
A California Toolkit to Transform Maternity Care

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

THIS COLLABORATIVE PROJECT WAS DEVELOPED BY:

MARCH OF DIMES
CALIFORNIA MATERNAL QUALITY CARE COLLABORATIVE
MATERNAL, CHILD AND ADOLESCENT HEALTH DIVISION;
CENTER FOR FAMILY HEALTH
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH



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

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Conflict of Interest: The contributing authors and reviewers do not have any affiliations or financial involvement that conflict with the material or recommendations presented in this toolkit.

SUPPORTING ORGANIZATIONS

Multiple professional associations are in support of this quality improvement toolkit designed to eliminate non-medically indicated (elective) deliveries before 39 weeks gestational age. Signed letters from the following organizations can be found in Appendix D.

- American Congress of Obstetricians and Gynecologists District II
- American Congress of Obstetricians and Gynecologists Illinois Section (District VI)
- American Congress of Obstetricians & Gynecologists District IX
- American Congress of Obstetricians & Gynecologists FACOG
- American Congress of Obstetricians & Gynecologists District XI
- Association of Women’s Health, Obstetric and Neonatal Nurses
- Association of Women’s Health, Obstetric and Neonatal Nurses –California

EXECUTIVE SUMMARY

Efforts to improve the quality and safety of perinatal care have received increased focus during recent years.¹⁻⁸ 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.⁷ The American Congress of Obstetricians and Gynecologists (ACOG) publications, (1979, 1999, 2009) have consistently advised against non-medically indicated elective deliveries prior to 39 weeks gestation.⁹⁻¹¹

Despite ACOG guidelines, elective early labor inductions and cesarean sections are common and increasing in the United States and are creating concern about trends in current obstetric practice.^{7, 12-15} Educating healthcare providers about morbidities associated with practice trends fosters evidence-based decision-making and leads to improved practices that reduce harm. *There are numerous maternal and fetal medical indications for deliveries prior to 39 weeks gestation. This toolkit, developed for clinicians, focuses on reducing non-medically indicated elective inductions and cesarean sections. In addition, the focus of this toolkit on less than (<) 39-week non-medically indicated elective deliveries is not meant to imply that elective deliveries after 39 weeks have been proven to be without risks for mothers and infants.*

Definitions of "full-term" and weeks of gestation that define safe birth are commonly misunderstood by the general public. A survey of insured women who recently gave birth found that only 25.2% of women defined full-term as 39-40 weeks.¹⁶ More importantly, 92.4% of women reported that giving birth before 39 weeks was safe.¹⁶ It is important to educate women about the potential negative outcomes of early deliveries and the critical fetal development that occurs during the last weeks of pregnancy.

Multiple national quality organizations, including The Joint Commission (TJC), National Quality Forum (NQF), and The Leapfrog Group (LFG), identified elective deliveries prior to 39 weeks (induction of labor and cesarean section) as a key quality indicator for obstetric hospital care.⁸ This toolkit is applicable to singleton pregnancies only, similar to national quality measures. Medical indications for deliveries <39 weeks, as defined by these national quality organizations, are listed in the Data Collection / QI Measurement section of the toolkit.

This toolkit incorporates policies and tools used successfully at multiple hospitals in the United States. It outlines best practices and provides support materials and guidance for implementing a quality improvement (QI) project around reducing elective deliveries before 39 weeks gestation. In addition, the toolkit provides methods to identify improvement opportunities and outlines techniques for measuring process and outcome improvements. It is organized into the following sections to facilitate improvements in hospitals at any stage of change for eliminating births <39 weeks.

- Making the Case: A comprehensive literature review about the importance of eliminating elective deliveries before 39 weeks
- Implementation: A step-by-step guide to assist hospital leaders with implementation efforts
- Data Collection and Quality Improvement: A guide for measuring and tracking QI effectiveness over time
- Clinician and Patient Education: Educational tools for clinicians and staff about consequences of early elective delivery; educational tools for patients about the importance of the last weeks of pregnancy
- Appendices: Sample Forms, Hospital Case Studies, QI Implementation Tools, Plan-Do-Study-Act (PDSA) Methodology, Implementation Resources and References

The March of Dimes, the California Maternal Quality Care Collaborative, and the California Department of Public Health, Maternal, Child, and Adolescent Health Division collaborated to develop and disseminate this toolkit. Academic and clinical leaders in California and across the United States contributed as writers and reviewers. The goal of this toolkit is to guide and support obstetrical providers, clinical staff, hospitals, and healthcare organizations to develop efficient and successful quality improvement programs to eliminate elective deliveries < 39 weeks gestation.

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MAKING THE CASE

Elective inductions of labor and elective cesarean section deliveries <39 weeks are increasing despite the ACOG guidelines that outline criteria for medically indicated births <39 weeks.^{12, 13, 17} The following literature review outlines complications associated with elective deliveries <39 weeks. In addition, this section includes results from leading institutions that implemented policies and practices to eliminate elective deliveries <39 weeks.¹⁸

DEFINITIONS FOR A COMMON LANGUAGE

Early term deliveries: The delivery of infants who are born between 37 0/7 through 38 6/7 weeks gestation.

Elective induction of labor: Induction of labor without an accepted medical or obstetrical indication before the spontaneous onset of labor or rupture of membranes.

Elective cesarean section: Scheduled primary or repeat cesarean section without an accepted medical or obstetrical indication before the spontaneous onset of labor or rupture of membranes.

Gestational age confirmation: Below are the ACOG criteria for determining term gestational age:

- “Ultrasound measurement at less than 20 weeks of gestation supports a gestational age of 39 weeks or greater.”¹¹
- “Fetal heart tones have been documented as present for 30 weeks by Doppler ultrasonography.”¹¹
- “It has been 36 weeks since a positive serum or urine human chorionic gonadotropin pregnancy test.”¹¹

Gestational weeks are often grouped into categories:

- **Late preterm** is defined as the period from 34 0/7 to 36 6/7 weeks gestation.
- **Early term** is defined as the period from 37 0/7 to 38 6/7 weeks gestation.

Scheduled: A planned induction or cesarean section that is scheduled for either elective or non-elective/medically indicated reasons.

ACCEPTED INDICATIONS FOR DELIVERY <39 WEEKS GESTATION

According to ACOG, the indications for delivery prior to 39 weeks gestation are not absolute, but should take into account maternal and fetal conditions, gestational age, cervical status and other factors. Furthermore, “labor can be induced for logistical or psychosocial indications, but gestation should be ≥39 weeks or a mature fetal lung test should be established. A mature fetal lung test result before 39 weeks of gestation, in the absence of appropriate clinical circumstances, is not an indication for delivery” because a mature fetal lung test does not mean the baby will not experience breathing difficulties after birth.¹¹ The Joint Commission, as part of its National Quality Core Measures program, has further defined conditions that may indicate the medical necessity for a delivery prior to 39 weeks gestation.¹⁹

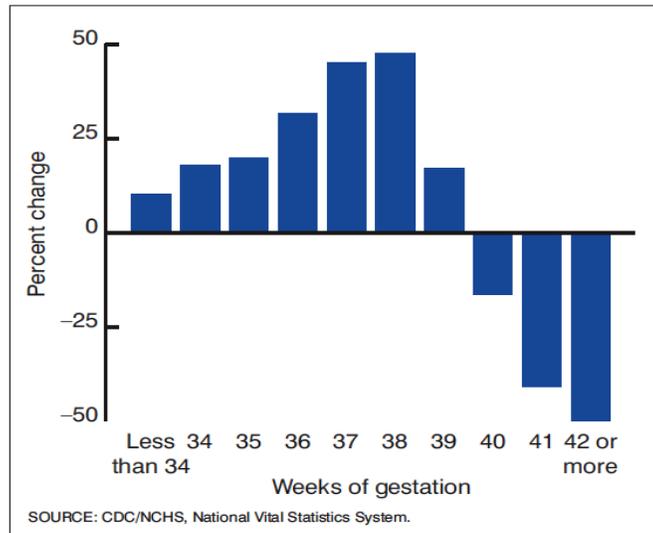
ACOG: “Examples of maternal or fetal conditions that may be indications for induction of labor”¹¹	The Joint Commission: National Quality Core Measure PC-01-- Specifications for “Conditions justifying delivery <39weeks”¹⁹
<ul style="list-style-type: none"> • Abruptio placenta 	<ul style="list-style-type: none"> • Placental abruption, placenta previa, unspecified antenatal hemorrhage
<ul style="list-style-type: none"> • Fetal demise 	<ul style="list-style-type: none"> • Fetal demise, fetal demise in prior pregnancy
<ul style="list-style-type: none"> • Post-term pregnancy 	<ul style="list-style-type: none"> • Post-term pregnancy
<ul style="list-style-type: none"> • Premature rupture of membranes 	<ul style="list-style-type: none"> • Rupture of membranes prior to labor (term or preterm)
<ul style="list-style-type: none"> • Gestational hypertension, preeclampsia, eclampsia, chronic hypertension 	<ul style="list-style-type: none"> • Gestational hypertension, preeclampsia, eclampsia, chronic hypertension
<ul style="list-style-type: none"> • Maternal medical conditions, e.g., diabetes, renal disease, chronic pulmonary disease, antiphospholipid syndrome 	<ul style="list-style-type: none"> • Preexisting diabetes, gestational diabetes • Renal disease • Maternal coagulation defects in pregnancy (includes anti-phospholipid syndrome) • Liver diseases (including cholestasis of pregnancy) • Cardiovascular diseases (congenital and other) • HIV infection
<ul style="list-style-type: none"> • Fetal compromise, e.g., severe Intrauterine Growth Restriction (IUGR), isoimmunization, oligohydramnios 	<ul style="list-style-type: none"> • IUGR, oligohydramnios, polyhydramnios, fetal distress, abnormal fetal heart rate • Isoimmunization (Rh and other), fetal-maternal hemorrhage • Fetal malformation, chromosomal abnormality, or suspected fetal injury

The list of indications by the Joint Commission (TJC) do not set a standard of care for who should or should not be electively delivered prior to 39 weeks gestation. For example, women with diet-controlled gestational diabetes (a TJC accepted indication) generally should not be induced prior to 39 or even 40 weeks unless complications are present.²⁰ Likewise most centers recommend a scheduled Cesarean delivery prior to 39 weeks for women with a prior vertical uterine incision.²¹ For the purposes of creating a quality measure that was not overly labor intensive to collect, TJC chose to utilize diagnoses that had ICD-9 codes no matter if some codes were over-inclusive (gestational diabetes) or simply not available (prior vertical cesarean section scar). TJC has noted during private conversations with CMQCC leaders that the list of codes is not exhaustive and anticipated that every hospital will have some cases of medically justified elective deliveries prior to 39 weeks that are not on the TJC list. Therefore, each hospital, hospital system or perinatal region should, based on the available evidence, set their own internal medical standards for conditions that justify a scheduled delivery prior to 39 weeks. Note that too loose an internal standard will become apparent once hospitals are publically compared. The *Guidelines for Perinatal Care*, 6th Edition similarly advise against elective cesarean deliveries until 39 weeks.²²

ELECTIVE DELIVERIES: A GROWING CONCERN

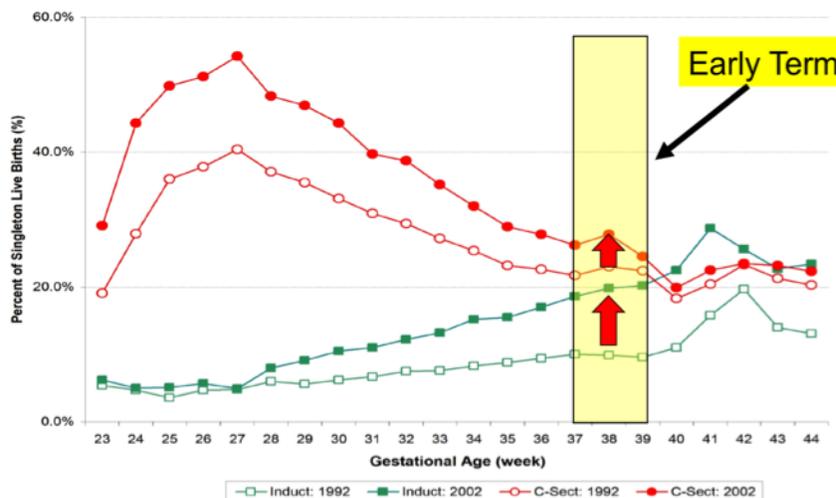
Rates of labor induction have increased dramatically from 9.5% in 1990 to 22.5% in 2006.¹⁷ Much of this rise has been attributed to an increase in elective inductions.²³ Data from the Hospital Corporation of America showed that 44% of deliveries at term in 2007 were scheduled cesarean sections or inductions and that 71% of these were elective.¹⁴ Deliveries between 37 and 38 weeks gestation have increased dramatically between 1990 through 2006 and account for approximately 17.5% of live births in the United States.²⁴ In Figure 1, the distribution of births by gestational age illustrates the changing distribution of births to a lower gestational age over a 16 year period. There was a sharp decline in deliveries occurring after 39 weeks with a concomitant sharp increase in births occurring particularly between 36-38 weeks gestation.

Figure 1: Change in Distribution of Birth by Gestational Age: United States, 1990-2006



The concomitant rise in deliveries between 37 and 39 weeks has been associated with an increase in obstetrical interventions such as induction of labor and cesarean sections.

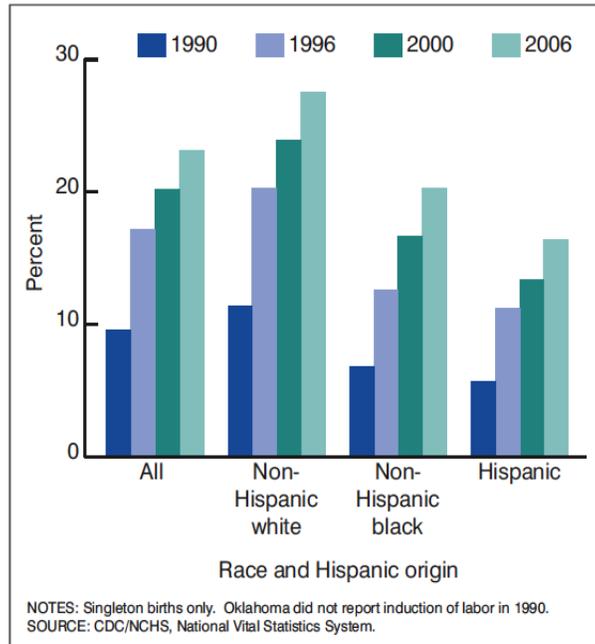
Figure 2: U.S. Cesarean Section and Labor Induction Rates Among Singleton Live Births by Week of Gestation, 1992 and 2002



Source: NCHS, final natality data. (Figure prepared by March of Dimes Perinatal Data Center, April 2006 and used with the permission of the March of Dimes)

The rise of induction of labor is present in all racial groups with the highest increase in Non-Hispanic whites.

Figure 3: Rise in Induction of Labor by Racial Groups in the U.S.



Martin JA, Hamilton BE, Sutton PD, Ventura SJ, et al. Births: Final data for 2006. National vital statistics reports; vol 57 no 7. Hyattsville, MD: National Center for Health Statistics. 2009.

Most concerning is that a large proportion of these early term births, regardless of race/ethnicity, may be due to scheduled, non-medically indicated interventions. For example, Intermountain Healthcare, based in Salt Lake City, reported that in 2001, 28% of their elective deliveries were performed prior to 39 weeks.¹⁸ Preliminary analysis indicates that elective early term deliveries vary from 8% to 44% among California hospitals.²⁵

Non-medically indicated (elective) deliveries described above are either induced and/or done by scheduled cesarean section and indicate that physician decisions may, in part, be driving higher rates of early elective deliveries. In addition, it has been suggested that women may not have an accurate perception of the benefits of carrying a baby to term.¹⁶ These two inter-related elements present a critical opportunity for quality improvement.

WHAT ARE THE RISKS OF DELIVERY BEFORE 39 WEEKS?

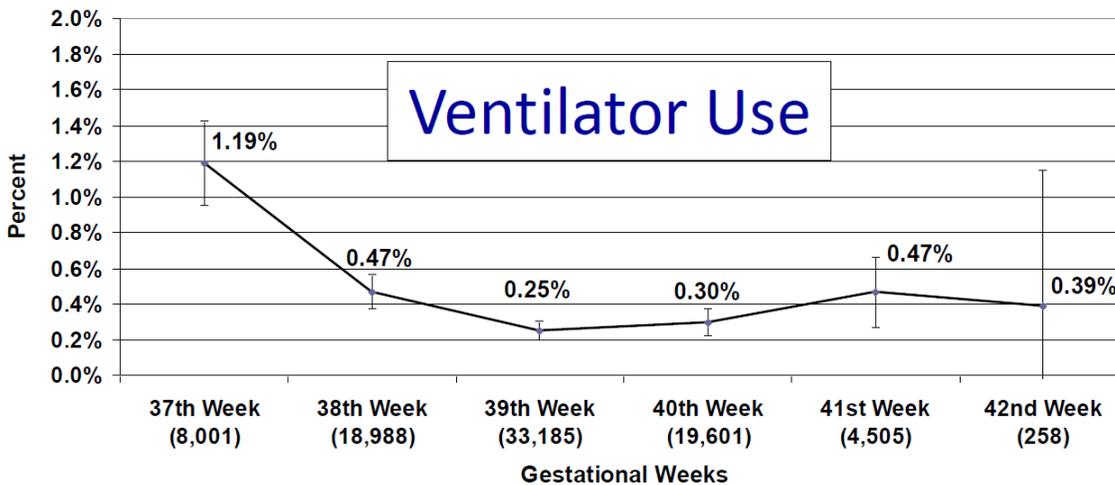
Multiple recent studies indicate that elective deliveries <39 weeks carry significant increased risk for the baby (odds ratios 2.0-3.0 compared to infants born between 39 and 41 weeks). (Table 2)²⁶⁻³⁰ The risk is highest for scheduled pre-labor cesarean sections at 37 weeks gestation, but is significant for all subgroups examined. Even babies delivered at 38 4/7 to 38 6/7 weeks have higher risk of complications than those delivered after 39 weeks.

Table 2: Complications of Elective Deliveries Between 37 and 39 Weeks ²⁶⁻³⁰
• 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

NEONATAL OUTCOMES OF EARLY TERM BIRTHS

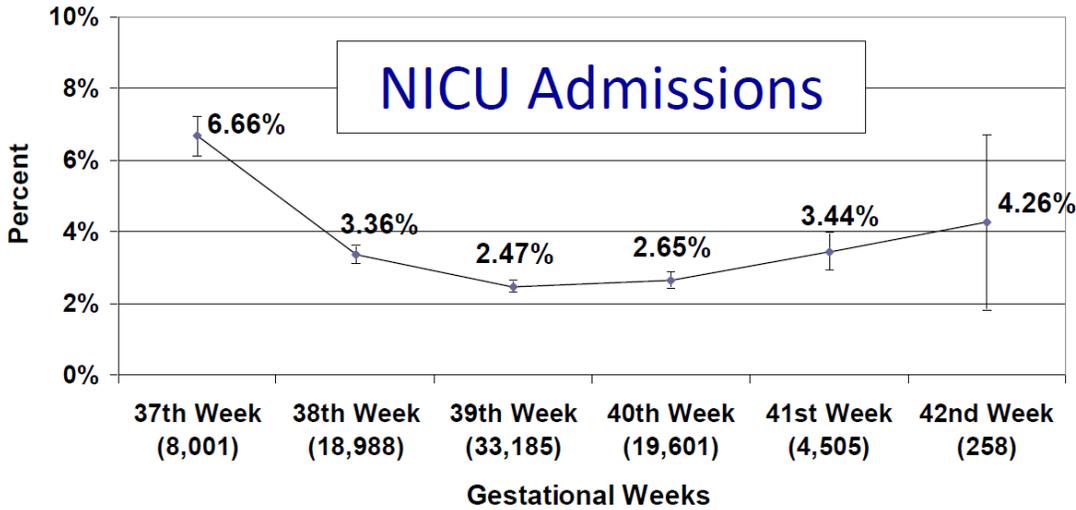
Intermountain Healthcare (IHC) Study—ICU Admissions, Ventilator Use: Intermountain Healthcare operates 21 hospitals in Utah and Southeast Idaho and performs approximately 30,000 deliveries annually (www.intermountainhealthcare.org). A recent study of this integrated healthcare system showed that rates of RDS (as indicated by ventilator use) was 22.5 times higher for infants born at 37 weeks and 7.5 times higher for infants born at 38 weeks compared with infants born at 39 weeks (Figure 4). The study also found increased rates of persistent pulmonary hypertension, NICU admissions and neonatal stays beyond 5 days in a <39-week elective induction group (Figure 5).¹⁸

Figure 4. Higher Ventilator Use Among Infants Delivered at 37 Weeks Gestation



Oshiro, B. et al. *Decreasing elective deliveries before 39 weeks of gestation in an integrated health care system.* *Obstet Gynecol*, 2009. **113**: p. 804-811. Permission to adapt and use granted.

Figure 5. Increased NICU Admissions among Infants Delivered at 37 Weeks Gestation



Oshiro, B. et al. *Decreasing elective deliveries before 39 weeks of gestation in an integrated health care system.* *Obstet Gynecol*, 2009. **113**: p. 804-811. Permission to adapt and use granted.

Hospital Corporation of America—NICU Admissions: Hospital Corporation of America (HCA) has 114 delivering hospitals in 21 states (<http://www.hcahealthcare.com>). The following table shows the risk of NICU admissions in 27 representative hospitals evaluating 17,794 births over a 3-month period in 2007. Percent of NICU admissions increased among all groups as gestation time of elective delivery decreased (Table 3).¹⁴

	37+0 to 37+6 weeks	38+0 to 38+6 weeks	39+0 to 39+6 weeks
Elective inductions (N)	112	678	2004
NICU admission %	15.2%	7.0%	6.0%
Elective cesarean births (N)	129	793	929
NICU admission %	20.1%	9.3%	8.0%
TOTAL elective deliveries (N)	241	1471	2933
NICU admission %	17.8% (p<0.001)	8.0% (p<0.001)	4.6%

Adapted from: Clark, S.L., et al., *Neonatal and maternal outcomes associated with elective term delivery.* *Am J Obstet Gynecol*, 2009. **200**(2): p. 156 e1-4. Permission to adapt and use granted.

