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California Maternal
Quality Care Collaborative

# Lowering NTSV CSR: Lessons from the West Coast 2020

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# Disclosure

The presenter has no financial disclosures to report

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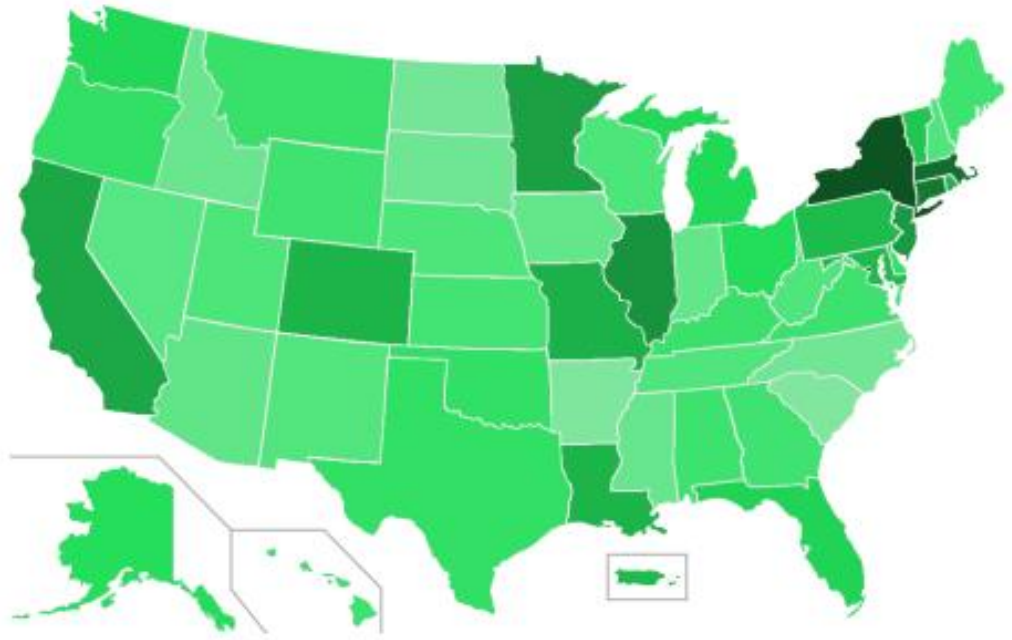
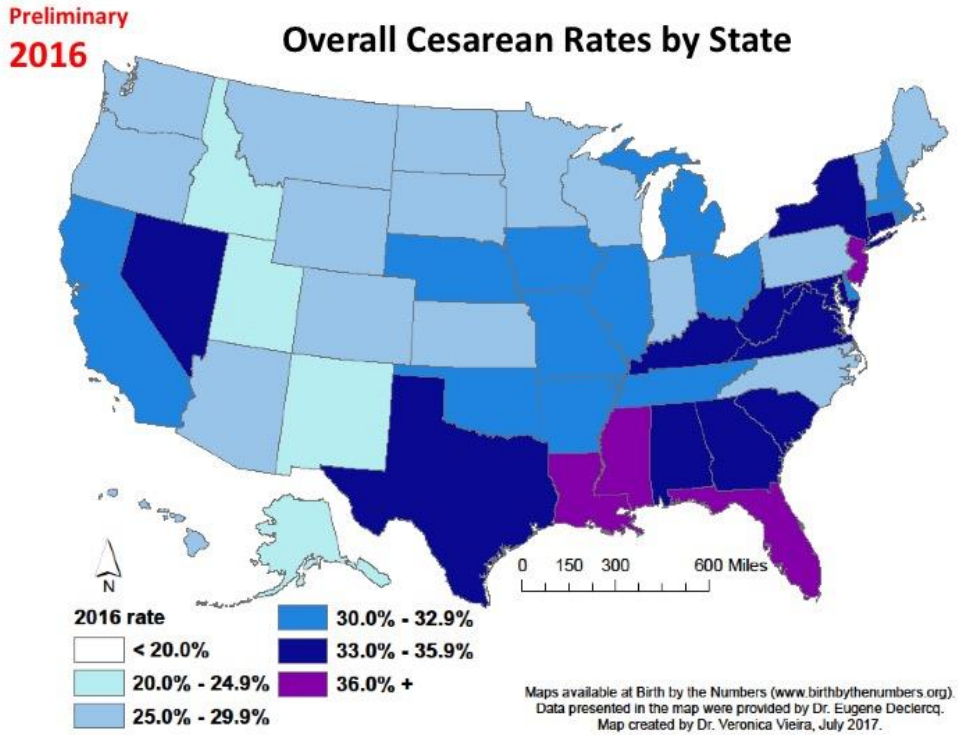
# Lesson 1: NTSV CSRs Vary by Hospital but Success is Possible

| NO. OF LAWYERS PER CAPITA BY STATE (2013) | | | | |
|---|---|---|---|---|
| Rank | State | Population | Lawyers | Lawyers Per 10,000 Residents |
| 1. | D.C. | 646,449 | 51,928 | 803.28 |
| 2. | New York | 19,651,127 | 166,317 | 84.63 |
| 3. | Massachusetts | 6,692,824 | 43,008 | 64.26 |
| 4. | Connecticut | 3,596,080 | 21,150 | 58.81 |
| 5. | Illinois | 12,882,135 | 62,496 | 48.51 |
| 6. | New Jersey | 8,899,339 | 40,993 | 46.06 |
| 7. | Minnesota | 5,420,380 | 24,091 | 44.45 |
| 8. | California | 38,332,521 | 163,163 | 42.57 |
| 9. | Missouri | 6,044,171 | 24,423 | 40.41 |
| 10. | Louisiana | 4,625,470 | 18,528 | 40.06 |

