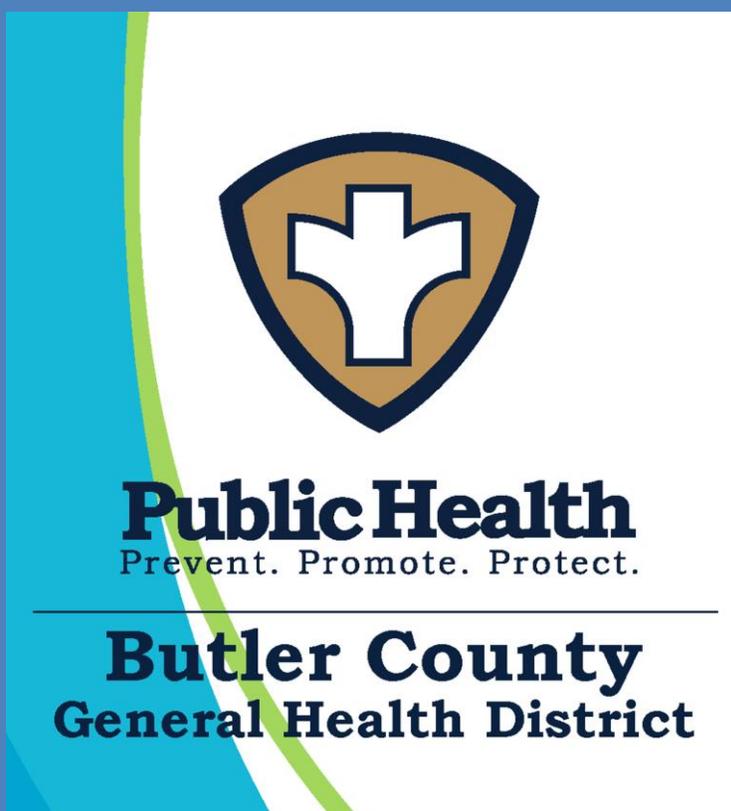


BUTLER COUNTY COMMUNITY SURVEY  
ON 17 ALPHA HYDROXYPROGESTERONE  
CAPROATE (17P)



October 2018

# Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

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# Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

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## Executive Summary

Butler County is among the urban counties in Ohio with the highest infant mortality rates, and in Butler County, the risk of an infant dying is two to three times greater for black babies compared with white babies.

In 2013, Butler County became one of 9 counties constituting the Ohio Equity Institute (also known as the Ohio Institute for Equity in Birth Outcomes) when this institute was established. Since then, the extensive analysis of birth outcomes data has provided insight into the local risk factors for infant mortality. This has driven the identification and implementation of evidenced-based interventions for addressing infant mortality and poor birth outcomes.

The overall rate of infant mortality in Butler County declined from 9.6 in 2013 to 5.2 in 2017. A similar decrease was observed in the non-Hispanic White infant mortality rate. However, infant mortality rates continue to rise in non-Hispanic Blacks and Hispanics, and the racial disparity in infant mortality persists. Results obtained from the analysis of local birth outcomes data, point to prematurity as a leading cause of infant mortality in Butler County, with preterm births occurring more frequently among non-Hispanic Black women compared with non-Hispanic White women. In 2017, 9.5% of births in Butler County were preterm. 8.5 % of non-Hispanic White births and 13.7% of non-Hispanic Black births were preterm.

The effects of preterm births on infant mortality and morbidity are well documented. Beyond the short and long-term health effects are huge adverse social and economic impacts. The socio-economic impacts of preterm births extend beyond individuals and families to the larger community and population. Though the mechanisms underlying the incidence of preterm births are not fully known, there is substantial knowledge of the risk factors and preventive measures for addressing preterm births. In 2011, the US Food and Drug Administration (FDA) approved the use of 17 Alpha Hydroxyprogesterone Caproate (17P) for preventing recurrent preterm births. However, challenges have been reported with accessing and utilizing this treatment.

