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Testimony for HCR 10/HR 11, Proposed HD1: Relating To Emergency Medical Services. Wireless Electrocardiogram Data Transmission; Pilot Project

The American Heart Association offers the following comments on HCR 10/HR 11, Proposed HD1:

- The stated goal of the resolution would be to establish a task force to review the city and county of Honolulu's wireless electrocardiogram project and data on costs, implementation, required staff, and other information gathered by Honolulu's EMS Department and the State DOH to evaluate the project's potential for expansion and improvement. That pilot program is currently in its startup phase. Honolulu city ambulances are expected to receive the equipment necessary to transmit ECG data to hospitals by early April 2008.

However, the proposed task force will likely have little data to review once the system is in place since that data will fall under the domain of the hospitals that receive it. Each hospital has its own protocols by which it treats STEMI patients, and therein lays one shortcoming of the proposed task force. Only the hospitals will have access to the patient outcomes and they are not named as members of the task force.

- The proposed HD1 dictates that the task force will consist of seven members. Those members include a representative of the House, a representative of the Senate, the City and County of Honolulu's EMS director or a designee, the state director of health or a designee, two cardiologists, and a representative from the Coalition for a Tobacco Free Hawaii. Unfortunately, those named will have little to discuss during the three meetings that are to be convened under the HD1. The EMS representatives will be able to report how many times they transmitted ECG data to hospitals, but beyond that there will be nothing by which to determine the program's effectiveness.

It would be more effective to identify those hospitals that elect to participate in the City and County of Honolulu EMS Department's pilot program and to have representatives of those hospitals (emergency room physicians as well as cardiologists) share and compare their resulting data and the protocols by which they used the ECG transmissions. Only then will useful information allow hospitals to possibly improve their protocols in treating STEMI patients.

- Hospitals would still be ultimately responsible for determining whether or not they will receive patients, even if those hospitals have not participated in the pilot project and even if the protocol that they use does not match the protocol determined as having the optimal results. In the ideal system for EMS and hospital emergency departments, standardized point-of-entry protocols (created by state-based coalitions of EMS personnel, emergency physicians, and cardiologists and supported by payers and administrators) would dictate which patients are transported to the nearest facility and which patients are transported to the nearest PCI-capable facility, in part based on the acquisition, interpretation, and transmission of pre-hospital 12-lead ECGs. Much of the challenge in optimizing STEMI systems of care lies in securing agreement among the

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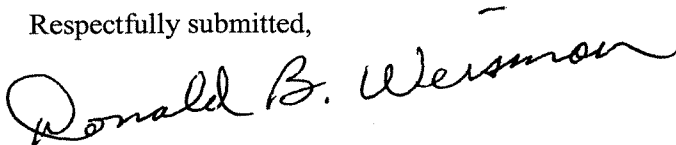
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integrated hospital staff as to who will receive ECG transmission data and how that data will be used. However, the proposed task force fails to include emergency department physicians in the discussions.

- Because the majority of PCI patients are not delivered to hospitals via the EMS system, and if the state is committed to improving the treatment of those patients, one way that the state could help to achieve improvement would be to invest funds in a campaign to educate the public to recognize the warning signs of a heart attack and to immediately call 9-1-1 for help.
- The issues inherent to the development of systems of care for STEMI patients are quite complex, with public health, economic, political, and social implications for our society. Attached, for your information, is the Executive Summary of American Heart Association Conference Proceedings on the development of Systems of Care for ST-Elevation Myocardial Infarction Patients. This report was published in the American Heart Association journal *Circulation* in May, 2007. As the report states, the American Heart Association is planning to convene stakeholders to identify initiatives that could be undertaken to improve care for STEMI patients and to consider the establishment of STEMI systems. Rather than duplicating those efforts as the task force outlined in the HD1 might do, we would recommend allowing the AHA's plans to first move ahead.

Respectfully submitted,



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LATE TESTIMONY

Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION

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Development of Systems of Care for ST-Elevation Myocardial Infarction Patients. Executive Summary. Endorsed by Aetna, the American Ambulance Association, the American Association of Critical-Care Nurses, the American College of Emergency Physicians, the Emergency Nurses Association, the National Association of Emergency Medical Technicians, the National Association of EMS Physicians, the National Association of State EMS Officials, the National EMS Information System Project, the National Rural Health Association, the Society for Cardiovascular Angiography and Interventions, the Society of Chest Pain Centers, and UnitedHealth Networks
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Circulation published online May 30, 2007;

DOI: 10.1161/CIRCULATIONAHA.107.184043

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 72514

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Development of Systems of Care for ST-Elevation Myocardial Infarction Patients

Executive Summary

Endorsed by Aetna, the American Ambulance Association, the American Association of Critical-Care Nurses, the American College of Emergency Physicians, the Emergency Nurses Association, the National Association of Emergency Medical Technicians, the National Association of EMS Physicians, the National Association of State EMS Officials, the National EMS Information System Project, the National Rural Health Association, the Society for Cardiovascular Angiography and Interventions, the Society of Chest Pain Centers, and UnitedHealth Networks

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Although the mortality benefit of early reperfusion with either fibrinolytic therapy or primary percutaneous coronary intervention (PCI) for patients with ST-segment elevation myocardial infarction (STEMI) has been well established,^{1,2} in the United States, there is great variation in which type of reperfusion treatment is chosen and in which patient it is administered.³ In fact, ≈30% of STEMI patients do not receive any reperfusion therapy despite its availability and the absence of contraindications to its use.⁴ Moreover, in those patients treated with reperfusion, fewer than 50% receive treatment with a door-to-needle time within 30 minutes, and only 40% are treated with a door-to-balloon time within 90 minutes⁵ as recommended by the American College of Cardiology (ACC)/American Heart Association (AHA) guidelines.⁶ In addition, sex and racial disparities in the delivery of STEMI care persist.⁷

