



A Campaign to Improve the Timeliness of Primary Percutaneous Coronary Intervention: Door-to-Balloon: An Alliance for Quality

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QUALITY IMPROVEMENT METHODS

A Campaign to Improve the Timeliness of Primary Percutaneous Coronary Intervention

Door-to-Balloon: An Alliance for Quality

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Objectives We sought to describe the rationale and methods for Door-to-Balloon (D2B): An Alliance for Quality, an international effort organized by the American College of Cardiology in partnership with the American Heart Association and 37 other organizations to rapidly translate research about how best to achieve outstanding D2B times for patients with ST-segment elevation myocardial infarction (STEMI) into practice.

Background The D2B time, the time between hospital arrival and primary percutaneous coronary intervention for patients with STEMI, is strongly associated with the likelihood of survival, yet the majority of patients are not treated within the guideline-recommended time of ≤ 90 min. Recent research has revealed key and underused strategies that are associated with achieving faster D2B times.

Methods The D2B Alliance has enrolled approximately 1,000 hospitals. Its goal is to achieve a D2B time of ≤ 90 min for at least 75% of non-transferred patients. The key strategies chosen by the D2B Alliance include having the emergency medicine physician activate the catheterization laboratory with a single call, having the team prepared within 20 to 30 min of the call; rapid data feedback; a team-based approach; and administrative support. The use of a pre-hospital electrocardiogram by emergency medical services personnel to activate the catheterization laboratory was also noted as an additional optional strategy. The project has many approaches to promote participation and adoption of effective strategies. An evaluation component is also described.

Conclusions The design of the D2B: An Alliance for Quality, a novel campaign to improve D2B time, is described. (J Am Coll Cardiol Intv 2008;1:97–104) © 2008 by the American College of Cardiology Foundation

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Delays in widespread adoption of new knowledge in health care are common. More than 10 years after the demonstration that beta-blocker treatment confers a survival advantage to patients who survived an acute myocardial infarction, beta-blocker drugs were prescribed for only about one-half of these patients (1). Similar observations have been made for many other treatments (2–7). A principal challenge in medicine is to accelerate the adoption of guideline-based recommendations and close the gap between ideal practice and usual practice.

See page 105

Door-to-balloon (D2B) time, the time between hospital arrival and primary percutaneous coronary intervention (PCI) for patients with ST-segment elevation myocardial infarction (STEMI), is strongly associated with the likelihood of survival and is an accepted measure of quality of care. The majority of patients are not treated within the guideline-recommended D2B time of 90 min or less (8), despite its importance. Moreover, even as other quality indicators have improved, D2B times at hospitals across the U.S. have not decreased substantially (9).

Abbreviations and Acronyms

ACC = American College of Cardiology

ACTION = Acute Coronary Treatment and Intervention Outcomes Network

AHA = American Heart Association

CMS = Centers for Medicare & Medicaid Services

D2B = door-to-balloon

NCDR = National Cardiovascular Data Registry

NHLBI = National Heart, Lung, and Blood Institute

PCI = percutaneous coronary intervention

STEMI = ST-segment elevation myocardial infarction

Recent research has revealed key strategies that are associated with faster D2B times, demonstrating how best to achieve outstanding performance (10–13). This paper describes the rationale and methods of D2B: An Alliance for Quality, an effort organized by the American

College of Cardiology (ACC) in partnership with the American Heart Association (AHA) and 37 other organizations to rapidly translate the research about how best to achieve outstanding D2B times for patients with STEMI into practice. The effort began with a focus on the U.S. but has a growing number of international participants.

Background

Many studies have demonstrated a continuous relationship between shorter D2B times and better survival for patients with STEMI who undergo primary PCI (14–18). Primary PCI has become the preferred method for reperfusion therapy over fibrinolytic therapy in hospitals with primary

PCI capability. This strategy is supported by a meta-analysis of 23 trials showing an absolute 2% reduction in mortality with primary PCI compared with fibrinolytic therapy (19). Further analysis, on the basis of the results of randomized trials comparing primary PCI and fibrinolytic therapy for patients with STEMI, demonstrates that when the time to perform primary PCI exceeds the time to administer fibrinolytic therapy by approximately 60 to 100 min, the advantage of primary PCI might be markedly attenuated or eliminated. The ACC/AHA Guidelines recommend that hospitals perform primary PCI for patients with STEMI in 90 min or less (20). Nevertheless, many patients experience delays in treatment, with the vast majority receiving treatment in excess of 90 min. In an investigation using the National Registry of Myocardial Infarction database, approximately two-thirds of patients were treated with times longer than 90 min, with one-third treated with times that exceeded 120 min (17).

