Clinical Research Using Practice-Based Evidence (PBE):
Comparison with Clinical Trials and Prospective Observational Designs

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History of the Problem

• How best to treat the patient in your office right now?

• “Scientific controlled studies” provide imperfect guidance

• Clinical medicine is untidy; many variables describe patients, providers, treatments, and practices

• Must consider clinical variability of patient populations, intervention combinations, and outcomes to improve real-world care
Objectives of Webinar

1. Describe models to conduct clinical research including comparative effectiveness research, randomized controlled trials, analysis of claims databases, electronic medical record databases, condition or treatment registries, and practice-based evidence (PBE) study design models.

2. Present clinical examples of findings from practice-based evidence studies related to quality and safety improvements and their implementation in practice.

3. Describe the critical role that front-line clinicians and patients/caregivers play in comparative effectiveness research and PBE studies.
Efficacy versus Effectiveness

• **Efficacy** – measures treatment benefit under the best possible circumstances (Can it work in controlled setting?)
  • Generation - Randomized Controlled Trials (RCT), explanatory

• **Effectiveness** – measures treatment benefit under ordinary practice (Does it work in real-life situation?)
  • Generation – effectiveness trials, pragmatic trials, observational studies, practice-based evidence studies
Comparative Effectiveness Research – What is it?

• Comparative effectiveness research is designed to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options used in routine care.

• Evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care in real-world situations.
Comparative Effectiveness Research – What types of evidence are used?

There are two ways that evidence is found:

1. **Systematic reviews of existing evidence.** Researchers look at all available evidence about benefits and harms of each treatment choice for different groups of people from existing clinical trials, clinical studies, and other research.

2. **New studies.** Researchers conduct studies that generate *new evidence* of effectiveness or comparative effectiveness of a test, treatment, procedure, or health-care service.
What We Have and What We Need

• We have *Efficacy* trials that determine whether an intervention produces a specified result(s) under well controlled conditions in a selected population – includes randomized controlled trials (RCTs)

• We need *Effectiveness* that trials measure outcomes of an intervention under “real world” conditions in an unselected clinical population. Hypotheses and study designs of an effectiveness trial are formulated based on conditions of routine clinical practice and on outcomes essential for clinical decisions.
Effectiveness Trials versus Randomized Controlled Trials (RCTs)

RCT

Progenitor of RCTs

Practice effects of RCT results

Effectiveness
Databases for Effectiveness Trials

- RCT databases
- Large claims databases, e.g., Medicare and Medicaid
- HMO or Veterans Administration databases from claims and electronic medical records
- Specific condition registries, such as arthritis registry
- Practice-based evidence study registries
Randomized Controlled Trial (RCT) Databases for Comparative Effectiveness Research (CER)

• *RCT databases* are considered the gold standard for *efficacy* and value of interventions

• *Advantages* include:
  
  ➢ High internal validity-causality, i.e., can claim that *treatment causes the outcome* since patients with *known confounders* are excluded and randomization eliminates *unknown confounders*
Randomized Controlled Trial (RCT) Databases for Comparative Effectiveness Research (cont)

Limitations include:

- Small sample sizes – too small to detect uncommon risks
- Follow-up periods too short to assess long-term benefits/risks
- Higher-risk patients are typically excluded so findings do not apply to all patients with that disease/condition
- Level of monitoring is more rigorous than done in routine practice
- High rates of treatment discontinuation/dropouts
Non-Randomized Controlled Trial Databases for Comparative Effectiveness Research (CER)

**Advantages** include:

- Cover thousands to millions of people including minority and elderly and all levels of severity of disease/condition being studied
- Ability to provide treatment exposures and adverse events, including hospitalizations and mortality, over extended periods of time
- Provide population and subpopulation-based estimates for various outcomes
- Many non-RCT databases exist in electronic form so some data elements may be exported for use in comparative effectiveness research analyses
Non-Randomized Controlled Trial Databases for Comparative Effectiveness Research (CER)

*Limitations* include:

- Little ability to capture patients’ severity of illness, functional and cognitive status, health behaviors (other than smoking), pain, etc. These can be important unmeasured confounders.
- Restricted access to database unless researcher is part of organization that owns the data (e.g., non-VA researchers cannot access VA databases).
- Often required variables are in text format so are not exportable from EMR.
Electronic Databases for Comparative Effectiveness Research

