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Completion Characteristics of Non-Hispanic Blacks with Tuberculosis and HIV

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2019

Abstract

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MSPH, Walden University, 2011

BS, Campbell University, 1995

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Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Tuberculosis (TB) and human immunodeficiency virus (HIV) are difficult conditions to manage, in tandem they pose even more challenges to public health programs in identifying coinfection to ensure that all TB cases are treated to completion of therapy (COT). The purpose of this study was to test variables that predicted COT among the HIV/TB coinfected population of non-Hispanic, U.S.-born Blacks alive at the time of diagnosis. Social determinants of health were the theoretical foundation used to guide the study based on data from the Report of Verified Cases of TB (RVCT) between 2009 and 2014. Relationships were tested between ethnic/racial group membership and the likelihood of COT, and whether any association to COT was moderated by COT eligibility; a Centers for Disease Control and Prevention calculated algorithm considering disease severity, site, age, and disease complexity. The research design was a longitudinal quantitative approach using binary logistic regression to identify correlated variables associated with COT in the final model. The results showed no statistically significant differences among racial/ethnic groups, age, and gender for COT. COT was moderated by COT eligibility; odds ratio (5.4 - 11.6) times more likely to complete therapy. This study supports positive social change for programs by providing data driven outcomes to providers that support outreach, patient education, and disease prevention. In addition, this research describes an evaluation metric based on performance to set a foundation for collaboration among partners who manage other comorbidities in the United States.

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Dedication

This project is dedicated to my late father and best friend Mr. George Thomas Green (Pops), who was my inspiration in striving for excellence in life and through education. How amazing that a person with the "least education" can provide such a wonderful foundation to support and educate others. This endeavor has been and will continue to be a TEAM-TIME TRIAL with my loving and supportive wife Sonja Tia-Patrice Green "*Team Green.*" To Ms. Roberta Green, Mrs. Roberta Gardner and Mrs. Charlotte Denise Walker, you are always on my mind and in my thoughts. Be peaceful in your rest. To George Terrence Green, thank you for showing me the way by sacrificing yourself to set the example.

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Chapter 1: Introduction to the Study

Background of the Study

Tuberculosis (TB) accounts for 9.4 million cases worldwide and is the leading cause of death by an infectious agent. Most of the reported cases come from Sub-Saharan Africa and areas of Europe driven by the human immunodeficiency virus (HIV) epidemic (Getahun, Gunneberg, Granich, & Nunn, 2010). The epidemiology of HIV infection begins with more than 33 million persons infected. Two-thirds of this population lives in Sub-Saharan Africa, and 80 percent of all HIV infections are sexually transmitted. Coinfection estimates are 30 percent of HIV-infected persons usually diagnosed with latent tuberculosis infection (LTBI) (Getahun et al., 2010).

The risk of exposure to TB is the same for all persons who are in close contact with a person that has the active disease; the problem is that risk factors increase for those who have pre-existing medical conditions. Also, episodes of homelessness, IV drug users, working in congregate settings such as churches, jails, drug treatment centers, and those who have immune-suppression conditions such as HIV also increase risk (Centers for Disease Control [CDC], 2014a). TB detection through by administering a tuberculin skin test or IGRA blood test helps practitioners in diagnosis; if positive, additional tests to include an x-ray should be performed to determine in TB infection has progressed to disease. Clinical presentations of TB and HIV infection accentuates the progression of the other resulting in compromised immune situation increasing the complexity of the treatment regimen and duration of treatment time (WHO, 2014a).

Understanding the epidemiology of HIV and TB disease specifically and in tandem is a critical construct of this project because environmental situations and the many platforms in which disease propagates makes interventions very difficult to design and very expensive (CDC, 2014a). Clarity in understanding how each variable interacts concerning completion of therapy could help practitioners focus limited resources efficiently by addressing variables significant to completion of therapy.

Alternatively, understanding those interactions that may not be as significant can is crucial in the redirection of funds, resources, and services. Program Collaboration & Services Integration (PCSI) may provide a framework for intervention implementation with the least amount time and resources. The CDC recommends such collaborations in their 2016 guidelines for improving programmatic standards of care (Sotgui et al., 2016).

In 1882, Dr. Robert Koch announced *Mycobacterium Tuberculosis* (MTB) as the cause of TB which was responsible for the deaths of one out of seven people in the United States and Europe (CDC, 2014a). In the more than 100 years since the discovery, TB has peaked since the 1960s and declined in recent years. During this time there has been a much-publicized decrease in active cases which has provided a false sense of security among Americans (CDC, 2014a).

In 1981, HIV detection and diagnosis began the clinical awareness in a gay man through the treatment of Kaposi's sarcoma, a rare form of cancer. In 1982, acquired immune deficiency syndrome (AIDS) caused by HIV infection began the era of the HIV/AIDS epidemic in the United States, which developed into one of the most resource-dependent health initiatives to date (CDC, 2014a). Both TB and HIV/AIDS are caused by microscopic organisms, bacteria and virus, respectively. Bacteria, viruses, parasites, and fungi are infectious disease organisms that

cause medical disorders and are the most common organisms that cause illnesses (WHO, 2014b). Many of these organisms live in the body and remain harmless to the individual and go unnoticed. Some unnoticed bacterial known as normal flora and serve as a benefit the body.

Other organisms can cause disease, and those disorders are among the reasons why health care is required (Mayo Clinic, 2014). Disease-causing microorganisms are often infectious, and transmission is an insect, animal bite, or other vectors. Some organisms may be passed from person to person through the air, water, or injection (CDC, 2014b). Signs and symptoms of infection or disease often include fever and fatigue (CDC, 2014b). Preventive vaccines help fight the spread and damage of several diseases causing organisms and protect the public from outbreaks.

For example, chickenpox, measles, and influenza all have vaccines that are accessible by most public health agencies and for distribution by the community (WHO, 2014b). TB is an organism that may cause degradation of the body or death if untreated (CDC, 2014b). Vaccination is not currently available as a preventive measure for TB (CDC, 2014b). HIV is one of the most culturally common nomenclatures to date; it can also lead to medical complications such as acquired immune AIDS or death (CDC, 2014a). MTB is spread from person to person through the air usually affecting the lungs. It may also impact other parts of the body such as the brain, kidneys, and lymph nodes depending on the site of infection (CDC, 2014a).

Signs and symptoms of TB vary significantly. Persons with TB often complain of a cough, chest pain, weight loss, and general malaise (CDC, 2014a). HIV has similar signs and symptoms of TB. HIV infected persons may complain of night sweats, weight loss, and general malaise which can make a speedy diagnosis difficult for practitioners because TB signs and

symptoms mimic several other illnesses and carry the moniker “the great imitator” (CDC, 2014a). The critical transmission factors for HIV are sexual intercourse or intravenous (IV) drug use in contrast to an airborne person to person transmission of TB (CDC, 2014a; Metcalf et al., 2014;).

Completion of therapy (COT) characteristics of Non-Hispanic Blacks with TB and HIV is one of several public health concerns for high-risk populations. TB and HIV are among the preventable conditions that have sparked collaborations with other countries and international partners in controlling the transmission and spread of TB and HIV respectively (CDC, 2014b). The National TB Control Program managed by the CDC has a mission to promote health and quality of life by preventing, controlling, and eventually eliminating infectious diseases such as TB in the United States (CDC, 2014b).

Global TB control is facing severe challenges in delivering the quality of care assessable to all persons regardless of barriers such as gender, age, and type of disease, social setting, and the ability to pay (WHO, 2014a). This study is needed because coinfection with TB and HIV makes domestic and international control activities very complex and demanding for keeping communities safe. These challenges must be addressed by national programs to focus on individually tailored approaches that address demographic trends and individual needs (WHO, 2014b).

The effects of understanding completion of therapy for non-Hispanic Blacks may improve outcomes through understanding variables associated with both positive and negative results. Understanding variables may produce positive social change by decreasing the incidence disparities among this population as well as decreasing overall TB transmission because

completion increases the cure probability of TB and dramatically reduces the transmission and the development of new cases and the potential for developing multi-drug resistant (MDR) forms of tuberculosis (CDC, 2014a). Significant sections of discussion for this chapter will include TB and HIV background, problem statement, research question and hypothesis, the purpose of the study, theoretical framework, terms and definitions, assumptions, limitations, the significance of the review, summary, and discussion.

Background

Before the 1960s, TB was one of the most significant causes of death in the world, but the development of tuberculosis drugs reduced prevalence in the United States resulting in a level of TB control (WHO, 2014c). Based on resources, funding, laboratory diagnostics, and expertise, countries of high prevalence were not able to control TB well which resulted in the development of MDR and extensively drug-resistant (XDR) TB cases. All forms of TB ultimately complicate treatment regimens in persons with HIV and increases their chances of adverse outcomes (WHO, 2014c). To address the severe problem associated with drug-resistant strains of TB, the CDC developed recommendations that all people newly diagnosed with HIV should be tested for TB as soon as possible.

The CDC recommends testing because HIV positive persons face a significant risk of progressing to TB disease if they exposed to MTB (CDC, 2014b). Although HIV-related TB is treatable and preventable, incidence rates continued to climb because resources are limited which ensure screening, testing, treatment regimens are started (CDC, 2014a). Drug interactions for overlapping medication toxicities and immune system inflammation further complicate treatment outcomes and completion of therapy. Sub-Saharan Africa has the highest incidence of

coinfection in the world accounting for 79 percent of all reported cases (WHO, 2014c). The rest of the world accounts for the remaining 21 of coinfections.

The WHO first reported TB as a world health problem in 1993 and implemented recommendations and strategies to incorporate directly observed therapy short-course (DOTS) as the best technique for managing TB. Directly observed therapy short-course consist of a health care representative watching patients under treatment ingest each dose of recommended therapy to ensure COT has been met (Bekker & Wood, 2010; CDC, 2014a; WHO, 2014a;). Although HIV testing is the recommendation for persons with active TB, compliance is reduced even in developed countries, resulting in the missed diagnosis of symptoms and providers failure to identify risk factors for HIV transmission (WHO, 2014b).

Kwan and Ernst (2011) stated the intersection between TB and HIV have deadly consequences and require robust interventions; without adequate TB control, the Healthy People 2050 target for TB elimination will not occur. The history of coinfection throughout the world is apparent, but coinfection in the United States does not have the overall research for the national TB program to provide a standard template that addresses comorbidities (Kwan & Ernst, 2011). Despite advances in medicine and overall health care, TB and HIV are collectively a powerful health concerns that remain a consistent challenge for public health programs and private providers to manage screening, testing, treatment regimens, care plans, and preventive activities (CDC, 2014a; WHO, 2014c).

Considering the complex nature of both TB and HIV diagnosis and treatment, public health officials have labeled the presence of both conditions as coinfection or comorbidities and have outlined several interventions that address both conditions through a protocol to increase

the chances of a positive outcome (CDC, 2014a). In 2014, the CDC reported 9,412 cases of TB in the United States that included cases from all 50 states and the District of Columbia (DC) and developed a public health message that TB is still alive and relevant in the country (Alami et al., 2014). In 2014 the CDC also reported an incident rate of 3.0 per 100,000 persons as a significant decrease compared to rates of 5.2% published in 2013 (CDC, 2014a).

Overall TB rates have declined since 1993 to the lowest rates in recorded history, but Asians, Hispanics, and Non-Hispanic Blacks represented the most significant proportion of disease disparity (Alami et al., 2014; CDC TB, 2014a; WHO TB, 2014a;). Disease burden among foreign-born persons in 2014 was 65% of the total reported cases (Alami et al., 2014, p. 35). In 2013, HIV status and test results were published for 88% of all reported TB cases in the United States. Seven percent or 543 persons with TB disease tested positive for HIV (CDC, 2013a). The CDC stated that progress had been made to close the gap among racial, ethnic minorities, and foreign-born persons, but they remain the groups disproportionately affected by TB.

TB is the number one cause of death among persons with HIV and the most common presenting illness accounting for more than 360,000 deaths in 2014 (WHO, 2014a). Persons living with HIV also have an increased burden of drug-resistance if their TB diagnosis is delayed (Alami et al., 2014). To complicate their situation further, multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB places an extraordinary clinical and mental burden on persons living with HIV (Alami et al., 2014; CDC, 2014a; WHO, 2014a;). In 1985, the United States Department of Health and Human Services (USDHHS) published the Heckler Report which documented health disparities among racial and ethnic minorities in the United States.

As a partial response to this publication, in 2010, the Affordable Care Act (ACA) reauthorized the Office of Minority Health to improve the health of racial and ethnic minorities through the development of health policies, programs, and interventions (HHS OMH, 2014).

The USHHS action plan uses the ACA foundation and initiatives such as Healthy People 2020, Let's Move First Lady Project, and the national HIV/AIDS strategy to energize their action plan into real-life interventions. Knowing HIV status of TB patients is a significant part of the CDC treatment and care recommendations.

Providers can determine treatment regimens and referrals to coordinate with other services to provide an integrated care plan to ensure completion of treatment and improve quality of life (QOL) (CDC, 2007). Pascopella et al., (2014) described frequencies and attributed analysis of TB testing and treatment in four Ryan White HIV clinics to highlight the importance of knowing TB status among HIV patients in their cross-sectional study of policies and practices.

This study complied with the Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings (2006). The lack of peer-reviewed studies that link advanced analysis to specific variables associated with completion of therapy among non-Hispanic Blacks is the gap in the literature that researchers recommend further empirical research is required (Abraham, Winston, Magee, & Miramontes, 2013). Over the past five years research has begun to address the gap in the literature concerning comorbidities among persons with TB. The primary reason why the investigation stalled is due to the high cost of treatment and care as well as having a surveillance methodology to support data (Chindelevitch et al., 2015).

Current literature reviews describe three studies related to coinfection, with only one U.S. study highlighting TB and HIV. Rodwell et al., (2010) used longitudinal surveillance data to test associations between TB and HIV coinfection and sociodemographic risk factors with polychotomous logistic regression. This is a sentinel study, very resource dependent, which began the inquiry towards identifying the completion of therapy variable as a covariate.

Understanding components of coinfection where completion of therapy is the dependent variable are not approached in previous studies. This study intends to shorten the current gap in the literature and provide a useful tool that could help identify variables associated with non-Hispanic Blacks and identify other high risk ethnic and racial groups to help providers develop interventions for these populations as described in 2016 CDC recommendations (CDC, 2014a).

Problem Statement

TB transmission among high-risk persons including Non-Hispanic Blacks is an increasing problem for screening, testing, treatment, and the completion of therapy in the United States. Treatment complexity, as well as reductions in funding, has weakened local TB control program's overall effectiveness to reduce health inequities (CDC, 2014a). Unknown HIV status makes completion of therapy and TB cure very challenging, expensive, and uncertain (CDC, 2013b). Collectively, TB and HIV/AIDS coinfection places an individual at higher risk for poor health, morbidity, and mortality (CDC, 2014a). National TB control statistics publication in 2007 for the years (1993-2005) only provide descriptive aggregated data analysis and does not address COT as the dependent variable (CDC, 2007a).

In the 2007 CDC publication researchers described a disproportionately high rate of TB among non-Hispanic Blacks as compared to non-Hispanic Whites. Decreases in local funding

have affected many TB programs abilities to ensure completion of therapy for persons with TB. The CDC suggests that program effectiveness is directly related to losses in resources such as incentives and enablers which have placed a significant burden on local and state programs to address their high-risk populations.

Also, decreases in programmatic capacity based on the same limited resources pose additional barriers for the management of TB cases. Effective case management is an essential resource for reducing incidence and prevalence rates among this population (CDC, 2014a). Increased case rates have prompted the CDC to support programs to employ creative public health initiatives that address the disproportionate rise and increases in urban TB outbreaks (CDC, 2014a). Coinfection requires that individuals receive specialized care and treatment regimens that include systematic program collaboration and service integration (PCSI) by community partners to maintain the continuity of care, and ensure the medical outcome is COT (CDC, 2014a).

Purpose of the Study

This study is a quantitative analysis of systematic data collected by the CDC Division of TB Elimination (DTBE) National TB Surveillance System (NTSS). It focuses on comparing associations and correlations of variables associated with completion of therapy for Report of Verified Cases of Tuberculosis (RVCT) identified racial/ethnic groups with TB and HIV focusing on non-Hispanic Blacks in the United States. By using advanced logistic regression analysis, I hope to identify factors that may correlate to an individual's ability to complete treatment for TB, which results in increase QOL. Aggregated data from the RVCT (2009-2014) database may provide the subject matter to fill the gap identified by the most recent studies.

Both descriptive and advanced studies could provide health care practitioners with data-driven evidence that helps foster initiatives and interventions (CDC, 2014b). Interventions subsequently may be used to stop disease transmission and intervene against disease propagation and degradation of health. Correlations and associations could provide a foundation for understanding individual variables that place race/ethnic groups at a higher risk for coinfection and not completing treatment. This project has the potential to impact and affect positive social change by providing public health practitioners variables that are significant to completion of therapy which may be used to improve the QOL and raise the standards of care offered by TB control programs. Increasing the probability of cure through disease intervention may improve health outcomes as well as address population health determinants.

Coinfection initiatives in Africa have addressed the burden and impact of HIV treatment on the weight of TB programs (Chindelevitch et al., 2015). Researchers in Scotland performed a longitudinal study describing risk factors for persons with HIV based on increased risk of developing TB, new infections, and reactivation of latent TB (McDonald, Smith-Palmer, Wallace, & Blatchford, 2015). One U.S.-based California study (Metcalf, 2013) began to cross-match incident TB cases reported in surveillance systems with HIV registries to compare characteristics of patients with coinfection for mortality and complications of persons not on antiretroviral therapy. Rodwell et al. (2010) sought to understand TB and HIV coinfection trends in San Diego County to identify associations between sociodemographic risk factors and TB and HIV coinfection.

In each study, researchers recognized the significance that comorbidities have of patient outcomes and the importance of surveillance and resource management, and expertise required

to improve outcomes. Comorbidity has been defined by the CDC as an emerging priority of program collaboration to meet the needs of at-risk populations (CDC, 2014c). Prussing et al. (2015) described coinfection among persons with HIV and viral hepatitis as another high-risk population within the New York City population that requires further investigation to develop interventions as defined by CDC for creative initiatives. Marks et al. (2011) published a critical study that examined the trends and risk factors associated with TB mortality to help pinpoint intervention opportunities. This study focused on the HIV variable regarding death which provided an excellent foundation for coinfection research.

In the past five years, researchers have begun to develop studies aimed at comorbidities, but the main factors that prevent local public health agencies from performing necessary data collection are lack of funding (CDC, 2014a; WHO, 2014c). In each study discussed, researchers agreed that more analysis that describes comorbidities were required to help develop strategies within high-risk communities that help practitioners better manage high incidence of cases. The CDC recommends that treatment completion for all persons with TB disease, LTBI, and coinfection among high-risk populations should be the highest priority for TB Control programs for testing, screening, and treatment in the United States (CDC, 2014c).

Rodwell et al. (2010) performed a study evaluating disparities in disease burden in Southern California to understand TB and HIV coinfection trends in San Diego County because they recognized the importance and symbiotic nature of both conditions. The Rodwell et al. (2010) study is only one of a few that asks and addressed several of questions that surround comorbidities of two health conditions. Briggs et al. (2015) and Chindelevitch et al. (2015) discussed program collaboration among TB and HIV programs and literature reviews for

prophylactic treatment regimens respectively, but neither addressed completion of therapy characteristics among high-risk persons to include minorities.

Researchers are beginning to place more emphasis on evaluating the potential impact of HIV treatment with integrated tuberculosis control programs on the overall burden of coinfection (Chindelevitch et al., 2015). Treatment complexity as well as reductions in funding, have weakened the overall effectiveness of local TB control programs to reduce health inequities among all persons at risk to include Non-Hispanic Blacks (CDC, 2014a).

Unknown HIV status can affect completion of therapy outcomes for TB and result in a less than adequate management plan for the patient, resulting in prolonged challenging treatment regimens, excessive costs, and uncertain outcomes (CDC, 2013a). Collectively, TB and HIV infection and AIDS places an individual at higher risk for morbidity, mortality, and degradation of health (CDC, 2013). National TB control statistics last published in 2007 for the years (1993-2005) show ethnic disparities through fundamental statistical analysis. Researchers only provided a descriptive analysis of these data which does not reflect inferences towards understanding why Non-Hispanic blacks are in a higher risk group (Alami et al., 2014).

There are disproportionately high rates of TB among non-Hispanic Blacks and foreign-born persons in the US. The description does not include completion of therapy effectiveness. Decreases in local programmatic funding magnify the importance of analysis to understand associations and inferences. Also, said funding has shown to decrease programmatic capacity to manage cases which is a crucial indicator for higher incidence and prevalence rates among this population based on incomplete contact investigations, staffing, and expertise (CDC, 2014a).

Disproportionate case rates among minorities have prompted the CDC to promote and support programs that employ creative public health initiatives to address rises in metropolitan TB cases and outbreaks (CDC, 2014c). Coinfection identified in a TB case or an outbreak requires an individual to receive specialized care and treatment regimens that include PCSI to maintain a continuity of care. A PCSI program helps community partners facilitate a consistent network of care where completion of therapy can be reached and maintained for all populations (CDC, 2014c).

The lack of peer-reviewed studies that link advanced analysis to specific variables associated with coinfection and completion of therapy among non-Hispanic Blacks is a significant gap in the literature, and my research may provide insight into data trends that support the development of community-based initiatives that are designed to reduce case rates and transmission of TB. Through the dissemination of findings, this study may provide leverage to the field of public health to create changes in policy that reduce health disparities.

The overall focus of my project is to identify relationships among variables available in the RVCT 2007 tool and make data open to the public health community that may influence social change as well as policy. The analysis of variables outlined and reported in the RVCT and described in the Annual Report of TB in the United States surveillance updated but reports are limited to aggregated descriptive components and frequencies to characterize populations.

Data reported in the RVCT consists of the mostly dichotomous variable which is appropriate for multiple regression analysis (Plichta, Kelvin, & Munro, 2013). The variables I chose to examine will be expanded to include dependent variable = completion of therapy; independent variables = HIV status and TB disease; covariates = age, gender, HIV status,

homelessness. Also, injection drug use, alcohol use, occupation, the resident of a correctional facility healthcare provides the type, multidrug-resistance, noninjecting drug use, disease site, previous TB, sputum culture finding, sputum smear finding, chest x-ray finding, status at diagnosis, directly observed therapy, and completion of therapy.

The standard variables discussed support all demographic, clinical, diagnostic, disease and treatment history components of this study. Early diagnosis and timely comprehensive treatment of persons living with HIV and TB are critical components to reducing TB related mortality (WHO, 2014a). Both CDC and WHO recommend screening for active TB among the 5 million persons living with HIV throughout the world.

Considering the gravity and complexity of diagnosis, treatment, and care, the overarching focus of this project is to identify characteristics of completion of therapy among coinfected Non-Hispanic Blacks in the United States. This study employed a longitudinal quantitative design to analyze secondary data for each person diagnosed with TB who has a documented HIV positive status. The dataset resides at the CDC in Atlanta in the National TB Surveillance System dated 2009-2014.

Data analysis will include all verified cases of TB among a subset for Non-Hispanic Blacks with HIV. The data collection design is a nonexperimental observational platform that will involve a systematic analysis of RVCT data to identify relationships, behavioral factors, and relative risks for completion of therapy among non-Hispanic Blacks in the United States.

Research Questions

Research Question 1: What is the relationship between and individual's ethnic/racial group membership among U.S.-born non-Hispanics with an HIVTB co-infection and the likelihood of completion of therapy?

$H_0$1: There is no relationship between individual's ethnic/racial group membership among U.S.-born non-Hispanics co-infected with HIV/TB and the likelihood of completion of therapy.

H_a1: There is a relationship between individual's ethnic/racial group membership among U.S.-born non-Hispanics co-infected with HIV/TB and the likelihood of completion of therapy.

Research Question 2: Is there a relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility?

Ho1: There is a relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility.

Ha2: There is relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility.

Theoretical Framework

Constructs from SDOH help provide and support the framework to establish conditions through relationships, demographics, workplace, risk factors and states that affect the quality of life of an individual (Glanz, Rimer, & Viswanath, 2008). The theoretical framework for

understanding relationships and impact of population groups for completion of therapy of a prescribed TB regimen for HIV positive non-Hispanic Blacks require a longitudinal data collection, extrapolation, and advanced analysis techniques to provide the best opportunity of understanding relationships and inferences.

The SDOH (Glanz et al., 2008; Wilkinson & Marmot, 2003). The SDOH framework focuses on quantitative data collection and analysis of secondary aggregated National Surveillance System data. Data variables for (HIV status, age, gender, housing status, substance abuse, homelessness, unemployment, demographics, diagnostic status, and previous history of treatment) are four essential components of the model and were evaluated for fit. Policymaking: local, state, and federal initiative to support collaboration among programs through funding and guidance to affect both individual and population health us vital to align resources and services. Public health and private providers such as CDC and WHO publish recommendations for programmatic activities that provide a roadmap to meet national objectives and goals for disease intervention.

