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RELATIONSHIPS BETWEEN SOCIAL DETERMINANTS OF HEALTH AND PATIENT READMISSIONS TO AN ACUTE-CARE HOSPITAL WITHIN 30 DAYS OF DISCHARGE

By

Wren Mosee Lester

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Submitted in partial fulfillment of the
Requirement for the degree of Doctor of Philosophy in Health Sciences
Seton Hall University
2019

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SETON HALL UNIVERSITY
SCHOOL OF HEALTH AND MEDICAL SCIENCES
Department of Interprofessional Health Sciences and Health Administration

APPROVAL FOR SUCCESSFUL DEFENSE
and
COMPLETION OF DISSERTATION MANUSCRIPT

Wren Mosee Lester has successfully defended and completed the text of the doctoral dissertation for the PhD in Health Sciences degree, during this Fall Semester 2019.

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Dedication

Dedicated in loving memory to my nephew

Jeremy Thomas Cross
September 6, 1996 – August 20, 2019

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ABSTRACT

RELATIONSHIPS BETWEEN SOCIAL DETERMINANTS OF HEALTH AND PATIENT READMISSIONS TO AN ACUTE-CARE HOSPITAL WITHIN 30 DAYS OF DISCHARGE

Background: The Hospital Readmission Reduction Program (HRRP) is a part of the Affordable Care Act (ACA), which addresses the cost and quality of health care. The HRRP and policy penalizes hospitals for excessive readmission rates. The overall purpose of the program is to improve the quality of care, reduce costs and improve operational efficiency in hospitals. (Zhang, 2014).

Purpose: The purpose of this study was to identify and examine what social determinants of health, at an *individual level* and *community level*, were associated with the likelihood of being readmitted into the hospital, within 30 days of discharge, for patients at a hospital in Hudson County, NJ.

Methods: A non-experimental design, with secondary data and observational analysis was used to conduct this study with de-identified patient level details (Cohen, 2000).

Description of the Data: There were over 77,000 patients in the database created from the Electronic Medical Records (EMR) of all patients discharged between 2009-2016, from one acute care hospital.

Results: The main statistical test used for the analysis was Two-Level Binary Logistic Regression. Preceding Chi-Square analyses were performed on the categorical social factors as well. Nine of the eleven social factors produced significant p values <.05. The Null Hypothesis was rejected for: Individual Factors: Race/Ethnicity, Insurance, Age, Gender, Smoking History, Language, and Community Factors: Income, Education and Food assistance.

Conclusions: The results of this study show a patient's 30-day readmission is influenced by the individual factors and community factors.

Key Words: Social Determinants of Health, 30-Day Readmission, Two-Level Binary Logistic Regression Analysis

INTRODUCTION

Background

The Patient Protection and Affordable Care Act (PPACA) of 2010 established Hospital Pay for Performance Programs, which include Title III – Improving the Quality and Efficiency of Health Care (Zhang, et al. 2014). This subsection discusses linking payment incentives to quality outcomes. The aim of these quality incentive programs is to improve health care outcomes and to reduce costs. One key component, not considered when designing the pay for performance program, was the impact that social determinants and social economic status may have on the health outcomes of the patient population. For example, Bharmal's et al. (2015) paper discussed several theoretical approaches to the SDOH. The Theory of Fundamental Causes (Link & Phelan, 1995) explains why the relationship between socioeconomic status (SES) and mortality has continued, despite the major refinements in health care delivery and innovation in treatment. Nonetheless, the program was launched, and hospitals have been the initial focus of these incentive programs. This is because that is where the largest percentage of Medicare spending occurs per patient (Zhang, 2014). Specifically, the Hospital Readmission Reduction Program (HRRP) became effective for discharges beginning on October 1, 2012. It penalizes hospitals, when patient's readmission rates are higher than the national threshold (American Hospital Association [AHA], 2015). The exorbitant spending related to high unnecessary re-hospitalization kept the focus on reducing costs and away from the social impact (Bharmal's et al., 2015).

The HRRP is one of the major components influencing a large percentage of spending of the value-based measures described in the PPACA. The HRRP is in response to health care costs that are spiraling out of control. Fuchs (2013) identified a relationship between health care spending and the Gross Domestic Product (GDP). As health care spending increases, so does the

GDP. Between 1950-1995, health care spending per capita grew at a rate of 4.7% per year, while the GDP increased at a rate of 2.1% (Fuchs, 2013). According to Fuchs (2013), if health care spending continues on the same trajectory through 2040, health care could comprise 30% of the GDP, presenting a significant concern for the federal budget and the U.S. economy (Centers for Medicare & Medicaid Services (2017).

As a result of extreme health-related costs, the Center for Medicare and Medicaid Services (CMS) was given the responsibility from Congress to administer the entire Hospital Value-Based Purchasing (HVBP) for hospitals nationally. HVBP became effective October 1, 2012, but it applied incentive payments beginning in Fiscal Year (FY) 2013. Incentive payments are given based on

(a) Performance level on a particular measure, and (b) improvement trend in an individual measure (U.S. Department of Health and Human Services, 2009).

The American Hospital Association (AHA) published a report in March 2015, which placed an emphasis on defining the different types of readmissions. The report attempts to discern between "avoidable" and "planned" (p. 3) readmissions, in measuring hospital performance. According to the AHA, the focus of measurement and calculation should be on the "avoidable" (p. 3) readmissions. The AHA (2015) noted that hospitals and other stakeholders have major concerns with the lack of risk adjustment for socioeconomic factors beyond the control of the hospital, when calculating each facility's readmission rate. These penalties can have lasting devastating effects on social- and community-based programs, adversely impacting a hospital's ability to sustain much-needed programs and affecting even the workforce to support these weaker communities.

Hospitals in these impoverished communities are often unfairly penalized, when they are the ones caring for the highest risk complex patients (AHA, 2015.)

The AHA has created a framework to classify four types of readmissions. (AHA, 2015).

1. A planned readmission related to the initial admission, such as a two-stage follow-up procedure that was deemed necessary to complete the surgical care process.
2. A planned readmission unrelated to the index admission, such as the removal of a tumor identified on the first admission.
3. An unplanned readmission unrelated to the first admission, such as a trauma from falling down a flight of stairs, when the index admission was for diabetes.
4. An unplanned readmission related to the index admission, such as a bowel laceration that occurred during a hysterectomy that caused the patient to have to return to the hospital for additional care.

At the start of the HRRP, the CMS included "all" types of readmission in their penalty calculation. Hospitals and caregivers expressed concerns and, subsequently, the CMS revised their methodology that now excludes the "planned" (p. 3) readmissions. The AHA argued that the CMS should remove the "unplanned unrelated" types, as well, because they do not imply anything about the delivery of care at the hospital, which is the main premise of the HRRP. Multiple researchers agreed that the CMS should include "unplanned related" (p. 3) readmissions into the calculation (AHA, 2015).

Significance

Hospital 30-Day Readmission is a critical clinical and policy issue impacting health care communities across the nation. The topic's potential influence on quality outcomes and reducing costs is so serious, that Congress felt the need to include it as one of the pay-for-performance measures (Fuchs, 2013).

The CMS estimates that hospital readmission rates account for $18 billion in spending per year for Medicare patients. A number of studies have been completed examining patient re-hospitalization, but little conclusive evidence to identify major contributing factors has been found, when focusing on the lowest-performing hospitals, such as those in Hudson County, New Jersey and the surrounding communities (AHA, 2015; Fuchs, 2013).

Statement of the Problem

New Jersey (NJ) ranked the highest in the country for hospital readmission in 2010, with a rate of 20%, with improvement to 17% in 2015, according to the Centers for Medicare and Medicaid Services website (2015). New Jersey also has the highest percentage of hospitals with penalties between October 1, 2014 and September 30, 2015. A total of 98% of New Jersey's 63 hospitals will receive a readmission penalty, both the highest in the country. Hudson County, NJ hospitals rank as the lowest performing. They were 55th out of 56 hospitals in the state. It is unclear why rates continue to be high, particularly for Hudson County hospitals. These statistics are reported in the Health Care Quality Strategies, Inc. report Medicare 30- Day All Condition Hospital Readmission Rates by State 2010-2015 (Healthcare Quality Strategies Inc., 2015).

Purpose of the Study

The purpose of this study was to identify and examine what social determinants of health, at an *individual level* and *community level*, were associated with the likelihood of being readmitted into the hospital, within 30 days of discharge for patients at a hospital in Hudson County, NJ.

For the purposes of this study, Social Determinants of Health include:

1. Race/ Ethnicity
2. Insurance Status
3. Age
4. Language
5. Gender
6. Smoking History
7. Income (Median Household)
8. Education Level
9. Unemployment
10. Neighborhood Crime Index
11. Food Assistance

Research Question

Was there a relationship between specific social determinants of health (SDOH) and the likelihood of readmission to a hospital within 30 days?

A. Individual Factors:

    1. Race/Ethnicity
    2. Insurance
    3. Age
    4. Language
    5. Gender
    6. Smoking History

B. Community Factors:

1. Education Level
2. Median Household Income
3. Unemployment Rate
4. Food Assistance
5. Neighborhood Crime Index

Theoretical Approaches

Social Ecological Theory drove the identification of the research topic, the creation of research questions, the guided the literature review, the design of the methodology, and the analysis approach for the study (Theories of Health Behavior, 2002). This study takes into consideration public health outcomes at two-levels, and emphasizes the interaction and integration of health determinants within and across levels. This approach is called the Ecological Theory. Ecological Theory stresses the importance of approaching health outcomes at more than one level. The theory focuses on the impact that the community has on the individual and the individual has on the community. Researchers must consider the interaction and integration of factors within and across levels. Ecological theory speaks about how behavior impacts and is impacted by two-levels of influence. A two-level, interactive perspective, supports the notion of developing two-level interventions when attempting to improve health outcomes and reduce readmissions.

The Bharmal et al. (2015) paper discussed several theoretical approaches to the SDOH. The Theory of Fundamental Causes (Link & Phelan, 1995) explains why the relationship between socioeconomic status (SES) and mortality has continued, despite the major refinements in health care delivery and innovation in treatment. Link and Phelan's (1995) Theory of Fundamental Causes has four major components: (a) influence of multiple disease outcomes, (b) the effects of disease outcomes through multiple risk factors, (c) access to flexible resources, and (d) relationships to fundamental causes and health outcomes persist over time, despite major changes in health care treatments, such as antibiotics, hand washing, new surgical procedures, and technology. This led Link and Phelan (1995) to designate SES as a fundamental cause of mortality. SES is related to multiple disease outcomes and processes that evolve over time. Link and Phelan's theory describes how individuals react differently, depending on available resources and social circumstances (Bharmal et al., 2015).

Conceptual Framework

This conceptual framework was created from an amalgamation of ecological theory and several frames in the literature (Figure 1.1). I used this conceptual framework as a basis to design the study, to organize, and analyze the data. It depicts an interaction between individuals and community and the impact they have on health outcomes. This framework accords with the Commission on Social Determinants of Health (CSDH) and Diderichsen's (1998) model that social factors play a role in health outcomes and must be addressed to achieve health equity. The framework depicts individual factors and community factors, all as major contributors to health outcomes. Although readmission to the hospital is not specifically listed, the same theory can be applied to the 30-day hospital readmission.

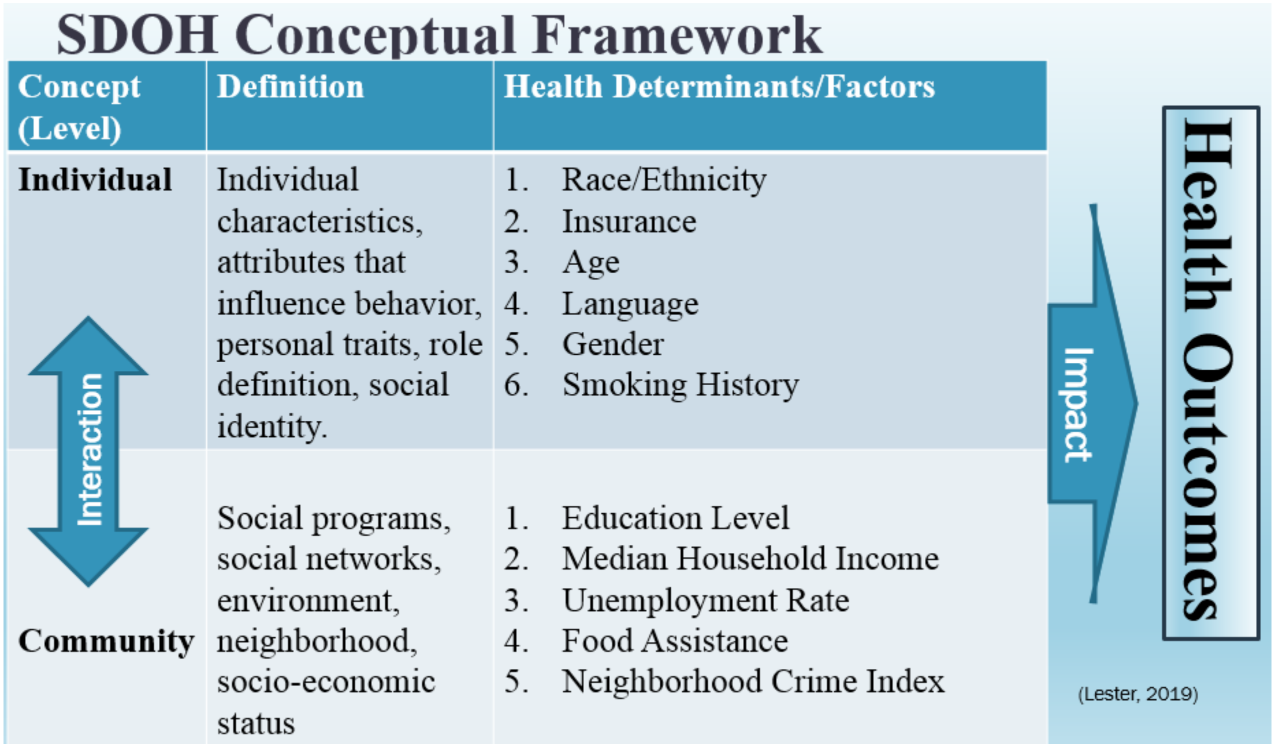

Figure 1. Social determinants of health (SDOH) Conceptual Framework (Lester, 2019).

Hypotheses:

INDIVIDUAL FACTORS

H1: There is a relationship between a patient's **RACE/Ethnicity** and being readmitted to the hospital within 30 days of discharge.

H2: There is a relationship between a patient's **INSURANCE** and being readmitted to the hospital within 30 days of discharge.

H3: There is a relationship between a patient's **AGE** and being readmitted to the hospital within 30 days of discharge.

H4: There is a relationship between a patient's **LANGUAGE** and being readmitted to the hospital within 30 days of discharge.

H5: There is a relationship between a patient's **GENDER** and being readmitted to the hospital within 30 days of discharge.

H6: There is a relationship between a patient's **SMOKING HISTORY** and being readmitted to the hospital within 30 days of discharge.

COMMUNITY FACTORS

H7: There is a relationship between a patient's community median household **INCOME** and being readmitted to the hospital within 30 days of discharge.

H8: There is a relationship between a patient's community **EDUCATION LEVEL** and being readmitted to the hospital within 30 days of discharge.

H9: There is a relationship between a patient's community **UNEMPLOYEMENT RATE** and being readmitted to the hospital within 30 days of discharge.

H10: There is a relationship between a patient's community **CRIME Index** and being readmitted to the hospital within 30 days of discharge.

H11: There is a relationship between a patient's community percent of **FOOD Assistance** and being readmitted to the hospital within 30 days of discharge.

Summary

The Hospital Readmission Reduction Program (HRRP) is a part of the Affordable Care Act (ACA), which addresses the cost and quality of health care. The HRRP and policy penalizes hospitals for excessive readmission rates. The overarching aim of the program is to improve quality of care, reduce costs and improve operational efficiency in hospitals. (Zhang, 2014). Criticism of the policy exists in the literature, stating that hospitals actually have little control over the complex factors that influence a patient's readmission, and that the readmission rate is not a good measure for health care quality services delivered in the hospital. (Zhang, 2014). On the contrary, supporters of HRRP believe that this policy forces large health care systems and hospitals to take some responsibility for post-acute care resources available to patients. It forces hospitals to consider the whole patient and to be accountable for the complete care, while not in the hospital.

The socioeconomic status (SES) of the patient keeps emerging as a factor influencing a patient's likelihood to be readmitted within 30 days of discharge. The World Health Organization (WHO) Conceptual Framework – Social Determinants of Health discusses in depth the relationships between social factors, such as income, education, occupation, social class, gender, race/ethnicity, with poor health outcomes including death (WHO, 2010). The Heiman article discusses the importance of healthy behaviors and their impact on health outcomes. Smoking history, diet and exercise are strong predictors of health outcomes, according to Heiman and in the literature.