# Lawyers versus CS per Capita

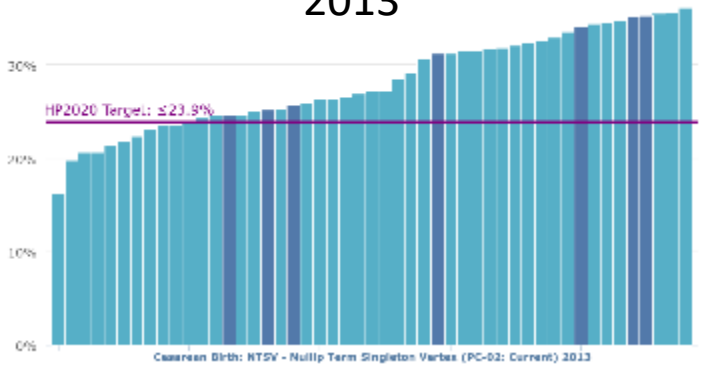




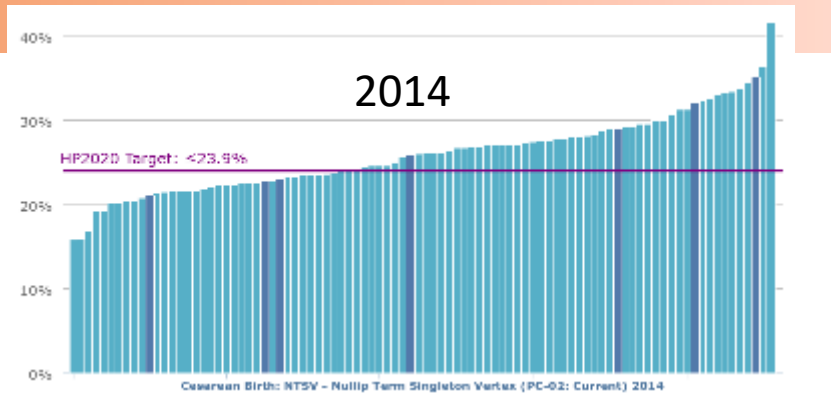

## But you need to check your zip code!

# The California Journey

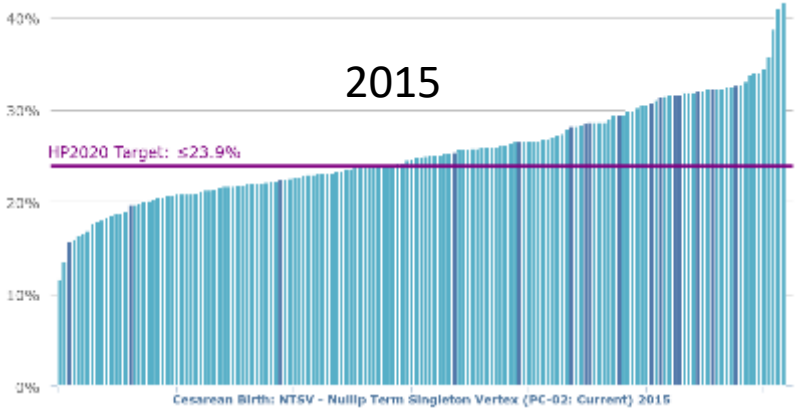
2013



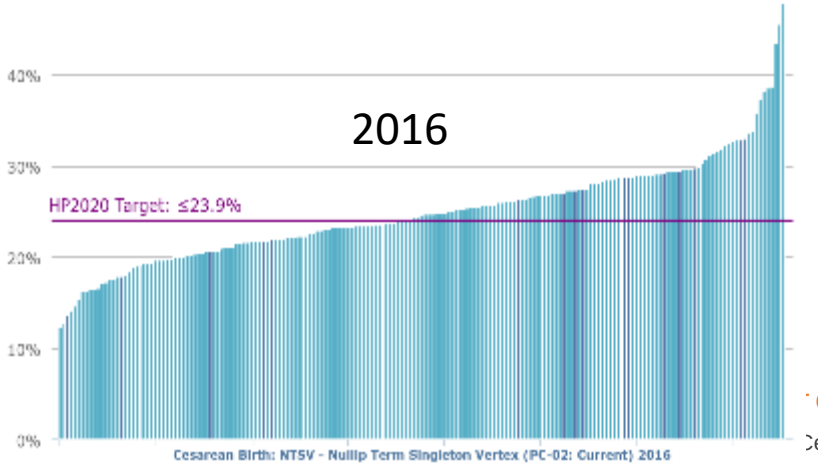

2014



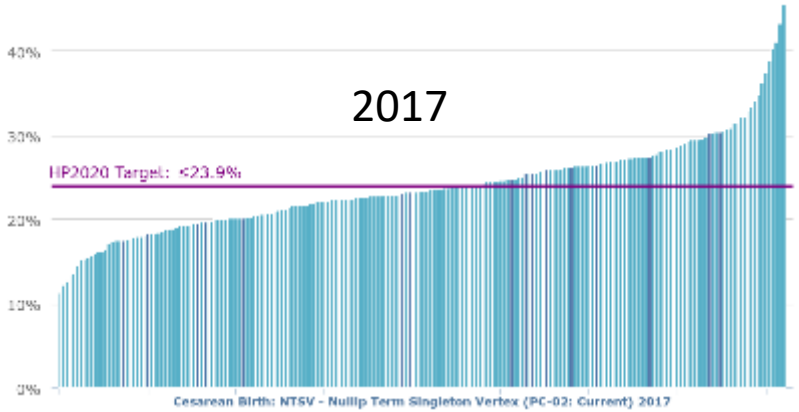

2015



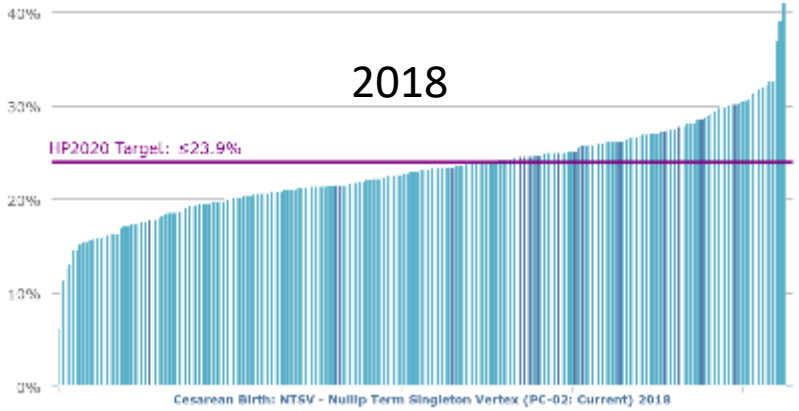

2016



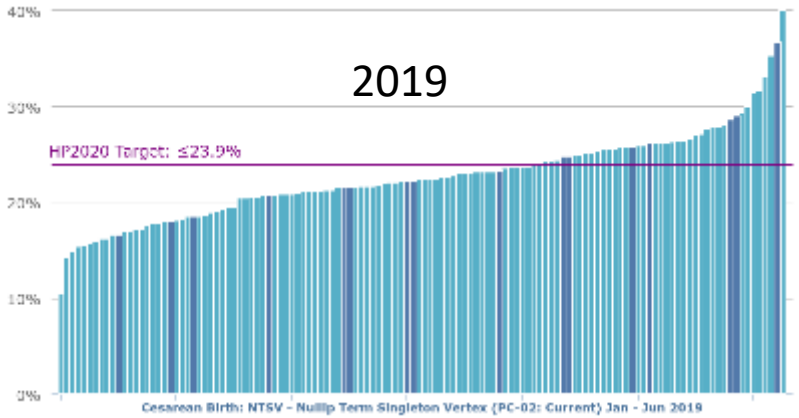

2017

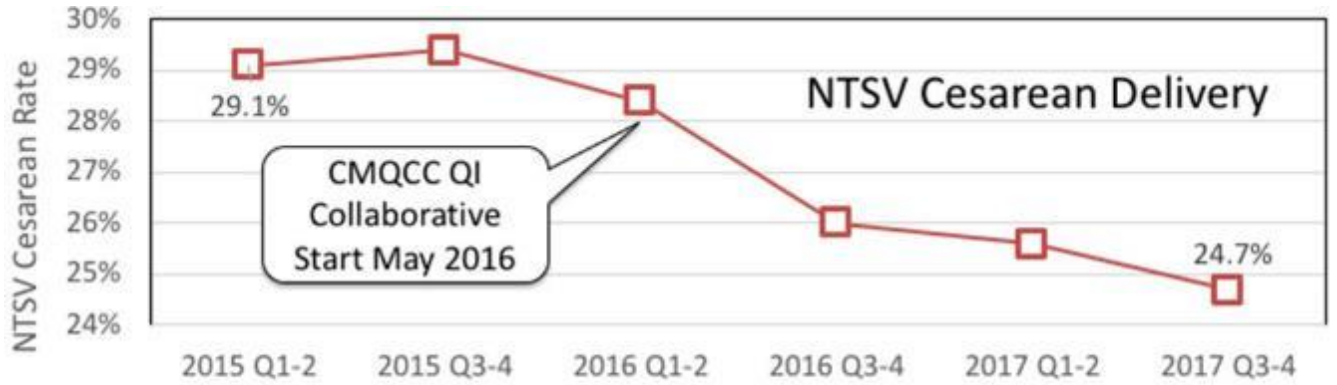


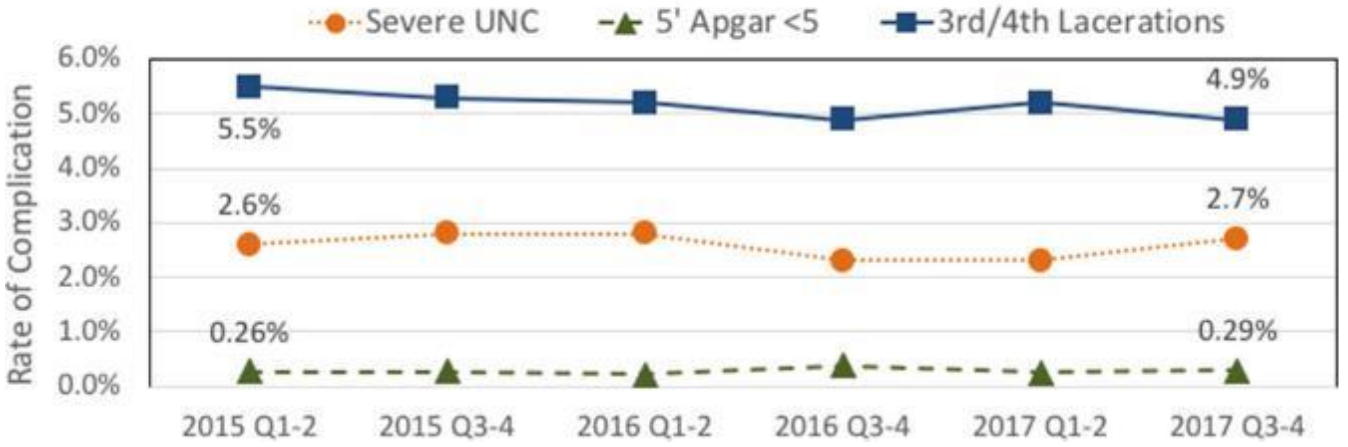

2018




2019






Main et al SMFM 2019, 46 hospitals met inclusion criteria with a mix of hospital types: university, community, and integrated health system; and high, medium and small delivery volume. They included an annual average of 115,000 births (of which 35% were NTSV).

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# Lesson 2: Individual Providers have as much variation as individual hospitals

# Lowering the cesarean section rate in a private hospital: comparison of individual physicians' rates, risk factors, and outcomes.

**STUDY DESIGN:**

We retrospectively reviewed detailed computerized delivery records (n = 16,230) collected from May 16, 1988, to July 30, 1995. We excluded physicians who had <100 deliveries at our institution during the study period. The physicians were divided into two groups depending on whether their individual cesarean section rates were greater than (control group) or less than 15% (target group). Various cesarean section rates, risk factors for abdominal delivery, labor management techniques, and neonatal outcome parameters were calculated for each group. The cesarean section rates of the two groups were analyzed by year to assess changes.

**RESULTS:**

As expected by study design, the overall cesarean section rate was markedly different between the two groups (13.8% vs

To the point: "Individual physician's lower cesarean sections are primarily obtained by labor management and attempting vaginal birth after cesarean delivery. These practice patterns did not appear to lead to any increase in perinatal morbidity or mortality."

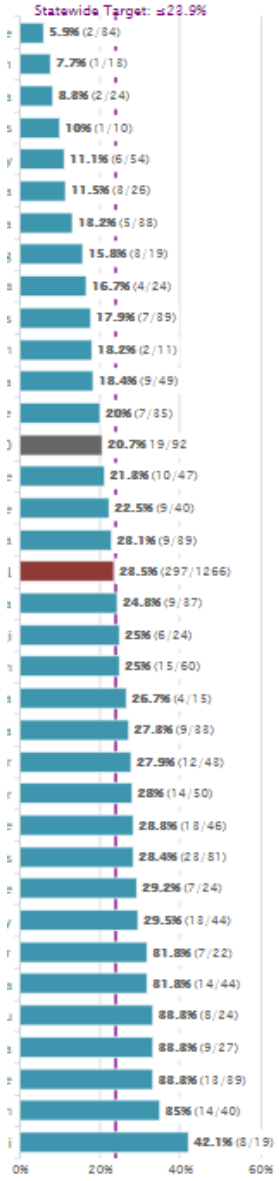
more epidural anesthesia, oxytocin induction, and trial vaginal births after cesarean delivery and more successful trial vaginal births after cesarean sections. Over the study period the cesarean section rate in the target group remained unchanged, whereas it steadily declined in the control group.

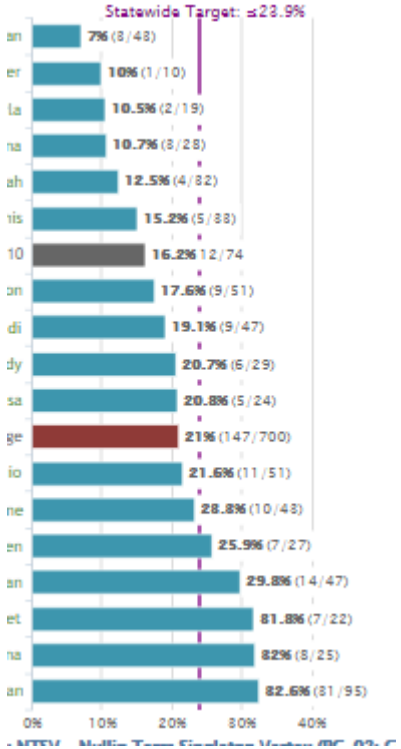
**CONCLUSIONS:**

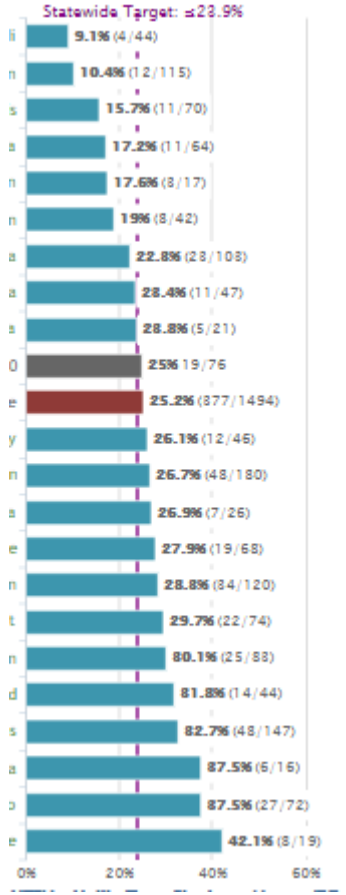
Individual physician's lower cesarean sections are primarily obtained by labor management and attempting vaginal birth after cesarean delivery. These practice patterns did not appear to lead to any increase in perinatal morbidity or mortality.

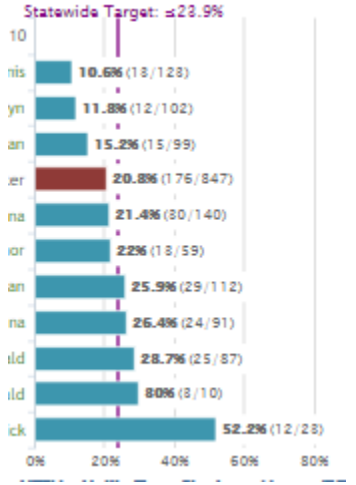
Lagrew and Adashek. Am J Obstet Gynecol. 1998 Jun;178(6):1207-14.