Furthermore, evidence from multiple randomized trials suggests that primary PCI is superior to fibrinolytic therapy in reducing the rates of death, reinfarction, intracranial bleeding, reocclusion of the infarct artery, and recurrent ischemia (even when interhospital transport to a PCI-capable center is required) when performed in a timely fashion by experienced

centers^{2,8}; however, fibrinolytic therapy is the mainstay of treatment in the United States and around the globe because it is more widely available.³ Of the nearly 5000 acute care hospitals in this country, ≈2200 have catheterization laboratories and among those, only 1200 are capable of performing PCI.⁹ Therefore, the delivery of timely primary PCI to the majority of STEMI patients is extremely challenging, particularly in rural areas. Most disturbing is the fact that up to 20% of patients with STEMI are not eligible for fibrinolytic therapy, and yet 70% of those patients do not receive primary PCI, although it is the only reperfusion option.^{4,10}

It is these considerations that have fueled the concept of systems and centers of care for STEMI patients and the mounting enthusiasm for the potential benefits of regional STEMI networks.^{11,12} In this context, “system” is defined as an integrated group of separate entities within a region providing specific services for the system that could include emergency medical services (EMS) providers, a community hospital(s), a tertiary center(s), and others. “Center” is defined as an entity such as a community or tertiary hospital that provides patient care services for a specific specialty or service.¹³ It is hoped that highly coordinated systems and

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Writing group reports are available online at <http://circ.ahajournals.org> (*Circulation*. 2007;115:e■■■■-e■■■■, e■■■■-e■■■■, e■■■■-e■■■■, e■■■■-e■■■■, e■■■■-e■■■■, e■■■■-e■■■■, e■■■■-e■■■■, e■■■■-e■■■■, e■■■■-e■■■■, and e■■■■-e■■■■).

The publication of these proceedings was approved by the American Heart Association Science Advisory and Coordinating Committee on April 18, 2007. A single reprint of the entire conference proceedings is available by calling 800-242-8721 (US only) or writing the American Heart Association, Public Information, 7272 Greenville Ave, Dallas, TX 75231-4596. Ask for reprint No. 71-0413. To purchase additional reprints, call 843-216-2533 or e-mail kelle.ramsay@wolterskluwer.com.

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(*Circulation*. 2007;115:000-000.)

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DOI: 10.1161/CIRCULATIONAHA.107.184043

centers across the continuum of care (from patient entry to discharge and encompassing EMS, emergency departments [EDs], community and tertiary hospitals, and payers) will improve both the quality of services and outcomes for STEMI patients. Of note, several pilot programs using different models of systems and centers, which will be detailed in subsequent sections, have met with early success.¹⁴⁻¹⁶

AHA Initiative

Given the concerns about the unmet need in the care of many of the nearly 400 000 patients with STEMI in the United States,¹⁷ the minority of STEMI patients treated with primary PCI despite its superiority if performed in a timely fashion, and the number of patients ineligible for fibrinolytic therapy, the AHA convened a multidisciplinary Acute Myocardial Infarction Advisory Working Group to develop recommendations for strategies to increase the number of STEMI patients with timely access to primary PCI. Although the focus was on primary PCI, it was noted that the strategies to be recommended must result in improved quality of care and outcomes for all STEMI patients and must ensure access and adherence to other important evidence-based therapies. To assist the group in developing the AHA's position and role in defining the optimal care for patients treated with primary PCI, PricewaterhouseCoopers was selected to prepare a report on the desirability, feasibility, and potential effectiveness of establishing (regional) systems and/or centers of care. Their research approach was both qualitative and quantitative and determined that developing systems and/or centers of care for STEMI patients treated with primary PCI would have significant policy and financial implications.¹³ It was clear, however, that nearly all stakeholders interviewed or surveyed supported a primary PCI certification program and agreed that the AHA's main focus should be on leveraging its relationships to ensure that the appropriate constituencies were involved.

On the basis of this report, the Advisory Working Group recommended that the next step after development of the initial consensus statement was to convene a conference for all stakeholders to begin to develop an implementation plan in concert with the recommendations that would emanate from the meeting. Because of the potential demographic, political, and financial impact of the development of strategies to increase the availability of timely primary PCI, the Advisory Working Group developed the following principles to guide this initiative:

1. Patient-centered care as the number 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 that 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; and
9. A reduction in disparities of healthcare delivery, such as those across economic, educational, racial/ethnic, or geographic boundaries.

AHA Conference: Development of Systems of Care for STEMI Patients

Conference Participants and Process

In late March 2006, the AHA convened a 3-day conference with multidisciplinary groups of physicians (noninvasive and interventional cardiologists, cardiac surgeons, emergency care and critical care practitioners, and internists), nurses, EMS personnel, community and tertiary hospital administrators (including representation from rural areas), payers, quality and outcomes experts, and government officials involved in the care of STEMI patients. These thought leaders were charged with reviewing the current state or system of care, developing the ideal implementation system, addressing the gaps and barriers between the current and ideal system, and formulating recommendations for research, programs, and policy from the perspective of the constituency they were to represent. Members of key organizations representing key constituents were in attendance:

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

The goals of the conference were as follows: (1) to achieve consensus on the guiding principles for the establishment of a system (urban/suburban and rural) of care for STEMI patients; (2) to develop the ideal implementation system from the perspective of each stakeholder (ie, patient, physician, EMS, ED, local hospital, tertiary center, and payer) in terms

of outcomes and quality of care; (3) to understand the barriers, gaps, and policy implications; and (4) to develop recommendations. Several provocative presentations, including "State of the Science," "The Trauma Center Model," and "The European Experience," in addition to pilot programs of systems and centers of care in Minnesota, North Carolina, and Boston, Mass, served as a framework for this conference and stimulated extensive interchange of ideas between all participants. After the plenary sessions, each stakeholder working group reviewed the current literature, engaged in thorough and challenging discussion, and generated summary documents that can be found in the online version of this issue of *Circulation*.^{18–27} The purpose of this executive summary is to capture the salient issues involved in the care of STEMI patients from the perspective of each constituent, to propose an agenda to improve the quality of care and outcomes of patients with STEMI, and to begin to outline the AHA's next steps in this ongoing initiative.