Interestingly, U.S. health care expenditures exceed $3 trillion dollars annually, while health outcomes lag behind other developed nations (Heiman, 2015). Heiman's article states that "Social Determinants have a significant impact on health outcomes." There are specific conditions in which people are "born, live, grow, work, and age" that effect their lifestyle, health behaviors, and access to health care facilities and providers. Social factors such as socioeconomic status, physical environment, education, race and poverty, all have an influence on one's health (Galea, 2011). Many studies' results show a relationship between poor health and low income, increased exposure to violence in the neighborhood, dilapidated housing, lack of recreation centers, surplus of garbage, and available technology/resources (Marmot, 2008).

Summary of Contributions Health Policy

Health disparities between different SES and racial groups have been established through many studies. As a result, ***Healthy People 2020*** was launched by the Office of Disease Prevention and Health Promotion (ODPHP). This extensive study concludes that social factors are associated with poor health outcomes. My study will contribute to the overall literature and current research, by including 30-Day Readmission to the list of possible poor health outcomes in the emerging conceptual frameworks. The advantage of using 30 Day Readmission is that the patient is not dead yet, as is the case with using mortality rate or infant death rates to predict the overall health of a community. Looking at re-hospitalizations also engages the large health care systems and hospitals to address and be accountable for the entire care continuum for patients and not just the point of view of the patient, while in the hospital for an acute stay (Heiman & Artiga, 2015).

This study focused on an extensive review of the literature to include health care spending's impact on health care policy, specifically the ACA and to compare critics versus supporters. It included a detailed look at relationships between various social factors and health outcomes, while focusing on 30-day readmission. The paper defined 30-Day Readmission as a health care quality outcome, according to the Yale New Haven Health Services Corporation Center for Outcomes Research & Evaluation's (YNHHSC/CORE). Multiple theoretical approaches and conceptual frameworks were examined to determine the basis for the proposed hypotheses. Contributions and gaps in the literature were discussed. The second half of the study covered the methodology, research design, discussion and conclusions.

Chapter Two

Literature Review

Health Care Spending Impact on Health Care Policy

Hospital readmissions are a key driver in health care quality, cost, and policy decision-making (Joynt, 2012). Prior to 2012, the re-hospitalization rate in the U.S. was so high and costly that it was considered a crisis and it accounted for a large percentage of overall health care spending (Joynt, 2012). Many of the readmissions to acute-care settings are deemed preventable. Hospital readmission rates vary widely across different types of hospitals (Joynt, 2012). According to Joynt, hospital location and social factors could influence the likelihood of the patient to be readmitted. The literature suggests the main factors impacting the variation in 30-day readmission rates has more to do with individual patient characteristics and community attributes, than the quality of the care while in the hospital (Joynt, 2012).

The challenge is that many of these socioeconomic factors are out of reach and nearly impossible for hospitals to control, especially those hospitals with high-risk communities. Barnett, Hsu, and McWilliams (2015) used logistic regression to examine an extensive list of 29 patient characteristics to look for relationships to hospital readmission. Logistic regression was applied to the survey data from the Health and Retirement Study (HRS) and the Medicare claims of 8,067 patients between 2009 and 2012. Barnett et al. (2015) added each subsequent characteristic to test independently, if each had a relationship to 30-day readmission, after CMS risk adjustments had been accounted for. They found that 22 out of 29 characteristics were significant for predicting hospital readmission. The factors driving the hospital readmission rate may be outside of the hospital's influence. Readmission rates may have more to do with social influence and less to do with the quality of care provided by the hospital. From a policy perspective, the Barnett et al. (2015) study results cause us to question whether these social determinants should be incorporated into the calculation measure to steer readmission penalties. Barnett et al. concluded by emphasizing that hospitals at the highest risk and in the most challenging communities require the most resources, are getting hit with the largest penalties, which take away from their much-needed resources. These hospitals need financial support to address their socioeconomic issues and they do not need penalties to take resources away (Barnett et al., 2015).

Boccuti's (2017) study discusses policy implications for the HRRP. Over the past several years from 2012-2017, since the program was implemented, a variation in readmission rates has persisted. As a result, certain types of acute-care facilities remain more likely to receive financial penalties than others. Hospitals within lower socioeconomic communities and major teaching hospitals typically endure more penalties than other hospitals. In 2017, the penalty amount increased, due to CMS expanding the medical conditions for penalties from three to six conditions. The fines are also based on a curve rather than a fixed target, causing a certain percentage of facilities to always be receiving an assessment, no matter how much their mean scores improve. Policymakers need to consider socioeconomic factors, when making these calculations to be sure that much-needed resources are not being taken away from these vulnerable hospitals and communities. According to Boccuti (2017), hospital leaders and researchers should urge Congress and local policymakers to review the current methodology for HRRP and contemplate revising the calculation to include risk adjustment for the safety-net hospitals, using performance targets instead of a curve, and engaging physicians, nurses, and other health care providers in the discussion (Boccuti, 2017).

Nagasako, Reidhead, Waterman, and Dunagan (2014) found that including social factors had a profound effect on a hospital's calculated readmission rate for patients with specific diagnoses, such as pneumonia, heart failure, and acute myocardial infarction. Nagasako et al., (2014) discussed whether adding socioeconomic factors to the HRRP financial penalty calculation would "level the playing field". Hospitals with a large percentage of high-risk patients for readmission would not be evaluated using the same criteria, as those hospitals that do not. Nagasako's study aimed to determine, if social factors increase the likelihood of readmission. They identified poverty rate, educational attainment, and housing status as three main social determinants affecting health outcomes. They concluded that these socioeconomic factors have a profound effect on patients' incidence of re-hospitalization. Furthermore, Nagasako et al. identified three diagnoses: acute myocardial infarction (AMI), congestive heart failure (CHF), and pneumonia (PN), as having significant differences in readmission rates, because they relate to the social markers described.

Although a number of methods have been suggested to prevent re-hospitalization, for example, building relationships with community health centers and a continuum of care programming, many of these approaches are very costly and difficult to implement. This is especially troubling, when these same hospitals are facing readmission-related penalties that strip resources away from the very problem they are trying to solve. Nagasako et al., (2014) agreed with Boccuti (2017) that "patient factors such as race, ethnicity, education, income, and payer mix have been found to be related to readmission risk" (p. 786). Nagasako et al. also suggested that the ethnic mix and location of a hospital could influence the likelihood of re-hospitalization. These findings have caused much discussion from all parties concerned. The question arises whether the CMS HRRP policy on readmission penalties should incorporate socioeconomic factors. If they add in the socioeconomic factors, then those hospitals with a high-risk patient mix could be excluded from costly penalties. The funds could then be reallocated to support programs to help their most high-risk patients. Conversely, including socioeconomic factors from the rate calculation could mask the differences in the readmission rates and health outcomes of patients/hospitals in the disadvantaged areas. Seeing these differences in outcomes could also spark the need for funding and additional support. The pivotal question now becomes, “Can the affected hospitals and/or health care providers deliver a level of care to their patients to address issues disproportionately influenced by socioeconomic factors?” (Nagasako et al., 2014, p.787).

The TrendWatch article by AHA (2016) supports what Boccuti (2017) and Joynt (2017) said about how risk adjustment should account for socioeconomic factors that are out of the control for hospitals. Many researchers agree that hospitals are constantly engaged in activities to reduce readmission rates, such as improving discharge planning, care coordination, follow-up phone calls, communication with long-term and primary care providers, and assisting with follow-up appointments and medication-related issues. However, Nagasako et al. (2014), AHA (2016), and The World Health Organization (WHO) (n.d.) suggest that hospital care and interventions are not the only factors in predicting a patient’s likelihood for readmission.

AHA (2015) reports show Medicare beneficiaries with six or more chronic conditions have a readmission rate of 25%, compared to 9% for those with one or no chronic conditions. More complex patients are at higher risk. The policies related to measuring health outcomes need to be careful not to unfairly penalize hospitals that are caring for more complex patients, who have very few resources at the time of their admission. Risk adjustment provides a “level playing field” (p. 2) according to the AHA (2015) report, which allows comparable measurement. Risk adjustment attempts to control for factors outside the control of the hospital, to isolate “quality of care” (p. 2) for comparison between hospitals, which is the ultimate goal for the CMS: quality and cost. Prior to 2014, HRRP adjusted for clinical factors, such as, age, gender, comorbidity, and patient frailty. At that time, the CMS did not apply similar risk adjustments to account for socioeconomic factors within and between a hospital’s service communities. AHA (2015) believes this is important to consider, because socially disadvantaged patients have less access to primary care, transportation, fresh food markets, insurance coverage, and social supports, all increasing the likelihood for poor health outcomes.

Heiman and Artiga (2015) supported the idea that improvement in health equity and outcomes require a “broader view to approaches that address social, economic, and environmental factors that influence health” (para. 1). Their research shows that these factors impact health outcomes in different gradations. Figure 2 depicts the percentage of influence that each factor has on premature death. Interestingly, they find that health care has the smallest impact, at 10%, compared to social environmental factors (20%) and individual behavior (40%), which outrank genetics.

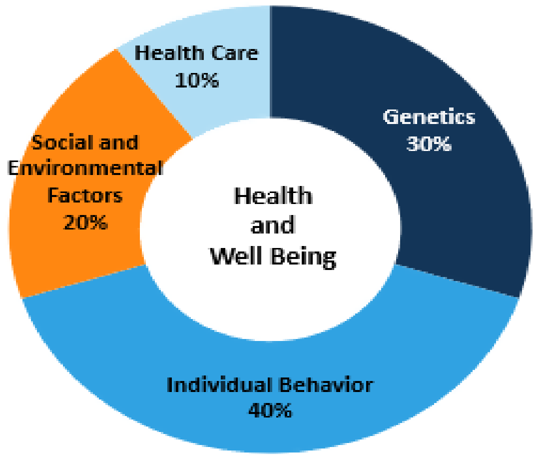

Figure 2. Impact of different factors on risk of premature death. Reprinted from *Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity* by H. J. Heiman, & S. Artiga, 2015. Copyright 2015 by Henry J. Kaiser Family Foundation.

Heiman and Artiga (2015) conducted a study at The Henry Ford Hospital in Detroit, Michigan. They found that patients living in low-income neighborhoods were 24% more likely to be re-hospitalized than those living in higher-income neighborhoods. Additional studies reported by the AHA (2015), that of 4,000 patients with certain chronic conditions, 60% of the variation in the readmission rates was attributable to community and patient social characteristics, such as marital status, employment status, and primary care providers per capita.

The CMS delayed including socioeconomic factors into its calculation for readmission, because they believed doing so would mask the disparities in the quality of care provided between different hospitals. Nagasako et al., (2014) agreed that there are pros and cons to adding the socioeconomic factors into the penalty's equation. The weakness in the methodology is hiding the visibility of the differences in health outcomes, thereby not bringing the problems to light, and conversely, the benefits are put into place to avoid unfair punishment for hospitals with the greatest need.

A heated debate among all stakeholders culminated with The National Quality Forum (NQF) establishing an expert panel called the Medicare Payment Advisory Commission (MedPAC) to review all the studies and research and come up with some recommendations for the US Senate to make a PPACA health care policy revision. Subsequently, in March 2015, a health care legislation bill was introduced to the 114th Congress by Representative James Renacci, called the Establishing Beneficiary Equity in the Hospital Readmission Program Act of 2015 (H.R.1343 114th Congress). This act was coupled with the Hospital Readmissions Program Accuracy and Accountability Act of 2014, introduced by Senator Joe Manchin, III. These two bills, the National Quality Forum's (NQF) expert panel, and MedPAC, all require HRRP's calculations, including additional socioeconomic factors, while making sure that the quality of care is still measured, and disadvantaged hospitals are not penalized unfairly.

The Medicare Payment Advisory Commission (MedPAC) (2013) recommended a solution to the debate: (a) CMS could provide peer comparisons of like hospitals rather than national comparisons, (b) CMS could continue the non-risk adjusted-rate comparisons for public reporting, so disparities could be visible and identified, (c) each hospital would have a fixed target expected readmission rate, based on the percent of patients receiving supplemental income security benefits, and (d) CMS could use the unadjusted rate for public reporting and the risk adjusted rate for applying a penalty (MedPAC, 2013).

Definition of 30-Day Readmission as a Health Care Quality Outcome

Yale New Haven Health Services Corporation Center for Outcomes Research & Evaluations (YNHHSC/CORE) (2017) was contracted by CMS to design the measurement methodology for 30-day readmission to be consistent with the existing CMS publicly reported measures for readmission (YNHHSC/CORE, 2017). Yale New Haven/CORE breaks down the 30-day readmission into three parts: (a) condition specific; (b) procedure specific; and (c) hospital-wide. This study focused on (c) hospital-wide readmission rate. The conditions are acute myocardial infarction (AMI), chronic obstructive pulmonary disease (COPD), heart failure (HF), pneumonia (PN), and stroke or cerebrovascular accident (CVA). The procedures are coronary artery bypass graft (CABG), total hip arthroplasty (THA), and total knee arthroplasty (TKA). The hospital-wide measure is called hospital-wide all-cause readmission (HWR) (YNHHSC/CORE, 2017).

YNHHSC/CORE recommends the following inclusions and exclusions for measuring a 30-day readmission. For the purposes of this research, the 30-day readmission was defined as patients who are readmitted within 30-days of their "index admission" (p. 1) and the days are only counted once within the 30-day time frame (YNHHSC/CORE, 2017). The patient must be alive upon discharge, with no transfers to another acute care hospital. Only patients who have unplanned readmissions will be counted in this study. Patients readmitted for follow-up cancer treatments will not be counted. The definition excludes all in-hospital deaths, transfers to another acute care hospital, planned follow-up for cancer treatments, planned rehabilitation, patients discharged against medical advice, and patients with missing data elements.

There is much debate in the literature, as to whether a 30-day readmission is an appropriate indicator of quality care delivery. Joynt (2012) discussed three reasons why 30-day readmission is <u>not</u> a good outcome measure for health and well-being. First, she claimed that many readmissions are *not* preventable by the hospital. She also found that much of what drives 30-day readmission is not related to hospital care but, rather, it is related to individual patient characteristics and resources in the community. She referenced a study done in Ontario hospitals, using detailed chart review that showed just 12% of readmissions were actually preventable, compared to the 59% found from large administrative data sets. Joynt (2012) stated that readmission rates have a "weak signaling value" (p. 1367) for highlighting quality of care. She found in her research that although total readmission rates vary significantly between different hospitals, truly preventable readmission rates did not (Joynt, 2012). Second, Joynt identified that hospitals with lower mortality rates have high readmission rates for CHF patients, possibly because these hospitals are providing better quality of care for these patients and prolonging their lives. The third reason she discussed is health care systems that invest resources into ambulatory and primary care, which is a sign of good quality, may be successful at keeping their healthiest patients out of the hospital, thereby driving the readmission rate up for sicker patients (Joynt, 2012).

More recently, Joynt (2017) examined whether Medicare Value Incentive Programs should take social risk into consideration. She posed three main questions: (a) "How do we monitor high quality of care across different social groups?" (b) "How does the evaluation process produce unbiased results, when evaluating each group?" and (c) "How do we ensure allocation of appropriate funds and resources for high-risk communities?" (Joynt, 2017, p. 511). To address the first question, Joynt suggested developing key quality and "resource-use" (p. 511) measures. The latter is a new concept. She also recommended developing disparity measures to include incentives for reducing them. Finally, Joynt (2017) recommended monitoring the financial implications for providers of care with the most high-risk patient populations through participation in newer programs, such as the Merit-Based Incentive Payment System (MIPS) and the Medicare Shared Saving Program (MSSP). To maintain fairness across health systems, Joynt recommended a careful review of each quality measure to determine if the "risk adjustment" (p. 511) is appropriate and meaningful. The author stated that it is not necessary to risk adjust across the board, nor is it okay to not account for any social factors. According to Joynt (2017), the adjustment should depend on the quality measure's relationship with social and behavioral factors. For example, using "compliance with annual mammogram" (p. 511) is not a metric so easily controlled by the caregiver, compared to administering aspirin to an AMI patient. In other words, a hospital could be held accountable for medication administration but not for ensuring the annual mammogram is completed. The annual mammogram compliance is driven by the patient's personal motivation, knowledge about breast health, and perhaps access to a center for women's health. Joynt (2017) emphasized that "further research should be done to ascertain which of these social determinants, along with targeted risk-adjustments, would be best to discern the 'true' difference in performance between hospitals and care providers" (Joynt, 2017, p. 511).

Definition of Social Determinants of Health (SDOH)

The World Health Organization defines SDOH as, "conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks" (WHO CSDH, (n.d.), p. 4). Adler and Prather (2015) provided another explanation for the social determinants of health. They described SDOH as patterns in health outcomes and longevity across social groups. Adler and Prather (2015) distinguished between biological/genetic determinants and social/behavioral determinants. They suggested that a better integration of the two determinants across health care delivery systems would improve the national goal of improving quality, reducing cost, and illuminating disparities in care (Adler & Prather, 2015). The authors went on to say how the U.S. spends much more on health care than other nations, yet we score poorly on key health outcomes compared to other nations. Adler and Prather (2015) pointed the blame at lack of funding and attention to the social and behavioral aspects of patient lives.

