Born Too Soon by Choice

Decreasing Late Preterm and Early Term Births

Decreasing Late Preterm and Early Term Deliveries Wednesday, November 17, 2010

The role of Clinical Community – ACOG

Richard Waldman, MD,FACOG

Disclosure Statement

I and my spouse have no relevant financial interests with commercial interests to disclose.

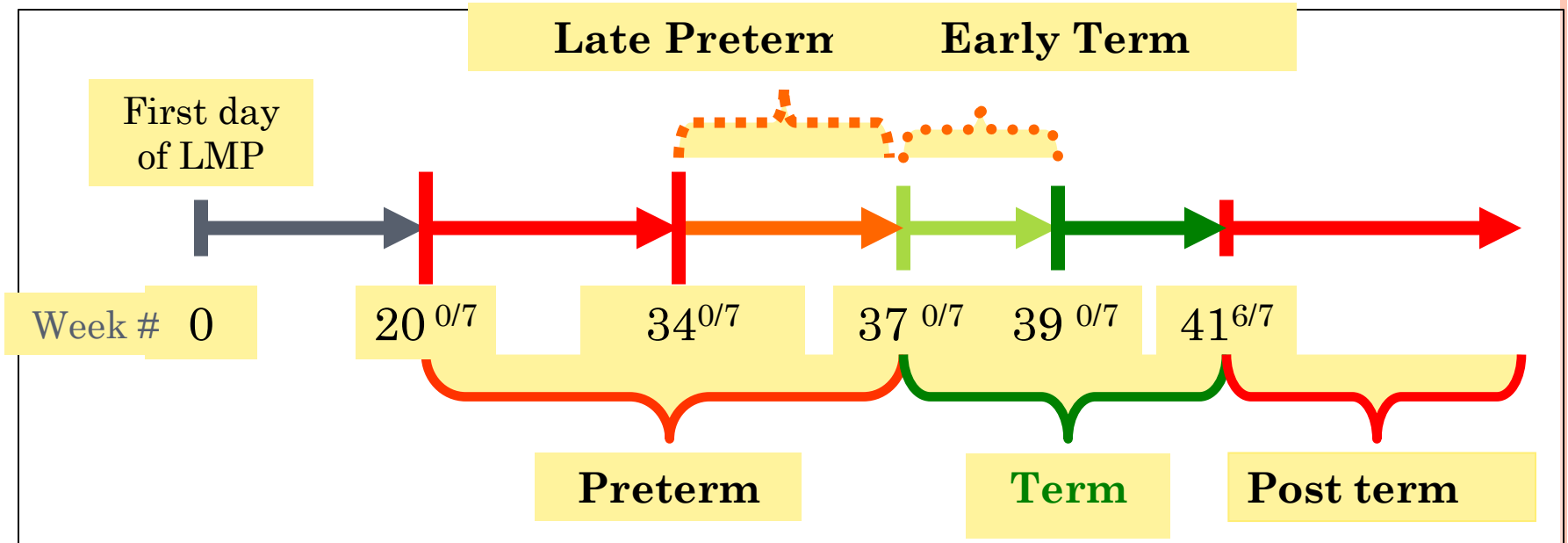
Objectives

1) Describe the increase in non-medically indicated (elective) deliveries before 39 weeks and identify the contributing factors.
2) Discuss the risks of early term deliveries and the benefits of delaying delivery beyond 39 weeks gestation.
3) Outline successful initiatives to reduce elective deliveries before 39 weeks at hospital, health system and statewide levels.

Questions to be Addressed

- Is this an important and significant problem?
- What are the potential benefits to performing elective inductions prior to 39 weeks?
- What are the potential benefits to performing elective repeat cesarean deliveries prior to 39 weeks?
- What are the risks to performing elective deliveries prior to 39 weeks?
- How do you get practitioners to change their clinical practice?

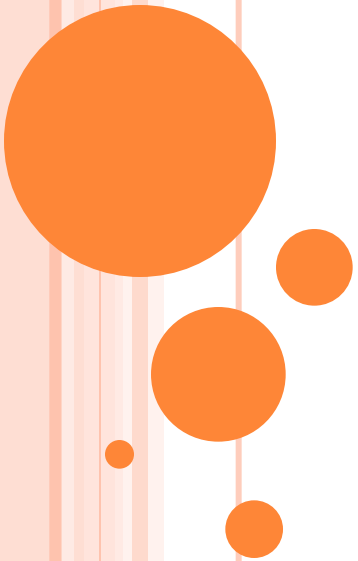
Terminology



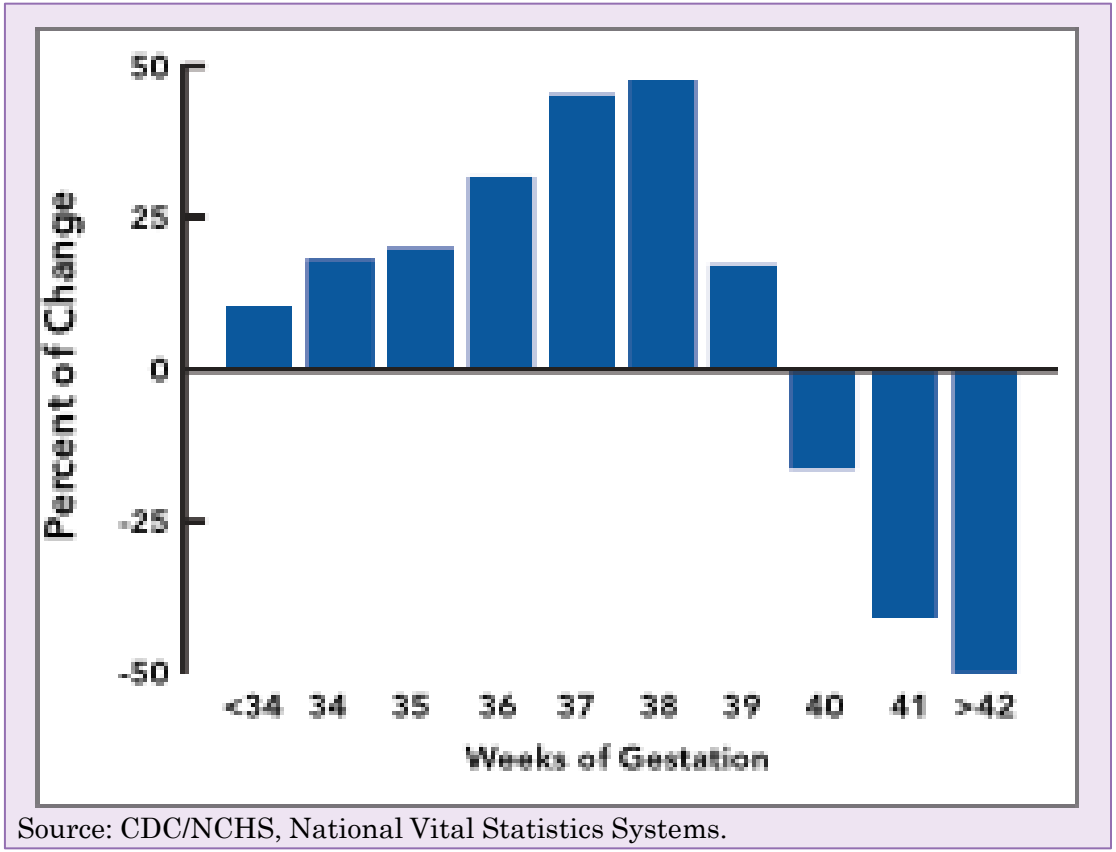
Modified from Drawing courtesy of William Engle, MD, Indiana University

Raju TNK. Pediatrics, 2006;118 1207.

Is this an important and significant problem?



