

From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: October 9, 2013 Public Hearing Written Testimony (ContentID - 147062)
Date: Friday, October 11, 2013 9:20:33 AM

1. Name: David Westerlund
2. Organization: West Branch Regional Medical Center
3. Phone: 989-343-3236
4. Email: dwesterlund@wbrmc.org
5. Standards: CC
6. Testimony: West Branch Regional Medical Center is an 88-bed acute care facility in rural West Branch, MI. Amending current CON rules and standards to allow the hospital to perform elective therapeutic cardiac catheterizations (stents) would be beneficial for the community. More than 65 percent of WBRMC's patient base is Medicare patients (65 and older) and as people age their need for health care services increase -- especially cardiac services. Current cardiac catheterization standards force many of WBRMC's elderly patients to drive out of the service area to have cardiac procedures performed. Amending the CON rule would not only allow patients to have this service performed without leaving the service area but would save lives.
7. Testimony:

From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: October 9, 2013 Public Hearing Written Testimony (ContentID - 147062)
Date: Thursday, October 10, 2013 3:15:54 PM

1. Name: Brian Witte
2. Organization: West Branch Regional Medical Center
3. Phone: 989-343-3790
4. Email: bwitte@wbrmc.org
5. Standards: OTHER
6. Testimony: Amending current CON rules related to as they apply to cardiac catheterization standards is essential to allow hospitals with this technology but without open heart services to serve patients closer to home. Although our hospital has the technology and the professional credentialed expertise to provide cardiac catheterization services, the current rules don't allow for this because we do not also provide open heart services. These rules are outdated given the current practice of these procedures and force patients, most of whom are elderly with limited income, to travel long distances outside their community to receive cardiac catheterization services. It is quite difficult for these patients both in terms of the taxing effect of travel and the burden of travel costs. We have the means to perform elective cardiac catheterization services locally. Please put the patients' needs and interests first and foremost and change the rules to allow hospitals with cardiac catheterization technology and expertise but that do not have open heart services to provide these procedures.
7. Testimony:

From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: October 9, 2013 Public Hearing Written Testimony (ContentID - 147062)
Date: Thursday, October 10, 2013 3:05:06 PM

1. Name: Joe Bell, RRT
2. Organization: West Branch Regional Medical Center
3. Phone: 989-343-3162
4. Email: jbell@wbrmc.org
5. Standards: CC
6. Testimony: I have been the Director of Cardiopulmonary Services West Branch Regional Medical Center for over 30 years. During that time I have seen many positive changes in the healthcare that we provide for the communities we serve including new technologies and services.

I believe it would be of great benefit to the patients in West Branch Regional Medical Center's service area as well as to the medical center if current CON rules and standards were changed to allow hospitals without on-site backup open heart surgical services to perform elective therapeutic cardiac catheterizations (stents).

There are many states that allow elective therapeutic cardiac catheterizations (stents) without on-site backup open heart surgical services and studies have shown that the morbidity/mortality of patients in both settings (hospitals with open heart cardiac backup and hospitals without on-site open heart cardiac backup) is virtually the same.

Five years ago WBRMC installed a state-of-the-art heart catheterization lab. WBRMC has two full time cardiologists on-site and several nurses trained in more advanced procedures.

The means and the need to perform elective therapeutic cardiac catheterizations (stents) are at WBRMC.....now it must have the CON rules and standards amended to do so.

I hope you will support these changes in the laws regarding this issue. I believe it will improve the care we give our patients and their families by keeping them close to home for services they need. I thank you for your consideration.

7. Testimony:

From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: October 9, 2013 Public Hearing Written Testimony (ContentID - 147062)
Date: Thursday, October 10, 2013 2:40:29 PM

1. Name: Edward Napierala
2. Organization: West Branch Regional Medical Center
3. Phone: 989-343-3271
4. Email: enapierala@wbrmc.org
5. Standards: CC
6. Testimony: West Branch Regional Medical Center (WBRMC) is asking the Michigan Department of Community Health to review current Certificate of Need rules and standards as they apply to cardiac catheterization laboratories without on-site backup open heart surgical services.

As CEO at West Branch Regional Medical Center, an 88-bed acute care facility in rural West Branch, MI, I feel amending current CON rules and standards to allow us to perform elective therapeutic cardiac catheterizations (stents) would be beneficial for our community. More than 65 percent of our patient base is Medicare patients (65 and older) and as people age their need for health care services increase -- especially cardiac services.

It is unfortunate that current cardiac catheterization standards force many of these elderly patients to drive out of our service area to have cardiac procedures performed.

In 2012, WBRMC transferred 92 patients with acute cardiac symptoms to hospitals with open heart surgical services. Many of these patients could have been treated at WBRMC—close to the patient's home—if CON rules allowed hospitals without on-site backup open heart surgical services to perform elective therapeutic cardiac catheterizations (stents).

There are many states that do allow elective therapeutic cardiac catheterizations (stents) without on-site backup open heart surgical services and studies have shown that the morbidity/mortality of patients in both settings (hospitals with open heart cardiac backup and hospitals without on-site open heart cardiac backup) is virtually the same.

Five years ago WBRMC installed a state-of-the-art heart catheterization lab. We have two full time cardiologists on-site and several nurses trained in more advanced procedures. So, the means and the need are here.....now we must have the CON rules and standards amended so that we can perform these more advanced cardiac procedures.

Edward Napierala, FACHE
Chief Executive Officer
West Branch Regional Medical Center

7. Testimony:

From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: October 9, 2013 Public Hearing Written Testimony (ContentID - 147062)
Date: Friday, October 11, 2013 11:14:19 AM

1. Name: Tom Oesch
2. Organization: West Branch Regional Medical Center
3. Phone: 1-989-343-3195
4. Email: toesch@wbrmc.org
5. Standards: CC
6. Testimony: It would help the patients in our surrounding area to be able to have cardiac stenting procedures done at our facility. We have an elderly population and presently they have to travel over an hour or more to get this procedure done. With two full time cardiologist's on staff, we have the ability to perform these tests.
7. Testimony:

From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: October 9, 2013 Public Hearing Written Testimony (ContentID - 147062)
Date: Monday, October 14, 2013 3:09:36 PM

1. Name: Annette Reeves
2. Organization: West Branch Regional Medical Center
3. Phone: 989-343-3280
4. Email: areeves@wbrmc.org
5. Standards: CC
6. Testimony: It would be of great benefit to the patients in West Branch Regional Medical Center's service area as well as to the medical center if current CON rules and standards were changed to allow hospitals without on-site backup open heart surgical services to perform elective therapeutic cardiac catheterizations (stents).
7. Testimony:

From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: October 9, 2013 Public Hearing Written Testimony (ContentID - 147062)
Date: Tuesday, October 15, 2013 3:33:49 PM

1. Name: Laura N Vaughn
2. Organization: West Branch Regional Medical Center
3. Phone: 989-343-3210
4. Email: lbradford@wbrmc.org
5. Standards: CC
6. Testimony: There are many states that allow elective therapeutic cardiac catheterizations (stents) without on-site backup open heart surgical services and studies have shown that the morbidity/mortality of patients in both settings (hospitals with open heart cardiac backup and hospitals without on-site open heart cardiac backup) are virtually the same.
7. Testimony:

From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: October 9, 2013 Public Hearing Written Testimony (ContentID - 147062)
Date: Monday, October 21, 2013 10:40:17 AM

1. Name: Dennis McCafferty
2. Organization: The Economic Alliance for Michigan
3. Phone: 248-596-1006
4. Email: DennisMccafferty@EAMOnline.org
5. Standards: CC
6. Testimony: Our members, both business and labor, believe that reasonable geographic access to this service in Michigan is already well established. Elective Angioplasty is currently provided at the existing 33 OHS program hospitals that are well distributed across the state and emergency Angioplasty is available at 12 additional hospitals, most of which are located in higher populated areas. The just approved Open Heart Surgical (OHS) Standards' provision for initiating new OHS programs in Michigan were not changed and it is highly unlikely that there will be any new OHS programs approved in Michigan. The Cardiac Catheterization Standards currently only permit Elective Angioplasty to be performed at hospitals with OHS programs. We would anticipate that this provision will again be challenged by those hospitals in Michigan who do not currently have and are not likely to get an OHS program but are very interested in the higher revenues generated by being able to perform Elective Angioplasty procedures.

Our members have three concerns related to allowing additional hospitals in Michigan without OHS programs being able to perform Elective Angioplasty:

- (1) Risk to patients when immediate, on-site access to OHS services is not available,
- (2) Recent clinical studies that suggest Elective Angioplasty does not offer any benefit in terms of death, myocardial infarction, or the need for subsequent revascularization compared with conservative medical treatment.
- (3) The demonstrated potential for excess, inappropriate, Elective Angioplasty procedures being performed on patients when many more hospitals are competing for the same or shrinking number of patients in need of this procedure.

We do not see the need for this standard to be reviewed but, if there is significant public comment supporting the need for a SAC to review this standard, we ask that the above three issues be included in the charge.

7. Testimony:

**SPECTRUM HEALTH**

Spectrum Health System
100 Michigan Street NE
Grand Rapids, MI 49503-2560

October 23, 2013

James Falahee, Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

RE: Cardiac Catheterization CON Standards

Dear Mr. Falahee,

This letter is written as formal testimony regarding the CON Review Standards for Cardiac Catheterization Services, which went into effect on February 27, 2012. Spectrum Health appreciates the opportunity to comment on these Standards.

Although we support the current standards, we would like to offer the following comments for your review concerning Michigan residents' proximity to cardiac catheterization services:

1. Access is not an issue with the vast majority of Michigan's residents. The existing 33 sites that are able to perform elective PCI and 12 additional hospitals that can perform emergency angioplasty are well distributed across the state so that geographic access is not a concern. By concentrating the elective PCI cases at fewer hospitals patients can expect to receive high quality services from physicians and staff that perform a high volume of cases.
2. Currently the Cardiac Catheterization standards only permit elective angioplasty to be performed at hospitals with open heart services (OHS). It is anticipated that this provision will once again be challenged by those hospitals who do not have, and likely will not get an OHS program, but would like to perform elective angioplasty due to the higher revenues associated with the ability to offer those services. We have concerns that by allowing additional hospitals to perform elective angioplasty without OHS programs that we will see unmanaged proliferation of PCI programs at community hospitals within a few miles of each other that would dilute volume and expertise raise costs and worsen rather than improve patient outcomes. Without a proliferation of cardiac catheterization services in

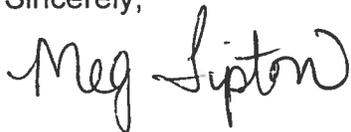
geographic area healthcare costs can be better managed and appropriate use criteria more effectively monitored and enforced.

3. Nation-wide the number of cardiac catheterization cases is on the decline. Fewer, not more, hospitals should offer cardiac catheterization services. Recent clinical studies have suggested that elective angioplasty does not offer any benefit in terms of myocardial infarction, mortality or the need for subsequent revascularization compared with a conservative approach to treating this patient population. There has been a demonstrated risk for inappropriate elective angioplasty when many more hospitals are competing for the same declining volume of patients who are in need of this type of procedure. Such practice also has a direct and negative impact on increasing the health care costs borne by the business community that ends of supporting more capacity than is necessary.

Furthermore, in the most recent SAC session, the members of the Open Heart Services SAC worked diligently over the course of six months to develop comprehensive quality measures by which programs could be equally measured as part of the Open Heart Standards. This commendable work is an important step in the direction that we support for other CON Standards. Consistent and uniform monitoring of program and operator quality is imperative as our practices, technology and procedure mix changes. We would like to propose that measurements using quality standards are included for the Cardiac Catheterization Standards during the upcoming review.

Spectrum Health appreciates the opportunity to comment on the CON Review Standards for Cardiac Catheterization Services. Anticipating that there will be interest in initiating a process of review in the upcoming 2014 review period, we will be pleased to participate in this process as appropriate.

Sincerely,



Meg Tipton

System Regulatory Consulting Specialist

Spectrum Health



October 22, 2013

James B. Falahee, Jr., J.D., Chairperson
Certificate of Need Commission
Capital View Building
201 Capital View Building
Michigan Department of Community Health
Lansing, MI 48913

RE: Cardiac Catheterization Services

Dear Chairman Falahee:

CHE-Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on what, if any, changes need to be made to the Certificate of Need Standards. We support the CON Commission's dedication to assuring residents of the State of Michigan have access to low cost, high quality health care resources. CHE-Trinity Health Michigan operates 12 hospitals that provide care to an estimated 1 in 11 Michigan residents.

CHE-Trinity Health Michigan supports the continued regulation of Cardiac Catheterization Services under Certificate of Need. CHE-Trinity Health Michigan believes the CON Commission should review, or establish a workgroup or SAC to review the allowance of elective angioplasty without onsite open heart surgery. Since the most recent Cardiac Catheterization CON Standards Advisory Committee, the American College of Cardiology Foundation has issued a consensus statement regarding Cardiovascular Angiography and Interventions that supports the permissibility of elective PCI in sites without open heart surgery. In the summary of this February 2012 statement, the ACCF affirmed:

““It is generally believed that elective and primary PCI are permissible in sites without cardiovascular surgery, if there is strict adherence to national guidelines.”
2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update;
Journal of the American College of Cardiology, Vol 59, No. 24, 2012

Other recent studies have shown similar support for allowing coronary interventions without onsite surgery. Some of the summaries from these studies concluded:

PCI performed at hospitals without on-site cardiac surgery was non-inferior to PCI performed at hospitals with on-site surgery with respect to 6-week mortality and major adverse events at 9 months. *Outcomes of PCI at Hospitals with or without On-site Cardiac Surgery;* New England Journal of Medicine, May 10, 2012

This meta-analysis provides evidence that rates of in-hospital mortality and emergency CABG surgery for primary and non-primary PCI are similar at centers with and without on-site surgery. *Percutaneous coronary intervention at centers with and without on-site surgery: a meta-analysis*; Journal of the American Medical Association, December 2011.

