Research Prioritization Topic Brief

Topic 6: “Coronary Artery Disease (CAD)”

Comparative effectiveness of coronary artery bypass surgery (CABG) and percutaneous coronary intervention (PCI) for treatment of adults with coronary artery disease.

PCORI Scientific Program Area: Assessment of Prevention, Diagnosis and Treatment Options

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<table>
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<tr>
<th>Criteria</th>
<th>Brief Description</th>
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| **Overview/definition of topic** | **DESCRIPTION OF CONDITION**  
- Coronary artery disease (CAD) is caused by atherosclerosis, a thickening or hardening of the coronary arteries, which can lead to narrowing and obstruction of blood flow to the heart muscle.  
- CAD can be present but not cause symptoms (asymptomatic).  
- CAD can result in chest pain (angina) or a heart attack (myocardial infarction or MI for short).  
- Treatment of CAD depends on the individual patient:  
  - All patients are given medications as needed for conditions they have that contribute to CAD, such as medications to prevent blood clots (blood thinners), treat high blood pressure, treat diabetes, and lower their cholesterol if it is too high.  
  - As the disease progresses, some patients require invasive treatments, such as percutaneous coronary interventions (PCI), or coronary artery bypass graft (CABG) surgery, which is even more invasive and with a longer recovery. |
| **Relevance to patient-centered outcomes** | **SYMPTOMS**  
- Shortness of breath  
- Chest pain (angina)  
- Heart attack (or MI), symptoms of which can include chest pain or crushing chest pain, pain and numbness down an arm, neck pain, back pain, jaw pain, nausea, sweating  
**OUTCOMES**  
- Quality of life (freedom from chest pain, ability to do self-care and activities), prevention of future heart attacks or strokes, survival, and prevention of complications (such as prolonged hospital stay, infection, bleeding) from the invasive treatments of PCI and CABG  
**PATIENT CHARACTERISTICS**  
- Characteristics include, sex, race, age, comorbidities (hypertension, diabetes, high cholesterol, chronic kidney disease, congestive heart failure), and lifestyle choices (heavy alcohol consumption, tobacco use, sedentary lifestyle).  
- These characteristics affect disease progression and thus treatment of the patient.  
**SEVERITY OF CAD**  
- Determined by assessing the number and location of vessels with CAD and the degree of constriction (stenosis) of the diseased vessels  
**PROCEDURE/HEALTH CARE CENTER VARIABLES**  
- PCI variables include choice of opening a vessel with balloon angioplasty or placing a stent (small device to help hold vessels open)  
- CABG variables include open-bypass (chest bone is opened), performed either  
  - “On pump” (heart is stopped, heart-lung bypass machine is used)  
  - “Off pump” (heart remains beating, no pump needed, heart does not need to be restarted but is technically more difficult for surgeon)  
- MIDCAB procedure, a relatively new type of bypass, is less invasive (chest bone is not opened); it involves:  
  - Small cuts made on the left side of the chest between the ribs  
  - Repair limited to one or two coronary arteries |
Performing “on pump” or “off pump”

- Centers where more PCI and CABG procedures are performed have better outcomes, suggesting that experience is an important factor in improving how well a patient does after the procedure.

### Burden on Society

<table>
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<tr>
<th>Recent incidence and prevalence in populations and subpopulations</th>
<th>INCIDENCE (NEW CASES)</th>
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<td>Rates of first heart attack or stroke in men rise from 3 per 1000 (aged 35-44) to 74 per 1000 (aged 85 to 94).²</td>
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<td>For women, comparable rates occur 10 years later in life.</td>
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<td>The gap between men and women narrows with advancing age.²</td>
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<td>600,000 Americans die from heart disease each year, which is one in every four deaths.³</td>
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<td>CAD is the most common type of heart disease, killing more than 385,000 people annually.³</td>
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**PREVALENCE (PROPORTION OF POPULATION LIVING WITH THE CONDITION)**

- Age-adjusted prevalence of CAD in a general US population was estimated at about 6% in 2010, with higher prevalence in certain subgroups including patients over 65 years of age (19.8%), patients with diabetes (35%), and patients with chronic kidney disease (38-65%).

### Effects on patients’ quality of life, productivity, functional capacity, mortality, use of health care services

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<th>QUALITY OF LIFE</th>
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<td>Quality of life is associated with not having chest pain (known as angina).</td>
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<td>o Patients undergoing CABG (rather than PCI) had less angina during the period from six months to three years after the procedure.</td>
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<td>o The amount of chest pain was the same for both procedures after three years.</td>
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<td>o Older patients had less angina in general.</td>
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### Burden

**BURDEN**

- Given the large number of CAD patients and the aging society, priority should be given to comparative-effectiveness research to determine the treatments with the best outcomes based on patient characteristics and severity of CAD.
## Options for Addressing the Issue

Based on recent systematic reviews, what is known about the relative benefits and harms of the available management options?

Knowledge about benefits and harms of treatment options, based on a recent systematic review,\(^5\) include:

**BENEFITS**
- Overall survival after PCI and CABG are now quite similar, with PCI being the less invasive option.
- Patients with 1-vessel disease (non-left anterior descending vessel) have better survival with PCI.
- Patients with 3-vessel, or left main, disease have better survival with CABG.
- In patients with diabetes and heart failure, there was no clear difference between PCI and CABG in terms of survival.

**HARMS**
- Risk of periprocedural heart attack was not significantly different with CABG compared to PCI.
- Risk of periprocedural stroke was higher with CABG compared to PCI.
- Complications were higher in older patients for both CABG and PCI.
- Patient results were worse for both procedures at hospitals where they were performed infrequently.

### What could new research contribute to achieving better patient-centered outcomes?

An AHRQ report in 2010\(^6\) identified four areas where future research is indicated to answer areas of uncertainty:

1. Studies of the comparative effectiveness and safety of PCI vs. CABG should be done using existing data (performing meta-analyses of individual patient data available from prior research projects).
2. Studies should evaluate the ability of tests to predict how well a person will do with different types of revascularization procedures. Such tests would include both invasive tests (arteriography) and noninvasive tests (magnetic resonance [MRI or computed tomography angiography], CT scan, and exercise treadmill testing).
3. Studies should enhance patient participation by asking for and measuring patient preferences as well as involving patients in decisions regarding their care.
4. Studies should develop performance measures that provide feedback to health care providers in order to improve outcomes for their patients.

### Have recent innovations made research on this topic especially compelling?

- Drug-eluting stents (DES) are a newer technology than bare-metal stents (BMS).
- Use of DES with PCI has increased markedly over the past decade.
- Most doctors who do PCI and CABG believe that there are fewer heart attacks and strokes in patients who receive DES (compared with BMS), but there are not enough data to support this belief.
- A 2007 AHRQ report\(^5\) included only one DES trial, but there are now six DES vs. CABG studies completed, with additional available data.
- An updated comparative-effectiveness report comparing DES with CABG could help determine whether DES is truly superior to BMS and further help define which populations of CAD patients do better with the less invasive PCI treatment (rather than CABG).

### How widely does care now vary?

**VARIABILITY IN CARE**
- Overall, there are fewer invasive procedures being done, and of those performed, rates for the less invasive PCI have increased.
An analysis of Medicare patients from 2001 to 2009 showed an increase for PCI of 1.3% per 1000 beneficiaries.
- During the same period, there was an annual decrease of CABG by 5%.

- An analysis of North Carolina data from 2003 to 2009 showed that rates of all invasive procedures per 100,000 population declined:
  - 24% decrease in catheterization rates
  - 16% decrease in PCI rates
  - 35% decrease in CABG rates

What is the pace of other research on this topic (as indicated by recent publications and ongoing trials)?

### RECENT PUBLICATIONS
- In a MEDLINE search over the past 5 years, 26,550 citations were identified related to treatment of CAD:
  - Randomized controlled trials (RCTs): 2853
  - Cohort studies: 9831
  - Systematic reviews: 1827
- In 2007, AHRQ published a comparative-effectiveness report of PCI vs. CABG for CAD; an addendum was published in February 2010 with meta-analysis of individual patient data from 10 of the 12 trials included in the 2007 report.
- In September 2010, AHRQ published a future research needs report about PCI vs. CABG for CAD.

### ONGOING TRIALS
- A search of ClinicalTrials.gov lists 167 ongoing trials.
- Several projects are evaluating comparisons of single modalities; for example, DES vs. BMS in subgroups (elderly, diabetes); off-pump vs. on-pump CABG.
- There are few RCTs of PCI vs. CABG due to the difficulty in recruiting cardiologists and cardiac surgeons who are willing to randomize patients.
- An indirect or network meta-analysis combining single-modality studies of DES vs. BMS and the various CABG modalities could be performed to increase the number of PCI vs. CABG studies available for comparison.

How likely is it that new CER on this topic would provide better information to guide clinical decision making?

### KEY UNCERTAINTIES IN CLINICAL DECISION MAKING
- Previous systematic reviews were based on older technologies (balloon angioplasty or BMS).
- DES use has increased over the past decade.
- Findings from RCTs may not translate to results in real-world settings, where patients with multiple comorbidities are treated for CAD.
- RCTs have not been large enough to evaluate effectiveness in subgroups.
- Provider and patient preferences—rather than evidence—are used in determining the choice of invasive therapy to treat individual CAD patients.

### REDUCING UNCERTAINTIES
- Updated CER comparing DES and BMS, by looking at earlier data from BMS vs. CABG studies and then newer data comparing DES vs. CABG, would reduce uncertainty about newer technologies.
- Pooling patient-level data would make it possible to have more information about optimal care for certain patient subgroups.
Providers may be able to help patients make more informed decisions with better evidence.

**Potential for New Information to Improve Care and Patient-Centered Outcomes**

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<th>What are the facilitators and barriers that would affect the implementation of new findings in practice?</th>
<th>FACILITATORS</th>
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| **FACILITATORS** | • Professional societies and patient advocacy groups help to implement new guidelines as more information is obtained.  
• Educational initiatives, similar to “Get With the Guidelines” for MI and heart failure care, could be implemented. |

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<th>BARRIERS</th>
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| • Physician and patient preferences, regardless of what the evidence may show, will always factor into decisions about the use of invasive procedures.  
• Some patients may choose a certain procedure due to insurance requirements, fear of surgery, or inability to take time away from work and caregiver responsibilities. |

<table>
<thead>
<tr>
<th>How likely is it that the results of new research on this topic would be implemented in practice right away?</th>
<th>FACILITATORS</th>
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| • Physician and patient preferences influence much of the variability in PCI and CABG use across the nation. This situation mandates additional research to increase our understanding of how particular types of disease, demographics, and comorbidities affect outcomes. This knowledge will help patients to optimize their treatments.  
• Implementation would require collaborative effort among professional societies and patient advocacy groups as well as health care providers in order to educate patients and determine the best care for them. |

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<th>Would new information from CER on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?</th>
<th>FACILITATORS</th>
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| • PCI and CABG have been the main invasive treatments for over two decades.  
• While advances in PCI and CABG techniques are still being developed, it is likely that results from CER on this topic will be relevant for several years.  
• Further, this is a prime group to work on this type of shared decision making model, because there are already strong professional societies and guideline groups in place. |

**References:**


**APPENDIX: Topic Questions**

*Nominated by ‘Web’*

1) How can we be certain that patients are being offered the proper treatment for coronary artery disease ... percutaneous coronary intervention vs. coronary artery bypass surgery? How can we know whether guidelines are being followed in every institution?

**Population:** All patients who have coronary artery disease, which would affect men and women of all ethnicities, but usually in the relatively elderly population.

**Importance:** We know outcomes are affected by approach ... PCI vs. CABG. Are we using concordant decision making to assure that patients are being referred for the proper treatment? Best care would be most cost-effective in the long run.

*Nominated by NIH*

Comparative effectiveness of PCI vs. CABG [specifically for]:

**Subpopulations:**
- Age >75 years
- Prior PCI
- Diabetes
- Women
- Congestive heart failure
- Stage 3 or 4 of chronic kidney disease

**Comparisons:**
- BMS vs. on-pump traditional CABG with arterial grafts
- DES vs. on-pump traditional CABG with arterial grafts

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