

Bundled PCI Services in a Non-Hospital Cath Lab: Environmental Scan/Annotated Bibliography

The research questions guiding the environmental scan and the search strategy are described in detail in the attached appendix. The components of the annotated bibliography below (with links and citations to sources) are grouped into topic areas with main points relevant to the proposal review outlined below.

BRIEF DESCRIPTION OF THE PROPOSAL

The “Bundled PCI Services in a Non-Hospital Cath Lab” proposal aims to reduce costs of Percutaneous Coronary Interventions (PCIs) by giving Medicare patients the option to have the procedure performed in a non-hospital outpatient cardiac catheterization (cath) lab. Clearwater Cardiovascular Consultants, the submitting organization, proposes Bundled PCI services to allow qualified non-hospital cath labs the ability to perform PCIs, beginning with CCC’s own established cath lab as a limited scale test case to develop appropriate criteria, with expansion to at least two additional cath labs in the next year.

SUBMITTING ORGANIZATION

Clearwater Cardiovascular Consultants

Clearwater Cardiovascular Consultants (CCC) is a cardiovascular medicine group founded in 1975, located in Clearwater, Florida, and comprised of 20+ physicians. Prior to 2016, CCC physicians provided PCI services at a hospital outpatient cardiac cath lab owned by Morton Plant Hospital (MPH), located near the emergency room/hospital outpatient lab. On January 1, 2016, CCC acquired this cath lab from MPH, retaining the same staff.

<http://www.ccicheart.com/>

<https://baycare.org/mph>

CURRENT ISSUES AND CONCERNS WITH MEDICARE PAYMENT FOR PCI

CCC proposes an approach that will reduce spending for Anchor PCI procedures by an estimated \$1,285 for a single vessel PCI and \$3,105 for a multi-vessel PCI by performing PCIs in more cost-effective facilities as appropriate. CCC proposes using several metrics to continue to evaluate quality of care, including CMS claims data, National Cardiovascular Data Registry (NCDR) metrics, and patient satisfaction surveys. CCC will use results from the Bundled PCI services to refine recommendations to CMS for inclusion/exclusion criteria for additional non-hospital cath labs that are amenable to the payment model.

Medicare Payment for PCI

2018 Procedure Payment Guide

Boston Scientific (2018). 2018 Hospital Inpatient, Hospital Outpatient, ASC and Physician Reimbursement Information. Retrieved 14 June 2018 from <https://www.bostonscientific.com/content/dam/bostonscientific/Reimbursement/PI/2018/2018%20Procedural%20Payment%20Guide.pdf> ([Link](#))

- Inpatient hospital payment varies depending on whether a bare metal or drug eluting stent (DES) is used and the severity of the patient's coronary disease with or without complications (CC) and major complications (MCC)
 - Drug eluting stent and angioplasty no CC \$12,750 (bare metal stent \$11,792)
 - Drug eluting stent and angioplasty with CC \$19,347 (bare metal stent \$18,366)
 - If 4 or more stents then patient put into MCC category
 - Medicare inpatient and outpatient rates in Clearwater Florida are about 6 percent lower due to area wage index adjustments.
- Outpatient APCs
 - \$10,510 for single vessel stent with one or two drug eluting stents (DES), (\$9,874 in Clearwater)
 - \$16,019 for two vessel and 2 DES, (\$15,050 in Clearwater)
 - Note not reimbursable in ASCs
- Physician payment \$620, note this is for the stent procedure alone and physicians may receive other payments for diagnostic related services that are part of the procedure.

Appropriate Use of PCIs

CCC is not currently providing PCI services to Medicare patients in their outpatient cath lab. In 2017, however, inclusion criteria and other measures for non-Medicare patients receiving PCI in the CCC outpatient cath lab exceeded the vast majority of National Cardiovascular Data Registry metrics including appropriateness use criteria (AUC) for PCI. Ninety-seven percent of CCC's PCI patients were evaluated using AUC, with 95.1 percent of those found appropriate, 4.4 percent uncertain (may be appropriate), and 0.6 percent found inappropriate (rarely appropriate).

Appropriateness of Percutaneous Coronary Intervention

Chan, P. S., et al. (2011) Appropriateness of Percutaneous Coronary Intervention. *JAMA*. 2011;306(1):53–61. doi:10.1001/jama.2011.916 ([Link](#))

Key Points

- Of 500,154 PCIs analyzed in the study, 71.1 percent were performed for acute indications. Of those, 98.6 percent were classified as appropriate, with 1.1 percent classified as inappropriate and the remaining 0.3 percent as uncertain.
- Among non-acute indications, 50.4 percent of PCIs were classified as appropriate, with 11.6 percent categorized as inappropriate and the remaining 38 percent as uncertain.
- 53.8 percent of inappropriate PCIs for non-acute indications were performed for patients without angina, 71.6 percent were for low-risk ischemia or based on results of non-invasive stress testing, and 95.8 percent were for patients with suboptimal antianginal therapy.
- Substantial variation among hospitals existed for the appropriateness of non-acute procedures, with a median hospital rate of inappropriate PCIs of 10.8 percent and an interquartile range of 6 to 16.7 percent.

Choosing Wisely Recommendation Analysis: Prioritizing Opportunities for Reducing

Inappropriate Care

Reed, S. J., Pearson, S. Institute for Clinical and Economic Review (2014). *Choosing Wisely Recommendation Analysis: Prioritizing Opportunities for Reducing Inappropriate Care* (pp 1-10). Retrieved from http://www.choosingwisely.org/wp-content/uploads/2015/05/ICER_PCI.pdf ([Link](#))

Key Points

- A 2011 study using data from the NCDR found that 12% of non-acute indications for PCI did not meet appropriateness criteria for PCIs.
- A retrospective study of a 2004 sample of Medicare claims data found only 44.5 percent of patients underwent stress testing before receiving an elective PCI, with rates ranging from 22 percent to 70 percent regionally.
- Medicare's annual spending for PCIs is reportedly variable and may be up to or greater than \$2 billion, even without including complications or follow-up care costs.
- Factors likely driving use of PCI in patients with stable ischemic heart disease (SIHD) include fee-for-service reimbursement which incentivizes expensive cardiology interventions, physician knowledge of current clinical standards, and patient education and demand for aggressive treatments.

Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease

Patel, M. R., et al. (2017) ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease. *Journal of the American College of Cardiology*. 2017;69(17): doi.org/10.1016/j.jacc.2017.02.001 ([Link](#))

Key Points

- Appropriate Use Criteria rating panel assessed whether revascularization for each indication was deemed to hold more potential benefits than adverse consequences, categorized as “appropriate care,” “may be appropriate care,” or “rarely appropriate care” depending on a score ranging from 1 to 9 (less to more appropriate).
- Scope of indication included clinical presentation, use of antianginal medication, noninvasive test results, confounding factors/comorbidities, extent of anatomic disease, prior surgeries, and invasive testing results/physiology.

CURRENT CARE DELIVERY OF PCIS

Medicare only provides payment for PCIs in hospital inpatient and hospital outpatient settings. Ambulatory surgery centers are currently ineligible for reimbursement for PCIs from Medicare.

Defining a Freestanding Cardiac Catheterization Clinic

Cardiac Catheterization in Freestanding Clinics: A Review

ECRI Evidence-based Practice Center. (2005). *Cardiac Catheterization in Freestanding Clinics: A Review (pp 1-119)*. Retrieved from <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/id28TA.pdf> ([Link](#))

Key Points

- As of 2001, a freestanding catheterization lab is one that is not attached to a hospital and where quick transportation of a patient to a hospital is not possible, as determined by the American College of Cardiology (ACC) and Society for Cardiac Angiography and Interventions (SCAI).
- Some hospitals build cath labs adjacent to their facilities, but many others are privately owned.
- Freestanding catheterization laboratories are responsible for establishing relationships with referral hospitals so that plans for emergency transfer of patients are established. Freestanding laboratories must also be equipped to perform onsite intubation and provide ventilator support.

Same-Day Discharge Medicare Beneficiary Costs

Costs Associated With Access Site and Same-Day Discharge Among Medicare Beneficiaries Undergoing Percutaneous Coronary Intervention: An Evaluation of the Current Percutaneous Coronary Intervention Care Pathways in the United States.

Amin, A.P. et al. Costs Associated With Access Site and Same-Day Discharge Among Medicare Beneficiaries Undergoing Percutaneous Coronary Intervention: An Evaluation of the Current Percutaneous Coronary Intervention Care Pathways in the United States. *JACC Cardiovasc Interv.* 2017 Feb 27;10(4):342-351. doi: 10.1016/j.jcin.2016.11.049. PubMed PMID: 28231901. ([Link](#))

Key Points

- Nearly 280,000 Medicare PCI patients eligible for same day discharge in the National Cardiovascular Cath-PCI Registry were analyzed.
- Transradial intervention (TRI) was performed in 9 percent of procedures, 13.5 percent of which were same-day discharge, and were associated with a lower adjusted cost of \$916.
- Same-day discharge (SDD) was found in only 5.3 percent of cases, 23.1 percent of which were TRIs, with a lower adjusted cost of \$3,502.
- The adjusted cost of TRIs with SDD was \$13,389, compared to a transfemoral intervention and non-same-day discharge cost of \$17,076, a savings of \$3,689.

Safety Risks Associated with PCIs Performed in a Non-Hospital Setting

The Ambulatory Approach: Answering questions about the shift in cardiology from inpatient to outpatient procedures.

Beekman, A. (2017, May/June). *The Ambulatory Approach: Answering questions about the shift in cardiology from inpatient to outpatient procedures.* Retrieved 12 June 2018 from <https://citoday.com/2017/06/the-ambulatory-approach/> ([Link](#))

Key Points

- Between 2004 and 2014, inpatient PCI procedures decreased by 45 percent from 365,788 to 201,142, with 2014 being the first year that physicians were paid more by Medicare for outpatient than inpatient procedures.
- Programs using most-commonly referenced SDD guidelines find 20 to 40 percent of elective PCI patients are candidates for SDD. Programs that achieve an SDD rate in the 80th percentile and above determine discharge eligibility based on patient response to the procedure.
- Ambulatory cath lab requirements vary from state-to-state which may restrict migratory strategies to optimize outpatient payments.
- Cost of equipment for a cath lab suite can reach \$2 million without including cost of the space itself and staffing needs. Staffing models must also ensure cath lab team can arrange speedy transport to acute care centers if necessary.

Growth in Percutaneous Coronary Intervention Capacity Relative to Population and Disease Prevalence.

Langabeer, J. R., et al. (2013). Growth in Percutaneous Coronary Intervention Capacity Relative to Population and Disease Prevalence. *Journal of the American Heart Association*, 2(6). doi:10.1161/jaha.113.000370 ([Link](#))

Key Points

- As of 2011, among the 4,050 short-term acute care hospitals in the United States, 39 percent are capable of performing PCIs.
- From 2003 to 2011 the number of cardiac cath labs has grown 12.9 percent, a growth of 2.3 new facilities per month.
- Geospatial analyses revealed that new centers are not equally -distributed throughout the United States, with the eastern half of the United States having more PCI facilities and capacity despite a lower density per population.
- The central regions of the United States have higher numbers of PCI centers relative to the population, but this also correlates with higher disease rates in those regions.

