Integration of Pre-Hospital Electrocardiograms and ST-Elevation Myocardial Infarction Receiving Center (SRC) Networks

Impact on Door-to-Balloon Times Across 10 Independent Regions

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Objectives The aim of this study was to evaluate the rate of timely reperfusion for ST-elevation myocardial infarction (STEMI) with primary percutaneous coronary intervention (PPCI) in regional STEMI Receiving Center (SRC) networks.

Background The American College of Cardiology Door-to-Balloon (D2B) Alliance target is a >75% rate of D2B ≤90 min. Independent initiatives nationwide have organized regional SRC networks that coordinate universal access to 9-1-1 with the pre-hospital electrocardiogram (PH-ECG) diagnosis of STEMI and immediate transport to a SRC (designated PPCI-capable hospital).

Methods A pooled analysis of 10 independent, prospective, observational registries involving 72 hospitals was performed. Data were collected on all consecutive patients with a PH-ECG diagnosis of STEMI. The D2B and emergency medical services (EMS)-to-balloon (E2B) times were recorded.

Results Paramedics transported 2,712 patients with a PH-ECG diagnosis of STEMI directly to the nearest SRC. A PPCI was performed in 2,053 patients (76%) with an 86% rate of D2B ≤90 min (95% confidence interval: 84.4% to 87.4%). Secondary analyses of this cohort demonstrated a 50% rate of D2B ≤60 min (n = 1,031), 25% rate of D2B ≤45 min (n = 517), and an 8% rate of D2B ≤30 min (n = 155). A tertiary analysis restricted to 762 of 2,053 (37%) cases demonstrated a 68% rate of E2B ≤90 min.

Conclusions Ten independent regional SRC networks demonstrated a combined 86% rate of D2B ≤90 min, and each region individually surpassed the American College of Cardiology D2B Alliance benchmark. In areas with regional SRC networks, 9-1-1 provides entire communities with timely access to quality STEMI care.   (J Am Coll Cardiol Intv 2009;2:339–46) © 2009 by the American College of Cardiology Foundation

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Timely primary percutaneous coronary intervention (PPCI) by experienced operators is superior to fibrinolytic therapy for the treatment of acute ST-elevation myocardial infarction (STEMI) (1,2). Recent quality improvement (QI) efforts have focused on simultaneously expanding access to PPCI and reducing door-to-balloon (D2B) times. However, this dual goal of access and quality remains challenging, because PPCI is a complex, multidisciplinary, and time-sensitive therapeutic intervention: the process is measured in minutes, outcomes are measured by short-term mortality, and teamwork and smooth transitions between various care-provider units seem to be critically important.

Abbreviations and Acronyms

AHA-ML = American Heart Association Mission: Lifeline

CCL = cardiac catheterization laboratory

D2B = door-to-balloon time

D2B Alliance = American College of Cardiology D2B: An Alliance in Quality

E2B = emergency medical services-to-balloon time

ED = emergency department

EMS = emergency medical services

PH-ECG = pre-hospital electrocardiogram (12-lead)

PPCI = primary percutaneous coronary intervention

QI = quality improvement

SRC = ST-elevation myocardial infarction receiving center

STEMI = ST-elevation myocardial infarction

A D2B time within 90 min represents the current benchmark for quality PPCI as promulgated in the American College of Cardiology/American Heart Association STEMI guidelines (1,2) and the Joint Commission Core Measures (3). Each 15-min incremental delay beyond a 90-min D2B time is associated with an increased risk of in-hospital death (4,5). However, nationally <50% of patients are treated within 90 min (6,7), underscoring the challenge in achieving this goal.

In 2006, the American College of Cardiology launched D2B: An Alliance in Quality (D2B Alliance) (8), a large-scale QI-initiative that engaged over 1,000 PPCI-capable hospitals across the nation to target a >75% rate of D2B ≤90 min. The D2B Alliance emphasized 6 evidence-based in-hospital strategies to improve the rate of timely reperfusion (9). A seventh evidence-based strategy involved the use of a 12-lead pre-hospital electrocardiogram (PH-ECG) to activate the cardiac catheterization laboratory (CCL), but

implementation was considered optional because of low use nationally (9).

