The Association of Maternal Pregnancy Complications and Sudden Infant Death Syndrome

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THE ASSOCIATION OF MATERNAL PREGNANCY COMPLICATIONS AND
SUDDEN INFANT DEATH SYNDROME

by

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A thesis submitted in partial fulfillment
of the requirements for the degree of
Master of Science in Public Health
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College of Public Health
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Keywords: SIDS, maternal risk factors, fetal hypoxia, prenatal outcomes, infant

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Sudden Infant Death Syndrome (SIDS) is the third leading cause of infant mortality between birth and the first year of life in the United States. Along with the identification of various maternal risk factors, the role of fetal hypoxia has been hypothesized to be one of many causal factors associated with SIDS. The purpose of this study was to develop a profile of the SIDS infant and assess whether six pregnancy complications consistent with fetal hypoxia were associated with the increased outcome of SIDS. The secondary data analysis of Florida linked birth to death certificate data specific to Hillsborough County and Duval County were analyzed retrospectively for the period of time between 1998 and 2000. Of the 86,342 births, 69 SIDS cases were identified, 34 in Hillsborough County and 35 in Duval County. A majority of the infants were White males with an average age of death of 80 days. The Chi-Square test for Independence with Cramer's V, odds ratios and 95% confidence intervals were calculated to determine if an association existed between pregnancy complications, specific maternal risk factors and SIDS. Eclampsia was the only statistically significant prenatal complication found in this cohort (OR=4.67: 95% CI 1.49, 14.57). Maternal tobacco use (OR= 3.13: 95% CI 1.83, 5.36) and late initiation into prenatal care were also found to
be significant in the SIDS cases, with the greatest risk occurring in women who did not receive prenatal care (OR=4.37; 95% CI 1.38, 13.89). These findings will assist with the development of a profile of infants who are at greater risk of dying of SIDS in Hillsborough County and Duval County as well as contribute to what is currently known about the association between fetal hypoxia and SIDS.
Chapter One

Introduction

Sudden Infant Death Syndrome (SIDS) is one of the leading causes of death of infants between one and 12 months of age (National Institute of Child Health and Human Development [NICHD], 2000), accounting for approximately 30% of all deaths in this age group (Beers & Berkow, 1999). While the exact cause of SIDS is unknown, organizations such as the American SIDS Institute (2002) have supported collaborative multidisciplinary research efforts with the aim of identifying potential risk factors associated with SIDS. In addition, the SIDS Alliance (2001) has partnered with the National Institute of Child Health and Human Development (NICHD) to develop research and education programs targeted at determining the cause of SIDS deaths as well as providing a national support center for SIDS families. The findings of clinical and epidemiological research have resulted in a decrease of approximately 2000 deaths per year, yet SIDS continues to claim the lives of almost 3000 infants in the United States each year (National Center for Health Statistics [NCHS], 2001).

In 1974, federal legislation passed the Sudden Infant Death Syndrome Act (PL 93-270) appointing the NICHD with the statutory responsibility of conducting SIDS research (Beggs, Bucks, Corwin, Dailey, Eaglestaff, Fifer & Jacobson, 2001). Since that time, reports have been produced revealing immense progress made in the understanding of SIDS. In 1999, United States Congress requested the development of a 5-year plan
with an objective to reduce the number of deaths caused by SIDS. As a result, the present strategic proposal was formulated with the following research initiatives:

1. The continuation of research on the cause(s) of SIDS, the development of abnormalities that increase vulnerability and result in high-risk infants, identification of genetic markers that may predict SIDS and determine whether SIDS is part of a larger family of nervous system disorders;
2. The analysis of epidemiological and physiological data to improve our understanding of environmental and other risk factors;
3. Community-based studies addressing health disparities resulting in fetal, infant and early childhood deaths; and
4. Improving risk reduction through the "Back to Sleep" campaign with continued research, monitoring, and outreach in at-risk communities (Sudden Infant Death Syndrome Alliance, 2001).

Recommendations made by the American Academy of Pediatrics (AAP) in 1992 are credited for the initial reduction of SIDS cases nationwide. In response to these guidelines, the NICHD, in partnership with the U.S. Public Health Service, the AAP, the SIDS Alliance, and the Association of SIDS and Infant Mortality Programs implemented the nationwide "Back to Sleep" campaign to increase awareness of the importance of infants being placed in the supine position when asleep. Prior to the launch of this campaign, it had been declared that infants who slept in the prone position were at greater risk for SIDS. As the sleep position changed through public awareness, the incidence of SIDS declined by 38% between 1992 and 1998 (Sudden Infant Death Syndrome (SIDS) Alliance, 2001). Nevertheless, the incidence of new cases continue despite the steady decline from 70% in 1992 to only 21% in 1997 of babies sleeping on their stomachs (United States Department of Health and Human Services [DHHS], 1999). Research
investigating other causes beyond environmental stressors is necessary for the further reduction of cases.

Sudden Infant Death Syndrome (SIDS) is defined as “the sudden and unexpected death of an infant under the age of one year that remains unexplained despite a thorough investigation, which includes an autopsy, examination of the death scene, and review of the clinical history” (Willinger, James & Catz, 1991). The current statute 406.11 of the state of Florida requires the Florida Medical Examiners Commission to have an established protocol for the investigation of sudden and unexplained deaths of infants in order to make a final diagnosis of Sudden Infant Death Syndrome. The Florida Administrative Code 11G-2.0031: SIDS Autopsy Protocol (1996) states that the medical examiner must inspect and document the environment where the infant was discovered, and complete a clinical history review of prenatal, delivery, and postnatal medical information. The specific details of the mandatory autopsy include a thorough examination of the status of the internal and external features, a complete skeletal survey and photographs of the body, and the collection of histological slides, bacterial and viral cultures and fluids and tissues for toxicology tests. The diagnosis of SIDS is made only after the death is classified as natural and congenital, infectious, environmental, or other unnatural causes of death including neglect or abuse are excluded (SIDS Autopsy Protocol of 1996).

Statement of Problem

Although the number of SIDS deaths in the state of Florida has gradually decreased, from 145 cases in 1996 to 96 cases in 2001, since the SIDS Autopsy Protocol went into effect, 710 infants have died of SIDS during this period of time (Florida
The risk factors associated with SIDS are likely to be multi-factorial, involving a combination of anatomical, physiological, environmental, and social factors (Hoffman & Hillman, 1992). In recent years, the relationship between prenatal complications and the risk factors associated with SIDS have not been well studied despite the contention that it is a greater challenge to assess postneonatal risk factors that it is to assess maternal risk factors (Hoffman & Hillman, 1992). The epidemiological research has focused on altering environmental risks in the postneonatal period by changing maternal behavior, instead of defining the underlying risk factors that occur before birth. While environmental factors, such as maternal tobacco use during pregnancy, are known to lead to poor health outcomes of the infant, the correlation to such consequences as intrauterine fetal hypoxia and anatomic and physiological abnormalities deserve greater attention from the epidemiological perspective since they have been associated with both adverse outcomes in pregnancy as well as SIDS.

**Purpose of Study**

The purpose of this study is to develop a profile of the SIDS infant as well as explore the relationship between prenatal complications associated with fetal hypoxia and the outcome of SIDS specific to the populations of Hillsborough County, Florida and Duval County, Florida between 1998 and 2000. Since the “Back to Sleep” Campaign, a majority of the research examining the association between prenatal factors and SIDS have consisted of retrospective studies, with the attention shifted towards the general hypothesis that an abnormality exists in infants who die of SIDS that originates during fetal development. Initially, this study will describe the demographics of the SIDS infant in addition to disclosing the association with the maternal risk factors of smoking and late
initiation into prenatal care. Next, the events during pregnancy known to cause fetal hypoxia will be analyzed to clarify what, if any, association they have with the outcome of SIDS in these populations. The research linking pregnancy complications with SIDS concentrates on how the adverse events affect fetal growth and development that result in a vulnerable infant. Since only a few publications have addressed the consequences of pregnancy-related events in the last decade, further research is needed to predict which babies are most vulnerable so that strategies can be developed to prevent SIDS deaths (Sudden Infant Death Syndrome Alliance, 2001).

It is hypothesized that adverse events that occur during pregnancy influence the health of the infant that may result in the outcome of SIDS. The likelihood of some sort of adverse event during the prenatal period is frequent enough to at least address the possibility that there could be a positive correlation to SIDS. Factors that warrant investigation include an understanding of the mother’s underlying diagnoses during pregnancy and how it compromises the normal growth and development of the fetus. Therefore, further attention should be focused on what takes place during this critical period of time that increases the potential for such a serious outcome.

**Definition of Terminology**

This research study discusses a vast amount of terminology related to pregnancy complications that may not be familiar to those outside the medical field, therefore, definitions of the variable terms are provided in this section.

*Abruptio Placentae.* (Beers & Berkow, 1999) The premature separation of a normally implanted placenta from the uterus due to unknown etiology. Abruptio placentae develops in 0.4 to 3.5% of all deliveries. It is associated with various
hypertensive, cardiovascular, and rheumatoid diseases and especially with use of cocaine in any form. Symptoms include hemorrhage, pain that becomes constant, albuminuria, anemia and contractions as the placenta tears from the uterine wall.

