Neonatal Outcomes in Relation to Birth Location: Ethical Implications For Clinical Practice and Research

- Frank A. Chervenak, M.D.
- Laurence B. McCullough, Ph.D.
- Amos Grünebaum, M.D.
- Robert L. Brent, M.D., Ph.D.
- Malcolm I. Levine, M.D.
- Birgit Arabin, M.D.

Research Issues in the Assessment of Birth Settings
Institute of Medicine and National Research Council
Obstetric Ethics
An Essential Dimension of Planned Home Birth

Frank A. Chervenak, MD, Laurence B. McCullough, PhD, and Birgit Arabin, MD

Clinical Opinion
Planned home birth: the professional responsibility response

Frank A. Chervenak, MD; Laurence B. McCullough, PhD; Robert L. Brent, MD, PhD, DSc (Hon); Malcolm I. Levene, MD, FRCP, FRCPH, F Med Sc; Birgit Arabin, MD
• The public is insufficiently educated in the importance of maintaining vital data.
  – Nigel Paneth

• CDC data birth certificate data are important when considering US births.
  – Brady Hamilton
  – Marian MacDorman
Questions

• Are there differences between hospital and home births, using Apgar scores and seizures as prognostic data for future outcome?

• If there are differences between hospital and home births:
  – are they due to location or attendants?
  – what are their ethical implications for clinical practice and research?
Materials & Methods

- Birth certificate data on all US births from 2007-2010
- In the United States, state laws require birth certificates to be completed for all births and federal law mandates national collection and publication of births and other vital statistics data.
- The NVSS is the largest US Dataset on births
- The vital statistics website allows for the creation of tables and subsets of data based on over 112 variables per birth:
  1. **Demographic**: 26 variables
  2. **Infant Health**: 30 variables
  3. **Maternal Life Style and Health Characteristics**: 18 variables
  4. **Medical Services Utilization**: 38 variables
Materials & Methods

- All births between 2007-2010 (n=16,693,978)
- Term singleton births (≥37 weeks and ≥2,500 gram) (n=13,997,597)
- Home birth was defined when birth was in the “Residence”
- A subset of births in the residence were those delivered by a midwife
- Home midwife deliveries were evaluated between those done by certified nurse midwives (CNM) and “other” midwives
- 5-Minute Apgar scores and seizures were used to assess immediate newborn outcomes
### 2007-2010 Term Singleton (≥37 weeks & ≥2,500) Birth Data

<table>
<thead>
<tr>
<th>Place of Birth</th>
<th>Total=13,997,597</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospital Births</strong></td>
<td>13,839,450</td>
</tr>
<tr>
<td></td>
<td>(98.87%)</td>
</tr>
<tr>
<td><strong>Home Births</strong></td>
<td>103,791</td>
</tr>
<tr>
<td></td>
<td>(0.74%)</td>
</tr>
<tr>
<td><strong>Other Births</strong></td>
<td>54,356</td>
</tr>
<tr>
<td></td>
<td>(0.39%)</td>
</tr>
<tr>
<td><strong>Hospital Births by Midwife</strong></td>
<td>1,118,578</td>
</tr>
<tr>
<td></td>
<td>(8.0%)</td>
</tr>
<tr>
<td><strong>Home Births by Midwife (CNM + “Other” MW)</strong></td>
<td>67,429 (65.0%)</td>
</tr>
<tr>
<td><strong>Home Births by “Other” Midwife</strong></td>
<td>46,429 (44.7%)</td>
</tr>
<tr>
<td><strong>Home Births by CNM</strong></td>
<td>20,900 (20.1%)</td>
</tr>
<tr>
<td><strong>Home Births by a Physician</strong></td>
<td>4,250 (4.1%)</td>
</tr>
</tbody>
</table>
5-Minute Apgar = 0-6 (Per 10,000 Births)
Hospital, Midwife & Home Births

OR: 2.8
95% CI: 2.7-2.9
P<0.001

OR: 1.9
95% CI: 1.8-2.1
P<0.001
5-Minute Apgar = 4-6 (Per 10,000 Births)
Hospital, Midwife & Home Births

