Regional Centers of Excellence for the Care of Patients with Acute Ischemic Heart Disease

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KEY POINTS

• Coronary artery disease (CAD) is the leading cause of death and disability in the United States. Specialized centers of care have been established for the treatment of patients with trauma or stroke. The number of specialized centers of care for patients with acute ischemic heart disease, however, is not commensurate with the magnitude of this public health problem.

• "Regional" care for patients with acute coronary syndrome (ACS) implies meaningful networking associations between community hospitals and rural hospitals that do not provide tertiary cardiovascular services and a tertiary cardiovascular service provider. The definition of networking ranges from being a merged affiliate (same hospital system) to sharing common patient care protocols as well as tracking, reporting, and auditing clinical practice guideline compliance, core measures, and clinical outcomes.

• A direct relationship exists between annual volumes of cardiovascular procedures (coronary bypass surgery, coronary angioplasty, or stenting)—for physicians or operators as well as for hospitals or facilities—and optimal clinical outcomes, including survival. Those doctors and hospitals that perform the highest annual volumes of procedures have the best outcomes.

• Medical resources are limited, and a critical shortage of both sub-specialized nurses for intensive cardiovascular care and cardiovascular physician providers is an ongoing issue. The current trend toward proliferation of smaller “heart centers,” supposedly for patient convenience, is counter to the well-established link between higher procedural volumes and better clinical outcomes and also further taxes the already limited resource pools of sub-specialty nurses and doctors.

• The prehospital phase of acute ST elevation myocardial infarction (STEMI) is critically important. The performance and transmission of a 12-lead electrocardiogram (ECG) by emergency medical service providers in the field at the point of first medical contact has been demonstrated to significantly reduce delays to the initiation of treatment for STEMI with either fibrinolytic therapy or primary percutaneous coronary intervention (PCI) and, thus, to reduce mortality.

• The current American College of Cardiology/American Heart Association (ACC/AHA) Clinical Practice Guidelines recommend that both “door-to-needle” (<30 minutes) and “door-to-balloon” (<90 minutes) treatment times not represent the “optimal” delays for treatment, but should be considered the “longest acceptable” delays for initiating therapy.

• Most concerns about the strategies to regionalize the care of patients with ACS have focused on the lack of a clear consensus regarding the specific nature of regionalization as well as on the economic and market impacts of such a strategy. The most likely initial focus of a regionalized strategy for ACS care would appear to be STEMI, which has more definitive electrocardiographic and clinical diagnosis criteria and represents a more widely acknowledged “medical emergency” for which efficacy of treatment is time dependent. The process for the credentialing of systems of care for STEMI patients has been developed by the American Heart Association as the Mission: Lifeline initiative, with individual states charged with the responsibility for creating regionalized centers and systems for excellence in care.

The past decade has witnessed a remarkable evolution both in our understanding of the pathogenesis of ACS and in therapeutic innovation for catheter-based technologies and adjunctive pharmacotherapies. Spontaneous plaque rupture is followed by platelet adherence, activation, and aggregation, with fibrin incorporation leading to thrombus propagation. The severity of the resultant clinical syndrome is manifest in direct proportion to the degree of restriction in coronary blood flow and ranges from asymptomatic (insignificant restriction) to non–ST elevation ACS (NSTEMI), including unstable angina and non–ST elevation myocardial infarction (STEMI), which are associated with severe coronary flow restriction, as well as STEMI, which is usually secondary to complete coronary occlusion. As the pathogenesis of coronary flow restriction is multi-factorial (platelets, thrombus, vasomotion, and mechanical obstruction), it is best addressed by a multi-modal approach to therapy (anti-platelet, anticoagulant, and fibrinolytic therapies and catheter-based PCI) implemented in a timely manner. Indeed, the rapid restoration of normal coronary blood flow—via pharmacologic and mechanical recanalization of an occluded coronary artery—limits the extent of myocardial necrosis and reduces mortality. However, a concerted, integrated approach to the therapy for ACS is complicated by the diversity and extent of resources required for the comprehensive treatment of this disease spectrum and by the various settings (urban/suburban and rural) in which care is delivered. The concept of regional centers of excellence for the care of patients with ACS has rapidly evolved and has become the focus of a collaborative initiative involving the American Heart Association and the American College of Cardiology as well as individual states which have been charged with regional organization. It is important to clearly define “regional” so that all of the constituents involved in the care of patients with ACS understand the concept and the implications. The term regional implies meaningful networking associations between community hospitals, rural hospitals, or both, which do not provide tertiary cardiovascular services (including PCI), and a tertiary cardiovascular service provider. The definition of “meaningful networking” includes, at one end of the spectrum, being a merged affiliate (same hospital system) and, at the other, merely sharing common protocols for patient care as well as tracking, auditing, and reporting clinical practice guideline compliance, core measures, and clinical outcomes. These “networks” should have well-defined and rehearsed systems for patient transport that will differ, depending on care being delivered in an urban, suburban, or rural setting.

