2020

Risk Factors of Infant Mortality Disparity in Indian River County, Florida

Cecilia Miguelina Escorbore
Walden University

Walden University

College of Health Sciences

This is to certify that the doctoral study by

Cecilia Escorbore

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

Review Committee
Dr. Loretta Cain, Committee Chairperson, Public Health Faculty
Dr. Joseph Robare, Committee Member, Public Health Faculty
Dr. Patrick Tschida, University Reviewer, Public Health Faculty

Chief Academic Officer and Provost
Sue Subocz, Ph.D.

Walden University
2020

Abstract

Risk Factors of Infant Mortality Disparity in Indian River County, Florida

by

Cecilia M. Escorbore

MPH, Walden University, 2015

BS, Lehman College of the City University of New York, 1997

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Public Health

Walden University

November 2020

Abstract

Infant mortality in the United States is a great concern to families, communities, and professionals in the public health field. More concerning is the infant mortality racial disparity, prevalent throughout the United States. The purpose of this study was to explore risk factors of infant mortality disparity in Indian River County (IRC), Florida. Using socioecological theory as the theoretical framework, this study explored whether there is an association between infant mortality among Black infants and geographic location as well as measures of socioeconomic status (age, educational level, health insurance status, and marital status) associated with infant mortality among Black infants in IRC, from 2012 to 2016. This study used secondary data from the Florida Department of Health, Bureau of Vital Statistics; a total of 1,169 births to Black mothers in IRC from 2012-2016 was the sample for this study. Logistic regression and chi-square test of independence were performed. The findings revealed no association between infant mortality among Black infants in IRC, and geographic location, defined by zip codes; there was no association between measures of socioeconomic status, defined by age, education level, health insurance status, marital status, and infant mortality among Black infants in IRC. Conversely, there was a statistically significant association between measures of federal assistance status; Women Infants and Children (WIC) with infant mortality among Black infants in IRC ($2, N = 43) = 6.98, p = .030$). This study can contribute to positive social change by helping the public health professional community better understand and confront health disparities related to Black infant mortality in IRC.

Risk Factors of Infant Mortality Disparity in Indian River County, Florida

by

Cecilia M. Escorbore

MPH, Walden University, 2015

BS, Lehman College of the City University of New York, 1997

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Public Health

Walden University

November 2020

APA 6th Edition

Dedication

This project is the culmination of hard work, perseverance, patience, and faith. Sometimes it is difficult to follow one's dreams and see them through a final product. I thank my family members and friends who understood how important this milestone was in my educational path, I am grateful for your support.

To my children Jean-Carlos, Uriel, and Nisseth; always follow your dreams. I have accomplished my educational dreams because I refused to give up! Let my accomplishments serve as proof that your dreams are important and worth fighting for. I love each one of you more than words can describe.

Lastly, to my husband Juan Tomas Escorbore: thank you for joining me on this journey. Your unconditional love has served as the support that I needed every step of the way. Tomas, thank you for lifting me up when it seemed like I was about to give up; thank you for believing in me when I doubted myself. I thank God for allowing me the opportunity to share this special moment with you.

Acknowledgments

Reaching this great accomplishment in my academic and professional career would not have been possible without the guidance, patience, and exceptional knowledge of my chair Dr. Loretta Cain Shields, and my committee member Dr. Joseph F. Robare. Thank you to my assigned University Research Reviewer Dr. Patrick Tschida. To Daniel Irwin with Florida Department of Health, Bureau of Vital Statistics and to Andrew Wentzell, Esq., IRB Coordinator, Biomedical/Public Health Research Section with Florida Department of Health; thank you both for your assistance with requesting the secondary data and receiving IRB approval for this project.

During a difficult time – the COVID-19 pandemic when all of us were experiencing uncertainty and the unknown, I found guidance and exceptional support from Dr. Timothy S. Allison-Aipa, and Dr. Betty Ezell. Thank you both for your knowledge and for helping me with this final stretch.

Lastly, I would like to acknowledge Walden University. I had the opportunity to complete my MPH as well as my DrPH with Walden University. Both programs allow individuals like me to accomplish lifelong dreams while still being a mother, full time professional, and everything else that comes with life. This accomplishment takes hard work but, it is also possible because of this carefully crafted Walden University program that I have been able to reach this milestone.

Table of Contents

List of Tables

List of Figures

Section 1: Foundation of the Study and Literature Review

Introduction

Infant mortality is defined by the Centers for Disease Control and Prevention (CDC, 2016) as the death of a baby before he/she lives to celebrate their first birthday. The infant mortality rate (IMR) is defined as the number of infant deaths that occur per every 1,000 live births (CDC, 2016). The IMR in the United States in the year 2016 was 5.8 per 1,000 live births (Central Intelligence Agency, 2017). Public health professionals engage in exploring strategies to address the health issue of reducing the IMR in the United States. Exploring the public health concern of infant mortality requires that public health professionals identify the reasons for infant mortality. Part of that exploration is the infant mortality disparity of White infants compared to Black infants. The disparity is more significant depending on where a person lives. An example of infant mortality disparity is notable in Indian River County, Florida (IRC). In this study, I explored risk factors of infant mortality disparity in IRC in a 5-year span, from 2012 to 2016. According to Florida Charts (2018) IMR in IRC for the year 2016 was 8.0 per 1,000 live births, but these rates are concerning for the Black population. That same year, the IMR for White infants was 6.5 per 1,000 live births, and for Black infants 24.8; in 2015, the IMR was 5.8 for White infants and 12.9 for Black infants; in 2014, the rate was 1.3 for White infants and 13.0 for Black; in 2013, the rate was 2.7 for White and 17.9 for Black; and finally, in 2012, the rate was 3.9 for White and 33.8 for Black per 1,000 live births (Florida Charts, 2018). These rates merit attention because of the significant disparity they reveal.

Problem Statement

Birth outcomes are related to infant mortality (IM), and sometimes IM is a direct result of an adverse birth outcome like a preterm birth or a low birth weight baby (CDC, 2018). The IMR is a key indicator of the overall health of a population (CDC, 2018). Infant mortality is disproportionately affecting the Black residents of IRC. In the state of Florida the IM rate was 6.1 in the year 2016 (Florida Charts, 2019) and the rate for the United States in 2018 was 5.7 per 1,000 (World Fact Book, 2019); this makes the rate for the state of Florida higher than that for the United States.

Based on these statistics, IM has affected the Black community disproportionately. As we can assess from the data provided in this section, IMR fluctuation has not been in favor of Black infants in this geographical area (Florida Charts, 2018). This study aims at exploring risk factors for the disparity and understanding how this community can benefit from interventions tailored to meet their needs. The IM disparity is not a new development to the public health field; many studies have been completed to learn about the factors that contribute to the IM (Goddeeris, Haider, & Paneth, 2014; Kothari et al., 2017) but the disparity remains an issue yet to be solved (Lu et al., 2010; Drummonds, Kotelchuck, Mallin, & Verbiest, 2016). The disparity in the area of IRC can be compared to IMRs found in third world countries. Examples include Azerbaijan with a rate of 23.80 in the year 2017 (Central Intelligence Agency, 2018); Indonesia with a rate of 22.70; North Korea with a rate of 22.10; Philippines with a rate of 21.40; and Guatemala with a rate of 21.30 (Central Intelligence Agency, 2018); lastly, Cuba—a small Caribbean island nation that has been under a

communist regime for more than 30 years—had an IMR of 4.4 in 2017 (Central Intelligence Agency, 2018). The fact that an area in the United States has IMR comparable to third world countries is alarming and requires further exploration. Another factor in the geographical area questioned is that the rate was declining but started to increase once again. It would be beneficial to understand what was going on in the area that was causing the rate to decrease. If these factors can be replicated, we can impact the IMR positively in IRC.

Purpose of the Study

The purpose of this study was to assess the risk factors associated with infant mortality among Black infants in IRC, Florida. If these factors can be clearly defined, professionals in the area of public health can design programs or interventions that address the contributing factors. The uniqueness of this study is that addressed the issue of IM only in IRC. Each community is unique, with its own challenges, cultural norms, and opportunities. According to the CDC (2018), the IMR is an important indicator of the overall health of a population. In this case, learning about the causes of IMR disparity in this geographical area could enlighten the public health leaders in the community about the overall health of the residents in this area and address the contributing factors. The results from this research project may provide additional insights about programs that should be designed for this population. A notable intervention that may work with this population is that of the life course perspective recommended by Lu and Johnson (2014), who discussed addressing IMR disparity from the perspective that the life course model

should be introduced to women before they become pregnant in an effort to enter a pregnancy healthy and have a positive outcome.

The results from this study can also aid in the education strategy to use with this population. The findings can assist public health leaders, stakeholders, and community members to identify strategies that will work with the population. There is the possibility that the interventions provided in the past for the population were not tailored to meet the needs of the population affected and that interventions were being replicated because they worked in other communities. A number of interventions have been studied with populations in reference to IMR but, there is an absence of work that discusses interventions tested for the disparity issue. The work of Wise (2008) suggested that preconception and interconception education can prove to be an adequate intervention for women at the time of pregnancy. This provides women with the opportunity to start thinking about their next pregnancy and addressing the health concerns that can negatively affect the development of their next child. Hernandez, Sappenfield, Goodman, and Pooler (2012) discussed the need to provide counseling to women of childbearing age around the issue of becoming healthy before conceiving. Lastly, a benefit of this study is also awareness about trends, the reason or reasons why IMRs fluctuate, in this case negatively for the Black community, seems to be a mystery. Understanding factors related to IMR disparity is imperative for the purpose of removing barriers. The results of this study may contribute to positive social change by contributing to the IRC public health community, stakeholders, and leaders in the area of maternal and child health, by providing strategies that can be replicated in this community to address and successfully

reduce the IMR disparity. Contributions may also aid funders to appropriate dollars for programs and services for the community strategically. This community lacks public health studies in the area of maternal and child health disparities. This study provides this community with a piece of work that has not been seen in this area in the past. This will be a tangible product to use as reference for important decisions that will impact generations to come.

Research Questions and Hypothesis

RQ1: Is geographic location, defined by zip codes in IRC, Florida associated with infant mortality among Black infants in IRC, Florida?

H_o1: Geographic location defined by zip codes is not associated with infant mortality among Black infants in IRC, Florida.

H_a1: Geographic location is associated with infant mortality among Black infants in IRC, Florida.

RQ2: Are measures of socioeconomic status (age, income, educational level, health insurance status, employment, marital status, family structure) associated with infant mortality among Black infants in IRC, Florida?

H_o2: Measures of socioeconomic status (employment, marital status, family structure) are not associated with infant mortality among Black infants in IRC, Florida.

H_a2: Measures of socioeconomic status (employment, marital status, family structure) are associated with infant mortality among Black infants in IRC, Florida.

RQ3: Are measures of federal assistance program status (Women Infants and Children - WIC) associated with infant mortality among Black infants in IRC, Florida?

H_o3: Measures of federal assistance program status (WIC) are not associated with infant mortality among Black infants in IRC, Florida.

H_a3: Measures of federal assistance program (WIC) are associated with infant mortality among Black infants in IRC, Florida.

Theoretical Framework

The theoretical framework for this study will be the socioecological theory. This theory was introduced by Urie Bronfenbrenner, to explain how all components in a child's environment affect how the child grows and develops. Bronfenbrenner was a co-founder of the National Head Start program in 1965 and is considered a pioneer in the area of finding key elements in society at large that influence health development and health outcomes (Alio et al., 2010; Glanz, Rimer, & Viswanath, 2015). This model helped understand how birth outcomes are affected by maternal and family characteristics, and how these characteristics are strongly motivated by the larger community and society (Alio et al., 2010). This theory posits that there are interconnected relationships among personal and environmental factors. The socioecological theory takes into consideration that individual, relationship, community, and societal levels of influence are important. These levels translate to the variables selected for this project: (a) on the individual level, the woman's educational status and the marital status; (b) on the relationship level, the family structure; (c) on the community level, the geographical location and the employment status; and (d) on the societal level, the health insurance status. This framework was helpful in understanding how people interact with their environments and how the factors of community, environment, and policy influence

behavior (Glanz et al., 2015). This theoretical framework could aid with the development of policies, programs, and education that make it convenient to change behavior and make long lasting choices that will benefit individuals in the geographical area described.

Nature of the Study

For this study, I used a quantitative approach to assess the factors that influence IMR disparity in the Black community associated with IM among Black infants in IRC from 2012 to 2016. Because I explored the relationship between the independent variable and dependent variable at a specific point in time, I chose a cross sectional approach. The independent variable for this study was the characteristics that may influence, affect, or be associated with the dependent variable. The independent variables were the geographic location, defined by zip codes in IRC, Florida and the socioeconomic status/factors: age, income, educational level, health insurance, employment, marital status, family structure. The dependent variable was the IMR disparity. The rationale for using this secondary data set was that all hospitals in Florida collect data when a baby is born and they send it electronically to the Florida Department of Health at the state level. These data were collected for the birth certificate and for the purpose of linking birth and death records. All the variables mentioned above are collected through this birth certificate process.

