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

Purple text represents the responses from measure developers.

Red text denotes developer information that has changed since the last measure evaluation review.

Brief Measure Information

NQF #: 3613e

Corresponding Measures:

De.2. Measure Title: Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

Co.1.1. Measure Steward: Centers for Medicare & Medicaid Services (CMS)

De.3. Brief Description of Measure: The percentage of ED patients with a diagnosis of STEMI who received appropriate and timely treatment. The measure will be calculated using electronic health record (EHR) data and is intended for use at the facility level in a CMS accountability program, through which it may be publicly reported.

1b.1. Developer Rationale: Primary PCI is the preferred revascularization approach, and for patients presenting to hospitals with on-site PCI capabilities guidelines recommend PCI be performed within 90 minutes. For patients presenting to hospitals with primary PCI capabilities, D2B time has shown marked improvements over time, and most hospitals are able to deliver PCI within 90 minutes of patient arrival. The median time to primary PCI in the National Cardiovascular Data Registry in 2014 was 59 min (10th, 50th, and 90th percentiles of 70, 60, and 48 min, respectively) (Masoudi et. al., 2017). In situations where a patient arrives at a non-PCI capable hospital but can be transferred for primary PCI to a PCI referral center, guidelines recommend that primary PCI be performed within 120 minutes (O'Gara et al., 2013). However, for patients transferred from non-PCI-capable hospitals to PCI-capable hospitals, a nationwide study of 14,518 showed that more than one-third of patients failed to meet recommended guidelines for door-to-balloon time (Dauerman et al, 2015).

In situations where it is unlikely or impossible for a patient to receive primary PCI within the 120-minute timeframe, guidelines recommend that fibrinolytic therapy be used for reperfusion and should be rapidly administered to reduce mortality and minimize morbidity; guidelines recommend that fibrinolytic therapy administration occur within 30 minutes of hospital arrival (O'Gara et al., 2013). CMS measures receipt of fibrinolytic therapy within 30 minutes of ED arrival (OP-2) and the time to transfer to a PCI referral center from a non PCI-capable facility (OP-3). Performance data on OP-2 and OP-3 suggest that opportunities remain for facilities to improve timely delivery of fibrinolytic therapy in the ED and expedited transfer to PCI-capable facilities. For the April 2018 through March 2019 data collection period, proportion of patients receiving fibrinolytics within 30 minutes in the OP-2 measure varied from 14% to 100%, with the weighted mean of 70.4%. Similarly, for patients undergoing transfer, for the April 2018 through March 2019 data collection period, performance scores on OP-3 varied from 19 minutes to 106 minutes, with a weighted mean of 54.22 minutes.

REFERENCES:

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S.4. Numerator Statement: ED STEMI patients aged 18 and older whose time from ED arrival to fibrinolysis is 30 minutes or fewer OR Non-transfer ED STEMI patients who received PCI at a PCI-capable hospital within 90 minutes of arrival OR ED STEMI patients who were transferred from a non-PCI capable hospital within 45 minutes of ED arrival at a non-PCI capable hospital.

S.6. Denominator Statement: ED patients 18 years of age and older with STEMI who should have received appropriate and timely treatment for STEMI.

S.8. Denominator Exclusions: The denominator exclusions were derived from the 2013 ACCF/AHA Guideline for the Management of STEMI (http://www.onlinejacc.org/content/accj/61/4/e78.full.pdf?download=true), which was also the basis of OP-2 (Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival) and OP-3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention). Denominator exclusions include the following conditions, which have to be documented as active in the patient's history at the time of the encounter: active bleeding or bleeding diathesis (excluding menses); ischemic stroke; known malignant intracranial neoplasm (primary or metastatic); known structural cerebral vascular lesion (e.g., AVM); significant facial and/or closed head trauma, any prior intracranial hemorrhage or other known intracranial pathology; suspected aortic dissection; active peptic ulcer; cardiopulmonary arrest; intubation; mechanical circulatory assist device placement; oral anticoagulant therapy prior to arrival (including streptokinase treatment); patients with advanced dementia; pregnancy; recent internal bleeding; recent major surgery; intracranial or intraspinal surgery, and severe neurologic impairment (based on Glasgow coma).

De.1. Measure Type: Process

S.17. Data Source: Electronic Health Records

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Most Recent Endorsement Date:

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? N/A

Preliminary Analysis: New Measure

Criteria 1: Importance to Measure and Report

1a. Evidence

1a. Evidence. The evidence requirements for a ***structure, process or intermediate outcome*** measure are 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**

Evidence Summary

- The developer provides a path that speeds reperfusion of cardiac muscle and improves outcomes, such as reduced mortality, bleeding events, and reinfarction, by providing timely fibrinolytic therapy or percutaneous coronary intervention [PCI]) for STEMI within the timeframe specified in clinical practice guidelines.
- The developer cites two separate guidelines to support the development of this measure:
    - The first clinical practice guideline released in 2013 by the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA), evaluates management of patients with STEMI. It provides recommendations for fibrinolytic therapy when there is an anticipated delay to performing primary PCI within 120 minutes of first medical contact. The developer provided four recommendations from this guideline to support the measure's clinical intent. All four recommendations were assigned Class I designation with Level of Evidence being A or B.
    - The second guideline, released in 2017 by the American College of Emergency Physicians (ACEP), evaluates management of patients with STEMI. It provides recommendations for the management of ED STEMI patients in need of reperfusion therapy provides recommendations for the treatment of STEMI. The developer provided two recommendations from this guideline to support the measure's clinical intent. The recommendation received Class III designation with Level of Evidence as B.
- The developer provided the Quantity, Quality and Consistency of the evidence for both the guidelines to support the measure's intent.

Exception to evidence

NA

Questions for the Committee:

For structure, process, and intermediate outcome measures:

- What is the relationship of this measure to patient outcomes?
- How strong is the evidence for this relationship?
- Is the evidence directly applicable to the process of care being measured?
- If derived from patient report, does the target population value the measured process or structure and find it meaningful?

Guidance from the Evidence Algorithm

Process measure based on systematic review (Box 3) à QQC presented (Box 4) à Quantity: moderate; Quality: moderate; Consistency: moderate (Box 5) à Moderate (Box 5b) à 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.

The developer noted that measure NQF #3613 is not implemented and therefore, performance scores are not available. In light of no performance data on this measure, the developer provided a summary of data from one citation as well as performance data from other similar measures including OP-2 (Fibrinolytic Therapy Received within 30-minutes of ED Arrival) and OP-3 ((Median Time to Transfer to Another Facility for Acute Coronary Intervention) that indicates opportunity for improvement

Disparities

The developer noted that since this measure is not yet implemented, they are limited to data from two systems and consequently, cannot assess systematic disparities in care in using only the data from testing. The developer cited evidence from a data analyses performed by Lewin examining the impact of patient and facility characteristics on use of fibrinolysis using a logistic regression model for 3,844 cases. The analysis used the 2014 data submitted to CMS's clinical data warehouse (CDW) They also cited evidence from the literature that suggests disparities in PCI.

Questions for the Committee:

Is there a gap in care that warrants a national performance measure?

If no disparities information is provided, are you aware of evidence that 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 to Support Measure Focus: For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Does it apply directly or is it tangential? How does the structure, process, or outcome relate to desired outcomes? For maintenance measures –are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission? For measures derived from a patient report: Measures derived from a patient report must demonstrate that the target population values the measured outcome, process, or structure.

- Appropriate evidence
- Meets evidence requirements
- sufficient evidence for impactability
- Multiple guidelines cited to support this measure concept. Guideline evidence suggests improved outcomes, like mortality, when appropriate care within the time frame.
- All evidence is acceptable.
- This measure is supported by systematic reviews, QQC and the evidence is graded. There is not any new information that is not included. The evidence base has not changed
- Strong evidence

1b. Performance Gap: Was current performance data on the measure provided? How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Disparities: Was data on the measure by population subgroups provided? How does it demonstrate disparities in the care?

- Not implemented
- Yes, a performance gap is demonstrated
- I am a little skeptical about the use of data from another measure and literature to justify the performance gap
- Is the measure isn't implemented, hard to determine gap. Disparity data is cited from 2014 (as are guidelines).
- Proxy acceptable for actual results. Overall for data collection related to disparities, needs to be reviewed is a broad way to determine how best to collect and use the data. This is not a measure by measure discussion at this point.
- This measure is not in use, so the performance gap and disparities are unknown. published data show a performance gap with disparities
- Performance gap exists, but top performance is not yet defined, it is not going to be 100%

1c. Composite Performance Measure - Quality Construct (if applicable): Are the following stated and logical: overall quality construct, component performance measures, and their relationships; rationale and distinctive and additive value; and aggregation and weighting rules?

- Yes
- N/A
- N/A
- N/A
- N/A

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

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

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.

Submitted measure specification follows established technical specifications for eCQMs (QDM, HQMF, and CQL) as indicated Sub-criterion 2a1.

Submitted measure specification is fully represented and is not hindered by any limitations in the established technical specifications for eCQMs.

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 at 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.

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

Evaluators: NQF Staff

Scientific Acceptability Staff Review

Reliability

The developer stated that separate reliability testing of data elements was not conducted because NQF guidance does not require separate reliability testing if validity of data elements is empirically tested.

Validity

- The developer noted that the machine-readable logic was used by each testing site to generate queries within their respective EHR systems. For the data validity testing, the developer compared the values for data used in the measure as abstracted manually from EHRs and the data extracted electronically.
- The developer assessed and reported data element validity on five characteristics of agreement between the electronically extracted data and manually abstracted data (the gold standard), which included Cohen's kappa, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Data element validity testing was conducted with two hospital systems each using a different EHR.
- The developer reported Kappa coefficients, which indicate a range of agreement across systems and data element categories, using thresholds described by Landis and Koch (1977). The developers noted that the numerator value agreements are fair for System 1 and substantial for System 2. The denominator value for System 1 indicates agreement equal to that expected by chance and the denominator value for System 2 indicates slight agreement. Denominator exclusions values are moderate for System 1 and substantial for System 2.

- The developer highlighted that in addition, qualitative interviews with staff at System 2 indicated a lack of familiarity with the Epic EHR system, to which they recently transitioned, which may have led to accuracy challenges for both the electronic extract as well as the manual abstraction. The manual abstraction challenges, specifically, would not affect programmatic calculation of the measure.
- For exclusion analysis, the developer examined the frequency of occurrence of exclusions at each system. In addition, the developers also assessed the data element validity of individual exclusions for the manually abstracted sample of 111 randomly selected patients using the same five same characteristics of agreement (Cohen's kappa, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV)). The developers reported that the frequency of occurrence for many exclusions is zero at both systems, which suggest that scores will not be substantially impacted by several of these exclusions.
- No risk-adjustment was conducted for this measure.

Questions for the Committee regarding reliability:

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

The staff is satisfied with the reliability testing for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The Feasibility Scorecard indicated that several data elements have issues with accuracy. Are the accuracy issues substantial enough to impact the validity of these data elements?
- The staff is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?
- The staff is satisfied with the composite construction. Does the Committee think there is a need to discuss and/or vote on the composite construction approach?

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)

2a1. Reliability-Specifications: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

- None
- No concerns
- no concerns
- N/A
- no concern
- Separate documentation of reliability was not required
- Concern about systematic underrepresentation of ER's without adequate EHRs.

2a2. Reliability - Testing: Do you have any concerns about the reliability of the measure?

- No
- Not applicable
- I consent to the staff recommendations
- N/A
- no
- N/A
- see above

2b1. Validity - Testing: Do you have any concerns with the testing results?

- No
- No significant concerns
- with only two sites tested and one site having only fair data element validity, validity is low
- Accuracy challenges are noted. Measure implementation would improve on this.
- no
- No
- Developer's reliability testing highlighted the issues with EHR transitions. ERs will have lower reliability than other sites of care. Truly emergent patients like STEMI and stroke are more likely to present to ERs NOT in their usual system of care than less urgent situations, and thus have less EHR data available.

