Elimination of Non-medically Indicated (Elective) Deliveries Before 39 Weeks Gestational Age

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www.CMQCC.org
www.prematurityprevention.org
Quality Improvement Tools

Funding

- Federal Title V block grant from the California Department of Public Health; Maternal, Child and Adolescent Health Division
- California Maternal Quality Care Collaborative
- March of Dimes
Objectives

1) Describe the increase in non-medically indicated (elective) deliveries before 39 weeks and identify the contributing factors.

2) Identify the risks of early term deliveries and the benefits of delaying delivery beyond 39 weeks gestation.

3) List and describe successful initiatives to reduce elective deliveries before 39 weeks at hospital, health system and statewide levels.

4) Describe a sample implementation plan for the prevention of elective deliveries before 39 weeks.

Key Points

1) Research has shown that early elective delivery without medical or obstetrical indication is linked to neonatal morbidities with no benefit to the mother or infant.

2) There are numerous maternal and fetal indications for deliveries PRIOR to 39 weeks gestation

3) In addition… this toolkit… is not meant to imply that elective deliveries AFTER 39 weeks have been proven to be without risks for mothers and infants.
**Terminology**

First day of LMP

- **Late Preterm**: 20 0/7
- **Early Term**: 34 0/7
- **Term**: 39 0/7
- **Early Term**: 37 0/7
- **Preterm**: 20 0/7
- **Post term**: 41 6/7

The "New" Term

Modified from Drawing courtesy of William Engle, MD, Indiana University

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**Rates of Induction of Labor by Race and Hispanic Origin**

Scheduled Delivery <39 wks in an Uncomplicated Pregnancy

- Since 1979, ACOG has cautioned against inductions before 39 weeks in the absence of a medical indication (Committee Opinion #22).
- ACOG has also noted that “a mature fetal lung maturity test result before 39 weeks of gestation, in the absence of appropriate clinical circumstances, is not an indication for delivery”. (Committee Practice Bulletins #97 and #107)

U.S. Cesarean Section and Labor Induction Rates

Source: NCHS, Final Natality Data, Prepared by March of Dimes Perinatal Data Center, April 2006.
Change in Distribution of Births by Gestational Age: United States, 1990-2006

Why are non-medically indicated (elective/planned) deliveries increasing in frequency?

Sounds like a good idea…

- Advanced planning
- Convenience
- Delivered by her doctor
- Maternal intolerance to late pregnancy
  - Excess edema, backache, indigestion, insomnia
- Prior bad pregnancy
- And, it’s okay right?


The Gestational Age that Women Considered it “Safe to Deliver”

<table>
<thead>
<tr>
<th>Weeks of Gestation</th>
<th>Women’s Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>34</td>
<td>13.7%</td>
</tr>
<tr>
<td>35</td>
<td>7.2%</td>
</tr>
<tr>
<td>36</td>
<td>30.8%</td>
</tr>
<tr>
<td>37</td>
<td>21.5%</td>
</tr>
<tr>
<td>38</td>
<td>19.2%</td>
</tr>
<tr>
<td>39</td>
<td>3.4%</td>
</tr>
<tr>
<td>40</td>
<td>4.2%</td>
</tr>
</tbody>
</table>

Obstet Gynecol 2009;114:1254
Lots of Pressures on Obstetricians

- Physician Convenience
  - Guarantee attendance at birth ("co-dependency")
  - Avoid scheduling conflicts
  - Reduce being woken at night
- ...what’s the harm?
  - Bad outcomes are unrecognized and rare
  - The NICU handles these issues just fine
- Limit my risk of a bad pregnancy outcome
- And…payment pressures to deliver own pts


“Non-Medical” Reasons* for Inductions <39 weeks

- Maternal intolerance to late pregnancy
  - Excess edema, backache, indigestion, insomnia
- Prior labor complication
- Prior shoulder dystocia
- Suspected fetal macrosomia
- History of rapid labor/lives far away
- Possible lower risk for mom or baby
  - Lower stillbirth rate, less macrosomia, less preeclampsia

* Not evidenced-based to show maternal or neonatal benefit
Risks of Non-medically Indicated (Elective) Delivery Before 39 weeks.