Literature Search Strategy

My literature search was completed through online search engines. The engines I used were from the Walden University Library, Google Scholar, and Medline. Statistical data were gathered from the CDC, National Institutes of Health (NIH), the Central

Intelligence Agency-World Fact Book, the U.S. Census Track, the State of Florida Department of Health, and the Florida Department of Health in IRC. All the journals were peer reviewed; the years published ranged from 2013 to 2018.

The terms I used to locate the peer-reviewed journals included *infant mortality, infant mortality disparity, social determinants of health, infant mortality in the south, infant mortality and protective factors, structural racism and infant mortality, infant mortality,* and *Black and White disparity.*

Introduction to IRC, Florida/Geographical Location

IRC is located on the East Central Coast of Florida, known as the Treasure Coast. The county seat is Vero Beach. IRC covers 503 square miles and has a population of 154,383 (2017). Twenty-nine percent of residents are 65 years and over, 11% higher than for Florida as a whole. Seventy-seven percent of residents are White, non-Hispanic, compared with 56% for Florida overall. Nine percent of residents are African-American, compared with 17% in the state as a whole.

Within unincorporated IRC is the community of Gifford, which spans approximately 3.5 square miles, with an estimated population of 6,689 in 2017. Sixty-nine percent of the Gifford population is African-American. The 2017 median household income in Gifford was $23,462, approximately one-half of that in the county as a whole (Census Reporter, 2017; Florida Department of Health in IRC, 2018). Twenty-nine percent of the Gifford population lives below the federal poverty level, compared with 13% for the county. The Community Disadvantage Index score is commonly used to summarize the general socioeconomic conditions of an area using a combination of

several measures. Scores range from 0 to 10, where 10 indicates the area is among the most disadvantaged in the country. The 2010, Community Disadvantage Index score for the Gifford Community was 10 (Florida Department of Health in IRC, 2018).

According to data collected in the U.S. Census Bureau's 2012 American Community Survey, the Vero Beach-Sebastian metro area had the highest level of income inequality in the country. In 2012, 33.8% of all household income was earned by the wealthiest 5% of households. This is higher than in any other metro area in the United States.

The community of Gifford, just north of Vero Beach city limits, was settled by Black homesteaders in the late 1800s. The community has endured many disparities, including land annexation, segregation, contaminated drinking water wells, substandard housing, and lack of economic opportunities. In the early 1960s, community leaders formed a local chapter of the National Association for the Advancement of Colored People (NAACP), as well as the Progressive Civic League of Gifford. These organizations have been instrumental in improving the health and quality of life of the community through coordinated efforts among a number of agencies and organizations. I have included this section in this study not only to describe the geographic area of IRC, but also to distinguish the disparity within the Gifford community. Because this study involved exploring contributing factors to infant mortality disparity in the area described, it is important to also emphasize some of the living conditions of the population in this geographic location within a county.

Literature Review

Infant Mortality and Racial Disparities

IM is a public health concern that continues to cause concern in communities across the nation. This alarming public health issue is not distributed equally among all racial classes. IM is defined as the death of a baby before reaching their first birthday (CDC, 2016). The IMR is defined as the death of a baby per 1,000 live births (CDC, 2016). This rate is used by public health professionals as a measuring instrument of the overall health of entire populations. IM has decreased in the United States in the past 2 decades, but the IMR disparity of Black and White infants has continued to widen (Matoba & Collins, 2017). Black infants die at a rate 2.2 times that of their White counterparts (Halfon & Lu, 2003). This is cause for necessary research to understand and address the causes of IM and to alleviate the burden faced by the Black community.

Matoba and Collins (2017) discussed the deficiency that is evident in the United States as it relates to maternal and child health, more specifically two characteristics, which include the IMR being higher in the United States than in developing countries and that Black infants have a 2.2 fold greater mortality rate than their White peers. These authors explored some of the risk factors associated with social circumstances of IM and discussed social implications associated with neighborhood-level factors, including crime rates, safety, segregation of the Black community, built environment, and institutionalized racism. Matoba and Collins (2017) linked these nontraditional risk factors with the poor birth outcomes experienced by the Black community across the United States. These authors also discussed how the high rates of short gestation in the

Black community are a serious risk and a common denominator for the Black population. Short gestation is defined as the preterm birth of a baby, before 37 weeks; this short gestation is also associated with low birth weight. The CDC (2018) explained that preterm birth can place a newborn at a higher rate of death or disability. These births resulted in about 17% of infant deaths in 2016 (CDC, 2018). Often, a preterm birth can result in a low birth weight baby or a very low birth weight baby (less than 2500 grams). These infants are not fully developed at birth, causing serious health complications that can lead to death and disability, and if these infants survive, they often do not reach developmental milestones in the same way as children that are not born preterm, and require a myriad of interventions to help them lead healthy lives (CDC, 2018).

Preterm birth and low birth weight are a significant cause of IM in the Black community, accounting for more than half of Black IM (Matoba & Collins, 2017). Christopher and Simpson's (2014) research suggested that equity is an important factor to examine as it relates to Black pregnant mothers receiving adequate health care before and during pregnancy. Similarly, Wallace et al. (2017) evaluated the association of racial inequity and structural racism and the link to attainment of health resources. These authors explained that being poor is a major risk factor for poor birth outcomes and that some other risk factors include the unequal distribution of household income, employment, imprisonment, and juvenile custody. Wallace et al. discussed how the White population for many centuries in the United States has enjoyed and benefited from socioeconomic advantages; the greater opportunity of income affords the White population with the benefit of attaining better living conditions, healthier environments to

live in, higher quality of health care received by medical providers, and a notable political power.

All of these factors contribute to the attainment of better health before pregnancy and during pregnancy. These factors are woven multilayered conditions that affect how a Black woman seeks and receives care during the perinatal period. The results of these conditions for the Black community is a complicated system that stems from structural racism and segregation that severely limits people of color, or the Black community from obtaining health services that promote and sustain health (Wallace et al., 2017). The IRC population has experienced these conditions in some of its communities, more specifically, the Gifford community, which is predominantly composed of Black residents and is geographically segregated (Florida Department of Health in IRC, 2014). The risk factors described by these authors suggest that for pregnant women the price of this inequity is devastating because their unborn child is placed at a disadvantage even before birth.

Along the same lines of the studies mentioned previously is the study of Loggins and Drummond-Andrade (2013), who concluded through their work that the IMR disparity would most likely continue through 2020. Implications for policy makers are important to aid in closing the gap of Black and White IM disparity. Policy makers can aid by designing policies that address the Black communities that are medically disenfranchised and medically underserved by funneling resources of medical care to these populations (Loggins & Drummond-Andrade, 2013). The area of IRC has

medically underserved sections that are either rural or segregated. These communities carry the burden of not having access to adequate medical care.

Social Determinants of Health and Infant Mortality

In recent years, researchers have started to identify conditions around IM that are related to social determinants of health (SDH). According to the World Health Organization (WHO), SDH are defined as the conditions in which we are born, grow, live, play, work, and age, as well as the systems in place to address those conditions/illnesses (WHO, 2018). Understanding SDH can help researchers, public health professionals, community leaders, stakeholders, and community residents to adequately address the needs of their community. SDH can also help to explore the historical context of communities to better understand why some conditions are in place and where we can start to have an honest conversation about what needs to change.

In a study completed by Komro, Livingston, Markowitz, and Wagenaar (2016) the issue of poverty and minimum wage was tackled. These authors investigate that the state minimum wage directly affects the low birth weight and infant mortality. Families that are struggling to meet basic necessities like paying the bills, putting food on the table for their family, are also struggling to obtain adequate health care; this may be in part because populations that are uninsured, underinsured, or medically disenfranchised deal with factors related to not being able to pay for medical office visit co-pays, prescriptions, or medical devises (The National Association of Community Health Centers, 2007). Minimum wage standards are an important contribution to the economic stance of a family, therefore allowing them access to the needed medical services to

promote healthy birth outcomes (Komiro et.al, 2016). The empirical evidence resulting from the information gathered by these researchers showed that if in 2014 all states had increased their minimum wage standard by just $1.00, this could have resulted in 2,790 fewer low birth weight births and 518 fewer postnatal deaths for that year (Komiro et.al, 2016).

The same topic of SDH, was studied by Reno and Hyder (2018). These authors completed a systematic scoping review of the literature available about SDH. The review revealed that across the United States, education was associated with lower levels of IM among Blacks, as was employment—specifically, gaining employment was a contributing factor to lower IM. Meanwhile, poverty was associated with higher rates of IM among the Black population (Reno & Hyder, 2018). Maternal health and prenatal care were found to be an important indicator of the birth outcome (especially how early the woman initiated prenatal care and the frequency and quality of the care), safe sleep practice was a factor that affected the postnatal mortality. Reno and Hyder concluded that if these conditions were not easily accessible by the Black population the risks of a preterm, low birth, and even death of a baby was higher. On an organizational level, the researchers determined that availability of medical providers is one of the most important factors to address positive birth outcomes and combat IM. In many rural areas, adequate prenatal care is not readily available, forcing mothers to travel outside of their regions to seek specialized medical care, in addition, hospital facilities in these same rural areas don't have the level of specialty needed like obstetricians, neonatologist, and perinatoligist; it coincides with communities that are not only rural but poor (Reno &

Hyder 2018). My study focused on a population similar to the one described by these authors; there are communities in IRC that are rural, living in poverty, and only having one hospital with a labor and delivery floor to choose from in the county. On a community level, the Reno and Hyder suggested that some of the critical factors include concentration of poverty in neighborhoods, racial segregation, and imprisonment rate. These factors affect all aspects of SDH. The high concentration of poverty in neighborhoods and the segregation go hand in hand with the problem of IM. In these neighborhoods, pregnant women are not able to access preconception education or adequate prenatal care. As a result, their pregnancies are placed in danger of poor birth outcomes or negative postnatal consequences (Reno & Hyder 2018). Multiple, layered variables in the lives of Black women place this vulnerable community at risk for poor birth outcomes and further exploration is merited (Reno & Hyder, 2018).

Racial Disparities in the Southern United States

In this project, I explored the risk factors associated with IM in the southern state of Florida, more specifically, IRC. This county has areas that are rural, experiencing difficulties with transportation, education, and employment. Some research has suggested that the southern U.S. states experience disproportionate outcomes related to health due in part to the historical context of inequality (Kirby, 2017). The main causes of IM in the southern United States include sudden unexpected infant death and preterm-related deaths, specifically preterm births at less than 37 weeks of gestation (Hirai, Sappenfield, Kogan, Barfield, Goodman, Ghandour, & Lu, 2014). Hirai et a. (2014) found that in the United States the southern states are disproportionately impacted by IM; on average

every year 1.2 extra per 1,000 live births die in the South or 1,600 in excess compared to other regions of the United States, and a large proportion of these deaths are of Black births (59%). In the South, the IMR for Black births is overwhelmingly explained by the same denominator as in other regions: preterm births (Brown-Speights, Goldfarb, Wells, Beitsch, Levine, & Rust, 2017; Hirai et al., 2014;). From the year 1999 to 2013, if Black infants died at the same rate of White infants a total of 5,245 Black baby lives would have been saved in the span of those years (Brown-Speights et al., 2017). It is clear that public health professionals, along with community leaders, stakeholders, and community residents, must work together to close this gap. Closing the gap requires that serious and difficult conversations happen with the groups mentioned above. These conversations include the difficult reality of segregation, structural racism, intergenerational poverty; without these conversations in communities where this is happening, it is difficult to initiate programs that address the need (Brown-Speights et al., 2017).

These conversations could start with community residents. In Gadsden county, Florida a rural county in the state, a study explored community awareness and perceptions of the community about IM. A total of eight focus groups over a span of 6 months were interviewed to learn about perceptions around IM in that severely affected county. In Gadsden county, the Black IMR in 2013 was 11 per 1,000 live births (Close, Suther, Foster, El-Amin, & Barttle, 2013). Close et al. (2013) found that this county experienced SDH, comparable to the same SDH discussed in this section as it relates to the Black community. Some of the same risks were reported by the researchers: this area is predominantly Black populated, with most living below the poverty level, lacking

education, living in unsafe and marginalized areas, and without a hospital; the only hospital in this area closed its doors from 2005 to 2010, forcing the community residents to only depend on using the County Health Department or traveling 25 miles to the County of Tallahassee for medical services (Close et al., 2013).

