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Preterm Birth Rates in Pregnant Women with Sexually Transmitted Infections: Cincinnati Public Health Centers 2005 and 2006 Deliveries

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Preterm birth rates in pregnant women with sexually transmitted infections: Cincinnati public health centers 2005 and 2006 deliveries

Culminating Experience Proposal
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Abstract

Objective: To evaluate the differences in prenatal maternal infections in women served by the City of Cincinnati health centers that have or have not had a preterm birth.

Methods: A retrospective and observational study of medical records of 738 patients seen at the City of Cincinnati health centers, who delivered in the years of 2005 and 2006. The usable data resulted in 668 total subjects. Data collected included types of health care visits prior to index pregnancy, if preconception/ reproductive health care was discussed, demographics, gestational age at first prenatal visit and at delivery, insurance at first prenatal visit and delivery, types of sexually transmitted diseases, and evaluation of periodontal disease.

Results: There was a significant difference in preterm births by race, resulting in the African American population with a higher percentage than the Hispanic and Caucasian populations (19.1% vs. 16.4% and 9.58%). There was also a significant difference between the Hispanic and African American population and the Hispanic and Caucasian population in regards to entry into prenatal care but no significant differences between preterm or term births. A significant difference was found in the type of insurance by race. Hispanic, Oriental/Asian, and Other populations had a higher percentage of being uninsured or self-pay at first prenatal visit and remained at a higher percentage at delivery of being uninsured or self-pay (p=< 0.0001). There was a significant difference between preterm birth and term births for gonorrhea (p= 0.0334). However, no significant differences existed between women with preterm and term births for other STI's and multiple sexually transmitted infections. Periodontal disease was also not significant between women with preterm and term births.
Conclusions: The African American populations in the Cincinnati health centers appear to be at greater risk for preterm births than the other populations served. A large portion of the health center population is without insurance at first prenatal visit but is able to obtain coverage by time of delivery, though there is a significant difference in obtaining health insurance for the Hispanic, Oriental/Asian, and Other populations. These results may be due to populations that are unable to provide appropriate documentation to achieve insurance coverage such as Medicaid. Gonorrhea and multiple sexually transmitted infections appear in a higher percentage of preterm births. This would indicate an untreated population and a need for interventions and education. Although periodontal disease did not result in a significant difference in preterm births, the low subject number would suggest a need for a change in prenatal evaluation and documentation of dental status as well as follow up on referrals to dental care.
Introduction

Preterm birth is defined as birth less than 37 weeks gestation. Classifications of preterm births include late preterm (34-36 weeks), moderately preterm (32-36 weeks) and very preterm (<32 weeks). These classifications are useful because they often correspond to clinical characteristics - increasing morbidities or illnesses with decreasing gestational age. Babies born too soon are often born too small. According to Martin et al. (2003) one in every thirteen babies in the United States are born with low birth weight and 67 percent of low-birth weight babies are premature. Babies weighing 5 pounds, 8 ounces or less at birth are considered low birth weight and are at increased risk for serious health problems, disabilities, and death. While the causes of preterm birth and low birth weight may be different in some cases, there is significant overlap within these populations of infants (March of Dimes, 2004).

Preterm births are a large concern to the medical profession, and continue to have an enormous cost impact to societal economics (The Centers for Disease Control and Prevention, CDC 2007; Institute of Medicine, 2006). According to the National Center for Health Statistics (NCHS) preliminary birth data for 2005, preterm births have increased 20% since 1990. Preterm births are consistently a leading cause of death for newborns. March of Dimes Peristat reports prematurity/ low birth weight accounted for 16.5% of all infant deaths in 2004. Those that survive are at a higher risk for long-term health, developmental, and behavioral problems. These health, developmental, and behavioral problems affect not only the child but also the family, and society. The cost in medical care, educational accommodations, and lost productivity for families of preterm births in the United States was at least $26.2 billion a year (Institute of Medicine, 2006; CDC, 2007).
Possible risk factors for preterm births include medical, behavioral, environmental, and demographic risks. Examples of medical risk factors include infection, especially genito-urinary infections, diabetes mellitus, hypertension, clotting disorders, vaginal bleeding, fetal anomalies, In vitro fertilization singleton pregnancies, low birth weight, obesity, and short inter-pregnancy intervals of less than 6-9 months (ACOG, 2001; Basso et al., 1998; Cnattingius et al., 1998; Elovitz et al., 2001; Goldenberg et al., 2002; Hedderson et al., 2003; Jackson et al., 2004; Lockwood et al., 2002; March of Dimes, 2008; Samadi et al., 1998; Shaw et al., 2001; Wadha et al., 2001; Xiong et al., 2001). Behavioral and environmental risk factors include late or no prenatal care, smoking, alcohol use, illicit drug use, diethylstilbestrol (DES) exposure, domestic violence, lack of social support, stress, and long working hours with long periods of standing (ACOG, 2001; Copper et al., 1996; Curry et al., 1998; Hoebel et al., 1990; Kaufman et al., 2000; Lundsberg et al., 1997; March of Dimes, 2008; McFarlane et al., 1996; Moore et al., 1998; Moore et al., 2000; Tough et al., 2001; Vintzileos et al., 2002). Demographic risk factors include race/ethnicity, age: younger than age 17 or older than age 35, and low socioeconomic status (ACOG, 2001; Leslie et al., 2003; March of Dimes, 2008; NCHS Health E Stats, 2007). Approximately one quarter of preterm births are the result of medical interventions to deliver the baby early due to maternal or fetal conditions (March of Dimes, 2008).

The 2007 Infant Mortality Leadership Summit brings together leaders from social services, faith-based organizations, public health, public policy, and health services within Greater Cincinnati. These sectors work both independently and collaboratively to prevent infant death, but despite the efforts the infant mortality rate continues to be higher than in comparable metropolitan areas and the United States overall. Some conclusions from the summit noted:
Infant mortality rate for Hamilton County and Cincinnati residents is extremely high compared to other metropolitan counties and the U.S. overall.

Nearly all of the common causes of infant mortality, including prematurity, SIDS, injury and infection are more prevalent when compared to the U.S. overall.

Many of these causes of infant mortality are preventable.

Premature birth is the largest single contributor to infant mortality risk.

There is a large problem of preterm births.

The Hamilton County Child Fatality Review Team reported 166 child deaths in 2006. One hundred and twenty-two or 73.5% were due to “natural” causes, with sixty-six deaths or 39.6% due to premature births. Of the sixty-six deaths, fifty-six or 84.8% were from the city of Cincinnati. One hundred-twelve deaths were children under the age of one with 79.5% from residents of the city of Cincinnati.

On the forefront of research are how maternal infections and/or the inflammation process relate to preterm births. Several studies (Azargoon & Darvishzadeh, 2006; Leitich et al., 2007; Pararas et al., 2006; Pretorius et al., 2007) reported similar results relating preterm birth to maternal infections and inflammation caused by various microorganisms that are related to sexually transmitted infections. Examples of an infection and microorganism include Bacterial vaginosis and/or the protozoa Trichomonas.

There have been many studies relating risk factors and preterm births, yet the causes of preterm birth is not completely understood which has resulted in continued research and a growing need to develop effective interventions that result in a decrease in preterm births.
Statement of Purpose

The purpose of the study is to evaluate the differences in prenatal maternal infections in women served by CHD health centers that have and have not had a preterm birth. The interest initiating the study is related to the high number of premature births in the city of Cincinnati and the evidence that reveals a strong relationship of prenatal infections as a risk factor for preterm births.
Literature Review

National Statistics on Prematurity

National Vital Statistics (2007) reports there has been a 20% increase in preterm births since 1990 with a 2% increase for 2005. The preterm birth rates between 2005 and 2006 were reported as essentially unchanged among non-Hispanic white at 11.7%, non-Hispanic blacks at 18.4% and an increase among Hispanic births from 12.1% to 12.2%. Since 1990, there has been a continual increase in premature births in the United States and it remains a significant health concern. According to National Vital Statistics System (NVSS, 2007), the preliminary birth data for the proportion of total births that were preterm increased from 9.7% in 1990 to 11.0% in 2005. Births occurring at 34-36 weeks gestation (late preterm) have had the greatest increase in preterm births, increasing from 6.8% to 8.1%. Additional vital statistic data include:

- Gestational age for live births for 2005: less than 32 weeks gestation (very preterm) were 2.03%, 32-33 weeks gestation were 1.62%, 34-36 weeks gestation were 9.09% (NVSS, 2007).
- Birth weight for live births for 2005: very low birth weight was 1.21%, low birth weight were 7.3% (NVSS, 2007).
- Entry into prenatal care: 2001 data: 83.4% first trimester, late or no prenatal care 3.7% (Health Resources and Services Administration [HRSA], 2003).

A preterm birth is highly correlated with infant mortality. In 2004, 36.5% of all infant deaths in the United States were from preterm-related causes of death. In 2004, the total infant deaths that were related to preterm births for Non-Hispanic black births was 46.3%, Non-Hispanic white 32.1%, American Indian or Alaska Native was 22.4%, Asian or Pacific Islander was 35.3%, total Hispanic was 33.4%, Mexican was 32.2% and Puerto Rican
was 40.7%, Central and South American was 35.7% (National Center for Health Statistics-Health E Stats [NCHS- Health E Stats], 2007).

The decline in infant mortality during the 20th century has leveled off in the first part of the 21st century (NCHS- Health E Stats, 2007). The lack of decline since 2000 is partly attributable to the increase in preterm and low birth weight births. March of Dimes (2008) defines low birth weight as babies born less than 5 pounds, 8 ounces (2500 grams). The increase in preterm and low birth weights is influenced by the increase of multiple births related to the use of assisted reproductive therapies, an increase in older mothers as well as improved medical management (Thompson et al., 2002; NCHS- Health E Stats, 2007). The Institute of Medicine of the National Acadamies (2006) reported more study is needed of the causes and consequences of preterm births that occur because of infertility treatments. The use of in vitro fertilization and other assisted reproductive technologies has risen dramatically in the past 20 years and has been associated with the trend to delay childbearing. Twins, triplets, or even more fetuses often result in these cases because multiple embryos are implanted or because ovulation is promoted and more eggs are fertilized. Among infants conceived using these methods, 61.7% of twins and 97.2% of triplets and other "higher-order" multiples were born preterm.

A multiple variety of risk factors are related to preterm birth and include medical, behavioral/environmental, and demographic. Three of the greatest risk factors commonly identified for preterm birth are a history of preterm birth, current multifetal pregnancy, some uterine and/or cervical abnormalities (ACOG, 2001; March of Dimes, 2008; Martin et al., 2003; Berkowitz et al., 1993).

Medical risk factors for preterm birth are infection, especially genito-urinary infections, diabetes mellitus, hypertension, clotting disorders, and vaginal bleeding, especially in the second
trimester and greater when occurring in more than one trimester. Other medical risk factors for preterm birth are fetal anomalies, in vitro fertilization singleton pregnancies, low prepregnancy weight, obesity, and short inter-pregnancy interval, less than 6-9 months (ACOG, 2001; Basso et al., 1998; Cnattingius et al., 1998; Elovitz et al., 2001; Goldenberg et al., 2002; Hedderson et al., 2003; Jackson et al., 2004; Lockwood et al., 2002; March of Dimes, 2008; Samadi et al., 1998; Shaw et al., 2001; Wadha et al., 2001; Xiong et al., 2001).

Demographic risk factors for preterm birth are race/ethnicity: Non-Hispanic black race, age: younger than age 17, or older than age 35, and low socioeconomic status (ACOG, 2001; Leslie et al., 2003; March of Dimes, 2008; NCHS Health E Stats, 2007). Behavioral and Environmental risk factors include late or no prenatal care, smoking, alcohol, use of illicit drugs, diethylstilbestrol (DES) exposure, domestic violence, lack of social support, stress, and long working hours with long periods of standing (ACOG, 2001; Copper et al., 1996; Curry et al., 1998; Hoebel et al., 1990; Kaufman et al., 2000; Lundsberg et al., 1997; March of Dimes, 2008; McFarlane et al., 1996; Moore et al., 1998; Moore et al., 2000; Tough et al., 2001; Vintzileos et al., 2002).

