OPQC
Ohio Perinatal Quality Collaborative

Improving Perinatal Outcome

Progesterone Supplementation Change Package

Ohio Department of Health

Ohio Department of Medicaid
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MedTAPP
Medicaid Technical Assistance and Policy Program

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Executive Summary

Preterm birth is a leading cause of infant mortality and days spent in the Neonatal Intensive Care Unit (NICU). The rate of preterm birth in the United States is alarmingly high. Two major risk factors for preterm birth are a prior preterm birth and a shortened cervix. Multiple research studies have shown that progesterone* treatment of women with these risk factors can reduce their risk of preterm birth by about one third. The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) issued guidelines supporting preventive treatment with progesterone in 2012, yet it remains underused.

In 2013, the Ohio Department of Health (ODH) and the Ohio Department of Medicaid (ODM) asked the Ohio Perinatal Quality Collaborative (QPQC) to initiate a progesterone promotion project intended to reduce preterm births in Ohio by 10% by July 1, 2016. OPQC worked closely with ODM, Medicaid Managed Care Plans (MCPs), and clinical teams from 23 prenatal clinics at the 20 largest maternity care hospitals in Ohio to address systemic and local barriers to finding and treating eligible women.

Multiple strategies were promoted to achieve:

- Early access to prenatal care
- Consistent and early recognition of women with a prior premature birth
- Adoption of a cervical length ultrasound screening protocol
- Expedited provision of progesterone supplementation
- Customized patient care to start and maintain women on progesterone

** In this Change Package, unless otherwise specified, the word progesterone refers to both natural Progesterone and to 17-alpha-Hydroxy-Progesterone Caproate.*

The Ohio Progesterone Project started in January 2014. In August 2015, a 6.6% decrease in the rate of all Ohio births before 32 weeks of gestation (recorded on IPHIS, the Ohio birth registry) occurred and has been sustained to the present. The decline was driven primarily by 20% reductions in the rates of birth before 32 weeks to women with a prior premature birth who were insured by Medicaid. We believe that the Ohio Progesterone Project is responsible for this decrease, evident especially in women who are African American and in women cared for in hospitals participating in the project.

This Change Package offers resources and tools to reduce preterm birth using the key drivers employed in the Ohio Progesterone Project to assure timely administration of progesterone.

Progesterone Project Key Driver Diagram (KDD)

Global Aim

Improve Newborn Outcomes by Reducing Premature Births

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%

Key Drivers

- Early access to prenatal care
- Consistent and early recognition of women with 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 OB history of preterm birth
- Align and communicate with EDs, WIC, CHW, MCPs* etc. to screen and refer when history of preterm birth has been identified
- Facilitate rapid new OB appointments
- Postpartum counseling on progesterone for those eligible in next pregnancy
- Use PRAF 2.0—Pregnancy Risk Assessment Form communication form as tool to communicate with the MCPs

- Work with Medicaid and Medicaid Managed Care Plans to identify women at risk and reduce administrative barriers
- Create a written protocol for identified candidates
- Start progesterone as soon as possible (according to ACOG and SMFM guidelines) after identification of eligible women

- Use sonographers trained in cervical length measurement
- Develop a practice protocol to selectively or universally screen cervical length (consider 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 is available and administered

* *ED – Emergency Department*
WIC – Women, Infants and Children Supplemental Nutrition Program
CHW – Community Health Workers
MCPs – Managed Care Plans

How to Use This Change Package and Tools

A 4 – 6 MONTH PLAN TO IMPLEMENT CHANGES AND TRACK IMPROVEMENT

MONTH ONE

Form a team that includes a prenatal care provider (obstetrician or other physician or midwife), a nurse, and an administrative staff member. Meet to set a SMART aim*. Review current processes for finding and treating women with prior preterm birth or short cervix.

MONTH TWO

Start with Key Driver #2, Consistent and Early Recognition of Prior Preterm Birth (Tool #3). Screen every pregnant woman to find those with a prior birth between 16 and 36 weeks of pregnancy. Use PDSA (Plan-Do-Study-Act*) methods to determine the best time, personnel and process for screening. Measure results to be sure that your process reliably finds all pregnant women who might benefit from progesterone.

MONTH THREE

Focus on Key Driver #4. Start by creating a Log (Tool #2) for all Progesterone candidates entering their clinical information to track their needs over time. Use PDSA methods to promote treatment beginning before 20 weeks of pregnancy. Use your log to alert you to other patient risks and barriers and any delays in progesterone starts.

MONTH FOUR

Continue to test and implement methods to expedite progesterone treatment: identify care managers, collaborate with managed care personnel, assign paperwork to specific staff members, order progesterone as early as possible and create an alert system from the log to ensure timelines. Track the number and percent of women eligible for progesterone who start treatment by 20 weeks of gestation.