Despite contemporary national data showing that many patients undergoing primary PCI are not treated within 90 min, some hospitals consistently achieve D2B times of 90 min or less for their patients. This observation led to a National Heart, Lung, and Blood Institute (NHLBI)-sponsored investigation of how the best-performing hospitals achieve their results. This research revealed a set of strategies that top-performing hospitals used to achieve guideline-based D2B times.

The NHLBI study employed a mixed methods approach, combining qualitative and quantitative research, to identify strategies that differentiated the top-performing hospitals. Qualitative research revealed 8 themes that emerged from interviews at 11 top hospitals (10). These themes included a commitment to an explicit goal to improve D2B times motivated by internal and external pressures, senior management support, innovative protocols, flexibility in refining standardized protocols, uncompromising individual clinical leaders, collaborative teams, data feedback to monitor progress and identify problems and successes, and an organizational culture that fostered resilience to challenges or setbacks in improvement efforts. The experiences of the top hospitals were used to develop flow diagrams and benchmark times that represent what can be achieved (12) as well as hypotheses about the strategies most strongly associated with faster D2B times.

Quantitative research was then used to test hypotheses from the qualitative work in a national sample of hospitals performing PCI to evaluate the magnitude and statistical significance of effects on D2B time. This research was accomplished with a survey of hospitals that perform primary PCI and submit publicly reported data to the Centers for Medicare & Medicaid Services (CMS) (11). The strategies with substantial and significant associations with faster D2B times were: 1) having emergency medicine physicians

activate the catheterization laboratory; 2) having a single call to a central page operator to activate the laboratory; 3) having the emergency department activate the catheterization laboratory while the patient is en route to the hospital on the basis of a pre-hospital electrocardiogram; 4) expecting staff to arrive in the catheterization laboratory within 20 to 30 min (vs. >30 min) after being paged; 5) having an attending cardiologist always on site; and 6) having staff in the emergency department and the catheterization laboratory use real-time data feedback. Despite the strong association of these strategies with faster times, however, only a minority of the hospitals surveyed were using them.

Thus, research showed that many patients do not receive timely primary PCI and identified underused strategies that are associated with shorter times at top-performing institutions. With this knowledge, the challenge was to develop an approach to disseminate best practice into routine practice, efficiently and effectively apply the approach in the U.S. and then internationally, and improve the timeliness of primary PCI for patients with STEMI.

The D2B Alliance

The D2B Alliance, initiated by the ACC and comprising a group of international organizations, clinicians, and hospitals, was developed to improve D2B times for patients with STEMI undergoing primary PCI. An overview of the timeline is shown in Figure 1. The goal of the D2B Alliance

is for participating hospitals to treat 75% of their nontransfer patients with STEMI receiving PCI within 90 min or less of hospital arrival.

The D2B Alliance was based on the following principles:

- 1) Treatment of patients within the guideline recommendations was feasible
- 2) Strong empirical evidence supports the effectiveness of specific strategies for reducing D2B time
- 3) Evidence-based strategies could be widely and rapidly adopted, changing the way care is delivered
- 4) Innovations shared among institutions would accelerate rapid improvements
- 5) Partnerships across the spectrum of organizations with an interest in outstanding care for patients with STEMI would support and sustain the effort
- 6) The initiative could be practical and accomplished efficiently with a minimum investment by hospitals

First phase—planning. The D2B Alliance was conceived in January 2006; the effort was divided into 4 distinct phases. First, in the planning phase, several working groups were established. The groups included volunteers and ACC staff representing a wide range of expertise, including perspectives from quality improvement, cardiology, emergency medicine, nursing, and hospital management. An evidence workgroup performed a systematic review of the published reports on improving D2B times and helped establish the core processes that would be promoted (21). A toolkit

