% Min	0.0%	3.5%

Distribution of Performance Rates for DFC and RSMR in the Time Period 2013Q4 to 2014Q3 (n=526)

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Pearson correlation coefficient between DFC and RSMR -0.09596 (P=0.0279)

**DFC = Defect Free Care*

***RSMR = Risk Standardize Mortality Rate*

*Cell is intentionally blank

[Response Ends]

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?)

[Response Begins]

Data Element Validity: The high agreement rate indicates a good understanding of data definitions and consistency between the auditors. It also provides assurance of the accuracy of the re-abstraction being performed by the auditing team.

Range of Agreement Rate	Score Status
Score ≥ 95%	Exceeds Expectations
85% < Score < 95%	Meets Expectations
Score ≤ 85%	Needs Improvement

Reference table with the range of agreement rates and meaning. Score of greater than 95% exceeds expectations, 85%- 95% meets expectation, below 85% needs improvement

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**

PABAK	Interpretation
0.00	Poor agreement

Interpretation scale - PABAK. Almost perfect agreement is a PABAK of 0.81 to 1.00

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

Pearson Correlation Coefficient Interpretation scale. A score of 0.7 to 1.0 indicates a strong linear relationship. Less than 0.3 indicates a poor linear relationship

Face validity: The individual components have been associated with better outcomes and are accepted quality measures in patient populations. As noted in Section 2a.12, we have good evidence of validity from the Chest Pain – MI Registry audit data.

Empirical validity: The median rate of delivering defect free care was 62.4% (IQR: 47.5% to 74.8%), and the median mortality rate at 30 days was 6.2% (IQR: 5.5% to 6.9%). There was a similar distribution of hospitals by volume across both measures. The negative correlation coefficient was significant and in the hypothesized direction, such that a higher group of patients receiving defect free care was associated with lower mortality rates. Yet, the correlation is relatively low (-0.096), 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 30-day mortality rates beyond whether defect free care was delivered in-hospital (e.g., unsuccessful procedure, lack of follow-up, poor medication adherence or access to care). Further, the 30-day time period started upon admission to the hospital thus the rates also accounted for in-hospital mortality. In sum, the empirical validation demonstrates there is a relationship, albeit statistically a small one, between defect free care and short-term mortality.

[Response Ends]

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.

[Response Begins]

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

[Response Ends]

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.

[Response Begins]

Overall

The median rate of performance for defect free care across all hospitals was 60.2%. There was considerable variation in providing defect free care, ranging from 42.6% to 73.6% for the first and third quartiles of hospitals, respectively (Table 6), and the distribution was left-skewed such that the majority of hospitals, between 60% to 100%, provided defect free care (Figure 2).

Table 6. Distribution of Performance for the Defect Free Care Measure

Description	DFC (%)
N	695
Mean	57.08%
Std Deviation	21.18%
*	*
100% Max	100.00%
99%	94.81%
95%	86.55%
90%	82.73%
75% Q3	73.56%
50% Median	60.19%
25% Q1	42.56%
10%	26.54%
5%	17.32%
1%	4.17%
0% Min	0.00%

Table 6. Distribution of Performance for the Defect Free Care Measure shows The median rate of performance for defect free care across all hospitals was 60.2%. There was considerable variation in providing defect free care, ranging from 42.6% to 73.6% for the first and third quartiles of hospitals, respectively

Note: *=intentionally left blank

Figure 2. Histogram of Performance of the Defect Free Care Measure

Across stratified analyses based on sex, age, race, and proportion of patients who are insured through Medicaid, we found significant overlap in the distribution of hospital performance, as detailed below.

Race/Ethnicity

The distribution of hospital performance was examined among White (non-Hispanic), Black (non-Hispanic), Hispanic and Other race patients. There was significant overlap in hospital performance with median performance ranging from 55.88% for patients who identify as Black non-Hispanic to 66.67% for Other race. Those who identify as White non-Hispanic and Hispanic had median performances of 61.43% and 59.09%, respectively (Table 7 and Figure 3).

Table 7. Distribution of the Performance of the Defect Free Care Measure Stratified by Race at the Hospital-Level (N=695)

Description	Hispanic	White non-hispanic	Black non-hispanic	Other
Mean	57.55%	57.97%	54.99%	59.36%
Std Deviation	31.44%	21.11%	30.01%	34.17%
*	*	*	*	*
100% Max	100.00%	100.00%	100.00%	100.00%
99%	100.00%	96.43%	100.00%	100.00%
95%	100.00%	87.61%	100.00%	100.00%
90%	100.00%	83.13%	100.00%	100.00%
75% Q3	81.82%	74.17%	77.78%	90.63%
50% Median	59.09%	61.43%	55.88%	66.67%
25% Q1	35.00%	43.36%	33.33%	33.33%

Description	Hispanic	White non-hispanic	Black non-hispanic	Other
10%	0.00%	28.13%	11.11%	0.00%
5%	0.00%	18.10%	0.00%	0.00%
1%	0.00%	2.80%	0.00%	0.00%
0% Min	0.00%	0.00%	0.00%	0.00%

Table 7. Distribution of the Performance of the Defect Free Care Measure Stratified by Race at the Hospital-Level (N=695). Columns are Hispanic, white non-hispanic, black non-hispanic, and other. The rows include mean, standard deviation, 50% median, 75% Q3, 25% Q1, 99%, 95%, 90%, 10%, 5%, 1% and 0% min.