Social factors, and physical conditions affect COT and is the framework for SDOH. Factors in which the population of concern is born, and lives all affect the QOL and outcomes in the public health model. Outcome variables described in the RVCT dataset for (age, gender, HIV status, homelessness, injection drug use, alcohol use, occupation, a resident of a correctional facility and type of healthcare provider) all contribute to overall health and were collected to evaluate COT. Clinical variables that contribute to the final disposition intended to improve the individual QOL are (multidrug-resistance, noninjecting drug use, disease site, previous TB,

sputum culture finding, sputum smear finding, chest x-ray finding, status at diagnosis, directly observed therapy and completion of therapy) and are important to understand associations.

Access to health services at public health and private clinics is influenced by barriers such as language, availability, costs, education, and preventive care. The study challenges programmatic activities and resources through analysis that identify variable associations that can be used to reverse-engineer an existing program to deliver the outcomes necessary to address coinfection. The result of intervention implementation and social change is directly related to SDOH core constructs. Individual behavior can play a significant role in health outcomes. Persons lost to follow-up, refused treatment, died, moved, or have a disposition as other fall under the completion of therapy subset of variables. The study will provide limited behavioral statistics because the researcher will not interview patients.

Secondary data analysis does offer the completion of therapy variable which suggests a relationship with the patient's ability to interact with their care plan. Biology and genetic factors affect specific populations such as age, sex, race, and HIV status. One of the most critical sections of the analysis design is trying to establish a connection related to individual characteristics. Do women and men have the same odds of completing therapy versus subpopulation of older adults? This study challenges the ideals of SDOH regarding how variables relate to behavior centered on completion of therapy.

The SDOH frame is an intervention theme which helps the practitioner identify variables linked to the RVCT database for disease interaction, intervention, and disruption of transmission. Each component described in the SDOH model outlined is an essential variable for consideration for evaluating the efficacy of public health intervention and programmatic activities (CDC,

2014c). The CDC has published studies that outline SDOH and health inequities as core guidance for co-morbidity activities among public health agencies and the private community. This framework will guide my design by showing graphics and narrative representations that help clarify the analysis process to challenge each research question.

Nature of the Study

A longitudinal quantitative design was used to analyze secondary data for a person diagnosed with TB with a documented HIV status in the United States. The dataset resides at the CDC in Atlanta in the National TB Surveillance System dated 2009-2014. Data analysis will be designed to include all verified cases of TB as well as a subset for non-Hispanic Blacks. The study design consisted of a non-experimental observational platform that will employ data collection of the RVCT with HIV status to identify relationships, behavioral factors, and relative risks for COT among Non-Hispanic Blacks in the United States.

The rationale for the study depends on obtaining an accurate estimate of the relationships between variables (Creswell, 2009). The longitudinal platform helped describe a point in time relationship where completion of therapy interacts with other covariates surrounding TB cases in the United States. Ideally, the quantitative investigation should identify cause and effect relationships between variables. Secondary data does not support cause and effect outcomes but does support correlations and associations that are displayed in odds ratios to describe how strongly the presences or absence of a variable associated with the presences or absence of a covariate (Scotia, 2010).

The primary source of data and information resided in the Division of TB Elimination CDC Atlanta National Surveillance System RVCT database. The dataset was in the form of

aggregated variables collected between 2009 and 2014 for all confirmed TB cases in the U.S. Data collection and analysis from 62 federally funded TB programs that report directly through their local surveillance systems to the NTSS in Atlanta Georgia for analysis. An Excel data requested initiated the process through an analysis plan to receive approval from CDC. The data was analyzed through the logistic regression methods to include fit of (*t* test, one-way analysis of variance ANOVA, F tests, linear regression, contingency tables, and Kaplan-Meier curves).

Each record was satisfied by the Health Insurance Portability and Accountability Act (HIPPA) definition of confidentiality with de-identified outcome variables. Demographic variables for age, gender, HIV status, homelessness, injection drug use, alcohol use, occupation satisfies the first group of analysis. The second group of variables for a medical condition, the resident of a correctional facility healthcare provides the type, multidrug-resistance, non-injection drug use, disease site, previous TB, sputum culture finding, sputum smear finding, chest x-ray finding, status at diagnosis, directly observed therapy, and completion of therapy to complete the analysis.

Variable Descriptions

The dependent variable of interest was COT, and the independent variables of interest are TB and HIV status framed under SDOH.

HIV status: laboratory confirmation (negative, positive, indeterminate, refused, not offered, unknown.

COT: bivariate, yes/no patient completed therapy within one year. (DHHS, 2014).

Age: categorical variable, broken down in years (0-4, 5-14, 15-24, 25-44, 45-64, 65+).

Gender: bivariate, gender of patient at birth.

Injection drug use: bivariate, the patient has NOT injected illegal drugs within the past 12 months.

Non-injection drug use: bivariate, the patient has/has not used non-injecting drugs within the past 12 months.

Alcohol use: bivariate, the patient has/has not used alcohol to excess within the past 12 months.

Homelessness: bivariate, the patient, was/was not homeless at any time during the past 12 months before the TB diagnosis.

Occupation: multivariate, primary work within past year (correctional employee, healthcare worker, migrant/seasonal worker, student, disabled, homemaker.

A resident of a correctional facility: bivariate, actively in correctional custody.

Healthcare provider type: bivariate, local health department or private provider.

Disease site: multivariate, site of disease (pulmonary, Extra pulmonary, both pulmonary/Extra pulmonary).

Previous TB: bivariate, the patient has/has not had a prior diagnosis of TB. Sputum culture finding multivariate, indicates a (positive, negative, not done, unknown).

Sputum smear finding multivariate, indicates a microscopic examination of sputum smear was (positive, negative, not done, unknown).

Chest X-ray finding multivariate, indicates an initial chest radiograph showed (normal, abnormal, not taken, unknown).

Status at diagnosis: bivariate, indicate patient was alive/dead at time of diagnosis.

DOT: multivariate, the patient received/did not receive directly observed therapy (self-administered, observed, both, unknown).

Multidrug-resistant: multivariate, yes/no patient is resistant to at least isoniazid and rifampin.

Methodology used was advanced regression analysis to help identify discussed relationships and correlations to be tested that support or refute meaningful interpretations.

Definitions

Tuberculosis: laboratory criteria for diagnosis isolation of M. tuberculosis, MTB complex from a specimen by nucleic amplification or culture, or clinical case criteria with a positive skin test, two or more TB drugs, positive chest X-ray.

AIDS: acquired immune deficiency syndrome: a severe disease of the immune system that is caused by infection with a virus (WHO, 2014b).

Coinfection: concurrent infection of a cell or organism with two organisms (CDC, 2014a).

Comorbidity: existing simultaneously with and usually independently of another medical condition (Merriam-Webster, 2015).

Completion of therapy: to undergo medical treatment of an illness or disease while receiving all recommended drug regimens (CDC, 2014a).

Demographics: statistical data relating to the population and groups within it (Oxford Dictionaries, 2015).

Diagnostic Status: determination of a diagnostic test outcome or condition.

Drug Resistance: an organism does not respond to the standard initial drug regimen (CDC, 2014a).

Extensively drug-resistant TB (XDR-TB): is a rare type of MDR TB that is resistant to isoniazid and rifampin, plus any fluoroquinolones and at least one of three injectable second-line drugs (CDC, 2014a).

Foreign-born: a person whose country of origin is outside the United State (CDC, 2014a).

Homelessness: a condition of people without a regular dwelling, often unable to acquire and maintain consistent, safe, secure and adequate housing (WHO, 2014b).

Human immunodeficiency virus: "HIV" the virus that causes HIV infection in humans (WHO, 2014b).

Intravenous: situated, performed, or occurring within or entering by way of a vein; also: used in or using intravenous procedures (Merriam-Webster, 2015).

Kaposi's sarcoma: a rare form of a relatively benign cancer that tended to occur in older people (CDC, 2014b).

Latent tuberculosis infection: a person diagnosed with TB infection with a laboratory diagnostic evaluation (CDC, 2014a).

MTB: Mycobacterium tuberculosis the organism that causes TB disease and Latent TB Infection LTBI (CDC, 2013).

Multidrug-resistant (MDR) TB: results from an organism that is resistant to at least isoniazid and rifampin, the two most potent TB drugs (CDC, 2014a).

Mycobacterium tuberculosis: the microscopic bacteria that cause TB disease (CDC, 2014a).

Previous History of Treatment: determination of TB treatment initiation from a clinical or diagnostic determination of TB disease (CDC, 201a).

Program Collaboration & Integration: a systematic consolidation of programmatic resources and services to improve health outcomes (CDC, 2014a).

Quality of Life: individuals' perceptions of their position in life in the context of the culture and value systems in which they live and about their goals, expectations, standards, and concerns (WHO, 2002).

Report of Verified Cases of Tuberculosis: an annual report published by the Centers for Disease Control & Prevention that describes TB in the United States.

Substance Abuse: overindulgence in or dependence on an addictive substance, especially alcohol or drugs (Miller & Hendrie, (2008).

The Great Imitator: the term given to TB disease based on the ability to mimic symptoms of other diseases and illnesses based on radiographic images including types of pneumonia, cancers, sarcoidosis, and HIV/AIDS (CDC, 2014a).

Unemployed: a person without a paid job but available to work (Merriam-Webster, 2015).

Assumptions

The research performed in this project consisted of secondary data from the National Tuberculosis Surveillance System (NTSS), and I have assumed that systematic data collection has occurred between 2009 and 2014 and definitions related to surveillance and demographic data have not significantly changed in meaning and scope. The guidance reflects that all 61 CDC reporting areas are required to report data regularly to NTSS, but individual platforms,

messaging, and systematic limitations may reflect in missing data points and variables. All reported TB cases and HIV positive status was validated by laboratory confirmation or will receive a "clinical" diagnosis based on physician findings.

Provider diagnoses that do not meet either the clinical or laboratory case definition will be considered part of the verification and was not count based on evidence of treatment gaps or disease is verified again for cases lost to follow-up. Confidence in surveillance system data reporting is critical to the integrity of analysis. The study was conducted based on the premise that provider diagnosis "not a component of the case definition" is correctly noted in the RVCT to reflect the actual incidence of cases and surveillance activities genuinely indicate the exact number of reported cases. Validation and acceptance of case definition is a critical component of this study because the researcher must be sure that data indeed describes the disparities among the population.

Scope and Delimitations

HIV status was addressed in this study because, in previous editions of the RVCT document, HIV status was not a required element. In 2009, HIV infection was systematically collected and now provides a robust independent variable associated to coinfection for analysis in conjunction with the completion of therapy variable. Non-Hispanic Blacks are a subpopulation at high risk for TB and HIV requiring health interventions to improve their QOL and completion of therapy outcomes as described by CDC reports (CDC, 2014a). Several populations qualify as high risks such as children, persons with other medical conditions, homeless, diabetes, alcohol use or illegal drugs, or not treated correctly for TB in the past.

Each population warrants evaluation in a separate study, but I wanted to address CDC recommendation criteria for "persons at highest risk," program collaboration, and resource management regarding intervention strategies. Some demographic, clinical, and laboratory variables will be excluded to reduce many variables within the data set. This study evaluated eight years of aggregated data collection that will consist of more than 87 thousand records. Also, TB and HIV data went through rigorous regression analysis, including the 2009 data reported descriptive study.

The most logical framework for this project was a longitudinal non-experiment design based on the extensive aggregated data set as described by (Creswell, 2009). The use of aggregated data will limit this study to quantitative methods and must rule out other designs based on the use of a finite data set leaving the researcher with no options regarding design such as qualitative approaches, or mixed methods. The SDOH model provided several core constructs that guided all analysis. Other models such as Health Belief Model, Precede-Proceed, or Trans Theoretical model rely on an interpretation of data from subjects and will not suit the static nature of secondary data.

Limitations

This study may have inherent limits in the chosen methodology of secondary data analysis. Although the data set will be a representation of all reported cases in the U.S., the entire data set could reflect the detail of data entry practices of each jurisdiction. Binomial logistic regression analysis will only provide data that helps identify associations rather than cause and effect as seen with other designs such as experimental methods (Creswell, 2007). The NTSS data

set should capture the one significant HIV status variable and should not require a merger with the HIV/AIDS database but is limited to a bivariate analysis.

The use of de-identified data prevents follow-up interviews and discussions from being performed with participants for clarifications. The source of the data, sample size, and agency reputation are not in question, but vague data could produce less than robust associations. Misclassification of a race could occur. Thus, the researcher may need to be aware of selection bias of the data set regarding changes with variable definitions such as "confirmed case" which may have changed over time: for example, change in provider diagnosis

Confounding is a significant concern because the completion of therapy dependent variable may have interactions with other factors; however, effects of an unmeasured, and or unknown variable. Large sample size and randomization may control the unknown variable (Creswell, 2009). One significant limitation of a non-experimental predictive design is the researcher may only rely on interpretations, observations, or interactions to conclude. The association for an increase in familywise error across statistical analysis was not controlled by Bonferroni Correction, thus this research is relatively preliminary, and replication is encouraged.

To address study restrictions, associations, correlations, inferences, large sample size, and practical significance may help address some limitations. Analysis were based on surveillance data that is aggregated from various reporting units around the United States. Thus, there may be some variability in data quality and completeness. Self-reporting of race may not be consistent and may vary depending on an individual's perception about race and ethnicity. Centers for Disease Control and Prevention, (2007). Report of Verified Case of Tuberculosis 2009 may have

missing records prior to 2009, because reporting was voluntary. California did not report HIV status from (2008 – 2010).

Significance of Study

Research among Non-Hispanic Blacks to identify risk factors associated with completion of therapy and co-infection could provide a better understanding for all public health and private practice providers in the challenges that high-risk populations have in improving health outcomes for TB. Understanding characteristics associated with completion of therapy among race/ethnic groups may be valuable to define how each subpopulation relates to the others as well as their relative risk for completion of therapy. Aggregated data from (2009-2014) RVCT could provide the subject matter to fill in the gap identified by the lack of literature and allow this research to make a unique contribution to the literature and field of study.

Both descriptive and advanced study could provide health care practitioners with data-driven evidence that helps foster initiatives and interventions (CDC, 2014a). Interventions subsequently could be used to stop disease transmission and intervene against disease propagation and degradation of health. Correlations and associations may provide a foundation for understanding the variables that place non-Hispanic Blacks are at a higher risk for co-infection and not completing treatment. This project may have the potential to impact and affect positive social change by providing public health practitioners variables that are significant to completion of therapy which improves the QOL and raises the standard of care for co-infected persons (CDC, 2014b).

Increasing the probability of cure through disease intervention may improve individual health outcomes as well as address population health determinants. Despite the decrease in death rates after receiving the antiretroviral therapy, they remain twice that of persons without HIV infection (Metcalf et al., 2013). Marks et al., (2011) reported HIV-infected TB patients have 4 to 11 times OR of TB diagnosis at death and a 3 to 20 times the odds ratio of death during TB treatment as HIV-uninfected patients.

Summary and Discussion

This chapter discussed a longitudinal design that described the similarities between TB and HIV as outcomes that cause significant health problems for affected individuals while highlighting non-Hispanic Blacks and other race/ethnic groups. As a single condition, each has specific clinical management strategies and regimens that make overall care and the completion of therapy difficult for providers.

In tandem, co-infection places additional clinical, physical, and operational challenges on the individual and provider that increases the negative impact on high-risk persons such as non-Hispanic Blacks. Ethnic and racial disparities among blacks and other high-risk populations continue to be disproportionate in the United States (CDC, 2014b) and describing variables of association and correlations may help provide data to understand risk factors better.

Chapter two will systematically review the literature on characteristics and peer-review research for co-morbidities related to high-risk persons such as foreign-born, Africans, Whites, Hispanics, U.S.-born, and missed opportunities in the national TB control program that could impact the standards of care for co-infected persons. This chapter will discuss literature search strategies, gaps in literature as well as sentinel studies that provide the foundation further

scientific evaluation. The section continues with highlights regarding the history of TB and HIV/AIDS and includes the significance of co-infection, associated problems, and epidemiology and treatment guidelines. The chapter concludes with a review of theoretical background and methods, PCSI relevance, and summary of risk related issues among non-Hispanic Blacks.

Chapter 2: Literature Review

Introduction

This chapter used the SDOH framework to highlight peer-reviewed research for the high-risk population with TB and HIV coinfection and challenges associated with surveillance, screening, testing, treatment, costs, and a variety of programmatic problems that impact the delivery of services. Also, this chapter outlined public health initiatives that address the problematic management strategies for comorbidities throughout the U.S. and describe several global initiatives that address the public health disparity of having two competing for health conditions and the impact of identifying resources to build capacity for short and long-term intervention. The purpose of this research was to use a quantitative framework outlined in SDOH essential components (policymaking, health services, individual behavior, and biology/genetics) conditions which people are born, live, work, age, and broader environmental factors that shape daily life (WHO, 2014a). Essential components of SDOH highlights advanced data analysis of the national RVCT data set. The ultimate intent of this study was to address the health inequity among race/ethnic groups to guide policies and political systems towards social change.

The importance of program collaboration to battle reductions in funds was discussed to show the further effect on completion of therapy and provide a foundation that teaches an essential need for new research on all co-morbidities including TB and HIV. The literature review was conducted to provide support for research questions discussed in chapter one. Even though TB rates have fallen in recent years in the United States, TB transmission among the high-risk population is still one of the highest concerns especially those living with HIV. People living with HIV are more likely than others to become sick with TB (CDC, 2014a).

High-risk populations such as non-Hispanic Blacks are one of the subgroups where new initiatives are needed to ensure testing, screening, evaluation, and treatment are available to improve completion of therapy outcomes resulting in the cure of TB (CDC, 2014a). Coinfection from TB and HIV requires complex treatment regimens and a cohesion of provider management to ensure adequate continuity of care to ensure completion of therapy for TB. Literature provides by CDC and WHO support guidance and promotes collaboration among health care delivery systems, but costs remain an essential barrier against co-morbidity initiatives (CDC, 2014a; WHO, 2014a). Considering complex treatment regimens and increased surveillance requirements for this population, decreases in funding across both TB and HIV programs makes management activities difficult for public health and private practice practitioners to provide services that reduce incidence among persons with co-infection (WHO, 2014c).

Literature Search Strategy

The literature review was conducted using several forms of scholarly research databases. Walden University Library resources provide a significant portion of obtaining peer-reviewed literature. The EBSCO database offered several of the disease-specific searches for TB and HIV. The links from EBSCO databases led directly to CINAHL, MEDLINE, and Health Source search engines for the keywords:

1. TB and HIV co-infection;
2. Non-Hispanic Blacks health disparities;
3. Comorbidities HIV/TB;
4. HIV disparities;
5. Completion of Therapy HIV/TB;

6. HIV among non-Hispanic Blacks;
7. TB among non-Hispanic Blacks;
8. High-risk populations;
9. Comorbidities, and
10. TB/HIV RVCT guidelines.

Many resources come from CDC.gov, ProQuest, Mayo Clinic.org, and the US Department of Health and Human Services. The scope of literature consists of retrospective research performed in the past five years. Most studies were longitudinal in design evaluating aggregated databases identifying epidemiological trends. Longitudinal studies covered a 10-year span and provided a retrospective linkage between TB cases with HIV.

Theoretical Foundation

Research evidence suggests that public health promotions are more effective when they are driven by behavioral and social science theories more so than those advertisements that lace a theoretical base (Glanz & Bishop, 2010). Glanz and Bishop stated that science theory challenges are a result of contemporary perspectives of multiple levels of SDOH and behavior. The health belief model (HBM), trans-theoretical model (TTM), and social cognitive theory (SCT) all contribute and help researchers translate raw theory into a framework used in health behavioral intervention research.

The HBM was developed in the 1950s by a public health service psychologist to explain the failure of individuals to get involved with their health care to prevent and detect disease (Glanz et al., 2008; Hochbaum 1958). The HBM came into existence during Hochbaum's US Public Health Service study which examined factors associated with TB screening programs.

This investigation was a part of a newly initiated behavior science section outlining constructs of the HBM model:

1. Perceived Susceptibility – an individual's belief about getting a disease or condition;
2. Perceived Severity – the seriousness of contracting an illness and associated outcomes such as death, disability, pain, and social consequences;
3. Perceived Benefits – change of behavior based on the individual's perception that benefits of actions will reduce the threat of disease;
4. Perceived Barriers – potential adverse effects of the preventive measure may affect the individual health action;
5. Cues of Action – preparedness, strategies; and
6. Self-efficacy – internal ability to act (Glanz et al., 2008).

The SCT involves reciprocal determinism, an interaction between people and their environment (Glanz et al.,). Bandura (1977) developed the latest edition of the theory previous called social learning theory. The SCT suggest that the environmental manipulation by an individual may be altered to suit the purpose of that individual, which emphasizes the human ability for collective action constructs of SCT;

1. Reciprocal Determinism – environmental factors that influence individuals;
2. Outcome Expectations – beliefs regarding values of consequences of choices;
3. Self-Efficacy – beliefs that an individual can perform behaviors;
4. Collective Efficacy – beliefs that specific actions bring results;
5. Observational Learning – learned behaviors with exposure to media or interpersonal displays through peer modeling;

6. Incentive Motivation – positive responses or rewards for behavior modification;
7. Facilitation – providing resources that make change possible;
8. Self-Regulation – controlling actions through corrective strategies and social support; and
9. Moral Disengagement – ways of thinking that justify suffering as acceptable and part of an individual's moral standards (Glanz et al., 2008).

The TTM involves several stages of change integrated with process principles of reform that cross many intervention theories which result in the term "transtheoretical" model. Prochaska and DiClemente (1982) conducted a study on smoking cessation where they developed the foundation behavior studies among smokers. Researchers concluded that behavior change played out in stages. Since the publication of this study, the model has grown into a tool to develop health interventions for persons with health and mental disorders, depression, eating disorders, obesity, and many other health conditions that require disease-specific interventions (Glanz et al., 2008). The TTM has undergone many refinements since first introduced in 1982 and has developed into the latest configuration. Six States of Behavior change:

1. Pre-contemplation – no intention to change behavior within six months;
2. Contemplation – plans to act within the next six months;
3. Preparation – intends to act in the next 30 days, has taken some steps towards starting;
4. Action – changed behavior for less than six months;
5. Maintenance – changed behavior for more than six months; and
6. Termination – no relapse or temptation 100 percent confidence (Glanz et al., 2008).

Ten Model constructs to determine processes of change consists of covert and overt activities that individuals use to get through the stated stages. The following ten operations have the most research support in the psychological community:

1. Consciousness-raising – increased awareness of an outcome;
2. Dramatic relief – increased emotional experiences;
3. Self-reevaluation – cognitive and affective assessments;
4. Environmental reevaluation – assessments of behavior on the environment;
5. Self-liberation – belief that one can change;
6. Social liberation – increase in social opportunities;
7. Counterconditioning – substituting good behavior for problem behavior;
8. Stimulus control – remove unhealthy habits adds good habits;
9. Contingency management – consequences for taking steps in positive or negative directions; and
10. Helping relationships – relationships that support healthy behavior change (Glanz et al., 2008).

In understanding models of health behavior, practitioners concentrate on the individual as an essential unit of research and practice. The individual is not the only element of an intervention but indeed is a critical component. Other practitioners are involved in this process such as groups, organizations, worksites, and communities contribute which are composed of individuals (Glanz et al., 2008). The HBM has been used in countless areas of health care and public health including studies for breast cancer, smoking cessation, risky sexual behaviors, and treatment completion studies. The core use of the HBM is in the adaptability it has for

incorporation into other models and frameworks. Vazini and Barati, (2014) published a study that used constructs of the HBM as a behavioral-analytic framework to predict behaviors related to diabetes.

Some challenges of using the HBM alone for future research is limited because it does not consider the emotional component of behavior (Glanz et al., 2008). Glanz et al. (2008) suggest that cues of action are a component missing from research and influences behavior when perceived threats and benefits are high, and perceived barriers are low. In contrast, the SCT focuses on the interaction of people and their environment as opposed to the focus of individuals as seen with HBM. The SCT constructs concentrate on people's ability to alter their environment to meet their individual needs showing the capacity to facilitate collective action. In contrast, the HBM highlights personal perceptions, modifying factors, and the likelihood of activity in the conceptual model which offers a framework that has been popular among researchers (Glanz et al., 2008).