Social determinants' link to health outcomes

What role do social determinants play in population health outcomes? A 2013 report by the National Research Council and the Institute of Medicine (IOM) relates that shorter life expectancy in the US is due to social and behavioral factors, such as smoking, drug use, sexually transmitted diseases, and obesity (Woolf & Aron, 2013). The IOM supports the same theory as Adler and Prather (2015) regarding the U.S. spending more on clinical health care than other countries, with far less spent on social services. The Bradley, Elbel, Elkins & Herrin (2011) analysis of data and charts from the Organization for Economic Cooperation and Development (OECD) concluded, like IOM and the AHRQ, that the U.S. spends more on health care financing and less on public or social programs, when compared to other countries. The U.S. life expectancy at birth and greater than 65 years is ranked lower than expected, compared to other industrialized nations, and the U.S. ranks worst regarding health care spending, as depicted in Figures 3 and 4 (Bradley, Elbel, Elkins & Herrin, 2011).

Adler and Prather (2015) cited the 1993 landmark study by McGinnis and Foege that found health outcomes, including death from a particular disease, were actually influenced by social and behavioral elements such as diet, smoking, exercise, environment, toxins, and irresponsible sexual behaviors.

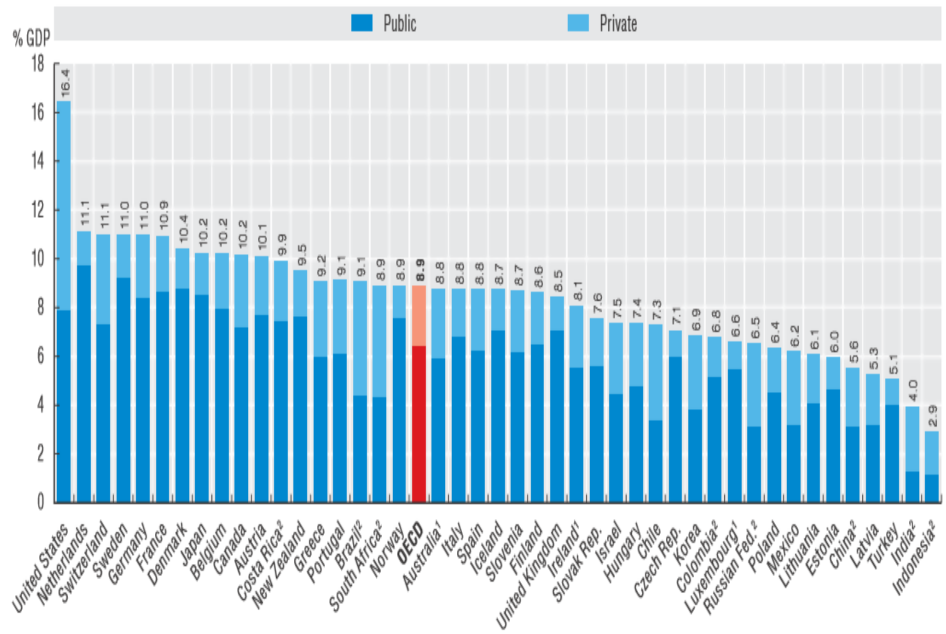

Figure 3. Health expenditure as a share of GDP, 2013 (or nearest year). Reprinted from OECD Health Statistics http://www.oecd.org/els/health-systems/health-data.htm.

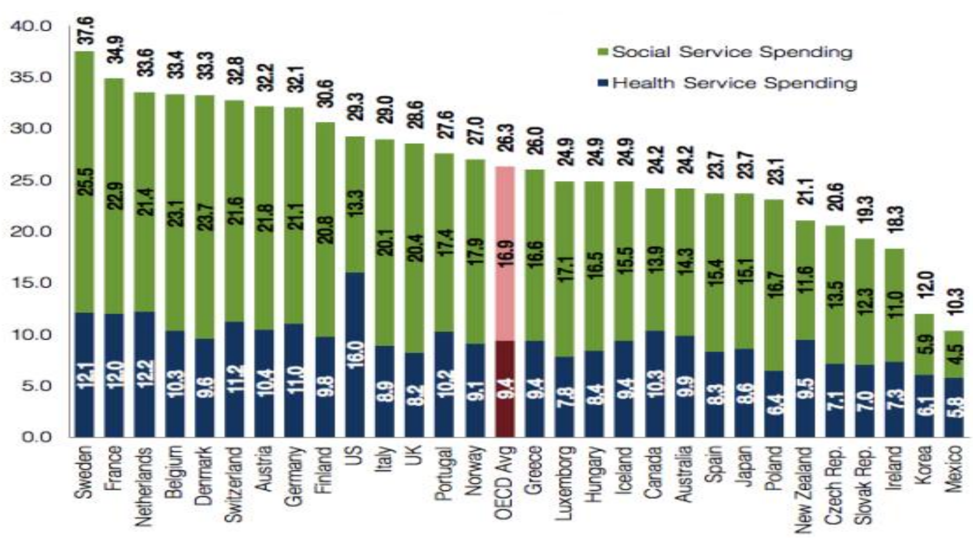

Figure 4. Total health and social services spending among OECD countries as a percentage of GDP, 2005. Reprinted from *Redrawing the Boundaries of Medicine: The Case for Social Determinants of Health* by O. K. Nguyen, 2016. Copyright 2016 by University of Texas Southwestern Medical Center.

Thus far, much of the discussion has been about what the Bharmal, Derose, Felician, and Weden (2015) study referred to as direct determinants. Another concept expressed by Bharmal et al., (2015) was that of the direct vs. upstream health care determinants. Brahmal et al. described proximal as any non-medical condition with the potential for impacting health outcomes that is in direct contact with the patient. “Upstream social determinants of health” are macro factors that comprise social-structural influences on health and health systems, like government policies, and the social, physical and economic environmental factors that determine health” (Brahmal et al., 2015, p. 1). Linkages between proximal and upstream causes are circuitous and complex, making it difficult to measure relationships or address these upstream factors in a meaningful way (Link & Phelan, 1995).

Researchers have investigated physicians’ perspectives on whether SDOH play a part in health outcomes. Nguyen (2016) discussed how physicians view the issue of SDOH and health care spending. First, she explained that, historically, and until the late 1980s, physicians had focused the practice of medicine on bio-medical knowledge and treatment of patients.

Nguygen (2016) explored the impact of what solely focusing on bio-medical/clinical aspects of the patient may have on achieving the overall goal of relieving pain, symptoms, and postponing death. She theorized that to ignore these social issues was averse to reaching these desired goals in totality. Nguyen (2016) noted that although The WHO’s definition is clear and understandable on a macro level, when thinking about countries, governments, and societies, as a whole, this definition is not useful in a practical sense for individual physicians delivering care to a patient. She referred to SDOH on a micro level, as those unmet health-related social needs that cannot be addressed in the doctor’s office setting but rather in the patient’s living environment, community, or behaviors. Nguyen categorized these unmet needs segmented by essential social need domains and expanded social need domains.

Can physicians have an impact? Nguyen (2016) emphasized the reasons why physicians should care about SDOH, when treating patients. Her research found that when physicians address both physical and social issues together, there is a synergistic effect on improving the patient's overall health. Next, Nguyen (2016) provided an analysis of the Organization for Economic Cooperation and Development data, where she demonstrated support of the AHA TrendWatch (2016) report, along with many other researchers (AHA, 2016), that the U.S. outspends all nations on health care and lags behind all nations on social service spending. The US spent $3 trillion, which equates to 16.4% of the GDP in 2013, and $9,256 per capita—almost double what some other industrialized nations are spending on healthcare. The U.S. is only one of two nations that spend more on health care than on social services.

The social services-to-health spending ratio is a strong predictor of health outcomes. According to Nguyen (2016), this holds true internationally and within the 50 U.S. states. A second study by Bradley et al., (2011) (also applying the social-to-health ratio) found links to reducing obesity, asthma, and mental/physical disability, when social spending increased by 20%. "Is a person's zip code a stronger predictor of a health than their genetic code?" (Heiman & Artiga, 2015, p. 3).

Theoretical Approaches and Conceptual Frameworks

Several theoretical approaches were reviewed to help me develop my thoughts related to the 30-day readmission problem. Each are described below. In particular, Social Ecological Theory drove the selection of the concept, the creation of the research questions, the details of the literature review, the design approach, and the data analysis plan for the study (Theories of Health Behavior, 2002). This study takes into consideration public health outcomes at two-levels, and emphasizes the interaction and integration of health determinants within and across levels. This approach is called the Ecological Theory. Ecological Theory stresses the importance of approaching health outcomes at more than one level. The theory focuses on the impact that the community has on the individual and the individual has on the community. Researchers must consider the interaction and integration of factors within and across levels. Ecological theory speaks about how behavior impacts and is impacted by two-levels of influence. A two-level, interactive perspective, supports the notion of developing two-level interventions when attempting to improve health outcomes and reduce readmissions.

The Bharmal et al., (2015) paper discussed several theoretical approaches to the SDOH. The Theory of Fundamental Causes (Link & Phelan, 1995) explains why the relationship between socioeconomic status (SES) and mortality has continued, regardless of the major refinements in health care delivery and innovation in treatment. The theory of fundamental causes has four major components: (a) influence of multiple disease outcomes, (b) the effects of disease outcomes through multiple risk factors, (c) access to flexible resources, and (d) relationships to fundamental causes and health outcomes persist over time, despite major changes in health care treatments, such as antibiotics, hand washing, new surgical procedures, and technology. This led Link and Phelan (1995) to designate SES as a fundamental cause of mortality. SES is related to multiple disease outcomes and processes that evolve over time. Link and Phelan's theory describes how individuals react differently, depending on available resources and social circumstances. For example, if one person is faced with an infectious disease like cholera, from a high SES community, they are more likely to have access to resources to avoid the infected areas, seek medical care, have knowledge about the dangers of the disease, and ultimately avoid coming into contact with another infected person. Due to the fact that other resources can be utilized in multiple ways, Link and Phelan (1995) call them flexible resources. Having the ability to use money, power, knowledge, prestige, and beneficial social relationships are at the core of the fundamental causes theory, because of peoples' ability to be flexible. This elasticity explains why SES's relationship to health outcomes persists over time. Fundamental cause theory is tied to the segmentation of social groups and their flexibility in interacting with health care resources. On an individual level, flexible resources can be conceptualized as the cause of causes or the risk of risks that shape individual health behaviors (Bharmal et al., 2015).

Link and Phelan (1995) presented empirical evidence from Fundamental Cause Theory's four components. Addressing components one and two, they shared multiple scientific studies to prove the relationship between SES and risks and protective factors for diseases and causes of death. The next key elements are high SES factors, such as how money, power, prestige, and beneficial social connections play an important role in staying healthy. It is difficult to test the relationship between SES factors, scientifically, because the researcher would have to remove the high-SES group's access to health-sustaining influences to see if their incidence of mortality or poor health would emerge. Link and Phelan (1995) considered another way to evaluate their theory, by looking at diseases that we have little to no knowledge about treatment, causes, or prevention. These diseases would not be impacted by high SES access to resources. The researcher could test to see if a condition, like autism, is evenly distributed across the population. On the other hand, highly preventable diseases, such as lung cancer, are very applicable to flexible resources and support the theory. The last component involves how new treatments, technologies, and surgical advances align with high SES groups' ability to gain new knowledge. Interestingly, in those disease categories where no new advancements have occurred, the outcomes have remained the same across the socioeconomic groups (Link & Phelan, 1995).

Theories of Power Related to SDOH and Health Outcomes

Social power plays a major role in health care population trends. SES determines the level of power for individuals and groups. An unequal distribution of resources aligns with the SES, whereby groups and individuals with at the lower end of the spectrum have less, and those at the upper end, have more access. This sliding scale is commonly referred to in the literature, as the gradation of health and health outcomes across the population (WHO, 2010).

According to Solar, Irwin, and Vega (2005), power plays a critical role in health inequities and health outcomes. They defined the power in two fundamental ways: *power to* and *power over*. Power to, is the ability to change your situation and power over, is the ability and authority to change another individual or a group's behaviors and interactions. This second type of power (power over) has been described in the literature as "coercion, dominance, and oppression" (Solar, Irwin, & Vega, 2005, p. 20). While these terms imply violence or obvious physical threats, power can also be discretely wielded, where groups in power control the agenda at a policy hearing, steering the development of key public policy in their favor, without the disadvantaged groups even realizing it is happening. Groups in power can do the same thing, by controlling mass media messages to the public, making the disadvantaged believe there are no problems, which averts conflicts and uprisings. Power to control people's thinking leads to controlling their decision making. Power in the wrong hands can have destructive effects on health outcomes.

Power is not always used to dominate or harm. It can also be used to bring groups together to act in concert. According to Arendt's philosophy, "power is politically distinguished by its character as a collective action, never the property of an individual" (Fay, 1994, p. 23). Her work emphasized the importance of changing the distribution of power within the population to help those at the lower spectrum. She posited that the power structure needs to be realigned across individuals and households, and communities, political parties, and governments, to close the health inequity gap.

Prior to developing its conceptual framework, The WHO established the Commission on Social Determinants of Health (CSDH), which performed a detailed review of relevant theory to serve as a basis for their conceptual framework. "The theoretical constructs debated by current social epidemiologists are as follows: 1) psychological approaches, 2) social production of disease/political economy of health, and 3) eco-social theory" (WHO CSDH, 2010, p. 4). All three constructs attempt to explain why health inequity exists. Where these theories differ, is their emphasis on particular facets of social or behavioral circumstances. The first, psychological theory focuses on how an individual's stress, perhaps from living in poverty, can increase susceptibility to disease. Literally, one's social environment, over time, can "affect neuroendocrine function in ways that increase the organism's vulnerability to disease" (Raphael, 2006, p. 15). Studies done by Wilkinson and Pickett (2006) show relationships between suppressed neuroendocrine function and health status. A person's rank in society can cause so much anxiety, by constantly worrying about what other possess and their own shortcomings, that it actually changes the brain's perception and makes us more vulnerable to disease (Wilkinson & Pickett, 2006).

Next, the social production/political economy of health can be described as "neo-material matrix of contemporary life" (Marmot, 2002, p. 15), implying that material things determine other aspects of life. Specifically, this approach theorizes that income and material possessions, or lack thereof, influence resources/access "available to individuals and affect the public infrastructure:

education, health services, transportation, environmental controls, availability of food, and quality of housing" (Marmot, 2002, p. 16). Last, Krieger's (2001) theory of "ecosocial" (p. 16) aims to "integrate social and biological" (p. 16) components to develop emerging priorities for social determinants and disease distribution across the population. Krieger's approach considers everything from the cellular level to complex group social interactions (Krieger, 2001).

The WHO continued examining three main perspectives to help inform its development of its conceptual framework: social selection, social causation, and life course (WHO, 2010). Social selection offers a new approach to looking at SDOH. Contrary to prior researchers' opinions, the selection perspective claims that one's health determines SES, not the other way around. The idea is that health drives an individual's social position. This includes both the unhealthy slide toward to the bottom, and the healthy rise to the top. Imagine using physical fitness versus obesity, with the star athlete versus the overweight teenager in a high school setting. The more physically fit individuals move up in SES, while the obese move down in SES. This concept is known as social mobility. A person's social status can change within his/her lifetime, intra-generationally, or it can change from the status of the parents' inter-generational social mobility. The literature suggests that health status can influence social mobility. Interestingly, Manor, Matthews, and Power (2003), stated that:

> "Social mobility does not widen health inequalities. People who are downwardly mobile because of their health, still have better health than the people in the class of destination. Consequently, the upwardly mobile lower the mean health status of the new class (p. 2217)."

Evidence for this perspective is inconsistent and more research is needed to draw firm conclusions.

The social causation perspective is similar to some of the previous research presented. Social factors are the main predictor for health inequities and poor health outcomes. The impact of these social factors may be indirect, interacting with individuals across the social levels and population in different ways. Some factors may have stronger relationships to health outcomes in certain cohorts than others. The social causation perspective considers material, psychological, and behavioral factors and the health system itself (WHO, 2010.).

The life course perspective addresses how SDOH play a role at each stage of life: infancy, childhood, adolescence, adulthood, and old age. This perspective explains how groups at each stage in the life cycle are impacted differently by SDOH and how they roll up collectively into the population health trends. This perspective also discusses how each cohort is influenced by various exposures during each life stage, with regard to health outcomes and disease trends in the population. It notes that disease exposure often occurs early in life but does not manifest itself until a later stage (WHO, 2010). The World Health Organization CSDH examined contemporary social epidemiological theories, frameworks, perspectives, and directions to incorporate into its conceptual framework for action.

Conceptual Frameworks

Diderichsen's (1998) model of mechanisms of health inequality (Figure 1.8) depicts pathways of social position/context in society, as exposures to disease. Like many previous researchers, Diderichsen (1998) opined that social position influences health outcomes. His model describes how social stratification presents differential exposure to health-damaging conditions, and access to resources, subsequently impacting or changing health outcomes that fluctuate along social segments. Using Diderichsen's model, we could argue that "both differential exposure and differential vulnerability may contribute to the relationship between social position and health outcomes" (Diderichsen, 1998, p. 24). Many of the philosophical aspects of the Diderichsen's model were used by the CSDH to develop their conceptual framework.

