The Ohio Progesterone Promotion Project
Jay D. Iams MD
OB Lead, Ohio Perinatal Quality Collaborative

This activity is jointly-provided by SynAptiv and the Colorado Hospital Association
Conflict of Interest Disclosure Statement

I have no financial interest or other relationships with the industry relative to the topics being discussed.

The Ohio Perinatal Quality Collaborative
Progesterone Project 2014 - 2017

Dr. Iams has no conflicts of interest to declare. He is employed by

• The Ohio State University via contracts with the
• Cincinnati Children’s Hospital Medical Center funded by the
• Ohio Departments of Health & Medicaid and MedTAPP,
  under the supervision of the
• Ohio Colleges of Medicine Government Resource Center to be
• Obstetrics Lead for the Ohio Perinatal Quality Collaborative.

The OPQC Progesterone Project is funded by the Ohio Department of Health (ODH) and the Ohio Department of Medicaid (ODM) and administered by the Ohio Colleges of Medicine Government Resource Center. The views expressed in this presentation are solely those of the authors and do not represent the views of the state of Ohio or federal Medicaid programs. This study includes data provided by ODH and ODM which should not be considered an endorsement of this study or its conclusions.

Mission: Through collaborative use of improvement science methods, to reduce preterm births & improve perinatal and preterm newborn outcomes in Ohio as quickly as possible.
OPQC’s Role
A Statewide Facilitator of Best Practices in Perinatal Care:
Let’s All Do What We Know Works Best

Regional Infant Mortality Initiatives

Mission: Through collaborative use of improvement science methods, to reduce preterm births & improve perinatal and preterm newborn outcomes in Ohio as quickly as possible.

Colorado Progesterone Project

Medical Interventions
Support medical interventions to identify risk and prevent preterm birth.

Early identification of pregnant mothers is vital to allow expanded risk screening, case management, enhanced services, and connections to community services.

Access to 17P
Promote appropriate access to and use of 17α-hydroxyprogesterone (17P) to help prevent preterm birth.

For women with a history of spontaneous preterm birth in a singleton pregnancy, appropriate use of 17P reduces the risk of recurrent preterm birth up to 42 percent.
Colorado Progesterone Project

ACOG & SMFM Rx Insurance Awareness Remove Barriers

Cervical Scans ACOG Rx

Recommendations

Encourage providers to follow the American Congress of Obstetricians and Gynecologists [7], Society for Maternal-Fetal Medicine [8], and American College of Nurse-Midwives [9] guidelines regarding administration of 17P to increase knowledge about a patient’s eligibility for 17P.

Increase insurance coverage for 17P.

Educate patients and providers on the eligibility and coverage for 17P across Colorado insurance plans.

Identify and remove barriers to administration of 17P, which may include lack of access to the medication at the health facility level, patient cost, barriers to the provision of 17P through home visitation programs, and other issues inhibiting access, such as geography. Work to address necessary policy or process changes.

Recommendations

Adopt standard education and credentials for persons who perform ultrasound examinations of the cervix in pregnancy, like the Cervical Length Education and Review (CLEAR) Certification, to ensure accuracy of cervical length measurement and identification of women at risk for preterm birth due to a short cervix [7].

Encourage providers to follow established American Congress of Obstetricians and Gynecologists guidelines to prevent preterm birth.

OPQC Quality Improvement Projects to Reduce Prematurity-Related Infant Deaths in Ohio

• 39 Weeks Project – Influenced Births @ 34-36 Weeks
• Antenatal Steroids Project – Rx to ~ 90% of Eligible
• Birth Registry Accuracy Project – CDC Supported

• OPQC Progesterone Project Goals 2014 - Present
  • **Find Women with Prior Premature Birth**
  • **Expand Use of Cervical Sonography**
  • **Make it Easy to Get Progesterone**

• **Primary Outcomes:**
  – **All Ohio Births before 32 & 37 Weeks Gestation**
Why Target 32 Week Births?