One of the most significant limitations of SCT is that the constructs are broad and confusing to focus on an intervention (Bandura, 1986; Glanz et al., 2008). The TTM has limitations as well but offers multiple constructs which help researchers develop frameworks for public health interventions. The theoretical foundation of HBM, SCT, and TTM are grounded in research and support determine behavior change (Glanz et al., 2008) This academic foundation collectively help researchers develop health equity promotions grounded in theory. Individual theories such as HBM, SCT, and TTM drive initiatives framed under SDOH that focuses core theoretical constructs on helping practitioners understand relationships between people and their environment (WHO, 2014c).

Equitable distribution of population health ensures reduced health care disparities among citizens. Improving overall population health outcomes have become one of the highest priorities among policymakers, health professionals, and community-based organizations both internationally and domestic (Sadana & Harper, 2011; WHO, 2014c). The WHO Commission on the SDOH reported all health-damaging experiences are not natural occurrences, instead of many are structural determinants generated from poor social policies, programs, unfair practices, and politics which promotes social, economic, and health discriminations. Each determinant can link to a condition associated where people live, grow, work, and age (WHO, 2014c). The WHO Commission set an agenda to address three areas in reducing health inequities that are a part of the 2020 initiatives to improve health outcomes:

1. Improve daily living conditions;
2. Address inequitable distribution of power, money, and resources; and
3. Measure and evaluate the problem.

Conceptual Foundation

The conceptual foundation of SDOH is evidence-based which focuses on relationships between determinants and outcomes (Sadana & Harper, 2011). The WHO and CDC support SDOH as their primary framework for health promotions and many studies reviewed in this research project using this context to describe how secondary data analysis help researchers to make inferences about health outcomes based on constructs of SDOH (CDC, 2014a; WHO, 2014a;). Co-infection research, although limited, has provided several studies which researchers have used to describe SDOH in their discussion based on CDC and WHO recommendations. Chindelevitch et al., (2015), Rodwell, (2010), Pascopella, (2014), and Metcalfe, (2013) all used

fundamental constructs of SDOH in their research to influence policy within their communities and improve QOL among their high-risk populations.

The four studies mentioned provide the bulk of coinfection research regarding TB and HIV, but Prussing et al., (2015) used SDOH through population-based surveillance to describe characteristics of viral hepatitis on health outcomes of persons with TB and HIV, which give some perspective on resource collaborations required for managing co-morbidities. The Prussing study showed how the researcher is trying to change policy and the way health services are delivered to make sure those at highest risk are reached.

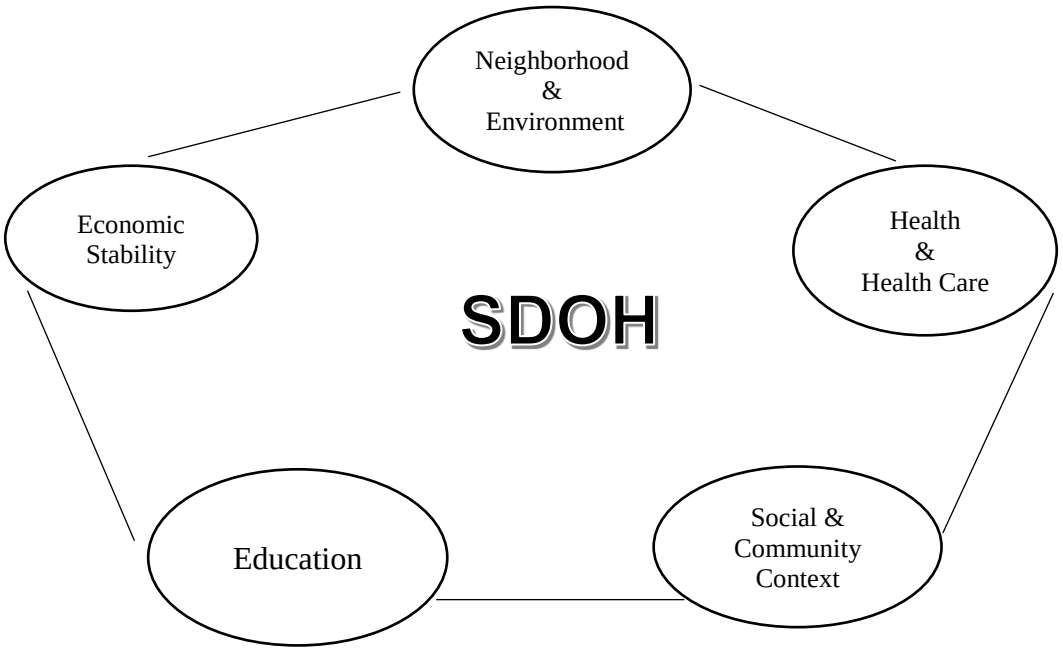

Figure 1. Social determinants of health. Note: Adapted from Healthypeople.gov.

Literature Review

In recent years, TB/HIV coinfection has become one of CDC's most discussed infectious diseases. The challenge to diagnose, treat and control in times of dwindling resources requires

creative and collaborative interventions to help reduce rates among high-risk populations (CDC, 2014a). Pascopella et al. (2014) conducted one of the most comprehensive research studies to assess opportunities for TB diagnosis and prevention among persons living with HIV. In this cross-sectional study, they evaluated policy and practices at four large Ryan White program-funded HIV clinics.

Pascopella et al. (2014) is a seminal study that addresses opportunities for TB diagnosis and prevention among persons living with HIV across more that on clinic or site. This study was one of the first to implement the program collaboration across a broad platform which provides a comprehensive analysis of coinfection in the United States. A review of literature performed by Briggs, Emerson, Modi, Taylor and Date (2015) provided a glimpse of co-infection research which outlined only Isoniazid therapy as a precaution among people living with HIV/AIDS. The researchers state that implementation of such a program has been "slow" in many high burden programs. Methods used were an advanced logistic regression with odds ratios. Researchers reviewed medical records from a 600-person random sample of HIV-infected patients who had experienced at least one visit in 2009 from four clinics in New York and Los Angeles metropolitan areas (Briggs et al., 2015). Researchers described testing and treatment for LTBI during the years of 2008-2010 and estimated odds ratios for obtaining TB services. Results indicated that 79 percent received testing and 21 percent did not (Briggs et al., 2015). Odds ratios describe test levels and degree of treatment after testing positive for TB.

Odds ratios suggested that among the four chosen clinics, routine testing of patients with LTBI did not always document treatment in a population at high risk for developing TB. Odds ratios for non-Hispanic ethnicities OR = 4.9 in comparison to non-Black race at OR = 1.7

(Briggs et al., 2015). Non-Hispanics were less likely to receive treatment for LTBI and Blacks were less likely to receive a chest x-ray to rule out TB. This study is significant to understanding co-infection through a systematic approach which serves as a positive outcome for researchers to build individual disease-specific designs.

The Pascopella et al., (2014) research is a sentinel study that provides the basis for a further investigation under the model of non-Hispanic Black characteristics for completion of therapy. Abraham, Winston, Magee and Miramontes (2012) not only highlighted the importance of managing co-infection in describing clinic deficiencies; they also identified the disparity among non-Hispanic persons compared to non-Blacks. Treatment is recommended to ensure that LTBI does not progress to active TB. (Alami et al., 2014; WHO, 2014a). Research determined that in big city clinics, HIV programs often test for TB, but follow-up for TB treatment is deficient in many circumstances requiring policy changes and practices (Pascopella et al., 2014).

The strength of this study lies in the clinic-based patient-level data where the use of specific variables is beneficial versus aggregated data which only allows the researcher collect data for other reasons (Creswell, 2009). This research shows that clinic-level data can be used to manage co-infection when the use of a surveillance system is in play. My project benefits from this programmatic review by using surveillance systems as a critical component to building an intervention design. Rodwell et al., (2010) sought to understand co-infection trends in San Diego County, California comma to identify sociodemographic risk factors associations among persons with TB and HIV co-infection.

Researchers described the importance that HIV has on TB disease and LTBI reactivation in the rate of disease progression. Rodwell et al., (2010) stated that TB disease also accelerates

HIV disease progression and reduces the effectiveness of HIV treatment. Researchers say that co-infection is a worldwide crisis and directly affects TB elimination for domestic and international partners. The methods used by researchers were an advanced analysis of the California TB Surveillance System data from 1993-2007 of 5,172 verified TB cases.

Cases were grouped by HIV status: positive, negative, or unknown. Of the stated instances 8.8 percent were infected with HIV (Rodwell et al., 2010). Poisson regression analysis was used to identify trends and associations between TB and HIV using social and demographic variables for analysis. Results of the study suggest that co-infection among Hispanics was significantly higher than those of non-Hispanic Whites and Blacks in San Diego, concluding that the burden of co-infection has shifted from Blacks to Hispanics in the past ten years (Rodwell et al., 2010).

Researchers approach the co-infection problem by identifying their high-risk population, which in fact had moved to implement interventions recommended by CDC (Rodwell et al., 2010). Researchers determined that their response should include a binational approach because over 80 percent of co-infection cases are Hispanic. Mexico lacks current resources and policy guidelines for contact tracing; collaboration with resources would be an excellent opportunity to strengthen their TB control program (Rodwell et al. 2010).

The strength of this study lies in the baseline data gathering of a co-infected case to identify associations. The weakness in their approach is retrospective in nature, whereas some key statistics cannot be measured (Creswell, 2009). The variables selected for use were appropriate under the rationale of their design to identify associations among variables. In response to the global concern to develop initiatives that address co-infection outside the United

States, McDonald, Smith-Palmer, Wallace, and Blatchford (2015) conducted a study in Scotland to access HIV infection as a contributing factor for TB as compared to other industrialized countries.

Researchers performed a longitudinal retrospective study in Scotland among co-infected persons between 2001-2010 to investigate risk factors for their high-risk population of persons usually born outside the country, Black or African ethnicity, and refugees, with extra-thoracic lymph node involvement or disseminated TB disease. Researchers extracted 4,097 records from the TB surveillance system database, and 6,790 HIV cases were anonymously linked together (McDonald et al., 2015). Statistical analysis with SPSS for logistic regression was performed to identify associations between co-infection cases and variables for ethnicity and refugee status.

The result described a low incidence of co-infection in Scotland, less than three percent having HIV, which was lower than expected. Most co-infected persons were foreign-born with an advanced pulmonary disease which is associated with high-risk transmission (McDonald et al., 2015). The strength of this methodology is that researcher recognized the link between HIV and TB as high risk and sought to investigate how it affected their community.

The results were not statistically significant, but the fact that those with co-infection were worse resulting in more advanced stages of disease is a confirmation that collaboration among programs is a must. The most significant weakness of the study is the bias regarding the HIV registry. Not all persons with TB are required to undergo an HIV test, which results in the potential of undiagnosed persons with HIV being missed and not included in the study sample. McDonald et al., (2015) used advanced logistic regression with predictor variables for ethnicity and refugee status which are strong indications for this data set and rationale for analysis.

Metcalfe et al., (2013) is one of the few published studies in the United States that attempts to understand the epidemiology of TB. Researchers in California cross-matched TB cases from a centralized state database with cases in the state HIV/AIDS registry for the period of 1993-2008. According to the researchers, effective management of co-infection requires an understanding of disease epidemiology to improve survival. The study population of 57,527 TB cases was analyzed, 3,904 cases had no HIV status. Although TB rates in California had declined during 1993-2008, rates among Hispanics and non-Hispanic Blacks were the highest (Metcalfe et al., 2013).

The method used in this study was primarily multivariate associations with a DV of "death" among TB/HIV patients using relative risk (RR) estimates and co-variates for a time period, age sex, race, ethnicity, foreign-born, and CD4+ count (Metcalf et al., 2013). Researchers concluded that foreign-born persons were at highest risk of death. Hispanics accounted for the highest number of co-infection cases at 57 percent while the instances involving Blacks and Whites declined during the period (Metcalf et al., 2013). The strength of the study is the detailed regression analysis to generate RR estimates for all categories. The most significant limitation of this study was that not all TB cases were a match with HIV status.

Thus, those unmatched reports were HIV-negative. Providers that did not adhere to the CDC guidance for AIDS which may reflect in statements and not be inclusive to this sample. The rationale the researchers used in this study is very much appropriate for identifying associations among co-infected persons in California. Abraham et al., (2013) performed a cross-sectional study using the NTSS data set from 2000-2009 to determine association for the high-risk African populations living in the United States.

This study used advanced logistic regression analysis to describe the characteristics of TB compared to other foreign-born persons residing in the United States. Although this study did not necessarily take the approach of co-infection, researchers determined that Africans are more likely to be HIV-positive and have advanced TB disease in other population (Abraham et al., 2013). The methods used in this study were bivariate analysis calculating odds ratios for HIV status, age, race, ethnicity, substance abuse, homelessness, site of disease, years in the U.S., and gender.

Researchers addressed many of the independent variables outlined in my research to identify association but did not account for the dependent variable of completion of therapy (Abraham et al., 2013). HIV-status was the dependent variable of choice but has similar characteristics in scope with non-Hispanic Blacks regarding determining relationships of HIV-status to include co-infection or not as a critical factory to the outcome for Africans. Also, researchers concluded that their research is the first to elicit characteristics of TB patients diagnosed in the US but born in Africa, which has a public health burden of syndemic TB and HIV cases and are three times higher than others foreign-born persons (Abraham et al., 2013).

The strength of this study was the importance researcher made to address at-risk populations in the US and highlighting HIV as a co-morbidity by suggesting that clinicians who treat TB need to understand “risk profiles” of their patient populations and develop an approach accordingly (Abraham et al., 2013).The most critical weaknesses observed in this research was the omission of data from California and Vermont for the study period. Other California patients had missing HIV data which added a level of collection bias to the study.

Nonetheless, this literature is essential to this design because it begins to touch the surface of co-infection indirectly with HIV-status and considers a national shift in policy as a strategy for disease intervention. Briggs et al., (2015) published a meaningful review of literature that took a systematic look at the use of isoniazid as a preventive therapy (IPT) among people living with HIV/AIDS. The methodology used was a review of 2,228 articles of Persons Living with HIV "PLHIV" eligibility for use in the study were those published between 1995 and 2013 that included variables mortality, morbidity, and retention of care IPT in low and middle-income countries.

After exhaustive abstract reviews, 2,132 articles did meet researcher inclusion criteria. At the end of a full theoretical investigation of the remaining 96 sections, only 55 meet the analysis criteria. Thirty-eight of those reports provided mortality data used in the study (Briggs et al., 2015). A total of eight Retrospective Control Trials (RCTs), nine cohort studies, two case-control studies, and three systematic reviews made the final selection for persons receiving IPT.

Researchers stated their purpose was to understand variables associated HIV-associated deaths: TB is the leading cause of death among persons with HIV/AIDS (CDC, 2014a; WHO, 2014a). Isoniazid preventive therapy has the potential capability of decreasing TB related deaths, but programs around the world have been slow to implement this strategy in both TB and HIV endemic settings (Briggs et al., 2015). The rationale described by the researchers for conducting an exhaustive literature review for suggests that prevention is one of the most critical activities to reduce the burden of HIV mortality for PLHIV. Briggs et al., (2015) recommend the best strategy for preventing TB disease is to include antiretroviral therapy (ART) as an early treatment regimen to reduce incidence rates.

Despite the success of noted by several studies in this review, researchers agreed that risks are significantly higher for PLHIV that those without HIV, suggesting that IPT strategies should be implemented to prevent TB as described by the WHO since 1998. The conclusion of the review supports CDC and WHO recommendations for IPT to PLHIV to reduce morbidity. There is a significant benefit to persons who test positive for TB, treatment should be offered to all PLHIV regardless of presumptive TB (Briggs et al., 2015). Most articles reviewed that were qualified by this study focused on the dependent variable of TB completion of therapy regimen for both TB disease and LTBI. HIV-status was usually the independent variable as a constant with covariates for age, gender, housing status, homelessness, unemployment, and previous treatment under the logistic regression design to determine odds ratios and correlations for the co-infection's population at risk.

The main problem with the review is consistency regarding limitation in data collection and unpublished data. Efficacy of treatment regimens, adherence to treatment, and adverse advents was not within the scope of this review. Briggs et al., (2015) was unable to address MDR TB in their study based on selection bias criteria for exclusion from the study, which further limited their ability to make conclusions for the variable. Briggs et al., (2015) could not address possible changes in case of definitions in their interpretations over time between 1995 and 2014.

The interpretation of case definition could have included or excluded cases from the study depending on the year they were recorded in the surveillance system, thus placing selection bias into their research which provided evidence for further investigation. The significance of the joint studies discussed in this section is the individual components each offers in the understanding of what elements, resources, epidemiology, and specific variables are required to

manage persons with co-infection and which sub-populations are at highest risk for a disease. After components evaluation, the design of interventions strategies and case management activities can take place.

Literature Review Related to Key Variables

What remains to be studied? Research gaps in literature related IPT in PLHIV varies in many countries placing a social burden on capturing short course, long-life, or repeated treatment/therapy. Under this design, a systematic data collection system to collect variables required to access all co-infection variables and co-morbidities is necessary. Also, researchers must include variables for isoniazid drug resistance and MDR-TB. Briggs et al., (2015) suggested that pediatric articles used in their research was limited to only five articles and required further investigation to determine associations of medication. Finally, literature reviews show several short course treatment regimens which have different efficacies and adverse event profiles.

Determining which settings are the most appropriate for each treatment regimen for resistance, duration and effectiveness require more investigations (Briggs et al., 2015). The rationale for the use of the SDOH depends on three key factors that help to ensure that the most productive in this investigation. The first and most compelling reason to use core theoretical constructs from HBM, SCT, and TTM as a foundation was the validity of the science through the long and prosperous history of empirical work that has yielded many of the accepted concepts in psychology. Progresses in health promotion and health behavior research has grown significantly with more precise metrics from the partnership among scientist and healthcare experts (Glanz et al., 2008).

The SDOH model is one of many strategies used to define and address the health care specific need to understand why particular populations are at higher risk for disease and adverse outcomes. The SDOH describe aspects of care, resources, support, covariates, dependent variables, and independent variables that may affect health outcomes such as completion of therapy. The correct tool must be chosen to correctly understand relationships between how populations groups experience both social and physical determinants (CDC, 2014a). The second reason is the recommendations of the WHO and CDC as guidance agencies that encourage public health practitioners to use a standardized approach and framework that is "place-based" where interventions are most effective (CDC, 2014a; WHO, 2014a).

The third reason for the usage of SDOH is directly related to the parameters of secondary analysis of a disease-specific database. The large RVCT NTSS dataset captures variables linked to the framework of SDOH regarding demographics, disease status, outcomes, medical history, social, and economic factors that provide the data for analysis. The data technique of advanced regression allowed for the evaluation of associations for each research question. The first research question in this study describes the dependent variable that relates to completion of therapy of prescribed TB medications. The behavior outlined in this matter is what place-based determinants interact with a co-infection that corresponds to a person either taking or not taking their medication to completion.

What behaviors - physical or social - associate with completion of therapy? The second research question asks; how is completion of therapy among race/ethnic groups affected by HIV? The third research question takes matter two a bit further concerning identifying specific demographic and clinical characteristics through analysis may jeopardize the relationship of TB,

completion of therapy, and HIV if control is present. Social Determinants of Health help to distill the variables necessary to confirm or deny any associations. The independent variables of HIV in research question two similarly corresponds to the same determinants outlined in SDOH and brings another variable into play that has several social components such as stigma that may have a significant association to completion of therapy.

The last research question helps to refine the search for specific associations by accounting for covariates that may contribute to the social status of any person. Prussing et al., (2015) begin to ask what relationships are familiar with disease-specific conditions, they challenged the existing research by accounting for two medical conditions and determining how they collectively affect the health of an individual. Psychological theory alone does not provide the platform necessary for retrospective analysis and must be well-developed and applicable to the methods of data collection and the variables collected (Glanz et al., 2008).

Summary and Conclusions

Demonstrated in this literature review were several essential studies that captured the complex nature of TB and HIV completion of therapy among at-risk populations. The SDOH model provided the theoretical framework in most public health interventions outline through relationships, demographics, risk factors, and conditions that affect the quality of life of an individual. Despite the decline in TB rates and improvements in HIV therapy, coinfection remains a health disparity that requires specialized strategies and interventions to reach populations such as Non-Hispanic Blacks and other high-risk populations in the United States.

Most research regarding co-infection exists outside the United States in Sub-Saharan Africa and other European countries. Surveillance is the dominant theme of the studies reviewed.

Outside the United States, surveillance activities are less advanced but examine large sample sizes and different interventions which are more technical regarding high volume study numbers and populations. Research is limited both outsides and inside the United States that targets smaller at-risk people seen in local and state jurisdictions. Smaller communities require specialized resources and activities to address demographic trends. The overall message of U.S.-based studies is the importance to reach high-risk populations, but resources and funding limit the effectiveness of an individual health department or state program.

Agencies such as the CDC and WHO provide guidance that describes the problem of reaching high-risk communities, including non-Hispanic Blacks, but they offer no definitive solutions regarding cost sharing activities or resources. What we know about co-infection is the importance of treatment, the importance of case management, and most important the completion of therapy. What we known about coinfection of at-risk populations including non-Hispanic Blacks is what variable or variables may contribute to improving completion of therapy.

This study may help bridge the gap in the peer-reviewed literature and provide a small piece of data to support researchers, practitioners, and public health professionals understand how RVCT data interacts with coinfection, completion of therapy, and other demographic covariates. Chapter 3 will describe the research design, population, recruitment, data collection procedures, instrumentation, materials, and statistical analysis used to determine associations among variables for completion of therapy, coinfection, demographic and clinical characteristics among races/ethnic groups.

Chapter 3: Methodology

Introduction

The purpose of this study was to explore quantitative analysis of systematic data collected by the CDC in the national TB surveillance system using the RVCT (2009-2014) data to evaluate the differences between race/ethnic groups in predictors of completion of treatment completion of therapy among U.S.-born patients with TB and HIV co-infection (Alami et al., 2014). This chapter includes a detailed description of the longitudinal research design and rationale, discussion of sample population and recruitment, the measure of variables, data analysis, instrumentation and materials, statistical analysis, procedures, ethical procedures, and summary.

Variables proposed for examination include age, gender, HIV status, homelessness, injection drug use, alcohol use, and occupation, a resident of a correctional facility, type of healthcare provider, multidrug-resistance, and noninjecting drug use. Other essential variables proposed for examination include disease site, previous TB, sputum culture finding, sputum smear finding, chest x-ray finding, and status at diagnosis, directly observed therapy, and completion of therapy.

Research Design and Rationale

Completion of therapy will serve as the dependent variable with a dichotomous designation of yes or no. The case definition per the RVCT outlined a clinical description, laboratory criteria for diagnosis, and case classification of confirmed that meets the clinical case definition or is laboratory confirmed (RVCT, 2009). Although the requirements were complicated, the case definition ensured that consistency of reporting was systematic throughout

all 62 reporting project areas in the United States. Independent variables evaluated in the study were numerous demographic and clinical characteristics of U.S.-born Non-Hispanic races with HIV and TB compared with U.S.-born non-Hispanic Whites.

Independent variables include age, gender, HIV status, homelessness, injection drug use, alcohol use, occupation, a resident of a correctional facility, health care provider type, multidrug-resistance, noninjecting drug use. As well as disease site, previous TB, sputum culture finding, sputum smear finding, chest x-ray finding, status at diagnosis, directly observed therapy, and completion of therapy (all independent variables discussed record as dichotomous and categorical entries). An evaluation of the moderating variable for HIV status as a dichotomous input after controlling for all noted independent variables. A longitudinal quantitative research design was used to analyze secondary of data for persons diagnosed with TB and HIV reported in the RVCT database.

The conceptual framework used in this model was taken from the CDC recommendations outlined in SDOH to identify intervention themes which may help practitioners identify agent, host, and environment for disease interaction intervention, and disruption of transmission (CDC, 2014a). The longitudinal research design could provide a flexible time dimension in capturing co-infection data from the CDC RVCT tool. This longitudinal model is not resource dependent regarding operational costs, personnel costs, and other costs such as incentives and enablers as associated with cohort designs (Creswell, 2009).

Although the design is straightforward in data collection methods and posed fewer resource constraints, gaining access to the data set was time-consuming and required several months for the CDC Analytic Steering Committee to approve my proposed analytic plan. Despite

the lengthy approval process, the timeline was consistent with the design choice and offers another component of project validation from a reputable agency. Literature reviews supported the use of cross-sectional designs in public health interventions mainly concerning TB therapy. Mitruka, Winston, and Navin (2012) used a cross-sectional methodology to outline predictors of failure in timely tuberculosis treatment completion in the United States.

Researchers used a Poisson regression analysis to assess predictors of failure in completion of therapy. Metcalfe et al., (2013) use a cross-sectional design and multivariate regression analysis to evaluate the potential impact of enhancing HIV treatment and tuberculosis control programs on the burden of tuberculosis. The longitudinal design choice was essential in measuring differences between or from a variety of people drawing inferences from existing differences between people subjects or phenomena (USC, 2016).

