

New study further supports use of progesterone to fight preterm birth (Update)

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A new study published today - World Prematurity Day - in the *American Journal of Obstetrics & Gynecology* provides additional support for treatment with vaginal progesterone to reduce the risk of preterm birth, neonatal complications and infant death in pregnant women with a short cervix. A shortened cervix is the most powerful predictor of preterm birth.

A meta-analysis of individual patient data by researchers at the Perinatology Research Branch of the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the Wayne State University School of Medicine and the Detroit Medical Center, further validates the use of vaginal progesterone to decrease the risk of preterm birth and improve perinatal outcomes in women with a single pregnancy found via sonography to have a short cervix. Vaginal progesterone therapy to reduce preterm birth was developed at the PRB in 2011.

The findings are welcome news in the fight against preterm birth, the leading cause of death in children younger than 5. The March of Dimes annual report on preterm birth for 2017 indicates that the rate of preterm birth in the United States climbed for the second consecutive year in 2016 after nearly a decade of decline.

The 2017 March of Dimes Premature Birth Report Card provides preterm birth rates and grades for all 50 states, plus the District of Columbia and Puerto Rico, based on birth data from the National Center for Health Statistics. The latest report card puts the national preterm

birth rate at 9.8 percent (a C grade), an increase from the rate of 9.6 percent in 2015. Preterm birth rates worsened in 43 states, the District of Columbia and Puerto Rico. Only four states received an A grade. Michigan, with its 10.1 percent rate, ranked worse than 26 states and received a C grade.

Among the 100 U.S. cities with the greatest number of births in 2015, Detroit had the second highest rate of preterm delivery with 13.9 percent. Only Cleveland, Ohio, had a higher rate of preterm birth with 14.9 percent. Both cities earned an F grade from the March of Dimes.

Births occurring before the 37th week of pregnancy are considered preterm. In preparation for birth, the cervix (lower part of the uterus) thins and shortens during pregnancy. In some women, the cervix shortens prematurely. The natural hormone progesterone, inserted in the vagina either as a gel or tablet, has been associated with a reduction of the risk for preterm birth associated with a short cervix in multiple studies conducted by National Institutes of Health and WSU investigators.

To confirm progesterone's effectiveness, the researchers investigated randomized controlled studies that compared women who received vaginal progesterone with those who received a placebo or no treatment for a single birth and a mid-trimester sonographic cervical length of less than 25 mm.

The study examined data from 974 women (498 assigned to vaginal progesterone and 476 assigned to placebo) who participated in one of five trials. The use of progesterone was associated with a significant reduction in the risk of preterm birth at less than 33 weeks gestation. Progesterone use also significantly decreased the risk of preterm birth from less than 36 weeks to 28 weeks gestation. Women who used progesterone delivered closer to their due date than did women supplied with placebos.

The use of progesterone also significantly decreased the rate of respiratory distress syndrome, neonatal death, low birthweight and admission to neonatal intensive care units for newborns with no deleterious effects on childhood neurodevelopment.

"This study addresses a controversy that emerged after the publication of another study in February 2016. Our meta-analysis demonstrates that vaginal progesterone reduces the rate of preterm birth from less than 28 weeks to less than 26 weeks in women with a sonographic short cervix. Moreover, vaginal progesterone reduces admission to NICU, respiratory distress syndrome and composite neonatal morbidity," said Roberto Romero, M.D., chief of the PRB and professor of Molecular Obstetrics and Genetics for the Wayne State University School of Medicine, lead author of the study. "Our results, coupled with those of cross-effectiveness research and implementation research, shows that universal cervical screening of the uterine cervix with the administration of vaginal progesterone is cost-effective and can be implemented in the real world."

An estimated 15 million babies are born preterm worldwide annually. Preterm birth and its attendant complications are responsible for nearly 1 million deaths each year. Complications of preterm birth are the leading cause of child mortality. Infants who do survive run the risk of further complications, including acute respiratory, gastrointestinal, infectious, central nervous system, hearing and vision problems, as well as long-term disabilities such as cerebral palsy.

More than 380,000 babies are born preterm in the U.S. each year, according to the March of Dimes. With the recent increase in the percentage of preterm births in the nation, 8,000 more babies were born prematurely in 2016.

The economic impact of premature birth in the U.S. is more than \$26

billion annually, according to the March of Dimes. This underscores the importance of addressing preterm birth on Nov. 17, World Prematurity Day.

The study's authors, including Sonia Hassan, M.D., associate dean for Maternal, Perinatal and Child Health and professor of Obstetrics and Gynecology for WSU, and director of the Center for Advanced Obstetrical Care and Research for the Perinatology Research Branch, have recommended universal transvaginal cervical length screening at 18 to 24 weeks gestation and administration of vaginal progesterone for women found to have a short cervix.

"This study confirms what we've previously shown - vaginal progesterone is a critical treatment for women and babies at high risk for preterm birth," said Dr. Hassan, who published the initial findings of the beneficial effects of vaginal progesterone on preterm birth. "This treatment is of particular importance to the pregnant women of Detroit and the State of Michigan."

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More information: "Vaginal Progesterone for Preventing Preterm Birth and Adverse Perinatal Outcomes in Singleton Gestations with a Short Cervix: A Meta-Analysis of Individual Patient Data," *American*

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