THE RELATIONSHIP BETWEEN COMMUNITY NEED AND 30-DAY READMISSION IN DIABETIC PATIENTS AFTER CORONARY ARTERY BYPASS GRAFT SURGERY

by

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Abstract

Short-term hospital readmissions have been directly linked to escalating healthcare costs. Coronary artery bypass graft (CABG) surgery has been identified as one of the most commonly performed procedures with a persistently elevated readmission rate despite known risk factors. Comorbid condition, diabetes mellitus, has been found to further increase the risks of readmission in the patient who underwent the CABG procedure. To date, the effects of community healthcare access needs have received little attention as a possible link to the persistently elevated short-term readmission rate in the diabetic patient after the CABG procedure. Therefore, this retrospective, quantitative study sought to explore the relationship between community healthcare access needs and 30-day hospital readmission rates in diabetic patients after Coronary Artery Bypass Graft Surgery.

Patient demographics (age, sex, race/ethnicity, employment status, marital status, health insurance, English language as primary language, housing status and high school graduate) and the community need index (CNI) score were examined. CNI score is the average of five barrier condition scores (employment, education, insurance, language, and housing) for each community based on zip code. The results of the study showed a lack of utility of the CNI score with the major findings: disabled diabetic patients were two times more likely to be readmitted than the non-disabled diabetic patient after CABG procedure regardless of community healthcare access needs.

Dedication

This work is dedicated in loving memory of my parents, Howard and Annie Sutton, and my sister, Donna Coleman, who left this world way too soon and would have loved to be here with me to celebrate and share in this moment.

Acknowledgements

The completion of this dissertation has been a laborious undertaking, and without my dissertation committee, who offered continued guidance, it would not be the dissertation that it is today. Words cannot express the appreciation and gratitude I have for my dissertation chair, Dr. Robert Denmark. As I waded through obstacles and crossroads, your long-term commitment and words of encouragement allowed for introspection and fortitude which was necessary to plow ahead. Dr. Robin Eubanks was instrumental in shaping my understanding of the larger purpose of higher education and the pursuit of meaningful research. A special thank you to Dr. Eubanks for her support and guidance in the early stages of establishing this work. Dr. Margaret Kilduff provided renewed perspectives on the project from its creation and energized me to delve more deeply into the topic by exploring different paths. Dr. Scott Parrott has transformed the study of statistics from mathematics into a deeper understanding of the underlying policy and social issues that were being examined.

Lastly, I would like to acknowledge the consistent support and encouragement from my best friend of 40 years, Kathleen McCladdie, Ed.D. Few people have the privilege of having such a supportive lifelong friend. Thanks, Kathy, for standing by me through the rough patches and encouraging me to not give up when the light at the end of the tunnel appeared very dim.

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CHAPTER 1

INTRODUCTION

The passage of the Patient Protection and Affordable Care Act (PPACA) in the United States in March 2010, signified the largest overhaul to the American healthcare system since the formation of Medicare and Medicaid in 1965 (Hannan et al., 2011; McHugh & Ma, 2013). A major goal of the PPACA is the containment of healthcare costs (Espinoza et al., 2016; Kocher & Adashi, 2011; Maniar et al., 2014). For example, the PPACA contains measures for adjustments in Medicare reimbursement based on quality of care provided:

SEC. 3001. HOSPITAL VALUE-BASED PURCHASING PROGRAM.

… Subject to the succeeding provisions of this subsection, the Secretary shall establish a hospital value-based purchasing program (in this subsection referred to as the 'program') under which the value-based incentive payments are made in a fiscal year to hospitals that meet the performance standards for the performance period for such fiscal year. Value-based incentive payments for discharges occurring on or after October 1, 2012.

Measures are selected that cover at least the following 5 specific conditions or procedures:
(a) Acute myocardial infarction (AMI).
(b) Heart failure.
(c) Pneumonia.
(d) Surgeries, as measured by the Surgical Care Improvement Project...
(e) Healthcare-associated infections, as measured by the prevention… (CMS, 2013)

While the containment of healthcare costs prior to the PPACA focused largely on the reduction of hospital length of stay (Carey, 2000), since the passage of PPACA, later referred to as the Affordable Care Act (ACA), there has been an increasing focus on containing Medicare costs by decreasing the rates of unplanned short-term hospital

readmission (USHR) after medical and surgical procedures (Desai et al., 2016; Gerhardt et al., 2013; Kocher & Adashi, 2011; Maniar et al., 2014; Wasfy et al., 2015). In October 2012, as noted in the legislative language above, the Centers for Medicare and Medicaid Services began reducing hospital reimbursements for excessive readmission (CMS, 2013). While some aspects of ACA reward hospitals with incentives, readmission statistics include possible penalties up to a maximum of 3% of a hospital's Medicare reimbursements (CMS, 2014). This makes medical facilities accountable for outcomes as well as costs associated with USHR.

USHRs place considerable financial burden on the Medicare system, costing this system approximately $26 billion annually (Currie & Lancey, 2011; Dungan, 2012; Hannan et al., 2011; Kim, Ross, Melkus, Zhao, & Boockvar, 2010). Despite the policy emphasis placed on decreasing USHRs among Medicare patients and the financial penalties, the overall 30-day readmission rate for Medicare patients had dropped only 0.6%, from 19.0% in 2010 when the ACA was initiated, to 18.4% in 2012; a decrease of roughly only $6 million (Gerhardt et al., 2013). Thereafter, the national all-cause hospital readmission rate for Medicare patients showed notable decline from 17.3% in 2013 to 15.2% in 2014 (Medicare, 2015).

Coronary artery bypass graft surgery (CABG), one of the most commonly performed surgical procedures, with a mean admission charge of roughly $100,000, has a documented high USHR rate (Bucerius et al., 2005; Carson et al., 2002; Espinoza et al., 2016; Hannan et al., 2011). The 2014 USHR rate for CABG nationally averaged 14.9%, which was higher than the readmission rate for general surgery patients, slightly less than the rate for pneumonia, and three times the rate for hip replacement (Medicare, 2015).

Even after adjusting for a mix of patient characteristics, noteworthy disparities in USHR rates exist in the post-CABG population in hospital readmission particularly those patients with comorbidities such as diabetes mellitus (Dungan, 2012; Espinoza et al., 2016; Fasten et al., 2001; Hannan et al., 2011; Lazar, H.L., 2012).

Diabetes mellitus (DM) has been associated with an increase in the risk for USHR in patients who have had CABG surgery (Dungan, 2012; Espinoza et al., 2016; Fasken et al., 2001; Hannan et al., 2011; Kim et al., 2010; Whang & Bigger, 2000). Lazar (2012) report that diabetic patients who have had CABG surgery have a greater than 20% increased likelihood of being readmitted into the hospital within the first year after surgery. Efforts to minimize risk factors for this diabetic population after CABG surgery, where the postoperative care is complex and varies widely among medical facilities, could have a major impact on USHR (Dungan, 2012; Kim et al., 2010). There is, however, a lack of consensus in the literature on the risk factors that increase odds of USHR for the diabetic patient after CABG surgery (Dungan, 2012; Espinoza et al., 2016; Fasken et al., 2001; Hannan et al., 2011; Kim et al., 2010).

Understanding what factors contribute to USHR in the diabetic population after CABG surgery is essential to developing effective counter measures. Armed with numerous predictors of USHR from prior research (Eby et al., 2015; Li et al., 2012; McHugh & Ma, 2013; Rubin, 2015), hospitals implemented protocols focused on modifiable factors within the hospital structure or medical delivery system, such as early scheduled follow-up care, with little improvement in the number of USHR. However, there are potential contributing factors that are external to the providing facility that should be considered, such as the community where patients reside and the environment in which

they receive care. Expanding the scope of predictors of USHR to include community healthcare service access factors may help hospital administrators develop interventions for diabetic patients after CABG surgery at high risk for USHR that will have a positive effect on the USHR rate.

Health disparity, based on socioeconomic barriers to healthcare access in communities, has been identified as a possible link to USHR for medical conditions and post-surgical complications that can be safely managed in an outpatient setting (Truven, 2014). The Community Need Index (CNI), a tool developed by Dignity Health in partnership with Truven Health Analytics (2014), is an index, calculated at zip code level, measuring socioeconomic barriers that affect healthcare access in a community. There are five socioeconomic barriers related to healthcare access accounted for in the CNI model which are used to indicate the overall health of a community: income, culture or language, education, insurance status, and housing. More specifically, the overall health of a community places emphasis on culture or language namely English as secondary language families, education being high school diploma or equivalency, unemployment, housing status (rent versus own), and insurance coverage (Truven, 2014). Insights into socioeconomic barriers to healthcare access in each community may reveal a correlation between healthcare access and USHR thus allowing for the creation and implementation of strategic steps to meet those community needs.

Statement of the Problem

USHRs have a negative impact on the quality of life of patients in addition to placing a substantial financial burden on the health care delivery system (Currie & Lancey, 2011; Dungan, 2012; Fasken et al., 2001; Hannan et al., 2011; Kim et al., 2010).

Readmission after major surgical procedures signifies an important outcome measure (Dungan, 2012; Hannan et al., 2011; Kim et al., 2010).

Patients who have had CABG surgery have one of the highest USHR rates of any surgical or medical procedure. The addition of comorbid DM substantially increases the risk for USHR (Dungan, 2012; Espinoza et al., 2016; Fasken et al., 2001; Hannan et al., 2011; Kim et al., 2010; Lazar, 2012; Li et al., 2012). Despite the identification of major risk factors shown to contribute to USHR in diabetic patients after CABG surgery, and utilization of these risk factors in clinical risk prediction models for readmission, the predictive capacity of USHR remains limited in this group (Hannan et al., 2011; Kim et al., 2010; Li et al., 2012). This limited discrimination suggests there may be other factors related to persistent USHR in the diabetic population after CABG surgery. There, however, has been little formal inquiry into socioeconomic indicators of healthcare access of a community as a factor in USHR. Examining communities' social and economic status via CNI score may show a correlation with high-need communities and USHR in the diabetic population after CABG surgery.

Purpose of the Study

This study examined whether there was a relationship between a single institution's rate of USHR and community socioeconomic factors, which can result in added burden to medical facilities. Utilizing Truven CNI data, this study examined the relationship between community healthcare service access via CNI score and retrospective data of 582 diabetic patients who have had CABG surgery, with and without USHR, in a Regional Medical Center in New Jersey between January 1, 2009 and December 31, 2014. The CNI tool, which utilizes five barriers to healthcare access to quantify the health of a community:

income, culture or language, education, medical insurance status and housing, was used to explore the relationship between socioeconomic indicators of healthcare access in a community and USHR in the diabetic patients who have had CABG surgery.

Research Questions

The body of literature on unplanned short-term hospital readmission (USHR) has lacked consistency in its examination of the individual and community-based antecedents of USHR among diabetic patients after CABG surgery. This may be a result of the lack of a systematic or theoretical framework. The research questions in this study were guided by Betty Neuman's (2002) Systems Theory on environmental stressors and well-being, and Truven Health Analytics' (2014) Community Need Index (CNI) tool, which assesses five barriers to healthcare access (i.e., income, culture or language, education, insurance status, and housing). Assessing individual barriers theoretically derived but not included in a framework has the potential to expand and improve the predictive capacity of readmissions risk models in the diabetic population after CABG surgery. This study has two research questions.

Research Question 1a

Is there a significant relationship between the combination of patient demographic variables (i.e., age, sex, race/ethnicity, employment status, education, language, housing, insurance status, and marital status) and the occurrence of unplanned short-term hospital readmission (USHR) in diabetic patients after CABG surgery?

H_{1o}. There is no significant relationship between the combination of patient demographic variables (i.e., age, sex, race/ethnicity, employment status, education, language, housing, insurance status, and marital status) and the occurrence of USHR in diabetic patients after CABG surgery.

Research Question 1b

Is there a relationship between the combination of patient demographic variables (i.e., age, sex, race/ethnicity, employment status, education, language, housing, insurance status, and marital status) with the addition of the CNI score and the occurrence of unplanned short-term readmission (USHR) in diabetic patients who have had CABG surgery?

H_{2o}. There is no significant relationship between the combination of patient demographic variables (i.e., age, sex, race/ethnicity, employment status, education, language, housing, insurance status, and marital status) with the addition of the CNI score and the occurrence of USHR in diabetic patients who have had CABG surgery.

Theoretical Framework

This study was guided by Betty Neuman's Systems Model, a wide-ranging holistic and system-based theoretical framework that focuses on the response of a patient to actual or perceived environmental stressors (Neuman, 2002). This model has a far-reaching, flexible framework that could guide the creation and implementation of concise strategies for prevention as an intervention including secondary and tertiary interventional measures

amenable to community need. Figure 1 depicts Neuman's Systems model showing how the patient's well-being is impacted by internal and external stressors which are labeled as intrapersonal, interpersonal and extra personal.

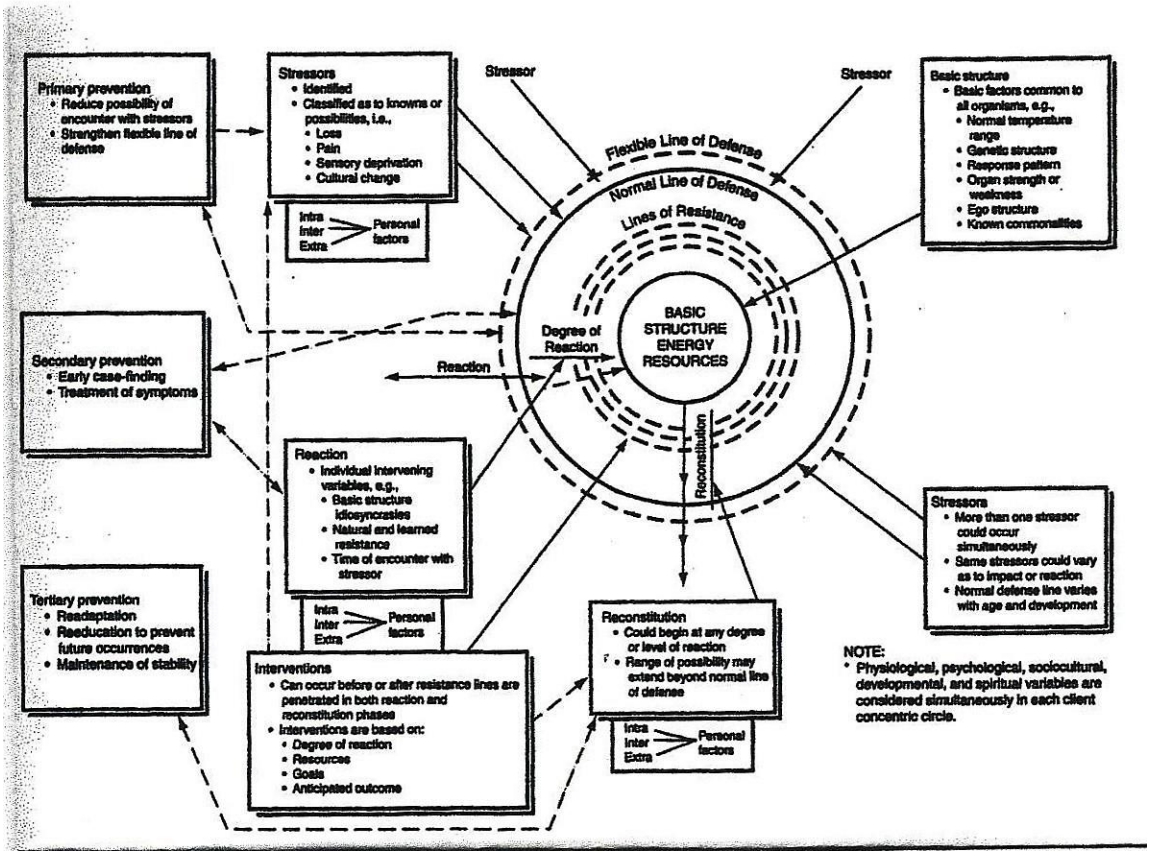


Figure 1. Betty Neuman Systems Model (Neuman, 2002).