Methodology

The target population proposed in this study consisted of all U.S.-born "counted" TB cases with HIV infection reported by local, state, and private providers in the United States that meet the clinical case definition and laboratory criteria for diagnosis, and case classification for confirmed entered in the National Tuberculosis Surveillance System (RVCT SSM, 2009). In 2014 the national TB case count was 9,421 reported to CDC for 50 states and the District of Columbia, 6 percent of reported TB cases were HIV positive (n = 492). The target sample population were TB patients reported to CDC during (2009 and 2014) coinfected with HIV and eligible to complete treatment (that is: not dead at diagnosis) was (n = 4,360) (CDC, 2013).

Among this population, age categories were broken down into 0-14 years, 15-44 years, > 44 years, and unknown. The sampling strategy deployed in this study was criterion-based for

subpopulations of U.S.-born Non-Hispanic races with HIV compared to U.S.-born Non-Hispanic whites. Criterion-based sampling involves selecting specific cases that meet a predetermined criterion of importance set by the researcher (Creswell, 2007).

The overarching reason for selecting this method was to tease out all HIV negative cases and isolate CDC outlines those persons at highest risk of death and degradation of health based on immunocompromised guidance. Guidance state that without treatment, opportunistic infections such as HIV and TB can work together to shorten lifespans (CDC, 2014a). Persons that were the U.S.-born with co-infection will provide the platform for the application of regression analysis

Procedures

A proposal for an analytic plan was submitted to the Division of Tuberculosis Elimination at CDC Atlanta on 2 February 2016 that was not approved base on an unclear analysis plan. I sent a revised analysis plan on 18 April 2016 which was agreed on 30 April 2016 to work with the NTSS 2009-2014 RVCT dataset with guidance from the division data steward and provide him with the completion of therapy dependent variable and other independent variables approved in the analytic plan. The data steward prepared and exported an Excel file conversion from the CDC standard SAS output that was imported and converted into an SPSS 21 Statistical Analytical Software output and secured by the data steward on the CDC secure server for future analysis after IRB approval for this project.

A study population sample comes from the CDC surveillance section which includes 78,543 total cases reported between 2009 and 2014. A cross-tabulation analysis for U.S.-born, HIV positive, non-Hispanic cases was performed in SPSS to yield a sub-population data set of

2,192 cases to validate that the power requirement for a robust analytic plan. The recommend power for binomial logistic regression is a minimum of 15 cases per variable (15 x 81) (*n*=1,215). If the data is skewed, the recommendation is 20 cases per variable or (*n*=1,620) (Field, 2009). The dataset consists of clinical and laboratory criteria described in the 2009 RVCT guidance document for confirmed cases. The variable for completion of therapy was recommended for recording by the data steward into a dichotomous format to account for reasons therapy was extended and accommodate treatment regimens that take longer than 12 months per data dictionary definition (RVCT, 2009).

Recruitment

The sampling frame for inclusion criteria will include all U.S.-born non-Hispanic racial groups to include U.S.-born Hispanics as a separate race. The CDC collects case reports from the 50 states and the District of Columbia (DC). All received case reports go through a passive surveillance process from health departments, and healthcare providers before submission go forward. Health departments conducted active surveillance activities through contact and interaction with healthcare facilities or individual providers to stimulate disease reporting (Alami et al., 2014). All cases were required to meet the case definition for clinic and laboratory confirmation with a recorded HIV positive status. One of the most crucial inclusion variables included in this study was age.

The age variable was recorded as categorical data to include children, adolescents, and senior adults. This criterion is critical to stratify data to ensure smaller errors in estimations (Creswell, 2009). Patient and county-level data and variables are not necessary for this project and were exempt from this analysis to ensure confidentiality of individual. Laboratory

diagnostics for molecular assays were not used and limited to documentation of positive smear and sputum culture findings in compliance with the laboratory definitions of a case.

Categorical Racial/Ethnic Groups

Categorical, racial and ethnic groups were defined for all verified cases of TB and HIV in the analysis. Five categories were outlined for race and Hispanics as a race was also collected in the data and described in the data dictionary. Ethnic groups were collected as Hispanic and non-Hispanic U.S.-born persons.

- All U.S.-born;
- U.S.-born Non-Hispanic Whites;
- U.S.-born Non-Hispanic Blacks;
- U.S.-born American Indian or Alaska native;
- U.S.-born Asian;
- U.S.-born Native Hawaiian and (other) Pacific Islander; and
- U.S.-born Hispanics.

Exclusion criteria included all foreign-born cases with and without HIV status. Close attention was made not to add cases with HIV negative status to refine the sub-population in the most precise terms and reduce the size of the overall data set. Besides, internal data cleaning and quality assurance techniques by CDC surveillance will help to ensure that any one case was not counted twice within any consecutive 12-month period.

However, case inclusion could occur in the data set if the individual was lost to supervision for more than 12 months status with TB disease verification for the second time. Genotype data was not relevant to this study because completion of therapy was not affected. In

contrast, drug resistance variables for MDR were significant because treatment times and regimens vary from drug-susceptible TB which may have associations with completion of therapy. These criteria completed the scrutiny of each RVCT data collection variable and series of responses pertinent to identify correlations all research questions related to co-infection and completion of therapy.

Power Analysis

The research design addressed correlations between variables of TB and HIV status and the completion of therapy within the sample population as the dependent variables. A power analysis using G*Power 3.1.9.2 statistical software will describe linear bivariate regression (Two-group) alpha = 0.05 and Power (1-B) probability set = 0.95 the total sample size requires 198 participants. Under the difference between slopes, statistical test total sample size (n=1,215) determine whether the slopes were significantly different from each other. Longitudinal data provided 2,192 cases which satisfied requirements. The ability to reject the null hypothesis depends on alpha, sample size, and effect size (Field, 2010).

Alpha is the probability of rejecting type I error, or the likelihood of rejecting the null hypothesis given the null hypothesis is true. Although alpha is considered arbitrary, it was chosen to challenge each hypothesis. Sample size, when increased, leads to more accurate estimates and the potential of finding what the researcher is looking for (Field, 2009). The choice to use a large sample size satisfied analysis requirement because the data set was robust which may lead to more accurate estimates. When the effect size is more significant, it can lead the researcher to understand the effect in the population (Field, 2009). In this study alpha = 0.05 was

a moderate effect and chosen to identify statistical significance to help in the decision making of public health practitioners (Creswell, 2009).

Data Access Procedure

The requirements to obtain access and permission to analyze the NTSS 2009-2014 data set for the sample population involved the submission of a completed formal Analytic Plan. The analytic plan was prepared and submitted to the surveillance manager at the Centers for Disease Control and Prevention Division of Tuberculosis Elimination (DTBE) Analytic Review Panel for scientific integrity and feasibility. The plan outlined the principal investigator, author, project supervisor, methods of analysis, study population key variables; IT issues, analytic approaches, hypotheses, data table shells, study limitations, proposed times for start and finish analysis, proposed finish manuscript, statistical software used, and references.

In the process, the analytic review panel consisted of surveillance staff, epidemiologic experts, and medical officers to access the plan for merit and overall scientific relevance. The first proposal was submitted February 2016 and was denied based on insufficient methods and project description. On March 15th a revised plan was submitted and subsequently approved on 20 April 2016 with comments from the review panel to move forward with completing training and system requirements. A data sharing agreement was required to receive final access including a timeline for publication of findings in a future edition of the CDC Morbidity and Mortality Weekly Report (MMWR).

The entire approval process took several months, and data download of the 2009-2014 data set was received on 15 May 2016. Agency stipulations require that all researchers must work on data at their work site. Making copies of the data set are not authorized at any time. A

Non-Research determination may be necessary to complete the agency process towards the end of the project period.

Instrumentation and Operationalization of Constructs

The CDC managed and sponsored RVCT database was fully implemented in 1983 as a national surveillance to collect information on new cases of active TB. All states in the U.S. report to this system through the RVCT form. Downloads from several sources including CDC.gov and many local and state public health links provide regular access for surveillance. The appropriateness to this study is the capability of the surveillance system to be used by the CDC to identify trends, create reports, and develop priorities for a public health agency to implement disease interventions (RVCT, 2009).

The basis for tool development depends on providing state and local TB control programs the ability to utilize reports and analysis from the RVCT to identify high-risk populations and identify outbreak trends within their jurisdictions. The CDC provides permission to use the surveillance tool for surveillance purposes, and confidentiality is following Section 308 (b) of the Public Health Service Act (42 U.S.C. 242m).

The CDC implemented the National Tuberculosis Indicators Project (NTIP) with collaboration from the California Department of Health to validate the selected objectives and standardize the measurements related to the progress of meeting national objectives and goals of the data points collected within the RVCT. A CDC team of experts TB Control staff from Colorado, New York State, Minnesota, and Tennessee worked to identify validity, reliability, and accuracy of each measure and designed a template. The data were submitted the National Tuberculosis Controllers Association (NTCA), the Advisory Council for the Elimination of

Tuberculosis (ACET), the TB education and Training Network (TBN). The Evaluation Working Group (EWG), and others to validate the indicators and guide the implementation of the RVCT (CDC, 2010).

The RVCT instrument was previously used in 2005 by CDC for the entire US population of 14,093 active TB cases. The RVCT variables were revised and validate several times and made available to cooperative agreement recipients for TB control funding in 2008 for (completion of therapy, laboratory reporting, clinical reporting, genotyping, and case management variables) used in the current RVCT form (CDC, 2010).

Operationalization Data Analysis Plan

To investigate the relationship between variables regression analysis is the technique of choice. The SPSS Statistical Software package 25 provided the platform for all analysis. Software package addresses the entire statistical process from planning, data collection, analysis, and reporting (IDRE, 2016). The analysis plan will begin with running the descriptive variable study for completion of therapy, HIV positive, TB case, and all demographic characteristics outlined in the data shell. Choosing the correct statistical test will consist of identifying the number of dependent variables completion of therapy =1 and matching the number of dependent variables described in the Institute for Digital Research and Education web page.

Paring of variables through matching with measures and tests to produce a systematic procedure of running each test under the regression platform. Listed below is the logic of analysis progression to identify associations or correlations with each research question and hypothesis noted below:

1. Descriptive Characteristics: frequencies, percentages, ages, cross-tabulations, mean, median mode, sum standard deviation, variance, range, minimum, maximum SE mean, skewness, and kurtosis, and ration statistics;
2. Binary Logistic Regression (BLR);
3. Characteristics of U.S.-born Non-Hispanic Races with HIV compared with U.S.-born Non-Hispanic whites: odds ratios, confidence interval, and probabilities; and
4. Bonferroni correction: multiple-comparison correction used when several dependent or independent statistical test are being performed on the same sample (Field, 2009).

Data cleaning techniques began with the CDC RVCT requirements for reporting cases to the NTSS database with passive and active surveillance. Benefits of using RVCT data increases access to the completeness of data, improved data for program planning and policy development, sharing of accurate information with patient and health facilities (RVCT, 2009). The CDC promotes active surveillance for health departments and providers to contact and interact with healthcare partners to stimulate disease reporting and improve the accuracy of data. In response to quality assurance, the CDC provides self-study modules that help participants learn how to complete the RVCT form accurately.

The RVCT expansion took place in 2009 which requires all agencies that report cases to counted cases of TB and suspected cases of TB or on a patient with LTBI (RVCT, 2009). Upon receipt of the RVCT dataset data cleaning began with the Excel data file. The first step is to cross-tabulate completion of therapy with HIV and TB status. Once dataset reduction has taken place, all additional variable not identified in the analysis will require a systematic removal.

Running multiple computation methods will describe patterns of missing data values for random or non-random values.

The next technique used was dummy coding of missing values for scale and nominal data. Running frequency analysis heled identify other variables and date accountability for each case. Data cleaning process: define error type, identify error instanced, correct errors, document error types, and modify data entry process to reduce future errors (Field, 2010). The rationale for inclusion of potential covariates and confounding variables helped minimize the number of variables chosen for the most productive model.

Integration of all clinical and other relevant variables was considered to control confounding (Bursac, Gauss, Williams & Hosmer, 2008). Development of a methodology to further address covariates and confounding began with the univariate analysis of each variable and based on the significance was selected for multivariate analysis. Fundamental parameters and result interpretation in this model were regression statistics including odds ratios, adjusted odds ratio, confidence interval, and p-values (McDonald et al., 2015).

Research Question 1: What is the relationship between and individual's ethnic/racial group membership among U.S.-born non-Hispanics with an HIVTB co-infection and the likelihood of completion of therapy?

$H_0$1: There is no relationship between individual's ethnic/racial group membership among U.S.-born non-Hispanics co-infected with HIV/TB and the likelihood of completion of therapy.

H_a1: There is a relationship between individual's ethnic/racial group membership among U.S.-born non-Hispanics co-infected with HIV/TB and the likelihood of completion of therapy.

Research Question 2: Is there a relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility?

Ho1: There is a relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility.

Ha2: There is relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility.

Threats to Validity

Internal validity was an essential consideration in this study because it challenges the experimenter's ability to conclude an outcome that is part of the actual result and no another factor (Creswell, 2009 p 162.) The primary focus under consideration for the design of this project was to minimize potential threats to internal validity through sound analytics and practices. Deciding which confounding variables to use may influence the dependent variable. Recoding imperfect variables such as completion of therapy helped avoid incomplete dependent variable analysis. Recoding all variables reduced the tendency for scores to regress toward the mean (Creswell, 2009).

Instrumentation changes in the RVCT database were implemented in 2009 reduced changes in outcomes because the data set analyzed was after following differences between 2009

and 2014. By using only cases who were eligible to complete treatment within 12 months that were alive at the beginning of therapy addresses experimental mortality. External validity was also significant to the study design. Creswell, (2009) stated to minimize and avoid drawing incorrect inferences from a sample population towards other and past and future situations.

This model required that the variable definition of the previous history of TB treatment is separated out as individual variables that do not interact with other independent variables. To avoid multiple treatment interferences with patients who recorded prior TB treatment was counted based on each episode related to completion of therapy and case count definition of new cases of TB (RVCT, 2015).

Ethical Procedures

Accessing data began by initiating a data usage agreement to gain access to the CDC RVCT 2009-2014 NTSS data set. I was required to submits a data analytic plan proposal to the Analytic Steering Committee (ASC) for research feasibility. My project was submitted January 2016 which was not approved based on ASC recommendation to clarify variables. A revision was made to address each variable for analysis and resubmit for further evaluation. A revised analytic plan was submitted 20 April 2016 and was approved on 30 April 2016 with stipulations to have the project completed within one year. In addition to developing a proposal, I was required to sign a data sharing agreement outlining use and scope of the data for my dissertation project.

The data sharing agreement provided confidentiality information, institutional responsibilities, and policies each researcher must follow to ensure proper stewardship of these data. In the agreement, I was identified as the principal investigator. The Project Supervisor was

noted Dr. David Anderson dissertation Chair from Walden University. Bob Pratt, the CDC data manager, began the initiation the preparation of the data set. Upon determining the three key individuals in the data sharing agreement, Bob Pratt, Andrew Heetderks, and I were approved on 17 April 2016.

The last document I completed was a non-research determination agreement which outlined that no research would be performed on human subjects and that a CDC agency IRB would not be required. The secondary use of research data has become more complicated with the development of new technologies, data sharing, storage, and database size (Tripathy, 2013). Confidentiality and security training were required and completed by attending an online training course.

In the agreement, I would only receive access to view data and run analysis on agency grounds while attached to the secure intranet when Walden University IRB approved this project. A Walden University IRB approval number was granted on 12 May 2018 for this project identification number (03-12-18-0019022). The NTSS data set is a de-identified aggregated surveillance system that houses state and county level demographic and clinical case management data. The only ethical concern using this level data will be to remove location date, that is, state and jurisdiction information substantially reducing the chance of anyone guessing a situation or individual within any jurisdiction.

If the data has no identifying information or is entirely devoid of such information or is appropriately coded so that the researcher does not have access to the codes, then it does not require a full review by the ethical board (Tripathy, 2013). The CDC agency approval is spelled out in the data usage agreement. Walden University requires IRB approval for this project. There

were no additional concerns with access and use of data by the agency. Upon completion of the surveillance project, all files archives are to remain onsite with analysis codes for future analysis, plans, and follow-up.

Summary

The preceding sections described the longitudinal quantitative research design that was used to investigate association and correlations of demographic and clinical characteristics of U.S.-born non-Hispanic Races with HIV compared with all U.S.-born non-Hispanic races. Access to NTSS 2009-2014 RVCT was used to access relationships to the dependent variable for completion of therapy. The statistical approach of regression analysis provides the platform to understand what variables and associations were most appropriate for at-risk populations co-infected with TB and HIV. Chapter four describes data collection, results, and summary of the analysis.

Chapter 4: Results

Introduction

The purpose of this study was to identify persons with TB and HIV coinfections and compare the NTSS surveillance database variables associated with completion of therapy. Advanced regression techniques were used to describe correlations and associations of reported TB cases to predictor variables in the TB registry. In addition, the study focused on the subgroups of U.S.-born non-Hispanic Blacks to determine what variables are associated with a significant odds ratio for completing or not completing therapy across all variables and ethnic/racial groups.

Chapter 4 outlines the systematic approach to data collection baseline descriptive statistics, variables collected, and justification for inclusion in the model. The chapter describes dependent and independent variables and their association to completion of therapy. Chapter 4 also defines completion of therapy eligibility as described by CDC for all cases based on a complex algorithm that supports TB guidelines for completion of therapy within 12 months as the standard of care.

Research Questions

The study was guided by the following two research questions that were focused on identifying variables associated with completion of therapy.

Research Question 1: What is the relationship between and individual's ethnic/racial group membership among U.S.-born non-Hispanics with an HIVTB co-infection and the likelihood of completion of therapy?

$H_0$1: There is no relationship between individual's ethnic/racial group membership among U.S.-born non-Hispanics co-infected with HIV/TB and the likelihood of completion of therapy.

H_a1: There is a relationship between individual's ethnic/racial group membership among U.S.-born non-Hispanics co-infected with HIV/TB and the likelihood of completion of therapy.

Research Question 2: Is there a relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility?

Ho1: There is a relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility.

Ha2: There is relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility.

Data Collection Sample Population

The data for this project were collected and housed by the Centers for Disease Control & Prevention Division of Tuberculosis Elimination Surveillance, Epidemiology, and Outbreak Investigation Branch at the Atlanta Georgia headquarters. I used NTSS RVCT data from 2009 thru 2014, note: the dependent variable completion of therapy (COT) and the reason therapy was stopped (STOPREAS) data may not be completed. Completion of therapy eligibility (COTELIG) was a unique variable created by CDC surveillance experts to help identify which cases were expected to complete therapy within 12 months.

Criteria for eligibility was determined by TB treatment guidelines and a predetermined algorithm based on clinical conditions, and outcomes associated with each individual case. Completion of therapy eligibility was coded for this project as a dichotomous predictor independent variable for all cases in the dataset and analysis. Completion of therapy eligibility was identified upon receipt of the NTSS dataset and determined as a key variable for analysis not originally selected in the project proposal. Experts at CDC were contacted, and I was provided an updated data dictionary that clearly outlined variables and methods for reporting variables in NTSS including the COTELIG variable. Thus, the COTELIG variable was implemented into the data analysis plan and coded appropriately for binomial logistic regression analysis.

The NTSS required a two-year time frame for treatment completion updates, because initial therapy and treatment completion could take up to two years based on several reporting variables i.e. multi-drug resistance, adverse effects, and other social events where the patient's treatment is delayed (CDC. 2014a). The Centers for Disease Control & Prevention's surveillance branch recommended a cutoff time frame of 2014 to ensure that data were the most complete and omit 2015-2016 based on incompleteness. The data set was approved and received in April 2018 to ensure that the data set is robust and complete.

Discrepancies in Data Collection

Discrepancies were observed in the data set from what was expected in the initial plan outlined in chapter 3. The completion of therapy variable contained two components with different CDC definitions that required careful consideration of use. The completion of therapy variable was described with a dichotomous outcome for a patient who completed therapy within a twelve-month period. In this definition the researcher must know that all patients should

complete therapy within 6-9 months as noted by national TB treatment guidelines (Nahid et al. 2016).

This assumption was applied to the data plan and the stated variable would provide the best data for analysis. The NTSS database collected completion of therapy and completion of therapy eligibility imputed variables into the data set for all cases. A case is categorized as completion of therapy eligible if it meets the following criteria:

- Patients eligible to complete therapy in ≤1 year had to have been alive at time of diagnosis and initiated therapy with ≥1 drug. Eligible patients did not have rifampin resistance; did not die in ≤1 year after initiating therapy; did not move out of the country in ≤1 year after initiating therapy; and did not have meningeal TB, bone or joint TB, or TB of the central nervous system, regardless of age; and
- Additionally, TB patients aged 0–14 years were ineligible to complete therapy in ≤1 year if they had disseminated disease (defined as miliary TB, a positive TB blood culture, or a positive nucleic acid amplification test NAAT on a blood specimen). Patients with culture-negative disease, those with an unknown culture status, and those with culture-positive disease but unknown initial drug-susceptibility test re-sults were included under the category of therapy of ≤1 year indicated (Report of Tuberculosis in the United States, 2017).

The algorithm takes into consideration site of disease, rifampin resistance, age of minors, whether a case moved out of country or died before therapy started or alive at diagnosis. This variable also was collected as a dichotomous input and recorded as (y/n) for the analysis. The CDC surveillance branch identifies completion of therapy eligibility as the most appropriate

variable for regression analysis, because there are many factors that would not allow a patient to complete therapy in one year which does support the best data for treatment outcomes. In addition, the reason therapy stopped is a variable which contains eight dispositions that show the final status of a case in terms of (completed, lost, refused, NOTTB, died other, unknown, and adverse) which describes all the reasons therapy was ended.

The reason therapy stopped variable was coded as a dichotomous output (y/n) and was not restricted by the one-year CDC definition and provided the analysis of the specific variables that described why therapy was not completed to provide a complete picture for treatment completion. Thus, the dependent variable used in this data plan was completion of therapy. The analysis of the reason therapy stopped was based on the most complete definition and recommendation of the CDC data manager to determine those cases that completed treatment at any time during their therapy.

The understanding that completion of therapy and completion of therapy eligibility data has the most value for the big picture is noted in this investigation and described in the methods section. However, the reason therapy stopped is a variable that can address an alternative outcome for completion of therapy. The reason therapy stopped is also a good choice to look at odds ratios as the dependent variable controlling for completion of therapy while using completion of therapy eligibility as the independent variable to complete the overall picture of describing associations to completion of therapy within 12 months (CDC, 2016). This analysis strategy helped access what cases finished therapy period. Some discrepancies were found in the data regarding the completeness of data points within the set. Although 99 percent of the cases were complete, 60 percent of the cases had at least one missing data point.

To address this issue a multiple imputation method was run in SPSS data analysis software to access missing data values. Some cases were deleted from the denominator through data trimming which did not contain complete HIV status, and/or U.S.- born designation in the sub-population data set. Those cases were <1 percent of the study population and did not pose any significant threat to power within the design.

A final sample size (N = 2,192) cases was produced. The multiple imputation approach handled the missing data points but was not necessary considering the completeness of the data set. Multiple imputation analysis used calculated averages and estimated calculations to impute missing data points. The software placed a systematic imputed dot throughout the final dataset all variables used in the study population to complete the analysis. Preliminary analysis was run with the multiple imputation data set and the trimmed cleaned final data set which produced no changes is outputs of associations. Multi-imputations technique was not necessary for this model, thus was not used in the final analysis. Primary data elements of interest were collected for age in categorical terms (00-14 years, 15-44 years, 45-64 years, 65+ years), and unknown status to satisfy analysis requirements of the model.

Predictor variables were gender, ethnic, race, age, previous TB, stop-died, site-pulmonary, sputum-smear, sputum-culture, site-plural, culture-lab, culture-other, nucleic acid amplification-test, x-ray, x-ray cavitation, TB test, sputum culture lab, homelessness, injection drug use, non-injection drug use, alcohol use, provider-type, primary occupation, first line drug resistance, resident of correctional facility, provider-type, directly observed therapy, directly observed therapy-site, directly observed therapy weeks, disease site, and completion of therapy eligibility. The dependent variable completion of therapy was already dummy coded into

dichotomous variables, but the reason therapy stopped multi-categorical variable was recoded for logistic regression to yield associations in odds ratios of positive and negative correlations/associations to treatment completion.

The sample population in this study represents all the reported cases of TB in the United States from 2009 thru 2014 to include both foreign-born and U.S.-born verified cases. The sub-group of TB/HIV co-infected cases accounted for n=4,609, (5.9%) of all cases in the larger population (*n*=78,543). Non-probability sampling sample selection was used to identify all cases for analysis.

