Dissemination & Implementation Science and Large Observational Data Sets

Beth M. McManus, PT, MPH, ScD
Associate Professor
Health Systems, Management and Policy
Colorado School of Public Health

Education Program Lead
Accords

ACCORDS – Adult and Child Consortium for Health Outcomes Research and Delivery Science
Objectives

- How can we use research with large observational data sets to inform:
  - Clinical practice
  - Policy
  - Validation of measurement and analytic approach
  - Development of (pragmatic) trials
Using Claims Data to Test the Effect of Part C Policy Change

HRSA MCHB (R40MC26814), Comprehensive Opportunities in Rehabilitation Research and Training (CORRT) K12 (K12 HD05593)
Part C of The Individuals with Disabilities Education Act (IDEA) authorizes states to provide early intervention services (EI) for infants and toddlers with a developmental delay or disability.

Recent budget crises have threatened sustainability of EI programming.

Thirteen states have responded by narrowing eligibility criteria.
Significance of Restricting Part C Eligibility

- States will face critical policy decisions about care for children dually-eligible for Medicaid and Part C
- Nearly all states have policies to reform Medicaid
- Will be viable option to control state spending
- But, will this approach reduce spending in the long-term?
General Approach to Using Big Data for Policy Analysis

- In 2007, CO restricted eligibility for Part C

- “Natural experiment” where CO is “treatment” state and NC is comparison
  - NC did not change its Part C eligibility
  - Similar population characteristics

- Data reflect Medicaid utilization 2006-2010

- Causal interpretation relies on exogeneity of CO’s policy change
  - Children with less severity will be affected more
Figure 1. Conceptual Model of Research Proposal

Outcomes: Substituted Part C Home Visits for Medicaid Clinic Visits (Aim 1)

- Continued Part C Home Visits
- Did Not Receive Therapy Services Through Medicaid

Hypothesized Increase in Therapy-Sensitive Utilization (Aim 2)

- No Effect on Therapy-Sensitive Utilization
- Increased Therapy Services
- Increased Therapy-Sensitive Utilization

Hypothesized Increase Costs (Aim 3)

- No change in cost
- Effect on costs unknown
- Increased costs

CO

- Dually Eligible
- No, Lost Part C

WA and NC

- Dually Eligible
- Yes

Pre-Policy Change

Post-Policy Change
Data Source

- **Centers for Medicare and Medicaid Extract (MAX) data files** for CO and NC for year 2006-2010
  - Child demographic, eligibility, and therapy encounter data extracted from personal summary and outpatient MAX files

- **Sample children**
  - 1) had a diagnosis of a *developmental condition*,
  - 2) were between birth and 35 mos of age at the time of the index diagnosis,
  - 3) were *continuously enrolled* in children’s Medicaid for at least 3 months before and at least 12 months after the index diagnosis.
Model Specification

- Used a **difference-in-differences** approach as a function of explanatory variables, state fixed effects, and an indicator for **post Part C change in CO**
  - Used to test hypotheses that Part C influences service use (Aims 1 & 2) and spending (Aim 3).
- **Two Part Model**
  - First: **logistic model** estimating probability of any PT/OT use
  - Second: **Generalized linear model** estimating service use (Aim 1) and spending (Aim 3)
  - Report marginal effects
# Results of Two-Part Model

<table>
<thead>
<tr>
<th>Natural Experiment Variables</th>
<th>Adjusted Spending Overall</th>
<th>Adjusted Spending Home Only</th>
<th>Adjusted Spending Clinic Only</th>
<th>Dosage Overall</th>
<th>Dosage Home Only</th>
<th>Dosage Clinic Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado</td>
<td>-91.02***</td>
<td>-35.54***</td>
<td>-60.63***</td>
<td>-1.601***</td>
<td>-0.182</td>
<td>-1.586***</td>
</tr>
<tr>
<td></td>
<td>(9.683)</td>
<td>(8.152)</td>
<td>(5.048)</td>
<td>(0.461)</td>
<td>(0.389)</td>
<td>(0.248)</td>
</tr>
<tr>
<td>Post-Period</td>
<td>34.60***</td>
<td>-5.610</td>
<td>29.54***</td>
<td>1.923***</td>
<td>0.294</td>
<td>1.283***</td>
</tr>
<tr>
<td></td>
<td>(10.26)</td>
<td>(8.868)</td>
<td>(5.841)</td>
<td>(0.421)</td>
<td>(0.354)</td>
<td>(0.244)</td>
</tr>
<tr>
<td>Colorado in Post-Period</td>
<td>-37.78***</td>
<td>-27.88***</td>
<td>-2.418</td>
<td>-1.316**</td>
<td>-0.882**</td>
<td>-0.270</td>
</tr>
<tr>
<td></td>
<td>(12.56)</td>
<td>(9.313)</td>
<td>(7.895)</td>
<td>(0.533)</td>
<td>(0.406)</td>
<td>(0.326)</td>
</tr>
</tbody>
</table>

Controlling for child’s race, developmental condition, sex, age, urbanicity, social disadvantage, number of chronic conditions, and quarter

