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## Community and Individual Risk Factors Associated with Tuberculosis Treatment Outcomes: CA, MD, and OH, [2017-2021].

Kadiatu Banjoko  
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# Walden University

College of Health Sciences and Public Policy

This is to certify that the doctoral dissertation by

Kadiatu Banjoko

has been found to be complete and satisfactory in all respects,  
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Walden University

2026

Abstract

Community and Individual Risk Factors Associated with Tuberculosis Treatment

Outcomes: CA, MD, and OH, [2017-2021].

by

Kadiatu Banjoko

MSPH, Tulane University, 2012

BS, Ohio State University, 2009

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health

Walden University

February 2026

## Abstract

There are unsuccessful treatment outcomes with Tuberculosis (TB) disease, although effective therapies exist. This study aimed to identify predictors of unsuccessful treatment using the socioecological model. A quantitative cross-sectional study and multinomial logistic regression analysis were used to measure the associations between long-term care (LTC), homelessness, correctional facility, Human Immunodeficiency Virus (HIV), diabetes, excess alcohol, illicit drug use, and TB treatment outcomes of death, lost to follow-up, and treatment refusal. The sample consisted of 7,589 individuals aged 15 and older with pulmonary TB between 2017 and 2021, residing in California, Ohio, and Maryland. Findings indicated a correlation between community factors (LTC, homelessness, correctional facility), individual factors (HIV, illicit drugs), and TB treatment outcomes. Homelessness was a predictor of death ( $Exp(B)=1.75$ , 95% CI: 1.24-2.48,  $p=.001$ ), loss to follow-up ( $Exp(B)=4.55$ , 95% CI: 2.82-7.33;  $p<.001$ ) and treatment refusal ( $Exp(B)=3.24$ , 95% CI: 1.42-7.37,  $p=.005$ ). Positive HIV was associated with death ( $Exp(B)=2.10$ , 95% CI: 1.24-3.56,  $p=.005$ ). The results of this study will inform stakeholders about the risk factors for unsuccessful treatment outcomes and lead to positive social change by improving treatment outcomes for populations experiencing disparities.

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## Dedication

This dissertation is dedicated to every girl who ever dreamed of the impossible. May God take you through your journey of faith, and may you pursue your dreams even when they seem impossible. I also dedicate this to the organizations that are impactful in TB prevention and control: the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and State and city health departments, especially those included in this study from California, Maryland, and Ohio. Your hard work does not go unnoticed.

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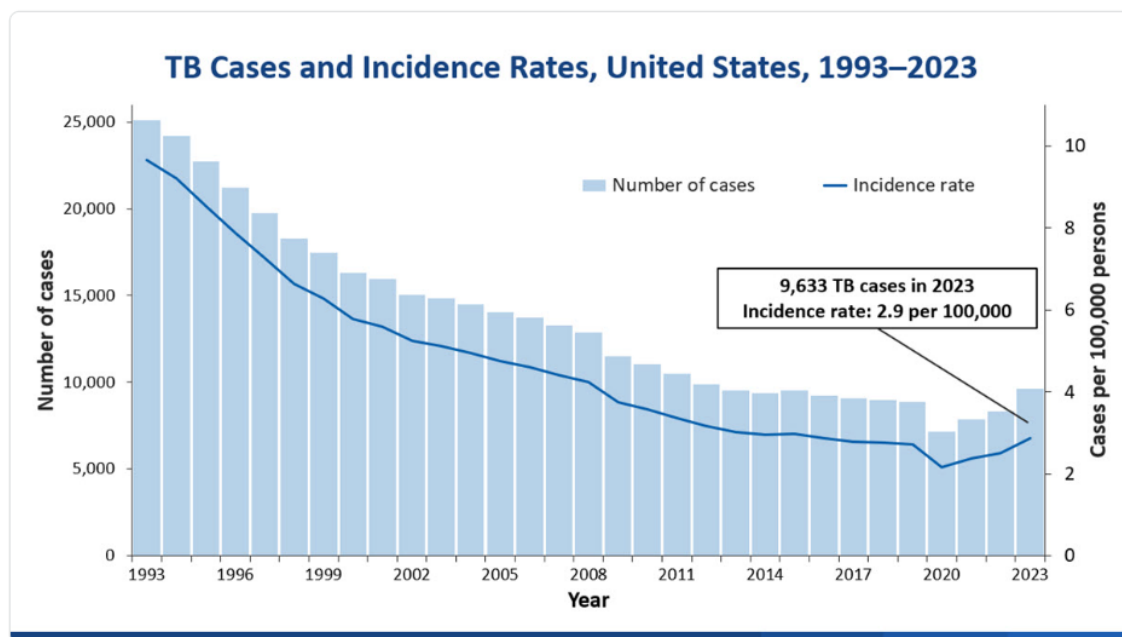
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## Chapter 1: Study Overview

Although tuberculosis (TB) outcomes have greatly improved, there are still unsuccessful treatment outcomes, especially among individuals who excessively consume alcohol, use illicit drugs, experience homelessness, have diabetes, and human immunodeficiency viruses (HIV) (Holden et al., 2019; Holden et al., 2020; Lee-Rodriguez et al., 2020; Korhonen et al., 2020). According to the Centers for Disease Control and Prevention (CDC, 2024), TB incidence rates in the United States decreased steadily from 1993 to 2020, reaching 2.2 per 100,000 population (Figure 1). During the COVID-19 pandemic in 2020, TB rates decreased to 2.2 per 100,000 from 2.7 per 100,000 in 2019.

### Figure 1

*TB Cases and Incidence Rates, United States, 1993-2023*



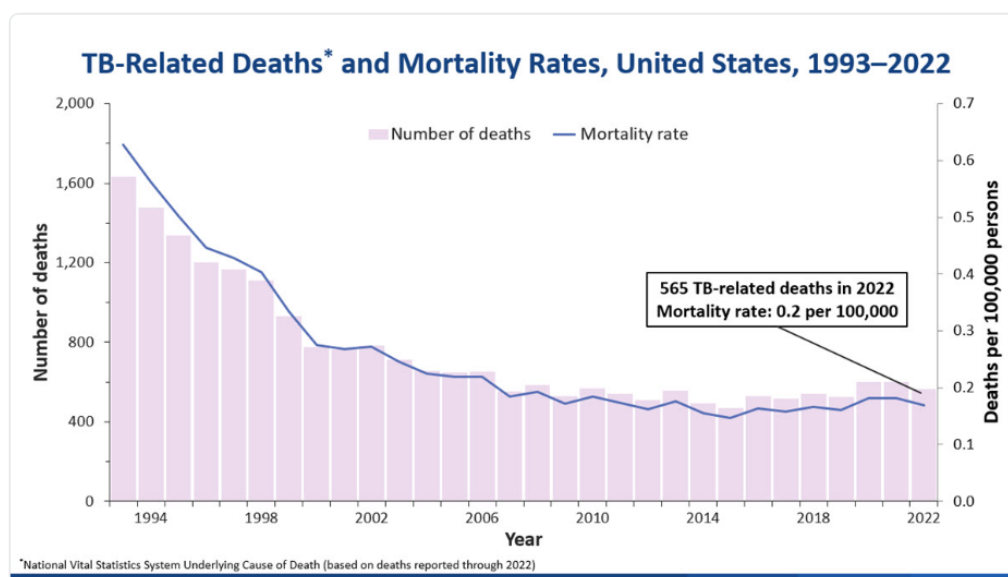
*Note. Reported Tuberculosis in the United States 2023.* <https://www.cdc.gov/tb-surveillance-report-2023/summary/national.html>

TB rates in the United States increased after 2020 to 2.4 per 100,000 in 2021 and 2.5 per 100,000 in 2022. By 2023, TB rates in the United States had increased to 2.9 per 100,000 (CDC, 2024b; Deutsch-Feldman et al., 2021). Overall, TB incidence rates increased from 2021 to 2023. In 2023, TB incidence rates were above the pre-pandemic rate of 2.7 in 2019 (CDC, 2024b).

TB mortality rates were 0.2 per 100,000 ( $n = 602$ ) in 2022, representing a 6.5% decrease from 2021 (CDC, 2024b; CDC, 2024d). Overall, TB mortality continues to decrease, although there were increases in the number of deaths in 2020 and 2021 (see Figure 2).

## Figure 2

*TB-Related Deaths and Mortality Rates in the United States, 1993-2022*



*Note. Reported Tuberculosis in the United States 2023.* <https://www.cdc.gov/tb-surveillance-report-2023/summary/national.html>

In 2021, the most recent year for which data on TB treatment completion were available, 86.8% of patients completed treatment within 1 year, while 6.2% completed treatment after 1 year in the United States (CDC, 2021b). The target for TB treatment completion in the United States is 95% by 2025. In addition to below-target TB treatment completion rates, “lost to follow-up”, death, and adverse reactions to treatment are other indicators of unsuccessful TB treatment outcomes (National Tuberculosis Surveillance System [NTSS], 2015). Diagnosis and successful treatment are crucial components of TB disease elimination in the United States, as unsuccessful outcomes can lead to death, drug resistance, and disease recurrence (Alsayed & Gunosewoyo, 2023; Schildknecht et al., 2023).

This study involved identifying and measuring risk factors for unsuccessful TB treatment outcomes among confirmed TB cases in the United States. The study is crucial because it contributes to understanding the risk factors associated with poor TB treatment outcomes.

It is essential to address underlying risk factors associated with unsuccessful treatment outcomes among high-risk populations in the United States. This includes risk factors for unsuccessful TB treatment outcomes and targeted interventions to improve treatment success. I aimed to measure associations between risk factors (LTC residency at diagnosis, correctional facility at diagnosis, homelessness within the past 12 months, HIV, diabetes, excess alcohol consumption within the past 12 months, and illicit drug use

within the past 12 months ) and TB treatment outcomes in California, Ohio, and Maryland. Advances in TB treatment outcomes will lead to positive social change in the United States in terms of programs to reduce unsuccessful treatment outcomes among at-risk populations.

Chapter 1 introduces the study, including background information, a problem statement, research questions and hypotheses, a theoretical framework, the nature of the study, definitions of key terms, assumptions, scope and limitations, the study's significance, and a summary.

## **Background**

TB remains one of the deadliest conditions caused by an infectious disease, with 1.6 million deaths globally in 2021 (WHO, 2022). It is caused by the bacterium *Mycobacterium tuberculosis* (MTB) and can lead to zoonotic diseases in animals and non-zoonotic diseases in humans (WHO, 2022). The focus of this study was PTB in humans. There are two types of TB: inactive via latent tuberculosis infections (LTBIs), and active TB (Cleveland Clinic, 2025). TB can exist in different forms because it can infect other sites and organs of the human body. Extrapulmonary TB involves infection of TB outside the pulmonary system, while pulmonary TB affects the lungs and is the most common site of TB infection in humans (Cleveland Clinic, 2025; WHO, 2022). Symptoms associated with pulmonary TB include night sweats, weight loss, persistent cough, fever, and fatigue (Cleveland Clinic, 2025; WHO, 2022). PTB is transmitted via respiratory droplets and requires airborne isolation to limit its spread. In exposure settings, quarantine of cases is essential to prevent person-to-person transmission.

Diagnosis of TB requires assessment of clinical presentations and laboratory tests. Screening tests for MTB include the Mantoux Tuberculin Skin Test and interferon-gamma release assay, which detect both active and latent infections. Sputum tests include Acid Fast Bacilli (AFB), which test sets of sputum for MTB. Blood tests include MTB Polymerase Chain Reaction, which detects MTB nucleic acid. Additionally, microscopy tests can be used to verify the presence of microorganisms once they have been isolated from cultures. Additionally, imaging tests, such as chest X-rays, may reveal disease in the lungs and pulmonary system and are used in conjunction with other tests to confirm a TB diagnosis (Mayo Clinic, 2025).

Treatment for TB varies based on patient factors, type of TB, whether the disease is active or latent, and susceptibility or resistance to medication. Treatment can last 4 to 9 months (CDC, 2025a; Saukkonen et al., 2024). Four monthly regimens include isoniazid (INH) and rifampin (RIF, a proxy for rifapentine), pyrazinamide (PZA), and fluoroquinolones (CDC, 2025b). Six- to nine-month regimens include RIF, INH, PZA, and ethambutol (EMB), collectively referred to as the "RIPE" regimen (CDC, 2025b; Saukkonen et al., 2024). TB-sensitive strains are easily treatable via first-line TB therapy. Multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB may require second-line drugs or more extended treatment regimens (Saukkonen et al., 2024). Although TB treatment is effective, unsuccessful treatment outcomes persist among high-risk groups such as individuals with HIV and diabetes, who have increased TB mortality rates (Armstrong et al., 2020; Houck et al., 2023; Lee-Rodriguez et al., 2020; Nguyen et al., 2019).

Although the most sensitive strains of TB are curable via therapy, unsuccessful outcomes associated with the disease persist. Successful TB treatment is crucial to TB control and global efforts to eliminate the disease. Incomplete TB treatment leads to resistant strains, disease recurrence, and unsuccessful prognosis, especially among patients with comorbidities (Alsayed & Gunosewoyo, 2023; Schildknecht et al., 2022). In low-transmission settings such as the United States, some groups, such as PEHs, people with excessive alcohol habits, those with HIV, and diabetic cases, are at increased disease risk and experience unsuccessful treatment outcomes when compared to the general population (Crosby et al., 2019; Holden et al., 2019; Houck et al., 2023; Pradipta et al., 2019).

Specific clinical and demographic risk factors influence TB treatment outcomes. TB treatment completion rates have leveled off since 2009 in the United States, but there are still groups that experience disparities in terms of TB treatment outcomes (Armstrong et al., 2020; Nguyen & Graviss, 2019a; Wu et al., 2022). Individuals demonstrating unsuccessful treatment outcomes include those who are 65 and older, male, homeless, drug users, have diabetes, and excessively consume alcohol (Di Gennaro et al., 2022; Holden et al., 2019; Houck et al., 2023; Korhonen et al., 2020; Wu et al., 2022). Understanding and targeting risk factors associated with unsuccessful treatment outcomes, including mortality, are crucial to successful cure and control, as well as elimination of TB.

Persons experiencing homelessness were more likely to have less access to care, which was linked with late symptom recognition and delays involving receiving care and

diagnosis, which led to unfavorable treatment outcomes (Agarwal et al., 2019; Lui et al., 2020). Additionally, death and delays in TB treatment resulted from HIV and weakened immunity in some cases (Coorey et al., 2022; Houck et al., 2022; Nguyen & Graviss, 2019a; Schechter et al., 2018). Diabetic patients experience increased mortality; however, mortality among patients with TB and diabetes comorbidity is not well understood, although some studies have cited synergic effects that may be responsible for increased mortality and morbidity in these cases. For persons who excessively consume alcohol, the probability of unsuccessful TB treatment increases by 10-20% over those who do not consume or moderately consume alcohol (Ragan et al., 2020; Wigger et al., 2022).

The WHO recommended that states with low TB incidences (<10 cases per 100,000) should focus on vulnerable groups, including people experiencing homelessness, those with HIV, and alcohol users. Specific sociodemographic and clinical risk factors are associated with unsuccessful treatment outcomes. Age greater than 65, male gender, homelessness, diabetes, excess alcohol consumption, and HIV were associated with unsuccessful treatment outcomes (Di Gennaro et al., 2022; Holden et al., 2019; Houck et al., 2023; Korhonen et al., 2020; Wu et al., 2022).

In 2021, the US TB incidence rate was 2.4 per 100,000, and in 2020, the TB incidence rate was 2.2 per 100,000 population, representing approximately a 9.4% increase from 2020 (CDC, 2024d; Filardo et al., 2022). The proportion of U.S. TB patients eligible for  $\leq 12$ -month therapy who completed treatment within one year rose from 63.4% in 1993 to about 89.9% in 2019. However, by 2021, the most recent year with complete data, only 86.8% completed therapy within one year, the lowest such rate

since 2008 (CDC, 2021a). There is a need to identify factors that are responsible for unsuccessful treatment outcomes to improve national TB goals. This study aligns with global goals to eliminate TB and improve outcomes for people with TB.

I aimed to address the knowledge gap regarding risk factors or predictors of unsuccessful TB treatment outcomes (see Table 1), which presents definitions of TB outcomes from the National TB Surveillance System (NTSS). I focused on California, Ohio, and Maryland, which all had treatment outcomes that were below the national average from 2017 to 2019 and the 2025 target of 95% treatment completion rates, as determined by the CDC. I examined data from 2017 to 2021 and determined associations between community factors, individual risk factors, and TB treatment outcomes. I selected participants who were positive for pulmonary TB (PTB) within selected locations.

**Table 1**

*TB Treatment Outcomes and Definitions Used by the NTSS*

Treatment Outcome	Definition
Completed	The primary reason therapy was ended and not resumed b/c therapy was completed.
Died	Primary reason therapy was ended and not resumed b/c the patient died.
Lost	Primary reason therapy was ended and not resumed b/c patient lost to follow-up
Adverse	Primary reason therapy was ended and not resumed b/c of an adverse treatment event
Moved	Discontinued - The primary reason therapy was ended and not resumed was that the patient moved.

Other	Primary reason therapy was ended and not resumed b/c of some other reason.
Refused	Primary reason therapy was ended and not resumed b/c patient was uncooperative or refused.
Unknown	The primary reason was unknown why therapy was ended and not resumed.

The impact of community and societal factors has rarely been studied, and even fewer studies have explored associations between individual and community factors and TB treatment outcomes. Most research on TB treatment outcomes has focused on clinical and demographic factors. The literature gap suggests that further studies are necessary to establish the relationship between specific risk factors and unsuccessful treatment outcomes. This study is the first in the United States to address these variables and their associations with TB treatment outcomes.

The urgency and relevance of this study were supported by the literature, which indicated that the relationship between TB treatment outcomes and certain risk factors was undefined. Therefore, it is crucial to measure risk factors associated with treatment outcomes among states that do not meet national average completion rates within 12 months and are below the 2025 95% treatment completion target. I aimed to describe and measure predictors of unsuccessful TB treatment outcomes using the social ecological model (SEM).

### **Problem Statement**

TB is a public health threat and a significant cause of morbidity and mortality worldwide (WHO, 2022). Current studies in low-transmission settings, such as the United States, showed an insufficient literature base to support the association between societal and community-level individual risk factors and TB treatment outcomes (Collins et al.,

2019; Gafar et al., 2019). Additionally, TB treatment completion rates failed to reach the desired threshold of 95%, and some states fell below the national average (CDC, 2021a). Although significant progress has been made in the United states with treatment completion which was at 89.9% for 2019, there are still unfavorable treatment outcomes such as high mortality that persist in specific risk populations including homeless, older individuals, HIV and individuals that consume excess alcohol, ( Alkabab et al., Amstrong et al., 2020; Coorey et al., 2022; Holden et al., 2020; Houck et al., 2023; Huangfu et al., 2019; Lee-Rodriguez et al., 2020; Marks et al., 2019; Nguyen & Graviss, 2019a, 2019b; Wigger et al., 2022). In low-TB-transmission settings, strategies to improve TB treatment outcomes and efforts towards TB elimination should focus on reducing latent tuberculosis infection (LTBI), reducing TB resistance, targeting high-risk populations for testing, conducting prompt contact investigations, and ensuring successful treatment of cases (Shrestha et al., 2019).

Known risk factors for TB include access to health care providers, correctional facilities, Long-Term Care (LTC), homelessness, HIV, diabetes, and drug use, which can impact TB treatment completion (Mitruka et al., 2016). Studies also showed that persons experiencing homelessness or persons who use illicit drugs may be less likely to seek primary care and management of their TB and diabetes comorbidity (Gupta et al., 2018). Previous studies have supported improvements in TB treatment outcomes and the identification and mitigation of risk factors associated with unsuccessful treatment. A meaningful gap identified was the lack of studies that measure the association between known risk factors for TB within the SEM framework. Therefore, the research problem

addressed in this study is the association between community factors (LTC, correctional facility, homelessness), individual factors (HIV, diabetes, excess alcohol, illicit drug use), and TB treatment outcomes.

### **Purpose**

This quantitative study aimed to identify risk factors associated with unsuccessful treatment outcomes among U.S. states that failed to meet the treatment completion target. The purpose of the study was to explore the association between correctional facilities, long-term care (LTC), diabetes diagnosis, HIV, homelessness, excess alcohol consumption, illicit drug use, and TB treatment outcomes (died, lost to follow-up, and refused treatment compared to treatment completion). The study focused on TB treatment outcomes among non-drug-resistant pulmonary TB cases while controlling for age, sex, ethnicity, and origin of birth. Lastly, the study results aimed to guide the prevention and control of unsuccessful TB treatment outcomes.

### **Research Questions and Hypotheses**

Research questions (RQ) and hypotheses (H) that guided this study were:

RQ1: Is there an association between LTC and TB treatment outcomes among patients with TB while controlling for sex, age, ethnicity, and origin of birth?

H<sub>0</sub>1: There is no association between LTC and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

H<sub>a</sub>1: There is an association between LTC and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

RQ2: Is there an association between correctional facilities and TB treatment outcomes among patients with TB while controlling for sex, age, ethnicity, and origin of birth?

H<sub>0</sub>2: There is no association between correctional facility and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

H<sub>a</sub>2: There is an association between correctional facilities and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

RQ3: Is there an association between homelessness and TB treatment outcomes among patients with TB while controlling for sex, age, ethnicity, and origin of birth?

H<sub>0</sub>3: There is no association between homelessness and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

H<sub>a</sub>3: There is an association between homelessness and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

RQ4: Is there an association between diabetes, HIV, excess alcohol consumption, illicit drug use, and TB treatment outcomes among patients with TB while controlling for sex, age, ethnicity, and origin of birth?

H<sub>0</sub>4: There is no association between diabetes, HIV, excess alcohol consumption, illicit drug use, and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

H<sub>a4</sub>: There is an association between diabetes, HIV, excess alcohol consumption, illicit drug use, and TB treatment outcomes while controlling for age, sex, ethnicity, and origin of birth among patients with TB.

### **Theoretical Framework for the Study**

I used the SEM created by Bronfenbrenner. The SEM is an ecological model derived from the tenets of child psychology and human development. It is a multilevel model that shows the interrelatedness between multiple levels of influence in facilitating behavior change and health outcomes. Tenets of SEM encompass various levels of influence, including societal, interpersonal, community, and individual levels, enabling interventions to be scaled simultaneously across these levels. There is interrelatedness or interconnectedness between the levels of influence, meaning that changes at one level can affect changes at another.

SEM was initially adopted to understand the role of the environment in human development and growth; however, the model has since evolved from its original constructs and is now widely used across diverse topics (Bronfenbrenner, 1994; Glanz, 2015; McLeroy et al., 1988). The constructs of SEM include societal factors, community, interpersonal relationships, and individual factors, and how each hierarchy of SEM affects health (McLeroy et al., 1988; Centers for Disease Control and Prevention (CDC), 2024a). The study used SEM to determine how community factors (LTC, correctional facility incarceration, homelessness), and individual factors (diabetes, HIV, excess alcohol, and illicit drug use) affect TB treatment outcomes. SEM creates a lens through which the research questions associated with this study were analyzed. A more detailed

description of the origins of SEM, the model construct and assumptions, study variables, and the barriers to applying SEM is provided in the following chapter. The extra barriers to applying SEM and the rationale for selecting SEM are discussed in Chapter 2.