2b4-7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data) 2b4. Meaningful Differences: How do analyses indicate this measure identifies meaningful differences about quality? 2b5. Comparability of performance scores: If multiple sets of specifications: Do analyses indicate they produce comparable results? 2b6. Missing data/no response: Does missing data constitute a threat to the validity of this measure?

- No
- No prohibitive concerns, though I remain skeptical about the impact from missing data.
- no concerns
- If the measure isn't continued to be implemented, concerns about continued data integrity (accuracy)
- Has the developer worked directly with the EHR developers to test? Acceptable but concerned only tested on 2 EHRs.
- No concerns
- The concerns mentioned about where the time data lives are representative of many hospitals with regard to PCI. Times for lytic administration and transfer are more likely to be valid.

2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment) 2b2. Exclusions: Are the exclusions consistent with the evidence? Are any patients or patient groups inappropriately excluded from the measure? 2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? Was the risk adjustment (case-mix adjustment) appropriately developed and tested? Do analyses indicate acceptable results? Is an appropriate risk-adjustment strategy included in the measure?

- Yes
- No adjustment for social risk, which has pros and cons. Lots of exclusions but appropriate for lytic therapy
- N/A
- N/A
- all acceptable
- Exclusions are consistent. There is no risk adjustment
- N/A

2c. Composite Performance Measure - Composite Analysis (if applicable): Do analyses demonstrate the component measures fit the quality construct and add value? Do analyses demonstrate the aggregation and weighting rules fit the quality construct and rationale?

- I would not see this as composite measure, only a measure that has three possible ways to meet the numerator requirements.
- N/A
- N/A
- N/A

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.
   - Since the measure has not been implemented, no difficulties in data collection have been identified, and the developer indicates that no fees, licensure, or other requirements are necessary to use this measure
   - Using a simulated data set, the submission demonstrates that the evaluation of 100% of the measure logic can be automated. The following table list the data elements with feasibility issues identified on the feasibility scorecard:

Data Element	Domains	Impact	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
PROC_PCI_TIME	Availability, accuracy	Numerator	Feasibility concerns were site specific and related the lack of internal interoperability of health record system. The site for which this was a concern indicated that PCI time	The recommendation is to keep the data element without modification. In order to report for this measure, sites must be able to provide PCI time metric values from their EHR. Coordination with EHR vendors to standardize data elements required for the measure prior to

Data Element	Domains	Impact	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
			metrics are captured in a system specific to their Cath lab. The site also indicated they are working to improve interoperability between the main EHR system and Cath lab systems; following system integration of their systems, feasibility of this data element will no longer be a concern.	implementation should mitigate this feasibility concern.
PROC_INSERT_TIME	Availability, accuracy	Numerator	Feasibility concerns were site specific and related the lack of internal interoperability of health record system. The site for which this was a concern indicated that PCI time metrics are captured in a system specific to their Cath lab. The site also indicated they are working to improve interoperability between the main EHR system and Cath lab systems; following system integration of their systems, feasibility of this data element will no longer be a concern.	The recommendation is to keep the data element without modification. In order to report for this measure, sites must be able to provide PCI time metric values from their EHR. Coordination with EHR vendors to standardize data elements required for the measure prior to implementation should mitigate this feasibility concern.
PROC_BALLOON_TIME	Availability, accuracy	Numerator	Feasibility concerns were site specific and related the lack of internal interoperability of health record system. The site for which this was a concern indicated that PCI time metrics are captured in a system specific to their Cath lab. The site also indicated they are working to improve interoperability	The recommendation is to keep the data element without modification. In order to report for this measure, sites must be able to provide PCI time metric values from their EHR. Coordination with EHR vendors to standardize data elements required for the measure prior to implementation should mitigate this feasibility concern.

Data Element	Domains	Impact	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
			between the main EHR system and Cath lab systems; following system integration of their systems, feasibility of this data element will no longer be a concern.	
D_ACTV_BLEED	accuracy	Denominator exclusion	Based on qualitative feedback, though this is captured within a structure field in the EHR, it is difficult to ascertain using a look-back period.	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.
D_ACTV_PEP_ULC	accuracy	Denominator exclusion	Based on qualitative feedback, though this is captured within a structure field in the EHR, it is difficult to ascertain using a look-back period.	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.
NDC_ANTICOAGULANT	Availability, Accuracy	Denominator exclusion	Based on qualitative feedback, medication administration records maybe be coded using a different system. In this case, sites would need to crosswalk medication coding to match RXNorm in the Value Set.	The recommendation is to retain the data element. The medication will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion. Coordination with EHR vendors should allow for the crosswalk of RXNorm codes that are used in the value sets.
D_SUS_ART_DSSC	workflow	Denominator exclusion	Feasibility concerns were site specific and related to provider workflow. The site for which this was a concern indicated that there may be variability in documentation by provider.	The recommendation is to keep the data element without modifications. Educational opportunities for sites eligible for reporting are recommended to encourage more accurate documentation practices.
D_CARDIOPUL_ARREST	Accuracy, workflow	Denominator exclusion	Based on qualitative feedback, though cardiopulmonary arrest on the encounter date may be feasible to extract, there are challenges with the	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.

Data Element	Domains	Impact	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
			look-back period of 30-minutes.	
D_CEREB_VASC_LSN	Accuracy, availability, workflow	Denominator exclusion	Based on qualitative feedback, though this is captured within a structure field in the EHR, it is difficult to ascertain using a look-back period.	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.
D_DEMENTIA	Accuracy, Availability, standards, workflow	Denominator exclusion	Based on qualitative feedback, though this is captured within a structure field in the EHR, it is difficult to ascertain using a look-back period.	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.
PROC_INTUB	Accuracy, availability, standards, workflow	Denominator exclusion	Based on qualitative feedback, intubation prior to arrival is likely to be documented in an EMS record and may not be available in a structured field in the EHR (this may vary by facility).	The recommendation is to retain the data element. Intubation must be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.
D_HYPTSN	Accuracy	Denominator exclusion	Though it is feasible to identify hypertension at the time of the encounter, severe uncontrolled hypertension is unlikely to be captured within a structured field within the EHR.	The recommendation is to remove the data element based on feasibility concerns and high prevalence. Sites noted that hypertension is common among STEMI patients and should not result in delay in treatment.
D_INTRCRN_NEO	Accuracy, workflow	Denominator exclusion	Based on qualitative feedback, though this is captured within a structure field in the EHR, it is difficult to ascertain using a look-back period.	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.
D_PR_ISCH_STK	Accuracy, Availability, workflow	Denominator exclusion	Based on qualitative feedback, though this is captured within a structure field in the EHR, it is	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical

Data Element	Domains	Impact	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
			difficult to ascertain using a look-back period.	history for the case to be identified as an exclusion.
D_MAJOR_SURG	Accuracy, Workflow	Denominator exclusion	Based on qualitative feedback, though this is captured within a structure field in the EHR, it is difficult to ascertain using a look-back period.	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.
D_MED_CIRC_ASST_DEV	Workflow	Denominator exclusion	Based on qualitative feedback, mechanical circulatory assist device placement prior to arrival is likely to be documented in an EMS record and may not be available in a structured field in the EHR (this may vary by site).	The recommendation is to retain the data element. Device must be listed as ACTIVE on the patient's medical history for the case to be identified as an exclusion.
D_FAC_HEAD_TR	Accuracy, Availability, workflow	Denominator exclusion	Based on qualitative feedback, though this is captured within a structured field in the EHR, it is difficult to ascertain using a look-back period.	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.
D_PATNT_FAM_REF	Accuracy, Availability, Standards, Workflow	Denominator exclusion	Based on feedback from both sites, patient and/or family refusal is unlikely to be documented in a structured field within the EHR or to occur for an emergent condition such as STEMI.	The recommendation is to remove the data element.
D_PREGNANCY	workflow	Denominator exclusion	Feasibility concerns were site specific and related to provider workflow. The site for which this was a concern indicated that there may be variability in documentation by provider.	The recommendation is to keep the data element without modifications. Educational opportunities for sites eligible for reporting are recommended to encourage more accurate documentation practices.
D_SEV_NEURO_IMPAIR	Accuracy, workflow	Denominator exclusion	Based on qualitative feedback, though this is captured within a structure	The recommendation is to retain the data element and remove the look-back period. The condition will have to be

Data Element	Domains	Impact	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
			field in the EHR, it is difficult to ascertain using a look-back period.	listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.
NDC_THROMB_REACT	Accuracy, Availability, workflow	Denominator exclusion	Based on qualitative feedback, medication administration records maybe be coded using a different system. In this case, sites would need to crosswalk medication coding to match RXNorm in the Value Set.	The recommendation is to retain the data element. The medication will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion. Coordination with EHR vendors should allow for the crosswalk of RXNorm codes that are used in the value sets.
PROC_INTRCRN_INTRSPN_SUR	Accuracy, Availability, workflow	Denominator exclusion	Based on qualitative feedback, though this is captured within a structured field in the EHR, it is difficult to ascertain using a look-back period.	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.
D_HIST_INTRCRN_HEM	Accuracy, workflow	Denominator exclusion	Based on qualitative feedback, though this is captured within a structured field in the EHR, it is difficult to ascertain using a look-back period.	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.
D_ISCH_STK	Accuracy, workflow	Denominator exclusion	Based on qualitative feedback, though this is captured within a structured field in the EHR, it is difficult to ascertain using a look-back period.	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.
D_REC_INT_BLEED	Accuracy, workflow	Denominator exclusion	Based on qualitative feedback, though this is captured within a structured field in the EHR, it is difficult to ascertain using a look-back period.	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical history for the case to be identified as an exclusion.
D_INTRCRN_OTHER	Accuracy, workflow	Denominator exclusion	Based on qualitative feedback, though this is captured within a structured field in the EHR,	The recommendation is to retain the data element and remove the look-back period. The condition will have to be listed as ACTIVE in the patient's medical

Data Element	Domains	Impact	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
			it is difficult to ascertain using a look-back period.	history for the case to be identified as an exclusion.
D_STEMI	workflow	Denominator	Data element is able to be captured within a structured field in the EHR. Qualitative feedback indicates that the definition of the data element should be specified to explicitly state that the diagnosis of STEMI must occur in the ED. Site indicated the potential for a diagnosis of STEMI to be overturned by a cardiologist in a catherization lab.	The recommendation is to keep the data element and explicitly specify that STEMI must be diagnosed in the ED.
ARRIV_CODE	Accuracy, Availability Standards workflow	Denominator	Feasibility concerns were site specific and related to provider workflow. The site for which this was a concern indicated that there may be variability in documentation by provider.	The recommendation is to keep the data element without modifications. Educational opportunities for sites eligible for reporting are recommended to encourage more accurate documentation practices.

Questions for the Committee:

- Are the required data elements routinely generated and used during care delivery?
- Are the required data elements available in electronic form, e.g., EHR or other electronic sources?
- Is the data collection strategy ready to be put into operational use?
- Does the eCQM Feasibility Score Card demonstrate acceptable feasibility in multiple EHR systems and sites?

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

RATIONALE:

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

Feasibility: Which of the required data elements are not routinely generated and used during care delivery? Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? What are your concerns about how the data collection strategy can be put into operational use?