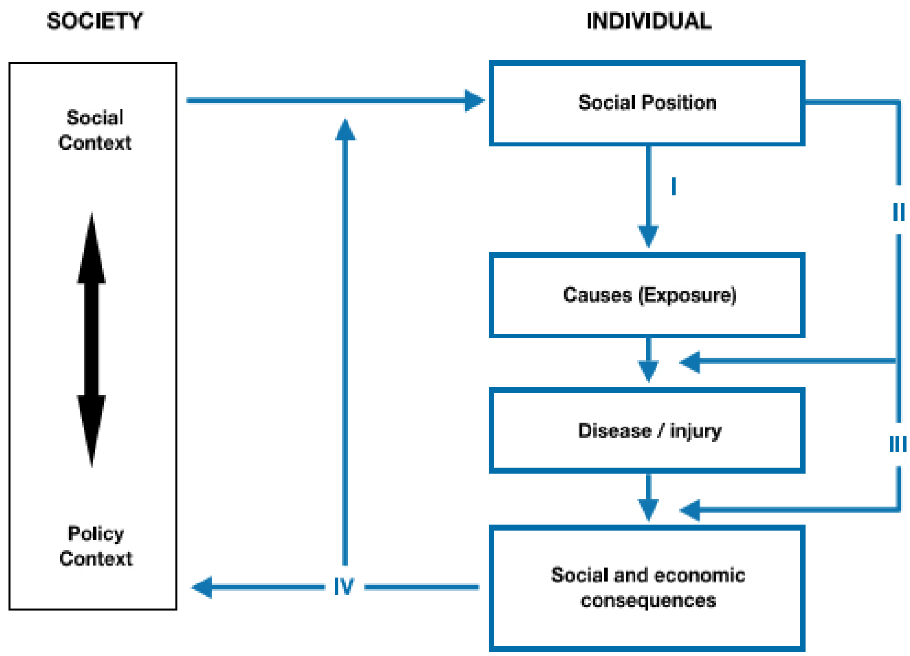

Figure 5. Diderichsen's model of the social production of disease. Reprinted from Understanding Health Equity in Populations—Some Theoretical and Methodological Considerations by F. Diderichsen, T. Evans, and M. Whitehead, 2001. In B. Arve-Parès (Ed.), *Promoting Research on Inequality in Health* (p. 24). Stockholm, Sweden: Council for Social Research. Copyright 2001 by Council for Social Research.

The second conceptual framework under consideration is CSHD's conceptual framework for action on the social determinants of health (Figure 1.9). The purpose of developing the CSDH's conceptual framework was to help guide health care policy. More specifically, the CSDH is intended to (a) identify SDOH and the inequities they may cause, (b) demonstrate any relationships between each of the SDOH, (c) explain any pathways through which inequities are accelerated and related to SDOH, (d) prioritize the SDOH for action, and (e) delineate where policy development is most needed to achieve results. The CSDH recognized that addressing all of these components in one pictorial schematic would be difficult and confusing for the reader. There were several iterations of the framework leading up to the final form.

Figure A. Final form of the CSDH conceptual framework

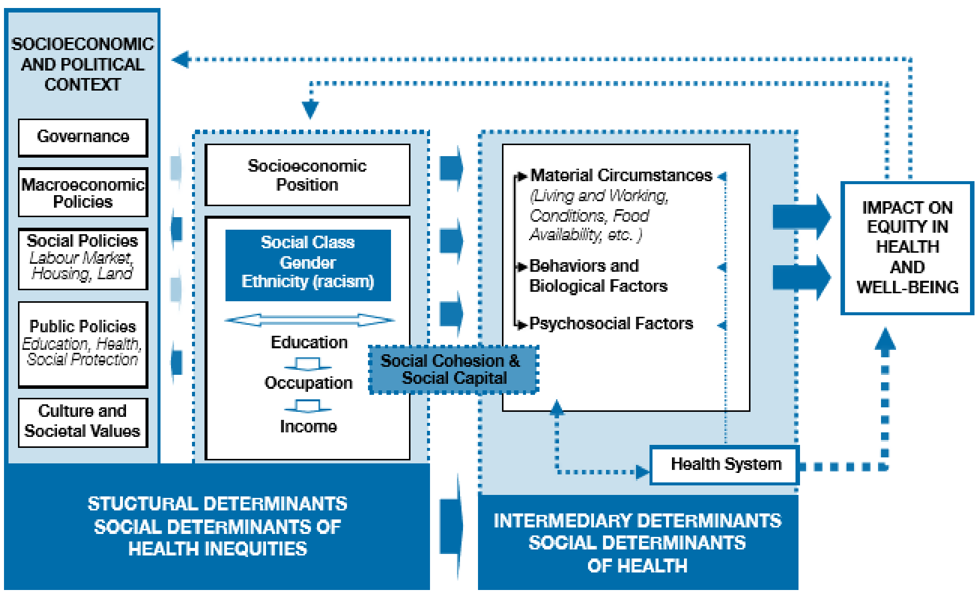

Figure 6. Final form of the CSDH conceptual framework. Reprinted from *A Conceptual Framework for Action on the Social Determinants of Health: Social Determinants of Health Discussion Paper 2* by The World Health Organization, 2010, p. 6. Copyright 2010 by the World Health Organization.

After extensive analysis and systematic investigation, the CSDH selected these key components: (a) socio-political context, (b) structural determinants and socioeconomic position, and (c) intermediary determinants. The CSDH conceptual framework is differentiated from other previous frameworks presented, by its focus on the three aspects above. By socio-political context, the CSDH means social stratification that drives employment opportunities, educational systems, and all other political/societal issues that influence the public's value structure. Health can be greatly affected by the distribution of resources and funding, such as insurance coverage, which is controlled by public policy and societal values. This was witnessed in 2017, with the national political agenda to repeal and replace the PPACA, which includes Medicaid expansion (WHO, 2010). Taking away this additional coverage could result in more than 20 million Americans losing their health insurance. The socioeconomic-political context is a crucial component and can have significant consequences.

The WHO CSDH conceptual framework is divided into two major components, structural mechanisms and intermediary mechanisms:

1. "Structural mechanisms are the root cause of stratification and social class divisions in society, thereby defining individual socioeconomic position within hierarchies of power, prestige, and access to resources. The factors with the strongest evidence of segregating individuals into different social positions are income, education, occupation, gender, social class, and race/ethnicity. The literature suggests (CSDH, 2010) that these factors are the true source of health inequities and differentials in health outcomes" (WHO CSDH, 2010, p. 36).
2. Intermediary mechanisms are stratified according to material circumstances, such as neighborhood, work environment, housing status, psychological, and behavioral factors. The framework assumes that people respond according to the different SES level they reside in. People in the lower spectrum are exposed to poorer living and working conditions, which in turn, causes poor health behaviors and outcomes (WHO CSDH, 2010, p. 36).

The interaction between both mechanisms impacts equity in health and well-being. The model implies that the structural factors are a stronger force in determining SES, than the intermediary determinants.

One last framework for consideration is Heiman and Artiga's (2015) (Figure 2.0) conceptual framework for social determinants of health. This framework shares the same views as the CSDH and Diderichsen's (1998) model that social factors play a role in health outcomes and must be addressed to achieve health equity. The framework depicts economic stability, neighborhood, physical environment, education, food insecurity, community, social context, and the health care systems as being major contributors to health outcomes. Although readmission to the hospital is not specifically listed, the same theory can be applied to the 30-day hospital readmission.

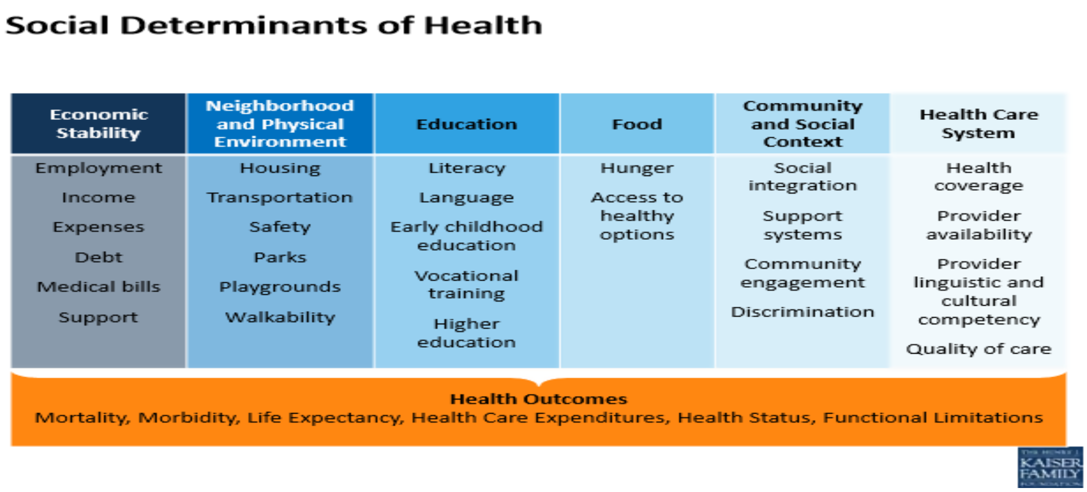

Figure 7. Social determinants of health. Reprinted from *Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity* by H. J. Heiman, & S. Artiga, 2015, p. 2. Copyright 2015 by The Henry J. Kaiser Family Foundation.

Why these specific factors?

Several conceptual frameworks reviewed throughout the literature are summarized in Figure 8. Organizations that Define Social Determinants of Health Factors. The chart shows the various social factors that each of these organizations include in their descriptions of SDOH. Multiple conceptual frameworks support these factors in the literature. Nagasako (2014) suggests these specific factors contribute to health outcomes. These factors were supported by Heiman's

SDOH Conceptual Framework (Heiman, 2015). World Health Organization and others reference several factors selected to analyze in this study (WHO, 2010).

Galea, Tracy, Hoggatt, DiMaggio, and Karpati (2011) stated they found that social factors, including education, racial segregation, social supports, and poverty accounted for more than a third of all deaths in the United States each year. Racial segregation is comparable to SDOH of Race/Ethnicity, which is race ethnicity. In addition, Heiman and Artiga (2015) described their conceptual framework for social determinants of health, which includes: economic stability, neighborhood and physical environments, education, food, community and social context, and health care system. Economic stability is defined using examples, such as income and medical bills, which can be aligned with status income or zip code. Next, their framework suggests that the neighborhood and social environment influence health outcomes, which can be associated with ZIP code as a proxy for conditions in which people live, or housing. Education and food are drivers, according to their framework, which is difficult to measure and is a weakness in the study design. However, language can be an indicator of literacy or the ability to understand medical instructions. Health care systems can be addressed, by looking at the cost of care, insurance, and gender.

The article, published by the Henry J. Kaiser Family Foundation, continues to cite research to show that “lower education levels are directly correlated with lower income, higher likelihood of smoking, and shorter life expectancy” (Heiman, 2015, p. 2). Heiman’s research concluded that the impact of individual behavior accounts for 40% of a person’s likelihood for premature death, this includes diet, alcohol, drug abuse, and smoking. Based on multiple researchers’ findings, this study will examine smoking history. Additional studies reported by the American Hospital Association (2015) of 4,000 patients with certain chronic conditions, 60% of the variation in the readmission rates was attributable to community and patient social characteristics, employment status, and primary care providers per capita (AHA, 2016).

<table>
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Social Determinants of Health (SDOH) Factors</th></tr>
<tr><th>Organizations</th><th>Factors</th><th>WHO</th><th>CDC</th><th>Kaiser Family Foundation</th><th>Healthy People 2020</th><th>APHA</th><th>CMS</th></tr>
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• World Health Organization (WHO)
• Kaiser Family Foundation
• Healthy People 2020
• American Public Health Association (APHA)
• Centers for Medicare and Medicaid Services (CMS)</td><td>INDIVIDUAL</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
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<tr><td>Neighborhood/
Environment</td><td></td><td></td><td>X</td><td>X</td><td></td><td>X</td></tr>
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Figure 8. Organizations Define Social Determinants of Health (SDOH) Factors

Lester's Conceptual Framework

This conceptual framework was created from an amalgamation of ecological theory and several frames in the literature depicted in Figure 1. I used this conceptual framework as a basis to design the study, to organize, and analyze the data. It depicts an interaction between individuals and community and the impact they have on health outcomes. This framework accords with the Commission on Social Determinants of Health (CSDH) and Diderichsen's (1998) model that social factors play a role in health outcomes and must be addressed to achieve health equity. The framework depicts individual factors and community factors, all as major contributors to health outcomes. Although readmission to the hospital is not specifically listed, the same theory can be applied to the 30-day hospital readmission.

Discussion of Gaps in the Literature

Many unanswered questions still remain, that are related to the extent of the impact of SDOH on health outcomes, such as the 30-day readmission. The debate over whether 30-day readmission is even an appropriate measure of quality still remains open and requires further investigation. The inclusion of risk adjustments in the CMS calculation is not resolved and requires more research to determine if the advantages of including them to even the playing field outweigh the disadvantages of masking the gaps between different communities. There are data quality and availability issues associated with finding the best method to account for these individual characteristics that are proposed in the literature, such as food insecurity, housing status, and education level. Further scientific investigation is needed. However, there are few studies due to the complicated methodologies, such as not being able to remove privilege or poverty to create a control group. Only older, limited data is available for researchers to analyze, or the data is very expensive. As a result, there are few comprehensive studies.

Research Objectives

The objective of this study is to identify and examine what social determinants of health, for patients in Hudson County, New Jersey, are associated with the likelihood of being readmitted into the hospital within 30 days of discharge. Identifying these factors will help health care providers develop tools and techniques to address and improve the health care outcomes and reduce readmissions in hospitals in Hudson County, New Jersey.

Chapter 3

Methods

Research Design

The study uses a non-experimental design with secondary data and observational analysis. Non-experimental design is most appropriate for this study because it attempts to explain the phenomenon of why a New Jersey hospital had an excessive 30-day readmission rate. Based on an extensive review of the literature, the researcher determined that the best way to conduct this study would be to examine the natural behaviors of patients discharged from an acute care hospital, by using a database containing patient details from 2009-2016. Secondary data analysis is applicable because the study groups' characteristics are already predetermined without manipulation, due to the use of a retrospective database with de-identified patient-level details (Cohen et al., 2000). In addition, several other federal and New Jersey State Department of Health reports and documents are reviewed to gather data and information for this study. This design is best used when the researcher has no ability or it would be unethical to change the behavior of the subjects in the study, for example, cause a patient to have an unplanned readmission or poor health outcome or experience low socio-economic status. A benefit of retrospective analysis is the ability to evaluate real life behaviors for prior activities, and circumstances, then perform an analysis to test for relationships. Secondary data analysis design uses data that has already been gathered but not necessarily for the purposes of the study at hand. The study includes a quantitative examination of relationships between New Jersey patients being re-hospitalized within 30 days of an inpatient stay and specific social determinants of health (SDOH). Statistical analysis utilizing SPSS software is applied to the data to test for significance and the relationship between the identified independent and dependent variables (Cook & Campbell, 1979).

Non-experimental observational study design with retrospective data analysis typically has strong external validity, which is the degree to which the research findings can be generalized to the greater environment outside of the study group (Diderichsen, 1998). In this case, the literature supports the importance of focusing on reducing re-hospitalization and that there may be strong relationships between specific social factors and health outcomes. On the other hand, internal validity could be a weakness in non-experimental studies, because it can be difficult to establish a clear cause-effect relationship in the absence of a pure control group. As in this study, a weakness exists with establishing a clear causal relationship between any one social factor and a re-hospitalization. A patient could be impacted by many independent variables at the same time (Cook & Campbell, 1979).

Sampling

The entire retrospective data set was used for this study minus any exclusions shown in Table 1.0. The sampling frame for **H1- H11** is raw data from one hospital in Hudson County, New Jersey extracted from the Electronic Medical records (EMR) of every single patient discharged between 2009-2016 for each hypothesis. This retrospective database of patients was analyzed to test for relationships between the independent variables and the dependent variables. The 30-Day Readmission rate was the dependent variable. The independent variable was **SDOH** defined as:

1. Race/ Ethnicity
2. Insurance Status
3. Age
4. Language

5. Gender
6. Smoking History
7. Income (Median Household)
8. Education Level
9. Unemployment
10. Neighborhood Crime Index
11. Food Assistance

An application was submitted and has been approved by Western Institutional Review Board (WIRB), which is the Jersey City Medical Center Internal Review Board contracted agency used for all research and hospital studies. The Board found that this research meets the requirements for a waiver of consent under 45 CFR 46.116(d). All data will be collected from electronic patient records retrospectively. There is no immediate risk to study subjects. Data security and the confidentiality of records will be maintained at all times. Database spreadsheets and reports are kept on a secure encrypted flash drive and stored in a locked drawer. The IRB application for Seton Hall University was submitted on September 26, 2018 and a waiver of consent was approved.