Anemia. (Beers & Berkow, 1999) Anemia during pregnancy is defined as hemoglobin (Hb) level of < 10 g/dL. However, any patient with an Hb level < 11 to 11.5 g/dL at onset of pregnancy must be treated as anemic, because the hemodilution that occurs during pregnancy reduces the Hb level to the anemic range. Anemia occurs in as many as 80% of gravid populations. Iron deficiency is responsible for 95% of cases of anemia during pregnancy. The deficiency is usually due to inadequate dietary intake (especially in teenage girls), to a previous pregnancy, or to the normal loss of iron in blood with menses (which approximates the amount normally ingested each month, so iron stores are never built up).

Eclampsia. (Thomas, 1993) The onset of seizures and a coma between the 20th week of pregnancy and the end of the first week postpartum. It develops in 1 of 200 patients with preeclampsia, or elevated blood pressure during pregnancy, and is usually fatal if untreated.

Fetal Hypoxia. (Washington, 2003) Deficiency of oxygen exchange between the mother and fetus that may be the result of a number of maternal risk factors including maternal infection, pregnancy-induced or chronic hypertension, Rh sensitization, chronic substance abuse, asthma, seizures. Fetal hypoxia is associated with long term complications, such as cerebral palsy, meconium aspiration syndrome, seizures and encephalopathy if left untreated.
Placenta previa. (Beers & Berkow, 1999) Implantation of the placenta over or near the internal os of the cervix. The placenta may cover the internal os completely (total previa) or partially (partial previa), or it may encroach on the internal os (low-lying placenta or marginal previa). Placenta previa occurs in 1 of 200 deliveries, usually in multiparas (women who have had more than one pregnancy), in patients who have had a cesarean section, or in patients with uterine abnormalities (e.g., fibroids) that inhibit normal implantation.

Pregnancy-Induced Hypertension (PIH). (Beers & Berkow, 1999) The development of hypertension, with an increase in systolic blood pressure of 30 mm Hg and/or diastolic of 15 mm Hg over baseline, proteinuria and edema during pregnancy. The two categories of PIH consist of preeclampsia and eclampsia, with preeclampsia being the progressive disease that leads to the more severe state of eclampsia. The result of hypertension is the reduction of blood flow to the placenta, which can then lead to fetal hypoxia and intrauterine growth retardation.

Uterine Bleeding. (Beers & Berkow, 1999) Bleeding from the uterus. Complications of pregnancy are the most common organic causes of abnormal bleeding in women of reproductive age and nearly half of patients with uterine bleeding and symptoms of pregnancy or a confirmed early pregnancy spontaneously abort the fetus.

Hypotheses

Hypothesis I: Anemia. Women with anemia during pregnancy are more likely to have an infant die of SIDS when compared to women without anemia during pregnancy.
Hypothesis II: Pregnancy-Induced Hypertension. Women with pregnancy-induced hypertension during pregnancy are more likely to have an infant die of SIDS when compared to women without pregnancy-induced hypertension during pregnancy.

Hypothesis III: Eclampsia. Women with eclampsia during pregnancy are more likely to have an infant die of SIDS when compared to women without eclampsia during pregnancy.

Hypothesis IV: Uterine Bleeding. Women with uterine bleeding during pregnancy are more likely to have an infant die of SIDS when compared to women without uterine bleeding during pregnancy.

Hypothesis V: Placenta Previa. Women with placenta previa during pregnancy are more likely to have an infant die of SIDS when compared to women without placenta previa during pregnancy.

Hypothesis VI: Abruptio Placentae. Women with abruptio placentae during pregnancy are more likely to have an infant die of SIDS when compared to women without abruptio placentae during pregnancy.

Hypothesis VII: Late Initiation into Prenatal Care. Women who initiate prenatal care late or not at all during pregnancy are more likely to have an infant die of SIDS when compared to women who do initiate prenatal care early in the pregnancy.

Hypothesis VIII: Smoking. Women who smoke during pregnancy have a greater risk of having an infant die of SIDS than a woman who does not smoke during pregnancy.

Hypothesis IX: Smoking as a Confounder. Smoking during pregnancy is a confounder between any of the pregnancy complications and the outcome of SIDS.
Chapter Two

Review of Literature

The preventive strategies created by Beggs et al. (2001) establish the foundation of the following review of literature. According to this strategic plan:

“The more we know about how risk factors contribute to SIDS pathogenesis, the more confident we can be that an infant will not succumb to SIDS…The early months are a time of rapid growth and development, with changing nutritional and sleep requirements. To prepare for these changes, the baby needs a healthy start during the prenatal period. What are the requirements for normal development? What factors increase the likelihood that the developmental process will go awry? How can we reduce that risk? Our knowledge of human development in fetal life and early infancy is quite limited. Although research on SIDS risk factors has identified prenatal and postnatal environmental characteristics and care practices that are critical to healthy outcomes, more research is needed” (p. 25).

Current Theory of the Etiology of SIDS

The premise directing innovative SIDS research today is based on the Triple Risk Model of SIDS, which implies that causality may be multi-factorial. According to this hypothesis, “SIDS results when the following three events take place simultaneously: 1) an underlying vulnerability in the infant; 2) a critical development period in state-related homeostatic control; and 3) an exogenous stressor(s) that exacerbate the infant’s underlying vulnerability” (Filiano & Kinney, 1994, p. 195). It is suggested by Filiano and Kinney (1994) that the vulnerability of babies who die of SIDS, which occurs in a critical period of development, is a result of an adverse condition during fetal development that prevents the normal response to environmental stressors. An objective
of the SIDS research sponsored by the NICHD is to clarify the role of fetal development in the etiology of SIDS by investigating the effect prenatal factors have on the infant.

A multidisciplinary approach to the triple risk hypothesis has been developed to determine what is unique in the cases of SIDS when compared to a healthy infant that causes the underlying vulnerability. Primarily, epidemiological studies support that the concept of the vulnerable infant is substantiated by the risk factors that develop as a result of a suboptimal fetal environment, including maternal smoking, maternal anemia, infection and drug use during pregnancy (Filiano & Kinney, 1994). Neuropathological research suggests that the vulnerability may result from an abnormality in brain development, originating during gestation, which causes a dysfunction in cardioventilation and arousal (Kinney et al., 1992). In a prospective study, Naeye & Blanc (1976) found that the likelihood of brain stem dysfunction is further evidenced by future SIDS victims that experience respiratory, feeding, and temperature regulation problems, and have an abnormal response to tactile stimulation.

Role of Hypoxia in the Outcome of SIDS

The concept of the underlying vulnerability of the infant is addressed in findings that lend support to the role of fetal hypoxia in SIDS (Buck et al., 1989). The support of the hypoxia hypothesis is validated by post-mortem studies of infants who died of SIDS that reported abnormal tissue findings consistent with chronic hypoxia (Naeye, 1980). In utero hypoxia is thought to have a permanent affect on the central nervous system of the fetus, particularly the brain stem which controls cardiorespiratory function (Filiano & Kinney, 1995).
The assessment of antenatal factors known to result in fetal hypoxia was collected from birth certificates and compared between the death certificates of SIDS infants and two sets of controls to determine if variation existed (Buck et al., 1989). The choice of ten antenatal variables was based on conditions that caused placental dysfunction and jeopardized a favorable uterine environment for the fetus. When compared to controls who died of other causes, Buck et al. (1989) found uterine bleeding not associated with placental complications was a significant risk factor of SIDS infants (OR=5.44, 95%=1.39, 21.35). The live control comparison observed a number of significant risk factors: placenta previa (OR= 6.84), eclampsia (OR= 5.52), and abruptio placentae (OR=4.58).

These findings were consistent with prior epidemiological research that account for an increased frequency of SIDS when associated with a history of pregnancy complications. Specifically, the pregnancy related events related to placenta previa, placenta abruption, and abnormal uterine bleeding (Standfast, Jereb &, Janerich, 1980). In the comparison of infants who died of SIDS to infants who died of other causes, Standfast et al. (1980) reported that 58% of the SIDS mothers had abnormal uterine bleeding when compared to only 17% in the cohort mothers. Furthermore, a similar association was found in the report of placenta previa and abruptio placentae in mothers whose infants later died of SIDS.

Events that occur during pregnancy that compromise the fetal environment can have a permanent effect on the infant. The adverse conditions involving the placenta, defined as placenta previa and placenta abruption are examples of such an event. Since
the placenta provides the major source of blood, oxygen, and nourishment to the fetus, any anomalies can lead to detrimental outcomes in the fetus (Beers & Berkow, 2000). The decrease in surface area of the placenta reduces oxygen and blood exchange between the maternal and fetal circulatory system and deficiency in oxygen transport to the fetus is believed to impinge on the cardiac, respiratory and nervous systems involved in the etiology of SIDS (Li & Wi, 1999). In a population-based case-control study using California linked birth and death certificate data, approximately 2100 SIDS cases were matched to controls by birth year to determine whether placental abnormalities were associated with SIDS. After potential confounders were controlled for using logistic regression, an association was found between these placental anomalies and a twofold increase in the risk of SIDS (OR=2.1 95% CI 1.3-3.1).

