Access to Progesterone for Prematurity Prevention: A Quality Improvement Collaborative

Preconference Special Interest Discussion

June 2014

March of Dimes

New York State Perinatal Association
**March of Dimes**
President Franklin Roosevelt’s personal struggle with polio led him to create the National Foundation for Infantile Paralysis at a time when polio was on the rise. Better known as the March of Dimes, the foundation established a polio patient aid program and funded research for vaccines developed by Jonas Salk, MD and Albert Sabin, MD. These vaccines effectively ended epidemic polio in the United States.

Its original mission accomplished, the foundation turned its focus to preventing birth defects and infant mortality. The March of Dimes has led the way to discover the genetic causes of birth defects, to promote newborn screening, and to educate medical professionals and the public about best practices for healthy pregnancy. We have supported research for surfactant therapy to treat respiratory distress and helped initiate the system of regional neonatal intensive care for premature and sick babies. Our recent Folic Acid Campaign achieved a dramatic reduction in the incidence of neural tube defects, birth defects of the brain and spine.

Since 2003, our fight to save babies has been strongly characterized by our Prematurity Campaign. The rising incidence of premature birth has demanded action, and the March of Dimes has responded by initiating an intensive, multi-year campaign to raise awareness and find the causes of prematurity.

www.marchofdimes.org

**New York State Perinatal Association**
The New York State Perinatal Association (NYSPA) is a state-wide alliance of health and human service professionals and consumers concerned with perinatal health issues from preconception through early childhood. NYSPA advocates for optimal perinatal care and parenting and promotes education and research, influences state priorities and encourages a multi-cultural and multi-disciplinary approach to maternal and child health.

The New York State Perinatal Association evolved out of calls for the New York State Association of Regional Perinatal Centers/Programs to create a multi-disciplinary group to provide evidence-based support for programs improving maternal and perinatal outcomes in the 1990s.

www.nysperinatal.org
Planning Committee for

*Access to Progesterone for Prematurity Prevention: A Quality Improvement Collaborative*

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Access to Progesterone for Prematurity Prevention: A Quality Improvement Collaborative

Panelists

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Presenters

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Introduction

BACKGROUND

For more than 75 years, the March of Dimes has worked to prevent premature birth, birth defects and infant mortality by funding research, providing patient and provider education, developing community programming, and advocating for policies that will improve the health of women and infants. We have made great strides; however, premature birth continues to be a great public health concern.

In fact, the United States has the highest preterm birth rate of any industrialized country. Preterm birth (< 37 weeks) affects nearly 500,000 babies born in our nation each year - one of every nine infants in the U.S. is born preterm. It is a leading cause of long-term neurological disabilities in children. Preterm birth-related causes of death accounted for 35% of all infant deaths in 2009, more than any other single cause, and cost the U.S. health care system more than $26 billion in 2005.

New York State earned a B on March of Dimes 2013 Premature Birth Report Card - an annual report that measures each state’s premature births against the national goal of 9.6% or less by 2020 - with a preliminary preterm birth rate of 10.7% in 2012. Based on confirmed 2011 preterm birth rates, 19 states outperformed New York in reducing preterm births, including California, Connecticut and Massachusetts. 5.7% of all preterm babies in the country were delivered in New York. It is estimated that preventing premature births could save New York State $1 billion annually.

Preterm birth can happen to any pregnant woman. In about 4 out of every 10 cases, the causes of preterm birth are unknown. Over the years, interventions such as bed rest, hydration, intensive prenatal care for high-risk women, and antibiotics and tocolytics to stop uterine contractions have been tested but proven largely unsuccessful.

One of the strongest clinical risk factors for preterm birth is prior preterm birth and is inversely proportional to the gestational age of the prior preterm delivery. Short cervical length measured by trans-vaginal ultrasound has also been associated with increased risk of preterm birth. Progesterone has shown promise in preventing preterm labor in women who have had a prior preterm singleton birth, but it has been underutilized by providers and relatively unknown to patients.

For the past several years, in conversations with providers and advocates alike, people kept asking the question: Why isn’t progesterone better utilized? There were some unsurprising responses such as “The drug is too costly” or “The drug is too difficult to get”. But there were also some surprising insights such as providers unfamiliar with appropriate indications for implementing the intervention to significant confusion over pre-authorization and billing
processes. As these conversations continued, it became increasingly clear that this issue needed to be addressed in a forum where stakeholders from across the State and with various roles within maternal and infant health could come together and discuss this phenomenon. The Access to Progesterone for Prematurity Prevention: A Quality Improvement Collaborative a Preconference Special Interest Discussion at the New York State Perinatal Association’s annual conference on Thursday, June 4 at the Desmond Hotel in Albany, New York was our effort to begin this dialogue among New York’s leaders in maternal and infant health.

