**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,....
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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