### **Nature of the Study**

I employed a quantitative cross-sectional design to address the research questions in this study. A quantitative research methodology enabled me to determine the mathematical relationship, specifically the significance, odds, and Confidence Interval (CI), between the dependent and independent variables. Additionally, the literature supported the use of a quantitative study, as prior studies had employed quantitative research methods to investigate the outcome variable (Alkabab et al., 2023; Baltas et al., 2023; Coorey et al., 2022).

The datasets used in this study were individual state-level data from California, Ohio, and Maryland. Data for the outcome variable, i.e., TB treatment outcomes (completed therapy, lost to follow-up, refused treatment, and died), were measured among TB cases with the independent variables factors, which include correctional facility, LTC, HIV, diabetes, excess alcohol consumption, and illicit drug use while controlling for age, sex, ethnicity, and origin of birth. Secondary data from California, Ohio, and Maryland for the five years from 2017 to 2021 for persons with TB were abstracted from state-level TB data. The sample included laboratory-confirmed cases of pulmonary TB and extrapulmonary TB for individuals 15 years old and above from the States of California, Ohio, and Maryland from 2017 to 2021. Multidrug-resistant (MDR) or extensively drug-resistant (XDR) TB cases were exempt from the study. Laboratory-

confirmed cases were included in the study, consisting of culture-positive, Nucleic acid-positive (NAA+), and culture or smear-positive confirmed TB cases.

The specific data points that were used to answer the research question included diabetes (DIABETES), correctional facility (CORRINST), long-term care (LONGTYPE), homeless (HOMELESS), non-IDU drug use (NONIDU/ IDU), HIV, excess alcohol (ALCOHOL), and treatment completion reason (STOPREAS) - (completed therapy, loss to follow-up, uncooperative or refused, adverse treatment event, died) covariates data include sex, age, ethnicity, and origin of birth. Additional variable descriptions are included in Table 2 of Chapter 3. Challenges and limitations of the study arose from secondary datasets, which may contain incomplete or missing data.

### **Definitions**

*Congregate Settings:* Institutional nonhealthcare settings where people reside close to each other. The congregate settings include correctional facilities (prisons and jails), homeless shelters, refugee camps, army barracks, hospices, dormitories, and nursing homes (WHO, 2022).

*Homeless:* An Individual or person who lacks a fixed, regular, and adequate nighttime residence, such as those living in emergency shelters, transitional housing, or places that are not meant for habitation. Also, persons who were homeless within the past twelve months of TB diagnosis.

*Extensive Drug-Resistant TB (XDR):* Resistance to any fluoroquinolone and at least one of three second-line injectable drugs (capreomycin, kanamycin, and amikacin), in addition to multidrug resistance.

*Extrapulmonary tuberculosis (ETB):* Any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs, e.g., pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges (WHO, 2022).

*High TB transmission setting or High TB burden countries:* 20 countries with the highest estimated numbers of incident TB cases, plus 10 countries with the highest estimated TB incidence that are not in the top 20 by absolute number (threshold: > 10,000 estimated incident TB cases per year; WHO, 2022).

*IDU:* Patient who injected illegal drugs within the past 12 months.

*Incidence:* number of new TB cases per year per 100,000 people.

*Low TB Transmission/Burden Settings:* Countries or distinct parts of countries characterized by a low burden of TB (TB incidence <10/100,000 population). These usually include high-income countries (WHO, 2022).

*Latent Tuberculosis (LTBI):* An inactive form of TB disease in which affected individuals do not show any signs or symptoms.

*Monoresistance:* Resistance to one first-line anti-TB drug only.

*Multidrug Resistance:* Resistance to at least both isoniazid and rifampicin.

*Non-IDU:* Patient who has not injected illegal drugs in the past 12 months.

*Polyresistance:* Resistance to more than one first-line anti-TB drug other than both isoniazid and rifampicin.

*Pulmonary Tuberculosis (PTB):* Any bacteriologically confirmed or clinically diagnosed case of TB involving lung parenchyma or the tracheobronchial tree (WHO, 2022).

*TB Elimination:* Elimination of TB as a public health problem is defined as < 1 notified TB case (all forms) per million people per year.

### **Assumptions**

I assumed the data were accurate and provided a rigorous, precise representation of the study information. I also assumed that the data were free of recall bias and manual errors. These assumptions were necessary because it was impossible to go back and find or rectify inaccuracies in the data. Data from state health departments were highly reliable and represented a valuable source of information regarding TB.

### **Scope and Delimitations**

The study's purpose was to determine the independent association between LTC, correctional facility, homelessness, diabetes, HIV, excess alcohol, illicit drug use, and TB treatment outcomes. The study was delimited in its scope to focus on variables spanning the SEM framework. Although smoking and COVID-19 are recognized risk factors for TB, the effects of these variables on TB treatment outcomes were not measured in this study due to the unavailability of data for these specific variables. Also, the study does not measure association due to synergy when multiple risk factors for TB treatment outcomes are present in the same case, which helped control the study's scope and narrow its focus. Other delimitations for the study included the study population, which consisted of individuals 15 years and older, and excluded individuals under 15 years of age. Such delimitations were necessary because the under-15 population included pediatric cases, which may have introduced selection bias and compromised the study's generalizability.

There were only three states included in the analysis, out of 50 States in the U.S. The States selected for analysis in this study belonged to the category with the highest number of TB case counts from 2017 to 2019. These states did not meet the national average for TB treatment completion from 2017 to 2019 and fell below the CDC's 2025 treatment completion target of 95%. In determining the eligibility criteria for States to participate in the study, it was noted that Baltimore cases were recorded separately from the Maryland treatment completion case count for 2017-2019 (see Figs. 4-6 below). The separate designations were based on funding and resource allocation by federal entities. However, this information was only helpful in determining which States to include in the study; the Maryland (MD) dataset contained all cases, including Baltimore case counts from 2017 to 2021.

Additionally, the CDC treatment completion case count for San Francisco and San Diego for 2017-2019 was reported separately from the California state treatment completion case count. This information was also relevant to the selection of states. However, the dataset analyzed in the study included all cases in California, including those from San Francisco and San Diego. The study excluded individuals under 15 years old and individuals from 47 other U.S. states, as the focus would be too broad. The study also included only cases of PTB or a combination of pulmonary and ETB. Cases with ETB only, and cases with MDR multidrug or XDR extensive drug-resistant cases of TB were excluded from the study. The generalizability of the study was limited to low-transmission settings and cases with sensitive, non-multidrug-resistant, or non-extensively drug-resistant pulmonary TB. The study examined whether there was any

association between the independent and dependent variables of this study. This study enabled more robust research to contribute to the body of knowledge on risk factors that affect unsuccessful TB treatment outcomes and was intended to help policymakers understand how to intervene to address poor TB treatment outcomes.

### **Limitations**

There were limitations in the study design, as cross-sectional studies offer less scientific validity than randomized studies. Additionally, TB treatment completion data are typically 2 to 3 years behind, meaning the years of study for these outcomes, from 2017 to 2021, are several years outdated and may not accurately reflect current TB treatment outcomes in the states in this study. Limitations that could affect the internal validity of the study include fields that are consistently left unfilled, which may result in a low cell count and lead to the omission of those variables from the study. This leads to a situation in which it is unknown whether there were true associations between those variables and TB treatment outcomes. Due to limited resources, I selected a cross-sectional study design for the analysis and utilized secondary datasets. The study's limitations include the body of evidence available to justify the study. Although the literature established that diabetes, HIV, and excess alcohol were linked to unsuccessful TB treatment outcomes, there was limited literature showing the association between LTC, homelessness, correctional facilities, and illicit drug use on TB treatment outcomes. There was limited literature showing how specific risk factors affect TB treatment outcomes in low TB transmission settings. Because the study did not involve human participant recruitment, informed consent was waived for individual participants.

Additional information bias, including recall and measurement errors, can also affect the study. Additional factors included the use of secondary data and incomplete or missing datasets that may have originated from the original data collectors. These concerns may be valid, but the reliability of the data source and the verification steps included in the validation by the data owners offset these concerns. There were also limitations to the study due to an inadequate minimum sample sizes for MD, and OH state-level analysis could not be conducted.

### **Significance**

The study enhanced understanding of TB treatment outcomes and informed interventions to promote positive social change. The study is crucial to identifying marginalized and at-risk populations for death, adverse consequences, loss to follow-up, and treatment refusal, which impacts positive social change. Additionally, the study has a significant impact on efforts to eliminate TB in the US, as it informs policies for further follow-up and the application of the study's evidence to promote successful TB treatment. For States to meet the CDC's 95% target for TB treatment completion, they must understand the treatment outcomes and risks that affect specific groups and develop policies and practices that remove barriers to treatment adherence.

### **Summary**

Chapter 1 of this study justified the study. The study demonstrated that a research project to investigate the relationships among community and individual risk factors and TB treatment outcomes, particularly in States below the TB treatment completion average and the 2025 target of 95% treatment completion set by the Centers for Disease Control

and Prevention, was justified. The chapter also described the study's theoretical framework, the research questions that guided it, and its purpose and nature. Because TB elimination in the U.S. is impacted by unsuccessful treatment outcomes, high-risk populations with unsuccessful treatment provide an opportunity to affect positive social change. The literature suggested that further studies were needed to define the association between the independent and dependent variables in this study. Furthermore, this chapter outlined the study's assumptions, limitations, and delimitations. Hence, this study's aim aligned with the national goal of improving TB treatment outcomes and contributing to the elimination of TB. Chapter 2 of this study includes the literature review.

## **Chapter 2: Literature Review**

The purpose of this study was to measure the association between residents of LTC, correctional facilities, homelessness, HIV, diabetes, excess alcohol consumption, illicit drug use, and TB treatment outcomes of death, lost to follow-up, and treatment refusal while controlling for age, sex, ethnicity, and origin of birth. I directly addressed the limited literature on associations between risk factors and TB treatment outcomes. The study population included PTB cases in California, Ohio, and Maryland.

Chapter 2 includes an introduction to the study, a description of the literature search strategy, and a discussion of the theoretical foundation. Additionally, this chapter includes a detailed review of the literature, including variables. The chapter ends with a summary and conclusion.

### **Literature Search Strategy**

Initial searches began in August 2023. I identified the current body of literature on TB treatment outcomes and risk factors in the United States from 2018 to 2024, as well as in low-TB-transmission settings. I used the Walden University Library, the Ohio State University Health Science Library, Google Scholar, PubMed, Embase, CINAHL, and ProQuest to search for articles published between 2018 and 2024 on this topic. I also conducted additional searches for sentinel articles and current guidelines on the WHO TB webpage and CDC TB websites.

Search terms included TB treatment outcomes, such as completed therapy, mortality or death, adverse outcomes, loss to follow-up, moving, and refusal. I used the

following key terms in this study: *tuberculosis*, *TB*, *risk factors*, *treatment outcome*, *therapy outcome*, *United States*, *USA*, and *US*.

## **Theoretical Foundation**

### **Origin of the SEM**

The SEM was created by Bronfenbrenner, a human developmental psychologist, in the early 1900s. The goal of the model was to guide health behavior change by providing a framework to foster multilevel interventions (Glanz, 2015). Since its early implementation, ecological models have focused on the influence of environmental and behavioral factors on health outcomes (Bronfenbrenner, 1994; Glanz, 2015; McCormack et al., 2016). These models explored the physical and social contexts that influence an individual's behavior at a multidimensional level (Bronfenbrenner, 1994; Glanz, 2015; McCormack et al., 2016). Bronfenbrenner's five levels of the ecological model were microsystems, mesosystems, ecosystems, macrosystems, and chronosystems (Bronfenbrenner, 1994; McCormack et al., 2016). McLeroy redefined the model to five levels of influence: interpersonal, intrapersonal, community, environmental, and policy (McLeroy et al., 1988). Additionally, the early utilization of the ecological model focused on understanding the factors that influence human development (Bronfenbrenner, 1994). However, the utilization of the ecological model and SEM, by extension, has championed adaptations in various fields, including health and disease prevention models, assault and violence prevention, and diverse topics and issues (Bronfenbrenner, 1994; CDC, 2024a; Glanz, 2015).

## **SEM Constructs and Assumptions**

The SEM has been widely used as a global prevention model to understand public health problems and outcomes, including specific topics such as HIV, TB, and smoking (Glanz, 2015; Kwena et al., 2023; Roux et al., 2022). SEM (see Figure 3) is an ecological prevention model with four levels of influence: Individual, interpersonal, community, and societal factors (CDC, 2024a; Ramosevac, 2021; Williams et al., 2022). The model describes the level of influence that impacts a specific outcome or behavior. The model's framework evolved from the idea that interventions can be adapted at each level of influence — individual, interpersonal, community, or societal — to change behaviors (Glanz, 2015). It is crucial to implement interventions at all levels of influence and to ensure they are initiated simultaneously at multiple levels, which is most effective (CDC, 2024a; Glanz, 2015). The individual-level factors include biological and personal attributes, such as substance abuse, age, and education (CDC, 2024a). Interpersonal factors, on the other hand, explained how relationships, social circles, and peer networks influence disease outcomes through connections with family and friends (CDC, 2024a). Community factors focus on the settings and how their environments influence disease outcomes (CDC, 2024a). In contrast, societal factors affect the population through policies or the lack thereof at the State or federal level (CDC, 2024a; McLeroy et al., 1988). Change is adopted through SEM at each level of influence through environmental or behavioral modification (CDC, 2024a; Glanz, 2015). SEM encompasses the effects of social and environmental factors on a desired outcome.

**Figure 3***SEM***Variables in the Study and the SEM**

I used the SEM by examining how community factors (LTC, homelessness, and correctional facilities) and individual risk factors (illicit drug use, HIV, diabetes, and alcohol) affected TB treatment outcomes. This study excluded the interpersonal relationships construct because the dataset lacked information on family support or friend networks to analyze it in the SEM. The justification for placing the variable in each category relied on how the variable was previously described in the literature or on the level description (CDC, 2024a).

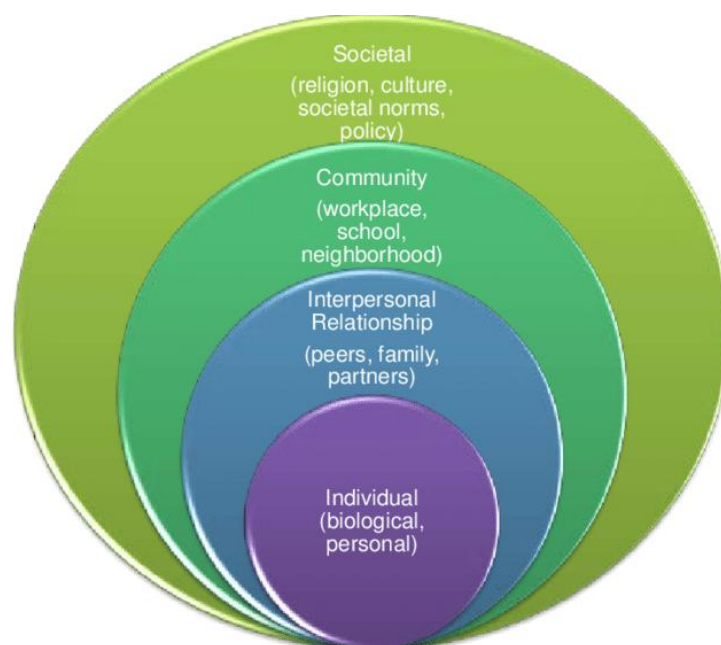
Community factors show that specific settings attribute the risk of TB to congregate settings. In this study, community factors included LTC, homelessness, and correctional facilities. Individual-level factors in this study included diabetes, HIV, excess alcohol, and illicit drug use.

Previous studies demonstrated the use of SEM in understanding risk factors associated with TB disease (Ramosevac, 2021; Roux, 2021; Roux et al., 2022; Williams et al., 2022). The model's multilevel construct (see Figure 4) enabled the identification and targeting of interventions across the ecological landscape of TB disease. Recent SEM

studies conducted in high-incidence settings were used to identify multivariable risk factors for TB prevention (Roux et al., 2022; Williams et al., 2022). SEM analyses were used to examine the social factors that influence TB treatment outcomes (Williams et al., 2022). In a dissertation study by Ramosevac (2021), SEM was used to understand factors associated with TB/ HIV/ homelessness among foreign vs US-born individuals in Georgia.

#### **Figure 4**

*SEM Framework with Levels of Influence*



#### **Rationale for Selection of the SEM**

According to Glanz (2015), ecological models are beneficial for targeting specific behaviors. Although ecological models have been used to target public health problems such as tobacco, HIV, and obesity, the implementation of SEM and its operationalization

were inconsistent. Another barrier to using ecological models is that they are non-specific, as models rather than theories (Glanz, 2015). However, using an ecological model provided the flexibility and adaptability needed to study ongoing changes in disease risk factors and narratives. The US is a low-incidence TB setting, and the use of SEM allows for in-depth analysis of risk factors that affect TB treatment outcomes. There was a need to understand the effects of each TB risk factor from a multidimensional social and ecological perspective. There was a need to include a comprehensive, multifaceted, evidence-based intervention to understand the risk factors for TB treatment outcomes. SEM was the model that best fit the research questions addressed by this study. The justification for using SEM relied on how previous literature and recent dissertations have utilized SEM to analyze risk factors and social determinants associated with TB (Ramosevac, 2021; Roux, 2021; Roux et al., 2022; Williams et al., 2022). The model's versatility enabled the study of numerous variables and subject matters using this framework. SEM in this study provided a unique framework for thinking and initiating interventions at all levels of society; however, it did not account for the specific problems associated with individuals who experienced single or multiple risk factors within the SEM framework. Another benefit of SEM is its connection to education, as individuals can also benefit from a multilevel approach to education and literacy. Additionally, patient engagement and interventions can be implemented at multiple levels (McCormack et al., 2016).

## **Literature Review Related to Key Variables and/or Concepts**

### **LTC and TB Treatment Outcomes**

A limited number of studies existed on the association between LTC and TB treatment outcomes in low TB transmission settings. Individuals in LTCs had an increased risk for TB disease exposure and transmission due to congregate settings of LTC facilities (CDC, 2023; Wu et al., 2022). Additionally, age was a risk factor for TB in LTCs. Older residents aged 65 or older may have weakened immune systems or other comorbidities that increase the risk of TB in this setting (CDC, 2023; Wu et al., 2022). This study was conducted to advance knowledge and understanding of the association between LTC and TB treatment outcomes.

### **Correctional Facility and TB Treatment Outcomes**

Congregate settings, such as correctional facilities, prisons, and detention centers, are associated with an increased risk of TB compared to the general population (CDC, 2021a; Collins et al., 2019; Laycock et al., 2021). Among individuals 15 years and older in 2021, 2.3% (179) of TB cases occurred while incarcerated (CDC, 2021a). Incarceration was a risk factor for unsuccessful treatment outcomes, including undocumented or incomplete treatment, and lack of follow-up (Mitruka et al., 2016; Pradipta et al., 2019). Homelessness, substance abuse, and untimely linkage to care were other risk factors common among incarcerated individuals (Evenden et al., 2019; Gupta et al., 2018; Mikuta et al., 2016). Studies have shown that timely detection of cases in congregate settings, along with screening, linkage to care, and treatment, is essential for managing cases in these settings (Gupta et al., 2018; Stewart et al., 2022). Congregate

prison settings were shown to impact unsuccessful treatment; however, the literature did not support whether death was an outcome associated with TB treatment among this patient population.

### **PEHs and TB Treatment Outcomes**

The literature supported that homelessness was a risk factor for TB due to most homeless people finding shelter in congregate settings (Coorey et al, 2022; Evenden et al, 2019; Holden et al, 2019; Langer et al, 2019). “Among persons aged  $\geq 15$  years with TB in 2021, 341 (4.5%) reported experiencing homelessness within the 12 months preceding TB diagnosis. This compares with 290 (4.3%) TB cases in 2020 among persons aged  $\geq 15$  years with reported homelessness in the past year” (CDC, 2022b, congregate settings, para. 1). The incidence of TB was more than ten times higher in persons experiencing homelessness compared to the general population (Marks et al., 2023; Parriott et al., 2018). The risk factors for TB in persons experiencing homelessness included latent TB, which was 7-20 times more persistent in persons experiencing homelessness, exposures and outbreaks, access to healthcare, late recognition of symptoms, and delayed diagnosis (Bedmar et al., 2022; Gupta et al., 2018; Langer et al., 2019; Marks et al., 2023). Delayed diagnosis was an indicator of TB deaths and, therefore, a significant risk factor among persons experiencing homelessness (Coorey et al., 2022; Langer et al., 2019). Other comorbidities such as HIV, substance abuse, and mental health issues were also prevalent among this population (Khan et al., 2018). Homelessness was linked to treatment outcomes of treatment failure, loss to follow-up, and increased mortality or

death (Agrawal et al, 2019; Di Gennaro et al, 2022; Holden et al, 2019; Lui et al, 2020; Pradipta et al, 2019).

### **Diabetes and TB Treatment Outcomes**

Studies have shown that diabetes is a significant risk factor associated with TB morbidity and mortality (Armstrong et al., 2020; Houck et al., 2023; Huber et al., 2022; Nguyen & Graviss, 2019b). In 2021, diabetes mellitus (23.9%) was the most reported medical risk factor among persons with TB disease (CDC, 2025a). Individuals with diabetes have two to four times the risk of developing TB (Baltas et al., 2023; Huber et al., 2022). Studies have shown that diabetes is associated with increased mortality in TB patients (Alkabab et al., 2023; Armstrong et al., 2020; Houck et al., 2023; Huangfu et al., 2019; Lee-Rodriguez et al., 2020). There was a 9.1% - 30% risk of death associated with TB-DM during TB treatment (Nguyen & Graviss, 2019a; Nguyen & Graviss, 2019b; Armstrong et al., 2020). Diabetes was linked to less favorable TB treatment outcomes overall and can result in delays in sputum conversion and prolonged treatment (Alkabab et al., 2023; WHO, 2022).

Conversely, other studies argue that diabetes was not an independent risk factor for unsuccessful TB treatment outcomes (Baltas et al., 2023; Coorey et al., 2022). A study by Baltas et al. 2023 stated that diabetes was not an independent predictor for unsuccessful treatment outcomes in people with TB. Coorey et al. 2022 found that diabetes was a risk factor for TB but was not associated with unsuccessful treatment outcomes. Lee-Rodriguez et al. (2020) stated that diabetes was associated with delayed mortality or mortality after one year. Although substantial evidence supported that

diabetes was linked to unsuccessful TB treatment outcomes and mortality, the association between diabetes and TB treatment outcomes still requires further research, as there are conflicting findings.

### **HIV and TB Treatment Outcomes**

According to the WHO (2022), in 2021, among the 10.6 million new active TB cases, 6.7% were also HIV-positive, and of the 1.6 million people who died from TB, 11.7% were HIV-positive (WHO, 2022). TB is one of the leading causes of death among people living with HIV because the evidence shows that HIV increases the risk of acquiring active TB (Lee-Rodriguez et al, 2020; Marks et al., 2019). HIV was linked to mortality in people with TB and especially in Blacks (Marks et al., 2019).