In the same year, a multidisciplinary group proposed the rationale for establishing STEMI Receiving Center (SRC) Networks, a concept that started on a "grassroots" level in response to the convergence of various external forces (10). Two types of regional STEMI networks were described: inter-hospital transfer and pre-hospital cardiac triage.

Pre-hospital cardiac triage (10) involves universal access via 9-1-1, the identification of STEMI patients by emergency medical services (EMS) personnel with PH-ECGs, and direct transport to the nearest SRC (designated PPCI-capable hospital). Ideally, EMS stabilization and transport of patients with a PH-ECG diagnosis of STEMI should occur almost simultaneously with CCL activation at the receiving hospital. Furthermore, EMS is allowed to bypass non-PPCI-capable hospitals when enroute to the designated PPCI-capable hospital (i.e., the SRC) within an organized regional network.

No comprehensive database evaluating pre-hospital cardiac triage within SRC networks exists in the U.S. However, because D2B time measurement is considered a reliable and nationally standardized performance measure for PPCI quality (11), this study analyzed registry data from 10 independently organized regions with the hypothesis that SRC networks focused upon pre-hospital cardiac triage could provide high rates of timely reperfusion.

Methods

Study design. Collaboration among 10 independently organized regional SRC networks meeting previously described criteria (10) (Table 1) led to this pooled analysis. Upon initiation of each regional network, a responsible agency was designated to collect and maintain a prospective observational registry focused on continuous QI for D2B times. A locally managed central database was not available for 2 SRC networks (Minneapolis/St. Paul and Royal Oak), but D2B datasets consistent with study criteria were obtained from each participating SRC in the region and aggregated.

Study setting. The 10 participating regional SRC networks from across the U.S. (Fig. 1) varied from urban to semi-

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Table 1. Criteria for SRC Hospitals and Networks

STEMI Receiving Center (SRC)

- PPCI-capable hospital approved by customary regulatory agencies
- On-site cardiothoracic surgery (unless regulatory waiver obtained)
- Coordinated interdepartmental policies directed at providing rapid PPCI as the "Plan A" or a backup "Plan B" involving timely fibrinolytics
- Each designated SRC hospital expected to receive all STEMI patients identified by EMS in their catchment area, regardless of race, gender, socioeconomic, or insurance status
- CCL available and accessible 24/7, regardless of emergency department diversion status for routine ambulance transports
- Hospital-based multidisciplinary committee meets regularly and promotes CQI on D2B times and other parameters as appropriate (e.g., E2B)

Regional SRC network criteria for pre-hospital cardiac triage

- Paramedics equipped with 12-lead PH-ECG machines to diagnose acute STEMI in all patients who call 9-1-1 and have symptoms suggestive of acute cardiac ischemia
- Regional protocol specifies that paramedics transport patients with presumed STEMI per PH-ECG to nearest designated SRC
- Parallel processing is emphasized, with patient transport and CCL activation occurring simultaneously whenever possible
- For all consecutive STEMI patients brought in by paramedics, hospitals designated as SRCs agree to submit D2B times (and other parameters as appropriate) to a central agency or committee providing oversight for the SRC network
- Regional multidisciplinary committee meets regularly and evaluates D2B times (and other parameters as appropriate [e.g., E2B]) to promote CQI

CCL = cardiac catheterization laboratory; CQI = continuous quality improvement; D2B = door-to-balloon; E2B = emergency medical services-to-balloon time; EMS = emergency medical services; PH-ECG = pre-hospital electrocardiogram; PPCI = primary percutaneous coronary intervention; STEMI = ST-elevation myocardial infarction.

rural, have a combined population exceeding 20 million, and collectively contain 166 paramedic receiving hospitals, of which 72 were designated SRCs (Table 2). Each regional SRC network database contained D2B times on all patients meeting the following criteria: STEMI identified by 9-1-1/EMS providers equipped with PH-ECGs, transported per EMS protocol to a designated SRC, and treated with PPCI. The 10 regional SRC databases excluded STEMI patients who self-transported to the emergency department (ED) or underwent inter-hospital transfer.

