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March 15, 2012

Eugene Washington, MD
Chair, Board of Governors
Patient-Centered Outcomes Research Institute

Dear Dr. Washington:

The American College of Cardiology (ACC) is pleased to have the opportunity to offer these brief comments on the Patient-Centered Research Outcomes Institute (PCORI) Draft National Priorities for Research and Research Agenda. The ACC is transforming cardiovascular care and improving heart health through continuous quality improvement, patient-centered care, payment innovation and professionalism. The College is a 40,000-member nonprofit medical society comprised of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The College is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The ACC provides professional education and operates national registries for the measurement and improvement of quality care. More information about the association is available online at <http://www.cardiosource.org/ACC>.

As we have stated in previous correspondence, the ACC is very supportive of the mission of PCORI in developing the agenda for this patient-centered outcomes research. Wise use of the PCORI funds can greatly further this very important next step in research. We are impressed by the deliberation of the PCORI Board of Governors in making sure that the foundations and the priorities for this research are set before any funds are distributed.

First, the document proposes that research priorities not name specific conditions. We support an approach that does not play diseases against one another and we are confident that the overwhelming volume of cardiovascular disease coupled with the statutory requirement to focus on high prevalence chronic disease will lead to strong support of patient-centered outcomes research in this area. After setting aside disease priorities, PCORI identifies five programmatic priorities as follows:

The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.

- Assessment of Prevention, Diagnosis, and Treatment Options.
- Improving Healthcare Systems.
- Communication and Dissemination.
- Addressing Disparities.
- Accelerating Patient-Centered and Methodological Research.

We feel that this list captures the areas of research that PCORI ought to be funding and corresponds well to efforts that are ongoing in the field of cardiovascular care.

Assessment of Prevention, Diagnosis, and Treatment Options

The assessment of various diagnosis and treatment options is the nature of being a physician. Over the past twenty years, the ACC and others have undertaken efforts to synthesize and analyze cardiovascular research and expert opinion. These efforts first led to clinical guidelines and then to performance measures and appropriate use criteria. These documents have formed a strong foundation for determining the correct course to take in addressing cardiovascular disease; however, they can be greatly improved by more research to identify the effect of various treatment strategies on patients with different presentations than those within the initial trial designs and integrating the impact of shared decision-making on patient outcomes. Diagnosis in cardiovascular disease can vary from patient history to complex imaging, and treatment of cardiovascular disease can range from drugs to procedures to surgery. Research that can further help physicians and patients identify what treatments work best will be of considerable importance.

Randomized clinical trials (RCTs) are an important part of the development of new services, but the environment in which they are performed sometimes requires arbitrary measures of success as well as artificial limitations of the study population. To improve upon the limitations and constraints of RCTs, and to provide innovative research strategies, PCORI should strongly consider research designs that incorporate the use of research on real patients using clinical registry data. Registry data are incredibly powerful because they are not subject to the limitations of clinical trials, and instead capture real-time medical patient information and practice trends, providing greater opportunity for deeper assessments of the patient experience. The ACC has invested considerably in registries that track quality data on patients with cardiovascular disease across the United States, and contain readily analyzable results. These registries now include data from thousands of patients who have undergone percutaneous coronary interventions, received implantable cardioverter defibrillators (ICDs), and received care for acute coronary syndrome. Research using registry data can play a very important role in part of the work of PCORI's research efforts in the assessment of

diagnostic and treatment options because of its value in representing more widely generalizable results, and should be considered an asset to proposed research designs.

Improving Healthcare Systems

Providing quality cardiovascular care requires the entire healthcare system, including physicians, nurses, hospitals, nursing homes, patients and family members/caretakers. Navigating through these systems is increasingly complex for patients, especially those with difficult or debilitating cardiovascular illness. The ACC has had considerable success in improving cardiac care delivery within healthcare systems, demonstrating the value that may be gained from the kind of research conducted at the ACC that uses registry data as a core component of study analysis.