Outcomes associated with HIV-TB include increased death (Houch et al., 2023; Nguyen & Graviss, 2019a, 2019b), delays in treatment completion, which are linked to adverse TB outcomes, were observed in individuals with HIV-TB coinfection (Coorey et al., 2022; Schechter et al., 2018). Evidence showed that when Antiretroviral Treatment (ART) was introduced as an intervention among at-risk HIV-TB or latent TB patients, more favorable outcomes were observed (Collins et al., 2019; Schechter et al., 2018). However, the timing of ART in individuals at risk was crucial to the success of treatment. Blacks were at increased risk for HIV compared to Whites, although HIV-TB rates were similar across Blacks and Whites (61% vs 57%), and mortality was comparable among Blacks and Whites (Marks et al., 2019). Targeted antiretroviral prophylaxis for individuals at high risk of HIV and latent TB infection was shown to reduce TB risk (Collins et al., 2019). In summary, individuals with HIV-TB experience adverse

outcomes and mortality, and there is a race disparity in risk, although the rates in Blacks and Whites are similar.

### **Illicit Drug Use and TB Treatment Outcomes**

Multiple studies have demonstrated that illicit drug use was a risk factor for TB, and a more extended injection history was an increased risk for TB and HCV (Armenta et al., 2017; Coorey et al., 2022; Mitruka et al., 2016). Drug abuse was linked to unfavorable TB treatment outcomes and was found to result in increased mortality, late diagnosis, resistance, and delayed treatment completion (Armenta et al., 2017; Coorey et al., 2022; Gupta et al., 2018; Laycock et al., 2021; Pradipta et al., 2018; Wigger et al., 2022). Studies also showed that people who abuse drugs were less likely to have documentation of treatment completion (Mitruka et al., 2016).

### **Excess Alcohol and TB Treatment Outcomes**

Individuals who misuse alcohol have an increased risk of progression to active TB disease (Gupta et al., 2018; Langer et al., 2019; Laycock et al., 2021; Ragan et al., 2020). Studies showed that between 10–20% of all TB deaths worldwide were attributed to alcohol use, and excess alcohol is associated with increased mortality in TB patients (Ragan et al., 2020; Wigger et al., 2022). Alcohol was identified as an independent risk factor for TB, with increased risk as consumption increases (Coorey et al., 2022; Wigger et al., 2022). Outcomes such as treatment failure, loss to follow-up, longer time to culture conversion, late diagnosis, and disease relapse are associated with alcohol use among individuals with TB (Ragan et al., 2020; Wigger et al., 2022). Excess alcohol consumption was associated with adverse treatment outcomes such as increased mortality

(Coorey et al., 2022; Holden et al., 2020; Wigger et al., 2022). Individuals who misuse alcohol were also more likely to experience delayed treatment completion and late diagnosis, which resulted in a resistant TB strain (Coorey et al., 2022; Gupta et al., 2018; Laycock et al., 2021; Wigger et al., 2022). Other factors, such as HIV, homelessness, and poor nutrition in this population, may also have a synergic effect on the outcomes experienced in individuals who misuse alcohol (Gupta et al., 2018).

### **Age and TB Treatment Outcomes**

In low-transmission settings, previous studies on TB treatment outcomes have shown an association between unsuccessful outcomes and specific age groups (Kohonen et al., 2020; Di Gennaro et al., 2022; Nguyen & Graviss, 2019a; Holden et al., 2019). The clinical and demographic factors associated with TB treatment outcomes were studied in all age groups, including children, youth, adolescents, young adults, and older adults (Korhonen et al., 2020; Wu et al., 2022; Pradipta et al., 2019). The group with the increased risk for mortality and severe disease of TB infection in the U.S. is children under the age of 15 (Jaganath et al., 2022). “1.1 million children develop TB worldwide with 230,000 deaths annually” (Jaganath et al., 2022, p. 1). “In 2021, the US had 4% new TB cases in children” (CDC, 2022a, TB incidence rate by group, para. 1). Children with parents from countries with high TB incidence experience disproportionately high TB (Cowger et al., 2019). The burden in children was associated with non-specific symptoms in children under five and difficulty in diagnosis and treatment of pediatric TB cases; this group may experience severe forms of the disease (CDC, 2022a; Cowger et al., 2019). However, the incidence of TB is higher in adults over 15 than in children (CDC, 2022a).

Age 18-24 years was a predictor of unsuccessful treatment outcomes in the U.S. (Pradipta et al., 2019). TB incidence increases with age, and studies in older individuals showed a disparity in treatment outcomes associated with individuals in the age group of 65 and older (Di-Gennaro et al., 2020; Korhonen et al., 2020). Individuals aged 65 and above were at a higher risk of treatment failure and adverse outcomes, including death (Di Gennaro et al., 2020; Holden et al., 2020; Korhonen et al., 2020; Pradipta et al., 2019; Wu et al., 2022). Due to multiple risk factors, such as living in congregate settings or in LTC and a less-than-adequate immune response, treatment failure may persist more often in this population (Wu et al., 2022). Adults 65 and older had the highest incidence rate in 2021 (CDC, 2024c). The population of this study focused on adults 15 years and older who have a higher incidence of TB than the under-15 population (CDC, 2024c). Although TB risks span all ages, mortality outcomes are higher amongst children, elderly individuals, and high-risk populations (Holden et al, 2020; Jaganath et al, 2022; Korhonen et al., 2020).

### **U.S.-Born Status, Origin of Birth, and TB Treatment Outcomes**

TB in non-US-born individuals is a significant risk factor. In the US, 71.4% of TB cases in 2021 and 73% in 2022 occurred in non-US-born persons, consistent with previous years, when, in 2019 and 2020, TB rates were approximately 70% in this population (CDC, 2022a; Deutsch-Feldman et al., 2021; Schildknecht et al., 2023). Studies showed a disproportionate rate of latent tuberculosis infection and active TB disease in individuals who were non-US-born compared to natives (CDC, 2022a; Jaganath et al., 2023; Langer et al., 2019; Schildknecht et al, 2023; Talwar et al., 2021).

Additionally, immigrants from high-burden TB settings (> 20 per 100,000 population) were at increased risk of developing the disease after immigrating to the US (Deutsch-Feldman et al., 2021; Schildknecht et al., 2023). Studies on treatment outcomes on immigrants in the US are sparse; however, in a low-transmission settings study, no difference in TB treatment outcomes among natives and foreign-born individuals was observed, although foreign-born incarcerated individuals had greater odds of non-documentation of TB treatment completion (Mitruka et al., 2016; Pradipta et al., 2019). Immigrants are vital drivers of TB in the US, and studies on treatment outcomes for this population are essential for TB prevention, control, and elimination in the United States.

### **Sex and TB Treatment Outcomes**

Males have a higher risk of TB compared to females. Men contribute 60% of TB cases globally and 65% of deaths (Horton et al., 2020). Sex was a risk factor for TB, and studies show that male gender was associated with higher TB mortality (Korhonen et al, 2020; Chidambaram, 2021). Male gender was also associated with unsuccessful TB treatment outcomes since males were less likely to seek timely TB treatment (Horton et al., 2020; Korhonen et al, 2020; Murphy et al, 2018). Other risks associated with the male gender were a higher number of sputum and culture-positive results after treatment, indicating treatment failure (Chidambaram, 2021).

### **Race, Ethnicity, and TB Treatment Outcomes**

The Black race was a risk factor for HIV-TB coinfection, although not a predictor of mortality (Marks et al., 2023). US data for 2021 showed that among non-US-born individuals, TB was more common amongst Asians, followed by Hispanic Latinos, and

Blacks or African Americans, then Whites (CDC,2025a; Deutsch-Feldman et al., 2021). The White race was associated with “presentation delay”, which is the time from the first symptom to seeking healthcare intervention (Evenden et al., 2019). In 2021, TB rates were nine times higher in Hispanic or Latino compared to Whites (Filardo et al., 2022). Additionally, the rates of TB amongst non-Hispanic blacks were eight times higher compared to non-Hispanic whites (Filardo et al., 2022).

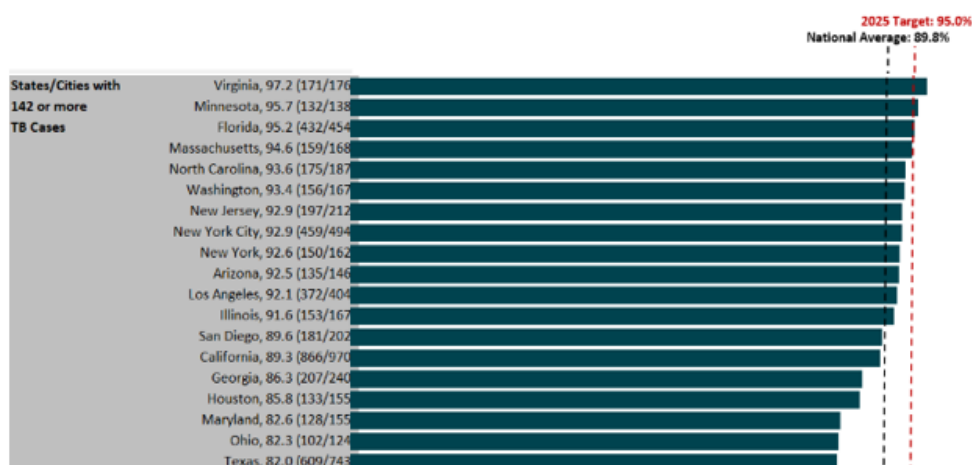
### **U.S. State Profile and TB Treatment Outcomes**

According to the CDC (CDC, n.d.-a; CDC, n.d.-b), data from 2017 to 2019 (see Figures 5, 6, and 7) showed that some states had treatment completion rates below the national average for newly diagnosed cases. States in the category with the most cases and below the national average treatment completion rate of 89.9% included San Diego, California; Georgia; Houston; Maryland; Ohio; and Texas (CDC, n.d.-a). In 2018, seven states and one city had a TB treatment completion rate below average. Among States and cities with 140 or more cases per year, California, North Carolina, Ohio, Arizona, San Diego, Texas, Massachusetts, and Maryland had treatment completion rates below the national average of 89.1% in 2018 and below the projected 95% target for 2025 (CDC, n.d.-b). In 2019, the national average treatment completion rate among newly diagnosed cases was 89.9%, up from the previous year. Eight locations had a treatment completion rate below the target. States and cities with TB of 132 or more cases that did not meet the national average were California, New York, Los Angeles, Ohio, San Diego, Texas, Massachusetts, and Maryland (CDC). States for analysis belong to the category with the highest number of TB cases from 2017 to 2019; that did not meet the national average for

TB treatment completion from 2017 to 2019 and fell below the CDC's 2025 treatment completion target of 95%. These States include California, Ohio, Texas, and Maryland. There was a need to assess risk factors for TB treatment completion in these States and develop a plan for TB treatment elimination, along with strategic goals to meet the 2025 expectations for TB treatment completion. Additionally, there existed opportunities for improvement of treatment completion among the homeless and incarcerated or other marginalized populations. Researchers should conduct risk-factor studies in the States most affected by TB to identify opportunities for improvement.

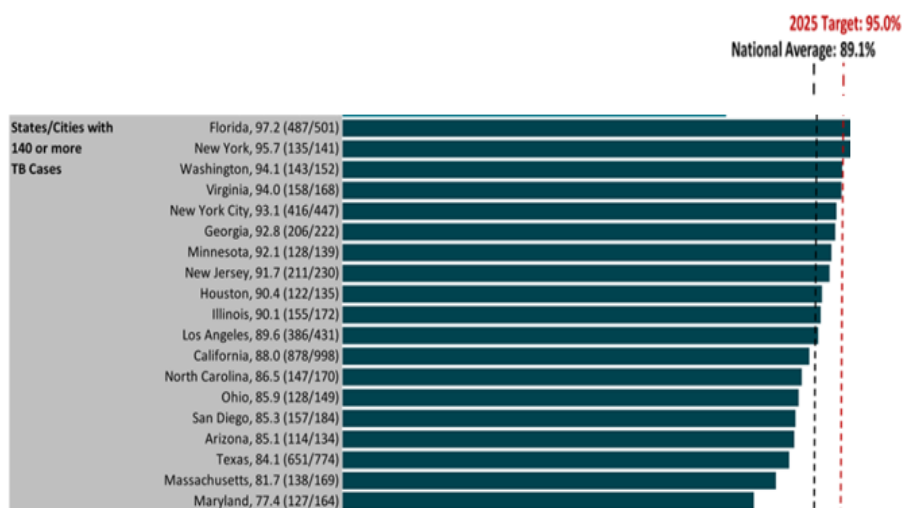
### Figure 5

*Percentage of Newly-Diagnosed TB Cases Completing Treatment  $\leq$  12 Months in the United States, 2017*

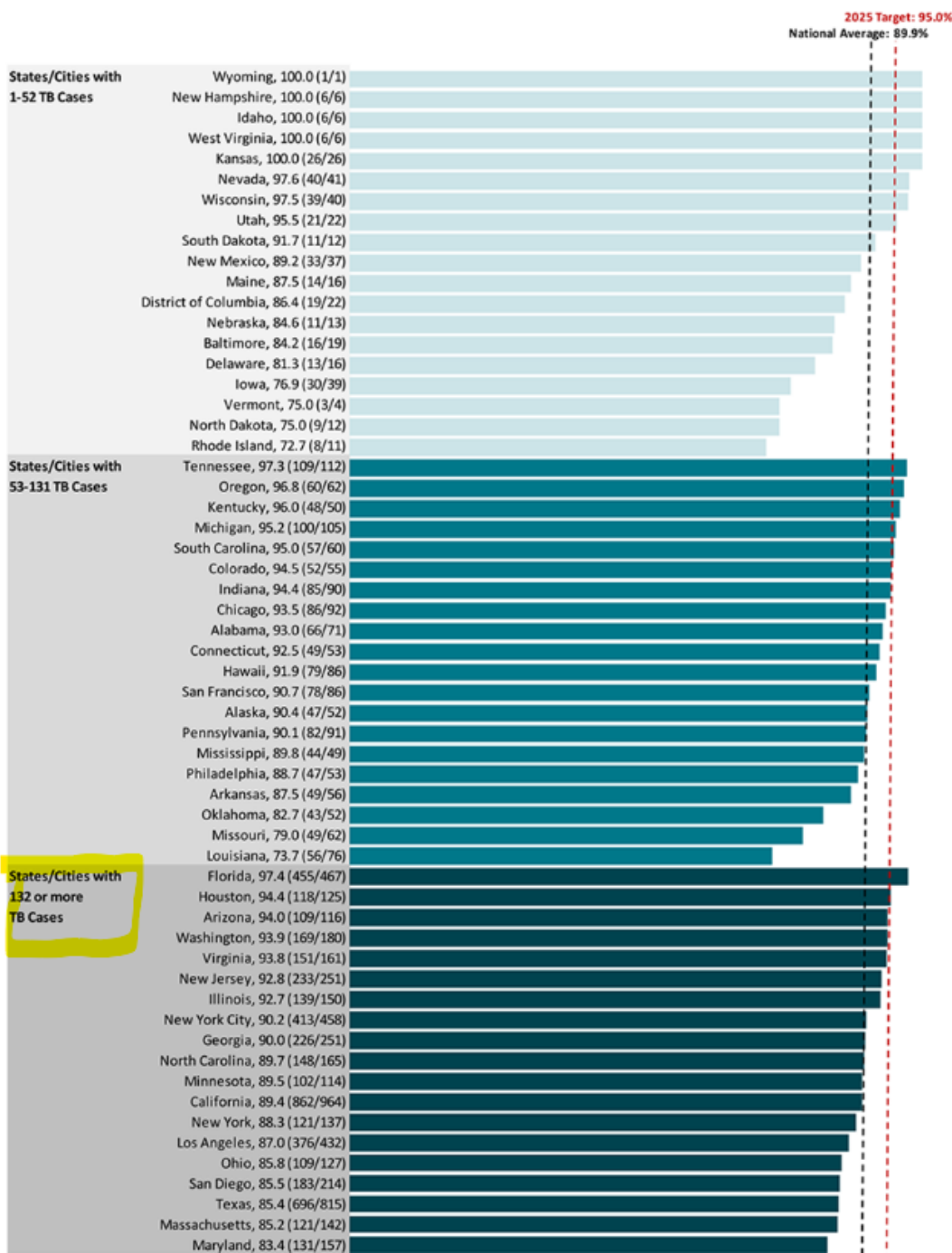


**Figure 6**

*Percentage of Newly-Diagnosed TB Cases Completing Treatment  $\leq$  12 Months in the United States, 2018*

**Figure 7**

*Percentage of Newly-Diagnosed TB Cases Completing Treatment  $\leq$  12 Months in the United States, 2019*



**California**

California was among the States below the national average for TB treatment among newly diagnosed cases in 2017, 2018, and 2019 (CDC, n.d.-a, n.d.-b; CDC, 2021a). According to the CDC, 89.4% of TB cases in California completed TB treatment

in 2019. In 2020, 13% of individuals with TB in California died. Consistent with global and national trends, there were decreased cases of TB in California in 2020, due to the COVID pandemic, which resulted in underreporting of TB cases due to overextension of public health resources (Louie et al., 2021). In 2021, California had a national incidence rate of almost 4.4 per 100,000 population, almost twice the national average of 2.4 per 100,000 population, according to the California Department of Public Health (CDPH, 2021). Risk factors for TB in California include progression from LTBI to active disease. 87% of TB cases in California in 2021 were due to progression of latent TB to active disease. Immigrant status, diabetes, and drug resistance were other identified risk factors (CDPH, 2021). The California TB Elimination Advisory Committee (CTEAC) has established strategic goals to achieve pre-elimination status by 2035 and ultimately eliminate TB by 2050. Additionally, specific interventions focus on LTBI testing and treatment (CPHD, 2021). Assessment of the risk factors for TB and their association with TB treatment outcomes will help determine areas of opportunity to help California achieve its TB elimination goals.

### ***Ohio***

In 2017, 2018, and 2019, Ohio's TB treatment completion rate was below the national average (CDC, n.d.-a; CDC, n.d.-b; CDC, 2021a). TB treatment completion rate in 2019 was 85.5% among homeless individuals. In 2019, the TB completion rate was 83.3% and 100% among incarcerated individuals (CDC, 2021a). In 2022, diabetes, excess alcohol consumption, and foreign-born persons were among the leading risk factors for TB in Ohio (Stokes, 2023). In 2022, 72% of TB cases in Ohio were associated

with a risk factor of diabetes (Stokes, 2023). Although TB rates decreased consistently from 2012 to 2022, a significant decline was observed in 2020, mainly due to the COVID-19 pandemic, as evidenced in other States and globally (Stokes, 2023). TB rates in Ohio returned to pre-pandemic levels in 2021, from 1.1 to 1.3 cases per 100,000 population; however, there was a slight decrease in 2022, with 1.2 cases per 100,000, which is below the national average of 2.5 cases per 100,000 in 2022 (Stokes, 2023). TB treatment data showed one TB-related death in 2022 (Stokes,2023). The State continues to focus on appropriate testing and treatment of cases addressing multidrug-resistant TB.

### ***Maryland***

TB treatment completion rates in Maryland improved in 2019, though they remained below the national average. TB treatment completion was 83.4% in 2019; among people experiencing homelessness, TB treatment was 100%, and among incarcerated individuals 15 years and older, treatment completion was also 100% (CDC, 2021a). However, in 2018 and 2019, the TB treatment completion rates were 77.4% and 83.4%, respectively (CDC,n.d.-b; CDC, 2021a). This study was relevant to understanding risk factors and TB treatment outcomes in Maryland.

### **Methodology and Instrumentation**

Quantitative and qualitative study design methods have been previously used to analyze TB treatment outcomes. However, in low-transmission settings, over 70% of studies assessing TB treatment outcomes in the literature review employed quantitative methods (Di Gennaro et al., 2022; Korhonen et al., 2020). Few studies used qualitative methodology to study perceptions of disease and prevention in high-incidence settings

(Laycock et al., 2021; Wu et al., 2022). In low-transmission settings, the most common study designs were cross-sectional surveys and retrospective cohort studies, which used national or state tuberculosis data. The National Tuberculosis Surveillance System (NTSS) served as a shared data source for U.S. studies that measured outcome variables (Armstrong et al., 2019; Marks et al., 2023; Nguyen & Graviss, 2019b).

Additionally, some studies focused on one outcome of mortality (Nguyen & Graviss, 2019b; Holden et al., 2020; Holden et al., 2022), while other studies focused on multiple outcomes, including successful treatment, loss to follow-up, and treatment failure (Di Gennaro et al., 2022; Gafar et al., 2019; Pradipta et al., 2019). Multiple studies focused on a single risk factor, such as diabetes or alcohol misuse (Armstrong et al., 2020; Ragan et al., 2020). Quantitative studies in the literature review employed multivariate or regression analysis statistical methods to measure the association between the study variables. Studies show NTSS was a highly reliable, consistent, and accurate source of U.S. TB data (Woodruff, 2023)

Based on the literature review and the research questions for this study, I used a quantitative cross-sectional study methodology and design to determine the effects of LTC, correctional facility, homelessness, HIV, diabetes, excess alcohol, and illicit drug use on TB treatment outcomes (completed, lost to follow-up, died, refused). Secondary data from state-level TB surveillance and multinomial logistic regression analyses using SPSS statistical software were used for the study.

## Summary and Conclusions

TB remains one of the deadliest infectious diseases, although there is a cure (WHO et al., 2022). As the world focuses on TB elimination and the End TB initiative, which is a global goal set by the World Health Organization, there is a need to identify marginalized populations for TB and develop interventions for people with unsuccessful treatment outcomes (Crosby et al., 2019; Holden et al., 2019; Holden et al., 2020; Korhonen et al., 2020; Pradipta et al., 2019; Rodriguez et al., 2020). Successful TB treatment outcomes are crucial to patient care and TB elimination (Holden et al., 2019; Gupta et al., 2018).

The literature review showed that individual and community factors affect TB risk and treatment outcomes. A summary of the key variables showed that TB increased with age; individuals 15 and older had a higher incidence of TB, and individuals 65 and older had a higher risk for death associated with the disease (Di Gennaro et al., 2020; Holden et al., 2020; Korhonen et al., 2020; Pradipta et al., 2019; Wu et al., 2022). Children were found to have a high burden of undiagnosed cases of TB and may experience more severe outcomes of the disease (CDC, 2025a; Cowger et al., 2019). Individuals in congregate settings (LTC, prison or correctional facility, and people experiencing homelessness may also have a higher risk of disease compared to the general population (Collins et al., 2019; Coorey et al., 2022; Evenden et al., 2019; Holden et al., 2019; Langer et al., 2019; Laycock et al., 2021; Marks et al., 2023; Parriott et al., 2018). Homelessness was linked to treatment outcomes of loss to follow-up, treatment failure, and death. Incarceration was linked to unsuccessful treatment outcomes of loss to

follow-up and incomplete treatment, but it is not well understood in terms of its effect on mortality.