***p<.01, **p<.05, *p<0.1
Conclusions

• The result of restricting Part C eligibility in CO was a reduction in per child / per quarter PT/OT dosage and a reduction in annual per child PT/OT spending.
  – As hypothesized, spending reductions were largely related to reductions in PT/OT visits in the home (i.e., Part C service use).
  – Some evidence (in unadjusted models) that there was an increase in PT/OT clinic-related spending suggesting Part C services were substituted for clinic-based therapies.
Challenges & Opportunities

• To examine therapy-sensitive utilization and overall Medicaid spending for children with a developmental condition:
  – Scientific workgroup of PT researchers and providers review ICD9 and CPT codes to create algorithm for therapy-sensitive utilization
Key Challenges

• **Data quality and cleaning**
  – Obtaining additional years of data
  – Merging 2006-2008 data with 2009-2010
  – Missing data
  – Washington

• **Analytics**
  – Large sample size
  – Model specification
Challenges & Opportunities

- **Limitations & Challenges**
  - Claims data: standardizing variables, identifying sample
  - Only 2 states which limits generalizability
  - Operationalizing therapy-access sensitive visits

- **Strengths and Opportunities**
  - Claims data: rich diagnostic and service use information
  - Important clinical, programmatic, and policy question
New Investigator Fellowship Training Initiative,
Foundation for Physical Therapy
Background

- Infants and toddlers with **developmental vulnerability** represent a heterogeneous group
  - often receives state Part C early intervention (EI).

- **Notable population heterogeneity** exists
  - **complicates unmet need and effectiveness research.**
  - Existing classification systems may have limited utility

- Relatively homogeneous **clinically policy relevant “sub-groups”** may create the apparent heterogeneity.

- Methodological challenges impede identifying these potential groups
Study Aims

• 1. Apply a previously validated classification system to describe infants and toddlers enrolled in early intervention
  
  \[ H_1: \text{Eight clinically relevant sub-groups will emerge along the domains of developmental and social risk} \]

• 2. Estimate EI dose, effectiveness, and cost-utility of EI services among EI sub-groups (i.e., preterm birth)
  
  \[ H_2: \text{There will be favorable cost-utility ratio for EI service use among EI-enrolled preterm infants} \]
H1: Clinically Relevant Sub-Groups (McManus et al, 2009)

Who is most likely to receive early intervention?

Figure 1. Typology to characterize heterogeneous population of infants and toddlers in early intervention.
H1: Clinically Relevant Sub-Groups (McManus et al, 2009)

Who is most likely to receive early intervention?

Figure 1. Typology to characterize heterogeneous population of infants and toddlers in early intervention.
**Study Sample**

- Children *discharged* from a state early intervention program in FY2013-FY2015.
  - Had entry and exit data
  - Captures children who move, “churn”

- Includes about 31,000 unique obs with complete information

- Top 1% of spending were excluded
Analytic Approach

• **Latent Class Analysis (LCA)**
  – Similar to cluster analysis, but has many advantages
  – Models *patterns* of responses
  – **Measurement Model**
    • Strength of the association between child / family characteristics and sub-group
  – **Structural Models**
    • Series of models to estimate the association between sub-groups and covariates and outcomes
      – Age at referral (linear regression)
      – Duration of EI services (linear regression)
      – Any PT (logistic regression)
      – Dosage and intensity of services (linear regression)
      – Cost-effectiveness (linear regression, estimate CER)

• Accounts for the skewed service use and spending data and clustering
EI Sub-Groups

- Preterm Infants with Severe DD, no social risk: 11.2%
- Autism (2 groups): with social risk: 16.1%
  Without social Risk: 5.7%
- NAS: 9.5%
- Mild DD, no social risk: 28.0%
- Moderate DD, some social risk (2 groups): English-speaking 9.9%
  Non-English speaking: 12.4%
- Department of Children and Families: 12.8%
## EI Service Use

<table>
<thead>
<tr>
<th>EI Sub-Groups</th>
<th>EI Referral Age (Months)</th>
<th>EI intensity (hrs / month)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean [95% CI]</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT Infants</td>
<td>7.7 [7.3, 8.2]</td>
<td>5.4 [5.3, 5.5]</td>
</tr>
<tr>
<td>Mild DD</td>
<td>16.6 [16.4, 16.8]</td>
<td>4.7 [4.6, 4.7]</td>
</tr>
<tr>
<td>Autism (no social risk)</td>
<td>15.8 15.3, 16.3]</td>
<td>6.0 [5.8, 6.1]</td>
</tr>
<tr>
<td>Autism (social risk)</td>
<td>15.6 15.3, 15.9]</td>
<td>5.8 [5.7, 5.9]</td>
</tr>
<tr>
<td>Moderate DD</td>
<td>15.8 15.2, 16.4]</td>
<td>5.0 [4.9, 5.1]</td>
</tr>
<tr>
<td>Moderate DD (non-English)</td>
<td>13.7 13.3, 14.1]</td>
<td><strong>6.2 [6.1, 6.2]</strong></td>
</tr>
<tr>
<td>NAS</td>
<td>10.0 9.3, 10.7]</td>
<td><strong>3.9 [3.9, 3.9]</strong></td>
</tr>
<tr>
<td>DCF</td>
<td>11.6 11.1, 12.1]</td>
<td>5.3 [4.3, 6.4]</td>
</tr>
</tbody>
</table>
## EI Spending and Total EI Hours

<table>
<thead>
<tr>
<th>EI Sub-Groups</th>
<th>EI Spending</th>
<th>Total EI Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean [95% CI]</td>
<td></td>
</tr>
<tr>
<td>PT Infants</td>
<td>8,151 [7,931, 8,378]</td>
<td>134 [130, 139]</td>
</tr>
<tr>
<td>Mild DD</td>
<td>8,821 [8,301, 9,374]</td>
<td><strong>86 [82, 91]</strong></td>
</tr>
<tr>
<td>Autism</td>
<td>8,751 [8,481, 9,031]</td>
<td>110 [103, 117]</td>
</tr>
<tr>
<td>Autism, Social Risk</td>
<td><strong>6,815 [6,107, 7,606]</strong></td>
<td>115 [111, 121]</td>
</tr>
<tr>
<td>Moderate DD</td>
<td>9,405 [9,043, 9,781]</td>
<td><strong>136 [129, 142]</strong></td>
</tr>
<tr>
<td>Moderate DD (Non-English)</td>
<td>8,119 [7,837, 8,410]</td>
<td>130 [125, 135]</td>
</tr>
<tr>
<td>NAS</td>
<td>8,349 [8,123, 8,582]</td>
<td>112 [108, 116]</td>
</tr>
<tr>
<td>DCF</td>
<td>8,176 [7,908, 8,453]</td>
<td>119 [114, 123]</td>
</tr>
</tbody>
</table>
## Cost-Utility Results: Preterm Infants

<table>
<thead>
<tr>
<th>Developmental Area</th>
<th>“Effect” per $1,000 spent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult interaction</td>
<td>2.68</td>
</tr>
<tr>
<td>Attention and memory</td>
<td>1.66</td>
</tr>
<tr>
<td>Perception and Concepts</td>
<td>3.48</td>
</tr>
<tr>
<td>Fine Motor</td>
<td>.005</td>
</tr>
<tr>
<td>Gross Motor</td>
<td>2.28</td>
</tr>
<tr>
<td>Expressive communication</td>
<td>1.59</td>
</tr>
<tr>
<td>Receptive Communication</td>
<td>2.89</td>
</tr>
<tr>
<td>Self-Care</td>
<td>2.98</td>
</tr>
<tr>
<td>Self-concept and Social Role</td>
<td>1.52</td>
</tr>
</tbody>
</table>

Development is measured using scaled BDI-2 scores (mean=10, SD=3) and modeled as difference between EI entry and EI exit.

CER were sig lower for **FM skills** (for all groups) and **expressive communication** than NAS group.

CER were sig higher for **GM skills** than moderate DD group and sig higher for **receptive communication** than mild DD group.
Opportunities & Challenges

• **Strengths and Opportunities**
  – Large, administrative database with rich service use and child characteristic data
  – Tested previously validated methods to categorize EI-enrolled children
  – Examined metrics that can inform clinical practice

• **Limitations and Challenges**
  – Communicating methods and results to key stakeholders
  – ‘scale-up’ of methods to multi-site data collection system
    • Different capacities for data collection
    • Inclusion of other key metrics (e.g., function, parent-reported measures)
  – How can we use this data to inform a pragmatic trial?
<table>
<thead>
<tr>
<th>Aim</th>
<th>Measure</th>
<th>Variables</th>
<th>Data Source</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Therapy Intensity</td>
<td>Any Home or Clinic Visit in a quarter. Number of home or clinic visits in a quarter,</td>
<td>Other therapy (outpatient) Medicaid files</td>
<td>Home visits reimbursed by Part C (not regular Medicaid).</td>
</tr>
<tr>
<td>2</td>
<td>Adverse Events</td>
<td>Indicator variable for therapy sensitive utilization in a given quarter (e.g. Hospitalizations; surgical procedures; durable medical equipment (DME), medications and subspecialists utilization.</td>
<td>Other therapy (outpatient) Medicaid files; prescription drug file; Medicaid Claims</td>
<td>Includes outcomes that are likely to be influenced by therapy services – access to DME, prolonged hospitalizations, increased medications, and complications post-surgically</td>
</tr>
<tr>
<td>3</td>
<td>Costs</td>
<td>Direct cost of utilization related to SHCN per quarter</td>
<td>Other therapy (outpatient) Medicaid files; Medicaid Claims</td>
<td>Direct cost of providing services related to SHCN. <strong>Includes:</strong> (1) <strong>direct therapy cost (either through Part C or Medicaid)</strong> and (2) Inpatient and other utilization related to treatment for SHCN.</td>
</tr>
</tbody>
</table>