In this pooled analysis, each region submitted data on the total number of SRC network patients undergoing PPCI, stratified by D2B ≤90 or >90 min. All consecutive patients were included, starting from the unique date of each SRC network launch through August 31, 2007. Institutional review board approval was obtained for the

aggregate analysis, which was restricted to de-identified data sets as defined by federal regulatory agencies (12).
SRC network performance measures. The primary end point of this analysis was the rate of D2B ≤90 min in patients with STEMI. Secondary analyses included the rate of D2B ≤60 min, ≤45 min, and ≤30 min. The rate of EMS-to-balloon (E2B) time ≤90 min was considered a tertiary end point, because only 5 of 10 regions tracked this parameter. "Time Zero" for E2B was previously defined as the date and time auto-stamped on the first PH-ECG that was consistent with an acute STEMI (10,13). Clinical outcomes data were not available.
Statistical methods. Descriptive analyses (Microsoft Excel, Redmond, Washington) were performed to calculate all end points. The proportion of D2B ≤90 min versus >90 min was reported both in aggregate and individually for each of the 10 regions. Other end points were reported only in aggregate.
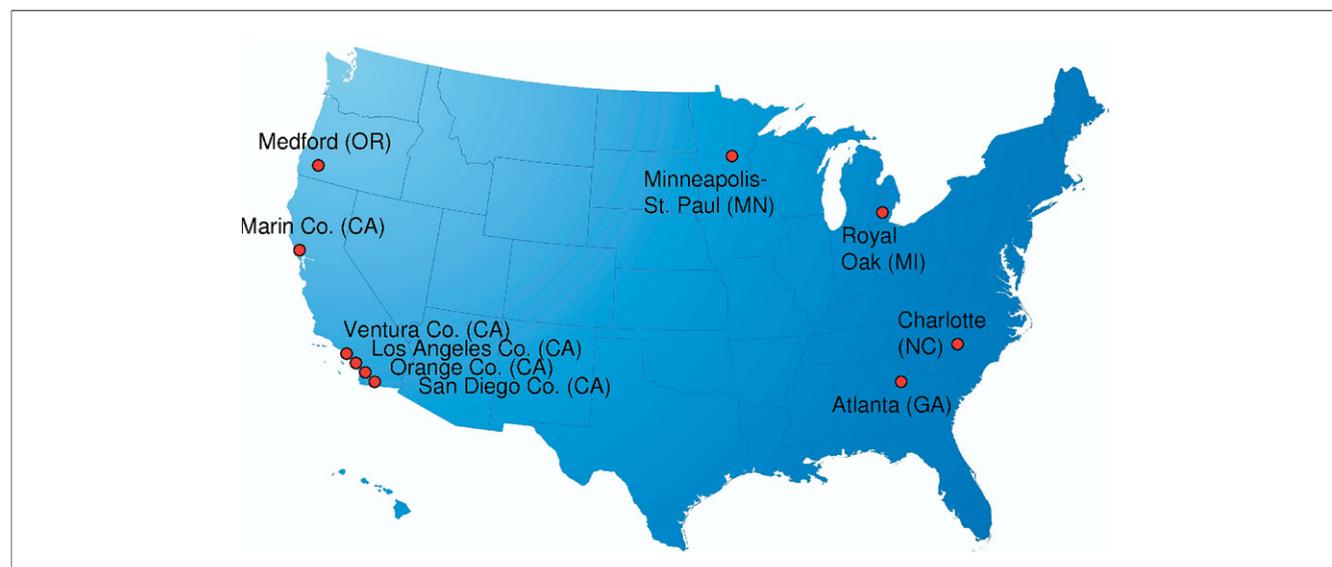

