Challenges and Opportunities in Quantifying the Quality of Care for Acute Myocardial Infarction

Summary From the Acute Myocardial Infarction Working Group of the American Heart Association/American College of Cardiology First Scientific Forum on Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke

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I. Background

Acute myocardial infarction (AMI) is a catastrophic manifestation of coronary artery disease that strikes more than 900,000 Americans each year. One fourth of afflicted patients die, and many survivors develop impaired functional status, anginal symptoms, and diminished quality of life. Fortunately, an explosion in scientific discovery and clinical research has created great potential for treating patients, and concurrent with these advances, there has been a marked decrease in AMI mortality. Yet the full benefit of scientific progress is often unrealized by patients because of the gap between knowledge and its application to clinical care.

To address this gap, the AMI Working Group of the first American Heart Association (AHA)/American College of Cardiology (ACC) Scientific Forum on Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke brought together national leaders and committed practitioners to share knowledge and insights on measuring and improving the quality of AMI care (see Acknowledgments for Working Group members). This group sought to create a comprehensive framework for quantifying the components of AMI care and to summarize current methodological considerations in quality assessment/improvement while formulating a research agenda to address unmet needs in the field. The present report supplements the overall insights gained from the conference with data specifically relevant to the quantification of care for AMI patients. Although new evidence may alter the relevance of specific measures, it is hoped that the principles described in this report will assist local and national organizations in their efforts to improve the quality of care for patients with AMI.

II. Conceptualizing Quality in the Treatment of AMI

As a means of conceptualizing the components of quality assessment, the Working Group on AMI embraced the approach of Donabedian, which considers 3 domains of quality: structure, process, and outcome. Structure refers to those aspects of care that exist independently of the patient. Examples include provider training and experience, availability of specialized treatments, nurse-to-patient ratios, treatment and discharge plans, and procedures to facilitate the rapid triage of AMI patients in the emergency department. Process refers to those actions performed in delivering care to patients and includes such concepts as the medications given and timing of their administration, the use of diagnostic and therapeutic procedures, and patient counseling. Outcomes are the events that occur as a result of the disease process and/or care provided. Examples include further progression of the disease (mortality, infarct extension, development of congestive heart failure, treatment complications), health status (subsequent functioning, symptoms, and quality of life), costs, and patient satisfaction (Figure).
III. Principles for the Selection of Quality Performance Measures

Performance measures are the discrete parameters for structure, process, or outcome, the attainment of which defines good quality care. Although new knowledge will necessitate changing specific measures over time, certain principles can facilitate the evaluation of proposed performance measures. Important attributes for performance measurements include:

1. The performance measure must be meaningful. Any potential performance measure must either be a meaningful outcome to patients or have a close linkage to such an outcome.

2. The measure must be valid and reliable. To successfully quantify healthcare quality, it must be possible to reliably and accurately measure the structure, process, or outcome of interest.

3. The measure can account for patient variability. Although more relevant to process and outcome measures, it is important that the results of potential performance measures may be adjusted so that differences observed among providers are attributable to the care provided rather than to the patients treated.

4. The measure can be modified by improvements in the healthcare system. To be useful for facilitating change, performance measures must be amenable to improvement by motivated providers. This requires that the potential measure have variability (ie, some systems do well when judged by the measure, and others do not) and that evidence supports the feasibility of institutions or practitioners improving their performance over time.

5. The measure is feasible. Quantifying healthcare quality can be complex and costly. Proposed performance measures should be sensitive to the logistical and fiscal implications of assessing quality.

The present report reviews the current state of the art in quality assessment/improvement and identifies future research priorities for measuring the quality of care in patients with AMI.

IV. Quantifying the Structure of Care

A. Overview

Structural aspects of AMI care include the systems responsible for the provision of care, the material resources on which those systems depend, and the organizational structures that guide the interaction of both. Patient-care systems include prehospitalization, emergency department, inpatient, discharge planning, and outpatient care. Material resources refer to the personnel (their number, training, and competence) and equipment available for patient treatment, whereas organizational systems encompass an institution’s policies and procedures, reminder systems, disease management programs, and quality measurement/improvement infrastructure. These structural aspects of medical care are important determinants of quality, and quantifying them can facilitate quality assessment. In fact, poor outcomes or processes of care imply flawed systems/structures of care, and conversely, efforts to improve process and outcome often lead to improvements in structure. This section describes methodological considerations for designing structural measures of healthcare quality and provides several current examples within different phases of myocardial infarction (MI) care.

B. Methodological Considerations

Several unique methodological considerations are warranted when applying the previously described selection principles to structural performance measures. First, the “outcome” of a structural measure may be improved adherence with process measures. For example, an effective system for rapidly triaging patients with chest pain in the emergency room may translate into shortened door-to-needle or door-to-balloon times as emergent reperfusion is provided.