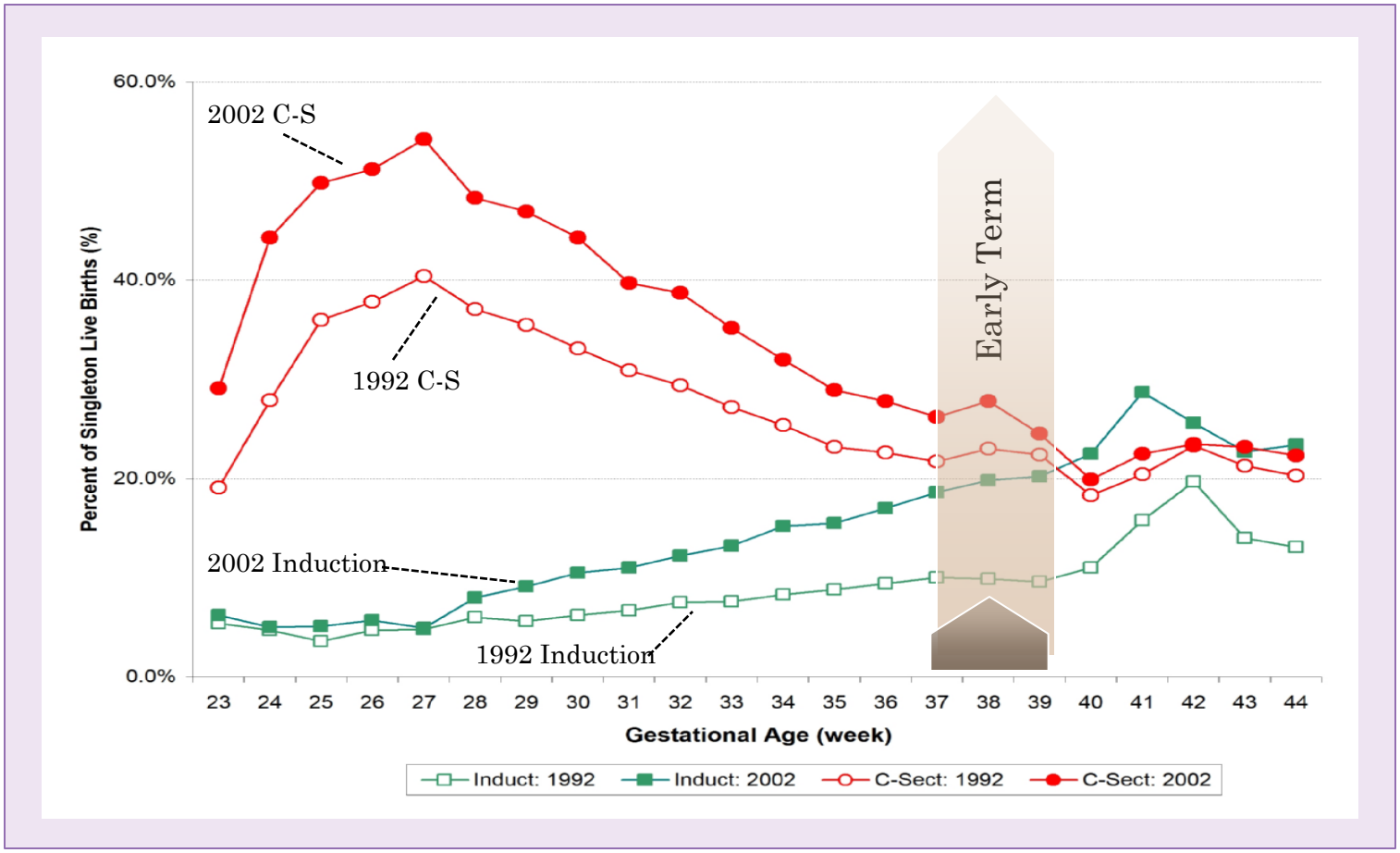
Change in Distribution of Births by Gestational Age: United States, 1990-2006



Source: CDC/NCHS, National Vital Statistics Systems.

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.

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



Source: NCHS, Final Natality Data, Prepared by March of Dimes Perinatal Data Center, April 2006.

How often are elective inductions or repeat cesarean deliveries done before 39 weeks?

- Study involving 19 centers in MFM Network completed between 1999 and 2002, involving 13,258 elective repeat cesarean births

  revealed **35.8% of elective repeat cesarean deliveries completed before 39 weeks**

- In 2007 study of 27 hospitals in HCA system, **28.3% of elective inductions were performed before 38 weeks**

ClarkSL et al. *Am J Obstet Gynecol* 2009; 156:e1-e4
Tita et al. *N Engl J Med 2009*; 360:111-20.

7,804 Nulliparous Women 2003-2006 Newark, Delaware

- 1. 44% induction rate
- 2. 40% of the inductions were elective
- 3. C/S rate 2.6X in induction group
- 4. 37 % had an unfavorable cervix
- 5. 20% of the c/s were for failed induction

Obstetrics & Gynecology:
July 2010 - Volume 116 - Issue 1 - pp 35-42
doi: 10.1097/AOG.0b013e3181e10c5c
Original Research
Labor Induction and the Risk of a Cesarean Delivery Among Nulliparous Women at Term
Ehrenthal, Deborah B. MD; Jiang, Xiaozhang MD, MS; Strobino,

Maternal Risks Also Associated with Labor Induction

- For nulliparous patients, relative risk of cesarean delivery with elective induction of labor ranges from 2 to 3-fold
- Nulliparous women undergoing elective induction of labor with low Bishop score face almost a 50% risk of cesarean delivery

EhrenthalDM et al *Obstet Gynecol* 2010; 116: 35-42
DunneC et al. *J Obstet Gynecol Can* 2009; 31: 1124-1130
ClarkSL et al. *Am J Obstet Gynecol* 2009; 156:e1-e4

Logistic Regression for Cesarean Delivery: Induction Compared with At or Above Induction Gestational Age

Week of Induction	Fully Adjusted OR (95% CI)
37 weeks	1.12 (0.92-1.36)
38 weeks	1.24 (1.08-1.43)
39 weeks	1.31 (1.18-1.47)
40 weeks	1.57 (1.42-1.74)
41 weeks	1.45 (1.25-1.68)

*Adjusted for parity, demographics, high risk status

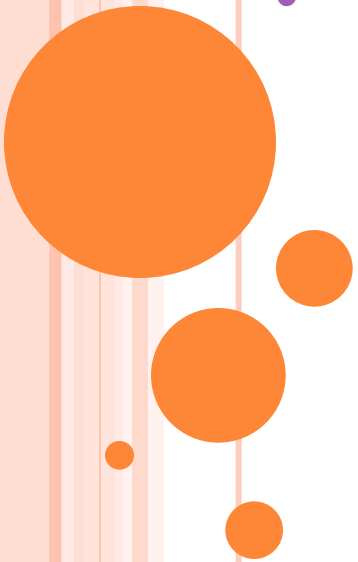
GlantzJC. *Obstet Gynecol* 2010; 115:70-76

Is this an important and significant problem?

- YES-involves a substantial proportion of obstetric practice in the United States

- Has quality and safety implications due to potential for increased maternal and neonatal morbidity

Why are Non-medically Indicated (Elective/Planned) Deliveries Increasing in Frequency?



Elective Induction: Sounds like a good idea…

Patient desires:

- Delivered by her doctor
- Spouse or family travel
- Advanced planning
- Mother lives far away;
- History of quick labors
- Prior bad pregnancy
- Maternal intolerance to late pregnancy

- Excess edema, backache, indigestion, insomnia
- Perception of decreased fetal movement

Clin Obstet Gynecol 2006;49:698-704

And, it's okay right?

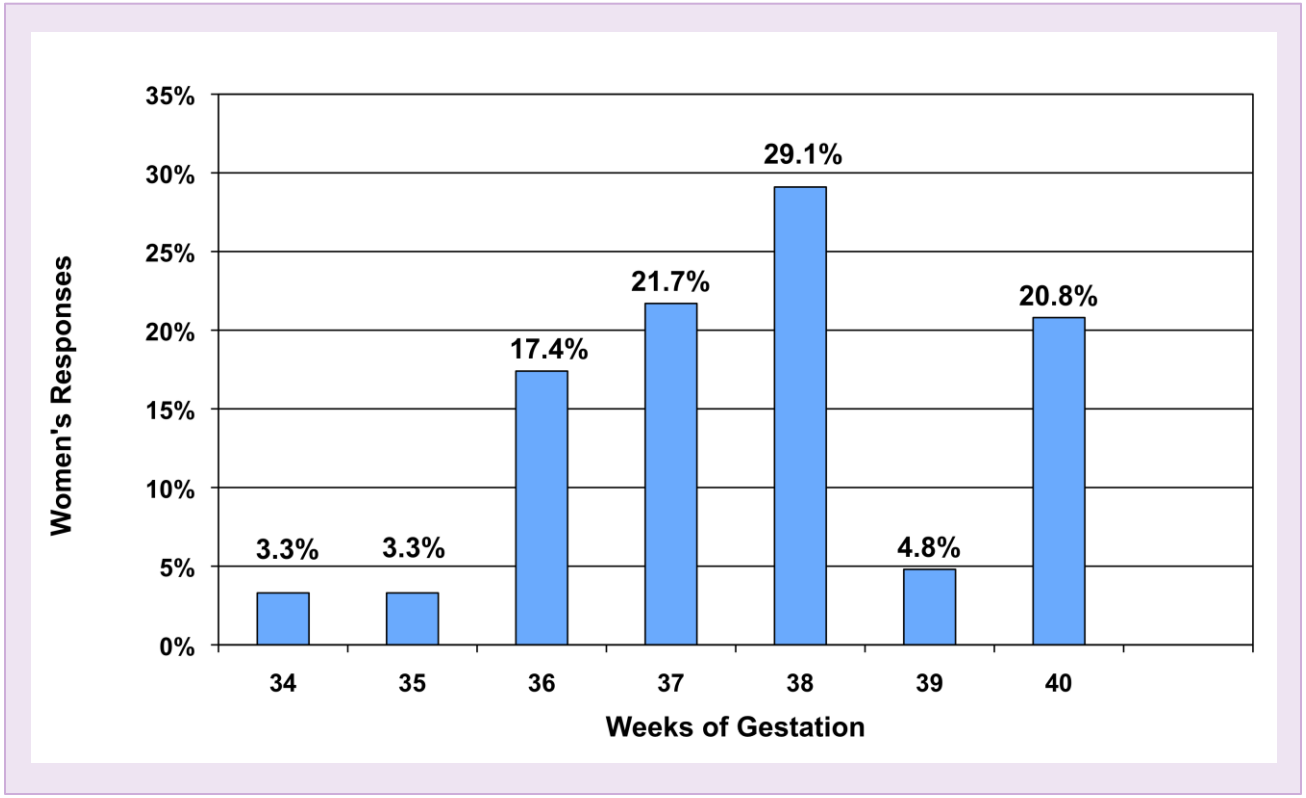
Women's Perceptions Regarding the Safety of Births at Various Gestational Ages