With the lack of resources described above, the focus group participants reported that they felt that they were unaware of how to take care of their bodies, that Black women wait to go to the doctor and end up going past their first trimester, that the health services in the county were difficult to access, that there was a lack of insurance, waiting times were too long, and that they were treated as an inferior class, they reported not having transportation, the medical providers talk in a way that is difficult to comprehend (using technical terms), lack of trust in the health care system was also a common theme (Close et al., 2013). The report about awareness and perception of community residents in this Florida county is consistent with the findings in this section about the lack of services and health equity available to the Black community.

Strategies and Approaches to Reduce Infant Mortality

Reducing the IMR in the Black community across the United States and especially in the severely affected south requires multilevel approaches that involve community leaders, stakeholders, community programs, and policy makers (Alio et al., 2010). Developing effective programs and interventions will require training all parties involved in the care of pregnant women and children in cultural competence, cultural humility, and cultural sensitivity, training on identifying stressors and having a plan to

address them; these stressors include domestic violence, mental health concerns, lack of basic resources like food (Alio et al., 2010).

Additional interventions also include utilizing community engagement tools like the GIS mapping, for the purpose of identifying areas that are carrying the burden disproportionately and funneling resources to that area (Detres, Lucio, Vitucci, 2014). These local maps produced by GIS aid communities in engaging and educating community residents, stakeholders, and policy makers. This allows for a conversation about the need for services in specific areas as well as helping the parties involved to interpret IM and prematurity data (Detres et al., 2014).

Lastly, integrating the life course model is also an approach recommended by doctors that have concentrated in the area of IM disparity as well as public health professionals (Lu, 2017). The life course model aims at looking at life as integrated continuums instead of disconnected stages. This approach has been adopted by Jacksonville-Duval County Magnolia Project in Florida. The project has utilized a lay health worker initiative using a “each one, teach one” strategy. Community members are trained in the neighborhoods affected. These members go back to the community to educate those around them about IM and how it affects their community disproportionately (Brady & Johnson, 2014). The Magnolia project trained more than 30 community leaders, stakeholders, and residents to understand the causes of IM in their community and to address it with those around them; this approach was also integrated in community agencies strategic plans and implemented throughout maternal and child health services in the county (Brady & Johnson, 2014).

Definition of Terms

Black population/community: Americans of African and especially of Black African ancestry (Merriam Webster Dictionary, 2019).

Florida Charts: Health statistics about Florida and its counties.

IRC (IRC): A county located in the Treasure Coast of Florida in the South East.

Infant mortality (IM): The death of a baby the first year of life, day 1 to 365 (CDC, 2018).

Infant mortality rate (IMR): The number of infant deaths per every 1,000 live birth (CDC, 2018).

Low birth weight: Infants born weighing less than 2500 grams.

Preterm birth: When a baby is born too early, before 37 weeks of gestation. These infants can have long-lasting effects, including breathing problems, feeding difficulties, cerebral palsy, developmental delays, vision problems, hearing problems and even death (CDC, 2018).

Social determinants of health (SDH): Social determinants of health are conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks (Healthy People, 2020).

Assumptions

The assumptions in this study are that the data collected from each birth and death record was accurately collected and sent to the Florida Department of Health at the state level. Another assumption is that the number of cases used for this study will be

representative of the population experiencing the IMR disparity in IRC. Additionally, that the data collected was collected from each mother at the time of her baby's birth in a non-biased manner and that the mothers provided honest and accurate answers about their demographic and socioeconomic status. These assumptions are made based on the fact that the data is collected at the hospital and then sent to the Florida Department of Health at the state level. Based on this assumption this secondary data would be the most appropriate and reliable since it provides data collected at a population level with processes in place that are adhered to at the hospital. Based on this information conclusions can be made in the study.

Scope and Delimitations

The study was conducted to explore risk factors of infant mortality disparity in IRC, Florida. The study did not look at any other county in the state of Florida. I examined what characteristics might have been associated with infant mortality disparity in the county. Findings of this study cannot be generalized to any other health conditions in infants. The findings cannot be generalized to any other populations in the rest of Florida. The findings are only relevant to one hospital in IRC due to the fact that this county only has one hospital with a maternity wing; there are no other hospitals that deliver infants in the county. Lastly, this study only concentrates on Black and White infants born alive who died before celebrating their first birthday; from day 1 to 364 days of life. No other racial groups were included in this study.

Significance and Potential for Social Change

Significance of the Study

The significance of this research is that it could add valuable evidence that could potentially contribute to improvement in the care of women before, during, and after pregnancy. If this study provides significant information for practitioners and clinicians about some of the risk factors of infant mortality in this county, then medical care can be tailored to the needs of the women who seek care. Medical care paths can be designed with risk factors in mind that address the specific issues discovered in this study. Trainings for professionals in the maternal and child health field can also be designed to help practitioners provide care in a way that helps pregnant women have a better experience and that fosters an open honest patient/professional relationship. If a woman feels that the professional caring for her and her unborn child cares about her situation she might be more open to expressing some of her struggles related to services she might not have access to but, may need for a positive birth outcome and a healthy baby who lives to celebrate his or her first birthday.

Potential for Social Change

This study has the potential to save lives and to give infants a powerful bright start in life. The findings of this study can change the way an entire community views services to pregnant women. If this community is able to make informed decisions about how medical services are going to be provided based on a study that is directly discussing their community this may be of benefit. Positive social change can also be viewed in the area of a community coming together to address the health needs of one of the most

vulnerable members of their community, infants. I know that it is not possible to control race in a population, but we can plan to uplift a specific population's living conditions. This research project can promote positive social change by planning community wide innovative initiatives that address social determinants of health (SDH). SDH can affect health outcomes including infant mortality disparity. My hopes are that those in a position of power in IRC, see the benefit in this research project and make decisions to invest dollars to change conditions that include access to adequate care, employment opportunities that can impact the overall health and well-being of a community and educational attainment that can open doors to economic opportunities.

Conclusion

In conclusion this study will provide valuable insights about risk factors affecting the IMR disparity in IRC, Florida. It is important to address this disparity for the purpose of changing how services are provided to a community as well as to improve the overall health of a population. The findings of this study will ultimately guide important decisions made by leaders, local funders, the county health department, as well as social service providers. If characteristics of the disparity are related to the conditions in which one racial group is born, lives, and ages, then the leaders in this community will have validation that funding needs to be invested to uplift the families in the community. Some of the findings can shape programs to address access to care, specialized medical care, education, job readiness, and possibly living conditions. This study will be a positive one for IRC and the future of their most vulnerable residents.

Section 2: Research Design and Data Collection

Introduction

The purpose of this study was to assess risk factors of infant mortality disparities in IRC, Florida among Black and White infants. The study was aimed at helping determining whether there was an association between demographic factors like geographic location (defined by IRC zip codes), socioeconomic status (defined by age, income, education level, health insurance status, employment status, marital status, family structure), and federal assistance program (defined by receiving WIC benefits). This was a quantitative study using secondary data obtained from the birth information collected at hospitals in the state of Florida. The data used was collected from women of childbearing age who delivered their baby between the years of 2012 and 2016 and reported being a resident of IRC. The topics detailed in this section of the study include the research study design, rationale, sample size, and methodology. In this section I also provide more information about the population, sample size, the type of procedure utilized to collect the data, and how the data collected is documented/handled.

Research Design and Rationale

The research design for this study was a quantitative cross-sectional research project using secondary data set from 2012-2016 from the State Florida Department of Health's electronic birth record system (Florida Charts, 2018). The secondary data set included a sample of 3,823 White mothers and 1,120 Black mothers who gave birth in IRC (Florida Charts, 2018). This chosen data set was adequate for my research project because the information gathered is of live birth of infants and the linked death of infants

the same years specified above. The dependent variable was infant mortality for White and Black women who delivered their babies in IRC from 2012-2016. The dependent variable described in this study provided birth outcomes for women of both races. The statistical analysis for this research project is a multiple regression to test the hypothesis. I also used a descriptive analysis of the population I studied. The questions I asked for this study were answered by using the data set described above from the State of Florida Department of Health. The data set was accessible with requested IRB permission.

The quantitative cross-sectional research design I used for this study is focused on the number of women that gave birth to a live infant in IRC from 2012-2016 and those women whose infants died before celebrating 365 days of life. I selected a cross-sectional study technique for this project because it would help to discover whether there is an association between infant mortality among Black infants and geographic location as well as measures of socioeconomic status (age, income, educational level, health insurance status, employment, marital status, and family structure) associated with infant mortality among Black infants in IRC, Florida from 2012 to 2016.

The independent variable for this study was geographic location (IRC) as well as measures of socioeconomic status (age, income, educational level, health insurance status, employment, marital status, and family structure). I selected the independent variable of geographic location and measures of socioeconomic status as listed above to help determine whether there is an association between risk factors of the dependent variable of infant mortality among White and Black women who reside in IRC and gave birth from 2012 to 2016.

I was given access to the answers obtained from mothers before hospital discharge related to establishing paternity as well as the record of birth. The variables relevant to this study were included in the answers recorded by the hospital staff responsible for collecting the information before mother and infant home discharge. The variables included geographic location as well as measures of socioeconomic status (age, income, educational level, health insurance status, employment, marital status, and family structure). For my research, I used SPSS and the information provided by the State Florida Department of Health.

Methodology

Population

The population for this study is women of childbearing age, between 15 and 44 years old, who delivered their babies during 2012-2016 and who self-reported that their primary county of residence in the state of Florida is IRC; this information is reported based on zip codes. IRC has 3 incorporated cities: Fellsmere, Sebastian, and Vero Beach. These cities are represented by 16 zip codes, including 32948, 32957, 32958, 32960, 32961, 32962, 32963, 32964, 32965, 32966, 32967, 32968, 32969, 32970, 32971, and 32978. The data included only White and Black women who met the criteria mentioned above and who had a live birth between the years of 2012 and 2016. Subsequently, the birth data were linked with the death data of infants born to Black and White mothers during the same time frame and living in the same county. This study use a large sample size (n = 4,943); therefore, the statistical tests had over 99% power to detect small differences. The sample size needed for this study is at least 610 participants/births; this

number is based on calculations completed using the G*Power 3.1.9.4 Statistical Power Analysis for a chi-square one-tailed test with a 0.80 power and 0.05 alpha degrees of freedom. Using the same G*Power 3.1.9.4 Statistical Power Analysis; a linear multiple regression: fixed model test was completed; the sample size needed for the test is 607 participants/births with 0.05 alpha degrees of freedom. The breakdown of the Black and White births in IRC, Florida from 2010-2016 is detailed in the sampling section below. section below.

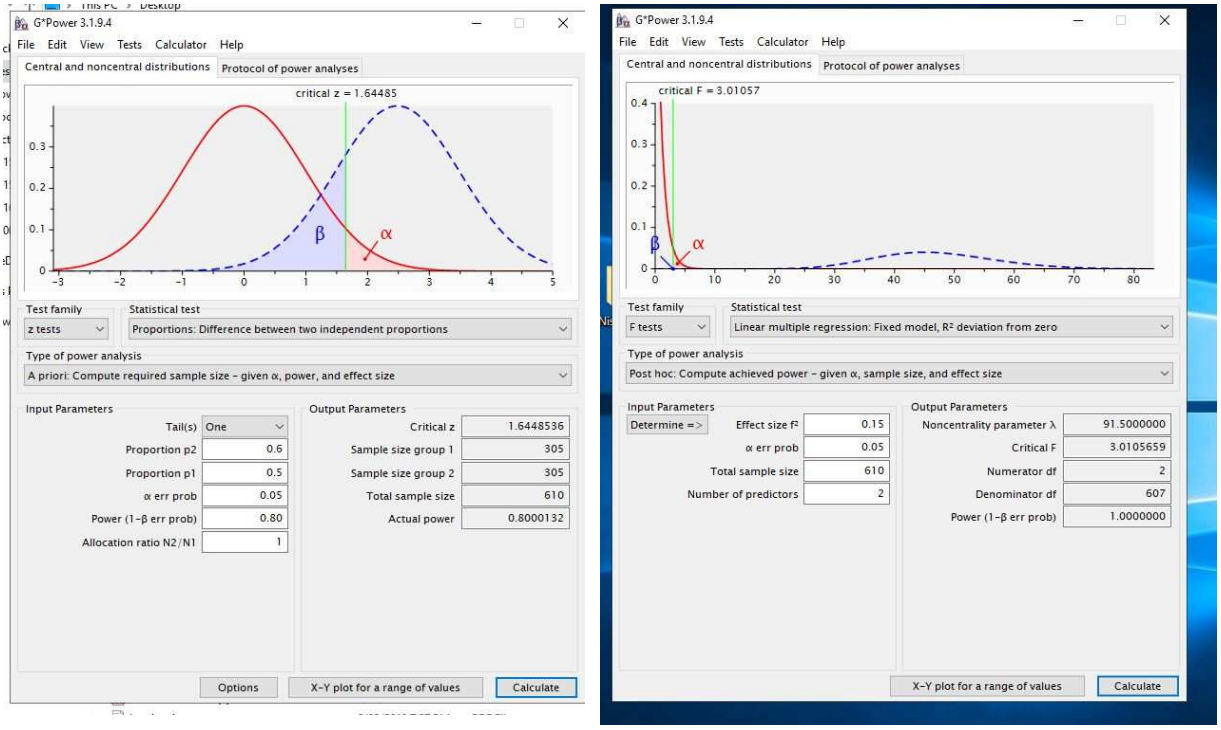

Figure 1. Black and White Births in IRC from 2010-2016.

