EARLY TERM BIRTHS: IMPLEMENTING CHANGE

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Associate Professor – Pediatrics
University of Louisville
Objectives

1. Building the case

2. Understanding QI and the March of Dimes Toolkit

3. Leading Transformation Efforts
BUILDING THE CASE
“We will not achieve even close to the level of quality and safety we need [in the U.S.] as long as we have individual practitioners and hospitals doing individual things.”

Lucian Leape, MD, Adjunct Professor of Health Policy
Harvard School of Public Health
Changing Gestation of Spontaneous Birth

Davidoff, et al. Semin Perinatol, 2006
Definitions

• Preterm – Less than 37 weeks
  • Late Preterm – 34 – 36 6/7

• Term – 37 – 41 6/7
  • Early Term – 37 – 38 6/7
  • Full Term – 39 0 41 6/7

• Post-term – 42 weeks and beyond

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>(Percent)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>37-38 weeks</td>
<td>27.59</td>
<td>27.85</td>
<td>28.60</td>
<td>28.29</td>
<td>28.29</td>
<td>24.50</td>
<td>19.66</td>
</tr>
<tr>
<td>39 weeks</td>
<td>27.47</td>
<td>26.62</td>
<td>25.85</td>
<td>25.54</td>
<td>25.25</td>
<td>24.32</td>
<td>21.72</td>
</tr>
<tr>
<td>40-41 weeks</td>
<td>27.22</td>
<td>27.52</td>
<td>27.24</td>
<td>27.30</td>
<td>27.90</td>
<td>32.26</td>
<td>36.68</td>
</tr>
</tbody>
</table>


Martin, et al. NSVR, 2011
A reduction in the number of non-medically indicated elective deliveries at $\geq 37$ to $<39$ weeks gestation will decrease neonatal morbidity and mortality, as well as reduce costs.

The rate of cesarean sections should decrease with fewer elective inductions, resulting in decreased LOS and costs.

The measure will assist health care organizations (HCOs) to track non-medically indicated early term elective deliveries and reduce the occurrence.
Neonatal and maternal outcomes associated with elective term delivery

Clark SL; Miller DD; Belfort MA; Dildy GA; Frye DK; Meyers JA


Decreasing Elective Deliveries Before 39 Weeks of Gestation in an Integrated Health Care System

Fig. 1. Rate of neonatal intensive care unit admissions for normal pregnancies by gestational age. Two standard deviations shown by vertical lines. Data from Intermountain Healthcare. Oshiro. Decreasing Elective Deliveries Before 39 Weeks. Obstet Gynecol 2009.

Decreasing Elective Deliveries Before 39 Weeks of Gestation in an Integrated Health Care System.
Oshiro, Bryan; Henry, Erick; Wilson, Janie; Branch, D; Varner, Michael

Obstetrics & Gynecology. 113(4):804-811, April 2009. DOI: 10.1097/AOG.0b013e31819b5c8c
Neonatal and maternal outcomes associated with elective term delivery

Clark SL; Miller DD; Belfort MA; Dildy GA; Frye DK; Meyers JA


### TABLE

Elective delivery and neonatal outcome

<table>
<thead>
<tr>
<th>Variable</th>
<th>37 wk</th>
<th>38 wk</th>
<th>39+ wk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective inductions</td>
<td>112</td>
<td>678</td>
<td>2004</td>
</tr>
<tr>
<td>NICU admissions</td>
<td>17</td>
<td>44</td>
<td>61</td>
</tr>
<tr>
<td>%</td>
<td>15.2 (P = .003)</td>
<td>7.0 (P &lt; .001)</td>
<td>6.0</td>
</tr>
<tr>
<td>Elective repeat cesarean</td>
<td>105</td>
<td>696</td>
<td>776</td>
</tr>
<tr>
<td>NICU admissions</td>
<td>21</td>
<td>58</td>
<td>62</td>
</tr>
<tr>
<td>%</td>
<td>20.0 (P &lt; .001)</td>
<td>8.3 (P = NS)</td>
<td>8.0</td>
</tr>
<tr>
<td>Elective primary cesareans</td>
<td>24</td>
<td>97</td>
<td>153</td>
</tr>
<tr>
<td>NICU admissions</td>
<td>5</td>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td>%</td>
<td>20.8 (P = NS)*</td>
<td>18.5 (P = NS)*</td>
<td>7.8</td>
</tr>
<tr>
<td>Total elective deliveries</td>
<td>241</td>
<td>1471</td>
<td>2933</td>
</tr>
<tr>
<td>NICU admissions</td>
<td>43</td>
<td>118</td>
<td>135</td>
</tr>
<tr>
<td>%</td>
<td>17.8 (P &lt; .001)</td>
<td>8.0 (P &lt; .001)</td>
<td>4.6</td>
</tr>
</tbody>
</table>

NICU, neonatal intensive care unit; NS, nonsignificant.