Table 1. Sampling methods

Hypothesis	**Sampling Frame (Source)**	**Sampling Method**	*n*
H1-H11	JCMC Data Base 2009-2016 discharges	The entire data set was used within the database minus exclusions	>77,000

The *Office of Disease Prevention and Health Promotion* defines social determinants of health as "conditions in the environments in which people are born, live, learn, work, play, worship, and age" (WHO CSDH, (n.d.), p. 4). that affect a wide range of health, functioning, and quality-of-life outcomes and risks". The strengths of the data are that it covers an eight year period 2009-2016, there are over 77,000 de-identified individual patients in the data base and there are numerous patient level details included to assess each of the independent variable levels. The data is extracted from patient clinical record documentation from health care providers for financial billing and reporting to the N.J. State Department of Health. Other databases will be used from public data sources, such as Hospital Compare (https://www.medicare.gov/hospitalcompare/search.html), Health Care Quality Insights Reports and Leapfrog Group Patient Safety public reporting website. http://www.leapfroggroup.org/

The weaknesses of the data are that there are many empty/missing 'cells' in the excel spreadsheet. It's a raw data file with several extreme outliers, for example one patient has a hospital length of stay of 2000 plus days (yes, the patient has been living in the hospital for over two years).

Measurement of variables

Measurement validity is a critical component of an effective research design. As a construct, Social Determinants of Health (SDOH) has Face Validity. In other words, upon initial review, age, gender, smoking, and income, all *seem* to be good measures or indicators of health status. Considering Content Validity and Criterion-Related Validity, The World Health Organization (WHO), The Office of Disease Prevention and Health Promotion (ODPHP) and The Center for Disease Control (CDC) all recommend very similar operational definitions for social determinants of health. For the purposes of the study, Predictive Validity is extremely important.

The main priority of the research is to create a solution that can assist hospitals and other health care professionals to design assessment tools to *predict* when a patient is at risk for 30-day readmission in order to take steps to prevent it in the future.

Construct validity:

This study's main purpose was to determine if a relationship exists between the two –levels of independent variables and the dependent variable. The operationalization of the construct, Social Determinants of Health, allows it to be observed and measured. Construct validity is the extent to which the operational definitions actually measure the idea of SDOH. The operational definitions include the patient's smoking history, race/ethnicity, insurance status, age, primary, language spoken, gender, and income. Multiple comparisons can be calculated comparing different groups of patients (independent variables) and their relationships to the dependent variable, by calculating 30-Day readmission rates for patients in the various groups. The World Health Organization (WHO) agrees by using an equivalent operationalized definition as "conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life" (WHO CSDH, (n.d.), p. 4).

Threats to Construct Validity are important to consider. For example, Mono-Method Bias could apply if the researcher only operationalized the measures in one way. In this study, the researcher tried to avoid this problem by defining SDOH using multiple variables. Another threat that does not apply, is Hypothesis Guessing which is when the participants guess what the expected outcome should be and change their behavior accordingly, not due to the intervention of the program. With the retrospective data base analysis, Hypothesis Guessing Threat would be irrelevant. Similarly, Evaluation Apprehension would not apply, because no patients were interacted with, so trying to either "look good" as study participants or becoming anxious because they performed poorly due to being observed was also not relevant. The threat that stands out the most in this study is Confounding Constructs and Levels of Constructs. The participants, although they were data points in a spreadsheet, were concurrently exposed to the SDOH. For instance, one patient could be a smoker, drink alcohol, belong to one ethnicity, low income, old, on Medicare and so on. Statistical regression may be required to discern which factor is causing the strongest effect on the outcome. Lastly, Conclusion validity confirms that the research design is appropriate and precise enough to identify accurately the cause (IV) and effects (DV). A G-Power analysis is the statistical tool used to determine conclusion validity (Power=.80 threshold).

Analytical Methods

Two-Level Binary Logistic Regression (TLBLR) was used in H1 – H11 to examine factors or covariates using the dependent and independent variables above. Preceding Chi-Square tests were computed to gain an idea of what to expect once the Two-Level BLR was done. Two-Level Binary Logistic Regression is the *best* fit because it allows the researcher to simultaneously analyze multiple independent variables or factors impacting a person as shown in Table 2. (Field, 2013)

Table 2

Hypotheses, Statistical Analysis Tests and Assumptions

Hypothesis	Test	Assumptions
H1: There is a relationship between a patient's RACE/Ethnicity and being readmitted to the hospital within 30 days of discharge.	Chi-Square test for Independence	Non- parametric (No Normal Distribution) Random Selection DV is Binary: Readmitted Y/N (Categorical) IV: Race/Ethnicity (Nominal/Categorical)
H2: There is a relationship between a patient's INSURANCE and being readmitted to	Chi-Square test for Independence	Non- parametric (No Normal Distribution) Random Selection

the hospital within 30 days of discharge.		DV is Binary: Readmitted Y/N (Categorical) IV: Payer: Medicare, Medicaid, Managed Care, Private, Charity (Nominal/Categorical)
H3: There is a relationship between a patient's AGE and being readmitted to the hospital within 30 days of discharge.	Chi-Square test for Independence	Non- parametric (No Normal Distribution) Random Selection DV is Binary: Readmitted Y/N (Categorical) IV: Age Group by Decade (Categorical)
H4: There is a relationship between a patient's LANGUAGE and being readmitted to the hospital within 30 days of discharge.	Chi-Square test for Independence	Non- parametric (No Normal Distribution) Random Selection DV is Binary: Readmitted Y/N (Categorical) IV: Languages: English, Spanish, Other (Nominal/Categorical)

Hypothesis	Test	Assumptions
H5: There is a relationship between a patient's GENDER and being readmitted to the hospital within 30 days of discharge.	Chi-Square test for Independence	Non- parametric (No Normal Distribution) Random Selection DV is Binary: Readmitted Y/N (Categorical) IV: Gender M/F (Categorical/Nominal)
H6: There is a relationship between a patient's SMOKING HISTORY and being readmitted to the hospital within 30 days of discharge.	Chi-Square test for Independence	Non- parametric (No Normal Distribution) Random Selection DV is Binary: Readmitted Y/N (Categorical) IV: Smoking History: Yes vs. No (Nominal/Categorical)
H7: There is a relationship between a patient's INCOME and being readmitted to the hospital within 30 days of discharge.	Two-Level Binary Logistic Regression	Non- parametric (No Normal Distribution) Random Selection DV is Binary: Readmitted Y/N (Categorical) IV: Median Household Income (Continuous)
H8: There is a relationship between a patient's EDUCATION and being readmitted to the hospital within 30 days of discharge.	Two-Level Binary Logistic Regression	Non- parametric (No Normal Distribution) Random Selection DV is Binary: Readmitted Y/N (Categorical) IV: Education (% Bachelors + in Community)(Continuous)
H9: There is a relationship between a patient's community UNEMPLOYEMENT RATE and being readmitted to the hospital within 30 days of discharge.	Two-Level Binary Logistic Regression	Non- parametric (No Normal Distribution) Random Selection DV is Binary: Readmitted Y/N (Categorical) IV: Unemployment Rate (Continuous)
H10: There is a relationship between a patient's community CRIME index and being readmitted to	Two-Level Binary Logistic Regression	Non- parametric (No Normal Distribution) Random Selection DV is Binary: Readmitted Y/N (Categorical)

the hospital within 30 days of discharge.		IV: Crime Index (Continuous)
Hypothesis	**Test**	**Assumptions**
H11: There is a relationship between a patient's community FOOD Assistance and being readmitted to the hospital within 30 days of discharge.	Two-Level Binary Logistic Regression	Non- parametric (No Normal Distribution) Random Selection DV is Binary: Readmitted Y/N (Categorical) IV: % Residents on Food Assistance (Continuous)
All Hypotheses H1-H11	Two-Level Binary Logistic Regression	Non- parametric (No Normal Distribution) Random Selection DV is Binary: Readmitted Y/N (Categorical) Two-Level both Community and Individual IV: (Categorical or Continuous)

The primary purpose of the study is to identify high risk factors associated with increased unplanned re-hospitalization. Once each hypothesis has been tested using the best fit statistical test, the results can be used to make predictions about the risk level of a patient for unplanned readmission, based on specific social factors. These factors could be included in admission assessments early in the patient's hospital stay to help organize discharge planning and post- acute care plans and referrals. The findings can also be used to influence health care policy on funding for much needed social programs in high risk communities, and on the ACA to make adjustments in the way essential hospitals in poorer communities receive penalties for excessive readmission rates, compared to their suburban counterparts.

Chapter 4: Results

The statistical test results and analysis of the findings are presented in this Chapter. Statistical tests were computed using SPSS Software (Field, 2013) on a retrospective database with de-identified patient level data. Specific statistical tests were selected based on the characteristics of the data, for example, the distributions and whether the dependent variable and independent variable data were categorical or continuous. The analytics in this chapter aim to identify and examine what social determinants of health, for patients in a Hudson County, New Jersey hospital, are associated with the likelihood of being readmitted into the hospital within 30 days of discharge. Identifying these factors can help health care providers develop tools and techniques to address and improve the health care outcomes and reduce readmissions in Hudson County, New Jersey. A detailed exploration of eleven social factors and their association with the odds of being readmitted to an acute care hospital is presented in the tables and charts below.

Description of the Data

The purpose of the study was to identify whether Social Determinants of Health (SDOH) are impacting patients' likelihood of being readmitted to an acute care hospital within 30 days of discharge. This study examines patients discharged between 2009 – 2016 from a large urban acute care hospital in Hudson County, NJ. There are over 77,000 patients in the database with eleven social characteristics delineated for each patient. The database was created from the Electronic Medical Records (EMR) of all patients discharged between 2009-2017. The year 2009 was chosen because that was the year the EMR was created and that is how far back the data went. The Hospitals' Decision Support/Data Analytics Department ran the report to create the database to include all social and demographic factors available on each patient. All patients included in the study were older than 18 years old. All duplicates, patients with multiple missing cells, and extreme outliers were removed from the database. All patients were completely de-identified. Eleven factors: 6 individual and 5 community characteristics were delineated for each patient.

The Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation (YNHHSC/CORE) was used to define inclusions and exclusions in the data set. These are consistent with existing CMS publicly reported measures for readmission (https://medicine.yale.edu/core/).

Table 3

Inclusions and exclusions for 30-day readmission

Inclusions	Exclusions
Patients readmitted within 30-days of their "index admission" and only counted once within the 30-day time frame. Alive upon discharge Not transferred to another acute care hospital. Not readmitted for follow-up cancer treatments	In-hospital deaths Transfers to another acute care hospital Planned follow-up for cancer treatments Planned rehabilitation Discharged AMA Patients with missing data elements

The dependent variable was 30-day readmission, a binary variable, meaning the patient is either readmitted within 30 days or not, yes or no. The independent variables are the social factors segmented by: **Individual:** Race/ Ethnicity, Insurance Type, Age, Primary Language Spoken, Gender, and Smoking History. **Community:** Education Level, Median Household Income, Unemployment Rate, Food Assistance, and Neighborhood Crime Index.

Two-level Binary Logistic Regression was the main statistical test used for the analysis. The preceding Chi-Square analyses were performed on the categorical social factors (the independent variables). The study includes a retrospective quantitative examination of relationships between a hospital in Hudson County, New Jersey patients being re-hospitalized within 30 days of an inpatient stay and specific social determinants of health (SDOH). Statistical analysis utilizing SPSS software was being applied to the data to test for significant and relationships between the identified independent and dependent variables (Cook and Campbell, 1979).

For the purposes of this study the following social determinants have been identified for analysis:

1) Race/ Ethnicity

2) Insurance Status

3) Age

4) Primary Language Spoken

5) Gender

6) Smoking History

7) Education Level

8) Median Household Income

9) Unemployment Rate

10) Food Assistance

11) Neighborhood Crime Index

Line charts of categorical independent variables are depicted below.

Race/ Ethnicity

The race/ethnicity variable is nominal and was segmented into the five largest categories identified in the patient database: 1) White, 2) Black/AA, 3) Latino/Hispanic 4) Asian, and 5) Mixed/Other shown in a race/ethnicity line graph in *Figure 9*. The line chart shows that Latino/ Hispanic have a higher readmission rate than the other race/ethnicity categories. Later, Chi-Square and two-level Binary Logistic Regression results are depicted to demonstrate whether statistical significance exists, as appropriate for each of the independent variables.

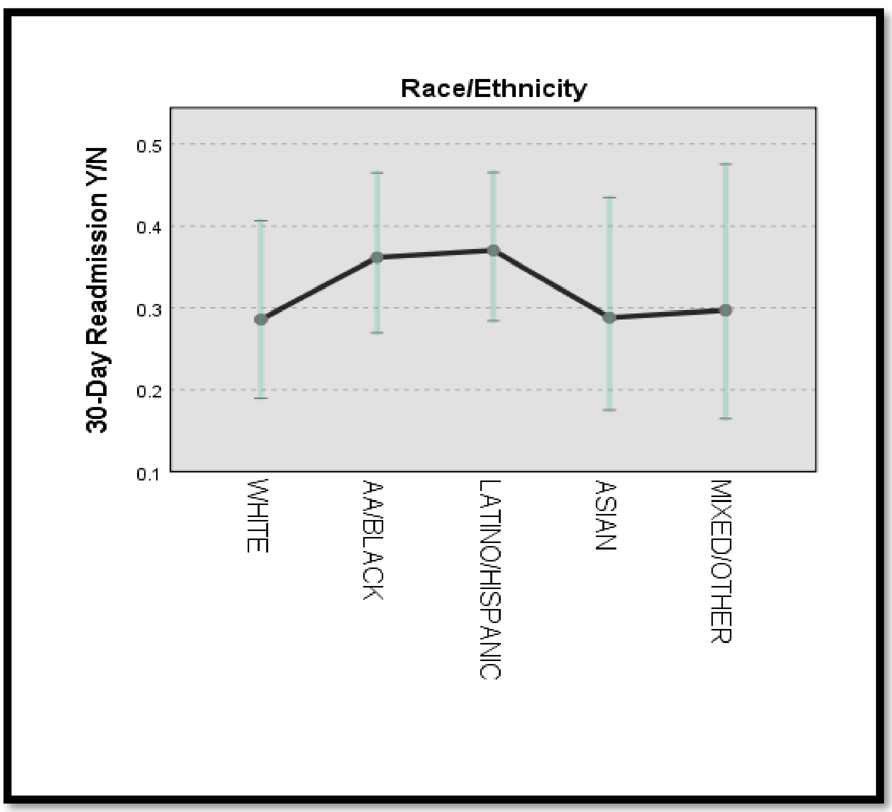

Figure 9. Race Ethnicity Line Grapi

Insurance Status

The insurance type factor, also nominal, was segmented into six main categories: 1) Medicare, 2) Medicaid, 3) Charity Care 4) private insurance 5) self-pay and 6) other. Figure 10 is a line graph of the insurance carriers. Private insurance is comprised of all commercial insurance, HMOs, and PPOs combined. Both Medicare, and Medicaid appear higher readmission rates than other types, with Medicaid being the highest. Statistical significance it tested later and those results are shared below.