A second consideration in evaluating structural measures is that the relevant outcome of interest, eg, survival or alleviation of symptoms, may be sufficiently downstream from the structural component of care that a link to meaningful outcomes may be technically difficult to establish. In this case, surrogate outcomes may be relied upon to establish the first criterion of performance measurement outlined above. For example, an effective discharge-planning program may successfully alter patient behavior such that a low-fat diet or smoking cessation is attained in a high percentage of patients, yet no significant impact on mortality may be observed. Despite the absence of a clear link to such a meaningful patient outcome, the structural performance measure may still be considered valuable in assessing and improving quality. Although careful deliberation is needed to endorse such structural performance measures, the attempt to quantify structural aspects of care should not be avoided simply because more direct linkages to outcome are not available. In fact, structural measures may have their greatest utility when attributable outcomes are unavailable because of small sample sizes that preclude the separation of observed outcomes from random variation. For example, a small, rural hospital with a rapid triage system that recognizes and transfers AMI patients presenting with cardiogenic shock for tertiary care may treat too few patients to appreciate a survival advantage when compared with similar hospitals that fail to have such an efficient system.

Finally, the AMI Working Group acknowledges that structural elements that ensure that the “average” patient is well treated may not adequately quantify the ability of a system to handle a unique or particularly ill patient. For example, a community hospital that implements a process for successfully administering aspirin to all AMI patients but does not have a plan to effectively care for, or transfer, a patient presenting with a ruptured papillary muscle may rarely have the opportunity for this structural omission to be identified.
To overcome these and other limitations in our present ability to evaluate structural components of care, the AMI Working Group recommended that additional research be directed in this area. Given the absence of clear recommendations in the guidelines for structural measures of quality and the absence of sufficient research on the development of structural measures for quantifying quality, the committee sought to review the literature and suggest several potential structural measures of quality that could serve as a starting point for future research.

C. Potential Structural Performance Measures

(1) Prehospital Care
Organized emergency medical response systems are critical to AMI care. Enhanced 9-1-1 systems can facilitate prompt medical responses, and trained emergency medical services personnel with defibrillators can improve survival for patients with prehospital cardiac arrest. Quality improvement activities have also been successful at the community level. A recent program to improve the quality of emergency medical service systems in Ontario was associated with reduced response times, improved survival rates, and low annual cost per life saved among patients suffering out-of-hospital cardiac arrest. Additionally, access to early 12-lead electrocardiograms can increase the sensitivity for diagnosing an AMI and alert emergency rooms to prepare for acute reperfusion when indicated. Quantifying the availability and success of such services is needed, but the explicit specification of such measures awaits further research and clarification.

(2) Emergency Department Care
Both the AHA/ACC guidelines and the National Heart Attack Alert Program recommend the development of emergency department protocols to promote the rapid identification and treatment of AMI patients. For example, computerized predictive instruments that provide real-time feedback to clinicians can reduce delays in the administration of thrombolytic therapy, although the effect on outcome is less clear. The potential for minimizing the door-to-needle time by accelerating or avoiding consultations between emergency physicians and other caregivers before the administration of therapy has also been documented. Additionally, protocols for identifying low-risk patients can allow for safe triage to lower-intensity care settings, and the development of specialized chest pain observation units has been associated with fewer hospital days and reduced costs.

(3) Hospital Management
Many AMI patients fail to receive appropriate treatments such as aspirin or β-blockers, whereas other patients receive no objective measures of their left ventricular function. Such errors of omission can be reduced by the use of reminder systems, and structured order forms and checklists have also been shown to improve drug prescribing and the delivery of preventive services. The use of computer order-entry systems can reduce medication errors and comprehensive discharge planning can reduce costs and readmissions for high-risk patients. "Critical pathways" have the potential to improve care, but effectiveness data confirming their value is lacking.

Furthermore, the characteristics of physicians and nurses can impact the quality of AMI care. On average, cardiologists demonstrate better knowledge of appropriate AMI care and have better patient outcomes than do generalist physicians. There is, however, substantial overlap in the abilities of generalist and specialist physicians, and existing studies are not sufficient to support a policy requiring that all AMI patients be treated by cardiologists.

The availability of specialized resources such as intra-aortic balloon counterpulsation and interventional cardiology may improve outcomes in particularly high-risk patient groups. A growing body of literature supports a volume-outcome relationship for optimal care, at the levels of both individual practitioners and institutions. As further evidence clarifies these relationships, the number of AMI cases treated, at both the provider and institutional levels, may evolve into structural performance measures. The implications of this development, especially for rural regions where the closest hospital may not be a high-volume hospital, will, however, need to be better understood.