State Statistics on Prematurity

Using the Ohio Department of Health’s information warehouse the following 2006 statistics for

- Birth weight for live births: very low birth weight (less than 1500 grams) was 2,405 or 1.6%, low birth weight (less than 2500 grams) was 13,190 or 8.8%, normal (2500-3999 grams) was 125,157 or 83.3%, high (4000 grams or more) were 11,955 or 8%, and unknown was 208 with no percentage calculated.
- Gestational age for live births: very preterm births (less than 32 weeks gestation) was 3,274 births or 2.2%, preterm births (less than 37 weeks gestation) 19,740 births or 13.1%, term births (37-42 weeks gestation) was 126,748 or 84.3%, and post term births (43 weeks and greater gestation) was 3,777 or 2.5%.

- Entry into prenatal care: the first trimester was 80,972 or 72.7%, the second trimester was 23,342 or 21%, the third trimester was 4,303 or 3.9%, none was 2,799 or 2.5%, and unknown was 39,094 or 26%.

The Ohio Department of Health’s Ohio Child Fatality Review Board has reported that natural deaths for 2005 accounted for 71% (1,229) of all deaths. Seventy-eight percent of natural deaths were to infants less than one year old. Prematurity was determined the cause of death in 533 births or 42%. Deaths from prematurity for the white population were 52% (279), the black population was 45% (240), other less than 1% (4), and unknown/missing was 2% (10).

**County Statistics on Prematurity**

Data from the Ohio Department of Health information warehouse for Hamilton County in 2006 statistics for:

- Birth weight for live births: very low birth weight births were 224 or 1.9%, low birth weight were 1,185 or 10.1%, normal 9,557 or 81.7%, high 956 or 8.2%, and unknown 26 no percentage calculated.

- Gestational age for live births: very preterm were 268 or 2.3%, preterm were 1,824 or 15.6%, term were 9,614 or 82.2%, and post term 263 or 2.2%.

- Entry into prenatal care: first trimester was 4,076 or 66.8%, second trimester was 1,138 or 18.6%, third trimester was 219 or 3.6%, none was 669 or 11%, and unknown was 5,622 or 48%.
The 2006 Hamilton County Family and Children First Council’s Child Fatality Review (CFCCFR) Team report revealed 166 deaths of children 17 years and younger. Of the 166 deaths, 122 or 73.5% were reported as “natural causes”. The largest contribution of deaths by natural cause was from prematurity, at 58.9%. Of the infants dying from prematurity, 53% were African American, 43.9% were Caucasian, and 3% were of unknown race. The report also revealed of the 112 children who died under the age of one 79.5% or 89 children were from the city of Cincinnati.

**Cincinnati Overview**

Cincinnati is the county seat for Hamilton County and is located in the Southwest corner of the State of Ohio. Cincinnati covers a total of 78 square miles, has 48 neighborhoods, and is located in Hamilton County. Demographics by the Census bureau for 2006 reported that Cincinnati had a total population of 303,000 with 53% females and 47% males. The median age was 34.9 years. Twenty-three percent of the population was under 18 years and 12% was 65 years and older. For people reporting one race alone, the racial demographics are: 52% White; 45% Black or African American; less than 0.5% American Indian and Alaska Native; 2% Asian; 2% Hispanic; less than 0.5% Native Hawaiian and Other Pacific Islander, and 1% Some other race. Two percent reported two or more races. In 2006, 28% of people were living in poverty. Forty-one percent of related children under 18 were below the poverty level, compared with 17% of people 65 years old and over. Twenty-three percent of all families and 46% of families with a female householder and no husband present had incomes below the poverty level.

The Cincinnati Health Department consists of five health centers that provide adult and pediatric primary care, dental, laboratory, pharmaceutical and nursing services to approximately 35,000 people per year. The five neighborhoods where the primary care health centers are
located are; Lower Price Hill, Madisonville, Millvale, Northside, and Over the Rhine. The health department serves persons who live within the city boundaries. The majority of clients served are low income, Medicare/Medicaid eligible, or medically indigent. Preterm births, low birth weight babies, and infant mortality have been a long-standing concern for the city of Cincinnati. March of Dimes Peristat 2004 data for Cincinnati reports in an average week 102 babies are born, with 16 born preterm, 12 born low birth weight, and two die before their first birthday. Between 1996 and 2004, the rate of preterm births was unchanged. The rate of preterm birth was highest for black infants at 17.9%, followed by Native Americans at 17.9%, Hispanics at 12.6%, whites at 12.1% and Asians at 6.9%. Infant mortality for 2004 as reported by March of Dimes Peristat was 16 per 1000 births with the infant mortality rate from prematurity 190.4 per 100,000 births, which accounted for 11.9% of all infant deaths. Between 1996 and 2004, the overall infant mortality rate in Cincinnati increased more than 15%.

City Statistics on Prematurity

The Cincinnati Health Department compiled a perinatal report for all Cincinnati Health Centers for the year 2007. Delivery outcome total deliveries were 422 with 52% African American, 24% white, 22% Hispanic/Latino, and 2% unknown. Birth weights: very low birth weight total was 9 or 2%, low birth weight total was 46 or 11%, and normal birth weight total was 364 or 87%. Fetal deaths 20 weeks or greater were a total of 11, miscarriages (less than 20 weeks gestation) were a total of 26, and congenital anomalies were a total of 10. Gestational age for live births, entry into preconception care by trimester, and infant deaths related to premature birth were not reported. Congenital abnormalities were not defined.

Prematurity is the most contributing factor for death of infants in Hamilton County with the major percentage of infant deaths from the city of Cincinnati. The data from the Ohio
Department of Health’s Ohio Child Fatality Review Board report coincides with the results found by the Hamilton County Child Fatality Review Team, The March of Dimes Peristat data, and the Child Research Policy Center. These results reflect that premature births were a large contributing factor to infant mortality and that the majority of deaths occurred to children under the age of one.

**Risk Factors**

According to March of Dimes (2007) and ACOG (2001) the three common risk factors that put women at greatest risk for preterm delivery are:

- Women who have had a previous preterm birth
- Women who are pregnant with twins, triplets, or more
- Women with certain uterine or cervical abnormalities

Risk factors associated with preterm birth are numerous and include preexisting maternal disorders, physical and social characteristics, age, problems in previous pregnancies such as spontaneous abortions, and problems that develop during the pregnancy or during labor and delivery (Merck, 2005). Other risk factors reported by March of Dimes (2007) and ACOG (2001) are:

**Behavioral and Environmental risk factors**

- Late or no prenatal care

**Preconception care**

Prevention and education is the theme found in the pediatric and family medicine publications emphasizing avoidance of pregnancy until high-risk variables are eliminated, therefore reducing the sequel of preterm births. As-Sanie et al. (2004) reported an effective program should focus on reducing high-risk sexual behaviors, present accurate, age-appropriate,
and culturally sensitive information about the risks associated with unprotected sexual activity, use of contraceptives, and strategies for prevention of pregnancy and sexually transmitted infections. Actively involve all participants and teach communication skills necessary to the patient to avoid social pressures that may influence sexual activity. There are many reports that major risk factors contributing to preterm birth are present before pregnancy. Hall (2000) suggested that a key strategy of interventions should begin with the early teen and preteen years. (Barash & Weinstein, 2002; Brundage, 2002; Hall, 2000; Johnson et al., 2006; Moos, 2004). The major risk factors of preterm birth include teenagers; conceiving less than 17 years of age, smoking, illicit drugs, poor nutrition, and vaginal infections.

For over a decade there have been ongoing public health campaigns addressing the preventable risk factors for preterm birth: smoking, alcohol, illicit drug use, poor nutrition, stress, and maternal infections (CDC; March of Dimes; Goldenberg, 2002). The social issues such as self-esteem, communication skills, abstinence, and unprotected sexual activity, avoidance of smoking, illicit drug use, promoting good nutrition, and encouraging academic achievement are suggested as intervention strategies that should be implemented at the pediatric level of early teen and preteen years (Hall, 2000).

CDC (2008) reports unintended pregnancies are associated with an increased risk of maternal morbidity and the adverse health behaviors associated with adverse birth outcomes such as late prenatal care, smoking, and alcohol use. In 2001, approximately one-half of pregnancies in the United States were unintended (Finer 2006, Perspectives on Sexual and Reproductive Health), and the United States has set a national goal of decreasing unintended pregnancies to 30% by 2010. A cohort study by Orr et al. (2000) of urban, clinic-attending, low-income, pregnant black women, unintended pregnancy had a statistically significant association with
preterm birth. After adjustment for behavioral and clinical risks, women with unintended pregnancies had almost twice the risk of a preterm delivery as women with intended pregnancies. Overall, 13.7% of all births to women in the sample were preterm. Unintended pregnancy was significantly associated with preterm delivery after controlling for clinical and behavior predictors of preterm delivery (adjusted RR=1.82, 95% CI 1.08, 3.08, P=0.026).

Vincent (1987) reports that numerous federal, state, and local efforts have been implemented to reduce unintended teenage pregnancies, such as increasing access to contraception, information through school and community based clinics for teens, implementing school sex education curricula and providing cognitive-behavioral skill building with small groups. The effectiveness of these strategies is documented as a gain in knowledge, attitude, and behavioral change but has not given evidence for long-term success in reducing, adolescent pregnancy. The public health model of a comprehensive school/community approach implemented in a South Carolina county for the years 1984-1986 resulted in the pregnancy rate of 14-17 year olds decreasing by half compared to teens not exposed to the interventions. Five components addressing modifiable factors contributing to unintended pregnancy were to increase decision-making skills, to improve interpersonal communication skills, enhance self-esteem, to align personal values with those of the family, church, and community, to increase knowledge of human reproductive anatomy, physiology, and contraception. Discontinuation of the program resulted in an increase in pregnancy rate to pre-intervention levels.

A report by Anderson et al. (2006) noted that women of childbearing age had an average of 6.4 visits a year to a physician’s office and these visits should be the opportunities to evaluate, educate, and promote preconception care.
Smoking during pregnancy has been a risk factor associated with many adverse outcomes to the fetus and the mother for decades. Smoking has been known to slow fetal growth and increase the risk of preterm birth (ACOG, 2005; CDC, 2007; March of Dimes 2008). Martin et al. (2006) reported 11.9 percent of babies born to smokers in the United States were low birth weight compared to 7.2 percent of babies born to nonsmokers in 2004.

Adverse effects to the fetus whose mothers smoked during pregnancy include:

- Sudden infant death syndrome (SIDS), CDC (2007) reports a baby of a smoker is three times more likely to die from SIDS than a baby of a non-smoker is.
- Withdrawal-like symptoms similar to a fetus exposed to illicit drug use. Law et al. (2003) suggest that babies of mothers who smoke during pregnancy undergo withdrawal-like symptoms, such as difficulty soothing and may be jitterier.
- Low birth-weight babies. A woman who smokes during pregnancy has double the chance of having a low birth-weight baby (Martin et al., 2006).
- Smoking is known to slow fetal growth. Smoking also increases the risk of preterm delivery (CDC, 2007).
- Increase chance of congenital birth defects. Malik et al. (2007) suggests that women who smoke anytime during the month before pregnancy to the end of the first trimester are more likely to have a baby with birth defects, particularly congenital heart defects.

Maternal medical complications associated with smoking during pregnancy include:

- Placenta previa (placenta that covers part or all of the uterus opening)
- Placental abruption (the placenta partially or almost completely peels away from the wall of the uterus prior to delivery)

- Premature rupture of the membranes (PROM). Rupture prior to 37 weeks gestation results in a premature birth.

- Drinking alcohol

The surgeon general of the United States, Dr. Richard H. Carmona in 2005 warned pregnant women and women who may become pregnant the risks of alcohol consumption during pregnancy. The process of alcohol consumed by the mother is passed through the placenta to the fetus. The fetus is not mature enough to quickly break down the alcohol or dispose of the alcohol rapidly which results in a higher alcohol level with longer exposure to alcohol than the mother (March of Dimes, 2008). According to March of Dimes (2008), numerous birth defects ranging from mild to severe are associated with alcohol consumption during pregnancy, which include the following:

- Mental retardation

- Learning, emotional, behavioral problems

- Birth defects of the heart, face and other organs

- Fetal alcohol syndrome (fetal alcohol syndrome is the most severe birth defect and involves a combination of mental and physical defects ranging from mild to severe).

