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ACC/AHA 2008 Statement on Performance Measurement and Reperfusion Therapy. A Report of the ACC/AHA Task Force on Performance Measures (Work Group to Address the Challenges of Performance Measurement and Reperfusion Therapy)

Frederick A. Masoudi, Robert O. Bonow, Ralph G. Brindis, Christopher P. Cannon, Jo DeBuhr, Susan Fitzgerald, Paul A. Heidenreich, Kalon K.L. Ho, Harlan M. Krumholz, Chris Leber, David J. Magid, David S. Nilasena, John S. Rumsfeld, Sidney C. Smith, Jr and Thomas P. Wharton, Jr

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ACC/AHA Performance Measures

ACC/AHA 2008 Statement on Performance Measurement and Reperfusion Therapy

A Report of the ACC/AHA Task Force on Performance Measures (Work Group to Address the Challenges of Performance Measurement and Reperfusion Therapy)

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This document is an official document of the American College of Cardiology (ACC)/American Heart Association (AHA) Task Force on Performance Measures. The task force formed a work group to address the challenges of performance measurement and reperfusion therapy.

1. Introduction

Acute reperfusion therapy, either with fibrinolytic therapy or percutaneous coronary intervention (PCI), is one of the most important treatments for patients with ST-segment elevation myocardial infarction (STEMI). Randomized clinical trials have shown that reperfusion therapy provided to eligible patients reduces the risk of death due to all causes.¹ The timeliness of reperfusion therapy is of central importance, because the benefits of therapy diminish rapidly with delays in treatment. Thus, ACC/AHA guidelines recommend that fibrinolysis be provided within 30 minutes of first medical system contact and that primary PCI be provided within 90 minutes of first medical system contact for patients presenting with STEMI.¹ These guideline recommendations have been translated into performance measures that are reported to the public by the Centers for Medicare & Medicaid Services (CMS) and the Joint Commission.^{2,3}

Measurement of the time to reperfusion therapy involves challenges that have hampered the acceptance of these performance measures among some clinicians and hospitals. On the basis of field testing of the existing measures, the most controversial aspects of the measures include the characteristics of the measures' population (ie, inclusions and exclusions) and the determination of the time at which measurement stops for patients receiving primary PCI. Furthermore, the current measures do not address some components of the quality of reperfusion (eg, appropriateness), do not include all important segments of the population receiving reperfusion (eg, those transferred from one facility to another for treatment), or do not include an assessment of prehospital factors (ie, starting measurement at the time of first system contact).

To address these challenges, a work group was convened with the goals of evaluating the current CMS and Joint Commission time-to-reperfusion measures; considering modifications to optimize measurement; assessing the alignment of the CMS and Joint Commission measures with those used by the National Cardiovascular Data Registry (NCDR) CathPCI Registry; and proposing further measures to increase the scope of the assessment of reperfusion therapy for STEMI.

This work group included representatives from the ACC/AHA Performance Measures Task Force; the ACC/AHA Practice Guidelines Task Force; the NCDR; the AHA's Get With the Guidelines program; the Society of Cardiovascular Angiography and Interventions; CMS; and the Joint Commission. Members of the work group have expertise in a wide range of relevant areas, including interventional cardiology, general cardiology, emergency medicine, performance-measure development and implementation, and clinical registry development.

The present document provides a historical perspective on the measurement of time to reperfusion, describes the balance of characteristics necessary for a usable performance measure of reperfusion therapy, summarizes the deliberations of the work group concerning several important issues in the measurement of time to reperfusion, and provides recommendations for additional performance measures for reperfusion therapy. It is intended to clarify the challenges related to measuring this important aspect of care for patients with STEMI, provide recommendations for optimizing the current reperfusion measures, and suggest the general characteristics of more comprehensive measures of reperfusion therapy.

2. History of the Time-to-Reperfusion Performance Measures

As a result of the efficacy of acute reperfusion therapy for STEMI and the importance of the timeliness of therapy, time to reperfusion emerged as an indicator of the quality of care for patients with STEMI. Reperfusion therapy has been a focus of quality assessment since the early 1990s, when the Health Care Financing Administration (HCFA, now CMS) launched the Cooperative Cardiovascular Project pilot study and the National Heart, Lung, and Blood Institute-supported National Heart Attack Alert Program was initiated.^{4,5} These programs were designed in part to measure the quality of reperfusion therapy with fibrinolysis for patients with STEMI. A measure of the proportion of ideal candidates who received fibrinolysis within 12 hours of presentation was evaluated in the Cooperative Cardiovascular Project, but this measure was not included in later projects, in part because of challenges in identifying a robust denominator for the measure.⁴ However, time to reperfusion for eligible STEMI patients persisted as a primary measure throughout the Cooperative Cardiovascular Project.

The CMS continued to include the time to reperfusion for STEMI as a performance measure in the National AMI Project, which assessed the quality of care for acute myocardial infarction nationwide between 1998 and 2001.⁶⁻⁸ Because primary PCI had emerged as an evidence-based reperfusion strategy, the measures for these efforts included

measures of the time to reperfusion for both fibrinolytic therapy and primary PCI. As with the Cooperative Cardiovascular Project, the measures for these projects only assessed the time to therapy among treated patients and did not include an assessment of the use of reperfusion among all potentially eligible candidates (underuse) or the use of reperfusion therapy among patients who were not candidates for therapy (overuse).

