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# The Delivery System Design of a Community Mental Health Center and Provision of Quality: Cardiometabolic Screening for Persons with a Severe Mental Illness Prescribed Atypical Antipsychotic Medication

### Abstract

Background: Persons with a severe mental illness (SMI) prematurely lose up to 25 years of life when compared to the general population. This patient population has increased morbidity and mortality due to higher than normal rates of obesity, hypertension, diabetes, and cardiovascular disease. Treatment of SMI often includes the use of atypical antipsychotic (AA) medication which has been associated with the development of cardiometabolic illnesses. In response to the higher rates of co-morbid, chronic physical illness, monitoring guidelines for cardiometabolic illness have been published. Despite these guidelines, screening rates for cardiometabolic illness in this population remain low. Neither community mental health nor primary care systems address the physical health concerns of persons with a severe mental illness, thus widening the quality gap for this at risk, vulnerable population. The Chronic Care Model provides a systems framework for addressing the wide range of health needs for chronically ill populations and has successfully been used in improving the quality of care for persons with chronic physical health conditions. Few published studies have used the Chronic Care Model as a framework to guide improving the quality of care for persons with a SMI.

Objective: The purpose of this study was to better understand how the delivery system design of a community mental health center affects quality outcomes for persons with a SMI treated on an AA medication that are at high risk for developing cardiometabolic illness.

Methods: This cross-sectional study used baseline patient health data of persons with a SMI to analyze cardiometabolic screening rates, based on the American Diabetes Association (ADA), American Psychiatric Association (APA), Association of Clinical Endocrinologists, and North American Association for the Study of Obesity second generation antipsychotic monitoring guideline. The guideline included history of cardiovascular disease and biologic monitoring at baseline, 12 weeks, and both baseline and 12 weeks. This retrospective study used existing data from an electronic health record. A member of the clinic data team electronically extracted study demographic variables. All other study variables were manually extracted by the study investigator. The theoretical basis for this study was supported by the Care Model, an adapted version of the Chronic Care Model.

Results: The study sample consisted of 190 patients. The mean patient age was 37.13 years with a SD  $\pm$  11.7 years and a range of 19 - 70 years. The majority of patients were men (58.4%) and most patients were single (90.5%). More than one-half of the patients (53.7%) represented a minority race, though most patients were not Hispanic (95.3%). Most patients were not currently employed (88.9%) and nearly one-half of the patients lived below the federal poverty guidelines (47.4%). Ninety percent of the patients were enrolled in the Medicare or State Medical Assistance program. More patients (61.6%) did not schedule their baseline or followup visit, but rather "walked" into the clinic without prior notice. The average number of visits during the initial treatment phase was 3.7  $\pm$  1.4 and more than one-third of patients had the same provider at baseline and follow-up (36.3%).

No patients received all recommended screening measures per the ADA and APA monitoring guideline. Biological measures (excluding history of cardiovascular disease) were evaluated for ten patients at baseline, three patients at follow-up and one patient at both baseline and follow-up. At baseline, rates for each screening measure were as follows: weight or BMI (64.2%), blood pressure (62.1%), fasting plasma glucose or hemoglobin A1c (27.9%), fasting lipid profile (8.4%) and family or personal history of cardiovascular disease (34.7%). At followup, rates of each cardiometabolic screening measure were as follows: weight or BMI (63.2%), blood pressure (61.6%), fasting plasma glucose or hemoglobin A1c (13.2%), fasting lipid profile (9.5%). Summaries of the unadjusted (r) and adjusted (beta) associations between combined delivery system design candidate variables and each of the quality outcome variables at baseline revealed associations between being a current smoker (r = .15, p = .041), having a clinic primary care provider (r = .21, p = .003), being a walk-in at baseline (r = .14, p - .048), and the number of screening measures. At follow-up, no statistically significant associations were observed.

Conclusion: Data suggest that the delivery system design of a community mental health center inadequately addresses screening for cardiometabolic symptoms of persons with SMI. Findings show that adherence to the full panel of ADA and APA recommended cardiometabolic screening measures for persons treated on an AA medication is abysmal. Even rates of common screening measures, such as blood pressure, are poor. The Care Model was a useful theoretical framework to guide the study. Results of the study indicate that SMI patients may interact with the health care system differently than patients with chronic medical conditions. It is feasible that the high rate of unscheduled visits, or "walk-in" visits and number of different providers caring for patients during the initial treatment phase contributes to poor quality care. Subsequent recommendations include developing an intervention study to evaluate quality outcomes using a) an integrated care delivery design specifically for SMI patients and b) expanding the Care Model components to include the health system organization, decision support, self-management support, and clinical information systems. It is critically important that care delivery systems for persons with SMI be integrated for optimal health outcomes.

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The Delivery System Design of a Community Mental Health Center and Provision of Quality: Cardiometabolic Screening for Persons with a Severe Mental Illness Prescribed Atypical Antipsychotic Medication

> A Dissertation Presented for The Graduate Studies Council The University of Tennessee Health Science Center

In Partial Fulfillment Of the Requirements for the Degree Doctor of Philosophy From The University of Tennessee

> By Dawn Marie Vanderhoef May 2012

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-Vincent Thomas "Vince" Lombardi

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#### ABSTRACT

**Background:** Persons with a severe mental illness (SMI) prematurely lose up to 25 years of life when compared to the general population. This patient population has increased morbidity and mortality due to higher than normal rates of obesity, hypertension, diabetes, and cardiovascular disease. Treatment of SMI often includes the use of atypical antipsychotic (AA) medication which has been associated with the development of cardiometabolic illnesses. In response to the higher rates of co-morbid, chronic physical illness, monitoring guidelines for cardiometabolic illness have been published. Despite these guidelines, screening rates for cardiometabolic illness in this population remain low. Neither community mental health nor primary care systems address the physical health concerns of persons with a severe mental illness, thus widening the quality gap for this at-risk, vulnerable population. The Chronic Care Model provides a systems framework for addressing the wide range of health needs for chronically ill populations and has successfully been used in improving the quality of care for persons with chronic physical health conditions. Few published studies have used the Chronic Care Model as a framework to guide improving the quality of care for persons with a SMI.

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## LIST OF ABBREVIATIONS

| AA    | Atypical Antipsychotic                                      |
|-------|---|
| AACE  | American Association of Clinical Endocrinologists           |
| ACIC  | Assessment of Chronic Illness Care                          |
| ADA   | American Diabetes Association                               |
| ADHD  | Attention Deficit Hyperactivity Disorder                    |
| ANCC  | American Nurses Credentialing Center                        |
| APA   | American Psychiatric Association                            |
| APRNs | Advanced Practice Registered Nurses                         |
| BMI   | Body Mass Index   |
| CATIE | Clinical Antipsychotic Trials of Intervention Effectiveness |
| CCM   | Chronic Care Model  |
| CM    | Care Model  |
| CMHC  | Community Mental Health Center                              |
| CMI   | Cardiometabolic Illness                                     |
| CNS   | Clinical Nurse Specialist                                   |
| CVD   | Cardiovascular Disease                                      |
| DSM   | Diagnostic Statistical Manual                               |
| EBP   | Evidence Based Practice                                     |
| ECA   | Epidemiological Catchment Area                              |
| EHR   | Electronic Health Record                                    |
| FDA   | Food and Drug Administration                                |
| FPG   | Fasting Plasma Glucose                                      |
| ICIC  | Institute for Health Care Improvement                       |
| IOM   | Institute of Medicine                                       |
| IRB   | Institutional Review Board                                  |
| LEP   | Limited English Proficiency                                 |
| MSN   | Master of Science Nursing                                   |
| NAASO | North American Association for the Study of Obesity         |
| NCEP  | National Cholesterol Education Program                      |
| NCS   | National Comorbidity Survey                                 |
| NIMH  | National Institute of Mental Health                         |
| NP    | Nurse Practitioner  |
| PA    | Physician Assistant   |
| PCP   | Primary Care Provider                                       |
| PMHNP | Psychiatric Mental Health Nurse Practitioner                |
| RWJF  | Robert Wood Johnson Foundation                              |
| SGA   | Second Generation Antipsychotic                             |
| SMI   | Severe Mental Illness                                       |
| SUD   | Substance Use Disorder                                      |
| US    | United States   |
| VA    | Veterans Administration                                     |
|       |   |

### **CHAPTER 1. INTRODUCTION**

Persons with a severe mental illness (SMI) prematurely lose 10 - 25 years of life as compared to the general population (Miller, Paschall, & Svendsen, 2006; Richardson et al., 2005). Cardiovascular disease is the most common cause of excessive mortality in this population (Richardson et al.). Causes of cardiovascular disease and premature death, such as hypertension, obesity, and diabetes, have been associated with use of atypical antipsychotic (AA) medication (Amiel, Mangurian, Ganguli, & Newcomer, 2008). Though it has been eight years since recommendations for cardiometabolic screening for persons treated on AA medication were first published, patients continue to go unscreened.

This chapter describes (1) critical issues in quality care for SMI patients, (2) the significance of the Care Model to ensure quality care delivery, and (3) the importance of following practice standards to improve health outcomes for all patients with a SMI. A broad overview of the problem will be presented, followed by the purpose of the study, research questions, the theoretical framework, operational definitions, and the significance of the study.

#### **Statement of the Problem**

Grave disparities in access to mental and physical health care exist for persons with a SMI creating an urgent need to integrate these two systems of care for this population (U.S. Department of Health and Human Services, 1999). One recommendation from The Institute of Medicine (IOM) involves focusing on quality of care to improve health outcomes for persons with a mental illness (2001). As a result, integration of physical and mental health care is a health care priority for the 21<sup>st</sup> century.

Access to health care in the United States (U.S.) is often difficult to obtain and delivered by complex and fragmented systems, which leads to suboptimal patient outcomes (Cebul, Rebitzer, Taylor, & Votruba, 2008). Historically, health care systems focused on treatment of acute and infectious diseases, as these were the leading causes of disability and death in the U.S. (Glasgow, Orleans, & Wagner, 2001). Currently, chronic illness affects almost one out of every two Americans (Von Korff, Gruman, Schaefer, Curry, & Wagner, 1997) or about one hundred million persons, half of whom have more than one chronic illness (Bodenheimer & Grumbach, 2007). This number is expected to increase at a rapid rate given the number of aging persons in the U.S. (Wagner, Austin et al., 2001). The cause of or increase in morbidity from chronic illness is often due to preventable lifestyle related behaviors (Hung et al., 2007). Persons who have a SMI have additional disease related and psychosocial barriers to achieving healthy lifestyle behaviors and therefore, interventions are needed to target this vulnerable population. A charge for healthcare delivery systems in the 21<sup>st</sup> century is to prevent and manage chronic disease (Glasgow et al., 2001). The Institute of Medicine (2001) identified a call

to action to improve the healthcare delivery system and shift care from a focus on acute to chronic conditions.

Chronic care management of persons with a SMI requires understanding that a diagnosis of a severe mental illness is an independent risk factor for the development of cardiovascular disease. Persons with schizophrenia and bipolar disorder have an increased risk for diabetes and obesity (Daumit, Pratt, Crum, Powe, & Ford, 2002) and develop cardiovascular disease at rates twice that of the general population (Hansen, Jacobsen, & Arnesen, 2001; Morden, Mistler, Weeks, & Bartels, 2009; Saha, Chant, & McGrath, 2007). This population has higher morbidity and mortality rates when compared to the general population (Daumit et al., 2002). In addition to unknown independent risk factors of cardiovascular disease, persons with a SMI have modifiable risk factors. For example, many individuals with a SMI have a low income, are on disability, and have limited access to healthy foods, resulting in higher rates of high-fat food intake. Additionally, persons with a SMI often smoke cigarettes, smoking at rates twice as high as the general population (Daumit et al., 2002; Lasser et al., 2000). For persons with schizophrenia, there is evidence of a vulnerability to nicotine addiction. This interaction makes quitting more difficult since it is suggested that nicotine can improve attention in this population (McEvoy & Allen, 2002). Unfortunately, though the risks of co-morbid physical health in persons with a SMI are well documented, care is typically not focused on chronic disease management of both the mental and physical illness.

Neither traditional community mental health nor primary care systems address the physical health concerns of persons with SMI, further increasing fragmentation and widening the quality gap for this at-risk, vulnerable population. Disparities in primary care exist for persons with SMI. Not only has treatment failed to achieve better physical health outcomes for persons with SMI, their care has been noted to be less than optimal. Persons with a SMI who present to a primary care provider are often under treated or not treated at all. Despite receiving more time with the provider during office visits, SMI patients do not typically receive screening and preventive services (Daumit et al., 2002). Subsequently, this population is developing chronic multimorbid health problems at alarming rates, requiring an immediate reform to the systems of care (Daumit et al., 2002).

Over the last 20 years there has been a national emphasis on identifying and treating mental illness which has resulted in new approaches to the treatment of mental illness. The U.S. declared the 1990's the decade of the brain. During this time, federal dollars were available to study treatment approaches and the brain (Frese, Stanley, Kress, & Vogel Scibilia, 2001). Additionally, in 1999 the U.S. Surgeon General published the first ever report on mental health (U.S. Department of Health and Human Services, 1999). This report cited that mental health is a public health problem that must be addressed by the nation and that mental health is vital to physical health. Following these two seminal events, in 2002 the President of the United States established the New Freedom Commission on Mental Health to analyze both public and private mental health systems. The New Freedom Commission on Mental Health report identified fragmented care, less than optimal outcomes, and high costs to treat SMI (Hogan, 2003). It was

during this time that many advances were made for the treatment of persons with a SMI. These events have advanced a movement to address the mental and physical treatment of persons with a SMI.

Addressing mental and physical healthcare treatment in a systematic way requires a common definition of SMI; however, persons with a SMI have been defined differently by various authors and an international agreement on how to define a SMI is lacking (Ruggeri, Leese, Thornicroft, Bisoffi, & Tansella, 2000). Goldman, Gattozi, and Taube (1981) state that deinstitutionalization of mentally ill patients created a necessity to develop a consensus for classifying persons with a SMI. During this time, many individuals were faced with living in the community; therefore, outpatient services for the treatment of persons with a SMI were developed. Various authors use different criteria to define a SMI and based on the inclusion criteria, the prevalence of a SMI can range from 4% to 88% of persons with a severe mental illness (Schinnar, Rothbard, Kanter, & Jung, 1990). The National Institute of Mental Health (1987) has a broad and widely accepted definition of SMI which includes various illnesses with identified timeframes. However, Narrow and colleagues (2000) have a more specific definition and cite just over 3% of adults have a SMI in the US with 1.5% having schizophrenia, 1% having bipolar disorder and 1% with treatment refractory depression. Various Medicaid payments are based on a global assessment of the patient, which includes The Diagnostic and Statistical Manual IV- Text Revision (DSM IV-TR) Axis I-V diagnosis and other functional rating scales. For purposes of this study, SMI is conceptualized as conditions within the DSM IV TR Axis I diagnosis: Schizophrenia, Schizoaffective Disorder, Psychotic Disorder Not Otherwise Specified, Bipolar Disorder or Major Depressive Disorder, Recurrent. Evaluating healthcare outcomes also requires an explicit understanding of how the course of illness in an affected population impacts how an individual engages with the healthcare system. Through a better understanding the illness trajectory for persons with SMI, models can be developed to predict the course of treatment that will enable providers to proactively plan care and achieve the best possible outcomes for this vulnerable population.

Persons with a SMI are considered a vulnerable population as are immigrants (persons who live in a country other than their country of origin). Immigrants can be U.S. born or foreign born. This patient population is much like persons with a SMI, both populations often have lower socioeconomic status, which includes factors such as income, education, occupation and these factors have been linked to mental health problems (U.S. Department of Mental Health and Human Services, 1999).

