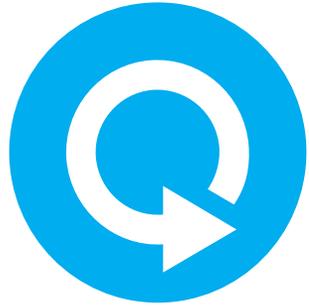


Emerging Therapies Workgroup: Tracking Outcomes



**FOUNDATION FOR
Health Care Quality**

John Vassall, MD; CEO, FHCQ
Vivienne Souter, MD; Medical Director, OB COAP
Kristin Sitcov; Executive Director Clinical Programs, FHCQ



FOUNDATION FOR Health Care Quality

CARE OUTCOMES ASSESSMENT PROGRAMS:

**CARDIAC
CARE OUTCOMES
ASSESSMENT PROGRAM (CARDIAC COAP)**

**SURGICAL
CARE OUTCOMES
ASSESSMENT PROGRAM (SURGICAL COAP)**

**SPINE
CARE OUTCOMES
ASSESSMENT PROGRAM (SPINE COAP)**

**OBSTETRICAL
CARE OUTCOMES
ASSESSMENT PROGRAM (OB COAP)**

**DR. ROBERT BREE
COLLABORATIVE**

**WASHINGTON
PATIENT SAFETY COALITION**

SMOOTH TRANSITIONS

The “COAP” Approach:

CONTINUOUS QUALITY IMPROVEMENT MODEL:



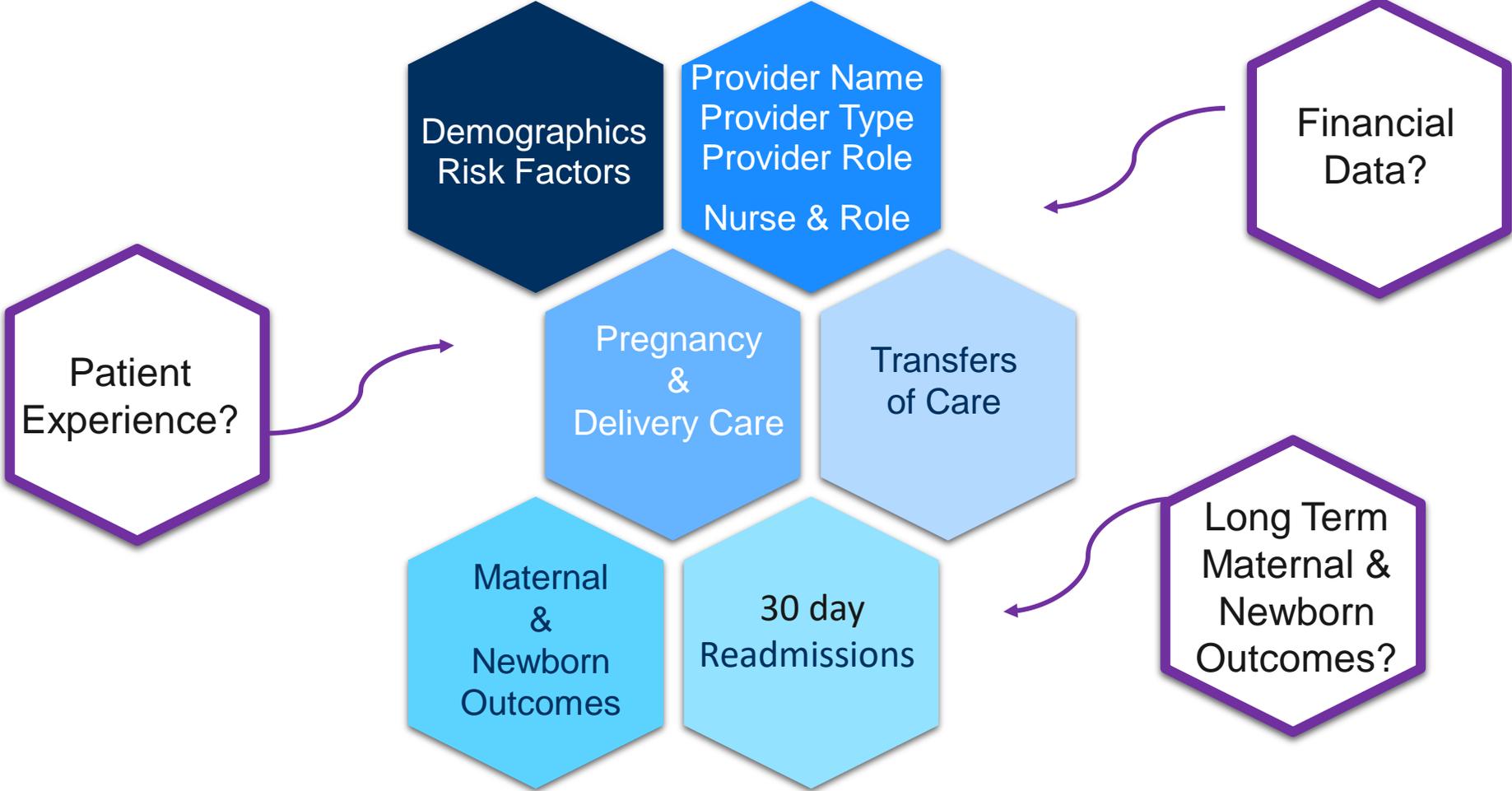
COLLABORATIVE: Benchmarking, transparency, comparative reporting, collaborative meetings, best practice sharing

