

“39 WEEKS AND OUT”: BEST PRACTICE OR BAD PRECEDENT?

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Disclosures



- Financial: None
- Non-Financial:
 - ▣ 26 years practice in MFM (Maternal-Fetal Midwifery)
 - ▣ Advocate for minimizing unnecessary intervention in absence of proven significant benefit

“Debate” at ACOG Annual Meeting 2016

“Why Not Induce Everybody At 39 Weeks?” (as opposed to waiting for spontaneous labor)



- Drs. Lockwood and Norwitz both agreed that, after “much reading,” “*It’s overwhelmingly evident that elective induction is the logical strategy*”



- Cited epidemiologic studies showing similar induction-related CS risk using cumulative risk measures
- To prevent maternal & neonatal morbidity, and stillbirths that would have occurred at 40-42 wks
- “Monte Carlo” simulation models favored 39 wk induction

Debater's Statements

- Dr. Norwitz

- *“Nature is a terrible obstetrician.”*
- *“My position is 39 weeks and out!”*

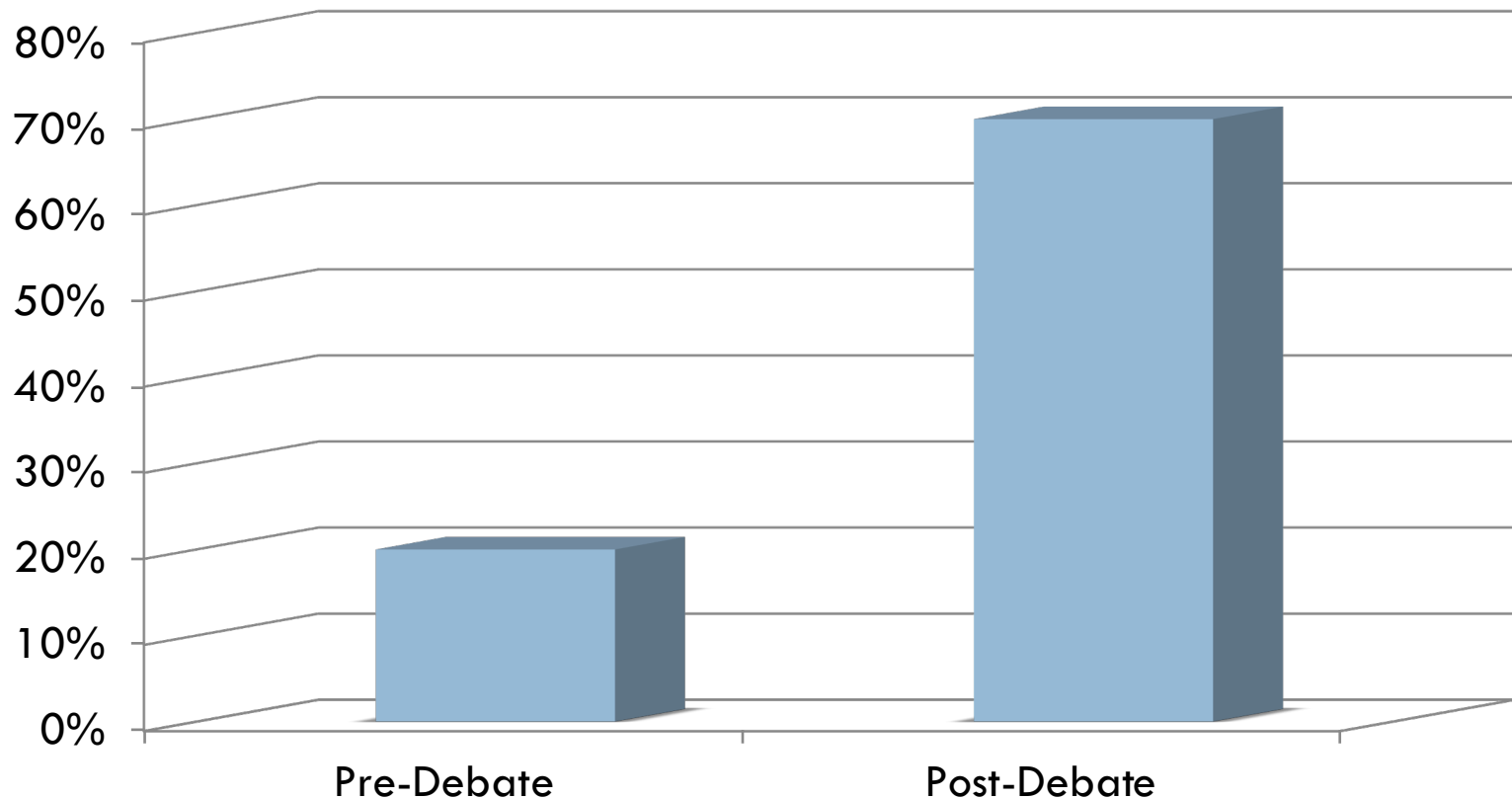
- Dr. Lockwood

- *“Current literature is equivocal and not easily applied to the general OB population...extensive research is needed before (routine 39 wk induction) can be safely and widely adopted.”*

Washington Post, June 27, 2016
Contemp OBGYN, May 17, 2016

What Did The ACOG Audience Think?