Sampling and Sampling Procedures

All of the birth data collected is collected at the hospital when a woman delivers her baby and before hospital discharge. The State of Florida utilizes an electronic birth

registration system; this system transmits the data electronically before each couplet is discharged home. Approximately 6,237 births happened to residents of IRC between the years of 2012 and 2016. Of these births, approximately 3,823 were to White mothers and 1,169 were to Black mothers (Florida Charts, 2018). The remaining 1,294 births were to mothers that did not self-identify as Black or White. These births are not included in this study.

All births that take place in the state of Florida, regardless of the venue being a hospital, birthing center, or home birth, require the completion of the electronic birth registration system. This system is administered by the State of Florida Department of Health. The data are collected as part of the vital statistics department and utilized to document the births and deaths of all infants in the state. The information collected also supports the provision of adequate birth and death certificates for all infants born in the state of Florida.

Mothers are not offered any incentive to provide this information at birth; all mothers are required to provide the information. The information is collected as a customary and systematic process mandated in all counties in Florida. The information collected is also utilized to establish paternity. Both mother and father are asked to certify that the information they are providing is accurate and they have to sign electronically in the presence of a hospital staff member who is also a Florida Notary Public. Once the information is collected it is sent electronically to the State Department of Health in Tallahassee, the capital of Florida.

Instrumentation of Constructs

The entity that developed the electronic birth record and the process to administer the form was the National Vital Statistics System in the United States. The legal authority for the registration of births, deaths, fetal deaths, and induced terminations is each state, in the case of this project, the state of Florida. The collection of vital statistics at the national level is dependent on a vital statistics cooperative program. This agreement/relationship between the states and the federal government allows the National Vital Statistics System the opportunity to collect vital statistics from all the states and jurisdictions. The state of Florida was the first in 1971 to transmit coded data to the National Vital Statistics System.

For the purpose of this project, I only worked with the Florida Department of Health at the State level to request the birth and linked death records for IRC births from 2012-2016. The variables I requested from the birth code book included:

- Event year
- Birth ID
- Mother's county of residence
- Mother's zip code
- Date of birth – month, day, year
- Birth weight
- Gestational week
- Mother's WIC Status
- Mother's marital status

- Mother's education level at birth of baby
- Principal source of birth payment – Medicaid, private insurance, self-pay
- Mother's race – Black
- Mother's race – White
- Live birth

Additionally, from the death code book, I requested data for the following:

- Event year
- Date of death – month, day, year
- Date of birth – month, day, year
- Birth ID
- Death ID
- County of residence
- Cause of death
- Age at death

The instrument used/questions asked for the U.S. Standard Certificate of Live Birth include questions such as age, race, demographics, socioeconomic status, as well as medical history of the mother and health status of the newborn.

The U.S. Standard Certificate of Live Birth has 10 sections. I used several sections that ask questions about the mother's health, race, demographic, address, socioeconomic status, education level, and the method of payment and if the mother was receiving WIC. I also used sections about the infant's health at birth (National Research Council, Committee on National Statistics, 2009). Permission to access the data was

obtained through a data usage agreement form. This form was to be completed by the person that would be utilizing the data as well as the institutional review board (IRB) at Walden University. Furthermore, the form also had to be signed by the chair; a payment had to be sent to the Florida Department of Health. Customarily the cost is $50.00 per year requested (each birth year and each death year linked) plus a $100.00 administrative fee. The total amount is calculated and disclosed to the party requesting the data by the State Florida Department of Health when all of the usage agreement are fulfilled and approved.

Operationalization of Constructs

The demographic/variables used in this study are listed below. The questions used the U.S. Standard Certificate of Live Birth. The characteristics are defined in this project as following:

Mother's race. Race is considered a categorical variable. In the section where questions about the mother are asked, the question is listed as "check one or more races to indicate what the mother considers herself to be," followed by these options: White, Black or African American, American Indian or Alaska Native, Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, Other Asia, (specify) Native Hawaiian, Guamanian or Chomorro, Samoan, Other Pacific Islander (specify), Other (specify).

Mother's education. Mother's education level is considered a categorical variable. In the section where questions about the mother's education level are asked, the question is listed as "check the box that best describes the highest degree or level of school completed at the time of delivery," with the following choices: 8th grade or less,

9^{th}-12^{th} grade no diploma, High school graduate or GED completed, Some college credit but no degree, Associate degree (e.g., AA, AS), Bachelor's degree (e.g., BA, AB, BS), Master's degree (e.g., MA, MS, MEng, Med, MSW, MBA), Doctorate (e.g., PhD, EdD) or professional degree (e.g., MD, DDS, DVM, LLB, JD).

Mother's address. The question about the mother's address elicits the following information: street and number; city, town, or location; apartment number; zip code; is the address also the residence; county; and city. For this particular variable, I looked only at zip codes. The zip codes would be a categorical variable.

Mothers' marital status. Mother's marital status is a categorical variable. The question is listed as "mother married (at birth, conception, or any time between), Yes or No" and "If no, has paternity been signed in the hospital, Yes or No."

Mother's payment method. Mother's payment method is a categorical variable. The question is listed as "principal source of payment for this delivery," with the possible responses as follows: private insurance, Medicaid, self-pay, other (specify).

Mother's WIC status. Mother's WIC status is a categorical variable. The question is listed as "did mother get WIC food for herself during this pregnancy"? Yes or No.

Data Analysis Plan

I analyzed my data using the SPSS version 25. Since the data utilized for this project is secondary data, my data preparation plan included learning about how the data is collected to ensure that the questions asked of the mother at birth were all answered, ensuring that the questions asked were clear and understandable. The type of data

analysis used for this project is inferential statistical analysis using hypothesis testing. This analysis is used as a method to draw a conclusion about the hypothesis and if an association is determined between infant mortality in IRC and race (Black & White mothers). For the statistical test using SPSS I used a multiple regression test using the Chi Square test as this was a correlation study. The null hypothesis would have been rejected if the p level is <.05. My research questions explored the risk factors of infant mortality disparity in IRC, Florida.

RQ1: Is geographic location, defined by zip codes in IRC, Florida associated with infant mortality among Black infants in IRC, Florida?

H_o1: Geographic location defined by zip codes is not associated with infant mortality among Black infants in IRC, Florida.

H_a1: Geographic location is associated with infant mortality among Black infants in IRC, Florida.

RQ2: Are measures of socioeconomic status (age, income, educational level, health insurance status, employment, marital status, family structure) associated with infant mortality among Black infants in IRC, Florida?

H_o2: Measures of socioeconomic status (employment, marital status, family structure) are not associated with infant mortality among Black infants in IRC, Florida.

H_a2: Measures of socioeconomic status (employment, marital status, family structure) are associated with infant mortality among Black infants in IRC, Florida.

RQ3: Are measures of federal assistance program status (i.e., WIC) associated with infant mortality among Black infants in IRC, Florida?

H_o3: Measures of federal assistance program status (i.e., WIC) are not associated with infant mortality among Black infants in IRC, Florida.

H_a3: Measures of federal assistance program (i.e., WIC) are associated with infant mortality among Black infants in IRC, Florida.

Threats to Validity

A possible threat to internal validity for this study could be associated with data collection and documentation. The answers asked of the mothers for the purpose of the birth certificate are asked by staff members that are trained at each hospital. If the person that is asking the questions is not trained adequately, there may be a threat to the validity of the data collected. Another threat can be associated with documentation. The staff member who gathers the information is responsible for entering it in the hospital electronic system that will eventually be sent to the State Department of Health.

Ethical Procedures

According to the NIH (2016), researchers have an ethical responsibility of protecting the identity of participants as well as maintaining any information that may identify the person participating in the study. The Participants must be protected from harm as well; this harm can be defined as physical, emotional, and or any type of identifying information shared with the public that may cause embarrassment to the participant (NIH, 2016). As it relates to this study, the information collected should not bring forth any harm in any way to the participants. For this study, I did not collect names and physical addresses; only zip codes were requested from the State of Florida

Department of Health. Thus, there was no danger of identifying who the participants of the study are.

The information collected from each participant at the hospital before couplet discharge is explained to the mothers before collecting. There is no hidden information kept from mothers; they know that it is a requirement to provide this information at the hospital to establish paternity and for the purpose of issuing a birth certificate. It is the responsibility of the hospital as well as the State of Florida Department of Health to safeguard the information collected from mothers at the hospital. The safeguarding of the information collected is ensured by having those that request the information comply with a set of requirements; including completing the data usage agreement form. This includes clearly explaining the purpose of the research and going through the IRB.

The person that collects the information at the hospital is a Florida Notary Public who also serves in the capacity of electronic record collector and is hired and trained by each Florida hospital that has a maternity/labor and delivery department. No data has been analyzed yet; I have not obtained the data/requested to use yet and or gone through the process of Walden University's IRB.

In order to use the data, I had to follow a set of steps that included (a) completing a Data Usage Agreement form provided electronically by the State of Florida Department of Health, (b) obtaining signatures from all parties that would be reviewing the data (my chair, my committee member, and Walden University IRB), (c) submitting the agreement form to Walden University's IRB for approval, and (d) making a payment of the total amount requested by the Florida State Department of Health.

Summary

This chapter provided information about the research questions, rationale, research design, description of variables, analysis of the data, possible threats to the validity, and methodology. A secondary data analysis was used from the archived electronic data obtained from the State of Florida Department of Health. The data set obtained aided in exploring the risk factors of infant mortality disparity in IRC, Florida. My data analysis included an inferential statistical analysis, utilizing the Chi square test ran in SPSS. The findings from this study has the potential to assist professionals in the area of maternal and child health in IRC to identify risk factors of infant mortality disparity and to design programs or interventions that will potentially help in decreasing or limiting the cases of infant mortality in IRC.

Section 3: Presentation of the Results and Findings

Introduction

The purpose of this study was to assess risk factors of infant mortality disparities in IRC, Florida among Black infants. The study was to determine whether there was an association between demographic factors like geographic location (defined by IRC zip codes), socioeconomic status (defined by age, income, education level, health insurance status, employment status, marital status, family structure), and federal assistance program (defined by receiving WIC benefits). Section 3 includes results of statistical analysis completed on secondary data collected from the Florida Department of Health for births in IRC, Florida, from 2012 to 2016. This section also includes evidence of risk factors associated with infant mortality in Black infants and socioeconomic status. The three research questions included in this study were:

RQ1: Is geographic location, defined by zip codes in IRC, Florida, associated with infant mortality among Black infants in IRC, Florida?

RQ2: Are measures of socioeconomic status (age, income, educational level, health insurance status, employment, marital status, family structure) associated with infant mortality among Black infants in IRC, Florida?

RQ3: Are measures of federal assistance program status (i.e., WIC) associated with infant mortality among Black infants in IRC, Florida?

Included in this section are descriptive statistics and demographics of the population studied, the results of statistical analyses performed, evaluation of the

statistical results; these evaluations are organized by each research question. The results include probability values and confidence intervals.

Data Collection of Secondary Data Set

The Florida Department of Health is responsible for collecting all birth and death data from 67 Counties in the state of Florida. Birth records are completed at the hospital of birth at each Florida County before the home discharge of mother and baby. The data collected include demographic information for both mother and father. The variables used in this study include geographic location as well as measures of socioeconomic status (age, income, educational level, health insurance status, employment, marital status, and family structure). The variables requested from the Florida Department of Health are only from IRC for the years 2012-2016. I received the secondary data from the Florida Department of Health, Bureau of Vital Statistics after an IRB process was approved by the Florida State Department of Health. A total cost of $475.00 had to be paid to the Department of Health. This amount was divided into two parts - $250.00 for IRB review and approval and $225.00 for the Department of Vital Statistics to release the secondary data. The data were received by a secure file with a password provided by the Florida Department of Health. Upon receipt and downloading of the file, the data revealed a total of 6,227 files of birth records for White and Black live births. These records correspond to the births in IRC, from 2012 to 2016. A total of 1,169 birth records were for Black live births. This study includes those 1,169 records; of those, a total of 26 deaths were recorded of Black infants.