Treatment of cases vary among public health programs in the U.S. and territories (CDC, 2014a). Subsequently, only outcomes were reported in terms of categorical outcomes recorded under the reason therapy was stopped variable in SPSS. Outcome variables for adverse events, died, lost, moved, refused, other, and completed treatment were recorded and used in these analyses. No other outcomes were attainable from the data and final analysis were recorded as a dichotomous variable either completed or not-completed.

Figure 1 describes the distribution of the dependent variable Completion of Therapy within 12 months. (COT) NEW_COT yes or no. The distribution has a negative skew -.819 and negative kurtosis -1.331 verifying the assumption that LR data often is not normally distributed and should be accounted for by increasing power to 50 cases per variable.

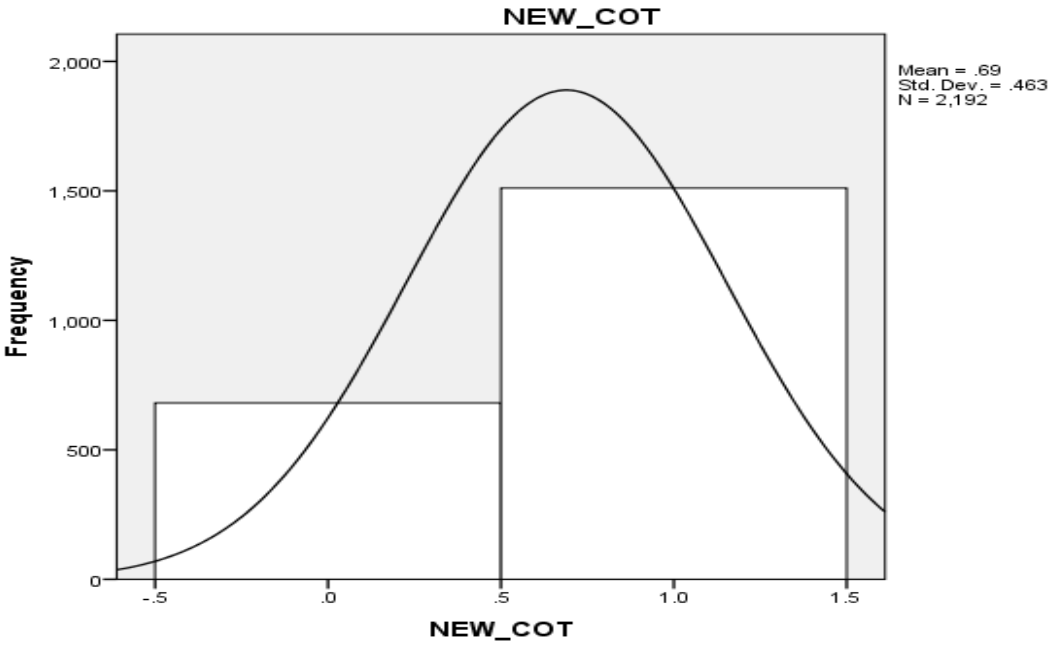

Figure 1. This picture describes completion of therapy within 12 months.

Table 1 describes the frequency accuracy of the predictive value of the model in systematically predicting outcomes for completion of therapy n=1,511 (68.9%) and does not complete therapy n=681 (31%).

Table 1

NEW_COT

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	681	31.1	31.1	31.1
	1	1511	68.9	68.9	100.0
	Total	2192	100.0	100.0	

Note: Classification Table

Figure 2 describes the distribution of the dependent variable Reason Therapy was Stopped NEW_STOPREAS yes or no. The distribution has a negative skew -1.710 and

negative kurtosis .926 verifying the assumption that LR data often is not normally distributed and should be accounted for by increasing power to 50 cases per variable.

Figure 2. The reason therapy was stopped (new reason therapy was stopped).

Table 2 describes the frequency accuracy of the predictive value of the model in systematically predicting outcomes for completion of therapy (*n* = 1,808) (82.59%) and does not complete therapy (*n* = 384) (17.5%).

Table 2

NEW_STOPREAS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	384	17.5	17.5	17.5
	1	1808	82.5	82.5	100.0
	Total	2192	100.0	100.0	

Note: Classification Table

Table 3 outlines descriptive analysis of both dependent variables (New_ completion of therapy & new_ reason therapy was stopped) for mean, mode, median, standard deviation, minimal, maximum outcome limits as well as skewness and kurtosis. The output suggests that both variables do not have a normal distribution and should be adjusted by increasing power to 50 cases per variable (*n*=1200).

Table 3

Statistics

		NEW_COT	NEW_STOPREAS
N	Valid	2192	2192
	Missing	0	0
Mean		.69	.82
Median		1.00	1.00
Mode		1	1
Std. Deviation		.463	.380
Skewness		-.819	-1.710
Std. Error of Skewness		.052	.052
Kurtosis		-1.331	.926
Std. Error of Kurtosis		.105	.105
Minimum		0	0
Maximum		1	1

Note: Descriptive statistics characteristics.

Results

Descriptive Statistics

Table 4 represents treatment completion is defined in terms of the primary reason treatment was stopped (RVCT, 2015). Health departments and private providers report through the NTSS database the final status of each case. Cases that completed treatment period (*n*=1,808), (82.5%) analysis were conducted using reason therapy stopped dependent variable

and each predictor variable under demographics, clinical diagnostics, and directly observed therapy. The intervention provided by individual TB control programs and private providers for treatment completion produced outcomes and reasons why therapy was stopped.

Table 4

Treatment Disposition Characteristics of Sample

	Category	Total	Percent
Therapy Reason Stop Treatment	Completed	1,808	83.8%
	Adverse	4	<1%
	Lost	49	2.1%
	Moved	8	<1%
	Other	21	<1%
	Refused	34	1.5%
	Died	268	12.2%
Stopped Treatment Died	*Disease*	*64*	*2.9%*
	Unknown	*19*	*<1%*
	Unrelated	*92*	*4.2%*
	Total Died	**175**	**7.6%**
	Not Diseased	2,017	92.0%
*Directly Observed Therapy	DOT Only	1,401	63.9%
	Self-Administered	140	6.4%
	Both DOT/SA	617	29.1%
	Not Recorded	151	6.1%
	Unknown	5	<1%
Directly Observed Therapy in Weeks	Mean	30.93	
	Median	29.00	
	Standard Deviation	15.89	
	Range Min	0.0	
	Range Maximum	144	

Note: Categorical levels to describe why treatment stopped and DOT outcomes.

Adverse Events

Table 5 represents adverse events were not the primary reason cases did not complete therapy at 4 cases (<1%) was attributed to this statistic. However, lost to follow-up (*n*=49), (2.2%), and refused (*n*=34), (1.6%) produced the largest disparity in outcomes. The primary reason where treatment was stopped was among those cases who died (*n*=268), (12.2%). Consideration for TB as the primary cause in the NTSS system was used in this model provide the best prospective of the extent of TB disease in persons with HIV. Less than (3%) of those cases who died were documented due to TB disease (*n*=64), (2.9%).

Table 5

Completion of Therapy (COT) Characteristics of Sample

	Category	Total	Percent
*Completion of Therapy within 1 year	Yes	1,511	68.9%
	No	295	13.5%
	Not Recorded	384	17.5%
*Completion Eligible within 1 year	Yes	1,799	82.1%
	No	393	17.9%
*Overall Final Disposition	Completed	1,808	82.5%
Reason Therapy Was Stopped	Adverse	4	<1%
	Died	268	12.2%
	Lost	49	2.2%
	Moved	8	<1%
	Other	21	1.0%
	Refused	34	1.6%
Note: Completion of Therapy within 12 months.	Totals = 2,192		100%

Descriptive and Demographic Characteristics of the Study Sample

The NTSS data set contained 78,543 total TB cases from 2008 thru 2014. Among total cases females accounted for 30,718 cases and males accounted for 47,782 cases. The overall case count for country of origin were, foreign-born (*n*=49,675, 63.2%) and US born (*n*=28,683, 36.5%). HIV positive cases were extracted from the overall data set (n=4,609, 5.9%) and uses in the analysis model. HIV negative cases (*n*=54,896, 69.9%) were not used in the analysis and removed from the data set through trimming. Variables for other HIV categories were recorded as: NOTOFFRD, REFUSED, TDUNK, IND, and UNK were (8.6%, 4.1%, .4%, <1%, and 1.4%) of the total population respectively and were removed from calculations and the model denominators.

To determine the best sub-group for the project, the target population was selected as co-infected cases TB/HIV. Table 3 outlined cross-tabulated cases with the US born variable to produce the appropriate population for the study. The analysis was describing as (U.S.-born, TB/HIV) which yielded the final study group of (*N*= 2,192) U.S.-born TB/HIV co-infected cases. Most of the study cases were males (*n*=1,581, 72.1%) and 27.8% (*n*=610) were females.

All cases were U.S.-born with an ethnic breakdown non-Hispanic (*n*=1,887, 86.1%) and Hispanic (*n*=305, 13.9%). Predictor variables for age in the population were described as characteristics in categories (0-04 years, 5-14 years, 15-24 years, 25-44 years, 45-64 years, 65+ years and unknown). The most significant group of cases was among the 25-44 years and the 45-64 years age groups (*n*=951), (43.4%) and (*n*=110), (50.4%) respectively. Gender characteristics were outlined as male (*n*=1,581, 72.1%) and female (*n*=610, 27.8%) with male as the highest disparity group.

TB cause was defined as the patient being dead or alive at the time of diagnosis (*n*=179), (7.7%) total cases who died. Case deaths due to TB were (*n*=64), (2.9%) and those cases not related to TB were n=92 (4.2%). Non-Hispanic Blacks had the largest TB disparity of all the ethnic groups at (*n*=1,532) cases (69.9%), Whites produced the second largest case count at (*n*=314), (14.3%), Hispanics as a race were (*n*=305), (13.9%), American Indian (*n*=21), (1.0%), Multi-cultural as a race n=9, (<1%), and Native Hawaiian or other Pacific Islander (*n*=7), (<1%). Unknown cases yielded only two cases out of (*N*=2,192) completing the descriptive ethnic and race analysis for the study population.

Univariate Analysis

Table 6 represents univariate analysis for core demographic variables. Sub-population variables to describe the final sample size including criterion variables for co-infection including U.S.-born, alive at time of diagnosis, HIV positive, and active TB case. HIV positive cases (*n*=2,192), (100%) gender (*n*=1,581) males, females (*n*=610), (85% and 28%). Ethnic groups were categorized into American Indian (*n*=21), Asian (*n*=4), Black (*n*=1,532), Native Hawaiian Pacific Islander (*n*=7), White (*n*=314), Hispanic as a Race(*n*=30), and Multiple Race (*n*=9) respectively. Age was categorized into six groups including (00-04) years, (05-14) years, (15-24) years, (25-44) years, (45-64) years, and (65+) years Age groups 45-64 years, n=1.104 and 65+ years, (*n*=951) provided the most significant populations identified in the analysis at (50%, and 43%). Other age categories combined were (<5%). Cause of TB was described for a case is the diagnosis at death was noted on the death record. TB cause (*n*=64), (2.9%) of the total population died with TB as the cause.

Table 6

Descriptive and Demographic Characteristics of Sample

	Category	Total	Percent
Sample size		2,192	100%
U.S.-Born		2,192	100%
HIV positive		2,192	100%
Gender	Male	1,581	85.1%
	Female	610	27.8%
Previous TB		148	6.3%
Ethnic Groups	Non-Hispanic	1,887	86.1%
	Hispanic	305	13.9%
Race	AMID	21	1.0%
	ASIAN	4	023%
	BLACK	1,532	69.9%
	NAHAW	7	<1 %
	WHITE	314	14.3%
	RACEHISP	305	13.9%
	MULT	9	<1%
Age Groups	00-04 years	3	<1%
	05-14 years	3	<1%
	15-24 years	64	2.9%
	25-44 years	951	43.3%
	45-64 years	1,104	50.4%
	65+ years	67	3.1%
TB Cause	Yes	64	2.9%
	No	92	4.2%
	Unknown	19	<1%

Note: Demographic variables and categorical designations for race, age, TB cause.

Table 7 described the sample size subset of the population through deductive analysis provided a dataset (*N*=2,192) whereas key clinical variables were collected that support the project model and risk factors important to clinicians for treatment completion (CDC, 2016). Site

of disease for pulmonary were (*n*=1,767), (80.6%) and not pulmonary (*n*=425), (19.4%). Laboratory diagnostics for smear status n=781 positive and n=1,150 negative. Providers recoded a not done status n=3. Nucleic acid amplification test positive (*n*=603), (27.5%), negative (*n*=199), (9.1%), not done (*n*=1,003), (45.8%), unknown (*n*=13), (<1%), and indeterminate (*n*=2), (<1%). The HIV status of confirmed cases is described by diagnostic outcomes for X-ray cavitation evaluation in terms of disease severity. X-ray cavitation (*n*=323), (13.8%) no cavitation (*n*=1,423), (60.8%).

Table 7

Clinical Descriptive Characteristics of Sample

	Category	Total	Percent
Sample size		2,192	100%
*Positive Culture Final Disposition	Yes	1,205	55.0%
Site Pulmonary	Yes	1,767	80.6%
Site Plural	Yes	104	4.7%
	No	2,080	95.3%
Specimen Smear	Negative	1,150	52.5%
	Positive	781	35.6%
	Not Done	257	11.7%
Sputum Culture	Positive	1,205	55.0%
	Not Done	273	12.5%
	Negative	709	32.3%
Nucleic Acid Amplification Test	Positive	603	27.5%
	Negative	199	9.1%
	Not Done	1,003	45.8%
	Unknown	13	<1%
	Indeterminate	2	<1%
	Category	Total	Percent
X-ray Cavitation	Yes	306	14.0%
	No	1,330	60.7%

(table continues)

	Unknown	11	<1%
	Not Recorded	545	24.9%
TB-Test	Positive	747	34.1%
	Negative	516	23.5%
	Not Done	864	39.4%
	Unknown	51	2.3%
HIV-Stat	Positive	2192	100%

Note: Key clinical variables necessary to determine completion of therapy.

Table 8 describes demographic characteristics for homeless (*n*=458), (20.9%), long-term care facility (*n*=65), (3.8%), and primary occupation unemployed (*n*=1,048), (48.5%) not seeking work (*n*=210), (9.6%), not recorded (*n*=45,5) (20.8%), health care worker, migrant worker, retired, and unknown collectively (<5%).

Table 8

Demographic Characteristics of Sample

	Category	Total	Percent
Homelessness	Yes	458	20.9%
	No	1,721	78.5%
	Unknown	12	<1%
Correctional Institution	Yes	178	8.1%
	No	2,005	91.5%
Long-Term Care Facility	Yes	65	3.0%
	No	2124	96.9%
	Unknown	2	<1%
Primary Occupation	Correctional	3	<1%
	Health Care Worker	29	1.3%
	Migrant Worker	8	<1%
	Not Seeking Work	210	9.6%
	Other	391	17.8%
	Retired	32	1.5%

(table continues)

	Unemployed	1,048	48.8%
	Unknown	16	<1%
	Not Recorded	445	19.7%

Note: Second level categorical demographic variables selected for analysis.

Table 9 describes substance abuse in terms of intravenous drug use (*n*=213), (9.7%), non-intravenous drug use (*n*=727), (33.2%), and alcohol use (*n*=585), (26.7%) of the sample population.

Table 9

Demographic Characteristics of Sample

	Category	Total	Percent
Intravenous Drug Use	Yes	213	9.7%
	No	1,954	89.1%
	Unknown	25	1.1%
Non-Intravenous Drug Use	Yes	727	33.2%
	No	1,439	65.6%
	Unknown	25	1.1%
Alcohol	Yes	585	26.7%
	No	1,583	72.2%
	Unknown	24	1.1%

Note: Key second level variables selected for analysis.

Table 10 describes provider disposition in terms of managing TB cases. Health department (*n*=1,397), (63.7%), Both HD/PRI (*n*=254), (11.6%), PRI/OTH (*n*=466), (21.3%), not recorded (*n*=65), (3.0%) and unknown (*n*=10), (0.5%).

Table 10

Provider Disposition Characteristics of Sample

	Category	Total	Percent
Provider Disposition	Health Department	1,397	63.7%
	Both HD/PRI	254	11.6%
	PRI/OTHER	466	21.3%
	Unknown	10	<1%
	Not Recorded	65	3.0%
Note: First level designations for delivery of services.	Total	2192	100%

Table 11 describes drug resistance among cases multi-drug resistance (*n*=14), (0.6%), no extensively-drug resistant cases were observed. First line drug resistance (*n*=15.8) (7.2%) not first line drug resistant (*n*=2,034), (92.8%).

Table 11

Clinical Descriptive Characteristics of Sample

	Category	Total	Percent
Multi-Drug Resistant	Yes	14	0.6%
	No	1,544	70.4%
	Not Recorded	624	28.5%
First Line Drug Resistant	No	2,034	92.8%
	Yes	158	7.2%

Note: First level variables used in completion of therapy algorithm.

Table 12 show all independent variables that have a significant Pearson's Correlated to the dependent variable new reason therapy stopped and are statistically significant at the (p=0.01) and (p=0.05) levels. Significant predictor variables were used in the binomial logistic regression on both levels (enter, forward LR).

Table 12

Correlations New Reason Therapy Was Stopped

Variable	Correlation	Sig.
New Intravenous Drug Use	.686**	.000
New Completion of Therapy Eligible	-.639**	.000
New Completion of Therapy	-.686**	.000
New Previous TB	-.043*	.000
New TB Test	.124*	.000
New Long-Term	-.047*	.000
New Occupation	-.101**	.000
New Initial INH	-.067*	.000
New Initial PZA	.080**	.000
New Stopped Treatment Died	-.376**	.000
New Multi-Drug Resistant	-.069**	.000

Note: Correlation is significant at the 0.01 level (2-tailed). Correlation is significant at the 0.05 level (2-tailed).

Table 13 show all independent variables that have a significant Pearson's Correlated to the dependent variable New Completion of Therapy and are statistically significant at the

(p=0.01) and (p=0.05) levels. Significant predictor variables were used in the binomial logistic regression on both levels (enter, forward LR).

Table 13

Correlations New Completion of Therapy

Variable	Correlation	Sig.
New Intravenous Drug Use	.066**	.000
New Completion of Therapy Eligible	-.555**	.000
New Reason Therapy Stopped	-.686**	.000
New Site Pulmonary	.065*	.002
New Site Plural	-.045*	.035
New TB Test	-.100*	.000
New Occupation	-.045**	.034
New Initial INH	.087**	.000
New Initial PZA	.082**	.000
New Moved	-.078**	.000
New Stopped Died	-.258**	.000
NEW_MDR	-.119**	.000
NEW_FIRSTLINE	-.057**	.000

Note: Correlation is significant at the 0.01 and 0.05 levels (2-tailed).

Evaluation of Statistical Assumptions (Binary Logistic Regression) Statistical assumption for binary logistic regression has unique components that drive the success of analysis and should be addressed to ensure that potential problems are eliminated or reduced (Field, 2009). Each assumption was addressed individually in terms of met and not met to qualify overall analysis methods.

- Assumption #1 the design should have one dichotomous dependent variable. (Assumption met).
- Assumption #2 the design should have one or more independent variable measured on the continuous or nominal scale. (Assumption met).
- Assumption #3 the study design should have independence of observations and the categories of the dichotomous dependent variable and all you're nominal. Independent variables should be mutually exclusive and exhaustive. (Assumption met).
- Assumption # 4 the design should have 15 cases minimum for the independent variable. (Assumption met).
- Assumption # 5 the data needs to have a linear relationship among the continuous. Independent variables and the logit transformation of the dependent variable. (Assumption met). No continuous variables were selected for analysis.
- Assumption # 6 the data must not show Multicollinearity. *(Assumption met).*
- Assumption # 7 the data set should have no significant outliers, high leverage points or highly influential points (Field, 2009). (Assumption met).

Statistical Analysis Findings

Research Question 1

What relationship between and individual's ethnic/racial group membership among U.S.-born non-Hispanics with an HIV/TB co-infection and the likelihood of completion of therapy. Tables 1-11 set the framework to determine the impact in answering the research question. Upon analysis descriptive outcomes provided the data, power, and variables that formed the foundation to determine which specific variables were correlated to both outcomes of completion of therapy and the reason therapy stopped. Tables 12 and 13 describe all key variables as they relate to both dependent variables which suggest that ethnic/racial group membership of U.S.-born non-Hispanic co-infected persons is not strongly correlated with either completion of therapy or the reasons therapy stopped. Based on the described outcomes, acceptance of the null-hypothesis is required because analysis suggest there is no association between race/ethnicity and completion of therapy for persons with co-infection in the United States.

Table 14 describes the completion of therapy in 12 months classification table which determines the predictive ability of the regression model to accurately predict dichotomous outcomes of the dependent variable overall 68.9 percent prediction for cases in the model.

Table 14

Completion of therapy (COT) SPSS (Enter)

Classification Table

Observed	NEW COT	Predicted	Correct	Percentage
Step 0	0	0	681	0
	1	0	1,511	100.0
Overall Percentage				68.9

Note: Constant is included in the model, the cut value is .500.

Table 15 describes the omnibus test for model fit to determine the significance of model improvement from the null-model prediction. Statistical significance p-value (<.001), chi-square (1307.843) which validates an improvement in the overall model

Table 15

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	1307.843	47	.000
	Block	1307.843	47	.000
	Model	1307.843	47	.000

Note: Stepwise regression analysis of model fit.

Table 16 describes the pseudo R-square Nagelkerke test which describes the proportion of variance in the predictor variables (.633) or 63 percent of the variance in the dependent variable is explained by the selection of independent variables placed in the final model.

Table 16

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	1408.658[a]	.449	.633

a. Estimation terminated at iteration number 20 because maximum iterations has been reached. Final solution cannot be found.

Table 17 describes the Hosmer and Lemeshow goodness of fit chi-square=11.235, df=8, and p-value=.189 which is greater than p-value=.005 and is conformation that model was improved by variables selected for the model and is a goodness of fit.

Table 17

Hosmer and Lemeshow Test

Step	Chi-square	df	Sig.
1	11.135	8	.189

Note: Goodness of fit metric, p-value must be (>.005).

Table 18 describes the logistic regression stepwise contingency table for the Hosmer and Lemeshow test for steps one through ten improving the predictive ability of the model to the expected values in the final model.

Table 18

Contingency Table for Hosmer and Lemeshow Test

		NEW_COT = 0		NEW_COT = 1		
		Observed	Expected	Observed	Expected	Total
Step 1	1	219	219.000	0	.000	219
	2	201	204.178	18	14.822	219
	3	92	77.302	127	141.698	219
	4	30	43.109	187	173.891	217
	5	31	34.296	189	185.704	220
	6	32	28.956	188	191.044	220
	7	25	25.006	203	202.994	228
	8	20	21.222	200	198.778	220
	9	20	17.675	209	211.325	229
	10	11	10.257	190	190.743	201

Note: Stepwise contingency table predicted outcomes of final regression model.

Table 19 describes the completion of therapy in 12 months classification table which determines the predictive ability of the regression model to accurately predict dichotomous outcomes of the dependent variable overall 87.5 percent prediction for cases in the model.

Table 19
Classification Table

Observed	NEW COT	Predicted	Correct	Percentage
Step 0	0	434	247	63.7
	1	26	1,485	98.3
Overall Percentage				87.5

Note: Constant is included in the model. The cut value is .500

Table 20 displays all variables not included in the final logistic regression equation. Each variable may be significant on its own in terms of completion of therapy and is noted with a p-value (<.005) but were not used to identify correlations with dependent variables.