TB incidence is high in non-US-born; however, there is not enough scientific evidence to support that immigrant status was an indicator of unsuccessful treatment outcomes (Jaganath et al., 2023; Langer et al., 2019; Schildknecht et al., 2023). Male gender was associated with mortality and unsuccessful treatment outcomes (Chidambaram, 2021; Korhonen et al., 2020). The literature established that diabetes was a risk factor for unsuccessful treatment outcomes (Alkabab et al., 2023; Armstrong et al., 2020; CDC, 2025a; Huangfu et al., 2019; Houck et al., 2023; Huber et al., 2022; Lee-Rodriguez et al., 2020; Nguyen & Graviss, 2019b). However, other studies have not supported this conclusion (Baltas et al., 2023; Coorey et al., 2022). Additionally, diabetes was the most common comorbidity among TB patients (CDC, 2025a). Further studies would help define the association between diabetes and TB treatment outcomes. The literature showed that HIV was one of the leading causes of death in TB patients. At the same time, alcohol misuse was linked to TB treatment outcomes of death, and alcohol misuse and substance abuse were indicators of unsuccessful treatment outcomes of treatment failure and loss to follow-up. Additionally, the role of multiple variables may present synergistic risks and inform understanding of TB treatment outcomes; however, this was beyond the scope of this study.

More studies on TB treatment outcomes are needed to fully evaluate the association between Long-Term Care (LTC) and TB treatment outcomes. There were limited studies in low-transmission settings that describe the association between LTC

and TB treatment outcomes. Variables that are strongly linked to TB mortality in the literature include age greater than 65 years, HIV, male gender, homelessness, and drug abuse. Substance or drug abuse, excessive alcohol, and homelessness were linked to other unsuccessful treatment outcomes of loss to follow-up, treatment failure, and incomplete treatment. This study addressed several gaps in the literature, including the role of diabetes in TB treatment outcomes and the association between community and individual risk factors and treatment outcomes.

Chapter 3 of this study introduces the methodology, including the population and sampling procedure, the recruitment and participation process, and the data collection methods. The section also includes instrumentation, operationalization, and threats to internal validity, followed by a summary.

### Chapter 3: Research Method

TB is a curable disease; however, it is the leading cause of infectious disease-related mortality globally (WHO, 2022). Death, adverse events, loss to follow-up, disease resistance, and treatment refusal are significant outcomes that contribute to problems associated with TB. There are risk factors associated with TB that facilitate unsuccessful treatment outcomes, which must be studied further. The purpose of this analysis was to explore associations between LTC, homelessness, correctional facility, diabetes, HIV, excess alcohol, illicit drug use, and TB treatment outcomes while controlling for age, sex, ethnicity, and origin-of-birth. I aimed to identify risk factors contributing to unsuccessful treatment outcomes by analyzing cases of PTB or PTB+ETB that resulted in unsuccessful outcomes, compared with individuals with successful outcomes. The study's sample population consisted of individuals from California, Ohio, and Maryland between 2017 and 2021. I aimed to provide insights regarding TB risk factors and their impact on treatment outcomes. This will aid in preventing and controlling the disease and in TB elimination efforts in the United States.

Chapter 3 includes the research design and rationale for the research questions. It also includes a description of covariates, independent variables, and dependent variables. I outline the methodology, including the study population and justification for archival data. The chapter also includes the data analysis plan, instrumentation, and operationalization of constructs, threats to internal and external validity, ethical considerations, and a summary.

## **Research Design and Rationale**

I used a quantitative cross-sectional study design with TB secondary datasets from California, Maryland, and Ohio. I considered three factors to determine the most suitable research design for the study: the study variables, the research questions, and support from the existing literature. The study included multiple independent variables (LTC, homelessness, correctional facility, diabetes, HIV, excess alcohol, and illicit drug use), a dependent variable with multiple categories (completion of treatment, refusal, loss to follow-up, and death), and covariates, which were sex, age, ethnicity, and origin of birth. Most of the variables in the study were measured numerically. The independent variables were categorical or nominal, and the dependent variable had more than 2 categories, making a multiple logistic regression appropriate. Additionally, the literature supported the use of quantitative over qualitative or mixed-methods studies, as quantitative designs were more frequently employed to examine TB treatment outcomes.

The literature supported the study's rationale and the need for research questions, as no recent comprehensive study had explored community and individual risk factors responsible for unsuccessful TB treatment outcomes in the California, Maryland and Ohio. Additionally, literature supported that individuals with HIV, diabetes, people who excessively consume alcohol, and PEHs experienced disparities involving unsuccessful TB treatment outcomes compared to the general population (Di Gennaro et al., 2022; Holden et al., 2019; Houck et al., 2023; Korhonen et al., 2020; Wu et al., 2022). However, no recent studies have explored Ohio, Maryland, and California. Another

justification for the study is that associations between correctional facilities, LTC, and unsuccessful TB treatment outcomes are unknown or have not been sufficiently studied.

Furthermore, the study was timely, as California, Maryland, and Ohio did not meet the CDC's 2025 TB treatment target of 95% based on 2019 data. This study included timely recommendations to improve TB treatment outcomes in these locations. California, Maryland, and Ohio had high numbers of TB cases between 2017 and 2019 that did not meet the national average for TB treatment completion.

Two drawbacks to a cross-sectional study design are that it does not establish causality and is used to establish the prevalence of a phenomenon at a specific time, rather than being generalizable to a broader time period (Pérez-Guerrero et al., 2024). There are advantages, however, to using Cross-sectional studies using secondary data. For example, they are less time-consuming than longitudinal or randomized controlled trials. In randomized controlled trials, outcome results may take time to emerge, as the effects of the intervention must be observed to draw meaningful conclusions. Cross-sectional studies using secondary data are also less expensive and can help alleviate resource constraints associated with randomized controlled trials. Sampling enabled a more robust sample size, which, in turn, affected the study's power.

I chose to use Cross-sectional methods due to their advantages. To guide this study, four research questions and four logistic regression models were formulated to investigate relationships between independent and dependent variables:

RQ1: Is there an association between LTC and TB treatment outcomes among patients with TB while controlling for sex, age, ethnicity, and origin of birth?

H01: There is no association between LTC and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

Ha1: There is an association between LTC and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

RQ2: Is there an association between correctional facilities and TB treatment outcomes among patients with TB while controlling for sex, age, ethnicity, and origin of birth?

H02: There is no association between correctional facility and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

Ha2: There is an association between correctional facilities and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

RQ3: Is there an association between homelessness and TB treatment outcomes among patients with TB while controlling for sex, age, ethnicity, and origin of birth?

H03: There is no association between homelessness and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

Ha3: There is an association between homelessness and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

RQ4: Is there an association between diabetes, HIV, excess alcohol consumption, illicit drug use, and TB treatment outcomes among patients with TB while controlling for sex, age, ethnicity, and origin of birth?

H04: There is no association between diabetes, HIV, excess alcohol consumption, illicit drug use, and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

Ha4: There is an association between diabetes, HIV, excess alcohol consumption, illicit drug use, and TB treatment outcomes while controlling for age, sex, ethnicity, and origin of birth among patients with TB.

## **Methodology**

### **Sampling and Sampling Procedures**

The study population consisted of confirmed PTB cases from California, Ohio, and Maryland from 2017 to 2021. Criterion sampling was used to include cases that meet a specific definition. According to Memon et al. (2025), criterion sampling is:

Selecting participants who meet specific, predefined criteria directly related to the research objectives (Edmonds & Kennedy, 2017). This method is particularly effective when researchers require a well-defined group of participants who share characteristics central to the study. To apply criterion sampling, researchers establish clear and justified criteria that align with the study's aims. The specificity of these criteria enhances the rigor of the research, ensuring that the selected participants contribute directly to answering the research questions (Andrade, 2021). Once the criteria are set, participants can be identified through approaches such as targeted recruitment, contacting relevant organizations, or utilizing professional databases and networks.” (p. 4)

Cases that met the criteria for confirmed PTB cases from 2017 to 2021 in the States of California, Maryland, and Ohio were included in the dataset for the study. The state TB dataset included active surveillance of confirmed TB cases from each State (CDC, 2021b). TB State data were derived from surveillance of yearly reported cases from territories, local, and State health departments. States' TB reports represent a highly reliable dataset.

Additionally, I used inclusion criteria to narrow the case samples. The study included laboratory-confirmed non-MDR or non-XDR cases of pulmonary TB from California, Maryland, and Ohio. I included participants aged 15 years and older with pulmonary TB who were alive at the time of diagnosis from 2017 to 2021 in the study. Cases with other forms of resistance, such as polyresistance and monoresistance, to at least one first-line drug were also included in the study. I excluded from the study cases with extrapulmonary TB only, MDR or XDR-TB strains, individuals with TB under age 15, cases outside 2017-2021, cases that were dead at diagnosis, and duplicate cases within 2017-2021.

### ***Sample Size Determination***

The minimum required sample size was determined using established heuristic criteria for regression modeling rather than formal power calculations. For multinomial logistic regression with a three-category outcome, two logits are estimated relative to the reference category, resulting in regression coefficients for each predictor across both logits. With 11 predictors (7 independent variables and four covariates), this yields 22 estimated regression parameters. Methodological guidance for logistic regression

commonly recommends a minimum number of observations per estimated parameter to ensure stable coefficient estimation and limit overfitting, with traditional rules suggesting approximately 10–15 observations per parameter (Peduzzi et al., 1996; Harrell, 2015), while later work emphasizes that these rules should be applied conservatively and in relation to model complexity and outcome distribution (Vittinghoff & McCulloch, 2007; van Smeden et al., 2016). Additionally, multinomial-specific research emphasizes the importance of sufficient observations across outcome categories to ensure reliable estimation of multiple logits (Pate et al., 2023). More generally, research on regression methodology focusing on model identification and inferential stability demonstrates that very small sample sizes are prone to unreliable inference, recommending a baseline minimum of approximately 25 observations to consistently identify regression patterns under moderate to high variance conditions (Jenkins & Quintana-Ascencio, 2020). Building on this evidence, a more conservative threshold of approximately 25 observations was adopted as a safer minimum per analytical unit to reduce instability further and enhance robustness. Based on these considerations, a minimum total sample size of approximately 550 observations ( $22 \times 25$ ) was deemed appropriate for the present analysis. The dataset comprised 11,161 participants, of whom 7,589 were eligible candidates, exceeding the minimum number required for the study. N=7589 cases that met the represented sampling population were included in the study.

### **Procedures for Recruitment, Participation, and Data Collection**

There was no direct recruitment of cases associated with the study. Study participants were obtained through state surveillance data. The instrument used to collect

TB data is the Reports of Verifiable Cases of TB (RVTC) form. The procedure for recruiting cases by State entities was facilitated by the RTVC form, which served as the primary instrument for collecting TB data for the State TB surveillance dataset. The form is included in Appendix A as an “Annotated RTVC Form.” The RTVC form was revised in 2009 and in 2020 and consists of different sections that capture demographic, clinical, laboratory information, and sensitive information, including HIV status, alcohol, drug use, residence in a correction facility, occupation status, homelessness, and demographic information such as date of birth and zip code (CDC, 2021b). The variables in this study were protected, and the data owners took measures to ensure participants' confidentiality. HIV status and other sensitive information are not traceable to specific individuals (NTSS, 2015). The RTVC form is comprehensive and provides a valid and reliable tool for reporting cases of TB in the U.S. and surrounding territories in real time (CDC, 2021b; NTSS, 2015).

The RTVC form is used by reporting entities, such as local, state, and territorial governments, to notify federal entities, including the CDC and the Division of Tuberculosis Elimination (DTBE), as well as the National Tuberculosis Surveillance System (NTSS), about TB cases (CDC, 2021b). Cases are verified at the State level using laboratory, clinical case definition, or provider diagnosis (“Healthy People 2030”, n.d.; NTSS, 2015). NTSS has been collecting surveillance data on confirmed TB cases since 1953 and is the sole source of comprehensive national TB data in the U.S. (CDC, 2021b; NTSS, 2015).

Participation by reporting entities is covered under sections 306 and 308(d) of the Public Health Service Act [42 U.S.C. 242k], which allowed reporting States and entities to report sensitive and case-identifying information to the CDC for national surveillance purposes (Armstrong, 2020; NTSS, 2015). An investigation by the reporting entities, along with the completion of pertinent forms, ensured that information on risk factors, testing, and other parameters covered in the surveillance system was recorded (CDC, 2021b). State-level TB surveillance data represent a reliable and comprehensive dataset on confirmed TB cases in the U.S. and were best suited for this study because of their historical use as a reliable source and because their goals and purpose aligned with the study.

### **Archival Data**

Consideration for the TB dataset was initially meant to be fulfilled by National Tuberculosis Surveillance Systems (NTSS); however, due to time constraints, State-level TB surveillance data were acquired from CA, MD, and OH. The datasets used in this study were state-level, containing Reports of Verifiable Cases of TB (RVTC) for each State (CDC, 2021b). Cases were verified using laboratory, clinical case definition, or provider diagnosis (CDC, 2021b; “Healthy People 2030”, n.d.). According to NTSS, data from laboratories, providers, hospitals, public health agencies, and state health departments from all 50 U.S. states and territories contribute to their datasets. The datasets contain demographic information, laboratory and testing information, risk factors, and other matrices. State-level data utilizes a web-based reporting system that ensures real-time reporting, although aggregate data may take years for complete analysis

or study. The dataset was collected to reduce TB and aid efforts toward TB elimination goals in the US (CDC, 2021b; NTSS, 2015).

State-level datasets for TB were obtained from the individual states with IRB approval. Once the IRBs were approved, the requester received confirmation to proceed with the data request and worked with the State epidemiologists to fulfill it.

### **Instrumentation and Operationalization of Constructs and Variables**

State-level TB data were received electronically from State epidemiologists via Excel sheets. Data cleaning, data merging, and operationalization of each variable were conducted consecutively. Descriptions of the variables are shown in Table 2. The response options for each variable are also listed in Table 2, along with the variable abbreviation in parentheses, as recorded in the dataset. All variables in the study consisted of categorical or nominal data, and the dataset included demographic (sex, age, race, ethnicity, and US-born status or origin of birth), comorbidities (HIV, diabetes), and risk factors (homelessness, alcohol, illicit drug use, LTC, correctional facility). Age was stratified into the following categories: 15-24, 25-34, 35-44, 45-54, 55-64, and 65+ years.

No variable was designated as a treatment outcome reason; however, the Stop Therapy (STOPREAS) variable includes options for why treatment was stopped. The options include (adverse, completed, died, loss to follow-up, moved, refused, unknown, and other). The reasons for treatment outcomes were derived from the STOPREAS variable. The outcomes “Not TB,” “unknown” (UNK), and “other” were not assessed in this study because they are not outcomes of interest. The outcome of adverse events was not assessed due to the small cell count of responses associated with that outcome.

**Table 2***Variables and Definitions*

Variable Name	Type of Variable	Level of Measurement	Options / Variable Definitions
Treatment completion (STOPREAS)	Dependent	Categorical	<p>COMPLETED- Primary reason therapy was ended and not resumed b/c therapy was completed.</p> <p>DIED- Primary reason therapy was ended and not resumed b/c the patient died.</p> <p>LOST- Primary reason therapy was ended and not resumed b/c patient loss to follow-up</p> <p>REFUSED- Primary reason therapy was ended and not resumed b/c patient was uncooperative or refused.</p>
Long-term care (LONGTERM)	Independent	Categorical	No- This patient was NOT a resident of a long-term care facility at the time

			<p>of the TB diagnostic evaluation.</p> <p>Y- This patient was a resident of a long-term care facility at the time of the TB diagnostic evaluation.</p> <p>UNK- Unknown whether this patient was a resident of a long-term care facility at the time of the TB diagnostic evaluation.</p>
Correctional Facility (CORRINST)	Independent	Categorical	<p>Y-Resident of Correctional Facility at Time of Diagnosis</p> <p>N- NOT a Resident of Correctional Facility at Time of Diagnosis</p>
Homeless (HOMELESS)	Independent	Categorical	<p>N-This patient was NOT homeless at any time during the past 12 months prior to the TB diagnostic evaluation</p> <p>Y-This patient was homeless at any time during the past 12 months prior to the TB diagnostic evaluation.</p> <p>the TB diagnostic evaluation</p>
Diabetes (RISKDIAB)	Independent	Categorical	<p>Y- This patient has a diagnosis of diabetes mellitus</p>

			(Type I or Type II) either before or at the time of TB diagnosis.
HIV Status (HIVSTAT)	Independent	Categorical	Neg- Laboratory HIV test result is negative. Pos - Laboratory HIV test result is positive.
Alcohol (ALCOHOL)	Independent	Categorical	N-This patient has not used alcohol to excess within the past 12 months. Y-This patient has used alcohol to excess within the past 12 months.
Illicit drug use/Injected drug use NONIDU/IDU	Independent	Categorical	N- This patient has NOT injected illegal drugs within the past 12 months. Y- This patient has injected illegal drugs within the past 12 months
Age (AGE3)	Covariate	Categorical	Patient age 15-24 years old at report date. Patient age 25-34 years old at report date. Patient age 35-44 years at report date. Patient age 65 or older at report date. Patient age unknown at report date.

Sex (SEX)	Covariate	Categorical	M- Patient's sex at birth is male. F- Patient's sex at birth is female. UNK- Patient's sex at birth is unknown.
U.S. born	Covariate	Categorical	N- Indicates the person was NOT born in the U.S. and neither parent was a U.S. citizen. Y- Indicates the person was U.S.-born (or born abroad to a parent who was a U.S. citizen). To be U.S.-born, the person must either 1) be born in 1 of the 50 states or the District of Columbia, or 2) be born outside the U.S. to at least one parent who was a U.S. citizen. UNK- Unknown whether the person was born in the U.S.
Ethnicity (ETHNIC)	Covariate	Nominal	HISP- Indicates this patient considers himself or herself to be of Hispanic origin NONHISP- indicates this patient considers himself or herself NOT to be of Hispanic origin

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### **Data Analysis Plan**

The data analysis software used in this study was IBM SPSS version 29. I used SPSS to conduct all statistical tests and answer the study's research questions. Data cleaning involved assessing missing values, excluding cases that did not meet the inclusion criteria, converting responses to binary values, and transforming the age measure from a ratio to a categorical variable. State-level TB surveillance data were assessed for missing values using SPSS's missing value analysis. Once I identified the missing values in the dataset, I conducted further assessment to determine whether the missing data levels were below the 5% or 10% thresholds. Studies suggest that missing data at a 5% level or below does not create significant bias in the study. In contrast, studies with more than 10% missing data may introduce bias (Dong, 2013). The dataset contained fewer than 10% missing values; therefore, no further steps, such as deleting cases or performing mean imputations, were taken to optimize the dataset. Table 3 shows the missing values associated with each variable.

Testing of each model assumption was conducted in SPSS for multinomial logistic regression. Additionally, I utilized SPSS to determine the association between LTC, correctional facility, homelessness, HIV, diabetes, excess alcohol consumption, illicit drug use, and TB treatment completion. Statistical analysis included multinomial logistic regression to estimate odds ratios ( $\exp(B)$ ). An  $\exp(B) > 1$  indicated that the odds of the outcome occurring increase with an increase in the predictor variable, while an

$\exp(B) < 1$  indicated that the odds of the outcome decrease with each increase in the predictor variable. I calculated the percentage odds in the study using the formula  $(1 - \exp(B)) * 100$ . Furthermore, I analyzed Pearson's chi-square statistic ( $X^2$ ) to determine how well the model fit the dataset. A Pearson correlation with  $p > .05$  indicated the model was a good fit. The confidence interval (CI) was also included in the analysis at the 95% confidence level.

Four research questions guided the study. The data analysis was framed by the study's research questions and hypotheses, and the calculated associations for each research question were incorporated into the interpretation of the results. Table 4 summarizes the variables and tests associated with each research question. Each research question and its corresponding statistical test are shown in the table. The covariates were selected based on previous studies that show that older age, male sex, non-Hispanic ethnicity, and non-U.S. origin of birth were associated risk factors for TB or associated with unsuccessful treatment outcomes (CDC, 2022a; 2022b; Di Gennaro et al., 2022; Korhonen et al., 2020; Schildknecht et al., 2023; Wu et al., 2022).

**Table 3**

*Missing Values of Variables*

N	Lab verified	Age	Sex	Race
Valid	7589	7589	7589	7589
Missing	0	0	0	0
	Origin of birth	Correctional facility	LTC	Homelessness
Valid	7570	7570	7574	7565
Missing	19	19	15	24
	Illicit drugs	Excess alcohol	Diabetes	HIV
Valid	7431	7433	7140	6957
Missing	158	156	449	632

	Site of TB	Treatment with (RIF, NIH, PZA, EMB( RIPE)	Reason TB therapy stopped	Pansuceptibility status
Valid	7589	7212	7332	7589
Missing	0	377	377	0

**Table 4***Research Questions, Variables, and Statistical Analysis*

Research Question	Data collected/ Variables	Statistical Analysis
RQ1	IND- long-term care  DEP- TB treatment outcomes (Completed therapy, died, lost to follow-up, and refused)  COV- age, race, ethnicity, and origin of birth	Multinomial logistic regression: Pearson chi-square statistic $X^2$ Significant result $p < .05$  Exp(B)- or Odds Ratio  CI – Confidence Interval
RQ2	IND- correctional facility or incarceration  DEP- TB treatment outcomes (Completed therapy, died, lost to follow-up, and refused)  COV- sex, age, race, ethnicity, and origin of birth	Multinomial logistic regression: Pearson chi-square statistic $X^2$ Significant result $p < .05$  Exp(B)- or Odds Ratio  CI – Confidence Interval
RQ3	IND – homelessness  DEP- TB treatment outcomes (Completed therapy, died, lost to follow-up, and refused)  COV- sex, age, race, ethnicity, and origin of birth	Multinomial logistic regression: Pearson chi-square statistic $X^2$ Significant result $p < .05$  Exp(B)- or Odds Ratio

		CI – Confidence Interval
RQ4	IND - HIV, diabetes, excess alcohol, and illicit drug use)	Multinomial logistic regression: Pearson chi-square statistic
	DEP- TB treatment outcomes (Completed therapy, died, lost to follow-up, and refused)	X <sup>2</sup> Significant result $p < .05$
	COV- sex, age, race, ethnicity, and origin of birth	Exp(B)- or Odds Ratio CI – Confidence Interval

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### Threats to Validity

Validity refers to the extent to which the study's findings accurately represent the intended concept or measure (Babbie, 2015). Internal validity refers to the extent to which the instruments, data, and measurements accurately represent the relationship and accuracy of the study's findings. It refers to the study's rigor, including its design, instrumentation, and measurement methods (Andrade, 2018; Babbie, 2015). External validity refers to the extent to which the study's findings can be applied to a broader population (Andrade, 2018; Babbie, 2015). External validity refers to the generalizability of the study (Babbie, 2015; Patino & Ferreira, 2018). Randomized trials have more internal validity than descriptive studies, such as cohorts or cross-sectional studies (Andrade, 2018).