MONTH FIVE

Identify causes of missed opportunities or late starts on progesterone to identify those most common. If late entry to prenatal care is a common cause of late treatment, work on Key Driver #1, Early Access to Prenatal Care. If you have a high-risk patient population, work on Key Driver #3, Adopt a Cervical Length Screening Protocol. If pregnant women have many needs and are in and out of care, work on Key Driver #5, Customize Care to Maintain Women on Progesterone.

MONTH SIX

Review your practice data to be sure that all women are screened for risk, all progesterone candidates are being tracked in a log, progesterone is started before 20 weeks and that your practice has systems implemented to screen for short cervical length and customize care. If you need to bring women in earlier for prenatal care, partner with managed care, infant mortality initiatives and other community groups that serve women of childbearing age.

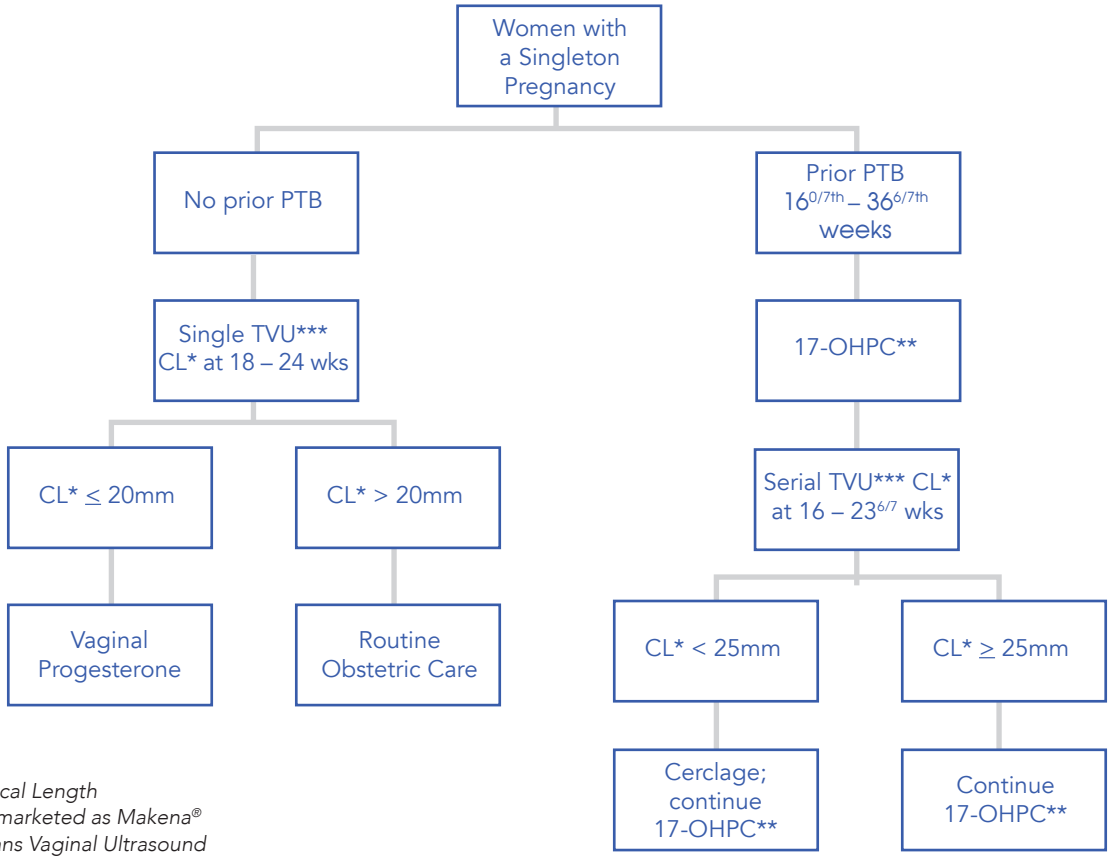
*See page 19

Identification of Candidates for Progesterone

Treatment with progesterone is indicated for women who have had one or more prior births between 16 and 36 weeks of pregnancy (17-hydroxy-progesterone caproate (Makena®)" by injection), and for women who have a short cervical length measured by transvaginal ultrasound in the current pregnancy (progesterone given as a vaginal capsule, suppository or gel). Prior preterm birth is the most common reason for treatment, accounting for about 90% of women treated in the Ohio Progesterone Project; about 6 – 10% of all pregnant women have a qualifying pregnancy history. Short cervix, defined as less than 20 mm before 24 weeks, occurs in about 2% of all pregnancies, can occur in any pregnancy, but is more common in women with a previous preterm birth.

