Welcome

- Attendees are automatically muted upon entry.
- The slides and webinar recording will be available in 2-3 days on the CMQCC website and Youtube channel.
- Participants will receive a survey evaluation link. If RNs will be requesting Continuing Education contact hours for this webinar, completion of the survey is required.
- Questions will be addressed at the of the webinar and can be typed in the Q&A box.

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Induction of labor: Variation, Successful Management, and Opportunities for QI

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Neither Dr. Main nor Dr. Lagrew have any any conflicts or disclosures

NEW ACOG STANDARD LABOR DEFINITIONS (2014)	
LABOR	Uterine contractions resulting in cervical change (dilation and/or effacement) Phases: • Latent phase – from the onset of labor to the onset of the active phase • Active phase – accelerated cervical dilation typically beginning at 6 cm
AUGMENTATION OF LABOR	The stimulation of uterine contractions using pharmacologic methods or artificial rupture of membranes to increase their frequency and/or strength following the onset of spontaneous labor or contractions following spontaneous rupture of membranes. If labor has been started using any method of induction described below (including cervical ripening agents), then the term, Augmentation of Labor, should not be used.
INDUCTION OF LABOR	The use of pharmacological and/or mechanical methods to initiate labor (Examples of methods include but are not limited to: artificial rupture of membranes, balloons, oxytocin, prostaglandin, Laminaria, or other cervical ripening agents) Still applies even if any of the following are performed: • Unsuccessful attempts at initiating labor • Initiation of labor following spontaneous ruptured membranes without contractions

Menard MK, Main EK, Currigan SM. Executive Summary of the reVITALize Initiative: Standardizing Obstetric Data Definitions. Obstet Gynecol 2014 July; 124:150-3.

Induction Definitions: Key Points

- **Induction of labor** includes all cases with any of the following:
  - Cervical ripening using medications (e.g. prostaglandins including misoprostol)
  - Cervical ripening using mechanical methods (e.g. balloons or other cervical dilators)
  - Artificial rupture of membranes before the onset of labor
  - Oxytocin/Pitocin® before the onset of labor. Note, if oxytocin is used in the setting of irregular contractions with intact membranes without cervical change, then it would be considered an Induction of Labor.
- **Augmentation of labor** occurs ONLY:
  - After the onset of spontaneous labor, defined as contractions with cervical change, or
  - After spontaneous rupture of membranes with contractions (with or without cervical change).
    Note, if there is spontaneous rupture of membranes and no contractions then administration of oxytocin is considered an induction of labor.

Link to full set of definitions: http://download.lww.com/wolterskluwer_vitalstream_com/PermaLink/AOG/A/AOG_124_1_2014_05_28_MENARD_14-107_SDC3.pdf

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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 9, 2018 VOL. 379 NO. 6

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.

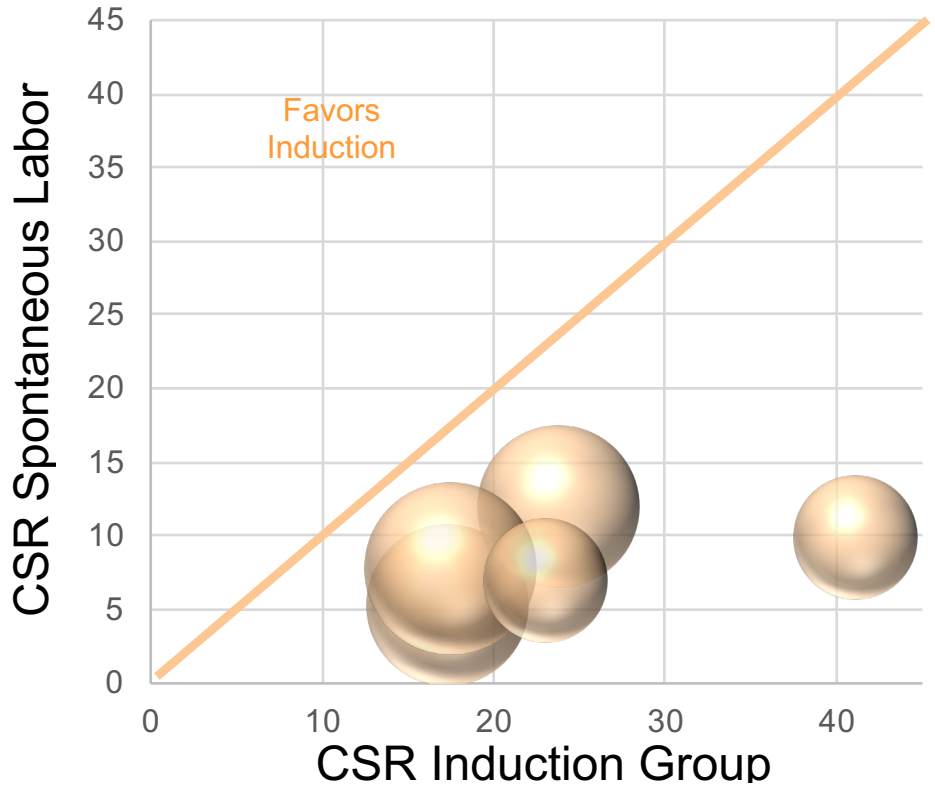
*A list of other members of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal–Fetal Medicine Units Network is provided in the Supplementary Appendix, available at NEJM.org.

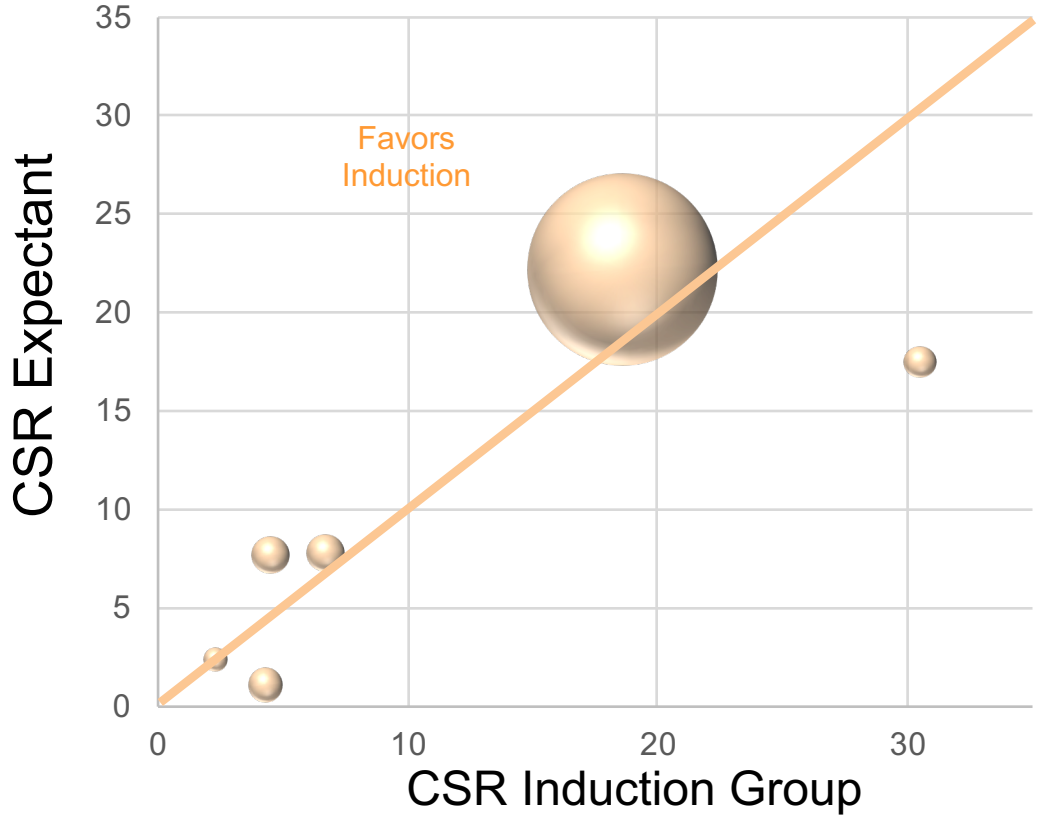
N Engl J Med 2018;379:513-23.
DOI: 10.1056/NEJMoa1800566

The ARRIVE TRIAL

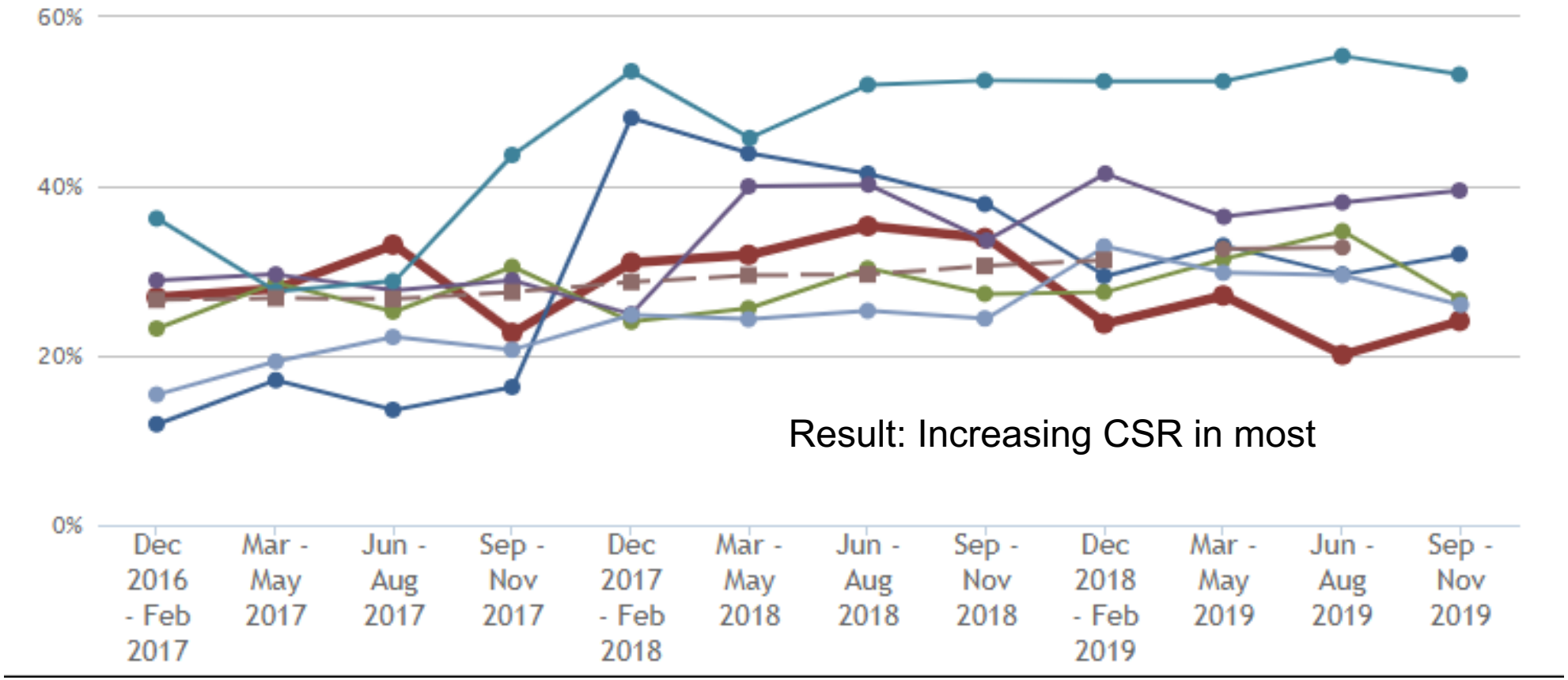
Can everyone universally adopt and get the same results?