Conference Working Groups

Patient and Public Perspective

It is generally agreed that the care provided to patients with STEMI is unlike most other hospital care. It usually involves rapid and complex decisions and, often, quick transport to a PCI-capable hospital for a critically ill patient for whom family and friends may not be present. The relationship of this critical and time-sensitive situation to the patient's wishes, fears, expectations, beliefs, and values should not be underestimated.

In addition, the role and responsibility of the patient at the onset of STEMI, before contact with the medical system, are of paramount importance. Currently, there is inadequate recognition by the patient and the lay community of the symptoms of STEMI and the urgency of activating EMS. The problem of delay after symptom onset, attributed to denial, preference for a "wait-and-see" approach, fear of a "false alarm," reluctance to "bother" or burden the medical system, and existing stereotypes for risk, has been longstanding; however, given the known benefits of early reperfusion, efforts to decrease this delay have been given increased attention. Regrettably, public awareness campaigns and community-based interventions have not yet been effective in reducing the time from symptom onset to first medical contact or in increasing the number of patients who activate EMS.²⁸ In fact, currently, $\approx 76\%$ of STEMI patients arrive at the hospital via self-transport or transport by family and friends.²⁹ Furthermore, there exist marked disparities in access to and quality of care delivered.

In the ideal system, patients and the public would recognize the symptoms of STEMI and the importance of time to treatment, be familiar with their community hospital's role in the delivery of STEMI care, and understand the implications involved in interhospital (rapid) transfer for PCI. Moreover, the patient would not be "penalized" by the reimbursement system if their symptoms were found not to be due to STEMI after activation of EMS and arrival in the ED. The ideal system would promote culturally competent educational efforts with clear and consistent messages and would include patient representatives on community planning coalitions.

Patient care across the continuum of services, from entry into the system to discharge back to the community provider, would be highly coordinated and patient-centered.

To achieve the ideal system for patients and the public, the gaps and barriers imposed by literacy level, socioeconomic factors, insurance status, preapproval policies of insurance plans, and instructions to patients provided by physicians and health plans regarding an action plan at the onset of symptoms of STEMI will need to be overcome. It will also be necessary to gain an increased understanding of the components of effective communication and educational interventions.

Physician Perspective

Currently, primary care and specialist physicians tend to work in isolation rather than in integrated networks in caring for STEMI patients, particularly at entry into the medical system. This is especially true in rural areas, where physicians may lack easy access to educational opportunities and a large volume of STEMI patients. Many physicians have experienced decreasing reimbursement for services,³⁰ and the potential financial impact of a loss of patients (and prestige) to PCI-capable centers is of concern. Furthermore, physician training in continuous quality improvement techniques has been lacking.

In the ideal system for physicians, multidisciplinary teams (including primary care, ED, and noninvasive and interventional cardiology physicians) would work together in a seamless fashion to ensure that evidence-based care is delivered to STEMI patients according to ACC/AHA guidelines at entry into the system, during the hospital stay, at discharge, and throughout long-term follow-up in the community setting. At every step, each physician would play an important and clearly defined role. Of utmost importance is the transitioning of care back to the community physician after the acute event.³¹

The ideal system would provide opportunities for all physicians to participate in community education for patients and for EMS providers. In addition, there would be opportunities for physicians to be leaders in continuous quality improvement initiatives for STEMI programs that include the acute and the follow-up phase of care. Physicians, nurses, EMS personnel, and other providers would work together to establish evidence-based protocols and demonstrate credible commitment to the goal of achieving timely infarct-artery patency for all STEMI patients.

To achieve the ideal system for physicians, the development of team-based methods for overcoming professional, financial, organizational, and regulatory gaps and barriers will be necessary. Furthermore, alignment of the goals and incentives for all physicians within all hospital settings will be required, with the realization that physicians drive both the quality and the cost of care.

EMS and ED Perspective

Currently, EMS regions are governed separately by state. There are more than 300 different regions in the United States, with nearly 1000 hospital-based EMS systems.³² Yet, hospital-based systems account for only 6% of the total, with fire-based services accounting for 45%, and other public third services and private operators making up the remaining 49%.¹³

EMS ambulances are staffed by various personnel and provide different levels of care (basic life support, advanced life support, and 12-lead ECG) and services, including mode of transport (ground versus air), in rural and urban areas. However, the AHA's advanced cardiovascular life support chest pain algorithm importantly contributes to the prehospital assessment, triage, and treatment of patients with suspected STEMI in most EMS systems.³³

Despite the fact that prehospital ECGs have been reported to decrease door-to-needle and door-to-balloon times,^{34,35} they are performed on fewer than 10% of STEMI patients,³⁶ and there is a discrepancy between reported availability³⁷ and documented use. Furthermore, there is little information on how these ECGs are integrated into the system of care for STEMI patients, and standardized training on the performance, interpretation, and transmission of ECGs is lacking.

Two current EMS policies have a negative impact on timely access to primary PCI for STEMI patients. First, the majority of community protocols traditionally have directed EMS teams to transport patients with chest pain to the nearest hospital, under the assumption that most hospitals could provide fibrinolytic therapy to STEMI patients. With the increasing use of primary PCI as the preferred reperfusion strategy, many communities are considering whether it is best to transport such patients to the nearest PCI-capable hospital instead.¹⁵ Second, transport between a non-PCI-capable hospital to one that provides the service is often the "next available" ambulance rather than a 9-1-1 system of activation.