All pregnant women should be screened by history at their initial prenatal visit to find those who might benefit from progesterone. This important step is more difficult than it appears because taking a thorough pregnancy history is complicated. See Key Driver #2. Cervical length measurement with trans-vaginal ultrasound is performed in most women at 18 – 22 weeks of pregnancy at the time of the routine "anatomy scan". Cervical length measurement should be offered to all pregnant women because almost 40% of women with short cervix have no risk factors for preterm birth. Women with a prior premature birth should undergo serial cervical sonography beginning at 16 weeks and ending at $23^{6/7}$ weeks to find those who are candidates for cervical cerclage in addition to progesterone treatment.

Algorithm for Use of Progestogens in Prevention of PTB in Clinical Care



** CL as Cervical Length*
*** Currently marketed as Makena®*
**** TVU as Trans Vaginal Ultrasound*

Treatment for Women with a Prior Preterm Birth

Clinical trials have shown that 17-alpha-hydroxy-progesterone caproate (17-OHPC) 250 mg IM weekly from 16 – 20 until 36 weeks is effective for treatment in women with a prior preterm birth. A short cervix can be treated with vaginal progesterone given daily as 200-mg capsule or suppository, or as 90-mg gel until 36 weeks of gestation. The SMFM algorithm recommends weekly injections of 17-OHPC for women with a prior spontaneous preterm birth, and vaginal progesterone for women without a prior preterm birth whose cervical length is 20 mm or less before 24 weeks of pregnancy. Vaginal progesterone may also be effective in women with a prior preterm birth, but this use requires further research.

Progesterone can be administered as a weekly injection or nightly vaginal suppositories.

Prescription and receipt of 17-OHPC injections is more complicated than it might seem. Injections given in the patient's home by a home health service require separate delivery of the medication, creating opportunities for miscommunication between the pharmacy, the home health service, the provider, the managed care company, and the patient. Administration of 17-OHPC in the office requires purchase by the clinic, hospital or provider. Choosing the best site of administration is therefore very important to pregnant women, pharmacies, insurers, and clinicians, and should be addressed to satisfy all concerned when progesterone is first prescribed. Insurance coverage may vary by the site of administration. Vaginal products are a reasonable alternative if the patient declines to use the injectable product or when there are significant barriers to obtaining it promptly. Some sites in the Progesterone Project chose to begin treatment with vaginal progesterone, switching to 17-OHPC injections when prescription barriers were resolved. Practices that buy 17-OHPC and arrange for patients to travel to the office each week for injections have found that in-office administration of progesterone allows close monitoring and increases compliance. However, weekly visits may be burdensome for patients with other children at home, or who have housing, transportation, telephone, or other barriers.

All Ohio Medicaid Managed Care Plans cover both 17-OHPC and most formulations of vaginal progesterone. All five Ohio MCPs removed their requirement for prior authorization of manufactured 17-OHPC in April 2016, but some specialty pharmacies and manufacturers continue to require it. Successful provision of 17-OHPC to pregnant women requires collaboration by managed care plans, pharmacies, home health care services, and maternity care practices. Tracking each woman's prescription and receipt of 17-OHPC by the clinical team is a key step in assuring administration of progesterone. In 2017, the Ohio Department of Medicaid will introduce the Pregnancy Risk Assessment Form version 2.0 (PRAF 2.0) for all pregnant women to improve communication among care providers, insurers and service agencies. This new form will improve identification and treatment of women eligible for progesterone. The PRAF 2.0 will also identify women with other risk factors.

Tracking each woman's prescription and receipt of 17-OHPC by the clinical team is a key step in assuring administration of progesterone.

Treatment for Women with a Prior Preterm Birth

Progesterone Screening And Treatment For Prior Preterm Birth

1st Contact Screening Questions asked of all new pregnant women. Those who might be eligible for Progesterone should be scheduled for an expedited appointment. Eligibility criteria should be determined by a medical professional at the 1st prenatal appointment with a doctor or certified nurse midwife.

Determine Prior Preterm Birth
Does she have a previous singleton live birth at 16-0/7 – 36-6/7 or stillbirth before 24 weeks that presented as labor, ruptured membranes, or advanced cervical effacement?

If "YES"

Expedite first appointment and discuss:

- Review of OB history
- Discuss Rx Options
- Determine Barriers
- Patient Preferences
- Treatment Options (*home or office care*)
- Enter patient info log for tracking subsequent visits

Perform ultrasound to determine gestational age

Verify insurance type

- Medicaid → Get same day Medicaid ID# from eligibility worker
- None → Determine prior authorization, co-pays, home care, etc.
- Private → Start progesterone treatment with follow-up

Determine treatment

- 17-OHPC injections
- Vaginal progesterone

Initiate prescription

PRAF 2.0 Rx can be initiated from this form (Tool #5)

Regardless of the method(s) chosen, the risk of premature birth should be assessed for all pregnant women as part of routine prenatal care.