Non-Randomized vs. Randomized Results





Mixed Response: Some Increased Induction/Some Not



Result: Increasing CSR in most

* Internal PSJH data

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 young patients (evidence strict protocol)

Well chosen group of providers (evidence control group CSR)

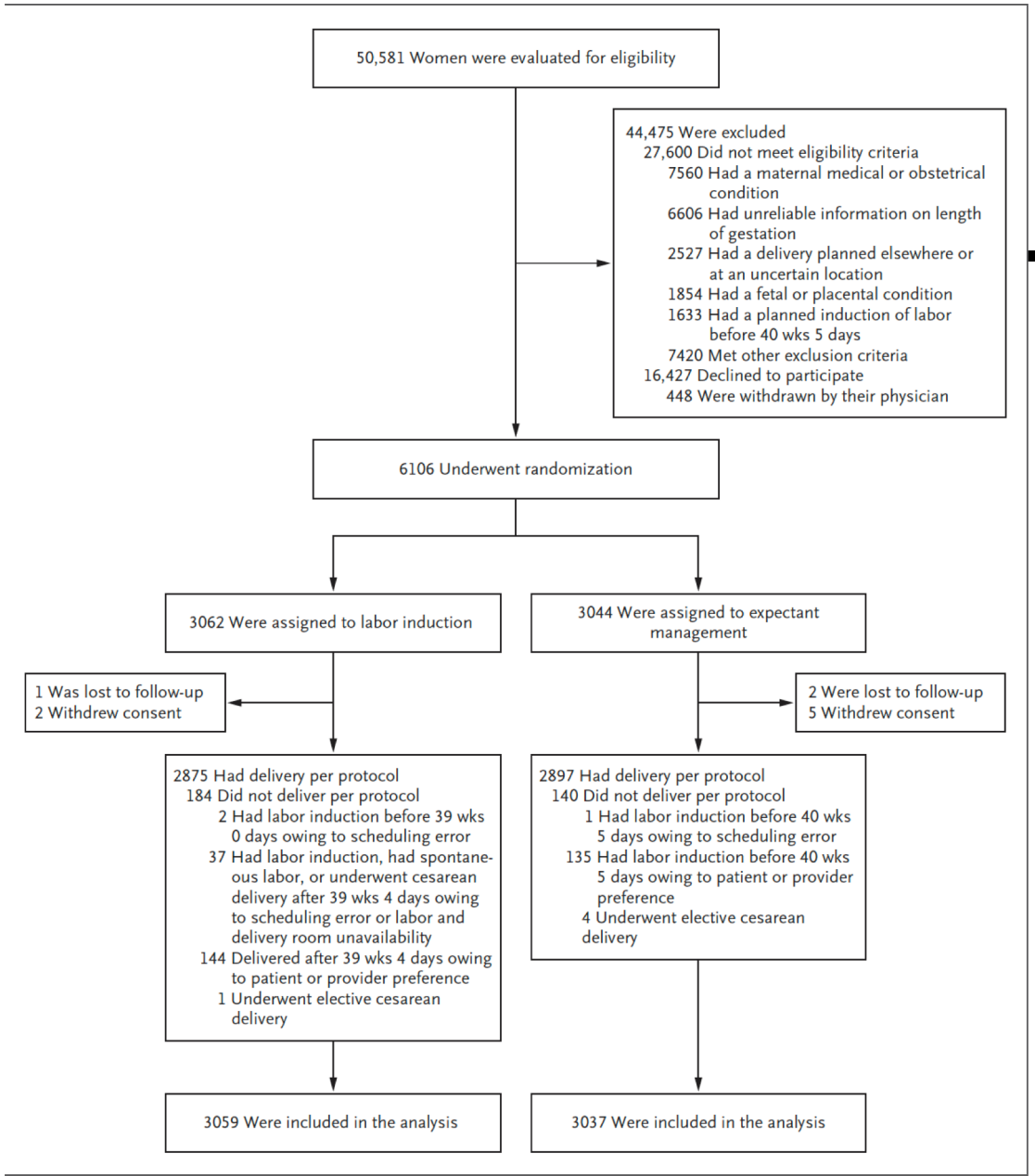
Standardized protocols for failed induction

Average “cost” to labor units for additional 6 hours

The ARRIVE trial raised several questions:

- Are the results ***generalizable*** to local patient population and to our providers?
- What were the protocols for induction and labor management, and can we duplicate them in other settings?
- Given the impact on length of labor (+6 hours), could the typical US hospital achieve the same results without significantly over burdening their staffing and room constraints?
- Why were certain complications so frequent (preeclampsia and chorioamnionitis)?
- Is the main effect seen from letting patients go past 41 0/7, should the routine induction be adjusted?

Randomization for ARRIVE trial



44,475 Were excluded (88%)
- 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

Keys for Induction Success

- Who you choose
  (parity and cervical ripeness)
- How you perform the induction
- Follow your success rates!

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Can you apply the Arrive Trial to your Hospital?

What will it take to be able to apply the Arrive Trial to my Hospital?

Population Analysis of CS Rates After Induction

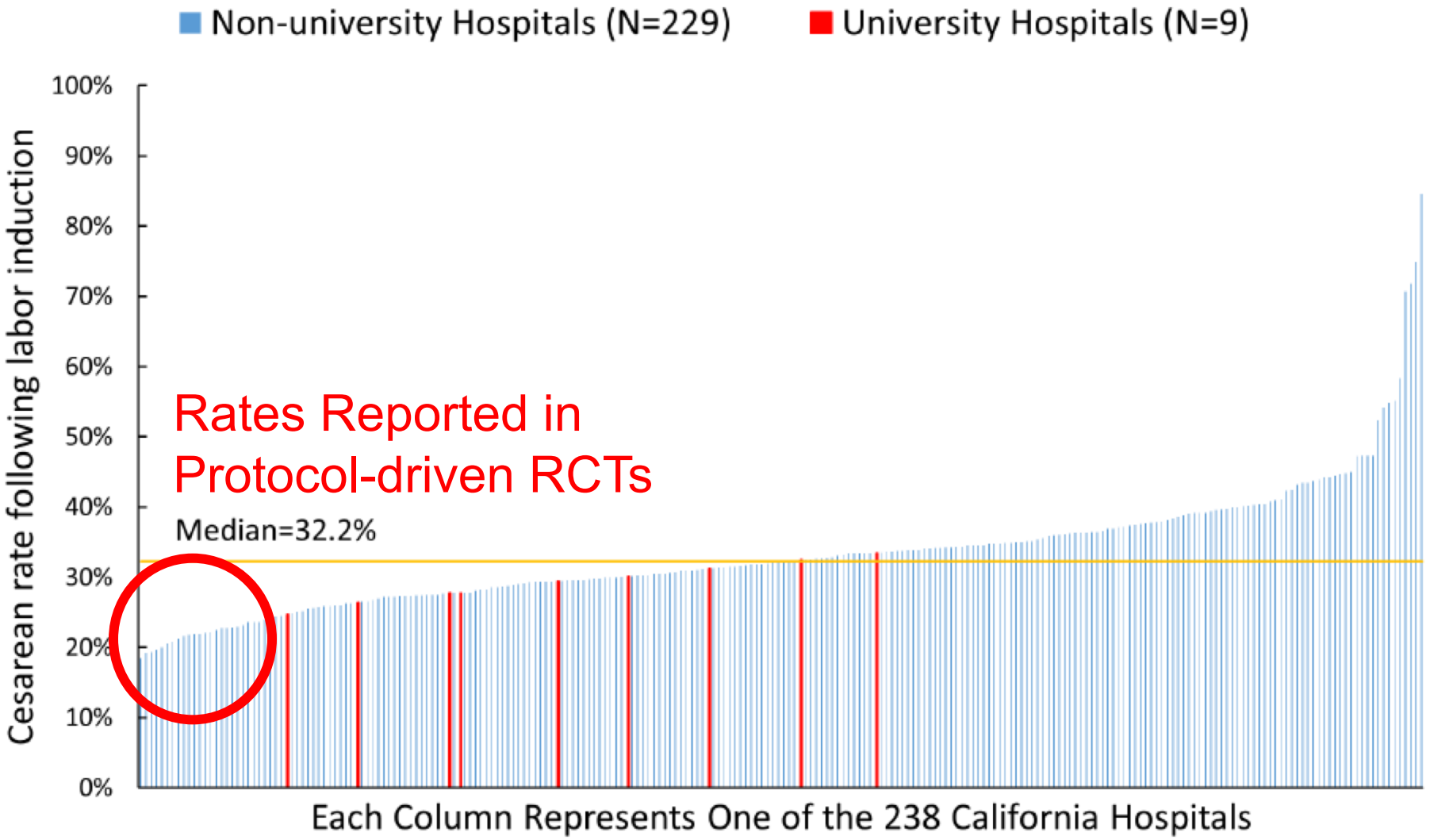
- Arrive Trial was limited to University and University-affiliated hospitals
- Are their numbers comparable to community hospitals where >90% of US birth occur?
- Analysis of all ~240 California hospitals

