PUBLIC COMMENT SUMMARY REPORT

Project Title: Development, Reevaluation, and Implementation of Outpatient Outcome/Efficiency Measures

Dates:

The Call for Public Comment ran from **Monday, February 18, 2019** through **Monday, March 18, 2019**.

The Public Comment Summary was prepared on **Monday, April 01, 2019**.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Yale-New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) to develop an electronic clinical quality measure (eCQM) that assesses the percentage of STEMI patients who presented and received appropriate treatment in the ED. The contract name is Development, Reevaluation, and Implementation of Outpatient Outcome/Efficiency Measures, Option Period Four. The contract number is HHSM-500-2013-13018I; the task order number is HHSM-500-T0002.

Project Objectives:

The project's primary objectives, as they relate to this public comment, included:

- Respecification of the OP-2 (Fibrinolytic Therapy Received within 30 Minutes of ED Arrival) measure concept, a chart-abstracted measure, to develop a de novo eCQM, including:
  - Providing feedback on electronic specification of the new measure, entitled *Appropriate Treatment for STEMI Patients in the ED*;
  - Making assessments on the measure's importance, face validity, feasibility, and usability; and,
  - Recommending improvements as needed.

In advance of public comment, the project team consulted with clinical experts and a multi-stakeholder technical expert panel (TEP) to develop the measure *Appropriate Treatment for STEMI Patients in the ED*. As part of the measure development process, we solicited comments from the public about the importance, face validity, feasibility, usability, and potential use of the draft measure.

Information About the Comments Received:

The project team conducted outreach to notify key stakeholders and the general public about the comment period for the Appropriate Treatment for STEMI Patients in the ED measure. This outreach included:

- Posting a notification about the measure on the CMS public comment website and asking for comments
- Sending emails to the following stakeholders and stakeholder organizations:
  - American College of Cardiology
  - American College of Emergency Physicians
  - American College of Physicians
  - American Heart Association
  - American Hospital Association
  - American Medical Association
  - American Medical Directors Association
  - Cerner

- Consumers Union Safe Patient Project
- Electronic Health Record Association
- Emergency Nurses Association
- Epic
- Federation of American Hospitals
- Healthcare Information and Management Systems Society
- Institute for Healthcare Improvement
- Institute for Healthcare Optimization
- Medisolv
- National Association of Emergency Medical Technicians
- National Association of Freestanding Emergency Centers
- National Association of Rural Health Clinics
- National Heart, Lung, and Blood Institute
- National Rural Health Association
- Office of the Assistant Secretary for Planning and Evaluation
- Pacific Business Group on Health
- Patient-Centered Primary Care Collaborative
- Society for Cardiovascular Angiography and Interventions
- Society of Academic Emergency Medicine
- U.S. Preventive Services Task Force

The project team also notified facilitators in the following groups and asked them to announce the public comment period in their email communications and at their meetings:

- Battelle's MIDS C3 meeting
- Weekly governance call for measure developers

The project team received comments about the Appropriate Treatment for STEMI Patients in the ED measure from two unique commenters. The following groups submitted responses during the public comment period:

1. One professional organizations (Emergency Nurses Association [ENA])
2. One trade association (Federation of American Hospitals [FAH])

Stakeholder Comments—General and Measure-Specific

Below, we summarize general and measure-specific stakeholder comments, along with the project team's responses to them. The comments are organized by their subject matter. In this summary, we paraphrase some of the comments; original comments and the responses to them can be found in this document's Public Comment Verbatim Report, which begins on page five.

One commenter stated the measure was conceptually important but had concerns about the evidence provided to support its rationale, the denominator exclusions, and references. The second commenter had mixed feedback, expressed concerns with the measure's feasibility, its numerator criteria, reliability, validity, and rationale. Both

comments did, however, demonstrate support for the measure concept and CMS's transition to electronic data collection.

General Comments

One commenter stated that the references cited in support of the measure are out of date, noting that guidelines on which the measure is based have not been updated in more than five years.

