Health Texas Babies Provider Intervention Workgroup
Subgroup #1 • Pre-39 Weeks
Final Deliverable / Intervention Action Plan

Healthy Texas Babies (HTB) Expert Panel (EP) Meeting Attendees: Please review the document below for content only. All HTB workgroup intervention deliverables will be consistently formatted following the July 30, 2011 EP meeting.

1.1 Detailed Intervention Description:

Goal: To eliminate non-medically indicated, non-spontaneous deliveries prior to 39 weeks' gestation. Non-medically indicated is defined as a lack of an obstetrical, maternal, or fetal condition necessitating delivery.

Outcome: Goal accomplishment will simultaneously improve the health and reduce the morbidity of mothers and their newborns in the State of Texas. This will reduce both short and long term expenditures for healthcare of this specific population via reduced hospital length of stay, neonatal ICU utilization, and chronic medical conditions attributable to iatrogenic prematurity.

Measurement of outcome: Elimination of non-medically indicated inductions of labor or cesarean delivery prior to 39 weeks' gestation.

Intervention: Adoption of guidelines for timing of delivery when conditions complicate pregnancy at or beyond 34 weeks' gestation as endorsed by the Society for Maternal-Fetal Medicine (SMFM) and by the Eunice Kennedy Shriver National Institute of Child Health and Development (NICHD) of the National Institutes of Health (NIH).

Activities:

1. Seek acceptance and implementation of these peer reviewed guidelines by:
   A. Federal
      - Centers for Disease Control and Prevention (Division of Reproductive Health)
      - Maternal and Child Health Bureau / Title V
      - Centers for Medicare and Medicaid Services (CMS)

   B. National
      - American Academy of Pediatrics (AAP)
      - American College of Obstetricians and Gynecologists (ACOG)

- Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN)
- March of Dimes
- National Institute of Child Health and Development (NICHD) of the National Institute of Health (NIH).
- Society for Maternal-Fetal Medicine (SMFM)

C. Texas
- Children's Hospital Association of Texas (CHAT)
- Consortium of Texas Certified Nurse Midwives (CTCNW)
- Texas Association of Health Plans (TAHP)
- Texas Association of Neonatal Nurse Practitioners (TxANNP)
- Texas Association of Obstetricians and Gynecologists (TAOG)
- Texas Department of State Health Services (DSHS)
- Texas Health and Human Services Commission (HHSC)
- Texas Hospital Association (THA)
- Texas Medical Association (TMA)
- Texas Nurses Association (TNA)
- Texas Pediatric Society (TPS)

D. Regional
- All programs for families
- DSHS Health Service Regions (HSR)
- Regional Hospital Associations
- Obstetrical Care Providers
- Payers
- Professional Societies
- Regional Perinatal Coalitions

E. Professional
- America's Health Insurance Plans (AHIP)
- DNV (Det Norske Veritas)
- The Joint Commission

2. Recommend peer review for quality improvement of any delivery via labor induction or cesarean section that falls outside of the nationally endorsed guidelines, accepting that there may be a valid reason for delivery not covered in these guidelines.
3. Provide feedback to providers when no valid indication for delivery prior to 39 weeks is established. Behavioral change should be effected via constructive educational feedback.
4. After a run-in period to educate and to improve or optimize practice as a primary tool; consider other enforcement mechanism to potentially include:
    a. Provide report cards that list non-medically indicated preterm deliveries prior to 39 weeks
    b. Denial of payment to hospital and provider for any non-medically indicated preterm deliveries prior to 39 weeks
5. Develop consistent messages for the public regarding the infant morbidity and mortality associated with non-medically indicated delivery before 39 weeks.

1.2 Are there best practices associated with this intervention? If so, please highlight.

Best practice has been determined by two national professional bodies, the Society for Maternal-Fetal Medicine (SMFM) and the Eunice Kennedy Shriver National Institute of Child Health and Development (NICHD), collaboratively as listed in Table 1 to include the grade of the recommendation.

1.3 Intervention - Desired Outcomes

Short-term (1-3 years):

A. Work with other organizations to increase awareness of the morbidity and mortality associated with non-medically indicated delivery at <39 weeks among providers of women's health care. Reduce the number of non-medically indicated inductions and elective cesarean deliveries prior to 39 weeks to almost zero within the next 2 years.
B. Develop consistent messages for the public regarding maternal infant morbidity and mortality associated with non-medically indicated delivery before 39 weeks.
C. Increase the awareness of the SMFM / NICHD guidelines for timing of delivery among providers of women's health care.
    a. Post them in every hospital L&D's nurses' station and medical staff Lounge.
    b. Category I CME/CNE programs at all hospitals.
D. Work with professional organizations to provide guidance for physicians and hospitals as they develop peer-review processes to identify deliveries that fall outside hospital guidelines.
E. Develop processes for regional QA/QI that can provide assistance to small hospitals or single practices

F. Develop standardized data definitions and processes for accurate data collection.
G. Collaborate with HHSC on development of data definitions and accurate data collection mechanisms

Long-term (5-7 years):

A. Work with other organizations to continuously review and update the guidelines as changes in the medical literature indicate.
B. Work with other organizations to develop continuing medical education opportunities to keep providers up-to-date.
C. After a period of 3-5 years, consider other enforcement mechanisms to potentially include:
    a. Report cards that list rates of non-medically indicated deliveries prior to 39 weeks for the individual provider and the place of birth.
    b. Denial of payment to hospital and provider for non-medically indicated deliveries prior to 39 weeks.

