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AHA Consensus Statement

Recommendation to Develop Strategies to Increase the Number of ST-Segment–Elevation Myocardial Infarction Patients With Timely Access to Primary Percutaneous Coronary Intervention

The American Heart Association's Acute Myocardial Infarction (AMI) Advisory Working Group

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Abstract—Although evidence suggests that primary percutaneous coronary intervention (PCI) is the preferred reperfusion strategy in the majority of patients with ST-segment–elevation myocardial infarction (STEMI), only a minority of patients with STEMI are treated with primary PCI, and of those, only a minority receive the treatment within the recommended 90 minutes after entry into the medical system. Market research conducted by the American Heart Association revealed that those involved in the care of patients with STEMI recognize the multiple barriers that prevent the prompt delivery of primary PCI and agree that it is necessary to develop systems or centers of care that will allow STEMI patients to benefit from primary PCI. The American Heart Association will convene a group of stakeholders (representing the interests of patients, physicians, emergency medical systems, community hospitals, tertiary hospitals, and payers) and quality-of-care and outcomes experts to identify the gaps between the existing and ideal delivery of care for STEMI patients, as well as the requisite policy implications. Working within a framework of guiding principles, the group will recommend strategies to increase the number of STEMI patients with timely access to primary PCI. **(*Circulation*. 2006;113:2152-2163.)**

Key Words: AHA Consensus Statements ■ myocardial infarction ■ revascularization ■ quality of health care ■ triage

Mounting evidence from randomized trials suggests that for patients with ST-segment–elevation myocardial infarction (STEMI), primary percutaneous coronary intervention (PCI) is superior to fibrinolytic therapy alone in reducing the composite end points of death, reinfarction, intracranial bleeding, reocclusion of the infarct artery, and recurrent ischemia. The benefits of primary PCI are greatest if it is performed in an expeditious manner after the onset of symptoms. This requires a highly coordinated effort, especially when interhospital transport is needed to provide PCI.[1,2] In the United States, however, only a minority of patients with STEMI receive primary PCI, and in those who do, fewer than 40% are treated within 90 minutes after arrival at the initial hospital as recommended (as a goal) by the American College of Cardiology (ACC)/American Heart Association (AHA) guidelines.[3] Given that the majority of hospitals do not have PCI capability, physicians, hospitals, and the Department of Public Health in several states have been faced with the challenge of providing primary PCI to STEMI patients in a timely fashion. In fact, several regions have established both triage and transfer protocols for PCI in patients with STEMI.[4,5]

The AHA, which is dedicated to reducing disability and death due to cardiovascular diseases and stroke, has recog-

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nized the unmet need in the care of many of the nearly 400 000 patients per year with STEMI in the United States and the potential benefits of regionalized care.[6,7] Therefore, the AHA convened a multidisciplinary group of experts, the Acute Myocardial Infarction (AMI) Advisory Working Group (AWG), to develop recommendations for a strategy to increase the number of STEMI patients with timely access to primary PCI and to explore the role the AHA should play in this endeavor. After review of the state of the science and the current status of reperfusion therapy in the United States (below), the AWG recommended that the AHA commit to exploring both systems and centers of care that would allow more rapid access to primary PCI for a greater number of patients. In this context, *systems* are defined as integrated, regionalized groups of separate entities that provide specific services for the system, which could include tertiary centers, community hospitals, emergency medical services (EMS) providers, and others. *Centers* are defined as entities that provide patient care services for a specific specialty or service, such as a community or tertiary hospital. The attainment of this goal will likely require cross-system regional collaboration that may or may not be in the interest of a single provider. Accordingly, this initiative could benefit from the attention, motivation, and expertise of the AHA. PricewaterhouseCoopers (PwC) was selected to prepare a report on the desirability, feasibility, and potential effectiveness of establishing (regional) systems and/or centers of care for STEMI patients with a focus on whether and how this might improve patient access to quality care and outcomes. The primary goal of the report was to assist the AHA in developing its position and role in defining the optimal care for patients treated with primary PCI.

After analysis of PwC's findings, the AWG recommended that the AHA convene all the stakeholders involved in the care of patients with STEMI to begin to discuss the issues involved in expanding access to timely primary PCI. This will be accomplished at a 3-day conference in Boston, Mass, beginning on March 30, 2006. The AWG then developed a list of principles (below) to guide the AHA in leading this initiative.

The purpose of this report is to briefly summarize the evidence supporting primary PCI as the preferred reperfusion strategy for patients with STEMI, share the market research supporting the development of systems and centers of care, define the guiding principles that will serve as the basis and framework for all subsequent discussions and recommendations, and issue a "call to action" to convene all constituents involved in the care of STEMI patients at the AHA conference, "Development of Systems of Care for STEMI Patients."