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Figure 3. Distribution of the Performance Rates of the Defect Free Care Measure Stratified by Race/Ethnicity at the Hospital-Level

Proportion of Non-White Patients

Hospitals (n=695) were stratified into quartiles by their proportion of non-White patients (median: 12.1%, IQR: 4.93% to 23.28%). Hospital performance across quartiles was similar regardless of the percent of non-White patients hospitals treated, with median performance ranging from 62.6% to 59.1% (Table 8; Figure 4).

Table 8. Distribution of Performance Rates for the Defect Free Care Measure Stratified by Hospital Quartiles of Non-White Patients (N=695)

Description	Non White (%)	Non White (%)	Non White (%)	Non White (%)
*	**Q1**	**Q2**	**Q3**	**Q4**
N	173	174	174	174
Mean	58.33%	58.98%	55.31%	55.69%
Std Deviation	21.66%	20.78%	20.25%	21.92%
*	*	*	*	*
100% Max	100.00%	94.04%	94.81%	98.34%

Description	Non White (%)	Non White (%)	Non White (%)	Non White (%)
99%	97.78%	93.28%	93.10%	96.88%
95%	87.50%	89.03%	86.05%	85.29%
90%	82.47%	85.63%	80.73%	81.48%
75% Q3	74.83%	74.76%	71.30%	70.94%
50% Median	62.63%	60.88%	57.14%	59.09%
25% Q1	45.45%	43.79%	39.66%	40.52%
10%	25.00%	30.92%	26.87%	25.00%
5%	18.71%	19.88%	20.19%	12.50%
1%	0.00%	7.32%	12.12%	0.00%
0% Min	0.00%	5.95%	7.34%	0.00%

Table 8. Distribution of Performance Rates for the Defect Free Care Measure Stratified by Hospital Quartiles of Non-White Patients (N=695). The columns describes Non white patients as a percentages stratified by quarteriles.

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Figure 4. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Quartiles of Non-White Patients at the Hospital-Level

Figure 4. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Quartiles of Non-White Patients at the Hospital-Level

Gender

The median hospital performance among female patients was 56.8% (IQR: 38.9% to 71.43%) while among male patients it was slightly higher at 62.2% (IQR: 44.3% to 75.1%) (Table 9 and Figure 5)

Table 9. Distribution of the Performance Rates for the Defect Free Care Measure Stratified by Gender at the Hospital-Level (N=695)

Description	Female	Male
*	*	*
Mean	54.68%	58.56%
Std Deviation	22.40%	21.36%
*	*	*
100% Max	100.00%	100.00%
99%	100.00%	94.23%
95%	87.50%	87.72%
90%	82.76%	83.81%
75% Q3	71.43%	75.15%
50% Median	56.83%	62.16%
25% Q1	38.93%	44.26%
10%	21.43%	28.13%
5%	16.67%	18.99%
1%	0.00%	1.33%
0% Min	0.00%	0.00%
*	*	*

Table 9. Distribution of the Performance Rates for the Defect Free Care Measure Stratified by Gender at the Hospital-Level (N=695)

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Figure 5. Distribution of the Performance Rates of the Defect Free Care Measure Stratified by Gender at the Hospital-Level

Age

The median hospital performance in delivering Defect Free Care among patients aged less than 65 years was 62.35% (IQR: 45.58% to 75.25%) while that among patients aged 65 years or greater was 57.58% (IQR: 39.39% to 72.41%) (Table 10 and Figure 6).

Table 10. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Age at the Hospital-level (N=695)

Age ≥ 65	*	*
Description	**Yes**	**No**
*	*	*
Mean	55.69%	59.09%
Std Deviation	21.71%	22.07%
*	*	*
100% Max	100.00%	100.00%
99%	99.07%	97.18%
95%	87.25%	89.92%
90%	83.20%	84.68%
75% Q3	72.41%	75.25%
50% Median	57.58%	62.35%
25% Q1	39.39%	45.58%
10%	25.00%	25.81%
5%	18.86%	15.79%
1%	0.00%	0.00%
0% Min	0.00%	0.00%
*	*	*

Table 10. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Age at the Hospital-level (N=695), The median hospital performance in delivering Defect Free Care among patients aged less than 65 years was 62.35% (IQR: 45.58% to 75.25%) while that among patients aged 65 years or greater was 57.58% (IQR: 39.39% to 72.41%)

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Figure 6. Distribution of the Performance Rates of the Defect Free Care Measure Stratified by Age Group at the Hospital-Level

Insurance

Hospitals (n=695) were stratified into quartiles by their proportion of patients with Medicaid as the primary insurance (median: 10.37%, IQR: 6.0% to 15.92%). Hospital performance was similar across hospitals stratified into quartile by the proportion of patients they care for who have Medicaid insurance coverage. Median hospital performance ranged from 56.39% (Quartile 4) to 64.73% (Quartile 3) (Table 11 and Figure 7).

