NATIONAL QUALITY FORUM

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Brief Measure Information

NQF #: 0290

Corresponding Measures:

De.2. Measure Title: Median Time to Transfer to Another Facility for Acute Coronary Intervention

Co.1.1. Measure Steward: Centers for Medicare and Medicaid Services

De.3. Brief Description of Measure: This measure calculates the median time from emergency department arrival to time of transfer to another facility for acute coronary intervention.

1b.1. Developer Rationale: The purpose of this measure is to document hospital performance for this evidence-based practice for patients with coronary interventions. The American Heart Association (AHA) estimates that 790,000 people experience a heart attack, or myocardial infarction, in the United States each year (Benjamin, 2017). Timely transfer for acute coronary intervention (ACI), such as a percutaneous coronary intervention (PCI), is associated with improved patient outcomes (Bucholz, 2016; Martin, 2016). National clinical practice guidelines support initiating PCI within 120 minutes or less (measured through door-to-balloon time) for ST-segment elevation myocardial infarction (STEMI) patients who need to be transferred from a non-PCI capable hospital to one at which PCI can be performed (O'Gara, 2013).

REFERENCES:

1) Benjamin E.J., Blaha M.J., Chiuve S.E., Cushman M., Das S.R., Deo R., et al. Heart Disease and Stroke Statistics—2017 Update: A Report From the American Heart Association. 2017; 135:e1–e458.

2) Bucholz E. M., N. M. Butala, S. L. Normand, Y. Wang, and H. M. Krumholz. Association of Guideline-Based Admission Treatments and Life Expectancy After Myocardial Infarction in Elderly Medicare Beneficiaries. Journal of the American College of Cardiology, 2015; 67:20: 2378–2391.

3) Martin L., M. Murphy, A. Scanlon, D. Clark, and O. Farouque. "The Impact On Long Term Health Outcomes for STEMI Patients During a Period of Process Change to Reduce Door to Balloon Time." European Journal of Cardiovascular Nursing, vol. 15, no. 3, 2016, pp. e37–44.

4) O'Gara PT, Kusher FG, Ascheim DD, Casey DE, Chung MK, Lemos JA, Ettinger SM, et al. 2013ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction: Executive Summary: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation, 2013; 127:1-88. Published online December 17, 2012.

S.4. Numerator Statement: This measure is reported as a continuous variable statement: Time (in minutes) from emergency department arrival to transfer to another facility for acute coronary intervention.

S.6. Denominator Statement: This measure is reported as a continuous variable statement: Time (in minutes) from emergency department arrival to transfer to another facility for acute coronary intervention.

S.8. Denominator Exclusions: Excluded Populations:

• Patients less than 18 years of age; or

• Patients receiving fibrinolytic therapy administration.

De.1. Measure Type: Process

S.17. Data Source: Electronic Health Records, Paper Medical Records

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Nov 15, 2007 **Most Recent Endorsement Date:** Dec 09, 2016

IF this measure is included in a composite, NQF Composite#/title:

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

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? Not applicable; this measure is not a paired or grouped measure.

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement endorsed measures are evaluated periodically to ensure that the measures still meets the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

Criteria 1: Importance to Measure and Report

1a. Evidence

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence since the prior evaluation.

1a. Evidence. The evidence requirements for a *structure, process or intermediate outcome* measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

- **Systematic Review of the evidence specific to this measure?** ☒ **Yes** ☐ **No**
- **Quality, Quantity and Consistency of evidence provided?** ☒ **Yes** ☐ **No**
- **Evidence graded?** ☒ **Yes** ☐ **No**

Summary of prior review in 2016

- The developer provided steps between the measure focus and the health outcome. Decreasing transfer time in STEMI patients requiring an acute coronary intervention from a non-PCI-capable hospital to a PCI-capable hospital has the potential to lead to reduced door-to-balloon time, which leads to a decrease in mortality.
- The developer provided the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction that includes two recommendations for the transfer of patients who require primary PCI, from a non-PCI-capable hospital to a PCI-capable hospital, in cases where primary PCI can be performed within 120 minutes of first medical contact (FMC):

    - "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." (**Class I, Level of Evidence**: **B**)
    - "Immediate transfer to a PCI-capable hospital for coronary angiography is recommended for suitable patients with STEMI who develop cardiogenic shock or acute severe HF, irrespective of the time delay from MI onset." (**Class I, Level of Evidence: B**)
- The developer provided a systematic review of the body of the evidence supporting the timely transfer of STEMI patients requiring a PCI. The details of the Quality, Quantity, and Consistency of the evidence provided was associated with the guideline (single randomized trial or non-randomized studies).

Changes to evidence from last review

☐ **The developer attests that there have been no changes in the evidence since the measure was last evaluated.**

☒ **The developer provided updated evidence for this measure:**

Updates:

- There was a focused update published in the Journal of the American College of Cardiology (2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction). This update does not change the recommendations provided in support of this measure.
- The developer identified 14 new articles that were published since the systematic review of the body of evidence (2016-2019).
- The developer states these articles are aligned with the existing evidence.

Questions for the Committee:

- The evidence provided by the developer is updated and directionally the same compared to that for the previous NQF review. Does the Committee agree there is no need for repeat discussion and vote on Evidence?

Guidance from the Evidence Algorithm

Process measure based on a systematic review (Box 3) → QQC presented (Box 4) → Quantity: low; Quality: moderate; Consistency: moderate (Box 5b) → Moderate rating

Preliminary rating for evidence: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

Maintenance measures – increased emphasis on gap and variation

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- Results appear to have stayed consistent from 2010 through 2018.
- The developer notes that "women, older patients, non-White patients, and Hispanic patients had longer median times to transfer than their male, younger, White, non-Hispanic counterparts."

Summary of performance data from 2016 review cycle:

In 2010-2011 a total of 421 facilities, representing 8,008 ED encounters, had results published on Hospital Compare. Data from 2010-11 indicated a median facility score of 56 minutes, with an interquartile range (IQR) of 45-70 minutes. In 2014-15, 425 facilities, representing 8,166 ED encounters had results published on Hospital Compare. Data from 2014-15 indicated a median facility score of 54 minutes, with an IQR of 42-69 minutes.

Updated performance data:

Encounter-level distribution of measure scores, median score is 55, IQR of 38-90 minutes

	Mean	**Min**	**5%**	**10%**	**25%**	**50%**	**75%**	**90%**	**95%**	**Max**
2018	85	1	22	27	38	55	90	186	274	521

Measure scores are in minutes, 459 facilities, representing 9,050 ED encounters, calendar year 2018, data from the CMS Clinical Data Warehouse

Facility-level distribution of measure scores, median score is 54, IQR of 43-70 minutes

	Mean	**Std Dev**	**Min**	**10%**	**25%**	**50%**	**75%**	**90%**	**Max**
2018	64	40	18	34	43	54	70	92	373

Measure scores are in minutes, 450 facilities, calendar year 2018, data from the CMS Clinical Data Warehouse

Disparities

Measure score by demographic characteristics

Characteristics	**Median Minutes**	**Mean Minutes**	**Encounters**
Age			
18-64	52	78	5,129
65+	59	95	3,921
Gender			
Male	52	80	6,180
Female	62	98	2,869
Race			
Black or African American	64	102	714
White	53	81	7,582
Other	76	148	273
Unknown	61	97	481
Ethnicity			
Hispanic or Latino	62	93	555
Non-Hispanic	54	85	8,495

Measure scores are in minutes, calendar year 2018, data from the CMS Clinical Data Warehouse

Questions for the Committee:

- Do the data presented demonstrate that there continues to be variation with STEMI patients that arrive at the ED and require transfer to another facility for acute coronary intervention? Is there opportunity for improvement?
- Is a national performance measure still warranted?
- Are you aware of evidence that additional disparities exist in this area of healthcare?

Preliminary rating for opportunity for improvement: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence

- Adequate evidence though not of strongest level
- yes it does
- no comments
- Existing Measure. Main evidence is 2013 ACCF/AHA Guideline for STEMI. Update - 2015 Focused Update on PCI in STEMI and 14 new articles aligning with previous data. I would rate evidence as High
- Strong evidence, but not that much quantity-wise. Moderate.
- There is some evidence that rapid transfer improves outcomes (there is better evidence that bypassing non-PCI hospitals to go directly to available PCI hospital improves outcomes)
- Agree the evidence is valid and does not need a deeper dialogue
- moderate
- Moderate evidence. No need to discuss
- no concerns about evidence

1b. Performance Gap

- IQR of 25-30 mins is notable
- longer transfer time and loner treatment times
- no comments
- There doesn't seem to be a significant change in median time to transfer since the last endorsement but there is a huge range of time to transfer. To me this indicates that there is still room for improvement. There are disparities for women and minorities. Agree when taken as a whole, the opportunity is moderate.
- Some gap, but not substantial. Moderate.
- Still a performance gap
- Seems to still be room for improvement within both the average and within differences based on disparities
- moderate
- There is a clear performance gap overall and medians vary by 10 to 20 minutes. differences in means are greater
- performance is fairly stable over the years. While it is hard to tell whether performance can still be improved, even maintaining current levels takes substantial effort. Disparities and variability persist.

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

2c. For composite measures: empirical analysis support composite approach

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. Reliability testing demonstrates if 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 enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Composite measures only:

2d. Empirical analysis to support composite construction. Empirical analysis should demonstrate that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct.

Complex measure evaluated by Scientific Methods Panel? ☐ **Yes** ☒ **No**

Evaluators: NQF Staff

Scientific Acceptability: Preliminary Analysis

Reliability

- Reliability was calculated using a signal-to-noise analysis with an ICC approach. Reliability was calculated across facilities and for small, medium, and large facilities.

	Reliability Statistic (ICC)	**95% Confidence Interval**
Overall (across facilities), N = 459	0.74	0.69-0.78
Small facilities (11-14 cases), N = 163	0.70	0.61-0.77
Medium facilities (15-20 cases), N = 148	0.77	0.69-0.83
Large facilities (21-113 cases), N = 148	0.89	0.85-0.92

- The reliability testing indicates moderate to good reliability for all sizes of facilities included in the measure.

Validity

- The developer states that this measure uses exclusion to arrive at a relevant patient population for measure calculation rather than as clinical exclusions per se. For this reason, it states that calculation with and without exclusions would be inappropriate.
- The developer provides an analysis of exclusion prevalence. The overwhelming majority of exclusions (61% of encounters) are due to "initial ECG interpretation." The proportion of these exclusions varies notably across facilities.

- Data element validity was established by assessing the level of agreement between facility abstraction and auditor abstraction (through the CMS Clinical Data Abstraction Center). Two methods were used to estimate the agreement: Kappa statistics (for categorical variables) and Pearson correlation coefficients (for continuous variables).
- All critical data elements were included in the testing. For categorical data elements, the Kappa statistics ranged from 0.33 to 1.0. All values indicated substantial (or higher) agreement with the exception of Transfer for Acute Coronary Intervention (0.33 -> fair agreement). For continuous data elements, the Pearson correlation coefficients ranged from 0.97 to 1.00, with all values indicating almost perfect agreement.
- The developer states it has seen improvement in Kappa values for two critical data elements ("initial ECG interpretation" and "reason for no fibrinolytic administration") since the previous submission. It interprets this to suggest improvement in documentation by emergency departments.

Questions for the Committee regarding reliability:

- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- Does the large number of exclusions due to "initial ECG interpretation" represent a significant threat to validity of the measure results?

Preliminary rating for reliability:	☐ **High**	☒ **Moderate**	☐ **Low**	☐ **Insufficient**
Preliminary rating for validity:	☐ **High**	☒ **Moderate**	☐ **Low**	☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a. Reliability

- Unclear how reliable abstracted time calculations are for initial ER presentation and transfer time/arrival time at second facility.
- yes
- no comments
- The "initial ECG interpretation" as an exclusion is vague. The responses to the question are "yes" or "no". They are included if yes. Is that yes the ECG was interpreted or yes the ECG was interpreted as STEMI? The measure worksheet doesn't say. The ICD-10 would help clarify but accepted codes are specified on page 70 of the submission and include non-specific cardiac operative codes. Worksheet specifies in S.14 that all cases are run through AMI Hospital Outpatient Algorithm
- Good specifications
- well documented
- No major concerns on reliability
- moderate
- No concerns
- no concerns
- More concern with underlying data accuracy around hospital transfer times
- yes

- none
- Signal to noise testing with reliability stat ranging from 0.7 to 0.89 (av 0.74) and larger facilities with higher reliability stat
- ICC approach with 0.74 overall, so moderate-to-high.
- Not sure why those with fibrinolytic contraindications are excluded
- Aligned with NQF
- no
- no concerns - moderate
- no

2b. Validity

- No
- yes
- none
- While the measure is related to time only there are comments about other data elements such as "initial ECG interpretation" and "reason for no fibrinolytic". Kappas for data elements ranged from 1.0 for ICD-10 and E/M codes to .33 for transfer for ACI. Most Kappas were high indicating good to excellent agreement between abstractors.
- Mix of low and high correlation (Kappa and Pearson). Moderate.
- No
- Aligned with NQF
- no
- No particular concerns
- No
- Hospital transfer times - unclear to me accuracy on these data points from abstracted data
- yes
- no comments
- Initial ECG interpretation as an exclusion concerned me at 1st but if the patient does not have ST elevation on the initial ECG, they should be excluded. Timely PCI for STEMI is the purpose of this measure.
- None.
- Missing data is a concern for ER cases. 2b7.2 is referred to but not in any of the documents
- Some aspects, like iniitla ECG interpretation seem vague and may be a threat to validity
- moderate
- No
- no concerns
- no concerns
- no
- no comment
- There was no risk adjustment
- Unknown.
- NA

- would like to see risk adjustment for this measure
- no
- This is not risk adjusted. No other threats.
- no concerns in general. the developer may need to explain what "initial ECG interpretation" means. I assume no evidence for STEMI on the ECG, which would not really be an exclusion.

Criterion 3. Feasibility

Maintenance measures – no change in emphasis – implementation issues may be more prominent

3. Feasibility is the 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.

The data elements for this measure are routinely generated as part of care delivery; however, they are not all captured in structured data fields, making conversation to an electronic or digital measure challenging. In particular, the data elements Initial ECG Interpretation, Reason for Not Administering Fibrinolytic Therapy and Transfer for Acute Coronary Intervention are not generally in structured fields. Application of the measure algorithm currently requires abstraction by someone other than the person obtaining the original information.

The developer reports that three of five members of the AMI and Stroke expert work group agreed that "the practical aspects of reporting this chart-abstracted measure do not place undue burden on facilities that collect the data."

Questions for the Committee:

- Is the data collection strategy feasible?

