Methods for observational comparative effectiveness research on healthcare delivery system strategies for asthma management: The SAFTINet project

Bethany Kwan, Marion Sills, Barbara Yawn, Brian Sauer, Diane Fairclough, & Lisa Schilling

AHRQ ARRA OS: Recovery Act 2009
Scalable Architecture for Federated Translational Inquiries Network (SAFTINet; AHRQ R01 HS019908 PI: Lisa Schilling, MD, MSPH)
- Distributed data network (DDN) of existing clinical and claims data
  - Support comparative effectiveness research (CER)
  - Enhanced with patient-reported outcome data
  - Focus on:
    - Safety net practices
    - Chronic disease
    - Healthcare delivery system (HDS) factors
Aims and Objectives

- Observational comparative effectiveness research (OCER) on healthcare delivery system (HDS) factors on health outcomes for children and adults with asthma
  - HDS factors: Medical home characteristics

- Hypothesis
  - There is a positive association between practices’ medical home characteristics and control of asthma in children and adults

- Presentation objectives
  - To describe select methodological challenges and approaches to addressing these challenges, in the context of SAFTINet OCER protocol development
An observational, longitudinal cohort study of primary care patients with asthma

- Primary data collection
  - Medical home characteristics (practice level)
  - Patient-reported asthma outcomes (self-report surveys)
- Secondary use of existing clinical and claims data

Practices
- 55 primary care practices
- 4 healthcare organizations

Patients
- Underserved populations (~30% Medicaid)
- 250,000 patients per year
- An estimated 20,000 have a diagnosis of asthma
Design Challenges

- Availability of complete data from multiple primary and secondary sources
  - Asthma cohort definitions (inclusion/exclusion criteria)
  - Asthma outcomes (asthma control)
- Determining exposure to a practice-level multi-faceted HDS variable
  - Assignment to practice
- Analysis
  - Clustered data
  - Confounding and bias
Challenges

- Accurately defining cohorts of patients with asthma and assessing outcomes based on multiple data sources
  - 100%: Electronic health records, administrative data (EHR)
  - ~30%: Medicaid claims and enrollment data
  - ??%: Patient-reported outcomes (PRO)

OCER goal: “real world” populations

- Inclusion of patients with ONLY complete data limits:
  - Sample size
  - Generalizability
  - Sensitivity and subgroup analysis
Approach

- Inclusion of all patients for whom data are available for a given outcome
Cohort definition: Active Asthma
- EHR: At least 2 diagnosis codes for asthma (493.xx) in any 18 month period (encounters at least 4 weeks apart)
- EHR: Age, gender, diagnosis codes for concomitant lung disease, cognitive impairment

Outcomes: Evidence of poor asthma control
- EHR/claims: Evidence of an asthma exacerbation in a 6-month period (inferred from utilization data)
- PRO: Asthma Control Test (subset)
  - Total score

Covariates
- EHR: Patient and practice demographics, tobacco exposure, comorbidities
Asthma exacerbation =
- A prescription for oral steroids; OR
- 3 asthma visits occurring in 14 days or less; OR
- An asthma-related ED visit; OR
- An asthma-related hospitalization
Exposure to medical home characteristics

Challenges

- Determining “exposure” to medical home characteristics
  - Measurement of medical home characteristics
    - Practice level vs patient level exposure
    - Assigning patients to practices
Exposure to medical home characteristics

Approach

- Practice level medical home characteristics
  - Medical home survey, assessed every 6 months at the practice level
  - Feasibility
- Patient exposure to medical home
  - Medical home characteristics of most common/most recent practice
  - ≥ 1 encounter 18 months prior to/6 months after measurement of medical home characteristics
Challenges

- Clustered data
  - Clustering of patients within a practice
- Observational studies → potential confounding
  - Practice vs patient level confounders
Approach
  o Mixed effects models:
    • Practice-level analysis of effects of medical home characteristics on patient-level asthma outcomes
  o Confounding
    • Theory-driven vs empirical covariate selection process
      • Directed acyclic graph approach
    • Selected potential confounders that were:
      • Known or suspected common causes of both asthma control and medical home characteristics
        • Patient level: Asthma Severity, Comorbidity
        • Practice level: Practice demographics
      • NOT in the causal pathway (e.g., medication adherence)
Conclusions