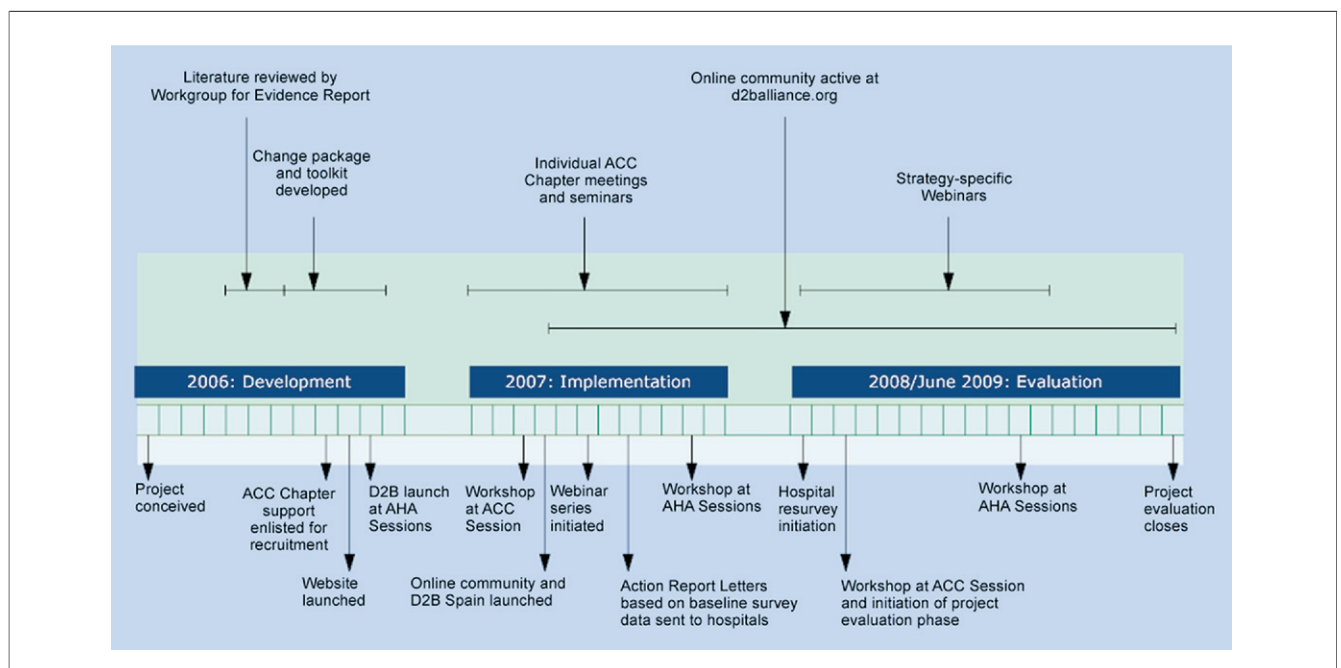


Figure 1. D2B Key Milestones and Timeline

ACC = American College of Cardiology; AHA = American Heart Association; D2B = door-to-balloon.

workgroup reviewed various tools and identified examples of those that would assist clinicians and hospitals (Online Appendix). A change package workgroup focused on recommendations for creating an environment that would foster a commitment to the goal of the D2B Alliance. A workgroup, focused on awarding credits for recertification and continuing medical education, developed a module in collaboration with the American Board of Internal Medicine. An evaluation workgroup developed a plan to assess the overall impact of the effort.

During the planning phase, national organizations were encouraged to join the D2B Alliance. Although managed and entirely funded by the ACC, the D2B Alliance was developed as a truly collaborative effort among many organizations. The partners would promote the D2B Alliance and, in some cases, participate actively with hospitals to help them achieve better performance. Because the achievement of outstanding D2B times requires teamwork, the enlisting of a diverse group of partners—including the AHA; various emergency medicine organizations; the NHLBI; the Agency for Healthcare Research and Quality; and others—was considered essential to the success of the project. There are now 38 collaborating organizations (Table 1).

