Clinical Effectiveness Research Innovation Collaborative

Methods innovation and practice-based approaches

**Issue.** The constantly increasing diversity and sophistication of healthcare interventions hold great promise for gains in patient health, but also raise substantial challenges to the pace and nature of research about the effectiveness of treatments. Clinical research is straining to keep up with the rapid and iterative evolution of medical interventions and the innovation that occurs in clinical practice. It has become clear that, while trials are key especially to pre-market assessment of safety and efficacy, depending on trials is impractical—in both time and cost—for the information needed on effectiveness and efficiency. Recent enhancements in the nation’s capacity for clinical effectiveness research (CER), and the characterization of the broad range of CER questions of national priority, underscore the need to accelerate the development and use of innovative approaches for learning about what works best for whom and under what circumstances. Such information is critical for clinical and policy decisions and requires more nimble and efficient approaches that take advantage of emerging statistical tools and techniques, research designs and analytic models that can be applied across broader population groups, and information developed as a natural byproduct of the care process. Accelerated initiative within the research community is essential for progress—particularly to improve the targeting, tailoring, sequencing of approaches to develop a totality of evidence. Efforts to enhance the use of genomic information, probability and other models that accelerate the timeliness and level of research insights gained, and the development of virtual intervention studies also offer increased prospects for transformative change in clinical outcomes research.

**Collaborative.** An *ad hoc* convening activity under the auspices of the IOM Roundtable, the Clinical Effectiveness Research Innovation Collaborative (CERIC) provides a venue for information exchange and knowledge sharing among researchers working to develop and apply innovative approaches to evidence generation for healthcare decisions. Work focuses on identifying key barriers to and opportunities for advancing the pace and progress of CER.
**Participants.** Individual researchers with research innovation interests, capacity, and activities from public and private organizations, leading academic research institutions, insurers, health product manufacturing companies, and product assessment companies. The aim is for an inclusive Collaborative—without walls—and participation in individual projects is structured according to interest, need, and practicality.

**Activities.** Projects completed, under way, or under consideration by CERIC include:

- **Field advancement mapping.** Cooperative development of a White Paper exploring the major institutional, organizational, and regulatory challenges and opportunities for expediting clinical effectiveness research.

- **Engaging health system leadership in CER.** A program of work that begins by engaging health system leadership on issues and opportunities to transform how evidence is generated and used to improve health and the value of delivered care as a fundamental part of their institutional processes, and provides a neutral forum to discuss and share insights from ongoing evidence application and development efforts.

- **Eliminating disparities.** An exploration of how features of a continuously learning health system can best address and close the gaps for our most salient health and health care disparities, with particular focus on opportunities from innovation in clinical effectiveness research.

**REPRESENTATIVE PARTICIPANTS**

**ORGANIZATIONS**

- Association of American Medical Colleges
- AstraZeneca
- Brigham and Women’s Hospital
- Bristol-Myers Squibb
- Cedars-Sinai Medical Center
- Center for Medical Technology Policy
- Duke Clinical Research Institute
- Harvard Medical School
- Harvard School of Public Health
- Institute for Clinical and Economic Review
- Institute for Clinical Research and Health Policy Studies, Tufts Medical Center
- Johnson & Johnson
- Kaiser Permanente
- Mayo Clinic
- Outcome Sciences Inc., University of California, Davis
- University of California, Irvine
- University of California, Los Angeles
- University of Minnesota School of Public Health
- University of Pennsylvania School of Medicine
- University of Pennsylvania School of Nursing
- University of Pittsburgh
- Vanderbilt University Medical Center
- World Health Information Science Consultants

**FEDERAL AGENCIES**

- U.S. Department of Health & Human Services
  - Agency for Healthcare Research and Quality
  - Centers for Medicare & Medicaid Services
  - Food and Drug Administration
  - National Institutes of Health
  - Office of the Secretary
- U.S. Department of Veterans Affairs