GOALS OF THE SESSION

The planning committee agreed that it was important to develop goals for the session in order to make the most of the limited time available for this discussion. The following goals were identified for the session.

1. Improve Patient & Provider Education Surrounding Indications for and Access to Progesterone Therapies for Prevention of Preterm Birth in New York State.

2. Develop Statewide Collaborative to Increase Utilization of Progesterone Therapies in New York State.


*The secondary goal of the session was to identify possible benchmarks and outcome measures.

ORGANIZATION OF THIS SUMMARY

Following this introductory chapter, Chapter 2 provides a review of the presentations that were given at the session. Chapter 3 identifies the major themes in the discussion, Chapter 4 summarizes the next steps for advocates, and Appendix A provides a detailed summary of the discussion as it occurred at the session.
Dr. Scarlett Karakash presented an overview of the current clinical landscape of progesterone, including the differences between progesterone as an injectable versus vaginal progesterone gel. Highlights from Dr. Karakash’s presentation are below.

- **Making the Case for Progesterone:**
  Studies suggest that progesterone may maintain uterine quiescence (preventing contractions) and cervical length in the latter half of pregnancy. Onset of labor at term and preterm is associated with functional withdrawal of progesterone activity at the level of uterus.

  A review of national birth certificate data for 2002 estimated that each year, approximately 30,000 pregnant women met the qualification and were considered eligible for progesterone. If these women received the appropriate treatment with progesterone, nearly 10,000 preterm births could have been prevented.

- **There are currently two kinds of progesterone treatment:**
  1. **Vaginal Progesterone Gel:** Vaginal progesterone gel is used to treat women with a short cervix. Treatment with vaginal progesterone in women with short cervix (< 25 mm) and history of prior preterm birth leads to a 42% decrease in the risk of preterm birth before 33 weeks (Number needed to treat /NNT 11) and 43% decrease in composite neonatal mortality and morbidity (NNT 13). A daily dose of Progesterone gel is administered via a tampon-like applicator in the vagina. Treatment begins between 20 and 23 weeks of pregnancy and can last until 37 weeks of pregnancy. Vaginal Progesterone has high uterine bioavailability and has fewer systemic side effects.

  2. **17 alpha-hydroxyprogesteronecaproate (17P):** 17P injections are used to treat women who have had a previous spontaneous preterm singleton birth and are currently pregnant with a single baby. Treatment with the injectable, synthetic form of progesterone has been shown to lead to a 50% decrease in perinatal mortality and 59% decrease in preterm birth before 34 weeks in women with prior history of preterm birth. It has also been shown to cause a 36% decrease in preterm birth before 34 weeks in women with short cervix. Weekly injections of 17P begin between 16 and 20 weeks of pregnancy and continue until 37 weeks.

- **Known Barriers to the Use of and Access to Progesterone:**
  1. **Cost:** While progesterone gel is currently available from several manufacturers costs $10-21 per applicator, 17P costs approximately $700 per IM dose in Albany (varies by location
within state and between states). The compounded formulation costs approximately $32 per IM dose.

2. **Accessibility**: The drug version of 17P is not covered by all insurance companies due to its cost. In addition, the ordering process for 17P is complicated, costly and time-consuming. The providers need prior authorization and often have to buy the drug themselves before applying for reimbursement. Significant support from state and regional health agencies is needed to ease the process of ordering the drug and covering the initial cost, allowing prompt access.

   The compounded formulation is not available at all pharmacies. In addition, concerns have been raised about the quality and safety of compounded sterile injectables as well as the compounding pharmacies’ right to recreate this drug in particular. The ongoing litigation around the drug manufacturer’s legal rights has impacted its utilization.

3. **Late Entry into Prenatal Care**: Eligible women who initiate prenatal care late in pregnancy are missed opportunities for this therapy since the initiation of therapy is recommended between 16 and 20+6 weeks gestation.

4. **Administration Barrier**: Eligible women need to agree to weekly IM injections and make consistent weekly visits to the provider’s office. Alternatively, home injections may need to be self-administered or with the help of a trained family member or a friend.

5. **Inappropriate and Inadequate Use**: Provider education is needed to reinforce the appropriate use of progesterone. A recent survey showed that 55% of providers who offer 17P recommended it to women without prior history of preterm birth but who had other risks for preterm delivery.

