Healthy Babies are Worth the Wait: Reducing Elective Induction before 39 weeks

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Disclosure Statement

- I have no conflict of interest or other disclosures
Learning Objectives

- Review the four new definitions of “term” delivery and the impact on neonatal outcomes
- Describe evidence-based benefits of delaying elective induction until 39 weeks
- List challenges to delaying elective inductions
- Describe evidence-based practices that address these challenges and ensure compliance

Definition of “Term” Pregnancy

- Prior to 2004 the definition of term pregnancy was based on WHO ICD-10 Classification of Disease as between 37 and 42 weeks.
  - Little consideration was given for any neonatal outcomes over this broad period of gestation which would further classify “term” pregnancy
  - This data was solely based on the distribution of deliveries on a spontaneous laboring group of low risk women
Deliveries by Gestation Age

Figure 1: Percent of Births by Gestational Age at Birth
Minnesota, 1994 and 2004

- 1994
- 2004

86%

Changes in Gestational Age at Delivery

US Trends in Cesarean Section and Induction: 1992 and 2002

Source: NCHS, Final Natality Data, Prepared by March of Dimes Perinatal Data Center, April 2006.

Distribution of Deliveries by Type

Neonatal Outcomes Associated with Late-Preterm Birth

- RDS
- TTN
- Pulmonary infection
- Unspecified respiratory failure
- Recurrent apnea
- Temperature instability
- Jaundice that delays discharge
- Bilirubin induced brain injury
- Hypoglycemia
- Rehospitalization for any cause
- Rehospitalization for neonatal dehydration
- Death
- Feeding difficulties
- Long term behavioral problems

Pediatrics, September 2006;118:1207
Mortality Rates Associated with Late-Preterm and Early-Term Deliveries

<table>
<thead>
<tr>
<th>Gestational Age</th>
<th>Neonatal Mortality Rate</th>
<th>Relative Risk (95%CI)</th>
<th>Infant Mortality Rate</th>
<th>Relative Risk (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>34</td>
<td>7.1/1000</td>
<td>9.5 (8.4-110.8)</td>
<td>11.8/1000</td>
<td>5.4 (4.9-5.9)</td>
</tr>
<tr>
<td>35</td>
<td>4.8/1000</td>
<td>6.4 (5.6-7.2)</td>
<td>8.6/1000</td>
<td>3.9 (3.6-4.3)</td>
</tr>
<tr>
<td>36</td>
<td>2.8/1000</td>
<td>3.7 (3.3-4.2)</td>
<td>5.7/1000</td>
<td>2.6 (2.4-2.8)</td>
</tr>
<tr>
<td>37</td>
<td>1.7/1000</td>
<td>2.3 (2.1-2.6)</td>
<td>4.1/1000</td>
<td>1.9 (1.8-2.0)</td>
</tr>
<tr>
<td>38</td>
<td>1.0/1000</td>
<td>1.4 (1.3-1.5)</td>
<td>2.7/1000</td>
<td>1.2 (1.2-1.3)</td>
</tr>
<tr>
<td>39</td>
<td>0.8/1000</td>
<td>1.00</td>
<td>2.2</td>
<td>1.00</td>
</tr>
<tr>
<td>40</td>
<td>0.8/1000</td>
<td>1.0 (0.9-1.1)</td>
<td>2.1</td>
<td>0.9 (0.9-1.0)</td>
</tr>
</tbody>
</table>

Benefits to Delaying Delivery to 39 weeks

- Fewer admission to NICU for respiratory complications – RDS, Apnea, TTN, Infection
- Reduced rate of early neonatal jaundice
- Reduced perinatal mortality
- Improved breastfeeding and maternal bonding
- Reduced incidence of long-term behavior problems
- Reduced re-hospitalization rates for all causes

Definition of Term Delivery

- Early term: 37 0/7 weeks through 38 6/7 weeks
- Full term: 39 0/7 weeks through 40 6/7 weeks
- Late term: 41 0/7 weeks through 41 6/7 weeks
- Post term: 42 0/7 weeks and beyond

Hierarchical Criteria to Establish Gestational Age

Historical Reasons for Early Elective Delivery and Challenges to Change

- **Early Elective Delivery**
  - Allows for timing of delivery by patients
  - Allows providers to arrange their delivery schedules
  - Allows patient to choose their delivering provider
  - Averts fears and anxiety of patients about uncertainty of delivery timing
  - Perception that bad outcomes after 37 weeks are rare and can be managed effectively with little morbidity
- Each of these is a potential source for reluctance of patients and providers to adopt a culture change that eliminates early elective delivery
Medical Indications for Late-Preterm or Early-Term Delivery

- Hypertensive disorders of pregnancy
- Oligohydramnios
- Prior classical cesarean or myomectomy
- Placenta previa and/or accreta
- Multiple Gestations
- Fetal growth restriction
- Pregestational diabetes with vascular disease
- Pregestational diabetes or gestational diabetes with poor control
- Placental abruption
- Chorioamnionitis
- Premature rupture of membranes
- Cholestasis of pregnancy
- Alloimmunization or pregnancy with known or suspected fetal effects
- Fetal congenital anomalies
- Certain maternal medical disorders with maternal risk for continued gestation

ACOG Committee Opinion, Number 561, April 2013

Timing of Elective Cesarean Delivery at Term and Neonatal Outcomes

- Cohort study of 24,077 repeat cesarean sections at term, 13,258 electively delivered and studied
  - Composite neonatal outcomes measured
    - Death, adverse respiratory outcome, hypoglycemia, sepsis, seizures, NEC, HIE, CPR, ventilation > 24 hrs, UAR pH < 7.0, 5-min Apgar < 3, admission to NICU, and hospital stay > 5 days

NICHD MFM Units Networks, NEJM; 360:111-120
Effect of Delay of Delivery to 39 weeks

- A delay of delivery from 37 to 39 weeks would reduce composite adverse neonatal outcomes by 48%
- A delay of delivery from 38 to 39 weeks would reduce composite adverse neonatal outcomes by 27%
- All outcomes including respiratory are significantly reduced by delaying delivery

Conclusions

- Elective repeat cesarean delivery is common before 39 weeks
- Decisions are driven by patient request and provider convenience
- Early deliveries are associated with preventable increased neonatal morbidity and health care costs
- Delaying elective cesarean delivery to 39 weeks is highly recommended
Neonatal Outcomes After Demonstrated Fetal Lung maturity Before 39 Weeks of Gestation

- Can you eliminate early term delivery adverse outcomes with demonstration of lung maturity?

- Retrospective cohort study of delivery at 36 0/7 to 38 6/7 weeks after FLM compared to 39 0/7 to 40 6/7 without FLM
  - 459 infants in study group
  - 13,339 in comparison group
  - Composite adverse outcomes measured


Comparison of Adverse Neonatal Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Adjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite Adverse Outcome</td>
<td>1.7 (1.1-2.6)</td>
</tr>
<tr>
<td>RDS</td>
<td>7.6 (2.2 – 26.6)</td>
</tr>
<tr>
<td>Respiratory Support</td>
<td>2.0 (1.1 – 3.6)</td>
</tr>
<tr>
<td>Surfactant Use</td>
<td>6.5 (1.04 – 41)</td>
</tr>
<tr>
<td>Ventilator Support</td>
<td>2.1 (0.6 – 8.0) NS</td>
</tr>
<tr>
<td>Sepsis</td>
<td>1.7 (1.1 – 2.7)</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>5.8 (2.4 – 14.3)</td>
</tr>
<tr>
<td>Treated Hyperbilirubinemia</td>
<td>11.2 (2.6 – 34)</td>
</tr>
<tr>
<td>Admission to NICU</td>
<td>1.7 (1.1 – 2.7)</td>
</tr>
<tr>
<td>Hospitalized &gt; 4 days</td>
<td>2.6 (1.8 – 3.9)</td>
</tr>
</tbody>
</table>
Conclusions

- Despite amniocentesis with documented fetal lung maturity, elective delivery before 39 weeks results in increased adverse neonatal outcomes including respiratory outcomes.
- Elective delivery before 39 weeks regardless of documented fetal lung maturity should be avoided.

Strategies to Reduce the Early Elective Delivery Rate

- Hospital/System Policy and Guidelines
  - Zero Birth Injury at Fairview Systems
  - Magee-Women’s Hospital at the University of Pittsburgh
  - Inter Mountain Health
- National Endorsement by Societies
  - American College of Obstetrics and Gynecology
  - American Academy of Pediatrics
  - March of Dimes Birth Defects Foundation
  - National Institute of Health and Human Development
- Legislative Mandate
  - Minnesota Statute
  - Washington State Statute
- National and State Collaboratives
  - Ohio Perinatal Quality Collaborative and Writing Committee
  - Premier Perinatal Safety Initiative
  - Minnesota Hospital Association – Road Map to a Perinatal Safety Program
Zero Birth Injury Initiative – Fairview System

- **Participating Sites**
  - Fairview Northland
  - Fairview Lakes
  - Fairview Southdale
  - Fairview Ridges *
  - University of Minnesota Medical Center – Fairview *
  - Red Wing Hospital – Fairview

* Indicated participation in the Premier Perinatal Safety Initiative (PPSI) as part of 18 sites nationally

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**Background: Zero Birth Injury Initiative**

- In 2008, Fairview Health System (FHS) initiated the Zero Birth Injury Initiative (ZBI):
  - Broad scope
    - Maternal-Fetal Medicine
    - Obstetricians
    - Family Practice
    - Neonatologists
    - Certified Nurse Midwives
    - Advanced Practice Nurses
  - Full support of Administration

- **Purpose**
  - Improve Perinatal (maternal and neonatal) process and clinical outcomes
  - Implement evidence-based education, guidelines and order sets
  - Reduce and ultimately eliminate preventable birth injuries
Zero Birth Injury Initiative – Fairview System