Agree With Routine 39-week Induction



What Did The Public Think?



□ Childbirth advocate groups were appalled

- *“Reinforces a centuries’ old, pre-feminist American obstetric view that birth is pathological”* (C. Pascucci; Improving Birth)
- *“Concerning and rash” to draw “broad conclusions” from “misleading, flawed research”* (R. Dekker; Evidence-Based Birth)



Washington Post, June 27, 2016

80 of 80 Washington Post readers' comments opposed routine 39wk IOL

- *“It's not surprising that it was a panel of men who would make such an anti-woman proposition.”*
- *“A critical voice is missing from this debate: the pregnant woman.”*
- *“While there are many terrifying components of this article, perhaps the most disconcerting is how swiftly the audience changed its majority opinion.”*
- *“Please don't print any more ‘manswers’.”*

Dr. Norwitz Adds Fuel to the Fire

“I think a lot of this gets very emotional”



Washington Post, June 27, 2016

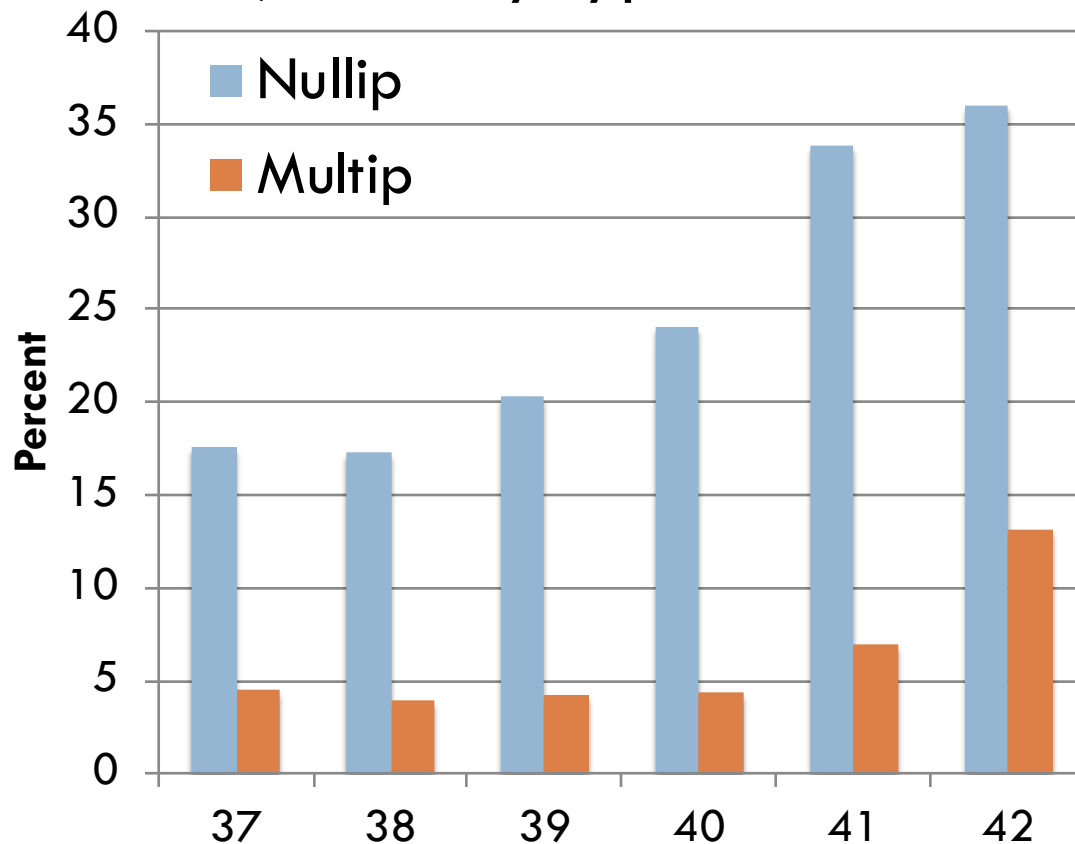
How did we get here?



