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ADVOCACY POSITION STATEMENT

ACC 2009 Advocacy Position Statement: Principles for Comparative Effectiveness Research

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Introduction

As the health care reform debate takes center stage, the concept of comparative effectiveness research (CER) has risen to the top of the agenda because of its potential to inform practice, improve care, and influence costs. The principles that follow are offered to the research, consumer, patient, medical, and policy communities to help lead to better health and health care through the support and dissemination of CER. For over 2 decades, the American College of Cardiology (ACC) has played a vital role in interpreting cardiovascular science, and, in conjunction with other organizations, has published clinical guidelines for the care of patients with cardiovascular disease. The College continues its strong support of research as the foundation for improvements in care and its delivery. These guiding principles are intended to preserve the essential elements of good health care: sound scientific foundation; effective communication among clinicians, patients, and their families; freedom from inappropriate influence or disparities in access or treatment; and a commitment to continuous quality improvement.

ACC Principles for Comparative Effectiveness Research

The ACC:

1. Strongly supports CER as an important means to provide useful information to patients and their health care providers for informed decision-making, and urges the widespread dissemination and use of CER results by health care providers and patients;
2. Advises that CER priorities be set by a multistakeholder board of consumers, patients, health care practitioners, researchers, employers, and health plan representatives in order to ensure that the nation's research agenda reflects the diverse needs of its citizens;

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3. Advises that CER priorities be based on the disease burden of the conditions in question (morbidity and mortality) and on the presence of more than 1 evidence-based diagnostic or therapeutic approach to each of those individual conditions;
4. Recognizes that the generation of new knowledge is only the first step in improving the quality, equity, and efficiency of medical care and must be coupled with a set of policies, programs, and payment reforms that facilitate implementation of this evidence;
5. Recognizes that improving the quality of medical care must be the first priority of CER, whereas reducing costs may be considered a secondary aim;
6. Recommends that CER be conducted with the highest scientific rigor (including addressing the impact of ethnic, racial, gender, economic, geographic, and genetic diversity on trial design), and under the supervision of experts in the design and management of this form of clinical cardiovascular research and recommends that cost analyses be conducted separately from the clinical research itself;
7. Proposes a distinct separation between the entities that generate CER and those that design and determine coverage and benefit programs;
8. Recognizes that as the policies and programs based on CER are implemented, they will require close monitoring to avoid adverse consequences related to restrictions on access, quality, or safety; and
9. Recognizes that CER will require substantial and long-term support and investment in order to sustain the generation of new knowledge and its implementation in practice.

The ACC's Role in Comparative Effectiveness Research

The ACC has a history of supporting the cycle of quality improvement through research translation and dissemination, and its clinical data registries are well positioned to support comparative effectiveness research (1). Specifically, the College can perform the following roles:

1. Inform CER priorities through guidelines, appropriate use criteria (AUC), and the National Cardiovascular Data Registry (NCDR);
2. Provide standardized data elements and definitions to facilitate exchange of research databases among investigators for CER;
3. Provide NCDR as a standardized infrastructure for conducting CER in cardiovascular care;
4. Implement system redesign quality improvement projects based on CER; and
5. Disseminate CER findings to patients through the ACC's membership of 37,000 physicians, nurses, physician assistants, pharmacists, and practice administrators.

The College also can build upon its core competencies to support CER as follows:

1. Develop systematic reviews of the evidence to produce and translate CER;
2. Develop a methodology for integrating CER into guidelines and AUC;
3. Develop a research network among NCDR participants; and
4. Engage in retrospective and prospective studies using NCDR.

Clinical practice guidelines and AUC provide a robust catalog of the existing evidence base, as well as the gaps in knowledge. In fact, nearly 50% of current clinical guideline recommendations are expert opinion, and even those with the highest level of evidence are primarily based on efficacy data (2). As such, these documents can help prioritize CER topics for additional study.

NCDR has a rich set of data elements and definitions and is complemented by American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) clinical data standards. A standardized nomenclature will be an important element to facilitate exchange of datasets among researchers and promote the ability to compare results between studies. In addition, NCDR can serve as a data archive that provides a unique and widely representative sample to conduct CER in cardiovascular care. NCDR has millions of patient records in its hospital and physician office databases that can be used to inform CER design, define the opportunities for further research, and provide data on the performance of interventions in real-world populations and systems.

The ACC has experience in implementation science through such projects as GAP, the Guidelines Applied in Practice, and D2B: The Alliance for Quality. These 2 projects were built on both published and rapid-cycle local interventions to drive improvements in care. CER will generate additional lessons about the relative merits of various interventions and, in many cases, CER will identify not necessarily the 1 best intervention, but rather a set of reasonable alternatives. The ACC can facilitate the uptake of this new knowledge through comprehensive educational programs, continuous interpretation of the evidence, and quality improvement initiatives that implement the science into practice; outreach to professionals, consumers, and patients via CardioSource and CardioSmart Web sites; and promulgation of shared decision-making. By doing so, the College can help CER achieve its potential benefit for patients and society.

Finally, the questions to be addressed by CER are of concern to cardiovascular specialists and patients around the world and are not just confined to the United States. As an international organization, the ACC is well positioned to bring together cardiovascular leaders from many countries to address these clinical conundrums. The ACC International Council's Task Force on Science and Quality would

provide an ideal venue for use of registries, sharing data, and planning studies or projects to address issues important to cardiovascular medicine on a global scale.

Summary and Conclusions

The ACC is strongly supportive of a robust CER program that will better inform the health care decision-making of patients and their health care professionals. The ACC also supports cost-effectiveness analyses that are based on high-quality comparative clinical effectiveness research. Since cost-effectiveness analyses vary depending on the assumptions used, and since such assumptions vary depending on the payer, multiple analyses for any technology or procedure may, in fact, be carried out. Furthermore, decisions on matters related to insurance coverage should not be made by an entity responsible for CER. The ACC stands ready to support CER through the College's NCDR registries and can play an important role in the dissemination and implementation of the findings resulting from such research through ACCF/AHA guidelines, AUC, and other documents, and through the College's growing efforts in the area of implementation science.

Ultimately, studying the comparative effectiveness of available diagnostic tools and therapies for any given condition is only 1 step in the translation of research into practice and should be considered in the broader context of basic research, clinical trials, and outcomes research. The ACC believes CER, when conducted correctly, is a useful tool that assists physicians and other providers in delivering high-quality, equitable, and effective health care to patients.

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