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

## Gaps, Barriers, and Implications

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The establishment of ST-elevation myocardial infarction (STEMI) systems of care that are intended to increase timely access to primary percutaneous coronary intervention (PCI) will affect the US healthcare system in a broad and fundamental way. The key reason for establishing STEMI systems of care is that although primary PCI is superior to fibrinolytic therapy when performed rapidly, timely access to primary PCI is currently limited. By establishing these systems, it is believed that patients with STEMI can be directed to PCI-capable hospitals through prehospital emergency medical services (EMS) protocols and emergency interhospital transfer arrangements, and as a consequence, outcomes will be improved. The establishment of STEMI systems of care in the United States will be challenging, however, and their success will be predicated on the ability to overcome a number of practical barriers.[1] In this article, we discuss several of these barriers, as well as the potential for STEMI systems of care to reduce mortality and their overall implications for the US healthcare system.

## Clinical Issues

The overall benefit of directing patients with STEMI to PCI-capable hospitals with prehospital EMS protocols or interhospital transfer arrangements has not been demonstrated definitively in the United States and raises concerns from a clinical perspective that need to be considered. First, the inherent delays required for performing primary PCI may limit its effectiveness when long transport times are anticipated and may influence the choice between reperfusion therapies.[2–5] Thus, STEMI systems of care that divert patients to PCI-capable hospitals may delay the delivery of reperfusion therapy for many patients compared with prompt treatment with fibrinolytic therapy at the closest hospital. At some point, the additional time required to perform primary PCI will eliminate its advantages over fibrinolytic therapy, and in some scenarios it could lead to higher mortality rates. Some studies suggest that primary PCI loses its advantages over fibrinolytic therapy when door-to-balloon times exceed door-to-drug times by 60 to 90 minutes.[5,6] Unless an improved system can be developed, patients presenting to non–PCI-capable hospitals may be at particular risk, because door-to-balloon times of 3 hours or more occur in 50% of cases when interhospital transfer is needed, based on recent National Registry of Myocardial Infarction data.[7] Although new strategies—so-called pharmaco-invasive approaches with fibrinolytic therapy and/or glycoprotein IIb/IIIa inhibitors before PCI—are being proposed to mitigate the effect of time delays by accelerating recanalization of the infarct artery with an initial pharmacological approach, these treatment strategies remain experimental,[8,9] and current studies do not support their use.

The superiority of primary PCI over fibrinolytic therapy may also not be consistent across all patient groups, with a minimal difference in mortality rates noted for many patient

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groups.[10] With the exception of high-risk patients, such as those with anterior myocardial infarction, cardiogenic shock, or late presentations, low-risk patients and those presenting early after symptom onset may derive little or no benefit from primary PCI compared with fibrinolytic therapy even under ideal settings, such as in clinical trials in which door-to-balloon times and operator experience with primary PCI are optimized. In the DANish multicenter randomized study on fibrinolytic therapy versus acute coronary angioplasty in Acute Myocardial Infarction (DANAMI)-2 trial, for example, primary PCI and fibrinolytic therapy demonstrated similar outcomes in the nearly 75% of patients identified as low risk.[11] In the PRimary Angioplasty in patients transferred from General community hospitals to specialized PTCA Units with or without Emergency thrombolysis (PRAGUE)-2 trial, patients presenting within 3 hours of symptom onset had similar outcomes regardless of the type of reperfusion therapy used.[12] A recent clinical trial in the very elderly population also showed similarities between the 2 reperfusion strategies.[13] Finally, even in patients in whom primary PCI has been proved to be superior to fibrinolytic therapy, the clinical benefits are restricted primarily to reductions in reinfarction and hemorrhagic stroke, with modest improvements in absolute mortality rates (≈1% to 2%).[14]

## Operational and Accountability Issues

A key operational challenge will be to improve utilization of EMS by patients. Patients who are transported by EMS have 2 advantages within STEMI systems of care: (1) They may have shorter times to reperfusion therapy because of earlier recognition of their condition, and (2) they may be preferentially directed to PCI-capable hospitals in a timely fashion if prehospital electrocardiography is performed.[15] In addition, there is the ability to provide immediate advanced life support to the patients who sustain sudden cardiac arrest. However, fewer than half of all STEMI patients use EMS.[15] The need for electrocardiographic diagnosis by EMS is even more critical because chest pain is a nonspecific symptom, and the vast majority of patients with chest pain who do use EMS do not have an STEMI.[16] The 20-city Rapid Early Action for Coronary Treatment (REACT) trial, an intensive, 18-month, community-based intervention to increase awareness of symptoms of myocardial infarction, showed no improvement in patient-related delays in seeking medical care (≈133 minutes after symptom onset) and only a modest increase in appropriate EMS utilization, which demonstrates how difficult it will be to overcome this barrier.[17] In addition, prehospital ECGs are rarely performed by EMS providers, potentially because of limited access to these devices and nonspecific symptoms in many patients.[16] Without improvements in EMS utilization and the use of prehospital electrocardiography, the potential of STEMI systems of care will be restricted.