Three primary types of electronic databases:

- Insurance claims databases, e.g., Medicare, Medicaid
- Large health systems with electronic medical record data, e.g., HMO and Veterans Administration databases
- Disease/condition or procedure-specific registries
Clinical Registry Electronic Databases for Comparative Effectiveness Research

- Systematically collected and stored health-related information on specific patient populations, most often defined by a particular disease/condition or procedure.
- **Advantages** include:
  - Designed to collect detailed information related to a particular disease/condition or procedure
- **Limitations** include:
  - Typically created as an add-on or separate database from those used for clinical care or payment
  - Limited information outside of particular condition or procedure
Basic Problem in Non-Randomized Studies

• **Confounding by Indication**
  - Therapies are administered in non-random fashion
  - Prognostic characteristics influence therapy used
  - Recipients of therapy are at high risk for outcomes
  - Users differ from non-users in key respects
Overcoming Selection Bias/Confounding by Indication

• Statistical adjustments:
  • Matching
  • Propensity score or instrumental variables
  • Covariate adjustments (e.g., Severity of Illness)

• Ongoing debate about the adequacy of adjustments
Practice-Based Evidence (PBE) Methodology

What makes this approach different? Why use PBE approach to create a Registry?
Issues Addressed Using PBE

• Patients, caregivers, and clinician providers report data

• Data come from existing EMR with standardized data elements about patient characteristics, treatments, processes, patient/caregiver-reported data, and multiple outcomes

• Data are part of routine documentation, so not an ‘add-on’

• Rapid patient accrual since documentation is standard of care

• Longitudinal and ongoing data accrual
Issues Addressed Using PBE (cont)

• Patient comparability is addressed with the Comprehensive Severity Index (CSI): disease-specific, physiologic-based, >2,200 criteria, >5,500 disease-specific criteria sets

• CSI addresses confounding by indication and selection bias

• PBE database includes all treatments with date/dose/intensity/route. Many details collected in point-of-care (POC) documents.

• PBE studies assess drug and non-drug combination therapies

• Findings of PBE-CER are more readily translated into practice
Practice-Based Evidence Designs

*Standardize documentation for:*

**Process Factors**
- Patient Education and Management Strategies
- Interventions and surgeries
- Medications

**Patient Factors**
- Psychosocial/demographic Factors
- Co-occurring Conditions
- Severity of Illness and Injury
- Genetic information
- Measured at Multiple Points in Time

**Primary Outcomes**
- Mortality or Adverse Events
- Health Status
- Motor and Cognitive Function
- Cost/Length of Stay
- Discharge Home
- Long-term Outcomes

**Control for:**

**Measure:**
7 Signature Features of PBE Registries

1. Hypotheses are broad

2. All interventions are considered to determine the relative contribution of each

3. Broad patient selection criteria maximize generalizability and transportability

4. Detailed characterization of the patient described by robust measures of patient severity, genetic information, and functional status
7 Signature Features of PBE Registries

5. Patient differences are controlled statistically rather than through exclusion or randomization

6. Facility and clinical/patient buy-in comes from use of trans-disciplinary Clinical Practice Team

7. Strength of evidence built through the research process

PBE findings are more generalizable and transportable than RCT findings
PBE Registry Hallmarks

• Decisions about data collection and analyses are made by front-line clinicians and patients/caregivers vs. researchers

• “Bottom-up” vs. “Top-down” approach

• Guidance from researchers (scientific advisory board) and patient/caregiver/provider experience
PBE Registry Hallmarks

- **Non-experimental**: Follows outcomes of treatments actually prescribed
- **Inclusive**: Uses patient populations undergoing routine clinical care
- **Pragmatic**: Uses actual clinical outcomes
- **Lower Cost** than RCTs
- **Faster** than RCTs
Practice-Based Evidence Designs

*Standardize documentation for:*  

**Process Factors**  
- Patient Education and Management Strategies  
- Interventions and surgeries  
- Medications

**Patient Factors**  
- Psychosocial/demographic Factors  
- Co-occurring Conditions  
- Severity of Illness and Injury  
- Measured at Multiple Points in Time