6. **Lack of Consensus**: Universal screening for cervical length is not recommended for routine screening for low risk women by national societies at this time. There is a general lack of consensus regarding universal cervical length screening and the appropriate populations to target with this screening.

7. **Unknown Barriers**: There is likely a complex interplay of various bio/psycho/social factors that further confound these problems. Further investigation will be needed as identified barriers are resolved.
CURRENT EFFORTS TO INCREASE ACCESS TO PROGESTERONE THERAPIES TO REDUCE PREMATURE BIRTH

Dr. Yogangi Malhotra presented an overview of current efforts to increase access to progesterone to reduce premature birth. Dr. Malhotra first reviewed ongoing efforts by the American Congress of Obstetricians and Gynecologists (ACOG) to develop educational materials for clinicians to improve the utilization of progesterone when clinically indicated. Dr. Malhotra next identified key state led initiatives designed to improve patient access to progesterone. This included discussion of programs currently underway in Louisiana, North Carolina, South Carolina and Ohio. A brief review of these efforts is provided below.

- **ACOG: Video Series and Resource Guide**
  ACOG and the Society for Maternal Fetal Medicine (SMFM) have published committee opinions that recommend use of vaginal progesterone for short cervix and 17P for women with history of preterm birth. In addition, ACOG District II 17P taskforce has created a Preventing Preterm Birth 17P Resource Guide and Preventing Preterm Birth Video Series, tailored specifically for the generalist obstetrician-gynecologist.

- **Louisiana: Streamlining Ordering Process**
  The Louisiana Department of Health and Hospitals' Birth Outcomes Initiative and the Louisiana Hospital Association have partnered in an effort to streamline the ordering process for 17P since 2009. A survey found that the providers were not billing properly and that the primary barrier was difficulty ordering the medication. A website called the 17P Louisiana Resource Center was created to ease the process of ordering and to provide guidelines for billing and reimbursement.

  The Division of Medical Assistance stated that it will continue to reimburse providers for 17P through the physician’s drug program. Louisiana covers both drug and compounded forms of progesterone to allow providers to stock this medication in their offices. In addition a 17P Resource Guide was published in partnership with ACOG District II and March of Dimes to bolster the provider education.

- **North Carolina: Financial Incentives for Risk Screenings & Evaluations**
  The North Carolina Division of Medical Assistance, the Division of Public Health and the Community Care of North Carolina (CCNC) together launched Pregnancy Medical Home (PMH) in 2011. CCNC has 14 local networks that developed an outcome-driven initiative that is monitored for specific standards. The providers receive financial incentives for risk screenings and evaluations. Additional in-person support is provided by pregnancy care managers at the local CCNC network and online management support with risk screening forms and PMH pathways. Prior to the launch of this program, in 2006, the North Carolina General Assembly began appropriating nonrecurring funds to improve access to 17P and an advisory council guided implementation activities.
➢ **South Carolina: Universal Authorization Form**

The South Carolina Department of Health and Human Services led a statewide effort with the March of Dimes, South Carolina Hospital Association, Blue Cross Blue Shield of South Carolina, and other key stakeholders to form the [South Carolina Birth Outcomes Initiative](#) (SCBOI). Included in SCBOI’s six core objectives for improving birth outcomes is a goal to make 17P “available to all at-risk pregnant women with no ‘hassle factor’”. To simplify the process, SCBOI developed the [Universal 17P Authorization Form](#). March of Dimes awarded a grant to the Medical University of South Carolina provides education to providers on appropriate use and access to 17P via the Progesterone Outreach Program.

➢ **Ohio: Breakthrough Series Model**

The Ohio Department of Health and Medicaid secured state general revenue and Medicaid funds to make 17P available as the standard of care for all Ohio women at risk of preterm birth. The [Ohio Perinatal Quality Collaborative](#) (OPQC) developed a statewide [Progesterone Project](#) in 2013 to promote identification and 17P treatment by applying Institute for Healthcare Improvement quality improvement techniques to enable clinics and providers to find and treat all eligible women, educating pregnant women and their caregivers about preterm birth, and assuring wide access to sonographers skilled in ultrasound measurement of the cervix. OPQC, OCPIM, Ohio Medicaid, the Ohio Hospital Association and Ohio March of Dimes are collaborating to improve access and to assure that compounded 17P is obtained only from credentialed pharmacies that are fully compliant with state regulations for compounders. The project was started in six metropolitan areas and will soon expand throughout the state.
CHAPTER 3
MAJOR THEMES FROM DISCUSSION

The following is an outline of the major themes that developed during the discussion and the issues that were important to participants within those themes.