Statistical analysis represents a comparison of each gestational age to the subsequent gestational age category.

*For 37 + 0 wk elective primary cesarean vs 39 + 0 wk elective primary cesarean, P = .027.

Late Preterm Infants, Early Term Infants, and Timing of Elective Deliveries

Table 6 -- Respiratory distress syndrome in late preterm and term infants

<table>
<thead>
<tr>
<th>Gestational age (weeks)</th>
<th>Incidence of respiratory distress syndrome (per 1000 infants)</th>
<th>Relative rate compared with following gestation</th>
</tr>
</thead>
<tbody>
<tr>
<td>34</td>
<td>30</td>
<td>2.1</td>
</tr>
<tr>
<td>35</td>
<td>14</td>
<td>2.0</td>
</tr>
<tr>
<td>36</td>
<td>7.1</td>
<td>3.9</td>
</tr>
<tr>
<td>37</td>
<td>1.8</td>
<td>3.0</td>
</tr>
<tr>
<td>38</td>
<td>0.6</td>
<td>7.5</td>
</tr>
<tr>
<td>39–41</td>
<td>0.08</td>
<td>Reference</td>
</tr>
</tbody>
</table>

Data from Madar J, Richmond S, Hey E. Surfactant-deficient respiratory distress after elective delivery at ‘term.’ Acta Paediatr 1999;88:1245

Timing of Elective Repeat Cesarean Delivery at Term and Neonatal Outcomes

Timing of elective repeat cesarean delivery at term and neonatal outcomes. Tita AT; Landon MB; Spong CY; Lai Y; Leveno KJ; Varner MW; Moawad AH; Caritis SN; Meis PJ; Wapner RJ; Sorokin Y; Miodovnik M; Carpenter M; Peaceman AM; OSullivan MJ; Sibai BM; Langer O; Thorp JM; Ramin SM; Mercer BM; Eunice Kennedy Shriver NICHD Maternal-Fetal Medicine Units Network


Figure 2. Timing of Elective Repeat Cesarean Delivery and the Incidence of the Primary Outcome According to the Number of Completed Weeks of Gestation.
# Timing of Elective Repeat Cesarean Delivery at Term and Neonatal Outcomes

## Table 2. Incidence of Adverse Neonatal Outcomes According to Completed Week of Gestation at Delivery.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Any adverse outcome or death</td>
<td>128/834 (15.3)</td>
<td>430/3909 (11.0)</td>
<td>524/6512 (8.0)</td>
<td>101/1385 (7.3)</td>
<td>57/505 (11.3)</td>
<td>22/113 (19.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Adverse respiratory outcome</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory distress syndrome</td>
<td>31/833 (3.7)</td>
<td>75/3904 (1.9)</td>
<td>58/6510 (0.9)</td>
<td>11/1381 (0.9)</td>
<td>4/504 (0.8)</td>
<td>2/113 (1.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Respiratory distress syndrome or transient tachypnea of the newborn</td>
<td>40/833 (4.8)</td>
<td>153/3904 (3.9)</td>
<td>178/6508 (2.7)</td>
<td>34/1381 (2.5)</td>
<td>24/504 (4.8)</td>
<td>7/113 (6.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Respiratory distress syndrome or transient tachypnea of the newborn</td>
<td>68/833 (8.2)</td>
<td>213/3904 (5.5)</td>
<td>222/6510 (3.4)</td>
<td>42/1381 (3.0)</td>
<td>26/504 (5.2)</td>
<td>9/113 (8.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Admission to the NICU</td>
<td>107/833 (12.8)</td>
<td>316/3905 (8.1)</td>
<td>382/6510 (5.9)</td>
<td>66/1381 (4.8)</td>
<td>40/504 (7.9)</td>
<td>16/113 (14.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Newborn sepsis:</td>
<td>58/833 (7.0)</td>
<td>156/3904 (4.0)</td>
<td>161/6508 (2.5)</td>
<td>37/1381 (2.7)</td>
<td>19/504 (3.8)</td>
<td>12/113 (10.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Proven case</td>
<td>3/833 (0.4)</td>
<td>3/3904 (0.1)</td>
<td>7/6508 (0.1)</td>
<td>2/1381 (0.1)</td>
<td>2/504 (0.4)</td>
<td>0/113 (0.2)</td>
<td>0.260</td>
</tr>
<tr>
<td>Treated hypoglycemia</td>
<td>20/833 (2.4)</td>
<td>35/3904 (0.9)</td>
<td>44/6508 (0.7)</td>
<td>11/1381 (0.8)</td>
<td>8/504 (1.6)</td>
<td>2/113 (1.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CPR or ventilation in 1st 24 hr</td>
<td>16/833 (1.9)</td>
<td>35/3904 (0.9)</td>
<td>27/6509 (0.4)</td>
<td>5/1381 (0.4)</td>
<td>2/504 (0.4)</td>
<td>0/113 (0.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ventilation in 1st 24 hr</td>
<td>16/833 (1.9)</td>
<td>34/3904 (0.9)</td>
<td>27/6509 (0.4)</td>
<td>5/1381 (0.4)</td>
<td>2/504 (0.4)</td>
<td>0/113 (0.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hospitalization ≥ 5 days</td>
<td>76/831 (9.1)</td>
<td>221/3904 (5.7)</td>
<td>237/6503 (3.6)</td>
<td>56/1381 (4.1)</td>
<td>38/504 (7.5)</td>
<td>13/113 (11.5)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* CPR denotes cardiopulmonary resuscitation, and NICU neonatal intensive care unit.
† The P value was calculated by the Cochran–Armitage test for trend for the period from 37 to 39 weeks only.
‡ Newborn sepsis includes both suspected infections (with clinical findings suggesting infection) and proved infections (as confirmed in a subgroup of neonates with positive cultures of blood, cerebrospinal fluid, or urine obtained by catheterization or suprapubic aspiration; cardiovascular collapse; or an unequivocal radiograph confirming infection in a neonate with clinical sepsis).
Timing of Elective Repeat Cesarean Delivery at Term and Neonatal Outcomes

