MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
CARDIAC CATHETERIZATION
STANDARD ADVISORY COMMITTEE (CCSAC) MEETING

Thursday, September 14, 2017

South Grand Building
333 S. Grand Ave,
1st Floor, Grand Conference Room
Lansing, MI 48933

APPROVED MINUTES

I. Call to Order

Chairperson David called the meeting to order at 9:30 A.M.

A. Members Present:

Ernest Balcueva – American Heart Association
Lynne F. Carter, MD – Blue Cross Blue Shield of Michigan
Shukri David, MD, Chairperson – Ascension | Michigan
Michele L. Davis – Electrical Workers' Joint Board of Trustees
Simon Dixon, MD – Beaumont Hospital
Hitinder S. Gurm, MD – University of Michigan
Henry E. Kim, MD – Henry Ford Health System
Ryan D. Madder, MD – Spectrum Health
Theodore L. Schreiber, MD – Detroit Medical Center
Kristopher J. Selke, DO – Mercy Health and St. Joseph Mercy Health System
Ibrahim Shah, MD – McLaren Greater Lansing
Sunita Vadakath, MD – MidMichigan Health

B. Members Absent:

None.

C. Michigan Department of Health and Human Services Staff present:

Tulika Bhattacharya
Amber Myers
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Declaration of Conflicts of Interests

No conflicts were declared.

III. Review of Agenda

Motion by Dr. Schreiber, seconded by Dr. Gurm to approve the agenda with the following additions: 1. Individual operator procedural volumes and compliance and 2. Charge 7. Motion Carried.

IV. Review and Approval of August 14, 2017 Minutes

Motion by Dr. Schreiber, seconded by Dr. Gurm to approve the minutes as presented. Motion Carried.

V. Report on Section 10(5)(i): The applicant hospital initiating elective PCI without on-site OHS services shall have Accreditation for Cardiovascular Excellence (ACE) accreditation or an equivalent body perform an on-site review within 3, 6, and 12 months after implementation. The applicant hospital shall submit the summary reports of the on-site review to the Department.

Ms. Bhattacharya provided an overview. (See Attachment A)

Discussion followed.

Motion by Dr. Selke, seconded by Dr. Schreiber to modify Section 10(5)(i) by inserting "initial" before "Accreditation" in the current language and BMC2 data should be reported to the state.

Motion failed in a roll call vote of 5- Yes, 6- No, and 1- Abstained.

Schreiber – Yes
Gurm – Yes
Selke – Yes
Dixon – Yes
Shah – Yes
David – No
Davis – No
Madder – No
Carter – No
Kim – No
Vadakath – No
Balcueva – Abstention

VI. Discussion of Charge #2: Determine if pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ambulatory surgical centers (ASCs) or only in licensed hospitals – 15-min. Power Point Presentation

Dr. Dipak Shah, Medical Director, Center for Atrial Fibrillation, Providence-Providence Hospital, provided an overview. (See Attachment B)

Discussion followed.

Dr. Dipak Shah will get additional information for the next meeting.

VII. Discussion of Charge #5: Review section 11 to determine if it is appropriate to incorporate additional interventional procedures that are performed in a cardiac catheterization laboratory but are not currently identified or weighted in section 11

Dr. Dixon provided an update. (See Attachment C)

Discussion followed.

Dr. Dixon will bring additional information for next meeting with a recommendation.

VIII. Discussion of Charge #6: Discussion of Charge #6: Consider revisions to clarify section 4(13)(a) and (b)

Dr. Selke provided an overview. (See Attachment D)

Discussion followed.

Motion by Dr. Selke, seconded by Dr. Gurm to add the requirement that a minimum of 36 primary PCI have been performed for the most recent 12 months prior to the date of application. Motion Carried in a vote of 12- Yes, 0- No, and 0- Abstained.

IX. Next Steps

Drs. David and Dipak Shah will report back on Charge #2 *"Determine if pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ambulatory surgical centers (ASCs) or only in licensed hospitals."*

Dr. Dixon will provide further information and recommendations on Charge #5 "*Review section 11 to determine if it is appropriate to incorporate additional interventional procedures that are performed in a cardiac*

catheterization laboratory but are not currently identified or weighted in section 11."

Dr. Shah will report on Charge #7 *"Consider requirements for replacing a cardiac catheterization service from one existing licensed hospital to another existing licensed hospital."*

Dr. Madder asked that a discussion on compliance be added to the next meeting agenda in regard to physicians having to demonstrate 100 diagnostic procedures.

X. Future Meeting Dates

October 19, 2017; November 9, 2017; & December 20, 2017.

XI. Public Comment

1. Arlene Elliott, Arbor Advisors
2. Dennis McCafferty, EAM

XII. Adjournment

Meeting adjourned at 12:21 P.M.

Cardiac Cath Standard Advisory Committee

Overview of Accreditation Requirements

Tulika Bhattacharya
Department of Health & Human Services

September 14, 2017

Cardiac Cath Services

- "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. Procedures include PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantations, transcatheter valve, other structural heart disease procedures, percutaneous transluminal coronary angioplasty (PTCA) and coronary stent implantation and left sided arrhythmia therapeutic procedures. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention.

- "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological problems in the heart. Procedures include the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). A hospital that provides diagnostic cardiac catheterization services may also perform implantations of cardiac permanent pacemakers and ICD devices.

Cardiac Cath Services

- "Primary percutaneous coronary intervention (PCI)" means a PCI performed on an acute myocardial infarction (AMI) patient with confirmed ST elevation or new left bundle branch block.
- "Primary PCI service without on-site OHS" means performing primary PCI on an emergent basis in a hospital having a diagnostic cardiac catheterization service.
- "Elective PCI services without on-site open heart surgery (OHS)" means performing PCI, percutaneous transluminal coronary angioplasty (PTCA), and coronary stent implantation on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup and published in circulation 2014, 129:2610-2626 and its update or further guideline changes.

Open Heart Surgery Service

- "Open heart surgery" means any cardiac surgical procedure involving the heart and/or thoracic great vessels (excluding organ transplantation) that is intended to correct congenital and acquired cardiac and coronary artery disease and/or great vessels and often uses a heart-lung pump (pumps and oxygenates the blood) or its equivalent to perform the functions of circulation during surgery. These procedures may be performed off-pump (beating heart), although a heart-lung pump is still available during the procedure.

- Open heart surgical case" means a single visit to an operating room during which one or more OHS procedures are performed.

** An applicant proposing to initiate either adult or pediatric OHS as a new service shall be a hospital and operating or approved to operate a diagnostic and therapeutic adult or pediatric cardiac catheterization service, respectively.

CC, OHS, Primary & Elective PCI

- 60 hospitals provide cardiac cath (CC) services
- 33 hospitals provide adult OHS & therapeutic CC service (of which 2 provides pediatric OHS/therapeutic CC also)
- 1 hospital provide pediatric OHS & therapeutic CC service
- 1 hospital provides Primary PCI w/o on-site OHS backup
- 14 hospitals provide Elective PCI w/o on-site OHS backup
- 11 hospitals provide diagnostic only CC service

Initiation of Elective PCI Service

- Section 4(11) states
  - *Cath lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI Services Without On-Site OHS including the SCAI/ACC/AHA Expert Consensus Document. The applicant hospital shall be liable for the cost of demonstrating compliance with these criteria in their application.*

✓ During application review phase, the applicant submits proof of meeting this requirement (accreditation by ACE or Corazon, or initiation of accreditation process).

✓ Before implementing elective PCI service (1st EPCI procedure), the applicant needs to be fully accredited and provide proof to the Department.

Project Delivery Requirements

- Section 10(5) states
  - *Compliance with the following primary and elective PCI requirements for hospitals providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service…*
- Section 10(5)(f) states
  - *Catheterization lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI including the SCAI/ACC/AHA Expert Consensus Document. The applicant hospital shall be liable for the cost of demonstrating compliance with these criteria.*

✓ This requirement applies to all therapeutic hospitals (with OHS) and hospitals with elective and primary PCI service w/o OHS. The elective and primary PCI hospitals demonstrate compliance through full accreditation by ACE or Corazon.

✓ The therapeutic hospitals (with OHS) can demonstrate compliance thru independent auditors' reports OR accreditation.

Project Delivery Requirements

- Section 10(5)(i) states
  - *The applicant hospital initiating elective PCI without on-site OHS services shall have Accreditation for Cardiovascular Excellence (ACE) accreditation or an equivalent body perform an on-site review within 3, 6, and 12 months after implementation. The applicant hospital shall submit the summary reports of the on-site review to the Department.*

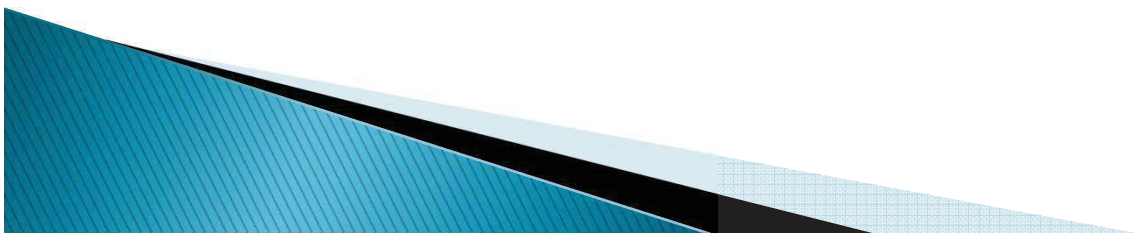
✓ This requirement applies to elective PCI hospitals w/o OHS only. The applicants submit reports of 3, 6, and 12-month on-site reviews by ACE or Corazon to the Department.

✓ After the first 12-month period, on-site reviews are not required.

✓ The elective PCI hospitals need to maintain accreditation (ACE or Corazon re-accreditation process) in order to continually demonstrate compliance with Sections 4(11) and 10(5)(f).

Questions & Comments

Tulika Bhattacharya, Manager
CON Evaluation Section
Email: bhattacharyat@michigan.gov
Phone: 517-241-3341



Attachment A

STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

RICK SNYDER
GOVERNOR

NICK LYON
DIRECTOR

May 10, 2016

Mr. T. Anthony Denton
University of Michigan Health System
300 North Ingalls, NIB04, SPC 5474
Ann Arbor, MI 48109

Re: Certificate of Need for
University of Michigan Health System
CON Application No. 16-0077
Facility No. 81-0060
Ann Arbor (Washtenaw County)

Dear Mr. Denton:

This is to inform you that the proposed project to replace one (1) of nine (9) Adult Cardiac Catheterization Laboratories (CCLs) has been reviewed and is approved with the following *conditions*.

PROPOSED PROJECT DESCRIPTION

Certificate of Need (CON) Application No. 16-0077 is proposed by The Regents of the University of Michigan, a Michigan Constitutional Corporation, located at 300 North Ingalls, Room 4A04, Box 0474, Ann Arbor, MI 48109. The authorized agent for this application is T. Anthony Denton, University of Michigan Health System, located at 300 North Ingalls, NIB04, SPC 5474, Ann Arbor, MI 48109.

The applicant, The Regents of the University of Michigan, proposes to initiate, replace, or expand a covered clinical service. Specifically, the applicant proposes to replace one (1) of nine (9) Adult CCLs, referred to by the applicant as an Electrophysiology Lab, at University of Michigan Health System, located at 1500 East Medical Center Drive, SPC 5474, Ann Arbor, MI 48109 (Washtenaw County).

The CCL to be replaced is located in the Frankel Cardiovascular Center of the hospital, Room 2A-171. The fully depreciated Siemens Axiom Artis DFC.EP being replaced was approved under CON No. 06-0266 that became operational on June 11, 2007. The proposed replacement equipment is a Siemens Artis Q.zen Biplane System. The existing equipment will be decommissioned and removed from the facility. Also, renovation of 880 square feet of existing space is required to accommodate the project.

PROPOSED PROJECT DESCRIPTION - continued

Upon completion of the proposed project, the applicant will continue to operate nine (9) general Adult CCLs and three (3) dedicated Pediatric CCLs at the hospital. At no time will the applicant operate more than this complement of CCLs at the hospital without prior CON approval.

CONDITIONS

1. The applicant shall participate in the Blue Cross Blue Shield of Michigan Cardiovascular Consortium Angioplasty Continuous Quality Improvement Project, the Department's designee for the data registry, as specified in Section 10(5) of the CON Review Standards for Cardiac Catheterization Services, effective September 14, 2015, and shall continue to participate annually thereafter for the life of that service.

2. The applicant shall provide the Department with proof of registration in the data registry prior to the implementation of this CON (i.e., performance of the first procedure).

3. The applicant shall provide to the Department within six (6) months of implementation of this CON (i.e., performance of the first procedure) documentation that the applicant complies with Section 10(5)(f) of the CON Review Standards for Cardiac Catheterization Services, effective September 14, 2015. Specifically, the applicant's Catheterization lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI including the SCAI/ACC/AHA Expert Consensus Document. Credible documentation includes:

   a. Accreditation by Accreditation for Cardiovascular Excellence (ACE) or Corazon, Inc.; or

   b. A signed and certified itemized report from a hospital-selected independent professional consultant attesting to the hospital's compliance with Section 10(5)(f).

PROPOSED PROJECT COSTS

Renovation & Remodeling – Clinical	$	626,000
Architect/Engineering Fees		77,978
Contingencies		353,882
Feasibility Study/Surveys		75,620
Covered Clinical Equipment		1,975,000
Movable Equipment (Medical & Non-Medical)		1,027,500
Fees (Consulting, Legal, Banking, etc.)		22,480
Other (Planning & Design)		41,600
Total Project Costs	$	4,200,000

PROPOSED SOURCE OF FUNDS

Unrestricted Cash	$ 4,200,000
Total Source of Funds	$ 4,200,000

COMMENTS

The Michigan Department of Health and Human Services has reviewed and determined that the project is in conformance with Public Act 368 of 1978, as amended, and applicable review standards. The basis for this decision is detailed under justification of approval.

JUSTIFICATION OF APPROVAL

1. The project is in compliance, as applicable, with Section 22225(1) and (2) of Public Act 368 of 1978, as amended.

2. The project meets the provisions and requirements for nonsubstantive review under Section 22233.

3. This application is in compliance with the CON Review Standards for Cardiac Catheterization Services, effective 09/14/2015.

4. The reasons and authority for these findings are set forth in the program and financial reports.

NOTIFICATION TO APPLICANT

In accordance with Rule 325.9403(1), the CON issued will be valid for a period of one (1) year from the effective date of this letter. If the project is not complete within the year, an enforceable contract or force account must be in place. An extension to execute the enforceable contract or force account may be granted by the Department for just cause in accordance with Rule 325.9403(2).

As applicable, Rule 325.9103(b) requires that an enforceable contract for any covered clinical equipment specify that the installation date will be within 24 months after the effective date of the CON. Rule 325.9417 requires that the period of time allowed to begin any construction (i.e., pouring of footings) be within 24 months from the effective date of approval. The CON is valid only as long as there is compliance with the provisions of Rule 325.9401, and is not transferable.

A CON is valid for the term of the lease as stated in this approval letter, if applicable, for a health facility or covered clinical equipment.