As part of efforts to increase access and utilization of 17P in eligible women in Butler County, and in so doing, reduce prematurity and infant mortality, the Butler County Community Health Advisory Committee conducted a community survey on progesterone (17P). This survey was aimed at assessing Butler County community's knowledge and willingness to use 17P. The population of interest was women in the childbearing age group who were resident in Butler County at the time of the survey. Eligible women were offered a self-administered paper questionnaire. Respondents included women attending a local community event, clients receiving services at the WIC office in the city of Hamilton in Ohio, and women enrolled in local home visitation programs. 160 women participated in the survey. However, 2 of these respondents did not meet the eligibility criteria and were excluded from the analyses.

In addition to basic demographic information, respondents were asked about their obstetric history, knowledge of the use of 17P to prevent preterm birth, and their willingness to use this treatment if

## Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

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prescribed by their obstetrician or OB provider. The results of this survey indicate that most women participating in this survey (65.8%) did not know of the use of progesterone (17P) for preterm birth prevention and only 43% were willing to take progesterone (17P) injections if prescribed by their OB provider.

The results of this survey call for the development of a targeted health promotion intervention. Though access to treatment is influenced by multiple factors, addressing gaps in knowledge and improving acceptability of treatment are key steps in ensuring access to 17P and reducing preterm births and infant mortality.

# Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

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## 1. Background and Rationale

Butler County is among the urban counties in Ohio with the highest infant mortality rates (IMR). As reflected in national and statewide infant mortality rates, non-Hispanic Black infants born in Butler County die at disproportionately higher rates than non-Hispanic White infants. As a result of this, Butler County became one of nine counties constituting the Ohio Equity Institute - also known as the Ohio Institute for Equity in Birth Outcomes (OEI) when this initiative was established in 2013. (1) Estimates from the Ohio Department of Health suggest that counties constituting the Ohio Equity Institute account for 59% of infant deaths in the state of Ohio. (2)

Butler County has seen a significant reduction in overall infant mortality rate (IMR) from 9.6 in 2013 to 5.2 in 2017. A similar reduction has been observed in non-Hispanic White infant mortality rates; however, over the same period, the rates in non-Hispanic Blacks and Hispanics have increased, and the racial disparity in infant mortality persists.(3) In 2017, the rate of deaths among non-Hispanic Black infants was estimated to be more than three times that of non-Hispanic White infants. (3)

Since the establishment of Butler County's Ohio Equity Institute (OEI) initiative in 2013, extensive epidemiologic analyses of birth outcomes data have been conducted and local drivers of poor birth outcomes identified. Based on these analyses, prematurity has been identified as an important risk factor for infant mortality in Butler County.(4) In 2017, 9.5% of births in Butler County were preterm with a much higher estimate of preterm births among Non-Hispanic Blacks (13.7%) and Hispanics(10.6%) compared with non-Hispanic Whites (8.5%). (3) These estimates of preterm births in Butler County as a whole and in non-Hispanic Black and Hispanic residents are above the Healthy People 2020 goal for preterm births. (5)

The CDC defines preterm births as births occurring before 37 weeks of gestation. (6) Births identified as preterm are associated with short and long term health and developmental challenges, as well as, economic costs. Infants born preterm, are at risk of experiencing breathing and feeding problems and may have developmental, hearing and visual challenges later in life.(6)

According to a report published by the Institute of Medicine (IOM), in 2005, premature births cost the United States approximately \$26.2 billion with an estimated cost of "\$51,600 per infant born preterm". This estimate includes the cost of medical care, educational interventions and lost productivity.(7) Building off the work done by the Institute of Medicine (IOM), Cradle Cincinnati - a collective effort to address infant mortality in Hamilton County, Ohio, estimated the cost of preterm births in this neighboring county as 93.6 million for initial medical costs, and \$13 million for educational interventions. According to this study, costs associated with preterm births account for approximately 17% of the county budget and city of Cincinnati's general fund budget.(8)

About 50% of preterm births occur without any medical intervention.(9) The causes of premature births are not fully known; however, several risk factors have been identified including being black, infections, stress, tobacco use, medical conditions, previous history of preterm birth and carrying more than one baby.(4) In 2011, the US Food and Drug Administration (FDA) approved the use of 17 Alpha Hydroxyprogesterone Caproate (17P) as treatment for preventing preterm births among pregnant women who are at risk for this.(10) The most effective and commonly used formulation of this drug- the intramuscular injection is estimated to reduce the risk of recurrent preterm births by approximately

# Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

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30%.(11) However, challenges have been noted with access to this treatment. (10) In February 2018, the FDA approved an easier to use and less painful form of this treatment known as the Makena auto injector.(12) This has the potential to increase acceptability and utilization of 17P.