Table 11. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Quartile of Hospital Percent Medicaid (N=695)

%Medicaid	*	*	*	*
Description	**Q1**	**Q2**	**Q3**	**Q4**
N	174	173	174	174
Mean	54.75%	58.88%	59.95%	54.74%
Std Deviation	21.12%	20.35%	21.11%	21.74%
*	*	*	*	*
100% Max	100.00%	93.10%	98.34%	96.88%
99%	97.50%	92.62%	97.78%	94.81%
95%	83.33%	88.89%	86.92%	85.00%
90%	78.70%	85.63%	83.53%	80.53%
75% Q3	71.11%	75.89%	75.22%	71.66%
50% Median	59.23%	60.00%	64.73%	56.39%
25% Q1	39.43%	44.26%	45.45%	41.86%
10%	25.15%	30.77%	29.09%	20.13%
5%	16.22%	23.02%	16.84%	14.81%
1%	0.00%	13.84%	5.95%	0.00%
0% Min	0.00%	0.00%	2.73%	0.00%
*	*	*	*	*

Table 11. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Quartile of Hospital Percent Medicaid (N=695). ospitals (n=695) were stratified into quartiles by their proportion of patients with Medicaid as the primary insurance (median: 10.37%, IQR: 6.0% to 15.92%). Hospital performance was similar across hospitals stratified into quartile by the proportion of patients they care for who have Medicaid insurance coverage. Median hospital performance ranged from 56.39% (Quartile 4) to 64.73% (Quartile 3)

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Figure 7. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Quartile of Hospital Percent Medicaid

Figure 7. Distribution of Performance Rates of the Defect Free Care Measure Stratified by Quartile of Hospital Percent Medicaid

[Response Ends]

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?

[Response Begins]

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.

[Response Ends]

Note: Applies to the overall composite measure.

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).

[Response Begins]

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.

[Response Ends]

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.

[Response Begins]

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.

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

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.

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

[Response Begins]

No, there is only one set of specifications for this measure

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

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.

[Response Begins]

Yes, the measure uses exclusions.

[Response Ends]

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?

[Response Begins]

The exclusions for this measure were minimal and comprised: patients <18 years of age, hospital submissions that did not pass the NCDR quality check, and patients who were ineligible for defect free care measure (e.g., contraindications, clinical studies, did not submit data).

[Response Ends]

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.

[Response Begins]

The table (5) 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 or those individuals enrolled in clinical trial studies.

Table 5. Study Cohort Assembly

Exclusions	Number of Hospital stays	Number of Hospital stays	Number of facilities	Number of facilities
*	#	%	#	%
Initial Sample	225884	12.18	760	59.42
Age<18	0	0.00	0	0.00
Remaining	225884	100.00	760	100.00
Hospital submission not pass the data quality check	0	0.00	0	0.00
Remaining	225884	100.00	760	100.00
Not eligible for the DFC measure	95605	42.32	65	8.55
Study Sample	130279	57.68	695	91.45

Table 5. Study Cohort Assembly. Columns are exclusions, hospital stays by number and percentage, and facilities by number and percentage. The rows are initial sample, under 18 years old, remaining, hospital submission not passing the data quality check, remaining, not eligible for this composite measure and finally, the remaining study sample (130,279 hospital stays and 695 facilities)

Note: * Indicates cell was intentionally left blank

[Response Ends]

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.

[Response Begins]

There are no discretionary exclusions, and these exclusions only pertain to variables that are 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.

[Response Ends]

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

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

[Response Begins]

No risk adjustment or stratification

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

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.

[Response Begins]

All of the components of this composite measure focus on the achievement of processes of care. We did not identify any clinical or patient factors for which risk adjustment of this composite would be required; rather, each component includes denominator exceptions (e.g., contraindications) when applicable.

[Response Ends]

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).

[Response Begins]

N/A

[Response Ends]

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

[Response Begins]

Other (specify)

[Other (specify) Please Explain]

N/A

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

2b.27. Provide risk model discrimination statistics.

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

[Response Begins]

N/A

[Response Ends]

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

[Response Begins]

N/A - this is not a risk model

[Response Ends]

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.

[Response Begins]

N/A - this is not a risk model

[Response Ends]

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

[Response Begins]

N/A - this is not a risk model

[Response Ends]

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?

[Response Begins]

N/A

[Response Ends]

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.

[Response Begins]

N/A - this is not a risk model

[Response Ends]

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.

[Response Begins]

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 defect free care measure with its components, including: Aspirin at Arrival, Aspirin prescribed at Discharge, Beta-Blocker Prescribed at Discharge, High Intensity Statin at Discharge, P2Y12 Inhibitor at Discharge, Evaluation of LV Systolic Function, ACEI or ARB for LVSD at Discharge, Reperfusion Therapy, Cardiac Rehabilitation Patient Referral From an Inpatient Setting, Door-to-needle Time, First Medical Contact-Device Time, Early troponin measurement after NSTEMI, Immediate Angiography After Cardiad Arrest, Door-in Door-out Time, Time to Primary PCI transferred patients.