When a patient's system is stable within their environment, the lines of defense are intact. Stressors can disturb the flexible and normal lines of defense resulting in an imbalance. In patients with chronic diseases such as DM, the normal and flexible lines of defense function as barriers to protect the diabetic patients from comorbid complications associated with DM as depicted in Figure 2. If the patient has repeated exposure to internal and external stressors, the body systems begin to break down due to weakened lines of defense.

Primary intervention in the Systems model focuses on prevention and is utilized when a stressor is suspected of causing an imbalance but has not been identified (Neuman, 2007). The emphasis is to keep stressors and their related responses from negatively affecting the body. Secondary prevention occurs after the patient has reacted to a stressor and includes treatments to bring stability to the patient's system. After the patient has been treated, any further action is referred to as tertiary prevention which focuses on supportive measures (Neuman, 2007).

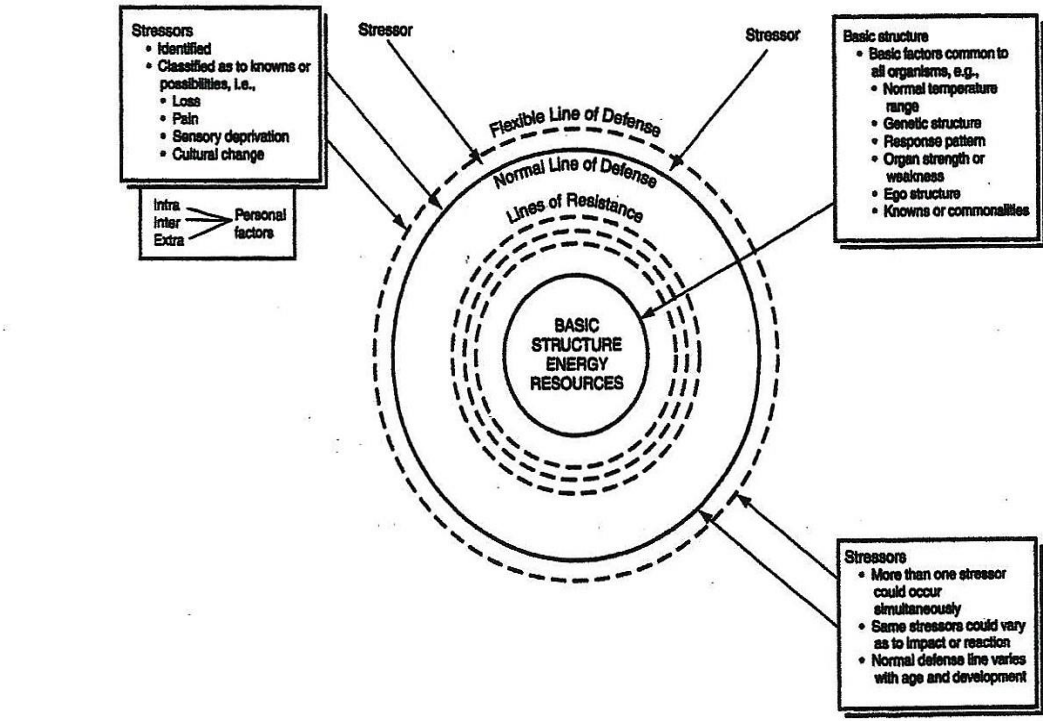


Figure 2. Emphasis on the environment in Betty Neuman's Systems Theory which is the study focus for the patient with Diabetes mellitus who have had CABG surgery.

Common stressors in patients with DM may include the intrapersonal stressor, hyperglycemia; the interpersonal stressor, minimal social support; and the extra personal stressor, restricted financial resources. Adding a surgical procedure and its aftercare to the

complex regimen of patients with DM can be overwhelming thus further weakening their lines of defense. Access to healthcare services in a given community, local transportation and financial stability are external factors that may lead to the breakdown of an individual's well-being (Neuman, 2007).

The CNI Tool developed by Truven Health Analytics (2014) reflects the concept of Betty Neuman's Systems Theory. Truven Health Analytics (2014) theorized that five barriers to healthcare access have a causal relationship regarding preventable hospitalization for controllable conditions. The healthcare access barriers are classified in the domains of patient characteristics and processes of care (Truven Health Analytics, 2014). Independent variables in this study are barriers to healthcare access identified in the Truven Health Analytics' and the external environment stressors identified in Neuman's Systems theory. USHR is the dependent variable.

Overview of Context and Methods

This was a quantitative retrospective readmission data study using archival data from medical chart reviews of 582 diabetic patients who were electively admitted for CABG between January 1, 2009 and December 31, 2014 at a regional care teaching hospital that provides comprehensive medical care to the local community and is a major referral and treatment center in Northern New Jersey.

DM status was categorized by its documentation in patients' charts, use of prescribed diabetic medications preoperatively, admission fasting plasma glucose (FPG) level and Hemoglobin A1C level (HbA1c). A total of 600 medical charts of diabetic

patients electively admitted for CABG were reviewed for the collection of pertinent laboratory data and documentation of applicable descriptive characteristics of each patient.

Significance of Study

Current healthcare policy and practice reform focus on USHR because they are common, costly and possibly preventable. Coronary artery disease (CAD) and DM are common chronic conditions associated with USHR. Coronary artery bypass graft (CABG) surgery is reported as one of the most common surgical procedures and DM is a controllable, comorbid condition known to complicate postoperative recovery in the CABG patient. Known inferior outcomes in patients with the dual diagnoses of CAD and DM increase the propensity for USHR. Examination of community socioeconomic factors in addition to known risk factors could be important to understanding if they are associated with inferior outcomes resulting in USHR in the diabetic population after CABG surgery.

The current literature on USHR in diabetic patients after CABG surgery in the United States focuses on varied patient populations, geographical locations, several healthcare settings, clinical characteristics and medical conditions (Currie et al., 2011; Dungan et al., 2012; Espinoza et al., 2016; Hannan et al., 2011; Lancey et al., 2015; Maniar et al., 2014). However, these studies do not explore the relationship of community healthcare service access factors and its possible role in the persistent USHR in diabetic patients after CABG surgery despite hospital-wide revised discharge protocols. Exploring the demographic and socioeconomic variables in conjunction with the CNI score may aid in the alignment of efforts to provide efficient, quality care to this population. It may also identify factors that, if addressed, can prevent post-discharge complications resulting in USHR which will improve outcomes for patients. Furthermore, identifying community-

based variables may benefit the healthcare facility and remedy the issue of hospitals being penalized for outcomes over which they may have little control. Hospitals will be able to strategize on a community level to identify access barriers related to USHR and create and implement measures to reduce USHR.

Definition of Terms

Community health – Community health refers to the "underlying social, economic and environmental conditions of a community such as provision of adequate timely healthcare services, individual and preventive healthcare services, and public health activities that target populations with at risk behaviors such as tobacco or alcohol abuse." (Truven, 2014).

Community need index (CNI) – Community need index (CNI) is a "tool using five socio-economic barriers to quantify access to healthcare in communities throughout the United States." (Truven, 2014).

(a) **Income** – Income barrier refers to the "percentage of elderly, children, and single parents living in poverty." (Truven, 2014).

(b) **Culture/Language** – Culture/language barrier refers to the "percentage Caucasian/non-Caucasian and percentage of adults over the age of 25 with limited English proficiency." (Truven, 2014).

(c) **Education** – Education barrier refers to the "percentage of people without high school diploma." (Truven, 2014).

(d) **Insurance status**– Insurance barrier refers to the "percentage of people uninsured or percentage unemployed." (Truven, 2014).

(e) **Housing** – Housing refers to the "percentage of people renting houses." (Truven, 2014).

Coronary artery bypass graft (CABG) surgery – Coronary artery bypass graft surgery is a "surgical bypass operation performed to shunt blood around an obstruction in a coronary artery that usually involves grafting one end of a segment of vein (as of the

saphenous vein) removed from another part of the body into the aorta and the other end into the coronary artery beyond the obstructed area to allow for increased blood flow—called also *coronary artery bypass."* (Merck Manual online dictionary, n.d.).

Coronary artery disease (CAD) – CAD is a "condition in which blood flow through the coronary arteries to the heart muscle is reduced by plaque and typically results in chest pain or heart damage—called also *coronary disease, coronary heart disease.*" (Merck Manual online dictionary, n.d.).

Diabetes mellitus (DM) – DM is a "disorder of carbohydrate metabolism caused by a combination of hereditary and environmental factors and usually characterized by impaired insulin secretion. Early symptoms may include excessive urine production, excessive thirst and hunger as well as blurred vision." (Merck Manual online dictionary, n.d.).

Home healthcare support – Home healthcare support is "part-time or intermittent medical social services provided in client's home ranging from medical supplies, medication administration to home health aides." (Medicare, n.d.).

Glycemic control – Glycemic control refers to "blood glucose control." (Merriam-Webster's online dictionary, n.d.).

Social support – Social support is "help from other people (family, friends, community) in life's difficult situations; like social network." (Rad et al. 2013).

Short-term hospital readmission – Short-term hospital readmission is a "hospital readmission within 30 days from initial discharge." (CMS, 2013).

CHAPTER II

REVIEW OF LITERATURE

Literature Review Summary

Public reporting and financial consequences motivate hospitals to implement interdisciplinary measures to decrease or prevent unplanned short-term hospital readmission (USHR). Readmissions after coronary artery bypass graft surgery (CABG) remain high in comparison to other surgical procedures, and the addition of comorbid diabetes mellitus (DM) has been shown to be a significant predictor of USHR (Dungan, 2012; Espinoza et al., 2016; Fasken et al., 2001; Hannan et al., 2011; Kim et al., 2010; Li et al., 2012; Maniar et al., 2016). Known predictors of USHR in CABG-DM are age, female gender, renal failure, stroke, obesity, postoperative atrial fibrillation and surgical wound infection (Espinoza et al., 2016; Giakoumidakis et al., 2014; Hannan et al., 2011; Maniar et al., 2016).

However, the literature suggests that additional predictors might include demographic characteristics (such as marital status, gender, and employment status) and social factors (such as overall community health, language, housing, and insurance status). Two hypotheses are proposed.

Introduction

Each year, nearly 20 percent of all Medicare patients are readmitted within 30 days after hospital discharge (New England Healthcare Institute [NEHI], 2012). USHR in the patients who have had CABG surgery is common and the comorbid condition, DM, increases the risk of USHR in this population (Dungan, 2012; Li et al., 2012; Wakefield &

Mehr, 2013). Although risk assessment models have been successfully utilized in shaping outcomes of care, substantial efforts are warranted to investigate additional factors associated with USHRs in the diabetic population after CABG surgery (Dungan, 2012; Li et al., 2012; Shahian et al., 2009; Wakefield & Mehr, 2013).

Overview of the Importance of Hospital Readmission Rates

Hospital readmission data are vital not only as a screening of the provided health care quality, but also as readmissions are costly and consume an enormous portion of health care expenses. They draw attention to the potential hazards of transitional care and management when the patient changes from inpatient to outpatient phases of healthcare (Goldfield et al. 2008).

On October 1, 2012, Centers for Medicare and Medicaid Services (CMS) initiated the Readmission Reduction Program. Readmission is defined as "*an admission to an acute care hospital within 30 days of a discharge from the same or another hospital"* (CMS, 2013). In an effort to lower healthcare costs and improve quality care, CMS began penalizing hospitals for readmissions reflecting "higher than peer rates" within 30 days of discharge for congestive heart failure (CHF), pneumonia, and acute myocardial infarction (AMI, or heart attack). The peer rate is a national average (CMS, 2013). CMS uses a 3-year rolling average in its readmission calculations. For Fiscal Year (FY) 2013, the excess readmission ratios were based on discharges during the 3-year period from July 1, 2008 through June 30, 2011 (Joynt and Jha, 2013; CMS, 2013). CMS has finalized the program's expansion to include total knee replacement, total hip replacement, and chronic obstructive pulmonary disease for FY 2015 (CMS, 2014). There is a possibility of

expansion to other classifications of diseases and inclusion of all-cause readmissions as well as adjustment of the timeframe to include 60 or 90 days.

The CMS Reduction Program conveys to all healthcare institutions that when a patient is discharged from their facility, the facility has some accountability in the continuum of care. Medicare payments to medical centers will be withheld if readmission rates are higher than peer rates (Aspenson, 2012; Meddings et al., 2016; van Walraven, Jennings & Forster, 2012). The message sent to hospitals is that medical facilities should increase efforts to provide effective interdisciplinary discharge care plans to prevent USHR related to the index admission.

The significant variation in medical facilities' readmission rates for post-surgery patients suggests the possibility that some of the readmissions are preventable (Bernheim, Grady & Lin, 2010). Disjointed and poorly organized healthcare provisions, risky shifts from inpatient to outpatient scenarios and medical mistakes are some of the factors reported as the cause of avoidable postoperative readmissions (Kocher & Adashi, 2011; Meddings et al., 2016; Rosen et al., 2013). Implemented interventions such as decreasing health personnel assignment, family inclusive discharge instructions, and early health care provider follow-up have been determined operational in depressing USHR (Jack et al. 2009).