Discrepancies

There was one discrepancy identified after receiving the secondary data set from the Florida Department of Health, Bureau of Vital Statistics. This discrepancy is related to income data. The birth record information obtained from the mother before hospital discharge does not include the mother's income or the mother's employment status. Although this information is not included in the secondary data set, the WIC status with an answer of "Yes" or "No" is an indication that the mother met the Federal Poverty Level established by the Federal program WIC. In order for a mother to qualify for WIC in Florida, she must meet income guidelines specific to the state (Florida Department of Health, 2020; see Table 1).

Table 1

Federal WIC Income Guidelines for the State of Florida

	WIC income eligibility based on income intervals				
Household size	Annual	Monthly	Twice-monthly	Bi-weekly	Weekly
1	$23,606	$1,968	$984	$908	$454
2	$31,894	$2,658	$1,329	$1,227	$614
3	$40,182	$3,349	$1,675	$1,546	$773
4	$48,470	$4,040	$2,020	$1,865	$933
5	$56,758	$4,730	$2,365	$2,183	$1,092
6	$65,046	$5,421	$2,711	$2,502	$1,251
7	$73,334	$6,112	$3,056	$2,821	$1,411
8	$81,622	$6,802	$3,401	$3,140	$1,570

Note. Adapted from "WIC Income Guidelines," by Florida Department of Health, 2020 (http://www.floridahealth.gov/programs-and-services/wic/wic-income.html). In the public domain.

Results for RQ1

RQ1 - Is geographic location, defined by zip codes in IRC, Florida associated with infant mortality among Black infants in IRC, Florida?

H_o1: Geographic location defined by zip codes is not associated with infant mortality among Black infants in IRC, Florida.

H_a1: Geographic location is associated with infant mortality among Black infants in IRC, Florida.

Secondary data from the Florida Department of Health Bureau of Vital statistics was analyzed from the years 2012-2016 using SPSS version 25.0. For RQ1, a chi-square test of independence was performed to examine the association between geographic location, defined by zip codes in IRC, Florida, and infant mortality among Black infants in IRC, Florida. A total of nine zip codes representing the geographic location of IRC cities were included in this study. The results show that the association between these variables was not statistically significant, χ^2 (8, N = 43) = 13.34, p = .101 (see Table 2). Therefore, the null hypothesis for RQ1 is accepted.

Table 2

Infant Mortality Among Black Infants and Zip Codes

	Mortality			
	No		Yes	
Zip code	O[a]	E[b]	O	E
32948	1	1.19	2	1.81
32958	2	1.19	1	1.81
32960	5	3.16	3	4.84
32962	3	2.37	3	3.63
32966	3	1.19	0	1.81
32967	2	5.53	12	8.47
32968	1	1.19	2	1.81
32970	0	0.79	2	1.21
33180	0	0.40	1	0.60

Note. [a]Observed count, [b]Expected count

Results for RQ2

RQ2: Are measures of socioeconomic status (age, income, educational level, health insurance status, employment, marital status, family structure) associated with infant mortality among Black infants in IRC, Florida?

H_o2: Measures of socioeconomic status (employment, marital status, family structure) are not associated with infant mortality among Black infants in IRC, Florida.

H_a2: Measures of socioeconomic status (employment, marital status, family structure) are associated with infant mortality among Black infants in IRC, Florida.

For RQ2, a logistic regression was performed with infant mortality among Black infants in IRC, Florida as the dependent variable and mother's characteristics such as educational level, age, Medicaid insured, receiving WIC, and being married as the predictor variables. The full model did not significantly predict infant mortality among Black infants in IRC (χ^2= 16.55, df = 30, p = .056; see Table 3). Therefore, the null hypothesis is accepted. Table 3 shows the model accounted for between 34% (Cox & Snell R^2) and 46% (Nagelkerke R^2) of the variance in infant mortality among Black infants in IRC. Table 4 gives the coefficients and the Wald statistic and associated degrees of freedom and probability values for each of the predictor variables. This shows that none of the predictors in the model reliably predicted infant mortality among Black infants in IRC.

Table 3

Model Summary

Step 1	χ^2	*df*	*p*	Cox & Snell R^2	Nagelkerke R^2
Model	16.55	30	.056	.34	.46

Table 4

Variables in the Equation

								95% CI for Exp(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1	Mother's Educational Level	-0.66	0.53	1.574	1	.210	0.517	.185	1.45
	Mother's Age	-0.02	0.06	0.09	1	.764	0.981	.868	1.11
	Medicaid	0.67	1.37	0.239	1	.625	1.956	.133	28.70
	WIC	17.56	3956.18	1.97e -5	1	.996	4.2e +7	0	∞
	Married	0.34	2.11	0.027	1	.870	1.411	.023	87.64
	Constant	2.43	2.65	0.839	1	.360	11.361	.063	2056.7

Note. Death 'Yes' coded as class 1.

Results for RQ3

RQ3: Are measures of federal assistance program status (i.e., WIC) associated with infant mortality among Black infants in IRC, Florida?

H_o3: Measures of federal assistance program status (i.e., WIC) are not associated with infant mortality among Black infants in IRC, Florida.

H_a3: Measures of federal assistance program (i.e., WIC) are associated with infant mortality among Black infants in IRC, Florida.

For RQ3, I performed a chi-square test of independence to examine the association between receiving WIC and infant mortality among Black infants in IRC, Florida. The association between these variables was statistically significant, χ^2 (2, N = 43) = 6.98, p = .030 (see Table 5). Specifically, mothers of Black infants in IRC, Florida, receiving WIC, were significantly more likely to experience infant mortality compared to other mothers of Black infants in IRC.

Table 5

Infant Mortality Among Black Infants and Receiving WIC

	Mortality			
	No		Yes	
WIC	O[a]	E[b]	O	E
Yes	5	8.30	16	12.70
No	12	7.91	8	12.09
Unknown	0	0.79	2	1.21

Note. [a]Observed count, [b]Expected count.

Descriptive statistics (see Table 6) show that, of the 1169 subjects who participated in this study, most were births from the year 2015 (20.70%, *n* = 242), reside outside of city limits (75.28%, *n* = 880), from zip code 32967 (42.69%, *n* = 499), earned a HS diploma/GED (49.70%, *n* = 581), not married (76.13%, *n* = 890), mother receiving WIC (76.30%, *n* = 892), and insured by Medicaid (77.07%, *n* = 901). Of the 26 mothers of Black infants in IRC who experienced infant mortality, most were neonatal in nature (78.26%, *n* = 18). The average age of these participants was 32 years and 9 months (*SD* = 6.03) with the youngest age at 19 years and 9 months and the oldest age at 53 years and 8 months.

Table 6

Participant Characteristics (N = 1169)

Categories	*n*	%
Year		
2012	240	20.53
2013	237	20.27
2014	239	20.44
2015	242	20.70
2016	211	18.05
Mother's Residence		
Indian River Fellsmere	30	2.57
Sebastian	54	4.62
Vero Beach	205	17.54
Outside of city limits	880	75.28
Mother's Zip Code		
32922	1	0.09
32948	35	2.99
32958	64	5.47
32960	177	15.14
32962	303	25.92
32963	3	0.26
32966	28	2.40
32967	499	42.69
32968	37	3.17
32970	14	1.20
33180	1	0.09

34948	1	0.09
34958	1	0.09
34960	1	0.09
34962	4	0.34
Mother's Education		
8th grade or less	5	0.43
9-12 Grade no diploma	179	15.31
High School or GED	581	49.70
Some College no degree	272	23.27
AA	66	5.65
BA	44	3.76
MA	7	0.60
Doctoral	9	0.77
Unknown	6	0.51

(table continues)

Categories	*n*	%
Mother Married		
No	890	76.13
Yes	279	23.87
Mother Receiving WIC		
No	275	23.52
Unknown	2	0.17
Yes	892	76.30
Mother's Insurance		
Charity	34	2.91
Corrections health	1	0.09
Medicaid	901	77.07
Medicare	2	0.17
Medicare acute	1	0.09
Private insurance	212	18.14
Self-pay	18	1.54
Infant Death Type		
Neonatal	19	73.08
Postnatal	7	26.92
Infant Mortality		
Yes	26	2.22
No	1143	97.78

Summary

In conclusion, there was no association between infant mortality among Black infants in IRC and geographic location, defined by zip codes in IRC; there was no association between measures of socioeconomic status, defined by age, education level, health insurance status, marital status and infant mortality among Black infants in IRC.

Conversely, there was a statistically significant association between measures of federal assistance status (i.e., WIC) with infant mortality among Black infants in IRC; (chi-square test of independence (2, $N = 43$) = 6.98, $p = .030$). Mothers of Black infants in IRC, receiving WIC, were more likely to experience infant mortality compared to other mothers of Black infants in IRC.

Section 4 provides an overview of the interpretations, limitations, recommendations, and conclusion that are relevant to this doctoral study. Section 4 also provides comparisons of findings to relevant literature.

Section 4: Application to Professional Practice and Implications for Social Change

Introduction

The purpose of this quantitative study was to assess risk factors of infant mortality disparities in IRC, Florida, among Black and White infants. In general, there was no association between infant mortality among Black infants in IRC and geographic location, defined by zip codes in IRC, nor was there any association between measures of socioeconomic status, defined by age, education level, health insurance status, marital status and infant mortality among Black infants in IRC. However, there was a statistically significant association between measures of federal assistance status (i.e., WIC) with infant mortality among Black infants in IRC. This section includes an interpretation of the findings, limitations of the study, recommendations for further research, and implications for professional practice towards positive social change.

Interpretation of Findings

The analyses of the secondary birth record from the Florida Department of Health, Bureau of Vital Statistics, birth records for Black infant (2012-2016) data, indicated no significant association between the geographic location in IRC (defined by zip codes) and infant mortality in Black infants as well as socioeconomic status (age, education level, health insurance status, marital status) and infant mortality in Black infants. But, the Florida Department of Health, Bureau of Vital Statistics, birth records for Black infant (2012-2016) data showed a significant association between measures of federal assistance status (i.e., WIC) with infant mortality among Black infants. In the

following subsection, findings are compared to the literature and I discuss the significant results.

Findings to Literature

Infant Mortality and Racial Disparities

The work of Matoba and Collins (2017) discussed the deficiency related to maternal and child health in the United States, specifically, risk factors associated with social circumstances of Infant Mortality (IM). Matoba and Collins discussed the twofold IM rate in Black infants compared to White infants. Some of the risk factors associated with IM based on their study are neighborhood level factors, including crime rates, safety, segregation of the Black community, built environment, and institutionalized racism. Matoba and Collins linked these nontraditional risk factors with the poor birth outcomes experienced by the Black community across the United States. Although their study does not specify zip codes; my study and theirs are similar in that they both address geographic location.

Although my study results did not yield a statistical significance with geographic location defined by IRC zip codes, there seems to be a trend with some zip codes. Specifically, data from five IRC zip codes (32948, 32967, 32968, 32970, and 33180) demonstrate a movement and/or pattern. All of these zip codes have a greater observed result than the expected. This seems to indicate some type of trend that may merit additional observation or just exploring the neighborhood characteristics. For example, if these neighborhoods have characteristics like the ones described by Matoba and Collins (2017), those risk factors may be contributing to the IM trend.

Social Determinants of Health and Infant Mortality

The work of Crear-Perry, Richardson, Tarver, & Theall (2017) evaluated the association of racial inequity and structural racism and the attainment of health resources. These authors specifically concluded that being poor and the unequal distribution of wealth is a major risk factor for adverse birth outcomes. My study was able to demonstrate that Black mothers living in IRC, who were receiving WIC at the time of birth of their infants, were at greater risk of experiencing infant mortality. The WIC program is a federally funded program; this program requires that pregnant mothers go through an application process and produce proof of income to demonstrate that they are below the federal poverty level. If approved, the WIC program provides monetary credits for nutritional foods to be purchased at food store/supermarkets that accept the WIC credits.

My study data analyses demonstrated that Black women in IRC who receive, and therefore qualify for, WIC experience IM at a higher rate than those who do not receive WIC (p = .030). From these results we can paint a broader picture that demonstrates that there is an association between income and IM in IRC. Similarly, Wallace et al. (2017) discussed the significant income inequality that has plagued the Black community for so many generations. These authors explained how the lack of attainment of wealth, prevents the Black pregnant woman from entering her pregnancy in a healthy state. The results of my study in reference to WIC also support that Black women are more likely to fall below the federal poverty level, therefore having more socioeconomic difficulties and difficulties securing health resources and dire necessities.

The study of Komoro, Livingston, Markiwitz, & Wagenaar (2016) addressed the issue of poverty. These authors discussed how families that are struggling, due to poverty and low minimum wages, struggle to obtain adequate health insurance and basic necessities like putting food on the table and paying their housing bills. This study concluded that in geographic locations where the minimum wage was higher, those areas had fewer infant deaths (Komiro, 2016). Similar to my study the pregnant women who were receiving WIC were more likely to experience an infant death. My study is utilizing the WIC eligibility as an indicator of a family meeting/falling below the federal guidelines of the poverty level. This result is closely associated with income guidelines.