# Physicians Variation is Also Present

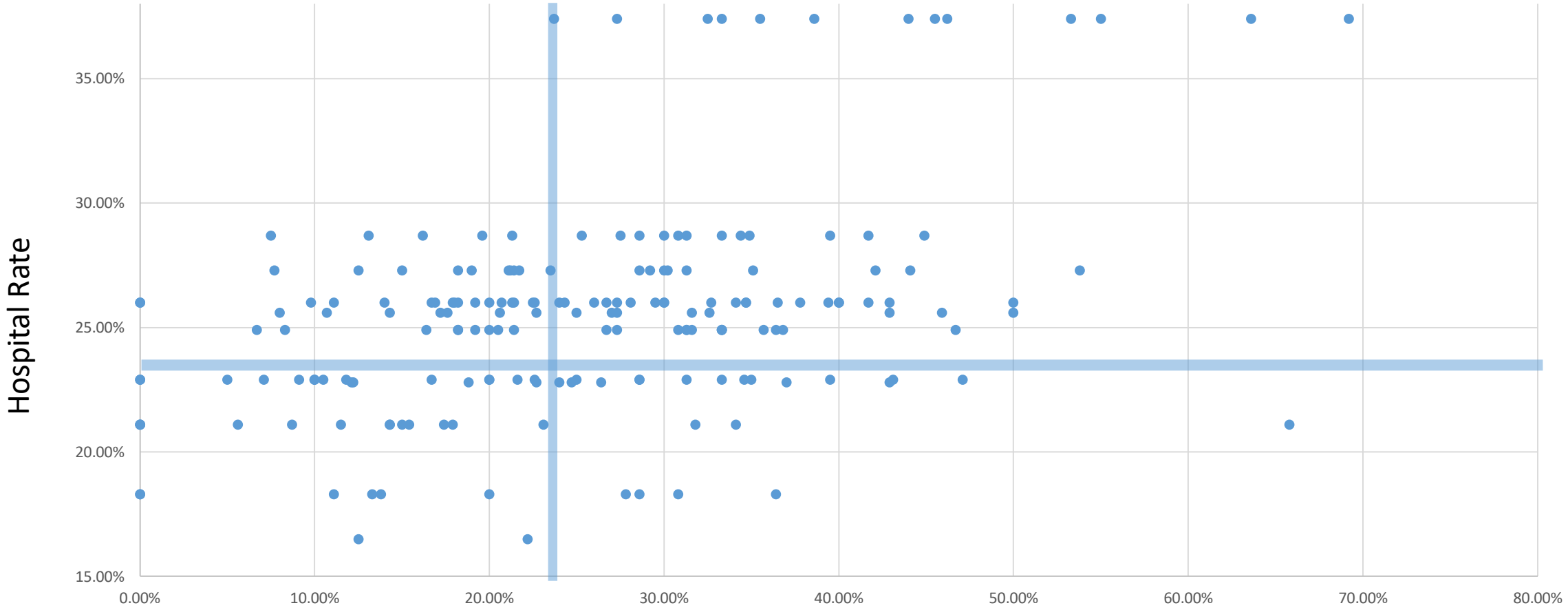


# Breaking Down Hospital Rates by Physician Rates

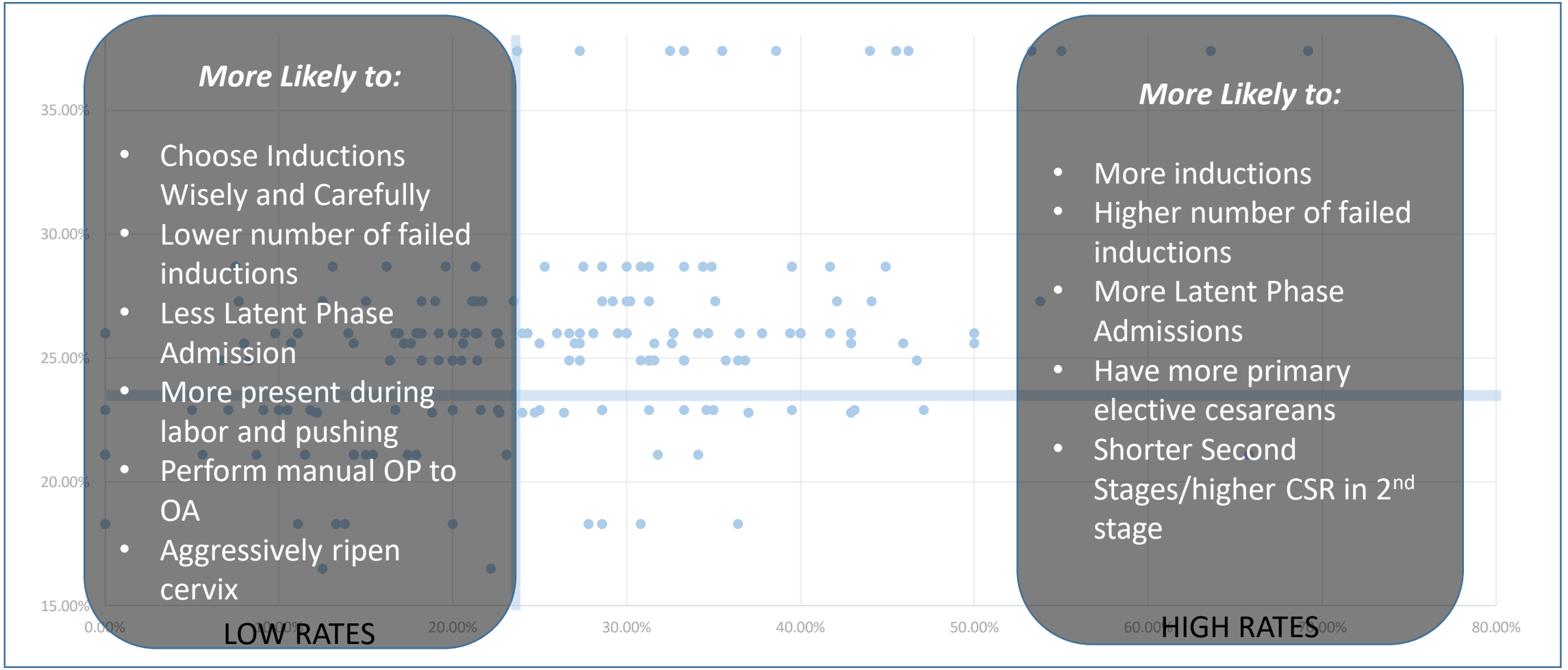



Transforming Maternity Care

A Toolkit to Support Vaginal Birth and Reduce Primary Cesareans

11 Hospitals, 1st 7 months of 2019

# How Do They Get Lower Rates?






11 Hospitals, 1st 7 months of 2019

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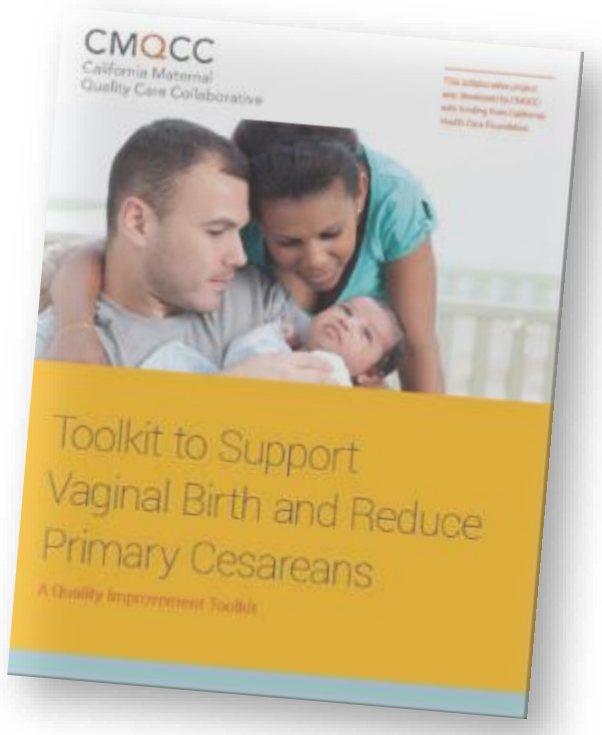
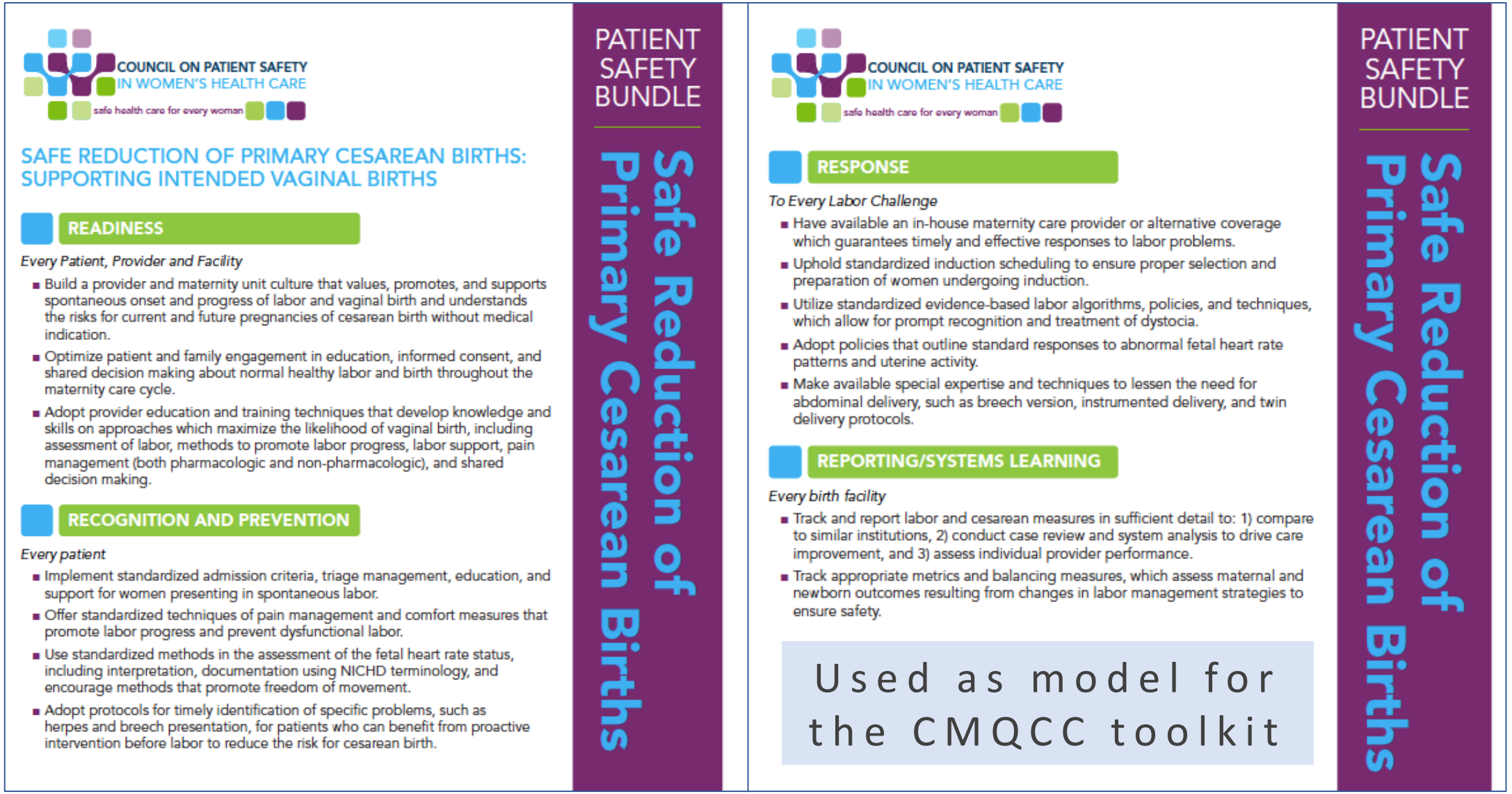
# Lesson 3: Following Guidelines Helps: Why reinvent when others have had success

# The CMQCC Toolkit

- Comprehensive, evidence-based "How-to Guide" to reduce primary cesarean delivery in the NTSV population
- Will be the resource foundation for the CA QI collaborative project
- The principles are generalizable to all women giving birth
- Released on the CMQCC website April 28, 2016
- Has a companion *Implementation Guide*



# National Cesarean Reduction Bundle



COUNCIL ON PATIENT SAFETY IN WOMEN'S HEALTH CARE
safe health care for every woman

## SAFE REDUCTION OF PRIMARY CESAREAN BIRTHS: SUPPORTING INTENDED VAGINAL BIRTHS

### READINESS

*Every Patient, Provider and Facility*

- Build a provider and maternity unit culture that values, promotes, and supports spontaneous onset and progress of labor and vaginal birth and understands the risks for current and future pregnancies of cesarean birth without medical indication.
- Optimize patient and family engagement in education, informed consent, and shared decision making about normal healthy labor and birth throughout the maternity care cycle.
- Adopt provider education and training techniques that develop knowledge and skills on approaches which maximize the likelihood of vaginal birth, including assessment of labor, methods to promote labor progress, labor support, pain management (both pharmacologic and non-pharmacologic), and shared decision making.

### RECOGNITION AND PREVENTION

*Every patient*

- Implement standardized admission criteria, triage management, education, and support for women presenting in spontaneous labor.
- Offer standardized techniques of pain management and comfort measures that promote labor progress and prevent dysfunctional labor.
- Use standardized methods in the assessment of the fetal heart rate status, including interpretation, documentation using NICHD terminology, and encourage methods that promote freedom of movement.
- Adopt protocols for timely identification of specific problems, such as herpes and breech presentation, for patients who can benefit from proactive intervention before labor to reduce the risk for cesarean birth.

PATIENT SAFETY BUNDLE

Safe Reduction of Primary Cesarean Births

COUNCIL ON PATIENT SAFETY IN WOMEN'S HEALTH CARE
safe health care for every woman

### RESPONSE

*To Every Labor Challenge*

- Have available an in-house maternity care provider or alternative coverage which guarantees timely and effective responses to labor problems.
- Uphold standardized induction scheduling to ensure proper selection and preparation of women undergoing induction.
- Utilize standardized evidence-based labor algorithms, policies, and techniques, which allow for prompt recognition and treatment of dystocia.
- Adopt policies that outline standard responses to abnormal fetal heart rate patterns and uterine activity.
- Make available special expertise and techniques to lessen the need for abdominal delivery, such as breech version, instrumented delivery, and twin delivery protocols.

### REPORTING/SYSTEMS LEARNING

*Every birth facility*

- Track and report labor and cesarean measures in sufficient detail to: 1) compare to similar institutions, 2) conduct case review and system analysis to drive care improvement, and 3) assess individual provider performance.
- Track appropriate metrics and balancing measures, which assess maternal and newborn outcomes resulting from changes in labor management strategies to ensure safety.

Used as model for the CMQCC toolkit

PATIENT SAFETY BUNDLE

Safe Reduction of Primary Cesarean Births

Which are “a walk in the park”, “rolling hills” or “climbing mountains”?

# Walk in the Park

- Adopt provider education
- Standardized pain management
- Track outcomes and balancing measures (for many on electronic systems)

# Rolling Hills

- Provider and unit culture which values and promotes vaginal birth
- Optimizing patient and family engagement in education, informed consent and shared decision making
- Standardized response to FHR abnormalities
- Timely identifications of specific problems such as herpes, breech, etc.
- Available in-house maternity care
- Special expertise for special conditions, e.g. breech version
- Track and report labor and cesarean in specific detail, assess individual performance

# Mountains to Climb

- Implement standard admission criteria, triage management for spontaneous labor
- Uphold standardized induction scheduling, proper selection and preparation
- Utilize evidence-based labor and induction algorithms
- Adopt policies standard responses to FHR patterns
- Reducing elective cesareans

# LESSON 4: Leadership - All Hands-on Deck

- Fallouts from weekly review discussed one-on-one with surgeon.
- Review weekly NTSV CSR by all senior leaders/ELT.
- Monthly MEC updates from Quality Council.
- Monthly meetings with Regional WC team to review/revise action planning.
- CE/CMO Hallway conversations with fallout physicians.
- OB Director daily walk through discussion with staff.
- CNO weekly walkthrough/touch base with labor and delivery staff.
- Making LAIP goals.
- Begin planning for Natural Labor Program.

# Opinion Leaders vs. Audit/Feedback

- 76 physicians in 16 community hospitals
- Looked at trial of labor
- After 24 months no difference between control and groups in audit and feedback group
- Opinion leader groups were 85% higher than controls and 46% higher than audit groups
- No adverse outcome differences

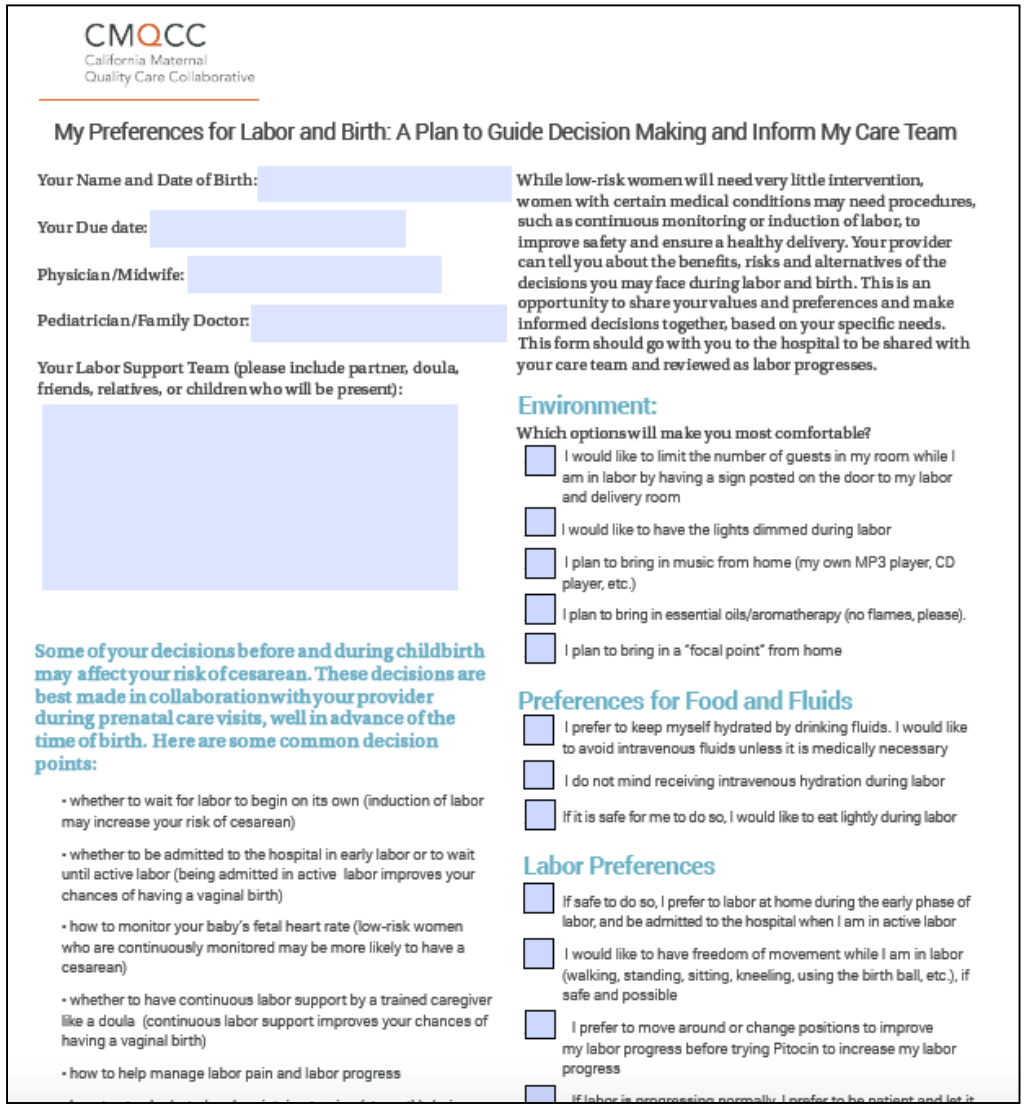
**Lomas et al, JAMA 1991;265:2202**

Readiness

# Sharing in decision making

# Birth Preferences Worksheet

- Collaborate with healthcare provider to determine birth preferences
- Tailor choices to what is available at each facility



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My Preferences for Labor and Birth: A Plan to Guide Decision Making and Inform My Care Team

Your Name and Date of Birth:

Your Due date:

Physician/Midwife:

Pediatrician/Family Doctor:

Your Labor Support Team (please include partner, doula, friends, relatives, or children who will be present):

While low-risk women will need very little intervention, women with certain medical conditions may need procedures, such as continuous monitoring or induction of labor, to improve safety and ensure a healthy delivery. Your provider can tell you about the benefits, risks and alternatives of the decisions you may face during labor and birth. This is an opportunity to share your values and preferences and make informed decisions together, based on your specific needs. This form should go with you to the hospital to be shared with your care team and reviewed as labor progresses.