Types of Hospital Readmissions

There are four distinct readmissions: 1) a planned readmission related to the index admission, 2) a planned readmission not related to the index admission, 3) an unplanned readmission related to the index admission, and 4) an unplanned readmission not related to the index admission (American Hospital Association, 2011). Due to the unpredictability of

unplanned, unrelated readmissions, medical policy cannot affect such admissions' occurrence. The latter type of readmission, unplanned and related to index admission, has been in the forefront of public policy efforts to reduce or prevent this type of readmission. This literature review will focus on USHR related to the initial admission of the diabetic patient who underwent CABG surgery.

Known Predictors of USHR across the Overall Patient Population

Recent empirical work on USHR has reinforced Betty Neuman's Systems Theory (Neuman, 2002) to some degree concerning USHR risk factor domains, as USHR risk factors have been consistently reported in studies falling into four risk domains: (a) patient demographic factors, (b) patient clinical conditions, (c) adverse post-surgical patient outcomes, and (d) macro-level hospital factors. Neuman's (2002) theory on environmental stressors and the response of an individual's well-being suggest the overall stability of the community as a possible factor in the decline of an individual's health after medical care.

Jencks, Williams and Coleman (2009), utilizing data from Medicare recipients, reported that congestive heart failure (CHF), pneumonia and chronic obstructive pulmonary disease (COPD) to be the most common conditions requiring USHR across the overall patient population. USHRs tend to be highest in patients who have experienced the adverse events of (a) catheter- associated urinary tract infection and (b) trauma and falls (Friedman, Encinosa, Jiang & Mutter, 2009; Kruse et al., 2013). An additional risk factor included sepsis from surgical interventions (Herwaldt et al., 2006; Kruse et al., 2013). Inferior inpatient care has also been correlated with higher unplanned readmission rates (Encinosa & Hellinger, 2008).

Known Risk Factors for USHR in Patients after CABG

Whether USHR in patients after CABG surgery is related to an exacerbation of a comorbid condition or related to the surgery itself, it still presents a challenge to the interdisciplinary team. Ten factors have been identified as significant predictors of USHR for patients after CABG surgery.

Demographic factors

Age (Ahmed, Tully, Baker & Knight, 2009; Chikwe et al., 2009; El Diasty et al., 2009; Espinoza et al., 2016; Faritous, Aghdaie, Yazdanian, Azarfarin & Dabbagh, 2011; Hannan et al., 2003; Hannan et al., 2010; Maganti, Rao, Brister, & Ivanov, 2009; Maniar et al., 2014; Toraman, Senay, Gullu, Karabulut & Alhan, 2010)

Female gender (Espinoza et al., 2016; Fasken,Wipke-Tevis & Sagehorn, 2001; Hannan et al., 2003; Koch et al., 1996; Maniar et al., 2014; Norhammer et al., 2004).

Clinical conditions

DM (Albert, Butler & Hall, 2009; Carson et al., 2002; Cwynar, O'Rourke et al., 2004; Espinoza et al., 2016; Furnary, Zerr, Grunkmeier & Starr, 1999; Hannan et al., 2011; Herlitz et al., 1996; Maniar et al., 2014; Pan, Hindler, Lee, Vaughn & Collard, 2006; Park et al., 2009)

Obesity - defined as a body mass index (BMI) of 30 or greater (Engel, McDonough & Smith, 2009; Espinoza et al., 2016; Kuduvalli, Grayson, Oo, Fabri, & Rashid, 2002; Maniar et al., 2014; Pan, Hindler, Lee, Vaughn & Collard, 2006; Yap et al., 2006)

Pulmonary disease (Adabag et al., 2009; Espinoza et al., 2016; Giakoumidakis et al., 2014; Maniar et al., 2014; Rajaei & Dabbagh, 2012).

Chronic renal insufficiency (CRI)/chronic renal failure (CRF) (Bove et al., 2004; Espinoza et al., 2016; Filsoufi et al., 2008; Maniar et al., 2014; Parikh et al., 2010).

Congestive heart failure (CHF) (Ahmed, Tully, Baker & Knight, 2009; Chikwe et al., 2009; El Diasty et al., 2009; Stewart et al., 2000; Espinoza et al., 2016; Maniar et al., 2014; Toraman, Senay, Gullu, Karabulut & Alhan, 2010).

Adverse post-surgical outcomes

Postoperative atrial fibrillation (Ahmed, Tully, Baker & Knight, 2009; Antunes, de Oliveira & Antunes, 2009; Chen, Krishnan, Sood, Kluger, & Coleman, 2010; Chikwe et al., 2009; El Diasty et al., 2009; Espinoza et al., 2016; Maniar et al., 2014; Reddy, 2001; Stewart et al., 2000; Tamis-Holland, Kowalski, Rill, Firoozi, & Steinberg, 2006).

Blood transfusion (Espinoza et al., 2016; Hannan et al., 2010; Maniar et al., 2014; Sato et al., 2009; Toraman, Senay, Gullu, Karabulut & Alhan, 2010).

Sternal wound and or saphenectomy wound infection (Espinoza et al., 2016; Hannan et al., 2003; Hannan et al., 2011; Lu, Grayson, Jha, Srinivasan & Fabri, 2003; Maniar et al., 2014; Stewart et al., 2000; Yap et al., 2006)

Known Risk Factors for USHR in Patients with DM

DM, like other chronic medical conditions, is associated with increased risk of USHR (Li et al., 2012). The 30-day readmission rate for individuals with DM is 20.3%, substantially higher than the 14.9% readmission rate for CABG and the 4.8% readmission rate for hip and knee replacement (Medicare, 2015). USHR is high as individuals with DM may struggle with controlling their glucose levels (Kim, Ross, Melkus, Zhao & Boockvar,

2011). Moreover, individuals with DM are likely to be overweight or obese and very often have comorbid medical conditions such as renal insufficiency, peripheral vascular disease (PVD) and CHF (Engel, McDonough & Smith, 2009; Hannan et al., 2011; Lancey et al., 2015; Parikh et al., 2010).

Overall compromised health in patients with DM was found to be associated with increased readmission (Howell, Coory, Martin & Duckett, 2009; Lancey et al., 2015). The most frequent condition responsible for readmission in patients with DM was CHF followed by complications of DM, septicemia and pneumonia (Kim, Ross, Melkus, Zhao & Boockvar, 2011). Prior to discharge from index admission, assessment and strategic planning of interdisciplinary measures could allow for successful outpatient management of comorbid chronic conditions (Hannan et al., 2011; Nam, Chesla, Stotts, Kroon & Janson, 2011).

Data indicates that many patients with DM with poor glycemic control often encounter barriers to care (Nam et al., 2011). Non-observance of health needs has been acknowledged as a barrier in both: the medical practitioners' failure to observe proof-centered medical guidelines and the diabetic patients 'failure to observe medically suggested treatment regimens (Grant & Meigs, 2006).

Known Risk Factors for USHR in Diabetic Patients after CABG

Diabetic patients have had worse surgical recovery outcomes following CABG surgery as opposed to their non-diabetic counterparts (Charlesworth et al. 2003, Sutton, 2010). They have higher mortality and occurrences of sepsis, stroke, sternal wound infections and renal failure, and amplified need for inotropic support (Kubal, Srinivasan,

Grayson, Fabri & Chalmers, 2005; Lancey et al., 2015; Luciani et al., 2003). Diabetic patients after CABG surgery have a higher risk of re-hospitalization and greater than 20.0% of their USHR will be cardiac related (Lancey et al., 2015; Whang & Bigger, 2000). Poor wound healing associated with DM may lead to higher rate of readmission for delayed wound healing and septic conditions (Sutton, 2010, Hannan et al., 2011; Stewart et al., 2000).

Studies on factors associated with USHR after CABG and DM similarly reported the coexistence of independent factors that increased the possibility of USHR (Giakoumidakis et al., 2014; Hannan et al., 2011; Lancey et al., 2015). Evaluating for prediction of USHR related to index admission in the diabetic population after CABG surgery is paramount in the identification and provision of necessary resources prior to hospital discharge. There were eight factors found to be significant predictors of USHR in diabetic patients after CABG surgery.

Demographic factors

Age (Ahmed, Tully, Baker & Knight, 2009; Chikwe et al., 2009; El Diasty et al., 2009; Espinoza et al., 2016; Faritous, Aghdaie, Yazdanian, Azarfarin & Dabbagh, 2011; Hannan et al., 2003; Hannan et al., 2010; Lancey et al., 2015; Maganti, Rao, Brister, & Ivanov, 2009; Toraman, Senay, Gullu, Karabulut & Alhan, 2010)

Female gender (Espinoza et al., 2016; Fasken,Wipke-Tevis & Sagehorn, 2001; Hannan et al., 2003; Lancey et al., 2015; Koch et al. 1996; Norhammer et al., 2004).

Clinical conditions

Obesity - defined as a body mass index (BMI) of 30 or greater (Engel, McDonough & Smith, 2009; Espinoza et al., 2016; Lancey et al., 2015; Kuduvalli, Grayson, Oo, Fabri, & Rashid, 2002; Pan, Hindler, Lee, Vaughn & Collard, 2006; Yap et al., 2006)

Pulmonary disease (Adabag et al., 2009; Espinoza et al., 2016; Giakoumidakis et al., 2014; Lancey et al., 2015; Rajaei & Dabbagh, 2012).

Chronic renal insufficiency (CRI)/chronic renal failure (CRF) (Bove et al., 2004; Espinoza et al., 2016; Filsoufi et al., 2008; Lancey et al., 2015; Parikh et al., 2010).

Adverse post-surgical outcomes

Postoperative atrial fibrillation (Ahmed, Tully, Baker & Knight, 2009; Antunes, de Oliveira & Antunes, 2009; Chen, Krishnan, Sood, Kluger, & Coleman, 2010; Chikwe et al., 2009; El Diasty et al., 2009; Espinoza et al., 2016; Lancey et al., 2015; Reddy, 2001; Stewart et al., 2000; Tamis-Holland, Kowalski, Rill, Firoozi, & Steinberg, 2006;).

Sternal wound and or saphenectomy wound infection (Espinoza et al., 2016; Hannan et al., 2003; Hannan et al., 2011; Lancey et al., 2015; Lu, Grayson, Jha, Srinivasan & Fabri, 2003; Stewart et al., 2000; Yap et al., 2006)

Discussion of Community Health and Readmission

Studies have shown a significant relationship between overall health and social support in patients with chronic conditions, but there are very few published data examining the relationship between patient demographics and community needs with USHR in the diabetic population after CABG surgery (Gallant, M.P., 2003; Kendall, E.,

Foster, M. M., Ehrlich, C., & Chaboyer, W., 2012). Examining the structure of a community and its targeted needs may shed light on additional predictors of USHR.

Overview of the Importance of Affordable Care Act (ACA) and Community Health

Public health policy in the United States is implemented through the ACA (Hannan et al., 2011; McHugh & Ma, 2013). The need to promote community health to all citizens is an important aspect of the ACA. Resources provided by the ACA aim to support the community through the development of channels through which leaders engage with communities to promote health and prevent spread of chronic diseases (Gallant, M.P., 2003; Kendall, E., Foster, M. M., Ehrlich, C., & Chaboyer, W., 2012) . Chronic diseases have been on the rise in the United States, and health centers have identified with readmission challenges that showcase the needs of the community (Gallant, M.P., 2003; Kendall, E., Foster, M. M., Ehrlich, C., & Chaboyer, W., 2012). This section will review the PPACA's impact on community health.

A major goal of the ACA is to improve primary care and improve health care performance (Hannan et al., 2011; McHugh & Ma, 2013). Community health necessitates adequate primary care which can be achieved through the influence of health reforms. Enhancing provisions of care to millions of American people would improve the extent to which primary care is better able to promote continued community health and reduce future costs associated with USHR (Rosenbaum, 2011).

Policymakers push for measures aimed at improving the collection of accurate demographic data which would lead to more accurate assumptions about a population. This population projection in a given community would provide a more realistic assessment of

the impact of future population growth (United Nations, 2013). Policymakers and planners view population in communities according to race/ ethnicities, language spoken and economic status. All communities do not have the same needs. Policymakers and planners view the diversity and try to formulate needs based on community assessments. The Affordable Care Act, in its 906 pages, does not define the term "population" in relation to policymaking and healthcare. The Healthcare System has taken on the challenge of what is a "population" from their perspective (CMS, 2017). Medical facilities provide treatment for episodic conditions, such as diabetic crisis, asthmatic attack, or exacerbation of congestive heart failure. In laymen's terms, hospitals "fix things that are broken". With this perspective of population, hospitals refer to their patient population according to medical conditions treated, such as diabetic patient, asthmatic patient, or heart failure patient. Involvement at a community level guided by state and county programs will take it a step further by creating and implementing preventive healthcare programs specifically geared towards all individuals in each community which would take into account both race/ethnicity and cultural background and medical conditions. This specificity could highlight healthcare disparities.

Major studies have been conducted throughout the United States revealing healthcare disparities across racial, socioeconomic and ethnic groups (National Library of Medicine, 2015). This problem brings to the forefront the possible impact that social determinants have on the health outcomes of these targeted populations without adequate access to primary healthcare. With the ACA's goal to promote primary care to both children and adults when necessary, there are challenges associated with the provision of primary care to patients by the physicians. In some cases, people in the United States have

trouble accessing primary care, because they do not have transportation, cannot afford the treatment, and sometimes coordination between the major medical centers and community-based centers becomes a challenge for the health system (Abrams et al., 2011). Challenges create a path towards developing better primary care to patients through the process of innovation. Patient-centered medical homes, an innovative solution to expand healthcare access and delivery, encourages health providers to offer easy and accessible health care to patients at the shortest time possible (Abrams et al., 2011).

The development of a good infrastructure is necessary in offering the best form of primary care to meet the expectations of all patients and physicians as well (Abrams et al., 2011). The identification of the individual patient's needs by healthcare professionals and the collaboration with community's leaders and federal government will ensure that all expectations are identified.

