



August 9, 2010

Sherry A. Glied
Assistant Secretary for Planning and Evaluation
Department of Health and Human Services, **Attention: CER Inventory**
Hubert H. Humphrey Building, Room 447-D
200 Independence Avenue, SW.
Washington, DC 20201

VIA Electronic Transmission

Dear Dr. Glied,

On behalf of the Partnership to Improve Patient Care (PIPC), we are providing comments in response to HHS' request for information on creating an inventory of comparative effectiveness research (CER) studies. PIPC is a diverse group of health care organizations representing patients, people with disabilities, physicians, and other health care providers, researchers and innovators, and groups. As a coalition, PIPC promotes comparative effectiveness research (CER) that supports patient access and informed health care decision-making while fostering continued medical progress.

We believe that CER holds great promise to improve the quality of health care through better information for patients and their health care providers leading to the best treatment options that meet their individual needs. PIPC strongly supported the inclusion of patient-centered CER in the Patient Protection and Affordable Care Act (PPACA), which provides a sound framework for independent, sustained, and objective research that is focused on the needs of patients and providers.

A database of available comparative effectiveness research could provide a useful tool to support health care decision-makers if developed with the appropriate safeguards, to minimize potential for harm. In particular, it is necessary to have a clear process based on strong consensus research standards for evaluating studies to be included in the database, to ensure this project does not confuse or mislead users by including studies that are low quality or unreliable -- particularly if these studies present results that differ from those of higher-quality research. Patients, caregivers, and physicians need timely access to the full body of relevant information, and they must have assurance that this information is accurate and reliable. PIPC believes the CER provisions in PPACA provide the necessary framework for ensuring the integrity, quality, and patient-centeredness of CER studies; and we encourage HHS to develop its plans for a CER inventory jointly with the new Patient-Centered Outcomes Research Institute (PCORI) created by PPACA.

To ensure that the CER studies included in the HHS database are technically excellent and appropriate, HHS should work with PCORI to gain agreement across a broad cross-section of stakeholders about the appropriate methods for different types of CER studies. The PCORI Methodology Committee is tasked with developing methods standards that can serve as an important building block for the type of CER inventory envisioned by HHS.

As stated in a 2005 Health Affairs article *Evidence-Based Decision Making: Global Evidence, Local Decisions*, "medical studies have undergone explosive growth: More than 11,000 publicly funded trials are under way in the United States alone. This has increased our ability to link decisions to evidence. Rapid growth of medical studies has also sharpened the need for tools that clinicians, patients, and policymakers can use to sort through the confusing and sometimes conflicting array of evidence." This underscores why PIPC fundamentally believes that an HHS CER inventory as a stand-alone initiative may be of limited usefulness to informing individual medical decisions. Therefore, we urge HHS to work through the PCORI, whose Board of Governors will include multiple



representatives from HHS, in developing a CER Inventory. It will ensure that the inventory is properly structured to meet the needs of the Institute and, more importantly, the patients and providers that it will be serving through development and support of a large-scale program for CER research and dissemination.

In addition, by developing the inventory in conjunction with PCORI, HHS can ensure that the diverse perspectives and needs of patients and providers are fully considered as the inventory is developed. In this way, PCORI could address questions like how the inventory will incorporate and assimilate studies on the same interventions that include different outcomes. For example, PIPC believes it is very important for CER to consider factors such as patient reported outcomes, quality of life, and productivity, but not all studies evaluate these outcomes. PIPC believes the incorporation of patient and provider perspectives is a basic strength of the new Institute that can help answer these types of questions and is essential in developing a new CER database.

Regarding the issue of encouraging participation, PIPC believes the two most important factors are engaging patients and providers in the process of developing and maintaining the CER inventory, and maintaining the quality of the inventory through clear standards for inclusion and explicit procedures for evaluating studies for inclusion.

Regarding data elements, we recommend that, among others, HHS should include elements to inform users about how subpopulations were considered in the study or analysis, and, if the researchers provided an opportunity for comment, a summary of and response to the comments. This would ensure the inventory is consistent with elements of PPACA that require consideration of patient differences in CER research and require opportunities for public comment. It also would be consistent language in the American Recovery and Reinvestment Act requiring CER fund recipients to provide “an opportunity for public comment on the research” to the extent feasible, and ARRA conference report language stressing the importance of ensuring “that subpopulations are considered” in CER.

Further, we agree that the process of cataloguing CER activities and infrastructure is critical to tracking ongoing and future investments in CER. Since part of PCORI’s mission is to set a broad CER research agenda, we believe this further justifies having this activity of CER inventory development fall under the work undertaken by PCORI. The resources devoted to PCORI can be utilized for this type of project and provide for its sustainability.

Until there is a basic agreement on CER methods, it is premature to develop an inventory of CER studies that can be of use to patients and clinicians. It is our concern that developing this list without the guidelines provided by standardized methods would only be of use to others than patients and doctors and could possibly be used inappropriately. Thus, we believe that HHS should integrate this project into the work which will be undertaken by PCORI. It is critical to get the sequence of necessary activities around CER right in order to make CER a tool to help patients and their doctors.

Sincerely,

A handwritten signature in black ink, appearing to read "Tony Coelho".

Tony Coelho
Chairperson
Partnership to Improve Patient Care