Threats to external and internal validity were considered in the design of this study. The threats of interaction effect of selection and experimental variables were considered in the study; however, there was no evidence to suspect that the way cases were selected, for example, about selections of laboratory confirmed cases only, and exclusion of cases that were not laboratory confirmed (physician diagnosed), would

present threats to external validity. Additionally, the age-group selection, which excluded individuals under 15, is not considered a threat to external validity and is unlikely to affect the outcome.

Several issues can arise when using pre-existing or secondary data.

Because I did not collect the data, there may be issues with missing data for specific variables, incomplete data, and human error that can affect the measurement and internal validity of the study. This study's internal validity threats included missing and incomplete data. According to the data owners, some fields may contain incomplete data, which can affect the analysis; therefore, careful consideration is required (NTSS, 2015). Internal and external validity may be affected by synergistic effects or bias, as well as multiple risk factors, which can cause a more significant effect or mask specific effects in the study. Threats to the generalizability of the study exist, as CA cases accounted for 87.7% of participants, potentially skewing the results and making them more representative of CA outcomes than of MD and OH outcomes. Sensitivity analyses were conducted by re-estimating the models with additional state adjustments to assess the robustness of the primary findings.

### **Ethical Procedures**

Walden University requires that all dissertation studies be reviewed by the Institutional Review Board (IRB) for approval. The board reviewed the ethical considerations of the study to ensure it met all safety standards for human research and adhered to the principles of the Belmont Report of respect for persons, beneficence, and justice (Nagai et al., 2022; U.S. Department of Health and Human Services, 1979;

Walden University, n.d.). The IRB determined the risk category for each study and the level of protection required, including assurance that all necessary safety measures were in place to protect human participants. The study received four IRB approvals: one from each of the states represented in the study (California, Maryland, and Ohio) and one from the Walden IRB, ensuring that there was no risk of harm to participants (see Appendices B, C, D, and E). The IRBs also ensured the research complied with the ethical principles in the Belmont Report (Department of Health, Education, and Welfare, 1979) and the Declaration of Helsinki (World Medical Association, 2013). There was minimal risk associated with this study, and because no cases were recruited, informed consent was waived (CITI Program, n.d.; Shah, 2024). Other protection measures included downloading datasets, storing files in a protected format, and ensuring that files were destroyed after the study's conclusion or after 5 years (CITI Program, n.d.). Additionally, measures were taken to ensure participant privacy by using de-identified data. The dataset was stored on a password-protected device, and the results were presented in a manner that minimized the stigmatization of specific groups.

### **Summary**

A rigorous methodology was employed in this study. The methodology chapter outlined the study's steps and presented the data analysis. The section outlined the study population, including the inclusion and exclusion criteria. The measures and instruments used in the study demonstrated rigor and were supported in the literature, thereby ensuring the study's internal validity. This section included definitions of the dependent and independent variables and the covariates.

The appropriate tests for the study and type of analysis were discussed in this chapter. Issues related to external validity were discussed, including the exclusion of some TB outcomes due to insufficient cell counts. TB treatment outcomes, such as adverse events and treatment discontinuation, were not analyzed in the study, potentially compromising external validity. The study is generalizable to any subpopulation similar to the sampled population, controlling for age, sex, ethnicity, and origin of birth. In conclusion, the methodology section clearly communicated and addressed the study's rigor, including its design, measurement, and analysis.

The following chapter focuses on data analysis and study results. It consists of the parameters associated with data collection and the study's trustworthiness. Additionally, the limitations of the study results are included in this section.

## Chapter 4: Results

I aimed to determine factors associated with unsuccessful treatment outcomes. I measured associations between LTC, correctional facility or incarceration status, homelessness, diabetes, HIV, excess alcohol consumption, illicit drug use, and TB treatment outcomes among individuals with PTB between 2017 and 2021 in California, Maryland, and Ohio while controlling for age, sex, ethnicity, and origin of birth. I investigated which risk factors were associated with unsuccessful treatment outcomes rather than TB treatment completion.

RQ1, RQ2, and RQ3 examine associations between setting or community factors (LTC, correctional facility status, homelessness) and TB treatment outcomes. RQ4 included four variables based on individual factors, which are HIV, diabetes, excess alcohol, and illicit drugs.

RQ1: Is there an association between LTC and TB treatment outcomes among patients with TB while controlling for sex, age, ethnicity, and origin of birth?

H<sub>0</sub>1: There is no association between LTC and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

H<sub>a</sub>1: There is an association between LTC and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

RQ2: Is there an association between correctional facilities and TB treatment outcomes among patients with TB while controlling for sex, age, ethnicity, and origin of birth?

H<sub>0</sub>2: There is no association between incarceration in correctional facilities and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

H<sub>a</sub>2: There is an association between incarceration in correctional facilities and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

RQ3: Is there an association between homelessness status and TB treatment outcomes among patients with TB while controlling for sex, age, ethnicity, and origin of birth?

H<sub>0</sub>3: There is no association between homelessness status and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

H<sub>a</sub>3: There is an association between homelessness status and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

RQ4: Is there an association between diabetes, HIV, excess alcohol consumption, illicit drug use, and TB treatment outcomes among patients with TB while controlling for sex, age, ethnicity, and origin of birth?

H<sub>0</sub>4: There is no association between diabetes, HIV, excess alcohol consumption, illicit drug use, and TB treatment outcomes while controlling for sex, age, ethnicity, and origin of birth among patients with TB.

H<sub>a</sub>4: There is an association between diabetes, HIV, excess alcohol consumption, illicit drug use, and TB treatment outcomes while controlling for age, sex, ethnicity, and origin of birth among patients with TB.

Chapter 4 presents information on the data collection process, the population, the statistical analysis, the interpretation of the results, and a summary of the findings.

### **Data Collection**

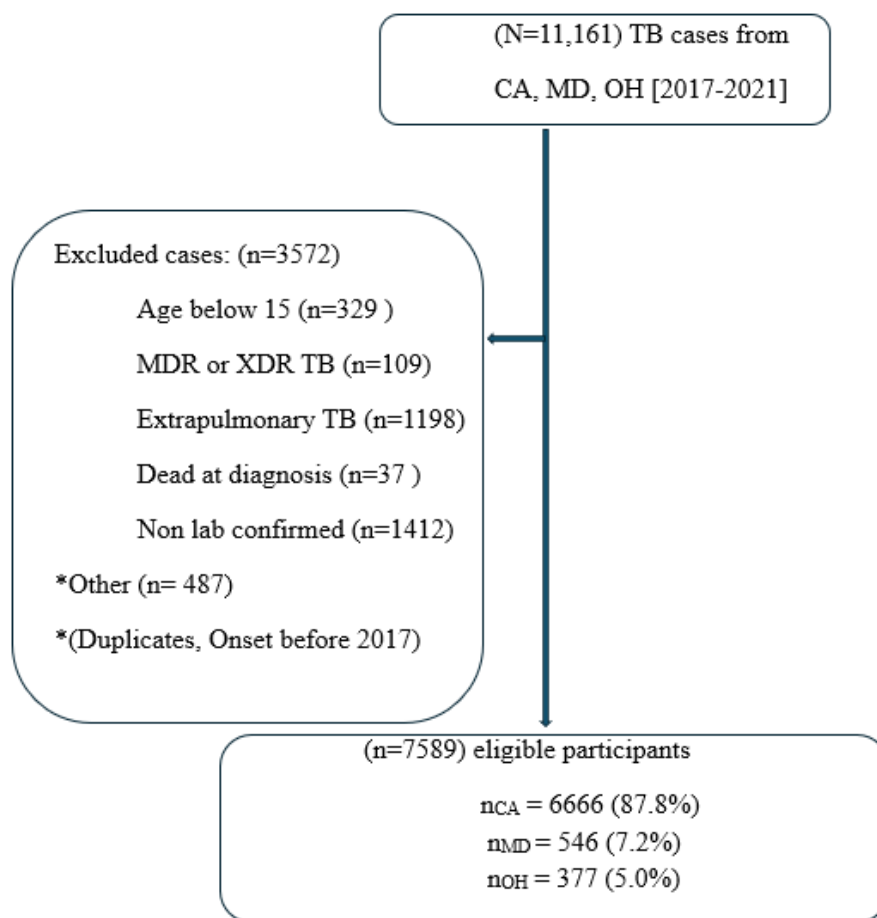
Data collection began in September 2024. IRB applications and requests for State TB data from California, Ohio, and Maryland were submitted to individual state health departments from September to December 2024. A data dictionary showing the variables of interest, along with a brief proposal, was submitted to each state health department between September and December 2024. The data request specified the need for TB data from 2017 to 2021 for each state (see Appendix F). State IRB approvals were obtained between October and December 2024. Data sets were received, cleaned, and prepped for analysis between December 2024 and March 2025. The total number of cases in the dataset for each state from 2017 to 2021 was 9,715 in California, 687 in Maryland, and 759 in Ohio.

There were deviations from the data collection and analysis plan. The research was initially intended to involve four states; however, only three participated. The initial proposal for the study also included an analysis of societal factors such as types of health providers, insurance status, and delayed treatment to measure access to care. These variables were excluded from the study due to data limitations. A total of 11,161

participants were eligible for the study. The total number of eligible participants from 2017 to 2021 was 6,666 in California, 546 in Maryland (n=546), and 377 in Ohio. The number of participants who met the inclusion criteria was 7,589 (see Figure 9).

### Figure 8

#### *Participants Who Were Eligible for the Study*



*Note.* Other (N = 480) includes duplicates (cases counted previously within 2017-2021) and individuals with onset before 2017 who were excluded from the study.

## Results

The baseline descriptive and demographic characteristics of the study population are presented in Table 5. There were (n=7589) participants who met the inclusion criteria. Of these, (n=6666) 87.8% were California participants, (n=546) 7.2% were Maryland participants, and (n=377) 5.0% were Ohio participants. The study's covariates include age, sex, place of birth, and ethnicity. Among all age categories, the highest-sampled category was 65+ (n = 2793), accounting for 36.8%. There were 8.0% participants in the 15-24 age group, 13.4% in the 25-34 age group, 10.5% in the 35-44 age group, 13.5% in the 45-54 age group, and 17.9% in the 55-64 age group. The mean age was 52.7, and the mean age category was 45-54. There were almost twice as many males (64%) as females (36%). Approximately 66% of participants were non-Hispanic, while Hispanics were about 34%. Non-U.S.-born individuals account for approximately 84% of participants, while U.S.-born individuals account for 16% of participants in the study. The sample is representative of the population, including individuals with pulmonary TB aged 15 years and above.

**Table 5**

*Descriptive Characteristics of Participants (n=7589)*

Characteristics	Value description	N	Percent (%)
Reason TB therapy was stopped	Completed Tx	6333	83.4
	Loss to follow-up	114	1.5
	Refused Tx	48	0.6
	Died	837	11.0
Age	15-24	604	8.0
	25-34	1017	13.4
	35-44	794	10.5

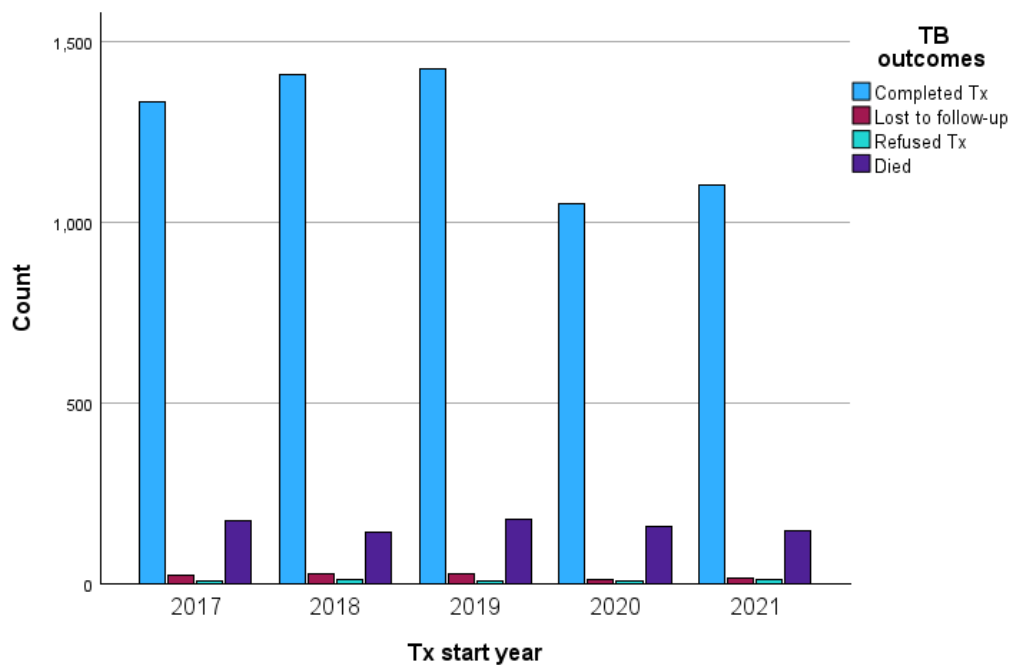
	45-54	1024	13.5
	55-64	1357	17.9
	65+	2793	36.8
Sex	Male	4866	64.1
	Female	2723	35.9
Ethnicity	Hispanic	2559	33.7
	Non-Hispanic	5026	66.2
Origin of birth	U.S.-Born	1246	16.4
	Non-U.S.-Born	6324	83.5
Correctional facility	Yes	162	2.1
	No	7408	97.6
Homelessness	Yes	408	5.4
	No	7157	94.3
Long Term Care (LTC)	Yes	174	2.3
	No	7400	97.5
Diabetes	Yes	2355	31.0
	No	4785	63.1
HIV status	Yes	288	3.8
	No	6669	87.9
Excess alcohol	Yes	548	7.2
	No	6885	90.7
Illicit drug	Yes	535	7.0
	No	6896	90.9
Site of TB disease	PTB	6400	84.3
	PTB+EP	1188	15.7
Pan-susceptibility status	Pan-susceptible	6549	86.3
	Resistant to at least one of INH, RIF, PZA, EMB	1016	13.4
Laboratory test type	Positive culture	7384	97.3
	Positive smear/tissue	3	0
	Positive NAA	202	2.7

---

Incarcerated individuals at the time of diagnosis accounted for 2.1% of participants, while those experiencing homelessness were 5.4%. Individuals in LTC accounted for 2.3% of participants. Diabetes was the most common risk factor, with thirty-one percent of the participants having diabetes before or at the time of diagnosis,

and 63% were non-diabetic. When diabetes was stratified by age, it accounted for 8% in the 15-24 age group, 15.4% in the 25-34 age group, 14.2% in the 35-44 age group, 14.3% in the 45-54 age group, 14.9% in the 55-64 age group, and 32.9% in the 65+ age group. The participant pool consisted of 3.8% of individuals who were HIV positive, and 7.2% of participants had excess alcohol use. The history of illicit drug use accounted for 7.0% of participants. Individual risk factors (HIV, diabetes, excess alcohol, and illicit drugs) were more predominant compared to community risk factors, which were based on setting (LTC, correctional facility, homelessness). Eighty-four percent of participants had Pulmonary TB only, while 15.7% had a combination of pulmonary and extrapulmonary TB. 86.3% of the participants had TB that was pan-susceptible and was treated with first-line drugs (INH, RIF, PZA, and EMB) while 13.4% were resistant to at least one first-line drug (INH, RIF, PZA, EMB). Most cultures (97.3%) were confirmed by laboratory culture, while some were confirmed by Nucleic Acid Amplification (NAA).

Figure 9 shows the number of TB cases that completed treatment for the years 2017-2021. Treatment completed was the most common outcome, followed by death. The average treatment completion rate slightly decreased in 2020 and 2021 compared to the previous years from 2017 to 2019. Lost to follow-up and treatment refusal were other outcomes experienced by cases, but were less common compared to treatment completion and death.

**Figure 9***TB Treatment Outcomes CA, MD, OH [2017-2021]***Statistical Assumptions**

Before analysis, I tested the assumptions for multinomial logistic regression models. The six assumptions tested include the dependent variable being measured on a nominal scale, multiple independent variables being measured on a nominal scale, independence of observations, no multicollinearity, linearity, and absence of outliers. (Leard Statistics, n.d.). Through observation, I determined that the data met the assumptions for a dependent nominal variable. Additionally, the independent variables were also nominal. There was independence of observations and mutual exclusivity of the dependent variables. Additional assumptions for the test of multicollinearity between independent and dependent variables, as well as the absence of outliers, were assessed

using SPSS. A multicollinearity test, conducted in SPSS, showed that all Variance Inflation Factor (VIF) scores were below 1.3, indicating no significant multicollinearity among the predictor variables. I assumed linearity because all variables of the study were nominal. There were no violations of the test's six assumptions. There were fewer than 10% missing values in the dataset, indicating less likelihood of bias (Dong & Peng, 2013).

### **Statistical Analysis**

Four independent multinomial logistic regression models were conducted to determine the association between the independent and dependent variables. All four models were statistically significant ( $p < .05$ ).

For RQ1, a multinomial logistic regression analysis was conducted to determine the association between (TB) treatment outcomes (completed treatment, died, refused, loss to follow-up) and the predictor variables: Long Term Care (LTC), age, sex, ethnicity, and origin of birth.

Based on the model-fitting information (Table 6), the null model, compared to the full model, was statistically significant and showed that the model with the variables performed better than the intercept-only (null) model. The variable model distinguished the factors associated with TB treatment outcomes ( $\chi^2(15) = 694.2, p < .001$ ). Based on the Pearson statistics shown in the “goodness of fit” (Table 7), the model was not a good fit for the data  $\chi^2(237) = 282.3, p < .023$ . For a model to show a good fit using Pearson statistics, the p-value must be greater than 0.05.

**Table 6***Model Fitting Estimate for RQ1*

Model	Model Fitting Criteria	Likelihood Ratio Tests		
	-2 Log Likelihood	Chi-Square	df	Sig.
Intercept Only	1268.614	694.280	15	<.001
Final	574.335			

**Table 7***Goodness of Fit for RQ1*

	Chi-Square	df	Sig.
Pearson	282.345	237	.023
Deviance	242.868	237	.383

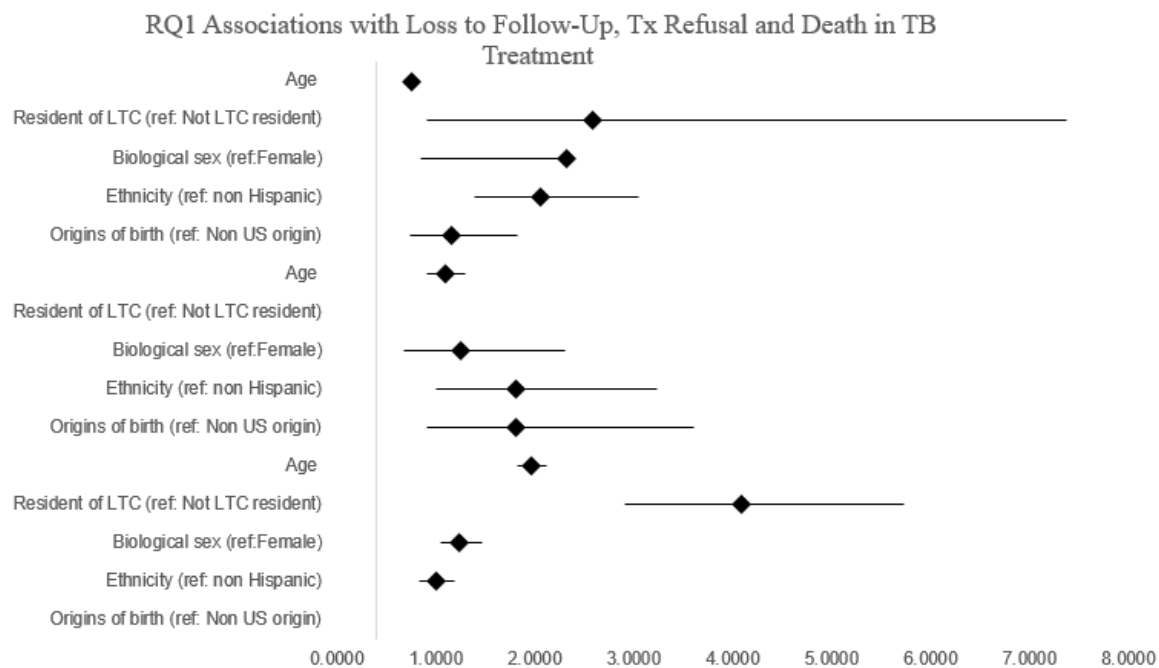
For the treatment outcome of “loss to follow-up” (instead of completing treatment), age, sex, and ethnicity were significant predictors,  $p < .05$ . Origin of birth and LTC were not statistically significant predictors of “loss to follow-up,”  $p > .05$ .

For every 10-year increase in age, the odds of a case being lost to follow-up (instead of completing treatment) decrease by approximately 23% ( $B = -0.269$ ,  $SE = 0.58$ ,  $Wald = 21.23$ ,  $df = 1$ ,  $Exp(B) = 0.764$ ,  $95\% C.I. = 0.68, 0.85$ ,  $p < .001$ ). Compared to females, male sex was associated with an increased odds of case being lost to follow-up (instead of completing treatment) by approximately 132% ( $B = 0.843$ ,  $SE = 0.23$ ,  $Wald = 12.64$ ,  $df = 1$ ,  $Exp(B) = 2.324$ ,  $95\% C.I. = 1.46, 3.69$ ,  $p < .001$ ). Compared to non-Hispanic, Hispanic ethnicity was associated with an increased odds of loss to follow-up (instead of completing treatment) by approximately 114% ( $B = 0.721$ ,  $SE = 0.20$ ,  $Wald = 12.97$ ,  $Exp(B) = 2.057$ ,  $df = 1$ ,  $95\% C.I. = 1.39, 3.04$ ,  $p < .001$ ).

For the treatment outcome of refused treatment, ethnicity was a significant predictor of treatment refusal,  $p < .05$ . Age, sex, origin of birth, and residence at Long-term care were not statistically significant predictors of treatment refusal (instead of completing treatment). Compared to non-Hispanics, Hispanic ethnicity was associated with an increased odds of treatment refusal (instead of completing treatment) by approximately 80.9% ( $B = 0.593$ ,  $SE = 0.29$ ,  $Wald = 3.950$ ,  $Exp(B) = 1.809$ ,  $df = 1$ , 95%  $CI = 1.00, 3.24$ ,  $p = .047$ ).

For the treatment outcome of died LTC, age, sex, and origin of birth were significant predictors,  $p < .05$ ; ethnicity was not a significant predictor of “died,”  $p > .05$ .