Figure 1. Location of 10 Independent Regional ST-Elevation Myocardial Infarction Receiving Center Networks

Table 2. Primary End Point and Demographic Data for 10 Independent SRC Networks

Region	PPCI Done (N)	% Rate D2B ≤90 min	Network Start Date	Population (Millions)	No. of SRCs vs. No. of Hospitals Total	No. of Paramedics (Approx.)	PH-ECG Interpretation Strategy
Orange Co., CA	563	85%	Feb-05	3.0	12 of 25	880	Computer
Los Angeles Co., CA	476	90%	Dec-06	10.0	30 of 74	2,500	Computer
Marin Co., CA	231	78%	Jun-03	0.3	1 of 3	177	Computer & Manual
San Diego Co., CA	210	86%	Jan-07	3.0	13 of 20	963	Computer
Minneapolis/St Paul, MN	168	97%	May-06	0.8	3 of 12	300	Computer & Manual
Royal Oak, MI (Southeast Oakland Co.)	112	80%	Apr-04	0.3	1 of 1	200	Computer & Manual
Charlotte, NC (Mecklenburg & Union Co.)	89	94%	Jan-07	1.0	3 of 7	244	Computer & Manual
Medford, OR (Jackson & Josephine Co.)	85	78%	Jan-06	0.3	1 of 4	138	Computer & Manual
Ventura Co., CA	67	85%	Jan-07	0.8	3 of 7	220	Computer
Atlanta, GA (Fulton Co.)	52	77%	Mar-07	0.8	5 of 13	200	Computer & Transmit
TOTAL	2,053	86%		20.3	72 of 166	5,822	

Three options for pre-hospital electrocardiogram (PH-ECG) interpretation: Computer: automated computer algorithm; Manual: direct interpretation by paramedic; Transmit: wireless transmission of PH-ECG to receiving hospital for physician interpretation.

Co. = county; other abbreviations as in Table 2.

Results

D2B times ≤90 min. There were 2,712 patients diagnosed with STEMI by PH-ECG. In the 2,053 (76%) who underwent PPCI, pooled data from all 10 independently managed regions demonstrated an 86% rate (95% confidence interval: 84.4% to 87.4%) of D2B ≤90 min. When assessed by individual region, the rate of D2B ≤90 min ranged from 77% to 97% (Table 2, Fig. 2).

D2B times ≤60, ≤45, and ≤30 min. Further analyses of the entire 2,053 patient cohort undergoing PPCI demonstrated a 50% rate of D2B ≤60 min (n = 1,031), 25% rate of D2B ≤45 min (n = 517), and an 8% rate of D2B ≤30 min (n = 155).
E2B times ≤90 min. There was a 68% rate of E2B ≤90 min in this study. The E2B times could be determined in 762 of 2,053 (37%) patients, because only 5 of 10 regions had records that included the time of the first PH-ECG consistent with STEMI: Los Angeles County (442 pa-
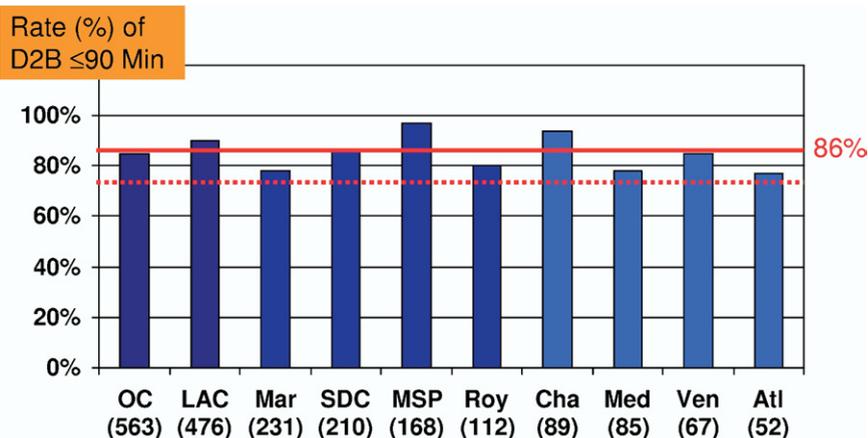

