Induction of Labor 2020

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Disclosure Statement

- None

ARRIVE TRIAL

Can we adopt and get the same results?

The NEW ENGLAND JOURNAL of MEDICINE

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Labor Induction versus Expectant Management in Low-Risk Nulliparous Women

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ABSTRACT

BACKGROUND

The perinatal and maternal consequences of induction of labor at 39 weeks among low-risk nulliparous women are uncertain.

METHODS

In this multicenter trial, we randomly assigned low-risk nulliparous women who were at 38 weeks 0 days to 38 weeks 6 days of gestation to labor induction at 39 weeks 0 days to 39 weeks 4 days or to expectant management. The primary outcome was a composite of perinatal death or severe neonatal complications; the principal secondary outcome was cesarean delivery.

RESULTS

A total of 3062 women were assigned to labor induction, and 3044 were assigned to expectant management. The primary outcome occurred in 4.3% of neonates in the induction group and in 5.4% in the expectant-management group (relative risk, 0.80; 95% confidence interval [CI], 0.64 to 1.00). The frequency of cesarean delivery was significantly lower in the induction group than in the expectant-management group (18.6% vs. 22.2%; relative risk, 0.84; 95% CI, 0.76 to 0.93).

CONCLUSIONS

Induction of labor at 39 weeks in low-risk nulliparous women did not result in a significantly lower frequency of a composite adverse perinatal outcome, but it did result in a significantly lower frequency of cesarean delivery. (Funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development; ARRIVE ClinicalTrials.gov number, NCT01990612.)

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Grobman at the Department of Obstetrics and Gynecology, Northwestern University, 250 E. Superior St., Suite 05-2175, Chicago, IL 60611, or at w-grobman@northwestern.edu.

*A list of other members of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal–Fetal Medicine Units Network is provided in the Supplementary Appendix, available at NEJM.org.

N Engl J Med 2018;379:513-23.
DOI: 10.1056/NEJMoa1800566

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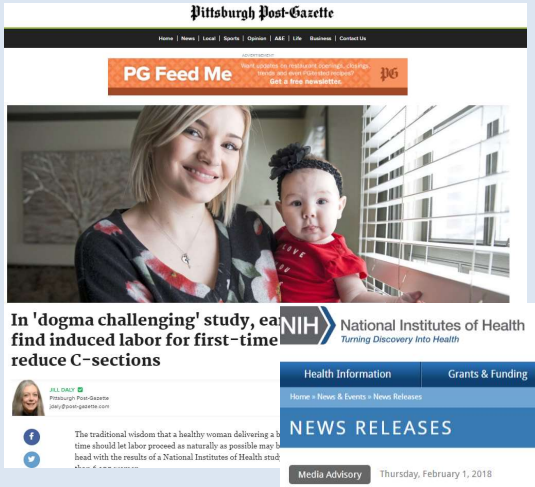
Immediate News:



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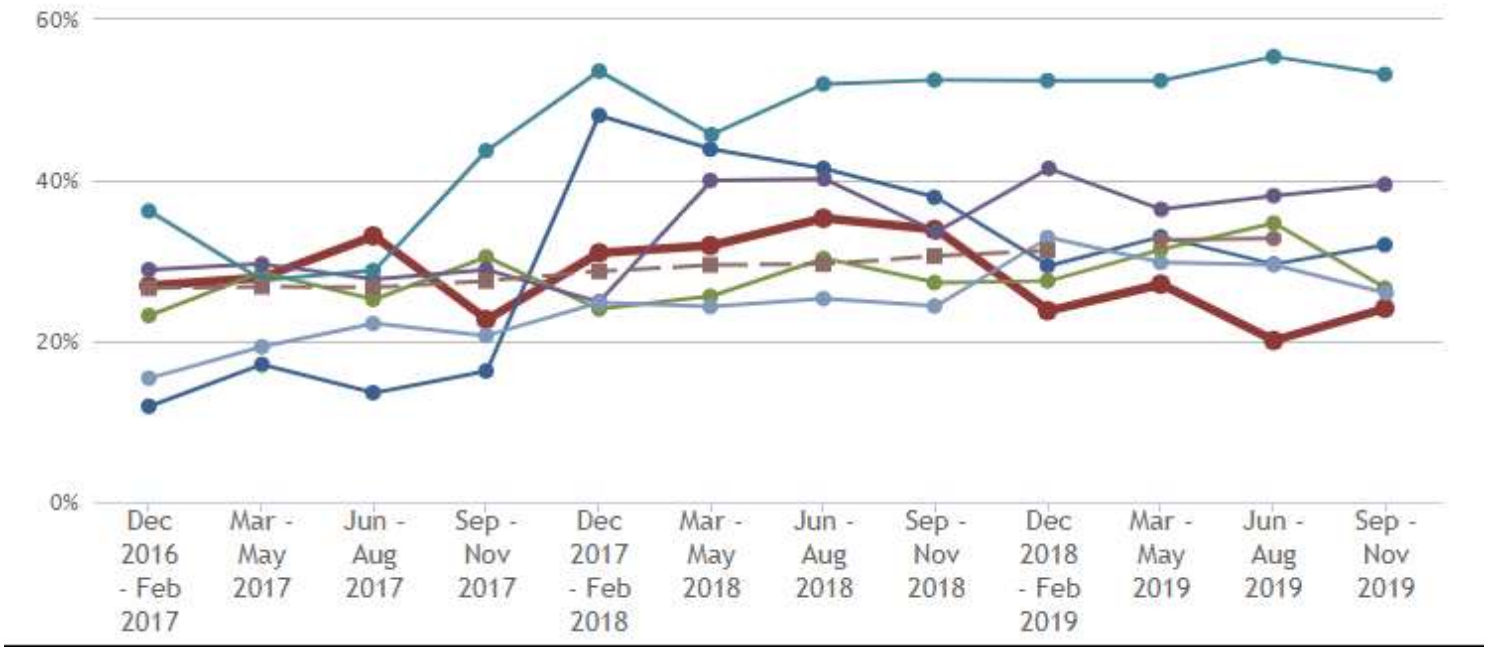
Mixed Response: Some Increased Induction/Some Not



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ACOG/SMFM Practice Advisory, August 15,2018

…Based on the findings demonstrated in this trial, it is reasonable for obstetricians and health-care facilities to offer elective induction of labor to low-risk nulliparous women at 39 weeks gestation. However, consideration for enactment of this elective induction of labor intervention should not only take into account the trial findings, but that this recommendation may be conditional upon the values and preferences of the pregnant woman, the resources available (including personnel), and the setting in which the intervention will be implemented. A collaborative discussion with shared-decision making should take place with the pregnant woman. Additionally, as induction of labor involves coordination between the health care provider and the infrastructure in which induction and delivery will occur, it is critical that personnel and facilities coordinate polices related to the offering of elective induction of labor.

What were the results and how good was the science of the ARRIVE Trial?

ARRIVE TRIAL SUMMARY

- The ARRIVE Trial was released on February 1st at the Society for Maternal Fetal Medicine Annual Meeting and published in NEJM August 2018 .
- The ARRIVE trial was a randomized controlled trial **comparing labor induction at 39 weeks to expectant management to 42 2/7 weeks** among low risk nulliparous women.
- The **primary outcome was a composite of perinatal outcomes** and the **secondary outcome was cesarean birth**.
- The trial included 3,000 women in each arm and was performed in University hospitals and their affiliated hospitals belonging to the NICHD Maternal Fetal Medicine Network

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.

Grobman WA et al. Labor Induction versus Expectant Management in Low-Risk Nulliparous Women N Engl J Med 2018;379:513-23.