(4) Discharge Planning
Comprehensive discharge planning, referral to cardiac rehabilitation, and patient education are all structural characteristics for which performance measures should be developed. One such program for patients recovering from an AMI was associated with improvements in exercise capacity and reductions in coronary risk factors. Nevertheless, the effectiveness of many case or disease management programs has yet to be tested. At present, no such structural measures have been formally tested with regard to all of the criteria suggested above, but evolving research may better clarify how best to quantify these aspects of care.

(5) Outpatient Care
Establishing effective communication between the inpatient and outpatient settings is essential. AMI may be the initial manifestation of coronary disease for patients and will trigger a range of secondary prevention treatments as outlined in recent guidelines. A mechanism for quantifying the success of transferring care between the inpatient and outpatient settings is an important opportunity for improving subsequent outcomes for which the locus of control is in the hands of the providers and institution providing AMI care. Further research to develop such a performance measure is sorely needed.

(6) Additional Considerations
Although much work is needed to define the performance measures for quantifying the structure of AMI care, the AMI Working Group was unanimous that an institutional commitment to measuring and improving AMI performance was certain to be one such measure. Without a commitment to understanding present performance, no opportunity for improvement is possible. Creating a system to track and improve performance over time as part of Quality Assessment/Quality Improvement (QA/QI) is essential. Recent qualitative work demonstrates that the hospitals that have been most successful in improving performance have clearly stated goals for their efforts, administrative support, clinician sup-
D. Past and Future Uses of Structural Performance Measures

To date, there has been little experience with developing valid, reliable measures of the systems and structures of care relevant to the treatment of AMI. The hospital accreditation surveys conducted by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) comprise the most well-known effort. This survey examines several hospital departments relevant to AMI care, including the cardiac catheterization unit; the cardiovascular, medical, and surgical intensive care units; the emergency, nursing, and pharmacy departments; and the step-down cardiology unit. Within each department, these surveys examine various functional domains, including patient assessment and treatment, discharge planning, managerial organization, and quality improvement. The review criteria used in these surveys are generic and generally have not been linked to improvements in specific aspects of AMI care.

Because of the limited attention given to quantifying the structure of AMI care, there are substantial variations between hospitals in the structure and systems used. Although the absence of valid, reliable measurement tools limits the utility of structural measures for accreditation or external reporting, examination of structure can be a critical aspect of quality improvement activities. Future research is needed to define performance measures for structural aspects of care in the setting of AMI treatment. Although current national efforts, including the Performance Measurement Coordinating Council (a joint effort of JCAHO, the National Committee for Quality Assurance, and the American Medical Association) and the ACC/AHA Joint Task Force on Performance Measures, have not addressed structural performance measures, it is hoped and anticipated that such measures will be adopted and implemented in the future.

V. Quantifying the Process of Care

A. Background

In contrast to the preliminary state of affairs in quantifying the structure of AMI care, measuring, reporting, and improving the process of care are well established. Several features of process measurement led to its growing use and importance. First, process measures are the most direct application of clinical trials and the guidelines that interpret these trials. Second, process measures are often readily quantifiable actions that occur in sufficient numbers—at least at larger centers—such that robust estimates of performance are statistically attainable. Finally, process measures are under the direct control (and accountability) of the practitioner and institution providing care.

There is substantial evidence that currently available process measurements can improve and can be associated with improved patient outcomes, and that “America’s best” hospitals perform these measures more often than other institutions. Despite the potential for process measures to be valuable tools in quantifying and improving quality, some hospitals with relatively poor apparent adherence will have excellent outcomes, whereas others with excellent compliance will have poor outcomes. Although the AMI Working Group acknowledged these limitations, it felt that minimizing variations in the process of healthcare delivery, where clear evidence defines a link between established performance measures and meaningful patient outcomes, could substantially improve the quality of AMI care.

B. Methodological Considerations

As noted in Section III (Principles for the Selection of Quality Performance Measures), strong evidence of a clinically meaningful benefit is essential to the choice of process measures, which usually requires unequivocal results from randomized, controlled trials. In addition, support of a quality measure by effectiveness data addressing the generalizability beyond the population studied in randomized, controlled trials is needed. Such data are particularly relevant for the elderly, a group that is chronically underrepresented in randomized controlled trials. Agencies that create and endorse performance measures generally begin with the guidelines developed by themselves or by other, national specialty societies. For example, the practice of the ACC/AHA Task Force on Performance Measures is to have writing groups use the ACC/AHA Clinical Guidelines as a basis for selecting potential processes to measure.