Maternal-Fetal Medicine Network—Elective Repeat Cesarean Section without Labor: A 19 hospital multi-center study from the Maternal-Fetal Medicine Network examined more than 16,000 elective uncomplicated repeat cesarean births from 37 to 40 weeks gestation.⁷ When compared with deliveries at 39 weeks, early deliveries were associated with significantly increased risk of composite neonatal adverse outcomes (any adverse outcome and/or neonatal death) and individual neonatal adverse outcomes, including respiratory complications and NICU admissions (Table 4). The majority of pre-39 week deliveries occurred at 38 4/7 through 38 6/7 weeks and had outcomes similar to those occurring at 38 0/7 to 38 3/7 weeks.

Table 4: Timing of Elective Repeat Cesarean Delivery at Term and Neonatal Outcomes (MFM Network)					
Outcome	37+0 to 37+6 Weeks		38+0 to 38+6 Weeks		39 Completed Weeks N=6512 (%) (Reference)
	N=834 %	Odds Ratio*	N=3909 %	Odds Ratio*	
Any adverse outcome or death	15.3%	2.1	11.0%	1.5	8.0%
Adverse respiratory outcome (overall)	8.2%	2.5	5.5%	1.7	3.4%
Respiratory Distress Syndrome (RDS)	3.7%	4.2	1.9%	2.1	0.9%
Transient Tachypnea of the Newborn (TTN)	4.8%	1.8	3.9%	1.5	2.7%
Admission to NICU	12.8%	2.3	8.1%	1.5	5.9%
Newborn sepsis (suspected or proven)	7.0%	2.9	4.0%	1.7	2.5%
Treated hypoglycemia	2.4%	3.3	0.9%	*1.3 (NS)	0.7%
CPR or ventilation in first 24 hours	1.9%	--	0.9%	--	0.4%
Hospitalization ≥5 days	9.1%	2.7	5.7%	1.8	3.6%

*All Odds Ratios are significant except "NS" (Not Significant)

Adapted from: Tita, A. et al. *Timing of elective cesarean delivery at term and neonatal outcomes*. The New England Journal of Medicine, 2009. 360: p. 111-20.

Figures 6 and 7 redisplay data from Table 4 and illustrate that neonatal complications were more frequent at 38 weeks gestation and significantly increased in frequency at 37 weeks gestation.⁷

Figure 6: Complication Rates in Infants of Scheduled Repeat Cesarean Births by Gestational Age (Weeks)

Adapted from: Tita, A. et al. *Timing of elective cesarean delivery at term and neonatal outcomes*. The New England Journal of Medicine, 2009. **360**: p. 111-20.

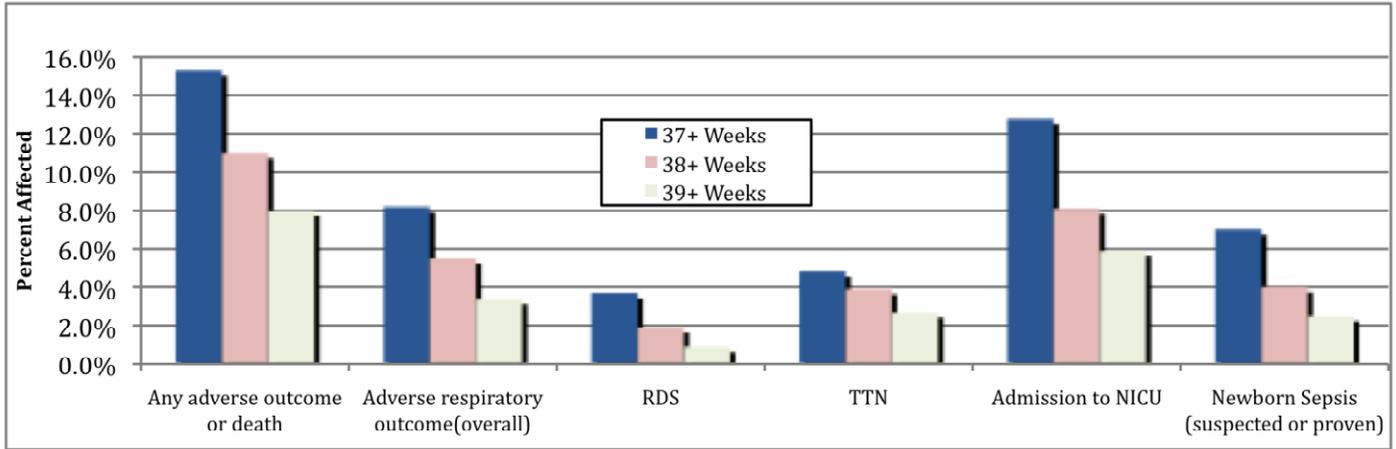
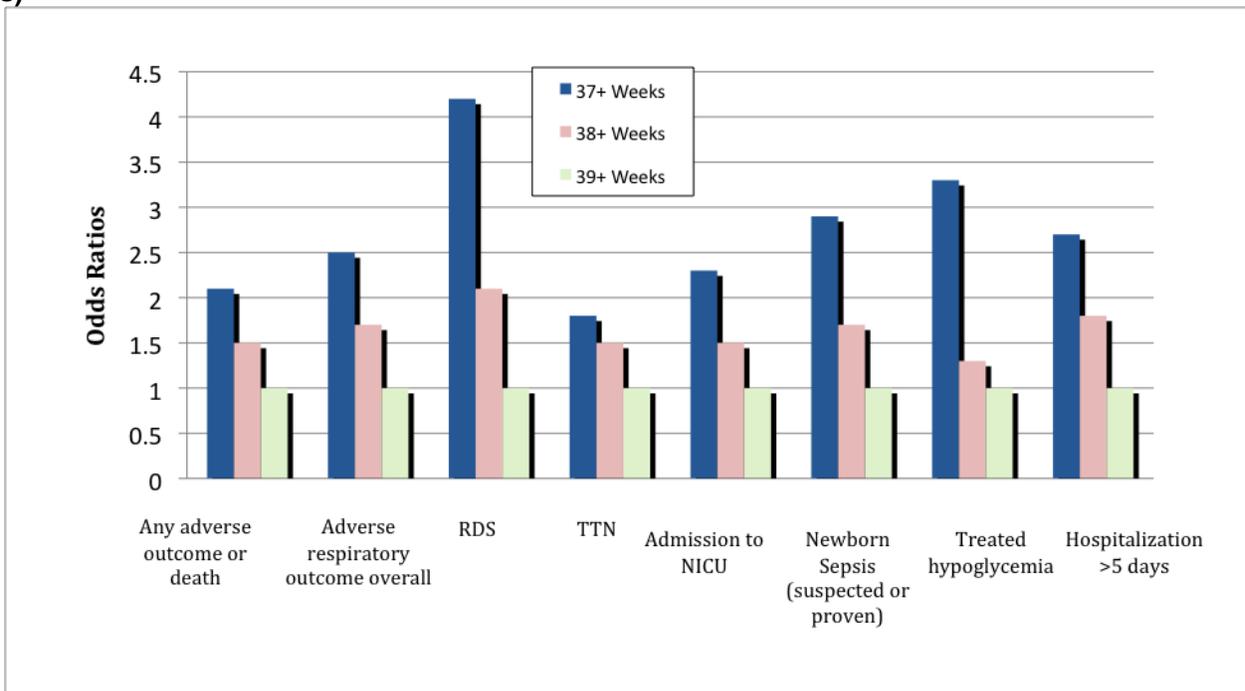


Figure 7 shows odds ratios to highlight the relative effect of gestational age on neonatal complication rates. Odds ratios range from 2 to 4 for all infants at 37+ weeks gestation.⁷

Figure 7: Odds Ratios for Complications in Infants of Scheduled Repeat Cesarean Birth by Gestational Age (Weeks)



Adapted from: Tita, A. et al. *Timing of elective cesarean delivery at term and neonatal outcomes*. The New England Journal of Medicine, 2009. **360**: p. 111-20.

University of Alabama, Birmingham—Fetal Lung Maturity Testing Before 39 Weeks and Neonatal Outcomes: A retrospective study performed at the University of Alabama, Birmingham compared women with singleton uncomplicated pregnancies who delivered babies with mature lung profiles at 36 to 38 compared with 39 weeks gestation (Table 5).³¹ They found that delivery before 39 weeks even with confirmed fetal lung maturity (FLM) was associated with increased neonatal morbidity, compared to delivery at 39 to 40 weeks.

Table 5: Adverse Neonatal Outcomes

Adverse neonatal outcome	< 39 weeks + FLM % (n=442)	39-40 weeks %(n=12281)	Adjusted [†] RR (95% CI)
Composite adverse outcome	5.9	2.5	1.6 (1.02, 2.6)
Composite adverse outcome II*	5.0	2.0	1.7 (1.01, 2.7)
Suspected or proven sepsis	5.7	2.2	1.7 (1.1, 2.8)
Respiratory support	2.9	1.0	1.8 (0.96, 3.5)
RDS	1.4	0.04	7.9 (2.0, 31)
Hypoglycemia	2.0	0.14	6.7 (2.5, 17.6)
NICU admission	5.9	2.3	1.7 (1.05, 2.7)
Hospitalization > 4 days	10.8	3.3	2.6 (1.8, 3.9)

* Excludes suspected sepsis

[†] Adjusted for maternal age, race, parity, medical complications, (hypertensive disorder or diabetes) and baby gender.

Bates E, Rouse D, Chapman V, Mann ML, Carlo W, Tita A. Fetal lung maturity testing before 39 weeks and neonatal outcomes. *Amer J Obstet Gynecol.* December 2009;201(6):S17. Permission to use granted.

Other Studies Evaluating Neonatal Morbidity

Studies completed during the mid-1990s have documented the risks associated with early elective deliveries.²⁷⁻³⁰ These researchers found significant increases in neonatal respiratory morbidity from cesarean births performed at <39 weeks, especially when performed prior to the onset of labor. In one of the largest studies, Morrison (1995, Cambridge, England) examined 33,289 deliveries that occurred at or after 37 weeks of gestation.²⁷ Rates of respiratory morbidity were 14 times higher in pre-labor cesarean births at 37 compared with 40 weeks gestation; at 38 weeks gestation, rates were still 8.2 times higher for pre-labor cesarean. No studies were identified where neonatal morbidity was decreased due to non-medically indicated (elective) delivery prior to 39 weeks. In addition, no studies have been identified that demonstrate that non-medically indicated (elective) delivery prior to 39 weeks improves neonatal outcomes.

Recent studies highlight concerns that late preterm and possibly early term deliveries may increase babies' risk of brain injury and long term neurodevelopmental abnormalities. Approximately 50% of cortical volume growth occurs between 34 and 40 weeks. At 37 weeks, the brain weighs only 80% of the weight at 40 weeks and gray matter volume increases at a rate of 1.4% per week between 36 and 40 weeks.³²⁻³⁴ Similarly, there is rapid growth of the cerebellum with approximately 25% of its volume developing after the late preterm period. MRI evaluation in preterm infants has shown an impairment of the cerebellar growth compared to term infants.³⁵

Maternal Risk

Overall, there was not significant clinical impact on maternal morbidity after the Intermountain Healthcare quality improvement program was instituted. The Intermountain Healthcare quality improvement study is the only one that systematically evaluated maternal morbidity after reducing elective deliveries before 39 weeks.¹⁸ Although the confidence intervals are extremely wide, researchers did not observe worse maternal outcomes but instead found a slight decrease in postpartum anemia and number of cesarean deliveries performed due to fetal distress. They also found a slight increase in mild preeclampsia (Table 6). There were no differences in infectious morbidity. In addition, no studies have been identified to demonstrate that non-medically indicated (elective) deliveries prior to 39 weeks improves maternal outcomes.

Table 6. Selected Maternal Outcome Data Before and After Initiation of the IHC <39 Week Elective Delivery Reduction Program (1999-2000 and 2001-2006)

Adverse Maternal Outcome	Before	After	OR	95% CI
Chorioamnionitis	0.69	0.72	1.04	0.88-1.24
Endometritis	0.18	0.21	1.19	0.85-1.67
Postpartum anemia	1.58	0.46	0.86	0.77-0.97
Cesarean delivery due to fetal distress	0.11	0.06	0.57	0.35-0.92
Preeclampsia	0.57	0.81	1.43	1.18-1.71

Oshiro, B. et al. *Decreasing elective deliveries before 39 weeks of gestation in an integrated health care system*. *Obstet Gynecol*, 2009. **113**: p. 804-811. Permission to use is granted.

Cost Analysis

A recent study by Robinson et al., using a decision analysis model based on the Maternal-Fetal Medicine Units Network study, “Timing of Elective Repeat Cesarean Delivery at Term and Neonatal Outcomes” analyzed over 82,000 deliveries occurring between 37-39 weeks for the incidence of adverse outcomes and related hospital costs and charges. They concluded that there were significant increases in neonatal morbidity and hospitalization costs in patients delivered by elective repeat cesarean section between 37 and 39 weeks.^{7, 36}

SUMMARY

Non-medically indicated (elective) deliveries before 39 weeks gestation carry significant risks for the baby with no known benefit to the mother. As seen in Table 5, the odds of serious neonatal complications increase with decreasing gestational duration. Common serious morbidities include respiratory complications, sepsis and hypoglycemia. Preliminary data indicate that these risks are not diminished despite amniocentesis documenting a mature lung profile. Clinicians are advised that a mature lung profile does not necessarily lessen the risk of morbidity.

QUALITY IMPROVEMENT INTERVENTIONS TO REDUCE ELECTIVE BIRTHS <39 WEEKS

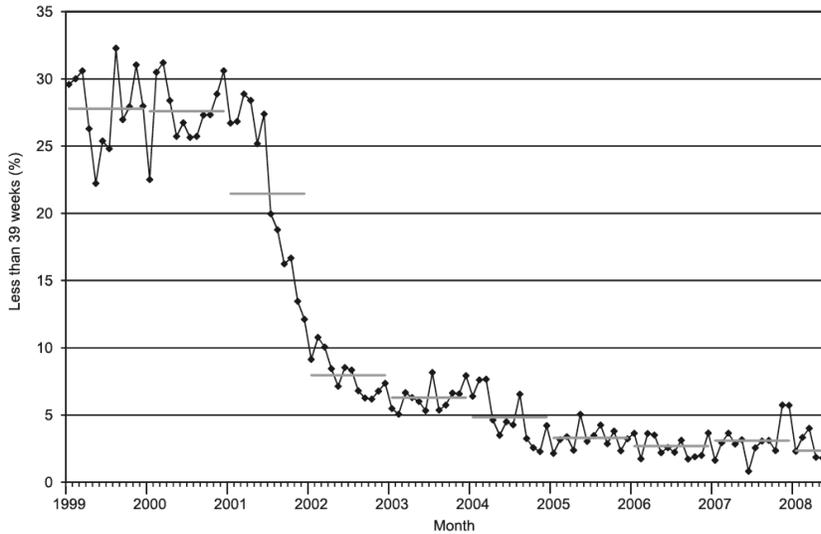
QI interventions have successfully decreased elective deliveries <39 weeks and associated maternal and neonatal mortality and morbidity. Three studies are reviewed below.

Intermountain Healthcare: Beginning in 2001, The Intermountain Healthcare Women and Newborn Clinical Integration Guidance Council reviewed neonatal outcomes and introduced a QI intervention to reduce elective inductions <39 weeks gestation in Intermountain Healthcare Hospitals in Utah and Southeastern Idaho.¹⁸

The QI group utilized a multidisciplinary team consisting of physicians, nurse leaders, statisticians, data managers and administrative leaders within the organization. During initial presentations about the QI intervention, there was opposition from obstetric and gynecology departments, which appeared to be due to lack of common knowledge about neonatal morbidities associated with elective inductions prior to 39 weeks gestation. To address this and other barriers, the QI group presented neonatal outcome data and implemented dispute resolutions directly through department chairs or perinatologists, instead of having nurses and clerical staff act as “gatekeepers.” Other key steps included development of a data collection system, consent forms, and education modules for both medical staff and patients. While Intermountain Healthcare is a vertically integrated healthcare system with salaried medical directors and perinatologists, most obstetrical providers were private practitioners not employed by the system. Performance was monitored system-wide, by facility, and for individual practitioners, and reports were issued regularly.

Within 6 months of baseline, elective deliveries <39 weeks dropped from 28% to 10%, and was <3% after six years (Figure 8).¹⁸ Note that percent here means percent of ALL elective (scheduled) births that occurred <39 weeks gestation, NOT percent of births between 37 and 39 weeks gestation that were elective (scheduled). The definition used in this study is consistent with the one endorsed by the National Quality Forum (NQF) and adopted by The Joint Commission (refer to Table 10).⁸ The definition utilized is an important distinction to make since not all studies are consistent in how they report these data. Hospital leaders who are working on reducing deliveries may find it useful to collect data utilizing both denominators (ALL deliveries <39 weeks and the subset of the number of deliveries between 37 0/7 and 38 6/7 weeks) in order to facilitate their ability to benchmark their results with others.

Figure 8: Percent* of Elective Deliveries before 39 Weeks Gestation



Oshiro, B., et al., *Decreasing Elective Deliveries Before 39 Weeks*. *Obstet Gynecol* 2009. The QI intervention project began in January 2001; data from Intermountain Healthcare. *Percent is defined as using a denominator of ALL elective (scheduled) births. Permission to use is granted.

Stillbirths: Stillbirth rates at each gestational age were tracked and calculated to address physician concerns that delaying elective deliveries to later than 39 weeks could increase the term stillbirth rate. Table 7 shows that stillbirth rates fell overall and for each gestational week past 37 weeks by >50%.

Table 7: Stillbirth Data from the Intermountain Healthcare Elective Induction Reduction before 39 Weeks QI Project (Before and After Periods)

Weeks of Gestation	1999–2000			July 2001 to June 2006			Odds Ratio	95% CI
	Stillbirths	Deliveries	%	Stillbirths	Deliveries	%		
37	17	4,117	0.41	22	13,077	0.17	0.406	0.22–0.77
38	19	9,954	0.19	21	28,209	0.07	0.390	0.21–0.72
39	10	13,752	0.07	28	51,721	0.05	0.744	0.36–1.53
40	10	7,925	0.13	14	24,140	0.06	0.459	0.20–1.03
41	2	1,938	0.10	3	5,571	0.05	0.522	0.09–3.12
All	58	37,686	0.15	88	12,2718	0.07	0.466	0.33–0.65

CI, confidence interval.

Oshiro, B., et al., *Decreasing elective deliveries before 39 weeks of gestation in an integrated health care system*. *Obstet Gynecol*, 2009. 113: p. 804-811. Permission to use is granted.

Magee Women’s Hospital (Fisch): Inductions were identified as a major quality issue at Magee Women’s Hospital, a large teaching facility with 9,300 births annually from both clinic and private practices.³⁷ Fisch et al. published a process improvement intervention similar to Oshiro et al. in the same issue of *Obstetrics and Gynecology* (April 2009) with findings similar to Oshiro et al.^{18, 37} Magee Women’s Hospital QI intervention focused on eliminating elective inductions both prior to 39 weeks and at later gestational ages in women with unfavorable cervical exams (Bishop Score <8 for nulliparas).

The QI intervention began in 2004 when Magee Women’s Hospital Departmental Quality Assurance Committee developed induction guidelines, based on ACOG standards, to limit inductions by gestational age and Bishop Score.¹⁰ Rates of inductions were measured at baseline (2004), then again in 2005 after staff were educated and asked to follow the guidelines voluntarily. A focus of Magee Women’s Hospital QI project was to strictly enforce these guidelines by involving key physician and nursing leaders in changing the process of induction scheduling. In 2006, the OB Process Improvement Committee, whose members included the hospital’s vice president for medical affairs, the medical director and nursing leaders of the Birth Center, along with stakeholders from other clinical disciplines (such as family practice, anesthesia, nursing), provided oversight for induction scheduling so that guidelines would be closely followed. The Committee’s oversight included support for induction schedulers—the guideline “messengers” and first-line enforcers—if they encountered resistance from obstetricians or their office staff. Nursing directors supported the schedulers by discussing the induction rationale with the attending physician and, when necessary, seeking approval for induction from the medical director. An important lesson is that education and feedback alone did not result in a reduction in elective inductions prior to 39 weeks. It was the implementation of the chain of support system which resulted in significantly fewer elective inductions prior to 39 weeks gestation when compared with baseline or compared with the first stage of QI improvement that included education and voluntary guidelines (Table 8).

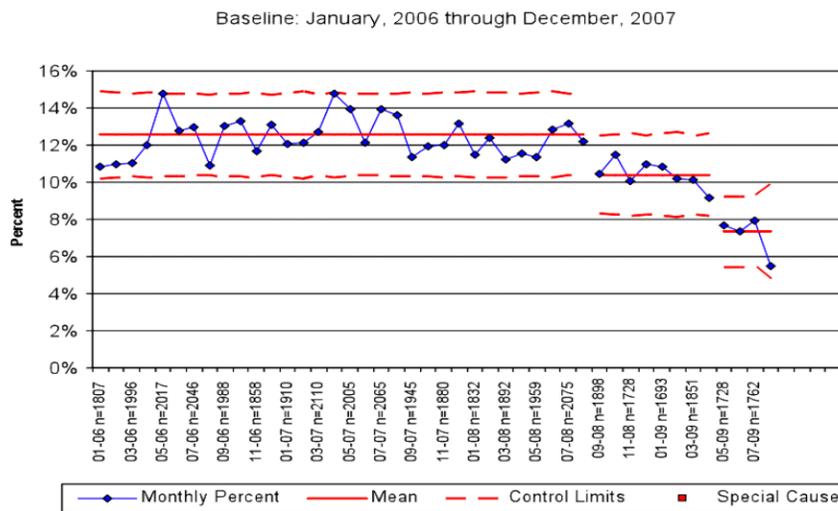
Table 8: Reduction of Induction Risks: A Departmental QI Project			
	3 months 2004	3 months 2005	14 months 2006-7
QI Approach	Baseline	Education and voluntary guidelines	Formal approval needed to schedule outside guidelines
Deliveries (N)	2,139	2,260	10,895
Elective Inductions <39wks (N)/ Total Elective Inductions (rate)	23 11.8%	21 10.0%	30 4.3% (p<0.001)
Elective Nullip Inductions (N)	29	33	87
Elective Nullip Inductions =>C/S (N)	10	5	12
Elective Nullip Inductions =>C/S (rate)	35.7%	15.2%	13.8% (p<0.01)
Total Induction Rate	24.9%	20.1%	16.6%

Adapted from: Fisch, J.M., et al., *Labor induction process improvement: a patient quality-of-care initiative*. *Obstet Gynecol*, 2009. **113**(4): p. 797-803. Permission to adapt and use is granted.