Another operational challenge will be the evaluation of STEMI systems of care to ensure that the anticipated changes in outcomes actually occur. This is discussed in detail in the preceding section of these conference proceedings.[18] This issue, which relates to both measurement of performance and accountability, will be particularly difficult to control and measure at a "systems" level, where interactions between EMS providers and hospitals become critical for STEMI systems of care to be successful. For example, under ideal circumstances, STEMI systems of care will direct patients with suspected STEMI rapidly and appropriately to PCI-capable hospitals. If done improperly, however, "overtriage," "undertriage," or "mistriage" of patients to PCI-capable hospitals may occur, leading to increased costs with no clinical benefit. Undertriage would result in worse outcomes by failing to direct patients with STEMI to available PCI-capable hospitals when possible within rapid time frames. Overtriage would result in wasted resources if a substantial number of patients without STEMI were sent to PCI-capable hospitals. Mistriage would result in worse outcomes by inefficiently triaging patients to PCI-capable hospitals only after substantial delays. As a result, fibrinolytic therapy would be underutilized in clinical scenarios in which it may have resulted in better outcomes than delayed primary PCI. However, in well-developed systems that utilize prehospital ECGs, the rate of such mistriage has been shown to be low.[19] The establishment of systems that monitor these potential problems requires a framework for defining denominator populations (ie, at-risk patients with suspected STEMI) and appropriateness. In addition, discussions about who will be ultimately accountable for the developing, collecting, benchmarking, and reporting of these measures are needed.

## Resource and Economic Issues

When establishing STEMI systems of care, stakeholders will need to recognize that there is great variation in EMS and hospital resources throughout the United States. Designing systems to best match the needs of a community given its resources will be challenging for policy makers and providers. Clearly, a "one-size-fits-all" strategy is not practical or achievable. For some communities, direct ambulance referral or emergency interhospital transfer protocols may be effective at preferentially directing STEMI patients to PCI-capable hospitals. Such systems have been developed successfully (but to a limited extent) using regional networks[19,20]; however, whether these approaches can be generalized to broader areas of the United States is unclear. For other communities, large geographic distances may severely restrict rapid access to cardiac catheterization facilities. In these areas, STEMI systems of care may need to selectively refer high-risk patients to PCI-capable hospitals and use fibrinolytic therapy for others.[21] Decisions about who will be responsible for (1) assessing local needs and resources and then (2) designing an optimal strategy for a particular community have not yet been resolved.

In addition, it is currently impossible at a national level to evenly match a population's needs with available resources. There is no population-based surveillance system of STEMI in the United States as in other countries, and it is unclear whether rates of STEMI are actually declining as some have postulated.[22,23] We also have very limited data regarding assessments of available resources. According to the 2002 national survey by the Health Resources and Services Administration, basic life support services are available to

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>90% of the US population, whereas advanced life support services are available to only 77%.[24]

There is also wide variation in training standards for first responders. In the case of hospital-based resources, it appears that nearly 80% of the US population lives within a 1-hour drive of a PCI-capable hospital[25]; however, this means that >43 million US adults do not have timely access to PCI-capable hospitals without the use of air transport. It also does not take into account whether these hospitals have the personnel resources to provide around-the-clock coverage for primary PCI if a patient were to arrive during off-hours or on weekends.

Understanding the current status of needs and resources across communities is a prerequisite to making new investments. Expanded EMS systems will likely be needed in many areas to account for an increased volume of calls associated with a STEMI system of care. Many EMS providers also will need new equipment, such as devices for acquiring prehospital ECGs, and additional training in its use. In a recent survey of 200 large cities across the United States, only 67% of EMS providers had prehospital electrocardiographs as part of their available equipment,[26] although more recent data suggest improvement. The availability of equipment for EMS providers in less-populated cities and rural areas is unknown but may be lower. Because prehospital ECG devices can cost up to $25 000 per machine,[27] supplying them to EMS providers could lead to substantial upfront costs for many communities. Device maintenance, wireless or remote transmission systems, and training for personnel to perform and potentially read prehospital ECGs will add further costs.

New investment in primary PCI programs will add even more to the costs of STEMI systems of care. Primary PCI is highly cost-effective (and potentially cost-saving) compared with fibrinolytic therapy in hospitals with well-established, high-volume elective PCI programs.[28,29] However, upfront investments in equipment and personnel costs will limit the availability and cost-effectiveness at hospitals where PCI programs need to be initiated or low volumes are expected.[28] From the systems level, it is unclear under what circumstances STEMI systems of care will be cost-effective for a community, but it is likely to depend on several factors, including the community's existing resources and anticipated STEMI volume.[30] Additional evaluation and discussion will be required to determine how much additional cost will be incurred and who will pay that cost. Although increased costs are a concern, there is the potential to reduce costs by instituting a more efficient system that delivers timely, evidence-based therapy to STEMI patients, particularly those at highest risk.