- None
- Given the number of required data elements, I do have concerns about the impact of missing or erroneous data.
- coding accuracy seems to have limited feasibility
- No major concerns. Do not operate an EHR and look forward to the committee's conversation
- agreement with document. Measurement should not change due to lack on interoperability.
- The look back data are not in the medical record and were dropped. Some variables were also dropped because they were not routinely recorded. I don't have concerns.
- See above comments

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**

OR

Planned use in an accountability program? ☒ **Yes** ☐ **No**

Accountability program details

- NQF #3613e is a new measure submitted for initial NQF endorsement; hence, the developer noted that the performance results are not currently in use in an accountability program and are not publicly reported, but the measure is intended for use at the facility level in an accountability program where it may be publicly reported.
- As per NQF Measure Evaluation Criteria and Guidance, if the measure is not in use at the time of initial endorsement, developers are required to present a credible plan for implementation within the expected timeframes -- at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement. Therefore, the developer noted that the measure is intended for use by CMS in an accountability program, such as the Hospital OQR Program, where it may be publicly reported. The measure's intended audience includes healthcare consumers, ED physicians and cardiologists, and ancillary medical staff, researchers, and ancillary staff (such as emergency medical services, 911 dispatch, administrators, and measure developers

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

- This measure has not been implemented.
- However, the developer notes that since measure NQF #3613 is not yet publicly reported, data on usability was collected via qualitative interview at two sites that field tested the measure. As part of the interviews, nine clinical and administrative staff were asked key questions about the measure's usability and attribution. Following implementation of the measure in a CMS accountability program, performance scores may be publicly reported with the opportunity for ongoing stakeholder feedback. Feedback received from stakeholder Q&A and data from public reporting will be used to reevaluate the measure specifications annually.

Additional Feedback:

The developer noted that this measure was reviewed by the Measure Applications Partnership (MAP) in December 2020. The Rural Health Workgroup agreed the measure is suitable for use with rural providers under the HOQR program. The MAP offered conditional support for rulemaking pending NQF endorsement. CMS will decide on whether and how to roll out this measure in consideration of MAP feedback and evaluation of appropriateness for inclusion in relevant rulemaking.

***Questions for the Committee**:*

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

How has the measure been vetted in real-world settings by those being measured or others?

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 developer noted that since NQF #3613 is a new measure, this measure has yet to be used in any long-term reporting programs that could be used to observe improvement.

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

NA - new measure

Potential harms

NA – new measure

Additional Feedback:

NA

***Questions for the Committee**:*

Do the benefits of the measure outweigh any potential unintended consequences?

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

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

4a1. Use - Accountability and Transparency: How is the measure being publicly reported? Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? For maintenance measures - which accountability applications is the measure being used for? For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided? 4a2. Use - Feedback on the measure: Have those being measured been given performance results or data, as well as assistance with interpreting the measure results and data? Have those being measured or other users been given an opportunity to provide feedback on the measure performance or implementation? Has this feedback has been considered when changes are incorporated into the measure?

- Not implemented
- No concerns
- no current use
- Good to hear about the MAP progress and plan for implementation. Would be nice to hear from the developer on why this will be implemented and original version was not
- a credible plan is provided.
- The measure in not in use now. Use and public reporting is planned.
- Potential use is appropriate.

4b1. Usability – Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations? 4b2. Usability – Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them.

- New measure
- Insufficient data
- difficult to judge based on the information
- Has usability to ensure timely access to care
- agree with document.
- No harms have been identified.
- Seems reasonable

Criterion 5: Related and Competing Measures

Related or competing measures

The measure is related to the following measure:

NQF #2377 Overall Defect Free Care for AMI

Harmonization

The developer noted that the measure specifications are harmonized to the extent possible. They added that the related measure NQF #2377 (Overall Defect Free Care for AMI), stewarded by the American College of Cardiology, measures the proportion of acute myocardial infarction patients aged above 18 years who receive optimal care based upon their eligibility for each performance measure. The measure concept of appropriate care for STEMI patients aligns with the STEMI eCQM concept; the measure population and settings of care, however, differ. For the STEMI eCQM, patients in the ED setting are included in the measure, whereas NQF #2377 evaluates both STEMI and non-

STEMI patients in the inpatient setting. Further, the related measure NQF #2377 is a composite measure that evaluates variables beyond time to fibrinolytics and PCI.

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

5. Related and Competing: Are there any related and competing measures? If so, are any specifications that are not harmonized? Are there any additional steps needed for the measures to be harmonized?

- Harmonized to the extent possible to NQF#2377
- No concerns
- I'm not convinced that the measure is meaningfully different to NQF 2377
- Good comparison from the developer on differences in measures
- no additional comments.
- 2377 is related but not competing.
- Agree with comments by developer on related measure.

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 06/10/2021

No NQF Members have submitted support/non-support choices as of this date.
No Public or NQF Member comments submitted as of this date.

Measure Number: 3613e

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

Measure is:

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

RELIABILITY: SPECIFICATIONS

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

***NOTE**: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.*

Briefly summarize any concerns about the measure specifications.

No concerns.

RELIABILITY: TESTING

Type of measure:

☐ **Outcome (including PRO-PM)** ☐ **Intermediate Clinical Outcome** ☒ **Process**

☐ **Structure** ☐ **Composite** ☐ **Cost/Resource Use** ☐ **Efficiency**

Data Source:

☐ **Abstracted from Paper Records** ☐ **Claims** ☐ **Registry** ☐ **Abstracted from Electronic Health Record (EHR)** ☒ **ee(HQMF) implemented in EHRs** ☐ **Instrument-Based Data** ☐ **Enrollment Data** ☐ **Other (please specify)**

Level of Analysis:

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

Submission document: "MIF_3613e" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

Reliability testing level ☐ **Measure score** ☐ **Data element** ☒ **Neither**

Reliability testing was conducted with the data source and level of analysis indicated for this measure ☒ **Yes** ☐ **No**

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?

☒ **Yes** ☐ **No**

Assess the method(s) used for reliability testing

Submission document: Testing attachment, section 2a2.2

The developer noted that separate reliability testing of data elements was not conducted since validity of data elements was empirically tested.

Assess the results of reliability testing

Submission document: Testing attachment, section 2a2.3

The developer noted that separate reliability testing of data elements was not conducted since validity of data elements was empirically tested.

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)

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)

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)

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

VALIDITY: TESTING

Validity testing level: ☐ Measure score ☒ Data element ☐ Both

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)

Method of establishing validity of the measure score:

☐ **Face validity**

☐ **Empirical validity testing of the measure score**

☒ **N/A (score-level testing not conducted)**

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)

Assess the method(s) for establishing validity

Submission document: Testing attachment, section 2b2.2

The developer noted that this measure is fully specified in machine-readable logic. For the data validity testing, the developer compared the values for data used in the measure as abstracted manually from EHRs and the data extracted electronically.

The developer assessed and reported data element validity on five characteristics of agreement between the electronically extracted data and manually abstracted data (the gold standard), which included Cohen's kappa, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Data element validity testing was conducted two hospital systems.

Assess the results(s) for establishing validity

Submission document: Testing attachment, section 2b2.3

The developer summarized data element validity testing for two hospitals systems – *System 1* and *System 2.* Overall, the data element validity data presented by the developer demonstrated moderate agreement across both hospital systems and the metrics assessed.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

Please describe any concerns you have with measure exclusions.

Submission document: Testing attachment, section 2b2.

No concerns.

Risk Adjustment

Submission Document: Testing attachment, section 2b3

19a. **Risk-adjustment method** ☒ **None** ☐ **Statistical model** ☐ **Stratification**

19b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☐ Yes ☐ No ☒ Not applicable

19c. **Social risk adjustment:**

19c.1 Are social risk factors included in risk model? ☐ Yes ☐ No ☒ Not applicable

19c.2 Conceptual rationale for social risk factors included? ☐ Yes ☒ No

19c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☒ No

19d. **Risk adjustment summary:** NA

19d.1 All of the risk-adjustment variables present at the start of care? ☐ Yes ☐ No

19d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☐ Yes ☐ No

19d.3 Is the risk adjustment approach appropriately developed and assessed? ☐ Yes ☐ No

19d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☐ Yes ☐ No

19d.5. Appropriate risk-adjustment strategy included in the measure? ☐ Yes ☐ No

19e**. Assess the risk-adjustment approach**

NA

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

Submission document: Testing attachment, section 2b4.

The developer noted that since they were limited to data from two systems, they could not assess statistical or clinically meaningful differences in performance based on data from testing.

Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.

Submission document: Testing attachment, section 2b5.

NA

Please describe any concerns you have regarding missing data.

Submission document: Testing attachment, section 2b6.

The developer noted that it was not possible within the EHR extracts to differentiate between missing data and a negative value; elements (for example, excluded conditions) without a value (for example, ICD-10 code) were interpreted as a negative value (for example, diagnosis not present) rather than missing.

ADDITIONAL RECOMMENDATIONS

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.

Developer Submission

NQF #: 3613e

Corresponding Measures:

De.2. Measure Title: Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

Co.1.1. Measure Steward: Centers for Medicare & Medicaid Services (CMS)

De.3. Brief Description of Measure: The percentage of ED patients with a diagnosis of STEMI who received appropriate and timely treatment. The measure will be calculated using electronic health record (EHR) data and is intended for use at the facility level in a CMS accountability program, through which it may be publicly reported.

1b.1. Developer Rationale: Primary PCI is the preferred revascularization approach, and for patients presenting to hospitals with on-site PCI capabilities guidelines recommend PCI be performed within 90 minutes. For patients presenting to hospitals with primary PCI capabilities, D2B time has shown marked improvements over time, and most hospitals are able to deliver PCI within 90 minutes of patient arrival. The median time to primary PCI in the National Cardiovascular Data Registry in 2014 was 59 min (10th, 50th, and 90th percentiles of 70, 60, and 48 min, respectively) (Masoudi et. al., 2017). In situations where a patient arrives at a non-PCI capable hospital but can be transferred for primary PCI to a PCI referral center, guidelines recommend that primary PCI be performed within 120 minutes (O'Gara et al., 2013). However, for patients transferred from non-PCI-capable hospitals to PCI-capable hospitals, a nationwide study of 14,518 showed that more than one-third of patients failed to meet recommended guidelines for door-to-balloon time (Dauerman et al, 2015).

In situations where it is unlikely or impossible for a patient to receive primary PCI within the 120-minute timeframe, guidelines recommend that fibrinolytic therapy be used for reperfusion and should be rapidly administered to reduce mortality and minimize morbidity; guidelines recommend that fibrinolytic therapy administration occur within 30 minutes of hospital arrival (O'Gara et al., 2013). CMS measures receipt of fibrinolytic therapy within 30 minutes of ED arrival (OP-2) and the time to transfer to a PCI referral center from a non PCI-capable facility (OP-3). Performance data on OP-2 and OP-3 suggest that opportunities remain for facilities to improve timely delivery of fibrinolytic therapy in the ED and expedited transfer to PCI-capable facilities. For the April 2018 through March 2019 data collection period, proportion of patients receiving fibrinolytics within 30 minutes in the OP-2 measure varied from 14% to 100%, with the weighted mean of 70.4%. Similarly, for patients undergoing transfer, for the April 2018 through March 2019 data collection period, performance scores on OP-3 varied from 19 minutes to 106 minutes, with a weighted mean of 54.22 minutes.

REFERENCES:

1. Centers for Medicare & Medicaid Services (2020). Hospital Compare facility-level data. Accessed from https://data.medicare.gov/data/hospital-compare.
2. 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.
3. Masoudi FA, Ponirakis A, de Lemos JA, Jollis JG, Kremers M, Messenger JC, Moore J, Moussa I, Oetgen WJ, Varosy PD, Vincent R N, Wei J, Curtis JP, Roe MT & Spertus JA. (2017). Trends in U.S. Cardiovascular Care: 2016 Report From 4 ACC National Cardiovascular Data Registries. Journal of the American College of Cardiology, 69(11), 1427–1450. Available at: https://doi.org/10.1016/j.jacc.2016.12.005.
4. 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.