State of the Science

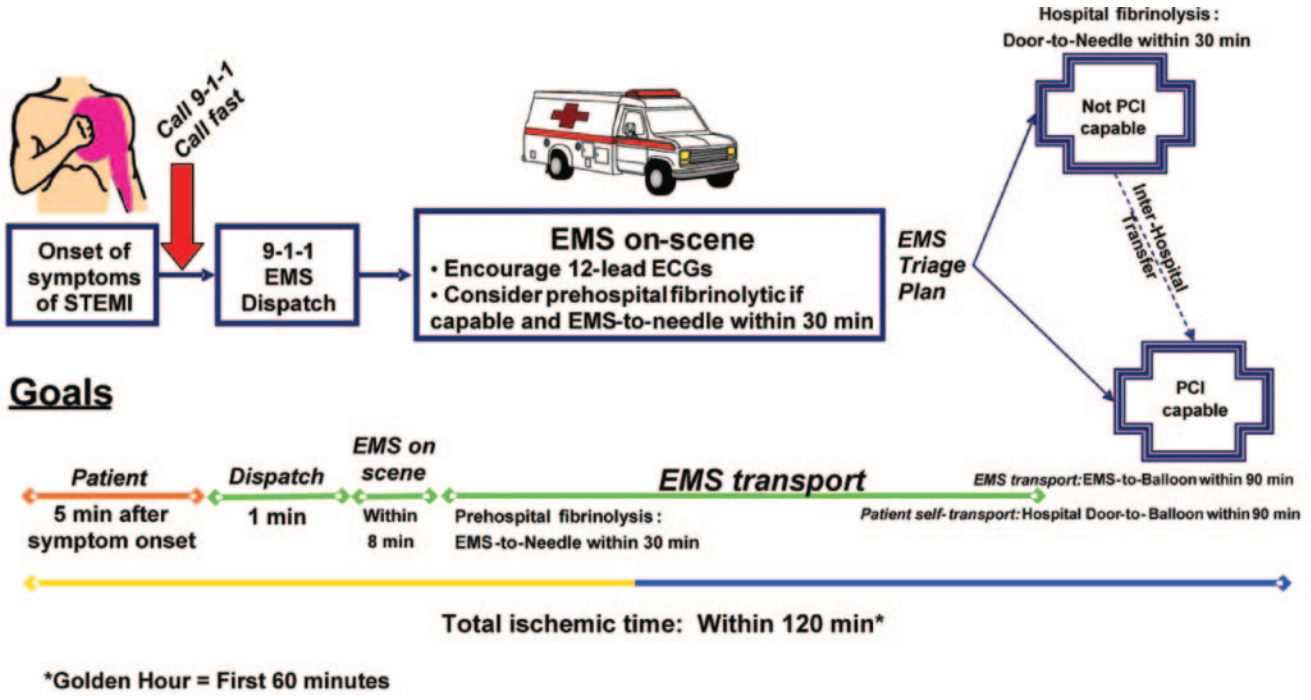
Reperfusion with either fibrinolytic therapy or PCI early after the onset of coronary occlusion in patients with STEMI has been shown unequivocally to improve short- and long-term patient outcomes.[8] Despite that evidence, several large-scale registries have reported that strategies for reperfusion therapy are not well implemented in many countries.[9,10] In the United States, approximately one third of patients with STEMI do not receive any reperfusion therapy despite its availability and the absence of any contraindication.[11] Furthermore, disparities exist with regard to delivery of reperfusion therapy, with lower rates reported for women and for black patients.[12,13]

The ability to achieve timely reperfusion for patients with STEMI is limited by the patient's ability to recognize their symptoms and to promptly contact the medical system, the time necessary to transport the patient to the hospital, the decision process on arrival, and the requisite time to implement the reperfusion strategy (Figure). Multimedia public education campaigns and community intervention programs aimed at reducing patient delay between symptom onset and hospital presentation and at increasing activation of EMS have not yet proven sufficiently effective.[14,15] Rapid transport of patients with STEMI to the most appropriate facility is hampered by several factors: A minority (10%) of EMS systems have 12-lead ECG capabilities[16]; a minority (4% to 5%) of EMS patients with chest pain have STEMI[17]; a mandate exists to deliver the patient to the nearest facility even when fibrinolysis may be contraindicated and the facility does not provide primary PCI; and transport times may be long in rural areas. If a patient is brought to a non–PCI-capable facility and primary PCI is necessary, it is not unusual for the patient to wait for the next available ambulance to gain access to PCI. Furthermore, critically ill patients often require stabilization before transport.

The decision about the appropriate reperfusion modality is most often made at the receiving facility. Even at institutions that frequently use both strategies, the decision process can be delayed, particularly if primary PCI is not routinely available at all times.[18] In addition, primary PCI has been underutilized in patients with cardiogenic shock and in those with contraindications to fibrinolytic therapy. Finally, relatively late presentation after symptom onset, comorbid conditions, the absence of chest pain, and presentation during off-hours have been reported to increase the time to reperfusion.[19]

Fibrinolytic Therapy Versus Primary PCI

The AWG reviewed the status of both pharmacological and catheter-based reperfusion therapy to identify the gaps between the current system and the ideal system(s) of care that will be developed, to recognize a subset of patients (ie, in rural areas) that may not be able to obtain timely PCI despite implementation of ideal systems, and to attempt to decrease the number of patients who do not receive any reperfusion therapy. This group also thoroughly reviewed the ACC/AHA Guidelines for the Management of Patients With STEMI and noted that the guidelines writing committee concluded that it was not possible to produce a simple algorithm for a reperfusion strategy given the heterogeneity of patient profiles and availability of resources in various clinical settings at various times of day.[20] The overarching recommendation from the ACC/AHA STEMI guidelines writing committee was for healthcare providers to aggressively attempt to minimize the time from entry into the medical system to implementation of the reperfusion strategy. This is best accomplished using the concept of medical system goals (Figure).



Options for transportation of patients with STEMI and initial reperfusion treatment (reproduced with permission from Antman et al[20]).