Immigrants are a vulnerable population who are at risk for poor physical and mental health (Derose, Escarce, & Lurie, 2007). In 2009 there were approximately 38.5million foreign born immigrants in the U.S. which represents about 1 in 8 residents (U.S. Census Bureau, 2010). Within the U.S., immigrants are a heterogeneous population with the highest percent coming from Latin America (53%) followed by Asia (28%) and Africa (4%) (U.S. Census Bureau). The upper Midwest region of the U.S. has less than 6% immigrant population in each state, with the exception of Illinois with 10-15% and Minnesota with 6-10% of the state population being foreign born immigrants (U.S. Census Bureau).

The length of time an immigrant resides in the U.S. is associated with higher rates of assimilation and acculturation. One study shows that the longer immigrants live in the US and the more acculturated they become and the more their health declines (Derose et al., 2007). These authors cite adoption of unhealthy habits, living in high risk environments and reduced access to medical services as a source of being at high risk for disease. Access to medical services and disparities in health care quality has also been identified by race, ethnicity, socioeconomic status, and language.

In 2000 there were over 281 million persons living in the U.S., 26 million of whom were non-English speakers; 9 million were linguistically isolated and 3 million spoke no English (U.S. Census Bureau, 2000). Language proficiency and the ability to speak English impacts access to health care. A recent national sample found that Spanish-speaking and black patients are less likely than non-Hispanic white patients to have had a mental health visit (Fiscella, Franks, Doescher, & Saver, 2002). Persons with limited English proficiency were also found to have fewer physician visits and receive less preventive care. Mohanty and colleagues (2005) found that immigrants are reported to have lower education, come from lower income levels, and self-report poorer health. Immigrants often express health in a cultural context; however, the diagnostic criteria for SMI are the same for all populations in the U.S. A recent meta-analysis showed that family history was the greatest risk factor for developing schizophrenia; however, foreign born migrants with dark skin are at higher risk as compared to controls (Cantor Graae & Selten, 2005).

The onset of a SMI occurs in early or middle adulthood, between 20 and 35 years of age. This age range is a time when most people are physically healthy and have limited contact with the health care system. Individuals with symptoms of a mental illness typically present in a primary care system with initial symptoms but receive ongoing treatment of a mental illness within the mental health system of care, most often a community mental health center (CMHC). This handoff increases fragmentation, creating the first of many opportunities for poor quality health care. Subsequently, seamless healthcare models focused on both mental and physical health are needed to improve outcomes for persons with SMI.

#### **Chronic Care Model**

The Chronic Care Model (CCM) provides a systems framework for addressing the wide range of health needs for chronically ill populations. This model was developed by Wagner and colleagues (1998) to address the lack of access to care and the poor quality associated with management of persons with chronic illnesses. The Chronic Care Model was introduced by Wagner and colleagues, in collaboration with the MacColl Institute for Healthcare Innovation after an extensive literature review on best practices for chronic illness management. The CCM is a comprehensive framework designed to be a functional blueprint (Glasgow et al., 2001) to help improve patient outcomes through six interrelated systems: organization of healthcare, community resources, selfmanagement support, delivery system design, decision supports, and clinical information systems (Coleman, Austin, Brach, & Wagner, 2009). The CCM defines the six broad areas that must be considered, but is not prescriptive (Glasgow et al., 2001), an abstract theory (Bodenheimer, Lorig, Holman, & Grumbach, 2002) or an explanatory theory (Wagner, Glasgow et al., 2001) Rather it is a multidimensional solution (Bodenheimer et al., 2002) that will guide practice through the interaction of the six systems to develop informed, empowered patients and a prepared proactive practice team that synergistically create productive interactions that lead to improved health outcomes. This framework is intended to be tailored to various chronic conditions and applied to a variety of care settings and populations (Hung et al., 2007; Glasgow et al., 2001). Further, the CCM is a framework that can be used to guide changes in health care delivery that enhance health outcomes (Piatt et al., 2006).

The CCM has been proposed as a way to integrate mental health care and primary care (Mulligan, 2003) and has been adapted to develop a bipolar care model (Kilbourne et al., 2008). As an adaptation of the CCM, the Institute for Health Care Improvement (ICIC) has proposed an Expanded CCM which widens the community portion of the model to include health determinants (Barr et al., 2003). The Care Model (CM) incorporates the IOM underpinnings of care that is patient centered, timely and efficient, evidence based, and safe and coordinated. It is postulated that because the purpose of the Robert Wood Johnson Foundation (RWJF) initiative was to examine the effectiveness of the CCM in medical homes, much of the current literature relates to the CCM introduced in 1998, rather than an adapted version. The Care Model includes the same six core systems as the CCM with the one difference that the CM includes the IOM quality underpinning, which leads to an informed, empowered patient and family as opposed to the CCM's informed, activated patient.

Seminal studies of the CCM focused on the interactions of the elements in the CCM with the health care system; however, a study by Sperl, Hillen et al. (2004) not only acknowledged interactions of the CCM, but also noted that a theoretical case can be made to examine individual components of the CCM. Several reasons support the case that individual elements of the CCM can be individually evaluated. For example, health care systems are complex. Change within a health care system is nonlinear with differing effects on the parts of the system. Subsequently, individual CCM components may need to be tested to detect intervention effectiveness. A second reason is that healthcare organizations do not have the resources to implement all aspects of the CCM simultaneously. Therefore, individual components of the CCM must be able to be studied to generate new knowledge and guide progress. Moreover, several studies have measured the impact of specific CCM components, such as self-management (Polonsky et al., 2003) and the delivery system design (Schmittdiel, Uratsu, Fireman, & Selby, 2009) on diabetic outcomes. Findings support the concept that the CCM can be examined by its individual components because changes to individual components can improve care outcomes (Nutting et al., 2007).

Blakely and Dziadosz (2008) note that the CCM has been used in the primary care setting for guiding care changes for persons with a SMI; however, few community mental health centers are familiar with the CCM. This study indicated that the CCM was successful in making practice changes to the structure and function of care for persons with a SMI. Kilbourne et al. (2008) also found elements of the CCM used in an adapted Bipolar Care Model to be successful in improving outcomes for persons with SMI.

As a highlight of the CCM, Wagner, Austin, and Von Korff (1996) acknowledge that the delivery system design is vital to providing quality care to patients. The delivery system design is the component of the CCM through which innovations in care delivery are implemented. Further, the delivery system design of a health care organization represents an opportunity to change the environment in which the care team, patient, and visit characteristics interact. While the delivery system design does not directly impact health outcomes (Oprea, Braunack, Mayer, Rogers, & Stocks, 2010), the CCM has been used to guide evidence based treatment for chronic conditions such as diabetes and attention deficit hyperactivity disorder (Nutting et al., 2007; Parchman, Zeber, Romero, & Pugh, 2007; Sperl, Hillen et al., 2004; Van Cleave & Leslie, 2008). Elements of the delivery system design in the CCM are present in a CMHC. Systematic exploration of the delivery system design, as conceptualized by the CCM, is a novel strategy to better understanding the factors affecting quality outcomes for persons with a SMI.

#### **Practice Standards**

The mental health system has various models to guide the delivery of care, which focus on treatment with an emphasis on recovery from a mental illness, rather than treatment of both physical and mental health concerns. Recovery models in mental health systems have transformed the expected outcomes for persons with a SMI. They have become the gold standard, enabling greater independence among this population (Frese et al., 2001). Prior to the 1970's, when deinstitutionalization occurred, persons with a SMI were often institutionalized for indefinite periods of time (Lamb & Bachrach, 2001). In the 1950's the discovery of Thorazine showed promise that persons who had been in institutions and hospitals could be treated for their mental illness in the community. Over the last 60 years the mental health system has shifted the focus of care from housing persons with a severe and persistent mental illness to treatment and recovery of persons with a SMI. Recovery models are similar to the CCM in that they aim to create the structures that instill hope, healing, empowerment, and connection (Jacobson & Greenley, 2001). An assumption of the CCM is that the health care system is a barrier to the treatment of chronic conditions and as with recovery models, shifting the focus of care can lead to quality outcomes based on system redesign (McEvoy & Barnes, 2007).

The delivery of care for persons with a SMI in a CMHC involves a multidisciplinary team approach to treatment. Individuals are often treated with medication by psychiatrists or Advanced Practice Registered Nurses (APRN's), who have specialty training in psychiatric mental health nursing. Other care team members include Master's or Bachelor's prepared therapists and case managers, crisis workers, and nursing staff. Team goals include treatment of the person's psychiatric illness and navigation of support for other medical and psychosocial needs. The visit frequency and intensity of treatment in the CMHC may vary based on the individual's severity of illness and current needs; however, it is well documented that persons with a SMI need ongoing psychopharmacologic treatment of their psychiatric illness. Similarly, in a primary care delivery system, persons with chronic physical illnesses receive ongoing pharmacotherapy to treat various conditions. SMI treatment involves all phases of the illness, including acute illness, maintenance, and relapse.

Historically, persons with a SMI were treated on first generation antipsychotic medication. When patients were treated on older, first generation medications, providers were concerned about premature death due to unknown factors related to the illness or suicide (Brown, 1997; Simpson & Tsuang, 1996). The use of Atypical Antipsychotic (AA) medications as first line treatments have improved psychiatric illness outcomes but have also increased cardiovascular health concerns for these patients. Two studies have demonstrated that AAs cause weight gain and elevated glucose and lipid levels, and put individuals at risk for metabolic syndrome (Hasnain et al., 2009; Patel et al., 2009). The cardiometabolic side effect profile of AA medications has further increased the morbidity and mortality for this population (Amiel et al., 2008).

The side effects related to AA medications have created heightened awareness of the physical health status of persons with a SMI. Studies over the last twenty years have shown that AAs have improved treatment of a SMI; however, these medications have also been associated with weight gain, hyperglycemia, and dyslipidemia (Morrato et al., 2010). A seminal study conducted by the National Institute of Mental Health (NIMH) Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) was designed to investigate the effectiveness of antipsychotic drugs in persons with schizophrenia (Lieberman et al., 2005). Since the initial study, many secondary analysis studies have been published. In one study, persons with schizophrenia who were male had a 34% higher risk of coronary heart disease (CHD) while females had a 50% higher risk (McEvoy, Meyer, Goff, Nasrallah, Davis, et al., 2005). Diabetes rates were 16% in males and 11% in females compared to 3% in the control population. Data from the CATIE study found that persons with schizophrenia are at higher risk for CHD. At baseline, therefore, cardiac risk factors should be evaluated and monitored. The rate at which persons with a SMI develop symptoms which can lead to cardiometabolic syndrome and cardiovascular disease has heightened mental health providers' awareness of the risk for persons with a SMI developing cardiometabolic disease.

In response to the alarming rates of obesity, hyperglycemia, hyperlipidemia, and hypercholesterolemia, in 2004 the Food and Drug Administration (FDA) published a warning letter for mental health providers addressing the risk factors of treating a person with an AA. The American Diabetes Association (ADA) along with the American Psychiatric Association (APA) developed an expert consensus statement on metabolic screening for persons treated on AA medications (American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, & North American Association for the Study of Obesity, 2004). It was hoped that mental health providers would begin to assess the physical health status of persons treated on AA medications. However, recent data suggest that in the eight years since the guideline was published only a small percentage of persons treated on these medications have been screened for cardiometabolic symptoms per the ADA and APA guidelines. Morrato et al. (2010) found that 60-80% of psychiatrists surveyed reported monitoring labs regularly; however, the study found a 26% compliance rate for baseline glucose screening and a 10% rate for lipids. Further, Morrato and colleagues (2010) found no significant increase in laboratory testing rates after the 2004 publication and highlighted the need for more research to address the gap between screening rates for an at risk population.

The reasons for adhering to the ADA and APA monitoring guidelines in community mental health centers are unknown. Several published studies have addressed cardiometabolic screening rates (Haupt et al., 2009; Hsu et al., 2008; Morrato, Newcomer, Allen, & Valuck, 2008; Morrato et al., 2010); however, there are no published studies addressing the impact of the delivery system on cardiometabolic symptom screening for persons with a SMI. While it is true that researchers are beginning to look at cardiometabolic outcomes in this patient population and ways to provide integrative care, the data are scant and few published studies exist. Understanding the system-related factors that affect recommended cardiometabolic screening and follow-up care is critical for improving outcomes for persons with SMI. If health systems, both mental and physical health, have the capability for detection of obesity, hypertension, and elevated serum lipid and glucose levels at an earlier point in their trajectory, persons with SMI can receive the recommended care to address modifiable risk factors through planned, timely, medical and behavioral interventions. Earlier intervention will not only result in better health outcomes, it will also reduce health care expenditures for this patient population. For the above reasons, it is imperative that more is known about how the health care system design affects adherence to best practices in order to reduce the disparities in care for persons with SMI.

### **Purpose of the Study**

The purpose of this study was to describe the impact of the delivery system design at a community mental health center and cardiometabolic screening in persons with severe mental illness taking atypical antipsychotic medication. Research questions include:

- 1. What are the baseline patient, provider, and visit characteristics of SMI patients prescribed an atypical antipsychotic medication?
- 2. What percent of SMI patients prescribed an atypical antipsychotic medication received cardiometabolic screening at a) baseline, b) follow-up, and c) both baseline and follow-up?
- 3. What delivery system characteristics are associated with receiving cardiometabolic screening at a) baseline; b) follow-up; and c) both baseline and follow-up?

#### **Theoretical Framework**

#### Quality

This study is guided by the use of the Care Model, an adapted version of the Chronic Care Model, and assumes that quality care is patient centered, timely and efficient, evidence based, and safe and coordinated. Consistent with the IOM's (2001) definition, quality is defined as the degree in which a mental health service encounter, for persons with a severe mental illness, is likely to lead to an outcome of evidenced based care as defined by the ADA and APA monitoring guidelines.

The quality of care provided to persons with a severe mental illness can be evaluated using the Donabedian model of structure, process, and outcome. As noted by Donabedian (1988), the elements of the structure, processes, and outcomes of care need to be cited in order for the elements of quality to be identified and clearly stated. The first quality care dimension from the Donabedian framework–structure–is defined as the CMHC The site where care is delivered is a specialty outpatient clinic which contains elements to provide care to persons with a SMI. The processes of care, the second element of the Donabedian framework, will identify which components of the delivery system design have an impact on care that is patient centered, timely and efficient, evidence based, and safe and coordinated. The process quality will evaluate the relationship between the patient, provider, and visits to evaluate whether or not the practice standard ADA and APA monitoring guidelines were followed. The outcome measure will determine the quality of care defined as whether persons with a SMI are screened for cardiometabolic symptoms, per the ADA and APA 2004 guidelines at baseline and 12 weeks.

#### **Chronic Care**

Persons with a severe mental illness are in need of ongoing treatment for their illness. Chronic care provided to this patient population often occurs in a community mental health center where services focus on the mental illness rather than the physical health of the individual. Chronic care for persons with a SMI, provided in community mental health centers, includes medication management by a health care provider, either psychiatrist or nurse practitioner. The chronic care delivered to persons with a severe mental illness includes the delivery system design of the mental health center which involves a relationship between the patient, provider, and visits. The Care Model provides a framework to evaluate the chronic care provided to persons with a severe mental illness, specifically evaluating the delivery system design. Within the Care Model, the delivery system design incorporates the patient, provider, and visits and allows for the evaluation of chronic care quality.

