Ohio Perinatal Quality Collaborative

Improving Rates of Progesterone Supplementation: Reducing the Risk of Premature Birth

Webinar for All Ohio

Jay D. Iams MD
OB Lead - Ohio Perinatal Quality Collaborative

November 6, 2014
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OPQC Continuing Education Program for Level 1 Hospitals in Ohio: Improving Rates of Progesterone Supplementation: Reducing the Risk of Spontaneous Preterm Birth

Presenters:

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Disclosure: Financial disclosure information (planning committee and presenters): Planning committee members/faculty were determined to have no conflicts of interest pertaining to this activity.

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Objectives:
• Discuss the responsibility of the perinatal team in reducing the Ohio preterm birth rate and related infant mortality.
• Describe effective interventions for early identification of progesterone candidates.
• Reduce barriers to the prescription and administration of progesterone supplementation.

Hardware/Software Requirements:
Compatible with Mac and Window users and common web browsers. High-speed access recommended though not required (responsiveness may be noticeably slower using dial-up connection).
Adobe Flash Player 9.x is required and Speakers/headphones required to listen to audio

Provider Contact Information:
If you should have any questions about the content of the meeting, please contact Dr. Jay Iams.
If you should have any questions regarding CME credit, please contact the CME office at cme@cchmc.org.
Jay Iams, MD
Professor Maternal-Fetal Medicine & Obstetrics and Gynecology
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Objectives

At the close of this presentation, I want you to want & be able to:

1. Accept Your Responsibility to Reduce Infant Mortality by Improving Receipt of Optimal Perinatal Care.

2. Adopt Systematic Steps to Improve Recognition of Women w/ Risk of PTB

3. Feel Comfortable Accessing OPQC’s Resources to Provide Progesterone
Infant mortality rates, Ohio & US, 1990-2012


Slide Courtesy of Dr. Beth Conrey Ohio Department of Health
Ohio **Total**, **White**, and **Black** IMR: 2000-2013*

* As of 06/2014: 2013 data is preliminary. For births and deaths, still awaiting out of State files (Ohio residents who had their babies in other States) to be completed.
The Timeline of Infant Mortality

When & Why Do Babies Die?

- Neonatal Death
  - Anomalies
  - Preterm Births
    - 2/3 of infant deaths

- Post-Neonatal Death
  - Sudden Unexpected Infant Death
  - 1/3 of infant deaths

Infant Death

2/3 of all Childhood Deaths (birth -18 yrs) occur during the first year of life

Infant Mortality

Slide courtesy of Dr. Arthur James
Percent of births and infant deaths by gestational age (weeks), Ohio, 2008

Live Births
- 88%
- 2%

Infant Deaths
- <32: 55%
- 32-33: 8%
- 34-36: 5%
- 37+: 8%

Source: Ohio Department of Health Vital Statistics linked birth/infant death data set
The Infant Mortality Rate Varies Across Ohio
March of Dimes 2013 Report Card
Premature Birth Rate
When Can Preterm Birth Be Attacked?

- **Before Pregnancy**
  - Social Determinants
    - Medical Care
- **Early Pregnancy**
  - Early Prenatal Care
- **Mid-Late Pregnancy**
  - Progesterone
  - Antenatal Corticosteroids
  - Scheduled Births
- **Infancy**
  - NICU Care

85%

15%
The Ohio Perinatal Quality Collaborative

Obstetrics

- 39-Week Scheduled Deliveries without medical indication

ANCS for women at risk for preterm birth
(24⁰/₇ - 33 ⁶/₇)
Done → Transition to BC Surveillance

Neonatal

- BSI: High reliability of line maintenance bundle

2013-2015

Progesterone for Preterm Birth Risk

Increase Birth Data Accuracy & Online modules

Spread to all maternity hospitals in Ohio

Use of human milk in infants 22-29 weeks GA

Neonatal Abstinence Syndrome
OPQC 39 Weeks Project in Sustain Phase
Decreasing Non-Medically Indicated Scheduled Deliveries Between 37 and 39 Weeks Gestation