Robert L. Goldenberg, MD, Elizabeth M. McClure, MEd, Anand Bhattacharya, MHS, Tina D. Groat, MD, MBA, and Pamela J. Stahl

VOL. 114, NO. 6, DECEMBER 2009 OBSTETRICS & GYNECOLOGY

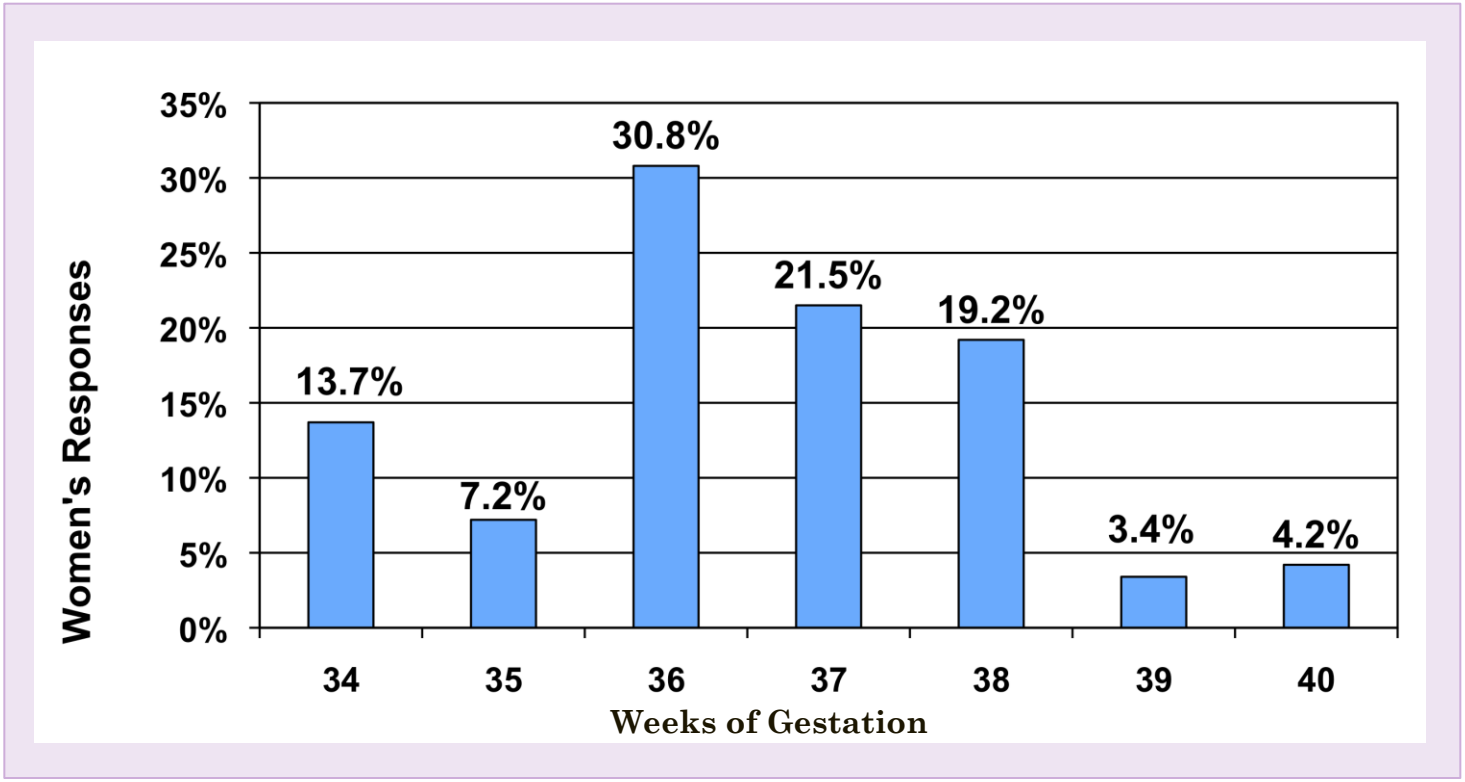
Obstet Gynecol 2009;114:1254

The Gestational Age that Women Considered a Baby to be Full Term



Obstet Gynecol 2009;114:1254

The Gestational Age that Women Considered it Safe to Deliver



Obstet Gynecol 2009;114:1254

What Motivates Some Obstetricians to Perform Elective Inductions?

- Physician convenience
  - Guarantee attendance at birth
  - Avoid potential scheduling conflicts
  - Reduce being woken at night
  - Monetary
  - Suspected macrosomia
- … what's the harm?
  - Amnesia due to rare occurrence
  - The NICU can handle it

Obstetricians are suckers for tears and want to keep our patients happy.

bstet Gynecol 2006;49:698-704

Suspected Fetal Macrosomia (Non-Diabetic Population)

- Does not reduce risk of shoulder dystocia
- Doubles risk of cesarean delivery
- 262 pregnancies EFW >90%
- Elective group:
  - 57% cesarean delivery rate
  - 5.3% shoulder dystocia
- Spontaneous labor group:
  - 31% cesarean delivery rate
  - 2.5% shoulder dystocia

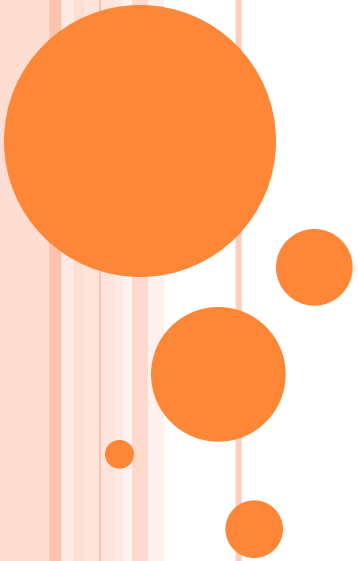
Combs et al. Obstet Gynecol 1993; 81:492-496

What are the potential benefits to performing elective repeat cesarean deliveries prior to 39 weeks?

- Benefits modest at best

- As with induction of labor, there are some valid reasons for doing repeat cesarean deliveries prior to 39 weeks

What are the Risks of Non-medically Indicated (Elective) Delivery Before 39 Weeks



Complications of Non-medically Indicated (Elective) Deliveries Between 37 and 39 Weeks

- 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

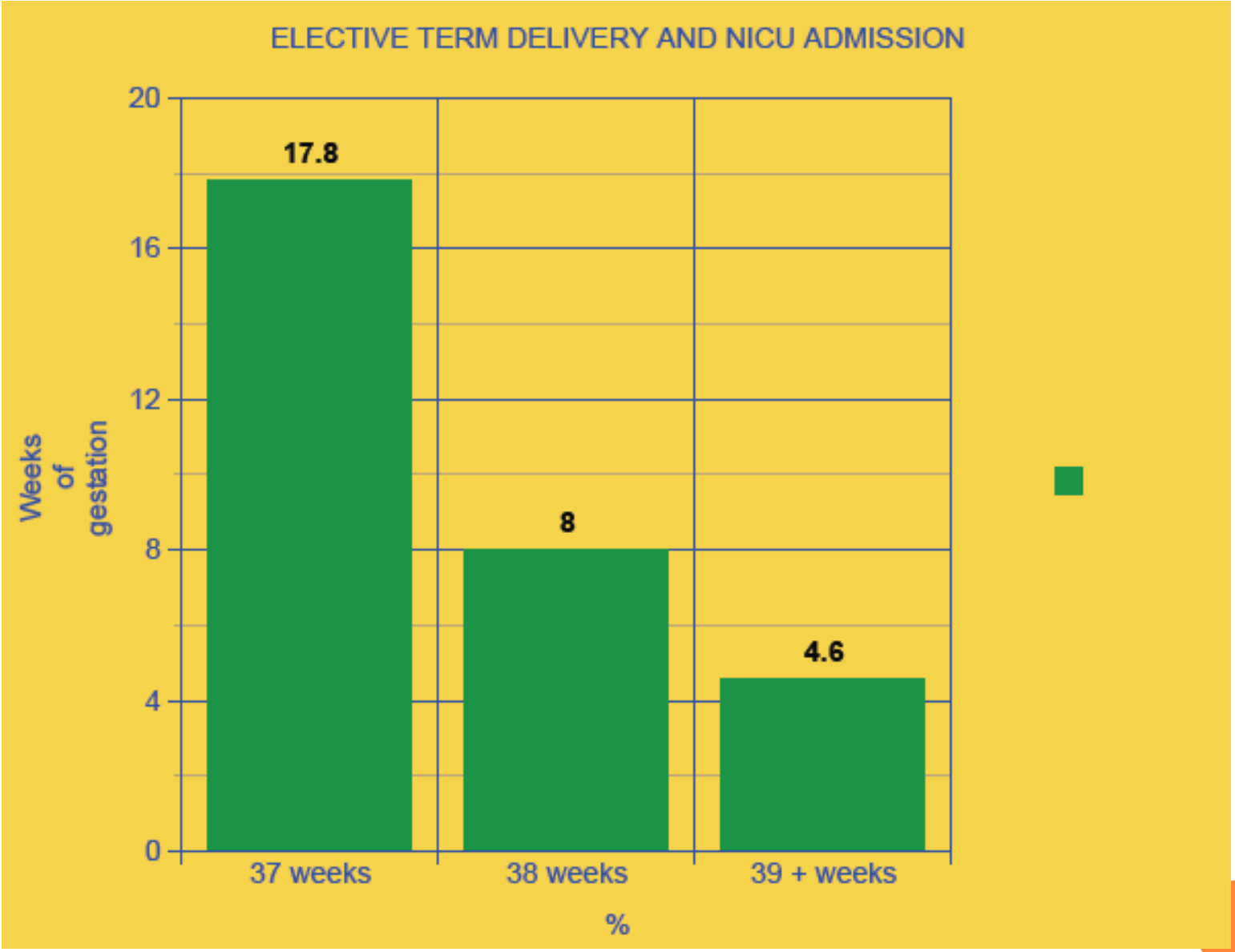
See Toolkit for more data and full list of citations
Clark 2009, Madar 1999, Morrison 1995, Sutton 2001, Hook 1997