The next steps in performance measurement development are to define the population of interest, the duration of time during which care for a patient will be assessed, and operationalizing the definition of each measure. Specification of data items is challenging. Data specification must not only reflect the range and type of data available and the data elements needed to capture application of the performance measure (ie, specifying the numerator), but they must also define those scenarios in which the performance measure was appropriately not applied (ie, restricting the denominator). After potential measures are created, field-testing for feasibility is needed. Finally, given that the importance of different measures varies by their intended use, a process of selection and final approval by the entity developing the performance measures is needed. In the example of the ACC/AHA Performance Measures, external review by practicing cardiologists and other specialty groups is elicited, and then final approval by the ACC’s Board of Governors and the AHA’s Scientific Advisory and Coordinating Committee is obtained before endorsement.

Once measures are constructed, their appropriate application must also be addressed. For example, when one intends to use a process measure to compare the performance of different providers (eg, individual practitioners or hospitals) or groups of providers (eg, hospitals or regions of hospitals), a sufficiently large number of potential candidates for the process measure must be available so that statistically meaningful comparisons can be performed. Thus, statewide comparisons are likely to be more meaningful than comparisons at the hospital or provider level.
TABLE 1. Current Process-of-Care Quality Performance Measures for AMI*

<table>
<thead>
<tr>
<th>Quality Performance Measure</th>
<th>Evidence for Process–Outcome Link†</th>
<th>Measurement Reliability and Validity</th>
<th>Measurement Burden</th>
<th>Estimated Compliance‡</th>
<th>Barriers to Change; Change Achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timely reperfusion</td>
<td>A</td>
<td>Good</td>
<td>Moderately high</td>
<td>30% within 30 minutes</td>
<td>High, but have been successfully addressed</td>
</tr>
<tr>
<td>Early aspirin administration</td>
<td>A</td>
<td>Good</td>
<td>Moderate</td>
<td>85%</td>
<td>Low to moderate; change achieved</td>
</tr>
<tr>
<td>Early β-blocker administration</td>
<td>A</td>
<td>Good</td>
<td>Moderate</td>
<td>69%</td>
<td>Moderately high; change achieved</td>
</tr>
<tr>
<td>Smoking cessation counseling</td>
<td>C (for outcome of smoking cessation)</td>
<td>Probably adequate</td>
<td>Moderate</td>
<td>43%</td>
<td>Moderate; change achieved</td>
</tr>
<tr>
<td>ACE inhibitor for depressed left ventricular ejection fraction</td>
<td>B</td>
<td>Good</td>
<td>Moderate</td>
<td>74%</td>
<td>Moderate; change achieved</td>
</tr>
<tr>
<td>β-Blocker at discharge</td>
<td>A</td>
<td>Good</td>
<td>Moderate</td>
<td>79%</td>
<td>Moderate to high; change achieved</td>
</tr>
<tr>
<td>Aspirin at discharge</td>
<td>A</td>
<td>Good</td>
<td>Moderate</td>
<td>86%</td>
<td>Low; change achieved</td>
</tr>
</tbody>
</table>

*These measures have not been officially endorsed by the AHA or ACC.
†A indicates randomized controlled trials plus effectiveness evidence beyond RCT populations; B, randomized controlled trials without effectiveness evidence; C, other evidence supporting process of care; and D, guideline recommendation only.
‡Data for estimated compliance from reference 53.

At the hospital level, it is important to have clarity about the purpose of performance measurement. Although publicly reported comparisons may not be appropriate (because of limited numbers of cases limiting the accuracy of estimated rates, the quality/accuracy of chart abstraction, etc), benchmarking internal performance against achievable benchmarks of care offers a unique opportunity to identify areas for improvement.50 Furthermore, the greater the frequency with which a performance measure can be applied, the greater the opportunity to perform rapid cycle efforts to improve performance. The minimum proportion of AMI cases to be eligible for a given care process so as to effectively conduct performance measurement/improvement has not yet been determined. The Working Group estimated that the minimal number of eligible cases is likely to be between 10% and 20%, according to the intended purpose for quantifying performance.

Several important considerations are relevant with regard to the acquisition of data for performance measurement. Clinical information contained within administrative data sets (eg, billing data) is not, in general, sufficiently rich to allow valid conclusions about the quality process to be drawn. This is likely to change dramatically over time as the use of electronic medical records increases. Currently, for inpatient processes of care such as AMI, the medical record must be reviewed to determine the appropriateness of a given process measure for a given patient (ie, important contraindications for the therapy were not present) and whether the process of care was applied. Structured medical record review can be carried out internally (by the institution where the medical record resides) or externally (by an entity specially commissioned to undertake such review). For internal review the responsibility for finding the details necessary to determine whether the process of care was correctly performed rests with the provider, as does the resource burden for abstraction.

Inclusion bias, nonuniformity, and limited reliability of reporting may be present, and without audits, the magnitude of this potential problem cannot be known. This is the case, for example, for those providers who participate in the National Registry of Myocardial Infarction quality performance measurement initiative or the ACC’s National Cardiovascular Database Registry.