- **Methods to Reduce Early Elective Deliveries to Zero**
  - Adoption of the Institute for Health Care Improvement (IHI) Elective Induction Bundle
  - Established a Induction Plan document that supported the criteria for Medical and Elective Induction at all sites
  - Established a “soft stop” and then a hard stop for inappropriate inductions
  - Educated patients, nurse, and providers on the benefits of delivery at >39 week if no medical indication for delivery
  - Adopted a peer review process for non-compliance with the guidelines of the initiative
  - Regularly communicated progress toward zero early elective deliveries to all stakeholders
IHI Elective Induction Bundle

- A bundle is a group of evidence-based interventions related to a disease or care process that, when executed together, result in better outcomes than when implemented individually.
- All components of the bundle must be met to achieve the desired better outcome.

- Elective Induction Bundle
  - Gestational Age > 39 weeks
  - Reassuring Fetal Status
  - Pelvic Exam prior to the start of Oxytocin
  - Recognition and management of Hyperstimulation
Indication for induction
Criteria for estimate of Gestational age
Patient information and consent

Elective Induction Bundle Compliance

Compliance by Parameter
Q1 2011 to Q4 2012

- Gestational Age greater than or equal to 39 weeks or If < 39 Weeks, medical indication noted
- Reassuring fetal status (prior to beginning the induction) check if documented by nso or med
- Pelvic examination documented – check if documented by nsg or med
- Tachypnoe – check if present and if present, is managed according to algorithm
- Bundle Achievement
Zero Birth Injury Elective Induction

Implement policies and processes designed to minimize non-medically necessary inductions before 39 weeks gestation.

Hospitals must have a hard-stop policy in place restricting inductions before 39 weeks, which applies to all births.

A policy that encourages providers to document final estimated date of delivery by 20 weeks gestation (including data from ultrasound measurement as applicable). This final estimated due date must be shared with the patient.

A policy that encourages patient education regarding elective inductions and requires documentation of the education patients receive. Report induction of labor data for all births covered by Minnesota Health Care Programs.

Hospitals need to submit the policy to the Department of Human Services for verification. If the hospital does not have a policy in place, or the policy has not been verified, delivering providers must include a form with each delivery claim when the delivery.

Minnesota Statute 256B.0625 subdivision 3g, Evidence-based Childbirth Program – 6/1/12
Early Elective Delivery Rate - Minnesota

Rate of Early Elective Deliveries among Minnesota HEN hospitals
69 (80%) of 86 hospitals reporting 88% decrease
(Q4 2010 - Q2 2013)

Quarter
(n = number of hospitals reporting)

Early Elective Deliveries in Minnesota

Number of Early Elective Deliveries (EED) in Minnesota birthing hospitals

Quarter
(n = number of hospitals reporting)
The Ohio Perinatal Quality Collaborative

- **Study objectives**
  - Reduce scheduled births between 36 0/7 – 38 6/7 weeks that lack an appropriate medical indication
- **Twenty Ohio maternity hospital participated**
  - Collected baseline data for 60 days
  - Instituted Institute for Healthcare Improvement Breakthrough Series Interventions - Bundles
  - Collected data for a 14 month intervention period


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The Ohio Perinatal Quality Collaborative

- **Methods**
  - Each site selected interventions appropriate for that site
    - Promotion of optimal determination of gestational age
    - Use of ACOG criteria for induction and timing of delivery
    - Increased awareness among pregnant women, nurse, and providers of the risks and benefits of birth at 36-38 weeks
    - Improved communication between obstetricians and pediatricians
    - Including scheduled deliveries within the culture of safety work
  - Each site reported their data throughout the period of the intervention and sites were compared for effectiveness in reductions in scheduled births without medical or obstetrical indication.
A retrospective study was designed to examine the effectiveness of 3 strategies to reduce early elective delivery at 27 participating hospitals.

- **Group 1** – Hard stop policy enforced by staff at time of scheduling deliveries
- **Group 2** – A “soft stop” policy that allowed scheduling by provider but incorporated local peer review with consequences for non-compliance
- **Group 3** – An “education only” approach including literature and recommendations by local and national authorities (This was also included in Group 1 and Group 2 above)

Comparative Effectiveness of Three Approaches to Reduce Early Elective Delivery

The overall reduction in early elective delivery was from 9.6% to 4.3%
There was no increase in stillbirth rate
There was a 16% decrease in NICU admissions
The greatest decline in early elective delivery occurred using a HARD STOP approach
Summary

- Infant Perinatal Outcomes are improved by eliminating early elective delivery before 39 weeks
- Adherence to national guidelines and evidence-based strategies for eliminating early elective deliveries is possible everywhere
- Barriers to implementation non-compliance can be eliminated through multiple strategies including legislative mandate, Hard Stop, and peer review

References

- ACOG Committee Opinion #579, Definition of Term Pregnancy, November 2013
- ACOG Committee Opinion #561, Nonmedically Indicated Early-Term Deliveries, April 2013
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