Ohio Perinatal Quality Collaborative (OPQC): The OPQC (www.opqc.net), sponsored by the Ohio Department of Job and Family Services with a grant from the Centers for Medicare and Medicaid Services, was initiated in July 2008 and involved the collaborative efforts of care providers, perinatal hospital leaders, payers, policy-makers and parents to reduce elective deliveries prior to 39 weeks gestation.³⁸ Hospitals participating in the collaborative were asked to collect and report data that showed formal documentation of 1) indications for inductions or cesarean births, and 2) gestational ages and criteria for determination. Rates of elective deliveries <39 weeks gestation were compared between hospitals that were and were not participating in the collaborative.

The rate of births scheduled between 36 1/7 and 38 6/7 weeks gestation without medical indications decreased from 25% to <5% within the 14-month data collection period (July 2008 to September 2009). Similarly, birth certificates from collaborating hospitals showed a decrease in inductions recorded without medical indications from 13% to 8%, and fewer infants born between 36 and 38 weeks gestation admitted to the NICU.

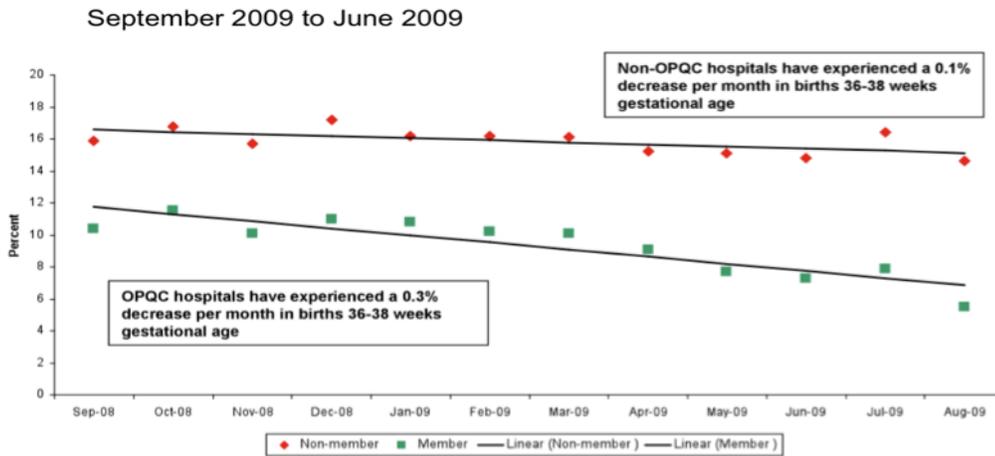
Figure 9. Percent of Ohio Births at 36 to 38 Weeks Induced Without Medical or Obstetric Indication



The Ohio Perinatal Quality Collaborative Writing Committee. A statewide initiative to reduce inappropriate scheduled births at 36 0/7-38 6/7 weeks' gestation. American Journal of Obstetrics Gynecology. 2010;202(243.e):1-8. Permission to use is granted.

The decrease in elective deliveries was greater in hospitals participating in the collaborative compared with those not participating.

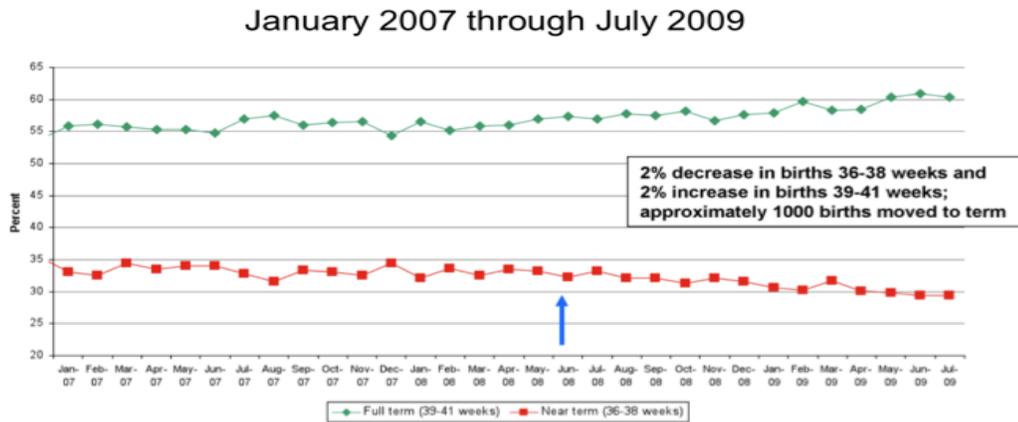
Figure 10: Ohio Births at 36 to 38 Weeks Gestation Following Induction Without Apparent Medical Indication for Delivery, by OPQC Member Status



The Ohio Perinatal Quality Collaborative Writing Committee. A statewide initiative to reduce inappropriate scheduled births at 36 0/7-38 6/7 weeks' gestation. American Journal of Obstetrics Gynecology. 2010;202(243.e):1-8. Permission to use is granted.

These data indicate that providers were not changing the diagnosis and adding a medical indication. Furthermore, these data show a decrease in the percentage of deliveries between 36 and 38 weeks and concomitant increase in the percentage of deliveries at 39 weeks and beyond.

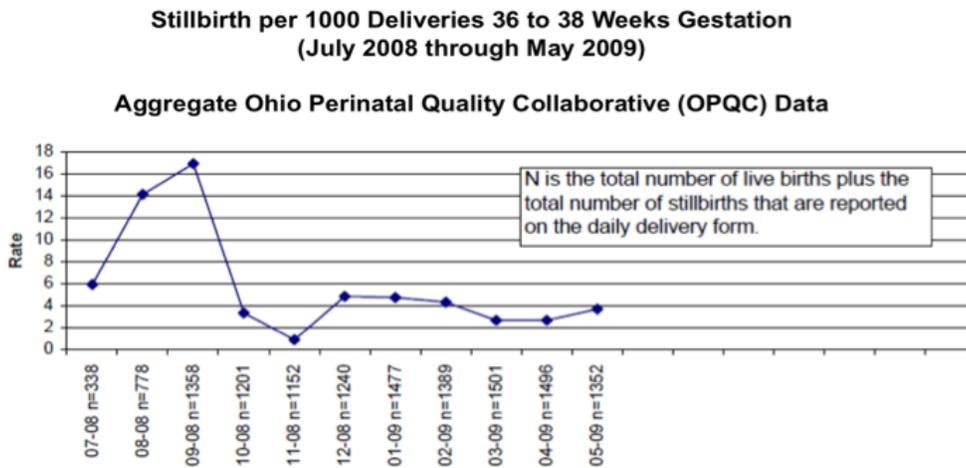
Figure 11: Gestational Age Distribution of Births at OPQC Member Hospitals, by Month



The Ohio Perinatal Quality Collaborative Writing Committee. A statewide initiative to reduce inappropriate scheduled births at 36 0/7-38 6/7 weeks' gestation. American Journal of Obstetrics Gynecology. 2010;202(243.e):1-8. Permission to use is granted.

Stillbirth rates declined after initiating the project as seen in the Intermountain Healthcare QI intervention (Figure 12).

Figure 12: Stillbirths among OPQC Participating Hospitals



The Ohio Perinatal Quality Collaborative Writing Committee. A statewide initiative to reduce inappropriate scheduled births at 36 0/7-38 6/7 weeks' gestation. American Journal of Obstetrics Gynecology. 2010;202(243.e):1-8. Permission to use is granted.

SUMMARY

QI interventions at the facility, system or regional levels have been shown to be effective in reducing elective deliveries <39 weeks gestation, particularly when interventions are data-driven, involve multidisciplinary teams, and reference specific guidelines that can be enforced. An important point to emphasize is that in both the Magee Women's Hospital and Intermountain Healthcare experience, successful implementation of the program required strong leadership and policy enforcement. Only when strong medical leadership supported strict enforcement policy were improvements in reducing elective deliveries <39 weeks realized. Importantly, there was not an increase in maternal, fetal, or neonatal morbidity or mortality after the programs were initiated.

Implementation Strategy

The implementation strategy in this section provides an overview diagram, an outline of the rapid cycle method, Mobilize, Assess, Plan, Implement, Track (MAP-IT), and an implementation checklist to guide eliminating non-medically indicated (elective) deliveries <39 weeks through change in practice and hospital guidelines. See Appendix C for the Plan, Do, Study, Act (PDSA) model.³⁸

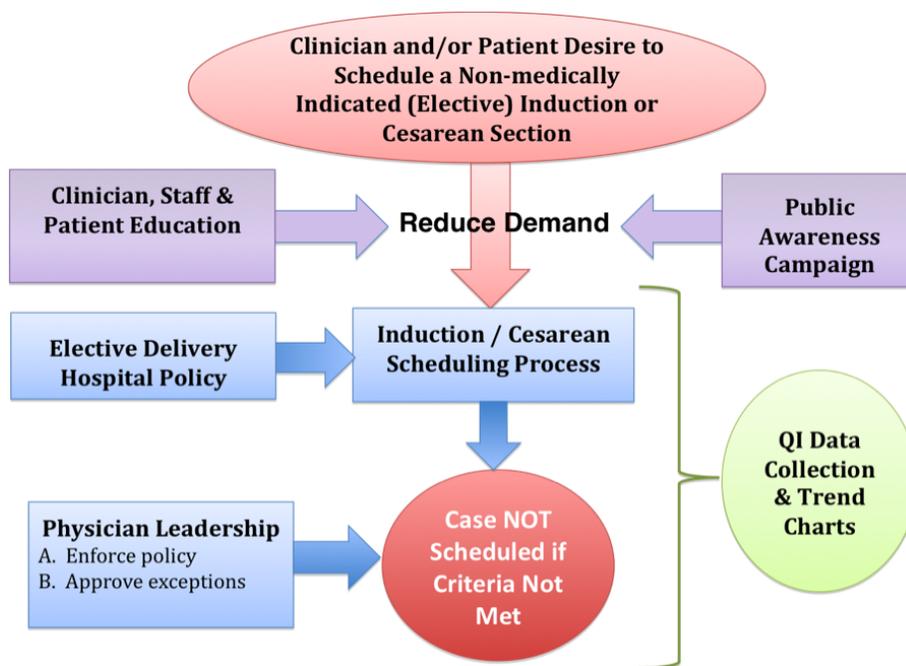
Effective implementation requires strategies and tactics that will drive improvement, mitigate barriers and measure process and outcome results.³⁹ Included in this section are sample documents that can be modified to address local hospital needs.

Although the principles and specific tools provided in this toolkit serve as a useful implementation guide, the toolkit should be tailored to the unique environment of each particular facility. In general, successful implementation includes strong leadership and collaboration among all stakeholders. Patients and practitioners must understand the risks involved with delivering <39 weeks when there is no medical indication. Policies must be established for consistent scheduling processes for inductions and cesarean deliveries. Strong medical leadership must support hospital staff in enforcing best practice. Finally, ambiguity should be expected. For example, gestational age dating may be ambiguous for patients with late prenatal care or those without an early ultrasound. Therefore, when issues or questions arise, they should be addressed and procedures adjusted accordingly.

THE BIG PICTURE

The flowchart below shows primary components to implement a project aimed at eliminating elective deliveries prior to 39 weeks.

Figure 13: Graphic Overview of Key Components



Reduce Demand

- **Clinician/Staff Education:** Provide clinicians with data about their patients' complications (maternal and neonatal). 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.
- **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.

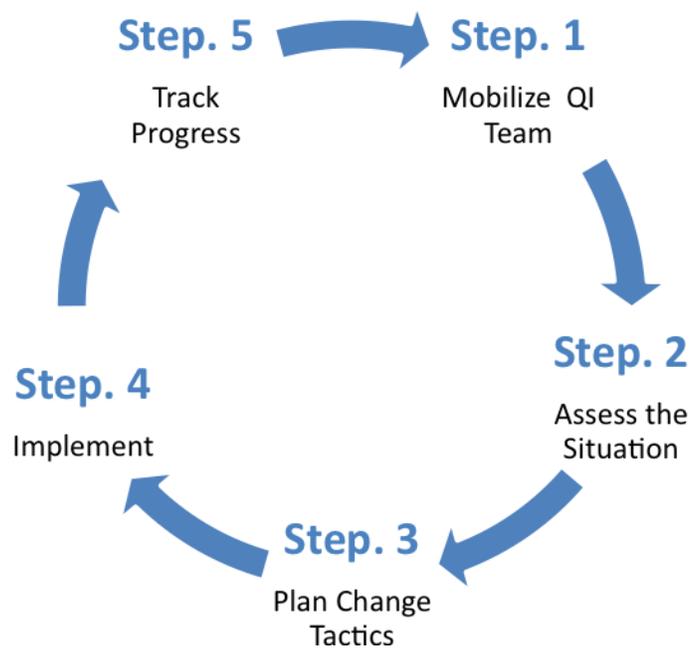
QI Data Collection & Trend Charts

- **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 the 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.

RAPID CYCLE QI METHODOLOGY Mobilize, Assess, Plan, Implement, Track (MAP-IT)⁴⁰

- **Step 1**
Mobilize QI Team
Recruit champions: clinical staff who visualize the ideal, set goals and follow through to realize defined aims.
- **Step 2**
Assess the Situation
Determine current practices for delivery scheduling; identify **QI Data**: criteria for approved induction and cesarean deliveries performed <39 weeks.
- **Step 3**
Plan Change Tactics
Policy, Scheduling Process, Empowered Physician Leadership: Change policies, oversight, scheduling processes, and other relevant policies and procedures (e.g., clinician and patient education) that support a protocol to reduce elective deliveries <39 weeks.
- **Step 4**
Implement
Convene department meetings to conduct **Clinician Education**, influence department culture, gather buy-in and support rollout of change tactics to accomplish the goal.
- **Step 5**
Track Progress
Analyze data and present results to clinical staff via **Trend Charts** on elective deliveries. Review and repeat steps; when necessary, revise newly implemented tactics to ensure sustainable results.

Figure 14: MAP-IT QI Methodology



Primary components are in bold italics and are outlined in the Big Picture Model on page 27.

Adapted with permission from: *Healthy people in healthy communities: A community planning guide using healthy people 2010*. Washington, D.C.: U.S. Department of Health and Human Services. The Office of Disease Prevention and Health Promotion.

IMPLEMENTATION CHECK LIST

Step 1: 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
 - Team members to consider
 - Obstetrician (department chair) - Pediatrician or neonatologist
 - Nurse midwives - Quality or nurse educator
 - L&D charge nurses - L&D manager
 - Director of women's services - Risk manager
 - Lead scheduler - Data analyst/decision support
- State goals clearly; start a MAP-IT Worksheet (see Appendix C)
 - 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)

Step 2: 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. (See data form contained in "Data Collection and QI Measurement" section)
 - 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 were used); 3) indication for delivery.
- Perform a baseline assessment 2-3 months before implementation using the Data Collection Form. (See "Data Collection and QI Measurement" section) Modify data collected as indicated based on the baseline assessment
- Identify barriers to change. (See barriers discussion in this section)
 - 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 knowledge of risks; attitudes about convenience for determining timing of birth
 - Others: _____
- Assess strategies for mitigating barriers, (See strategies discussion in this section)
 - 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

Step 3: Plan Change Tactics

- Develop revised scheduling processes and delivery guidelines based on ACOG criteria.
 - Adopt or modify scheduling algorithm and forms. (See this section.)
 - Basic information documented in forms:
 - Gestational age and how it was determined
 - Reason for scheduling
- 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.
- Implement process to obtain informed patient consent for the procedure. (See this section and Appendix A.)
- Integrate patient education about the importance of the last weeks of pregnancy. (See “Patient Education” section.)
- 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 (See this section and Appendix A.)

Step 4: Implement

- Convene department meetings to secure buy-in and to educate staff about new policies and procedures
- Conduct Obstetrical (OB), clinical provider and staff education
 - See slides in the “Clinician Education” section
 - Outline key points to be used by hospital and office staff when discussing criteria for <39 week delivery (See “Patient Education” section)
- Integrate patient education
 - Distribute patient education materials prior to admission, e.g., at physician offices, prenatal classes, and tours (See “Patient Education” section)
 - 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

Step 5: Track Progress

- Use data and audit tools to track the number of elective deliveries <39 weeks and other key measures. (See “Data Collection and QI Measurement” section)
- 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 on-going data collection to ensure the changes are routinely followed
- Repeat MAP-IT steps and re-adjust the plan after implementing small tests of change

BARRIERS AND STRATEGIES TO MITIGATE BARRIERS

The use of multiple, tailored strategies and tactics to mitigate barriers is the most effective approach to implementation.^{39, 41, 42} Three successful strategies include: 1) discourse (communication); 2) education (formal and informal); and 3) data (audit and trend charts).⁴³ Tactics are the tools to implement strategies and include, for example: new or updated scheduling forms (or some other type of “reminder” document) are communication tactics; grand rounds and toolkits are education tactics; data collection forms are data collection tactics.

Tactics for resolving three common barriers to eliminating non-medically indicated (elective) deliveries prior to 39 weeks are described below.

CLINICIAN BARRIERS: PHYSICIANS WHO ARE RESISTANT

Some physicians are early adopters (change behaviors readily when new data emerges) while other are late adopters (resistant to behavior change).⁴⁴ Late adopters change when they are persuaded to see that risks outweigh perceived benefits of practice.^{45, 46}

Strategies:

Arrange for a respected **physician leader** to talk with reluctant physicians to better understand their position on the issue. Generally, resistance to change around <39 week deliveries is due to:

1. Perception of little or no harm to the baby or increased risk to the mother. Provide a summary of evidence from literature in this toolkit; provide data and feedback on your hospital outcomes in general and specifically on the physicians’ practices.
2. Increased inconvenience. The new/updated scheduling process may be different, with more requirements than before its implementation. It is important to publicize the scheduling process well in advance; train schedulers and nursing staff to facilitate its implementation; streamline the process making it easy for physicians and their office staff to schedule patients.

Some physicians remain resistant to change despite education. Policies and procedures enable (and empower) nurses and clerical staff to consult the department chair, perinatologist, or medical director when physicians are not following scheduling criteria. However, nurses and clerical staff should not be solely responsible for approving or denying physician scheduling requests.

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.

Strategies:

Garner support from **senior administrative leaders** within your organization.

- Meet with risk management officers, quality or safety officers—administrators responsible for reducing institutional risk and liability.
 - Describe project goals; outline the compelling research that elective deliveries prior to 39 weeks should be eliminated
 - Provide statements from Joint Commission, ACOG and March of Dimes to highlight the national prominence of the issue
 - Outline the implementation plan and contents of the toolkit; ask for advice about helping the hospital meet compliance in this area

- Highlight the importance of an early survey (baseline data collection and analysis) to see current hospital trends and the need for resource allocation to accomplish this first step toward compliance
- Meet with department leaders including Nursing and Medical Directors in the Neonatal Intensive Care Unit (NICU) to identify whether data on the number of infants admitted between 37 0/7 and 38 6/7 weeks gestation is being collected
 - Use available data about NICU admissions, keeping in mind that static numbers of NICU admissions for infants of this gestational age does not preclude opportunities for improvement
- Network and connect with other local leaders who are working on similar projects; learn their methods for identifying and allocating resources to meet project goals

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.¹⁶

- Enlist childbirth educators to inform women and their families that the last weeks of pregnancy are important; this information can be disseminated during hospital tours
- Enlist office staff of outpatient providers to give a copy of “Why the Last Weeks of Pregnancy Count” to all women
- Provide a copy of this toolkit to outpatient providers’ offices to reinforce information among clinicians and office staff
- Develop community education campaigns; speak at women’s church group meetings; provide handouts during local community fairs; contact the local newspaper to announce the hospital’s project; host a booth in the hospital lobby where information is distributed to health professionals and hospital visitors
- Document informed consent discussions with patients in the medical record to ensure that women are aware of the risks of early delivery to their infants

Form 1: Scheduling

BEST MEDICAL CENTER
SAMPLE SCHEDULING FORM FOR INDUCTIONS AND CESAREAN SECTIONS
 Call (XXX) XXX-XXXX or Fax (XXX) XXX-XXXX

Name _____ Phone _____
 OB Provider _____ G/P _____
 Type of Delivery Planned: Induction; C/S Desired Date/Time: _____

DATING.....

EDC: _____ Gestational Age at Date of Induction or C/S: _____ (week+day)

EDC Based on: US 10-20 weeks; Doppler FHT+ for 30 weeks; +hCG for 36 weeks
 Other dating criteria: _____ (details)

By ACOG Guidelines, women should be 39 wks or greater before initiating an elective (no indication) delivery. ACOG also states that a mature fetal lung test in the absence of clinical indication is not considered an indication for delivery.

Fetal Lung Maturity test result: _____ Date: _____

INDICATION.....

Obstetric and Medical Conditions (OK if <39 weeks)
(need to deliver <39 weeks dependent on severity of condition)

- Abruption
- Previa
- Preeclampsia
- Gestational HTN
- GDM with Insulin
- ≥41+0 weeks
- PROM
- Fetal Demise (current)
- Fetal Demise (prior)
- Oligohydramnios
- Polyhydramnios
- IUGR
- Non-reassuring fetal status
- Isoimmunization
- Fetal malformation
- Twin with complication

- Heart disease
- Liver disease (e.g. cholestasis of preg.)
- Chronic HTN
- Diabetes (Type I or II)
- Renal disease
- Coag/Thrombophilia
- Pulmonary disease
- HIV infection

Other: _____

 Perinatology consult
 obtained and agrees
 with plan:

 (consultant name)

Scheduled C/S (≥39 wks)

- Prior C/S
- Prior classical C/S
- Prior myomectomy
(may be earlier with fetal lung maturity test)
- Breech presentation
- Other malpresentation
- Patient choice
- Other: _____
- Twin w/o complication
(ok ≥38 wks)

Elective Induction (≥39wks)

- Patient choice/social
- Macrosomia
- Distance
- Other: _____

Description/Details: _____

CERVICAL EXAM (for inductions).....

Date of Exam: _____ (within 7 days of date of induction)

Bishop Score: circle each element of the exam below and add:

Score	Dilation	Effacement	Station	Consistency	Position
0	Closed	0-30%	-3	Firm	Posterior
1	1-2	40-50%	-2	Medium	Midposition
2	3-4	60-70%	-1, 0	Soft	Anterior
3	5-6	80%	+1, +2	-----	-----

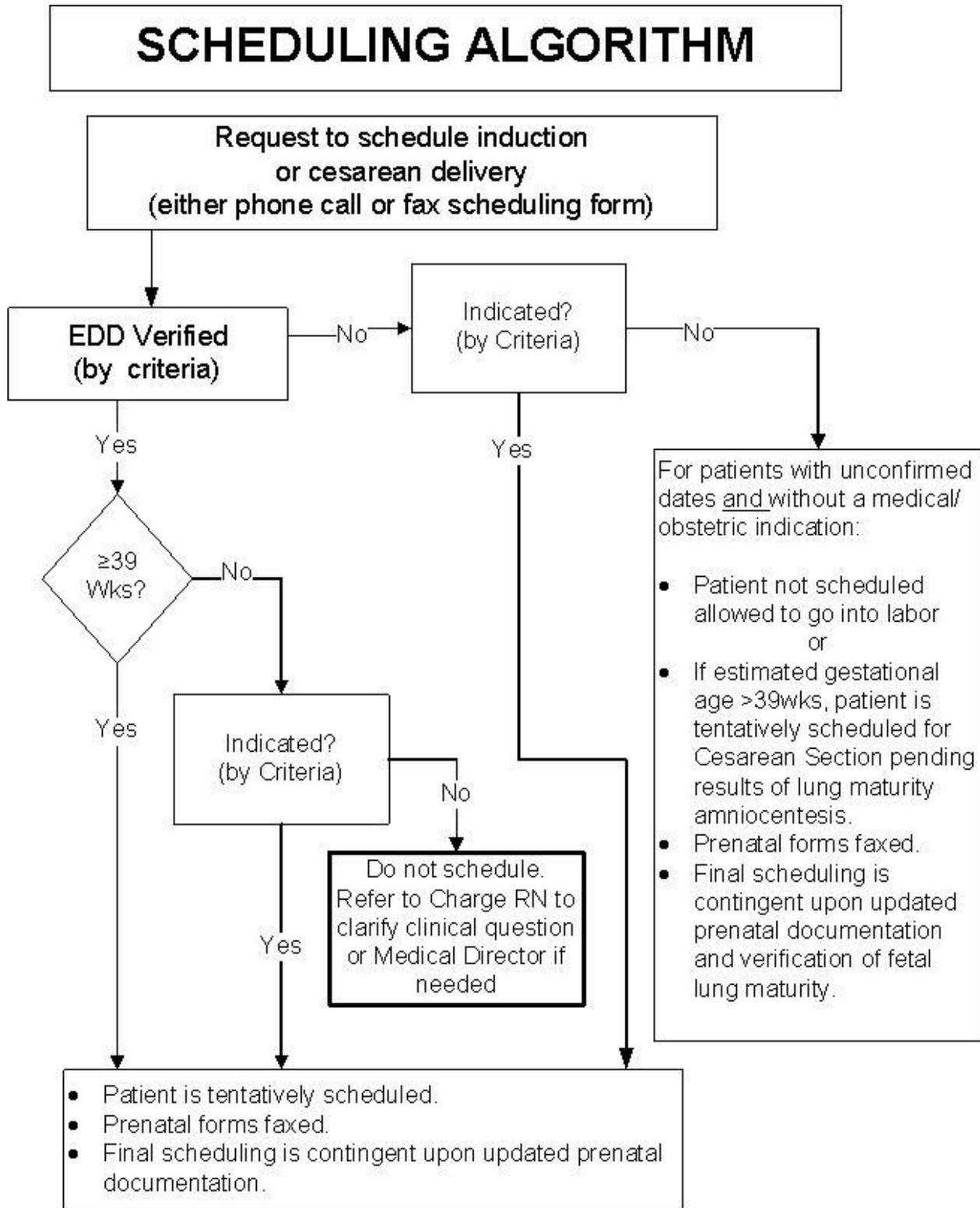
Total Score: _____

This section is used only by those hospitals using cervical exam criteria for scheduling inductions.

SCHEDULING OFFICE USE.....

Scheduled? by: _____ Confirmed Date/Time: _____
 Referred to Dept Chair? PrenatalRecordpresentinLD: Yes

Figure 15: Scheduling Algorithm



SAMPLE POLICY AND PROCEDURE

POLICY INDEX:	Page 1 of 3
POLICY TITLE: Cesarean Section/Induction of Labor Scheduling Policy	
DEPARTMENT AND USERS DISTRIBUTION: Maternal Child Health, Labor and Delivery	

Original Date of Issue: _____

Reviewed Date							
Revised Date							

PURPOSE

The purpose of this policy is to eliminate non-medically indicated (elective) deliveries prior to 39 weeks.

POLICY STATEMENT

Non-medically indicated cesarean section or induction of labor prior to 39 completed weeks gestation requires approval of the Obstetrics and Gynecology department chair or designee. Note: Amniocentesis and documentation of fetal lung maturity is not an indication for delivery <39 weeks.

DEFINITIONS

Medical and obstetric indications for cesarean section or induction of labor that DO NOT require approval from the OB/GYN department chair or designee include:

<u>INDICATION</u>	
<u>Obstetric and Medical Conditions (OK if <39 weeks)</u> <i>(need to deliver <39 weeks dependent on severity of condition)</i>	<u>Scheduled C/S (≥39 wks)</u>
<input type="checkbox"/> Abrupton <input type="checkbox"/> Previa <input type="checkbox"/> Preeclampsia <input type="checkbox"/> Gestational HTN <input type="checkbox"/> GDM with Insulin <input type="checkbox"/> ≥41+0 weeks <input type="checkbox"/> PROM <input type="checkbox"/> Fetal Demise (current) <input type="checkbox"/> Fetal Demise (prior) <input type="checkbox"/> Oligohydramnios <input type="checkbox"/> Polyhydramnios <input type="checkbox"/> IUGR <input type="checkbox"/> Non-reassuring fetal status <input type="checkbox"/> Isoimmunization <input type="checkbox"/> Fetal malformation <input type="checkbox"/> Twin with complication	<input type="checkbox"/> Heart disease <input type="checkbox"/> Liver disease (e.g. cholestasis of preg.) <input type="checkbox"/> Chronic HTN <input type="checkbox"/> Diabetes (Type I or II) <input type="checkbox"/> Renal disease <input type="checkbox"/> Coag/Thrombophilia <input type="checkbox"/> Pulmonary disease <input type="checkbox"/> HIV infection <input type="checkbox"/> Other: _____ <div style="border: 1px solid black; padding: 5px; width: fit-content;"> Perinatology consult obtained and agrees with plan: _____ (consultant name) </div>
	<input type="checkbox"/> Prior C/S <input type="checkbox"/> Prior classical C/S <input type="checkbox"/> Prior myomectomy <i>(may be earlier with fetal lung maturity test)</i> <input type="checkbox"/> Breech presentation <input type="checkbox"/> Other malpresentation <input type="checkbox"/> Patient choice <input type="checkbox"/> Other: _____ <input type="checkbox"/> Twin w/o complication <i>(ok ≥38 wks)</i> <u>Elective Induction (≥39wks)</u> <input type="checkbox"/> Patient choice/social <input type="checkbox"/> Macrosomia <input type="checkbox"/> Distance <input type="checkbox"/> Other: _____

MONITORING

Data will be collected using the hospital Data Collection Form. These data will be aggregated and shared with the clinicians on a regular basis.

POLICY INDEX:	Page 2 of 3
POLICY TITLE: Cesarean Section/Induction of Labor Scheduling Policy	
DEPARTMENT AND USERS DISTRIBUTION: Maternal Child Health, Labor and Delivery	

PROCEDURES

1. Confirmation of Gestational Age

Gestational age needs to be confirmed using one of the ACOG criteria:

- “Ultrasound measurement at less than 20 weeks of gestation supports a gestational age of 39 weeks or greater.”¹¹
- “Fetal heart tones have been documented as present for 30 weeks by Doppler ultrasonography.”¹¹
- “It has been 36 weeks since a positive serum or urine human chorionic gonadotropin pregnancy test.”¹¹

If the patient does not meet ACOG’s criteria for confirmation of gestational age, an amniocentesis to confirm fetal lung maturity after 39 weeks or allowing the patient to go into labor should be considered.

2. Scheduling

- a) Provider or designee contacts the L&D scheduler with the request to schedule the induction or cesarean section. (This may be a phone call or the faxing of the scheduling form.)
- b) The provider or designee provides the L&D scheduler with the woman’s name and other patient identifiers as necessary, indication for the procedure, and the gestational age at the time of the scheduled cesarean section or induction. Note: All components of the hospital scheduling form must be communicated prior to the procedure being scheduled.
- c) If the gestational age is < 39 weeks, the L&D scheduler compares the information provided to them to the predetermined list of medical and obstetric indications for cesarean sections and induction of labor prior to 39 weeks. If the indication is on the list then the procedure is defined as medically indicated and gets scheduled.
- d) If the indication provided does not appear on the approved list AND gestational age is <39 weeks on the requested scheduled procedure date, the L&D scheduler will inform the provider. Note: If the provider requests that the non-medically indicated cesarean section or induction of labor be performed prior to 39 weeks, then the L&D scheduler will inform the provider that he is not authorized to schedule the procedure without documented permission from the OB/GYN department chair or designee.
- e) Women who have medical indications for delivery have priority over women having elective cesarean sections and inductions of labor. These decisions are the discretion of the L&D unit charge nurse in consultation with the designated physician leader.

POLICY INDEX:	Page 3 of 3
POLICY TITLE: Cesarean Section/Induction of Labor Scheduling Policy	
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3. Informed Consent

All patients with a scheduled non-medically indicated (elective) delivery (either cesarean section or induction of labor) prior to 39 weeks will have an informed consent discussion.⁴⁷ The informed consent discussion must be documented in the medical record. The informed consent discussion will include the usual discussion of risks and benefits of induction of labor or cesarean section and also include a discussion of the risks to the baby of being born electively prior to 39 weeks gestation. Note: Hospital leaders may choose to develop an informed consent form to be signed by the patient after her provider has discussed the treatment with her and before the procedure is performed. See Appendix A for sample consent forms developed for use at other hospitals around the country.

REFERENCES

ACOG. (2009). Induction of labor. American Congress of Obstetricians and Gynecologist Practice Bulletin No. 107. *Obstet Gynecol.* 114(2), pp. 386-97.

ACOG. (2004). Informed Consent. American Congress of Obstetricians and Gynecologist Committee Opinion Number 439. August 2004:1-8.

GUIDELINES FOR INFORMED CONSENT DISCUSSIONS

Informed consent is a process for promoting patient autonomy in medical care decision making that includes ongoing, shared information and developing choices for each individual patient. The informed consent process should first establish that the patient is capable of medical decision making and include a discussion between the patient and her care provider about the risks, benefits and complications of the recommended course of treatment and the risks, benefits and complications of any alternative approaches.⁴⁷ Informed consent discussions should be documented in the medical record and hospital leaders may choose to develop an informed consent form to facilitate the documentation process. Informed consent discussions take place before the procedure is performed. Agreement by the patient to a therapeutic plan should be voluntary.

The preferences of patients have significant ethical authority but are not without limits. Physicians have an obligation to not perform actions that are known to cause harm and may refuse to perform procedures that have no documented medical benefits even when requested by their patients.⁴⁸ Therefore, a patient's negative right to refuse unwanted interventions is a powerful patient right. However, the positive right to receive any desired intervention is limited because it is the physician who is granted the authority and license to order diagnostic tests, prescribe medications or perform surgery.⁴⁹

Providers who choose to perform elective deliveries prior to 39 weeks need to supplement the information they currently discuss with patients regarding the risks of induction or augmentation of labor or cesarean delivery. The supplemental information should include patient education materials that describe the risks to the infant who is delivered prior to 39 weeks. The information outlined earlier in the toolkit and in the patient education section can be utilized by clinicians to guide the content of the important discussions, which support a women's ability to make an informed decision.

See Appendix A for sample consent forms developed for use at other hospitals around the country. When selecting procedures, consideration of risks to benefits shifts based on the medical condition of each woman and infant. Thus, informed consent discussions need to be tailored to the specific medical condition of each woman and infant.

Data Collection and QI Measurement

Measuring and reporting key data during the QI implementation process informs leaders and teams about progress and guides strategies for change tactics and further implementation revisions.^{39, 43} This section outlines process and outcome measures that are specific to eliminating elective deliveries <39 weeks gestation. In addition, national quality measures that tend to dictate data reporting to outside entities are highlighted.⁸ The following data collection and measurement section helps support hospitals in meeting and tracking these national objectives.

DATA COLLECTION

As previously outlined in the MAP-IT section, one critical step of successful implementation is defining a data collection plan and refining the data collection process through trial and feedback.

A common mistake is that leaders spend a great deal of time and energy collecting too much data, only to find that they have not collected data on the most critical elements. Thus, data collection should be tailored and minimized to analyze the most important issues surrounding the elimination of non-medically indicated (elective) deliveries. Consider selecting 2-3 quality measures that will inform and support driving change. Selecting too many measures at one time can be overwhelming and frustrating. Identify measures that fit the capacity of the team and add new measures as the initial quality measures are achieved.

Data Collection Planning

- Identify data to be collected, how it will be captured, by whom, and how often.
- Select 2-3 quality measures that can be tracked over time. Examples of types of quality measures and measurement specifications are described in this section and can be collected using the sample Data Collection Form also contained in this section.
- Calculate measures approximately every month based on the customized measurement specifications.
- Collect at least 2-3 months of pre-implementation baseline data. This can be done retrospectively by chart review or prospectively, as other parts of the project are being established, e.g., mobilizing the leaders who will support implementation efforts.
- Develop trend charts to display and communicate results with team members on a regular basis.

Typically, facilities collect data to understand both process and outcome measures. QI results are not immediately apparent when patient outcomes are used as a measure, because outcomes are usually slower to change than processes. Therefore, the first months of QI projects typically focus on process measures.

Baseline Data

Before the project begins, baseline data should be collected. These baseline data help assess the situation and identify areas for improvement. For example, clinicians may not know their volume of elective deliveries prior to 39 weeks because clinicians may not be recording indications for induction and cesarean sections. Similarly, clinicians may not be recording how gestational age is confirmed. Thus, another potential benefit of baseline data collection may be an improvement in the accuracy and completeness of the documentation of the indications of induction or cesarean section and gestational age.

Data Collection

Completion of the sample QI Data Collection Form contained in this section can be utilized to assess implementation progress and to calculate chosen measures. Almost all data fields on the sample QI Data Collection Form can be populated using data collected on the Sample Scheduling Form. Delivery outcomes data can usually be obtained from the L&D logbook.

Trend Charts

Data can be an important tool to inform and to motivate hospital staff. Trend charts are developed to highlight desired QI data measures and are utilized to communicate the amount of progress that has or has not been made toward achieving the end goal.

SELECTING QUALITY MEASURES

The types of measures selected by hospital leaders are based on the project characteristics and national requirements. Examples of quality measures include: 1) Process, 2) Structure, 3) Outcome, and 4) Balancing measures. Table 9 provides definitions of process, outcome and national quality measures for a QI project to eliminate non-medically indicated (elective) deliveries prior to 39 weeks. Examples of these types of measures and types of collection tools are also described.

Measure Type Definitions	Measure Examples	Collection Tools
<p>Process Measures:</p> <ul style="list-style-type: none"> • Are key steps in the workflow that collectively impact outcomes. • Are critical elements of all effective QI implementation plans because they provide immediate feedback on progress being made toward long-term goals. • Rarely provide information about patient outcomes. • May not be easy to identify process measures that are the most critical to success. 	<ul style="list-style-type: none"> • Is the indication for the induction charted? • Does the charted indication meet the scheduling criteria? • Is gestational age charted? • Is it ≥ 39 weeks? • How many mothers had elective deliveries prior to 39 weeks? • What proportion of 37-39-week births had an elective induction or cesarean section? 	<ul style="list-style-type: none"> • It is important to structure the scheduling form in a manner that makes data points easy to identify and collect. • Process flow charts help a team outline all of the processes that affect outcomes.
<p>Outcome Measures:</p> <ul style="list-style-type: none"> • Identify good and bad consequences for the patient (unintended consequences are equally important). • Are the ultimate measure of the success of all QI projects. However, true adverse outcomes are often rare or difficult to collect; therefore, time intervals between rare events are another way to measure outcomes. • Often require a separate data collection approach than that used for collecting process measures. 	<ul style="list-style-type: none"> • Number of elective <39-week births admitted to the NICU. • Frequency of RDS or other neonatal morbidity. • Measurements of the number of shoulder dystocias (balancing measure). 	<ul style="list-style-type: none"> • Outcome measures require some data choices and a very large sample size. Thus, they are typically done in large multi-center trials that provide data for use by smaller centers. • Most centers want to identify one or two outcome measures to keep staff focused on the goal. For example, Intermountain Healthcare collected data on the number of infants electively delivered prior to 39 weeks and NICU admissions.
<p>National Quality Measures:</p> <ul style="list-style-type: none"> • Serve as benchmarks and may be required for outside regulatory agencies like TJC. • May or may not be directly part of the QI data process. 	<ul style="list-style-type: none"> • TJC and the LeapFrog Group both have quality measures for elective deliveries < 39 weeks. 	<ul style="list-style-type: none"> • These organizations provide detailed data collection specifications described later in this section.

QI Data Collection Form for Singleton Scheduled Inductions and Cesarean Sections

Admit Date	Name	OB Initials	Scheduled Induction or Cesarean Section	Bishop Score	Dates			OB/Medical Condition	Sched CS	Outcomes	
					GA (week & day)	Dates confirmed by sono < 20 wk	Mature fetal lung test			Delivery: Spon Vag=SV OPVag=OV Cesarean=CS	NICU Admit
1/1/10	Smith, J	EM	Ind	8	39 + 1	X	PROM	Prior CS Prior Classical CS Prior Myomec Breach/TTrans. Patient Choice	OV	No	
1/5/10	Jones, M	JG	CS		36 + 1	X	Placenta Previa	Elective Ind Choice/Social Macrosomia Distance Other: _____	CS	Yes	
1/6/10	Lee, M	CO	CS		38 + 5	X		Oligo/Polyhydram IUGR Non-reassuring Fetal Status Isoimmunization Heart Dx Liver Dx Renal Dx Coagulation Dx Pulmonary Dx HIV	OV	No	
1/6/10	Carpenter, A	JG	Ind	8	40 + 4	X		Abruption/Previa Chorionamnionitis Fetal Demise Gestational HTN Chronic HTN GDM Diabetes (Type I or II) PROM >41 wks Prior fetal demise	SV	No	
<p>Comments:</p> <ol style="list-style-type: none"> The last two columns are outcome measures that help reinforce the change process. The lung maturity testing column is included as an option to document lung maturity for scheduled deliveries with a medical/OB indication, e.g. placenta previa. Lung maturity testing as a column on this log is not meant to imply that elective induction at <39 weeks is acceptable if there is a mature lung test (this is contrary to ACOG guidelines) This data collection tool is for women with one fetus since the national guidelines for <39 weeks are specified for singletons only; multiples have different gestational age guidelines. A hospital may choose to collect data on multiples if they want to track this population. <p>Form options:</p> <ol style="list-style-type: none"> NICU length of stay may be tracked instead of or in addition to NICU admission. Bishop Score and Fetal Lung Maturity Test do not relate to the recommended QI measures but may be of interest to QI project leaders. These columns can be removed or revised based on local hospital guidelines. Data collection may be limited to women who give birth >=37 weeks 0 days gestation or extended to include all women who give birth. 											

MEASURE SPECIFICATIONS AND GUIDELINES

Outlined below are the specific quality measures that can be used to assess critical elements of the non-medically indicated (elective) deliveries <39 weeks. The numerators and denominators that are used to compute the measures are defined. In addition, there is information about how to obtain the necessary data to support the calculation of the following quality measures.

- Measures 1 and 2 are among the first measurements performed to identify how well clinicians document and collect data on women with the most accurate measurement of gestational age and indications for scheduled deliveries.
- Measures 3 and 4 are done to analyze the *specific issue*: how many inductions between 37 0/7 days to 38 6/7 weeks are non-medically indicated (elective) and how many cesarean births are non-medically indicated (elective)?
- Measure 5 summarizes the whole project: how many inductions or cesarean births between 37 0/7 days to 38 6/7 weeks are non-medically indicated (elective)?
- Measure 6 is essentially identical to TJC measure. It calculates of ALL low-risk women (without a medical condition) between 37 0/7 days to 38 6/7 weeks, how many have inductions or cesarean births that are non-medically indicated (elective)?
- Measure 7 tracks an important outcome of the project – reduction in the number of infants admitted to the neonatal intensive care unit (NICU).

RECOMMENDED PROCESS MEASURES

Measurement 1: Percent of women with scheduled induction/cesarean section and gestational age confirmed by sonogram

- Purpose:** Identify how well clinicians document gestational age using the most accurate measurement technique.
- Numerator:** Number of women from the denominator with “Gestational Age Confirmed by Sonogram” checked on Data Collection Form
- Denominator:** Total number of women with scheduled induction/cesarean section (at all gestational ages)
- Target:** 100% of women with scheduled induction/cesarean section will have gestational age confirmed by sonogram recorded on the Data Collection Form. (Once the target of 100% is routinely reached, this measure is no longer needed.)

Measurement 2: Percent of women with scheduled induction/cesarean section and a medical or obstetric indication charted

- Purpose:** Identify how well clinicians document indications for scheduled deliveries.
- Numerator:** Number of women from the denominator with a medical or obstetric indication recorded on the Data Collection Form (in either “Indication” column)
- Denominator:** Total number of women with scheduled induction/cesarean section (at all gestational ages)
- Target:** 100% of women with scheduled induction/cesarean section will have a medical or obstetric indication recorded on the Data Collection Form. (Once the target of 100% is routinely reached, this measure is no longer needed.)

Measurement 3: Percent of inductions between 37 0/7 and 38 6/7 weeks that are non-medically indicated (ELECTIVE).

- Purpose:** Identify how many inductions in the Early Term time period are non-medically indicated (elective).
- Numerator:** Number of women from the denominator with an indication in the “Elective” column on the Data Collection Form; **excludes** active labor or pre-labor rupture of membranes
- Denominator:** Total number of women with singleton births and a scheduled induction between 37 0/7 and 38 6/7 weeks
- Target:** 0% of women with singleton births will have scheduled non-medically indicated (ELECTIVE) delivery between the gestational period of 37 0/7 and 38 6/7 weeks.

Measurement 4: Percent of scheduled cesarean sections between 37 0/7 and 38 6/7 weeks that are non-medically indicated (ELECTIVE.)

- Purpose:** Identify how many scheduled cesarean sections occur in the Early Term time period that are non-medically indicated (elective).
- Numerator:** Number of women from the denominator with an indication in the “Elective” column on the Data Collection Form; **excludes** active labor or pre-labor rupture of membranes
- Denominator:** Total number of women with singleton births and a scheduled cesarean section between 37 0/7 and 38 6/7 weeks
- Target:** 0% of women with singleton births will have scheduled non-medically indicated (ELECTIVE) cesarean section between 37 0/7 and 38 6/7 weeks.

Measurement 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)

- Purpose:** Summarizes the whole project – Identifies how many scheduled inductions AND scheduled cesarean section occur in the Early Term time period that are non-medically indicated (elective).
- Numerator:** Number of women from the denominator with an indication in the “Elective” column on the Data Collection Form; **excludes** active labor or pre-labor rupture of membranes (Add numerators from Measures 3 and 4)
- Denominator:** Total number of women with singleton births and a scheduled induction or cesarean section between 37 0/7 and 38 6/7 weeks (Add denominators from Measures 3 and 4)
- Target:** 0% of women with singleton births will have scheduled non-medically indicated (ELECTIVE) induction or cesarean section between 37 0/7 and 38 6/7 weeks.

OPTIONAL PROCESS MEASURE

Measurement 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)

Note: Optional and requires additional data beyond the data collection form to create the denominator and is essentially identical to the Joint Commission measure PC-01.

- Purpose:** Changes the denominator from Measure 5 and asks of ALL low-risk women (without a medical condition) in Early Term time period, how many have inductions or cesarean births that are elective?
- Numerator:** Number of women from the denominator with scheduled induction or cesarean section and an indication in the “Elective” column on the Data Collection Form; **excludes** active labor or pre-labor rupture of membranes (note: this is the same numerator as Measure 5)
- Denominator:** Total number of ALL low-risk women (singleton deliveries between 37 0/7 and 38 6/7 weeks) without a known medical indication. This is obtained from another source other than the data collection from most hospitals would use labor log system (paper or electronic)
- Target:** 0% of low-risk women will have a scheduled non-medically indicated (ELECTIVE) induction or cesarean section prior to 39.0 weeks.

RECOMMENDED OUTCOME MEASURE

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

- Purpose:** Tracks reduction in the number of infants admitted to the NICU or transferred to another hospital.
- Numerator:** Number of infants from women in the denominator admitted to the NICU (or transferred to another hospital)
- Denominator:** Total number of women with singleton births and a scheduled induction or cesarean section between 37 0/7 and 38 6/7 weeks (same denominator as Measure 5)
- Target:** 0% of infants will be admitted to the NICU.

Measurement 7 – Alternate:

An alternative or additional measure that more accurately tracks outcomes and costs is the measurement of NICU length of stay (NICU-LOS) for newborns born between 37 0/7 days to 38 6/7 weeks. However, the NICU-LOS measure is more difficult to collect.

OVERVIEW OF NATIONAL QUALITY MEASURES

Outlined below are national quality measures recommended by the Joint Commission and Leapfrog to reduce elective deliveries prior to 39 weeks. This toolkit has been designed to support hospital leaders' efforts to achieve their quality improvement goals and meet national guidelines. At present benchmarks do not exist but will be set by these national organizations once data have been collected and analyzed.

THE JOINT COMMISSION

National Quality Core Measures: Perinatal Care Measure Set—
PC-01 Elective Delivery (April 2010 specifications)

<http://manual.jointcommission.org/releases/archive/TJC2010A1/MIF0166.html>

Description: Of all 37-39 week singleton births without a medical or obstetric medical condition, how many mothers are having electively scheduled deliveries (induction or cesarean section)?

Type of measure: Process

Numerator: Number of women (delivering singleton newborns between ≥ 37 and < 39 weeks gestation without a medical/obstetric indication (Table 10), and not in active labor or with spontaneous rupture of membranes) with a cesarean section or an induction of labor

Denominator: Total number of women delivering singleton newborns between ≥ 37 and < 39 weeks of gestation without a medical/obstetric indication (Table 10), and not in active labor or with spontaneous rupture of membranes

Sampling: Yes, per protocol. (Entire population is also accepted.)

Comment: This measure is likely to be the most widely accepted national measure definition but requires data collection based on chart review. Data collection can be facilitated with well-designed logbooks described earlier. The Joint Commission quality measure is newly developed, so additional tweaking is most likely to occur over the next few years. For example, it is likely that new exclusions may be added after hospital leaders have more experience with data collection.

THE LEAPFROG GROUP

Normal Deliveries-1: Elective Delivery Prior to 39 Completed Weeks Gestation (April 2009 specifications)⁵⁰

Description: Of all births > 37 weeks without a medical or obstetric condition, how many women with singleton births at 37-39 weeks are having electively scheduled deliveries (induction or cesarean section)?

Type of measure: Process

Numerator: Number of women with singleton births (≥ 37 gestation during the reporting period with excluded populations (medical or obstetric conditions, Table 10) with a cesarean section or an induction of labor and < 39 weeks gestation

Denominator: Total number of women with singleton births ≥ 37 weeks gestation during the reporting period with excluded populations (medical or obstetric conditions, Table 10)

Sampling: No

Comment: The Leapfrog measure specifications may be superseded by those outlined by TJC.

Table 10: Comparison of National Specifications for Medical Conditions that May Justify a Scheduled Delivery Prior to 39 weeks Gestation		
ACOG¹¹: “Examples of Conditions That May be Indications for Induction of Labor”	NQF⁸ and LeapFrog⁵⁰: “Specifications for Early Medically-Indicated Delivery” (with ICD9 codes)	TJC¹⁹: “Conditions Justifying Delivery <39 weeks” (PC-01 version 04/10) (with ICD9 codes)
Abruption	Placental abruption, placenta previa, unspecified antenatal hemorrhage (641.x)	<same as NQF>
Chorioamnionitis	<i>No ICD9 included</i>	<i>No ICD9 included</i>
Fetal demise	Fetal demise (656.41, V27.1)	<same as NQF> plus pregnancy with diagnosis of stillbirth (V23.5)
Gestational hypertension, preeclampsia, eclampsia, chronic hypertension	Any hypertensive disorder (642.x)	<same as NQF>
Pre-labor rupture of membranes (PROM)	Ruptured membranes (658.11)	<same as NQF> plus delayed delivery after rupture of membranes (658.21)
Post-term pregnancy	Post-dates (645.x)	<same as NQF>
Diabetes mellitus	Preexisting diabetes mellitus (648.0), gestational diabetes (648.8)	<same as NQF>
Renal disease	Renal disease (646.2)	<same>
Chronic pulmonary disease	<i>No ICD9 included</i>	<i>No ICD9 included</i>
Antiphospholipid syndrome	Maternal coagulation defects in pregnancy, (649.31)	<same as History>
Other maternal diseases	Liver diseases (646.71), congenital cardiovascular disorders (648.5), other cardiovascular diseases (648.6)	<same as NQF>
<i>Not included</i>	<i>Not included</i>	Asymptomatic HIV infection (V08), HIV disease (042)
Fetal compromise	<i>Not included</i>	Fetal distress (656.31), abnormal fetal heart rate (659.71)
Severe fetal growth restriction	Intrauterine growth restriction (IUGR) (656.51)	<same as NQF>
Isoimmunization	Isoimmunization related to Rh (656.11) or related to other types (656.21)	<same as NQF> plus fetal-maternal hemorrhage (656.01)
Oligohydramnios	Oligohydramnios (658.01)	<same as NQF>
<i>Not included</i>	Polyhydramnios (658.11)	<same as NQF>
<i>Not included</i>	Multiple gestation (651.x)	<same as NQF>
<i>Not included</i>	Malpresentations (breech, face, brow, transverse, unstable lie or high head at term (652.x)	<i>Not included, except for unstable lie (652.01)</i>
<i>Not included</i>	<i>Not included</i>	Fetal central nervous system malformation or chromosomal abnormality, suspected damage to the fetus from viral or other diseases in the mother, drugs, radiation (655.01, 655.11, 655.31, 655.41, 655.51, 655.61)

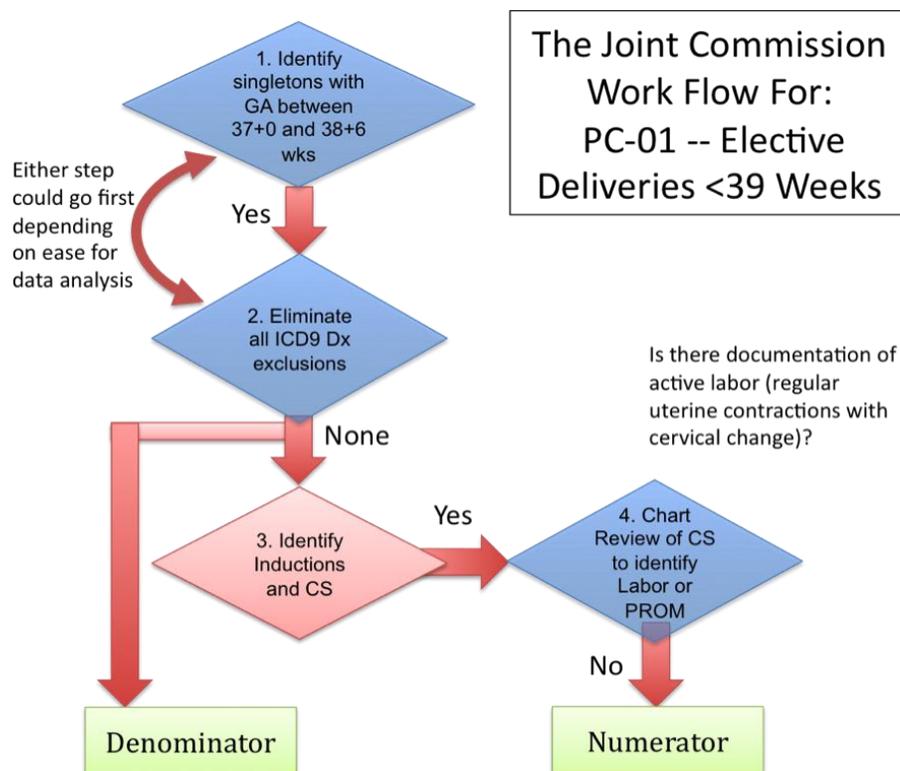
Data Collection for Quality Measurement

Data collection to track the number of non-medically indicated (elective) deliveries performed before 39 weeks gestation at individual hospitals include some data elements that are available in administrative data sets and other data elements that are not. The data elements that are available in Patient Discharge Diagnosis (PDD) datasets include ICD9 diagnosis and procedure codes. Limitations of PDD datasets include the lack of any codes for gestational age; poor coding for induction of labor (often confused with labor augmentation); and the absence of a code for labor (which is a critical required element for assessment of whether the cesarean section was elective (scheduled or indicated.) Although there is an ICD9 diagnosis code for rupture of membranes there is no evidence that this code is consistently used when a repeat cesarean section is performed or when labor is induced at term.⁵¹⁻⁵³ The lack of consistent coding of the presence of rupture of membranes will affect the ability of administrative data to accurately capture the number of women who had an elective delivery prior to 39 weeks.

The data elements that are available on the birth certificate include gestational age, birth method and a limited number of diagnoses. However, there is some concern as to the accuracy of the gestational age that is recorded. For example, hospitals vary as to how they identify the final or best gestational age that gets recorded on the birth certificate. Furthermore, maternal diagnoses are variably recorded on the birth certificate.^{51, 52} Birth certificate data typically is not helpful to hospital leaders but are useful for state public health surveillance programs since these data provide the ability to perform some population tracking such as following the portion and trends of all births occurring between 37 to 39 weeks of gestation.

In recognition of the limitations of administrative data sets, The Joint Commission Perinatal Core Measure PC-01 has outlined data collection steps that require primary chart review for at least some of the data elements.¹⁹ (Refer to Figure 16)

Figure 16. The Joint Commission Work Flow For: PC-01 – Elective Deliveries <39 Weeks



To circumvent the limitations in administrative datasets, hospital leaders have begun to utilize standardized data collection forms that prompt them to capture the key data that are required by the Joint Commission. An example is the “QI Data Collection form for Singleton Scheduled Inductions and Cesarean Sections.” This sample form is meant to be used in conjunction with the sample scheduling form. When both forms are used together they help the front-line leaders streamline data collection and minimize the need for data collection from chart review.

The Joint Commission allows hospital leaders to monitor compliance with PC-01 “Elective Deliveries <39 Weeks” by sampling approximately 200 cases per year.¹⁹ However, for the purposes of supporting the goals of a QI project (Rapid Change Cycles using either MAP-IT or PDSA), it is preferable to collect data on all cases during the baseline and active implementation phases of the project. More comprehensive data collection provides leaders with the necessary information to identify practice patterns, obtain trend data, and have more accurate statistics. Once the QI project goals have been achieved, the frequency of monitoring can be reduced to maintenance monitoring based on the needs of the local leader. The tools developed and included in this toolkit are meant to facilitate the hospital leader’s data collection efforts and decisions and should be tailored to the individual population needs. Table 11 summarizes four commonly available data collection sources of key data elements for measuring non-medically indicated deliveries prior to 39 weeks.

**Table 11:
Data Element Sources with Combined Rankings of Availability and Reliability⁵⁰⁻⁵²**

Data Element	Medical Record (chart)	Labor Logbook or Unit-level Electronic Data (e.g. Fetal monitor systems)	Patient Discharge Diagnosis record (e.g. UB-92)	Birth Certificate
Singleton	Good	Good	Good	Good
Mother’s age	Good	Good	Good	Good
Gestational age	Good	Good	Not available	Fair
Maternal diagnoses	Good	Fair-Good	Fair-Good	Fair-Poor
Cesarean section	Good	Good	Good	Good
Induction	Good	Good	Fair (often confused with augmentation)	Fair (often confused with augmentation)
Labor present prior to CS or induction	Good	Fair	Not available	Not available
Rupture of membranes present prior to CS or induction	Good	Good	Sometimes available	Not available

Good = estimated >95% present and accurate
 Fair = estimated 50-70% present and accurate
 Fair-Poor = estimated 20-70% present and accurate

Clinician Education

Effective QI implementation begins with educating clinical providers and support staff about changes that are necessary for improving care.⁴⁴ This section provides resources to educate clinical staff about the consequences and dangers of elective deliveries <39 weeks and includes professional education slides and clinician frequently asked questions (FAQs).

CLINICIAN SLIDE PRESENTATION

A slide deck with presentation notes was developed to help engage clinical professionals in eliminating non-medically indicated (elective) deliveries <39 weeks. Institutions are encouraged to tailor this presentation to fit the culture and needs of their audience. The presentation outlines the research on the risks associated with early term deliveries and the quality improvement steps an institution can complete to reduce non-medically indicated scheduled deliveries. Copies of the slides are contained in Appendix E and a downloadable version of the toolkit and slide deck can be found at www.marchofdimes.com and www.cmqcc.org.

CLINICIAN FREQUENTLY ASKED QUESTIONS (FAQ's)

Q 1: *Will delaying elective deliveries to 39 weeks increase the rate of other complications (e.g., stillbirth, macrosomia or preeclampsia)? (This is a question about possible unanticipated harms.)*

A1. No.

Several recent intervention trials address these concerns. Oshiro, et al.¹⁸ note that delaying elective induction until 39 weeks is associated with the following benefits:

- Decreased stillbirth rate by >50%, with greatest improvement in the 37-38 week groups
- Decreased rates of postpartum anemia, meconium aspiration, Apgar scores <5 at 1 minute, and cesarean deliveries due to fetal distress
- No change in rates of chorioamnionitis, endometritis, macrosomia, meconium aspiration syndrome, neonatal ventilator use, respiratory distress syndrome, or neonatal sepsis
- Oshiro et al. note a slight increase in the rate of preeclampsia; however, Fisch et al. report that preeclampsia rates were unchanged when the number of early inductions decreased^{18, 37}

Q 2: *Does early induction prior to 39 weeks benefit the babies of a women with a history of large babies or impending or suspected macrosomia?*

A 2: No.

Macrosomia—particularly “impending” macrosomia—is controversial as an indication for induction. According to the ACOG Technical Bulletin on Macrosomia, retrospective studies did not show a reduction in shoulder dystocia in infants born to women who were induced, but there was a doubling of the cesarean section rate.⁵⁴ In a prospective trial, the incidence of shoulder dystocia in infants was identical between those women who were induced and those who were allowed to spontaneously labor without a change in the cesarean section rate.⁵⁵ Macrosomia rates remained stable after inductions prior to 39 weeks were eliminated. Macrosomia is not an acceptable medical indication for induction.

Q 3. *Is it beneficial to induce diabetic women prior to 39 weeks?*

A 3. Generally, no.

Women with gestational diabetes and good control on diet are not at increased risk for perinatal complications prior to 41 weeks, compared to the general population. Therefore delivery is generally considered elective prior to 41 weeks.

Women with diabetes and good control on medications (e.g., insulin or oral agents) who are clinically stable may be offered delivery after 39 weeks but prior to their due date. Amniocentesis for lung maturity is recommended prior to 39 weeks. However, even when there is a mature fetal lung test, there is an association with increased neonatal morbidity if an infant is delivered prior to 39 weeks, compared to delivery at 39 to 40 weeks.³¹

Q 4: *Do women with an indication for induction, such as well-controlled chronic hypertension, benefit from delivery prior to 39 weeks?*

A 4. Generally, no.

Most women with stable conditions do not need to be induced prior to 39 weeks. If their clinical picture changes, induction prior to 39 weeks should be considered.

Q 5: *Why do elective cesarean sections have more neonatal complications than elective inductions?*

A 5: Physiologic changes occur during the last few weeks of pregnancy to prepare the fetal lungs for birth.⁵⁶ Active labor and vaginal birth further stimulate lung maturation and clearance of fluid from the neonate's lungs. Delivery prior to 39 weeks worsens this transition considerably. A recent study by Tita et al. showed increased neonatal morbidity and mortality with declining gestational age. Overall, 10% of all infants experienced complications when born electively before 39 weeks.⁷

Q 6: *How should one proceed with elective delivery if there is a dating discrepancy? How can dating discrepancies between the last menstrual period and ultrasound be resolved?*

A 6: Dating discrepancies usually do not matter with spontaneous labor. However, with elective delivery before 39 weeks, the more conservative gestational dating parameter should be used. When performed in a skilled unit, the margin for error for a second-trimester ultrasound is 10 or fewer days. Beyond that, pregnancies are generally re-dated by the scan. Clinical correlation can help determine the best dating.¹¹ When this occurs and clinicians review dating with a patient, it is common for patient to state she is unsure of her menstrual dating. When patients are unsure of menstrual dating, ultrasound dating is the best parameter. On a population basis, genetic screening tools use ultrasound dating because it is more accurate than patient recollection.

Q 7: *Why do ACOG guidelines recommend that fetal lung maturity be determined by amniocentesis when elective delivery is planned and when gestational age is questionable, even when gestational age appears to be >39 weeks?*

A 7: ACOG's recommendations aim to protect patients and physicians. Therefore, amniocentesis should be performed to confirm fetal maturity in patients undergoing any elective delivery if they are not term based on ACOG-defined dating criteria.¹¹ For instance, a patient presenting for care at 32 weeks (dated by late sonogram) is subject to ultrasound standard error of ± 3 weeks. Based on that error range, the patient would not meet ACOG criteria for elective delivery at term, even if the single scan indicated a gestational age of 39+2 weeks.

Q 8: *Are there disadvantages to determining lung maturity by amniocentesis when elective birth is planned prior to 39 weeks?*

A 8: Yes.

Lung maturity is only one aspect of newborn health. Feeding, temperature control and jaundice are other issues that affect early term infants. ACOG guidelines state that mature fetal lung study on amniotic fluid is not an indication for an elective delivery prior to 39 weeks.¹¹ A recent study compared neonatal outcomes for elective repeat cesarean births performed at 37-38+6 versus 39+ weeks in women with confirmed mature amniotic fluid analysis.³¹ The related risks of neonatal issues were nearly 2-6 times greater in younger age groups. In addition, even when there is a mature fetal lung test there is an association with increased neonatal morbidity if an infant is delivered prior to 39 weeks, compared to delivery at 39 to 40 weeks.

Q 9: *Is there a difference between augmentation and induction?*

A 9: Yes.

Augmentation is defined as administration of oxytocin in a woman who is already in labor as a treatment for an arrest or protraction disorder.

Induction is defined by ACOG as attempting “to achieve a vaginal delivery by stimulating uterine contractions before the onset of spontaneous labor.”¹¹ Induction also encompasses cervical ripening.

Patients with irregular contractions without cervical change are not considered to be in labor. Therefore, the use of oxytocin in this setting would be an induction, not augmentation.

Q 10: *Should informed consent be obtained for any elective inductions before 39 weeks? What if there is a medical indication?*

A 10: Yes.

This is an evolving area. The 2009 ACOG Practice Bulletin on induction of labor supports obtaining informed consent from all women who are induced.¹¹

Any induction consent discussion should include the risks of the induction to the infant. Informed consent discussions need to be documented in the medical record. Informed consent discussions should occur whether the induction is elective or medically indicated. A standardized form that documents the informed consent discussion can assist providers with documentation while educating both medical staff and patients about associated perinatal risks.

Q 11: *In a multi-provider system, how is compliance documented and compared among the different physicians and other clinicians?*

A 11: Review the documentation; chart reviews and check lists can identify areas for improvement. The easier it is to document, the better compliance will be. As with an operating room “time out,” it may be necessary to deny patient admissions if documentation items are absent (e.g., informed consent).

Q 12: *How do hospitals handle situations in which the doctor wants to induce prior to 39 weeks and provides an indication that cannot be confirmed in the chart, such as pregnancy-induced hypertension with normal blood pressure or ruptured membranes with no evidence of leaking or ferning?*

A 12: These types of scenarios can be a challenge and can impact quality of patient care. Hospital and OB department leaders must guide development of appropriate definitions of preeclampsia, for example, to avoid misuse of clinical terms. QI implementation based on evidence-based decisions at the leadership level leads to higher quality standardized care that is consistent among OB providers.

When justifiable disagreements occur, nurses and other staff should not be expected to question a provider; policies for documentation and approval processes should be designed to assess any persistent concerns around inductions. We recommend that when there is a disagreement that a process is developed for resolving these conflicts in a positive manner. When disagreements occur these can provide important learning opportunities and, with that in mind, details that led to the disagreement can be monitored and tracked by a perinatal quality improvement committee. Reviewing why these types of disagreements occur is important if several providers are empowered to determine exceptions to the policy and procedure.

Q 13: *Are there incentives to improve provider documentation?*

A 13: Yes.

One of the benefits of well-designed, standardized documentation and checklists is that they save time for the OB. From an incentive standpoint, adequate documentation allows the most efficient care of their patient (i.e., care does not start until the documentation is complete). From a disincentive standpoint, failure to comply with documentation standards may invoke time-consuming re-credentialing reviews.

Q 14: *Did any of the studies identify the need to change staffing levels?*

A 14: No specific studies have examined impact of staffing level with the elimination of elective deliveries before 39 weeks. However, multiple studies have demonstrated that reducing elective inductions in patients with unfavorable Bishop Scores have decreased the patients' time in labor and delivery by an average of 4 to 6 hours.

Failed inductions that result in cesarean sections increase postpartum length of stay. One reason Intermountain Healthcare began its induction project was to specifically reduce inductions and length of stay in L&D and postpartum.

Q 15: *Can we expect doctors to move their patients to other hospitals with less restrictive induction/cesarean policies?*

A 15: Perhaps.

It may be helpful to stress patient safety as the key issue and to inform doctors that tracking deliveries prior to 39 weeks is becoming a common quality measure among multiple national organizations, including ACOG. In addition, multiple states are planning to publicly report compliance with these measures. Thus, it is a matter of time before hospital leaders at other hospitals in their community will also begin to implement this change.

Q 16: What about using membrane stripping to induce labor before 39 weeks gestation?

A 16: Membrane stripping is a type of induction procedure and should not be performed for elective induction of labor prior to 39 weeks.

A recent Cochrane review found: “Routine use of sweeping of membranes from 38 weeks of pregnancy onwards does not seem to produce clinically important benefits.”⁵⁷ The large majority of the studies included in the review included women who were after 39 weeks gestation; stripping of membranes was being performed in an effort to prevent post-date pregnancies.

If there is a medical indication that necessitates early delivery, then more effective induction of labor methods should be utilized. Stripping of membranes prior to 39 weeks is not recommended.

ADDITIONAL RESOURCE WEBSITE LINKS ARE HIGHLIGHTED IN THE APPENDICES.

Patient Education

Deliveries are scheduled for non-medical reasons prior to 39 weeks gestation more frequently.⁷
¹² Women request earlier deliveries without knowing the negative clinical implications. A survey of insured women who recently gave birth (Goldenberg 2009) found that 25.2% of women defined full-term as 39-40 weeks; however, 92.4% of women reported that giving birth before 39 weeks was safe.¹⁶ This section outlines available resources, key patient talking points, common patient questions and websites to reference while educating women about the importance of reaching 39 or more weeks gestation.

KEY PATIENT EDUCATION MESSAGES

Many women are unaware that critical fetal brain growth and development occurs during the last weeks of pregnancy:

- A baby's brain at 35 weeks weighs two-thirds of what it will weigh at 39-40 weeks.
- The volume of the brain's white matter increases five-fold during weeks 35-41.
- Lower-brain functions mature first; the cerebral cortex is last to develop. The cerebral cortex controls higher-order functions such as cognition, perception, reason and motor control
- Cerebral cortex volume at 34 weeks is 53% of the volume it is at 39-40 weeks.
- A baby's brain organizes during the late preterm period, including critical development of synapses, axon growth, dendrites, and neurotransmitters.
- Evidence of late preterm brain immaturity is seen in problems with breathing, apnea, heart rate, sleeping, and feeding.

PATIENT EDUCATION RESOURCE MATERIALS



March of Dimes bilingual booklet “Why the Last Weeks of Pregnancy Count”

This brochure explains the importance of avoiding scheduled induction or cesarean section for non-medical reasons before 39 weeks of pregnancy. It describes a baby's growth and development in the last few weeks of pregnancy and includes questions a woman can ask her provider about scheduled deliveries. The booklet is recommended for use with the Late Preterm Brain Development Card. Content is 11 pages in each language (English & Spanish). The booklet (#09-2428-09) is available by calling 1-800-367-6630 or online at marchofdimes.com/catalog. Information also is available at:

http://marchofdimes.com/prematurity/index_women_48590.asp

and in Spanish at: http://nacersano.org/prematuro/9323_10953.asp

March of Dimes Late Preterm Brain Development Card

This card is for health care providers to use during discussions with patients who are considering elective induction or cesarean section before 39 weeks for convenience. The card should not simply be passed out to pregnant women. Providers need to discuss the information with their patients.

The card shows graphic representations of fetal brain growth and maturation in the last months of pregnancy. Bullet points summarize the increased risks for late preterm compared with term infants. The card clearly states that its purpose is strictly informational and is not intended to be used as medical advice. It is particularly useful for educating women with limited knowledge about pregnancy and fetal development, especially first time and adolescent moms.

The card (#37-2229-09) is available by calling 1-800-367-6630 or online at marchofdimes.com/catalog. Information is also available at: http://marchofdimes.com/prematurity/index_women_48590.asp

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

A baby's brain at 35 weeks weighs only two-thirds of what it will weigh at 40 weeks.

35 weeks **40 weeks**

- In the last six weeks of pregnancy, your baby's brain adds connections needed for balance, coordination, learning and social functioning. During this time, the size of your baby's brain almost doubles.
- Babies born early have more learning and behavior problems in childhood than babies born at 40 weeks.
- Babies born early are more likely to have feeding problems because they can't coordinate sucking, swallowing and breathing as well as full-term babies.
- Babies born early are likely to have breathing problems, like apnea. Apnea is when a baby stops breathing.
- Babies born early are more likely to die of sudden infant death syndrome (SIDS). SIDS is when a baby dies suddenly and unexpectedly, often during sleep.

To order our catalog or multiple copies of our materials, call 1-800-367-6630. #37-2229-07 Late Preterm Brain Development Card 1/08

March of Dimes materials are for information purposes only and are not to be used as medical advice. Always seek medical advice from your health care provider. Our materials reflect current scientific recommendations at time of publication. Check marchofdimes.com for updated information. Modeled after a fetal brain card developed by the Healthy Babies Are Worth the Wait™ Initiative.

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Healthy Babies are Worth the Wait™ Toolkit for Community Partners

This kit is designed for use by clinical and public health providers and other community healthcare entities interested in taking action to prevent preterm birth by educating pregnant women and the general public. Additional materials to help ensure that moms-to-be have the care and information they need to maintain healthy, full-term pregnancies, in order to give their babies the best possible start in life, can also be found on the prematurity prevention website at:

<http://www.prematurityprevention.org/professionals.html>

Thinking About Inducing Your Labor: A Guide for Pregnant Women

This online brochure from the National Agency for Healthcare Research and Quality provides patient information on elective inductions:

<http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=353>

Lamaze International has multiple resources for expectant parents.

One online resource is the Healthy and Safe Birth Practice #1 entitled Let Labor Begin on Its Own. This resource can be found on-line at:

<http://www.lamaze.org/ChildbirthEducators/ResourcesforEducators/CarePracticePapers/LaborBeginsOnItsOwn/tabid/487/Default.aspx>

Elective Induction

This online information from IHC provides information for women on elective inductions:

<http://intermountainhealthcare.org/services/womennewborn/pregnancy/labordelivery/Pages/ElectiveInduction.aspx>

PATIENT EDUCATION TALKING POINTS

Labor is an important process for a baby's health. For example, labor signals the baby's lung cells to shift from being fluid producing cells to fluid absorbing cells.

It is best to stay pregnant until at least 39 weeks.

If your pregnancy is healthy and you are considering scheduling your baby's birth, it is best to stay pregnant for at least 39 weeks. Babies born too early may have more health problems at birth and later in life than babies born full term. Being pregnant at least 39 weeks gives your baby's brain and body all the time they need to grow.

Why do babies need time (at least 39 weeks)?

- Important organ growth—including the brain, lungs and liver—occurs during the last weeks of pregnancy.
- Babies born at 39 weeks are less likely to have vision and hearing problems after birth than babies born earlier.
- Babies need 39 weeks to gain weight in the womb; babies born at healthy weights can stay warmer than babies who are born too small.
- Babies need 39 weeks to learn to suck and swallow well and stay awake long enough to eat; babies born early often cannot do these things.

Why can scheduling an early birth be a problem?

Experts are learning that scheduling an early birth for non-medical reasons can cause problems for mom and baby. For example:

- **Your due date may not be exactly right.** Sometimes it's hard to know just when you got pregnant. If you schedule to induce labor or have a cesarean section birth and your date is off by a week or two, your baby may be born too early.
- **Inducing labor may not work.** If your labor is induced, the medicine your doctor or midwife gives you may not start your labor. When this happens, you may need to have a cesarean section.

- **A cesarean section can cause problems for your baby.** Babies born by cesarean section may have more breathing and other medical problems than babies born by vaginal birth. (Most babies are born by vaginal birth. The mother's uterus contracts to help push the baby out through the vagina, also called the birth canal.)
- **Cesarean sections can cause problems during future pregnancies.** Once you have a cesarean section, you may be more likely to have a cesarean section in future pregnancies. The more cesarean sections you have, the more problems you and your baby may have, including problems with the placenta.
- **A cesarean section is major surgery for mom.** It takes longer for you to recover from a cesarean section than from a vaginal birth. You can expect to spend 2-4 days in the hospital after a cesarean section, but you need 4-6 weeks to fully recover after you go home. You may experience complications from the surgery, such as infections or bleeding. Recovery is more painful, and breastfeeding can be more difficult. It is important to stay in touch with your health care provider even after you go home.

It is hard to plan for anything when it comes to children.

- The reality is that from now on, you can anticipate changes in your child's life or development, but you can rarely plan on them or schedule when they will occur.
- Labor and delivery is just like crawling and walking. We know an approximate time frame, but not an exact date. So you can anticipate that labor will occur spontaneously sometime around 39 weeks, but you can't pin point the specific date and time.
- The people in your life who will support you and your baby should also know that flexibility is critical.
- Waiting can be hard, but waiting allows your baby's brain to grow and allows you time to rest before labor starts.

COMMON PATIENT QUESTIONS

What questions should I ask when my doctor/certified nurse midwife...

- **Suggests delivery before 39 weeks?**
 - Is there a problem; what is the problem?
 - Can I wait until 39 weeks? If not, then why not?
- **Suggests induction?**
 - Why do you need to induce my labor?
 - How will my labor be induced? What are the risks of induction?
 - Will this increase my risk of a cesarean section?
- **Discusses cesarean section?**
 - Why do you need to deliver my baby by cesarean section?
 - What are the risks compared to a vaginal delivery?

OTHER QUESTIONS

How is my due date determined?

Your care provider probably gave you an estimated due date for your baby. This is the date that your baby is expected to be full-term (39-40 weeks) and ready to be born. Remember that due dates are estimates. Your body may go into labor on its own earlier or later than that date. Your due date is based on several factors:

- Information about your last menstrual period
- Results from various lab tests
- The size of your baby based on ultrasound results

What happens if my labor starts before 39 weeks?

When labor starts naturally (on its own) it is called “spontaneous.” If spontaneous labor starts prior to 37 weeks gestation, doctors will usually try to stop the labor. They will usually try to stop labor before 37 weeks since the baby is premature; the baby needs more time in the womb or uterus. However, if spontaneous labor starts after 37 weeks gestation, it means that your baby is ready to be born. Thus, your doctor will not try to stop spontaneous labor after 37 weeks gestation. Keep in mind that the due date is only an estimate.

When is it okay to have a scheduled delivery?

Your care provider uses guidelines from national experts to make a safe decision about whether or not a scheduled delivery is right for you and your baby. If you don't meet these guidelines, your provider may recommend waiting for spontaneous labor to help time your delivery. For example, deliveries are scheduled when the health of the mother, the baby, or both are at risk; these scheduled deliveries have a “medical indication” or reason. Some medical indications might be that the mother has high blood pressure or the baby is experiencing problems. Healthcare providers must weigh the risks and benefits of early scheduled delivery and make sure that the safety of the mother and baby are the priority.

What is “early term delivery”? Can early delivery—when it is so close to my due date—really hurt my baby?

“Early term” is gestation between 37 0/7 and 38 6/7 weeks. Babies born during this time are usually healthy, but they are at higher risk for medical problems compared to babies who are full term (39-40 weeks gestation).

Because a baby's lungs and brain are still growing in late pregnancy, delivery at 36-38 weeks gestation puts the baby at higher risk for each of the following:

- **Admission to intensive care.** Babies born early term are 2 to 3 times more likely to be admitted to intensive care than babies born at 39 weeks. Admission to intensive care means your baby will be in the hospital for a longer period of time and may have problems with breastfeeding or bonding with you.
- **Trouble with breathing.** Babies born early term sometimes need help breathing and must be connected to a machine called a ventilator because their lungs are not fully developed.
- **Trouble staying warm.** Babies born early term often need to spend time in a warming area (incubator) to keep their body safely warm.

What does “the cervix is not ready” mean?

The cervix is a band of tissue at the base of the uterus. During vaginal birth, the baby moves through the cervix and then through the vagina (birth canal). When spontaneous labor occurs, the cervix softens, thins, and opens (dilates). Your care provider can tell whether the cervix is dilated enough for the baby to be born. If the cervix is not ready, it means that it is not softened, thinned or dilated.

What happens if my water breaks before 39 weeks but labor is not starting?

If your water breaks and you are more than 34 weeks, it usually is OK to deliver. In general, waiting may increase the risk of infection or other problems.

Why do babies born by elective cesarean sections before 39 weeks have more complications than babies born by elective inductions before 39 weeks?

During the last weeks of pregnancy, a baby’s lungs mature and prepare for breathing oxygen. During labor and vaginal birth, the process of preparing the lungs for breathing continues. When a baby is born by elective cesarean section, there is little or no labor. Cesarean section also lacks the physical compression or squeezing process of a vaginal birth, which helps clear the baby’s lungs of fluid so that they can breathe oxygen. Babies born by cesarean section are at a higher risk for breathing problems after birth than babies born by vaginal birth.

Appendix A – Other Sample Forms

Form 3: March of Dimes Scheduling Template (Used with permission of the March of Dimes.)

Induction / Cesarean Delivery Scheduling Form

Requesting Physician _____ Today's Date _____

Patient's Name _____ Age _____ G _____ P _____

Medical Record # _____ Requested Procedure Date _____ AM PM

Gestational Age on Date of Procedure _____

Method of Delivery Planned: Cesarean delivery: Primary or Repeat
 Induction: Fetal presentation _____ EFW _____ gms Bishop Score _____

Reasons for Scheduled Delivery: *Check all appropriate indications below*

Level 1

- Chorioamnionitis
- Preeclampsia / HELLP
- Abruptio placenta
- Bleeding D/T marginal placenta previa
- Non-reassuring fetal testing
- PROM
- Fetal hydrops / isoimmunization
- Oligohydramnios
- Blood group sensitization
- Fetal compromise (severe IUGR)
- Fetal anomaly
- Maternal medical conditions
- Gestational hypertension
- Multifetal gestation

Level 2

- ≥41 weeks gestation / Postterm pregnancy
- Gestational diabetes
- IUGR – reassuring testing
- Fetal demise
- Maternal HIV

Level 3

- Fetal malpresentation / Unstable lie
- History of HSV
- Prior myomectomy
- Prior vertical or T-incision C/S
- Prior C/S - VBAC not indicated
- Macrosomia (EFW greater than 4000 gms)

AND
Gestational age ≥ 39 weeks*

Level 4

- History of rapid labor
- Distance from hospital
- Term with favorable cervix
- Psychological factors
- Maternal request
- Prior C/S
 - Patient declines VBAC
 - VBAC not available

AND
Gestational age ≥ 39 weeks*

Other indication _____

Clinical indications (with supporting data) _____

Confirmation of gestational age:

EDC _____ determined by: *Check all that apply*

- Ultrasound obtained at < 20 weeks on _____ date @ _____ gestational age weeks confirms gestational age
- Known date of conception on _____ date associated with infertility treatment

For Level 3 or 4 indications, if EDC was not determined by above methods, then identify documentation of fetal maturity:

Amniocentesis performed on _____ Results: _____

* Provide explanation if scheduling Level 3 or 4 at < 39 weeks _____

Please fax form to _____

Procedure scheduling determination:

- Level 1 or Level 2 indication scheduled as requested
 Medically indicated procedure necessitates delivery prior to 39 weeks gestation
- Level 3 or Level 4 procedure scheduled as requested
 Gestational age ≥ 39 weeks on scheduled procedure date per ACOG recommendation
- Level 3 or Level 4 procedure scheduling request requires further review
 - Gestational age < 39 weeks on scheduled date of procedure
 - Gestational age or fetal maturity not determined using established criteria

Completed by _____



This chart is provided for your convenience to assist in calculating the Bishop Score. The final score should be entered on the front of the form where indicated. Vaginal exams should have been performed at least within the last 7 days.

Bishop Score

Score	Dilation (cm)	Effacement (%)	Station* (-3 to +3)	Cervical Consistency	Cervical Position
0	Closed	0-30	-3	Firm	Posterior
1	1-2	40-50	-2	Medium	Midposition
2	3-4	60-70	-1	Soft	Anterior
3	≥ 5	≥ 80	+1, +2	-	-

*Station reflects a -3 to +3 scale-modified from Bishop EH Pelvic Scoring for Elective Induction, Obstet Gynecol 1964, 24(267)
Please state -5 to +5 for all other purposes.

Form 4: Tallahassee Scheduling Process (Permission to use is granted.)

Tallahassee Memorial Hospital
Women's Pavilion

Title: Induction of Labor Scheduling Process

Policy: Unless medically indicated, induction of labor prior to 39 completed weeks gestation will require approval of the OB/GYN Department chair.

Medical Indications for induction of labor include (ACOG & IHC):

- Abruptio placentae
- Chorioamnionitis
- Fetal Demise
- Pre-eclampsia or Gestational hypertension (BP \geq 140/90 times two six hours apart or B/P >160/110)
- eclampsia
- Premature rupture of membranes
- Post Term Pregnancy (\geq 41 weeks)
- Maternal medical conditions (i.e., Diabetes with insulin, renal disease, chronic hypertension, lupus, antiphospholipid syndrome, PUPPS, thromboembolism)
- Fetal compromise (i.e., IUGR, oligohydramnios, severe congenital anomalies, abnormal antenatal testing, previous stillbirth)
- Logistic or psychosocial (*with documentation of fetal lung maturity)

Confirmation of Gestational Age (ACOG):

1. Fetal heart tones have been documented for 20 weeks by non-electronic fetoscope or for 30 weeks by Doppler
2. It has been 36 weeks since a positive serum or urine human chorionic gonadotropin (HCG) pregnancy test was performed by a reliable laboratory
3. An ultrasound measurement of the crown rump length, obtained at 6-12 weeks, supports a gestational age of at least 39 weeks
4. An ultrasound obtained at 13-20 weeks confirms the gestational age of at least 39 weeks determined by clinical history and physical examination
5. Amniocentesis and documentation of fetal lung maturity

Purpose: This policy will allow for the safe delivery of obstetric care and the efficient utilization of organizational resources when elective delivery of a pregnancy is being considered.

Scheduling:

1. Provider or designee will call L&D administrative coordinator @ 431-0057 or in her absence, the Labor & Delivery Unit Coordinator @ 431-0100 .
2. Provider/designee will give indication for procedure and gestational age at day of scheduled induction.
3. L&D will accommodate no more than 5 scheduled inductions on any weekday and no more than three scheduled inductions on a weekend day. Scheduled inductions include induction of labor by any method.

4. When the need for cervical ripening is identified by the provider, two patients may be scheduled to be admitted the evening before the scheduled induction for cervical ripening.
5. Patient's with medical indications will have priority over elective inductions which may delay an elective scheduled induction at the discretion of the L&D unit coordinator.
6. Elective inductions will be scheduled no more than 7 days in advance and on a first-come first-served basis.
7. Inductions must have a **complete & updated** prenatal record (including ultrasound reports and prenatal flow sheets) faxed to 431-0065 at the time of scheduling.

Cancellation:

1. Each day the administrative coordinator or Unit Coordinator will review the next day's schedule for inductions. If there are inductions scheduled and no updated prenatal record obtained, a call will be made to the office to fax the updated prenatal record by 3pm that day. (Calls will be made on Fridays for inductions scheduled for Sat., Sun., or Mon.).
2. When the prenatal record is not faxed to L&D by 3pm the day before the scheduled induction, the patient & MD will be called to let them know that her scheduled time for her induction has been delayed because her prenatal record has not been faxed to L&D and that as soon as the MD's office faxes her prenatal record to L&D (431-0065) she will be called in for her induction.
3. The night shift L&D Unit Coordinator will assess the available resources for upcoming day shift.
4. When resources are not available due to staffing shortage or high acuity/census, scheduled inductions will be evaluated and prioritized related to their indication and delayed as needed.
5. Patients will be notified of the postponement as soon as possible.
6. Providers will be notified by 8am.
7. When a request for a medically indicated induction is made and the maximum number of scheduled inductions has been met, the L&D Unit Coordinator will have the authority to delay a previously scheduled elective induction.
8. The L&D Unit Coordinator will notify the involved provider with options for accomplishing the elective induction that has been delayed.

Admission :

1. Inductions will be admitted on their scheduled day at 6am only if prenatal record and orders are on the chart.
2. If the MD/CNM has not examined the patient on admission or prior to initiation of pitocin, a nurse will examine the patient to document presentation and bishop score. The MD/CNM must confirm the nurse's exam within 2 hours of admission.
3. Initiation of pitocin for an elective induction will begin only after induction bundle criteria #1, #2 and #3 are met (see below):

Bundle criteria:

Elective Induction :

1. Gestational age ≥ 39 weeks
2. Reassuring Fetal Heart Rate Pattern prior to initiation of Pitocin
3. Bishop score prior to initiation of Pitocin. (IHC recommendation is for bishop score ≥ 8 for multipara and bishop score ≥ 10 for primipara)

4. Identification and intervention(s) for hyperstimulation (see hyperstimulation algorithm)

References:

ACOG Practice Bulletin #10 (1999) Induction of Labor.

www.uptodate.com Oct. 4, 2006 "Induction of Labor: Indications, techniques, and complications."

IHI Impact.(2006): Idealized Design of Perinatal Care

Intermountain Healthcare (IHC) 2006. "Management of Elective Labor Induction."

Dev: 2/07

Form 5: Tallahassee Consent (Permission to use is granted)



YOUR LABOR INDUCTION

Labor induction is usually done with a medication called Oxytocin or Pitocin®. With your practitioners order, our staff will start the medication at a standard dose and increase it over time to achieve labor progress. While you are getting the medication, we will closely monitor the baby's heart rate and your contractions. The length of labor depends on how dilated or "ripe" your cervix is at the start of the induction. In general the more dilated you are, the quicker your labor. Also, if this is not your first birth, labor may be faster for you.