Figure 2. D2B ≤90 Min by Region

The rate of door-to-balloon (D2B) ≤90 min for 10 independent regional ST-elevation myocardial infarction (STEMI) receiving center (SRC) networks organized in descending order, on the basis of total number of patients (N) in each region that were pre-hospital electrocardiogram(+) for STEMI and underwent primary percutaneous coronary intervention through August 31, 2007. Regional databases with >400, 400 to 100, and <100 primary percutaneous coronary intervention patients are denoted in **dark blue**, **blue**, and **light blue**, respectively. **Dashed red line** represents D2B Alliance benchmark rate of 75%. **Solid red line** denotes 86% rate of D2B ≤90 min for all 10 regions combined (n = 2,053). Atl = Atlanta, Georgia; Cha = Charlotte, North Carolina; LAC = Los Angeles County, California; Mar = Marin County, California; Med = Medford, Oregon; MSP = Minneapolis/St. Paul, Minnesota; OC = Orange County, California; Roy = Royal Oak, Michigan; SDC = San Diego County, California; Ven = Ventura County, California.

Table 3. Summary of Primary, Secondary, and Tertiary End Points

End Point	Rate (%)	For Analysis (n)
D2B ≤90 min	86%	2,053
D2B ≤60 min	50%	2,053
D2B ≤45 min	25%	2,053
D2B ≤30 min	8%	2,053
E2B ≤90 min	68%	762

D2B = door-to-balloon; E2B = emergency medical services-to-balloon time.

tients), Minneapolis/St. Paul (100), Medford (85), Charlotte (71), and Ventura County (64).

Discussion

Acquisition of a PH-ECG represents an evidence-based yet underused strategy to reduce D2B times (1,9). Furthermore, a recent American Heart Association (AHA) scientific statement (14) concluded "the central challenge for health-care providers is not to simply perform a PH-ECG, but to use and integrate the diagnostic information from a PH-ECG with systems of care."

This 10-region QI analysis showed that successful use and broad translation of PH-ECGs could be achieved with the creation of regional SRC networks focused on pre-hospital cardiac triage. Analysis of 2,053 consecutive STEMI patients treated with PPCI demonstrated an 86% rate of D2B ≤90 min (Table 3), thus providing proof-of-concept for the conclusions in the AHA statement (14). Importantly, these individual regions included from 1 to 30 SRCs, and each independently exceeded the D2B Alliance benchmark rate of 75% (8).

Further evidence that regional SRC networks possess substantial capacity to consistently deliver very rapid PPCI-focused reperfusion was demonstrated by the finding that one-half (50%) of the STEMI patients identified by PH-ECG had a D2B ≤60 min, one-quarter (25%) had a D2B ≤45 min, and 8% had a D2B ≤30 min. These data are important, because "Time Is Muscle" remains a fundamental principle of STEMI-care (15). These results are also consistent with the most recent guidelines (1), which strongly endorse a continued focus on faster reperfusion times, better systems of care, and an expanded use of the PH-ECG. Most recently, a registry analysis demonstrated additional in-hospital mortality reductions as D2B times are reduced from 90 to 30 min (16).

Another unique finding of the current analysis was demonstrated by the 68% rate of E2B ≤90 min for patients treated in the 5 regions that prospectively tracked this variable (Table 3). Following initial proposals (10,13), our data provides the first evidence that the rate of E2B ≤90 min may represent an appropriate metric for assessing the performance of coordinated regional STEMI care systems. A theoretical construct for achieving an E2B ≤90 min in urban/suburban settings is the 30-30-30 goal, wherein the 3 provider units (EMS, ED, CCL) work in rapid succession and each complete their unique duties within 30 min (13).