In contrast to internal review, external record reviews provide more reliable measurements,51 but completeness is always subject to the lack of standards and the variability of medical record documentation. In addition, the burden of abstraction is shifted from the provider to the measurer. For quality performance measurement of AMI processes of care, both methods of record abstraction have been used (see below). When external and internal record reviews are used independently to determine quality performance, however, preliminary evidence suggests that the results are comparable.52

C. Potential Performance Measures for the Process of Care

Multiple agencies are currently engaged in performance measurement. Table 1 outlines currently used performance measures for quantifying quality in the provision of AMI care. These measures have been determined to adhere to the principles outlined above and have been used to quantify and compare quality among different regions of the country as part of public reporting and among different hospitals as part of local quality improvement efforts. The exact specifications by which different accrediting agencies apply these measures may differ, although recent efforts are toward consolidation of such specifications. Table 1 also estimates current compliance (levels <100% reflect the opportunity for improvement) and barriers to such improvement.53 Because the process of performance development and measurement is dynamic,
several measures are currently under consideration for future use. These are briefly outlined in Table 2.

**D. Past and Future Uses of Process Performance Measures**

Multiple organizations are now quantifying performance in the care of AMI patients. The efforts of these organizations differ in their goals, the perspective of their analyses, and the specifications of their measures. Accordingly, the scope, purpose, and approach of different organizations are changing rapidly. Although a complete description of current performance measures is beyond the scope of the present statement, Table 3 describes the most active organizations in quantifying healthcare quality for AMI and provides current web site references so that interested readers can acquaint themselves with each organization’s most current efforts.

### TABLE 2. Proposed Process-of-Care AMI Performance Measures of Quality*

<table>
<thead>
<tr>
<th>Quality Performance Measure</th>
<th>Evidence for Process–Outcome Link†</th>
<th>Measurement Reliability and Validity</th>
<th>Measurement Burden</th>
<th>Estimated Compliance‡</th>
<th>Barriers to Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration of reperfusion</td>
<td>A</td>
<td>Concerns about reliability and validity</td>
<td>High</td>
<td>67% (any reperfusion)</td>
<td>High, but have been successfully addressed</td>
</tr>
<tr>
<td>Cholesterol measurement before or after discharge</td>
<td>C</td>
<td>Probably good when obtained from medical record; lab database reliability unknown</td>
<td>Moderate</td>
<td>Unknown</td>
<td>Moderate</td>
</tr>
<tr>
<td>Cholesterol management at or after discharge</td>
<td>B</td>
<td>Probably good when obtained from medical record; pharmacy database reliability unknown</td>
<td>Moderate</td>
<td>Unknown</td>
<td>Moderate to high</td>
</tr>
<tr>
<td>Avoidance of calcium channel blocker for patients with contraindication</td>
<td>C</td>
<td>Good</td>
<td>Moderate</td>
<td>82%</td>
<td>Opportunity for improvement limited</td>
</tr>
<tr>
<td>Counseling about risk factors other than smoking</td>
<td>D</td>
<td>Concerns about documentation variability and completeness</td>
<td>Moderate</td>
<td>Unknown</td>
<td>Moderate</td>
</tr>
<tr>
<td>Referral for cardiac rehabilitation program</td>
<td>C</td>
<td>Unknown</td>
<td>Moderate to high</td>
<td>Unknown</td>
<td>Moderate to high</td>
</tr>
<tr>
<td>Administration of influenza vaccines</td>
<td>D</td>
<td>Unknown</td>
<td>Moderate to high</td>
<td>Unknown</td>
<td>Moderate to high</td>
</tr>
<tr>
<td>Management of complications of AMI (e.g., shock, heart failure)</td>
<td>C</td>
<td>Good for occurrence, unknown for appropriateness</td>
<td>High</td>
<td>Unknown</td>
<td>High</td>
</tr>
</tbody>
</table>

*These measures have not been officially endorsed by the AHA or ACC.
†A indicates randomized controlled trials plus effectiveness evidence beyond randomized controlled trial populations; B, randomized controlled trials without effectiveness evidence; C, other evidence supporting process of care; and D, guideline recommendation only.
‡Data for estimated compliance from reference 53.