Main Results

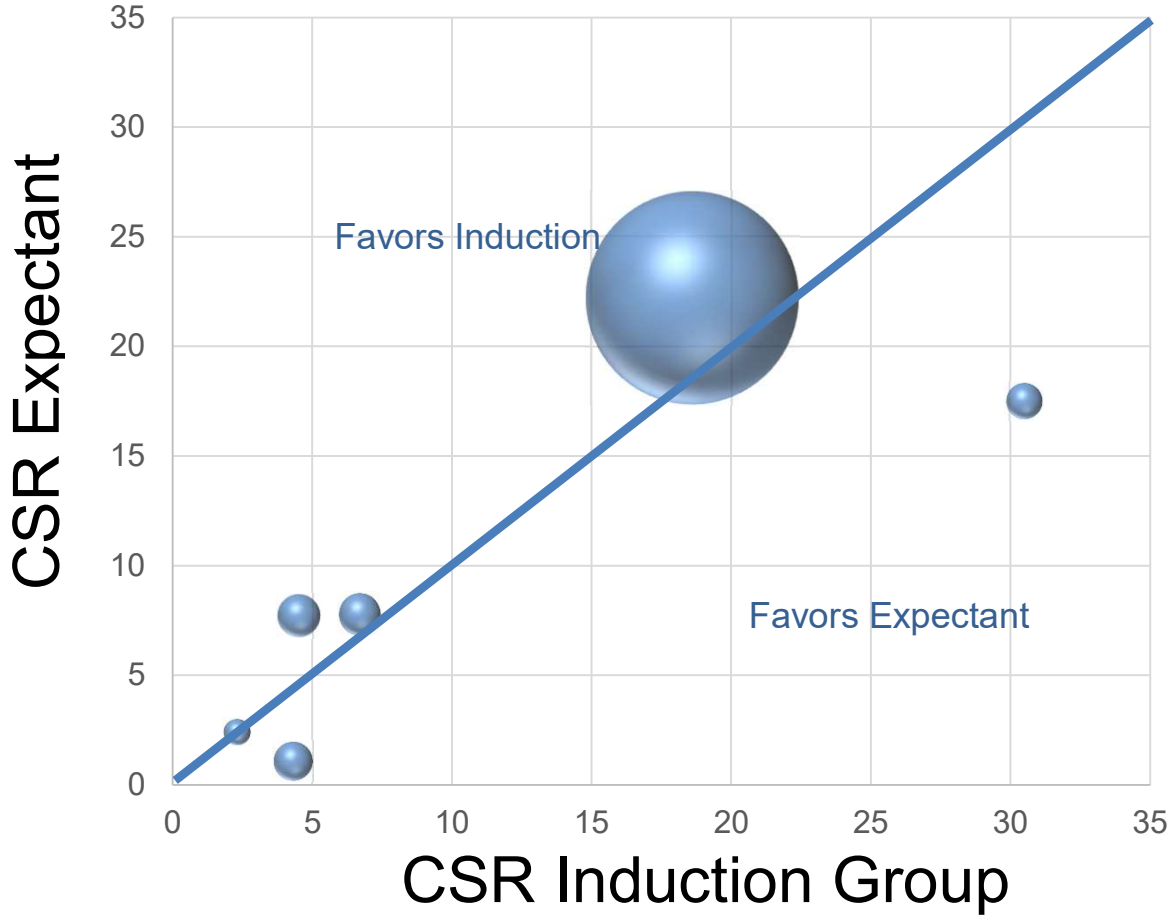
- **Delivery** in the IOL group was significantly earlier than in the EM group (**39.3 weeks** [IQR 39.1 to 39.6] vs **40.0 weeks** [IQR 39.3 to 40.7]; *P* < .001)*. (4 days less)*
- **Preeclampsia and gestational hypertension** occurred in **9%** of the IOL group versus **14%** of the EM group. *(5% lower risk)*
- Among newborns, 3% in the IOL group needed **respiratory support** versus 4% in the EM group. *(No difference)*
- The primary **(adverse) perinatal outcome** occurred in 4.4% of the IOL group versus 5.4% of the EM group (RR 0.81, 95% CI 0.64 to 1.01; ***P* = .06**). *(Trending less)*
- **Frequency of CD also was significantly lower (3.6%) in the IOL group (18.6% vs 22.2%; RR 0.84, 95% CI 0.76 to 0.93).**

Summary of the ARRIVE trial

- This was a well executed randomized control trial
- Important findings elective induction at 39 in nulliparous can reduce cesarean section rates by 3.6% and not harm mothers and babies
- Well chosen group of patients (evidence strict protocol)
- Well chosen group of providers (evidence control group CSR)
- Standardized protocols for failed induction
- Average “cost” to labor units for additional 6 hours

Why were we skeptical?

RCT Results for Elective Induction with Expectant Management



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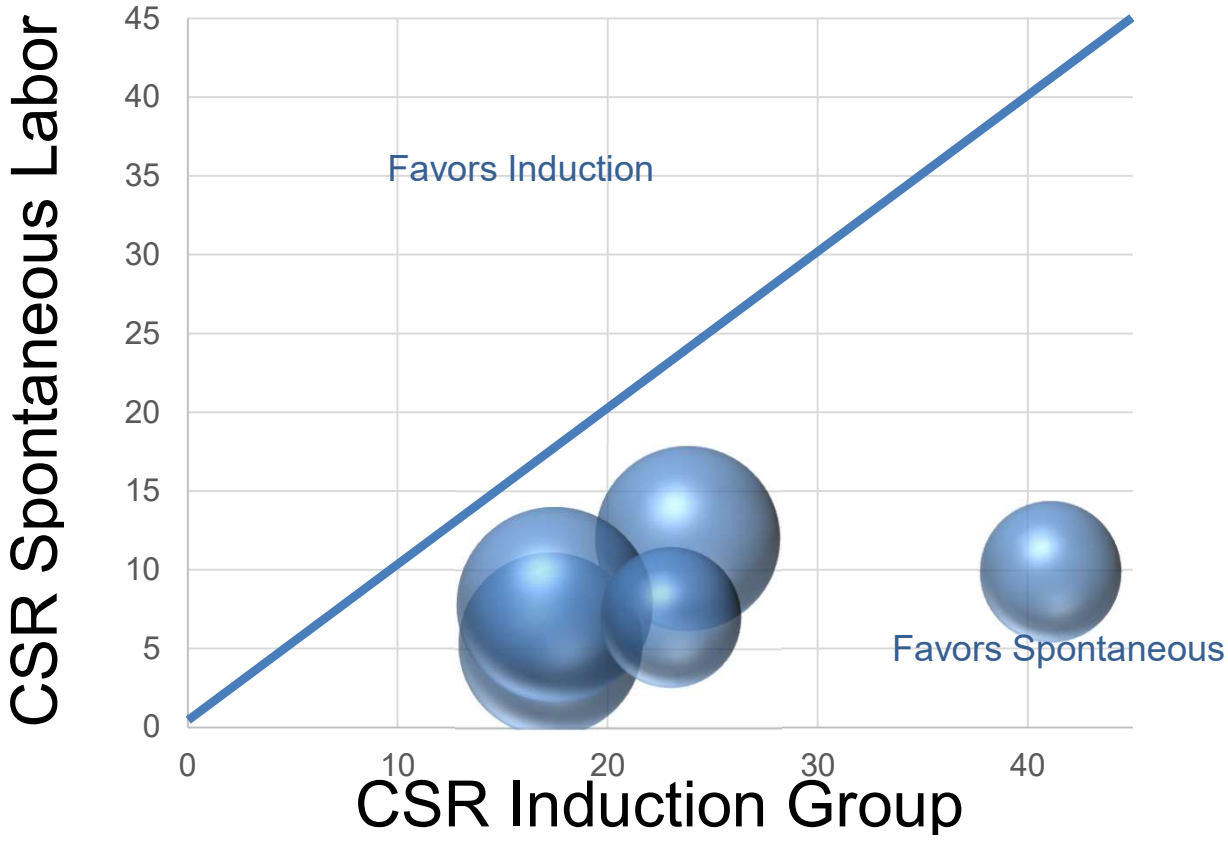
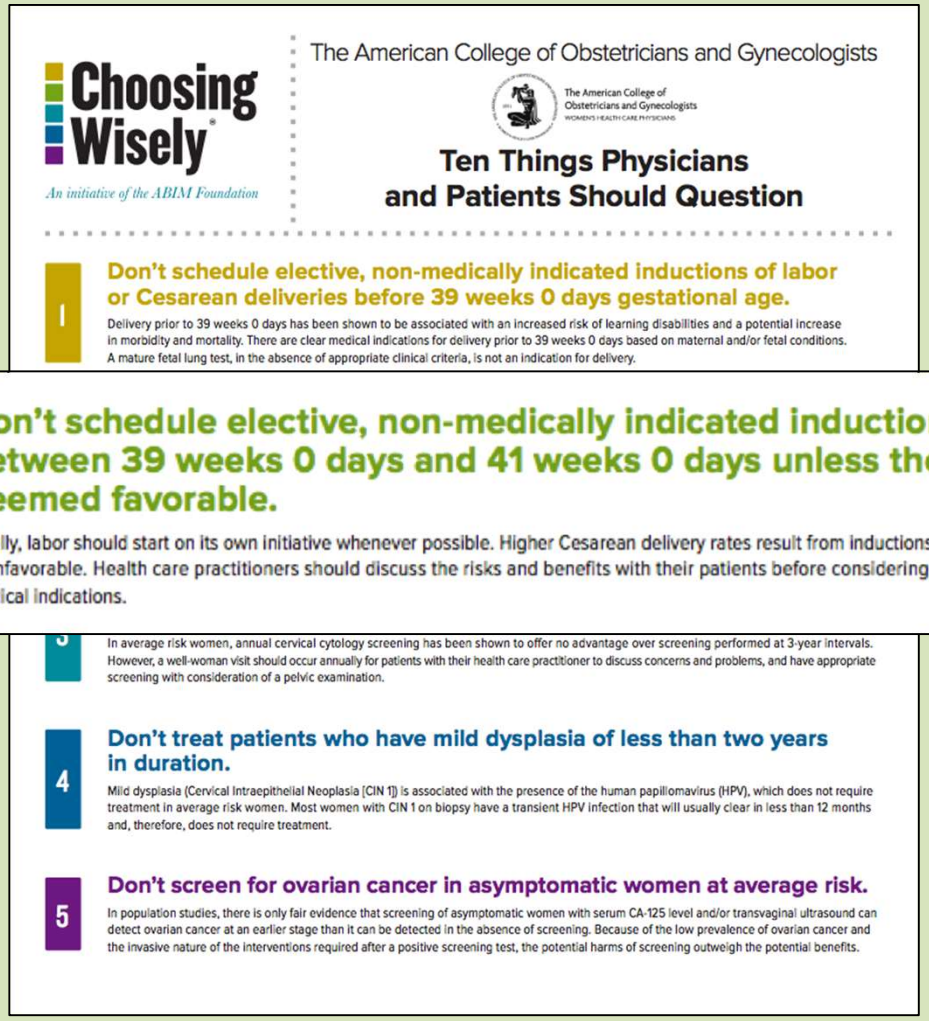
Same group, same month, ***different publication***…

