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

Policy Recommendations

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The establishment of timely access to primary percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI) patients holds great promise for improving quality of care and patient outcomes. As described in other sections of these conference proceedings, there are significant barriers to the establishment of the ideal system. Changes in policy will be required to overcome many of the obstacles that preclude the delivery of optimal care for all STEMI patients. Short- and long-term policy recommendations that can foster an ideal STEMI system environment are described below. These recommendations focus on how to maximize opportunities to improve the care of STEMI patients by enhancing the processes that are currently available but not fully implemented.

Short-Term Policy Recommendations

Evaluation of Resources for STEMI Systems and Access to Primary PCI by State and by Region

To ensure that states have the resources available to effectively adopt an ideal system will require that a state or region interested in implementing such a system evaluate their existing resources and analyze how many financial and human resources they would be willing to commit. A state or region should evaluate its emergency medical services (EMS) capabilities and identify the number and location of primary PCI-capable hospitals within a safe distance that would allow for timely treatment of a STEMI patient with primary PCI. It should also assess the total number of STEMI patients that

their hospitals receive on an annual basis. This information would help to better identify whether the existing primary PCI hospitals could handle the volume of patients who may be eligible for primary PCI.

Evaluation of State Regulations and Pending Legislation

Another factor that should be considered when implementing a STEMI system is how existing state regulations and pending legislation may positively or negatively affect the implementation of a STEMI system. For example, in the state of Arizona, the director of the Arizona Department of Health Services, in consultation with the medical director of EMS, can establish protocols related to the transport of patients based on the patient's condition.¹ This type of regulation can help further the implementation of a STEMI system by allowing advocates to work with the EMS director to implement primary PCI protocols for EMS. In contrast, the Illinois Department of Public Health will investigate a hospital in an EMS system that goes on "bypass status" due to overcrowding in the emergency department to determine whether the action was reasonable.² If the Department of Public Health determines the action to have been an improper diversion by the hospital, the hospital incurs a fine. In this instance, it would be important to work together with the Department of Public Health to establish the importance of diversion to primary PCI hospitals.

Similarly, approximately 50% of states in the United States have certificate-of-need programs that may affect how a

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STEMI system is implemented. Cardiac certificate-of-need laws are intended to regulate the number of hospitals that deliver cardiac catheterization and cardiac surgery procedures, and hospitals must justify their community needs, capital expenditures, and staff requirements to the state health planning agency. These needs must consider STEMI patients and ideal systems of care.

Constituents Should Be Brought Together to Develop Strategies for Implementing an Ideal STEMI System

STEMI systems need to be flexible to account for variations in geography and resources that exist among states and regions. Before implementing such a system, constituents involved in STEMI care who represent different interests should discuss how they can or cannot implement the framework discussed in other sections of this article in developing a STEMI system. Constituents should include representation from state EMS, hospital administration, emergency department staff, cardiologists, nurses, and payers. By bringing together the constituents, it will be possible to discuss resource availability, the desired protocols and procedures for diversion or interhospital transfer, whether or not an oversight committee should be established, and how quality improvement for STEMI patients will be assessed.

Constituents should also consider how they might seek to involve patient representatives in this process to achieve patient and family input and support for the STEMI system model. As discussed in "The Patient and Public Perspective" section of these conference proceedings,³ patients and their families may not understand why a transfer or bypass to a primary PCI-capable hospital is preferable. Identifying some of the consumer concerns with the systems at the onset may help to positively affect the patient and family experience in bypassing their preferred hospital or in interhospital transfer.

Implement the Sharing of "Lessons Learned" From Regions That Have Piloted STEMI Systems

Although some regions have successfully adopted a STEMI systems approach, there currently is no data repository in which to catalog examples of protocols used or transfer policies or to review assessment of why elements of the STEMI system succeeded or failed in a region. Devising a way to share "lessons learned" and best practices could potentially reduce some of the financial costs associated with a systems approach. Ideally, this information could be found in a national data repository.

Develop Standardized Protocols and Tool Kits for Assessment

Although there needs to be flexibility in how states or regions implement a STEMI system, standardized protocols across the continuum of care (EMS, emergency department, and STEMI referral and STEMI receiving hospitals) and tools for assessment should be developed. These tools could serve to create a standard, help reduce some of the financial costs associated with creating a STEMI system, and create some uniformity in how care is coordinated and delivered. These tools could also foster quality assurance and quality improve-

ment initiatives and measurement of structure, process, and outcomes.