1.4 Data Elements to be Collected and Evaluated

Pre-Intervention:

A. Statewide survey of facilities that deliver babies to determine if policies are in place to identify and deter non-medically indicated deliveries prior to 39 weeks.
B. Statewide number of NICU admissions for infants with gestational age:
    a. 32 – 33 6/7 weeks
    b. 34 – 36 6/7 weeks
    c. 37 – 38 6/7 weeks
C. Statewide number of labor inductions and cesarean deliveries performed at gestational ages:
    a. 32 – 33 6/7 weeks
    b. 34 – 36 6/7 weeks
    c. 37 – 38 6/7 weeks

Monitoring:

A. Track the dissemination and adoption of the “guidelines for timing of delivery” by various professional societies in Texas
B. Track the number of NICU admissions for infants with gestational age:
    a. 32 – 33 6/7 weeks
    b. 34 – 36 6/7 weeks
    c. 37 – 38 6/7 weeks
C. Track the number of labor inductions and cesarean deliveries performed at gestational ages:
    a. 32 – 33 6/7 weeks

b. 34 – 36 6/7 weeks
c. 37 – 38 6/7 weeks

D. Track the dissemination of educational materials geared to the public's perception of non-medically indicated deliveries prior to 39 weeks.
E. Monitor the development of methods to track non-medically indicated deliveries prior to 39 weeks specific to provider, practice group, hospital and hospital chain
F. Track the development of peer review processes at the local and regional level

Post-Intervention:

A. Statewide survey of facilities that deliver babies to determine if policies are in place to identify and deter non-medically indicated deliveries prior to 39 weeks.
B. Statewide number of NICU admissions for infants with gestational age:
   a. 32 – 33 6/7 weeks
   b. 34 – 36 6/7 weeks
   c. 37 – 38 6/7 weeks
C. Statewide number of labor inductions and cesarean deliveries performed at gestational ages:
   a. 32 – 33 6/7 weeks
   b. 34 – 36 6/7 weeks
   c. 37 – 38 6/7 weeks
D. Number of non-medically indicated deliveries by provider, practice group, hospital and hospital chain in Texas
E. Tracking of potential unintended effects (e.g. stillbirth, maternal morbidity and mortality)

Process evaluation:

A. Workgroup progress report at one year after program initiation.
B. Once developed, survey to have an evaluation component.

1.5 Has the intervention been implemented in Texas or in other areas of the United States? If yes, please provide specific details and contact information.

Although the exact intervention noted here has not been implemented, below are some examples of interventions that have addressed some of the components of the proposed intervention.

A. The Seton Family of Hospitals in Austin and Central Texas has implemented practices in labor and delivery units aimed at reducing the rate of birth trauma, which included elimination of elective labor inductions before 39 weeks of gestation.

B. The March of Dimes is currently implementing Healthy Babies are Worth the Wait (HBWW) in Houston with plans for expansion to Dallas in late 2012. In HBWW sites, community health leaders, including hospitals, health departments and local March of Dimes staff partner to work together to implement multiple (bundled) interventions known to impact preterm birth; to improve systems of care in their community so that these interventions reach the patients who need them; and to promote awareness of preterm birth across all the community, including providers, patients and the public.

C. The Texas Chapter of the March of Dimes is participating in a national March of Dimes Big 5 Prematurity Collaborative. Six hospitals across Texas are participating in a one-year pilot test of the Less than 39 Weeks Toolkit and distribution of educational materials to patients regarding non-medically indicated (elective) deliveries prior to 39 weeks gestational age. First quarter 2011 shows substantial improvements in the rate of elective deliveries.

D. The March of Dimes is partnering with the Texas Association of Obstetricians and Gynecologists (TAOG) and ACOG to host a statewide train the trainer for obstetricians to learn more about reducing late preterm births so that they can then speak peer-to peer with other obstetricians and gynecologists.

1.6 Possible Partners (both public and private)

A. Federal
- Centers for Disease Control and Prevention (Division of Reproductive Health)
- Maternal and Child Health Bureau/Title V
- Centers for Medicare and Medicaid Services (CMS)

B. National
- American Academy of Pediatrics (AAP)
- American College of Obstetricians and Gynecologists (ACOG)
- American Medical Association (AMA)
- Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN)
- Det Norske Veritas (DNV)
- March of Dimes
- National Institute of Child Health and Development (NICHD) of the National Institute of Health (NIH).
- National Medical Association (NMA)
- National Perinatal Association (NPA)
- Society for Maternal-Fetal Medicine (SMFM)
- The Joint Commission (Accreditation and Certification Operations)

C. Texas
- Consortium of Texas Certified Nurse Midwives (CTCNW)
- Texas Association of Health Plans (TAHP)
- Texas Association of Neonatal Nurse Practitioners (TxANNP)
- Texas Association of Obstetricians and Gynecologists (TAOG)
- Texas Department of State Health Services (DSHS)
- Texas Health and Human Services Commission (HHSC)
- Texas Hospital Association (THA)
- Texas Medical Association (TMA)
- Texas Nurses Association (TNA)
- Texas Pediatric Society (TPS)

D. Regional
- All programs for families
- DSHS Health Service Regions (HSR)
- Hospitals
- Obstetrical Care Providers
- Payers
- Professional Societies
- Regional Perinatal Coalitions

E. Professional
- America's Health Insurance Plans (AHIP)
- DNV (Det Norske Veritas)
- The Joint Commission

1.7 Recommended appropriate assessment tools (e.g. Perinatal Periods of Risk (PPOR))

A. None currently available but should reflect data collection described in 1.3 & 1.4
B. Birth certificate data to include appropriate data points / granularity
C. Develop standardized data definitions and processes for accurate data collection Leverage current reporting processes (e.g., electronic medical records or birth certificate data) for these purposes
D. Tools for local peer review may need to be developed

E. March of Dimes "Eliminations of Non-Medically Indicated (Elective) Deliveries Before 39 Weeks Gestational Age
F. TAOG toolkit to support HB 1393

1.8 Recommended Lead Agency for Intervention

A. A collaborative between the Texas Health and Human Services Commission (HHSC), the Texas Department of State Health Services (DSHS), and Texas licensing boards with support and leadership from statewide professional organizations and a statewide coalition.

1.9 Target Audience(s) – define for each specific activity included in the intervention

Activities:

A. Any other interested stakeholders
B. Federal, State and Local Policy Makers
C. General Public
D. Hospitals
E. Partner Organizations
F. Payers
G. Private Business
H. Statewide Professional Associations
I. The Joint Commission / DNV
J. Women's Healthcare Providers

1.10 Recommended Time Period for Implementation by Activity

Item	Activity	Start Date	End Date
1.	Appropriate vetting of deliverable for modification, approval or veto.	7/30/2011	TBD
2.	Identify other interested/impacted stakeholder groups and appropriate representatives	8/1/2011	TBD
3.	Develop process for getting endorsement of stakeholder groups regarding indications for late preterm birth deliveries as endorsed by the Society for Maternal - Fetal Medicine (SMFM) and the National Institute of Child Health and Development (NICHD) of the NIH.	8/1/2011	TBD
4.	Develop criteria to evaluate birth prior to 39 weeks by scheduled induction or cesarean section without medical indications as identified by SMFM and NICHD.	Actual Publication Date	TBD
5.	Develop a workgroup to review the data currently available on birth certificates and make recommendations for modification if appropriate	8/1/2011	TBD
6.	Develop communication plan to increase awareness among providers of women's health care of morbidity	9/1/2011	TBD

	and mortality associated with delivery prior to 39 weeks by scheduled induction or cesarean section ***without*** medical indications for early delivery.		
7.	Develop communication plan to increase awareness of the SMFM/NICHD indications for late preterm delivery among providers of women's health care	9/1/2011	TBD
8.	Develop/adopt/adapt consistent messages for the public regarding maternal and infant morbidity and mortality associated with non-medically indicated delivery (prior to 39 weeks)	8/1/2011	TBD
9.	Develop process to provide feedback to providers who schedule inductions/cesarean sections prior to 39 weeks without establishing indication(s) for early delivery	11/1/2011	TBD

1.11 Required Resources - (e.g. financial, human, in-kind, etc.)

A. Birth certificate with sufficient granularity to track indications for delivery prior to 39 weeks
B. Funding for personnel and infrastructure to support the initiative, including the associated tracking, awareness campaign, education, and report cards. Professional organizations can provide expertise, but unlikely to provide financial support.
C. Legislation and appropriation to support the initiative, as needed
D. Mechanism for solo and small practices peer review
E. Peer review instruments and process
F. Providers and healthcare facilities would require additional resources to comply
G. Staff/stakeholder time

1.12 Possible Challenges to Implementation

A. Identification of appropriate representatives for additional stakeholder groups
B. Committee member time constraints
C. Buy-in among all stakeholder groups (e.g., payers, providers, patients, and healthcare systems) regarding SMFM/NICHD indications for delivery prior to 39 weeks
D. Adequate funding for initiative
E. Ability of small providers to implement these activities regardless of desire to do so
F. Accurate pregnancy dating
G. Additional strain on the health care system (e.g., night and weekend coverage to deal with more unscheduled deliveries)

1.13 Communication Strategies – including who, what, when, where, how

Develop a comprehensive communication plan to support both adoption and implementation of established guidelines for timing delivery when conditions complicate pregnancy at or beyond 34 weeks gestational age as endorsed by the Society for Maternal-Fetal Medicine and by the National Institute of Child Health and Development of the NIH with the goal to eliminate non-indicated, non-spontaneous deliveries prior to 39 weeks of gestational age. The targeted audiences include, initially, high-level stakeholders and perinatal health care professionals.

A. Phase I: Adoption of the guidelines
    a. Establish a task force drawn from the HTB expert panel with representatives from DSHS, HHSC, TMA, THA, TNA, ACOG, SMFM, March of Dimes, and other interested stakeholders who support the guidelines and their implementation (i.e., identify "champions").
    b. Enlist the "champions" of the initiative to present to the above listed stakeholders to promote the adoption of the guidelines. The message should include but is not limited to:
        i. A review of the guidelines and the research and organizations that support them
        ii. A review of Texas perinatal statistics – number of deliveries prior to 39 weeks; number of admits to NICUs; costs; etc.
        iii. Impact of non-medically indicated deliveries prior to 39 weeks on the overall health of Texas and Texans, (e.g., length of stay, number of cesarean deliveries, cost of care in neonatal intensive care units (NICU), cost of care for the first year of life, Medicaid cost data since they represent 55% of births in Texas).
        iv. A review of HB 1983
        v. The plan for possible enforcement strategies (peer review, report cards, reduced payments)
        vi. The work of the HTB initiative to include how this plan ties into and supports the activities of the other established workgroups
    c. Prepare a "standardized" presentation that could be utilized by the "champions" at stakeholder meetings or other opportunities as they present themselves.

B. Phase II: Implementation of the guidelines (once the guidelines have been adopted)
    a. Leverage key stakeholder adoption/endorsement of the guidelines to influence perinatal healthcare professionals.
    b. Develop key messaging and a possible campaign that focuses on the direct provider of care's motivation for compliance. The message can include but is not limited to:
        i. The review of the guidelines and their research base
        ii. The impact on positive patient outcomes – healthy baby/healthy mom
        iii. A recognition of the impact that external forces may have on their decision making

iv. Possible rewards for compliance
v. Enforcement strategies

c. Utilize a multi-media approach to disseminate the information:
i. PSAs: Featuring mom/healthcare professional interactions
ii. Social media: Facebook, Text4baby, etc.
iii. Electronic communication: For education (online activities, webinars, etc.)

1.14 Detailed Implementation Steps (how this intervention should be operationalized)

A. Develop an inventory of statutes or administrative rules related to requesting data to identify gaps in authority to determine potential legislative needs
B. Disseminate these guidelines and recommendations to all stakeholders (professional societies, governmental agencies, payers, and the general public).
C. Achieve buy-in and endorsement by obstetrical care providers, professional societies, hospitals and payers.
D. Develop systems that would identify women falling outside accepted criteria that providers are scheduling for labor induction or Cesarean delivery prior to 39 weeks gestation (e.g. – checklist for admission). This would trigger a query to the provider as to why the patient is being scheduled and if it is outside the accepted guidelines generate an automatic peer-review.
E. Develop patient education that would commence early in pregnancy, and be reinforced throughout pregnancy as to the importance of avoiding non-medically indicated delivery prior to 39 weeks gestation.
F. Track and publish non-medically indicated deliveries prior to 39 weeks gestation by:
    a. Provider
    b. Practice group
    c. Hospital
    d. Hospital chain
G. Add collection of this data to the State of Texas birth certificate.
H. Consider the appointment of a small group to meet with The Joint Commission / DNV and petition The Joint Commission / DNV to make this a priority for hospitals to monitor.
I. Ask ACOG to consider issuing a practice bulletin after SMFM/NICHD guidelines are published.

1.15 Plan for sustainability

Once launched and following a run-in period of approximately 2 years the program will require the following if it is to be sustained:

A. Acquisition of data specific to provider, practice group, hospital, and hospital chain that is collected and reported in an ongoing basis.

B. All outliers have mandated peer review.
C. A mechanism of peer review for small practices / delivery services.
D. The data is published or available to the public.
E. The data is available to payers to potentially deny payment or drop providers from insurance plans.
F. The criteria in Table 1 should be reviewed at least every two years to ensure the guidelines / criteria still represents best practices / standards of care. (Will require additional review after ACOG decision on July 16, 2011.)
G. To promote legislative support for this implementation in order to support sustainability.

1.16 Plan for scalability to acknowledge that resources available for implementation may vary

This plan could be launched as a demonstration project in specific urban and rural locations and compare pre and post implementation rates of non-medically indicated labor induction or cesarean section prior to 39 weeks. However, we submit that the project is ready for statewide implementation. The buy-in by DSHS, HHSC, and major payers will ensure its success. If the Joint Commission / DNV would join and make this a priority for hospitals to monitor and reduce non-medically indicated labor inductions and Cesarean deliveries prior to 39 weeks, it would assist us in accelerating both implementation and sustainability. To implement statewide you would need buy-in from TAOG, ACOG, and hospital-systems. There needs to be a mechanism to monitor implementation.

1.17 Relevant literature related to pre-39 week delivery

Source	Sample	Study Design Description	Objective	Results
Ashton DM. *Elective delivery at less than 39 weeks.* **Curr Opin Obstet Gynecol. 2010**;22(1):506-10	Literature review/ discussion. 20 publications.	**Literature review/discussion.** 2007-2010.	• Discuss the prevalence and impact of elective deliveries occurring prior to 39 weeks' gestation • Discuss concern that many of these procedures are not performed within the parameters of existing clinical guidelines.	• Studies report rates of 28-35.8% of elective deliveries occurring before 39 weeks and reveal that they also contribute to increased rates of late-preterm births (34 0/7 – 36 6/7). • (37 0/7 – 38 6/7 weeks) deliveries are associated with increased neonatal morbidity, neonatal intensive care unit admissions, and associated hospital costs compared to deliveries occurring at 39-40 weeks. • Prevention of early-term elective deliveries has not demonstrated an increased risk for stillbirth. • Hospital quality improvement programs have successfully reduced occurrence of early-term and late-preterm deliveries, neonatal morbidity, and mortality.
Bailit JL, Gregory KD, Reddy UM, Gonzalez-Quintero VH, Hibbard JU, Ramirez MM, Branch W, Burkman R, Haberman S, Hatjis CG, Hoffman MK, Kominiarek M, Landy HJ, Learman LA, Troendle J, Veldhuisen PV, Wilkins I, Sun L, Zhang J. *Maternal and neonatal outcomes by labor onset type*	115,528 deliveries	**Secondary data analysis/ Retrospective cohort study.** • EMR data from 10 US institutions in the Consortium on Safe Labor 2002 through 2008. • Deliveries stratified by labor onset type (spontaneous, elective	• To determine maternal and neonatal outcomes by labor onset type and gestational age.	• Neonatal intensive care unit admissions and sepsis improved with each week of gestational age until 39 weeks ($P < .001$). • After adjusting for complications, elective induction of labor was associated with a lower risk of ventilator use (odds ratio [OR], 0.38; 95% CI, 0.28 – 0.53) compared to spontaneous labor. • Elective induction of labor was associated with a lower risk of sepsis (OR, 0.36; 95% CI, 0.26 – 0.49) compared to spontaneous labor. • Elective induction of labor was associated with a lower risk of neonatal intensive care unit admissions (OR, 0.52; 95% CI, 0.48 – 0.57) compared to spontaneous labor. • The relative risk of hysterectomy at term was 3.21 (95% CI, 1.08 – 9.54) with elective induction compared to spontaneous labor. • The relative risk of hysterectomy was 1.16 (95% CI, 0.24 – 5.58) with indicated induction compared to spontaneous labor. • The relative risk of hysterectomy was 6.57 (95% CI, 1.78 – 24.30)

Source	Sample	Study Design Description	Objective	Results
and gestational age. **Am J Obstet Gynecol. 2010** Mar;202(3): 245.e1–245.e12.		induction, indicated induction, unlabored cesarean). • Neonatal and maternal outcomes were examined by labor onset type and gestational age.		with cesarean without labor compared to spontaneous labor.
Caughey AB, Sundaram V, Kaimal AJ, Cheng YW, et al *Maternal and Neonatal Outcomes of Elective Induction of Labor.* Evidence Report/Technology Assessment No. 176. (Prepared by the Stanford University-UCSF Evidenced-based Practice Center under contract No. 290-02-	• Literature review of 3,722 potentially relevant articles • 76 articles met inclusion criteria.	**Systematic literature review.** • Searched MEDLINE (1966-2007) • Bibliographies of prior systematic reviews • Included studies for English language studies of maternal and fetal outcomes after elective induction of labor. • Evaluated the	To examine the evidence regarding four Key Questions: 1. What evidence describes the maternal risks of elective induction versus expectant management? 2. What evidence describes the fetal/neonatal risks of elective induction versus expectant management? 3. What is the	• Expectant management of pregnancy was associated with an approximately 22% higher odds of cesarean delivery than elective induction of labor (OR 1.22, 95% CI 1.07-1.39; absolute risk difference 1.9, 95% CI: 0.2-3.7%). • The majority of these studies were in women ≥ 41 weeks of gestation (OR 1.21, 95% CI 1.01-1.46). • In women <41 weeks of gestation, there were three trials which reported no difference in risk of cesarean delivery among women who were induced as compared to expectant management (OR 1.73; 95%CI: 0.67-4.5, *P*=0.26), but all of these trials were small, non-U.S., older, and of poor quality. • Odds of cesarean delivery of women who were expectantly managed compared to elective induction of labor were not statistically different (OR 1.28; 95% CI 0.65-2.49). • Women not expectantly managed were more likely to have meconium-stained amniotic fluid than those who were electively

Source	Sample	Study Design Description	Objective	Results
0017.) **AHRQ Publication** No. 09-E005. Rockville, MD.: Agency for Healthcare Research and Quality. **2009** Mar.		quality of included studies. • Synthesized study data using random effects models. • Evaluated the potential clinical outcomes and cost-effectiveness of elective induction of labor versus expectant management of pregnancy labor at 41, 40, and 39 weeks' gestation using decision analytic models.	evidence that certain physical conditions/ patient characteristics are predictive of a successful induction of labor? 4. How is a failed induction defined?	induced (OR 2.04; 95% CI: 1.34-3.09). • Observational studies reported a consistently lower risk of cesarean delivery among women who underwent spontaneous labor (6%) compared with women who had an elective induction of labor (8%) with a statistically significant decrease when combined (OR 0.63; 95% CI: 0.49-0.79), but used the wrong control group and did not appropriately adjust for gestational age. • Increased parity and decreased gestational age were associated with successful labor induction (58% of the included studies defined success as achieving a vaginal delivery anytime after the onset of the induction of labor; induction was considered a failure when it led to a cesarean delivery). • Women electively induced had better overall outcomes among both mothers and neonates as estimated by total quality-adjusted life years (QALYs) as well as by reduction in specific perinatal outcomes such as shoulder dystocia, meconium aspiration syndrome, and preeclampsia. • Induction of labor was cost-effective at $10,789 per QALY with elective induction of labor at 41 weeks of gestation, $9,932 per QALY at 40 weeks of gestation, and $20,222 per QALY at 39 weeks of gestation utilizing a cost-effectiveness threshold of $50,000 per QALY.
Caughey AB, Sundaram V, Kalmal AJ, Glenger A, Cheng YW, McDonald KM, Shaffer BL, Owens, DK, Bravata DM. *Systematic Review: Elective Induction of Labor Versus Expectant Management of*	Reviewed 6117 potentially relevant articles; 36 met inclusion criteria: 11 randomize controlled trials (RCTs) and 25 observational studies.	**Systematic literature review**. • MEDLINE (1966 - February 2009) • Web of Science • CINAHL • Cochrane Central Register of Controlled Trials (through March 2009)	• To compare the benefits and harms of elective induction of labor and expectant management of pregnancy.	• Overall, expectant management of pregnancy was associated with a higher odds ratio (OR) of cesarean delivery than was elective induction of labor (OR, 1.22 [95% CI, 1.07 to 1.39] • Absolute risk difference, 1.9 percentage points [CI, 0.2 to 3.7 percentage points]) in 9 randomized controlled trials (RCTs) • Women ≥ 41 completed weeks of gestation who were managed expectantly had a higher risk for cesarean delivery (OR, 1.21 [CI, 1.01 to 1.46]) • This difference was not statistically significant in women at < 41 completed weeks of gestation (OR, 1.73 [CI, 0.67 to 4.5]). • Women who were expectantly managed were more likely to have meconium-stained amniotic fluid than those who were electively

