Pediatrix Medical Group – BabySteps and the Clinical Data Warehouse

- Pediatrix Medical Group
  - Reese H Clark MD
  - Dan Ellsbury MD
  - Alan Spitzer MD

- Duke Clinical Research Institute
  - Brian Smith MD MPH MHS
  - Danny Benjamin MD PhD MPH
Pediatricsx Medical Group

- 1200 neonatologists
- 278 NICUs
- 33 states
- 20-25% of infants admitted to NICUs in the US
Pediatrics Electronic Medical Record (EMR)

- Launched in 1996
- BabySteps - proprietary system developed by Pediatrics
- Clinical documentation system used to create clinical notes
- Used across 278 Pediatrics sites
- Data collected daily until discharge.
- Used for research, education, and quality improvement
Clinical Data Warehouse

- Data transferred daily from BabySteps
- > 600,000 infants
- 11,000,000 patient days
- Reports on aspects of care, morbidities and mortality at individual centers
- Queried by FDA, NIH, and academic neonatology programs.
BabySteps to Research Database

Data Entered Into BabySteps at Each Pediatrix NICU – PHI

Clinical Data Warehouse – PHI

Intermediate Clinical Database – No PHI

Research Database – No PHI

PHI removed

Free text removed
Variables in Research Database

- Demographics
  - Inborn status
  - Birth weight
  - Gestational age
  - Sex
  - Race/ethnicity
  - Admit year
  - Apgar scores

- Maternal variables
  - Maternal age
  - Maternal serologies
  - Delivery type
  - Duration of rupture of membranes
  - Medications (antibiotics, steroids)
Variables in Research Database

- **Diagnoses**
  - Congenital anomalies
  - Necrotizing enterocolitis
  - Spontaneous intestinal perforation
  - Patent ductus arteriosus/ligation
  - Intraventricular hemorrhage
  - Chronic lung disease

- **Labs**
  - Lab values – chemistries, LFTs, hematology
  - Culture results

- **Respiratory**
  - Support
  - FiO2
Variables in Research Database

- Therapeutics
  - Drug name
  - Start/stop day
- Feedings
  - Type
  - Start/stop days
  - Volume
- Outcomes
  - Mortality
  - Day of discharge
  - Discharge growth parameters
**Publications**

**Diagnosis**

**Nutrition**
Publications

- **Epidemiology**
  - Walker, et al. Elevation in plasma creatinine and renal failure in premature neonates without major anomalies: terminology, occurrence and factors associated with increased risk. *J Perinatol*
Publications – Drug Safety


- Clark. Empiric use of ampicillin and cefotaxime, compared with ampicillin and gentamicin, for neonates at risk for sepsis is associated with an increased risk of neonatal death. *Pediatrics* 2006.


Publications - Effectiveness

Publications - Prescribing


- Clark. The changing pattern of inhaled nitric oxide use in the neonatal intensive care unit. *J Perinatol*

- Linn. Increasing supplemental thyroid hormone use among premature infants born at 23 to 32 weeks gestation. *Am J Perinatol*
## Prescribing Practices

<table>
<thead>
<tr>
<th>Rank</th>
<th>Medication name</th>
<th>Days exposed</th>
<th>Rank</th>
<th>Medication name</th>
<th>Days exposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ampicillin</td>
<td>186,799</td>
<td>7</td>
<td>Beractant</td>
<td>36,410</td>
</tr>
<tr>
<td>2</td>
<td>Gentamicin</td>
<td>171,388</td>
<td>8</td>
<td>Metoclopramide</td>
<td>27,541</td>
</tr>
<tr>
<td>3</td>
<td>Cefotaxime</td>
<td>55,455</td>
<td>9</td>
<td>Dopamine</td>
<td>25,839</td>
</tr>
<tr>
<td>4</td>
<td>Caffeine</td>
<td>48,814</td>
<td>10</td>
<td>Ranitidine</td>
<td>23,905</td>
</tr>
<tr>
<td>5</td>
<td>Furosemide</td>
<td>47,278</td>
<td>11</td>
<td>Indomethacin</td>
<td>20,605</td>
</tr>
<tr>
<td>6</td>
<td>Vancomycin</td>
<td>44,218</td>
<td>12</td>
<td>Dexamethasone</td>
<td>20,398</td>
</tr>
</tbody>
</table>

Clark, Pediatrics, 2006.
Comparative Effectiveness

Antibiotic Selection: 1st 3 days of Life

Clark RH, Pediatrics, 2006
Comparative Effectiveness

- Adjusted OR for death for cefotaxime vs. gentamicin = 1.5 [1.4, 1.7]

Clark RH, Pediatrics, 2006
Cefotaxime Use

- Cefotaxime (Day 0, 1 or 2)
- Cefotaxime (Day 3 to 7)
- Cefotaxime Start Day > 7th day
- Any Report of Cefotaxime

Year of Discharge vs Percent of Discharges

Duke Clinical Research Institute
Ongoing Therapeutics Projects using Pediatrix Clinical Data Warehouse

- Outcomes by antifungal following *Candida* infections
- Safety of antifungals – liver function tests
- Outcomes following use of ibuprofen vs. indomethacin for treatment of PDA
- Blood culture and antimicrobial timing
- Neonatal Therapeutics and Incorporation of Best Practices
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>How specific is your demographic information?</td>
<td>yes</td>
</tr>
<tr>
<td>Can you document therapeutic use and indication?</td>
<td>yes</td>
</tr>
<tr>
<td>Can you document hospitalizations due to AEs?</td>
<td>n/a</td>
</tr>
<tr>
<td>Can you identify AEs to drugs, dose, schedule, formulation and route?</td>
<td>yes</td>
</tr>
<tr>
<td>Can you determine con meds?</td>
<td>yes</td>
</tr>
<tr>
<td>Can you determine OTC meds in patients who reported an AE?</td>
<td>n/a</td>
</tr>
<tr>
<td>At the origin of the AE, what type of physician did the patient see?</td>
<td>yes</td>
</tr>
<tr>
<td>Where was the AE reported?</td>
<td>yes</td>
</tr>
<tr>
<td>Is there verification of cause of death?</td>
<td>no</td>
</tr>
<tr>
<td>Will you be able to know the distribution of AEs across age subpopulations?</td>
<td>yes</td>
</tr>
<tr>
<td>Is there comparative pediatric AE reporting in adult vs. non-adult facilities?</td>
<td>no</td>
</tr>
</tbody>
</table>
### FDA questions - Does your database/network/system...

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have staff that routinely monitors, investigates and verifies specific AEs?</td>
<td>no</td>
</tr>
<tr>
<td>Investigates the cause of AEs through epidemiologic or genomic studies?</td>
<td>no</td>
</tr>
<tr>
<td>Automatically detects AEs through criteria that trigger an investigation?</td>
<td>no</td>
</tr>
<tr>
<td>Link data to EMRs?</td>
<td>no</td>
</tr>
<tr>
<td>Record age of patients with great granularity?</td>
<td>yes</td>
</tr>
<tr>
<td>Record growth data (weight, height, head circumference)?</td>
<td>yes</td>
</tr>
<tr>
<td>Record birth history of patients?</td>
<td>yes</td>
</tr>
<tr>
<td>Record AEs in high-level terms, preferred terms, low-level terms?</td>
<td>no</td>
</tr>
<tr>
<td>Register a unique patient identifier that permits long-term data analysis?</td>
<td>yes*</td>
</tr>
<tr>
<td>Record costs of visits to hospitals, clinics, or ED?</td>
<td>no</td>
</tr>
<tr>
<td>Record costs of treating AEs?</td>
<td>yes*</td>
</tr>
</tbody>
</table>