**Preeclampsia/Eclampsia**

The maternal exposure to preeclampsia/eclampsia during pregnancy is another known complication that leads to similar results of fetal hypoxia that may make infants more susceptible to SIDS. Preeclampsia is a result of pregnancy induced hypertension that can lead to a more severe form of eclampsia that in time can reduce the blood flow and oxygen supply from the mother to the placenta. A strong association exists between preeclampsia and fetal growth retardation as a result of the lack of nutrition to the fetus (Voto et al., 1999). In addition, preeclampsia leads to a reduction in placental size and can cause abruptio placentae, or separation from the uterine wall, which can lead to fetal hypoxia.

In a comparison of SIDS infants to matched live controls, Li & Wi conducted a study to ascertain whether preeclampsia/eclampsia during pregnancy increased the risk of
SIDS in infants. The analysis of linked birth and death certificate data revealed 49 cases of SIDS whose mother experienced pre-eclampsia/eclampsia during pregnancy. The results showed an association with a 50% increased risk of SIDS in infants when compared to non-SIDS controls (OR=1.5, 95%CI 1.1, 2.0) after controlling for potential confounders (Li & Wi, 2000). Although consistency of these findings are not statistically significant, Buck et al. (1989) reported a threefold increase in the association between preeclampsia/eclampsia and SIDS cases when compared to controls who died of other causes (OR =3.1 95% CI 0.4, 25.7) or live controls (OR=3.4, 95% CI 0.8, 14.0).

Risk Factors that Prompt Complications in Pregnancy

The identification of risk factors has been an effective means towards determining what is currently known about SIDS, yet it is important to note that the risk factors associated with SIDS should not be mistaken as the cause of SIDS nor are reliable in predicting the outcome (SIDS Network, 1995). The awareness of risk factors is beneficial in modifying behavior and establishing preventative measures to decrease the outcome of SIDS. While a number of risk factors have been developed as a result of two decades of SIDS research, the focus of this study will remain on those related to maternal behaviors and underlying health problems during pregnancy, specifically the findings of pregnant women that include maternal tobacco use, anemia, and late initiation into prenatal care.

Maternal Tobacco Use during Pregnancy

Smoking during pregnancy has been associated with a number of perinatal complications that have likewise been linked to SIDS. Women who smoke while pregnant have a dose-dependent, increased risk for placenta previa, placenta abruptio,
preeclampsia, and premature rupture of membranes (Schuler-Maloney & Lee, 1998). Support from the literature suggests that smoking is related to an increased incidence of placental previa, as much as 5 per 1000 in nonsmokers in comparison to 20 per 1000 in smokers (Andres & Day, 2000). A meta-analysis of studies conducted by Ananth, Smulian & Vintzileos (1999) concentrating on the association between pregnancy complications and smoking demonstrated a 90% increase in the incidence of abruptio placentae, with the attributable risk ranging from 15-25%. Furthermore, women who smoke with preeclampsia were at greater risk of the development of abruptio placentae.

Mothers who smoke during pregnancy are three times more likely to have a SIDS baby, and exposure to passive smoke doubles the risk (SIDS Alliance, 1998). The adverse effects of smoking have been shown to increase the arousal threshold during quiet sleep, which may lead to the weakened ability of the infant to respond to life threatening events (Horne et al., 2002). Furthermore, nicotine has been proven to decrease the blood flow into the placenta along with increase fetal carbon monoxide and carboxyhemoglobin concentrations resulting in fetal hypoxia (Bulterys et al., 1990). In a prospective study that obtained smoking frequency and amount from a questionnaire at three different intervals during pregnancy, approximately 25,000 live infants were followed from birth to the first year to study the smoking habits of women during pregnancy and the later outcome of their infant (Wisborg, Kesmodel, Hendriksen, Olsen & Secher, 2000). The death records and hospital records were reviewed to ascertain the cause of death as SIDS. Crude findings revealed that infants of smokers were three times more likely to die of SIDS compared to infants on non-smokers (OR 3.5 95% CI 1.4, 8.7) with the risk increasing with the number of cigarettes smoked each day (p< .0.05). After
adjustments were made for maternal age, birth weight, and gestational age, the risk remained with smokers being 2.9 times more likely to have an infant die of SIDS when compared to non-smokers (Wisborg et al., 2000).

*Anemia*

An extension of the fetal hypoxia hypothesis includes the possible interaction between maternal tobacco use and anemia during pregnancy and the outcome of SIDS. A nested case-control study of the US Collaborative Perinatal Project cohort by Bulterys, Greenland & Kraus (1990) found a dose-response relationship between smoking and low hematocrit that was also greater than multiplicative when both variables were present. Infants were at greatest risk of SIDS if the mother smoked more than ten cigarettes a day and had a hematocrit less than 30% (OR= 4.0 95% CI 2.1, 7.4), but low hematocrit in nonsmokers was not an increased risk (Bulterys et al., 1990). It is hypothesized that the lack of oxygen supply (caused by maternal anemia) to the fetus is intensified by the introduction of nicotine in the system. This effect, along with the hypothesis that smoking decreases the necessary nutrients required for central nervous system development, may predispose an infant to greater risk of SIDS.

*Late Initiation of Prenatal Care*

The health of a pregnant woman has a profound affect on the health of the developing fetus and newborn (Beggs et al., 2001). The goal of prenatal care is not only to monitor the development of the fetus during pregnancy, but to assess for high risk factors that may have a negative effect on the pregnancy outcome. While the various potential for risk factors do not endanger the pregnancy to the same extent, it is important that they are identified early in the prenatal period so that appropriate interventions are
established to ensure the well being of the mother and child. The schedule of visits is generally every four weeks during the first two trimesters (the first 28 weeks of gestation), then every two weeks until the 36th week of gestation, and then every week until birth (Olds, London & Ladewig, 1996).

The lack of adequate prenatal care is considered to be one of the most indirect significant risk factors associated with SIDS since all of the complications noted in this review can not only be modified and/or prevented, but if acquired, can be monitored closely under medical supervision. In comparison to other causes of infant mortality, the odds ratio of the delay in prenatal care is higher in infants who died of SIDS (OR=2.2 – versus- OR=1.6) (Peterson, Van Belle & Chin, 1979). An inverse correlation was found in the rate of SIDS and the time in which initiation of prenatal care began. Standfast et al. (1980) show that the SIDS rate was highest among those with no prenatal care, with the rate of 4.4 per 1000 in infants who received no prenatal care, which then decreased to 1.04 per 1000 if prenatal care was initiated in the first three months (Table 5).

Analysis of over 10 million live births from the National Center for Health Statistics data in the United States between 1995 and 1997 also revealed that a relationship exists between the absence of prenatal care and postneonatal death in women with high-risk pregnancy conditions (Vintzileos, Ananth, Smulian, Scorza, & Knuppel, 2002). The rates of postneonatal death increased from 2 per 1000 with prenatal care to 7.5 per 1000 in its absence. Additional findings show a 1.8 fold increase among African American women and a 1.59 fold increase in White women, with the association increasing in the following conditions: pregnancy-induced hypertension, maternal anemia, and abruptio placentae (Vintzileoa et al., 2002).
Contribution to the Literature

The establishment of the triple risk hypothesis, specifically the concept of the vulnerable infant, has provided an agenda for past and future research in terms of the relationship between complications in pregnancy and the outcome of SIDS. The prenatal risks involved with anemia, placental abnormalities, uterine bleeding, pregnancy induced hypertension, and eclampsia all share a common link to the mechanisms involved with fetal hypoxia, and consequently are related to SIDS. The early initiation into prenatal care provides the best opportunity to detect high-risk behaviors, such as smoking, as well as other risk factors associated with poor infant outcomes.

While a greater part of the SIDS research supports the hypothesis of the triple risk model, a bulk of the literature focus on the exogenous stressors that have an influence on SIDS. The publications on the cause of the vulnerable infant have been limited in recent years, and are assumed to be nonexistent in the populations under study. The present study will investigate the women and infants of Hillsborough County and Duval County to develop the profile of the SIDS infant, establish the likelihood of significant maternal risk factors, and determine if specific conditions that can cause fetal hypoxia during the prenatal period exist and consequently increase the risk of an infant becoming vulnerable during the first months of life.
Chapter Three

Methods

In 1991, former Governor Lawton Chiles passed Florida Legislation promoting the Healthy Start program with the intent of reducing infant mortality and low birth weight babies in addition to improving health outcomes of pregnant women. In over a decade, more than 30 coalitions have been established statewide consisting of representatives of the community that develop and implement programs to enhance maternal and child health. In order to plan and evaluate the Healthy Start programs in each of the participating counties, the Florida Department of Health, the Agency for Health care Administration, the Lawton and Rhea Chile Center for Healthy Mothers and Healthy Babies and the University of Florida Perinatal Data Research Center have worked collaboratively to develop the data linking birth and death records to Healthy Start prenatal screens.

As illustrated in Tables 1 and 2, the counties of Hillsborough and Duval have been chosen for this research because of the similarities they have in population size, demographic characteristics and live birth and death rates for 2000 (Unites States Census Bureau, 2000 & Florida Department of Health, 2000). This correlational study was based on a retrospective review of the data sets provided by the Healthy Start Coalition of Hillsborough County and the Northeast Florida Healthy Start Coalition in Duval County. The sections of The Birth and Fetal Death records linked to Healthy Start prenatal screens
and Infant Deaths that were of relevance to this study consisted of the birth files and
death records of infants in Hillsborough County and Duval County between January 1,
1998 and December 31, 2000. Specifically, the cohort for analysis focused on the
maternal complications in pregnancy listed on the birth certificate and the cause of death
of the infant recorded on the death certificate.

