

Wednesday, June 10, 2009

Dear Federal Coordinating Council Members:

The Partnership to Improve Patient Care (PIPC) appreciates this opportunity to respond to your recently released draft definition and prioritization of comparative effectiveness research (CER).

PIPC is a diverse coalition of over 40 organizations representing patients, healthcare providers, research institutions and medical research companies. PIPC was formed in November 2008 to advance proposals for CER that are focused on supporting providers and patients with the information they need, improving healthcare quality and supporting continued medical progress. Our members are united by a common set of CER principles in support of this goal.

Our partnership appreciates the Federal Coordinating Council's posting of its draft CER definition, prioritization criteria and strategic framework as a further step in promoting openness and transparency. Providing continued openness and transparency in the Council's activities and those of the Department of Health and Human Services will ensure that the perspectives of patients, providers and other stakeholders are considered.

We also commend the focus on the expressed needs and perspectives of patients and providers in your draft definition. PIPC reaffirms our belief that CER must focus on communicating research results to patients, providers and other decision-makers, not making centralized coverage and payment decisions or recommendations. This focus is consistent with the goal of CER as described in HHS' press release announcing the Federal Coordinating Council, which stated, "Such research will give clinicians and patients valid information to make decisions that will improve the performance of the U.S. health care system."

We support your recognition of the importance of having patients and providers play a central role in defining their own healthcare needs. Too often in healthcare, the determination of "what's best for the patient" is made by others, while the patient's views of his or her own needs is ignored or minimized. By identifying the importance of expressed needs, the Council takes an important step towards policy that truly is centered on the needs of the patient and caregiver.

PIPC also supports the broad scope of research included in the Council's definition, which states, "Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions." This definition is consistent with PIPC's principles in support of CER and reflects the views expressed by many stakeholders at FCC listening sessions. PIPC believes that in order to improve patient care, CER research should examine the range of issues that affect the quality of patient care. This includes the range of medical tests and treatments, as well as questions related

to healthcare delivery and organization such as benefit designs and care management programs. All of these healthcare elements affect patients' quality of care.

While PIPC supports the focus on patient and provider needs in the draft definition, we also are concerned that, in stating that the purpose of CER is “to inform patients, providers and decision-makers,” the Council’s draft definition of CER has the potential to shift the focus of research away from patients and providers towards other decision-makers such as health insurance companies, government agencies and other policy-makers. The strategic framework released on HHS’ web site on June 1 includes language that underscores this concern. In particular, PIPC is troubled by language in the framework that describes CER research priorities that respond to the “expressed public and federal needs for CER,” and “potential capacity for translation through Federal delivery systems and public private partnerships.”

This shift in focus likely will result in research projects that do not address the clinical information needs of patients and providers, and instead lead to research that is used to restrict patient access to treatment options. This concern is heightened by recent commentary describing the link between CER and these types of access restrictions. For example, a recent *Washington Post* commentary says, “What's known as comparative effectiveness research, which tracks what works and what doesn't, would also require outside boards directing doctors and hospitals about what procedures they could and couldn't use.”

The language of your CER definition and strategic framework document is inconsistent with the goal of CER as described by HHS in its press release announcing the Coordinating Council. PIPC is opposed to the shift in focus to CER that restricts patient access to medical care or treatment choices. We strongly urge the Council to delete the language referencing “decision-makers” and “federal” needs as a CER focus. PIPC also urges you to revise the strategic framework so that it focuses on communication and dissemination strategies, rather than use of CER by government agencies.

Consistent with focus on patient and provider needs, we urge the Council to clarify that research will examine clinical outcomes, not cost-effectiveness. As reflected in the wide range of views expressed during the Coordinating Council listening sessions, inclusion of cost-effectiveness remains very controversial. Cost-effectiveness analysis traditionally has been a tool used by insurance companies and government payers to impose access restrictions based on broad population averages, and some of the most common CEA tools obscure differences in patient subgroups by including all patients in a single, average “value” determination. Particularly given the importance that the American Reinvestment and Recovery Act (ARRA) and the Coordinating Council have placed on considering the needs of patient subpopulations, PIPC recommends that the Council clarify that it will focus on clinical outcomes.

PIPC looks forward to continue working with the Council to foster good and fair processes that will allow future comparative clinical effectiveness research to improve the health and well being of all Americans.



Once again, thank you for the opportunity to participate in this transparent comment process.

Sincerely yours,

A handwritten signature in black ink that reads "Tony Coelho". The signature is written in a cursive style with a large, sweeping initial "T".

Tony Coelho
Chairman
Partnership to Improve Patient Care (PIPC)