Innovations in Care

Sustaining Improvement in Door-to-Balloon Time Over 4 Years

The Mayo Clinic ST-Elevation Myocardial Infarction Protocol

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Background—American College of Cardiology/American Heart Association guidelines recommend a door-to-balloon time (DTB) <90 minutes for nontransferred patients with ST-elevation myocardial infarction (STEMI) who undergo primary percutaneous coronary intervention. Systems of care to achieve and sustain this DTB performance over several years have not been previously reported.

Methods and Results—The Mayo Clinic STEMI protocol was implemented in April 2004 and included activation of the cardiac catheterization laboratory by the emergency medicine physician; a single call system to activate the catheterization laboratory; catheterization laboratory staff arrival within 20 to 30 minutes of activation; and real-time performance feedback within 24 to 48 hours. Data were collected on nontransferred STEMI patients. The preimplementation group (June 2002 to March 2004) comprised 96 patients with a median DTB of 97 (interquartile range, 82, 130) minutes, and 40% had a DTB <90 minutes. The postimplementation group (May 2004 to March 2008) comprised 322 patients with a median DTB of 67 (interquartile range, 55, 82) minutes, and 81% had a DTB <90 minutes. Postimplementation DTB was significantly shorter than preimplementation DTB (P<0.001). In the 4-year follow-up after protocol implementation, the DTB performance remained stable over time (P=0.41).

Conclusions—The Mayo Clinic STEMI protocol implemented strategies to reduce DTB for nontransferred patients with STEMI. DTB was significantly reduced, and the results were sustained over the 4-year follow-up period. Our experience demonstrates the effectiveness and durability of process changes targeting timeliness of primary percutaneous coronary intervention. (Circ Cardiovasc Qual Outcomes. 2009;2:508-513.)

Key Words: diagnosis ■ myocardial infarction
experienced by the patient. A multidisciplinary team identified the following barriers:

1. The emergency medicine physician was required to call a cardiologist to evaluate the patient and ECG before the catheterization laboratory could be activated.
2. There was no standardized protocol for communication between the ED and catheterization laboratory staff, which led to multiple redundant phone calls.
3. The catheterization laboratory team was activated by paging each team member and waiting for a response sequentially. This process could take 20 to 30 minutes just to alert the entire catheterization team of an emergency case.
4. There were no formal expectations or goals for when the catheterization laboratory should be prepared to receive the patient after activation, resulting in the ED making repeated phone calls to the catheterization laboratory to determine whether the patient could be transferred.
5. There was no process or mechanism to provide feedback to staff on DTB performance, to identify barriers, or to develop iterative improvements.

**Design of the Initiative**

In January 2004, a multidisciplinary team was formed to improve timeliness of primary PCI among patients with STEMI. This team consisted of staff from the ED, quality office, ECG laboratory, emergency communication center (ECC), which manages and dispatches all regional ambulances, coronary care unit, and catheterization laboratory. This team initially reviewed historical DTB performance and agreed that there was a significant gap between routine care and ideal care. A current-state value stream map of patient flow was constructed, and quality improvement methods including plan, do, study, act (PDSA), and lean were applied to optimize patient flow and eliminate non-value-added steps or waste. This led to the development of a future-state value stream map for ideal patient flow, which led to a series of practice changes implemented over the subsequent 100 days, named the Mayo Clinic STEMI protocol (Table 1).

The Mayo Clinic STEMI protocol implemented multiple changes to the entire system of care and patient flow from the ED to the catheterization laboratory. Rather than calling for an “urgent” ECG and waiting for the ECG technician to come to the ED for every patient with suspected acute coronary syndrome, we assigned a dedicated ECG technician to the ED. This was a reallocation of existing ECG technicians, rather than an incremental hiring of staff. The ECG technician dedicated to the ED is expected to perform an ECG on all patients with suspected acute coronary syndrome with a target door-to-ECG time of <10 minutes. The ECG technician was also given the responsibility for obtaining immediate review of the ECG by an ED physician, rather than simply leaving the ECG on the medical chart for ad hoc review.