The initial identification of subjects was determined by the infant’s cause of death
disclosed as Sudden Infant Death Syndrome. The codes for this diagnosis, depending on
the cohort year, were categorized as either ICD-9 code 798.0 or ICD-10 code R95.
Secondly, women who gave birth during this time who reported any of the six pregnancy
complications of interest on the birth certificate were selected (See Appendix A). The six
pregnancy complications, identified as anemia, pregnancy-induced hypertension,
eclampsia, uterine bleeding, placenta previa and abruptio placentae, were chosen based
on their association with fetal hypoxia. The cohorts were studied to discover the
frequency of SIDS deaths, and in these cases, whether or not the mother was diagnosed
with any prenatal complications. Additional analysis was performed to compare these
SIDS cases to the overall prevalence of specified pregnancy complications in this cohort
to determine whether the complications in pregnancy were more frequent in cases of
SIDS deaths when compared to the overall prevalence of such events.

Subjects

The infants with an ICD-9 code of 798.0 or ICD-10 code R95 who had a linked
death to birth certificate in Hillsborough County or Duval County between 1998 and
2000 were selected to determine the number of SIDS cases. Further investigation
determined if the mothers of these infants reported any pertinent medical history or
complications during pregnancy. Subsequently, the record of women during this period of time who indicated complications during pregnancy was determined. The final sample size consisted of the 69 infants who died of SIDS, 34 from Hillsborough County and 35 from Duval County, and the total number of women who gave birth in these counties (n=86,342) between 1998 and 2000, with particular attention placed on those women who were reported to have one or more of the specified complications during pregnancy (n=6249). The sample represented a variety of social, economic and cultural backgrounds of women in two comparable counties in the state of Florida who delivered babies during the period of 1998 to 2000.

*Measures*

The pregnancy complications were measured by a set of defined codes, as illustrated in Appendix A, in the data dictionary of the document titled The Birth and Fetal Death Records Linked to Healthy Start Prenatal Screens and Infant Deaths (1998-2000). The codes were based on information obtained from the birth certificate under the categories of either Medical History Factors for Pregnancy (BMEDFAC) or Complications of Labor and Delivery (BCOMPFAC). The choice of complications during pregnancy was based on those cited in previous studies that are associated with fetal hypoxia. The diagnoses include: anemia, eclampsia, hypertension/pregnancy-associated, placenta previa, abruptio placentae, and uterine bleeding. The cause of death as SIDS was determined by the established ICD-9 code 798.0 or ICD-10 code R95 indicated on the death certificate.

In order to create a demographic profile of infants who died of SIDS in Hillsborough County and Duval County, the frequency of gender (BSEX), race
(BCRACE), and age (DDOD-BDOB), and time of year were analyzed. Other risk factors associated with both complications in pregnancy and SIDS, defined as maternal tobacco use and initiation into prenatal care, were also examined. The measure of tobacco use (BTOBUSE) and quantity (BTOBNUM) was determined in these populations, which were analyzed further to determine if this variable served as a confounder between each of the pregnancy complications and the outcome of SIDS. In addition, the month prenatal care was initiated (BPNCBGN) and the number of prenatal visits (BPNVIS) was studied to investigate whether the impact of late prenatal care and infrequent prenatal care was associated with poor infant outcomes.

Data Collection

The data was collected from the delivery cohort of the Birth and Fetal Death Records Linked to Healthy Start Prenatal Screens and Infant Deaths for the consecutive years between 1998 and 2000. The data sets for both Hillsborough County and Duval County were analyzed to determine the demographic profile, pregnancy complications, maternal risk behaviors, and cause of death of these cohorts. Except for the cause of death, the compilation of this information relied solely on the documentation made by the health care provider and the self-report by the mother at time of delivery, which was then recorded on the birth certificate. The cause of death was based on findings of the medical examiner that were subsequently documented with a specific ICD-9 or ICD-10 code on the death certificate filed with the state of Florida.

Data Analysis

The objective of the analysis was to explore the frequency and demographic profile of infants who died of SIDS and the incidence of prenatal complications in the
women who gave birth between 1998 and 2000 in Hillsborough County and Duval County. Initially, frequencies were obtained for the variables of race, age of death, and gender of the infant and the tobacco use, time of initiation into prenatal care, and pregnancy complications of the mother from Statistical Package for Social Sciences (SPSS). Chi-Square analysis and values of Cramer’s V were performed using Statistical Analysis Software (SAS) Version 8.01 to address each of the hypotheses and determine whether a correlation existed between the independent variables of pregnancy complications, maternal tobacco use, and history of prenatal care and the dependent variable of SIDS. In order to measure the association between the variables from an epidemiological perspective, a crude odds ratio was determined for each of the pregnancy complications, maternal tobacco use, and initiation into prenatal care and the outcome of SIDS with 95% confidence interval calculations to determine significance of findings.

Protection of Human Subjects

A feature of secondary data analysis prevented the necessity of direct contact with the participants in the study sample. The identification of participants was not known by the researcher throughout the investigation of these established cohorts. A written protocol was submitted to the Institutional Review Board (IRB) at the University of South Florida requesting approval to conduct the research. A written letter was received by the researcher stating that the project met the federal criteria to qualify as an exempt study because there was not direct involvement with human participants (Appendix B).
Chapter Four

Results

The present research was a retrospective study based on a secondary data analysis of the Birth and Fetal Death Records Linked to Healthy Start Prenatal Screens and Infant Deaths of Hillsborough County and Duval County for the time between 1998 and 2000. The purpose was to investigate the relationship between complications and risk factors in pregnancy associated with fetal hypoxia and the outcome of SIDS. The first section presents a description of the sample and demographic profile of infants who died of SIDS in the chosen counties. The second section analyzes the hypotheses of the study. The first six hypotheses are related to the specified complications in pregnancy, defined as anemia, eclampsia, pregnancy induced hypertension, placenta previa, abruptio placentae, and uterine bleeding and their association with SIDS. The seventh and eighth hypotheses address maternal tobacco use and prenatal care respectively and their association with SIDS. Lastly, the ninth hypothesis examined the role of maternal smoking and its possible confounding relationship between the specified prenatal complications as a group and SIDS.

Descriptive Statistics of Sample

According to the data files of the Birth and Fetal Death Records Linked to Healthy Start Prenatal Screens and Infant Deaths document, the sample consisted of
86,342 births - 45,877 (53%) in Hillsborough County and 40,465 (47%) in Duval County, between 1998 and 2000. Of the 86,342 births, the rate of having at least one of the specified pregnancy complications was 72.37 per 1000 births (n=6,249). The classification of the 6,249 pregnancy complications, as noted in Table 3, was as following: anemia; 24.13%, pregnancy-induced hypertension; 49.62%, eclampsia; 13.20%, uterine bleeding; 2.7%, placenta previa; and 6.27%, abruptio placentae; 4.00%. On average, 33.63% of the women with one of the six pregnancy complications of interest reported more than one condition on the birth certificate. Of the women with anemia, 30.90% reported more than one complication, in addition, 30.18% with pregnancy-induced hypertension, 45.23% with eclampsia, 37.87% with uterine bleeding, 43.88% with placenta previa and 26.8% of those with abruptio placentae were found to have more than one complication during pregnancy. The examination of the births that later resulted in SIDS revealed that 8.69% of the women had more than one of the pregnancy complications, of these, 4.34% reporting anemia or pregnancy induced hypertension, 1.5% with eclampsia or abruptio placentae. There were no reports of uterine bleeding or placenta previa among these cases of SIDS.

The overall rate of SIDS was 0.80 per 1000 births (n=69). As shown in Table 4, the cases of SIDS consisted of 65.21% males and 34.78% females, of which 60.86% were White, 37.68% were Black, and 1.45% were categorized as Native American. The average age at death was approximately 80 days. The report of tobacco use during pregnancy was 26.08% among the SIDS cases, with approximately 61.11% of those who smoked admitting to smoking at least ½ a pack a day and 38.89% smoking at least 1 pack per day. Among the SIDS cases, 73.13% of the women initiated prenatal care in the first
trimester, 17.91% in the second trimester, and 8.95% at the seventh month or not at all. The highest percent (17.39%) of the prenatal care visits consisted of the recommended number for a healthy pregnancy of 12, yet 40.61% of women received 10 or less prenatal care visits.

The crude risk ratios used to measure the association for each of the pregnancy complications and maternal risk factor and the outcome of SIDS are shown in Tables 5 through 13. Of the six complications of interest, significance was found in women with eclampsia being 4.7 times more likely to have an infant die of SIDS when compared to women without eclampsia (95% CI 1.67, 16.29). The risk behaviors of maternal smoking and late initiation into prenatal care were also found to have a positive association with 95% confidence in the outcome of SIDS. Further analysis of the initiation into prenatal care showed the highest risk among those who receive no prenatal care (OR=4.37, 95% CI 1.38, 13.89) when compared to those who initiated prenatal care sometime during the pregnancy.