An applicant is required to file another CON to renew a lease for a health facility if the total renewal lease cost exceeds the covered capital expenditure threshold or as otherwise stated in the applicable CON review standards.

For covered clinical equipment, an applicant is required to file another CON to renew a lease as required in the applicable CON review standards. In the case of an equipment lease in which the applicant purchases the equipment at the end of the lease, the CON is valid until the equipment is replaced.

If the total project costs exceed the approved amount in this CON by 15 percent of the first $1 million and 10 percent of the excess over $1 million, the applicant is required to seek an amendment to the approved CON in accordance with Rule 325.9415. Additionally, if the scope of the project or method and terms of financing of the project changes, an amendment or new review will be required in accordance with Rule 325.9413.

As part of this CON approval, and in accordance with applicable CON review standards, the applicant is required to obtain and maintain statistical data in order to complete and submit a MDHHS Annual Survey. The annual survey is available online at www.michigan.gov/con.

In addition to the rules stated in this letter, the applicant must conform and comply with all CON Administrative Rules. This CON is not to be construed as approval for any other state or federal regulatory review, licensing, or certification. The rules and contact information for other state regulatory agencies are available online at www.michigan.gov/con.

A Project Implementation Progress Report (PIPR) form must be completed and returned no later than 12 months from the date of the final decision letter signed by the Director. Failure to submit this report may result in the imposition of sanctions in accordance with MCL 333.22247. The form is available online at www.michigan.gov/con.

If this decision is marked proposed decision, it will be followed by the Director's final decision in accordance with Section 22231 of Public Act 368 of 1978, as amended.

If this is a final decision, the decision will be signed and dated by the Director or the Director's designee. The final signed decision date is the official effective date of this CON.

Thank you for your cooperation in the planning process.

Sincerely,

Nick Lyon
Director

NL: jld

Final Decision Date: 5/16/16

cc: Abigail Mitchell, CON, MDHHS
James Scott, BCHS, MDLARA
Bruce Matkovich, Radiation Safety Section, MIOSHA, MDLARA

Attachment A

STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

RICK SNYDER
GOVERNOR

NICK LYON
DIRECTOR

March 1, 2016

Mr. David Spivey
St. Mary Mercy Hospital
36475 Five Mile Road
Livonia, MI 48154

Re: Certificate of Need for
St. Mary Mercy Hospital
CON Application No. 15-0259
Facility No. 82-0190
Livonia (Wayne County)

Dear Mr. Spivey:

This is to inform you that the proposed project to initiate Elective Percutaneous Coronary Intervention (EPCI) services without on-site Open Heart Surgery (OHS) services has been reviewed and is approved with the following *conditions*.

PROPOSED PROJECT DESCRIPTION

Certificate of Need (CON) Application No. 15-0259 is proposed by Trinity Health-Michigan d/b/a St. Mary Mercy Hospital, a Michigan domestic non-profit corporation (CID No. 766003), located at 36475 Five Mile Road, Livonia, MI 48154. The authorized agent for this application is David Spivey, St. Mary Mercy Hospital, located at the same address.

The applicant, Trinity Health-Michigan d/b/a St. Mary Mercy Hospital, proposes to initiate, replace, or expand a covered clinical service. Specifically, the applicant proposes to initiate EPCI services without on-site OHS services at St. Mary Mercy Hospital, located at 36475 Five Mile Road, Livonia, MI 48154 (Wayne County). St. Mary Mercy Hospital currently provides Adult Diagnostic Cardiac Catheterization and Primary PCI (PPCI) services.

The applicant states that the proposed EPCI service will be provided in the two (2) existing Cardiac Catheterization Laboratories (CCLs) situated in the Heart and Vascular Institute, located in Building 2C, North Wing, on the second floor of the hospital. According to the applicant they are utilizing existing CCL equipment and there are no project costs associated with this project.

PROPOSED PROJECT DESCRIPTION - continued

Upon completion of the proposed project, the applicant will operate an elective PCI service without on-site OHS services and continue to operate two (2) CCLs. At no time will the applicant expand cardiac catheterization services or operate more than two (2) CCLs at the hospital without prior CON approval.

CONDITIONS

1. The applicant shall participate in the Blue Cross Blue Shield of Michigan Cardiovascular Consortium Angioplasty Continuous Quality Improvement Project, the Department's designee for the data registry, as specified in Sections 4(10) and 10(5) of the CON Review Standards or Cardiac Catheterization Services, effective September 14, 2015, and shall continue to participate annually thereafter for the life of that service.

2. The applicant shall provide to the Department prior to implementation of this CON (i.e., performance of the first EPCI procedure) documentation that the applicant complies with Sections 4(11) and 10(5)(f) of the CON Review Standards for Cardiac Catheterization Services, effective September 14, 2015. Specifically, the applicant's Catheterization lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI including the SCAI/ACC/AHA Expert Consensus Document. Credible documentation is limited to verification of Accreditation by Accreditation for Cardiovascular Excellence (ACE) or Corazon, Inc.

3. The applicant shall provide the services approved under this CON so long as the applicant is substantively and actively participating in the data registry in a timely and accurate manner consistent with the Standards and certified by the data registry coordinating center, including, but not limited to, data on all consecutive PCI cases as is necessary to comprehensively assess and provide comparative analyses of case selection, processes and outcome of care, and trend in efficiency.

4. The applicant shall provide the Department with the FINAL/executed written agreement with the open-heart surgery facility specified in the application prior to the implementation of this CON (i.e., performance of the first EPCI procedure). The applicant also shall provide the Department notification of any subsequent changes to the written agreement so long as the applicant is providing the service approved under this CON.

5. The applicant hospital initiating elective PCI without on-site OHS services shall have Accreditation for Cardiovascular Excellence (ACE) or Corazon, Inc., perform an on-site review within 3, 6, and 12 months after implementation of this CON (i.e., performance of the first EPCI procedure) and submit the summary reports of the on-site review to the Department.

PROPOSED PROJECT COSTS

Total Project Costs	$ 0

PROPOSED SOURCE OF FUNDS

Total Source of Funds	$ 0

COMMENTS

The Michigan Department of Health and Human Services has reviewed and determined that the project is in conformance with Public Act 368 of 1978, as amended, and applicable review standards. The basis for this decision is detailed under justification of approval.

JUSTIFICATION OF APPROVAL

The facts submitted by the applicant in the CON application are assumed to be true. Based upon these facts, the Department makes the following findings with respect to Part 222:

Part 222	Findings
22225(1)	Section Met
(2)(a)	Section Met
(b) (i)	Not Applicable
(ii)	Section Met
(iii)	Not Applicable
(iv)	Not Applicable
(c)	Section Met
(d)	Not Applicable
(e)	Section Met
22227	Not Applicable
22230	Not Applicable

The reasons and authority for these findings are set forth in the program and financial reports.

NOTIFICATION TO APPLICANT

In accordance with Rule 325.9403(1), the CON issued will be valid for a period of one (1) year from the effective date of this letter. If the project is not complete within the year, an enforceable contract or force account must be in place. An extension to execute the enforceable contract or force account may be granted by the Department for just cause in accordance with Rule 325.9403(2).

As applicable, Rule 325.9103(b) requires that an enforceable contract for any covered clinical equipment specify that the installation date will be within 24 months after the effective date of the CON. Rule 325.9417 requires that the period of time allowed to begin any construction (i.e., pouring of footings) be within 24 months from the effective date of approval. The CON is valid only as long as there is compliance with the provisions of Rule 325.9401, and is not transferable.

A CON is valid for the term of the lease as stated in this approval letter, if applicable, for a health facility or covered clinical equipment. An applicant is required to file another CON to renew a lease for a health facility if the total renewal lease cost exceeds the covered capital expenditure threshold or as otherwise stated in the applicable CON review standards. For covered clinical equipment, an applicant is required to file another CON to renew a lease as required in the applicable CON review standards. In the case of an equipment lease in which the applicant purchases the equipment at the end of the lease, the CON is valid until the equipment is replaced.

If the total project costs exceed the approved amount in this CON by 15 percent of the first $1 million and 10 percent of the excess over $1 million, the applicant is required to seek an amendment to the approved CON in accordance with Rule 325.9415. Additionally, if the scope of the project or method and terms of financing of the project changes, an amendment or new review will be required in accordance with Rule 325.9413.

As part of this CON approval, and in accordance with applicable CON review standards, the applicant is required to obtain and maintain statistical data in order to complete and submit a MDHHS Annual Survey. The annual survey is available online at www.michigan.gov/con.

In addition to the rules stated in this letter, the applicant must conform and comply with all CON Administrative Rules. This CON is not to be construed as approval for any other state or federal regulatory review, licensing, or certification. The rules and contact information for other state regulatory agencies are available online at www.michigan.gov/con.

A Project Implementation Progress Report (PIPR) form must be completed and returned no later than 12 months from the date of the final decision letter signed by the Director. Failure to submit this report may result in the imposition of sanctions in accordance with MCL 333.22247. The form is available online at www.michigan.gov/con.

If this decision is marked proposed decision, it will be followed by the Director's final decision in accordance with Section 22231 of Public Act 368 of 1978, as amended.

If this is a final decision, the decision will be signed and dated by the Director or the Director's designee. The final signed decision date is the official effective date of this CON.

Thank you for your cooperation in the planning process.

Sincerely,

Timothy J. Bulin for Nick Lyon

Nick Lyon
Director

NL: jld

Final Decision Date: 3-7-16

cc: Abigail Mitchell, CON, MDHHS
James Scott, BCHS, MDLARA
Dr. Gurm, University of Michigan Health System

CCSAC -Ambulatory Devices

DIPAK P. SHAH, MD

MEDICAL DIRECTOR, CENTER FOR ATRIAL FIBRILLATION

PROVIDENCE-PROVIDENCE PARK HOSPITAL

09/14/2017

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH CERTIFICATE OF NEED (CON) REVIEW STANDARDS

FOR CARDIAC CATHETERIZATION SERVICES

"Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory. Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the bedside or in settings outside the laboratory or **the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology laboratory or operating room.**

ASC (CMS)

- An ASC must be certified and approved to enter into a written agreement with CMS. Participation as an ASC is limited to any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. An unanticipated medical circumstance may arise that would require an ASC patient to stay in the ASC longer than 24 hours, but such situations should be rare.

Addendum AA -- Final ASC Covered Surgical Procedures for CY 2017 (Including Surgical Procedures for Which Payment is Packaged)

HCPCS Code		Short Descriptor	Subject to Multiple Procedure Discounting	July 2017 Payment Indicator	July 2017 Payment Weight	July 2017 Payment Rate
33206		Insert heart pm atrial	Y	J8	171.7594	$7,729.69
33207		Insert heart pm ventricular	Y	J8	169.0505	$7,607.78
33208		Insrt heart pm atrial & vent	Y	J8	173.0402	$7,787.33
33210		Insert electrd/pm cath sngl	Y	G2	81.6168	$3,673.00
33211		Insert card electrodes dual	Y	J8	125.6987	$5,656.82
33212		Insert pulse gen sngl lead	Y	J8	126.1978	$5,679.28
33213		Insert pulse gen dual leads	Y	J8	170.9117	$7,691.54
33214		Upgrade of pacemaker system	Y	J8	168.507	$7,583.32
33215		Reposition pacing-defib lead	Y	G2	28.3614	$1,276.35
33216		Insert 1 electrode pm-defib	Y	J8	115.8743	$5,214.69
33217		Insert 2 electrode pm-defib	Y	J8	121.4486	$5,465.55
33218		Repair lead pace-defib one	Y	G2	30.7522	$1,383.94
33220		Repair lead pace-defib dual	Y	G2	30.7522	$1,383.94
33221		Insert pulse gen mult leads	Y	J8	282.7891	$12,726.36
33222		Relocation pocket pacemaker	Y	A2	17.154	$771.98
33223		Relocate pocket for defib	Y	A2	17.154	$771.98
33224		Insert pacing lead & connect	Y	J8	171.5475	$7,720.15

Addendum AA -- Final ASC Covered Surgical Procedures for CY 2017 (Including Surgical Procedures for Which Payment is Packaged)

33225		L ventric pacing lead add-on	N	N1		
33226		Reposition l ventric lead	Y	G2	28.3614	$1,276.35
33227		Remove&replace pm gen singl	Y	J8	125.6641	$5,655.26
33228		Remv&replc pm gen dual lead	Y	J8	169.1336	$7,611.52
33229		Remv&replc pm gen mult leads	Y	J8	275.1537	$12,382.74
33230		Insrt pulse gen w/dual leads	Y	J8	432.1536	$19,448.21
33231		Insrt pulse gen w/mult leads	Y	J8	594.7232	$26,764.33
33233		Removal of pm generator	N	G2	81.6168	$3,673.00
33234		Removal of pacemaker system	N	G2	30.7522	$1,383.94
33235		Removal pacemaker electrode	N	G2	30.7522	$1,383.94
33240		Insrt pulse gen w/singl lead	Y	J8	429.9213	$19,347.75
33241		Remove pulse generator	N	G2	30.7522	$1,383.94
33249		Insj/rplcmt defib w/lead(s)	Y	J8	593.5518	$26,711.61
33262		Rmvl& replc pulse gen 1 lead	Y	J8	426.0314	$19,172.69
33263		Rmvl & rplcmt dfb gen 2 lead	Y	J8	430.2751	$19,363.67
33264		Rmvl & rplcmt dfb gen mlt ld	Y	J8	596.2254	$26,831.93
33270		Ins/rep subq defibrillator	Y	J8	591.2686	$26,608.86
33271		Insj subq impltbl dfb elctrd	Y	J8	131.7999	$5,931.39
33273		Repos prev impltbl subq dfb	Y	G2	30.7522	$1,383.94
33282		Implant pat-active ht record	Y	J8	136.272	$6,132.65
33284		Remove pat-active ht record	N	G2	6.4771	$291.49

ASC Advantages and Disadvantages

Advantages	Disadvantages
Higher reimbursement. An ASC provides the opportunity to perform procedures that are accompanied by reimbursement structures that can rival those currently offered in the hospital setting.	**Conversion Costs.** ASCs must be constructed to meet specific building codes and standards. Converting an existing space or building a new space to these standards can be costly.
Diversified revenue stream. Owning an ASC space can help diversify a revenue stream by allowing complementary practices, such as interventional radiology or vascular surgeons, to practice in concert with other cardiac services.	**Payor Negotiations.** Complex negotiations, driven by varied payment systems, the medical community, and medical directors. Each market can vary in terms of acceptance of the ASC concept and comfort with the clinical aspects of care.
Recruiting. An ASC can be attractive to potential physician candidates, as it can support physician interests in practicing more broadly and performing a greater variety of procedures than a traditional medical office space allows.	**Time.** The time needed to construct an ASC and the time to negotiate with a payor are important considerations. Similar negotiations in other hospital-based specialties moving to the ASC model indicate the process can take 18-24 months.
Stability. Market stability can be achieved by building an ASC as a 'center' of specialty care, elevating the status in the community and position in contracting negotiations.	**Future Uncertainty.** Evolving payment methodologies by payors requires constant oversight of payment policy changes that could dramatically affect future reimbursement.