Complicating these economic issues further is the fact that patients with acute myocardial infarction are typically insured (≈95%) and relatively "profitable" for hospitals that provide cardiovascular services. In fact, for many hospitals, cardiovascular services are responsible for up to 40% of general revenue, and these services are used to subsidize other less profitable but essential services, such as burn care.[31] Reimbursement structures will need to change to avoid the significant pressure for hospitals to keep and care for patients with STEMI at their own facilities to ensure financial viability. If not, these issues will further fragment the healthcare delivery system and prevent the cooperative effort across hospitals that is needed for successful STEMI systems of care. Additional concerns may come from payers as well. As discussed in the "Payer Perspective" section,[32] STEMI systems of care will need to be designed carefully so as not to place patients at financial risk for their hospitalized care if they are directed to noncontracted providers. Issues related to reimbursement, especially those tied to interhospital transport, will also need to be resolved well in advance of patient arrival to prevent additional time delays during treatment.

Finally, in addition to aligning economic incentives for both non–PCI-capable and PCI-capable hospitals to participate in STEMI systems, there needs to be careful monitoring for the potential expansion of interventional cardiology services within communities where nearby providers already exist. Development of cardiac catheterization laboratories and primary PCI programs could lead to greater utilization of these services in a variety of other clinical settings, such as elective PCI, where there is less evidence that outcomes are improved.[33] Safeguards against the proliferation of a "medical arms race" would be needed, including the ability for STEMI systems to potentially limit the expansion of new PCI programs. As noted previously and by others, detailed and evidence-based criteria for the creation of a STEMI-receiving hospital will need to be established.[34]

## Policy Issues

There will be significant political challenges to establishing STEMI systems of care at a national level. Regulatory authorities that control EMS and hospital services vary across states, counties, and cities, which makes it difficult to organize care efficiently. Regulations, such as certificate-of-need laws, are also different across regions. The presence or absence of certificate-of-need laws can have an important impact on how systems are designed. Without certificate-of-need laws, it will be difficult for regulatory authorities to organize primary PCI programs based on need. A commonly cited failure of urban trauma system development has been the designation of too many centers because of an inability of regulatory authorities to centralize services.[35] This can potentially weaken the overall system and lead to duplication of services.

Patients also may have strong preferences regarding where they receive care.[36] This may be a problem, especially for patients who are preferentially directed to PCI-capable hospitals that are far away. One solution may be to retransfer individuals who are stabilized soon after their procedure, but the costs associated with this strategy are unknown. Addressing this issue and developing widespread public support for these systems early in the process will be critical for STEMI systems of care to succeed. This will be especially important because there has been a traditional lack of desire for state-sponsored healthcare planning in the United States. Allowing these systems to be designed and implemented in a manner that respects local regulations and cultures will be extremely challenging.

Finally, it will be important for regulators and the public to determine the overall goal of STEMI systems of care more specifically. This will include specific determinations of the

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extent of additional investments that are available and the populations and regions that will be targeted. These issues may raise concerns of equity or rationing, particularly for rural and underserved communities, which could be denied timely access to these systems in portions of the United States. In those areas, alternative strategies for maintaining access to quality of care for patients with STEMI will need to be considered.

## Conclusions

Improving outcomes for patients with STEMI in the United States is an important public health goal. Recent data point to significant underutilization of evidence-based therapies in STEMI patients and persistent disparities in the use of treatments across race, gender, and geography. Optimization of the care of STEMI patients through the establishment of systems of care could be of great value. STEMI systems of care need to be designed not only to reduce mortality by increasing timely access to primary PCI but also to promote broader use of reperfusion therapy in all eligible patients and to enhance access and adherence to other important evidence-based therapies. In the United States, there is currently a lack of robust evidence available to support the widespread use of strategies that preferentially direct eligible patients to PCI-capable hospitals through prehospital EMS protocols or interhospital transfer arrangements, although in Europe, such systems have been implemented successfully.[37]

The unstructured and competitive nature of the US healthcare system, unlike those of other countries, also raises practical barriers to the implementation of these systems. The heterogeneous nature of EMS providers and hospitals across the United States will require that these systems be flexible enough to adapt to the local needs and resources of different communities. The costs and cost-effectiveness of STEMI systems of care remain unclear. As outlined in the recommendations throughout these conference proceedings, before STEMI systems of care can be implemented on a large scale, there is a clear need for additional evidence of their "real-world" effectiveness gathered from careful study of some pilot implementation communities, as well as a better understanding of their broader implications for the US healthcare system. Ultimately, a well-designed system of care will improve care for patients with STEMI through improved prehospital diagnosis and "smart triage" of patients, with transport to the most appropriate facility for each individual in the shortest amount of time.

## 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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