Response: Thank you for providing feedback on the evidence base for the *Appropriate Treatment for STEMI Patients in the ED* measure. In developing the measure, we conducted a thorough evaluation of clinical practice guidelines and the peer-reviewed literature for the measure and consulted with our TEP to ensure that the studies and guidelines referenced are those that are used in the contemporary management of STEMI patients.

Measure-Specific Comments

We received several comments on the measure specifications and the appropriateness of measure exclusions. These comments are organized by themes and summarized below.

Measure Feasibility

One commenter strongly encouraged further feasibility assessment of collecting the required data elements from electronic health record systems (EHRs) for the measure beyond soliciting input during the measure development public comment period. The commenter expressed their concern that the complexity of the measure, particularly the complexity of the numerator and exclusions, may significantly impact an individual hospital's ability to successfully collect and report the data required for the measure.

Response: Thank you for providing feedback on the feasibility of calculating the *Appropriate Treatment for STEMI Patients in the ED* measure. The project team developing this measure will collect data on the feasibility of capturing all data elements used in the calculation of this measure through completion of a feasibility scorecard. We will also discuss this concern about the feasibility of capturing the more complex elements for this measure with the project's TEP to ensure they are appropriately specified and available in structured electronic health record (EHR) fields.

One commenter stated that a key variable for the STEMI eCQM will be the time of symptom onset to determine which patients will be captured in the measure's initial patient population. The commenter stated that the STEMI eCQM is not a distinct measure and would require alterations in documentation or thorough chart review to calculate.

Response: Thank you for providing feedback on the feasibility of calculating the *Appropriate Treatment for STEMI Patients in the ED* measure. The project team developing this measure will collect data on the feasibility of capturing all data elements used in the calculation of this measure through completion of a feasibility scorecard. We will also discuss your concerns about the feasibility of capturing time of symptom onset with our TEP to ensure they are appropriately specified and available in structured EHR fields.

Appropriateness of Measure Exclusions

One commenter expressed concern over the denominator exclusion of patients with cardiopulmonary arrest within 30 minutes of ED arrival, asking for the rationale for excluding this population.

Response: Thank you for providing feedback on the exclusions for the *Appropriate Treatment for STEMI Patients in the ED* measure. Given the myriad potential causes of cardiopulmonary arrest, and the array of interventions and procedures that may be necessary to achieve return of spontaneous circulation (ROSC) in the ED, the project team developing this measure felt that the inclusion of such patients in the denominator would dilute the sample of STEMI patients in which the timeliness of care could be validly assessed.

Measure Rationale

One commenter stated that it is not clear why 30 minutes or fewer is the gold standard for fibrinolytic therapy when the American Heart Association (AHA) recommends administration in 1 hour or less. Similarly, this commenter stated that that patients are excluded from the numerator if they do not receive percutaneous coronary intervention (PCI) within 90 minutes, when the standard is 120 minutes.

Response: Thank you for providing feedback on the rationale for the *Appropriate Treatment for STEMI Patients in the ED* measure. The 30-minute timeframe by which fibrinolytic therapy must be administered aligns with recommendations from the 2013 American College of Cardiology Foundation (ACCF)/AHA Guideline for the Management of STEMI, which are the most recent comprehensive guidelines available from the ACC and AHA.

One commenter requested clarification on the evidence used for one of the numerator actions, which states "ED STEMI patients who were transferred to a PCI-capable hospital within 45 minutes of ED arrival at a non-PCI capable hospital." The commenter noted that the 2013 ACCF/AHA Guideline for the Management of STEMI recommends "Immediate transfer to a PCI-capable hospital for primary PCI is the recommended triage strategy for patients with STEMI who initially arrive at or are transported to a non–PCI-capable hospital, with an FMC-to-device time system goal of 120 minutes or less." The commenter requested evidence to demonstrate why the optimal time to transfer to a PCI-capable hospital was within 45 minutes.