**Measure:**

**Primary Outcomes**  
- Change in CSI/discharge CSI  
- Discharge Disposition  
- Length of Stay  
- Post-discharge Outcomes
Examples of Severity Systems to Address Selection Bias/Confounding by Indication

Diagnostic/Procedure Based Systems
- Clinical definition of severity
  - Body Systems Count
  - Charlson Comorbidity Index (1-yr death)
- 3 Disease Staging (hosp death)
- Patient Management Categories (hosp death)
- Resource definition of severity
  - Case Mix Groups [CMGs] (rehab LOS, $)
  - Acuity Index Method (LOS)
  - APR DRGs (hosp $)
  - Patient Management Categories (hosp $)
  - Refined DRGs (hosp LOS, $)

Physiologic/Clinically Based Systems
- 2 Apache II & III (ICU death)
- 2 Medisgroups (Atlas) (hosp death)
Comprehensive Severity Index (CSI®) to account for selection bias/confounding by indication

• Severity defined as “physiologic complexity” presented to medical personnel due to the extent and interactions of a patient’s diseases”

• *Disease-specific:* 5,500 disease-specific groups; over 2,200 distinct criteria. ICD-10 codes trigger disease-specific patient signs, symptoms, and physical findings used to score disease-specific and overall severity levels

• *No treatments used* as criteria

• *Comprehensive* (all diseases)

• *Clinically credible:* computes disease-specific and overall severity levels
CSI Severity Indicators

• Measures severity at *multiple time points*
• Physiological signs and symptoms of a disease
  - Vital signs
  - Laboratory values
  - Radiology findings
  - Other physical findings
• Severity indicators are specific to each disease or condition based on ICD-10 coding
## Cerebral Palsy Severity Criteria – ages 2-4 years

### Outpatient - Outpatient Matrix Detail Report
**Matrix: 6104 – NEUROLOGY-CP – CEREBRAL PALSY - 2-4 years**

<table>
<thead>
<tr>
<th>Category</th>
<th>Indicator</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>30 - Orthostasis</td>
<td>No orthostasis</td>
<td></td>
<td>Orthostasis</td>
<td></td>
</tr>
<tr>
<td>Digestive</td>
<td>42 - Dyphagia</td>
<td>Dyphagia NOS, No dyphagia</td>
<td>Unable to swallow solids</td>
<td>Unable to swallow liquids; aspiration of secretions</td>
<td></td>
</tr>
<tr>
<td>Digestive</td>
<td>493Nausea/vomiting (pediatric)</td>
<td>Nausea</td>
<td>Occasional vomiting (&lt;=4 episodes in 24 hours)</td>
<td>Frequent vomiting (5-8 episodes in 24 hours or 4 episodes per day for two consecutive days)</td>
<td>Persistent vomiting (&gt;8 episodes in 24 hours) Greater than minimal bile in emesis</td>
</tr>
<tr>
<td>General</td>
<td>495 - Percent Unintentional Weight Loss</td>
<td></td>
<td>0.0 &lt; X &lt;= 4.0%</td>
<td>4.0 &lt; X &lt;= 10.0</td>
<td>10.0 &lt; X &lt;= 100.0</td>
</tr>
<tr>
<td>Lab - Arterial Blood Gases</td>
<td>490 - Highest PCO2</td>
<td>0.0 &lt; X &lt;= 44.0</td>
<td>44.0 &lt; X &lt;= 49.0</td>
<td>49.0 &lt; X &lt;= 300.0</td>
<td></td>
</tr>
<tr>
<td>Lab - Chemistry</td>
<td>159 - Highest fasting glucose</td>
<td>0.0 &lt; X &lt;= 105.0 mg/dl</td>
<td>105.0 &lt; X &lt;= 180 mg/dl</td>
<td>180 &lt; X &lt;= 300 mg/dl</td>
<td>X &gt;= 301 mg/dl</td>
</tr>
<tr>
<td>Lab - Chemistry</td>
<td>160 - Lowest fasting glucose</td>
<td></td>
<td>55.0 &lt; X &lt;= 59.0 mg/dl</td>
<td>44.0 &lt; X &lt;= 55.0 mg/dl</td>
<td>X &lt;= 44.0 mg/dl</td>
</tr>
<tr>
<td>Lab - Chemistry</td>
<td>149 - Highest sodium</td>
<td>134.0 &lt; X &lt;= 145.0 mEq/L</td>
<td>145.0 &lt; X &lt;= 148 mEq/L</td>
<td>148 &lt; X &lt;= 152 mEq/L</td>
<td>X &gt;= 153 mEq/L</td>
</tr>
<tr>
<td>Lab - Chemistry</td>
<td>150 - Lowest sodium</td>
<td>134.0 &lt; X &lt;= 145.0 mEq/L</td>
<td>130.0 &lt; X &lt;= 134 mEq/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab - CSF</td>
<td>576 - CSF Fluid - Opening Pressure</td>
<td>X &lt; 200.0 mm H2O</td>
<td>X &gt;= 201.0 mm H2O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab - CSF</td>
<td>575 - CSF Fluid - Protein</td>
<td>X &lt;= 40.0 mg/dl</td>
<td>X &gt; 40 mg/dl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab - CSF</td>
<td>574 - CSF Fluid - Glucose</td>
<td>X &gt;= 40.0 mg/dl</td>
<td></td>
<td>&lt; 40.0 mg/dl</td>
<td></td>
</tr>
<tr>
<td>Lab - CSF</td>
<td>573 - CSF Fluid - WBC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Musculo-Skeletal</td>
<td>232 - Stiff Neck</td>
<td>Stiff neck, No stiff neck</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Musculo-Skeletal</td>
<td>225 - Muscle Abnormality</td>
<td>Muscle weakness NOS, Muscle abnormality NOS</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Cerebral Palsy Severity Criteria – ages 2-4 years (cont pg 2)