CLINICIAN LED: Management committees determining strategic direction; comprised of multidisciplinary clinicians and stakeholders

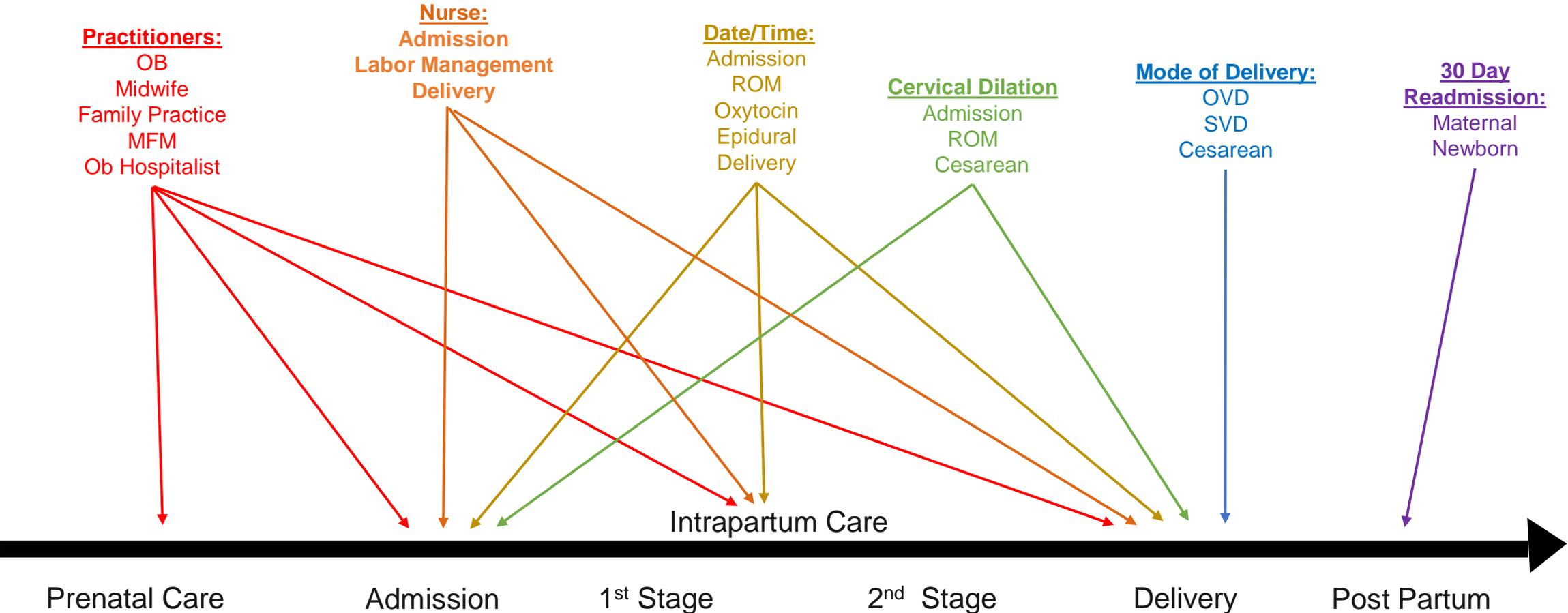
CLINICAL DATA: High-quality chart abstracted data, timely reporting at the aggregate, system, site, provider and patient level

- **Comparison** of outcomes before and after implementation of initiatives and programs
- **Examination** of balancing measures to assess both intended and unintended consequences of changes in practice on patients, staffing, other resources
- **Evaluation** of the influence of site and practice culture on outcomes
- **Monitor** resource implications / costs

OB COAP Data Includes:



Continuum of fields in OB COAP Database



Current OB COAP Participants:

- Currently ~ 35,000 births added to database annually and >200,000 records in the database
- 20 Hospitals in WA & MT representing all levels of maternal & neonatal care (I-IV)
- Planned community births (home/birth center) from Midwives Association of WA State
- Urban, suburban, rural communities; sites with fewer than 200 and more than 4000 births/year
- All obstetrical provider types: OB, FP with & without cesarean privileges, MFM, Hospitalists, CNM, LM/CPM



Two real world examples

Antenatal Steroids at 34-36 weeks for pregnancies at risk for preterm term birth

Elective induction of labor at 39 weeks

Antenatal Steroids at 34-36 weeks for pregnancies at risk for preterm birth

Late Preterm Steroids

- Antenatal steroid administration has clear benefit for babies born <34 weeks
- Does antenatal betamethasone at 34⁺⁰-36⁺⁵ weeks for pregnancies at risk of preterm birth (birth <37 weeks) reduce newborn complications?