- Induction: How to define success
- The stillbirth question
- Retrospective versus prospective data
 - ▣ The ARRIVE trial
- Does one size fit all?

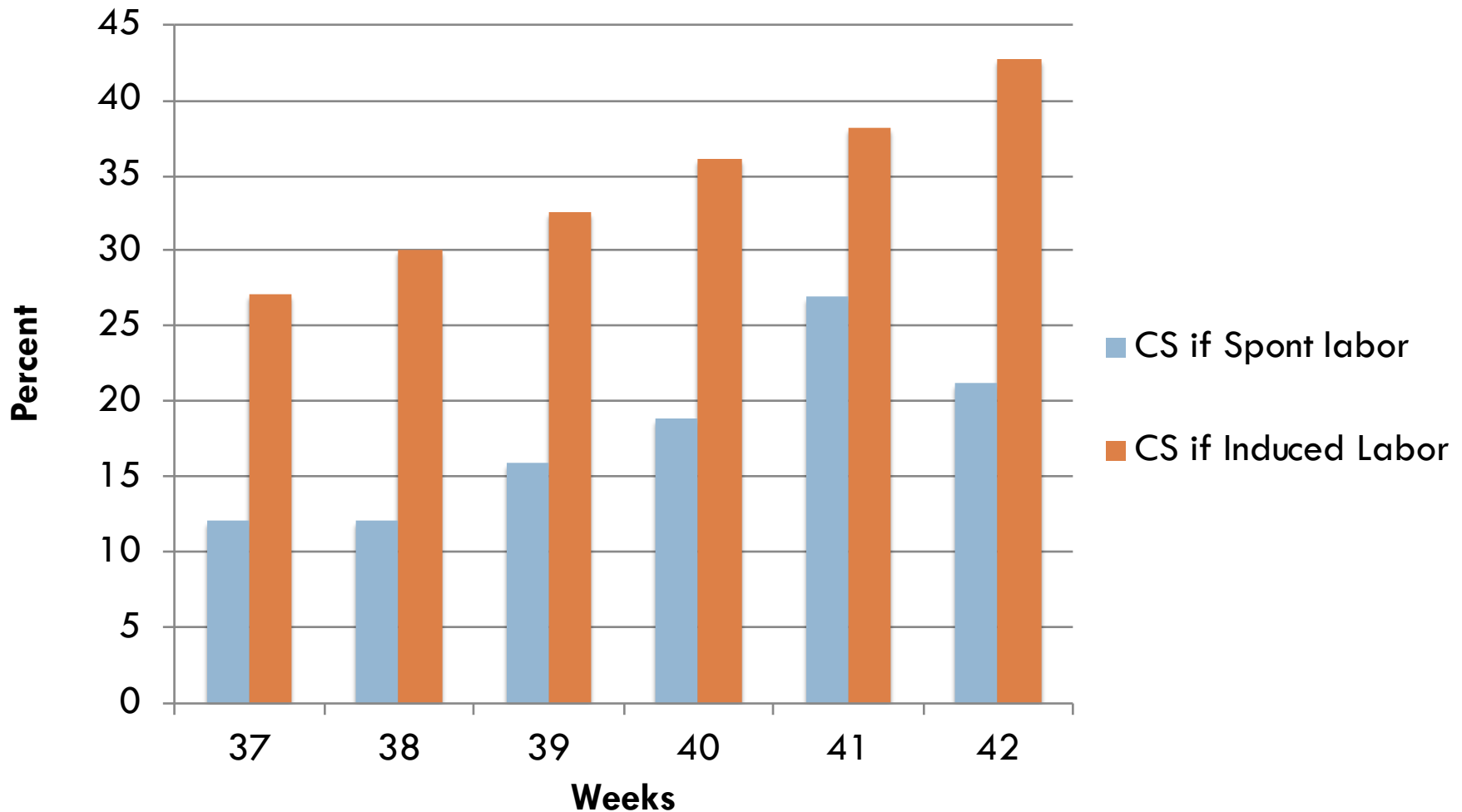
Parity and Labor

Cesarean section in singleton, vertex,
term, with any type of labor onset

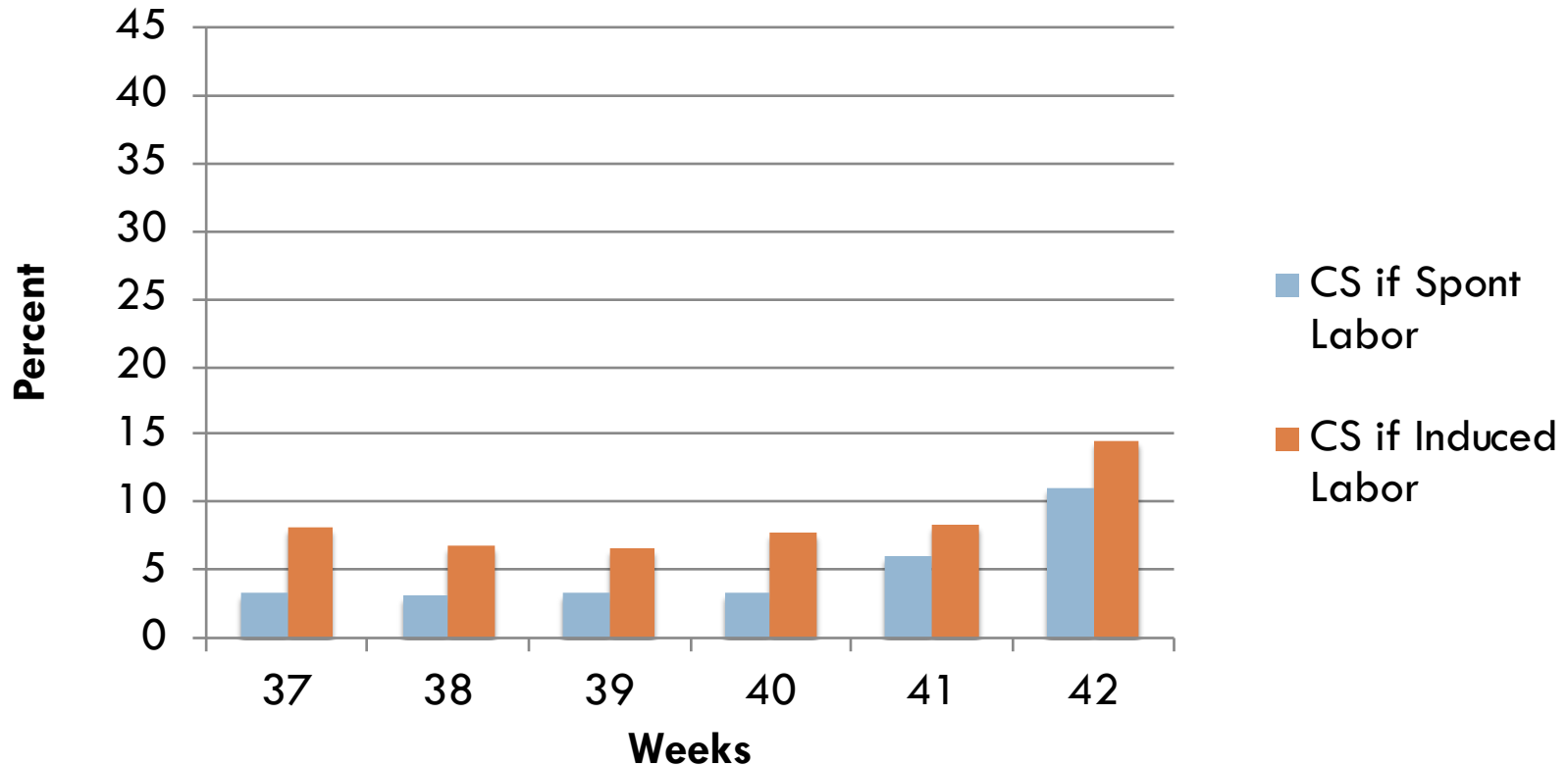


1. Higher risk of CS if nulliparous
2. Higher risk of CS with higher GA

NULLIPARAS: Spont vs Induced Labor



MULTIPARAS: Spont vs Induced Labor



Same pattern as nullips but much lower absolute risks

If Compared by Week

- By week, induction of labor roughly doubles the likelihood of cesarean compared with spontaneous onset of labor
 - Odds ratio 1.8-1.9 for adjusted data in other studies

BUT PERHAPS THIS ISN'T THE
RIGHT COMPARISON

Induction vs Expectant Management

- Can choose to induce labor but cannot choose to spontaneously labor during a given week.
- Options:
 - ▣ 1. Outcomes after induction vs spont labor at a given wk
 - Applies only if spont labor begins that week
 - ▣ 2. Induction vs cumulative risk of outcomes over ensuing weeks (those continuing at risk = expectant management)
 - Aggregates population outcomes and spreads risk over subsequent weeks
 - Including when CS risk is higher