Key Driver #1: Early Access to Prenatal Care

Women face many challenges to early prenatal care. Those who didn't plan to become pregnant may not be aware that they are pregnant until after the first trimester. Ambivalent feelings may delay care until the reality of the pregnancy is accepted. Concerns about cost, insurance, childcare, and transportation may affect the decision to seek early prenatal care.

The Progesterone Project teams found that a late start on progesterone was often caused by late entry to care. Women seeking prenatal care before 16 weeks had greater opportunity to initiate progesterone before 20 weeks, the optimal start time.

TOOL #1: PRETERM BIRTH PREVENTION RESOURCES FOR PATIENTS

The patient education materials below are on the OPQC website: **www.opqc.net**

Preterm birth is the leading cause of infant death in Ohio. Babies born preterm, before 37 weeks of pregnancy, can experience major health problems and lifelong disabilities. While anyone can have a preterm birth, some women are at greater risk. If you are pregnant or planning to have a baby, it's important to know whether you might be someone whose risk is greater, and how progesterone can help you give your baby a healthy start.

LEARN ABOUT WAYS YOU CAN GIVE YOUR BABY A HEALTHY START

Visual Fact Sheet: Know Your Risks for Preterm Birth

Preventing Preterm Birth: A Guide for Pregnant Women

How Progesterone Can Help You Prevent an Early Delivery

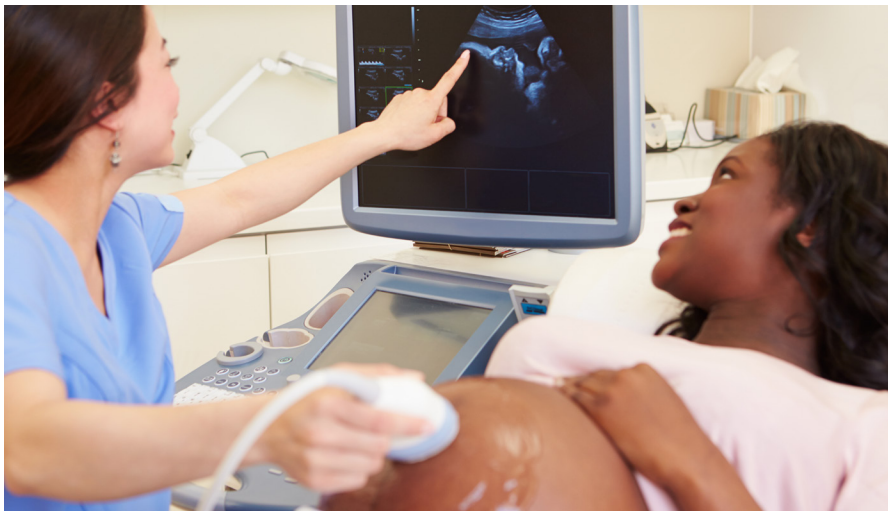
Common Questions and Answers about Progesterone

Watch this video for one family's story about how progesterone treatment helped them.

Examples from Practice:

- Using lists of admitting physicians from local hospitals, supply patient and provider education materials to all types of health care settings within the area.
- Partner with health fairs and community events to provide them with patient education materials.
- Increase opportunities for women to enter prenatal care early and easily. Promote programs such as Help Me Grow, support group prenatal care such as Centering Pregnancy®, mobile and school clinics, expanded office hours. Provide child care and transportation for women seeking pregnancy tests.
- Use social media to encourage early prenatal care; use memorable titles, e.g.,"Go Before You Show!"
- Engage trusted messengers such as community health workers to promote awareness of prematurity as a life changing event for mothers and fathers as well as babies.

Key Driver #2: Consistent Early Recognition of Women with Prior Preterm Birth



Most women who may benefit from progesterone have had a previous pregnancy that ended more than 4 weeks early, defined as a singleton live birth between $16^{0/7}$ and $36^{6/7}$ weeks or an early stillbirth before 24 weeks, that presented as labor, ruptured membranes, or advanced cervical dilation or effacement. Screening to find women eligible for progesterone can occur at sites offering pregnancy tests, on the phone for a first prenatal appointment, and in Urgent Care Centers and Emergency Departments when a pregnancy is identified. Remarkably, some women who are at risk and eligible for progesterone don't describe their previous birth as being premature. This can occur when the infant's birth weight was more than 4 pounds, when the infant didn't require NICU care, or went home on time with the mother. The initial review of prior pregnancies should therefore cast a broad net. The screening questions in Tool #3 are straightforward and can be asked by appointment staff, scripted into calls for prenatal appointments, programmed into electronic medical records and used in paper screening surveys, asking questions such as, "Have you ever had a baby born a month early or earlier? Did any of your newborn infants go to the special care unit? Did you ever go home before the baby was ready to be discharged?"