CURRENT PAYMENT STRUCTURE

CCC claims that the current lack of technical facility fee reimbursement in the Medicare Physician Fee Schedule for PCI services for non-hospital settings necessitates changes to the payment model. Outpatient PCIs are currently paid separately for both the physician professional fee and the hospital outpatient facility fee. CCC's proposed model would incorporate shared risk while lowering costs to Medicare and beneficiaries. Providers assume risk through fixed cost reimbursement and 90-day episode risk-sharing similar to BPCI Advanced model.

The FY 2018 Reimbursement Outlook: The Cath Lab Impact

Truesdell, K. (2017). The FY 2018 Reimbursement Outlook: The Cath Lab Impact. Cath Lab Digest. 10(25). Retrieved from <https://www.cathlabdigest.com/article/FY-2018-Reimbursement-Outlook-Cath-Lab-Impact> ([Link](#))

Key Points

- Over the last three years CMS has focused on restricting high-cost, device-dependent procedures into Comprehensive Ambulatory Payment Classifications.
- Though margins are increasing for outpatient coronary procedures, the margin is still less than that in the inpatient setting, where reimbursement can be up to \$6,000 more than in an outpatient setting.
- Regardless of admission status, cath lab costs related to supplies and pharmaceuticals are similar across settings.

Inpatient or Outpatient Status for Elective Percutaneous Coronary Intervention

Kumbhani, D. J., & Marso, S. P. (2016). Inpatient or Outpatient Status for Elective Percutaneous Coronary Intervention. Circulation: Cardiovascular Interventions. doi.org/10.1161/CIRCINTERVENTIONS.116.003699 ([Link](#))

Key Points

- Significant financial advantages exist for performing inpatient PCIs.
- NCDR PCI mortality model found patient risk not currently a large factor in patient disposition post-PCI procedure.
- PCIs are defined as “appropriate care,” “may be appropriate care,” and “rarely appropriate care” based on current AUC methodology.
- PCI appropriateness benchmarking against other hospitals, as well as national initiatives by third-party payers resulted in 50 percent reduction in inappropriate (“rarely appropriate”) use of PCIs from 2009 to 2014.

2018 CMS Hospital Outpatient and Ambulatory Surgical Center Reimbursement Prospectus

Abbott (2018) CMS Hospital Outpatient and Ambulatory Surgical Center Reimbursement Prospectus. Retrieved on 15 June 2018 from https://www.vascular.abbott/content/dam/bss/divisionalsites/av/docs/reimbursement/OP-PS-ASC-Guide-Abbott-25216_ZincApproved-01-12-18.pdf ([Link](#))

Key Points

- From 2017 to 2018, payment for an outpatient single-vessel drug-eluting stent PCI increased by 7.8 percent, from \$9,748 to \$10,510.
- A multi-vessel procedure increased by 8.4 percent, from \$14,776 to \$16,019.

Trends in Coronary Revascularization Procedures Among Medicare Beneficiaries Between 2008 and 2012

Culler, S.D., Kugelmass, A.D., Brown, P. P., Reynolds, M. R., & Simon, A. W. (2014). Trends in Coronary Revascularization Procedures Among Medicare Beneficiaries Between 2008 and 2012. *Circulation*. 2015;131:362-370, doi.org/10.1161/CIRCULATIONAHA.114.012485 ([Link](#))

Key Points

- The number of non-admission PCIs performed on Medicare beneficiaries has grown from 60,405 to 106,495 during the study period, and was offset by a decline in PCI admissions overall from 363,384 to 295,434.
- Twenty point two percent more facilities were documented as performing non-admission PCIs by the end of the study period, while inpatient PCI facilities only grew by 8.2 percent.
- Mortality rates for Medicare PCI encounter rose slightly during the study period from 1.7 to 1.9 percent, however rates have not been adjusted for changes in severity of illness over time.

Temporal Trends in the Risk Profile of Patients Undergoing Outpatient Percutaneous Coronary Intervention

Vora, A.N. et al. (2016). Temporal Trends in the Risk Profile of Patients Undergoing Outpatient Percutaneous Coronary Intervention. *Circulation: Cardiovascular Interventions*. 2016; doi.org/10.1161/CIRCINTERVENTIONS.115.003070 ([Link](#))

Key Points

- In 2013, a PCI procedure using a drug-eluting stent was reimbursed \$11 497 as an inpatient, but \$7763 as an outpatient.
- The Recovery Audit Contractor (RAC) program potentially caused incentives to bill all PCI procedures under outpatient Ambulatory Payment Classification regardless of risk.
- Between Q3 2009 and Q2 2014, 47.6 percent of patients that qualified for outpatient reimbursement were not admitted after a PCI procedure. This rate increased from 32.8 percent to 66.3 percent during the study period.
- Mean length of stay for patients not admitted decreased from 1.06 days to 0.97 days, while mean length of stay among patients who were admitted increased from 2.42 days to 3.23 days.
- Median predicted mortality increased from 0.10 percent to 0.11 among patients not admitted, and from 0.14 percent to 0.18 percent among patients admitted.

CURRENT PAYMENT PROBLEMS & SOLUTIONS

CCC has proposed a global bundled price for Anchor procedures of \$10,000 for single vessel PCI procedures and \$14,000 for multi-vessel procedures, as they have been successfully providing such procedures for managed care payers since 2016. CCC is also proposing 90-day episode risk sharing similar to the manner that BPCI has modeled Advanced Outpatient PCI procedures.

Costs Associated with Building a Cath Lab

National Cardiovascular Partners (NCP)

Fresenius Medical Care North America. *National Cardiovascular Partners*. Retrieved on 12 June 2018. ([Link](#))

Key Points

- NCP has been involved in the creation of 23 hybrid ASC-Cath Labs since 2006, pioneering the model.
- Partners remain majority stakeholders in their hybrid centers and are offered both clinical and financial control.
- NCP continues to manage administrative duties of the center after completion.

