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Regional systems of care demonstration project: Mission: Lifeline STEMI Systems Accelerator: Design and methodology

Akshay Bagai, MD, MHS, Hussein R. Al-Khalidi, PhD, Matthew Sherwood, MD, Daniel Muñoz, MD, Mayme L. Roettig, RN, MSN, James G. Jollis, MD, and Christopher B. Granger, MD

Duke Clinical Research Institute, Durham, NC

Abstract

ST-segment elevation myocardial infarction (STEMI) systems of care have been associated with significant improvement in use and timeliness of reperfusion. Consequently, national guidelines recommend that each community should develop a regional STEMI care system. However, significant barriers continue to impede widespread establishment of regional STEMI care systems in the United States. We designed the Regional Systems of Care Demonstration Project: Mission: Lifeline STEMI Systems Accelerator, a national educational outcome research study in collaboration with the American Heart Association, to comprehensively accelerate the implementation of STEMI care systems in 17 major metropolitan regions encompassing >1,500 emergency medical service agencies and 450 hospitals across the United States. The goals of the program are to identify regional gaps, barriers, and inefficiencies in STEMI care and to devise strategies to implement proven recommendations to enhance the quality and consistency of care. The study interventions, facilitated by national faculty with expertise in regional STEMI system organization in partnership with American Heart Association representatives, draw upon specific resources with proven past effectiveness in augmenting regional organization. These include bringing together leading regional health care providers and institutions to establish common commitment to STEMI care improvement, developing consensus-based standardized protocols in accordance with national professional guidelines to address local needs, and collecting and regularly reviewing regional data to identify areas for improvement. Interventions focus on each component of the reperfusion process: the emergency medical service, the emergency department, the catheterization laboratory, and inter-hospital transfer. The impact of regionalization of STEMI care on clinical outcomes will be evaluated.

For patients with ST-segment elevation myocardial infarction (STEMI), the mortality benefit of early reperfusion is well established.^{1,2} Furthermore, primary percutaneous coronary intervention (PCI) is recognized as the preferred reperfusion method if it can be performed in a timely manner.³ In 2004, the American College of Cardiology (ACC) Foundation/American Heart Association (AHA) guidelines intensified timeliness goals for primary PCI by lowering the acceptable door-to-balloon time to <90 minutes and redefining

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Reprint requests: Christopher B. Granger, MD, Duke Clinical Research Institute, Duke University Medical Center, Box 3409, 2400 Pratt St, Durham, NC 27701. christopher.granger@duke.edu.

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“time zero” as first medical contact, defined as time of hospital arrival for self-transported patients and time of first emergency medical services (EMS) contact with patients in the field for EMS-transported patients.⁵ Data from national registries indicated a failure in systematic achievement of these guideline goals, particularly among STEMI patients presenting to hospitals without PCI capability and undergoing interhospital transfer for primary PCI.^{6,7} Several system-related barriers were identified as key reasons for failure to achieve timely reperfusion, including lack of multidisciplinary coordination between various points of patient contact (EMS, non-PCI hospitals, and PCI hospitals).

These considerations fueled the evolution of systems and centers of care for STEMI patients, with many medical centers extending care coordination beyond the traditional boundaries of a hospital.^{8–10} A *system* is defined as an integrated group of entities within a region coordinating the provision of diagnostic and treatment services. An STEMI care system includes EMS providers, referral centers/non-PCI hospital(s), receiving centers/primary PCI hospital(s), and others.¹¹ Each entity has a predefined action plan based on regional consensus about how to best implement professional society recommendations with the aim to provide optimal care to the maximum number of eligible patients. Other important features of a regional care system include common data collection, data sharing, ongoing feedback, and quality improvement.