Some of your decisions before and during childbirth may affect your risk of cesarean. These decisions are best made in collaboration with your provider during prenatal care visits, well in advance of the time of birth. Here are some common decision points:

- whether to wait for labor to begin on its own (induction of labor may increase your risk of cesarean)
- whether to be admitted to the hospital in early labor or to wait until active labor (being admitted in active labor improves your chances of having a vaginal birth)
- how to monitor your baby's fetal heart rate (low-risk women who are continuously monitored may be more likely to have a cesarean)
- whether to have continuous labor support by a trained caregiver like a doula (continuous labor support improves your chances of having a vaginal birth)
- how to help manage labor pain and labor progress

## Environment:

Which options will make you most comfortable?

- ☐ I would like to limit the number of guests in my room while I am in labor by having a sign posted on the door to my labor and delivery room
- ☐ I would like to have the lights dimmed during labor
- ☐ I plan to bring in music from home (my own MP3 player, CD player, etc.)
- ☐ I plan to bring in essential oils/aromatherapy (no flames, please).
- ☐ I plan to bring in a "focal point" from home

## Preferences for Food and Fluids

- ☐ I prefer to keep myself hydrated by drinking fluids. I would like to avoid intravenous fluids unless it is medically necessary
- ☐ I do not mind receiving intravenous hydration during labor
- ☐ If it is safe for me to do so, I would like to eat lightly during labor

## Labor Preferences

- ☐ If safe to do so, I prefer to labor at home during the early phase of labor, and be admitted to the hospital when I am in active labor
- ☐ I would like to have freedom of movement while I am in labor (walking, standing, sitting, kneeling, using the birth ball, etc.), if safe and possible
- ☐ I prefer to move around or change positions to improve my labor progress before trying Pitocin to increase my labor progress
- ☐ If labor is progressing normally, I prefer to be patient and let it

# Key Strategies for Using Data to Reduce Cesareans

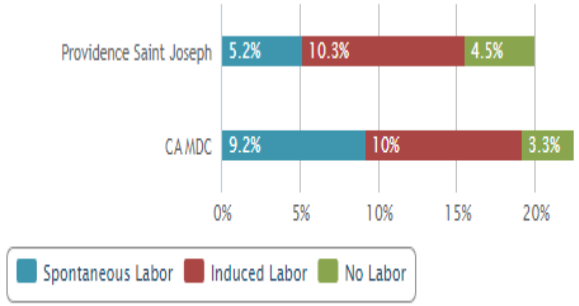
Reporting

- Make data compelling to Providers
- Assist organizations to understand data associated with their hospital
- Assist providers to understand their CS rates
- Engage women, employers, and the general public in the improvement process

# 5 months Pre/Post 2/1/2020

## What Drives Our Nulliparous Term Singleton Vertex (NTSV) CS Rate of 20.0%?

The NTSV CS rate is comprised of 3 major, mutually exclusive sub-populations (Spontaneous labor resulting in CS, Induced Labor Resulting in CS, and CS with no Labor). This breakdown of the NTSV CS rate should help determine where QI efforts can best be applied. The most common issue among most hospitals is a high rate of CS during NTSV spontaneous labor. Some hospitals may also have a high rate during induced labor.




Period: Feb - Jun 2020 (5 months)

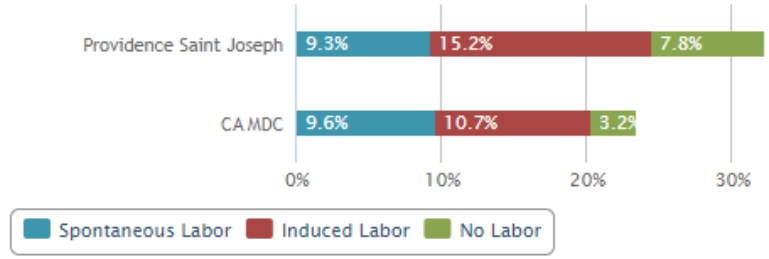
PDF Download

Start Date 02/01/2020 Duration 5 Months

Comparison Population All CA MDC Go

## What Drives Our Nulliparous Term Singleton Vertex (NTSV) CS Rate of 32.3%?

The NTSV CS rate is comprised of 3 major, mutually exclusive sub-populations (Spontaneous labor resulting in CS, Induced Labor Resulting in CS, and CS with no Labor). This breakdown of the NTSV CS rate should help determine where QI efforts can best be applied. The most common issue among most hospitals is a high rate of CS during NTSV spontaneous labor. Some hospitals may also have a high rate during induced labor.




PNG (image) CSV (Excel)

| | Spontaneous Labor | Induced Labor | No Labor | Total NTSV CS Rate |
|---|---|---|---|---|
| | 9.3% | 15.2% | 7.8% | 32.3% |
| CA MDC | 9.6% | 10.7% | 3.2% | 23.5% |

# Weekly NTSV CSR Review (sent to all Ministry Leaders)

SJO NTSV Executive Summary by week

July 2020

| Week: | N: # NTSV fallouts | D: # of cases | % for week | Documented c/s reason | Attending | Decision making MD/Nurse | notes | Recommendation | ACOG Criteria met |
|---|---|---|---|---|---|---|---|---|---|
| July 3-9 | 2 | 20 | 10% | | | | | | |
| 1 | | | | Non-Reassuring FHR | | | 38.3 weeks decels in office; attempted ind. multiple prolonged decels | | Yes |
| 2 | | | | Failed Induction | | | 40.1 weeks sent from MFT for ind. | | No |
| July 10-16 | 5 | 25 | 20% | | | | | | |
| 1 | | | | Non-Reassuring FHR | | | 40 weeks labor (lates, temp, mec) | | Yes |
| 2 | | | | Non-Reassuring FHR | | | 39.2 weeks admitted for decels | | Yes |
| 3 | | | | Maternal Request | | | 37.2ind for elevated BP's. 2+ day labor and patient requested for maternal exhaustion an 8cm for 5 hrs | | |
| 4 | | | | 2nd Stage Labor Dystocia | | | 40.5 ind. | | Yes |
| 5 | | | | 2nd Stage Labor Dystocia | | | 40.4 ind | | Yes |
| July 17-23 | 6 | 36 | 16.7% | | | | | | |
| 1 | | | | Non-Reassuring FHR | | | 39 weeks admitted for Dec. FM | | Yes |

Response

## CMQCC Labor Dystocia Checklist (ACOG/SMFM Criteria)

**1. Diagnosis of Dystocia/Arrest Disorder (all 3 should be present)**

- ☐ Cervix 6 cm or greater
- ☐ Membranes ruptured, then
- ☐ No cervical change after at least 4 hours of adequate uterine activity (e.g. strong to palpation or MVUs > 200), or at least 6 hours of oxytocin administration with inadequate uterine activity

**2. Diagnosis of Second Stage Arrest (only one needed)**

**No descent or rotation for:**

- ☐ At least 4 hours of pushing in nulliparous woman with epidural
- ☐ At least 3 hours of pushing in nulliparous woman without epidural
- ☐ At least 3 hours of pushing in multiparous woman with epidural
- ☐ At least 2 hour of pushing in multiparous woman without epidural

**3. Diagnosis of Failed Induction (both needed)**

- ☐ Bishop score ≥6 for multiparous women and ≥ 8 for nulliparous women, before the start of induction (for non-medically indicated/elective induction of labor only)
- ☐ Oxytocin administered for at least 12-18 hours after membrane rupture, without achieving cervical change and regular contractions. *Note: At least 24 hours of oxytocin administration after membrane rupture is preferable if maternal and fetal statuses permit

# Most Important?

***A Culture that values vaginal delivery***

# LESSON 5: Nursing has a Critical Role

- Refresh labor techniques training/Spinning Baby/2nd Stage
- Strip review at shift change
- Review oxytocin policies and procedures for timely advancement of oxytocin and restarting after tachysystole/decelerations.
- Work with medical leadership to invoke hard stop labor admissions before 4 cm without medical indications.
- Scripted discussions from labor evaluation area

# Peanut Ball

Recognition

- Decrease length of labor
- Decreasing CS rate in patients with epidurals

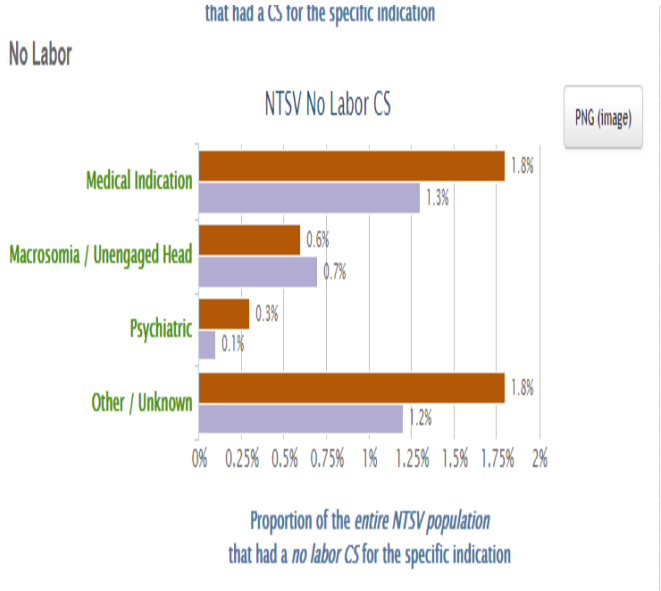
Tussey, C. M., Botsios, E., Gerkin, R. D., Kelly, L. A., Gamez, J., & Mensik, J. (2015). Reducing length of labor and cesarean surgery rate using a peanut ball for women laboring with an epidural. *The Journal of Perinatal Education*, *24*(1), 16-24. http://dx.doi.org/10.1891/1058-1243.24.L16

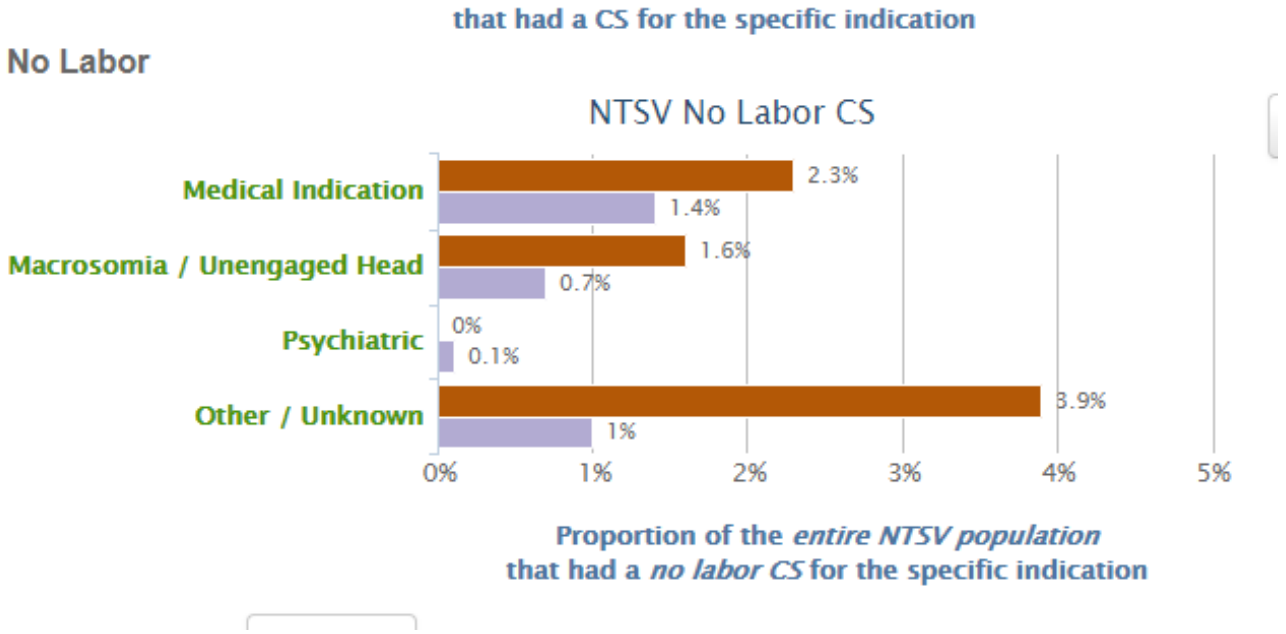
# LESSON 6: Elective Cesarean Reduction – Just enough to prevent success