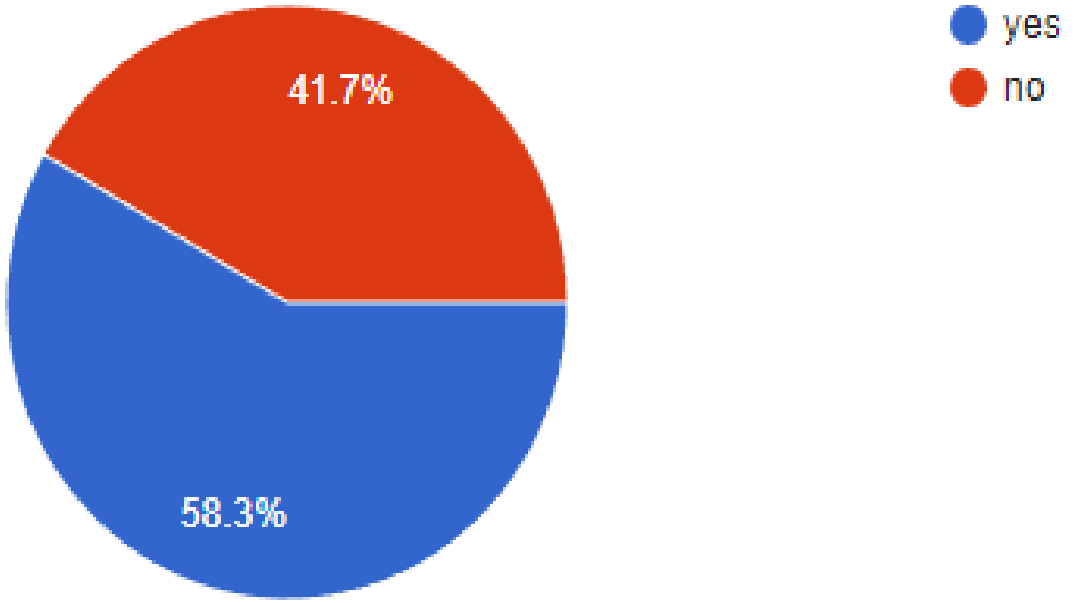
T. Kirby Business Consult. Cardiosource WorldNews Jan 2016

Survey

- Sent out a survey to 50 Electrophysiologists in Michigan
- 24 responses
- Three YES/NO questions with comments:
  - Should pacemaker implantation be allowed in an ASC?
  - Should ICD implantation be allowed in an ASC?
  - Should pacemaker and/or ICD replacement be allowed in an ASC?

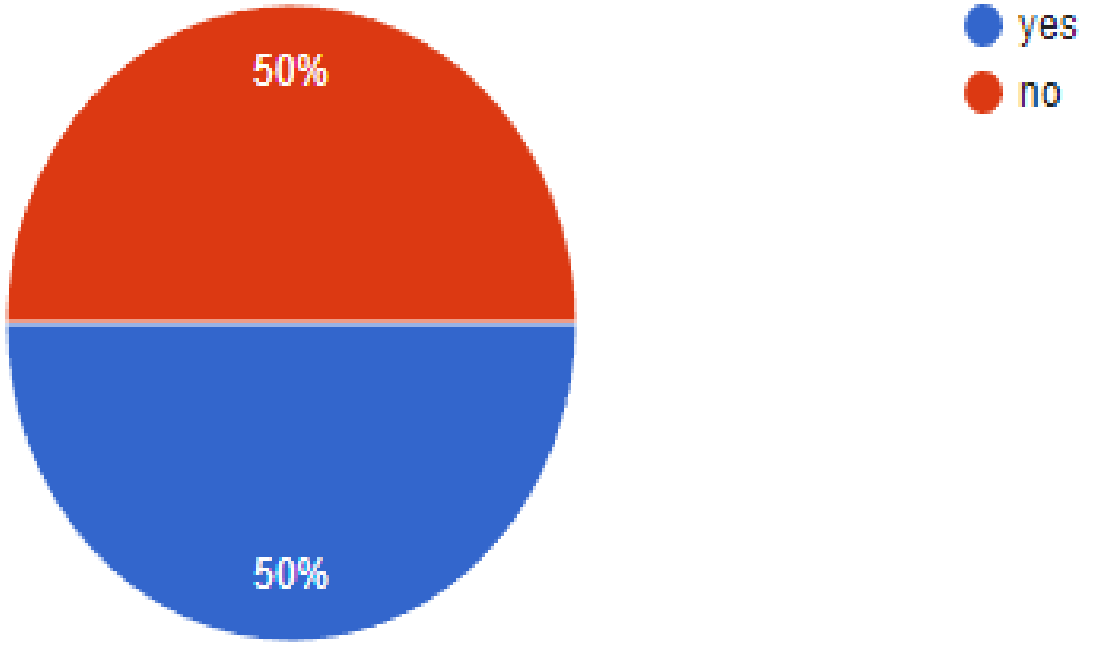
Should pacemaker implantation be allowed in an ASC?

24 responses



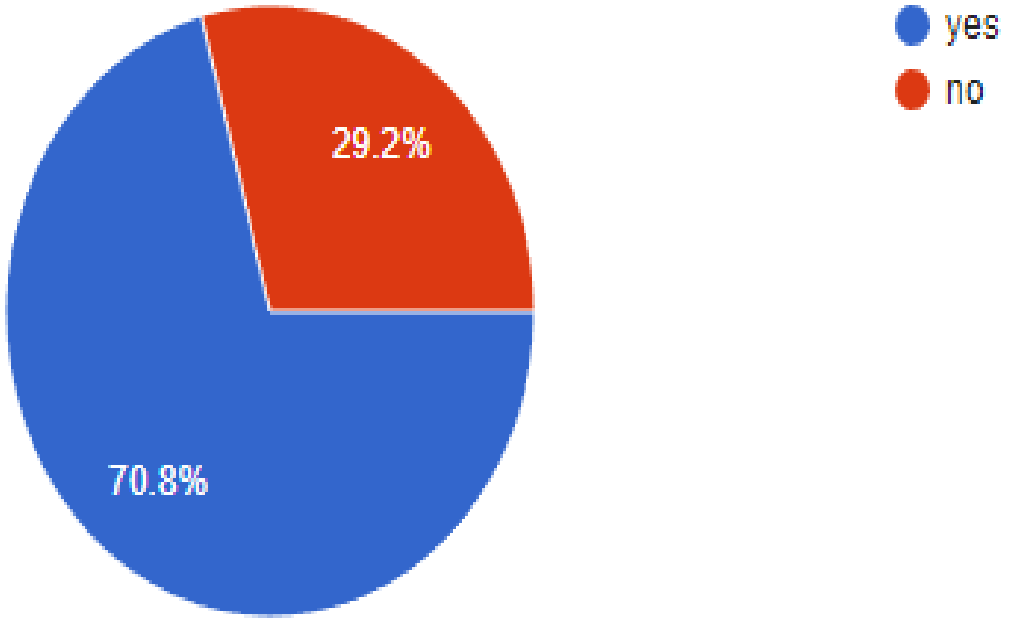
Should ICD implantation be allowed in an ASC?

24 responses



Should pacemaker and/or ICD replacement be allowed in an ASC?

24 responses



Comments from the survey

FOR ASC

- Only if there are standards for the ASC (sterility and safety) as well as patient selection
- Same day discharge for implants routinely being done
- Why should hospitals only have this economic advantage

AGAINST ASC

- Sterility
- More data required (infection rates)
- Possible complications and not being prepared

Arrhythmia/Electrophysiology

Complication Rates Associated With Pacemaker or Implantable Cardioverter-Defibrillator Generator Replacements and Upgrade Procedures

Results From the REPLACE Registry

Jeanne E. Poole, MD; Marye J. Gleva, MD; Theofanie Mela, MD; Mina K. Chung, MD; Daniel Z. Uslan, MD; Richard Borge, MD; Venkateshwar Gottipaty, MD, PhD; Timothy Shinn, MD; Dan Dan, MD; Leon A. Feldman, MD; Hanscy Seide, MD; Stuart A. Winston, DO; John J. Gallagher, MD; Jonathan J. Langberg, MD; Kevin Mitchell, RN, BS; Richard Holcomb, PhD; for the REPLACE Registry Investigators

REPLACE Registry

Background—Prospective studies defining the risk associated with pacemaker or implantable cardioverter-defibrillator replacement surgeries do not exist. These procedures are generally considered low risk despite results from recent retrospective series reporting higher rates.

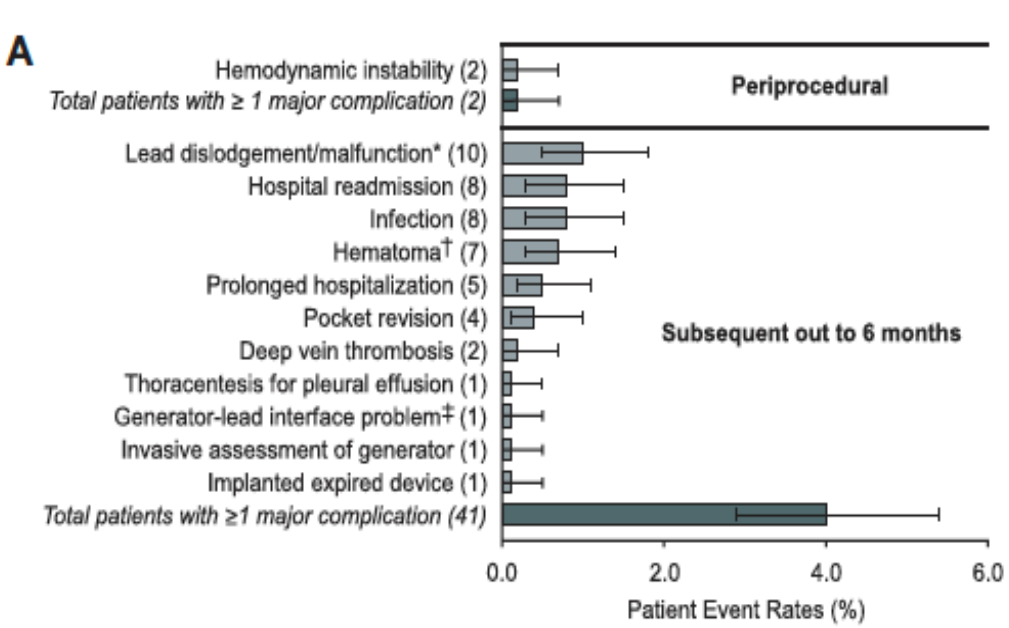
Methods and Results—We prospectively assessed predefined procedure-related complication rates associated with elective pacemaker or implantable cardioverter-defibrillator generator replacements over 6 months of follow-up. Two groups were studied: those without (cohort 1) and those with (cohort 2) a planned transvenous lead addition for replacement or upgrade to a device capable of additional therapies. Complications were adjudicated by an independent events committee. Seventy-two US academic and private practice centers participated. Major complications occurred in 4.0% (95% confidence interval, 2.9 to 5.4) of 1031 cohort 1 patients and 15.3% (95% confidence interval, 12.7 to 18.1) of 713 cohort 2 patients. In both cohorts, major complications were higher with implantable cardioverter-defibrillator compared with pacemaker generator replacements. Complications were highest in patients who had an upgrade to or a revised cardiac resynchronization therapy device (18.7%; 95% confidence interval, 15.1 to 22.6). No periprocedural deaths occurred in either cohort, although 8 later procedure-related deaths occurred in cohort 2. The 6-month infection rates were 1.4% (95% confidence interval, 0.7 to 2.3) and 1.1% (95% confidence interval, 0.5 to 2.2) for cohorts 1 and 2, respectively.

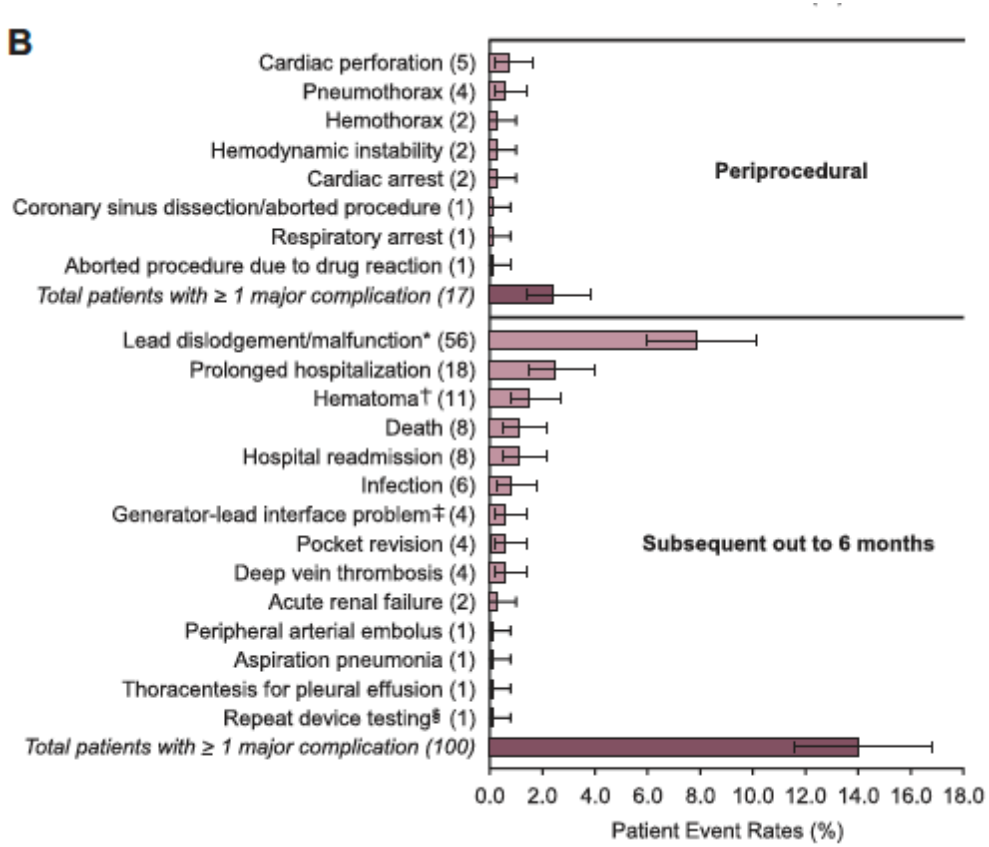
Conclusions—Pacemaker and implantable cardioverter-defibrillator generator replacements are associated with a notable complication risk, particularly those with lead additions. These data support careful decision making before device replacement, when managing device advisories, and when considering upgrades to more complex systems.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00395447.

(*Circulation*. 2010;122:1553-1561.)