Identifying CS Rates After Labor Induction

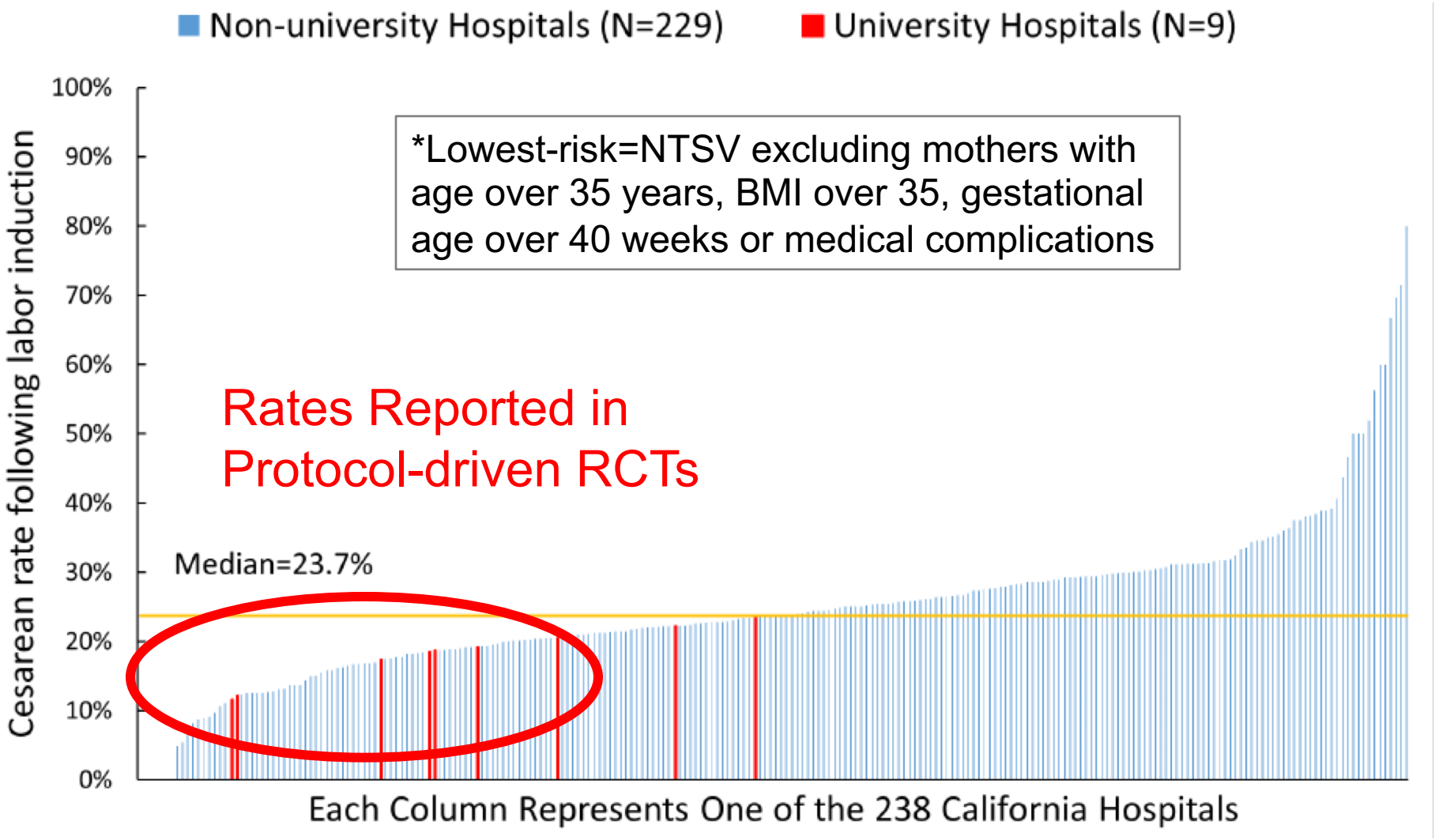
- Data: Neither Hospital Discharge codes nor BC codes are perfect
- Analysis of 46,916 women using ACOG reVITALize definitions of induction (chart reviews)

Identification of Induction	Sensitivity	Specificity	Accuracy
Hospital Discharge Codes ONLY	68.7%	96.7%	89.4%
Birth Certificate Codes ONLY	60.7%	97.8%	88.1%
EITHER BC OR Discharge Codes	87.0%	95.0%	92.9%
BOTH BC OR Discharge Codes	42.4%	99.5%	84.7%

Cesarean Rate Following Labor Induction in Nulliparas:
Large Variation Among Hospitals

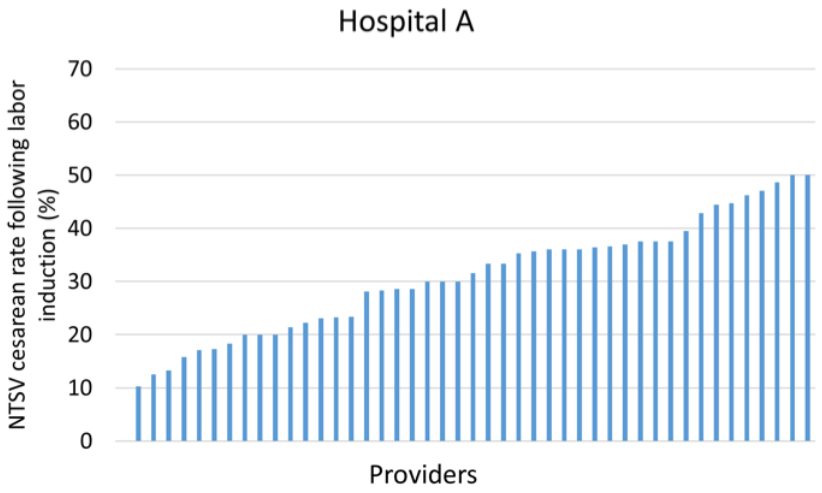


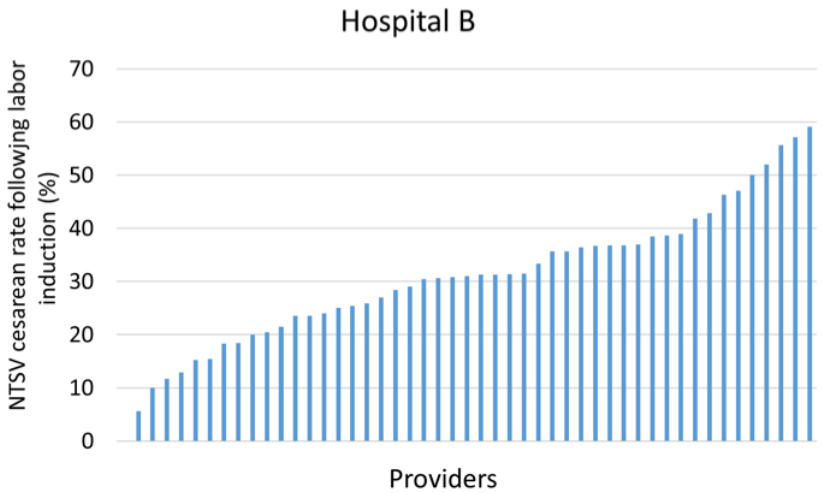
CS Rate Following Labor Induction in Lowest-Risk* Nulliparas: Large Variation Among Hospitals

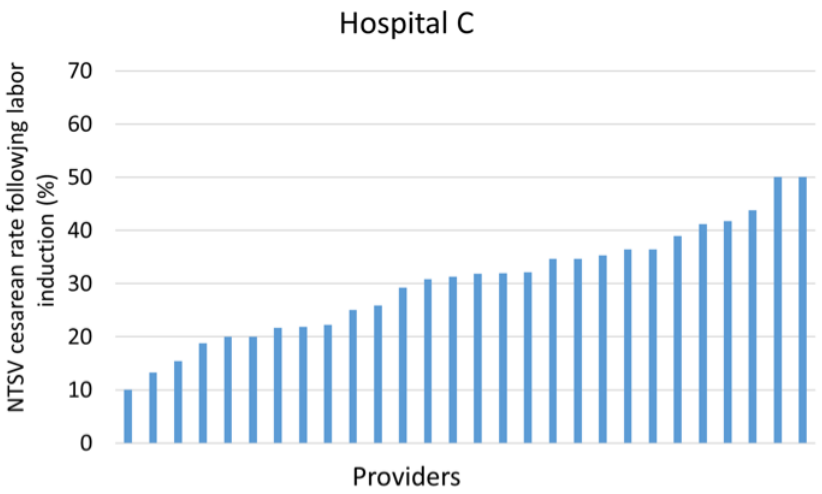


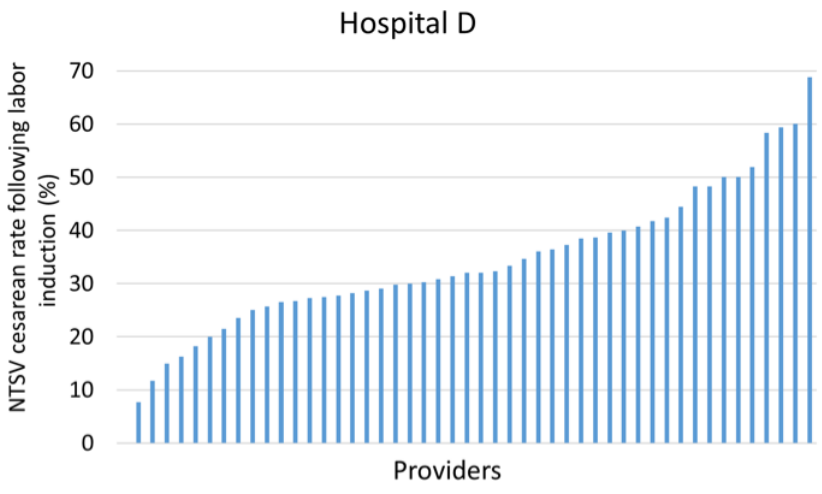
Variation in Provider Cesarean Rate After Nullip Induction

(4 hospitals without CNM or FP, only providers with >10 nullip inductions)