After reviewing the ECG and performing a brief history and physical examination, the ED physician activates the catheterization laboratory if STEMI is diagnosed, without needing to call a cardiologist to review or approve the activation. The target for door-to-catheterization laboratory activation is <15 minutes. The ED physician activates the catheterization laboratory by making one phone call to the ECC. The ECC sends out an alphanumeric page to all members of the on-call catheterization laboratory team, which displays the message: “ED STEMI” patient location, and procedural start time, which is 30 minutes from the time of activation. Using the ECC is advantageous compared to the hospital telephone operator because the ECC manages all external requests for emergency transport by ground and air ambulances, has 24×7 coverage, answers all calls on the first ring, and records the entire telephone conversation, which is retrievable for future review.

Saint Mary’s Hospital has 5 operational catheterization labs during regular hours. During regular hours, the catheterization laboratory charge nurse calls back to acknowledge the activation, and initiates patient transfer because the catheterization team is already in-house. During off-hours, defined as a presentation between 1700 and 0659 or on weekends or national holidays, catheterization team members are required to call back within 5 minutes to the ECC to confirm the page or another page is sent. If there is no response to the second page from a specific staff member, then the ECC places a telephone call to that individual’s home telephone or cell phone. If this is unsuccessful, another team member on back-up duty is directly called. All catheterization staff are required to arrive at the hospital within 20 to 30 minutes after activation. The target for door-to-ED departure is <45 minutes.

**Implementation of the Initiative**

Saint Mary’s Hospital is an academic tertiary center, and primary PCI is standard reperfusion strategy for all nontransferred patients with STEMI 24×7. The Mayo Clinic STEMI protocol was implemented in April 2004. The multidisciplinary team and senior leadership communicated the new system of care to all staff in the ED, coronary care unit, and
catheterization laboratory to mitigate any barriers or resistance to implementation.

Time metrics were collected prospectively after the implementation of the protocol. The ED registration staff used a wireless laptop to collect demographic information and register patients at the bedside on arrival. These personnel had a 2-hour training session, were provided a STEMI pager, and were charged with real-time prospective collection of time metrics using a web-based data collection form for all patients with a STEMI activation (similar to their charting responsibility for Trauma codes).

Performance data are sent by electronic mail to all physician and allied staff involved in the specific patient’s care within 24 to 48 hours of every case. In addition, the multidisciplinary team overseeing the quality improvement initiative is copied on all electronic mail. These electronic mails include the patient name, identifier number, method of patient arrival (ambulance or self-transport), hospital arrival date and time, initial ECG time, catheterization laboratory activation time, catheterization laboratory start time, first balloon or device time, and total DTB. Any documented reasons for delays are also listed. Any cases that are outliers routinely stimulate discussions among physicians and nurses. The discussions focus on barriers as well as opportunities for improvement. In the majority of cases, discussions are held via electronic mail or telephone, and ad hoc meetings to review cases are held 2 to 4 times per year. The multidisciplinary quality improvement team also reviews each outlier case to provide their insights.

Success of the Initiative
To evaluate the success of the protocol, we compared the DTB performance pre- and postimplementation. Eligible patients included those who presented with onset of symptoms for ≤12 hours and who were found to have either new or presumed new ST-elevation or left bundle branch block (LBBB). ST-elevation was defined as ≥1 mm elevation of ST segments in 2 or more limb leads or ≥2 mm on 2 or more contiguous precordial leads. Door time was defined as time stamped on the triage sheet on patient arrival to the ED. Balloon time was the time documented in the catheterization procedure note as the time of first device used to open the coronary artery including balloon, stent, or thrombectomy device.