Morbidity of Late Preterm Infants in Massachusetts

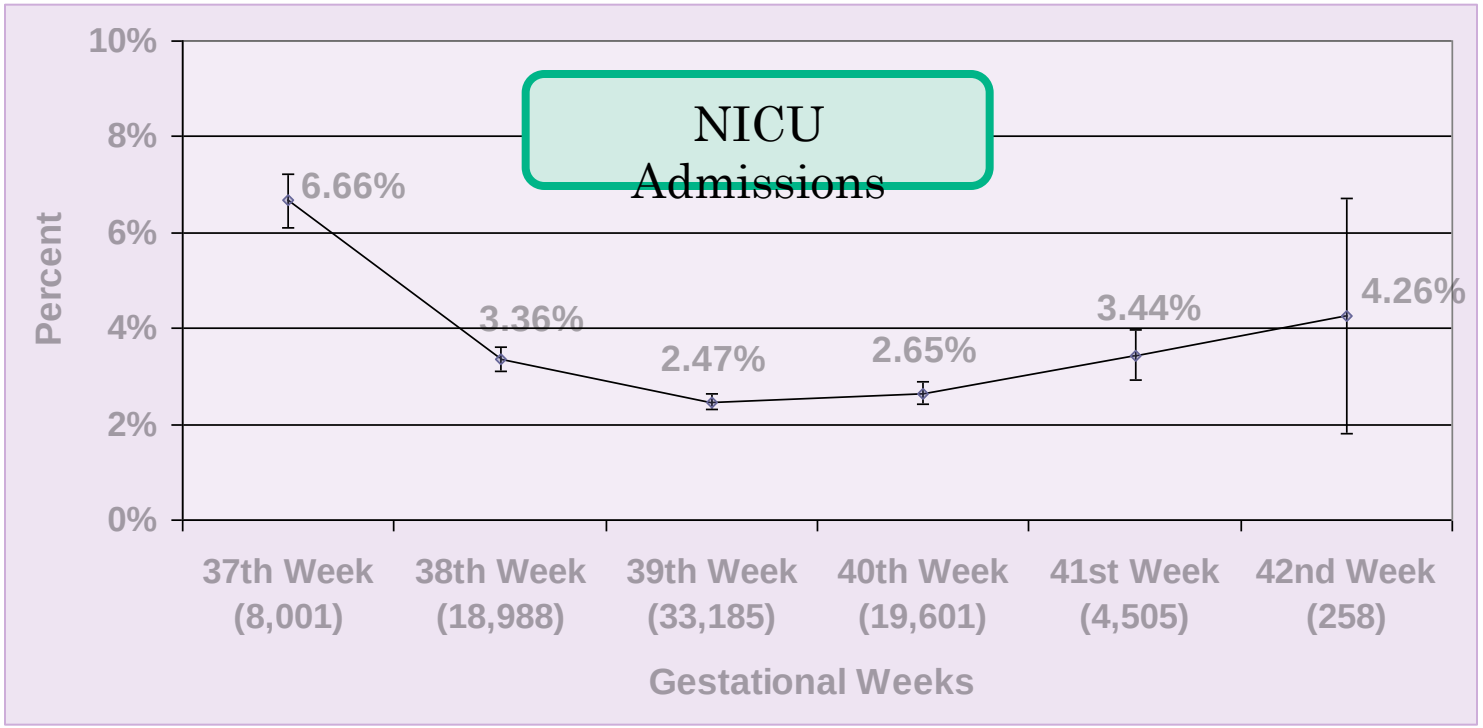
- Late preterm infants: **22.2%** vs Term infants: **3%**
  - Sample: Term (377,638), Late Preterm (26,170)
- **Morbidity** rates doubled for each gestational week earlier than 38 weeks

40 wks:	2.5%
39 wks:	2.6%
38 wks:	3.3%
37 wks:	5.9%
36 wks:	12.1%
35 wks:	25.6%
34 wks:	51.9%

Shapiro-Mendoza CK et al. Effect of late-preterm birth and maternal medical conditions on newborn morbidity risk.
Pediatrics. 2008;121:e223–e232


ELECTIVE TERM DELIVERY AND NICU ADMISSION
Weeks of gestation
20
16
12
8
4
0
17.8
8
4.6
37 weeks
38 weeks
39 + weeks
%

NICU Admissions By Weeks Gestation Deliveries Without Complications, 2000-2003



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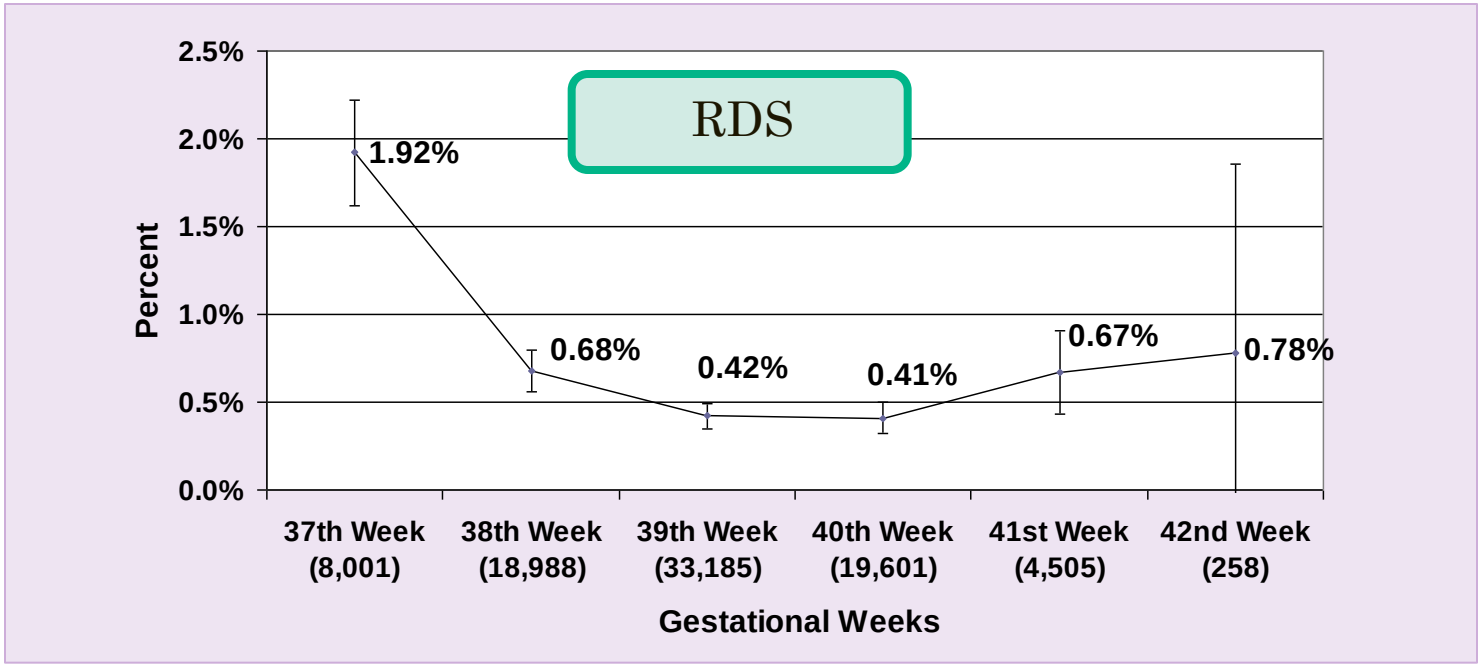
Oshiro et al. Obstet Gynecol 2009;113:804-811.