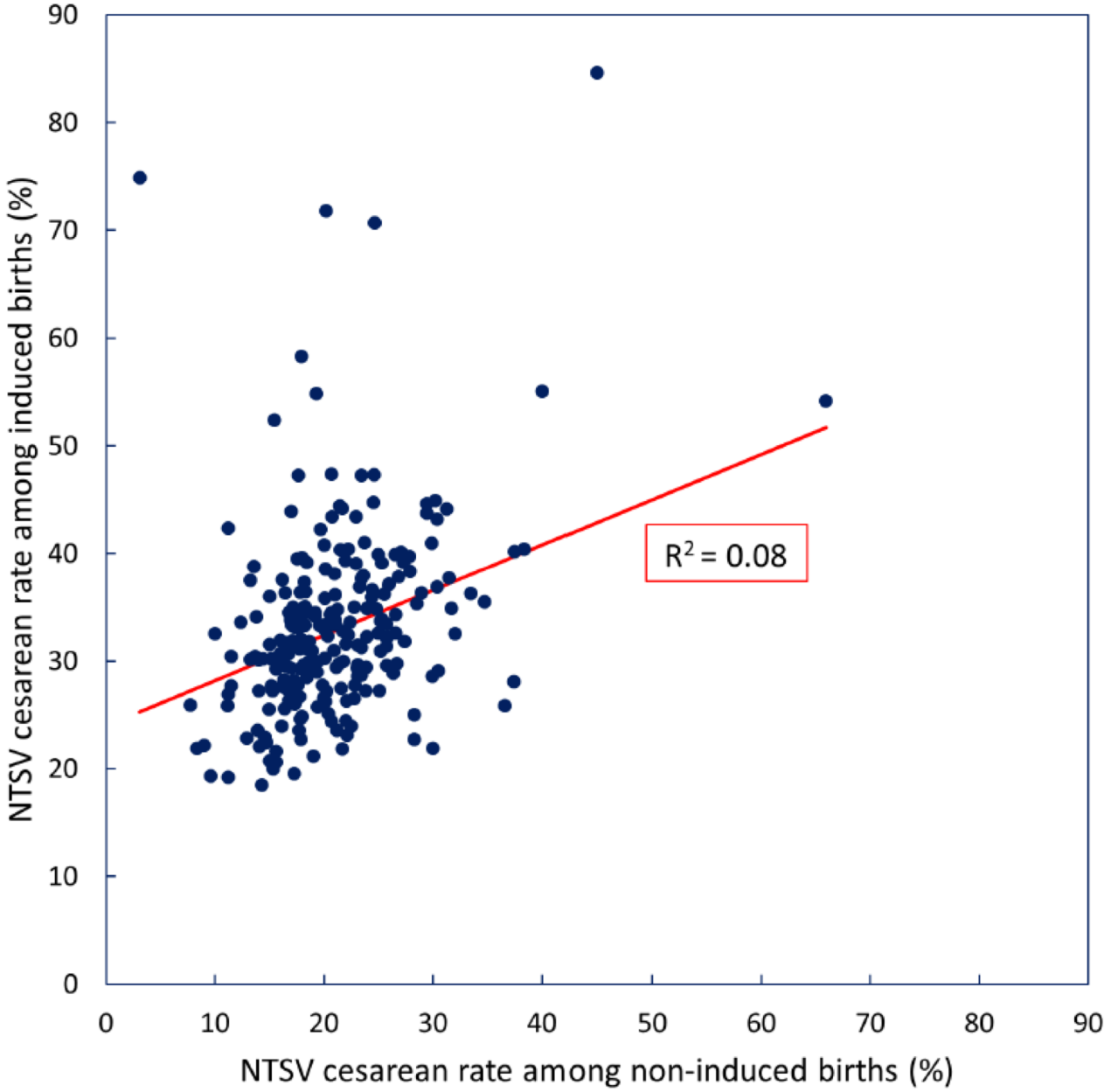






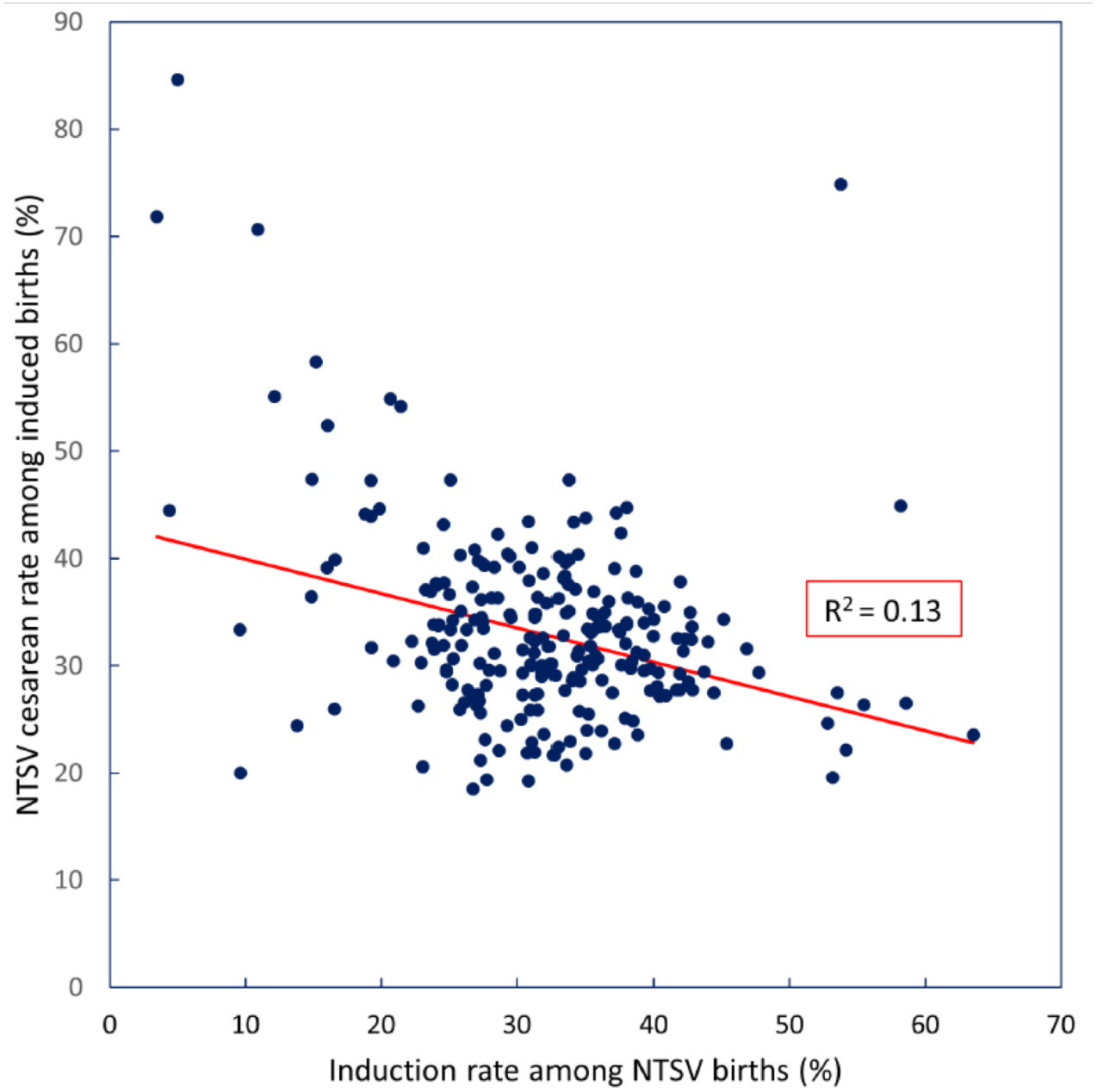


Does NTSV CS Rate Following Induction Correlate with NTSV CS Rate Among Labor Patients?



Very poor correlation, suggesting that induction management is very different than labor management

Does NTSV CS Rate Following Induction Correlate with Induction rate among NTSV Patients?



Very poor correlation, suggesting that the rate of successful vaginal delivery following induction does not improve with higher rates of induction in nullips

What to do?

QI Actions:

- Standardize labor protocols for induction of labor
- Standardize criteria for “Failed Induction”
- Highlight provider’s practices who have low CS rates after induction

Metrics: Maternal Data Center (California, Oregon, Washington)

- Follow Nulliparous CS rate after labor induction as a quality measure
- Share provider-level rates of Nulliparous CS after labor induction
- Compare Nulliparous CS rate after labor induction by race/ethnicity

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

Society for Maternal-Fetal Medicine

OBSTETRIC CARE CONSENSUS

Number 1 • March 2014

Safe Prevention of the Primary Cesarean Delivery

New National Guidelines for Defining Labor Abnormalities and Management Options

CMQCC

Table 3. Recommendations for the Safe Prevention of the Primary Cesarean Delivery

Recommendations	Grade
Induction of labor	
Before 41 0/7 weeks of gestation, induction of labor generally should be performed based on maternal and fetal medical indications. Inductions at 41 0/7 weeks of gestation and beyond should be performed to reduce the risk of cesarean delivery and the risk of perinatal morbidity and mortality.	1A Strong recommendation, high quality evide
Cervical ripening methods should be used when labor is induced in women with an unfavorable cervix.	1B Strong recommendation, moderate quality ev
If the maternal and fetal status allow, cesarean deliveries for failed induction of labor in the latent phase can be avoided by allowing longer durations of the latent phase (up to 24 hours or longer) and requiring that oxytocin be administered for at least 12–18 hours after membrane rupture before deeming the induction a failure.	1B Strong recommendation, moderate quality ev

Safe prevention of the primary cesarean delivery. Obstetric Care Consensus No. 1. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:693–711.

Defining Failed Induction of Labor

Grobman et al Am J Obstet Gynecol 2018;218:122.e1-8.

- MFMU Network: 10,677 women who were induced
  - 96% of women entered active phase when:
  - Cervical ripening complete
  - ROM
  - And,15 hours of oxytocin
- No clinical fetal or maternal harm with this length of latent phase
- Limitation: Analysis not limited to nullips or term

What to do?

QI Actions:

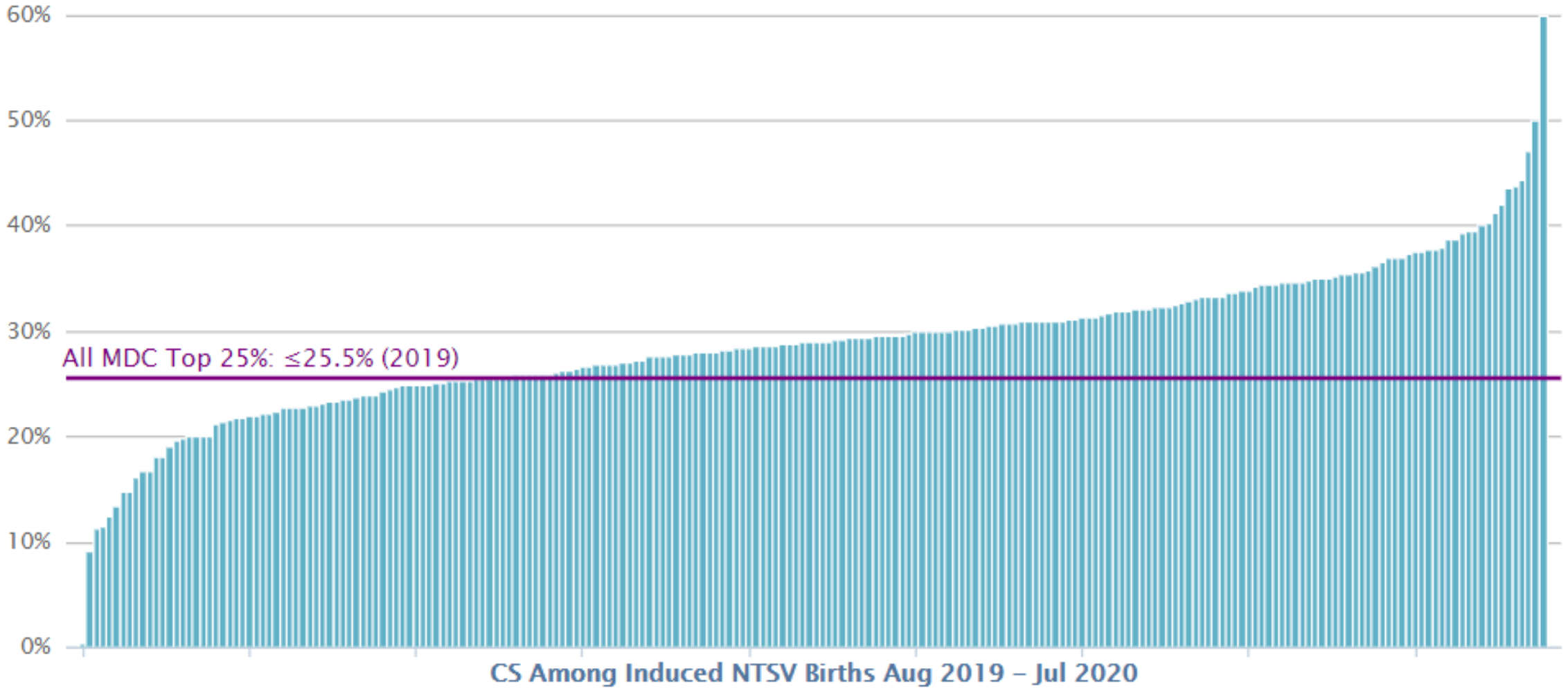
- Standardize labor protocols for induction of labor
- Standardize criteria for “Failed Induction”
- Highlight provider’s practices who have low CS rates after induction

Metrics: Maternal Data Center (California, Oregon, Washington)