Other adverse outcomes related to alcohol consumption during pregnancy include:

- Increase risk of miscarriage

- Increase risk of low birth weight

- Increase risk of stillbirth
Studies by Bertrand et al. (2004), Chiafarino et al. (2006), Kesmodel et al. (2002), and Parrazini et al. (2003) report women consuming greater than three alcoholic drinks a week are at a greater risk of alcohol related injury to the fetus, preterm births, low birthweight babies, and small for gestational age babies. Alcohol consumption during pregnancy has no proven safe amount. It is recommended to not drink during pregnancy, quit as soon as one becomes pregnant, and if planning to become pregnant do not drink at all.

- Illicit drug use

The Substance Abuse and Mental Health Administration 2005 survey revealed 4 percent of pregnant women use illicit drugs such as marijuana, cocaine, ecstasy, and other amphetamines, and heroin. Birth defects are also associated with illicit drug use and babies experience withdrawal like symptoms demonstrated as jitteriness, drowsiness, and breathing problems (March of Dimes, 2008).

Marijuana use during pregnancy has shown adverse outcomes to the fetus include:

- Altered neurological development
- Altered responses to visual stimuli
- Increase in tremors
- High pitched crying
- Long-term effects include limitations in performing tasks requiring sustained attention and memory and are at greater risk of poor performance than non-exposed children are. As an exposed child progresses through school, they are more likely to demonstrate cognitive and behavioral problems such as problem-solving skills, memory, and unable to maintain attention than a non-exposed child (National Institute on Drug Abuse, 2005).
Amphetamine use during pregnancy includes:

- Increase risk of poor fetal growth
- Increase risk in small for gestation age even for full term births
- Smaller head circumference
- Increase risk of preterm birth
- Increase risk of placental problems

Heroin use during pregnancy results in serious complications for the pregnancy and the fetus and includes:

- Poor fetal growth
- Premature rupture of membranes
- Premature delivery
- Stillbirth

Infants display withdrawal symptoms such as trembling, diarrhea, irritability. Cocaine use during pregnancy increases the risk of miscarriage, poor fetal growth, mental retardation, cerebral palsy, and death (March of Dimes, 2008).

- Exposure to the medication DES

CDC recommends women exposed to DES in utero should be referred to an obstetrician gynecologist for preconception counseling and pregnancy management and patients who were exposed to DES in utero are at an increase risk for the following:

- Clear cell adenocarcinoma of the vagina and cervix
- Reproductive tract abnormalities resulting in an increase chance of preterm births
- Pregnancy complications such as infertility, ectopic pregnancies, and miscarriage
• Domestic violence (including physical, sexual, or emotional abuse)

A literature review by Pallitto (2004) on Domestic violence and maternal, infant, and reproductive health, though some studies were flawed, found an association between abuse and low birth weight, intrauterine growth retardation, perinatal or infant death, and antepartum hemorrhage. Palitto concluded that “The evidence of association between abuse and other reproductive health consequences was mixed, but several methodologically rigorous studies demonstrated the connection between abuse and gynecological and sexual problems, an increased risk of STD and HIV-infection, delayed prenatal care, reduced condom use, and greater likelihood of having an unintended pregnancy, as well as higher levels of stress, depression, and physical health problems.”

A hospital based survey on physical abuse during pregnancy conducted by Rodrigues et al. (2008), in which 2660 women were interviewed and assessed using the Abuse Assessment Screen, compared mothers of preterm infants with mothers of term infants. The study found violence was associated with preterm birth even after controlling for variables of age, marital status, education, income, parity, planned pregnancy, antenatal care, smoking, alcohol, and illicit drug use (odds ratio= 3.14, 95% CI, 2.00-4.93). The conclusion was that the risk of preterm delivery was a larger risk among women with physical abuse during pregnancy independent from the socio demographic and behavioral risk factors associated with preterm birth.

• Lack of social support

The John D. and Catherine T. MacArthur Research Network on Socioeconomic Status and Health (1998) defined various types of support (i.e., assistance/help) that people receive from others and is generally classified into two (sometimes three) major categories: emotional, instrumental (and sometimes informational) support.
• Emotional support refers to the things that people do that make us feel loved and cared for, that bolster our sense of self-worth (e.g., talking over a problem, providing encouragement/positive feedback); such support frequently takes the form of non-tangible types of assistance.

• Instrumental support refers to the various types of material assistance that others may provide (e.g., help with childcare/housekeeping, provision of transportation or money). Informational support represents a third type of social support (one that is sometimes included within the instrumental support category) and refers to the help that others may offer through the provision of information.

• Social support: the literature review revealed many studies relating a variety of definitions and the relationship to preterm birth. One example is a randomized study by Moore et al. (1998) assigning 1554 women receiving prenatal care in a public clinic into intervention and control groups. The study tested the effect of telephone calls from registered nurses to low-income pregnant women on the rates of low birth weight (LBW) and preterm births. Women in the intervention group received telephone calls from a registered nurse, one or two times weekly from 24 weeks through 37 weeks of gestation. Low birth weight rates were 10.9% in the intervention group and 14.0% in the control group. For gestational age less than 37 weeks, rates were 9.7% in the intervention group and 11.0% in the control group. In the subgroup of low-income black women 19 years of age and older, a statistically significant difference was found in preterm birth rates before 37 weeks, the rates were 8.7% in the intervention group versus 15.4% in the controls. There was no difference in LBW or preterm births between intervention
and control groups in the total sample. In a secondary analysis of black subjects
19 years of age and older, there was a significant difference in preterm birth rates.

- Extremely high levels of stress

Women exposed to different kinds of stress, the timing of the event causing stress and
high levels of stress, certain types of severe or long-term stress put women at a higher risk of
preterm birth. Divorce, death in the family, serious illness, or job loss as negative life events may
be at risk for preterm birth (March of Dimes, 2008). Severe or long lasting stress events are less
likely to result in preterm birth than those exposed to catastrophic events such as earthquakes and
women who worked within two miles of the World Trade Center attack in September 2001. The
women exposed to the World Trade Center attack or to earthquakes demonstrated shorter
gestation periods in women exposed to the events in the first trimester compared to exposed
women of later gestation times. Chronic stressors such as homelessness or serious financial
problems as reported by March of Dimes (2008) are risk factors for preterm birth.

Though the effect of stress on preterm birth is not completely understood, one stress
related hormone, Corticotrophin is a prostaglandin-producing hormone, which is produced in the
brain and placenta and is closely related to labor (March of Dimes, 2008). Other studies have
used perceived stress, clinical factors, and corticotrophin-releasing hormone (CRH) levels in
maternal plasma as associated risks for preterm birth. Ruiz et al. (2002) determined that the
measurement of CRH has potential as an early biological marker of preterm birth.

- Long working hours with long periods of standing

Employment outside the home has not been linked to premature birth in most studies.
However, there have been reports of women who find their jobs physically or emotionally
stressful and may face some risk (March of Dimes 2008). Physically demanding work does not
PRETERM BIRTH RATES

seem to be associated with adverse pregnancy outcomes, whereas working at night during pregnancy may increase the risk of preterm delivery. A study by Pompeii et al. (2005) examining the effect of shift work on uterine activity would help to clarify the possibility of a causal effect on preterm birth. The results were a 50% elevation in the risk of preterm delivery was observed among women who reported working at night (10:00 PM to 7:00 AM). A 40% reduction in risk was observed among women working at least 46 hours per week, regardless of period of exposure. No elevations in small-for-gestational-age birth were observed among women exposed to any of the four types of occupational exertion; standing, lifting, night work, or long work hours during 3 periods of pregnancy. No increase in preterm delivery was demonstrated among women who lifted repeatedly or stood at least 30 hours per week, with no changes in risk estimates over the course of pregnancy. The repeated lifting and the long-standing hours seemed to have less of an impact on preterm birth than those working night hours.

Medical conditions during pregnancy risk factors

- Infections (such as urinary tract, vaginal, sexually transmitted and other infections)

*Maternal inflammation/infection*

A resurgent of interest in maternal infections, long recognized as a risk factor related to premature births, has generated studies suggesting changes in screening of maternal reproductive infections during preconception care and prenatal care of symptomatic as well as asymptomatic women (McGregor et al., 1995).

A suspected cause responsible for preterm birth with a pathological link is inflammation and/or infection. Inflammation is the body’s response to an insult. As noted by Romero et al. (2007) clinical inflammation has been classically defined by the presence of five cardinal signs all of which reflect the effects of chemokines, cytokines, as well as other inflammatory mediators
on blood vessels and tissues. The process of bacteria transfer to the amniotic fluid is known as microbial invasion and is considered a pathological finding. Romero also discusses infection as a cause of premature labor and notes it as a frequent and important factor in premature labor and delivery. This article describes the history of inflammation, a brief synopsis of the inflammation process, covers in detail the pathophysiologic effect of inflammation, infection, the microbiology of intrauterine infection, cytokine’s purpose in maintaining pregnancy, and suggesting the fetus’s response as a survival technique if/when exposed to the microbial invasion of the amniotic fluid by initiating a preterm labor. Inflammation is a risk factor of preterm births by creating an inflammatory process with the release of cytokines and increased prostaglandin production and is implicated as a risk factor in several other reports (Gibbs et al., 1992; Goldenberg et al., 2000; Romero et al., 2007).

**Urinary Tract Infections**

Cline et al. (2000) reported an update in maternity care addressing diagnosis and treatment, noting the importance for physicians to understand the effects of infections on mothers and fetuses. Infections in the report included asymptomatic bacteriuria (occurring in 2% to 7% of pregnancies). Cline et al. (2000) also reported that women with asymptomatic bacteriuria have up to a 28% greater risk of progressing to pyelonephritis, an ascending urinary tract infection, which puts the mother and fetus at risk. Cystitis was reported to occur in 1% to 2% of all pregnancies and acute pyelonephritis occurred in 1% to 2% of all pregnancies. Due to physiologic changes in the urinary tract, the risk is more common in the second and third trimesters. Asymptomatic bacteriuria, cystitis, and pyelonephritis are all detectable by a urine culture and treatable by antibiotic therapy.
Sexually Transmitted Infections

The table below shows the estimated number of pregnant women in the United States who are infected with specific sexually transmitted diseases (STD)/infections each year.

<table>
<thead>
<tr>
<th>STDs</th>
<th>Estimated Number of Pregnant Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial vaginosis</td>
<td>1,080,000</td>
</tr>
<tr>
<td>Herpes simplex virus 2</td>
<td>880,000</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>100,000</td>
</tr>
<tr>
<td>Trichomoniasis</td>
<td>124,000</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>13,200</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>16,000</td>
</tr>
<tr>
<td>HIV</td>
<td>6,400</td>
</tr>
<tr>
<td>Syphilis</td>
<td>&lt;1,000</td>
</tr>
</tbody>
</table>

http://www.cdc.gov/std/STDFact-STDs&Pregnancy.htm#common

Bacterial Vaginosis

For decades Bacterial vaginosis (BV) has been a suspected risk factor in preterm births and is considered a risk factor for preterm birth in regards to genital tract infections. A study by Pretorius et al. (2007) noted that infection is present in up to 40% of spontaneous preterm labors. Azargoon and Darvishzadeh (2006) researched BV and trichomoniasis as risk factors in preterm birth. The subjects of the study consisted of 1223 pregnant women with gestational age of 16 - 36 weeks from Amir-Almomenin General Hospital in Semnan, Iran. BV was detected at a higher rate than trichomoniasis 16.0% and 5.5% respectively. The study included collecting the vaginal pH balance and a significant finding was a correlation between vaginal pH and positivity for BV and Trichomoniasis. All patients with BV and trichomoniasis had a vaginal pH > or = 5. Patients with BV were reported to have a significant correlation between vaginal pH > or = 5 with preterm labor birth (OR: 5.82; CI: 2.96 - 11.39) and preterm prelabor rupture of membranes (OR: 4.11; CI: 1.62 - 10.12). There was no significant correlation between trichomoniasis with preterm labor birth (OR: 0.73; CI: 0.22 - 2.17) and preterm prelabor rupture of membranes (OR:
1.22; CI: 0.29 - 5.05). Though not defined in the article a normal vaginal pH balance according to Tortora et al. (1992) is normally less than four.