RDS By Weeks Gestation
Deliveries Without Complications, 2000-2003



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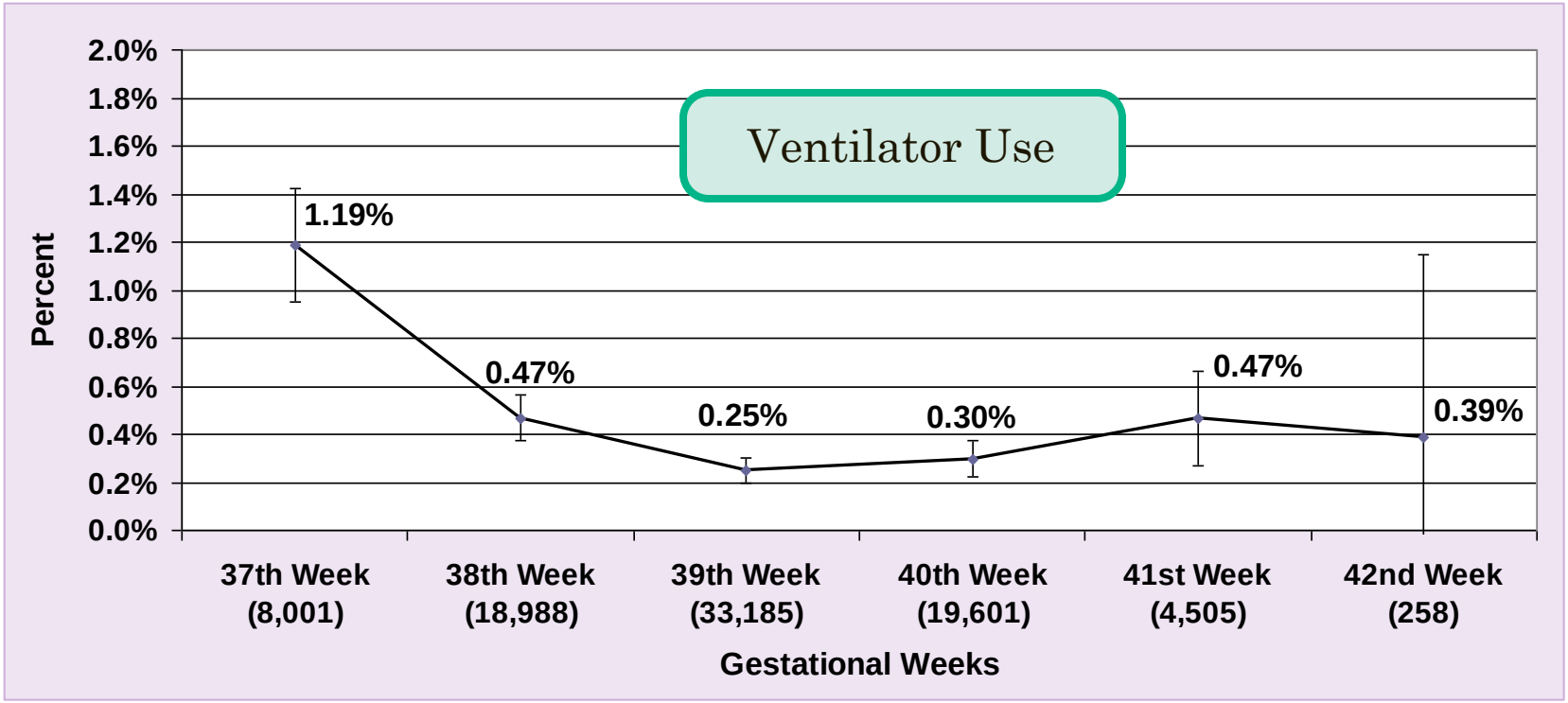
Oshiro et al. Obstet Gynecol 2009;113:804-811.

Ventilator Usage By Weeks Gestation Deliveries Without Complications, 2000-2003



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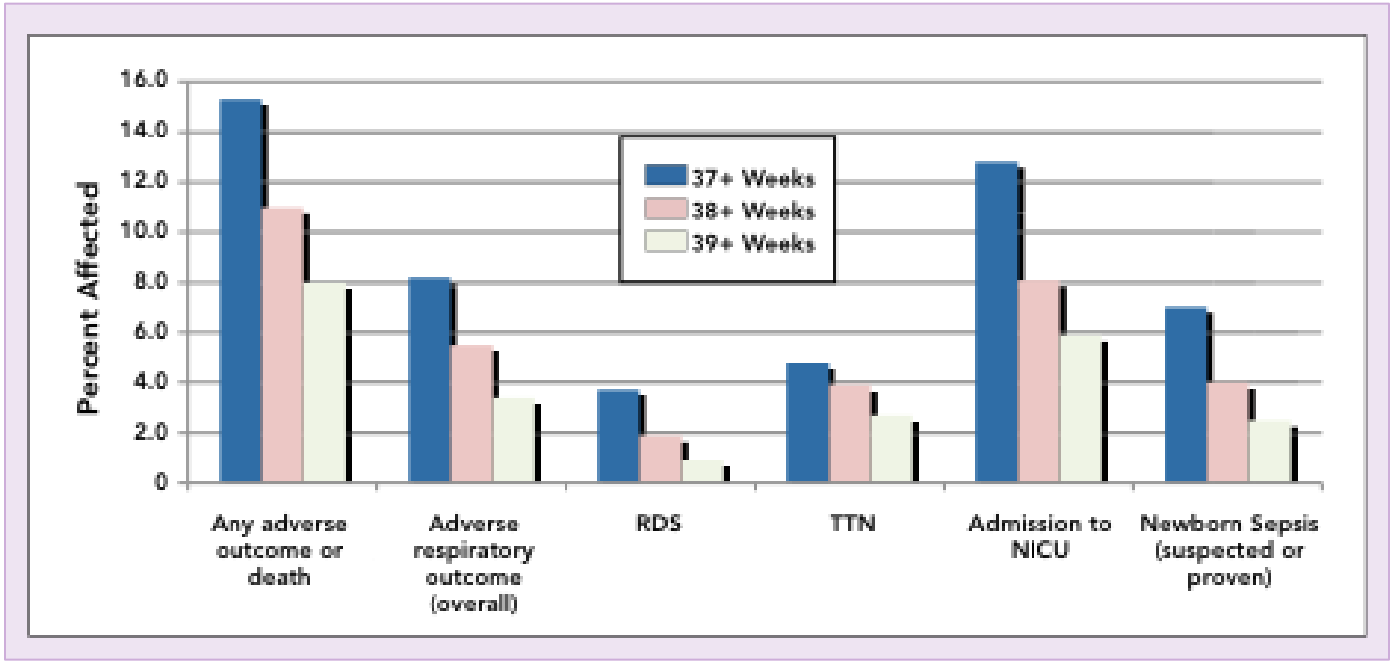
Oshiro et al. Obstet Gynecol 2009;113:804-811.

Adverse Neonatal Outcomes According to Completed Week of Gestation at Delivery: Absolute Risk



Adapted from Tita AT, et al. NEJM 2009;360:111

Timing of Fetal Brain Development

- Cortex volume increases by 50% between 34 and 40 weeks gestation. (Adams Chapman, 2008)

- Brain volume increases at rate of 15 mL/week between 29 and 41 weeks gestation.
- A 5-fold increase in myelinated white matter occurs between 35-41 wks gestation.
- Frontal lobes are the last to develop, therefore the most vulnerable.
  (Huttenloher, 1984; Yakavlev, Lecours, 1967; Schade, 1961; Volpe, 2001).

What are the risks to performing elective deliveries prior to 39 weeks?

- **Substantial** neonatal risks
  - Increased risk of respiratory morbidity
  - Increased risk of NICU admission

- Maternal risks also exist such as increased risk of cesarean delivery among nulliparous women especially those with an unfavorable cervix

What are the potential benefits to performing elective inductions prior to 39 weeks?

- Benefits are modest at best

- Induction prior to 39 weeks may be appropriate if there is increasing maternal or fetal risks associated with delaying delivery

"There are numerous maternal and fetal indications for deliveries prior to 39 weeks gestation."

Maternal/Fetal Indications for Induction of Labor

- Abruptio placentae
- Chorioamnionitis
- Fetal demise
- Gestational hypertension
- Preeclampsia/eclampsia
- PROM
- Fetal compromise (e.g. severe IUGR, isoimmunization, oligohydramnios)
- Maternal medical conditions (e.g. diabetes, chronic hypertension, renal disease, antiphospholipid syndrome)

ACOG Practice Bulletin 107, August 2009

Reasons for Performing Elective Repeat Cesarean Deliveries Prior to 39 Weeks

- Extensive uterine scar (e.g. prior classical incision, transfundal incision for myomectomy)
- Known placenta previa with accreta
- Other-
  - Patient convenience
  - Home a long distance from hospital
  - Physician convenience
  - Logistical issues, e.g. difficulty scheduling

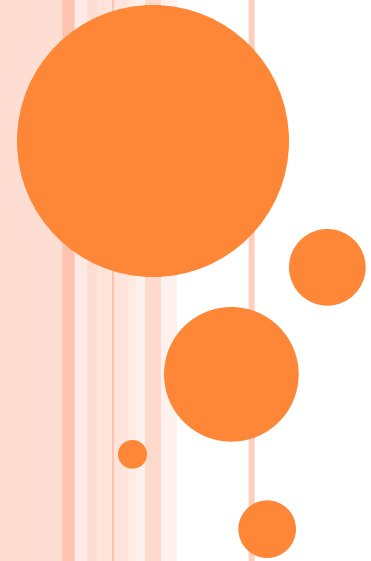
Summary: Reasons to Eliminate Non-medically Indicated (Elective) Deliveries Before 39 Weeks

- Reduction of neonatal complications
- No harm to mother if no medical or obstetrical indication for delivery
- Now a national quality measure:
  - National Quality Forum (NQF)
  - Leapfrog Group
  - The Joint Commission (TJC)

Why don't practitioners follow the "39 week rule"?

