



The Society for Cardiovascular Angiography and Interventions

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**Incoming President
of the
Society for Cardiovascular Angiography and Interventions**

**Presentation to The
Federal Coordinating Council for Comparative Effectiveness**

Listening Session

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**The Hubert Humphrey Building
Washington, DC**

Good afternoon. I am Dr. Steven R. Bailey, the Incoming President of the Society for Cardiovascular Angiography and Interventions (SCAI). I am also the Chair of the Division of Cardiology, Professor of Medicine and Radiology, and the Janey Briscoe Distinguished Chair at the University of Texas Health Sciences Center at San Antonio.

I am here representing SCAI, a nonprofit medical society whose mission is to promote excellence in invasive and interventional cardiovascular medicine through physician education, representation, and quality standards that enhance patient care.

As our mission states, our first priority is enhancing the care that patients receive. That means advocating for our patients' safety, their access to care, and research that puts their best interests first. This is the premise of our viewpoint on comparative effectiveness.

We strongly support the goals of comparative effectiveness research, and we will be active participants in developing comparative effectiveness research paradigms and protocols. Our guiding principle in this effort will be to put the interests and needs of patients – all patients – first.

You might say that Interventional Cardiology has been engaged in comparative effectiveness research for some time. Many of our members have been investigators on trials that have compared newer and more innovative procedures to conventional medical therapy and surgical techniques, for example. Many such studies have shaped the way patients are cared for today, but we all recognize that such studies have limitations.

That's why we are here today, to look at how to go forward. Let me make a few suggestions.

First, let's look critically at clinical endpoints. We must make sure to focus on the key goals of procedures and not lump together dissimilar outcomes. In our field we have seen:

- angioplasty for patients with stable angina measured against a goal of reducing death and myocardial infarction (MI) when the intervention in the population studied has always been promoted for the goal of reducing symptoms, not a reduction in death and MI.
- numerous studies comparing CABG and angioplasty that lump death, stroke and repeat revascularizations into the same clinical endpoint despite the obvious important differences in these outcomes.
- carotid stenting in high-risk patients compared to the surgical patients in a lower-risk population.

Next, comparative effectiveness studies must be large enough and powered sufficiently to develop meaningful data for clinical subpopulations. The appropriate treatments for patients with cardiovascular disease vary based on age, gender, race, and other patient variables. Effectiveness studies must study and identify the important clinical parameters that would affect outcome in order to be helpful in determining the proper course of treatment for individual patients. In too many cases, the study outcomes are applicable only to the studied group, which is often highly defined and homogeneous. Very often, trials study older white men who are economically stable and with less severe symptoms, leaving us to generalize, often inappropriately, in the treatment of patients who are young, not male, not Caucasian, or not economically stable.

SCAI supports the gathering of the data needed for decisions about comparative effectiveness. The Society began the first registry of cardiovascular interventions nearly 25 years ago and now partners with the American College of Cardiology on the Cath/PCI registry, among other data registries.

As we embark on comparative effectiveness research, we should be careful to avoid bias in study design. One example is the prevailing assumption that conventional medical therapy is the gold standard. Let's not assume that interventions must be shown to be superior to medication even when the medical therapy is not well defined or studied. We are strong proponents of "first do no harm," just as we understand that conventional

medical therapy is neither risk free nor consistently applied. Additionally, clinicians need to consider that patients outside of a clinical trial setting are less compliant with their medical regimens, resulting in practice-based outcomes that often do not coincide with those found in highly regulated study environments.

It is crucial that all entities conducting comparative effectiveness research, including government agencies, maintain an open and transparent process in developing their studies. The input of SCAI and other expert groups has dramatically improved many studies, including the recent Horizon Scan AHRQ published on peripheral interventions. We suggest that all government-sponsored comparative effectiveness reports be posted as drafts, that the public be given at least 30 days to comment on these frequently lengthy and complex documents, and that comments from the public be available for public reporting. This is the process that CMS uses for making national coverage decisions, and it is well established.

As I've stated, we support comparative effectiveness research and believe it has the potential to improve the U.S. healthcare system. All therapeutic options should be studied, including prevention and early detection strategies, and all options should be compared to the clinically relevant endpoints. We welcome the opportunity to work with the government so that the results of this research are meaningful for a large spectrum of patients and reflective of an ability to deliver the right treatment for each individual patient regardless of disparities that might exist. Great strides have been made in the field of cardiovascular disease. We must continue advances in an effective, efficient and evidence-based path.