Community needs in the United States are enhanced by the ACA through the development of public programs designed to assist people with lower socioeconomic status (Abrams et al., 2011; Chwastiak et al., 2014; Rosenbaum, 2011). According to Rosenbaum (2011), the ACA has enhanced the process of securing health insurance among low income American citizens, therefore promoting the Medicaid enrollment to American citizens in need. The government has expanded the programs to help people access medical health with minimum out-of-pocket costs. Primary care in local communities and preventative measures such as waived Medicare co-insurance payments or deductibles for annual wellness visits, School-based Health Clinics and oral healthcare prevention education campaign were developed to help people secure better health conditions (Chwastiak et al., 2014). Taking into consideration the soaring chronic medical conditions such as DM,

hypertension and cardiovascular disease, the ACA has focused on developing projects that aid in the promotion of health and prevention of chronic conditions that affect public health. Some of the projects include grants for Medicaid beneficiaries that provide incentives for participation in healthy lifestyle campaigns, provision for annual wellness visits with personalized health maintenance plans as well as adult immunizations without cost sharing (Chwastiak et al., 2014; Dungan, 2012; Hannan et al., 2011; Kim et al., 2010). The goal of the health promotion campaigns is to create a difference in the lives of families based on the support they receive from the community reducing USHR, as patients are able to receive convenient, timely healthcare services within the community where they reside.

Truven Health Analytics (2014) realized the need for further research on broader issues that may have an impact on USHR, thereby began assessing socioeconomic factors in each community in the United States. Each community has its specific needs, and the identification of these needs are vital to the creation and implementation of successful healthcare support.

Community Need Index (CNI)

The Community Need Index was developed to help identify factors that significantly affect community members' access to healthcare (Truven, 2014). The information from Truven Health Analytics correlates the barriers of healthcare access in a community by averaging levels of individual attainments that may contribute and have an impact on people's health. The five barriers include: income (elderly, single parents living in poverty), language (limited English proficiency), education (high school graduate), insurance status (uninsured, unemployed), and housing status (rent, own). A score is assigned to each barrier condition with the number 1 signifying less community need and

the number 5 representing more community need. The scores of each barrier condition are then aggregated and averaged for final CNI score for each barrier condition. A final score of 1 indicates a community with the lowest socioeconomic barriers to healthcare access and a score of 5 represents a community with the most socioeconomic barriers to healthcare access (Truven, 2014).

Truven Health Analytics (2014) reports that unemployed people were found to be members of the community who often developed chronic diseases followed by elderly people who live under poverty, as well as African-Americans living in United States. Truven (2014) also identified other minority races and lack of education as having a significant effect on community healthcare access. Dungan (2012) stated similar findings in a retrospective study on the effect of diabetes on hospital readmissions. Education disparity, extreme age and socioeconomic barriers were found to be factors associated with USHR in patients with DM (Dungan, 2012; Truven, 2014).

Safety-Net Hospital System

Safety-net hospital systems have played a major role in providing significant health services to low-income, medically, and socially vulnerable patients regardless of their ability to pay for services. They are often seen as providers of last resort and expected by their communities and government agencies to provide necessary but unprofitable services regardless of the presence of sufficient revenue sources to support these services (Johnson, 2014). Government agencies have recognized the role of these safety-net health systems and provided supplemental funding to offset some of the unreimbursed services. However, with the expectation that most people will have some form of medical coverage under the ACA, changes in the amount of supplemental funding may be reduced (Johnson, 2014).

Importance of Coordinated Efforts

Research indicates that coordinated efforts among patients, family members, medical institutions, healthcare practitioners and community groups have shown to support an enhanced compliance and improved post-discharge environment of patients (Hersh, Masoudi & Allen, 2013). Secondary care providers, including family members and friends who stay with the patient, are often excluded in discharge scheduling, even though they may be the chief care providers to the patient at home (Sutton, 2010). On occasion, the primary care provider and treating hospital personnel fail to effectively communicate with each other prior to a patient's discharge home which results in a disjointed transitional care plan from inpatient to outpatient status (Kocher & Adachi, 2011; Rosen et al., 2013).

Information about a patient's medical history and care plan is not always accessible to home-based clinicians. Most significant is the lack of cohesiveness between inpatient and outpatient care and the healthcare provider's responsibility to the patient after initial discharge. Care culpability and responsibility is disseminated among clinicians and family members. Minus distinct culpability and responsibility, health snags that could be prevented are overlooked, leading to USHR (Friedman, Encinosa, Jiang & Mutter, 2009).

Importance of Health Insurance

Data indicate that there are varied components to health insurance, and they are not equally available to patients (CMS, 2013). The benefit of visiting nurse services to access wounds, reinforce education, relay pertinent assessment to a healthcare professional, and confirm proper understanding of DM care can be a valuable component especially to patients after CABG surgery who may not have grasped the full scope of their discharge

care instructions. A prescription plan is another component that may or may not be included.

Many patients are discharged from health facilities without having a clear understanding and appreciation of their ailments and treatment plans (Dungan, 2012; Hersch et al., 2013). Without a clear, concise plan in non-technical language, the patient can mistakably ignore essential treatment plans (Donze et al., 2013; Dungan, 2012; Hersch et al., 2013). It has also been postulated that the lack of coordinated care provision between primary facility personnel and secondary care providers could result in USHR (Bell, Brener & Gunraj, 2011).

Importance of Social and Home Healthcare Support

DM self-care after CABG surgery involves a complex regimen of lifestyle modifications and incorporating familial or community support may aid in an optimal post-discharge environment (Dungan, 2012; Rad, G. S., Bakht, L. A., Feizi, A., & Mohebi, S., 2013). With the increasing incidence of DM complications after CABG surgery resulting in USHR, it is paramount to explore the social support system and community health needs for possible correlation.

Accessible care may not be within the means of this patient population. Treatment plans provided in non-technical terms via spoken and written format followed by patient reiteration is crucial to gauge a basic understanding (Rad, G. S., Bakht, L. A., Feizi, A., & Mohebi, S., 2013). Important post-discharge components such as lack of social or medical support and transportation to medical center may not be available which may lead to complications resulting in USHR. Diabetic patients who have had CABG surgery would

benefit from early discussion about available community health services for DM education and management prior to hospital discharge.

Importance of Glycemic Control

Glycemic control may be seen as a predictor of both medical and lifestyle adherence and less socioeconomic barriers to care (Dungan, 2012). Preadmission laboratory data may shed light on how optimal or suboptimal the DM self-care may be and alert medical personnel to target these patients along with community health services for further education (Dungan, 2012; Rad, G. S., Bakht, L. A., Feizi, A., & Mohebi, S., 2013). Arranging earlier postoperative office visits with community healthcare providers and hospital personnel will aid in the capture of early exacerbation of comorbid conditions thus enabling early intervention to avert USHR.

Conclusion

Public health policy aims at promoting community health needs through the ACA. DM is a chronic condition that requires extensive self-care and often continued medical assistance. Available and accessible community health services may play a role in whether diabetic population who have had CABG surgery presents with an acute-care USHR. Medicare (2015) data continues to support that USHR in this population remain significant which signifies the need to identify other factors that may affect USHR in this population.

Assessing the overall community healthcare access via CNI scores may reveal factors relevant to each specific community that significantly contribute to USHR in diabetic patients who have had CABG surgery. Studies have shown that disadvantaged people record the highest number of USHRs compared to people who are socially and economically established in the general population (Dungan, 2012; Fasken et al., 2001;

Stewart et al., 2000). Socioeconomic factors such as ethnical background, employment, and living standards may have an association with USHR in the diabetic population who underwent CABG surgery. Examining the relationship between CNI score and USHR in this population may reveal the level at which the community healthcare access affects USHR in this at-risk population.

CHAPTER III

METHODOLOGY

Introduction

This was a retrospective, quantitative readmission data study that utilized a correlational research design to explore the relationship between community barriers to healthcare access and unplanned short-term hospital readmission (USHR) in diabetic patients who have been discharged after having had coronary artery bypass graft surgery (CABG).

Study Design

The study used archival data from medical records of 582 patients with diabetes mellitus (DM) who were electively admitted for CABG surgery, between January 1, 2009 and December 31, 2014 at a regional care teaching hospital in Northern New Jersey and documented readmission status within 30 days to the index facility.

Truven Health Analytics (2014) Community Need Index (CNI) score was obtained from Dignity Health and the Truven website for each patient by entering their zip code into an integrative computer program from Dignity Health and Truven Health Analytics at http://cni.chw-interactive.org/. CNI assigns a score to barrier conditions identified and tested by both Dignity Health and Truven Health (employment, culture and language, education, insurance status and housing), which are then aggregated and averaged to create a final healthcare access index for a given community. A score of 1.0 indicates a community with the least barriers to healthcare access thus having few needs while the maximum score of 5.0 shows a community with significant barriers to healthcare access and indicates high community need (Truven, 2014).

This study utilized a correlational research design to examine a relationship between potential independent variables: age, sex, race/ethnicity, employment status, marital status, insurance status, language, housing, education, zip code, CNI score and USHR, the dependent variable. The dependent variable, USHR, is dichotomous, therefore, a binary logistic regression analysis was used in this study (Williams, 2011).

Setting

The setting was a major teaching hospital within a large metropolitan area in Northern New Jersey. Individual demographic and clinical data were abstracted from a combination of electronic and paper medical records from January 1, 2009 through December 31, 2014. Permission was obtained from the Institutional Review Board at Rutgers Biomedical and Health Sciences and the regional care teaching hospital prior to any retrospective data collection.

Sample

The study sample was $n = 582$ diabetic patients electively admitted for CABG surgery with the primary medical diagnosis of coronary artery disease (CAD) to a single institution in Northern New Jersey between the dates of January 1, 2009 and December 31, 2014. A power analysis was utilized to determine the minimum number of patients for adequate study power (Clincalc, n.d.). The primary endpoint was binomial – only two possible outcomes, USHR or no USHR. The incidence of USHR in the known population, diabetic patients who have had CABG surgery, is 14.9% nationally (Medicare, 2015). Power was computed at an Odds ratio with alpha = 0.05 and power = 0.80. The anticipated incidence of USHR in the study group was 9%. The anticipated sample size of $n = 582$ was more than adequate to achieve the stated level of power.

Permission was obtained from the Institutional Review Board (IRB) at Rutgers Biomedical and Health Sciences and the regional care medical center prior to the collection of the archival data. Upon approval by the IRB at both institutions, hospital medical record data of 600 patients were electronically transferred from hospital organization's database to the investigator's secure password protected computer using Microsoft Excel format.

The investigator used as a sampling frame, a patient roster of the DM patient population (N = 600) who were hospitalized for CABG surgery at a regional care Medical Center between January 1, 2009 and December 31, 2014. The patient roster listed the patients in numerical order by their patient identification number. This roster was used as a primary source for transferring pertinent medical data to Society of Thoracic Surgery (STS) Adult Cardiac Surgery National Database for public reporting. The medical record data for the index admission contained demographic information, individual medical record number (MRN) and hospital encounter identifiers along with dates of admission and discharge. Core measure data was merged based on individual MRN and demographics from the original electronic medical record.

The investigator reviewed participants' medical chart data to ensure that (a) data for all study variables were available and (b) selected patients met the study criteria. The data sort included the patients' names, sex, date of birth and address to ensure a unique MRN per individual patient. Social security number was used for further confirmation if the initial data appeared to have a patient with more than one unique MRN. If a patient had more than one MRN, each chart was individually reviewed and then merged to the latest MRN on file. The data sort was then de-identified by the principal investigator. If subsequent admissions were documented during the 5-year sample timeframe for one

patient, those admissions were not added to avoid the inclusion of that individual patient more than once.

Inclusion Criteria

Study inclusion criteria were: (a) 28 years of age or older at the time of CABG surgery, (b) a primary medical diagnosis of CAD with comorbid DM, and (c) elective admission to the hospital and discharged home. The clinical conditions for inclusion are displayed in Table 1.

Table 1: Clinical conditions for inclusion

Clinical condition	**Clinical definition** (Merck Manual Professional Version online, n.d.)
Primary medical diagnosis: Coronary artery disease (CAD)	CAD is a "condition in which blood flow through the coronary arteries to the heart muscle is reduced by plaque and typically results in chest pain or heart damage—called also *coronary disease, coronary heart disease."*
Comorbid condition: Diabetes mellitus (DM)	DM is a "disorder of carbohydrate metabolism caused by a combination of hereditary and environmental factors and usually characterized by impaired insulin secretion. Early symptoms may include excessive urine production, excessive thirst and hunger as well as blurred vision."

Exclusion Criteria

Study exclusion criteria were: (a) patients discharged to acute rehab, subacute rehab or another medical center, and (b) patient data missing any of the study variables.

Study Variables

There were 10 patient characteristics used as independent variables in this study in addition to the Community Need Index (CNI) score as calculated by Truven Health

Analytics (2014). The independent variables and dependent variable are briefly summarized in this section and discussed in more detail in Table 2. Figure 3 displays variables used in the model prediction.

Independent Variables

The independent variables aligned with Truven Health Analytics (2014) composite Community Need Index (CNI) score and were placed in three categories: patient characteristics domain; clinical condition; and CNI score. The patient characteristics domain included the independent variables of (a) age, (b) sex, (c) race/ethnicity, (d) marital status, (e) employment, (f) insurance, (g) education, (h) culture/ language, (i) housing, and (j) zip code. All the subjects in the study have both coronary artery disease (CAD) and diabetes mellitus (DM). DM was confirmed by documented patient verification of their use of anti-diabetic medications, laboratory data detailing fasting plasma glucose and hemoglobin A1C levels, and snapshot of diabetic control over a 3-month period respectively. Table 3 further defines the above-mentioned laboratory data which may be of interest for future research.

Table 2. Independent variables

Variable name	**Variable definition** (Merriam-Webster's online dictionary, n.d.)	**Variable type and operational definition**
Patient characteristics		
Age	Age is the "part of life from birth to a given time."	Continuous; Measured in years.
Sex	Sex is defined as "either of the two forms of individuals that occur in most species distinguished as female or male by reproductive organs and structures."	Categorical: 0 = Male 1 = Female
Race/Ethnicity	As per hospital policy: "Race refers to physical characteristics of a group. Ethnicity is defined as large groups of people who have shared cultural characteristics, such as language, religion, or other aspects of a culture."	Categorical: 1 = African American/ Black 2 = Caucasian/ White 3 = Hispanic Latino 4 = Asian + Other
Employment status	Employment is an "activity in which one engages; a job or profession."	Categorical: 1 = Not currently working 2 = Currently employed 3 = Retired 4 = Disabled
Marital status	Marital status is the "state of being married or not married —used on official forms to ask if a person is married, single, divorced, or widowed."	Categorical: 1 = Married/ With Partner 2 = Divorced 3 = Widowed 4 = Single
Health insurance	Health insurance is "insurance against loss through illness of the insured."	Categorical: 1 = Blue Cross/ Blue Shield 2 = Commercial 3 = HMO 4 = Medicaid 5 = Medicare 6 = Self pay 7 = Uninsured/ Indigent

Table 2 (contd.)