Racial Disparities in the Southern United States

According to Kirby (2017), geographic areas that are rural in nature pose more risk factors for pregnant women and infant mortality. My study did not find a statistical significance with Black infant mortality and geographic location defined by zip code in IRC. However, he five zip codes listed above have a common trend. It would be beneficial to further investigate whether these zip codes are located in rural areas; IRC has some areas that are considered rural where transportation is a challenge, there is a presence of food desserts, and employment opportunities are not readily available.

Analyzing and Interpreting the Findings in Theory Context

The theoretical framework selected for this study was the socioecological theory, based on the rationale that there are interconnected relationships among personal and environmental factors; this theory takes into account that individual, relationship, community, and societal levels of influence are important and impact health outcomes.

My goal with this study was to add to the body of knowledge that focuses on the society at large and influences health development and health outcomes. The research questions on this current study align with the socioecological theory by addressing variables like the mother's education level, marital status, geographic location, and health insurance status. The variables listed above may contribute to the socioecological theory because these variables are interconnected to societal level characteristic. The mother's education level may be a result of the quality of education available and/or the lack of educational options available in a neighborhood.

The geographic location may be a contributing factor to a myriad of factors, for example, access to adequate medical care, especially if the geographic location is in a rural area. Another factor related to geographic location is whether a pregnant woman has access to stores that are not all fast food stores, whether a woman/family can access healthy foods, and whether the area is not considered a food desert. Lastly, that the geographic location a pregnant woman lives in is not plagued with violence, therefore preventing a person from outside exercise and taking their children outside for play activities. This is an important link to a healthy individual. If a person is not able to access their outside environment, their overall health could suffer. Additionally, the health insurance a pregnant woman is able to access is closely tied to the services available in her geographic location. Some areas in the United States have not expanded Medicaid, and this may impact whether a woman has adequate access to health insurance.

The link between the key elements of the socioecological theory and this study include the birth outcome being dependent on the socio level of the parents/mother as

well as the ecology/geographic location where the mother lives and what resources are available and attainable in that area. The area a mother lives in may be affected by policies implemented by local authorities and, these policies may be adversely affecting the health outcomes of Black babies.

Limitations of the Study

Utilizing a secondary data set creates a number of limitations; the data is not initially collected by the person completing the study, and therefore the researcher must conform to the data provided and hope that the study can successfully utilize data that was originally purposed for a different reason. Additionally, this data set from the Florida Department of Health, Bureau of Vital Statistics, was only obtained for IRC, and the data analyzed is only for Black women and infants who self-reported their information; of the total population provided in the secondary data set, 1,294 births were to mothers that did not self-identify as Black or White. These births are not included in this study. When a study utilizes self-reported data, there is the risk of the participant underreporting their personal information for a number of reasons; these can include being embarrassed about their social status and or their family situation like not being married and or even qualifying for a federally funded program. Because this study is only concentrating on a limited population in IRC, this study is not representative of the entire U.S. Black birth/infant mortality population.

Recommendations

My study concentrated on secondary analysis of data from Black births in IRC, Florida who are residents of IRC, had a birth between the years 2012 and 2016, and

experienced a death of their baby before he or she lived to celebrate their first birthday. Findings from this research study would suggest that further research would be beneficial to expand the geographic location included in the study. A number of options would be beneficial to add to the body of knowledge about contributing factors of IM. An example is a regional study to include counties around IRC (Martin and St. Lucie Counties to the south and Okeechobee County to the west). Including those counties would yield a study of 4 counties and possibly provide a broader picture of contributing factors associated with IM disparity. Additionally, a different study including all births to Black women in the entire state of Florida could also be beneficial to use for the southern states. These states are similar and unique in factors like rural geographic areas as well as socioeconomic status of the Black population. A study of the entire state of Florida could possibly be generalized to the southern region of the United States.

Lastly, a study with mixed methods; a qualitative and quantitative study could explore the same variables, but provide in-depth information about the lived experiences of the population. A mixed method study could guide how policies are developed around the individual needs of the Black women who participate in the study. Learning directly from the participants about their needs, what are some of the challenges that they face when seeking care could help design programs, educational material, develop policies that address the unique needs of the Black population seeking maternal and child health services. All of these factors could also assist health care workers and social service programs in IRC provide adequate services to the community by designing appropriate programs.

Implications for Professional Practice and Social Change

My study examined risk factors of infant mortality in IRC, Florida, specifically the disparity of Black infant deaths. My study looked at the geographic location as well as socio-economic factors that affect the birth outcomes of Black infants. The core of this study was to understand if there is a risk factor that is not being addressed for the Black community that could potentially improve birth outcomes and save lives.

Professional Practice

As it relates to professional practice, the findings of this study can help professionals to design programs, interventions, policies, and procedures that address the Black mothers that live in IRC, Florida, before, during, and after the birth of their babies. It seems important for professionals in IRC, who specialize in the area of maternal and child health to strategize about the health and needs of women of childbearing age. An example of a program design is preconception health; this model could address the needs of the mother before she becomes pregnant as well as the mother planning when she should conceive. Another example is also educational programs that address the need for the Black community in IRC to access adequate education levels to place them on the same level plain as their White counterparts. Securing professional education that facilitates an opportunity to seek employment with equal pay, benefits, employer sponsored health insurance, and job security could allow for the Black women in IRC, to start a pregnancy in a position of advantage; compared to starting a pregnancy with a lack of education, employment, and a living condition that is not conducive to raising a baby in a healthy environment.

Professionals in the area of maternal and child health in IRC, can advocate for funding to be allocated for programs as mentioned above, that address maternal and child health. The findings of this study could be beneficial in allocating resources to the zip codes identified in this study results as demonstrating a possible trend. Professionals can also have discussions about Black women who receive WIC. This office can design resources that provide additional support to women who seek and qualify for WIC services. Knowing that Black women in IRC, Florida who receive WIC have a higher chance of experiencing the death of a baby, culturally appropriate education can be tailored to possibly aid Black mothers with the tools they need to protect their babies. This study can be the start of a body of literature that can be used as a resource to address the needs of maternal and child health—more specifically, the health needs of Black pregnant mothers. Lastly, professionals in the area of public health in IRC, Florida, can advocate for additional studies in the area of IM for Black babies in the area.

Positive Social Change

Positive social change can be accomplished by making an impact on the lives of Black families. Saving Black babies lives requires that an entire community bands together to address a number of structural challenges faced by Black mothers. As this study has demonstrated, mothers that receive WIC are more at risk of experiencing the death of their infant; community leaders, stakeholders, and those professionals that work in the area of maternal and child health can move toward positive social change by dedicating time and effort to this public health concern and having honest productive conversations about eliminating the health disparity. Addressing this concern is a

multilevel approach; this approach includes social determinants of health including a person's living environment. Positive social change includes helping neighborhoods achieve safe levels of living, adequate access to healthy foods by addressing food desert, food insecurities, especially in rural areas. Additionally, positive social change will be accomplished by action on the part of public health leaders, community residents, stakeholders, and those that have the resources to allocate funding for programs (like the Board of County Commissioners, Children's Services Council, United Way, and other funders in the area). Action will come in the form of designing innovative programs that help Black mothers' access adequate health insurance, and programs that produce strategies to also address poverty levels which affect many health adversities like infant mortality in the Black community as a major disparity. One important strategy is to offer programs in IRC where Black community members can attain higher quality education and in turn obtain employment that can open the doors to quality living.

Conclusion

The main purpose of this secondary quantitative study was to assess risk factors of infant mortality disparities in IRC, Florida among Black infants. This would be assessed by geographic location, defined by zip codes in IRC, measures of socioeconomic status, defined by age, education level, health insurance status, marital status, and measures of federal assistance status, defined by Women Infants and Children program (WIC). Chi-square test for independence and logistic regression test were performed; results revealed no association between geographic location defined by zip codes in IRC and Black infant mortality, no association between socioeconomic status

indicators like age, education level, health insurance status, marital status, and Black infant mortality in IRC. However, there was a strong association between women receiving WIC and infant mortality for Black infants in IRC. Preventing infant mortality in Black infants and closing the gap in racial disparity is an important public health concern. Further research can aid in addressing this racial disparity for this population in IRC, Florida.

More research is imperative in this area, it is important to bring this public health concern to the attention of national, state, and local governments in an effort to bring awareness about the racial disparity and to promote sustainable policies that address the need to eliminate this disparity. Annually the public health professional community sets standards and expectations about population health. These standards include maternal and child health expectations. Healthy People Initiative establishes indicators for health topics every 10 years. For the year 2020 Healthy People established a goal of an IMR for the United States of 6.0 with a baseline of 6.7 (Healthy People.gov 2020). The notable factor about this goal is that 10 years ago in 2010 the IMR was 6.1. This indicates that the United States didn't really move the mark in a positive direction in a span of 10 years. Nonetheless, these indicators are for the entire United States. If we were to look at the Black IMR, the numbers would indicate a grim picture. Public health education about the loss of infants in this country is vital to this group who is carrying the burden of this devastating health outcome. If we as a professional public health community want to contribute towards eliminating racial health disparities, we must engage in exploring studies like this one and addressing innovative approaches to address and eliminate health

disparities like the devastating one of infant mortality in disproportionate rates specifically the Black infant mortality.

References

Alio, A., Richman, A. R., Clayton, H. B., Jeffers, D. F., Wathington, D. J., & Salihu, H. M. (2010). An ecological approach to understanding Black-White disparities in perinatal mortality. *Maternal and Child Health Journal, 14*:557-566. doi:10.1007/s10995-009-0495-9

Brady, C., & Johnson, F. (2014). Integrating the life course into MCH service delivery: from theory to practice. *Maternal and Child Health Journal, 18,* 380-388. doi:10.1007/s10995-013-1242-9

Brown-Speights, J. S., Sittig-Goldfarb, S., Wells, B. A. Beitsch, L., Levine, R. S., & Rust, G. (2017). State-level progress in reducing the Black-White infant mortality gap, United States, 1999-2013. *American Journal of Public Health, 107*(5), 775-782. doi:10.2105/ajph.2017.303689

Census Reporter. (2017). *IRC, Florida Gifford Census Tract*. Retrieved from https://censusreporter.org/profiles/16000US1225925-gifford-fl/

Centers for Disease Control and Prevention. (2016). *Infant mortality*. Retrieved from https://www.cdc.gov/reproductivehealth/maternalinfanthealth/infantmortality.htm

Centers for Disease Control and Prevention. (2018). *Premature birth*. Retrieved from https://www.cdc.gov/features/prematurebirth/index.html

Central Intelligence Agency. (2017). World fact book – North America: United States. Retrieved from https://www.cia.gov/library/publications/the-world-factbook/geos/us.html

Christopher, G. C, & Simpson, P. (2014). Improving Birth Outcomes Requires Closing the Racial Gap. *American Journal of Public Health, 104*(S1). doi:10.2105/AJPH.2013.301817

Close, F., Suther, S., Foster, A., El-Amin, S., & Battle, A. M., (2013). Community perceptions of Black infant mortality: A qualitative inquiry. *Journal of Health Care for the Poor and Underserved, 24*(3), 1089-101. doi:10.1353/hpu.2013.0118

Detres, M., Lucio, R., & Vitucii, J. (2014). GIS as a community engagement tool: Developing a plan to reduce infant mortality risk factors. *Maternal and Child Health Journal, 18,* 1049-1055. doi: 10.1007/s10995-013-1337-3

Elder, T. E., Goddeeris, J. H., Haider, S. J., & Paneth, N. (2014). The changing character of the Black-White infant mortality gap, 1983-2004. *American Journal of Public Health*, *104*(Suppl. 1), S105-S111. doi:10.2105/AJPH.2013.301349

Florida Charts. (2018). *Infant deaths*. Retrieved from http://www.flhealthcharts.com/charts/DataViewer/InfantDeathViewer/InfantDeathViewer.aspx?indNumber=0053

Florida Department of Health. (2020). *WIC income guidelines*. Retrieved from http://www.floridahealth.gov/programs-and-services/wic/wic-income.html

Glanz, K., Rimer, B. K., & Viswanath, K. (Eds.). (2015). *Health behavior: Theory, research, and practice* (5th ed.). San Francisco, CA: Jossey-Bass.