Antenatal Betamethasone for Women at Risk for Late Preterm Delivery

C. Gyamfi-Bannerman, E.A. Thom, S.C. Blackwell, A.T.N. Tita, U.M. Reddy, G.R. Saade, D.J. Rouse, D.S. McKenna, E.A.S. Clark, J.M. Thorp, Jr., E.K. Chien, A.M. Peaceman, R.S. Gibbs, G.K. Swamy, M.E. Norton, B.M. Casey, S.N. Caritis, J.E. Tolosa, Y. Sorokin, J.P. VanDorsten, and L. Jain, for the NICHD Maternal-Fetal Medicine Units Network*

	Betamethasone Group	Placebo Group	RR (95% CI)
Newborn Complication Composite	11.6%	14.4%	0.80 (0.66-0.97)
Neonatal Hypoglycemia	24.0%	15.0%	1.60 (1.37-1.87)

The **NEW ENGLAND**
JOURNAL *of* **MEDICINE**

ESTABLISHED IN 1812

APRIL 7, 2016

VOL. 374 NO. 14

Antenatal Betamethasone for Women at Risk
for Late Preterm Delivery

C. Gyamfi-Bannerman, E.A. Thom, S.C. Blackwell, A.T.N. Tita, U.M. Reddy, G.R. Saade, D.J. Rouse, D.S. McKenna, E.A.S. Clark, J.M. Thorp, Jr., E.K. Chien, A.M. Peaceman, R.S. Gibbs, G.K. Swamy, M.E. Norton, B.M. Casey, S.N. Caritis, J.E. Tolosa, Y. Sorokin, J.P. VanDorsten, and L. Jain, for the NICHD Maternal-Fetal Medicine Units Network*

- Newborn complications are much higher at 34 weeks compared to 36 weeks
- More than 50% of late preterm babies in OB COAP are born at 36 weeks
- The complication rate at 36 weeks is relatively low (16% respiratory complications in OB COAP)
- The study was underpowered to evaluate the effect by gestational week

Primary Outcome: Newborn Complication Composite

Gestational age at randomization	Betamethasone N(%)	Placebo N(%)	RR (95% CI)	Interaction P
34-35 weeks	129 (14.0)	168 (18.2)	0.77 (0.62-0.95)	0.27
≥36 weeks 0 days	36 (7.1)	34 (7.1)	1.0 (0.64-1.6)	

Severe Respiratory Complications

Gestational age at randomization	Betamethasone N(%)	Placebo N(%)	RR (95% CI)	Interaction P
34-35 weeks	60 (6.5)	75 (8.1)	0.80 (0.58-1.10)	0.22
≥36 weeks 0 days	19 (3.8)	14 (2.9)	1.28 (0.65-2.52)	

ACOG COMMITTEE OPINION

Number 713 • August 2017

(Reaffirmed 2018)

(Replaces Committee Opinion No. 677, October 2016)

Committee on Obstetric Practice

This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Obstetric Practice in collaboration with committee members Yasser Y. El-Sayed, MD, Ann E.B. Borders, MD, MSc, MPH, and the Society for Maternal–Fetal Medicine's liaison member Cynthia Gyamfi-Bannerman, MD, MSc.

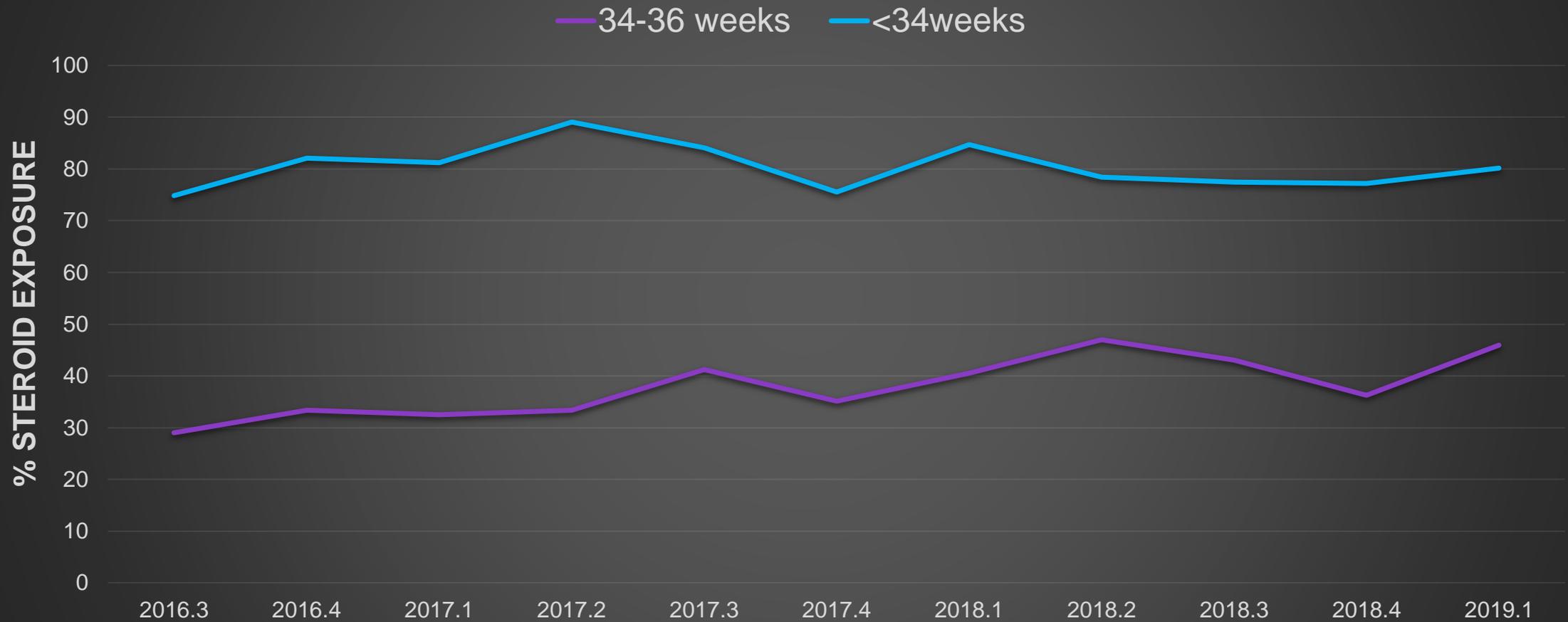
INTERIM UPDATE: This Committee Opinion is updated as highlighted to reflect a limited focused change to clarify that, among specific populations, antenatal corticosteroids should be administered when a woman is at risk of preterm delivery within 7 days.