- Study Design: This study is based on data from an obstetric cohort of women delivering at 25 US hospitals from 2008 through 2011. Nulliparous women who had a term singleton gestation in the cephalic presentation were eligible for this analysis if they underwent a labor induction.
- Looked at standard application of definition of failed induction in NTSV patients
- THEY HAD A CSR OF 33% IN THIS GROUP!

Grobman et al, American Journal of Obstetrics & Gynecology 2018 218, 122.e1-122.

Non-RCT Results for Elective Induction





Choosing Wisely®

An initiative of the ABIM Foundation

The American College of Obstetricians and Gynecologists

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

Ten Things Physicians and Patients Should Question

1 Don't schedule elective, non-medically indicated inductions of labor or Cesarean deliveries before 39 weeks 0 days gestational age.

Delivery prior to 39 weeks 0 days has been shown to be associated with an increased risk of learning disabilities and a potential increase in morbidity and mortality. There are clear medical indications for delivery prior to 39 weeks 0 days based on maternal and/or fetal conditions. A mature fetal lung test, in the absence of appropriate clinical criteria, is not an indication for delivery.

2 Don't schedule elective, non-medically indicated inductions of labor between 39 weeks 0 days and 41 weeks 0 days unless the cervix is deemed favorable.

Ideally, labor should start on its own initiative whenever possible. Higher Cesarean delivery rates result from inductions of labor when the cervix is unfavorable. Health care practitioners should discuss the risks and benefits with their patients before considering inductions of labor without medical indications.

3

In average risk women, annual cervical cytology screening has been shown to offer no advantage over screening performed at 3-year intervals. However, a well-woman visit should occur annually for patients with their health care practitioner to discuss concerns and problems, and have appropriate screening with consideration of a pelvic examination.

4 Don't treat patients who have mild dysplasia of less than two years in duration.

Mild dysplasia (Cervical Intraepithelial Neoplasia [CIN 1]) is associated with the presence of the human papillomavirus (HPV), which does not require treatment in average risk women. Most women with CIN 1 on biopsy have a transient HPV infection that will usually clear in less than 12 months and, therefore, does not require treatment.

5 Don't screen for ovarian cancer in asymptomatic women at average risk.

In population studies, there is only fair evidence that screening of asymptomatic women with serum CA-125 level and/or transvaginal ultrasound can detect ovarian cancer at an earlier stage than it can be detected in the absence of screening. Because of the low prevalence of ovarian cancer and the invasive nature of the interventions required after a positive screening test, the potential harms of screening outweigh the potential benefits.

Released March 2016

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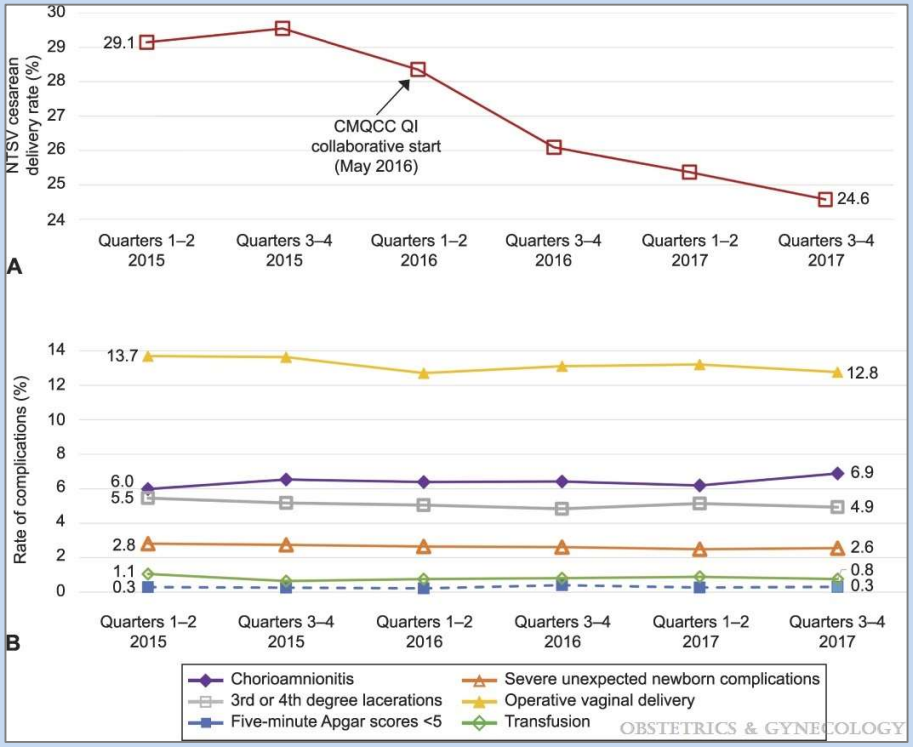
Safety Assessment of a Large-Scale Improvement Collaborative to Reduce Nulliparous Cesarean Delivery Rates