To facilitate rapid initiation of reperfusion therapy, the medical system goal for patients receiving fibrinolysis is a door-to-needle (or medical contact–to-needle) time of within 30 minutes; for those undergoing PCI, a door-to-balloon (or medical contact–to-balloon) time of <90 minutes is recommended.[20] No evidence exists that there is a threshold effect for the benefit of shorter times to reperfusion, which underscores the fact that the goals delineated in the STEMI guidelines are not "ideal" times but rather the longest times that should be considered acceptable by the medical system. Another important physiological principle is that the goal of reperfusion is to restore flow in the infarct artery not only as quickly as possible but also as completely as possible, which includes attaining enhanced myocardial perfusion in the infarct zone.[21] A variety of treatments are used for both pharmacological and catheter-based methods of reperfusion to optimize epicardial and myocardial reperfusion.

Comparisons of pharmacological and PCI strategies in the literature are confounded by a number of methodological difficulties. For example, an overview of 23 trials that compared fibrinolysis with PCI had a total sample size of only 7739 patients and spanned a 10- to 15-year period that concluded before the advent of substantial improvements in both pharmacological and PCI strategies. These limitations notwithstanding, the rate of the composite end point of death/myocardial infarction/cerebrovascular accident was 13% in the fibrinolysis trials and 8% in the PCI trials, which represents a 5% absolute risk difference and a 38% relative risk difference ($P<0.0001$). Much of the difference in this composite end point was driven by the rate of recurrent myocardial infarction, although there was a significant difference in both short- and long-term mortality.[1]

When selecting the type of reperfusion strategy, clinicians have to consider 4 critical questions[20]:

1. *The time from onset of symptoms.* Data exist that indicate that there is a time-dependent decrease in the efficacy of fibrinolytic therapy after the onset of symptoms.[22] In contrast, the ability to produce a patent infarct artery is much less dependent on symptom duration in patients undergoing primary PCI, although mortality is time dependent even with PCI.[20] However, the delay to PCI should be considered even in patients who present relatively late (>2 to 3 hours) after the onset of symptoms.
2. *The risk of STEMI.* The benefit of primary PCI rises with increasing risk of STEMI. When the estimated mortality in patients treated with fibrinolysis is extremely high, as in the setting of cardiogenic shock, compelling evidence exists that favors the PCI strategy. As the estimated mortality rate with fibrinolysis declines, the relative mortality advantage of PCI also declines, with equipoise being attained at approximately a 3% estimated mortality rate with fibrinolysis.[23]
3. *Risk of fibrinolytic therapy.* When both fibrinolysis and PCI are available, the higher the patient's risk of bleeding with fibrinolytic therapy, the more strongly the decision should favor PCI.[20] However, it is important to consider relative versus absolute contraindications to fibrinolytic therapy, particularly in patients in whom timely access to primary PCI is not currently feasible. In addition, in the setting of cardiogenic shock, fibrinolytic therapy is less effective.[20]
4. *Time required for transport to a skilled PCI laboratory.* Critical to the success of the PCI-based strategy are the experience and location of the PCI laboratory, as well as the experience of the operator. Trials that support an advantage of PCI over fibrinolysis were performed in centers with highly experienced teams committed to a rapid delivery of reperfusion therapy. For example, in the DANAMI-2 (DANish trial in Acute Myocardial Infarction-2) and PRAGUE-2 (PRimary Angioplasty after

transport of patients from General community hospitals to catheterization Units with/without Emergency thrombolytic infusion-2) studies, patients who were transferred from community hospitals to an invasive center underwent PCI with a door-to-balloon time that averaged 26 minutes once they arrived at the invasive center.[24,25] The time for transportation from the community hospital to the invasive center averaged 32 minutes in DANAMI-2 and 48 minutes in PRAGUE-2. By contrast, reports from the National Registry of Myocardial Infarction in the United States for patients with STEMI who undergo transfer for PCI show an unacceptably long time between initial presentation at the first hospital to balloon inflation at an invasive center, at a median of 180 minutes.[19] This is composed of a median of 120 minutes for decision making in the first hospital plus transportation and arrival in the PCI hospital, and 53 minutes between PCI hospital arrival and balloon inflation. An additional report from the National Registry of Myocardial Infarction that evaluated the times to implementation of reperfusion strategies during regular work hours versus off-hours and for weekday (Monday through Friday) versus weekend (Saturday or Sunday) presentations showed important differences between fibrinolytic therapy and PCI.[26] The door-to-needle time during regular hours was 33.2 minutes and increased slightly to 34.3 minutes during off-hours. In contrast, door-to-balloon times during regular hours were 94.8 minutes but increased by 21.3 minutes to 116.1 minutes during off-hours. Longer off-hours door-to-balloon times were primarily due to a longer interval between obtaining the ECG and patient arrival at the catheterization laboratory.

