

Expanding Coverage for Cardiovascular Procedures in the Ambulatory Surgery Center

Modernizing ASC Policy



National Cardiovascular Partners

Participants

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About NCP

- National Cardiovascular Partners creates, sustains and grows **independent, outpatient cardiac catheterization and vascular labs** in unique business partnerships with physicians.
- NCP has partnered with over 300 physicians in 21 outpatient cardiac catheterization & vascular labs in Texas, Arizona, California, Louisiana and Kansas.
- NCP physician partners have performed over 100,000 outpatient cases

CMS should expand access to ASCs for Medicare beneficiaries needing certain cardiac procedures

Objective: Expanding the range of endovascular cardiology procedures that are covered and paid in the ASC to create a seamless site of service for diagnosis and treatment consistent with care for many commercially insured patients.

Why? Expanded access is good for patients:

- Procedures performed in an ASC are less expensive and a single point of service is more convenient for patients
- Modernizing the coverage and payment rules will bring Medicare up to date with commercial payers

How? NCP recommendations include:

- Broaden the definition of surgical procedure
 - Create consistency among endovascular procedure on the CPL
- Adding a number of diagnostic and interventional procedures to the ASC payment list
 - Supported by claim analysis
- Minor changes in ASC methodology to align with OPPS

CPT groupings are too limiting and have resulted in outdated payment policies that do not reflect changes in technology

- Since the CY 2008 Final Rule was published, access to cardiac catheterization (specifically PCI) in sites without on-site surgery has increased dramatically
- Clinical guidelines support performing most procedures in an ASC-like (non-hospital) setting*

Change in the availability of PCI without on site surgery	2007	2013
States allowing both primary and elective allowed	28	45
States allowing primary PCI only	12	4
Not allowed	10	1

JACC Vol. 63, No.23 2014

- The American Medical Association has also recognized the limits of the CPT groupings in defining “surgery”

“[T]he listing of a service or procedure in a specific section of the book should not be interpreted as strictly classifying the service or procedure as ‘surgery’ or ‘not surgery’ for insurance purposes. The placement of a given service in a specific section of the book may reflect historical or other considerations (e.g., **placement of the percutaneous peripheral vascular endovascular interventions in the Surgery/Cardiovascular System section, while the percutaneous coronary interventions appear in the Medicine/Cardiovascular section**).” CPT 2017 Professional Edition, American Medical Association, 2017, xii

CMS has broad authority to modernize payment policies by expanding the ASC covered procedures list to reflect advances in treatment and technology

CMS has requested feedback regarding “additional criteria we might use to consider when a procedure that is surgery-like could be included on the ASC CPL.” 82 FR 33655

- NCP supports CMS proposal to use the CPT surgical range of codes “as a guide rather than a requirement.”
- This approach should prioritize addressing inconsistencies in coverage of clinically similar procedures.
 - For example, the current definition excludes many cardiac catheterization procedures while similar procedures on peripheral vessels are included. In both cases, endovascular techniques are used to diagnose and treat, including the use of stents, damaged or diseased vessels.

This approach is also consistent with the American Medical Association, which included in the 2017 CPT Professional Edition:

“[T]he listing of a service or procedure in a specific section of the book should not be interpreted as strictly classifying the service or procedure as ‘surgery’ or ‘not surgery’ for insurance purposes. The placement of a given service in a specific section of the book may reflect historical or other considerations (e.g., ***placement of the percutaneous peripheral vascular endovascular interventions in the Surgery/Cardiovascular System section, while the percutaneous coronary interventions appear in the Medicine/Cardiovascular section***).” CPT 2017 Professional Edition, American Medical Association, 2017, xii



NCP Recommendations



NCP recommendations for ASC coverage and payment

Coverage and payment for the codes identified on the following pages would provide a more seamless point of service for diagnosis and treatment of certain cardiac conditions, would reflect recent clinical advancements, and would better align Medicare with commercial payers.