Antenatal Corticosteroid Therapy for Fetal Maturation

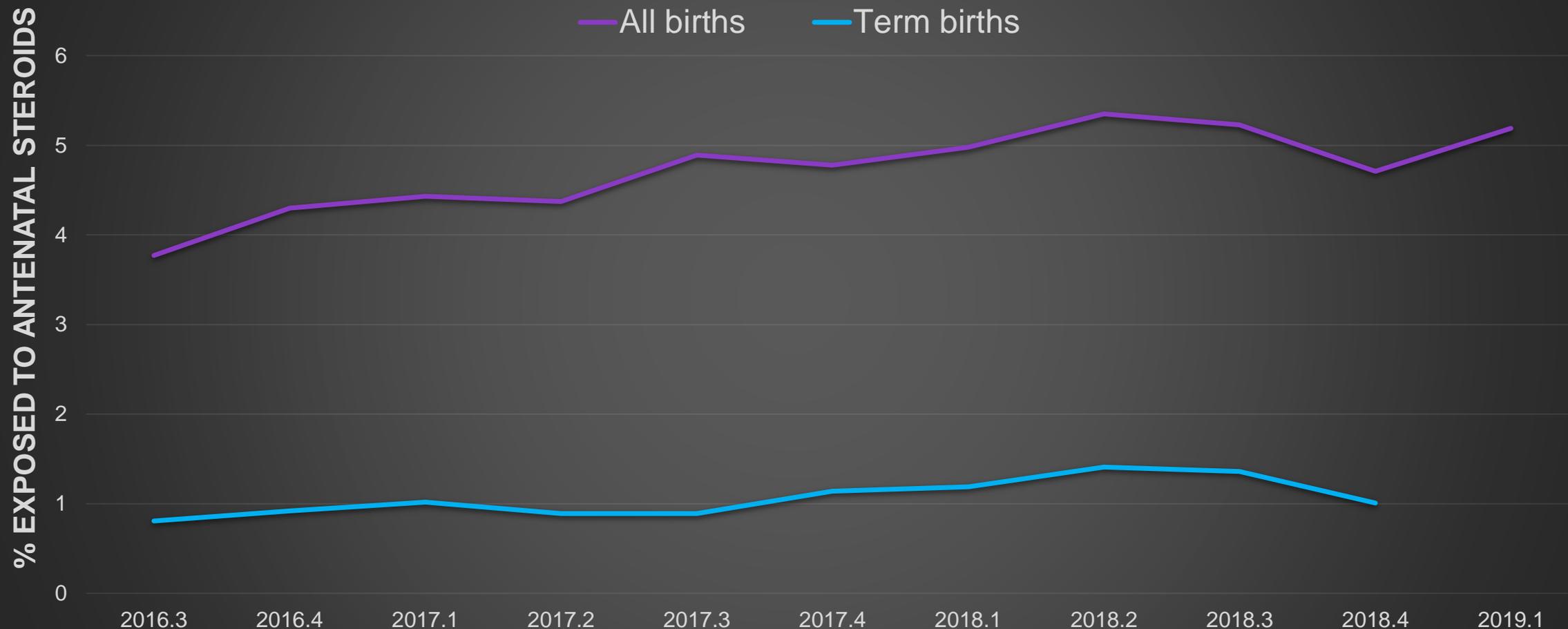
ABSTRACT: Corticosteroid administration before anticipated preterm birth is one of the most important antenatal therapies available to improve newborn outcomes. A single course of corticosteroids is recommended for pregnant women between 24 0/7 weeks and 33 6/7 weeks of gestation who are at risk of preterm delivery within 7 days, including for those with ruptured membranes and multiple gestations. It also may be considered for pregnant women starting at 23 0/7 weeks of gestation who are at risk of preterm delivery within 7 days, based on a family's decision regarding resuscitation, irrespective of membrane rupture status and regardless of fetal number. Administration of betamethasone may be considered in pregnant women between 34 0/7 weeks and 36 6/7 weeks of gestation who are at risk of preterm birth within 7 days, and who have not received a previous course of antenatal corticosteroids. A single repeat course of antenatal corticosteroids should

What happened in the OB COAP Population?

