



American Recovery and Reinvestment Act Investments in Comparative Effectiveness Research for Data Infrastructure

The Need: Research Infrastructure

The American Recovery and Reinvestment Act (Recovery Act) funds for the Office of the Secretary, Health and Human Services (HHS) provide a unique opportunity for a meaningful and sustainable investment in building the foundation for comparative effectiveness research (CER) infrastructure. Significant investment in this activity is unlikely to come from any other source and will fundamentally change the landscape for CER.

The overarching goal of funding CER is to improve health outcomes by producing evidence to enhance medical decisions made by patients and their medical providers on the relative strengths and weaknesses of various medical interventions. Comparative effectiveness research will give clinicians and patients valid information used to make decisions that will improve the performance of the U.S. health care system. Additionally, comparative effectiveness research will improve health outcomes and the safety, quality, affordability, and accessibility of health care, including behavioral health care and long-term care. This research supports the strategic goal of high-quality, affordable health care for Americans by sustaining the objective from the HHS strategic plan to improve health care quality, safety, cost, and value by studying the agreed-upon definition of CER as determined by the Federal Coordinating Council.

The Solution: Data Infrastructure

Through enhancement of existing infrastructure as well as development of new databases, networks, and registries, both public and private CER endeavors will be sustainable and multiplicative. Importantly, investment in data infrastructure can align with investments in health information technology, providing a platform for research endeavors that can strongly impact broad populations and conditions. Subcategories of investment considered essential are:

- Longitudinal claims databases — Research databases that link claims data for individual patients over a long period of time.
- Distributed data networks — Clinical electronic health record data networks and health information exchanges for CER.
- Patient registries — Databases that prospectively collect clinical data on patients with specific diseases or on specific tests or procedures.

Data infrastructure programs are listed below:

Enhance Availability and Use of Medicare Data to Support Comparative Effectiveness Research

Centers for Medicare & Medicaid Services

This program will enhance the Chronic Conditions Warehouse to support CER by adding Medicare and Medicaid data back to 1999 with census track and race and ethnicity codes to facilitate study of health disparities. Enhancement of this data warehouse will also enable research on the elderly and persons with multiple chronic conditions, two populations historically under-represented in research.

Build a Medicaid Analytic eXtract (MAX) Data Repository Designed to Support Comparative Effectiveness Research for Medicaid and Children's Health Insurance Program Populations

Centers for Medicare & Medicaid Services

This program will focus on building a parallel Medicaid and Children's Health Insurance Program research database with data dissemination capability to support CER projects.

Clinically Enhanced State Data for Analysis and Tracking of Comparative Effectiveness Impact

Agency for Healthcare Research and Quality

This program will provide organizations that collect statewide all-payer, hospital-based encounter-level data (inpatient, emergency department, and ambulatory surgery) capacity to significantly broaden and supplement existing population-based data for producing the evidence base for comparative effectiveness and evaluating efforts to implement comparative effectiveness where the evidence already exists.

Creation of an All-Payer, All-Claims Database to Enable Innovative Comparative Effectiveness Research

Office of the Assistant Secretary for Planning and Evaluation, Centers for Medicare & Medicaid Services

This program will focus on the creation of an all-payer database that builds on existing claims streams to support research to allow for the greatest power in analysis, ensuring that the data infrastructure is equipped to address the needs of multiple priority populations, multiple priority types of interventions, and a breadth of conditions.

Distributed Data Research Networks, Including Linking Data

Agency for Healthcare Research and Quality

This program will focus on electronic health record-driven distributed research networks along with linking clinical and administrative data to investigate comparative effectiveness of medications, treatments, and strategies to improve health outcomes.

Community Health Applied Research Network

Health Resources and Services Administration

This program will provide funds for research nodes that will serve as a platform from which to conduct investigations on treatments, interventions, and models of care.

Building Patient Registries to Track Health Outcomes and Measure Quality and Performance

Agency for Healthcare Research and Quality

This program will focus on developing registries for researching health outcomes for effectiveness research and performance measurement and benchmarking.