For every ten-year increase in age, the odds of death (instead of completing treatment) increased by approximately 96% ( $B=0.676$ ,  $SE=0.03$ ,  $Wald=315.1$ ,  $df=1$ ,  $Exp(B)=1.966$ , 95%  $C.I. = 1.82, 2.11$ ,  $p < .001$ ). Compared to a Non-resident of LTC, a LTC resident at diagnosis was associated with an increased odds of death (instead of completing treatment) by approximately 308% ( $B = 1.407$ ,  $SE=0.17$ ,  $Wald=65.56$ ,  $df=1$ ,  $Exp(B)=4.084$ , 95%  $CI=2.905, 5.741$ ,  $p < .001$ ). Compared to females, male sex was associated with increased odds of death (instead of completing treatment) by approximately 24% ( $B=0.218$ ,  $SE=0.08$ ,  $Wald=6.819$ ,  $df=1$ ,  $Exp(B)=1.244$ , 95%  $C.I. = 1.05, 1.46$ ,  $p=0.009$ ). Compared to individuals of non-U.S. origin of birth, individuals with U.S origin of birth had increased odds of death (instead of completing treatment) by approximately 42% ( $B= 0.350$ ,  $SE= 0.11$ ,  $Wald=9.711$ ,  $df=1$ ,  $Exp(B)= 1.419$ , 95% $C.I.= 1.13, 1.76$ ,  $p=0.002$ ). A forest plot of the RQ1 odds ratio and confidence intervals is shown in Figure 9.

**Figure 9***RQ1 Forest Plot*

For RQ2, I conducted a multinomial logistic regression analysis to determine the association between TB treatment outcomes (completed treatment, died, refused, loss to follow-up) and the predictor variables: incarceration status, age, sex, ethnicity, and origin of birth. Based on the model-fitting information (Table 8), the fit between the “intercept only model” and the full model improved with the addition of the variables. The model was statistically significant and successfully distinguished the factors associated with TB treatment outcomes ( $\chi^2(15) = 686.2, p < .001$ ). Based on the Pearson statistics shown in the “goodness of fit” (Table 9), the model was not a good fit for the data  $\chi^2(216) = 260.6, p < .020$ .

**Table 8***Model Fitting Estimate for RQ2*

Model	Model Fitting Criteria	
	-2 Log Likelihood	Likelihood Ratio Tests
Intercept Only	1228.830	Chi-Square df
Final	542.616	686.214 15 Sig. <.001

**Table 9***Goodness of Fit for RQ2*

	Chi-Square	df	Sig.
Pearson	260.658	216	.020
Deviance	215.368	216	.499

For the treatment outcome of loss to follow-up, correctional facility at time of diagnosis, age, sex, and ethnicity were statistically significant predictors of loss to follow-up (instead of treatment completion),  $p < .05$ . Origin of birth was not a statistically significant predictor of loss to follow-up (instead of completing treatment),  $p > .05$ . Compared to individuals who are not incarcerated, persons in correctional facilities have an increased odds of case being lost to follow-up (instead of completing treatment) by approximately 745.7% ( $B = 2.135$ ,  $SE = 0.26$ ,  $Wald = 64.43$ ,  $Exp(B) = 8.457$ ,  $df = 1$ , 95% C.I. = 5.02, 14.24,  $p < .001$ ). For every 10-year increase in age, the odds of a case being lost to follow-up (instead of completing treatment) decrease by approximately 17.9% ( $B = -0.197$ ,  $SE = 0.06$ ,  $Wald = 10.65$ ,  $df = 1$ ,  $Exp(B) = 0.821$ , 95% C.I. = 0.72, 0.92,  $p = .001$ ). Compared to females, male sex was associated with increased odds of

being lost to follow-up (instead of completing treatment) by approximately 95 % (B=0.668, SE=0.24, Wald=7.662, df=1, Exp(B)=1.950, 95%C.I.=1.21, 3.12, p=.006). Compared to non-Hispanics, Hispanic ethnicity was associated with increased odds of being lost to follow-up instead of completing treatment. by 71% (B=0.539, SE=0.20, Wald=6.733, Exp(B)= 1.714, df=1, 95%C.I.=1.14, 2.57, p=.009).

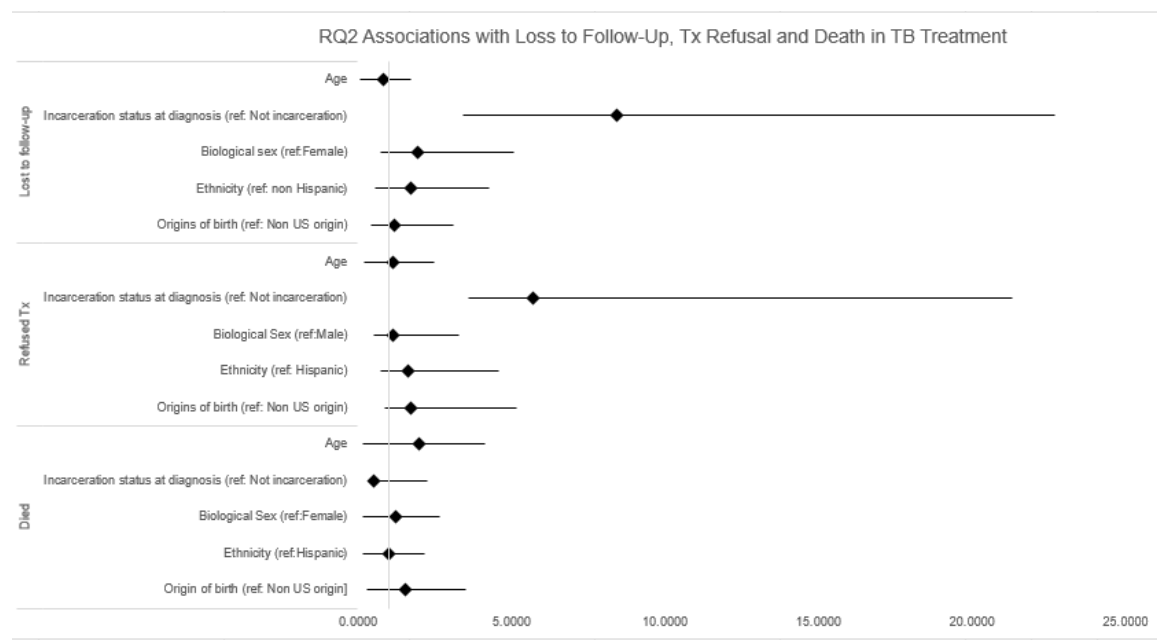
Correctional facility/Incarceration status was a statistically significant predictor of treatment refusal (instead of completing treatment),  $p < .05$ . Age, sex, ethnicity, and origin of birth were not statistically significant predictors of treatment refusal (instead of completing treatment),  $p > .05$ . Compared to non-incarcerated individuals in correctional facilities at the time of diagnosis, persons in correctional facilities have an increased odds of treatment refusal instead of completing treatment by 499% (B=1.740, SE=0.51, Wald=11.46, Exp(B)= 5.99, df=1, 95%C.I.= 2.08, 15.6,  $p < .001$ ).

Age, sex, and origin of birth were statistically significant predictors of death (instead of completing treatment),  $p < .05$ , while incarceration status and ethnicity were not statistically significant predictors of death (instead of completing treatment),  $p > .05$ . For every 10-year increase in age, the odds of death (instead of completing treatment) increase by approximately 100% (B = 0.691, SE = 0.38, Wald = 328.2, df = 1, Exp(B) = 1.996, 95% C.I. = 1.85, 2.15,  $p < .001$ ). Compared to females, male sex is associated with increased odds of death (instead of completing treatment) by approximately 23% (B= 0.207, SE= 0.08, Wald= 6.202, df=1, Exp(B)=1.230, 95%C.I.= 1.04, 1.44,  $p=0.013$ ). Compared to non-U.S.-born individuals, individuals with U.S. origin of birth have an increased odds of death (instead of completing treatment) by approximately 53.4% (B

0.422, SE 0.11, Wald 16.84, df=1, Exp(B)= 1.571, 95%C.I.= 1.26, 1.95,  $p < .001$ ). A forest plot of the RQ2 odds ratio and confidence intervals is shown in Figure 9.

**Figure 10**

*RQ2 Forest Plot*



For RQ3, I conducted a multinomial logistic regression analysis to determine the association between Tuberculosis (TB) treatment outcomes (completed treatment, died, refused, loss to follow-up) and the predictor variables of homelessness, age, sex, ethnicity, and origin of birth.

Based on the model-fitting information (Table 10), the null model, compared to the full model, was statistically significant and distinguished the factors associated with TB treatment outcomes ( $\chi^2 (15) = 673.0$ ,  $p < .001$ ). Based on the Pearson statistics shown

in the “goodness of fit” (Table 11), the model was not a good fit for the data  $\chi^2 (255) = 382.8, p < .001$ .

**Table 10**

*Model Fitting Estimate for RQ3*

Model	Model Fitting Criteria		
	-2 Log Likelihood	Likelihood Ratio Tests	
Intercept Only	1308.990	Chi-Square	df
Final	635.921	673.069	15
			Sig.
			<.001

**Table 11**

*Goodness of Fit RQ3*

	Chi-Square	df	Sig.
Pearson	382.833	255	< .001
Deviance	263.881	255	.263

For the TB treatment outcome of loss to follow-up, age, homelessness, sex, and ethnicity were statistically significant predictors of loss to follow-up (instead of treatment completion),  $p < .05$ . Origin of birth was not a statistically significant predictor of loss to follow-up (instead of completing treatment),  $p > .05$ . For every 10-year increase in age, the odds of case being lost to follow-up (instead of completing treatment) decrease by approximately 23% ( $B = -0.269$ ,  $SE = 0.06$ ,  $Wald = 19.76$ ,  $df = 1$ ,  $Exp(B) = 0.764$ , 95% C.I. = 0.67, 0.86,  $p < .001$ ). Compared to non-homeless persons, homeless individuals within the past 12 months of diagnosis had approximately 355% increased odds of being lost to follow-up (instead of completing treatment) ( $B = 1.516$ ,  $SE = 0.24$ ,  $Wald = 38.67$ ,

Exp(B) = 4.553, df = 1, 95% CI = 2.82, 7.33,  $p < .001$ ). Compared to females, male sex was associated with increased odds of being lost to follow-up (instead of completing treatment) by approximately 100% (B=0.696, SE=0.24, Wald=8.369, df=1, Exp(B)=2.007, 95%C.I.=1.25, 3.21,  $p = .004$ ). Compared to non-Hispanic individuals, Hispanic ethnicity was associated with approximately 85% increased odds of being lost to follow-up (instead of completing treatment) (B = 0.619, SE = 0.20, Wald = 8.952, Exp(B) = 1.856, df = 1, 95% CI = 1.23, 2.78,  $p = 0.003$ ).

Homelessness was a statistically significant predictor of treatment refusal (instead of completing treatment),  $p < .05$ . Age, sex, ethnicity, and origin of birth were not statistically significant predictors of treatment refusal (instead of completing treatment),  $p > .05$ . Compared to non-homeless persons, Persons experiencing homelessness within the past 12 months of diagnosis had increased odds of treatment refusal instead of completing treatment, increased by 224% (B=1.177, SE=0.41, Wald=7.905 Exp(B)=3.246, df=1, 95%C.I.= 1.42, 7.37,  $p < 0.005$ ).

Age, homelessness, sex, and origin of birth were statistically significant predictors of death (instead of completing treatment),  $p < .05$ , while ethnicity was not a statistically significant predictor of death (instead of completing treatment),  $p > .05$ .

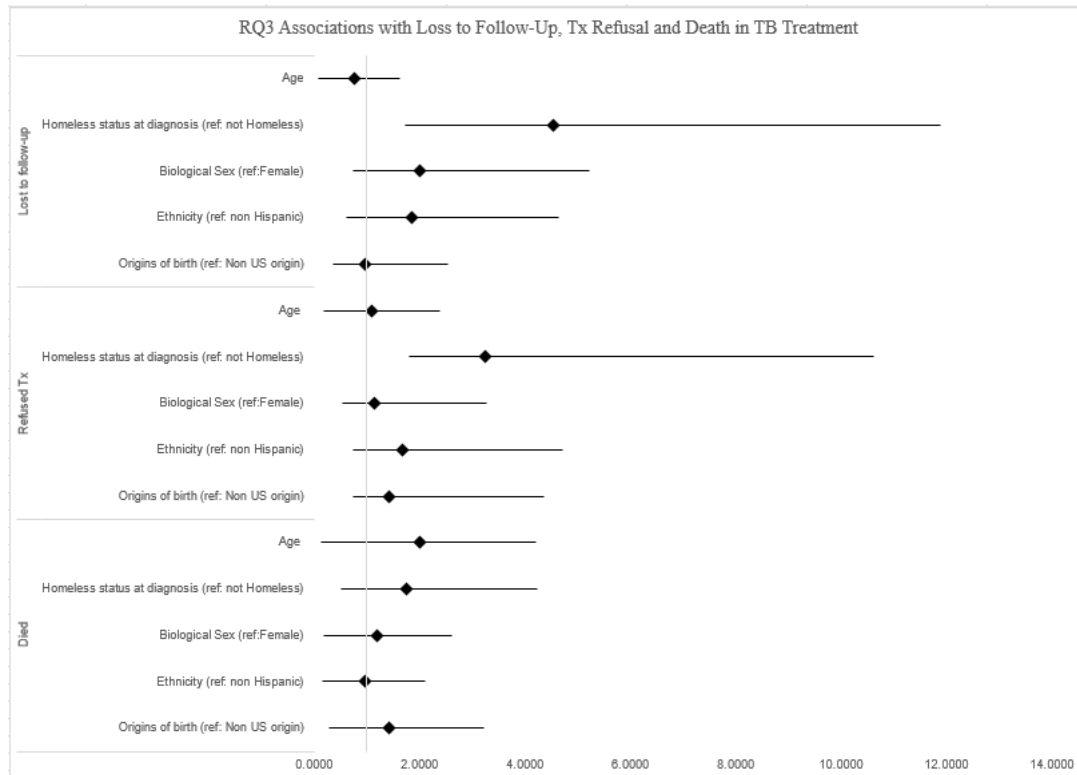
For every 10-year increase in age, the odds of death increase instead of completing treatment. increase by approximately 102% (B=0.705, SE = 0.39, Wald = 333.60, df = 1, Exp(B) = 2.024, 95% C. I. = 1.87, 2.18,  $p < .001$ ). Compared to non-homeless persons, Persons experiencing homelessness within the past 12 months of

diagnosis have increased odds of death (instead of completing treatment) by 76% ( $B=0.566$ ,  $SE=0.17$ ,  $Wald=10.38$ ,  $df=1$ ,  $Exp(B)=1.761$ ,  $95\%C.I.=1.24, 2.48$ ,  $p=.001$ ).

Compared to females, males had an increased odds of death (instead of completing treatment) by approximately 19.9% ( $B=0.182$ ,  $SE=0.08$ ,  $Wald=4.731$ ,  $df=1$ ,  $Exp(B)=1.199$ ,  $95\%CI=1.01, 1.41$ ,  $p=.030$ ). Compared to non-U.S. Origin of birth, persons with U.S origin of birth had increased odds of death (instead of completing treatment) by approximately 43% ( $B=0.360$ ,  $SE=0.11$ ,  $Wald=9.991$ ,  $df=1$ ,  $Exp(B)=1.433$ ,  $95\%C.I.=1.14, 1.79$ ,  $p<.002$ ). A forest plot of the RQ3 odds ratio and confidence intervals is shown in Figure 9.

**Figure 11**

*RQ3 Forest Plot*



For RQ4, a multinomial logistic regression analysis was conducted to examine the association between TB treatment outcomes (completed treatment, died, refused, or lost to follow-up) and the predictor variables: diabetes, HIV, excess alcohol consumption, illicit drug use, age, sex, ethnicity, and origin of birth.

Based on the model-fitting information (Table 12), the null model, compared to the full model, was statistically significant and distinguished the factors associated with TB treatment outcomes ( $\chi^2(24) = 501.6, p < .001$ ). Based on the Pearson statistics shown in Table 13, the “goodness of fit” table, the model was not a good fit for the data ( $\chi^2(984) = 1221.8, p < .001$ ).

**Table 12**

*Model Fitting Estimate for RQ4*

Model	Model Fitting Criteria			
	-2 Log Likelihood	Likelihood Ratio Tests		
Intercept Only	1520.504	Chi-Square	df	Sig.
Final	1018.877	501.627	24	<.001

**Table 13**

*Goodness of Fit for RQ4*

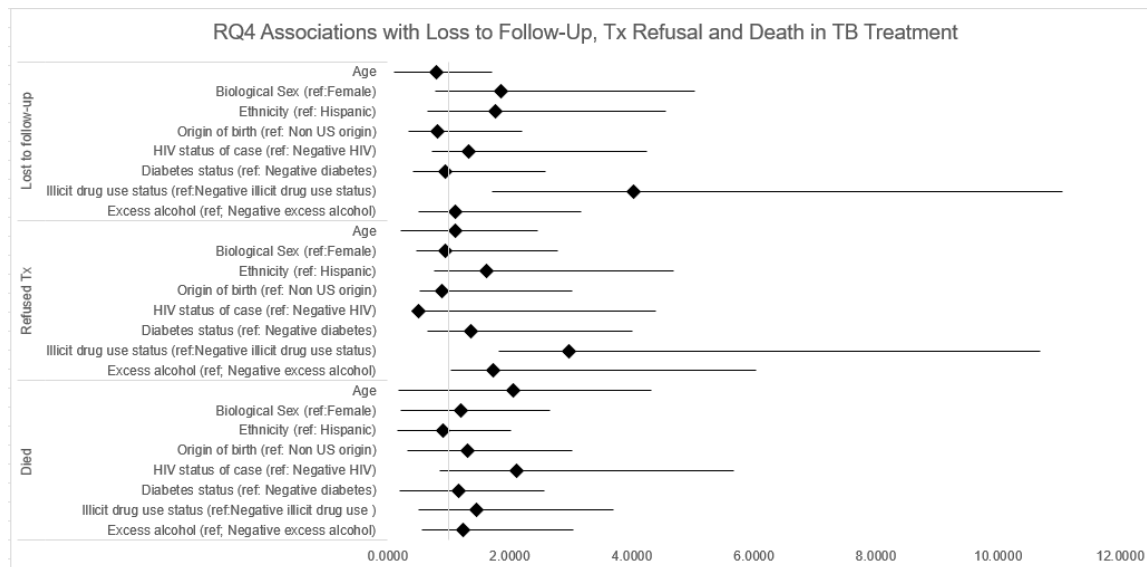
	Chi-Square	df	Sig.
Pearson	1221.884	984	<.001
Deviance	593.284	984	1.000

For the TB treatment outcome of loss to follow-up, age, sex, ethnicity, and illicit drug use were statistically significant predictors of loss to follow-up (instead of treatment completion),  $p < .05$ . Origin of birth, diabetes status, excess alcohol consumption, and HIV

were not statistically significant predictors of loss to follow-up (instead of completing treatment),  $p > .05$ . For every 10-year increase in age, the odds of being “loss to follow-up” (instead of completing treatment) decrease by approximately 21% ( $B = -0.230$ ,  $SE = 0.07$ ,  $Wald = 9.670$ ,  $df = 1$ ,  $Exp(B) = 0.794$ , 95% C.I. = 0.68, 0.91,  $p < .002$ ). Compared to females, males had increased odds of being lost to follow-up (instead of completing treatment) by approximately 85% ( $B = 0.620$ ,  $SE = 0.27$ ,  $Wald = 5.115$ ,  $df = 1$ ,  $Exp(B) = 1.859$ , 95% C.I. = 1.08, 3.18,  $p = .024$ ). Compared to non-Hispanics, Hispanic ethnicity was associated with approximately 76% increased odds of being lost to follow-up (instead of completing treatment) ( $B = 0.567$ ,  $SE = 0.23$ ,  $Wald = 5.773$ ,  $Exp(B) = 1.762$ ,  $df = 1$ , 95% CI = 1.11, 2.79,  $p = .016$ ). Compared to individuals who do not use illicit drugs, individuals with positive illicit drug use status have an increased odds of being lost to follow-up (instead of completing treatment) by approximately 303% ( $B = 1.396$ ,  $SE = 0.28$ ,  $Wald = 24.50$ ,  $Exp(B) = 4.037$ ,  $df = 1$ , 95% C.I. = 2.32, 7.01,  $p < .001$ ). A forest plot of the RQ4 odds ratio and confidence intervals is shown in Figure 9.

Figure 12

## RQ4 Forest Plot



Illicit drug use status was a statistically significant predictor of treatment refusal (instead of completing treatment),  $p < .05$ . Age, sex, ethnicity, origin of birth, diabetes status, excess alcohol consumption, and HIV status were not statistically significant predictors of treatment refusal (instead of completing treatment),  $p > .05$ .

Compared to individuals who do not use illicit drugs, individuals with positive illicit drug use status at time of diagnosis have increased odds of treatment refusal instead of completing treatment by approximately 197% ( $B=1.089$   $SE=0.48$ ,  $Wald=5.008$ ,  $Exp(B)= 2.973$ ,  $df=1$ ,  $95\%C.I.= 1.14, 7.71$ ,  $p < .025$ ).

Age and HIV status were statistically significant predictors of death (instead of completing treatment),  $p < .05$ , while ethnicity, sex, origin of birth, illicit drug use status, diabetes status, and excess alcohol consumption were not statistically significant predictors of death (instead of completing treatment),  $p > .05$ .

For every 10-year increase in age, the odds of death (instead of completing treatment) increase by approximately 105% ( $B=0.721$ ,  $SE = 0.048$ ,  $Wald = 225.3$ ,  $df = 1$ ,  $Exp(B) = 2.057$ , 95% C.I. = 1.87, 2.26,  $p<.001$ ). Compared to individuals who are not HIV positive, individuals with positive HIV status at time of diagnosis have increased odds of death (instead of completing treatment), increased by approximately 110% ( $B=0.746$ ,  $SE= 0.26$ ,  $Wald= 7.771$ ,  $df=1$ ,  $Exp(B)=2.108$ , 95% C.I.= 1.24, 3.56,  $p=.005$ ).

After adjusting for state in sensitivity analyses, the exponentiated coefficients ( $Exp(B)$ ) showed minor changes in magnitude; however, the direction of the associations and the statistical significance of the key predictors remained unchanged. These findings suggest that the primary results are robust to state-level adjustment. A summary of the initial model findings is presented in Table 14, while the adjusted model with states as an additional covariate is illustrated in Table 16.

### **Summary**

A table of the independent variables associated with TB treatment outcomes is shown in Table 14. Additionally, covariates associated with TB treatment outcomes are shown in Table 15. For RQ1, younger age, male sex, and Hispanic ethnicity were predictors of “lost to follow-up”, while ethnicity was associated with treatment refusal. Increase in age, long-term care (LTC) resident, male sex, and US origin of birth were associated with the outcome of death. In determining the association between LTC and TB treatment outcomes while controlling for age, sex, ethnicity, and origin of birth, LTC was associated with the outcome of death; therefore, I rejected the null hypothesis.

For RQ2, younger age, correctional facility residency at diagnosis, male sex, and Hispanic ethnicity were associated with loss to follow-up, and correctional facility residency was also associated with treatment refusal. Older age, male sex, and US origin of birth were associated with death. In determining the association between correctional facility and TB treatment outcomes while controlling for age, sex, ethnicity, and origin of birth, correctional facility was associated with loss to follow-up and treatment refusal; therefore, I rejected the null hypothesis.

