

The Progesterone Project

Hosted By: The Ohio Department of Health: Bureau of
Child and family health services

Jo Bouchard, Bureau Chief



OPQC: The Ohio Perinatal Quality Collaborative

Dr. Jay Iams – Beth White – Dr. Dave McKenna – Hetty Walker

- **OPQC's Mission: To Improve Infant Health**
 - *Use Improvement Science Methods to Reduce Preterm Births and Improve Outcomes of Preterm Newborns in Ohio As Quickly As Possible*
- **What Causes Perinatal & Infant Mortality?**
 - **Preterm Birth = 75% of deaths in 1st month**
 - **Birth Defects**
 - **SUID et al**



notes from previous slide #2

DR. IAMS INTRODUCES PANELISTS AND MAKES 2 POINTS:

1. OPQC'S MISSION
2. OPQC PICKED PRETERM BIRTH BECAUSE PTB IS A MAJOR CAUSE OF INFANT MORTALITY



OPQC Obstetrical & Neonatal Projects

2014



OBSTETRICS

NEONATAL

39-Week Scheduled Births without medical indication

ANCS for women at risk for preterm birth (24^{0/7} - 33^{6/7})

Blood Stream Infection Highly reliable line maintenance bundle

Use of human milk in infants 22-29 wks GA

Increase Birth Data Accuracy & Online modules

Spread to all maternity hospitals in Ohio

Progesterone for Preterm Birth Risk

6 OCHA Pilot NAS

Neonatal Abstinence Syndrome

notes from previous slide #4

DR. IAMS NOTES

- 1. PEDS + OB COLLABORATION
- 2. MEDICAL MODEL FOR PROJECT SELECTION
- 3. LEARN FROM PAST PROJECTS
- 4. WE'LL TALK ABOUT PROGESTERONE

Models of Care for Preterm Birth

- **Tertiary – After Preterm Labor Starts**
 - Improve Outcomes in Preterm Infants **Steroids**
 - No Effect on Incidence
- **Secondary – Find & Reduce Risk**
 - Before and During Pregnancy
 - In Individuals and Groups
- **Primary – Up Stream Risk Prevention**
 - In Populations
 - In Systems

BandAid

Down
Stream
Band
Aids

BandAid

notes from previous slide #6

DR. IAMS NOTES

1. MEDICAL MODEL HAS 3 POINTS OF ENTRY
2. WE'RE TALKING SECONDARY CARE RE:
PROGESTERONE
3. MANY IN AUDIENCE ARE WISELY CHOOSING
UPSTREAM PREVENTION





BandAid

The Down Stream Band Aids

BandAid

- **Antenatal Steroids**

- Given to the Mom *before* a preterm birth
- Reduce rates of infant death & severe illness
- *Publication of results promotes use*

- **Progesterone Supplementation for:**

- Women with a prior preterm birth
- Women with short cervix in this pregnancy

notes from previous slide #8

- DR. IAMS LISTS 2 DOWN STREAM BAND-AIDS
- AND NOTES THAT
- PUBLICATION OF RESULTS → DRIVES MORE USE





So Just What Does OPQC Do, Anyway?

OPQC Works Intensively with Teams That Commit to Create & Sustain Change

OPQC Does:

- **Promote Accepted Practice Guidelines**
- **Collect & Report Data from / to OPQC Sites**
- **Share Whatever Works**
- **Teach Methods to Change Care Patterns**
- **Monitor Outcomes**

OPQC Does Not:

- **Tell Doctors & Nurses How to Practice**
- **Issue Guidelines**
- **Grade Your Care Site**
 - **OPQC is Not The Police.**
- **Share Your Data with Anyone, Ever.**
 - *You* can share whenever you want to, but **OPQC won't.**

notes from previous slide #10

- BETH EMPHASIZES THAT OPQC DOES INTENSIVE TIME-LIMITED PROJECTS – OPQC CAN SHARE THE PRACTICE GUIDELINES THAT ARE THE BASIS FOR OUR PROJECTS, BUT WE CAN'T DO INTENSIVE Q-I WORK ALL OVER THE STATE



How Does OPQC Design Projects?

The Key Driver Diagram

What Do We Want?