Since the initiation of the CMS measurement projects, national performance for the timeliness of acute reperfusion has generally improved. Between the Cooperative Cardiovascular Project (1994 to 1995) and the National AMI Project Baseline (1998 to 1999), the mean time to fibrinolysis among eligible patients improved by 7 minutes and the time to PCI by 12 minutes.⁷ Between 1998 to 1999 and 2000 to 2001, fibrinolysis times increased slightly (by 4 minutes, to a median of 45 minutes), whereas time to PCI continued to improve (by 19 minutes, to a median of 107 minutes).⁶ Thus, although data on national trends in the timeliness of reperfusion have been encouraging, there are clearly persistent gaps in the provision of reperfusion therapy that justify ongoing measurement.

Since the time of the National Heart Care Project, reperfusion measures have evolved. In 2002, CMS and the Joint Commission collaborated to develop aligned measures for use by both organizations. These measure sets included institutional times to treatment for patients with STEMI who received therapy, as well as the proportion of patients treated in a timely fashion for both fibrinolysis and PCI. Although for a time, the threshold to define timely PCI was set at 120 minutes, more definitive recommendations contained in the STEMI guidelines motivated a revision to a 90-minute threshold in July 2006.⁹ Beginning in 2004, the measures reported institutional mean times to reperfusion; however, because of the undue influence of outliers on the mean, median times were substituted in January 2006.

In 2006, the ACC/AHA published the specifications of performance measures for acute myocardial infarction, which included several measures concerning the provision of reperfusion therapy for STEMI.¹⁰ These measures included time-to-reperfusion measures for fibrinolysis and primary PCI that were closely aligned with existing CMS and Joint Commission measures, with 2 notable exceptions. First, the ACC/AHA measures excluded patients for whom a clinical reason for delaying therapy was documented. Subsequently, the CMS and Joint Commission adopted this same exclusion. Second, the ACC/AHA performance measure set included a measure of the provision of reperfusion therapy to eligible candidates for treatment, which to this point has not been adopted by CMS and the Joint Commission.

Several constituencies have promoted timely reperfusion as a measure of quality of care, some of which report these statistics nationally. Currently, they are part of the CMS and Joint Commission core performance-measures set for acute myocardial infarction.² These measures, which include institutional median times to fibrinolysis and PCI, as well as the proportion of patients receiving fibrinolysis within 30 minutes of arrival and PCI within 90 minutes of arrival, are reported to the public on the Hospital Compare World Wide

Web site.¹¹ The NCDR also includes measures of timely reperfusion for primary PCI, albeit using somewhat different numerator and denominator definitions and different data-element definitions.¹² The AHA's Get With the Guidelines program has also collected time-to-reperfusion data for patients with STEMI.¹³ Because of the known gaps in reperfusion therapy quality¹⁴ and an understanding of the factors associated with faster PCI times,¹⁵ the ACC, in collaboration with several other national organizations, launched the D2B (Door-to-Balloon) Alliance for quality, which was designed to disseminate effective strategies to improve the time to primary PCI.¹⁶ With increasing public availability of data on quality measures and a growing penetration of pay-for-performance programs based on widely used performance measures, an increasing focus on timely reperfusion measures and the consistency of the definitions of these measures has been inevitable.

3. Attributes of Performance Measures of Time to Reperfusion

Performance measures and guideline recommendations are not synonymous.¹⁷ Guidelines identify processes of care that should generally be used in patients with a given condition, with varying levels of the strength of recommendations to be considered by the clinician. Performance measures identify aspects of care for which the failure to provide a particular process of care is judged as poor clinical performance. An understanding of the characteristics of performance measures provides fundamental insights into the process of developing and modifying measures used for the assessment of clinical performance.

Timely reperfusion for STEMI, defined in current guidelines as the provision of fibrinolysis within 30 minutes of first medical contact or of PCI within 90 minutes of first medical contact, has been incorporated in the guidelines as a class I recommendation on the basis of the wealth of data demonstrating the association of rapid treatment with better outcomes.¹ Such strong, evidence-based support alone is necessary but not sufficient to consider this process of care as a performance measure. The criteria for robust process performance measures have been articulated by the ACC/AHA Performance Measures Task Force.¹⁷ Beyond support by clinical trials and guidelines, the task force report suggests that performance measures must also be (1) interpretable; (2) actionable; (3) characterized by well-defined numerators and denominators; (4) valid (face, construct, and content); (5) reliable/reproducible; and (6) feasible. In general, although current reperfusion measures generally meet these criteria, certain aspects of these attributes merit further discussion.

Despite well-defined numerators and denominators, no performance measure will perfectly classify eligible patients or appropriately ascertain treatment in all patients. Like diagnostic tests, performance-measure numerators and denominators have variable sensitivity and specificity, and in general, improvements in sensitivity usually result in lower specificity and vice versa. Thus, changes in the denominator that increase sensitivity will ensure that a larger number of the patients who are truly eligible to receive a process of care will

be included in the measure; however, such a change will simultaneously increase the inclusion of patients who are ineligible for treatment. For example, a relatively stringent definition of the electrocardiographic (ECG) criteria needed for inclusion in the measure will increase the likelihood that patients included in the measure truly have STEMI. On the other hand, such criteria will necessarily result in larger numbers of patients with ST-segment elevation who are excluded inappropriately.