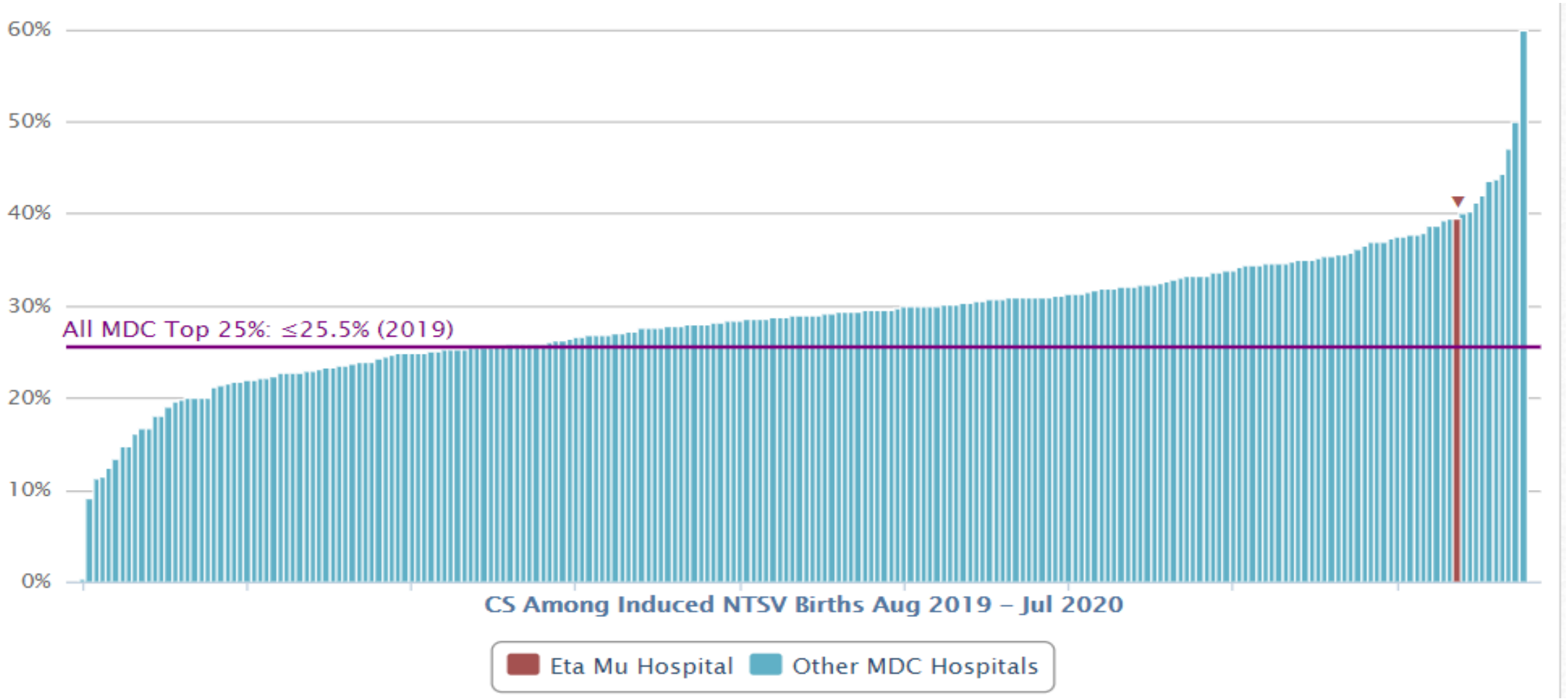
- Follow Nulliparous CS rate after labor induction as a quality measure
- Share provider-level rates of Nulliparous CS after labor induction
- Compare Nulliparous CS rate after labor induction by race/ethnicity

CS after Labor Induction Varies Greatly Across Hospitals

MDC Data for All CA Hospitals for Last 12 Months

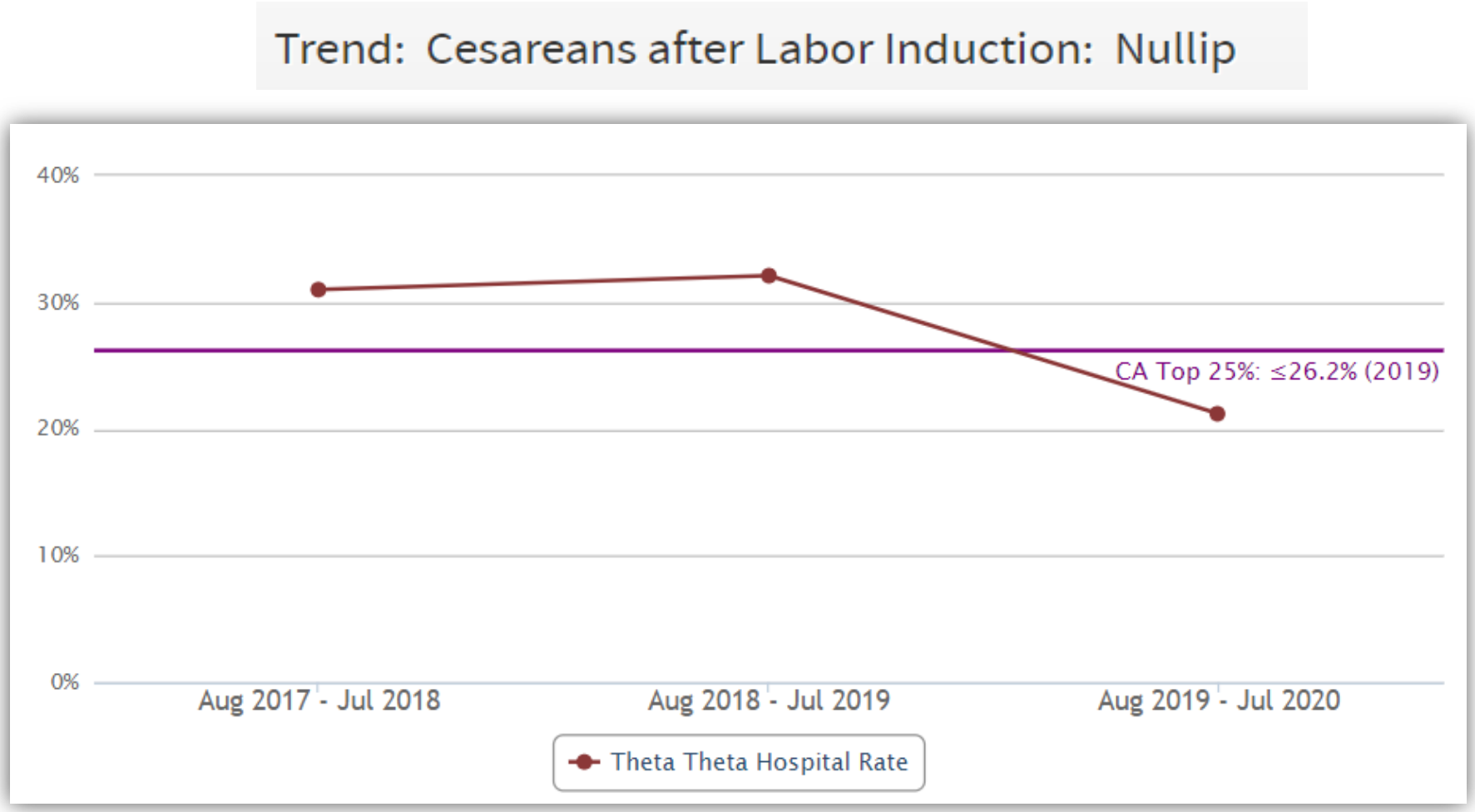


Where stands my hospital?



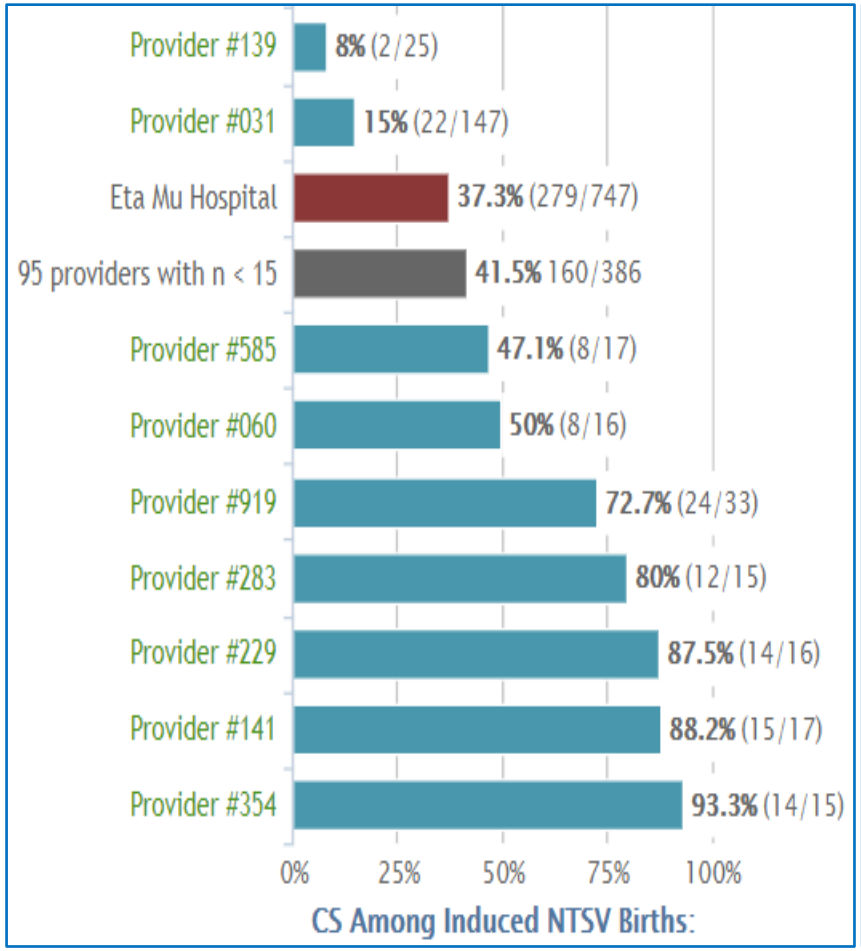
MDC Steps: Landing Page / Hosp. Clinical Performance Measures / Cesareans after Labor Induction: Nullip / In Left Sidebar: All Hospitals