- **Intended Outcomes:**
  1. Reduce Preterm Birth.
  2. Reduce Perinatal/Neonatal Deaths.

- **Education:**
  1. **Social Media:** Utilize social media to reach target audience and raise awareness about progesterone therapies. Take advantage of existing blogs, websites and text messaging, such as March of Dimes Share Your Story or Text4Baby, to provide information about progesterone therapies to target audience.
  2. **Toolkits:** Replicate March of Dimes “39 Weeks” program in order to provide educational materials for providers and patients on progesterone therapies. Adapt the program model to provide educational materials on progesterone therapies for insurers.
  3. **Teachable Moments:** Take advantage of opportunities presented during prenatal and antepartum care as well as during the NICU stay to improve awareness on progesterone as an intervention for preterm birth.
  4. **Collaborate:** Partner with stakeholders - like ACOG & RPCs – to raise awareness and improve utilization of progesterone therapies as well as to identify and breakdown logistical barriers.
  5. **Data:** Improve data by ensuring data collection on fetal deaths, NICU data is linked, and birth certificates include information on preterm birth history and risk factors.

- **Access:**
  1. **Home Visitation:** Utilize opportunity to improve patient compliance and increase access to progesterone therapies.
  2. **Insurance Coverage:** Confirm availability of in-network providers for primary insurance providers in New York State and identify which insurance providers cover progesterone
therapies. Compile list of protocols required by Medicaid and other primary insurers in New York State in order to be approved for progesterone therapies (i.e., approval time, supplemental submissions, etc.).

- Suggested clinicians document specific incidents to help illustrate the severity of the problem. Once there is sufficient documentation, meet with the Medicaid Plan Directors, Managed Care Organizations, and insurance administrators in order to discuss prior authorization issues and potential remedies.

3. **Patient Compliance:** Develop methods to improve initial implementation of progesterone therapy as well as patient adherence to weekly injection schedule.

- **Roles of Stakeholders:**
  1. **New York State Department of Health:** Engage with the State Department of Health to formulate policies and provide education to improve access to progesterone therapies.
  2. **County Department of Health:** Determine whether County Departments of Health should play more central roles in providing access to progesterone therapies.
  3. **Medicaid Plan Directors:** Partner with Medicaid Matters and other advocates in order to engage with Medicaid Plan Directors to improve access to progesterone therapies.
  4. **Insurance Companies:** Educate insurers on importance of progesterone therapies. Address concerns that specific insurers are blocking access to treatment with nuisance protocols.
  5. **Pharmaceutical Companies:** Clarify what role pharmaceutical companies will play in improving access to progesterone therapies.
  6. **Case Managers:** Work with organizations like APN to engage case managers with patient logistics/compliance.
Chapter 4

Next Steps

Below are three action items that were discussed and agreed upon at the session. It is hoped that participants will drive this effort by pursuing the action items listed below over the next several months and will continue the conversation that was begun at this session within their own organizations and other stakeholders. The action items are in no particular order.

1. Engage managed care providers and associations in conversations about improving utilization of progesterone therapies to reduce preterm birth.
   a. Get progesterone therapy on the agenda of an upcoming meeting of the managed care directors.

2. Develop listserv of session participants.
   a. Distribute report of session outcomes to listserv.
   b. Utilize listserv to provide occasional updates on key efforts undertaken by advocates to improve utilization of progesterone therapies in New York.

3. Schedule phone conference for session participants within 6 months in order to continue discussions and share any new information.
APPENDIX A

STAKEHOLDER DISCUSSION

The following is a synthesis of the major questions asked and points made during the panel led discussion. This in no way encapsulates the full discussion that occurred and is meant only to highlight certain portions of the conversation that generated high levels of participation.

**Question:** How do you plan to use social media to improve utilization of progesterone?

**Discussion:** We can use the websites and blogs of individual organizations, with the help of key players like the New York State Department of Health, March of Dimes, and ACOG, to increase awareness about progesterone as an intervention for preterm birth.

- We can develop handouts for patients that are advertised on social media.
- We can take advantage of teachable moments in the NICU where we can discuss things like progesterone in addition to inter-pregnancy spacing for preterm birth, etc.
- This isn’t just a patient education issue. Patients who are knowledgeable of progesterone have been told by their providers that they do not meet the clinical indicators when they actually do. Provider education is equally important.