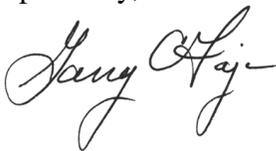
Compared with facilities with on-site surgical backup, the risk of hospital death, non-fatal myocardial infarction, and need of emergent coronary artery bypass grafting was similar in those lacking on-site surgical backup. *Outcomes of nonemergent percutaneous coronary intervention with and without on-site surgical backup: a meta-analysis*; Journal of Therapeutics, Mar-Apr 2011.

CHE-Trinity Health Michigan supports a change to the existing Cardiac Catheterization Services standards to allow elective PCI in hospitals that have CON approval and have been performing primary PCI without onsite open heart surgery services for at least two years. Specifically, CHE-Trinity Health Michigan supports changes that would allow elective PCI in an adult cardiac catheterization program that:

- Has been approved for and has performed primary PCI for at least 24 months
- Demonstrates it is currently meeting all of the volume, quality and project delivery requirements for its existing diagnostic and primary PCI program
- Projects a minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterizations based on data from the most recent 12-month period preceding the application
- Participates in the NCDR CathPCI registry
- Agrees and assures that it will not perform transcatheter aortic valve replacements

CHE-Trinity Health Michigan is committed to offering its resources support this review process and would be pleased to participate in a Standards Advisory Committee should the CON Commission decide to establish one to consider this issue.

Respectfully,



Garry C. Faja
President and CEO
Saint Joseph Mercy Health System
Southeast Michigan Region



Roger W. Spoelman
Regional President and CEO
Mercy Health West Michigan



To: Michigan Department of Community Health

From: Metro Health Hospital

Date: October 22, 2013

Re: CON Review Standards for Cardiac Catheterization Services

With regard to the CON Review Standards for Cardiac Catheterization Services, Metro Health Hospital, like many other organizations in Michigan, continues to support the position that Section 3 of the Standards regarding the "Requirements to initiate cardiac catheterization services" subsection (2)(c) should be eliminated for the reason that the medical scientific evidence no longer supports the notion that on-site open heart surgical back-up capacity is necessary to protect patient safety while undergoing therapeutic cardiac catheterization procedures. Specifically, since this issue was last considered by the Commission, the American College of Cardiology has revised its own standards to make clear that it does not believe that open heart surgical back up for such procedures should be generally required. In addition, the attached clinical studies show that the medical evidence supporting the safety of providing therapeutic cardiac catheterization services without surgical back-up continues to mount.

To the extent that there remain, a small handful of services under the current definition of "therapeutic cardiac catheterization services" where open heart back-up can provide value, we believe that the standards of practice which exist within our state medical community will dictate that such procedures only be done in appropriate locations and that the Commission does not need to regulate such care. However, if the Commission desires to do so, a very limited requirement for open heart back-up on site for health care providers who intent to perform these very specific procedures could be left in the Standards while still eliminating the very broad requirement which currently exists.

Failure to eliminate this requirement continues to harm communities and patients where an open heart program either does not exist or is limited to only one hospital location. Patients are forced to receive care in a way that is both inconvenient and more costly because of the need to travel to multiple locations, seeking care from different health care providers in a way that increases costs to both the patients and the institutions providing the care.

We appreciate the Commission's time to consider this information and to consider the necessary and important change in these standards. Thank you.

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Cath Lab Digest

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*Nice Summary
Gr. you*

Percutaneous Coronary Intervention without On-Site Open Heart Surgery: A "State of The Union" for 2013

Percutaneous Coronary Intervention without On-Site Open Heart Surgery: A "State of The Union" for 2013

- [Volume 21 - Issue 1 - January 2013](#) ^(M)
- Posted on: 1/7/13
- 0 Comments

(M)

Issue Number: [Volume 21 - Issue 1 - January 2013](#) ^(M)
Section: Your Path to Program Success: Expert Advice
Start Page: 38
End page: 39
Author(s):

Amy Newell, Vice President, Corazon, Inc., Pittsburgh, Pennsylvania

^(M)Hard to believe that it has been a little over three years since our article, "A 'State of the Union': Percutaneous Coronary Intervention (PCI) Without On-Site Open Heart Surgery," appeared in *Cath Lab Digest* in May of 2009. Fortunately, much has improved across the country relative to access to life-saving PCI, and in fact, regulatory changes are still occurring across the country in response to the recent 2011 PCI guideline update¹, even today!



Published in November 2011, the PCI guidelines elevated the classification (from a Class III to a IIb indication) and level of evidence supporting elective PCI being performed in a hospital with open-heart surgery off-site (PCI with SOS). The societies have based their latest guidelines on the success and preliminary outcomes from the most recent national CPORT-E trial, and have considered other national studies such as a Mayo Clinic meta-analysis.

^(M)Corazon has found that, in response to the 2011 published guidelines, many individual state regulating bodies have begun to revise, or are in discussions to consider, revisions to their current PCI regulations. This is not to say the process for offering PCI with SOS will be any less difficult for hospitals in those states, but perhaps having the medical professional societies as a champion to drive change within a particular region will



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Percutaneous Coronary Intervention without On-Site Open Heart Surgery: A "State of Th... Page 2 of 3

provide the support necessary to impact change and ultimately save the lives of patients with acute myocardial infarction (MI). Also, the promotion of elective PCI with SOS within the latest guidelines can support the provision of more timely access to care to those patients requiring coronary ischemic management.

Our experience across the United States continues to suggest a change in the perception and acceptance of PCI with SOS. Many of our clients interested in offering this service will first ask, is it feasible and/or reasonable to consider such an expansion? In addition to making the business case, several critical program components must be taken into consideration, such as physician commitment and expertise, staff training and competencies, emergency medical support, the ability to offer 24/7/365 access to the service for the acute MI patient population, and the creation of a formal tertiary relationship with an open-heart provider, just to name a few.

When truly considering these questions, many hospital administrators fully recognize the obstacles they may face, whether they are challenges from the state health department, opposition from cardiac full-continuum of care (inclusive of open-heart surgery) competitors, or even the lack of aforementioned critical program components. However, increasing immediate access to best-practice care delivery for heart attack victims could serve as the motivation for an official evaluation of program feasibility, followed by a strategic plan for the expansion.

Despite the limitations, growing support to allow elective PCI with off-site open heart surgical support is sweeping the United States due to outcomes data that clearly proves elective PCI is just as safe at the community provider with SOS compared to tertiary centers that provide on-site open heart surgery. Of course, for the acute MI patient population, we cannot understate the evidence of primary PCI being first choice of treatment and superior to thrombolytic therapy.

Corazon closely tracks the state activity of PCI with SOS. Listed below are several states that have endorsed varying levels of practice and in some cases, have begun to take the necessary, although daunting, steps to affect change within their states. Let's look across the country, and more specifically at the east coast, recognizing that PCI continues to remain a hotbed of activity (Figure 1).

For several years, New Jersey has permitted hospitals without on-site open-heart surgery to offer primary PCI, though only 12 hospitals have been granted permission to offer elective PCI with SOS, under the auspice of CPORT-E trial participation. Recently, several New Jersey hospitals have developed a consortium to engage the New Jersey Department of Health to create revisions that will allow hospitals without on-site open-heart surgery to provide elective PCI without having to participate in a national registry, and without limiting the "number" of elective PCI providers. Although New Jersey has taken on this daunting task, it may take several months or even years, for the State to come to a consensus allowing elective PCI with SOS to be offered beyond those facilities currently providing services.

Pennsylvania is a non-certificate of need (CON) state. This allows those hospitals wanting to expand into additional and often more advanced cardiovascular services such as open-heart surgery, to do so without a formal CON application that usually demonstrates services based on particular need. As is common in many non-CON states, Pennsylvania does have prohibitory department of health (DOH) codes limiting PCI with SOS. In 2001,

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the Commonwealth of Pennsylvania was approached by many community providers asking to offer PCI at their facilities with SOS. After many meetings with officials at the Commonwealth DOH and the engagement of legal support, ten programs were permitted to initiate PCI as part of a demonstration project to offer both emergent and elective PCI. There were specific criteria that each selected facility was required to meet, and specific quality metrics that were collected and reported to the Commonwealth as part of an independent settlement agreement specific to each organization. In essence, the Commonwealth was granting 'exceptions' to the codes and no two agreements were the same. It has been almost 12 years since these programs began offering PCI services and thousands of successful outcomes have been recorded. One must ask, "Has the burden been met?" In 2008, the Commonwealth was once again challenged by additional providers wanting to offer elective PCI with SOS. It responded by permitting those facilities to commence services. However, in this particular subgroup, the facilities agreed to participate in the CPORT-E study, and do so at their own expense. Recently, approximately six of these providers have initiated discussions with the Department of Health to develop a standard for those currently offering PCI, both PCI with surgery on-site and off-site, as well for those hospitals considering expanding acute MI services to include elective PCI. The Pennsylvania DOH does recognize the recent changes published by the professional societies. The DOH will be working over the next several months with those hospitals to assure that standard care practices and quality review processes are developed and maintained moving forward.

South Carolina has also recognized the revised 2011 PCI guidelines and is proposing the adoption of those guidelines into their existing State Health Plan, and in fact, presented the proposed changes to the States Health Plan in November 2012.

Alabama has also proposed written changes encompassing the same 2011 guidelines, and has extrapolated physician and quality criteria directly from the guidelines that must be met in order to provide this life-saving service. The state has recently reported that the new language, which is now posted for public comment, is available for review and comment through January 2013.

The Maryland Healthcare Commission continues to debate whether or not to lift certain geographic restrictions, as well address the recent PCI guidelines that would allow other community-based providers without SOS to expand their services beyond primary or emergent PCI.

Over this past year, Kentucky has drafted criteria and is awaiting a decision by the State that will formally recognize and adopt these criteria into their current State Health Plan. A decision was made to "maintain the current status" in November of 2012.

We continue to recognize those states, such as Georgia and Florida, that have risen above bureaucracy and stalemate politics, and have allowed community-based hospitals to expand cardiovascular services beyond diagnostic services only. In these states, even emergent PCI with expansion to elective PCI with SOS services is being developed in many communities. In Georgia, Corazon continues to act as a "third-party verifier," and at the request of the hospital, our team will provide an annual quality review to ensure PCI providers continue to meet necessary program requirements, and in many cases, excel in quality outcomes. Our team often receives information about the number lives saved due to those programs' ability to offer life-saving PCI service.

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Percutaneous Coronary Intervention without On-Site Open Heart Surgery: A State of IL... page 4 of 5

Most states in the center of the country have little to no restrictions governing PCI at a facility without on-site open-heart surgery, and this has not changed. However, there are exceptions to this rule.

In 2009, California, a non-CON state, addressed elective PCI without SOS by allowing up to six hospitals that met defined state requirements to participate in an ongoing pilot project. Those facilities approved to offer elective PCI had to meet the CDPH (California Department of Public Health) written requirements/criteria. In addition, the hospitals had to submit an application to be considered and selected to participate within the pilot program. The CDPH will look at all aspects of the pilot programs from costs, safety, and quality outcomes. In addition, the department (at their discretion) has indicated that it may charge the pilot facilities a fee for oversight, should it be deemed necessary from a funding standpoint. The California pilot program end date is scheduled for January 2014, at which time, the CDPH will evaluate and determine the future of PCI with SOS in California. The Department will submit a written report 90 days after the completion of the pilot program, and then decide whether or not additional programs wanting to offer PCI without SOS will be permitted.

Although changes continue to occur across the United States regarding PCI without open-heart surgery on-site, we cannot understate the value of developing a solid plan for any program expansion. Careful planning and continued market surveillance, coupled with a savvy administration and collaboration among physicians, clinicians, and future partners is no doubt "mission critical" for a successful program expansion. We continue to recommend that any program looking to expand cardiovascular services to PCI submit to the American College of Cardiology (ACC)-National Cardiovascular Data Registry (NCDR) CathPCI Registry. Not only does participation in the Registry provide an organization with benchmarking opportunities, but it will continue to drive national recognition and quality excellence among other providers. In many of the states above, existing or proposed criteria includes mandatory participation in the ACC-NCDR National Registry.

As many community-based providers consider expansion to PCI with SOS, and given all of the recent literature supporting its safety and efficacy, we should perhaps no longer debate whether the burden has been met, but rather move forward, considering the positive impact of these changes to programs across the country, especially in terms of improved access to life-saving care for the patients who need it most.

Amy Newell is a Vice President at Corazon, Inc., focused on strategic program development for the heart, vascular, neuro, and orthopedic specialties, offering consulting, recruitment, interim management and physician practice & alignment services. To learn more, visit www.corazoninc.com or call (412) 364-8200. To reach Amy, email anewell@corazoninc.com.

Reference

1. Levine GN, Bates ER, Blankenship JC, Bailey SR, Bittl JA, Cercek B, Chambers CE, Ellis SG, Guyton RA, Hollenberg SM, Khot UN, Lange RA, Mauri L, Mehran R, Moussa ID, Mukherjee D, Nallamothu BK, Ting HH; American College of Cardiology Foundation; American Heart Association Task Force on Practice Guidelines; Society for Cardiovascular Angiography and Interventions. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice

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Guidelines and the Society for Cardiovascular Angiography and Interventions. *J Am Coll Cardiol.* 2011 Dec 6;56(24):e44-122. doi: 10.1016/j.jacc.2011.08.007.