The manner in which data are collected has an important impact on the feasibility, cost, and performance of the measure. The underlying data for the performance measures for CMS and the Joint Commission have been designed to allow for abstraction by nonclinicians. Although in some cases, individuals with clinical experience may perform the abstraction, this is not uniformly the case. Although abstractors receive training to optimize the accuracy of abstraction, they may not be able to apply clinical decision-making skills during abstraction. Furthermore, the burden of abstraction depends substantially upon the detail and construction of the underlying data definitions and the need to adjudicate conflicts in clinical documentation. Using the time-to-reperfusion performance measures as an example, inclusion ECG criteria are not ascertained by a direct interpretation of the ECG; rather, the abstractor reviews the medical record and determines whether the interpretations provided by the clinicians in the record indicate that the patient meets ECG criteria for acute reperfusion. Abstraction rules have been developed to facilitate the adjudication of conflicts in documented interpretations. As another example, in defining the time at which a reperfusion device is used, the data-element and abstraction instructions must account for the variability with which these data are recorded in medical records from numerous institutions.

The data elements for process performance measures should also be designed to minimize the extent to which documentation can be used to avoid the spirit of the measure (ie, gaming). Performance measurement may unintentionally generate incentives for creative recordkeeping, particularly when the stakes of measurement are high and the perceived risks posed to the patient are low. Both concerns about gaming and the extent to which even the possibility of gaming may undermine the credibility of a measurement system support the development of data elements and definitions that are resistant to gaming. Credible and transparent audit processes would also reduce the likelihood of gaming.

Finally, the wide range of organizations interested in performance measurement has led to the proliferation of numerous measures sets for different conditions, which in many circumstances are not aligned. The lack of alignment among measures sets increases the burden of documentation and data collection, inevitably resulting in confusion. Furthermore, failure of alignment may have important implications for performance-based rankings. A recent analysis comparing time-to-PCI measures between the CMS and Joint Commission measures and the NCDR measures found only moderate agreement between door-to-PCI times between the 2 measures in the same hospitals.¹⁸ The benefits of alignment are therefore substantial. This alignment should take into account

not only the measure macrospecifications (eg, numerator and denominator statements) but also the microspecifications (eg, data-element definitions). A failure of alignment at either level results in systematic differences in the patient populations included and the assessments of the processes of care applied, as well as differences in the measured performance within an institution.

In summary, performance measures differ significantly from guideline recommendations in that performance measures must meet multiple additional criteria beyond a strong basis in evidence. The development of performance measures must also include a consideration of the inevitability of some degree of misclassification; the burden of abstraction necessary for measurement; the possibility of gaming; and the importance of measure alignment. These factors were explicitly considered in the discussions of the present committee about possible modifications to the time-to-reperfusion measures. Ultimately, it is also important to keep in mind the goals of the reperfusion performance measures, which are to provide a quantitative assessment of this important process of care, introduce accountability for performance in providing timely reperfusion, improve the quality of care, and reduce adverse outcomes of patients with STEMI.

4. Specific Challenges to Measuring Time to Reperfusion

During the implementation of the CMS and Joint Commission performance measures for acute reperfusion for STEMI, several issues have been raised regarding the characteristics of the measures and the data elements underlying the measures. Although the range of questions that has emerged is broad, 3 themes merit specific consideration: the measure inclusions, the measure exclusions, and the determination of the time at which measurement stops for patients receiving primary PCI. The present work group addressed each of these explicitly in its discussions and recommendations.

4.1. Measures Inclusions

Reperfusion measures will ideally include all patients who were treated with a primary reperfusion strategy for STEMI. These patients should be treated as rapidly as possible. The criteria for inclusion in the current CMS and Joint Commission time-to-reperfusion performance measures are delineated in Appendix A, Table A1. Two aspects of these criteria merit discussion. First, as mentioned above, the ECG findings are derived from abstraction of the ECG interpretation in the medical record rather than a *de novo* interpretation of the ECG by a clinician. Although ECG interpretations by clinicians may more precisely identify those patients who meet strict guidelines-based criteria for primary reperfusion strategies, this approach is currently not feasible because of the resources required for clinician abstraction of the primary data. Furthermore, because abstraction focuses on the documented interpretation(s) of the ECG tracing rather than the ECG itself, the definitions used to guide the abstractors in the ECG interpretation are necessarily complex. The CMS and the Joint Commission have recently streamlined this data element.

Regardless of the definitions used, any criteria used to classify ECGs will misclassify patients to some extent. For example, a tracing that shows 1.5 mm of ST-segment elevation in inferior leads II, III, and aVF with reciprocal ST-segment depressions in the anterior leads would be classified appropriately, presuming the documentation of the interpretation accurately reflects these findings. However, for the purposes of measurement, the tracing could be classified as not showing ST-segment elevation for several reasons, including vague documentation (eg, “ST-segment abnormalities in the inferior and anterior leads”) or even misinterpretation of the tracing (eg, “ST-segment elevation, consider pericarditis”). Although definitions based on the interpretations of documented ECGs are likely to have more potential for misclassification than those based on standardized criteria applied to de novo tracing interpretations, the latter approach is not plausible owing to the resources necessary to achieve this standard.