Preliminary rating for feasibility: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

- No concerns.
- none
- no comments
- Developers cite challenges related to creating an EHR version of the indicator - specific example is Reason for Not Administering Thrombolytic - data currently located in unstructured fields of the patient record. Initial ECG interpretation and Transfer for Acute Coronary Intervention will require specific vendor adaptations to capture this information (p. 100). AMI and Stroke Expert Work Group indicted that certain data element availability is highly dependent on the EHR used by each facility.
- Moderate based on information provided.
- Feasible for smallish numbers of cases per institution
- concerned about the feasibility of non-structured data - espeically when one of them 'initial ecg interpretation' may be a threat to validity
- moderate
- feasibility is moderate because manual abstraction is required.
- no concerns

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported? ☒ **Yes** ☐ **No**

Current use in an accountability program? ☒ **Yes** ☐ **No** ☐ **UNCLEAR**

Accountability program details

- Publicly reported on Hospital Compare
- Currently in use in CMS's Hospital Outpatient Quality Reporting Program

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- Those being measured receive quarterly results through CMS's Hospital Compare website.
- Stakeholders may provide feedback via the ServiceNow Q&A tool on QualityNet. They may also submit comments through the annual rulemaking process for the Outpatient Prospective Payment System (OPPS). The developer states it has received no feedback to date and no comments during calendar years 2016-2019.
- The developer indicates it is willing to consider feedback and has a process for incorporating changes into the measure.

Additional Feedback: No additional feedback.

Questions for the Committee:

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- The data presented in the previous submission and the data submitted in this submission appear to have remained stable over time.
    - Data from 2010-11 indicated a median facility score of 56 minutes, with an interquartile range (IQR) of 45-70 minutes.
    - Data from 2014-15 indicated a median facility score of 54 minutes, with an IQR of 42-69 minutes.
    - Data from 2018 indicate a median facility score of 54 minutes, with an IQR of 43-70 minutes.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- The developer states no unintended consequences or findings have been identified.

Potential harms

- The developer does not report any potential harms.

Additional Feedback: No additional feedback

***Questions for the Committee**:*

- Are you aware of any unintended consequences related to this measure?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability and use: ☐ **High** ☐ **Moderate** ☒ **Low** ☐ **Insufficient**

RATIONALE: Based on performance information provided, it is not clear that care, as measured by this measure, has been improving.

Committee Pre-evaluation Comments:
Criteria 4: Usability and Use

4a. Use

- no issues
- no
- no comments
- Currently publicly reported (Hospital Compare). Feedback obtained via ServiceNow Q&A tool and a literature review performed on any proposed revisions. Can also submit feedback via Outpt Prospective Payment System annual rulemaking process.
- Pass. Used in two accountability programs.
- Appropriate.
- major use re hospital compare
- moderate
- The measure is publicly reported and used in accountability programs
- no concerns

4b. Usability

- No changes in performance for last decade despite public reporting. Usability appears low

- none
- no comments
- Existing measure in use since 2009. No unintended consequences noted
- Moderate to low.
- Potential harms are related to inappropriate interventions to meet the standard of 120 or 90 minutes.
- with noted disparities, a risk adjusted model may be more beneficial, espcially with the significance of hospital compare implementation
- moderate
- No harms have been identified but times have not declined since 2010
- no concerns

Criterion 5: Related and Competing Measures

Related or competing measures
Related measure: 0288 Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival

Harmonization
NQF 0290 and 0288 are related measures with the same patient population but different outcome focus. The target patient population is harmonized.

Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

- No issues
- yes
- no
- 0288 Fibrinolytic in 30 min of ED arrival - focus of this measure is not the same as transfer for PCI. Initial population is the same. No competing measures
- Related measures, but harmonized.
- No issues.
- 0288 Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
- harmonized to the degree possible

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: June 12, 2020

- Comment by: **Federation of American Hospitals**

  The Federation of American Hospitals (FAH) appreciates the opportunity to comment on this measure prior to the Standing Committee's evaluation. Specifically, the FAH asks the committee to consider whether a measure that has been endorsed since 2007 should be required to submit testing on the measure score validity and not just data element validity. For example, it would be

useful to understand if this process measure is either correlated to other performance measures, distinguishes differences in quality between hospitals, or is evaluated through some other empiric approach to demonstrate that it is a valid indicator of quality. Given the generally high performance scores and the potential burden of data collection, the FAH believes that it is important that this question be addressed for measures that are widely used over many years.

- **No NQF Members have submitted support/non-support choices as of this date.**

Scientific Acceptability: Preliminary Analysis Form

Measure Number: 0290

Measure Title: Median Time to Transfer to Another Facility for Acute Coronary Intervention

Type of measure:

☒ **Process** ☐ **Process: Appropriate Use** ☐ **Structure** ☐ **Efficiency** ☐ **Cost/Resource Use**
☐ **Outcome** ☐ **Outcome: PRO-PM** ☐ **Outcome: Intermediate Clinical Outcome** ☐ **Composite**

Data Source:

☐ **Claims** ☐ **Electronic Health Data** ☒ **Electronic Health Records** ☐ **Management Data**
☐ **Assessment Data** ☒ **Paper Medical Records** ☐ **Instrument-Based Data** ☐ **Registry Data**
☐ **Enrollment Data** ☐ **Other**

Level of Analysis:

☐ **Clinician: Group/Practice** ☐ **Clinician: Individual** ☒ **Facility** ☐ **Health Plan**
☐ **Population: Community, County or City** ☐ **Population: Regional and State**
☐ **Integrated Delivery System** ☐ **Other**

Measure is:

☐ **New** ☒ **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?** ☒ **Yes** ☐ **No**

   Submission document: "MIF_xxxx" document, items S.1-S.22

2. **Briefly summarize any concerns about the measure specifications.**

   No concerns.

RELIABILITY: TESTING

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

3. **Reliability testing level** ☒ **Measure score** ☐ **Data element** ☐ **Neither**
4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure** ☒ **Yes** ☐ **No**

5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of patient-level data conducted?

   N/A

6. **Assess the method(s) used for reliability testing**

   Submission document: Testing attachment, section 2a2.2

   Reliability was calculated using a signal-to-noise analysis with an ICC approach. Reliability was calculated across facilities and for small, medium, and large facilities.

7. **Assess the results of reliability testing**

   Submission document: Testing attachment, section 2a2.3

	Reliability Statistic (ICC)	**95% Confidence Interval**
Overall (across facilities), N = 459	0.74	0.69-0.78
Small facilities (11-14 cases), N = 163	0.70	0.61-0.77
Medium facilities (15-20 cases), N = 148	0.77	0.69-0.83
Large facilities (21-113 cases), N = 148	0.89	0.85-0.92

   The reliability testing indicates moderate to good reliability for all sizes of facilities included in the measure.

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☐ **Not applicable** (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

   Submission document: Testing attachment, section 2a2.2

   ☐ **Yes**

   ☐ **No**

   ☒ **Not applicable** (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and all testing results):

    ☐ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has not been conducted)

    ☐ **Low** (NOTE: Should rate LOW if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

    ☐ **Insufficient** (NOTE: Should rate INSUFFICIENT if you believe you do not have the information you need to make a rating decision)

11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**

    Precise unambiguous specifications (Box 1) → Empirical reliability testing (Box 2) → Testing conducted at score level (Box 4) → Method described and appropriate (Box 5) → Results demonstrate moderate to good reliability (Box 6b) → Moderate rating

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. **Please describe any concerns you have with measure exclusions.**

    Submission document: Testing attachment, section 2b2.

    The developer states that this measure uses exclusion to arrive at a relevant patient population for measure calculation rather than as clinical exclusions per se. For this reason, it states that calculation with and without exclusions would be inappropriate.

    The developer provides an analysis of exclusion prevalence. The overwhelming majority of exclusions (61% of encounters) are due to the Initial ECG Interpretation data element. The proportion of these exclusions varies notably across facilities.

13. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

    Submission document: Testing attachment, section 2b4.

    No concerns.

14. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**
    Submission document: Testing attachment, section 2b5.
    Not applicable.

15. **Please describe any concerns you have regarding missing data.**

    Submission document: Testing attachment, section 2b6.

    No concerns.

16. **Risk Adjustment**

    16a. **Risk-adjustment method** ☒ **None** ☐ **Statistical model** ☐ **Stratification**

    16b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

    ☐ Yes ☐ No ☒ Not applicable

    16c. **Social risk adjustment:**

    16c.1 Are social risk factors included in risk model? ☐ Yes ☐ No ☒ Not applicable

    16c.2 Conceptual rationale for social risk factors included? ☐ Yes ☐ No

    16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☐ No

    16d.**Risk adjustment summary:**

    16d.1 All of the risk-adjustment variables present at the start of care? ☐ Yes ☐ No

    16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☐ Yes ☐ No

    16d.3 Is the risk adjustment approach appropriately developed and assessed? ☐ Yes ☐ No

    16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☐ Yes ☐ No

    16d.5.Appropriate risk-adjustment strategy included in the measure? ☐ Yes ☐ No

    16e**. Assess the risk-adjustment approach**

<u>For cost/resource use measures ONLY</u>: (N/A for this measure)

17. **Are the specifications in alignment with the stated measure intent?**

    ☐ **Yes** ☐ **Somewhat** ☐ **No (If "Somewhat" or "No", please explain)**

18. **Describe any concerns of threats to validity related to attribution, the costing approach, carve outs, or truncation (approach to outliers):**

VALIDITY: TESTING

19. **Validity testing level:** ☐ **Measure score** ☐ **Data element** ☒ **Both**
20. **Method of establishing validity of the measure score:**
    - ☒ **Face validity**
    - ☐ **Empirical validity testing of the measure score**
    - ☐ **N/A (score-level testing not conducted)**
21. **Assess the method(s) for establishing validity**

    Submission document: Testing attachment, section 2b2.2

    Data element validity was established by assessing the level of agreement between facility abstraction and auditor abstraction (through the CMS Clinical Data Abstraction Center). Two methods were used to estimate the agreement: Kappa statistics (for categorical variables) and Pearson correlation coefficients (for continuous variables).

    Score-level validity was assessed using face validity. Face validity results from previous submission in 2016 were carried forward.

    The face validity presented would not fully satisfy NQF validity testing requirements, especially for a maintenance measure; however, the score-level testing is not required if data-element testing is submitted. The analysis of the testing submission will focus on the data-element validity testing.

22. **Assess the results(s) for establishing validity**

    Submission document: Testing attachment, section 2b2.3

    All critical data elements were included in the testing. For categorical data elements, the Kappa statistics ranged from 0.33 to 1.0. All values indicated substantial (or higher) agreement with the exception of Transfer for Acute Coronary Intervention (0.33 -> fair agreement). For continuous data elements, the Pearson correlation coefficients ranged from 0.97 to 1.00, with all values indicating almost perfect agreement.

    The developer states it has seen improvement in Kappa values for two critical data elements ("initial ECG interpretation" and "reason for no fibrinolytic administration") since the previous submission. It interprets this to suggest improvement in documentation by emergency departments.

23. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

    Submission document: Testing attachment, section 2b1.

    - ☐ **Yes**
    - ☐ **No**
    - ☒ **Not applicable** (score-level testing was not performed)

24. **Was the method described and appropriate for assessing the accuracy of ALL critical data elements?**

    NOTE that data element validation from the literature is acceptable.

    Submission document: *Testing attachment, section 2b1.*

    - ☒ **Yes**
    - ☐ **No**
    - ☐ **Not applicable** (data element testing was not performed)

25. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

☐ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

☐ **Low** (NOTE: Should rate LOW if you believe that there are threats to validity and/or relevant threats to validity were not assessed OR if testing methods/results are not adequate)

☐ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level is required; if not conducted, should rate as INSUFFICIENT.)

26. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**

    All threats to validity assessed (Box 1) → Empirical validity testing (Box 2) → Testing not conducted at score level (Box 5) → Testing conducted at data element level (Box 9) → Method described and appropriate (Box 10) → Moderate to high confidence that data used in measure are valid (Box 11a) → Moderate rating (Moderate is highest possible rating)

FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

27. **What is the level of certainty or confidence that the empirical analysis demonstrates that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct?**

    ☐ **High**

    ☐ **Moderate**

    ☐ **Low**

    ☐ **Insufficient**

28. **Briefly explain rationale for rating of EMPIRICAL ANALYSES TO SUPPORT COMPOSITE CONSTRUCTION**

ADDITIONAL RECOMMENDATIONS

29. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**

    No additional concerns.

Evidence and Performance Gap – 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.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

NQF_0290_MeasureEvidenceForm.docx,NQF_0290_MeasureEvidenceForm_Re-endorsement_Spring2020-637218749767213004.docx

1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

Yes

1a. Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 0290
Measure Title: Median Time to Transfer to Another Facility for Acute Coronary Intervention
IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Click here to enter composite measure #/ title

Date of Submission: 04/09/2020

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

- ☐ Health outcome: Click here to name the health outcome
- ☐Patient-reported outcome (PRO): Click here to name the PRO
  PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors
- ☐ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

☒ Process: This measure calculates the median time from emergency department arrival to time of transfer to another facility for an acute coronary intervention for ST-segment elevation myocardial infarction (STEMI) patients that require a percutaneous coronary intervention (PCI).

☐ Structure: Click here to name the structure

☐ Other:

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

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

This measure is not a health outcome/PRO performance measure.

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

This measure is not a health outcome/PRO performance measure.

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

INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURE

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

2020 Re-endorsement

The American Heart Association (AHA) estimates that 790,000 people experience a heart attack, or myocardial infarction, in the United States each year (Benjamin, 2017). Timely transfer for acute coronary intervention (ACI), such as a percutaneous coronary intervention (PCI), is associated with improved patient outcomes (Bucholz, 2016; Martin, 2016). National clinical practice guidelines support initiating PCI (measured through door-to-balloon time) within 120 minutes or less for ST-segment elevation myocardial infarction (STEMI) patients who need to be transferred from a non-PCI capable hospital to one at which PCI can be performed (O'Gara, 2013).]

REFERENCES:

1) Benjamin E.J., Blaha M.J., Chiuve S.E., Cushman M., Das S.R., Deo R., et al. Heart Disease and Stroke Statistics—2017 Update: A Report From the American Heart Association. 2017; 135:e1–e458.
2) Bucholz E. M., N. M. Butala, S. L. Normand, Y. Wang, and H. M. Krumholz. Association of Guideline-Based Admission Treatments and Life Expectancy After Myocardial Infarction in Elderly Medicare Beneficiaries. Journal of the American College of Cardiology, 2015; 67:20: 2378–2391.
3) Martin L., M. Murphy, A. Scanlon, D. Clark, and O. Farouque. "The Impact On Long Term Health Outcomes for STEMI Patients During a Period of Process Change to Reduce Door to Balloon Time." European Journal of Cardiovascular Nursing, vol. 15, no. 3, 2016, pp. e37–44.
4) O'Gara PT, Kusher FG, Ascheim DD, Casey DE, Chung MK, Lemos JA, Ettinger SM, et al. 2013ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction: Executive Summary: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation, 2013; 127:1-88. Published online December 17, 2012.