### TABLE 3. Organizations Involved in the Measurement of Quality in AMI

<table>
<thead>
<tr>
<th>Organization</th>
<th>Web Site*</th>
<th>Perspective</th>
<th>Most Relevant Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centers for Medicare &amp; Medicaid Services (formerly the Health Care Financing Administration)</td>
<td><a href="http://www.cms.gov">www.cms.gov</a></td>
<td>Payer</td>
<td>National Heart Care Project</td>
</tr>
<tr>
<td>Joint Commission on the Accreditation of Healthcare Organizations</td>
<td><a href="http://www.jcaho.org">www.jcaho.org</a></td>
<td>Hospital</td>
<td>ORYX Initiatives</td>
</tr>
<tr>
<td>American Medical Association</td>
<td><a href="http://www.ama-assn.org">www.ama-assn.org</a></td>
<td>Physician</td>
<td>Physician Consortium for Quality Improvement</td>
</tr>
<tr>
<td>National Quality Forum</td>
<td><a href="http://www.qualityforum.org">www.qualityforum.org</a></td>
<td>Payer</td>
<td>Hospital Performance Measures Project</td>
</tr>
<tr>
<td>American Heart Association</td>
<td><a href="http://www.americanheart.org">www.americanheart.org</a></td>
<td>Hospital</td>
<td>Get with the Guidelines</td>
</tr>
<tr>
<td>American College of Cardiology</td>
<td><a href="http://www.acc.org">www.acc.org</a></td>
<td>Physician</td>
<td>ACC/AHA Task Force on Performance Measures</td>
</tr>
<tr>
<td>Veterans Affairs Health System</td>
<td><a href="http://www.va.gov">www.va.gov</a></td>
<td>Hospital</td>
<td>Guidelines Applied in Practice</td>
</tr>
<tr>
<td>National Committee for Quality Assurance</td>
<td><a href="http://www.ncqa.org">www.ncqa.org</a></td>
<td>Health Plan</td>
<td>Healthplan Employers Data and Information Set (HEDIS)</td>
</tr>
</tbody>
</table>

*Web addresses shown were verified on February 18, 2003.
VI. Outcome Measures

A. Background
A broad range of patient outcomes may be affected by the quality of care delivered to patients with AMI (Figure). These can be classified into clinical events (eg, death, heart failure, recurrent MI), health status (eg, symptoms, functional status, quality of life), patient satisfaction, and healthcare costs. The AMI Working Group did not consider physiological measures (eg, cholesterol levels, blood sugar control in diabetic patients, or blood pressure control in hypertensive patients) as patient outcomes. Although such surrogate measures may be effective tools for monitoring the success of important processes of care, they are relatively silent from the patient’s perspective. The goal in treating these physiological states is to prevent the mortality and impaired quality of life that are the consequences of such pathophysiological abnormalities.

B. Methodological Considerations
Three major methodological issues were considered by the AMI Working Group: the time period during which the outcome was assessed, the impact of patient characteristics on outcome, and the statistical robustness of outcome measures.

(1) Assessment Time Period
Defining the appropriate time period during which outcomes should be collected is challenging. Considerations such as the ease of data collection and the attribution to responsibility to a particular provider favor collecting outcomes over a short time period, such as 30 days after hospital admission. Some may opt to use the in-hospital stay because of convenience, but that is a nonstandardized period of assessment. In any case, the potentially modifiable component of short-term outcomes may be small, particularly for very elderly patients or patients with significant comorbidity. More importantly, the full impact of the structures and processes of care, from the emergency medical response through acute reperfusion to long-term secondary prevention, may not be manifest until years after the event. Finally, the transition between inpatient and outpatient care and the application of secondary prevention measures may be at least as important as many acute care decisions.

Despite these limitations of short-term outcomes, it was also recognized that assessing quality of care from a longer-term prospective is controversial, particularly because a longer timeframe significantly reflects outpatient treatment decisions that may not be under the direct control of the acute healthcare provider. The AMI Working Group felt, however, that even when initial in-hospital providers are not in charge of care after discharge, they do assume a responsibility for appropriate communication to patients’ primary care physicians. Furthermore, if a hospital is identified as having poor long-term patient outcomes, then internal reflection can help identify whether this is due to inpatient or outpatient processes of care. Ultimately, this should trigger quality improvement in both the structure and processes of care that can lead to better outcomes. When weighing these considerations, the AMI Working Group felt that although measurement of in-hospital or 30-day outcomes provided some opportunity to improve care, greater emphasis on longer-term outcomes (preferably at 1 year) would most effectively facilitate more substantive improvements in quality.

(2) Impact of Patient, Rather Than Provider, Characteristics on Patient Outcomes
Patients’ outcomes after AMI are influenced by a host of patient-specific factors, including demographics (eg, age, sex), disease severity (eg, type of MI, underlying coronary anatomy, ventricular function before and after the MI), comorbid illness (eg, diabetes, chronic obstructive pulmonary disease), treatment factors, and chance. The goal in quality assessment is to distinguish the modifiable, provider-related component from these other confounding clinical factors. The statistical methodology needed for appropriately risk-adjusting provider outcome comparisons has been the subject of several recent reviews; it requires building multivariate models to weight the most important patient-specific factors so that deviations in outcome can be attributed to the care provided rather than the patients cared for.