Enthusiasm for more widespread implementation of STEMI care systems has been spurred in part by endorsements from national professional societies.¹² In 2007, the AHA launched “Mission: Lifeline,” a community-based initiative to improve systems of care for STEMI patients, and in 2009, the ACC Foundation/AHA STEMI guidelines codified this approach as a new Class I recommendation that “each community should develop a STEMI system of care.”¹³ Recommended system features included (1) ongoing multidisciplinary team meetings that include EMS, (2) evaluation of outcomes and quality improvement data by non-PCI and PCI hospitals, (3) a process for prehospital STEMI identification and activation, (4) destination protocols for PCI hospitals, and (5) transfer protocols for patients who arrive at non-PCI hospitals.

Implementation of STEMI care systems has been associated with significant improvement in overall use and timeliness of reperfusion,^{14–16} generating further interest in more widespread implementation across the country. In this manuscript, we describe the rationale and methods of the Regional Systems of Care Demonstration Project: Mission: Lifeline STEMI Systems Accelerator Project, an effort led by the Duke Clinical Research Institute (DCRI) in partnership with the AHA to accelerate the development of care systems to efficiently diagnose and treat STEMI in 17 selected major metropolitan regions across the United States. We then describe an analytical plan to evaluate the impact of implementing regional STEMI care systems on both care process and clinical outcomes including reperfusion times and inhospital mortality.

Current status of STEMI care systems in the United States

In addition to large regional^{9,17,18} and statewide¹ initiatives, several local and community level “grassroots” STEMI systems have sprouted across the country.¹⁹ In a recent survey of 381 unique systems across 47 states, 202 involved a single PCI hospital, 150 encompassed 2 to 5 PCI hospitals, and 29 included >5 PCI hospitals.²⁰ There is extensive heterogeneity in organization, protocols, and practices across systems, with variability in (1) paramedic training, (2) availability of prehospital electrocardiograms (ECGs), (3) ability to transmit ECGs to receiving hospitals, (4) catheterization lab activation processes, (5) protocols for bypassing non-PCI-capable hospitals with direct transport to PCI-capable hospitals, (6) reperfusion strategy at non-PCI centers, (7) data registry participation, and (8)

consistent processes for feedback.²⁰ With such variation in EMS and hospital resources, in geography, in population density (urban vs rural), and in transport distances, a “one-size-fits-all” system design is neither practical nor achievable in the United States.²¹

Barriers to implementation of STEMI care systems in the United States

Several barriers impede successful establishment and implementation of STEMI care systems in the United States. In a recent survey, the most common barriers identified were hospital competition, EMS transport and finances, competition between cardiology groups, lack of data collection and feedback, lack of infrastructure support and funding, and lack of bed availability.²⁰ Other barriers include lack of unified regional EMS and transfer center protocols, lack of a neutral broker between competing health systems, and lack of a central data repository for comparison of process elements between receiving centers.

Competition and financial issues

Medical care in the United States is traditionally organized by hospitals, physician practices, and EMS agencies. In regions with multiple hospitals and physician groups, intense competition hinders establishment of a coordinated effort to achieve reperfusion in the most regionally efficient manner. Time and opportunity may be wasted as EMS providers attempt to navigate complicated referral networks, tied to traditionally entrenched interhospital and physician relationships.²² Patients with cardiovascular diagnoses, particularly acute myocardial infarction, are relatively profitable for hospitals that provide cardiovascular services. Born out of a concern for revenue loss when STEMI patients are diverted directly to a PCI hospital or transferred immediately from the emergency department (ED) of non-PCI hospitals, non-PCI hospitals can feel a financial disincentive to participate in regional systems.

ST-segment elevation myocardial infarction care system development requires new investment. In the current model, it is unclear who should make the upfront investment in equipment and personnel. For example, EMS agencies face higher demand in the form of increased calls and interhospital transfers. With this demand also comes the need to acquire new or updated equipment and training. As EMS reimbursement is fixed regardless of level of care, increased investment and greater care intensity go financially unrewarded. At present, PCI hospitals are the most frequent source of funding for STEMI systems.²⁰ Additional funding comes from a broad array of industry, government, and foundation services. To align incentives for both non-PCI and PCI hospitals to participate in STEMI systems, some have suggested creation of a single prospective payment that covers the care continuum from first medical contact to interhospital transfer, if appropriate, to allow EMS and both hospitals to share gains resulting from care coordination.²³