NCP recommends:

1. **Add to the ASC CPL major diagnostic and interventional cardiac catheterization procedures that are safe when performed in the HOPD**
 - Claims analysis shows little evidence of hospital admission, emergency room visit, or death. Recent clinical guidelines support provision of these services in non hospital settings for appropriate patients (Attachment A & B)
 - Clinically similar procedures are already payable when performed in the ASC (Attachment C)
2. Add to the ASC CPL certain cardiac catheterization procedures that are allowed in the physician office and the HOPD, but more frequently performed in the HOPD.
 - Attachment D
3. Separately pay for procedures currently packaged in the ASC but performed frequently without another major procedure, OR create a “conditional packaging” policy for ASCs consistent with the current OPPS policy to allow for reimbursement for procedures that are performed more than half the time without another major procedure.
 - Separate payment for procedures packaged in the ASC, but separately payable in both the physician office and OPPS (conditionally packaged). Claims analysis suggests these procedures are performed more than half the time in the OPPS without another major procedure (Attachment E)
4. Coverage for procedures allowed in both the OPPS and physician office, but are performed a majority of the time in the physician office.
 - Payment based on the MPFS rate (attachment F)

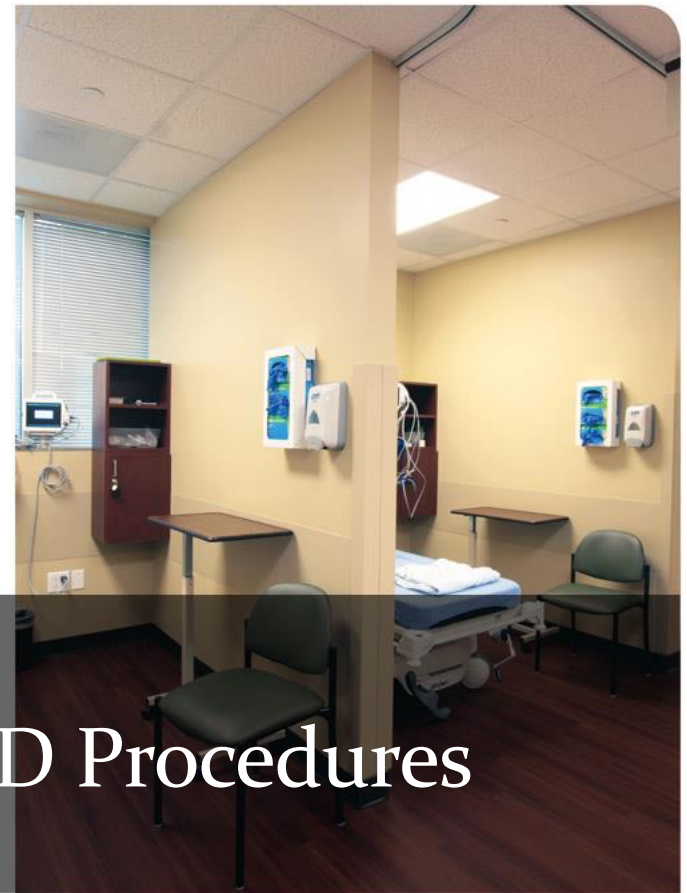
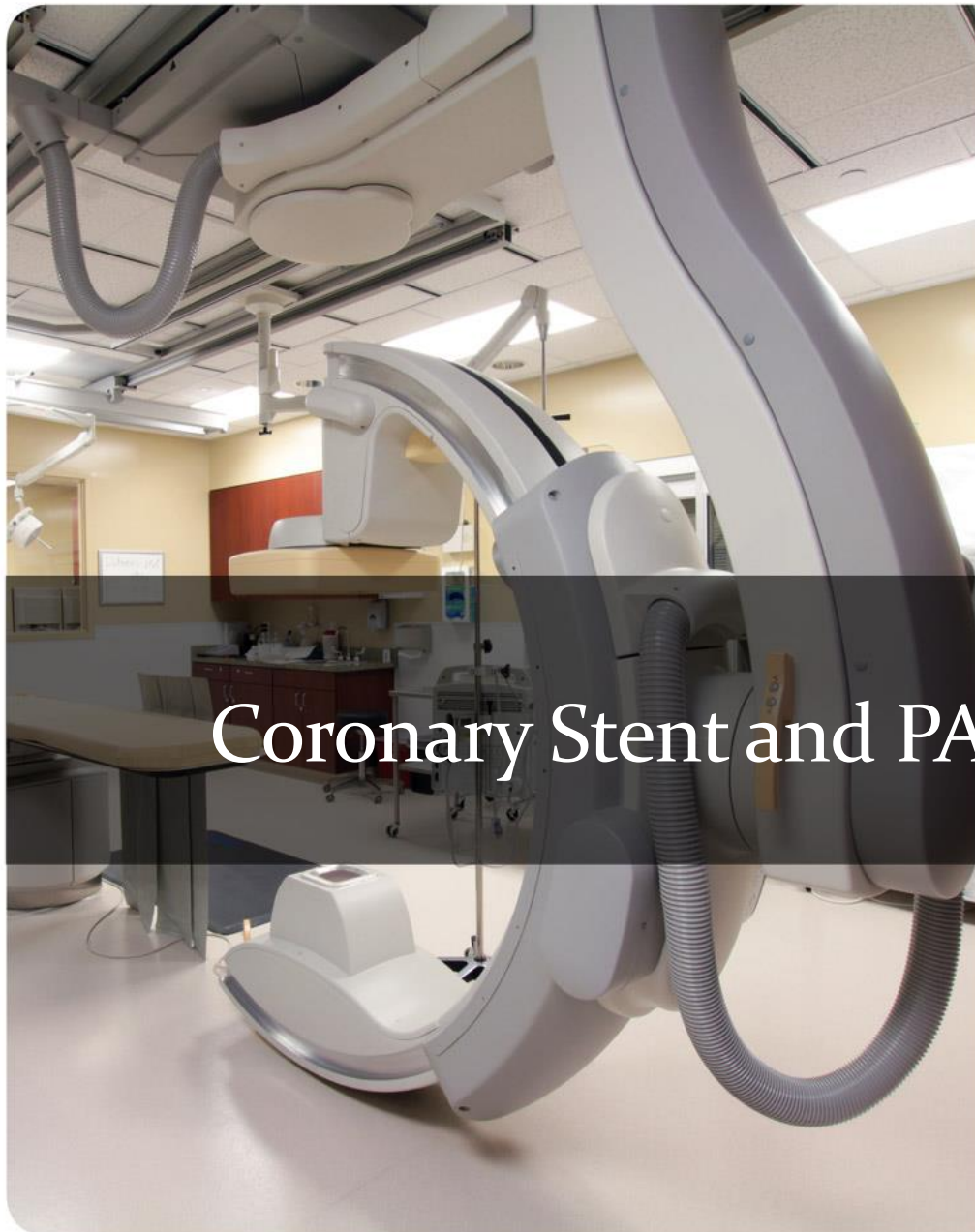
1. Add to the ASC CPL major diagnostic and interventional cardiac catheterization procedures that are safe when performed in the HOPD