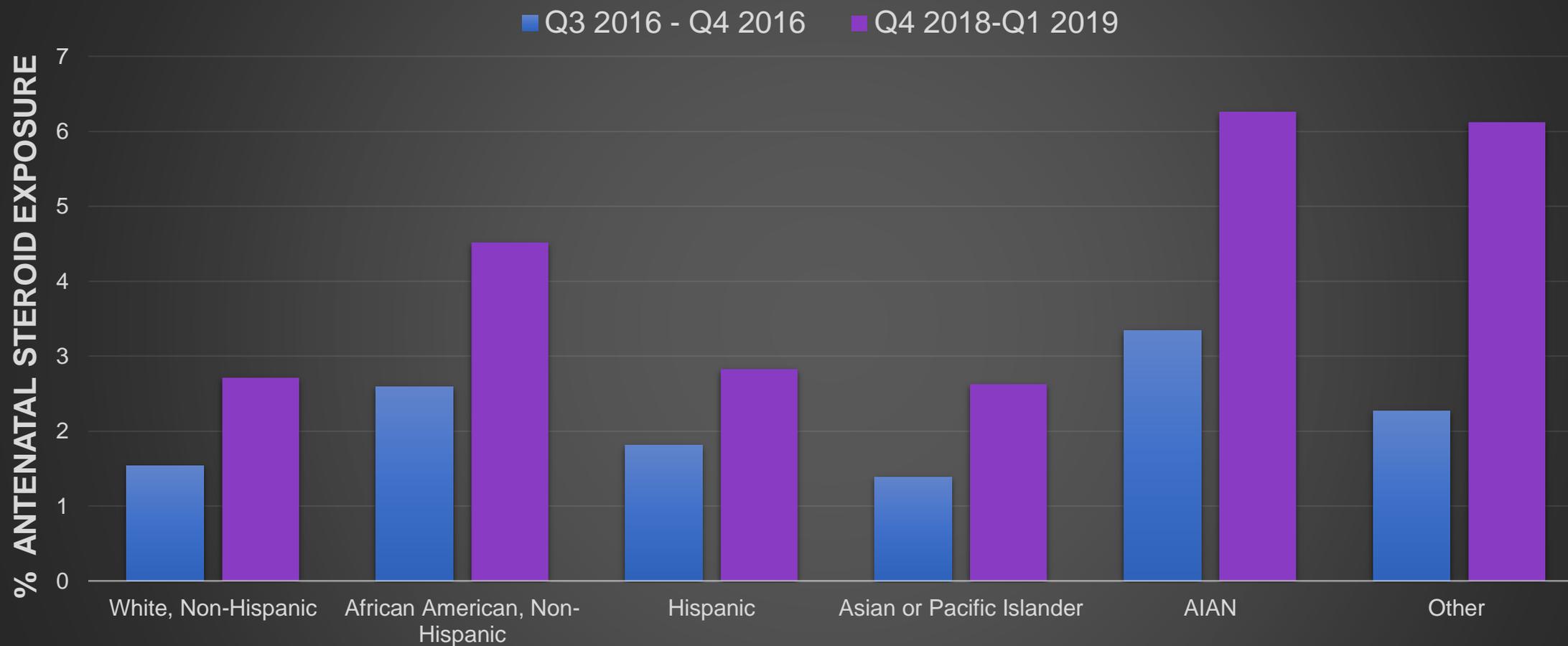
Steroid Exposure by Gestational Age at Birth