Analyses of Hypotheses I-VI

Initial analysis was performed to determine if Hillsborough County and Duval County differed in terms of the type of pregnancy complications. When grouping all the maternal diagnoses together, it was concluded that the two counties were different in the distribution of each of the six pregnancy complications, defined as anemia, eclampsia, pregnancy induced hypertension, placenta previa, abruptio placentae, and uterine bleeding (p<.0001) with a Cramer’s V of 0.4, which suggests a strong measure of association exists. Because the distribution of the frequencies was so different between the two counties, further analysis was performed to ensure that the county did not serve
as a confounder between each of the pregnancy complications and the outcome of SIDS. Chi square tests were performed separately for each county for the variables of anemia, PIH, and eclampsia. Statistical significance was found in Duval eclampsia cases only (Chi Square 8.67, p=0.0032). A Breslow Day Test of Homogeneity was done to determine if the odds ratios were significantly different between the two counties. Because each of the tests were proven to be insignificant, it was concluded that the county in which the SIDS infant was born was not a confounder between the pregnancy complication and the outcome of SIDS, and the odds ratios illustrated in Tables 5-7 denote the measure of association.

The first six hypotheses addressed the research question as to whether an association existed between each of the pregnancy complications, and the outcome of SIDS. A Chi-Square test was performed on each of the pregnancy complications using SAS, with the strength of the relationship reported in Cramer’s V values. In order to keep the overall $\alpha$ of .05 under control, a modified Bonferroni procedure identified as a Holm procedure, was used to test these hypotheses in a family-wise approach. The Holm procedure only declared statistical significance in the relationship between the complication of eclampsia and SIDS ($p<.05$), yet Cramer’s V showed the strength of the association was valued at 0.01, which is generally considered to be a rather weak association.

*Analysis of Hypothesis VII*

An association exists between women who do not receive prenatal care and the outcome of SIDS (Chi-Square 7.45, $p<.05$, Cramer’s V=.01). Further analysis was performed to investigate the relationship between early initiation into prenatal care,
defined as months 1-4, and late or no prenatal care. An association exists between women who receive prenatal care at month 5 or later and the outcome of SIDS (Chi-Square 11.22, p<.05, Cramer’s V= .01).

Analysis of Hypothesis VIII

An association exists between women who smoke and the outcome of SIDS (Chi-Square 29.28, p<.0001), strength of the association is minimal (Cramer’s V= .02).

Analysis of Hypothesis IX

It was hypothesized that smoking may act as a potential confounder between the pregnancy complications and the outcome of SIDS. Table 14 shows a crude breakdown of the population based on smoking status with the adjusted odds ratio after controlling for smoking. The purpose of using the Cochran Mantel-Haenszel Statistics was to determine if the group of pregnancy complications was independent of the SIDS cases when adjusting for smoking. Further analysis was performed using SAS to determine the results of the Breslow-Day Test for Homogeneity of the Odd Ratio, which was found to be insignificant at p=.7301. The null hypothesis of homogeneity between the odds ratios is accepted; therefore, there is no difference in the odds ratios between those who smoke and the nonsmokers. It is concluded that smoking is not a confounder in this study and that a woman with one of the pregnancy complications is 2.2 more likely to have an infant die of SIDS when controlling for smoking status (95% CI= 1.13-4.31).
Chapter Five

Discussion

For over three decades, fetal hypoxia has been hypothesized to be a predisposed factor that increases an infant’s risk of dying from SIDS. In spite of this, the studies that have tested this hypothesis have been limited. The main purpose of the current study was to present additional information on the prevalence of pregnancy complications associated with fetal hypoxia and the relationship each has on the future outcome of SIDS. An extension of this analysis assisted in the development of a descriptive profile of the SIDS infant unique to the populations of Hillsborough County, Florida and Duval County, Florida. Specifically, the characteristics of race, gender, age of death, and the inquiry of particular maternal risk factors were revealed to assist with the proper interventions that can be established to reduce the frequency of SIDS in each of these populations.

The Profile of the SIDS Infant

The demographic profile of the infants who died of SIDS in Hillsborough County and Duval County reveal the highest frequency among males, with 62.22% being White and 33.33% being Black. It is unclear as to the reason, but these results are similar to past research that have found a 50% increased risk of male infants dying of SIDS when compared to females (Hoffman & Hillman, 1992). The analysis of each population shows that 78.78% of SIDS infants are White in Hillsborough County compared to
51.42% in Duval County; a finding that completely contradicts the current research that
proclaims that African American infants are nearly two-and-a-half times more likely to
die of SIDS than white infants (SIDS Alliance, 1998). From the perspective that supports
the environmental influences of SIDS, it has been hypothesized that the racial differences
in these counties may be the result of intense program development and intervention
supported by the ‘Back to Sleep Campaign’ that was initiated by the Healthy Start
programs prior to 1998. During this time, emphasis may have been placed on the Black
population because research had strongly suggested that this is where the greatest effort
was needed to decrease the rates of infant mortality (Perrin, Stanley, Myers, Bernecki-
Dejoy, Harris, & Perrin, 2002).

The average infant’s age at death is approximately 80 days, with 61.01% of the
deaths taking place between the months of October and March. This is a mind provoking
finding considering that the correlation of SIDS deaths during the winter months are
often related to cold climate, heavier bedding, and heated houses (Hillman & Hoffman,
1992). Such climate is rare in this part of the country, yet the findings are consistent with
other publications that examine environmental factors. The age of the infant at death has
led to a number of etiological inferences; however it is important to consider the actual
gestational age at birth since the stage of anatomical and physiological development may
differ (Hoffman & Hillman, 1992). Furthermore, studies have also taken a closer look
into racial differences and maternal tobacco use among those who die earlier, yet the
efforts made to confirm these results have not been remarkable (Haglund & Cnattingius,
Summary of Maternal Pregnancy Complications

Of the 86,342 births in Hillsborough County and Duval County between 1998 and 2000, 6,249 reported having at least one of the pregnancy complications associated with fetal hypoxia and 2,102 had more than one. Overall, the incidence of placental abnormalities in these two counties were consistent with the current literature which states the occurrence of placenta previa is approximately 1 in 200 births and abruptio placentae occurs in 0.4-3.5% of births (Beers & Berkow, 1999). Considering the significance of uterine bleeding in other studies and the likelihood that it is associated with a placental abnormality, it is surprising that the frequency of this diagnosis was so low. Standfast et al. (1980), report that abnormal uterine bleeding “stands out as being strongly associated with SIDS at 58%”, yet the sample size of SIDS mothers was considerably smaller than the current study (p. 1064). Furthermore, abnormal uterine bleeding was the only significant risk factor reported by Buck et al. (1989) when the comparison was made between SIDS infants and non-SIDS controls.

The findings of the current study show that uterine bleeding only occurred in 0.19% of women who reported one of the complications in pregnancy associated with fetal hypoxia and none were reported among the SIDS cases. Further scrutiny of the data dictionary that was developed as part of the document titled The Birth and Fetal Death records Linked to Healthy Start Prenatal Screens and Infant Deaths revealed a possible explanation for these findings. The diagnosis of uterine bleeding was measured under the variable of Medical History Factors for Pregnancy and the diagnoses of placenta previa and abruptio placentae were categorized as a Complication of Labor and Delivery. As a result, it could not have been assumed that a connection could be made between the
complaint of uterine bleeding and the occurrence of one of the placental abnormalities. Additionally, the code for “other excessive bleeding” that was located in the same section of Complications of Labor and Delivery may have been used for the uterine bleeding that occurs with placenta previa and abruptio placentae, but the lack of definition for this code made it impossible to make such an assumption for analysis purposes.

The mothers of Duval County had significantly higher rates of anemia (17.11%-vs 7.03%) and eclampsia (12.02%-versus-1.25%) when compared to Hillsborough County. The complication most reported by the mothers of Hillsborough County was pregnancy-induced hypertension (PIH= 34.84%). Taking into consideration the severity of the condition and the fact that only 1 in 200 patients with preeclampsia will eventually develop eclampsia, it is interesting to note the findings of the relationship between PIH and eclampsia in this study. In Duval County, 921 women reported having PIH during their pregnancy, 751 reported eclampsia, and 11% of those with PIH reported having eclampsia. Whereas in Hillsborough County, 2180 women experienced PIH and only 78 reported the diagnosis of eclampsia. The rate of those with PIH in Hillsborough County who also reported eclampsia was approximately 1.46%. The possible explanation for such a discrepancy may be a result of self-report bias on the birth certificate.

It is speculated that the education received by the obstetric patient during prenatal care may not have provided a clear differentiation between the risk of hypertension and how it may result in more severe problems such as preeclampsia or eclampsia. Furthermore, the terminology describing hypertension, preeclampsia and eclampsia may have been used interchangeably, and with the only choice on the birth certificate being eclampsia, this option may have triggered recall of such terminology. Because of the
potential of this possibility, it may be necessary to use caution in the upcoming interpretation of the SIDS outcomes. It is recognized that the most accurate method for preventing this discrepancy would be to validate the information documented on the birth certificate against medical records of the prenatal care visits, yet such a measure is beyond the scope of the study since strict measures to protect patient confidentiality have made it difficult to obtain such information.