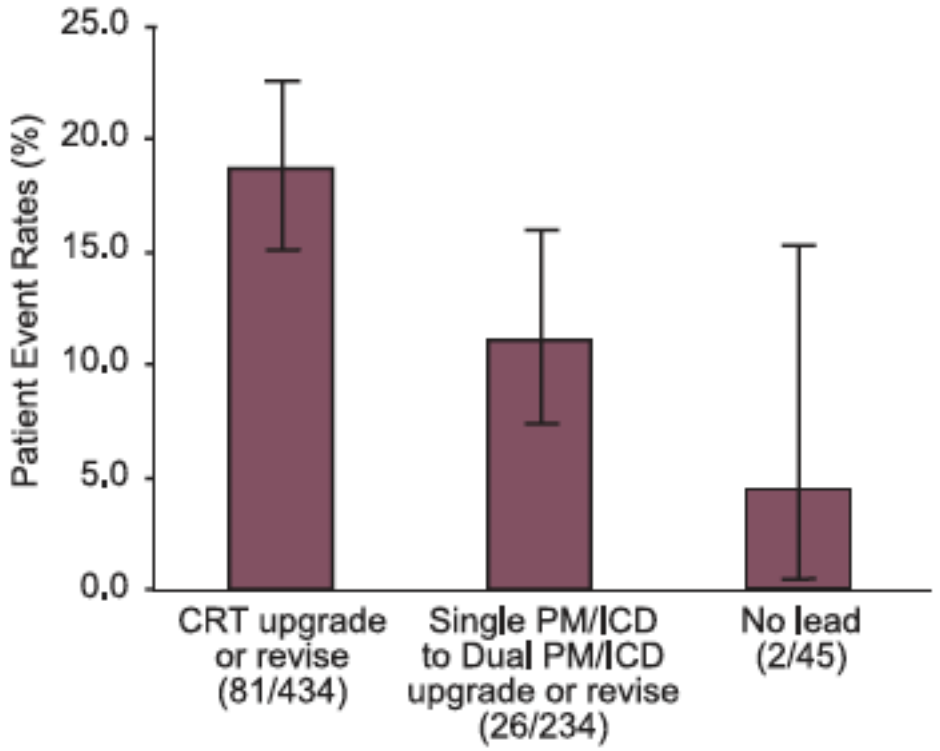
REPLACE Registry





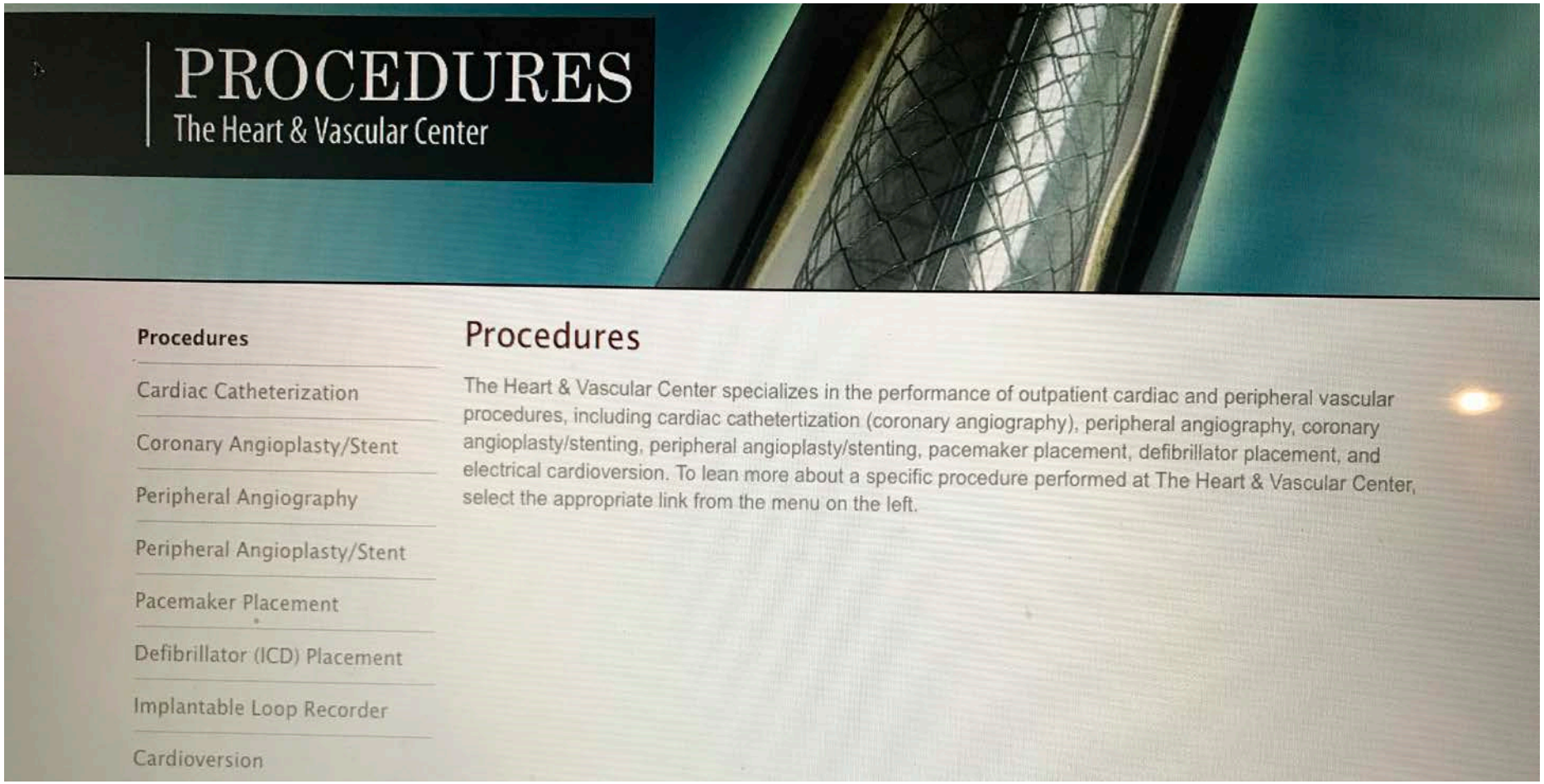
[*Circulation*. 2010;122:1553-1561.

REPLACE Registry



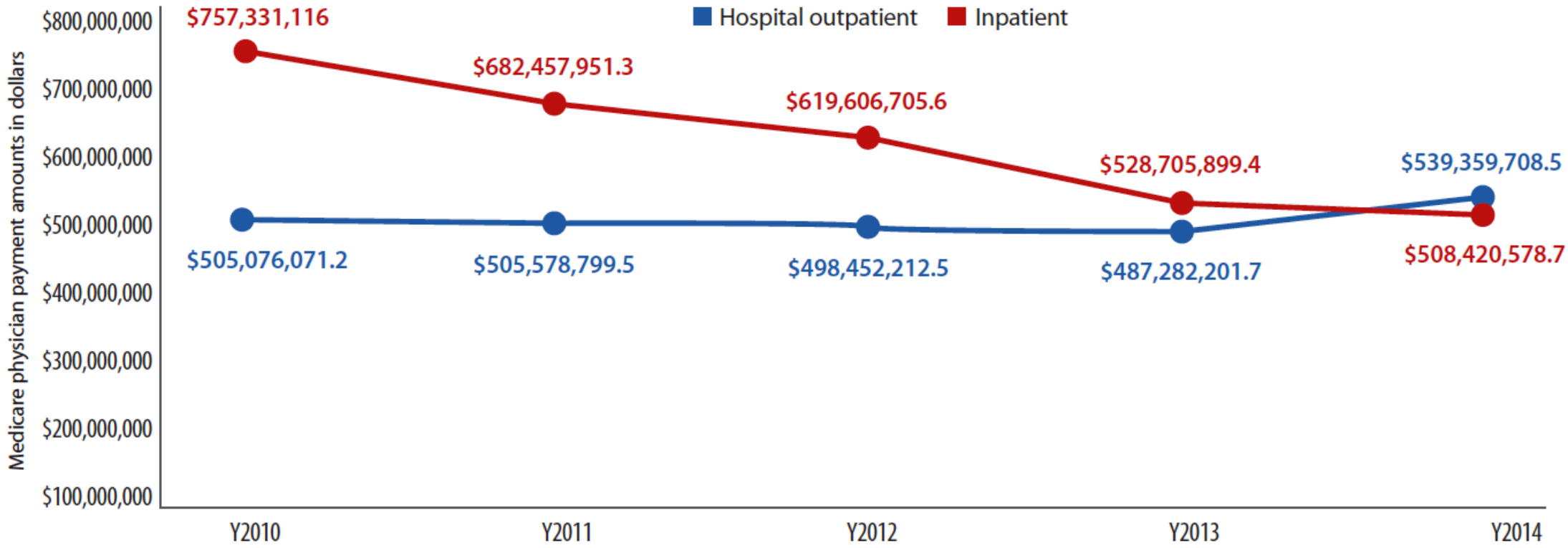
(*Circulation*. 2010;122:1553-1561.

But its already being done…

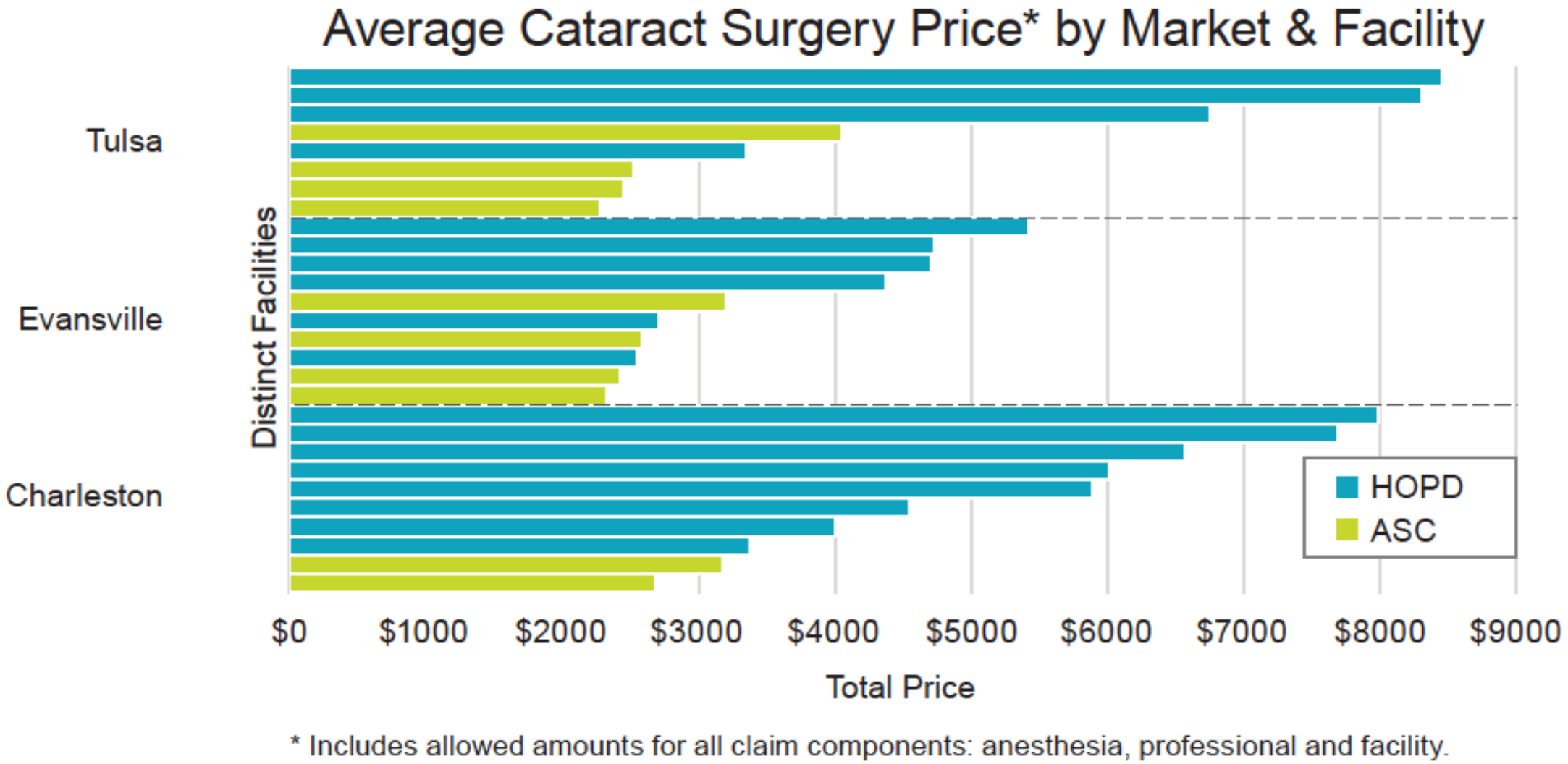


MORE OUTPATIENT CARDIOLOGY TREATMENT

More patients are receiving interventional cardiology treatment in hospital outpatient settings as evidenced by Medicare payments to physicians (total dollars paid to physicians) for hospital outpatient cardiology services. In 2014, payments to physicians for hospital outpatient cardiology services exceeded payments to physicians for hospital inpatient cardiology services.



Source: *Physician/Supplier Procedure Summary, 2013–2014.*



https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/ambulatory-centers-cost.aspx

Annual Savings from Procedures Performed in ASCs

% of Common ASC Procedures Currently Performed at ASCs	48%
Current Annual Savings	$37.8 B
Potential Additional Annual Savings	$38.2 B
Potential Additional Annual Savings from Optimal Migration to ASCs	$55.6 B

https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/ambulatory-centers-cost.aspx

Data

Ambulatory surgical visits of Medicare beneficiaries were compared for hospital-based and freestanding ambulatory surgical centers (ASCs).

The main outcomes were time in surgery, time in operating room, time in postoperative care, and total perioperative time.

	Hospital ASC	Fresstanding ASC	p
Periop Time	135 min	83 min	<0.01
Surgery Time	30 min	19 min	<0.01
OR Time	54 min	34 min	<0.01
Postop Time	74 min	48 min	<0.01

Hair et al Am J Surgery 2012.

Attachment B

Review of Charge #5:
Additional Interventional Procedures

Simon R. Dixon, MBChB, FACC, FRACP

Beaumont Hospital - Royal Oak

September 14, 2017

Charge #5

- Review section 11 to determine if it is appropriate to incorporate additional interventional procedures that are performed in a cardiac catheterization laboratory but are not currently identified or weighted in section 11.

Section 11

Current methodology for determining procedure equivalents

Procedure Type	Procedure equivalent	
	Adult	Pediatric
Diagnostic cardiac catheterization/peripheral sessions	1.5	2.7
Therapeutic cardiac catheterization/peripheral sessions	2.7	4.0
Complex percutaneous valvular sessions*	4.0	7.0
* Complex percutaneous valvular sessions includes, but is not limited to, procedures performed percutaneously or with surgical assistance to repair or replace aortic, mitral and pulmonary valves such as transcatheter aortic valvular implantation (Tavi) procedures. These sessions can only be performed at hospitals approved with OHS services.		