The Ohio Perinatal Quality Collaborative
The Progesterone Project 2014→ Now

- Create Community Change to Increase Awareness of PTB as a Major Cause of Infant Mortality
- Increase Pathways to Early Prenatal Care
- Recognize Possible Candidates at First Contact
  - Accelerate Appts If ? Risk, THEN Review OB History
- Eliminate Barriers to Prescription of Progesterone
  - Systemic & Site Specific
- Track Receipt of Progesterone After Rx
KEY DRIVER DIAGRAM

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

IMPROVE NEWBORN OUTCOMES BY REDUCING PREMATURE BIRTHS

KEY DRIVERS

- Early access to prenatal care
- Consistent and early recognition of prior preterm birth
- Adopt a cervical length ultrasound screening protocol
- Expedite progesterone supplementation
- Customize patient care to start and maintain women on progesterone

INTERVENTIONS

- Screen women for prior preterm birth
- Align and communicate with EDs, WIC, CHWs, MCPs, etc. to screen and refer women with history of preterm birth
- Accelerated 1st OB appointments
- Postpartum counseling re progesterone for those eligible in next pregnancy
- Work with Medicaid and Medicaid Plans to identify women at risk and reduce administrative barriers
- Create a written protocol for identified candidates
- Rx progesterone as soon as possible (according to ACOG and SMFM guidelines) after identification of eligible woman
- Use sonographers trained in cervical length measurement
- Develop a practice protocol to selectively or universally screen CxL based on population risk
- Educate on benefits of progesterone and use evidence-based counseling methods
- Involve key support individuals
- Connect women to insurance, home care, social services, etc. to ensure progesterone available & administered

Key Drivers

- Early Access to Prenatal Care
- Recognize Women with Prior Preterm Birth
- Adopt a Cervical Length Screening Protocol
- Expedite Progesterone Rx to Eligible Women
- Adopt a Progesterone Protocol for Care Site
- Remove Administrative Barriers to Receiving Progesterone Supplementation
- Track Receipt of Progesterone
Key Driver:

**Early Access To Prenatal Care**

- Awareness of Prematurity \(\rightarrow\) Dead Babies
  - Health Workers, Home Visitors, Churches
- Create Communities Where There Are None
  - Moms2B = Food Prep + Prenatal Visit + Socialize
- One Call Center for Any PNV Appointment
- Maintain Medicaid Eligibility – Notify if Preg
- Transportation & Child Care
  - Role for Managed Care Plans

---

Key Driver:

**Identify Women with Prior Preterm Birth**

- Identify Risk at 1st Contact or Prenatal Visit
  - Accelerated 1st Appointment if Any Prior PTB
- Liberal Screen for Spontaneous PTB
  - Preterm Labor and P-PROM
  - Advanced Cervical Dilation
  - Anything Spontaneous at 16 \(\rightarrow\) 36 Weeks
  - Born Alive or Stillborn – Why?
Key Driver:
Identify Women with Short Cervix

• Adopt a Cx Sono Screening Algorithm for All
  • Abdominal Screen: Cx Length > 35 mm = No TVUS
  • Universal – Screen All w/ TVUS at 18-22 weeks
  • One Algorithm for Rx and Follow Up

• Credentialed Sonographers to Measure Cervix
  • CLEAR: SMFM + ACOG + AIUM + ACR + ACOOG
    https://www.perinatalquality.org/CLEAR/

  • FMF
    http://www.fetalmedicine.com/fmf/online-education/05-cervical-assessment/

See the OPQC Cervical Ultrasound Training Module @ opqc.net

Key Driver:
Prescribe Progesterone to Eligible Women

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

• Adopt Site-Specific Progesterone Rx Protocol
  – Hx SPTB
  – Short Cervix

• Patient-Centered Care
  – Flexible Interpretation of Rx Guidelines
    Injection @ Home or Clinic? Injection or Vaginal?
Background: Barriers to Progesterone Rx

- **2004-11: Compounded 17-P – Few Barriers**
- **2011 FDA Approved 17-P – Many Barriers**
  - High Cost – 100 x higher than compounded Rx
  - Compounded vs. Manufactured
    - New England Compounding Scandal
  - Multi-Steps Needed From Rx to Injection
    - Site of Injection – Home Delivery vs. In-Office
    - Delivery of Medication Not Linked to Injection
    - “Specialty” Pharmacies
- **ORPHAN DRUG STATUS**
- **2014 – 2016 Alere = Single source of c-17P**