<table>
<thead>
<tr>
<th>Category</th>
<th>Indicator</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Musculo-Skeletal</td>
<td>222 - Arthralgias</td>
<td>No arthralgias</td>
<td>Arthralgias</td>
<td>Chronic limited range of motion. Acute decreased extension</td>
<td></td>
</tr>
<tr>
<td>Musculo-Skeletal</td>
<td>221 - Joint Range of Motion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurology</td>
<td>246 - Muscle Jerking</td>
<td>No muscle jerking</td>
<td>Chronic choreoathetoid movements, Chronic rigidity</td>
<td>Violent, continuous movements, Rigidity of movement (new onset), Choreiform movements (new onset), Myoclonic jerking, Athetoid movements</td>
<td></td>
</tr>
<tr>
<td>Neurology</td>
<td>240 - Seizures</td>
<td>No seizures</td>
<td>Tremors, Febrile seizures, Chronic seizures</td>
<td>Seizures (non-febrile)</td>
<td>Complex seizures</td>
</tr>
<tr>
<td>Neurology</td>
<td>248 - Urinary Incontinence</td>
<td>No incontinence, Chronic incontinence</td>
<td>New onset incontinence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurology</td>
<td>498 - Mental Status</td>
<td></td>
<td>Irritable, Restless, Agitated</td>
<td>Lethargic, Confused or disoriented</td>
<td>Unresponsive, Obtunded</td>
</tr>
<tr>
<td>Neurology</td>
<td>251 - Sensation Alteration</td>
<td>Tingling, No sensation alteration</td>
<td>Numbness, Decreased sensation</td>
<td>Acute loss of sensation</td>
<td></td>
</tr>
<tr>
<td>Neurology</td>
<td>254 - Alternating Movements</td>
<td>Normal alternating movements</td>
<td>Poor alternating movements</td>
<td>Alternating movements impossible</td>
<td></td>
</tr>
<tr>
<td>Neurology</td>
<td>252 - Motor Alteration</td>
<td>No motor alteration Independent</td>
<td>Assisted</td>
<td></td>
<td>Acute complete loss of motor function; acute paralysis, no mobility</td>
</tr>
<tr>
<td>Neurology</td>
<td>243 - Alternating Levels of Consciousness</td>
<td>No altered level of consciousness</td>
<td>Altered or changing levels of consciousness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>270 - Headache</td>
<td>No headache</td>
<td>Headache NOS, Frontal headache</td>
<td>Recent onset of headache (&lt;1 month) with aura, blurred vision, nausea, vomiting, Severe headache, Persistent headache, Early morning headache</td>
<td>New onset of headache with altered level of consciousness</td>
</tr>
</tbody>
</table>


