

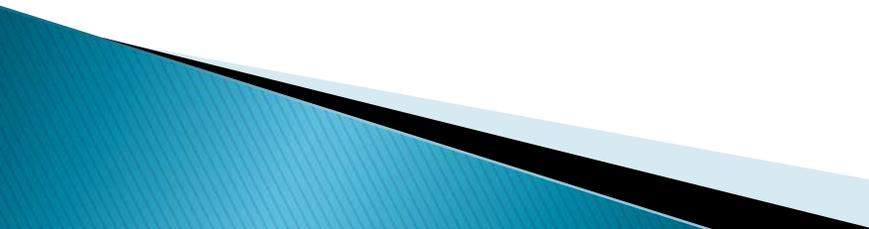


Introduction to APEC

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Quality and Patient Safety

Focus of:

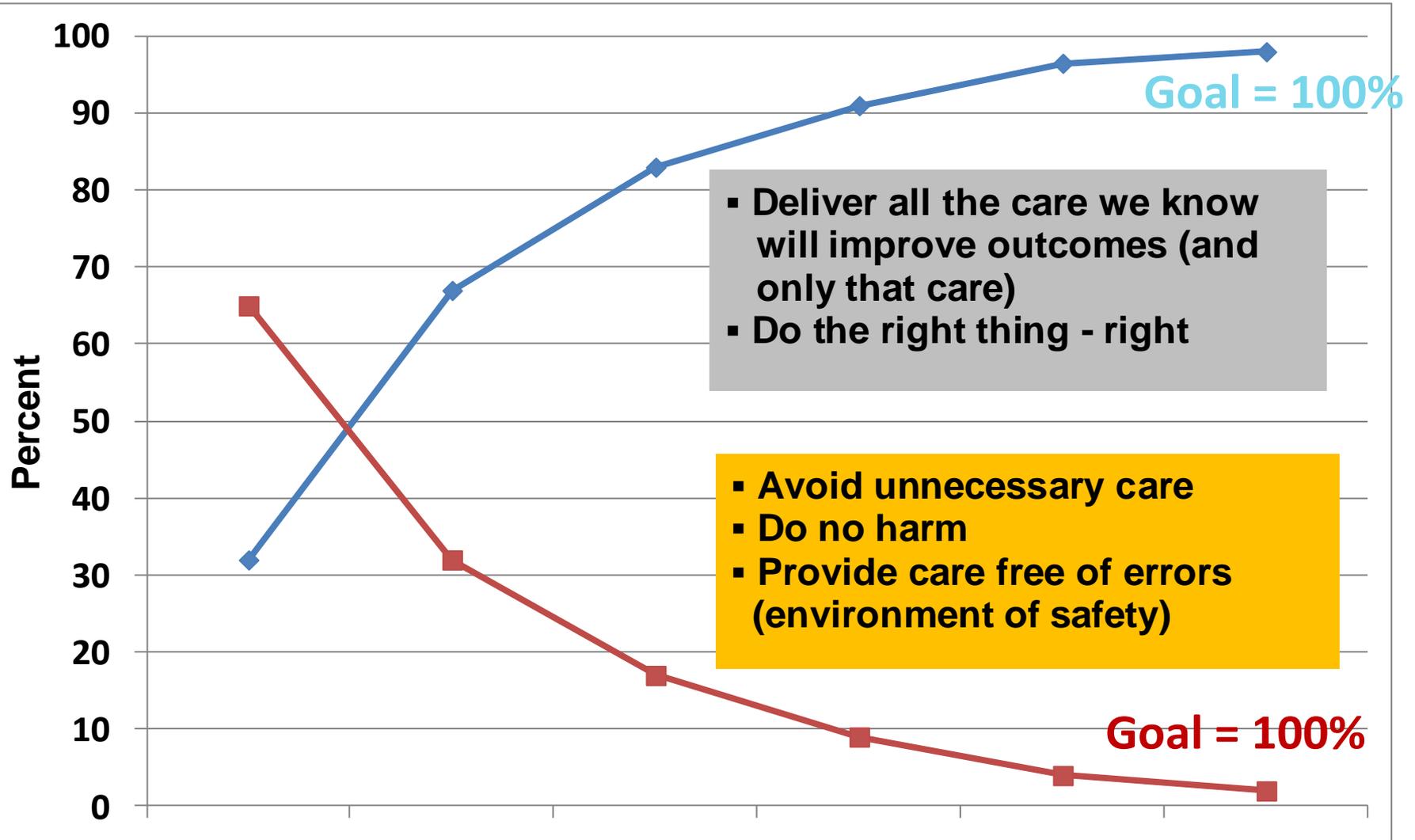
- ▶ Federal agencies
 - ▶ State agencies
 - ▶ Private insurers
 - ▶ Hospitals
 - ▶ Joint Commission
- 