Of patients identified by PH-ECG with presumed STEMI, 24% percent were not treated with PPCI, as compared with a 14% rate reported by a large inter-hospital transfer network (17). However, the exact rate of false-positive CCL activations could not be determined in our 10-region analysis. The relative frequency in which the CCL team was never activated by the on-duty ED physician (despite a PH-ECG with presumed STEMI) or clinical scenarios of angiography without PPCI was not tracked. Also, uncertainty about the best definition of false-positive CCL activations continues to exist (17).

Baseline rates of D2B ≤90 min for each region before SRC network implementation were unavailable, except for Los Angeles County. Analysis of D2B times during 2005 at 4 major Los Angeles County hospitals showed a <50% rate of D2B ≤90 min for EMS-transported STEMI patients, even though PH-ECG use by EMS providers was routine (18). However, after the formal implementation of a regionalized SRC network protocol in Los Angeles County on December 1, 2006, there was an immediate, substantial, and sustained improvement in reperfusion times for EMS-transported STEMI patients demonstrated by a 90% aggregate rate of D2B ≤90 min for 30 hospitals newly designated as SRCs (Fig. 3). The strong association between high rates of D2B ≤90 min and SRC network implementation is clinically significant, and it is unlikely to have been caused by unmeasured confounders across 30 different hospitals in Los Angeles County.

Our primary finding, an 86% rate of D2B ≤90 min for pre-hospital cardiac triage patients across 72 hospitals, compared favorably with various national databases. Registry data from 1999 to 2002 demonstrated that the rate of D2B ≤90 min had remained stagnant nationally at approximately 40% (6). Recent events, such as the 2004 STEMI guidelines promulgating a D2B ≤90 min (2), mandatory reporting of D2B times as a Joint Commission core measure (3), and the 2006 launch of D2B: An Alliance in Quality (8) seem to have had a favorable impact nationally. For example, multiple recent analyses (which include both self-transported and EMS-transported STEMI patients) revealed a 55% to 70% rate of D2B ≤90 min nationally (19–22). A likely explanation for the substantially higher rate of D2B ≤90 min demonstrated in our 10-region SRC network analysis is that self-transported STEMI patients included in these 4 national registries often encountered reperfusion delays as a consequence of ED overcrowding, a major health care issue documented nationally by a 2006 Institute of Medicine report (23).

Two recent studies further bolster our findings. First, a regionalized STEMI system from Ottawa (Ontario, Canada) demonstrated a 79.7% rate of D2B ≤90 min in 135
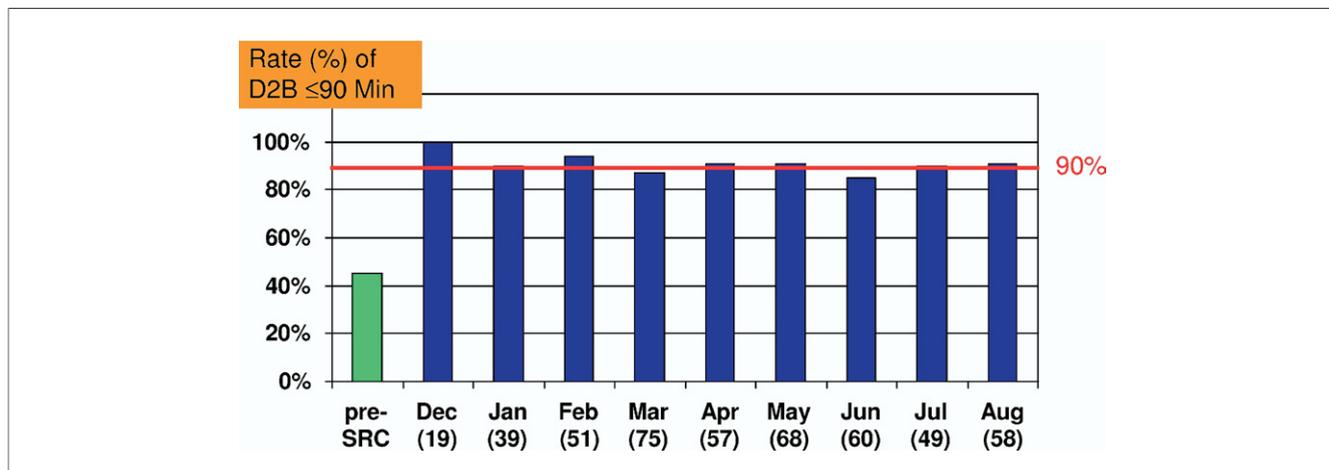
Figure 3. Los Angeles County SRC Network Rate of D2B ≤90 min