The current methodology was introduced in 2011

The procedure equivalent appears to have been determined based on time in hours

Definition Therapeutic Procedures

- Section 2 (1) (q)
  - PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantation, left sided arrhythmia procedures

Additional procedures: Watchman, CTO, Impella, paravalular leak closure, alcohol septal ablation, PFO/ASD, S-ICD

Methodology

- Hospital programs were asked to provide the median procedure time for selected cardiac and EP procedures
- Procedure time data = room-in to room-out
- For each procedure, an average of the available data points was used
- Procedures with average procedure time >2.7 hours (162 minutes) considered complex and assigned weighting 4.0 equivalents

Procedure Time Data - Cath

Procedure	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Mean
PCI	100			70	88		86
PCI for CTO	157	136	240	124			164
Impella	154	155		150	128		147
TAVR	188		138	120	126		143
MitraClip	240	200	240	150	177		201
Alcohol septal ablation	165			120			142
Paravalvular leak	277						277
Watchman	135	120			95		117
ECMO		123					123

Highlighted in red = procedure time >2.7 hours (162mins)

Procedure Time Data - EP

Procedure	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Mean
EP Study	115		60				88
Pacemaker	105		60				83
ICD	101		90			111	100
Subcutaneous-ICD	146						146
Biv-ICD	158		120			167	148
AF ablation	312		150			199	220
VT ablation	263		240			344	282
Lead extraction	235		180			187	200

Highlighted in red = procedure time >2.7 hours

Recommendations

Procedure	Adult	Pediatric
Diagnostic cardiac catheterization/peripheral sessions	1.5	2.7
Therapeutic cardiac catheterization/peripheral sessions	2.7	4.0
Complex therapeutic procedures (PCI for chronic total occlusion, MitraClip, paravalvular leak closure, TAVR non-femoral, AF ablation, VT ablation, ICD/pacemaker lead extraction)	4.0	7.0

Recommendation #1

Change “Complex percutaneous valvular sessions” category to include other complex therapeutic procedures including those listed above

For discussion: Watchman and TAVR since both fall within 2.7 hour time

Definition Therapeutic Procedures

- Section 2 (1) (q)
  - PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantation, left sided arrhythmia procedures

Recommendation #2
Modify definition of therapeutic procedures to include peripheral interventions, and complex cardiac interventions

Definition Therapeutic Procedures

- Therapeutic procedures include:
  - Coronary: PCI, PTCA, stent, atherectomy, laser (for non-CTO)
  - Valve/Structural: Balloon valvuloplasty, PFO/ASD closure, Watchman, atrial septostomy, alcohol septal ablation (?femoral TAVR)
  - EP: Pacemaker, ICD, S-ICD, ablation (non-AF/VT)
  - Peripheral: PTA, atherectomy, stent, IVC filter, catheter directed thrombolysis
  - Other: Impella, ECMO

Definition Therapeutic Procedures

- Complex therapeutic procedures include:
  - Valve/Structural: TAVR (trans-aortic/apical), mitral/tricuspid valve repair or replacement, paravalvular leak closure
  - EP: AF or VT ablation, ICD/PPM lead extraction

Revisions highlighted in red

Definition Therapeutic Procedures

- Exclusions:
  - Intracoronary administration of drugs where that is the only intervention
  - FFR/CFR/IVUS/OCT without a coronary intervention

Revisions highlighted in red

Back up

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Attachment D

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EXPERT CONSENSUS DOCUMENT

SCAI/ACC/AHA Expert Consensus Document

2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

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James C. Blankenship, MD†
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Introduction

In 2007, the Society for Cardiovascular Angiography and Interventions (SCAI) published an Expert Consensus Document titled "The Current Status and Future Direction of Percutaneous Coronary Intervention without On-Site Surgical Backup" (1). This document summarized the available data on the performance of percutaneous coronary intervention (PCI) without on-site surgery in the United States (US), reviewed the existing literature, examined the recommendations for the performance of PCI in this setting from several professional organizations abroad and from experienced programs in the US, defined the best practices for facilities engaged in PCI without on-site surgery and made recommendations for the future role of PCI without on-site surgery.

Since publication of that document, new studies, meta-analyses, and randomized trials have been published comparing PCI with and without on-site surgery. In addition, the total number of PCIs performed annually has decreased, reports about the overuse of PCI have emerged, and appropriate use criteria for coronary revascularization have been published. A noteworthy change occurred in the 2011 PCI guideline in which elective PCI was upgraded to Class IIb and primary PCI was upgraded to Class IIa at facilities without on-site surgery (2). Several tables on the structure and operation of programs without on-site surgery from the 2007 SCAI Expert Consensus Document were used in the 2011 PCI guideline recommendations. Finally, new updates of the ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards and the ACCF/AHA/SCAI Clinical Competence in Coronary Artery Interventional Procedures have been published (3,4).

Although many of the concerns about the safety of PCI without on-site surgery have been resolved, there are new issues to consider as the delivery of PCI continues to evolve in the US. Accordingly, the SCAI, ACCF, and AHA have engaged in this effort to re-evaluate the current status of PCI without on-site surgery in the US. The specific goals of this effort were to:

1. Determine current trends in the prevalence of PCI without on-site surgery in the US;
2. Summarize new literature related to the performance of PCI without on-site surgery;
3. Review existing guidelines, expert consensus documents, competency statements and other documents related to PCI without on-site surgery and summarize all relevant information into a single resource document;

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Authors' relationships with industry are available in Appendix 1. Peer reviewers' relationships with industry are available in Appendix 2.

The American College of Cardiology requests that this document be cited as follows: Dehmer GJ, Blankenship JC, Cilingiroglu M, Dwyer JG, Feldman DN, Gardner TJ, Grines CL, Singh M. SCAI/ACC/AHA expert consensus document: 2014 update on percutaneous coronary intervention without on-site surgical backup. J Am Coll Cardiol 2014; 63:2624–41.

This article is copublished with *Catheterization and Cardiovascular Interventions* and *Circulation*.

4. Outline the current best practice methods and requirements for facilities engaged in performing PCI without on-site surgery; and
5. Evaluate the role of PCI without on-site surgery within the current US healthcare system.

Trends in the Performance of PCI

Although the use of PCI in the US had grown considerably since the early 1980s, data from the Nationwide Inpatient Sample cited by the Agency for Healthcare Research and Quality shows that the annual volume of PCI procedures peaked in 2006 and has since declined by over 30% (5). Numerous factors have contributed to this decline, including a reduction in restenosis by drug-eluting stents, a greater emphasis on medical therapy for the treatment of stable coronary artery disease, enhanced primary and secondary prevention efforts, a reduction in the incidence of ST-segment elevation myocardial infarction (STEMI), the increasing use of techniques such as fractional flow reserve to better evaluate lesion severity and the development and application of appropriate use criteria (5,6). As a result of these factors, many operators and hospitals now have low-volume practices. Using data from 2008, Maroney et al. estimated that 61% of interventional cardiologists performed 40 or fewer Medicare fee-for-service PCIs annually (7). Clinical data from 1298 facilities reporting to the National Cardiovascular Data Registry (NCDR) show that 49% of facilities performed ≤400 PCIs and 26% performed ≤200 PCIs annually (Fig. 1) (8). Approximately 33% of facilities had no on-site surgery, and among these, 65% (282 facilities) had an annual case volume of ≤200 PCI procedures.

Across the US, PCI without on-site surgery has increased since 2007. The writing committee assessed the current use of PCI without on-site surgery from a survey of ACC Governors for each state, data from industry sources and direct contact with physicians in various states (Fig. 2). Currently, 45 states allow both primary and elective PCI without on-site surgery, 4 states allow only primary PCI without on-site surgery, and 1 state prohibits PCI without on-site surgery. PCI without on-site surgery is regulated by the State Department of Health in 34 states but is unregulated in the remaining 16 states. Elective PCI without on-site surgery was allowed at selected facilities in 9 states but only as part of statewide demonstration projects or to allow participation in the Cardiovascular Patient Outcomes Research Team (CPORT) Nonprimary PCI (CPORT-E) trial (9). Since the conclusion of CPORT-E, the use of PCI without on-site surgery is being re-evaluated in several of these states. PCI without on-site surgery is currently performed in 19 of the 65 cardiac catheterization laboratories within the Veterans Health Administration (10).

Recent Literature on PCI Without On-Site Surgery

Since 2006, 11 original studies and 3 meta-analyses on the topic of PCI without on-site surgery have been identified by a computerized systematic literature search using Medline (PubMed and Ovid) and Cochrane Databases (9,11–23).

Primary PCI without on-site surgery. Seven studies and 2 meta-analyses of primary PCI showed no difference for in-hospital or 30-day mortality between sites with and without on-site surgery (Table 1). None of the individual studies examining the occurrence of emergency CABG surgery after primary PCI showed a difference between sites with and without on-site surgery. However, 1 meta-analysis showed that sites without on-site surgery had a lower occurrence of emergency CABG surgery after

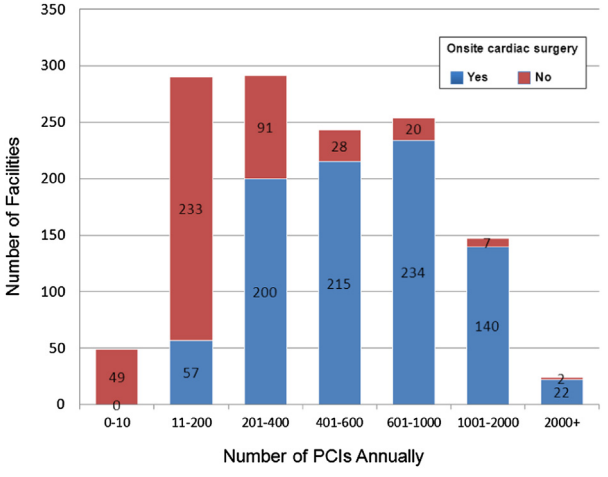

Figure 1. PCI Volume at Facilities With and Without Cardiac Surgery

Reproduced from Dehmer et al. (8) with permission.

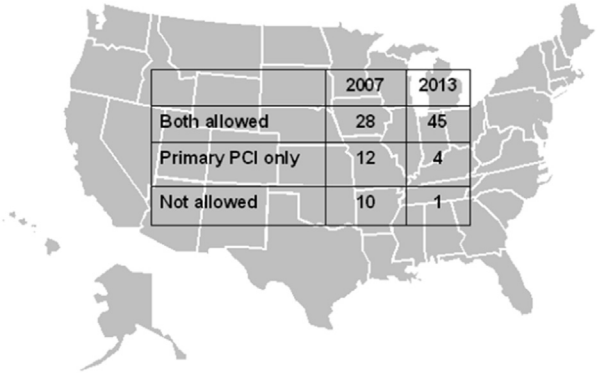

Figure 2. Change in the Availability of PCI Without On-Site Surgery From 2007 to 2013

The numbers shown indicate the number of states where primary and nonprimary PCI without on-site surgery are allowed.

Attachment D
JACC Vol. 63, No. 23, 2014
June 17, 2014:2624–41

Table 1. Studies on Primary PCI Without On-Site Surgery Published Since 2006

Author (Year)	Sites	On-Site Surgery	No. of Patients in Arm	Mortality		Emergency CABG		Comments
				Incidence %	OR (95% CI)	Incidence %	OR (95% CI)	
Carlsson (2007) (12)	Multicenter SCAAR registry	No	857	7.0	1.05 (0.79–1.40)	0.1		30-day mortality is reported; Incidence of emergency CABG is for all patients (primary and nonprimary PCI)
		Yes	4,595	6.7		0.2		
Peels (2007) (13)	Single center	No	336	2.1	2.17 (0.26–17.8)	0	0.10 (0.00–2.51)	
		Yes	103	0.97		1.0		
Pereira (2008) (14)	Multicenter Portuguese registry	No	1,214	5.0	0.79 (0.55–1.14)	1.8	1.52 (0.90–2.56)	Cardiogenic shock mortality was 53.4% with on-site surgery and 50.9% without (NS)
		Yes	1,470	4.0		2.7		
Kutcher (2009) (15)	Multicenter NCDR registry	No	1,934	5.1	0.97 (0.79–1.20)	0.7	0.60 (0.35–1.03)	In-hospital mortality reported. Only 42% of sites without on-site surgery performed ≥36 primary PCIs annually compared with 80% of sites with on-site surgery
		Yes	31,099	5.2		1.2		
Pride (2009) (16)	Multicenter NRMI database	No	1,795	3.3	0.86 (0.61–1.23)			Propensity matched patient cohort. In-hospital mortality reported and only for patients undergoing primary PCI. Incidence of emergency CABG not reported
		Yes	1,795	3.8				
Hannan (2009) (17)	Multicenter New York State database	No	1,729	2.3	1.22 (0.76–1.94)	0.06	0.17 (0.02–1.38)	Propensity matched patient cohort. In-hospital/30-day mortality reported
		Yes	1,729	1.9		0.35		
Singh (2009) (18)	3 sites	No	667	2.5	0.80 (0.42–1.54)	0.7	1.25 (0.33–4.68)	Propensity matched patient cohort of nonelective PCI defined as acute MI within 24 h or cardiogenic shock.
	Mayo Clinic experience	Yes	667	3.1		0.6		
Meta-analyses								
Zia (2011) (19)		No	8,703	6.1	0.93 (0.83–1.05)	3.0	0.87 (0.68–1.11)	9 studies included in the analysis
		Yes	97,386	7.6		3.4		
Singh (2011) (20)		No	16,489	4.6	0.96 (0.88–1.05)	0.22	0.53 (0.35–0.79)	11 studies included in the analysis
		Yes	107,585	7.2		1.03		

CABG, coronary artery bypass graft surgery; NCDR, National Cardiovascular Data Registry; NRMI, National Registry of Myocardial Infarction; OR, odds ratio; PCI, percutaneous coronary intervention; SCAAR, Swedish Coronary Angiography and Angioplasty Registry.

primary PCI (odds ratio, 0.53; 95% confidence interval 0.35–0.79) (20).

PCI without on-site surgery for conditions other than STEMI. Eight studies examined nonprimary PCI at sites with and without on-site surgery (Table 2). The majority of studies and meta-analyses showed no difference in mortality or a need for emergency CABG at sites without on-site surgery. One study at a high-volume facility performing only elective PCIs and staffed by high-volume interventionalists showed a lower mortality at the facility without on-site surgery (OR, 0.11; 95% CI 0.01–0.79) (21). However, the baseline clinical and angiographic characteristics of the study groups with and without on-site surgery were sufficiently different that a meaningful adjusted analysis could not be performed, and there is therefore the possibility of a case selection bias.