Response: Thank you for providing feedback on the specifications for the *Appropriate Treatment for STEMI Patients in the ED* measure. The 2013 ACCF/AHA Guideline for the Management of STEMI recommends a time window from first medical contact (FMC) to device of 120 minutes or fewer for patients with STEMI who initially arrive at or are transported to a non-PCI-capable hospital and are subsequently transferred to a PCI-capable hospital for primary PCI. The 45-minute timeframe used in the draft STEMI eCQM specifications is distinct from this parameter, however, and more closely reflects the door-in, door-out (DIDO) time—that is, the time from ED arrival at a non-PCI-capable hospital to time of departure from the same ED (for transfer to a PCI-capable hospital). Current guidelines recommend a DIDO time of 30 minutes or fewer; the project team felt, however, that this 30-minute window may not be feasible for all sites, so we specified the draft measure with a transfer time target of 45 minutes or fewer.

Measure Scientific Reliability

One commenter expressed concern about the complexity of the measure's exclusions and felt that there would be an increased risk for errors in data capture and calculation, which could distort results and misrepresent the quality of care provided by hospitals. The commenter recommended comprehensive testing for reliability and validity of the STEMI eCQM, including at the individual data element level.

Response: Thank you for providing feedback on data collection and testing of the *Appropriate Treatment for STEMI Patients in the ED* measure. The project team developing this measure will conduct data element validity testing of the STEMI eCQM's specifications, which will assess its reliability and validity. We will also discuss your concerns about the potential for missing data with our TEP to ensure the key data elements are appropriately specified and available in structured EHR fields.

Preliminary Recommendations

The STEMI eCQM project team will review the commenters' suggestions with CMS and the measure's TEP, identifying modifications to the measure specifications to address feedback on the initial patient population, numerator criteria, and denominator exclusions. We will also provide details on measure testing and integrate additional guidance into the measure rationale as appropriate. We will make recommendations for next steps based on discussions with CMS and the TEP.

Overall Analysis of the Comments and Recommendations

Feedback on the *Appropriate Treatment for STEMI Patients in the ED* measure was highly informative—there was support for the measure concept and transition to electronic data collection, with a number of requests for clarification. Both commenters expressed concern over the feasibility of select data elements of the measure and requested further explanation regarding for the inclusion of several elements. We thank commenters for providing their feedback and perspectives on this important measure.

Public Comment Verbatim Report

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Response
03/18/2019	The Federation of American Hospitals (FAH) appreciates the opportunity to submit comments on the draft CMS Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED) electronic clinical quality measure (eCQM). FAH's comments on the proposed measure are outlined below. FAH strongly encourages CMS to assess the feasibility of collecting the required data elements from electronic health record systems (EHRs) for the measure beyond soliciting for input during this comment period. FAH is concerned that the complexity of the measure and, particularly the complexity of the numerator and exclusions, may significantly impact an individual hospital's ability to successfully collect and report the data required for the measure. For example, it is not clear how easy it will be to capture whether the patient arrives at a PCI-capable hospital vs. a non-PCI capable hospital. Thorough assessments of each data element and the required calculations and logic must be vetted across several hospitals and vendor systems to truly understand whether it is ready to be implemented in EHRs. If the measure is not determined to be feasible in the majority of vendor systems currently used, then it would be prudent for CMS to delay further testing and implementation until these gaps in EHRs data capture and reporting can be addressed. In addition to thorough feasibility assessments, determinations on whether the measure is reliable and valid must be completed. As noted above, the numerator and exclusions could be complex and as a result, there is increased risk for missing data and errors in data capture and calculation that could distort results and misrepresent the quality of care provided by hospitals. Comprehensive testing for reliability and validity, including at the individual data element level, must be completed prior to implementation in any federal program. FAH also requests clarification on the evidence used for one of the numerator requirements, specifically, "ED STEMI patients who were transferred to a PCI-capable hospital within 45 minutes of ED arrival at a non-PCI capable hospital". On review of the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction, the relevant recommendation states: "Immediate transfer to a PCI-capable hospital for primary PCI is the recommended triage strategy for patients with STEMI who initially arrive at or are transported to a non–PCI-capable hospital, with an FMC-to-device time system goal of 120 minutes or less." FAH was unable to find any other recommendations in the guideline that expressly state that the optimal time to transfer to a PCI-capable hospital was within 45 minutes and FAH requests that this requirement be fully vetted with clinical experts to determine if the timeframe does not set unreasonable expectations for a timely transfer. Since the numerator can also be met if a patient receives fibrinolytic therapy within 30-minutes, there is the potential for a hospital to choose not to transfer a patient if they cannot	Claudia Salzberg, PhD; Federation of American Hospitals	Thank you for providing feedback on the evidence, feasibility, specifications, and testing for the STEMI eCQM measure. We appreciate the concerns you highlighted in your comments. The project team developing this measure will collect data on the feasibility of capturing all data elements used in the calculation of this measure through completion of a feasibility scorecard. In spring 2019, we will conduct data element validity testing of the STEMI eCQM's specifications, which will assess its reliability and validity. The 2013 ACC/AHA Guideline for the Management of STEMI recommends a time window from first medical contact (FMC) to device of 120 minutes or fewer for patients with STEMI who initially arrive at or are transported to a non-percutaneous coronary intervention (PCI)-capable hospital and are subsequently transferred to a PCI-capable hospital for primary PCI. The 45-minute timeframe used in the draft STEMI eCQM specifications is distinct from this parameter, however, and more closely reflects the door-in, door-out (DIDO) time—that is, the time from ED arrival at a non-PCI-capable hospital to time of departure from the same ED (for transfer to a PCI-capable hospital). Current guidelines recommend a DIDO time of 30 minutes or fewer; we felt that this 30-minute window may not be feasible for all sites, so we specified the measure with a transfer time of fewer than 45 minutes. We will also discuss your concerns about the feasibility of capturing the more complex elements in this measure with our technical expert panel to ensure they are appropriately specified and available in structured electronic health record (EHR) fields.