Data collection and clinical outcomes

Despite the success of STEMI regionalization programs in improving care processes, the degree to which these programs have affected population-wide outcomes has been more difficult to demonstrate.^{1,2} Sound policymaking requires both an assessment of community-wide outcomes and an understanding of optimal STEMI system configurations. This can only occur with comprehensive data collection into a single data repository. Participation in national registries and quality improvement programs provides caregivers with standardized tools for data collection and risk adjustment as well as feedback on how their care compares with that of their peers. Such feedback systems are critical to continuous quality improvement.²⁵ Collaboration with private or public foundations, including partnership with the AHA and Mission: Lifeline can help support hospital costs of data collection and abstraction.

Lack of standardized protocols

The heterogeneity of EMS providers and hospitals across the United States requires that STEMI systems flexibly adapt to the local needs and community-specific resources. For some communities, direct ambulance referral or emergency interhospital transfer protocols may be effective at preferentially directing STEMI patients to PCI hospitals. For other communities, large geographic distances may prohibit rapid access to primary PCI facilities, and use of fibrinolytic therapy may be the preferred initial reperfusion strategy. Although details will vary across sites, each system is best served by a predetermined plan of action at each point of patient contact and care. Predefined standardized protocols, for example, for interhospital transfer, are now available for STEMI systems to customize to their own needs and requirements (<https://cee.dcri.duke.edu/stemi-accelerator/OPs%20Manual%202-12.pdf>).

Regional systems of care demonstration project: Mission: Lifeline STEMI Systems Accelerator Project

The Regional Systems of Care Demonstration Project is a national educational outcomes research study initiated by the DCRI in collaboration with the AHA. The goals of this demonstration project are to (1) comprehensively accelerate the implementation of STEMI care systems in 17 selected large metropolitan regions across the United States; (2) facilitate effective delivery of STEMI care in a timely, coordinated, and consistent manner; and (3) improve clinical outcomes of STEMI patients by broadly improving use and timeliness of reperfusion therapy.

Region selection

Participating regions were selected through a competitive application process refereed by the AHA and the DCRI Center for Educational Excellence. Candidate regions were identified by health care professionals and administrators familiar with national and regional emergency cardiac system development, the ACC National Cardiovascular Data Registry (NCDR) data, the AHA Affiliate quality improvement field representatives, and requests from specific regional leaders. We focused on 2 geographic settings: highly populated metropolitan and suburban regions, and medium and large metropolitan regions also serving rural geographies. Among the 21 regions selected according to existing gaps in regional care, system readiness (participation of most PCI centers and agreement to contribute STEMI data to a centralized data repository, willingness to be collaborative in a regional plan and common database, and ability to perform and communicate prehospital ECGs), and likelihood of intervention success, 17 participated in the program. Table I lists the participating regions, with the number of EMS agencies, non-PCI hospitals, and PCI hospitals in each region. Detailed information regarding each participating region is available at <https://www.dcri.org/cee/stemi/participating-sites/>.

Study intervention

The study intervention draws upon specific resources that effectively augmented regional organization in prior experience²² and includes multiple strategies (Table II). All interventions are conducted with the common goal of identifying regional gaps, barriers, and inefficiencies in STEMI care and to devise strategies to implement proven recommendations and protocols to improve quality and consistency of care. Although the interventions focus on each component of the reperfusion process: the EMS, the ED, the catheterization laboratory, and interhospital transfer, the Accelerator Project places special emphasis on improving treatment times for EMS presenting patients through early paramedic diagnosis and single call prehospital activation of the catheterization laboratory and for patients requiring interhospital transfer through strategies to reduce door-in-door-out (DIDO) times

at non-PCI hospital EDs. A complete list of recommendations for optimization of STEMI care in regional systems is provided in the Accelerator manual (<https://cee.dcri.duke.edu/stemi-accelerator/OPs%20Manual%202-12.pdf>). Study interventions are performed before, during, and after each of the regional meetings. (see Table III for study timelines).

