UWNQC

Utah Women & Newborns Quality Collaborative

Maternal Committee Progress 2019

The Maternal Committee focuses on reducing Preterm Birth statewide. One strategy to reduce preterm birth is identifying women at risk for preterm birth and offer access to treatment that can reduce their risk of a preterm birth. This treatment includes use of a progesterone, 17-P. The committee has been collecting hospital data on the use of the progesterone 17-P and conducted an audit on Intermountain and Birth Certificate data. One of the committee members launched a project through the Intermountain Leadership Institute on how to improve the tracking of women who have been offered and are taking 17-P.

In October, the results of the PROLONG (Progestin's role in Optimizing Neonatal Gestation) study were published in the American Journal of Perinatology. PROLONG was a randomized, double-blind, placebo-controlled clinical trial evaluating 17-OPIC (17-hydroxyprogesterone Caproate or Makena®) in patients with a history of prior spontaneous singleton preterm delivery. The trial did not show a reduction in preterm birth or a reduction in the neonatal morbidity and mortality index. Nine members of the FDA's Bone, Reproductive and Urologic Drugs Advisory Committee voted to recommend that the FDA pursue withdrawal of approval for Hydroxyprogesterone Caproate injection (Makena®/17-P) for the prevention of preterm birth in pregnant women, while 7 of the committee members voted to leave the product under accelerated approval and to require a new confirmatory trial.

The UWNQC Reduce Preterm Birth committee plans to convene to discuss next steps on the future of 17P and determine the focus for 2020. ACOG and SMFM has statements on the Prolong Study/17P: ACOG statement on Prolong/17p 10-25 and SMFM Statement on 17P October 2019.