Scope of the Problem

The approach of creating specialized centers of care for treating victims of trauma and, more recently, stroke has been shown to improve clinical outcomes. Trauma victims treated in trauma centers had significantly lower mortality compared with patients treated in a non–trauma center. Specialized centers for the care of patients who had suffered a stroke have been instituted with the standard of care established by the American Heart Association and with a formal process provided through the Joint Commission on Accreditation of Healthcare
The Case for Regionalized Care

Both where and how patients with acute ischemic heart disease are treated has been the subject of an ongoing debate. The divergence of opinion ranges from belief that “the real issue is not whether the creation of specialized centers for care of ACS patients would provide an important advance, but how to create them,” to the contention that “clear, compelling evidence of the benefits of ACS regionalization within the United States and a better understanding of its potential consequences are needed before implementing a national policy of regionalized ACS care.”

Proponents assert that the treatment of patients with ACS at regional centers with dedicated facilities will save lives by providing higher-quality care and by improving access to new technologies as well as to specialist physicians. These beliefs are, in large part, based on prior experiences with regard to trauma and stroke treatments in the United States as well as on experiences gleaned from multiple European countries, where regionalized systems for ACS care are in place. Although efficiency of process and high quality of outcomes have been demonstrated in several European systems, the “generalizability” of these data to current practice in the United States has been questioned. As European health systems are characterized by centralized financing as well as control of hospital and emergency transportation organizations, they avoid many of the financial reimbursement “barriers” present in the U.S. health care system. Furthermore, the logistics of providing regionalized care in the United States, where the population is more geographically dispersed, present additional challenges. Nevertheless, several states and municipalities have initiated programs for the regionalized care of patients with ACS.

The American Heart Association (AHA), in conjunction with the American College of Cardiology (ACC), has initiated a national program (Mission: Lifeline) to provide timely primary PCI to more patients with STEMI and to create both systems and centers of care, with the goal of reducing deaths from CAD and stroke by 25% by the year 2010. These initiatives have been, in part, prompted by recent studies that demonstrated shortfalls in the use of quality-assured, guideline-driven care for patients with ACS as well as wide variability in treatments administered on the basis of age, gender, race, geographic location, and time of presentation.

A treatment-risk “paradox” has, indeed, been demonstrated with regard to the use of both proven, guideline-based medical therapies (specifically early administration of thienopyridine, platelet glycoprotein [GP] IIb/IIIa inhibitors, or both) and early angiography and coronary revascularization in patients who present with NSTEACS. Although randomized clinical trials have demonstrated that the benefit of an early invasive treatment strategy in NSTEACS is directly proportional to patient risk profile, the propensity to receive such treatment has been greatest in those patients at lower risk. Similarly, treatment with clopidogrel, platelet GP IIb/IIIa inhibitors, or both, in addition to transfer for angiography at a non–PCI capable facility, is inversely proportional to patient risk strata. This observation may have arisen from physician misconceptions about benefit–harm trade-offs or concerns about treatment complications. Indeed, one analysis suggests that at least 25% of opportunities to initiate guideline-based care are missed in contemporary community practice. Finally, the process of care for patients with ACS has been further complicated by the fact that for many U.S. hospitals, the provision of treatment for CAD is the major determinant of their financial well-being. Profitability from a cardiovascular service line is often used to offset deficits incurred by the provision of other important but less profitable services such as mental health, obstetrics, and emergency medicine.

Potential Advantages of Regional Centers

In general, a patient experiences a better clinical outcome when treated in a center that frequently encounters the particular health problem that the patient has (“Practice makes perfect”). A direct relationship has been demonstrated between physician–operator as well as facility procedural volumes and optimal clinical outcomes with both elective or primary PCI and coronary bypass surgery. A similar relationship has been demonstrated between hospital ACS patient volume and clinical outcomes as well as adherence to ACC/AHA guidelines. Doctors and hospitals performing the highest volumes of procedures demonstrate the best clinical outcomes, including survival benefit. Higher-volume PCI centers demonstrate lower risk-adjusted in-hospital mortality as well as less frequent need for emergency coronary bypass grafting (CABGs), even in the current era of coronary stenting. Indeed, the relative benefit of primary PCI versus fibrinolysis for the treatment of STEMI may be completely lost when primary PCI is performed in a low-volume institution. Data from the New York statewide database demonstrate that physician–operator volume significantly influences the success rate of primary PCI procedures and that hospital volume influences (by 50%) in-hospital mortality following the procedure. These observations have led to the belief that PCI “generally should not be conducted in low-volume hospitals unless there are substantial overriding concerns about geographic or socioeconomic access” and to recommendations for hospitals performing primary PCI for STEMI to satisfy specific minimum requirements for volume of procedures.

A pooled analysis of multiple studies involving over one million PCI procedures confirms the relationship between lower procedural volumes (<200 cases) with an increase in both in-hospital mortality and the requirement for emergency CABG following PCI. Other studies have suggested that institutional volumes more than 200 cases yearly may be too low. For example, an analysis of 37,848 PCI procedures, performed at 44 centers in 2001–2002 as part of the Greater Paris area PTCA (percutaneous transluminal coronary angioplasty) registry, demonstrated an increased incidence of major adverse cardiovascular events (MACEs) following elective as well as primary PCI procedures in centers performing less than 400 procedures yearly. In addition, in-hospital mortality increased following primary PCI procedures in lower-volume (<400 PCI/year) programs. These investigators concluded that “tolerance of low-volume thresholds for angioplasty centers with the purpose of providing primary PCI in acute myocardial infarction should not be recommended, even in underserved areas.” More recently, the relationship between institutional volume and clinical outcomes has been demonstrated in centers providing primary PCI without on-site cardiac surgical facilities. No differences in outcomes were observed in the ACC-NCDR (National Cardiovascular Data Registry) among primary PCI centers stratified on the basis of cardiac surgical capacity (with vs. without). However, a significant reduction in risk-adjusted mortality was observed in the highest tertile of primary PCI institutional volume (mean, 83 processes per year) among centers without surgical capacity in C-PORT (Community Hospital-Based, Prospective, Randomized Trial). Thus, the established link between procedural volumes and quality outcomes persists despite the advent of coronary stenting and improvements in adjunctive pharmacotherapies. Finally, mortality was reduced among patients with...
ADHERENCE TO PRACTICE GUIDELINES