Pre-regional meeting—Elements essential to intervention success are established before the regional meeting. These include bringing together leading regional health care providers and institutions, identifying and establishing regional leadership, and identifying specific local barriers and opportunities according to the perspectives of local partners including but not limited to the AHA local quality improvement staff, state chapters of the ACC, and regional administrative leaders. In partnership with local AHA staff, 2 national faculty members with experience in regional STEMI system organization are appointed to each region to serve as advisors and neutral brokers of competition (online Appendix A). In the weeks before the regional meeting, telephone discussions are conducted with interventional cardiologists, EMS directors, and senior hospital administrators. Based upon these discussions, customized meeting plans are developed targeting regional issues. These initial calls enable establishment of protocols likely to be acceptable to all parties within a region. Permission is obtained to present aggregate data from hospitals participating in the NCDR. This permits identification of both the successes and the gaps in care, an exercise that guides refinement of the regional system.

Regional meeting—Regional meetings are conducted on-site in all 17 regions. Attendees include cardiologists and emergency medicine physicians from PCI-capable and non-PCI-capable hospitals, EMS directors, senior hospital administrators, and regional AHA and department of health representatives. These meetings follow a format with proven past success in establishing regional systems. Led by the 2 national systems faculty, science and guidelines underlying regional STEMI care systems are reviewed. Region-specific data are examined. ST-segment elevation myocardial infarction cases specific to the region are discussed to identify local systematic barriers to care and opportunities for improved collaboration. Cases focus on the use of prehospital ECGs for early STEMI identification, availability of ECG transmission and over read, strategies to reduce false activation rates, single call catheterization laboratory activation, and interhospital transfer via EMS with strategies to reduce DIDO times at the non-PCI hospital. Faculty experts encourage attendees to discuss and suggest potential regional solutions.

During the meeting, the national faculty gradually transition leadership of the meeting to preidentified regional leaders. Further discussions are directed to establish elements fundamental to successful regional emergency cardiac care systems, including (1) strong and diverse regional leadership, (2) strong support from hospital systems and administrators to include all hospitals and EMS agencies within the region, (3) common regional protocols, (4) funding, (5) data collection and feedback, (6) maintaining referral lines, and (7) empowering paramedics and emergency physicians to initiate reperfusion. Engagement with Mission: Lifeline and identified opportunities to obtain recognition and accreditation are also discussed. The final goals of the meeting are to identify and plan next steps for successful implementation led by the regional leaders and supporting institutions. The regional leaders, EMS agencies, and STEMI coordinators from each PCI hospital are charged to work together and with local AHA representatives to develop and implement consensus-based region specific STEMI care protocols.

Postregional meeting—Following the regional meeting, contact is maintained with regional leadership through regular calls to support continued progress and provide additional consultation on an as-needed basis. Progress is tracked by quarterly data review

and feedback. Additional support to strengthen regional organizations is provided through funding and protocols.

Data and analytics

The Mission: Lifeline STEMI Accelerator Project is designed to increase the application of evidence-based strategies, enhance the use and timeliness of reperfusion therapy, and improve patient outcomes. In addition, the project is intended to generate knowledge about how best to disseminate and translate research about health care delivery into practice. Traditionally, the standard approach to outcome evaluation has centered on individual institutional performance; however, optimal evaluation of integrated STEMI care systems requires focus on system performance as a whole.²

Data sources—Adoption of evidence-based strategies and establishment of a regional STEMI care system will be evaluated using regional and PCI hospital surveys. The regional survey is designed to gather data on regional leadership, composition, operations, and resources (online Appendix B). The PCI hospital survey (online Appendix C) assesses STEMI care processes including use of prehospital ECG, activation of the catheterization laboratory, EMS feedback, data collection, and catheterization laboratory operations at each participating PCI hospital within the region. Both surveys are administered at baseline before region enrollment and again at follow-up occurring approximately 18 months after region enrollment.