Women who say Yes, or are uncertain of the answers to any of these questions should meet as soon as possible with a physician, midwife or nurse to take a more detailed history of prior pregnancies to identify the eligibility criteria for progesterone treatment.

Examples from Practice:

See Tool #3

- Every woman requesting a prenatal visit is asked the questions listed above to accelerate the 1st visit for women who might be eligible for progesterone.
- At the initial prenatal visit, a detailed, confidential review of all prior pregnancies is obtained and gestational age is confirmed by ultrasound to assure that progesterone treatment can be started before 20 weeks for eligible women.
- Questions added to the outpatient electronic health record intake for the first OB appointment include, "Have you ever delivered a baby between 16 and 36 weeks?"

  If the answer is 'yes', the provider cannot close the encounter without addressing the risk of preterm delivery.

Key Driver #2: Consistent Early Recognition of Women with Prior Preterm Birth

TOOL #2: PROGESTERONE LOG

The Ohio Progesterone Project learned that writing a prescription for progesterone is too often followed by one or more barriers to starting and maintaining treatment. Tracking each woman's prescription and receipt of 17-OHPC or vaginal progesterone is a key step. Project teams found it helpful to create a "progesterone log" to enable ongoing management, to track initiation and actual receipt of prescriptions, follow up on any delays, assure home care, and to initiate reminders and active care management.

First Name	Last Name	Pt. ID#	Phone Number	EDC	Date Progesterone Ordered	Progesterone ordered 17-OHPC/ Makena/ Vaginal	Follow-up needed

TOOL #3: SCREENING QUESTIONS FOR PRETERM BIRTH HISTORY

Questions to Assess Need for Accelerated Prenatal Appointment

Front office/non-medical scheduling staff

- Have you ever had a baby born a month or more early? ☐ YES ☐ NO
- Have you had a miscarriage after 4 months? ☐ YES ☐ NO
- Have you had a baby in NICU? ☐ YES ☐ NO
- Have you ever been treated with Progesterone? ☐ YES ☐ NO
- Have you ever been told your cervix was short, weak, or incompetent? ☐ YES ☐ NO
- Have you ever had a stitch or cerclage placed in your cervix? ☐ YES ☐ NO

If the answer is YES to any of these questions, make an appointment as soon as possible for a 1st prenatal visit and dating ultrasound.

Key Driver #3: Adopt Cervical Length Ultrasound Screening Protocol

Most premature births occur in women without a history of preterm birth. Among the many risk factors for early birth, a short cervix identified by ultrasound between 18 and 24 weeks of gestation is the only one for which progesterone treatment is helpful.

Cost effectiveness studies support universal screening for short cervix using cervical length by transvaginal ultrasound (TVU) between 18 and 24 weeks gestational age, at the time of an ultrasound to assess fetal anatomy. The screening cervical length measurement should be done before 24 weeks.

In nearly half of all preterm births, women have no apparent risk factors.

Cervical length screening with transvaginal ultrasound is ideally performed by personnel who have been trained by either the Cervical Length Education and Review (CLEAR) Program sponsored by ACOG, SMFM, AIUM, ACOOG, and ACR (perinatalquality.org), or the Fetal Medicine Foundation (fetalmedicineusa.com). Transvaginal ultrasound is preferred because transabdominal ultrasound imaging of the cervix is less sensitive. ACOG and SMFM recommend treatment with vaginal progesterone if the transvaginal ultrasound measured cervical length is 20 mm or shorter in women without a prior preterm birth, or 25 mm or less in women who also have a history of preterm birth.

Examples from Practice:

- Provide education materials at the 1st visit to new prenatal patients about the reasons for offering routine cervical length ultrasound screening to all pregnant women.
- Measure cervical length routinely in transabdominal scans, to be followed by transvaginal ultrasound if the cervix is less than 30 mm or cannot be measured.
- Women with a history of preterm delivery or cervical procedure are screened routinely with transvaginal ultrasound from 16 to 24 weeks of gestation to identify those who need a cervical cerclage.

Key Driver #3: Adopt Cervical Length Ultrasound Screening Protocol

To prepare ultrasound professionals to meet the challenges of reducing preterm birth, OPQC supported the development of an online educational module. The module (Tool # 4) has a compelling introduction to the contribution of preterm birth to infant mortality and uses an interactive format to customize the user experience for sonographers, nurses and physicians. The module can be accessed at https://opqc.net/PTB-Module, and is posted on OPQC.net.