NCP proposes 20 interventional, including PCI, and 10 diagnostic cardiac catheterizations procedures for addition to the ASC CPL (see attachment A & B).

- When these procedures are performed in the HOPD, there is very little evidence of hospital admission, emergency room visit, or death. ***They are “safe” when performed in the OPPS***
- Recent clinical guidelines support provision of these services in non-hospital settings except for high risk patients at the physician’s discretion

Claims data for PCI (See attachment A for full analysis)

HCPCS	Description	# procedures in 2016	# procedures in 2015	Resulted in inpatient admission within 1 day	ER visit within 1 day	Mortality within 30 days
C9600	Percutaneous transcatheter placement of a drug eluting intracoronary stent(s) with coronary angioplasty when performed; single major coronary artery or branch	106,128	107,316	1.9%	2.3%	0.4%
92928	Perc transcatheter placement of intracoronary stent; single major coronary artery or branch	12,616	17,533	2.5%	2.6%	0.8%



Coronary Stent and PAD Procedures



NCP has established admission criteria and a screening process that promotes safe and effective patient care in the outpatient setting

Patient Selection

Admission Criteria	Contraindications
<ul style="list-style-type: none">• Physician's order for the procedure with a provisional diagnosis• History and Physical performed within the last 30 days• Patient must be 18 years of age or older• Diagnostic test results, as required. (Must be within 30 days of procedure)• ASA Classification documented. (ASA 1, 2 or 3) *• Patient must demonstrate ability to use judgement and follow instructions• A responsible adult must be available to accompany patient	<ul style="list-style-type: none">• Creatinine > 2.0 (unless on Dialysis)• Potassium > 5.8 (unless on Dialysis)• Weight > 450 lbs• Hemoglobin < 8.0 (unless chronic anemia)• INR > 1.8• Active, untreated infection• Hx of Anaphylactic shock with Iodine exposure• Unable to lie flat due to Hypoxia• Type C Lesions• Unprotected Left Main• Acute Coronary Syndrome

**American Society of Anesthesiologists Patient Classification*

Appropriateness of Care

<ul style="list-style-type: none">• Outcomes Metrics<ul style="list-style-type: none">– Coronary Normal Rate– PAD Pre-Procedure Testing• Peer Review• Credentialing process	<ul style="list-style-type: none">• Internal Governance<ul style="list-style-type: none">– Medical Advisory Committee Review– Governing Body Review• Physician Executive Council
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NCP's PCI experience is consistent with published studies

Adverse event and complication rates are low, and PCI in an ASC setting is safe and convenient for patients.