#### **Delivery System Design**

The Care Model was selected for this study because it includes the IOM underpinnings of quality care, which include care that is patient-centered, timely and efficient, evidence based, and safe and coordinated. The elements within the delivery system design are present in a CMHC. The delivery system design elements include the care team consisting of the patient and provider. The other element of the delivery system design are visits. These elements are not unique to a CMHC setting and collectively influence the quality provided to patients with a severe mental illness.

Chronic care that is patient-centered, timely and efficient, evidence based, and safe and coordinated, provided to persons with a severe mental illness in a community mental health center can be evaluated for outcomes of evidence based quality care. When quality care provided within the delivery system design includes the patient, provider, and visit, productive interactions are an outcome. An informed, empowered patient and family have productive interactions with prepared, proactive practice teams.

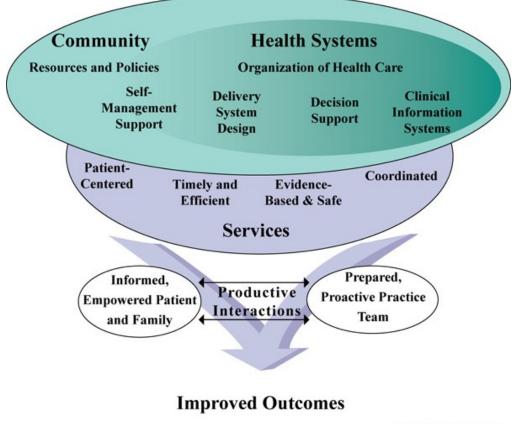
#### **Care Outcomes**

Within the community mental health center, the structure of the delivery system design land the process of how the patient, provider and visits are structured leads to the outcome of quality care for persons with a severe mental illness. The care outcome is patient screening per the ADA and APA guidelines and referral to primary care if a positive screening includes elevated blood pressure, serum glucose, or lipids. **Figure 1.1** displays the Care Model, the adapted version of the CCM, which was used to guide this study and describes how the elements of the delivery system design influence cardiometabolic screening.

#### Significance of the Study

Persons with a SMI have not only increased morbidity and mortality due to unknown risk factors, but also several modifiable risk factors, which if addressed, could decrease the number of life years lost prematurely. A growing body of research has identified that psychopharmacologic treatment for a SMI has increased the risk of cardiometabolic symptoms in this population, placing individuals at higher risk for premature death. While research has identified problems related to the side effects of AA medications, no studies exist that have examined the delivery system design of a community mental health center and the impact on cardiometabolic screening.

The delivery system design of a community mental health center has the same components as identified by Wagner and colleges in the Chronic Care Model (1996). Within the delivery system design of a CMHC, the care team and visits can be examined to explore the effect on cardiometabolic screening in persons with a SMI. To date, one study has used the Chronic Care Model to examine organization of the delivery of



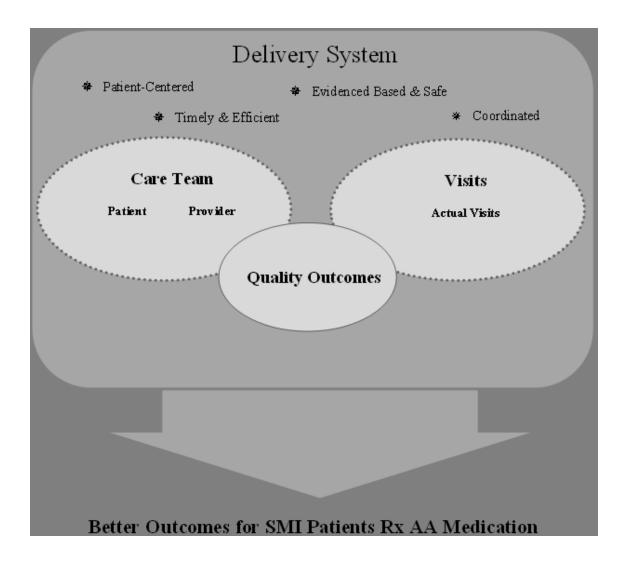
Developed by The MaColl Institute

### Figure 1.1. The Care Model

Reprinted with permission. The MacColl Center (2012). The Improving Chronic Illness Care Model Elements. In ICIC's Expanded Chronic Care Model. Retrieved on March 2, 2010 from: <u>http://www.improvingchroniccare.org/index.php?p=ICIC\_Expanded&s=156</u>.

behavior health services (Blakely & Dziadosz, 2008). These authors found that implementation of the CCM in a mental health agency can help guide change in the delivery of behavioral health care. Bauer et al. (2006) and Kilbourne et al. (2009) have successfully used adapted versions of the chronic care model to guide care changes with persons treated for bipolar disorder.

This study will use the Care Model, an adapted version of the CCM, to guide the examination of the delivery system design of a community mental health center to identify characteristics of persons with a SMI who are screened and referred for cardiometabolic symptoms. The study findings will inform the current body of literature about screening for cardiometabolic symptoms and add a novel aspect of using the CM elements to guide future work with a focus on the delivery system design. To date no published studies have specifically examined the characteristics of the delivery system design of a CMHC to explore screening and referral for cardiometabolic symptoms in persons with a SMI. The conceptual framework used to guide this study is shown in **Figure 1.2**.



## Figure 1.2. Delivery System Design Quality

Conceptual framework: concepts, conceptual linkages and levels of conceptual abstraction.

Sources: The MacColl Center (2012); Wagner, E. H., Austin, B. T., Davis, C., Hindmarsh, M., Schaefer, J., & Bonomi, A. (2001); Wagner, E. H., Glasgow, R. E., Davis, C., Bonomi, A. E., Provost, L., McCulloch, D., . . . Sixta, C. (2001); Wagner, E. H. (1998); Wagner, E. H., Austin, B. T., & Von Korff, M. (1996).

### CHAPTER 2. REVIEW OF THE LITERATURE

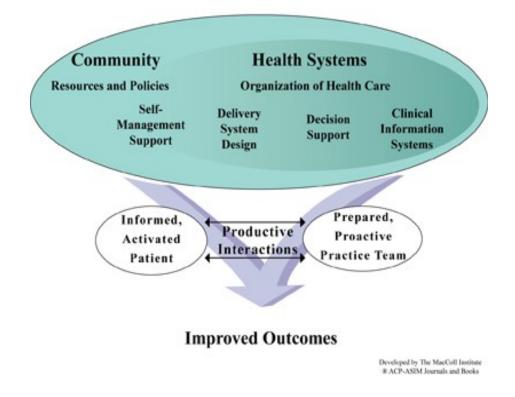
The first section of this chapter focuses on the conceptual framework that was used to guide this study. The second section of this chapter provides a review of the literature centered on the characteristics of the conceptual framework used in this study, specifically the delivery system design. Finally, each of the characteristics within the delivery system design; the care team, visits, and quality outcomes are discussed.

#### **Chronic Care Model**

In 1996 Wagener and colleagues introduced the Chronic Care Model (CCM) to guide transformation of health care from a system focused on acute illness, to a system focused on prevention and chronic disease management. The Chronic Care Model was developed in collaboration with the MacColl Institute for Healthcare Innovation after extensive literature review on best practices for chronic illness (**Figure 2.1**). The CCM is intended to guide improvement of patient outcomes through six interrelated systems: organization of healthcare, community resources, self-management support, delivery system design, decision supports, and clinical information systems (Coleman, Austin, Brach, & Wagner, 2009).

The CCM conceptualizes health care systems being part of the community in which care is provided (Wagner, Austin et al., 2001). The CCM elements were developed using the research literature and by health care experts who provide chronic care to individuals with various chronic conditions (Improving Chronic Illness Care, 2012). The community resources and policies are part of the development of community partnerships. Self-management support focus empowers patients to play a central role in the management of their chronic illness. Decision support is the use of evidence based practice guidelines in daily practice. A clinical information system is the development of information systems that prompt patients and providers and performance of the care team. Finally, the delivery system design defines the roles of team members to provide planned, evidence-based care. Collectively the six elements create a productive interaction between an informed activated patient and a proactive practice team to improve both functional and clinical outcomes.

The CCM defines the six broad areas that must be considered but is not prescriptive (Glasgow, Orleans, & Wagner, 2001; Hung et al., 2007), an abstract theory (Bodenheimer, Lorig, Holman, & Grumbach, 2002) or explanatory theory (Wagner, Glasgow et al., 2001). Rather it is a multidimensional solution (Bodenheimer et al., 2002) that will guide practice through the interaction of the six systems to develop informed activated patients and a prepared proactive practice team. This framework is intended to be tailored to various chronic conditions and applied to a variety of care settings and populations (Glasgow et al., 2001). The interaction between the six elements of the CCM has the ability to improve the quality of preventive and chronic care delivered to patients and populations.



## Figure 2.1. The Chronic Care Model

Reprinted with permission. Wagner, E. H. (1998). Chronic disease management: What will it take to improve care for chronic illness? *Effective Clinical Practice*, 1(1), 2-4.

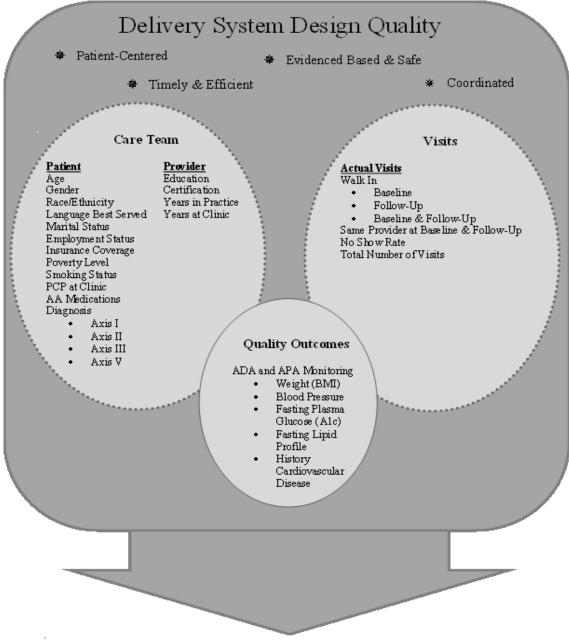
As a highlight of the CCM, Wagner, Austin, and Von Korff (1996) acknowledged that the delivery system design is vital in providing quality care to patients. Sperl, Hillen et al. (2004) acknowledged interactions of the CCM but also noted that a theoretical case can be made to examine individual components of the CCM. For example, health care systems are complex and it may be difficult to organize changes needed that comprise all six systems in the CCM. Further, organizations have implemented components of the CCM and showed an improvement in care (Schmittdiel, Uratsu, Fireman, & Selby, 2009; Sperl Hillen et al., 2004). A study conducted by Nutting and colleagues (2007) provided data to support the claim that systems do not implement all aspects of the CCM. In this study, the findings suggest that implementation of elements of the CCM leads to improvement in care of persons with diabetes. Polonsky et al. (2003) also found that focusing on self-management support, as an element of the CCM, improved care of person with diabetes. Finally, a study of effective diabetes care showed that one aspect within the delivery system design, care management, can improve outcomes for persons with diabetes (Schmittdiel et al., 2009).

Wagner, Glasgow and colleagues (2001) intended for the CCM to be used in various disease states and populations in a variety of settings and to guide transformation of care to persons with a chronic condition. The model supports care that is evidence based, population based, and patient centered (Glasgow et al., 2001) as well. This model is consistent with the Institute of Medicine's (2001) aims of health care systems to provide care that is safe, effective, patient centered, timely, efficient and equitable. To address the unique needs of various patient populations in a variety of settings, the CCM may need to be adapted to assess quality outcomes. The adaptation of the CCM is encouraged by Wagner, Glasgow and colleagues and versions of an expanded CCM that include components such as health determinants have been developed (Barr et al., 2003).

The Institute for Health Care Improvement (ICIC) adapted the CCM to include four of the six IOM aims of care called the Care Model (CM). After reviewing the literature and adapted versions of the CCM, this study used the CM (**Figure 1.1**) to guide the development of the conceptual framework for this study (**Figure 2.2**). Given the national initiatives on patient safety, quality and measurement of health outcomes at the individual and system level, the incorporation of the IOM's underpinnings is critical.

The CM includes the same six elements as the CCM, but it proposes productive interactions of an informed empowered patient and family, not an informed activated patient and prepared proactive practice teams. The CM also proposes the interplay of the key six elements of the model along with the quality initiatives of patient centered, timely and efficient, evidence based, and safe and coordinated care. The CM proposes to not simply produce functional and clinical outcomes like the CCM, but rather produce improved functional and clinical outcomes.

Traditionally, the belief was that with an increase in knowledge patients would better adhere to treatment (Wagner et al., 1996), which in turn would translate to improved health outcomes. However, with activation or knowledge, change does not occur. The ability to foster self-efficacy, empowerment, and health literacy to aid patients



Better Outcomes for SMI Patients Rx AA Medication

### Figure 2.2 Study Variables within the Study Conceptual Framework

Sources: The MacColl Center (2012); Wagner, E. H., Austin, B. T., Davis, C., Hindmarsh, M., Schaefer, J., & Bonomi, A. (2001); Wagner, E. H., Glasgow, R. E., Davis, C., Bonomi, A. E., Provost, L., McCulloch, D., . . . Sixta, C. (2001); Wagner, E. H. (1998); Wagner, E. H., Austin, B. T., & Von Korff, M. (1996). health literacy to aid patients in management of illness is central to bringing about change and evaluating adherence rates. Another important factor to consider is that patients do not impact outcomes without other persons in their life. The CM includes the family, which broadly defined can include any important person in the patient's life. Support from important family members, friends, or significant others will impact quality outcomes.

Collectively, with the inclusion of the IOM quality aims and focus on productive interactions of an informed, empowered patient and family, the CM is more consistent with achievement of improved functional outcomes. While no new elements were added to the already adapted CCM, called the CM, the synthesis of the concepts, as described above, are unique to this author.

The CCM developed in 1998 has been used with funding and support from the Robert Wood Johnson Foundation's (RWJF) Improving Chronic Illness Care (ICIC) program (Hung et al., 2007). Inherent receiving funding support from the RWJF in the development of a new model to guide proving preventive and chronic illness care, there are several strengths and weakness. Additionally, given the young nature of this model there are identified gaps in the database and clinical literature along with weaknesses of this model.

The ability to receive support and funding from a nationally recognized agency such as the RWJF is a strength that the CCM can build upon. The financial and resource support obtained by working with a large agency strengthens the ability to develop, test, and modify quality initiatives, such as the CCM. Development of the CCM at a time that is consistent with the IOM's (2001) goals to transform health care from a reactive to a proactive system of care with a focus on chronic conditions is timely. Both the IOM and the CCM have a similar goal to narrow the quality chasm of health care delivery systems.

As described by Wagner, the CCM can address the tyranny of the urgent (Bodenheimer & Grumbach, 2007). For example, health care systems have not had models to address health prevention and chronic illness care that can systematically evaluate quality outcomes. Most health care systems react to what patients request and providers focus on the urgent problem, which is consistent with the dual task theory (Wagner et al., 1996). The dual task theory would suggest that providers are invested in patients and not missing an acute problem or being held liable for omission of care. Therefore, care is structured to focus on urgent, acute problems. The CCM has the ability to provide a framework to challenge old ways of providing care and to systematically evaluate outcomes.

In 2001 it was cited that the CCM model was being used by over 300 diverse health care systems in quality improvement efforts related to care of asthma, congestive health failure, depression, and diabetes, and to the prevention of frailty in the elderly (Wagner, Glasgow et al., 2001). Data to support the feasibility and acceptability of the CCM to guide improvement efforts are beginning to be published (Wagner, Austin et al., 2001). Coleman and colleagues (2009) reported after review of the evidence on the CCM that all studies that used elements of the CCM to evaluate quality showed improvement. This finding suggests that the CCM provides a framework for incremental evaluation to guide interventions or changes. If findings suggested that as a part of an interacting system all six elements of the CCM need to be studied or changes need to be made collectively, this would limit the utility of the model. Systems are complex and often access to all parts of a system is impractical.