## Cerebral Palsy Severity Criteria – ages 2-4 years (cont pg 3)

<table>
<thead>
<tr>
<th>Category</th>
<th>Indicator</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senses</td>
<td>321 - Vision Abnormalities</td>
<td>Vision impairment NOS, Vision worse than 20/60 in either eye</td>
<td>Diplopia; double vision with onset &lt;1 month, Blurred vision with onset &lt;1 month, Nystagmus with onset &lt;1 month, Strabismus with onset &lt;1 month</td>
<td>Orbital pulsations</td>
<td>Orbital pulsations</td>
</tr>
<tr>
<td>Senses</td>
<td>340 - Orbital Pulsations</td>
<td>No orbital pulsations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Senses</td>
<td>339 - Proptosis</td>
<td>No proptosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Senses</td>
<td>337 - Eyelid Abnormality</td>
<td>Eyelid abnormality NOS</td>
<td>Style, Ptosis, Lid lag, Chalazion</td>
<td>Swollen lacrimal gland</td>
<td></td>
</tr>
<tr>
<td>Senses</td>
<td>322 - Vision Loss</td>
<td></td>
<td>Areas of depressed vision, Gradual loss of portion of visual field, Hemianopsia, Tunnel vision Floaters Myopia 20/200 vision no correctable with lenses</td>
<td>Acute complete vision loss of either eye, Acute partial vision loss of either eye</td>
<td></td>
</tr>
<tr>
<td>Vital signs</td>
<td>1 - Highest pulse</td>
<td>0.0&lt;X&lt;=119.0 bpm</td>
<td>119.0&lt;X&lt;=159.0 bpm</td>
<td>159.0&lt;X&lt;= 2.00 bpm</td>
<td>X&gt;200 bpm</td>
</tr>
<tr>
<td>Vital signs</td>
<td>2 - Lowest pulse</td>
<td>59.0 &lt; X bpm</td>
<td></td>
<td>44.0 &lt;X&lt;= 59.0 bpm</td>
<td>0.0 &lt; X&lt;=44.0 bpm</td>
</tr>
<tr>
<td>Vital signs</td>
<td>3 - Highest systolic BP</td>
<td>0.0&lt;X&lt;=115.0mmHg</td>
<td>115.0&lt;X&lt;=123.0 mmHg</td>
<td>123.0&lt;X&lt;=141 mmHg</td>
<td>&gt;141 mmHg</td>
</tr>
<tr>
<td>Vital signs</td>
<td>4 - Lowest systolic BP</td>
<td>X≥90 mmHg</td>
<td>79.0&lt;X&lt;= 89.0 mmHg</td>
<td>59.0&lt;X&lt;=79.0 mmHg</td>
<td>0.0&lt;X&lt;=59.0mmHg</td>
</tr>
<tr>
<td>Vital signs</td>
<td>5 - Highest diastolic BP</td>
<td>0.0&lt;X&lt;=75.0 mmHg</td>
<td>75.0&lt;X&lt;=83.0mmHg</td>
<td>83.0&lt;X&lt;=93.0 mmHg</td>
<td>&gt;93mmHg</td>
</tr>
<tr>
<td>Vital signs</td>
<td>6 - Highest temperature</td>
<td>0.0&lt;X&lt;=100.4°F</td>
<td>100.4&lt;X&lt;=103.0°F</td>
<td>103.0&lt;X&lt;=105.0°F</td>
<td>&gt;105°F</td>
</tr>
</tbody>
</table>

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Pediatric Bronchiolitis Registry

Children Hospitalized with RSV

Birth at 33-35 weeks Gestational Age is significantly associated with higher intubation rates, longer Intensive Care Unit stays, and longer hospital Length of Stay (prompted guideline change for prophylaxis).
Pediatric Bronchiolitis Registry

**Outcome = Cost**

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Age in months (.0001)</td>
<td>+ Admitted to PICU (.0001)</td>
</tr>
<tr>
<td>+ MCSIC (.0001)</td>
<td>+ Arterial line (.04)</td>
</tr>
<tr>
<td></td>
<td>+ Central line (.003)</td>
</tr>
<tr>
<td></td>
<td>+ Continuous nebulization (.0002)</td>
</tr>
<tr>
<td></td>
<td>+ Interaction: chest pt &amp; atelectasis (.005)</td>
</tr>
<tr>
<td></td>
<td>+ Intubation (.0001)</td>
</tr>
<tr>
<td></td>
<td>+ Ipratropium bromide (.005)</td>
</tr>
<tr>
<td></td>
<td>+ Lasix (.0001)</td>
</tr>
<tr>
<td></td>
<td>+ Ribavirin (.0001)</td>
</tr>
<tr>
<td></td>
<td>+ Steroids (.0003)</td>
</tr>
</tbody>
</table>

n=722  \[ R^2 = .73 \]

Assessment Procedures

## Prematurity and RSV Hospital Outcomes

### Significant Differences by Gestational Age Groups

33-35 week GA infants had highest hospital resource use

<table>
<thead>
<tr>
<th></th>
<th>≤32 wks</th>
<th>33-35 wks</th>
<th>36 wks</th>
<th>≥37 wks</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intubation</strong></td>
<td>21.4%</td>
<td><strong>38.7%</strong></td>
<td>20%</td>
<td>12.1%</td>
<td>0.002</td>
</tr>
<tr>
<td><strong>ICU LOS</strong></td>
<td>5.8 days</td>
<td><strong>7.7 days</strong></td>
<td>4.2 days</td>
<td>3.8 days</td>
<td>0.021</td>
</tr>
<tr>
<td><strong>Hospital LOS</strong></td>
<td>6.8 days</td>
<td><strong>8.4 days</strong></td>
<td>4.9 days</td>
<td>4.1 days</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Admitted to ICU</strong></td>
<td>39.3%</td>
<td><strong>48.4%</strong></td>
<td>30.0%</td>
<td>27.9%</td>
<td>0.101</td>
</tr>
<tr>
<td><strong>HX of Hosp. for RSV/Bronchiolitis</strong></td>
<td>14.3%</td>
<td><strong>16.1%</strong></td>
<td>6.7%</td>
<td>6.1%</td>
<td>0.137</td>
</tr>
</tbody>
</table>

RSV Hospital Outcomes and Policy Changes

Conclusions

• 33-35 week Gestational Age infants had highest hospital resource use

• 36 week infants have risk similar to full term infants

• Changed guidelines for immunoprophylaxis for 33-35 week infants

• Changed guidelines for intubation – try ‘stimulating’ first
Traumatic Brain Injury Registry 2008 – 2011; 2,130 patients

What Treatments Are Associated with Better Outcomes at Rehabilitation Discharge For Traumatic Brain Injury?
# Clinical Research Point-of-Care (POC) documentation - Physical Therapy

![Image of TBI-PBE Physical Therapy Form]

## Session Info
- **Patient Name:** Jane Patient
- **Clinician ID:** 1 2 3
- **Start Time:** 1:00 PM
- **Date:** 09/08/08
- **Total Session Time:** 30 minutes
- **# of Session Participants:**
  - Patients: 1
  - PT: 1

## TBI-PBE Physical Therapy Form v.10.1.08

### Activities
- Pre-Functional Activity
- Therapeutic Exercise
- Developmental Sequencing
- Equipment Management
- Sed Mobility
- Sitting
- Standing
- Transfers
- Wheelchair Mobility
- Post-Gait
- Advanced Gait
- Stars
- Community Mobility
- Preparations
- Casting/Splints
- Evaluation of Patient Home
- Formal Assessment
- Rating

### Interventions/Devices
- Berg
- PROM
- Knee

### Environment
- Right
- Left

### Interventions Codes
- Neurological:
  - 01 Task Practice
  - 02 Balance Training
  - 03 Motor Relearning/Awareness Exercises
  - 04 Motor Control/Coordination

- **Berg Total Score:**
- **If "0" for Berg score do the sitting score**

- **Sitting Score:**

- **Submit completed Berg Form with this POC**

- MUSCULAR/SKELETAL:
  - 11 Strengthening
  - 12 Range of Motion
  - 13 Manual Therapy

- CARDIO/PULMONARY:
  - 16 Breathing
  - 17 Aerobic/Conditioning Exercises

- **Overall Endurance Education:**

- **18 Patient Family/Caregiver:**

- **Cognitive/Psychological:**
  - 22 Cognitive Training/Behavioral

- **Perceptual Training/Behavioral:**

- **Other:**

### Assistive Devices
- Ambulation Devices:
  - 37 Ankle Assistive Device
  - 38 Unilateral Ambulation Device
  - 39 Bilateral Ambulation Device
  - 40 Knee Extension Assistance
  - 41 Swedish Knee Cage

- Training Devices:
  - 43 Body Weight Support
  - 44 Slide Board
  - 45 PTO Frame
  - 46 Step Ladder

- Equipment/Splinting:
  - 26 Initial Assessment

### Environment Key
- 1 Quiet
- 2 Minimal Stimulating
- 3 Moderately Stimulating
- 4 Maximally Stimulating

---

Research CP -- Webinar #2: Clinical Research
## Discharge Rasch-Adjusted FIM Motor Regression: Variance Explained

<table>
<thead>
<tr>
<th>Step R²</th>
<th>Adm Cog &lt;=6</th>
<th>Adm Cog 7-10</th>
<th>Adm Cog 11-15</th>
<th>Adm Cog 16-20</th>
<th>Adm Cog &gt;=21</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pat/Inj</td>
<td>0.38</td>
<td>0.48</td>
<td>0.48</td>
<td>0.54</td>
<td>0.71</td>
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<tr>
<td>Pat/Inj + POC total</td>
<td>0.41</td>
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<td>0.48</td>
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<td>Pat/Inj + POC act/LOE</td>
<td>0.74</td>
<td>0.70</td>
<td>0.62</td>
<td>0.62</td>
<td>0.76</td>
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<tr>
<td>Pat/Inj + meds</td>
<td>0.41</td>
<td>0.48</td>
<td>0.48</td>
<td>0.55</td>
<td>0.72</td>
</tr>
<tr>
<td>Pat/Inj + POC act/LOE + meds</td>
<td>0.74</td>
<td>0.70</td>
<td>0.63</td>
<td>0.63</td>
<td>0.76</td>
</tr>
<tr>
<td>Pat/Inj + POC act/LOE + meds + sites</td>
<td>0.74</td>
<td>0.71</td>
<td>0.63</td>
<td>0.65</td>
<td>0.78</td>
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</tbody>
</table>
## All Regressions Summary:
### Patient and Injury Significant Covariates

Red = negative coeff, p<.05; Green = positive coeff, p<.05

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Cog &lt;=6</th>
<th>Cog 7-10</th>
<th>Cog 11-15</th>
<th>Cog 16-20</th>
<th>Cog &gt;=21</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FIM Cog</strong></td>
<td>LoS dcM</td>
<td>dcM dcH fuC</td>
<td>LoS dcM dcC</td>
<td>LoS dcM fuM</td>
<td>LoS dcM</td>
</tr>
<tr>
<td><strong>FIM Motor</strong></td>
<td>LoS dcM</td>
<td>dcM dcH fuC</td>
<td>LoS dcM dcC</td>
<td>dcM dfH</td>
<td>LoS dcM</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>LoS dcM</td>
<td>dcM dcH fuC</td>
<td>LoS dcM dcC</td>
<td>dcM dfH fuC</td>
<td>dcM dfH</td>
</tr>
<tr>
<td><strong>Avg LOE</strong></td>
<td>LoS dcM</td>
<td>dcM dcC fuC</td>
<td>LoS dcM dcC</td>
<td>LoS dcM fuC</td>
<td>dcC fuC</td>
</tr>
<tr>
<td><strong>Inj to Adm</strong></td>
<td>LoS dcM</td>
<td>dcM dcC fuC</td>
<td>LoS dcM fuC</td>
<td>LoS fuM</td>
<td>LoS fuM</td>
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<tr>
<td><strong>HS, No Dplma</strong></td>
<td>fuC</td>
<td>fuM fuC</td>
<td>fuM fuC</td>
<td>fuM fuC</td>
<td>fuM fuC</td>
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<tr>
<td><strong>BI CSI</strong></td>
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<td>LoS</td>
<td>LoS</td>
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<tr>
<td><strong>non-BI CSI</strong></td>
<td>dcM</td>
<td>LoS dcH</td>
<td>LoS dcM fuM</td>
<td>LoS</td>
<td>LoS dcH</td>
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<tr>
<td><strong>Black Race</strong></td>
<td>fuM</td>
<td>fuM fuC</td>
<td>fuM fuC</td>
<td>fuM fuC</td>
<td>fuM fuC</td>
</tr>
</tbody>
</table>

Rehab Length of Stay (LoS) | Discharge FIM Motor (dcM) | 9-Month FIM Motor (fuM) | Discharge FIM Cognitive (dcC) | 9-Month FIM Cognitive (fuC)
## All Regressions Summary:
Regressions Summary: Treatment Significant Covariates

Red = negative coeff, p<.05; Green = positive coeff, p<.05

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Adm Cog &lt;=6</th>
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<th>Adm Cog 11-15</th>
<th>Adm Cog 16-20</th>
<th>Adm Cog &gt;=21</th>
</tr>
</thead>
<tbody>
<tr>
<td>OT Education/Sexuality Min/Wk</td>
<td>dcH fuM fuC</td>
<td>dcH</td>
<td>LoS dcH</td>
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<td>LoS</td>
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<tr>
<td>OT Home IADLs Min/Wk</td>
<td>dcM dcH</td>
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<tr>
<td>OT Physical Impairments Min/Wk</td>
<td>dcM fuM</td>
<td>dcM fuM</td>
<td>dcM fuM</td>
<td>dcM</td>
<td>LoS</td>
</tr>
<tr>
<td>PT Advanced Gait, Gait, Community Mobility, Stairs Min/Wk</td>
<td>dcM fuM</td>
<td>dcM</td>
<td>dcH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT Equip Mgmt, WC/Bed Mobility, Casting, Sitting, Trnsfrs, Develop Seq Min/Wk</td>
<td>dcM fuM</td>
<td>LoS dcM dcC</td>
<td>dcM dcH</td>
<td>dcM dcC</td>
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</tr>
<tr>
<td>PT Formal Assessment Min/Wk</td>
<td>LoS</td>
<td>fuM</td>
<td>LoS fuM</td>
<td>LoS dcH fuM</td>
<td>LoS</td>
</tr>
<tr>
<td>ST Education Min/Wk</td>
<td>dcH</td>
<td>LoS dcH fuC</td>
<td>LoS dcH</td>
<td>dcC dcH</td>
<td>dcH</td>
</tr>
<tr>
<td>ST Basic Motor/Speech Min/Wk</td>
<td>dcM</td>
<td></td>
<td></td>
<td>LoS dcM dcC</td>
<td>fuM</td>
</tr>
<tr>
<td>ST Problem Solving, Math, Money, Memory, Orientation Min/Wk</td>
<td>dcM dcC fuM</td>
<td>dcM dcC fuM</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>% Stay Atypical Antipsychotics</td>
<td>LoS dcM dcC</td>
<td></td>
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</tr>
</tbody>
</table>

Rehab Length of Stay (LOS) 9-Month FIM Motor (fuM) 9-Month FIM Cognitive (fuC) Discharge FIM Motor (dcM) Discharge FIM Cognitive (dcC) Discharge to Home (dcH)

Red = negative coeff, p<.05  Green = positive coeff, p<.05
TBI Rehabilitation Outcomes and Potential Policy Changes

Conclusions

• *Shorter time from injury to rehabilitation admission* are associated with better functional and cognitive outcomes.

• *More time spent in complex activities* (e.g., advanced gait, stairs, problem solving, money management, home Instrumental Activities of Daily Living) at the beginning of the stay is associated with better functional and cognitive outcomes.
Summary

• PBE methodology provides a structured way to design registries for patients in routine care settings; balance between population-based approach and individualized decision-making

• PBE registries develop comprehensive databases of patient, treatment, and outcome differences

• PBE findings associated with better outcomes are easily transferable for use in other sites because all patients with a condition are included in a PBE registry

• CPRN Registry supports PBE studies