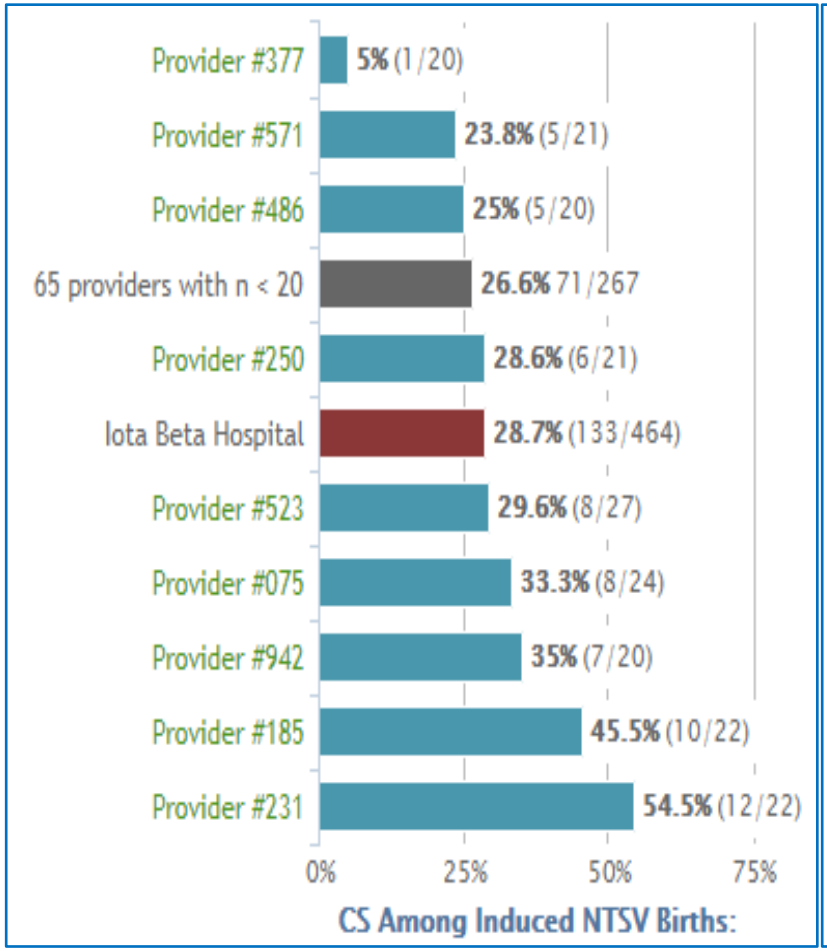
Track Progress over Time

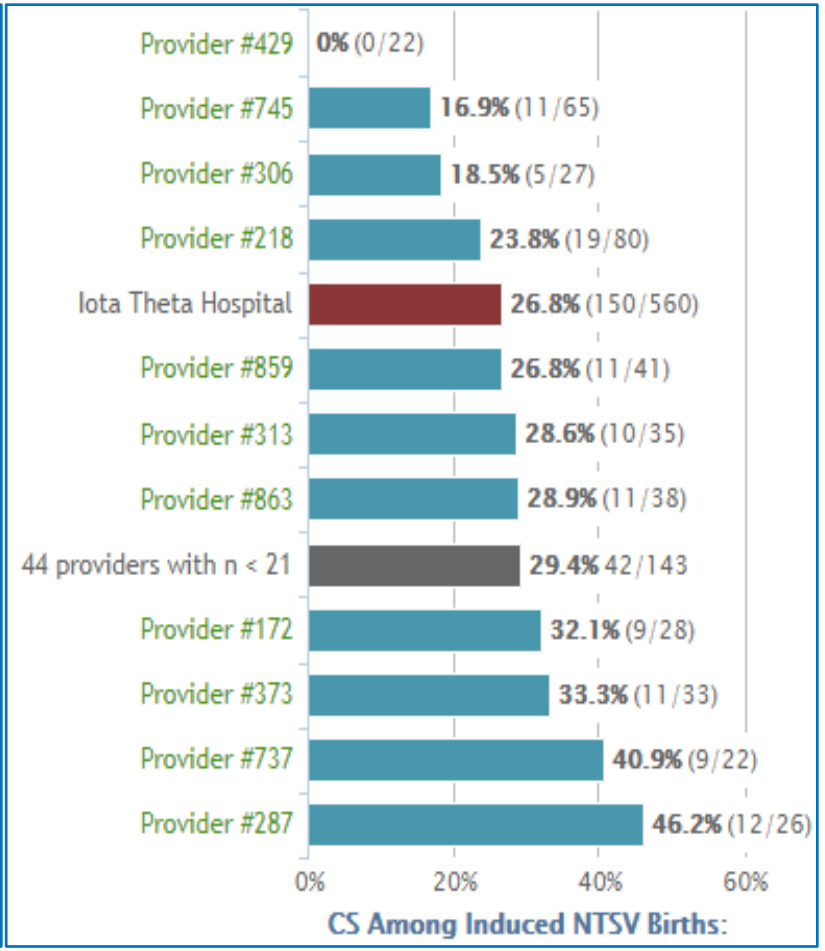


MDC Steps: Landing Page / Hosp. Clinical Performance Measures / Cesareans after Labor Induction: Nullip / In Left Sidebar: Trend Line

In-Hospital Variation among Providers







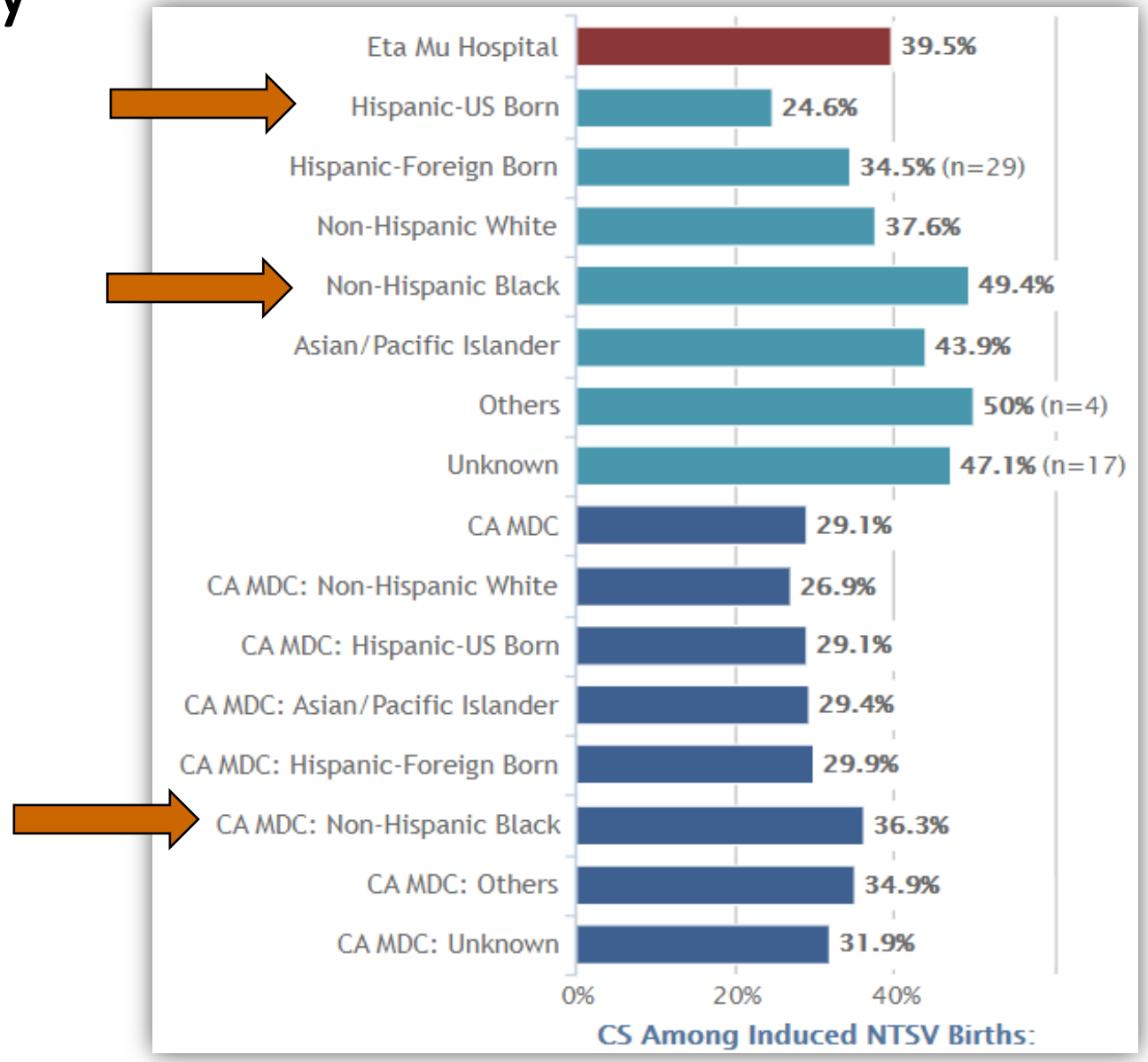
MDC Steps: Landing Page / Provider Performance Measures / Click Column Label “CS among NTSV Induced Births”

Variation by Race/Ethnicity

Compare differences within your hospital

Why does the care provided differ so dramatically:

- Compared to other patients cared for at hospital?
- Compared to state averages?



MDC Steps: Landing Page / Hospital Clinical Performance Measures / Cesareans after Labor Induction: Nullip / In Left Sidebar: By Race/Ethnicity

Keys for Induction Success

- Who you choose
  (parity and cervical ripeness)
- How you perform the induction
- Follow your success rates!

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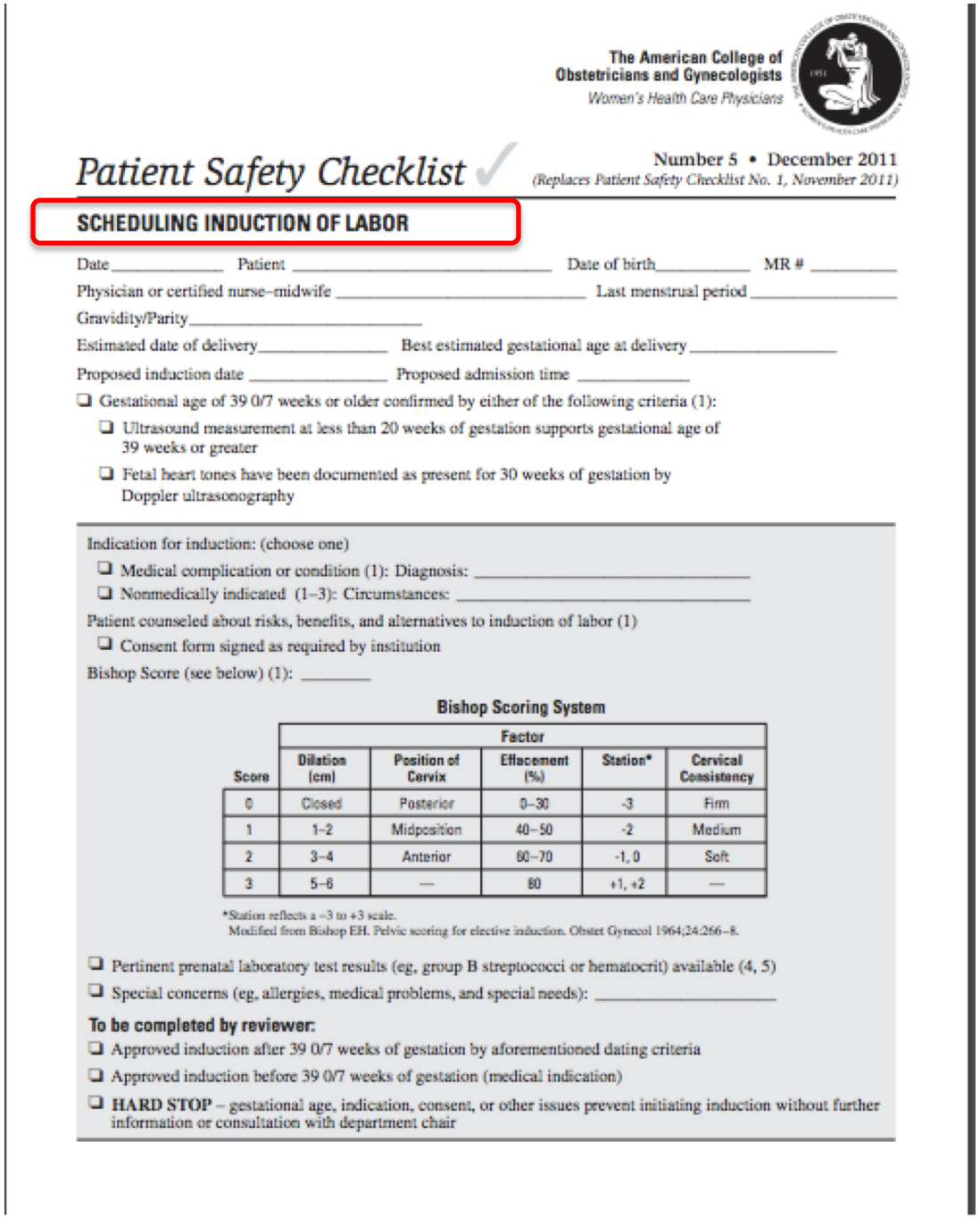
The Dilemma: Can we meet the increased demand for induction of labor without causing a significant financial and safety issues for our institutions?