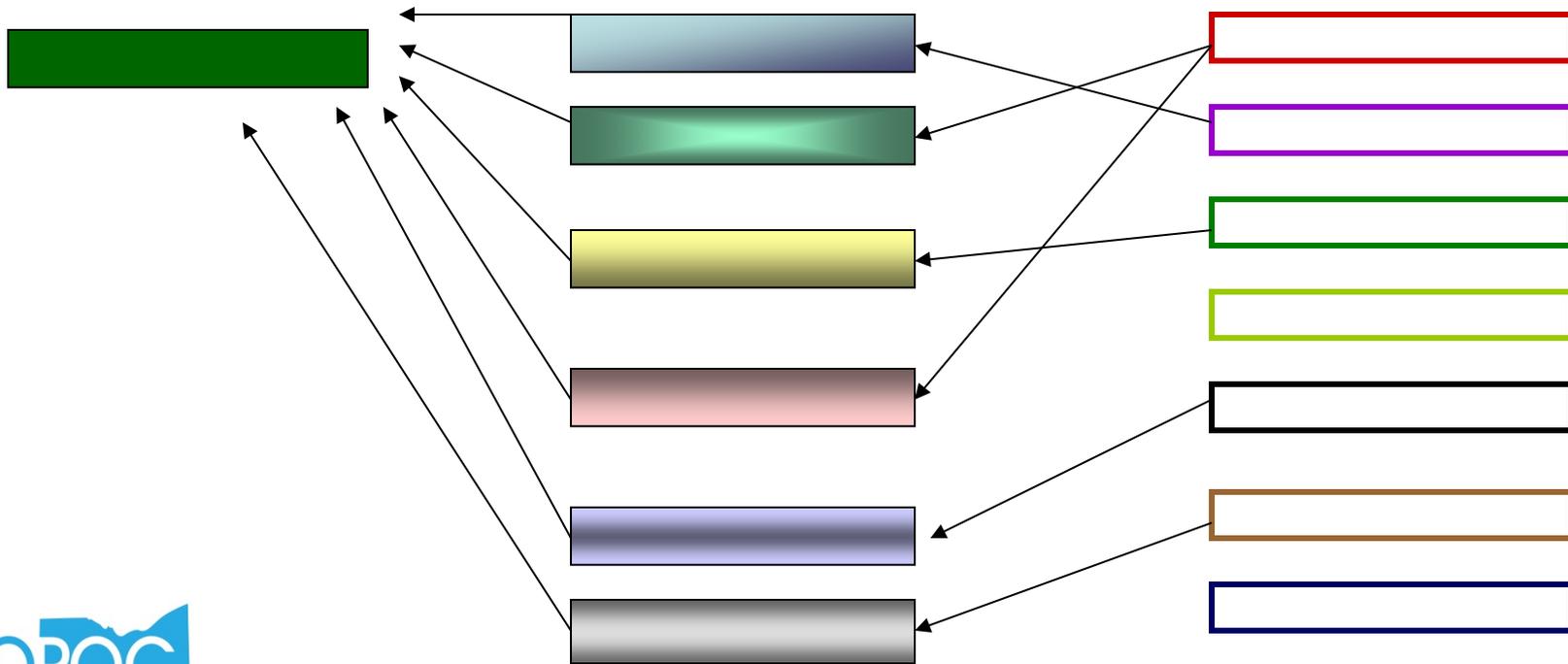
Measurable Outcome

What Will Make It Happen?

Key Drivers

How Can We Change the Drivers?

Interventions



notes from previous slide #12

- BETH DESCRIBES HOW OPQC DOES PROJECTS
- THE IHI MODEL USES THE KEY DRIVER APPROACH



How Can We Reach Every County & City?