Second, the ECG criteria for the CMS and Joint Commission measures apply only to the ECG obtained closest to arrival at the hospital, including any ECGs obtained within the hour before arrival. Thus, those patients who develop STEMI after presenting with an ECG closest to arrival that is not consistent with STEMI are not included. Ideally, a comprehensive assessment of performance in delivering timely reperfusion would include all patients with STEMI. However, whereas the time of hospital arrival can be identified relatively easily in the medical record, determining the appropriate “start” time for patients who develop STEMI after their presentation is relatively challenging. The current CMS and Joint Commission measures attempt to strike a balance between the interest in including as many patients as possible and the practical aspects of the limitations of medical records abstraction. However, this criterion represents an area of nonalignment with the measures of time to reperfusion currently used in the NCDR ACTION-Get With the Guidelines and CathPCI registries, which include patients with STEMI that develops while they are in the hospital.

4.1.1. Measures Inclusions—Work Group Conclusions

1. The work group supports current efforts by CMS and the Joint Commission to simplify the current ECG interpretation data element to the extent possible, acknowledging that it must provide adequate guidance to nonclinical abstractors in identifying possible candidates for acute reperfusion. These modifications should be tested to determine the impact on the populations of patients included in the measures.
2. The goals of prompt reperfusion are to restore blood flow in a completely occluded artery, clinically manifested as a STEMI. Ideally, the performance measure would include those patients with STEMI that evolves after arrival at the hospital or that develops in the hospital. Until it is possible to enact this modification in practice, the patient population in the current CMS and Joint Commission measure should be contained entirely within the populations of the NCDR and AHA Get With the Guidelines programs to the extent possible, which will facilitate comparisons between measures sets and institutions.

4.2. Measures Exclusions

Even among those patients presenting with STEMI, not all are appropriate for inclusion in a performance measure of time to reperfusion. Accordingly, some patients meeting the above inclusion criteria are ultimately excluded from the measures denominators on the basis of the criteria enumerated in Appendix A2, 3 of which merit further examination.

First, patients who present at one hospital and are transferred for reperfusion (usually PCI) to another are currently excluded, in part because of the logistical difficulties in collecting the time of arrival at one center and the time of reperfusion in another and a lack of consensus on the appropriate attribution of a measure that involves more than 1 institution. As a result, however, an important segment of the patient population that receives reperfusion is systematically excluded from the measure. Furthermore, centers that uniformly transfer patients for primary PCI are thus not included in the current reperfusion measures.

Second, there are many clinically sound reasons why clinicians may not pursue a primary reperfusion strategy in patients with STEMI. Among those patients who receive reperfusion after the guideline-recommended time threshold (30 minutes for fibrinolysis or 90 minutes for PCI), documented clinical reasons justifying a delay in reperfusion therapy qualify as an exclusion from the measure denominator. Because it is often difficult to infer what clinicians are thinking based on the medical record, rules have been developed to ascertain this conclusion. For practical purposes, these rules cannot require clinical judgment regarding the documented reason for delay. With the exception of a small number of discrete events that consistently result in significant but clinically appropriate reasons for delay (eg, cardiac arrest), the reason must also be explicitly linked in the records documentation to a delay in providing reperfusion. Finally, the exclusion applies only to patient-related reasons for a delay in the provision of reperfusion therapy (eg, refusal to provide consent for PCI) and not system-centered reasons (eg, catheterization laboratory staff late to arrive). System-centered reasons for delay are not permitted because these are the very issues that measurement is intended to identify and eliminate.

This exclusion is intended to account for frequently encountered scenarios in clinical care, such as the performance of diagnostic tests to exclude an alternative diagnosis or contraindication to therapy. However, this exclusion does not allow for the assessment of care in those patients who receive optimally timely therapy after the reason for delay has been resolved, because it is not practical to identify the appropriate “start” time in such patients with standard chart documentation. At the same time, there are concerns about the potential for overdocumentation of reasons for delay, in part because the validity of documented reasons cannot be considered practically in records abstraction. Currently, data are not available to determine the variation in the documentation of delays of reperfusion therapy.

Importantly, assessment for patient-centered reasons for delay is only applied to those patients for whom reperfusion was provided outside of the guideline-recommended time threshold. An important reason for this approach is that it

substantially reduces the abstraction burden by obviating the assessment of delays in patients who receive timely therapy. This approach has variable implications on the measures of the proportion of patients receiving therapy compared with the measures of the median reperfusion time. Specifically, a patient who received PCI in 85 minutes after a delay of 25 minutes for the purposes of performing imaging to exclude acute aortic dissection would contribute positively to the measure of the proportion of patients receiving PCI within 90 minutes; however, the time of 85 minutes, which includes the 25-minute delay, would contribute to the institutional median time calculation.

Finally, the measure excludes those patients for whom PCI was not used as a primary reperfusion strategy. Thus, for example, patients who undergo PCI after first receiving fibrinolytic therapy (eg, “rescue” PCI) or those whose symptoms and ST elevation resolve early after presentation and before PCI are excluded if the documentation is adequate to ascertain that the PCI was not part of a primary reperfusion strategy. These exclusions are intended to enhance the degree to which the measure denominator includes only those patients for whom PCI is the primary reperfusion strategy. However, the construction of a data element suitable for abstraction that accounts for the variation in terminology that might be used in clinical documentation to describe these situations and that simultaneously limits the inappropriate exclusion of patients who receive primary PCI has been challenging.

