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Experts in High-Risk Pregnancy Respond to the Published Results of the PROLONG Trial

Clinical Guidance Underscores the Importance of an Individualized Approach in Caring for Patients with a Previous Preterm Birth

October 25, Washington, DC – The Society for Maternal-Fetal (SMFM) released the following statement in response to the published results of “Progestin’s Role in Optimizing Neonatal Gestation,” more commonly referred to as the PROLONG trial, which was recently published in the [*American Journal of Perinatology*](#).

“The PROLONG trial assessed the effectiveness of weekly injections of 17-alpha-hydroxyprogesterone caproate (17-OHPC) in reducing the incidence of recurrent preterm birth and neonatal morbidity. Between 2009 and 2018, this study enrolled more than 1,700 pregnant patients from nine countries and ultimately concluded that 17-OHPC does not decrease recurrent preterm birth or neonatal morbidity.

A previous large randomized control trial (Meis, 2003) also examined the effectiveness of 17-OHPC. Unlike PROLONG, this study found a 34% reduction in the incidence of recurrent preterm birth and significant reductions in several neonatal complications.

In comparing the conflicting results of the PROLONG and Meis trials, one important consideration is the different populations studied. The Meis trial included a larger proportion of patients with additional risk factors for preterm birth. For example, 20% of the patients in the Meis trial reported smoking, compared to 8% in the PROLONG Trial. Other meaningful differences in the populations included:

- Race/Ethnicity
- Number of previous preterm births
- Marital status
- Reported substance use

SMFM has reviewed the results of the PROLONG trial and has released the [*SMFM Statement: Use of 17-alpha hydroxyprogesterone caproate for prevention of recurrent preterm birth*](#), which recommends that obstetric care providers use an individualized approach as they counsel patients regarding the use of 17-OHPC. It is reasonable for providers to continue to use 17-OHPC in the context of a shared decision-making model that includes consideration of risk level for recurrent PTB. Important factors to discuss include: uncertainty regarding the benefit, the lack of short-term safety concerns, the possibility of injection site pain, extra patient visits, and substantial costs.

Further, SMFM recommends additional research on 17-OHPC to identify populations in whom it is likely to be effective.

SMFM's complete, updated clinical guidance will be published in the *American Journal of Obstetrics and Gynecology*, can be found on the [SMFM website](#), and will be addressed on Tuesday, October 29, 2019 at meeting of the Food and Drug Administration's Bone, Reproductive and Urologic Drugs Advisory Committee.

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About SMFM

The Society for Maternal-Fetal Medicine (SMFM) is a non-profit, membership organization based in Washington, DC. With more than 3,500 physicians, scientists and women's health professionals around the world, the Society supports the clinical practice of maternal-fetal medicine by providing education, promoting research and engaging in advocacy to optimize the health of high-risk pregnant women and their babies. SMFM hosts an annual scientific meeting in which new ideas and research related to high-risk pregnancies are unveiled and discussed. For more information, visit www.smfm.org.