**Hypotheses of Association between Pregnancy Complications and SIDS**

The statistical approach in this study included the Chi-Square Test of Independence and the Cramer’s V value. The six pregnancy complications associated with fetal hypoxia that were the focus of the study included anemia, eclampsia, pregnancy induced hypertension, uterine bleeding, placenta previa and abruptio placentae. Generally speaking, it is difficult to compare the findings of this study to others that investigate similar associations between these pregnancy complications and SIDS because the complexity of their analyses allowed for more optimal control of potential confounders by the use of multivariate analyses. With that being said, the preliminary findings of these populations are not in agreement with other studies. The frequency of uterine bleeding and placenta previa are absent in the cases of SIDS and statistical significance is found only in the complication of eclampsia with the magnitude of the strength being minimal. Although the use of the Holm’s test was conducted to keep the \( \alpha \) level at .05 for the entire group of pregnancy complications, it is questionable as to the validity of these findings considering the dilemma mentioned previously of the probable report bias and confusion of terminology between hypertension and the more severe diagnoses of preeclampsia and eclampsia. Because of the possibility of
misdiagnosis, an analysis was performed beyond the original calculation by grouping eclampsia and pregnancy-induced hypertension together as one category to determine if infants were more likely to die of SIDS. Once they were combined, it is worthy to note that significance found in eclampsia alone was eliminated, and together the findings were not significant (p value=0.09). Additional research is needed to determine the accuracy of the self-report on the birth certificate. It is recommended that a more in depth examination of medical records be carried out to verify the extent of the severity of hypertension in these counties as well as determine the prevalence of uterine bleeding that occurs simultaneously with one of the placental abnormalities.

*Hypotheses of Maternal Tobacco Use*

The selection of the risk factors related to maternal tobacco use was chosen for analysis because it is related to the adverse events that occur during pregnancy as well as the outcome of SIDS. The toxic effect of nicotine and other materials in cigarettes are known to decrease the blood flow from the placenta to the fetus, and smoking increases the risk of adverse events such as hypertension and placental abnormalities (Schuler-Maloney & Lee, 1998). It also augments the probability that these conditions will cause some degree of fetal hypoxia.

On a national level, it is estimated that approximately 12% of all women report smoking during pregnancy (Centers for Disease Control & Prevention, [CDCP], 2001). In an analysis of similar data used in this study, it has been estimated that infant deaths would decline by 12.52% if women in Florida received adequate prenatal care and did not smoke during pregnancy (Thompson, Simmons & Graham, 2002). According to the current study, 10% of the women who gave birth between 1998 and 2000 in Hillsborough
County and Duval County reported smoking on the birth certificate. The women who reported smoking during pregnancy were 3 times more likely to have an infant die of SIDS when compared to nonsmokers (95% CI =1.83, 5.36). This is an unadjusted risk that does not take factors such as age, socioeconomic status, race, or education level into consideration. However, the smoking status of the mother was obtained before the outcome of SIDS was known, it is impossible that misclassification of smoking or outcome has occurred in this analysis. The only concern is that the self-report of smoking during pregnancy may be underestimated, yet this would not decrease the present strength of the association, it would only make it more pronounced.

Interestingly, the number of smokers in this cohort (n=8,723), 6.6% experienced at least one of the six pregnancy complications of interest in the study compared to 7.3% of nonsmokers. Because the rates of pregnancy complications are higher among nonsmokers, caution should be used in the interpretation of these results. A possible explanation of these findings may be related to the fact that 90% of those with a pregnancy complication were classified as non-smokers. The factor of smoking was tested to determine if confounding existed between pregnancy complications and SIDS. Because the frequency of each of the six complications was so small in the SIDS cases, the diagnoses were grouped together. The results showed that smoking was not a confounder between the two variables, and that a risk remains between the two variables even after controlling for tobacco use. When taking the influence of self report into consideration, it is possible that the women who smoked during pregnancy and experienced a complication were aware of the association between the exposure to smoking and the risks involved, therefore had may not reported the tobacco use but
perhaps felt obliged to report the pregnancy complications since verification of the medical record was feasible.

**Hypothesis of Late Initiation into Prenatal Care**

Women who initiated prenatal care during the second half of their pregnancy (months 5-9) are 3 times more likely to have an infant die of SIDS when compared to those who receive prenatal care in the first four months of pregnancy. (95% CI= 1.39, 4.66) and the risk increases to 4.37 for those who receive no prenatal care (95% CI= 1.37, 13.89). While it is possible that women do not recall the exact number of prenatal care visits, 40.6% received less than 10 visits, when the recommended number with no symptoms of a high-risk pregnancy is 12 visits. These results are consistent with other studies that affirm the mothers of SIDS cases are more likely to initiate prenatal care after the first trimester (Peterson et al., 1979; Buck et al., 1991). In addition, the risk rate of 4.37 in those with no prenatal care is equivalent to findings based on the same type of analysis reported by Standfast et al. (1980).

**Limitations of Study**

The major limitations of this research design are related to the secondary analysis of state managed birth and death certificate data. The quality of the data sets is questionable since it relies heavily on the accurate self-report of the mother and thorough documentation of the health care provider at time of delivery. Although the diagnoses of interest have shown substantial inference to causality in other studies, it is believed that these results were determined because of the opportunity to verify the data on the birth certificate to the documentation on the medical record. The correctness of methods involved in verification of information, data cleansing and management were constrained
in this study due to the fact that it was based on a secondary data analysis and the access
to medical records was not possible. Furthermore, the codes assigned to each of the
pregnancy complications were restricted, the source of data entry is unknown, and the
method in which the data was entered was impractical and difficult to analyze.

Combining Hillsborough County and Duval County was effective in increasing
the sample size, yet this does not change the fact that the independent and dependent
variables of the study are considered to be rare. The rate of SIDS is approximately 0.8
per 1,000, and a majority of the measured pregnancy complications occur in less than 8
per 1,000 births in these counties. It is necessary to increase the population further if the
intention is to increase the exposures and outcomes, yet it is essential that the choice of
additional populations be comparable to these current counties in order to preserve the
generalizability and external validity of the findings.

Lastly, while the choice of the univariate analyses has been beneficial in
apprehending a broad understanding of the associations that exist within the populations
of Hillsborough County and Duval County, the discovery of the subtle relationships
require more complex techniques of analyses that will measure and control for extraneous
factors and assist in a more thorough understanding of the interactions that exist. The
improvement in both research design and analysis in future studies should address other
determinants that may influence these results and facilitate the refinement of the
associations that have been presented, if they do indeed exist.

**Implications**

Over thirty years ago, a panel of physicians collaborated to review evidence of
infants who died suddenly and unexpectedly in the postneonatal period. While the
identification of the term Sudden Infant Death Syndrome or SIDS was simple, the issue involved in the classification of infants has not been an easy task. SIDS remains a ‘diagnosis of exclusion’, and despite the vast amount of research from multiple health disciplines, the definition continues to be imprecise and adaptable to each pathology department across the nation (Beckwith, 2003).

While the problem with the definition of SIDS continues, immense progress has been made in recent years to reduce the number of infants who die of SIDS. Research has proven that SIDS is undeniably multifactorial and that it is influenced by various potential factors as evidenced by the triple risk model. Because the model begins with the vulnerable infant, a preference was made to focus on events that occur during pregnancy that may lead to the outcome of the vulnerable infant. Since the medical recommendations, public awareness campaigns, and education on prevention have not been effective in the complete eradication of SIDS, the events surrounding fetal development and birth call for additional research regarding their role in SIDS. The outcome of SIDS continues to devastate approximately 9 families a day when a baby is found dead of “unexplained” reasons. The findings of this study have contributed to the current evidence relating prenatal events to SIDS. The public health implications can guide the necessary intervention towards a greater awareness and more effective preventable measures in hopes to eliminate SIDS overall.

Recommendations for Future Study

The obvious goal of SIDS research is to determine the etiology of the event, establish preventative measures and to improve maternal and child health so that SIDS will no longer exist. For these objectives to be successful, research such as this must
continue so that the framework of knowledge and resources can expand beyond what is currently known. The findings of this current study can direct in future proceedings specific to the populations of Hillsborough County and Duval County, Florida. While the birth and death certificate data has proven beneficial in developing a broad depiction of the prenatal events that occur, it is recommended that a more detailed investigation of other types of records be explored to verify the findings of this study. Although lengthy and expensive, the most accurate method to obtain vital information on the events that take place during pregnancy as well as identify potential factors that categorize a woman as high risk is to follow them prospectively from initiation into prenatal care. Furthermore, the benefits of the periodic assessment of women in this population will not only assist in the development of a high risk profile, but will provide an optimal opportunity and environment to educate the woman on the importance of maintaining good health during pregnancy. An alternative method, though not as accurate, would be to examine the medical records and interview the mothers at time of delivery, when the events of the pregnancy are easily remembered and attainable.