4.2.1. Measures Exclusions: Work Group Conclusions

1. An additional measure that includes patients who are transferred from one hospital to another for the purposes of receiving reperfusion should be developed and implemented (see below).
2. An exclusion that accounts for patient-centered reasons for delaying reperfusion therapy is clinically necessary; however, surveillance to assess the extent to which this exclusion is used (and potentially overused) will be important to determine the impact of this exclusion on patient care and whether this exclusion is practical to maintain. Specifically, this surveillance should include the frequency distribution of the application of this exclusion among centers to identify outliers. There should also be an audit mechanism to determine the clinical appropriateness of delays among records in which this exclusion was applied; this audit process should be transparent and should include components that are systematic (eg, among all outliers) and random. Finally, a means of adjudicating audit failures is a necessary component of an audit process.
3. The exclusion of patients who receive PCI that is not part of a primary reperfusion strategy is also appropriate; however, an audit process to assess the extent of the use of this exclusion would also be appropriate.
4. The intensity of audit efforts (items 2 and 3 above) will depend on the purpose of the measure, with effective audit processes dedicated to measures used for the purposes of public accountability and/or reimbursement. An audit process may be unnecessary for measures used solely for the purposes of quality improvement.

5. As times to reperfusion decline nationally, the assessment of patient-centered reasons for delay should be considered for all records rather than the current restriction to those cases for which reperfusion is provided outside of the standard guideline-recommended time window. Given current rates of performance, and acknowledging the abstraction burden that this change would represent, the work group does not currently endorse this change.

4.3. Time of Device Use for PCI

The determination of the time of PCI (ie, when measurement stops) is central to the reperfusion measure. The commonly used term “door-to-balloon time” has decreasing clinical relevance with the proliferation of additional devices used to establish reperfusion for STEMI (eg, stents and thrombectomy devices). The current measure specifications, which acknowledge this growing complexity, consider the first use of any device primarily intended to result in reperfusion as the “balloon” time. Several aspects of this approach to the measures should be considered.

First, with respect to identifying the time at which measurement both starts and stops, various sources of clock time may be used, including ECG machines, emergency department documentation, and catheterization laboratory logs. The lack of synchronization of the clocks integral to establishing time landmarks for the reperfusion measures will result in the misclassification of the time to reperfusion due to errors in the accurate identification of the start time, end time, or both. Ultimately, accurate system-wide timekeeping has important implications not only for measures of the time to reperfusion for STEMI but also for other measures of performance (eg, timing of antibiotics for pneumonia) and other important aspects of patient care. Thus, synchronization of timekeeping devices to an external standard is an important goal for health systems.

Second, although the measure accounts for evolving technology, it does not identify the time at which reperfusion is established. For example, in cases in which the angiogram initially demonstrates normal or near-normal flow in the infarct-related artery or in which a wire, guiding catheter, or contrast injection reestablishes flow, the current measure specification mandates that the time of angiography or wire insertion is not considered the time of treatment. Conversely, however, the measure does not require that the first attempt at reperfusion be successful to count toward the time of PCI. Thus, the current measure should be considered a measure of a process (ie, delivering a device intended to result in reperfusion) rather than an outcome (ie, normal coronary flow).

There are specific advantages of using the process of device use over the outcome of successful reperfusion. First, the approach is consistent with the underlying guideline recommendation that the “door-to-balloon” time in patients with STEMI should be less than 90 minutes. Second, whereas the time of device use is a factor that can usually be identified by nonclinical abstractors, the ascertainment of adequate flow in the infarct-related artery raises substantial concerns regarding abstraction burden and reliability. Finally, it does not generate a penalty in those situations in which flow cannot be restored despite appropriate and timely treatment.

On the other hand, the use of device time has disadvantages as well. First, because the goal of primary PCI is to restore flow in the infarct-related artery, there is face validity to the measurement of this time. Second, in cases in which adequate flow is present spontaneously or results from the use of a wire, the operator may use more time in the consideration of the approach to device therapy without significant adverse consequences for the patient.

Alternative approaches were also considered, including measurement of door-to-catheterization laboratory time or door-to-first angiogram time. The advantages of these approaches are that the times are typically easier to determine from the medical record, the need to ascertain reasons for delay after angiography is obviated, and these constructions render the discussion about device use versus flow restoration moot. However, these approaches do not account for the importance of care provided within the catheterization laboratory and are not consistent with guideline recommendations, which focus on the total time from presentation to PCI.

4.3.1. Time of Device Use for PCI: Work Group Conclusions

1. Systems that provide reperfusion therapy should synchronize all devices (eg, ECG machines and electronic catheterization laboratory documentation systems) involved in establishing time landmarks in the reperfusion measures to a consistent external standard (eg, satellite synchronization with atomic clocks).
2. After consideration of the relative benefits and limitations of the various approaches, the work group supports a measure that focuses on the time of first device use rather than the time of restoration of flow or the time of other "upstream" events (eg, time to first angiography).

5. Proposals for Future Measures of Time to Reperfusion

As discussed above, the existing measures focus on the time to reperfusion among treated patients without specific documented exclusions; however, these measures do not address other important aspects of the delivery of reperfusion therapy. Ultimately, the family of measures that focus on reperfusion should be aligned with guidelines, which both recommend strategies of care and emphasize the importance of time in implementing these strategies. These measures should also be comprehensive, addressing decision making about the delivery of reperfusion in potential candidates for therapy and including as many eligible patients as possible in measurement. To expand the extent to which measurement provides a comprehensive assessment of the approach to therapy, the work group proposed recommendations for the development of 3 additional measures. These recommendations will be provided for consideration to the ACC/AHA Performance Measures Task Force, which has developed process performance measures for the care of patients with acute myocardial infarction.¹⁰