Application of evidence-based strategies (eg, medical therapy, referral to cardiac rehabilitation, etc), timeliness of reperfusion therapy, and clinical outcomes will be assessed via patient-level data entered in the Acute Coronary Treatment and Intervention Outcomes Network Registry-Get With the Guidelines (ACTION Registry-GWTG). The ACTION Registry-GWTG, described previously, is a comprehensive acute myocardial infarction database, jointly owned and managed by the ACC and AHA.²⁷ This database permits assessment of both individual hospital and regional level performance, with inclusion of prehospital, ED, catheterization laboratory, and in-hospital management and outcome data. All participating PCI-capable hospitals in each region will submit 18-month STEMI patient data into the ACTION Registry-GWTG, starting 3 months before the study intervention. Patients at PCI hospitals represent most STEMI patients in the region eligible for reperfusion therapy, as most STEMI patients treated at non-PCI hospitals are transferred to PCI hospitals before discharge.⁸ All participating PCI-capable hospitals sign a data use agreement, permitting aggregation of their data into the regional database. The Duke Institutional Review Board approved the Accelerator project and determined that the work meets the definition of research not involving human subjects and satisfies the HIPAA Privacy Rule.

Primary analysis cohort—Regions with >70% of their regional PCI hospitals participating in the Accelerator program will be included in the primary analysis. The primary analysis cohort will consist of all patients with ischemic symptoms lasting >10 minutes within 24 hours before presentation and an ECG with diagnostic ST-segment elevation at all ACTION Registry-GWTG-participating PCI hospitals during the 18-month study period.

Outcomes of interest—Among patients treated with primary PCI, first medical contact to device activation (FMC-to-device) time will be evaluated. For patients who arrive directly to a PCI hospital, either via self or by EMS, the proportion of patients with FMC-to-device 90 minutes will be determined. For patients who require an inter-hospital transfer before their receipt of primary PCI, the proportion of patients with FMC-to-device 120 minutes

and the DIDO times at the non-PCI hospital will be determined. For patients who receive fibrinolysis for initial reperfusion, door-to-needle time and proportion of patients with door-to-needle time ≤ 30 minutes will be evaluated. All-cause in-hospital mortality rates will also be determined. Other clinical outcomes to be evaluated include in-hospital bleeding, stroke, congestive heart failure, and cardiogenic shock.

Statistical analysis plan—Descriptive statistics for continuous and categorical variables will be presented as median (interquartile range) and number (percentage), respectively. Patient characteristics and process measures will be compared using Wilcoxon rank sum test for 2-group comparison (Kruskal-Wallis test for >2 -group comparison) and χ^2 tests as appropriate. The Cochran-Armitage test for trend will be used to assess changes in rates over time. To consider whether changes in treatment time and clinical outcomes varied by region, linear mixed-effects model will be performed to adjust for clustering of patients within regions. Performance data will be compared in 3-month intervals starting 3 months before the intervention stratified according to treatment and presentation to PCI hospital (fibrinolysis or primary PCI; presentation to PCI hospital by self, EMS, or transfer). Outcomes data such as all-cause in-hospital mortality will be analyzed using logistic regression model adjusted for baseline covariates via propensity score model.

Using the data from the ACTION Registry-GWTG, timing of reperfusion, and in-hospital mortality will also be compared among regions participating in the Mission: Lifeline Accelerator project and other regions enrolled in ACTION Registry-GWTG but not participating in the Mission: Lifeline Accelerator project. In-hospital mortality outcomes among regions not enrolled in ACTION Registry-GWTG but having existing STEMI care systems will be compared with regions participating in the Accelerator project. Data analyses will be performed at the DCRI. SAS version 9.2 (SAS Institute, Inc, Cary, NC) will be used for all analyses. $P < .05$ will be considered statistically significant.