Previous Endorsements

The early use of primary angioplasty in patients with ST-segment myocardial infarction (STEMI) results in a significant reduction in mortality and morbidity. The earlier primary coronary intervention is provided, the more effective it is (Brodie, 1998 and DeLuca, 2004). National guidelines recommend the prompt initiation of percutaneous coronary intervention (PCI) in patients presenting with ST-segment elevation myocardial infarction (Antman, 2004). Patients transferred for primary PCI rarely meet recommended guidelines for door-to-balloon time (Nallamothu, 2005). Times to treatment in transfer patients undergoing primary PCI may influence the use of PCI as an intervention (Nallamothu, 2005). Current recommendations support a door-to-balloon time of 90 minutes or less (Krumholz, 2008).

2016 Re-endorsement

The early use of primary angioplasty in patients with STEMI results in a significant reduction in mortality and morbidity. The earlier primary percutaneous coronary intervention (PCI) is provided, the more effective it is (Rathore, 2009). National guidelines recommend the prompt initiation of PCI in patients presenting with STEMI (O'Gara, 2013). Current recommendations support a door-to-balloon time of 120 minutes or less in patients that need to be transferred from a non-PCI-capable hospital to a PCI-capable hospital (O'Gara, 2013). In a nationwide study of 14,518 patients transferred from non-PCI-capable hospitals to PCI-capable hospitals, more than one-third of patients failed to meet recommended guidelines for door-to-balloon time (Dauerman et al, 2015).

Studies have shown that delays in treatment are associated with an increased risk-adjusted in-hospital mortality in a continuous, non-linear fashion (Rathore, 2009). A reduction in door-to-balloon time from 150 minutes to 120 minutes was associated with 1.4% lower mortality; the risk of mortality continued to decrease with reductions in door-to-balloon time (Rathore, 2009). Because elevated transfer time has been shown to be a significant predictor of delay in the initiation of PCI (Dauerman et al, 2015), decreasing transfer time in STEMI patients requiring an acute coronary intervention has the potential to lead to reduced door-to balloon time.

REFERENCES:

1) Dauerman HL, Bates ER, Kontos MC, Li S, Garvey JL, Henry TD, Manoukian SV, Roe MT. Nationwide analysis of patients With ST-segment-elevation myocardial infarction transferred for primary percutaneous intervention: findings from the american heart association mission: lifeline program. Circ Cardiovasc Interv. 2015:8(5):pii: e002450. doi: 10.1161/CIRCINTERVENTIONS.114.002450.
2) O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013;61(4):e78-140.
3) Rathore SS, Curtis JP, Chen J, et. al. Association of door-to-balloon time and mortality in patients admitted to hospital with ST elevation myocardial infarction: national cohort study. BMJ : British Medical Journal. 2009;338:b1807. doi:10.1136/bmj.b1807.

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

☒ Clinical Practice Guideline recommendation – ***complete sections 1a.4, and 1a.7***

☐ US Preventive Services Task Force Recommendation – ***complete sections 1a.5 and 1a.7***

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

☒ Other – ***complete section 1a.8***

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

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1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

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

2020 Re-endorsement

In 2016, the Journal of the American College of Cardiology published a focused update specific to multivessel PCI and thrombus aspiration in patients with STEMI undergoing primary PCI. These updates do not impact this measures clinical intent. The 2013 guideline recommendations remain as the measures definitive source. Citation for the focused update follows:

Glenn N. Levine, G. N., Bates, E. R., Blankenship, J. C., Bailey, S. R., Bittl, J. A., Cercek, B, … Zhao, D. X. (2016, March). 2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction. *Journal of the American College of Cardiology*, 67(10), 1235-1250. Retrieved from http://www.onlinejacc.org/content/67/10/1235. DOI: 10.1016/j.jacc.2015.10.005

Previous Endorsements

Antman EM, Anbe DT, Armstrong PW, Bates ER, Green LA, Hand M, Hochman JS, Krumholz HM, Kushner

FG, Lamas GA, Mullany CJ, Ornato JP, Pearle DL, Sloan MA, Smith SC Jr. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Management of Patients With Acute Myocardial Infarction). 2004.

The clinical practice guideline provided is based on its relevance to the measure. The guideline, released in 2013 by the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA), evaluates management of patients with STEMI. Citation for the guideline follows:

O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013 Jan 29;61(4):e78-140. Guideline available at: http://content.onlinejacc.org/article.aspx?articleid=1486115

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

"if PCI is chosen, the delay from patient contact with the healthcare system (typically, arrival at the ED or contact with paramedics) to balloon inflation should be less than 90 minutes." (Antman et al., Page 593)

The American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) guideline for the management of ST-elevation myocardial infarction provides recommendations for the transfer of patients who require primary PCI (pPCI), from a non-PCI-capable hospital to a PCI-capable hospital, in cases where pPCI can be performed within 120 minutes of first medical contact (FMC). Two recommendations support the measure's clinical intent:

- 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. (Class I, Level of Evidence: B; pg. e86)
- Immediate transfer to a PCI-capable hospital for coronary angiography is recommended for suitable patients with STEMI who develop cardiogenic shock or acute severe HF, irrespective of the time delay from MI onset. (Class I, Evidence: B; pg. e97)

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

B ABC Scale

The recommendations received a Class I, Level B designation, indicating that the transfer of STEMI patients who require PCI to a PCI-capable hospital should occur immediately when the anticipated time from FMC-to-balloon is expected to be less than 120 minutes, and that patients who develop cardiogenic shock or acute severe heart failure (HF) should immediately be transferred to a PCI-capable hospital. These are strong recommendations supported by the evidence. The grade level of *B* does not indicate that the evidence supporting the guideline is weak, as the clinical questions addressed in the guideline do not lend itself to clinical trials.

The following grading scale applies to recommendations from the guideline:
Recommendation A: Class I: Benefit >>> Risk – Procedure/Treatment should be performed/administered
Recommendation B: Class I: Benefit >>> Risk – Procedure/Treatment should be performed/administered

The following evidence scale applies to recommendations from the guideline:
Recommendation A: Level B: Data derived from a single randomized trial or nonrandomized studies

Recommendation B: Level B: Data derived from a single randomized trial or nonrandomized studies

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

- Level A (randomized controlled trial/ meta-analysis):

High quality randomized controlled trial that considers all important outcomes. High-quality meta-analysis (quantitative systematic review) using comprehensive search strategies.

- Level B (other evidence):

A well-designed, nonrandomized clinical trial. A nonquantitative systematic review with appropriate search strategies and well-substantiated conclusions. Includes lower quality randomized controlled trials, clinical cohort studies, and case-controlled studies with nonbiased selection of study participants and consistent findings. Other evidence, such as high-quality, historical, uncontrolled studies, or well-designed epidemiologic studies with compelling findings, is also included.

- Level C (consensus/expert opinion):

Consensus viewpoint or expert opinion. Expert opinion is sometimes the best evidence available.

Additional grading scale for the recommendations:
Class IIa: Benefit >>Risk additional studies with focused objectives needed. ***It is reasonable*** *to perform/administer treatment*
Class IIb: Benefit ≥ Risk additional studies with broad objectives needed: additional registry data would be helpful. Procedure/Treatment ***may be considered****.*
Class III No Benefit: Procedure/Test: not helpful, Treatment: no proven benefit
Class III Harm: Procedure/Test: excess cost w/o benefit or harmful, Treatment: harmful to patients

Additional evidence scales:
Level A: Multiple populations evaluated. Data derived from multiple randomized clinical trials or meta-analyses.
Level C: Very limited populations evaluated. Only consensus opinions of experts, case studies, or standard of care.

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

ACCF/AHA Task Force on Practice Guidelines. Manual for ACCF/AHA Guideline Writing Committees: Methodologies and Policies from the ACCF/AHA Task Force on Practice Guidelines. American College of Cardiology and American Heart Association. 2006. Available at:

- http://assets.cardiosource.com/Methodology_Manual_for_ACC_AHA_Writing_Committees.pdf
- http://my.americanheart.org/professional/StatementsGuidelines/PoliciesDevelopment/Development/Methodologies-and-Policies-from-the-ACCAHA-Task-Force-on-Practice-Guidelines_UCM_320470_Article.jsp.

ACC/AHA Task Force on Practice Guidelines, (2010, June). Methodology Manual and Policies From the ACCF/AHA Task Force on Practice Guidelines. American College of Cardiology Foundation and American Heart Association. Retrieved from:

- http://my.americanheart.org/idc/groups/ahamah-public/@wcm/@sop/documents/downloadable/ucm_319826.pdf
- https://professional.heart.org/idc/groups/ahamah-public/@wcm/@sop/documents/downloadable/ucm_319826.pdf

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

☒ Yes → ***complete section 1a.7***

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

_____

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

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

This measure is not based on a United States Preventive Services Task Force Recommendation.

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

This measure is not based on a United States Preventive Services Task Force Recommendation.

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

This measure is not based on a United States Preventive Services Task Force Recommendation.

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

This measure is not based on a United States Preventive Services Task Force Recommendation.

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

This measure is not based on a United States Preventive Services Task Force Recommendation.

Complete section 1a.7

_____

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

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

Guidelines are evidenced based; details are provided in **section 1a.7**.

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

Guidelines are evidenced based; details are provided in **section 1a.7**.

Complete section 1a.7

_____

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

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

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

Methodologic Approach for the Systematic Review that Supports the 2013 Guideline

Members of the writing committee were appointed by the ACCF/AHA Task Force on Practice Guidelines (Task Force) and selected from the American College of Physicians, American College of Emergency Physicians, and

Society for Cardiovascular Angiography and Interventions, representing various areas of medical expertise. Strict adherence to the Task Force Relationship with Industry (RWI) policy was maintained throughout the consensus process. The focus of the guideline is the management of patients with STEMI; particular emphasis has been placed in areas such as reperfusion therapy and organization of regional systems of care. Panel members extensively reviewed the relevant literature focusing on publications through November 2010, with additional selected references added through August 2012. Evidence supporting each guideline recommendation was weighted and ranked against the ACCF/AHA grading system. Recommendations have been developed using evidence-based methodologies created by the Task Force.

Per the ACC/AHA preamble in the 2015 Focused Update, revised guideline recommendations are issued "on the basis of recently published data. This update is not based on a complete literature review from the date of previous guideline publications, but it has been subject to rigorous, multilevel review and approval, similar to the full guidelines".

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

Grade for the evidence provided from the guideline can be found in **section 1a.4.3.**

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

Grade for the evidence provided from the guideline can be found in **section 1a.4.3.**

1a.7.4. What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range:

It is inferred that the time period covered by the body of evidence is 2002-2012, as this is the period covered by the evidence cited for recommendations A and B.

QUANTITY AND QUALITY OF BODY OF EVIDENCE

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

The guideline does not explicitly indicate the specific number or type of study designs included in the body of evidence; however, the recommendations are Level B, and are based on data from a single randomized trial or non-randomized studies. Recommendation A references four unique citations, with evidence from one randomized trial, and one meta-analysis. Recommendation B references one unique citation with evidence from a single randomized trial.

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

The recommendations from the guideline are Class I, indicating that the benefits clearly outweigh the risks and the recommendations can be applied to most patients in most circumstances. The two Level B recommendations are based on randomized control trials and a meta-analysis. The evidence presented has no important limitations and further evidence is unlikely to change the confidence in the estimate of the the effect.

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

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

The guideline does not provide details about the estimates of benefit and consistency across studies in the body of evidence.

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

The guideline does not provide details about potential harms associated with the timely transfer of STEMI patients requiring a PCI.

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

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

In addition to the guideline cited above, a review of the clinical literature was conducted during the measure contractor's annual review of the literature for additional evidence and/or new studies that relate to the measure. Citations and summaries included in this review can be found in **section 1a.8.2**. Some of these studies have been published since the period of guideline development. Results cited in these studies are consistent across studies and with the guidelines cited above.

1a.8 OTHER SOURCE OF EVIDENCE

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

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

In addition to the guideline cited above, a review of the clinical literature and related policy was conducted during the measure contractor's annual review of the literature for additional evidence and/or new studies that support the measure's intent. The measure contractor identified relevant peer-reviewed publications by searching the PubMed MEDLINE database from January 1, 2016 to December 31, 2019, limiting included results to those published in the English language and that had abstracts available in PubMed. The search initially identified 58 articles; a further review by the contractor's clinical and measure-development team resulted in the inclusion of 14 articles in the body of evidence below. Citations and summaries for the 14 items included in this review can be found in **section 1a.8.2**.

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

Alnsasra, H., Zahger, D., Geva, D., Matetzky, S., Beigel, R., Iakobishvili, Z., … Shimony, A. (2017). Contemporary determinants of delayed benchmark timelines in acute myocardial infarction in men and women. *Am J Cardiol*, 120(10), 1715-1719.

An analysis of data from two multicenter studies explored factors associated with treatment delay for AMI patients. Independent determinants of delayed acute coronary interventions (ACI) for non-STEMI patients included: female sex, age over 75 years, atypical chest pain, and renal failure. Only 37.5% of STEMI patients had primary percutaneous coronary intervention (PCI) within the guideline-recommended 90-minute treatment window, with no significant sex-related differences. Timely electrocardiograms (ECGs), defined as those ECGs performed within 10 minutes of first medical contact following arrival at the ED, occurred in fewer than half of all STEMI and non-STEMI patients, with no significant sex-related differences. These findings support the continued reporting of OP-3 and highlight factors associated with delay.

Askandar, S., Bob-Manuel, T., Singh, P., & Khouzam, R.N. (2017). Shorter Door-To-Balloon ST-Elevation Myocardial Infarction Time: Should There Be a Minimum Limit? *Curr Probl Cardiol.*, 42(6), 175-187.

Clinical consensus supports the current timeframe for restoring myocardial perfusion within 90 minutes of ED arrival, as measured by door-to-balloon time (DTB). A review of relevant literature suggests that protocols aiming to reduce patient DTB under the current 90-minute standard do not decrease mortality rates and may

actually increase the likelihood of performing percutaneous coronary intervention (PCI) unnecessarily (Askander et al., 2017). The authors suggest there may be hazards associated with trying to push the DTB to much shorter than the current recommendations.

Bennin CK, Ibrahim S, Al-Saffar F, et al. Achieving timely percutaneous reperfusion for rural ST-elevation myocardial infarction patients by direct transport to an urban PCI-hospital. *J Geriatr Cardiol.* (2016);13(10):840-845.

This study calculated the odds of achieving first medical contact (FMC)-to-device (FMC2D) for STEMI patients directly transported by emergency medical services (EMS) from three rural counties within a 50-mile radius of a PCI-capable hospital. The study's authors found that the recommended FMC2D, of within 90 minutes, is achievable for rural STEMI patients with the use of protocol-driven EMS ground transportation. These findings suggest EMS can bypass non-PCI capable hospitals to head directly to a facility with access to PCI. If additional evidence supports this practice, CMS may consider re-evaluating the role of EMS in the measure specifications for OP-3, and whether OP-3 is valuable for rural facilities as currently specified.