The process of care as measured by ACC/AHA guideline adherence has been linked to both in-hospital and late (6–12 month) survival following presentation of ACS. An analysis of hospital composite guideline adherence quartiles demonstrated an inverse relationship between the adherence to guideline-compliant care and the risk adjusted in-hospital mortality rate. For every 10% increase in guideline adherence, a 10% relative reduction in in-hospital mortality was observed (Fig. 36-1). This observation supports the central hypothesis of hospital quality improvement—that better adherence with evidence-based care practices will result in better outcomes for patients. The current system of nonregionalized care has been suboptimal in promoting and achieving guideline adherence, even in the case of those ACS patients who present with “high-risk” indicators.

For example, only 33.8% and 44.2% of patients with elevated serum troponin levels in the CRUSADE (Can Rapid Risk Stratification of Unstable angina patients Suppress Adverse outcomes with Early implementation of the ACC/AHA guidelines) registry received early (<24 hours) GP IIb/IIa inhibition or early (<48 hours) cardiac catheterization, respectively. Similarly, although a direct correlation exists between the presence and magnitude of serum troponin elevation and in-hospital mortality, no correlation was observed between troponin levels and the performance of early (<48 hours) coronary angiography (Fig. 36-2), which has a class I ACC/AHA guideline recommendation for patients with NSTEACS with “high-risk” indicators (including elevated troponin). Both compliance with clinical practice guidelines and the ability to monitor or audit adherence to guidelines appear to be enhanced in higher-volume, regional programs. Adherence to guidelines was improved following establishment of an integrated, regional program for ACS care and was highest among the cohort of patients who received revascularization through PCI. Finally, guideline-adherent care of patients without STEMI was significantly greater in centers with cardiac surgical capabilities compared with those without those capabilities. Lower-volume, small community hospitals are unlikely to allocate their capital resources and personnel to adequately track, collate, and report clinical outcomes or process measures (guideline compliance). Certainly, from the perspectives of national and regional payers and the Centers for Medicare and Medicaid Services, monitoring and auditing data derived from multiple small hospitals versus those from fewer, larger networked systems have different levels of complexity. Indeed, in a recent survey commissioned by the AHA, only slightly more than half the hospitals queried were systematically tracking times to STEMI treatment (“door-to-needle” or “door-to-balloon” times), infection rates, re-admission or stroke rates (to 30 days after the procedure), recurrent MI, or mortality following either PCI or coronary bypass surgery. This observation is made more meaningful by the fact that multiple national initiatives such as Get with the Guidelines, the Cardiac Hospitalization Atherosclerosis Management (CHAMPS), the...
Guidelines Applied to Practice (GAP) project, the National Registry of Myocardial Infarction (NRM1), and the CRUSADE (ACTION) registry have recently placed emphasis on system quality through systematic measurement of both care processes and clinical outcomes. The positive impact of these programs may be reflected in increased compliance with guidelines for early (≤24 hours) as well as predischarge medical therapies, in addition to the use of diagnostic angiography and revascularization. Similarly, the door-to-balloon (D2B) alliance, initiated in November 2006, has resulted in increased use of recommended strategies for process improvement as well as a greater proportion of patients being treated within the recommendations of the guidelines.

PERCUTANEOUS CORONARY INTERVENTION CENTERS WITHOUT ON-SITE CARDIAC SURGICAL FACILITIES

The current trend toward the proliferation of "PCI centers" which lack on-site cardiac surgical facilities for the performance of primary PCI in STEMI may be associated with suboptimal clinical outcomes. In an analysis of 625,854 Medicare patients who underwent PCI, in-hospital and 30-day mortality was significantly increased in those centers without on-site cardiac surgical facilities and was primarily confined to hospitals performing a low number (≤500) of PCI procedures in Medicare patients. Even in the context of a completely integrated community hospital—tertiary hospital system, the performance of primary PCI without on-site cardiac surgical facilities was associated with a trend toward increased hospital mortality compared with primary PCI performed at the tertiary center despite exclusion of the sickest patients (with refractory cardiogenic shock or ventricular arrhythmias) from PCI at the community center. Although single-center studies have reported excellent outcomes in patients undergoing primary PCI at hospitals without on-site cardiac surgical facilities, the one randomized trial that compared fibrinolysis to primary PCI at hospitals without surgery on-site was flawed by an inadequate sample size and by a majority of patients enrolled at a single site. More recently, large registry data suggested a similar risk for mortality following both primary PCI and nonprimary PCI performed at hospitals with versus without cardiac surgical facilities. Nonetheless, a significant mortality benefit following primary PCI in nonsurgical centers was achieved only by those institutions in the highest tertile of procedural volumes. Furthermore, the requirement for repeat revascularization appears to be increased at both 30 days and 1 year following primary PCI at hospitals without on-site cardiac surgical facilities. On the basis of these and other data, the current ACC/AHA guidelines for the performance of PCI designate a class III (practice may be harmful and is not recommended) indication for elective PCI and a class IIB (usefulness is less well established by evidence or opinion) for primary PCI in hospitals without on-site cardiac surgical facilities and point out the need for additional evidence base.

