

The Effectiveness of 17P in Reducing the Risk of Subsequent Preterm Birth in Women with a History of Preterm Birth: Updates from PRAMS 2012-2013

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Background

17 Alpha-Hydroxyprogesterone Caproate or 17P is a prescription drug, made up of the hormone progesterone, that is prescribed to pregnant women in order to prevent preterm birth (<37 weeks' gestation) (Petrini et al., 2005). Previous studies have shown that 17P is successful in reducing the risk of preterm birth in those women who are considered to be the most at risk (Bastek, Adamczak, Hoffman, Elovitz, & Srinivas, 2012). The major known risk factor for preterm birth is having had a prior preterm birth. Other known risk factors include race/ethnicity, low socioeconomic status, presence of a short cervix, obesity, tobacco use while pregnant, being unmarried or without paternal support, and older maternal age (Barton et al., 2011) (Timofeev, Singh, Istwan, Rhea, & Driggers, 2013). Past studies have also demonstrated that among women who are considered to be at the highest risk for preterm birth, the timing of 17P initiation as well as 17P cessation are important. Therefore, the longer a pregnant woman receives 17P, the better her birth outcomes will be (Rebarber et al., 2007). Unfortunately, prior studies have also identified major gaps and barriers in the availability of 17P to those women who would otherwise be considered eligible to receive the drug. These barriers include high cost of the drug and the method of drug allocation (Cohen et al., 2011) (Rebarber, Fox, Klausner, Saltzman, & Roman, 2013).

In South Carolina, there are also barriers to obtaining accurate claims data surrounding 17P utilization because the drug is most often given in outpatient or home settings. Also, little is known about the methods that providers are currently using or have used in the past when prescribing and administering 17P, and what is known about these methods demonstrates variation from provider to provider. Furthermore, due to the lack of available data, there has not been a baseline established for 17P uptake in South Carolina. Using what knowledge we have, in this study, we aim to evaluate the effectiveness of 17P in preventing subsequent preterm birth in South Carolina in women who have had a prior preterm birth and determine additional risk factors that may impact the effectiveness of the drug. Additionally, we aim to observe the sociodemographic characteristics of pregnant women in South Carolina who received 17P and had a prior preterm birth in the years 2012 and 2013.

Methods

- The data from the 2012-2013 South Carolina Pregnancy Risk Assessment Monitoring System (PRAMS) as well as 2012-2013 South Carolina Birth Certificate Data were used to examine the effectiveness of 17P in the prevention of preterm birth in eligible pregnant women as well as the sociodemographic characteristics of pregnant women who did and did not receive 17P.
- The sociodemographic characteristics of pregnant women in South Carolina who did and did not receive 17P were compared and analyzed using chi-squared tests.
- Unadjusted absolute and relative risks for subsequent preterm birth (<37 weeks' and <35 weeks' gestation) in women who had a prior preterm birth were estimated to compare the risk of subsequent preterm birth in women who self-reported either receiving or not receiving 17P during her most recent pregnancy.
- Adjusted regression analyses were performed, but due to sample size limitations, results may be unstable.
- Finally, informative interviews were performed with South Carolina-based Maternal Fetal Medicine Specialists and with Alere Health (also known as Optum), a company that provides in-home healthcare.

Results

- After examining the sociodemographic characteristics of South Carolina pregnant women, it was evident that adequacy of prenatal care utilization had a large impact on the effectiveness of 17P (Figure 1).
- The adequacy of prenatal care utilization during pregnancy was measured using the Kotelchuck Index which we combined into two categories: Adequate or less prenatal care, and Adequate Plus prenatal care. Usually, if a woman receives Adequate Plus prenatal care, this means that she is experiencing a high risk pregnancy and will have more prenatal care visits than women experiencing a low risk pregnancy.
- Adequacy of prenatal care utilization was not found to have much of an impact on the risk of having a subsequent preterm birth (<37 weeks' gestation) in women that had received weekly shots of 17P. This may be due to the protocol of ceasing the use of 17P at 35 weeks' gestation that some providers adopted in 2012 and 2013.
- For mothers who received Adequate Plus prenatal care, the risk of having a subsequent early preterm birth (<35 weeks' gestation) was reduced by five times in women that had received weekly shots of 17P compared to women who did not receive weekly shots of 17P.