Table 20

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	NEW_IDU	9.545	1	.002
		NEW_COTELIG	674.855	1	.000
		NEW_PREVTB	12.524	1	.000
		NEW_SITEPULM	9.187	1	.002
		NEW_SITEPLR	4.442	1	.035
		NEW_TBTEST	21.915	1	.000
		NEW_OCCUPATN	4.517	1	.034
		NEW_INITINH	16.428	1	.000
		NEW_INITPZA	14.714	1	.000
		NEW_MOVED	13.324	1	.000
		NEW_STOPDIED	146.274	1	.000
		NEW_MDR	31.263	1	.000
		NEW_FIRSTLINE	7.084	1	.008
		RACEHISP	10.379	6	.110
		RACEHISP (1)	1.430	1	.232
		RACEHISP (2)	1.806	1	.179
		RACEHISP (3)	2.264	1	.132
		RACEHISP (4)	6.586	1	.010
		RACEHISP (5)	.755	1	.385
		RACEHISP (6)	.020	1	.886
		ETHNIC (1)	6.586	1	.010
		STOPREAS	1032.977	6	.000
		STOPREAS (1)	8.891	1	.003
		STOPREAS (2)	1032.977	1	.000
		STOPREAS (3)	677.466	1	.000
		STOPREAS (4)	111.207	1	.000
		STOPREAS (5)	17.815	1	.000
		STOPREAS (6)	47.045	1	.000
		OCCUPATN	7.808	4	.099
		OCCUPATN (1)	.575	1	.448

(table continued)

	.451	1	.502
OCCUPATN (2)			
OCCUPATN (3)	2.782	1	.095
OCCUPATN (4)	4.517	1	.034
PROVTYPE	90.019	4	.000
PROVTYPE (1)	.583	1	.445
PROVTYPE (2)	2.116	1	.146
PROVTYPE (3)	76.341	1	.000
PROVTYPE (4)	73.940	1	.000
DOT	46.885	4	.000
DOT (1)	.646	1	.421
DOT (2)	6.950	1	.008
DOT (3)	1.170	1	.279
DOT (4)	37.646	1	.000
DOTSITE	24.884	4	.000
DOTSITE (1)	1.030	1	.310
DOTSITE (2)	3.321	1	.068
DOTSITE (3)	13.919	1	.000
DOTSITE (4)	7.731	1	.005
DIS_SITE	19.852	2	.000
DIS_SITE (1)	8.672	1	.003
DIS_SITE (2)	7.173	1	.007
AGE3	7.959	5	.159
AGE3(1)	1.354	1	.245
AGE3(2)	1.792	1	.181
AGE3(3)	.482	1	.488
AGE3(4)	1.778	1	.182
AGE3(5)	.308	1	.579

Note: Residual Chi-Squares are not computed because of redundancies.

Table 21 describes all variables retained in the equation and are evaluated in the analysis one variable at a time while controlling for other variables in the model to determine the final model configuration. A binomial logistic regression analysis was performed to ascertain the effects of : NEW_IDU, NEW_COTELIG, NEW_PREVTB, NEW_SITEPULM,

NEW_SITEPLR, NEW_TBTEST, NEW_OCCUPATN, NEW_INITINH, NEW_INITPZA, NEW_MOVED, NEW_STOPDIED, NEW_MDR, NEW_FIRSTLINE, RACEHISP, STOPREAS, OCCUPATN, PROVTYPE, DOT, DOTSITE, DIS_SITE, and AGE3 on the likelihood that cases complete therapy. Chi-Square = 1307.843, df =47, p<.0005. The model explained 63.3 percent (Nagelkerke R square) of the variance in COT and correctly classified 87.5 percent of cases. Sensitivity was 63.7 percent and specificity were 98.5 percent. Of the twenty-one predictor variables only five were statistically significant: COTELIG, PREVTB, INITINH, MOVED, and DIS-SITE 1 (as shown in Table 16). Cases that were COTELIG were 5.4 times more likely to complete therapy within 12 months. Individuals that took INH as a part of the initial treatment regimen for at least two weeks increase their odds of COT by 5.9 times. Cases having a previous diagnosis of TB decreases their odds of completing therapy -2.3 times. Having moved outside of normal reporting jurisdiction decreases odds of COT 42.5 times. Cases having pulmonary and plural TB decreases their likelihood of COT decreased by 45.9 percent. Based on analysis, the null hypothesis is accepted because no demographic variables were retained in the final model to include ethnicity/race, gender, and age which are key first level independent variables. Alternatively, the completion of therapy eligibility and several clinical factors were strongly correlated to completion of therapy and were retained in the final model.

Table 21

Variables in the Equation

								95% C.I. for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	NEW_IDU	-.409	.226	3.262	1	.071	.664	.426	1.035
	NEW_COTELI	1.696	.245	47.92	1	.000	5.453	3.375	8.811
	NEW_PREVT	-.609	.269	5.135	1	.023	.544	.321	.921
	NEW_SITEPU	1.042	.819	1.620	1	.203	2.836	.570	14.120
	NEW_SITEPL	22.578	25942.59	.000	1	.999	.000	.000	.
	NEW_TBTEST	.057	.147	.150	1	.698	1.059	.794	1.411
	NEW_OCCUP	-.731	.467	2.449	1	.118	.481	.193	1.203
	NEW_INITIN	1.790	.553	10.44	1	.001	5.989	2.025	17.715
	NEW_INITPZ	.019	.416	.002	1	.964	1.019	.451	2.303
	NEW_MOVED	-.858	.216	15.86	1	.000	.424	.278	.647
	NEW_STOPDI	8.025	5748.015	.000	1	.999	3057.404	.000	.
	NEW_MDR	20.382	8784.099	.000	1	.998	.000	.000	.
	NEW_FIRSTLI	-.138	.253	.298	1	.585	.871	.531	1.430
	RACEHISP			4.496	6	.610			
	RACEHISP (1)	.119	.831	.021	1	.886	1.127	.221	5.748
	RACEHISP (2)	20.773	18412.48	.000	1	.999	1.05E+9	.000	
	RACEHISP (3)	-.312	.213	2.136	1	.144	.732	.482	1.112
	RACEHISP (4)	-.429	.268	2.553	1	.110	.651	.385	1.102
	RACEHISP (5)	-1.365	.927	2.169	1	.141	.255	.041	1.571
	RACEHISP (6)	16.541	4889.737	.000	1	.997	1.051E+9	.000	.
	STOPREAS			.000	6	1.000			
	STOPREAS (1)	12.988	20922.553	.000	1	1.000	437117.599	.000	.
	STOPREAS (2)	35.886	7322.136	.000	1	.996	3.85E+15	.000	.
	STOPREAS (3)	6.293	7966.911	.000	1	.999	540.716	.000	.
	STOPREAS (4)	12.762	9191.880	.000	1	.999	348587.2	.000	.
	STOPREAS (5)	-1.312	12882.49	.000	1	1.000	.269	.000	.
	STOPREAS (6)	2.429	10570.57	.000	1	1.000	11.351	.000	.
	OCCUPATN			2.435	3	.487			
	OCCUPATN1	-1.399	.998	1.968	1	.161	.247	.035	1.743

(table continued)

		40192.97	.000	1	1.000	8190.584	.000	
OCCUPATN2	18.221	0						
OCCUPATN3	-.570	.528	1.168	1	.280	.565	.201	1.590
PROVTYPE			5.310	4	.257			
PROVTYPE1	.719	1.049	.469	1	.493	2.052	.262	16.050
PROVTYPE 2	.434	.950	.209	1	.648	1.544	.240	9.945
PROVTYPE 3	.678	.935	.527	1	.468	1.970	.315	12.309
PROVTYPE 4	.305	.943	.104	1	.747	1.356	.214	8.611
DOT			8.701	4	.069			
DOT 1	11.562	2181.13	.000	1	.996	.000	.000	.
DOT 2	13.687	2181.192	.000	1	.995	.000	.000	.
DOT 3	13.328	2181.192	.000	1	.995	.000	.000	.
DOT 4	13.224	2181.192	.000	1	.995	.000	.000	.
DOTSITE			9.909	4	.042			
DOTSITE 1	-1.642	1.272	1.668	1	.196	.194	.016	2.339
DOTSITE 2	-.431	1.333	.104	1	.747	.650	.048	8.860
DOTSITE 3	-1.494	1.315	1.291	1	.256	.225	.017	2.954
DOTSITE 4	-.411	1.342	.094	1	.759	.663	.048	9.199
DIS_SITE			14.53	2	.001			
DIS_SITE 1	-.615	.186	10.98	1	.001	.541	.376	.778
DIS_SITE 2	.808	.844	.917	1	.338	2.244	.429	11.741
AGE3			6.611	5	.251			
AGE3(1)	18.909	23021.92	.000	1	.999	160E+8	.000	.
AGE3(2)	-.264	.620	.181	1	.670	.768	.228	2.590
AGE3(3)	-.471	.497	.900	1	.343	.624	.236	1.653
AGE3(4)	-.179	1.607	.012	1	.912	.836	.036	19.523
AGE3(5)	-.113	.498	.052	1	.820	.893	.336	2.371
Constant	23.229	7640.103	.000	1	.998	.000		

Note: Variable(s) entered on step 1: NEW_IDU, NEW_COTELIG, NEW_PREVTB, NEW_SITEPULM, NEW_SITEPLR, NEW_TBTEST, NEW_OCCUPATN, NEW_INITINH, NEW_INITPZA, NEW_MOVED, NEW_STOPDIED, NEW_MDR, NEW_FIRSTLINE, RACEHISP, STOPREAS, OCCUPATN, PROVTYPE, DOT, DOTSITE, DIS_SITE, AGE3.

Table 22 describes the completion of therapy in 12 months classification table which determines the predictive ability of the regression model to accurately predict dichotomous outcomes of the dependent variable overall 68.9 percent prediction for cases in the model.

Table 22

Completion of Therapy Variable (COT) SPSS (Forward LR)

Classification Table

Observed	NEW COT	Predicted	Correct	Percentage
Step 0	0	0	681	0
	1	0	1,511	100.0
Overall Percentage				68.9

Note: Constant is included in the model cut value is .500

Table 23 describes the pseudo R-square Nagelkerke test which describes the proportion of variance in the predictor variables (.633) or 63 percent of the variance in the dependent variable is explained by the selection of independent variables placed in the final model.

Table 23

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	1408.658[a]	.449	.633

Note: Estimation terminated at iteration number 20 because maximum iterations have been reached. Final solution cannot be found.

Table 24 displays all variables not included in the final logistic regression equation. Each variable may be significant on its own in terms of completion of therapy and is noted with a p-value (<.005) but were not used to identify correlations with dependent variables.

Table 24

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	NEW_IDU	9.545	1	.002
		NEW_COTELIG	674.855	1	.000
		NEW_PREVTB	12.524	1	.000
		NEW_SITEPULM	9.187	1	.002
		NEW_SITEPLR	4.442	1	.035
		NEW_TBTEST	21.915	1	.000
		NEW_OCCUPATN	4.517	1	.034
		NEW_INITINH	16.428	1	.000
		NEW_INITPZA	14.714	1	.000
		NEW_MOVED	13.324	1	.000
		NEW_STOPDIED	146.274	1	.000
		NEW_MDR	31.263	1	.000
		NEW_FIRSTLINE	7.084	1	.008
		RACEHISP	10.379	6	.110
		RACEHISP (1)	1.430	1	.232
		RACEHISP (2)	1.806	1	.179
		RACEHISP (3)	2.264	1	.132
		RACEHISP (4)	6.586	1	.010
		RACEHISP (5)	.755	1	.385
		RACEHISP (6)	.020	1	.886
		ETHNIC (1)	6.586	1	.010

(table continued)

OCCUPATN	7.808	4	.099
OCCUPATN (1)	.575	1	.448
OCCUPATN (2)	.451	1	.502
OCCUPATN (3)	2.782	1	.095
OCCUPATN (4)	4.517	1	.034
PROVTYPE	90.019	4	.000
PROVTYPE (1)	.583	1	.445
PROVTYPE (2)	2.116	1	.146
PROVTYPE (3)	76.341	1	.000
PROVTYPE (4)	73.940	1	.000
DOTSITE	24.884	4	.000
DOTSITE (1)	1.030	1	.310
DOTSITE (2)	3.321	1	.068
DOTSITE (3)	13.919	1	.000
DOTSITE (4)	7.731	1	.005
DIS_SITE	19.852	2	.000
DIS_SITE (1)	8.672	1	.003
DIS_SITE (2)	7.173	1	.007
AGE3	7.959	5	.159
AGE3(1)	1.354	1	.245
AGE3(2)	1.792	1	.181
AGE3(3)	.482	1	.488
AGE3(4)	1.778	1	.182
AGE3(5)	.308	1	.579
DOT	46.885	4	.000
DOT (1)	.646	1	.421
DOT (2)	6.950	1	.008
DOT (3)	1.170	1	.279
DOT (4)	37.646	1	.000
STOPREAS	1032.977	6	.000
STOPREAS (1)	8.891	1	.003
STOPREAS (2)	1032.977	1	.000
STOPREAS (3)	677.466	1	.000
STOPREAS (4)	111.207	1	.000
STOPREAS (5)	17.815	1	.000
STOPREAS (6)	47.045	1	.000

Table 25 describes the logistic regression stepwise contingency table for the Hosmer and Lemeshow test for steps 1 through 8 improving the predictive ability of the model to the expected values in the final model.

Table 25

Contingency Table for Hosmer and Lemeshow Test

		NEW_COT = 0		NEW_COT = 1		
		Observed	Expected	Observed	Expected	Total
Step 1	1	350	350.000	0	.000	350
	2	34	34.000	0	.000	34
	3	297	297.000	1511	1511.000	1808
Step 2	1	273	273.000	0	.000	273
	2	176	176.000	55	55.000	231
	3	232	232.000	1456	1456.000	1688
Step 3	1	291	291.000	0	.000	291
	2	158	158.000	55	55.000	213
	3	36	35.018	99	99.982	135
	4	196	196.982	1357	1356.018	1553
Step 4	1	295	295.000	0	.000	295
	2	156	155.316	55	55.684	211
	3	42	41.712	109	109.288	151
	4	188	188.972	1347	1346.028	1535
Step 5	1	299	299.000	0	.000	299
	2	157	155.729	59	60.271	216
	3	37	37.233	105	104.767	142
	4	42	40.186	176	177.814	218
	5	32	31.185	214	214.815	246
	6	114	117.667	957	953.333	1071
Step 6	1	155	155.000	0	.000	155
	2	216	216.000	0	.000	216
	3	97	96.261	83	83.739	180
	4	67	65.552	257	258.448	324
	5	32	32.915	214	213.085	246
	6	114	115.273	957	955.727	1071
Step 7	1	156	156.000	0	.000	156
	2	216	216.000	0	.000	216
	3	97	96.216	83	83.784	180

(table continued)

	4	67	65.295	257	258.705	324
	5	31	32.300	214	212.700	245
	6	114	115.189	957	955.811	1071
Step 8	1	179	179.000	0	.000	179
	2	218	219.348	3	1.652	221
	3	99	97.157	168	169.843	267
	4	41	39.366	173	174.634	214
	5	40	41.628	264	262.372	304
	6	104	104.501	903	902.499	1007

Note: Stepwise contingency table predicted outcomes of final regression model.

Table 26 describes the completion of therapy in 12 months classification table which determines the predictive ability of the regression model to accurately predict dichotomous outcomes of the dependent variable overall 87.4 percent prediction for cases in the model.

Table 26

Classification Table

			Predicted		
Observed			NEW_COT		Percentage Correct
			0	1	
Step 1	NEW_COT	0	384	297	56.4
		1	0	1511	100.0
	Overall Percentage				86.5
Step 2	NEW_COT	0	449	232	65.9
		1	55	1456	96.4
	Overall Percentage				86.9
Step 3	NEW_COT	0	449	232	65.9
		1	55	1456	96.4
	Overall Percentage				86.9
	NEW_COT	0	451	230	66.2
Step 4		1	55	1456	96.4

(table continued)

	Overall Percentage				87.0
Step 5	NEW_COT	0	415	266	60.9
		1	19	1492	98.7
	Overall Percentage				87.0
Step 6	NEW_COT	0	420	261	61.7
		1	19	1492	98.7
	Overall Percentage				87.2
Step 7	NEW_COT	0	421	260	61.8
		1	19	1492	98.7
	Overall Percentage				87.3
Step 24	NEW_COT	0	430	251	63.1
		1	25	1486	98.3
	Overall Percentage				87.4

Note: The cut value is .500

Research Question 2

Is there a relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility? In Table 26, a binomial logistic regression (Forward LR) analysis was performed to ascertain the effects of: NEW_IDU, NEW_COTELIG, NEW_PREVTB, NEW_SITEPULM, NEW_SITEPLR, NEW_TBTEST, NEW_OCCUPATN, NEW_INITINH, NEW_INITPZA, NEW_MOVED, NEW_STOPDIED, NEW_MDR, NEW_FIRSTLINE, RACEHISP, STOPREAS, OCCUPATN, PROVTYPE, DOT, DOTSITE, DIS_SITE, and AGE3 on the likelihood that cases complete therapy. Chi-Square = 1260.996, df =14, p<.0005.

The model explained 61.6 percent (Nagelkerke R square) of the variance in COT and correctly classified 87.4 percent of cases. Sensitivity was 63.1 percent and specificity 98.3 percent. Of the twenty-one predictor variables only five were statistically significant: COTELIG,

PREVTB, INITINH, MOVED, and DIS-SITE 1 (as shown in Table 16). Cases that were COTELIG were 5.1 times more likely to complete therapy within 12 months. Individuals that took INH as a part of the initial treatment regimen for at least two weeks increase their odds of COT by 5.3 times. Cases having a previous diagnosis of TB decreases their odds of completing therapy -3.3 times. Having moved outside of normal reporting jurisdiction decreases odds of COT 38.3 times. Cases having pulmonary and plural TB decreases their likelihood of COT decrease by 48.5 percent. Based on the analysis, the null hypothesis is rejected because completion of eligibility and clinical variables were retained in the final model which indicated correlations and well as strong associations to completion of therapy within 12 months. Analysis show a relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility. The alternative hypothesis is accepted. So how does all this impact your hypothesis.

Table 26

Variables in the Equation

							95% C.I. for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	STOPREAS			.000	6	1.000			
	STOPREAS1	.000	2145.618	.000	1	1.000	1.000	.000	.
	STOPREAS2	22.830	6892.573	.000	1	.997	8215.522	.000	.
	STOPREAS3	.000	7316.793	.000	1	1.000	1.000	.000	.
	STOPREAS4	.000	8970.866	.000	1	1.000	1.000	.000	.
	STOPREAS5	.000	1573.730	.000	1	1.000	1.000	.000	.
	STOPREAS6	.000	1115.041	.000	1	1.000	1.000	.000	.
	Constant	21.203	6892.573	.000	1	.998	.000		
	NEW_COTE	2.004	.196	10.116	1	.000	7.417	5.047	10.899

(table continued)

Step 2[b]	STOPREAS			.000	6	1.000			
	STOPREAS1	-.118	2123.517	.000	1	1.000	.889	.000	.
	STOPREAS2	22.922	6761.689	.000	1	.997	9010.150	.000	.
	STOPREAS3	1.771	7185.613	.000	1	1.000	5.876	.000	.
	STOPREAS4	-.063	8836.621	.000	1	1.000	.938	.000	.
	STOPREAS5	.049	1540.182	.000	1	1.000	1.051	.000	.
	STOPREAS6	.204	1076.039	.000	1	1.000	1.226	.000	.
	Constant	23.089	6761.689	.000	1	.997	.000		
Step 3[c]	NEW_COTE	2.022	.198	10.219	1	.000	7.551	5.122	11.132
	NEW_MOVE	-.880	.202	19.025	1	.000	.415	.279	.616
	STOPREAS			.000	6	1.000			
	STOPREAS1	.182	2092.541	.000	1	1.000	1.200	.000	.
	STOPREAS2	22.941	6717.054	.000	1	.997	9182.051	.000	.
	STOPREAS3	1.755	7142.438	.000	1	1.000	5.786	.000	.
	STOPREAS4	-.006	8779.714	.000	1	1.000	.994	.000	.
	STOPREAS5	-.024	1534.112	.000	1	1.000	.976	.000	.
	STOPREAS6	.318	1069.123	.000	1	1.000	1.375	.000	.
	Constant	23.033	6717.054	.000	1	.997	.000		
Step 4[d]	NEW_COTE	2.032	.199	10.366	1	.000	7.631	5.167	11.270
	NEW_INITI	1.733	.447	15.038	1	.000	5.657	2.356	13.581
	NEW_MOVE	-.884	.203	19.016	1	.000	.413	.277	.615
	STOPREAS			.000	6	1.000			
	STOPREAS1	.113	2091.550	.000	1	1.000	1.120	.000	.
	STOPREAS2	22.904	6673.115	.000	1	.997	8852.982	.000	.
	STOPREAS3	1.712	7098.569	.000	1	1.000	5.543	.000	.
	STOPREAS4	-.052	8737.394	.000	1	1.000	.949	.000	.
	STOPREAS5	-.094	1536.052	.000	1	1.000	.910	.000	.
	STOPREAS6	.314	1061.381	.000	1	1.000	1.368	.000	.
	Constant	24.706	6673.115	.000	1	.997	.000		
Step 5[e]	NEW_COTE	1.884	.222	71.862	1	.000	6.581	4.257	10.174
	NEW_INITI	1.663	.450	13.657	1	.000	5.277	2.184	12.749
	NEW_MOVE	-.912	.205	19.832	1	.000	.402	.269	.600
	DIS_SITE			11.909	2	.003			
	DIS_SITE (1)	-.605	.176	11.832	1	.001	.546	.387	.771
	DIS_SITE (2)	-.162	.187	.752	1	.386	.850	.589	1.227
	STOPREAS			.000	6	1.000			
	STOPREAS1	.051	2088.381	.000	1	1.000	1.052	.000	.
	STOPREAS)	22.961	6638.556	.000	1	.997	9370.675	.000	.

(table continued)

	STOPREAS3	1.628	7065.224	.000	1	1.000	5.093	.000	.
	STOPREAS4	-.038	8699.043	.000	1	1.000	.962	.000	.
	STOPREAS5	-.174	15379.690	.000	1	1.000	.840	.000	.
	STOPREAS6	.267	1067.216	.000	1	1.000	1.306	.000	.
	Constant	24.416	6638.556	.000	1	.997	.000		
Step 6[f]	NEW_COTE	1.717	.229	56.389	1	.000	5.568	3.557	8.716
	NEW_INITI	1.634	.455	12.892	1	.000	5.123	2.100	12.497
	NEW_MOVE	-.931	.204	20.771	1	.000	.394	.264	.588
	NEW_MDR	20.323	8944.183	.000	1	.998	.000	.000	.
	DIS_SITE			13.298	2	.001			
	DIS_SITE (1)	-.644	.177	13.292	1	.000	.525	.372	.743
	DIS_SITE (2)	-.247	.187	1.746	1	.186	.781	.541	1.127
	STOPREAS			.000	6	1.000			
	STOPREAS1	.044	2087.786	.000	1	1.000	1.045	.000	.
	STOPREAS2	22.971	6643.721	.000	1	.997	9463.451	.000	.
	STOPREAS3	1.515	7066.220	.000	1	1.000	4.550	.000	.
	STOPREAS4	-.031	8702.609	.000	1	1.000	.969	.000	.
	STOPREAS5	-.091	14925.731	.000	1	1.000	.913	.000	.
	STOPREAS6	.258	1060.316	.000	1	1.000	1.294	.000	.
	Constant	24.206	6643.721	.000	1	.997	.000		
Step 7[g]	NEW_COTE	1.715	.230	55.542	1	.000	5.556	3.539	8.723
	NEW_SITEP	22.357	2630.410	.000	1	.999	.000	.000	.
	NEW_INITI	1.641	.455	13.012	1	.000	5.160	2.116	12.585
	NEW_MOVE	-.936	.204	20.981	1	.000	.392	.263	.585
	NEW_MDR	20.327	8942.794	.000	1	.998	.000	.000	.
	DIS_SITE			12.850	2	.002			
	DIS_SITE (1)	-.635	.177	12.850	1	.000	.530	.375	.750
	DIS_SITE (2)	-.231	.188	1.507	1	.220	.794	.549	1.148
	STOPREAS			.000	6	1.000			
	STOPREAS1	.049	2087.986	.000	1	1.000	1.051	.000	.
	STOPREAS2	22.975	6646.535	.000	1	.997	9507.483	.000	.
	STOPREAS3	1.514	7068.932	.000	1	1.000	4.543	.000	.
	STOPREAS4	-.031	8705.688	.000	1	1.000	.969	.000	.
	STOPREAS5	-.088	1492.627	.000	1	1.000	.916	.000	.
	STOPREAS6	.258	1063.151	.000	1	1.000	1.294	.000	.
	Constant	24.215	6646.535	.000	1	.997	.000		
	NEW_COTE	1.643	.233	49.765	1	.000	5.173	3.277	8.166

(table continued)

Step 8[h]	NEW_PREV	-.547	.257	4.551	1	.033	.578	.350	.956
	NEW_SITEP	22.394	2642.709	.000	1	.999	.000	.000	.
	NEW_INITI	1.671	.455	13.474	1	.000	5.318	2.179	12.979
	NEW_MOVE	-.946	.205	21.291	1	.000	.388	.260	.580
	NEW_MDR	20.358	8946.718	.000	1	.998	.000	.000	.
	DIS_SITE			13.963	2	.001			
	DIS_SITE (1)	-.663	.177	13.963	1	.000	.515	.364	.730
	DIS_SITE (2)	-.246	.189	1.688	1	.194	.782	.540	1.133
	STOPREAS			.000	6	1.000			
	STOPREAS	.178	2093.494	.000	1	1.000	1.195	.000	.
	STOPREAS2	22.984	6620.985	.000	1	.997	9588.297	.000	.
	STOPREAS3	1.471	7044.514	.000	1	1.000	4.353	.000	.
	STOPREAS4	-.039	8683.334	.000	1	1.000	.962	.000	.
	STOPREAS5	-.120	1492.727	.000	1	1.000	.887	.000	.
	STOPREAS6	.273	1062.999	.000	1	1.000	1.313	.000	.
	Constant	24.142	6620.985	.000	1	.997	.000		

Note: Variable(s) entered on step 1: STOPREAS.
Note: Variable(s) entered on step 2: NEW_COTELIG.
Note: Variable(s) entered on step 3: NEW_MOVED.
Note: Variable(s) entered on step 4: NEW_INITINH.
Note: Variable(s) entered on step 5: DIS_SITE.
Note: Variable(s) entered on step 6: NEW_MDR.
Note: Variable(s) entered on step 7: NEW_SITEPLR.
Note: Variable(s) entered on step 8: NEW_PREVTB.