Adoption of routine transvaginal ultrasound measurement of cervical length for all pregnant women at 18 and 24 weeks was associated with a significant reduction in premature births in one large center (Grobman, Ayala & Miller, 2016). Some clinics omit routine screening in women who have a history of 2 or more births at term. Risk assessment to identify and limit transvaginal screening to women at highest risk is not cost-effective (Einerson, Grobman & Miller, 2016). Regardless of the method(s) chosen, the risk of premature birth should be assessed for all pregnant women as part of routine prenatal care.

TOOL #4: CERVICAL LENGTH ULTRASOUND ONLINE MODULE

"Studies of routine screening for short cervix using vaginal ultrasound to identify pregnant women who are eligible for progesterone treatment have shown this to be a cost-effective strategy to reduce preterm birth."
– Jay D. Iams MD, Emeritus Professor of Obstetrics & Gynecology at The Ohio State University and OB Lead, OPQC

You can access the **Cervical Length Ultrasound Online Module** at **opqc.net/PTB-Module**.

Key Driver #4: Expedite Progesterone Supplementation

In women with a prior spontaneous premature birth, it is helpful to write a prescription for 17-OHPC as early as possible, even before 16 weeks, so that treatment can begin at 16–20 weeks and continue until 36 weeks of gestation. In women found to have a short cervix, vaginal progesterone should be prescribed as soon as possible, up to 24 weeks. Initiating treatment after 24 weeks has uncertain benefit.

OPQC Progesterone Teams reported many barriers to getting women started on 17-OHPC, including changes in formulations, availability and coverage. Many of these barriers had solutions, but were often time consuming to figure out and implement. **Managed Care Plans are responsible for helping providers overcome delays in treatment** for pregnant women on Medicaid. Because the successful use of progesterone requires a coordinated sequence of actions by people from multiple locations, the Ohio Progesterone Project clinics found it very helpful to designate one nurse as their "Progesterone Navigator", as someone familiar not only with the medications and indications for treatment, but also the various pathways to administration, as a medical vs. pharmacy benefit, given at home or in the clinic, and by whom.

To reduce the risk of preterm birth, progesterone should be started before 20 weeks gestational age, 24 weeks at the latest.

COMMON BARRIERS TO EXPEDITING PROGESTERONE THERAPY WITH POTENTIAL SOLUTIONS:

EARLY ARRIVAL, BUT LOST TO FOLLOW-UP.
Some women who arrive early for care do not return for subsequent appointments or are lost to follow-up by home care.

Potential solutions:

- Log progesterone candidates into a spreadsheet or paper log (Tool #2) to simplify follow up. Assist these high-risk patients by collaborating with Managed Care Plans, using Care Managers, outreach and reminders. Try connecting them to community resources (home visiting, community health workers, etc.).
- Program phone numbers from the OB practice, pharmacy and home visiting into patients' mobile phones so they can more readily answer calls to set up progesterone care.

Key Driver #4: Expedite Progesterone Supplementation

DELAYS IN INSURANCE AUTHORIZATION. Ohio has eliminated prior authorization for 17-OHPC and vaginal progesterone by Medicaid, but due to the current high cost of manufactured 17-OHPC, Medicaid Managed Care Plans, pharmacy and home care must all be involved and coordinated for women to easily receive once a week injections at home.

Potential solutions:

- Start the process as early as possible (some suppliers allow an order as early as 13 weeks) and schedule the start at 16 weeks.
- For Medicaid patients use the online Ohio Medicaid Pregnancy Risk Assessment Communication & Ordering Form (PRAF 2.0) and fax to both the Managed Care Plan and the pharmacy (if needed).
- Order 17-OHPC using normal purchasing channels to buy a supply of the product and give injections in the office ("buy and bill"). Or write a prescription for Medicaid patients and get the patient-specific prescription sent to your office for weekly injections.
- Vaginal products are a reasonable alternative if the patient declines to use the injectable product or when there are insurmountable hurdles to obtaining it promptly. Some sites started treatment with vaginal progesterone, and then switched to 17-OHPC injections when the various prescription barriers were resolved.
- Micronized progesterone 200 mg capsules USP (Prometrium®) is marketed as an oral capsule for gynecologic use. One capsule, used off-label as a vaginal suppository every evening at bedtime, reduced preterm birth before 34 weeks by more than 40% in one of the largest studies of women with short cervix (Fonseca et al., N Engl J Med. 2007). A generic version is available.
- Vaginal gels 90mg at bedtime available at many local pharmacies.
- Compounded suppositories 200 mg at bedtime can be obtained from compounding pharmacies.

LATE ARRIVAL TO CARE. When women who are progesterone candidates come to prenatal care for the first time after 16 weeks gestational age, it is important to begin therapy as soon as possible.