- Hospital: OR: 2.2, 95% CI: 2.1-2.4, P<0.001
- Home (All): OR: 2.0, 95% CI: 1.8-2.1, P<0.001
5-Minute Apgar = 0-3 (Per 10,000 Births)
Hospital, Midwife & Home Births

- Hospital: OR: 4.9, 95% CI: 4.6-5.2, P<0.001
- Home (All): OR: 33.6, 95% CI: 18.9-5.2, P<0.001
5-Minute Apgar = 0 (Per 10,000 Births)

Hospital, Midwife & Home Births

OR: 48.0
95% CI: 43.8-52.6
P<0.001

OR: 18.0
95% CI: 13.6-23.9
P<0.001
Low Apgar Scores
Term Births US Birth Certificate Data 2007-2010

Home Other MW: 0.67% (Apgar <4), 2.46% (Apgar 4-6), 3.13% total
Home CNM: 0.57% (Apgar <4), 1.21% (Apgar 4-6), 1.78% total
US Hospital: 0.20% (Apgar <4), 0.76% (Apgar 4-6), 0.96% total
Neonatal Seizures (Per 10,000 Births) All Births
Hospital, Midwife & Home Births

<table>
<thead>
<tr>
<th>Setting</th>
<th>OR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>2.20</td>
<td>3.0-5.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Home (All)</td>
<td>8.59</td>
<td>3.7-7.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hospital MW</td>
<td>1.63</td>
<td>3.7-7.5</td>
<td></td>
</tr>
<tr>
<td>Home MW</td>
<td>8.56</td>
<td>3.7-7.5</td>
<td></td>
</tr>
</tbody>
</table>
Seizures
US Midwife Deliveries: Hospital vs Home

Midwife Hospital Births

Midwife Hospital Births

Midwife Hospital Births

Midwife Hospital Births

93.58% 6.42%

1 in 15.8

1 in 3.9

All Midwife Births

Neonatal Seizures

1 in 15.8

1 in 3.9

26.42% 73.58%
Hospital vs Home Singleton Term Births (2007-2010)  
(n=14,152,576)

<table>
<thead>
<tr>
<th></th>
<th>Stillbirths</th>
<th>Apgar 0-3</th>
<th>Apgar 0-6</th>
<th>Seizures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital (All)</td>
<td>1 in 7,143</td>
<td>1 in 508</td>
<td>1 in 104</td>
<td>1 in 4,545</td>
</tr>
<tr>
<td>Home (All)</td>
<td>1 in 145</td>
<td>1 in 104</td>
<td>1 in 38</td>
<td>1 in 1,164</td>
</tr>
<tr>
<td>Hospital Midwife</td>
<td>1 in 12,500</td>
<td>1 in 565</td>
<td>1 in 109</td>
<td>1 in 6,235</td>
</tr>
<tr>
<td>Home Midwife</td>
<td>1 in 654</td>
<td>1 in 298</td>
<td>1 in 57</td>
<td>1 in 1,168</td>
</tr>
</tbody>
</table>
Neonatal Death Rates in Term Infants with Five-Minute Apgar Scores of 0 to 3, 4 to 6, and 7 to 10, According to Gestational Age.
Casey NEJM 2001
What Are The Implications Of A Low 5-Minute Apgar In A Term Birth?