Variable name	**Variable definition** (Merriam-Webster's online dictionary, n.d.)	**Variable type and operational definition**
Patient characteristics		
Language	Language is a "system of words or signs people use to express thoughts and feelings to each other. English is primary language spoken at home."	Dichotomous 0 = No 1 = Yes
Housing	Housing refers to "dwellings provided for people."	Categorical 1 = Rent 2 = Own
Education	Education is the "knowledge, skill, and understanding that you get from attending a school, college, or university." The patient is a high school graduate.	Dichotomous 0 = No 1 = Yes
Community Characteristics		
Community Need Index (CNI) score	CNI score is the "average of five barrier condition scores (employment, education, culture and language, education, insurance and housing) based on the patient's community of residence." A score of 1.0 reveals a community with the lowest socio-economic barriers (low needs) while a score of 5.0 shows a community with the high need (Truven, 2014).	Individual score for each community between 1.0 and 5.0

Table 3. Future Variables of Interest: Laboratory Diagnostics

Clinical Data	**Clinical Definition (Labs, n.d.)**	**Variable type and Normal Values**
Hemoglobin A1c level	A1c is a "lab test that shows the average level of plasma blood glucose over the previous 3 months." It shows how well you are controlling your diabetes (Labs, n.d.).	Ordinal: Normal or controlled: A value less than or equal to 6% indicates controlled diabetes.
Fasting plasma glucose level (FPG)	FPG is a "carbohydrate metabolism test which measures plasma or blood glucose levels after overnight fasting" (Labs, n.d.).	Ordinal: Normal or controlled: A value between 70-100 mg/dL indicates a normal blood glucose level or controlled diabetes.

Dependent Variable

Unplanned short-term hospital readmission (USHR) was the dependent variable in this study. USHR was defined as an admission to the study hospital within 30 days of discharge from the initial admission. Electronic medical records were analyzed for readmission within 30 days and confirmed in the STS Adult Cardiac Surgery Database for Public Reporting. However, the STS database does not indicate if the subjects were readmitted to another facility. This dichotomous variable was coded as 0 = no, did not have an USHR and 1 = yes, did have an USHR.

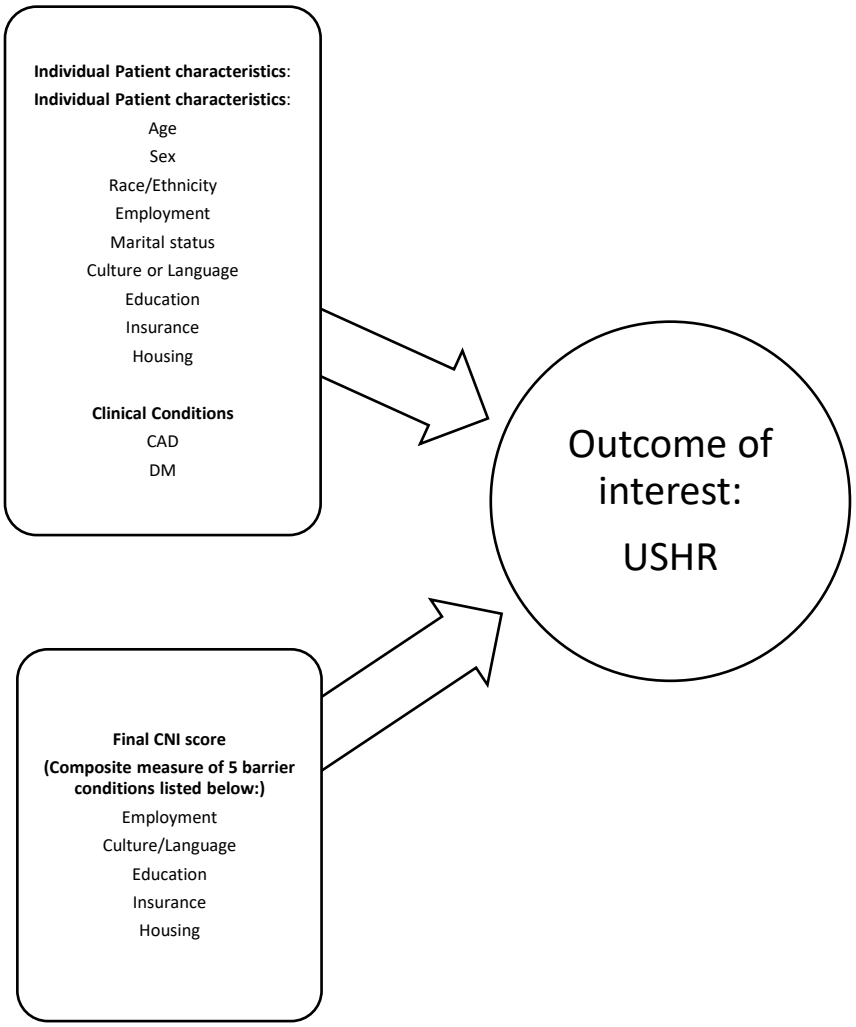


Figure 3.

Conceptual model identifying variables that have been reported as influencing community need (Truven Health Analytics, 2014) and the clinical conditions explored for a relationship to unplanned short-term hospital readmission (USHR).

Data Analysis

The investigator manually entered patient data from a sample of 600 consecutive, electively admitted patients into a Statistical Package for Social Science (SPSS) 22.0 data file. Once all of the data was entered, the investigator reviewed the SPSS data set and corrected any data entry errors. Outliers were not a serious concern with this data set, as all but one variable (i.e., age) are dichotomous, categorical, or ordinal (Treiman, 2014) and thus easily identified in a box plot.

Descriptive statistical analysis was conducted on the study variables prior to performing further analyses. Frequencies and percentages were reported for the patient characteristics. All the subjects had clinical conditions, CAD and DM. The means, standard deviations, and minimum and maximum scores were reported for the one interval variable, age.

Research Question 1a

Is there a significant relationship between the combination of patient demographic variables (i.e., age, sex, race/ethnicity, employment status, education, language, housing, insurance status, and marital status) and the occurrence of unplanned short-term hospital readmission (USHR) in diabetic patients after CABG surgery?

$H_{1o.}$ There is no significant relationship between the combination of patient demographic variables (i.e., age, sex, race/ethnicity, employment status, education, language, housing, insurance status, and marital status) and the occurrence of USHR in diabetic patients after CABG surgery.

To assess this research question, a binary logistic regression was used due to the dichotomous dependent variable, USHR, and the prediction hypothesis (Hosmer, Lemeshow, & Sturdivant, 2013; Stoltzfus, 2011).

Odds ratios were calculated to represent odds that the outcome (USHR) will or will not occur based on the presence or absence of the combination of predictor variable values. Evaluations of the logistic regression model included the overall model evaluations (the percentage of correct predictions). The statistical results reported for the binary logistic regression analysis included (a) the model chi-square (χ^2) statistic, to indicate whether there was statistically significant improvement in the adjusted versus baseline model; (b) the Hosmer and Lemeshow goodness-of-fit chi-square (χ^2) statistic, which was non-significant if the data show a good fit to the model; and (c) classification table results (Hosmer et al. 2013). The contribution of each independent variable was evaluated via a Wald statistic and odds ratio for all predictors reported. Significance of the binary logistic regression model and for each individual predictor was determined by results that were significant at $p < .05$ (Hosmer et al., 2013). For significant variables, predicted probabilities of an event occurring were determined by Exp (β) (Tabachnick and Fidell, 2012).

Research Question 1b

Is there a significant relationship between the combination of patient demographic variables (i.e., age, sex, race/ethnicity, employment status, education, language, housing, insurance status, and marital status) with the addition of the CNI score and the occurrence of unplanned short-term readmission (USHR) in diabetic patients who have had CABG surgery?

H_{2o}. There is no significant relationship between the combination of patient demographic variables (i.e., age, sex, race/ethnicity, employment status, education, language, housing, insurance status, and marital status) with the addition of the CNI score and the occurrence of USHR in diabetic patients who have had CABG surgery.

To assess this research question, the raw CNI score was included in the logistic regression equation established in the prior analysis to determine whether there was significant improvement in the prediction of USHR beyond the individual's demographic characteristics.

CHAPTER IV

RESULTS

Patients' demographic characteristics

There were 600 participants' chart data reviewed, with complete information on the demographic variables of interest, as well as CNI score and readmission status in 582 files. Most respondents were male (n = 421, 72.3%) and of Caucasian race (n = 246, 42.3%). More than half of the patients were married (n = 360, 61.9%) and had either Medicare (n = 210, 36.1%) or HMO insurance (n = 176, 30.2%). Most spoke English as a primary language at home (n = 395, 67.9%) and were either retired (n = 277, 47.6%) or currently employed (n = 167, 28.7%). Very few participants did not have a high school degree (n = 62, 10.7%). The average age was 63.07 (*SD* = 9.79), with the youngest patient aged 28 and the oldest patient aged 89. Table 4 shows the patients' demographic characteristics. Figure 4 displays the distribution of raw CNI scores of the 582 study patients. The CNI score was on average 3.58 (SD = 1.02), median = 3.80, IQR (1.60). Of the total of 582 subjects, the proportion of subjects readmitted was 17.4% (n=101).

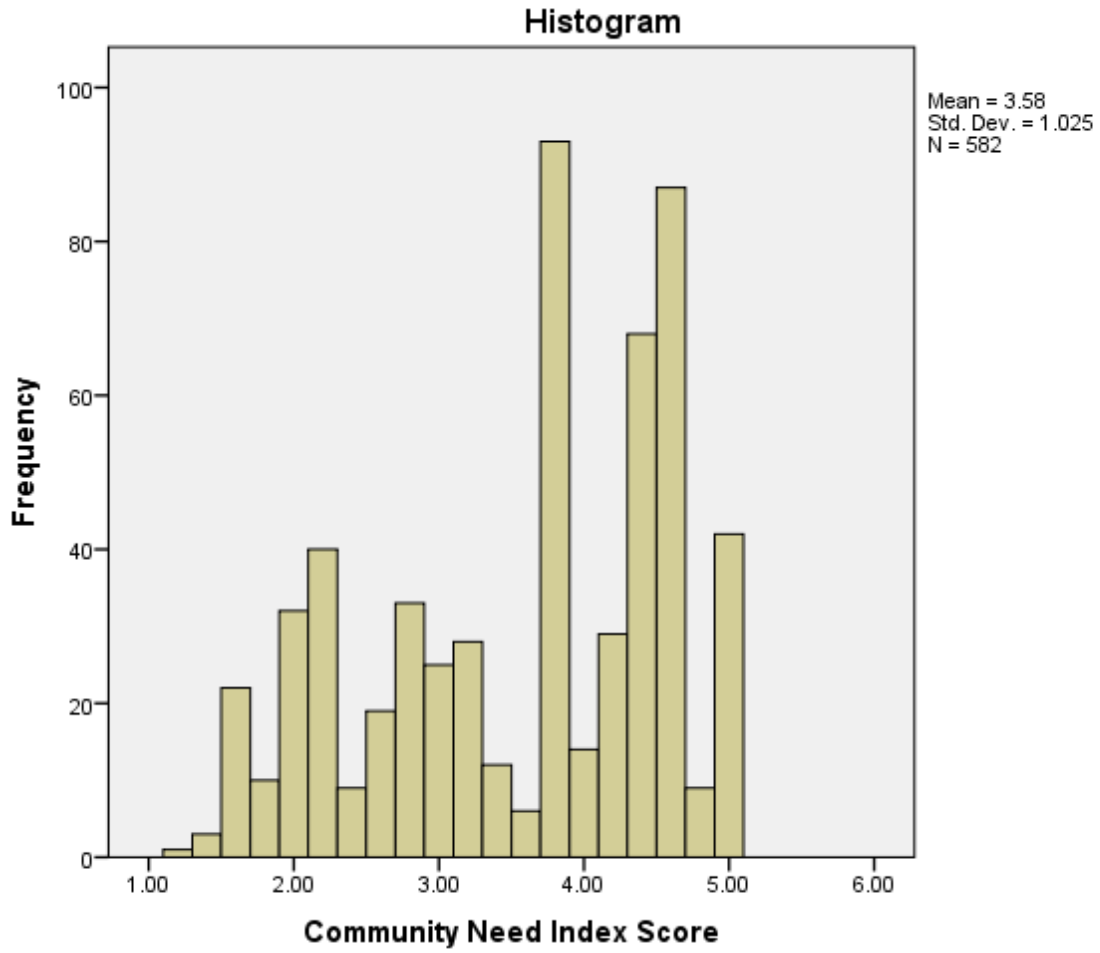
Table 4. Patients' Demographics (n = 582)

Characteristic		Frequency	%
Sex			
	Male	421	72.3
	Female	161	27.7
Race/Ethnicity			
	African American	117	20.1
	Caucasian	246	42.3
	Hispanic	73	12.5
	Other	146	25.1
Marital Status			
	Married/With Partner	362	62.2
	Divorced	51	8.8
	Widowed	30	5.2
	Single	139	23.9
Insurance			
	Blue Cross/ Shield	70	12.0
	Commercial	29	5.0
	HMO	176	30.2
	Medicaid	24	4.1
	Medicare	210	36.1
	Self-Pay	23	4.0
	Uninsured/Indigent	50	8.6
English Language			
	No	187	32.1
	Yes	395	67.9
Housing			
	Rent	326	56.0
	Own	256	44.0

Table 4 contd.

Characteristic		Frequency	%
Employment			
	Not working	100	17.2
	Currently employed	167	28.7
	Retired	277	47.6
	Disabled	38	6.5
High school Education			
	No	62	10.7
	Yes	520	89.3
Mean Age		63.07	
Mean CNI		3.58	
Readmission		101	17.4

Figure 4. Raw Community Need Index Score Distribution



Independent Variables Screening Process

The purpose of the screening was to identify associations between the patient demographic characteristics and unplanned short-term hospital readmission (USHR) to identify potential predictors in a model of USHR. For the non-dichotomous independent variables, we examined the association with 30-day Readmission using chi-square. For continuous and dichotomous variables, we examined the relationship with 30-day Readmission using Pearson's correlation.