Choi Y, Lee YJ, Shin SD, et al. The impact of recommended percutaneous coronary intervention care on hospital outcomes for interhospital-transferred STEMI patients. *Am J Emerg Med.* (2017);35(1):42928.

One study evaluated the impact of compliance with AHA's recommendation for reperfusion therapy on patient outcomes (specifically in-hospital mortality). The study's authors showed that only 30% of participants with a STEMI were treated in compliance with the AHA guidelines for timely transfer, and for PCI with and without thrombolysis. Alignment with AHA guidance was associated with lower in-hospital mortality for patients for whom the time between symptom onset and hospital arrival was within 30 minutes; there was no reduction in mortality risk for other patients transferred for STEMI care undergoing PCI. These findings support the continued reporting of OP-3, in that many facilities are not aligning with AHA's recommendations for timely reperfusion treatment, and supports the measure's rationale, as there was an association between guideline adherence and lower mortality among study participants.

Choi SW, Shin SD, Ro YS, et al. Effect of Emergency Medical Service Use and Inter-hospital Transfer on Time to Percutaneous Coronary Intervention in Patients with ST Elevation Myocardial Infarction: A Multicenter Observational Study. Prehosp Emerg Care. 2016 Jan-Feb;20(1):66-75.

This study examined the effects on time-to-percutaneous coronary intervention (PCI) based on EMS use and inter-hospital transfers in ST-segment elevation myocardial infarction (STEMI) patients with symptom onset less than 24 hours across 29 emergency departments. Timely PCI was achieved in 20.3% of the patients. EMS use significantly increased the odds of timely primary PCI to patients directly transported to a primary PCI center, but not in patients transferred from another hospital. These findings support the importance of reporting OP-3, since door-to-balloon time continues to be high for patients who are transferred from a non-PCI-capable hospital to a PCI-capable hospital.

Langabeer, J. R., 2nd, D. T. Smith, M. Cardenas-Turanzas, B. L. Leonard, W. Segrest, C. Krell, T. Owan, M. D. Eisenhauer and D. Gerard. Impact of a Rural Regional Myocardial Infarction System of Care in Wyoming. J Am Heart Assoc. 2016 May 20; 5(5).

This study supports the continued reporting of OP-3, demonstrating that reducing door-to-balloon time improves outcomes for patients with AMI. This can be achieved by facility-level process improvements. Process-improvement strategies for STEMI patients implemented in a tertiary hospital were associated with a 37-minute decrease in door-to-balloon time and lower 12-month mortality; there was no effect, however, on length of stay or likelihood of readmission. These findings supplement the evidence base for OP-3, indicating that timely PCI is associated with improved outcomes for STEMI patients, and that facility-level process improvements can reduce door-to-balloon time.

Mancone, M., N. M. van Mieghem, F. Zijlstra and R. Diletti. Current and novel approaches to treat patients presenting with ST elevation myocardial infarction. Expert Rev Cardiovasc Ther. 2016 Aug; 14(8):895-904.

Several studies discussed evidence-based interventions for improving AMI care through reduced door-to-balloon time in rural or remote areas; these articles collectively suggest potential improvement in OP-3 performance for rural facilities. A pre-/post-intervention study evaluated a coordinated rural, statewide initiative in Wyoming that was designed to decrease transfer time for PCI patients. The post-intervention median symptom onset-to-arterial reperfusion time decreased by 92 minutes; receiving center door-to-balloon time decreased by 11 minutes. The initiative also increased the use of PCI, from 47% to 60%, making it the dominant reperfusion strategy at participating facilities. These results suggest that OP-3 may not require risk-adjustment by county designation (e.g., rural, urban, suburban), as rural hospitals may be able to reduce door-to-balloon time through facility-level process improvements, making PCI a viable option for first-line reperfusion treatment.

Martin, L., M. Murphy, A. Scanlon, D. Clark and O. Farouque. The impact on long term health outcomes for STEMI patients during a period of process change to reduce door to balloon time. Eur J Cardiovasc Nurs. 2016 Apr; 15(3):e37-44.

This article states access to care via a pre-hospital telemedicine system for STEMI patients could allow facilities to achieve the recommended 90-minute door-to-balloon time metric for acute coronary intervention, providing timely access to PCI for rural populations that would not otherwise have access to this treatment. This article suggests facility-level process improvements and utilization of innovative technology could improve facility performance for OP-3 while concomitantly improving patient health outcomes.

Mentias, A., Raza, M. Q., Barakat, A. F., Youssef, D., Raymond, R., Menon, V., … Kapadia, S. R. (2017). Effect of shorter door-to-balloon times over 20 years on outcomes of patients with anterior ST-elevation myocardial infarction undergoing primary percutaneous coronary intervention. *Am J Cardiol*, 120(8), 1254-1259.

A single-center study assessed changes in health outcomes between 1995 and 2014 for patients with anterior STEMIs. Mentias et al. (2017) observed a reduction in median DTB times, median length of hospital stay, and improved 30-day and 1-year mortality rates, despite a significant rise in the prevalence of smoking, hypertension, and obesity during the same window. Results of this study align with the clinical intent of OP-3, demonstrating the relationship between DTB time and improved patient outcomes.

Mont'Alverne-Filho, J. R., C. R. Rodrigues-Sobrinho, F. Medeiros, F. C. Falcao, J. L. Falcao, R. C. Silva, K. J. Croce, J. C. Nicolau, M. Valgimigli, P. W. Serruys and P. A. Lemos. Upstream clopidogrel, prasugrel, or ticagrelor for patients treated with primary angioplasty: Results of an angiographic randomized pilot study. Catheter Cardiovasc Interv. 2016 Jun; 87(7):1187-93.

Another study evaluated the impact of first medical contact for STEMI patients requiring PCI. The median contact-to-balloon time varied significantly by the source of first medical contact: 89 minutes for emergency medical services (EMS), 107 minutes for non-PCI capable hospitals, and 65 minutes for PCI-capable hospitals. In-hospital mortality, however, did not differ significantly despite the differences in the time from first contact to treatment initiation. There was an increased risk of a lower degree of reperfusion (thrombolysis in myocardial infarction [TIMI]-flow grade of less than III) in patients presenting to non-PCI capable hospitals. This article supports the rationale for OP-3, as there is evidence that patients with a shorter contact-to-balloon time have better degree of reperfusion than those who have a longer contact-to-balloon time. This confirms that timely transfer is closely tied to improved clinical outcomes.

Solhpour, A., K. W. Chang, S. A. Arain, P. Balan, C. Loghin, J. J. McCarthy, H. Vernon Anderson and R. W. Smalling. Ischemic time is a better predictor than door-to-balloon time for mortality and infarct size in ST-elevation myocardial infarction. Catheter Cardiovasc Interv. 2016 Jun; 87(7):1194-200.

Solhpour et al., investigated the long-term impact of a pre-hospital ECG program on treatment times for patients with STEMI undergoing PCI. Implementation of the program—which incorporated innovative approaches to care, including tele-transmission, early activation of the catheterization lab, and direct routing—saw a reduction in door-to-balloon time from 92.5 minutes to 40.5 minutes. This article supports the clinical intent of OP-3.

Sorensen JT and M Maeng. Regional systems-of-care for primary percutaneous coronary intervention in ST-elevation myocardial infarction. Coron Artery Dis. 2015 Dec;26(8):713-22.
This article details how regional STEMI networks provide optimal treatment for patients with primary PCI, based on several trials that have shown that pre-hospital ECG recording and early diagnosis combined with direct referral to a primary PCI center reduces treatment delay. Evidence that a reduction in treatment delay (due to direct referral to primary PCI centers) is associated with a lower mortality and morbidity.

Studnek, J.R., Infinger, A., Wilson, H., Niess, G., Jackson, P. & Swanson D. (2018). Decreased time from 9-1-1 call to PCI among patients experiencing STEMI results in a decreased one year mortality. Prehosp Emerg Care., 22(6), 669-675.
https://www.tandfonline.com/doi/abs/10.1080/10903127.2018.1447621?journalCode=ipec20
Studnek et al. (2018) examined the association between time from symptom onset to acute coronary intervention (here, noted as the 911 call-in time to initiation of percutaneous coronary intervention [PCI] initiation) and mortality at one year for 550 patients with ST-segment elevation myocardial infarction (STEMI). Total time from 911 call to PCI was calculated for each patient, and mortality status within one year following the procedure was documented. Mean reperfusion time was significantly lower in patients alive at one year versus deceased at one year, representing a 30% increase in mortality for every 10-minute delay in the reperfusion window. Results from this research suggested a linear relationship between time to PCI and mortality in the pre-hospital environment, with the probability of survival decreasing significantly as time to PCI increases. The article's authors validate the OP-3's intent, emphasizing the minimization of median time to transfer for acute coronary intervention.

Zorbozan, O., Cevik, A. A., Acar, N., Ozakin, E., Ozcelik, H., Birdane, A., and Abu-Zidan, F. M. (2018). Predictors of mortality in ST-elevation MI patients: A prospective study. *Medicine (Baltimore)*, 97(9), e0065. doi: 10.1097/MD.0000000000010065.
Zorbozan et al. (2018) conducted a single-site, prospective study of ST-segment elevation myocardial infarction (STEMI) patients who underwent percutaneous coronary intervention (PCI). The authors identified four predictors of 30-day mortality: (1) age, (2) systolic blood pressure, (3) score on the Modified Shock Index, and (4) time from consultation to activation of the catheterization lab. That time to activation of the catheterization lab is a significant, independent predictor of mortality supports the rationale for continued reporting of OP-3.

Anderson LL, French WJ, Peng SA, Vora AN, Henry TD, Roe MT, Kontos MC, Granger CB, Bates ER, Hellkamp A, and Wang TY. Direct transfer from the referring hospitals to the catheterization laboratory to minimize reperfusion delays for primary percutaneous coronary intervention insights from the national cardiovascular data registry. Circulation: Cardiovascular Interventions. 2015; 8(9): e002477. doi: 10.1161/CIRCINTERVENTIONS.114.002477.
Anderson et al. studied 33,901 patients with STEMI transferred for pPCI in the Acute Coronary Treatment and Intervention Outcomes Network Registry—Get With The Guidelines from July 2008 to December 2012. The majority of patients (78.2%) were transferred directly to the catheterization laboratory (cath lab), while the remaining were transferred first to the emergency department. The study found patients transferred directly to the cath lab had significantly lower door-to-balloon time compared to the patients transferred first to the emergency department. A multivariable logistic regression further revealed transferring directly to the cath lab was associated with significantly faster reperfusion and lower mortality risk (odds ratio 0.58, 95% confidence interval 0.51-0.66, P<0.0001).

Dauerman HL, Bates ER, Kontos MC, Li S, Garvey JL, Henry TD, Manoukian SV, Roe MT. Nationwide analysis of patients with ST-segment–elevation myocardial infarction transferred for primary percutaneous intervention: Findings from the American Heart Association mission: Lifeline program. Circulation: Cardiovascular Interventions. 2015; 8(5): e002450. doi: 10.1161/ CIRCINTERVENTIONS.114.002450.
Dauerman et al. identified hospital-level, patient-level, and process characteristics of timely versus delayed PCI from a diverse national sample. Timely initiation of PCI is based on the American College of

Cardiology/American Heart Association recommendation of door-to-device times within 120 minutes for transfer patients. Patients with a transfer time greater than 60 minutes were excluded from the study. 65% of patients met the recommended door-to-device time </= 120 minutes. Only 37% of the hospitals were high-performing (the study identifies high performing hospitals as having 75% or more of transfer STEMI patients with a first door-to-balloon time within 120 minutes). In addition to known predictors of delay, delays observed in this study were attributed to STEMI referral hospitals' rural location, longer estimated transfer time, and lower annual PCI hospital STEMI volumes.

Simon EL, Griffin P, Medepalli K, Griffin G, Williams CJ, Hewit M, Lloyd TS. Door-to-balloon times from freestanding emergency departments meet ST-segment elevation myocardial infarction reperfusion guidelines. The Journal of Emergency Medicine. 2015; 46(5): 734-740. doi: 10.1016/ j.jemermed.2013.08.089.

Simon et al. conducted a dual-center retrospective cohort review of all patients 18 years and older who were diagnosed with STEMI and presented to the main hospital-affiliated freestanding emergency departments (FEDs) from July 2007 to August 2008. The purpose of this study was to determine the proportion of STEMI patients who arrived to a FED and were subsequently transferred for PCI and met the door-to-balloon reperfusion guidelines of 90 minutes. There were 47 patients that met the study inclusion criteria. The median door-to-balloon time was 83 minutes. Of the 47 patients included in the study, 78.7% of the patients achieved a door-to-balloon time of 90 minutes or less.

Thilo C, Blüthgen A, and von Scheidt W. Efficacy and limitations of a STEMI network: 3 years of experience within the myocardial infarction network of the region of Augsburg-HERA. Clinical Research in Cardiology. 2013; 102(12): 905-914. doi: 10.1007/s00392-013-0608-8.

Thilo et al used the HERA Registry to investigate logistics, adherence to standards, time intervals, and mortality for pPCI in STEMI patients in a mixed urban and rural area. The study was comprised of 826 consecutive patients and 143 (17.3 %) patients from the sample presented in cardiogenic shock. Six hundred and eighty patients (82 %) received pPCI and 45 patients (5 %) received acute bypass surgery. For patients receiving pPCI, in-hospital mortality was 6.2 %, 28.0 % for shock patients, and 2.1 % for non-shock patients. The median first medical contact-to-balloon time was 135 minutes and median door-to-balloon time was 70 minutes. For patients whose first medical contact was by an emergency physician, when stratified by location, the median door-to-balloon time was 38 minutes with direct transfer to cath lab (n = 70), 69 minutes with direct transfer to the ICU (n = 240), and 132 minutes with direct transfer to the ER (n = 91, $p < 0.01$). The study concluded direct transfer to cath lab reduces door-to-balloon times by 49 %.

Vora AN, Holmes DN, Rokos I, Roe MT, Granger CB, French WJ, Antman E, Henry TD, Thomas L, Bates ER and Wang TY. Fibrinolysis use among patients requiring interhospital transfer for ST-segment elevation myocardial infarction care a report from the US national cardiovascular data registry. JAMA Internal Medicine. 2015; 175(2): 207-215. doi: 10.1001/jamainternmed.2014.6573.