The Institute of Medicine's Answer: *Measurable Performance in Six Dimensions*

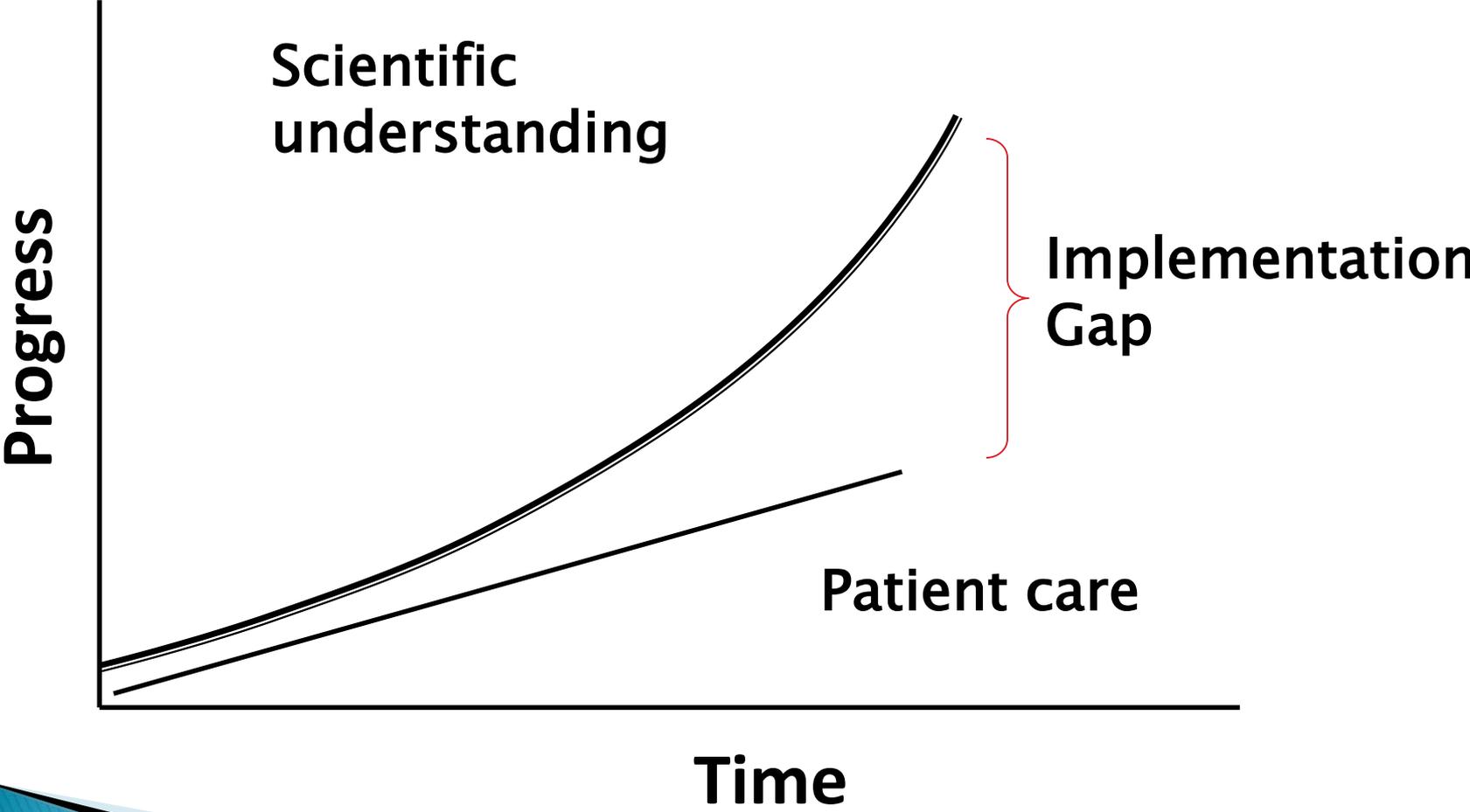
“The STEEEP Model”