The preimplementation time period included data from June 2002 to March 2004. Trained nurses from the Quality office retrospectively collected DTB performance metrics for STEMI patients undergoing primary PCI from data that was reported to the Center for Medicare and Medicaid Services (CMS). The postimplementation time period included data from May 2004 to March 2008, and DTB performance data were prospectively collected by trained ED and cardiology allied staff. During the postimplementation period, data were collected for all patients who had a STEMI activation. Our primary analysis looked at patients who had a final diagnosis of STEMI and who underwent primary PCI from data that was reported to the Center for Medicare and Medicaid Services (CMS). The knots were predetermined as the 5th, 35th, 65th, and 95th percentiles of the given date range,14 those values being 7/14/04, 8/26/05, 11/18/06, and 11/27/07. The likelihood ratio test of the spline was used to test whether there were inconsistencies or trends over time.

Results
The preimplementation group, which served as the historical controls, comprised 96 patients with STEMI treated with primary PCI from June 2002 to March 2004. The postimple-
A postimplementation group consisted of 322 nontransferred patients with STEMI treated with primary PCI from May 2004 to March 2008. The inclusion and exclusion criteria for the postimplementation group are summarized in Figure 1.

Baseline characteristics for both groups are outlined in Table 2, with the greatest difference being that the preimplementation group had a higher frequency of prior myocardial infarction ($P < 0.001$). The preimplementation group also was significantly more likely to have hypertension, diabetes, and a higher serum creatinine.

The outcomes for both groups are summarized in Table 3. The preimplementation group had a median DTB of 97 (interquartile range [IQR], 82, 130) minutes. A total of 40% of patients had DTB times of <90 minutes, and 8.3% had DTB times of <60 minutes. For the postimplementation group, median DTB was 67 (IQR, 55, 82) minutes. A total of 81% of these patients had DTB times of <90 minutes, and 39% had DTB times of <60 minutes. Median DTB were lower in the postimplementation group as compared to the preimplementation group ($P < 0.001$). In addition, the percentage of patients with DTB <60 minutes and DTB <90 minutes were significantly higher in the postimplementation group ($P < 0.001$). For the postimplementation group, the measured time intervals for their initial management are as follows: the median door-to-ECG time was 8 (IQR, 5, 11) minutes, the median door-to-catheterization laboratory activation time was 14 (IQR, 9, 24) minutes, and the median door-to-ED departure time was 36 (IQR, 28, 47) minutes.

We also analyzed how regular- versus off-hours performance differed both pre- and postimplementation. There was no significant difference in the proportion of patients arriving during off-hours between the preimplementation and postimplementation groups (64% versus 63%; $P = 0.97$; see Table 2). DTB was significantly longer for preimplementation patients whether they arrived during regular- or off-hours. For off-hours patients, the preimplementation group had a median (IQR) DTB of 103 (86, 134) minutes versus 70 (59, 86) minutes for the postimplementation group ($P < 0.001$). For patients arriving during regular hours, the median (IQR) DTB was 91 (76, 119) minutes versus 59 (47, 77) minutes for pre- and postimplementation groups, respectively ($P < 0.001$; Figure 2).

In addition, we analyzed the relationship between DTB time and in-hospital mortality for the postimplementation group, and found a nonsignificant trend of higher mortality

Table 2. Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Preimplementation (n=96)</th>
<th>Postimplementation (n=368)</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, male</td>
<td>65 (68)</td>
<td>230 (71)</td>
<td>0.48</td>
</tr>
<tr>
<td>Age, y</td>
<td>64±14</td>
<td>64±14</td>
<td>0.75</td>
</tr>
<tr>
<td>Tobacco use</td>
<td></td>
<td></td>
<td>0.32</td>
</tr>
<tr>
<td>Former</td>
<td>25 (26)</td>
<td>93 (29)</td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>35 (37)</td>
<td>94 (30)</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>68 (71)</td>
<td>184 (59)</td>
<td>0.040</td>
</tr>
<tr>
<td>History of prior MI</td>
<td>33 (34)</td>
<td>49 (15)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>65 (68)</td>
<td>191 (62)</td>
<td>0.30</td>
</tr>
<tr>
<td>Diabetes</td>
<td>25 (26)</td>
<td>51 (16)</td>
<td>0.026</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>11 (11)</td>
<td>38 (12)</td>
<td>0.93</td>
</tr>
<tr>
<td>CHF on exam</td>
<td>7 (7)</td>
<td>18 (6)</td>
<td>0.55</td>
</tr>
<tr>
<td>Serum creatinine, mg/dL</td>
<td>1.1 (1.0, 1.2)</td>
<td>1.0 (0.9, 1.2)</td>
<td>0.044</td>
</tr>
<tr>
<td>Presenting off-hours</td>
<td>61 (64)</td>
<td>204 (63)</td>
<td>0.97</td>
</tr>
</tbody>
</table>

