Progesterone Basics:

Screening and Identifying Candidates

Objectives

After this training, you should be able to:

1) Identify candidates for progesterone treatment

2) Know how to obtain progesterone

Greater Columbus Infant Mortality Task Force

- Formed in November 2013

- Charged with developing a community plan to reduce the rate of infant mortality in Columbus/Franklin County

- The goal: reduce the infant mortality rate by nearly 40 percent by 2020, from the 2011 benchmark rate of 9.8 infant deaths per 1,000 live births to 6 per 1,000, and cut the racial disparity gap in half

Greater Columbus Infant Mortality Task Force

- Recommendations and implementation plan released in June 2014

- Plan included 8 recommendations

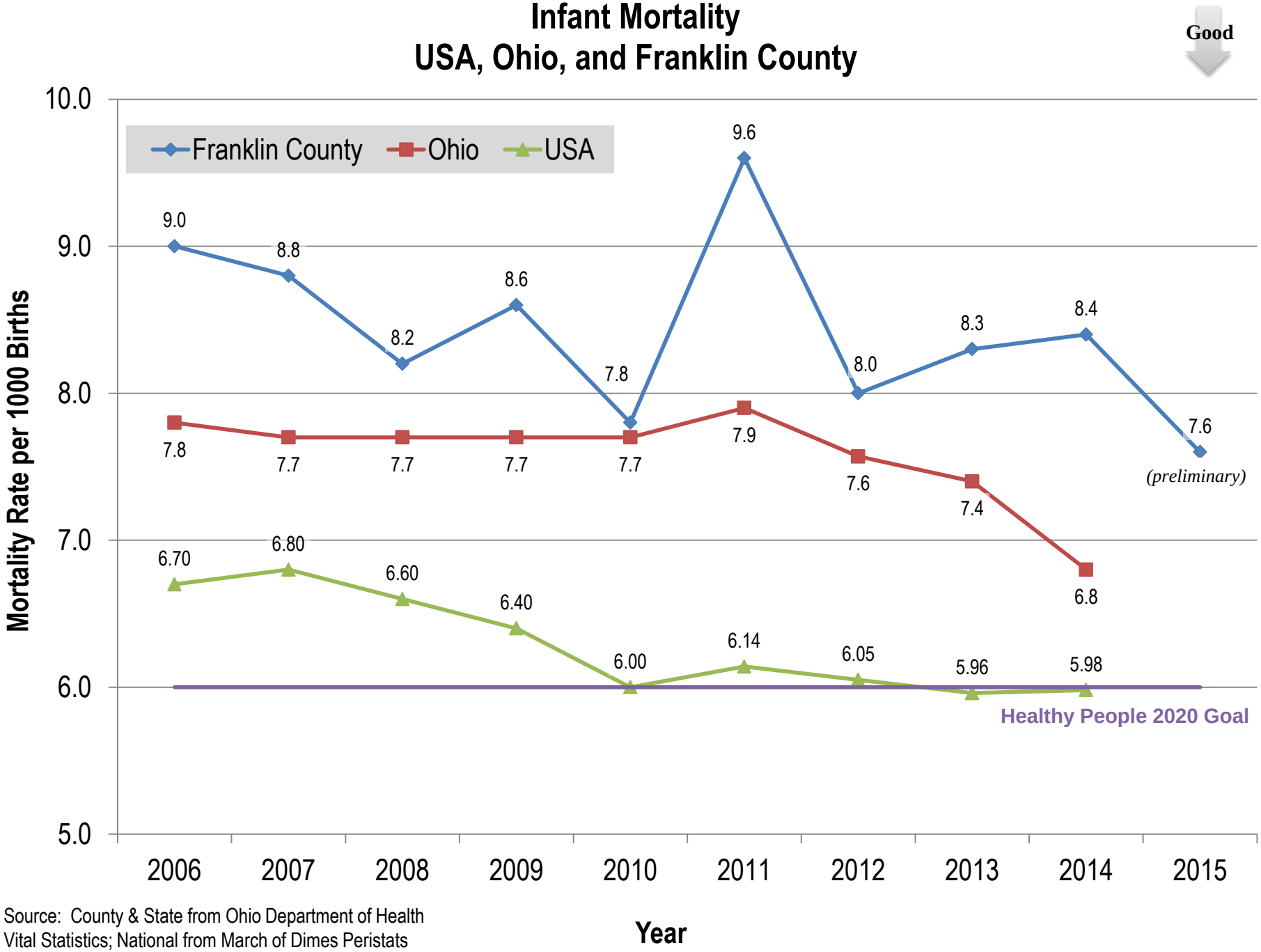
- Recommendation #5: Ensure Highest Standards of Quality for Perinatal Care
    - Strategy #1: Increase the percentage of eligible women receiving progesterone