The design of rigorous observational CER on HDS strategies in the real world requires:

- Planning phase (can be lengthy)
- Measurable, clinically meaningful outcomes
- Application of a process that limits bias
- Advanced analytic techniques
Acknowledgments

- Agency for Healthcare Research and Quality
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  - Intermountain Healthcare
  - Metro Provider Community Network
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  - Salud Family Health Centers
  - University of Colorado Denver
  - University of Utah, Center for High Performance Computing
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  - Monica Federico, MD
  - Robert Valuck, PhD, RPh
  - Wilson Pace, MD
Thank you!

Questions?

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<thead>
<tr>
<th>Domain</th>
<th>Example Goals</th>
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<tbody>
<tr>
<td>Personal Clinician &amp; Sustained Partnership</td>
<td>• Clearly link patients to a clinician and/or care team so both the patient and provider/care team recognize each other as partners in care.</td>
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<td>Personal Clinician Led/ Team-Based Care</td>
<td>• Team-based care led by clinician</td>
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<td>Coordinated and Integrated Care</td>
<td>• Link patients with community resources to facilitate referrals and respond to social service needs.</td>
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<td>Patient/Family-Centered Care/Support Shared Decision-Making</td>
<td>• Assess and respect patient and family values and expressed needs.</td>
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<td>Quality Improvement &amp; Safety</td>
<td>• Establish and monitor metrics to evaluate improvement efforts and outcomes and provide feedback.</td>
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<td>Use of Organized Care &amp; Evidence-based Medicine</td>
<td>• Use point of care reminders based on clinical guidelines.</td>
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<td>Access</td>
<td>• Provide scheduling options that are patient- and family-centered and accessible to all patients.</td>
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<td>Engaged Leadership</td>
<td>• Provide visible and sustained leadership overall culture change and specific strategies to improve quality and sustain and spread change.</td>
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<td>Registries, Performance Reporting and QI Programs</td>
<td>• Use of patient tracking registries to monitor and inform clinical interventions for persons with specific health care needs.</td>
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**Overview: Comparison of Methods**

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<thead>
<tr>
<th></th>
<th>Randomized Trial</th>
<th>Observational CER</th>
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<tbody>
<tr>
<td><strong>Research Question</strong></td>
<td>What is the effect of receiving care in a medical home on asthma control?</td>
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<tr>
<td><strong>Methods</strong></td>
<td>Primary data collection: surveys, interviews, random assignment to condition, prospective follow-up</td>
<td>Primary data collection, Secondary data use, Assessment of existing medical home features</td>
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<td><strong>Cohort definition:</strong></td>
<td>Surveys, diagnostic interviews, chart review</td>
<td>Infer persistent asthma based on diagnosis codes and problem lists</td>
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<td>persistent asthma</td>
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<td><strong>Outcomes: Asthma Control</strong></td>
<td>Regular schedule of: Pulmonary function testsPatient reported control</td>
<td>Patient-reported control, Evidence of asthma exacerbations</td>
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<tr>
<td><strong>Covariates</strong></td>
<td>Surveys</td>
<td>Infer from EHR/claims</td>
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<td><strong>Exposure to medical home</strong></td>
<td>Intervention with well-defined Time 0</td>
<td>Cross-sectional self-report survey</td>
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## Overall Design and Timeline

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<tr>
<td>Cohort definition</td>
<td>At least 2 diagnoses for asthma within any 18 month period</td>
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<td>DoCCS administered</td>
<td>DoCCS 1</td>
<td>DoCCS 2</td>
<td>DoCCS 3</td>
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<td>Assignment of patient to a practice</td>
<td>Related to 1st DoCCS</td>
<td>At least 1 encounter at practice in 2 year period</td>
<td>Related to 2nd DoCCS</td>
<td>Related to 3rd DoCCS</td>
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<td>Outcomes measured</td>
<td>6 month block</td>
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