[Response Ends]

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.

[Response Begins]

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

[Response Ends]

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.

[Response Begins]

The Pearson correlation coefficients between the defect free care measure and its components are available in Tables 12 and 13.

Note: * indicates cell was intentionally left blank

Table 12. Distribution of Overall Defect Free Care and its Components at the Hospital-Level (N=695)

Description	Defect Free Care %	Aspirin at arrival %	Immediate angiography after cardiac arrest %	Door-to-needle time %
Mean	0.5708	0.9685	0.8745	0.3940
Std Deviation	0.2118	0.0645	0.2252	0.4441
*	*	*	*	*
100% Max	1.0000	1.0000	1.0000	1.0000
99%	0.9481	1.0000	1.0000	1.0000
95%	0.8655	1.0000	1.0000	1.0000
90%	0.8273	1.0000	1.0000	1.0000
75% Q3	0.7356	1.0000	1.0000	1.0000
50% Median	0.6019	0.9875	1.0000	0.0385
25% Q1	0.4256	0.9646	0.8000	0.0000
10%	0.2654	0.9259	0.5714	0.0000
5%	0.1732	0.8750	0.5000	0.0000
1%	0.0417	0.6957	0.0000	0.0000
0% Min	0.0000	0.2963	0.0000	0.0000

Table 12. Distribution of Overall Defect Free Care and its Components at the Hospital-Level (N=695). The columns are description, defect free care %, aspirin at arrival %, immediate angiography after cardiac arrest %, door to needle time %. The rows. The rows describe the mean, standard deviation, and percentiles (99, 95, 90, 75, 50, 10, 5, 0 percent)

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Description	Early Troponin Measurement After STEMI %	First medical contact-device time %	Door-in-door-out time %	Time to primary PCI among transferred patients %
Mean	0.9073	0.8325	0.0367	0.6101
Std Deviation	0.1835	0.1307	0.1324	0.3327
*	*	*	*	*
100% Max	1.0000	1.0000	0.7561	1.0000
99%	1.0000	1.0000	0.6667	1.0000
95%	1.0000	1.0000	0.3333	1.0000
90%	1.0000	1.0000	0.0000	1.0000
75% Q3	1.0000	0.9200	0.0000	0.9000
50% Median	0.9841	0.8519	0.0000	0.6667
25% Q1	0.9316	0.7660	0.0000	0.3889
10%	0.6349	0.6667	0.0000	0.0000

Description	Early Troponin Measurement After STEMI %	First medical contact-device time %	Door-in-door-out time %	Time to primary PCI among transferred patients %
5%	0.4778	0.6061	0.0000	0.0000
1%	0.0400	0.3750	0.0000	0.0000
0% Min	0.0000	0.0000	0.0000	0.0000

Table 12 continued. Distribution of Overall Defect Free Care and its Components at the Hospital-Level (N=695). The columns are description, early troponin measurement after STEMI, first medical contact device time, door in door out time, time to primary PCI among transferred patients. The rows. The rows describe the mean, standard deviation, and percentiles (99, 95, 90, 75, 50, 10, 5, 0 percent)

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Description	Reperfusion therapy %	Evaluation of LV systolic function %	ACE-I or ARB for LVSD at discharge %	Aspirin at discharge %
Mean	0.9554	0.9606	0.8006	0.9756
Std Deviation	0.0769	0.0649	0.1747	0.0409
*	*	*	*	*
100% Max	1.0000	1.0000	1.0000	1.0000
99%	1.0000	1.0000	1.0000	1.0000
95%	1.0000	1.0000	1.0000	1.0000
90%	1.0000	1.0000	1.0000	1.0000
75% Q3	1.0000	0.9923	0.9412	1.0000
50% Median	0.9780	0.9735	0.8182	0.9899
25% Q1	0.9342	0.9507	0.7105	0.9700
10%	0.8872	0.9190	0.6000	0.9352
5%	0.8485	0.8816	0.5000	0.8889
1%	0.7200	0.7500	0.2000	0.7931
0% Min	0.0000	0.0000	0.0000	0.6667

Table 12 continued. Distribution of Overall Defect Free Care and its Components at the Hospital-Level (N=695). The columns are description, reperfusion therapy, evaluation of LV systolic function, ACI inibitors or ARB for LVSD at discharge, aspirin at discharge The rows. The rows describe the mean, standard deviation, and percentiles (99, 95, 90, 75, 50, 10, 5, 0 percent)

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Description	Beta Blocker at Discharge %	High Intensity Statin at Discharge %	P2Y12 Inhibitor at Discharge %	Cardiac Rehab Referral From An Inpatient Setting %
Mean	0.9492	0.8605	0.8778	0.7883