Infant Mortality

- Definition: The death of a baby before his or her first birthday

- Infant Mortality Rate: The number of infant deaths for every 1,000 live births

Infant Mortality
USA, Ohio, and Franklin County



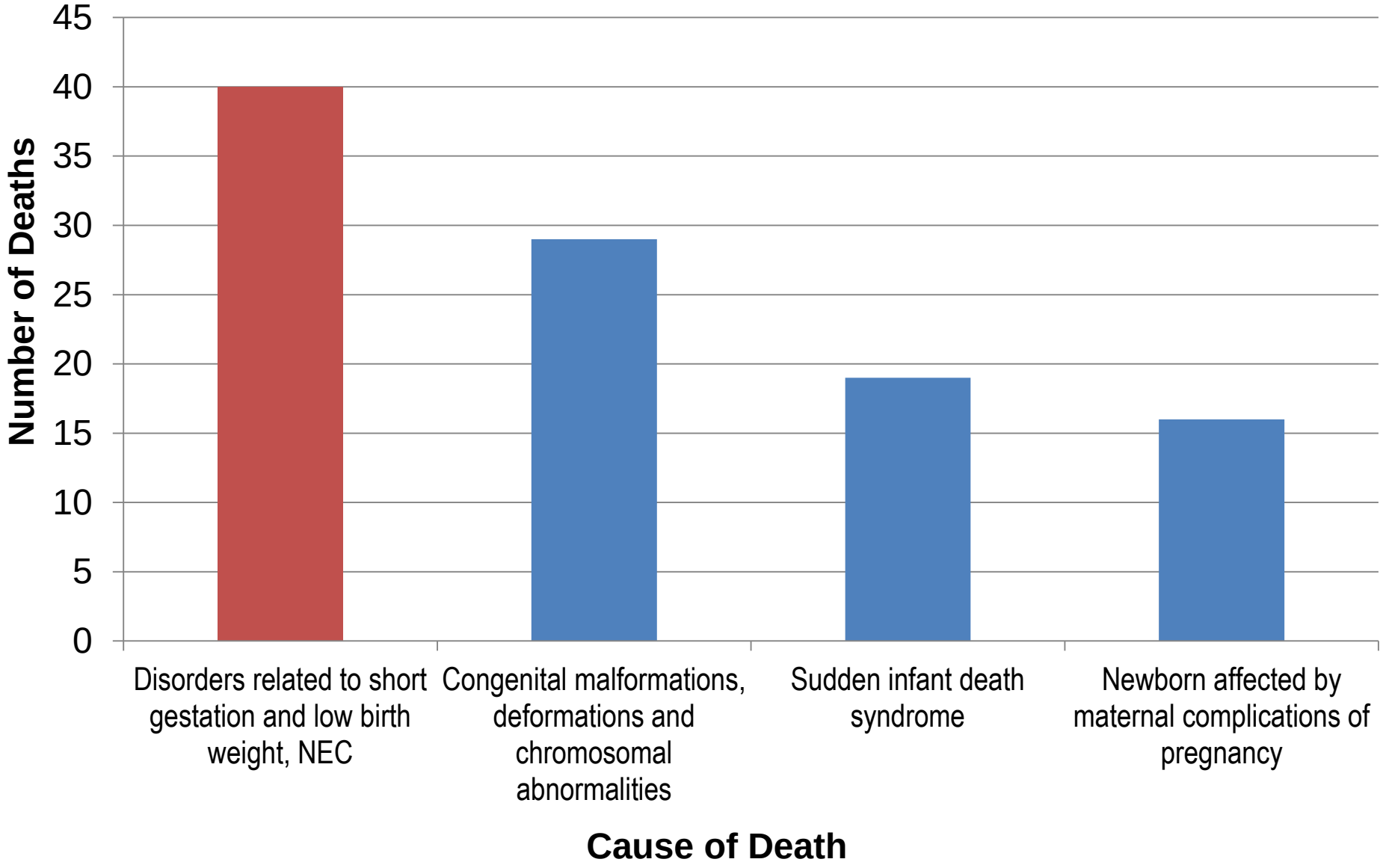
Source: County & State from Ohio Department of Health Vital Statistics; National from March of Dimes Peristats

Prematurity

- Prematurity is the leading cause of Infant Mortality

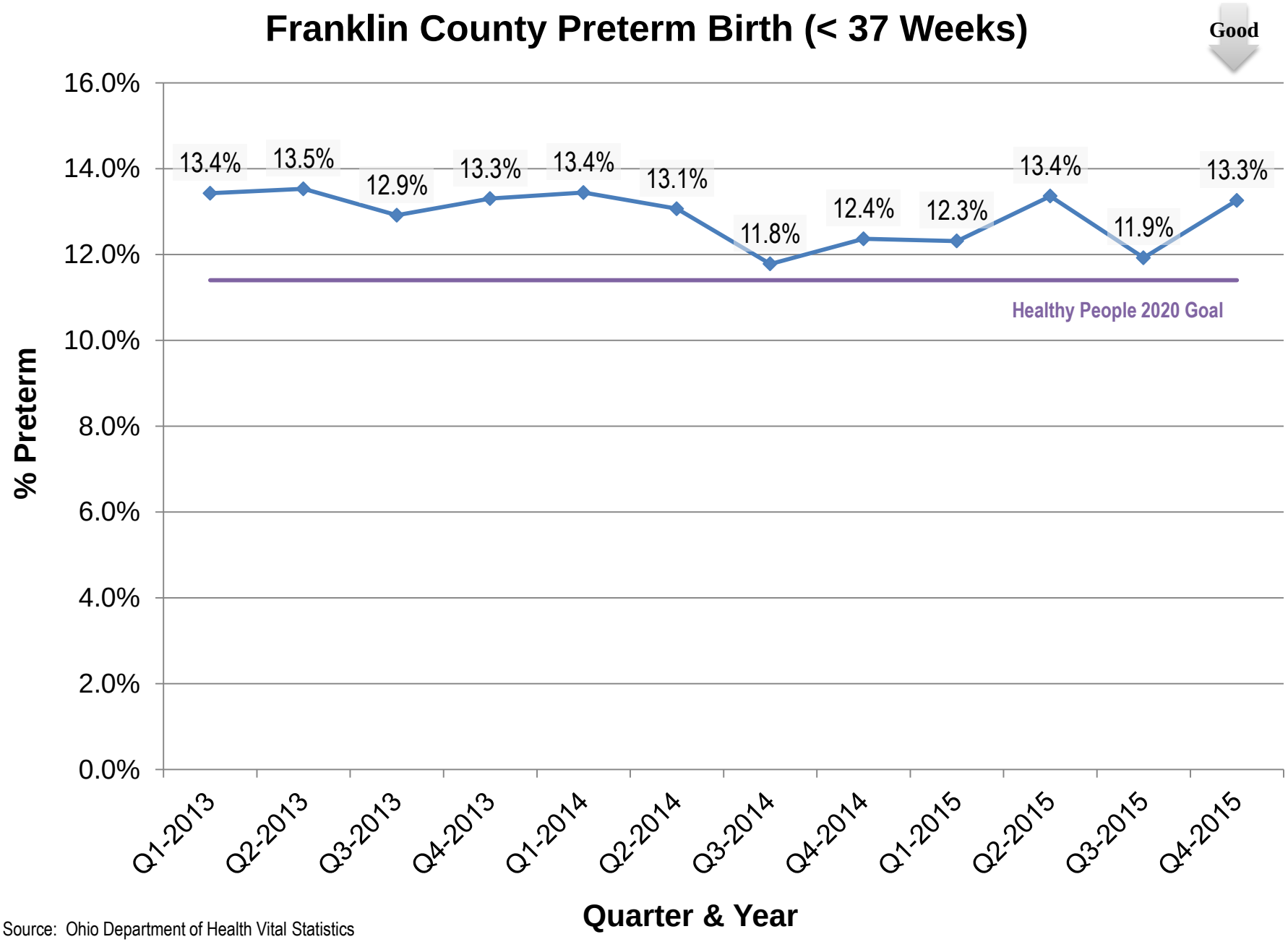
- Definition: Birth of an infant before 37 weeks of pregnancy

Leading Causes of Infant Mortality
Franklin County 2014



*The rankable causes of infant deaths are a subset of the CDC, National Center for Health Statistics, National Vital Statistics System. **Preliminary Data Source: Ohio Department of Health, Office of Vital Statistics. Analyzed by Columbus Public Health, Office of Epidemiology.

Franklin County Preterm Birth (< 37 Weeks)



Source: Ohio Department of Health Vital Statistics

Spontaneous vs Indicated

- Spontaneous PTB: live birth between $16^{0/7}$- $36^{6/7}$ weeks or a stillbirth between $16^{0/7}$- $24^{0/7}$ weeks presenting as labor, ruptured membranes, or advanced cervical dilation or effacement

- Indicated PTB: physician delivered the patient because of a medical issue (IUGR, Oligohydraminios, NRFWB, Diabetes, Preeclampsia)

Who is at Risk for Preterm Birth?

Women Who:

- Have had >1 premature baby
- Have had a “short” cervix, a cerclage (“stitch”) or were on progesterone therapy with another pregnancy
- Used fertility drugs to help get pregnant, even if they only had one baby
- Have had treatment for an abnormal pap smear
- Have a history of urinary tract infections
- Have a history of sexually transmitted infections
- Are African American or Black
- Are very overweight or very underweight
- Have gum disease

How Do We Find Them?

Ask these questions:

1) Are you pregnant with one baby?
2) Were any of your other babies born more than a month early?
3) Have you been on progesterone in a past pregnancy?

Patient History, Screening, & Assessment

- Identify patients as early as possible (based on history, risk factors and cervical length screening)

- Make screening for history of spontaneous preterm birth part of routine prenatal intake & patient history (like screening for diabetes or hypertension)

- Provide staff education to every person in your office who has patient contact (intake coordinator, residents, nurses, scheduler, medical assistant…) Everyone should be able to screen for history of spontaneous preterm birth and alert the heath care provider if identified

Patient History, Screening, & Assessment

- If patient history is unclear, may need to request previous delivery records

- Empower your patients by educating them on Prematurity and Progesterone therapy for current and future pregnancies

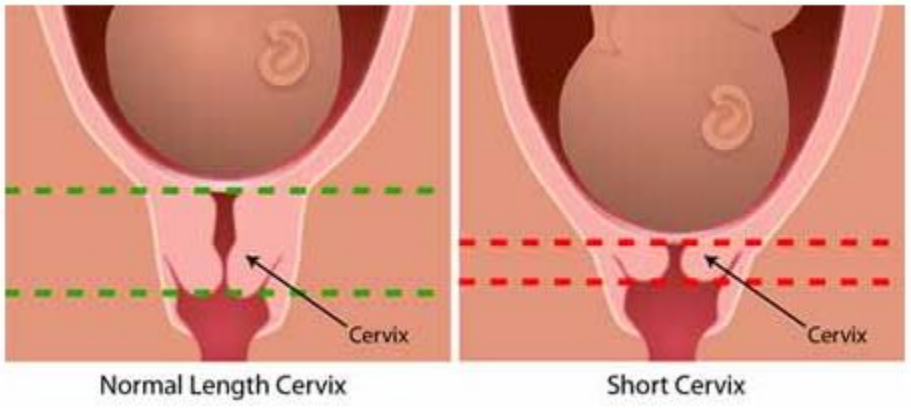
- Provide patients with strong supportive knowledge about the use and compliance of progesterone therapy from $16^{0/7}$-$36^{6/7}$ weeks gestation (posters, education materials, face to face explanation)

Cervical Length Screening

- Transvaginal ultrasound can be used to measure cervical length and identify women at risk for preterm birth

- Universal vs. Selective Screening (see algorithm)

  1) Universal: all women 2)Selective: women with risk factors



Source: *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

- Watch this video from the University of Pittsburgh Medical Center "Using Transvaginal Ultrasound to Help Prevent Pre-term Birth"

How Do We Help Them?

- Progesterone is a hormone made by the placenta during pregnancy. It can safely help the pregnancy to continue longer

- Some pregnant women need more progesterone than their bodies make. Providers can prescribe these women supplemental progesterone

- Progesterone can be given as:

  1) a shot once a week 2) a vaginal suppository every night 3) a vaginal capsule every night 4) vaginal gel every night

Identification of Candidates for Progesterone

Who?

- Women who have had a previous spontaneous preterm birth and currently have a singleton pregnancy
  - Studies have shown that progesterone does not reduce spontaneous PTB in women with twins or triplets

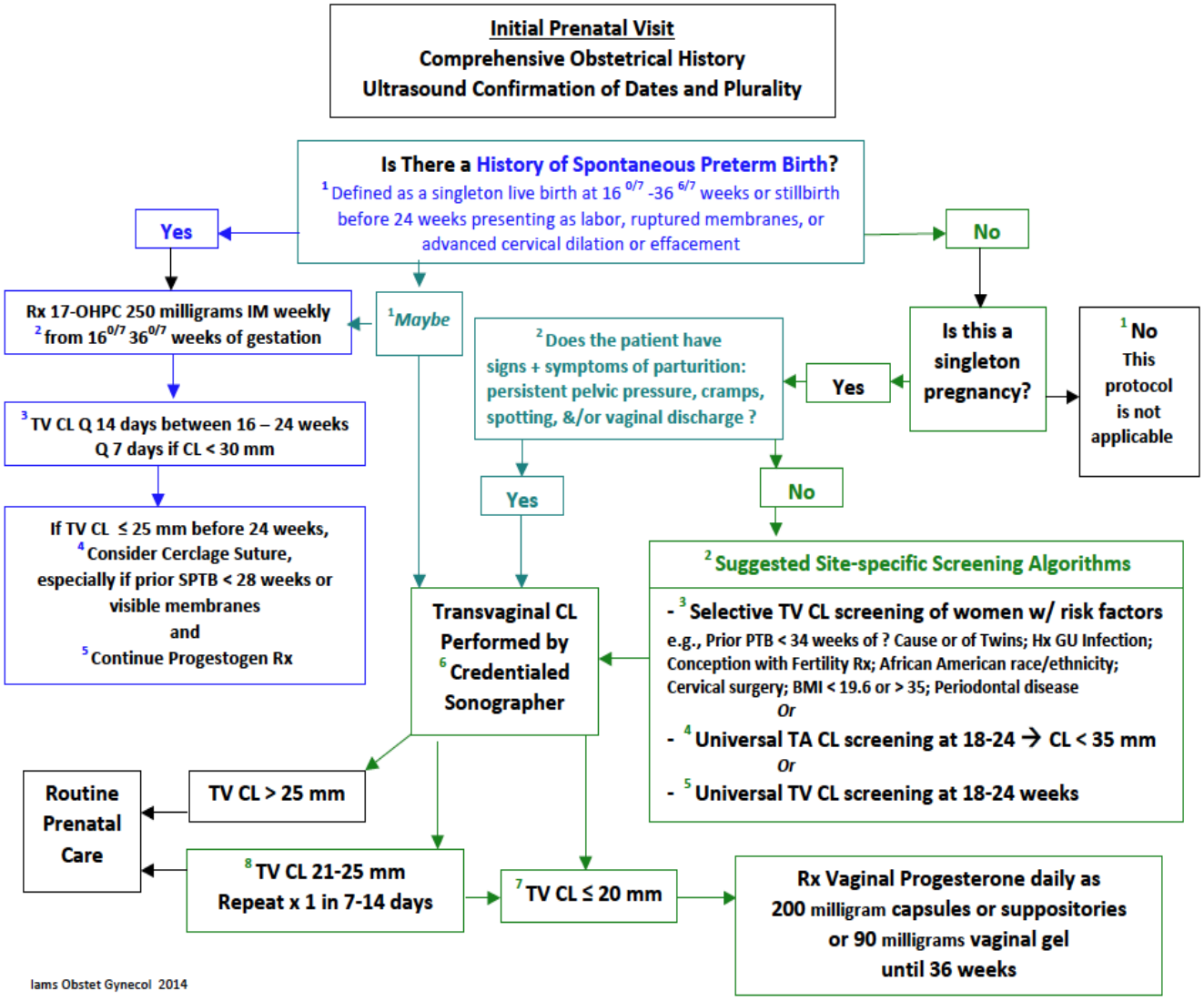
- Women who are found to have a short cervix (≤20mm) before 24 weeks in their current pregnancy

Identification of Candidates for Progesterone

Does your clinic have a progesterone protocol?

Do you know what it is?

Here is one recently published protocol, but you can change it to fit your practice.



What Kind of Progesterone for Which Patient?

Standard Answers:

1) History of spontaneous preterm birth:
    - 17-OHPC 250 mg IM weekly from 16-36 weeks
2) Short Cervix ≤ 20 mm:
    - Vaginal progesterone 200 mg (suppositories or capsules) or 90 mg vaginal gel every night from diagnosis to 36 weeks

But it depends on what insurance will cover:

1) 17-OHPC: Makena versus compounded
2) Vaginal: Which forms?

What Kind of Progesterone for Which Patient?

- Currently there are differences among the 5 Medicaid Managed Care Plans and Medicaid Fee For Service (FFS) in terms of:
    1) Which forms of progesterone they will cover
    2) Whether they require prior authorization (PA)
    3) The gestational age range for progesterone treatment initiation

- Work is on-going to align and simplify the process