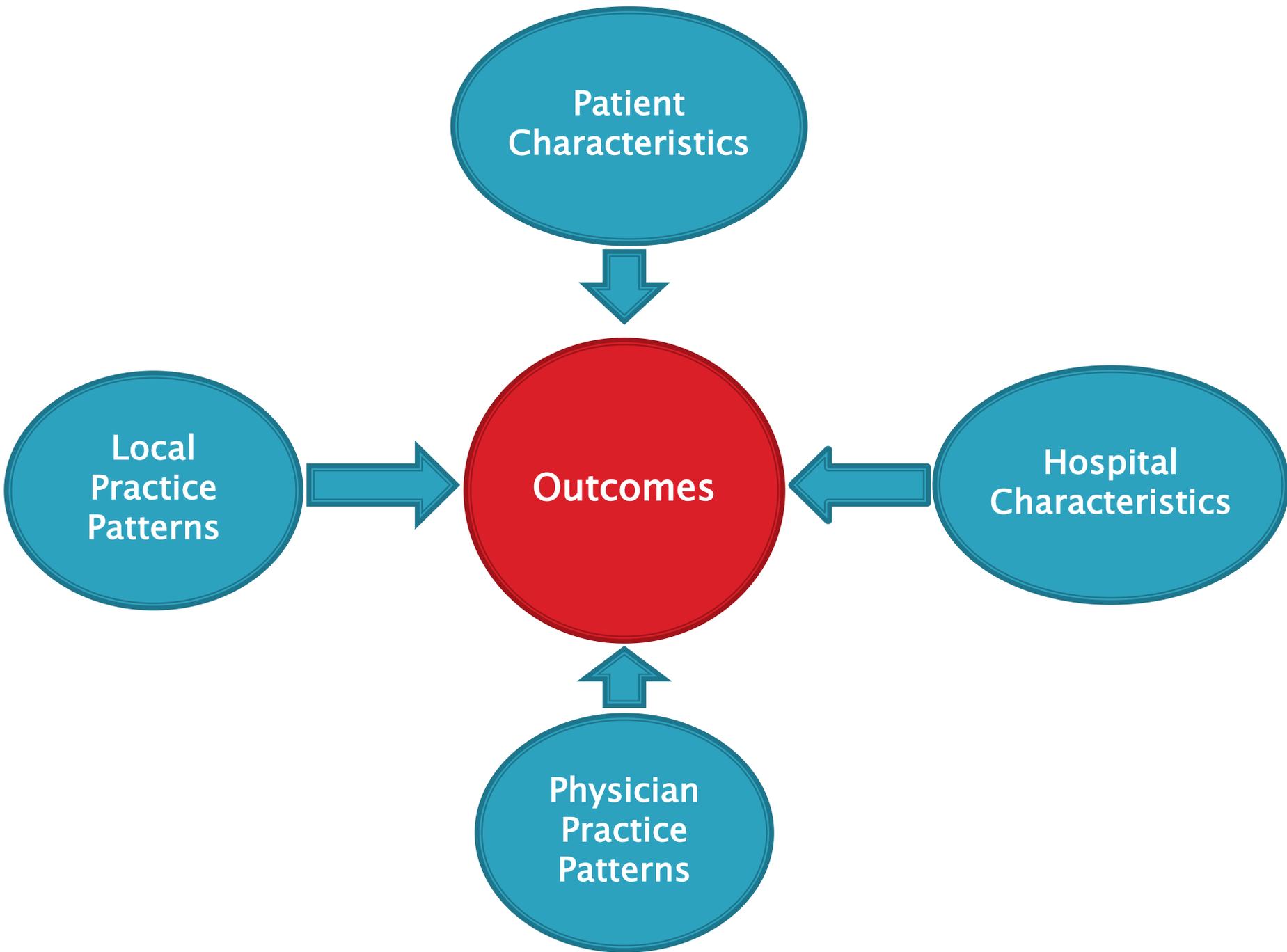
- **Safe** – patients should not be harmed by the care that is *intended* to help them
- **Timely** – unnecessary waits and harmful delays should be reduced (access)
- **Effective** – care should be based on sound scientific knowledge
- **Efficient** – care shouldn't be wasteful
- **Equitable** – shouldn't vary in quality because of patient characteristics
- **Patient-centered** – care should be responsive to individual preferences, needs, and values