Financial Considerations for Office-Based Intervention Labs

Kho, H. & Ahn, S. Financial Considerations for Office-Based Intervention Labs. *Endovascular Today*. 2014 Jan; 55-58. ([Link](#))

Key Points

- Office-based interventions for vascular specializations offer reimbursements up to ten times greater than that of traditional outpatient endovascular cases.
- Practices with available space can see build-out costs as low as \$100,000 while those with space challenges may cost over \$1,000,000.
- Refurbished equipment can bring costs as low as \$500,000 in terms of additional set-up, with supplies to stock the intervention suite ranging from \$100,000 to \$300,000 depending on anticipated volume.
- Staffing concerns must address administrative needs related to quality control and compliance, as well as coding and billing. Delayed billing or coding issues may cause cash flow problems for a new practice.

Sustainability and Profitability of Cath Labs

Cath Lab Profitability

Graver, R. (2017). Cath Lab Profitability. *Cath Lab Digest*. 8(25), 12-15. Retrieved from <https://www.cathlabdigest.com/article/Cath-Lab-Profitability> ([Link](#))

Key Points

- Healthcare policies such as the Two-Midnight Rule, Observational Status Notification, and Comprehensive Ambulatory Payment Classifications created new challenges in terms of managing inpatient and outpatient care.
- Between 2014 and 2015, hospitalizations accounted for 25% of total Medicare costs of performing PCIs. Reducing the length of stay by even one night would reduce total costs by \$1,169 per case, with the operating margin improving from -1% to 6%.
- Terumo Corp and MedAxiom are currently working with a number of labs to support cardiovascular groups in transitioning to the Cath Lab Patient Care Pathway Program with aims of reducing length of stay, cost per case, and enhancing operational efficiency.

Outpatient Cath Labs Suffer Under a System Favoring Hospitals

Rogoski, R. R. (20097). Outpatient Cath Labs Suffer Under a System Favoring Hospitals. *Diagnostic and Intervention Cardiology*. Retrieved on 12 June 2018 from <https://www.dicardiology.com/article/outpatient-cath-labs-suffer-under-system-favoring-hospitals> ([Link](#))

Key Points

- As of 2009 there were only about 100 independent cath labs in the United States.
- Hospitals such as Midwest Cardiovascular Center operate two cath labs and perform procedures on as many as ten patients a day. However, emergency surgery is facilitated by the attached St. Anthony's Medical Center.
- Minimally-invasive catheterizations have become possible to perform safely in an outpatient setting due to technological advancements, thinner catheters, and more affordable imaging equipment.
- Decreasing Medicare reimbursements as well as lack of equity in reimbursements between outpatient and hospital settings has reduced profit margins for cath labs.

EVALUATION OF SIMILAR MODELS

CCC proposes a similar model as the BPCI Advanced Outpatient PCI Participants model. CMS would calculate a target price, then perform semiannual reconciliation comparing actual cost per patient episode to the target price. If the Total Stop Loss Limited Variance per Patient Episode is positive, CMS would pay 50 percent of the value to the Bundled PCI Provider. If it is negative, the provider would pay 50 percent to CMS.

CMS Bundled Payments for Care Improvement Initiative Models 2-4: Year 3 Evaluation & Monitoring

Dummit, L. et al. The Lewin Group (October 2017). *CMS Bundled Payments for Care Improvement Initiative Models 2-4: Year 3 Evaluation & Monitoring* (pp 222-228). Retrieved from <https://downloads.cms.gov/files/cmimi/bpci-models2-4yr3evalrpt.pdf> ([Link](#))

Key Points

- For PCIs during the first eight quarters of the BPCI initiative, no statistically significant changes were found in total Medicare payments for inpatient hospitalization during the 90-day PDP for BPCI versus the comparison group.
- Other findings for BPCI included a significant reduction in home health visits, as well as a decrease in Part B payments for imaging/lab and evaluation visits.
- Since relatively few PCI episodes include post-acute care, BPCI hospitals are limited in their ability to reduce total episode payments. Providers are instead largely focused on reducing internal costs during admission.
- There was no significant reduction in inpatient length of stay, averaging 4 days for both BPCI participants and the comparison group.
- Because cost of supplies does not vary greatly between vendors, it was difficult to reduce supply costs through better purchasing techniques. In addition, number of stents varies across PCI procedures, making it difficult to control hospital costs.
- Additional procedures done as medically appropriate care following a PCI can count as readmissions even though they were not related to the initial PCI. These procedures often cannot be appropriately postponed until the BPCI episode has ended.

PCI Appropriateness in New York

Masoudi, F. A., Curtis, J. P., & Desai, N. R. (2017). PCI Appropriateness in New York. *Journal of the American College of Cardiology*, 69(10), 1243-1246. doi:10.1016/j.jacc.2017.01.009 ([Link](#))

Key Points

- In 2011, New York's PCI initiative proposed reimbursement dependent on appropriateness of the procedure. Beginning in July 2013, PCIs performed for Medicaid patients that were deemed inappropriate would not be reimbursed.
- Although the policy was dropped in April 2016 and no payments were ever denied, between 2010 and 2014, inappropriate PCIs among Medicaid patients declined by 75%.

- The National Cardiovascular Data Registry (NCDR) leverages data quality programs, including audits, to assess accuracy of data submitted to national registries, which inform appropriate use criteria assessment.
- Appropriate Use Criteria (AUC) limitations contribute to being more useful at the quality improvement and population-level, rather than as a standard for patient-level accountability, and unintended consequences of using them to deny payment may include limiting patient access for patients incorrectly categorized as inappropriate cases.

Changes in Percutaneous Coronary Interventions Deemed “Inappropriate” by Appropriate Use Criteria

Hannan, E. L. et al. (2017). Changes in Percutaneous Coronary Interventions Deemed “Inappropriate” by Appropriate Use Criteria. *Journal of the American College of Cardiology*, 69(10), 1234-1242. doi: 10.1016/j.jacc.2016.12.025 ([Link](#))

Key Points

- In an effort to reduce rates of PCIs classified as inappropriate, New York State’s Department of Health announced a policy of withholding reimbursement for PCIs that did not demonstrate clinical appropriateness.
- From 2010 and 2014, the percentage of PCIs deemed inappropriate for patients without Acute Coronary Syndrome (ACS) or prior Coronary Artery Bypass Graft (CABG) surgery dropped from 18.2 percent to 10.6 percent for all patients, and from 15.3 percent to 6.8 percent for Medicaid Primary patients.
- Two-thirds of all hospitals decreased their rate of inappropriate PCIs by 2.9 percent or more, while half of all hospitals decreased their rate by more than 6.9 percent.
- It is difficult to attribute these declines solely to improvements in quality efforts, as national publicity surrounding NYC Department of Health’s decision to withhold reimbursement was likely a factor as well.

QUALITY METRICS OR OUTCOMES

CCC proposes continuing the current metrics and registries to continue to track outcomes. Such outcomes include death, major adverse cardiac events (MACE), myocardial infarctions (MI), stroke, and in-stent restenosis within 90 days of procedure. Further tracked complications include falls, infections, sentinel events, serious vascular complications, and returns to the surgery/lab. Patient satisfaction will also continue to be tracked.

Unplanned admissions after outpatient cardiac catheterization

Clark, V. L. and Dolce, J. (1993), Unplanned admissions after outpatient cardiac catheterization. *Clin Cardiol*, 16: 823-826. doi:10.1002/clc.4960161113 ([Link](#))

Key Points

- 15 percent of unplanned admissions following consecutive outpatient cardiac catheterizations resulted in hospital admission after the procedure over a 1 year timeframe. As such, facilities that allow potential inpatient admission must be available.
- 33 percent of these patients required immediate percutaneous transluminal coronary angioplasty, 48 percent had severe cardiac disease requiring intervention, 15 percent of patients suffered complications from the procedure, and 4 percent were patients whose procedures were completed too late for same-day discharge.
- Patients over 65 were more likely to be admitted with complications.
- Though the study does not specifically address free-standing catheterization facilities, the data lends support to recommendations against free-standing labs.

A Contemporary View of Diagnostic Cardiac Catheterization and Percutaneous Coronary Intervention in the United States

Dehmer, G. J., et al. (2012). A Contemporary View of Diagnostic Cardiac Catheterization and Percutaneous Coronary Intervention in the United States. *Journal of the American College of Cardiology*, 60(20), 2017-2031. doi:10.1016/j.jacc.2012.08.966 ([Link](#))

Key Points

- Data from the national Cardiovascular Data Registry were used to summarize six quarters from January 1, 2010 to June 30, 2011, involving 1,110,150 patients and 941,248 PCIs.
- 32.6 percent of facilities did not have on-site cardiac surgery available, including 83 percent of facilities that performed fewer than 200 PCIs annually.
- Patients aged 65 years or older accounted for 38.7 percent of all PCIs.
- 52 percent of elective PCI patients underwent a stress study prior to the procedure.
- Radial access accounted for 8.3 percent of diagnoses, and 6.9 percent of PCI procedures.
- Primary PCI door-to-balloon time was a median of 64.5 minutes for nontransfers and 121 minutes for transfers.

Ambulatory Outpatient Percutaneous Coronary Intervention

Moussa, I. D. (2015, July/August). *Ambulatory Outpatient Percutaneous Coronary Intervention*.

Retrieved 12 June 2018 from https://citoday.com/pdfs/cit0715_TP_Moussa.pdf ([Link](#))

Key Points

- Patients suitable for same-day discharge report significantly higher rates of satisfaction and incur lower costs for PCI procedures.
- No significant differences in prevalence of death or rehospitalization within 2 days and after 30 days after PCIs was found between same-day discharges and overnight stays.
- Elderly patients are not found to be worse candidates for same-day discharge than younger patients, although women are at a higher-risk for complications.
- An observation period of four-to-six hours properly captures all patient risk categories post-procedure.

**Appendix: Environmental Scan for PTAC Proposals:
Bundled PCI Services in a Non-Hospital Cath Lab
Submitted by Clearwater Cardiovascular Consultants**

Research Questions Guiding Search		Sources (Last 5 years unless otherwise stated)	Keywords and Search Terms (Used individually or in combination)
1	Who or what is the submitting organization?	Google, Wikipedia, organization websites and proposal links and citations	<ul style="list-style-type: none"> • Clearwater Cardiovascular Consultants • Morton Plant Hospital • ER • Patient Satisfaction
2	What is the clinical care “problem” and/or the payment “problem” the proposed model is trying to solve or address?	Proposal, key references cited in the proposal, Google/Scholar, PubMed	<ul style="list-style-type: none"> • PCI Payment • Inpatient vs. Outpatient • Medicare
3	What is current practice/ standard of care/evidence-based guidelines? Adherence to guidelines?	National Guideline Clearinghouse, PubMed, Cochrane, AHRQ, USPSTF, relevant professional organizations/ associations/ societies	<ul style="list-style-type: none"> • Cost of PCIs in inpatient and outpatient settings • Profitability of Cath Labs • Safety • Appropriate Use
4	What are the current payment methodology and relevant regulations/rules, legislative environment, controversies?	MedPAC, Federal Register, Google/Scholar, PubMed, CMS	<ul style="list-style-type: none"> • BPCI • PCI Reimbursement • Inpatient vs. Outpatient • Freestanding Cath Clinic Regulations
5	Is there evidence that current practices and payments are problematic?	Google/Scholar, Pubmed	<ul style="list-style-type: none"> • Cath Lab Profitability • Appropriate Use PCIs • Quality • Safety
6	What is the basis/evidence that problem is relevant to Medicare: i.e., size of population within Medicare and/or costs	Google/Scholar, Pubmed	<ul style="list-style-type: none"> • Medicare • CMS • PCIs • Readmissions
7	Are there evaluations of the model or similar models of care and/or payment? Pilot studies?	Google, Pubmed, CMS.gov,	<ul style="list-style-type: none"> • BPCI • CMI Care Improvement Initiative • New York Health Department
8	Have there been alternative models/ solutions to the problem(s) and any evaluations of these?	Google, PubMed, CMS.gov	<ul style="list-style-type: none"> • BPCI • Ambulatory Surgery Centers

Research Questions Guiding Search		Sources (Last 5 years unless otherwise stated)	Keywords and Search Terms (Used individually or in combination)
9	Is there support for the validity of quality metrics or outcomes used in the model?	Google/Scholar, NQF, NCQA, Commission on Cancer (COC)	<ul style="list-style-type: none"> • PCI Patient Satisfaction • Risk Factors • Rehospitalizations
10	Are there tools (proprietary or non-proprietary) involved in the model? Evidence for use, costs, effectiveness of such tools?	Google/Scholar	<ul style="list-style-type: none"> • NCDR • CathPCI Registry
11	Miscellaneous – Any evidence behind statements and claims in proposal?	References cited in proposal, Google/Scholar	

Additional Keywords related to clinical scenario, patient population, disease/ conditions, setting:

outpatient cardiac cath labs in the united states census, number of cardiac labs in the United States, comparisons of inpatient vs. outpatient vs. freestanding

Keywords related to payment model/ methodology:

Keywords related to CMS/ CMMI:

Specific names of tools, models, organizations, awards, mentioned in proposal text:

Clearwater Cardiovascular Consultants (CCC), Morton Plant Hospital (MPH), The Joint Commission, Accreditation Association for Ambulatory Health Care. Inc (AAAHC), NCDR, ACC/AHA/SCAI Appropriate Use Criteria, CathPCI

Clearwater Cardiovascular and Interventional Consultants BUNDLED PCI SERVICES IN A NON-HOSPITAL CATH LAB

Review of Safety Criteria for Non-Hospital Catheterization Labs

The Preliminary Review Team (PRT) reviewing the *Bundled PCI Services in a Non-Hospital Cath Lab (Bundled PCI Services)* proposal submitted by Clearwater Cardiovascular and Interventional Consultants (CCC) is interested in understanding the following question:

Does the literature indicate what safety criteria are used by non-hospital cath labs that are doing PCI for non-Medicare patients?

The American College of Cardiology (ACC) and the Society for Cardiac Angiography and Interventions (SCAI) define a freestanding catheterization laboratory as one that is not physically attached to a hospital, and by which quick transport of a patient to a hospital by gurney is not possible (ECRI, 2005). Historically, attempts to answer questions comparing complication rates of diagnostic and intervention catheterization procedures in freestanding clinics versus hospital-based clinics have largely gone unanswered (ECRI, 2005). However, several organizations have developed standards and guidelines related to best practices and appropriate use of percutaneous coronary interventions (PCIs) in non-hospital settings.

The Accreditation for Cardiovascular Excellence (ACE) Standards has developed criteria for cardiac catheterization laboratories (CCL). ACE is an independent organization sponsored by SCAI and the ACC Foundation (ACCF). ACE evaluates and monitors facilities that provide cardiovascular care. ACE offers accreditation to facilities that meet criteria for the equipment used, leadership structure, physician extenders and cardiology fellows, nursing personnel, technologists and other personnel, reporting results, procedures, patient outcomes, quality assurance, and radiation safety (ACE, 2015).

Cardiac catheterization laboratories with ACE accreditation must adhere to a number of standards, including annually performing no less than 400 diagnostic coronary angiograms and 150 PCIs (36 of which are primary PCIs for acute myocardial infarction), though lower volumes may be acceptable for CCLs operating in remote areas. Outcomes must be equivalent to national benchmarks established by the National Cardiovascular Data Registry (NCDR) CathPCI Registry. (ACE, 2015).

An estimated 25 to 35 percent of all hospital, non-hospital, and mobile diagnostic cardiac catheterization labs in the US operate without cardiothoracic surgical backup (Bashore et al., 2012). Since 2001, most restrictions on diagnostic cardiac catheterization for freestanding laboratories without surgical backup have been lifted. However, exceptions include pediatric patients and patients with pulmonary edema or complex congenital heart disease, who are recommended to be catheterized in labs with surgical backup.

Exclusion criteria on therapeutic procedures are more comprehensive, and certain characteristics established by SCAI in 2007 can identify high-risk patients who may be unsuitable candidates for PCI in a facility without surgical backup (Bashore et al., 2012). The ACE standards gives examples of high risk PCI patients that should not be performed in facilities without surgical backup including patients with decompensated CHF, known clotting disorders, left main coronary artery stenosis that is greater than 50 percent or 3 vessel CAD and for patients with high-risk PCI stenoses. Otherwise, elective and primary PCIs are permissible as long as the CCL adheres to national guidelines, which include a working relationship with a facility with cardiovascular surgical services, as well as an emergency department to

which the patient can be transported within 20 minutes (ACE, 2015; Bashore et al., 2012). Additional requirements include review of coronary angiograms before elective procedures take place by a cardiac surgeon, submission of data to a national registry such as NCDR ACTION-GWTG or NCDR-CathPCI, and implementation of a quality-assurance monitoring program integrated with facility quality-improvement efforts (ACE, 2015).

Additionally, SCAI and ACC have published guidelines with the American Association for Thoracic Surgery (AATS), American Heart Association (AHA), American Society of Echocardiology (ASE), American Society of Nuclear Cardiology (ASNC), Society of Cardiovascular Computed Tomography (SCCT) and Society of Thoracic Surgeons (STS). These guidelines discuss appropriate criteria to administer PCI services. A panel for rating these guidelines comprised of 5 cardiac surgeons, 5 intervention cardiologists, 6 cardiologists not directly involved with performing revascularization, and 1 outcomes researcher who scored each clinical indication for coronary revascularization based on whether potential benefits exceeded potential negative consequences of the treatment. Indications were scored on a scale from 1-9, ranging from 1-3, rarely appropriate care, 4-6, may be appropriate care, and 7-9, appropriate care (Patel et al., 2017).

Further information on PCIs regarding catheterization lab criteria, regulations, quality management, safety concerns, and appropriate use criteria are highlighted below.

Cath Lab Criteria and Regulations

ACE Standards for Catheterization Laboratory Accreditation

Accreditation for Cardiovascular Excellence (2015). ACE Standards for Catheterization Laboratory Accreditation. Retrieved from cvexcel.org ([Link](#))

- Standards pertain to all core functions of all CCLs, specifically diagnostic cardiac studies and percutaneous coronary intervention (PCI).
- Laboratories without on-site surgery are excluded from performing certain diagnostic and therapeutic procedures, including procedures for congenital heart disease, high-risk elective PCI procedures, and primary PCI procedures if adequate hospital services for acute MI are not present.
- High-risk patients include those with decompensated CHF, recent cerebrovascular accidents, known clotting disorders, left ventricular ejection fraction of 30 percent or less, chronic kidney disease, or serious ongoing ventricular arrhythmias.
- Facilities without on-site surgery must also demonstrate surgical backup at all hours for urgent cases and for electives at mutually agreed times, confirmed availability of surgery, and transport provider able to begin transfer within 20 minutes.
- ACE also requires full-service laboratories perform no less than 400 diagnostic coronary angiograms and 150 PCIs annually, of which 36 are primary PCIs for acute myocardial infarction. Outcomes must be equivalent to national benchmarks established by NCDR CathPCI Registry, although exceptions can be made for remote area labs.

Cardiac Catheterization in Freestanding Clinics: A Review

ECRI Evidence-based Practice Center (2005). *Cardiac Catheterization in Freestanding Clinics: A Review*. Contract No. 290-02-0019 ([Link](#))

- As of 2005, 13 states had regulations that prohibited the performance of cardiac catheterization in a freestanding setting, with two states having certain exceptions for diagnostic procedures.
- Available evidence demonstrated no difference in complication rates of diagnostic catheterization between freestanding clinics and hospital outpatient settings. However, risk-adjustment was not possible to compensate for patient-characteristics.
- Patients at freestanding clinics did not have the option for combined diagnostic and PCI procedures during a single visit.
- As of 2005 no specific documentation existed pertaining to training and credentialing of personnel in freestanding catheterization clinics. It is assumed that personnel follow identical credentialing protocols as those in hospital environments.
- No uniform criteria exist that exclude patients from catheterization procedures in freestanding clinics, however, more stringent exclusion criteria is recommended by ACC/SCAI experts for freestanding clinics without cardiac surgical support.

Cardiac Catheterization Laboratory Standards Update

Bashore et al. (2012). American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update: A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents. *Journal of the American College of Cardiology*, 59(24): 2221-2305. ([Link](#))

- Since 2001, almost all restrictions on diagnostic cardiac catheterization for freestanding laboratories without surgical backup have been lifted. Pediatric patients and patients with pulmonary edema or complex congenital heart disease should still not be treated without surgical backup.
- Certain therapeutic procedures are still recommended for exclusion, however, elective and primary PCIs are permissible as long as the facility strictly adheres to national guidelines, including a working relationship with a facility with cardiovascular surgical services, as well as emergency transportation services.
- Facilities must also document adherence to national risk stratification and medication guidelines, as well as a functioning Quality Improvement program and demonstrable national volume guideline fulfillment.

Percutaneous Coronary Interventions

United HealthCare Services (2018). Percutaneous Coronary Interventions. UnitedHealthCare Medicare Advantage Policy Guideline. Retrieved from [uhcprovider.com](#) ([Link](#))

- UnitedHealthCare follows Medicare guidelines for determining coverage for PCI procedures.
- Diagnostic catheterization is usually performed within 30 days of the PCI, with no repeat necessary unless patient's condition changes.

Quality Measurement and Improvement in the Cardiac Catheterization Laboratory

Frey, P., Connors, A., & Resnic, F. S. (2012). Quality Measurement and Improvement in the Cardiac Catheterization Laboratory. *Circulation*. DOI: 10.1161/circulationaha.111.018234 ([Link](#))

- Requirements for quality monitoring in cardiac cath labs vary with state regulations.
- ACC/AHA/SCAI 2005 guidelines recommend all institutions establish peer review of quality and outcomes at the individual and institutional level for PCI procedures.
- Benchmarks should be established against PCI registries and national statistics.
- Outcomes such as post procedural mortality, stroke, and vascular complications can be risk adjusted and compared to regional and national registries like ACC-NCDR CathPCI.

Quality Management

Decision Memo for Cardiac Catheterization Performed In Other Than A Hospital Setting

Centers for Medicare & Medicaid Services (2006). Decision Memo for Cardiac Catheterization Performed In Other Than A Hospital Setting. Retrieved from cms.gov ([Link](#))

- The ACC/SCA&I Clinical Expert Consensus Document: Cardiac Catheterization Laboratory Standards discusses recommended requirements for performing cardiac catheterizations in freestanding facilities.
- The freestanding facility should have a formal relationship with a tertiary hospital for the emergency transfer of patients, have equipment for intubation and ventilatory support, and have quality assurance and quality improvement programs in place. In addition, the physicians must be able to perform endotracheal intubations and insert an intra-aortic balloon pump.
- Patient selection is critically important in freestanding facilities without surgical backup, and is specifically addressed in the document. The consensus document recommends that only diagnostic cardiac catheterizations be performed in freestanding facilities and lists patient inclusion and exclusion criteria; no therapeutic procedures are recommended.
- The ACC/SCA&I Document reported that major complication rate for diagnostic cardiac catheterizations is estimated between 1% and 2%, which the experts feel is acceptably low.

Ambulatory Outpatient Percutaneous Coronary Intervention

Moussa, I. D. (2015, July/August). *Ambulatory Outpatient Percutaneous Coronary Intervention*. Retrieved 12 June 2018 from https://citoday.com/pdfs/cit0715_TP_Moussa.pdf ([Link](#))

- Patients suitable for same-day discharge report significantly higher rates of satisfaction and incur lower costs for PCI procedures.
- No significant differences in prevalence of death or rehospitalization within 2 days and after 30 days after PCIs was found between same-day discharges and overnight stays.
- Elderly patients are not found to be worse candidates for same-day discharge than younger patients, although women are at a higher-risk for complications.
- An observation period of four-to-six hours properly captures all patient risk categories post-procedure.

Trends in U.S. Cardiovascular Care: 2016 Report from 4 ACC National Cardiovascular Data Registries

Masoudi, F.A., Ponirakis, A., de Lemos, J.A., Jollis, J.G., Kremers, M., & Messenger, J.C., et al. (2017). Trends in U.S. Cardiovascular Care: 2016 Report from 4 ACC National Cardiovascular Data Registries. *Journal of the American College of Cardiology*. DOI: 10.1016/j.jacc.2016.12.005 ([Link](#))

- Procedure-related complications were reported in Diagnostic Catheterization and Percutaneous Coronary Intervention (CathPCI)[®]
- 667,424 patients who underwent PCI in 2014 were included in the CathPCI[®] program; mean age of 64.6 years (SD ± 12.3).
- In 2011, unadjusted rates of acute kidney injury was 2.3%; in 2014, it was 2.6%.
- In 2011, rates of blood transfusion was 1.9%; in 2014, rate was 1.4%.
- In 2014, post-procedural stroke occurred in 0.2% of procedures; emergency CABG surgery was performed after 0.2% of procedures; and vascular access site injury occurred in 1.3% of procedures.

Contemporary Mortality Risk Prediction for Percutaneous Coronary Intervention: Results from 588,398 Procedures in the National Cardiovascular Data Registry

Peterson, E.D., Dai, D., DeLong, E.R., Brennan, J.M., Singh, M., & Rao, S.V., et al. (2010). Contemporary Mortality Risk Prediction for Percutaneous Coronary Intervention: Results from 588,398 Procedures in the National Cardiovascular Data Registry. *Journal of American College of Cardiology*, 55(18): 1923–1932. DOI:10.1016/j.jacc.2010.02.005 ([Link](#))

- PCI in-hospital mortality was 1.27%, ranging from 0.65% in elective PCI to 4.81% in STEMI patients.
- Older patients experienced higher unadjusted in-hospital mortality rates (2.25%) compared to younger patients (0.76%).
- Among 204,111 Medicare patients who underwent a PCI procedure between January 2005 and December 2006, 4,068 (1.99%) died in-hospital and 6,011 (2.94%) died within 30 days of the procedure.
- NCDR CathPCI Registry catalogs data on patient characteristics, clinical features, angiographic and procedural details, and in-hospital outcomes.

Safety Concerns and Appropriate Use

Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease

Patel, M. R., et al. (2017) ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease. *Journal of the American College of Cardiology*, 69(17). DOI: 10.1016/j.jacc.2017.02.001 ([Link](#))

- Appropriate use of PCI for one-vessel disease:
 - PCI is appropriate when patient has ischemic symptoms and is on two or more antianginal drugs.
 - PCI is also appropriate if the patient is on only one antianginal drug with proximal left anterior descending (LAD) or Proximal Left Dominant Left Circumflex Artery (LCX) involvement present and there are intermediate- or high-risk findings on noninvasive testing.
 - PCI may be appropriate in other indications, except when patient is not on AA therapy, has no proximal LAD or Proximal Left Dominant LCX involvement, and has low-risk findings on non-invasive testing.
- Appropriate use of PCI for two-vessel disease:
 - PCI is appropriate when patient has ischemic symptoms and is on two or more antianginal drugs.
 - PCI is appropriate when patient has ischemic symptoms and is on one antianginal drug as well as tests that results in intermediate, high-risk, or indeterminate findings.
 - PCI may be appropriate in all other cases except when a patient is asymptomatic and presents with low-risk findings on noninvasive testing without proximal LAD involvement.

Federal Register

Federal Register Volume 82, Issue 239, pg 59412-59413, Final Rule. *Government Publishing Office*. [Online] December 14, 2017. [Cited: February 25, 2018.] www.gpo.gov. 82 FR 59216. ([Link](#))

- PCIs were among the procedures requested for addition to the CY 2018 list of ASCD covered surgical procedures.
- Although it was acknowledged that the procedure may be low risk in some ways, concerns were raised that the procedure may be a safety risk to the Medicare population in an ASC setting, and thus coverage was refused for inclusion.