Data are presented as n (%), mean±SD, or mean (IQR). MI indicates myocardial infarction; CHF, congestive heart failure.

Table 3. Study Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Preimplementation (n=96)</th>
<th>Postimplementation (n=322)</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTB, min</td>
<td>97 (82, 130)</td>
<td>67 (55, 82)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DTB &lt;60 min</td>
<td>8.3</td>
<td>39</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DTB &lt;90 min</td>
<td>40</td>
<td>81</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Data are presented as median (IQR) or %.
rates for longer DTB times (P=0.11; Figure 3). This study was not designed with enough power to compare in-hospital mortality rates pre- and postimplementation. The crude unadjusted in-hospital mortality rates were 4.2% for the preimplementation group and 5.9% for the postimplementation group, and this was not statistically significant (P=0.51).

In the postimplementation time period, 46 patients with a final clinical diagnosis of STEMI did not undergo primary PCI. To assess our management of STEMI activations for all STEMI patients, whether or not they underwent primary PCI, we performed a secondary analysis of all 368 nontransferred patients with STEMI. To perform this analysis, patients who did not ultimately undergo PCI had their DTB right-censored at the last benchmark time (eg, door-to-ED departure). A Kaplan–Meier analysis was performed for this larger postimplementation group, and median DTB was 69 (IQR, 56, 87) minutes. A total of 77% of these patients had DTB times of <90 minutes, and 35% had DTB times of <60 minutes. Even with this broader postimplementation group, median DTB were lower in the postimplementation group as compared to the preimplementation group (P<0.001). In addition, the percentage of patients with DTB <60 minutes and DTB <90 minutes remained significantly higher in the postimplementation group (P<0.001).

Trend Analysis for Sustaining DTB Performance
An analysis was conducted on our primary postimplementation group to test whether improved DTB performance was sustained over the four years following implementation of the STEMI protocol (Figure 4). A Cox proportional hazards model showed that DTB performance was stable over time and there was no evidence of a trend for increasing or decreasing DTB during this period (P=0.41). It is noted that the IQR for the last quarter of the preimplementation period was wider than those of the other periods, and a sensitivity analysis after removing these observations did not affect the median DTB or IQR.

Summary of the Experience
Our report shows that a quality improvement initiative to improve DTB for nontransferred patients with STEMI achieved and sustained improvements in DTB over 4 years. Before the implementation of the protocol, median DTB was 97 minutes with 40% of patients having a DTB time of <90 minutes. After implementation, the median DTB decreased to 67 minutes, and 81% had a DTB time of <90 minutes. These results meet the goals set by the Door-To-Balloon Quality Alliance.

In 2002, CMS began public reporting of DTB for STEMI patients as a core measure for hospitals. Williams et al15 published an analysis of the first 2 years of these national data, and showed that DTB exceeded the guideline recommendations of <90 minutes. Multiple studies from individual institutions have documented challenges in achieving the Door-to-Balloon Quality Alliance goals of DTB <90 minutes in at least 75% of patients.8–13 Many of these studies have attempted to improve DTB by implementing 1 or 2 isolated strategies, as opposed to implementing all the core strategies recommended by the Door-to-Balloon Quality Alliance.