Research Question 1

What is the relationship between and individual's ethnic/racial group membership among U.S.-born non-Hispanics with an HIVTB co-infection and the likelihood of completion of therapy? Tables 14-26 set the framework to determine the impact in answering the research question. Upon analysis descriptive outcomes provided the data, power, and variables that formed the foundation to determine which specific variables were correlated to both outcomes'

completion of therapy and the reason therapy stopped. Tables 25 and 26 describe all key variables as they relate to both dependent variables which suggest that ethnic/racial group membership of U.S.-born non-Hispanic co-infected persons is not strongly correlated with either completion of therapy or the reasons therapy stopped. Based on the described outcomes, acceptance of the null-hypothesis is required because analysis suggest there is no association between race/ethnicity and completion of therapy for persons with co-infection in the United States.

Table 27 describes the frequency accuracy of the predictive value of the model in systematically predicting outcomes for completion of therapy (*n*=1,808), (82.5%) and does not complete therapy (*n*=384), (17.5%).

Table 27

Dependent Variable Stop Reason (STOPREAS) SPSS (Enter)

Classification Table

Observed	NEW COT	Predicted	Correct	Percentage
Step 0	0	0	681	0
	1	0	384	0
Overall Percentage			1,808	100

Note: Constant is included in the model. The cut value is .500

Table 28 displays all variables not included in the final logistic regression equation. Each variable may be significant on its own in terms of completion of therapy and is noted with a p-value (<.005) but were not used to identify correlations with dependent variables.

Table 28

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	NEW_IDU	7.762	1	.005
		NEW_COTELIG	894.295	1	.000
		NEW_PREVTB	3.998	1	.046
		NEW_SITEPULM	.418	1	.518
		NEW_SITEPLR	.425	1	.514
		NEW_TBTEST	33.553	1	.000
		NEW_OCCUPATN	22.396	1	.000
		NEW_INITINH	2.885	1	.089
		NEW_INITPZA	14.023	1	.000
		NEW_MOVED	.452	1	.502
		NEW_STOPDIED	310.396	1	.000
		NEW_MDR	10.288	1	.001
		NEW_FIRSTLINE	.133	1	.715
		RACEHISP	8.249	6	.220
		RACEHISP (1)	.938	1	.333
		RACEHISP (2)	.851	1	.356
		RACEHISP (3)	4.025	1	.045
		RACEHISP (4)	4.853	1	.028
		RACEHISP (5)	.138	1	.710
		RACEHISP (6)	.594	1	.441
		ETHNIC (1)	4.853	1	.028
		OCCUPATN	28.158	4	.000
		OCCUPATN (1)	2.134	1	.144
		OCCUPATN (2)	.212	1	.645
		OCCUPATN (3)	5.046	1	.025
		OCCUPATN (4)	22.396	1	.000
		PROVTYPE	121.465	4	.000
		PROVTYPE (1)	3.457	1	.063
		PROVTYPE (2)	.193	1	.660
		PROVTYPE (3)	95.761	1	.000
		PROVTYPE (4)	104.304	1	.000
		DOTSITE	21.766	4	.000
		DOTSITE (1)	.071	1	.790
		DOTSITE (2)	.527	1	.468

(table continued)

DOTSITE (3)	16.246	1	.000
DOTSITE (4)	4.406	1	.036
DIS_SITE	.501	2	.778
DIS_SITE (1)	.327	1	.567
DIS_SITE (2)	.275	1	.600
AGE3	26.340	5	.000
AGE3(1)	.638	1	.424
AGE3(2)	3.025	1	.082
AGE3(3)	12.035	1	.001
AGE3(4)	.638	1	.424
AGE3(5)	8.935	1	.003
NEW_COT	1032.977	1	.000
DOT	118.135	4	.000
DOT (1)	5.854	1	.016
DOT (2)	40.743	1	.000
DOT (3)	.425	1	.515
DOT (4)	74.158	1	.000

Note: Residual Chi-Squares are not computed because of redundancies.

Table 29 describes the omnibus test for model fit to determine the significance of model improvement from the null-model prediction. Statistical significance p-value (<.001), chi-square (1452.004) which validates an improvement in the overall model.

Table 29

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	1452.004	42	.000
	Block	1452.004	42	.000
	Model	1452.004	42	.000

Note: Stepwise regression analysis of model fit.

Table 30 describes the pseudo R-square Nagelkerke test which describes the proportion of variance in the predictor variables (.801) or 81 percent of the variance in the dependent variable is explained by the selection of independent variables placed in the final model.

Table 30

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	582.213[a]	.484	.801

Note: Estimation terminated at iteration number 20 because maximum iterations have been reached. Final solution cannot be found.

Table 31 describes the Hosmer and Lemeshow goodness of fit chi-square=8.000, df=8, and p-value=.434 which is greater than p-value=.005 and is conformation that model was improved by variables selected for the model and is a goodness of fit.

Table 31

Hosmer and Lemeshow Test

Step	Chi-square	df	Sig.
1	8.000	8	.434

Note: Goodness of fit metric, p-value must be (>.005).

Table 32 describes the logistic regression stepwise contingency table for the Hosmer and Lemeshow test for steps 1 through 10 improving the predictive ability of the model to the expected values in the final model.

Table 32

Contingency Table for Hosmer and Lemeshow Test

		NEW_STOPREAS = 0		NEW_STOPREAS = 1		
		Observed	Expected	Observed	Expected	Total
Step 1	1	214	206.948	5	12.052	219
	2	116	128.302	103	90.698	219
	3	53	48.054	166	170.946	219
	4	1	.696	215	215.304	216
	5	0	.000	220	220.000	220
	6	0	.000	207	207.000	207
	7	0	.000	217	217.000	217
	8	0	.000	217	217.000	217
	9	0	.000	218	218.000	218
	10	0	.000	240	240.000	240

Note: Stepwise contingency table predicted outcomes of final regression model.

Table 33 describes the completion of therapy in terms for reasons therapy was stopped in 12 months classification table which determines the predictive ability of the regression model to accurately predict dichotomous outcomes of the dependent variable overall 93.2 percent prediction for cases in the model.

Table 33
Classification Table

Observed	NEW STOPREAS	Predicted	Correct	Percentage
Step 0	0	302	82	78.6
	1	66	1,742	96.3
Overall Percentage				93.2

Note: Constant is included in the model. The cut value is .500

In Table 33, a binomial logistic regression (Enter) analysis was performed on the STOPREAS variable to ascertain the effects of: NEW_IDU, NEW_COTELIG, NEW_PREVTB, NEW_SITEPULM, NEW_SITEPLR, NEW_TBTEST, NEW_OCCUPATN, NEW_INITINH,

NEW_INITPZA, NEW_MOVED, NEW_STOPDIED, NEW_MDR, NEW_FIRSTLINE, RACEHISP, STOPREAS, OCCUPATN, PROVTYPE, DOT, DOTSITE, DIS_SITE, and AGE3 on the likelihood that cases complete therapy.

Chi-Square = 1454.091, df =42, p<.0005. The model explained 80.2 percent (Nagelkerke R square) of the variance in COT and correctly classified 93.6 percent of cases. Sensitivity was 80.7 percent and specificity 96.3 percent. Of the twenty-one predictor variables only three were statistically significant: COTELIG, INITPZA, and DIS-SITE 1 (as shown in Table 16). Cases that were COTELIG were 11.4 times more likely to complete therapy within 12 months. Cases that took PZA as a part of the initial treatment regimen for at least two weeks increased their odds of COT by 4.3 times. Cases having pulmonary and plural TB (DIS_SITE 1) decreases their likelihood of COT increased odds 3.9 times. Variables NEW_MDR and New_ FIRSTLINE statistical significance were (.051, .057) respectively and are record as ***marginally*** significant. Both variable, if considered significant would increase odds of COT: NEW_MDR by 5.2 times and NEW_FIRSTLINE by 2.1 times.

Research Question 1

What is the relationship between and individual's ethnic/racial group membership among U.S.-born non-Hispanics with an HIVTB co-infection and the likelihood of completion of therapy? Based on analysis, the null hypothesis is accepted because no demographic variables were retained in the final model to include ethnicity/race, gender, and age which are key first level independent variables. Alternatively, the completion of therapy eligibility and several clinical factors were strongly correlated to completion of therapy and were retained in the final model.

Table 34

Variables in the Equation

								95% C.I. for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	NEW_IDU	-.018	.324	.003	1	.955	.982	.520	1.854
	NEW_COTELI	2.436	.256	90.66	1	.000	11.422	6.918	18.858
	NEW_PREVT	.143	.368	.151	1	.698	1.154	.561	2.371
	NEW_SITEPU	-.110	1.256	.008	1	.930	.896	.076	10.503
	NEW_SITEPL	19.974	26.473	.000	1	.999	47.00	.000	.
	NEW_TBTEST	.452	.246	3.382	1	.066	1.572	.971	2.544
	NEW_OCCUP	-.328	.563	.339	1	.560	.720	.239	2.172
	NEW_INITINH	-.317	.784	.163	1	.686	.728	.157	3.385
	NEW_INITPZ	1.479	.541	7.472	1	.006	4.387	1.520	12.663
	NEW_MOVED	-.259	.317	.668	1	.414	.772	.415	1.436
	NEW_STOPDI	19.902	4.	.000	1	.997	.000	.000	.
	NEW_MDR	1.664	.853	3.801	1	.051	5.278	.991	28.107
	NEW_FIRSTLI	.775	.407	3.625	1	.057	2.171	.977	4.822
	RACEHISP			2.546	6	.863			
	RACEHISP (1)	1.680	1.326	1.605	1	.205	5.363	.399	72.090
	RACEHISP (2)	-9.459	188.395	.000	1	1.000	.000	.000	.
	RACEHISP (3)	.279	.326	.734	1	.391	1.322	.698	2.505
	RACEHISP (4)	.027	.400	.004	1	.947	1.027	.469	2.248
	RACEHISP (5)	.458	1.488	.095	1	.758	1.580	.085	29.224
	RACEHISP (6)	16.376	894.362	.000	1	.985	.000	.000	.
	OCCUPATN			1.800	3	.615			
	OCCUPAT (1)	20.064	102.445	.000	1	.998	51791	.000	.
	OCCUPAT (2)	-9.936	402.849	.000	1	1.000	.000	.000	.
	OCCUPAT (3)	1.194	.890	1.800	1	.180	3.300	.577	18.882
	PROVTYPE			6.618	4	.158			
	PROVTYPE (1)	-2.193	2.003	1.200	1	.273	.112	.002	5.650
	PROVTYPE (2)	-1.480	1.911	.600	1	.439	.228	.005	9.641
	PROVTYPE (3)	-1.655	1.895	.763	1	.382	.191	.005	7.838
	PROVTYPE (4)	-2.168	1.897	1.307	1	.253	.114	.003	4.708
	DOTSITE			3.845	4	.427			
	DOTSITE (1)	16.874	1213.911	.000	1	.999	.000	.000	.
	DOTSITE (2)	18.142	1213.911	.000	1	.999	.000	.000	.
	DOTSITE (3)	17.933	1213.911	.000	1	.999	.000	.000	.

(table continued)

								.
DOTSITE (4)	17.545	1213.911	.000	1	.999	.000	.000	
DIS_SITE			19.81	2	.000			
DIS_SITE (1)	1.379	.311	19.85	1	.000	3.971	2.159	7.303
DIS_SITE (2)	1.069	1.284	.693	1	.405	2.912	.235	36.072
AGE3			2.440	5	.785			
AGE3(1)	10.015	2316.747	.000	1	1.000	.000	.000	.
AGE3(2)	.642	.968	.440	1	.507	1.901	.285	12.682
AGE3(3)	.545	.686	.631	1	.427	1.724	.450	6.612
AGE3(4)	21.158	215.004	.000	1	.999	1537.292	.000	.
AGE3(5)	.235	.681	.119	1	.730	1.265	.333	4.804
NEW_COT	30.845	1164.928	.001	1	.979	242.490	.000	.
DOT			23.45	4	.000			
DOT (1)	16.135	1281.681	.000	1	.990	101.676	.000	.
DOT (2)	18.857	1281.680	.000	1	.988	1547740	.000	.
DOT (3)	18.056	1281.680	.000	1	.989	694.580	.000	.
DOT (4)	16.766	1281.680	.000	1	.990	1911858	.000	.
Constant	-3.078	12191.45	.000	1	1.000	.046		

Note: Variable(s) entered on step 1: NEW_IDU, NEW_COTELIG, NEW_PREVTB, NEW_SITEPULM, NEW_SITEPLR, NEW_TBTEST, NEW_OCCUPATN, NEW_INITINH, NEW_INITPZA, NEW_MOVED, NEW_STOPDIED, NEW_MDR, NEW_FIRSTLINE, RACEHISP, OCCUPATN, PROVTYPE, DOTSITE, DIS_SITE, AGE3, NEW_COT, DOT.

Table 34

Dependent Variable Stop Reason SPSS (Forward LR)

Classification Table

Observed	NEW _STOPREAS	Predicted	Correct	Percentage
Step 0	0	0	484	0
	1	0	1,808	100.0
Overall Percentage				82.5

Note: Constant is included in the model. The cut value is .500

Table 35 displays all variables not included in the final logistic regression equation. Each variable may be significant on its own in terms of completion of therapy and is noted with a p-value (<.005) but were not used to identify correlations with dependent variables.

Table 35

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	NEW_IDU	7.762	1	.005
		NEW_COTELIG	894.295	1	.000
		NEW_PREVTB	3.998	1	.046
		NEW_SITEPULM	.418	1	.518
		NEW_SITEPLR	.425	1	.514
		NEW_TBTEST	33.553	1	.000
		NEW_OCCUPATN	22.396	1	.000
		NEW_INITINH	2.885	1	.089
		NEW_INITPZA	14.023	1	.000
		NEW_MOVED	.452	1	.502
		NEW_STOPDIED	310.396	1	.000
		NEW_MDR	10.288	1	.001
		NEW_FIRSTLINE	.133	1	.715
		RACEHISP	8.249	6	.220
		RACEHISP (1)	.938	1	.333
		RACEHISP (2)	.851	1	.356
		RACEHISP (3)	4.025	1	.045
		RACEHISP (4)	4.853	1	.028
		RACEHISP (5)	.138	1	.710
		RACEHISP (6)	.594	1	.441
		ETHNIC (1)	4.853	1	.028
		OCCUPATN	28.158	4	.000
		OCCUPATN (1)	2.134	1	.144
		OCCUPATN (2)	.212	1	.645
		OCCUPATN (3)	5.046	1	.025
		OCCUPATN (4)	22.396	1	.000
		PROVTYPE	121.465	4	.000
		PROVTYPE (1)	3.457	1	.063
		PROVTYPE (2)	.193	1	.660
		PROVTYPE (3)	95.761	1	.000

(*table continued*)

PROVTYPE (4)	104.304	1	.000
DOTSITE	21.766	4	.000
DOTSITE (1)	.071	1	.790
DOTSITE (2)	.527	1	.468
DOTSITE (3)	16.246	1	.000
DOTSITE (4)	4.406	1	.036
DIS_SITE	.501	2	.778
DIS_SITE (1)	.327	1	.567
DIS_SITE (2)	.275	1	.600
AGE3	26.340	5	.000
AGE3(1)	.638	1	.424
AGE3(2)	3.025	1	.082
AGE3(3)	12.035	1	.001
AGE3(4)	.638	1	.424
AGE3(5)	8.935	1	.003
NEW_COT	1032.977	1	.000
DOT	118.135	4	.000
DOT (1)	5.854	1	.016
DOT (2)	40.743	1	.000
DOT (3)	.425	1	.515
DOT (4)	74.158	1	.000

Note: Residual Chi-Squares are not computed because of redundancies.

Table 36 describes the pseudo R-square Nagelkerke test which describes the proportion of variance in the predictor variables (.788) or 78.8 percent of the variance in the dependent variable is explained by the selection of independent variables placed in the final model.

Table 36

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	932.921[a]	.395	.653
2	762.818[a]	.440	.728
3	721.497[a]	.451	.745
4	683.392[a]	.460	.761
5	665.330[a]	.464	.768
6	642.050[a]	.470	.777
7	627.391[a]	.474	.783
8	619.958[a]	.475	.786
9	615.807[a]	.476	.788

Note: Estimation terminated at iteration number 20 because maximum iterations have been reached. Final solution cannot be found.

Table 37 describes the logistic regression stepwise contingency table for the Hosmer and Lemeshow test for steps 1 through 9 improving the predictive ability of the model to the expected values in the final model.

Table 37

Hosmer and Lemeshow Test

Step	Chi-square	df	Sig.
1	.000	0	.
2	.000	2	1.000
3	22.371	5	.000
4	16.358	6	.012
5	15.803	6	.015
6	22.536	6	.001
7	20.676	7	.004
8	16.300	7	.023
9	12.454	7	.087

Note: Goodness of fit metric, p-value must be (>.005).

Table 38 describes the logistic regression stepwise contingency table for the Hosmer and Lemeshow test for steps 1 through 9 improving the predictive ability of the model to the expected values in the final model.

Table 38

Contingency Table for Hosmer and Lemeshow Test

		NEW_STOPREAS = 0		NEW_STOPREAS = 1		
		Observed	Expected	Observed	Expected	Total
Step 1	1	384	384.000	297	297.000	681
	2	0	.000	1511	1511.000	1511
Step 2	1	273	273.000	65	65.000	338
	2	111	111.000	232	232.000	343
	3	0	.000	55	55.000	55
	4	0	.000	1456	1456.000	1456
Step 3	1	175	163.264	8	19.736	183
	2	98	109.736	57	45.264	155
	3	79	90.736	143	131.264	222
	4	32	20.264	144	155.736	176
	5	0	.000	1044	1044.000	1044
	6	0	.000	222	222.000	222
	7	0	.000	190	190.000	190
Step 4	1	199	188.374	11	21.626	210
	2	90	102.008	65	52.992	155
	3	71	78.318	137	129.682	208
	4	24	15.299	203	211.701	227
	5	0	.000	689	689.000	689
	6	0	.000	333	333.000	333
	7	0	.000	259	259.000	259
	8	0	.000	111	111.000	111
Step 5	1	220	212.117	19	26.883	239
	2	112	133.385	136	114.615	248
	3	52	38.498	161	174.502	213
	4	0	.000	92	92.000	92
	5	0	.000	647	647.000	647
	6	0	.000	318	318.000	318
	7	0	.000	247	247.000	247
	8	0	.000	188	188.000	188

(table continued)

Step 6						
	1	207	194.627	3	15.373	210
	2	126	149.421	149	125.579	275
	3	51	39.952	164	175.048	215
	4	0	.000	90	90.000	90
	5	0	.000	647	647.000	647
	6	0	.000	320	320.000	320
	7	0	.000	247	247.000	247
	8	0	.000	188	188.000	188
Step 7	1	214	202.600	4	15.400	218
	2	87	104.221	80	62.779	167
	3	67	67.334	143	142.666	210
	4	16	9.845	209	215.155	225
	5	0	.000	109	109.000	109
	6	0	.000	576	576.000	576
	7	0	.000	291	291.000	291
	8	0	.000	228	228.000	228
	9	0	.000	168	168.000	168
Step 8	1	212	202.566	5	14.434	217
	2	92	108.380	83	66.620	175
	3	67	64.971	144	146.029	211
	4	13	8.083	215	219.917	228
	5	0	.000	115	115.000	115
	6	0	.000	564	564.000	564
	7	0	.000	298	298.000	298
	8	0	.000	219	219.000	219
	9	0	.000	165	165.000	165

Note: Stepwise contingency table predicted outcomes of final regression model.

Table 39 describes the reason therapy was stopped classification table which determines the predictive ability of the regression model to accurately predict dichotomous outcomes of the dependent variable overall 92.6 percent prediction for cases in the model.

Table 39

Classification Table

Observed			Predicted		
			NEW_STOPREAS		Percentage Correct
			0	1	
Step 1	NEW_STOPREAS	0	384	0	100.0
		1	297	1511	83.6
	Overall Percentage				86.5
Step 2	NEW_STOPREAS	0	273	111	71.1
		1	65	1743	96.4
	Overall Percentage				92.0
Step 3	NEW_STOPREAS	0	273	111	71.1
		1	65	1743	96.4
	Overall Percentage				92.0
Step 4	NEW_STOPREAS	0	283	101	73.7
		1	64	1744	96.5
	Overall Percentage				92.5
					90.5
	New _STOPREAS	1			88.5
					87.2
					86.5
					82.3
Step 5	NEW_STOPREAS	0	276	108	71.9
		1	60	1748	96.7
	Overall Percentage				92.3
Step 6	NEW_STOPREAS	0	278	106	72.4
		1	60	1748	96.7
	Overall Percentage				92.4
Step 7	NEW_STOPREAS	0	293	91	76.3
		1	73	1735	96.0
	Overall Percentage				92.5

(table continued)

Step 8	NEW_STOPREAS	0	294	90	76.6
		1	74	1734	95.9
	Overall Percentage				92.5
Step 9	NEW_STOPREAS	0	292	92	76.0
		1	71	1737	96.1
	Overall Percentage				92.6

Note: The cut value is .500

Research Question 2

Is there a relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility? Based on the analysis, the null hypothesis is rejected because completion of eligibility and clinical variables were retained in the final model which indicated correlations and well as strong associations to reason therapy was stopped. Analysis show a relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility. The alternative hypothesis is accepted.

Table 40 describes all variables retained in the equation and are evaluated in the analysis one variable at a time while controlling for other variables in the model to determine the final model configuration. A binomial logistic regression (Forward LR) analysis was performed on the STOPREAS variable to ascertain the effects of: NEW_IDU, NEW_COTELIG, NEW_PREVTB, NEW_SITEPULM, NEW_SITEPLR, NEW_TBTEST, NEW_OCCUPATN, NEW_INITINH, NEW_INITPZA, NEW_MOVED, NEW_STOPDIED, NEW_MDR, NEW_FIRSTLINE, RACEHISP, STOPREAS, OCCUPATN, PROVTYPE, DOT, DOTSITE, DIS_SITE, and AGE3

on the likelihood that cases complete therapy. Chi-Square = 1422.419, df =14, p<0.0005. The model explained 79.0 percent (Nagelkerke R square) of the variance in COT and correctly classified 93.6 percent of cases. Sensitivity was 77.3 percent and specificity were 96.6 percent. Of the twenty-one predictor variables only six were statistically significant: NEW_COTELIG, NEW_INITPZA, NEW_MDR, NEW_FIRSTLINE, DIS_SITE 1, AND DIS_SITE 2, (as shown in Table 16). Cases that were COTELIG were 11.6 times more likely to complete therapy within 12 months. Cases that took PZA as a part of the initial treatment regimen for at least two weeks decreased their odds of COT by 3.4 times. Cases that were resistant to first line TB drugs were 3.5 times more likely to complete therapy. Cases with DIS_SITE 1 (extra pulmonary only) were 3.6 times more likely to complete therapy Cases with DIS_SITE 2 (both pulmonary and extra pulmonary) were 3.2 times more likely to complete therapy. Cases diagnosed with MDR TB increased were 12.2 times more likely to complete therapy period.

Additional Statistical Significance

Other predictor variables with strong association were (previous TB and moved) were both negatively associated to completion of therapy and the reason therapy stopped. Analysis suggest that cases were at higher odds for not completing treatment if they were a previous case, have moved during treatment, or were not eligible to complete treatment. In contrast, variables for the initiation of TB drugs (INH, and PZA), MDR TB, and site of disease 1 were all positively associated with increasing the odds of completing treatment.

In the overall model, six statistically significant predictor variables (*PREVTB, INITINH, INITPZA, MDR, DIS_SITE 1, and COTELIG*) have strong positive and negative associations to completion of treatment either within 12 months or at any time. Based on logistic regression

analysis, the null hypothesis was rejected. There are six NTSS variables that provide the most significant odds ratios associated with completion within 12 months or at any other time during treatment.