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ORIGINAL ARTICLE

Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery

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ABSTRACT

BACKGROUND

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Performance of percutaneous coronary intervention (PCI) is usually restricted to hospitals with cardiac surgery on site. We conducted a noninferiority trial to compare the outcomes of PCI performed at hospitals without and those with on-site cardiac surgery.

METHODS

We randomly assigned participants to undergo PCI at a hospital with or without on-site cardiac surgery. Patients requiring primary PCI were excluded. The trial had two primary end points: 6-week mortality and 9-month incidence of major adverse cardiac events (the composite of death, Q-wave myocardial infarction, or target-vessel revascularization). Noninferiority margins for the risk difference were 0.4 percentage points for mortality at 6 weeks and 1.8 percentage points for major adverse cardiac events at 9 months.

RESULTS

A total of 18,867 patients were randomly assigned in a 3:1 ratio to undergo PCI at a hospital without on-site cardiac surgery (14,149 patients) or with on-site cardiac surgery (4718 patients). The 6-week mortality rate was 0.9% at hospitals without on-site surgery versus 1.0% at those with on-site surgery (difference, -0.04 percentage points; 95% confidence interval [CI], -0.31 to 0.23; $P=0.004$ for noninferiority). The 9-month rates of major adverse cardiac events were 12.1% and 11.2% at hospitals without and those with on-site surgery, respectively (difference, 0.92 percentage points; 95% CI, 0.04 to 1.80; $P=0.05$ for noninferiority). The rate of target-vessel revascularization was higher in hospitals without on-site surgery (6.5% vs. 5.4%, $P=0.01$).

CONCLUSIONS

We found that PCI performed at hospitals without on-site cardiac surgery was noninferior to PCI performed at hospitals with on-site cardiac surgery with respect to mortality at 6 weeks and major adverse cardiac events at 9 months. (Funded by the Cardiovascular Patient Outcomes Research Team [C-PORT] participating sites; ClinicalTrials.gov number, NCT00549796.)

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PCI WITH OR WITHOUT ON-SITE CARDIAC SURGERY

THE POTENTIAL NEED FOR EMERGENCY cardiac surgery to treat complications related to percutaneous coronary intervention (PCI) suggests that performance of PCI may be best limited to hospitals with on-site cardiac surgery. Among Grüntzig's first 50 PCI procedures, 10% of patients required emergency coronary-artery bypass grafting (CABG).¹ Although the need for emergency surgery subsequently diminished dramatically (by 2002, the incidence was 0.15%),² concern about the safety and quality of PCI performed without the availability of on-site cardiac surgery has persisted. Hospitals in which PCI is performed but that do not have cardiac surgery programs could have more adverse events and poorer outcomes for a number of reasons (including low institutional volume of PCI procedures and inexperienced staff), in addition to the need for emergency CABG.

Despite these concerns, many hospitals without on-site cardiac surgery developed stand-alone programs for the performance of primary PCI after studies showed that primary PCI was associated with better outcomes than medical therapy in the treatment of myocardial infarction with ST-segment elevation³ and could be performed safely and effectively at such hospitals.⁴ Door-to-balloon times may be shorter, and outcomes consequently better, if primary PCI is widely available. It has further been suggested that, given the relatively low volume of primary PCI procedures at some hospitals, the addition of other PCI procedures (including elective PCI and PCI for acute coronary syndromes without ST-segment elevation) could help sustain and improve these programs.

In addition, previous studies have shown that, for patients with acute coronary syndromes presenting to centers without any revascularization capability, appropriate use of PCI and CABG is limited and outcomes are suboptimal.^{5,7} Extension of PCI capability to such hospitals could improve access to appropriate care, particularly in areas where recruitment and retention of cardiologists may be difficult⁸ and treatment options for patients are limited.

The Cardiovascular Patient Outcomes Research Team (CPORT) Non-Primary PCI (CPORT-B) trial was designed to help address these issues. CPORT-B was a randomized noninferiority trial that compared outcomes of PCI procedures (excluding primary PCI) at hospitals with and those without on-site cardiac surgery.

METHODS

STUDY DESIGN AND OVERSIGHT

The CPORT-B trial was designed by the study chairman and the protocol-development committee and was funded through financial support provided by participating sites to the Johns Hopkins University and through in-kind support that included the provision of local study coordinators at each site. There was no support from the makers of equipment used in catheterization laboratories or of that used for PCI. The protocol was approved by each participating hospital's institutional review board and the Johns Hopkins institutional review board. Data were gathered by local research coordinators, reviewed for accuracy by central study coordinators at Johns Hopkins, and analyzed by the authors. The authors vouch for the accuracy and completeness of the data and the analysis and for the fidelity of this report to the trial protocol, which is available with the full text of this article at NEJM.org.

TRIAL PARTICIPANTS

Patients were eligible for participation in the trial if they presented for diagnostic cardiac catheterization at 1 of 60 participating hospitals without on-site cardiac surgery located in 10 U.S. states (Maryland, New Jersey, Pennsylvania, Ohio, Georgia, Texas, North Carolina, Illinois, Oregon, and Alabama). During the trial period, patients who did not undergo randomization, whether or not they met the inclusion criteria for the trial, were included in a registry that recorded a limited set of data that excluded identifying private information.

Patients 18 years of age or older with stable coronary artery disease or an acute coronary syndrome were included in the trial. Patients with an acute myocardial infarction with ST-segment elevation were excluded, as were those with an ejection fraction of less than 20% and those who required PCI of an unprotected lesion in the left main coronary artery. In addition, interventionalists could exclude any patient whom they deemed to be at too high a risk for PCI. For each trial participant, all lesions requiring PCI had to be considered treatable at the hospital without on-site cardiac surgery before randomization. Patients who had previously participated in the trial were excluded. Full inclusion and exclusion criteria are available in Table S1 in the Supplementary Appendix, available at NEJM.org.

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PARTICIPATING HOSPITALS AND INTERVENTIONALISTS

Interventionalists were required to meet criteria for competency developed by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Society for Cardiac Angiography and Interventions (SCAI).⁹ Participating centers were required to have primary PCI programs available 24 hours per day, 7 days per week, and to be capable of performing 200 PCI procedures annually. Most sites required a waiver from the state department of health to participate. All such waivers allowed for a first-year PCI volume of 100 procedures, increasing to 200 in the second year.

Each site had a formal agreement with a tertiary-care hospital partner specifying that the tertiary-care institution would accept emergency transfers from the enrolling site. However, participants in the trial who were randomly assigned to undergo PCI at a hospital with on-site surgery could have the PCI procedure at any tertiary-care hospital. A formal agreement with an advanced cardiac life-support service capable of transporting patients requiring intraaortic balloon counterpulsation was also required, with an anticipated response time of 30 minutes or less.

Before commencing recruitment, all participating sites were required to complete a formal PCI development program. This program included the development of detailed care plans and pathways, order sets, and logistics and the training of staff in the care of patients undergoing PCI. Details of this program are available in the Supplementary Appendix.

TRIAL PROCEDURES

Before undergoing diagnostic catheterization, study participants provided written informed consent. After catheterization, if PCI was required and all lesions were considered to be treatable at the hospital without on-site cardiac surgery, the participant was randomly assigned in a 3:1 ratio to undergo PCI at either the enrolling site (without on-site cardiac surgery) or another facility with on-site cardiac surgery. Randomization was performed with the use of an automated telephone-response system on a per-site basis in random permuted blocks (of 4, 8, or 12). Patients who were considered to be at too high a risk according to the study-exclusion criteria or in the judgment of the treating physician did not undergo randomization but instead underwent PCI, CABG, or other therapy as clinically indicated.

After randomization, all trial participants were to undergo PCI according to their randomized assignment. The timing of the index PCI procedure depended on individual case acuity, the need to perform PCI on a different day than the visit to the catheterization laboratory to minimize procedural risk (i.e., staged procedure), and scheduling and transportation constraints, but the procedure was to be performed as soon as possible for each participant. All treatments, devices, and drugs were administered and laboratory studies carried out according to routine practice; no specific PCI protocol was prescribed. However, the use of cutting balloons was limited to in-stent restenosis and atherectomy devices were not permitted at hospitals without on-site cardiac surgery.

Participants were contacted by telephone (or mail, if necessary) at 6 weeks and 3, 6, and 9 months after study entry to identify adverse events. Medical records required to document identified events were obtained as needed.

TRIAL OUTCOMES

Two coprimary outcomes were identified: all-cause mortality 6 weeks after the index PCI and the composite rate of major adverse cardiac events, including death from all causes, Q-wave myocardial infarction, and target-vessel revascularization, 9 months after the index PCI. Additional outcomes included the PCI success rate and the incidence of cardiac surgery, bleeding, stroke, renal failure, and any subsequent revascularization.

Except as noted, definitions of data elements followed those in the American College of Cardiology National Cardiovascular Data Registry module on cardiac catheterization, version 3.02.²⁰ Q-wave myocardial infarction was defined as the development of new Q waves in any two contiguous leads. Target-vessel revascularization was defined as any revascularization intervention (PCI or CABG) occurring in a treated vessel at any time after the index intervention. In randomly assigned participants who did not undergo an index PCI, any revascularization was considered a target-vessel revascularization. Bleeding was defined as any bleeding that required blood transfusion, except for transfusions associated with cardiac surgery. Vascular repair included thrombin injection, ultrasound-guided compression, and surgical repair. Further details of study definitions are available in the Supplementary Appendix.

All events were reported by the enrolling site to the central coordinating center and were con-

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firmed by coordinating-center staff with the source medical records submitted. Occasionally, a review of source documents resulted in the identification of unreported events or the withdrawal of submitted events. A central review committee reviewed electrocardiographic findings without knowledge of the participant's randomized assignment.

STATISTICAL ANALYSIS

The CPORT-B trial was designed as a noninferiority trial. On the basis of previous studies, the 6-week all-cause mortality rate was estimated at 0.8%^{11,12} and the rate of major adverse cardiac events at 9 months was estimated at 12.0%.¹³⁻¹⁶ Noninferiority margins for the difference in event rates were set at 0.4 percentage points for the 6-week end point and 1.8 percentage points for the 9-month end point. With dual primary end points, the required number of participants for a one-sided test for noninferiority with an alpha level of 0.05 and a beta level of 0.80 was determined to be 18,360.

The primary outcome analysis was performed on data from the intention-to-treat population. Asymptotic normal approximations to the sample proportions were used to generate confidence intervals and P values for noninferiority. Categorical variables were compared with the use of Fisher's exact test or a chi-square test. A per-protocol analysis was also performed, which included only participants who underwent PCI at the site to which they were assigned. All statistical analyses were performed with the use of SAS software, version 9.2.

States that required a waiver from the department of health for trial participation typically specified that the participating hospitals should stop performing PCI when trial enrollment was completed. To allow the creation of a follow-up registry in these states, enrollment continued after the recruitment goal of 18,360 participants was reached. Ultimately, 18,867 participants underwent randomization.

RESULTS

STUDY POPULATION

Enrollment began on April 7, 2006, and ended on March 31, 2011. During that period, there were 99,479 patient visits for diagnostic catheterization at the participating hospitals. Among the 76.1% of patients who provided consent to participate,

21,165 were judged to require PCI after catheterization, and 18,867 underwent randomization (Fig. 1). Excluded were 2298 patients (10.9%) who required PCI but were judged to be at too high a risk for study participation. Reasons for the judgment that the risk was too high are shown in Figure S1 in the Supplementary Appendix. Overall, patients in the registry had fewer risk factors and less severe coronary disease than randomly assigned trial participants (Table S2 in the Supplementary Appendix).

Of the patients who underwent randomization, 319 did not undergo an index PCI. The proportion of patients who did not undergo an index PCI was higher among participants assigned to hospitals with on-site cardiac surgery than among those assigned to hospitals without on-site surgery. Reasons included referral for surgical or medical therapy and lesion resolution (Table S3 in the Supplementary Appendix). Crossovers between study groups were infrequent but were more frequent among participants randomly assigned to hospitals with on-site cardiac surgery (Fig. 1).

The baseline characteristics of the participants are shown in Table 1. There was a higher incidence of prior PCI in participants randomly assigned to hospitals without cardiac surgery on site. In addition, the rate of emergency catheterization was higher, and the rate of urgent catheterizations lower, among participants assigned to hospitals with on-site cardiac surgery.

The median annual volume of catheterizations per hospital was 150 procedures (interquartile range, 99 to 216). The median annual volume of primary PCIs was 51 procedures (interquartile range, 35 to 74). The participation of 12 hospitals was terminated during the trial because of low volume. Data from these sites were included in the data analysis.

PROCEDURE CHARACTERISTICS

A higher percentage of PCIs were staged among participants assigned to hospitals with on-site cardiac surgery than among those assigned to hospitals without on-site surgery, probably because of the need for transfer (Table 2). As a result, the number of visits to the catheterization laboratory that were needed to complete PCI was higher among participants assigned to hospitals with on-site cardiac surgery. In addition, drug-eluting stents were used more frequently in hospitals with on-site cardiac surgery.