As noted above, because a minority of STEMI patients use EMS for entry into the medical system,²⁸ the majority have their first medical contact on entry into the ED. This poses a challenge to ED personnel, because EDs are often overcrowded, and patients arriving by ambulance typically receive attention and treatment faster than patients who transport themselves. Although the ACC/AHA guidelines recommend that the initial ECG be obtained within 10 minutes of arrival of a patient with chest pain, ED capacity and staffing may result in delay, and patients presenting with atypical symptoms may wait considerably longer. Depending on local practice patterns, multiple consultations with primary care physicians and cardiologists may be required before a reperfusion strategy is initiated.

In the ideal system for EMS and EDs, standardized point-of-entry protocols (created by state-based coalitions of EMS personnel, emergency physicians, and cardiologists and supported by payers and administrators) would dictate which patients are transported to the nearest facility and which patients are transported to the nearest PCI-capable facility, in part based on the acquisition, interpretation, and transmission of prehospital 12-lead ECGs. The catheterization laboratory team would be activated by EMS personnel in the field or by emergency physicians after receiving transmitted ECGs. Patients transported to a non-PCI-capable hospital by EMS would remain on the stretcher with EMS personnel in attendance until the decision about whether to transport to a PCI-capable hospital has been rendered. For patients who transport themselves to a non-PCI-capable hospital and require primary PCI, activation of EMS via a 9-1-1 system would occur. An ideal system would also foster a coordinated

curriculum to teach EMS providers and ED staff to care for STEMI patients and provide feedback on performance or compliance with guidelines.

To achieve the ideal system for EMS, a complete understanding of the technological and financial barriers to acquiring prehospital ECGs will need to be obtained, because equipment costs and reliability of data transfer have been major barriers to widespread implementation. Protocols on how prehospital ECGs should be performed and interpreted (and by whom) will need to be established. Standardized point-of-entry protocols based on local geography and resources will need to be developed that integrate the prehospital, interhospital, and receiving-hospital care. For those patients transported directly to PCI-capable hospitals, it will be important to determine the safety of longer transport times and whether the added time to reperfusion will negate the benefit of primary PCI in specific patient subsets.

To achieve the ideal system for EDs, a thorough assessment of the staffing patterns, overcrowding issues, and ability to avoid time "on diversion" (periods during which the ED is not accepting new patients brought in by ambulance) will need to occur. Ongoing training of ED staff on STEMI care and ECG interpretation will be necessary. Reperfusion checklists, standard pharmacological regimens and order sets, clinical pathways, and single-call activation systems will require collaborative input from multidisciplinary teams.

Non-PCI-Capable (STEMI Referral) Hospital Perspective

Because the majority of STEMI patients present to hospitals that do not have the capability to perform primary PCI, it is these facilities that will play a pivotal role in increasing the number of patients with timely access to mechanical reperfusion. Currently, several states have allowed increasing numbers of hospitals without cardiac surgery on site to offer primary PCI to STEMI patients, even in catheterization laboratories that do not perform nonemergency ("elective") PCI procedures. Alternatively, some STEMI patients are transported from non-PCI-capable to PCI-capable hospitals after evaluation and initial treatment despite the inherent delay to reperfusion and often without standardized protocols to guide rapid triage and transfer. In a few states, non-PCI-capable hospitals are "bypassed" by EMS, and patients presumed to have STEMI are transported directly to hospitals capable of performing primary PCI.

Although a few early observational studies from single institutions and 1 underpowered randomized trial demonstrated the potential efficacy and safety of performing primary PCI at hospitals without cardiac surgery on site,^{38,39} there is concern that the proliferation of primary PCI in this setting has the potential to result in the creation of low-volume institutions⁴⁰ that would have difficulty sustaining a PCI program because of cost and lack of personnel to provide continuous coverage. In the ideal system, standardized point-of-entry protocols would dictate those STEMI patients to be transported directly to a PCI-capable facility based on specific criteria for risk, contraindications to fibrinolysis, and the proximity of the nearest PCI service. Those patients transported by EMS or who arrive via self-transport or via family or friends at a non-PCI-capable hospital would be treated

according to standardized triage and (potential) transfer protocols. Incentives would be provided to rapidly treat STEMI patients in accordance with ACC/AHA guidelines and transfer them to the PCI-capable hospital for primary PCI by use of reperfusion checklists, standard pharmacological regimens and order sets, and clinical pathways, with attention to details such as eliminating continuous intravenous infusions and tubing. In addition, rapid and efficient data transfer to the PCI-capable hospital and data collection and feedback would be integrated into the system of care. Finally, after the patient's discharge from the PCI-capable hospital, integrated plans for the return of the patient to the local community for follow-up care would be provided routinely.

To achieve the ideal system for non-PCI-capable hospitals, the integral role of these hospitals within the system must be recognized. Hence, the designation of "STEMI referral hospital" would promote these facilities as "haves" rather than as "have-nots" and minimize any potential halo effect on other services vital to the local community. This designation of "STEMI referral hospital," based on specific criteria, would garner prestige. It will also be necessary to eliminate financial disincentives to transfer STEMI patients to "STEMI-receiving hospitals." Finally, as discussed previously, the frequently unacceptably long interhospital transportation time must be reduced.

PCI-Capable (STEMI-Receiving) Hospital Perspective

A STEMI-receiving hospital is defined as any hospital that performs primary PCI and currently receives STEMI patients through 1 of 3 pathways: directly from home or community, via transport by EMS, or via transport from a STEMI referral hospital. Each presentation offers opportunities for improving time to treatment and access to primary PCI. At these STEMI-receiving hospitals, time to reperfusion is delayed by the decision-making process on arrival, particularly if both fibrinolytic therapy and primary PCI are routinely used, by overcrowding and shortage of staff in the ED, and by the time to activate and assemble the catheterization laboratory team, particularly during off-hours and on weekends.^{41,42} In fact, late presentation after symptom onset, comorbid conditions, and the absence of pain have been shown to be independent predictors of increased time to reperfusion.⁵ Furthermore, not all hospitals that perform PCI provide the service continuously.⁴³ Finally, the lack of standardized treatment protocols and single-call catheterization laboratory activation systems contribute to the delay in achieving infarct-artery patency.