	2013	2014	2015	2016	2017	Total
Left Heart Cath (LHC) Procedures Performed	5775	5930	6071	6526	6988	31,290
Percutaneous Coronary Intervention (PCI) Procedures Performed	643	728	650	675	854	3550
% of PCI Procedures	11.1%	12.3%	10.7%	10.3%	12.2%	11.3%
Complication Rate	0.3%	0.8%	0.9%	0.3%	0.8%	0.6%

NCP data shows that catheterization procedures are not over utilized in the ASC setting compared to the HOPD

Normal Rate (Benchmark: 30%)		
2012	2,713 Patients	30%
2013	3,751 Patients	26%
2014	5,519 Patients	23%
2015	5,669 Patients	24%
2016	6,526 Patients	27%
2017	6,988 Patients	28%

In the ACC-NCDR (Registry), the proportion of patients undergoing elective diagnostic catheterization who were found to have minimal obstructive disease (<20% stenosis) was 39.2%. (Patel, M.R., N Engl J Med 362:886–895).

2017 Normal Rate	
January	25.2%
February	29.3%
March	26.6%
April	27.4%
May	24.2%
June	28.6%
July	29.7%
August	27.7%
September	25.9%
October	27.7%
November	28.5%
December	28.2%



Cardiac catheterization procedures, including PCI, can be safely performed in an ASC (Resources, staff and equipment)



Dallas, TX

- Staff to patient ratio 1:2
- Medication reconciliation
- Lower cost
- Lower complication rate
- Better clinical outcomes

- Fixed Angio Suite
- Hemodynamic Monitoring
- Control Room
- Hospital Standards
- Physician Friendly Set-up



Cardiac catheterization procedures, including PCI, can be safely performed in an ASC (Resources, staff and equipment)

Tyler, TX



Medicare Health and Safety Requirements

Required Standards	ASCs	HOPDs	NCP
Compliance with State licensure law	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Governing body and management	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Surgical services	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Quality assessment and performance improvement	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Environment	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Medical staff	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Nursing services	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Medical records	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Pharmaceutical services	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Laboratory and radiologic services	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Patient rights	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Infection control	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Patient admission, assessment and discharge	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Source: 42 CFR 416 & 428

The Joint Commission Commitment to Safety and Quality

Phoenix ASC, LP
Cardiac Surgery Center of Phoenix
Phoenix, AZ

has been Accredited by



The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the
Ambulatory Health Care Accreditation Program

December 13, 2016

Accreditation is customarily valid for up to 36 months.


Craig L. Jones, FACHE
Chair, Board of Commissioners

ID #592230
Print/Reprint Date: 12/15/2016


Mark R. Chassin, MD, FACP, MPP, MPH
President

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While clinical outcomes are consistent with hospital facilities, patient satisfaction surveys suggests patients prefer the ASC setting