- “For 132,228 infants born at term (37 weeks of gestation or later), the mortality rate was 244 per 1000 for infants with five-minute Apgar scores of 0 to 3, as compared with 0.2 per 1000 for infants with five-minute Apgar scores of 7 to 10.” Casey BM, et al. New Engl J Med 2001
- “A five-minute Apgar score <7 has a consistent association with prevalence of neurologic disability and with low cognitive function in early adulthood.” Ehrenstein V, et al. BMC Pregnancy Childbirth. 2009
- “The strong association of low Apgar scores with death and CP in this population with a low occurrence of low scores shows that the Apgar score remains important for the early identification of infants at increased risk for serious and fatal conditions.” Moster D, et al. J Pediatr 2001
- “A 5-min Apgar < 7 is associated with increased risk of neonatal respiratory distress, need for mechanical ventilatory support and NICU, and hypoxic-ischemic encephalopathy.” Salustiano EM, et al. Review Assoc Med Bras 2012
- “The association of Apgar score <7 at five minutes with increased risks of neurologic disability seems to persist many years postnatally.” Ehrenstein V, et al. Clin Epidemiol. 2009
- “In term infants, low Apgar scores were associated with a high risk for CP; OR 62 (95% CI 52-74) at score <=6 at 5 minutes.” Obstet Gynecol. 2006 Dec;108(6):1499-505. Thorngren-Jerneck, K et al
- “A low 5 min Apgar score was associated with a higher risk of childhood cancers diagnosed shortly after birth.” Li J, et al. BMJ Open. 2012
What are the implications of neonatal seizures in a term birth?

- “Neonatal seizures...were among the risk factors for cerebral palsy.” McIntyre S, et al. Dev Med Child Neurol 2012 Nov 26


Neonatal seizures ... were found to be important and independent predictors of development of epilepsy in patients with cerebral palsy. Mert GG. Et al. Pediatr Neurol. 2011 Aug;45(2):89-94.


CDC 2010 Birth Data
Risk Factors

- Home MW: 15.26%
- Hospital: 46.19%

Categories:
- Prior Preterm
- Tobacco
- Diabetes
- Prior Poor Outcome
- Hypertension
- Prior Cesarean
- Breech
- <11lb weight gain
Average 5-Minute Apgar Scores

- Hospital MD: 8.97
- Hospital CNM: 8.96
- Home Midwife: 9.29
Distribution of High 5-Minute Apgar: 9&10
NVSS Data 2007-2010

What would Virginia Apgar say?
Conclusions

2007-2010 NVSS Data

• Home births overall as well as home births by midwives had significantly more stillbirths, lower 5-Minute Apgar scores, and higher seizure rates (=hypoxic-ischemic encephalopathy HIE) when compared to hospital births.

• Differences are attributable to location (home births) and not the birth attendant.

• Hospital birth prevents the occurrence of stillbirths, low 5-Minute Apgar scores, and seizures/HIE compared to home births.

• These data understate the rate of low 5-Minute Apgar scores, stillbirths, and seizure rates/HIE among home births, because outcomes of patients with an intent of home birth that were transported from home to a hospital (with likely more adverse outcomes) are not included among home births but shifted to the hospital outcome data.
Clinical Ethics
Professional Responsibility

• Given the preventable adverse outcomes of planned home birth:
  – Physicians and other healthcare professionals should discourage planned home birth
  – There is no obligation to offer home birth

• Competent and compassionate care must be provided to women who are transferred to the hospital from an attempted home birth

• Hospitals and healthcare professionals should ensure the safety of hospital births and consider creating an alternative birthing environment in the hospital
It is impossible to bring the hospital to the home
It is possible to bring the home to the hospital

"G-d give us the strength to change the things we can, the serenity to accept the things we cannot, and the wisdom to know the difference
Table 1  Timeline of implementation of patient safety changes.