LIMITED MEDICAL RESOURCES

The current trend toward the proliferation of small "heart centers" supposedly for patient convenience is counter to the well-established link between higher procedural volumes and better clinical outcomes; in addition, this taxes the already critically limited resource pools, including specialized nurses and subspecialty-trained physicians. Patients with more complex cardiovascular diseases (congestive heart failure [CHF], acute myocardial infarction [AMI]) fare better with care from subspecialty physicians (cardiologists) compared with care provided by generalists. One strategy for dealing with the mismatch between the emerging evidence in favor of an interventional (catheter-based) approach to the treatment of ACS and the current availability of such care is to establish regionalized centers for ACS care. Such centers would provide state-of-the-art radiographic equipment, a broad array of interventional supplies, and an experienced ancillary staff. Both subspecialty nurses and trained cardiologists are in limited supply. The proliferation of small "heart centers" that focus on PCI, with duplication of services, further taxes the limited resource pools and undermines the ability of established tertiary care centers to provide quality care. Indeed, the development of more PCI programs, particularly those without on-site cardiac surgical facilities, appears unnecessary in the context that the majority (>80%) of the adult U.S. population lives within a 60 minute commute to an existing PCI center. In fact, a recent study indicated that the expansion of PCI-capable hospitals was generally confined to urban and suburban regions and that this had a limited effect on increasing patient access to such care.

Benefit of Catheter-Based Therapy for Acute Coronary Syndrome

ST ELEVATION MYOCARDIAL INFARCTION

The current ACC/AHA guidelines for the treatment of STEMI promote reperfusion therapy (both fibrinolysis and PCI), with the choice of strategy based on resource availability and the anticipated time course for treatment implementation. The relative advantage of PCI versus fibrinolytic therapy depends on several factors. First, as primary PCI entails an obligation delay for implementation (versus fibrinolysis), the relative advantage of PCI depends on the relative delay to definitive treatment (balloon inflation). Pooled analyses of multiple randomized controlled clinical trials suggest that the survival advantage in favor of PCI is inversely proportional to the relative delay in PCI implementation and that the advantage may be lost if the PCI-related delay (door-to-balloon minus door-to-needle time) exceeds 60 to 110 minutes. Differences between these analyses may be explained by differences in patient risk profile. Indeed, a survival advantage in favor of PCI is evident only when the risk of death at 30 days following fibrinolytic therapy exceeds approximately 4%; Longer relative delays may still be associated with a PCI-related survival advantage in those patients at highest risk for death following fibrinolysis. Thus, accurate risk assessment should be part of any STEMI treatment triage algorithm. The relative survival advantage of PCI versus fibrinolysis is also dependent on the case volume experience of both the operator (cardiologist) and the hospital facility. As noted previously, the best clinical outcomes and the greatest relative advantage of PCI are obtained by the highest-volume operators and institutions. The link between case volume and optimal outcomes has been established both for physician operators and hospitals and is evident with or without the availability of on-site cardiac surgical facilities. Transport to a center capable of performing PCI yields superior clinical outcomes compared with on-site (community hospital) fibrinolytic therapy when the randomization (treatment decision) to balloon time approximates 90 to 120 minutes. Importantly, no adverse outcomes related to patient transport have been observed in these analyses. Despite the observation that the vast majority (>80%) of individuals in the United States who experienced STEMI in the year 2000 lived within a 60-minute commute to an established PCI center, more recent data regarding patients who first present with STEMI to a community hospital (non-PCI facility) and are subsequently transported to a PCI facility demonstrate excessive delays to definitive treatment. Indeed, initial presentation to a non-PCI center has been identified as a major determinant of prolonged door-to-balloon times and reflects the lack of a well-defined integrated system with protocol-driven algorithms for care and dedicated transport facilities. Of concern is the fact that door-to-door-to-balloon times (door at non-PCI facility to balloon at PCI facility) for patients requiring transport were a median of 180 minutes and only 15% received PCI within 120 minutes from initial presentation. Not surprisingly, although the diagnosis of STEMI as well as in-hospital mortality rates associated with STEMI have declined over
The rapid transport of patients with STEMI to the nearest PCI-capable facility for care may, however, be limited by several factors. First, only a minority (≤55%) of EMS–transported patients with chest pain actually have STEMI. Second, only a minority (~10%) of EMS systems have 12-lead ECG capabilities. Third, a precedent “mandate” exists for the transport of patients with suspected STEMI to the nearest facility, even when fibrinolysis may be contraindicated and the facility does not provide primary PCI. Fourth, evolution toward a more integrated process of pre-hospital care is complicated by the fact that there are 329 different EMS regions in the United States with more than 993 hospital-based EMS systems. Remarkably, hospital-based EMS systems represent only 6.5% of all EMS providers, with the remainder comprising private, third-party systems (48.6%) and fire station–based systems (44.9%). Although the transport time to a specialized PCI center may appear long, it can be more than counterbalanced by an integrated EMS system with pre-notification. A doubling of the recommended transport time has been proposed for patients with suspected STEMI who are transported to a “center of excellence” where the target door-to-balloon time is 60 minutes or less. Such efficiency of process can be achieved only through an integrated system for STEMI care that incorporates pre-hospital ECG for earlier diagnosis and expedited triage. Indeed, recent data involving ambulance-based diagnosis of STEMI in the field with pre-hospital activation of the cath lab and direct transport to the interventional center have demonstrated reduced symptom onset-to-balloon times and improved survival. Finally, more uniform evolution toward integration in process of STEMI care has been impeded by diverging incentives, the lack of coordinated objectives, and ostensibly competing strategies. For example, in many regions, particularly those without requirements for a state-regulated certificate of need—there has been a proliferation of new cath labs for the provision of primary PCI in centers without on-site cardiac surgical support. Conversely, other regions, including Minneapolis, North Carolina, Los Angeles, and Boston, have developed integrated EMS systems with focus on pre-hospital diagnosis and triage to an established center of excellence proficient in primary as well as elective PCI.