Antenatal Steroid Exposure

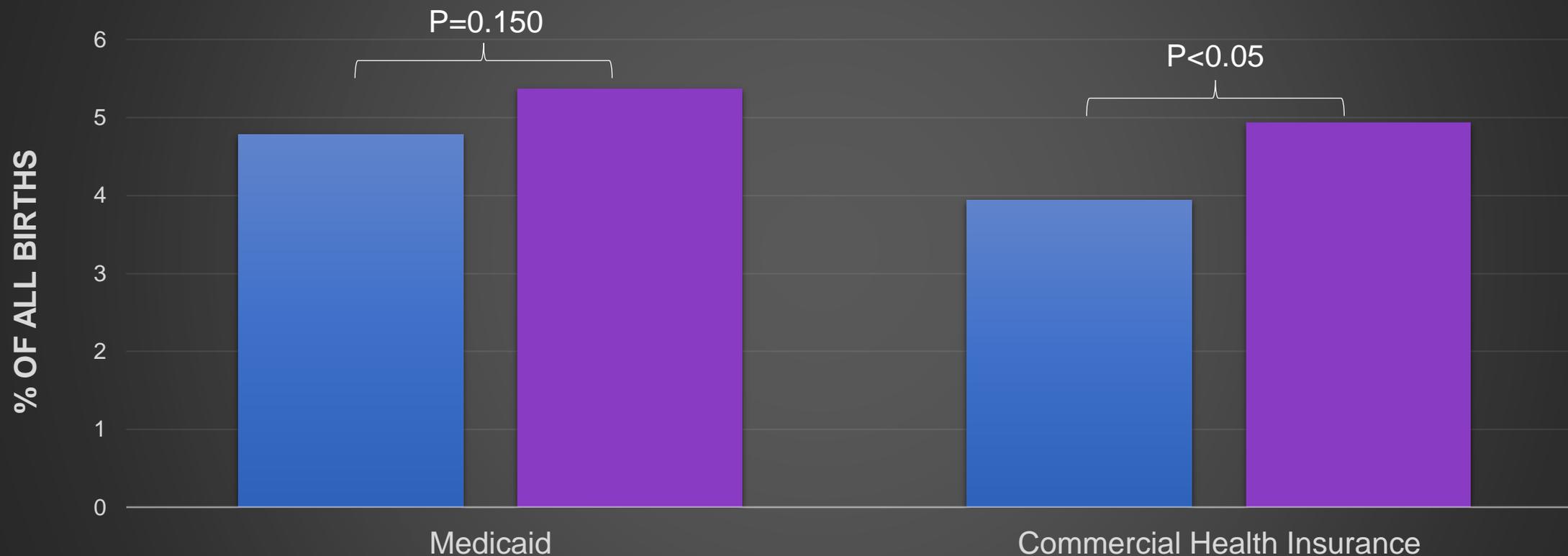


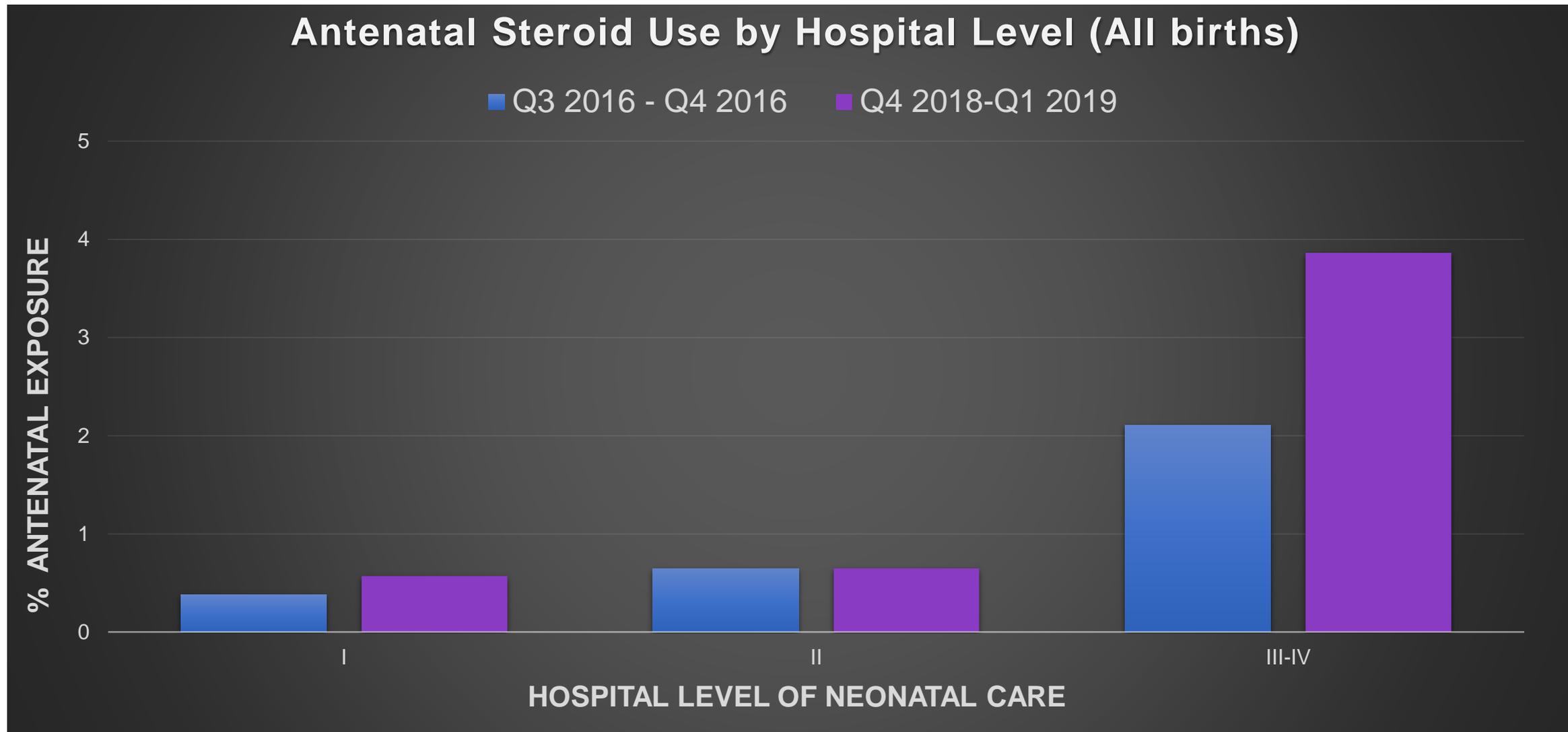
Antenatal Steroid Use by Race and Ethnicity