Potential solutions:

- Give the first injection of 17-OHPC in the office from stock product (see above "buy and bill"), and then continue on branded, compounded (if available) or vaginal.
- Use vaginal products (see above).

TOOL #5: OHIO MEDICAID PREGNANCY RISK ASSESSMENT COMMUNICATION & PROGESTERONE ORDERING FORM (PRAF 2.0)

Beginning in 2017, the Ohio Department of Medicaid and their Managed Care Plan partners will use a single electronic form for every Medicaid insured pregnant woman to insure that the communication and key steps needed to initiate Medicaid insurance coverage for prenatal care, to identify issues needing care management, and serve as a prescription of the appropriate formulation of progesterone. This online form will replace the old paper-based form.

Key Driver #5: Customize Care to Maintain Women on Progesterone

Progesterone and 17-OHPC act to prevent, not treat the early onset of labor, so getting started and continuous use are essential. Both formulations have drawbacks. Women who are candidates for treatment are often disappointed to learn that taking a capsule or tablet by mouth is not an option. This means that involving the pregnant woman and often her family in decision-making about treatment are especially important to assure continuous use.

Care for women at risk for preterm birth starts with clear information about treatment options, listening carefully to the patient to the options that best suit her situation. A Progesterone treatment plan should consider her living situation, schedule, insurance coverage, and any other concerns, including attention to concerns she may have been reluctant to express. The preferred progestogen formulation (injection or vaginal) and site of administration (home or clinic) recommended by her doctor or insurance carrier is a beginning point for discussion that may be influenced by her acceptance of weekly injections or nightly suppositories as well as any cultural and family customs.

OPQC endorses current protocols that recommend injections of 17-OHPC for women with a history of preterm birth and vaginal progesterone for short cervix. However, there is some evidence that vaginal suppositories may be effective in women with prior preterm birth. Vaginal products are much less costly, are preferable to injections for some women and can be obtained the same day that a prescription is written. In many instances, the provision of vaginal progesterone may be the only viable option due to barriers to timely receipt of 17-OHPC. Some providers choose to begin treatment with vaginal progesterone until 17-OHPC is available.

Progesterone can be administered as a weekly injection, or as a capsule gel or suppository given every night.

For both patients and providers, prescription of progesterone in any form is a unique experience. The prescription can rarely be filled by a familiar pharmacy on the day it was written and is never taken by mouth. The steps required to deliver and then administer the medication to the patient are numerous, requiring communication and collaboration by many people asking many questions before providing an important medication to a pregnant woman. Once written, the prescription must be tracked closely to assure receipt and continued use. It isn't surprising that women and their families have questions about each step in the process. New information about progesterone treatment will continue to shape treatment and insurance options for several years. OPQC frequently updates its website with information for both patients and providers.

References

- The Breakthrough Series: IHI's Collaborative Model for Achieving Breakthrough Improvement. IHI Innovation Series white paper. Boston: Institute for Healthcare Improvement; 2003. (Available on www.IHI.org)

- Massoud MR, Nielsen GA, Nolan K, Nolan T, Schall MW, Sevin C. *A Framework for Spread: From Local Improvements to System-Wide Change*. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2006. (Available on www.IHI.org)

- Society for Maternal-Fetal Medicine Publications Committee, with assistance of Vincenzo Berghella. Progesterone and preterm birth prevention: translating clinical trials data into clinical practice. Am J Obstet Gynecol 2012;206:376–86. Erratum in Am J Obstet Gynecol 2013;208:86.

- American College of Obstetricians and Gynecologists. Prediction and prevention of preterm birth. Practice Bulletin No. 130. Obstet Gynecol 2012;120:964–73.

- Iams JD, Identification of candidates for progesterone. Why, Who, How & When? Obstet Gynecol 2014;123:1317–26.

- Conde-Agudelo A, Romero R. Vaginal progesterone to prevent preterm birth in pregnant women with a sonographic short cervix: clinical and public health implications. Am J Obstet Gynecol. 2016;214 (2):235-42.

- National Academy for State Health Policy and the National Initiative for Children's Healthcare Quality Preventing Preterm Birth Through Progesterone: How Medicaid Can Help Increase Access (http://www.nichq.org/blog/2016/may/preventing_preterm_birth).

- Son M, Grobman WA, Ayala NK, Miller ES A universal mid-trimester transvaginal cervical length screening program and its associated reduced preterm birth rate. Am J Obstet Gynecol. 2016 Mar;214(3):365.e1-5.

- Einerson BD, Grobman WA, Miller ES. Cost-effectiveness of risk-based screening for cervical length to prevent preterm birth. Am J Obstet Gynecol. 2016 Jul;215(1):100.e1-7.