Caughey 2006



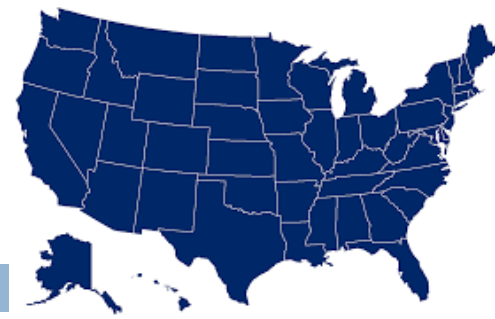
- Retrospective analysis of 19,000 deliveries over 15 years at UCSF in California
 - ▣ Compared with elective induction at any week, **higher** cumulative risk of CS with expt man in nulliparas
 - Adjusted ORs for CS 1.3 to 1.9 in expectant group
 - ▣ Not significant in multiparas
- For unclear reasons, Caughey defined the expt group as starting the week after the induction group
 - ▣ Biases toward induction

Glantz 2010



- Retrospective analysis of 38,000 deliveries over 4 years in the Finger Lakes Region (FLR)
- Defined the expectant group as starting the week of the induction group
- Results: compared with elective induction, **lower** cumulative risk of CS with expectant management
 - Regardless of parity
 - Adjusted OR ≈ 0.8 for nullips, ≈ 0.7 for multips

Cheng 2012



- Retrospective: 440,000 low-risk US nullips in 2005
 - ▣ Expt group started the week after the induction group
 - ▣ CS odds ratio 0.9 with 39 wk induction
 - Actual CS freq at 39 wks: 26.2% (ind) vs 28.4% (expt)
 - NNT = 45 Inductions to prevent one CS
- Reported improved neonatal outcomes with induction
 - ▣ Very low freq of outcomes → NNTs ranged from 208 to 909

Stock 2012



- 1.2 million Scottish births 1981-2007
 - ▣ Expt group started the week after the induction group
 - ▣ No difference in CS
 - ▣ NICU admissions 2% higher in induction group
 - ▣ Perinatal mortality higher in expectant group
 - 0.06% (ind) vs 0.19% (expt) at 39 wks; adj OR 0.26 (NNT = 770)

Other Retrospective Studies

- Other studies using various definitions: no difference or lower rates of CS and mat/neo morbidity
 - Morbidity uncommon in all groups, thus very high NNTs
- Cochrane 2012 meta-analysis of 22 RCTs: Small benefit to induction
 - OR = 0.9 for CS in IOL vs expt (mostly when postdates)
 - Perinatal deaths “were rare with either policy”
- Osmundson and Gibson reported increased time & resource use with induction

Osmundson, Obstet Gynecol, 2010, 2011
Cochrane Systematic Review, 2012
Darney, Obstet Gynecol, 2013
Gibson, AJOG, 2014; Bailit, AJOG, 2015

Recent RCTs in Nulliparas

- Nielsen (2005): 1 1 6 with favorable cx
 - ▣ CS 6.9% (IOL) vs 7.3% (expt)—very low; not sig
- Miller (2015): 1 6 2 with unfavorable cx
 - ▣ CS 31% (IOL) vs 18% (expt); $P=0.09$
 - Underpowered, but authors conclude induction “did not double the CS rate”
 - ▣ No difference in maternal or neonatal outcomes
- Walker (2016): 619 AMA women
 - ▣ No differences in CS or mat/neo outcomes

Nielsen, J Mat-Fetal Neonat Med, 2005
Miller, Obstet Gynecol, 2015
Walker, NEJM, 2016

Grobman et al: “ARRIVE” RCT

- Abstract presented at Feb 2018 SMFM meeting
 - ▣ 6106 low-risk nullips at 41 MFMU hospitals randomized to 39wk IOL vs Expt Man up to 42 2/7 wks
- 39wk IOL had lower risk of
 - ▣ CS: 18.6% vs 22.2%
 - ▣ HTN: 9.1% vs 14.1%
 - ▣ Resp morb: 3.0% vs 4.2%
 - ▣ No other significant differences in outcomes
 - Perinatal death, low Apgar, meconium, infection, lac, PPH

Grobman WA, et al. A randomized trial of elective induction of labor at 39 weeks compared with expectant management of low-risk nulliparous women. Am J Obstet Gynecol 2018; 218:S601.

Generalizability?