**Table 14**

*Variables evaluated as possible risk factors for TB treatment outcomes ( $p < .05$ ) -Primary*

*Model*

<b>Variable</b>	<b>P-value</b>	<b>Odds Ratio (95% CI)</b>	<b>Odds Ratio (%)</b>
<b>Died</b>			
LTC Resident at diagnosis	<.001	4.08 (2.905 - 5.741)	308%
HIV positive at diagnosis	.005	2.10 (1.248-3.561)	110%
Homeless in the past year	.001	1.76 (1.248-2.484)	76%
<b>Lost to follow-up</b>			
Correctional facility resident at diagnosis	<.001	8.45 (5.021-14.243)	745.70%
Homeless in the past year	<.001	4.55 (2.824-7.331)	355%
Illicit drug use in the past year	<.001	4.03 (2.323-7.015)	303%
<b>Refused Tx</b>			
Correctional facility resident at diagnosis	<.001	5.99 (2.081-15.610)	499%
Homeless in the past year	.005	3.24 (1.428-7.374)	224%
Illicit drug use in the past year	.025	2.97 (1.145-7.719)	197%

The RQ3 model showed that younger age, homelessness status within a year of diagnosis, male sex, and Hispanic ethnicity were associated with the treatment outcome

of loss to follow-up. In contrast, homelessness status was associated with treatment refusal. Older age, homelessness, male sex, and US origin of birth were associated with the treatment outcome of death. In determining the association between history of homelessness status and TB treatment outcomes while controlling for age, sex, ethnicity, and origin of birth, homelessness status was associated with outcomes of loss to follow-up and death; therefore, I rejected the null hypothesis.

**Table 15**

*Covariates evaluated as possible risk factors for TB treatment outcomes,  $p < .05$  for RQ1, RQ2, RQ3, and RQ4 models*

Covariate	P-value	95% CI		% Odds
		Lost to Follow-up		
Age		0.682-0.857	23%	
	<.001	0.729-0.924	17.9%	
	<.001	0.679-0.860	23%	
	<.001	0.687-0.918	21%	
	<.001			
Hispanic Ethnicity	<.001	1.390-3.046	114%	
	.009	1.141-2.575	71%	
	.003	1.238-2.784	85%	
	.016	1.110-2.798	76%	
Male sex	<.001	1.460-3.699	132%	
	.006	1.215-3.129	95%	
	.004	1.252-3.217	100%	
	.024	1.086-3.182	85%	
US Origin of birth		<b>Died</b>		
	0.002	1.139-1.768	42%	
	<.001	1.266-1.950	53.4%	
	.002	1.146-1.791	43%	
	.063*	0.986-1.727	-	

	<.001	1.82-2.118	96%
Age	<.001	1.852-2.150	100%
	<.001	1.877-2.183	102%
	<.001	1.872-2.260	105%
	0.009	1.056-1.466	24%
Male sex	.013	1.045-1.447	23%
	.030	1.018-1.413	19.9%
	<b>.071*</b>	<b>0.985-1.458</b>	-
		<b>Refused Tx</b>	
		1.008-3.244	80.9%
	.047	<b>0.900-2.974</b>	-
Hispanic Ethnicity	<b>.1007*</b>	<b>0.934-3.044</b>	-
	<b>.083*</b>	<b>0.868-3.054</b>	-
	<b>.129*</b>		

*Note.* (\*) indicates models or values that are not statistically significant ( $p > .05$ )

From the RQ4 model, younger age, male sex, Hispanic ethnicity, and illicit drug use were associated with increased odds of loss to follow-up. In contrast, illicit drug use was associated with increased odds of treatment refusal. Increased age and positive HIV status were associated with increased odds of death. In determining the association of diabetes, HIV, excess alcohol, and illicit drug use with TB treatment outcome (loss to follow-up, treatment refusal, and death) while controlling for age, sex, ethnicity, and origin of birth, Illicit drug use was associated with outcomes of loss to follow-up and treatment refusal. HIV status was associated with the outcome of death. The null hypothesis was rejected for these two variables. Diabetes and excess alcohol consumption were not associated with any unsuccessful outcomes; the null hypothesis was accepted. Across all four models, younger age, male sex, and Hispanic ethnicity were associated with a higher likelihood of loss to follow-up. Across three of four models, an increase in age, male sex, and U.S origin of birth was associated with mortality.

**Table 16**

*Variables evaluated as possible risk factors for TB treatment outcomes ( $p < .05$ ) -Adjusted*

*Model with State as Covariate.*

<b>Variable</b>	<b>P-value</b>	<b>Odds Ratio (95% CI)</b>	<b>Odds Ratio (%)</b>
<b>Died</b>			
LTC Resident at diagnosis	<.001	4.02 (2.857 - 5.662)	302%
HIV positive at diagnosis	0.005	2.14 (1.263-3.269)	114%
Homeless in the past year	0.001	1.85 (1.313-2.632)	85%
<b>Lost to follow-up</b>			
Correctional facility resident at diagnosis	<.001	9.39 (5.531-15.956)	839.00%
Homelessness in the past year	<.001	5.02 (3.069-8.214)	402%
Illicit drug use within the past year	<.001	4.16 (2.376-7.304)	316%
<b>Refused Tx</b>			
Correctional facility resident at diagnosis	<.001	6.05 (2.187-16.768)	505%
Homelessness in the past year	0.004	3.44 (1.495-7.955)	244%
Illicit drug use within the past year	0.018	3.18(1.218-8.312)	218%

The sensitivity analysis (Table 16) demonstrated that the primary associations are robust to state adjustment, meaning they were not driven by unmeasured state-level confounding. However, because California accounted for the majority of cases, the findings are most directly applicable to California. While Maryland and Ohio contributed

information to the pooled analysis, their smaller sample sizes limited state-specific inference, so I do not claim full generalizability to those states.

Chapter 5 reiterates the study's nature and purpose, summarizes the findings, and provides an interpretation of the results. The chapter also highlights the study's limitations and provides recommendations.

## **Chapter 5: Discussion, Conclusions, and Recommendations**

I aimed to identify risk factors associated with unsuccessful PTB outcomes, so stakeholders can implement interventions to improve treatment success. I used a quantitative cross-sectional design. My primary focus was to determine individual associations between homelessness, LTC, correctional facility status, HIV, diabetes, excess alcohol consumption, illicit drug use, and TB treatment outcomes.

I obtained secondary data to analyze risk factors associated with death, treatment refusal, and loss to follow-up among patients who were treated for PTB. There were 11,161 participants available for analysis, of whom 7,589 met the inclusion criteria. I employed a multinomial logistic regression analysis, incorporating a chi-square test, odds ratio (Exp(B)), p-values, confidence intervals, and descriptive statistics to identify relationships, themes, and patterns between the dependent and independent variables. A cross-sectional design was employed to examine population characteristics at a single point in time. The study provided valuable information to address disparities related to predictors of unsuccessful TB treatment outcomes.

### **Interpretation of the Findings**

Increased age over 65, HIV, and homelessness were associated with death of individuals with TB (Di Gennaro et al., 2020; Di Gennaro et al., 2022; Gupta et al., 2018; Holden et al., 2020; Houck et al., 2023; Korhonen et al., 2020; Pradipta et al., 2019; Wu et al., 2022). The study was consistent with previous findings, which showed male sex was associated with increased death. Homelessness was associated with loss to follow-up. In this study, illicit drug use was associated with loss to follow-up and treatment

refusal. It is unknown whether there are correlations between treatment refusal and delayed or undocumented treatment completion.

Excess alcohol consumption and illicit drug use were linked with increased odds of TB mortality in previous studies; however, that association was not detected in this study. The study also did not show a relationship between diabetes and increased mortality. Study findings deviate from previous findings in that excess alcohol consumption and diabetes were not associated with unsuccessful treatment outcomes.

There were no recent studies that showed the relationship between LTC and TB treatment outcomes in low transmission settings; hence, this was a gap that this study filled, showing there was a 4 times higher odds of death associated with LTC status. The reason could be age as an underlying factor or synergistic interrelations with other comorbidities, because older individuals and those with comorbidities are more likely to be residents of LTCs. Age increases are associated with TB deaths (Di Gennaro et al., 2020; Holden et al., 2020; Korhonen et al., 2020; Pradipta et al., 2019).

I explored associations between incarceration/correctional facility status and TB treatment outcomes. Incarceration status was linked with poor TB treatment outcomes among individuals with drug-susceptible TB (Evenden et al., 2019; Pradipta et al., 2019). Incarceration was linked with unsuccessful treatment outcomes, including loss to follow-up (Mitruka et al., 2016; Pradipta et al., 2019).

There were 8.4 times the odds of loss to follow-up among individuals who were incarcerated during diagnosis. It is unclear from this study if participants were lost to follow-up while still incarcerated or after they were released. Future studies are needed to explore these findings further.

Findings in this study were consistent with previous studies, which showed homelessness was associated with death and loss to follow-up. This study adds to the literature that homelessness is also associated with treatment refusal. I showed there were 355% odds of loss to follow-up among PEHs, 225% odds of treatment refusal, and 76% odds of death.

HIV was associated with death among TB patients. There were 110% odds of death for TB cases with HIV. Illicit drug use was associated with the odds of loss to follow-up by 303% and treatment refusal odds by 197%. More studies are needed to fully understand the associations between illicit drug use and TB treatment outcomes. Literature showed a strong association between diabetes and death. Baltas et al. (2023) showed that diabetes was not associated with death among TB patients. The findings in this study differed from those in previous studies, as diabetes was not associated with death or other unsuccessful treatment outcomes. The findings of this study, which revealed no associations between diabetes and unsuccessful tuberculosis treatment outcomes, may warrant further investigation. Excess alcohol consumption was associated with death and treatment failure as well as presentation delay. I found that excess alcohol consumption was not associated with any unsuccessful treatments.

The interpretation of findings based on the SEM framework's theoretical model reveals that community factors, including correctional facility, homelessness, and LTC, were associated with unsuccessful TB treatment outcomes. Correctional facilities and homelessness were strongly linked to increased odds of loss to follow-up and treatment refusal, while LTC and homelessness were linked to increased odds of death. Homelessness was associated with all unsuccessful TB outcomes. At the individual level, illicit drug use and HIV were associated with unsuccessful TB treatment outcomes. Illicit drug use was associated with loss to follow-up and treatment refusal, while positive HIV status was associated with the outcome of death. Correctional facilities had the highest risks of loss to follow-up and treatment refusal, followed by homelessness. There was an 8-fold increase in the odds of loss to follow-up among people in correctional facilities compared to those not in correctional facilities. There was a 5.9 times increased odds of treatment refusal associated with people in a correctional facility at the time of diagnosis compared to those not in a correctional facility. LTC had the highest odds of death, with 4 times the odds of death for LTC residents compared to non-LTC residents at the time of diagnosis

### **Limitations of the Study**

The study is generally limited in its applicability to low-TB-transmission settings, cases that are not MDR or XDR-resistant, and individuals aged 15 years and older. Since two of the States, MD and OH, had sample sizes below the minimum required for the study, the study findings should be applied to these States with caution. Not all disease

outcomes were explored in the study. The study's generalizability is limited to the outcomes included in the analysis. Specific limitations of the study that may affect its validity or reliability include the retrospective design, which relied on secondary data that may be subject to recall bias, missing data, and data entry errors. Not all resistance cases were excluded from the study; mono and poly resistance cases were included in the study, and only MDR or XDR cases were excluded. Additionally, the type of extrapulmonary TB was not explicitly addressed, nor was the potential impact on treatment outcomes. Pradipta et al. (2019) showed that cases with pulmonary and extrapulmonary TB were associated with the outcome of death. The outcome of death for pulmonary TB versus pulmonary and extrapulmonary TB was not assessed separately in this study. Cases with pulmonary TB and extrapulmonary TB were included in the study, regardless of the site of disease or difficulty treating specific disease sites, which may impact TB treatment outcomes. Comorbidity data were not included in the analysis, which may influence treatment outcomes.

### **Recommendations**

Recommendations for political leaders include focusing policies that would prioritize treatment monitoring, follow-up, and availability of resources, including direct observed therapy for all TB patients and particularly for cases with multiple risk factors for poor treatment outcomes. Healthcare administrators and public health officials should also implement policies tailored to facilitate the more effective removal of barriers that contribute to poor TB treatment outcomes. These policies or programs may include optimizing current policies on Direct Observed Therapy (DOTS) implementation, and

assigning case workers for homeless individuals, as well as individuals who participate in illicit drug use.

Recommendations include conducting additional studies on TB data after 2021, exploring outcomes across all age groups, and analyzing all cases regardless of resistance status and extrapulmonary TB, to provide more robust data on TB treatment outcomes. State health departments and public health departments should focus on outcomes such as HIV, homelessness, age, and LTC, which are significant risk factors for mortality associated with TB. Additionally, a specific targeted focus on individuals with illicit drug use and homelessness could help reduce outcomes of loss to follow-up and treatment refusal. Interventions for these at-risk populations may include access to care, with a focus on targeted strategies to support continued treatment completion (Parriott et al., 2018).

At the community level, programs should also focus on reducing congregate risk factors such as overcrowding that could facilitate TB transmission. Assigning case workers in these settings could help with adherence to TB treatment regimens. Community factors in this study, such as homelessness, correctional facilities, and LTC, were linked to the risk of congregate settings, and recommendations for successful treatment outcomes should consider the facilities and partners to design patient-centered interventional frameworks to support treatment completion for individuals with this risk. Health departments should also determine if cases are in deprived areas with limited resources to sustain treatment completion (Nguipdop-Djomo et al., 2020). The use of existing recommendations, including the use of direct observed treatment protocols for

persons experiencing homelessness and shorter therapy, could help with the successful treatment of at-risk groups.

### **Implications**

I aimed to identify factors associated with unsuccessful TB treatment outcomes, with the goal of improving successful treatment outcomes to achieve a 95% treatment completion rate. The study identified factors at the community and individual levels associated with unsuccessful treatment outcomes. LTC, correctional facility, and homelessness were community factors associated with unsuccessful treatment outcomes, including death, loss to follow-up, and treatment refusal. A key finding of the study is that although community factors (LTC, homelessness, correctional facility) frequency of cases was low, they had the highest risk or odds for unsuccessful outcomes of loss to follow up, treatment refusal, and death. Therefore, when patients present with these risks, practitioners, policymakers, public health officials, and healthcare providers should take special precautions and preemptive measures to address TB treatment, with a focus on potential treatment failures in patients with these risk factors.

Individual factors, including illicit drug use and HIV, were associated with unsuccessful outcomes of loss to follow-up, treatment refusal, and death. The study directly contributed to identifying the risk factors for poor treatment outcomes, which can be used to provide positive social change. The study provides findings to inform conversations and strategies for improving TB treatment outcomes. Interventions that contribute to successful treatment outcomes also contribute to positive social change and improved outcomes, leading to treatment completion for affected risk groups. The

The study's implications are also relevant to TB elimination in low-transmission settings.

### **Conclusion**

Using community and variables, I was able to determine risk factors that are associated with unsuccessful treatment outcomes of death, loss to follow-up, and treatment refusal. The data show that LTC, homelessness, and HIV are associated with poor TB treatment outcomes of death. Furthermore, incarceration in a correctional facility at the time of diagnosis, illicit drug use, and homelessness status are associated with treatment refusal and loss to follow-up. Covariate analysis shows that increased age, male sex, and U.S origin of birth were associated with increased outcome of death. Older age, male sex, and Hispanic ethnicity were also associated with loss to follow-up. There were no unsuccessful treatment outcomes related to diabetes and excess alcohol consumption in this study. As the U.S. moves toward a national goal of a 95% TB treatment completion rate and TB elimination, a focus on efforts to promote successful treatment completion for the risk factors associated with poor treatment outcomes will help the U.S. achieve its TB public health goals and bring about positive social change for the population at risk.

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Patient's Name \_\_\_\_\_ State Case No. \_\_\_\_\_ **REPORT OF VERIFIED CASE OF TUBERCULOSIS**

**REPORT OF VERIFIED CASE OF TUBERCULOSIS**

<b>17. Sputum Smear</b> (select one) <input type="checkbox"/> Positive <input type="checkbox"/> Not Done <input type="checkbox"/> Negative <input type="checkbox"/> Unknown		Date Collected: Month Day Year <input type="text"/> <input type="text"/> <input type="text"/>	
<b>18. Sputum Culture</b> (select one) <input type="checkbox"/> Positive <input type="checkbox"/> Not Done <input type="checkbox"/> Negative <input type="checkbox"/> Unknown		Date Collected: Month Day Year <input type="text"/> <input type="text"/> <input type="text"/>	
		Date Result Reported: Month Day Year <input type="text"/> <input type="text"/> <input type="text"/>	
Reporting Laboratory Type (select one): <input type="checkbox"/> Public Health Laboratory <input type="checkbox"/> Commercial Laboratory <input type="checkbox"/> Other			
<b>19. Smear/Pathology/Cytology of Tissue and Other Body Fluids</b> (select one) <input type="checkbox"/> Positive <input type="checkbox"/> Not Done <input type="checkbox"/> Negative <input type="checkbox"/> Unknown		Date Collected: Month Day Year <input type="text"/> <input type="text"/> <input type="text"/>	
		Enter anatomic code (see list): <input type="text"/>	
Type of exam (select all that apply): <input type="checkbox"/> Smear <input type="checkbox"/> Pathology/Cytology			
<b>20. Culture of Tissue and Other Body Fluids</b> (select one) <input type="checkbox"/> Positive <input type="checkbox"/> Not Done <input type="checkbox"/> Negative <input type="checkbox"/> Unknown		Date Collected: Month Day Year <input type="text"/> <input type="text"/> <input type="text"/>	
		Enter anatomic code (see list): <input type="text"/>	
		Date Result Reported: Month Day Year <input type="text"/> <input type="text"/> <input type="text"/>	
Reporting Laboratory Type (select one): <input type="checkbox"/> Public Health Laboratory <input type="checkbox"/> Commercial Laboratory <input type="checkbox"/> Other			
<b>21. Nucleic Acid Amplification Test Result</b> (select one) <input type="checkbox"/> Positive <input type="checkbox"/> Not Done <input type="checkbox"/> Negative <input type="checkbox"/> Unknown <input type="checkbox"/> Indeterminate		Date Collected: Month Day Year <input type="text"/> <input type="text"/> <input type="text"/>	
		Date Result Reported: Month Day Year <input type="text"/> <input type="text"/> <input type="text"/>	
Enter specimen type: <input type="checkbox"/> Sputum OR If not Sputum, enter anatomic code (see list): <input type="text"/>		Reporting Laboratory Type (select one): <input type="checkbox"/> Public Health Laboratory <input type="checkbox"/> Commercial Laboratory <input type="checkbox"/> Other	
<b>Initial Chest Radiograph and Other Chest Imaging Study</b>			
<b>22A. Initial Chest Radiograph</b> (select one) <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal* (consistent with TB) <input type="checkbox"/> Not Done <input type="checkbox"/> Unknown		<input type="button" value="Cavity Reset"/> <input type="button" value="Military Reset"/>	
* For ABNORMAL Initial Chest Radiograph: Evidence of a cavity (select one): <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Evidence of miliary TB (select one): <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
<b>22B. Initial Chest CT Scan or Other Chest Imaging Study</b> (select one) <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal* (consistent with TB) <input type="checkbox"/> Not Done <input type="checkbox"/> Unknown		<input type="button" value="Cavity Reset"/> <input type="button" value="Military Reset"/>	
* For ABNORMAL Initial Chest Radiograph: Evidence of a cavity (select one): <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Evidence of miliary TB (select one): <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
<b>23. Tuberculin (Mantoux) Skin Test at Diagnosis</b> (select one) <input type="checkbox"/> Positive <input type="checkbox"/> Not Done <input type="checkbox"/> Negative <input type="checkbox"/> Unknown		Date Tuberculin Skin Test (TST) Placed: Month Day Year <input type="text"/> <input type="text"/> <input type="text"/>	
		Millimeters (mm) of induration: <input type="text"/>	
<b>24. Interferon Gamma Release Assay for Mycobacterium tuberculosis at Diagnosis</b> (select one) <input type="checkbox"/> Positive <input type="checkbox"/> Not Done <input type="checkbox"/> Negative <input type="checkbox"/> Unknown <input type="checkbox"/> Indeterminate		Date Collected: Month Day Year <input type="text"/> <input type="text"/> <input type="text"/>	
		Test type: _____ Specify _____	
<b>25. Primary Reason Evaluated for TB Disease</b> (select one) <input type="checkbox"/> TB Symptoms <input type="checkbox"/> Abnormal Chest Radiograph (consistent with TB) <input type="checkbox"/> Contact Investigation <input type="checkbox"/> Targeted Testing <input type="checkbox"/> Health Care Worker <input type="checkbox"/> Employment/Administrative Testing <input type="checkbox"/> Immigration Medical Exam <input type="checkbox"/> Incidental Lab Result <input type="checkbox"/> Unknown			

Patient's Name \_\_\_\_\_ (Last) \_\_\_\_\_ (First) \_\_\_\_\_ (M.I.) State Case No. \_\_\_\_\_