S.4. Numerator Statement: ED STEMI patients aged 18 and older whose time from ED arrival to fibrinolysis is 30 minutes or fewer OR Non-transfer ED STEMI patients who received PCI at a PCI-capable hospital within 90 minutes of arrival OR ED STEMI patients who were transferred from a non-PCI capable hospital within 45 minutes of ED arrival at a non-PCI capable hospital.

S.6. Denominator Statement: ED patients 18 years of age and older with STEMI who should have received appropriate and timely treatment for STEMI.

S.8. Denominator Exclusions: The denominator exclusions were derived from the 2013 ACCF/AHA Guideline for the Management of STEMI (http://www.onlinejacc.org/content/accj/61/4/e78.full.pdf?download=true), which was also the basis of OP-2 (Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival) and OP-3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention). Denominator exclusions include the following conditions, which have to be documented as active in the patient's history at the time of the encounter: active bleeding or bleeding diathesis (excluding menses); ischemic stroke; known malignant intracranial neoplasm (primary or metastatic); known structural cerebral vascular lesion (e.g., AVM); significant facial and/or closed head trauma, any prior intracranial hemorrhage or other known intracranial pathology; suspected aortic dissection; active peptic ulcer; cardiopulmonary arrest; intubation; mechanical circulatory assist device placement; oral anticoagulant therapy prior to arrival (including streptokinase treatment); patients with advanced dementia; pregnancy; recent internal bleeding; recent major surgery; intracranial or intraspinal surgery, and severe neurologic impairment (based on Glasgow coma).

De.1. Measure Type: Process

S.17. Data Source: Electronic Health Records

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Most Recent Endorsement Date:

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? N/A

1. 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

STEMIeCQMNQFEvidenceAttach04022021.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.

1a. Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 3613e

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

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Not applicable

Date of Submission: Spring 2021

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

☐ Outcome:

☐ Patient-reported outcome (PRO): PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health- related behaviors. (A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)

☐ Intermediate clinical outcome (*e.g., lab value*): ☒ Process: The percentage of emergency department (ED) patients, aged 18 years and older, with a diagnosis of ST-elevation myocardial infarction (STEMI) who received appropriate and timely treatment.

☐ Appropriate use measure:

☐ Structure:

☐ Composite:

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Providing timely fibrinolytic therapy or percutaneous coronary intervention [PCI]) for STEMI within the timeframe specified in clinical practice guidelines speeds reperfusion of cardiac muscle and improves outcomes, such as reduced mortality, bleeding events, and reinfarction.

1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

Not applicable, as this measure is not derived from patient-reported data.

****RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) ****

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

This measure is not a health outcome/PRO-PM.

1a.3. SYSTEMATIC REVIEW (SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

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

☒ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

Systematic Review	Evidence
Source of Systematic Review: **Title** **Author** **Date** **Citation, including page number** **URL**	The clinical practice guidelines provided are based on their relevance to the measure. The first 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 The second guideline, released in 2017 by the American College of Emergency Physicians (ACEP), evaluates management of patients with STEMI. Citation for the guideline follows: *Promes SB, Glauser JM, Smith MD, Torbati SS, and Brown MD. Clinical Policy: Emergency Department Management of Patients Needing Reperfusion Therapy for an ST-Segment Elevation Acute Myocardial Infarction (STEMI). American College of Emergency Physicians. 2017 Jun 28. Guideline available at: https://www.acep.org/globalassets/new-pdfs/clinical-policies/reperfusion-acute-stemi-2017.pdf*

Systematic Review	Evidence
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	The ACCF/AHA guideline for the management of STEMI provides recommendations for fibrinolytic therapy when there is an anticipated delay to performing primary PCI within 120 minutes of first medical contact. Four recommendations support the measure's clinical intent: 1. In the absence of contraindications, fibrinolytic therapy should be administered to patients with STEMI at non-PCI-capable hospitals when the anticipated first medical contact-to-device time at a PCI-capable hospital exceeds 120 minutes because of unavoidable delays (81, 87, 88). (Class I, Level of Evidence: B; pg. e86) 2. When fibrinolytic therapy is indicated or chosen as the primary reperfusion strategy, it should be administered within 30 minutes of hospital arrival (89-93) (Class I, Level of Evidence B; pg. e86). 3. In the absence of contraindications, fibrinolytic therapy should be given to patients with STEMI and onset of ischemic symptoms within the previous 12 hours when it is anticipated that primary PCI cannot be performed within 120 minutes of first medical contact (81, 306-311). (Class I, Level of Evidence: A; pg. e94) 4. EMS transport directly to a PCI-capable hospital for primary PCI is the recommended triage strategy for patients with STEMI, with an ideal FMC- to-device time system goal of 90 minutes or less (70-72). (Class I, Level of Evidence: B; pg. e86). The ACEP guideline for the management of ED STEMI patients in need of reperfusion therapy provides recommendations for the treatment of STEMI. Two recommendations support the measure's clinical intent: Fibrinolytics may be administered to patients when door-to-balloon time is anticipated to exceed 120 minutes. (Level B recommendation; pg. 727)

Systematic Review	Evidence
	To decrease the incidence of major adverse cardiac events (MACE), patients with STEMI should be transferred to a PCI-capable hospital as soon as possible. (Level B recommendation; pg. 729)
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	**ACCF/AHA Guideline** All relevant recommendations from the guideline received a Class I designation. The evidence (Level of Evidence A) strongly and unambiguously supports the recommendation to give fibrinolytic therapy to patients with STEMI when it is anticipated that primary PCI, the preferred treatment approach, cannot be performed within 120 minutes of first medical contact. Additionally, there is a broad consensus in the medical community (Level of Evidence B) supporting the recommendations to administer fibrinolytic therapy to patients with STEMI when indicated within 30 minutes of hospital arrival. The ACCF/AHA Task Force on Practice Guidelines asserts that a recommendation with Level of Evidence B or C does not imply that the recommendation is weak, as many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Despite a limited pool of randomized control trials (RCTs), there may be clear clinical consensus that a particular test or therapy is useful or effective. Collectively, the evidence supports these recommendations, demonstrating consensus within the clinical community that fibrinolytic therapy is reasonable for patients with STEMI at a non-PCI-capable hospital when the anticipated first medical contact-to-device time at a PCI-capable hospital exceeds 120 minutes. **The following evidence scales apply to recommendations from the guideline:** Two levels of evidence: Level A and Level B *Level A:* Data derived from multiple randomized clinical trials or meta-analyses *Level B:* Data derived from a single randomized trial or nonrandomized studies **ACEP Guideline** The relevant recommendations from the guideline received a Level B designation. The evidence (Class of Evidence II and III) reflects moderate clinical certainty and demonstrate a strong consensus across studies supporting the recommendation to administer fibrinolytic therapy to STEMI patients when the anticipated door-to-balloon time exceeds 120 minutes and to transfer patients to a PCI-capable facility as soon as possible, to decrease the incidence of MACE. **The following evidence scales apply to recommendations from the guideline:** Two classes of evidence: II and III *Class of Evidence II:* Non randomized trial. *Class of Evidence III:* Data derived from case series.

Systematic Review	Evidence
Provide all other grades and definitions from the evidence grading system	**ACCF/AHA Guideline** **Additional evidence scales:** *Level C:* Very limited populations evaluated. Only consensus opinions of experts, case studies, or standard of care. **ACEP Guideline** **Additional evidence scales:** *Class of Evidence I:* Randomized, controlled trial or meta-analysis of randomized trials.
Grade assigned to the **recommendation** with definition of the grade	**ACCF/AHA Guideline** All relevant recommendations from the guideline received a Class I designation. The evidence (Level of Evidence A) strongly and unambiguously supports the

Systematic Review	Evidence
	recommendation to give fibrinolytic therapy to patients with STEMI when it is anticipated that primary PCI, the preferred treatment approach, cannot be performed within 120 minutes of first medical contact. Additionally, there is a broad consensus in the medical community (Level of Evidence B) supporting the recommendations to administer fibrinolytic therapy to patients with STEMI when indicated within 30 minutes of hospital arrival. The ACCF/AHA Task Force on Practice Guidelines asserts that a recommendation with Level of Evidence *B* or *C* does not imply that the recommendation is weak, as many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Despite a limited pool of randomized control trials (RCTs), there may be clear clinical consensus that a particular test or therapy is useful or effective. Collectively, the evidence supports these recommendations, demonstrating consensus within the clinical community that fibrinolytic therapy is reasonable for patients with STEMI at a non-PCI-capable hospital when the anticipated first medical contact-to-device time at a PCI-capable hospital exceeds 120 minutes. The following grading scale applies to recommendations from the guideline: *Recommendation 1, 2,3, and 4: Class I:* Benefit >>>Risk Procedure/Treatment should be performed/administered. ACEP Guideline The relevant recommendation from the guideline received a Level B designation. The evidence (Class of Evidence III) reflect moderate clinical certainty and demonstrate a strong consensus across studies supporting the recommendation to administer fibrinolytic therapy to STEMI patients when the anticipated door-to-balloon time exceeds 120 minutes. The following grading scale applies to recommendations from the guideline: *Recommendation 1 and 2: Level B:* Recommendations for patient care that may identify a particular strategy or range of strategies that reflect moderate clinical certainty (e.g., based on evidence from one or more Class of Evidence II studies or strong consensus of Class of Evidence III studies).

Systematic Review	Evidence
Provide all other grades and definitions from the **recommendation** grading system	**ACCF/AHA Guideline** **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 **ACEP Guideline** **Additional grading scale for the recommendations:** *Level A:* Generally accepted principles for patient care that reflect a high degree of clinical certainty (e.g., based on evidence from one or more Class of Evidence I or multiple Class of Evidence II studies). *Level C:* Recommendations for patient care that are based on evidence from Class of Evidence III studies or, in the absence of any adequate published literature, based on expert consensus. In instances in which consensus recommendations are made, "consensus" is placed in parentheses at the end of

Systematic Review	Evidence
	the recommendation.
Body of evidence: ***Quantity—how many studies?*** ***Quality—what type of studies?***	*Quantity:* **ACCF/AHA Guideline** The guideline does not explicitly indicate the specific number or type of study designs included in the body of evidence; however, it does reference several randomized control trials and prospective studies. In addition, one of the recommendations is Level A, which is defined as data from multiple randomized clinical trials or meta analyses; two of the recommendations are Level B, which is defined as data derived from a single randomized trial or nonrandomized studies. These three recommendations on fibrinolytic use included 13 unique citations. **ACEP Guideline** The body of evidence supporting the recommendation includes seven case series studies, and one nonrandomized control trial, as indicated by their Class of Evidence III designation. *Quality:* **ACCF/AHA Guideline** The guideline provides three Class I recommendations, indicating that the benefits clearly outweigh the risks and the recommendation can be applied to most patients in most circumstances. The one Level A recommendation is based on multiple RCTs with no important limitations or exceptionally strong evidence from observational studies, and further evidence is unlikely to change the confidence in the estimate of the effect. The two Level B recommendations are based on nonrandomized or a single RCT; although randomized trials may not be available, there is a clear clinical consensus of the estimate of the effect. **ACEP Guideline** The guideline provides one Level B recommendation, indicating that the recommendation is based on moderate clinical certainty and that there is clear consensus among the evidence.
Estimates of benefit and consistency across studies	**ACCF/AHA Guideline** Given the high costs associated with complications of STEMI and the subsequent rehabilitation, the overall net benefit of timely fibrinolytic therapy and PCI treatment is a reduction in cost and a reduction in morbidity. **ACEP Guideline** Use of PCI and fibrinolytic therapy, when there is an anticipated delay in door- to-balloon time, has the potential to improve long-term outcomes, including reduction in major adverse cardiac events. *Recommendation 2*, ACEP acknowledges that patients may deteriorate in route to a PCI-capable facility, leading to negative outcomes.