---

Key Driver:

Remove Barriers to Receipt of Progesterone

- Site and Patient Barriers
  - Late Entry to Prenatal Care
    - Dating Scan @ the Mall → Gender Scan @ 21 wks
  - Personnel Unfamiliar w/ Dx & Rx
    - An Uncommon Dx in Most Prenatal Clinics
  - Rx Does Not = Receipt of Progesterone
    - Grandma Says No – Cultural Barriers
    - Rx Not Filled at Local Pharmacy
    - Ouch! I Don’t Like Shots! Ick! I Don’t Like Vaginal Rx!
- TRACK RECEIPT w/ Clinic Log – Check Weekly!
Key Driver: Remove Barriers to Receipt of Progesterone

• Systemic Barriers
  – Multiple Insurers & Medicaid Managed Care
    • Multiple Prenatal Risk Forms and Rx Protocols
    • Prior Authorization by Insurers & Pharmacies
  – Specialty Pharmacies or Buy & Bill?
  – Home Health Delivery of Drug by Company A
  – Home Care Injection by Company B
  – Orphan Drug Rebate$
**OPQC Progesterone Project**

**Step 1:** Jan 2014 → Jan 2016
- **24 Prenatal Care Sites**
- Hand Collected Data All Progesterone Candidates
  - Gest Age & Indication.
  - Progesterone Rx’d?
  - Gestational Age at Rx?
    - Target < 17 and < 20 wks
  - Source of Payment?
  - Gestational Age at Birth?
  - Any Barriers to Rx?

**Step 2:** Jun 2015 → June 2016
- **20 Hospitals**
- Birth Registry Data on All Preterm Births
  - Hx of Preterm Birth?
    - Progesterone Rx’d?
- Birth Registry Data All Ohio Births
  - % < 37 & < 32 Weeks
    - By Insurance & Race

**Indications for Progestogen Rx**

- 5% Short Cervix
- 85-90% Prior Spontaneous Preterm Birth
Was P Rx Offered / Accepted / Declined?
October 2013 – Sept 2015

Rx Accepted 65% 17P / 35% Vaginal P

---

Data From Outpatient Sites 2014 - 2016

- 7% New Prenatal Visits Eligible for Rx
- Of Women Rx’d Progestogen
  - 65% Rx’d before 20\(\frac{6}{7}\) weeks
  - 70% Rx’d before 24\(\frac{6}{7}\) weeks
- Eligible but MISSED = 30%
  - Late Entry to Prenatal Care after 20-24 Weeks
  - Delayed Rx – BARRIERS!
  - Declined or Not Offered after 20 / 24 weeks
  - Lost after identified as eligible – Lost Medicaid!
Log of Barriers to Progesterone Rx

- **Protocol Confusion**: 17OHPC, Makena, Vaginal P
  - Docs & Nurses, Pharmacists, Managed Care Plans
  - *Patient Centered! vs. Follow a Protocol! (which protocol?)*
  - No Compounded 17 P after April 2016 → CHAOS for 17P

- **5 Different Managed Care Plans**
  - Variable Protocols, Expert Advice, Payment, Prior Authorization

- **Patient Issues**
  - Transportation, Child Care, Family Support, Vag vs. 17P
  - Late Entry into Care

- **Communication**: Patient – Clinic – Pharm – MCP

Overcoming Barriers to Rx of Progesterone

- **Barrier Navigator**: Call 614-293-8949
  - Case by Case Resolution of Barriers

- **System Change**: 5 Managed Care Plans in Ohio
  - MC Plans & Pharmacies & Home Care: 17OHPC Billed as Medical (MCP) or Pharmacy Benefit
  - **Who Gets the $$$?**

- **Solution**: A Single Medicaid Pregnancy Risk ID Form was Developed for All 5 MCP’s
Outcomes

Clinical Practice and Quality

A Statewide Progestogen Promotion Program in Ohio


This project was funded and supported by the Ohio Department of Medicaid and the Ohio Department of Health.