The rate of PCI failure was lower among par-

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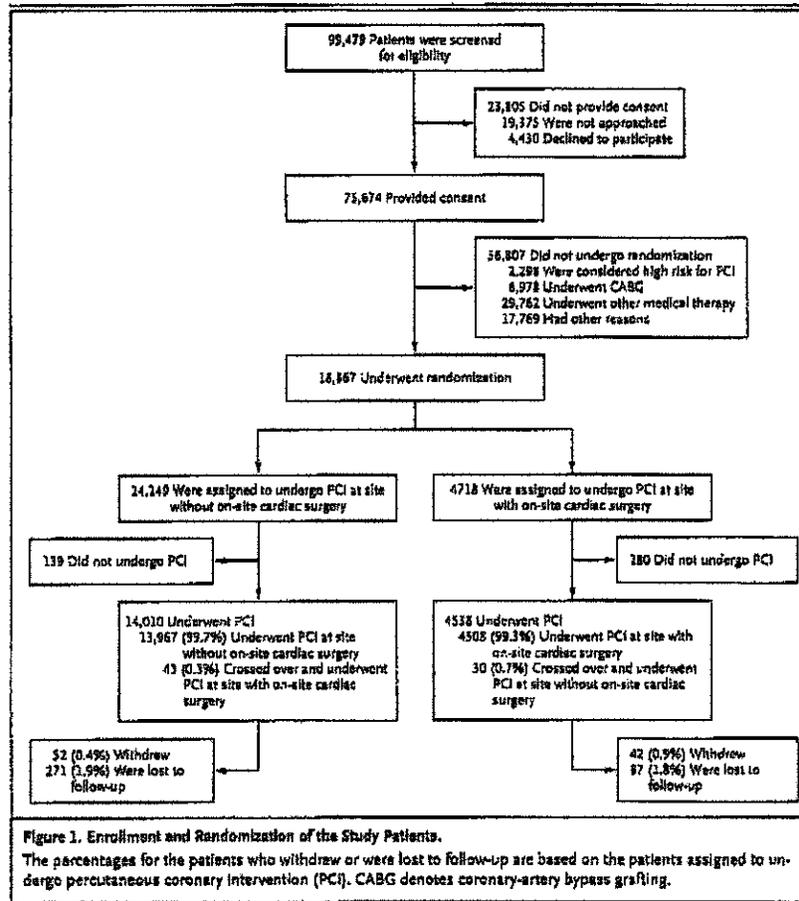
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Participants treated at hospitals with on-site cardiac surgery (Table 2). Emergency CABG was associated with high mortality but was rarely performed; it was performed more frequently among participants assigned to hospitals with on-site cardiac surgery. The incidence of unplanned re-catheterization and PCI before discharge was greater at hospitals without on-site cardiac surgery.

OUTCOMES

At 6 weeks after the index PCI, 132 participants assigned to hospitals without on-site cardiac surgery had died and 46 participants assigned to

hospitals with on-site cardiac surgery had died. The event rates in the two groups were 0.9% and 1.0%, respectively (difference in event rates, -0.04 percentage points; 95% confidence interval [CI], -0.31 to 0.23; P=0.004 for noninferiority) (Table 3).

At 9 months, there were 1716 major adverse cardiac events in participants at hospitals without on-site cardiac surgery and 529 such events in patients at hospitals with on-site cardiac surgery (12.1% vs. 11.2%; difference in event rates, 0.92 percentage points; 95% CI, 0.04 to 1.80; P=0.05 for noninferiority) (Table 3). There were no significant differences in all-cause mortality or Q-wave

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Table 1. Baseline Characteristics of the Study Patients.*

Characteristic	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)
Age—yr	63.9±11.9	64.0±12.0
Male sex—no. (%)	9046 (63.9)	2970 (63.0)
White race—no. (%)†	11,185 (79.1)	3778 (80.1)
Medical history—no. (%)		
Hypertension	11,950 (84.5)	4024 (85.3)
Hypercholesterolemia	11,367 (81.3)	3865 (81.9)
Smoking (current or former)	8,719 (61.6)	2964 (62.8)
Diabetes	5,485 (38.8)	1868 (39.6)
Family history of CAD	7,730 (54.6)	2623 (55.6)
Heart failure	1,531 (10.8)	518 (11.0)
Prior myocardial infarction	6,011 (42.5)	2030 (43.0)
Prior PCI‡	4,506 (31.8)	1430 (30.3)
Prior CABG	1,852 (13.1)	632 (13.4)
Prior stroke or PVD	2,447 (17.3)	868 (18.4)
Angiographic findings at baseline		
One-vessel CAD—no. (%)	5,097 (36.0)	1,645 (34.9)
Two-vessel CAD—no. (%)	5,087 (36.0)	1,741 (36.9)
Three-vessel CAD—no. (%)	3,959 (28.0)	1,326 (28.1)
Left main CAD—no. (%)	463 (3.3)	178 (3.8)
Graft disease—no. (%)	1,323 (9.4)	456 (9.7)
Left ventricular ejection fraction—%	54.2±10.6	54.3±10.7
Procedure status at time of catheterization—no. (%)§		
Elective	10,350 (73.2)	3414 (72.4)
Urgent¶	3,291 (23.3)	1127 (23.9)
Emergency‡	493 (3.5)	175 (3.7)
Clinical status at time of catheterization—no. (%)		
STEMI	390 (2.8)	147 (3.1)
NSTEMI	3,471 (24.5)	1210 (25.7)
Unstable angina	5,196 (36.7)	1665 (35.3)
Stable angina	2,011 (14.2)	636 (13.5)
Atypical chest pain	723 (5.1)	268 (5.7)
Other	2,356 (16.7)	790 (16.8)

* Plus-minus values are means ±SD. CABG denotes coronary-artery bypass grafting, CAD coronary artery disease, NSTEMI non-ST-segment elevation myocardial infarction, PCI percutaneous coronary intervention, PVD peripheral vascular disease, and STEMI ST-segment elevation myocardial infarction.

† Race was self-reported.

‡ P<0.05 for the comparison between groups.

§ For procedure status at time of catheterization, data were missing for 15 patients treated at hospitals without on-site cardiac surgery and 2 patients treated at hospitals with on-site cardiac surgery. The definitions for "urgent" and "emergency" were those used in the American College of Cardiology National Cardiovascular Data Registry module on cardiac catheterization, version 3.02.¹⁰

|| P<0.01 for the comparison between groups.

¶ For clinical status at time of catheterization, data were missing for 2 patients in each study group. "Other" includes patients presenting with heart failure, arrhythmia, positive stress tests, syncope, and other non-chest-pain syndromes and patients undergoing cardiovascular risk assessment before a noncardiac surgical procedure.

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Table 2. Characteristics of the Index Procedure.*

Characteristic	No On-Site Cardiac Surgery	On-Site Cardiac Surgery	P Value
PCI staged — no./total no. (%)†	3652/14,010 (26.1)	3084/4538 (68.0)	<0.001
Single-vessel PCI — no./total no. (%)	11,212/14,010 (80.0)	3716/4538 (81.9)	
Multivessel PCI — no./total no. (%)	2937/14,010 (21.0)	1002/4538 (22.1)	
No. of catheterization laboratory visits needed to complete index PCI	1.28	1.73	<0.001
No. of days from randomization to index PCI — median (IQR)	0 (0–3)	1 (0–3)	<0.001
Stent use — no./total no. (%)			0.03
DES only	10,074/14,010 (71.9)	3343/4538 (73.7)	
BMS only	2790/14,010 (19.9)	877/4538 (19.3)	
Both DES and BMS	596/14,010 (4.3)	156/4538 (3.4)	
Balloon only	550/14,010 (3.9)	162/4538 (3.6)	
PCI success — no./total no. (%)			0.007
By patient‡			
Complete success	12,714/14,010 (90.7)	4148/4538 (91.4)	
Partial success	808/14,010 (5.8)	253/4538 (5.6)	
Failure	482/14,010 (3.4)	113/4538 (2.5)	
By lesion§			0.04
Success	19,886/21,292 (93.4)	6499/6907 (94.1)	
Failure	1406/21,292 (6.6)	408/6907 (5.9)	
Emergency procedures			
Emergency PCI — no./total no. (%)	23/14,010 (0.2)	6/4538 (0.1)	
Death associated with emergency PCI — no. of deaths/total no. of emergency PCI procedures (%)	1/23 (4.3)	0	
Emergency CABG — no./total no. (%)	13/14,010 (0.1)	10/4538 (0.2)	0.11
Death associated with emergency CABG — no. of deaths/total no. of emergency CABG procedures (%)	2/13 (15.4)	2/10 (20.0)	

* Data are for all randomly assigned patients who underwent PCI. BMS denotes bare-metal stent, DES drug-eluting stent, and IQR interquartile range.

† Staged PCI indicates that PCI was performed on a different day than the visit to the catheterization laboratory to minimize procedural risk.

‡ Thirty patients (6 in hospitals without on-site cardiac surgery and 24 in hospitals with on-site cardiac surgery) did not have valid postprocedure data available on coronary-artery flow (according to the Thrombolysis in Myocardial Infarction [TIMI] scale, which ranges from 0 to 3, with 0 indicating no flow and 3 normal flow) or percentage of residual stenosis. These 30 patients were excluded from the analysis of PCI success by patient. Complete success was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20% in all treated lesions. Partial success was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20% in at least one (but not all) treated lesions. Failure was defined as no treated lesions with a postprocedure TIMI flow grade of 3 and residual stenosis of more than 20%.

§ Success by lesion was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20%. Failure was defined as a postprocedure TIMI flow grade of less than 3 or residual stenosis of more than 20%.

myocardial infarction between the two groups, but there was a significant difference in the rate of target-vessel revascularization — 6.5% among participants at hospitals without on-site cardiac surgery versus 5.4% among those at hospitals with on-site cardiac surgery ($P=0.01$).

Several exploratory analyses were conducted (Table 3). If CABG was not considered to qualify as target-vessel revascularization when it was per-

formed as an initial procedure (i.e., for participants who did not undergo the intended index PCI), the rates of major adverse cardiac events at 9 months among participants at hospitals without and those with on-site cardiac surgery were 11.9% and 10.5%, respectively. In per-protocol analyses (excluding participants who crossed over), the death rates at 6 weeks were 0.9% and 0.8%, respectively, and the rates of major adverse cardiac

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Table 3. Trial Outcomes.*

Outcome	No On-Site Cardiac Surgery no./total no. (%)	On-Site Cardiac Surgery no./total no. (%)	Difference in Rate (Asymptotic Two-Sided 95% CI)		P Value
			Noninferiority	Superiority	
Primary end point (intention-to-treat population)					
Death at 6 wk	132/14,149 (0.9)	46/4718 (1.0)	-0.04 (-0.31 to 0.23)		0.004
90-day outcomes					
Death	454/14,149 (3.2)	150/4718 (3.2)			
TVR	935/14,149 (6.5)	253/4718 (5.4)			0.01
Q-wave myocardial infarction	434/14,149 (3.1)	144/4718 (3.1)			
Major adverse cardiac event	1716/14,149 (12.1)	529/4718 (11.2)	0.92 (0.04 to 1.80)		0.05
Exploratory analyses (intention-to-treat population)					
Major adverse cardiac event, including withdrawal and loss to follow-up	2026/14,149 (14.3)	653/4718 (13.8)	0.48 (-0.18 to 1.14)		0.01
CARC as initial procedure not included in TVR definition					
TVR	873/14,149 (6.2)	218/4718 (4.6)			<0.001
Major adverse cardiac event	1678/14,149 (11.9)	495/4718 (10.5)	1.37 (0.51 to 2.23)		0.21
TVR according to stent type					
DES only	484/10,074 (4.8)	120/3343 (3.6)			0.005
BMS only	223/2790 (8.0)	53/877 (6.0)			
Both DES and BMS	39/596 (6.5)	8/156 (5.1)			
Balloon only	138/550 (25.1)	34/162 (21.0)			
Per-procedural analyses					
Death at 6 wk	129/13,967 (0.9)	38/4508 (0.8)	0.08 (-0.18 to 0.34)		0.05
TVR	860/13,967 (6.2)	202/4508 (4.5)			<0.001
Major adverse cardiac event at 9 mo	1676/13,967 (12.0)	467/4508 (10.4)	1.64 (0.77 to 2.51)		0.42

* Major adverse cardiac events included death, target-vessel revascularization (TVR), and Q-wave myocardial infarction. BMS denotes bare-metal stent, and DES drug-eluting stent.

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Event	6 Wk			9 Mo		
	No On-Site Cardiac Surgery (N=14,149) no. (%)	On-Site Cardiac Surgery (N=4718) no. (%)	P Value	No On-Site Cardiac Surgery (N=14,149) no. (%)	On-Site Cardiac Surgery (N=4718) no. (%)	P Value
CABG						
All	48 (0.6)	69 (1.5)	<0.001	216 (1.5)	107 (2.3)	<0.001
Emergency	15 (0.1)	10 (0.2)		14 (0.1)	11 (0.2)	
Bleeding	486 (3.4)	150 (3.2)		754 (5.3)	247 (5.2)	
Vascular repair	52 (0.4)	20 (0.4)		151 (1.1)	55 (1.2)	
Stroke	40 (0.3)	8 (0.2)		87 (0.6)	23 (0.5)	
Renal insufficiency	72 (0.5)	20 (0.4)		131 (0.9)	37 (0.8)	
Unplanned catheterization	613 (4.3)	130 (3.2)	<0.001	2102 (14.9)	566 (12.0)	<0.001
Any subsequent revascularization	378 (2.7)	127 (2.7)		1200 (8.5)	329 (7.0)	0.001

events at 9 months were 12.0% and 10.4%, respectively.

CABG was performed more frequently among trial participants at hospitals with on-site cardiac surgery than among participants at hospitals without such access (Table 4). The incidence of unplanned catheterization at 6 weeks and 9 months and the incidence of any subsequent revascularization at 9 months were higher among participants at hospitals without on-site cardiac surgery (Table 4).