Antenatal Steroid Exposure by Insurance Type

■ Q3 2016 - Q4 2016 ■ Q4 2018-Q1 2019

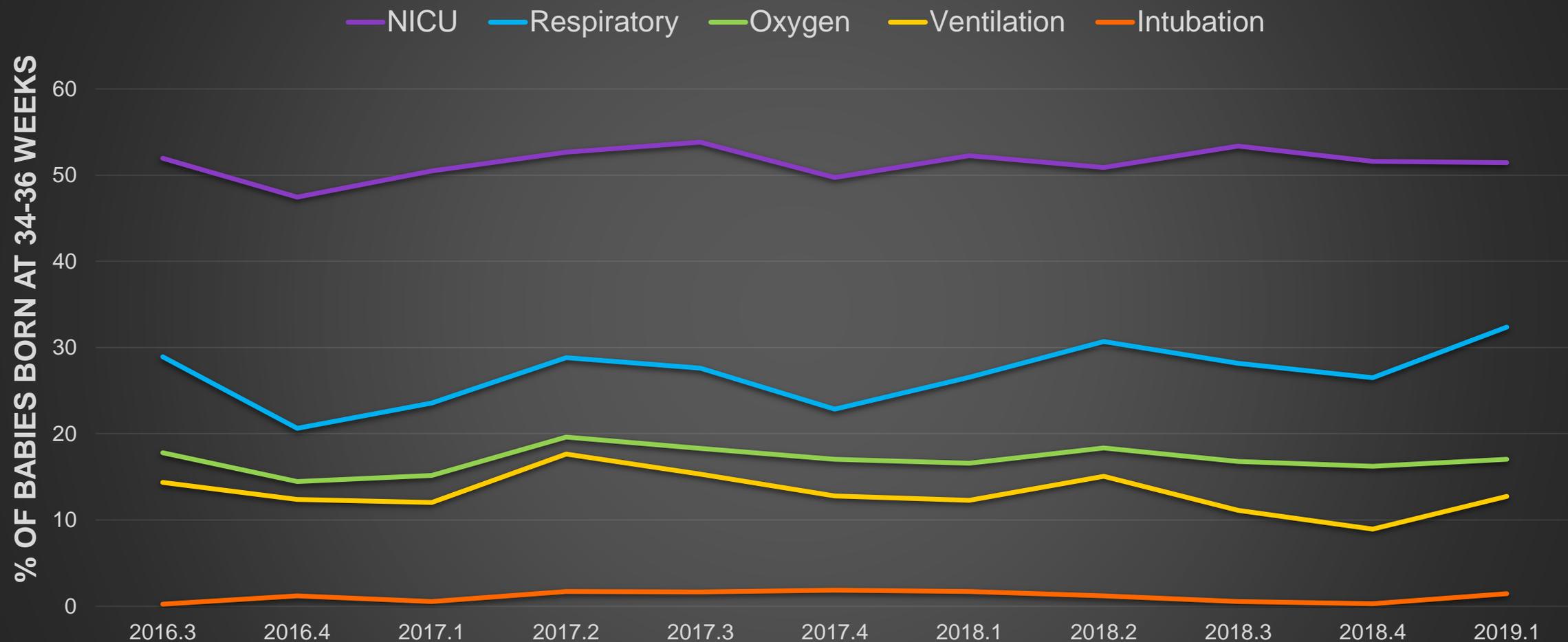




Why is this so important to monitor?

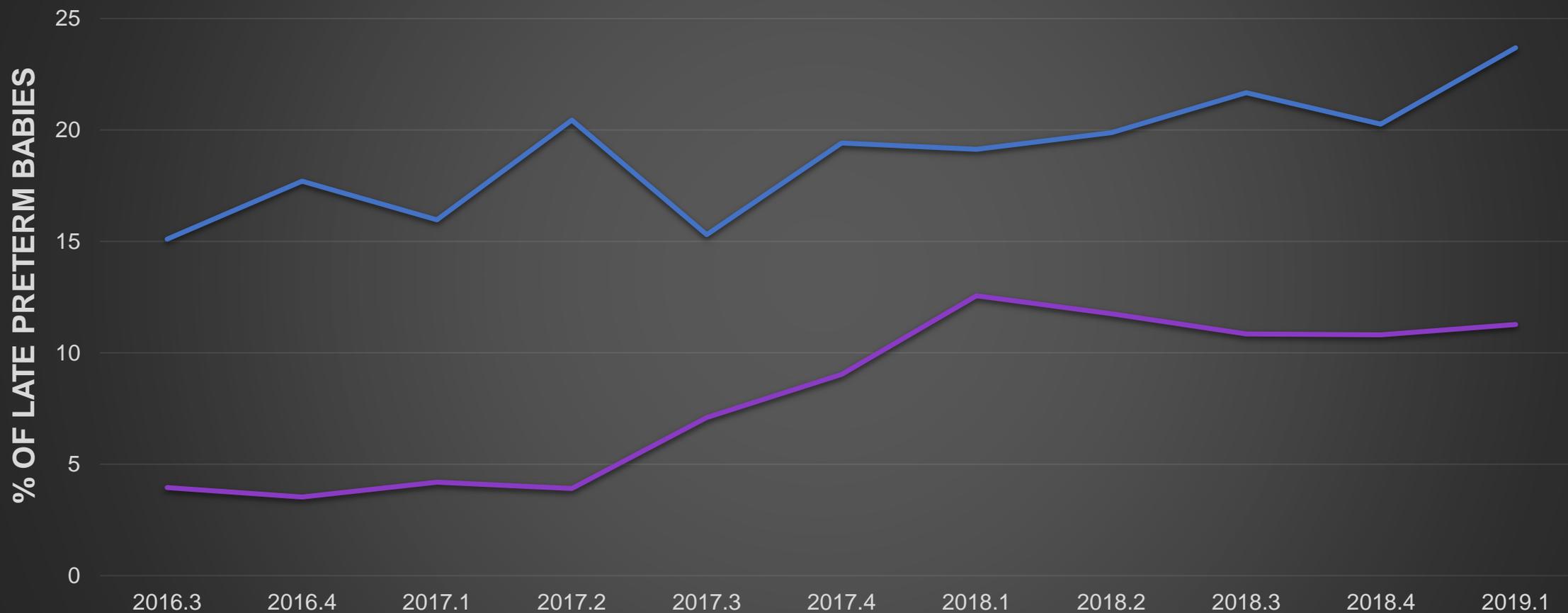
- More than 1 in 20 of all singleton babies in OB COAP is exposed to steroids
- Of these exposed to antenatal steroids:
 - 45.3% are born at 34-36 weeks
 - 21.0% are born at term
 - 33.7% are born at <34 weeks
- Antenatal steroid exposure may not be entirely benign for the baby –concerns about neurodevelopment, metabolic disease in later life, and growth effects, in addition short-term and potentially long-term effects of neonatal hypoglycemia.

Outcomes in Late Preterm Babies

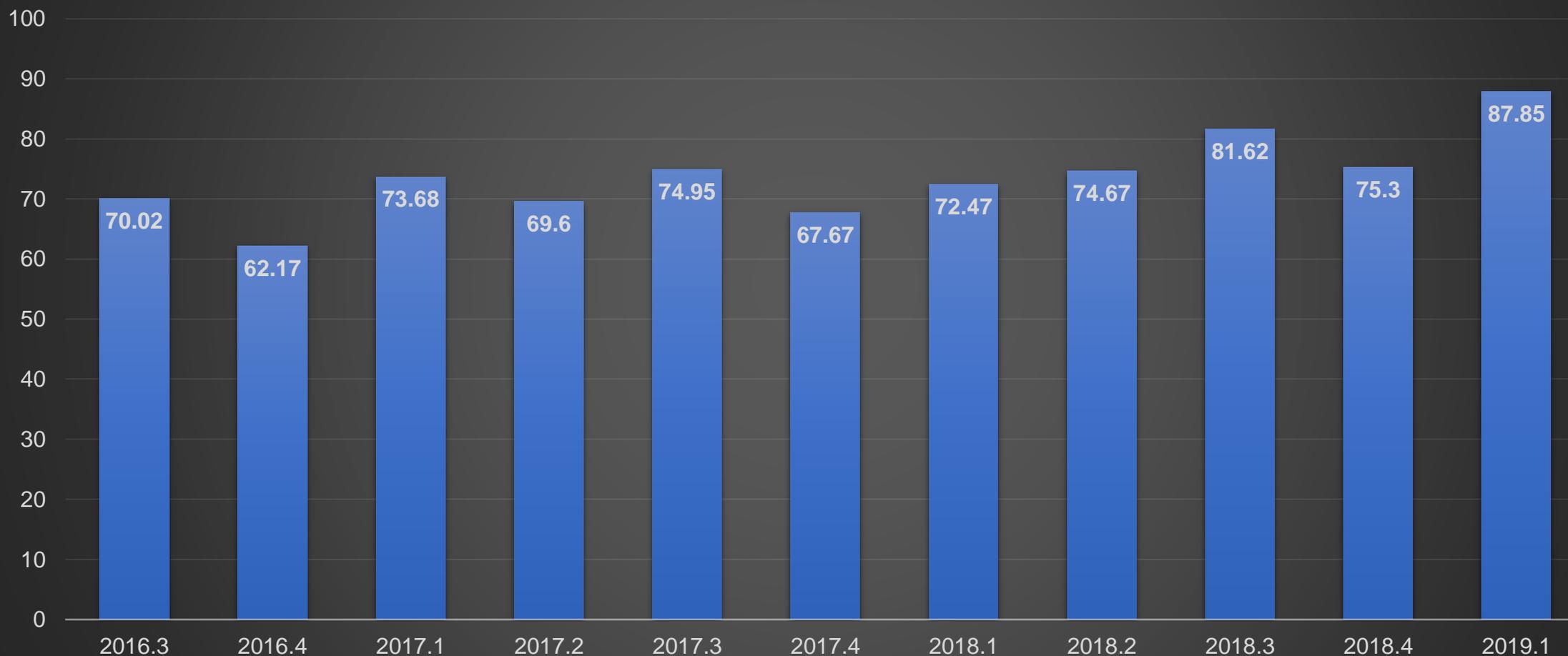


Outcomes for Late Preterm Babies

— Glucose Instability — Temperature Instability



Median Length of Stay (hours) for Late Preterm Babies



Elective induction of labor at 39 weeks

“The ARRIVE Trial”

Study Aim:

To assess the perinatal consequences of induction of labor at 39 weeks in singleton nulliparous pregnant people.

Outcomes:

Primary Outcome: perinatal death or severe neonatal complications

Secondary outcome: cesarean birth

Results:

Primary outcome: 4.3% in the induction group and 5.4% in the expectant management group (RR 0.80; 95% CI 0.64-1.00)

Secondary outcome: 18.6% in the induction group and 22.2% in the expectant management group (RR 0.84; 95% CI 0.76-0.93)

Conclusion:

Induction of labor at 39 weeks in nulliparas is associated with a reduction in the cesarean birth

Notably:

Average age = 23 years. Average age in OB COAP is 28.1 years in the NTSV population

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

William A. Grobman, M.D., Madeline M. Rice, Ph.D., Uma M. Reddy, M.D., M.P.H., Alan T.N. Tita, M.D., Ph.D., Robert M. Silver, M.D., Gail Mallett, R.N., M.S., C.C.R.C., Kim Hill, R.N., B.S.N., Elizabeth A. Thom, Ph.D., Yasser Y. El-Sayed, M.D., Annette Perez-Delboy, M.D., Dwight J. Rouse, M.D., George R. Saade, M.D., Kim A. Boggess, M.D., Suneet P. Chauhan, M.D., Jay D. Iams, M.D., Edward K. Chien, M.D., Brian M. Casey, M.D., Ronald S. Gibbs, M.D., Sindhu K. Srinivas, M.D., M.S.C.E., Geeta K. Swamy, M.D., Hyagriv N. Simhan, M.D., and George A. Macones, M.D., M.S.C.E., for the Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network*

What happened in the OB COAP Population?

Transition to PowerBI Slide

Conclusions

- Randomized trials are the gold standard for testing new therapies in medicine
- They are usually performed in relatively narrow populations under strict management conditions
- Monitoring how these therapies are implemented in the real world and their consequences (both intended and unintended) for patient outcomes and for health care resources is a crucial and largely underappreciated issue.
- Data registries and quality improvement programs can fill this gap
- Stepped-wedge (cluster randomized) trials – could be conducted in the context of a quality collaborative like OB COAP

Questions