In Butler County, there have been anecdotal reports of women who could potentially benefit from 17P having a lack of knowledge of its existence or availability, and not being offered this by their providers. This and the relatively high percentage of preterm births in Butler County's non-Hispanic Black and Hispanic populations have led to an increased interest in developing measures to increase the community's knowledge, acceptability and access to 17P. However, there is a dearth of local data or information on the knowledge and attitudes of our community regarding this form of treatment, and on provider attitudes, knowledge or practices. A collective decision was made to conduct a community survey on progesterone to gain insight into the knowledge and attitudes of women in Butler County regarding the use of this treatment for preventing preterm births. Results from this survey will be used to inform a health promotion intervention that will address gaps in knowledge, and increase the acceptability of and access to progesterone (17P).

## 2. Methods

The survey instrument was a self-administered questionnaire that was developed as a Google form. In order not to exclude respondents who did not have internet access, the form was printed out and offered to eligible women. The questionnaire consisted of 8 questions which covered basic demographic characteristics (race, ethnicity), insurance type, basic obstetric history, awareness of the use of 17 Alpha Hydroxyprogesterone Caproate (17P) for preterm birth prevention and acceptability i.e. willingness to use 17P.

To be eligible to take the survey, the following criteria had to be met: being female, age 16-49 and resident in Butler County at the time of taking the survey. There were a total of 160 responses received. Two of these were excluded from the analyses because they were completed by women who did not meet the inclusion criteria and indicated that they took the survey on behalf of their daughters. The survey was conducted from March 17, 2018 to May 12, 2018. The first wave was conducted at the Families First Annual Community Baby Shower in the city of Middletown - an event largely patronized by women in the childbearing age group. Following this, the survey was offered to clients seeking services at the WIC office in the City of Hamilton, and women enrolled in various local home visitation programs.

Responses from the paper based questionnaires were individually entered and captured via the Google form and this generated basic descriptive statistics. The data were downloaded and further analyzed in Excel.

## 3. Results

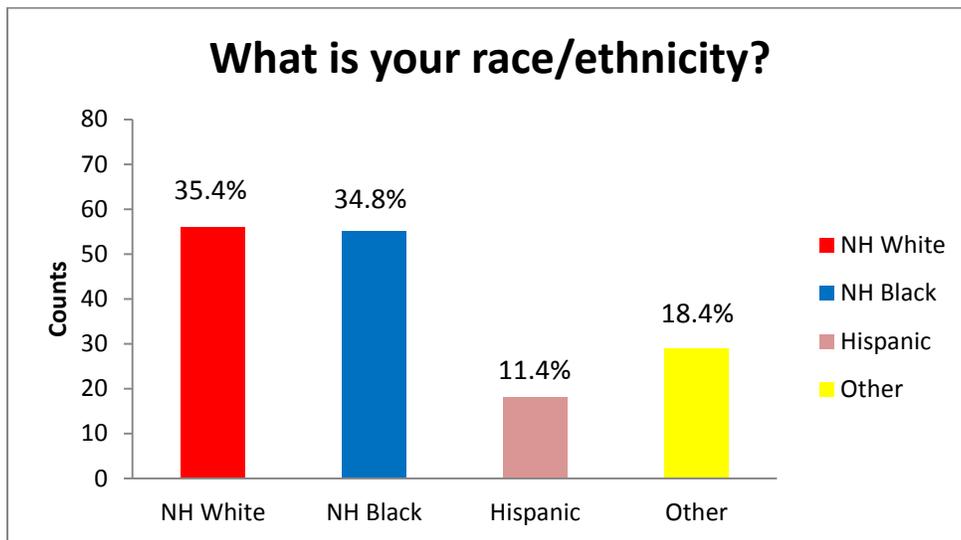
### 3.1 Characteristics of Respondents

Of 158 women surveyed, 56 identified themselves as non-Hispanic White and 55 as non-Hispanic Black. Hispanics constituted the minority of respondents (18).

# Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

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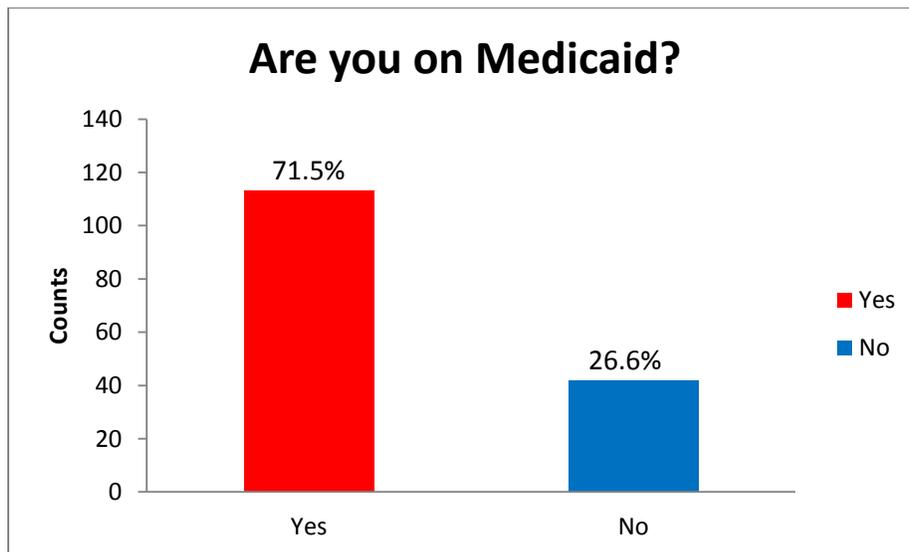
Figure 1



The number of respondents who identified themselves as “other” was 27. The racial descriptions provided by this group included African, mixed race, Asian and Indian.

### 3.2 Type of Insurance

Figure 2



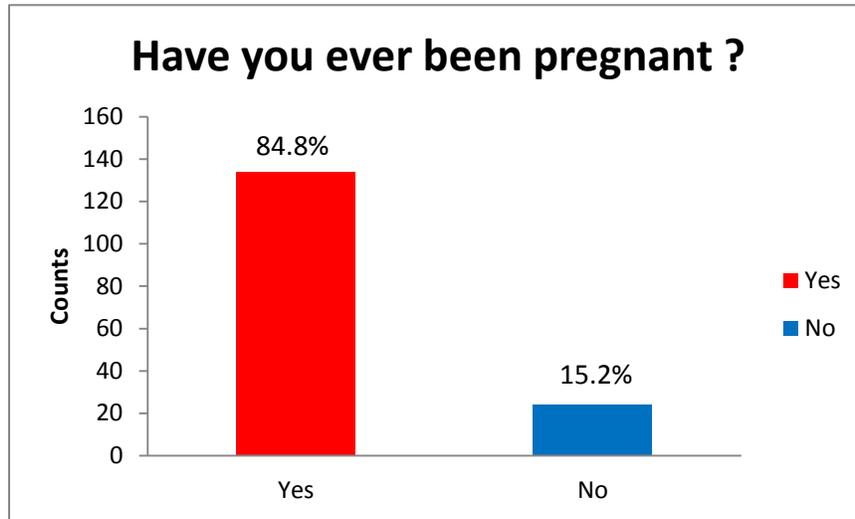
The majority of women participating in this survey were enrolled in the Medicaid program with only 26.6% not enrolled in Medicaid. This may be explained by the fact that the women participating in this survey were receiving services from agencies and programs that typically serve lower income individuals and families.

# Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

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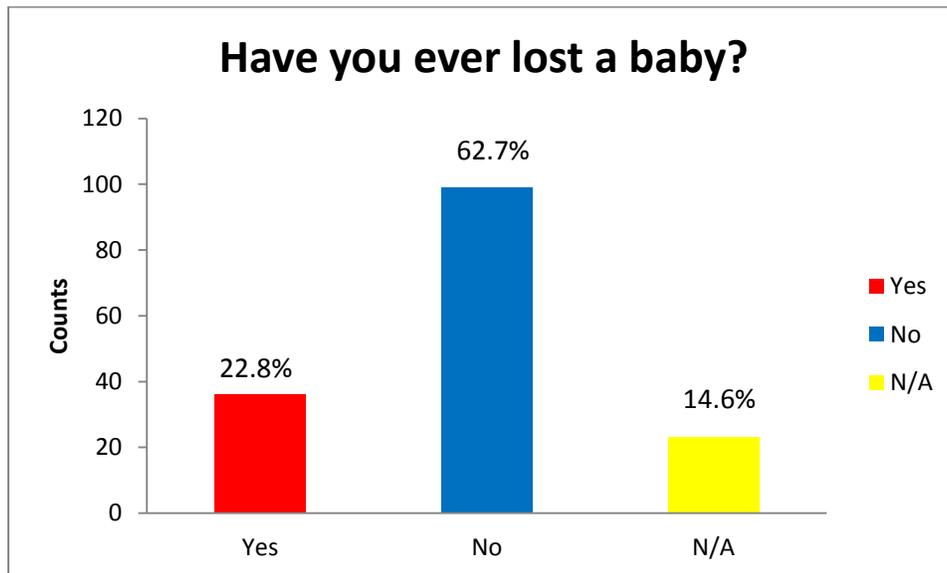
## 3.3 Obstetric History

Figure 3



The majority of survey respondents 134 (84.8%) had been pregnant before. 22.8% of the women participating in the survey had experienced the loss of a baby and 19.6 % had experienced a preterm birth.