DISCUSSION

We compared clinical outcomes between trial participants undergoing PCI at a hospital with on-site access to cardiac surgery and participants undergoing PCI at a hospital without such access. We found that outcomes at hospitals without on-site cardiac surgery were noninferior to those at hospitals with cardiac surgery on site, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months. There were no significant differences between the two study groups at 9 months with respect to rates of death or Q-wave myocardial infarction, but trial participants treated at hospitals without on-site cardiac surgery more frequently required target-vessel revascularization.

The short-term results from this trial are concordant with the findings in previous registry

studies and meta-analyses.^{23,24} The longer-term outcomes are similar to those in a small randomized trial of low-risk PCI at two hospitals,²⁵ which showed equivalent safety at the hospitals with and those without on-site cardiac surgery but more frequent target-vessel revascularization at 6 months among participants treated at the sites without cardiac surgery.

The definition of target-vessel revascularization used in the CPORT-E trial included any revascularization (PCI or CABG) after the index PCI. In addition, for randomly assigned participants who did not undergo an index PCI, any subsequent revascularization of the target vessel, whether by PCI or CABG, was considered a target-vessel revascularization. The inclusion of initial CABG as a target-vessel revascularization is consistent with the intention-to-treat approach, which is based on randomized treatment assignments, regardless of the treatment received. When CABG was not counted as a target-vessel revascularization in these trial participants, hospitals without on-site cardiac surgery were inferior to those with on-site access with respect to the rate of major adverse cardiac events at 9 months (Table 3). The per-protocol analysis also showed a higher rate of major adverse cardiac events in hospitals without on-site cardiac surgery. These differences are small and within the range of noninferiority margins used in recent comparative trials of stent types, from 1.5 percentage points (relative difference,

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19%)²⁰ to 3.5 percentage points (relative difference, 43%).²¹

In all analyses, the rate of target-vessel revascularization was higher among participants who underwent PCI at a hospital without cardiac surgery on-site, regardless of the definition of target-vessel revascularization and regardless of stent type. The reason for this is not clear from the current study but may reflect a lower initial success rate and a more conservative approach by interventionalists practicing at relatively inexperienced centers that began PCI programs only as part of the CPORT-B trial.

There are a number of important limitations arising from the design and conduct of the CPORT-B trial. Participants were carefully selected and were excluded if they were deemed to be at high risk. It is possible that the population studied is different from the general population requiring PCI, although a comparison of baseline characteristics with those reported in the National Cardiovascular Data Registry²⁷ suggests that this is not the case (Table S4 in the Supplementary Ap-

pendix). For outcomes of PCI at hospitals without on-site cardiac surgery to be similar to those at hospitals with on-site cardiac surgery, it may be necessary for such centers to participate in a formal PCI development program and for interventionalists who perform the procedures to meet the criteria for competency developed by the ACC, AHA, and SCAI.

In summary, the CPORT-B trial compared the clinical outcomes of PCI performed at hospitals with access to on-site cardiac surgery with outcomes of PCI performed at hospitals without such access. Outcomes at hospitals without on-site cardiac surgery were noninferior to those at hospitals with cardiac surgery on site, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months.

Disclosures provided by the authors are available with the full text of this article at nejm.org.

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ORIGINAL ARTICLE

Nonemergency PCI at Hospitals with or without On-Site Cardiac Surgery

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ABSTRACT

BACKGROUND

From Boston University School of Medicine, Cardiovascular Medicine, Department of Medicine, Boston Medical Center (A.K.J.); Harvard Medical School (S.-L.T.N., D.E.C., L.M.), Harvard School of Public Health (S.-L.T.N.), Boston University (J.M.M.), Beth Israel Deaconess Medical Center (D.E.C.), Tufts University School of Medicine, St. Elizabeth's Medical Center (J.P.C.), Massachusetts Department of Public Health (N.M., I.K.R., M.B.), and Cardiovascular Medicine, Department of Medicine, Brigham and Women's Hospital (L.M.) — all in Boston; and Cardiovascular Center, South Shore Hospital, Weymouth, MA (A.D.M.). Address reprint requests to Dr. Jacobs at the Section of Cardiology, Boston Medical Center, 88 E. Newton St., Boston, MA 02118, alice.jacobs@bmc.org.

Emergency surgery has become a rare event after percutaneous coronary intervention (PCI). Whether having cardiac-surgery services available on-site is essential for ensuring the best possible outcomes during and after PCI remains uncertain.

METHODS

We enrolled patients with indications for nonemergency PCI who presented at hospitals in Massachusetts without on-site cardiac surgery and randomly assigned these patients, in a 3:1 ratio, to undergo PCI at that hospital or at a partner hospital that had cardiac surgery services available. A total of 10 hospitals without on-site cardiac surgery and 7 with on-site cardiac surgery participated. The coprimary end points were the rates of major adverse cardiac events — a composite of death, myocardial infarction, repeat revascularization, or stroke — at 30 days (safety end point) and at 12 months (effectiveness end point). The primary end points were analyzed according to the intention-to-treat principle and were tested with the use of multiplicative noninferiority margins of 1.5 (for safety) and 1.3 (for effectiveness).

RESULTS

A total of 3691 patients were randomly assigned to undergo PCI at a hospital without on-site cardiac surgery (2774 patients) or at a hospital with on-site cardiac surgery (917 patients). The rates of major adverse cardiac events were 9.5% in hospitals without on-site cardiac surgery and 9.4% in hospitals with on-site cardiac surgery at 30 days (relative risk, 1.00; 95% one-sided upper confidence limit, 1.22; $P < 0.001$ for noninferiority) and 17.3% and 17.8%, respectively, at 12 months (relative risk, 0.98; 95% one-sided upper confidence limit, 1.13; $P < 0.001$ for noninferiority). The rates of death, myocardial infarction, repeat revascularization, and stroke (the components of the primary end point) did not differ significantly between the groups at either time point.

CONCLUSIONS

Nonemergency PCI procedures performed at hospitals in Massachusetts without on-site surgical services were noninferior to procedures performed at hospitals with on-site surgical services with respect to the 30-day and 1-year rates of clinical events. (Funded by the participating hospitals without on-site cardiac surgery; MASS COMM ClinicalTrials.gov number, NCT01116882.)

*The investigators in the Randomized Trial to Compare Percutaneous Coronary Intervention between Massachusetts Hospitals with Cardiac Surgery On-Site and Community Hospitals without Cardiac Surgery On-Site (MASS COMM) are listed in the Supplementary Appendix, available at nejm.org.

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SINCE CORONARY BALLOON ANGIOPLASTY was introduced into clinical practice in 1977, marked advances in technology, technique, adjunctive pharmacotherapy, and operator experience have resulted in higher rates of procedural success and lower rates of complications.^{1,2} Emergency coronary-artery bypass grafting (CABG), which was initially required in 6 to 10% of procedures,^{3,4} has become a rare event, with an incidence of 0.1 to 0.4% in contemporary studies.^{4,6}

Moreover, as data supporting the use of primary PCI for patients with ST-segment elevation myocardial infarction (STEMI) have emerged, the need for timely access to the procedure has justified the expansion of emergency PCI to hospitals that do not have the capability for on-site cardiac surgery.⁷⁻⁹ Although there are limited data^{10,11} to support the practice of nonemergency PCI at hospitals that do not have the capability for on-site cardiac surgery, there is concern about the ratio of risk to benefit in this setting, as reflected in the class IIb (level of evidence B) recommendation in the 2011 PCI guidelines.¹²

The Cardiovascular Patient Outcomes Research Team (CPORT) Non-Primary PCI (CPORT-B) trial, which was reported after publication of the 2011 PCI guidelines, directly compared the outcomes of PCI procedures (excluding primary PCI for STEMI) between hospitals with on-site cardiac surgery and those without on-site cardiac surgery, in a prospective, randomized, controlled trial.¹³ PCI performed at hospitals without on-site cardiac surgery was noninferior to PCI performed at hospitals with on-site cardiac surgery with respect to mortality at 6 weeks and the rate of major adverse cardiac events at 9 months.

The Randomized Trial to Compare Percutaneous Coronary Intervention between Massachusetts Hospitals with Cardiac Surgery On-Site and Community Hospitals without Cardiac Surgery On-Site (MASS COMM) was designed in 2006, in collaboration with the Massachusetts Department of Public Health, to provide evidence on which to base regulatory policy decisions about performing nonemergency PCI in hospitals without on-site cardiac surgery. The aim of the trial was to compare the short-term safety and 12-month outcomes of PCI (excluding primary PCI for STEMI) at hospitals without on-site cardiac surgery, as compared with hospitals with on-site cardiac surgery.

METHODS

STUDY OVERSIGHT

MASS COMM was a prospective, multicenter, randomized, controlled, noninferiority trial. The design of the study has been reported previously.¹⁴ The study was designed by the investigators (see the Supplementary Appendix, available with the full text of this article at NEJM.org) and was funded by the participating hospitals without on-site cardiac surgery. The trial was conducted under the principles outlined in the Declaration of Helsinki. The institutional review board at each participating hospital approved the study, and each patient provided written informed consent for participation in the study. The third author and the last author had full access to the data and vouch for the integrity of the analyses presented, and all the authors vouch for the fidelity of this report to the trial protocol, which is available at NEJM.org. The PCI procedures were performed according to the standards of care at each site, and only devices approved by the Food and Drug Administration were used.

STUDY PARTICIPANTS

We recruited patients who were undergoing diagnostic catheterization for known or suspected coronary artery disease at hospitals without on-site cardiac surgery. To participate in MASS COMM, each hospital that did not have on-site cardiac surgery was required to have approval from the Massachusetts Department of Public Health and to meet minimum requirements for the numbers of PCI procedures performed at the site and by the participating operators. The criteria for participation and for the numbers of PCI procedures performed at the hospital and by the operators are listed in Tables S1 and S2 in the Supplementary Appendix. The key exclusion criteria were a left ventricular ejection fraction of less than 20% and target lesions with any of the following features: unprotected left main coronary-artery stenosis of more than 50% of the luminal diameter, treatment with a procedure other than balloon angioplasty before placement of the stent, a saphenous-vein graft location, or a vessel serving the only viable myocardium¹⁴ (Fig. S1 in the Supplementary Appendix).

Patients were assessed for eligibility and were randomly assigned, in a 3:1 ratio, to undergo PCI

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at the hospital without on-site cardiac surgery or to be transferred for PCI to a participating hospital with on-site cardiac surgery. Randomization was performed with the use of sealed envelopes, with stratification according to hospital and history of or no history of diabetes mellitus.

END POINTS

The coprimary end points were the incidence of major adverse cardiac events at 30 days (safety end point) and at 12 months (effectiveness end point) after the procedure. The end point of major adverse cardiac events was a composite of death from any cause, myocardial infarction, repeat coronary revascularization, or stroke. Follow-up clinical assessment of the patients was performed in person at 30 days and at 12 months.

Secondary end points included death from any cause, repeat revascularization, stroke, ischemia-driven target-vessel and target-lesion revascularization, definite or probable stent thrombosis (defined according to the Academic Research Consortium criteria), emergency CABG, emergency or urgent PCI, and major vascular complications.²⁴ Events were adjudicated by an independent clinical events committee, whose members were unaware of the study assignments; the committee was administered by Harvard Clinical Research Institute.

The clinical events committee assessed all lesions in a random sample of 10% of enrolled patients, and the results of their assessment were used in analyses of the proportion of lesions that were treated successfully, the proportion of patients in whom the procedure was successful, the proportion of patients with complete revascularization, and the proportion of lesions that were judged to have met the criteria for class I or II recommendations in the PCI guidelines regarding anatomical indications for PCI.¹⁸ Successful treatment of the lesion was defined as residual stenosis of the target lesion of less than 20%; procedural success was defined as residual stenosis of the target lesion of less than 20% and no occurrence of in-hospital major adverse cardiac events. Complete revascularization was defined as the successful treatment, according to the criteria of procedural success, of all epicardial vessels with more than 70% and less than 100% stenosis. An independent data and safety monitoring board comprised noninvasive and

interventional cardiologists and a biostatistician (all residing outside Massachusetts).

STATISTICAL ANALYSIS

The primary end points were compared for noninferiority, whereas all other end points were compared for differences. The noninferiority of hospitals without on-site cardiac surgery as compared with hospitals with on-site surgery with respect to the 30-day rate of major adverse cardiac events (safety analysis) and the 12-month rate of major adverse cardiac events (effectiveness analysis) was assessed with the use of the Farrington-Manning²⁷ test, with noninferiority margins for relative risk of 1.5 for the safety analysis and 1.3 for the effectiveness analysis. A P value of less than 0.05 for both end points was required to determine noninferiority overall.

Formal noninferiority testing was performed in the intention-to-treat population (all patients who underwent randomization). For patients who missed the 12-month follow-up visit, we obtained data on death from state vital statistics records²⁸ and successfully linked 99% of the records (see the Supplementary Appendix). For patients with other missing data (Table S3 in the Supplementary Appendix), we used multiple imputation of major adverse cardiac events before generating the Farrington-Manning one-sided 95% upper confidence interval for relative risk and the noninferiority P value.

With the assumption that the rates of major adverse cardiac events in the two groups would be 6 to 7% at 30 days (safety end point) and 15 to 16% at 12 months (effectiveness end point), we estimated that we would need a sample of 3447 patients who could be evaluated for the study to have 80 to 85% power to show the noninferiority of hospitals without on-site cardiac surgery with respect to the safety end point and 85 to 88% power to show noninferiority with respect to the effectiveness end point.^{24,18}

To provide additional statistical power, the original trial design included a cohort of 1200 patients who would be chosen randomly (and who would then provide written informed consent) from the patient pool undergoing routine PCI at the hospitals with on-site cardiac surgery. Because of slow enrollment, recruitment of this cohort was stopped after 164 patients had been enrolled, and the data were not included in the

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analysis of the primary end point. Calculation of the final sample size assumed that these patients would not be included in the primary analysis. Descriptive comparisons of the 164 patients in this cohort with the first 164 patients who underwent randomization are presented in Tables S4 and S5 in the Supplementary Appendix.