Two randomized trials of nonprimary PCI have now been published. The CPORT-E trial randomized over 18,000 patients in a 1:3 ratio to undergo PCI at hospitals with and without on-site cardiac surgery, respectively (9). High-risk patients were excluded, as was the use of atherectomy devices. The trial had 2 primary endpoints: 6-week mortality and 9-month incidence of major adverse cardiac events (composite of death, Q-wave myocardial infarction, or target-vessel revascularization). The 6-week mortality rate was 0.9% at hospitals without on-site surgery compared with 1.0% at those with on-site surgery ($p = 0.004$ for noninferiority). The 9-month rates of major adverse cardiac events were 11.2% and 12.1% at hospitals with and without on-site surgery, respectively ($p = 0.05$ for noninferiority). A similar, but smaller randomized study of nonemergency PCI was performed in Massachusetts hospitals (11). 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%,

Table 2. Studies on Nonprimary PCI Without On-Site Surgery Published Since 2006

Author (Year)	Sites	On-Site Surgery	No. of Patients in Arm	Mortality		Emergency CABG		Comments
				Incidence %	OR (95% CI)	Incidence %	OR (95% CI)	
Carlsson (2007) (12)	Multicenter SCAAR registry	No	7,981	0.81	1.23 (0.91–1.65)	0.1		30-day mortality is reported; Incidence of emergency CABG is for all patients (primary and nonprimary PCI)
		Yes	20,930	0.66		0.2		
Frutkin (2008) (21)	2 sites	No	1,090	0.09	0.11 (0.01–0.79)	0.2	6.10 (0.55–67.3)	Nonrandomized comparison of 2 sites. Stable and unstable angina plus NSTEMI included. In-hospital mortality shown
		Yes	3,317	0.8		0.03		
Pereira (2008) (14)	Multicenter Portuguese registry	No	4831	0.5	1.43 (0.85–2.41)	0.7	3.14 (2.13–4.63)	
		Yes	5584	0.7		2.1		
Kutcher (2009) (15)	Multicenter NCDR registry	No	6,802	0.8	0.99 (0.76–1.30)	0.2	0.69 (0.40–1.16)	72% of sites without on-site surgery performed <200 PCIs annually compared with 6% among sites with on-site surgery
		Yes	268,312	0.8		0.3		
Pride (2009) (22)	Multicenter NRMI registry	No	1,282	1.0	0.76 (0.37–1.58)			Only patients with NSTEMI included in study cohort
		Yes	1,282	1.3				
Singh (2009) (18)	3 sites Mayo clinic experience	No	1,842	0.2	0.57 (0.17–1.95)	0	1.00 (0.02–50.4)	Propensity matched patient cohort
		Yes	1,842	0.4		0.2		
Aversano (2012) (9)	Multicenter randomized trial	No	14,149	0.9		0.1		Mortality reported after 6 weeks and incidence of emergency CABG shown.
		Yes	4,718	1.0		0.2		
Jacobs (2013) (11)	Multicenter randomized trial	No	2,774	0.7	1.96 (0.58–6.64)	0.3	2.30 (0.3–18.6)	All-cause and cardiac mortality at 30 days were no different. PCI without on-site surgery was not inferior
		Yes	917	0.3		0.1		
Meta-analyses								
Zia (2011) (19)		No	28,552	1.6	1.03 (0.64–1.66)	1.0	1.38 (0.65–2.95)	6 studies included in the analysis
		Yes	881,261	2.1		0.9		
Singh M (2011) (20)		No	30,423	0.9	1.15 (0.93–1.41)	0.17	1.21 (0.52–2.85)	9 studies included in the analysis
		Yes	883,865	0.8		0.29		
Singh PP (2011) (23)		No	1,812	0.17	2.3 (0.60–12.97)	0.11	0.47 (0.07–3.19)	4 studies included in the analysis but only 2 with data on mortality and CABG; Risk ratios rather than OR are reported in this analysis
		Yes	4,039	0.72		0.02		

CABG, coronary artery bypass graft surgery; NCDR, National Cardiovascular Data Registry; NRMI, National Registry of Myocardial Infarction; OR, odds ratio; PCI, percutaneous coronary intervention; SCAAR, Swedish Coronary Angiography and Angioplasty Registry.

respectively, at 12 months (relative risk, 0.98; 95% one-sided upper confidence limit, 1.13; $p < 0.001$ for non-inferiority). The individual rates of death, myocardial infarction, repeat revascularization and stroke did not differ significantly between the groups at either time point.

Three meta-analyses conducted primarily with registry data have examined the use of nonprimary PCI at facilities with and without on-site surgery (19,20,23). Overall, the mortality rate and need for emergency CABG surgery did not differ between hospitals with and without on-site surgery. In 1 meta-analysis, after adjusting for publication bias, the mortality rate for nonprimary PCI was 25% higher at centers without on-site surgery compared with centers that had on-site surgery (OR, 1.25; 95% CI, 1.01–1.53; $p = 0.04$) (20). However, it is important to note that these meta-analyses preceded the publication of the 2 randomized trials (9,11). Therefore, based on these recent studies, there is no indication of increased mortality or a greater need for emergency CABG for either primary or nonprimary PCI at sites without on-site cardiac surgery.

Guidelines, Competency Documents, Policy Statements, and Other Programs

Since 2007, there have been several new documents published that provide guidance for the performance of PCI without on-site surgery. Each new document builds incrementally upon the recommendations from prior documents with slight modifications based on new information. The recommendations for PCI programs without on-site surgery are maturing and becoming uniform over time through the vetting of these recommendations by numerous separate writing committees and undergoing extensive external reviews during document development. Key recommendations for PCI without on-site surgery from those documents are briefly summarized below and have been combined to develop the unified recommendations in this document.

2009 Focused Guideline Update on the Management of Patients with STEMI and Guideline Update on PCI

The 2009 focused update of the ACC/AHA guidelines for the management of patients with STEMI and the ACC/AHA/SCAI guidelines on PCI has been superseded by newer separate guidelines for STEMI and PCI (2,24,25). However, a number of the recommendations from the 2009 document regarding triage and transfer of patients and the development of local STEMI systems have been incorporated into the current document.

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

Compared with prior guidelines, the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention stipulated new classification ratings for both primary and elective PCI at hospitals without on-site cardiac surgery (2). Primary PCI was assigned a Class IIa recommendation (*Level of Evidence: B*) stating that primary PCI is "reasonable," provided appropriate planning for program development has been accomplished. Previously, this was assigned a Class IIb recommendation. Elective PCI, previously assigned a Class III recommendation, was given a Class IIb recommendation (*Level of Evidence: B*) stating it "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". Elective PCI without on-site cardiac surgical backup was considered appropriate only when performed by experienced operators, with complication rates and outcomes equivalent or superior to national benchmarks. Importantly, the ACCF/AHA/SCAI PCI guidelines state, "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery." The guideline assigns a Class III recommendation (*Level of Evidence: C*) to performing primary or elective PCI in hospitals without on-site cardiac surgery without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital and without appropriate hemodynamic support capability for transfers. The 2011 PCI guideline document adapted personnel, facility, operator and structural requirements for PCI without on-site surgery from the 2007 SCAI Expert Consensus document (1). New facility and operator volume requirements were not addressed in the 2011 PCI guidelines but deferred to the 2013 PCI Clinical Competency document (4). In 2011, ACCF/AHA also published a Guideline for Coronary Artery Bypass Surgery that did not discuss the performance of PCI without on-site surgery (26).

2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update

Similar to the 2011 PCI guidelines, this document presented requirements for PCI at facilities without on-site cardiac surgery that were derived from the 2007 SCAI expert consensus document with some modifications (3). This document also presented criteria for excluding patients, based on risk and lesion characteristics, from PCI at facilities without on-site cardiac surgery. The document prescribed the quality assurance/quality improvement (QA/QI) program necessary for all cardiac catheterization laboratories with specific recommendations for structure, process, and outcome variables appropriate for monitoring. Moreover, it recommended that all major complications be reviewed by the QA/QI committee at least every 6 months and that any individual operator with complication rates above benchmarks for 2 consecutive 6-month intervals should have the issue directly addressed by the QA director with a written plan for remediation. The document also recommended that a random sample of cases from all operators should be reviewed at least annually.

2013 ACCF/AHA/SCAI Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures

In addition to defining numerous requirements for operator competency, new operator, and facility PCI volume requirements were established (4). Reflecting the overall decline in PCI volumes, this document recommended that laboratories performing both primary and elective PCI, with and without on-site cardiac surgery, should perform a minimum of 200 PCIs annually. Laboratories performing <200 cases annually must have stringent systems and process protocols in place with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. The existence of laboratories performing <200 PCIs annually that are not serving

isolated or underserved populations should be questioned, and any laboratory that cannot maintain satisfactory outcomes should be closed. This recommendation was based on an extensive review of studies that identified a signal suggesting worse outcomes in laboratories performing <200 PCIs annually. The writing committee recommended that operators perform a minimum of 50 PCIs annually (averaged over 2 years), including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200 total and >36 primary PCI procedures annually. However, it was emphasized that individual operator volume is but one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, the operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance. Operators who cannot maintain these case volume recommendations at their primary practice site should maintain privileges and continue to perform PCI procedures at a high-volume institution with on-site surgical backup to meet annual volume requirements. It was also recommended that operators should be board certified in interventional cardiology and maintain certification, with the exception of operators who have received equivalent training outside the US and are ineligible for board certification in the US.

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

This document did not specifically comment on PCI without on-site cardiac surgery but supported the 2011 ACCF/AHA/SCAI PCI guidelines recommendations (25). It recommended that primary PCI be performed in high-volume, well-equipped centers with experienced interventional cardiologists, and skilled support staff.

2010 European Society of Cardiology and European Association for Cardio-Thoracic Surgery Guidelines

In contrast to the 2011 ACC/AHA/SCAI PCI guidelines, the 2010 European Society of Cardiology and the European Association for Cardio-Thoracic Surgery guidelines on myocardial revascularization do not comment on PCI without on-site surgery or issues related to institutional or operator competency (27). However, the European guidelines continue to stress the importance of full disclosure regarding the lack of availability of on-site cardiac surgery and the inadvisability of performing PCI for high-risk patients/lesions at facilities that do not have on-site surgical backup.

The European guidelines for STEMI do not provide specific recommendations regarding PCI at centers without on-site surgery (28). Rather, emphasis is placed on the development of networks between hospitals with differing levels of technology, connected by an efficient emergency transport system. To maximize staff experience, the guidelines recommend that primary PCI centers perform procedures 24 h a day, 7 days a week for all STEMI patients.

Other models mentioned in the European guidelines, although not ideal, include weekly or daily rotation of primary PCI centers or multiple primary PCI centers in the same region. Hospitals that cannot offer a 24/7 service for primary PCI should be allowed to perform primary PCI in patients already admitted for another reason and who develop STEMI during their hospital stay. These hospitals should, however, be discouraged from initiating a service limited to daytime or within-hours primary PCI, because this generates confusion with Emergency Medical Services (EMS) operators and is unlikely to match the door-to-balloon time and quality of intervention of focused 24/7 primary PCI centers. In a survey of European countries, the mean population served by a single primary PCI center varied between 0.3 and 7.4 million inhabitants. In countries offering primary PCI services to the majority of their STEMI patients, this population varied between 0.3 and 1.1 million per center (29). In small service areas, experience can be suboptimal due to an insufficient number of STEMI patients, but the optimal size of a catchment area could not be clearly defined. For geographical areas where the expected transfer time to a primary PCI center makes it impossible to achieve satisfactory reperfusion times, thrombolysis with subsequent immediate transfer to a primary PCI center has been endorsed. Although there is a risk of intracranial bleeding, a potential role for this strategy in selected circumstances has been emphasized (30).

Other Guidelines and Recommendations

The 2007 SCAI Expert Consensus Document summarized the recommendations from the British Cardiac Society and British Cardiovascular Intervention Society, the Cardiac Society of Australia and New Zealand (CSANZ), the Spanish Society of Cardiology, the Brazilian Society of Hemodynamics and Interventional Cardiology (*Sociedade Brasileira de Hemodinamica e Cardiologia Intervencionista*) and from several other countries (31–39). Since 2007, only the guidelines from CSANZ have been updated, most recently in 2011 (32). CSANZ guidelines state that primary PCI without on-site surgery should be performed: (a) by operators and institutions meeting the overall requirements and standards of primary PCI centers; (b) by institutions with a proven plan for rapid transport to a cardiac surgical center; (c) in a timely fashion (<90 min); and (d) using rigorous case selection criteria. The CSANZ guidelines acknowledged that rural patients might have limited access to diagnostic angiography and PCI, and providing these services at institutions without on-site surgery by appropriately trained individuals facilitates equity of access, which should result in improved quality of care. However, the CSANZ guidelines also specifically state that rural and regional centers should not perform

elective, high-risk PCI procedures if they are located more than 1 hour travel time from cardiac surgery centers.

AHA Policy Statement on PCI Without Surgical Backup

In March 2012, the AHA issued a policy statement on PCI without surgical backup defining two major reasons for providing PCI without on-site surgery (40). First, PCI without on-site surgery is considered reasonable if the intent is to provide high quality timely primary PCI for patients with STEMI. The statement recommended that each community and facility in the community have an agreed-upon plan for how STEMI patients are to be treated. The plan should indicate hospitals that should receive STEMI patients from EMS units capable of obtaining diagnostic electrocardiograms, the management at the initial receiving hospital and written criteria and agreements for the expeditious transfer of patients from nonPCI-capable to PCI-capable facilities. Second, PCI without on-site surgery is a reasonable consideration for providing local care to patients and families who do not want to travel significant distances or who have certain preferred local physicians. This is an important consideration, but the policy statement emphasized that evolving evidence suggests that such centers should have mechanisms in place to ensure high quality care. In addition to emphasizing the current guideline classifications for PCI without on-site surgery, the AHA policy statement provided recommendations for states wishing to address the issue of PCI without on-site surgery through the regulation of legislation.

Mission Lifeline

The Mission Lifeline program developed in 2006 from a series of conferences sponsored by the AHA and has continued to mature (41–43). The goal of Mission Lifeline is to improve the quality of care and outcomes for patients with STEMI and to improve healthcare system readiness and response to STEMI. An important focus of Mission Lifeline is to increase the number of patients with timely access to primary PCI. Criteria for the structure and operation of a STEMI referral and STEMI-receiving hospitals are part of the Mission Lifeline initiative and apply to facilities without on-site surgery.

Door-to-Balloon Alliance

The Door-to-Balloon (D2B™) effort began in January 2006 when the ACC recognized the need to reduce D2B times for patients with STEMI. This led to the development of a national initiative to achieve D2B times $\leq$90 min for at least 75% of nontransfer primary PCI patients with STEMI in participating hospitals performing primary PCI. This alliance consists of a nationwide network of hospitals, physician champions and strategic partners committed to improving D2B times. Participation in the Alliance provides the necessary tools; information and support for helping hospitals achieve the D2B treatment goals and encourages the use of real-time performance feedback on D2B times to drive the quality improvement effort (44). The D2B program has been highly successful, having achieved its initial goals (45).

Access to Primary PCI in the United States

Data from the American Hospital Association and the 2000 US Census were used to estimate the proportion of the adult population ($\geq$18 years of age) who lived within 60 min of a PCI hospital (46). An estimated 79.0% lived within a 1 hour drive of a PCI hospital, with a median driving time of 11.3 min. Even among those living closer to non-PCI hospitals, 74% would experience $<$30 min of additional delay with a direct referral to a PCI hospital. Approximately 5 years later, Concannon et al., using similar data sources and methodology, showed that despite a 44% relative increase in the number of facilities capable of performing PCI, the number of adults within a 1 hour drive of a PCI facility increased to only 79.9%, with the median driving time reduced by $<$1 min to 10.5 min (47). Access in rural areas remained far less than in urban areas, with driving times reduced for only 9% of the population compared with the earlier survey. These findings mirrored a smaller experience in Michigan where expansion of primary PCI to 12 hospitals without on-site surgery increased access for only 4.8% of the population (48). Finally, Horwitz et al. showed that hospitals are more likely to introduce new invasive cardiac services when neighboring hospitals already offer such services and confirmed that the increase in the number of hospitals offering invasive cardiac services has not led to a corresponding increase in geographic access (49). In total, these data support the argument that the addition of more PCI centers has not substantially improved access to PCI services for most patients.