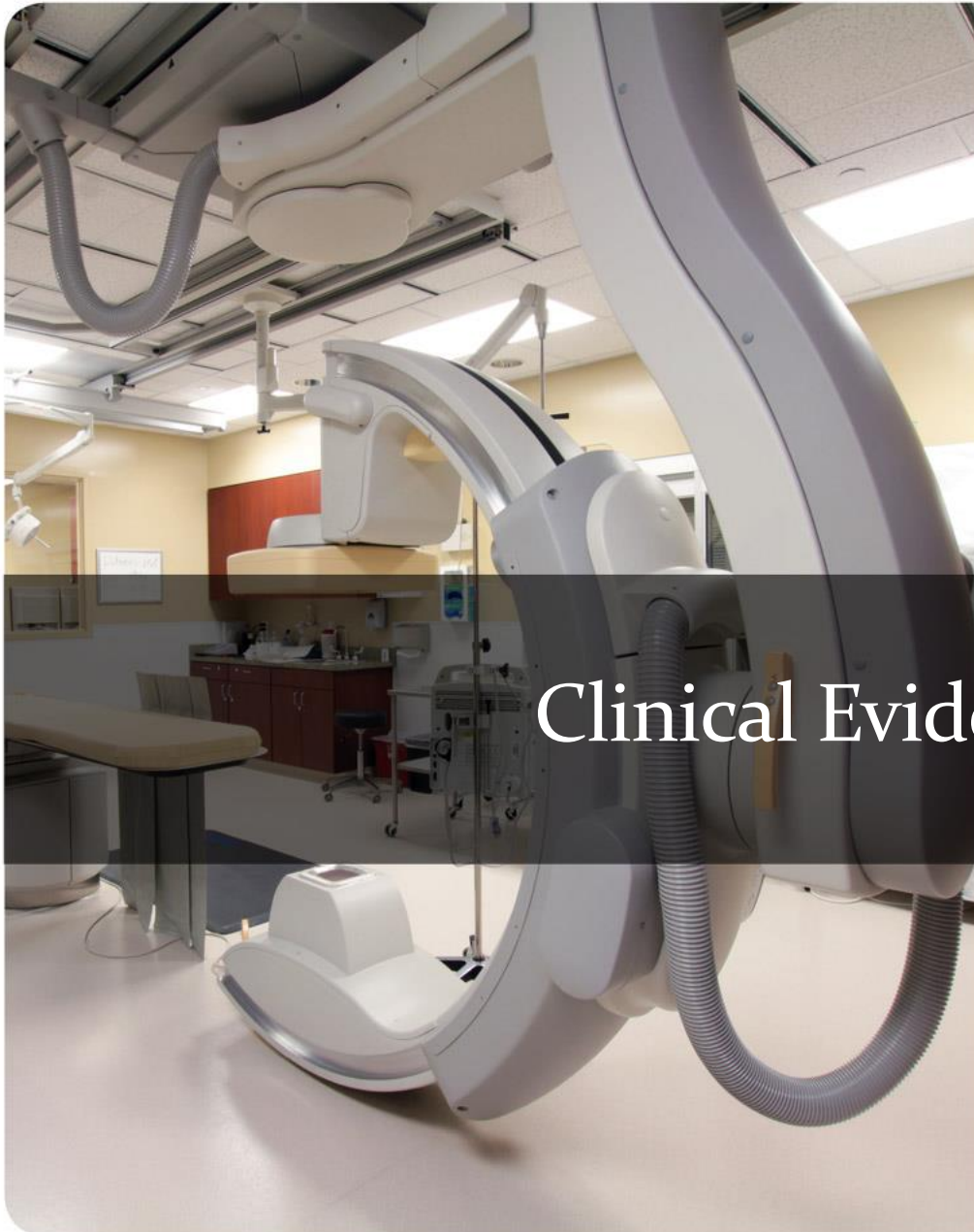
	2013	2014	2015	2016	YTD 2017	HCAHPS*
Overall Satisfaction	98.3%	98.6%	98.3%	97.6%	98.5%	72%
Patient Would Recommend NCP	99.0%	99.0%	98.8%	98.5%	99.0%	71%
Survey Return Rate	86.9%	73.6%	77.5%	67.9%	71.4%	29%

**HCAHPS -Hospital Consumer Assessment of Healthcare Providers and Systems*

3. Make ASC Policy Consistent with OPPS Policy

Create consistency between OPPS and ASCs in payment for non ancillary services through separate payment or the creation of a parallel conditional packaging policy

- Conditional packaging was introduced to the OPPS because it was determined that quite a few policy packaged codes were actually performed on days when no other major procedures were performed, indicating that the procedures were not ancillary to another procedure. Conditional packaging allowed for separate payment under these circumstances.
 - The ASC system has never been updated with a policy parallel to conditional packaging.
- The list of procedures in attachment D “policy packaged” in the ASC and therefore, unpaid. But as shown in the data, they are performed frequently without any major procedure.
 - The volume of these procedures performed alone suggest they should be eligible for separate payment.
- We recommend that CMS either:
 - Assign these procedures a status indicator for separate payment, or
 - Create a status indicator analogous to “Q2” in the OPPS for conditional packaging and modify the ASC pricer logic to pay separately only when no other major procedure appears on the same ASC claim.
- We note that these procedures are permitted in the ASC regardless of the artery or vessel defined in the descriptors and can be performed in the physician office (though office procedures are low volume.)