Main, Elliott K.; Chang, Shen-Chih; Cape, Valerie; Sakowski, Christa; Smith, Holly; Vasher, Julie

Obstetrics & Gynecology133(4):613-623, April 2019.
doi: 10.1097/AOG.0000000000003109



Maternal and Neonatal Outcome Measures	2015	2017	2017 vs 2015 cOR (95% CI)	2017 vs 2015 aOR (95% CI)*
Hospitals with greatest absolute decline in NTSV cesarean delivery rate (n=19 hospitals)				
Mean change −10.9 percentage points (range −17.1 to −7.1)				
NTSV cesarean delivery rate	2,701/8,666 (31.2)	1,646/7,982 (20.6)	0.58 (0.54–0.62)†	0.54 (0.50–0.58)†
Chorioamnionitis	466/8,666 (5.4)	394/7,982 (4.9)	0.91 (0.79–1.04)	0.90 (0.78–1.04)
Transfusions	96/8,666 (1.1)	89/7,982 (1.1)	1.01 (0.75–1.35)	1.00 (0.74–1.35)
Severe unexpected newborn complications‡	182/5,762 (3.2)	113/5,035 (2.2)	0.70 (0.55–0.89)†	0.71 (0.55–0.92)†
3rd- or 4th-degree lacerations among vaginal births	315/5,965 (5.3)	313/6,336 (4.9)	0.92 (0.78–1.08)	0.94 (0.79–1.11)
Operative vaginal delivery	856/5,965 (14.4)	869/6,336 (13.7)	0.94 (0.85–1.04)	0.95 (0.85–1.06)
5-min Apgar score less than 5	29/8,661 (0.33)	30/7,975 (0.38)	1.12 (0.67–1.87)	1.16 (0.66–2.03)

Trend of nulliparous, term, singleton, vertex (NSTV) cesarean delivery (A) and other complications (B) in the California Maternal Quality Care Collaborative (CMQCC) supporting vaginal birth quality improvement (QI) collaborative (N=56 hospitals), 2015–2017. Unexpected newborn complications analysis included only 51 hospitals (see Methods for explanation).Main. Safety Assessment for Reducing Cesarean Deliveries. Obstet Gynecol 2019.

Randomization for ARRIVE trial

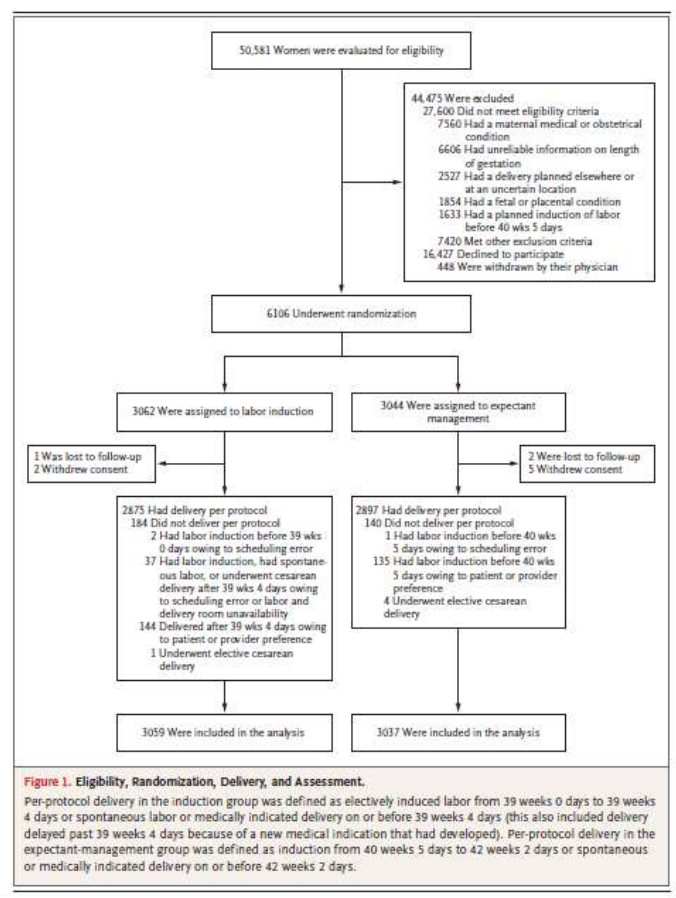


Figure 1. Eligibility, Randomization, Delivery, and Assessment.

Per-protocol delivery in the induction group was defined as electively induced labor from 39 weeks 0 days to 39 weeks 4 days or spontaneous labor or medically indicated delivery on or before 39 weeks 4 days (this also included delivery delayed past 39 weeks 4 days because of a new medical indication that had developed). Per-protocol delivery in the expectant-management group was defined as induction from 40 weeks 5 days to 42 weeks 2 days or spontaneous or medically indicated delivery on or before 42 weeks 2 days.

44,475 Were excluded
27,600 Did not meet eligibility criteria
7560 Had a maternal medical or obstetrical condition
6606 Had unreliable information on length of gestation
2527 Had a delivery planned elsewhere or at an uncertain location
1854 Had a fetal or placental condition
1633 Had a planned induction of labor before 40 wks 5 days
7420 Met other exclusion criteria
16,427 Declined to participate
448 Were withdrawn by their physician