Vora et al. assessed the association of estimated interhospital drive times with reperfusion strategy selection among the 22,481 transferred patients with STEMI in the United States between July 1, 2008, and March 31, 2012. 42.6% of transfer patients treated with pPCI satisfied the first door-to-balloon time of 120 minutes when the interhospital driving time surpassed 30 minutes. 52.7% of eligible patients with drive times exceeding 60 minutes received fibrinolysis. Of the patients eligible for fibrinolysis or pPCI with driving times ranging from 30-120 minutes, 34.3% received pretransfer fibrinolysis, with a median door-to-needle time of 34 minutes. Although there was not a significant mortality difference for patients treated with pPCI compared to those treated with fibrinolysis (3.7% vs 3.9%; adjusted odds ratio, 1.13; 95% CI, 0.94-1.36), there was a higher bleeding risk for patients who received fibrinolysis (10.7% vs 9.5%; adjusted odds ratio, 1.17; 95% CI, 1.02-1.33). The authors concluded neither fibrinolysis nor pPCI were being adequately administered within guideline-recommended reperfusion targets. In addition, the authors concluded that patients who are unlikely to receive timely pPCI should receive pretransfer fibrinolysis, followed by early transfer for angiography as an alternative in situations where potential benefits of timely reperfusion outweigh bleeding risk.

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

The purpose of this measure is to document hospital performance for this evidence-based practice for patients with coronary interventions. The American Heart Association (AHA) estimates that 790,000 people experience a heart attack, or myocardial infarction, in the United States each year (Benjamin, 2017). Timely transfer for acute coronary intervention (ACI), such as a percutaneous coronary intervention (PCI), is associated with improved patient outcomes (Bucholz, 2016; Martin, 2016). National clinical practice guidelines support initiating PCI within 120 minutes or less (measured through door-to-balloon time) for ST-segment elevation myocardial infarction (STEMI) patients who need to be transferred from a non-PCI capable hospital to one at which PCI can be performed (O'Gara, 2013).

REFERENCES:

1) Benjamin E.J., Blaha M.J., Chiuve S.E., Cushman M., Das S.R., Deo R., et al. Heart Disease and Stroke Statistics—2017 Update: A Report From the American Heart Association. 2017; 135:e1–e458.

2) Bucholz E. M., N. M. Butala, S. L. Normand, Y. Wang, and H. M. Krumholz. Association of Guideline-Based Admission Treatments and Life Expectancy After Myocardial Infarction in Elderly Medicare Beneficiaries. Journal of the American College of Cardiology, 2015; 67:20: 2378–2391.

3) Martin L., M. Murphy, A. Scanlon, D. Clark, and O. Farouque. "The Impact On Long Term Health Outcomes for STEMI Patients During a Period of Process Change to Reduce Door to Balloon Time." European Journal of Cardiovascular Nursing, vol. 15, no. 3, 2016, pp. e37–44.

4) O'Gara PT, Kusher FG, Ascheim DD, Casey DE, Chung MK, Lemos JA, Ettinger SM, et al. 2013ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction: Executive Summary: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation, 2013; 127:1-88. Published online December 17, 2012.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. *(This is required for maintenance of endorsement. Include mean, std dev, min, max, interquartile range, 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 (4b1) under Usability and Use.*

Differences in measures scores were assessed at both the encounter- and facility-level using Clinical Data Warehouse (CDW) data for the period January 1, 2018 to December 31, 2018. This included 9,050 encounters across 450 ED facilities with eligible cases. Across all encounters, the median performance score was 55 minutes with an interquartile range from 38 minutes to 90 minutes (Table 1). The median performance score at the facility level was 54 minutes with an interquartile range from 43 minutes to 70 minutes (Table 2).

Table 1. Encounter level distribution of measure scores

Median time to transfer to another facility for ACI

Facilities: 459

ED encounters: 9050

Mean: 85 minutes

Median: 55 minutes

Minimum: 1 minutes

Maximum: 521 minutes

5th percentile: 22 minutes

10th percentile: 27 minutes

25th percentile: 38 minutes

50th percentile: 55 minutes

75th percentile: 90 minutes

90th percentile: 186 minutes

95th percentile: 274 minutes

Analysis capped at 521 minutes, which reflects the 99th percentile.

Source: Data from the CMS Clinical Data Warehouse (CDW). Data were obtained from the Health Care Quality Analytics and Reporting (HCQAR) program and contained records for the time period 1/1/2018 thru 12/31/2018.

Table 2. Distribution of Facility Measure Scores (minutes)

Facilities: 450

Mean: 64

Std. Dev.: 40

Min: 18

10th Percentile: 34

25th Percentile: 43

Median: 54

75th Percentile: 70

90th Percentile: 92

Max: 373

Analysis capped at 521 minutes, which reflects the 99th percentile.

Source: Data from the CMS Clinical Data Warehouse (CDW). Data were obtained from the Health Care Quality Analytics and Reporting (HCQAR) program and contained records for the time period 1/1/2018 thru 12/31/2018.

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, 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.

Data have been included in Section 1b.2 (Tables 1 &2); these data represent national performance over time, from January 1, 2018 to December 31, 2018. Data were obtained from the Clinical Data Warehouse via HCQAR.

1b.4. 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. *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) 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 (4b1) under Usability and Use.*

The relationship of patient characteristics on time to transfer from the ED to another facility for ACI was evaluated using data submitted to the Clinical Data Warehouse (CDW). Women, older patients, non-White patients, and Hispanic patients had longer median times to transfer than their male, younger, White, non-Hispanic counterparts (Table 3).

Table 3. Measure score by demographic characteristics (Measured as minutes to transfer)

Characteristics	Median minutes	Mean minutes(a) minutes	Encounters n
Age			
18-64	52	78	5,129
65+	59	95	3,921
Gender(b)			
Male	52	80	6,180
Female	62	98	2,869
Race			
Black or African American	64	102	714
White	53	81	7,582
Other	76	148	273
Unknown	61	97	481
Ethnicity			
Hispanic or Latino	62	93	555
Non-Hispanic	54	85	8,495

(a) Analysis capped at 521 minutes, which reflects the 99th percentile.

(b) Four cases excluded because gender equaled 'unknown'.

Source: Data from the CMS Clinical Data Warehouse (CDW). Data were obtained from the Health Care Quality Analytics and Reporting (HCQAR) program and contained records for the time period 1/1/2018 thru 12/31/2018.

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, 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 1b.4

Disparities identified in 1b.4 (Table 3) have been documented in the literature and represent areas for improvement in care (Graham, 2016, Langabeer II, 2018, Pilgrim et al., 2015).

References:

1) Graham, G. (2016), Racial and Ethnic Differences in Acute Coronary Syndrome and Myocardial Infarction Within the United States: From Demographics to Outcomes. Clinical Cardiology, 39: 299-306.

2) Langabeer II JR, Henry TD, Fowler R, Champagne-Langabeer T, Kim J, Jacobs AK. Sex-Based Differences in Discharge Disposition and Outcomes for ST-Segment Elevation Myocardial Infarction Patients Within a Regional Network. Journal of Women´s Health. 2018, 27(8): 1001-1006.

3) Pilgrim T, Heg D, Tal K, Erne P, Radovanovic D, Windecker S, et al. (2015) Age- and Gender-related Disparities in Primary Percutaneous Coronary Interventions for Acute ST-segment elevation Myocardial Infarction. PLoS ONE 10(9): e0137047. https://doi.org/10.1371/journal.pone.0137047

2. Reliability and Validity—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.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area *(check all the areas that apply):*

Cardiovascular, Cardiovascular : Coronary Artery Disease (AMI)

De.6. Non-Condition Specific*(check all the areas that apply):*

Care Coordination, Safety, Safety : Complications

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

Adults, Elderly, Populations at Risk

S.1. Measure-specific Web Page *(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.)*

https://www.qualitynet.org/outpatient/specifications-manuals

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure **Attachment:**

S.2b. Data Dictionary, Code Table, or Value Sets *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*

Attachment**:** 0290_Annual_Update_Code_Set_-2019-.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

Yes

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

No substantive changes to the measure specifications were made in the 12 months preceding this annual update. However, minor text updates were made to remove redundancy in the numerator statement and simplify language in the denominator exclusions, but there is no change to the measure intent.

S.4. Numerator Statement *(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.*

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

This measure is reported as a continuous variable statement: Time (in minutes) from emergency department arrival to transfer to another facility for acute coronary intervention.

S.5. Numerator Details *(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 S.2b)*

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

NQF #0290 is a continuous measure; therefore, the numerator and denominator details contained in Section S.5 and S.7 are the same.

The following data elements are used to define the measure population:

- E/M Code
- ICD-10-CM Principal Diagnosis Code
- Initial ECG Interpretation
- Transfer for Acute Coronary Intervention

The measure population includes patients with a diagnosis of acute myocardial infarction (AMI) and ST-segment elevation on the electrocardiogram (ECG) performed closest to emergency department (ED) arrival who are transferred from the ED to a short-term general hospital for inpatient care, or to a federal healthcare facility specifically for an acute coronary intervention (ACI). Patients are included in the measure population if:

- Initial ECG Interpretation is equal to "Yes"; and
- Fibrinolytic Administration is equal to "No"; and
- Transfer for Acute Coronary Intervention is equal to "[1] There was documentation the patient was transferred from this facility's emergency department to another facility specifically for acute coronary intervention."

Median times to transfer within a three-month period are aggregated, on a rolling basis, for AMI patients who are transferred for ACI.

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

This measure is reported as a continuous variable statement: Time (in minutes) from emergency department arrival to transfer to another facility for acute coronary intervention.

S.7. Denominator Details *(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 S.2b.)*

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

NQF #0290 is a continuous measure; therefore, the numerator and denominator details contained in Section S.5 and S.7 are the same.

The following data elements are used to define the measure population:

- E/M Code
- ICD-10-CM Principal Diagnosis Code
- Initial ECG Interpretation

• Transfer for Acute Coronary Intervention

The measure population includes patients with a diagnosis of acute myocardial infarction (AMI) and ST-segment elevation on the electrocardiogram (ECG) performed closest to emergency department (ED) arrival who are transferred from the ED to a short-term general hospital for inpatient care, or to a federal healthcare facility specifically for an acute coronary intervention (ACI). Patients are included in the measure population if:

• Initial ECG Interpretation is equal to "Yes"; and

• Fibrinolytic Administration is equal to "No"; and

• Transfer for Acute Coronary Intervention is equal to "[1] There was documentation the patient was transferred from this facility's emergency department to another facility specifically for acute coronary intervention."

S.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

Excluded Populations:

• Patients less than 18 years of age; or

• Patients receiving fibrinolytic therapy administration.

S.9. Denominator Exclusion Details *(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 S.2b.)*

The following data elements are used to define the measure exclusions:

• Birthdate

• Fibrinolytic Therapy Administration

S.10. Stratification Information *(Provide all information required to stratify the measure results, if necessary, including 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 with at S.2b.)*

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

No risk adjustment or risk stratification

If other:

S.12. Type of score:

Continuous variable

If other:

S.13. Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*

Better quality = Lower score

S.14. Calculation Algorithm/Measure Logic (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)*

Measure algorithm is available in the attached Measure Information Form. Measure algorithm is as follows:

1. Start. Run all cases that are included in the AMI Hospital Outpatient Population Algorithm and pass the edits defined in the Data Processing Flow through this measure. Proceed to Initial ECG Interpretation.

2. Check Initial ECG Interpretation.

a. If Initial ECG Interpretation is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If Initial ECG Interpretation equals No, the case will proceed to a Measure Category Assignment of B. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

c. If Initial ECG Interpretation equals Yes, the case will proceed to Fibrinolytic Administration.

3. Check Fibrinolytic Administration.

a. If Fibrinolytic Administration is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If Fibrinolytic Administration equals Yes, the case will proceed to a Measure Category Assignment of B. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

c. If Fibrinolytic Administration equals No, the case will proceed to Transfer for Acute Coronary Intervention.

4. Check Transfer for Acute Coronary Intervention.

a. If Transfer for Acute Coronary Intervention is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If Transfer for Acute Coronary Intervention equals 2 or 3, the case will proceed to a Measure Category Assignment of B. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

c. If Transfer for Acute Coronary Intervention equals 1, the case will proceed to ED Departure Date.

5. Check ED Departure Date.

a. If ED Departure Date is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If ED Departure Date equals UTD, the case will proceed to a Measure Category Assignment of Y. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

c. If ED Departure Date equals Non-UTD Value, the case will proceed to ED Departure Time.

6. Check ED Departure Time.

a. If ED Departure Time is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If ED Departure Time equals UTD, the case will proceed to a Measure Category Assignment of Y. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

c. If ED Departure Time equals Non-UTD Value, the case will proceed to Arrival Time.

7. Check Arrival Time.

a. If Arrival Time equals UTD, the case will proceed to a Measure Category Assignment of Y. Return to Transmission Data Processing Flow: Clinical in the Data Transmission Section.

b. If Arrival Time equals Non-UTD Value, the case will proceed to the Measurement Value.

8. Calculate the Measurement Value. Time in minutes is equal to the ED Departure Date and ED Departure Time (in minutes) minus the Outpatient Encounter Date and Arrival Time (in minutes).

9. Check the Measurement Value.

a. If Measurement Value is less than 0 minutes, the case will proceed to a Measure Category Assignment of X and will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If Measurement Value is greater than or equal to 0 minutes, the case will proceed to Reason for Not Administering Fibrinolytic Therapy.

10. Check Reason for Not Administering Fibrinolytic Therapy.

a. If Reason for Not Administering Fibrinolytic Therapy is missing, the case will proceed to a Measure Category Assignment of X and the case will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If Reason for Not Administering Fibrinolytic Therapy equals 1, 2, or 3, the case will proceed to a Measure Category Assignment of D1, the OP-3a Overall Rate. Initialize the Measure Category Assignment for OP-3b and OP-3c equal to B. Do not change the Measure Category Assignment that was already calculated for the overall rate of OP-3a. Proceed to Reason for Not Administering Fibrinolytic Therapy.

11. Check Reason for Not Administering Fibrinolytic Therapy.

a. If Reason for Not Administering Fibrinolytic Therapy equals 1 or 2, the case will proceed to a Measure Category Assignment of D2, the OP-3c Quality Improvement Rate. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If Reason for Not Administering Fibrinolytic Therapy equals 3, the case will proceed to a Measure Category Assignment of D, the OP-3b Reporting Rate. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

Submission Threshold

In order to reduce the burden on hospitals that treat a low number of patients but otherwise meet the submission requirements for a particular quality measure, hospitals that have five or fewer cases in a quarter (both Medicare and non-Medicare) for any measure set (i.e., Stroke) will not be required to submit patient level data for the entire measure set for that quarter. (Hospital Outpatient Quality Reporting Specifications Manual, Release Notes Version: 13.0a)

S.15. Sampling *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

Sampling is a process of selecting a representative part of a population in order to estimate the hospital's performance without collecting data for its entire population. Using a statistically valid sample, a hospital can measure its performance in an effective and efficient manner. Sampling is a particularly useful technique for performance measures that require primary data collection from a source such as the medical record. Sampling should not be used unless the hospital has a large number of cases in the outpatient population because a fairly large number of cases are needed to achieve a representative sample of the population. For the purpose of sampling outpatient department quality measures, the terms "sample," "effective sample," and "case" are defined below:

• The "sample" is the fraction of the population that is selected for further study.

