In the past 2 decades, we have seen dramatic changes in the care of patients with ST-elevation–myocardial infarction (STEMI). Randomized, controlled trials in the early 1990s showed that primary percutaneous coronary intervention (PCI) was superior to fibrinolytic therapy, and a 2003 meta-analysis of 23 clinical trials firmly established primary PCI as the preferred treatment for STEMI patients. However, studies also showed that the effectiveness of primary PCI decreased if there was a substantial time delay. A meta-regression analysis by Nallamothu et al showed that the comparative advantage of primary PCI over fibrinolytic therapy was lost if the added procedural and logistical complexity of primary PCI resulted in more than a 60-minute time delay in reperfusion. On the basis of this analysis, a 90-minute door-to-balloon time goal was established, and the 2004 American College of Cardiology/American Heart Association (ACC/AHA) STEMI guideline writers challenged caregivers by recommending that STEMI patients presenting to a facility where PCI could not be administered within 90 minutes of first contract should receive fibrinolytic therapy instead of primary PCI.

The use of primary PCI steadily increased, yet a 2002 study showed that only about a third of patients who received primary PCI for STEMI had a door-to-balloon time of less than 90 minutes. Some hospitals succeeded in improving door-to-balloon times, and research by Bradley et al identified strategies that were associated with consistently better results. These strategies became the focus of D2B: An Alliance for Quality, a national campaign sponsored by the ACC and 26 other organizations, including the AHA. Starting in 2006, the D2B Alliance recruited more than 1000 hospitals nationwide, with a goal of achieving a door-to-balloon time of less than 90 minutes in more than 75% of patients. Door-to-balloon times began to improve dramatically, and, by 2010, 91% of patients receiving primary PCI in the United States had a door-to-balloon time of less than 90 minutes.

The D2B Alliance addressed the timeliness of primary PCI for patients presenting to a PCI hospital, but not all hospitals are PCI-capable. How should we treat patients with STEMI who present to non-PCI hospitals? Randomized, controlled trials have shown that transferring patients for primary PCI is more effective than fibrinolytic therapy, but it remains unclear whether these results coming from specialized centers can be reproduced in practice and how much transfer delay is acceptable. In 2004, the transfer times from non-PCI hospitals to PCI-capable hospitals remained unacceptably high, with only about 4% of transferred patients having a first door-to-balloon time of less than 90 minutes. A more recent study showed that the time to transfer a STEMI patient from a non-PCI hospital (the door-in–door-out time) was 68 minutes, and prolonged times were associated with higher in-hospital mortality.

To address these broader issues, the 2007 Focused Update of the 2004 ACC/AHA STEMI guidelines called for systems of care to improve coordination between PCI hospitals, non-PCI hospitals, and emergency medical services. Also in 2007, the AHA launched Mission: Lifeline, a national initiative to encourage communities across the nation to develop regional strategies for coordinating the care that occurs before the patient reaches a primary PCI center.

In 2 decades, we have made enormous progress, yet more research is needed and more leadership will be required to design the best strategies for treating patients with STEMI. Three articles in this issue of Circulation: Cardiovascular Quality and Outcomes advance our knowledge on how systems of care and regional coordination can improve the care of STEMI patients.

Jollis et al report the results of a comprehensive survey of hospitals participating in the Mission: Lifeline Program. The purpose of the survey was to examine the characteristics of the currently established systems of care and to delineate remaining challenges. A total of 381 unique systems involving 899 PCI hospitals from 47 states responded to the survey. Responses helped to identify 5 broad interventions that are likely to improve treatment times: (1) direct activation of catheterization laboratories by paramedics and emergency physicians, (2) destination or hospital-bypass protocols, (3) improved interhospital transfer protocols, (4) data collection using available national databases, and (5) timely feedback to healthcare providers involved in STEMI care.

The survey revealed several opportunities to improve regional coordination of care. More than half of the systems reported the availability of 12-lead ECGs in their vehicles, but the ability to transmit ECGs to the receiving hospitals from all ambulances was available in only 35% of systems. Just 61% of systems had protocols to allow for diversion to a PCI hospital on the basis of a prehospital ECG, and only 35% had a mechanism for providing feedback to healthcare personnel within 24 hours.

Common barriers to system building were competition among hospitals and among physician groups, lack of...
funding, and challenges related to data collection. The most common source of funding for STEMI systems was the PCI hospital. According to the survey, third-party payers did not have a role in funding of STEMI systems. The authors suggested that payment methods such as a single prospective payment, which would allow gain-sharing among hospitals, might remove barriers and facilitate the development of less fragmented systems of care.

A second article in this issue comes from investigators in Australia. In an intriguing study, they created a model to compare interventions for STEMI system building using Geographical Information Systems to analyze hospital location, population distribution, road network data, and estimated travel times. In Australia, only 12% of hospitals have primary PCI capability, yet this analysis showed that 93% of the population has timely access to some form of reperfusion therapy, mainly fibrinolytic therapy (for 53% of the population). They estimated that establishing 10 new primary PCI facilities (a 25% increase) would result in only a modest 3.7% improvement in timely access to primary PCI. Greater gains were seen with improvements in interhospital transfer protocols and prehospital emergency medical service (EMS) triage and diversion. In major cities, the model suggested that implementing EMS diversion protocols would improve timely PCI for 23.8% of the population. In remote areas, gains could be realized by using prehospital fibrinolytic therapy. The method for Geographical Information Systems modeling appeared to provide useful insights for planning better systems of care.