(3) Impact of Chance on Patient Outcomes
It was, however, recognized by the Working Group that even if perfect risk-adjustment models were available, chance could likely obscure true differences in quality among providers. This randomness in biology makes accurate measurement of healthcare quality by using outcomes challenging. The compensating factor for random occurrences is the number of outcomes observed. As this increases, the relative influence of chance on an outcome measure diminishes. With regard to MI care, however, the number of patients treated (and number of events seen) by most hospitals is often limited, making accurate, reliable, and precise quality differentiation challenging. Despite these limitations, the AMI Working Group felt that efforts to measure and report, at least internally, long-term outcomes could create important opportunities for self-analysis and subsequent quality improvement. Because of sample size and risk-adjustment limitations, however, mortality may not be appropriate for public reporting.

C. Potential Performance Measures for Outcomes

(1) Mortality
Survival is clearly a meaningful end point for patients and society. In-hospital survival rates are readily assessed, and postdischarge vital status can be obtained by querying the National Death Index and/or through direct patient contact. Yet the complexity of creating linkages to these data sources requires resources that may exceed the capacity of smaller hospital and provider systems. Furthermore, the validity of this outcome is compromised by current limitations in risk adjustment. Ongoing research is contributing substantial insight into the appropriate models, but even the best current models are unable to attain C-statistics (a coarse index of the discrimination of such models) that exceed 0.80 (range, 0.5 to 1.0). As noted in the preceding section, even if perfect risk adjustment methodologies were available, the limited yearly hospital volume of AMI patients (and the relatively low event rate) makes identification of superior and inferior outliers difficult. In fact, statistical simulations demonstrate that a quality assessment scheme based on hospital mortality
outcomes may have a predictive error rate approaching 50%. Thus, mortality outcomes may reasonably correlate with the quality of care at system or regional levels but are limited when the number of events is lower, such as at the hospital or individual provider level. Given the methodological limitations noted, the AMI Working Group concluded that mortality (at 30 days and 1 year) could be useful for internal quality improvement but that the imperfection of existing risk-adjustment techniques, the potential for non-modifiable mortality (especially in high-risk groups), statistical instability in small samples, and the play of chance conspire to make mortality end points inappropriate for public reporting, especially for comparing individual providers.

(2) Repeat Hospitalizations
In addition to mortality, repeat hospitalization could be an appealing outcome measure of disease progression (Figure) given its relatively easy quantification, the frequency of its occurrence, and its meaningfulness to patients and healthcare systems (due to increased costs). Concerns about using this outcome as a marker of healthcare quality, however, include the potential to underestimate significant event rates because not all significant events result in a hospitalization. Furthermore, hospitalization rates may be strongly associated with bed availability, thus undermining the interpretation of this outcome. In addition, some readmissions may be planned and therefore not necessarily representative of a negative outcome. Combining hospitalization with mortality, because patients who die during the follow-up period are no longer subject to readmission, may mitigate the first of these concerns. Deaths contribute relatively little to this combined outcome; however, the import of this outcome is more diluted than its description would imply. As noted for mortality, however, few data are available to create robust risk-adjustment models for readmission, and thus, patients’ characteristics combined with chance may undermine the usefulness of readmissions in reflecting the quality of care provided.

Given these potential benefits and challenges of quantifying readmission, the Working Group recommends that rehospitalization after AMI be examined when the group examining this outcome can link the analysis to a meaningful quality improvement process. If hospitalizations are to be included in an outcomes assessment, then a window of at least 3 to 6 months after the index admission is recommended. This quality metric will ensure that AMI hospital stays are not shortened to the point of harm and that appropriate longitudinal care plans are established for patients. Although it may eventually be possible to judge healthcare plans on longer-term cardiac event rates (measured in years) as a measure of successful secondary prevention care, given the present lack of information systems and risk-assessment schemes to measure and evaluate these end points, these recommendations remain a goal rather than a reality, and external reporting of such outcomes data is not advocated.

(3) Health Status
Health status includes the symptoms, function, and quality of life of patients after their acute AMI care. These outcomes are clearly meaningful to patients and society. Several mechanisms of quantifying health status are available and include physician-assigned (eg, the Canadian Cardiovascular Society classification) and patient-centered measures (eg, the Seattle Angina Questionnaire). Yet these assessments can be resource intensive and difficult to perform in routine practice. Furthermore, limited research has been directed toward developing risk-adjustment models for these outcomes, and until this methodological work is done, separating patient characteristics from the quality of treatment cannot be accomplished. Although the AMI Working Group clearly recognized the benefits of quantifying patients’ perspectives of their disease status and noted that such insights could be invaluable to healthcare systems seeking to maximize the quality of their treatment of patients with coronary disease, current challenges in collection and analysis preclude recommending health status as a performance measure for external reporting. It is, however, one of the most important research priorities for advancing the field of quality assessment and improvement.