Quality Care and Patient Safety



Bridging the Implementation Gap





Standardized Care

↑ quality = ↓ variation and ↓ cost



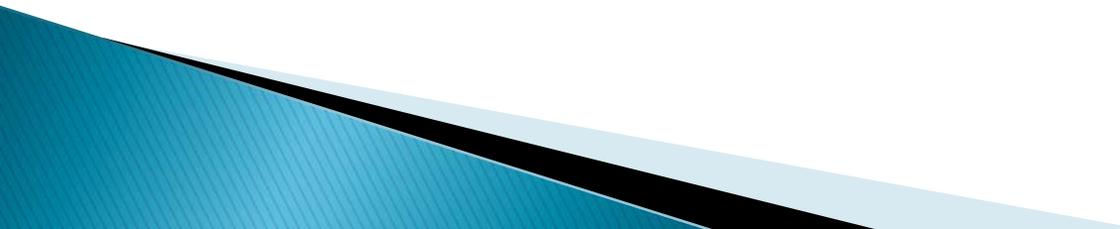
Importance of Standardization

- ▶ **Protocols and Checklists**
 - Provide evidence-based care management guidance
 - Promote team communication
 - Ensure quality care
 - Improve patient safety and outcomes

ACOG CO #629

“Protocols and checklists should be recognized as a guide to the management of a clinical situation or process of care that will apply to most patients.”

Optimal Quality Indicators

- ▶ Associated with meaningful outcomes
 - ▶ Related to outcomes influenced by physician behavior and the health system
 - ▶ Are valid and reproducible
 - ▶ Measurable and inexpensive to assess on a large scale.
 - ▶ Readily acceptable to practicing physicians as a meaningful marker of quality
- 



APEC Partnership

- ▶ Alabama Medicaid Maternity Care Program
- ▶ Alabama Department of Public Health
- ▶ University of Alabama at Birmingham
- ▶ University of South Alabama
- ▶ Statewide OB Providers and Hospitals
- ▶ Patients

APEC Mission Statement



To lower infant mortality and improve maternal and infant health in Alabama through:

1. Implementation and utilization of evidence-based obstetric care guidelines
2. Assessment of meaningful quality benchmarks
3. Enhanced communication and collaboration with providers, both primary and subspecialty, and patients