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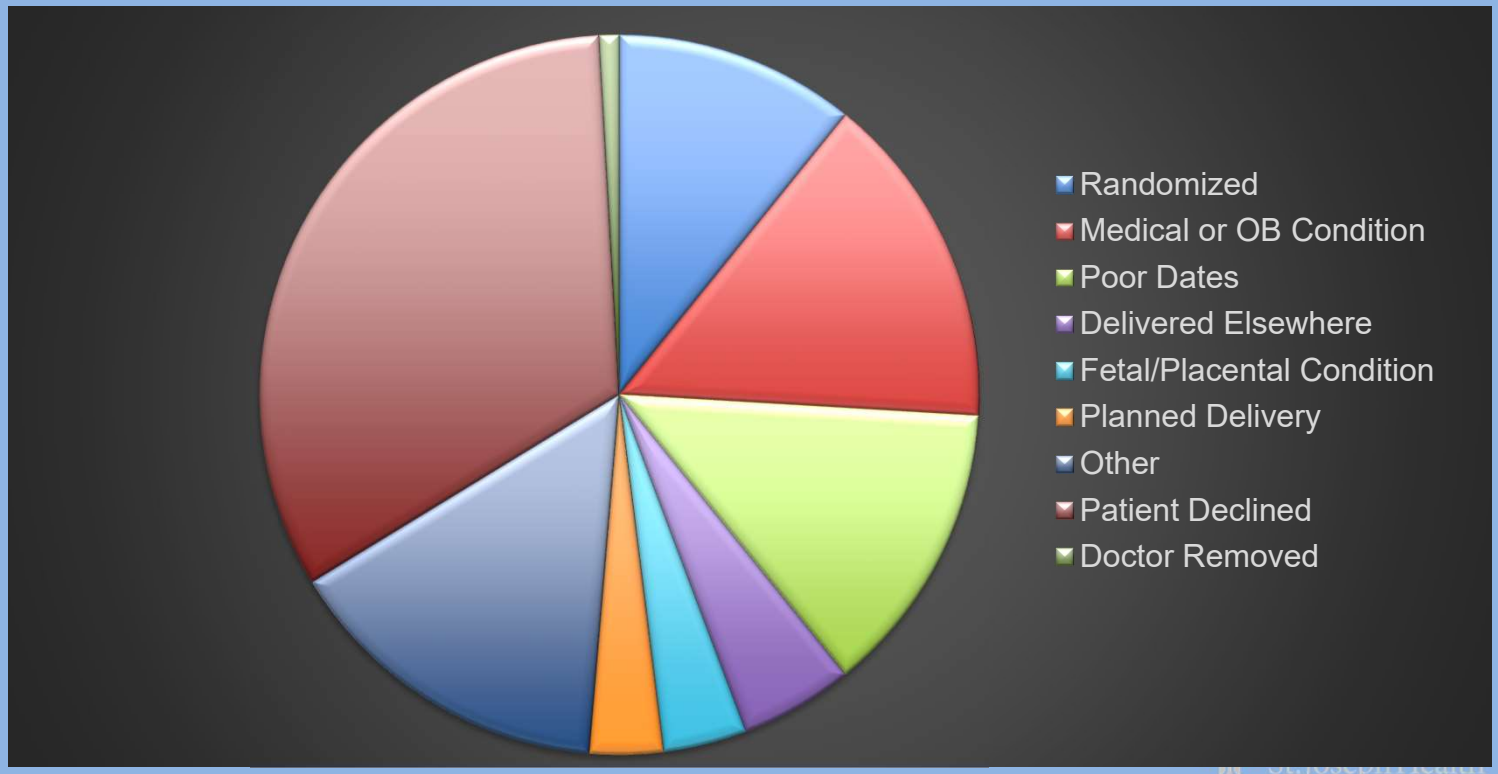
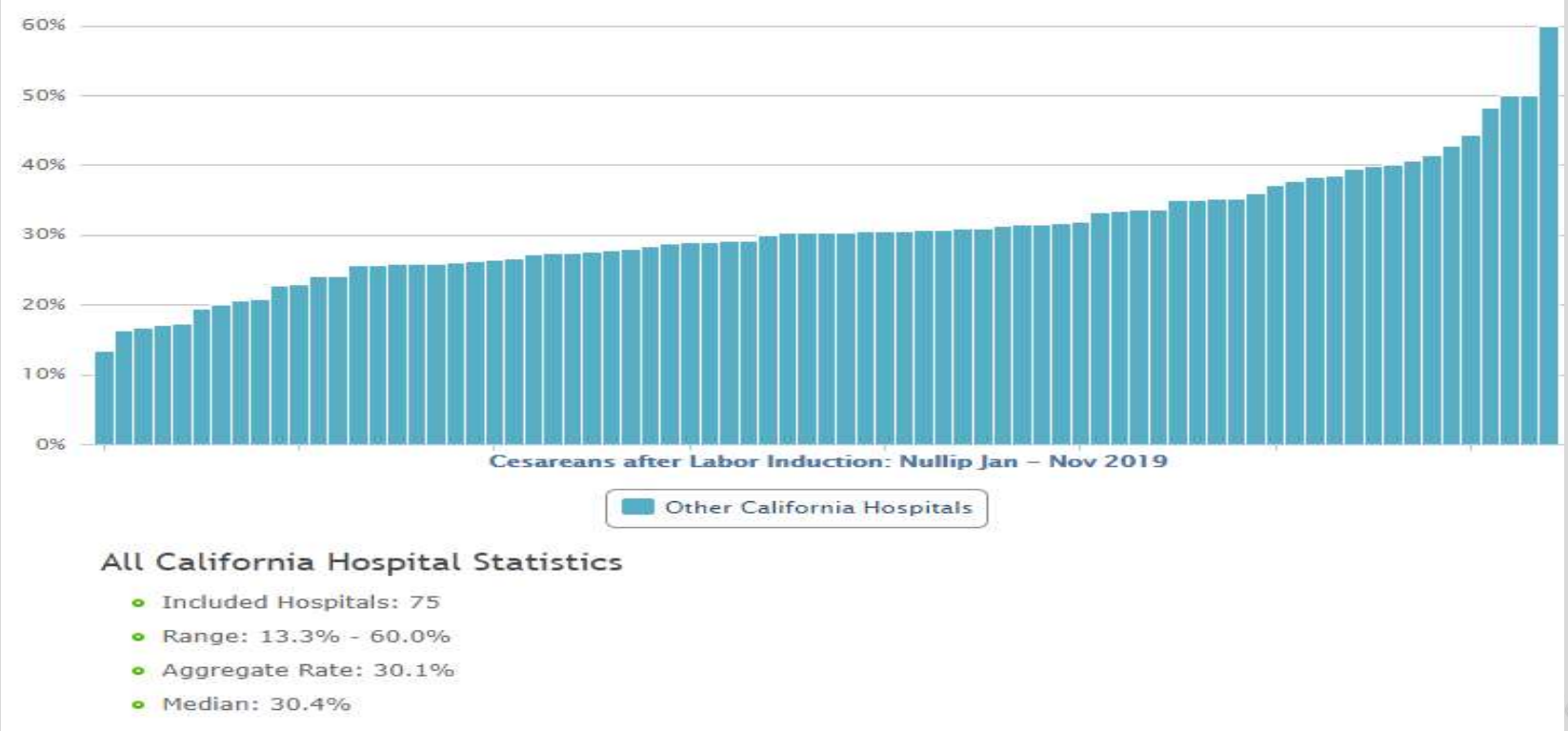
ARRIVE Population Screened: 12.1% Randomized



Hospitals Vary by CSR Following NTSV Induction



LET’S LOOK AT SOME MORE DATA

Effect of Labor Type

	Multiparous (Parity 1+)				Nulliparous (Parity 0)			
	Induction - with cervical ripening	Induction - without cervical ripening	Spontaneous	Spontaneous with augmentation	Induction - with cervical ripening	Induction - without cervical ripening	Spontaneous	Spontaneous with augmentation
	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall
Volume %	1,808 8.21%	2,135 9.70%	6,245 28.37%	2,606 11.84%	2,341 10.64%	696 3.16%	3,348 15.21%	2,830 12.86%
CSR	8.1%	3.7%	6.5%	4.1%	29.4%	20.5%	10.8%	15.5%

Plot by Avg. Labor Cost and Hours Elapsed by Labor Type

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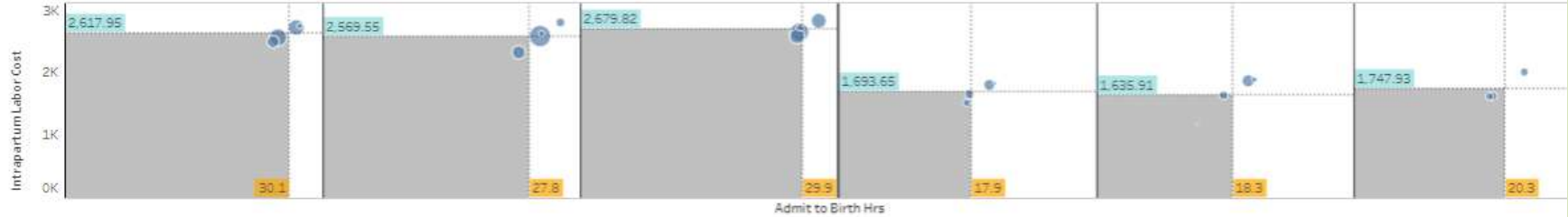
Effect of Gestational Age: Induced Labors

	Nulliparous (Parity 0)					
	Induction - with cervical ripening			Induction - without cervical ripening		
	39	40	41	39	40	41
Volume %	640 24.05%	654 24.58%	736 27.66%	234 8.79%	226 8.49%	171 6.43%
CSR	29.4%	30.4%	29.8%	18.4%	19.9%	26.9%

Plot by Avg. Labor Cost and Hours Elapsed by Labor Type



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Effect of Gestational Age: Spontaneous Labor

	Nulliparous (Parity 0)					
	Spontaneous			Spontaneous with augmentation		
	39	40	41	39	40	41
Volume %	1,215 26.14%	1,052 22.63%	234 5.03%	936 20.14%	992 21.34%	219 4.71%
CSR	10.2%	10.2%	17.1%	12.4%	17.8%	27.4%