EMS Agencies Should Be Encouraged to Upgrade to 12-Lead ECG Field Devices

Ideally, most EMS vehicles should be equipped with 12-lead ECG capability, and EMS personnel should be trained on these devices; however, the uniform adoption of the 12-lead ECG and the appropriate training currently may not be feasible from a financial and staff resource perspective. Some states may require federal or state funding to facilitate the adoption and training of personnel on ECG interpretation. In the interim, it may be possible to encourage state EMS medical directors to upgrade to a 12-lead ECG system when they need to change their equipment. Funding gaps, implementation strategies, and assurance of reliability and adequate training will need to be addressed.

EMS Should Use One Standard Algorithm for Prehospital Assessment, Triage, and Treatment of Patients

As stated in the "Emergency Medical Services and Emergency Department Perspective" section of these conference proceedings,⁴ EMS, as part of a multidisciplinary team, should develop protocols for the prehospital assessment, triage, and treatment of patients with suspected STEMI, using the American Heart Association advanced cardiovascular life support chest pain algorithm for guidance. The use of this standard algorithm will facilitate higher-quality patient care and is a necessary component of a STEMI system.

Development of a National STEMI Center Certification Program and Criteria

It will be important to assess the feasibility of developing criteria for both STEMI referral and STEMI-receiving hospital certification in accordance with the American College of Cardiology/American Heart Association practice guidelines to promote timely access to reperfusion therapy and increased access to primary PCI for all STEMI patients. As noted previously, performance and outcomes measures will need to be developed to ensure alignment of anticipated and actual improvement in the quality of care and outcomes for STEMI patients.

Long-Term Policy Recommendations

Quality Improvement Measures for Eligible PCI Patients Must Be Developed and Incorporated Into Quality Improvement Programs

A significant barrier to increasing patient access to primary PCI has been the lack of data regarding the transfer of patients who are eligible for PCI. The diversity of patterns of patient access to primary PCI, including whether the patient was diverted or transferred from another hospital, has served to inhibit the adoption of national standards. Additionally, patient choice concerning where they are treated has complicated this matter further.

Improvement in patient access to primary PCI will require the development and adoption of national standards for the treatment of patients with primary PCI. Examples of process-

of-care measures that could be included in an ideal STEMI system were discussed in the “Evaluation and Outcomes” section of these conference proceedings.⁵ Such measures should be part of quality improvement programs and would be consistent with the recently issued Institute of Medicine (IOM) report entitled “Hospital-Based Emergency Care: At the Breaking Point.”⁶ This would facilitate efforts to capture accurate and timely feedback of data on STEMI reperfusion and could provide a better understanding of the cost-effectiveness of implementing a systems approach. Additionally, this information will allow healthcare providers and institutions to track their performance improvement. This could also provide the federal or state legislature with compelling data on why the adoption of a STEMI system could provide patients with a higher quality of care, which potentially would lead to better patient outcomes.

Work With Quality Improvement Organizations to Have Quality Measures Included in Future Scopes of Work

The Centers for Medicare and Medicaid Services (CMS) has contracts with more than 50 quality improvement organizations (QIOs) throughout the country that are responsible for working with consumers, physicians, hospitals, and other caregivers to refine care-delivery systems. This allows CMS to ensure that patients receive quality care, particularly patients from underserved populations. The QIOs provide technical assistance to hospitals to improve their scores in CMS quality initiatives.

Last year, the IOM published its report entitled “Medicare’s Quality Improvement Organization Program: Maximizing Potential.”⁷ In this report, the IOM stated that the QIOs have the potential to play a significant role in improving the quality of health care delivered to patients. According to the IOM, the primary focus of QIO programs should be to provide technical assistance in the area of performance measurement and quality improvement (in light of the increased use of public reporting initiatives, including pay-for-performance), rather than also focusing its efforts on beneficiary education and communication and the protection of the Medicare trust fund. Although CMS officials have stated that the IOM report does include sound ideas to improve the QIO program,^{8,9} the agency has not reported which policy recommendations it may adopt. As the largest payer of cardiac services, inclusion of process-of-care measures for STEMI into future scopes of work set forth by the CMS could play a critical role in the evaluation of the effectiveness of STEMI systems of care.

Inclusion of Process-of-Care Measures in Quality Improvement Initiatives/Pay-for-Participation/Pay-for-Performance Programs

The development of process measures for PCI by transfer or direct transport will facilitate the collection of data and reporting of measures. To collect a broad sample of data, it is worthwhile to explore whether these quality initiatives should be linked to financial incentive programs, such as mandatory reporting, pay-for-participation, pay-for-performance, or pay-for-quality programs. Interest in using these programs has increased greatly and could facilitate the steady adoption of quality measures that would form a part of an optimal STEMI system.