• "Effective sample" refers to the part of the sample that makes it into the denominator of an outpatient measure set. This is defined as the sample for an outpatient measure set minus all the exclusions and contraindications for the outpatient measure set in the sample.

• A "case" refers to a single record (or an encounter) within the population. For example, during the first quarter a hospital may have 100 patients who had a principal diagnosis associated with the OP-1, 2, 3, 4, and 5 measures. The hospital's outpatient population would include 100 cases or 100 outpatient records for these measures during the first quarter.

To obtain statistically valid sample data, the sample size should be carefully determined, and the sample cases should be randomly selected in such a way that the individual cases in the population have an equal chance of being selected. Only when the sample data truly represent the whole population can the sample-based performance outpatient measure set data be meaningful and useful. Each hospital is ultimately responsible for adhering to the sampling requirements outlined in this manual.

As a general rule/policy of CMS, providers are encouraged to submit as many cases as possible up to the entire population of cases if reasonably feasible. For example, if the raw data can be easily extracted from an existing electronic database or the abstraction burden is manageable, providers should consider submitting the entire population of cases that meet the initial selection criteria. Otherwise, a statistically valid sample can be selected.

S.16. Survey/Patient-reported data *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*

Specify calculation of response rates to be reported with performance measure results.

This measure does not use survey data.

S.17. Data Source *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*

If other, please describe in S.18.

Electronic Health Records, Paper Medical Records

S.18. Data Source or Collection Instrument *(Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

An electronic data collection tool is made available from vendors or facilities can download the free CMS Abstraction & Reporting Tool (CART). Paper tools for manual abstraction, which are posted on www.QualityNet.org, are also available for the CART tool. These tools are posted on www.QualityNet.org.

S.19. Data Source or Collection Instrument *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

Available at measure-specific web page URL identified in S.1

S.20. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*

Facility

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*

Emergency Department and Services

If other:

S.22. COMPOSITE Performance Measure - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

Not applicable; this is not a composite measure.

2. Validity – See attached Measure Testing Submission Form

NQF_0290_MeasureTestingForm.docx,HMDM_Testing_form_OP3_new_form_4_16-637230077496726681.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include

information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

No - This measure is not risk-adjusted

Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*)**:** 0290

Measure Title: Median Time to Transfer to Another Facility for Acute Coronary Intervention

Date of Submission: 4/16/2020

Type of Measure:

☐ Outcome (*including PRO-PM*)	☐ Composite – ***STOP – use composite testing form***
☐ Intermediate Clinical Outcome	☐ Cost/resource
☒ Process *(including Appropriate Use)*	☐ Efficiency
☐ Structure	

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

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 in question 1.7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for all the sources of data specified and intended for measure implementation.* ***If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

Measure Specified to Use Data From: (*must be consistent with data sources entered in S.17*)	**Measure Tested with Data From:**
☒ abstracted from paper record	☒ abstracted from paper record
☐ claims	☐ claims
☐ registry	☐ registry
☒ abstracted from electronic health record	☒ abstracted from electronic health record
☐ eMeasure (HQMF) implemented in EHRs	☐ eMeasure (HQMF) implemented in EHRs
☐ other: Click here to describe	☐ other: Click here to describe

1.2. 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*).

Encounter-level data from the CMS Clinical Data Warehouse (CDW) and Clinical Data Abstraction Center (CDAC) were used to test this measure. Data were obtained from the Health Care Quality Analytics and Reporting (HCQAR) program.

We limited analyses to facilities reporting more than 10 cases between January 1, 2018 and December 1, 2018, resulting in the reduction of facilities from 2,009 to 459. Limiting analyses to a subset of facilities is consistent with reporting requirements outlined in Hospital OQR Specifications Manual (v.13.0a). Hospitals that have five or fewer cases in a quarter (both Medicare and non-Medicare) for any measure set are not be required to submit patient level data for the entire measure set for that quarter. We opted to consider facilities with more than ten patients in a calendar year, assuming that some hospitals would exceed the minimum threshold of 5 patients in one ore more quarters.

CDW Data

The CDW file contained data from January 1, 2018 to December 31, 2018 for all emergency department (ED) encounters with at least one of the following Current Procedural Terminology (CPT) codes for evaluation and management (E/M): 99281, 99282, 99283, 99284, 99285, or 99291. Included were encounters in which patients were 18 years or older, as of the date of the encounter, with a principal diagnosis associated with an acute myocardial infarction, identified by using any of the following International Classification of Diseases version 10 (ICD-10) codes: I21.01, I21.02, I21.09, I21.11, I21.19, I21.21, I21.29, I21.3, I21.4, I21.9, I21.A1, I21.A9, I22.0, I22.1, I22.2, I22.8, I22.9, I97.190, I97.191, I97.790, or I97.791

The measure, *Median Time to Transfer to Another Facility for Acute Coronary Intervention*, is a continuous measure. As such, exclusions will be termed 'measure exclusions' rather than 'denominator exclusions' or 'numerator exclusions'.

Measure exclusion flags were contained within the CDW file for each encounter, as applicable.

Measure exclusions are as follows, in a step-wise progression:

- *Initial ECG Interpretation* equal to "No"[1]
- *Fibrinolytic Administration* is equal to "Yes"
- *Transfer for Acute Coronary Intervention* is equal to "[2] there was documentation the patient was admitted to observation status prior to transfer"
- *Transfer to Acute Coronary Intervention* is equal to "[3] There was documentation the patient was transferred from this facility's emergency department to another facility for reasons other than acute coronary intervention, or the specific reason for transfer was unable to be determined from medical record documentation"
- *Reason for Not Administering Fibrinolytic Therapy* is equal to "[1] Documented contraindication/reason"
- *Reason for Not Administering Fibrinolytic Therapy* is equal to "[2] Cardiogenic Shock"
- *Reason for Not Administering Fibrinolytic Therapy* is equal to "[2] There was documentation the patient was admitted to observation status prior to transfer"
- *ED admission time and date and ED departure time and date* 'UTD' or missing

The measure score, the *median time to transfer to another facility for acute coronary intervention*, was calculated, using CDW data, for encounters in which patients met the following criteria:

- *Initial ECG Interpretation* is equal to "Yes"
- *Fibrinolytic Administration* is equal to "No"

[1] To be included in the measure, there needs to be the following: ST-segment elevation or LBBB on the ECG performed closest to ED arrival.

- *Transfer for Acute Coronary Intervention* is equal to "[1] There was documentation the patient was transferred from this facility's emergency department to another facility specifically for acute coronary intervention"
- *Reason for Reason for Not Administering Fibrinolytic Therapy is equal to "*[3] No documented contraindication/reason or Unable to determine (UTD)"
- *Valid values for ED admission time and date and ED departure time and date*

CDAC

CDAC data for OP-3 for all encounters selected for audit between January 1, 2018 to December 31, 2018 were used to assess data element validity by comparing CDW data to manually abstracted CDAC data (gold standard).

1.3. What are the dates of the data used in testing? January 1, 2018 – December 31, 2018

1.4. What levels of analysis were tested? (*testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: (*must be consistent with levels entered in item S.20*)	**Measure Tested at Level of:**
☐ individual clinician	☐ individual clinician
☐ group/practice	☐ group/practice
☒ hospital/facility/agency	☒ hospital/facility/agency
☐ health plan	☐ health plan
☐ other: Click here to describe	☐ other: Click here to describe

1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample*)

The number of measured entities (hospital EDs) varies by testing type; see Section **1.7** for details.

1.6. How many and which patients were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

There were 9,050 patient encounters, comprised of 9,049 unique patients, after exclusions, between January 1, 2018 and December 31, 2018. Patients' demographic characteristics are provided in Table 1.

Table 1. Patient characteristics after exclusions (Total facilities = 459)

Patient Characteristics	n	%
Total number of encounters	9,050	100.0
Average age	63.0	14.0 (std dev)
18-35	191	2.1
36-64	4,938	54.6
65+	3,921	43.3
Sex		
Male	6,180	68.3
Female	2,869	31.7
Unknown	1	<0.1
Race		
Black or African American	714	7.9
White	7,582	83.8

Other	273	3.0
Unknown	481	5.3
Ethnicity		
Hispanic or Latino	555	6.1
Non-Hispanic	8,495	93.9

Source: Data from the CMS Clinical Data Warehouse (CDW). Data were obtained from the Health Care Quality Analytics and Reporting (HCQAR) program and contained records for the time period 1/1/2018 thru 12/31/2018.

NOTE: Total percent may not sum to 100 due to rounding error.

1.7. 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 reported below.

Reliability Testing, Exclusion Analyses, Identification of Meaningful Differences in Performance, Missing Data

Data Source: CDW [maintained by the Centers for Medicare & Medicaid Services (CMS)]
Dates: 1/1/2018 to 12/31/2018
Number of Facilities: 495
Total encounters: 29,116
Encounters after exclusions: 9050
Level of Analysis: Encounter, facility
Patient Characteristics: Gender (% Male): 68.3; Mean Age (Years): 63.0 (St. Dev.:14.0); Race (% Minority): 16.2

Validity Testing – Data Element Validity
Data Source: CDAC (and CDW, described above)
Dates: 1/1/2018 – 12/31/2018
Number of Facilities: 61
Total encounters: 269
Encounters after exclusions: 84
Level of Analysis: Data element
Patient Characteristics: Gender (% Male): 61.3; Mean Age (Years): 64.1 (St. Dev.: 14.3); Race (% Minority): 14.5

Validity Testing – *Face Validity – Not tested*

Risk Adjustment Strategy
N/A- No risk adjustment or stratification was performed.

1.8 What were 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.

We assessed patient-level SDS factors as part of the regression model reported in Section **1b.4**, which provides an overview of disparities in care for patient sub-populations. We based this analysis on SDS variables included in the CDW data:

- Age
- Gender
- Race
- Ethnicity

While an analysis of SDS factors is important in understanding differences in care for patient sub-populations, this measure is a process measure that is neither risk-adjusted nor risk-stratified. We determined that risk adjustment and risk stratification were not appropriate based on the current evidence base and the measure construct. Additional information on this determination is provided in Section **2b3.2**.

2a2. RELIABILITY TESTING

***Note**: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)

☐ **Critical data elements used in the measure** (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)

☒ **Performance measure score** (e.g., *signal-to-noise analysis*)

2a2.2. For each level 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*)

Reliability was calculated using a signal-to-noise analysis in which the reliability estimate represents the ratio of signal to noise for each facility's score, and therefore is an estimate of measure score precision. Specifically, an ICC approach was used, as described in *Reliability, repeatability and reproducibility: analysis of measurement errors in continuous variables* (Bartlett 2008). Encounters in each facility were randomly split into two groups. One-way ANOVA was applied to estimate between facility variance and the variance of measurement error. Reliability was calculated as the ratio between facility variance and the sum of facility variance and the variance of measurement error. Reliability estimates range from zero and one, with a one representing zero measurement error, and variability in variance is due to pure facility difference, while a zero representing all variance in measurement is due to measurement errors.

Reliability for NQF #0290 was calculated across facilities and extreme values for measure score were censored at the 99th percentile (521 minutes). Censoring outlier cases limits the biasing effects of these cases while not rewarding facilities for poor performance. In addition, we calculated reliability for small, medium, and large facilities, based on denominator sizes of 11 to 14 cases, 15 to 20 cases, and 20 and 113 cases respectively.

See Section **2b.2** for validity testing of data elements.

REFERENCE:

1) Bartlett, J.W. & Frost, C. Reliability, repeatability and reproducibility: analysis of measurement errors in continuous variables. 2008.

2a2.3. For each level of testing checked above, what were the statistical results from reliability testing? (e.*g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

The ICC was calculated using the following equation:

$$\text{ICC} = \frac{variance_{facility}}{variance_{facility} + variance_{error}}$$

Across facilities (overall):

Table 2. Reliability

Reliability statistic	.74 (.69, .78)

*Intraclass correlation coefficient (ICC), 95% CI

ICC = facility variance /(facility variance plus error variance)

The measure score reliability for NQF #0290 during the January 1, 2018 - December 31, 2018 data collection period was 0.74. Reliability is the equivalent of the intraclass correlation coefficient (ICC) and values can range from zero to one. The ICC was calculated using the following equation:

Across facilities grouped by denominator size:

Table 2. Reliability

Small facilities, 11 to14 cases (n=163)	.70 (.61, .77)
Medium facilities, 15 to 20 cases (n=148)	.77 (.69, .83)
Large facilities, 21 to 113 cases (n=148)	.89 (.85, .92)

*Intraclass correlation coefficient (ICC), 95% CI

ICC = facility variance /(facility variance plus error variance)

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)

Calculated using an HLM model, a reliability score of 0.74 is indicative of good measure reliability (Koo et al., 2016). The result of this test indicates that the measure is able to identify true differences in performance between facilities. Depending on the denominator size within facilities, the reliability score ranged from .70 to .89. This, again, is indicative of good measure reliability within small, medium, and large facilities, as defined by denominator cases per facility.

Reference:
Koo TK, Li MY. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. *Journal of Chiropractic Medicine*. 2016;15(2):155–163.

2b1. VALIDITY TESTING

2b1.1. What level of validity testing was conducted? (*may be one or both levels*)

☒ **Critical data elements** (*data element validity must address ALL critical data elements*)

☐ **Performance measure score**

☐ **Empirical validity testing**

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

good from poor performance) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

2b1.2. 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)*

Validity of critical data elements was evaluated by assessing the level of agreement between facility abstraction and auditor (CDAC) abstraction. The test statistics measure agreement between two sources of data for the same observation, after accounting for agreement by chance. For this test, CDAC is considered to be an authoritative source to which facility abstraction (CDW) is compared. Test values range from 0.00 to 1.00, where a value of 0.00 indicates zero agreement between two sources and a value of 1.00 indicates complete agreement between two sources. To estimate the statistical significance associated with the test statistics, p-values were calculated. For NQF measure #0290, kappa statistics (categorical variables) and Pearson correlation coefficients (continuous variables) were used to estimate the level of agreement between CDAC's abstraction of the critical data elements and the facility's abstraction of critical data elements.

Landis & Koch, 1977 offer the following classification of kappa interpretation:

<0	Poor agreement
0.00–0.20	Slight agreement
0.21–0.40	Fair agreement
0.41–0.60	Moderate agreement
0.61–0.80	Substantial agreement
0.81–1.00	Almost perfect agreement

Similar interpretation is appropriate for Pearson correlation coefficients.

Face validity was systematically assessed in 2016 by surveying five EWG members, with backgrounds in healthcare administration, management, and clinical expertise in radiology, cardiology, and emergency medicine. The following statements related to measure score face validity were posed to the EWG:

1. Patients who are transferred to another facility for an acute coronary intervention (ACI) can be accurately captured using chart-abstracted data.
2. The measure successfully assesses the timely transfer of AMI patients requiring an ACI.