Halfon, N., & Lu, M. C. (2003). Racial and ethnic disparities in birth outcomes: A life-course perspective. *Maternal and Child Health Journal, 7*(1) 13-30. https://doi.org/10.1023/A:1022537516969

Healthy People 2020. (2019). Understanding social determinants of health. Retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health

Hernandez, L., Sappenfield, W., Goodman, D., & Pooler, J. (2012). Is effective contraceptive use conceived prenatally in Florida? The association between prenatal contraceptive counseling and postpartum contraceptive use. *Maternal & Child Health Journal, 16(2)*, 423-429. doi:10.1007/s10995-010-0738-9

Hirai, A. H., Sappenfield, W. M., Kogan, M. D., Barfield, W. D., Goodman, D. A., Ghandour, R. M., & Lu, M. C., (2014). Contributors to excess infant mortality in the U.S. South. *American Journal of American Journal of Preventative Medicine, 46*(3), 219-227. doi:10.1016/j.amepre.2013.12.006

Hyder, A., & Reno, R., (2018). The evidence base for social determinants of health as risk factors for infant mortality: A systematic scoping review. *Journal of Health Care for the Poor and Underserved, Volume 29, Number 4, November 2018, PP. 1188-1208*

Kirby, R.S., (2017). The Us Black-White infant mortality gap: Marker of deep inequities. *American Journal of Public Health, May 2017, Vol 107 No5*

Komiro, K.A., Livingston, M.D., Markowitz, S., Wagernaar, A.C., (2016). The effect of an increased minimum wage on infant mortality and birth weight. *American Journal of Public Health August 2016, Vol 106, No.8*

Kothari, C. L., Romph, C., Bautista, T., & Lenz, D. (2017). Perinatal periods of risk analysis: Disentangling race and socioeconomic status to inform a Black infant

mortality community action initiative. *Maternal & Child Health Journal*, *21*, 49–58. https://doi.org/10.1007/s10995-017-2383-z

Loggins, S., & Drummond-Andrade, F. C. (2013). Despite an overall decline in U.S. infant mortality rates, the Black/White disparity persists: Recent trends and future projections. *Journal of Community Health, 39,* 118-123. http://doi.org/10.1007/s10900-013-9747-0

Lu, M.C. (2017). Racial and ethnic disparities in birth outcomes: A life-course perspective. US Department of Health and Human Services. Retrieved from http://nacpm.org/wp-content/uploads/2017/01/DrLuSlides.pdf

Matoba, N., & Collins, J. W. (2017). Racial disparity in infant mortality. *Seminars in Perinatology, 41,* 354-359. doi:10.1053/j.semperi.2017.07.003

National Association of Community Health Centers (2007). *Access Denied, A Look at America's Medically Disenfranchised.*

National Institutes of Health (2016). *Guiding Principles for Ethical Research, Pursuing Potential Research Participants Protections.* Retrieved from https://www.nih.gov/health-information/nih-clinical-research-trials-you/guiding-principles-ethical-research

National Research Council, Committee on National Statistics. (2009). *Vital statistics: Summary of a workshop.* Washington, DC: National Academies Press. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK219884/

Wallace, M., Crear-Perry, J., Richardson, L., Tarver, M., & Theall, K., & (2017). Separate and unequal: Structural racism and infant mortality in the US. *Health*

and Place, 45, 140-144. doi:10.1016/j.healthplace.2017.03.012

World Health Organization (2018). *About Social Determinants of Health*. Retrieved from http://www.who.int/social_determinants/sdh_definition/en/

Appendix A: Permission for Vital Statistics Data Access

HPE/HPEVS Review Sheet: Request for Vital Statistics Data Access

DATE: November 4, 2019

TO: K[illegible]nes, Bureau Chief/State Registrar, Bureau of Vital Statistics (HPEVS)

FROM: Gary Sammet, Operation Manager, Bureau of Vital Statistics (HPEVSPH)

SUBJECT: Research Study --Tracking Number: 2019047 New ☒ Renewal Changes ☐

Applicant: Cecilia Escorbore

Agency/Organization: **Walden University**

Study Title: Risk Factors of Infant Mortality Disparity in Indian River County, Florida

Study Purpose: "The project will explore the infant mortality rate disparity in Indian River County, Florida. This study will specifically take a look at the disparity of infant deaths experienced in this County. Black babies die at a higher rate that white babies in the County (based on the data available on Florida Charts) ; the study will concentrate on the years 2012 to 2016. "

Type of Data Requested: Confidential Yes ☒ No☐ Identifiable Yes ☐ No☒

Year(s) of Data Requested: 2012-2016

Event(s) Requested: Birth, infant death

REQUIRED CRITERIA	YES	NO
Demonstrates scientific merit or business need	☒	☐
Data security procedures	☒	☐
Data destruction schedule	☒	☐
Third-Party Release	☐	☒
Request for waiver or reduction of the fees	☒	☐
Request for follow back	☐	☒
DOH IRB Approval Required	☒	☐
Study results used for presentation or publication	☒	☐

COMMENTS:

RECOMMENDATIONS: **Approve with fee reduction**

2019047

Florida HEALTH

Vital Records Data Use Agreement

Background and Purpose

The Bureau of Vital Statistics at the Florida Department of Health (DOH) may release vital records data to entities with an approved Vital Records Data Use Agreement (Data Use Agreement) for purposes authorized by section 382.025, Florida Statutes. All persons with data access must sign the Data Use Agreement outlining the terms and conditions for using vital records data. A data use agreement is specific to the individual project and all projects require annual review.

The Bureau of Vital Statistics at the DOH conducts a detailed review of every application for access to vital records data and makes a determination on a case by case basis. Requests for confidential data will be granted only if the project meets the statutory criteria, the criteria above, and the project cannot be reasonably completed with de-identified information.

Approved applicants are held to the highest ethical standards and must agree to the stipulations detailed in the Data Use Agreement.

Vital Records Data Use Agreement

Florida HEALTH

Date: *10/2/2019*

I. Project Director Information

Name of Requestor: *Cecilia M. Escorbore*

Title: *Walden University Doctoral Student (candidate 3/2020)*

Requestor's Organization/Agency: *Walden University*

Mailing Address: *100 South Washington Avenue # 900, Minneapolis, MN 55401*

Telephone Number: *(866) 492-5336*

Fax Number:

E-Mail Address:

Contact Person (if different from Project Director):

Contact Person's Telephone Number:

Contact Person's E-Mail Address:

RECEIVED
NOV 0 4 2019
Public Health Statistics
Bureau of Vital Statistics

Does this application update a previous Data Use Agreement? ☐ **Yes** ☒ **No**

If yes, provide Study Number of previous Data Use Agreement:

II. Project Summary

Provide a brief title for your project or study: *Risk Factors of Infant Mortality Disparity in Indian River County, Florida*

Purpose of the Project: *This is a capstone research project that is a partial requirement for my Doctor of Public Health Degree (DrPH). The project will explore the infant mortality rate disparity in Indian River County, Florida. This study will specifically take a look at the disparity of infant deaths experienced in this County. Black babies die at a higher rate that white babies in the County (based on the data available on Florida Charts) ; the study will concentrate on the years 2012 to 2016. The data will only concentrate on black and white births. Socio economic status/variables will be analyzed. The factors that will be analyzed include : geographic location defined by zip codes in Indian River County ; age of mother ; education level ; health insurance status (medicaid or private insurance) ; marital status, WIC at the time of baby's birth..*

Intended Use of the Data: *The data will be used to assess the risk factors associated with infant mortality among black and white babies in Indian River County, Florida. The data will aid in helping leaders in the community to design programs and or interventions that could address the infant mortality rate in the County and hopefully help in decreasing the disparity and maintaining it at a low rate.*

Please describe your plan for the release of results, including plans for public dissemination, if any:
The release of results will be included as part of the capstone project. These projects are published on ProQuest. Proquest is a database that holds a collection of dissertations, scholarly journals, newspapers, reports, and ebooks. This project will become part of Proquest once approved by the project chair, and the University. Additionally, the results of the project are reviewed and approved by the University's Institutional Review Board. Currently there is no plan to disseminate with any other entity.

The publication must cite the DOH as the data source. A disclaimer must also be included that "any published findings and conclusions are those of the authors and do not necessarily represent the official position of the Florida Department of Health."

The Project Director is the Data Custodian for this project; however, there are some circumstances which may allow another person to be the Data Custodian.
[The Data Custodian is responsible for observance of all conditions of use and for establishment and maintenance of physical and electronic security arrangements to prevent unauthorized use. This individual must have the legal authority to keep the information confidential and maintain confidentiality. If the custodian is changed, the organization must promptly notify the DOH Division of Public Health Statistics and Performance Management.

Are you the Data Custodian for this project? ☒ Yes ☐ No

If no, please indicate the name of the Data Custodian and their relationship to the requestor's organization:

Is the requested data needed for work being performed under contract with the DOH? ☐ Yes ☒ No

If yes, then please provide the DOH contract manager's name:

III. Data Requested and Specifications

Data Requested	Data Specifications	Data Format
☒ Birth ☐ Fetal Death ☐ Death with cause-of-death ☐ Death without cause-of-death ☐ Marriage ☐ Dissolution of Marriage	☒ Years (Specify) ***2012 - 2016*** ☐ Statewide Data ☒ County Only (Specify) ***Indian River County***	☐ Photocopies ☒ Electronic Transfer (Secure FTP)

IV. Variables and/or Linking (Matching) of Data

List the specific variable names being requested here or in an attachment to the data use agreement : *Variables requested from* VW_birth_2004_w_ideath – *See List below* :

Birth_DATE_OF_BIRTH_YEAR
Birth_MOTHER_RES_CITY_CODE
Birth_MOTHER_RES_COUNTY_CODE
Birth_MOTHER_RES_ZIP
Birth_MOTHER_DOB
Birth_MOTHER_EDCODE
Birth_MOTHER_MARRIED
Birth_MOTHER_WIC_YESNO
Birth_PRINCIPAL_SOURCE_PAY
Birth_MOTHER_RACE_WHITE
Birth_MOTHER_RACE_BLACK
Death_INFANT_DEATH_TYPE
Death_DATE_OF_DEATH
Death_DATE_OF_DEATH_YEAR
Death_RACE_WHITE
Death_RACE_BLACK
Death_LINK_BIR_DOB
Death_LINK_BIR_DOB_YEAR

Will the data requested be linked or matched with any other data sources ? ☐ **Yes** ☒ **No**

If yes, describe in detail any linking of requested vital statistics data with any other data sources. Specify the data sources, the variables which will be used for linking, (SSN, name, etc.), and which variables will be kept in the linked file.

If the applicant will be linking the data, provide a detailed description of the linking methodology to be used. If the requestor will need DOH to match or link records, describe how the data needing to be matched or linked will be provided.

V. Security and Confidentiality

The release of information that may lead to the identification of individuals or be traced back to an individual record is prohibited. However, statistical and research results based on the data provided by the Bureau of Vital Statistics pursuant to this Agreement may be released. Any person(s) who access, disclose or use personally

identifiable information in a manner or for a purpose not authorized by this agreement may be subject to civil and criminal sanctions contained in applicable federal and state statutes.

Only the listed Data Custodian or authorized users listed on this agreement may access data. Describe where data will be stored and how data will be accessed by authorized users. Data will be stored electronically on a lap top owned by Cecilia Escorbore, the student requesting the data. Laptop access will be locked with password protection.

Do you agree to each of the following requirements?

1) The files will be used only to accomplish the research project described in this agreement. ☒ Yes ☐ No
2) These files, or any files extracted or derived from them, will not be released to other organizations or individuals who have not been named in this agreement. ☒ Yes ☐ No
3) No attempt will be made to link information from any other source to records for specific individuals for whom records are included in these files, unless authorized by this agreement. ☒ Yes ☐ No
4) No listing of information from individual records, with or without identifiers, will be published or otherwise released. ☒ Yes ☐ No
5) No statistical tabulations or research results will be released which reveal information about identifiable individuals. ☒ Yes ☐ No
6) Statistical and research results derived from these files may be published. However, no results may be copyrighted by the author without the permission of the Bureau of Vital Statistics. ☒ Yes ☐ No

RECEIVED
NOV 0 4 2019
Public Health Statistics
Bureau of Vital Statistics

VI. Data Destruction Schedule

Consistent with Florida law, applicants must make provisions for the destruction of records at the conclusion of their project, or when the data is no longer required. Maintaining the privacy of the individuals whose personal information is included in vital records is required to preserve the integrity of the data sharing process.

Please detail the manner and timeline for destruction. If you are following a data destruction policy set by your organization or agency, please attach that policy to your application.

The data destruction schedule will be 12 weeks from the date of receipt or as soon as the statistical analyses is completed using the SPSS system. The quarters at Walden University run 12 weeks. This is the amount of time needed to run all of the statistical tests and interpret the data as well as document and receive approval from the project Chair, Committee Member, and Univerity Research Reviewer.

VII. Data Use by Others

Will any sub-contractors affiliated with this project use the data during the course of the project?
☐ Yes ☒ No

If yes, each sub-contractor or other individual will need to complete a separate Data Use Agreement. Please identify the individuals of the sub-contractor who will have access or be using the data and describe the work they will perform.