(4) Costs
Costs are a highly relevant outcome from the perspective of providers and society. However, from the perspective of patients in the current American healthcare system, costs are largely hidden. The AMI Working Group did not feel that costs were an appropriate metric with which to assess the quality of health care at this time, although it may have value for internal quality improvement efforts intended to improve the efficiency of care.

(5) Patient Satisfaction
Although highly relevant to healthcare systems that seek to retain patients, patients’ satisfaction with care is of unclear import to patients themselves and to society. Much work is needed to better measure patient satisfaction. Although progress is being made in generic assessments of patient satisfaction (eg, Consumer Assessment of Health Plans [CAHPS]), only the treatment satisfaction scale of the Seattle Angina Questionnaire quantifies this domain in a disease-specific fashion. More work is needed to better understand how to validly capture patients’ satisfaction with their care for an AMI. In addition, few risk-adjustment models are available, and the highly skewed nature of data creates significant methodological challenges to the use and reporting of patient satisfaction data. Hence, although patient satisfaction is clearly important to the reputation of a provider or an institution within a community, it is not sufficiently mature methodologically or sufficiently meaningful as an outcome to be endorsed by the AMI Working Group as a measure of quality.

D. Past and Future Uses of Outcome Performance Measures
Few efforts at using outcomes in the quantification of healthcare quality in the treatment of AMI are available for review. Furthermore, the challenges in data collection, risk-adjustment, and interpretation make it unlikely that major accrediting bodies will endorse outcome measures in the near future. However, the AMI Working Group felt that this is one
of the most important opportunities for future research and that the development of improved information systems is likely to create important opportunities for collecting such outcomes in the future. Furthermore, as risk-adjusted methods for providing outcomes data to providers are developed, they are likely to provide valuable insights into the need for more careful evaluation of current processes and structures of care that, in turn, will lead to improved outcomes over time.

VII. Recommendations for Future Research
The demand for quality assessment and improvement in health care has quickly outstripped medicine’s knowledge of how to meet this demand with methodologically rigorous techniques that cover the full spectrum of healthcare delivery, structure, process, and outcomes. Accordingly, the Working Group identified several important research priorities. These include:

- A greater focus on measuring and interpreting outcomes, particularly longer-term outcomes
- The development of new and improved risk-adjustment techniques for a variety of outcomes, including mortality, health status, hospital admissions, and costs
- Expanded research into the transition of care from the inpatient to the outpatient setting
- Increased efforts toward the efficient collection and attribution of long-term outcomes

- More research to translate the results of analyses into improvements in healthcare delivery, including:
  - Recognizing and acting on opportunities to improve care
  - Examining models of increased accountability within an individual organization
  - Evaluation of alternative optimal performance feedback methodologies

- More research into measuring and improving the structures of care, including:
  - How to quantify the links between structure, process, and outcomes
  - Examining the interaction of different systems of care and how to optimize changes in current systems in the most nimble and effective manner
  - Learning how to quantify the quality of transitions from the inpatient to the outpatient condition

- Greater clarity of the purpose of performance measures so that those who develop them are explicit about their purpose as the properties of the measures may change

- Greater coordination among those designing performance measurement systems with particular attention on how to minimize the financial burden on those being measured to participate in meaningful quality improvement efforts

- Greater attention by those creating clinical practice guidelines to the need for eventually creating performance measures so that those recommendations that are most important for improving patient outcomes are highlighted and that the inclusion/exclusion criteria of appropriate patients are clearly delineated

- More research to quantitatively measure appropriateness measures for diagnostic and therapeutic procedures after AMI

- More work identifying how to measure and improve the incorporation of patient preferences into the process of medical decision-making (although current efforts are aimed at decreasing the variability of treatment from established guidelines, the variability in care should be wide when this variability is due to patient preferences.)

Summary and Conclusions
Quality performance measurement and improvement have been in place for AMI for several years, particularly within the process-of-care domain. Through the use and analysis of these measures, physicians, hospitals, oversight agencies, researchers, and consumers have learned about how quality care can be measured, about variability in care, and about the effectiveness of current practice patterns. Most importantly, quality performance measurement for AMI has provided a focus and direction for those devoted to improving care. Despite evidence of early success from these efforts, there remains substantial additional work yet to do. The Working Group believes that if the true potential for American health care is to be realized, substantial national funding and support for strengthening the scientific foundation of quality measurement and improvement are needed for our country to effectively translate the accumulating evidence of medicine into routine clinical practice.

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Challenges and Opportunities in Quantifying the Quality of Care for Acute Myocardial Infarction: Summary From the Acute Myocardial Infarction Working Group of the American Heart Association/American College of Cardiology First Scientific Forum on Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke

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