In the ideal system, prehospital ECG diagnosis of STEMI, ED notification, and catheterization laboratory activation would occur according to standard algorithms that would facilitate a short ED stay or transport directly from the field to the catheterization laboratory. Similarly, single-call systems from STEMI referral hospitals with universal patient acceptance by STEMI-receiving hospitals would result in immediate activation of the catheterization laboratory team without the need for additional review or determination of bed availability. Primary PCI would be provided as routine treatment for appropriate STEMI patients 24 hours per day and 7 days per week. Each STEMI-receiving hospital would have a written commitment from the hospital's administration

to support the program. A multidisciplinary group with representation from the ED, EMS, the cardiac catheterization laboratory, the quality improvement team, and the coronary care unit that includes both physicians and nurses would meet regularly to identify problems and implement solutions. A formal continuing education program that includes practical implementation training for staff would be designed and instituted. A mechanism for monitoring program performance, process measures, and patient outcomes would be established.

To achieve the ideal system for STEMI-receiving hospitals, a better understanding is required of the extent of a shift in STEMI patients cared for by STEMI-receiving hospitals and the impact of reallocation of resources and capacity. Criteria for STEMI-receiving hospital certification would be developed that would include hospital and physician volume, continuous primary PCI service, and door-to-balloon time goals, and the designation would preclude time "on diversion."

Payer Perspective

Increasing the number of STEMI patients with access to primary PCI will likely require rethinking and restructuring by purchasers (organizations, such as employers, that provide funds for care) and payers (organizations, such as health plans or insurance companies, that directly contract with purchasers, providers, and practitioners) of how services are purchased, how payments are made, and how accountability is maintained. Currently, there are scarce data on the proportion of STEMI patients transferred from STEMI referral to STEMI-receiving hospitals for primary PCI, and commercial insurers have less influence over data collection and referral in the emergency setting. The complex aspect of payment relates to transferred patients, and different payers have different policies. For Medicare patients, the STEMI referral hospital receives payment only for ED services if the patient is not admitted before discharge and per diem payment for inpatient services at a rate of the diagnosis-related group amount divided by the geometric mean length of stay; the STEMI-receiving hospital is paid the diagnosis-related group amount as if there had been no preceding care.^{44,45} Despite there being 9 standard measures of quality of care for STEMI patients, there are no standard measures for the appropriateness or rate of revascularization. Time to reperfusion is a standard performance measure for patients definitively treated in the initial hospital but not for transferred patients. Although the Centers for Medicare and Medicaid Services completed a demonstration with Premier (an organization owned by not-for-profit hospitals) of a "pay-for-results" model for acute myocardial infarction measures, neither time from onset of symptoms to reperfusion nor appropriateness of revascularization was included.⁴⁶

In the ideal system for payers, once regional coordinated and integrated systems of care for STEMI patients were developed based on existing guidelines, local payers could then apply appropriate financial incentives and disincentives that would reimburse the appropriate amount for the appropriate care at the right time in the right setting. All payer performance data would be available and in the public domain for all STEMI referral and STEMI-receiving hospitals. An integrated single payment that is shared among the referring, transporting, and receiving providers would en-

courage coordination and integration of care, encourage collaboration between providers and practitioners, and allow the 2 hospitals and transfer system to potentially share gains from removing inefficiencies in the transfer process (although the latter strategy has risks that are not fully understood).⁴⁷

To achieve the ideal system for payers, an organizational structure that accepts integrated payments would need to be developed and would require revisiting prohibitions on paying for referrals. Furthermore, local payer contract arrangements that would result in financial penalties to patients if they were transported to nonparticipating providers would need to be eliminated. Payers should play a leading role in encouraging measures that are consistent across payers and others who require reporting and in promoting consistent and accurate data collection and public availability of all payer data. Payers should also consider adjusting payments to reward reporting of data and participation in performance improvement alliances and review payment policies for situations where the payment system may have the inadvertent and unintended effect of providing a disincentive to provide the best care.

Evaluation and Outcomes

As with any care system, process improvement strategies may not be implemented successfully or, worse, may lead to unintended adverse consequences. As such, it will be critically important to carefully monitor the impact of any new care plans and tactics on clinical outcomes. In fact, as noted above, measurable patient outcomes and an evaluation mechanism to ensure that quality-of-care measures reflect changes in evidence-based research are 2 of the principles guiding this AHA STEMI initiative.

Although there are many approaches to the evaluation of care, the writing group thought that Donabedian's classic triad of structure-process-outcome⁴⁸ provides an ideal model that identifies the major domains of health care and defines the programmatic features needed to achieve success. The specific metrics for each domain are detailed in a subsequent section of these conference proceedings²⁵; however, several points should be emphasized. In addition to the outcomes measures of mortality, nonfatal adverse events, and patient-reported health status, the impact of care on non-health-related measures such as patient satisfaction and economic impact should be considered. In addition, outcomes measures should also include potential unanticipated consequences of changes in care, longitudinal measures (at 6 or 12 months), and both positive and negative "halo" effects on other areas of cardiac care.

Moreover, stakeholder providers should participate in national data collection and quality improvement programs that offer standardized tools for data collection and risk adjustment, as well as feedback on how care compares with benchmarks and with care provided by peer groups. As regional STEMI care delivery systems mature, the individual hospital-centered quality improvement program will need to expand to collaborative, community-wide oversight programs. The evaluation of STEMI care at both the hospital and system levels, by plotting the progress of each quality indicator over time, will allow determination of whether the system is moving in the right direction and potentially provide public metrics that could be used for quality assur-

ance, or perhaps to alter provider reimbursement rates (pay-for-quality programs). Finally, metrics for evaluating STEMI care will likely need to evolve as the field evolves.