It is recommended that funding increase at the state level for community-based organizations such as Healthy Start to develop social marketing schemes that will target the women who are smoking during their pregnancy and initiating prenatal care later than the recommended time. The evaluation of Healthy Start sponsored programs have proven to be quite beneficial in the reduction of infant mortality since home visits to new mothers were implemented (Florida Department of Health, 2000-2003), yet flexibility and resources are necessary to ensure coverage of the population during the prenatal period as well as after the infant is born. In conclusion, the community needs to take
aggressive measures to reach these women and guarantee that they are receiving the necessary healthcare if work constraints and time limitations are preventing the early initiation into prenatal care
References


Bibliography


Table 1
2000 Demographic Profile by County

<table>
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<tr>
<th>Characteristic</th>
<th>Hillsborough</th>
<th>Duval</th>
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<tbody>
<tr>
<td>Total Population</td>
<td>998,948</td>
<td>778,879</td>
</tr>
<tr>
<td>Male</td>
<td>488,772 (48.9%)</td>
<td>377,781 (48.5%)</td>
</tr>
<tr>
<td>Female</td>
<td>510,176 (51.07%)</td>
<td>401,098 (51.49%)</td>
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<td>White</td>
<td>750,903 (75.2%)</td>
<td>512,469 (65.8%)</td>
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<td>Black</td>
<td>149,923 (15.0%)</td>
<td>216,780 (27.8%)</td>
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<td>Asian</td>
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<td>21,137 (2.7%)</td>
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<td>Hispanic/Latino</td>
<td>179,692 (18.0%)</td>
<td>31,946 (4.1%)</td>
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<tr>
<td>Age under 5</td>
<td>68,444(6.85%)</td>
<td>56,247 (7.22%)</td>
</tr>
</tbody>
</table>

Table 2
2000 Vital Statistics of Resident Live Births and Deaths by County

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Hillsborough (% of FL)</th>
<th>Duval (% of FL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Live Births</td>
<td>14,662(14.9%)</td>
<td>12,169(15.7)</td>
</tr>
<tr>
<td>White</td>
<td>11,146(13.4%)</td>
<td>74289(13.2%)</td>
</tr>
<tr>
<td>Black</td>
<td>2982(22.6%)</td>
<td>4223(22.4%)</td>
</tr>
<tr>
<td>Other</td>
<td>494 (24.8%)</td>
<td>511(23.1%)</td>
</tr>
<tr>
<td>Total Neonatal Deaths</td>
<td>65 (5.3%)</td>
<td>73(5.0%)</td>
</tr>
<tr>
<td>White</td>
<td>22(3.0%)</td>
<td>40(3.6%)</td>
</tr>
<tr>
<td>Black</td>
<td>42(9.9%)</td>
<td>31 (10.4%)</td>
</tr>
<tr>
<td>Other</td>
<td>1(2.0%)</td>
<td>2(4.0%)</td>
</tr>
<tr>
<td>Total Infant Deaths</td>
<td>118(9.7%)</td>
<td>116(7.9%)</td>
</tr>
<tr>
<td>White</td>
<td>46(6.2%)</td>
<td>62(5.6%)</td>
</tr>
<tr>
<td>Black</td>
<td>71(16.8%)</td>
<td>51(17.1%)</td>
</tr>
<tr>
<td>Other</td>
<td>1(2.0%)</td>
<td>3 (6.1%)</td>
</tr>
</tbody>
</table>
Table 3
Frequency of Pregnancy Complication by County and Year

<table>
<thead>
<tr>
<th>Pregnancy Complication</th>
<th>Hillsborough</th>
<th>Total (%)</th>
<th>Duval</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1998</td>
<td>1999</td>
<td>2000</td>
<td>Total (%)</td>
</tr>
<tr>
<td>Anemia</td>
<td>156</td>
<td>143</td>
<td>140</td>
<td>439 (7.03%)</td>
</tr>
<tr>
<td>PIH</td>
<td>620</td>
<td>806</td>
<td>754</td>
<td>2180 (34.89%)</td>
</tr>
<tr>
<td>Eclampsia</td>
<td>22</td>
<td>26</td>
<td>30</td>
<td>78 (1.25%)</td>
</tr>
<tr>
<td>Uterine Bleeding</td>
<td>39</td>
<td>25</td>
<td>35</td>
<td>99 (1.58%)</td>
</tr>
<tr>
<td>Placenta Previa</td>
<td>67</td>
<td>77</td>
<td>50</td>
<td>194 (3.10%)</td>
</tr>
<tr>
<td>Abruptio Placentae</td>
<td>48</td>
<td>49</td>
<td>61</td>
<td>158 (2.53%)</td>
</tr>
<tr>
<td>Total (n=6249)</td>
<td>952</td>
<td>1126</td>
<td>1070</td>
<td>3148 (50.38%)</td>
</tr>
</tbody>
</table>

PIH=Pregnancy Induced Hypertension
Table 4
Distribution of Infants who died of SIDS by County between 1998-2000.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hillsborough</th>
<th>Duval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>34</td>
<td>35</td>
</tr>
<tr>
<td>Male</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>Female</td>
<td>14</td>
<td>10</td>
</tr>
<tr>
<td>White</td>
<td>26</td>
<td>16</td>
</tr>
<tr>
<td>Black</td>
<td>8</td>
<td>18</td>
</tr>
<tr>
<td>Indian</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Age at Death (in days)</td>
<td>93.5+/−68</td>
<td>66.6+/−107</td>
</tr>
<tr>
<td>Maternal Smoking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>No</td>
<td>23</td>
<td>27</td>
</tr>
<tr>
<td>Number of Cigarettes Smoked</td>
<td>10.5/day</td>
<td>9.25/day</td>
</tr>
<tr>
<td>Month PNC began</td>
<td>2.78</td>
<td>2.2</td>
</tr>
<tr>
<td>Number of PNC visits</td>
<td>12</td>
<td>9.37</td>
</tr>
</tbody>
</table>
### Table 5
Maternal anemia during pregnancy and the risk of SIDS

<table>
<thead>
<tr>
<th>Anemia</th>
<th>SIDS</th>
<th>Non-SIDS</th>
<th>Crude OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>3</td>
<td>1508</td>
<td>OR= 2.55 (0.81, 11.18)</td>
</tr>
<tr>
<td>No</td>
<td>66</td>
<td>84765</td>
<td></td>
</tr>
<tr>
<td>Total(^a)</td>
<td>69</td>
<td>86273</td>
<td></td>
</tr>
</tbody>
</table>
\(^a\) Subjects with missing data were excluded

### Table 6
Maternal hypertension associated with pregnancy and the risk of SIDS

<table>
<thead>
<tr>
<th>PIH</th>
<th>SIDS</th>
<th>Non-SIDS</th>
<th>Crude OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>3</td>
<td>3101</td>
<td>OR= 1.22 (0.39, 3.72)</td>
</tr>
<tr>
<td>No</td>
<td>66</td>
<td>83172</td>
<td></td>
</tr>
<tr>
<td>Total(^a)</td>
<td>69</td>
<td>86273</td>
<td></td>
</tr>
</tbody>
</table>
\(^a\) Subjects with missing data were excluded

### Table 7
Maternal eclampsia during pregnancy and the risk of SIDS

<table>
<thead>
<tr>
<th>Eclampsia</th>
<th>SIDS</th>
<th>Non-SIDS</th>
<th>Crude OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>3</td>
<td>755</td>
<td>OR= 4.67 (1.67, 16.29)</td>
</tr>
<tr>
<td>No</td>
<td>66</td>
<td>85518</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>69</td>
<td>86273</td>
<td></td>
</tr>
</tbody>
</table>
\(^a\) Subjects with missing data were excluded
Table 8  
Maternal uterine bleeding during pregnancy and the risk of SIDS

<table>
<thead>
<tr>
<th>Uterine Bleeding</th>
<th>SIDS</th>
<th>Non-SIDS</th>
<th>Crude OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>0</td>
<td>144</td>
<td>OR = 0.00</td>
</tr>
<tr>
<td>No</td>
<td>69</td>
<td>84129</td>
<td></td>
</tr>
<tr>
<td>Totala</td>
<td>69</td>
<td>86273</td>
<td></td>
</tr>
</tbody>
</table>

a Subjects with missing data were excluded

Table 9  
Maternal placenta previa during pregnancy and the risk of SIDS

<table>
<thead>
<tr>
<th>Placenta Previa</th>
<th>SIDS</th>
<th>Non-SIDS</th>
<th>Crude OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>0</td>
<td>168</td>
<td>OR = 0.00</td>
</tr>
<tr>
<td>No</td>
<td>69</td>
<td>86105</td>
<td></td>
</tr>
<tr>
<td>Totala</td>
<td>69</td>
<td>86273</td>
<td></td>
</tr>
</tbody>
</table>

a Subjects with missing data were excluded

Table 10  
Maternal abruptio placentae during pregnancy and the risk of SIDS

<table>
<thead>
<tr>
<th>Abruptio Placentae</th>
<th>SIDS</th>
<th>Non-SIDS</th>
<th>Crude OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1</td>
<td>254</td>
<td>OR = 5.04 (0.69, 35.62)</td>
</tr>
<tr>
<td>No</td>
<td>68</td>
<td>86019</td>
<td></td>
</tr>
<tr>
<td>Totala</td>
<td>69</td>
<td>86273</td>
<td></td>
</tr>
</tbody>
</table>

a Subjects with missing data were excluded
Table 11
Maternal tobacco use during pregnancy and the risk of SIDS