All five respondents agreed or strongly agreed to the above statements. The measure was deemed to have a high degree of validity. Face validity was not re-tested for this 2020 submission.

REFERENCE:

1) Landis, J. & Koch, G. The Measurement of Observer Agreement for Categorical Data. *Biometrics*, 33(1), 159-174. 1977.

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

Results of data element validity testing indicate substantial to almost perfect levels of agreement between the CDAC's abstraction of data elements and facilities' abstraction of critical data elements for the same encounters. Continued inclusion of a case in measure score calculation is dependent upon earlier data element values reported by the abstractor, and therefore, it is possible that cases may have populated values for critical data elements after they have been excluded from the group of eligible encounters. For this reason, test statistics were only calculated for cases that remained eligible for the measure at the corresponding step in the algorithm. For example, if a case had a value of "No" for *Initial ECG Interpretation* (thus excluding them from the group of

eligible encounters) but also had populated values for later data elements such as fibrinolytic administration, the case would not be considered in any calculations after *Initial ECG Interpretation*. Agreement between CDAC (gold standard) and CDW cases are contained in Table 3. Chance-adjusted agreement is presented in Table 4.

Table 3. Agreement on data elements

Data element	CDAC cases	Matching CDW cases	Agreement (%)
Age	269	269	100.0
E/M code	269	269	100.0
ICD-10_CM principal diagnosis code	269	269	100.0
Initial ECG interpretation	268	242	90.3
Fibrinolytic administration	93	89	95.7
Transfer for ACI	92	81	88.0
Reason for no fibrinolytic administration	84	73	86.9
ED arrival date	84	83	98.8
ED arrival time	84	84	100.0
ED discharge date	84	82	97.6
ED discharge time	84	74	88.1

Source: Data from the CMS Clinical Data Warehouse (CDW) and Clinical Data Abstraction Center (CDAC) were used during validity testing. Data were obtained from the Health Care Quality Analytics and Reporting (HCQAR) program and contained records for the time period 1/1/2018 thru 12/31/2018.

Table 4 Chance-adjusted agreement on data elements

Categorical Data Element	Kappa	Kappa p-value	Accuracy	Sensitivity	Specificity	PPV	NPV
E/M code[a]	1.0	0.00	1.00	1.00	1.00	1.00	1.00
ICD-10_CM principal diagnosis code[a]	1.0	0.00	1.00	1.00	1.00	1.00	1.00
Initial ECG interpretation[a]	.80	0.00	0.90	0.87	0.96	0.98	0.80
Fibrinolytic administration[a]	.66	0.12	0.99	0.99	1.00	1.00	0.50
Transfer for ACI[a]	.33	0.13	0.92	0.72	0.77	0.73	0.78
Reason for no fibrinolytic administration[a]	.69	0.00	0.92	0.87	0.88	0.91	0.91

Continuous Data Element	PCC	PCC p-value
Age[b]	1.00	0.00
ED arrival date[b]	1.00	0.00
ED arrival time[b]	.97	0.00
ED discharge date[b]	.98	0.00
ED discharge time[b]	.97	0.00

a. The test statistic to assess validity for this data element is a Kappa score.
b. The test statistic to assess validity for this data element is a Pearson's correlation.

2b1.4. What is 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?*)

Results of the quantitative analysis are positive and support the validity of the measure and its calculation. Based on the Landis and Koch classification scale, described in Section **2b2.2**, there was substantial to almost perfect agreement between facility and auditor abstraction of data elements. Kappa values ranged from .69 -1.00 for all data elements except 'transfer for ACI' which had a Kappa value of .33 and 'fibrinolytic administration' which had a Kappa value of .66. This suggests strong validity for most of the data elements necessary for the measure

calculation. It is encouraging that, since 2016, Kappa values for initial ECG interpretation has increased from .63 to .80 and reason for no fibrinolytic administration from .39 to .69. This may reflect an improvement in documentation by EDs.

_____

2b2. EXCLUSIONS ANALYSIS

NA ☐ no exclusions — *skip to section 2b3*

2b2.1. Describe the method of testing exclusions and what it tests (*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*)

We tested measure exclusions to determine the prevalence of each, by facility, and at an aggregate level. The analysis tested measure exclusions using CDW data from January 1, 2018 thru December 31, 2018. Exclusions include all cases meeting one or more criteria listed in Section **1.2**, above.

The face validity of measure exclusions was assessed in 2016 through a survey of five EWG members. The EWG provided feedback on the appropriateness of the three measure exclusions criteria: patients without ST-segment elevation on the ECG performed closed to ED arrival, patients receiving fibrinolytic therapy, and patients who were not transferred to another facility for ACI. Results of the survey supported the face validity of the exclusions and exceptions for NQF #0290 and indicated that they were consistent with prevailing gold standards of care or are necessary to support measure calculation. Face validity of the measure exclusions was not re-assessed in 2020.

Exclusions and performance scores. The Median Time to Transfer to Another Facility for Acute Coronary Intervention (ACI) measure is intended to measure median time to transfer to another facility for ACI for patients with ST-segment elevation myocardial infarction (STEMI). As such, the measure is limited to patients with STEMIs. Similarly, since the measure focused on patients with STEMI whom are appropriate for ACI, patients receiving fibrinolytic therapies are excluded from the measure. Finally, the measure targets patients with STEMIs transferred to another facility, as timing from ED arrival to ACI is critical to achieving a positive outcome. In other words, to get to the population of interest, one must remove some types of patients from the population of interest. In this way, these aren't clinical exclusions per se, but rather a series of steps to identify patients who are relevant for the measure.

It is sometimes appropriate to calculate the performance score with and without exclusions to determine if the exclusions impact the performance score in unanticipated ways. We did not calculate the measure score with and without exclusions for this measure. In order to test the impact of exclusions on the measure score, we would need to calculate the measure with these cases included. For example, rather than limiting the measure to those with ST-segment elevation, we would include all cardiac patients regardless of ECG finding. In the case of this measure, calculating the measure score with all patients would not be appropriate since the associated intervention, the ACI, is intended only for those with STEMI. Similarly, calculating the measure score including all STEMI patients, regardless of fibrinolytic receipt, is not appropriate because patients receiving a fibrinolytic agent are typically not candidates for an ACI.

2b2.2. What were 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*)

We examined overall frequencies and proportions of cases for each measure exclusion among all encounters across the 459 facilities submitting data to the CDW between January 1, 2018 and December 31, 2018. The initial patient population included 29,116 encounters where a patient (age 18 years or older) presented with an AMI to the ED. A total of 20,022 encounters were excluded from the measure (68.8 percent). The vast majority of

encounters, 60.9 percent, were excluded because of the initial ECG interpretation (n=17,721). Table 7 provides detailed information regarding measure exclusions.

Table 7. Overall Occurrence and Distribution across Facilities for Measure Exclusions

Measure Exclusion*	Value	Encounters excluded % (n)	Total N after each successive exclusion	Distribution Across Facilities (%)		
				25th	50th	75th
Total Encounters			29,116			
Initial ECG Interpretation	No	60.9 (17,721)	11,395	18	30	52
Fibrinolytic Administration	Yes	2.6 (296)	11,099	0	0	0
Transfer for Acute Coronary Intervention	No	9.2 (1,026)	10,073	0	1	3
Reason for not receiving fibrinolytic administration	1, 2	9.7 (979)	9,094	0	1	3
Total encounters excluded		68.8 (20,022)				
Total encounters remaining			31.2 (9,094)			
ED Discharge Date OR ED Discharge Time OR ED Arrival Date OR ED Arrival Time = UTD	UTD	.35 (32)	9062			
ED Discharge Date, ED Discharge Time, ED Arrival Date, and/or ED Arrival Time missing	Match	.13 (12)	9050			
TOTAL ENCOUNTERS ELIGIBLE FOR MEASURE = 9,050						

2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., 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*)

As seen in Table 7, the frequency of exclusions varied across facilities, particularly for *Initial ECG Interpretation*. Measure exclusions are in alignment with clinical guidelines and also ensure that all cases included in the measure have sufficient information to calculate the measure score. After identification of cases for patients 18 years and older with a principal diagnosis associated with acute myocardial infarction and ST-segment elevation on the ECG closest to ED arrival, measure exclusions were applied:

- *Initial ECG Interpretation* is measure exclusion criterion. Cases for patients where *Initial ECG Interpretation* equals "No" are excluded from the initial patient population (n=29,116 encounters). Overall, 60.9 percent of encounters are excluded based on *Initial ECG Interpretation*. There is notable variability in the proportion of cases excluded based on *Initial ECG Interpretation* values across facilities, with an interquartile range of 18 percent to 52 percent. Only cases for patients with ST-segment elevation on the ECG closest to ED arrival are included in the measure calculation because in such cases there is a clear clinical need for rapid administration of fibrinolytic therapy.

- *Fibrinolytic Administration* is an exclusion applied to the 11,395 encounters remaining after exclusion of encounters without ST-segment elevation. Overall, 2.6 percent of remaining encounters (n=296) are excluded based on *Fibrinolytic Administration* occurring. Only cases for patients who do not receive fibrinolytic therapy are included in the measure calculation because timely transfer is emergent for these cases; whereas, the need for timely transfer would be less emergent for cases that received alternative therapy.

- *Transfer for Acute Coronary Intervention* is an exclusion applied to encounters not receiving fibrinolytics (n=11,099). Cases for patients where *Transfer for Acute Coronary Intervention* equals "[2] There was documentation the patient was admitted to observation status prior to transfer" or "[3] There was documentation the patient was transferred from this facility's emergency department to another facility for reasons other than acute coronary intervention, or the specific reason for transfer was unable to be determined from medical record documentation" are excluded. Overall, 9.2 percent of remaining encounters (n=1,026) are excluded from the measure calculation based on *Transfer for Acute Coronary Intervention*. There is a small amount of variability in the proportion of cases excluded based on *Transfer for Acute Coronary Intervention* values across facilities, with an interquartile range of 0 percent to 3 percent. Only cases for patients who are transferred for ACI are included in the measure calculation because the measure score is dependent upon this criterion.

- *Reason for Not Administering Fibrinolytic Therapy* is an exclusion applied to encounters whom are transferred and have not received fibrinolytics (n=10,073). Cases where the *Reason for Not Administering Fibrinolytic Therapy* equals "[1] Documented contraindication/reason" or "[2] Cardiogenic Shock" are excluded. Overall, 9.7 percent of remaining encounters (n=979) are excluded from the measure calculation based on the *Reason for Not Administering Fibrinolytic Therapy*. There is a small amount of variability in the proportion of cases excluded based on *Reason for Not Administering Fibrinolytic Therapy* values across facilities, with an interquartile range of 0 percent to 3 percent.

- *Temporal variables.* Encounters in which *ED departure date, ED departure time, ED arrival date and/or ED departure time* are removed from the measure calculation because valid values for these variables are necessary to calculate the measure score. Only 32 encounters were removed as a result of time and/or date being 'UTD'. An additional 12 encounters were excluded because the ED arrival date, ED arrival time, ED departure date, and/or ED departure time were missing. Removal of these cases have a negligible impact on the measure score.

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b4.

2b3.1. What method of controlling for differences in case mix is used?

☒ **No risk adjustment or stratification**

☐ **Statistical risk model with** Click here to enter number of factors **risk factors**

☐ **Stratification by** Click here to enter number of categories **risk categories**

☐ **Other,** Click here to enter description

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.
Not applicable.

2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

This measure is a process measure for which we provide no risk adjustment or stratification. We determined risk adjustment and stratification were not appropriate based on the measure evidence base and the measure construct. As a process-of-care measure, timely transfer for ACI should not be influenced by SDS factors; rather, adjustment would potentially mask such important inequities in care delivery. Variation across patient populations is reflective of differences in the quality of care provided to the disparate patient population included in the measure's eligible population.

During the measure maintenance process, we perform an annual review of the literature, to identify articles and clinical practice guidelines published in the last 12 months, which includes a scan for potential patient subpopulations for which there are differences in the clinical decision to transfer for ACI. Literature currently available cites data collected prior to 2016, the last time this measure was under review. The findings continue to suggest that women experience longer transfer times from a non-primary coronary intervention (PCI)-capable hospital to a PCI-capable hospital, after adjusting for other sociodemographic, clinical, and organizational factors (Langabeerll et al, 2018; Stehli et al, 2019). Since 2016, the measure development team has not been contacted by the public or other stakeholders with concerns related to SDS factors and need for risk adjustment, supporting the conceptual model upon which the measure is based.

REFERENCES:

1) LangabeerII JR, Henry TD, Fowler R, Champagne-Langabeer T, Kim J, Jacobs AK. Sex-Based Differences in Discharge Disposition and Outcomes for ST-Segment Elevation Myocardial Infarction Patients Within a Regional Network. *Journal of Women's Health*. 2018, 27(8): 1001-1006.
2) Stehli J, Martin C, Brennan A, Dinh DT, Lefkovits J, Zaman S. Sex Differences Persist in Time to Presentation, Revascularization, and Mortality in Myocardial Infarction Treated with Percutaneous Coronary Intervention. *Journal of the American Heart Association.* 2019. *8(10). Accessed 12/5/2019 at https://www.ahajournals.org/doi/10.1161/JAHA.119.012161*

2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*) **Also discuss any "ordering" of risk factor inclusion**; for example, are social risk factors added after all clinical factors?
Not applicable - No risk adjustment or stratification was performed.

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

- ☐ **Published literature**
- ☐ **Internal data analysis**
- ☐ **Other (please describe)**

2b3.4a. What were the statistical results of the analyses used to select risk factors?
Not applicable - No risk adjustment or stratification was performed.

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors *(e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of*

unique variation in the outcome, assessment of between-unit effects and within-unit effects.) **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**
Not applicable - No risk adjustment or stratification was performed.

2b3.5. 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*)
Not applicable - No risk adjustment or stratification was performed.

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.
If stratified, skip to 2b3.9

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**
Not applicable - No risk adjustment or stratification was performed.

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):
Not applicable - No risk adjustment or stratification was performed.

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:
Not applicable - No risk adjustment or stratification was performed.

2b3.9. Results of Risk Stratification Analysis:
Not applicable - No risk adjustment or stratification was performed.

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.*e., what do the results mean and what are the norms for the test conducted*)
Not applicable - No risk adjustment or stratification was performed.

2b3.11. Optional Additional Testing for Risk Adjustment (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)
Not applicable - No risk adjustment or stratification was performed.