A third article in this issue is from the APEX-AMI (The Assessment of Pexelizumab in Acute Myocardial Infarction Trial) investigators. This randomized trial was designed to test the efficacy of pexelizumab, a humanized monoclonal antibody C5 complement inhibitor in patients with STEMI undergoing primary PCI. The trial enrolled 5745 STEMI patients treated with primary PCI at 296 sites in 17 countries. The trial showed no effect of the study drug but provided a useful window into the care of STEMI patients treated with primary PCI.

In their analysis, the investigators compared STEMI patients transferred for primary PCI with those who presented directly to a PCI hospital. The main outcome was a 90-day composite of death, shock, or heart failure. Sixty-six percent of nontransferred patients had a first door-to-balloon time of less than 90 minutes, as compared with 19% in the transferred patients. The time from arrival at the first hospital to the time of arrival at the PCI hospital, defined as the D1D2 time, was 84 minutes. At the PCI hospital, transferred patients had a median arrival time to balloon time of only 45 minutes, as compared with a median door-to-balloon time of 76 minutes for the patients arriving directly to the PCI hospital, reflecting the advantage of advance activation of the catheterization laboratory for the transferred patients.

The 90-day primary outcome was not different between the transfer and nontransfer groups (10.3% and 10.2%, respectively). Unadjusted D1D2 time was strongly associated with 90-day outcomes in patients transferred for primary PCI. However, after multivariable adjustment, no significant association was observed. The difference in symptom onset to balloon time was only 45 minutes longer in the transferred patients, again due to advance activation of the catheterization laboratory team in the transferred patients.

This trial demonstrates that first door-to-balloon time can be shortened in transferred patients through advance activation of the catheterization laboratory personnel at the PCI hospital, partially diminishing the transfer time delay. The trial also introduces the D1D2 time as an accurate and potentially useful measure to monitor the quality of interhospital transfer protocols.

Where should we go from here to improve STEMI care? One option would be to increase the number of PCI-capable hospitals. The analysis by Ranasinghe et al suggests that this option would not improve access to timely primary PCI. In fact, from 2001 to 2006, the proportion of US hospitals with PCI capability increased by 44% (from 25.5% of hospitals to 36.2%), yet the percentage of the population residing within 60 minutes of a PCI-capable hospital only increased by 0.9%. Adding more PCI hospitals seems to create duplication rather than improved access to primary PCI for STEMI patients. Furthermore, increasing the number of PCI-capable hospitals to perform a constant number of total PCI procedures dilutes the pool of experience for interventional cardiologists and technical staff. Simply adding new PCI-capable hospitals creates new challenges related to staffing needs and interventional cardiology call coverage, and many regions are already struggling with these issues. Rather than adding more PCI-capable hospitals, more regional coordination and consolidation would provide a better way to improve care while addressing these very real and practical challenges.

Because of stubbornly persistent transfer delays, some commentators have suggested increasing the use of fibrinolytic therapy for STEMI patients presenting to non-PCI hospitals. This may be a solution for remote geographic regions where transfer times cannot be reduced. However, the Jollis survey suggests that there are still opportunities to decrease transfer times through prehospital diversion protocols and more efficient transfer processes. American physicians are risk-adverse, and I suspect that the small but real risk of intracranial hemorrhage with fibrinolysis will continue to provide a strong motivation to treat STEMI patients with primary PCI, despite lingering problems with prolonged transfer times.

The Jollis survey reported that 84% of systems participated in a national data registry, yet only 68% of systems routinely tracked the time from first medical contact to reperfusion. Better measurement, feedback, and reporting will clearly drive improvement. However, challenges remain on how to accurately collect data on care that starts beyond the walls of a hospital. Because these data will be publicly reported and will determine rates of reimbursement, it will be important to define statistical methods that set a high bar for quality while recognizing that there is margin of error when you measure complex patterns of care in the real world.

Interestingly, Jollis et al found that only 18% of the surveyed systems were designed or influenced by state legislation. Without legislation or regulation, most regions
lack a strong driving force for cooperation and coordination. In many communities, good intentions and scientific knowledge are not enough to overcome the barriers that impede the development of STEMI systems of care. As hospitals compete, interventional cardiologists are often caught in the middle, yet we must continue to push for common sense solutions that will yield the best care for our patients.

We now have abundant knowledge from surveys, modeling, observational studies, and trials that can inform and guide the design of systems of care for STEMI patients. Mission: Lifeline has helped us down the road toward better-organized care, but barriers related to competition and finances continue to impede progress. It is now “mission critical” that we work collaboratively to create high-quality regional systems of care for patients with STEMI.

Disclosures
Dr Brush is a member of the Board of Trustees of the American College of Cardiology and a member of an advisory board for United Healthcare.

References
Improving ST-Elevation–Myocardial Infarction Care
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