Also in the planning phase, the intervention was developed and involved a number of key features. First, as a condition of enrollment, a hospital's administration was required to commit to reaching the performance goal of the project. Second, upon enrollment, participating hospitals received a toolkit and change packet that provided a step-by-step approach to reduce D2B times rooted in recently published evidence (10,11,13). Specifically, hospitals were strongly encouraged to implement evidence-based strategies to improve times. Third, at the time of enrollment, participating hospitals used a Web-based survey (Online Appendix) to complete a baseline assessment of their current use of key strategies that are pertinent to D2B times. Fourth, these survey data were analyzed and compared with the recommended approach to reducing D2B time as evidenced in the literature, and hospitals were given individually tailored "action plans" to reduce D2B times. Fifth, hospitals were offered common educational initiatives, including D2B Alliance workshops, Web-based seminars, and access to an online community of all participating hospitals. Sixth, the D2B Alliance partners, such as the AHA, Tenet, Hospital Corporation of America, VHA, Inc., Premier, Inc., as well as ACC local organizations (chapters) serving almost every state, were supported in their efforts to publicize the initiative and assist hospitals in their efforts to make improvements. The ACC chapters are a critical component of the D2B Alliance because they involve a strong network of physician champions in each state who can motivate and facilitate changes at the hospital and physician level.

Table 1. D2B Alliance Strategic Partners

Collaborator*	
American Heart Association	
BlueCross BlueShield Association and participating companies	
Christiana Care Health System	
Expecting Success	
Hospital Corporation of America	
Novant Health	
Prairie Cardiovascular	
Saint Barnabas Health Care System	
The Society for Cardiovascular Angiography and Interventions	
Society of Chest Pain Centers	
South Carolina Hospital Association	
Tenet Healthcare	
UnitedHealthcare	
University HealthSystem Consortium	
VHA, Inc.	
WellPoint	
Sponsor†	
Aetna	
American College of Cardiovascular Administrators	
American College of Emergency Physicians	
Emergency Medicine Cardiac Research and Education Group	
Florida Quality Improvement Organization	
Institute for Healthcare Improvement	
Premier, Inc.	
Visionary supporter‡	
Agency for Healthcare Research and Quality	
Alliance for Cardiac Care Excellence	
American Academy of Emergency Medicine	
The Joint Commission	
American Health Quality Association	
National Association of EMS Physicians	
National Heart, Lung, and Blood Institute	
Society for Academic Emergency Medicine	

*Institutions that agree to publicly endorse and actively promote door-to-balloon (D2B), permit the American College of Cardiology to use their logo and name in promotional efforts, and commit to a recruitment goal related to D2B participation of 20% of primary percutaneous coronary intervention hospitals in their network. †Institutions that agree to publicly endorse and actively promote D2B and permit the American College of Cardiology to use their logo and name in promotional efforts. ‡Institutions that agree to publicly endorse D2B but do not actively engage in promotion.

A systematic review of the published data (21) on improving D2B times identified several key strategies that were considered for inclusion in the initiative. With these findings, the D2B Alliance focused on the most potent strategies that could be implemented inexpensively and rapidly by every hospital. The key strategies chosen by the D2B Alliance are shown in Table 2 and include having the emergency medicine physician activate the catheterization laboratory with a single call, having the team prepared within 20 to 30 min of the call, rapid data feedback, a team-based approach, and administrative support. The use of a pre-hospital electrocardiogram by emergency medical services personnel to activate the catheterization laboratory

Table 2. Strategies for Hospitals to Reduce D2B Times

Key strategies
Activation of the catheterization laboratory by emergency medicine physicians
Establishment of a single-call system for activating the catheterization laboratory
Expectation that the catheterization team be available within 20 to 30 min of being paged
Use of data monitoring and prompt data feedback to emergency department and catheterization laboratory staff
Senior management support and organizational environment that fosters and sustains organizational change directed at improving D2B time
Team-based approach from ambulance to balloon, within a culture of continuous quality improvement
Optional strategy
Use of pre-hospital electrocardiogram to activate the catheterization laboratory
D2B = door-to-balloon.

was noted as an additional optional strategy. Recognizing that activation on the basis of a pre-hospital electrocardiogram might be particularly challenging and not fully within a hospital's control, the D2B Alliance did not include this strategy as a core strategy despite its strong association with shorter D2B times. Other strategies, such as having a cardiologist in the hospital at all times, were controversial and/or costly and complex to implement and therefore were not incorporated into the core recommendations of the campaign even though they had been identified as having a strong association with faster times.