A relationship between the onset of symptoms and the time to initiation of reperfusion has been established previously for fibrinolytic-treated patients. Although the data remain somewhat controversial, the bulk of the evidence also suggests that prolonged times from symptom onset to balloon inflation are associated with an increased risk of mortality.[20] The Zwolle Group reported, after adjustment for baseline characteristics, that each 30-minute delay between the onset of symptoms and balloon inflation was associated with a relative risk of 1-year mortality of 1.08 ($P=0.04$).[27] Furthermore, it has been reported that in patients undergoing primary PCI at a single center between 1984 and 2003, door-to-balloon times $\geq$2 hours versus $<$2 hours were associated with a higher mortality at 7 years in high-risk but not in low-risk patients and in patients who presented early ($\leq$3 hours) but not in those who presented late ($>$3 hours) after symptom onset.[28]

Healthcare systems in many communities have adopted a variety of approaches for more timely delivery of reperfusion therapy for STEMI. Those communities that are supported predominantly by single, close-knit EMS and ambulance systems have generally adopted the practice of obtaining a prehospital 12-lead ECG and then initiating prehospital fibrinolysis, except for patients for whom PCI would clearly be preferable (eg, those with cardiogenic shock).[29] Other communities, typically urban in location, have adopted a strategy of direct transportation for all STEMI patients to a dedicated primary PCI center that is available 24 hours a day, 7 days per week.[4]

No large-scale randomized trials comparing such reperfusion strategies have been reported to date; however, it is recognized by the writing committee for the ACC/AHA Guidelines for the Management of Patients With STEMI and the AWG that the critical considerations in the delivery of primary PCI are the interrelated issues of timeliness and access. If timely access to primary PCI is available, the evidence suggests that PCI is the preferred reperfusion strategy, especially in those presenting late after symptom onset, those who are considered high risk, and those in whom fibrinolysis is contraindicated. Thus, primary PCI is the focus of this AHA initiative. Facilitated PCI, which involves prompt performance of PCI after an initial preparatory pharmacological regimen, has not been proven to be an effective or safe alternative to primary PCI.[30] In fact, in the Assessment of the Safety and Efficacy of a New Treatment Strategy with Percutaneous Coronary Intervention trial (ASSENT-4 PCI), a randomized trial of tenecteplase before PCI versus primary PCI alone that tested the strategy of facilitated PCI in patients with STEMI, the primary end point of death, heart failure, and shock at 90 days was significantly higher in patients treated with combination therapy.[31] A hybrid approach, referred to as a pharmacoinvasive reperfusion strategy, that involves initial treatment with fibrinolytic therapy followed routinely by cardiac catheterization and PCI as indicated on a nonurgent basis has also been proposed as an approach to reperfusion for STEMI,[8] but at the present time, the evidence supporting such a strategy is not robust.

Market Research Findings

Given the evidence that timely performance of primary PCI is superior to fibrinolytic therapy in the majority of patients with STEMI, the future design for the provision of cardiac services will play a critical role in providing prompt access to this therapy. However, it is anticipated that multiple barriers and problems will be encountered if the current environment is disrupted by the establishment of systems and centers of care, particularly to the degree that those systems exclude certain providers. Spending and utilization growth have made cardiac services a multibillion dollar business and a critical component of the operations of acute care providers. In many urban hospitals, cardiac-related diagnosis and treatment account for roughly 40% of net revenues. These financial trends have fueled cardiac competition among hospitals and have resulted in an outgrowth of physician-owned cardiac specialty hospitals in several markets.

PwC was directed by the AHA to carefully explore all strategies that could potentially increase the number of STEMI patients with access to timely primary PCI with a minimum negative impact on existing care in a particular local area. Specifically, the analysis was to include an assessment of the market and financial impact for hospitals that provide these services.

Research Methods

The research approach was both qualitative and quantitative. Phone interviews and Web-based surveys were conducted to gauge support and solicit input from key stakeholders. The interview and survey instruments were designed in a collab-

TABLE 1. STEMI-Related State Statutes[36]

State	Reference	Statute
Arizona	Ariz Rev Stat §36-2205 (1998)	The Department of Health Services, in consultation with the medical director of EMS, can establish protocols relating to the transportation of patients based on the patient's condition.
Delaware	Del Code Ann tit 16, §97 (1996)	A voluntary and inclusive statewide trauma care system has been established and provides for the creation of a statewide trauma plan specifically addressing prehospital care.
Florida	Fla Stat §212.055 (2003)	Certain counties are authorized to levy surtax to fund trauma care. Florida law also sets boundaries for state trauma system plans.
Illinois	Ill Rev Stat ch 730 §5/5-9, ch 705 §105/27.6, ch 20 §3960/6.01 (1996)	The Department of Public Health will investigate a hospital in an EMS system that goes on "bypass status" to determine whether the action was reasonable. Hospitals improperly diverting will receive a fine.
Nebraska	Neb Rev Stat §71-2017 and 71-2029 (1997)	The statewide trauma system allows facilities to be designated for care based on the patient's intensity of injury.
Oklahoma	Okla Stat tit 63 §1-2530 (2003)	The Trauma Systems Improvement and Development Act requires facilities to meet standards set by the state Board of Health to designate themselves as trauma centers.

orative effort, with input from AWG members. Each instrument was pilot tested with appropriate audiences before survey launch. Additional information about the research methods and the financial modeling is included in the Appendix.

Key Findings

Policy

Certification of primary PCI centers could impact payers, especially Medicare, which is the single largest payer of cardiac services and influences how, when, and where cardiac care services are delivered. For hospitals, Medicare often represents more than half of the payer mix. The Centers for Medicare and Medicaid Services (CMS), which administers the Medicare program, has put into place pay-for-performance programs intended to align financial incentives with desired improvements in patient care. As the agency that ensures access to care for more than 40 million elderly Americans, it must consider how a diversion or certification policy might affect access to care, not only for patients with STEMI but also for those with other disorders who are currently cared for at hospitals without primary PCI capability.