Complications of Non-medically Indicated (Elective) Deliveries Between 37 and 39 Weeks

- Increased NICU admissions
- Increased transient tachypnea of the newborn (TTN)
- Increased respiratory distress syndrome (RDS)
- Increased ventilator support
- Increased suspected or proven sepsis
- Increased newborn feeding problems and other transition issues

See Toolkit for more data and full list of citations
Timing of Elective Repeat Cesarean Delivery at Term and Neonatal Outcomes

- 13,258 elective repeat cesarean births in 19 large centers
- 35.8% done <39 weeks gestation
- Increased risk of neonatal morbidity
  - Respiratory, hypoglycemia, sepsis, NICU admissions, hospitalization > 5 days
  - Even among babies delivered between 38 and 39 weeks

Tita AT, et al, NEJM 2009;360:111

Adverse Neonatal Outcomes According to Completed Week of Gestation at Delivery: Absolute Risk

Tita AT, et al, NEJM 2009;360:111
Neonatal outcomes at 37 and 38 weeks are very similar (or worse) than those at 41 and 42 weeks...

Best outcomes are at 39 and 40 weeks!
NICU Admissions By Weeks Gestation
Deliveries Without Complications, 2000-2003

RDS By Weeks Gestation
Deliveries Without Complications, 2000-2003

Ventilator Usage By Weeks Gestation Deliveries Without Complications, 2000-2003

Timing of Fetal Brain Development

- Cortex volume increases by 50% between 34 and 40 weeks gestation. (Adams Chapman, 2008)
- Brain volume increases at rate of 15 mL/week between 29 and 41 weeks gestation.
- A 5-fold increase in myelinated white matter occurs between 35-41 wks gestation.
- Frontal lobes are the last to develop, therefore the most vulnerable.

Mean IQ Scores in 6 yo Children from Healthy Term Pregnancies

13,824 healthy term infants followed for an average of 6.5 years. IQ scores adjusted for multiple factors including: sex, birthweight for gestational age, maternal height and age at birth, smoking and drinking during pregnancy, parental marital status, number of children in the household, parental education and occupation.


Cerebral Palsy among Term and Postterm Births

Norwegian birth cohort of 1,682,441 singleton term births without congenital anomalies followed for a minimum of 4 years (maximum of 20 years) with identified CP in the National Health Insurance Registry.

Moster et al. JAMA 2010;304:976-982.
Caveats on CNS Outcomes…

- Best outcomes are at 40 weeks.
- Note that these studies are associations and cannot show NOT causation.
- Nonetheless, the onus is on us to show that earlier birth is better…

Examples of Successful Programs to Reduce Non-medically Indicated (Elective) Deliveries Before 39 weeks of Gestation

- Magee Women’s Hospital (Pittsburgh)
- Intermountain Healthcare (Utah)
- Hospital Corporation of America (HCA)
- Ohio State Department of Health
Magee-Women’s Hospital’s Experience

- Magee-Womens Hospital is the largest maternity hospital in Western Pennsylvania, performing more than 9,300 deliveries in 2007.
- A rise in the use of induction, reaching a high of 28% in 2003, L&D too busy!
- In 2006, a process improvement initiative changed the induction scheduling process and strictly enforced the guidelines.
- “Elective”: not before 39 weeks and without cervical ripening agents if 39+0 to 40+6).

Fisch et al Obstet Gynecol 2009;113:797

Magee Women’s Experience with Guidelines

<table>
<thead>
<tr>
<th></th>
<th>Baseline 3mos 2004</th>
<th>Voluntary 3mos 2005</th>
<th>Enforced 14mos 2006-7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deliveries</td>
<td>2,139</td>
<td>2,260</td>
<td>10,895</td>
</tr>
<tr>
<td>Elective Inductions &lt;39wks (N)</td>
<td>23</td>
<td>21</td>
<td>30</td>
</tr>
<tr>
<td>Elective Inductions &lt;39wks (rate)</td>
<td>11.8%</td>
<td>10.0%</td>
<td>4.3% (p&lt;0.001)</td>
</tr>
<tr>
<td>Total Induction Rate</td>
<td>24.9%</td>
<td>20.1%</td>
<td>16.6%</td>
</tr>
</tbody>
</table>

“Voluntary”: educational program and dept. recommendations  
“Enforced”: Department standard requiring approval by the Perinatal Committee Chair before scheduling non-standard indications for inductions

Fisch et al Obstet Gynecol 2009;113:797
Magee Women’s Experience

“The importance of strong physician and nursing leadership cannot be overstated. The change in the induction scheduling process that began to enforce the guidelines strictly in late 2006 was spearheaded by the OB Process Improvement Committee, whose members included the hospital’s Vice President for Medical Affairs, the Medical Director of the Birth Center, and the nursing leadership for the Birth Center.”