Systematic Review	Evidence
What harms were identified?	**ACCF/AHA Guideline** The guideline does not provide details about potential harms associated with fibrinolytic therapy and PCI treatment for patients with STEMI, that were identified in the body of evidence. **ACEP Guideline** For *Recommendation 1*, the ACEP guideline states that patients may not receive the recommended therapy within the appropriate timeframes, as identified in the guideline, required for optimal outcomes due to the challenges associated with obtaining time estimates in the context of an emergency. For

Systematic Review	Evidence
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	There have been no newly identified studies which change the conclusions of the systematic review in the clinical practice guidelines.

1a.4 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.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

Not applicable—evidence for the STEMI eCQM was presented in **Section 1a.3**.

1a.4.2 What process was used to identify the evidence?

Not applicable—evidence for the STEMI eCQM was presented in **Section 1a.3**.

1a.4.3. Provide the citation(s) for the evidence.

Not applicable—evidence for the STEMI eCQM was presented in **Section 1a.3**.

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.*

Primary PCI is the preferred revascularization approach, and for patients presenting to hospitals with on-site PCI capabilities guidelines recommend PCI be performed within 90 minutes. For patients presenting to hospitals with primary PCI capabilities, D2B time has shown marked improvements over time, and most hospitals are able to deliver PCI within 90 minutes of patient arrival. The median time to primary PCI in the National Cardiovascular Data Registry in 2014 was 59 min (10th, 50th, and 90th percentiles of 70, 60, and 48 min, respectively) (Masoudi et. al., 2017). In situations where a patient arrives at a non-PCI capable hospital but can be transferred for primary PCI to a PCI referral center, guidelines recommend that primary PCI be performed within 120 minutes (O'Gara et al., 2013). However, for patients transferred from non-PCI-capable hospitals to PCI-capable hospitals, a nationwide study of 14,518 showed that more than one-third of patients failed to meet recommended guidelines for door-to-balloon time (Dauerman et al, 2015).

In situations where it is unlikely or impossible for a patient to receive primary PCI within the 120-minute timeframe, guidelines recommend that fibrinolytic therapy be used for reperfusion and should be rapidly administered to reduce mortality and minimize morbidity; guidelines recommend that fibrinolytic therapy administration occur within 30 minutes of hospital arrival (O'Gara et al., 2013). CMS measures receipt of fibrinolytic therapy within 30 minutes of ED arrival (OP-2) and the time to transfer to a PCI referral center from a non PCI-capable facility (OP-3). Performance data on OP-2 and OP-3 suggest that opportunities remain for facilities to improve timely delivery of fibrinolytic therapy in the ED and expedited transfer to PCI-capable facilities. For the April 2018 through March 2019 data collection period, proportion of patients receiving fibrinolytics within 30 minutes in the OP-2 measure varied from 14% to 100%, with the weighted mean of 70.4%. Similarly, for patients undergoing transfer, for the April 2018 through March 2019 data collection period, performance scores on OP-3 varied from 19 minutes to 106 minutes, with a weighted mean of 54.22 minutes.

REFERENCES:

Centers for Medicare & Medicaid Services (2020). Hospital Compare facility-level data. Accessed from https://data.medicare.gov/data/hospital-compare.

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.

Masoudi FA, Ponirakis A, de Lemos JA, Jollis JG, Kremers M, Messenger JC, Moore J, Moussa I, Oetgen WJ, Varosy PD, Vincent R N, Wei J, Curtis JP, Roe MT & Spertus JA. (2017). Trends in U.S. Cardiovascular Care: 2016 Report From 4 ACC National Cardiovascular Data Registries. Journal of the American College of Cardiology, 69(11), 1427–1450. Available at: https://doi.org/10.1016/j.jacc.2016.12.005.

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.

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.*

This measure is not implemented. Performance scores are not provided.

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.

The literature suggests that approximately 50% of patients who are eligible for fibrinolytic therapy receive it, because their transfer time to a PCI-capable hospital exceeded 60 minutes; of those who receive fibrinolytic therapy, about 30% are appropriately administered the therapy within the guideline-recommended window of 30 minutes following ED arrival. Further, the median door-to-needle time for patients receiving fibrinolysis in advance of transfer to another facility for PCI is 34 minutes, which is outside the recommended window.

Performance data from CMS on OP-2 (Fibrinolytic Therapy Received within 30-minutes of ED Arrival) suggest there is an opportunity for facilities to improve the appropriate treatment for patients with STEMI who received fibrinolytic therapy in the ED. The data indicate that, while facility-level OP-2 scores have improved since the measure was first implemented in the CMS Hospital OQR Program in 2010, performance is still highly variable. During the April 2012–March 2013 data collection period, performance scores ranged from 0% to 100%, with a weighted mean of 59.1% (that is, on average, 59.1% of STEMI patients who received fibrinolytic therapy did so within 30 minutes of ED arrival). For the April 2018 through March 2019 data collection period, performance scores also ranged from 14% to 100%, with the weighted mean rising to 70.4%. This translates to a 19.1% (or 11.3 percentage point) improvement in the weighted mean of OP-2 performance scores from April 2012 to March 2019.

Performance data from CMS on OP-3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention) suggest there is an opportunity for facilities to improve the median time to transfer for acute coronary intervention. Though data indicate that, while facility-level OP-3 scores have improved since the measure was first implemented in the CMS Hospital OQR Program in 2010, performance is still highly variable. During the April 2012–March 2013 data collection period, performance scores ranged from 9 to 161 minutes, with a weighted mean of 62.73 minutes (that is, on average, 62.73 minutes passed from the time of ED

admission to transfer for acute coronary intervention). For the April 2018 through March 2019 data collection period, performance scores ranged from 19 minutes to 106 minutes, but the weighted mean decreased to 54.22 minutes, which still lags existing guidelines. This translates to an 8.51-minute decrease (or 15.7 percentage points) in the weighted mean of OP-3 performance scores from April 2012 to March 2019.

REFERENCES:

Vora AN, Holmes DN, Rokos I, Roe MT, Granger CB, French WJ, Antman E, Henry TD, Thomas L, Bates ER, 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 Intern Med. 2015;175(2):207–215. doi:10.1001/jamainternmed.2014.6573.

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.*

This measure is not yet implemented. We are limited to data from two systems and consequently, cannot assess systematic disparities in care in using only the data from testing.

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

An analysis performed by Lewin of the 2014 data submitted to CMS's clinical data warehouse (CDW) examined the impact of patient and facility characteristics on use of fibrinolysis using a logistic regression model for 3,844 cases. When compared to patients treated in facilities with fewer than 50 beds (a proxy for facility size), patients treated in facilities with 101 to 250 beds (OR=1.74, p=0.002) and 251 to 500 beds (OR=2.02, p=0.017) were significantly more likely receive fibrinolytic therapy within 30 minutes of ED arrival. Patients aged 40 to 50 (OR=3.80, p=0.03), 50 to 60 (OR=3.85, p=0.03), 60 to 70 (OR=3.44, p=0.04), and 70 to 80 (OR=3.10, p=0.06) were significantly or marginally significantly more likely than patients aged 18 to 30 to receive fibrinolytic therapy within 30 minutes of ED arrival. African-American patients were significantly less likely than their white peers to receive fibrinolytic therapy within 30 minutes of ED arrival (OR=0.60, p=0.001), as were Hispanic patients (OR=0.65, p=0.03), when compared to those patients of non-Hispanic origin. Finally, female patients were less likely than male patients receive fibrinolytic therapy within 30 minutes of ED arrival (OR=0.77, p< 0.001).

In addition to disparities in fibrinolytic therapy, the literature also suggests disparities in PCI. In a Get With the Guidelines study of 7,445 patients undergoing PCI for STEMI, after adjusting for confounders, African Americans were less likely to receive PCI within 90 minutes, when compared to their White counterparts (OR: 0.84; 95% confidence interval [CI]: 0.70-0.99; p=0.04) (Cavendar et al., 2013). Another study by Huded and colleagues found that women have higher D2B times than men (median D2B 112 minutes for women vs. 104 minutes for men, p=0.023) and higher proportion of women do not receive care in accordance with clinical guidelines (69% vs. 77%, P=0.019) (Huded et al., 2018). Door-in-door-out (DIDO) times for patients with STEMI have been found to be significantly longer for women (8.9 minutes longer than the mean), African Americans (9.1 minutes longer than the mean), and rural facilities (15.3 minutes longer than the mean) (Herrin et al., 2011).

REFERENCES:

1. Cavender MA, Rassi AN, Fonarow GC, Cannon CP, Peacock WF, Laskey WK, Hernandez AF, Peterson ED, Cox, M, Grau-Sepulveda M, Schwamm LH & Bhatt DL (2013). Relationship of race/ethnicity with door-to-balloon time and mortality in patients undergoing primary percutaneous coronary intervention for

ST-elevation myocardial infarction: findings from Get With the Guidelines-Coronary Artery Disease. Clinical cardiology, 36(12), 749–756. Available at: https://doi.org/10.1002/clc.22213.

2. Herrin J, Miller LE, Turkmani DF, Nsa W, Drye EE, Bernheim, SM, Ling SM, Rapp MT, Han LF, Bratzler DW, Bradley EH, Nallamothu BK, Ting HH, & Krumholz, HM. (2011). National performance on door-in to door-out time among patients transferred for primary percutaneous coronary intervention. Archives of internal medicine, 171(21), 1879–1886. Available at: https://doi.org/10.1001/archinternmed.2011.481.

3. Huded CP, Johnson M, Kravitz K, Menon V, Abdallah M, Gullett TC, Hantz S, Ellis SG, Podolsky SR, Meldon SW, Kralovic DM, Brosovich D, Smith E, Kapadia SR, & Khot UN. (2018). 4-Step Protocol for Disparities in STEMI Care and Outcomes in Women. Journal of the American College of Cardiology, 71(19), 2122–2132. Available at: https://doi.org/10.1016/j.jacc.2018.02.039.

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):*

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

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

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.)*

Not applicable - the measure has not been posted on CMS´s website.

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 an eMeasure **Attachment:** STEMIeCQM_MATOutput_08262020-637453604397904411.zip

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: STEMIeCQM_ValueSets_08262020.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.

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.

N/A

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).*

ED STEMI patients aged 18 and older whose time from ED arrival to fibrinolysis is 30 minutes or fewer OR Non-transfer ED STEMI patients who received PCI at a PCI-capable hospital within 90 minutes of arrival OR ED STEMI patients who were transferred from a non-PCI capable hospital within 45 minutes of ED arrival at a non-PCI capable hospital.

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).*

The numerator is defined by procedural, RxNorm, and SNOMEDCT codes included in the value sets for this measure; these detailed lists can be found in the value set Excel workbook attachment (see S.2b), as well as value sets published on the Value Set Authority Center (https://vsac.nlm.nih.gov/authoring). OIDs to the value sets for each numerator action are included, below:

Fibrinolytic Therapy within 30-minutes of ED Arrival OID: 2.16.840.1.113883.3.3157.4020

PCI within 90-minutes of ED Arrival for Non-Transfer Patients OID: 2.16.840.1.113883.3.3157.2000.5

Arrival Code

As determined by facility standard operating procedure (SOP)

Discharge to Another Facility Within 45-minutes of ED Arrival As determined by facility SOP

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

ED patients 18 years of age and older with STEMI who should have received appropriate and timely treatment for STEMI.