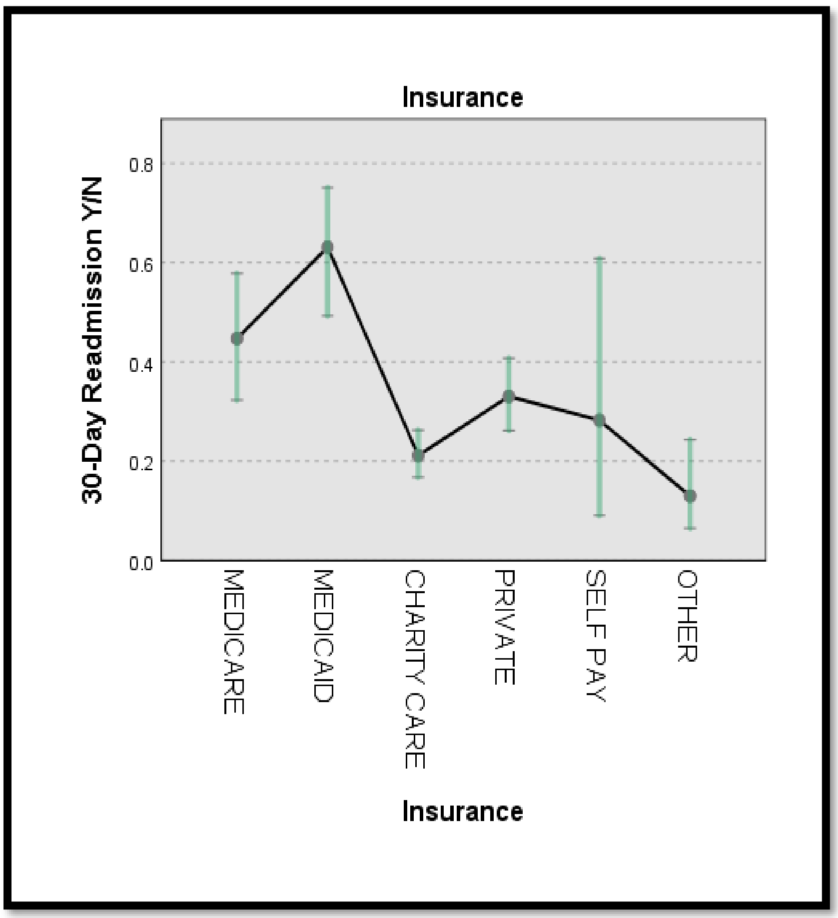

Figure 10. Insurance Type Line Graph

Age

The Age variable was grouped into decades. Patient ages range between 19-99 years shown in just below in *Figure 11*. From looking at the graph it appears that 30-day readmission increases and age increases. Age was divided into the following subsections:

Subsection 1: 19-29
Subsection 2: 30-39
Subsection 3: 40-49
Subsection 4: 50-59
Subsection 5: 60-69
Subsection 6:70-79
Subsection 7: >80

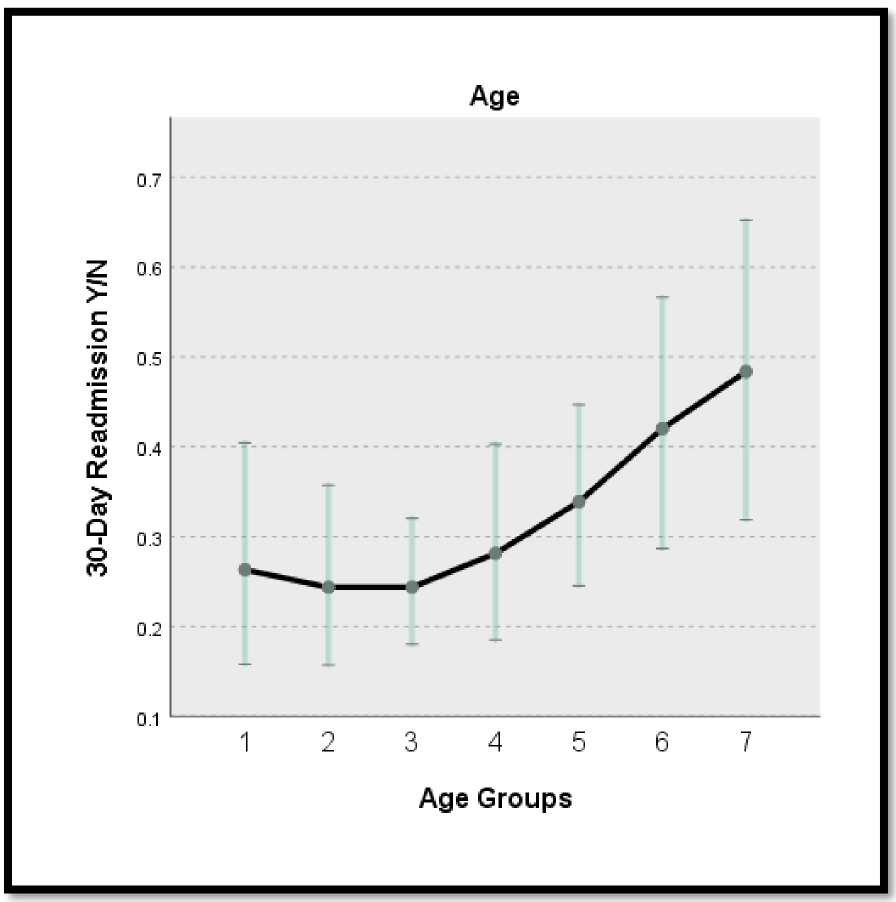

Figure 11. Age Line Graph

Language

Primary language spoken is divided into two categories: 1) English, 2) Spanish. English and Spanish are the two most common languages spoken in the data base. *Figure 12*. Language Line Graph appears to show that patient who speak Spanish as a primary language are readmitted more frequently that those that speak English. Statistical analysis is done to test for significance using Chi-Square and TLBLR below.

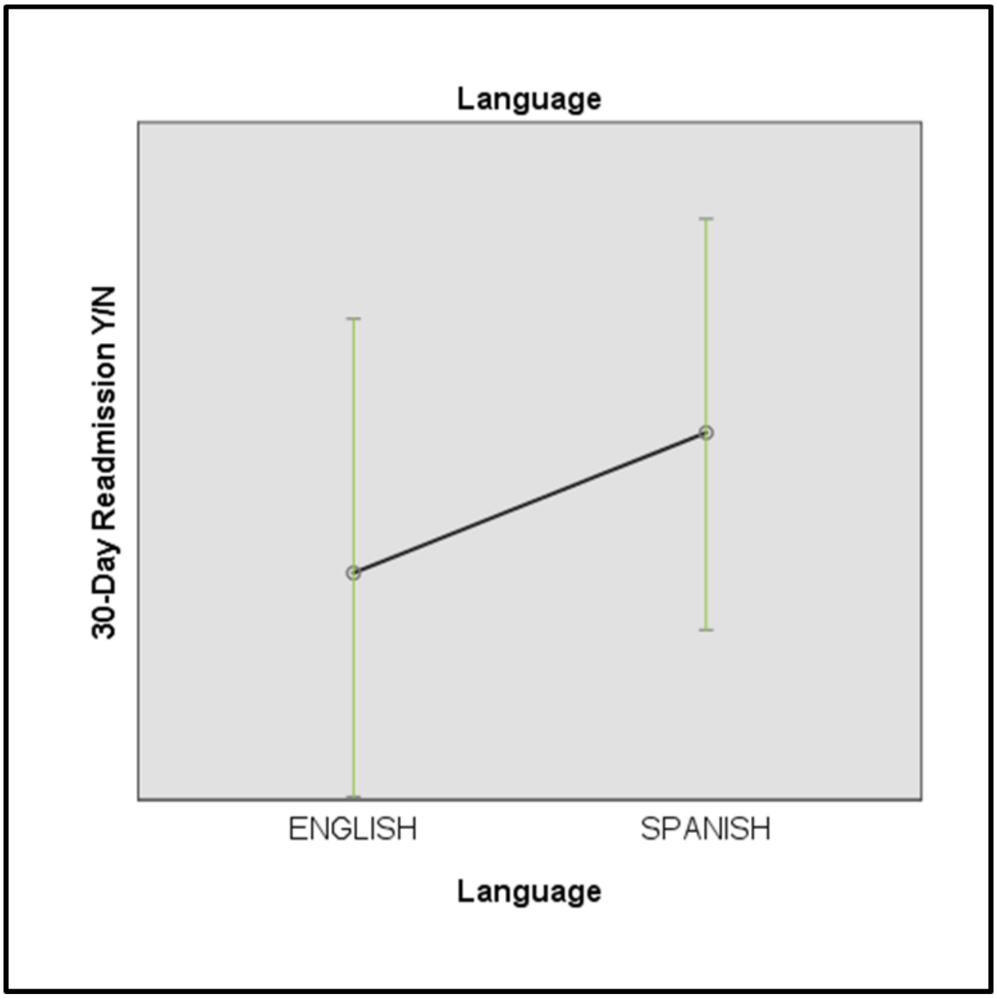

Figure 12. Language Line Graph

Gender

Gender is comprised of two categories 1) Male and 2) Female. *Figure 13* is a line chart of the percent of male vs. female in the data base vs. 30-Day Readmission. Males seem to be readmitted more frequently than females in the graph shown in Figure 6. Subsequent Chi-Square and Binary Logistic Regression will be completed to test for statistical significance.

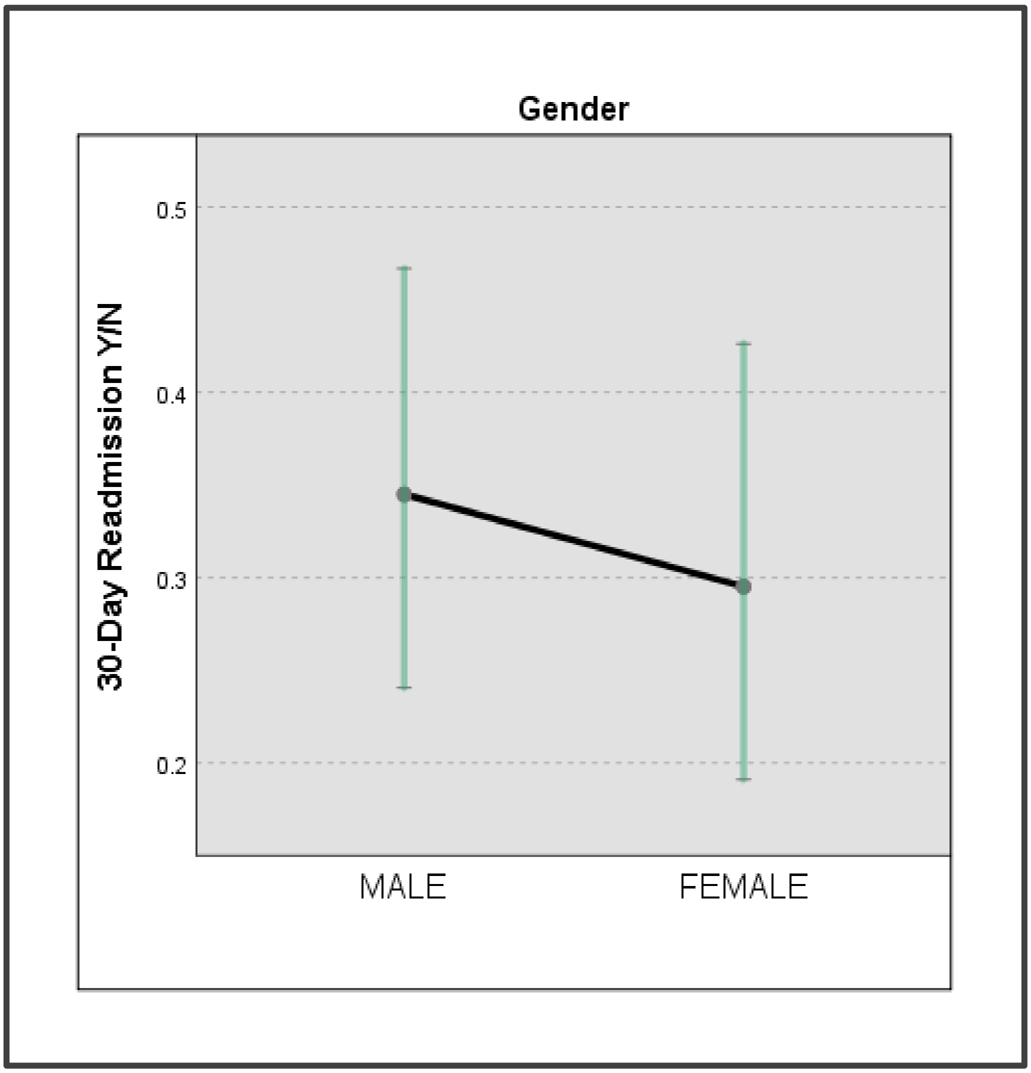

Figure 13. Gender Line Graph

Smoking

The smoking variable was divided into two categories, patients with a smoking history and non-smoking patients, as shown in *Figure 14.* Smoking History vs. 30-Day Readmission bar chart of the percentage of smokers vs. non-smokers vs. 30-Day Readmission. The chart clearly shows that the percentage of smokers readmitted within 30 days of discharge is much higher than non-smokers. Results following Chi-Square and Two Level Binary Logistic Regression computation are shared later to test for statistical significance.

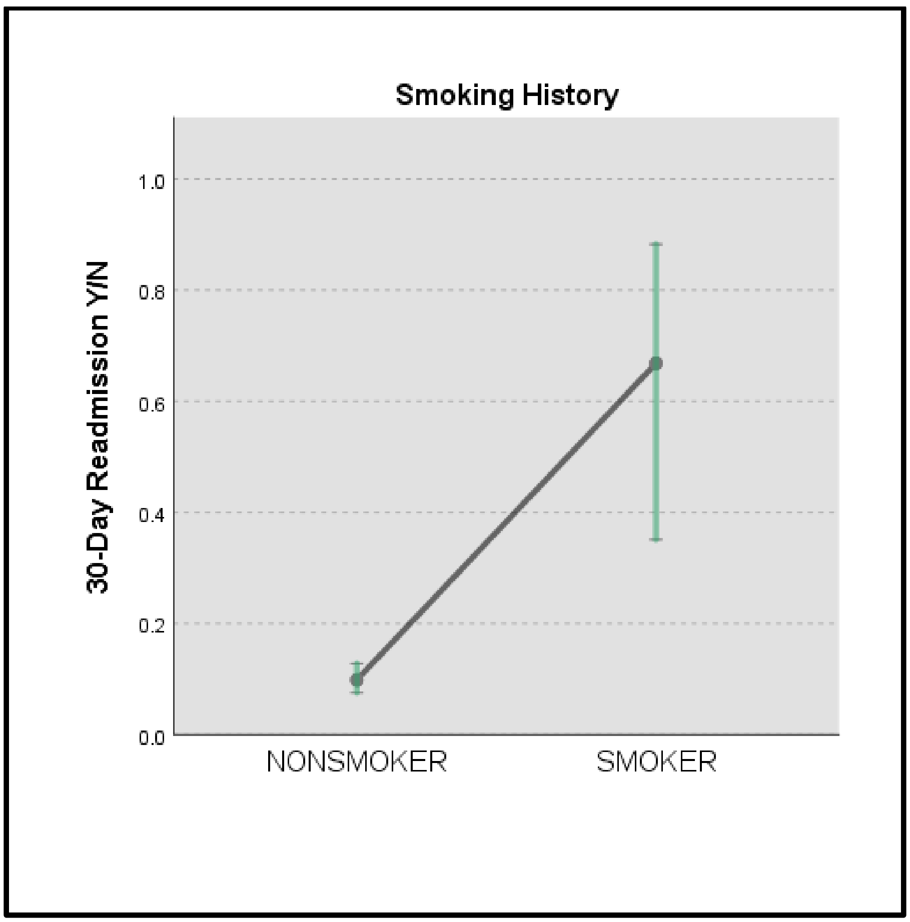

Figure 14. Smoker vs. Non-Smoker Line Graph

Results of Statistical Analysis

Statistical analysis was performed to test each hypothesis. The main statistical test for the analysis used was Two-Level Binary Logistic Regression. Preceding Chi-Square analyses were performed on the categorical social factors (the independent variables) to gain insight into what to expect once the Two-Level Binary Logistic Regression is completed. Table 2 above depicts each hypothesis, the proposed test and the data assumptions for why the particular statistic test was selected. Two-Level Binary Logistic Regression was chosen to test Hypotheses 1-11, because the dependent variable, 30 Day Readmission, is dichotomous and the independent variables are both categorical and continuous. Binary Logistic Regression is best suited to test for relationships between the eleven social factors IVs and the DV. Chi-square tests was used to test the Categorical Independent Variables to comprehend what to anticipate for these IV before running the full Two-Level Binary Logistic Regression (Field, 2013).

Table 4

Pearson Chi-Square Test for Dichotomous Variables

Independent Variables	**Chi-Square Value**	***df***	***Chi Square pValue***	**Cramer's V Value**	**Cramer's V pValue**
Race/Ethnicity	66.503	4	.000	.029	.000
Insurance Type	217.964	3	.000	.053	.000
Language	5.406	2	.067	--	--
Age	96.825	6	.000	.035	.000
Gender	21.488	1	.000	.017	.000
Smoking History	32177.730	1	.000	.644	.000

Chi-Square was used to examine whether a relationship exists between race/ethnicity and 30-Day Readmission. The results are shown in Table 4. The relationship between these variables is significant, $X^2(4) = 66.503$, $p < .01$, p=.000. Race/Ethnicity Category*30 Day Readmission in Figure 9 displays a line chart Latinos/Hispanics followed by Blacks/African Americans were the highest. Cramer's V analysis was used following the significant Chi-Square Test to analyze the strength of the relationship between two or more nominal variables: Race/Ethnicity and 30-Day readmission. The results are shown in Table 4. The Cramer's V value =.029, which indicates a weak association or small effect.

Chi-Square was used to examine whether a relationship exists between insurance and 30-Day Readmission. The results are presented in Table 4. The relationship between these variables is significant, $X^2(3) = 217.964$, $p < .01$, p Value=.000. There is a relationship between Hudson County, New Jersey patient's type of insurance and readmissions to hospitals within 30 days of discharge. The likelihood of being readmitted to the hospital within 30 days is not equally distributed throughout Hudson County, New Jersey. We can reject the null Hypothesis and predict that there is an association between a patient's insurance and a patient's likelihood of being readmitted. Cramer's V is best used when there are more than two categories in one of the variables to test for the strength of the association of the IV to the DV (Field, 2013). Cramer's V value is .053, as shown in Table 4, represents a weak association between Insurance and 30-Day Readmission. (Field, 2013).