In the initial examination of the association of non-dichotomous variables independent variables with 30-Day readmission using chi square, there were found to be

no statistically significant associations. Screening within the non-dichotomous categorical variables was considered in hopes of identifying possible avenues for recoding that would convert insignificant predictors into significant predictors for readmission. Marital status was recoded into "divorced" or not because "divorced" appeared to be potentially relevant. Employment status was recategorized into "disabled" or not because "disabled" appeared to be potentially relevant to the prediction model. Race/ethnicity was recategorized into "Caucasian" or not because this study sought to highlight healthcare disparity in underserved communities. Insurance was recategorized into "HMO" or not. Language was recategorized into English or not because English is considered a dominant spoken language in the study area.

After determining the need to recode some of the non-dichotomous variables, the following screening steps were taken:

- Recoding Non-Dichotomous Categorical Variables
- Identifying Potential Predictors for the Models
- Collinearity Screening among Selected Predictor Variables

Step 1: Recoding Non-Dichotomous Categorical Variables

The purpose for recoding some of the non-dichotomous variables was to identify subgroups within the individual characteristics that could be useful for predicting USHR. This screening process was exploratory, but also principle driven. Statistical significance with a p value < 0.20 was used as a cutoff for potential inclusion in the predictive models. All theoretically important variables were forced into the model.

Cross-tabulations reported in Table 5 were examined to identify subgroups within the following variables: Marital status, Employment, Race and Insurance, for associations that might not be clear when analyzing total groups and 30-Day Readmission.

The criteria for screening in and out:

- Theoretical or practical importance –CNI score was used in the model because it was the primary independent variable of interest. The 4 categories of race/ethnicity were reclassified using Caucasian as a reference with all others grouped together since the crux of this study highlighted known health disparities for non-Caucasian patients based upon demographics in a community population (Truven, 2014).
- Statistical significance, p value < 0.20, was used as a cutoff for including predictor variables in the model.

Table 5. Patients' Demographics and Relationships between 30-Day Readmission and Independent Categorical Variables (N=582)

		30-Day Readmission					
Variable		No	Row %	Yes	Row %	Chi Square	p-value
Sex							
	Male	345	81.9	76	18.1	0.52	0.541
	Female	136	84.5	25	15.5		
Race							
	African American	98	83.8	19	16.2	0.30	0.960
	Caucasian	201	81.7	45	18.3		
	Hispanic	61	83.6	12	16.4		
	Other	121	82.9	25	17.1		
Marital Status							
	Married/ Partner	303	83.7	59	16.3	1.69	0.640
	Divorced	39	76.5	12	23.5		
	Widowed	25	83.3	5	16.7		
	Single	114	82.0	25	18.0		

Table 5 contd.

	30-Day Readmission					
Variable	No	Row %	Yes	Row %	Chi Square	p-value
Insurance						
Blue Cross/ Shield	59	84.3	11	15.7	3.34	0.765
Commercial	27	93.1	2	6.9		
HMO	142	80.7	34	19.3		
Medicaid	19	79.2	5	20.8		
Medicare	173	82.4	37	17.6		
Self-Pay	20	87.0	3	13.0		
Uninsured/Indigent	41	82.0	9	18.0		
English Primary Language						
No	160	85.6	27	14.4	1.63	0.201
Yes	321	81.3	74	18.7		
Housing						
Rent	265	81.3	61	18.7	0.95	0.329
Own	216	84.4	40	15.6		
Employment						
Not working	84	84.0	16	16.0	7.08	0.070
Employed	144	86.2	23	13.8		
Retired	227	81.9	50	18.1		
Disabled	26	68.4	12	31.6		
High school Education						
No	51	82.3	11	17.7	0.01	0.932
Yes	430	82.7	90	17.3		
Dichotomized CNI						
CNI > 3.7	283	82.7	59	17.3		0.938
CNI < 3.7	198	82.5	42	17.5		

Employment was re-categorized into "disabled" yes or no, because "disabled "appeared to be potentially relevant to readmission compared to the other subcategories in employment based on large differences within the subcategory with respect to 30-day Readmission. Marital status was also re-categorized into "divorced", yes or no, because "divorced" appeared to be potentially relevant to USHR based on subgroup differences.

Upon visual inspection of the Figure 4 CNI histogram and Table 6, the raw CNI scores of the study patients had a bimodal distribution. Further examination of the frequency plot showed a sharp increase between CNI score of 3.6 and CNI score 3.8. The decision was made to convert the distribution to binary variables (i.e. 0 = "high, > 3.7" and 1 = "low, < 3.7") with cutoff at 3.70.

Table 6. Patients' Demographics and Relationships between 30-Day Readmission and Independent Variables: Age, CNI (N = 582)

Variable		30-Day Readmission		Sig
Age		No	Yes	.734
	Mean	63.00	63.37	
	Std. Deviation	9.78	9.89	
Raw CNI	Mean	3.58		.949
	Std. Deviation	1.02		

Step 2: Identifying Potential Predictors for the Models

After an extensive review of the correlational analyses and cross-tabulations of the dichotomous and recoded non-dichotomous variables, the final variables to be included in the regression model were: Caucasian (reclassified), Disabled, English, Age, and Community Need Index as shown in Table 7. The decision to include Age was based on

reports that advanced age has an impact on changing prevalence and severity of comorbidities which may influence hospital readmission (Piccirillo et al., 2008).

Table 7. Correlations for Relationships of Demographic Characteristics Selected for Final Regression Model and 30-day Readmission

		Community Need Index	Caucasian	Disabled	English	Age	30-day Readmission
Community Need Index	Pearson Correlation	1					
Caucasian	Pearson Correlation	-.517**	1				
Disabled	Pearson Correlation	.109**	-.114**	1			
English	Pearson Correlation	-.210**	.537**	.003	1		
Age	Pearson Correlation	-.114**	.125**	-.190**	-.024	1	
30-day Readmission	Pearson Correlation	.003	.021	.099*	.053	.014	1

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

The final set of independent variables to be included in the predictive model were: Age, disabled (reference – No), English as Primary (reference – Yes), Race (reference – Caucasian), and CNI (raw and dichotomized in separate models).

Step 3: Collinearity Screening among Selected Predictor Variables

The independent variables selected for inclusion in the final predictive model were screened for collinearity and found to have no correlations of $r \geq 0.7$, which was determined to be the strength of relationships of concern (see Table 7).

Research Question 1a

Is there a significant relationship between the combination of patient demographic variables (i.e., Age, Caucasian (reclassified), Disabled status, and English as Primary Language) and the occurrence of unplanned short-term hospital readmission (USHR) in diabetic patients after CABG surgery?

$H_{1o.}$ There is no significant relationship between the combination of patient demographic variables (i.e., Age, Caucasian reclassified), Disabled status, and English As Primary) and the occurrence of USHR in diabetic patients after CABG surgery.

To answer the first research question, a binary logistic was used with the occurrence of USHR in diabetic patients after CABG surgery as the binary dependent variable and the patient demographic characteristics identified above as the independent variables. The baseline model, exclusive of independent variables, included predictions based purely on whichever category occurred most often in this dataset. The model always guessed "no"

because more patients were not readmitted than were (481 patients compared to 101 patients). The overall percentage told us that this approach to prediction was correct 82.6% of the time. The classification table results are presented in Table 8.

Table 8. Classification Table for Binary Logistic Baseline Model

		Predicted		
		Re-admission		Percentage Correct
Observed		No	Yes	
Re-admission	No	480	0	100.0
	Yes	101	0	0.0
Overall Percentage				82.6

Note: The cut off value is 0.500

For the model including the covariates, the overall model was not statistically significant, χ^2 (4) = 7.34, p = 0.119, indicating that including the identified covariates into the model, did not improve the model's ability to identify individuals who were readmitted within 30 days. The classification table with the added covariates was identical to the table with no covariates added.

For individual predictors, disabled was a statistically significant predictor at Wald (1) = 5.982, p = 0.014, while Age, Caucasian, and English as Primary Language did not contribute significantly to the model. The odds of unplanned readmission within 30 days is 2.56 (95% CI 1.205-5.429) times greater in the disabled diabetic patient than the non-disabled diabetic patient. The results are presented in Table 9.

Table 9. Independent Variables in Model 1

							95% C.I. for Odds Ratio)	
Variable	B	S.E.	Wald	df	Sig.	Odds Ratio	Lower	Upper
Age	.010	.012	.721	1	.396	1.010	.987	1.034
Race (Ref – Caucasian)	-.004	.264	.000	1	.988	1.004	.594	1.871
Disabled (Ref – No)	.939	.384	5.982	1	.014	2.558	1.205	5.429
English (Ref – Yes)	-.317	.288	1.210	1	.271	1.373	.414	1.281
Constant	-2.175	.787	7.638	1	.006	.114		

Research Question 1b

Is there a significant relationship between the combination of patient demographic variables (i.e., Age, Caucasian (reclassified), Disabled status, and English as primary language) with the addition of the CNI score (raw and dichotomized) and the occurrence of unplanned short-term readmission (USHR) in diabetic patients who have had CABG surgery?

H_{2o}. There is no significant relationship between the combination of patient demographic variables (i.e., Age, Caucasian (reclassified), Disabled status, and English as primary language) with the addition of the CNI score (raw and dichotomized) and the occurrence of USHR in diabetic patients who have had CABG surgery.

To answer the second research question, the CNI score (raw and dichotomized) was added as an independent variable in the logistic regression Model 1. As with the classification table for the baseline model reported in Table 8, the model had an overall accuracy of 82.6% and could not predict any 30-day readmission. The classification table with the added covariates was identical to the table with no covariates added.

The overall model was not statistically significant, $\chi^2(4) = 7.380$, $p = 0.194$. CNI was not a statistically significant predictor, Wald (1) .037, p = .848, indicating the raw CNI score was not a good predictor of unplanned 30-day hospital readmission. Of the five predictor variables: age, race, disabled, English as primary language, and raw CNI, only disabled was statistically significant as shown in Table 10. The disabled diabetic patient had 2.55 higher odds of short-term unplanned hospital readmission than non-disabled

diabetic patients. Table 11 shows the final analysis with a dichotomized CNI. Dichotomized CNI was not a significant predictor, Wald (1) .001, p = .978. As previously shown in Model 1, the odds of unplanned hospital readmission within 30 days is 2.56 (95% CI 1.205-5.437) times greater in the disabled diabetic patient than the non-disabled diabetic patient.

Table 10. Independent Variables in Model 2 with Raw CNI

							95% C.I. for Odds Ratio)	
Variable	B	S.E.	Wald	df	Sig.	Odds Ratio	Lower	Upper
Age	.010	.012	.734	1	.392	1.010	.987	1.034
Race (Ref – Caucasian)	.032	.303	.011	1	.915	.968	.594	1.754
Disabled (Ref – No)	.936	.384	5.922	1	.015	2.549	1.205	5.414
English (Ref – Yes)	.312	.289	1.167	1	.280	.732	.415	1.290
CNI	.024	.128	.037	1	.848	1.025	.797	1.317
Constant	-2.254	.890	6.420	1	.011	.105		

Table 11. Independent Variables in Model 2 with Dichotomized CNI

							95% C.I. for Odds Ratio	
Variable	B	S.E.	Wald	df	Sig.	Odds Ratio	Lower	Upper
Age	.010	.012	.717	1	.397	1.010	.987	1.034
Race (Ref – Caucasian)	-.001	.282	.000	1	.997	.999	.574	1.738
Disabled (Ref – No)	.940	.384	5.974	1	.015	2.559	1.205	5.437
English (Ref – Yes)	-.317	.289	1.210	1	.271	.728	.414	1.282
CNI (Ref – High, > 3.70)	.007	.245	.001	1	.978	1.007	.623	1.327
Constant	-2.178	.797	7.480	1	.006	.113		

CHAPTER V

DISCUSSION

Public health agencies often define a population according to demographic characteristics (i.e. race/ethnicity, language) while healthcare delivery systems typically define population according to medical conditions (i.e. diabetic or heart disease patients). Although there may be differing definitions of "population" amongst policymakers and healthcare agencies, recognizing community needs can provide a strategy to increase community resources to improve health status (CMS, 2017). Relating the two descriptions of "population" and the known high readmission rates in diabetes mellitus (DM) and patients who have had coronary artery bypass graft (CABG) surgery (CMS, 2013), this study was designed to examine the relationship between Community Need Index (CNI) and 30-day readmission in diabetic patients who underwent coronary artery bypass graft (CABG) surgery.

Summary of Findings

There were 600 participants' chart data reviewed, with complete information on the demographic variables of interest in 582 charts, as well as CNI score and readmission status. All participants had diagnosed diabetes mellitus and coronary artery disease with an elective admission for coronary artery bypass graft surgery. There were no significant associations between the dependent variable, unplanned short-term hospital readmission (USHR), and initial, un-recoded independent demographic variables: age, race/ethnicity, sex, marital status, insurance, English as primary language, housing, employment, raw CNI and high school education.

Cross-tabulations of the non-dichotomous variables using Chi square and Pearson's correlations for continuous and dichotomous variables suggested there may be subgroups within the larger population significantly associated with readmission. The screening process yielded 5 variables for the final predictive model: Age, Race/Ethnicity, English language, Disabled status and CNI (raw and dichotomized).

Binary logistic regression was used for hypothesis testing to examine the relationship between the final independent variables in Model 1: Age, Race/Ethnicity, English language, and disabled status and the dichotomous dependent variable, USHR. Recoded independent variables in Model 1: Age, Race/Ethnicity and English language did not have a significant association with dependent variable, USHR. However recoded variable, Disabled status, had a significant relationship with readmission. Binary logistic regression was used for hypothesis testing to examine the relationship between the final independent variables in Model 2: Age, Race/Ethnicity, English language, disabled and CNI score (raw and dichotomized) and the dichotomous dependent variable, USHR. The recoded variables in Model 2: Age, Caucasian as reference, English language and CNI score did not have a significant relationship with unplanned readmission. However, disabled, remained significant in the Model 2 as well as Model 1.

Discussion

Cardiac surgery consumes a large portion of healthcare resources and given the escalating healthcare expenses amid reduced allocation of funding, cost containment efforts remain compulsory (Sutton, 2010). For this reason, the Centers for Medicare and Medicaid (CMS) began reducing hospital reimbursements for 30-day readmissions which

was signed into legislation in October 2012 (CMS, 2013). Hospital Readmissions Reduction Program (HRRP) penalized hospitals for 30-day readmissions for the following conditions: heart failure, heart attack, pneumonia, chronic lung problems, coronary artery bypass graft surgery, and elective hip and knee replacements (CMS, 2017).