Temporal trends displayed by month **(blue)** for the rate of door-to-balloon (D2B) ≤90 min in Los Angeles County (California) December 1, 2006 through August 31, 2007. The network started with 3 hospitals and grew rapidly to 30 designated ST-elevation myocardial infarction (STEMI) receiving centers (SRCs) within this time period. (N) denotes number of patients with D2B data for each given month. **Red line** denotes overall 90% rate of D2B ≤90 min (n = 476). An approximate baseline from a 2005 survey (17) of pre-hospital electrocardiogram-identified STEMI patients is depicted as "Pre-SRC" **(green)**.

patients identified by EMS and transported directly to the city's 1 designated SRC (24). Furthermore, the Ottawa program provided additional evidence that pre-hospital cardiac triage is preferred over a strategy of inter-hospital transfer, because only 11.9% of patients transferred between hospitals achieved a first-door-to-balloon ≤90 min. Four other comprehensive inter-hospital transfer networks have also not been able to exceed a 50% rate of *first* door-to-balloon ≤90 min (25–28).

Second, data from the 2007 ACTION (Acute Coronary Treatment and Intervention Outcomes Network) registry demonstrated only a 17.6% use rate of the PH-ECG in patients with STEMI. Importantly, patients with a PH-ECG had a significantly shorter median D2B time compared with those without (63 min vs. 81 min, p < 0.0001) (29). The quartile of patients with the fastest reperfusion in this cohort had D2B times of 49 min or less, a finding that was consistent with our 10-region experience.

Across the nation, efforts to create regional STEMI networks continue to accelerate through the convergence of many independent initiatives beyond the D2B Alliance. For example, a 2006 Institute of Medicine report recommended "the emergency care system of the future should be highly regionalized, coordinated, and accountable" (23). In 2007, the AHA Mission: Lifeline (AHA-ML) initiative (30) began to translate the current "grassroots" initiative of regionalized STEMI care into an organized national effort.

The EMS-organized pre-hospital cardiac triage networks have enabled paramedics to diagnose STEMI and thus identify patients that should enter a priority track to the closest available PPCI team, a key systems feature needed in the current era of ED overcrowding and ambulance diversions (23). In contrast, current barriers to timely identifica-

tion of cardiac ischemia by ED triage staff are significant, with a recent registry analysis of non-STEMI patients demonstrating that only 34% receive an ECG within 10 min of arrival (31).

Finally, PPCI-capable hospitals must recognize that EMS is responsible for the delivery of approximately one-half of all STEMI patients (32), and thus EMS is in a unique and powerful position to foster collaboration among competing hospitals and drive QI in a region. An EMS agency can ensure consistently fast reperfusion for patients who call 9-1-1 by creating protocols in which STEMI patients are transported only to designated SRCs that have agreed to submit D2B and E2B data (and other appropriate parameters) back to the organization responsible for regional quality oversight.