Description	Beta Blocker at Discharge %	High Intensity Statin at Discharge %	P2Y12 Inhibitor at Discharge %	Cardiac Rehab Referral From An Inpatient Setting %
Std Deviation	0.0685	0.1412	0.1160	0.2515
*	*	*	*	*
100% Max	1.0000	1.0000	1.0000	1.0000
99%	1.0000	1.0000	1.0000	1.0000
95%	1.0000	1.0000	1.0000	1.0000
90%	1.0000	0.9854	1.0000	0.9940
75% Q3	0.9937	0.9522	0.9609	0.9639
50% Median	0.9735	0.9020	0.9013	0.8868
25% Q1	0.9329	0.8182	0.8267	0.7131
10%	0.8687	0.6944	0.7407	0.3936
5%	0.8125	0.6011	0.6915	0.1644
1%	0.6538	0.3276	0.4865	0.0000
0% Min	0.5000	0.0000	0.0000	0.0000

Table 12 continued. Distribution of Overall Defect Free Care and its Components at the Hospital-Level (N=695). The columns are description, beta blocker at discharge, high intensity stating at discharge, P2Y12 inhibitor at discharge, cardiac rehab referral from an inpatient setting. The rows. The rows describe the mean, standard deviation, and percentiles (99, 95, 90, 75, 50, 10, 5, 0 percent)

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Table 13. Pearson Correlation Coefficient between Defect Free Care and its Component

Component	Correlation Coefficient (r)
Aspirin at arrival	0.3578
Immediate angiography after cardiac arrest	0.1167
Door-to-needle time	-0.06 (p=0.63)
Early troponin measurement after STEMI	0.3012
First medical contact-device time	0.3310
Door-in-door-out time	0.10 (p=0.28)
Time to primary PCI among transferred patients	0.2714
Reperfusion therapy	0.2667
Evaluation of LV systolic function	0.3592
ACE-I or ARB for LVSD at discharge	0.4391
Aspirin at discharge	0.4873
Beta blocker at discharge	0.5609
High-intensity statin at discharge	0.6134
P2Y12 inhibitor at discharge	0.5442

Component	Correlation Coefficient (r)
Cardiac rehab referral from an inpatient setting	0.7279

Table 13. Pearson Correlation Coefficient between Defect Free Care and its Component. This table describes the correlation coefficient (r) for each measure that makes up this composite measure.

[Response Ends]

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.

[Response Begins]

The results of the empirical validity testing demonstrate a correlation between all components of the measure and the overall performance of defect free care. Most elements have a moderate correlation to the overall composite measure, with some having a very strong (e.g., cardiac rehabilitation referral) and weaker (e.g., door-to-needle time) correlations. While there is variation across all components, we feel all components are important aspects in delivering defect free care. The inclusion of all variables is also explained through achieving face validity.

All components have been identified as critical for patient's improved outcome, thus remain in the Defect Free Care measure. As mentioned earlier, in alignment with the 2017 STEMI Performance measures publication, the three measures from the earlier Defect Free Care composite were removed or modified (Statin Prescribed at Discharge; Time to Primary PCI; and Adult Smoking Cessation Advice Counseling). There were "topped-out" measures.

Adult Smoking Cessation Advice Counseling: This measure is being retired because perfect scores are consistently achieved and the measure appears to have reached a ceiling effect. Therefore, given absence of room for further improvement, the writing committee opted to omit this measure from the inpatient performance measure set for AMI (realizing also that a separate outpatient CAD measure set will likely address smoking cessation advice/counseling).

Methodology changes were made to **Statin Prescribed at Discharge** and **Time to Primary PCI**, prompting a new metric naming convention. The changes were made to reflect the new evidence and updated guideline recommendations, to strengthen the measure construct, or to expand the measures to include new proven pharmacotherapies.

Statin Prescribed at Discharge: This measure was removed from the composite and revised to reflect the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults, which recommended statin use for all patients with established atherosclerotic cardiovascular disease, including patients with AMI. Thus, the new measure replacing it is: High Intensity Statin at Discharge.

Time to Primary PCI: The measure has been modified from the original application, where it had measured from "door to balloon" time. The methodology has been updated to now start the timing from the moment of first medical contact. Thus a new measure was added to the composite, "first medical contact to device time".

[Response Ends]

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.

[Response Begins]

This is an all-or-none composite, thus no empirical analyses pertinent to aggregations or weighting were conducted. The components mentioned throughout the application are part of the composite measure indicator definition, not the composite of different measures.

While only some of the components in the composite may not have had a moderate to strong correlation to the overall composite, all are based on Class IA or B recommendations and represent optimal clinical care for patients admitted for STEMI or NSTEMI treatment.

[Response Ends]

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.

[Response Begins]

This is an all-or-none composite, thus no empirical analyses pertinent to aggregations or weighting were conducted. The components mentioned throughout the application are part of the composite measure indicator definition, not the composite of different measures. 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.

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

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

[Response Begins]

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)

[Response Ends]

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.

[Response Begins]

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

[Response Ends]

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.

[Response Begins]

N/A. All data elements are from an electrotonic source (registry).