*Chlamydia*

Cline et al. (2000) reported Chlamydia trachonatis organism may be isolated in 5% of pregnant women and asymptomatic pregnant women with increased risk factors including: age less than 25 years, women with a new sexual partner or with more than one sexual partner, and recommends screening for Chlamydia in the third trimester. However, there was no mention of an increase in preterm birth associated with Chlamydia infection. Other reports by Claman et al. (1995) found seropositive women were more likely to have a preterm birth than seronegative women (24% (5/21) versus 7% (6/82) seropositive and seronegative respectively with a p value = 0.029, OR 3.96, 95% CI, 1.08 to 14.57). The positive predictive value of a seropositive result for preterm birth was 31%, the negative predictive values of a seronegative result for preterm birth was 8%. A more current study involving low birth weight deliveries in minority and high-risk women from Goldenberg et al. (2000) noted, “Women with Chlamydia infection during the second trimester of pregnancy are two to three times as likely as uninfected women to have a preterm birth”.

*Gonorrhea*

Cline et al. (2000) also reported that gonorrhea in pregnancy can be asymptomatic. Cervicitis, endometritis, or systemic illness may occur due to infection with gonorrhea and is associated with septic abortion and neonatal infections. Testing for gonorrhea is recommended in the first and third trimester.
Herpes Simplex Virus (HSV)

Infection with genital herpes during pregnancy according to Cline et al. (2000) has been associated with spontaneous miscarriage, premature delivery, and neonatal herpes. The greatest risk for the fetus and neonatal morbidity occurs in women experiencing their first episode of HSV during the latter stages of pregnancy because they cannot pass protective antibodies to the fetus across the placenta and excrete HSV from the cervix in higher titers.

Syphilis

Systemic infections of syphilis according to Cline et al. (2000) is associated with preterm labor, stillbirth, and congenital infections of newborns and recommends all pregnant women should be screened for syphilis at their first prenatal visit and again at delivery. In high prevalence populations, an additional screening is recommended at 28 weeks gestation.

Yeast/Candida

Very few if any research indicates yeast/Candida as a risk factor for preterm birth though an article by Meizoso et al. (2007) noted, “The pathogenic significance of fetal contamination by Candida appears to depend largely on gestational age. Candida infection of the fetus can result in prematurity and death. The importance of early and accurate diagnosis of intraamniotic infection with Candida is emphasized”.

Trichomonas

Cline et al. (2000) reported trichomonas might increase the risk of preterm delivery or cause premature rupture of membranes. Cotch et al. (1997) conducted a race specific study involving five university-affiliated hospitals in the United States, with 13,816 women (5,241 black, 4,226 Hispanic, and 4,349 white women) enrolled at mid-gestation, tested for trichomonas vaginalis by culture, and followed up until delivery. “The attributable risk of trichomonas
vaginalis infection associated with low birth weight in blacks was 11% compared with 1.6% in Hispanics and 1.5% in whites.” The conclusion was that women infected with trichomonas in the second trimester were statistically more inclined to deliver preterm births and have low birth weight babies. They also concluded black women with trichomonas infection were more prone to low birth weight babies than Hispanics or whites.

- High blood pressure

  Restriction of blood flow to the uterus, which decreases the nutritional and oxygen supply to the fetus, is associated with high blood pressure. The lack of nutrition and oxygen to the fetus leads to slow growth, low birth weight, and preterm birth. The mother can experience a stroke, placental abruption. According to the Merck Manual (2005), uncontrolled hypertension increases the risk of placental abruption by 2-10 percent. With proper medical care such as preventative care and/or early intervention can decrease or eliminate the risks to the fetus and the mother (March of Dimes, 2008; Merck Manual, 2005).

- Diabetes

  The Merck Manual indicates pregnant women with preexisting insulin dependent diabetes have an increase risk of pyelonephritis, pregnancy induced hypertension, fetal death, fetal growth restriction, major fetal abnormalities. Good control of blood glucose can decrease or almost eliminate the risks attributed to diabetes.

- Clotting disorders

  As indicated by Lockwood (2002) “Inherited thrombophilias are the leading cause of maternal thromboembolism and are associated with an increased risk of certain adverse pregnancy outcomes including second- and third-trimester fetal loss, abruptions, severe intrauterine growth restriction, and early-onset, severe preeclampsia.” Stillbirth, severe (3rd
percentile) intrauterine fetal growth restriction (IUGR), abruption, and severe, early-onset, preeclampsia complicate up to 0.2–3% of pregnancies and are leading causes of perinatal morbidity and mortality (Kingdom, et al. 1997).

- Being underweight before pregnancy

The Merck Manual (2005) reports a Body Mass Index (BMI) under 19.8 kg/m² before pregnancy is considered underweight and is a risk factor for an underweight fetal birth. The recommendation is for these women to gain between 12.5 to 18 kg during the pregnancy. The statistics from CDC’s Pediatric and Pregnancy Nutrition Surveillance System (2005) reports prepregnancy underweight is associated with low birthweight. Underweight women have the highest prevalence of the following indicators:

- Less than ideal or recommended weight gain based on their Prepregnancy BMI (22.8%)
- Low Birth weight (9.3%)
- Preterm (15%)
- Full Term Low Birthweight (5.5%)

- Obesity

The Merck Manual (2005) reports a Body Mass Index (BMI) over 29.0 kg/m² before pregnancy are considered overweight and is a risk factor for maternal health issues such as hypertension, diabetes, post term pregnancy, fetal macrosomia and an increase need for cesarean section delivery. The recommendation for overweight women is to limit weight gain during pregnancy to less than 7 kg. The March of Dimes Peristats (2008) report as well that preterm births are not directly related to maternal obesity, but obesity does lead to other maternal medical complications. A recent study examining the association between prepregnancy body mass index and neonatal mortality while accounting for the timing of delivery and subtypes of preterm birth from Denmark by Nohr et al. (2007) concluded, “High maternal weight seems to increase the
risk of neonatal mortality, especially in infants born after preterm premature rupture of membranes (PROM). Inflammation and infection related to obesity may be part of the causal pathway. The results of increased neonatal mortality of mothers who were overweight were: preterm infants (n=3,934, 136 deaths), neonatal mortality in infants born after preterm premature rupture of membranes (PROM) was significantly increased if they were born to an overweight or obese mother (CI 1.4–8.7, and 5.7, CI 2.2–14.8). There were no associations between high BMI and neonatal mortality in infants born after spontaneous preterm birth without preterm PROM or in infants born after induced preterm delivery.

- Short time period between pregnancies (less than 6 to 9 months between birth and the beginning of the next pregnancy)

Numerous studies have found that short interpregnancy intervals, ranging from less than 3 months to less than 18 months, are associated with an increased risk of adverse birth outcomes, including low birth weight, preterm births, small for gestational age, neonatal death, and infant mortality (Smith, et al. 2003).

A cohort study by DeFranco et al. (2007) reviewed birth certificates from the state of Missouri with a study population of 156,330 women who had 2 births from 1989-1997. The risk of preterm birth and its recurrence increases with short inter-pregnancy intervals, even after adjustment for coexisting risk factors. The study showed the importance of counseling women with either an initial term or preterm birth to wait at least 12 months between delivery and subsequent conception.

- Being pregnant with a single fetus after in vitro fertilization

Changes in the obstetric management of pregnancy with increases in induction and cesarean delivery, and an increase in the use of assisted reproductive technologies (ART) may
also have played a role in the increase in low birthweight (MacDorman et al., 2005). Studies suggest that about one-third of women between 35 and 39 and about half of those over age 40 have fertility problems (March of Dimes, 2008) and women over 35 are more likely to undergo fertility treatment, which also increases the chance of twins (as well as triplets and other multiples). As women age fertility decreases and women over the age of 35 experience more difficulty with conceiving and naturally have an increased chance of having twins. Women, especially the older population (over age 35 years) are prone to seek ART due to the naturally occurring difficulty with conceiving which will also increase the chance of multiples and preterm birth.

- Certain birth defects in the baby

  A current study by Siobhan et al. (2007) concluded birth defects are associated with preterm birth and low birth weight after controlling for multiple confounding factors, including shared risk factors and pregnancy complications, when using propensity-scoring adjustment in multivariable regression analysis. The independent effects of risk factors on perinatal outcomes such as preterm birth and low birth weight, usually complicated by numerous confounding factors, may benefit from the application of this methodology, which can be used to minimize bias and account for confounding. Furthermore, this suggests that clinical and public health interventions aimed at preventing birth defects may have added benefits in preventing preterm birth and low birth weight. A singleton liveborn infant with a birth defect was 2.7 times more likely to be delivered preterm before 37 weeks of gestation, 7.0 times more likely to be delivered preterm before 34 weeks, and 11.5 times more likely to be delivered very preterm before 32 weeks. A singleton liveborn with a birth defect was 3.6 times more likely to have low birth
weight at less than 2,500 g and 11.3 times more likely to be very low birth weight at less than 1,500 g.

- Bleeding from the vagina

Vaginal bleeding during the first trimester of pregnancy is common but bleeding during the second or third trimester can mean there is a complication. A study by Yang et al. (2004) investigating a relationship between vaginal bleeding during pregnancy and preterm birth. The overall results revealed a modest association between vaginal bleeding and preterm birth. Bleeding in the first trimester was associated with early preterm birth (less than 34 weeks gestation) and preterm birth related to premature rupture of membranes. Bleeding in both trimesters was associated to preterm birth due to preterm labor. Bleeding of multiple episodes, on multiple days, and with more total blood loss was associated with a twofold increase risk of early preterm birth, premature rupture of membranes, and preterm birth. The study also found bleeding among African-American women is less predictive of preterm birth when compared to white women.

- Periodontal disease

Research in maternal periodontal disease is increasingly proving to be a risk factor in preterm birth. Results of a study by Pitiphat et al. (2008) suggest periodontitis is an independent risk factor for poor pregnancy outcome among middle class women. This study consisted of 72.7% Caucasian women, 65% of which had an annual household income > $70,000. Data indicated that 3.8% had periodontitis, 6.4% delivered preterm, 5.4% delivered small for gestational age babies, and 11% had poor pregnancy outcomes. The odds ratio associated with periodontitis was 1.74 (95% CI 0.65-4.66) for preterm delivery. A 5-year prospective study by Offenbacher et al. (2001) demonstrated the more severe the periodontal disease the higher the
risk of preterm birth and/or low birth weight babies. Periodontally healthy mothers had a prevalence of births less than 28 weeks gestational age at 1.1%. Mothers with mild periodontal disease had a prevalence of births less than 28 weeks gestational age at 3.5% and mothers with moderate-severe periodontal disease were the highest at 11.1%.

Several current and past reports (Allsworth & Peipert, 2007; Boggess, 2005; Pretorius et al., 2007) strongly suggest infections of the female reproductive tract and implications of maternal periodontal disease may be contributing factors in causing preterm births. Several reports (Hillier et al., 1995; Wadhwa et al., 2001) indicate a higher percentage of maternal reproductive tract infections are found in the African American and Hispanic populations as well as in low-income households. One possible mechanism could be isolation of periodontal microorganisms and gram-negative anaerobes have been isolated from the amniotic fluid, suggesting a hematogenous spread may involve the translocation of cytokines or bacteria to the uterus (Hill et al., 1984; Hillier et al., 1995).

Demographic risk factors

- Maternal age (younger than 17 years and older than 35 years)

Younger than 17 years

Though the preliminary data for 2006 from NCHS reports a considerable increase in teenage births (15-19 years of age) after a steady decline between 1991-2005. The overall birthrate for teenagers rose 3%. The 10-14 year age group was the only age group not experiencing an increase in birth rates while the 15-17 year age group had an increased risk of 3%. Teen pregnancies are more likely to have preterm births compared to women 20 years and older. March of Dimes (2008) reported between 2002 and 2004, preterm birth rates averaged 14.3% for women under age 20 compared to 11.7% for women ages 20 to 29. Teenage
pregnancies are at a greater risk for preterm birth due to behavioral risk factors such as smoking. March of Dimes (2008) reported that in 2004, 14.2% of pregnant teens ages 15 to 19 smoked, compared to 10.2% of all pregnant women. Smoking doubles a woman’s risk of having a low-birthweight baby and increases the risk of pregnancy complications, premature birth, and stillbirth. Teens are least likely of all maternal age groups to get early and regular prenatal care. From 2000 to 2002, an average 7% of mothers ages 15 to 19 years received late or no prenatal care (compared to 3.8% for all ages).