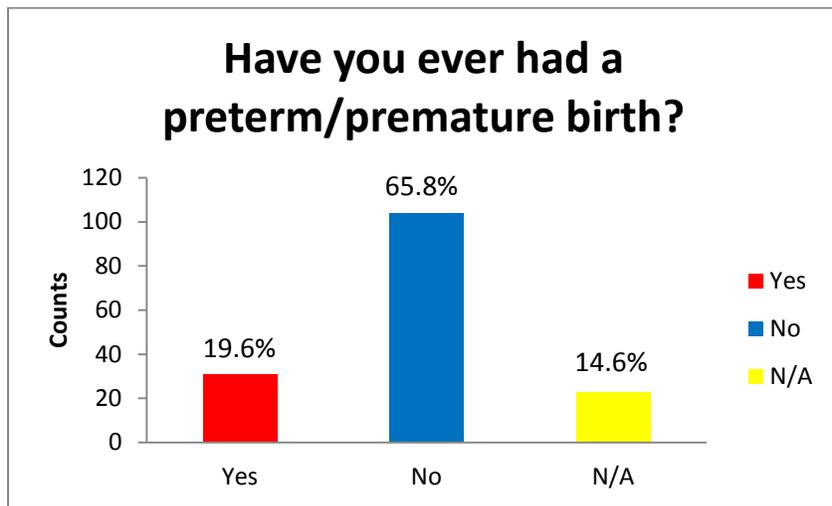
Figure 4



# Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

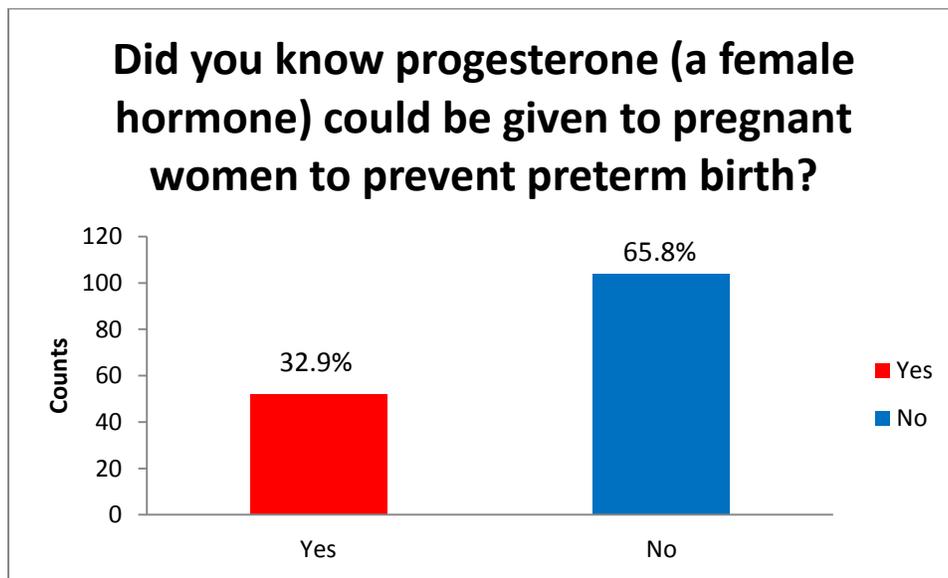
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Figure 5



## 3.4 Knowledge and acceptability of Progesterone(17P) for preterm birth prevention

Figure 6

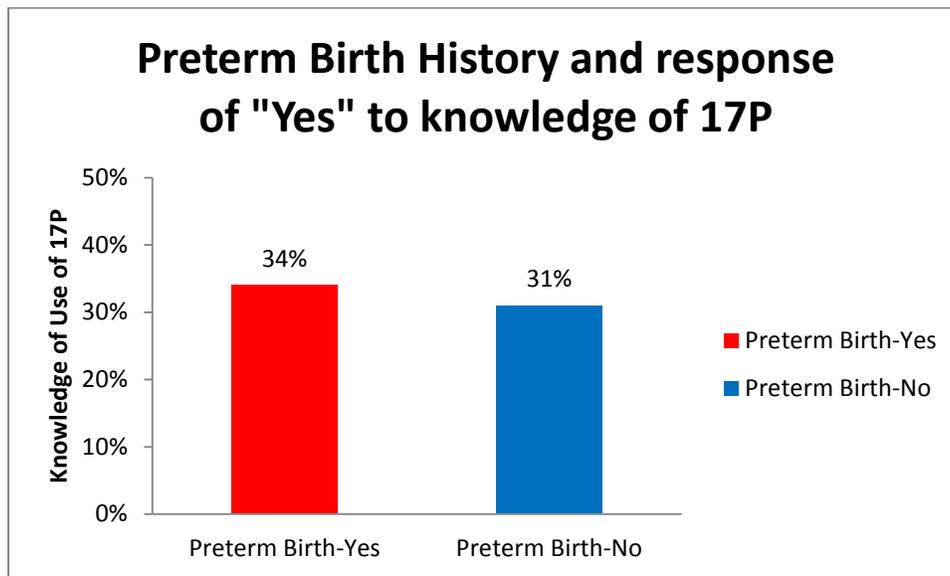


A large proportion of respondents (65.8%) did not know of the use of progesterone (17P) for preventing preterm births. Among 156 women who provided responses to this question, the minority 52 (32.9%) knew of the use of progesterone (17P) for preterm birth prevention.

# Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

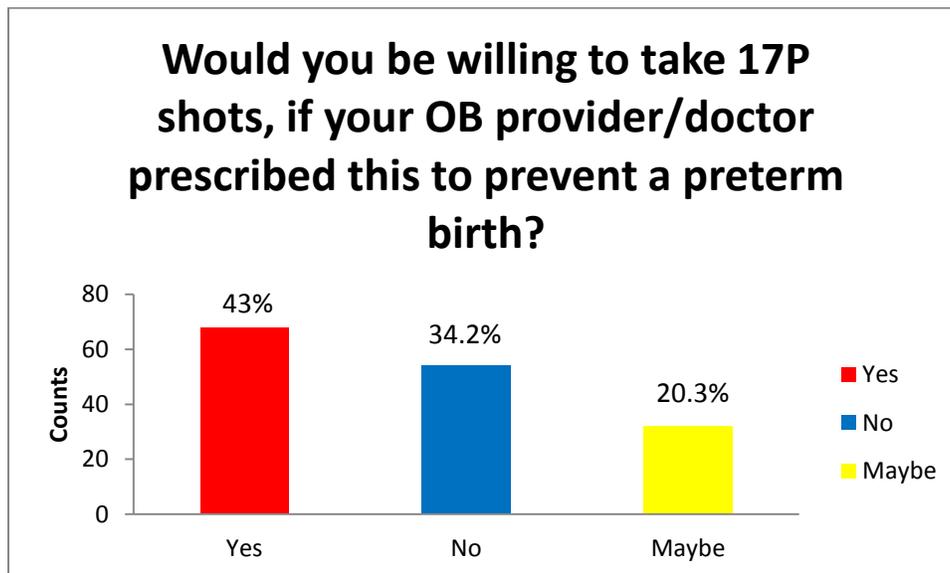
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Figure 7