Single Hospital: NTSV CSR Increased 25% to 35%

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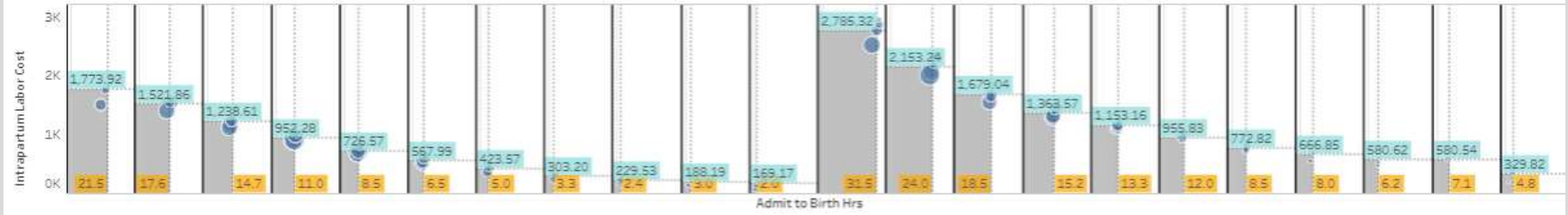
NSTV CSR Highly Correlated with CSR After Induction

Another Hospital Example

Centimeters on Admission

	Multiparous (Parity 1+)											Nulliparous (Parity 0)										
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10
	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall	Overall
Volume %	582 2.70%	1,646 7.65%	1,718 7.98%	2,603 12.10%	2,317 10.77%	1,414 6.57%	899 4.18%	521 2.42%	352 1.64%	205 0.95%	218 1.01%	1,214 5.64%	2,174 10.10%	1,368 6.36%	1,620 7.53%	1,182 5.49%	610 2.83%	350 1.63%	185 0.86%	119 0.55%	109 0.51%	111 0.52%
CSR	35.2%	14.5%	7.5%	4.2%	3.1%	2.3%	1.7%	1.2%	0.3%	0.5%	0.0%	36.2%	24.2%	16.0%	12.3%	9.8%	11.1%	7.4%	5.4%	3.4%	7.3%	6.3%

Plot by Avg. Labor Cost and Hours Elapsed by Admit Cx Dilation



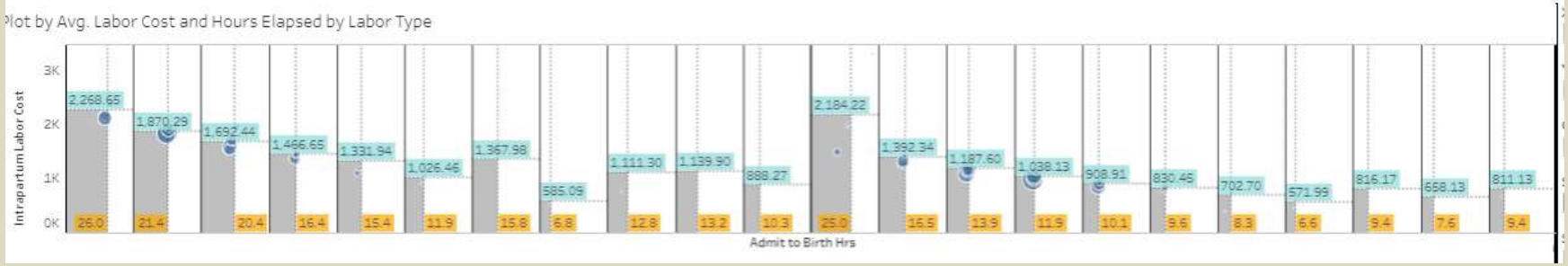
Centimeters on Admission-Nulliparous Induction

	Nulliparous (Parity 0)																			
	Induction - with cervical ripening											Induction - without cervical ripening								
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	9	10
Volume %	865 28.86%	1,006 33.95%	256 8.64%	101 3.41%	49 1.65%	17 0.57%	4 0.13%	3 0.10%	1 0.03%	3 0.10%	2 0.07%	56 1.89%	179 6.04%	176 5.94%	170 5.74%	61 2.06%	10 0.34%	11 0.37%	2 0.07%	1 0.03%
CSR	36.6%	27.5%	16.8%	17.8%	16.3%	29.4%	0.0%	0.0%	0.0%	0.0%	50.0%	35.7%	26.3%	18.8%	12.9%	14.8%	20.0%	9.1%	0.0%	0.0%

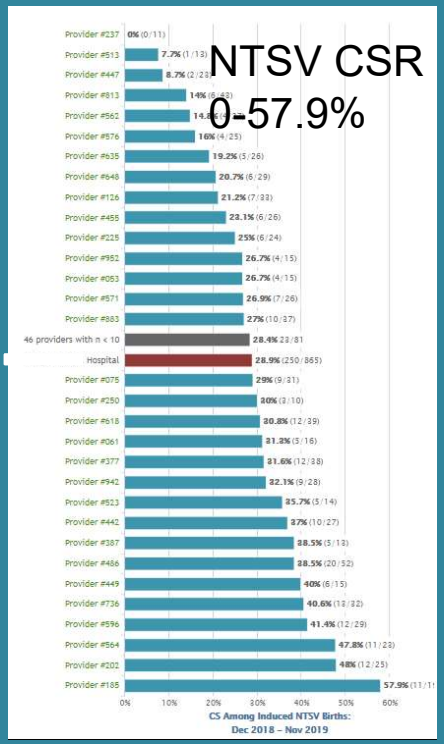
lot by Avg. Labor Cost and Hours Elapsed by Labor Type

Centimeters on Admission-Multiparous

	Multiparous (Parity 1+)																					
	Induction - with cervical ripening											Induction - without cervical ripening										
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10
Volume %	305 7.91%	795 20.61%	401 10.40%	198 5.13%	52 1.35%	17 0.44%	3 0.08%	4 0.10%	3 0.08%	2 0.05%	1 0.03%	53 1.37%	212 5.50%	530 13.74%	743 19.26%	398 10.32%	97 2.51%	24 0.62%	8 0.21%	4 0.10%	5 0.13%	2 0.05%
CSR	16.4%	8.1%	4.2%	3.0%	3.8%	0.0%	0.0%	0.0%	0.0%	50.0%	0.0%	17.0%	5.7%	4.5%	3.1%	2.0%	2.1%	4.2%	0.0%	0.0%	0.0%	0.0%



Providers Vary in their CSR After Induction



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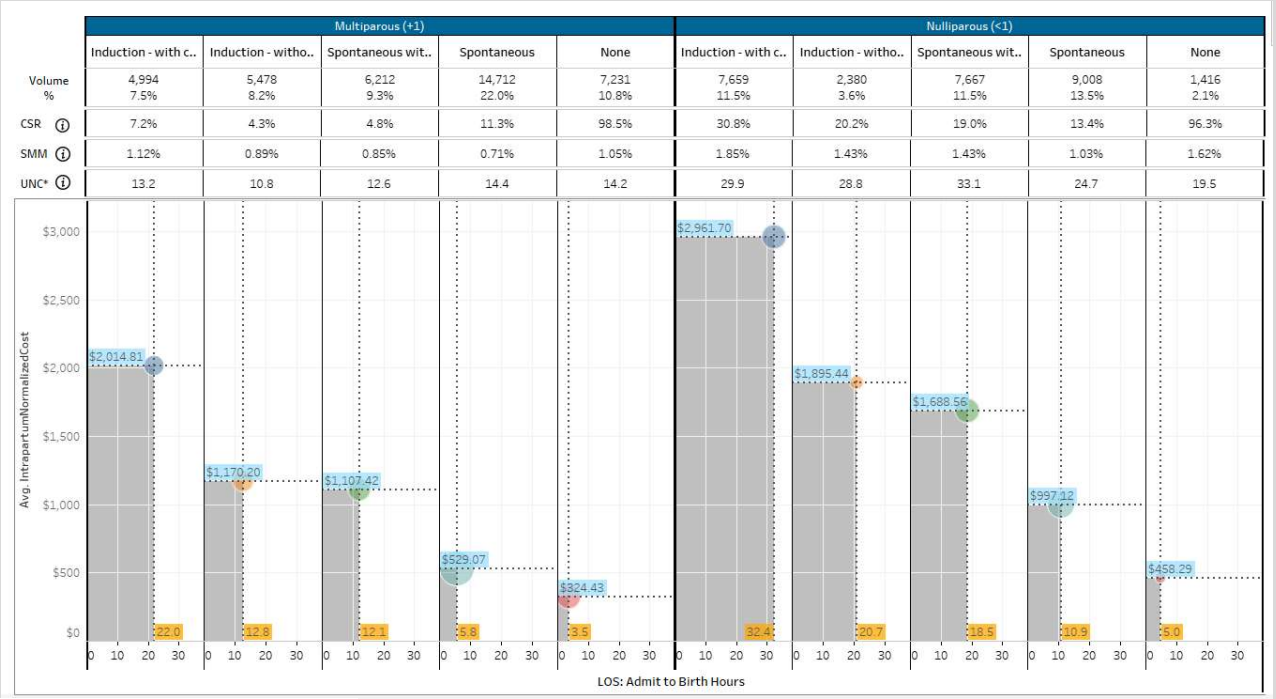
VALUE= QUALITY/COST