- Reasons already cited:
  - Patient convenience
  - Practitioner convenience
  - Monetary concerns
  - Logistical concerns
- Practitioners may not be aware of the problem in their own practice:
  - Don't take care of newborns so may not be aware of issue
  - Unless large numbers of women induced electively before 39 weeks, practitioner may not have awareness that neonatal morbidity is an issue

How do you get practitioners to change their clinical practice?



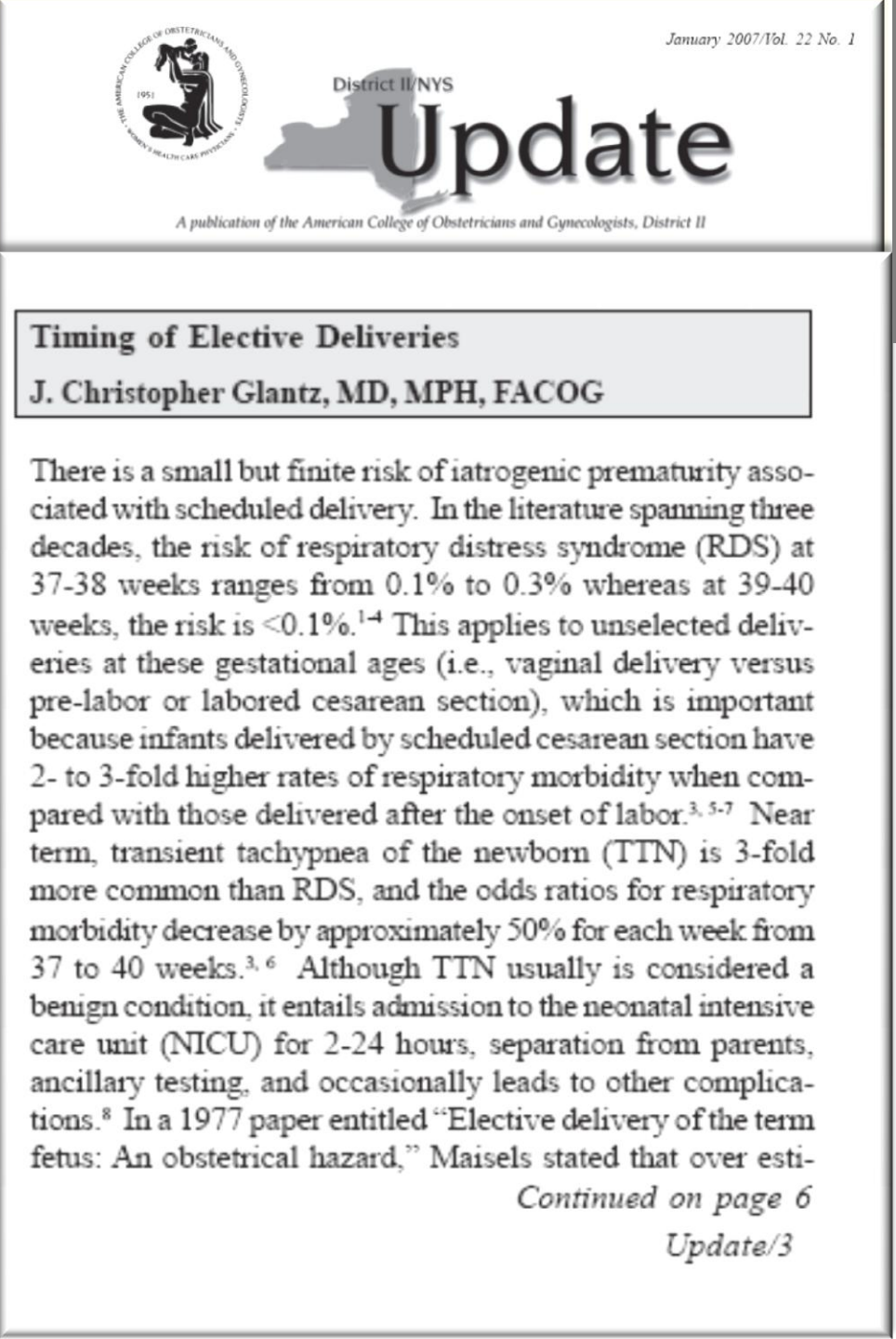
Role of ACOG in Reducing Inductions Before Term

- Several publications starting in 1978 have clearly stated the need to avoid premature deliveries unless there are substantial risks to mother or fetus with delay of delivery
- Further, 2 Practice Bulletins on labor induction and a Committee Opinion have strongly recommended confirmation of the gestational at 39 weeks of greater
- Other publications have also recommended a similar approach for elective repeat cesarean deliveries

Approaches to Gain Acceptance

- Conduct educational programs

Approaches to Gain Acceptance of the 39 Week Rule



January 2007/Vol. 22 No. 1

District II/NYS Update

A publication of the American College of Obstetricians and Gynecologists, District II

Timing of Elective Deliveries

J. Christopher Glantz, MD, MPH, FACOG

There is a small but finite risk of iatrogenic prematurity associated with scheduled delivery. In the literature spanning three decades, the risk of respiratory distress syndrome (RDS) at 37-38 weeks ranges from 0.1% to 0.3% whereas at 39-40 weeks, the risk is <0.1%.[1-4] This applies to unselected deliveries at these gestational ages (i.e., vaginal delivery versus pre-labor or labored cesarean section), which is important because infants delivered by scheduled cesarean section have 2- to 3-fold higher rates of respiratory morbidity when compared with those delivered after the onset of labor.[3, 5-7] Near term, transient tachypnea of the newborn (TTN) is 3-fold more common than RDS, and the odds ratios for respiratory morbidity decrease by approximately 50% for each week from 37 to 40 weeks.[3, 6] Although TTN usually is considered a benign condition, it entails admission to the neonatal intensive care unit (NICU) for 2-24 hours, separation from parents, ancillary testing, and occasionally leads to other complications.[8] In a 1977 paper entitled "Elective delivery of the term fetus: An obstetrical hazard," Maisels stated that over esti-

Continued on page 6

ACOG

District II Newsletter

January 2007

ACOG

THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

COLLABORATE

In the long history of humankind... those who learned to collaborate and improvise most effectively have prevailed

Charles Darwin

ACOG – Collaboration

- March of Dimes (MOD)
- National Institute of Child Health and Development (NICHD)
- Society for Maternal Fetal Medicine (SMFM)
- American Academy of Pediatrics (AAP)
- American Academy of Family Physicians (AAFP)
- American College of Nurse-Midwives (ACNM)
- Association of Women's Health, Obstetric

Approaches to Gain Acceptance of the "39 Week Rule"

- Devise system- or hospital-wide guidelines with a representative committee involving affected stakeholders, e.g. OBs, CNMs, and RNs
- Monitor compliance
- Eventually replace the guideline with an unequivocal policy
- Devise "hard stops"' or penalties to enforce policy

Examples of Successful Programs to Reduce Non-medically Indicated (Elective) Deliveries Before 39 Weeks of Gestation

- Magee-Women's Hospital (Pittsburgh)
- Intermountain Healthcare (Utah)
- Ohio State Department of Health
- HCA

Magee-Womens Hospital Approach

- University of Pittsburg Medical Center with 9300 deliveries and an induction rate of 28% in 2003
- Examined results of process improvement from 2004-2007 to reduce inductions performed before 39 weeks as well as other morbidity such as cesarean deliveries for nulliparas undergoing induction
- Needed to use 2 strategies to get desired results

FischJM et al. *Obstet Gynecol* 2009;113:797-803

Magee Women's Hospital Experience with Guidelines

	Baseline 3mos 2004	**Voluntary** 3mos 2005	**Enforced** 14mos 2006-7
Deliveries	2,139	2,260	10,895
Elective Inductions <39wks (N) **Elective Inductions <39wks (rate)**	**11.8%**	**10.0%**	**4.3%** (p<0.001)
Elective Nullip Inductions =>C/S (rate)	**35.7%**	**15.2%**	**13.8%** (p<0.01)
Total Induction Rate	**24.9%**	**20.1%**	**16.6%**

Fisch et al. Obstet Gynecol 2009;113:797

Effects of Induction Strategies on Key Rates

	2004	2005	2006
Strategy 1 → Strategy 2			
Elective inductions < 39 weeks (%)	11.8	10.0	4.3
Cesarean Deliveries, Nulliparous Women Undergoing elective induction	34.5	15.2	13.8

FischJM et al. *Obstet Gynecol* 2009;113:797-803

Intermountain Healthcare's Experience

- Intermountain Healthcare is a vertically integrated healthcare system that operates 21 hospitals in Utah and southeast Idaho and delivers approximately 30,000 babies annually.
- Computerized L&D system.
- MFMs hired by system, but OBs are independent.
- January 2001: 9 urban facilities participated in a process improvement program for elective deliveries.
- 28% of elective deliveries were occurring before 39 completed weeks of gestation.