Table 3. Odds Ratios for Adverse Neonatal Outcomes According to Completed Week of Gestation at Delivery.*

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Wk 37</th>
<th>Wk 38</th>
<th>Wk 39</th>
<th>Wk 40</th>
<th>Wk 41</th>
<th>Wk ≥42</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any adverse outcome or death</td>
<td>2.1 (1.7–2.5)</td>
<td>1.5 (1.3–1.7)</td>
<td>Reference</td>
<td>0.9 (0.7–1.1)</td>
<td>1.4 (1.0–1.8)</td>
<td>2.5 (1.5–4.0)</td>
</tr>
<tr>
<td>Adverse respiratory outcome</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory distress syndrome</td>
<td>4.2 (2.7–6.6)</td>
<td>2.1 (1.5–2.9)</td>
<td>Reference</td>
<td>1.1 (0.6–2.0)</td>
<td>1.0 (0.4–2.8)</td>
<td>2.3 (0.6–9.7)</td>
</tr>
<tr>
<td>Transient tachypnea of the newborn</td>
<td>1.8 (1.2–2.5)</td>
<td>1.5 (1.2–1.9)</td>
<td>Reference</td>
<td>0.9 (0.6–1.3)</td>
<td>1.7 (1.1–2.7)</td>
<td>2.2 (1.0–4.8)</td>
</tr>
<tr>
<td>Respiratory distress syndrome or transient</td>
<td>2.5 (1.9–3.3)</td>
<td>1.7 (1.4–2.1)</td>
<td>Reference</td>
<td>0.9 (0.6–1.2)</td>
<td>1.5 (1.0–2.4)</td>
<td>2.4 (1.2–4.9)</td>
</tr>
<tr>
<td>tachypnea of the newborn</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admission to the NICU</td>
<td>2.3 (1.9–3.0)</td>
<td>1.5 (1.3–1.7)</td>
<td>Reference</td>
<td>0.8 (0.6–1.0)</td>
<td>1.3 (0.9–1.9)</td>
<td>2.5 (1.5–4.4)</td>
</tr>
<tr>
<td>Newborn sepsis‡</td>
<td>2.9 (2.1–4.0)</td>
<td>1.7 (1.4–2.2)</td>
<td>Reference</td>
<td>1.0 (0.7–1.5)</td>
<td>1.4 (0.8–2.2)</td>
<td>4.1 (2.2–7.6)</td>
</tr>
<tr>
<td>Treated hypoglycemia</td>
<td>3.3 (1.9–5.7)</td>
<td>1.3 (0.8–2.0)</td>
<td>Reference</td>
<td>1.2 (0.6–2.4)</td>
<td>2.6 (1.2–5.7)</td>
<td>2.8 (0.7–11.7)</td>
</tr>
<tr>
<td>Hospitalization ≥5 days</td>
<td>2.7 (2.0–3.5)</td>
<td>1.8 (1.5–2.2)</td>
<td>Reference</td>
<td>1.0 (0.8–1.4)</td>
<td>1.9 (1.3–2.7)</td>
<td>2.9 (1.6–5.3)</td>
</tr>
</tbody>
</table>

* NICU denotes neonatal intensive care unit.
† All outcomes are adjusted for maternal age (as a continuous variable), race or ethnic group, number of previous cesarean deliveries, marital status, payer, smoking status, and presence or absence of diet-controlled gestational diabetes mellitus.
‡ Newborn sepsis included both suspected infections (with clinical findings suggesting infection) and proved infections (as confirmed in a subgroup of neonates with positive cultures of blood, cerebrospinal fluid, or urine obtained by catheterization or suprapubic aspiration; cardiovascular collapse; or an unequivocal radiograph confirming infection in a neonate with clinical sepsis).
Adverse Outcomes
Variations in Mortality and Morbidity by Gestational Age among Infants Born at Term

Table II. Adjusted odds ratios for infant mortality by gestational age in completed weeks

<table>
<thead>
<tr>
<th>Gestational age</th>
<th>Neonatal death</th>
<th>Postneonatal death*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rate per 1000</td>
<td>Adjusted OR (95% CI)</td>
</tr>
<tr>
<td>37 weeks</td>
<td>0.66</td>
<td>1.8 (1.6-2.0)</td>
</tr>
<tr>
<td>38 weeks</td>
<td>0.42</td>
<td>1.2 (1.1-1.3)</td>
</tr>
<tr>
<td>39 weeks</td>
<td>0.33</td>
<td>0.9 (0.9-1.0)</td>
</tr>
<tr>
<td>40 weeks</td>
<td>0.34</td>
<td>reference</td>
</tr>
<tr>
<td>41 weeks</td>
<td>0.40</td>
<td>1.1 (1.0-1.3)</td>
</tr>
</tbody>
</table>

ORs were estimated from multiple logistic regression models adjusted for sex, parity, maternal age, education, marital status, smoking, diabetes, chronic hypertension, gestational hypertension (including preeclampsia), eclampsia, mode of delivery, induction, and birth weight for gestational age z-score.

*On the basis of infants who survived the neonatal period.
Timing of elective repeat cesarean delivery: a cost analysis

TABLE 2
Mean costs/charges by adverse outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean cost* (US dollars)</th>
<th>Increased cost over referent</th>
<th>Mean chargesa (US dollars)</th>
<th>Increased charge over referent</th>
</tr>
</thead>
<tbody>
<tr>
<td>No adverse event</td>
<td>41,442 (800-1400)</td>
<td>Referent</td>
<td>3435</td>
<td>Referent</td>
</tr>
<tr>
<td>Respiratory distress syndrome</td>
<td>58,731 (5500-25,000)</td>
<td>41-fold</td>
<td>158,732</td>
<td>46-fold</td>
</tr>
<tr>
<td>Transient tachypnea of newborn</td>
<td>6918 (2200-7400)</td>
<td>5-fold</td>
<td>18,206</td>
<td>5-fold</td>
</tr>
<tr>
<td>Admission to NICU</td>
<td>24,391 (5700-12,000)</td>
<td>17-fold</td>
<td>35,368</td>
<td>10-fold</td>
</tr>
<tr>
<td>Newborn sepsis (proven cases)</td>
<td>219,386 (NA)</td>
<td>152-fold</td>
<td>535,089</td>
<td>156-fold</td>
</tr>
<tr>
<td>Treated hypoglycemia</td>
<td>24,221 (1500-10,000)</td>
<td>17-fold</td>
<td>63,741</td>
<td>19-fold</td>
</tr>
<tr>
<td>Ventilation required in first 24 h</td>
<td>130,905 (35,000-50,000)</td>
<td>91-fold</td>
<td>385,014</td>
<td>112-fold</td>
</tr>
<tr>
<td>Hospital length of stay &gt; 5 d</td>
<td>23,433</td>
<td>16-fold</td>
<td>55,794</td>
<td>16-fold</td>
</tr>
</tbody>
</table>

* Costs and charges in US dollars over referent.

There were only 4 cases of confirmed sepsis in 2007 Florida Healthcare Cost and Utilization Project State Inpatient Database. All costs/charges adjusted for inflation to 2009 US dollars according to 2007-2009 Hospital Related Services Consumer Price Index reported as mean (G1-G3).

NA: not applicable; NICU: Neonatal Intensive Care Unit.


TABLE 2 Mean costs/charges by adverse outcomes

Timing of elective repeat cesarean delivery: a cost analysis

<table>
<thead>
<tr>
<th>Adverse outcome</th>
<th>37 wk of completed gestation</th>
<th>38 wk of completed gestation</th>
<th>39 wk of completed gestation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cost (per 100 neonates)</td>
<td>Charge (per 100 neonates)</td>
<td>Cost (per 100 neonates)</td>
</tr>
<tr>
<td>Respiratory distress syndrome</td>
<td>$356,209</td>
<td>$918,141</td>
<td>$253,089</td>
</tr>
<tr>
<td>Transient tachypnea of newborn</td>
<td>$170,524</td>
<td>$414,443</td>
<td>$165,596</td>
</tr>
<tr>
<td>Admission to NICU</td>
<td>$437,988</td>
<td>$752,275</td>
<td>$330,128</td>
</tr>
<tr>
<td>Newborn sepsis (proved cases)</td>
<td>$231,418</td>
<td>$556,204</td>
<td>$166,035</td>
</tr>
<tr>
<td>Treated hypoglycemia</td>
<td>$198,910</td>
<td>$488,275</td>
<td>$164,742</td>
</tr>
<tr>
<td>Ventilation required in first 24 h</td>
<td>$390,220</td>
<td>$1,068,542</td>
<td>$260,757</td>
</tr>
<tr>
<td>Hospital stay &gt;5 d</td>
<td>$344,357</td>
<td>$820,010</td>
<td>$269,588</td>
</tr>
</tbody>
</table>

TABLE 3  Costs/charges by adverse outcome incidence.

Timing of elective repeat cesarean delivery at term and neonatal outcomes: a cost analysis.
Robinson CJ; Villers MS; Johnson DD; Simpson KN
American Journal of Obstetrics & Gynecology.
Timing of elective repeat cesarean delivery: a cost analysis

<table>
<thead>
<tr>
<th>Variable</th>
<th>Savings for 100 neonates delivered at 39 wk rather than 37 wk</th>
<th>Savings for 100 neonates delivered at 39 wk rather than 38 wk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse event</td>
<td>Cost savings Referent</td>
<td>Charge savings Referent</td>
</tr>
<tr>
<td>Respiratory distress syndrome</td>
<td>$160,408</td>
<td>$434,831</td>
</tr>
<tr>
<td>Transient tachypnea of newborn</td>
<td>$11,499</td>
<td>$31,019</td>
</tr>
<tr>
<td>Admission to NICU</td>
<td>$158,348</td>
<td>$220,332</td>
</tr>
<tr>
<td>Newborn sepsis (proved cases)</td>
<td>$65,383</td>
<td>$159,496</td>
</tr>
<tr>
<td>Treated hypoglycemia</td>
<td>$38,724</td>
<td>$102,519</td>
</tr>
<tr>
<td>Ventilation required in first 24 h</td>
<td>$194,194</td>
<td>$572,368</td>
</tr>
<tr>
<td>Hospital length of stay &gt;5 d</td>
<td>$120,949</td>
<td>$287,975</td>
</tr>
</tbody>
</table>

Note: NICU, neonatal intensive care unit. All costs/charges adjusted for inflation to 2000 US dollars according to 2007-2009 Hospital Related Services Consumer Price Index.

Inductions

KY Cabinet for Health & Family Services, 2012
Cesarean Sections

KY Cabinet for Health & Family Services, 2012
Cost - Neonatal
Advisory Committee on Infant Mortality
If elective cesarean or labor induction is considered before 39 weeks' gestation, the ACOG recommend fetal pulmonary maturity confirmation, a surrogate for physiologic maturation. If fetal pulmonary maturity is not proved, however, it may be inferred from any of the following criteria:

- FHT have been documented for 20 wks by non-electronic fetoscope or for 30 wks by Doppler.
- It has been 36 wks since a positive serum or urine HCG pregnancy test result by a reliable laboratory.
- US measurement of the crown-rump length at 6 to 11 wks of gestation supports a gestational age >= 39 wks.
- US measurements at 12 to 20 weeks of gestation support a clinically determined gestational age of 39 weeks or greater.
Approach – Clinical Effectiveness

- “Hard stop”
  - Adoption of a policy
  - Policy enforcement
- “Soft stop”
  - Adoption of a policy
  - Peer review committee
- “Education only”

Ohio PQC

↑ (arrow indicates OPQC startup)

Arrow indicates OPQC startup; dotted line indicates aggregate rate of participants; _____ line indicates the mean rate; - - - - - line indicates control limits of the rate.


A statewide initiative to reduce inappropriate scheduled births at 36(0/7)-38(6/7) weeks' gestation. Donovan EF; Lannon C; Bailit J; Rose B; Iams JD; Byczkowski T; Ohio Perinatal Quality Collaborative Writing Committee

Fig. 3. Percent of elective deliveries before 39 weeks of gestation. Data from Intermountain Healthcare. Oshiro. Decreasing Elective Deliveries Before 39 Weeks. Obstet Gynecol 2009.
Approach – Clinical Effectiveness

Reduction in elective delivery at <39 weeks of gestation: comparative effectiveness of 3 approaches to change and the impact on neonatal intensive care admission and stillbirth.
Clark SL; Frye DR; Meyers JA; Belfort MA; Dildy GA; Kofford S; Englebright J; Perlin JA

Approach – Clinical Effectiveness

500,000 NICU Days

$1,000,000,000 per year

ELIMINATION OF NON-MEDICALLY INDICATED (ELECTIVE) DELIVERIES BEFORE 39 WEEKS GESTATIONAL AGE

A MARCH OF DIMES TOOLKIT
Clinician or Patient Desire to Schedule an Elective Induction or Cesarean Section

Clinician, Staff and Patient Education

Public Awareness Campaign

Reduce Demand

Elective Delivery Hospital Policy

Induction or C-section Scheduling Process

QI data collection and Trend Charts

Physician Leadership
A. Enforce Policy
B. Approve Exceptions

Case NOT scheduled if criteria not met
Reduce the Demand

Clinician/Staff Education
• Provide clinicians with data about their patients’ complications
• Emphasize avoiding elective deliveries <39 weeks.