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Response
	reasonable meet the 45-minute requirement while still satisfying the measure by providing fibrinolytic therapy. In those instances, the choice could be to allow the hospital to achieve higher performance rather than prioritizing the best treatment pathway for a patient. This numerator requirement could have unintended consequences if not based on strong evidence and supported by a clinical guideline. FAH requests that CMS evaluate this possibility further. In conclusion, FAH urges CMS to carefully assess the evidence for the numerator requirements, feasibility, reliability, and validity of this eCQM prior to implementation in a federal program. Misrepresenting the quality of care must be avoided and careful evaluations of each testing area must be completed to ensure that it does not occur. If you have any questions about our comments or need further information, please contact the FAH staff at (202) 624-1500. Thank you for the opportunity to comment.		
03/18/2019	**Rationale:** It isn't clear why 30 minutes or fewer is the gold standard for fibrinolytic therapy when AHA says 1st hour. Of concern also is the percentage of hospitals that can actually meet this standard. Similarly, that patients are excluded from the numerator if they do not receive PCI within 90 minutes when the standard is 120 seems unsupported by evidence. **References:** It appears that the guidelines have not been updated in over 5 years; references are old. **Denominator Exclusions:** The exclusion of patients who have had CPR is understandable, but it is not clear why patients that have had cardiopulmonary arrest within 30 minutes of ED arrival are excluded. **Overall:** Conceptually, this is a good measure. A key variable will be the time of symptom onset in determining who will be pulled into the sample. This is not currently a distinct measure and would require alterations in documentation or thorough chart review; this may not reduce the burden of chart abstraction.	Emergency Nurses Association	Thank you for providing feedback on the evidence and specifications for the STEMI eCQM measure. We appreciate the concerns you highlighted in your comments. The 30-minute timeframe by which fibrinolytic therapy must be administered aligns with recommendations from the 2013 ACCF/AHA Guideline for Treatment of STEMI. In developing the measure, we conducted a thorough evaluation of clinical practice guidelines and peer-reviewed literature for the measure and consulted with our technical expert panel (TEP) to ensure that the studies and guidelines referenced are those used in the administration of care. Given the myriad potential causes of cardiopulmonary arrest, and the array of interventions and procedures that may be necessary to achieve return of spontaneous circulation (ROSC) in the ED, the project team developing this measure felt that the inclusion of such patients in the denominator would dilute the sample of STEMI patients in which the timeliness of care could be validly assessed. We will also discuss your concerns about the rationale and specifications with our technical expert panel to ensure the measure is appropriately specified and available in structured EHR fields.