Lessons From OPQC's 39 Week & ANCS Projects

- Do Projects in *WAVES of 10 – 15 sites*
- Share What Others Have Learned
- Link Similar Communities
- Connect Data Collectors, Users, & Analysts
- **Use the Birth Certificate as a Q.I. Instrument**
 - Use → Promotes Accuracy → Promotes Use
 - Rapid Data Turnaround Is Essential



notes from previous slide #14

- BETH DESCRIBES HOW OPQC HAS
 1. INITIATED AND THEN
 2. DISSEMINATED THE 39 WEEK AND ANCS PROJECTS IN WAVES = THE AUDIENCE WILL BE IN ONE OF THE COMING WAVES
 3. AND PLANS TO DO SAME W/ PROGESTERONE
(continued next slide)

Continued notes from slide #14

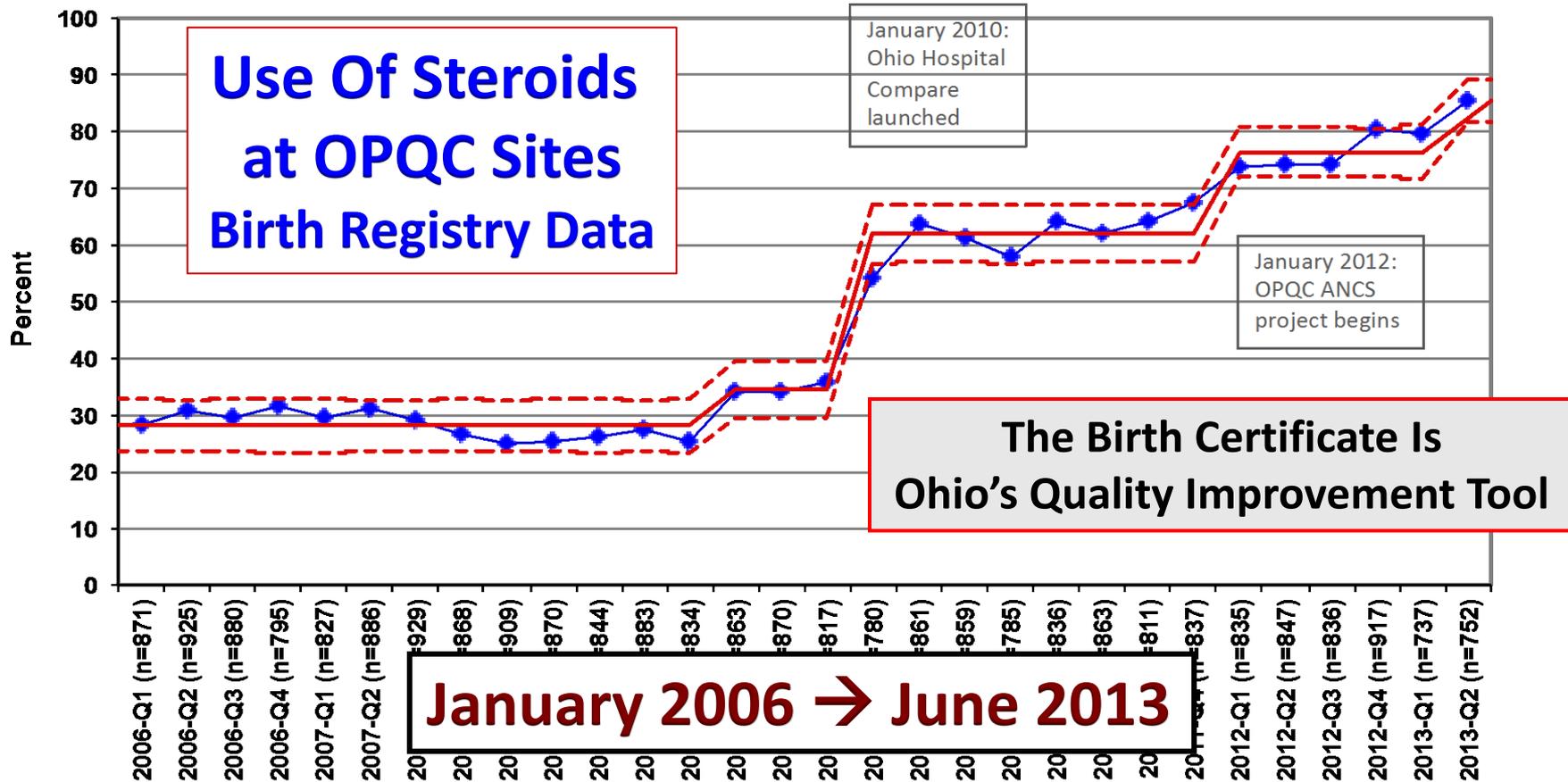
4. OPQC LEARNS AND SHARES – LINKS COMMUNITIES
W/ COMMON CHARACTERISTICS

5. BIRTH CERTIFICATE CAN BE USED LOCALLY AS WELL
AS STATEWIDE

notes from previous slide #17

- BETH SHOWS HOW THE 39-WEEK PROJECT ROLLED OUT
- MAKES THE POINT THAT COMMUNITIES DO NOT HAVE TO WAIT FOR THE OPQC PROJECT TO COME TO THEM – THEY CAN HAVE INFO ASAP – ONLY HAVE TO WAIT FOR THE Q-I PART OF OPQC