VIII. Fees

Prior to generating the data, the DOH will provide an estimate of the costs incurred in its preparation. Once the request is approved and payment received, the data will be provided. A waiver or reduction of the fees authorized by section 382.0255(1), Florida Statutes, will be considered only if the intended use of the data will have a direct health-related benefit to Florida citizens. If a waiver or reduction of the fees is requested, describe how use of the data is a direct benefit to Florida citizens.

As a student I am requesting that the fees for usage of this data is waived or reduced because the study will benefit the Indian River County community by helping with designing programs that are adequate to address the infant mortality disparity experienced in the County. This study will also help leaders make informed decisions about the funding that is allocated for maternal and child health in the community.

IX. Contact with Human Subjects

No contacts of any kind can be made with any person named on a certificate or data file or related persons without the written permission of the Bureau of Vital Statistics and review by the DOH Institutional Review Board (IRB). If the project requires DOH IRB review, applicants must first submit a signed and notarized Data Use Agreement along with the protocol for review to the Bureau of Vital Statistics. A Data Use Agreement may be rejected if the research protocol involves intrusive follow-back of research subjects.

Will the project involve direct contact with individuals or establishments mentioned on the record?
☐ Yes ☒ No

If so, describe the need for such activity and the types of individuals or establishments who will be contacted.

X. All Staff Accessing the Information

List name, title, affiliation and role in this project for each authorized user:
Loretta R. Cain, MPH, PhD - Project Chair

XI. Use and Consent of the Data

Vital records data may only be used for the specific purpose(s) described in this agreement. All persons with data access must maintain the confidentiality of the data and prevent release to unauthorized parties. All publications, tabular presentations, maps or depictions of cartographic information must aggregate results to protect the identity of individuals and comply with applicable state and federal laws. The Division of Public Health Statistics and Performance Management, Bureau of Community Health Assessment, Section of Public Health Reporting shall be notified immediately by phone (850-245-4037) after discovery of any use or disclosure of the data not provided for by this agreement.

As the signatory for this agreement as the Data Custodian, the Data Custodian bears full responsibility for adhering to all data confidentiality, security policies, and the terms of this agreement. The Data Custodian serves as the point of contact for receiving, maintaining, protecting, and ultimately destroying the data provided by DOH. Data may be used by the custodian only for the purpose stated in this agreement and may not be used for any other purpose. No entity with data access may link vital records data with any other source of information without the written authorization of the Bureau of Vital Statistics. Additionally, proper physical, computer and system security safeguards will be maintained by the signatory's requestor's organization/agency pursuant of the agreement.

Physical Security

The requestor's organization shall ensure that DOH data are used and stored in an area that is physically safe from access by unauthorized persons during working hours and non-working hours. The requestor's organization agrees to safeguard DOH data from loss, theft, or inadvertent disclosure and, therefore, agrees to:

1. Secure all areas of the organization's facilities where employees assist in the administration of the program's use or disclose DOH data. Ensure that authorized individuals only access these secure areas

with properly coded key cards, authorized door keys or access authorization; and access to premises is by official identification.

2. Issue identification badges to workers who assist in the administration of the organization's programs and require the organization's workers to wear these badges at organization's facilities where DOH data are stored and used.

3. Store paper records with DOH data in locked spaces, such as locked file cabinets, locked file rooms, locked desks, or locked offices in facilities which are multi-use, meaning that where the requestor's organization and non-requestor's organization functions in one building in work areas that are not securely segregated from each other.

4. Use all reasonable measures to prevent non-authorized personnel and visitors from having access to, control of, or viewing DOH data.

Computer Security Safeguards

The requestor's organization agrees to comply with the general computer security safeguards, system security controls, and audit controls in this section.

General Computer Security Safeguards:

1. Encrypt portable computer devices, such as but not limited to, laptops and notebook computers, that process and/or store DOH data with an encryption solution that is full-disk utilizing a minimum algorithm of 256 bit AES or 3DES (Triple DES) if AES is unavailable.

2. Encrypt workstations where DOH data are stored using an encryption product that utilizes a minimum algorithm of 256 bit AES, or 3DES (Triple DES) if AES is unavailable, and is recognized as an industry leader in meeting the needs for the intended solution.

3. Ensure that only the minimum necessary amount of DOH data is downloaded to a laptop or hard drive when absolutely necessary for current business purposes.

4. Encrypt all electronic files that contain DOH data when the file is stored on any removable media type device (i.e., USB thumb drives, floppies, CD/DVD, portable hard drives, etc.) using an encryption product that utilizes a minimum algorithm of 256 bit AES, or 3DES (Triple DES) if AES is unavailable, and is recognized as an industry leader in meeting the needs for the intended solution.

5. Ensure that all emails sent outside the requestor's organization's e-mail environment that include DOH data are sent via an encrypted method using an encryption product that is recognized as an industry leader in meeting the needs of the intended solution.

6. Ensure that all workstations, laptops and other systems that process and/or store DOH data have a commercial third-party anti-virus software solution and are automatically updated when a new anti-virus definition/software release is available.

7. Ensure that all workstations, laptops and other systems that process and/or store DOH data have current security patches applied and are up-to-date.

8. Ensure that all DOH data are wiped from all systems and backups when the data is no longer legally required. The requestor's organization shall ensure in writing that the wipe method conforms to the US Department of Defense standards for data destruction.

9. Ensure that any remote access to DOH data are established over an encrypted session protocol using an encryption product that is recognized as an industry leader in meeting the needs of the intended solution. The requestor's organization shall ensure all remote access is limited to the minimum necessary and maintains the principles of least privilege.

System Security Controls

In order to comply with the following system security controls, requestor's organization agrees to:

1. Ensure that all systems containing DOH data provide an automatic timeout after no more than 15 minutes of inactivity.

2. Ensure that all systems containing DOH data display a warning banner stating that data is confidential, systems are logged, and system use is for business purposes only. Users shall be directed to log off the system if they do not agree with these requirements.

3. Ensure that all systems containing DOH data log successes and failures of user authentication and authorizations granted. The system shall log all data changes and system accesses conducted by all users (including all levels of users, system administrators, developers, and auditors). The system shall have the capability to record data access for specified users when requested by authorized management personnel. A log of all system changes shall be maintained and be available for review by authorized management personnel.

4. Ensure that all systems containing DOH data uses role-based access controls for all user authentications, enforcing the principle of least privileges.

5. Ensure that all data transmissions over networks outside of the requestor's organization's control are encrypted end-to-end using an encryption product that is recognized as an industry leader in meeting the needs for the intended solution when transmitting DOH data. Encrypt DOH data at the minimum of 256 bit AES or 3DES (Triple DES) if AES is unavailable.

6. Ensure that all systems that are accessible via the Internet or store DOH data interactively use a comprehensive third-party real-time host-based intrusion detection and prevention program or are protected at the perimeter by a network based IDS/IPS solution.

Any failure of persons listed in this agreement to abide by the terms of this agreement constitutes a breach and may result in legal action and/or the demand for immediate return of all data obtained hereunder and the destruction under the supervision of the DOH of all copies of the data in the requestor's, the organization's, employees, agents, assigns, or subcontractor's possession. All actions brought under this agreement will be in the State of Florida. In any action brought by the DOH under this agreement in which the DOH prevails, the DOH shall be entitled to its attorney's fees and court costs.

***** All persons who come in direct contact with vital statistics data are required to sign this agreement. If additional signatures are required, please provide them on the last page of this agreement.**

Project Director's Name (Please Print): Cecilia Escorbore

Project Director's Signature (Notarization Required):
Cecilia Escorbore

Attest (If applicant is a corporation): _____
(As Corporate Secretary)

Subscribed and sworn before me Cecilia Escorbore ***this*** 29 ***day of*** October ***20*** 19.

Notary Public, State of _____ _____ _____
Notary Public Signature ***(Affix Notary Stamp)***

CYNTHIA J DAY
Notary Public - State of Florida
Commission # FF 976346
My Comm. Expires Jul 9, 2020

FOR OFFICE USE ONLY

Fees Waived: Yes ☐ No ☐ Fees Reduced: Yes ☐ No ☐

DOH IRB Recommendation: Yes ☐ No ☐

RECEIVED
NOV 04 2019
Public Health Statistics
Bureau of Vital Statistics

Florida Department of Health Reviewers:

Danny Green **(Reviewer 1)**

Marie Bailey **(Reviewer 2)**

Florida Department of Health Authorization:

_____ 11/7/19

Ken Jones
State Registrar/Bureau Chief
Bureau of Vital Statistics

Date

This agreement shall expire one year from the date above. If the agreement is not renewed, all vital records data must be handled in accordance with the Data Destruction Plan .

Florida HEALTH

Vital Records Data Use Agreement

Signatures below, by individuals who will access vital records data as authorized users, acknowledging agreement to the terms of this Data Use Agreement.

Name Loretta R. Cain, MPH, PhD – Dissertation Chair
(Please Print)

Signature: _____

Name:
(Please Print)

Signature: _____

RECEIVED
NOV 0 4 2019
Public Health Statistics
Bureau of Vital Statistics

Name:
(Please Print)

Signature: _____

Name:
(Please Print)

Signature: _____

Name:
(Please Print)

Signature: _____

Appendix B: Florida Department of Health Institutional Review Board Approval

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Vision: To be the Healthiest State in the Nation

Ron DeSantis
Governor

Scott Rivkees, MD
State Surgeon General

March 30, 2020

To: Cecilia Escorbore

Protocol Title: Risk Factors of Infant Mortality Disparity in Indian River, County, Florida
Submission Type: Initial Review
Review Type: Full Board Review

Approval Date: March 30, 2020
Expiration Date: March 29, 2021

NOTIFICATION OF INSTITUTIONAL REVIEW BOARD APPROVAL
Initial approval by the convened IRB

The Department of Health Institutional Review Board **approved** your study. The study is approved for implementation. As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. Failure to complete an application for continuing review at least 60 days in advance of expiration is considered non-compliance by the Department of Health, and may result in closure of the study, reporting to institutional officials, and reporting to federal regulatory authorities, and suspension of funding, if funded by DOH.

Under federal regulations, if the IRB does not approve an application to continue research prior to expiration, then authorization to continue research expires automatically and all research must stop. Federal regulations do not allow any "grace" period or allow research to continue once authorization expires (except in limited circumstances).

The IRB has approved exactly what was submitted. Any revisions to this protocol or consent form, no matter how minor, must be presented to the IRB for review and approval before implementation of the changes, except where necessary to eliminate hazard to human subjects. If a change is required to eliminate an immediate hazard, the IRB should be notified as soon as possible but no later than 10 working days.

Please keep in mind:

- Report all problems listed below as soon as possible, but no later than five working days.
- If you need to make changes to your study, complete the modification application.
- If you have to make a change to eliminate hazard to human subjects and there is not time to submit a modification, notify the IRB as soon as possible but no later than five working days.

If you have questions, want to offer suggestions, or talk with someone about this or other projects, please contact at the Department of Health IRB at
or toll-free in Florida

Florida Department of Health
Division of Community Health Promotion
4052 Bald Cypress Way, Bin A-13 • Tallahassee, FL 32399
PHONE: 850/245-4100 • FAX: 850/414-6091
FloridaHealth.gov

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Ron DeSantis
Governor

Scott Rivkees, MD
State Surgeon General

Vision: To be the Healthiest State in the Nation

Thank you for your cooperation with the IRB.

Sincerely,

Bonnie Gaughan-Bailey, MPA, ASQ-CQIA
Biomedical Research Section
Public Health Research

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

Federal Wide Assurance#: 00004682

Florida Department of Health
Division of Community Health Promotion
4052 Bald Cypress Way, Bin A-13 • Tallahassee, FL 32399
PHONE: 850/245-4100 • FAX: 850/414-6091
FloridaHealth.gov

PHAB Accredited Health Department
Public Health Accreditation Board

Reportable Events

Report the following problems to IRB Staff, as soon as possible, but within five business days:

- Adverse events and adverse outcomes which in the opinion of the principal investigator are both unexpected and related and suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized.
- Any interim analysis or safety monitoring report indicating the frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
- Any breach of confidentiality.
- Any change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
- Any change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
- Any incarceration of a participant in a protocol not approved to enroll prisoners.
- Any event that requires prompt reporting to the sponsor.
- Any sponsor imposed suspension for risk.
- Any protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm or has the potential to recur.
- Any unanticipated adverse device effect.
- Any non-compliance identified by Department of Health audit or monitoring.
- Any investigation by FDA or OHRP or other federal agency of research (not just including this study) by any researcher on the study.
- Any loss of license or hospital privileges by any researcher on the study.

Contact IRB staff to obtain answers to questions, express concerns, and convey suggestions regarding the HRPP by emailing or calling

Appendix C: Florida Department of Health

The data used in this study was obtained from the Florida Department of Health. The findings and conclusions of this study are those of the author and do not necessarily represent the official position of the Florida Department of Health.

Appendix D: Walden Institutional Review Board Approval Number

Walden University IRB approval number for this study is 06-04-20-0436591.