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).*

The denominator is defined by E&M, SNOMEDCT, and ICD-10-CM diagnosis codes included in the value sets for this measure; these detailed lists can be found in the value set Excel workbook attachment (see S.2b), as well as value sets published on the Value Set Authority Center (https://vsac.nlm.nih.gov/authoring). OIDs to the value sets for the denominator are included, below:

Emergency Department Visit

OID: 2.16.840.1.113883.3.464.1003.101.12.1085

STEMI

OID: 2.16.840.1.113883.3.3157.4017

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

The denominator exclusions were derived from the 2013 ACCF/AHA Guideline for the Management of STEMI (http://www.onlinejacc.org/content/accj/61/4/e78.full.pdf?download=true), which was also the basis of OP-2 (Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival) and OP-3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention). Denominator exclusions include the following conditions, which have to be documented as active in the patient's history at the time of the encounter: active bleeding or bleeding diathesis (excluding menses); ischemic stroke; known malignant intracranial neoplasm (primary or metastatic); known structural cerebral vascular lesion (e.g., AVM); significant facial and/or closed head trauma, any prior intracranial hemorrhage or other known intracranial pathology; suspected aortic dissection; active peptic ulcer; cardiopulmonary arrest; intubation; mechanical circulatory assist device placement; oral anticoagulant therapy prior to arrival (including streptokinase treatment); patients with advanced dementia; pregnancy; recent internal bleeding; recent major surgery; intracranial or intraspinal surgery, and severe neurologic impairment (based on Glasgow coma).

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.)*

Specific details can be referenced in the value set Excel workbook attachment (see S.2b), as well as value sets published on the Value Set Authority Center (https://vsac.nlm.nih.gov/authoring). OIDs to the value sets for each exclusion are included, below:

The absolute contraindication denominator exclusions:

Active bleeding or bleeding diathesis (excluding menses)

OID: 2.16.840.1.113883.3.3157.4036

Intracranial or intraspinal surgery

OID: 2.16.840.1.113883.3.3157.4056

Ischemic stroke

OID: 2.16.840.1.113883.3.464.1003.104.12.1024

Known malignant intracranial neoplasm (primary or metastatic)

OID: 2.16.840.1.113883.3.3157.4009

OID: 2.16.840.1.113883.3.3157.4010

Known structural cerebral vascular lesion (e.g., AVM)

OID: 2.16.840.1.113883.3.3157.4025

Significant facial and/or closed head trauma, intracranial hemorrhage, or other known intracranial pathology

OID: 2.16.840.1.113883.3.3157.4026

Suspected aortic dissection

OID: 2.16.840.1.113883.3.3157.4028

Active peptic ulcer

OID: 2.16.840.1.113883.3.3157.4031

Cardiopulmonary arrest

OID: 2.16.840.1.113883.3.3157.4048

For streptokinase/anistreplase: prior exposure or prior allergic reaction to these agents

OID: 2.16.840.1.113883.3.3157.4059

Intubation

OID: 2.16.840.1.113762.1.4.1045.69

Mechanical circulatory assist device placement

OID: 2.16.840.1.113883.3.3157.4052

Oral anticoagulant therapy

OID: 2.16.840.1.113883.3.3157.4045

Patients with advanced dementia

OID: 2.16.840.1.113883.3.3157.4043

Pregnancy

OID: 2.16.840.1.113883.3.3157.4055

Recent internal bleeding

OID: 2.16.840.1.113883.3.3157.4036

Recent major surgery

OID: 2.16.840.1.113883.3.3157.4056

Severe neurologic impairment (based on Glasgow coma scale)

OID: 2.16.840.1.113883.3.3157.4058

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.)*

Not applicable - this measure does not stratify its results.

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:

Other (specify):

If other: Percentage

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 = Higher 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.)*

This measure calculates the percentage of ED patients with a STEMI diagnosis who received appropriate treatment (PCI, fibrinolytic therapy, transfer to PCI-capable hospital). The measure is calculated based on EHR data, as follows:

1. System check E/M Code; if E/M code represents care provided in the ED, proceed
2. Calculate Patient Age (Outpatient Encounter Date - Birthdate)
3. Patient Age >= 18, proceed
4. System check ICD-10-CM Principal Diagnosis Code;

5. Apply denominator exclusions to remove patients excluded from the measure denominator; all remaining cases are equal to the denominator count, proceed
6. System check Fibrinolytic Administration; if "Yes," proceed; if no
7. System check PCI Received; if "Yes," proceed; if no
8. System check Transferred for PCI; if "Yes," proceed;
9. System check Fibrinolytic Administration Date and Time; if a Non-Unable to Determine (UTD) value, proceed
10. System check Arrival Time; if a Non-UTD value, proceed
11. System calculates Time to Fibrinolysis (Fibrinolytic Administration Time minus Arrival Time)
12. System check Time to Fibrinolysis; if >= 0 min and <= 30 min, include in the numerator. If > 30 min and = 360 min or missing, proceed
13. System check PCI Received, Date and Time; if a Non-UTD value, proceed
14. System check Arrival Time; if a Non-UTD value, proceed
15. System calculate Time to PCI (PCI Procedure Time minus Arrival Time)
16. System check Time to PCI; if >=0 min and <=90 min, record as the numerator; if >90 minutes and <=360 min or missing, proceed
17. System check Transferred for PCI, check Transfer for PCI Date; if a Non-UTD value, proceed
18. System check Transfer for PCI Time; if a Non-UTD value, proceed
19. System check Arrival Time; if a Non-UTD value, proceed
20. System calculate Time to Transfer for PCI; if >=0 min and <=45 min, include in the numerator.
21. Measure = aggregated numerator counts / aggregated denominator counts [The value should be recorded as a percentage].

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.

This measure relies exclusively on electronic health record (EHR) data; sampling of beneficiaries is not required.

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

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.

This is not an instrument-based measure.

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)*

No data collection instrument provided

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)*

Outpatient 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.)*

N/A

Validity – See attached Measure Testing Submission Form

STEMIeCQM_NQFTestingAttach_v1.0-637453608766224975.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.

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.

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.

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

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

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

Date of Submission: TBD

Type of Measure:

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

*cell intentionally left blank

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:	☒ other: Electronic extract of EHR data

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*).

Not applicable

1.3. What are the dates of the data used in testing? EHR data from 2018 (Site 1) and 2019 (Site 2).

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:	☐ other:

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*)

To field test the STEMI eCQM, the study team contracted with two hospital systems. *System 1*, located in a major Texas metropolitan area, uses Cerner as its EHR vendor. Every year, *Site 1* sees more than 700,000 emergency visits across 19 EDs. In 2018, *System 1* treated 1,030 STEMI patients across 11 EDs within the health system; some of the hospitals in System *1*'s health system are PCI-capable facilities.

System 2 is located in a metropolitan area in Minnesota. In 2019, *System 2* treated 133 STEMI patients across the ED on its main campus, who either presented at or were transferred to the facility. *System 2* uses EPIC as its EHR vendor; some facilities within the health system are PCI-capable.

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*)

Table 1, below, displays characteristics of the 1,030 patients included in the analysis for *System 1* and the 133 patients included in the analysis for *System 2*. EHR data from 111 randomly selected patients at each site were manually abstracted to assess data element validity.

Table 1. Characteristics of Patients Included in STEMI eCQM Beta Testing EHR Extracts

Variable	*System 1* (N 1,030) Frequency (%)	*System 2* (N 133) Frequency (%)
Age: 18–29	9 (0.87)	2 (1.50)
Age: 30–39	35 (3.40)	2 (1.50)
Age: 40–49	131 (12.72)	11 (8.27)
Age: 50–59	289 (28.06)	32 (24.06)
Age: 60–69	294 (28.54)	31 (23.31)
Age: 70–79	177 (17.18)	25 (18.80)
Age: A80+	95 (9.22)	30 (22.56)
Sex: Females	265 (25.73)	51 (38.35)
Sex: Males	765 (74.27)	82 (61.65)
Race: Black or African American	152 (14.76)	3 (2.26)
Race: White	415 (40.29)	122 (91.73)
Race: Asian	33 (3.20)	1 (0.75
Race: Other	381 (36.99)	7 (5.26)
Ethnicity: Hispanic or Latino	163 (15.83)	2 (1.60)
Ethnicity: Not Hispanic or Latino	867 (84.17)	123 (98.40)

* Race Unknown for 49 (4.8%) patients at System 1

† Ethnicity missing for 8 patients at System 2

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.

Not applicable

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.

Social risk factors of race and ethnicity are available in the EHR at both sites. The patient address can further be linked to income and other community characteristics (Table 1). However, we note that outcomes for a process measure for ED STEMI patients should not be influenced by sociodemographic status or social risk factors; rather, adjustment on such factors would risk masking such important inequities in care delivery. Variation across populations is reflective of differences in the

appropriateness of care provided to the disparate population included in the measure's denominator. Thus, no validity analysis for these variables were performed.

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*)

As noted in **2a2**., above, separate reliability testing of data elements is not required if validity of data elements was empirically tested.

See section **2b2** for validity testing of data elements.

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*)

See section 2b2 for validity testing of data elements.

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?*)

See section 2b2 for validity testing of data elements.

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)*

This measure is fully specified in machine-readable logic, and the intent of this data validity testing was to compare the values for data used in the measure as abstracted manually from EHRs and the data extracted electronically.

Although the machine-readable logic is intended to be directly translated to an EHR query there are currently several barriers to running it in hospital EHRs. Most notably, while the measure includes only data elements collected in the routine course of care and stored in structured data fields, the data elements are stored in several parts of the EHR that may not share a common data model or be fully

interoperable; for instance, the cardiac catheterization lab information system was not fully interoperable with the primary EHR at all sites. Therefore, the sites testing the measure by necessity conducted the electronic data pull in ways best suited to each site, using the measure logic as appropriate and supplementing it with additional programming when needed. This is consistent with the approach sites typically take to implement eCQMs but is noted here to assist with interpretation of the results.

The baseline socio-demographic characteristics and prevalence of numerator elements, denominator elements, and denominator exclusions within the electronically extracted data were reported. A random sample of 111 charts were manually abstracted at each site by experienced chart abstractors and the results compared with the electronic abstract.

Five characteristics of agreement between the electronically extracted data and manually abstracted data (the gold standard) and were calculated to assess data element validity and reported; these are Cohen's kappa, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Cohen's kappa is a measure of agreement between the electronic extract and manual abstract that adjusts for the possibility of agreement by chance. Possible values range from -1.00 to 1.00, with 0.00 representing agreement equal to that expected by chance. Sensitivity measures the ability of the electronic extract to correctly identify presence of a diagnostic or procedure code in the manual abstract. Possible values range from 0.00 to 1.00 with higher values representing greater sensitivity. Specificity measures the ability of the electronic extract to correctly identify absence of a diagnostic or procedure code in the manual abstract. Possible values range from 0.00 to 1.00 with higher values representing greater specificity. PPV is the probability that cases with presence of a diagnostic or procedure code in the electronic extract also have a diagnostic or procedure code in the manual abstract. Possible values range from 0.00 to 1.00 with higher values representing stronger PPV. NPV is the probability that cases with absence of a diagnostic or procedure code in the electronic extract also do not have a diagnostic or procedure code in the manual abstract. Values range from 0.00 to 1.00 with higher values representing stronger NPV. In addition, prevalence of individual data fields was provided to provide context for interpretation of the measures of agreement.

At the conclusion of beta testing an exit interview was conducted with each of the sites to ascertain specific barriers to extracting the data that they experienced.

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

Table 2, below, summarizes data element validity results for *System 1* for all variables used in measure calculation. As all validity metrics are influenced by prevalence, we also report the frequency of occurrence in the manual extract Table 2 as well as refer the reader to the frequency of the exclusion conditions in the electronic extract, reported in *Table 6* in section 2b.2.