- ARRIVE's 18.6% IOL CS rate in low-risk nullips is much lower than expected
 - ▣ Of 12 US studies, the mean IOL CS rate was 28%*
 - ▣ Mean IOL CS rate in Calif is 32%†
 - ▣ For FLR nullips was 33%
 - *Are MFMU hospitals representative?*
 - ▣ “Hawthorne Effect”: are patients managed differently when known to be in a study?
 - *“It has to be a real induction of labor — not one that ends at five o'clock.” C. Lockwood*
- A mean CS rate may not apply to a given hospital

*Caughey, Glantz, Leone, Cheng, Darney, Miller, Wolfe, Gibson, Osmundson, Bailit, Neilson, Walker

†Main, California Maternal Quality Care Collaborative, 2018

Have We ARRIVED at Consensus?

- After many conflicting retrospective studies and small RCTs, ARRIVE adds legitimacy to those who choose 39wk IOL
 - ▣ Number of 39wk IOLs to prevent 1 CS from expectant management (NNT) $\rightarrow 100/3.4 = 29$
 - ▣ No differences in most perinatal/maternal outcomes
- "I think it will change practice in a good way, but it's not a one-size-fits-all, so there is not a standard recommendation. It doesn't mean everyone should undergo labor at 39 weeks."
(R. Silver, ARRIVE co-author)

Stillbirth



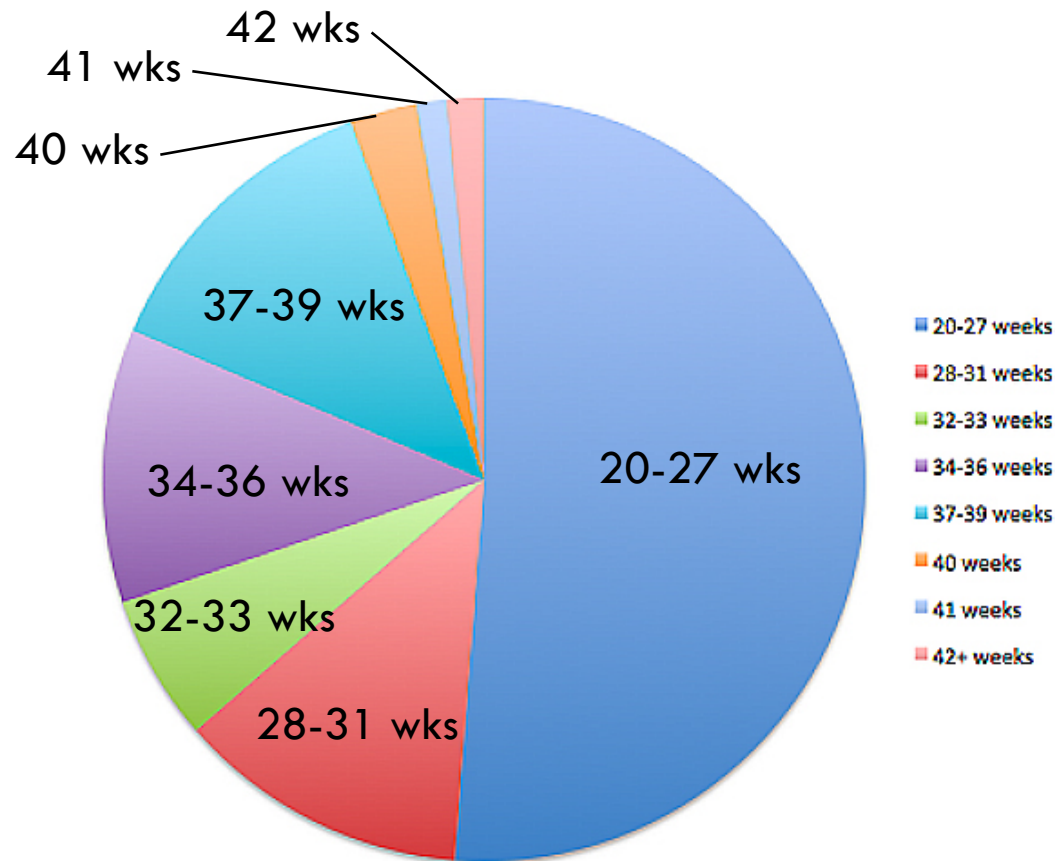
“Stillbirth is a hugely underappreciated problem. There are anywhere between 25,000 to 30,000 stillbirths a year in the United States.”