Study limitations. Although we were unable to report on clinical outcomes, the study primary end point (D2B ≤90 min) is strongly associated with low in-hospital mortality (4,5). Thus on the basis of the classic Donabedian model (33) of quality, it is reasonable to expect better patient outcomes when regional STEMI networks provide improvements in both structure and process-of-care.

This 10-region SRC network data focused on achieving high rates of D2B ≤90 min represented an early experience that is consistent with accepted standards of QI methodology (34,35). Although conventional experimental study information (i.e., patient characteristics and comorbidities, comprehensive pre-network D2B rates, E2B rates for all 10 regions, a standardized approach to tracking false-positive CCL-activations, variable resources for source data audits, or incomplete regionalization in certain areas) was not available, this deficiency should not detract from the finding

that high rates of D2B ≤90 min are consistently achievable in "real world" SRC networks.

Similarly, the inclusion of only "successful" SRC networks in this analysis is also appropriate, because the initial uptake of QI initiatives is often patchy and limited to "innovators and early adopters"(36). Furthermore, although not all existing SRC networks in the U.S. agreed to participate in our pooled analysis, we are not aware of any pre-hospital cardiac triage systems in the U.S. with low rates of D2B ≤90 min. Finally, concerns about selection bias on the patient level are mitigated by the inclusion within each SRC network database of all consecutive patients diagnosed with presumed STEMI by paramedics.

Future directions. Based upon this successful SRC network experience across 10 independent regions, we propose 3 areas of focus as STEMI regionalization expands across the nation. In reporting time-zero for E2B, our analysis used the PH-ECG time as previously defined (10,13), whereas the most recent STEMI guidelines use time of EMS arrival on scene (1). In reality, the true patient-centered time-zero for STEMI systems is time of 9-1-1 call, and hence this time-point represents the ideal starting point of E2B that should be tracked in future analyses. Time of EMS alarm/dispatch (usually occurring within a few minutes of 9-1-1 call initiation) is generally documented by paramedics and represents a reasonable surrogate for this ideal time-zero.

Second, any STEMI registry supporting the AHA-ML initiative and tracking overall resource use needs to broaden its entry criteria as previously proposed (37). Subsequent events for all patients with a PH-ECG interpreted as presumed STEMI need to be prospectively tracked. This approach, as performed in our 10-region study, provides the true denominator of STEMI system activations.

Third, minimizing false-positive CCL activations is of potential interest for both interventional cardiologists and hospital administrators. The automated computer algorithm (Table 2) was the most frequently used in this study of the 3 existing PH-ECG interpretation strategies (14), because it could be rapidly implemented across large EMS systems and was considered reasonably accurate (10). However, given the real-world occurrence of incorrect computer algorithm analyses for various technical reasons, some regions have taken a Bayesian approach (38) and set strict criteria for paramedic diagnosis of STEMI and CCL activation. For other regions, PH-ECG activation of the CCL has evolved into a 2-step process in which the on-duty ED physician served as the filter after radio communication with EMS. The ED physician then decided in real-time (24/7) which pre-hospital "STEMI Alert" merits conversion to an in-hospital "Code STEMI" involving CCL activation before patient arrival and which patients need further assessment in the ED to determine whether CCL activation is warranted (39). Simultaneous use of all 3 PH-ECG interpretation strategies might be the best approach in the future, because evidence suggests that the accuracy of in-hospital Code STEMI activation can be further optimized by PH-ECG wireless transmission and physician interpretation (Wi-PI) (14,39). Further study is warranted.

Conclusions

Our 10-region "grassroots" D2B and E2B dataset involving 72 hospitals, despite inherent limitations, provided credible evidence supporting the AHA-ML vision of a national network of coordinated and efficient STEMI systems that are supported by a comprehensive national registry (30,37). The key systems achievement of SRC networks is the successful integration of PH-ECG identification of STEMI patients with immediate transport and early activation of the CCL team. In areas with regional SRC networks, 9-1-1 provides entire communities with timely access to quality STEMI care.

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