Table 2. Data Element Validity for *System 1*

Condition	Kappa Coefficient (95% C.I.)	Sensitivity (95% C.I.)	Specificity (95% C.I.)	Positive Predictive Value (95% C.I.)	Negative Predictive Value (95% C.I.)	Prevalence (%)
STEMI	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)	0.88 0.82, 0.94)	*	88.29
Intracranial hemorrhage	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0
Intracranial neoplasm	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0

Condition	Kappa Coefficient (95% C.I.)	Sensitivity (95% C.I.)	Specificity (95% C.I.)	Positive Predictive Value (95% C.I.)	Negative Predictive Value (95% C.I.)	Prevalence (%)
Major surgery	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0
Pregnancy	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0
Internal bleeding	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0
Suspected aortic dissection	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0
Mortality	0.00 (0.00, 0.00)	*	0.94 (0.89, 0.98)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)	0
Reaction to thrombolytics	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0
Intracranial or intraspinal surgery	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0
Peptic ulcer	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0
Bleeding or bleeding diathesis	-0.01 (-0.02, 0.00)	0.00 (0.00, 0.00)	0.99 (0.97, 1.00)	0.00 (0.00, 0.00)	0.99 (0.97, 1.00)	0.90
Structural cerebral vascular lesion	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)	*	0.99 (0.97, 1.00)	0.90
Significant facial and/or closed head trauma	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)	*	0.99 (0.07, 1.00)	0.90
Ischemic stroke	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	0.90
Mechanical circulatory assist device placement	0.00 (0.00. 0.00)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)	*	0.99 (0.97, 1.00)	0.90
Severe neurological impairment	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)	*	0.97 (0.94, 1.00)	2.70
Other known intracranial pathology	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)	*	0.97 (0.94, 1.00)	2.70
Dementia	0.39 (-0.15, 0.93)	0.25 (0.00, 0.67)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	0.97 (0.94, 1.00)	3.60
Intubation	-0.02 (-0.04, 0.01)	0.00 (0.00, 0.00)	0.99 (0.97, 1.00)	0.00 (0.00, 0.00)	0.95 (0.90, 0.99)	5.41
Oral anticoagulant therapy	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)	*	0.95 (0.90, 0.99)	5.41
Cardiopulmonary arrest	0.25 (-0.05, 0.56)	0.18 (0.00, 0.41)	0.99 (0.97, 1.00)	0.67 (0.13, 1.00)	0.92 (0.86, 0.97)	9.91
Fibrinolytic therapy	-0.02 (-0.04, 0.00)	0.00 (0.00, 0.00)	0.98 (0.96, 1.00)	0.00 (0.00, 0.00)	0.97 (0.94, 1.00)	2.70
Transfer	0.74 (0.40, 1.00)	0.60 (0.17, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	0.98 (0.96, 1.00)	4.50

Condition	Kappa Coefficient (95% C.I.)	Sensitivity (95% C.I.)	Specificity (95% C.I.)	Positive Predictive Value (95% C.I.)	Negative Predictive Value (95% C.I.)	Prevalence (%)
PCI	0.30 (0.11, 0.49)	0.76 (0.67, 0.86)	0.54 (0.37, 0.72)	0.81 (0.73, 0.90)	0.47 (0.31, 0.64)	72.07

*cell intentionally left blank

Table 3 below aggregates these results for *System 1* at the level of the numerator, denominator, and denominator exclusions.

Table 3. Validity of Numerator and Denominator Data Elements for *System 1*

Data Element	Kappa Coefficient Mean (S.D.)	Sensitivity Mean (S.D.)	Specificity Mean (S.D.)	PPV Mean (S.D.)	NPV Mean (S.D.)
Numerator	0.34 (0.38)	0.45 (0.40)	0.84 (0.26)	0.60 (0.53)	0.81 (0.29)
Denominator	0.00	1.00	0.00	0.88	*
Denominator Exclusions	0.51 (0.49)	0.54 (0.49)	1.00 (0.1)	0.84 (0.36)	0.99 (0.02)

*cell intentionally left blank

Table 4 below summarizes data element validity results for *System 2* for all variables used in measure calculation. As all validity metrics are influenced by prevalence, we also report the frequency of occurrence in the manual extract in Table 4 as well as refer the reader to the frequency of the exclusion conditions in the electronic extract, reported in *Table 6* in section 2b.2.

Table 4. Data Element Validity for System *2*

Condition	Kappa Coefficient (95% C.I.)	Sensitivity (95% C.I.)	Specificity (95% C.I.)	Positive Predictive Value (95% C.I.)	Negative Predictive Value (95% C.I.)	Prevalence (%)
STEMI	0.24 (-0.15, 0.62)	1.00 (1.00, 1.00)	0.14 (0.00, 0.40)	0.95 (0.90, 0.99)	1.00 (1.00, 1.00)	93.69
Intracranial hemorrhage	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Intracranial neoplasm	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Major surgery	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Pregnancy	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Internal bleeding	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Suspected aortic dissection	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Mortality	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Reaction to thrombolytics	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00

Condition	Kappa Coefficient (95% C.I.)	Sensitivity (95% C.I.)	Specificity (95% C.I.)	Positive Predictive Value (95% C.I.)	Negative Predictive Value (95% C.I.)	Prevalence (%)
Intracranial or intraspinal surgery	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Peptic ulcer	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Bleeding or bleeding diathesis	0.00 (0.00, 0.00)	*	0.98 (0.96, 1.00)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)	0.00
Structural cerebral vascular lesion	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Significant facial and/or closed head trauma	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)	*	0.96 (0.93, 1.00)	3.60
Ischemic stroke	0.00 (0.00, 0.00)	*	0.99 (0.97, 1.00)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)	0.00
Mechanical circulatory assist device placement	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Severe neurological impairment	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Other known intracranial pathology	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Dementia	0.00 (0.00, 0.00)	*	0.93 (0.88, 0.98)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)	0.00
Intubation	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Oral anticoagulant therapy	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)	*	0.96 (0.93, 1.00)	3.60
Cardiopulmonary arrest	0.40 (0.22, 0.58)	0.79 (0.61, 0.97)	0.76 (0.67, 0.85)	0.41 (1.00, 1.00)	0.95 (0.89, 1.00)	17.12
Fibrinolytic therapy	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
Transfer	*	*	1.00 (1.00, 1.00)	*	1.00 (1.00, 1.00)	0.00
PCI	0.06 (0.02, 0.10)	0.20 (0.12, 0.28)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	0.16 (0.09, 0.24)	86.49

Table 5 below aggregates these results for *System 2* at the level of the numerator, denominator, and denominator exclusions.

*cell intentionally left blank

Table 5. Validity of the Numerator and Denominator Data Elements for *System 2*

Data Element	Kappa Coefficient Mean (S.D.)	Sensitivity Mean (S.D.)	Specificity Mean (S.D.)	PPV Mean (S.D.)	NPV Mean (S.D.)
Numerator	0.69 (0.54)	0.73 (0.46)	1.00 (0.00)	1.00 (0.00)	0.72 (0.48)
Denominator	0.24	1.00	0.14	0.95	1.00

Data Element	Kappa Coefficient Mean (S.D.)	Sensitivity Mean (S.D.)	Specificity Mean (S.D.)	PPV Mean (S.D.)	NPV Mean (S.D.)
Denominator Exclusions	0.73 (0.44)	0.89 (0.30)	0.98 (0.05)	0.83 (0.37)	0.99 (0.02)

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?*)

As described in 2.b1.2 the machine-readable logic was used by each testing site to generate queries within their respective EHR systems. Although the data are routinely collected during clinical care and stored in the EHR, they reside in different systems and the sites had to generate several individual queries to gather all the appropriate data fields. Thus, the accuracy of the data variables as compared with the manually abstracted data reflects not only on the accuracy of information contained within the EHR, but also on its accessibility.

Kappa coefficients as reported in Table 2-5 indicate a range of agreement across systems and data element categories, using thresholds described by Landis and Koch (1977). Numerator value agreements are fair for *System 1* and substantial for *System 2.* The denominator value for *System 1* indicates agreement equal to that expected by chance and the denominator value for *System 2* indicates slight agreement. Denominator exclusions values are moderate for *System 1* and substantial for *System 2*.

For both *System 1* and *System 2*, denominator results reflect occurrences of STEMI diagnosis recorded in the EHR that were later identified in the manual abstraction to have occurred outside the ED (i.e., "in house" STEMI). This is an issue that can be attributed to incorrect querying of the local EHR data when translating the measure logic. This issue can be mitigated with an increase in prevalence of readily accessible common data model (CDM) platforms which would allow for accurate translation of measure logic without needing substantial local coding at the individual sites to execute a query. Alternatively, this disagreement can arise from not having a readily available flag in the EHR data to identify an ED diagnosis and differentiate it from the admission or discharge diagnosis for the hospitalization. This issue could be mitigated in measure implementation through generation of specific flags by EHR vendors to identify an ED diagnosis. In addition, qualitative interviews with staff at *System 2* indicated a lack of familiarity with the Epic EHR system, to which they recently transitioned, which may have led to accuracy challenges for both the electronic extract as well as the manual abstraction. The manual abstraction challenges, specifically, would not affect programmatic calculation of the measure.

For both *System 1* and *System 2,* the numerator results, specifically the slight agreement result for PCI, is driven by the current lack of integration of PCI data in the EHR. Qualitative interviews with *System 1* indicated plans for imminent implementation of an integrated system that will connect PCI procedure information to the EHR. We would anticipate improvement in accuracy in this data element following such integration.

Overall, results demonstrate moderate agreement across systems and metrics assessed.

This assessment took place in the "current state" environment in which interoperability among components of a hospital's EHR is not always achieved and is not required. Although currently inadequate, we expect once implemented electronic data retrieval will be feasible for all data elements. Further, health information technology (IT) industry advancements, such as those being implemented by one of the sites that participated in beta testing to integrate PCI data into the EHR, coupled with compliance with regulatory actions, such as the CMS and Office of the National Coordinator for Health Information Technology (ONC) recent interoperability rules that require hospitals to make patients' clinical information available through a Fast Healthcare Interoperability Resources (FHIR) application programming interface (API) by December 2022, will support efficient and accurate capture of the required data elements. These interoperability rules require hospitals to

make the full scope of patient data as defined in the USCDI version 1 available in standardized FHIR format, in accordance with the US Core Implementation Guide. This transition to a common data model supported by a specific FHIR IG will support integration of patient data across settings within the hospital and facilitate queries across the ER and cath lab settings.

Other key features of this eCQM, such as the code sets and measure logic, were readily interpreted by both sites as assessed by the feasibility scorecard attached to the measure submission form and the exit interviews conducted at the sites. We therefore do not interpret the findings of this beta-testing as indicating any barriers to implementation that are not already being addressed.

References: Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics 1977; 33: 159-74

2b2. EXCLUSIONS ANALYSIS

NA ☐ no exclusions — *skip to section 2b4*

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 examined the frequency of occurrence of exclusions at each system. As reported above, we also assessed the data element validity of individual exclusions in the manually abstracted 111 randomly selected patients using the five same characteristics of agreement.

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*)

Table 6, below, summarizes the frequency of each exclusion across testing systems in the electronic extract. The prevalence of exclusions in the manual extract and parameters of agreement are shown in Table 2 and 4.