*Older than 35*

The birth rate for women 35-39 years of age has increased to the highest rate since 1964. According to the NCHS 2006 preliminary report, there has been a 2% increase to 47.3 births per 1,000 women with a 3% increase between 2005 and 2006. An increase also occurred for women 40-44 years to the highest since 1968 with a 3% increase to 9.4 births per 1,000 women. For women 45-49 years, the rate was unchanged at 0.6 births per 1,000. The number of births increased 1% for women aged 40-44 years and 6% for women aged 45-49. Preterm births increase in the older pregnant population where a 2005 government study found that women over age 40 were 40% more likely to have preterm births than younger women. Other studies have found that women between 35 and 39 also have an increased risk of premature delivery, though their risk may be lower than that of women over age 40. Some studies also suggest that women in their 40s may be at increased risk of having a low birth weight infant (March of Dimes 2008).

- **Race/ethnicity**

There are decades of studies reporting race and ethnicity as a strong risk factor relating to preterm birth and infant mortality. Consistently the African-American population experiences the greatest degree of preterm births, low birth weight babies, and infant mortality. Preterm birth has
been the leading cause of death for black infants for more than a decade. For those babies that do survive, approximately 25 percent of them live with serious long-term medical, behavioral, and learning problems.

The total infant deaths in 2004 related to preterm births for Non-Hispanic black births was 46.3%, Non-Hispanic white 32.1%, American Indian or Alaska Native was 22.4%, Asian or Pacific Islander was 35.3%, total Hispanic was 33.4%, Mexican was 32.2% and Puerto Rican was 40.7%, Central and South American was 35.7% (National Center for Health Statistics-Health E Stats [NCHS- Health E Stats], 2007). March of Dimes (2008) reported that the infant mortality rate is more than twice as high for black Americans than for white Americans and the preterm birth rate for black women is 17.6 percent, which is higher than the national average of 12.3% between 2002 and 2004. As the editorial note in the Centers for Disease Control and Prevention (CDC, 2007) report on infant mortality and low birth weight among black and white infants states “The specific causes for increased low birth weight and preterm delivery might differ for blacks and whites. The etiology of black-white disparities in low birth weight is complex and is not explained entirely by demographic risk factors such as maternal age, education, or income. Factors that might contribute to the disparity include racial differences in maternal medical conditions, stress, and lack of social support, bacterial vaginosis, previous preterm delivery, and maternal health experiences that might be unique to black women”.

- Low socioeconomic status

Health Insurance

Health insurance coverage affects how people use health care services. According to the Institute of Medicine (2006), health insurance status is the single most important influence in determining whether health care is accessible to children when they need it. Additionally,
uninsured women receive fewer prenatal services and report greater difficulty in obtaining needed care than women with insurance. The uninsured are less likely to have a usual source of medical care and more likely to delay or forgo needed health care services (Kaiser Foundation, 2007). According to March of Dimes Peristat (2008):

- During 2004-2006 (average), about 1 in 8 women of childbearing age (13.2%) was uninsured in Ohio.
- During 2004-2006 (average), about 1 in 13 children less than 19 years of age (7.4%) was uninsured in Ohio.
- According to the latest survey from the National Governor’s Association, 30.1% of births in Ohio were covered under Medicaid in 2002.

Ohio Department of Job and Family Services (2006) reported that in Ohio Medicaid paid for around 32% of all Ohio births in 2003. The non-Medicaid population had a lower rate of low birth weight births than in the Medicaid population (7.5% versus 10%) and infants born with low birth weight continued to consume more than half of Medicaid birth expenditures (53%).

Summary

Prevention is the ideal line of defense yet with knowledge of the risk factors and efforts to address the risk factors it appears to have had minimal change in preterm births and infant death rates, especially among the black race and women of low socio economic status, who have the largest percentages of preterm births (CFCCFR, 2006).

With the above literature reviews, it appears there is a relationship between maternal infections and preterm births. The literature indicates a need for continued research. With the use of improved collection and laboratory techniques, there could be more definitive data between maternal infections, and the inflammation process and preterm births.
Methods

The study design is a retrospective, observational study of medical records to evaluate the relationship of prenatal infections in women who had preterm births compared to women who had a term birth. The subjects are obstetrical patients from the five CHD health centers who delivered in the years 2005 and 2006. Exclusions consist of patients listed as delivering a baby but have missing charts and/or delivery data. Medical records were viewed on the clinic site or were transferred for review at a central location approved by the Cincinnati Health Department Medical Director. Of the 738 subjects listed as having delivered, charts for 36 subjects were unable available for review. Of the remaining 702 subjects, there were 668 subjects with usable data for the study. The information collected were retrieved from 363 charts for 2005 with 351 containing usable data and 339 charts for 2006 with 317 containing usable data resulting in 668 subjects for the study.

Electronic encounter records available in CHD were used to identify pregnant women who delivered in the years 2005 and 2006. Review of charts were used to identify race, ethnicity, age, census tract, and health insurance status.

Data collection by medical record review was used to identify the purpose/type of the visit prior to index pregnancy. The following was also collected by medical record review; complaints of symptoms or a diagnosis of an infection (viral, fungal, and/or bacterial), periodontal disease (at preconception and prenatal visits), sexually transmitted infection (STI) screening, interventions, treatment and/or referral for care of symptoms and/or diagnosis of infection, gestational age and gestational weight. Institutional review board (IRB) approval was obtained by Wright State University and Cincinnati Health Department. A letter of permission to
access medical records and CHD electronic encounter forms was obtained. Data collection forms had no patient identifiers as outlined by HIPAA regulations.

Questions

- Research Question 1. Determine the distribution of the different types of preconception/preventative care visits. Defined as a visit to a CHD health center that occurred prior to the first day of the last menstrual period of the index pregnancy which were broken down into urine pregnancy tests, sexually transmitted infection visits, gynecological visits, birth control (either oral birth control prescription visits or Depo-Provera injections), family planning, prenatal visit prior to index pregnancy, other (immunizations, sick visits, work physicals, etc).

- Research Question 2. Did the preconception/preventive care visit that immediately preceded the first prenatal visit include discussion of and/or addressing reproductive health issues?

- Research Question 3. Percentages of preterm births by demographics of patients by race, age, and location (census tract/neighborhood).

- Research Question 4. Average gestational age at first prenatal visit and at delivery by race.

- Research Question 5. Percentage of patients with insurance at first prenatal visit and with insurance at delivery by race.

- Research Question 6. Percentage of patients having one or more of the following infections: bacterial vaginosis, Chlamydia, gonorrhea, genital herpes, HIV, syphilis, and trichomonas categorized by whether the birth was preterm.

- Research Question 7. Percentage of patients evaluated for periodontal disease categorized by whether the birth was preterm.
Excel and Statistical Analysis Software (SAS) were utilized to analyze the research questions listed above. Descriptive statistics including prevalence and incidence were determined. Chi Square or Anova were utilized to determine differences between populations. T test/Least Significant Different test (LSD) were preformed when ANOVA results were significant to separate where the similarities differ in that category. A p-value of <.05 was considered significant.
Results

The chart review totaled 702 women who delivered in the years 2005 and 2006. When the chart review was completed, women without gestational delivery information were excluded from the analysis. The remaining 668 women were analyzed and 110 (16.5%) women delivered a preterm birth and 558 (83.5%) women delivered a term birth.

Research Question 1. Determine the distribution of the different types of preconception/preventative care visits

The most frequent type of preconception/preventative care visit for preterm and term births were gynecological visits, at 31% for preterm births and 32.6% for term births. The least frequent type of visit was family planning at 1% for preterm births and 4% for term births. Four hundred thirty five subjects contained data for analysis and 233 had no previous visits prior to index pregnancy. The results were not significant relating the type of visit to preterm delivery of the index pregnancy with the p Value = 0.5969 (Table 1).

Table 1. Most recent health center visit prior to index pregnancy

<table>
<thead>
<tr>
<th>Reason for visit</th>
<th>Preterm</th>
<th>Term</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy test/UPT</td>
<td>6</td>
<td>32</td>
<td>38</td>
</tr>
<tr>
<td>STI</td>
<td>5</td>
<td>33</td>
<td>38</td>
</tr>
<tr>
<td>Gyn visit</td>
<td>31</td>
<td>119</td>
<td>150</td>
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<tr>
<td>Birth control</td>
<td>10</td>
<td>72</td>
<td>82</td>
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<tr>
<td>Other</td>
<td>15</td>
<td>98</td>
<td>113</td>
</tr>
<tr>
<td>Family Planning</td>
<td>1</td>
<td>4</td>
<td>5</td>
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<tr>
<td>Prenatal</td>
<td>2</td>
<td>7</td>
<td>9</td>
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</table>

Most recent visit type p Value= 0.5969
Research Question 2. Did the preconception/preventive care visit that immediately preceded the first prenatal visit include discussion of and/or addressing reproductive health issues?

Discussion of reproduction/contraception discussed at the preventative care visit that immediately preceded the first prenatal visit of the index pregnancy was found to be 72% overall, with no significant difference between preterm births and term births ($p = 0.3132$). There were 435 subjects with data for analysis. The remaining 233 subjects had no previous CHD health visits (Figure 1).

![Bar chart](chart.png)

Figure 1. Reproduction/Contraception discussed at visit prior to index prenatal visit; $p$ Value = 0.3132.
Research Question 3. Percentages of preterm births by demographics of patients by race, age, and neighborhood

There was a significant difference in percentages of preterm births by race ($p= .0201$). The African American population had a significantly larger percentage of preterm births at 19.1% than the Hispanic population at 16.4%, and the Caucasian population at 9.6% (Table 2).

Table 2. Preterm and term births by maternal race % within preterm and term births of total Cincinnati public health population.

<table>
<thead>
<tr>
<th>Population</th>
<th>Preterm</th>
<th>Term</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>African American *</td>
<td>70</td>
<td>19.1</td>
</tr>
<tr>
<td>Mixed *</td>
<td>2</td>
<td>50.0</td>
</tr>
<tr>
<td>Oriental/Asian</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Hispanic/Spanish</td>
<td>20</td>
<td>16.4</td>
</tr>
<tr>
<td>Caucasian *</td>
<td>16</td>
<td>9.6</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>25.0</td>
</tr>
</tbody>
</table>

Preterm birth by Maternal Race  $p$ Value = 0.0201
* = comparisons of significant difference at 0.05 level
There was no significant difference in overall maternal age of preterm or term births. Six hundred sixty-seven subjects were used for analysis. The mean age was 23 years for preterm and term births (p= 0.8259; Table 3). There was no significant difference in mean age by race (p= 0.4870; Table 3).

Table 3. Mean age preterm and term total population and mean age by race

<table>
<thead>
<tr>
<th></th>
<th>Mean age</th>
<th>Std Dev</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preterm</td>
<td>109</td>
<td>23</td>
</tr>
<tr>
<td>Term</td>
<td>558</td>
<td>23</td>
</tr>
<tr>
<td>African American</td>
<td>366</td>
<td>23</td>
</tr>
<tr>
<td>Mixed</td>
<td>3</td>
<td>22</td>
</tr>
<tr>
<td>Oriental/Asian</td>
<td>1</td>
<td>30</td>
</tr>
<tr>
<td>Hispanic/Spanish</td>
<td>122</td>
<td>24</td>
</tr>
<tr>
<td>Caucasian</td>
<td>167</td>
<td>23</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
<td>25</td>
</tr>
</tbody>
</table>

Mean age p Value = 0.8259 Mean age by race p Value = 0.4870

The neighborhoods with greater than 2.5% total births (noted by *) were found to be the neighborhoods where the city health centers are located, with the exception of the Westwood neighborhood. The preterm births of the CHD population compared to the overall City of Cincinnati preterm births (Child Research Policy Center; Appendix F), of the same neighborhoods, was found to be a small percentage of preterm births for the CHD population. The two exceptions were the West Price Hill and Westwood neighborhoods of which had a higher percentage of preterm births. The West Price Hill neighborhood, which has 11.8% preterm birth rate for CHD population compared to overall city 2.3%-8.4%. The Westwood CHD
population had a higher percentage of preterm births than the overall city report for the same neighborhood 14.5% versus 8.5%- 10.7%. As the neighborhoods became farther away from the health centers, a decrease in total birth population was seen in the CHD health centers, although not significant (Table 4). There were neighborhoods in the city with preterm births in which CHD had no population served.