When knowledge of the use of 17P for preterm birth prevention was compared among women who had experienced a preterm birth and those who had never experienced a preterm birth, the results indicated that approximately a third of women in both categories had heard of the use progesterone (17P) in preventing preterm births.

Figure 8



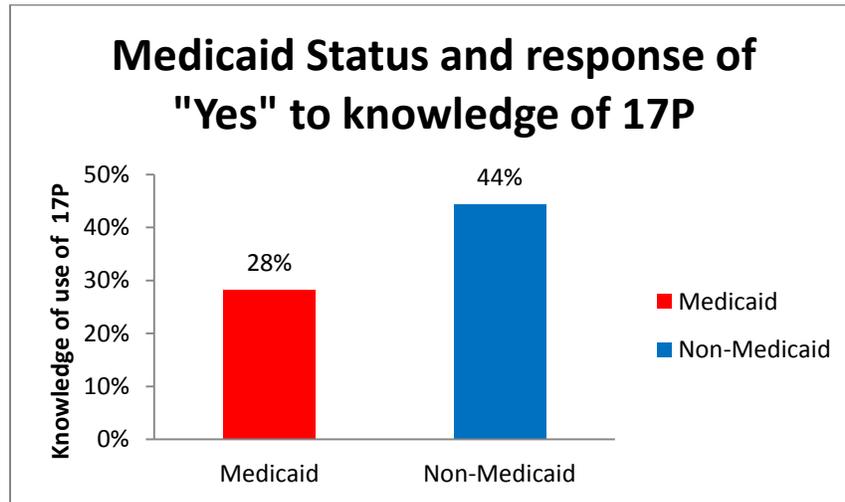
Less than half of women participating in this survey (43%) indicated a willingness to use progesterone (17P) shots if prescribed by their provider to prevent a preterm birth. Approximately 34% indicated an unwillingness to use progesterone if prescribed by their OB provider, and 20% were uncertain about

# Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

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their willingness to use this form of treatment. Women who were uncertain about their willingness to accept this treatment were given the opportunity to explain their responses; however, very few clarified this. Among the few reasons provided by this group of respondents was a fear of side effects.