The Assessment of Chronic Illness Care (ACIC) survey was developed by Wagner and colleagues to assess the organizational and team presence of the CCM (Bonomi, Wagner, Glasgow, & Von Korff, 2002). The original survey is a 25 item instrument that measures the six CCM elements and was found to be sensitive to organizational change and changes in quality measures of chronic care (Parchman, Zeber, Romero, & Pugh, 2007). Two studies found that the ACIC scores for elements of the CCM are associated with improvements in quality care for persons treated by diabetes (Parchman, et al, 2007; Solberg et al., 2006).

The CCM has been used in many studies to evaluate outcomes for people with diabetes. The use of CCM has been shown to be significantly associated with quality outcomes of lower hemoglobin A1C levels and lipid levels (Nutting et al., 2007; Piatt et al., 2006). Studies have also shown that use of the CCM increases the adherence to clinical practice recommendations. Siminerio, Piatt, and Zgibor (2005) found use of the CCM with rural patients improved adherence to the standard of care for diabetic patients with lower hemoglobin A1C levels and lipid levels. Others found diabetes care improved through use of the CCM by lowering rates of hemoglobin A1C levels and increasing rates of eye examination referral, dietary counseling, and micro albumin assessment (Chin et al., 2004). Improvements were also noted in a feasibility study (Bray et al., 2005) for measures of lipid panel assessment, aspirin use, and documentation of a foot examination.

A strength of the CCM relates to the adaptability of the model. For example, the model has been adapted to evaluate outcomes for persons with Bipolar Disorder, called the Bipolar-CCM. The CCM has been adapted specifically to evaluate the outcomes for persons with Bipolar Disorder in two Veterans Affairs Medical Centers (VAMC), one in the Northeast (Bauer et al., 2006) and one in the Midwest (Kilbourne et al., 2009). Both studies suggest that the B-CCM may be an effective model in the treatment of persons with Bipolar Disorder; however, studies are limited and the generalizability of the findings from a VAMC population to persons treated in a community mental health center are questionable. Further evaluate of outcomes by these authors and others will help provide a body of evidence to evaluate the effectiveness of this model.

Adaptation of the CCM to treat older adults who have depression and comorbid physical health conditions has been cited. Three programs that guide the treatment of older adults with depression and comorbid physical health conditions include the Improving Mood Promoting Access to Collaborative Treatment (IMPACT) program, the Prevention of Suicide in Primary Care Elderly Collaborative Trial (PROSPECT), and the Program to Encourage Active and Rewarding Lives for Seniors (PEARLS) (McEvoy & Barnes, 2007). These authors note that the effectiveness of these programs is related to the structure, follow-up, and coordination of care.

Van Cleave and Leslie (2008) provide a theoretical case to use elements of the CCM to treat attention-deficit/hyperactivity disorder (ADHD), which is identified by these authors as a chronic condition commonly diagnosed in childhood. All six elements of the CCM are identified as a "pillar' and examples of how each element is applied to ADHD is provided. For example, the delivery system design is applied to chronic ADHD care by creating relationships with primary care for referrals and follow-up treatment. While this is not an empirically tested approach, the theoretical case, using clinical examples to demonstrate the applicability of the CCM to treatment of ADHD is discussed.

Limitations or gaps noted in the literature on the CCM relate to the generalizability to persons with a SMI treated in a community mental health center. Only one published study on the use of the CCM in behavioral health has been published. This study found that the CCM can be used to restructure care and help persons with a mental illness better manage their illness and improve social functioning (Blakely & Dziadosz, 2008). These authors state that the CCM should be further explored to assess whether application of the model to persons with a mental illness can better manage both their physical and mental health.

A weakness of the CCM relates to those organizations that use all or parts of this model to evaluate quality related outcomes. Most of the organizations who have implemented this model are part of the Breakthrough Series (BTH) and the motivation to organize and implement quality improvement initiatives in these systems is high (Wagner, Austin et al., 2001). It has been postulated that organizations with upper management support to implement quality evaluation projects will be successful regardless of the model used.

Coleman and colleagues (2009) acknowledge the effectiveness of the model but do provide a discussion of limitations. First, the CCM is a framework that cannot be immediately replicated. Second, the practical nature and cost effectiveness of this model have not been fully examined and further research is needed. Finally, organizations that are not part of the BTH need to evaluate the model in a systematic, rigorous manner. It is important to reiterate that this model is slightly a decade old and many studies are underway and their findings have not been published.

#### **Conceptual Framework**

The CCM and adapted CM were used to guide the development of the conceptual framework in this study. While the CCM was developed to guide changes in care provided in the primary care setting, the elements as described in the CCM are also present in the mental health system of care. Specifically, the delivery system design, as described in the CCM and adapted CM, contains elements of a care

team and visits. Both elements are present in all health care delivery systems. Further, the conceptualization of a care team as a patient and provider is not unique to a primary system of care.

The other element in the delivery system design is visits. As part of the CCM, visits are planned or scheduled; however, in the mental health system of care visits are scheduled or due to crisis. The conceptualization of planned visits in a mental health system might develop over time as the delivery system design is better understood. It is vital to better understand which elements of the delivery system design impact various components of care delivered to persons with a SMI and influence patient centered, timely and efficient, evidence based, and safe and coordinated care.

#### **Delivery System Design**

The delivery system design, a characteristic of a health system, includes structures and processes of care delivery that support quality patient care. A delivery system design of a community mental health center includes the care team, comprised of the patient and provider and the visits. The interaction of the care team and visits has an impact on patient care quality outcomes. This section of the literature review focuses on the care team, visits, and quality outcomes related to the delivery of mental health services in a community health center, to persons with a severe mental illness who are treated on Atypical Antipsychotic (AA) medication.

#### Care Team

The care team, a component of the delivery system design, is composed of the patient and provider. Elements related to the patient are: age, gender, race and ethnicity, language best served, marital status, employment and insurance, tobacco use, diagnosis, AA medication use, and whether primary care services are provided within the clinic or outside the clinic. Elements related to the provider include provider characteristics: degree, certification, number of years practicing as a mental health provider, and number of years providing care at a community mental health center.

#### Patient

Persons with a severe mental illness have characteristics that affect the delivery of quality mental health services within a community mental health center. The characteristics that affect quality related to the individual patient include: age, gender, race and ethnicity, language best served, marital status, employment and insurance, tobacco use, diagnosis, AA use, and if primary care services are provided within the clinic or by a provider outside of the clinic.

The onset of a severe mental illness tends to happen early in life, often at a time when individuals are transitioning from adolescent stages of development to adulthood. There are known gender, race and ethnicity differences in the onset and treatment of severe mental illness. Often persons treated in urban areas are from diverse areas or are immigrants and do not speak English as a first language. It is known that limited English proficiency impacts health seeking patterns, access to care, and health outcomes. Marital status, employment status, and insurance also impact access to care and health outcomes. Additionally, persons with a severe mental illness have high rates of smoking, co-morbid physical health conditions, are treated on AA medications and seek primary care less frequently. The patient characteristics noted affect quality outcomes and it is important that they be understood and explored.

*Age*. In the U.S. 74.3% of the population is over 18 years of age (U.S. Census Bureau, 2010) and persons with a SMI are often diagnosed in young adulthood. Onset of a SMI, in early adulthood, prevents individuals from developing and experiencing normal emotional growth and development. Various psychiatric illnesses have a slight variation in onset of the illness, which also impacts the illness trajectory. Several prevalence of mental illness studies have been conducted, which provide data about the age of onset of a SMI. The diagnosis of a mental illness is guided by the Diagnostic and Statistical Manual IV - Text-Revision (DSM IV- TR), which is the latest diagnostic manual.

Three large lifetime prevalence of Diagnostic and Statistical Manual (DSM) disorder studies in national samples have been conducted since the 1980's. The first study conducted was the Epidemiological Catchment Area (ECA) survey, which was funded by the National Institute of Mental Health (NIMH). This study surveyed a total of 20,291 US residents age 18 and older (Bourdon, Rae, Locke, Narrow, & Regier, 1992). This study used the DSM -III criteria for identification of prevalence rates of mental disorders. The ECA survey found that about 1 in 5 adults had a mental disorder in a six month time frame and about 1 and 3 adults had a lifetime prevalence of a mental disorder; however, 17.6% received care within six months of the survey (Bourdon et al., 1992).

According the ECA survey, lifetime prevalence of Schizophrenia is 1.5%, of Major Depression is 5.9%, and Bipolar Disorder, and with mania is 0.8% (Bourdon et al., 1992). The ECA survey found that mean age of onset of major depression is 23 years for males and 25 years for females and for Bipolar Disorder, age 18 for males and age 20 for females (Burke, Burke, Regier, & Rae, 1990). Merikangas and colleagues (2007) used the NCS-R data and found mean age of onset for any Bipolar Disorder (Bipolar I or II) was 20.8.

The National Comorbidity Survey included a sample of 5877 U.S. adults and used the DSM III-R to identify persons with a mental disorder. This study found lifetimes rates of major depression to be highest in adults age 35-44 years of age: 14.7% of males and 23.8% of females (Kessler, McGonagle, Swartz, Blazer, & Nelson, 1993).

The most recent study, The National Comorbidity Survey Replication (NCS-R) was conducted using the last DSM-IV and included 9,282 English speaking persons over age 18 years of age (Wang et al., 2005). These authors note the differences in the delivery of mental health services and change in the DSM version III and IV, with IV placing more emphasis on the impact of the disorder has on psychosocial functioning may identify differing rates of mental disorders.

The Epidemiologic Catchment Areas Study from 1980 and the National Comorbidity Survey (NCS) in the 1990's had similar findings about prevalence rates of mental disorders. Kessler and colleagues (2005) used the NCS-R data and found the mean age of onset of a mood disorder is age 30, and the prevalence of Major Depressive Disorder is 16.6%. The prevalence of Bipolar I or II Disorder is 3.9%. Lifetime risk of any mental disorder is 46.4% and after age 60, the risk of a mood disorder declines. The NCS reported a prevalence rate of psychotic illness of 2.2% and persons from a younger age group are found to have higher rates of schizophrenia (Kendler, Gallagher, Abelson, & Kessler, 1996). A psychotic disorder, major depressive disorder, and a bipolar disorder are all defined as a SMI.

Studies that examine rates of screening for cardiometabolic illness in persons with a SMI related to age are less prevalent. One study conducted with Veterans Administration patients found that older age was associated with less lipid and glucose monitoring (Copeland et al., 2010).

*Gender*. In the U.S. 49.1 % of the total population is female compared to 50.9% which are male (U.S. Census Bureau, 2010). It is well documented in the literature that health disparities related to gender exist. The ECA survey and NCS-R survey both found that woman are diagnosed with depression at higher rates than men (Burke et al., 1990; Kessler et al., 2005). The finding that Major Depression has a higher lifetime prevalence in females (21.3%) compared to males (12.7%) was also noted in the NCS-R (Kessler et al., 1994). These authors found that lifetime prevalence rates of Bipolar Disorder with mania were similar for men and women, 1.6% for males and 1.7% for females. Data from the NCS I found rates of schizophrenia were not significantly higher in females than males (Kendler et al., 1996).

A secondary analysis of the National Comorbidity Survey Replication (NCS-R) data found that women are more likely than men to receive mental health treatment for two disorders classified as a SMI; Major Depressive Disorder and Bipolar Disorder (Wang et al., 2005).

In relation to gender and screening for cardiometabolic symptoms, few studies have examined male and female differences. Two large retrospective analyses from claims data found that gender did not impact lipid testing but males received less glucose testing then females (Haupt et al., 2009; Morrato, Newcomer, Allen, & Valuck, 2008). Moeller and colleagues (2011) found women were more likely to have both lipid and glucose screening. In a Veterans Administration population, Kilbourne et al. (2007) found that women were less likely to have lipid monitoring and male nonwhite patients received less glucose screening.

*Race and Ethnicity*. In the United States 74.4% of the population is white, Non-Hispanic, followed by Hispanic / Latino at 16.3%, Black at 12.6% and Asian at 4.8% (U.S. Census Bureau, 2010). According to the U.S. Census, the fastest growing race was Asians, which grew 14.7 million. From the 2000 Census to the 2010 Census, Hispanics grew by 43% to 50.5 million.

The NCS-R data found that Blacks and Hispanics have lower prevalence rates for depression compared to non-Hispanic whites, which are consistent with the findings from the ECA study (Kessler et al., 1994). Other authors also found, using the NCS-R data, that the risk of having a mood disorder was lower for non-Hispanic blacks and Hispanics when compared to non-Hispanic whites (Kessler et al., 2005).

A study that examined access to care and adequacy of treatment in depressed persons found being non-Hispanic white was associated with accessing and receiving adequate mental health care as compared to other ethnic and racial minority groups (Alegria et al., 2008). The NCS-R also found that coming from a racial or ethnic minority was associated with having unmet mental health needs and receiving less than adequate care (Wang et al., 2005). Asians were also found to have the lowest use of mental health service utilization when compared to White, Hispanic, and Native American racial and ethnic groups but was similar to Blacks (Lee, Martins, Keyes, & Lee, 2011). This study had few Asian subjects who were born in the U.S. and high rates of recent immigration.

A large National Survey of 134,875 adults had similar findings that Mexican Americans, Hispanic-Latinos, and Asians had lower rates of mental health service utilization, as compared to Whites (Harris, Edlund & Larson, 2005). This same study found that American Indians and Native Alaskans had disproportionately high rates of mental health problems and African Americans had better mental health than Whites.

Medication selection and mental health services utilization have been found to have different patterns based on race and ethnicity. A large national data set on outpatient claims visits for persons treated on an AA or typical antipsychotic found different treatments in ethnic populations (Daumit et al., 2003). This study found that more Hispanics and African Americans had a psychotic disorder diagnosis. However, Whites received more than half of the AA prescriptions as compared to African Americans, who received half the number and Hispanics who received one third the number of AA prescriptions. African Americans had a psychotic disorder diagnosis more frequently, as compared to Whites.

A smaller study that used secondary data had similar findings. African Americans received AA medications at 49% of the visits as compared to Whites who received an AA medication 66% of the time (Herbeck et al., 2004). A study of Texas Medicaid claims also found that African Americans were less likely to receive a prescription for an

AA compared to whites (Opolka, Rascati, Brown, & Gibson, 2004). These studies used data from the late 1990s and early 2000s, at which time fewer AA medications were on the market, which might explain some disparities in prescribing.

Copeland et al. (2009) did not find that race or ethnicity were associated with different testing rates for cardiometabolic symptoms; however, this study does point out that African Americans and Hispanics did receive more follow-up diabetes treatment. Hispanic patients are at higher risk for diabetes and were found to have lower screening rates, as compared to the national recommendations (Mangurian, Goss, & Newcomer, 2010). It is unclear why non-White minority populations access health care at lower rates and receive lower care quality (Saha, Chant, McGrath, 2007).

*Language Best Served*. In the United States (U.S.), ethnically diverse populations or minority populations, both who are immigrants and those who are U. S. born are on the rise. Persons who speak a language other than English in U.S. homes is 18%, but of those who do not speak English in the home, over half report speaking English very well (U.S. Census Bureau, 2000). Many individuals who do not speak English are from an ethnically diverse minority population (Sentell, Shumway, & Snowden, 2007). Individuals from minority populations, whose first language is not English, often settle in urban areas. Health care centers that are located in urban areas treat ethnically diverse, minority populations. English proficiency has been associated with mental health service utilization (Bauer, Chen, & Alegra, 2010).