<table>
<thead>
<tr>
<th>Tobacco Use</th>
<th>SIDS</th>
<th>Non-SIDS</th>
<th>Crude OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>18</td>
<td>8705</td>
<td>OR= 3.13 (1.83, 5.36)</td>
</tr>
<tr>
<td>No</td>
<td>51</td>
<td>77318</td>
<td></td>
</tr>
<tr>
<td>Totalª</td>
<td>69</td>
<td>86273</td>
<td></td>
</tr>
</tbody>
</table>
ª Subjects with missing data were excluded

Table 12
Late Initiation into prenatal care and the risk of SIDS

<table>
<thead>
<tr>
<th>Month of Initiation</th>
<th>SIDS</th>
<th>Non-SIDS</th>
<th>Crude OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-9 or none</td>
<td>13</td>
<td>6879</td>
<td>OR= 2.70 (1.39, 4.66)</td>
</tr>
<tr>
<td>1-4</td>
<td>54</td>
<td>77235</td>
<td></td>
</tr>
<tr>
<td>Totalª</td>
<td>69</td>
<td>86273</td>
<td></td>
</tr>
</tbody>
</table>
ª Subjects with missing data were excluded

Table 13
Lack of prenatal care during pregnancy and the risk of SIDS

<table>
<thead>
<tr>
<th>Month of Initiation</th>
<th>SIDS</th>
<th>Non-SIDS</th>
<th>Crude OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>3</td>
<td>890</td>
<td>OR= 4.37 (1.38, 13.89)</td>
</tr>
<tr>
<td>1-9</td>
<td>64</td>
<td>83224</td>
<td></td>
</tr>
<tr>
<td>Totalª</td>
<td>67</td>
<td>86273</td>
<td></td>
</tr>
</tbody>
</table>
ª Subjects with missing data were excluded
Table 14
Pregnancy Complication and the risk of SIDS while controlling for smoking

<table>
<thead>
<tr>
<th>PG COMP</th>
<th>SIDS</th>
<th>Non-SIDS</th>
<th>PG COMP</th>
<th>SIDS</th>
<th>Non-SIDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>2</td>
<td>577</td>
<td>Yes</td>
<td>8</td>
<td>5662</td>
</tr>
<tr>
<td>No</td>
<td>16</td>
<td>8128</td>
<td>No</td>
<td>43</td>
<td>71656</td>
</tr>
<tr>
<td>Total</td>
<td>18</td>
<td>8723</td>
<td>Total</td>
<td>51</td>
<td>77318</td>
</tr>
</tbody>
</table>

CRUDE OR= 1.76  
95% CI (.41, 7.62)  

CRUDE OR=2.35  
95% CI (1.11, 5.00)  

ADJUSTED OR=2.2  
95% CI (1.13, 4.31)  

\(^a\) Subjects with missing data were excluded
Appendices
# Appendix A

## Modified Description of Data Fields

The following fields are from the BIRTH CERTIFICATE:

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
</table>
| BLINK   | De-identified Number for Births  
A random number between 1000000 and 1999999  
If the same number appears more than once, this indicates that the same birth was matched to duplicate prenatal screens. |
| BDOB    | Date of Birth  
Month: 01-12 or 99 for Not classifiable  
Day: 01-31 or 99 for Not classifiable  
Year: 1998, 1999, or 2000 |
| BCNTYOB | County of Birth  
26......Duval  
39......Hillsborough |
| BSEX    | Child’s Sex  
1......Male  
2......Female  
9......Not classifiable |
| BCHRACE | Child’s Race  
1......White  
2......Black  
3......Indian (See Appendix H)  
4......Chinese  
5......Japanese  
6......Hawaiian  
7......Other entries  
8......Filipino  
9......Not reported  
0......Other Asian or Pacific Islander  
The child’s race is determined by using the mother’s race and father’s race. See Appendix E for details. |
| BTOBUSE | Tobacco Use  
1......Yes  
2......No  
9......Not classifiable |
| BTOBNUM | Number of Cigarettes Smoked  
00......None  
01-97......As shown  
98......98 or more  
99......Not classifiable |
### Appendix A (Continued)

<table>
<thead>
<tr>
<th>BMEDFAC</th>
<th>Medical History Factors for Pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to seventeen 2-digit codes are recorded in this field.</td>
<td></td>
</tr>
<tr>
<td>00....None</td>
<td>10....Eclampsia</td>
</tr>
<tr>
<td>01....Anemia (Hct. &lt; 30/Hgb &lt; 10)</td>
<td>11....Incompetent cervix</td>
</tr>
<tr>
<td>02....Cardiac disease</td>
<td>12....Previous infant 4000+ grams</td>
</tr>
<tr>
<td>03....Acute or chronic lung disease</td>
<td>13....Previous preterm or small-for-</td>
</tr>
<tr>
<td>04....Diabetes gestational-age infant</td>
<td></td>
</tr>
<tr>
<td>05....Genital herpes</td>
<td>14....Renal disease</td>
</tr>
<tr>
<td>06....Hydramnios/Oligohydramnios</td>
<td>15....Rh sensitization</td>
</tr>
<tr>
<td>07....Hemoglobinopathy</td>
<td>16....Uterine bleeding</td>
</tr>
<tr>
<td>08....Hypertension, chronic</td>
<td>17....Other specified</td>
</tr>
<tr>
<td>09....Hypertension, pregnancy-associ</td>
<td>99....Not classifiable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BCOMPFAC</th>
<th>Complications of Labor &amp; Delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to sixteen 2-digit codes are recorded in this field.</td>
<td></td>
</tr>
<tr>
<td>00....None</td>
<td>09....Prolonged labor (&gt; 20 hrs)</td>
</tr>
<tr>
<td>01....Febrile (&gt; 100 F or 38 C)</td>
<td>10....Dysfunctional labor</td>
</tr>
<tr>
<td>02....Meconium, moderate/heavy</td>
<td>11....Breech/Malpresentation</td>
</tr>
<tr>
<td>03....Premature rupture of membranes</td>
<td>12....Cephalopelvic disproportion</td>
</tr>
<tr>
<td>(&gt; &gt; 12 hrs)</td>
<td>13....Cord prolapse</td>
</tr>
<tr>
<td>04....Abruptio placenta</td>
<td>14....Anesthetic complications</td>
</tr>
<tr>
<td>05....Placenta previa</td>
<td>15....Fetal distress</td>
</tr>
<tr>
<td>06....Other excessive bleeding</td>
<td>16....Other specified</td>
</tr>
<tr>
<td>07....Seizures during labor</td>
<td>99....Not classifiable</td>
</tr>
<tr>
<td>08....Precipitous labor (&lt; 3 hrs)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BMOPNBGN</th>
<th>Month of Pregnancy Prenatal Care Began</th>
</tr>
</thead>
<tbody>
<tr>
<td>0........None</td>
<td></td>
</tr>
<tr>
<td>1-8........First through eighth month</td>
<td></td>
</tr>
<tr>
<td>9........Ninth month or later</td>
<td></td>
</tr>
<tr>
<td>U.........Not classifiable</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BNOPNVIS</th>
<th>Number of Prenatal Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>00........None</td>
<td></td>
</tr>
<tr>
<td>01-48........As shown</td>
<td></td>
</tr>
<tr>
<td>49........49 or more</td>
<td></td>
</tr>
<tr>
<td>99........Not classifiable</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DDOD</th>
<th>Decedent’s Date of Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month: 01-12........Jan-Dec</td>
<td></td>
</tr>
<tr>
<td>99........Not classifiable</td>
<td></td>
</tr>
<tr>
<td>Day: 01-31........Day of month</td>
<td></td>
</tr>
<tr>
<td>99........Not classifiable</td>
<td></td>
</tr>
<tr>
<td>Year: 1998 or 1999</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DCAUSDTH</th>
<th>Underlying Cause of Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Four-digit cause of death code assigned in conjunction with the International Classification of Diseases, Ninth Revision (ICD-9), World Health Organization.</td>
<td></td>
</tr>
</tbody>
</table>
MEMO: Patricia Myers, MSPH  
700 Dockview Way, #1126  
Tampa, FL 33602  
FROM: Institutional Review Board / KK:cas  
SUBJECT: Exemption Certification for Protocol No. 101139  
DATE: May 22, 2003

On February 4, 2003, it was determined that your project entitled, "The Impact of Adverse Prenatal Events on Sudden Infant Death" met federal criteria which exempts it from the regulations specified in the Common Rule.

On May 14, 2003 you requested the following change(s):
A change in study title from "The Impact of Adverse Prenatal Events on Sudden Infant Death" to "The Association of Maternal Pregnancy Complications and Sudden Infant Death Syndrome"

These changes have been noted in the file and do not impact the eligibility for exemption. The study continues to have Exempt Certification. Please remember that any grants connected to this project must be submitted to the Institutional Review Board for review.

Because the study has been certified as exempt, you will not be required to complete continuation or final review reports. However, it is your responsibility to notify the IRB prior to making any changes to the study. Please note that changes made to an exempt protocol may disqualify it from exempt status and may require an expedited or full review.

If you have any questions, please contact the Division of Research Compliance at (813) 974-5638.