E. Norwitz

Washington Post, June 27, 2016
RGH Grand Rounds, 2017

Fetal Mortality

23,500 fetal deaths (stillbirths) reported in 2013



Perinatal Mortality

- Cumulative risk is the accepted standard
 - ▣ Prospective mortality ratio at/continuing past a given GA

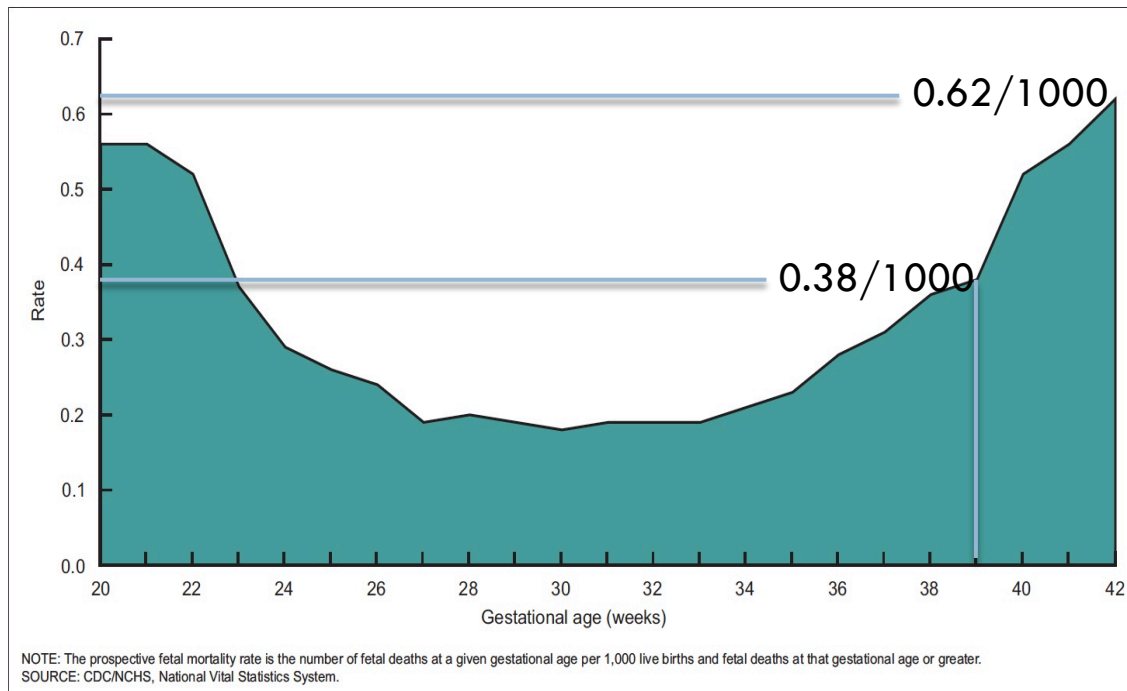


Figure 8. Prospective fetal mortality rate, by single weeks of gestation: United States, 2013

Sounds worrisome

RR 39→42wks = 1.6

Excess Risk 39→42wks
= 0.24 deaths per
1000 deliveries
= 1 per 4166 del

Does not sound
very worrisome

Perinatal Death and IOL/Expt Man

- Darney (362,000 Calif del in 2006)
 - ▣ Non-significant decrease in perinatal death with induction
- Gibson (131,000 del, US sample, 2002-2008)
 - ▣ No difference in perinatal death rates
- Rosenstein (3.8 million Calif del 1997 to 2006)
 - ▣ Calculated higher cumulative stillbirth rate with expt man
- Grobman (ARRIVE: 6100 US RCT, 2018)
 - ▣ No difference in perinatal mortality
- *No evidence of substantial benefit re stillbirth*

“It’s not about feelings—it’s about data. This is evidence-based obstetrics.” (unnamed obstetrician)