Gaps, Barriers, and Implications

The underlying premise behind the development of systems (and centers) of care for patients with STEMI is that although primary PCI is superior to fibrinolytic therapy when performed rapidly, timely access to primary PCI is currently limited. The conference reached a consensus that establishment of regional systems of care that include prehospital EMS protocols and emergency interhospital transfer agreements between STEMI referral and receiving hospitals will improve access to primary PCI and thereby improve outcomes; however, as detailed throughout these conference proceedings, it is widely recognized that the development of such systems will be extremely challenging, and their success will depend on the ability to overcome existing barriers and gaps in the evidence base.

Some of the issues that will require careful consideration and additional evaluation and that have been recognized and thoroughly discussed throughout the conference include the impact of the inherent time delay in bypassing non-PCI-capable hospitals or in interhospital transfer on the benefits of primary PCI compared with fibrinolytic therapy in certain subsets of patients (eg, those at low risk), improving EMS and prehospital ECG utilization and integration across wide variation in EMS and community resources, measurement of performance and accountability at a systems level, realignment of financial incentives, and issues specific to rural and underserved communities that relate to disparities in care. These gaps and barriers have served as the underpinnings for the AHA's recommendations for research, programs, and policies detailed below (Table) and for the initial implementation strategies that will support this initiative.

Policy Considerations and Implications

Clearly, changes in existing policy and consideration of new policy will need to occur to foster the development of optimal care for patients with STEMI. The policy writing group discussed both short- and long-term policy recommendations and focused on maximizing opportunities to enhance the processes that are currently available but not fully implemented. In the near term, each region and state will need to evaluate its resources for STEMI systems and its access to primary PCI. Each state should also evaluate its pending legislation. Standardized protocols and toolkits for assessment across the continuum of care will need to be developed and introduced into practice. In addition, the development of a national STEMI center certification program and of criteria for both STEMI referral and STEMI-receiving hospitals should be a priority.

In the longer term, quality improvement measures for STEMI patients treated with primary PCI must be developed and incorporated into quality improvement programs. It will be important to work with quality improvement organizations to have quality measures included in future scopes of work and to include process-of-care measures in quality improvement initiatives, pay-for-participation programs, and pay-for-performance programs. These measures would need to be sensitive to the interdependence among system constituent

TABLE. Consensus Recommendations

Recommendation	Level of Implementation			Time Frame			Writing Group
	National/ Federal	State	Local	Short-Term (<6 mo)	Mid-Term (<12 mo)	Long-Term (>1 y)	
Research							
Quantify the characteristics, frequency, natural history, and effectiveness of interventions with patients who have early prodromal symptoms of STEMI	X			X			Patient
Conduct patient/family surveys about ways to improve management for STEMI before, during, and after PCI for the acute event	X	X			X		Patient
Conduct research on patient and family preferences regarding transfer to a STEMI-receiving hospital (ie, outside of their community)	X				X	X	Patient
Determine the most effective communication methods to bring about changes in patient/bystander action (decreased delay and appropriate system access)	X					X	Patient
Evaluate other options to EMS; for example, does calling a gatekeeper about symptoms (available 24 hours per day/7 days per week) result in less of a time delay than calling EMS?	X			X	X		Patient
Assess the role of decision support and information technology in the home and its impact on patient/bystander delay and EMS utilization	X					X	Patient
Invest in further research and application of information technology to facilitate access to early recognition of symptoms/diagnosis/treatment	X				X	X	Patient
Determine the role of health information technology in expediting patient consent and transfer of medical records	X					X	Patient; STEMI referral hospital; STEMI-receiving hospital
Study the psychological, medical, logistical, social, and financial impact on patients and families of patients transferred out of their community (ie, transfer to a STEMI-receiving hospital directly by EMS or via interhospital transfer)	X	X				X	Patient
Determine how realignment of physicians from STEMI referral hospitals to STEMI-receiving hospitals will affect patient care		X	X		X		Physician
Determine how STEMI-receiving hospitals will realign their services to accommodate the added volume of STEMI patients	X				X		STEMI-receiving hospital
Determine whether direct transport of STEMI patients to a STEMI-receiving hospital (that is not the closest hospital) is safe	X		X		X		EMS/ED
Evaluate the feasibility of emergency patient transfer in rural communities		X	X	X			EMS/ED
Determine the best approach to use of prehospital ECG (ie, interpreted in field, transmitted to ED)	X		X		X		EMS/ED
Evaluate 12-lead ECG systems and reliability of data transfer			X		X		EMS/ED
Evaluate the efficacy of extending programs such as "Get With the Guidelines" and "Guidelines Applied to Practice" to include providers, hospitals, and EMS systems in improving adherence to STEMI guidelines	X					X	EMS/ED
Programs							
Establish community networks where constituents (physicians, patients, EMS, administrators, payers) meet to ensure that appropriate referrals occur reliably			X		X		Patient; Physician; Payer
Provide administrative infrastructure support within the hospital to emergency physicians, nurses, and cardiology leaders that includes protected time for activities related to STEMI system management			X		X		EMS/ED; Physician
Develop novel and expedited methods of patient consent and medical information transfer		X			X		Patient; Physician
Develop programs for seamless interface with patients and their local primary care providers after discharge from STEMI-receiving hospital			X			X	Patient; Physician; Payer
Develop protocols that allow EMS-diagnosed STEMI patients to bypass the ED and go directly to the cardiac catheterization laboratory when appropriate	X	X	X		X		EMS/ED; Physician; STEMI-receiving hospital
Develop algorithms for standardized treatment protocols and clinical pathways in ED and STEMI referral and receiving hospitals according to ACC/AHA guidelines	X	X	X		X		EMS/ED; Physician; STEMI referral hospital; STEMI receiving hospital
Develop algorithms for EMS care that include point-of-entry plan and role at STEMI referral and receiving hospitals according to ACC/AHA guidelines			X		X		EMS/ED; Physician; STEMI referral hospital; STEMI-receiving hospital
Develop and test the effectiveness of educational campaigns to decrease patient delay and increase the use of EMS based on access to a primary PCI-capable hospital destination (ideally building on current campaigns), including education about hospital capability for PCI and implications for management patients will receive if they access care for symptoms	X	X				X	Patient; EMS/ED
Implement prospective education with patients and families about the system of care they will access when seeking evaluation of STEMI symptoms in a regional system of care (based on access to primary PCI for STEMI)	X	X	X			X	Patient