	Multiparous (+1)					Nulliparous (<1)				
	Induction - with c..	Induction - witho..	Spontaneous wit..	Spontaneous	None	Induction - with c..	Induction - witho..	Spontaneous wit..	Spontaneous	None
Volume %	4,994 7.5%	5,478 8.2%	6,212 9.3%	14,712 22.0%	7,231 10.8%	7,659 11.5%	2,380 3.6%	7,667 11.5%	9,008 13.5%	1,416 2.1%
CSR	7.2%	4.3%	4.8%	11.3%	98.5%	30.8%	20.2%	19.0%	13.4%	96.3%
SMM	1.12%	0.89%	0.85%	0.71%	1.05%	1.85%	1.43%	1.43%	1.03%	1.62%
UNC*	13.2	10.8	12.6	14.4	14.2	29.9	28.8	33.1	24.7	19.5

	Nulliparous (<1)			
	Induction - with c..	Induction - witho..	Spontaneous wit..	Spontaneous
Volume %	7,659 11.5%	2,380 3.6%	7,667 11.5%	9,008 13.5%
CSR	30.8%	20.2%	19.0%	13.4%
SMM	1.85%	1.43%	1.43%	1.03%
UNC*	29.9	28.8	33.1	24.7

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THE DILEMMA: CAN WE MEET THE INCREASED DEMAND FOR INDUCTION OF LABOR WITHOUT CAUSING A SIGNIFICANT FINANCIAL AND SAFETY ISSUES FOR OUR INSTITUTIONS?

Possible solutions to control resource utilization

- ✓ Restrict elective induction privileges to those providers who demonstrate that they can reduce cesareans in similar fashion to the providers in the ARRIVE trial.
- ✓ Strict scheduling process to limit burden and even out delivery unit volumes (nights/weekends)
- ✓ LEAN processes of induction to assure admission with complete information, timely start to oxytocin
- ✓ Active management of labor with prompt augmentation for arrest disorders
- ✓ Strict adherence to failed induction guidelines
- ✓ Consider sending inductions home after 12 hours if tracing reassuring
- ✓ Outpatient cervical ripening in patients whom appropriate (since these are low risk should be majority of patients)
- ✓ Inpatients needing cervical ripening: use mechanical and hormonal

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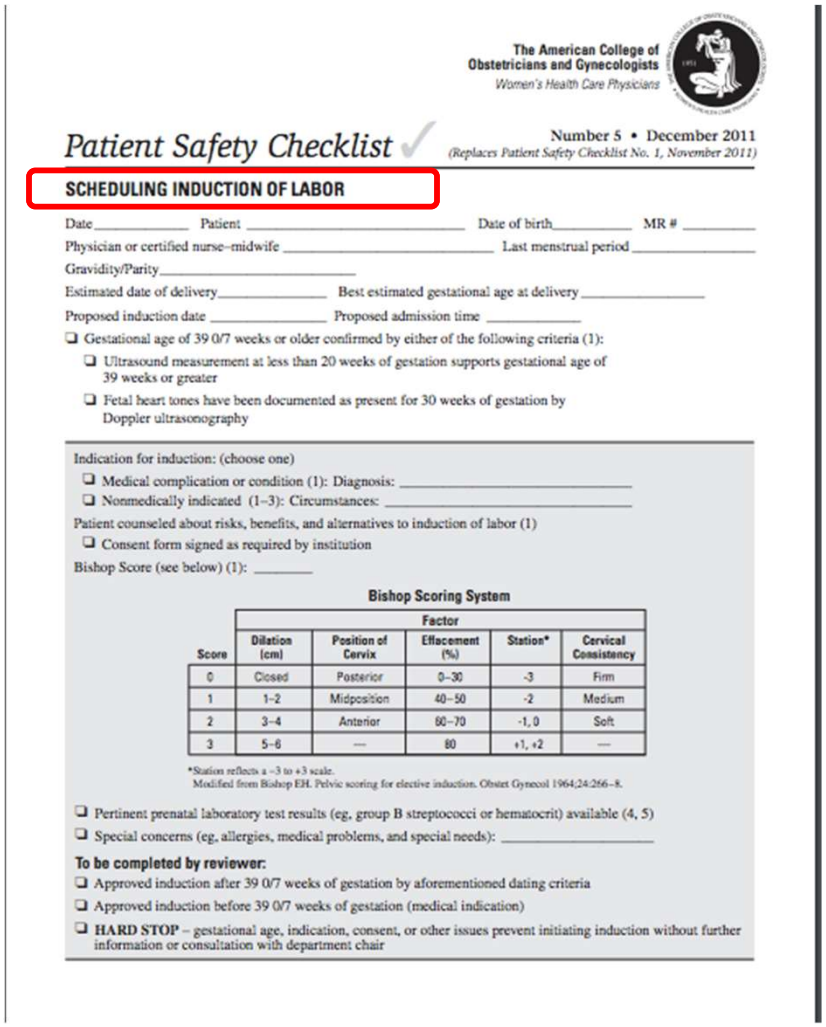

The American College of Obstetricians and Gynecologists
Women's Health Care Physicians

Patient Safety Checklist

Number 5 • December 2011
(Replaces Patient Safety Checklist No. 1, November 2011)

SCHEDULING INDUCTION OF LABOR

Date_____ Patient _____ Date of birth_____ MR # _____

Physician or certified nurse–midwife _____ Last menstrual period _____

Gravidity/Parity_____

Estimated date of delivery_____ Best estimated gestational age at delivery _____

Proposed induction date _____ Proposed admission time _____

❑ Gestational age of 39 0/7 weeks or older confirmed by either of the following criteria (1):

- ❑ Ultrasound measurement at less than 20 weeks of gestation supports gestational age of 39 weeks or greater
- ❑ Fetal heart tones have been documented as present for 30 weeks of gestation by Doppler ultrasonography

Indication for induction: (choose one)

- ❑ Medical complication or condition (1): Diagnosis: _____
- ❑ Nonmedically indicated (1–3): Circumstances: _____

Patient counseled about risks, benefits, and alternatives to induction of labor (1)

- ❑ Consent form signed as required by institution

Bishop Score (see below) (1): _____

Bishop Scoring System

	Factor				
Score	Dilation (cm)	Position of Cervix	Effacement (%)	Station*	Cervical Consistency
0	Closed	Posterior	0–30	-3	Firm
1	1–2	Midposition	40–50	-2	Medium
2	3–4	Anterior	60–70	-1, 0	Soft
3	5–6	—	80	+1, +2	—

*Station reflects a –3 to +3 scale.
Modified from Bishop EH. Pelvic scoring for elective induction. Obstet Gynecol 1964;24:266–8.