Data From All Ohio Maternity Hospitals
January ‘06 → July ‘14
105 of 107 Hospitals Participated in the OPQC 39 Week Project

Source: Ohio Department of Health, Vital Statistics

Monthly Percent
Baseline Average Percent
Control Limits

Sep. 2008: 39-Week project begins
Jan. 2010: Ohio Hospital Compare launch
5% Goal
Birth Registry Documentation of Antenatal Steroid Use Aggregate Rate in 19 OPQC Sites 2006 - 2014

Red Arrow: ODH’s Ohio Hospital Compare

Blue Arrow: OPQC ANCS Project

Birth Registry Data 2006 → 2014

Source: Ohio Department of Health, Vital Statistics

Quarterly Percent  Baseline Average Percent  Control Limits
SMFM CLINICAL GUIDELINE

Progesterone and preterm birth prevention: translating clinical trials data into clinical practice

Society for Maternal-Fetal Medicine Publications Committee, with the assistance of Vincenzo Berghella, MD

Common Theme: Find More & Rx Progesterone

ACOG PRACTICE BULLETIN

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN—GYNECOLOGISTS

NUMBER 130, OCTOBER 2012

Prediction and Prevention of Preterm Birth

(Replaces Practice Bulletin Number 31, October 2001 and Committee Opinion No. 419, October 2008)
Progesterone to Prevent PTB in Singletons

- Keirse ‘90 Meta-Analysis - 40% ↓
- Fonseca ‘03 RCT Vag P at risk- 35% ↓
- Meis ‘03 RCT 17P Hx SPTB – 35% ↓
- Fonseca ‘07 RCT Vag P Cx ≤ 15mm – 45% ↓
- O’Brien ‘07 RCT Vag P Hx PTB – No effect
- Hassan ‘11 RCT Vag P Cx 10-20 mm- 45% ↓
- Grobman ’12 RCT 17 P Cx < 30 mm - No effect
Goals of The Ohio Progesterone Project

• Reduce Ohio PTB Related Infant Mortality
• Find Women with Risk Histories
• Expand Use of Cervical Sonography
• Make it Easy to Get Progesterone
• Outcome Measures
  o Births < 32, 35, and 37 Weeks

Infant Mortality Rate!
**SMART AIM**

**BY July 1, 2016, DECREASE THE RATE OF PREMATURE BIRTHS in Ohio less than 37 weeks by 10%, and less than 32 weeks by 10%**

**GLOBAL AIM**

**REDUCE INFANT MORTALITY IN OHIO BY REDUCING PREMATURE BIRTHS**

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**Key message:** Women at risk of preterm birth are a high-risk population that needs to be identified and actively managed.
Identification of Candidates for Progesterone

Why, Who, How, and When?

■ Why?
  ▪ Preterm Birth → Largest Contributor to Infant Mortality
  ▪ Preterm Birth → Largest Driver of Disparity in PTB

■ Who?
  ▪ Women with a Prior Preterm Birth
  ▪ Women with Very Short Cervical Length

■ How? Find & Rx Candidates for Progestogens

■ When? ASAP – in Ohio & in Each Pregnancy
Find a Progesterone Protocol You Like And Use It.

Here’s One.

Find One That Fits Your Practice.
Fundamental Principles

- Only You Can Prevent Preterm Birth
- Every Pregnancy Has Some Risk of PTB
- Preterm Parturition Starts Early in 1\textsuperscript{st} or 2\textsuperscript{nd} Trimester
- Short Cervix = Preterm Parturition
- Progesterone Can \textit{Slow} Preterm Parturition
  - \textit{It does not prevent the process}
- Starting Progestogen Rx ASAP is Very Important
- Finding & Treating Requires Time, So HURRY UP
What Formulations of Progestogens Should Be Used?

Standard Answers:
- Hx SPTB: 17-OHPC 250 mg IM Q 7d 16 → 36 wks
- Short Cx ≤ 20 mm: Vag P, 200 mg QHS, Dx → 36 wks

But Life is Not That Simple
- 17-OHPC – Manufactured vs. Compounded
  - Cost vs. Hassle
- Vaginal P – multiple formulations - which to Rx?
- *Who pays for what, when, & after how much hassle?*
Identification of Candidates for Progesterone

Why, Who, How, and When?

- Initiate Progesterone ASAP for Hx SPTB
  - Accelerated 1st Prenatal Visit
  - Presumptive Eligibility for Antenatal Care

- Adopt a Local Management Protocol
  - For Hx SPTB
  - For Short Cervix
  - Test them via OPQC!

- Make “Screen for PTB Risk” ≈ GBS, Rh, GDM
Identification of Candidates for Progesterone

Initial Prenatal Visit
Comprehensive Obstetrical History
Ultrasound Confirmation of Dates and Plurality

OB History – Adopt a Broad Definition of Prior PTB.
Why?
• Spontaneous vs. Indicated is not that simple.
• Gestational age window = 16 – 36 weeks.
  • Liveborn and Stillbirths at 16 – 24 weeks.
• When in doubt, choose Rx or Cervical Surveillance
What About Women with No Prior Preterm Birth?

Options for Cervical Length Screening

- **Select IN** - Women with Risk Factors
  - G-U Infections, Cx Dysplasia, Fertility Rx, Hx ≥ 2 EAbs, Fam Hx PTB, African Americans, Depression, extremes of BMI, ...

- **Select OUT** - Low Risk Women
  - All but Multiparas w/ > 1 Term Birth or Cx > 35 on TA Scan

- **Universal** – Screen all between 18 - 24 weeks

None have been tested in the real world

- Philadelphia – **1.1%** of ✉️ w/o Hx PTB had Cx ≤ 20 mm
OPQC Progesterone Project

- Kickoff Learning Session January 2014
- Sites Recruited from Prior OPQC Projects
  - Engaged New QI Teams from Outpatient Care Sites at Ohio’s 20 Largest Maternity Hospitals

- 1st Learning Session June 2014
  - What Have We Learned?
  - Where Are the Problems?
    - Late to Prenatal Care
    - Pharmaceutical Fears
    - Insurance / Medicaid Coverage
Why Are We Missing P-Eligible Women?
What Have Sites Told OPQC About That?

- Do Providers Know About Progesterone? Yes.
- Do Providers Know What to Rx? Yes, mostly.
- Do Providers Know the Rx Gets to Patient? Not So Much.
- Do Providers Know Why Women Don’t Seek Care ‘til It’s Too Late? Yes, mostly.
  - Do Providers Know What They Can Do To Overcome That? Not So Much.
What Can We Do About “Late for Care”? 

- **No Appointment Needed!**
  - 1st Visits Welcomed Anytime in Cincinnati

- **Community Open Houses with Food Prep**
  - “Moms2B” in Columbus Builds Social Networks

- **Business Community Involvement**
  - Ohio Metro Counties Have High Infant Mortality
    - High Infant Mortality = A Measure of Community Health
  - Bring Your Business Here? No Way! Goin’ to Georgia!

- **Hospital Geographic Responsibility for Health**
Improving Access to Progesterone in Ohio

- Drive Community Changes to Increase Awareness of PTB as Cause of Infant Mortality
- Increase Avenues to Enter Prenatal Care
- Recognize Candidates at First Contact
- Accelerate Appts & THEN get detailed OB Hx
- Track Receipt of Progesterone After Rx
- Think Outside the Medical Paradigm to Find Eligible Women Late To Prenatal Care
What Can You Do to Reduce Infant Mortality Related to Preterm Birth?

- Educate Yourselves, Your Team and Patients, Before and After Pregnancy, About PTB + IM
  - Posters – Websites – Handouts – Progest + LARC
- Find Risk Factors Before & During Pregnancy
- Adopt a Protocol to Find P-Eligible Women
- Promote Breast Milk = Medicine for Preterm
- Promote LARC as Post Partum Contraception
OPQC Education for Consumers

Preventing Preterm Birth
A Guide for Pregnant Women

The Facts about Birth Before 37 Weeks

- Premature birth
- Birth before 37 weeks
- Premature birth increases
- Premature birth increases the risk of

Steps You Can Take to Help Your Baby

1. Take steps to prevent premature birth
2. Ask your doctor
3. Follow steps

Knowing the Facts Can Help Your Baby

Steps to Reduce Your Risk of Preterm Birth

1. Reduce stress
2. Get regular exercise
3. Avoid smoking
4. Eat a healthy diet

Questions and Answers about Preterm Birth

When is a baby born before 37 weeks of pregnancy called preterm birth?

What are the main risk factors for preterm birth?

How do I know preterm birth is a problem for me?

Is it possible to reduce the risk of preterm birth?

What are the signs of preterm labor?

Steps to Reduce Your Risk of Preterm Birth

1. Get regular exercise
2. Eat a healthy diet
3. Avoid smoking
4. Reduce stress

Progesterone May Help You Prevent an Early Birth

Progesterone is a hormone that helps maintain pregnancy. It helps prevent the lining of the uterus from being shed. In some women, progesterone levels may be low. Using progesterone may help prevent preterm birth in these women.

A short cervix is a problem for some women. It can be a sign that a woman is at risk for preterm birth. Knowing the facts can help you and your doctor decide if steps to prevent preterm birth are needed.

Resources

- March of Dimes
- National Institute of Child Health and Human Development
- National Institute of Allergy and Infectious Diseases
- Centers for Disease Control and Prevention

The cervix is the lower end of the uterus that opens into the vagina. It is normally about 3.5 cm (1.4 inches) long. The cervix is considered to be short if the length is less than 2 cm long before 24 weeks of gestation. The chances for having a preterm birth are higher in women who have a shortened cervix but may not mean you will definitely deliver early.

During pregnancy the cervix remains closed and long. It acts as a supportive door and also helps keep infection out. Later in pregnancy, around 30 weeks, the cervix normally begins to shorten and thicken. This is called effacement. A vaginal ultrasound is used to measure the cervical length and is measured in millimeters (mm) or centimeters (cm). After your bladder is emptied, an ultrasound probe is placed in the vagina and a picture is taken of the cervix.

- The length of your cervix is measured from the inside of the uterus to its external opening into the vagina. A normal length is 33 mm.

- The cervix is labeled short if the length is less than 2 cm long before 24 weeks of pregnancy.

A short cervix increases the chance that you will deliver early. The shorter your cervical length the higher the chance of having a preterm birth. This is just one of the risk factors for early birth. A previous preterm delivery, smoking, and other risk factors may also increase your chances of delivering preterm.

Depending on your personal risk factors, your doctor may recommend progesterone and/or a cervical stitch (cervicostomy). It’s very important to tell your doctor or nurse promptly if you have any warning symptoms such as cramps, pelvic pressure, bloody/white discharge, persistent lower backache, or “not feeling right” as this may change your plan of care.
Reducing Preterm Birth
Evidence-Based Strategies to Improve Outcomes

Progesterone treatment and cervical length measurement screening are key tools to lowering Ohio’s high infant mortality rate.

Cervical Length Measurement: A Vital Tool in Reducing Preterm Birth in Ohio

- Risk factors for preterm birth:
  - Previous preterm delivery
  - Advanced maternal age
  - Prior preterm labor
  - Multiple gestation
  - Male fetal presentation
  - Maternal history of preterm birth

- Benefits of cervical length measurement:
  - Early identification of women at risk
  - Ability to intervene early
  - Potential for reduction in preterm birth rate

- Implementation strategies:
  - Education and training for healthcare providers
  - Development of guidelines and protocols
  - Use of technology for continuous monitoring

- Outcomes:
  - Reduced preterm birth rates
  - Improved maternal and infant health outcomes

- Resources for implementation:
  - National Institute of Child Health and Human Development
  - National Institutes of Health
  - Centers for Disease Control and Prevention

- Future directions:
  - Integration of cervical length measurement into routine prenatal care
  - Further research to understand cervical length changes during pregnancy

OPQC Progesterone Education for Providers

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OPQC Progesterone Education for Providers
Clinical Expert Series

Identification of Candidates for Progesterone
Why, Who, How, and When?

Jay D. Iams, MD

The short cervix and preterm birth: 8 key questions and evidence-based answers

An expert review of screening, identification, and management for both nulliparous women and those with a history of spontaneous preterm birth

Tracy A. Manuck, MD
Spreading the Progesterone Project Throughout Ohio
https://opqc.net/projects/progesterone%20joining

Interested in Joining OPQC’s Progesterone Project?

**OPQC Progesterone Efforts and Next Steps**

OPQC is currently working with 25 outpatient clinics affiliated with the 20 OPQC charter sites. These sites are enthusiastically testing ways to reduce preterm births through the appropriate use of progesterone in women at risk of preterm birth. We are learning about barriers, challenges, and how to streamline data forms for tracking improvement.

By early winter 2015, OPQC expects to invite additional practices to join this work. In the meantime, we encourage all OB practices to learn with us in the following ways:

- Talk with other clinicians at your practice about your current processes for putting patients on Progesterone using the Prediction and Prevention of Preterm Birth ACOG Practice Bulletin 130 October 2012 as a guide.
- Use the same resources and materials* that our pilot sites use to inform their efforts.
- Use the same data forms that our pilot sites use as part of OPQC quality improvement efforts:
  - Keep a [Progesterone Log](#) and use the [Progesterone Candidate Form](#) and [Monthly Form](#) to collect data for quality improvement.
  - The [OPQC Progesterone measurement table](#) will help you to calculate improvements in identification and treatment of women eligible for Progesterone.
- Document any [Administrative Barriers to Progesterone](#) using the easy on-line form. Results are confidential and will help us work with statewide agencies to accelerate results.

**Please sign up [here](#) if you would like to participate in the next Progesterone quality improvement project, join an informational call or ask to receive information about the next Wave.**

Questions or more information? Email us at [opqc@cchmc.org](mailto:opqc@cchmc.org).

* Materials List (click on name to view)
  - [Project Description](#)
  - [Key Driver Diagram](#)
  - [Preparing Your Improvement Team](#)
  - [Identifying Your Team’s Aim](#)
  - [The Model for Improvement YouTube Videos](#)
  - [January 2014 Learning Session Presentations](#)
  - [Action Period Presentations](#)
  - [Clinic Systems Inventory Tool](#)
Recommendations

- **Publish The Data for Your County & Your State:**
  - Infant Mortality, Preterm Birth, & Smoking.
  - Scheduled Births < 39 Weeks – 1% goal.
  - Multi-fetal Pregnancy Rates.
  - Antenatal Corticosteroids.
  - Include Racial Disparity Rates for All the Above.

- **Track All Over Time** – Use Graphs, Not Tables.

- **Promote Public Awareness**
  - Risks of Preterm Birth
  - Prevention with Progesterone
  - Availability of Cervical Ultrasound
OPQC

Important Contact Information

• **Our web site:** [www.opqc.net](http://www.opqc.net)
  - Home page: Announcements! Training Information! Sign up for our newsletter!
  - Patients & Providers: Providers → Preterm birth & Progesterone
  - Projects: Progesterone

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