The competing strategies—one focused on building more small PCI centers and the other on more efficient and effective use of existing PCI centers through pre-hospital–EMS integration—have drawn support from divergent financial incentives among different stakeholders in the process of care. Only recently have sophisticated modeling techniques been used to compare the relative efficacy and cost of these “build more” versus “use more effectively” strategies for PCI facilities as they specifically pertain to the care of STEMI patients. Interestingly, and importantly, the strategy focused on EMS integration, pre-hospital diagnosis, and triage and better use of already existing PCI facilities was found to be more effective and less costly than the strategy of proliferating new PCI facilities (Fig. 36-4). The coordination of strategies as well as the integration of essential pre-hospital and hospital resources for ACS care at the state level has been the focus of the national Mission: Lifeline initiative of the AHA in conjunction with the ACC.

**NON-ST ELEVATION ACUTE CORONARY SYNDROME**

Despite therapy with aspirin, unfractionated or low-molecular-weight heparin, nitrates, and β-blockers, patients with NSTEMI remain at appreciable risk for death (~6%), recurrent MI (~11%), or need for coronary revascularization (~50%-60%) for up to 1 year following diagnosis. In the context of therapeutic innovation in catheter-based technology and adjunctive pharmacotherapy, the cumulative weight of data from randomized controlled trials supports the use of an early invasive treatment strategy (angiography followed by revascularization, if feasible) versus conservative treatment strategy (medical therapy with angiography for spontaneous or provoked ischemia). Furthermore, the ACC/AHA guidelines clearly recommend risk
assessments before triage for invasive treatment. The relative benefit of invasive (versus conservative) treatment is directly proportional to patient risk profile as reflected by the Thrombolysis in Myocardial Infarction (TIMI) study group: PURSUIT (Platelet GP IIb/IIIa in Unstable Angina: Receptor Suppression using Integrilin); and, GRACE (Global Registry of Acute Coronary Events) risk stratification schemes. In addition, the magnitude of benefit attributable to the invasive (versus conservative) treatment strategy appears to be inversely correlated with the duration of delay from presentation to revascularization and directly correlated with both the relative extent of revascularization in the active treatment (versus the control or conservative) groups as well as the duration of clinical follow-up.

Recent data suggest that earlier (<24 hours following presentation) revascularization provides greater benefit as reflected by a reduction in the occurrence of cardiovascular death, MI, or stroke compared with later (>36 hours) revascularization, particularly in patients with NSTEACS at highest risk. Similarly, pooled patient-level data from the FRISC II (Fast Revascularization during InStability in Coronary disease), ICTUS (Invasive versus Conservative Treatment in Unstable coronary Syndromes), and RITA-3 (Randomized Intervention Treatment of Angina 3) randomized trials show durable long-term (5 years) relative clinical benefit for the invasive (versus conservative) treatment strategy (Fig. 36-5). The major source of controversy is no longer the choice of treatment strategy (invasive versus conservative) but rather the fact that although the benefit of an early invasive strategy is proportional to patient risk, the propensity to receive such treatment is greatest in patients at lower risk. This treatment–risk paradox may be caused by physician misconceptions regarding benefit–harm tradeoffs or concerns about treatment complications and has been observed in relationship to the performance of angiography, PCI, or both as well as the use of platelet inhibitor therapies.

Finally, the transport of patients from a non-PCI facility to one capable of performing PCI for NSTEACS was also inversely proportional to patient risk strata. The importance of the treatment–risk paradox is further magnified by the observation that compliance with the current ACC/AHA guidelines (including early angiography) is inversely correlated with in-hospital mortality for ACS. Furthermore, evidence-based therapies (anti-platelet agents, β-blockers, lipid-lowering agents, angiotensin-converting enzyme [ACE] inhibitors) initiated before hospital discharge are associated with an incremental survival advantage in follow-up. The fact that performance measures (compliance with guidelines) relate process of care to mortality presents an opportunity to define strategies that enhance compliance and use of current guidelines.