APEC Goals

1. Help guide OB providers via evidence-based practice guidelines and decision trees
2. Identify meaningful quality benchmarks
3. Develop data collection measures
4. Review quality data and provide feedback to individual providers and institutions
5. Develop mechanisms to help providers in achieving benchmarks

Ultimate Goal: Improve Pregnancy Outcomes



Guideline Components

- ▶ Evidenced-based
- ▶ One page quick view summary sheet
- ▶ Longer narrative version
 - Rationale
 - Supporting evidence



Guideline Components

- ▶ **Benchmarks for performance assessment**
 - Linked to each guideline
 - Meaningful
 - Modifiable factors
 - Rationally achievable



Program Benefits

- ▶ Improvement in outcomes
- ▶ Improvement in access to care
 - Guidance available regardless of zip code
- ▶ Statewide guidelines for care
- ▶ Meaningful incentive development



Program Weakness

- ▶ Data Collection and analysis
- ▶ Claims data
 - Inaccurate
 - Too many variables to measure provider performance

Independent data collection system needed



APEC Guidelines Scheduling Deliveries Prior to 39 weeks Gestation

Increasing rates of elective deliveries have been noted over the past two decades with 37-38 week deliveries accounting for 17.5% of all live births across the US (Davidoff MJ, 2006). Studies have shown that elective deliveries <39 weeks result in increased infant morbidities including higher NICU admissions, transient tachypnea of the newborn, neonatal respiratory distress syndrome, ventilator support, suspected or proven sepsis, and feeding problems. (Tita ATN, 2009) (Bates E, 2010). Moreover, many have raised concerns about the correlation between deliveries <39 weeks and the risk of brain injury or long-term neurodevelopmental abnormalities. At 37 weeks, the brain weighs only 80% of what it will at 40 weeks and gray matter volume increases at a rate of 1.4% per week between 36 and 40 weeks (Guihard-Costa AM, 1990) (Kinney, 2006) (Huppi PS, 1998). In addition, 25% of the cerebellar volume develops after 35 weeks (Limperopoulos C, 2005).

The purpose of this APEC guideline is to assist the provider and the facility in developing and implementing systems to decrease the rate of <39 week elective deliveries—including both inductions and cesareans. The goal is to improve outcomes for mothers and babies. Key components of such an initiative include reducing demand through education, changing delivery scheduling processes, and collecting and reporting outcome measures and trends. While some people have been concerned that an initiative such as this

Box 1. Medical/Obstetric Indications for Scheduled Deliveries <39 weeks

- Abruptio
- Previa
- Placenta accreta/increta/percreta
- Prior classical cesarean or myomectomy
- Preeclampsia/eclampsia
- Fetal Anomaly
- Gestational HTN
- GDM with insulin or poor control
- Non-gestational diabetes

Hospital with induction rates for <39 week elective deliveries dropping from 11.8% to 4.3% in two years. The Ohio Perinatal Quality Collaborative (OPQC) made up of 20 Ohio maternity hospitals, implemented a policy to eliminate deliveries <39 weeks gestation without medical or obstetric indication and found a decline of these deliveries from 25% in July 2008 to <5% in August 2009.

These publications demonstrate that programs designed and implemented to eliminate elective deliveries <39 weeks gestation are successful when they are driven by data, involve multidisciplinary teams and reference and enforce specific guidelines.

Quality Indicators/Benchmarks

- GA at delivery
- Delivery indication
- Neonatal outcomes

APEC Guidelines
Scheduling Deliveries Prior to 39 weeks Gestation

APEC Summary Page

<u>Documentation</u>	
Provide patient education on early delivery <39 weeks of gestation.	
❖ Document in medical record discussion of risks early delivery at 36 0/7-38 6/7 weeks.	
Confirm gestational age.	
❖ Document GA in medical record along with method used to establish GA.	
An amniocentesis for fetal lung maturity should only be done if there is a medical indication that would support its performance and a positive result would lead to delivery.	
❖ Document amniocentesis and lung maturity result in medical record if done.	
For induction document:	
❖ Cervical exam	
❖ Informed consent	
For cesarean document:	
❖ Indication	
❖ Informed consent	
<u>Medical/Obstetric Indications for Scheduled Deliveries < 39 weeks</u>	
❖ Abruptio	❖ Cholestasis of pregnancy
❖ Previa	❖ HIV infection (Delivery at 38 weeks considered standard and no lung maturity required) IUGR
❖ Placenta accreta/increta/percreta	❖ Non-reassuring Fetal Status
❖ Preeclampsia/eclampsia	❖ Isoimmunization with concern for fetal anemia
❖ Fetal Anomaly	❖ Multifetal gestation with complication (Delivery of twin gestation at 38 weeks may be a reasonable alternative even in the absence of complications)
❖ Gestational HTN	❖ Maternal medical condition—cardiac, pulmonary, GI, autoimmune, neurologic—with deterioration or worsened by pregnancy
❖ Preeclampsia/eclampsia	❖ Acute fatty liver
❖ Prior classical cesarean or myomectomy	
❖ GDM with insulin or poor control	
❖ Pre-gestational diabetes	
❖ PROM	
❖ Oligohydramnios	
<u>Recommendations for the Timing of Medically Indicated Delivery</u>	
<u>Condition</u>	<u>Recommended GA & Range</u>
Placenta/uterine issues	
Placenta Previa – No prior bleeding	37 ⁰ (36 ⁰ - 37 ⁶)
Placenta Previa – Multiple prior bleeding episodes	36 ⁰ (34 ⁰ - 36 ⁶)
Vasa Previa Suspected	36 ⁰ - 37 ⁶
Prior Classical/Vertical Cesarean/Prior uterine rupture	37 ⁰ (36 ⁰ - 37 ⁶)
Prior Myomectomy (not hysteroscopic)	38 ⁰ (37 ⁰ - 38 ⁶)
Fetal Issues	
Growth Restriction (<5th)	
Normal testing (BPP, Dopplers, No maternal co-morbidities)	37 ⁰ (37 ⁰ - 37 ⁶)
Abnormal Dopplers, oligohydramnios, or maternal co-morbidities#	34 ⁰ - 36 ⁶
Growth Restriction (5th-9th)-Normal testing	
	39 ⁰ - 39 ⁶
Twins	
Di-Di—Normal growth	38 ⁰ (38 ⁰ - 38 ⁶)
Di-Di—IUGR of one or both	37 ⁰ (36 ⁰ - 38 ⁶)
Di-Di—Abnormal Doppler, oligohydramnios, maternal co-morbidities#	34 ⁰ - 36 ⁶



APEC Guidelines Prior Spontaneous Preterm Birth

Preterm birth is defined as delivery before 37 weeks gestation. Prematurity is the leading cause of perinatal mortality in the US and is the major reason why we lag behind other developed nations in infant mortality rates. Approximately 70% of neonatal deaths, 36% of infant deaths, and 25-50% of cases of long-term neurologic impairment in children can be attributed to preterm birth.(ACOG, 2012a) The estimated cost of preterm births exceeds \$26.2 billion annually with an average cost of care for a preterm birth ten times greater than that of a full term birth, \$32,325 to \$3,325 respectively. (CDC, 2008) In 2013, preterm birth occurred in 11.4% of 4 million births in the US and 15.1% of 58,000 births in the state of Alabama. ("March of Dimes 2014 Premature Birth Report Card," 2014) Alabama, Louisiana, Mississippi, and Puerto Rico each received a report card grade of "F" from the March of Dimes in 2014 for high preterm birth rates.

Spontaneous preterm birth (sPTB) is defined as delivery before 37 weeks as a result of spontaneous labor or rupture of membranes. Women with a prior sPTB are at high risk for another preterm birth with recurrence rates ranging from 25-50%. This risk is highest in women with a short cervix (<25 mm) with the risk inversely related to the cervical length. Studies have demonstrated the effectiveness of progesterone in the prevention of recurrent preterm birth in singleton pregnancies. (da Fonseca, Bittar, Carvalho, & Zugaib, 2003; Fonseca et al., 2007; Hassan et al., 2011; Meis et al., 2003) In a study by Owen, cerclage was found to delay preterm birth and prevent previable delivery in women

Quality Indicators/Benchmarks

- Progesterone treatment in women with a current singleton pregnancy and a prior singleton sPTB who present for care by 20 weeks of gestation.
- Cervical length ultrasound in women with a prior sPTB <34 weeks of gestation who present for care before 22 weeks.
 - APEC acknowledges that not all providers and patients will have equal access to cervical length screening according to the schedule outlined above. This indicator is being examined in order to identify opportunities to remove barriers to care and enhance resource provision to patients throughout the state.

Alabama Perinatal Excellence Collaborative

This document should not be construed as dictating an exclusive course of treatment or procedure to be followed.

APEC Guidelines Prior Spontaneous Preterm Birth

17 α -hydroxyprogesterone caproate clinical eligibility:

- Singleton pregnancy.
- Prior singleton spontaneous preterm birth <37 weeks of gestation.

Patients must meet the FDA-approved indication for 17-P defined as current singleton pregnancy with a **history of singleton spontaneous preterm birth less than 37 weeks** of gestation.

Prior Spontaneous PTB assessment and treatment

- ❖ Confirm currently pregnant a singleton gestation with a prior history of a singleton spontaneous preterm birth less than 37 weeks of gestation.
- ❖ Counsel on the beneficial effects of progesterone therapy.
- ❖ Initiate progesterone therapy at 16 to 20 weeks and continue therapy to 36 weeks of gestation.
- ❖ Prior SPTB < 34 wks: Offer cervical length screening at 16-18 weeks and every 2 weeks up through 22 weeks.
- ❖ Cervical length < 25 mm candidate for cerclage.
- ❖ Patients with a visibly abnormal cervix should be referred to MFM specialist for evaluation.

Progesterone Formulations

Indications for Use	Progesterone formulation	Dosage	Trial reference
Prior sPTB	17 α-hydroxyprogesterone caproate*	250mg IM weekly	(Meis et al., 2003)
Prior sPTB or short cervical length (<20 mm)	Vaginal suppositories#	100 mg vaginal suppository every night	(da Fonseca et al., 2003)
Prior sPTB or short cervical length (<20 MM)	Micronized capsules†	200 mg vaginally daily	(Fonseca et al., 2007)
Short cervical length between 10 and 20 mm	8% vaginal progesterone gel	90 mg vaginally daily	(Hassan et al., 2011)

Progesterone Availability

17-P is available through the Alabama Medicaid Pharmacy Plan as the commercial brand Makena. For patients who have not yet received Medicaid approval, or who do not qualify for the Alabama Medicaid Maternity Care Program, 17-P can be obtained through the Makena Care Connection patient assistance program 1-800-847-3418. Compounded 17-P is available only with prior approval from Medicaid.

#Progesterone vaginal suppositories are not clinically available but can be obtained from compounding pharmacies for patients desiring that mode of therapy.

†Micronized progesterone capsules are marketed generically and are the same medication as the commercial brand Prometrium. Progesterone gel is marketed as 8% Crinone gel; it is not currently available generically. Neither of these formulations is currently FDA approved for a preterm birth prevention indication. Prometrium is covered by the Alabama Medicaid Pharmacy Plan, Crinone gel is not.

Quality Indicators/Benchmarks

- ❖ Progesterone treatment in women with a current singleton pregnancy and a prior singleton sPTB who present for care by 20 weeks of gestation.
- ❖ Cervical length ultrasound in women with a prior sPTB who present for care before 22 weeks.

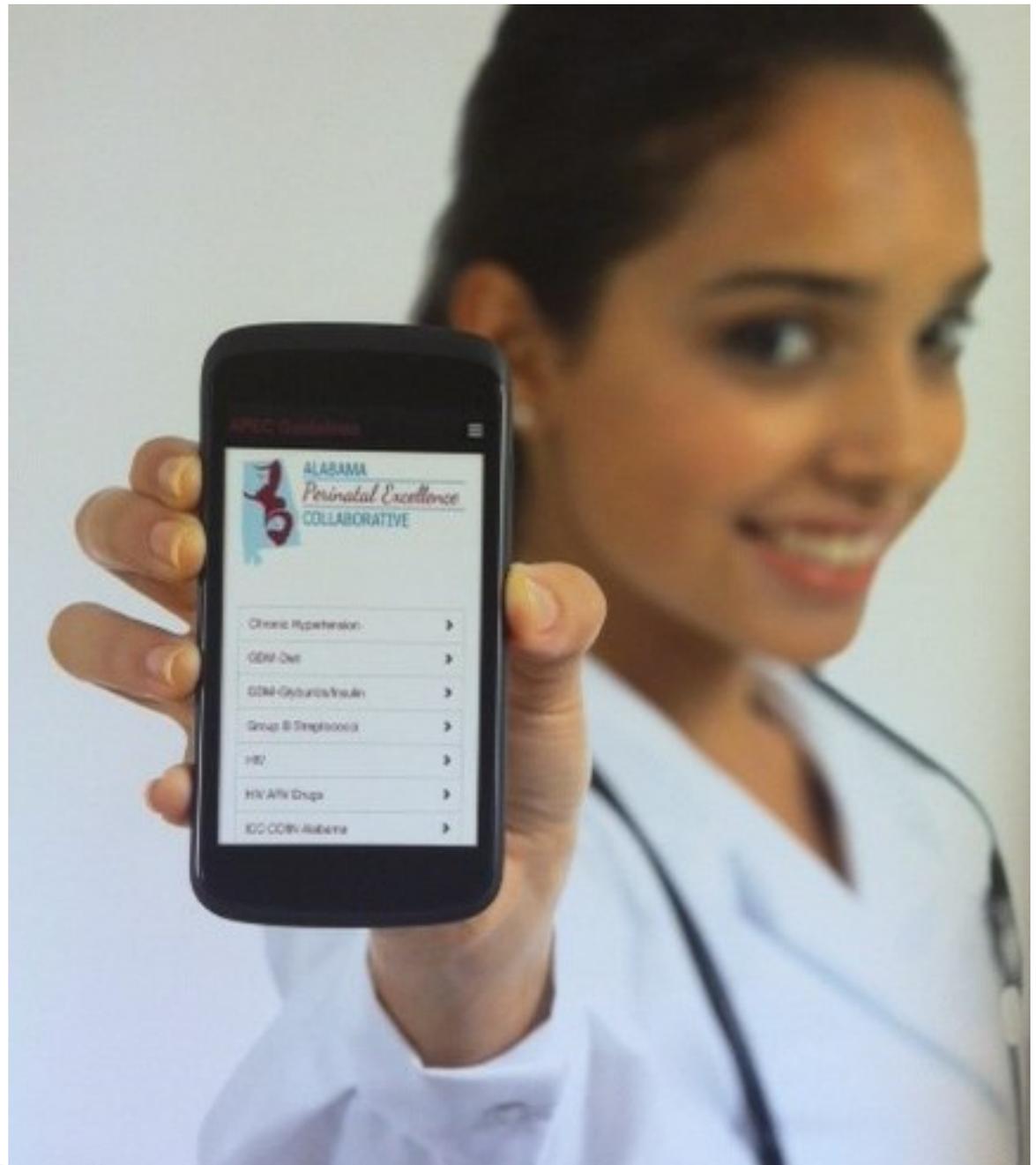
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Smart Phone APP Available

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