For example, after research showed that patients experiencing ST elevation myocardial infarction (STEMI) were much more likely to live if their arteries were opened as quickly as possible, the ACC and others embarked on a nationwide Door To Balloon campaign to reduce the time from arrival in the emergency room to the percutaneous coronary intervention (PCI) to less than 90 minutes. In the six years since ACC launched this national campaign, the median time from door to balloon has dropped by one-third.¹ This kind of improvement was only possible through the collaborations of multiple parts of the healthcare system, including cardiologists, emergency physicians, emergency medical technicians, and hospital.

More recently, the ACC has taken on another system problem, the difficult transfer for patients as they leave a hospital. The Hospital to Home program has operated as a community to share best practices but would benefit considerably from expanded research on what actually to evaluate what works most effectively to keep patients from being readmitted shortly after being discharged from a hospital.

While the ACC has invested considerably in improving these healthcare systems, we believe that there is a strong need for additional support from organizations like PCORI. Since these system changes are not related to a new drug or device or technique, such research efforts receive limited private industry support. The successes of Door to Balloon can be repeated given the right research. PCORI can play an essential role in filling this gap.

Communication and Dissemination

Methods of communicating and disseminating research findings may seem obvious, but not all methods lead to the appropriate adoption of research results and outcomes. The ACC has employed several approaches to communication and dissemination - from broad-scale national

¹ Original Articles - Health Services and Outcomes Research: Improvements in Door-to-Balloon Time in the United States, 2005 to 2010
Harlan M. Krumholz, Jeph Herrin, Lauren E. Miller, Elizabeth E. Drye, Shari M. Ling, Lein F. Han, Michael T. Rapp, Elizabeth H. Bradley, Brahmajee K. Nallamothu, Wato Nsa, Dale W. Bratzler, and Jephtha P. Curtis
Circulation. 2011;124:1038-1045, published online before print August 22 2011,
doi:10.1161/CIRCULATIONAHA.111.044107

quality initiatives to enhanced, individual lifelong learning programs. The identification and understanding of the target audience is essential component to this. While the ACC's primary target audience is the clinical and non-clinical caregiver, we are also very interested in the role that communication of this research to patients plays in the decision making process. Specifically, we hope to explore shared decision-making techniques and tools to help physicians and patients understand a patient's preferences for care in relation to the specific risks and benefits of each option available to them. The future of healthcare relies on this patient-centered perspective and the ACC fully supports the opportunity for additional research in this area.

Addressing Disparities

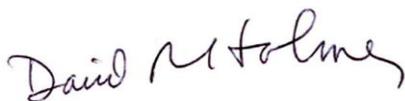
Disparities in care based on race, gender, and economic status are a sad fact of our healthcare system. The ACC strongly endorses efforts to understand these disparities and to improve the care and health status for all. In an effort to address these disparities in cardiovascular care, the ACC formed the Coalition to Reduce Disparities in Cardiovascular Outcomes (CREDO). CREDO aims to give health care providers information and tools to equitably treat their diverse patient populations with or at risk of cardiovascular disease. It seems clear that that these disparities are not just a result of differing levels of access to care but are instead a combination of access and different responses to treatment. The efforts of CREDO would be enhanced by further funding of research to identify these differences and study the effectiveness of their treatments.

Accelerating Patient-Centered and Methodological Research

We strongly support the continued efforts to improve the research infrastructure. This last priority will prove valuable for each of the other priorities by improving the quality of research and analysis that will feed into each of these priorities. While the ACC, as a specialty organization, has not focused on these particular efforts, we believe them to be very important.

We once again thank PCORI for their efforts to be inclusive of the entire healthcare community in your foundational efforts to set priorities. We look forward to many future discussions and most importantly look forward to the fantastic research that is sure to be funded by this organization. If you have any questions or comments about our positions, please contact Brian Whitman, Associate Director of Regulatory Affairs at bwhitman@acc.org or (202) 375-6396.

Sincerely,



David R. Holmes, Jr., MD, FACC
President