The Chi-Square test was computed, with the results shown in Table 4, to test the relationship between language and 30-Day Readmission with the results, $X^2(2) = 5.406$, $p > .05$, p value= .067, which is <u>not</u> significant. Therefore, we fail to reject the Null Hypothesis.

Significant results for gender are shown in Table 4 (Chi Square – Gender vs. 30-Day Readmission) $X^2(1) = 21.488$, $p < .01$. supports rejecting the Null Hypothesis, that there is a relationship between Gender and 30-Day Readmission.

The last factor under examination is smoking history. Chi-square was again used to test for a relationship between smoking and 30-day readmission. The result was significant, as illustrated in Table 4, as $X^2(1) = 32177.730$, $p < .0.1$, p Value=.000. Cramer's V analysis was performed to evaluate the strength of the association between smoking and 30- Day Readmission with the results shown in Table 4. The Cramer's V value is 0.644, which indicates a strong association between smoking history and being readmitted to the hospitals within 30 days of discharge. This result supports that there is a relationship between smoking and being readmitted to the hospital within 30 days of discharge.

Two- Level Binary Logistic Regression (TLBLR) Analysis

Two-Level Binary Logistic Regression was the statistical test used to analyze whether relationships exist between eleven social factors, all together, and being readmitted to an acute care hospital within 30 days of discharge. Two-Level Binary Logistic Regression was chosen to test Hypotheses 1-11 because the dependent variable, 30-Day Readmission is dichotomous, and the independent variables are both categorical and continuous and control confounding variables. The results of this analysis can be found in Table 5 below (Field, 2013).

Analysis by Hypotheses

Two-Level Binary Logistic Regression - Variables in the Equation Table 5, displays the significance for each of the independent variables and the sub-categories within each IV and the Odds Ratio.

H1: There is a relationship between a patient's RACE/ETHNICITY and readmissions to hospitals within 30 days of discharge.

Race/ethnicity category the subcategory Latino/Hispanics and Black/African American were significant with a p value of .001 and 0.000 ($p<.05$) with an Latinos/Hispanics OR 1.282 and Blacks/AA 1.235, which can be interpreted as Latinos/Hispanics and Black/African Americans in Hudson County, NJ are 1.282 and 1.235 times more likely to be readmitted to an acute care hospital within 30 days compared to other races/ethnicities.

H2: There is a relationship between a patient's INSURANCE and readmissions to hospitals within 30 days of discharge.

All sub-categories for Insurance Type were significant with a p value .000 ($p<.05$). Medicaid $p<.001$ had the highest Odds Ratio (OR) of 1.67 meaning Medicaid patients 1.67 times the odds of being readmitted within 30-days than patients with other insurance in Hudson County, NJ.

H3: There is a relationship between a patient's AGE and readmissions to hospitals within 30 days of discharge.

Age analysis using Chi-Square was significant $X^2(6) = 96.852$, $p <.0.1$, p Value=.000. The Two-Level Binary Logistic Regression Results: Subcategory 6: (70-79 years old): p value = .001, with an OR of 1.745. Subcategory 7: (> 80 years old): p value = .000 with an OR 1.756. Meaning the chances of being readmitted to the hospital within 30 days is 1.756 the odds for 70-79 year olds and 1.745 the odds for 80 plus year old than younger patients.

H4: There is a relationship between a patient's LANGUAGE (English, Spanish, Other) and readmissions to hospitals within 30 days of discharge.

The Chi-Square result for Language was NON-significant $X^2(2) = 5.406, p >.05$, *p value= .067*. The MLBLR calculation are significant. Subcategory Spanish: p value = .000, with an OR of 1.206. Meaning Spanish speaking patients have 1.206 the odds of being readmitted within 30 days compared to English speaking patients.

H5: There is a relationship between a patient's GENDER and readmissions to hospitals within 30 days of discharge.

Gender (Male) was also significant with a p Value<.001, p=.0045 and an Odds Ratio of .869 which is less than one, meaning Males have .869 times the odds of being readmitted than females.

H6: There is a relationship between a patient's SMOKING HISTORY and readmissions to hospitals within 30 days of discharge.

The Chi-Square result for Smoking History was significant $X^2(1) = 32177.730$, p<.01,

p Value=.000. MLBLR Results: Subcategory #1 Smoking History: p value = .000, with an OR of 10.176. Smokers had a significant p value of .000 with an odds ratio of 10.176 , meaning smokers had chances of readmission 10.176 times the odds of non-smokers. This a very high OR suggesting a strong relationship between smoking and re-hospitalization. (Field, 2013)

H7: There is a relationship between a patient's community median household INCOME and being readmitted to the hospital within 30 days of discharge.

The median household income TLBLR finding was significant at all subcategory levels.

Income Subcategory: <$49K poverty level: significant p value of .000 and highest OR 2.477. Meaning patients who live in a community with a median house hold income of <$49K have 2.477 the odds of being readmitted within 30 days than other income levels.

H8: There is a relationship between a patient's community EDUCATION LEVEL and being readmitted to the hospital within 30 days of discharge.

The TLBLR produced significant findings for education level. Education: p value = .000, with an OR of 1.013. Meaning there is a relationship between the education level of the community in which a patient lives, and the likelihood of them being readmitted to the hospital with 30 days of discharge, with an OR 1.013.

H9: There is a relationship between a patient's community UNEMPLOYEMENT RATE and being readmitted to the hospital within 30 days of discharge.

The TLBLR produced Non-significant findings for unemployment rate. Unemployment Rate: p value = .212 with an OR of 1.045.

H10: There is a relationship between a patient's community CRIME Index and being readmitted to the hospital within 30 days of discharge.

Non-significant findings for crime index were also found. Crime Index: p value = .457, with an OR of .995.

H11: There is a relationship between a patient's community percent of FOOD Assistance and being readmitted to the hospital within 30 days of discharge.

The TLBLR results were significant for food assistance. Food Assistance: p value = .000, with an OR of 1.182 Meaning there is a relationship between percentage of people needing food assistance of the community in which a patient lives and the likelihood of them being readmitted to the hospital with 30 days of discharge, with an odds of 1.182 compared to patient living in neighborhoods with low percentage of people requiring food assistance.

Table 5

Two-Level Binary Logistic Regression - Variables in the Regression Equation

Model Term	pValue	OR
Intercept	0.000	0.064
Insurance: Self-Pay	0.048	0.658
Insurance: Private	0.000	0.776
Insurance: Charity Care	0.000	0.508
Insurance: Medicaid	0.000	1.670
Insurance: Medicare		
Gender: FEMALE	0.045	0.869
Gender: MALE		
Race: Other/Mixed	0.470	1.102
Race: Asian	0.648	1.049
Race: Latino/Hispani	0.001	1.282
Race: Black/AA	0.000	1.235
Race: White		
Age: >80	0.000	1.756
Age: 70-79	0.001	1.545
Age: 60-69	0.013	1.248
Age: 50-59	0.508	1.041
Age: 40-49	0.589	0.958
Age: 30-39	0.150	0.936
Age: 19-29		
Language: Spanish	0.000	1.206
Langusge: English		
SMOKE: Yes	0.000	10.176
SMOKE: No		
Income: <$49K	0.000	2.477
Income: $50K-59K	0.036	1.376
Income: $60K - $69K	0.000	2.252
Income: $70K- $79K	0.040	1.384
Income: $80K-99K	0.000	1.219
Income: $100K		
Education Level: Bachelors	0.000	1.013
UnemploymentRate	0.212	1.045
CrimeIndex	0.457	0.995
FoodAccess	0.015	1.182

Probability distribution: Binomial
a. Target: 30-Day Readmission Y/N

Table 6

Hypotheses Summary

Individual Hypotheses	**Conclusions**
H1: There is a relationship between a patient's RACE/ETHNICITY and readmissions to hospitals within 30 days of discharge.	Reject the Null Hypothesis
H2: There is a relationship between a patient's INSURANCE and readmissions to hospitals within 30 days of discharge.	Reject the Null Hypothesis
H3: There is a relationship between a patient's AGE and readmissions to hospitals within 30 days of discharge.	Reject the Null Hypothesis
H4: There is a relationship between a patient's LANGUAGE (English, Spanish, Other) and readmissions to hospitals within 30 days of discharge.	Reject the Null Hypothesis
H5: There is a relationship between a patient's GENDER and readmissions to hospitals within 30 days of discharge.	Reject the Null Hypothesis
H6: There is a relationship between a patient's SMOKING HISTORY and readmissions to hospitals within 30 days of discharge.	Reject the Null Hypothesis

Community Hypotheses	Conclusions
H7: There is a relationship between a patient’s community median household INCOME and being readmitted to the hospital within 30 days of discharge.	Reject the Null Hypothesis
H8: There is a relationship between a patient’s community EDUCATION LEVEL and being readmitted to the hospital within 30 days of discharge.	Reject the Null Hypothesis
H9: There is a relationship between a patient’s community UNEMPLOYEMENT RATE and being readmitted to the hospital within 30 days of discharge.	Fail to Reject Null Hypothesis
H10: There is a relationship between a patient’s community CRIME Index and being readmitted to the hospital within 30 days of discharge.	Fail to Reject Null Hypothesis
H11: There is a relationship between a patient’s community percent of FOOD Assistance and being readmitted to the hospital within 30 days of discharge.	Reject the Null Hypothesis

Summary Chapter 4

The primary reason for this study was to identify whether Social Determinants of Health (SDOH) are impacting a patient’s likelihood of being readmitted to an acute care hospital within 30 days of discharge. Table 6 above summarizes the eleven hypotheses under investigation. Following analysis using Chi-Square and Two-Level Binary Logistic Regression, 9 of the 11 social factors produced significant p values <.05, allowing the Null Hypothesis to be rejected for

- Individual: Race/Ethnicity, Insurance, Age, Gender, Smoking History, Language
- Community: Income, Education and Food assistance.

In addition to p values, an Odds Ratio was computed to determine the odds of patients being readmitted within 30-Days of Discharge. The Cramer's V and Nagelkerke R Square calculation accounted for the amount of variation in the dependent variable that can be explained by the independent variables. A detailed discussion of the interpretation of the results, conclusions, health care policy implications, recommendations for practice, study limitations, and implications for future research will be provided in Chapter 5.

Chapter 5

Discussion and Conclusions

The primary aim of this research is to explore what social determinants of health, for patients in Hudson County, New Jersey, are associated with the likelihood of being readmitted into the hospital within 30 days of discharge. The results of this study support the findings from Barnett's and other research that there is an association between patient characteristics' and hospital readmission rates. Chapter 5 contains a detailed discussion of the interpretation of the results from Chapter 4, recommendations for current practice, study limitations, implications for future research, conclusions, and health care policy implications.

The Research Question under investigation was:

Is there a relationship between specific social determinants of health (SDOH) and the likelihood of readmission to a hospital within 30 days?

INDIVIDUAL FACTORS	COMMUNITY FACTORS
1) Race/Ethnicity	1) Education Level
2) Insurance	2) Median Household Income
3) Age	3) Unemployment Rate
4) Language	4) Food Assistance
5) Gender	5) Neighborhood Crime Index
6) Smoking History	

Ecological Theory and SDOH Framework

Interaction between an individual and community emerged as a theme in the literature and was further supported by the Ecological Theory. The Ecological Theory was used as a basis for designing my SDOH Framework. Ecological Theory and my SDOH Framework accord with the study findings they both stress the importance of approaching health outcomes at different levels and how individuals have an impact on and are impacted by the community in which they live. The study results indicate that community attributes such as income, education and food assistance influence readmission. The data suggests individual factors such as race/ethnicity, insurance, age, gender, smoking history, language have a relationship to readmission. Joynt (2017) and Barnett et al. (2015) both agree. They discuss the criticality of interaction between individuals and the communities in which people live. The variation in 30-day readmission rates had more to do with individual patient characteristics and community attributes than the quality of the care while in the hospital (Joynt, 2017).

My Social Determinants of Health Conceptual Framework depicted in Figure 1 was created from an amalgamation of several Conceptual Frames found in the literature (see Figure 8). Ecological Theory was used as a basis to develop the my conceptual SDOH Framework as well. My Social Determinants of Health Conceptual Framework was used to select specific independent variables and guide the analysis of the data. My framework depicts two levels: Individual and Community with a two-way arrow showing an interaction between the levels. Each level is aligned with social factors with an arrow pointing toward health outcomes to depict the impact that the factors within the levels have on health outcomes. 30-day hospital readmission is considered a health outcome in this conceptual frame and in the literature.

Interpretation of Results

Should 30-Day Readmission be used as a quality indictor?

Whether or not 30-day readmission should even be a measure for quality of care while in the hospital came up in the literature several times. Unfortunately, many of the social factors that predict poor health outcomes, like the one's below, are outside the control of the hospital (Barnett 2015). The Null Hypothesis was rejected for: Individual: Race/Ethnicity, Insurance, Age, Gender, Smoking History, Language. Community: Income, Education and Food assistance. This calls into questions whether readmission rate should even be used as an indicator of quality hospital care and thereby used as a basis for such large financial penalties against hospitals. According to Joynt (2017), the main factors that impacted the variation in 30-day readmission rates had more to do with individual patient characteristics and community attributes than the quality of the care while in the hospital.

Two-Level Binary Logistic Regression (BLR) was the primary statistical test used to analyze a retrospective data base of over 77,000 patients from a large urban hospital in Hudson County, New Jersey. Preceding Chi-Square tests were run on the data to provide further insight into what could be expected, once the Binary Logistic Regression was computed. Subsequent analyses were also applied such as an Odds Ratio, which predicts the chances of occurrence, and Cramer's V and Nagelkerke R-Square, that are both used to measure the magnitude of the effect of the IVs on the DV (Field, 2013)

My Thoughts on WHY these findings?

Social position and social power control access to health care. Income, education, employment, gender and race dictate social position and power to obtain resources. Social stratification limits power and access to resources to those in the lower rungs. The unequal distribution of factors impacting health outcomes across social groups/neighborhoods influences access and knowledge. Individual's experiences and exposure can make people more vulnerable to disease and more likely to be exposed to harmful situations (neighborhood, employment, food access, crime). Cultural norms and behaviors can lead to poor health habits. According to WHO "Health status and outcomes among oppressed racial/ethnic groups are often significantly worse than those registered in more privileged groups" (WHO, 2010, p.34,). Social power plays a major role in health care trends. Income, socio-economic status (SES), education, and race determine the level of power for individuals and groups, controlling access to health care resources (WHO, 2010).

Income <$49K poverty level had significant p value of .000 and highest OR 2.477. Meaning patients who live in a community with a median house hold income of <$49K have 2.477 the odds of being readmitted within 30 days than other income levels. This suggests that low income contributes to an unequal distribution of resources which aligns with the income/SES and insurance, whereby groups and individuals at the lower end of the spectrum have less, and those at the upper end, have more access to care (WHO, 2015). Likewise with Education: p value = .000, with an OR of 1.013. Meaning there is a relationship between the education level of the community in which a patient lives, and the likelihood of them being readmitted to the hospital with 30 days of discharge, with an OR 1.013. "Patient factors such as race, ethnicity, education, income, and payer have been found to be related to readmission" (Nagasako et al., 2014, p.2). This sliding scale is commonly referred to in the literature, as the gradation of health and health outcomes across the population (WHO, 2015). The results of this study are supported by the WHO. Race/Ethnicity, Income, Education and Insurance Status were all found to have a relationship to hospital readmission. Income, insurance and socio-economic status determine how much access people have to health care and resources.

Smokers had a significant finding they chances of readmission 10 times the odds of non-smokers. Food Assistance was a relationship between the needing food assistance of the community in which patients' live and the likelihood of them being readmitted to the hospital with 30 days of discharge, with a higher odds compared to others. The US spent more on Health Care Delivery than on Social Service programs, like smoking cessation and food assistance programs, in recent years. However, research revealed that social characteristics and healthy behaviors were the most important determinants of health outcomes like readmission (Heiman & Artiga, 2015). Both Gender and Language were significant. The data suggests a relationship exists. The literature suggests people with limited English proficiency have difficulty navigating the health care systems and are more likely to be readmitted. Barnett (2015) found that 22 out of 29 characteristics were significant for predicting hospital readmission.

Crime Index and Unemployment Crime Index and Unemployment: Both factors were non-significant indicating no relationship with 30-day readmission. These findings disagree with the literature which state that violence in the community or neighborhood and employment have an impact on health outcomes. Further review and analysis into why these finding would be needed to discover why.

Health Care Policy Implications

The results of this study support the findings from Barnett's research on patient characteristics' association with hospital readmission rates. We can conclude that for this study, nine out of the eleven social factors under review had significant relationships. Patient social characteristics are key drivers of the health outcomes and in this case, their likelihood to be readmitted to the hospital. This is important because Center for Medicare/Medicaid Services (CMS) penalizes health care organizations who have excessive readmission rates. CMS currently only adjusts its calculation for penalties, based on Age, Sex, Discharge Diagnosis and Recent Diagnoses (Barnett, 2015).

