

## Building Infrastructure for Comparative Effectiveness Protocols “BICEP”

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### Infrastructure Description

The Building Infrastructure for Comparative Effectiveness Protocols (BICEP) combines data architecture with standardized processes for obtaining and defining heterogeneous patient and system characteristics. The data architecture is a single analytic database including electronic data from a variety of clinical data tables linked by unique patient identifiers, with standardized definitions, coding, and locations of data elements from each source.

### Specific Aims

1. Identify sources and define the key elements of information that are relevant for CER on complex patients in primary care.
2. Develop extraction, mapping, linking, and triangulation methods to routinely obtain and convert key raw data elements from multiple electronic clinical sources into a single standardized format within a shadow research database.
3. Develop algorithms for de-identifying individual patient information while preserving content needed for CER.
4. Develop methods for a balanced stratification and risk adjustment of numerous heterogeneous patient and system characteristics; poly time-interdependent interventions; and numerous non-prioritized outcomes.

### Pilot Study

The BICEP health data infrastructure allowed project investigators to assess the comparative effectiveness of poly, time-interdependent “Medical Intervention Clusters” (second-line dual medication therapy options) to treat heterogeneous subgroups of patients with type 2 diabetes and complex comorbidities. Heterogeneous subgroups were identified using patient demographics, behavioral characteristics (smoking status, weight), lab results, system characteristics (practice, provider,

### Infrastructure Goal:

Develop an ambulatory care health data infrastructure (including multiple data sources and innovative methods) that shadows the real-time patient record and use it to conduct comparative effectiveness research (CER) on the real-world clinical management of complex patients in primary care settings.

### Data Sources:

Practice management systems (demographics, scheduling, billing); electronic health records (problems, office measures, medications, smoking history, orders, notes, encounters; structured forms; scanned documents); payer claims; laboratory systems; credentialing systems; U.S. Census; disease registries; geographic information systems.

### Data Access

Data are available through the Inter-University Consortium for Political and Social Research (ICPSR). Users must complete a restricted use agreement for access.

### Strategies Addressed from the HHS Strategic Framework on Multiple Chronic Conditions

- 1.B. Define appropriate health care outcomes
- 1.D. Implement and effectively use HIT
- 3.A. Identify best practices and tools
- 4.B. Understand the epidemiology of MCCs
- 4.C. Increase clinical research

## Building Infrastructure for Comparative Effectiveness Protocols “BICEP” (Continued)

payer), comorbidity, and concurrent use of medications. Innovative methods used include triangulation of disease concepts from multiple clinical sources, comorbidity adjustment using clinical sources, and categorization of serial and concurrent “Medical Intervention Clusters.”

This pilot demonstrated that pragmatic trials using this infrastructure are feasible. The change in mean HgbA1C differed significantly among dual therapy treatment groups and persisted with adjustment for a wide variety of covariates, including multiple chronic conditions, concurrent therapies, primary care visits after baseline, and laboratory metrics, such as micro-albumin and lipid levels.

### Publications (as of September 2013)

Publications currently in preparation.

### Posters and Presentations

Lynch J, Masters M, Rosen J, Pasquale K, Greenberg L, Harris B. Comparative effectiveness of dual therapeutic regimens for diabetes: A BICEP pragmatic clinical trial. Poster presented at: Leveraging knowledge and action to improve health care quality. 6th Annual Conference of the Agency for Healthcare Research and Quality; 2012 Sept 9–12; Bethesda, MD.

Lynch J, Masters M. Complex patients with diabetes and hypertension: Comparison of EHR data and comorbidity scores. Poster presented at: Leading Through Innovation & Collaboration. 6th Annual Conference of the Agency for Healthcare Research and Quality; 2011 Sept 18–21; Bethesda, MD.

Lynch J, Masters M. Methods for assembling useful data for observational comparative effectiveness research on complex patients. Poster presented at: Annual Meeting of the Agency for Healthcare Research and Quality National Practice Based Research Network (PBRN); 2011 Jun 22–24; Bethesda, MD.

Lynch J, Masters M. CER Methods for overcoming privacy issues: Removing identifiers and dealing with missing data. Poster presented at: Annual Meeting of the Agency for Healthcare Research and Quality National Practice Based Research Network (PBRN); 2011 Jun 22–24; Bethesda, MD.