Introducing the ASCERT Study

What is the ASCERT Study?
The American College of Cardiology Foundation (ACCF) and The Society of Thoracic Surgeons (STS) are embarking on a unique and exciting partnership to study comparative effectiveness of percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG) surgery for the treatment of stable coronary artery disease. ASCERT stands for the American College of Cardiology Foundation-The Society of Thoracic Surgeons Collaboration on the Comparative Effectiveness of Revascularization Strategies. As you may know, the National Heart, Lung, and Blood Institute of the National Institutes of Health (NIH) has just awarded a grant to the ACCF in partnership with the STS to study these two forms of coronary revascularization. This study will compare catheter-based and surgery-based procedures using existing clinical databases from the ACCF and STS, as well as the Centers for Medicare and Medicaid Services’ MEDPAR administrative data. By linking these three databases, the study will help physicians and their patients make better decisions and improve healthcare for patients with coronary artery disease.

As stated in our grant, the aims of this study are to:

- Create separate PCI and CABG prediction models of death and non-fatal events long-term after initial revascularization in the setting of chronic coronary artery disease.
- Characterize patients undergoing CABG vs. PCI by developing propensity scores for CABG in patients undergoing isolated CABG or PCI not in the setting of an acute myocardial infarction. Describe these patients in both groups across the range of their propensity scores.
- Compare long-term survival, hospitalization for MI, renal failure, stroke and repeat revascularization using propensity score methods.
- Select a random sample of patients undergoing CABG or PCI for detailed angiographic analysis to create a SYNTAX score. In this sample, attempt to model the SYNTAX score based on covariates available in the STS and ACCF databases. Use these data to consider the presence of residual confounding based on angiographic severity defined by the SYNTAX score.
- Assess long-term outcomes by age, gender, comorbidity, and severity of disease.
- Assess resource use and long-term costs in each group using MEDPAR. The cost and incremental cost-effectiveness of CABG compared to PCI will be considered for the whole matched group and for subgroups as defined above. The outcome will be in cost per life year gained and cost per quality adjusted life year gained.

Dr. William Weintraub and Dr. Fred H. Edwards are principal investigators on this study. Dr. Weintraub is also chair of the ACCF’s National Cardiovascular Data Registry (NCDR) CathPCI Registry Steering Committee. Dr. Edwards, from The Society of Thoracic Surgeons, is chair of the STS Workforce on National Databases. Duke Clinical Research Institute (DCRI) will perform the analysis for clinical outcomes and Christiana Care Center for Outcomes Research (CCOR) will perform the analysis for economic outcomes. In addition, PERFUSE Angiographic Core Laboratories and Data Coordination Center will perform detailed angiographic analysis on 2,000 angiograms of patients who have undergone PCI in order to determine their SYNTAX score. Led by Drs. Weintraub and Edwards, a steering committee of investigators representing
ACC, STS, DCRI, CCOR and PERFUSE will be responsible for the administration and conduct of this study. This two year award has been issued under the American Recovery and Reinvestment Act of 2009.

This study will be a model for comparative effectiveness research using non-randomized data, permitting extensive assessment of long-term clinical and economic outcomes after coronary revascularization, obtained from the largest and most comprehensive clinical databases available for revascularization in the world.

**Why is this Study Important and Why Should We Participate?**

In the United States, more than 1,000,000 coronary revascularization procedures are performed every year. Some patients are best served with PCI, while others are undoubtedly better served with surgery. Between these two groups, however, lies a large population in which the optimal treatment is not well-defined. This study will attempt to bring clarity to the therapeutic decisions required for patients in this group. We will search for the specific patient characteristics that favor one mode of treatment over the other.

Being awarded this grant is a tribute to the many people across the country who over the years have been able to contribute to the STS and NCDR registries to allow us to address critical research questions. This study is an example of exactly how participation in registries can lead to tangible improvements in patient care. Participating in this study is a way to help shape the future of cardiovascular care.

**How Will Our Hospital Participate in this Study?**

We are inviting approximately 100 hospitals to take part in a sub-study, whereby a subset of 2,000 patients will be evaluated for SYNTAX score, which is a relatively new way to describe the severity of coronary blockages. Because a high SYNTAX score is predictive of higher event rates among PCI patients, and is consequently indicative of higher relative treatment benefit for CABG, this score represents a potentially valuable prognostic guide for treatment selection. However, the SYNTAX score relies on detailed angiographic data that are not commonly collected. To adequately capture the impact of the SYNTAX score on prognosis, 2,000 patients belonging to the subpopulation of patients who have angiographic data available in the catheterization section of the NCDR will be selected for core lab determination of SYNTAX score; half of these patients will be randomly selected from the CABG patients and will also belong to the STS Adult Cardiac Surgery Database and half will have received PCI.