Regional Centers of Care for Patients with ST Elevation Myocardial Infarction

The technology available to EMS providers that allows transmission of a pre-hospital 12-lead ECG makes the diagnosis of STEMI evident at the time and place of first medical contact. The integration of EMS and the incorporation of the pre-hospital phase for ACS evaluation and diagnosis are integral components of a regionalized system for STEMI care. In addition, STEMI is the logical initial objective for a regionalized ACS treatment strategy in that five of Medicare’s 10 quality indicators focus on STEMI care. Thus, several system process or quality measures are already in place to provide a performance incentive to define “regional networks” for STEMI care. The development of such regional networks for STEMI care should facilitate adherence to guidelines as well as the ability to monitor, audit, and evaluate data. As previously noted, combinations of evidence-based therapies (anti-platelet agents, β-blockers, lipid-lowering agents, ACE inhibitors) provide incremental survival advantage to 1 year following

### Figure 36-4

Comparative effectiveness of ST elevation myocardial infarction regionalization strategies. Hospital-based (expansion of PCI-capable facilities) versus EMS-based (regionalization with EMS integration for existing PCI facilities) demonstrates that the EMS-based strategy is less costly and more effective. PCI, percutaneous coronary intervention; EMS, emergency medical system; QALYs, quality-adjusted life years. (Reproduced with permission from Concannon TW, Kent DM, Normand SL, et al: Comparative effectiveness of ST-segment elevation myocardial infarction regionalization strategies, Circ Cardiovasc Qual Outcomes 3:1–8, 2010.)

### Figure 36-5

presentation of ACS, especially STEMI. Greater adherence to guidelines has been observed in hospitals with higher volumes of STEMI cases, in centers with on-site cardiovascular surgical facilities, and following the implementation of national process of care and quality initiatives (D2B Alliance). Smaller centers are unlikely to allocate the resources necessary to optimally track, audit, and report these measures.

**MODEL SYSTEMS OF CARE**

A regionalized approach to the provision of primary PCI therapy for STEMI has been successfully implemented in major metropolitan areas of the United States, for example, Minneapolis. Through partnership with community hospitals in standardized protocol-driven algorithms for care, designated transport systems, and enhanced multidisciplinary communication (among the EMS, the emergency physician, and the interventional cardiologist), the Minneapolis Heart Institute at Abbott Northwestern Hospital has demonstrated the ability to promptly assess and treat STEMI patients coming from a broad area (90–120 minute transit). By focusing on collaboration and integration of resources, community hospitals initiate adjunctive pharmacotherapies in patients who present with STEMI and emergently transport these patients to the interventional team waiting at Abbott Northwestern Hospital (Fig. 36-6). These data demonstrate regional systems in the United States can achieve results equivalent to those of smaller European centers with organized transfer systems (Table 36-1). Similar results have been duplicated in other regional STEMI systems. A statewide approach is being used in North Carolina with RACE (Reperfusion of Acute Myocardial Infarction in North Carolina Emergency Department). The Initiative uses standardized protocols and integrated systems for the treatment and timely transfer of patients with STEMI in five regions in North Carolina. The RACE program demonstrated a significant improvement in time to treatment at both PCI and non-PCI hospitals, resulting in increased timely access to PCI on a statewide level. The significance of these regional programs resulted in a new class I recommendation in the recent ACC/AHA guidelines for STEMI that “each community should develop a STEMI system of care.” This experience stands in stark contrast to the National Presentation of ACS, especially STEMI.

![Figure 36-6](image_url) Demographic distribution of multiple community hospitals participating in a network for providing primary percutaneous coronary intervention (PCI) for ST elevation myocardial infarction with Minneapolis Heart Institute in Minneapolis, MN. A protocol-driven algorithm for adjunctive pharmacotherapies is illustrated for patients originating within a 90-minute radius for ground transport (Zone 1) (A) or for those patients originating within a 90- to 120-minute radius (Zone 2) (B). Participating centers have an established, rehearsed mechanism for patient transport. Angiographic and clinical outcomes following transport are comparable with those observed in patients admitted directly to the Abbott Northwestern Hospital in Minneapolis (see Table 36-1).
SECTION 3 Coronary Intervention

The discrepancy between current practice and what can be achieved through collaboration and avoidance of duplication of services calls for the development of an optimal process for ACS care. The striking limitations of the current process for STEMI care is evidenced by the absence of any improvement in times to treatment despite widespread dissemination of “benchmark” goals for therapy (door-to-fibrinolytic infusion time or door-to-balloon time) in the Registry of Myocardial Infarction 3 (NRMI 3) and NRMI 4 data regarding patients with STEMI who first present to a community hospital and are subsequently transported to a tertiary facility for PCI\(^69\). In the absence of a well-defined, integrated system with protocol-driven algorithms for care and dedicated transport facilities, the median door-to-balloon time from NRMI 3 and NRMI 4 is 180 minutes, and only 15% of patients receive PCI therapy within 120 minutes.\(^69\) The discrepancy between current practice and what can be achieved through collaboration and avoidance of duplication of services calls for the development of an optimal process for ACS care.

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<table>
<thead>
<tr>
<th>TABLE 36-1 Time to Treatment and 30-day Mortality for Minneapolis and Iowa Heart Centers Regional STEMI Programs at Minneapolis and Iowa Heart Centers</th>
<th>Minneapolis Heart</th>
<th>Iowa Heart</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCI</td>
<td>Total time to treatment</td>
<td>64 (44, 83)</td>
<td>59 (46, 71)</td>
</tr>
<tr>
<td>Zone 1</td>
<td>95 (81, 117)</td>
<td>102 (90, 121)</td>
<td>0.0008</td>
</tr>
<tr>
<td>Zone 2</td>
<td>123 (101, 152)</td>
<td>136 (122, 167)</td>
<td>0.0001</td>
</tr>
<tr>
<td>PCI</td>
<td>5.4</td>
<td>5.7</td>
<td>0.86</td>
</tr>
<tr>
<td>30-day mortality (%)</td>
<td>Zone 1</td>
<td>5.3</td>
<td>3.4</td>
</tr>
<tr>
<td>Zone 2</td>
<td>6.6</td>
<td>5.8</td>
<td>0.68</td>
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PCI, percutaneous coronary intervention.