- ❑ Pertinent prenatal laboratory test results (eg, group B streptococci or hematocrit) available (4, 5)
- ❑ Special concerns (eg, allergies, medical problems, and special needs): _____

To be completed by reviewer:

- ❑ Approved induction after 39 0/7 weeks of gestation by aforementioned dating criteria
- ❑ Approved induction before 39 0/7 weeks of gestation (medical indication)
- ❑ **HARD STOP** – gestational age, indication, consent, or other issues prevent initiating induction without further information or consultation with department chair

Scheduling Checklist

Critiquing a Failed Induction

1. Induction in the face of unripe cervix (Bishop score < 8 primip and < 6 multip)
2. Inadequate documentation of cervical ripening procedure and timing
3. Adequate trial defined by latent phase at least 12-18 hours of oxytocin and ruptured membranes

ACOG/SMFM Consensus on Safe Labor.

Is There a Place for Outpatient Pre-induction Cervical Ripening?

- "If trials like the National Institute of Child Health and Human Development's ARRIVE trial show that delivery for all women at 39 weeks provides a significant advantage in pregnancy outcomes, the number of women who require induction of labor will considerably increase. Strategies to improve patient/family satisfaction, decrease resource allocation and costs, and assure safety are paramount. ***Although there are many potential candidates, it seems that outpatient pre-induction cervical ripening with the Foley catheter meets these criteria in a properly selected group of low-risk women.***"

Leopold B, Sciscione A. Obstet Gynecol Clin North Am. 2017 Dec;44(4):583-591.

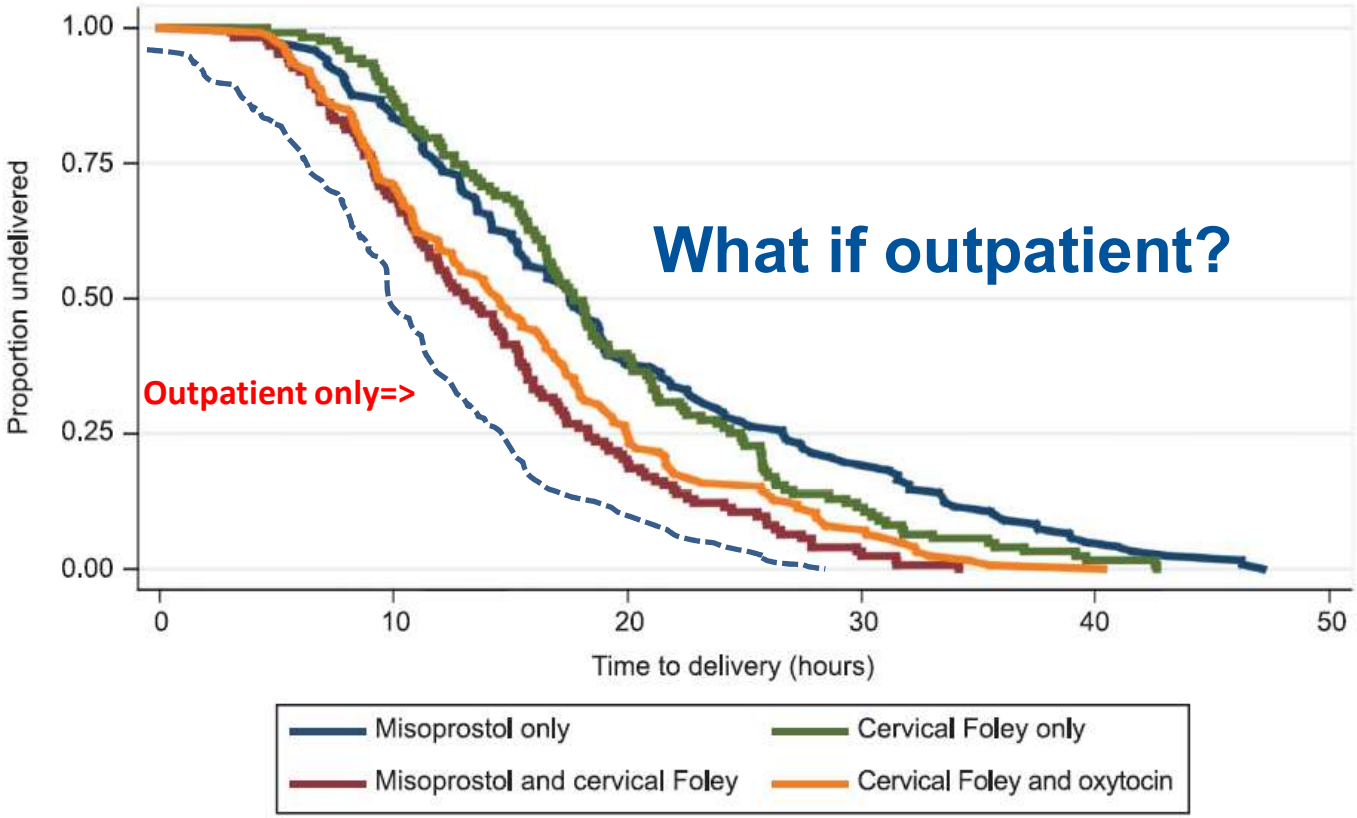

Fig. 2. Estimated time to delivery by study group. This figure displays the Kaplan-Meier survival curves for time to delivery for the four induction method groups, $P<.001$.

Levine. Randomized Trial of Four Induction Methods. Obstet Gynecol 2016.

***Safety of the balloon catheter for cervical ripening in outpatient care*: complications during the period from insertion to expulsion of a balloon catheter in the process of labor induction: a systematic review.**

- We included randomized controlled trials and cohort studies containing original data on fetal and maternal morbidity in pregnant women during cervical ripening with a balloon catheter. Only articles for which authors were able to give data for this exact time frame were included.
- In total 26 studies were included reporting on 8292 women. The estimated prevalence of the analyzed adverse events in the random effects model was between 0.0 and 0.26%, of which 'pain/discomfort' had the highest prevalence.

Diederen M, et al. BJOG. 2018 Aug;125(9):1086-1095.


SO WHAT
SHOULD WE DO?

The ARRIVE trial cannot be ignored…

CONCLUSIONS

Induction of labor at 39 weeks in low-risk nulliparous women did not result in a significantly lower frequency of a composite adverse perinatal outcome, but it did result in a significantly lower frequency of cesarean delivery. (Funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development; ARRIVE ClinicalTrials.gov number, NCT01990612.)

In summary, we found that elective labor induction at 39 weeks of gestation did not result in a greater frequency of perinatal adverse outcomes than expectant management and resulted in fewer instances of cesarean delivery. These results suggest that policies aimed at the avoidance of elective labor induction among low-risk nulliparous women at 39 weeks of gestation are unlikely to reduce the rate of cesarean delivery on a population level; the trial provides information that can be incorporated into discussions that rely on principles of shared decision making.[24-27]

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Safety/Cost Concerns

The extra 6 hours of labor associated with your elective inductions may overwhelm the labor and delivery unit and be cost prohibitive

The extra burden on nursing and facilities will take resources away from other patient care

Overfull units may lead to safety issues

Our analysis suggest an average of $91/ an hour for labor and delivery time the $546 extra per patient would likely cause serious viability to continue offering services

Best Practice Solutions

- Restrict elective induction privileges
- Strict scheduling process to limit burden and even out delivery unit volumes (nights/weekends)
- LEAN processes of induction to assure timely start to oxytocin
- Active management of labor with prompt augmentation for arrest disorders
- Strict adherence to failed induction guidelines
- Consider sending inductions home after 12 hours if tracing reassuring
- Outpatient cervical ripening
- Inpatients needing cervical ripening: use mechanical and hormonal

One last warning…

From my midwife colleague: "If you had given us this group of low risk patients, like in the ARRIVE trial, we would have had a 5-10% cesarean section rate!"

Providence St. Joseph Health

Questions and Discussion

Please share your thoughts!

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