Fisch et al Obstet Gynecol 2009;113:797

Intermountain Healthcare’s Experience

- Intermountain Healthcare is a vertically integrated healthcare system that operates 21 hospitals in Utah and Southeast Idaho and delivers approximately 30,000 babies annually.
- Computerized L&D system.
- MFM hired by system, but OBs are independent.
- January 2001: 9 urban facilities participated in a process improvement program for elective deliveries.
- 28% of elective deliveries were occurring before 39 completed weeks of gestation.

% Non-medically Indicated Deliveries <39 Weeks, January 1999 – December 2005

Stillbirths Before and After Implementation of Guidelines at Intermountain Healthcare


<table>
<thead>
<tr>
<th>Weeks of Gestation</th>
<th>Stillbirths</th>
<th>Deliveries</th>
<th>%</th>
<th>Stillbirths</th>
<th>Deliveries</th>
<th>%</th>
<th>Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>37</td>
<td>17</td>
<td>4,117</td>
<td>0.41</td>
<td>22</td>
<td>13,077</td>
<td>0.17</td>
<td>0.406</td>
<td>0.22–0.77</td>
</tr>
<tr>
<td>38</td>
<td>19</td>
<td>9,954</td>
<td>0.19</td>
<td>21</td>
<td>28,209</td>
<td>0.07</td>
<td>0.390</td>
<td>0.21–0.72</td>
</tr>
<tr>
<td>39</td>
<td>10</td>
<td>13,732</td>
<td>0.07</td>
<td>28</td>
<td>51,721</td>
<td>0.05</td>
<td>0.744</td>
<td>0.36–1.53</td>
</tr>
<tr>
<td>40</td>
<td>10</td>
<td>7,925</td>
<td>0.13</td>
<td>14</td>
<td>24,140</td>
<td>0.06</td>
<td>0.459</td>
<td>0.20–1.03</td>
</tr>
<tr>
<td>41</td>
<td>2</td>
<td>1,938</td>
<td>0.10</td>
<td>3</td>
<td>5,571</td>
<td>0.05</td>
<td>0.522</td>
<td>0.09–3.12</td>
</tr>
<tr>
<td>All</td>
<td>58</td>
<td>37,086</td>
<td>0.13</td>
<td>88</td>
<td>12,2718</td>
<td>0.07</td>
<td>0.406</td>
<td>0.35–0.65</td>
</tr>
</tbody>
</table>

HCA Study

- HCA: Largest healthcare system in the US with approx 220,000 births annually.
- Cohort study of 27 pilot hospitals in 2007-2009
- Self-selected to either:
  - Group 3—"Education only", provision of literature and ACOG recommendations
  - Group 2—Education and "Soft stop", compliance left to individual physicians, cases reviewed in peer review sessions
  - Group 1—Education and "Hard stop", <39 wk elective procedures are not scheduled unless department criteria are met, exceptions thru chain of command
- Careful distinction among “planned” deliveries between “indicated” and “elective” deliveries

Neonatal Outcomes for HCA Trial

- Stillbirth Rate unchanged:
  - 2007: 0.69%
  - 2009: 0.71%
  - Not significant
- Term NICU Admissions:
  - 2007: 8.9%
  - 2009: 7.5% (decreased 16%)
  - $P<0.001$ $RR=0.85$

Common Themes

- All started with education provided to obstetricians regarding ACOG guidelines and best practices.
- Modest change at most, until physicians were held accountable, nurses were empowered, and guidelines were enforced (“Hard stop”).
- Medical leadership important.
Eliminating Non-medically Indicated (Elective) Delivery Prior to 39 Weeks in “Our Hospital”:

What are the steps to make this happen?

- **Clinician and/or Patient Desire to Schedule a Non-medically Indicated (Elective) Induction or Cesarean Section**
  - Clinician, Staff & Patient Education
  - Elective Delivery Hospital Policy
  - Physician Leadership
    - A. Enforce policy
    - B. Approve exceptions
- **Reduce Demand**
- **Induction / Cesarean Scheduling Process**
- **Case NOT Scheduled if Criteria Not Met**
- **Public Awareness Campaign**
- **QI Data Collection & Trend Charts**
Support for this Initiative comes from across the board

- ACOG strong support
- National Quality Organizations
  - Joint Commission, Leapfrog, NQF measures
- March of Dimes
- Many state collaboratives in California
- State Medicaid programs are exploring options
  - “Do not pay”, withholds, incentives, pre-auths
  - Commercial Insurance has acted in other states

A tool to educate patients

If your pregnancy is healthy, it’s best if your baby is born at 40 weeks.

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ifmarchofdimes.com
First Steps (Fundamentals)

- Gather baseline data of <39wk scheduled deliveries and outcomes
- Implement list of “approved” indications
  - Have departmental criteria for making certain diagnoses (e.g. hypertensive complications of pregnancy)
  - Identify strong medical leadership to handle “appeals” for exceptions
  - This list DOES NOT imply that all folks with these diagnoses SHOULD be delivered before 39 weeks
- Implement criteria for establishing gestational age >39 weeks

How Do You Measure Elective Deliveries <39 weeks?
(The Joint Commission Measure Definition)

<table>
<thead>
<tr>
<th>TJC (PC-01) v2011A (latest for 2011)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Denominator</strong></td>
</tr>
<tr>
<td>37+0 to 38+6 week births without a STANDARD medical or OB complication</td>
</tr>
<tr>
<td><strong>Numerator</strong></td>
</tr>
<tr>
<td>Inductions and CS NOT in Active Labor or with ROM</td>
</tr>
<tr>
<td><strong>Benchmark</strong></td>
</tr>
<tr>
<td>?? &lt;5-6%</td>
</tr>
</tbody>
</table>

https://manual.jointcommission.org/bin/view/Manual/WebHome
Caveats about the Indication List

- The Joint Commission list was developed for ease of data collection utilizing ICD-9 codes.
- If there is not an ICD-9 code for an indication, they did not list it (e.g. prior classical CS).
- Everyone understands that there are cases in which earlier delivery is indicated and but the indication is NOT on the list—but these should be uncommon.
- No one is expecting a ZERO rate.
- Off-list indications should be prospectively scrutinized.
Confirmation of Term Gestation

- Ultrasound measurement at less than 20 weeks of gestation supports gestational age of 39 weeks or greater (confirming LMP)
  - Ultrasound-established dates should only take precedence over LMP-established dates when the discrepancy is greater than 7 days in the first trimester and 10 days in the second trimester

Number 101, February 2009
ACOG/AAP: Guidelines for Perinatal Care, 7th Ed. 2011 (in press)

What about “late to care” patients?

- Late to Care (after 20 weeks):
  - And dates only by Ultrasound after 20 wks
  - Recommend FLM before scheduled elective procedure
  - For repeat CS in uncomplicated pregnancy would need to have discussion of risks/benefits
- In one prior low transverse CS patients, little harm to await labor before the CS…
Implementation Discussion
FAQ’s / Common Barriers

- Physician Autonomy— “I’m a Board Certified OB/GYN, I can do what I want”…
- Scheduling problems— “I have to get it done at 39+0 and all the slots are filled”
- Patient preference— “But she really wants me to deliver her and I will be away…”
- What difference does a day or two make? (i.e., is 38+6 really bad?)
- Need to have rules for EDC, (what to do with multiple US EDCs, when to adjust, etc)

Physician “Autonomy” in OB

- Protocols and strong guidelines are used extensively in Internal Medicine and Surgery
  - Door-to-cath times, use of ASA and B-blockers
  - Pre-operative antibiotics and VTE prevention
  - Stroke: very strict protocols
  - Publicly reported, payment-based standards
- OB has been “below the radar” because this movement has been driven by Medicare (which does not pay for OB)—but now it has taken up by commercial insurers and Medicaid
- MediCal will adopt OB Quality Measures this year
Implementation Discussion

FAQ’s / Common Barriers

- Physician Autonomy— “I’m a Board Certified OB/GYN, I can do what I want”…
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- What difference does a day or two make? (i.e., is 38+6 really bad?)
- Need to have rules for EDC, (what to do with multiple US EDCs, when to adjust, etc)

What about 38 weeks + 4 to 6 days?

- Tita (NEJM 2009;360:111) (MFM Network)
  - Examined 2,463 scheduled CS babies in this age range
  - Respiratory outcomes worse than 39 weeks (RR=1.21 95% CI 1.04-1.4, p=0.01), similar to 38 weeks as a whole

- Wilminik (AJOG 2010;202:250.e1-8) (Netherlands)
  - Examined 5,046 scheduled CS babies in this age range
  - Respiratory outcomes worse than 39 weeks (RR=1.4 95% CI 1.1-1.8, p=0.01), similar to 38 weeks as a whole
Implementation Discussion
FAQ’s / Common Barriers

- Physician Autonomy—“I’m a Board Certified OB/GYN, I can do what I want”…
- Scheduling problems—“I have to get it done at 39+0 and all the slots are filled”
- Patient preference—“But she really wants me to deliver her and I will be away…”
- What difference does a day or two make? (i.e., is 38+6 really bad?)
- Why not do an amniocentesis for lung maturity studies?