5.1. Time to Reperfusion Among Patients Transferred for PCI

The current CMS and Joint Commission reperfusion performance measures exclude patients who are received in transfer

from other acute care institutions. As a result, care provided by those hospitals that routinely transfer patients with STEMI for primary PCI is not included in the measures of time to PCI. However, the time to PCI is equally important in patients who are transferred from one institution to another, and the process of transfer has the potential to prolong the time to PCI. In the current era, total door-to-balloon time for these transferred patients is less than 2 hours in a little more than a quarter of patients, between 2 and 4 hours in a little more than half of patients, and 4 hours or greater in about 20% of patients.¹⁹ There are many ways to improve these times. In hospitals that do not have PCI facilities, it is important to know the expected time to primary PCI if they transfer the patient in order to make the best treatment decisions for those who are eligible for fibrinolytic therapy. Moreover, knowledge of these times is critically important to the development of strategies to eliminate delays. In settings where geographic barriers make it difficult to transfer patients quickly, it is still important to know what times are being achieved as a means to assess decision-making and to focus on whether there are any opportunities to reduce any unnecessary wait times. It is difficult to identify a precise time beyond which there is an unacceptable delay, but knowledge of the times is central to improving the systems of transfer. The intent of such a measure is to illuminate performance from the patient's perspective. Because of the value of understanding the care for patients who are transferred for this time-sensitive therapy, the work group recommends that such patients be included in additional measures. This should include measures of (1) time from presentation to discharge in the presenting institution ("door-in/door-out") and (2) time from presentation at the first facility to time of PCI in the receiving facility ("first-door-to-PCI"). This recommendation is made with acknowledgment of the following considerations in development and implementation:

1. Historically, patients who were transferred were excluded because of the difficulty in ascertaining the time of presentation at one institution and the time of PCI in another. Specific approaches to addressing this barrier should be considered. Of note, this issue is not relevant to a "door-in/door-out" measure.
2. Issues of identifying the provider responsible for the results (ie, attribution) and reporting should be addressed during measure development. It should be specified whether performance on this measure should be attributed to the transferring institution, the receiving institution, or both institutions. Additionally, if attributable to the receiving institution in whole or in part, it should be specified whether patients received in transfer should be reported separately. The present writing group advocates attribution to both facilities.
3. The times to PCI for patients who are transferred for reperfusion should be reported separately from times for those who are not transferred.
4. In cases in which a patient has a contraindication to reperfusion therapy, the clinician does not have the option of considering fibrinolysis rather than transfer, even if the transfer will be delayed. Thus, reporting of the time to PCI in patients who are transferred should be stratified by the presence or absence of contraindications to fibrinolytic therapy.

5.2. Proportion of Reperfusion-Eligible Patients Receiving Therapy

Measuring the time to reperfusion among patients who receive this therapy does not address the decision to provide reperfusion therapy among eligible patients. Recent data suggest that although the proportion of eligible patients receiving therapy has increased significantly over time, gaps in this process of care persist.²⁰ The work group thus proposed the development of a measure that would quantify the proportion of those patients who are eligible for therapy. This recommendation is made with acknowledgment of the following barriers to development and implementation:

1. The element defining the ECG criteria for inclusion in the denominator of this measure must be more explicit than that used for the current measures and must conform more exactly to the ECG criteria requirements specified by the guidelines. Because the existing measure specifically includes those patients who receive some form of reperfusion therapy, failures in the specificity of the ECG element have limited impact on measurement. However, a measure that is intended to identify patients who should have received therapy places greater emphasis on the specificity of the criteria used to identify the denominator. The current measures require relatively general mention of ST-segment elevation or ECG evidence of myocardial injury, whereas a measure identifying reperfusion-eligible patients would require the identification of ST elevation greater than 0.1 mV in at least 2 contiguous precordial leads or at least 2 adjacent limb leads, as recommended in the guidelines.²¹ The need for this greater detail must be balanced with the greater burden of abstraction and feasibility of abstraction at this level of detail by nonclinical staff.
2. Contraindications that would disqualify patients from these measures must be considered, particularly for fibrinolytic therapy, for which the adverse consequences of treatment in patients with contraindications are substantial. This includes consideration of whether a discrete list of absolute contraindications should be developed rather than relying solely on the explicit documentation of a contraindication to therapy.
3. The impact of more specific ECG criteria (point 1 above) and contraindication definitions (point 2 above) on the institution-level sample size must be assessed during measure testing. By reducing the numbers of patients included in the measure, these factors may limit applicability, especially to relatively low-volume centers.
4. Concurrent assessment of the provision of fibrinolysis or coronary angiography in patients not meeting guideline criteria for reperfusion (“overuse” and “false-positives”) could inform internal institutional quality improvement. The writing group acknowledges the challenges of identifying such cases reliably from retrospective abstraction of clinical data.

5.3. Time From First Medical System Contact to Reperfusion

Beginning in 2004, the ACC/AHA STEMI guideline recommendations for both fibrinolysis and primary PCI recommend that patients receive therapy within a limited time from first medical system contact rather than from the time of presentation at an acute care facility.^{1,22} However, the current time-to-reperfusion measures reported by CMS and the Joint

Commission and those endorsed by the ACC/AHA use the time of hospital presentation as the “start time.” The time of hospital presentation at a healthcare institution has been used as the index time for several reasons. Practically, systematic approaches to collecting data on the time of first system contact have not been assessed or validated, whereas the time of presentation at an institution is routinely available in records. Furthermore, the appropriate definition of first medical system contact (eg, emergency medical services system activation versus time of first in-field ECG) is a topic of substantial debate. The use of time of presentation, the standard that has been used in previous measures, also provides consistency across time. Finally, issues of accountability with the time of first system contact are substantially more complicated than those surrounding the current reperfusion measures. Specifically, because current public reporting efforts focus on institutions rather than systems, measures that include the time from first system contact could potentially penalize institutions for issues beyond their control.