- Signed consent by patient acknowledging the unique risks and benefits to future health and pregnancies.
- Attendance at Free Elective Cesarean Section Class prior to case being scheduled. (Tarzana Class is available until course created at Burbank). Registration Link
  - https://psjhcrmwebsites.microsoftcrmportals.com/home?region=CALA&ministry=%7BB2583C4A-9DA6-479C-8FA8-D2FBD5A0F849%7D

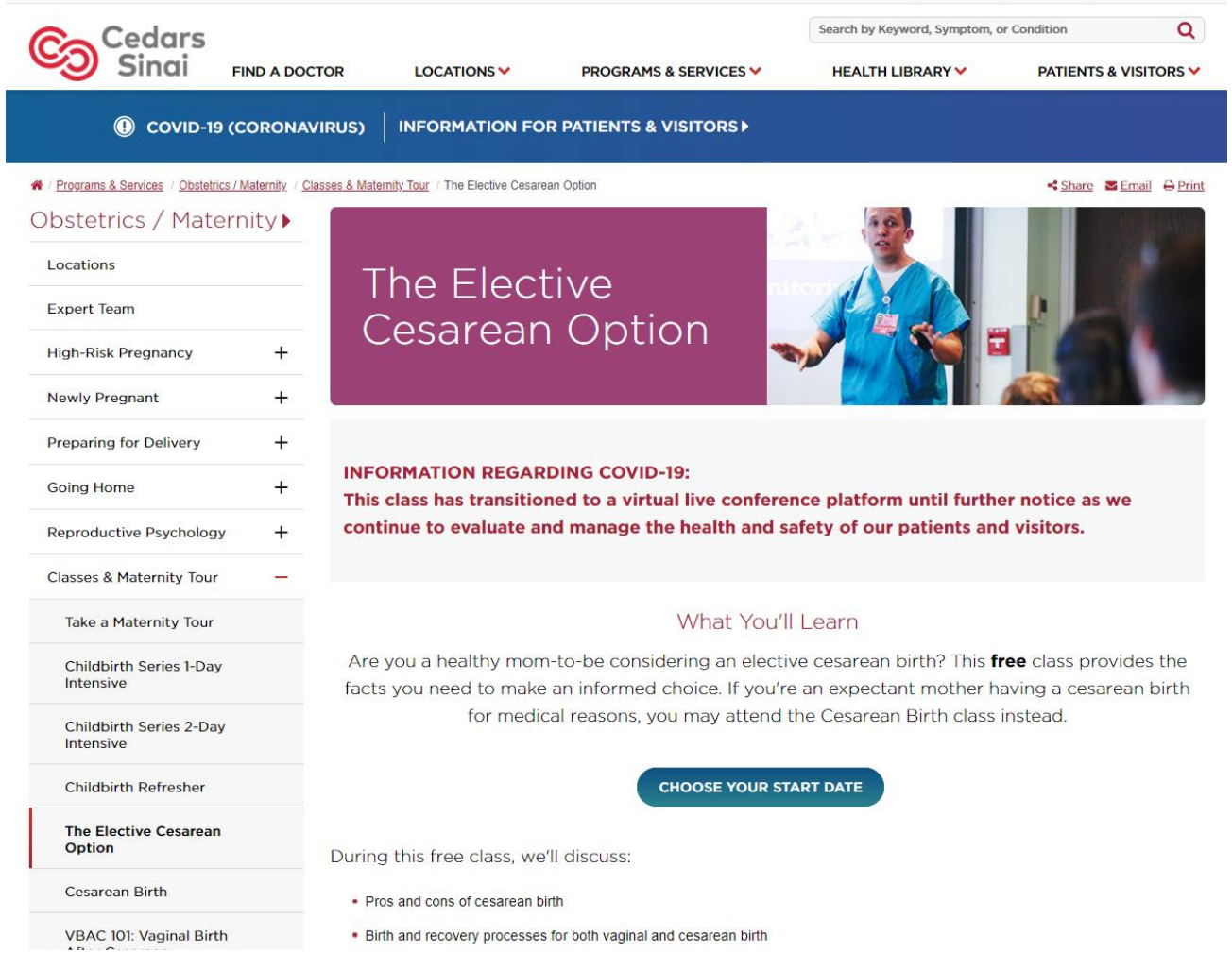
- Mandatory second opinion by MFM prior to case being scheduled.
- Approval for CS Macrosomia only if meets ACOG criteria, otherwise consider elective.

# No Labor: 5 months Pre/Post 2/1/2020



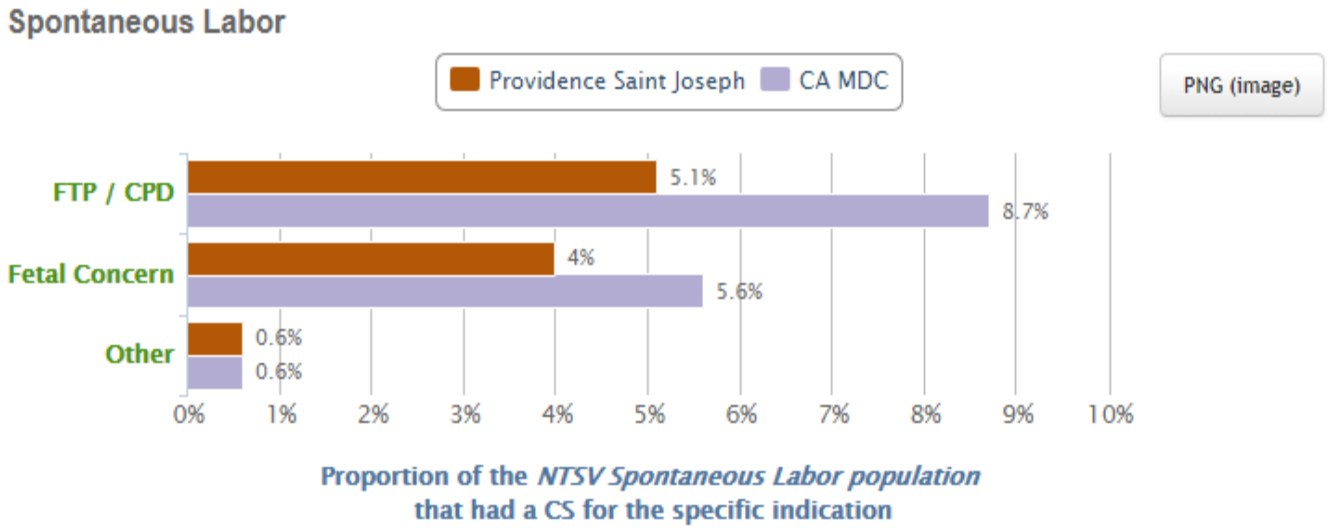
# Informed Consent prior to Scheduling

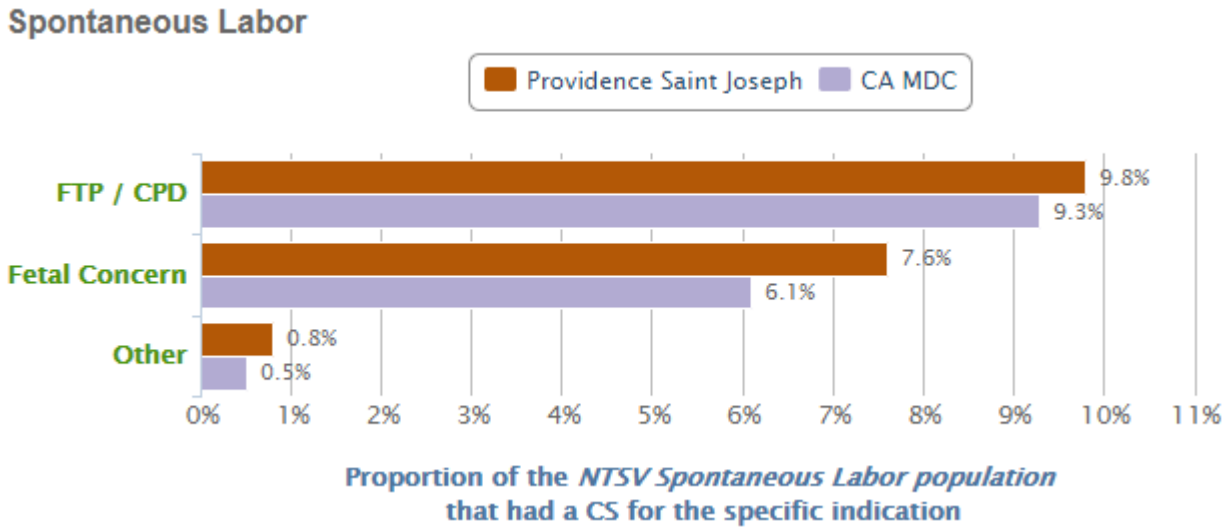


# LESSON 7: Rates of Fetal Intolerance to Labor/Failure to Progress/Descent Account for a Large Amount of Variability

- Mandatory raining on NICHD categories/5 Tier FHR Analysis with management planning.
- Strip review by hospitalists and nursing on all changes of shift.
- All FIL cesareans have medical director review for appropriateness.
- Cord gases for FIL cesareans.
- Hard stop for labor admissions prior to 4 cm unless medical indication.
- Timely augmentation following appropriate policy procedure review.
- Avoidance of laboring down and varying pushing techniques.
- Operative Vaginal Delivery training.
- Manual Rotation of Occiput Posterior/Transverse (define hospitalist role).

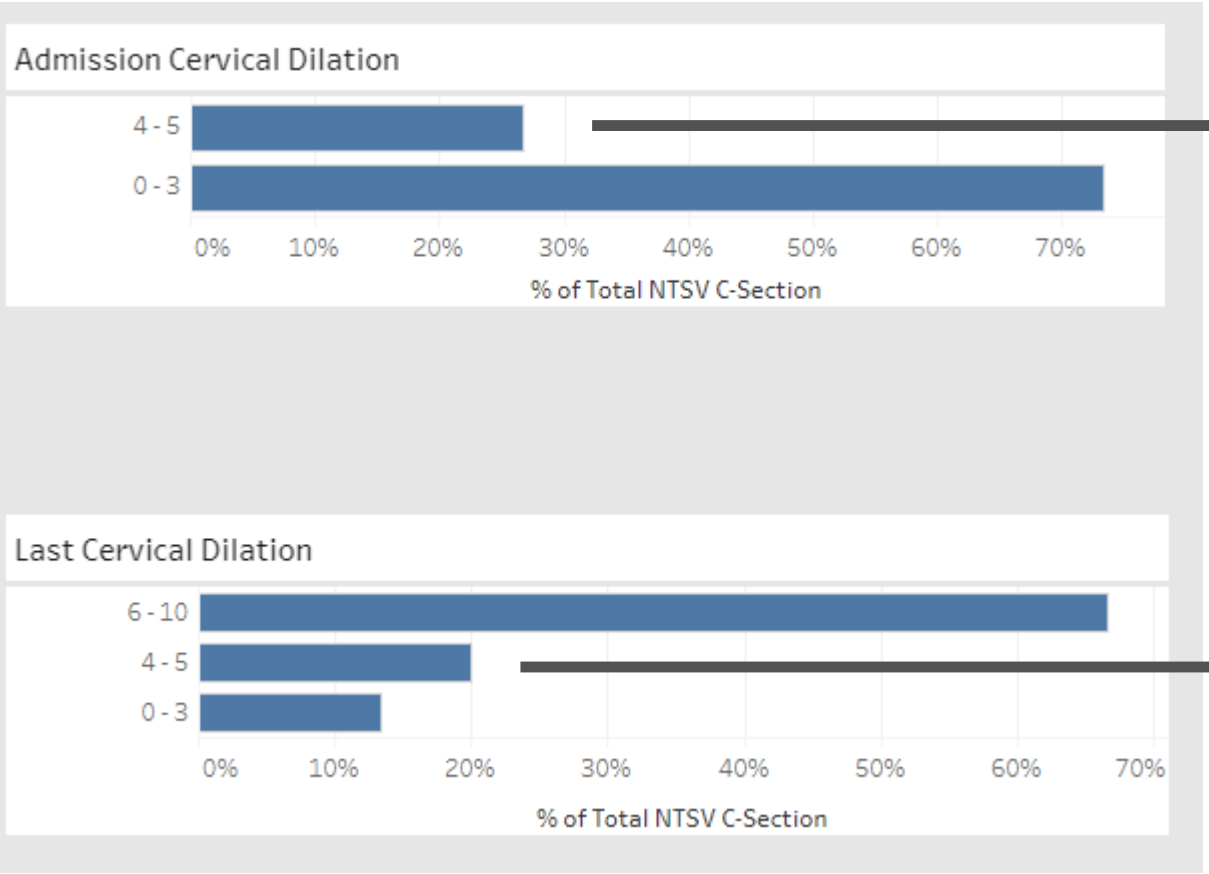
# Spontaneous Labor: 5 months Pre/Post 2/1/2020