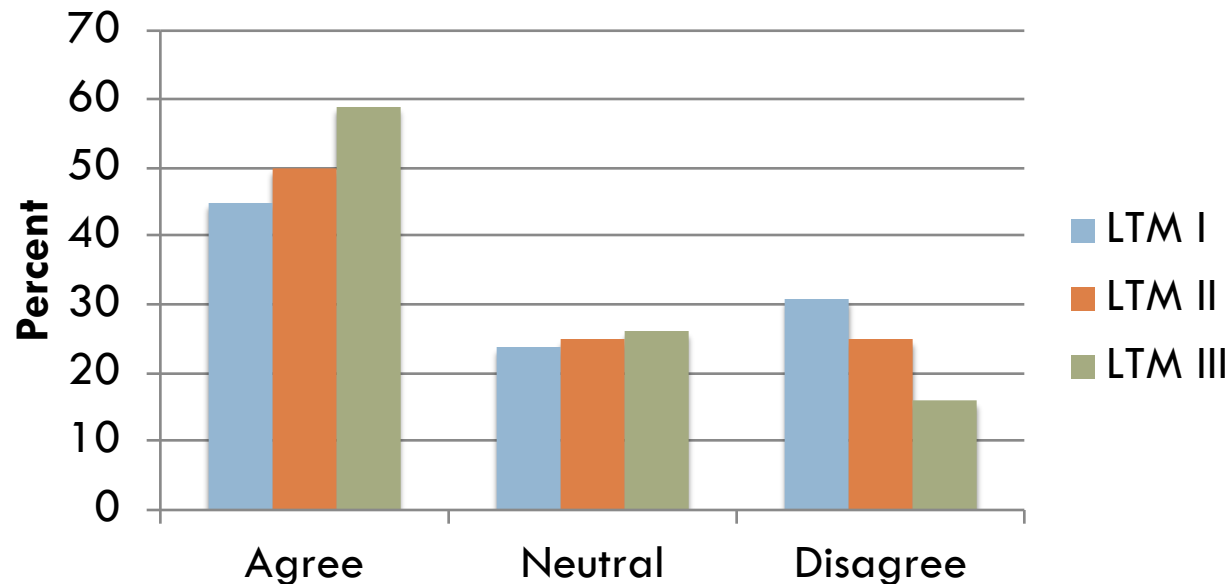


“The philosophy of “evidence-based medicine” has swept U.S. medical practice. The mother’s body disappears from analytical view; images of fetal safety are marketing tools; technology magically wards off the unpredictability and danger of birth.”

Listening To Mothers (LTM I, II, &III)

- Childbirth Connection, Boston University School of Public Health, and Harris Interactive
 - ▣ Surveys of 1500-2400 women published in 2002, 2006, 2013

“Giving birth is a natural process that should not be interfered with unless medically necessary”



Populations versus Individuals

- Variation: One size seldom fits all
 - ▣ Patient-doctor-hospital-region-state variation
 - ▣ Mathematical models treat everyone as if average
- Counseling
 - ▣ Directive vs non-directive
 - ▣ Statistical vs clinical significance



Playing the Odds



- Patients view “risk” in many different ways
 - ▣ Percents, fractions, absolute/excess/attributable risk, RR, OR, NNT, comparative, categories, analogies, etc.
 - ▣ Assign different values to different outcomes
 - Values may change over time
 - ▣ Different utilities to “gamble”



Do You Feel Lucky?

- Let's assume two things:
 1. *In a given week*, CS is at least 50% more likely after IOL than after spontaneous labor
 2. Chance of spont labor at 39wks \approx 40wks \approx 41wks \approx 33%
- If she chooses 39wk IOL but would have spontaneously labored that week \rightarrow increases her CS risk by $\geq 50\%$
 - ▣ Thus, by declining IOL, she has a 33% chance of lowering her CS risk, but a 67% chance of reaching 40 wks

Do You Feel Lucky?



- At 40 wks: she may decide to be induced or to wait
 - ▣ Still a 33% chance of labor with lower CS risk than IOL
 - ▣ Expectant CS risk now converging on 39wk IOL CS risk
- If she reaches 41 wks, she *still* has higher CS risk with IOL during that week, but in retrospect, also a higher CS risk than had she been induced to 39wks
 - ▣ Need crystal ball or time machine
- *Bottom Line: Women can make choices besides “All or None”*

The Effect of Routine 39-Week Induction: Current Status

- Stats for 12,200 term del in FLR in 2015
 - ▣ TOTAL
 - 28% Induced
 - 23% Augmented
 - 31% Labor without oxytocin
 - 18% Scheduled CS
 - ▣ 27% had SVD with no oxytocin (i.e., approx 1 in 4 had a “normal” L&D)
 - Varied by parity and risk factors

Projected Impact of Routine 39-Week Induction

- FLR 2015 data (13,227 total mothers at any GA)
 - ▣ Observed induction rate = 28%
- If all mothers not scheduled for 39 wk CS were induced at 39wks:
 - ▣ Regional induction rate would increase to 68%
 - Total intervention rate (induc + sched CS) = 87%
 - Cost, LOS, and strain on L&D resources = ?

Conclusions



- Compared with expectant management, 39wk IOL is associated with similar outcomes
- Be wary of applying population data to individuals
- Routine 39 week delivery would markedly increase intervention and medicalization of childbirth
- Women's preferences are important!
- *It's far from overwhelmingly evident that elective induction is the logical strategy.*

Washington Post Reader's Response to Dr. Norwitz

□ *“Nature may be a lousy obstetrician,
but she’s a great midwife!”*

J Corbett, 6/28/16



“Oh, great, more innovative variations on things.”