[Response Ends]

3.04. Describe any efforts to develop an eCQM.

[Response Begins]

No efforts to develop an eCQM are underway at the time of submission (Fall 2022).

[Response Ends]

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.

[Response Begins]

There were no difficulties that were noted with regard to data collection, availability of data, missing data, and the frequency of data

collection, same patient confidentiality, time and cost of data collection, for other feasibility/implementation issues. However, the

NCDR has a robust data collection process as outlined below.

Participating hospitals report patient demographics, medical history, risk factors, hospital presentation, initial cardiac status,

procedural details, medications, laboratory values and in-hospital outcomes. The majority of the 19 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.

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.

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 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.

There is no sampling of patient data allowed within the contractual terms of participation in the CPMI Registry in NCDR. The registry

is designed to include 100 percent of consecutive adult patients who have an acute MI at participating institutions. Section 2.b of

the NCDR Master Agreement with participants includes 'Participant Responsibilities': "b. Use of ACCF Data Set and ACCF-Approved

Software. Participant will submit a data record on each patient who receives medical care and who is eligible for inclusion in the

Registries in which Participant is participating under this Agreement." Adult patients, ages 18 years and older, who have an acute MI.

Patients are selected for inclusion by reviewing existing medical records and no direct interaction with the patient will be required

outside of the normal course of care. There will be no discrimination or bias with respect to inclusion on the basis of sex, race, or

religion.

Patient confidentiality is preserved as the data are in aggregate form. The CPMI Registry dataset, comprised of approximately 157,

data elements was created by a panel of experts using available ACC-AHA guidelines and performance measures, data elements and

definitions, and other evidentiary sources. Private health information (PHI), such as social security number, is collected. The intent

for collection of PHI is to allow for registry interoperability and the potential for future generation of patient-level drill downs in

Quality and Outcomes Reports. Registry sites can opt out of transmitting direct identifiers to the NCDR, however, so inclusion of

direct identifiers in the registry is at the discretion of the registry participants themselves. When using the NCDR web-based data

collection tool, direct identifiers are entered but a partition between the data collection process and the data warehouse maintains

the direct identifiers separate from the analysis datasets. The minimum level of PHI transmitted to the ACCF when a participant opts out of submitting direct identifiers meets the definition of a Limited Dataset as such term is defined by the Health Insurance Portability and Accountability Act of 1996.

Data collection within the NCDR conforms to laws regarding protected health information. Patient confidentiality is of utmost

concern with all metrics. The proposed measure does not include a patient survey. Physician and/or institutional confidentiality is

maintained by de-identified dashboard reports. There is no added procedural risk to patients through involvement in the CPMI

Registry. No testing, time, risk, or procedures beyond those required for routine care will be imposed. The primary risk associated

with this measure is the potential for a breach of patient confidentiality. The ACCF has established a robust plan for ensuring

appropriate and commercially reasonable physical, technical, and administrative safeguards are in place to mitigate such risks.

Data are maintained on secure servers with appropriate safeguards in place. The project team periodically reviews all activities

involving protected health information to ensure that such safeguards including standard operating procedures are being followed.

The procedure for notifying the ACCF of any breach of confidentiality and immediate mitigation standards that need to be followed

is communicated to participants. ACCF limits access to Protected Health Information, and to equipment, systems, and networks that

contain, transmit, process or store Protected Health Information, to employees who need to access the PHI for purposes of

performing ACCF's obligations to participants who are in a contractual relationship with the ACCF. All PHI are stored in a secure

facility or secure area within ACCF's facilities which has separate physical controls to limit access, such as locks or physical tokens.

The secured areas are monitored 24 hours per day, 7 days per week, either by employees or agents of ACCF by video surveillance, or

by intrusion detection systems.

Each participant who has access to the NCDR website must have a unique identifier. The password protected webpages have

implemented inactivity time-outs. Encryption of wireless network data transmission and authentication of wireless devices

containing NCDR Participant's information ACCF's network is required. Protected Health Information may only be transmitted off of

ACCF's premises to approved parties, which shall mean: A subcontractor who has agreed to be bound by the terms of the Business

Associate Agreement between the ACCF and the NCDR Participant.

[Response Ends]

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

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.

[Response Begins]

This measure was developed and designed to be used across other organizations and by other measure implementers. The fee and licensing information include below is specific to NCDR program requirements:

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. For calendar year

2021, the annual pricing for hospitals, NCDR Analytic and Reporting Services, and licensing of measure specifications ranges from $2,900-$50,000.

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.

There is no added procedural risk to patients through their hospital's involvement in the CPMI Registry. No testing, time, risk, or procedures beyond those required for routine care will be imposed.

[Response Ends]

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

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.

NQF-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**

[Response Begins]

Public Reporting

[Public Reporting Please Explain]

ACC's National Cardiovascular Data Registry (NCDR) 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.

ACC Patient Navigator: The ACC has launched a national scale program, the Patient Navigator Program: Focus MI, to improve the care and outcomes of

myocardial infarction patients and further reduce avoidable readmissions beyond 30 days. The ACC CPMI registry is a part of this

program.