Evidence-based medicine reports predictive risk assessment algorithms for early readmission in diabetic patients after CABG which include: atrial fibrillation, age, female gender, obesity, pulmonary disease, sternal wound infection, and renal disease (Benuzillo et al., 2018; Fanari, Z., Elliott, D., Russo, C. A., Kolm, P., & Weintraub, W. S., 2017; Lancey et al., 2015). Many hospitals created and implemented protocols to combat early readmission rates by addressing these known risk factors, but the readmission rates remained elevated at roughly 15% (Medicare, 2015). Formal inquiry into socioeconomic indicators of healthcare access in this subset population was sparse prompting this pilot retrospective study to examine communities' social and economic status with patient demographics and unplanned readmission in the diabetic patient after CABG.

Understanding health determinants, such as social and economic factors can lead to improved health outcomes and reduced health disparities (WHO, 2018). The U.S. Department of Health and Human Services (2016) refer to social determinants of health as influences, or social factors and the physical environment of which we live, learn, work and play. Changing local, state and federal level policies that affect where community members live, work and play may enable community members to make better choices that can lead to better health outcomes. Tobacco policies are an example. At the local, state and federal levels, studies have shown that the implementation of smoke-free environment laws can curb smoking and reduce the prevalence of cigarette smokers at work (CDC, 2016).

Another policy impact for reference are seatbelt laws. Updated policy laws, increased education and enhanced technology have increased seatbelt use from a documented 11% in 1981 to nearly 85% in 2010. (CDC, 2010). These examples show that policies at local, state and federal levels can affect individual and community health.

Healthy People 2020 is a federal government health agenda whose goals include: health equity, elimination of health disparity, health improvement of all groups, and creation of social and physical environments that promote good health. The organizing framework of social determinants of health (SDOH) addressed five key areas: economic stability, education, social and community context, health and health care, and neighborhood and built environment. The five key areas included in the federal government's agenda are tied to the barrier conditions used in Truven's Community Need Index interactive tool to assess barriers to healthcare access. Dignity Health in conjunction with Truven Health Analytics created the CNI interactive tool in 2004 to assist in the gathering of vital socio-economic indicators in communities (Truven, 2014). This tool has been strongly linked to variations in community healthcare needs over the past decade and reported as a strong indicator of a community's requirements for healthcare services (Truven, 2015).

Reported data from Truven analytics showed that hospitals that serve a disproportionate high number of minority patients were likely to receive a penalty under the Hospital Readmission Reduction Program (HRRP) due to the complex social risk factors noted in this population subset (Truven 2015). Figueroa et al (2018) reported that minority-serving hospitals had quarterly reductions in readmissions at a rate of 0.44% from April 2010 to September 2012 during the implementation period of HRRP. All other

hospitals had quarterly reductions in readmissions at a rate of 0.36%. Despite the greater reduction in readmission rates compared to their peers, nearly 85% of minority-serving hospitals were penalized in fiscal year 2013 versus roughly 69% of all other hospitals (Figueroa, 2018). Figueroa's study included 2,677 hospitals as non-minority serving and 283 as minority-serving. The minority-serving hospitals were found to be major teaching medical centers, public hospitals or located in Southern United States (Figueroa, 2018).

Minority-serving hospitals were often hit with Medicare payment reductions regardless of the individual hospital's improvement in readmissions, because CMS does not consider readmission reduction improvements when assessing penalties. As a result, minority-serving hospitals, often safety-net facilities, are compared to all other hospitals including those in affluent areas with patients with less complexities. This is important, because it basically shows that even if a hospital markedly improve readmission rates and still rank in the bottom tier, they will continue to get penalized up to 3% of hospital's Medicare payments.

Safety-net hospitals provide a large amount of care to low-income, indigent and uninsured patients. Education and income can influence the ability of some populations to obtain medical care. The inability to read or understand information for state-funded programs may play a role in an individual's failure to enroll in subsidized programs. The effects of these barriers coupled with other determinants, such as advanced age, sex, race/ ethnicity and native language spoken, may negatively compound the ability to access health care services and predict health outcomes for people with disabilities and other disadvantaged groups (Drum, C., Krahn, G., & Bersani, H., 2009).

This retrospective study at a major teaching hospital in New Jersey highlighted elective admissions while examining the relationship between community need and readmission in diabetic patients after CABG surgery. Examining the elective admissions in this retrospective study may allow for the elimination of confounding variables that are associated with inpatients. Confounding variables could still present in retrospective studies but often times there are not good records of confounders. Consequently, it is not known if confounding variables had an effect at the time. Demographic factors in this retrospective study: Age, Race, Community need index and English as a primary language, did not show any significance in unplanned short-term readmission. Although advanced age has been reported in multiple studies as a risk factor in unplanned early readmission in patients who have had CABG surgery, this study did not reveal advanced age as having any significance in unplanned readmission. Assessments of elderly patients' health status ranging from independence status, risk of malnutrition and the presence of walking difficulties cannot be quantified in a retrospective chart review unless specifically reported. Secondly, the status of the patients' documented disability and the extent of how it interfered with their ability to perform activities of daily living prior to admission were not documented in the reviewed data. Despite the functional disabilities experienced at time of discharge, many of the multidisciplinary team members may not be aware of patients' resources and who, if anyone, will be able to assist in their care post discharge for an extended period (Boyd et al., 2008).

Studies on patients with disabilities reported increased risks of hospitalization and readmissions in the absence of home care, but these studies focused on all-cause readmission not specific to diabetic patients after cardiac surgery (Bowles, K., Naylor, M.,

& Foust, J., 2002; Naylor, Aiken, Kurtzman, Olds, & Hirschnan, K., 2011; Xu H., Covinsky K., Stallard E., Thomas J., & Sands L., 2010). This retrospective study did not quantify the absence or presence of home care post discharge but corroborated that disabled patients are at increased risk for short-term readmission. Electively admitted patients appeared to have some indication of better general health status when examining demographic factors and community assessment except for the disabled diabetic patients. The disabled diabetic patients electively admitted for CABG surgery were shown to be vulnerable to readmission regardless of CNI score. The interactive CNI tool was user-friendly and may be good for some things, but for this subpopulation, there are factors other than those captured in the Truven tool that appear to be driving readmission rates.

W**hy does this matter?** It matters because the CNI interactive tool is used by multiple non-profit hospitals across the United States to assess healthcare inequity, and it is recognized by CMS and public agencies.

CMS created and implemented regulatory levers to reduce readmission rates but did not foresee the potential unintended consequence. Penalty payments in hopes of reducing readmission rates may have exacerbated the healthcare inequity leaving safety-net hospitals with fewer resources to make adequate improvements. From 2013 to 2016, readmission rates only dropped roughly 0.1% (CMS, 2017). Studies have shown that readmission reductions have plateaued prompting health policy experts to suggest retiring Hospital Readmissions Reduction Program (HRRP) (Figueroa, 2018; CMS, 2017). Healthcare administrators and policymakers echo that most hospitals have done all they can do to prevent unplanned readmissions, and they may not be fully equipped to provide outpatient services beyond the hospital walls. In response to these concerns from hospitals

and policymakers, CMS made changes to the Readmission Reduction program to assess penalties based on a hospital's performance in relation to other facilities with similar proportion of patients who are dually eligible for Medicare and Medicaid. Researchers agreed that CMS changes to HRRP was a positive one but also recommended looking at poverty within census tracts where the hospitals operate as well as examine other social demographic issues associated with poverty such as increased prevalence of illicit drug use, behavioral issues and linguistic minorities (Carey, 2016; Figueroa, 2017). CMS' focus appeared to shift to penalties offset leaving unanswered questions as to why the readmission rates may have plateaued. Additionally, CMS will begin accounting for patients' socioeconomic status in 2019 so that the Readmission Reduction Program remains nondiscriminatory for safety-net hospitals (CMS, 2017).

The implications of the study findings are: CNI interactive tool may be useful in evaluating those individuals in an inpatient setting but the elective or outpatient component may be misleading; and using the CNI score to adjust for socioeconomic factors may not highlight healthcare disparity in non-urgent, elective settings. There could also be a peculiarity in patients with both diabetes and a disability. Of note, CMS maybe should take into account a hospital's census of disabled individuals. Providing risk scores for every admitted patient would be a benefit. It would allow for further examination and greater ability to target the population with increased readmission risk via community outreach or supplemental outpatient care. Elective admissions have shown to be relatively healthier with less risk of readmission unless they are disabled. This study suggests that the focus should be on providing resources to this subset of patients after assessing the total needs of the patient prior to the initial elective admission and reassessed prior to discharge.

Upcoming changes to the CMS readmission reduction program in 2019 may not have a significant affect at the major teaching hospital of this retrospective study. A patient's early readmission to a hospital may not be indicative of the care received at the medical facility. Social conditions could be partially the blame and simply cannot be coded in a standardized manner, such as if a patient cannot drive or too weak to care for self. Therefore, the creation and implementation of updated pre-admission screening assessments and discharge protocols are warranted. Also, it is necessary to explore documented associated chronic conditions present on admission and whether the conditions are stable or uncontrolled.

Study Limitations

This was a retrospective examination of patients' medical records. It was impossible to account for unknown variables not readily apparent in the medical record. The use of secondary data collection was limiting because of the possibility of incomplete or missing vital data and inaccurate reporting on behalf of the patient or the personnel inputting data into the medical record. Another limiting factor with chart review in this study was the inability to assess the severity of preoperative diabetes status and possible DM-related complications, thereby not adequately adjusting for it in the study. Unlike the true experimental design, the correlational research design cannot be used to infer causality (Bowling, 2014).

The study included the records of 600 consecutive diabetic patients who underwent CABG surgery in a single institution in Northern New Jersey. To be included in the study, the patients would have had to be electively admitted with preadmission history and

physical exam with comprehensive lab work performed within four weeks prior to surgery. The decision to narrow the criteria to elective admissions was based on the assumption that hospitalized patients may have additional comorbid conditions, higher symptom burdens and organ systems requiring treatment which may impact discharge status and potential USHR. This study did not address the return to acute care facility that may not result in a hospitalization. The patient may have been seen in the emergency department or urgent care center and discharged home. Furthermore, it did not address the possible readmission to an acute care hospital other than the index hospital.

The CNI integrative score was taken from data presented in 2015 whereas the patient demographics were taken from January 2009 through December 2014. Many hospitals began implementing changes to discharge process in December 2010 which may have influenced short-term readmissions for patients presenting in 2011 and beyond. Lastly, this was a retrospective study obtained from a single institution and therefore further multicentered research is necessary.

Conclusion

The 30-day readmission rate for diabetic patients who have had CABG surgery remain high despite known predictors of readmission. Hospitals and communities must ban together to further explore how the needs of the community can be met. Need characteristics including additional diagnoses, level of disability and cognitive status are important assessments prior to admission that may have a role in the post discharge scenario and likelihood for short-term readmission. Betty Neuman's Systems Model is fluid; Her model can be reformulated as necessary to suit the work environment with the

goal to eliminate client stressors and achieve positive outcomes. Earlier recognition of possible stressors may be achieved by fostering closer relationships in coordination with community health organizations. The entire patient and their environment must take precedence over just managing readmission rates. Measurements that score the entire patient's well-being could be instrumental in keeping the patient stable in their environment and possibly preventing hospital readmission.

Unmet needs of the patient are often unaddressed especially if the reliance is on patient self-reporting. Secondly, admission and billing records are not designed to describe causal pathways for readmission. Further research is warranted to continue to evaluate the relationship between community need and 30-day readmission in this subset population. Examining the status of diabetes, whether controlled or uncontrolled, as well as the duration of the chronic condition and its comorbidities may be useful. A prospective, qualitative study would allow for more direct patient-centered personal data and a better snapshot of their unmet needs and whether it is a consequence of a recent hospital stay or precipitated the elective hospital admission. This type of study would allow for the capture of issues or concerns by the healthcare practitioner that are not coded in a standardized manner and therefore overlooked when assessing patient needs.

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APPENDIX A. IRB Approval Letters: Newark Beth Israel Medical Center

Newark Beth Israel Medical Center | **RWJBarnabas HEALTH**

Darrell K. Terry, Sr., MHA, MPH, FACHE
President and Chief Executive Officer

Date: August 1, 2016

IRB Approval

To: Qiana Sutton, PA
Cardiothoracic Surgery

Re: IRB #2016.23
The Relationship Between Community Need and 30-Day Re-Admission in Diabetic Patients after Coronary Artery Bypass Graft Surgery

Dear Ms. Sutton:

The above mentioned protocol (2016.23) was reviewed by the NBIMC Institutional Review Board on July 21, 2016 and expedited approval was granted. Concurrently, the HIPAA waiver was also granted.

Please take note of the following:

Expiration date: **July 20, 2017.**
A request for extension must be completed at least 30 days prior to the above expiration date.

Amendments
Any changes in study procedures, subject population, recruitment or the consent process must be submitted for IRB approval **prior** to implementation.

Serious Adverse Events
a. Any fatalities or life threatening adverse events related or possibly related to the research, occurring in an NBIMC subject must be reported to the IRB within 24 hours.
b. Non-fatal or non-life threatening serious adverse events occurring in a NBIMC subject must be reported to the IRB within ten (10) working days.
c. Non-NBIMC reports (ex. sponsor safety sheets) must be submitted to the IRB office within thirty (30) days of receipt.

Thank you for your cooperation.

Robert Lahita, MD PhD
Chairman, Institutional Review Board

Please note that research MAY NOT be initiated until final approval is obtained from the Institutional Research Committee (IRC).

201 Lyons Avenue
at Osborne Terrace
Newark, NJ 07112

973.926.7000

Newark Beth Israel Medical Center | **RWJBarnabas HEALTH**

Darrell K. Terry, Sr., MHA, MPH, FACHE
President and Chief Executive Officer

IRB Approval

Date: June 19, 2017

To: Qiana Sutton, PA
Cardiothoracic Surgery

Re: IRB #2016.23
The Relationship Between Community Need and 30-Day Re-Admission in Diabetic Patients after Coronary Artery Bypass Graft Surgery

Dear Ms. Sutton:

Receipt is acknowledged of a completed request for extension with supporting materials for the above mentioned protocol (2016.23). This information was reviewed by the NBIMC Institutional Review Board on June 15, 2017 and expedited approval was granted. It was noted that this renewal request is for data analysis only.

Please take note of the following:

Expiration date: **June 14, 2018**
A request for extension must be completed at least 30 days prior to the above expiration date.

Amendments
Any changes in study procedures, subject population, recruitment or the consent process must be submitted for IRB approval **prior** to implementation.