The work group acknowledges, however, that the goal of evolution toward measuring the time of first system contact to reperfusion is appropriate for several reasons. First, with evolving health information technology, determining the time of first system contact is likely to become easier and more consistent. Second, the measures should remain consistent with guidelines whenever possible, presuming that practical barriers can be overcome. Finally, as systems of care to provide reperfusion proliferate,^{23,24} an understanding of the performance of these systems becomes increasingly important. Measuring the performance of systems is likely to foster the collaboration among multiple systems, including emergency medical services, that is necessary to ensure optimal quality of care.

Although the work group agrees that performance measurement should migrate toward an approach of using the time of first system contact, it currently advocates the development of such measurement for quality-improvement purposes rather than for public reporting, with an explicit goal of addressing the issues described above as part of the implementation process. Such implementation testing would lay the foundation for the use of measures of time from first system contact to reperfusion as measures for the purposes of public accountability.

5.4. Time to Reperfusion for Patients Developing STEMI in the Hospital

The current CMS and Joint Commission reperfusion measures exclude those patients without ST-segment elevation or left bundle-branch block on the ECG closest to the time of arrival. Thus, those patients with STEMI who develop pathological ECG abnormalities after presentation with an ECG that does not show ST-segment elevation or left bundle-branch block either in the emergency department or initially at admission do not contribute to the measurement. Given that the institutional capacity to address the care of such patients in a timely manner may vary based on the manner of presentation, understanding the care of this patient population would be valuable for the purposes of quality improvement. This recommendation is made with the acknowledgment that measurement in this population

requires further testing before it can be recommended for incorporation in external reporting.

The appeal of restricting the reperfusion measures to those patients with STEMI on emergency department presentation lies in the ease of identifying the “start time” from the perspective of the system (ie, time of hospital arrival). The measure should include explicit recommendations regarding the means of identifying the measure start time, with acknowledgment of the possibility of inaccuracies of ECG time stamps among institutions and the potential challenges of ascertaining event timing from progress notes and other types of documentation.

6. Future Considerations for Measuring Time to Reperfusion: Electronic Health Records and Clinical Registries

Ultimately, many of the central challenges in measuring the time to reperfusion and the barriers to expanding measurement to broader populations derive from the difficulty in obtaining the underlying data from chart abstraction of markedly variable sources of information. Advances that successfully reduce the burden and increase the accuracy of data abstraction thus have the capacity to revolutionize the measurement of clinical performance around the time to reperfusion.

Electronic health records (EHRs) provide a platform for automated data collection, with the potential to reduce abstraction time and increase the fidelity of data abstraction. A recent study, however, moderates any enthusiasm that EHRs represent a panacea to the challenges of the problems of measuring quality of care.²⁵ The study assessed the quality of outpatient heart failure care and found that an EHR had limited sensitivity for clinically important contraindications to therapy, which resulted in important underestimates of clinical performance. This finding emphasizes the importance of considering performance measurement in the development of EHRs, with an emphasis on data standardization and the inclusion of specific data elements that underlie the assessment of clinical performance.

Finally, clinical data registries and quality-improvement initiatives (eg, NCDR and Get With the Guidelines) have the potential to facilitate assessment of the quality of care. Beyond the importance of data standardization, 2 additional issues are specifically germane to registries. First, the extent to which registries are adopted will depend in large part on the integration of the registry within clinical care in real time. Duplicative data entry raises barriers to participation and may diminish the accuracy of the data collected, which may be compounded if data entry in different sources is performed by different personnel. Second, the specifications developed for clinical registries and quality-improvement initiatives should maintain alignment with existing measures whenever possible, particularly those already in use for public reporting. Failure of alignment creates confusion regarding the specifications of the measures and “measurement fatigue.”

National clinical data registries and quality-improvement initiatives also create important opportunities for improving performance measurement. First, these efforts can be used to pilot test measures before widespread implementation, which would facilitate the identification of specific barriers to implementation and the refinement of data-element definitions. Second, as with EHRs, registries can be used to collect specific encoded clinical data elements, which enhances the clinical validity of performance measures and decreases the burden of ascertaining the data necessary to calculate performance.

Thus, EHRs and clinical registries have important potential for transforming performance measurement. In the future, the widespread implementation of these innovations has the potential to generate a more accurate and broader understanding of the delivery of life-saving therapy in practice and to facilitate the provision of the right treatment for the right patient in a timely manner.

7. Conclusions

Because of the substantial impact of acute reperfusion on outcomes after STEMI and an understanding of the significant room for improvement, increasing attention has been focused on the measurement of care for patients receiving this critical therapy. Over the last decade and a half, national quality assessment and public reporting efforts have measured the time to reperfusion for fibrinolysis and PCI using metrics that have evolved over time. The work group, the deliberations of which are summarized here, reviewed the existing measures with recommendations for modifications to optimize the performance and acceptance of these measures. Furthermore, this group provided recommendations for expanding the scope of the measurement of the process of reperfusion therapy. These recommendations are provided with the recognition that any measure, new or old, will not perform perfectly when implemented. Despite any limitations, however, formal assessment of the process of delivering reperfusion is necessary to understand what must be done to achieve the common goal of optimizing patient outcomes.