Each research question was addressed in these analyses. Clinical, demographic, and outcome variables have shown both positive and negative associations to the completion of therapy for this TB/HIV co-infected population. Variables that were not used in the equation provided evidence that some predictors are statistically significant as a single variable. If associated variables were added alone into the equation, each would have an independent association to both dependent variables but were excluded based on overall significance from the final logistic regression model. Statistical significance was noted among individual independent *variables not used in the equation*. Analysis did show a significant p-value associated with the dependent variable completion of therapy within 12 months. Completion of treatment is influenced by several demographic, clinical, and outcome variables described in the NTSS dataset. Most importantly of the individual variables to note is a significance among non-Hispanic Blacks p-value = .000, score = 6.586, df = 1 suggests that being Black has an association with completion of treatment or not completing treatment which require further investigation. The association also suggests that non-Hispanic Blacks have some level of disparity described in the literature review section that may require specific public health interventions.

Analysis of the dependent variable reason therapy was stopped when applied to the model showed statistical similar associations noted among *variables not in the equations* as well. Findings identified several demographics, clinical, and outcome independent variables with

association when applied to the completion of treatment at any time the reason therapy stopped dependent variable was individually significant. Two statistically significantly variables for race/ethnicity were observed. Non-Hispanic Blacks and Hispanics as a race were statistically significant as individual predictors only and are not included in the final model. Non-Hispanic Blacks p-value = .045, score = 4.025, df = 1 and Hispanics as a race p-value = .028, score = 4.853, df = 1.

The output suggests that both variables are associated to completion of treatment at any time and they both require further investigation to determine if there are negatively or positively correlated to completing treatment at any time. In addition, two demographics for age categories were identified as significant among variables not in the equation. Age3 groups (15-24 years and 65+ years) were significant p-value = .001, score = 12.035, df = 1 and p-value = .003, score = 8.935, df = 1 respectively. Both outcomes suggest that both age categories have an association to the reason therapy stopped as individual predictors only and are not included in the final model.

Table 40

Variables in the Equation

								95% C.I. for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	NEW_COT	21.460	103.994	.000	1	.983	20.196	.000	.
	Constant	-.257	.077	11.054	1	.001	.773		
Step 2[b]	NEW_COTELI	2.172	.180	14.792	1	.000	8.778	6.170	12.490
	NEW_COT	20.682	101.877	.000	1	.984	9591.782	.000	.
	Constant	-1.435	.138	108.122	1	.000	.238		
Step 3[c]	NEW_COTELI	2.482	.203	14.639	1	.000	11.967	8.040	17.811
	DIS_SITE			37.143	2	.000			
	DIS_SITE (1)	1.349	.258	27.390	1	.000	3.853	2.325	6.386
	DIS_SITE (2)	1.133	.241	22.087	1	.000	3.105	1.936	4.981

(table continued)

	NEW_COT	20.695	1011.738	.000	1	.984	9725017 98.681	.000	.
	Constant	-2.113	.193	119.455	1	.000	.121		
Step 4[d]	NEW_COTELI	2.416	.209	13.034	1	.000	11.199	7.428	16.883
	DIS_SITE			33.588	2	.000			
	DIS_SITE (1)	1.354	.268	25.443	1	.000	3.872	2.288	6.553
	DIS_SITE (2)	1.090	.249	19.207	1	.000	2.974	1.827	4.843
	NEW_COT	27.832	118.760	.001	1	.981	122.888	.000	.
	DOT			29.786	4	.000			
	DOT (1)	12.745	841.246	.000	1	.988	3428.266	.000	.
	DOT (2)	15.424	841.245	.000	1	.985	4993.562	.000	.
	DOT (3)	14.654	841.245	.000	1	.986	2311837.233	.000	.
	DOT (4)	13.494	841.245	.000	1	.987	7252.549	.000	.
	Constant	16.776	841.245	.000	1	.984	.000		
Step 5[e]	NEW_COTELI	2.588	.221	13.917	1	.000	13.302	8.623	20.520
	NEW_FIRSTLI	1.428	.343	17.331	1	.000	4.172	2.130	8.174
	DIS_SITE			31.675	2	.000			
	DIS_SITE (1)	1.292	.273	22.448	1	.000	3.640	2.133	6.213
	DIS_SITE (2)	1.126	.255	19.467	1	.000	3.084	1.870	5.087
	NEW_COT	26.355	113.549	.000	1	.982	2798.385	.000	.
	DOT			29.074	4	.000			
	DOT (1)	12.555	837.905	.000	1	.988	2832.093	.000	.
	DOT (2)	15.300	837.904	.000	1	.985	4410.356	.000	.
	DOT (3)	14.564	837.904	.000	1	.986	2118.572	.000	.
	DOT (4)	13.376	837.904	.000	1	.987	6442.148	.000	.
	Constant	16.906	837.904	.000	1	.984	.000		
Step 6[f]	NEW_COTELI	2.378	.226	11.676	1	.000	10.779	6.922	16.787
	NEW_STOPDI	19.779	476.312	.000	1	.997	.000	.000	.
	NEW_FIRSTLI	1.384	.353	15.351	1	.000	3.990	1.997	7.972
	DIS_SITE			29.289	2	.000			
	DIS_SITE (1)	1.262	.278	20.644	1	.000	3.532	2.049	6.086
	DIS_SITE (2)	1.105	.259	18.183	1	.000	3.019	1.817	5.017
	NEW_COT	26.444	1188.164	.000	1	.982	3050738 20852.157	.000	.
	DOT			26.032	4	.000			
	DOT (1)	12.576	841.023	.000	1	.988	2897.266	.000	.
	DOT (2)	15.277	841.023	.000	1	.986	4314.806	.000	.

(table continued)

	DOT (3)	14.649	841.023	.000	1	.986	2311.834	.000	.
	DOT (4)	13.443	841.023	.000	1	.987	6894.229	.000	.
	Constant	-16.733	841.023	.000	1	.984	.000		
Step 7[g]	NEW_COTELI	2.348	.228	10.645	1	.000	10.465	6.688	16.375
	NEW_OCCUPATN	-1.102	.298	13.645	1	.000	.332	.185	.596
	NEW_STOPDI	19.927	478.925	.000	1	.997	.000	.000	.
	NEW_FIRSTLI	1.284	.357	12.972	1	.000	3.613	1.796	7.268
	DIS_SITE			24.976	2	.000			
	DIS_SITE (1)	1.188	.280	17.952	1	.000	3.282	1.894	5.686
	DIS_SITE (2)	1.021	.262	15.224	1	.000	2.776	1.662	4.637
	NEW_COT	26.520	112.825	.001	1	.982	32987	.000	.
	DOT			25.182	4	.000			
	DOT (1)	12.616	837.175	.000	1	.988	3015.049	.000	.
	DOT (2)	15.435	837.174	.000	1	.985	5056.099	.000	.
	DOT (3)	14.820	837.174	.000	1	.986	2799.908	.000	.
	DOT (4)	13.628	837.174	.000	1	.987	8293.887	.000	.
	Constant	-16.689	837.174	.000	1	.984	.000		
Step 8[h]	NEW_COTELI	2.395	.233	10.980	1	.000	10.971	6.953	17.310
	NEW_OCCUP	-1.145	.302	14.403	1	.000	.318	.176	.575
	NEW_INITPZ	1.192	.446	7.152	1	.007	3.295	1.375	7.895
	NEW_STOPDI	19.989	470.592	.000	1	.997	.000	.000	.
	NEW_FIRSTLI	1.275	.360	12.570	1	.000	3.579	1.769	7.242
	DIS_SITE			27.015	2	.000			
	DIS_SITE (1)	1.235	.284	18.952	1	.000	3.438	1.972	5.994
	DIS_SITE (2)	1.108	.266	17.323	1	.000	3.030	1.798	5.106
	NEW_COT	26.519	11.364	.001	1	.982	328.814	.000	.
	DOT			25.250	4	.000			
	DOT (1)	12.741	835.409	.000	1	.988	341.073	.000	.
	DOT (2)	15.489	835.408	.000	1	.985	5325.445	.000	.
	DOT (3)	14.880	835.408	.000	1	.986	2891.294	.000	.
	DOT (4)	13.647	835.408	.000	1	.987	8445.814	.000	.
	Constant	17.923	835.408	.000	1	.983	.000		
Step 9[i]	NEW_COTELI	2.456	.237	107.62	1	.000	11.654	7.328	18.533
	NEW_OCCUP	-1.143	.303	14.231	1	.000	.319	.176	.578
	NEW_INITPZ	1.212	.445	7.405	1	.007	3.361	1.404	8.048
	NEW_STOPDI	20.028	473.096	.000	1	.997	.000	.000	.
	NEW_MDR	1.607	.810	3.936	1	.047	4.989	1.020	24.408

(table continued)

NEW_FIRSTLI	.933	.387	5.813	1	.016	2.543	1.191	5.429
DIS_SITE			28.522	2	.000			
DIS_SITE (1)	1.286	.288	19.996	1	.000	3.619	2.060	6.360
DIS_SITE (2)	1.170	.270	18.752	1	.000	3.223	1.898	5.475
NEW_COT	26.851	117.177	.001	1	.982	4584.794	.000	.
DOT			26.622	4	.000			
DOT (1)	12.634	834.306	.000	1	.988	3015.516	.000	.
DOT (2)	15.478	834.305	.000	1	.985	5295.543	.000	.
DOT (3)	14.885	834.305	.000	1	.986	2912.029	.000	.
DOT (4)	13.540	834.305	.000	1	.987	759.590	.000	.
Constant	17.997	834.305	.000	1	.983	.000		

Note: Variable(s) entered on step 1: NEW_COT.
Note: Variable(s) entered on step 2: NEW_COTELIG.
Note: Variable(s) entered on step 3: DIS_SITE.
Note: Variable(s) entered on step 4: DOT.
Note: Variable(s) entered on step 5: NEW_FIRSTLINE.
Note: Variable(s) entered on step 6: NEW_STOPDIED.
Note: Variable(s) entered on step 7: NEW_OCCUPATN.
Note: Variable(s) entered on step 8: NEW_INITPZA.
Note: Variable(s) entered on step 9: NEW_MDR.

Table 41 outlines the summary of outputs for stepwise forward logistic regression statistically significant variables that were strongly correlated with reason therapy was stopped. Associations to the dependent variable through the analysis of odds ratios and probabilities were described to show the likelihood for an individual to complete therapy while controlling for all other variables in the final regression model.

Table 41

Statistically Significant Independent Variables (NEW_STOPREAS enter)

Significant Variable	Odds Ratio	Probability
NEW_COTELIG,	11.4 times more likely	92% COT
**NEW_NOTCOTELIG	.094 times less likely	9% COT
NEW_INITPZA,	4.3 times more likely	81% COT
DIS_SITE 1,	3.9 times more likely	80% COT

Note: **Denotes chance of not completing therapy.

Table 42 outlines the summary of outputs for binomial logistic regression statistically significant variables that were strongly correlated to completion of therapy within 12 months. Associations to the dependent variable through the analysis of odds ratios and probabilities were described to show the likelihood for an individual to complete therapy within 12 months while controlling for all other variables in the final regression model.

Table 42
Statistically Significant Independent Variables (NEW_COT enter)

Significant Variable	Odds Ratio	Probability
NEW_COTELIG,	5.4 times more likely	84% COT
*NEW_NOTCOTELIG	.183 times less likely	15% COT
PREVTB	.544 times less likely	35% COT
NEW_INITINH,	5.9 times more likely	86% COT
NEW_MOVED	.425 times less likely	30% COT
DIS_SITE 1	.451 times less likely	31% COT

Note: *Denotes chances of not completing therapy.

Table 43 outlines the summary of outputs for stepwise forward logistic regression statistically significant variables that were strongly correlated with reason therapy was stopped.

Associations to the dependent variable through the analysis of odds ratios and probabilities were described to show the likelihood for an individual to complete therapy while controlling for all other variables in the final regression model.

Table 43
Statistically Significant Independent Variables (STOPREAS Forward LR)

Significant Variable	Odds Ratio	Probability
NEW_COTELIG,	11.6 times more likely	92% COT
*NEW_NOTCOTELIG	.092 times less likely	8% COT
NEW_INITPZA,	3.4 times more likely	77% COT
NEW_MDR,	4.9 times more likely	92.4% COT
NEW_FIRSTLINE,	3.5 times more likely	78% COT
DIS_SITE 1,	3.6 times more likely	78% COT
DIS_SITE 2,	3.2 times more likely	76% COT

Note: *Denotes chances of not completing therapy.

Table 44 outlines the summary of outputs for stepwise forward logistic regression statistically significant variables that were strongly correlated with completion of therapy within 12 months. Associations to the dependent variable through the analysis of odds ratios and probabilities were described to show the likelihood for an individual to complete therapy while controlling for all other variables in the final regression model.

Table 44
Statistically Significant Independent Variables (NEW_COT Forward LR)

Significant Variable	Odds Ratio	Probability
NEW_COTELIG,	5.1 times more likely	83.6% COT
*NEW_NOTCOTELIG	.084 times less likely	8% COT
NEW_INITINH	5.3 times more likely	84.1% COT
NEW_PREVTB,	.578 times less likely	37% COT
NEW_MOVED,	.388 times less likely	28% COT
DIS_SITE 1,	.515 times less likely	34% COT

Note: *Denotes chances of not completing therapy.

Summary

Research question one asks, what relationship between and individual's ethnic/racial group membership among U.S.-born non-Hispanics with an HIVTB co-infection and the likelihood of completion of therapy? Logistic regression identifies no significant associations among ethnic/race, age, or gender in the overall model to the completion of therapy within 12 months or at any time during treatment. No ethnic or racial group was correlated with having a significant odds ratio over any other group. The lack of a statistically significance outcome in the final model suggests that the null hypothesis should be accepted to state no U.S.-born non-Hispanic co-infected ethnic/racial groups are more likely to complete therapy within 12 months or at any other time during treatment across all races.

Research question two asks, is there a relationship/association for completing therapy among TB/HIV co-infected U.S.-born non-Hispanics with an HIV/TB co-infection moderated by completion of therapy eligibility? Logistic regression shows both dependent variables completion of therapy and the reason therapy stopped produced association to other several predictor variables. Although ethnicity/race, age, and gender were not significant in the overall regression model, clinical and other demographic variable were strongly associated with completion of treatment.

Chapter 5 describes a detailed interpretation of findings, study limitations, recommendations, positive social change implications, and conclusion.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

This chapter describes statistical significance of 20 key variables with strong correlations and direct associations to completion of therapy and the reason therapy stopped. Positive and negative associations were recorded as odds ratios for the likelihood of completing therapy within 12 months as defined by CDC. The project outlines the stop-reason variable which describes seven categorical reasons therapy was stopped and recoded in the data set as a dichotomous dependent variable completion of therapy at any time during treatment. A summary and interpretation of key findings are discussed which includes individual variable analysis, interpretation, and significance of outputs as they relate to eligibility for completion for all cases. Positive and negative aspects of each correlated key variable is discussed focusing on strengths and limitations of the model and design. The chapter will conclude with national and local recommendations for future initiatives as well as programmatic implications for social change.

The purpose of this study was to identify and determine key independent variables correlated and associated with completion of therapy with a focus on non-Hispanic Blacks in the United States. A longitudinal analysis was performed with the NTSS data set Report of Verified Cases of TB 2009 thru 2014 for key demographic, clinical, and outcome variables. The nature of this study was to use an advanced logistic regression model to help provide the foundation to calculate odds ratios to identify ethnic/racial disparity among groups that were at higher or lesser odds for completing therapy. In contrast, the overarching secondary intent of the study was to describe all statistically significant variables and combinations of variables that correlate to positive or negative outcomes for completion of therapy among this high-risk population. The

study was conducted to provide a perspective for completion of therapy characteristics that may help TB control practitioners describe expected outcomes to patients and staff based on current statistics using odds ratios and probabilities outlined in this study. Practitioners can use statistics to show meeting programmatic performance measures translates to positive outcomes that includes treatment completion.

Interpretation of Findings

The findings of this study are intended to provide data that adds to the emerging co-infection concerns for public health practitioners to understand TB disease epidemiology and variables associated with completion of therapy. Marks et al., (2007) presented a poster at the national TB conference that described and acknowledged the problem of managing patients with other comorbidities who died before they finished treatment. The poster presentation highlighted coinfection complications and the importance of health care partnerships through program collaboration and system integration.

Currently, public health practitioners investigate the common theme for TB in the US by focusing on high-risk foreign-born populations where resources and funding are concentrated. Foreign-born persons have a higher risk of developing TB primarily because many countries have greater risk-factors, higher rates, and incidence cases. This epidemiology has prompted a creative public health initiative for this high-risk population (WHO, 2014b). As a result, more focus has been placed on research and targeted interventions for the foreign-born population in the United States (CDC, 2014a). Colson (2014) began to describe characteristics of U.S.-born cases recording differences in attitudes among non-Hispanic Blacks and Whites which provided a framework for further investigation. McDonald et al. (2015) were one of the first researchers to

use national surveillance data for TB/HIV co-infection in Scotland. Efforts have waned in the U.S. based on overall research costs and the struggle to facilitate inter-agency collaborations (CDC, 2014a).

The foundation for my study was based on the gaps in data and co-infection literature that focuses on U.S.-born populations. In addition, this study was designed to extend the knowledge gained from research performed in Scotland that focused analysis on coinfection and risk-factors in completing therapy. Completion of therapy is the expectation result and focus for many TB control programs. Understanding those specific variables that contribute to completion of therapy is a critical next step for TB control.

After conducting an exhaustive literature review, my investigation did not find any other researchers to implement the TB/HIV coinfection model to access odds ratios for completing therapy for U.S.-born cases. Thus, provided the foundation for my project and support for future projects focusing on co-morbidities. The final analysis was grounded in the SDOH theoretical framework and evidence-based methods that establish conditions through relationships, demographics, workplace, and risk factors to evoke change and affect the quality of life (Glanz et al., 2008).

In the context of SDOH framework, data analysis suggests that ethnicity/race, gender, and age were not statistically significant in the logistic regression model as expected from reported disparities among racial groups (Magee et al., 2007). All variables considered, each individual TB case had the same odd ratio for completing therapy among cases reported in the NTSS database. My interpretation of the results is that public health equity for completion of therapy is present across all ethnic/racial groups and provides some evidence of programmatic

success for progress towards TB elimination. The most significant variables associated with COT were clinical and demographic predictors for eligibility to complete therapy, previous history of TB, site of disease, initiation of INH within the first two weeks of diagnosis and moved at any time during treatment.

Non-Hispanic Blacks had twice as many cases of coinfection than non-Hispanic White and many more times than other racial and ethnic group. There is an obvious disparity among non-Hispanic Blacks, but results provide no evidence of greater or lesser odds ratios for completing therapy or completing therapy at any time during treatment. As a parallel analysis, the reason therapy stopped was statistical significance for completion of therapy eligibility, initiation of pyrazinamide within the first two weeks, pulmonary disease site, multi-drug resistance, and start of initial four drug regimen (INH, RIF, PZA, and EMB) to increase the odds ratio for completing therapy at any time during treatment.

The results show a large correlation to the completion of therapy eligibility variable and statistical significance for cases who were eligible to complete therapy in 12 months versus those cases that were not eligible to complete therapy. The analysis methodology states if all predictor variables are held constant, completion of therapy eligibility cases are 11.4 times more likely to complete therapy. Data analysis shows no negative odds ratios were associated with the reason therapy stopped which suggests with all variables considered, cases are more likely to finish therapy at some point during treatment if they have not died, refused therapy, were lost to follow-up, experienced an adverse event, or moved. These findings can be interpreted as positive outcomes for the national TB control program in the United States.

Limitations of the Study

The study provided several conditions and situations that limited the generalizability of outcomes. The use of secondary analysis brought inherited data misclassification concerns to the project. Analysis are based on surveillance data that is aggregated from various reporting units around the U.S. Thus, there may be greater variability in data quality and completeness. The race/ethnicity variable was the most glaring issue with the NTSS dataset, because the multi-race selection was added to the RVCT in 2010 and may not capture all cases from 2009.

The CDC (2007a) Report of Verified Case of Tuberculosis 2009 may have missing records prior to 2009, because reporting was voluntary. Self-reporting of race may not be consistent and may vary depending on an individual's perception about race and ethnicity. California did not report HIV status from (2008 – 2010). Based on this condition, California cases were deleted from the denominator and the data set was re-evaluated completeness and statistical power.

Data from 2008 and 2009 may not reflect those truly unemployed. A consistent definition of current variables including unemployed were not fully implemented until 2010. The COT variable may take up to two years for updating, some completion of therapy variables for 2016 may be incomplete. To account for possible incomplete completion of therapy data points, a cross matching technique was performed and was determined to have no missing variables. Cases with "unknown" U.S. status were removed from denominator using a trimming statistical technique to complete the dataset and was re-evaluated for appropriate statistical power.

Binomial logistic regression analysis brought some limitation to the study, because the technique cannot show causation. The statistical output can only describe predictor variable

correlations and Exp. (Beta) as an odds ratio. Inferences and associations are the limitation of these analysis. Despite this limitation, validity of outcomes and trustworthiness of results are generalizable to the theoretical model and quantitative methods (Creswell, 2009).

Recommendations

This study has provided a small platform to continue the future investigation and validation of U.S.-born TB/HIV coinfected cases as well foreign-born and other high-risk populations. Further research is needed via the multiple regression model for the reason therapy stopped dependent variable to understand how completion of therapy correlates to each categorical level i.e. (completed, adverse, died, lost, moved, other, and refused).

In addition, a comprehensive research design focused on comparing means of U.S.-born and foreign-born cases with both HIV/TB co-infection and negative HIV status to further describe and understand predictor variables associated with completion of therapy and completion of therapy at any time during treatment. Each project will help identify if any ethnic/racial groups are at risk of not completing therapy and describe the conditions that best support positive outcomes through analysis of each correlated predictor variable. Research could also be expanded to evaluating the more than 300 RVCT clinical and demographic variables not used in my current study to show a comprehensive picture of TB control performance measures in the United States.

Future studies have the potential to provide a longitudinal evaluation of the most important metric in national TB elimination model to cure disease and intervene against further transmission (CDC, 2014a; WHO, 2014a). Finding of this study as well as future projects may contribute to guidelines and policies that support public health initiatives that address disparities

noted from proposed analysis. Stakeholders, as well as policy maker, and public health partners as suggested to (PCSI) to offset expenses of performing systematic analysis of the NTSS. The findings of this study also recommend that merging of databases should be considered long-term for all infectious disease programs to address emerging concerns for all co-morbidities that affect health and QOL.

Positive Social Change

The implications of this study are relevant for the individual, families, organizations and society in regards of understanding fundamental TB principles and circumstances that place an individual at risk for completing or not completing therapy. Odd ratios are metrics that are easy to digest and translatable to persons that are not familiar with medical terms and language. In contrast to other medical outcomes that are heavy with scientific jargon, risk factors such as odds ratios clarify relationships of positive and negative associations against normal outcomes. Having an easier subject matter in TB education design, may help practitioners translate to a better understand of TB processes and outcomes for all involved.

Furthermore, statistical outcomes suggest and equality for completion of treatment which encourages all ethnic/racial groups that no group is at a higher risk for not completing therapy over the other. More importantly, these data suggest that the public health care system work, as well as private provider management of TB are consistent on a national basis. This information is very useful when marketing testing and treatment interventions to high-risk population such as persons with TB and HIV co-infections and other co-morbidities.

A positive change marketing strategy for the future could include: any persons that enters treatment with no other significant medical complications and eligible to complete therapy have 11.4 times the odds of completing therapy within 12 months regardless of age, gender, and race. In addition, person that are not eligible to complete have a 92.3 percent less chance of completing therapy within 12 months. The odds ratios described in this study may encourages practitioners to advocate to persons with non-complicated TB to complete therapy. Practitioners could also consider strongly encouraging complicated cases to remain in therapy until complete because they are at the highest odds for not completing treatment.

Methodological and theoretical frameworks for advanced binomial logistic regression and SDOH are appropriate foundations for this study. Statistical methods for the analysis of dichotomous dependent and independent variables described the relationships required to identify significant correlations (Field, 2009). Each outcome in the final analysis described associations which were displayed as EXP (B) odds ratios. Validation of stated methods and statistical model provides the best foundation for peer-reviews, evaluation of data, and acceptance among practitioners. Future projects should include the theoretical framework outlined in this study to continue the process of understanding characteristics of completion of therapy.

Conclusion

In conclusion, the developmental research outlined in this project is intended to help public health practitioners and health care providers understanding characteristics of completion of therapy for U.S.-born TB/HIV cases with co-infection. The overarching theme of the investigation was highlight treatment outcomes as a baseline performance indicator to see how

well programs have managed TB over time in terms of treatment completion. The analysis described in the project will hopefully spark an interest in public health research that expands completion of therapy and reason therapy stopped outcomes across all populations including foreign-born and other groups not defined in this project.

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