In a secondary analysis, we estimated survival free from major adverse cardiac events with the use of the Kaplan–Meier method, and the data are shown according to treatment group in Figures S2 and S3 in the Supplementary Appendix. In another secondary analysis, we accounted for variation among study sites by estimating the between-hospital variance (with standard deviation) and the adjusted relative risks and upper 95% confidence limit for each primary end point, using mixed-model logistic regression, with site considered as a random effect (see the Supplementary Appendix).

Baseline characteristics and secondary end points were compared between the groups with the use of two-sample *t*-tests for continuous outcomes and chi-square or Fisher's exact tests for dichotomous outcomes; all reported *P* values are two-sided. Two-sided 95% confidence intervals are reported for percentages based on the normal approximation to the binomial distribution. All statistical analyses were conducted at the Harvard Clinical Research Institute with the use of SAS software, version 9.1.3, with Service Pack 2 (SAS Institute).

RESULTS

PARTICIPATING SITES AND INTERVENTIONALISTS

A total of 10 hospitals without on-site cardiac surgery and 7 hospitals with on-site cardiac surgery participated in MASS COMM. Of the 68 operators who participated in the trial, 34 performed PCI at hospitals with on-site cardiac surgery only, and 34 performed procedures at both types of hospitals.

PATIENTS

Between July 7, 2006, and September 29, 2011, a total of 3691 eligible patients were randomly assigned to undergo PCI at a hospital without on-site cardiac surgery (2774 patients) or at a hospital with on-site cardiac surgery (917 patients) (Fig. 1). A total of 37 patients who underwent

randomization did not undergo PCI (13 in the group assigned to hospitals without on-site cardiac surgery and 24 in the group assigned to hospitals with on-site cardiac surgery), and 24 patients (8 and 16 in the two groups, respectively) crossed over and underwent PCI at a site other than the one to which they had been assigned (Fig. S4 in the Supplementary Appendix); the reasons are listed in the Supplementary Appendix. The median follow-up period was 360 days in both groups.

The baseline clinical characteristics were generally similar in the two groups (Table 1). Angiographic and procedural characteristics reported by the treatment sites are shown in Table 2. The characteristics of the as-treated population (Tables S6 and S7 in the Supplementary Appendix), in which patients were classified according to the actual treatment received, were similar to those of the intention-to-treat population. The median time from randomization to PCI was 0.1 days in the group assigned to PCI at hospitals without on-site cardiac surgery as compared with 0.6 days in the group assigned to hospitals with on-site cardiac surgery ($P < 0.001$), with 6 patients (0.2%) and 12 patients (1.3%), respectively, undergoing PCI more than 3 days after randomization.

PRIMARY SAFETY END POINT

The rate of major adverse cardiac events at 30 days was 9.5% among patients assigned to undergo PCI at hospitals without on-site cardiac surgery as compared with 9.4% among patients assigned to undergo PCI at hospitals with on-site cardiac surgery (relative risk, 1.00; 95% one-sided upper confidence limit, 1.22; $P < 0.001$ for noninferiority). There were no significant differences between the two groups in the rates of the components of the end point — death from any cause, myocardial infarction, repeat revascularization, and stroke (Table 3). The analysis of the as-treated population showed similar results (Table S8 in the Supplementary Appendix).

PRIMARY EFFICACY END POINT

The 12-month rates of major adverse cardiac events in the intention-to-treat population were 17.3% in the group assigned to hospitals without on-site cardiac surgery and 17.8% in the group assigned to hospitals with on-site cardiac surgery (relative risk, 0.98; 95% one-sided upper confi-

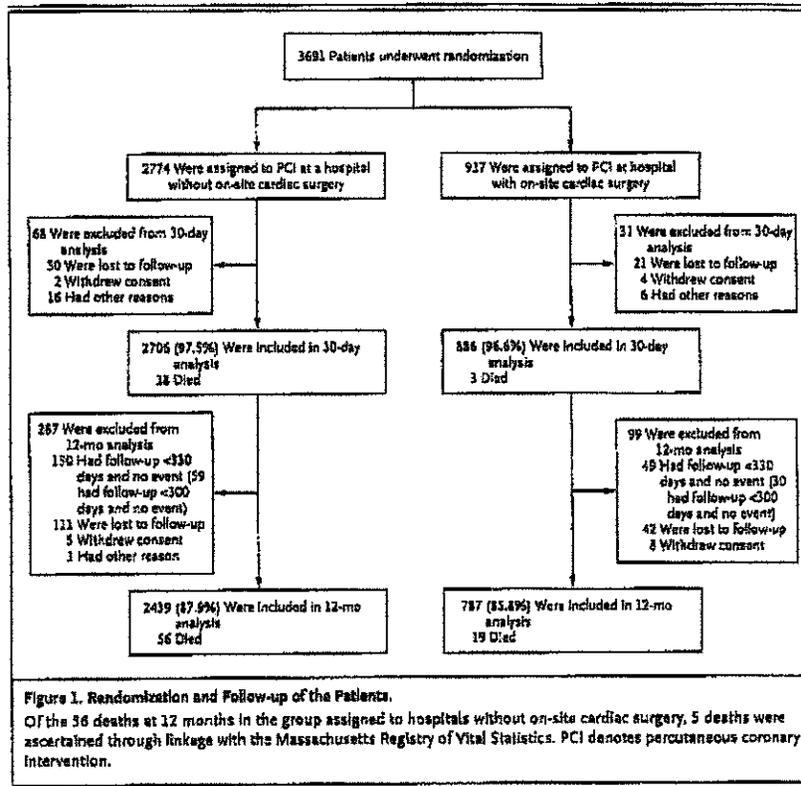
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dence limit, 1.13; $P < 0.001$ for noninferiority) (Table 3). Like the safety analysis, the effectiveness analysis showed no significant differences between the two groups in rates of the components of the end point — death from any cause, myocardial infarction, repeat revascularization, or stroke. The as-treated analysis showed similar results (Table S8 in the Supplementary Appendix).

SECONDARY ANALYSES

Revascularization Procedures

There were no significant differences between the two groups with respect to the rate of emergency CABG or the rate of emergency or urgent PCI at 30 days. The rates of ischemia-driven target-vessel revascularization were also similar in the two groups at 30 days and 12 months (Table 3).

Treatment Effect Accounting for Between-Hospital Variation

The rate of major adverse cardiac events varied across hospitals by 14 percentage points at 30 days and by 17 percentage points at 12 months (Fig. S5 and S6 in the Supplementary Appendix). The estimated between-hospital variance components (\pm SD) were 0.187 ± 0.126 and 0.065 ± 0.060 for the 30-day and 12-month log-odds rates, respectively, of major adverse cardiac events. This translates into a median odds of 1.3, which suggests that the odds of a major adverse cardiac event at 12 months at one randomly selected hospital could be 1.3 times as high as the odds at another randomly selected hospital; at 30 days, the median odds was 1.5. After adjustment for this variation, the relative risks of major adverse cardiac events in the group

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Table 1. Baseline Characteristics of the Patients.*

Characteristic	PCI at Hospitals without On-Site Cardiac Surgery (N=2774)	PCI at Hospitals with On-Site Cardiac Surgery (N=917)
Age—yr	64.71±11.84	64.16±11.81
Female sex—no. (%)	883 (31.8)	308 (33.6)
Race or ethnic group—no. (%)†		
White	2526 (91.3)	852 (92.9)
Black	51 (1.8)	9 (1.0)
Hispanic	117 (4.2)	35 (3.8)
Other	80 (2.9)	21 (2.3)
Most recent left ventricular ejection fraction—%‡	55.36±10.27	56.00±9.65
Medical history—no./total no. (%)		
Diabetes mellitus	878/2774 (31.7)	295/917 (32.2)
Smoking (current or former)	1641/2733 (60.0)	543/897 (60.5)
Hypercholesterolemia	2268/2740 (82.8)	733/902 (81.3)
Transient ischemic attack	67/2751 (2.4)	20/904 (2.2)
Stroke	77/2758 (2.8)	32/907 (3.5)
Congestive heart failure	225/2763 (8.1)	65/910 (7.1)
Peripheral vascular disease	281/2714 (10.4)	92/884 (10.4)
Previous myocardial infarction	653/2706 (24.1)	180/893 (20.2)
Previous PCI	802/2769 (29.0)	250/917 (27.3)
Previous CABG	130/2763 (4.7)	64/914 (7.0)
Indication for index PCI—no./total no. (%)		
STEMI >72 hr before PCI of infarct-related or non-infarct-related artery	39/2774 (1.4)	5/916 (0.5)
Non-STEMI	527/2774 (19.0)	157/916 (17.1)
Unstable angina	1242/2774 (44.8)	429/916 (46.8)
Stable angina	748/2774 (27.0)	257/916 (28.1)
Silent ischemia	145/2774 (5.2)	42/916 (4.6)
Other	89/2774 (3.2)	28/916 (3.0)

* Plus-minus values are means ±SD. There were no significant differences between the groups with the exception of previous myocardial infarction (P=0.02) and ST-segment elevation myocardial infarction (STEMI) more than 72 hours before PCI of infarct-related or non-infarct-related artery (P=0.04). CABG denotes coronary-artery bypass grafting, and PCI percutaneous coronary intervention.

† Race or ethnic group was self-reported.

‡ Data on the most recent left ventricular ejection fraction were available for 2767 patients in the group assigned to PCI at hospitals without on-site cardiac surgery and 916 in the group assigned to PCI at hospitals with on-site cardiac surgery.

assigned to hospitals without on-site cardiac surgery, as compared with the group assigned to hospitals with on-site cardiac surgery, were consistent with those of the primary results: a relative risk of 1.02 (95% one-sided upper confidence limit, 1.22) at 30 days and a relative risk of 0.98 (95% one-sided upper confidence limit, 1.12) at 12 months.

ANGIOGRAPHIC REVIEW COHORT

A total of 376 patients (289 in the group assigned to hospitals without on-site cardiac surgery and 87 in

the group assigned to hospitals with on-site cardiac surgery) were randomly selected for blinded angiographic review. There were no significant differences between the two groups with respect to the rates of procedural success, the proportion of patients with complete revascularization, or the proportion of lesions classified as meeting the criteria for class I or II recommendations in the PCI guidelines regarding anatomical indications for PCI (Table 4). The as-treated analysis showed similar results (Table S9 in the Supplementary Appendix).

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Table 2. Lesion and Procedural Characteristics.*

Characteristic	PCI at Hospitals without On-Site Cardiac Surgery (N=2774 patients and 4058 lesions)	PCI at Hospitals with On-Site Cardiac Surgery (N=917 patients and 1294 lesions)
No. of vessels treated		
Mean per patient	1.17±0.40	1.17±0.41
Distribution — no. of patients/total no. (%)		
1 vessel	2319/2748 (84.4)	743/881 (84.3)
2 vessels	400/2748 (14.6)	127/881 (14.4)
≥3 vessels	29/2748 (1.1)	11/881 (1.2)
No. of lesions treated		
Mean per patient	1.47±0.77	1.43±0.70
Distribution — no. of patients/total no. (%)		
1 lesion	1814/2748 (66.0)	597/881 (67.8)
2 lesions	676/2748 (24.6)	203/881 (23.0)
≥3 lesions	258/2748 (9.4)	81/881 (9.2)
Location of vessel — no. of patients/total no. (%)		
Left main coronary artery	17/2748 (0.6)	9/881 (1.0)
Left anterior descending artery	1247/2748 (45.4)	408/881 (46.3)
Circumflex artery	905/2748 (32.9)	263/881 (29.9)
Right coronary artery	1037/2748 (37.7)	350/881 (39.7)
Diameter of reference vessel		
No. of lesions evaluated	4013	1248
Mean diameter — mm	2.99±0.56	2.92±0.49
Length of lesion		
No. of lesions evaluated	4010	1243
Mean length — mm	15.12±8.73	14.34±7.95
Lesion stenosis		
Baseline		
No. of lesions evaluated	4022	1255
Mean stenosis — %	85.66±11.03	85.22±10.84
Final		
No. of lesions evaluated	4021	1256
Mean stenosis — %	2.46±12.04	1.51±9.68
TIMI grade 3 — no. of lesions (%)		
Before the procedure	3347/4016 (83.3)	1087/1237 (87.9)
Final	3933/3981 (98.8)	1225/1243 (98.6)
Type of stent — no. of patients (%)		
Bare-metal	878/2690 (32.6)	220/895 (24.6)
Drug-eluting	1714/2690 (63.7)	620/895 (69.3)
Both	60/2690 (2.2)	13/895 (1.5)
Unknown	38/2690 (1.4)	42/895 (4.7)

* Plus-minus values are means ±SD. The data on characteristics of the procedures and lesions were reported by each site. There were no significant differences between the two groups with respect to these characteristics except for the mean diameter of the reference vessels, the percentage of lesions with Thrombolysis in Myocardial Infarction (TIMI) grade 3 before the procedure, the type of stent (all $P<0.001$), and the final percentage of lesion stenosis ($P=0.003$).

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NONEMERGENCY PCI AT HOSPITALS WITH OR WITHOUT CARDIAC SURGERY

Table 1. Major Adverse Cardiac Events at 30 Days and 12 Months.