TABLE. Continued

Recommendation	Level of Implementation			Time Frame			Writing Group
	National/ Federal	State	Local	Short- Term (<6 mo)	Mid- Term (<12 mo)	Long- Term (>1 y)	
Policy							
Assess current state legislation and local policies that impact system of care for STEMI patients		X	X	X			Patient; Policy
Evaluate state regulations and pending legislation		X		X			Policy
Evaluate resources by state and by region and determine access to primary PCI		X	X	X			Policy
Provide EMS with sufficient personnel, training, and resources to ensure that a prehospital 12-lead ECG can be acquired from patients with suspected STEMI	X	X	X			X	EMS/ED; Physician
Empower ED physicians in STEMI-receiving hospitals to activate catheterization laboratory resources within a standardized clinical pathway without fear of reprisal for false-positive activation			X	X			EMS/ED
Develop standardized protocols and toolkits for assessment	X	X			X		Policy
Develop scripted interrogation protocols/prearrival instructions for telephone-guided cardiopulmonary resuscitation and administration of aspirin while EMS is en route to the scene			X		X		EMS/ED
Develop and provide EMS with 1 standard algorithm for prehospital assessment, triage, and treatment of STEMI patients		X	X		X		EMS/ED; Policy
Reimbursement							
Ensure that reimbursement rates for interfacility STEMI patient transport reflect the increased level of response capability	X	X				X	EMS/ED; Payer
Ensure that transferring hospitals and transport systems are fairly paid for the costs of evaluating the patient, arranging the transfer, and providing care	X		X		X		Payer
Ensure that care for patients who are determined not to have STEMI, including EMS transport/transfer, is adequately reimbursed without penalty	X					X	Patient; Payer
Ensure alignment of reimbursement policies to encourage providers to participate in a patient-centered integrated system	X					X	Patient; Physician
Align financial incentives with desired outcomes	X					X	Physician; Payer
Work toward addressing reimbursement barriers that affect the implementation of a STEMI system	X					X	Policy
Consider adjusting payments to reflect reporting of data and participation in performance improvement alliances	X		X			X	Payer; Policy
Include process-of-care measures in quality improvement initiatives/pay for participation/pay for performance	X					X	Policy
Quality/outcomes/data							
Develop quality measurement(s) to assess the effectiveness of physicians and other healthcare providers in counseling patients on early activation of EMS and long-term adherence to discharge recommendations according to ACC/AHA guidelines	X				X		Physician
Develop quality improvement measures for eligible STEMI patients and incorporate into quality improvement programs	X					X	Policy evaluation/outcomes
Develop data collection and quality improvement systems to oversee the continuum of STEMI patient care	X	X	X			X	EMS/ED; Evaluation/outcomes
Work with quality improvement organizations to have quality measures included in future scopes of work	X					X	Policy
Provide formal feedback to all participants in a STEMI system as part of an organized quality improvement process			X			X	EMS/ED; Evaluation/outcomes
Training							
Provide (regional) education on STEMI to physician constituents		X	X	X			Physician
Provide continued emergency medical dispatcher training and certification requirements		X	X	X			EMS/ED
Provide training to ED personnel to interpret ST-segment elevation on ECG			X	X			EMS/ED
Patient education							
Partner with managed care plans to help develop explicit language for their patients about what symptoms constitute an "emergency" that requires activation of EMS without preapproval	X				X		Patient; Payer
Ensure appropriateness and consistency of instructions that health plans and providers give patients regarding definitions of emergencies and accessing EMS	X				X		Patient; Payer

components. Finally, addressing reimbursement barriers that affect the implementation of STEMI systems may require creation of a demonstration project to test the hypothesis that a change in the reimbursement structure could provide incentives for the timely interhospital transfer of STEMI patients. A demonstration could also help to identify additional barriers or unintended consequences of a STEMI system of care.

Next Steps

On the basis of the detailed recommendations from each constituent writing group noted in the Table, the AHA has formulated an initial action plan to continue this initiative.

EMS System Assessment and Improvement

The AHA will participate in a needs assessment and analysis of the effectiveness of EMS for STEMI patients as part of a STEMI system of care. This assessment and analysis will identify competencies and related gaps for STEMI care in the EMS setting and will include an evaluation of the EMS infrastructure and policies. The identification of resources (eg, number of advanced cardiac life support vehicles per field), the percentage of responders and dispatchers trained in STEMI protocols, the presence and utilization of 12-lead ECGs on EMS vehicles, mandates to deliver patients to the nearest hospital, protocols for interhospital transfers and call system (eg, 9-1-1 versus next available vehicle), and diversion policies to STEMI-receiving hospitals will be determined.

On the basis of the above assessment, the AHA will facilitate the development of an implementation plan to build the appropriate infrastructure to serve STEMI patients that can be tailored, when necessary, to the appropriate region or state. The implementation phase will address funding, training (using AHA emergency cardiovascular care products), and evaluation of existing process measures and patient outcomes. The AHA, with input from stakeholders, will include the identification of key "next steps," such as the development and testing of future measures, and other activities necessary to further continuous improvement.