Table 6. Frequency of Exclusions at *System 1* and *System 2*

Condition	System 1 Frequency (%) N 1,030	System 2 Frequency (%) N 133
Intracranial hemorrhage, intracranial, neoplasm, or significant facial and/or closed head trauma	0 (0.00)	0 (0.00)
Major surgery	2 (0.19)	0 (0.00)
Pregnancy	**0 (0.00)**	**0 (0.00)**
Internal bleeding	0 (0.00)	0 (0.00)
Suspected aortic dissection	0 (0.00)	0 (0.00)
Mortality	53 (5.15)	0 (0.00)
Reaction to thrombolytics	0 (0.00)	0 (0.00)
Intracranial or intraspinal surgery	0 (0.00)	0 (0.00)
Peptic ulcer	0 (0.00)	0 (0.00)
Bleeding or bleeding diathesis	1 (0.10)	2 (1.50)
Structural cerebral vascular lesion	0 (0.00)	0 (0.00)

Condition	System 1 Frequency (%) N 1,030	System 2 Frequency (%) N 133
Condition	**System 1 Frequency (%) N=1,030**	**System 2 Frequency (%) N=133**
Ischemic stroke	2 (0.19)	2 (1.50)
Mechanical circulatory assist device placement	0 (0.00)	0 (0.00)
Severe neurological impairment	0 (0.00)	0 (0.00)
Other known intracranial pathology	0 (0.00)	0 (0.00)
Dementia	3 (0.29)	8 (6.02)
Intubation	15 (0.15)	0 (0.00)
Oral anticoagulant therapy	0 (0.00)	0 (0.00)
Cardiopulmonary arrest	20 (1.94)	45 (33.83)
Total Excluded Cases	**76 (7.38)**	**54 (40.60)**

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 shown in *Table 6*, the frequency of occurrence for many exclusions are zero at both systems, suggesting that scores will not be substantially impacted by several of these exclusions. A few exclusions, however, were relatively more prevalent such as cardiopulmonary arrest, mechanical intubation and ED mortality. Data accuracy improvement in capturing these variables can be expected in implementation, as these exclusions in particular are interventions or events that occurred in the ED and could be relatively easily identified with minor changes to the EHR data structure. Despite the large number of exclusions and low frequency for many, clinician interviews at both systems suggested that these exclusions improve face validity of the measure because the excluded conditions impact clinical decision making regarding appropriate treatment for ED STEMI patients. Thus, several low prevalence yet clinically relevant exclusions have been retained in the final measure specifications.

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 2b5.

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

- ☒ **No risk adjustment or stratification**
- ☐ **Statistical risk model with risk factors**
- ☐ **Stratification by risk categories**
- ☐ **Other,**

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.

Not applicable.

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.

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.

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.

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.

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.

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):

Not applicable.

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

Not applicable.

2b3.9. Results of Risk Stratification Analysis:

Not applicable.

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.

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.

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)*

We are limited to data from two systems and consequently, cannot assess statistical or clinically meaningful differences in performance based on data from testing.

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*)

We are limited to data from two systems and consequently, cannot assess the distribution of performance across US hospitals based on data from testing.

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?*)

We are limited to data from two systems and consequently, cannot assess statistical or clinically meaningful differences in performance based on data from testing. However, prior literature suggests the opportunity for quality measurement and improvement.

CMS currently measures and publicly reports receipt of fibrinolytic therapy within 30 minutes of ED arrival (OP-2) and time to transfer to another facility for acute coronary intervention from a non-PCI capable facility (OP-3). Performance data on OP-2 and OP-3 suggest that opportunities remain for facilities to improve timely delivery of fibrinolytic therapy in the ED and expedited transfer to PCI capable facilities. For the April 2018 through March 2019 data collection period, the proportion of patients receiving fibrinolytics within 30 minutes in the OP-2 measure varied from 14% to 100%, with the weighted mean of 70.4%.

In situations where a patient arrives at a non-PCI capable hospital but can be transferred for primary PCI to a PCI referral center, guidelines recommend that primary PCI be performed within 120 minutes (O'Gara et al., 2013). For patients undergoing transfer, for the April 2018 through March 2019 data collection period, performance scores on OP-3 varied from 19 minutes to 106 minutes, with a weighted mean of 54.22 minutes. Also, a nationwide study of 14,518 patients showed that more than one-third of patients failed to meet recommended guidelines for door-to-device time often as a result of prolonged door-in-door-out times (Dauerman et al, 2015).

The median time to primary PCI at facilities with PCI in the National Cardiovascular Data Registry in 2014 was 59 min (10th, 50th, and 90th percentiles of 70, 60, and 48 min, respectively) (Masoudi et. al., 2017). Although, hospitals have been consistently performing well on this measure, the STEMI eCQM aims to focus on all time bound facets of emergent STEMI care, and combining time to thrombolysis, transfer time to PCI and time to PCI at a PCI capable facility in a single measure helps holistically measure the provision of care to STEMI patients and ensures that the timeframe recommended in guidelines for each reperfusion modality is met.

REFERENCES

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Centers for Medicare & Medicaid Services (2020). Hospital Compare facility-level data. Accessed from https://data.medicare.gov/data/hospital-compare.

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.

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.

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.

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 non-responders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

It was not possible within the EHR extracts to differentiate between missing data and a negative value; elements (for example, excluded conditions) without a value (for example, ICD-10 code) were interpreted as a negative value (for example, diagnosis not present) rather than missing.

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*)

Not applicable. See **2b6.1.**

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 non-responders) 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*)

Not applicable. See **2b6.1.**

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.

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

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**.

ALL data elements are in defined fields in electronic health records (EHRs)

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).

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: STEMIeCQM_NQFFeasibilityScorecard_08262020.xlsx

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.

This measure has not yet been implemented, so no difficulties in data collection have been identified.

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 2017 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)
Plan	Public Reporting Quality Improvement (external benchmarking to organizations) Not in use

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

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

This is a new measure that has not been implemented.

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 is a new measure that has not been implemented. The measure is intended for use at the facility level in an accountability program where it may be 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.*)

The measure is intended for use by CMS in an accountability program, such as the Hospital OQR Program, where it may be publicly reported. The measure's intended audience includes healthcare consumers, ED physicians and cardiologists, and ancillary medical staff, researchers, and ancillary staff (such as emergency medical services, 911 dispatch, administrators, and measure developers).

The measure was reviewed by the Measure Applications Partnership (MAP) in December 2020. The Rural Health Workgroup agreed the measure is suitable for use with rural providers under the HOQR program. During the MAP public comment period, the Society for Cardiovascular Angiography and Interventions (SCAI) noted the measure would "add value and improve patient outcomes that will likely become a de facto standard of care in this highly complex area." University of Colorado Medicine and AdvaMed also supported the measure, and the Federation of American Hospitals and American Medical Association conditionally supported the measure. Ultimately, the MAP offered conditional support for rulemaking pending NQF endorsement.

CMS will make a determination on whether and how to roll out this measure in consideration of MAP feedback and evaluation of appropriateness for inclusion in relevant rulemaking.

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.

This measure is not yet publicly reported. Data on usability was collected via qualitative interview at two sites that field tested the measure. As part of the interviews, nine clinical and administrative staff were asked key questions about the measure's usability and attribution, including:

- Do providers see value in treatment for STEMI patients in the ED?
- Are there unintended consequences associated with implementation of this measure?
- How will facilities use information from the measure to improve quality and efficiency of care?
- What current and future challenges exist in implementing the measure?
- Do providers think the measure should be attributed to an individual provider or a facility?

Following implementation of the measure in a CMS accountability program, performance scores may be publicly reported with the opportunity for ongoing stakeholder feedback. Feedback received from stakeholder Q&A and data from public reporting will be used to reevaluate the measure specifications annually.

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.

Not applicable—this measure has not yet been implemented.

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.

When addressing provider usability and the potential impact of the STEMI eCQM on quality of care, participants from both sites indicated that the measure's results would be useful and are consistent with internal performance metrics currently in use. Respondents indicated that they did not foresee any negative unintended consequences to measure implementation, other than potential changes in workflow to record the data elements in a form that can more easily be electronically extracted. Those with whom the measure developer spoke did not have concerns about interpretation of STEMI eCQM's measure scores. Aside from ED physicians and cardiologists, participants suggested that other ancillary medical staff and researchers—such as emergency medical services (EMS), 911 dispatch, administrator, and measure developers—may find the measure useful.

Both sides agreed that they would participate in optional reporting of this measure. All participants thought that the measure would be useful to patients, though there was variability on whether performance scores

would influence consumer decision- making; some participants felt that patients were less likely to make decisions based on facility performance for emergent care.

All participants with whom the measure developer spoke supported public reporting of the STEMI eCQM at the facility level, given the multiple points of care impacted by performance, including system influences that are beyond one provider's control.

Participants stated that provider-level performance scores could be used for internal quality improvement; given external confounders, however, reporting a single provider's performance would not be appropriate to report publicly.

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

Not applicable; this measure has not yet been implemented.

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

Not applicable; this measure has not yet been implemented.

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.

Overall, interview participants from both sites believe that the face validity, feasibility, usability, and attribution of the STEMI eCQM were adequate, though there were opportunities for refinements. Based on feedback received during testing of the measure, updates were made to the specifications to add greater specificity for definitions of several data elements, including ED Arrival Time, Time to PCI, and STEMI; limit the list of exclusions to only those captured during the patient encounter's in the ED (i.e., remove the look-back periods); and, remove exclusions that are unlikely to impact the time to treatment for emergent conditions such as STEMI (such as hypertension and patient refusal).

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.

As a new measure, this measure has yet to be used in any long-term reporting programs that could be used to observe improvement.

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.

This is a new measure and as such, there are no unexpected findings to report based on implementation of the measure.

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

Not applicable; this measure has not yet been implemented.

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)

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

*Note: this measure is related to NQF #2377 - Overall Defect Free Care for AMI (NQF #2377)—American College of Cardiology. This was not coming up as an option for 5.1a, so we have included this measure in this section.

Median Time to Fibrinolysis—CMS

Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival—CMS

Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (OP-2)—CMS

Primary PCI Received within 90 Minutes of Hospital Arrival—CMS

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.

The STEMI eCQM expands on the OP-2 (Fibrinolytic Therapy Received within 30 Minutes of ED Arrival) measure by including other forms of treatments appropriate for ED AMI patients with STEMI. OP-2 specifically measures the delivery of fibrinolytic therapy while the STEMI eCQM also captures PCI treatment and transfer. Further, while both OP-2 and OP-3 (Median Time to Transfer to Another Facility for ACI) focus on the timeliness of care, the STEMI eCQM also examines the appropriate treatments administered for STEMI patients presenting to the ED. Though the STEMI eCQM is intended to eventually replace OP-2 and OP-3, the three measures align where possible (like the interventions considered for treatment, time to treatment, and denominator exclusions). Although these measures are aligned to the extent feasible, the STEMI eCQM relies on electronic health record data that would measure all eligible STEMI patients eligible for treatment, whereas OP-2 and OP-3 are chart-abstracted measures that rely on sampled data. The related measure NQF #2377 (Overall Defect Free Care for AMI), stewarded by the American College of Cardiology, measures the proportion of acute myocardial infarction patients aged above 18 years who receive optimal care based upon their eligibility for each performance measure. The measure concept of appropriate care for STEMI patients aligns with the STEMI eCQM concept; the measure population and settings of care, however, differ. For the STEMI eCQM, patients in the ED setting are included in the measure, whereas NQF #2377 evaluates both STEMI and non-STEMI patients in the inpatient setting. Further, the related measure NQF #2377 is a composite measure that evaluates variables beyond time to fibrinolytics and PCI.

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.)

The STEMI eCQM does not conceptually address both the same measure focus and the same target population as NQF-endorsed measure(s).

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.

No appendix **Attachment:**

Contact Information

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

Co.2 Point of Contact: Janis, Grady, janis.grady@cms.hhs.gov, 410-786-7217-

Co.3 Measure Developer if different from Measure Steward: Yale/Yale New Haven Health System Center for Outcomes Research and Evaluation (CORE)

Co.4 Point of Contact: Faseeha, Altaf, faseeha.altaf@yale.edu, 860-752-5471-

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.

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Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released:

Ad.3 Month and Year of most recent revision:

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

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

Ad.6 Copyright statement: Limited proprietary coding is contained in the Measure specifications for user convenience. Users of proprietary code sets should obtain all necessary licenses from the owners of the code sets.

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This performance measure is not a clinical guideline and does not establish a standard of medical care and has not been tested for all potential applications. The measure and specifications are provided without warranty.

Ad.8 Additional Information/Comments: N/A