End Point	PCI at Hospitals without On-Site Cardiac Surgery (N=2774)	PCI at Hospitals with On-Site Cardiac Surgery (N=927)	Relative Risk (95% CI) ^a	P Value ^b
	no./total no. (%)			
Primary and points				
Composite of major adverse cardiac events at 30 days	256/2706 (9.5)	83/886 (9.4)	1.00 (1.22)	<0.001
Components of 30-day end point				
Death	18/2708 (0.7)	3/883 (0.3)	1.96 (0.58–6.64)	0.44
Cardiac cause	14/2700 (0.5)	2/884 (0.2)	2.29 (0.52–10.06)	0.39
Noncardiac cause	4/2690 (0.1)	1/883 (0.1)	1.31 (0.15–11.73)	1.00
Myocardial infarction	176/2692 (6.5)	57/882 (6.5)	1.01 (0.76–1.35)	1.00
Q-wave	6/2688 (0.2)	2/882 (0.2)	0.98 (0.20–4.87)	1.00
Non-Q-wave	170/2691 (6.3)	55/882 (6.2)	1.01 (0.75–1.36)	1.00
Repeat coronary revascularization	73/2689 (2.7)	31/883 (3.5)	0.77 (0.51–1.17)	0.23
Emergency or urgent PCI	7/2774 (0.3)	2/917 (0.2)	1.16 (0.24–5.56)	1.00
Emergency CABG	7/2687 (0.3)	1/882 (0.1)	2.30 (0.28–18.65)	0.69
Stroke	12/2691 (0.4)	1/882 (0.1)	3.99 (0.51–30.21)	0.21
Composite of major adverse cardiac events at 12 mo	423/2439 (17.3)	140/787 (17.8)	0.98 (1.13)	<0.001
Components of 12-mo end point				
Death	56/2424 (2.3)	19/783 (2.4)	0.95 (0.57–1.60)	0.89
Cardiac cause†	26/2372 (1.1)	11/772 (1.4)	0.77 (0.38–1.55)	0.45
Noncardiac cause†	25/2368 (1.1)	8/769 (1.0)	1.01 (0.46–2.24)	1.00
Myocardial infarction	204/2373 (8.6)	60/770 (7.8)	1.10 (0.84–1.45)	0.55
Q-wave	10/2330 (0.4)	3/764 (0.4)	1.08 (0.10–3.93)	1.00
Non-Q-wave	194/2370 (8.2)	57/768 (7.4)	1.10 (0.83–1.46)	0.54
Repeat coronary revascularization	202/2372 (8.5)	76/769 (9.9)	0.86 (0.67–1.11)	0.24
Emergency or urgent PCI	7/2774 (0.3)	2/917 (0.2)	1.16 (0.24–5.56)	1.00
Emergency CABG	7/2330 (0.3)	1/762 (0.1)	2.27 (0.28–18.42)	0.69
Stroke	23/2333 (1.0)	6/764 (0.8)	1.24 (0.51–3.04)	0.63
Secondary and other end points				
Ischemia-driven target-lesion revascularization				
At 30 days	16/2689 (0.6)	12/882 (1.4)	0.98 (0.51–1.88)	1.00
At 12 mo	117/2364 (4.9)	38/766 (5.0)	1.00 (0.70–1.43)	1.00
Ischemia driven target-vessel revascularization				
At 30 days	41/2689 (1.5)	13/882 (1.5)	1.03 (0.56–1.92)	1.00
At 12 mo	133/2366 (5.6)	41/766 (5.4)	1.05 (0.75–1.48)	0.86
Stent thrombosis				
At 30 days	16/2695 (0.6)	7/883 (0.8)	0.75 (0.31–1.81)	0.48
At 12 mo	27/2364 (1.1)	16/771 (2.1)	0.55 (0.30–1.02)	0.07
Major vascular complications at 30 days	41/2687 (1.5)	13/882 (1.5)	1.04 (0.56–1.92)	1.00

^a The relative risks, 95% confidence intervals (CIs), and P values were calculated according to the intention-to-treat principle, with multiple imputation for missing data. The composite end points of major adverse cardiac events at 30 days and 12 months are shown with one-sided 95% CIs and one-sided P values based on the Farrington-Manning test of noninferiority. All other confidence intervals are two-sided and are based on the normal approximation to the binomial distribution.

[†] The additional deaths that were found through linkage to data from the Massachusetts Data Analysis Center are not included in the numbers of deaths from cardiac causes and the numbers of deaths from noncardiac causes.

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Table 4. Adjudicated Procedural Characteristics in the Angiographic Review Cohort.*

Characteristic	PCI at Hospitals without On-Site Cardiac Surgery (N=289 patients and 392 lesions)	PCI at Hospitals with On-Site Cardiac Surgery (N=87 patients and 106 lesions)	Relative Risk (95% CI)	P Value
Successful treatment of lesion — no. of lesions (%)†	366/383 (95.6)	102/105 (97.1)	0.98 (0.95–1.02)	0.59
Procedural success — no. of patients (%)‡	235/289 (81.3)	65/87 (74.7)	1.09 (0.95–1.24)	0.22
Complete revascularization — no. of patients (%)§	174/289 (60.2)	52/87 (59.8)	1.01 (0.83–1.23)	1.00
Met indication criteria for PCI — no. of lesions (%)¶	369/392 (94.1)	97/106 (91.5)	1.03 (0.97–1.10)	0.37

* A random sample of 350 patients was selected for adjudication of procedure characteristics by a clinical events committee, whose members were unaware of the group assignments.

† Successful treatment of the lesion was defined as residual stenosis of the target lesion of less than 20%.

‡ Procedural success was defined as residual stenosis of the target lesion of less than 20% and no occurrence of in-hospital major adverse cardiac events.

§ Complete revascularization was defined as the successful treatment, according to the criteria of procedural success, of all epicardial vessels with more than 70% and less than 100% stenosis.

¶ Included here are the number of treated lesions that met the class I or II recommendations for anatomical indications for PCI, according to the PCI guidelines of the American College of Cardiology Foundation–American Heart Association–Society for Cardiovascular Angiography and Interventions.

DISCUSSION

We compared the safety and effectiveness of non-emergency PCI performed at hospitals in Massachusetts without on-site cardiac surgery with those of non-emergency PCI performed at hospitals with on-site cardiac surgery. Hospitals without on-site cardiac surgery were required to have performed a minimum of 300 diagnostic cardiac catheterization procedures per year and to have an ongoing program to support primary PCI. All the operators were required to be board-certified in interventional cardiology and to have performed a minimum of 75 PCI procedures annually. In both the intention-to-treat analysis and the as-treated analysis, we found no significant differences in the coprimary end points of the 30-day and 12-month rates of major adverse cardiac events — a composite of death from any cause, myocardial infarction, repeat revascularization, or stroke — between hospitals without on-site cardiac surgery and those with on-site cardiac surgery.

These data now add to the growing body of evidence from single-center experience,²⁰ registry data,^{8,21} and the randomized CPORT-B trial,²² all of which showed favorable outcomes among patients undergoing elective or non-emergency PCI at hospitals without on-site cardiac surgery. MASS COMM adds to and extends the results of the CPORT-B trial. The blinded angiographic review

of a random subgroup of patients allowed for a comparison of clinical practice patterns between the groups. We observed that the practices of lesion selection (according to indications in PCI guidelines), the completeness of revascularization, and procedural success were generally similar, independently of the treatment assignment. Although the rate of use of drug-eluting stents was slightly higher in hospitals with on-site cardiac surgery, this did not translate into differences in the rates of repeat revascularization at 1 year.

We did, however, observe that there was heterogeneity among hospitals within treatment groups with respect to the coprimary end points. Although accounting for between-hospital variation in the primary comparison did not change the overall findings of the study, it does have important implications with respect to monitoring of the performance of individual sites as new PCI programs are initiated.

Expansion of non-emergency PCI to hospitals without on-site surgery may be met with enthusiasm for several reasons. With a larger number of hospitals that can perform the procedure, patients have a wider choice of hospitals and a greater opportunity to remain in their own community. In addition, the added volume of PCI procedures at hospitals without on-site cardiac surgery could help support active primary PCI programs.

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However, additional issues will need thoughtful consideration. The potential consequence of not having a cardiac surgical team on-site to evaluate the patient and discuss the safest and most effective revascularization strategy when an urgent decision is needed is unclear. Without such a team on-site, the "Heart Team" approach for patients with complex multivessel disease, an approach recommended in the PCI guidelines,¹² is not possible. Moreover, registries generally include only patients who have undergone PCI, and data from patients with coronary artery disease who are not selected for revascularization are limited. Several studies have shown that in patients with STEMI and in those with non-STEMI who do not undergo PCI, treatment according to class I guideline recommendations is provided less often at sites without on-site cardiac surgery than at sites with on-site cardiac surgery.^{8,11,13} Finally, it is unclear where and by whom interventional cardiology trainees will obtain experience as PCI procedures move from centers with approved training programs to community hospitals.

There are several limitations related to the design and conduct of MASS COMM. Although data were available from more than 97% of the patients at 30 days, data from the 12-month follow-up visit were not available for 13% of the patients. To mitigate the effect of missing data, we performed multiple imputation for the coprimary end-point analysis and ascertained vital status by linking records to state vital statistics data.²³ Furthermore, although the study inclusion

criteria were broad, patients with certain clinical and anatomical characteristics were excluded,¹⁴ and thus, the findings in this study should not be generalized to these subgroups. Finally, the study was powered to detect noninferiority with respect to the two coprimary composite end points but was not powered to detect noninferiority with respect to the individual components of the primary end point, such as death or stroke.

In conclusion, nonemergency PCI performed at hospitals in Massachusetts without on-site cardiac surgery was noninferior to PCI performed at hospitals with on-site cardiac surgery with respect to the rate of major adverse cardiac events at 30 days (safety analysis) or at 12 months (effectiveness analysis). These data suggest that performance of PCI in hospitals without on-site cardiac surgery that have established programs for PCI and the requisite experience in performing the procedure, at both the hospital level and the level of individual operators, may be considered an acceptable option for patients presenting to such hospitals for care.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

We thank Richard Kuntz, M.D., for the initial trial design proposal; Donald Balm, M.D., for input in the trial design and assistance with convening trial investigators; Paul Dreyer, M.D., for support and oversight of the trial; Ann Lovett for facilitating the linkage to Massachusetts Data Analysis Center data; Katherine Aguirre for overall project management and assistance with earlier versions of tables and figures; and the trial participants and research staff at all sites for their commitment and dedication to this study.

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One Hurley Plaza
Flint, Michigan 48503

October 21, 2013

James B. Falahee, Jr, J.D.
Chair, Michigan Certificate of Need Commission
Michigan Department of Community Health
Capitol View Building
201 Townsend Street
Lansing, Michigan 48913

Dear Mr. Falahee:

We are writing on behalf of Hurley Medical Center to request the CON Commission consider revisions to the Review Standards for Cardiac Catheterization Services to allow institutions that do not have open heart programs to provide elective coronary angioplasty services.

Hurley Medical Center is a 443-bed public non-profit teaching medical center serving the Genesee, Lapeer, and Shiawassee counties. We are very conscious of our role as a safety-net hospital for our community and strive to meet the needs of this vulnerable community. Hurley is a provider of last resort, delivering a sizable amount of health care to the uninsured, underinsured, and other underserved groups. We have been responsible for providing over 66% of the region's uncompensated healthcare. The population we serve is socio-economically disadvantaged and vulnerable to health disparities produced as a result of poor access to regular medical check-ups, chronic disease management and the lack of a medical home.

Currently, Hurley provides Percutaneous Coronary Intervention (PCI) on an emergent basis without having Open Heart Surgery on-site. We provide high quality care and have a track record of achieving excellent outcomes in these critically ill patients. We believe that there needs to be a change in the rules to allow hospitals like Hurley to perform elective interventions.

Clinical practice has changed significantly from when PCI was first introduced and was performed only at hospitals with cardiac surgery on-site. Technology advances with improved catheters, wires, and stents along with the growing expertise of cardiologists to manage complications has resulted in significant decline in the occurrence of complications and emergency surgery. More than 500 centers in 39 U.S. states currently allow elective PCI without Surgery on Site with varying requirements.



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Flint, Michigan 48503

Since June, 2011 when the CON Commission last visited this proposed change there have been further evidence supporting the performance of elective coronary angioplasties in hospitals without on-site Open Heart Surgery. Well-conducted research has verified the safety and efficacy of performing PCI at hospitals without cardiac surgery.

1. The 2011 **ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention** states that “Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (Level of Evidence: B)” placing it in CLASS IIb category. This is a strong recommendation from the American College of Cardiology (ACC), which represents the best judgment of the profession.
2. The 2012 multi-site clinical trial **Cardiovascular Patient Outcomes Research Team Elective (C-PORT E) Angioplasty Study** conducted at 60 hospitals without on-site cardiac surgery located in 10 U.S. states (Maryland, New Jersey, Pennsylvania, Ohio, Georgia, Texas, North Carolina, Illinois, Oregon, and Alabama) found elective PCI could be performed safely and effectively at hospitals without on-site cardiac surgery. The study showed that outcomes at hospitals without on-site cardiac surgery were non-inferior to those at hospitals with cardiac surgery on site, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months.
3. **MASS COMM** prospective trial that the Massachusetts Department of Health solicited was a special initiative among the state’s community hospitals to test the ability to offer PCI without on-site cardiac surgery. Patients were followed out to one year to identify 30-day and one-year risk of major adverse cardiac events (MACE), including death, MI, repeat revascularization, and stroke. Results were similar to the C-PORT E trial, demonstrating non-inferiority of elective PCI at centers without surgical backup compared to those with on-site surgery.

