



April 13, 2009

Re: Comments to the Federal Coordinating Council on Comparative Effectiveness Research (CER)

Submitted electronically to the coordinatingcouncil@hhs.gov

Dear Sir or Madam:

Kaiser Permanente offers the following comments in response to the request from the Federal Coordinating Council on Comparative Effectiveness Research (CER) for public comment that will inform the June 30, 2009, report to the President and the Congress on recommendations for CER to be conducted or supported with funds from the American Recovery and Reinvestment Act of 2009 (AARA).

The Kaiser Permanente Medical Care Program (which offers services to the public under the Program's trade name "Kaiser Permanente") is America's largest private integrated healthcare delivery system. It comprises: Kaiser Foundation Health Plan, Inc. (and its local subsidiaries, collectively "Health Plan"), the nation's largest not-for-profit health plan; the nonprofit Kaiser Foundation Hospitals ("Hospitals"); and the Permanente Medical Groups ("Medical Group"), eight independent physician group practices that contract exclusively with Health Plan to meet the health needs of Kaiser Permanente's 8.7 million members in nine states and the District of Columbia. In addition to nearly all ambulatory and hospital care, most pharmacy, diagnostic and laboratory services are performed within Kaiser Permanente by Health Plan, Hospitals or Medical Group physicians and employees in Health Plan or Hospitals-owned facilities.

Kaiser Permanente can contribute to the national capacity to identify what works in health care, develop standards for systematic reviews of evidence, and methodologies for developing trustworthy clinical practice guidelines.

As the largest, private integrated system in the United States, Kaiser Permanente offers a continuous learning system that uniquely positions us to perform comparative effectiveness and safety research. Resources that we bring to the table include:

- Stable and diverse (racially/ethnically, socio-economically) membership of over 8 million individuals, across the United States, and the potential to link to larger family clusters for research through those individuals;
- A payment structure that distinguishes Kaiser Permanente from more traditional payment systems that provides strong incentives for in-plan use and virtually eliminates payment incentives that could influence care management decisions;
- Rich, longitudinal, clinical electronic databases that capture virtually complete health care delivery, payment, decision-making and behavioral data in detail to support primary, secondary and tertiary clinical care across inpatient, outpatient and emergency department settings;

- Kaiser Permanente's computer systems, which manage very large amounts of data, and Kaiser Permanente members' use of online tools at a rate of 45 million encounters per year;
- Planned expansion of databases to include genetic and environmental exposure data;
- Committed and experienced research community of full time investigators and hundreds of clinicians engaged in research;
- Sufficient numbers of individuals with diverse disease conditions, e.g., asthma, HIV, diabetes, rare conditions, etc. to provide statistically meaningful results; and
- External, well-established partnerships with traditional academic centers and research networks in which Kaiser Permanente brings unequalled value to the research collaboration.

For 40 years, Kaiser Permanente has taken advantage of its unique research environment to conduct drug safety research. In 1969, the Food and Drug Administration (FDA) funded a large study of surveillance for adverse drug effects. Since then, Kaiser Permanente has conducted drug, device and vaccine effectiveness and safety studies and with these, has developed and applied state-of-the-art research methodologies.

The following are just a few examples of Kaiser Permanente's experience in comparative effectiveness research:

- Kaiser Permanente researchers have created the largest database ever to address the safety of maternal medication use during pregnancy, and potential effects upon the developing fetus.
- Kaiser Permanente researchers participated in the nation's largest post-marketing safety surveillance for vaccines, the CDC-funded Vaccine Safety Datalink (VSD) project.
- Kaiser Permanente's research includes studies on the effectiveness of:
 - Venlafaxine versus other medications in the treatment of depression;
 - Use of financial incentives to increase adherence with guideline recommended care in depression;
 - Various anti-hypertensive agents as secondary-line therapy in hypertension;
 - Drug-eluting versus bare metal stents in patients with coronary heart disease;
 - Bariatric surgery versus usual medical therapy in obese patients with type 2 diabetes mellitus;
 - Different diabetes treatment approaches;
 - Treatment responses to darbopoetin versus epoetin, drugs used in cancer patients to treat anemia and increase hemoglobin levels; and
 - Converting statin therapy from brand name Zocor to generic lovastatin.

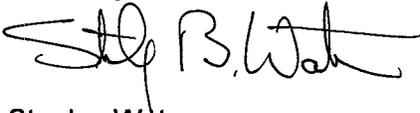
More recently, Kaiser Permanente's researchers, physicians, and operational leadership have recognized the benefit to the communities we serve of pursuing research in comparative effectiveness and safety. Over the last year, Kaiser Permanente's research leadership has been developing a concept for a virtual center to study comparative effectiveness and safety, recognizing that such a center can capitalize on its unique ability to conduct in-depth studies of questions of drug, device and biologic safety and comparative effectiveness. The center would offer the potential for addressing these questions, translating the findings into the operations of our program, evaluating their

impact and publishing and disseminating them back into the community for the benefit of all.

In conclusion, Kaiser Permanente looks forward to participating in this major CER initiative to transform health care, and we appreciate the opportunity to contribute to the Federal Coordinating Council on Comparative Effectiveness Research (CER)'s efforts to develop recommendations to accelerate the development and dissemination of CER.

If you have questions, please contact me at (510) 625-4724 or by email at Stanley.Watson@kp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Stanley Watson". The signature is written in a cursive style with a large, stylized initial "S" and "W".

Stanley Watson
Vice President, Kaiser Foundation Research Institute