<table>
<thead>
<tr>
<th>Year of implementation</th>
<th>Patient safety items</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>Consultant review</td>
</tr>
<tr>
<td>2003</td>
<td>Labor and delivery team training</td>
</tr>
<tr>
<td>2003</td>
<td>Electronic intrapartum medical records</td>
</tr>
<tr>
<td>2003</td>
<td>Chain of communication protocol</td>
</tr>
<tr>
<td>2004</td>
<td>Dedicated gynecology attending</td>
</tr>
<tr>
<td>2005</td>
<td>Limitation of misoprostol to non-viable fetus</td>
</tr>
<tr>
<td>2005</td>
<td>Standardized oxytocin protocol</td>
</tr>
<tr>
<td>2005</td>
<td>Premixed and safety color-coded magnesium sulfate and oxytocin solution</td>
</tr>
<tr>
<td>2005</td>
<td>Electronic templates for shoulder dystocia and operative deliveries</td>
</tr>
<tr>
<td>2005</td>
<td>Early identification of potential obstetric professional liability cases</td>
</tr>
<tr>
<td>2005</td>
<td>Obstetric patient safety nurse</td>
</tr>
<tr>
<td>2006</td>
<td>Electronic labor and delivery whiteboard to simplify sign out</td>
</tr>
<tr>
<td>2006</td>
<td>Physician assistants added to labor and delivery staff</td>
</tr>
<tr>
<td>2006</td>
<td>Electronic fetal monitoring interpretation certification</td>
</tr>
<tr>
<td>2006</td>
<td>Electronic antepartum medical records</td>
</tr>
<tr>
<td>2006</td>
<td>Routine thromboprophylaxis for all cesarean deliveries</td>
</tr>
<tr>
<td>2006</td>
<td>Obstetric emergency drills</td>
</tr>
<tr>
<td>2007</td>
<td>Recruitment of laborist</td>
</tr>
<tr>
<td>2009</td>
<td>Oxytocin initiation checklist</td>
</tr>
<tr>
<td>2009</td>
<td>Postpartum hemorrhage kit</td>
</tr>
<tr>
<td>2009</td>
<td>Internet-based reading assignment and testing</td>
</tr>
<tr>
<td>2009</td>
<td>Elimination of scheduled labor induction below 39 weeks without medical indications</td>
</tr>
</tbody>
</table>
PATIENT SAFETY SERIES

Effect of a comprehensive obstetric patient safety program on compensation payments and sentinel events

Amos Grunebaum, MD; Frank Chervenak, MD; Daniel Skupski, MD

FIGURE 3
Sentinel events by year (per 1000 deliveries)

PATIENT SAFETY SERIES

Effect of a comprehensive obstetric patient safety program on compensation payments and sentinel events

Amos Grunebaum, MD; Frank Chervenak, MD; Daniel Skupski, MD

**Figure 2**
Compensation payments by year

Reduction of cesarean delivery rates after implementation of a comprehensive patient safety program

Amos Grunebaum*, Joachim Dudenhauen, Frank A. Chervenak and Daniel Skupski

Department of Obstetrics and Gynecology, New York Weill Medical College of Cornell University, New York, NY, USA

In 2003, we started to implement a stepwise comprehensive patient safety program (Table 1) which included a uniform oxytocin policy (begun in 2005) and other changes, and which in due course showed an eventual decrease in compensation payments [12].
The safest form of home birth is a hospital-based home birth

- Women may opt for home birth if over-medicalization and unjustified interventions continue
- Hospitals should create an alternative birthing environment:
  - “Home-like” setting
  - Continuity of care
  - Empathy
  - Professional skills
  - Continuous compassionate support
- Obstetricians should be trained in and consistently demonstrate professional and humanistic skills
- Obstetricians should learn to avoid unnecessary interventions
Planned Home Birth and the Ethical Obligations of Obstetricians/Midwives: Informed Consent

• Increased risk of stillbirths and seizures/HIE
• Length of time it takes to transport to the hospital
• Limitations of staffing during emergencies such as shoulder dystocia, fetal distress, neonatal respiratory issues
Research Ethics

- Given the preventable increased risks of planned home birth and its unacceptable risk/benefit ratio for fetal and neonatal patients, required human subjects protection cannot be achieved.
- Therefore, randomized controlled trials to compare outcomes between planned home births and hospital births are ethically impermissible.
Obstetric Ethics

An Essential Dimension of Planned Home Birth

Frank A. Chervenak, MD, Laurence B. McCullough, PhD, and Birgit Arabin, MD
Neonatal Outcomes in Relation to Birth Location: Ethical Implications For Clinical Practice and Research

- Frank A. Chervenak, M.D.
- Laurence B. McCullough, Ph.D.
- Amos Grünebaum, M.D.
- Robert L. Brent, M.D., Ph.D.
- Malcolm I. Levine, M.D.
- Birgit Arabin, M.D.

Research Issues in the Assessment of Birth Settings
Institute of Medicine and National Research Council