Data submission requirements for the project were intentionally minimal in an effort to reduce the barriers to enrollment in the D2B Alliance. Because hospitals have many options to collect and report data, the initiative chose to afford hospitals maximum flexibility on how to collect performance data for internal data feedback. For the purpose of the project, hospitals were encouraged to measure times with standards established by the CMS for D2B time included in the Hospital Quality Alliance, which are data most institutions already submit. Additionally, hospitals were alerted to opportunities to participate in registries, such as the National Cardiovascular Data Registry (NCDR)-CathPCI Registry, Acute Coronary Treatment and Intervention Outcomes Network (ACTION) Registry, and the AHA Get With the Guidelines program, because they have each developed approaches to support participating institutions with data (22-24).

Second phase—participation. The second phase of the project was a drive for participation that began officially with the D2B Alliance public announcement in November 2006 at the AHA Scientific Sessions. The launch of the D2B Alliance was accompanied by considerable media coverage. Articles reached more than 200 newspapers, including a front-page feature in *USA Today*. Television coverage included the network evening news.

The launch initiated a robust appeal for hospital participation. To enroll in the D2B Alliance, hospitals completed a form online committing the institution to the goal of the project and signaling endorsement by senior leadership. Each hospital also named a clinician leader as a contact for

the project and agreed to complete a baseline survey of their current D2B practices.

The ACC and its partners sought to enroll as many hospitals as possible that perform primary PCI. Support for the enrollment process was enlisted from the 39 ACC chapters, each with a leadership structure that is governed by a member of the ACC. The governor and chapters recruited their local hospitals, and a competitive spirit was fostered among chapters that enhanced hospital enrollment. Many partners also participated actively in communicating with clinicians and hospitals. Emergency medicine organizations played an important role in reaching their constituency and encouraging participation. The announcement of deadlines, such as the March 2007 deadline for inclusion in the public release of the list of participating hospitals, also helped the recruitment effort (25).

Although recruitment focused on hospitals in the U.S., enrollment was not nationally restricted, and there is current representation from 9 other countries. Moreover, the Spanish Cardiology Society joined the D2B Alliance, organized an official launch in April 2007, and is coordinating the enrollment and engagement of all Spanish hospitals performing primary PCI. Additional countries are considering a similar commitment.

Currently, approximately 1,000 hospitals are enrolled in the D2B Alliance, representing approximately two-thirds of the nation's PCI hospitals and a higher percentage of all the primary PCIs performed in the country. The names of these hospitals are listed on the D2B Alliance website (26). The characteristics of the hospitals enrolled in the D2B Alliance as of July 1, 2007, in the U.S. are listed in Table 3.

Third phase—intervention. The third phase of the project, which began in parallel with efforts to enroll hospitals, was the intervention. From the outset, a kit with a description of the project and tools was made available on the D2B Alliance website. Educational sessions that disseminated information about innovative approaches and provided information about experiences at various sites were conducted. The online community was launched in April 2007 using a product of the Institute for Healthcare Improvement, with

Table 3. Characteristics of the Hospitals in the U.S. Enrolled in the D2B Alliance

Characteristics	n	%
Total	915	100.0
Number of beds		
Unknown	18	2.0
<300	420	46.0
300 to 600	369	40.3
>600	108	11.8
Mean (SD)	362.9 (233.6)	
Ownership		
Unknown	18	2.0
Government	85	9.3
Not-for-profit	654	71.5
For profit	158	17.3
Region		
New England	32	3.5
Middle Atlantic	100	10.9
South Atlantic	167	18.3
East North Central	186	20.3
East South Central	75	8.2
West North Central	68	7.4
West South Central	121	13.2
Mountain	63	6.9
Pacific	103	11.3
Teaching status		
Unknown	18	2.0
Teaching	505	55.2
Non-teaching	392	42.8

Includes hospitals enrolled before July 1, 2007.
D2B = door-to-balloon.

the intent of providing a venue for the exchange of information among D2B Alliance participants. The baseline survey was conducted, and hospital-specific action plans were provided to each participating hospital on the basis of the survey data.