Financial Considerations for Facilities Providing PCI Without On-site Surgery

Medicare payments to hospitals for invasive cardiac procedures have generally remained favorable, although physician reimbursement has decreased. Per-case revenue margins for PCI are typically higher than the overall hospital operating margins, and PCI improves the hospital case mix index. PCI programs bring prestige to an institution, and STEMI is one of the most prestigious diseases for treatment (50,51). The push to develop rapid STEMI care has led many to currently advocate for EMS bypassing non-PCI hospitals; there is even consideration being given to triaging patients based on D2B metrics. Exclusion from providing STEMI care might be a lesser financial concern than the loss of downstream revenue from additional testing in patients suspected of having an acute coronary syndrome. This includes not only testing performed to exclude CAD as the cause of chest pain but also testing to evaluate noncardiac causes of chest pain.

Table 3. Facility Requirements for PCI Programs Without On-Site Surgery

General Recommendations	Source
Requisite support equipment must be available and in good working order to respond to emergency situations.	PCI-GL PCI-CS ML
Should demonstrate appropriate planning for program development and should complete both a primary PCI development program and an elective PCI development program. Program developments to include routine care process and case selection review.	AHA D2B
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services such as intensive care, advanced imaging (CT, MR and other vascular imaging), respiratory care, blood bank and nephrology consultation with access to dialysis.	PCI-GL, PCI-CS ECD
The institution should have systems for credentialing and governing the PCI program. On-site data collection, quality assessment, quality improvement and error management are essential. Each institution must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes. A quality improvement program should routinely 1) review quality and outcomes of the entire program; 2) review results of individual operators; 3) include risk adjustment; 4) provide peer review of difficult or complicated cases; and 5) perform random case reviews. The review process should assess the appropriateness of the interventional procedures. Evaluation should include the clinical indications for the procedure, technical performance and the quality and interpretation of the coronary angiograms.	PCI-CS, AHA, PCI-GL ECD
Written agreements for emergency transfer of patients to a facility with cardiac surgery must exist. Transport protocols should be tested a minimum of 2 times per year involving both the referring and receiving facility. Develop agreements with a ground or air ambulance service capable of advanced life support and IABP transfer that guarantees a transport vehicle will be on-site to begin transport in ≤30 min *and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery*. Tertiary facility must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery or intervention. *Tertiary centers should be able to establish cardiopulmonary bypass on emergency transfer patients within <120 min of an urgent referral.*	PCI-GL, AHA PCI-CS ECD *New*
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is highly recommended.	PCI-GL PCI-CS ML
Appropriate inventory of interventional equipment, including guide catheters, balloons and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. *Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve is required.* Rotational or other atherectomy devices and the treatment of CTOs should not be performed in facilities without on-site surgery.	PCI-GL, PCI-CS *New*
Meticulous clinical and angiographic selection criteria for PCI (Table 5).	PCI-GL, AHA
Participation in a national data registry, such as the ACC NCDR in the United States is required. This allows benchmarking, risk adjustment and facilitates outcomes analysis of local data.	PCI-GL ECD AHA
A program should be in place to track and ensure treatments with ACC/AHA guideline-based Class I therapies, both acutely and at discharge.	PCI-CS, ML
Full service laboratories (both primary and elective PCI, with and without on-site cardiac surgery) performing <200 cases annually must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. Both physicians and staff should have the opportunity to work at a high volume center to enhance their skills. The continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations should be questioned and any laboratory that cannot maintain satisfactory outcomes should be closed.	PCI-CS
Geographic isolation exists if the emergency transport time to another facility is >30 min.	*New*
Satisfactory outcomes should be defined by each local facility as part of their quality review process and should be based on national or regional benchmarks. Programs that fail to meet their established criteria for satisfactory performance for 2 consecutive quarters must undertake efforts to improve engaging outside experts if necessary. Failure to improve quality metrics should also be grounds for program closure regardless of the location.	ML PCI-CS D2B
As part of the local continuous quality improvement program, there should be a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of improvement opportunities.	PCI-GL

Continued on the next page

This can be an additional financial motivator for developing PCI facilities (52). How the further bundling of payments and reimbursements on a global or capitated basis by accountable care organizations (ACO) will affect PCI programs is unclear at this time, but given the concerns about the cost of healthcare, increases in payments are unlikely (53,54). However, even in an ACO environment, hospitals might benefit from keeping cardiovascular procedures in-house where they have the ability to control costs rather than transferring patients to tertiary hospitals.

The Volume-Outcome Relationship for PCI and the Certificate of Need

There are 26 states with Certificate of Need (CON) regulations for the development of cardiac catheterization laboratories, but the effect of such regulations is uncertain. Ho et al. found that the removal of state cardiac CON regulations was associated with an increase in the number of hospitals performing CABG and PCI, but the statewide number of procedures was unchanged. The average procedure volume per hospital for both CABG and PCI therefore declined (55). Despite this, they found no

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Table 3. Continued

STEMI Treatment Recommendations	
Each community should develop a STEMI system of care that follows standards at least as strong as those developed for Mission Lifeline, including: • Performance of primary PCI as the first-choice treatment for STEMI to ensure streamlined care paths and increased case volumes. • A process for prehospital identification and activation. • Protocols for triage, diagnosis and cardiac catheterization laboratory activation should be established within the primary PCI hospital/STEMI-Receiving Center. • A single activation phone call should alert the STEMI team. Criteria for EMS activation of the cardiac catheterization laboratory should be established in conjunction with EMS providers. • Transfer protocols for patients who arrive at STEMI referral centers who are in cardiogenic shock and/or are primary PCI candidates ineligible for fibrinolytic drugs.	2009 PCI-GL 2011 PCI-GL ML D2B
STEMI receiving centers should be available and on-call 24 hours/7 days a week (no diversion) to perform primary PCI. Primary PCI should not be performed at facilities unless it is provided on a 24/7 schedule.[a] The cardiac catheterization laboratory staff and interventional cardiologist should arrive within 30 min of a STEMI activation call. Facilities should have a plan for triage and treatment of simultaneous presentation of STEMI patients.	PCI-GL, AHA ML
STEMI receiving centers should perform a minimum of 36 primary PCI procedures annually, and these procedures should ideally be performed at facilities that perform a minimum of 200 total PCI procedures annually.	PCI-GL PCI-CS ML
Facilities performing only primary PCI should perform a minimum of 36 primary PCIs annually and work in collaboration with a high volume PCI facility to ensure good outcomes	PCI-GL PCI-CS
There should be a recognized STEMI-Receiving Center liaison/system coordinator to the system and a recognized physician champion.	ML
The STEMI-Receiving Centers should participate in the Mission Lifeline-approved data collection tool, ACTION Registry-Get with the Guidelines™.	ML D2B
They should also participate in the regional Mission Lifeline Stakeholder group (if available) to contribute to the development of a regional STEMI System of Care Plan	ML
Monthly multidisciplinary team meetings to evaluate outcomes and quality improvement data. Operational issues should be reviewed, problems identified, and solutions implemented. The following measurements should be evaluated on an ongoing basis: a. Door-to-first device time, nontransfer patients b. STEMI Referral Hospital ED door-to-balloon (first device used) time c. First medical contact to balloon inflation (first device used) time, nontransfer patients d. First medical contact to balloon inflation (first device used) time, transfer patients e. Proportion of eligible patients receiving reperfusion therapy f. Proportion of eligible patients administered guideline-based class I therapies g. Proportion of patients with field diagnosis of STEMI and activation of the Cardiac Catheterization Laboratory for intended primary PCI who i. do not undergo acute catheterization because of misdiagnosis ii. undergo acute catheterization and found to have no elevation in cardiac biomarkers and no revascularization in the first 24 h h. In-hospital mortality	ML

Italics font: New or modified recommendation in the document.

[a]Required for U.S. facilities but might not be possible for all facilities worldwide.

ACC, American College of Cardiology; AHA, American Heart Association policy statement; CT, computed tomography; CTO, chronic total occlusion; D2B, Door-to-Balloon Alliance; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; EMS, emergency medical systems; GL, Guidelines; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; ML, Mission Lifeline; MR, magnetic resonance; New, New recommendation in this document; NCDR, National Cardiovascular Data Registry; PCI-CS, 2013 PCI Competency Statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and STEMI, ST-segment elevation myocardial infarction.

evidence that CON regulations lowered procedural mortality rates for CABG or PCI. In other studies, CON regulation of cardiac catheterization was associated with care that was judged more appropriate, whereas the removal of CON regulation of cardiac surgery has been associated with an increase in low-volume cardiac surgical centers and increased mortality (56,57). Concerns have been raised that the proliferation of small centers performing complex procedures that have a small but definite risk of important complications might dilute the ability to provide efficient high quality service (52,58). Reduced mortality has been associated with an increased volume of primary PCI procedures in centers, higher volume operators, total volume of PCIs in centers, and the commitment of a center to provide PCI rather than fibrinolytic therapy (59–63). Lieu et al. reported that redundant or low-volume primary PCI programs were cost ineffective (64). Elective PCI at centers without on-site surgery was more expensive than PCI at centers with on-site surgery in one case-matched study (65). In addition, the high fixed costs of a cardiac surgery program in the face of decreasing surgical volumes is leading to the consolidation of numerous smaller surgery programs, depriving some PCI programs of surgical backup.

The issue of a PCI volume-outcome relationship was extensively reviewed in the 2013 PCI Competency document for centers with and without on-site surgery and for primary and elective PCI (4). The document concluded that in the current era, volume-outcome relationships are not as robust as in the past when balloon angioplasty was the only treatment modality. However, an institutional volume threshold of <200 PCIs annually appeared to be

consistently associated with worse outcomes. Primary PCI volume ≤ the guideline-recommended minimum of 36 annually was associated with worse in-hospital mortality in a recent series of over 86,000 patients in the NCDR (66). The cutoff points of <200 total PCIs annually and ≤36 primary PCIs annually has important implications because 26% of the PCI facilities submitting data to the NCDR performed ≤200 total PCIs annually and 38% performed ≤36 primary PCIs annually (8,66). Recent data suggested a modest volume-outcome relationship for variables other than mortality, but these data have limitations and are not consistent across all studies (4). Although there was an association between annual PCI volumes <200 and worse outcomes, there was no association between higher annual hospital volumes and improved outcomes at higher volume PCI centers. There was less evidence to support a threshold for individual operator volume for both elective and primary PCI.

Recommendations

We have provided recommendations for PCI without on-site surgery that are a composite of recommendations from the 2007 SCAI Expert Consensus Statement, the 2011 PCI guidelines, the 2012 Expert Consensus Document on Cardiac Catheterization Laboratory Standards, the 2013 PCI Competency statement and recommendations from the policy statement of the American Heart Association and requirements for the Mission Lifeline program and D2B Alliance (1–4,40,43,44). Redundant recommendations from these documents were consolidated, and the writing committee included several new recommendations consistent with evolving practice standards.

Facility Requirements for PCI Programs Without On-Site Surgery

Facility requirements are similar to those presented in past documents but now include a greater emphasis on the presence of quality review programs for facilities and operators, as described in the 2013 PCI competency document (4) (Table 3). Diagnostic modalities such as IVUS and especially fractional flow reserve previously considered desirable for facilities without on-site surgery have now increased in importance and are necessary for all PCI centers.

The 2013 PCI Competency Document identified a signal suggesting that an institutional volume threshold of <200 PCIs/year was associated with worse outcomes. Therefore, the 2013 Competency Document recommended that the continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations be questioned and that any laboratory that cannot maintain satisfactory outcomes should be closed. Past documents have not specified any criteria for geographic isolation. The writing committee suggests it be defined not by distance but by the time required for emergency transport of a STEMI patient to another facility. Hospitals justify the creation of new PCI centers without on-site surgery by stating that they improve access for geographically under-served populations and allow patients to be cared for in close geographic proximity to their own families and physicians. However, multiple low-volume and partial-service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access (46–49). If the transfer time is ≤30 min, it is reasonable

Table 4. Personnel Requirements for PCI Programs Without On-Site Surgery

Personnel Recommendations	Source
Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.	PCI GL PCI-CS
Coronary care unit nursing staff must be experienced and comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, management of IABP, *management of in-dwelling arterial/venous sheaths and identifying potential complications such as abrupt closure, recurrent ischemia and access site complications.*	PCI-GL PCI-CS *New*
Personnel should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.	PCI-GL
Operators should have ABIM board certification in interventional cardiology and maintain certification, with the exception of operators who have gone through equivalent training outside the United States and are ineligible for ABIM certification and recertification exams.	PCI CS
Interventional cardiologists should perform a minimum of 50 coronary interventional procedures per year (averaged over a 2-year period) to maintain competency.	PCI-CS
Primary PCI should be performed by experienced operators who perform a minimum of 50 elective PCI procedures per year and, ideally, at least 11 primary PCI procedures per year. Ideally, these procedures should be performed in institutions that perform more than 200 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.	PCI-CS ML
Facilities should develop internal review processes to assess operators performing <50 PCIs annually. Individual operator level volume is one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, individual operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance.	PCI-CS
It is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by existing physicians until it is determined their skills, judgment and outcomes are acceptable.	*New*

Italics font: New or modified recommendation in the document.
ABIM, American Board of Internal Medicine; ML, Mission Lifeline; PCI-CS, 2013 PCI Competency Statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; IABP, intra-aortic balloon pump; New, new recommendation in this document; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

Attachment D
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to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital. For transport times longer than 30 min, performing PCI on-site is likely to be quicker than a transfer. The development of PCI facilities within a 30-min emergency transfer time to an established facility is therefore strongly discouraged.

What constitutes a reasonable transport time for a patient requiring emergency surgery has not been consistently addressed in prior documents. Both CPORT-E and MASS-COMM studies provide guidance contained in their on-line supplementary materials (9,11). Both require a transport vehicle to be available to begin transport within 30 min and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery. MASS-COMM further recommends that surgical intervention begin within 120 min. Given the existing data on the distribution of PCI facilities in the US, the performance of elective PCI at facilities that cannot meet these transfer times is discouraged (46,47).