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/ Rational Planning for "Induction Capacity"

Critiquing a Failed Induction

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

Defining Failed Induction

- Nulliparous women remaining in the latent phase for 12 hours compared with women who had exited the latent phase had significantly increased rates of chorioamnionitis (12.1% compared with 4.1%) and endometritis (3.6% compared with 1.3%) and increased rates of neonatal intensive care unit admission (8.7% compared with 6.3%).
- Similar patterns were present for multiparous women at 15 hours.
- ***With ruptured membranes a latent phase (obtaining 6 cm) after initiation of oxytocin of at least 12 hours for nulliparous women and 15 hours in multiparous women is a reasonable criterion for diagnosing a failed induction***

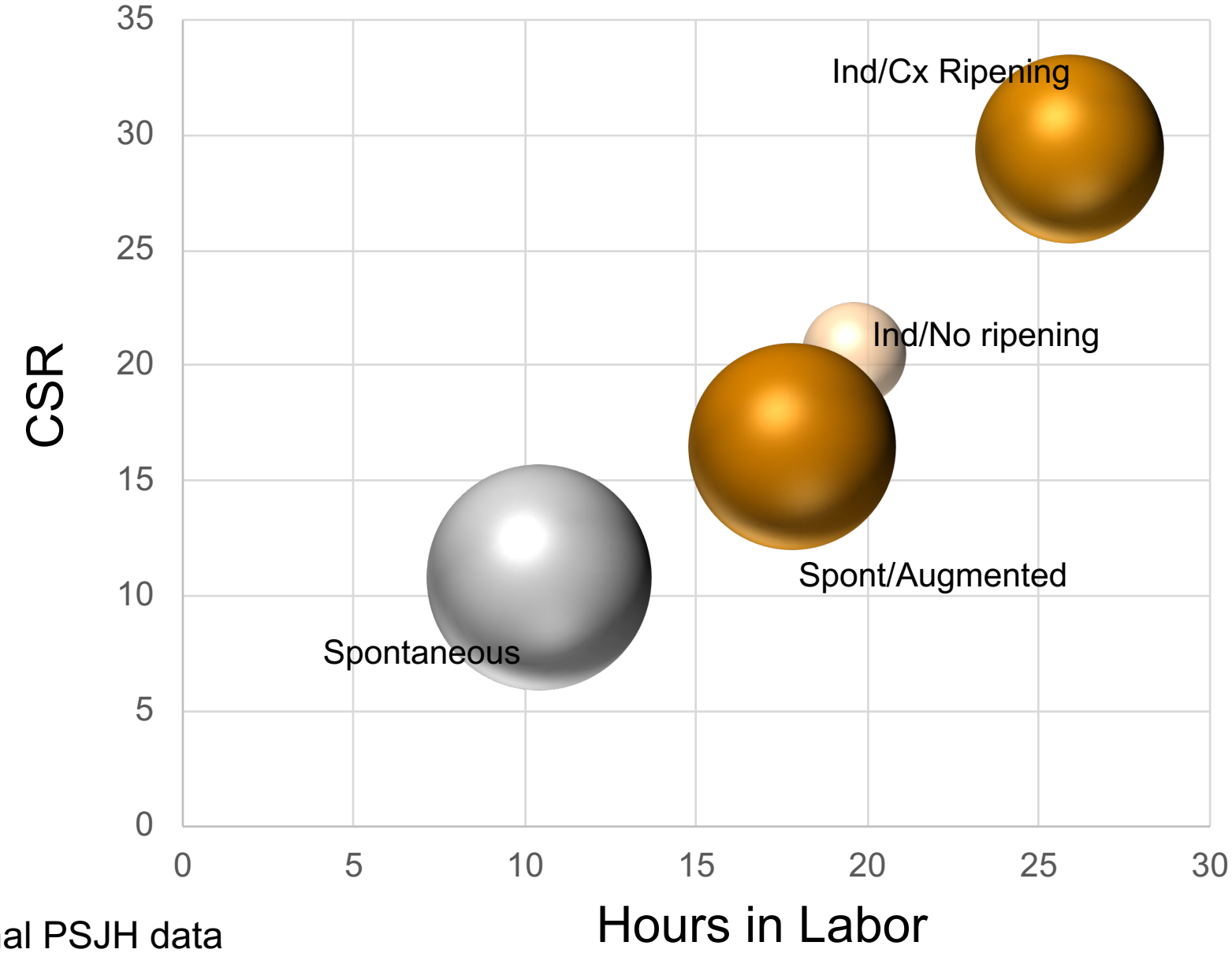
Kawakita T et al. . Obstet Gynecol. 2016 Aug;128(2):373-80.

At what GA should we induce?

- Gestational age (39 vs. 40 wks) lowers CSR by (≈3-4%)
- Type of labor (spontaneous vs. induced) (≈10-15%)
- Centimeters on admission (≈10-15%)

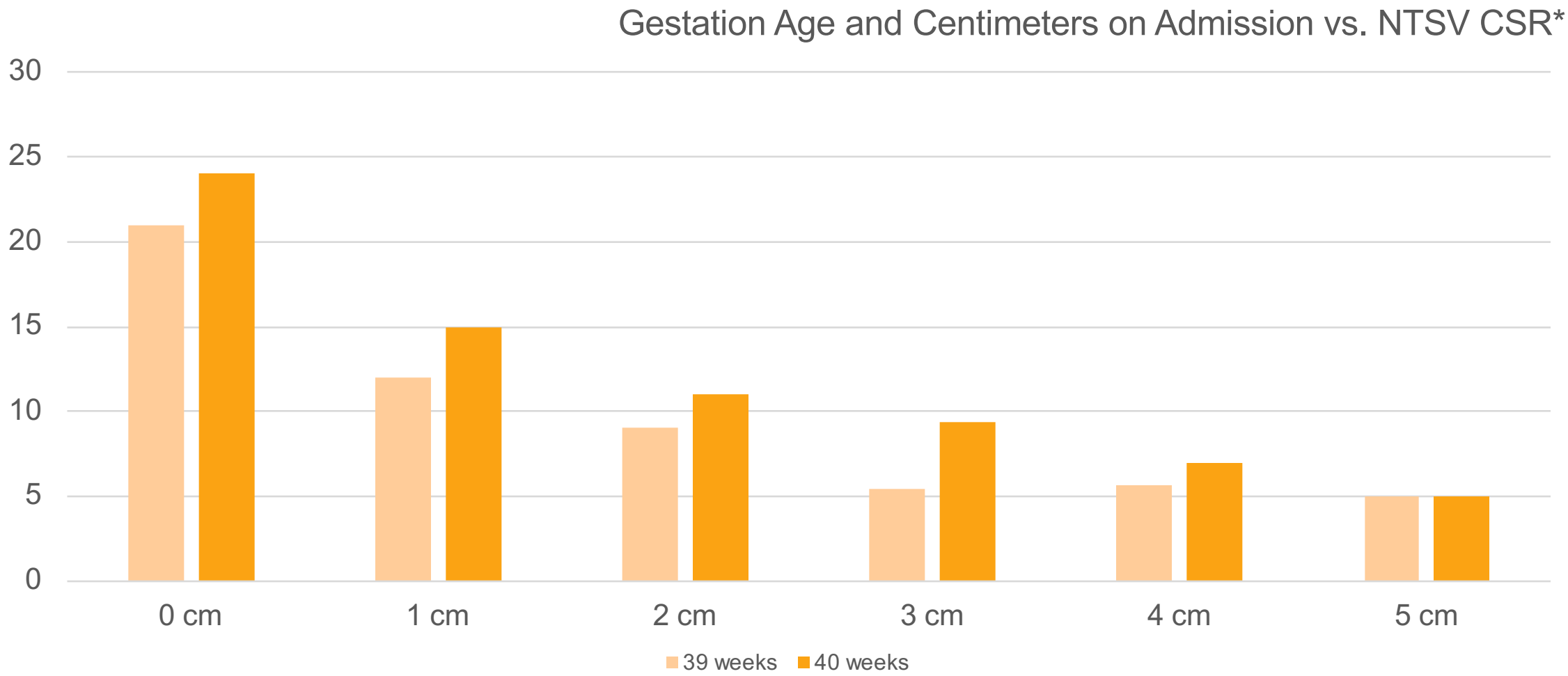
- Therefore: *Consider schema for inductions of attempting to only start induction oxytocin with ripe cervix, proceeding with induction in unripe cervix until 40 3/7th weeks to allow as many spontaneous labors as possible. Use outpatient cervical ripening to avoid resource overload on labor and delivery.*

NTSV: Hours in Labor and CSR



* Source internal PSJH data

Admission Dilation has Greatest Impact



* Source internal PSJH data

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.

ARRIVE Trial Technique

TABLE 4
Delivery admission resource utilization stratified by randomized group assignment

Variables	Induction of labor (n = 3059)	Expectant management (n = 3037)	*P* value	RR (95% CI)
Maternal				
Labor and delivery duration, d	0.83 (0.53, 1.2)	0.57 (0.37, 0.85)	< .001	—
Cervical ripening	62.8	28.7	< .001	2.19 (2.06–2.33)
Oxytocin infusion	84.5	73.3	< .001	1.15 (1.12–1.18)
Intrauterine pressure catheter	41.8	36.6	< .001	1.14 (1.07–1.21)

TABLE 7
Absolute differences per 1000 women in types of resources that significantly differed between groups

Ripening agent	846	370	476
Balloon catheter	404	186	218
Laminaria	1	0	1
Cervidil	62	23	39
PGE1 or gel	378	161	218
Oxytocin infusion	845	733	112
Intrauterine pressure catheter	418	366	52

GROBMAN ET AL AM J OBSTET GYNECOL 222;4, P369.E1-369.E11, APRIL 01, 2020

Rationale of Outpatient Cervical Ripening

1. Mechanical methods as effective with respect to achieving ripeness and cesarean delivery rates in controlled studies
2. Balloon ripening can be used outpatient since tachysystole is not associated
3. Better experience comes from patients having less cramping and not spending the night in the hospital
4. Less cost since monitoring and nursing care not used for 8-12 hours while awaiting ripening of the cervix

41

What if outpatient?