Several partners have integrated the D2B Alliance into their activities in novel ways. Many ACC chapters have incorporated D2B into their annual meetings. For example, the Michigan chapter of the ACC convened a meeting of representatives from all PCI centers in the state and developed a coordinated effort to implement the D2B Alliance intervention. The NCDR has promoted the D2B Alliance and is developing targeted quality improvement activities to support the effort. The AHA made D2B a major initiative within its Get With the Guidelines program. The University HealthSystem Consortium included D2B in a targeted quality improvement project to improve the timeliness of care for patients with STEMI. Some organizations, such as UnitedHealthcare and the BlueCross BlueShield Association, have incorporated participation as a requirement for their Center of Excellence programs. The NHLBI and the Agency for Healthcare Research and

Quality have promoted the effort through education and conferences. Tenet and the Hospital Corporation of America have made D2B a core quality improvement initiative within their organizations.

Evaluation

The D2B Alliance is designed to improve the timeliness of primary PCI, and the evaluation is intended to assess the effect of the initiative. In addition, the project is intended to generate knowledge about how best to disseminate and translate research about health care delivery into practice. The baseline and follow-up surveys will enable an assessment of how implementation of key hospital strategies has changed over the course of the project. The baseline survey was administered as close as possible to the enrollment date but not later than May 2007. The follow-up survey will be administered to hospitals approximately 1 year after enrollment, ranging from January to March 2008 on the basis of each hospital's enrollment date. The evaluation seeks to analyze the following outcomes:

Changes in the use of the evidence-based strategies

Changes in D2B times

Hospital views about the role of the D2B Alliance in fostering changes, and remaining barriers to improve D2B times

Multiple data sources will be used for the evaluation. The change in the use of evidence-based strategies will be evaluated with the baseline and follow-up surveys. For the evaluation of the change in D2B times, the data sources will include the local and national registries and the data from the Hospital Quality Alliance (27). Many of the hospitals participating in the D2B Alliance also participate in at least 1 of the national registries (i.e., NCDR, AHA Get With the Guidelines) that are collecting data on D2B times. The use of registries and Hospital Quality Alliance data will allow the comparison of D2B Alliance hospitals with those that do not participate. Additionally, almost all of the hospitals participating within the D2B Alliance are also submitting data to the CMS for public reporting of D2B times. These data will provide the best opportunity to determine whether hospital performance has changed substantially since the project launch in November 2006. We will be able to compare participating and non-participating hospitals and identify those who had the most marked improvement in performance. We will also work with hospitals outside the U.S. so that they might obtain comparable data to similarly determine the effectiveness of the program and benchmark against the progress in other countries.

Next Steps

To date, the D2B Alliance has been successful in uniting a broad-based coalition of practitioners, hospitals, and organizations that have agreed to work with the ACC to improve D2B times. This effort employed methods that emphasized evidenced-based strategies, minimized burdens on the participants, and demonstrated the feasibility of rapidly launching a focused initiative to improve care on an international scale.

As the next steps in this project are contemplated, participants and collaborating organizations have suggested the need to facilitate more effective use of pre-hospital electrocardiogram capability and to improve the transfer times between hospitals for patients with STEMI. Thus, there is a need to improve door-to-reperfusion therapy time for all patients, including those that present at hospitals without PCI capability. For the many patients who receive care at hospitals that do not have PCI capability, the decision about treatments with fibrinolytic therapy or transfer for PCI must be made quickly, and there are aspects of this care that can be improved. Currently, among those transferred for primary PCI, the median D2B time (door of the first hospital to balloon at the second hospital) is 3 h (28). The next step in the D2B Alliance could be to extend the focus to all hospitals and clinicians to ensure that all patients with STEMI are treated as rapidly and appropriately as possible, allowing the guidelines to set the standards. Ultimately, future efforts can then focus on improving time from symptom onset to hospital arrival.

There are lessons to be learned from the experience of creating and implementing the D2B Alliance that might have important implications for future quality improvement campaigns in other areas. The D2B Alliance can provide evidence about the success of the initiative and how best to disseminate and translate research about health care delivery into practice. Lessons from this effort will be documented, and their generalizability to other treatments, processes, and conditions should be tested. Without strategies that ensure rapid, effective, and widespread application of newly proven therapies, delayed and inadequate adoption of such innovations will limit the efficiency of our health care system in making the best use of medical knowledge.

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APPENDIX

For examples of tools that would assist clinicians and hospitals and a Web-based survey for participating hospitals, please see the online version of this article.

A Campaign to Improve the Timeliness of Primary Percutaneous Coronary Intervention: Door-to-Balloon: An Alliance for Quality

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