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Oshiro, B. et al. Obstet Gynecol 2009;113:804-811.

Intermountain Health Care Approach

- Process improvement project started in 2001 in 9 urban hospital facilities in Utah and Idaho
- Educational process for obstetricians, CNMs, and and nurses
- Monitored compliance with electronic medical record system
- Also provided brochures to patients describing the policy and its benefits

OshiroBT et al. *Obstet Gynecol* 2009; 113:804-811

Common Themes Noted in Intermountain Healthcare's Experience

- Education provided to obstetricians regarding ACOG guidelines, best practice.
- Little change until physicians were held accountable, nurses were empowered, and guidelines were enforced.
- Medical leadership important.

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% Non-medically Indicated Deliveries <39 Weeks, January 1999 – December 2005

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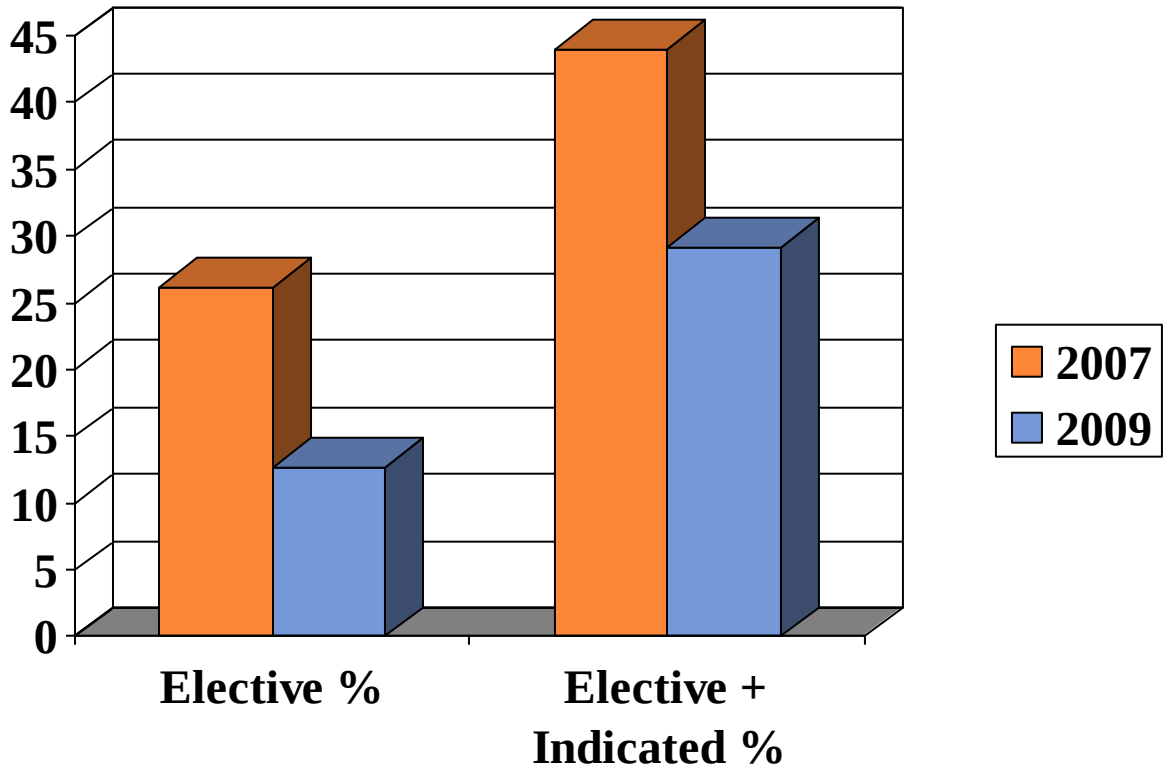
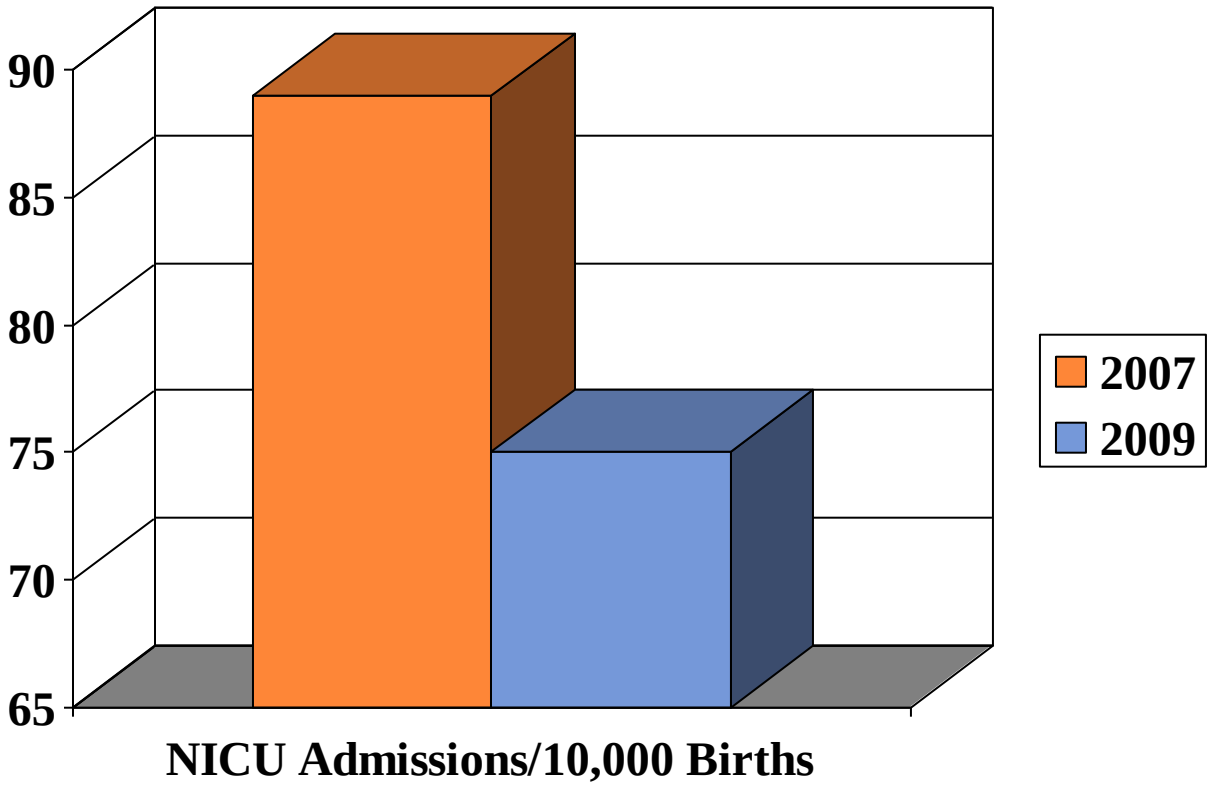
ELECTIVE TERM DELIVERY PART II (CLARK ET AL AJOG 2010)

- A repeat of the previous study after 2 years of educational efforts/policy changes
- 2007 vs. 2009
- Same facilities/same months of the year
- We do not employ our obstetricians
- We do not have a captive insurance group
- Change possible only through education/persuasion/leadership