Results from the Minneapolis Heart Institute and Iowa Heart regional STEMI networks, which include the PCI center at Abbott Northwestern Hospital in Minneapolis and the Mercy Medical Center in Des Moines, Iowa, in Zone 1 hospitals \(N = 21\) up to 60 minutes from the PCI center. These patients have an expected door-to-balloon time of <90 minutes and are treated with aspirin 325 mg, clopidogrel 600 mg, unfractionated heparin, and primary PCI. Zone 2 patients are treated with a pharmaco-invasive approach, which includes the medications above plus half-dose tenecteplase \(N = 32\) hospitals from 60 to 120 miles in Iowa or 60 to 210 miles from the PCI center in Minnesota).

Total time to treatment and 30-day mortality by zone in Minnesota and Iowa are shown. Despite geographic differences, overall time to treatment and 30-day mortality rates are remarkably similar and demonstrate the ability to expand the benefits of primary PCI for up to 210 miles from a PCI center.

form of guidelines.\textsuperscript{101} Indeed, these recommended times to treatment (30 minutes for door-to-fibrinolytic infusion; 90 minutes for door-to-balloon) are not "ideal" times but, rather, the longest times that should be considered acceptable by the medical system.\textsuperscript{102,103} Nevertheless, little improvement in overall times to treatment or that portion of patients who received CPG compliant care has been observed with the current process for ACS care in the authors' institution.\textsuperscript{95,101} Considering the direct relationship between treatment delays and both short-term and long-term mortality following infarction, the need for improvement in the current process for ACS care is obvious.\textsuperscript{108} The realization that "all hospitals are not equal" for the care of patients with STEMI and the demonstration of improved patient outcomes in specialized centers for care of both trauma and stroke have shattered the antiquated concept that patients with suspected MI should be transported to the nearest hospital.\textsuperscript{105} Several U.S. cities, including Boston and Los Angeles, have begun directing public EMS to transport such patients only to a limited few "centers of excellence" for heart attack care.\textsuperscript{107}

In addition to concentrating high-volume expertise and technology, these centers are also integrated with the EMS so that the diagnosis of infarction can be made more rapidly and the "system" for providing PCI is more responsive. The pre-hospital care for ACS, especially STEMI, is critically important. The hospitals with the shortest door-to-balloon times in the United States integrate pre-hospital diagnosis (transmitted ECG) with a multi-disciplinary "team" approach, in which the emergency physician activates the cardiac cath lab before cardiology consultation.\textsuperscript{17} Indeed, the facilitation of in-hospital PCI treatment for those patients with a transmitted pre-hospital ECG has resulted in a significant reduction in door-to-balloon times as well as improvement in survival.\textsuperscript{79,103} Recent multi-center data indicate that the use of centers that receive patients with STEMI along with pre-hospital ECG has resulted in 86% of patients being treated with door-to-balloon times less than 90 minutes in diverse regions across the United States.\textsuperscript{107}

**TABLE 36-2 State of Ohio Mission: Lifeline Credentialing Criteria for Non–Percutaneous Coronary Intervention Hospitals and ST Elevation Myocardial Infarction Referral Centers**

- Appropriate protocols and standing orders should be in place for the identification of ST elevation myocardial infarction (STEMI). At a minimum, these protocols should be present in the Intensive Care Unit/Coronary Care Unit and Emergency Department (ED).
- Each ED should maintain a standardized reperfusion STEMI care pathway that designates primary percutaneous coronary intervention (PCI) as the preferred reperfusion strategy if transfer of patients to a primary PCI hospital/STEMI-receiving center can be achieved within times consistent with ACC/AHA (American College of Cardiology/American Heart Association) guidelines.
- Each ED should maintain a standardized reperfusion STEMI care pathway that designates fibrinolysis in the ED (for eligible patients) when the system cannot achieve times consistent with ACC/AHA guidelines for primary PCI.
- If reperfusion strategy is for primary PCI transfer, a streamlined, standardized protocol for rapid transfer and transport to a STEMI-receiving center should be operational.
- If reperfusion strategy is for primary PCI transfer, all patients should be transported to the most appropriate STEMI–receiving center, where the expected first-door-to-balloon (first device used) time should be within 90 minutes (considering ground versus air transport, weather, traffic).
- When transferring a patient to a primary PCI hospital, the mean or median door-to-door-to-balloon time should be within 90 minutes.
- The STEMI-referal center should have an ongoing quality improvement process, including data measurement and feedback, for the STEMI population and collect and submit Mission: Lifeline required data elements (using the ACTION Registry–GWTG Limited Form*).
- A program should be in place to track and improve treatment (acutely and at discharge) with ACC/AHA guideline–based class I therapies.
- A multi-disciplinary STEMI team, including the EMS, should review hospital-specific STEMI data on a quarterly basis.
- Door-to-first electrocardiogram (ECG) time: The goal should be less than 10 minutes.
- The proportion of STEMI–eligible patients who receive any reperfusion (PCI or fibrinolysis) therapy (goal approximately 100%)
- STEMI–referal center ED door-to-ED discharges (goal within 30 minutes)
- STEMI–referal center ED door-to-balloon (first device used) time should be within 120 minutes (including transport time).
- Each hospital should install synchronized clocks (preferably atomic clocks) in the ED, synchronize the ECG machine times to the atomic clocks, daily and educate team members to use only the atomic clocks when documenting time segments.
- STEMI (thrombolysis in MI) risk score, a simple risk stratification tool that categorizes a patient's risk of death and ischemic events, should be used to provide a basis for therapeutic decision making.