An important policy question to consider is, when these patient characteristics with strong associations with hospital readmission and other poor health outcomes are not evenly distributed across hospital patient populations, should CMS treat all hospitals the same? Should an adjustment be made in the calculation of penalties for the hospitals serving a disproportionate number of high-risk patients? This is a critical issue for hospital administrators because fines are generated by reducing their annual reimbursement by 3%, which is equivalent to millions of dollars. In 2014, the second year of the Hospital Readmission Reduction Program (HRRP), 2610 hospitals were fined a total of $428 million collectively for higher than expected readmission rates. Unfortunately, many of the social factors that predict poor health outcomes are outside the control of the hospital (Barnett, 2015). This study and other research show that the higher the prevalence of these predictive social factors, the higher the odds of a readmission occurring. This calls into questions whether readmission rate should even be used as an indicator of quality care and also used as a basis for such large financial assessments. The money being spent to pay these fines, could be reallocated to pay for much needed social programs, like smoking cessation counseling, Limited English Proficiency (LEP), college preparation, and food insecurity programs (Barnett, 2015). These hefty fines are depleting the resources needed to pay for social programs and exacerbating the problem. It is also important to be cautious not to mask the disparities in high risk communities, where resources and funding are desperately needed to support high-risk groups. We also do not want to hold hospitals in high-risk communities to a lower standard of quality and expectation to provide adequate discharge planning and coordination of care.

Healthcare Data Management is a key component of the SDOH problem. Slabodkin's article discusses the criticality of data collection during the initial intake assessment of patients in the hospital, to include the key predictors in the electronic medical record. One of the issues is lack of access to standardized data that could be aggregated across multiple health systems. We have no standardized "clinical vocabulary" across Electronic Medical Record Systems. Therefore, aggregating the information remains difficult. Having this information on every patient would improve clinical decision making and the predictability of the patients' outcome and allow for population predictions for resource allocation and policy development. Clinical electronic systems for medical information are not currently designed to collect many of the meaningful social determinants, like employment, physical living environment, and food insecurity. Collecting this data electronically could be very helpful in identifying trends and improving the overall health of the population (Slabodkin, 2017). One suggestion would be to use each hospitals' historical performance or baseline data and require a percentage improvement over last period's performance, rather than applying the same formula of expected vs. actual across the board. (Slabodkin, 2017).

Recommendations for Practice

The literature contains extensive discussion about how and what individual practitioners can do to impact readmission rates. Nguyen (2016) emphasized the reasons why physicians should care about SDOH, when treating patients. Her research found that when physicians address physical and social issues together, there is a synergistic effect on improving the patient's overall health (Nguyen, 2016). Historically, until the late 1980s, the practice of medicine had been focused on bio-medical knowledge and treatment of patients by physicians. The results of this study support including specific social characteristics into the overall admission assessment and treatment plan developed by care providers, when caring for hospitalized patients (Nguyen, 2016). Knowing and understanding social factors about the patients may help the doctors and nurses predict which patients are more at risk for a readmission, thereby taking steps to actively prevent it. The literature also talks about conducting a thorough discharge planning process beginning on the first day of admission. Connecting to and coordinating with the post-acute care team, home health and primary care providers reduces chances of readmission, according to Barnett.

Specifically, the following suggestion for improving current practice are listed below:

1) Involve patients and family members in health care decisions.
2) Promote an Advanced Medical Home Model that addresses wide array of individuals' needs, including environmental and socioeconomic factors contributing to their ongoing health.
3) Utilizing social workers, nurses and non-clinical navigators to support, advocate for, and motivate chronically ill patients using an innovative 'point-driven' financial rewards system.

4) Establishing a Community Health Trust of local businesses, local DOH, schools, banks, gyms, and advocacy groups.
5) Improve discharge planning
6) Care coordination
7) Help connect high utilizers of hospital EDs with primary care providers.
8) Follow-up phone calls
9) Communication with long-term care facilities
10) Contacting primary care providers and assisting with follow-up appointments
11) Facilitating medication-related issues

Knowing and understanding social factors about the patients, and the communities in which they live may help the doctors and nurses predict which patients are more at risk for a readmission and thereby take steps to actively prevent it (Hines & Barrett, 2015). Social determinants of health play a key role in this movement toward care across the continuum and Accountable Care Organizations.

Study Limitations

Although the use of a retrospective database has its advantages, one limitation for using this method is that the data was collected prior to developing the research questions. Therefore, the database may or may not contain the needed information to answer the research questions completely. There are several social factors discussed in the literature as having a potential impact on health outcomes. However, they are not necessarily all available in the retrospective data base retrieved for this study from the patient electronic medical records. A second constraint involves extraneous variables and confounding variables not present in the data base that may be influencing the patient's odds of being readmitted. These phantom factors could be the strongest predictors and we would never know, because they are either suppressed or not available in the data base. Another key limitation is that the data base is from one hospital in Hudson County, NJ and may not be generalizable to a larger population in the state or the U.S.. Raw data files also often have extreme outliers that may skew the results. Another key limitation is that the database does not contain information on whether each patient was re-admitted to another hospital, which could minimize the re-hospitalization rate. A final weakness in the study is that with the retrospective data analysis the researcher was unable to ask the patients questions to probe deeper into whether they thought they had to return to the hospital for care. It's possible that their explanation had nothing to do with any social factors but possibly some other reason.

Implications for Future Research

Further investigation into the extent of the impact of social factors on health outcomes is still needed. Exploration into whether 30-Day Readmission is even an appropriate measure of quality for hospitals merits further examination. The inclusion of risk adjustments in the CMS calculation is not resolved and requires more research to determine if the advantages of including SDOH to "even the playing field" between hospitals, outweighs the disadvantages of masking the gaps between different communities. Masking these differences could mistakenly limit the allocation of much needed funding and social programs. There is a need for scientific studies on this topic, which can pose methodological complications, when trying to set up a control group vs. an experimental group, when dealing with social factors. For example, creating or removing food insecurity or exposure to poverty and poor living environments could be considered unethical. Much could be gained from future comprehensive prevalence studies on the local and state level, comparing between communities to identify specific needs and a method to prioritize those needs. The field would be greatly enhanced with more studies on the effectiveness of medical care and community collaboration to address these unmet social needs across populations.

Summary of Conclusions

The conclusions found in this study indicate that significant relationships exist between SDOH and being readmitted to an acute care hospital. Nine of the eleven social factors produced significant p values <.05.

The Null Hypothesis was rejected for:

Individual: Race/Ethnicity, Insurance, Age, Gender, Smoking History, Language.

Community: Income, Education and Food assistance.

Failed to reject the null hypothesis for:

Community: Unemployment Rate and Crime.

Many of these social factors are not under the direct control of the hospitals where these patients are being discharged. However, hospitals are being held accountable for preventing re-hospitalization and lowering their readmission rates. In fact, The Center for Medicare/Medicaid Services (CMS) mandates that Acute Care Hospitals pay large fines, when they experience high readmission rates, even when the readmissions are out of the hospital's direct control and non-preventable (CMS). This study provides evidence in support of changing the CMS policy to take SDOH into consideration, when applying financial penalties to hospitals, in particular urban hospitals with ethnically diverse communities, and large Medicaid populations. Nagasako et al. (2014) discussed whether adding socioeconomic factors to the financial penalty calculation would, "level the playing field". Hospitals with a large percentage of high-risk patients for readmission would not be evaluated using the same criteria as those hospitals that do not (Nagasako et al., 2014). The funds lost to penalties could be reallocated to much needed social programs to help the at-risk hospitals provide social services. These social service programs could perhaps prevent future readmissions.

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Appendix

Appendix A

SETON HALL UNIVERSITY
1856

September 26, 2018

Wren M. Lester

Dear Mr. Lester,

The Seton Hall University Institutional Review Board has reviewed your research proposal entitled "Relationships Between Social Determinants of Health and Patient Readmissions to an Acute-Care Hospital within 30 Days of Discharge" and has categorized it as exempt.

Enclosed for your records is the signed Request for Approval form.

Please note that, where applicable, subjects must sign and must be given a copy of the Seton Hall University current stamped Letter of Solicitation or Consent Form before the subjects' participation. All data, as well as the investigator's copies of the signed Consent Forms, must be retained by the principal investigator for a period of at least three years following the termination of the project.

Should you wish to make changes to the IRB approved procedures, the following materials must be submitted for IRB review and be approved by the IRB prior to being instituted:

- Description of proposed revisions;
- *If applicable*, any new or revised materials, such as recruitment fliers, letters to subjects, or consent documents; and
- *If applicable*, updated letters of approval from cooperating institutions and IRBs.

At the present time, there is no need for further action on your part with the IRB.

In harmony with federal regulations, none of the investigators or research staff involved in the study took part in the final decision.

Sincerely,

Mary F. Ruzicka, Ph.D

Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

cc: Dr. Ning Jackie Zhang

Office of Institutional Review Board
Presidents Hall • 400 South Orange Avenue • South Orange, NJ 07079 • Tel. 973 313 6314 • Fax 973 275 2361 • www.shu.edu

REQUEST FOR APPROVAL OF RESEARCH, DEMONSTRATION OR RELATED ACTIVITIES INVOLVING HUMAN SUBJECTS

Proposal Title: **RELATIONSHIPS BETWEEN SOCIAL DETERMINANTS OF HEALTH AND PATIENT READMISSIONS TO AN ACUTE-CARE HOSPITAL WITHIN 30 DAYS OF DISCHARGE**

CERTIFICATION STATEMENT:
In making this application, I(we) certify that I(we) have read and understand the University's policies and procedures governing research, development, and related activities involving human subjects. I (we) shall comply with the letter and spirit of those policies. I(we) further acknowledge my(our) obligation to (1) obtain written approval of significant deviations from the originally-approved protocol BEFORE making those deviations, and (2) report immediately all adverse effects of the study on the subjects to the Director of the Institutional Review Board, Seton Hall University, South Orange, NJ 07079.

Wren M. Lester

PRINCIPAL INVESTIGATOR -RESEARCHER

Aug 10, 2018

DATE

My signature indicates that I have reviewed the attached materials of my student advisee and consider them to meet IRB standards.

9/10/18

Ning Jackie Zhang, MD, PhD, MPH, Committee Chair
Associate Dean for Academic Affairs
Professor of Health Sciences and Administration
RESEARCHER'S FACULTY ADVISOR

DATE

The request for approval submitted by the above researcher(s) was considered by the IRB for Research Involving Human Subjects Research at the ___ Sept 2018 ___ meeting

The application was approved ✓ not approved ___ by the Committee. Special conditions were ___ were not ✓ set by the IRB. (Any special conditions are described on the reverse side.)

Mary F. Ruzicka, Ph.D

DIRECTOR, SETON HALL UNIVERSITY INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

9/26/18

DATE

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Certificate of Approval

THE FOLLOWING WERE APPROVED

INVESTIGATOR: Wren M. Lester, MS

BOARD ACTION DATE: 11/21/2017
PANEL: 5
STUDY APPROVAL EXPIRES: 11/21/2018
STUDY NUM: 1180801
WIRB PRO NUM: 20172634
ONLINE TRACKING: 11-1915539
INVEST NUM: 229116
WO NUM: 1-1045015-1
CONTINUING REVIEW: Annually
SITE STATUS REPORTING: Annually
INST. NUM:

SPONSOR: Wren Lester
PROTOCOL NUM: Quality2017-02
AMD. PRO. NUM:
TITLE:
Relationships between social determinants of health and patients' likelihood to be readmitted to an acute care hospital within 30 days of discharge.

APPROVAL INCLUDES:
Investigator
Administrative Letter (11-21-2017))
Protocol (11-09-2017)

WIRB APPROVAL IS GRANTED SUBJECT TO:
The Board found that this research meets the requirements for a waiver of consent under 45 CFR 46.116(d).

WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:
Jersey City Medical Center, 355 Grand Street, Jersey City, New Jersey 07302

If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. Although a participant is not obliged to give his or her reasons for withdrawing prematurely from the clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights.

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789
This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB), OHRP/FDA parent organization number IORG 0000432, IRB registration number IRB00000533. WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Full AAHRPP Accreditation

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3. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate. (Due to the unique circumstances of research conducted at international sites outside the United States and Canada, when there is a local IRB and WIRB approved materials are reviewed by the local IRB and translated into the local language, the following requirements regarding consent forms bearing the WIRB approval stamp and regarding certification of translations are not applicable.)
   a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.
   b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB unless other arrangements have been made and approved by WIRB.
   c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.

4. Enrollment of limited readers and non-readers: unless consent has been waived or the protocol excludes enrollment of limited readers or non-readers, involve an impartial witness in the consent process when enrolling limited or non-readers and document the participation of the impartial witness using the designated signature lines on the WIRB-approved consent form. In the absence of designated signature lines, download the WIRB standard impartial witness form from www.wirb.com.

5. Enrollment of pregnant partners that do not have the capacity to consent for themselves and require consent be provided by a legally authorized representative: unless the protocol excludes the enrollment of pregnant partners that do not have capacity to consent for themselves, obtain consent from the pregnant partners legally authorized representative and document consent using the pregnant partner legally authorized representative signature lines on the WIRB-approved consent form. In the absence of designated signature lines, download the WIRB standard legally authorized pregnant partner form from www.wirb.com.

6. Obtain pre-approval from WIRB for changes in research.

7. Obtain pre-approval from WIRB for planned deviations and changes in research activity as follows:
   - If the research is federally funded, conducted under an FWA, or is a clinical investigation of a drug or biologic, then all planned protocol deviations must be submitted to WIRB for review and approval prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects [(DHHS 45 CFR § 46.103(b)(4); (FDA 21 CFR § 56.108(a)(4); ICH 3.3.7].
   - However, if the research is a clinical investigation of a device and the research is not federally funded and not conducted under an FWA, then only planned protocol deviations that may adversely affect the rights, safety or welfare of subjects or the integrity of the research data should be submitted to WIRB for review and approval prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects [(DHHS 45 CFR § 46.103(b)(4); (FDA 21 CFR § 56.108(a)(4); ICH 3.3.7].

   The reason for these different requirements regarding planned protocol deviations is that the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) drug and biologic divisions have adopted the regulatory interpretation that every planned protocol deviation is a change in research that needs prior IRB review and approval before implementation; however, the FDA device division operates under a distinct regulation (See 21 CFR 812.150(a)(4).

   Deviations necessary to eliminate apparent immediate hazards to the human subjects should be reported within 10 days.

8. Report the following information items to the IRB within 5 days:
   a. New or increased risk
   b. Protocol deviation that harmed a subject or placed subject at risk of harm
   c. Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
   d. Audit, inspection, or inquiry by a federal agency
   e. Written reports of federal agencies (e.g., FDA Form 483)
   f. Allegation of Noncompliance or Finding of Noncompliance
   g. Breach of confidentiality
   h. Unresolved subject complaint
   i. Suspension or premature termination by the sponsor, investigator, or institution
   j. Incarceration of a subject in a research study not approved to involve prisoners
   k. Adverse events or IND safety reports that require a change to the protocol or consent
   l. State medical board actions
   m. Unanticipated adverse device effect
   n. Information where the sponsor requires prompt reporting to the IRB

   Information not listed above does not require prompt reporting to WIRB.

   Please go to www.wirb.com for complete definitions and forms for reporting.

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9. Provide reports to WIRB concerning the progress of the research, when requested.

10. Ensure that prior to performing study-related duties, each member of the research study team has had training in the protection of human subjects appropriate to the processes required in the approved protocol.

Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.

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Mabel P. LaForgia, RN, DNP, RWJ Barnabas Health (RWJBH)
Wren M. Lester, MS, Jersey City Medical Center
Ning J. Zhang, Seton Hall University

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September 30, 2019

Wren M. Lester MS

SUBJECT: CONFIRMATION OF CLOSURE AND CONCLUSION OF IRB OVERSIGHT

Principal Investigator: Wren M. Lester MS
Sponsor: Wren Lester
IRB Study No.: 1180801
Institution Tracking No.:
Sponsor Pr. No.: Quality2017-02 IRB Pr. No.: 20172634

Western Institutional Review Board (WIRB) acknowledges receipt of a study closure notification for the above-referenced study. Accordingly, WIRB has closed the above-referenced study effective September 30, 2019. WIRB oversight of the investigator's conduct of this protocol has ended.

Western Institutional Review Board closes studies when it receives notification of all of the following (Study Closure form is available at www.wirb.com).

1. All subjects have finished their final visits and follow-up,
2. The sponsor or the sponsor representative has indicated the study is closed at the site, and
3. If the study was conducted under a Federalwide Assurance (FWA), all data analysis at the site is completed.

Sites must have active on-going IRB approval in order to enroll subjects, perform any study interventions, collect/report new data, and/or, if under an FWA, analyze identified data at the site.

Please note, sites that have only completed enrollment (i.e., closed to accrual) cannot be closed if data relating to subjects is still being collected.

If you believe that this study closure was requested in error, please contact us immediately to avoid a substantial gap in IRB oversight for the above-referenced research at Wren M. Lester MS's site.

cc: Mabel P. LaForgia RN, DNP, RWJ Barnabas Health (RWJBH)
Ning J. Zhang , Seton Hall University
WIRB, Study File

Appendix B

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