The new outpatient drug benefit is expected to spike growth in Medicare spending unmatched by growth in the federal budget. Owing to this, Medicare could face budgetary pressures that may negatively impact payment for hospitals and physicians. Attempts to correct the current discrepancy in payment for procedural versus evaluation and management services that fueled the wave of new specialty hospitals may also impact cardiac services. This wave has created a debate in the industry about the quality and cost-effectiveness of specialty hospitals and their effect on community hospitals. In response to concerns raised by the American Hospital Association, Congress put an 18-month moratorium on new physician-owned specialty hospitals in place. As part of that moratorium, the Medicare Payment Advisory Commission (MedPAC),[32] the commission that advises Congress on Medicare issues, is reviewing how cardiac care should be delivered and paid for. Depending on how a system is structured, regionalization of care for STEMI patients could put financial stress on hospitals that depend on cardiac care to subsidize unprofitable services.

Simultaneously, Congress and MedPAC[33] are interested in improving quality and moving ahead with a pay-for-performance strategy that focuses, in part, on cardiac care. For example, 5 of Medicare's 10 quality indicators focus on AMI care. MedPAC is currently reviewing the types of data collected on AMI to determine how to extend pay-for-performance metrics. Movement to a system of care for STEMI patients could be complementary to Medicare's move toward pay-for-performance if it increases quality for Medicare beneficiaries and reduces costs from unnecessary readmissions without unreasonably restricting access.

Commercial payers are also quickly moving toward pay-for-performance metrics. In fact, the Leapfrog Group has collected summaries of more than 100 pay-for-performance programs.[34] As healthcare costs increase, all payers want to see more evidence that their patients are receiving timely and appropriate care. In some cases, payers are contracting only with "centers of excellence" in an attempt to divert their patients to hospitals that provide higher quality of care. These factors will influence how a system of care for STEMI patients could be developed.

In addition to the impact of federal programs and legislation, the differing state regulatory frameworks and the landscape of "certificate of need" (CON) programs must be taken into account when one considers a primary PCI certification program. Intended to manage healthcare costs by controlling supply, CON laws provide an avenue for state health planning agencies to review access to and quality and costs of healthcare services before the development of any additional services. Approximately half the states have cardiac-specific CON requirements. CON laws regulate the number of hospitals that deliver cardiac catheterization and cardiac surgery procedures. In a state where CON is mandated for cardiac care, hospital programs must justify their community needs (eg, volume projections, use rates, and access to care), capital expenditures, staffing requirements, and impact on providers to the state health planning agency for consideration. Once

TABLE 2. Response to Interview/Survey Question: Would You/Your Organization Support the Establishment of a Certification/Designation Program for the Treatment of Myocardial Infarction Through Primary Angioplasty?

Interview/Survey Cohort	Yes, %	No, %	Don't Know, %
Physicians (n=100)	75	14	11
Urban hospitals (n=14)	72	7	21
Rural hospitals (n=5)	60	20	20
EMS (n=2)	50	0	50

TABLE 3. Operating Margin and Case-Mix Index 2002

	Overall	PCI Procedures	Cardiac Surgical Procedures
Operating margin			
Community hospitals	4.3%	3.6%	8.7%
System-affiliated hospitals		9.5%	14.1%
Case-mix index	1.3	2.7	5.9

the formal CON application is submitted, the state agency evaluates these criteria before granting an approval determination.

However, the evolution of technology in health care has resulted in a recent shift in decision making about where cardiac services can be delivered. Since 1994, 6 states have repealed their CON requirements for cardiac surgery, and in a program originally developed by the Cardiovascular Patient Outcomes Research Team (C-PORT) at Johns Hopkins Hospital and Health System, 50 hospitals from Queens, NY, to rural Massachusetts are piloting programs that allow them to perform angioplasty procedures without an on-site cardiac surgery program.[35]

A review of state EMS laws showed that 6 states have statutes relevant to primary PCI centers (mainly with regard to trauma care; Table 1).[36] These statutes will have to be considered in the approach to certification, specifically when incorporating the EMS component.

EMS regions are governed separately by state and create their own protocols. There are 329 different regions in the United States, with >993 hospital-based EMS systems.[37] Hospital-based EMS systems only make up 6.51% of the total number of EMS systems (48.6% are private, third-party systems and 44.89% are fire station based). This variation among states will add to the complexity of incorporating the prehospital component of any proposed certification program.

Stakeholder Interviews/Surveys

The majority of physicians, hospitals, and EMS officials interviewed support a primary PCI certification program. As Table 2 indicates, there was strong support among providers; however, many expressed concerns. For example, some rural hospitals, operating with fewer resources than their larger urban counterparts, are concerned about their ability to achieve certification and maintain cardiac revenue streams, an important subsidy for other service lines. Some physicians and urban hospitals questioned the need for such certification and redundancy with existing programs. Other unintended consequences discussed included a negative halo effect caused by the diversion of EMS such that hospitals without the primary PCI certification might find themselves bypassed for other services as well.

Federal policymakers interviewed shared concerns that some hospitals may see this effort as a threat that ultimately eliminates their cardiac business. Furthermore, the additional cost of another certification may not be perceived as a good investment by certain hospitals. Federal policymakers were also concerned about the potential to increase the number of uninsured patients who are transferred to accredited centers. Specifically, certification may create "patient dumping" issues if providers use their noncertification as an excuse to transfer uninsured patients to certified centers. Such transfers under a reorganized system might allow them to avoid penalties under the Emergency Medical Treatment and Active Labor Act (EMTALA).[38]

Respondents were also questioned about the design of the potential program and specifically about a systems-versus-centers approach (ie, certification of a PCI-capable hospital). Overall, respondents did not believe access and quality were mutually exclusive and did not provide a consensus of opinions as to whether a systems or centers approach would be optimal.