Clinical Evidence



BUILD
SOMETHING



Randomized controlled clinical trials show that Percutaneous Coronary Intervention (PCI) outcomes at sites without surgical backup are the same

Two randomized clinical trials support the safety of non-emergent procedures in ASC-like settings (sites without onsite surgical backup)

CPORT-E: N Engl J Med 2012; 366: 1792-1802

18,867 patients with stable CAD or ACS underwent non-emergency PCI at a hospital with (n = 4,718) or without (n = 14,149) on-site cardiac surgery from April 2006 to March 2011.

Findings: Elective percutaneous coronary intervention (PCI) performed at hospitals without on-site cardiac surgery is non-inferior to similar procedures performed at hospitals with surgical capabilities.

9 Month Outcomes

	No on-site surgery (n= 14,149)	On-site surgery (n=4,718)	P value
Death	3.2%	3.2%	
TVR	6.5%	5.4%	0.01 (for superiority)
MI	3.1%	3.1%	
MACE	12.1%	11.2%	0.01 (for non-inferiority)

Summary of randomized controlled studies cont.

MASS COMM: N Engl J Med 2013; 368: 1498-1508

3,691 patients who presented for elective PCI at hospitals in Massachusetts without on-site surgery capabilities between July 7, 2006, and September 29, 2011. The patients were randomized in a 3:1 fashion to undergo PCI at the initial hospital (n = 2,774) or be transferred to another with on-site surgical back-up (n = 917).

Findings: Patients undergoing non-emergency percutaneous coronary intervention (PCI) experience similar outcomes whether they are treated at hospitals that possess on-site cardiac surgery capabilities or do not offer such services.

30 Day Outcomes

	No on-site surgery (n= 2,774)	On-site surgery (n=917)	P value
MACE	9.5%	9.4%	<0.001 (for non-inferiority)
DEATH	0.7%	0.3%	0.39
MI	6.5%	6.5%	1.00
Repeat revascularization	2.7%	3.5%	0.25
Stroke	0.4%	0.1%	0.21

1 Year Outcomes

	No on-site surgery (n= 2,774)	On-site surgery (n=917)	P value
MACE	17.3%	17.8%	<0.001 (for non-inferiority)
DEATH	2.3%	2.4%	0.89
MI	8.6%	7.8%	0.55
Repeat revascularization	8.5%	9.9%	0.24
Stroke	1.0%	0.8%	0.83

Recent observational study findings support PCI at facilities without on-site surgery for all indications

Outcomes and Temporal Trends of Inpatient Percutaneous Coronary Intervention at Centers With and Without On-site Cardiac Surgery in the United States (Kashish Goel, MD1; Tanush Gupta, MD2,3; Dhaval Kolte, MD, PhD4; et al JAMA Cardiol. 2017;2(1):25-33. doi:10.1001/jamacardio.2016.4188)

A national inpatient sample (N = 6,912,232) was used to identify patients who underwent inpatient PCI in the United States from January 1, 2003, to December 31, 2012. Of these PCIs, 396,741 (5.7%) were conducted at centers without on-site cardiac surgery.

Findings: There was a 7-fold increase in the proportion of PCIs at centers without on-site cardiac surgery from 2003 to 2012 in the United States, with the adjusted in-hospital mortality after inpatient PCI being similar at centers with and without on-site cardiac surgery. ***These data provide evidence that PCI at centers without on-site cardiac surgery may be safe in the modern era.***

Summary of evidence: Meta analyses

Three studies conducted primarily with registry data have examined the use of non-emergent (non-primary) PCI at facilities with and without on-site surgery.

Findings: Overall, mortality and the need for emergency CABG surgery did not differ between hospitals with and without on-site surgery.

	On-site surgery	No. of Patients	<u>Mortality</u>		<u>Emergency CABG</u>		Comments
			Incidence	OR (95% CI)	Incidence	OR (95% CI)	
Zia (2011)	No	28,552	1.6%	1.03 (0.64-1.66)	1.0	1.38 (0.65-2.95)	6 studies included in analysis
	Yes	881,261	2.1%		0.9		
Singh M (2011)	No	30,423	0.9%	1.15 (0.93-1.41)	0.17	1.21 (0.52-2.85)	9 studies included in analysis
	Yes	883,865	0.8%		0.29		
Singh PP (2011)	No	1,812	0.17%	2.3 (0.60-12.97)	0.11	0.47 (0.07-3.19)	4 studies included in analysis (2 with data on mortality and CABG); RR calculated rather than OR
	Yes	4,039	0.72%		0.02		

- **How can NCP help?**
- **What additional data or information do you need?**