**REPORT OF VERIFIED CASE OF TUBERCULOSIS**

**REPORT OF VERIFIED CASE OF TUBERCULOSIS**

<p><b>17. Sputum Smear</b> (select one)</p> <p><input type="checkbox"/> Positive <input type="checkbox"/> Not Done  <input type="checkbox"/> Negative <input type="checkbox"/> Unknown</p>	<p>Date Collected:</p> <p>Month Day Year  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p>	
<p><b>18. Sputum Culture</b> (select one)</p> <p><input type="checkbox"/> Positive <input type="checkbox"/> Not Done  <input type="checkbox"/> Negative <input type="checkbox"/> Unknown</p>	<p>Date Collected:</p> <p>Month Day Year  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p>	<p>Date Result Reported:</p> <p>Month Day Year  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Reporting Laboratory Type (select one): <input type="checkbox"/> Public Health Laboratory <input type="checkbox"/> Commercial Laboratory <input type="checkbox"/> Other</p>
<p><b>19. Smear/Pathology/Cytology of Tissue and Other Body Fluids</b> (select one)</p> <p><input type="checkbox"/> Positive <input type="checkbox"/> Not Done  <input type="checkbox"/> Negative <input type="checkbox"/> Unknown</p>	<p>Date Collected:</p> <p>Month Day Year  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p>	<p>Enter anatomic code (see list): <input type="text"/> <input type="text"/></p> <p>Type of exam (select all that apply):  <input type="checkbox"/> Smear <input type="checkbox"/> Pathology/Cytology</p>
<p><b>20. Culture of Tissue and Other Body Fluids</b> (select one)</p> <p><input type="checkbox"/> Positive <input type="checkbox"/> Not Done  <input type="checkbox"/> Negative <input type="checkbox"/> Unknown</p>	<p>Date Collected:</p> <p>Month Day Year  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p>	<p>Enter anatomic code (see list): <input type="text"/> <input type="text"/></p> <p>Date Result Reported:</p> <p>Month Day Year  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Reporting Laboratory Type (select one): <input type="checkbox"/> Public Health Laboratory <input type="checkbox"/> Commercial Laboratory <input type="checkbox"/> Other</p>
<p><b>21. Nucleic Acid Amplification Test Result</b> (select one)</p> <p><input type="checkbox"/> Positive <input type="checkbox"/> Not Done  <input type="checkbox"/> Negative <input type="checkbox"/> Unknown  <input type="checkbox"/> Indeterminate</p>	<p>Date Collected:</p> <p>Month Day Year  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p>	<p>Date Result Reported:</p> <p>Month Day Year  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Reporting Laboratory Type (select one): <input type="checkbox"/> Public Health Laboratory <input type="checkbox"/> Commercial Laboratory <input type="checkbox"/> Other</p> <p>Enter specimen type: <input type="checkbox"/> Sputum  OR  If not Sputum, enter anatomic code (see list): <input type="text"/> <input type="text"/></p>
<b>Initial Chest Radiograph and Other Chest Imaging Study</b>		
<p><b>22A. Initial Chest Radiograph</b> (select one)</p> <p><input type="checkbox"/> Normal <input type="checkbox"/> Abnormal* (consistent with TB) <input type="checkbox"/> Not Done <input type="checkbox"/> Unknown</p> <p>* For ABNORMAL Initial Chest Radiograph: Evidence of a cavity (select one): <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown  Evidence of miliary TB (select one): <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown</p>	<p><b>Cavity Reset</b> <b>Miliary Reset</b></p>	
<p><b>22B. Initial Chest CT Scan or Other Chest Imaging Study</b> (select one)</p> <p><input type="checkbox"/> Normal <input type="checkbox"/> Abnormal* (consistent with TB) <input type="checkbox"/> Not Done <input type="checkbox"/> Unknown</p> <p>* For ABNORMAL Initial Chest Radiograph: Evidence of a cavity (select one): <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown  Evidence of miliary TB (select one): <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown</p>	<p><b>Cavity Reset</b> <b>Miliary Reset</b></p>	
<p><b>23. Tuberculin (Mantoux) Skin Test at Diagnosis</b> (select one)</p> <p><input type="checkbox"/> Positive <input type="checkbox"/> Not Done  <input type="checkbox"/> Negative <input type="checkbox"/> Unknown</p>	<p>Date Tuberculin Skin Test (TST) Placed:</p> <p>Month Day Year  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p>	<p>Millimeters (mm) of induration: <input type="text"/> <input type="text"/></p>
<p><b>24. Interferon Gamma Release Assay for Mycobacterium tuberculosis at Diagnosis</b> (select one)</p> <p><input type="checkbox"/> Positive <input type="checkbox"/> Not Done  <input type="checkbox"/> Negative <input type="checkbox"/> Unknown  <input type="checkbox"/> Indeterminate</p>	<p>Date Collected:</p> <p>Month Day Year  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Test type: _____  Specify: _____</p>	
<p><b>25. Primary Reason Evaluated for TB Disease</b> (select one)</p> <p><input type="checkbox"/> TB Symptoms  <input type="checkbox"/> Abnormal Chest Radiograph (consistent with TB)  <input type="checkbox"/> Contact Investigation  <input type="checkbox"/> Targeted Testing  <input type="checkbox"/> Health Care Worker  <input type="checkbox"/> Employment/Administrative Testing  <input type="checkbox"/> Immigration Medical Exam  <input type="checkbox"/> Incidental Lab Result  <input type="checkbox"/> Unknown</p>		

Patient's Name \_\_\_\_\_ State Case No. \_\_\_\_\_ **REPORT OF VERIFIED CASE OF TUBERCULOSIS**

**REPORT OF VERIFIED CASE OF TUBERCULOSIS**

**26. HIV Status at Time of Diagnosis** (select one)  
 Negative  Indeterminate  Not Offered  Unknown  
 Positive  Refused  Test Done, Results Unknown

If POSITIVE, enter:  
 State HIV/AIDS Patient Number: \_\_\_\_\_ City/County HIV/AIDS Patient Number: \_\_\_\_\_

**27. Homeless Within Past Year** (select one)  
 No  Yes  Unknown

**28. Resident of Correctional Facility at Time of Diagnosis** (select one)  No  Yes  Unknown  
 If YES, (select one)  
 Federal Prison  Local Jail  Other Correctional Facility  
 State Prison  Juvenile Correction Facility  Unknown  
 If YES, under custody of Immigration and Customs Enforcement? (select one)  
 No  Yes

**29. Resident of Long-Term Care Facility at Time of Diagnosis** (select one)  No  Yes  Unknown  
 If YES, (select one)  
 Nursing Home  Residential Facility  Alcohol or Drug Treatment Facility  Unknown  
 Hospital-Based Facility  Mental Health Residential Facility  Other Long-Term Care Facility

**30. Primary Occupation Within the Past Year** (select one)  
 Health Care Worker  Migrant/Seasonal Worker  Retired  Not Seeking Employment (e.g. student, homemaker, disabled person)  
 Correctional Facility Employee  Other Occupation  Unemployed  Unknown

**31. Injecting Drug Use Within Past Year** (select one)  No  Yes  Unknown

**32. Non-Injecting Drug Use Within Past Year** (select one)  No  Yes  Unknown

**33. Excess Alcohol Use Within Past Year** (select one)  No  Yes  Unknown

**34. Additional TB Risk Factors** (select all that apply)  
 Contact of MDR-TB Patient (2 years or less)  Incomplete LTBI Therapy  Diabetes Mellitus  Other Specify \_\_\_\_\_  
 Contact of Infectious TB Patient (2 years or less)  TNF- $\alpha$  Antagonist Therapy  End-Stage Renal Disease  None  
 Missed Contact (2 years or less)  Post-organ Transplantation  Immunosuppression (not HIV/AIDS)

**35. Immigration Status at First Entry to the U.S.** (select one)  
 Not Applicable  
 • "U.S.-born" (or born abroad to a parent who was a U.S. citizen)  
 • Born in 1 of the U.S. Territories, U.S. Island Areas, or U.S. Outlying Areas  
 Immigrant Visa  Tourist Visa  Asylee or Parolee  
 Student Visa  Family/Fiancé Visa  Other Immigration Status  
 Employment Visa  Refugee  Unknown

**35CA. If arrived in the US within the last 12 months, did patient arrive with a TB A/B-notification?** (select one)  No  Yes  Unknown  
 If Yes, enter Alien Number: \_\_\_\_\_

**36. Date Therapy Started**  
 Month \_\_\_\_\_ Day \_\_\_\_\_ Year \_\_\_\_\_

**37. Initial Drug Regimen** (select one option for each drug)

	No	Yes	Unk	No	Yes	Unk	No	Yes	Unk
Isoniazid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ethionamide	<input type="checkbox"/>	<input type="checkbox"/>	Moxifloxacin	<input type="checkbox"/>	<input type="checkbox"/>
Rifampin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Amikacin	<input type="checkbox"/>	<input type="checkbox"/>	Cycloserine	<input type="checkbox"/>	<input type="checkbox"/>
Pyrazinamide	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Kanamycin	<input type="checkbox"/>	<input type="checkbox"/>	Para-Amino Salicylic Acid	<input type="checkbox"/>	<input type="checkbox"/>
Ethambutol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Capreomycin	<input type="checkbox"/>	<input type="checkbox"/>	Other	<input type="checkbox"/>	<input type="checkbox"/>
Streptomycin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ciprofloxacin	<input type="checkbox"/>	<input type="checkbox"/>	Specify _____		
Rifabutin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Levofloxacin	<input type="checkbox"/>	<input type="checkbox"/>	Other	<input type="checkbox"/>	<input type="checkbox"/>
Rifapentine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ofloxacin	<input type="checkbox"/>	<input type="checkbox"/>	Specify _____		

**Comments:**  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Patient's Name \_\_\_\_\_ State Case No. \_\_\_\_\_ **REPORT OF VERIFIED CASE OF TUBERCULOSIS**

**REPORT OF VERIFIED CASE OF TUBERCULOSIS**

**26. HIV Status at Time of Diagnosis** (select one)  
 Negative  Indeterminate  Not Offered  Unknown  
 Positive  Refused  Test Done, Results Unknown

If POSITIVE, enter:  
 State HIV/AIDS Patient Number: \_\_\_\_\_ City/County HIV/AIDS Patient Number: \_\_\_\_\_

**27. Homeless Within Past Year** (select one)  
 No  Yes  Unknown

**28. Resident of Correctional Facility at Time of Diagnosis** (select one)  No  Yes  Unknown  
 If YES, (select one)  
 Federal Prison  Local Jail  Other Correctional Facility  
 State Prison  Juvenile Correction Facility  Unknown  
 If YES, under custody of Immigration and Customs Enforcement? (select one)  
 No  Yes

**29. Resident of Long-Term Care Facility at Time of Diagnosis** (select one)  No  Yes  Unknown  
 If YES, (select one)  
 Nursing Home  Residential Facility  Alcohol or Drug Treatment Facility  Unknown  
 Hospital-Based Facility  Mental Health Residential Facility  Other Long-Term Care Facility

**30. Primary Occupation Within the Past Year** (select one)  
 Health Care Worker  Migrant/Seasonal Worker  Retired  Not Seeking Employment (e.g. student, homemaker, disabled person)  
 Correctional Facility Employee  Other Occupation  Unemployed  Unknown

**31. Injecting Drug Use Within Past Year** (select one)  No  Yes  Unknown

**32. Non-Injecting Drug Use Within Past Year** (select one)  No  Yes  Unknown

**33. Excess Alcohol Use Within Past Year** (select one)  No  Yes  Unknown

**34. Additional TB Risk Factors** (select all that apply)  
 Contact of MDR-TB Patient (2 years or less)  Incomplete LTBI Therapy  Diabetes Mellitus  Other Specify \_\_\_\_\_  
 Contact of Infectious TB Patient (2 years or less)  TNF- $\alpha$  Antagonist Therapy  End-Stage Renal Disease  None  
 Missed Contact (2 years or less)  Post-organ Transplantation  Immunosuppression (not HIV/AIDS)

**35. Immigration Status at First Entry to the U.S.** (select one)  
 Not Applicable  
 • "U.S.-born" (or born abroad to a parent who was a U.S. citizen)  
 • Born in 1 of the U.S. Territories, U.S. Island Areas, or U.S. Outlying Areas  
 Immigrant Visa  Tourist Visa  Asylee or Parolee  
 Student Visa  Family/Fiancé Visa  Other Immigration Status  
 Employment Visa  Refugee  Unknown

**35CA.** If arrived in the US within the last 12 months, did patient arrive with a TB A/B-notification? (select one)  No  Yes  Unknown  
 If Yes, enter Alien Number: \_\_\_\_\_

**36. Date Therapy Started**  
 Month \_\_\_\_\_ Day \_\_\_\_\_ Year \_\_\_\_\_

**37. Initial Drug Regimen** (select one option for each drug)

	No	Yes	Unk	No	Yes	Unk	No	Yes	Unk
Isoniazid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ethionamide	<input type="checkbox"/>	<input type="checkbox"/>	Moxifloxacin	<input type="checkbox"/>	<input type="checkbox"/>
Rifampin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Amikacin	<input type="checkbox"/>	<input type="checkbox"/>	Cycloserine	<input type="checkbox"/>	<input type="checkbox"/>
Pyrazinamide	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Kanamycin	<input type="checkbox"/>	<input type="checkbox"/>	Para-Amino Salicylic Acid	<input type="checkbox"/>	<input type="checkbox"/>
Ethambutol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Capreomycin	<input type="checkbox"/>	<input type="checkbox"/>	Other	<input type="checkbox"/>	<input type="checkbox"/>
Streptomycin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ciprofloxacin	<input type="checkbox"/>	<input type="checkbox"/>	Specify _____		
Rifabutin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Levofloxacin	<input type="checkbox"/>	<input type="checkbox"/>	Other	<input type="checkbox"/>	<input type="checkbox"/>
Rifapentine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ofloxacin	<input type="checkbox"/>	<input type="checkbox"/>	Specify _____		

**Comments:**  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

## Appendix B: California IRB Approval



Darci Delgado, PsyD.  
Interim Chair

State of California—Health and Human Services Agency  
Committee for the Protection of Human Subjects



GAVIN NEWSOM  
Governor

10/30/2024

Nancy Rea, PhD  
Walden University

**Project Title:** Societal, Community and Individual Risk Factors Associated with Tuberculosis Treatment Outcomes in the United States [2017-2021].  
**Project Number:** 2024-173

Dear Dr. Rea:

The Committee for the Protection of Human Subjects (CPHS) has determined that your proposed project is Exempt under the federal Common Rule. This decision does not imply any approval of the proposed activities by CPHS. Protocols determined to be Exempt are not subject to CPHS oversight or continuing review. This decision is issued under the California Health and Human Services Agency's Federalwide Assurance #00000681 with the Office of Human Research Protections (OHRP).

If you later wish to make any changes in your protocol such that the project may no longer meet the federal requirements to be considered Exempt, you must submit a new application to CPHS, as your current protocol is no longer active in our records. Please contact our office if you need assistance determining which application you should submit.

If you have any questions, you may call our office at (916) 651-5599 or email us at [CPHS@chhs.ca.gov](mailto:CPHS@chhs.ca.gov)

Sincerely,

A handwritten signature in black ink, appearing to read 'Agnieszka Rykaczewska'.

Agnieszka Rykaczewska  
Committee for the Protection of Human Subjects Administrator

## Appendix C: Maryland IRB Approval



Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

October 24, 2024

Nancy K. Rea, PhD, MHSA, CPH  
Walden University  
100 Washington Ave South, Suite 1210  
Minneapolis, MN 55401

REF: Protocol #24-48

Dear Dr. Rea:

Your proposal entitled, "Societal, community and individual risk factors associated with TB treatment outcomes in the United States [2017-2021]" was received by the Institutional Review Board (IRB) and processed by expedited review. It has been determined that your proposal qualifies as exempt research in accordance with 45 CFR 46.104(d)(4). No further IRB review is required unless you modify your proposal.

Thank you for your responsiveness to the IRB process and continued success in future endeavors. If you have any questions, please feel free to contact Gay Hutchen, IRB Administrator at 410-767-8448.

Sincerely,

A handwritten signature in black ink, appearing to read "Deanna L. Kelly", is written over a light blue horizontal line.

Deanna L. Kelly, PharmD, BCPP  
Chairperson  
Institutional Review Board

cc: Gay Hutchen  
PHPA

## Appendix D: Ohio IRB Approval

Protocol Number 2024-30  
Original Review 9/24/2024  
Continuing Review

**THE OHIO DEPARTMENT OF HEALTH  
HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD**  
*(FWA00001963, IRB00002180)*

**ACTION OF THE REVIEW BOARD  
(CERTIFICATION)**

With regard to the employment of human subjects in the proposed research entitled:

**ODH IRB 2024-30:** "Societal, Community, and Individual Risk Factors Associated with Tuberculosis Treatment Outcomes in the United States (2017-2021)"

CDC of HHS Federal Project Number (if any):  
Principal Investigator: Nancy Rea, PhD, MHSA, CPH  
Agency: Walden University

The Institutional Review Board has taken the following action:

Approved     Expedited Review     Waiver of Written Consent  
 Disapproved     Full Board Review     Exempt  
 Tabled

Requirements:

Any publication resulting from the approval of this protocol must state the following "This study includes data provide by the Ohio Department of Health which should not be considered an endorsement of this study or its conclusions."

**This application has been approved for the period of one (1) year and will expire on September 24, 2025.** Renewals are the sole responsibility of the principal investigator. No reminders will be sent.

Additionally, it is the responsibility of the principal investigator to:

- 1) obtain approval before making procedural changes;
- 2) maintain the confidentiality of the research participants' identities; and
- 3) retain a copy of each signed consent form for at least three (3) years beyond the termination of the subject's participation in the proposed activity.

Date: September 25, 2024

Signed: \_\_\_\_\_



CC: Investigator, Division Chief/Bureau Chief

## Appendix E: Walden University IRB Approval



Dear Kadiatu Banjoko,

This email is to notify you that the Institutional Review Board (IRB) confirms that your doctoral capstone entitled, "Societal, community and individual risk factors associated with TB treatment outcomes in the United States 2017-2021," meets Walden University's ethical standards. Since this project will serve as a Walden doctoral capstone, the Walden IRB will oversee your capstone data analysis and results reporting. Your IRB approval number is 06-28-24-0744801, which expires when your student status ends.

This confirmation is contingent upon your adherence to the exact procedures described in the final version of the documents that have been submitted to [IRB@mail.waldenu.edu](mailto:IRB@mail.waldenu.edu) as of this date. This includes maintaining your current status with the university, and the oversight relationship is valid only while you are an actively enrolled student at Walden University. If you need to take a leave of absence or are otherwise unable to remain actively enrolled, this is suspended.

If you need to make any changes to the project staff or procedures, you must obtain IRB approval by submitting the IRB Request for Change in Procedures Form. You will receive confirmation with a status update of the request within 10 business days of submitting the change request form and are not permitted to implement changes prior to receiving approval. Please note that Walden University does not accept responsibility or liability for research activities conducted without the IRB's approval, and the University will not accept or grant credit for student work that fails to comply with the policies and procedures related to ethical standards in research.

When you submitted your IRB materials, you made a commitment to communicate both discrete adverse events and general problems to the IRB within 1 week of their occurrence/realization. Failure to do so may result in invalidation of data, loss of academic credit, and/or loss of legal protections otherwise available to the researcher.

Both the Adverse Event Reporting form and Request for Change in Procedures form can be obtained on the Tools and Guides page of the Walden website: <https://academicguides.waldenu.edu/research-center/research-ethics/tools-guides>

Doctoral researchers are required to fulfill all of the Student Handbook's Doctoral Student Responsibilities Regarding Research Data regarding raw data retention and

dataset confidentiality, as well as logging of all recruitment, data collection, and data management steps. If, in the future, you require copies of the originally submitted IRB materials, you may request them from Institutional Review Board.

Both students and faculty are invited to provide feedback on this IRB experience at the link below:

<https://www.surveymonkey.com/r/B6FDTJT>

Sincerely,

Libby Munson

Research Ethics Support Specialist

Research Ethics, Compliance, and Partnerships

Walden University

100 Washington Avenue South, Suite 1210

Minneapolis, MN 55401

Email: [irb@mail.waldenu.edu](mailto:irb@mail.waldenu.edu)

Phone: (612) 312-1283

Fax: (612) 338-5092

Information about the Walden University Institutional Review Board, including instructions for application, may be found at this

link: <http://academicguides.waldenu.edu/researchcenter/orec>

Appendix F: Data Dictionary to Request Data from CA, MD, and OH

Variable	Variable description	Why Variable is needed	How variable would be utilized	Output
Age	Patient age at time of diagnosis.	Individuals 15 years and older are included in the study. The variable may be used to evaluate epidemiologic trends associated with age.	Covariate	Age in Years
Sex	Patient sex at birth.	The variable is needed as a control variable and the variable may be used to evaluate epidemiologic trends associated with sex.	Covariate	Male Female
Race	Patient identified or reported race.	The variable is needed as a control variable. The variable may be used to evaluate epidemiologic trends associated with race.	Covariate	Race American Indian or Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander (NHOPI) White Other Race Unknown
Ethnicity	Self reported or identifying ethnicity of the case.	The variable is needed as a control variable. The variable may be used to evaluate epidemiologic trends associated with ethnicity.	Covariate	Hispanic or Latino Not Hispanic or Latino Unknown
U.S Born	To describe the patients US born status.	The variable is needed as a control variable since non US born have more reported TB than US born individuals. May be used for evaluation of epidemiologic trends.	Covariate	Yes No Unknown
Site of TB disease (DIS_SITE)	The primary site of TB disease.	To determine pulmonary vs other sites of disease the study is limited to pulmonary cases of TB	To meet the inclusion criteria	BOTH EXTRAPULM ONLY PULM ONLY UNK

Case classification	A case that meets the clinical case definition or is laboratory confirmed	To determine laboratory vs clinical cases since only laboratory confirmed cases of TB are included in the study.	To meet the inclusion criteria	Clinical confirmed Laboratory confirmed
Status at Diagnosis	Patient was alive at time laboratory results confirming a TB diagnosis were known to the provider, or TB medications were started	To determine cases were alive at time of diagnosis	To meet the inclusion criteria	Alive Dead
Provider Type (PROVTYPE)	Calculated variable for type of health care provider.	To measure access to care	Independent Variable	Both Health Dept Private Provider Unknown/ Oth
Date of illness onset/Symptom start date	Date signs and symptoms started for this TB episode.	To calculate delayed treatment / access to care	measure access to care. The calculated date between symptom start date and treatment stratment start date would be used to calculate delayed treatment.	MM/DD/YY
Treatment start date / Therapy start date	Date the patient began multidrug therapy for confirmed or possible TB disease	To calculate delayed treatment / access to care	Will be utilized as a proxy to measure access to care.	MM/DD/YY
Date therapy stopped	Date the patient began multidrug therapy for confirmed TB disease	To calculate duration of treatment	to evaluate the dependent variable	MM/DD/YY
Long Term Care (LTC)	Patient was a resident of long-term care facility when TB diagnostic evaluation was performed or initiated.	To determine cases who were in LTC	Independent Variable	Yes No Unknown

Correctional Facility	Patient has ever been incarcerated or detained in a jail, prison, or other detention center at time of diagnosis	To determine cases who were in a correctional facility	Independent Variable	federal prison state prison juvenile correctional facility other unknown
Homelessness	Patient has experienced homelessness in the 12 months leading up to TB diagnosis.	To determine cases who experienced homelessness	Independent Variable	Yes No Unknown
Diabetes	Patient had diabetes when TB diagnostic evaluation was performed or initiated.	To determine cases that were diabetic	Independent Variable	Yes No Unknown (UNK)
HIV	Serologic test for human immunodeficiency virus infection	To determine cases that had HIV	Independent Variable	Yes No Unknown
Excess Alcohol	Patient heavily used alcohol in the past 12 months.	To determine case with excess alcohol use	Independent Variable	Yes No Unknown
NonIDU?	Patient used noninjection drugs in the past 12 months not prescribed by a health care provider or approved by FDA for over-the-counter dispensing.	To measure illicit drug use	independent variable	Yes No Unknown

IDU	Patient used injection drugs in the past 12 months not prescribed by a health care provider.	To measure illicit drug use	Independent Variable	Yes No Unknown
Treatment Stop Reason (STOP RES)	To document treatment outcome	To determine the outcome variable if cases completed treatment, died,	Dependent Variable	Adverse Completed Died Lost Moved Other Refused Unknown
Susceptibility Testing	The recorded susceptibility or resistance mechanism of the TB strain	To determine that cases do not have resistance strains of TB as only sensitive cases are included in the study	To meet the inclusion criteria	Resistant Susceptible Unknown
History of Previous Illness	To document history of previous TB disease or LTBI	To ensure cases are only counted once in the dataset within a 12 month period	To meet inclusion criteria	Yes MM/DD/YY No Unknown
First line TB therapy	To document type of treatment included RIPE	To ensure that cases treated with first line TB therapy are included in the study and to excluded resistant cases	To meet the inclusion criteria	Yes No Unknown
Second line TB therapy	To document type of treatment included second line TB regimen	To ensure patients treated with second line therapy are excluded from the study	To meet the inclusion criteria	Yes No Unknown