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Appendix A. Inclusion and Exclusion Criteria for CMS and the Joint Commission Reperfusion Measures (Effective 10/1/08–3/31/09 Discharges)

Table A1. Inclusion Criteria for CMS and the Joint Commission Reperfusion Measures

PCI
ICD-9-CM principal diagnosis code of AMI and
ICD-9-CM procedure code of PCI and
ST-segment elevation or LBBB on ECG performed closest to arrival* and
PCI performed within 24 hours of arrival
Fibrinolysis
ICD-9-CM principal diagnosis code of AMI and
ST-segment elevation or LBBB on ECG performed closest to arrival* and
Fibrinolytic therapy performed within 6 hours of arrival and
Fibrinolysis is the primary reperfusion therapy

AMI indicates acute myocardial infarction; CMS, Centers for Medicare & Medicaid Services; ECG, electrocardiogram; ICD-9-CM, International Classification of Diseases 9th Revision Clinical Modification; LBBB, left bundle-branch block; and PCI, percutaneous coronary intervention.

*Per the CMS and the Joint Commission data-element definitions.

Table A2. Exclusion Criteria for CMS and the Joint Commission Reperfusion Measures

PCI
Patients less than 18 years of age
Patients who have a length of stay greater than 120 days
Patients with comfort measures only documented on day of or day after arrival
Patients enrolled in clinical trials
Patients received as a transfer from an acute care facility where they were an inpatient or outpatient
Patients received as a transfer from one distinct unit of the hospital to another distinct unit of the same hospital
Patients received as a transfer from the emergency department of another hospital
Patients administered a fibrinolytic agent before PCI
PCI described as nonprimary by a physician/APN/PA
Patients who did not receive PCI within 90 minutes and had a reason for delay documented by a physician/APN/PA (eg, social, religious, initial concern or refusal, cardiopulmonary arrest)
Fibrinolysis
Patients less than 18 years of age
Patients who have a length of stay greater than 120 days
Patients with comfort measures only documented on day of or day after arrival
Patients enrolled in clinical trials
Patients received as a transfer from an acute care facility where they were an inpatient or outpatient
Patients received as a transfer from one distinct unit of the hospital to another distinct unit of the same hospital
Patients received as a transfer from the emergency department of another hospital
Patients who did not receive fibrinolytic therapy within 30 minutes and had a reason for delay documented by a physician/APN/PA (eg, social, religious, initial concern or refusal, cardiopulmonary arrest)

APN indicates advanced practice nurse; PA, physician assistant; and PCI, percutaneous coronary intervention.

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Appendix B. Author Relationships With Industry and Other Entities

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Ralph G. Brindis	None	None	None	None	None	None
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(Continued)

Appendix B. Continued

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Glenn N. Levine	Official Reviewer-AHA Content	The Medicines Co.	BMS	None	None	None	None
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Mazen Abu-Fadel	Reviewer-ACCF Cath Committee	None	None	None	None	None	None
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John Webb	Reviewer-ACCF Cath Committee	None	None	None	None	None	None
Morton Kern	Reviewer-ACCF PCI Guideline	Merit Medical	Radi Volcano	None	None	None	None

(Continued)

Appendix C. Continued

Name	Representation	Consultant	Speakers' Bureau	Research Grant	Expert Witness	Ownership/Equity Interest	Institutional, Organizational, or Other Financial Benefit
Elliott M. Antman	Content Reviewer—ACCF STEMI Guideline	sanofi-aventis Momena Pharmaceuticals, Inc	Dr Antman is a senior investigator in the TIMI Study Group, which received grants from the following sources: Accumetrics, Amgen, AstraZeneca Pharmaceuticals, Bayer Healthcare, Beckman Coulter, Biosite, Bristol-Myers Squibb Pharmaceutical Research Institute, CV Therapeutics, Eli Lilly and Company – PI,* GlaxoSmithKline, Inotek Pharmaceuticals Corp, Integrated Therapeutics Corp, Merck & Co, Millennium Pharmaceuticals, Novartis Pharmaceuticals Corp, Nuvelo, Ortho-Clinical Diagnostics, Pfizer, Roche Diagnostics Corp, Roche Diagnostics GmbH, sanofi-aventis – PI,* Sanofi-Synthelabo Recherche, Schering-Plough Research Institute, the National Institutes of Health	None	None	None	sanofi-aventis Eli Lilly and Company
Paul W. Armstrong	Content Reviewer—ACCF STEMI Guideline	Hoffman-La Roche* sanofi-aventis* TargeGen	None	Hoffman-La Roche* Boehringer Ingelheim* sanofi-aventis* Portola*	None	None	None
Eric R. Bates	Content Reviewer—ACCF STEMI Guideline	Hoffman-La Roche	None	None	None	None	None
Mary M. Hand	Content Reviewer—ACCF STEMI Guideline	None	None	None	None	None	None
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ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; BMS, Bristol-Myers Squibb; Cath, catheterization; MI, myocardial infarction; NC, North Carolina; PCI, percutaneous coronary intervention; PI, principal investigator; STEMI, ST-elevation myocardial infarction; and TIMI, Thrombolysis In Myocardial Infarction.

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Disclosures

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