Serious Adverse Events
a. Any fatalities or life threatening adverse events or unanticipated problems related or possibly related to the research must be reported to the IRB as soon as possible but no later than 48 hours.
b. Non-NBIMC reports (ex. sponsor safety sheets) must be submitted to the IRB office within thirty (30) days of receipt.

Thank you for your cooperation.

Robert Lahita, MD PhD
Chairman, Institutional Review Board

201 Lyons Avenue
at Osborne Terrace
Newark, NJ 07112

973.926.7000

APPENDIX B. IRC Approval Letter Newark Beth Israel Medical Center

Newark Beth Israel Medical Center | **RWJBarnabas HEALTH**

Darrell K. Terry, Sr., MHA, MPH, FACHE
President and Chief Executive Officer

IRC Approval

Date: December 13, 2016

To: Qiana Sutton, PA
Cardiothoracic Surgery

Re: IRB #2016.23
The Relationship Between Community Need and 30-Day Re-Admission in Diabetic Patients after Coronary Artery Bypass Graft Surgery

Dear Ms. Sutton:

The Institutional Research Committee (IRC) has reviewed the above referenced study (2016.23) and approval has been granted. Research activities may now be initiated.

Please note that this review from the IRC is for the initial review of your study only. There will be no other subsequent review from the committee unless otherwise warranted. Please ensure that you adhere to the continuing review deadlines and reporting requirements outlined in the IRB approval letter and as per IRB policies and guidelines.

Thank you for your cooperation.

Joshua Rosenblatt, MD
Chair, Institutional Research Committee

201 Lyons Avenue
at Osborne Terrace
Newark, NJ 07112

973.926.7000

Major teaching affiliate of Rutgers New Jersey Medical School

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APPENDIX C. IRB Approval Letters: Rutgers Biomedical and Health Sciences

RUTGERS THE STATE UNIVERSITY OF NEW JERSEY eIRB ELECTRONIC INSTITUTIONAL REVIEW BOARD

Institutional Review Board - New Brunswick
335 George Street
Suite 3100, 3rd Floor
New Brunswick, NJ 08901
Phone: 732-235-9806

Institutional Review Board - Newark
65 Bergen Street
Suite 511, 5th Floor
Newark, NJ 07107
Phone:973-972-3608

DHHS Federal Wide Assurance Identifier: FWA00003913
IRB Chair Person: Cheryl Kennedy
IRB Director: Carlotta Rodriguez
Effective Date: 2/1/2017
Approval Date: 2/1/2017
Expiration Date: 1/31/2018

eIRB Notice of Approval for Initial Submission # Pro20160000860

STUDY PROFILE

Study ID: Pro20160000860

Title: THE RELATIONSHIP BETWEEN COMMUNITY NEED AND 30-DAY READMISSION IN DIABETIC PATIENTS AFTER CORONARY ARTERY BYPASS GRAFT SURGERY

Principal Investigator: Qiana Sutton

Co-Investigator(s): Robert Denmark
Robin Eubanks
Margaret Kilduff

Other Study Staff: Robert Denmark

Sponsor: Department Funded

Approval Cycle: Twelve Months

Risk Determination: Minimal Risk

Review Type: Expedited

Expedited Category: (5)

Records: 600

CURRENT SUBMISSION STATUS

Submission Type: Research Protocol/Study

Submission Status: Approved

Approval Date: 2/1/2017 **Expiration Date:** 1/31/2018

Pregnancy Code: No Pregnant Women as Subjects **Pediatric Code:** No Children As Subjects **Prisoner Code:** No Prisoners As Subjects

Protocol: Community Need and 30-Day Readmission **Other Materials:** Community Need and 30-Day Readmission_Data Sheet

*** Retrospective Chart Review:** If applicable, records may be accessed to review information dating: **From:** 1/1/2009 **To:** 12/31/2014

*** Study Performance Sites:**

Other Rutgers School of Health Professions Department of Interdisciplinary Studies 65 Bergen St. Newark, NJ 07112

Newark Beth Israel Medical Center 201 Lyons Avenue Newark, NJ 07112

ALL APPROVED INVESTIGATOR(S) 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. **Continuing Review:** Approval is valid until the protocol expiration date shown above. To avoid lapses in approval, submit a continuation application at least eight weeks before the study expiration date.

3. **Expiration of IRB Approval:** If IRB approval expires, effective the date of expiration and until the continuing review approval is issued: **All research activities must stop unless the IRB finds that it is in the best interest of individual subjects to continue. (This determination shall be based on a separate written request from the PI to the IRB.) No new subjects may be enrolled and no samples/charts/surveys may be collected, reviewed, and/or analyzed.**

4. **Amendments/Modifications/Revisions**: If you wish to change any aspect of this study, including but not limited to, study procedures, consent form(s), investigators, advertisements, the protocol document, investigator drug brochure, or accrual goals, you are required to obtain IRB review and approval prior to implementation of these changes unless necessary to eliminate apparent immediate hazards to subjects.

5. **Unanticipated Problems**: Unanticipated problems involving risk to subjects or others must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: https://orra.rutgers.edu/hspp

6. **Protocol Deviations and Violations**: Deviations from/violations of the approved study protocol must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: https://orra.rutgers.edu/hspp

7. **Consent/Assent**: The IRB has reviewed and approved the consent and/or assent process, waiver and/or alteration described in this protocol as required by 45 CFR 46 and 21 CFR 50, 56, (if FDA regulated research). Only the versions of the documents included in the approved process may be used to document informed consent and/or assent of study subjects; each subject must receive a copy of the approved form(s); and a copy of each signed form must be filed in a secure place in the subject's medical/patient/research record.

8. **Completion of Study:** Notify the IRB when your study has been stopped for any reason. Neither study closure by the sponsor or the investigator removes the obligation for submission of timely continuing review application or

final report.

9. The Investigator(s) did not participate in the review, discussion, or vote of this protocol.

RUTGERS eIRB

Arts & Sciences IRB - New Brunswick
335 George Street
Suite 3100, 3rd Floor
New Brunswick, NJ 08901
Phone: 732-235-2866

Health Sciences IRB - New Brunswick/Piscataway
335 George Street
Suite 3100, 3rd Floor
New Brunswick, NJ 08901
Phone: 732-235-9806

Health Sciences IRB - Newark
65 Bergen Street
Suite 511, 5th Floor
Newark, NJ 07107
Phone: 973-972-3608

DHHS Federal Wide Assurance Identifier:
FWA00003913
IRB Chair Person: Cheryl Kennedy
IRB Director: Carlotta Rodriguez
Effective Date: 11/15/2017

eIRB Notice of Approval for 2018 Review for Pro20160000860

STUDY PROFILE

Study ID: Pro20160000860

Title: THE RELATIONSHIP BETWEEN COMMUNITY NEED AND 30-DAY READMISSION IN DIABETIC PATIENTS AFTER CORONARY ARTERY BYPASS GRAFT SURGERY

Principal Investigator:	Qiana Sutton		
Co-Investigator(s):	Robert Denmark Robin Eubanks Margaret Kilduff	**Other Study Staff:**	Robert Denmark
Sponsor:	Department Funded	**Approval Cycle:**	Twelve Months
Risk Determination:	Minimal Risk		
Review Type:	Expedited	**Expedited Category:**	(5)
Records:			600

CURRENT SUBMISSION STATUS

Submission Type:	Continuation(CR00006686)	**Submission Status:**	Approved
Report type:	Continuing Report	**Study Status:**	Active - Closed to Enrollment: Data analysis only (data analysis being performed by or on behalf of Rutgers Investigators)
Review Type:	Expedited	**Review Category:**	(8)(c)
Approval Date:	11/15/2017	**Expiration Date:**	11/14/2018

Pregnancy Code:	No Pregnant Women as Subjects	**Pediatric Code:**	No Children As Subjects	**Prisoner Code:**	No Prisoners As Subjects

Protocol:	Community Need and 30-Day Readmission	2/1/2017 10:25 AM	0.04	**Other Materials:**	Community Need and 30-Day Readmission_Data Sheet.pdf	0.01

*** Retrospective Chart Review:** If applicable, records may be accessed to review information dating: **From:** 1/1/2009 **To:** 12/31/2014

*** Study Performance Sites:**

Other Rutgers Site: Rutgers School of Health Professions Department of Interdisciplinary Studies 65 Bergen St. Newark, NJ 07112

Newark Beth Israel Medical Center: 201 Lyons Avenue Newark, NJ 07112

ALL APPROVED INVESTIGATOR(S) 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. **Continuing Review:** Approval is valid until the protocol expiration date shown above. To avoid lapses in approval, submit a continuation application at least eight weeks before the study expiration date.
3. **Expiration of IRB Approval:** If IRB approval expires, effective the date of expiration and until the continuing review approval is issued: **All research activities must stop unless the IRB finds that it is in the best interest of individual subjects to continue. (This determination shall be based on a separate written request from the PI to the IRB.) No new subjects may be enrolled and no samples/charts/surveys may be collected, reviewed, and/or analyzed.**
4. **Amendments/Modifications/Revisions**: If you wish to change any aspect of this study, including but not limited to, study procedures, consent form(s), investigators, advertisements, the protocol document, investigator drug brochure, or accrual goals, you are required to obtain IRB review and approval prior to implementation of these changes unless necessary to eliminate apparent immediate hazards to subjects.
5. **Unanticipated Problems**: Unanticipated problems involving risk to subjects or others must be reported to

the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: https://orra.rutgers.edu/hspp

6. **Protocol Deviations and Violations**: Deviations from/violations of the approved study protocol must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: https://orra.rutgers.edu/hspp

7. **Consent/Assent**: The IRB has reviewed and approved the consent and/or assent process, waiver and/or alteration described in this protocol as required by 45 CFR 46 and 21 CFR 50, 56, (if FDA regulated research). Only the versions of the documents included in the approved process may be used to document informed consent and/or assent of study subjects; each subject must receive a copy of the approved form(s); and a copy of each signed form must be filed in a secure place in the subject's medical/patient/research record.

8. **Completion of Study:** Notify the IRB when your study has been stopped for any reason. Neither study closure by the sponsor or the investigator removes the obligation for submission of timely continuing review application or final report.

9. The Investigator(s) did not participate in the review, discussion, or vote of this protocol.

Rutgers University eIRB: Notification Letter to Study Staff

eIRB@ored.rutgers.edu

Fri 9/28/2018 2:35 PM

To: Qiana Sutton <suttonqi@shp.rutgers.edu>;

RUTGERS eIRB

Arts & Sciences IRB - New Brunswick
335 George Street
Suite 3100, 3rd Floor
New Brunswick, NJ 08901
Phone: 732-235-2866

Health Sciences IRB - New Brunswick/Piscataway
335 George Street
Suite 3100, 3rd Floor
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Phone: 732-235-9806

Health Sciences IRB - Newark
65 Bergen Street
Suite 511, 5th Floor
Newark, NJ 07107
Phone: 973-972-3608

DHHS Federal Wide Assurance Identifier: FWA00003913
IRB Chair Person: Cheryl Kennedy
IRB Director: Carlotta Rodriguez
Effective Date: 9/28/2018

eIRB Notice of Approval for 2018 Review for Pro20160000860

STUDY PROFILE

Study ID: Pro20160000860

Title: THE RELATIONSHIP BETWEEN COMMUNITY NEED AND 30-DAY READMISSION IN DIABETIC PATIENTS AFTER CORONARY ARTERY BYPASS GRAFT SURGERY

Principal Investigator:	Qiana Sutton		
Co-Investigator(s):	Robert Denmark Robin Eubanks Margaret Kilduff	**Other Study Staff:**	Robert Denmark
Sponsor:	Department Funded	**Approval Cycle:**	Twelve Months
Risk Determination:	Minimal Risk		

Review Type: Expedited **Expedited Category:** (5) **Records:** 600

CURRENT SUBMISSION STATUS

Submission Type:	Continuation(CR00008592)	**Submission Status:**	Approved
Report type:	Continuing Report	**Study Status:**	Active - Closed to Enrollment: Data analysis only (data analysis being performed by or on behalf of Rutgers Investigators)
Review Type:	Expedited		
Approval Date:	9/26/2018	**Expiration Date:**	9/25/2019

Pregnancy Code:	No Pregnant Women as Subjects	**Pediatric Code:**	No Children As Subjects	**Prisoner Code:**	No Prisoners As Subjects

Protocol: Community Need and 30-Day Readmission

*** Retrospective Chart Review:** If applicable, records may be accessed to review information dating: **From:** 1/1/2009 **To:** 12/31/2014

*** Study Performance Sites:**

Other Rutgers Site Rutgers School of Health Professions Department of Interdisciplinary Studies 65 Bergen St. Newark, NJ 07112

Newark Beth Israel Medical Center 201 Lyons Avenue Newark, NJ 07112

ALL APPROVED INVESTIGATOR(S) 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. **Continuing Review:** Approval is valid until the protocol expiration date shown above. To avoid lapses in approval, submit a continuation application at least eight weeks before the study expiration date.

3. **Expiration of IRB Approval:** If IRB approval expires, effective the date of expiration and until the continuing review approval is issued: **All research activities must stop unless the IRB finds that it is in the best interest of individual subjects to continue. (This determination shall be based on a separate written request from the PI to the IRB.) No new subjects may be enrolled and no samples/charts/surveys may be collected, reviewed, and/or analyzed.**

4. **Amendments/Modifications/Revisions**: If you wish to change any aspect of this study, including but not limited to, study procedures, consent form(s), investigators, advertisements, the protocol document, investigator drug brochure, or accrual goals, you are required to obtain IRB review and approval prior to implementation of these changes unless necessary to eliminate apparent immediate hazards to subjects.

5. **Unanticipated Problems**: Unanticipated problems involving risk to subjects or others must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: https://orra.rutgers.edu/hspp

6. **Protocol Deviations and Violations**: Deviations from/violations of the approved study protocol must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: https://orra.rutgers.edu/hspp

7. **Consent/Assent**: The IRB has reviewed and approved the consent and/or assent process, waiver and/or alteration described in this

protocol as required by 45 CFR 46 and 21 CFR 50, 56, (if FDA regulated research). Only the versions of the documents included in the approved process may be used to document informed consent and/or assent of study subjects; each subject must receive a copy of the approved form(s); and a copy of each signed form must be filed in a secure place in the subject's medical/patient/research record.

8. **Completion of Study:** Notify the IRB when your study has been stopped for any reason. Neither study closure by the sponsor or the investigator removes the obligation for submission of timely continuing review application or final report.

9. The Investigator(s) did not participate in the review, discussion, or vote of this protocol.

—

Study.PI Name:
Study.Co-Investigators: