Pursuit of the “Holy Grail”—Measuring Outcomes for Term Babies

Elliott K. Main, MD
Director, California Maternal Quality Care Collaborative
Clinical Professor of OB GYN, UCSF and Stanford University

Jeffrey B. Gould MD, MPH
Principle Investigator CPQCC / CMQCC
Professor of Pediatrics, Stanford University
This is All About Getting the Right Balance...

- Balancing Interests: Mother / Baby
- Balancing Focus: All Babies / Specific Group
- Balancing Definition: Narrow / Comprehensive
- Balancing Data Collection: Accuracy / Burden
- Balancing Coding: Over-coding / Under-coding
What is the Most Important Pregnancy Outcome for Mothers and their Families?

“A Good ‘Take-Home’ Baby...”

Avoiding Cesarean or Episiotomy or moderate Maternal Morbidities do not come close
If Baby Outcomes Are So Important Why Are We Not Measuring Them?

Some of the issues...

- Which babies?
- What outcomes?
- Low rates of poor outcomes
- What poor outcomes are related to care?
Which Babies?

- All Babies versus Term Babies?
- Preterm infants have a wide range of outcomes related to gestational age, birth weight, intrauterine environment and other factors
- Not able to consider them as a homogeneous group
- Important principle: Some populations (e.g. premies) are not expected to go home or have perfect outcomes
Survey of Prior Attempts to Measure Term Baby Outcomes

- Rate of Term Baby NICU admissions (or Term baby NICU LOS)
- AHRQ PSI 17: Birth Trauma Rate (injury to the infant)
- “Ideal Delivery” Rate (Gregory et al) (births without major complications)
- Neonatal Composite outcome measures (MFMU Network)
AHRQ PSI 17: Birth Trauma

Figure 1. Distribution of all neonatal birth trauma and birth trauma considered to be a Patient Safety Indicator by AHRQ, 2004-2005.

Rates (per 1,000)
All Trauma: 25.9
PSI 17: 2.45

CS v. Vag (OR)
All Trauma: 0.55
PSI 17: 1.71

Critique:

- Small subset of all birth traumas
- Very low rate: 2 per thousand births
- Dominated by non-specific codes
- Easy to “show improvement” by adjusting coding practices
- Narrow view of birth outcomes...

But it is easy to calculate!
Gregory et al: “Ideal Delivery”

- Neonatal death, transfer
- Birth trauma (all codes)
- RDS, other respiratory problems
- Hypoxia, convulsions, ICH
- Neonatal infection

Total rate 9.8%

Many complications had short LOS...

Gregory KD, Friedman M, Shah S, et al. Global measures of quality- and patient safety-related childbirth outcomes: should we monitor adverse or ideal rates?
Critique:

- Better
- Seemingly high rate (~10%)
- Includes a lot of cases with short LOS, suggesting they were minor issues
- Not field tested
Research Neonatal Composites: MFMU Network

Critique:
- Dominated by Respiratory and Sepsis diagnoses
- Equivalent to NICU admissions

(in this study of early repeat CS results were not representative)

Chiossi G et al., Timing of Delivery and Adverse Outcomes in Term Singleton Repeat Cesarean Deliveries. Obstet Gynecol 2013;121:561–9)

<table>
<thead>
<tr>
<th>Neonatal outcome</th>
<th>Count</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1</td>
<td>0.08</td>
</tr>
<tr>
<td>Respiratory distress syndrome</td>
<td>49</td>
<td>3.8</td>
</tr>
<tr>
<td>Transient tachypnea of the newborn</td>
<td>69</td>
<td>5.3</td>
</tr>
<tr>
<td>Necrotizing enterocolitis</td>
<td>1</td>
<td>0.08</td>
</tr>
<tr>
<td>Sepsis</td>
<td>92</td>
<td>7.1</td>
</tr>
<tr>
<td>Mechanical ventilation</td>
<td>30</td>
<td>2.3</td>
</tr>
<tr>
<td>Seizure</td>
<td>1</td>
<td>0.08</td>
</tr>
<tr>
<td>Hypoxic–ischemic encephalopathy</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Neonatal intensive care unit admission</td>
<td>212</td>
<td>16.4</td>
</tr>
<tr>
<td>5-min Apgar score 3 or less</td>
<td>1</td>
<td>0.08</td>
</tr>
<tr>
<td>Composite outcomes</td>
<td>217</td>
<td>16.7</td>
</tr>
</tbody>
</table>
CMQCC Approach

- Started with: “Healthy Term Newborn” ("96%")
- Reframed as the inverse: “Unexpected Newborn Complications” ("4%")
- Wanted to set aside “pre-existing conditions”
Settings in which the families expectations are lowered:
  - Preterm, small for dates, multiple gestations
  - Congenital malformations, big or small
  - Fetal diagnoses, Drug withdrawal

#1 Goal for all families:
The Devil is **always** in the Details...

- Use administrative data to minimize data burden
- NICU admission is a not a code (and grounds for admission vary greatly from unit to unit (and even shift to shift)
- Separate out Severe from Moderate complications
- Identify diagnosis categories (“buckets”) to facilitate QI projects
- Provide safeguards for over-coding and under-coding
UNC Denominator: Inclusions / Exclusions

- **Include:** Singleton livebirths (ICD10)
  
  BWt ≥2.5kg and GA≥37 weeks

- **Exclusions:**
  
  - All congenital malformations (Q codes)
  - Congenital disorders (from E and G codes)
  - Fetal-placental Conditions, Infections, IUGR, Hydrops, Rh sensitization (from A and P codes)
  - Maternal Drug Use and withdrawal symptoms (from P codes)
Complications were categorized from the viewpoint of the Family:

**Frame 1 (Severe):** “Would I be fearful of my baby’s survival or long term outcome if my baby had...”

**Frame 2 (Moderate):** “Would I be upset if my baby had....”

Note that the concept of preventability is not used.
UNC Numerator: Severe Complication “Buckets”

- **Severe Birth Trauma / Neurologic** (e.g. intracranial hemorrhages, nerve injuries, Apgars at 5’ or 10’ ≤3, organ injuries, major fractures, hypoxic ischemic encephalopathy, coma, leukomalacia, EEG)

- **Severe Infection** (e.g. severe sepsis, sepsis with LOS>4 days)

- **Severe Respiratory** (e.g. Pulmonary hemorrhage, Mec aspiration with symptoms, ventilator, chest tubes, nitric oxide, ECMO)

- **Severe Shock/Resuscitation** (e.g. ATN, cardiogenic shock, insertion of arterial monitoring devices)

- **Transfer to a Higher Level of Care** (indicates a major morbidity and results in a major disruption to the family)
UNC: Coding Strategies

- After examining coding practices for hospitals around the state, “needs” appeared:

  - **Over-coding** Protection:
    - Sepsis vs. “R/O Sepsis”—Added a requirement for a prolonged newborn LOS: LOS >4 days

  - **Under-coding** Protection:
    - Diagnoses are not always recorded (e.g. a systematic exclusion of hypoxia codes) however procedure codes are almost always coded as they tie to billing.
    - Utilize both diagnosis and procedure codes for a “bucket” whenever appropriate (e.g. nitric oxide, EEG, ventilator, ECMO)
UNC Numerator: Moderate Complication “Buckets”

- **Moderate Birth Trauma / Neurologic** (e.g. facial nerve injury, clavical fracture; **With LOS requirement**: CT MRI, suspected to be affected by delivery, unspecified birth injury)

- **Moderate Respiratory** (e.g. RDS, interstitial emphysema, pneumothorax, CPAP; **With LOS requirement**: TTN, atelectasis, apnea, other respiratory distress)

- **Severe Shock/Resuscitation** (e.g. ATN, cardiogenic shock, insertion of arterial monitoring devices)
UNC: Coding Strategies-2

- **Over-coding** Protection:
  - A number of moderate complication diagnoses required a longer LOS than usual to indicate that it was consequential—Added a requirement for a prolonged newborn LOS: LOS >4 days for a Cesarean and >2 days for a vaginal birth

- **Under-coding** Protection:
  - Some cases had very few codes but very long LOS...suspicious for a morbidity
  - Screened these cases first for neonatal jaundice, phototherapy, and a series of codes for social problems (e.g. homelessness, child welfare custody, residential institution)
  - If none of these codes, these cases were considered moderate morbidity
Fig. 5: Frequency Distribution of UNC Measure In California Hospitals (2011)

**Total Unexpected Newborn Complications**

- California Mean = 39.3/1,000 (3.9%)

Significant variation noted in both large and small hospitals
Revised Specifications
NQF #716: Unexpected Newborn Complications
(aka Healthy Term Newborn)

Table 2: Sub-Measure Calculations

An additional feature is the ability to calculate several sub-measures to direct Quality Improvement efforts. These “buckets” include like-diagnoses from both severe and moderate categories. Hospital level comparisons show significant variation in these categories. This Sub-measure analysis allows hospitals to focus on specific care practices to drive QI. See Appendix 6 for details on the Sub-Category groupings.

<table>
<thead>
<tr>
<th>Neonatal Complication Sub-Categories</th>
<th>Proportion of Total Complications (California 2011)</th>
<th>Rate of each Complication Category (per 1,000 births)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory</td>
<td>35.5%</td>
<td>13.5</td>
</tr>
<tr>
<td>Infection</td>
<td>16.7%</td>
<td>6.3</td>
</tr>
<tr>
<td>Transfer to Higher Level of Care</td>
<td>14.9%</td>
<td>5.6</td>
</tr>
<tr>
<td>Neurologic/Birth Injury</td>
<td>12.6%</td>
<td>4.8</td>
</tr>
<tr>
<td>Shock/Resuscitation</td>
<td>12.0%</td>
<td>4.5</td>
</tr>
<tr>
<td>Long LOS (without clear diagnosis)</td>
<td>8.4%</td>
<td>3.2</td>
</tr>
</tbody>
</table>
Unexpected Newborn Complications: NQF Validation Studies: Anisha Abreo, MPH

• Face Validity:
  – In a comparison trial for neonatal morbidity by gestational age
    UNC tracked very closely to NPIC (major East Coast perinatal
    data set) analysis using NICU admissions and major
    complications

• Formal Reliability Testing
  – NQF requirement using RAND statistical tools
  – Tests ability to discriminate among hospitals (variation and
    frequency)
    – Good is 0.8, excellent is 0.9
    – Mean Reliability among 220 California hospitals =0.92

• Stability within a hospital over time
  – Tested for 3 6-month periods with minimal variation noted in
    >90% of California hospitals
Figure 3A: Neonatal Special Care, Ventilation and Combined Respiratory Morbidities (NPIC)
Odds Ratios by Gestational Age in Completed Weeks

Figure 3B: Neonatal Composite Morbidities (California)
Odds Ratios by Gestational Age in Completed Weeks
Unexpected Newborn Complications: NICU Levels

<table>
<thead>
<tr>
<th>Labels</th>
<th>Regional</th>
<th>Intermediate</th>
<th>Community</th>
<th>Basic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min</td>
<td>1.6%</td>
<td>0.9%</td>
<td>1.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Q1</td>
<td>2.7%</td>
<td>2.6%</td>
<td>2.0%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Median</td>
<td>3.8%</td>
<td>3.7%</td>
<td>2.7%</td>
<td>2.7%</td>
</tr>
<tr>
<td>Q3</td>
<td>5.9%</td>
<td>4.6%</td>
<td>4.4%</td>
<td>3.6%</td>
</tr>
<tr>
<td>Max</td>
<td>10.6%</td>
<td>8.2%</td>
<td>12.0%</td>
<td>7.5%</td>
</tr>
<tr>
<td>IQR</td>
<td>3.2%</td>
<td>2.0%</td>
<td>2.4%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Upper Outliers</td>
<td>0.0%</td>
<td>100.0%</td>
<td>300.0%</td>
<td>200.0%</td>
</tr>
<tr>
<td>Lower Outliers</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
NPIC UNC Results: Hospital Sub-groups

Graph 2: Comparative Unexpected Newborn Complication (UNC) Rates Summary by Subgroup

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Database Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>AO</td>
<td>4.3%</td>
</tr>
<tr>
<td>AR</td>
<td>4.3%</td>
</tr>
<tr>
<td>NL</td>
<td>3.1%</td>
</tr>
<tr>
<td>NS</td>
<td>2.9%</td>
</tr>
<tr>
<td>C</td>
<td>3.2%</td>
</tr>
<tr>
<td>G</td>
<td>4.5%</td>
</tr>
</tbody>
</table>

There are currently six subgroup categories:

- **AO**: Academic OB Level II and III
- **AR**: Academic Regional Perinatal Centers
- **NL**: Non-Academic Large (≥ 1,100 annual livebirths)
- **NS**: Non-Academic Small (< 1,100 annual livebirths)
- **C**: Council of Women’s and Infants’ Specialty Hospitals (CWISH)
- **G**: Georgia Regional Perinatal Centers
Unexpected Newborn Complications (Total)

Normal Term Births per Hospital
Does UNC Need Risk Adjustment?

- Differences between NICU levels could indicate a need
  - Case mix? More maternal disorders HTN, DM?
  - More aggressive treatments?

- Under active investigation

- At this point, we are recommending that comparisons be made between hospitals at the same level rather than compared to all
UNC: Effects of Race / Ethnicity

<table>
<thead>
<tr>
<th>Race</th>
<th>Rate</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Total Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic, Native Born</td>
<td>3.90%</td>
<td>3,865</td>
<td>99,210</td>
<td>116,855</td>
</tr>
<tr>
<td>Hispanic, Foreign Born</td>
<td>3.61%</td>
<td>3,534</td>
<td>98,003</td>
<td>114,771</td>
</tr>
<tr>
<td>Non-Hispanic White</td>
<td>4.19%</td>
<td>4,770</td>
<td>113,972</td>
<td>134,320</td>
</tr>
<tr>
<td>Non-Hispanic Black</td>
<td>4.49%</td>
<td>916</td>
<td>20,381</td>
<td>26,307</td>
</tr>
<tr>
<td>Asian / Pacific Islander</td>
<td>3.39%</td>
<td>2,210</td>
<td>65,161</td>
<td>76,701</td>
</tr>
<tr>
<td>Others</td>
<td>4.91%</td>
<td>516</td>
<td>10,500</td>
<td>26,825</td>
</tr>
<tr>
<td><strong>OVERALL</strong></td>
<td>3.88%</td>
<td>15,811</td>
<td>407,227</td>
<td>495,779</td>
</tr>
</tbody>
</table>

Race and ethnicity have only modest effects. Perhaps because of elimination of preexisting conditions?

All California Births: 2014 (CMQCC Maternal Data Center)
Individual Hospital Ratios of Black to White UNC Rates

California Hospitals with at least 100 Black term infants

Black Race may be a factor among individual hospitals.....

All California Births: 2014 (CMQCC Maternal Data Center)
Generally, 50-60% of UNC morbidities fall into the Severe category.
UNC By Subcategory ("Bucket")

- Neurologic or Birth Injury: 0.51% (Hospital Severe), 0.5% (Hospital Moderate), 0.75% (CA Statewide Severe), 0.75% (CA Statewide Moderate)
- Infection: 2.16% (Hospital Severe)
- Respiratory: 1.27% (Hospital Severe), 1.55% (CA Statewide Severe)
- Shock: 0% (Hospital Severe), 0.09% (Hospital Moderate), 0% (CA Statewide Severe)
- Transfer: 0.13% (Hospital Severe), 0.78% (CA Statewide Severe)
- Long LOS (No Jaundice or Social Issue): 0% (Hospital Severe), 0.13% (Hospital Moderate), 0.13% (CA Statewide Severe)

(CMQCC Maternal Data Center Screen Shot)
But can we do anything about it?

- 4 Case studies showing ability to improve care and reduce rates
UNC High Rate: Case Study 1

- High rate of Moderate Respiratory Comps
- Drill Down to individual cases
- High rate of CPAP use
- **Chart review:** staff were billing for CPAP when called to the delivery room and providing a few minutes of bag and mask resuscitation
UNC High Rate: Case Study 2

- High rate of Moderate Birth Injury Comps
- Drill Down to individual cases
- High rate of Fracture of Clavicle (1%)
- **Chart review:** Excess cases were localized to 2 obstetricians who had high rates of elective low-vacuum deliveries
UNC High Rate: Case Study 3

- High rate of Severe Infection Comps
- Drill Down to individual cases
- High rate of Septicemia
- **Chart review:** GBS infections in 37week births without knowledge of GBS status or chemoprophylaxis; no antibiotic treatment of maternal temps of 38.3C to 38.5C for several hours in labor
UNC High Rate: Case Study 4

• High rate of Severe Infection Comps
• Drill Down to individual cases
• High rate of Sepsis with treatment for 5 days
• **Chart review:** Sepsis was diagnosed by c-reactive protein (cultures were negative). Their sepsis protocol was leading to probable overtreatment compared to other nurseries. Changed protocol and case rate fell significantly.
In each pilot hospital, after successful intervention to reduce NTSV Cesarean births (down 15-22%), Unexpected Newborn Complications measure was either unchanged or reduced, reassuring the medical staff.
Lack of Relationship between UNC and NTSV CS Rate

How UNC Might be Used
This is All About Getting the Right Balance...

- Balancing Interests: Mother / Baby
- Balancing Focus: All Babies / Specific Group
- Balancing Definition: Narrow / Comprehensive
- Balancing Data Collection: Accuracy / Burden
- Balancing Coding: Over-coding / Under-coding
UNC Conclusions

- Reflects a patient/family viewpoint but also resonates with physicians
- More variation than expected
- More improvement opportunities than expected
- Sensitive to both obstetric practice and neonatal care
UNC Summary

- Validated term baby outcome measure
- Able to drill-down and examine reasons for higher levels / improvement opportunities
- May need to adjust for NICU level, but note large variation within levels
- Suitable to be used as a balancing measure for primary or NTSV Cesarean rate
Thank You

may you be in balance...

main@CMQCC.org