Establishing Local Initiatives

The AHA will convene stakeholders at the state and/or local levels to identify initiatives that could be undertaken to improve care for STEMI patients and to consider the establishment of STEMI systems. These same stakeholders would meet regularly so that initiatives to improve STEMI care could be evaluated on an ongoing basis, thereby facilitating necessary midcourse corrections or identification of additional priority areas specific to a region or state. The AHA will explore staffing options for these initiatives throughout the country in selected areas.

The stakeholders will include but are not limited to representation from the following: patients and their caregivers; physicians (EMS, ED, interventional, and noninterventional); advanced cardiovascular nurses and nurse practitioners hospital associations; public and private payers; EMS medical directors; paramedics; EMS regulatory agencies; rural hospitals; STEMI referral hospitals; STEMI-receiving hospitals; policy makers; state health departments; and quality improvement organizations. This broad cross section of

stakeholders would help to ensure that there is "buy in" for interested parties and would help to ensure that any efforts undertaken to improve quality of STEMI care are viable.

The stakeholder evaluation will include but will not be limited to the following:

- Analyzing the current STEMI-related activities taking place at a regional or state level
- Assessing the financial impact of STEMI systems implementation
- Determining the current percentage of the population that has access to ideal STEMI care
- Assessing how EMS and hospital regulations or legislation may serve to enable or hinder the development of STEMI systems within a state and identifying how to overcome regulatory or legislative barriers
- Assessing the potential for overutilization of STEMI services or procedures
- Identifying underserved populations and developing strategies to mitigate disparities in access to care
- Determining feasibility of having interstate diversion or transfers where this would lead to ideal care
- Developing action plans to further patient access to ideal STEMI care

Objective Evaluation of Existing Models

The AHA will convene a group of thought leaders to review existing STEMI system-of-care regional pilot programs (ie, those in Minnesota; Boston, Mass; and North Carolina) and determine whether additional pilot programs are necessary to develop informed recommendations for what an ideal STEMI system-of-care model should include. The existing pilot programs will be evaluated for the following:

- Financial impact on STEMI referral and STEMI-receiving hospitals and EMS
- Rural implications and inclusion
- Overutilization and potential for false-positives
- Disparate population impact
- Resource allocation in regional area
- Allocation of resources within STEMI-receiving hospital to accommodate additional patient volume
- Other criteria as deemed appropriate

Explore Development of National STEMI Center Certification Program and/or Criteria

The AHA, in collaboration with other patient-focused organizations, will develop recommendations for certification of STEMI referral and STEMI-receiving hospitals. Initial steps will include the following:

- Convening an expert advisory working group
- Developing appropriate criteria for certification
- Developing performance and outcomes measurements for use in quality improvement of pay-for-quality/pay-for-participation programs
- Determining the need for possible additional market research

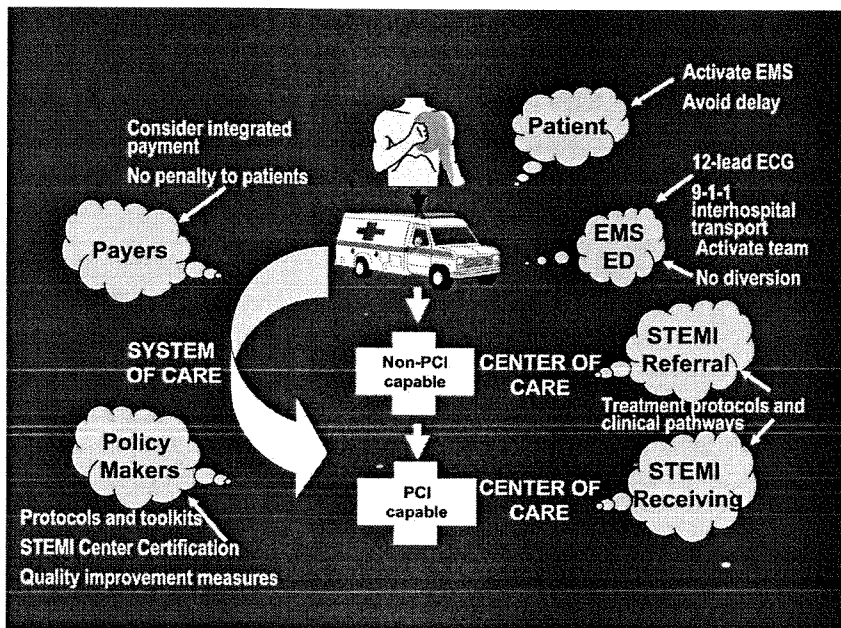


Figure. Improving access to timely care for STEMI patients: the ideal system.

- Exploring a partnership with an accreditation organization for implementation of criteria in STEMI referral and STEMI-receiving hospitals
- Publishing recommendations

Conclusions

The issues inherent to the development of systems of care for STEMI patients are quite complex, with public health, economic, political, and social implications for our society. Yet, few issues are more important with regard to cardiovascular health and outcomes. Improvements in systems of care that increase timely access and adherence to evidence-based therapies, although initially focused on STEMI patients, will ultimately impact the care of all

patients with acute coronary syndromes. The gathering of the multiple constituencies involved in the care of STEMI patients at this conference has fostered the realization that there is considerable overlap among stakeholders in the vision of the ideal system and in the strategies needed to achieve it (Figure). A successful endeavor will require a partnership among patients, physicians, nurses, EMS personnel, hospital administrators, payers, and policy makers. With the ideal system of care in clear focus, it is time to forge this partnership and begin to remove the gaps in our knowledge and the barriers to implementation and to improve the outcomes and quality of care for all STEMI patients.

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This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the disclosure questionnaire, which all writing group members are required to complete and submit.

*This table includes the disclosures for all writing group members of the entire conference proceeding on "Development of Systems of Care for ST-Elevation Myocardial Infarction Patients." Members are presented here in alphabetical order.

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KEY WORDS: AHA Conference Proceedings ■ myocardial infarction ■ point-of-care systems ■ angioplasty ■ reperfusion

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Journal of the American Heart Association