The majority of respondents believed that a systems approach would increase coordination of care, reduce redundancies, and provide a consistent level of emergency care to all communities; however, they also believed that a systems approach would be difficult to implement and could lead to conflicting policies among the various providers. As noted earlier, rural respondents believed that a systems approach might exclude them in spite of the high quality of their programs.

The centers approach also received mixed reviews. Although some respondents believed that the focus of a centers approach would improve outcomes, others believed associated access issues would delay treatment and negatively impact outcomes. Others were concerned that a centers approach might shift focus from community interest to return on investment.

Respondents did agree on the impact a primary PCI certification program would have on individual healthcare stakeholders. All interview/survey cohorts agreed that the hospitals and health systems would be affected most intensely, ahead of both consumers and physicians. It was predicted that payers, both public and private, would be the least impacted. This point was validated in conversations with health plan officials who indicated that they already certify and designate centers along these lines when negotiating rates for nonacute conditions. However, it was acknowledged that payers, both public and private, would need to play a role in ensuring the viability of non-PCI/STEMI hospitals if regionalization were to be implemented.

The impact on hospitals and health systems will primarily involve a need for collaboration with their physicians to meet established certification guidelines and performance standards. When physician respondents were asked which performance standards would be most relevant for a primary PCI certification program, the most often cited responses were quality outcomes, treatment times, and volume, and the majority of hospital leaders interviewed indicated they were

TABLE 4. STEMI Certification Program Impact Study: Market Descriptions

	Small Market	Middle Market	Large Market
Market	City No. 1	City No. 2	City No. 3
Population	195 000	823 000	1 100 000
No. of hospitals	8	14	10
No. of hospitals with cardiac surgery capabilities	2	7	4
2004 Inpatient PCI volume	153	614	883

already tracking and reporting most AMI-specific outcome measures in view of the Joint Commission on Accreditation of Healthcare Organizations and CMS performance standards for AMI.

US Market Impact

Although a certification program would likely increase quality of care, it also could financially benefit hospitals that qualify for the certification and subsequently experience increased patient volume. However, it also could financially disrupt some hospitals. As previously discussed, cardiac services supplement low margins in other services for many hospitals (Table 3). The operating margin for PCI procedures was 3.6% and 9.5% for community hospitals and system-affiliated hospitals, respectively, in 2002. For comparative purposes, cardiac surgery procedures yielded an operating margin of 8.7% and 14.1%, respectively. This range compares favorably to the overall operating margin for all hospitals in the United States during 2002 (4.3%). For system-affiliated hospitals, which constitute the majority of hospitals, margins on cardiac surgical procedures are more than 3 times higher than overall margins. As such, any shift in cardiac services will have a profound financial impact. When national averages are applied to a community of system-affiliated hospitals, the loss of 100 inpatient PCI cases would create a $350 000 to $450 000 loss in contribution margin (the margin a hospital uses to offset fixed costs). A similar-volume loss of cardiac surgery procedures would result in a contribution margin loss of $1 million to $1.25 million. Under these circumstances, a hospital would be forced to absorb fixed costs in other typically less profitable service lines.

A loss of PCI or cardiac surgical volumes would lower a hospital's case-mix index, which would lower its overall Medicare reimbursement. A reduced case-mix index could also affect commercial insurance reimbursement. In all markets, reactions from the public, changes in managed care contracting practices, and the ability to reallocate or eliminate direct operating expenses will exacerbate the financial impact of program participation and volume shifts.

To better illustrate the potential outcome associated with a primary PCI certification, PwC modeled the impact on 3 distinct markets in actual cities in the United States selected on the basis of population, level of cardiac services, and number of hospitals (Table 4). The model accounted for the capacity of a system-wide approach and the various indirect financial outcomes discussed in this report. It was projected that the certification program would create a 25% shift in cardiac volumes. The 25% volume shift was used consistently in all 3 of the market examples to demonstrate the effect of cardiac cases moving from institutions within a service area.

The small-market example currently has 8 hospitals, 2 of which are capable of performing cardiac surgery. Conservatively speaking, the total market for cardiac surgery and PCI procedures is worth approximately $2.6 million in contribution margin. If a primary PCI certification program were developed, it is likely that both of the cardiac surgery–capable institutions would be eligible for and would seek the certification. Under this set of assumptions, should just 1 facility be selected as a program participant, 25%, or $640 000, of the potential contribution margin directly attributable to cardiac and PCI procedures could change hands. Furthermore, it is highly probable that the certification would indirectly impact other cardiac services in the market. If we assume that 25% of other cardiac service volumes (cardiac catheterization procedures, other PCI procedures, cardiac medicine) would move from the other providers in the market to the selected facility, each nonselected facility would stand to lose, on average, approximately $160 000 in contribution margin.

In the middle-market example, there are 14 hospitals, 7 of which are capable of performing cardiac surgery. Conservatively speaking, the total market for cardiac surgery and PCI procedures is worth approximately $14 million in contribution margin. Again, it is likely that each of the cardiac surgery–capable institutions would be eligible for and would seek the certification. Should 3 of these facilities be selected for program participation, each of the 2 nonselected hospitals would stand to lose $700 000 in contribution margin. With the forecasted shift of 25% of other cardiac service volumes from other providers in the market to the selected facilities, each nonselected facility would stand to lose, on average, approximately $450 000 in contribution margin.