Table 4. Preterm, Term, and total Births by Neighborhood (census tract), percentage within preterm and term births of total CHD health centers population.

<table>
<thead>
<tr>
<th>Neighborhood</th>
<th>Preterm</th>
<th></th>
<th>Term</th>
<th></th>
<th>Total</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>West End *</td>
<td>8</td>
<td>7.3</td>
<td>14</td>
<td>2.5</td>
<td>22</td>
<td>3.3</td>
</tr>
<tr>
<td>Over the Rhine *</td>
<td>10</td>
<td>9.1</td>
<td>26</td>
<td>4.7</td>
<td>36</td>
<td>5.4</td>
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<tr>
<td>Mt. Auburn</td>
<td>2</td>
<td>1.8</td>
<td>8</td>
<td>1.4</td>
<td>10</td>
<td>1.5</td>
</tr>
<tr>
<td>Fairview /Clifton Hts</td>
<td>0</td>
<td>0.0</td>
<td>6</td>
<td>1.1</td>
<td>6</td>
<td>0.9</td>
</tr>
<tr>
<td>Camp Washington</td>
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<td>0.9</td>
<td>4</td>
<td>0.7</td>
<td>5</td>
<td>0.8</td>
</tr>
<tr>
<td>University Hts.</td>
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<td>0.0</td>
<td>5</td>
<td>0.9</td>
<td>5</td>
<td>0.8</td>
</tr>
<tr>
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<td>0.2</td>
<td>1</td>
<td>0.2</td>
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<tr>
<td>Walnut Hills</td>
<td>4</td>
<td>3.6</td>
<td>11</td>
<td>2.0</td>
<td>15</td>
<td>2.3</td>
</tr>
<tr>
<td>Evanston</td>
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<td>4</td>
<td>0.7</td>
<td>5</td>
<td>0.8</td>
</tr>
<tr>
<td>Evanston/East Walnut Hills</td>
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<td>1</td>
<td>0.2</td>
<td>1</td>
<td>0.2</td>
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<tr>
<td>East Walnut Hills</td>
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<td>0.4</td>
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</tr>
<tr>
<td>East End</td>
<td>0</td>
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<td>0.4</td>
<td>2</td>
<td>0.3</td>
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<tr>
<td>Mt. Washington</td>
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<td>0.2</td>
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<td>0.3</td>
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<tr>
<td>Neighborhood</td>
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<td>Term</td>
<td>Total</td>
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<td>-----------------------------------</td>
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</tr>
<tr>
<td></td>
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<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
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<td>1.4</td>
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</tr>
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<td>4.7</td>
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<tr>
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<td>2.3</td>
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<tr>
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<tr>
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<td>Term</td>
<td></td>
<td>Total</td>
<td></td>
</tr>
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<td>------------------------------</td>
<td>---------</td>
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</tr>
<tr>
<td></td>
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<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>East Price Hill             *</td>
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<td>3.7</td>
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<td>48</td>
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<td>61</td>
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<tr>
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<td>79</td>
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<td>95</td>
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<td>9</td>
<td>1.6</td>
<td>9</td>
<td>1.4</td>
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<tr>
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<td>0.9</td>
<td>5</td>
<td>0.8</td>
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<tr>
<td>Anderson Township</td>
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</tr>
<tr>
<td>Colerain Township</td>
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<td>0.0</td>
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<td>0.4</td>
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<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Golf Manor</td>
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<td>0.2</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Green Township</td>
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<td>0.2</td>
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<tr>
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<td>0.7</td>
<td>5</td>
<td>0.8</td>
</tr>
<tr>
<td>Mariemont</td>
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<td>0.0</td>
<td>1</td>
<td>0.2</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>North College Hill</td>
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<td>0.2</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Reading</td>
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<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Springfield Township</td>
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<td>1.8</td>
<td>2</td>
<td>0.4</td>
<td>4</td>
<td>0.6</td>
</tr>
<tr>
<td>St. Bernard</td>
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<td>0.0</td>
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<td>0.2</td>
<td>1</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Research Question 4. Average gestational age at first prenatal visit and at delivery by race.

The average gestational age at first prenatal visit for the total population was not significant between preterm or term births. The mean gestation days for preterm births was 113 and for term births 108 \((p= 0.4036; \text{ Table 5})\). There was significant difference in gestation days at first prenatal visit by race \((p < 0.0001)\). The differences were between the Hispanic and African American population and the Hispanic and Caucasian population with Hispanic population entering prenatal care later in the pregnancy than the African American or Caucasian populations (Table 5).

Table 5. *Mean gestation (days) first prenatal visit total population and by race*

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>age</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preterm</td>
<td>110</td>
<td>113</td>
<td>57</td>
</tr>
<tr>
<td>Term</td>
<td>557</td>
<td>108</td>
<td>54</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>366</td>
<td>101.1</td>
<td>52.5 *</td>
</tr>
<tr>
<td>Mixed</td>
<td>4</td>
<td>94.8</td>
<td>63</td>
</tr>
<tr>
<td>Oriental/Asian</td>
<td>1</td>
<td>196</td>
<td>.</td>
</tr>
<tr>
<td>Hispanic/Spanish</td>
<td>122</td>
<td>131.3</td>
<td>52.7*</td>
</tr>
<tr>
<td>Caucasian</td>
<td>167</td>
<td>110.7</td>
<td>54.4 *</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
<td>113.1</td>
<td>69.2</td>
</tr>
</tbody>
</table>

Mean gestation (days) first prenatal visit total population \( p \text{ Value } = 0.4036 \)
Mean gestation (days) first prenatal visit by race \(* p \text{ Value } = < 0.0001 \)
There was a significant difference between preterm and term gestation age at delivery, as expected, with the mean preterm gestational age of 231 days and term gestational age of 275 days \( (p = < 0.0001; \text{ Table 6}) \). There was no significant difference for preterm or term gestation age for delivery by race (Table 6).

Table 6. *Mean Delivery gestation (days) total population preterm and term and average gestation days by race.*

<table>
<thead>
<tr>
<th>Gesture Age*</th>
<th>n</th>
<th>age</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preterm</td>
<td>110</td>
<td>231</td>
<td>31</td>
</tr>
<tr>
<td>Term</td>
<td>558</td>
<td>275</td>
<td>8.2</td>
</tr>
<tr>
<td>Race **</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>366</td>
<td>267</td>
<td>23.1</td>
</tr>
<tr>
<td>Mixed</td>
<td>4</td>
<td>260</td>
<td>22.0</td>
</tr>
<tr>
<td>Oriental/Asian</td>
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<td>285</td>
<td>.</td>
</tr>
<tr>
<td>Hispanic/Spanish</td>
<td>122</td>
<td>268</td>
<td>25.2</td>
</tr>
<tr>
<td>Caucasian</td>
<td>167</td>
<td>272</td>
<td>15.5</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
<td>273</td>
<td>15.2</td>
</tr>
</tbody>
</table>

*Mean delivery gestation (days) total population preterm and term \( p \text{ Value} = < 0.0001 \)**

**Average gestation days at delivery by race \( p \text{ Value} = 0.1023 \)**
Research Question 5. Percentage of patients with insurance at first prenatal visit and with insurance at delivery by race.

Insurance type at first prenatal visit and delivery was not significantly different between preterm and term births ($p = 0.1711$ and $0.3479$, respectively). The uninsured or self-pay patients comprised 61.8% of pregnant women at the first prenatal visit and 23.1% at delivery (Table 7). There was a significant difference (as noted by *) between insurance types at delivery and maternal race. Hispanic, Oriental/Asian, and Other had a higher percentage of being uninsured or self-pay patients at first prenatal visit and remained at a higher percentage of being uninsured or self-pay at delivery ($p = <0.0001$; Table 8).

Table 7. Total insurance type at first prenatal visit and delivery

<table>
<thead>
<tr>
<th>Insurance type</th>
<th>First prenatal visit</th>
<th>Delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>None/Self pay</td>
<td>413</td>
<td>61.8</td>
</tr>
<tr>
<td>Medicaid</td>
<td>252</td>
<td>37.7</td>
</tr>
<tr>
<td>Private</td>
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<td>0.45</td>
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</table>

Total insurance type first prenatal visit $p$ Value = 0.1711  Delivery $p$ Value = 0.3479
Table 8. Percentage of Patients with insurance at delivery by race

<table>
<thead>
<tr>
<th>Race</th>
<th>Insurance type</th>
<th>First prenatal visit</th>
<th>Delivery</th>
</tr>
</thead>
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</table>

*= Percentage of patients with insurance at first prenatal visit and delivery by race p Value = 0.0001
Research Question 6. Percentage of patients having one or more of the following infections: bacterial vaginosis, chlamydia, gonorrhea, genital herpes, HIV, syphilis, and trichomonas categorized by whether the birth was preterm.

With regards to maternal infections, there was a significant difference between preterm birth and term births for gonorrhea ($p = 0.0334$). There was no significant difference found between preterm births and other maternal STI infections. Women with multiple STI’s were higher within those who had preterm births than term births (13.6% vs. 10.4%) but the $p$ value was not significant ($p= 0.3199$; Table 9).

Table 9. Percentage of preterm births with one or more of the following infections

<table>
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<tr>
<th>Factor</th>
<th>Preterm</th>
<th></th>
<th>Term</th>
<th></th>
<th>Total</th>
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<th>$p$ Value</th>
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<td>$n$</td>
<td>%</td>
<td>$n$</td>
<td>%</td>
<td>$n$</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>Bacterial Vaginosis</td>
<td>11</td>
<td>10.2</td>
<td>71</td>
<td>10.7</td>
<td>82</td>
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<td>Chlamydia</td>
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<td>16.7</td>
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<td>13.7</td>
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<td>Multiple STI’s</td>
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<td>58</td>
<td>10.4</td>
<td>73</td>
<td>10.9</td>
<td>0.3199</td>
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</table>
Research Question 7. Percentage of patients evaluated for periodontal disease categorized by whether the birth was preterm.

There was no significant difference in periodontal disease between women who had preterm births and women who had term births ($p = 0.1912$). However, of the 668 subjects only 365 were evaluated for periodontal disease (Figure 2). Numerically, women with preterm births had a higher percentage of periodontal disease than women with term births (22.2% vs. 15.1%).

![Figure 2](image_url)

*Figure 2.* Percentage of patients evaluated for periodontal disease categorized by whether the birth was preterm.
Discussion

Main findings

The number of women who received prenatal care from CHD health centers for the years 2005 and 2006 totaled 738 women. When chart review was completed, women without gestational delivery information were excluded from the analysis. The remaining 668 women were used for analysis. This population of pregnant women included, by race, 54.8% (366) African American, 25% (167) Caucasian, 18.3% (122) Hispanic/Spanish, 1.2% (8) Other, 0.6% (4) Mixed, 0.15% (1) Oriental/Asian. These results are consistent with a Cincinnati Health Department perinatal report for all CHD health centers for the year 2007. The total deliveries for 2007 were 422 with 52% African American, 24% white, 22% Hispanic/Latino, and 2% unknown (CHD 2007).

Research Question 1. Determine the distribution of the different types of preconception/preventative care visits

The first question answers the question as to what types of preconception/preventative care visits occurred prior to the first day of the last menstrual period of the index pregnancy. The visits were categorized into urine pregnancy tests, sexually transmitted infection visits, gynecological visits, birth control (oral birth control prescription visits, condom, and/or Depo-Provera injections), family planning, prenatal visit prior to index pregnancy, other (immunizations, sick visits, work physicals, etc). The most frequent type of preconception/preventative care visit for preterm and term births were gynecological visits with 34.5%, and the least frequent type of visit was family planning with 1.2%. The results were not significant relating the type of visit to preterm or term births of the index pregnancy (p= 0.5969; Table 1). Though no studies were found differentiating the types of physician’s office visits,
Anderson et al. (2006) noted in a report that women of childbearing age have an average of 6.4 visits per year to a physician’s office and these visits should be used as opportunities to promote preconception care. A survey from 2004 as reported by Johnson et al. (2006) noted 84% of the women of childbearing age (18-44) had health care visits the previous year and 55% received preventative health care in any given year provided opportunities for medical care providers to incorporate preconception care into the visits.

Research Question 2. Did the preconception/preventive care visit that immediately preceded the first prenatal visit include discussion of and/or addressing reproductive health issues?