Conclusion

The Regional Systems of Care Demonstration Project: Mission: Lifeline STEMI Accelerator, initiated by the DCRI in collaboration with the AHA and local cooperating regional teams, is a national educational outcomes research study. Its central goal is to markedly accelerate the implementation of STEMI care systems in 17 selected large metropolitan regions across the United States, with an aim to improve use and timeliness of reperfusion therapy and to improve clinical outcomes in STEMI.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table I

Regional leader(s) and number of PCI hospitals, non-PCI hospitals, and EMS agencies in each participating region

Region	Regional leader(s)	PCI hospitals (n)	Non-PCI hospitals, (n)	EMS agencies (n)
Great Rivers				
Columbus, OH	Ernest Mazzaferri, Jr, MD	15	25	500
Pittsburgh, PA	Bruce MacLeod, MD	16	20	30
Philadelphia, PA	Elliot Barnathan, MD	13	8	1
Wilkes-Barre–Scranton, PA	Steven Voyce, MD; John Ellis, MD	4	8	88
Metropolitan Louisville (Kentuckiana) KY/IN	Jesse Adams, MD	7	10	9
Founders				
New York City, NY	Norma Keller, MD; Jacqueline Tamis-Holland, MD; Glenn Asaeda, MD; John Freese, MD	25	12	27
Northern New Jersey, NJ	Mark Zucker, MD; Mark Merlin, MD; Steven Sheris, MD	23	3	249
Hartford, CT	Richard Kamin, MD; C. Steven Wolf, MD	4	6	35
Greater South East				
Tampa, FL	Robert Sanchez MD; Xavier Prida MD	15	15	7
Atlanta, GA	Michael A. Ross, MD; Mike Jernigan, EMT-P	17	4	40
Midwest				
St Louis, MO	Richard G. Bach, MD; Michael J. Lim, MD; George M. Kichura MD; Stuart T. Higano, MD	17	5	67
West				
Kern County, CA	Lynne Ashbeck, MS, RD; Ross Elliott, EMT	3	7	7
Hawaii, HI	William Dang, Jr, MD	5	14	5
South West				
Colorado Front range, CO	Jeb Burchenal, MD; Fred Severyn, MD	26	20	76
Houston, TX	James McCarthy, MD; Todd Caliva	33	20	54
San Antonio, TX	Craig Manifold, DO; Dudley Wait	15	21	23
North Central Oklahoma, OK	Charles Bethea, MD; Tim Cathey, MD	18	30	40

Table II**Study interventions**

1. Bring together leading regional health care providers and institutions in a collaborative fashion.
 2. Identify and establish regional leadership in emergency cardiac care that includes key physicians and administrators in emergency medicine and cardiology.
 3. Appoint 2 national faculty members per region to serve as advisors and neutral brokers of competition in partnership with the local AHA staff. Faculty members bring expertise in regional STEMI system organization, implementation of regional process changes, and utilization of outcomes data to drive improved system performance.
 4. Establish regional commitment to STEMI care improvement from all stakeholders: EMS providers, ED physicians, EMS administrators, non-PCI hospital and PCI hospital administrators, state and local government agencies, and professional organizations.
 5. Conduct a comprehensive regional evaluation of current STEMI care, including a geographical map of the region with PCI and non-PCI hospitals.
 6. Hold regional leader and national faculty preintervention conference calls to recruit and plan regional education meeting.
 7. Conduct and facilitate a regional meeting to launch the effort with both national faculty and regional leaders to harness representation from all entities and multidisciplinary teams caring for the STEMI patient (EMS, non-PCI hospital, PCI hospital, administration, physicians, nurses, paramedics, quality improvement officials).
 8. Develop consensus-based standardized protocols for EMS and transfer-in patients in accordance with national professional guidelines to address local needs.
 9. Discuss specific local STEMI case examples that follow patients from first medical contact to device activation in the PCI hospital.
 10. Review quarterly regional STEMI care data with feedback from the NCDR, and regional AHA Mission: Lifeline teams.
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Table III

STEMI Systems Accelerator study timelines

STEMI Systems Accelerator timeline	
Q1 2012	Site application and selection
Q2-Q4 2012	Site enrollment and preregional meeting intervention
Q3-Q4 2012	Regional meetings
Q4 2012-Q2 2013	Baseline quarter data collection
Q1 2013-Q1 2014	Postmeeting intervention
Q4 2013-Q2 2014	Final quarter of data collection

Q, Quarter.