Patient Education
• Provide women with educational materials that define “full term” and emphasize the importance of full 39 weeks of gestation
• Have structured informed consent discussion that outlines risk of non-medically indicated elective deliveries prior to 39 weeks gestation.

Public Awareness Campaign
• Support clinician efforts to educate women and their families through public awareness campaigns, e.g., health fairs and multimedia social marketing.
Key Change Tactics

Elective Delivery Hospital Policy

- Policy and procedure guides scheduling and oversight to eliminate elective deliveries <39 weeks.
  - Establish standards that follow ACOG and national quality criteria.
  - Establish policies for approving appropriate exceptions to standards that are guided by strong physician leadership.
  - Establish policies that provide clear direction to nursing staff and clerks for scheduling process.
Key Change Tactics

Induction/Cesarean Scheduling Process

• Create and use standard forms for scheduling that collect gestational age and indication for delivery
  • Both pieces of information determine whether the requested interventions are defined as medically indicated.
• Refer all exceptions to physician leadership per hospital policy.

Physician Leadership

• Policy establishes “medical ownership”
• Department quality committee chairs or other identified leaders approve all exceptions to the elective delivery policy.
QI Data Collection & Trend Charts

Targeted QI Data Collection

- Select QI data measures that track the amount of improvements made to both processes and outcomes
  - These measures guide the QI implementation process.
- Collect data using a Scheduling Form, the Data Collection Form, log books, fetal monitor system reports or electronic medical records.

Trend Charts

- Create charts to display desired QI data measures
- Display and discuss charts with clinicians and staff.
Tools of the Trade

- Flow Charts or Diagrams
- Cause-and-Effect Diagrams
- Check Sheets
- Histograms
- Pareto Diagrams or Charts
- Run Charts
- Control Charts
Request to schedule an induction or C-section

- EDD Verified
- ≥39 Wks?

Indicated?

- Patient is tentatively scheduled
- Prenatal forms faxed
- Final schedule pending updated prenatal records

For pts w/ unconfirmed dates and w/o medical/obstetrical indication:
- Patient not scheduled and allowed to go into labor
  - OR
- If EGA > 39 wks, pt is tentatively scheduled for C-section pending results of lung maturity amniocentesis
- Prenatal forms faxed
- Final scheduling contingent upon updated prenatal records and verification of lung maturity

Do not schedule. Refer to Charge RN to clarify clinical question or Medical Director if needed
## Affinity Diagram

<table>
<thead>
<tr>
<th>PEOPLE</th>
<th>PROCESS</th>
<th>EQUIP</th>
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Fishbone Diagrams
Data related challenges identified at LS2

Challenges related to mom being at an outlying hospital (15)
Inadequate number of data collectors (13)

Barriers to Human Milk Usage

- Lack of RN: 38, 23%
- Inadequate Lactation: 21, 36%
- Inadequate amount: 20, 48%
- Challenges related to: 15, 58%
- Inadequate number: 13, 48%
- Maternal feelings: 10, 66%
- Maternal illness and: 9, 72%
- Slow initiation of: 9, 77%
- Restrictive NICU: 6, 83%
- A need for MD/RN: 6, 87%
- Lack of:...
- Decreased maternal:...
- Neonate too unstable:...
Run charts

- Shows process changes over time.
- UCL = Upper Control Limit
- LCL = Lower Control Limit
- This process is in control
  - Within control limits
  - Randomly distributed above and below the mean.
Ohio Birth Certificate Data
Scheduled Inductions at 36° - 38° Weeks’ Without Documented Indication
January 2006 – November 2009

% without a listed indication

Ohio BC tracks scheduled inductions Not C - Sections

Baseline Jan 2006 → Aug 2008 / Project Begun 9-1-08
Rapid Cycle QI Methodology: MAP-IT

Step 1 - Mobilize QI Team
Step 2 - Assess the Situation
Step 3 - Plan Change Tactics
Step 4 - Implement
Step 5 - Track Progress
Implementation Checklist

Mobilize a QI Team

• Recruit QI champions.
  • Ideal: Labor & delivery (L&D) manager and/or perinatal QI nurse AND OB/GYN chair
• Schedule QI champions’ meeting: Date: Time:
  • Review toolkit to eliminate elective deliveries <39 weeks gestation.
  • Discuss preliminary hospital data as outlined in Step 2.
  • Identify QI team members to recruit.
• Recruit QI team to support the QI champions; team members commit to regular meetings until goals are accomplished.
Implementation Checklist

Mobilize a QI Team

• State goals clearly; start a MAP-IT Worksheet
  • Suggested language: “By _____ (choose a realistic date) all inductions of labor and scheduled cesarean deliveries before 39 weeks performed at _____ (name of hospital) will have a medical or obstetric indication ____”

• Schedule first QI team meeting to review <39 week toolkit, assess the situation (Step 2), perform baseline assessment, develop implementation plan of action with timeline and benchmark(s).
Assess the Situation

- Review ACOG’s indications for induction of labor and dating criteria.
- Collect data: Data collection over time will provide the QI team with specific data to track implementation progress.
  - Identify number of elective deliveries <39 weeks: induction of labor and cesarean section.
  - Identify: 1) gestational age; 2) method of gestational age determination (and whether ACOG criteria was used); 3) indication for delivery.
- Perform a baseline assessment 2-3 months before implementation. Modify data collected as indicated based on the baseline assessment.
Implementation Checklist

Assess the Situation

• Identify barriers to change.
  • Policy and/or leadership barriers, e.g., lack of scheduling criteria or enforcement oversight
  • Clinician and patient barriers, e.g., clinicians’ and women’s lack of knowledge of risks: attitudes about convenience for determining timing of birth
Implementation Checklist

Assess the Situation

• Assess strategies for mitigating barriers.
  • Assess the type of feedback clinicians receive:
    • Are the clinicians informed how many infants they cared for who were born <39 weeks are admitted to the Neonatal Intensive Care Unit?
  • Critique the scheduling process for labor induction and cesarean sections, including:
    • Is gestational age recorded when procedure is scheduled?
    • Is the method of gestational age assessment recorded?
    • Is the reason for induction or cesarean known and recorded?
    • Are the scheduling personnel aware of the ACOG indications for induction of labor and cesarean delivery?
    • How are scheduling problems currently handled?

• Engage additional stakeholders and leaders who have influence and can drive change.
Plan Change Tactics

• Develop revised scheduling processes and delivery guidelines based on ACOG criteria.
  • Adopt or modify scheduling algorithm and forms.
  • Basic information documented in forms:
• Establish appeal process for deliveries <39 weeks when criteria are not in guidelines or are questionable.
• Institute interventions for physicians who fail to follow guidelines.
• Appoint physician leader(s) to enforce scheduling process and approve exceptions.
Implementation Checklist

Plan Change Tactics

• Implement process to obtain informed patient consent for the procedure.

• Integrate patient education about the importance of the last weeks of pregnancy.

• Obtain agreement from obstetricians and key personnel on scheduling process and criteria.

• Document the medical indication for the delivery.

• Standardize dating criteria, e.g., consider obtaining ultrasounds before 20 weeks on all patients.

• Amend hospital policy and procedures to support elimination of elective deliveries <39 weeks.
Implementation Checklist

Implement

• Convene department meetings to secure buy-in and to educate staff about new policies and procedures.

• Conduct Obstetrical, clinical provider and staff education.
  • Outline key points to be used by hospital and office staff when discussing criteria for <39 week delivery.

• Integrate patient education
  • Distribute patient education materials prior to admission
  • Encourage clinicians to discuss with their patients the risks of delivery prior to 39 weeks during prenatal visits.

• Arrange “kick off” meeting to launch the new philosophy, policies and procedures.
Implementation Checklist

Track Progress

• Use data and audit tools to track the number of elective deliveries <39 weeks and other key measures.
• Report to staff and providers regularly; obtain input and suggestions about:
  • Outcome and process data
  • Issues, concerns, and recommendations from all clinicians and staff
• Make adjustments to the data plan, protocol, and forms as needed.
• Perform ongoing data collection to ensure the changes are routinely followed.
• Repeat MAP-IT steps and re-adjust the plan after implementing small tests of change.
The Quality Improvement Cycle

Plan: Set goals, predict, plan data collection

Act: Implement, evaluate, decide next cycle

Do: Test the plan, document problems, reassess and revise

Study: Complete data analysis, review lessons, decide action

PDSA

The cycles are linked for continuous improvement
Measurements

1. Percent of women with scheduled induction/cesarean section and gestational age confirmed by sonogram
2. Percent of women with scheduled induction/cesarean section and a medical or obstetric indication charted
3. Percent of inductions between 37 0/7 and 38 6/7 weeks that are ELECTIVE
4. Percent of scheduled cesarean sections between 37 0/7 and 38 6/7 weeks that are non-medically indicated (ELECTIVE.)
Measurements

5. Percent of inductions AND scheduled cesarean sections between 37 0/7 and 38 6/7 weeks that are non-medically indicated (ELECTIVE.) (Measures 3 and 4 combined)

6. Percent of low-risk women between 37 0/7 to 38 6/7 weeks that have either a scheduled induction or cesarean that is non-medically indicated (ELECTIVE)

7. Number of infants admitted to the NICU or transferred to another hospital for care after a scheduled elective induction or cesarean section between 37 0/7 and 38 6/7 weeks.
TRANSFORMATION EFFORTS

IF I HAD A HAMMER!
Barriers and Mitigation Strategy

The use of multiple, tailored strategies and tactics to mitigate barriers is the most effective approach to implementation.

Three successful strategies include:
1. discourse (communication)
2. education (formal and informal)
3. data (audit and trend charts)
Clinician Barriers: Physicians Who Are Resistant

• Early adopters
  • Change behaviors readily when new data emerges

• Late adopters
  • Resistant to behavior change
  • Change when they are persuaded to see that risks outweigh perceived benefits of practice.
Transformation Efforts

Strategies

• Arrange for a respected physician leader to talk with reluctant physicians to better understand their position on the issue.

• Publicize the scheduling process well in advance

• Streamline the process making it easy for physicians and their office staff to schedule patients.

• Enable and empower nurses and clerical staff to consult the department chair, perinatologist, or medical director when physicians are not following scheduling criteria.
Transformation Efforts

Resource Barriers: Time and Staff Limitations

• Strategies that **optimize resource allocation** and a realistic data collection plan address common hospital limitations: competing work priorities for nurse leaders; limited time to develop the forms, organize meetings, revise policies and procedures, and to collect and analyze data.

Context Barriers: Patients Request Elective Procedures

• Patients are often unaware of the risks of early delivery and may pressure clinicians for early <39 week deliveries.
Disseminating Innovations in Health Care

Three basic clusters of influence that correlate with the rate of spread of a change:

1. Perceptions of the innovation
2. Characteristics of the people who adopt the innovation or fail to do so
3. Contextual factors, especially involving communication, incentives, leadership and management

Berwick. JAMA, 2003
Disseminating Innovations in Health Care

From Description to Prescription

1. Find sound innovation
2. Find and support innovators
3. Invest in early adopters
4. Make early adopter activity observable
5. Trust and enable reinvention
6. Create slack for change
7. Lead by example

Berwick. JAMA, 2003
What drives change? Barriers to and incentives for achieving evidence-based practice

10 Step Model for Inducing Change in Professional Behavior
1. Promote awareness of innovation
2. Stimulate interest and involvement
3. Create understanding
4. Develop insight into own routines
5. Develop positive attitude to change
6. Create positive intentions/decision to change
7. Try out change in practice
8. Confirm value of change
9. Integrate new practice into routines
10. Embed new practice in organization

Grol and Wensing, MJA, 2004
Leading Change: Why Transformation Efforts Fail

- Error 1: Not Establishing a Great Enough Sense of Urgency
- Error 2: Not Creating a Powerful Enough Guiding Coalition
- Error 3: Lacking a Vision
- Error 4: Undercommunicating the Vision by a Factor of Ten
- Error 5: Not Removing Obstacles to the New Vision
- Error 6: Not Systematically Planning for, and Creating, Short-Term Wins
- Error 7: Declaring Victory Too Soon
- Error 8: Not Anchoring Changes in the Corporation’s Culture

John P. Kotter, Emeritus, Konosuke Matsushita Professor of Leadership at Harvard Business School in Boston.

Kotter. HBR, 2007
Eight Steps to Transform Your Organization

1. Establishing a sense of urgency
2. Forming a powerful guiding coalition
3. Creating a vision
4. Communicating the vision
5. Empowering others to act on the vision
6. Planning for and creating short term wins
7. Consolidating improvements and producing still more change
8. Institutionalizing new approaches

Kotter. HBR, 2007
# Choosing Strategies for Change

## Methods for dealing with resistance to change

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Description</th>
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<tbody>
<tr>
<td>Education + Communication</td>
<td>Where there is a lack of information or inaccurate information and analysis</td>
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<tr>
<td>Participation + involvement</td>
<td>Where the initiators do not have all the information they need to design the change and where other have considerable power to resist</td>
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<tr>
<td>Facilitation + Support</td>
<td>Where people are resisting b/c of adjustment problems</td>
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<tr>
<td>Negotiation + Agreement</td>
<td>Where someone or some group will clearly lose out in a change and where that group has considerable power to resist</td>
</tr>
<tr>
<td>Manipulation + Co-optation</td>
<td>Where other tactics will not work or are too expensive</td>
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<tr>
<td>Explicit + Implicit Coercion</td>
<td>Where speed is essential and the change initiators possess considerable power</td>
</tr>
</tbody>
</table>

Kotter and Schlesinger. HBR, 2008
1. Building the case

2. Understanding QI and the March of Dimes Toolkit

3. Leading Transformation Efforts
“The level of civilization attained by any society will be determined by the attention it has paid to the welfare of its children.”

- B.F. Andrews