Discussion of reproduction/contraception discussed at the preventative care visit that immediately preceded the first prenatal visit of the index pregnancy was found to be 72% overall. There was no difference between preterm and term births (p= 0.3132; Figure 1). This may be due to the study population of pregnant women and the categories of visits primarily being obstetrical and gynecological in origin. The remaining 113 (26%) subjects were seen for “other” reasons. It would be interesting to evaluate the entire childbearing population in the CHD health centers for preconception care discussion with the attending medical personnel. As noted in a study by Heyes, et al. 2004, although primary care practitioners agreed that the subject of preconception care was important there were many factors noted in preventing the delivery of preconception care in a primary care setting. It is unsure what percentages of the pregnancies were unintended and how many unintended pregnancies resulted in preterm birth. It would be interesting to discover whether the pregnancy was intentional to assess the unintended pregnancy rate and the rate of preterm births related to unintended pregnancies. This may lead to addressing appropriate preconception care discussions with specifically targeted patient populations. The literature reports approximately one-half of pregnancies in the United States are unintended
PRETERM BIRTH RATES

(Finer, 2006). Although a high percentage of visits included reproduction/contraceptive discussions, the results are limited to a select study population. The results do not represent the extent of age appropriate preconception care by all medical professions at every visit throughout CHD health center patient population, as is encouraged by the literature (As-Sanie et al., 2004; Brundage, 2002; Hall, 2000; Johnson et al., 2006).

Research Question 3. Percentages of preterm births by demographics of patients by race, age, and neighborhood

Demographic risk factors for preterm birth are race/ethnicity: Non-Hispanic black race; age: younger than age 17, or older than age 35; and low socioeconomic status (ACOG, 2001; Lesli, et al., 2003; March of Dimes, 2008; NCHS Health E Stats, 2007). For racial differences in preterm births, the African American population was found to have a larger percentage of preterm births at 19.1% than the Hispanic population with 16.4%, and the Caucasian population with 9.58% with a p Value = 0.0201 (Table 2). These results are consistent with national and local data as reported by the National Vital Statistics (2007) that preterm birth rates between 2005 and 2006 were reported as essentially unchanged among non-Hispanic white at 11.7 %, non-Hispanic blacks at 18.4% and an increase among Hispanic births from 12.1% to 12.2%. The March of Dimes Peristat 2004 data for Cincinnati reports the rate of preterm birth highest for black infants at 17.9%, followed by Native Americans at 17.9%, Hispanics at 12.6%, whites at 12.1% and Asians at 6.9%.

The neighborhoods with greater than 2.5% total births (noted by *) were found to be the neighborhoods where the city health centers are located, with the exception of the Westwood neighborhood. The preterm births of the CHD population compared to the overall City of Cincinnati preterm births (Child Research Policy Center; Appendix F), of the same
neighborhoods, was found to be a small percentage of preterm births for the CHD population. The two exceptions were the West Price Hill and Westwood neighborhoods of which had a higher percentage of preterm births. The West Price Hill neighborhood, which has 11.83% preterm birth rate for CHD population compared to overall city 2.3%-8.4%. The Westwood CHD population had a higher percentage of preterm births than the overall city report for the same neighborhood 14.54% versus 8.5%-10.7%. As the neighborhoods became farther away from the health centers, a decrease in total birth population was seen in the CHD health centers, although not significant (Table 4). There are preterm births from neighborhoods where study subjects did not reside close to CHD health centers. One such example is the Fay Apartments, the CHD health center had 16 deliveries, all of which were term, but the statistics from Child Research Policy Center has the Fay Apartments listed in the 13.3%-18.6% preterm birth rate for that City of Cincinnati neighborhood (Appendix F).

Research Question 4. Average gestational age at first prenatal visit and at delivery by race.

There was no significant difference in overall population maternal age of preterm or term births. Six hundred sixty-seven subjects were used for analysis. The mean age was 23 years for preterm (109) and term (558) births (p = 0.8259; Table 3). In addition there was no significant difference in mean age by race (p = 0.4870; Table 3). March of Dimes (2008) reported between 2002 and 2004, preterm birth rates averaged 14.3% for women under age 20 compared to 11.7% for women ages 20 to 29.

The average gestational age at first prenatal visit for the total population was not significantly different between preterm or term births. The mean gestational days at the first prenatal visit for preterm births was 113 days and for term births 108 days (p = 0.4036; Table 5), which are both in the fourth month of pregnancy. In 2001, HRSA reported entry into prenatal
care at 83.4% for the first trimester and late or no prenatal care at 3.7%. The ODH 2006 state statistics for entry into prenatal care the first trimester was 72.7%, and for Hamilton County was 66.8%. The CHD patients in this study have their first prenatal visit in the second trimester on average.

There was a significant difference in gestational days at first prenatal visit by race. The differences were between the Hispanic and African American populations and the Hispanic and Caucasian population, with the Hispanic population presenting later in the pregnancy ($p < 0.0001$; Table 5). As reported by Martin et al. (2003) in 2002, blacks (75%) and Hispanics (77%) were less likely to receive prenatal care in the first trimester than whites (89%) and Asian/Pacific Islanders (85%).

There was a significant difference between preterm and term gestational age at delivery as would be expected. The mean preterm gestational age was 231 days and the term gestational age was 275 days ($p < 0.0001$; Table 6). There was no significant difference for preterm or term gestation age for delivery by race (Table 6). The gestational age was not analyzed for the different levels of preterm birth although the mean gestation age at delivery was 231 days or 33 weeks and term delivery was 275 days or 39 weeks.

Research Question 5. Percentage of patients with insurance at first prenatal visit and with insurance at delivery by race.

Insurance type at first prenatal visit and delivery was not significantly different between preterm and term births. The p value for first prenatal visit was = 0.1711 and at delivery was = 0.3479. Uninsured or self-pay patients comprised 61.8% of the first prenatal visit and dropped to 23.1% at delivery (Table 7). These results are most likely due to the patients with no insurance at the first prenatal visit acquiring Medicaid coverage by the time of delivery.
There was a significant difference between insurance delivery type and maternal race. Hispanic, Oriental/Asian, and Other had a higher percentage of being either uninsured or self-pay patients at the first prenatal visit than the African American or Caucasian races and remained at a higher percentage of being either uninsured or self-pay patients at delivery (p <0.0001; Table 7). This is important because uninsured women receive fewer prenatal services and report greater difficulty in obtaining needed care than women with insurance (Kaiser Foundation, 2007). In addition, the uninsured are less likely to have a usual source of medical care and more likely to delay or forgo needed health care services according to the Kaiser Foundation (2007).

Research Question 6. Percentage of patients having one or more of the following infections: bacterial vaginosis, chlamydia, gonorrhea, genital herpes, HIV, syphilis, and trichomonas categorized by whether the birth was preterm.

There was significant difference between preterm birth and gonorrhea (p = 0.0334; Table 8). The results of gonorrhea as a significant STI related to preterm birth in this population may indicate a prevalence of gonorrhea in the community at large. Cline et al. (2000) reported that gonorrhea in pregnancy can be asymptomatic and that cervicitis, endometritis, or systemic illness may occur due to infection with gonorrhea and is associated with septic abortion and neonatal infections. Testing for gonorrhea is recommended in the first and third trimester. The data was not analyzed to determine what trimester the gonorrhea was detected and the relationship of the trimester to preterm birth. The concern would be if the gonorrhea was asymptomatic and testing was not done before the third trimester of delivery. This can lead to inflammation creating a risk factor for preterm birth (Gibbs et al., 1992; Goldenberg et al., 2000; Romero et al., 2007). There was no other significant difference found between preterm births and term births with other STI’s, although preterm births occurred at a slightly higher percentage in women with STI’s than
the total population. Women with multiple STI’s were higher within those having preterm births than term births, although the difference was not significant (13.64% versus 10.39%; p = 0.3199; Table 8).

**Research Question 7. Percentage of patients evaluated for periodontal disease categorized by whether the birth was preterm.**

There was no significant difference in periodontal disease between women who had preterm births and women who had term births (p= 0.1912; Figure 2). Although not significant, women having a preterm birth had a higher prevalence of periodontal disease than those who had a term birth (22.2% versus 15.1%; Figure 2). However, of the 668 subjects only 365 (55%) were evaluated for periodontal disease. Since there was a small number of patients available for analysis it may be more of a risk factor as indicated in literature (Pitiphat et al., 2008). Pitiphat et al. (2008) suggests that periodontitis is an independent risk factor for poor pregnancy outcomes among middle class women. In addition Offenbacher et al. (2001) demonstrated that the more severe the periodontal disease the higher the risk of preterm birth and/or low birth weight babies.

**Limitations and strengths of the study**

The limitations of the study include the small sample size, especially in the number of women who had a preterm birth. There was missing data involving gestation age at delivery and the lack of periodontal status description on initial prenatal assessment and follow up on referral to dental care. Another limitation of the study is the absence of adjusting for other preterm risk factors such as; smoking, alcohol use, illicit drug use, inter-pregnancy intervals, and medical diagnosis such as diabetes. Additionally, the study is limited to CHD health center deliveries and is not representative of Cincinnati overall. Strengths of the study include the utilization of the data for further interventions and/or improvements in the community and improvements in the
CHD health centers methods of data collection and reporting. Another strength includes the comprehensive data collected related to the pregnant population, that can be used for further evaluation of interventions, which may have an impact on prevention and practice for this population in the CHD health centers.

**Further research**

Since this study was limited to the obstetrical population it may be of interest to research/evaluate where preconception opportunities/interventions may be of most benefit in the pediatric population and at what age to begin the intervention/discussions with the patient and/or parent. Further evaluation of the patient population regarding a decrease in preventative care visits pertaining to age and or loss of Medicaid/insurance coverage due to age which may led to outreach interventions and or support for Medicaid coverage for women of childbearing age. It may be of interest to research/evaluate the type of reproductive health discussions that may or may not occur with male patients. Another interest for further research would be to investigate the unintended pregnancy rate in this population. Other further investigations should include investigation of periodontal disease in the fertile age population and the effect on preterm or low birth weight deliveries. Finally, another interest for research would be to compare the CHD data with other health care centers serving a similar population of low socioeconomic women in Cincinnati.

**Conclusions**

This retrospective study compared demographics, types of CHD visits, discussion of preconception/reproductive health issues, insurance status, infections, and periodontal disease in preterm and term pregnancies. The findings in this study revealed significant differences with the African American population having a larger percentage of preterm births than the other
populations served by the CHD health centers. There was also a significant difference between the Hispanic and African American population and the Hispanic and Caucasian population in regards to entry into prenatal care with the Hispanic population seeking prenatal care later when compared to other populations served by CHD health centers. Insurance was another aspect which revealed a significant difference, though not in relation to preterm births but in relationship to race, with the Hispanic, Oriental/Asian, and Other populations having a higher percentage of being uninsured or self-pay patients at first visit and at time of delivery. Mothers infected with gonorrhea were found to have a significant difference in preterm births compared to term births and mothers with multiple sexually transmitted infections though not significantly different had a higher percentage of preterm births compared to term births. The findings from this research indicate interventions are needed pertaining to the African American population for preterm births and the importance for the overall population to enter prenatal care earlier, especially the Hispanic population. The research indicates a large percentage of patients had no medical insurance at first prenatal visit although most were able to obtain insurance by delivery. This indicates a needed intervention for access to medical insurance or promotion of affordable health care for overall population in the effort to increase preconception care but also to the populations found unable to obtain insured health care prenatal or at delivery. The findings relating to sexually transmitted infections and preterm births may indicate an under treated population in the community leading to the need for intervention, treatment, and education to increase public awareness. Periodontal disease was not significant in this study, however further studies with a larger sample size may reveal a stronger relationship.