See Also:

The Percentage of OHIO BIRTHS Before 32 Weeks TO AFRICAN AMERICAN WOMEN WITH A PRIOR PREMATURE BIRTH Declined By 23.7%

The Percentage of OHIO BIRTHS Before 32 Weeks TO WOMEN INSURED BY MEDICAID WITH A PRIOR PREMATURE BIRTH Declined By 21.2%
Percentage of ALL OHIO BIRTHS Before 32 Weeks DECLINED by 6.6%, or 2.8% per year in Ohio. Nat’l Rate of Decline = 1.8% per year.

Percentage of OHIO BIRTHS Before 32 Weeks to WOMEN WITH A PRIOR PREMATURE BIRTH Declined By 20.5%.

ALL OHIO BIRTHS < 32 Weeks Gestation
No Change Jan 2012 – Aug 2015
Change Sept 2015 Sustained through May 2017

OPQC Progesterone Project
All OH Hospitals
Aggregate
Percent Birth Before 32 Weeks Gestation
ODH Birth Registry

Start Date
Jan 2014
Change Date
Sept 2015
How Did We Do It?

- Standard Protocols
  - P Rx & Cx US
  - Be Flexible
- Quick Screen for PTB
  - Go to Head of Line
- Log ALL P-Eligible
  - Track Rx, Delivery, Receipt, & Maintain.
- Designate P-Navigator
  - Who Knows the System & the People
- Communication

Box 1. Steps Toward Efficient Identification and Prescription of Progestogens

- Use a prompt system to identify women eligible for progestogens.
- Accelerate first prenatal visits for women who might be candidates for progestogens.
- Do routine early dating scans for all new pregnant patients.
- Adopt a uniform protocol to perform ultrasound cervical length screening, including at least one ultrasonographer credentialed or trained to do transvaginal ultrasound measurement of cervical length.
- Use a log to track prescription and receipt of progestogens.
- Designate a progestogen “navigator” to monitor and address problems with administration.

OPQC Progesterone Project

Lessons Learned

- We Did Not Reduce **ALL** PTB in Ohio
  - % PTB to Women Hx SPTB < Expected
  - % PTB to Women w/ Short Cx < Expected
- Systemic Barriers Were >>> Expected
  - Orphan Drug Rebates Eluded Investigation
- Communication Among Providers is Key
- Department of Medicaid *Drove* Change
- OPQC Sites *Executed* Changes that ODM Enabled
OPQC Progesterone Project

**Ongoing Work**

- **Spread to All Ohio Prenatal Care Providers**
  - Federally Qualified Health Centers
  - Ohio’s Highest Risk Counties and Neighborhoods
  - Ohio ACOG, OHA, Regional Infant Mortality Teams
- **Create Credible Messengers to Drive Demand**
  - CHW, Home Visitors, Churches, Centering Preg
- **Early Entry to Prenatal Care**
- **Transportation and Child Care**
- **e-PRAF2.0** – A Communication Form for All Medicaid-Insured Pregnant Women

**Key Driver:**

*Remove Barriers to Receipt of Progesterone*

- **The Biggest Systemic Barrier**
  - Progesterone Rx
  - Clinician
  - State Medicaid
  - County Medicaid Agent
  - Medicaid Managed Care Plan
  - Mngd Care Plan Transport Service
  - Grandmas
  - Clinician’s Nurse
  - Home Health Service Nurse
  - Specialty Pharmacy
  - Specialty Pharmacy’s Home Delivery
  - MCP or Hospital System’s Home Delivery
Upcoming Issues
Progestogen Prophylaxis of Premature Birth

• February 2018 – Makena® Patent “Expires”
  – New Formulation or Delivery System = Extended
• Delalutin® is back as a Gynecological Rx
• ? Cervical Sonography: Protocols & Sensitivity
• 17-OHPC vs. Vaginal Progesterone
  – No Large Head to Head Randomized Trials
  – Meta-Analyses – Is Vaginal P Superior to 17P?
  – New Studies & Analyses → Variable Conclusions

• Mechanism of Action Still Uncertain

It takes a village...
• COLORADO PPT FINAL TO BE SUBMITTED TO GRC on 8/22.

FINAL DUE TO COLORADO 8/25.

PRAF SLIDES KEPT IN RESERVE IN CASE COLORADO WANTS TO SEE.

jdi