*This pared down version of the ACTION Registry-GWTG is a 50% reduction in the data collection and was created to allow more hospitals to participate in the registry as well as in the AHAs Mission: Lifeline Program. Current registry participants and new participants, who choose the more comprehensive version, will be designated as ACTION Registry-GWTG Premiere participants. ACTION Registry-GWTG Premiere, which includes the registry’s most robust set of data elements, will remain the most comprehensive choice for monitoring data in ACS, looking at all the acute MI (AMI) performance measures and all test measures, including dosing errors and lipid metrics.

STEMI networks. Monitoring adherence to guidelines may be performed by established “systems” rather than by individual hospitals or centers. Treatment, outcome, and performance data acquisition and analysis will be standardized, with appropriate and timely feedback to participating systems and centers. Individual states have been charged with development of regional coordinators to provide oversight, monitoring, and support for participating systems and centers. The process for the “development of systems of care for patients with STEMI” has, indeed, been initiated already by the AHA and is forthcoming.

The interventional cardiologist should meet ACC/AHA criteria for competence. Interventional cardiologists should perform at least 11 primary PCI procedures per year and 75 total PCI procedures per year. The TIMI risk score, a simple risk stratification tool that categorizes a patient’s risk of death and ischemic events, should be used to provide a basis for therapeutic decision making.

Protocols for triage, diagnosis, and cardiac catheterization laboratory activation should be established within the primary PCI hospital/STEMI–receiving center. A single activation phone call should alert the STEMI team. Criteria for EMS activation of the Cardiac Catheterization Laboratory should be established in conjunction with EMS offices.

The STEMI–receiving center should be available 24 hours/7 days a week to perform primary PCI.

The cardiac catheterization laboratory staff, including an interventional cardiologist, should arrive within 30 minutes of the activation call.

There should be universal acceptance of patients with STEMI (no diversion). There should be a plan for triage and treatment for simultaneous presentation of patients with STEMI.

The interventional cardiologist should meet ACC/AHA criteria for competence. Interventional cardiologists should perform at least 11 primary PCI procedures per year and 75 total PCI procedures per year.

For patients presenting at the primary PCI hospital, the mean or median door-to-balloon time should be within 90 minutes.

When transferring a patient from a non-PCI hospital, the mean or median door-to-door-to-balloon time should be within 90 minutes.

• The interventional cardiologist should participate in the Mission: LifeLine–approved data collection tool, ACTION Registry–GWTG.
• A program should be in place to track and improve treatment (acutely and at discharge) with ACC/AHA guideline–based class 1 therapy.
• There should be a recognized STEMI–receiving center liaison or system coordinator in the system and a recognized physician champion.

There should be regularly scheduled (i.e., monthly) multidisciplinary team meetings to evaluate outcomes and quality improvement data. Operational issues should be reviewed, problems identified, and solutions implemented. The following measurements should be evaluated on an ongoing basis:

- Door-to-balloon (first device used) time, non-transfer, within 90 minutes
- STEMI–referral center ED door-to-balloon (first device used) time, transfer within 90 minutes
- First Medical contact to balloon inflation (first device used), non-transfer, within 90 minutes
- First medical contact to balloon inflation (first device used) transfer
- Proportion of eligible patients receiving reperfusion therapy
- Proportion of eligible patients administered guideline–based class I therapies
- Proportion of patients with field diagnosis of STEMI and activation of the cardiac catheterization laboratory for intended primary PCI that:
  - Do not undergo acute catheterization because of misdiagnosis
Undergo acute catheterization and are found to have no elevation in cardiac biomarkers and no revascularization in the first 24 hours.

In-Hospital Mortality

• Each hospital should install synchronized clocks (preferably atomic clocks) in the ED and catheterization laboratory, synchronize the ECG machine and the atomic clocks daily, and educate team members to use only the atomic clocks when documenting time segments.

• The TIMI risk score, a simple risk stratification tool that categorizes a patient’s risk of death and ischemic events, should be used to provide a basis for therapeutic decision making.

• All primary PCI hospitals should commit to a level of financial support for the implementation and sustainability of regional coordinators.

• All primary PCI hospitals should be involved in education outreach to non-PCI hospitals and local EMS agencies. Hospitals should also be involved in education of the public about recognition of signs and symptoms and activation of 9-1-1 services.


| ACC, American College of Cardiology; AHA, American Heart Association; ECG, electrocardiogram; EMS, emergency medical system; GWTG, Get With The Guidelines; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; TIMI, thrombolysis in MI. |

### REFERENCES


36 Regional Centers of Excellence for the Care of Patients with Acute Ischemic Heart Disease