TERM DELIVERIES
HCA PILOT FACILITIES



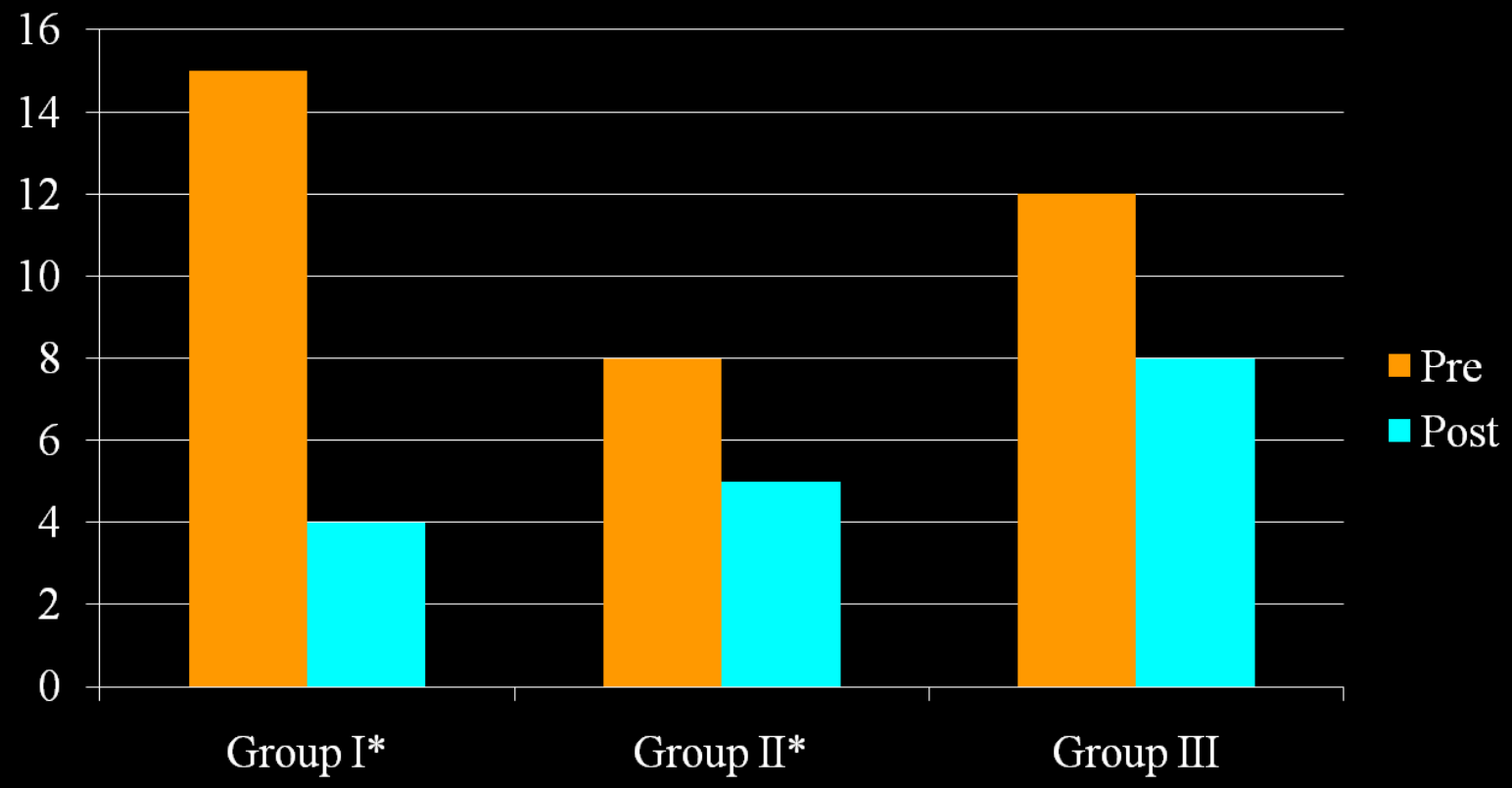
TERM NICU ADMISSIONS HCA PILOT FACILITIES



OPTIONS

- Not allowed by policy with hospital staff as enforcers
- Not allowed by policy but M.D. may do it if they want – all exceptions go to Peer Review
- Allowed at M.D. discretion but discouraged by intensive education

Reduction in Elective Delivery



Alleviating Obstetricians' Fears About Delaying Delivery

- Obstetricians in several of these studies voiced concerns regarding a potential increase in perinatal mortality and maternal morbidity.

Wouldn't Keeping Women Pregnant for Longer Increase Their Risk of Adverse Outcomes?

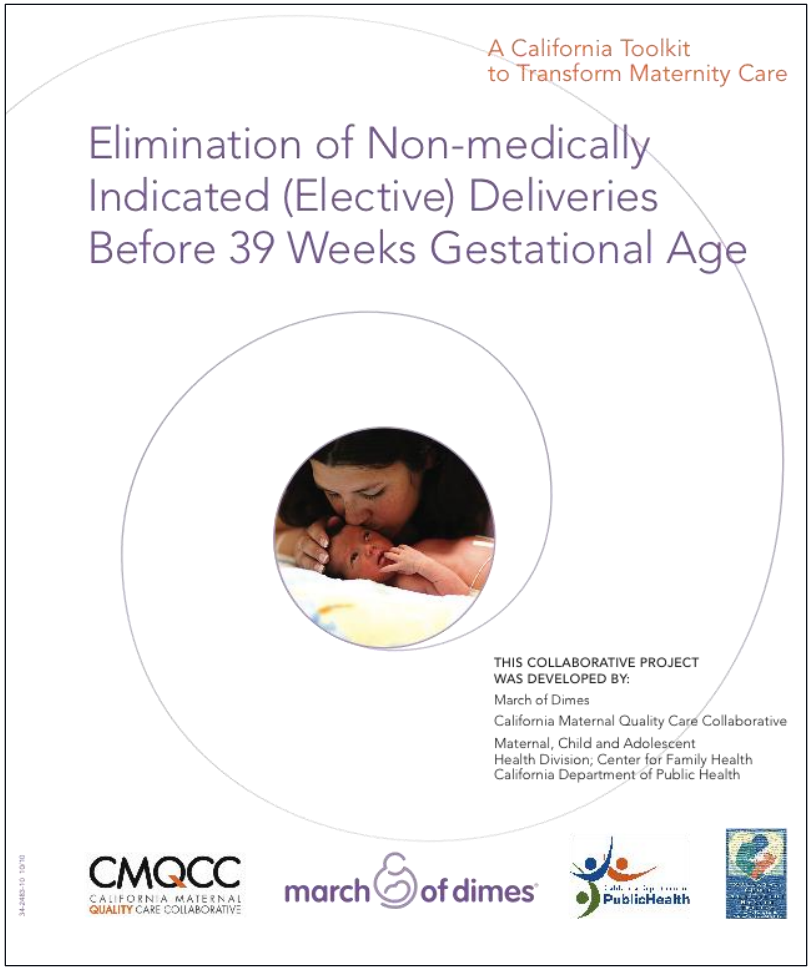
- The experience in Ohio and Utah has shown that morbidity remained the same for macrosomia, preeclampsia, and maternal infections.
- Decreases were seen in stillbirth, low apgar scores, cesarean section for fetal distress, meconium aspiration and postpartum anemia.

Stillbirths Before and After Implementation of Guidelines at Intermountain Healthcare

1999-2000				July 2001 to June 2006				
Weeks of Gestation	Stillbirths	Deliveries	%	Stillbirths	Deliveries	%	Odds Ratio	95% CI
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	122,718	0.07	0.466	0.33-0.65

Oshiro, B. et al. Obstet Gynecol 2009;113:804-811.

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



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Loma Linda University School of Medicine

Catholic Healthcare West

California Perinatal Quality Care Collaborative (CPQCC)

March of Dimes

Editorials:

No Time for Complacency: Labor Inductions, Cesarean Deliveries, and the Definition

Obstetrics & Gynecology:
July 2010 - Volume 116 - Issue 1 - pp 4-6
doi: 10.1097/AOG.0b013e3181e598d4

No Time for Complacency

Institutional/Regional/ State

- 1. Strong leadership from practitioners and nursing staff committed to improving the quality of care
- 2. Involving all relevant stakeholders (eg, faculty, private practitioners, nursing, hospital administrators) in development and implementation of reforms
- 3. Overcoming initial resistance and gaining buy-in through education of physicians, nursing staff, and patients on the excess risk associated with elective early term delivery

No Time for Complacency Institutional/Regional/ State

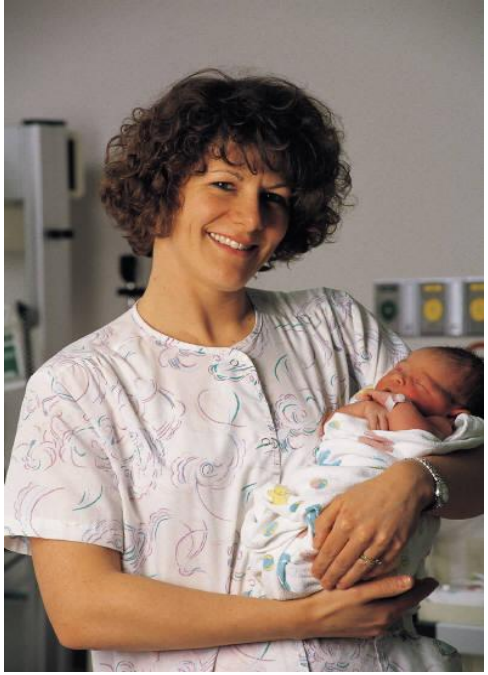
- 4. Framing program goals not as an effort to restrict practice but to improve quality, meet best-practice standards, ensure optimal outcomes, and promote safety
- 5. Providing frequent, detailed feedback on process measures and outcomes

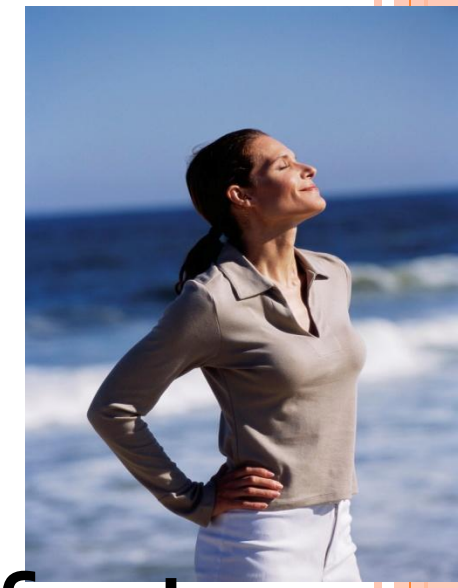
Conclusions

- Avoiding elective deliveries before 39 weeks has sound clinical data to support this goal
- Changing physician behavior is challenging at times; occasionally resorting to mandates and firm policies is required

How do you get practitioners to change their clinical practice?

- Ultimately one needs to make process a policy with “hard stops”, i.e. strict enforcement
- Or if necessary you may need to enter a penalty phase.





Healthy Women and Infants: Priceless