Preterm births have a significant impact on society overall, there are no absolute demographic or socioeconomic boundaries and the causes of premature births are both known
and unknown. Preterm births have a great impact on all of society and to the medical profession in relationship to infant mortality, health care costs, lost employer productivity, and life-long disabilities (CDC, 2007; Institute of Medicine, 2006; March of Dimes, 2008). This study further highlights the need for interventions involved with preterm birth and gives specific data for Cincinnati that can help target the most needed interventions for this community.
References


McGregor, J., French, J., Parker, R., Draper, D., Patterson, E., Jones, W., Thorsgard, K.,


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Appendix (A)

Public Health Competencies

**Analytic/Assessment Skills**

- Defines a problem
- Determines appropriate uses and limitations of both quantitative and qualitative data
- Selects and defines variables relevant to defined public health problems
- Identifies relevant and appropriate data and information sources
- Evaluates the integrity and comparability of data and identifies gaps in data sources
- Applies ethical principles to the collection, maintenance, use and dissemination of data and information
- Partners with communities to attach meaning to collected quantitative and qualitative data
- Makes relevant inferences from quantitative and qualitative data
- Obtains and interprets information regarding risks and benefits to the community
- Applies data collection processes, information technology applications, and computer systems storage and retrieval strategies
- Recognizes how the data illuminates ethical, political, scientific, economic, and overall public health issues

**Basic Public Health Sciences Skills**

- Identifies the individual’s and organization’s responsibilities within the context of the Essential Public Health Services and core functions
- Defines, assesses, and understands the health status of populations, determinants of health and illness, factors contributing to health promotion and disease prevention, and factors influencing the use of health services
- Understands the historical development, structure, and interaction of public health care systems
- Identifies and applies basic research methods used in public health
- Applies the basic public health sciences including behavioral and social sciences, biostatistics, epidemiology, environmental public health, and prevention of chronic and infectious diseases and injuries
- Identifies and retrieves current relevant scientific evidence
- Identifies the limitations of research and the importance of observations and interrelationships
- Develops a lifelong commitment to rigorous critical thinking

**Communication Skills**

- Communicates effectively both in writing and orally, or in other ways
- Solicits input from individuals and organizations
- Advocates for public health programs and resources
- Effectively presents accurate demographic, statistical, programmatic, and scientific information for professional and lay audiences
- Listens to others in an unbiased manner, respect points of view of others, and promotes the expression of diverse opinions and perspectives
Cultural Competency Skills

- Utilizes appropriate methods for interacting sensitively, effectively, and professionally with persons from diverse cultural, socioeconomic, educational, racial, ethnic and professional backgrounds and person of all ages, and lifestyle preferences.
- Identifies the role of cultural, social, and behavioral factors in determining the delivery of public health services.
- Develops and adapts approaches to problems that take into account cultural differences.
- Understands the dynamic forces contributing to cultural diversity.
- Understands the importance of a diverse public health workforce.
## Study data collection form

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</tr>
<tr>
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</tr>
<tr>
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<tr>
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<td>______________</td>
</tr>
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<td>(First prenatal visit) ____________________</td>
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<td>__</td>
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<tr>
<td>Prior pregnancies: Number Fetal losses*</td>
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<td>Prior with serious congenital malformation*</td>
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<td>Date of pregnancy prior to index pregnancy</td>
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### Visit dates for index pregnancy*

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<tr>
<td>Next most recent CHD preconception visit</td>
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<td>First CHD well visit</td>
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<td>Risk screening performed?</td>
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<tr>
<td>Second prenatal visit: Seen by physician?</td>
<td>(Y/N)</td>
</tr>
<tr>
<td>Most recent preconception visit</td>
<td>Sick or well</td>
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</table>
Primary provider seen?* ______________________________

Reason for visit ________________________________________________

Preconception WIC participation? (Y/N) __ Number of prenatal visits ___

Smoke Y/N____ Cessation addressed Y/N_____

Alcohol use Y/N_____ Cessation addressed Y/N____

Drug use Y/N_____ If yes what____________ Cessation addressed Y/N____

Symptoms or diagnosis of an infection (viral/ bacterial/fungal) Y/N___

Diagnosis/symptoms__________________________ Gestation age____________

If treated with what (antibiotic/antiviral/antifungal/antiprotozoa/OTC)___________

Periodontal disease Y/N____ Referral Y/N ____ If yes referral results_______

Sexually transmitted infection (STI) screening Y/N____

Diagnosed with:

Bacterial vaginosis Y/N_____ Chlamydia Y/N___ gonorrhea Y/N___ herpes Y/N____ HIV
Y/N____ trichomoniasis Y/N____ syphilis Y/N____

Counseled on prevention of infection: cytomegalovirus Y/N____ toxoplasmosis Y/N___
parvovirus Y/N____ Environmental risks Y/N____

Gestation age at delivery (in weeks) ________ infant delivery wt (grams)________
Appendix (C)

*Data definitions*

**Race:** Use CHD coding system
- White
- Black or African American
- Asian
- Native Hawaiian or other Pacific Islander
- American Indian or Alaskan Native
- Spanish
- Other
- Mixed

**Health insurance:** none, Medicaid, Medicare, private

**Index pregnancy:** Pregnancy that identified this mother/baby for chart review

**Number of fetuses:** Is this a multiple birth – twins, triplets, other? Count all fetuses even if there is a fetal death.

**Gravidity:** Total number of pregnancies including index pregnancy

**Parity:** Total number of live births, excluding index pregnancy

**Fetal losses:** Total number of pregnancies during which the fetus died prior to birth, excluding the index pregnancy

**Serious congenital malformation:** malformation of heart, kidney, liver, gastrointestinal tract or brain or chromosomal defect

**Prior live born losses:** number of infants born alive who subsequently died, excluding index pregnancy

**CHD preconception visit:** a visit to a CHD clinic that occurred prior to the first day of the last menstrual period of the index pregnancy

**Primary provider seen:** Profession of the individual seeing the patient regarding the chief complaint

**First prenatal visit:** The pre-registration visit, the first visit to the health center for this pregnancy

**Standing orders (risk screening) etc...**

**Infections other than STI**

**Clinic visits other**
Appendix (D)

### Statistical Neighborhoods

<table>
<thead>
<tr>
<th>Neighbhd</th>
<th>Neighbhd</th>
</tr>
</thead>
<tbody>
<tr>
<td>QUEENSBORO CDT</td>
<td>SOUTH HAVEN HILLS</td>
</tr>
<tr>
<td>WESTEND</td>
<td>WEST END</td>
</tr>
<tr>
<td>CEDAR-RIVERFRONT</td>
<td>CEDAR-RIVERFRONT-EAST WOOD HILLS</td>
</tr>
<tr>
<td>OVER THE RINE</td>
<td>LOWER PRICE HILL</td>
</tr>
<tr>
<td>11TH ST</td>
<td>EAST END</td>
</tr>
<tr>
<td>11TH ST</td>
<td>ELIZABETH</td>
</tr>
<tr>
<td>15TH ST</td>
<td>COLONNADE</td>
</tr>
<tr>
<td>17TH ST</td>
<td>EAGLE HAVEN</td>
</tr>
</tbody>
</table>
| 19TH ST | EVANS |}

#### 1990 SNA (Statistical Neighborhood Approximations)

Prepared by Department of City Planning, Cincinnati, Ohio August 1999

Appendix (E)

2000 Census Tracts
And Jurisdictions

Premature Births (<38 weeks) by Neighborhood (%)  
City of Cincinnati 1990-2000

Child Policy Research Center
Source: Ohio Birth Certificates

http://www.cincinnatichildrens.org/assets/0/78/1067/1395/1833/1835/1847/4a6afe01-8e23-4d73-b4a2-deafea870309.PDF
<table>
<thead>
<tr>
<th>Preterm Birth Rates</th>
<th>Sayler Park</th>
<th>Lower Price Hill</th>
<th>East Price Hill</th>
<th>South Fairmount</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.3%-8.4%</td>
<td>West Price Hill</td>
<td>Westwood</td>
<td>Fairview-Clifton Hts</td>
<td>North Fairmount-</td>
</tr>
<tr>
<td></td>
<td>University Hts</td>
<td>Avondale</td>
<td>Northside</td>
<td>English Woods</td>
</tr>
<tr>
<td></td>
<td>Mt. Adams</td>
<td>Corryville</td>
<td>Madisonville</td>
<td>East End</td>
</tr>
<tr>
<td></td>
<td>Evanston-Walnut Hills</td>
<td>Evanston</td>
<td>Winton Place</td>
<td>Kennedy Heights</td>
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<tr>
<td></td>
<td>Hyde Park</td>
<td>Walnut Hills</td>
<td>College Hill</td>
<td>West End *</td>
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<tr>
<td></td>
<td>Hartwell</td>
<td>Clifton</td>
<td>CBD-Riverfront</td>
<td>Over the Rhine</td>
</tr>
<tr>
<td></td>
<td>Mt. Lookout/Columbia-Tusculum</td>
<td>Mt. Airy</td>
<td>Roselawn</td>
<td>Mt. Auburn</td>
</tr>
<tr>
<td></td>
<td>Tusculum</td>
<td>Carthage</td>
<td>North Avondale-</td>
<td>Camp Washington</td>
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<tr>
<td></td>
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<td>Pleasant Ridge</td>
<td>Paddock Hills</td>
<td>South Cumminsville-</td>
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<tr>
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<td>Oakley</td>
<td>East Walnut Hills</td>
<td>Millvale *</td>
</tr>
<tr>
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<td>Linwood</td>
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<td>Fay Apts</td>
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<td>California</td>
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<td>Winton Hills</td>
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<tr>
<td></td>
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<td>Mt. Washington</td>
<td></td>
<td>Bond Hill</td>
</tr>
</tbody>
</table>
Appendix (G)

**Project Timeline**

Submit proposal for exempt review to the Screening Committee via Office of Research and Sponsored Programs May 8, 2007 for review at the May 25, 2007 meeting. Upon approval to proceed will begin reviewing charts no later than the first week of June 2007 and have data collected by December 2007. Data analysis completed by first week of February 2008 with the first draft of manuscript ready for submission by the end of March 2008 for review by the Guidance Committee chair and the Guidance Consultant. Completed manuscript anticipated to be presented early April 2008 with the oral presentation by the end of April 2008.
Dear Dr. Paton and Dr. Rickabaugh:

Ms. Elizabeth Singhoffer has the permission of the Cincinnati Health Department to perform her research project, “Compare the preterm birth in women with prenatal infections with the preterm birth of women without prenatal infections”, as part of the project, “Missed opportunities to provide preconception care designed to improve pregnancy outcomes (prematurity, congenital malformations, fetal mortality, and infant mortality”. The project has been approved by the Cincinnati Health Department Institutional Review Board.

As part of her research, Ms. Singhoffer has the permission of the Cincinnati Health Department to retrieve data from the AS400 computer system and to review the charts of patients at the Cincinnati Health Department’s five primary care health centers. Ms. Singhoffer has already received the required departmental H.I.P.A.A. training.

We look forward to working with Ms. Singhoffer on this project.

Sincerely,

Lawrence S. Holditch, M.D.
Medical Director
Cincinnati Health Department
DATE: June 1, 2007

TO: Elizabeth Singhoffer, P.I., Student Public Health

FROM: B. Laurel Elder, Ph.D, Chair
      WSU Institutional Review Board

SUBJECT: SC# 3408
         'Comparing Preterm Birth Rates in Women with Prenatal Infection to Women without Prenatal Infection'

At the recommendation of the Screening Committee, your study referenced above has been recommended for exemption. Please note that any change in the protocol must be approved by the IRB; otherwise approval is terminated.

This action will be referred to the Full Institutional Review Board for ratification at their next scheduled meeting.

NOTE: This approval will automatically terminate one (1) year after the above date unless you submit a "continuing review" request (see http://www.wright.edu/rsp/IRB/CR_sc.doc) to RSP.

If you have any questions or require additional information, please call me at 775-2425.

Thank you!

Enclosure
Title: 'Comparing Preterm Birth Rates in Women with Prenatal Infection to Women without Prenatal Infection'

Principal Investigator: Elizabeth Singhoffer, P.I., Student
Public Health
Sara Paton, Ph.D., M.S., Fac. Adv.
Community Health

The Institutional Review Board Screening Committee Coordinator has approved an exemption with regard to the use of human subjects on this proposed project.

REMEMBER: Federal regulations require prompt reporting to the IRB of any changes in research activity [changes in approved research during the approval period may not be initiated without IRB review (submission of an amendment), except where necessary to eliminate apparent immediate hazards to subjects] and prompt reporting of any serious or on-going problems, including unanticipated adverse reactions to biologicals, drugs, radioisotope labeled drugs or medical devices.

NOTE: This approval has been assigned an "SC" number in our system, which means the WSU Screening Committee concurs that this protocol is exempt under federal regulations.

Signed

Chair, WSU-IRB

Approval Date: May 23, 2007
IRB Mtg. Date: June 18, 2007