
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

Elliott Main, MD^{a,b}; Bryan Oshiro, MD^c; Brenda Chagolla, RN, MSN, CNS^d; Debra Bingham, Dr.PH, RN^a; Leona Dang-Kilduff, RN, MSN^e; Leslie Kowalewski^f.

From California Maternal Quality Care Collaborative (CMQCC)^a; California Pacific Medical Center^b; Loma Linda University School of Medicine^c; Catholic Healthcare West^d; California Perinatal Quality Care Collaborative (CPQCC)^e; and March of Dimes^f.

Suggested Citation:

Main E, Oshiro B, Chagolla B, Bingham D, Dang-Kilduff L, and Kowalewski L. Elimination of Non-medically Indicated (Elective) Deliveries Before 39 Weeks Gestational Age. (California Maternal Quality Care Collaborative Toolkit to Transform Maternity Care) Developed under contract #08-85012 with the California Department of Public Health; Maternal, Child and Adolescent Health Division; First edition published by March of Dimes, July 2010.

Funding for the development of this toolkit was provided by:

Federal Title V block grant Funding from the California Department of Public Health; Maternal, Child and Adolescent Health Division was used by the California Maternal Quality Care Collaborative to develop the toolkit; and March of Dimes.

The California Toolkit to Transform Maternity Care called “Elimination of Non-medically Indicated (Elective) Deliveries Before 39 Weeks Gestational Age” was reviewed by the California Department of Public Health (CDPH); Maternal, Child and Adolescent Health (MCAH) Division. The toolkit is considered a resource, but does not define the standard of care in California. Readers are advised to adapt the guidelines and resources based on their local facility’s level of care and patient populations served and are also advised not to rely solely on the guidelines presented here.

Copyright information:

© California Department of Public Health. The material in this toolkit may be reproduced and disseminated in any media in its original format, without modification, for informational, educational and non-commercial purposes only. A nominal sum to cover costs of reproduction and distribution can be assessed. Any modification or use of the materials in any derivative work is prohibited without prior written permission of the California Department of Public Health.

For correspondence, please contact

March of Dimes

Leslie Kowalewski
1050 Sansome Street, 4th Floor
San Francisco, CA 94111
Phone (415) 217-6366
FAX: (415) 788-2802
email: lkowalewski@marchofdimes.com
Website: www.marchofdimes.com

CMQCC

Kathryn Melsop, MS
Managing Editor
Transforming Maternity Care Series
Stanford University
Medical School Office Building
251 Campus Drive
Palo Alto, CA 93405
Phone: (650) 725-6108
FAX: (650) 721-5751
email: melsop@cmqcc.org
Website: www.cmqcc.org

CDPH Maternal, Child & Adolescent Health Division

Connie Mitchell, MD, MPH
1615 Capitol Avenue
PO Box 997420, MS 8306
Sacramento, CA 95899-7420
Phone: (916) 650-0327
email: connie.mitchell@cdph.ca.gov
Website: www.cdph.ca.gov

ACKNOWLEDGEMENTS

San Bernardino Public Health Department used Title V block grant funding from California Maternal, Child and Adolescent Health Division to develop a “Labor Induction Toolkit” in collaboration with local hospitals and health experts. Their work contributed to the development of this statewide toolkit. We thank Lony Castro, MD for her leadership as Chair of the Maternal Morbidity and Mortality Labor Induction Education Project Advisory Council. The public health department and hospitals in San Bernardino continue to implement and field test tools to improve maternal and neonatal outcomes.

REVIEW COMMITTEE

Diane Ashton, MD, MPH, FACOG; March of Dimes, Deputy Medical Director (White Plains, NY)
Jennifer Baptiste-Smith, MPH; San Bernardino Public Health Department (San Bernardino)
Scott Berns, MD, MPH, FAAP; March of Dimes, Senior VP Chapter Program Support (White Plains, NY)
Debra Bingham, DrPH, RN, LCCE; California Maternal Quality Care Collaborative (CMQCC), Executive Director (Palo Alto)
James Byrne, MD; Santa Clara Valley Medical Center, Chief, Obstetrics and Maternal Fetal Medicine, (San Jose)
Brenda Chagolla, RNC, MSN, CNS; Catholic Healthcare West, Manager, Patient Safety & Clinical Risk (Rancho Cordova)
Leona Dang-Kilduff, RN, MS, CDE; CDAPP; Mid-Coastal Regional California Diabetes and Pregnancy Coordinator at Stanford University School of Medicine (Palo Alto)
William Gilbert, MD; Sutter Health Sacramento, CMQCC Executive Committee (Sacramento)
Jeffrey B. Gould, MD, MPH, PI CPQCC; CMQCC Executive Committee (Stanford)
Rory Jaffe, MD, MBA; Executive Director, California Hospital Patient Safety Organization (Sacramento)
Leslie Kowalewski, March of Dimes, California Chapter Associate State Director & Director Big 5 State Prematurity Initiatives (San Francisco)
Elliott Main, MD; CMQCC, Chairman and Chief of Obstetrics Department of Ob/GYN California Pacific Medical Center (San Francisco)
Peyton Mason-Marti, MPH; March of Dimes, California Chapter, State Director of Programs (San Francisco)
Connie Mitchell, MD, MPH; CDPH, California Maternal, Child and Adolescent Health Division (Sacramento)
Barbara Murphy, MS, RN; Director of Perinatal Programs, CMQCC Executive Committee (Palo Alto)
Bryan Oshiro, MD; Vice-Chairman, Dept. Ob/GYN Medical Director, Perinatal Institute, Loma Linda University Medical Center/Children's Hospital (Loma Linda)
Gretchen Page, MPH CNM; Manager, Community Grants, Loma Linda University Medical Center /Children's Hospital (Loma Linda)
Steven Parry, MD; FACOG, MCBWARD, Medi-Cal Benefits Branch, Medical Consultant II (Sacramento)
Karen Ramstrom, DO, MSPH; CDPH, Maternal, Child, Adolescent Health Division Policy Branch Chief, (Sacramento)
Leona Shields, PHN, RN, NP, MFT; Nurse Consultant III Specialist, Maternal, Child and Adolescent Health Division (Sacramento)
Stephanie Turner, Senior Vice President, Risk Management; Optima Healthcare Insurance Services (Roseville)
Lucy Van Otterloo, RN, MSN; Community Perinatal Network, CMQCC (Whittier)
John Wachtel, MD, FACOG; Adjunct Clinical Professor Department of OB/GYN at Stanford Medical School, ACOG District IX Patient Safety Officer and Chair, Patient Safety and Quality Improvement Committee, (Menlo Park)

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.

TABLE OF CONTENTS

Acknowledgements	Page 1
Supporting Organizations	Page 2
Executive Summary	Page 3
<u>Table of Contents</u>	
List of Tables	Page 6
List of Figures	Page 7
List of Forms	Page 8
Making the Case	Page 9
Definitions for a Common Language	
Accepted Indications for Delivery <39 Weeks Gestation	
Elective Deliveries: A growing concern	
What are the Risks of Deliveries Before 39 Weeks?	
Maternal Risk	
Cost Analysis	
Quality Improvement Interventions to Reduce Elective Births <39 Weeks	
Implementation Strategy	Page 26
The Big Picture	
Rapid Cycle QI Methodology: Mobilize, Assess, Plan, Implement, Track (MAP-IT)	
Implementation Checklist	
Barriers and Strategies to Mitigate Barriers	
Sample Scheduling Form	
Sample Scheduling Algorithm	
Sample Policy and Procedure	
Guidelines for Informed Consent Discussions	
Data Collection / QI Measurement	Page 39
Data Collection	
Selecting Quality Measures	
QI Data Collection Form	
Measure Specifications and Guidelines	
Overview of National Quality Measures	
Comparison of National Specifications for Medical Conditions	
Data Collection for Quality Measurement	
Clinician Education	Page 50
Clinician Slide Presentation	
Clinician Frequently Asked Questions (FAQs)	
Patient Education	Page 57
Key Patient Education Messages	
Patient Education Resource Materials	
Patient Education Talking Points	
Common Patient Questions	
Appendices	Page 64
Appendix A – Other Sample Forms	
Appendix B – Hospital Case Studies	
Appendix C – QI Implementation Tools	
Appendix D – Letters of Support	
Appendix E – Clinician Slide Presentation	
References by Topic	
Website Resource Links	
References in Order of Citation	

List of Tables

Table 1: Examples of Medical Indication for Delivery Prior to 39 Weeks Gestation	Page 11
Table 2: Complications of Elective Deliveries Between 37 and 39 Weeks	Page 14
Table 3: Risk of NICU Admissions for Elective Deliveries at 37-39 Weeks (HCA)	Page 15
Table 4: Timing of Elective Repeat Cesarean Delivery at Term and Neonatal Outcomes (MFM Network)	Page 16
Table 5: Adverse Neonatal Outcomes	Page 18
Table 6: Selected Maternal Outcome Data Before and After Initiation of the IHC <39 Week Elective Delivery Reduction Program (1999-2000 and 2001-2006)	Page 19
Table 7: Stillbirth Data from the Intermountain Healthcare Elective Induction Reduction Before 39 Weeks QI Project (Before and After periods)	Page 21
Table 8: Reduction of Induction Risks: A Departmental QI Project	Page 22
Table 9: Examples of Quality Measures	Page 41
Table 10: Comparison of National Specifications for Medical Conditions that May Justify a Scheduled Delivery Prior to 39 Weeks Gestation	Page 47
Table 11: Data Element Sources with Combined Rankings of Availability and Reliability	Page 49
Table 12: Plan-Do-Study-Act (PDSA) Method Summary	Page 87

List of Figures

Figure 1: Change in Distribution of Birth by Gestational Age: United States 1990-2006	Page 12
Figure 2: U.S. Cesarean Section and Labor Induction Rates Among Singleton Live Births by Week of Gestation, 1992 and 2002	Page 12
Figure 3: Rise in Induction of Labor by Racial Groups	Page 13
Figure 4: Higher Ventilation Use among Infants Delivered at 37 Weeks Gestation	Page 14
Figure 5: Increased NICU Admissions among Infants Delivered at 37 Weeks Gestation	Page 15
Figure 6: Complication Rates in Infants of Scheduled Repeat Cesarean by Gestation Age (Weeks)	Page 17
Figure 7: Odds Ratios for Complications in Infants of Scheduled Repeat Cesarean Birth by Gestational Age (Weeks)	Page 17
Figure 8: Percent of Elective Deliveries Before 39 Weeks of Gestation	Page 21
Figure 9: Percent of Ohio Births at 36 to 38 Weeks Induced Without Medical or Obstetric Indication	Page 23
Figure 10: Ohio Births at 36 to 38 Weeks Gestation Following Induction Without Apparent Medical Indication for Delivery, by OPQC Member Status	Page 24
Figure 11: Gestational Age Distribution of Births at OPQC Member Hospitals, by Month	Page 24
Figure 12: Stillbirths among OPQC Participating Hospitals	Page 25
Figure 13: Graphic Overview of Key Components	Page 27
Figure 14: MAP-IT QI Methodology	Page 28
Figure 15: Scheduling Algorithm	Page 34
Figure 16: The Joint Commission Work Flow for: PC-01 – Elective Deliveries <39 Weeks	Page 48
Figure 17: Percentage of Tallahassee Memorial Hospital Deliveries by Gestation Age	Page 79
Figure 18: Blank Ishikawa “Fishbone” Diagram	Page 84
Figure 19: Example of a Completed Ishikawa “Fishbone” Diagram	Page 84
Figure 20: Plan-Do-Study-Act Cycle	Page 85

List of Sample Forms

Form 1: Scheduling	Page 33
Form 2: Data Collection	Page 42
Form 3: March of Dimes Scheduling Template	Page 65
Form 4: Tallahassee Scheduling Process	Page 67
Form 5: Tallahassee Consent	Page 70
Form 6: MAP-IT Worksheet	Page 83

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

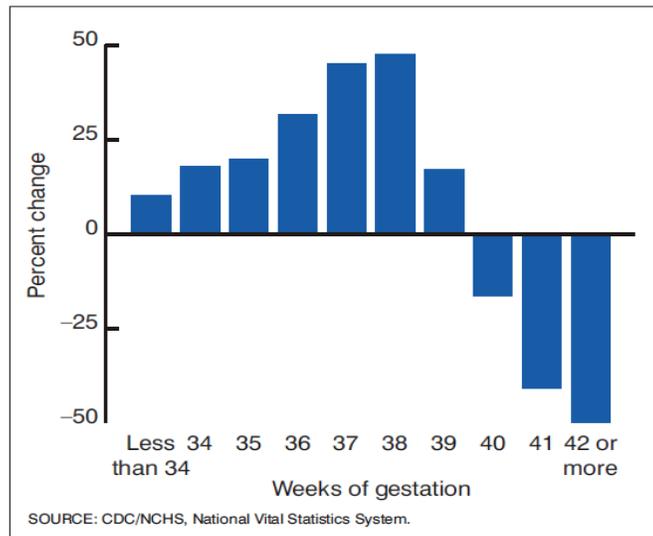
Table 1: Examples of Medical Indications for Delivery Prior to 39 Weeks Gestation	
ACOG: “Examples of maternal or fetal conditions that may be indications for induction of labor”¹¹	The Joint Commission: National Quality Core Measure PC-01-- Specifications for “Conditions justifying delivery <39weeks”¹⁹
<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

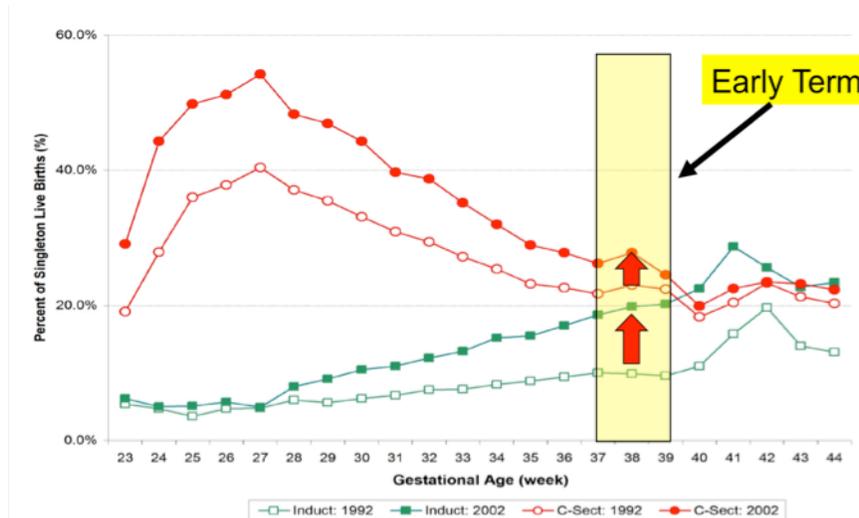
Rates of labor induction have increased dramatically from 9% in 1989 to 21.2% in 2004. Much of this rise has been attributed to an increase in elective inductions.²³ Data from the Hospital Corporation of America showed that 44% of deliveries at term in 2007 were scheduled cesarean sections or inductions 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.

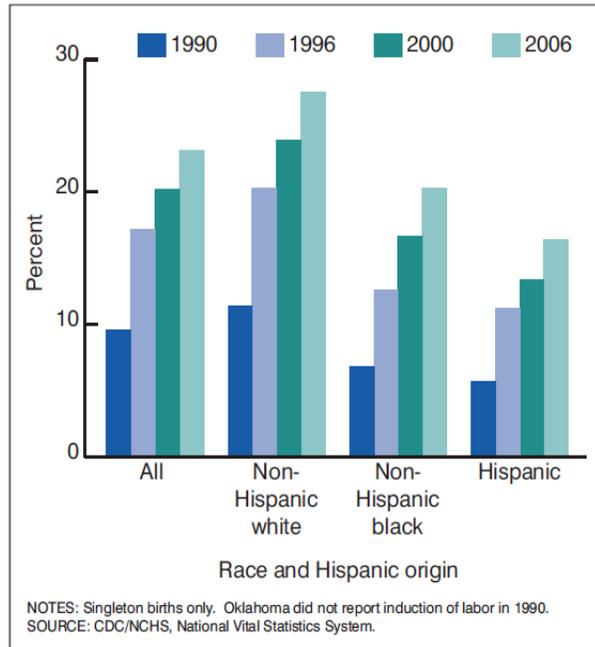
Figure 2: U.S. Cesarean Section and Labor Induction Rates Among Singleton Live Births by Week of Gestation, 1992 and 2002



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?

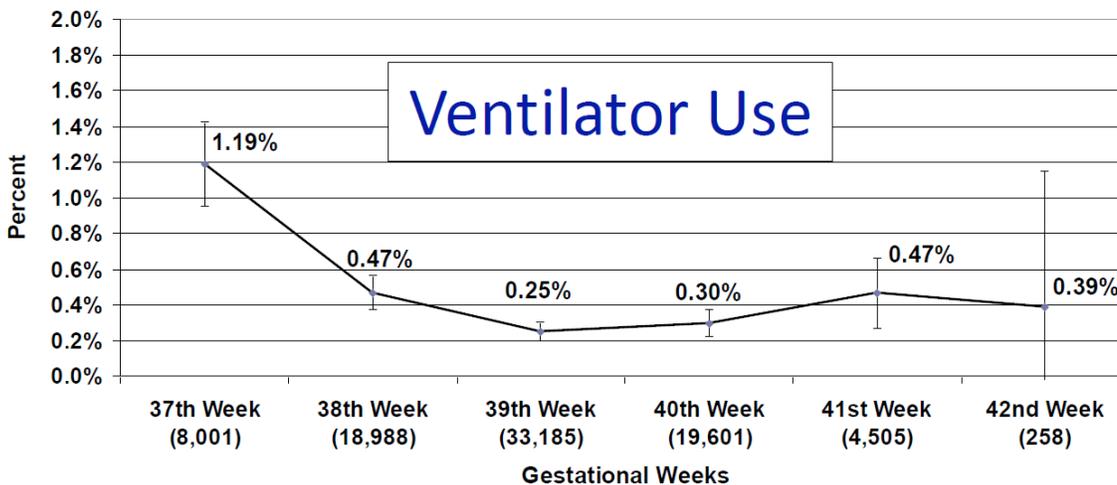
Multiple recent studies indicate that elective deliveries <39 weeks carry significant increased risk for the baby (odds ratios 2.0-3.0 compared to infants born between 39 and 41 weeks). (Table 2)²⁶⁻³⁰ The risk is highest for scheduled pre-labor cesarean sections at 37 weeks gestation, but is significant 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

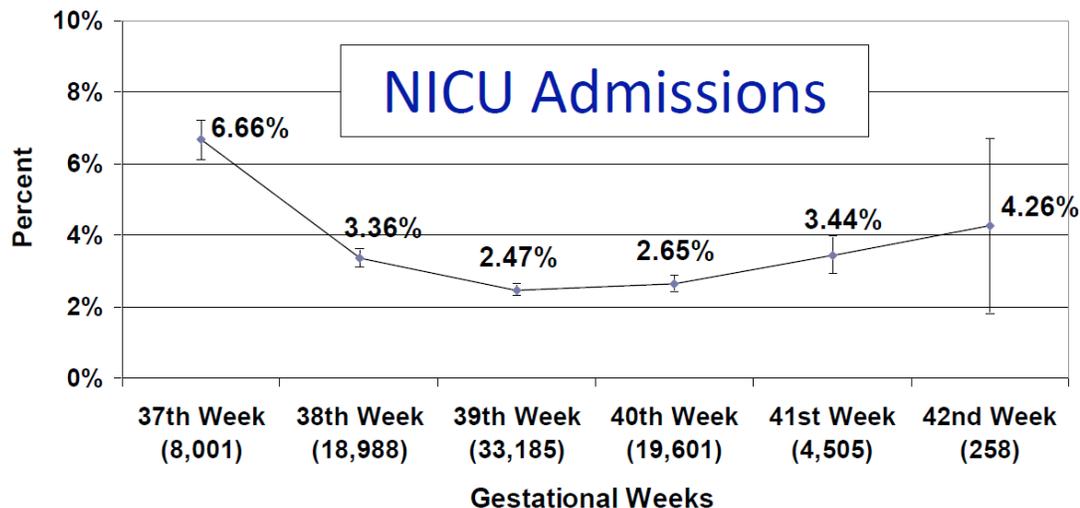
Intermountain Healthcare (IHC) Study—ICU Admissions, Ventilator Use: Intermountain Healthcare operates 21 hospitals in Utah and Southeast Idaho and performs approximately 30,000 deliveries annually (www.intermountainhealthcare.org). A recent study of this integrated healthcare system showed that rates 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.

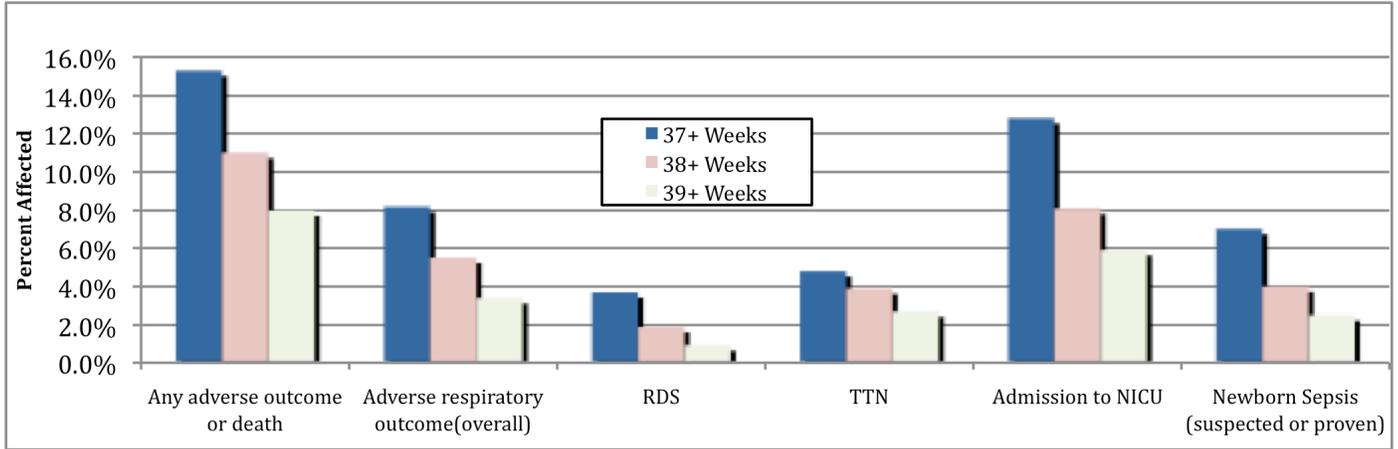
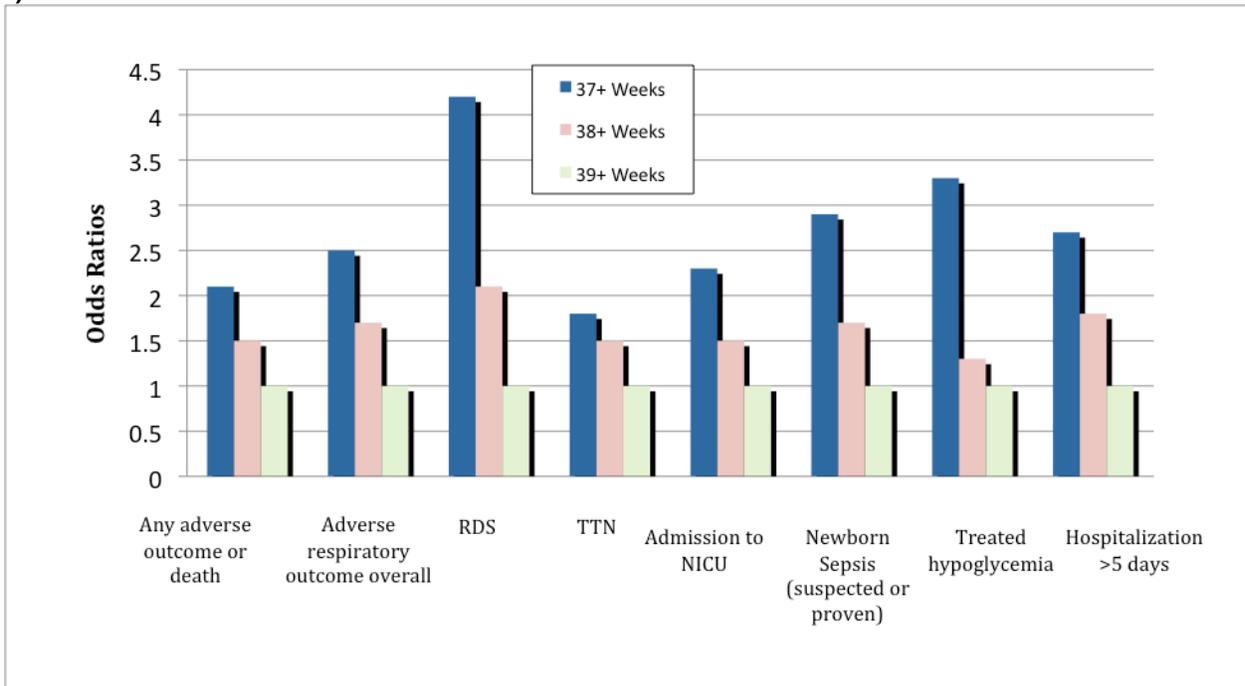


Figure 7 shows odds ratios to highlight the relative effect of gestational age on neonatal complication rates. Odds ratios range from 2 to 4 for all infants at 37+ weeks gestation.⁷

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

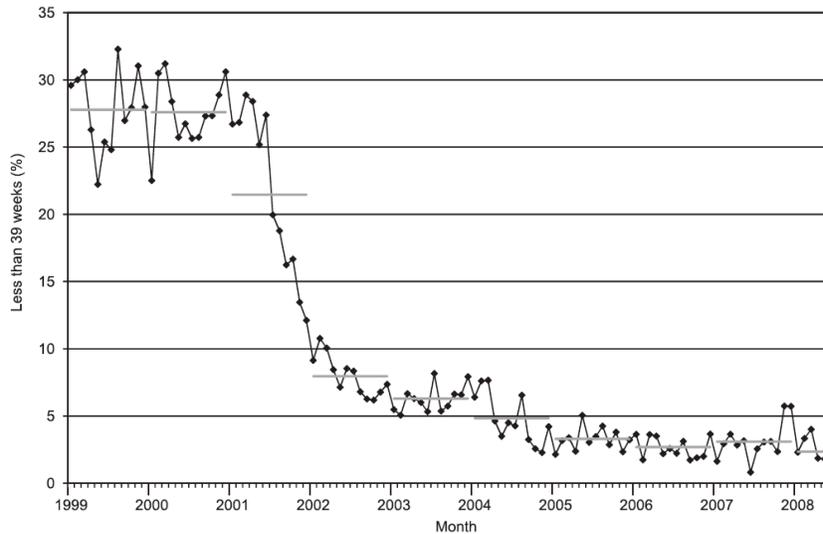
QI interventions have successfully decreased elective deliveries <39 weeks and associated maternal and neonatal mortality and morbidity. Three studies are reviewed below.

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).

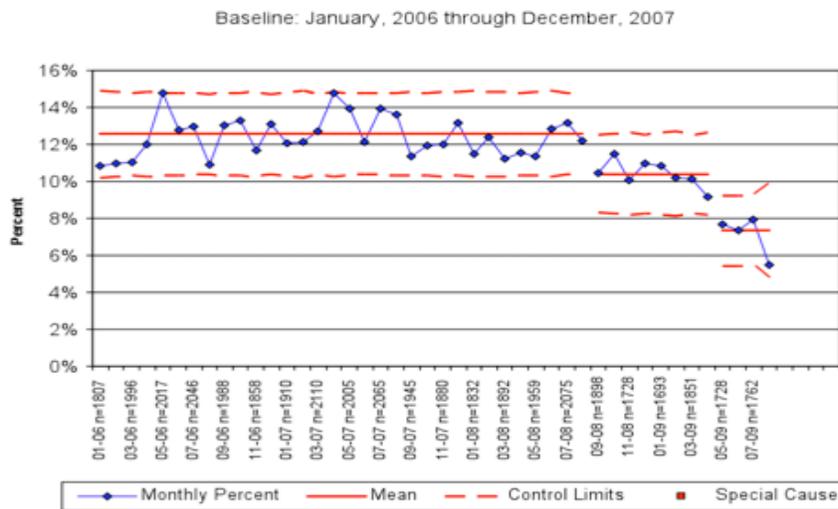
	3 months 2004	3 months 2005	14 months 2006-7
QI Approach	Baseline	Education and voluntary guidelines	Formal approval needed to schedule outside guidelines
Deliveries (N)	2,139	2,260	10,895
Elective Inductions <39wks (N)/ Total Elective Inductions (rate)	23 11.8%	21 10.0%	30 4.3% (p<0.001)
Elective Nullip Inductions (N) Elective Nullip Inductions =>C/S (N) Elective Nullip Inductions =>C/S (rate)	29 10 35.7%	33 5 15.2%	87 12 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.

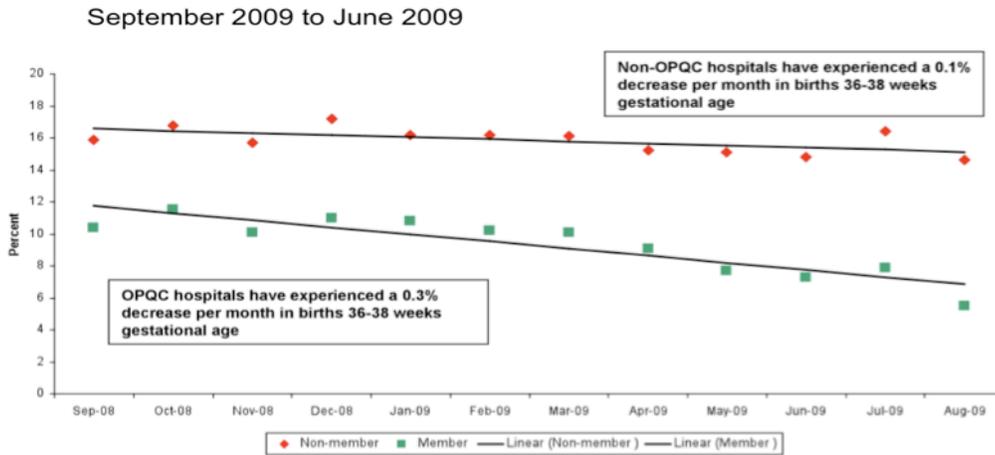
Figure 9. Percent of Ohio Births at 36 to 38 Weeks Induced Without Medical or Obstetric Indication



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.

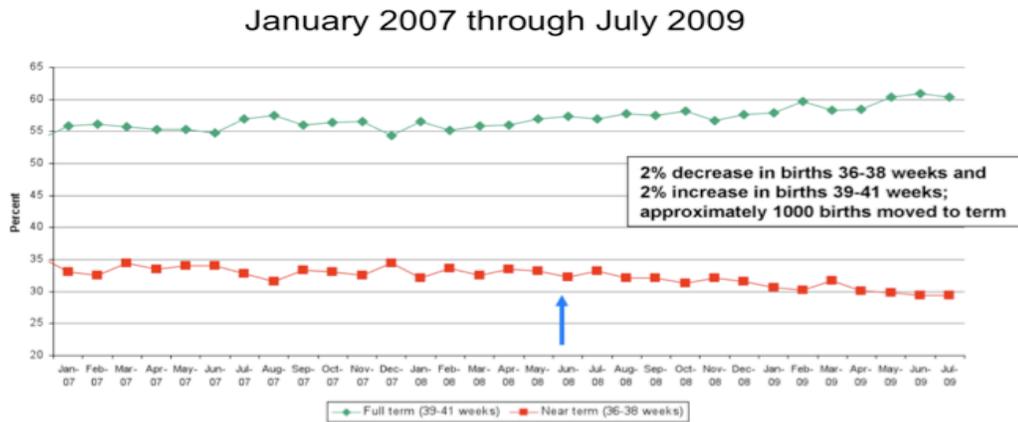
Figure 10: Ohio Births at 36 to 38 Weeks Gestation Following Induction Without Apparent Medical Indication for Delivery, by OPQC Member Status



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.

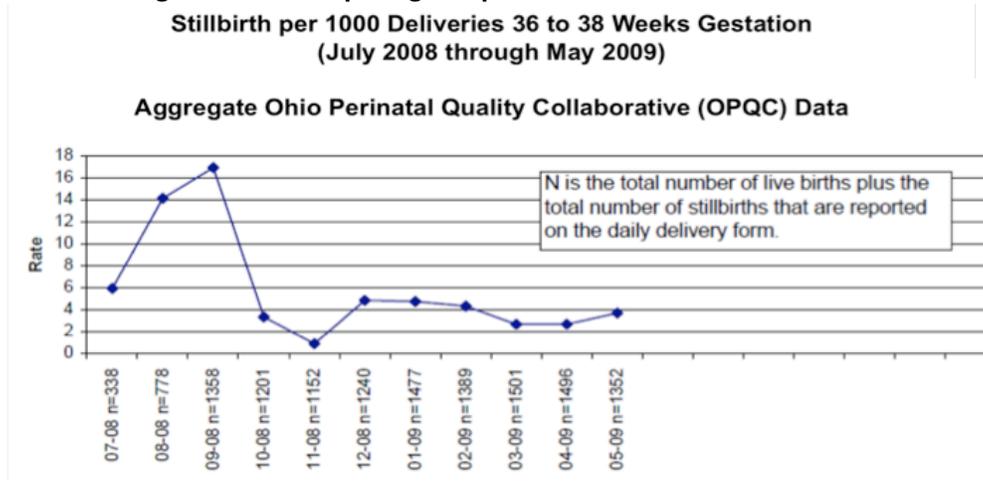
Figure 11: Gestational Age Distribution of Births at OPQC Member Hospitals, by Month



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.