NCDR Public Reporting

https://cvquality.acc.org/ncdr-home/acc-public-reporting

NCDR Chest Pain MI

https://cvquality.acc.org/NCDR-Home/registries/hospital-registries/chest-pain-miregistry

ACC Patient Navigator

https://cvquality.acc.org/initiatives/patient-navigator

Professional Certification or Recognition Program

[Professional Certification or Recognition Program Please Explain]

The Chest Pain – MI Registry™ Performance Achievement Award program recognizes hospitals participating in the registry who have demonstrated sustained, top level performance in quality of care and adherence to guideline recommendations. Through full participation in the registry, hospitals engage in a robust quality improvement process, using data to drive improvements and positively impact patient outcomes for heart attack patients. The Performance Achievement Award Program uses the NQF endorsed Defect Free Care to consider the performance of hospitals in the Chest Pain – MI Registry. All NCDR participating hospitals can see their hospital profile on Find Your Heart a Home. Patients and caregivers use this website to compare hospitals that are affiliated with the American College of Cardiology. Hospitals that receive the Performance Achievement Award will see their level displayed on this site under their hospital profile.

Professional Certification or Recognition Program

https://cvquality.acc.org/NCDR-Home/registries/hospital-registries/actionregistry/action-registry-performance-achievement-awards

Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

[Quality Improvement with Benchmarking (external benchmarking to multiple organizations) Please Explain]

NCDR ChestPain-MI Registry: The CPMI Registry captures patients who are diagnosed with STEMI and NSTEMI at participating hospitals. 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. There are over 850

participating sites.

This measure is in use as part of the Bundle Payments for Care Improvement program. The Centers for Medicare & Medicaid Services (CMS) Bundled Payments for Care Improvement (BPCI) Advanced program is a voluntary model that incentivizes participants to improve quality of care and care coordination and to reduce the cost of care in up to 34 outpatient and inpatient clinical episodes, which are listed on the CMS Innovation Center website. BPCI Advanced qualifies as an advanced alternative payment (APM) model under the CMS Quality Payment Program. Clinicians who participate in this model and meet relevant payment or patient thresholds can also qualify for the Advanced APM bonus and be exempt from the Merit-Based Incentive Payment System (MIPS). Model Year 4 (beginning Jan. 1, 2021) provides participants with an opportunity to report quality performance on a combination of up to five claims-based and registry-based measures, including several ACC quality measures, for each clinical episode.

[Response Ends]

4a.02. Check all planned uses.

[Response Begins]

Public reporting

[Response Ends]

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?

[Response Begins]

N/A

[Response Ends]

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.

[Response Begins]

N/A

[Response Ends]

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.

[Response Begins]

Performance results are distributed to all CPMI 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.

[Response Ends]

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.

[Response Begins]

Results are provided as part of quarterly performance report which includes a rolling 4 quarters of data.

Participating hospitals in the CPMI registry report on the following: STEMI and NSTEMI patient demographics; provider and facility characteristics; adverse event rates; AMI performance measures and select quality measures and outcomes; medication dosing errors and risk adjusted metrics; transfer facility therapies and reperfusion strategies; 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.

[Response Ends]

4a.07. Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.

[Response Begins]

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.

[Response Ends]

4a.08. Summarize the feedback obtained from those being measured.

[Response Begins]

ACC has Clinical Quality Associates available to all registry participants to answer questions, record feedback and troubleshoot data collection issues. Below is a summary of the feedback received for this measure.

1. The individual performance measure, Metric 21 (Cardiac Rehabilitation Referral), was updated based on the 2018 ACC/AHA Clinical Performance and Quality Measures for Cardiac Rehabilitation. The change requires the transmission of the referral to the cardiac rehabilitation center. Prompting facilities to develop a quality improvement initiative to improve their compliance.
2. It takes great perseverance from the facilities to obtain the desired score with an 'All or nothing' measurement methodology.
3. Metric 2 (DFC) provides insight into care provided into each individual patient with the facility's clear goal of providing perfect care for the AMI patient population.

4. Metric 2 (DFC) is used in the evaluation of the Performance Achievement Award program, providing evidence and affirmation to their community of the facility's stellar care.
5. Metric 2 (DFC) provides transparency to the public using a four-star rating system (Public Reporting).
6. Facilities state the measure is easily interpreted.
7. Providing a clear path to process improvement and/or tangible evidence of perfect care provided.
8. Facilities have communicated that Metric 2 (DFC) was instrumental in documentation improvement process.
9. Metric 2 (DFC) provides an 'at a glance' view of the fourteen individual measures and enables the facility to identify quickly which care process require further evaluation.

[Response Ends]

4a.09. Summarize the feedback obtained from other users.

[Response Begins]

No other feedback obtained other that listed in 4a.08.

[Response Ends]

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.

[Response Begins]

Based on feedback from the participants regarding measures, we identify updates required for denominator exceptions and exclusions.

[Response Ends]

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.

[Response Begins]

Performance rates for the composite measure have increased over time, corresponding to a growing denominator.