In the large-market example, there are 10 hospitals, 4 of which are capable of performing cardiac surgery. The total market for cardiac surgery and PCI procedures is worth approximately $17.6 million in contribution margin. Again, it is likely that each of these 4 institutions would be eligible for and would seek the certification. Should 2 of these facilities be selected for program participation, each of the 2 nonselected hospitals would stand to lose $1.1 million in contribution margin. If we assume that 25% of other cardiac service volumes would move from the other providers in the market to the selected facilities, each nonselected facility would stand to lose, on average, approximately $840 000 in contribution margin.

Losses of PCI and cardiac surgery volumes could have a substantial direct financial impact on community and system-affiliated hospitals. These losses would be multiplied by changes in the overall case-mix index and other indirect, or halo, effects. These changes could ultimately impact a hospital's financial viability and limit access to healthcare services in general.

Losses to individual hospitals would need to be weighed against the benefits, in terms of reduced mortality and morbidity, to the nearly 400 000 patients who experience STEMI each year in the United States, against the cost savings to the global healthcare system, and against the economic value added to the population. However, modeling lives and costs saved if more patients had access to primary

PCI will require extensive additional study and will have to be based on the ideal system(s) and centers of care recommended after stakeholder consensus has been achieved. Therefore, PwC did not perform these analyses. The AWG reviewed a report on the estimated economic gains from declining mortality in the United States in which the authors estimated that a single percent reduction in mortality from cancer or heart disease would be worth nearly $500 billion to current and future Americans.[39] If one assumes that even half of the 33% of STEMI patients who do not receive any reperfusion therapy would be able to undergo primary PCI, with an absolute risk reduction of 4% (compared with no reperfusion), then 2640 lives per year would be saved. In addition, when performed at experienced centers in a timely fashion, primary PCI, compared with fibrinolytic therapy, saves 20 lives for every 1000 patients treated.[2] If one assumes that even half of the 31% of STEMI patients who receive fibrinolytic therapy would undergo primary PCI, with an absolute risk reduction of 2%, another 1240 lives would be saved. Therefore, implementation of strategies to increase the number of patients with access to primary PCI in a timely fashion could save nearly 4000 (or more) lives per year. In fact, in a study evaluating the projected cost-effectiveness of primary PCI, it was noted that the strategy was cost-effective at hospitals with existing catheterization laboratories under a wide range of assumptions and was cost-ineffective at low-volume or redundant laboratories, which supports the regionalization of cardiac services in urban areas.[40]

Role of the AHA

The majority of respondents believed that a coordinated effort between the AHA and an independent accreditation or medical specialty society would be the optimal structure for designing the program. The groups believed that the primary focus of the AHA should be on leveraging its relationships to ensure that the appropriate people are involved. Respondents in general said that because of the local nature of health care, the program should be developed as a broad framework that could be adapted to local processes and regulations. The experience of the American Stroke Association (a division of the AHA) with stroke certification,[41] which was developed in a similar fashion, would benefit that process. Although respondents believed the AHA should be at the forefront of organizing the program, there was a consensus that it should not regulate it. Proponents believe the AHA should remain the driving force for medical science and advocacy in cardiac care and should work with a separate entity for accreditation oversight. A certification program would ultimately benefit from the AHA's ability to bring together all interested constituents and its proficiency in disseminating information through local affiliates.

Conclusions

With a recognized need to improve the care of STEMI patients from its current state, key stakeholders would support a primary PCI certification program, with the understanding that some community hospitals might experience a negative financial impact. Each of the interview cohorts had common themes that resonated throughout the facilitated discussions. Rural hospitals, which depend heavily on cardiac service revenues, are concerned with their ability to maintain cardiac services under a new designation. They will likely advocate for longer ranges in transport time standards because of the greater distances between centers in rural settings. Urban hospitals believe that a certification program will assist with increasing patient volume and increased marketing efforts for their facilities. EMS providers recognize certification as an opportunity for additional training and education, both for their staff and for the hospitals. Health plans are already supporting similar programs for non–acute care providers and could use the certification program as a means to negotiate reimbursement rates.

Guiding Principles

In view of the evidence-based treatment recommendations for patients with STEMI and the demographic, political, and financial implications inherent in the establishment of systems of care to increase the number of patients with timely access to primary PCI, the AWG developed principles (below) to guide this initiative. A system of care for STEMI patients must have the following components:

1. Patient-centered care as the No. 1 priority
2. High-quality care that is safe, effective, and timely
3. Stakeholder consensus on systems infrastructure
4. Increased operational efficiencies
5. Appropriate incentives for quality, such as "pay for performance," "pay for value," or "pay for quality"
6. Measurable patient outcomes
7. An evaluation mechanism to ensure quality-of-care measures reflect changes in evidence-based research, including consensus-based treatment guidelines
8. A role for local community hospitals so as to avoid a negative impact that could eliminate critical access to local health care
9. A reduction in disparities of healthcare delivery, such as those across economic, education, racial/ethnic, or geographic lines

Next Steps: Role of AHA and Call to Action

The AWG agreed that the next step in the process after the development of this initial consensus statement was to convene a conference for all stakeholders to begin to develop an implementation plan (which may include a call for pilot studies or targeted research) for the establishment of systems (and centers) of care to increase the number of patients with timely access to primary PCI. The conference, "Development of Systems of Care for STEMI Patients," will be held in Boston, Mass, from March 30 to April 1, 2006. The goals of the conference are as follows:

1. To convene representatives from major stakeholders in the care of STEMI patients
2. To achieve consensus on the guiding principles for the establishment of a system (urban/suburban and rural) of care for STEMI patients
3. To develop the ideal implementation system from the perspective of each stakeholder (ie, patient, physician, EMS, emergency department, local hospital, tertiary center, payer) and in terms of outcomes and quality of care
4. To understand the barriers, gaps, and policy implications
5. To develop recommendations

Below is a partial list of participating key stakeholder organizations:

- *Patient:* Centers for Disease Control and Prevention; National Heart, Lung, and Blood Institute
- *Physicians:* AHA Councils on Cardiopulmonary, Perioperative, and Critical Care; Cardiovascular Nursing; Cardiovascular Surgery and Anesthesia; Clinical Cardiology; ACC; American College of Emergency Physicians; American College of Physicians; Society for Cardiovascular Angiography and Interventions; The Society of Thoracic Surgeons
- *Nurses:* AHA Council on Cardiovascular Nursing; American Association of Critical-Care Nurses; Emergency Nurses Association
- *EMS:* American Ambulance Association; Association of Air Medical Services; National Association of State EMS (NAEMS) Directors; NAEMS Physicians; National EMS Information Systems; National EMS Management Association
- *Community hospital/regional center:* National Rural Health Association; Society for Chest Pain Centers; state hospital associations
- *Payers:* Aetna; CMS; Blue Cross Blue Shield Association; United Health Care
- *Evaluation/outcomes:* AHA Quality of Care and Outcomes Research Interdisciplinary Working Group; Agency for Healthcare Research and Quality; Food and Drug Administration; Joint Commission on Accreditation of Healthcare Organizations

The AHA is issuing a call to action to improve both the implementation and the timeliness of reperfusion with primary PCI for STEMI patients in the United States. It is clear there is a need for improvement along the continuum of the treatment pathway beginning with patient education, through EMS systems, to hospital-based strategies. This initiative is fueled by the concern about the number of patients who do not receive evidence-based therapy for STEMI and by the results of market research that indicate that those involved in the care of STEMI patients support the concept of developing ideal systems of care. The AHA is committed to mobilizing healthcare providers, policy makers, and payers to explore relative advantages, costs, and implications for the global healthcare system in pursuit of improved outcomes and quality of care delivered to patients with STEMI.

Appendix

PwC's Research Methods and Sources

Hospitals interviewed included a geographically diverse population of rural and urban hospitals, including some academic medical centers. This sample included hospitals both with and without cardiac surgery capabilities. Health plan interviews were conducted to capture opinions from the largest private payers. In all, 30 interviews were conducted.

A Web-based survey was performed with a random sample of members of the AHA Council on Clinical Cardiology to gain a thorough understanding of current clinical treatment patterns for STEMI patients in markets across the United States. E-mail surveys were received from 101 respondents.

Multiple databases were used to analyze the policy landscape for STEMI care. The MediRegs database was used to conduct stored searches that examined specific key words (eg, cardiac, centers of excellence, primary angioplasty, acute myocardial infarction, heart attack, diversion protocol, bypass, cardiac systems, and certificate of need) on a weekly basis. The search spanned the entire reimbursement library, with access to more than 40 000 documents. MediRegs's reimbursement library contains Federal legislation (US Code and public laws, Code of Federal Regulations, Federal Register); CMS, Office of Inspector General (OIG), Department of Health and Human Services, Public Health Service, Occupational Safety and Health Administration (OSHA), Food and Drug Administration (FDA), CDC, Drug Enforcement Agency, Social Security Administration (SSA), Department of Defense (DOD), and state administrative codes; CMS manuals, program memos, forms, and rulings; CMS Medicaid and managed care policy; CMS contractor local medical review policies and bulletins; OIG reports, advisory opinions, fraud alerts, and corporate integrity agreements; FDA guidelines and product approvals; OSHA directives, standard interpretations, and fact sheets; SSA manuals and rulings; DOD TRICARE and CHAMPVA (Civilian Health and Medical Program of the Department of Veterans Affairs) manuals; court and administrative decisions, including all Provider Reimbursement Review Board, CMS administrator, and Departmental Appeals Board decisions and court cases back to 1991; General Accounting Office reports; and comprehensive collections of individual state legislation, HIPAA (Health Insurance Portability and Accountability Act of 1996), Prospective Payment System, EMTALA, and Stark information. In addition to the databases, the 2004 National Directory of Health Planning, Policy and Regulatory Agencies, the 15th edition published by the American Health Planning Association, was used for the CON research.

PwC's financial model analyzed a shift in cardiac volume at 25% of business by diagnosis-related groups in the following services for cardiac care: open heart (104 to 109), cardiac catheterization (124 to 125), PCI (516, 526), PTCA (517, 518, 527), and cardiac medicine (110, 111, 115 to 117, 121 to 123, 126, 127, 130 to 145). Data sources for this modeling included the following:

- 2001, 2002, and 2003: all payer state discharge data from 25 states, 2003 Medicare hospital market area file, CMS 2003
- MEDPAR (Medicare Provider Analysis and Review) data, CMS June 2002
- TEFRA (Tax Equity and Fiscal Responsibility Act of 1982) Medicare enrollment file
- 2004 and 2009 demographic projections, Solucient Market Planner Plus; Claritas Inc

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Writing Group Disclosures

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Eric Bates	University of Michigan	None	None	Genentech, Boehringer Ingelheim, Roche, PDL BioPharma	None	None	None

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