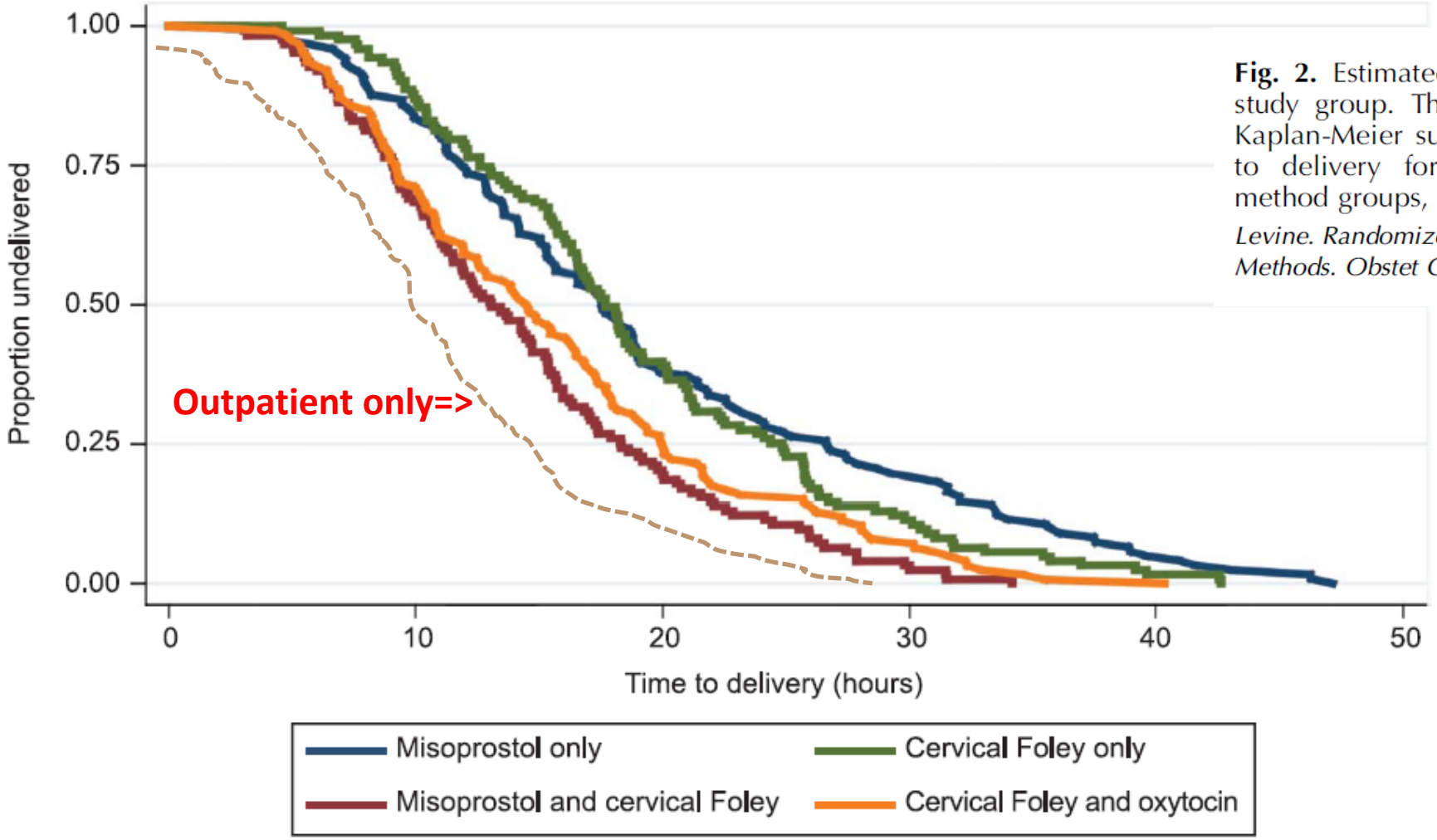


Fig. 2. Estimated time to delivery by study group. This figure displays the Kaplan-Meier survival curves for time to delivery for the four induction method groups, $P<.001$.

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

Adverse Event Frequency

Table 2. Adverse events during cervical ripening phase time frame with a transcervical balloon catheter

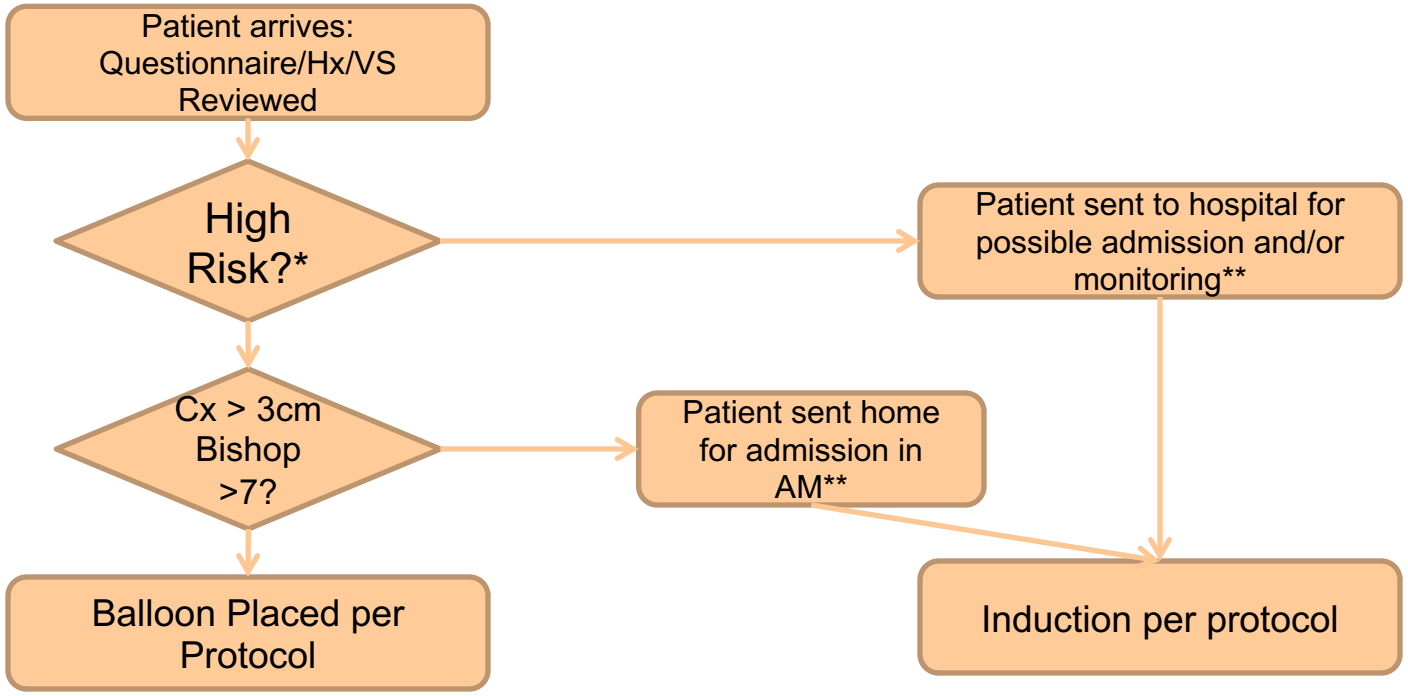
Adverse events	No. of studies reporting on adverse event (Total sample size)	Occurrence of AE in ripening period	Reference numbers of studies that report on occurrence of AE in ripening period
Pain, discomfort	17 (5754)*· ***	31***	10,14–17,22
Unintended amniotomy	12 (2989)	19	18,19
Vaginal bleeding	18 (6566)*	18**	7,10,15,17–22,37
Balloon displacement	10 (2397)	12	8,9,20,37
Non-reassuring fetal heart rate	17 (5351)	15	9,18,19,23,24
Allergic reaction	16 (6832)	2	15,20
Voiding problems	10 (3522)*	2	10
Balloon rupture	12 (3222)*	1	10
Uterine hypertonus	14 (3707)	1	7
Uterine hyperstimulation	20 (4812)	1	23
Decreased fetal movements	11 (4318)*	1	10
Malpresentation	16 (6046)	4	24,25,33
Intrapartum infection	15 (5023)	0	–
Placental abruption	16 (6154)*	0	–
Uterine tachysystole	19 (4450)	0	–
Uterine rupture	23 (7916)	0	–
Cord prolapse	21 (6960)	0	–
Fetal death	24 (8189)	0	–
Maternal death	22 (6875)	0	–
Genital laceration	13 (4420)	0	–

AE, adverse event; DBC, double balloon catheter.
*Kruit et al.[10]: only data for outpatient group on this adverse events.
**de Oliveira e Oliveira et al.[17]: one women with vaginal bleeding, this woman was excluded from their analysis but included in this review. The sample size of the intention-to-treat was maintained.
***Salim et al.[16]: only data for DBC group on this adverse event; one women with discomfort in the DBC group, this woman was excluded from their analysis but included in this review. The sample size of the intention-to-treat was maintained.

Event	
Pain	**1:185**
Bleeding	**1:364**
Rupture of Membrane	**1:157**
NRFHR	**1:365**
Uterine Hypertonus	**1:3,707**
Tachysystole	**1:4,812**
Fetal Death	**0:8189**

Diederen,M., et al BJOG 2018; 125:1086-95.

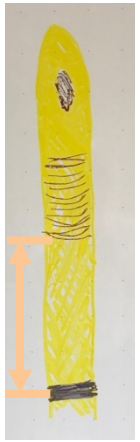
In Office Balloon Placement

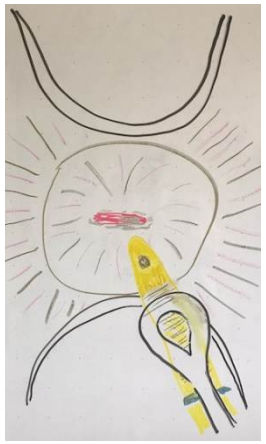


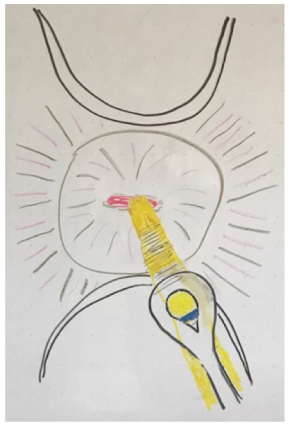
*Positive questionnaire, abnormal vital signs or history (Preeclampsia, Premature Rupture of Membranes, Equivocal AP Testing, Oligohydramnios, etc.)

** Patients admitted into hospital, if no prior uterine surgery or other complication consider combination cervical ripening with misoprostol and foley catheter balloon

Mark

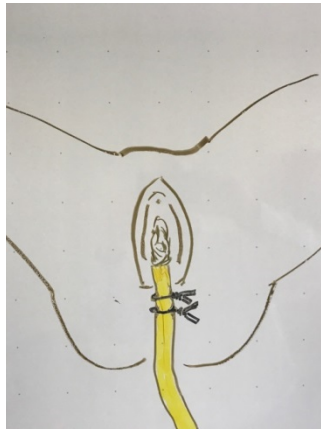


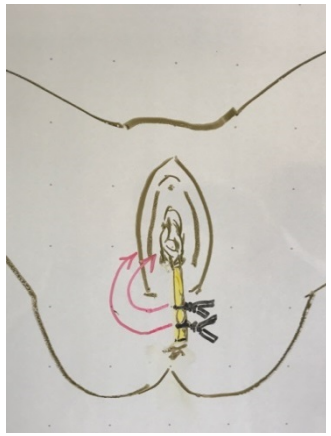




Place thru cervical canal

Inflate balloon
Tie off catheter at vaginal entrance





Cut off Foley Tail
Tuck into vagina

Lessons Learned From Experience

- Majority of patients can have balloon placed/ stenosis rare
- Proper placement above internal os has very good success
- No fetal monitoring needed since no tachysystole risk, monitoring only for other indications
- If inpatient for monitoring you can use misoprostol or oxytocin and Foley balloon concurrently
- Only about 5% come in labor before morning
- Balloon usually sitting in vagina in the morning, can have induction started if balloon not expelled
- Patients much happier with the process and less tired since slept at home
- Relieves significant burden on L&D Staff and Physicians

Thank You!

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