Potential Explanations and Implications

- Receiving more than the average amount of prenatal care visits could contribute to patient compliance as well as give the patient weekly emotional support that may positively contribute to a woman's overall health.
- The effectiveness of 17P may be dependent on a pregnancy being high risk. In this study, receiving Adequate Plus prenatal care is likely acting as a proxy for the presence of a high risk pregnancy.
- A major limitation of this study is that PRAMS is the only source of information for data about 17P. Therefore, due to only having limited data, the sample size is also too small to yield truly reliable results.
- Another limitation of PRAMS is that the data is self-reported which may have resulted in differential reporting. For example, women who had an early preterm birth (<35 weeks' gestation) may have been more likely to report that they had received 17P due to the trauma from having such a premature baby. Whereas, women who had their baby closer to term may not have been as sensitive to the question.
- Finally, PRAMS does not ask detailed questions regarding 17P treatments that the women received. It only asks if the mother received 17P at any point during their pregnancy. Consequently, there may have been women who reported receiving 17P that didn't receive the shots weekly or throughout their pregnancy as recommended.

Conclusion

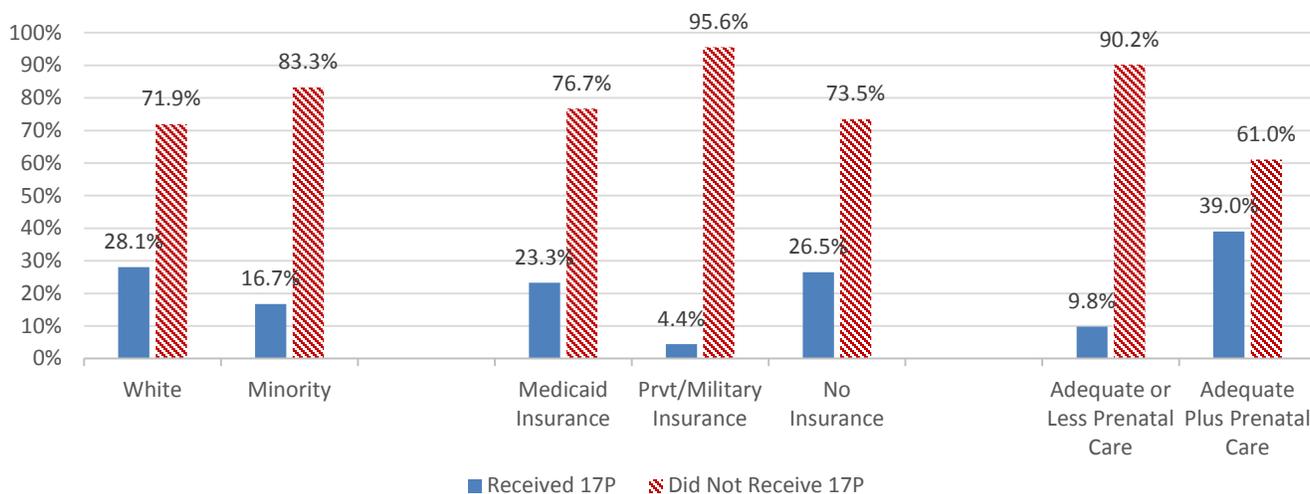
- In the past, 17P has been shown to be effective in reducing the risk of preterm birth in women who have had a prior preterm birth, but our results are not so straightforward. The results of our study demonstrate that 17P seems to be effective in reducing the risk of early preterm birth (<35 weeks' gestation) when combined with Adequate Plus prenatal care in comparison to the combination of 17P with Adequate or less prenatal care.

Possible Infographics:

*****In 2012 and 2013 only around **20%** of South Carolina pregnant women who had a history of preterm birth received 17P during their pregnancy.

*****Around **40%** of the pregnant women who received 17P also had Adequate Plus prenatal care.
 ***** The risk of having an early preterm birth was **5** times less when weekly shots of 17P were combined with Adequate Plus prenatal care.

Figure 1. Sociodemographic Characteristics of High Risk South Carolina Pregnant Women who Did and Did Not Receive 17P During Their Most Recent Pregnancy, SC PRAMS 2012-2013.



Data Source:

Pregnancy Risk Assessment Monitoring System
 S.C. Department of Health and Environmental Control.

Literature Sources:

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