Quality indicators that are developed should be incorporated into hospital voluntary reporting programs. In fact, the IOM report “Hospital-Based Emergency Care: At the Breaking Point”⁶ does explore the idea of convening a panel of experts to develop measures that could be used in evaluating the performance of individual providers within the system, as well as the system as a whole, to improve the quality of emergency care provided. The report also notes that once these measures are developed and tested, they could be used in pay-for-performance programs. Therefore, one possibility for a more widespread adoption of these measures could be to gradually incorporate them into pay-for-participation programs by both private and public payers. These measures will facilitate the gathering and evaluation of data as to whether or not there is an increase in the number of patients being directed to PCI-capable hospitals. However, these measures would need to be sensitive to the interdependence among system components (ie, EMS transport time is related to whether a STEMI-receiving hospital’s emergency department is on diversion).

Additionally, as STEMI measures for physicians are developed, they could also be incorporated into existing voluntary reporting or pay-for-reporting programs. For example, the Tax Relief and Health Care Act of 2006 authorized the establishment of a physician quality reporting system by CMS.¹⁰ The program, known as the physician quality reporting initiative (PQRI),¹¹ establishes a financial incentive for eligible professionals to participate in this voluntary quality reporting program. Those eligible professionals who successfully report on the designated set of quality measures on claims for dates of service from July 1, 2007, to December 31, 2007, may earn a bonus payment of 1.5% of total allowed charges for covered Medicare physician fee schedule services. This program, like other quality improvement initiatives, is intended to facilitate the agency’s effort to improve patient health and outcomes by preventing chronic disease complications, avoiding unnecessary hospitalization, and improving the quality of care delivered. The program is voluntary and consists of 74 evidence-based measures, including measures for STEMI.

However, the American Heart Association believes that any measures that are used in pay-for-performance, pay-for-reporting, or pay-for-quality programs must adhere to 4 principles. These principles state that these programs should¹² (1) promote health care that is safe, effective, patient-centered, timely, efficient, and equitable; (2) use rigorous methodological approaches to measure quality of care (quality-of-care measures should be risk-adjusted, standardized, and evidence-based); (3) promote quality-of-care systems and quality infrastructure; and (4) implement evaluation mechanisms to determine whether program goals are achieved or whether inadvertent adverse consequences have resulted.

Working Toward Addressing Reimbursement Barriers That Affect the Implementation of a STEMI System

As discussed in the “Gaps, Barriers and Implications” and the “Payer Perspective” sections of these conference proceed-

ings,^{13,14} development of an ideal STEMI system will involve overcoming some significant financial disincentives that are associated with the participation of non-PCI-capable hospitals in such a community program. These hospitals may be concerned that diversion of patients or interhospital transfer will put them out of the “heart business,” which can often provide a lifeline for a hospital’s financial success and may help to subsidize other less lucrative services. Therefore, nationwide adoption of this system approach will necessitate a change in how health care is reimbursed for eligible PCI patients.

The most attractive proposition for payment reform would be to create a single prospective payment that covers care from activation of 9-1-1 to transfer of a patient, which would allow both hospitals and EMS to share gains that would result from the coordination of patient care and would remove the inefficiencies inherent in the payment system. Such a payment system could potentially provide incentive for interhospital transport by EMS to have the same priority as a patient 9-1-1 transport. However, this type of reimbursement change will require a significant restructuring of the payment system.

The first step might be to create a demonstration project that would test the hypothesis that a change in the reimbursement structure could provide an incentive for the interhospital transfer of patients. This demonstration would also provide an opportunity to apply the protocols delineated in other sections of these conference proceedings at a regional level. This demonstration project could pay all key players for their role in facilitating the transfer of eligible patients to a primary PCI-capable hospital and would provide for an evaluation process. Data provided from this demonstration could then provide advocates of a STEMI system with the necessary information to determine whether this type of coordination is in fact possible, whether it can improve the quality of care delivered to patients, and whether the treatment is cost-effective.

A demonstration could also help to identify additional barriers or unintended consequences of a STEMI system of care. For example, such a demonstration could provide a better understanding of whether a non-PCI-capable hospital would lose prestige as a result of transferring a patient to a primary PCI-capable hospital. Moreover, it could provide information on whether the non-PCI-capable hospital will lose future business for other modality services to the primary PCI-capable hospital and whether the primary PCI-capable hospital makes a concerted effort to refer STEMI patients back to their community hospitals and physicians. On the basis of the data that result from this demonstration, one could apply “lessons learned” to advocate for appropriate changes in national reimbursement.

Disclosures

Potential conflicts of interest for members of the writing groups for all sections of these conference proceedings are provided in a disclosure table included with the Executive Summary.

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