The current restriction impacts patients' access to care and a reversal of this regulation will particularly benefit underinsured and poor patients who are often the least likely to undergo PCI due to barriers accessing specialized cardiac services such as geography, distance, culture, race, language, poverty and lack of education.

The coupling of diagnostic catheterization and coronary intervention means that if a lesion is identified during the diagnostic catheterization, our patients have to be moved to another facility for the therapeutic procedure to be done. Our inability to provide elective intervention forces our patients to be transferred away from their medical home - which is the complete opposite approach of the current health care and payment reform efforts. Clinical care is also compromised due to:



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- Exposure to higher doses of blood thinners and radiation
- Multiple invasive punctures which can lead to complications and an increased risk of infection
- Duplicate testing
- Increase in the overall length of stay

We believe that hospitals like Hurley Medical Center be allowed to perform elective coronary angioplasty guided by criteria set by the Society for Cardiovascular Angiography and Interventions (SCAI) and closely monitor clinical outcomes and quality. Our ability to continue to provide advanced cardiac services and fulfill our commitment to our at-risk community is contingent on our ability to add services like elective PCI that have a positive contribution margin.

We strongly advocate that the Commission revisit the current standards and modify them to allow Hurley to provide the most current, clinically sound and cost effective cardiac care to our patient population.

Thank you for the opportunity to comment.

A handwritten signature in cursive script, appearing to read "Sunita", written in black ink above a horizontal line.

Sunita Vadakath MD, FRCA, MPA
Service Line Administrator
Cardiology and Internal Medicine

A handwritten signature in cursive script, appearing to read "F. Michael Jaggi", written in black ink above a horizontal line.

F. Michael Jaggi DO, FACP, FACEP
Vice President and
Chief Medical Officer



October 23, 2013

Corporate Planning

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James B. Falahee, Jr, J.D.
CoN Commission Chairperson
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Dear Commissioner Falahee:

Henry Ford Health System (HFHS) would like to offer comments on the proposed Certificate of Need (CoN) review Standards for Cardiac Catheterization.

HFHS strongly supports continued regulation of Cardiac Catheterization however we are advocating for either a Workgroup or a Standard Advisory Committee (SAC) to be formed to review Section 3 in the current Standards as it relates to performing elective PCI without on-site open heart surgery.

In 2011, the last Cardiac Cath. SAC presented a recommendation to the Commission that would allow for elective PCI without on-site surgery. This recommendation was ultimately removed from the final standards primarily due to some Commissioners' concerns regarding the ACC guidelines. Since that time new research has been published and ACC and AHA have updated their guidelines further supporting elective PCI without on-site surgery.

- November 7, 2011 the American College of Cardiology and American Heart Association published updated guidelines which recognize the appropriateness of offering these services in facilities without open heart surgery on-site.
- Four major studies on the safety and efficacy of performing elective PCI without on-site open heart surgery have been released, all showing this procedure to be safe and effective, with no difference in quality or outcome than with programs located in facilities with open heart surgery on-site.

Just as the Open Heart Surgery Standards were updated to add quality measures, HFHS suggests that the Cardiac Catheterization Standards could be updated to include specific outcomes, complications, process, and appropriateness of utilization measures. All of these quality measures are currently used by BMC² to work with existing programs to continuously improve quality and outcomes and to ensure appropriate utilization through review of all elective PCIs.

We look forward to working with the Commission and the Department to discuss these issues further.

Respectfully,

A handwritten signature in blue ink that reads "Karen E. Kippen".

Karen E. Kippen
Director, Planning & CON Strategy



Eric D. Fischer
Director, Strategic Planning

October 24, 2013

Mr. James B. Falahee, Jr, J.D.
Certificate of Need Commission Chairperson
Capital View Building
201 Townsend Street
Lansing, Michigan 48913

The Detroit Medical Center
Old Hutzel Hospital
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Dear Chairman Falahee;

The Detroit Medical Center (DMC) appreciates the opportunity to provide testimony regarding the proposed Certificate of Need Cardiac Catheterization Review Standards.

The Detroit Medical Center supports the prior Cardiac Catheterization Standard Advisory Committee's and the CON Commission recommendations with the exception of the CON Commission not allowing for elective PCI without on-site open heart surgery based on their concerns regarding the ACC guidelines.

The Detroit Medical Center strongly supports allowing elective PCI without on-site open heart surgery based on new research and newly published guidelines by the ACC.

- Since the last Standard Advisory Committee Meeting, the American College of Cardiology and American Heart Association published updated guidelines which changed the classification of elective PCI without on-site open heart surgery which further supports the usage of offering elective PCI in hospitals without open heart surgery on-site.

- There have been four major studies on the safety and efficiency of performing elective PCI without on-site open heart surgery that have been released with all of these studies showing this procedure to be effective and safe with no difference in quality or outcome than with programs located in hospitals with open heart surgery on-site.

- The Department has clarified to the CON Commission from their earlier position that they do have the ability to enforce the quality and volume provisions in the Cardiac Catheterization Standards that were included in the SAC's recommendation to allow elective PCI without on-site cardiac surgery. Furthermore, the ACC/NCDR currently collects data on every single PCI performed in the State of Michigan. As an insurance of safety and quality the ACC/NCDR tracks outcomes, complications, process measures and appropriate utilization. BMC/2 reviews all elective PCI data and uses this data to work with existing programs to continuously improve quality and outcomes.

Recently the open heart standards were updated to add true quality measures. Similar measures as stated above should be added to the cardiac catheterization standards.

Thank you for the opportunity to provide these comments.

Sincerely,

A handwritten signature in blue ink that reads "Eric D. Fischer".

Eric D. Fischer
Director, Strategic Planning

www.dmc.org

Children's Hospital of Michigan • Detroit Receiving Hospital • Harper University Hospital • Huron Valley-Sinai Hospital • Hutzel Women's Hospital • Karmanos Cancer Institute • Kresge Eye Institute • Michigan Orthopaedic Specialty Hospital • Rehabilitation Institute of Michigan • Sinai-Grace Hospital • University Laboratories

From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: October 9, 2013 Public Hearing Written Testimony (ContentID - 147062)
Date: Wednesday, October 23, 2013 3:37:29 PM
Attachments: [PCIStudies10-23-13.doc](#)

1. Name: Patrick O'Donovan
2. Organization: Beaumont Health System
3. Phone: 248 551 6406
4. Email: podonovan@beaumont.edu
5. Standards: CC
6. Testimony: On behalf of Beaumont Health System, I would like to offer the following comments pertaining to the Cardiac Catheterization Certificate of Need Review Standards, which are up for review in 2014:

The 2010-2011 SAC did an admirable job reviewing and making recommendations regarding the Cardiac Cath Standards. All of the recommendations made by the SAC were adopted by the Commission, except for the recommendation to allow elective PCI without on-site cardiac surgery. It appears there were two major reasons the Commission did not adopt this SAC recommendations:

- Even though it was widely known that the American College of Cardiology (ACC) was going to change their classification for elective PCI without on-site surgery, the ACC had not yet done so at the time the Commission took proposed action on the Cardiac Cath standards in September 2011.

- o Comments: In November 2011, the ACC published updated guidelines which changed the classification of elective PCI without on-site open heart surgery to a Class IIb procedure (instead of contraindicated, it is now considered an acceptable and reasonable approach). Since then, there have been at least four major studies showing that this practice is safe and effective, and that there is no difference in outcomes between those PCI programs with and without on-site cardiac surgery. One of these studies (MASS COM) was done to provide Massachusetts state public health officials with evidence to support a change in PCI state regulations. Please see attached document which chronicles the history of published clinical studies and ACC guidelines for elective PCI.

- The Department initially expressed reservations about their ability to enforce the quality/volume provisions that were included in the SAC's recommendation to allow elective PCI without on-site cardiac surgery. The Department later clarified that they would be able to enforce the provisions; however the Commission chose not to re-visit their decision not to accept the SAC recommendation.

- o Comments: There is an opportunity to improve C.O.N.'s ability to monitor quality and utilization. The ACC/NCDR collects data on every single PCI performed in the State of Michigan and tracks outcomes, complications, process measures, and appropriateness of utilization. BMC2 uses this data to work with existing programs to continuously improve quality and outcomes and to ensure appropriate utilization. Because of this quality rigor that is in place regardless of C.O.N., allowing PCI w/o on-site surgical back-up will not result in excess utilization.

Finally, it is contrary to quality patient care to transfer a patient in need of PCI to another institution, if the referring institution already has the capability to treat the patient safely, effectively and efficiently.

As the Commission knows a SAC is made up of experts and it is very rare for the Commission to reject a SAC recommendation without compelling evidence to support that decision. In this case the concerns of the Commission should now be addressed, and we urge the Commission to adopt the SAC recommendation to allow elective PCI without on-site cardiac surgery.

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Elective PCI

Timeline of Published Clinical Studies

October 23, 2013

Apr. 2000: ***CPORT (AHA meeting) (1)*** ***(JAMA 4/02)***

- *Primary PCI with no SoS better than thrombolytics*

Oct. 2004: ***MEDPAR database (2)*** ***(JAMA 10/04)***

- *Primary PCI with no SoS equivalent*
- *Elective PCI with no SoS worse*

2005: ***ACC/AHA guideline (3)*** ***(JACC 2005)***

- *Primary PCI no SoS Class IIb*
- *Elective PCI no SoS Class III (contraindicated)*

Apr. 2008: ***NCDR (ACC meeting) (4)*** ***(JAMA 2009)***

- *Registry >300,000, no difference primary/elective*

November 2010 – May 2011 ***Cardiac Cath SAC***

June – September 2011 ***CON Commission Deliberation and Decision***

Nov. 7 2011: ***ACC/AHA Guideline (5)*** ***(JACC 2011)***

- *Primary PCI no SoS Class IIa*
- *Elective PCI no SoS Class IIb*
- *See table 1 for ACC Class descriptions*

Guideline modification does not reflect the following data

Nov. 11 2011: *CPORT E (AHA meeting) (6)* *(NEJM 5/12)*

- *randomized trial, 18,000pts elective PCI*
- *No difference at 6weeks*

Dec 14 2011: *Metaanalysis (7)* *(JAMA '11)*

- *100,000 STEMI*
- *900,000 elective/urgent*
- *No difference*

March 2012: *CPORT E (ACC meeting) (8)* *(NEJM 5/12)*

- *9 month follow up, no difference*

March 2013: *MASSCOM (ACC meeting) (9)* *(NEJM 3/13)*

- *2700pts elective PCI*
- *No difference 30d/12mo*

Summary and Conclusions

1. History leading to Primary PCI with no SoS

- *Rate of emergent CABG had become rare (<1%)*
- *Transferring patients who “walk in” to a PCI center wastes valuable time*
- *This was shown to be safe (1, 2), and in the 2005 Guidelines (3) was made a Class IIb.*
- *Elective PCI with no SoS was not well studied, and thus was given a Class III*

2. The SAC in 2011 recommended allowing elective PCI based on a large study published in JAMA (4) showing efficacy and safety in the National CV Data Registry

- *At the time of the CON decision, however, this was still a Class III in the guidelines (“not recommended”) simply due to the fact that the updated guideline reflecting the new literature was yet to be published.*
- *Shortly after the CON decision, the updated ACC/AHA guideline (5) upgraded Primary PCI to a Class IIa, Elective to IIb. This only reflects the NCDR publication, which again, was published in 2009 and available during SAC meeting*

3. Subsequent to the guideline update in 2011, 3 major papers have been published, ALL supporting elective PCI with no SoS

- *C PORT E is a randomized study with 6wk/9mo followup (6, 8)*
- *MASSCOM (9) is also a randomized study showing safety/efficacy*
- *Metaanalysis (7) of 1 million patients examining PCI with no SoS (both elective and emergent) showed safety/efficacy*

4. Conclusion

- *We now have 5 major publications supporting elective PCI with no SoS*
- *Only reason it is currently a IIb (weaker recommendation) is that updated guideline in 2011 was based mainly on ONE study which was available to the writers at that time*
- *Based on the abundance of studies published since then, and how guidelines assign classification of recommendations (see table below), we could argue that elective PCI with no SoS should be a Class I (A) treatment, which is the highest recommendation possible (based on multiple randomized trials and metanalysis supporting it)*
- *In other words, the current 2011 Guidelines are already outdated*
- *A change in elective PCI CON standard is warranted (consistent with the 2011 SAC recommendation)*

Table 1. Applying Classification of Recommendations and Level of Evidence

		SIZE OF TREATMENT EFFECT			
		CLASS I <i>Benefit >>> Risk</i> Procedure/Treatment SHOULD be performed/ administered	CLASS IIa <i>Benefit >> Risk</i> <i>Additional studies with focused objectives needed</i> IT IS REASONABLE to perform procedure/administer treatment	CLASS IIb <i>Benefit ≥ Risk</i> <i>Additional studies with broad objectives needed; additional registry data would be helpful</i> Procedure/Treatment MAY BE CONSIDERED	CLASS III <i>Risk ≥ Benefit</i> Procedure/Treatment should NOT be performed/administered SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL
ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> ■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> ■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
	LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> ■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> ■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
	LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> ■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> ■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations†		should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	is not recommended is not indicated should not is not useful/effective/beneficial may be harmful

From: DoNotReply@michigan.gov
To: [MDCH-ConWebTeam](#)
Subject: October 9, 2013 Public Hearing Written Testimony (ContentID - 147062)
Date: Thursday, October 24, 2013 2:16:34 PM

1. Name: Sean Gehle
2. Organization: Ascension Health - Michigan
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: CC
6. Testimony: Ascension Health - Michigan supports continued regulation of Cardiac Catheterization services and recommends no changes to the standard.
7. Testimony: