Ohio Perinatal Quality Collaborative Improving Rates of Progesterone Supplementation: Reducing the Risk of Premature Birth

Webinar for All Ohio

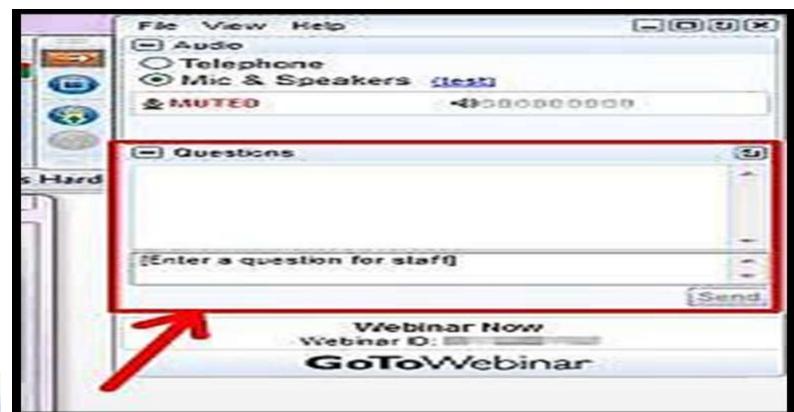
Jay D. lams MD

OB Lead - Ohio Perinatal Quality Collaborative

November 6, 2014



Please sign in with the names & organization of everyone on the call in the question box









CME Requirements for Internet-based Activities

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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:

Jay lams, MD

Professor Maternal-Fetal Medicine & Obstetrics and Gynecology
Wexner Medical Center,
The Ohio State University
Obstetric Lead OPQC

Beth White, MSN, CNS
BEACON Quality Improvement Coordinator



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

Commercial Support:

Commercial support received: None

If at any time during this activity you feel that there has been commercial or promotional bias, please indicate on the online evaluation.

Continuing Education:

CME:

Cincinnati Children's Hospital Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Cincinnati Children's designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credit(s) TM . Physicians should claim only the credit commensurate with the extent of their participation in the activity



Social Work:

Cincinnati Children's Hospital Medical Center Social Service is an approved provider of social work continuing education by the State of Ohio Counselor, Social Worker and Marriage and Family Therapist Board (RSX069302). This presentation is approved for 1.0 (one) clock hour.

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 lams. If you should have any questions regarding CME credit, please contact the CME office at cme@cchmc.org.



Jay lams, MD

Professor Maternal-Fetal Medicine & Obstetrics and Gynecology
Wexner Medical Center,
The Ohio State University
Obstetric Lead OPQC





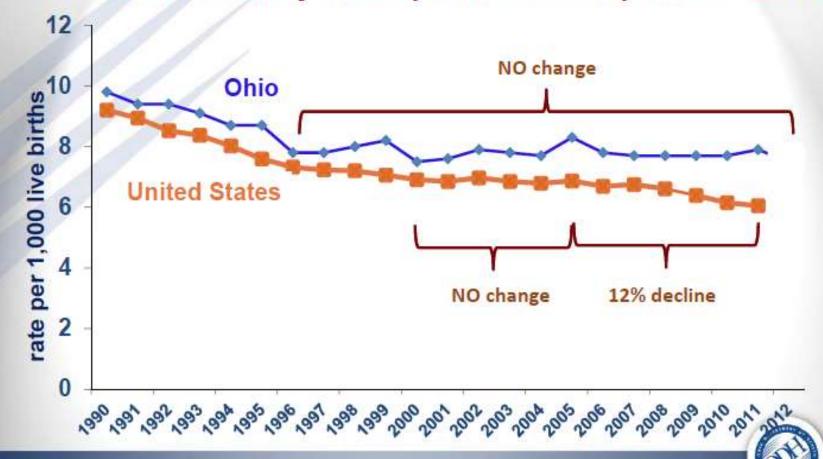
Objectives

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

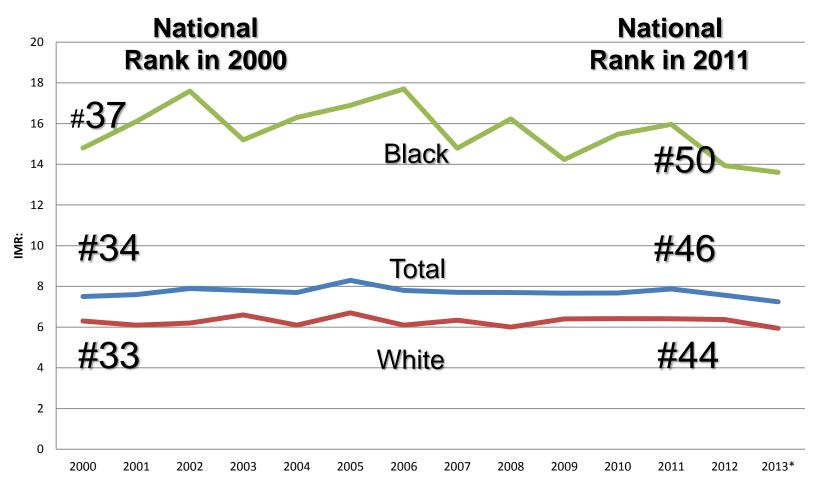
- Accept Your Responsibility to Reduce Infant Mortality by Improving Receipt of Optimal Perinatal Care.
- Adopt Systematic Steps to Improve Recognition of Women w/ Risk of PTB
- 3. Feel Comfortable Accessing OPQC's Resources to Provide Progesterone



Infant mortality rates, Ohio & US, 1990-2012

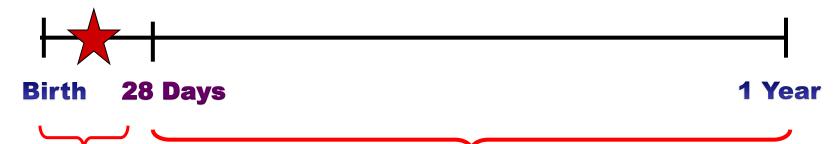


Ohio Total, White, and Black IMR: 2000-2013*



^{*} 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

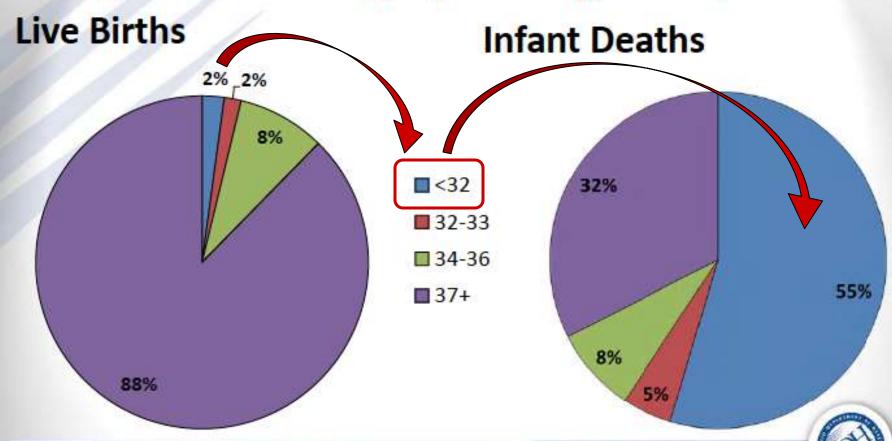
- Anomalies
- Preterm Births
- 2/3 of infant deaths

Post-Neonatal Death

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

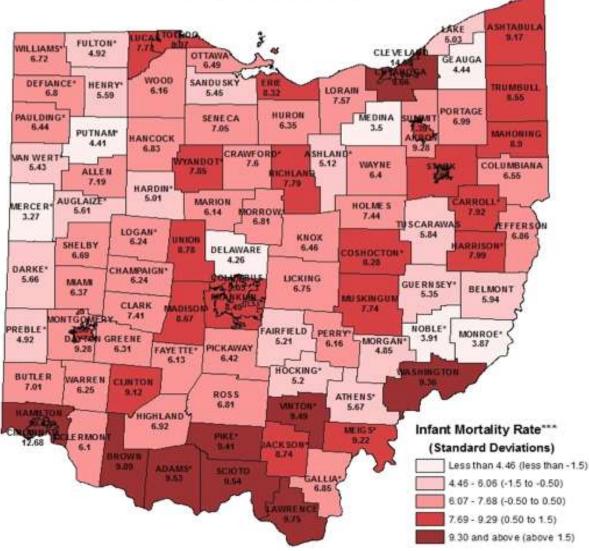
Infant Death

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



Infant Mortality Rate** by County and Selected Cities of Ohio, 2006-2010

The
Infant
Mortality
Rate
Varies
Across
Ohio









March of Dimes 2013 Report Card <u>Premature Birth Rate</u>



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

ANCS for women at risk for preterm birth

 $(24^{0/7} - 33^{6/7})$

Done → Transition to BC

Surveillance

Neonatal

BSI:

High reliability of line maintenance bundle

Use of human milk in infants 22-29 weeks GA

2013-2015

Spread to all maternity hospitals in Ohio

Progesterone for Preterm **Birth Risk**



Neonatal Abstinence Syndrome

Increase Birth Data **Accuracy &** Online modules

39-Week

Scheduled

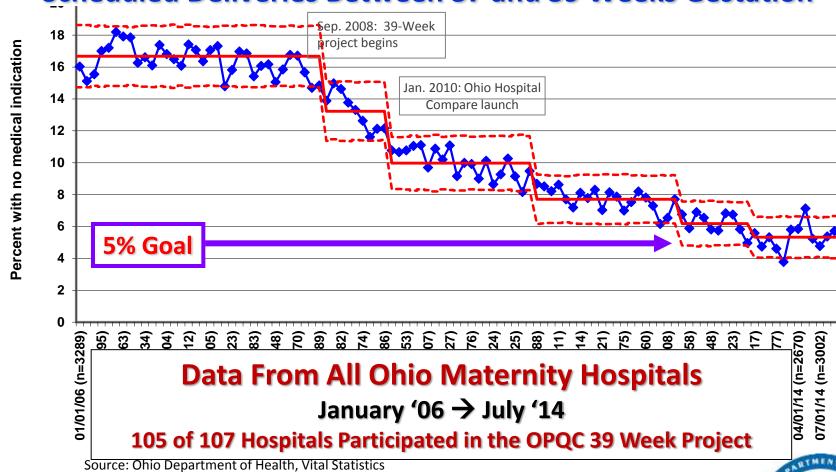
Deliveries

without medical

indication

OPQC 39 Weeks Project in Sustain Phase

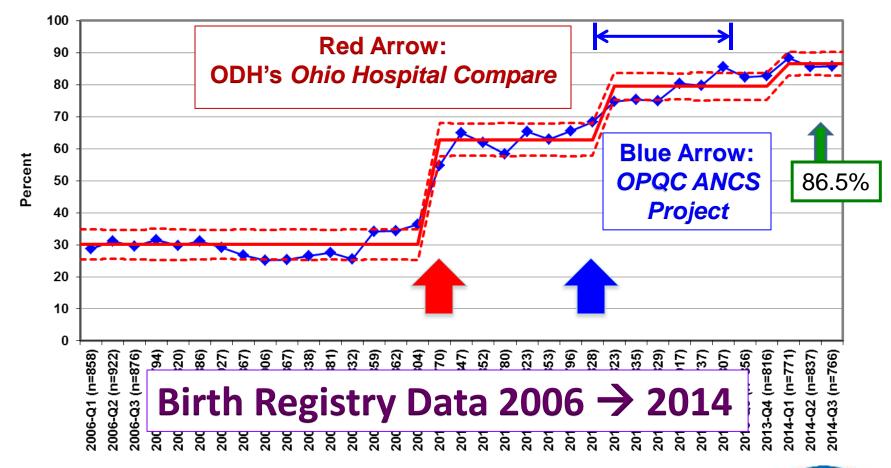
Decreasing Non-Medically Indicated
Scheduled Deliveries Between 37 and 39 Weeks Gestation





Control Limits

Birth Registry Documentation of Antenatal Steroid Use Aggregate Rate in 19 OPQC Sites 2006 - 2014







Source: Ohio Department of Health, Vital Statistics

Baseline Average Percent



SMFM April 2012

ACOG October 2012



SMFM CLINICAL GUIDELINE

www.AJOG.org

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



PRACTICE BULLETIN

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN—GYNECOLOGISTS

NUMBER 130, OCTOBER 2012

(Replaces Practice Bulletin Number 31, October 2001 and Committee Opinion No. 419, October 2008)

Prediction and Prevention of Preterm Birth

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
 - Births < 32, 35, and 37 Weeks

Pilot in Big 20



Spread to

All

Ohio



Infant Mortality Rate!







INTERVENTIONS

PROGESTERONE PROJECT KEY DRIVER

Revision Date: 09-19-14

DIAGRAM DRIVERS

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 Consistent and early recognition of prior preterm birth

Adopt a cervical length ultrasound screening protocol

Expedite progesterone supplementation

Use patientcentered medication management

Screen women for OB history of preterm birth

· Align and communicate with EDs, WIC, etc. to screen and refer when history of preterm birth

- Facilitate rapid new OB appointments
- Postpartum counseling on progesterone for those eligible in next pregnancy
- Use sonographers trained in cervical length measurement
- Develop a practice protocol to selectively or universally screen cervical length (consider population risk)
- Create a written protocol for identified candidates
- Start progesterone as soon as possible (according to ACOG and SMFM guidelines) after identification of eligible woman
- Follow up with women to check on continued use of progesterone as prescribed
- Educate on benefits of progesterone and use evidence-based counseling methods (e.g. Motivational Interviewing) if there are concerns
- Involve key support individuals
- Connect women to insurance, home care, social services, etc. to ensure progesterone available &administered

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



Why, Who, How, and When?

■ Why?

- Preterm Birth → Largest Contributor to Infant Mortality
- Preterm Birth \(\rightarrow\) 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

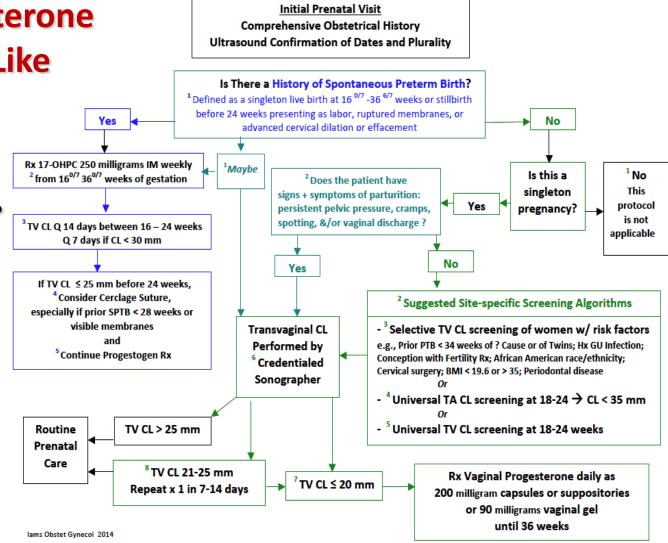
Why, Who, How, and When?



Find a Progesterone Protocol You Like And Use It.

Here's One.

Find One
That Fits
Your
Practice.



Why, Who, How, and When?

Fundamental Principles

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





Why, Who, How, and When?

What Formulations of Progestogens Should Be Used?

Standard Answers:

- **Hx SPTB:** 17-OHPC 250 mg IM Q 7d $16 \rightarrow 36$ wks
- Short Cx ≤ 20 mm: Vag P, 200 mg QHS, Dx \rightarrow 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?



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





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



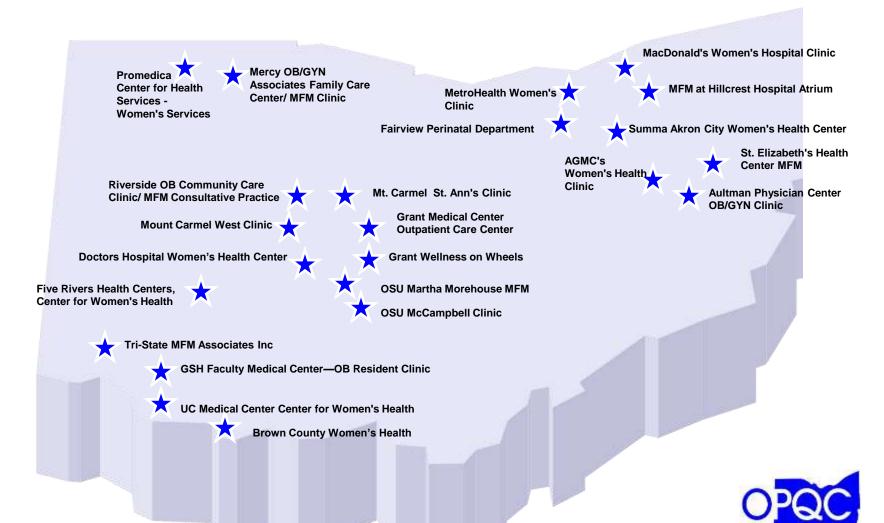
- None have been tested in the real world
 - Philadelphia 1.1% of \(\bar{\pi} \) w/o Hx PTB had Cx ≤ 20





- 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

OPQC Progesterone Project Pilot Clinics 2014



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



Preventing Preterm Birth

A Guide for Pregnant Women

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The Facts about Birth Before 27 Weeks

- Proventient, or training under Soldier and Advantage Company Actions assessed

Preterm birth occurs when a baby is born before 17 weeks of pregnancy. Full-term birth

is 40 weeks.



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Progesterone May Help You Prevent an Early Birth

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Knowing the Facts Can Help Your Baby

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Questions and Answers about Preterm Birth

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OPQC Education for Consumers

Short Cervix: What Does It Mean? Should I Be Worried?



The cervix is the lower end of the uterus that opens into the vagina. It is normally about 35 mm or 1 1/2 inches long. The cervix is considered to be 'short' if the length of the cervix is less than 20 mm long before 24 weeks of gestation. The chances for having a preterm birth are higher in women who have a shortened cervix but it does not mean you will definitely deliver early.

During pregnancy the cervix remains closed and long. It acts like a supportive door and also helps keep infection out. Later in pregnancy, around 30 weeks, your cervix normally begins to soften and shorten. This is called effocement. 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 into 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 "35mm.



The cervix is labeled 'short' if the length is less than 20 mm 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 of 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 (cerclage). It's very important to tell your doctor or nurse promptly if you have any warning symptoms such as cramps, pelvic pressure, thin/watery/pink/mucous discharge, persistent low backache, or "not feeling right" as this may change your plan of care.



OPQC Progesterone Education for Providers

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

Present birth is the leading cause of newborn death in Chin.

Program women with a previous sponsareau

present birth or with a abort cents. In their current programs,

Programmore, a responsers backed by nuclonal policial rest from the American College of Observe bru and Gyrecologies (ACOG) and the Society for Maxemail Teral Medicine (SAFM). can reduce the risk of preserve blints to no? is. for women with either a previous sport areout presentiation or ston cards. Programme should be part of the solution, along with smoking pergeton and other studitional efforts, to reduce

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Transvaginal Uterasound (TVU): A Break through in Protorm Birth Provention

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Transvaginal Ultrasound Requires allevel of **Technical Expertise**

To prevent quality - assurance concerns with user local observation and accountings, it is important abort the somigraphers are which your practice or clinic depends are properly trailined Am Improperly performed TVU can Vical larget immersion can need to unneeded treatment or a missed apparently to grower preparently of the White sample of the missed capture and the property trailing of the date include the recthologic details that TVU requires. for accurate can call largeth measurement, there are publicated advication and conductating appointments assisted to help accognization improve thair skills.

Improve Accuracy with Curvical Langth Accreditation

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Watch Hyagriv Simhan, MD, University of Pittsburgh Medical Center's Magee-Women's Hospital, explain in a 3-minute video how TVU can help prevent preterm birth at https://opgc.net/patientsproviders/%20Preterm%20 Birth%20and%20Prevention.



Clinical Expert Series



Identification of Candidates for Progesterone

Why, Who, How, and When?

Jay D. Iams, MD

The NEW ENGLAND JOURNAL of MEDICINE

CLINICAL PRACTICE

Caren G. Solomon, M.D., M.P.H., Editor

Prevention of Preterm Parturition

Jay D. lams, M.D.

Universal or selective cervical length screening?

Doing nothing is no longer an option, say the authors. Cervical length assessment should be provided to a larger population of women to identify and treat those with cervical shortening.

BY KARA B. MARKHAM, MD, AND JAY D. IAMS, MD

Fact Sheet



17 Alpha-hydroxyprogesterone caproate (17P)

Making the Case for 17P

Nearly 500,000 babies are born preterm in the United States each year.

Preterm birth (PTB), or birth less than 37 weeks gestation, puts infants at a higher risk of death and is the leading cause of long-term neurological disability in children. Additionally, PTB-related health expenses cost the U.S. healthcare system more than \$26 billion each year.

Preventing PTB is critical to fostering the long-term health and development of infants across the country.

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 <u>25 outpatient clinics</u> affiliated with the <u>20 OPQC charter sites</u>. 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 <u>Progesterone Log</u> and use the <u>Progesterone Candidate Form</u> and <u>Monthly Form</u> to collect data for quality improvement. The <u>OPQC Progesterone measurement table</u> will help you to calculate improvements in identification and treatment of women eligible for Progesterone.

• Document any <u>Administrative Barriers to Progesterone</u> using the easy on-line form. Results are confidential and will help us work with statewide agencies to accelerate results.

Please sign up <u>here</u> 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.

* Materials List (click on name to view)

Prevention of Preterm Parturition by Jay D. lams, M.D. (N Engl J Med 2014; 370:254-261January 16, 2014)

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

<u>Action Period Presentations</u>

Clinic Systems Inventory Tool



Recommendations

- Publish The Data for Your County & Your State:
 - Infant Mortality, Preterm Birth, & Smoking.
 - Scheduled Births < 39 Weeks 1% goal.</p>
 - 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



OPQC Important Contact Information

- Our web site: <u>www.opqc.net</u>
 - Home page: Announcements! Training Information! Sign up for our newsletter!
 - Patients & Providers: Providers Preterm birth & Progesterone
 - Projects: Progesterone
- Jay lams jay.iams@osumc.edu
- Hetty Walker <u>hetty.walker@osumc.edu</u>
- Want more information? info@opqc.net
- Follow us on Twitter: opqc@OhioPQC
- Join us on Facebook: www.facebook.com/ohioperinatalqualitycollaborative



Identification of Candidates for Progesterone Why, Who, How, and When? Obstet Gynecol June 2014

Citations

- 1. lams JD. Prevention of preterm parturition. N Engl J Med 2014;370:254-61.
- 2. lams JD. Identification of candidates for progesterone. Why, who, how, and when? Obstet Gynecol 2014; 123:1317–26.
- 3. McManemy J, Cooke E, Amon E, et al. Recurrence risk for preterm delivery. Am J Obstet Gynecol 2007;196:576.e1-576.e6.
- 4. Laughon SK, Albert PS, Leishear K, Mendola P. The NICHD Consecutive Pregnancies Study: recurrent preterm delivery by subtype. Am J Obstet Gynecol. 2014;210;131.e1–131.e8.
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- 6. Stillbirth Collaborative Research Network Writing Group. Causes of death among stillbirths. JAMA 2011;306:2459–68.
- 7. Markham K, Walker H, Lynch CD, lams JD. Preterm birth rates in a prematurity prevention clinic after adoption of progestin prophylaxis. Obstet Gynecol 2014;123:34–9.
- 8. lams JD, Goldenberg RL, Mercer BM, et al. The Preterm Prediction Study: recurrence risk of spontaneous preterm birth. Am J Obstet Gynecol 1998;178:1035-40.

OPQC's Partners



