[Response Ends]

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

[Response Begins]

There were no unintended consequences to individuals or populations identified.

[Response Ends]

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

[Response Begins]

Sites have reported being able to develop process improvement mechanisms and improve their documentation practices as a result of implementing this measure.

[Response Ends]

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

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 NQF endorsed. Please review and update questions 5.01, 5.02, and 5.03 accordingly.

5.01. Search and select all NQF-endorsed related measures (conceptually, either same measure focus or target population).

(Can search and select measures.)

[Response Begins]

3613e: Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

[Response Ends]

5.02. Search and select all NQF-endorsed competing measures (conceptually, the measures have both the same measure focus or target population).

(Can search and select measures.)

[Response Begins]

3613e: Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

0132: Aspirin at arrival for acute myocardial infarction (AMI)

0137: ACEI or ARB for left ventricular systolic dysfunction- Acute Myocardial Infarction (AMI) Patients

0142: Aspirin prescribed at discharge for AMI

0160: Beta-blocker prescribed at discharge for AMI

0163: Primary PCI received within 90 minutes of hospital arrival

0288: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival

0639: Statin Prescribed at Discharge

0642: Cardiac Rehabilitation Patient Referral From an Inpatient Setting

[Response Ends]

5.03. If there are related or competing measures to this measure, but they are not NQF-endorsed, please indicate the measure title and steward.

[Response Begins]

Cannot save measures above.

These individual measures of the proposed composite measure have been previously endorsed:

0132 Aspirin on arrival for acute MI

0137 ACEI or ARB for left ventricular systolic dysfunction AMI patients

0142 Aspirin prescribed at discharge for AMI

0160 Beta-blocker prescribed at discharge for AMI

0163 Primary PCI received within 90 min of hospital arrival

0288 Fibrinolytic therapy received within 30 minutes of ED arrival

0639 Statin prescribed a discharge

0642 Cardiac rehabilitation patient referral from an inpatient setting

Not previously endorsed measures that are part of the proposed composite measure:

Evaluation of LVEF

Reperfusion Therapy

Adult smoking cessation/counseling at discharge

[Response Ends]

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

[Response Begins]

Yes

[Response Ends]

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

[Response Begins]

Specifications are harmonized to the extent possible.

[Response Ends]

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.

[Response Begins]

While the composite measure has no competing measure, there are competing measures at the individual level. However, the composite measure is superior because it encompasses the entire spectrum of care for MI patients.

[Response Ends]

Appendix

Supplemental materials may be provided in an appendix. :

Available in attached file

Contact Information

Measure Steward (Intellectual Property Owner): American College of Cardiology

Measure Steward Point of Contact: Mccoy, Kristina, kblankinship@acc.org
Mayfield, Jarrott, jmayfield@acc.org

Measure Developer if different from Measure Steward: American College of Cardiology
Measure Developer Point(s) of Contact: Mccoy, Kristina, kblankinship@acc.org
Mccoy, Kristina, kblankinship@acc.org
Mayfield, Jarrott, jmayfield@acc.org

Additional Information

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.

[Response Begins]

Available in attached file

[Response Ends]

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

Describe the members' role in measure development.

[Response Begins]

At the time of initial endorsement of this measure, the following groups oversaw the development of this measure:

SQOC—Leadership committee that oversaw broad issues and approved submission of given metric to NQF.

Fred Masoudi, David Malenka, Thomas Tsai, Matt Reynolds, David Shahian, John Windle, Fred Resnic, John Moore, Deepak Bhatt, James Tcheng, Jeptha Curtis, Paul Chan, Matt Roe, John Rumsfeld

Clinical SubWorkgroup-oversaw NQF application components

Jeptha Curtis-chair

Deepak Bhatt, James Jollis, John. Rumsfeld, Fred. Masoudi

ChestPain-MI (formerly ACTION) Registry Committee-Provides strategic direction for the Registry and monitors research and clinical activities.

James Jollis, Deepak Bhatt, Robert McNamara, Ivan Rokos, Michael Ross, Michael Kontos, Steve Manoukian, Harper Stone, Harry Dauerman, Gregg Fonarow, Martha Radford, James de Lemos, Tracy Wang

[Response Ends]

3. Indicate the year the measure was first released.

[Response Begins]

2014

[Response Ends]

4. Indicate the month and year of the most recent revision.

[Response Begins]

1/2021

[Response Ends]

5. Indicate the frequency of review, or an update schedule, for this measure.

[Response Begins]

With dataset revisions and based on new evidence.

[Response Ends]

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

[Response Begins]

This measure is reviewed continuously and updated to reflect current guidelines and when the CPMI registry undergoes data set updates.

[Response Ends]

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

[Response Begins]

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[Response Ends]

8. State any disclaimers, if applicable. Otherwise, indicate "N/A".

[Response Begins]

N/A

[Response Ends]

9. Provide any additional information or comments, if applicable. Otherwise, indicate "N/A".

[Response Begins]

The American College of Cardiology thanks NQF for the opportunity to submit and their continued partnership in the field of quality and measurement.

[Response Ends]