If your cervix is already fairly dilated, your practitioner may start your induction by breaking the bag of water. If your cervix is closed and not shortening, we may schedule cervical ripening the day before your induction. This procedure will soften and begin to dilate your cervix. Ripening will make the Oxytocin more effective when it is begun. Sometimes, the ripening process will trigger the onset of your labor.

WHY ARE LABOR INDUCTIONS PERFORMED?

Labor inductions are performed for many reasons. Clearly, some reasons are more urgent than others. Here are just a few examples:

- ✦ A woman is well past her due date
- ✦ A woman is experiencing medical problems that place her or her baby at risk, such as high blood pressure, diabetes, rupture of the bag of water, etc.
- ✦ The baby or babies may be small or the amniotic fluid too low
- ✦ Though less common elective labor induction may be done for convenience or discomfort of the mother after 39 weeks

WHAT ARE THE POTENTIAL RISKS AND BENEFITS OF LABOR INDUCTION?

It is always important to consider the potential benefits and risks of any procedure. The risks include, but are not limited to, the following:

- ✦ Labor inductions may carry a greater risk of cesarean birth delivery than do labors that start on their own, especially with an "unripe" cervix.
- ✦ Induction usually results in longer labors and may lead to a higher chance of a vacuum or forceps delivery.
- ✦ All medications have possible side effects or unintended adverse reactions. For example, it is possible to cause contractions that are too frequent and may affect the baby's heart rate. This is why careful monitoring of your baby's heart rate is necessary during labor induction.

If you are considering an elective induction, the risks may outweigh the possible benefits especially, if this is a first time labor.

CONSENT FOR INDUCTION OF LABOR

Indication for Induction: _____

I have read the above information and I have had the chance to ask my practitioner questions. All of my questions have been answered to my satisfaction. I wish to proceed with the induction.

Patient Signature

Date

Witness Signature

Date

PATIENT IDENTIFICATION

Appendix B - Hospital Case Studies

POMONA VALLEY HOSPITAL MEDICAL CENTER
Pomona, California
Case Study: Reducing non-medically indicated (elective)
Deliveries prior to 39 weeks gestation

Background

Pomona Valley Hospital Medical Center is a 453 bed, nonprofit, teaching hospital that delivered 8,063 babies in 2007. Obstetric (OB) and Neonatology coverage is available 24/7 with immediate availability of maternal-fetal medicine specialists. Births have steadily decreased (6,848 in 2009), consistent with other delivering facilities locally and throughout the state. Medi-Cal provides reimbursement for 76% of patients.

In 2008, both medical and nursing leadership sought solutions for the increasing number of elective deliveries before term, resulting in longer Labor and Delivery stays, and a climbing Neonatal Intensive Care Unit (NICU) admission rate (13%). In 2007 the FDA listed oxytocin as a high-risk medication and the National Quality Forum (NQF) published 17 new perinatal quality measures including one that would monitor elective deliveries before 39 weeks; these two events reinforced the need for change.⁵⁸⁻⁶⁰

Using an Evidence-based Practice Model, a multidisciplinary quality improvement team examined national standards and available literature to draft tools, which were reviewed and amended by a core group of physicians and nurses. The ACOG guidelines, Association of Women's Health and Obstetric and Neonatal Nurses (AWHONN) Practice Monograph (Simpson, 2008) and a checklist-based method for the use of oxytocin (Clark, 2007) provided the evidence and outline for the needed changes.^{3 10} The QI team developed new clinician guidelines, along with supporting consents and checklists to reduce elective inductions. Specifically, the guidelines focused on the applicability of written informed consent, safety, liability, productivity and reducing nurse/physician conflict. A new oxytocin protocol was formatted by nurse champions (Director, Clinical Nurse Specialist, Nurse Educator, front-line managers and staff RNs) and approved by the multidisciplinary Perinatal Committee in October 2008.

Implementation of the new protocol was announced and publicized well in advance for a selected kick-off date (April 1, 2009). Department meetings and other outreach and education measures facilitated initiation and ongoing change (see Key Steps, below). Specific methods were used to ensure compliance, including communication with physician offices about missing patient documentation and follow-up visits to offices every two weeks to review and redistribute packets

of required documents for scheduling an induction (see Key Steps, below). A data tracking system was developed to monitor the number of women with elective inductions who required a cesarean section and the number of infants admitted to the NICU. Outcome and compliance results were shared with individual physicians during one-on-one discussions or group meetings. Thus, all physicians were given feedback on their rate of conformity with the new protocols and the effect their behaviors had on patient outcomes. Additional feedback was provided to non-compliant physicians in a formal letter from the Medical Director, which outlined their areas of non-compliance with the national and local guidelines.

Key Steps

- Develop a multidisciplinary Quality Improvement (QI) team that includes physicians and nurses
- Establish new policy and guidelines that require the following to schedule inductions:
 - Prenatal Record with gestational age documented per ACOG guidelines
 - Indication for induction
 - Documented Bishop Score
 - Prenatal Informed Consent for Augmentation
 - Informed Consent for Induction
 - OB H&P Short Form
 - Preprinted Physician Orders for Induction
- Educate stakeholders, and reinforce guidelines:
 - Joint Commission's Quality Measures were presented during OB Department meetings along with an algorithm to assist practitioners in identifying appropriate cases
 - Changes in the induction process and the new limitations for scheduling elective procedures was presented during a luncheon for physician office staff; sample packets and a checklist of forms were provided
 - The March of Dimes brochure "Why the Last Weeks of Pregnancy Count" was distributed to physician offices to promote patient education (brochures were available in English or Spanish)
 - Published articles in the OB department newsletter to reinforce guidelines
 - Reinforced changes through a self-study program for labor nurses including in-services and rounding by the nurse educator and CNS

Barrier and Solutions

Barrier:

The labor nurses and operating room (OR) scheduler encountered conflict from physicians when told they could not schedule elective procedures prior to 39 weeks.

Solutions:

1. **Involve leaders:** After all physicians were fully apprised of the new protocol for inductions; those who disagreed were referred to the Chief of OB and the Medical Director who were responsible for answering the physician's questions and determining if an exception was warranted.
2. **Support new roles:** Nurses and schedulers were obligated only to remind the physician about the new hospital policies and ensure that patients met the induction and cesarean section criteria prior to scheduling or assisting with these procedures. In addition, the staff was reminded it was not their responsibility to defend the policies or argue with the physicians over the new limitations for elective procedures. All disputes were to be referred to physician leadership for resolution.
3. **Reinforce policy through education:** Active communication via letters, fliers, meetings and memos clarified specific questions that arose during implementation of new policies and procedures

Outcomes

One year after implementation, there were no elective inductions performed before 39 completed weeks of gestation. Additionally, preliminary data revealed the total number of inductions fell by 17% and cesarean sections due to failed inductions decreased by 21%. This improvement in practice change was observed during the first quarter of 2010 compared with the same period in 2009.

Lessons Learned

- Gather support and involve all stakeholders early in the change process.
- Perform ongoing monitoring and follow-up with physicians; early support and involvement from physicians is essential.
- Provide continued support and active communication to clerical staff in physician offices and community clinics.
- Participate in a collaborative that provides a forum for hospital leaders to obtain expert and peer mentoring on the change strategies and tactics to increase implementation effectiveness and sustained improvements over time.
 - Pomona Valley Hospital leaders participate in the San Bernardino County Maternal Morbidity and Mortality Labor Induction Education Project (MMMLIEP) as members of the Advisory and the Stakeholders Council. Participation in MMMLIEP provides the leaders with collaborative support and recognition for their efforts. The MMMLIEP project is supported and led by San Bernardino County/Department of Public Health/Maternal and Child Health and has received funding through the California Department of Public Health, Maternal, Child and Adolescent Health Division, and technical assistance through California Maternal Quality Care Collaborative (CMQCC).

Future Plans

- Continue to support OB offices and community clinics adherence to scheduling guidelines by providing packets with required induction forms and educational information for patients.
- Develop improved QI tracking tool to monitor compliance.
- Involve Nursing Shared Governance Quality Council in ongoing audits to reinforce completion of all required documentation before starting inductions.
- Present outcome data to nurses and physicians; acknowledge magnitude of efforts and success with change process.
- Expand the project to other hospitals; develop and offer a professional educational package for Level I & II Outreach Hospitals in the community who contract for maternal transport services with Pomona Valley Hospital Medical Center. The initial offering will be “How to eliminate elective deliveries before 39 weeks.”

For more Information about the Pomona Valley Hospital project or the MMMLIEP collaborative contact:

Hospital Project Contact:

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TALLAHASSEE MEMORIAL HOSPITAL

Tallahassee, Florida

Case Study: Reducing non-medically indicated (elective) deliveries prior to 39 weeks gestation

Background

Tallahassee Memorial Hospital (TMH), a private not-for-profit community teaching hospital, has an average of 4,000 deliveries and 600-700 Neonatal Intensive Care Unit (NICU) admissions each year. In 2006, a Neonatologist voiced concern about the increasing number of infants admitted to the NICU at 36-38 weeks gestation. The Women and Children's Service Line administrator noted a corresponding increase in inductions, failed inductions and cesarean sections. The Tallahassee Memorial Hospital Performance Improvement (PI) team established an Obstetric (OB) Performance Improvement (PI) team in May 2006 to address these clinical concerns.

To reduce non-medically indicated (elective) deliveries prior to 39 weeks, the OB PI team changed the policy around inductions and began educating physicians, certified nurse midwives (CNMs) and nurses about the increase in rates of inductions and NICU admissions. The OB PI team convened the OB Task Force, PI and department meetings to engage staff in discussion and actively involve them in developing new procedures and forms to improve safety and outcomes. With feedback from the collaborative meetings, the OB PI team rewrote hospital policy to include an induction/augmentation bundle criteria that outlined processes to reduce non-medically indicated (elective) deliveries before 39 weeks gestation (see Policy Change Section below). In order to induce labor electively at <39 weeks, a clinician needs both approval by an OB/GYN chairperson and L & D nurse manager. The benefits of these requirements were policy enforcement by the Chairperson instead of by the nursing and scheduling staff, and patient education about risks of inductions prior to 39 weeks gestation during the process of informed consent.

After initial meetings and document changes, the OB PI team continued presentations to educate physicians, CNMs and their office managers about increases in inductions and NICU admissions. Their presentations outlined the changes to both the policy itself and to associated documents, including preprinted order sets and patient informed consent forms. Over the course of two years, the team held bi-monthly, 30-minute meetings for ongoing discussion. The team continued education and engagement with posters, bulletin boards and newsletters to maintain ongoing communication about change.

Key Steps

- Identify specific problem, create relevant change plan, set measurable goals
- Create multiple, ongoing forums for discussion and education; communicate reasons and methods for change in clear, precise language
- Convene collaborative interdisciplinary teams that include clinicians and administration
- Join external Quality Improvement initiatives (e.g., the Institute for Healthcare Improvement (IHI) Perinatal Improvement Initiative provided tools for our efforts)
- Implement “small tests of change” (e.g., start bundle criteria with one doctor; spread change to all physician groups.)

Barriers and Solutions

Barrier: Physicians and midwives were opposed to documenting Bishop Scores and estimated fetal weight (EFW).

Solutions:

1. **Involve Leaders:** Physician “champions” and the OB Department Chair supported the change and gave clinicians “friendly reminders” to document these measures. If providers remained non-compliant, the OB Department Chair sent a formal letter, which provided encouragement, ongoing education and policy reinforcement.
2. **Change Documents and Forms:** To ensure on-going compliance with documentation, the OB PI team added a data entry field for the Bishop Score on the preprinted order sets for cervical ripening, induction of labor and labor admission.
3. **Consider Reasonable Compromises:** After discussion and negotiation about clinician resistance to documenting EFW, it was agreed that infants would be assessed for weight categories: Small for Gestational Age (SGA), Average for Gestational Age (AGA), or Large for Gestational Age (LGA). Data entry fields were added to the form for the EFW estimation categories.
4. **Reward Teamwork, Foster Morale:** Leaders recognized and acknowledged that data collection was “labor intensive” and required additional time and staff resources. They overcame this barrier by scheduling “chart audit lunches” during which nursing staff, Clinical Nurse Specialist (CNS), and the PI advisor retrieved chart data.

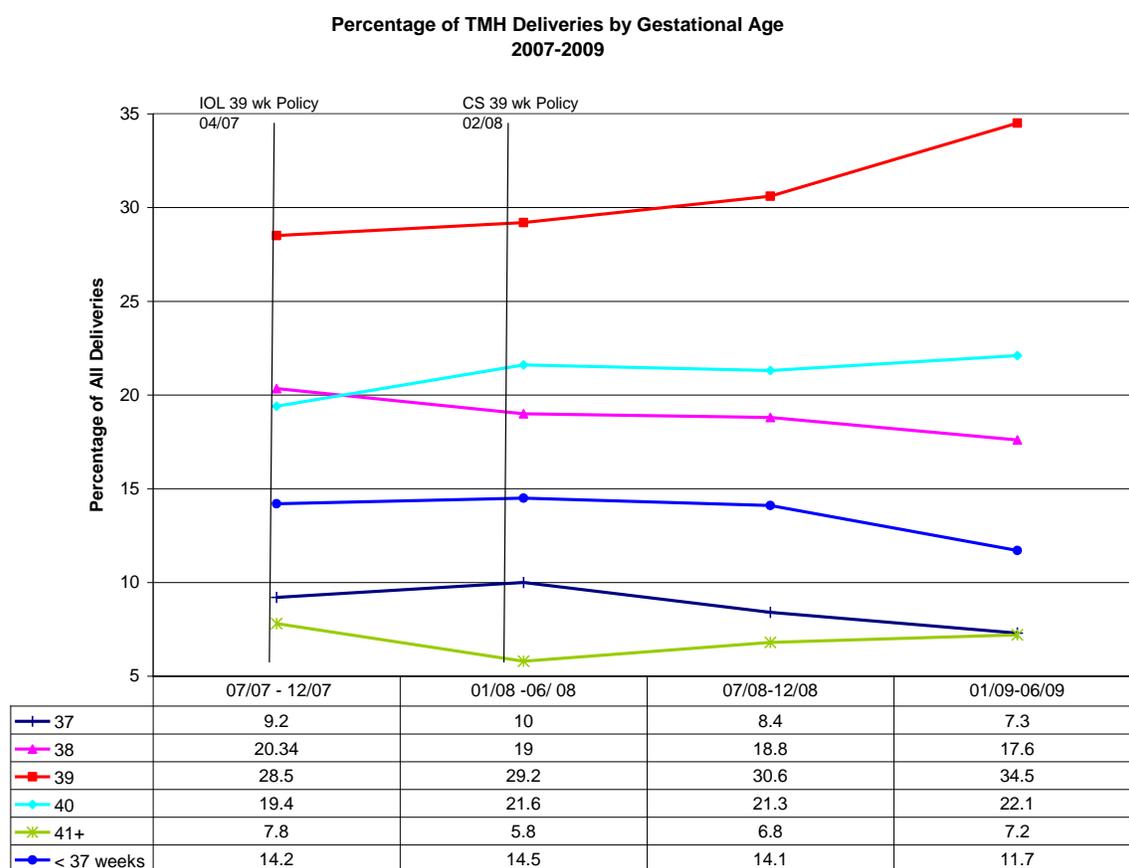
Outcomes

After two years of participating in the Perinatal IHI initiative, the failed induction rate at TMH decreased from 22.6% to 15.6% and the primary c-section rate decreased from 21.5% to 17.5%.

Additional successes included:

- Implementation of a scheduling policy whereby no elective inductions or cesarean sections can be scheduled before 39 weeks
- Informed consent process for all patients undergoing induction
- Mandatory nurse education that improved competency for identification of non-reassuring FHR pattern and management of tachysystole (hyperstimulation)

Figure 17: Percentage of Tallahassee Memorial Hospital Deliveries by Gestation Age



(Permission to use is granted.)

Policy Change: Induction and Augmentation Bundle Criteria

1. Administration of oxytocin for elective labor induction can begin only after the following criteria are documented:
 - a. Gestational age is greater than 39 weeks, 0 days
 - b. Reassuring Fetal Heart Rate pattern (FHR) (Category I)
 - c. Cervical assessment (Bishop Score)
2. Administration of oxytocin for labor augmentation can begin only after the following criteria are documented:
 - a. Estimated Fetal Weight (EFW)
 - b. reassuring FHR (category I or category II)
 - c. cervical assessment (Bishop Score)

Clinicians: be prepared to identify and manage tachysystole during labor.

Lessons Learned

- Identify key staff and clinicians to act as ‘Performance Improvement Champions’.
- Keep team meetings frequent, short, and focused.
- Develop and implement a policy on induction of labor that sets clear guidelines and improves compliance among physician and midwife.
- Communicate with physicians, midwives, nurses and staff frequently using multiple methods: posters, bulletin boards newsletters and regular meetings.
- Maintain consistent data monitoring and focus on “ownership” of data collecting, analysis and reporting by CNS, PI advisor and other OB PI team members.

Future Plans

In May 2009, it was determined that the successes achieved in reducing inductions and NICU rates warranted continued, but less costly, monitoring and oversight. As a result, the OB PI initiative merged with the OB Task Force Committee (an OB Department subcommittee) and participation in the Institute for Healthcare Improvement collaborative was discontinued. The OB Task Force Committee continues to meet on a regular basis and includes representatives from each physician group. OB PI initiatives are consistently on the agenda for each meeting.

During the last quarter of 2009 the “failed induction rate” began to climb. More intensive data collection was re-instated to track compliance to the induction policies. Labor and Delivery Quality council members and the CNS began to perform the data collection and analysis for this issue. The TMH nursing department continues to implement the “Shared Governance” model, which encompasses nursing councils for each unit related to Practice, Quality, Education and Evidence Based Practice/Research Advancement and assesses current practices in order to

develop quality improvement projects that follow our shared mission for achieving “World Class” medical care.

For more information about the Tallahassee project contact:

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Appendix C – QI Implementation Tools

Form 6: MAP-IT Worksheet

MAP-IT WORKSHEET

Change Project MAP-IT Worksheet

MAP-IT Action Plan for: _____ (Hospital Name)

Date Created: _____ Developed by: _____

Aims Statement or Objective: *By (month)____ (day)____ (year)____ no infants less than 39 weeks will be electively delivered.*

M: Mobilize

A: Assess

P: Plan

I: Implement

T: Track

First Cycle Due Date: _____

Guidry, M., Vischi, T., Han, R., & Passons, O. *Healthy people in healthy communities: A community planning guide using Healthy People 2010*. Washington, D.C.: U.S. Department of Health and Human Services. The Office of Disease Prevention and Health Promotion.

<http://www.healthypeople.gov/Publications/HealthyCommunities2001/default.htm>.

FISHBONE CAUSE and EFFECT DIAGRAM

Fishbone Diagram:

A fishbone diagram may help leaders identify the effect of various components have on a problem. This analysis can support leaders' efforts to develop their implementation plan.

Figure 18: Blank Ishikawa “Fishbone” Diagram

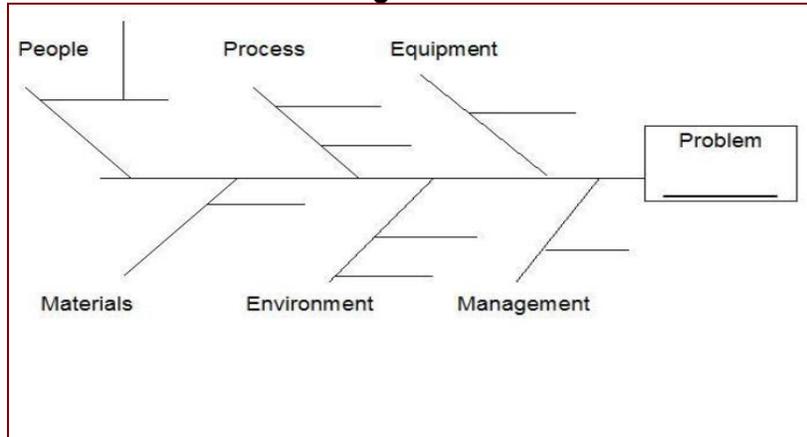
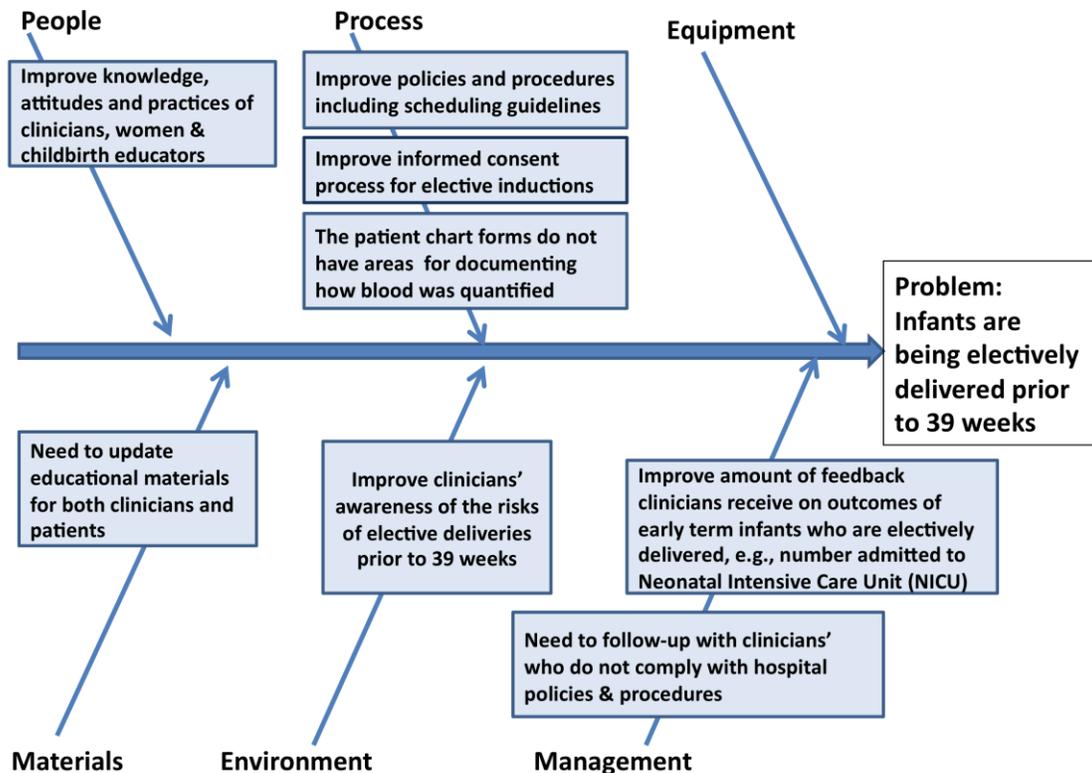


Figure 19: EXAMPLE of a Completed Ishikawa “Fishbone” Diagram

Note: Components of the diagram will vary at individual hospital.

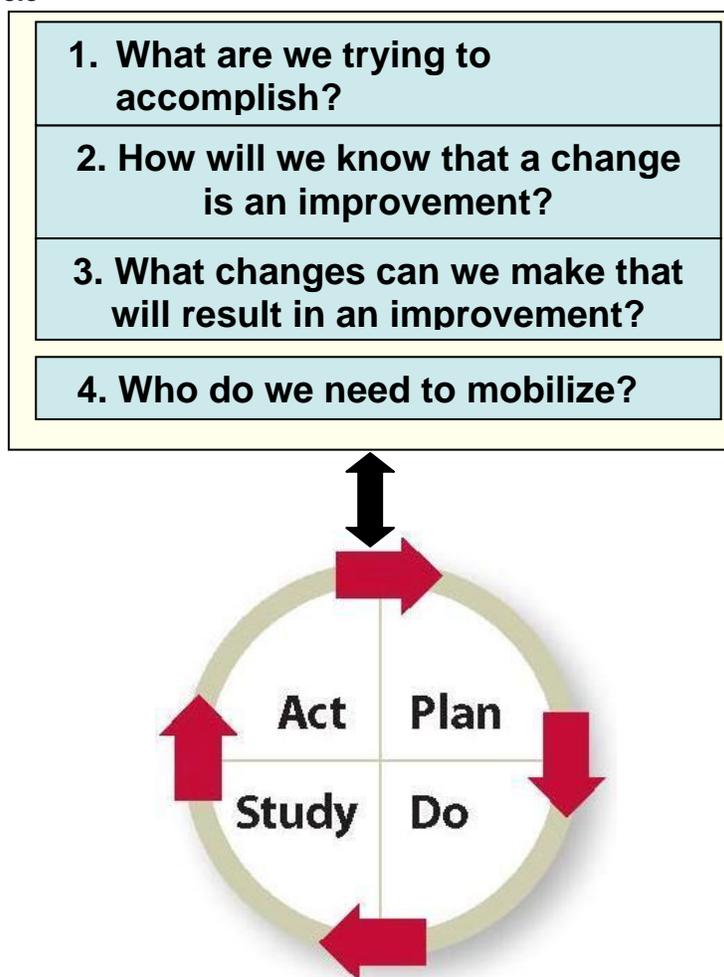


PLAN-DO-STUDY-ACT (PDSA) METHOD

Background: A commonly used implementation and evaluation method is the PDSA cycle, which has been the foundation for many collaborative quality improvement (CQI) programs.^(2,3) The PDSA cycle is effective in real world settings and applicable to data collection on a wide range of conditions. Additionally, it is reliable for implementing and testing on a small scale, which is critical in settings where failure is risky. Hospital QI department leaders can help identify the preferred method for use in your setting; other structured improvement approaches, such as Six Sigma's Define – Measure – Analyze – Improve – Control (DMAIC) have been shown to be equally or possibly more effective.^{58, 59}

Regardless of the QI methodology, the key initial step is to identify specific elements that hinder or foster high quality of care. Four fundamental questions need to be addressed when developing a CQI program:

Figure 20: PDSA Cycle



Answer the questions in any order, but realize that every process for change is iterative; we rarely get it right the first time around. Be observant; make modifications as you go, reintroduce plans and actions, then observe again. “That’s the way we do things around here” can be a common response to a problem, but it seldom succeeds.

Systematic Approach for Leaders: By approaching problems systematically, everyone works smarter, not just harder. One benefit of the systematic approach includes collecting meaningful data that outlines outcomes, processes and structures that are in need of evaluation and manipulation. As a result, leaders and teams develop strategies and tactics that are evidence-driven, and they can effectively identify and mitigate barriers, test systems and modify implementation for another cycle of change toward improvement.

Improvement cycles should be repeated as many times as needed in order to gather sufficient data to indicate signs of improvement. In general, affecting change involves creative thinking. Specific activities include:

- Evaluate the purpose.
- Visualize the ideal.
- Remove “the current way of doing things” as an option.
- Challenge the boundaries.
- Embed improvements (making it easier to make the right choice for patients).
- Influence the culture.
- Look for ways to smooth the flow of activities.

Small tests of change help leaders and teams see that their efforts are moving toward improvement. At each small test-of-change cycle, data collection and analysis is designed to inform leaders and teams about process and patient outcome measures. Charts, flow charts, Pareto charts, and formal Failure Modes and Effects Analysis (FMEA) show results to leaders and teams about the direction of change.⁶⁰ Results in QI may not be immediately apparent when patient outcomes are used as a measure, because they are usually slower to change. Therefore, the first months of QI projects typically focus of process measures.

Table 12: PDSA Summary	
Plan	<ul style="list-style-type: none"> • State the objectives of the cycle. • Make predictions about what will happen next and why. • Develop a plan to carry out the changes: Who? What? Where? What data needs to be collected?
Do	<ul style="list-style-type: none"> • Introduce the change(s). • Collect data. • Document problems and unexpected observations. • Begin analysis of the data.
Study	<ul style="list-style-type: none"> • Complete the analysis of the data. • Summarize what was learned.
Act	<ul style="list-style-type: none"> • What modifications should be made? • What will happen in the next cycle?

APPLYING THE PDSA CYCLE TO ELECTIVE DELIVERIES <39 WEEKS

The PDSA process for CQI can be applied when implementing a plan to reduce or eliminate elective deliveries <39 weeks. Below are action items and details to address during this process.

PLAN

Action Items	Details
Convene multidisciplinary QI team of key stakeholders.	Key stakeholders may include: <ul style="list-style-type: none"> • Physicians/Nurses/Clerical staff • Risk/Quality management
Determine outcome measure(s) and data collection process.	<ul style="list-style-type: none"> • NICU admissions for babies delivered <39 weeks • Morbidities measures: neonatal and maternal • Electronic records, chart reviews, logs • Ongoing monitoring and evaluation of morbidities associated with <39 week deliveries
Determine process measure(s) and data collection process.	<ul style="list-style-type: none"> • Scheduling process, including documentation to identify gestational age, indication for elective delivery • Process of oversight, guidelines enforcement and communication chain that prohibit elective deliveries <39 weeks
Align scheduling process with process to identify whether elective deliveries are appropriate and can be scheduled.	<ul style="list-style-type: none"> • Step 1: Check that gestational age and medical indication are documented in scheduling form. • Step 2: If criteria are missing or do not match specific guidelines (outlined in a checklist, for example), first level of communication is triggered (e.g. call to OB provider to request information). • Step 3: Additional chains of communication are triggered so that scheduling criteria are met and resolved.
Develop or adopt scheduling form(s).	Identify who fills out forms and who reviews forms for required elements for scheduling.
Aim for consensus on key concepts.	<ul style="list-style-type: none"> • What is the appeal process for cases not covered by the guidelines? • Outline consequences if a provider refuses to follow the guidelines.
Develop departmental policy.	Policy reflects scheduling, documentation, oversight and enforcement processes to reduce or eliminate elective inductions and cesarean sections prior to 39 weeks gestation that are not medically indicated
Collect baseline outcome and process measure data to identify areas in need of attention; collecting data before implementation allows specific analysis of change after implementation.	<ul style="list-style-type: none"> • Conduct chart reviews of scheduled inductions and cesarean deliveries for a minimum of 2 months prior to implementation. • Assess the level of understanding of the issues by providers and patients • Assess barriers to change
Conduct educational presentations and grand rounds for key stakeholders.	<ul style="list-style-type: none"> • Neonatal risks of early term birth • Successful QI projects that reduced elective early term births
Develop a plan and timeline for implementation.	First implementation plan runs for 1-2 months; first evaluation (Study) is completed within 1-2 months.

DO

Action Items	Details
Communicate new department policy.	Identify point persons to communicate policy with each group; e.g. department chair, QI committee chair or MD project lead communicates with OB providers; nursing director communicates with nursing staff.
Implement use of new processes and forms for a predetermined pilot period of time.	Implement new processes and forms for 1-2 months; evaluate within 1-2 month time period.

STUDY

Action Item	Details
After predetermined pilot period, review and assess effectiveness of policy and forms implementation; analyze impact on obstetrical service, process and patient outcomes.	Depending on the intent and resources of the department, this action item can be conducted as in-depth analysis or a less intensive overview of trends of process and outcome measures including: <ul style="list-style-type: none"> • Review of elective procedures • Indications • Neonatal outcomes

ACT

Action Items	Details
Reconvene QI team to identify additional changes to continue improvement process.	<ul style="list-style-type: none"> • Edit scheduling forms and guidelines. • Clarify implementation plan. • Provide additional guidance to providers about department policy, scheduling and documentation requirements.
Inform staff of changes	Process measures may require additional change over time; process measures can change during the implementation process; however outcome measures remain more constant.
Obtain ongoing feedback on strengths and areas for improvement.	Feedback reminds everyone about the importance of the project, fosters teamwork and gives everyone a voice. Providing feedback can be as simple as posting monthly data in prominent spots in L&D; data can include process and outcome measures, i.e. number of elective births and number of NICU admissions in that population.

Appendix D – Letters of Support



CHAIR
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VICE CHAIR
Eva Chalas, MD

TREASURER
Howard L. Minkoff, MD

SECRETARY
Nicholas Kulbida, MD

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4 (Long Island)
Allen E. Ott, MD

5 (Syracuse/Utica)
Carla Liberatore, MD

6 (Buffalo)
Mark A. Weissman, MD

7 (Hudson Valley)
Christine M. Herde, MD

8 (Bronx)
Cynthia Chazotte, MD

9 (Albany)
Eileen E. Joyce, MD

10 (Rochester)
Dianne M. Edgar, MD

June 23, 2010

On behalf of the American Congress of Obstetricians and Gynecologists, District II, We congratulate the March of Dimes (MOD), the California Maternal Quality Care Collaborative (CMQCC), and the California Maternal, Child and Adolescent Health Division, for the development of the *California Quality Improvement Toolkit*. The goal of the toolkit is to eliminate non-medically indicated deliveries prior to 39 weeks gestation. We support the use of this important resource to improve the health and safety of our patients.

This toolkit is an excellent example of an effective “how-to guide” for physicians and other healthcare providers. However, if a hospital or physician practice already has the means to implement such a program, this toolkit will confirm the approaches already being used. For those needing assistance, this toolkit provides the initiative and insight to develop a quality program.

District II is committed to enhancing patient safety, improving outcomes and reducing liability risk for ob-gyns in New York. The *California Quality Improvement Toolkit* provides a mechanism to achieve this. ACOG District II hopes to partner with the New York State Department of Health to educate healthcare providers and distribute the toolkit statewide.

Sincerely,

Scott D. Hayworth, MD, FACOG
Chair, ACOG District II

Richard L. Berkowitz, MD, FACOG
Co-Chair, ACOG District II Patient Safety Committee

James Woods, MD, FACOG
Co-Chair, ACOG District II Patient Safety Committee

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ACOG
THE AMERICAN CONGRESS
OF OBSTETRICIANS
AND GYNECOLOGISTS

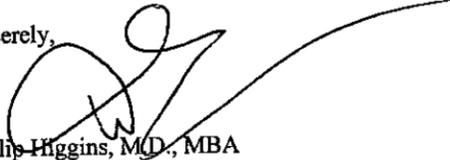
July 14, 2010

On behalf of the Illinois Section (District VI) of the American Congress of Obstetricians and Gynecologists (ACOG), I applaud the March of Dimes (MOD), the California Maternal Quality Care Collaborative (CMQCC), and the California Maternal, Child and Adolescent Health Division, Center for Family Health, California Department of Public Health (CMCAHD-CDPH) for the development of the Toolkit entitled, "Elimination of Non-medically Indicated (Elective) Deliveries Before 39 Weeks Gestational Age". We support the use of this Toolkit as a valuable resource to improve the health and safety of mothers and babies.

In our ongoing effort to reduce perinatal morbidity, ACOG has advocated against elective deliveries prior to 39 weeks gestational age for many years. The Toolkit which is based on established ACOG guidelines, includes: (1) a cogent rationale for eliminating purely elective deliveries prior to 39 weeks, including the importance of accurate dating of gestational age, (2) a user-friendly guide that both supports best practices and provides a template for hospitals and providers to assist them in implementing changes in policy and practice, (3) tools for data collection and analysis, and (4) educational materials for implementation, from FAQ sheets to a Power Point presentation for educating staff.

As the premier organization dedicated to the well-being of women, ACOG understands that the Toolkit engenders a process that enhances safety, improves quality of care, and maximizes healthy outcomes for mothers and babies. We are pleased that this valuable resource is going to be implemented in our own state of Illinois, and that together, we can improve perinatal outcomes. Again, we commend the March of Dimes, CMQCC, and the CMCAHD-CHPH for this effort.

Sincerely,



Phillip Higgins, MD., MBA



The American Congress of Obstetricians and Gynecologists District IX California

April 15, 2010

On behalf of the American Congress of Obstetricians and Gynecologists, District IX, I want to applaud you on the production of the **CALIFORNIA QUALITY IMPROVEMENT TOOLKIT: Elimination of Non-Medically Indicated (Elective) Deliveries Before 39 Weeks Gestational Age**. The District IX Advisory Council strongly supports the use of this important resource and believes that following these recommendations will improve the health and safety of our patients.

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IMMEDIATE PAST CHAIR

Frank R. Gamberdella, MD

JR. FELLOW CHAIR

Jennifer Salcedo, MD

EXECUTIVE DIRECTOR

Margaret Merritt

Since 1979, ACOG has advised against *elective* deliveries before 39 weeks gestation. As the executive summary so aptly points out, this toolkit does not define the standard of care in California, but rather advises users to adapt these guidelines and this toolkit based on their local facility level of care and patient population. The toolkit is based on ACOG Guidelines, and develops the case for implementation with four separate and important sections. First, it eloquently makes a case for deliveries after 39 weeks to improve the health of our infants and children. There is a need for effective pregnancy dating and appropriate timing of delivery. Second, the toolkit is a how-to implementation guide. If a hospital or a physician practice already has the means to implement such a program this toolkit will confirm the approaches already being used. For those facilities needing assistance, this toolkit provides the initiative and insight into developing a quality program. The third section provides suggestions on data analysis. And finally, the fourth section provides the educational tools for implementation, from FAQ sheets to a Power Point presentation for educating the hospital staff.

It is important to understand that we are recommending a process to enhance safety, to improve quality, and to increase healthy outcomes. This toolkit does NOT confuse the at times necessary role of early delivery for maternal or neonatal indications. It is important for clinicians to document the indication for admission or delivery in all patients. This toolkit will help in all regards. We commend March of Dimes, the California Maternal Quality Care Collaborative and the California Department of Public Health.

Sincerely,

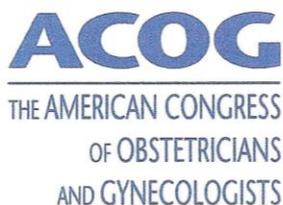
Hal C. Lawrence, III, MD, FACOG
Vice President, ACOG Practice Activities Division

Jeanne A. Conry, MD, PhD
Chair, ACOG District IX

John S. Wachtel, MD
Chair, ACOG District IX Committee on Patient Safety and Quality Improvement

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Women's Health Care Physicians
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THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS
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June 15, 2010

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LIASION
Shelly Holmstrom, MD

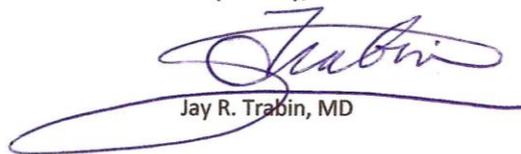
PAST-CHAIR
Ed Carney, MD

On behalf of the Florida Section of the American Congress of Obstetricians and Gynecologists (ACOG), I congratulate the March of Dimes (MOD), the California Maternal Quality Care Collaborative (CMQCC), and the California Maternal, Child and Adolescent Health Division; California Department of Public Health (CMCAHD-CDPH) for the development of the *California Quality Improvement Toolkit* with its goal to eliminate non-medically indicated deliveries prior to completion of 39 weeks gestation. We are delighted that this valuable resource is being considered for implementation in our own State.

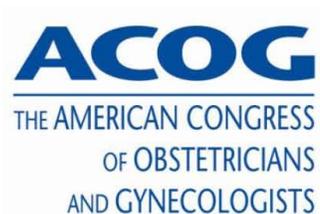
As you know, in its ongoing effort to reduce perinatal morbidity, ACOG for many years has advocated against elective deliveries prior to 39 weeks. The *Toolkit* has produced very encouraging results and we believe that we can similarly reduce perinatal adverse outcomes by implementing that program in Florida. It is especially noteworthy that the *Toolkit*, which is based on established ACOG guidelines, neither defines the standards for the State nor does it impose punitive measures. What it does accomplish includes: (1) It explains the cogent rationale for purely elective deliveries only after 39 weeks and encourages the practice of accurate gestational age dating; (2) It serves to support and reinforce correct approaches already undertaken by some physicians and hospitals, and provides a practical template for implementation of those approaches by others; (3) It provides guidelines for data collection and analysis; and (4) It even offers useful FAQ sheets and a Power Point presentation for educating hospital personnel.

As the premier organization dedicated to the well-being of women, ACOG understands that the *Toolkit* engenders a process that enhances safety, improves quality, and maximizes healthy outcomes. This program will be useful in many capacities, from encouraging documentation of gestational age on hospital admission, to the collection and dissemination of outcome data. Again, we applaud the MOD, CMQCC, and CMCAHD-CDPH in their efforts to improve perinatal outcomes and appreciate the opportunity to apply this in Florida.

Respectfully,



Jay R. Trabin, MD



ACOG DISTRICT XI

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April 26, 2010

On behalf of the American Congress of Obstetricians and Gynecologists, District XI, I want to offer our support for the March of Dimes, "CALIFORNIA QUALITY IMPROVEMENT TOOLKIT: Elimination of Non-Medically Indicated (Elective) Deliveries Before 39 Weeks Gestational Age."

We commend the March of Dimes, the California Maternal Quality Care Collaborative, and the California Department of Public Health for their leadership in producing this toolkit. ACOG has advised against **elective** deliveries before 39 weeks gestation for many years, and this toolkit is based on ACOG Guidelines.

This toolkit provides with guidelines based on local level of care and patient populations. It emphasized the need for effective pregnancy dating and appropriate timing of delivery. This toolkit is a how-to guide for hospitals or physicians to provide the initiative and insight into developing a quality program at the local level. It also provides suggestions for data analysis and educational materials for hospital staff.

District XI is committed to providing safety, quality and increased healthy outcomes for our patients. This toolkit provides a mechanism to achieve this, without confusing the necessary role of early delivery for maternal or neonatal indications. ACOG District XI is partnering with the Texas Chapter of the March of Dimes to educate healthcare providers and distribute the toolkit.

Sincerely,

A handwritten signature in black ink that reads "John C. Jennings, M.D." in a cursive script.

John C. Jennings, MD
Chair
District XI ACOG



May 11, 2010

Dear Healthcare Provider,

The Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN) California Section elected officers were asked to review the toolkit titled "A California Toolkit to Transform Maternity Care: Eliminating Non-Medically Indicated (Elective) Deliveries Before 39 Weeks Gestational Age". This toolkit was a collaborative project developed by the California Maternal Quality Care Collaborative, March of Dimes, and the California Department of Public Health: Maternal Child and Adolescent Health Division.

We have reviewed the contents of the toolkit and feel this will serve as an important resource for healthcare providers and for hospitals. It will help to reduce and/or eliminate neonatal morbidities, such as respiratory complications, sepsis, and hypoglycemia.

On behalf of the AWHONN California Section, we are pleased to submit our letter of support for this toolkit.

Barbara Sewell
Barbara Tewell, RNC-OB, MSN
President
AWHONN
California Section

Kristi Gabel
Kristi Gabel, RNC-OB, MSN, CNS
Secretary/Treasurer
AWHONN
California Section



Promoting the health of women and newborns.

May 26, 2010

California Maternal Quality Care Collaborative (CMQCC)
Medical School Office Building
251 Campus Drive, MS 5415
Stanford, CA 94305

To Whom It May Concern:

On behalf of the 23,000 members of the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) and the millions of families they serve, I applaud the production of, "A California Toolkit to Transform Maternity Care: Eliminating Non-medically Indicated (Elective) Deliveries Before 39 Weeks Gestational Age" and "Obstetric Hemorrhage Toolkit: Obstetric Hemorrhage Care Guidelines and Compendium of Best Practices." AWHONN and its California Section support the use of these resources to advance the health of women and newborns.

AWHONN supports the American Congress of Obstetricians and Gynecologists (ACOG) recommendations that advise against non-medically indicated deliveries prior to 39 weeks completed gestation. Further, because of AWHONN's extensive research related to late preterm infants, it is clear that these babies are at risk for a host of potentially serious health problems. There is a growing need for effective pregnancy dating and appropriate timing of delivery. Health care providers and their patients must be made aware of the evidence that spontaneous labor is associated with fewer complications than induced labor, and that there are risks to the infant when born just a few weeks early.

AWHONN also supports the mission of CMQCC to eliminate preventable maternal mortality and morbidity and to eliminate racial and ethnic disparities. As such, the "Obstetric Hemorrhage Toolkit," will provide an equally important contribution to improving care in the state of California.

We commend CMQCC, the March of Dimes, the California Department of Health, the California Perinatal Quality Care Collaborative, and Stanford University on these collaborations that are making comprehensive and standardized resources available to obstetric care providers.

Sincerely,

A handwritten signature in cursive script that reads 'Karen Peddicord'.

Karen Peddicord, RNC, PhD
Chief Executive Officer

Appendix E – Clinician Slide Presentation

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MEDICAL PRACTICE

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Website Resource Links

California Maternal Quality Care Collaborative	http://www.cmqcc.org
Hospital Corporation of America	http://www.hcahealthcare.com
Institute for Healthcare Improvement	www.ihl.org
Intermountain Health	www.intermountainhealthcare.org
Lamaze International	www.lamaze.org
March of Dimes	www.marchofdimes.com
Ohio Perinatal Quality Collaborative	www.opqc.net

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