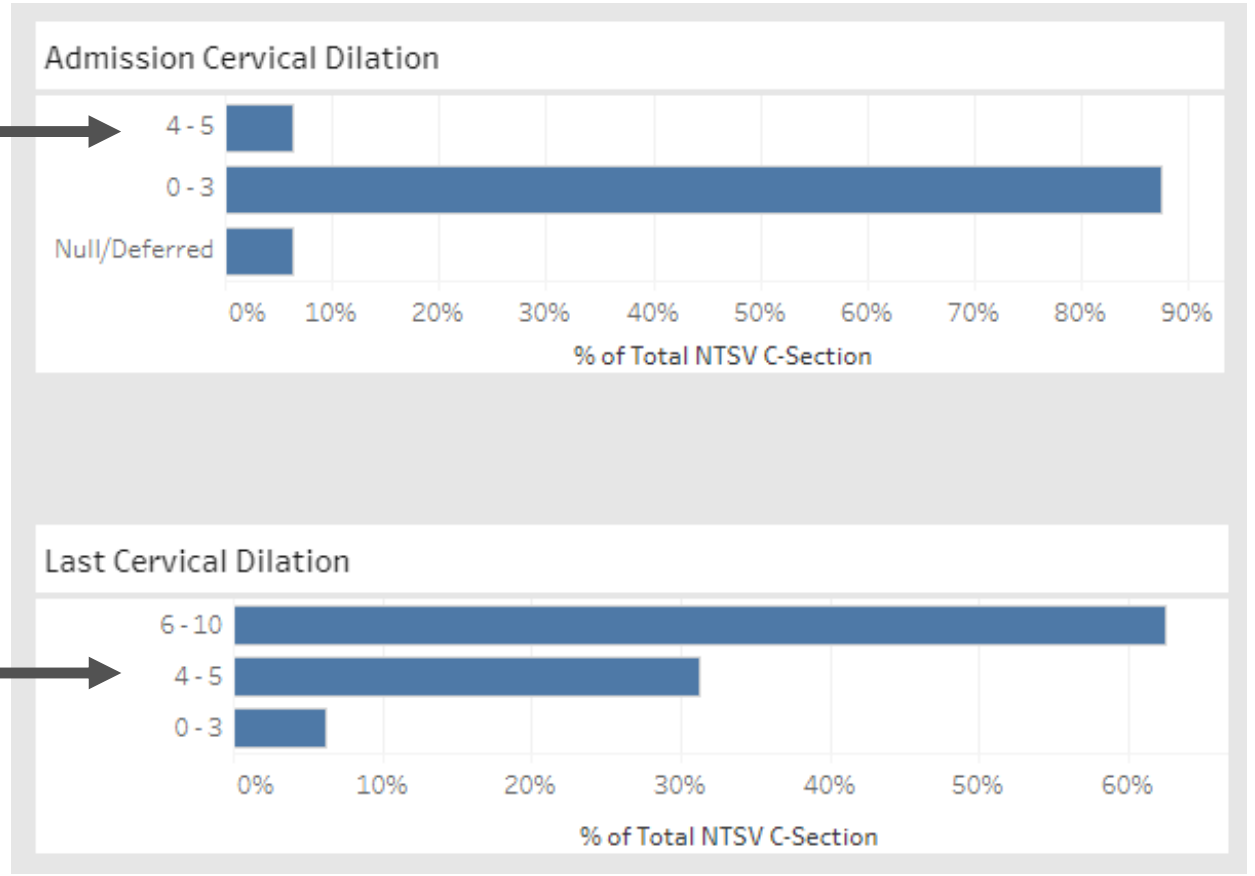


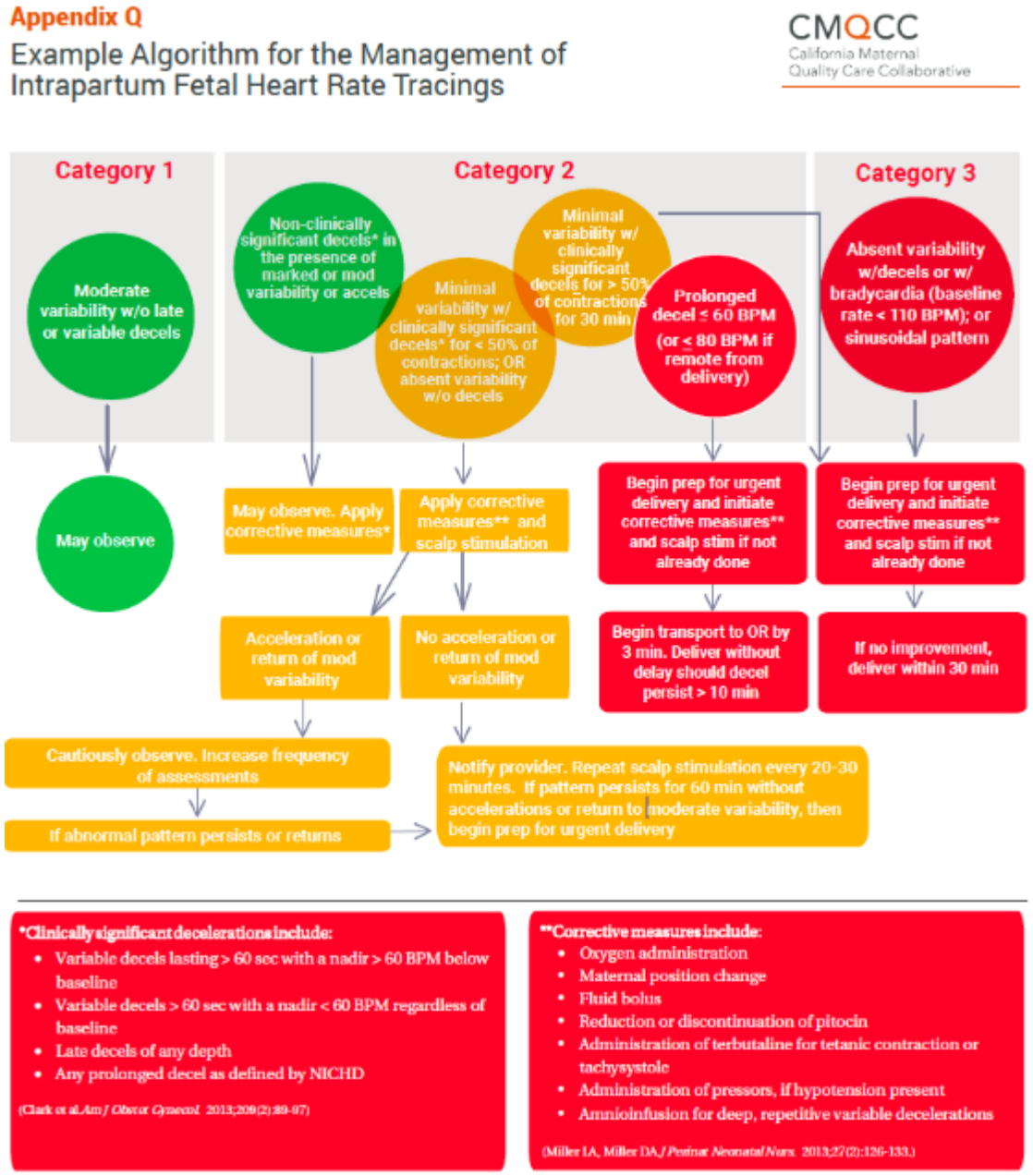
# Cervix Data: 5 months Before and After 2/1/2020

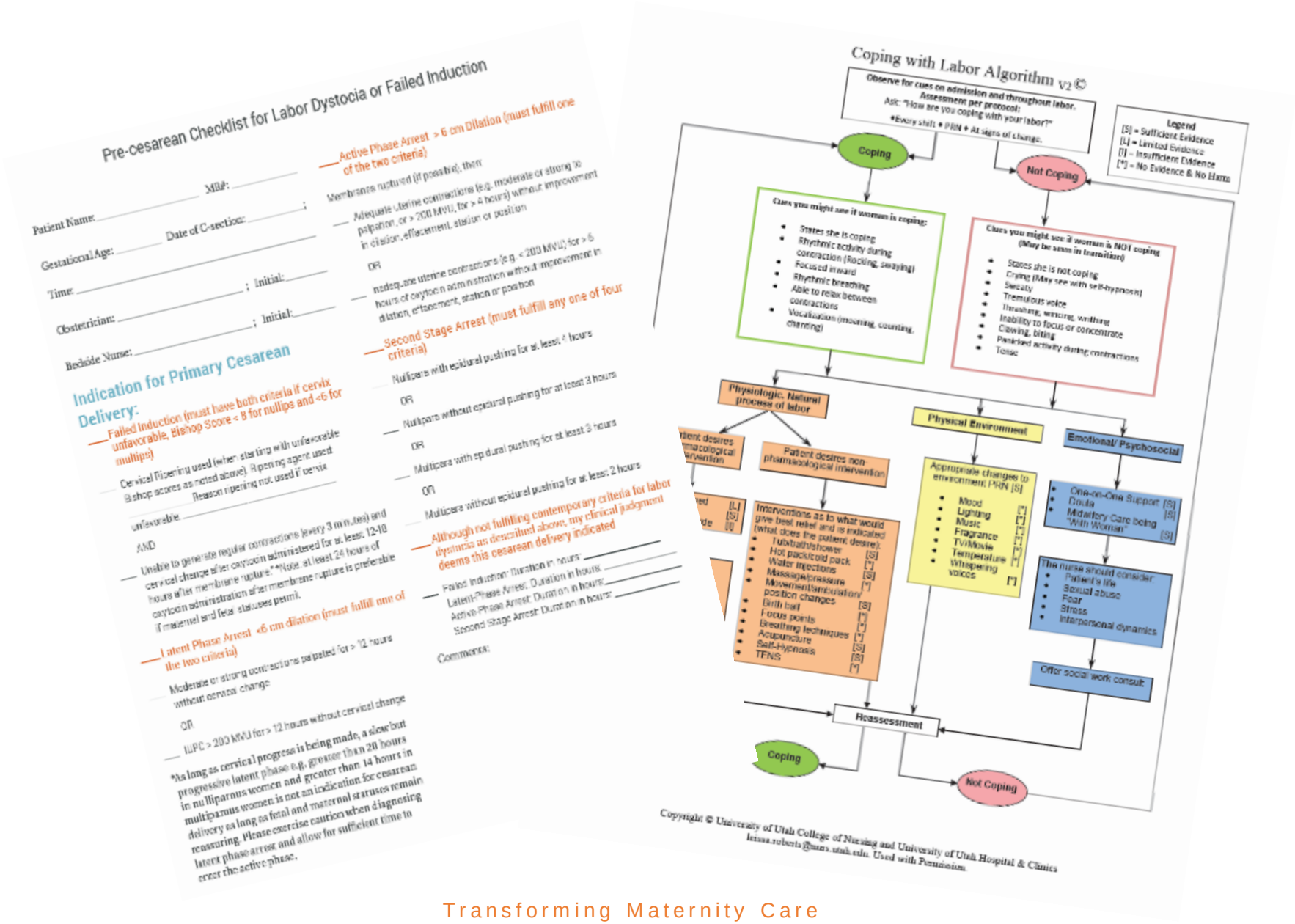
(Note more admissions prior to 4 cm and more CS done before 6 cm)



Example Algorithm: Management of Intrapartum FHR Tracings





## Pre-cesarean Checklist for Labor Dystocia or Failed Induction

Patient Name: _____ MR#: _____

Gestational Age: _____ Date of C-section: _____

Time: _____

Obstetrician: _____ ; Initial: _____

Bedside Nurse: _____ ; Initial: _____

### Indication for Primary Cesarean Delivery:

__ Failed Induction (must have both criteria if cervix unfavorable, Bishop Score < 8 for nullips and <6 for multips)

__ Cervical Ripening used (when starting with unfavorable Bishop scores as noted above). Ripening agent used: _____ Reason ripening not used if cervix unfavorable: _____

AND

__ Unable to generate regular contractions (every 3 min, last) and cervical change after oxytocin administered for at least 12-18 hours after membrane rupture.* *Note: at least 24 hours of oxytocin administration after membrane rupture is preferable if maternal and fetal statuses permit.

__ Latent Phase Arrest <6 cm dilation (must fulfill one of the two criteria)

__ Moderate or strong contractions palpated for > 12 hours without cervical change

OR

__ IUPC > 200 MVU for > 12 hours without cervical change

*As long as cervical progress is being made, a slow but progressive latent phase e.g. greater than 20 hours in nulliparous women and greater than 14 hours in multiparous women is not an indication for cesarean delivery as long as fetal and maternal statuses remain reassuring. Please exercise caution when diagnosing latent phase arrest and allow for sufficient time to enter the active phase.

__ Active Phase Arrest > 6 cm Dilation (must fulfill one of the two criteria)

__ Membranes ruptured (if possible), then

__ Adequate uterine contractions (e.g. moderate or strong to palpation, or > 200 MVU, for > 4 hours) without improvement in dilation, effacement, station or position

OR

__ Inadequate uterine contractions (e.g. < 200 MVU, for > 6 hours of oxytocin administration without improvement in dilation, effacement, station or position

__ Second Stage Arrest (must fulfill any one of four criteria)

__ Nullipara with epidural pushing for at least 4 hours

OR

__ Nullipara without epidural pushing for at least 3 hours

OR

__ Multipara with epidural pushing for at least 3 hours

OR

__ Multipara without epidural pushing for at least 2 hours

__ Although not fulfilling contemporary criteria for labor dystocia as described above, my clinical judgment deems this cesarean delivery indicated

__ Failed Induction: Duration in hours: _____

__ Latent-Phase Arrest: Duration in hours: _____

__ Active-Phase Arrest: Duration in hours: _____

__ Second Stage Arrest: Duration in hours: _____

Comments: _____

## Coping with Labor Algorithm V2 ©

Observe for cues on admission and throughout labor.
Assessment per protocol:
Ask: "How are you coping with your labor?"
•Every shift • PRN • At signs of change.