Enhancing Cancer Registry Data Systems for Comparative Effectiveness Research

Centers for Disease Control and Prevention

This program will focus on the power of cancer surveillance systems that can be significantly enhanced for comparative effectiveness analyses and clinical research by expanding the current infrastructure.

Registry of Patient Registries

Agency for Healthcare Research and Quality

This program will establish a registry of patient registries with research purposes, thus enabling researchers who are considering a new registry to identify similar studies and avoid unnecessary duplication of research questions or populations.

Building U.S. Food and Drug Administration Comparative Effectiveness Research Clinical Data and Standards Infrastructure, Tools, Skills, and Capacity

U.S. Food and Drug Administration

Under this program, the U.S. Food and Drug Administration (FDA) will develop policies, standards, infrastructure, and tools for standardizing clinical study data to enable analyses across multiple studies. This activity will support scientifically sound assessments of medical interventions consistent with FDA's public health responsibility. Although current FDA regulations generally limit public sharing of the primary data from commercial sponsors, FDA has options for supporting CER including sharing of data with sponsor permission.

Persons with Multiple Chronic Conditions Data and Research

Agency for Healthcare Research and Quality, Indian Health Service

- **Expansion of Research Capability to Study Complex Patients** — The Agency for Healthcare Research and Quality will solicit grant applications from organizations that propose to build or enhance partnerships and datasets that will improve the capacity to study comparative effectiveness of different management strategies for patient-centered care of patients with multiple chronic illnesses.
- **Comparative Effectiveness Research to Optimize Prevention and Health Care Management for the Complex Patient** — This program will focus on the priority conditions as detailed in Agency for Healthcare Research and Quality's comparative effectiveness program.
- **Creating and Disseminating Public Use Data Sets** — This program will address the specific priority population of patients with multiple chronic conditions. Investment in infrastructure should permit performance of high-quality research on complex patient populations to provide evidence for which interventions are most valuable and how a patient's particular circumstances determine these relative values.
- **Comparative Effectiveness Research to Enhance the Delivery of Services Within the Indian Health Service** — This program will be conducted within existing Special Diabetes Program for Indians grantee sites to compare the effectiveness of disease treatment and prevention strategies for diabetes and cardiovascular disease as provided by physicians, nurse practitioners, physician assistants, advanced practice pharmacists, and registered dietitians.
- **Comparative Effectiveness of Quality Improvement Efforts Focused on Chronically Ill Adults among American Indian/Alaska Native Communities** — This program focuses on evaluation of prevention and treatment strategies for chronic diseases within American Indian/Alaska Native communities.

Pediatric Care Networks and Comparative Effectiveness Research

Health Resources and Services Administration

This program will enhance the electronic health record infrastructure of pediatric care networks for comparative effectiveness research.

Public Use Data Files

Centers for Medicare & Medicaid Services

Consistent with the confidentiality requirements of the Privacy Act and the Health Insurance Portability and Accountability Act, the Centers for Medicare & Medicaid Services propose to create public use files containing detailed but de-identified data for the Medicare population, including claims (inpatient and outpatient hospital, skilled nursing facilities, home health, hospice, physician/suppliers, durable medical equipment, and prescription drugs), beneficiary-level enrollment/entitlement/demographic information, and data from the Medicare Current Beneficiary Survey.

Strategic Plan for Developing Comparative Effectiveness Research Data Sets

Centers for Medicare & Medicaid Services

This project will be used to develop a strategic plan for the use of all types of Centers for Medicare & Medicaid Services data, including Medicare fee-for-service claims, Medicare Advantage encounter data, and Medicaid claims. The analysis would focus on maximizing Centers for Medicare & Medicaid Services data in all formats for comparative effectiveness research, including the public use files, limited data sets, and research-identifiable files. Contracts will be awarded for this opportunity.

Funding Methods: Grants, contracts, and cooperative agreements

Project Durations: Various

Funding Amount: \$219 million

Further details about grant funding announcements can be found on www.grants.gov or <http://www.gold.ahrq.gov/>. Information on contract solicitations can be found at www.fbo.gov.