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE
2b4.1. 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 related to performance gap in 1b)*

Differences in measures scores were assessed at both the encounter- and facility-level using CDW data for the period January 1, 2018 to December 31, 2018. This included 9,050 encounters across 459 ED facilities with more than 10 eligible encounters. These results are in Tables 8 and 9. In addition, we conducted analyses to determine if differences exist in measure scores based on age, gender, race, or ethnicity. These results are in Table 10. Additional details of this analysis are provided in Section **2b5.2**.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., *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*)

Table 8. Encounter level distribution of measure scores

Median time to transfer to another facility for ACI	
Facilities	459
ED encounters	9050
Mean	85 minutes
Median	55 minutes
Minimum	1 minutes
Maximum[a]	521 minutes
5th percentile	22 minutes
10th percentile	27 minutes
25th percentile	38 minutes
50th percentile	55 minutes
75th percentile	90 minutes
90th percentile	186 minutes
95th percentile	274 minutes

[a] Analysis capped at 521 minutes, which reflects the 99th percentile.
Source: Data from the CMS Clinical Data Warehouse (CDW). Data were obtained from the Health Care Quality Analytics and Reporting (HCQAR) program and contained records for the time period 1/1/2018 thru 12/31/2018.

Table 9. Distribution of Facility Measure Scores

Mean	Std. Dev.	Min.	10th Percent	Lower Quartile	Median	Upper Quartile	90th Percent	Max[a]
64 min	40 min	18	34	43	54	70	92	373

[a] Analysis capped at 521 minutes, which reflects the 99th percentile.

Source: Data from the CMS Clinical Data Warehouse (CDW). Data were obtained from the Health Care Quality Analytics and Reporting (HCQAR) program and contained records for the time period 1/1/2018 thru 12/31/2018.

Table 10. Measure score by demographic characteristics

Characteristics	Median minutes	Mean minutes[a] minutes (95% CI)	Encounters n
Age			
18-64	52	78 (0, 232)	5,129
65+	59	95 (0, 281)	3,921
Gender[b]			
Male	52	80 (0, 242)	6,180
Female	62	98 (0, 280)	2,869
Race			
Black or African American	64	102 (0, 304)	714
White	53	81 (0, 237)	7,582
Other	76	148 (0, 436)	273
Unknown	61	97 (0, 289)	481
Ethnicity			
Hispanic or Latino	62	93 (0, 256)	555
Non-Hispanic	54	85 (0, 255)	8,495

[a] Analysis capped at 521 minutes, which reflects the 99th percentile.
[b] Four cases excluded because gender equaled 'unknown'.
Source: Data from the CMS Clinical Data Warehouse (CDW). Data were obtained from the Health Care Quality Analytics and Reporting (HCQAR) program and contained records for the time period 1/1/2018 thru 12/31/2018.

2b4.3. What is 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? (i.*e., what do the results mean in terms of statistical and meaningful differences?*)

The measure was able to detect substantial variation in facility performance. The facility measure scores, located in Table 9, ranged from 18 minutes to 373 minutes with a median of 54 minutes. Fifty percent of facilities fell within the interquartile range of 43 minutes to 70 minutes. The mean ± SD facility measure score was 64.0 minutes ± 40.0 minutes. By reporting a measure mean (benchmark value), this provides an opportunity for outlying facilities to identify underperformance related to timely transfer for ACI in cases when it is clinically appropriate. These results are similar to those seen in prior measure testing activities.

We also identified differences in measure scores based on demographic characteristics. Women, older patients, non-White patients, and Hispanic patients had longer median times to transfer than their male, younger, White, non-Hispanic counterparts. These disparities have been documented in the literature and represent areas for improvement in care in the future (Graham, 2016, Langabeerll, 2018, Pilgrim et al., 2015).

References:

Graham, G. (2016), Racial and Ethnic Differences in Acute Coronary Syndrome and Myocardial Infarction Within the United States: From Demographics to Outcomes. *Clinical Cardiology*, 39: 299-306.

LangabeerII JR, Henry TD, Fowler R, Champagne-Langabeer T, Kim J, Jacobs AK. Sex-Based Differences in Discharge Disposition and Outcomes for ST-Segment Elevation Myocardial Infarction Patients Within a Regional Network. Journal of Women's Health. 2018, 27(8): 1001-1006.

Pilgrim T, Heg D, Tal K, Erne P, Radovanovic D, Windecker S, et al. (2015) Age- and Gender-related Disparities in Primary Percutaneous Coronary Interventions for Acute ST-segment elevation Myocardial Infarction. PLoS ONE 10(9): e0137047. https://doi.org/10.1371/journal.pone.0137047

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS
If only one set of specifications, this section can be skipped.

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 eMeasures). 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.***

2b5.1. 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; what statistical analysis was used*)
Not Applicable - this measure uses only one set of specifications.

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)
Not Applicable - this measure uses only one set of specifications.

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.*e., what do the results mean and what are the norms for the test conducted*)
Not Applicable - this measure uses only one set of specifications.
.

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data

minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

This measure is calculated using chart-abstracted data. To limit the effects of missing data, abstractors cannot submit a value of "missing" for individual data elements. When they submit a value of "missing" the case is rejected from the abstraction tool. While abstractors cannot submit missing data, they may submit a value of "UTD" for select data elements for which missing information may be more likely; for example, temporal variables such as ED arrival and departure dates and times. We assessed each variable to determine the frequency of missing data. Results are reported in 2b7.2.

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each*)

There were 32 encounters of encounters with 'UTD' for ED arrival or departure dates or times within the CDW. For these encounters, the measure calculation is not feasible. Thus, the encounters were dropped from the analytic file. In addition, 12 encounters within the CDQ had ED arrival date and times that matched their ED discharge date and time were dropped from the analytic file. These 44 encounters accounted for approximately .5 percent of eligible cases.

For the key variables - ECG performed, fibrinolytic administration, and transfer out - valid values were available for all cases in the analytic file received from HCQAR.

2b6.3. What is 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 nonresponders) and how the specified handling of missing data minimizes bias**?** (i.*e., 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, provide rationale for the selected approach for missing data*)

For the key variables - ECG performed, fibrinolytic administration, and transfer out - valid values were available for all cases in the analytic file received from HCQAR. There were 44 encounters (0.5 percent) of encounters with 'UTD' for ED arrival or departure dates or missing on ED arrival and/or departure dates and/or times. For these encounters, the measure calculation is not feasible. Since only 44 encounters out of 9,094 had unusable data, the impact on the measure results is negligible.

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.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

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

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

Some data elements are in defined fields in electronic sources

3b.2. 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 other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

NQF #0290 assesses the time interval from ED arrival to transfer to another facility for ACI for patients with confirmed AMI. Challenges in interpreting and operationalizing the current measure's algorithm make it difficult to respecify this measure for an EHR reporting program since some data elements of the measure currently rely on logic and inferences that abstractors have been trained to interpret. The most significant challenge related to the measure's algorithm involves the Reason for Not Administering Fibrinolytic Therapy data element, which requires a contraindicated/reason for not administering fibrinolytic therapy which is currently located in unstructured fields of the patient record.

Additionally, the potential for e-specification will also require special attention to the Initial ECG Interpretation and Transfer for Acute Coronary Intervention. Abstractors often rely on ECG print-outs and medical notes to determine the presence of ST-segment elevation on an ECG, and if a transfer was specifically for ACI.

Use of EHR data will require vendors to develop mechanisms to capture ECG findings, which are currently used to define the measure's denominator, in a structured field; because of the complicated nature of ECG interpretation, results included in a structured field should come from a review by an eligible provider rather than the ECG machine´s output. Because the reason for patient transfer effectively excludes patients from the measure, these data will also need to be captured and made available for measurement within the EHR workflow.

The AMI and Stroke expert work group (EWG) considers NQF #0290 to be wholly feasible as it is currently specified, but considers e-specification to be moderately feasible. They concur that the key data elements for NQF #0290 are not readily available in a structured format within all EHR systems. In particular, EHR systems may need a new structured field for Initial ECG Interpretation, Reason for Not Administering Fibrinolytic Therapy, and Transfer for Acute Coronary Intervention, which are not perceived to be a standard feature for most systems at this time.

Based on EWG feedback, the availability of the information from the data elements is highly dependent upon the EHR system used in each facility. If they cannot be translated into structured fields, then the data elements must be manually chart abstracted.

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. 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.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

An online survey of five members of the AMI and Stroke EWG with expertise in cardiology, radiology, emergency medicine, and emergency nursing was conducted to assess the face validity, feasibility, use, and usability of NQF #0290. All participants agreed or strongly agreed that patients who are transferred to another facility for an ACI can be accurately captured using chart abstracted data. Additionally, three of five participants agreed that practical aspects of reporting this chart-abstracted measure do not place undue burden on facilities that collect the data. Those that did not agree indicated the burden will vary between facilities and depend on how well their health record system is constructed. In addition, those that did not agree specifically noted that requiring details about the logistics of a patient transfer as well as the documentation of contraindications may pose a burden on facilities as this is not something that is normally documented in ED workflow.

3c.2. Describe 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)*.

No fees, licensure, or other requirements are necessary to use this measure; however, CPT codes, descriptions, and other data are copyright 2013 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS\DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

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.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

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 performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)

	Public Reporting Hospital Compare http://www.medicare.gov/hospitalcompare/search.html Hospital Outpatient Quality Reporting (OQR) Program https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1192804531207 Hospital Compare http://www.medicare.gov/hospitalcompare/search.html Hospital Outpatient Quality Reporting (OQR) Program https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1192804531207

4a1.1 For each CURRENT use, checked above (update for <u>maintenance of endorsement</u>), provide:

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

Public Reporting:
Name of program and sponsor: CMS Hospital OQR Program
Purpose: The Hospital OQR Program is a pay for quality data reporting program implemented by CMS for outpatient hospital services. In addition to providing hospitals with a financial incentive to report their quality of care measure data, the Hospital OQR Program provides CMS with data to help Medicare beneficiaries make more informed decisions about their health care. Hospital quality of care information gathered through the Hospital OQR Program is publicly available on the Hospital Compare website.
Accountable entities and patients: The publicly reported values (on Hospital Compare) are calculated for all facilities in the United States that meet minimum case count requirements. The number of facilities that met minimum case count criteria (>10 cases) between 1/1/2018 and 12/31/2018 was 450. The number of facilities meeting minimum case count criteria by year is presented in Section 1b.2. Facilities eligible to report this measure are subject to the Outpatient Prospective Payment System (OPPS) guidelines.

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)
This measure is publicly reported.

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*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.*)

This measure is publicly reported.

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

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.

Data for NQF 0290 are publicly available on CMS's Hospital Compare website, which are refreshed quarterly.

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

Stakeholders can connect with CMS's contractors for NQF 0290 via the QualityNet Q&A tool (https://cms-ocsq.custhelp.com/app/answers/list/c/89), through which they can submit questions about the specifications for NQF 0290 and on the data used to calculate their performance score.

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

Feedback received from stakeholders (via the ServiceNow Q&A tool) is used to revise the measure specifications. Following receipt of a suggestion to adjust the specifications, a literature review is performed to determine if the proposed change aligns with the empirical evidence base for the measure; feedback from the expert work group is obtained to evaluate the change to the specifications. To date, we have received no significant concerns raised by stakeholders about the measure specifications through the ServiceNow Q&A tool.

In addition, stakeholders may submit comments on the measure through the Outpatient Prospective Payment System (OPPS) annual rulemaking process. No comments were received for this measure during the Calendar Year (CY) 2016 -2019 OPPS rulemaking cycles.

4a2.2.2. Summarize the feedback obtained from those being measured.

There has been no feedback received for NQF 0290 since the last annual update.

4a2.2.3. Summarize the feedback obtained from other users

Results of an assessment of face validity, using survey responses from members of the expert work group, indicate that a diverse group of stakeholders, a majority of whom were not involved in the measure's development, support the usability of NQF 0290.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

CMS's contractors use feedback received from stakeholders (through the QualityNet Q&A tool) to revise the specifications for NQF 0290. Following receipt of a suggestion to adjust the specifications for NQF 0290, CMS's contractors perform a review of the literature to determine if the proposed change aligns with the empirical evidence base for the measure; qualitative feedback from the expert work group is collected to evaluate the impact a change would have on the specifications and nationally reported results.

To date, we have received no significant concerns raised by stakeholders about the measure specifications through the QualityNet Q&A tool.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b 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, what are the reasons? 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.

Not applicable, as there is demonstrated improvement in measure performance over time.

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

Measure testing did not identify any unintended consequences. Similarly, no evidence of unintended consequences to individuals or populations has been reported by external stakeholders since its implementation. The potential for unintended consequences will continue to be monitored through an annual review of the literature as well as an ongoing review of stakeholder comments and inquiries.

4b2.2. Please explain any unexpected benefits from implementation of this measure.

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.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

0288 : Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

Yes

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

NQF #0290 and NQF #0288 are both in the Hospital OQR Program. These measures have the same initial patient population – patients with AMI and ST-segment elevation on the ECG performed closest to hospital arrival. While the target populations are the same, the focus of the measures is different. NQF #0288 focuses on the timely administration of fibrinolytic therapy and NQF# 0290 focuses on the timely transfer of patients who require a PCI. These two measures share several key data elements (i.e., Initial ECG Interpretation, Fibrinolytic Administration, and Arrival Time). The specifications for these two measures are generally aligned, where possible.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):
Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)
No competing measures that address both the same measure focus and target population as NQF #0290 were identified.

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Attachment:

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): Centers for Medicare and Medicaid Services

Co.2 Point of Contact: Annese, Abdullah-Mclaughlin, Annese.Abdullah-Mclaughlin@cms.hhs.gov, 410-786-2995-

Co.3 Measure Developer if different from Measure Steward: Mathematica

Co.4 Point of Contact: Madeline, Pearse, Mpearse@mathematica-mpr.com, 510-830-3729-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

The contractor has convened an EWG, which evaluates and provides feedback on measure-development and maintenance efforts for a set of five AMI and one stroke measure. Specifically, the EWG provides direction and feedback through all phases of project activities, including expansion of the measures to additional CMS quality reporting programs, updates to the current specifications of these six measures, review of quantitative testing results, feedback on qualitative testing questions (i.e., results of EWG member questionnaires), and support for endorsement of the measures by the National Quality Forum (NQF).

The following is a list of the contractor's EWG members:

Kenneth Bricker, DO

Minneapolis VA Medical Center

Cathy Olson, MSN, RN

Emergency Nurses Association (ENA), Institute for Quality, Safety, and Injury Prevention, Director

David Seidenwurm, MD

American Society of Neuroradiology (ASNR); American College of Radiologists (ACR)

Stephen Traub, MD

Mayo Clinic, Department of Emergency Medicine, Chair

Paul D. Varosy, MD, FACC, FAHA, FHRS

VA Eastern Colorado Health Care System, Director of Cardiac Electrophysiology

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2008

Ad.3 Month and Year of most recent revision: 01, 2019

Ad.4 What is your frequency for review/update of this measure? Annually

Ad.5 When is the next scheduled review/update for this measure? 01, 2020

Ad.6 Copyright statement: This measure does not have a copyright.

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Ad.8 Additional Information/Comments: