



AMERICA'S ESSENTIAL HOSPITALS

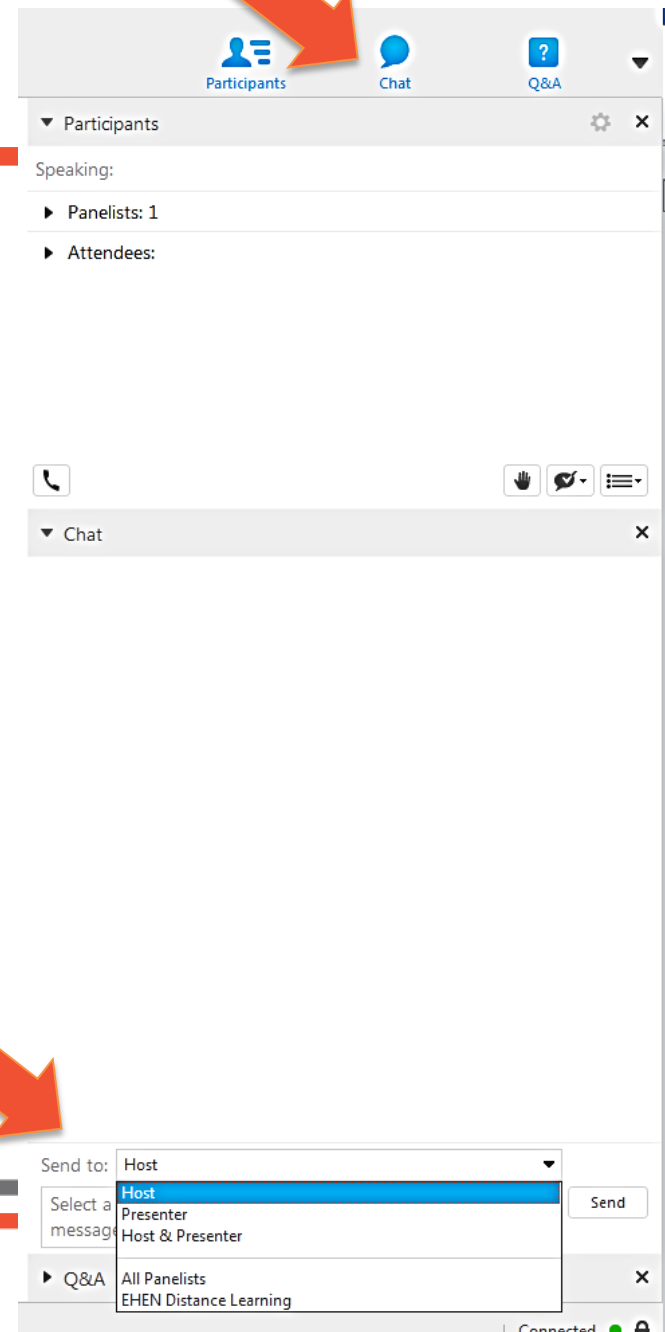
Eliminating Early Elective Deliveries at Care New England

June 10, 2015



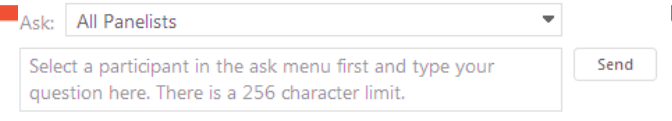
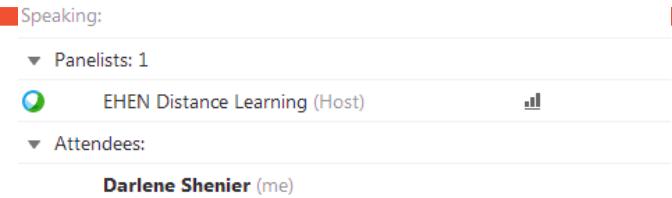
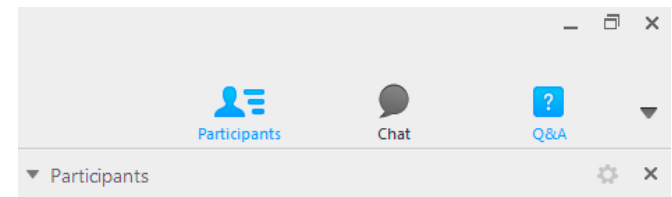
CHAT FEATURE

The chat tool is available to ask questions or comments at anytime during this event.



RAISE YOUR HAND

- If you wish to speak telephonically, please “raise your hand”. We will call your name, when your phone line is unmuted





AGENDA

- Introduction
- Eliminating Early Elective Deliveries at Care New England
 - » Womens & Infants Hospital of Rhode Island
- Q&A
- Upcoming events





SPEAKERS



James O'Brien, MD
Medical Director of Inpatient
Obstetrics,
Womens & Infants Hospital

Assistant Professor of Obstetrics
and Gynecology (Clinical),
*Warren Alpert School of Medicine
at Brown University*



Robert M. Insoft, MD
SVP, Quality & Medical Affairs
Chief Medical Officer
Staff Neonatologist,
Womens & Infants Hospital

Associate Professor Pediatrics,
Brown University Alpert Medical School

Elimination of Elective Early Term Delivery

Healthy Babies are Worth the Wait

James O'Brien, MD

Medical Director of Inpatient Obstetrics
Women & Infants Hospital of RI

Robert Insoft, MD

Senior VP – Quality and Medical Affairs
Women & Infants Hospital of RI

Women & Infants Hospital



Disclosures

- James O'Brien, MD

- I am a member of the March of Dimes Speakers Bureau
- I have no other actual or potential conflict of interest in relation to this program/presentation.

- Robert Insoft, MD

- I have no actual or potential conflicts of interest in relation to this program/presentation.

Objectives

- Review the history of the definition of term pregnancy & evidence of the NN risks associated with elective early-term delivery.
- Review the processes implemented at other institutions and at WIH to eliminate/mitigate elective early-term deliveries.
- Discuss our institutional data and success to date.
- Review steps for developing & sustaining a program in your institution.

Elimination of Elective Early Term Delivery

**BACKGROUND
HISTORY & TRENDS**

Background

■ Dating continuum in pregnancy

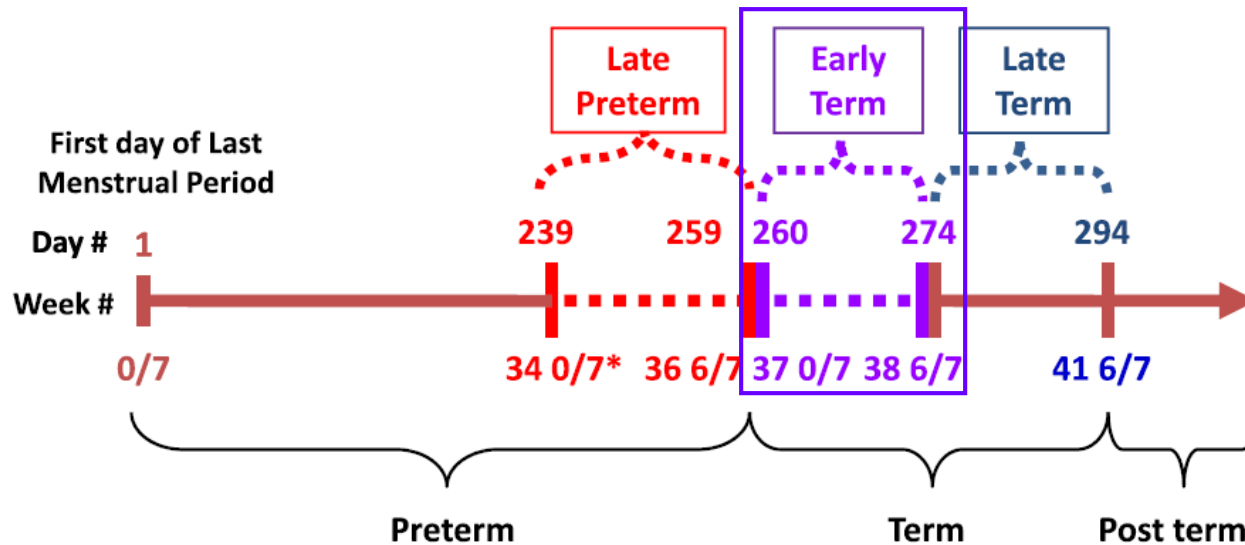


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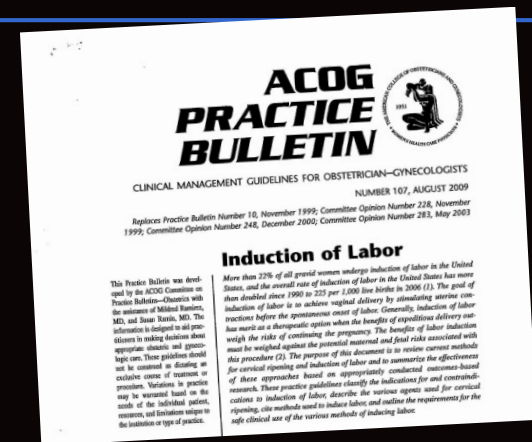
Early term deliveries comprise 23% of annual deliveries in US or approximately 920K births.

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Background

■ ACOG's Standard

- Since 1979 ACOG has cautioned against induction of labor at less than 39 weeks gestation without medical indication
- Confirmation of GA is CRITICAL
 - ***US < 20 weeks gestation to confirm or establish GA***
 - Documentation of fetal heart tones for 30 weeks using Doppler
 - Confirmation of 36 weeks since + pregnancy test
- Even a mature fetal lung test before 39 weeks, in the absence of appropriate clinical circumstances, is not an indication for delivery.



Rethinking the Definition of “Term Pregnancy”

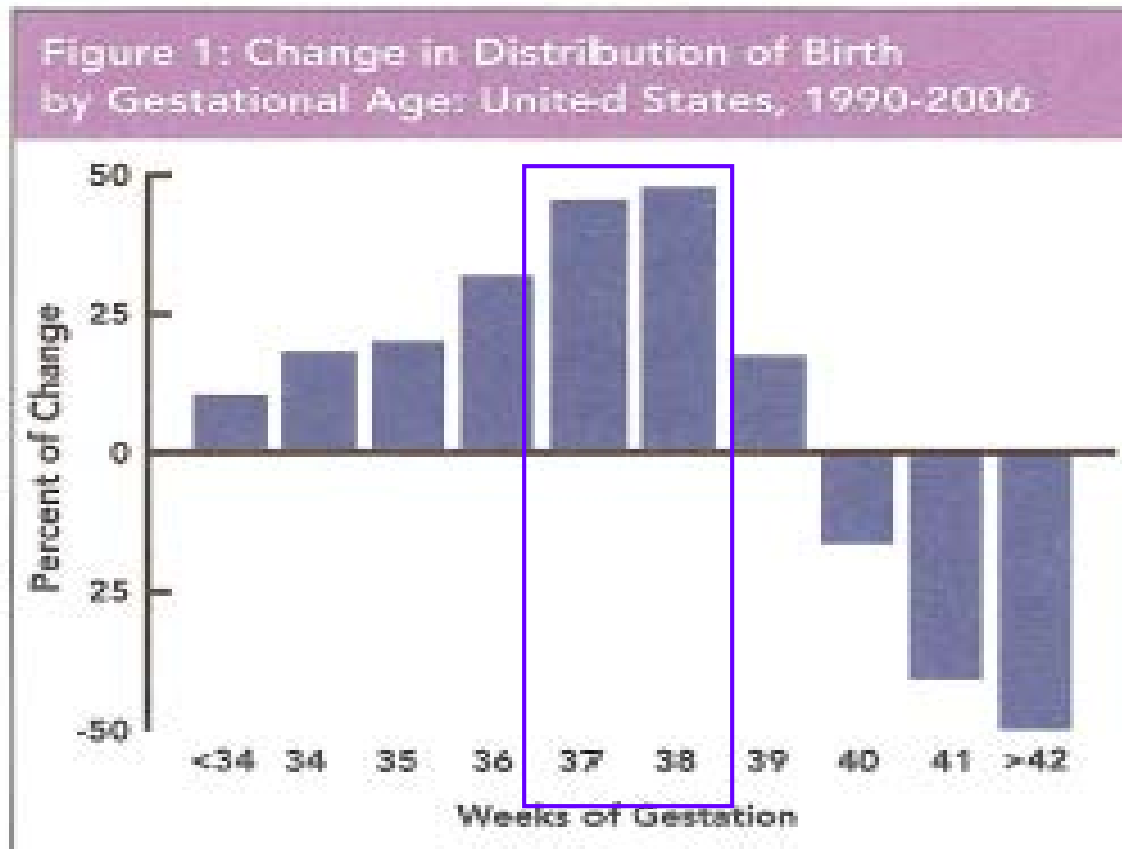
Alan R. Fleischman, MD, Motoko Oinuma, BA, and Steven L. Clark, MD

Obstet Gynecol 2010; 116:136



- “Term birth (37-41 weeks of gestation) has previously been considered a **homogeneous group**....”
- “Examination of the history.... reveals the definition of term birth was determined somewhat **arbitrarily**.”
- “....a growing body of evidence suggesting that **significant differences exist in the outcomes** of infants delivered within this 5-week interval.”

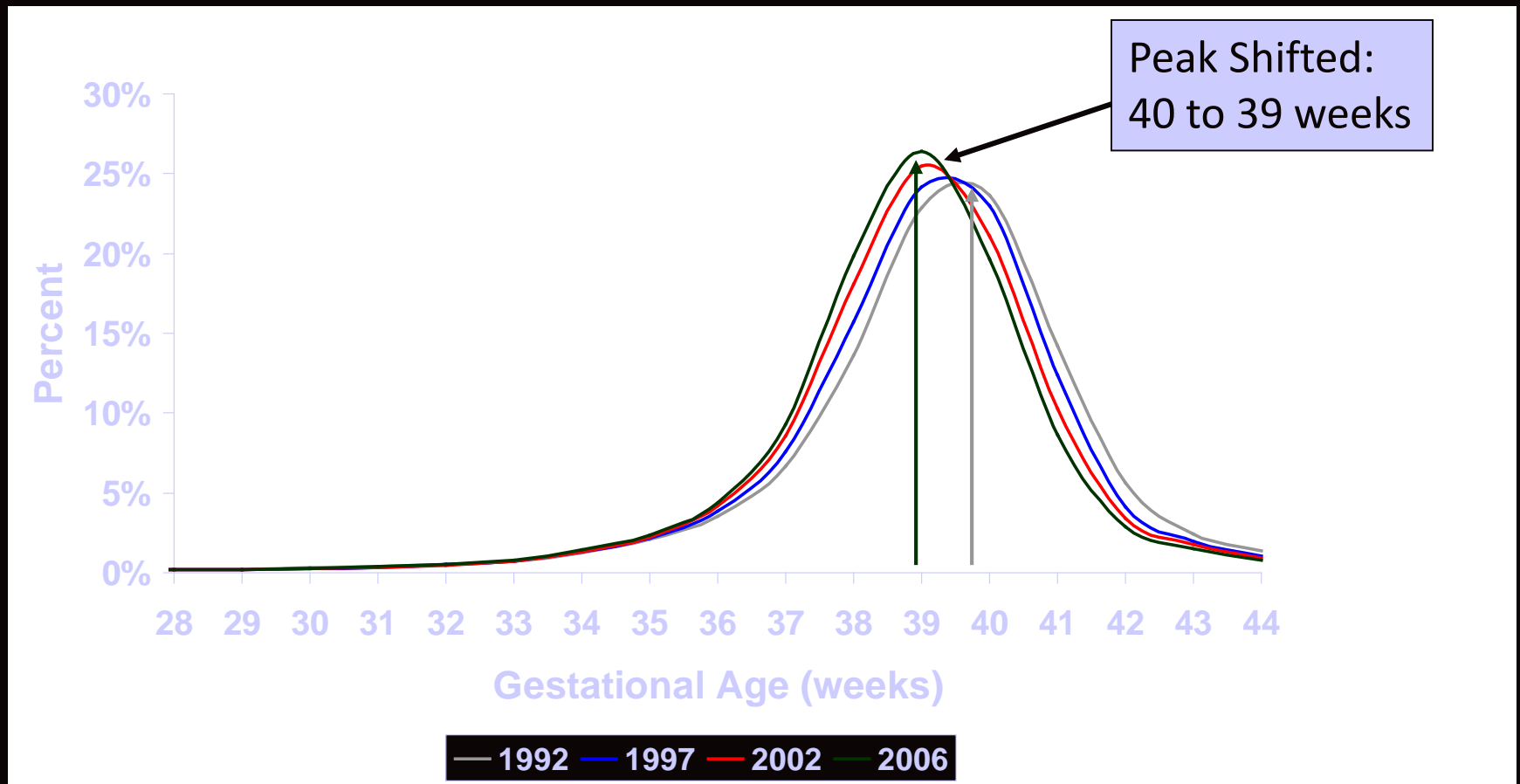
Trends



Source: CDC/NCHS, National Vital Statistics System.

Close to 50% increase in births at 37 and 38 weeks GA from 1990 to 2006

Changing Distribution of Singleton Live Births in US 1992 - 2006

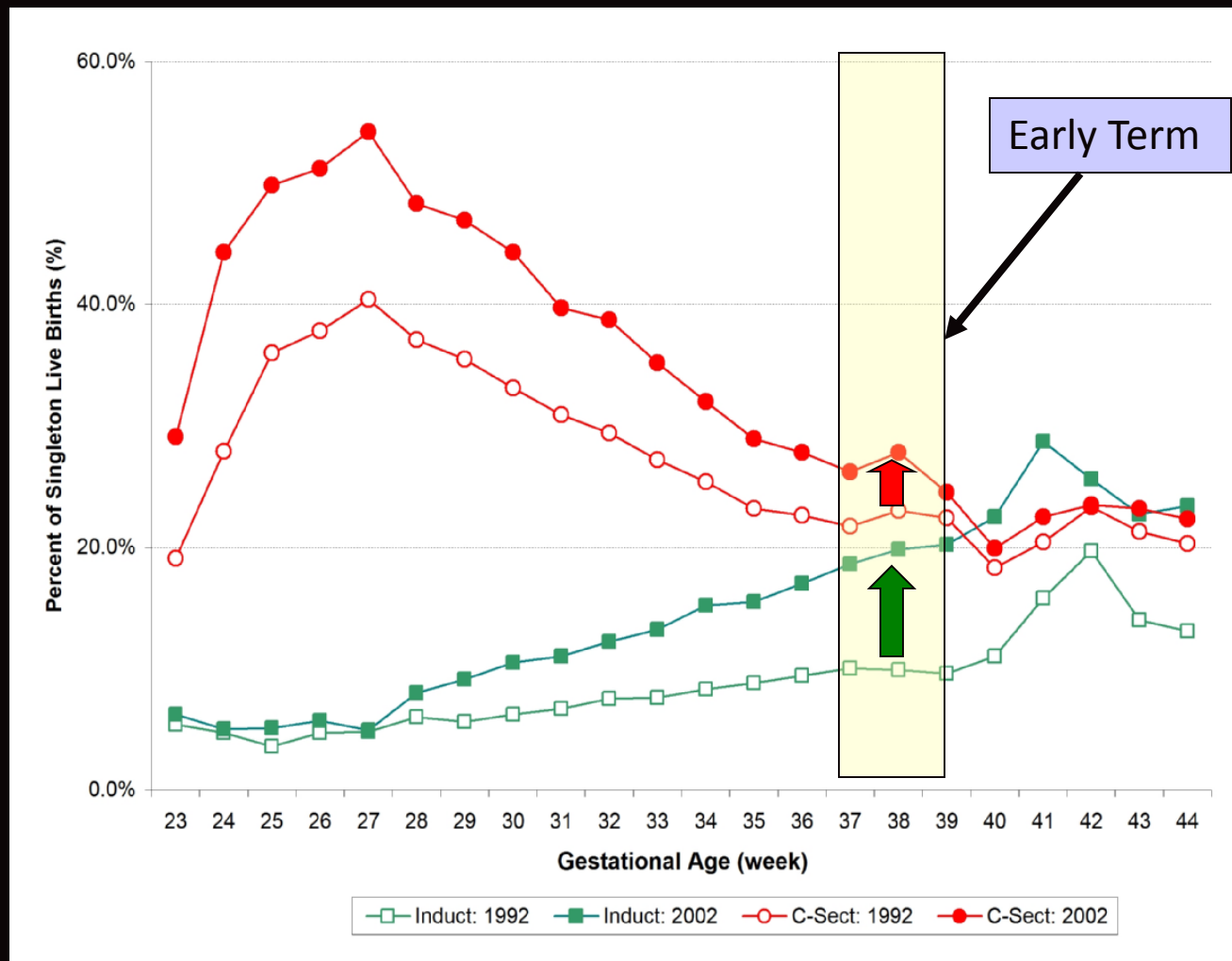


Source: National Center for Health Statistics, Final Natality Data

Prepared by March of Dimes Perinatal Data Center, 2009

CS & IOL Rates

Singleton Live Births by Week of Gestation 1992 & 2002



Elimination of Elective Early Term Delivery

**PATIENT & PROVIDER
FACTORS**

Factors Driving Elective Early Term Delivery

Patient

- Advanced Planning
- Convenience
- Delivery by preferred provider
- Maternal intolerance to late pregnancy
- Prior pregnancy with poor outcome (e.g. SB)

Provider

- Advanced Planning
- Convenience
- Guarantee presence at delivery
- 'Normalization of deviance' with lack of awareness of ACOG recommendations
- NN success



‘Normalization of Deviance’ in Elective Early Term Deliveries

- ‘Term is term’ with anecdotally favorable experience
 - Most infants delivered at 37 weeks do not require additional newborn care
 - One-third of infants at 37 weeks who do require additional care are not immediately transferred to NICU and many OB providers not aware
 - Most morbidity is short term
 - Because absolute numbers are low these poor outcomes may not be seen by individual providers, groups of providers or facilities with lower volumes

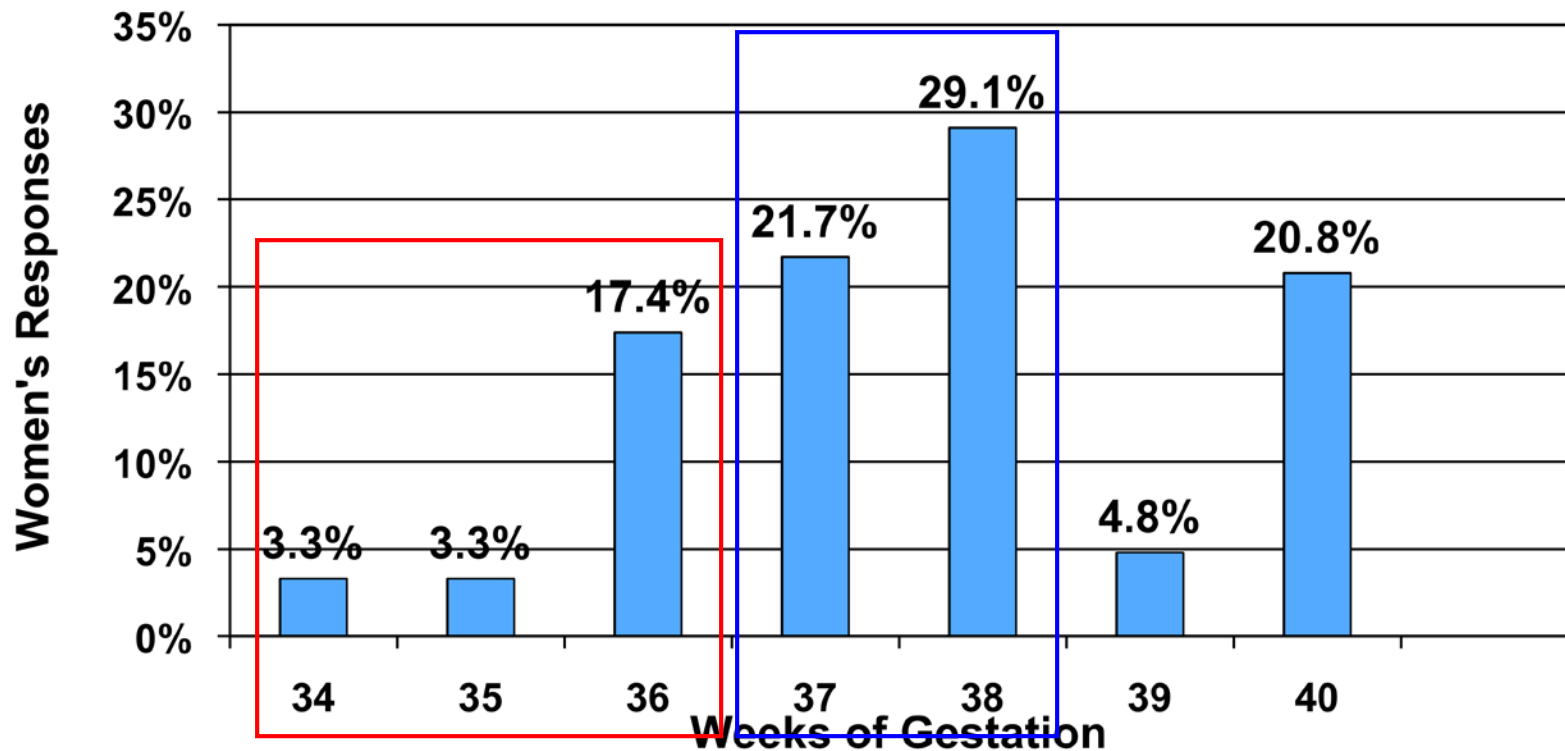
Background

Patient Perception

Women's Perceptions Regarding the Safety of Births at Various Gestational Ages

Goldenberg RL, McClure EM, Bhattacharya A, Groat TD, Stahl PJ. *Obstet Gynecol* 2009;114:1254-58

Gestational Age that Women Consider a Baby Full Term



24% considered late preterm & another 50% considered early term as full term

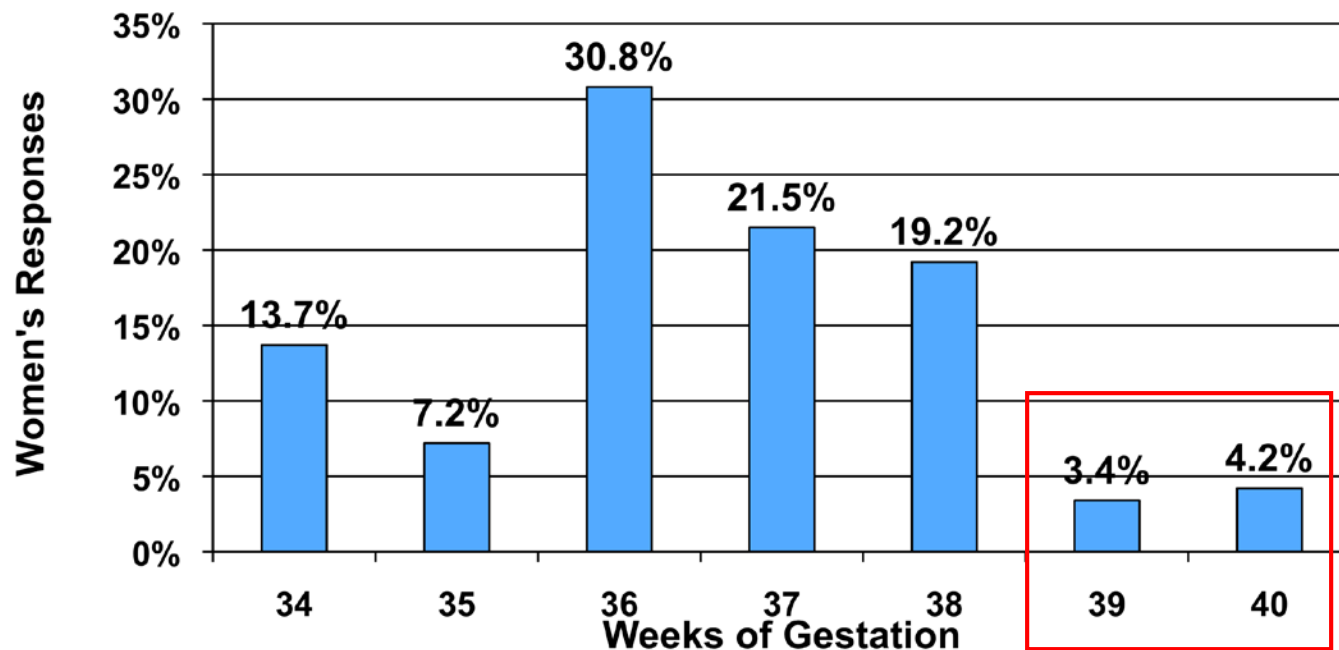
Background

Patient Perceptions

Women's Perceptions Regarding the Safety of Births at Various Gestational Ages

Goldenberg RL, McClure EM, Bhattacharya A, Groat TD, Stahl PJ. *Obstet Gynecol* 2009;114:1254-58

Gestational Age Women Considered It Safe to Deliver



Elimination of Elective Early Term Delivery

OUTCOMES

Adverse NN Outcomes

Increased AO & NICU Admissions with decreasing GA

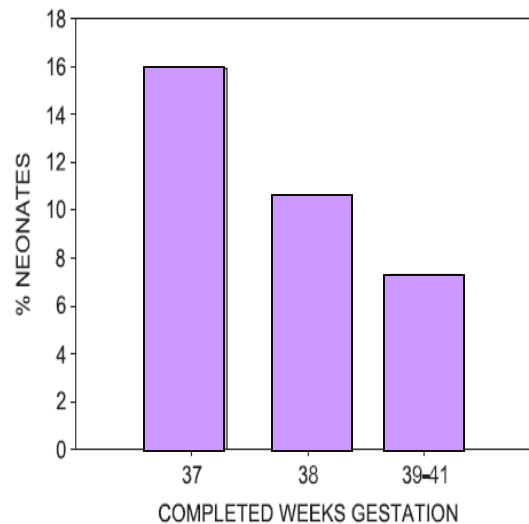
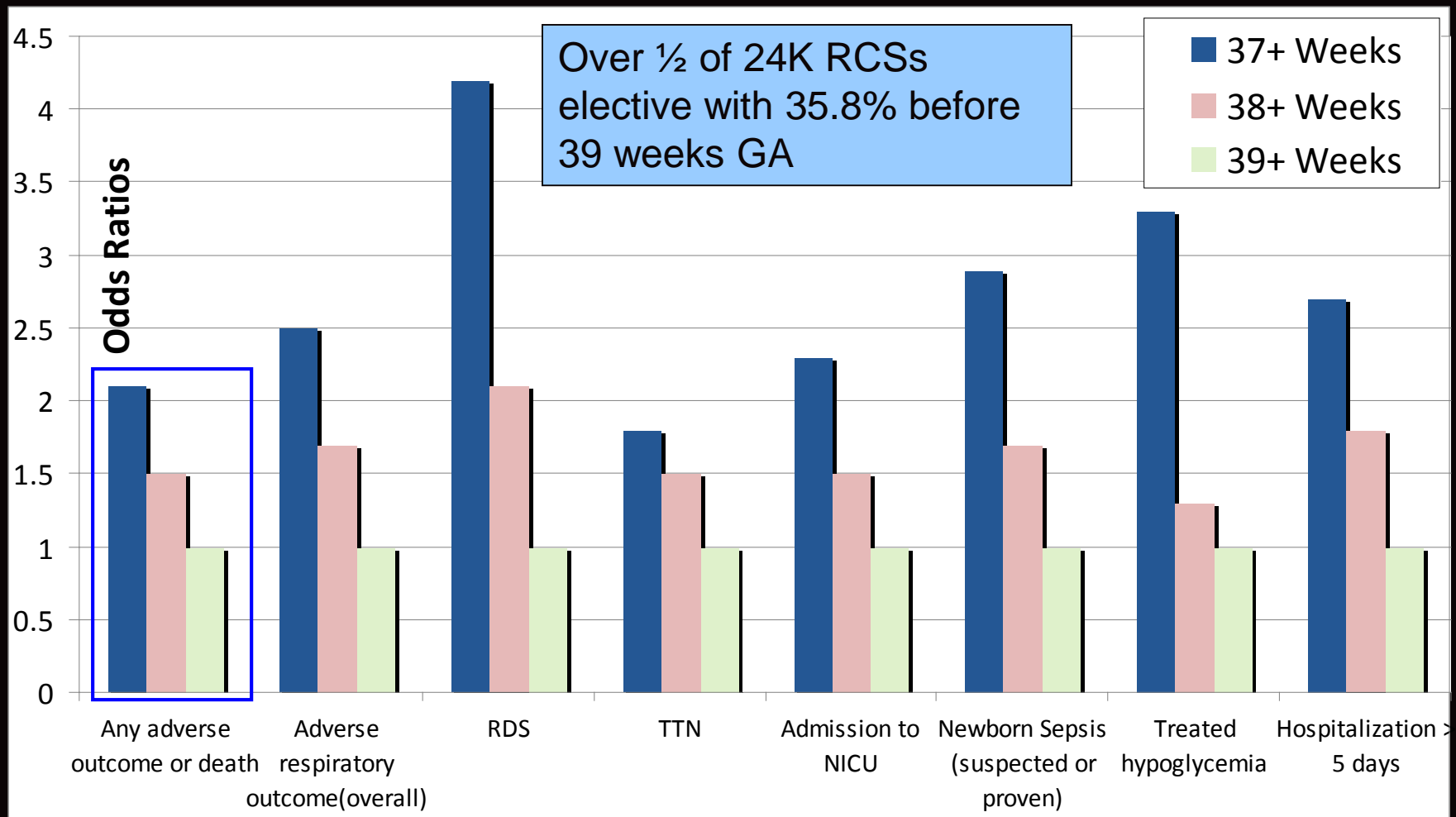


Fig. 1. Adverse neonatal outcomes and newborn intensive care admissions for early term deliveries compared with neonates delivered between 39 and 41 completed weeks' gestation. (Data from Clark SL, Miller DD, Belfort MA, et al. Neonatal and maternal outcomes associated with elective term delivery. *Am J Obstet Gynecol* 2009;200:156,e1-4; and Tita AT, Landon MB, Spong CY, et al. Timing of elective repeat cesarean delivery at term and neonatal outcomes. *N Engl J Med* 2009;360:111-20.)

Adverse Outcomes by GA



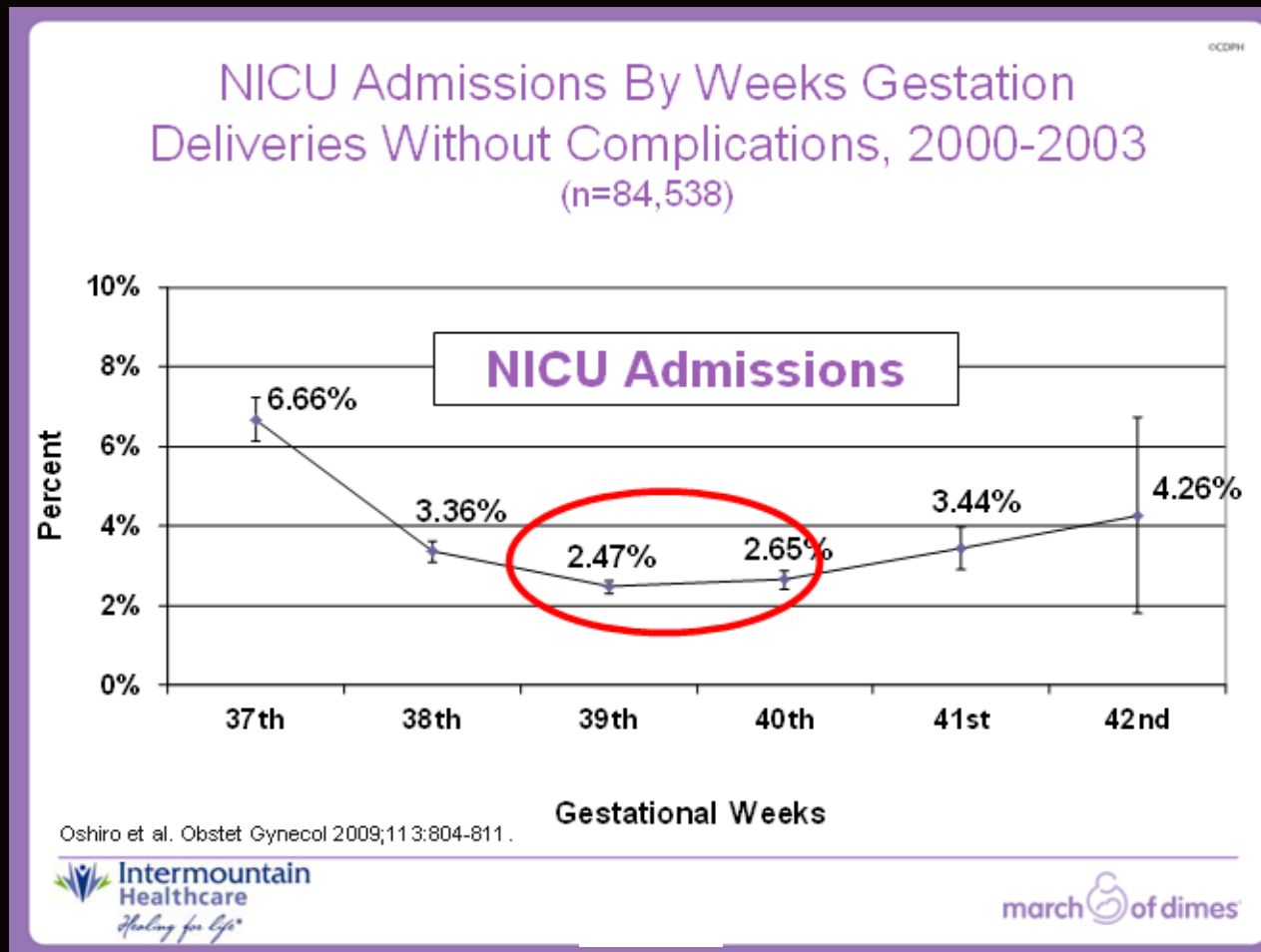
Tita AT et al. Timing of Elective Repeat Cesarean Delivery at Term and Neonatal Outcomes. NEJM 2009; 360(2):111-20

Outcomes between 38'4 to 38'6 weeks

- Wilmink (AJOG 2010;202:250.e1-8)
 - Evaluated 7 years of data from Netherlands Perinatal Registry including 1.3M births
 - National guidelines require calculation of GA based on LMP & verified by 1st trimester US (96% compliance)
 - Reported on 21K scheduled elective CS with 12K (56.6%) performed < 39'0 weeks
 - Respiratory outcomes worse than 39 weeks (RR=1.4 95% CI 1.1-1.8, p=0.01), similar to 38 weeks as a whole

Outcomes

NICU Admissions



Outcomes

Respiratory Morbidities

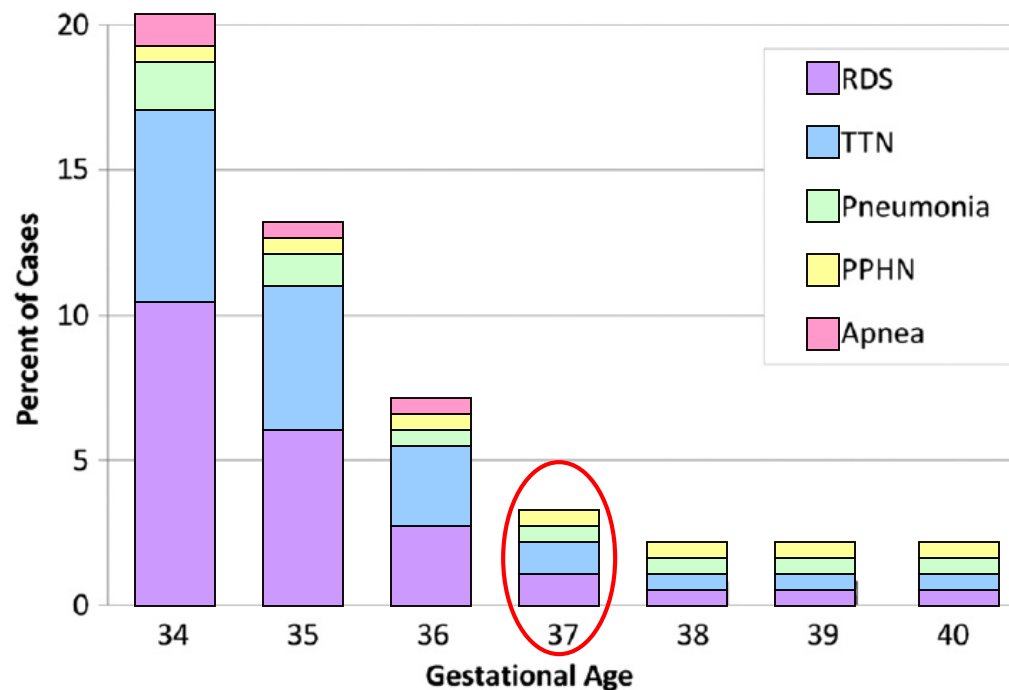
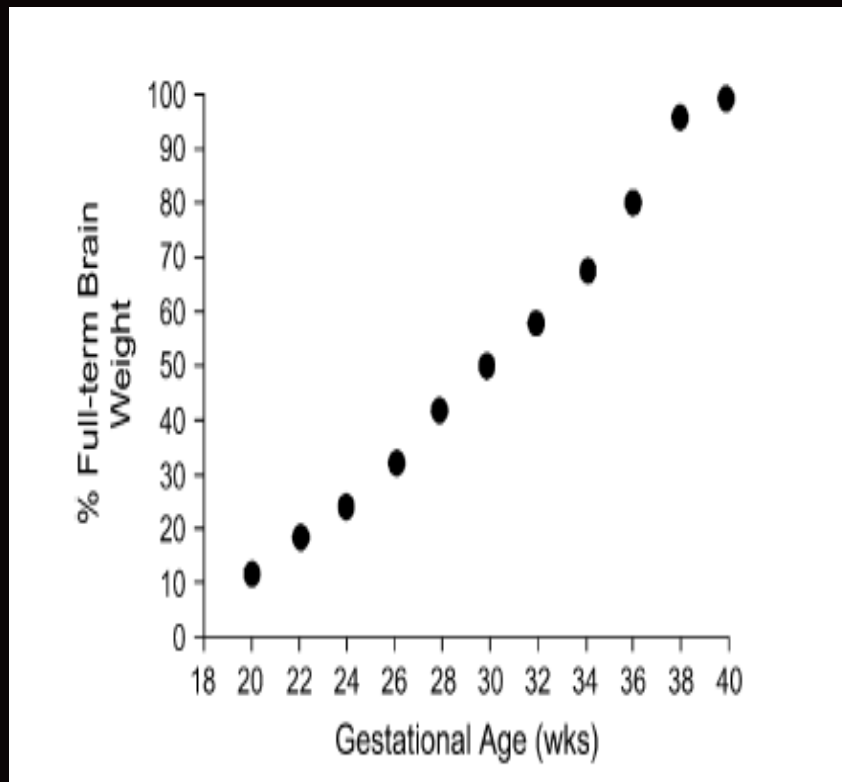
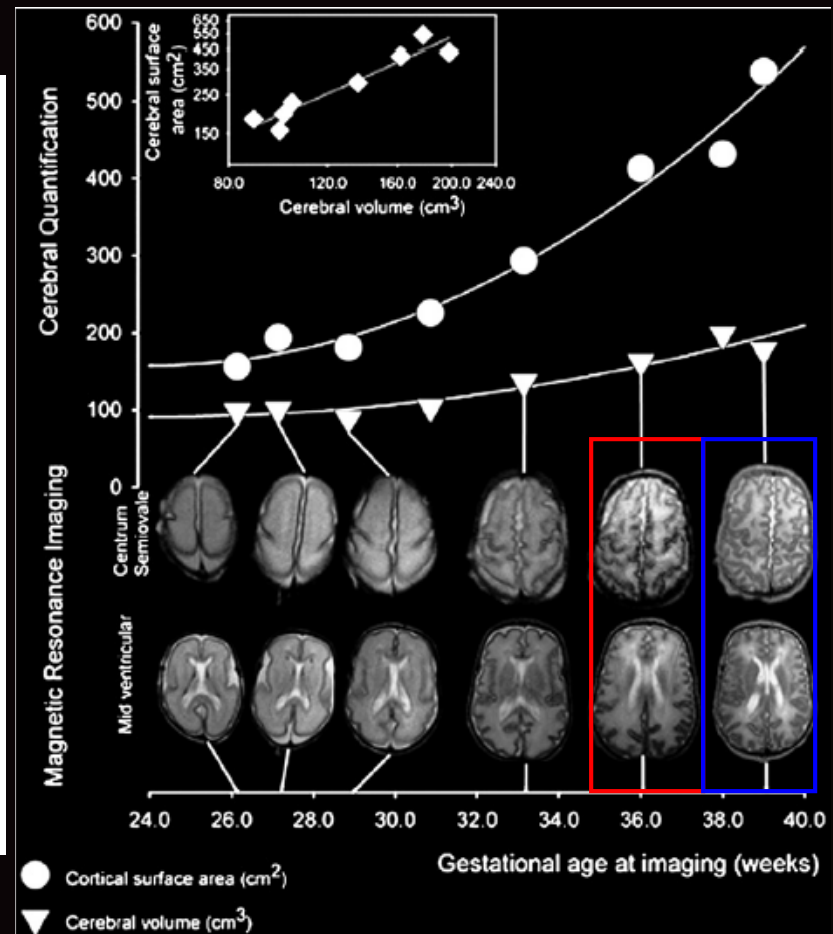


Fig. 2. Respiratory morbidity according to gestational age. $n = 233,844$. PPHN, persistent pulmonary hypertension of the newborn; RDS, Respiratory Distress Syndrome; TTN, transient tachypnea of the newborn. (Data from Hibbard JU, Wilkins I, Sun L, et al. Consortium on Safe Labor, Respiratory morbidity in late preterm births. JAMA 2010;304:423.)

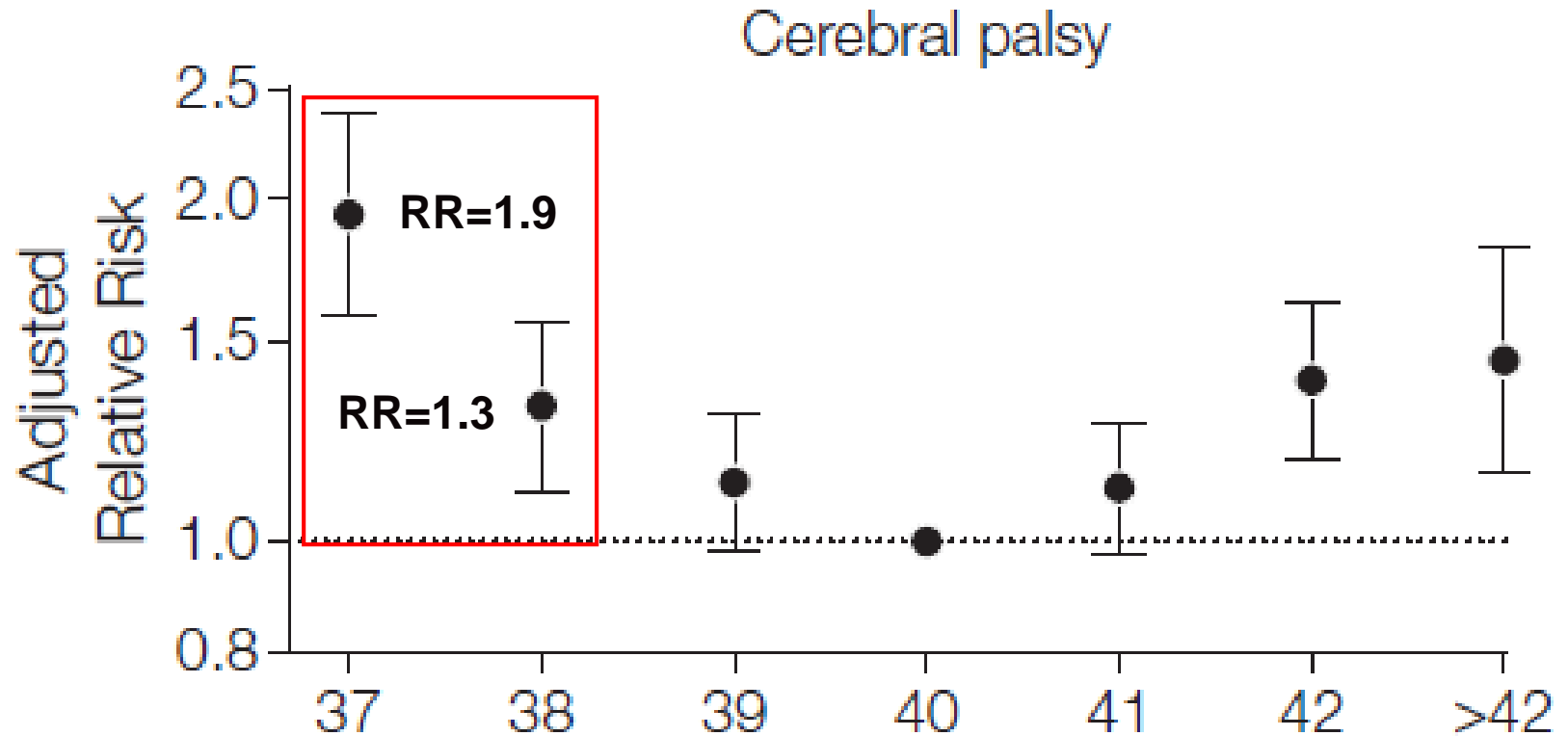
Neurodevelopmental Outcomes by GA



Adams Chapman. Clin Perinatol 2006;33:947-64



Cerebral Palsy & GA



Moster et al. JAMA. 2010;304(9):976-82

A review of over 1.6M Norwegian births between 37 & 44 weeks GA from 1967-2001 showed increased RR of CP at 37 & 38 weeks GA

Outcomes

Delayed Delivery & SB

Intervention Study	Total Population Studied	Stillbirth Findings
Oshiro (2009) ¹ (large health system)	160,394	Decline during Intervention period
Clark (2010) ² (large health system)	433,551	No change during Intervention period
Ehrenthal (2011) ³ (single hospital)	24,028	Increase noted at 37 and 38 weeks
Benedetti (2012) ⁴ (state of Washington)	505,445(>37 wk only)	No change during intervention period

¹Obstet Gynecol 2009;113:804–11

²Am J ObstetGynecol 2010;203:449.e1-6

³Obstet Gynecol 2011;118:1047–55

⁴Obstet Gynecol 2012;119:656-7

Elimination of Elective Early Term Deliveries

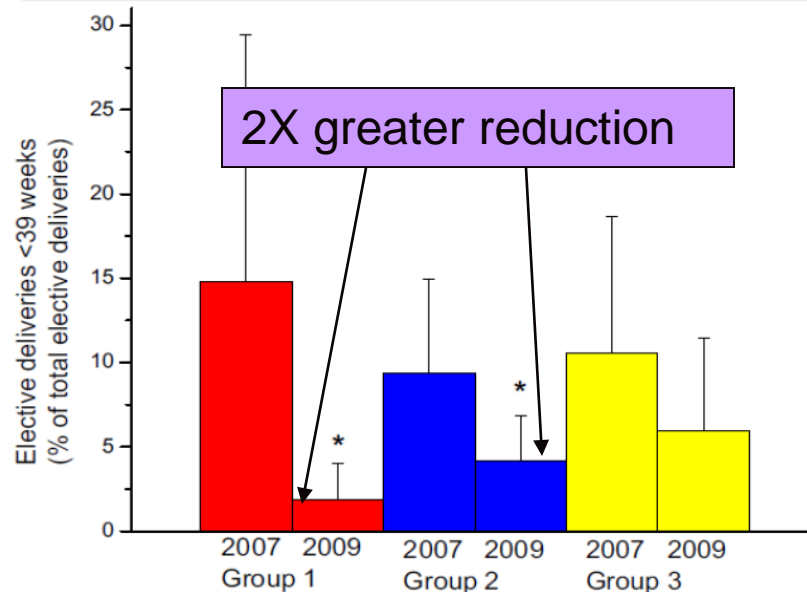
**HARD STOP
POLICY**

Hospital Corporation of America

- **Hard Stop** – specific policy & strict enforcement
- **Soft Stop** – similar policy with self enforcement
- **Education only** – literature/internal & professional association recommendations

FIGURE 1

Reduction in elective delivery by group, 2007-2009



Clark. Reduction of elective delivery at <39 weeks of gestation. Am J Obstet Gynecol 2010.

16% reduction in term NICU admissions

1/2M NICU day reduction & \$1B annual savings if 'hard stop' adopted nationally

Elimination of Elective Early Term Deliveries

WIH PROGRAM

WIH Guideline

- Policy approved in 1983
 - 4 revisions since – most recent two revisions in 2008 & 2009
- US to either confirm LMP dates or establish dating is valid up to 20 weeks GA
- If dating established by US \geq 20 weeks patient requires:
 - Amniocentesis to confirm lung maturity OR
 - Onset of labor
- Important Message to patients & providers: Early PNC & US to confirm dates

WIH Guideline

■ US parameters to confirm or establish dates

Fetal pulmonary maturity can be inferred, and an elective cesarean section may be scheduled or an elective induction performed, if a gestational age of 39 weeks (by menstrual dates) is confirmed by any of the following criteria:

- 1) Fetal heart tones documented for 30 weeks by Doppler or 20 weeks by nonelectric fetoscope.
- 2) 36 weeks since a serum or urine human chorionic gonadotropin pregnancy test was found to be positive.
- (3) Ultrasound measurement of crown-rump length at 6'0 to 9'6 weeks of gestation (+ or – 4 days) supporting a gestational age of greater than or equal to 39 weeks.
- (4) Ultrasound measurement of crown-rump length at 10'0 to 13'6 weeks of gestation (+ or – 7 days) supporting a gestational age of greater than or equal to 39 weeks.
- (5) Ultrasound measurements at 14'0 to 20'0 weeks of gestation (+ or – 10 days) supporting a gestational age of greater than or equal to 39 weeks.

Ultrasound confirmation of gestational age should be in agreement with menstrual dates within 4 days when performed at 6 to 9'6 weeks, within 7 days at 10'0 to 13'6 weeks or within 10 days when performed at 14'0 to 20'0 weeks.

In the event menstrual dates are unknown or are inconsistent with ultrasound measurements, the following may be used to assume fetal pulmonary maturity and schedule an elective cesarean section or elective induction:

■ US dating range from 6'0 to 9'6 weeks GA differs from ACOG (*based on 8% differential*)

WIH Approval Process

Booked Cesarean Deliveries

- 4 step process

Step 1

- Paperwork submitted for review with OR booking
 - Elements of prenatal chart
 - 1st US performed

Final EDD ____/____/____

- ☐ Patient may be booked at or after 39 Wks for Elective Delivery
39 Weeks as of ____/____/____
- ☐ Patient may be booked at ____ Wks for other medical indication.
Indication _____
____ Weeks as of ____/____/____

Elective CS Confirmation

Patient Name _____

MD Name _____

LMP ____/____/____ EDD ____/____/____

Ultrasound Confirmation

1st Trimester Date ____/____/____ GA ____wk ____days
Confirms EDD ☐ Changes EDD ☐
New EDD based on U/S ____/____/____

2nd Trimester Date ____/____/____ GA ____wk ____days
Confirms EDD ☐ Changes EDD ☐
New EDD based on US ____/____/____

Final EDD ____/____/____

- ☐ Patient may be booked at or after 39 Wks for Elective Delivery
39 Weeks as of ____/____/____
- ☐ Patient may be booked at ____ Wks for other medical indication.
Indication _____
____ Weeks as of ____/____/____

Date Booked ____/____/____ at ____ Wks ____ Days

Not Approved _____

Tentatively Approved _____ Pending _____

Approved _____

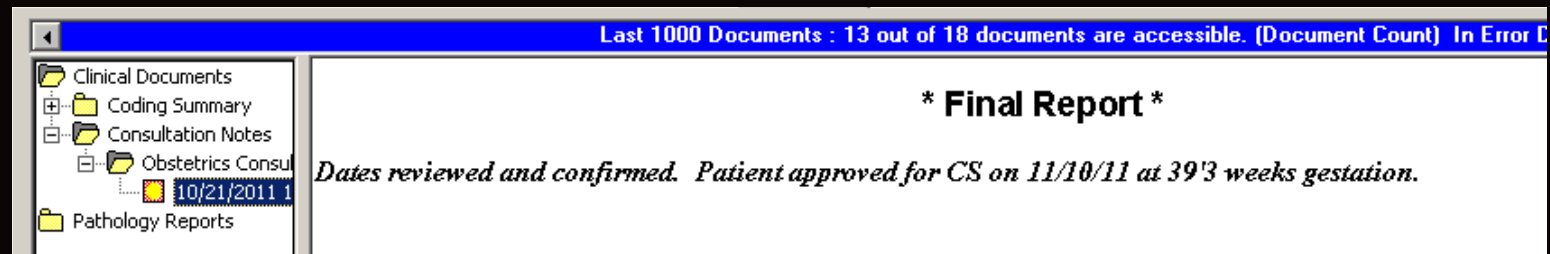
Date ____/____/____

WIH Approval Process

Booked Cesarean Deliveries

Step 1 (cont'd)

- Dates validated with EMR dating tool
 - Confirmed – consult note in EMR



- Not confirmed – email to provider/surg coordinator requesting further information or rescheduling

WIH Approval Process

Booked Cesarean Deliveries

Step 1 (cont'd)

■ Outcomes

- ❑ New information confirms dating & patient approved for originally scheduled date
- ❑ New EDD is established and patient rescheduled
- ❑ Valid medical/obstetrical indication is identified and patient is approved for CS prior to 39'0 weeks gestation

A review of 492 booked cases over 4 months showed a 15.6% rate of follow up email to providers for clarification

WIH Approval Process

CS Precheck

Step 2

- Review of cases on EMR for upcoming week begins Wednesday before
 - Confirmation of pre-reviewed cases
 - New bookings faxed and verified by MDIO

Weekly CS Log			Week of ____/____/____ to ____/____/____						
Date	Case	Patient	MD	MRN	Time	GA	Indication	Approved	
M	1								
	2								
	3								
	4								
	5								
	6								
	7								
	8								
Tu	1								
	2								
	3								
	4								
	5								
	6								
	7								
	8								
Wed	1								

WIH Approval Process

CS Precheck

Step 3

- Day before CS review of charts for consult note by ASU nurses

Step 4

- Final check on day of surgery by periop nurses
 - *Only check utilized with previous system*

WIH Data

January 2011 – December 2014

Total CS	5,463
Consults	5,463
CS < 39'0 wk	870
Late US w amnio	53

16% of cases < 39'0 weeks GA

<u>Indications</u>	
<i>Twins</i>	301
<i>Uterine sx</i>	134
<i>Placenta</i>	107
<i>HBP</i>	100
<i>IUGR</i>	28
<i>Cholestasis</i>	26
<i>Oligohydramnios</i>	22
<i>PPROM</i>	27
<i>Quads/Triplets</i>	8
<i>Other w amnio</i>	13
<i>Other s amnio</i>	68

Timing of Indicated Late-Preterm and Early-Term Birth

Catherine Y. Spong, MD, Brian M. Mercer, MD, Mary D'Alton, MD, Sarah Kilpatrick, MD, PhD, Sean Blackwell, MD, and George Saade, MD

Noted 'high level evidence is lacking' in making these decisions and that 'guidance offered in this report is based on expert opinion in many cases'.

■ Goals

- ❑ Review available information for specific conditions to determine potential risks/benefits of late-preterm and early-term births vs continued pregnancy.
- ❑ Determine the optimal GA for delivery of affected pregnancies when possible

NICHD Workshop - Categories

- Placental or uterine
 - Previa/accreta
 - Prior classical CS/myomectomy
- Fetal
 - IUGR
 - Multiple gestation
 - Anomalies
- Maternal
 - GHTN/PEC
 - GDM/DM
 - Prior SB
 - PPROM/PROM

Although providing valuable information on many clinical topics did not address:

- Cholestasis
- History of uterine rupture or dehiscence
- Vasa Previa

Amniocentesis

Diagnosis

Elective \geq 39'0 wks (Late US)	53
Elective < 39'0 wks (Late US)	6
Hx SB	6
Cholestasis	3
Poor OB Hx	2
Hx Classical CS	3
Di-Di Twins	1
Placenta Previa	1
Hx Uterine Dehiscence	1
Short Intergestational Interval	1
Abdominal Pain (Unknown)	1
Thrombophilia	1
Type 1 DM	1
Other	6
Total	86

Neonatal Outcomes After Demonstrated Fetal Lung Maturity Before 39 Weeks of Gestation

Elizabeth Bates, MD, Dwight J. Rouse, MD, MSPH, Merry Lynn Mann, BS, Victoria Chapman, MPH, Waldemar A. Carlo, MD, and Alan T. N. Tita, MD, PhD

Obstet Gynecol 2010; 116:1288-95

Conclusions:

Neonates delivered at 36 to 38 weeks after confirmed FLM are at higher risk of adverse outcomes than those delivered at 39 to 40 weeks.

- Adjusted Odds Ratio – 1.7
- Respiratory Distress Syndrome – OR 7.6
- Hyperbilirubinemia – OR 11.2
- Hypoglycemia – OR 5.8

Elimination of Elective Early Term Deliveries

**DEVELOPING A
PROGRAM**

Essential Elements

- Know the definitions
 - CMS requirements for all hospitals to submit aggregate data quarterly beginning in 2013
 - TJC in 2014 for hospitals $\geq 1,100$ deliveries
- Identify clinical leaders & champions
- Use appropriate pregnancy dating tools
- Develop consistent 'hard stop' process
 - MOD Toolkit
- Provider and patient education
 - MOD materials

Definitions

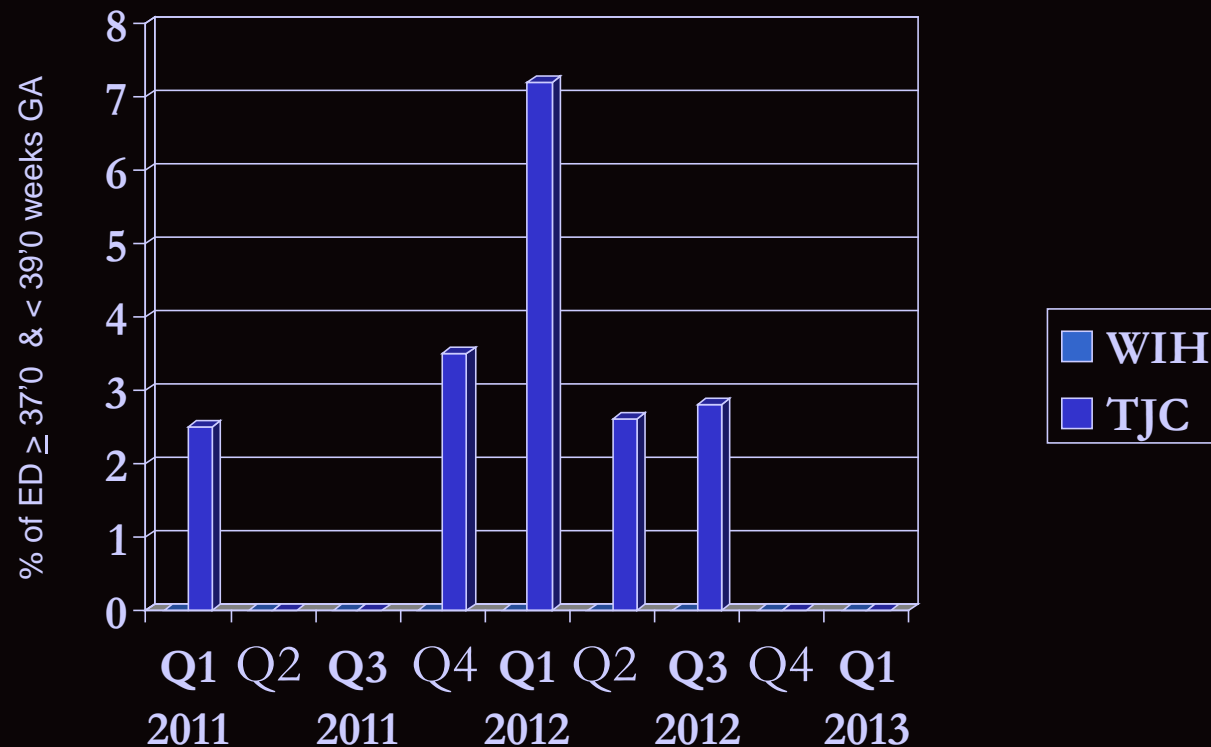
Determining the Rate of Elective Deliveries Before 39 Weeks of Gestation

Methodology Matters

Mark W. Tomlinson, MD, and Laurel Durham, RN

- Several studies use different denominators
 - All deliveries
 - Deliveries at 37-39 weeks gestation
- Consider using the Joint Commission definition
 - ED > or = 37 & < 39 completed weeks gestation
Deliveries at ≥ 37 & < 39 completed weeks gestation
- TJC methodology will show higher rates due to small denominator
- TJC definitions & ICD-9 codes and have limitations

Discrepancy with TJC Process

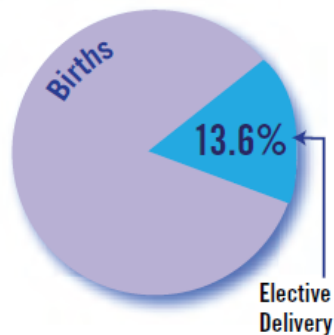


TJC Approach

Proceedings from the National Summit on Overuse

September 24, 2012

Organized by The Joint Commission
and the American Medical Association-
Convened Physician Consortium for
Performance Improvement® (PCPI®)



– The Joint Commission
Annual Report on Quality
and Safety, 2012 (2011
data)

Early Term Non-Medically Indicated Elective Delivery
Chair, Bryan T. Oshiro, M.D., Loma Linda University
Medical Center and Children's Hospital

- Standardize the calculation of GA & data source used
- Make EED indications & exclusions as comprehensive as possible
- Standardize data collection
- Recommend ACOG continue work of guidelines on best method to establish GA



The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS



Society for
Maternal-Fetal Medicine

COMMITTEE OPINION

Number 579 • November 2013

**The American College of Obstetricians and Gynecologists Committee on Obstetric Practice
Society for Maternal-Fetal Medicine**

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Definition of Term Pregnancy

- Early term – 37'0 to 38'6 weeks
- Full term – 39'0 to 40'6 weeks
- Late term – 41'0 to 41'6 weeks
- Postterm – 42'0 weeks and beyond

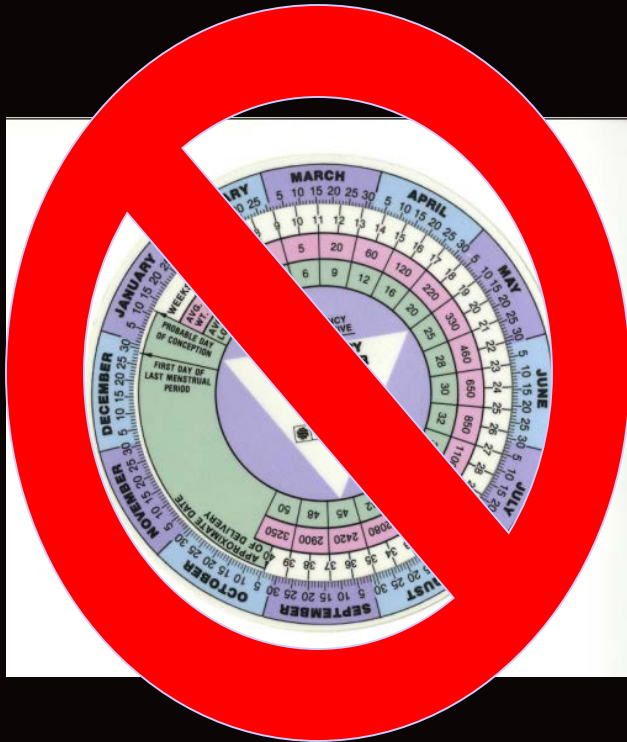
ACOG Committee Opinion 611

Method for Estimating Due Date

- Ultrasound measurement of the embryo or fetus in the *first trimester (up to and including 13'6 weeks of gestation)* is the most accurate method to establish or confirm gestational age.
- If pregnancy resulted from assisted reproductive technology (ART), the ART-determined gestational age should be used to assign the estimated due date (EDD).
- As soon as EDD established using LMP and/or first accurate US it should be discussed with the patient and documented with any subsequent change only in rare circumstances.

Appropriate Dating Tools

- Pregnancy 'wheels' should be abandoned in favor of electronic EDD calculators



MedCalc: Pregnancy Due-Dates Calculator

Last menstrual period : Monday, April 30, 2012

Calculate Forward Reset This Form

Conception Occurred : Monday, May 14, 2012
(about two weeks after last menstrual period)

First Trimester Ends (12 weeks) : Monday, July 23, 2012

Second Trimester Ends (27 weeks) : Monday, November 5, 2012

Estimated Due Date (40 weeks) : Monday, February 4, 2013

Calculate Backward

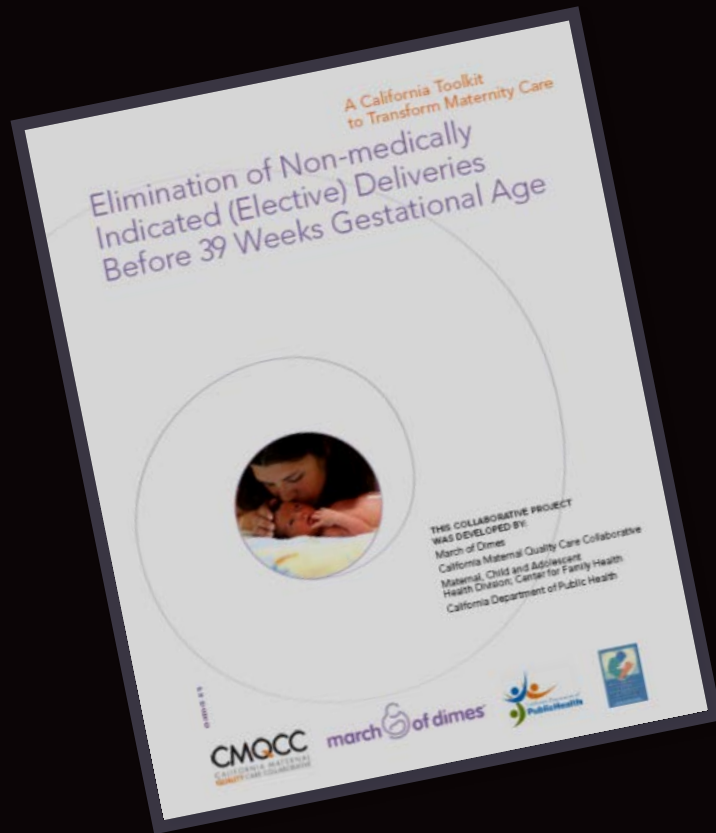
On Monday, January 28, 2013, you will be 39 weeks pregnant.

Calculate Date --> Weeks Calculate Weeks --> Date

DISCLAIMER: All calculations must be confirmed before use. The authors make no claims of the accuracy of the information contained herein; and these suggested doses are MedCalc.com nor any other party involved in the preparation or publication of this site shall be liable for any special, consequential, or exemplary damages resulting in whole material.

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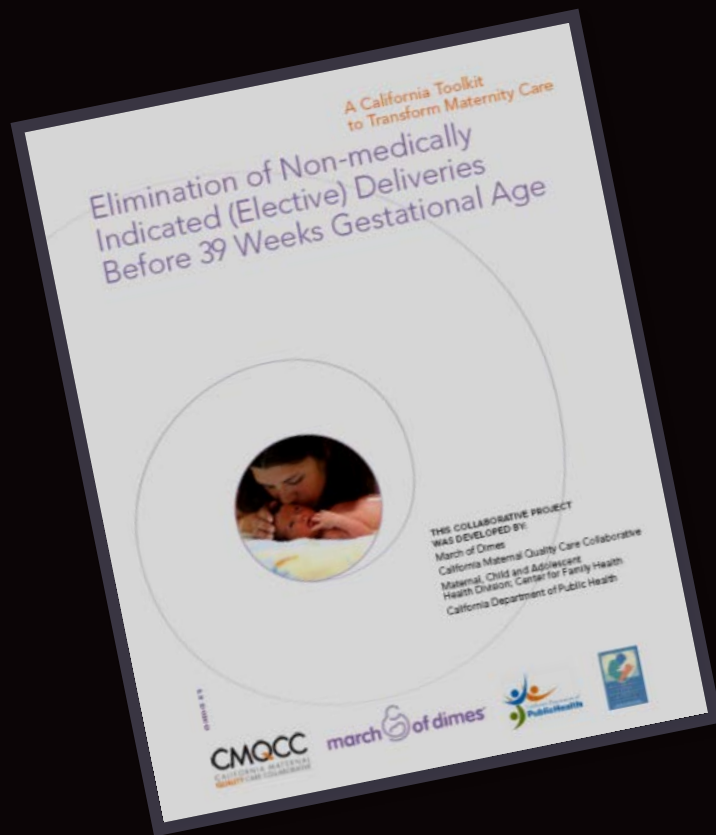
Key Change Components



- Identify physician & nursing champions
- Create or revise hospital policy using 'hard stop'
- Establish professional consensus on 'Indications for Early Delivery'
- Secure buy-in & collect data to drive change & review progress



What Providers Can Do



- Educate patients about risks of delivery before 39'0 weeks
- Perform US before 20 weeks to confirm GA on all patients
- Educate your staff on hospital's scheduling process
- Take the lead on promoting best practice



Summary

- Accepted definition of term pregnancy was somewhat arbitrarily determined
- A combination of patient convenience, practice patterns, neonatal success and rare adverse outcomes have driven increased numbers of elective early term delivery
- Careful review of the evidence shows significant increases in NN/infant morbidity & mortality associated with early term delivery

Summary

- Elimination/mitigation of elective early term delivery is possible
- Organizations that implement 'hard stop' policies have the most success
- Provider & patient education are the cornerstones of a successful program
- Data collection on process and clinical outcomes essential component

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3. Peristats, March of Dimes:2010
4. ACOG Practice Bulletin #97; September 2008 *Fetal Lung Maturity*
5. Oshiro BT et al. Decreasing Elective Deliveries Before 39 Weeks of Gestation in an Integrated Health Care System. Obstet Gynecol 2009;113:804-11
6. Shapiro-Mendoza CK et al. Effect of late-preterm birth and maternal medical conditions on newborn morbidity risk. Pediatrics 2006;121:e223-232
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Questions



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