- Fonseca EB, Celik E, Parra M, et al. Progesterone and the risk of preterm birth among women with a short cervix. N Engl J Med. 2007 Aug 2;357(5):462-9v.

- Stringer EM, Vladutiu CJ, Batra P et al. Operationalizing 17α-hydroxyprogesterone caproate to prevent recurrent preterm birth. Obstet Gynecol 2016;128:1397-1402.

- Iams JD, Applegate MS, Marcotte MP et al. A Statewide Progestogen Promotion Program in Ohio. Obstet Gynecol 2017;129:337-346.

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Women's Health Center at Summa Akron City Hospital

Canton Metro Area
Aultman Medical Group Maternity and Women's Health

Cincinnati Metro Area
Tri-State Maternal Fetal Medicine Associates, Inc.
Faculty Medical Center - OB Resident Clinic GSH (TriHealth)
Brown County Women's Health
Center for Women's Health, University of Cincinnati Medical Center/UC Health

Cleveland Metro Area
Fairview Perinatal Department (Cleveland Clinic)
Maternal Fetal Medicine Clinic at Hillcrest Hospital Atrium (Cleveland Clinic)
MetroHealth Women's Clinic
MacDonald Women's Hospital Clinic (Women's Health Clinic & OB Faculty Clinic MacDonald 1200)

Columbus Metro Area
Riverside OB Community Care Clinic and MFM Consultative Practice
Doctors Hospital Women's Health Center
Grant Medical Center Outpatient Care Center
Mount Carmel St Ann's OB/GYN Clinic
Mount Carmel West Outpatient Clinic
OSU McCampbell Clinic
OSU Upper Arlington MFM
OSU East Prematurity Clinic

Dayton Metro Area
Five Rivers Health Centers, Center for Women's Health (Miami Valley Hospital)

Toledo Metro Area
Mercy OB/GYN Associates Family Care Center/MFM Clinic
ProMedica Center for Health Services - Women's Services (ProMedica Toledo Hospital)

Youngstown Metro Area
St. Elizabeth Boardman's Health Center

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Appendix

[i]Smart Aim

A **S**pecific, **M**easurable, **A**ction oriented, **R**ealistic, **T**imely (**SMART**) statement of expected results of an improvement process (a statement of a specific, intended goal). Include:

- A general description of what you hope to accomplish
- Specific patient population who will be the focus
- Some guidance for carrying out the activities to achieve aim

[ii]Quality Improvement Method

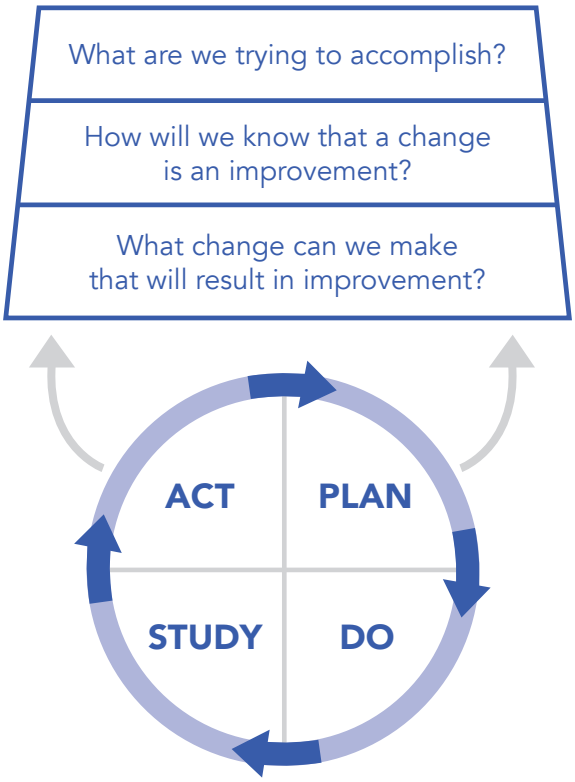
The work of quality improvement teams participating in the OPQC project is guided by the Model for Improvement. The Model asks three key questions as teams test changes in care processes: *What are we trying to accomplish? How will we know that a change is an improvement? What changes can we make that will result in improvement?*

The final element is the Plan-Do-Study-Act (**PDSA**) cycle in which a change to be tested or implemented is planned and carried out, outcomes are monitored and analyzed, and then, based on the lessons learned, the change is fully implemented or the next change cycle is planned.

The PDSA Cycle Video; Speaker: Robert Lloyd, PhD, Institute for Healthcare Improvement; can be found at: www.youtube.com/watch?v=xzAp6ZV5ml4.

Langley, Nolan, Norman, and Lloyd P. Provost. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*. New York: Jossey-Bass Inc., 1996

Model for Improvement



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