The Door-to-Balloon Quality Alliance is a national quality improvement initiative started in 2006.7 This alliance involves more than 1000 US hospitals with PCI capability, and was formed to disseminate evidence-based strategies for primary PCI from qualitative and quantitative research from best-performing hospitals. The primary goal of the alliance is for hospitals to reliably achieve DTB of <90 minute in at least 75% of nontransferred patients with STEMI. The key strategies recommended by the Door-to-Balloon Quality Alliance include: ED activation of the catheterization laboratory without needing cardiology review or approval, using a single-call system for catheterization laboratory activation, catheterization team arrives at the hospital during off-hours within 20 to 30 minutes of being paged, prompt data feedback to all staff, senior management and organizational support for these changes, and a team-based approach to all aspects of STEMI care. We had implemented all of these strategies as part of the Mayo Clinic STEMI protocol in April 2004.

Our experience for nontransferred STEMI patients is the first report of DTB performance over a 4-year time period after implementing improvements in systems of care. The Mayo Clinic STEMI protocol was developed to be a reliable system of care that can be sustained over several years with little additional cost. The use of rigorous time goals, priority parking for off-site personnel, direct wireless phone communication between ED nursing and catheterization laboratory nursing, and use of elevator control bypass key for patient transport were all implemented without any additional cost. The single group page used to activate the catheterization laboratory team required a single programming change, but the pagers were already in use by the clinical team. The real-time data collection involved hiring a half-time database coordinator, while the real-time feedback involved hiring a half-time nurse coordinator to review and abstract the data.

Our improvements were sustainable for several reasons. First, we implemented a protocol that included broad-based improvements in our entire system of care, with little change in operational cost. We were able to sustain these improvements largely because of our strong interdepartmental relationships, as well as a solid communication system.

Interdepartmental relationships are crucial to the success and sustainability of a protocol such as this. We developed a
multidisciplinary team approach and prioritized timely reperfusion therapy and optimal patient care, rather than any parochial interests of a single group or person. In addition, we maintain a collegial environment where the ED and cardiology staff are able to work together to improve processes in an organizational fashion. This collegiality has been fostered from the initial foundation of the Mayo Clinic. Additionally, our institution continually strives for improved patient-centered care. We feel that these organizational values contributed to successfully implementing such a broad-based change in clinical practice.

The communication and feedback process is also very important to the sustainability of our protocol. We allow for every case to be reviewed in a timely and systematic fashion through electronic mail feedback. This allows us to review every case within a short amount of time, and not wait for monthly or quarterly meetings to discuss the cases. Discussion is encouraged and routinely generated through this process. There is no evidence for notification fatigue and, on the contrary, providers have come to expect an electronic mail documenting overall door-to-balloon time performance and component time metrics within 24 to 48 hours of every case. Any barriers can be discussed on a case-by-case basis, face-to-face meetings can be held as needed, and the data that is generated allows the multidisciplinary leadership to monitor progress and discuss ways to prevent barriers in the future. We believe that the reliable, immediate feedback of time performance is a critical strategy to foster communication, promote a team-work approach to problem solving, and sustain performance.

Limitations
When we instituted our STEMI protocol, we implemented several changes simultaneously. Hence, it is impossible to differentiate which of these changes made the greatest difference in performance. Differences in the preimplementation and the postimplementation groups attributable to the limitations of the study design cannot be accounted for. These include nonrandomization, time trends, and the retrospective data collection for the preimplementation group.

Also, we realize that the preimplementation group does not include certain STEMI patients if they were excluded from CMS reporting, such as out-of-hospital arrest patients. However, we did include all of these patients in our prospective postimplementation group to create an assessment of our protocol on “all-comers” with STEMI who underwent primary PCI. This may bias the preimplementation data, likely toward a shorter DTB and lower short-term mortality, because the CMS data excludes the more complicated patients.

Conclusions
The Mayo Clinic STEMI protocol implemented multiple improvements in our system of care for nontransferred patient with STEMI and achieved DTB <90 minutes for >75% of patients over a 4-year time period. Our study shows what is possible to achieve and sustain for improving timeliness of reperfusion therapy for patients treated with primary PCI.

Disclosures
None.

References
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doi: 10.1161/CIRCOUTCOMES.108.839225

Circulation: Cardiovascular Quality and Outcomes is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-7705. Online ISSN: 1941-7713

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