Births at 24-33 completed weeks receiving any antenatal steroids, by quarter, Aggregate results for 20 OPQC charter sites



Source: Ohio Department of Health, Vital Statistics

◆ Quarterly Percent — Baseline Average Percent - - - Control Limits

notes from previous slide #19

BETH NOTES THAT RATES WENT UP
WITH PUBLICATION OF HOSP DATA
AND AGAIN WITH THE OPQC Q-I
PROJECT





The Ohio Progesterone Project

- **Goal: Reduce Ohio PTB & Related Infant Mortality**
- **Find Women with Prior Preterm Birth**
- **Find Women with Short Cervix**
- **Make it Easy to Get Progesterone**
 - **Create and Pay for Protocols**
- **Outcome Measures**
 - **Preterm Birth Rate**
 - Hand Collected Data
 - Medicaid Data
 - Birth Registry Data – Births < 32 and 37 Weeks
 - **Process Measures**
 - **Infant Mortality Rate**



notes from previous slide #21

DR. IAMS BRINGS BACK TO PROGESTERONE OVERVIEW OF PLAN

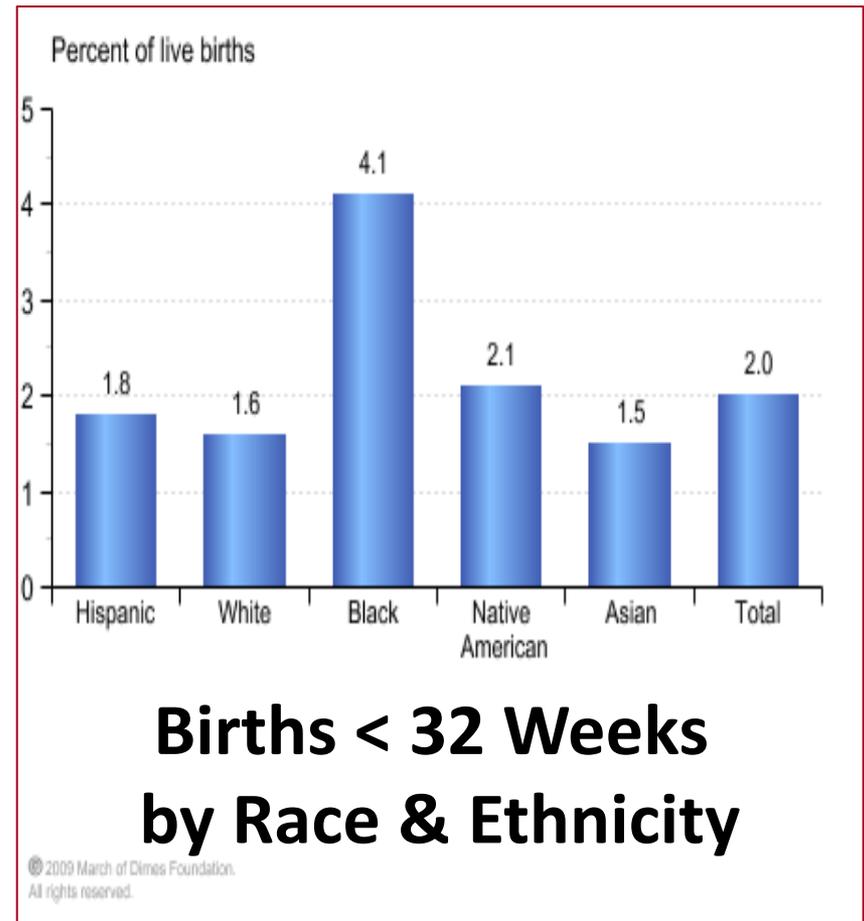


Early Preterm Birth

Who Are These Women?

Births Before 32 Weeks

- Highest Rates of Neonatal & Infant Morbidity & Mortality
- More Likely to Recur
- Cervix Often Short
- Progesterone Helps
- Happens in Any Woman
 - More Often in African American Women



notes from previous slide #23

- DR. IAMS HIGHLIGHTS THE IMPORTANCE OF THE EARLY, PRE-32 WEEK BIRTHS AND HOW IT IS SO PROMINENT IN AFRICAN AMERICANS
- INTRODUCES DR. McKENNA AND MONTGOMERY COUNTY PLAN



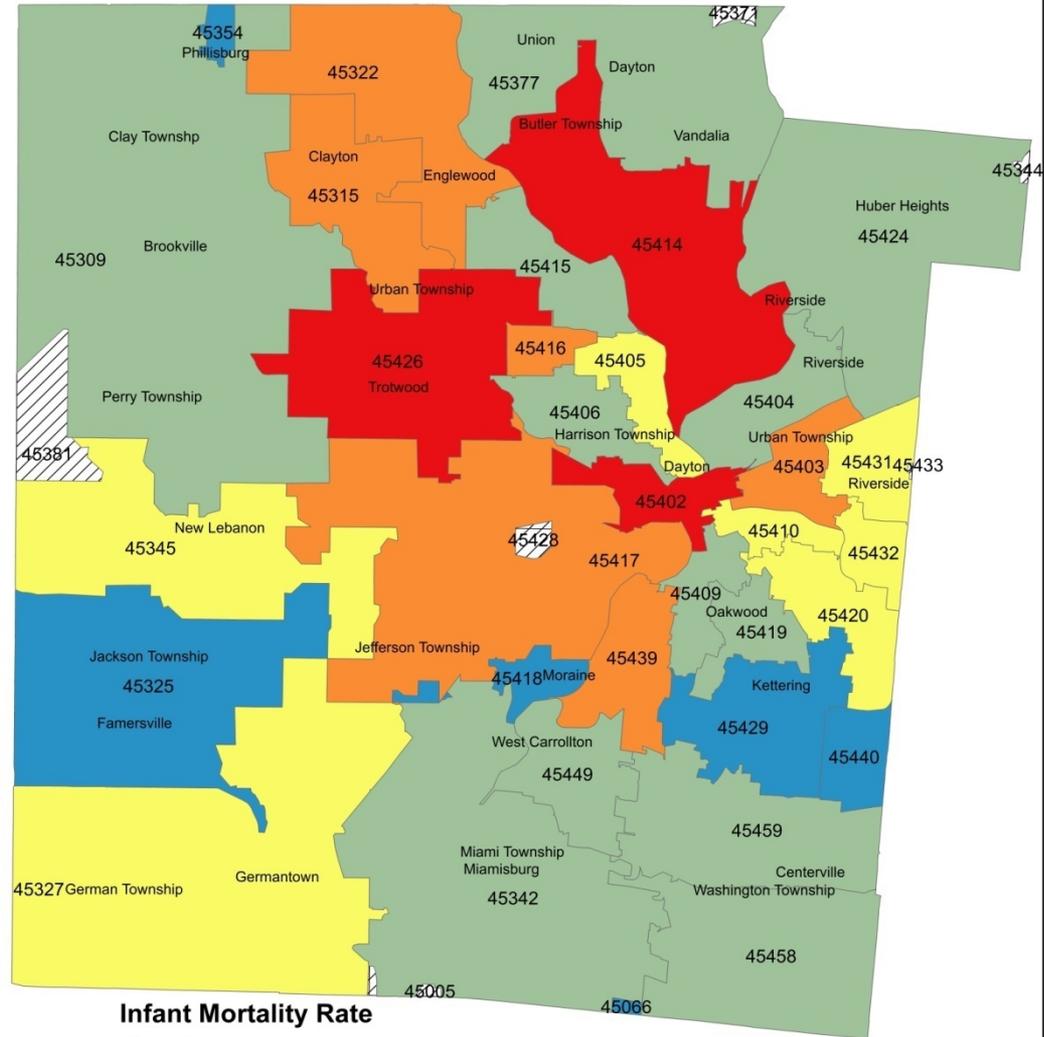
Montgomery County Infant Mortality Rates 2000 - 2011



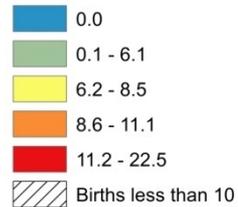
notes from previous slide #25

- Dr. McKenna:
- As bad as Ohio is, Dayton is even worse!
- Montgomery County's 2011 IM rate is much worse than the state at 8.8 (the state was 7.87). In 2011 the black infant mortality rate was 17.1, almost 3 times the rate of whites (2.85). **(43)**

Infant Mortality Rate 2009-2011 Montgomery County, OH



Infant Mortality Rate



notes from previous slide #27

Dr. McKenna: IMR overall I would mention here that disparities exist not only by race, but also by location. (17)

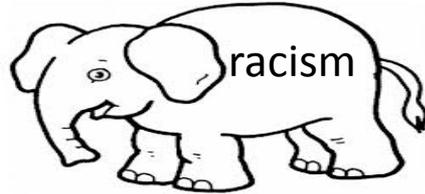


notes from previous slide #29

- Dr. McKenna:
- The Montgomery County Infant Mortality Coalition was established in August of 2012. The purpose of the coalition is to engage local, state and national partners to reduce the infant morbidity and mortality rates in Montgomery County. The coalition is made up of individuals from public health, the health care industry, private industry, and faith-based organizations. The IM Coalition is still seeking to engage more non-traditional partners to better address the social determinants of health. (74)

Equity Institute Training

Upstream Strategies



Downstream Strategies

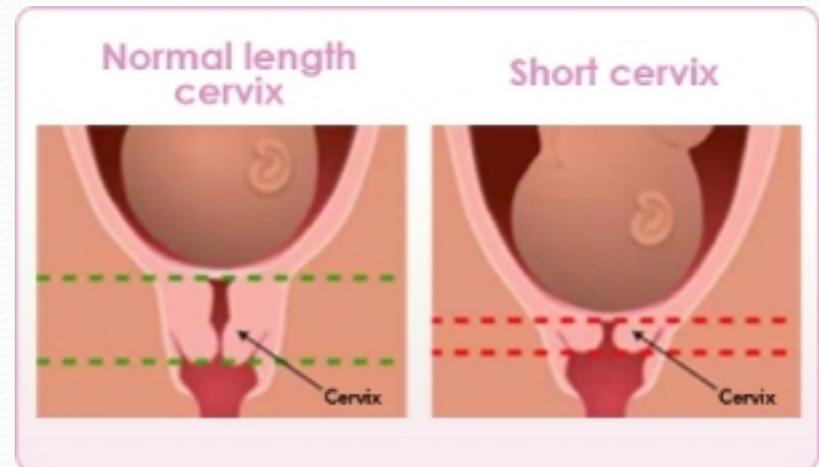


Prevention Vehicles



notes from previous slide #31

- Dr. McKenna:
- Okay, so let me introduce our infant mortality conceptual framework and talk about where the Equity Institute fits.
- Most of us have heard the allegory of the 2 public health workers who went for a walk along their city's river, when suddenly * they discover a population in peril, floating toward the cliff of oblivion. (Pay no attention). They both immediately agree they need rescue vehicles to access the population, * and as a well-prepared health department they have several such vehicles of various kinds stashed along the river. The 1st begins loading her boat with needed supplies—life preservers. * And, as she's about to launch downstream to begin pulling victims out, she notices her colleague pushing off in the opposite direction with an odd assortment of supplies. * She has a fence, a warning sign, and weirder still she's taking jobs and education programs. And yes, she's taking the elephant in the room—or boat I guess—racism and racial healing strategies.
- “What are you doing!? And, where are you going!?” The 1st public health worker asks. And the answer comes back. I'm going upstream to stop more people from falling in, in the 1st place.



DSM

Image credit: National Institutes of Health, 2011

notes from previous slide #33

Dr. McKenna REMINDS AUDIENCE OF THE 2
GROUPS OF WOMEN WHO ARE ELIGIBLE FOR
PROGESTERONE

Progesterone therapy for a) Mothers with
previous pre-term birth, b) Short Cervix (DX at
ultrasound)



DSM

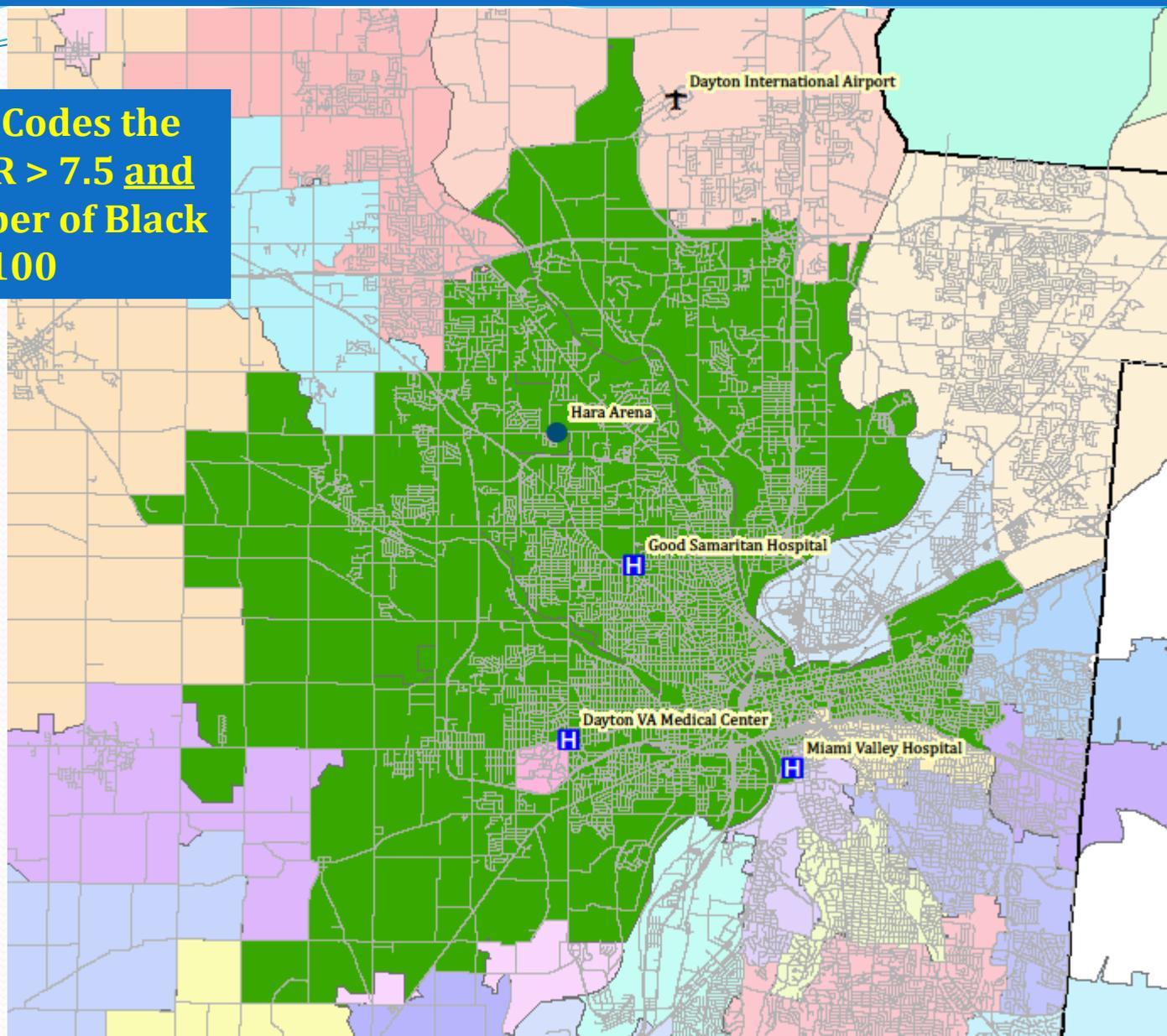
notes from previous slide #35

Dr. McKenna:

Progesterone Therapy: 2 types –
injections (in cases of prior preterm
birth); vaginal suppositories (in cases of
DX short cervix)

Dayton & Montgomery County Infant Mortality Initiative Target Area

For 9 Zip Codes the
Black IMR > 7.5 and
the Number of Black
Births > 100



notes from previous slide #37

Dr. McKenna: Nine Dayton / Montgomery County Zip Codes have Black IMR > 7.5 and the Number of Black Births > 100

NOTE FROM Dr. Iams: ARE THE GREEN ZONES = THE HIGH IMR ZIP CODES?

COLOR CODING IS NOT CLEAR ON THE SLIDE



Community Health Centers
of Greater Dayton



notes from previous slide #39

Dr. McKenna EMPHASIZES THE PARTNERSHIPS

Potential Clinical Partners for our initiatives: 1) Community Health Centers of Greater Dayton (CHCGD): Victor Cassano Health Center; 2) Samaritan Centers for Women: Life Stages; 3) Five Rivers Health Centers: Center for Women's Health

Progesterone To Reduce Preterm Birth Risk

Limitations & Barriers

- A Band-Aid that slows the process - Downstream
 - **Not prevention**
- Women who may benefit are not that easy to find
 - **Prior Preterm Birth = 16 through 36 weeks**
 - **Short Cervix = Detected by transvaginal scan**
- Not Just a Prescription at the Pharmacy
 - **Many barriers to obtaining, paying for, & using P**

notes from slide #41

- HETTY INTRODUCES THE IDEA THAT IT'S NOT JUST AS EASY AS WRITING AN RX – THERE ARE ISSUES!

What You Can Do Now

- Publish the Data for Your County:
 - **Infant Mortality, Preterm Birth, & Smoking.**
 - **Racial Disparity Rates for All Outcomes.**
- Track All Over Time – Use Graphs, Not Tables
- Promote Public Awareness
 - Risks of Preterm Birth
 - Reduced Risk with Progesterone
 - Availability of Cervical Ultrasound

Women
Asking,
*Do I
Need
Progesterone?*

notes from slide #43

- HETTY EMPHASIZES THE KEY POINTS FOR PROGESTERONE
1. PUBLICIZE YOUR LOCAL DATA ON INFANT MORTALITY – KEEPING IT QUIET IS NOT A PATH TO IMPROVEMENT – PEOPLE WANT TO KNOW AND ARE MOTIVATED TO HELP WHEN THEY LEARN HOW HIGH THE INFANT MORTALITY IS IN OHIO
 2. PROMOTE GRAPHS OVER TIME, NOT PER CENT RATES PER YEAR
 3. PROMOTE THE IDEA THAT THERE IS NOW SOMETHING THAT CAN HELP



Frequent Questions About Progesterone

- What Is Progesterone?
- How Does It Work?
- Who Needs Progesterone?
- Are There Any Risks ?
 - To the Baby?
 - To the Mother?
- Why Isn't It Easy to Get Progesterone?
- How Much Does It Cost?

notes from slide #45

**HETTY INTRODUCES
QUESTION LIST, BUT WAITS
AND WAITS LONGER
FOR AUDIENCE TO ASK THE
FIRST QUESTION**



What is Progesterone?

Why is it Used in Pregnancy?

- Progesterone is the hormone that supports pregnancy.
 - Can't have a pregnancy without it
- Large amounts made by the placenta (afterbirth)
- Clinical studies in women who have a previous preterm birth or a short cervix show *a 35% decrease in preterm birth* when they are treated with progesterone from 4 to 8 months

How Does Progesterone Work?

- We Don't Exactly Know How It Works, or Why It Works in Some Women, But Not Others.
- *Theories*
 - It Keeps the Uterus Quiet
 - It Reduces Inflammation in the Uterus and Cervix
 - It Promotes Strength of the Cervix

Are There Any Risks to Treatment with Progesterone?

- Mother

- Allergy to Peanuts
- Pain at Injection Site
- Vaginal Irritation

- Baby

- None noted so far
 - Used 1975 – 1980: No long term effects noted
 - 2003 – present: No short term effects – 1st 5 yrs