Legend
[S] = Sufficient Evidence
[L] = Limited Evidence
[I] = Insufficient Evidence
[*] = No Evidence & No Harm

Coping

Not Coping

Cues you might see if woman is coping:
- States she is coping
- Rhythmic activity during contraction (Rocking, swaying)
- Focused inward
- Rhythmic breathing
- Able to relax between contractions
- Vocalization (moaning, counting, chanting)

Cues you might see if woman is NOT coping (May be seen in transition)
- States she is not coping
- Crying (May see with self-hypnosis)
- Sweaty
- Tremulous voice
- Thrashing, writhing, writhing
- Inability to focus or concentrate
- Clawing, biting
- Panicked activity during contractions
- Tense

Physiologic, Natural process of labor

Patient desires pharmacological intervention

Patient desires non-pharmacological intervention

Interventions as to what would give best relief and is indicated (what does the patient desire):
- Tub/bath/shower [S]
- Hot pack/cold pack [*]
- Water injections [S]
- Massage/pressure [*]
- Movement/stimulation/ position changes [S]
- Birth ball [S]
- Focus points [*]
- Breathing techniques [*]
- Acupuncture [S]
- Self-Hypnosis [S]
- TENS [*]

Physical Environment

Appropriate changes to environment: PRN [S]
- Mood [*]
- Lighting [*]
- Music [*]
- Fragrance [*]
- TV/Movie [*]
- Temperature [*]
- Whispering voices [*]

Emotional/ Psychosocial

- One-on-One Support [S]
- Doula [S]
- Midwifery Care being "With Woman" [S]

The nurse should consider:
- Patient's life
- Sexual abuse
- Fear
- Stress
- Interpersonal dynamics

Offer social work consult

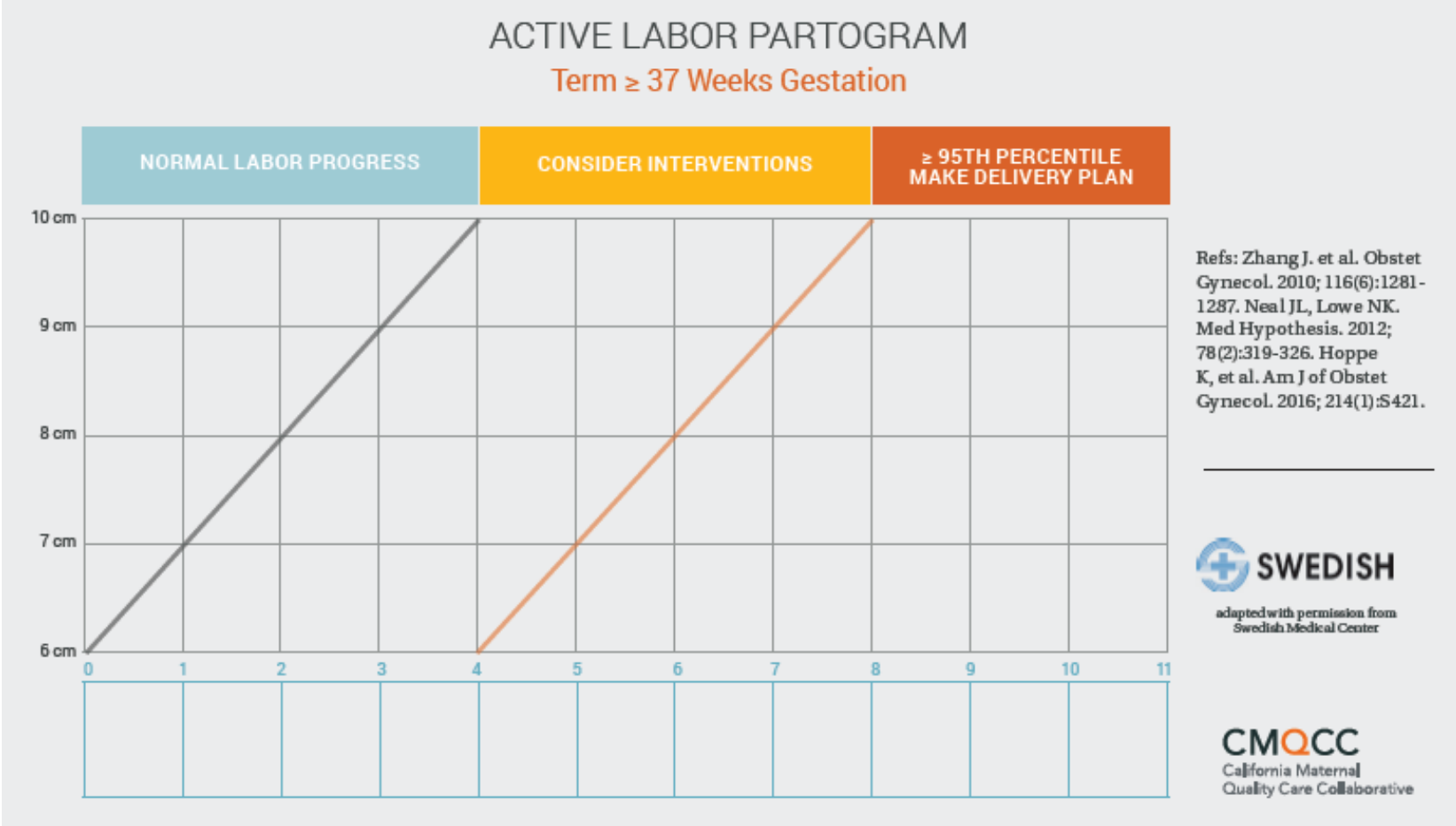
Reassessment

Coping

Not Coping

# Active Labor Partogram

Response



# LESSON 7: It's How You Conduct Induction of Labor

- Hard stop for oxytocin or ROM prior to achieving ripe cervix.
- Outpatient cervical ripening unless medically indicated.
- Follow standard recommendations for medical inductions.
- Combination cervical ripening for all inpatients.
- Allowing elective inductions at 39 0/7ths weeks for patients with ripe cervices and physicians who have nulliparous CSR after induction of <25%.
- Elective induction with aggressive cervical ripening at 40 3/7$^{th}$ for all other patients and physicians.
- Induction progress reports at all hand off huddles.

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.

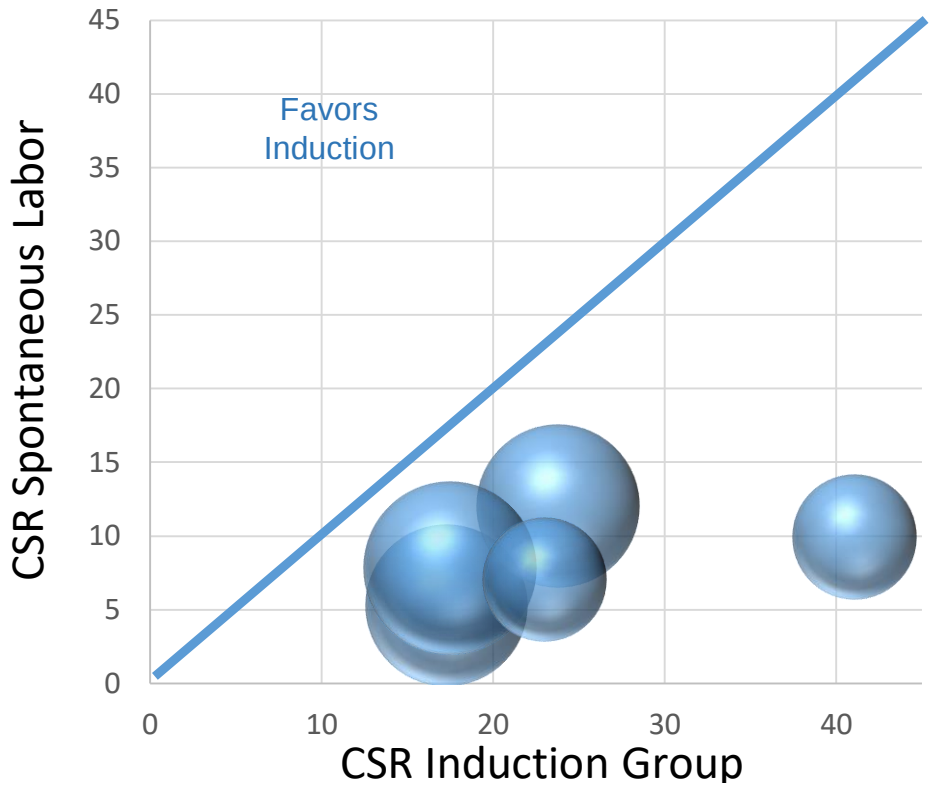
N Engl J Med 2018;379:513-23.
DOI: 10.1056/NEJMoa1800566

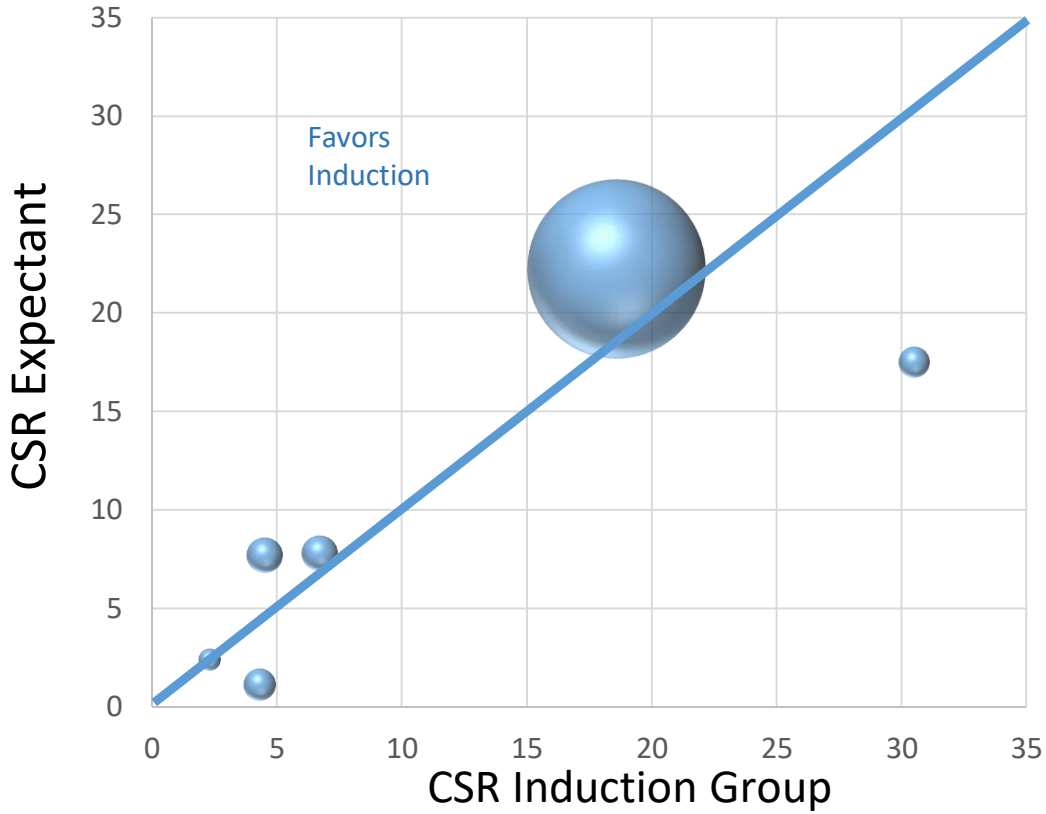

CMQCC
California Maternal Quality Care Collaborative

# The ARRIVE TRIAL

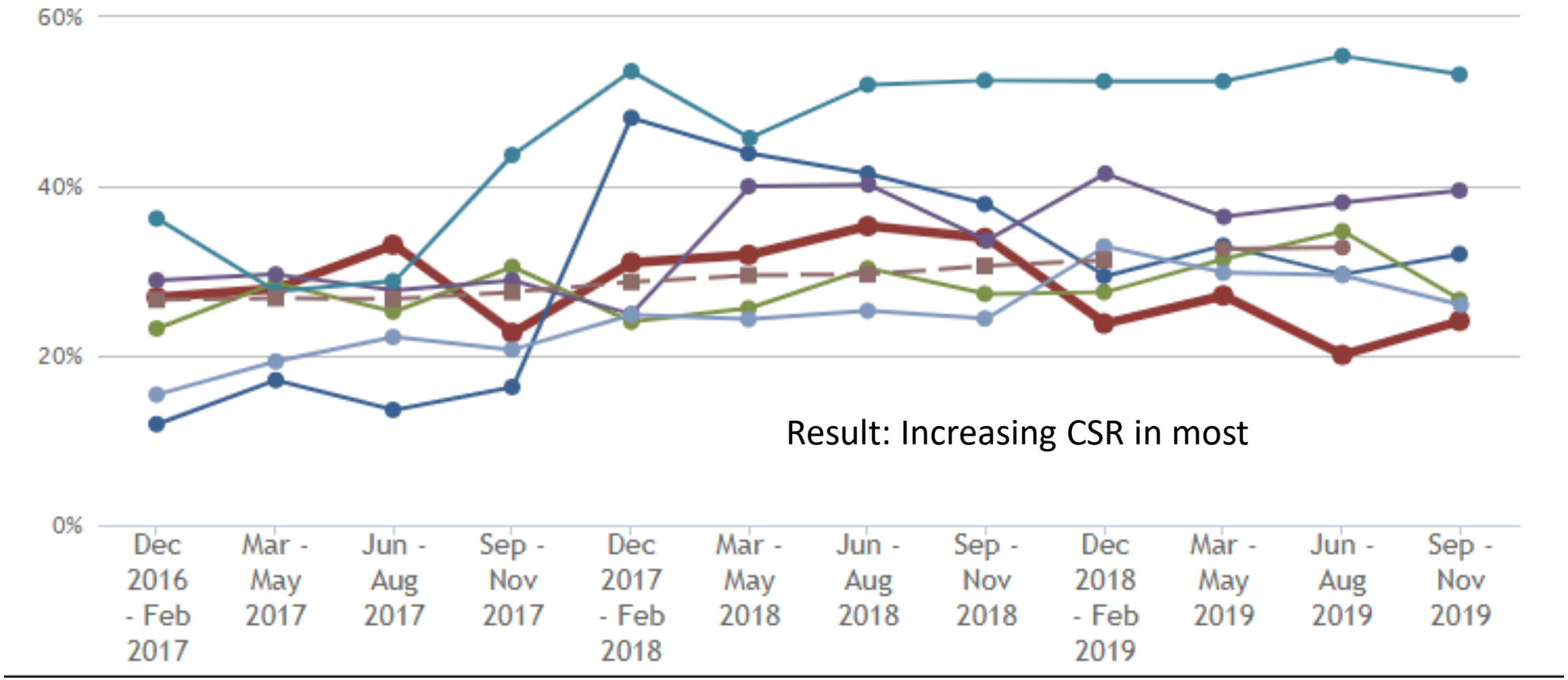
Can everyone universally adopt and get the same results?

# Non-Randomized vs. Randomized Results



# Mixed Response: Some Increased Induction/Some Not




Result: Increasing CSR in most

* Internal PSJH data

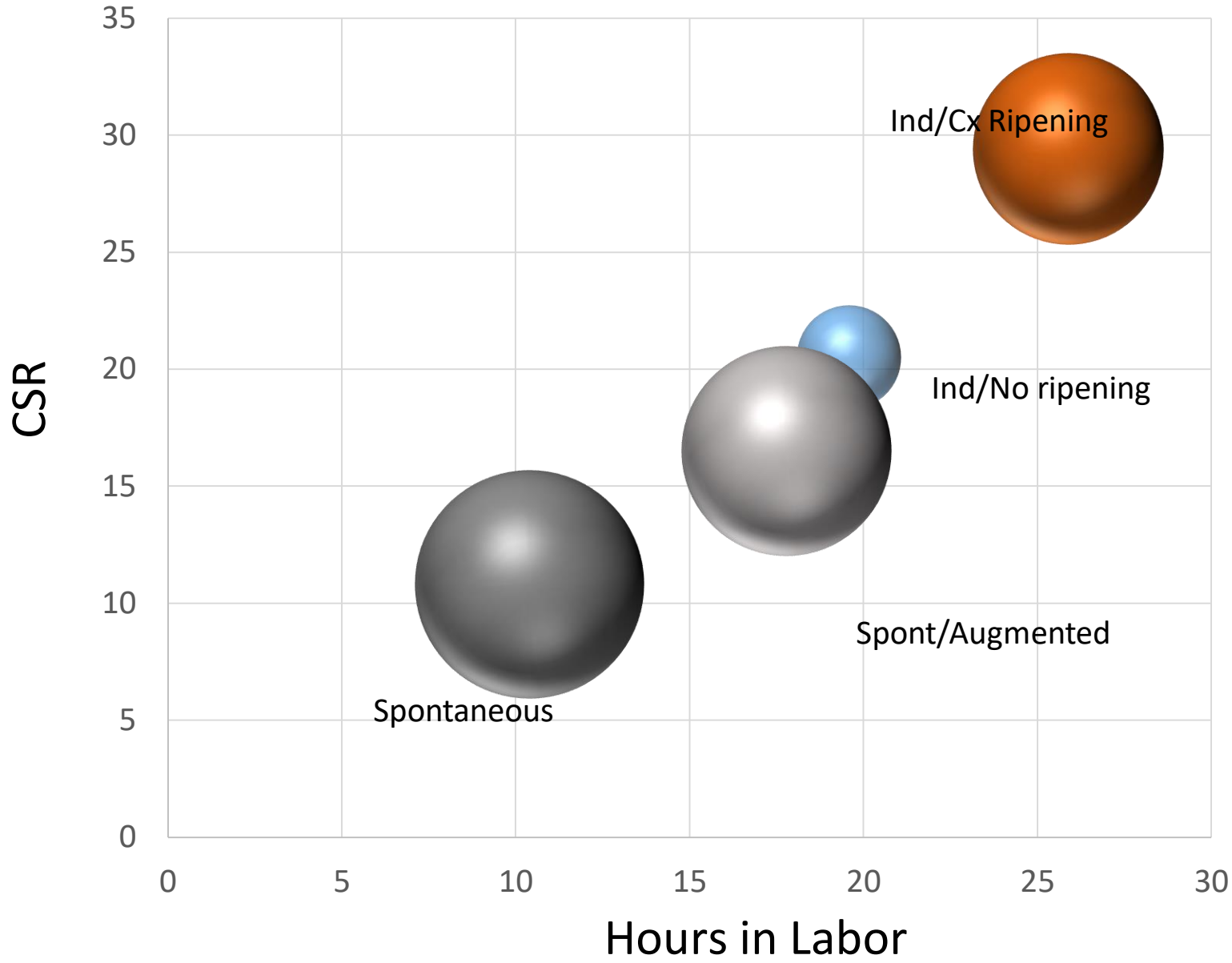
# Summary of the ARRIVE trial

- 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:

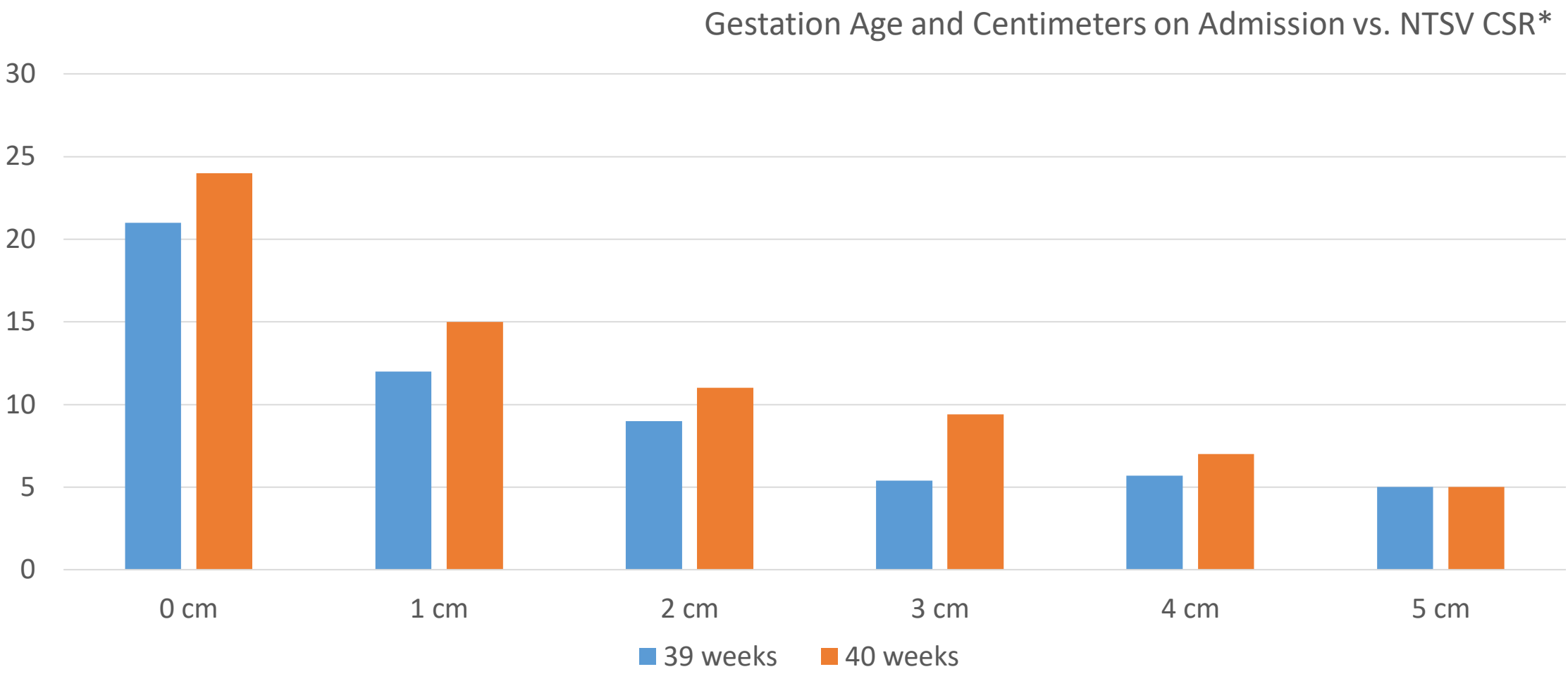
- Are the results ***generalizable*** to local patient population and to our providers?
- What were the protocols for induction and labor management, and can we duplicate them in other settings?
- Given the impact on length of labor (+6 hours), could the typical US hospital achieve the same results without 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?

# NTSV: Hours in Labor and CSR




* Source internal PSJH data

# Admission Dilation has Greatest Impact




* Source internal PSJH data

# 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):375-80.

# 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

# What if outpatient?

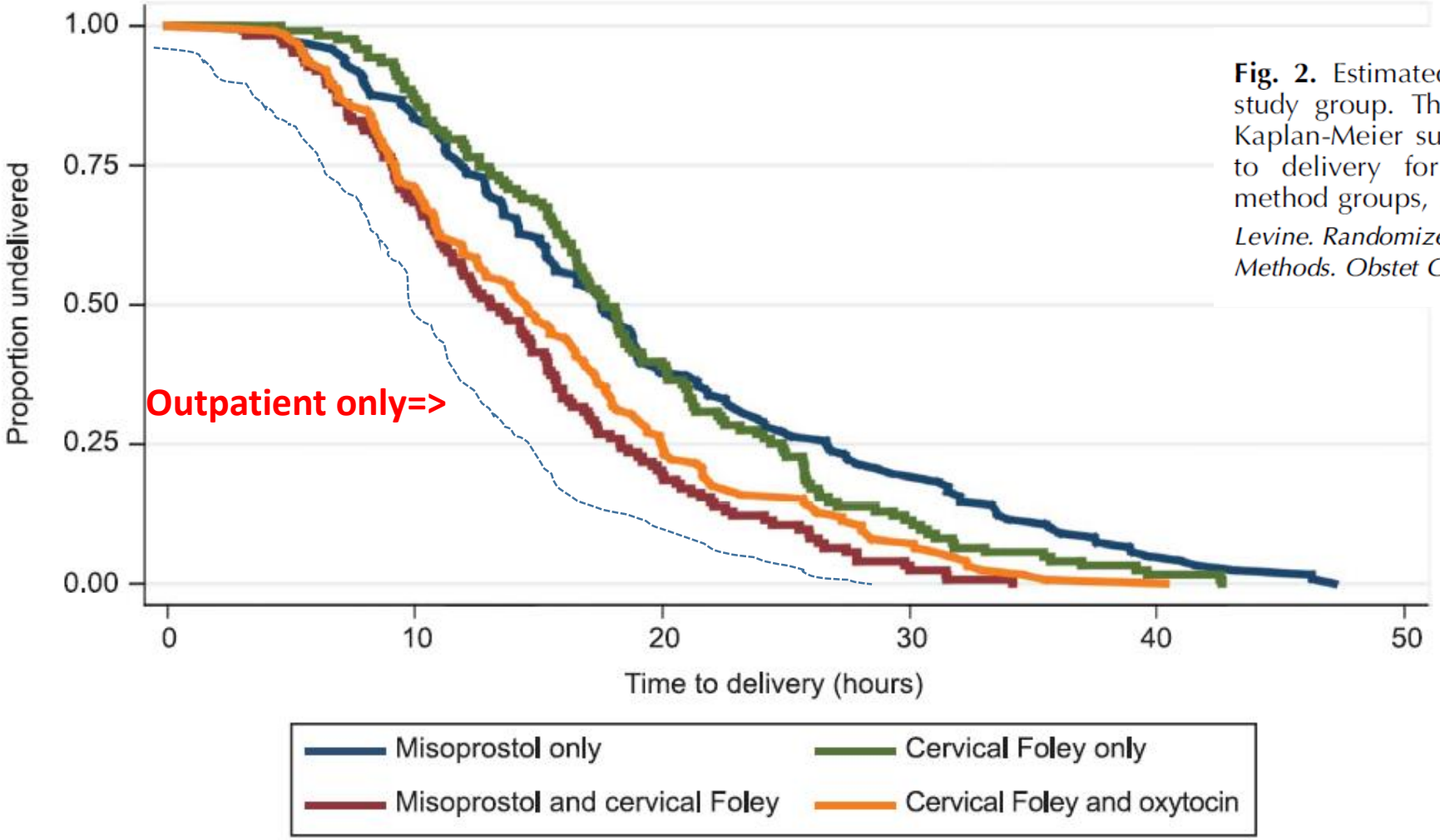



**Fig. 2.** Estimated time to delivery by study group. This figure displays the Kaplan-Meier survival curves for time to delivery for the four induction method groups, $P<.001$.

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

# Adverse Event Frequency Balloon Cervical Ripening

**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.

# Keys for Induction Success

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

# Last Thoughts

# Take-home Lessons from Our Experience

- Rates vary by hospital, but success is possible
- Rates vary by individuals, they practice differently
- Following guidelines help
- You needs leadership at every level
- RNs have a critical role
- Elective CS cause small but important role
- FIL/FTP make up a significant amount of variability
- How you do inductions is the most important thing
- *Oh, one more very, very important thing*…

# Avoid the Success Bump!

- Your initial efforts by using data transparency, fun new laboring techniques, heightened awareness, etc. often lead to success over 9-12 months.  Then complacency sets in and you take your eye off the ball…
- Long term success and changing the culture likely to take 24 months or greater.
- Building in natural labor techniques, hard wired data feedback, etc. will be needed to cement the gains and maintain NTSV cesarean section rates under 23.9%.

# Thank You!

Visit:  CMQCC.org