**Question:** How do we get insurance companies to partner with us? Our target population is predominantly covered by Medicaid and the Medicaid prior authorization requirements are ridiculous.

**Discussion:** Can you explain the prior authorization process?

- First you order the medication while you wait for prior authorization from the insurance provider. Generally, you will have to complete additional forms and provide supplemental information. While you are waiting for the prior authorization, which can take a while, the window for effective intervention shrinks.
- We should bring this issue to New York’s Medicaid and Commercial plan directors. This would be a good concern to raise with them at one of their upcoming meetings. We should begin to work on getting this on their agenda.
- Including the managed care side of the house in these discussions is critical since Medicaid is administered through managed care in New York. If the managed care plans and associations had a better understanding of this issue, we could probably fixed the current logistical problems.
We need to document specific incidents where the prior authorization process negatively impacted patient care and/or outcomes. This will help to identify and solve the problems. Current Medicaid regulations indicate that there is no wait, but that doesn’t seem to be the reality for clinicians and patients.

There can be up to a 3-4 week turn around on pre authorization from certain insurers.

**Question:** What about making 17P a county managed program, where the county Department of Health serves as the access point for services for patients?

**Discussion:** The New York State Department of Health is transitioning to a medical home model for care. Shifting the progesterone issue to the county health departments wouldn’t necessarily work within this new framework of care. We need to improve access through more traditional avenues so that we stay within the medical home construct.

We need to put access points where patients are willing and able to go.

Getting to weekly visits is difficult. We need to consider logistics.

Case managers should be helping with this through managed care.

In some cases, the only assistance high risk women have received is a bus token.

**Question:** Could we revamp an existing program – like 39 Weeks – to address the progesterone issue?

**Discussion:** We should mimic successful program models for this issue. No need to reinvent the wheel.

This needs to be a perinatal project. We need to incorporate an evaluation process for fetal deaths; it is not just births, it is also deaths. We need to have better linkage of NICU module with SPDS to evaluate the process. We need to add some items to the birth certificate.

We need to empower patients to take charge of their care. We need to use social media – we have found that underserved women have and use smart phones. We might consider using radio for public service announcements in addition to social media. We should use some of our regional systems and networks to get the message out. We should try to address patient education and access in a single plan that uses the communication methods that young women use.

**Discussion:**

Text4Baby may be a place to put this. Text4Baby as it exists now is very general. There has been talk about whether there should be a specialized Text4Baby, like Text4Baby for preterm birth or Text4Baby for diabetics.
**Question:** What role should patient education play in this?

**Discussion:** Patient education is a huge opportunity. We can collaborate with stakeholders within communities. Patient education can be spread through our grassroots networks. We need to get the information out to them through our collaborative.

- There is a role for RPC to play in this. We need to listen to the providers as well.
- RPC’s can play a huge role. Education is only one issue

**Question:** What commitment is there from the pharmaceutical companies to help us address this issue? Where are we with them? Do they want to buy into this?

**Discussion:** Pharmaceuticals are doing some things. Progesterone is a very controversial issue with them right now because lots of things remain undecided with respect to the FDA and ongoing litigation. We don’t know how those issues will be resolved.¹

- We don’t know what is really going on. There are specific things that we need to address, and we should look into role that the collaborative could play. We would hope that there are some areas that we can begin to address.

**Question:** Has any work begun on changing regulations on prior authorization?

**Discussion:** We need to schedule a meeting with the managed care directors to tackle that.

- We need to have very clear goal and clear plan, we don’t want to go there asking for ABC when we also needed to ask for XYZ
- It sounds like we are pretty close to that conversation. We should make some outreach to get on that agenda as soon as possible. Even if we get there and ask for ABC and then find out we also need XYZ, that’s ok. We don’t need every detail in order. We should go ahead and get on the agenda
- It takes a bit to get on the agenda.
- It took 6 months to get a reimbursement code for another issue and that was lightning speed. The hardest thing is to get on the agenda.

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¹ On Wednesday, July 9, it was announced that Lumara Health (formerly K-V Pharmaceuticals) had settled its lawsuit against the Food and Drug Administration (FDA). Lumara alleged in its suit that the FDA was unlawfully allowing the compounding of 17P. Details of the settlement are not public. The FDA did, however, release a statement, clarifying its June 2012 statement, that Makena should be used instead of a compounded version of 17P, except where there is a specific, documented medical need on the part of the patient (e.g. allergy).