Source	Sample	Study Design Description	Objective	Results
Pregnancy. **Ann Intern Med. 2009**;151(1):252-63.		• Bibliographies of included studies • Previous systematic reviews		induced (OR, 2.04 [CI, 1.34 to 3.09]).

Joseph KS. *Theory of obstetrics: An epidemiologic framework for justifying medically indicated early delivery.* **BMC Pregnancy Childbirth. 2007** Mar 28;7(1):4.	Literature review/ discussion.
	84 publications.
		Literature review/discussion.
		1963-2006.
			Discuss issues facing obstetric practice:
			• a disconnect between patterns of gestational age-specific growth restriction and gestational age-specific perinatal mortality
			• the increase of induction and cesarean
				• The fetuses at risk approach is a causal model that brings coherence to the listed perinatal issues.
				• Under this formulation, pregnancy complications, labor induction/cesarean delivery, birth, revealed small-for-gestational age, and death show coherent patterns of incidence.
				• Provides theoretical justification for medically indicated early delivery, the cornerstone of modern obstetrics.
				• Permits a conceptualization of the number needed to treat and a calculation of the marginal number needed to treat.
				• Data from the United States showed that between 1995–96 and 1999–2000:
				  ○ Rates of labor induction/ cesarean delivery increased by 45.1 per 1,000
				  ○ Perinatal mortality decreased by 0.31 per 1,000 total births among singleton pregnancies at ≥28 weeks of gestation

Source	Sample	Study Design Description	Objective	Results
			delivery (though obstetric models of perinatal death show declines in mortality with increasing gestation duration) • intersecting perinatal mortality curves.	○ The marginal number needed to treat was 145 (45.1/0.31), showing that 145 excess labor inductions/cesarean deliveries in 1999–2000 (relative to 1995–96) were responsible for preventing 1 perinatal death among singleton pregnancies at ≥28 weeks gestation.
Oshiro BT, Henry E, Wilson J, Branch W, Varner MW. *Decreasing Elective Deliveries Before 39 Weeks of Gestation in an Integrated Health Care System.* **Obstet Gynecol. 2009**;113(1):804-11.	• 122,718 deliveries July 2001-June 2006. • 37,686 deliveries 1990-2000.	**Case study.** • Review of EMR of 9 labor and delivery units of an integrated health care system in Utah. • Prevalence of early term deliveries was tracked and reported back regularly.	• To develop and implement a program to decrease the number of early term elective deliveries. • Monitor relevant clinical outcomes.	• Prevalence of early term elective deliveries was 28% of all elective deliveries at baseline. • The incidence of near-term elective deliveries decreased to less than 10% within 6 months of initiating the program, and after 6 years continues to be less than 3%. • Reduced length of stay in labor and delivery. • No adverse effects on secondary clinical outcomes.
Osmundson S, Ou-Yang RJ, Grobman WA.	204 nulliparous women with unfavorable cervix	**Retrospective cohort study.** • Nulliparous	• To compare outcomes of labor between	• Primary outcome of cesarean delivery was not statistically different between women who were expectantly managed and those who underwent elective labor induction (34.3% vs. 43.1%,

Source	Sample	Study Design Description	Objective	Results
Elective Induction Compared With Expectant Management in Nulliparous Women With an Unfavorable Cervix. **Obstet Gynecol. 2011**;117(3):583-7.		women with a singleton gestation who had an unfavorable cervix (modified Bishop scores <5) and delivered between 2006-2008. • 102 nulliparous women who underwent elective induction of labor between 39-40 5/7 wks of gestation vs. • 102 nulliparous women who were expectantly managed beyond 39 wks gestation.	nulliparas with an unfavorable cervix who underwent either elective labor induction or expectant management beyond 39 weeks of gestation.	respectively, *P*=0.16). • Increased meconium in expectantly managed group (36.3% vs. 7.0%, *P*<.001). • No significant differences in other maternal (e.g. chorioamnionitis, operative vaginal delivery, 3rd/4th degree lacerations, postpartum hemorrhage) or neonatal (arterial cord pH <7.0, Apgar score <7 at 5 min, NICU admission) outcomes. • Women who underwent elective induction had longer duration of labor and delivery between admission and delivery (median 16.5 vs. 12.7 hrs, *P*<.001).
Reddy UM, Bettegowda VR, Dias T, Yamada-Kushnir T, Ko CW, Willinger M. *Term Pregnancy: A Period of Heterogeneous Risk for Infant Mortality.*	46,329,018 singleton live births	**Secondary data analysis/ Retrospective cohort study.** • National Center for Health Statistics U.S. period-linked birth and infant	• To estimate the trend of maternal racial and ethnic differences in mortality for early-term (37 0/7 to 38 6/7 weeks' gestation) compared with	• Infant mortality rates have decreased for early-term and full-term births between 1995 and 2006. • At 37 weeks' gestation, Hispanics had the greatest decline in infant mortality rates (35.4%; 4.8 per 1,000 to 3.1 per 1,000); • For whites, 22.4% (4.9 per 1,000 to 3.8 per 1,000); • Blacks had the smallest decline (6.8%; 5.9 per 1,000 to 5.5 per 1,000) as a result of stagnant neonatal mortality rate. • At 37 weeks compared with 40 weeks of gestation, neonatal

Source	Sample	Study Design Description	Objective	Results
Obstet Gynocol. 2011 Jun;117(6):1279-87.		death data from 1995-2006. • Analyzed live birth data. Infant mortality rates, neonatal mortality rates, and post-neonatal mortality rates were calculated according to gestational age, race and ethnicity, and cause of death.	full-term births (39 0/7 to 41 6/7 weeks' gestation)	mortality rates increase. • For Hispanics, neonatal mortality RR 2.6 (95% CI 2.0-3.3); • For whites, neonatal mortality RR 2.6 (95% CI 2.2-3.1); • For blacks, neonatal mortality RR 2.9 (95% CI 2.2-3.8). • Neonatal mortality rates are still increased at 38 weeks' gestation. • At both early- and full-term gestations, neonatal mortality rates for blacks are 40% higher than for whites and for postneonatal mortality rates 80% higher • Hispanics have a reduced postneonatal mortality rate when compared with whites.
Reddy UM, Ko CW, Raju TNK, Willinger M. *Delivery Indications of Late-Preterm Gestations and Infant Mortality Rates in the United States.* **Pediatrics. 2009** Jul;124(1):234-40.	3,483,496 singleton births.	**Secondary data analysis/ Retrospective cohort study.** • Used 2001 US Birth Cohort Linked birth/death files • Categorized delivery indications as: 1. maternal medical conditions; 2. obstetric complications; 3. major	• To characterize the delivery indications for late preterm births and their potential impact on neonatal and infant mortality rates.	• Of the 292,627 late-preterm births, the first 4 categories (those with indications and isolated spontaneous labor) accounted for 76.8%. • The remaining 23.2% (67,909) were classified as deliveries with no recorded indication. • Factors significantly increasing the chance of no recorded indication were older maternal age; non-Hispanic, white mother; ≥13 years of education; Southern, Midwestern, and Western region; multiparity; or previous infant with a ≥4000g birth weight. • Neonatal and infant mortality rates were significantly higher among deliveries with no recorded indication compared with deliveries secondary to isolated spontaneous labor but lower compared with deliveries with an obstetric indication or congenital anomaly.

Source	Sample	Study Design Description	Objective	Results
		congenital anomalies; 4. isolated spontaneous labor; and 5. no recorded indication.		
Salim R and Shalev E. *Health implications resulting from the timing of elective cesarean delivery.* **Reprod Biol Endocrin. 2010** Jun 21;8(1):68.	Literature review/ discussion. 29 publications.	**Literature review/discussion.** • 1987- December 2009 • PubMed, MEDLINE, EMBASE, and Conchrane Library databases	• To debate the common recommendation of elective cesarean delivery at 39 weeks of gestation.	• Between 38 and 39 weeks of gestation, ~10%-14% of women go into spontaneous labor; meaning that a considerable number of women scheduled for an elective cesarean delivery at 39 weeks will deliver earlier in an unscheduled, frequently emergency, cesarean delivery. • The incidence of maternal morbidity and mortality is higher among women undergoing non-elective cesarean deliveries than among those undergoing elective ones. • Complications may be greater among women after numerous repeat cesarean deliveries and among older women. • Other than reducing the frequency of non-elective cesarean deliveries, bringing forward the timing of elective cesarean delivery to 38 weeks may occasionally prevent intrauterine fetal demise which has been shown to increase with increasing gestational age and to avoid other fetal consequences related to the emergency delivery. • All these considerations need to be weighed against the medical

Source	Sample	Study Design Description	Objective	Results
				and the economic impact of the increase in neonatal morbidity resulting from births at 38 weeks compared to 39 weeks.

Table 1: Guidance regarding timing of delivery when conditions complicate pregnancy at or after 34 weeks' gestation **Important Note: In press – Obstetrics and Gynecology**

Placental and uterine issues	Gestational age* for delivery	Grade of recommendation ^^
• Placenta previa**	36-37 weeks	B
• Placenta accreta/increta/percreta**	34-35 weeks	B
• Prior classical cesarean (upper segment uterine incision)**	36-37 weeks	B
• Prior myomectomy necessitating cesarean delivery**	37-38 weeks (may require earlier delivery, similar to prior classical cesarean, in situations with more extensive or complicated myomectomy)	B
• Prior uterine rupture**	36-37 weeks	B
Fetal issues		
• Fetal growth restriction-singleton	***38-39 weeks:*** • Otherwise uncomplicated, no concurrent findings ***34-37 weeks:*** • Concurrent conditions (oligohydramnios, abnormal Doppler studies, maternal risk factors, co-morbidity) ***Expeditious delivery regardless of gestational age*** • Persistent abnormal fetal surveillance suggesting imminent fetal jeopardy	 B B
• Fetal growth restriction-twin gestation	***36-37 weeks****:* • Dichorionic-diamniotic twins with isolated fetal growth restriction ***32-34 weeks****:* • Monochorionic-diamniotic twins with isolated fetal growth restriction • Concurrent conditions (oligohydramnios, abnormal Doppler studies, maternal risk factors, co-morbidity)	 B B

Placental and uterine issues	Gestational age* for delivery	Grade of recommendation ^^
	Expeditious delivery regardless of gestational age • Persistent abnormal fetal surveillance suggesting imminent fetal jeopardy	B
• Fetal congenital malformations**	***34-39 weeks:*** • Suspected worsening of fetal organ damage • Potential for fetal intracranial hemorrhage (eg Vein of Galen aneurysm, Neonatal alloimmune thrombocytopenia) • When delivery prior to labor is preferred (eg EXIT procedure) • Previous fetal intervention • Concurrent maternal disease (eg preeclampsia, chronic hypertension) • Potential for adverse maternal effect from fetal condition ***Expeditious delivery regardless of gestational age*** • When intervention is expected to be beneficial • Fetal complications develop (abnormal fetal surveillance, new onset hydrops fetalis, progressive/new onset organ injury) • Maternal complications develop (mirror syndrome)	B B
• Multiple gestations: Dichorionic/Diamniotic**	38 weeks	B
• Multiple gestations: Monochorionic/Diamniotic**	34-37 weeks	B
• Multiple gestations: Di/Di or Mono/Di with single fetal death**	If occurs at or after 34 weeks, consider delivery (recommendation limited to pregnancies at or after 34 weeks. If occurs before 34 weeks, individualize based on concurrent maternal/fetal conditions)	B
• Multiple gestations: Monochorionic/	32-34 weeks	B

Placental and uterine issues	Gestational age* for delivery	Grade of recommendation ^^
Monoamniotic**		
• Multiple gestations: Monochorionic/ Monoamniotic with single fetal death**	When the demise of one fetus is identified (recommendation limited to pregnancies at or after 34 weeks. If occurs before 34 weeks, individualize based on concurrent maternal/fetal conditions)	B
• Oligohydramnios – isolated and persistent**	36-37 weeks	B
Maternal and Obstetrical issues		
Maternal issues		
• Chronic hypertension – no medications**	38-39 weeks	B
• Chronic hypertension – controlled on medication**	37-39 weeks	B
• Chronic hypertension – difficult to control (requiring frequent medication adjustments)**	36-37 weeks	B
• Gestational hypertension***	37-38 weeks	B
• Preeclampsia – severe**	At diagnosis (recommendation limited to pregnancies at or after 34 weeks)	C
• Preeclampsia – mild**	37 weeks	B
• Diabetes – pregestational well controlled**	LPTB/ETB not recommended	B
• Diabetes – pregestational with vascular disease**	37-39 weeks	B
• Diabetes – pregestational, poorly controlled**	34-39 weeks (individualized to situation)	B
• Diabetes – gestational well controlled on diet**	LPTB/ETB not recommended	B
• Diabetes – gestational well controlled on medication**	LPTB/ETB not recommended	B
• Diabetes – gestational poorly controlled on medication**	34-39 weeks (individualized to situation)	B

Placental and uterine issues	Gestational age* for delivery	Grade of recommendation ^^
Obstetrical issues		
• Prior stillbirth-unexplained**	LPTB/ETB not recommended Consider amniocentesis for fetal pulmonary maturity if delivered at 37-38 weeks	B C
• Spontaneous Preterm Birth: Preterm Premature Rupture Of Membranes (PROM)**	34 weeks (recommendation limited to pregnancies at or after 34 weeks)	B
• Spontaneous Preterm Birth: Active preterm labor**	Delivery if progressive labor or additional maternal/fetal indication	B

***Gestational age** is in completed weeks, thus "34 weeks" includes 34 weeks and 0 days through 34 weeks and 6 days.
**Uncomplicated, thus no fetal growth restriction, superimposed preeclampsia, etc. If these are present, then the complicating conditions take precedence and earlier delivery may be indicated
***Maintenance antihypertensive therapy should not be used to treat gestational hypertension
LPTB: Late preterm birth at 34 weeks 0 days through 36 weeks 6 days
ETB: Early term birth at 37 weeks 0 days through 38 weeks 6 days

^^ **Grade of Recommendations** are based on the following: Recommendations and/or conclusions are based on (A) good and consistent scientific evidence; (B) limited or inconsistent scientific evidence; (C) primarily on consensus and expert opinion. The recommendations regarding expeditious delivery for imminent fetal jeopardy were not given a grade. The recommendation regarding severe preeclampsia is largely based on expert opinion, however higher level evidence is not likely to be forthcoming as this condition is believed to carry significant maternal risk with limited potential fetal benefit from expectant management after 34 weeks.

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