Figure 9

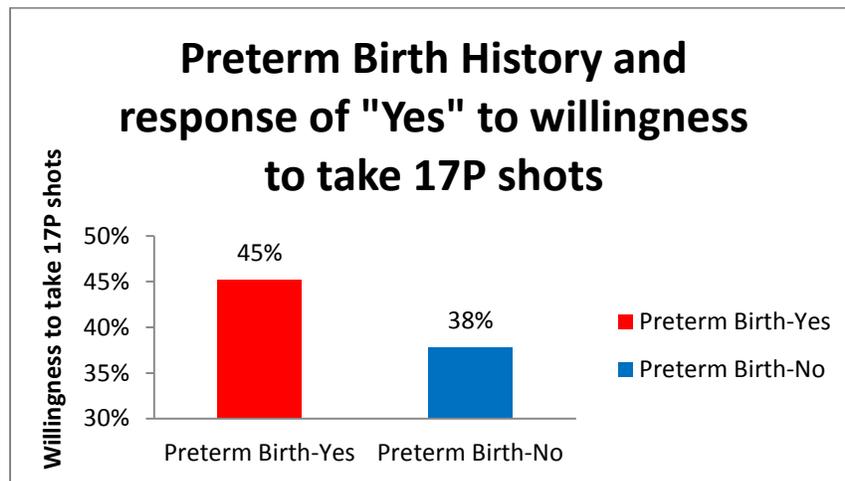


Increasing access to 17P treatment for preterm birth prevention is a key infant vitality effort of the Ohio Department of Health and the Ohio Department of Medicaid. This effort is being implemented with the Ohio Perinatal Quality Collaborative (OPQC). (12) OPQC's Progesterone project focuses on increasing access to 17P and identifying, testing and sharing evidence-based solutions with providers serving Medicaid-insured women. Our knowledge of this ongoing effort generated an interest in exploring the differences in the knowledge of 17P among Medicaid-enrolled women compared with non-Medicaid women. The results indicated that Medicaid-enrolled women were less likely to know of the use of progesterone (17P) in preventing preterm births. These results should be considered in light of the fact that majority of survey respondents were Medicaid-insured (113) compared with 42 respondents who were not enrolled in Medicaid.

# Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

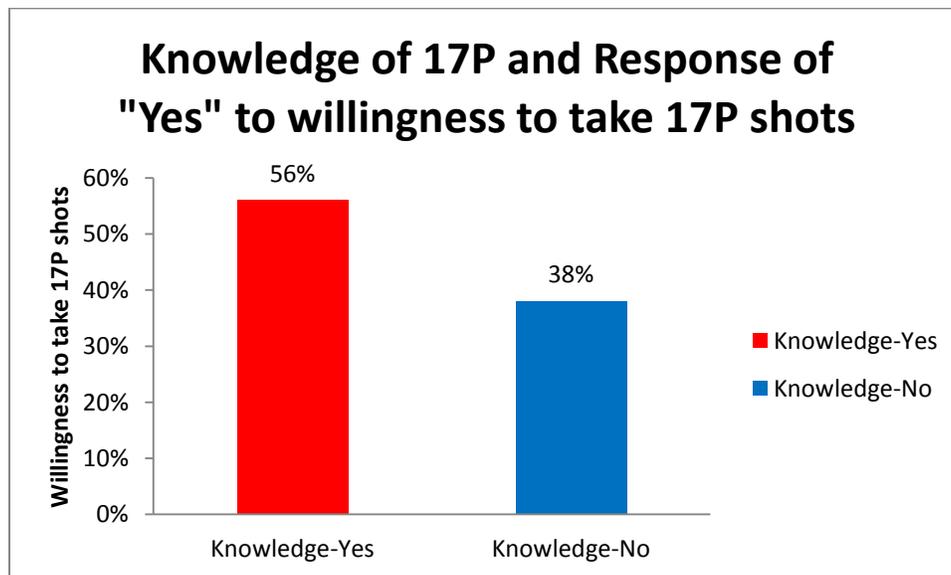
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Figure 10



An analysis comparing “willingness to use progesterone(17P)” among women who had been pregnant before but had never experienced a preterm birth with those who had experienced a preterm birth, indicated that a greater percentage of women who had experienced a preterm birth were willing to use 17P, if prescribed, compared with women who had never lost a baby.

Figure 11



As expected, women who knew of the use of progesterone (17P) in preventing preterm births were more willing to use this form of treatment compared with women who did not have knowledge of its use in preterm birth prevention.

# Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

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## Conclusion

The most significant findings of the community survey on progesterone were: approximately two-thirds of women surveyed lacked awareness of the use of progesterone (17P) for preventing preterm births and less than half of women surveyed indicated a willingness to use progesterone shots if prescribed by their provider to prevent a preterm birth. As part of the effort to reduce preterm births and infant mortality in Butler County, the findings from this survey will be used to direct an educational intervention specifically designed to increase the community's knowledge and acceptability of progesterone (17P) for preterm birth prevention.

# Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

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## Butler County Community Survey on 17 Alpha Hydroxyprogesterone Caproate (17P)

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approval-of-makena-hydroxyprogesterone-caproate-injection-subcutaneous-auto-injector-to-reduce-the-risk-of-preterm-birth-in-certain-at-risk-women/