The 2013 PCI competency document also states that any laboratory that cannot maintain satisfactory outcomes should be closed; however, there is currently no national definition for "satisfactory outcomes". The writing committee recommends that these be defined by each PCI center, including those with on-site surgery, as part of their quality review process, using national benchmark

Table 5. Recommendations for Off-Site Surgical Backup and Case Selection

Recommendations—Cardiologist–Cardiac Surgeon Interactions	Source
Interventional cardiologists must establish a working relationship with cardiac surgeons at the receiving facility.	PCI-GL ECD
Cardiac surgeons should have privileges at the referring facility to allow review of treatment options as time allows.	PCI-GL ECD
Ideally, face-to-face meetings between cardiothoracic surgeons and cardiologists involved should occur on a regular basis *(Heart Team approach) especially for the discussion of management of patients undergoing nonprimary PCI who have left main, three-vessel CAD or two-vessel CAD with involvement of the LAD or comorbidities such as diabetes, depressed LV function or complex anatomy.*	PCI-GL ECD *New*
Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.	PCI-GL ECD
Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should not be done at that time.	PCI-GL ECD
Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.	PCI-GL ECD
Interventional cardiologist should be familiar with and have immediate access to appropriate life support devices, such an intraaortic balloon pumps, and should be qualified for handling emergencies such as pericardial tamponade and embolization.	PCI-GL ECD
Hospital administrations from both facilities endorse the transfer agreement.	PCI-GL ECD
Transferring physicians obtain consent for surgery from patients or appropriate surrogates.	PCI-GL ECD
Initial informed consent for PCI discloses that the procedure is being performed without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery and state that a written plan for transfer exists. *Consent for PCI should be obtained before the procedure and before any sedatives are given. Consent for PCI obtained while the patient is on the table is not informed consent and is unacceptable in non-emergency situations.*	PCI-GL ECD *New*
Recommendations—Case Selection and Management	
Avoid intervention in patients with: • >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired. • Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography. • Lesions in areas other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms). • Lesions with TIMI flow grade 3 in patients with left main or three-vessel disease where bypass surgery is likely a superior revascularization strategy compared with PCI. • Culprit lesions in more distal branches that jeopardize only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention. • *Chronic total occlusion.* *The management of patients with STEMI resuscitated from sudden cardiac death is complex, and decisions about the need for immediate PCI with or without therapeutic hypothermia or possible transfer to a tertiary facility for treatment should be individualized.*	PCI-GL ECD *New*
Emergency transfer for coronary bypass surgery patients with • High-grade left main or three-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support. • Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer.	PCI-GL ECD

Italics font: New or modified recommendation in the document.

CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; IABP, intraaortic balloon pump; LV, left ventricle; New, new recommendation in this document; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction.

Table 6. Patient and Lesion Characteristics That Could Be Unsuitable for Nonemergency Procedures at Facilities Without On-Site Cardiac Surgery

High-risk patients	Source
• Decompensated congestive heart failure (Killip Class ≥3) without evidence for active ischemia.	PCI-GL
• Recent (<8 weeks) cerebrovascular accident.	AHA
• Advanced malignancy.	ECD
• Known clotting disorders.	
• LVEF ≤30%.	
• Chronic kidney disease (creatinine >2.0 mg/dL or creatinine clearance <60 mL/min).	
• Serious ongoing ventricular arrhythmias.	
• Patients with left main stenosis (>50% diameter) or three-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal or mid segments of all major epicardial coronary arteries), treatment of any or all stenoses. Scoring systems, such as SYNTAX, may be useful in defining the extent of disease and type of revascularization procedure.	
• Patients with a single-target lesion that jeopardizes an extensive amount of myocardium.	
• Patients undergoing intervention on the last remaining conduit to the heart.	
High-risk lesions	
• Unprotected left main stenosis.	PCI-GL
• Diffuse disease (>20 mm in length).	
• Extremely angulated segment (>90%) or excessive proximal or in-lesion tortuosity.	ECD
• More than moderate calcification of a stenosis or proximal segment	*New*
• Inability to protect major side branches.	
• Degenerated older vein grafts with friable lesions.	
• Substantial thrombus in the vessel or at the lesion site.	
• Any other feature that could, in the operator's judgment, impede successful stent deployment.	
• Anticipated need for rotational or other atherectomy device, cutting balloon or laser.	
The characteristics listed above identify high-risk patient and lesion features but are not absolute contraindications to performing PCI at a facility without on-site surgery. For example, an elevated creatinine level increases the procedure risk for the patient, but this is not unique to facilities without on-site surgery and treatments to mitigate this complication can be used at all facilities. Ultimately, the operator should consider all factors and make a decision about the suitability of the patient for PCI at the facility.	*New*
Strategy for surgical backup based on lesion and patient risk	
• High-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery.	PCI-GL
• High-risk patients with nonhigh-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.	
• Non-high-risk patients with high-risk lesions require no additional precautions.	
• Non-high-risk patients with nonhigh-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery.	

Italics font: New or modified recommendation in the document.
CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; LVEF, left ventricular ejection fraction; New, new recommendation; PCI, percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery.

data. Programs failing to meet established criteria for satisfactory performance for two consecutive quarters must undertake efforts to improve their performance, engaging outside experts if necessary. Failure to improve quality metrics should lead to program closure regardless of the location. To ensure proper assessment and monitoring, laboratories are required to submit data to a national data registry, have regular meetings to discuss key performance metrics and develop plans for the correction of any deficiencies. Especially with facility PCI volumes decreasing, it becomes increasingly difficult to determine whether there are significant differences in the data reports from year to year. For example, to detect (with statistical certainty) a doubling of in-hospital mortality from 1% to 2% at a hospital with an annual case volume of 200 PCIs, nearly 4 years of continuous data collection would be required. This does not negate the importance of data submission to a national registry that can help identify trends, but it emphasizes why these same data must be carefully evaluated and adjudicated at the local facility. The importance of unbiased local or external peer review cannot be overemphasized (67,68). Implementation of the SCAI Quality Toolkit and certification by Accreditation for Cardiovascular Excellence (ACE) are recommended as resources for improving quality (69,70).

Personnel Requirements for PCI Programs Without On-Site Surgery

Recognizing the potential for isolation and the advantage of clinical experience, the 2007 SCAI Expert Consensus Document included a recommendation that operators at PCI programs without on-site surgery perform at least 100 total and 18 primary PCIs annually, a recommendation that might not be achievable in the current environment. The 2013 PCI Competency Document moves away from strict volume requirements to focus more on achieving quality metrics for facilities and individual operators. As noted earlier, the 2013 Competency document recommended that operators perform a minimum of 50 PCIs annually (averaged over 2 years), including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200

total and >36 primary PCI procedures annually (Table 4). Again acknowledging the importance of experience, the 2007 SCAI Expert Consensus Document suggested that initial operators at a new program without on-site surgery should have a lifetime experience of >500 PCIs as primary operator after completing a fellowship. In the current environment of decreasing PCI volumes and in view of the recommendations of the 2013 PCI competence document, this number would be difficult to achieve. Nevertheless, it is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by more experienced physicians until it is determined that the skills, judgment and outcomes of these new cardiologists are acceptable.

Requirements for Off-Site Surgical Backup

Recommendations for the interactions between cardiologists and cardiac surgeons are listed in Table 5. A limitation of programs performing PCI without on-site surgery is the lack of on-site access to a cardiac surgeon for consultation about revascularization options. This makes the concept of a Heart Team consultation more difficult to achieve and could necessitate performing only diagnostic catheterization until a case review with a cardiac surgeon can be performed. The application of telemedicine consultations with a heart surgeon could facilitate these interactions. In reality, many of the nonemergency patients who merit discussion by a Heart Team are not optimal candidates for PCI at facilities without on-site cardiac surgery. It is important to emphasize that the role of the cardiac surgeon is not confined to the treatment of PCI complications but includes the participation in decisions about revascularization options. Recommendations for case selection at facilities without on-site surgery are shown in Table 5, and criteria for identifying high-risk lesions and patients are contained in Table 6. There are statistical models for identifying PCI patients at higher risk for mortality or emergency CABG that could be helpful for identifying patients who should not undergo PCI at facilities without on-site surgery (18,71). However, these models have not been tested or applied on a large scale to determine the advisability of performing a PCI at facilities without on-site surgery.

The Delivery of PCI Services in the Future

As a result of the additional randomized studies on PCI without on-site surgery and the recent change in guideline recommendations, the performance of PCI without on-site surgery in the US has gained greater acceptance, and questions about its safety in the presence of a proven, well defined, and protocol driven approach have diminished. PCI programs should be evaluated based on their ability to: (a) sustain adequate quality metrics, (b) provide access to elective and emergency PCI procedures that would otherwise be unavailable in their service area, and (c) maintain the operator and institutional volumes recommended in the 2013 PCI Competency Document. For the future, the focus must now shift to developing a rational plan for the distribution of PCI services. Small PCI programs with large fixed costs are inefficient and unnecessary if they do not improve access in areas of need. However, it is unlikely that issues of system-wide efficiency will be addressed without central planning on the state or federal level. This writing group reaffirms the statement from the 2011 ACCF/AHA/SCAI PCI Guidelines that "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery" and suggests that new programs offering PCI without on-site surgery are inappropriate unless they clearly serve geographically isolated populations. The writing group recognizes the need for ongoing study and surveillance of all PCI programs through participation in national databases encourages public reporting of their results and acknowledges that further declines in PCI volumes might necessitate the closure of PCI programs in the future.

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Key Words: ACC Clinical Expert Consensus Document ■ angioplasty ■ consensus ■ coronary artery bypass surgery.

Appendix 1. Author Relationships With Industry and Other Entities (Relevant)—SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
James C. Blankenship	Geisinger Medical Center—Director, Cardiac Catheterization Laboratory	None	None	None	• Abiomed* • AstraZeneca* • Boston Scientific* • Kai Pharmaceutical* • Novartis* • Schering Plough • The Medicines Company* • Volcano*	• SCAI—Vice President*	None
Mehmet Cilingiroglu	Arkansas Heart Hospital	None	None	None	None	None	None
Greg J. Dehmer (Chair)	Texas A&M College of Medicine, Scott & White Clinic Cardiology Division—Professor of Medicine; Director of Cardiology	None	None	None	None	None	None
James G. Dwyer	Heart and Vascular Center of Northern Arizona	None	None	None	None	None	None
Dmitriy N. Feldman	New York Presbyterian Hospital/Cornell	• Gilead • Maquet	• Abbott Vascular • Bristol-Myers Squibb* • Daiichi-Sankyo • Eli Lilly • Pfizer • The Medicines Company*	None	None	None	None
Timothy J. Gardner	Christiana Care Health System—Medical Director	None	None	None	None	None	None
Cindy L. Grines	Harper University Hospital—Vice President	• Abbott Vascular • Bristol-Myers Squibb • Lilly USA • Merck • The Medicines Company • Volcano*	None	None	None	• *Journal of Interventional Cardiology*†	None
Mandeep Singh	Mayo Clinic	None	None	None	None	None	None

This table represents all healthcare relationships of committee members with industry and other entities that were reported by authors, including those not deemed to be relevant to this document, at the time this document was under development. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx for definitions of disclosure categories or additional information about the ACCF Disclosure Policy for Writing Committees.

*No financial benefit.

†Significant relationship.

ACC indicates American College of Cardiology; AMA, American Medical Association; FDA, U.S. Food and Drug Administration; NHLBI, National Heart, Lung, and Blood Institute; SCAI, Society for Cardiovascular Angiography and Interventions.

Attachment D
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Appendix 2. Peer Reviewer Relationships With Industry and Other Entities (Relevant)—SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Peer Reviewer	Representation	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Eric R. Bates	Content Reviewer—AHA and Content Reviewer—ACCF/AHA/SCAI PCI Guideline	University of Michigan Hospitals and Health Centers—Professor of Medicine	• AstraZeneca • BMS • Daiichi-Sankyo • Eli Lilly • Merck/ Schering-Plough • Sanofi-aventis	None	None	None	None	None
Ashequl M. Islam	Official Reviewer—SCAI	Baystate Medical Center—Program Director, Interventional Cardiology Fellowship	• Edwards Lifesciences	• Daiichi-Sankyo • Eli Lilly	None	None	None	None
Hani Jneid	Official Reviewer—ACCF Task Force on Clinical Expert Consensus Documents	Baylor College of Medicine - MEDVAMC—Associate Professor of Medicine	None	None	None	None	None	None
Steven P. Marso	Official Reviewer—SCAI	Saint Luke's Mid America Heart Institute; University of Missouri-Kansas City—Professor of Medicine	None	None	None	None	• Amylin* • St. Jude Medical* • Terumo Medical* • The Medicines Company* • Volcano Corporation*	None
Laura Mauri	Official Reviewer—AHA	Harvard Medical School—Associate Professor of Medicine; Brigham & Women's Hospital	• Medtronic • St. Jude Medical	None	None	• Abbott Vascular* • Boston Scientific* • Bristol-Myers Squibb* • Cordis Corporation* • Daiichi-Sankyo* • Eli Lilly* • Medtronic* • Sanofi-aventis*	None	None
Srinivas Murali	Official Reviewer—ACC Board of Governors	Allegheny General Hospital—Director, Division of Cardiovascular Medicine	• Advisory Board • Actelion • Gilead Pharma	• Actelion	None	• Gilead Pharma • St. Jude Medical	None	None
Barry Uretsky	Official Reviewer—SCAI	University of Arkansas for Medical Sciences—Clinical Professor of Medicine	None	None	None	• St. Jude Medical*	None	None
Howard Walpole	Official Reviewer—ACCF Board of Trustees	Okyanos Heart Institute—Chief Medical Officer	None	None	None	None	None	None
Thomas M. Bashore	Content Reviewer—ACCF/AHA/SCAI Clinical Competence Statement on CIP	Duke University Medical Center—Professor of Medicine; Clinical Chief, Division of Cardiology	None	None	None	None	None	None

Continued on the next page

Appendix 2. Continued

Peer Reviewer	Representation	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
James A. Burke	Content Reviewer—ACCF Interventional Section Leadership Council	Lehigh Valley Heart Specialists—Associate Chief of Cardiology	None	None	None	None	None	None
John G. Byrne	Content Reviewer—ACCF Interventional Section Leadership Council	Brigham & Women's Hospital—Chief, Division of Cardiac Surgery; Harvard Medical School—Professor	None	None	None	None	None	None
Joaquin E. Cigarroa	Content Reviewer—ACCF Interventional Section Leadership Council and ACCF/AHA CABG Guideline	Oregon Health & Science University—Associate Professor of Medicine	None	None	None	None	• Catheterization and Cardiovascular Intervention† • Portland Metro Area AHA†	None
Frederick E. Grover	Content Reviewer—ACCF Surgeons Section Leadership Council	University of Colorado—Professor and Chair, Department of Surgery	• Somahlution†	None	None	None	None	None
Maureen B. Julien	Content Reviewer—ACCF Interventional Section Leadership Council	Hospital of the University of Pennsylvania—Nurse Practitioner	None	None	None	None	None	None
Glenn N. Levine	Content Reviewer—ACCF/AHA/SCAI PCI Guideline and ACCF/AHA/SCAI Clinical Competence Statement on CIP	Baylor College of Medicine—Professor of Medicine	None	None	None	None	None	None
Pasala S. Ravichandran	Content Reviewer—ACCF Surgeons Section Leadership Council	Oregon Health & Science University—Associate Professor	None	None	None	None	None	None
Sidney C. Smith, Jr.	Content Reviewer—ACCF Individual	Center for Cardiovascular Science and Medicine—Professor of Medicine; Director	None	None	None	None	None	None

This table represents the relationships of reviewers with industry and other entities that were disclosed at the time of peer review and determined to be relevant. It does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review.

According to the ACCF/AHA, a person has a *relevant* relationship IF: a) The *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or b) The *company/entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in the *document*, or makes a competing drug or device addressed in the *document*; or c) The *person or a member of the person's household*, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the *document*.

*Significant relationship.

†No financial benefit.

ACCF indicates American College of Cardiology; AHA, American Heart Association; CABG, Coronary Artery Bypass Graft Surgery; CIP, Coronary Interventional Procedures; PCI, Percutaneous Coronary Intervention; SCAI, Society of Cardiovascular Angiography & Interventions.