These angiograms will be analyzed by the angiographic core laboratory in order to create a SYNTAX score. Angiograms will be sent from originating facilities and tracked upon receipt at the core laboratory. Using the captured variables, a SYNTAX score will be calculated for each angiogram. The data will be transferred to the Duke Clinical Research Institute (DCRI) as an encrypted tab delimited ASCII file on a schedule to be determined.

**What is Required to Participate in this Study?**

All hospitals considering participation in this study must participate in both the NCDR CathPCI Registry and the STS Adult Cardiac Surgery Database. Participation in the study will involve preparing angiogram films for select patients receiving PCI or CABG procedures between 2004
and 2007 from a list that the Duke Clinical Research Institute (DCRI) will develop. DCRI will send each study site a list of cases identified by an NCDR unique record identifier that the site can use to determine which patients to include in the study. The NCDR unique record identifier will enable the study site hospitals to identify the actual patients, but the patient’s name is known only to the hospital where the procedure was performed. Only the study sites can link the NCDR unique record identifier to the patient; however, for the purposes of this study no direct patient identifiers will be used. The study site will prepare angiograms for transmission to PERFUSE Angiographic Core Laboratories and Data Coordination Center (“PERFUSE”). Each study site will send their approximately 20 angiograms to PERFUSE.

What is the Timeframe for this Study?
Data collection for the ASCERT Sub-Study begins January 2, 2010 and will be completed by no later than June 30, 2010. Each site will be asked to send approximately 20 angiograms for SYNTAX scoring.

Will Hospitals be Paid for their Study Participation?
In order to compensate hospitals for the time and effort involved in participation, including potentially submitting the sub-study to an Institutional Review Board (IRB), they will be compensated $200 per patient angiogram. Payment will be made on a quarterly basis following validation of angiograms received by PERFUSE.

Will We Need to Submit this to Our Hospital’s Institutional Review Board?
The ASCERT Study protocol, grant application, Principal Investigator and Site Information have been approved by ACCF’s independent IRB, Chesapeake Research Review, Inc. (CRRI) in Columbia, Maryland. In accordance with 45 CFR 46.116(d) of the federal regulations CRRI’s IRB has waived the requirement for obtaining consent for this study. The IRB has also waived HIPAA Authorization, in accordance with 45 CFR 164.512(i).

We expect that many hospitals will need to submit their request to participate in this sub-study to their own institution’s IRB. ASCERT study staff will be glad to provide protocol information, verification of CRRI IRB approval, or facilitate this process in any other way. We suggest that hospitals seek expedited IRB review if possible, as patient privacy is protected and the study does not involve any intervention for the patient.

What Steps are You Taking to Protect Patient Privacy?
Patient privacy will be protected at all times. Hospitals will be sent a list of patients identified by an NCDR unique record locator that they can use to determine which patients to include in the study. The NCDR unique record locator will enable the study site hospitals to identify the actual patients, but the patients’ name will be known only to the hospital where the procedure was performed. Only the study sites can link the NCDR unique record locator to the patient, however, for the purposes of this study no direct patient identifiers will be used. The study site will prepare angiograms for transmission to PERFUSE Angiographic Core Laboratories and Data Coordination Center in Boston, Massachusetts. At that time, study participants will be required to remove all HIPAA identifiers before sending the angiograms to PERFUSE so that PERFUSE staff who are completing the SYNTAX scores will not know the identity of the patient. PERFUSE will track all angiograms and proceed to perform angiographic analysis in
order to determine a SYNTAX score. PERFUSE will record the SYNTAX scores on a Case Report Form (CRF) that will then be entered into a database, which they will then transfer to DCRI, the ASCERT study’s analytic center. This will include the NCDR unique record locator.

PERFUSE will maintain these angiograms until all appropriate quality controls are completed, and then will return any physical materials (such as DVDs) to the originating hospital study sites. PERFUSE will permanently archive copies of the blinded digital angiograms. The DCRI analytic center will link the SYNTAX score data to the study data in order to complete the analysis and the study.

**How Can I Get More Information?**
Please call our NCDR Service Center at 1-800-257-4737 or email us at ncdr@acc.org.

**How Much Time do we Have to Decide about Participating?**
In order to participate, ACCF must have received your signed addendum by no later than December 1, 2009. This will enable us to provide training in order to begin data collection promptly on January 2, 2010.

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Disclaimer:
*The project described above is supported by Award Number RC2HL101489 from the National Heart, Lung, And Blood Institute. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Heart, Lung, And Blood Institute or the National Institutes of Health.*