Fetal lung maturity testing before 39 weeks and neonatal outcomes

<table>
<thead>
<tr>
<th>Adverse neonatal outcome</th>
<th>&lt;39 weeks + FLM % (n=442)</th>
<th>39-40 weeks % (n=12881)</th>
<th>Unadjusted RR (95% CI)</th>
<th>Adjusted† RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite adverse outcome</td>
<td>5.9</td>
<td>2.5</td>
<td>2.4 (1.6, 3.5)</td>
<td>1.6 (1.02, 2.6)</td>
</tr>
<tr>
<td>Composite adverse outcome II</td>
<td>5.0</td>
<td>2.0</td>
<td>2.5 (1.8, 3.8)</td>
<td>1.7 (1.01, 2.7)</td>
</tr>
<tr>
<td>Suspected or proven sepsis</td>
<td>5.7</td>
<td>2.2</td>
<td>2.6 (1.7, 3.8)</td>
<td>1.7 (1.1, 2.8)</td>
</tr>
<tr>
<td>Respiratory support</td>
<td>2.9</td>
<td>1.0</td>
<td>2.8 (1.6, 5.0)</td>
<td>1.8 (0.96, 3.5)</td>
</tr>
<tr>
<td>RDS</td>
<td>1.4</td>
<td>0.04</td>
<td>35.0 (11, 114)</td>
<td>7.9 (2.0, 31)</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>2.0</td>
<td>0.14</td>
<td>15.0 (7.0, 32)</td>
<td>6.7 (2.5, 17.6)</td>
</tr>
<tr>
<td>NICU admission</td>
<td>5.9</td>
<td>2.3</td>
<td>2.5 (1.7, 3.7)</td>
<td>1.7 (1.05, 2.7)</td>
</tr>
<tr>
<td>Hospitalization &gt;4 days</td>
<td>10.8</td>
<td>3.3</td>
<td>3.3 (2.4, 4.4)</td>
<td>2.6 (1.8, 3.9)</td>
</tr>
</tbody>
</table>

*Excludes suspected sepsis; †Adjusted for maternal age, race, parity, medical complications (hypertensive disorder or diabetes) and baby gender.

Conclusion: Gestational age and Fetal Lung Maturity (FLM) tests are related but independent predictors of fetal maturity.

Elective delivery with known fetal lung maturity prior to 39 wks is still associated with increased neonatal morbidity

<table>
<thead>
<tr>
<th>Neonatal Outcome</th>
<th>Mature Amnio (36+0 to 38+6)</th>
<th>Control (Inductions &gt;39)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>1,081</td>
<td>9,068</td>
<td></td>
</tr>
<tr>
<td>NICU Admit (%)</td>
<td>9.6</td>
<td>3.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>NICU LOS-days</td>
<td>4.24</td>
<td>4.26</td>
<td>NS</td>
</tr>
<tr>
<td>Total Resp Morbidity (%)</td>
<td>7.3</td>
<td>1.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>RDS (%)</td>
<td>0.7</td>
<td>0.02</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>TTN (%)</td>
<td>4.3</td>
<td>1.2</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Other Resp Morbidity (%)</td>
<td>3.0</td>
<td>0.6</td>
<td>0.5</td>
</tr>
<tr>
<td>Ventilator (%)</td>
<td>1.1</td>
<td>0.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sepsis (%)</td>
<td>0.2</td>
<td>0.02</td>
<td>NS</td>
</tr>
<tr>
<td>Hypoglycemia (%)</td>
<td>2.3</td>
<td>0.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Neonatal Deaths (%)</td>
<td>0</td>
<td>0.01</td>
<td>NS</td>
</tr>
</tbody>
</table>

2011 SMFM Abstracts #58

What about FLM for Elective Delivery <39wks?

- Summary of recent studies:
  - Show serious morbidity with babies born before 39 weeks even with “mature” FLM studies
  - This should not be a surprise as much of the near-term morbidity is not related to surfactant deficiency

**ACOG:** “A mature fetal maturity test result before 39 weeks of gestation, in the absence of appropriate clinical circumstances is not an indication for delivery.”

Summary:
Reasons to Eliminate Non-Medically Indicated (Elective) Deliveries Before 39 Weeks

- Reduction of neonatal complications
- No harm to mother if no medical or obstetrical indication for delivery
- Strong support from ACOG
- Now a national quality measure for hospital performance:
  - National Quality Forum (NQF)
  - Leapfrog Group
  - The Joint Commission (TJC)

QUESTIONS?