Language barriers are one possible source of limited access to care and lower care quality. An inability to understand the language in which health care is provided creates a health encounter with a higher likelihood of misunderstanding and lack of follow through with treatment recommendations. Having Limited English Proficiency (LEP) and presenting for mental health treatment creates a higher likelihood of miscommunication and variations in care. A psychiatric diagnosis is made by communicating with an individual and this specialty area does not rely on diagnostic tests to make a diagnosis, rather on direct communication (Sentell et al., 2007). Patients with LEP are at higher risk of health care disparities when seeking mental health services (Kim et al., 2011).

Several studies have shown that LEP is associated with a decrease in perceived need for mental health treatment or awareness of having any mental health problems among Hispanic and Asian adults (Bauer et al., 2010; Kim et al., 2011; Sentell et al., 2007). Kim and colleagues found that Latinos live in the U.S. longer, as compared to Asians, but have lower LEP. These researchers found that both Asian immigrants had lower mental health utilizations rates when compared to U.S. born Asians. In contrast, this same study found that Latino immigrants had slightly higher rates of mental health utilization as compared to those who are U.S. born. Health service rates were 39.4% of Latinos, of which 85% were immigrants. Additionally, just over 34% of the study population were Asians, of which 94.9% were immigrants and had LEP.

A large study of non-Hispanic and Hispanic adults found that persons who did not speak English in the home were less likely to receive recommended general health care services (Cheng, Chen, & Cunningham, 2007). This study highlighted that non-Hispanic whites who spoke English were more likely to receive eligible care than English speaking Hispanics who spoke English at home. Bauer and colleagues (2010) found racial and ethnic disparities in treatment of persons with depressive disorders; however, they did not find significant differences in quality of care based on LEP. Persons with LEP are found to be less insured, have lower education (Bauer et al., 2010; Cheng et al., 2007), be male, not married, and have a family income below 200% poverty (Cheng et al., 2007).

*Marital Status*. Persons with a SMI have a chronic mental disorder which has episodes of acute exacerbation of illness and periods of stable illness. As with any chronic illness, psychosocial support is important in coping with the disease. Because persons with a SMI have an illness onset in young adulthood, many do not develop long term interpersonal relationships and do not marry.

Data from the NCS-R found the risk of developing a mental disorder or receiving treatment is higher for persons who have marital disruption, were previously married, or are single (Kendler et al., 1996; Kessler et al., 2005; Wang et al., 2005). Never being married is an indicator of delaying mental health treatment and having delays in treatment after initial contact (Wang et al., 2005). Marital status can, in some cases be used as an indication of social support which can be a protective factor when being treated for a mental disorder.

*Employment, Income, and Insurance*. Persons with a SMI have a disorder that has periods of stability and episodes of acute illness. The chronic nature of a SMI prevents many persons from having sustained gainful employment. Many persons with a SMI have a difficult time coping with the stress of holding down a job, have significant medication side effects which prevent or limit their ability to function and / or lack interpersonal skills to maintain employment. Because of an inability to work, many persons with a SMI are on disability or have no income pending a disability application. Persons with a SMI who are working and have no income, also do not have insurance. Having a chronic mental illness and the nature of the illness prevents many people from getting married, which is a source of potential insurance benefits.

The NCS-R studies have shown that persons who are unemployed, are uninsured, and have lower income are at risk for developing a mental disorder or receiving treatment for a mental disorder (Kendler et al., 1996; Kessler et al., 2005; Wang et al., 2005).

**Tobacco Use**. High rates of smoking have been reported in persons with a SMI. A comorbidity study found that 74% of persons with a SMI had a history of smoking at one point in their life (Sokal et al., 2004). These authors also note that this patient population is also at risk for developing emphysema due to second hand smoke and higher

associations with other persons who have SMI. Furthermore, smoking has been found to place SMI patients at higher risk for coronary heart disease (Osborn, Nazareth, & King, 2006).

Rates of smoking for persons with a SMI have been reported as much as two to three times that of the general population, and in one study more than 30% smoked more than a pack a day, and only 14% were ready for smoking cessation (Dixon et al., 2007). These studies suggest the importance of assessing tobacco use and offering smoking cessation options for persons with a SMI.

**Diagnosis**. It is known that persons with a SMI prematurely lose 10 - 25 years of life as compared to the general population (Miller, Paschall, & Svendsen, 2006; Richardson et al., 2005). Cardiovascular disease is the most common cause of excessive mortality in this population (Capasso, Lineberry, Bostwick, Decker, & St Sauver, 2008; Richardson et al., 2005). Persons with SMI have a high prevalence of comorbid cardiometabolic risk factors which place these patients at risk for cardiovascular disease, which is in part due to independent risk factors in addition to modifiable risks(Morden, Mistler, Weeks, & Bartels, 2009). Studies have shown that persons with a SMI have two or more chronic conditions which include hypertension, hyperlipidemia, obesity, or diabetes (Jones et al., 2004; Kilbourne et al., 2008).

Persons with a SMI had higher rates of hypertension, heart disease, and asthma as compared to the general population, with pulmonary illness being the most prevalent (Jones et al., 2004). These findings are consistent with findings reporting that persons are diagnosed with diabetes at a younger age, have a higher body mass index, and are smokers, as compared to those who do not have a SMI (Vinogradova, Coupland, Hippisley Cox, Whyte, & Penny, 2010). Finally, a seminal study, Patient Outcomes Research Team (PORT) found that persons with schizophrenia had more complaints related to high blood pressure, bowel and breathing problems than the general public (Dixon, Postrado, Delahanty, Fischer, & Lehman, 1999).

These studies underscore the importance of assessing the physical health comorbidities of persons with a SMI. High rates of cardiometabolic illness in persons with SMI along with increase in cardiometabolic risk factors associated with treatment on an AA highlight the urgency for screening and preventive care in this patient population.

*Atypical Antipsychotic Medication*. Persons with a SMI are treated on first line medications known as AA medications. Several studies have been conducted since the advent of AA medication in the early 1980's that evaluated the cardiometabolic risks and side effects from this class of medication.

A seminal study noted that "novel" or "atypical" antipsychotic medications were associated with weight gain (Allison & Casey, 2001). This study was one of the first that examined antipsychotic induced weight gain and noted that studies are lacking that report rates of "diabetes, heart disease, dyslipidemia, and so on among patients gaining various degrees of weight" (Allison & Casey, p. 29). This study also noted the potential for stopping medication and relapse due to side effects, namely weight gain.

In 2004 the American Diabetes Association (ADA), American Psychiatric Association (APA), American Association of Clinical Endocrinologists (AACE), and North American Association for the Study of Obesity (NAASO) report provided information about the atypical antipsychotic medication, known as second generation antipsychotic (SGA) medication and the risk of metabolic abnormalities. From this paper, it is noted that Clozapine and Olanzapine have the highest risk for weight gain, risk of diabetes, and worsening lipid profile. Risperidone and Quetiapine have less risk, and Aripiprazole and Ziprasidone have no effect.

A national, multisite National Institute of Mental Health (NIMH) study called the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) examined discontinuation rates of antipsychotic medications over 18 months (Stroup et al., 2003). This was the first and largest study of its kind that provided data about persons who have schizophrenia and use discontinuation rates on older, typical antipsychotic medication and the newer, AA. Persons treated on Olanzapine discontinued the medication at the highest rates due to metabolic effects and on average, persons switched a typical antipsychotic medication at six months (Lieberman et al., 2005). Additional data were collected which allowed for meta-analysis of the data and other secondary data analysis about metabolic effects of AAs.

**Primary Care Provider.** The data support that the risk of co-morbid medical illness is prevalent in persons with SMI and it is important for mental health providers to be aware of metabolic illness (Suppes, McElroy, & Hirschfield, 2007). Several studies support the recommendation that integrative services would increase screening rates (De Hert et al., 2011; Khatana, Kane, Taveria, Bauer, & Wu, 2011; Mitchell, Delaffon, Vancampfort, Correll & De Hert, 2012; Motsinger, Slack, Weaver, & Reed, 2006). Barriers to screening have been postulated to be related to payment (Batscha, Schneiderhan, Kataria, Rosen, & Marvin, 2010; Kilbourne et al., 2007). Haupt et al. (2009) is consistent with the findings from Shi and colleagues (2009) who found that persons who had a primary care visit had higher screening rates as did persons who were older or had a preexisting metabolic disorder.

### Provider

Characteristics of advanced practice registered nurse (APRN) psychiatric nurses are not well documented and little is known about workforce data (Hanrahan et al., 2003). No current studies have published quality outcomes for person with a SMI who received care from a psychiatric APRN.

A recent national survey of Psychiatric Mental Health Advanced Practice from 1,899 respondents provided data about psychiatric APRN provider characteristics and basic employment data (Drew & Delaney, 2009). Findings indicate that of the respondents, the following are board certified by the American Nurses Credentialing Center (ANCC) in the following Psychiatric Mental Health Certifications: 56.9% are adult clinical nurse specialists and 12.0% are child and adolescent clinical nurse specialist, and 22.0% are adult nurse practitioners and 9.1% are family nurse practitioners. Less than 6.6% are dually certified in adult and child and less than 8.0% are dually adult certified (family nurse practitioner and adult clinical nurse specialist or nurse practitioner). From this study, 87.8% are female and 90.3% are White, followed by 2.1% Black/African American. The majority of psychiatric APRN's are self-employed (26.3%), followed by those who work for a public community mental health agency (25.6%). The APRN's who work with adults are reimbursed more often by Medicare (57.7%) or Medicaid (45.7%), which is statistically significant. Those APRN's working with adults most frequently treat depressive disorders (36.5%), followed by Bipolar Disorder (11.5%) and Schizophrenia and other psychosis (3.6%), all of which are classified as a SMI. Data from an ANCC survey in 2003/2006 reported that the years of experience psychiatric APRNs have is: 0-5 years, 4.1%; 6-10 years, 4.5%, 11-15 years, 8.9%, 16-20 years, 14.8%, 21-25 years, 20.6% and 26-30 years 18.2% (Hanrahan, Delaney, & Stuart, 2011).

Only one study cited the use of nurse practitioners (NPs) and physician assistants (PAs) and quality of care for diabetic patients (Ohman Strickland et al., 2008). The findings of this study were that NPs were twice as likely to assess hemoglobin A1C levels and more likely meet the lipid treatment guideline, as compared to medical doctors or PAs. No studies exist that discuss NP characteristics related to the care of persons with a SMI and quality outcomes. In contrast, three survey studies were conducted to assess psychiatrists' awareness of adverse metabolic effects on persons with bipolar illness (Ketter & Haupt, 2006; Newcomer, Nasrallah, & Loebel, 2004; Suppes et al., 2007). Most published data about treatment of mental illness and practice patterns has been conducted with psychiatrists.

The survey conducted by Suppes and colleagues (2007) included 390 respondents which found the age of the psychiatrist to be age 40-59, and represented all regions of the country with the East being more represented than the Midwest. In this study 94% of psychiatrists were aware of the risk of metabolic syndrome and 76% reported making a diagnosis of metabolic syndrome. The respondents were aware that elevated glucose and triglycerides, abdominal obesity, low HDL cholesterol and elevated blood pressure make up the diagnosis of metabolic syndrome. It was reported that baseline measures of family history of diabetes and cardiovascular disease were obtained over 75% of the time, blood pressure and body mass index over 60% of the time, and plasma glucose and lipid profile were obtained over 50% of the time. Waist circumference was obtained less than 20% of the time.

These findings are inconsistent with a meta-analysis of 48 studies that found in 39 of the studies that blood pressure was monitored at baseline about 50% of the time,

cholesterol 41.5%, glucose 44%, and weight 47.9% as compared to lipids and glycosylated hemoglobin less that 25% of the time (Mitchell et al., 2012). The gap in reporting screening and the actual screening rates needs to be further studied (Morrato et al., 2010) given the wide dissemination of the recommended screening guidelines and low rates of screening (Haupt et al., 2009).

Ketter and Haupt (2006) conducted a mailed self-administered questionnaire and analyzed the first 298 surveys that were returned. This survey asked fewer questions about provider characteristics and more about monitoring for metabolic concerns in bipolar patients. The study survey reported monitoring the following at baseline; weight (2%), fasting plasma glucose (13%), and fasting lipid profile (9%). In this study, there were higher rates of monitoring fasting plasma glucose and lipid profile quarterly or annually, at 71%. In this survey, 88% of respondents reported monitoring weight at some time, 80% did not monitor waist circumference. This study did not report rates of monitoring blood pressure.

The Atypical Antipsychotic Therapy and Metabolic Issues (AtAMI) National Survey conducted in 2003 included 300 psychiatrists who treated patients with a psychotic disorder (Newcomer et al., 2004). In this study the mean years in practice was 18, and the majority of respondents were in an outpatient practice followed by a 'solo' practice and treated 100-300 patients per month. The findings of this study indicated psychiatrists had awareness of metabolic issues, but rates of screening were not consistent with self-report. For example, rates of screening were as follows: blood pressure (17%), weight changes (31%), waist circumference (2%), changes in lipids (11%), and changes in blood glucose (21%).

### Visits

The Chronic Care Model identifies visits as part of the delivery system design. Visits in the current health system tend to be urgent or scheduled visits, where the provider responds to a health complaint. However, the current system of care that is reactive and responds to the patient rather than planned care which identifies patient treatment needs related to chronic disease care (Wagner, Austin et al., 2001). Visits in community mental health centers tend to be crisis, scheduled, or on a walk in basis. Currently no studies have examined the use of planned visits for persons with a SMI.

Studies have identified that mental health patients, specifically those with a SMI have high rates of 'no shows' and drop out of care. Persons with a mental illness have no-show rates of about 20%, which is about twice the rate in other specialties and up to 50% of patient who fail appointments drop out of care (Mitchell & Selmes, 2007). A single missed appointment has a high association with dropping out of treatment and in this study, first appointment fail rates were 36% and follow-up appointment fail rates were 40% (Killaspy, Banerjee, King, & Lloyd, 2000). However, studies have shown that persons who do not show for an initial appointment and do not follow through with care

have higher functional impairments and are in greater need of mental health services (Centorrino et al., 2001; Killaspy et al., 2000; Zivin et al., 2009).

Research has demonstrated that being a younger male, unmarried with children increases no show rates (Zivin et al., 2009). A large epidemiological survey study also found that being young, with low income and lack of insurance for mental health treatment increases rates of treatment drop out (Edlund et al., 2002). In contrast, the NCS-R survey found that being young, married and with lower education levels was associated with dropping out of treatment at higher rates after two visits (Olfson et al., 2009). This same study found that after the third visit, being Hispanic with low income, from lower socioeconomic status, and without health insurance was associated with higher treatment drop out. A smaller study found that psychiatric patients who live alone, are more acutely ill, have less education, and who have a major affective disorder drop out of treatment at higher rates (Centorrino et al., 2001).

The study by Centorrino and colleagues (2001) found that routinely scheduled appointments for psychotherapy had higher rates of adherence compared to non-routinely scheduled medication management appointments. This study suggests that persons with a severe mental illness have a chronic illness and that visits, consistent with the chronic care model, that are planned or scheduled have a positive impact on adherence. Delivering care, specifically planning visits in a routine manner, may improve visit adherence, which would also have an impact on quality of care.

# **Quality Outcomes**

Quality outcomes for persons with a SMI treated on an AA medication can be measured against current evidence based practices and guidelines. The characteristics of quality outcomes for SMI patients treated on an AA medication can be defined by the American Diabetes and American Psychiatric Association monitoring guidelines.

Persons diagnosed with a severe mental illness are treated on medication to help achieve remission of symptoms and many persons are treated on antipsychotic medication. Antipsychotic medications are the first line biological treatment for schizophrenia and have an indication for treatment for bipolar disorder and augmentation for major depressive disorder with psychosis or a recurrent major depressive disorder cite. Since the 1950's persons with schizophrenia have been treated on first generation antipsychotic medication; however, in 1989 the first second generation antipsychotic, or atypical antipsychotic medication was approved (ADA et al., 2004). Since 1989 nine other atypical antipsychotic medications have been approved by the United States Food and Drug Administration (FDA). It has been noted that the newer, atypical antipsychotic medications have benefits over older, typical antipsychotic medication; however, there have been reports of weight gain, diabetes, and changes in lipid levels (ADA et al., 2004).

In 2004 the U.S. Food and Drug Administration sent out a letter to "Healthcare Practitioner" warning prescribers about atypical antipsychotic drugs and the risk of

hyperglycemia and diabetes mellitus. The pharmaceutical companies also changed the drug labeling of antipsychotic medication in 2004 (Food and Drug Administration ,2004).

In response to the cardiometabolic concerns and the relationship of the atypical antipsychotic medications to major medical illnesses, the American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists and North American Association for the Study of Obesity published a monitoring protocol for patients on AA medication (ADA et al., 2004). The monitoring protocol recommends screening at baseline, four weeks, eight weeks, 12 weeks, quarterly, annually, and every five years. The recommended screening at baseline and 12 weeks include: 1. personal or family history of cardiovascular disease (baseline assessment only); 2. weight (body mass index); 3. waist circumference; 4. blood pressure; 5. fasting plasma glucose; and 6. fasting lipid profile.

Despite the FDA prescriber letter, drug label change and publication of the ADA, APA, AACE, and NAASO monitoring protocol, screening rates for individuals treated on AAs remains low. Three large claims data studies on rates of screening for lipid levels and glucose levels all showed that screening rates for persons on an AA are low and rates did not increase as much as expected after the warning and published monitoring protocol (Busko, 2009; Haupt et al., 2009; Morrato et al., 2010).

The study by Haupt et al. (2009) found that baseline lipid testing and follow-up at week 12 pre-guideline were about 8% and 10% as compared to 7% and 9%. Pre-guideline baseline glucose testing rates were about 17% as compared to 23% post-guideline and at 12 week follow-up pre-guideline rates were 15% and post-guideline rates were 18%. A study by Morrato and colleagues (2010) also found low rates of baseline testing before the warning; 26% had baseline serum glucose and 10% had baseline lipid testing. Post warning did not improve glucose testing rates and a small, but statistically significant increase of 1.7% in baseline lipid screening was reported.

The other pre-guideline and post-guideline claims data study by Busko (2009) found, at a statistical significance, that there were modest improvements with baseline lipid levels of 8.4% and post-guideline levels of 10.5% and baseline glucose levels of 17.3% and post-guideline rates of 21.8%. Only one study found higher rates of screening by psychiatrists and supported that this specialty area is more aware of the need to screen and does so at higher rates (Moeller et al., 2011).

Atypical Antipsychotic medication prescribing trends found that post warning, prescribing of Olanzapine was prescribed less, but Aripiprazole prescriptions increased (Haupt et al., 2009). Several studies noted that switching medication was a strategy to deal with cardiometabolic risk factors (Mangurian et al., 2010; Shi et al., 2009). It is noted that persons with a severe mental illness (SMI) have more contact with the mental health system of care (De Hert et al., 2011). The ADA and APA guideline (ADA et al., 2004) does provide monitoring guidelines; however, resistance to evidence based practices (EBP) in psychiatry exists.

Making a diagnosis in psychiatry is less of an exact science and the Diagnostic Statistical Manual (DSM IV -TR) provides criteria; but individuals often have overlap or mixed symptoms (Levine & Fink, 2006; Hannes, Pieters, Goedhuys, & Aertgeerts, 2010; Williams & Garner, 2002; Maier, 2006). Also, in psychiatry the patient, provider relationship has been shown to help individuals improve (Williams & Garner; Hannes et al., 2006). One study found that psychiatrists were skeptical of the ability of research to be applied into practice because many randomized control trials exclude patient profiles that are seen in the community (Hannes et al., 2010). Others note that in psychiatry EBP is difficult to apply when this patient population needs holistic, culturally-specific care that develops out of the relationship (Williams & Garner, 2002).

### Summary

The review of the literature presented in this chapter identifies the current research on quality outcomes in persons with a severe mental illness, specifically related to cardiometabolic screening for persons treated on an AA medication. While the review of literature identifies studies on screening rates, a gap in the literature about the delivery system design of a mental health center and its effect on cardiometabolic screening for persons with a severe mental illness is identified. The study investigator hopes the findings of this study will contribute to the state of science about the delivery system design of a community mental health center and identify further research questions that can be explored which could have an impact on the quality of care provided to this patient population.

# CHAPTER 3. METHODOLOGY

This chapter includes the research questions for this study, followed by the methods used to answer these questions. The research questions for this study were developed through a synthesis of the literature and theoretical framework described in Chapters 1 and 2. Included in this chapter are the study design, setting, sample, variables, procedures, analysis, and methodological assumptions and limitations.

# **Research Questions**

The research questions for this study include:

- 1. What are the baseline patient, provider, and visit characteristics of SMI patients prescribed an atypical antipsychotic medication?
- 2 What percent of SMI patients prescribed on an atypical antipsychotic medication received cardiometabolic screening at a) baseline, b) follow-up, and c) both baseline and follow-up?
- 3. What delivery system characteristics are associated with receiving cardiometabolic screening at a) baseline, b) follow-up, and c) both baseline and follow-up?

# **Study Design**

This study was designed to measure the effect of the delivery system design of a community mental health center (CMHC) on the provision of quality care for SMI patients who are at high risk for developing cardiometabolic illnesses. A cross-sectional design using baseline and 12 week ( $\pm$  4 weeks) patient health information (PHI) data was used. The initial treatment phase is defined as the first 16 weeks of treatment.

This descriptive cross-sectional study used existing SMI patient health information for the retrospective analysis of screening rates based on the American Diabetic Association (ADA), American Psychiatric Association (APA), American Association of Clinical Endocrinologists (AACE), and North American Association for the Study of Obesity (NAASO) monitoring protocol for persons treated on a second generation antipsychotic (SGA) medication. The monitoring guideline will be referred to as the ADA and APA screening guideline. Evaluation of baseline, 12 week, and both baseline and 12 week adherence to the ADA and APA guideline will be evaluated. In addition, rates of screening for each individual measure within the ADA and APA guideline were evaluated. Per the ADA and APA guidelines, persons should be screened at 12 weeks; however, due to appointment adherence rates and scheduling of mental health patients in a CMHC, the 12 week screening will be evaluated at 12 weeks ± 4 weeks. The initial treatment phase is defined as the first 16 weeks. Thus, the first 16 weeks defines the initial treatment phase.

This study design used retrospective data collection of existing data from an electronic health record (EHR). Retrospective electronic health record studies lack an approach to methodological consistency. Data in the electronic health record were not entered for research purposes but rather for documentation of patient encounters. Extracted retrospective data have not been systematically reviewed and therefore do not allow for replication, without significant data collection efforts (Dean et al., 2009; Gearing, Mian, Barber, & Ickowicz, 2006; Panacek, 2007). In psychiatry, retrospective research has been underutilized possibly due to unclear benefits and methodology limitations (Gearing et al., 2006).

While there are identified limitations to retrospective data collection, the systematic use of electronic health record data allows for analysis of clinical encounters to assess quality outcomes. Electronic health record data are often used in clinical research, and published studies outline best practices when using raw clinical data (Engel, Henderson, Fergenbaum & Colantonio, 2009). However, a strength of retrospective data collection, using clinical information extracted from an electronic health record, is the ability to access large volumes of information on a cohort or subgroup within the cohort (Dean et al., 2009; Roos, Roos, Fisher, & Bubolz, 1990). Retrospective studies using electronic medical records are inexpensive and allow for access to real word data (Dean et al., 2009).

Guidelines developed by several authors (Gearing et al., 2006; Panacek, 2007) were used to address data validity in this study. Clear guidelines on how data were extracted were developed prior to data collection and followed throughout the study. All missing data was coded the same. The inclusion and exclusion criteria were followed and the identified variables were collected in a systematic manner. The clearly defined variables were manually extracted from the electronic medical record by the study investigator or electronically extracted by the data extractor. Missing data were treated as random events, occurring by chance rather than deliberate omission. All study variables were analyzed, and those without variability were excluded. Thus, candidate attribute variables were identified and used in the analysis.

### **Study Setting**

The data for this study were obtained from a Community Clinic located in the Midwest region of the United States (U.S.). The clinic was founded in 1966 with a mission to provide primary care services to children and low income families. The clinic is owned and governed by a public university and since inception the mission has expanded to advance the well-being of people experiencing health disparities. The clinical services include medical, dental, mental health, social work, pro bono legal work, and a reading program for children. The clinic is located in an urban neighborhood that is home for immigrant populations from Southeast Asia, East Africa, and Central America.

During the study inclusion period of 01/01/2010 - 12/31/2010, the clinic provided behavioral, dental, and medical care to 11,821 unique individuals. There were 3,714 unique persons served during this period, who received at least one behavioral, dental, and medical service. During this time, 1,886 unique persons received only behavioral health care and of that number, 977 encounters were a new patient visit, unique to behavioral health. In 2010, 93% of patients were considered indigent with 92% having a form of public insurance.

# **Study Sample**

The study inclusion criteria are: a) newly admitted to behavioral health between January 1, 2010 and December 31, 2010; b) had a new intake and one follow-up visit within the first 12 weeks of treatment; c) age 18 or older; d) had a primary Axis I Diagnostic and Statistical Manual IV Text Revision (DSM IV TR) Disorder including one of the following: Major Depressive Disorder, Bipolar I or II Disorder, Schizophrenia, Schizoaffective Disorder or Psychotic Disorder NOS; and e) treated on an AA medication. Study exclusion criteria are: a) an existing clinic patient; b) started on an AA medication after the first visit; c) had primary Axis I DSM IV TR disorder of Major Depressive Disorder, Bipolar I or II, Schizophrenia, Schizoaffective Disorder or Psychotic Disorder the first visit; and d) under 18 years of age. The study period was from 01/01/2010 - 04/22/2011. Time inclusion was determined by having a CPT billing code of 90801 (new intake) and at least one 90862 (follow-up) visit for medication management within 12 weeks of the 90801. Having a co-morbid Axis I or II psychiatric condition or an Axis III medical condition did not exclude an individual.

### Instruments

Care delivery system design variables for this study were selected from the electronic health record guided by Care Model and the American Diabetes Association and American Psychiatric Association monitoring guidelines. Selections of care team, visit, and quality outcome variables were guided by a review of the literature in Chapters 1 and 2. The care team defined as the patient includes 16 variables and the provider includes five variables. The visits include six variables. There are five baseline and four 12 week quality outcome variables.

Study variables and quality outcome variables in relation to the theoretical framework are provided in **Figure 2.1**. A description of study variables for the care team, including the patient and provider, visits, and quality outcomes follows and includes operational definitions, new variables, and location of variables in the electronic health record.

# **Care Team Variables**

# Patient

The care team variables are elements of the delivery system design. The first component of the care team is the patient. Specifically, the patient variables studied include: age, gender, race, ethnicity, language best served, marital status, employment status, type of insurance, federal poverty level, smoking status, clinic primary care provider, AA medication, and DSM IV-TR axis I-III and V diagnosis. **Table 3.1** provides a description of the patient variables, measures, scoring guidelines, and location in the electronic medical record.

### Age

Age, specifically age in years, is associated with the onset of a severe mental illness. The mean age of onset of a mood disorder is 30 (Kessler et al., 2005) and younger adults have higher rates of schizophrenia (Kendler, Gallagher, Abelson & Kessler, 1996). After the age of 60, the risk of having a mood disorder declines (Kessler et al., 2005). At admission to the clinic, the patient is asked to self-report date of birth which is calculated into age in years. Thus, patient age in years at baseline was analyzed.

### Gender

Gender differences exist in rates of mood and thought disorders. Women are diagnosed with depression at higher rates than men (Berke et al., 1990; Kessler et al., 2005). Women are also more likely to receive mental health treatment for Major Depressive Disorder and Bipolar Disorder (Wang et al., 2005). A national survey study found rates of Schizophrenia are not-significantly higher in females than males (Kendler et al., 1996). At admission to the clinic, the patient is asked to self-report gender, male or female. Thus, patient gender at baseline was analyzed and male gender is identified as the candidate attribute.

# Race and Ethnicity

Racial and ethnic disparities exist related to seeking mental health treatment and rates of treatment of mental disorders. Blacks and Hispanics have lower rates for depression compared to non-Hispanic whites (Kessler et al., 1994; Kessler et al., 2005). Non-Latino whites have higher access to and receive adequate mental health treatment compared to other ethnic and racial minority patients. (Alegria et al., 2008). Additionally, coming from a racial or ethnic minority is associated with having unmet mental health needs and receiving less than adequate care (Wang et al., 2005). At admission to the clinic, the patient is asked to self-report race and ethnicity. Patient race

| Care Team: Patient Variables | Measure and Scoring Guidelines                                  | EHR Module/Field |
|------------------------------|---|------------------|
| Age                          | Measure: Age at baseline  | Demographics     |
|                              | Score: Number of years  |                  |
| Gender                       | Measure: Self-reported gender at baseline                       | Demographics     |
|                              | Score: $0 =$ Female $1 =$ Male                                  |                  |
| Race                         | Measure: Self-reported race at baseline                         | Additional data  |
|                              | Score: White: $0 = no; 1 = yes$                                 |                  |
| Hispanic Ethnicity           | Measure: Self-reported ethnicity at baseline                    | Additional data  |
|                              | Score: Hispanic: $0 = no; 1 = yes$                              |                  |
| Marital Status               | Measure: Self-reported marital status at baseline               | Additional data  |
|                              | Score: Married: $0 = no; 1 = yes$                               |                  |
| Employment                   | Measure: Self-reported employment status at baseline            | Additional data  |
|                              | Score: Working: $0 = no; 1 = yes$                               |                  |
| Language Best Served         | Measure: Self-reported language preference at baseline          | Additional data  |
|                              | Score: English: $0 = no$ , $1 = yes$                            |                  |
| nsurance                     | Measure: Self-reported or proof of insurance status at baseline | Insurance        |
|                              | Score: Public insurance: $0 = no; 1 = yes$                      |                  |
| Federal Poverty Guideline    | Measure: Proof of household income at baseline                  | Additional data  |
|                              | Score: Below federal poverty guideline: $0 = no; 1 = yes$       |                  |

# Table 3.1. Care Team: Patient – Measures, Scoring Guidelines and Electronic Health Record for Study Variables

# Table 3.1.(Continued)

| Care Team: Patient Variables                        | Measure and Scoring Guidelines  | EHR Module/Field     |
|---|---|----------------------|
| Tobacco Use   | Measure: Self-reported and documented by medical assistant or LPN at baseline | Patient chart        |
|   | Score: Current smoker: $0 = no$ ; $1 = yes$                                   |                      |
| Axis I Diagnosis                                    | Measure: Diagnosis by the medical provider at baseline                        | Patient chart        |
|   | Score: Mood disorder: $0 = no; 1 = yes$                                       |                      |
| Axis III Diagnosis                                  | Measure: Diagnosis by the medical provider at baseline                        | Patient chart        |
|   | Score: Cardiometabolic Illness (CMI): 0 = no; 1 = yes                         |                      |
| Primary Care Provider (PCP)                         | Measure: Clinic primary care provider   | Patient chart        |
|   | Score: $0 = no; 1 = yes$  |                      |
| Name of Atypical Antipsychotic<br>(AA) at Baseline  | Measure: Highest risk AA medication   | Patient chart/Medcir |
|   | Score: Low weight gain: $0 = no$ ; $1 = yes$                                  |                      |
| Name of Atypical Antipsychotic<br>(AA) at Follow-Up | Measure: Highest risk AA medication   | Patient chart/Medcir |
|   | Score: Low weight gain: $0 = no$ ; $1 = yes$                                  |                      |

is self-reported as: African American, Cambodian, European American, Hmong, Laotian, Mexican, Ojibwe, Other American Indian Tribes, Somali, Vietnamese, or Other. Ethnicity is self-reported as: Hispanic or Non-Hispanic. White race and Non-Hispanic are identified as the candidate attributes. Thus, patient race and ethnicity at baseline were analyzed.

# Language Best Served

Language barriers are one possible source of limited access and lower mental health care quality. Several studies have shown that limited English proficiency is associated with decreased perceived need for mental health treatment or awareness of having any mental health problems among Hispanic and Asians adults (Bauer et al., 2010; Kim et al., 2011; Sentell et al., 2007). At admission to the clinic, the patient is asked to self-report preferred language. Self-reported language best served was reported as Somali, English, Spanish, Vietnamese, Ormo, Hmong, Cambodian, or Other. English speaking was identified as the candidate attribute. Thus, language best served was analyzed.

### Marital Status

The risk of developing a mental health disorder or receiving treatment is higher for persons who have marital disruption, were previously married, or are single (Kendler et al., 1996; Kessler et al., 2005; Wang et al., 2005). Never being married is an indicator of delaying mental health treatment and having delays in treatment after initial contact (Wang et al., 2005). At admission to the clinic, the patient is asked to self-report marital status. Marital status was self-reported as: single, married, divorced, separated, life partner, legal separation, or unknown. Single/widowed/divorced was identified as the candidate attribute. Thus, marital status was analyzed.

### **Employment, Income and Insurance**

Persons with a severe mental illness have a chronic mental disorder which includes periods of stability and episodes of illness. Persons who are unemployed, uninsured, and have a lower income are at risk for developing a mental disorder and receiving treatment for the disorder (Kendler et al., 1996; Kessler et al., 2005; Wang et al., 2005). On admission to the clinic, the patient is asked to supply information or self-report employment status, income, and insurance. Employment status was self-reported as: full-time, part-time, or none. Unemployment was identified as the candidate attribute. Candidate attributes were not selected for income and insurance due to lack of variability. Thus, employment status, poverty level, and insurance were analyzed.

# Tobacco Use

Persons with a severe mental illness smoke at higher rates than the general population. Rates of smoking have been reported in persons with a severe mental illness as many as two to three times the general population, 30% of which smoke more than one pack a day (Dixon et al., 2007). Before seeing a medical provider at each visit, the patient is asked by the rooming medical assistant or licensed practical nurse to self-report current smoking status. Tobacco use was self-reported to the medical assistant or licensed practical nurse as: current smoker, former smoker, or never. Current smoker was identified as the candidate attribute. Thus, current smoking status was analyzed.

# **Primary Care Provider**

Persons with a severe mental illness have a high risk for co-morbid physical health problems. Persons who have a primary care provider have higher physical health screening rates (Haupt et al., 2009; Shi et al., 2009). Patients can access primary care services at the clinic or see an outside primary care provider. Documentation in the electronic health record identifies if a patient had a primary care visit at the clinic within the initial treatment period. Having a clinic primary care provider was identified as the candidate attribute. Thus, if the patient had a primary care provider visit during the initial treatment phase was analyzed.

### Diagnosis

The Diagnostic and Statistical Manual IV Text Revision (DSM IV TR) provides diagnostic criteria to make a mental disorder diagnosis. The diagnoses are documented on a five Axis system. Axis I is the major mental disorder, Axis II is a personality disorder, Axis III is the medical disorder, and Axis V is the global assessment of functioning. At baseline, the psychiatric provider makes Axis I-V diagnosis and documents the diagnoses in the medical record.

For Axis I, Mood Disorders included Major Depressive Disorder, Bipolar I Disorder, or Bipolar II Disorder; and Thought Disorders included Schizophrenia, Schizoaffective Disorder, or Psychotic Disorder NOS). A secondary Axis I diagnosis was confirmed through documentation of a substance use disorder (SUD) by the psychiatric provider.

Axis III diagnosis was confirmed through documentation by the psychiatric provider of one or more cardiometabolic illnesses (CMI), including hypertension, obesity, diabetes, or hyperlipidemia. Persons with a severe mental illness have higher comorbid cardiometabolic risk factors (Morden, Mistler, Weeks & Bartels, 2009) and are diagnosed with two or more chronic conditions which include hypertension, hyperlipidemia, obesity, or diabetes (Jones et al., 2004; Kilbourne et al., 2008). Assessing

the physical health co-morbidities and functional level are important when treating persons with a severe mental illness.

Axis V is documented as the global assessment of functioning which is a number 1-100. The global assessment function indicates the overall functional level of a patient, which can serve as in indicator of ability to present for appointments and engage in treatment. Axis II is a diagnosis of personality disorder, which can also serve as an indicator of a patients' ability to engage in treatment. Candidate attributes for diagnosis includes documented Mood Disorder, Axis I SUD, and one or more CMIs. Axis II and V do not have an identified candidate attribute. Thus, Axis I primary and secondary SUD, and Axis III diagnosis of a CMI were analyzed.

# Atypical Antipsychotic Medication

Persons with a severe mental illness are treated on first line medications known as atypical antipsychotic medications. Atypical antipsychotic medications have been associated with hypertension, obesity, and diabetes, leading to cardiovascular disease (Amiel, Mangurian, Ganguli & Newcomer, 2008). Of the atypical antipsychotic medications on the market, all are known to increase risk of weight gain, diabetes, and worsening lipid profile; however, some place persons at higher risk than others. Highest risk AA medications include Quetiapine Fumarate, Olanzapine, Risperidone, or Clozapine. High risk AA medications include Aripiprazole, Ziprasidone, or Paliperidone. Therefore atypical antipsychotic medication can be placed into two categories; those that have the highest risk of cardiometabolic side effects and those that have a high risk. At baseline and follow-up, the psychiatric provider prescribed a high risk or highest risk atypical antipsychotic medication. Highest risk AA medication was identified as the candidate attribute. Thus, AA medication at baseline and follow-up was analyzed.

### Provider

Within the delivery system design care team, the final variable of interest is the provider. Specifically, the provider variables of interest include: highest level of education; American Nurses Credentialing Center certification; Second Nurse Practitioner certification; Length of time in practice as an Advanced Practice Nurse; and Length of time at the clinic. The variables, measures, scoring guidelines and location in the electronic health record are found in **Table 3.2**.

# Education

To become an Advanced Practice Psychiatric Mental Health Provider, the minimum level of education is a Master of Science in Nursing. Some Advanced Practice Psychiatric Providers have additional education such as a Doctor of Nursing Practice,

| Care Team: Provider Variables  | Measure and Scoring Guidelines  |
|--|---|
| Highest Level of Education   | Measure: Master of Science in Nursing<br>Score: $0 = no; 1 = yes$     |
| American Nurses Credentialing Center<br>(ANCC) Psychiatric Certification | Measure: Nurse Practitioner certification<br>Score: $0 = no; 1 = yes$ |
| Second Nurse Practitioner Certification                                  | Measure: Second Nurse Practitioner certification                      |
|  | Score: $0 = no; 1 = yes$  |
| Years in Practice as Advanced Practice                                   | Measure: Novice in practice   |
| Nurse  | Score: $0 = no; 1 = yes$  |
| Years in Practice as Advanced Practice                                   | Measure: Novice at clinic   |
| Nurse at Clinic  | Score: $0 = no; 1 = yes$  |

# Table 3.2.Care Team: Provider – Measures and Scoring Guidelines for StudyVariables

Educational Doctorate or Doctor of Philosophy. The Doctor of Nursing Practice has been developed and implemented as the new clinically focused doctoral degree. No current workforce data is available about clinical outcomes by Advanced Practice Psychiatric Providers who have a Master's degree, compared to those with a Doctorate Degree. However, one can postulate that the additional education and obtaining a clinical doctorate would improve patient care outcomes. Having a Master's in Nursing as the highest level of education is identified as the candidate attribute. Thus, highest level of education was analyzed.

# Certification

Advanced Practice Psychiatric Mental Health Providers are prepared as Psychiatric Clinical Nurse Specialists or Psychiatric Nurse Practitioners. According to the National Organization of Nurse Practitioner (NONPF) competencies, Psychiatric Nurse Practitioners are required to complete course work in advanced health assessment and have clinical hours in physical health assessment (NONPF, 2003). Some Nurse Practitioners have a dual certification in a medical specialty, such as Family Nurse Practitioner, Adult Nurse Practitioner, or Acute Care Nurse Practitioner. One can postulate that Psychiatric Nurse Practitioners and those psychiatric providers who have a secondary medical nurse practitioner certification are more astute to the medical presentation of a patient. Having a Psychiatric Nurse Practitioner Certification and a Secondary Medical Nurse Practitioner Certification are identified as candidate attributes. The type of Psychiatric Certification and having a Secondary Medical Nurse Practitioner Certification are identified as the candidate attributes. Thus, Psychiatric Certification and Secondary Nurse Practitioner Certification were analyzed.

## Years in Practice as Advanced Practice Nurse

New providers who recently became certified have been exposed to current practice guidelines, as compared to those in practice for many years. Having five or less years of experience as a Psychiatric Advanced Practice Nurse is defined as a novice in practice and the candidate attribute. Thus, number of years in practice was analyzed.

### Years in Practice as Advanced Practice Nurse at Clinic

Providers who are new to a health system require time to understand flow of patient care and may be less aware of both medical and physical care of a psychiatric patient. Having five or less years of experience in practice at the clinic is defined as a novice at the clinic and the candidate attribute. Thus, number of years in practice at the clinic was analyzed.

### Visits

The delivery system design includes the care team and visits. The visit variables of interest are the actual visits the patient encountered during the first 16 weeks of treatment. Specifically, the actual visits of interest are: Walk in baseline; Walk in follow-up; Walk in at baseline and follow-up; No shows; Walk-ins, Hospitalizations; Sum of visits; and Sum of number of providers. **Table 3.3** provides a description of the description of the visit variables, measures, scoring guidelines, and location in the electronic health record.

# Walk-In Visits

Visits in a community mental health center tend to be crisis, scheduled, or on a walk-in basis. When a patient walks in for care other than at the scheduled visit time, the provider often reacts and responds to the patient rather than following a plan of care. Planned care for chronic conditions allows a provider to identify patient needs for the chronic condition (Wagner, Austin et al., 2001). Having a walk-in visit at baseline, follow-up, and both baseline and follow-up were identified as the candidate attribute variable. Thus, walk-in visits at baseline, follow-up, and both baseline and follow-up were analyzed.

### Same Provider at Baseline and Follow-Up

When a patient has the same psychiatric provider throughout the initial treatment phase it allows for the development and implementation of a treatment plan. Same provider at baseline and follow-up was identified as the candidate attribute. Thus, same provider at baseline and follow-up were analyzed.

### No Show Rate

Persons with a severe mental illness have been found to have a high no show and drop of care at high rates. No show rates among persons with a severe mental illness are about twice that of other specialties and up to 50% of those who fail an appointment drop out of care (Mitchell & Selmes, 2007). Having one or more no shows during the initial treatment phase was identified as the candidate attribute. Thus, the number of no shows during the initial treatment phase was analyzed.

# Total Number of Visits

The initial treatment phase is defined as the first 16 weeks of treatment. Psychiatric visits are scheduled based on patient acuity; however, during the initial

| Visit Variable                        | Measure and Scoring<br>Guidelines            | EHR Module/Field              |  |
|---------------------------------------|--|-------------------------------|--|
| Walk In Baseline                      | Measure: Walk in baseline                    | Patient chart/Chief           |  |
|                                       | Score: $0 = no; 1 = yes$                     | complaint                     |  |
| Walk In Follow-Up                     | Measure: Walk in follow-up                   | Patient chart/Chief           |  |
|                                       | Score: $0 = no; 1 = yes$                     | complaint                     |  |
| Walk In Baseline &<br>Follow-Up       | Measure: Walk in baseline & follow-up visit  | Patient chart/Chief complaint |  |
|                                       | Score: $0 = no; 1 = yes$                     |                               |  |
| No Show - One or More                 | Measure: One or more no shows first 16 weeks | Patient chart/Chief complaint |  |
|                                       | Score: $0 = no; 1 = yes$                     |                               |  |
| Same Provider Baseline<br>& Follow-Up | Measure: Same provider baseline & follow-up  | Patient chart/Chief complaint |  |
|                                       | Score: $0 = no; 1 = yes$                     |                               |  |
| Total                                 | Measure: Sum of all visits-first 16 weeks    | Patient chart/Chief complaint |  |
|                                       | Score: $0 = no; 1 = yes$                     |                               |  |

Table 3.3.Visit Measures and Electronic Health Record Fields for StudyVariables

treatment phase it is likely that a patient is seen every four to six weeks. Thus, the number of visits during the initial treatment phase was analyzed.

# **Quality Outcomes**

Quality outcomes include AA screening rates at baseline, follow-up and both baseline and follow-up. The AA screening rates were analyzed based on the American Diabetes Association (ADA) and American Psychiatric Association (APA) 2004 recommendations for cardiometabolic screening and monitoring for persons treated on an AA medication at baseline and 12 weeks. Complete screening at baseline and follow-up, in addition to individual screening measures were analyzed. A positive screening is guided by the definition of an elevated blood pressure, elevated plasma glucose or lipid profile, as defined by the National Cholesterol Education Program (NCEP) (2002). The ADA and APA guidelines and NCEP criteria are provided in **Table 3.4**.

The ADA and APA monitoring guidelines include six screening measures at baseline and five measures at 12 weeks. This study identified the initial treatment phase as the first 16 weeks of treatment; therefore, baseline is first visit and follow-up is the last visit within 16 weeks. Baseline and follow-up screening measures are considered complete if the screening measure was completed within four weeks of the baseline or follow-up visit. Because waist circumference is not measured at the community mental health center, this measure was excluded from analysis. Therefore, the full provision of quality care is defined as having all five baseline measures and all four 12 week measures. Baseline screening measures include four biological measures and screening for personal or family history of cardiovascular disease.

Biological measures include: weight or body mass index, waist circumference, blood pressure, fasting plasma glucose or hemoglobin A1c, and fasting lipid profile. According to the ADA and APA monitoring guideline, body mass index should be measured; however, due to a priori knowledge, either weight or body mass index was measured. Additionally, per the monitoring guideline, fasting plasma glucose should be measured; however, due to the frequency of measuring hemoglobin A1c, either fasting plasma glucose or hemoglobin A1c was measured. The one non-biological measure, which is to be screened at baseline only, is a personal or family history of cardiovascular disease. At 12 weeks, or follow-up the following biological measures are to be screened: weight or body mass index, waist circumference, blood pressure, fasting plasma glucose or hemoglobin A1c, and fasting lipid profile.

The screening measure of family or personal history of cardiovascular disease was included in the baseline measure, and if completed at baseline accounted for a follow-up. Therefore, five possible screening measures exist at baseline and follow-up. The four biological screening measures (weight or body mass index, blood pressure, fasting plasma glucose or hemoglobin A1c, and fasting lipid profile) were recorded using the exact documented measurement or a missing variable. An order for fasting plasma glucose or hemoglobin A1c, and fasting lipid profile was completed by the psychiatric

Table 3.4. **Quality Outcome Measures** 

| Measures at Baseline & Follow-<br>Up                         | Measure / Defining Level for Positive<br>Screen**   | Scoring Guideline | EHR Module/Field                     |
|--|---|-------------------|--------------------------------------|
| Personal/Family History of<br>Cardiovascular Disease (CVD)†* | Personal/family history CVD   | 0 = no, 1 = yes   | Patient chart/Narrative              |
| Body Mass Index (BMI)*                                       | BMI - Weight in kg/height in m2 $\geq$ 30kg/m <sup>2</sup>  | 0 = no, 1 = yes   | Patient chart/Vitals                 |
| Waist Circumference*   | Waist circumference / Men: >40 inches<br>Women: ≥35 inches  | Not measured      | Not measured                         |
| Blood Pressure*  | Blood pressure / Systolic pressure of<br>≥140 mmHg / Diastolic pressure ≥90 mmHg                                | 0 = no, 1 = yes   | Patient<br>chart/Narrative/Path labs |
| Fasting Plasma Glucose (FPG)*                                | Order or completed FPG / value $\geq 110 \text{ mg/dl}$<br>or A1c order / value $\geq 8\%$                      | 0 = no, 1 = no    | Patient<br>chart/Narrative/Path labs |
| Fasting Lipid Profile*                                       | Order or completed fasting lipid<br>profile/cholesterol >200 mg/dl;<br>triglycerides >150 mg/dl; LDL >130 mg/dl | 0 = no, 1 = yes   | Patient<br>chart/Narrative/Path labs |

\*Baseline Measure Only.

\*ADA and APA (2004) Metabolic Monitoring Schedule. \*\*National Cholesterol Program (2002). National Institute of Health. National Heart, Lung and Blood Institute. NIH Publication. NCEP ATP III Criteria.

medical provider. Assessment and documentation of personal or family history of cardiovascular disease was completed by the psychiatric medical provider. Measurement of weight, height, and body mass index were completed and documented by a medical assistant, licensed practical nurse, or registered nurse.

The quality outcome candidate attribute was defined as the total number of screening measures performed by the provider at baseline and follow-up. Thus, number of screening measures at baseline, follow-up, and both baseline and follow-up were analyzed.

# Procedure

### **Protection of Human Subjects**

Prior to data collection, Institutional Review Board (IRB) approval was obtained from the University of Tennessee Health Science Center (UTHSC) (Appendix A). The study met the criteria to be an exempt study and a waiver of Health Insurance Portability and Accountability Act authorization was approved. The community mental health center is within a community health care center, affiliated with an Academic Health Science Center; therefore, additional approval was required. A research proposal and the IRB approval letter from UTHSC was submitted to the clinic Chief Clinical Officer for review with the clinic research team. Prior to receiving any data the study was approved by both UTHSC and the clinic research team.

After IRB approval from UTHSC and the clinic research team, a written data request was submitted to the clinic data team whose membership included a data manager, who served as the data extractor for the study, the director and assistant director of information technology, billing administrator, and a clinician. In addition, meetings with the clinic data team and data extractor occurred to discuss study variables and method for electronic data extraction, prior to receiving any data. To store the data, a member of the Information Technology department within the Academic Health Center of the University created a shared user directory on the secure network. The password protected shared user directory was only accessible to the study primary investigator (PI) and the study data extractor, an employee of the University, in the Office of Technology Services and a member of the clinic data team. A folder within this directory named "DSD" was created to store the data. Data were stored on the directory "DSD" folder and on a password protected encrypted memory stick which was kept in the possession of the PI at all times.

### **Data Collection**

All patient and visit data used in this study were collected from an electronic health record (EHR). Seven of the nine Advanced Practice Registered Nurse Psychiatric

Mental Health Providers, completed the consent form (Appendix B) and paper survey (Appendix C). Two providers were no longer employed by the clinic. Data on one of the two providers was obtained by clinic administration, and the other provider data could not be obtained.

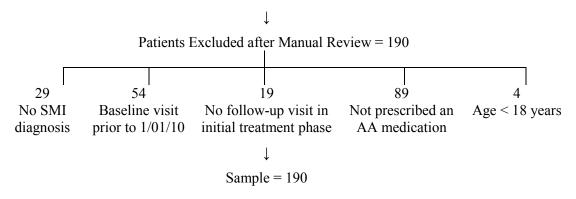
Patient and visit data were entered by staff of the community mental health center located in the community clinic. Psychiatric services were provided by psychiatrists, advanced practice registered nurses with a specialty in psychiatric mental health nursing, registered nurses, licensed practical nurses, or medical assistants. Demographic patient data was entered by the front desk and administrative staff. The only data entered by registered nurses, licensed practical nurses, or medical assistances include: weight, height, blood pressure, and tobacco status. The clinic EHR is used by both psychiatric and medical providers, without any restrictions on access to data. The EHR does not have required fields that must be completed before completing an encounter; therefore, some data fields had missing data. All missing data were coded using the number "99."

The initial study sample was identified by electronic extraction of records queried by the data extractor and met the study inclusion criteria: a) had a severe mental illness defined as one of the following DSM IV TR codes: Within the Axis I diagnosis inclusion criteria for the study, the following diagnostic codes were included: 295.70, 295.90, 295.60, 295.30, 295.10, 295.20, 296.2X, 296.0, 296.40, 296.4X, 296.5X, 295.7 or 298.9; b) age 18 or greater; c) treated on a AA medication: Abilify (Aripiprazole), Clozaril (Cloazpine), Fanapt (Iloperidone), Geodon (Ziprasidone), Invega (Paliperidone), Lurasidone (Latuda), Risperdal (Risperidone), Risperdal Consta, Saphris (Asenapine), Seroquel (Quetiapine) and Zypreza (Olanzapine);. d) had a visit coded as a 90801 (new) and at least one visit coded as 90862 (follow-up) within the first 12 weeks of treatment; e) newly admitted to behavioral health services during the study period, January 1, 2010 to December 31, 2010. After query by data extractor using all inclusion criteria, 385 patients were identified. After manual review of all 385 patient records, 195 patients were excluded for the following reasons: 29 patients did not have a SMI diagnosis, 54 patients were not new to the system (established patient), 19 patients did not have a follow-up visit, 89 patients were not on an antipsychotic medication, and 4 were younger than 18 years of age. Figure 3.1 provides a summary of the study sample.

The study variables extracted by the data extractor, using a specific written query included the following patient characteristics: Axis I, medication, age, gender, race, ethnicity, marital status, employment status, language best served, percent of poverty, insurance, and tobacco status. These variables were the original data generated in the demographics and patient administration modules within the EHR. The raw data provided to the investigator were the data values exactly as they were entered into the EHR and these data values were placed into an excel spreadsheet. The excel spreadsheet from the data extractor was merged with the excel spreadsheet created by the study PI to manually collect study variables.

An excel spreadsheet was created and used to collect data. Four tabs were created within the excel spreadsheet to organize the data. The tab named "dxmed" had a locked top row with labels for the following patient variables: axis I, axis II, axis III, axis V,

### Patients Extracted from EMR Database Using Inclusion Criteria = 385



### Figure 3.1. Study Sample

primary care provider, medication baseline, medication follow-up, and hospitalization. Axis I diagnosis and medication were also electronically extracted from the EHR by the data extractor and were used as a quality check with the data extracted manually. The tab named "labs" had a locked top row with the following quality outcome and patient variables: weight, body mass index, blood pressure, glucose, A1C, cholesterol, LDL, HDL, triglycerides, referral, and personal and family history of cardiovascular disease. The tab named "visits" had a locked top row with the following visit variables: visit date, provider at baseline, provider at follow-up, walk in baseline, walk in follow-up, scheduled, no show, walk in, and total number of providers. The final tab labeled "demo" included patient variables that were extracted from the EHR by the data extractor, using a query code, included age, gender, race, ethnicity, marital status, employment status, language best served, percent of poverty, insurance, and tobacco status.

The study variables from the "dxmed" tab were manually extracted by the study PI from the clinical console module patient chart located within the EHR. The diagnosis variables were extracted and written in the columns on the excel spreadsheet using the diagnosis name for axis I, II, III and the number for axis V. The in clinic primary care variable was extracted and coded '1' for yes and '0' for no. The AA medication name was extracted and coded on the excel spreadsheet using a number that was assigned to each medication. The variable hospitalization was coded as "0" for no hospitalization or the number of hospitalizations within the initial treatment period.

The study variables from the "labs" tab were manually extracted from the clinical console module, patient chart within the vitals tab or laboratory tab. Each quality outcome variable was manually extracted and the exact number was placed into the assigned column in the excel spreadsheet. Missing values were coded using "99." The referral variable was coded as "1" for yes, and "0" for no, for a positive screening value. The variable of documentation of personal or family history of cardiovascular disease was coded as "1" for yes, and "0" for no.

The study variables from the "visits" tab were manually extracted from the clinical console within the chart module. The chief complaint area documents the type of visit and this was crossed check by looking at the appointment type and reason for the encounter. The appointment type is not a required field; therefore, it is not a reliable source of visit data. The provider at baseline and follow-up were coded based on a pre-assigned number. The number of providers in the initial treatment phase was identified and coded as a whole number. The number of scheduled, walk-ins, no shows were identified and coded as a whole number. Walk in at baseline and walk in at follow-up were coded with "1" for yes, and "0" for no.

A written procedure outlining the method for manual data extraction of "demodx," "labs," and "visits" was developed and provided to the data extractor. An online randomizer was used to identify ten percent of the records that would be checked for accuracy. The data extractor checked the records and found an accuracy rate of greater than 99 percent. After the data was collected and checked for accuracy, the patient record number was deleted. The de-identified data set was imported into Statistical Package for the Social Sciences (SPSS) version 20.0 for analysis.

# Analysis

After the data were cleaned, the de-identified data set was imported into SPSS version 20.0 for analysis. Because this is a descriptive study, a formal power analysis was not conducted (M. Dietrich, personal communication, March 17, 2011).

To answer research question one: "What are the baseline patient, provider, and visit characteristics of SMI patients prescribed an atypical antipsychotic medication?" the following statistical methods were used. Data values were tested for normality using the Fisher test of normality. Continuous study variables (both candidate and quality outcome) not meeting the assumptions of normality were summarized using the median,  $25^{th}$  and  $75^{th}$  interquartile range, and minimum and maximum. Of the three continuous candidate variables, age and Axis V diagnosis did not meet the assumption of normality. Normally distributed study variables were summarized using the mean  $\pm$  standard deviation. All nominal and ordinal values were summarized using count and percent (frequency distribution). To further describe delivery system characteristics, cross tabulations were used.

To answer research question number two: "What percent of SMI patients treated on an atypical antipsychotic medication received cardiometabolic screening at a) baseline, b) follow-up, and c) both baseline and follow-up?" the following statistical methods were used. The individual quality outcome variables were reported using count and percent (frequency distribution) at baseline, follow-up, and both baseline and followup.

To answer the final research question: "What delivery system characteristics are associated with receiving cardiometabolic screening at a) baseline, b) follow-up, and c)

both baseline and follow-up?" the following statistic methods were used. First, the patient characteristics were assessed for variability in responses. Seven of the 16 variables, which include ethnicity, language best served, marital status, insurance, percent of poverty, Axis II and V, were excluded due to lack of variability. The next step was to generate candidate variables for use in the analysis. The categorical candidate patient, provider, and visit variables were transformed to the presence or absence of their respective attribute, coded as 1 = yes and 0 = no. The only continuous candidate variable was age. It was not normally distributed. The square root transformation met that assumption and was used in the analyses. Finally, the individual quality outcome variables at baseline, follow-up, and both baseline and follow-up were generated. The three new continuous quality outcome variables contained the number of quality outcome variable had a possible range from zero to five.

Multiple linear regression was deemed most appropriate for addressing the final research question because the candidate variables were either binomial (only 2 possible categories for each) or were measured on an interval/ratio scale that met normal distribution assumptions. There were at least 10 cases for each candidate variable, and the quality outcome variable at baseline, follow-up, and baseline and follow-up were continuous. Prior to conducting the multiple linear regression analyses, inter-correlations among all of the patient and visit candidate variables were generated using Pearson correlation coefficients. Provider candidate variables were generated using the Spearman Rho correlation coefficients, as it is the correlation coefficient indicated for variables with 30 or fewer cases (Polit, 2010, page 202). Not only of interest themselves, an evaluation of collinearity (r > 80) between any two variables may be detected. None of the correlations indicated a problem with collinearity. Finally, unadjusted (bivariate) correlations of each candidate variable with each outcome variable and adjusted (simultaneous multiple linear regress) associations between the patient and visit candidate, and quality outcome variables were generated. Because there were only nine providers in the study, a multiple regression was not conducted using those data. In addition, because the visit characteristics could only be known at follow-up, unadjusted and adjusted associations of those characteristics with the number quality outcomes was generated baseline, baseline walk in at baseline only and both baseline and follow-up walk in and same provider follow-up only. Analysis of multivariate residuals did not identify prediction problems, which is cited as a potential problem that needs to be addressed when using multiple linear regression (Polit, 2010).

Within each multiple regression, multicollinearity of the candidate variables was assessed using the Variance Inflation Factor (VIF) and tolerance statistics. Neither VIF nor tolerance statistics indicated problems with multicollinearity defined by a VIF of over 10 or tolerance of < 0.1 (Polit, 2010) for any of the regressions. All candidate variables proposed by the model used in this study were used in both the unadjusted (bivariate) and adjusted (multivariate) analyses. To use only statistically significant unadjusted findings in the adjusted analysis results in an overfitting of the data specific to the study used. Similarly, backward or step out multiple regression techniques were not used due to the

risk of overfitting data and concerns related to lack of replicability (personal communication, Mary Dietrich, March 19, 2012).

### **Methodological Assumptions**

There are three major assumptions that exist in this study. The first assumption is related to the use of the CM as the conceptual framework to guide this study. The CM has not been used in any previous studies that examine a mental health center and the rates of screening for cardiometabolic symptoms. It is postulated that the components of the CM, as discussed and which have been shown to be successful to redesigning primary care environments, are also present in a CMHC.

The second assumption of this study is that the delivery system design as described in the CM is present in a CMHC setting. It is assumed that the care team and visits, within the delivery system design, will have an effect on the rates of screening and referral for cardiometabolic symptoms. The third and final assumption made is that the identified CMHC that is used to gather data is similar to other CMHC's that are cited in the literature. The rates of screening for cardiometabolic symptoms, in the identified CMHC will be compared to national studies and published rates of screening.

### **Methodological Limitations**

The major limitation to this study is apparent in the study design. This study is a retrospective, cross-sectional, descriptive study. There are limitations inherent in this type of study. For example, the data that will be collected is pre-existing and will be retrieved from an electronic medical record. This type of design has threats to internal validity, specifically data integrity. Additionally, the data will be collected from one CMHC located in the Mid-West Region of the U.S., which will place limitations on the generalizability of the findings. Finally, only one component of the CM will be examined and may not have the ability to provide information on the agency and the ability to identify barriers to screening and referral for cardiometabolic symptoms.

# CHAPTER 4. RESULTS

The study purpose was to examine the impact of the delivery system design of a community mental health center on the provision of quality care provided to persons with severe mental illness. Specifically, the aim of the study was to examine characteristics of the community mental health care team and visits on adherence to recommended monitoring protocol for newly admitted patients treated on Atypical Antipsychotic (AA) medication. The investigator first evaluated the descriptive characteristics of the care team which included the patient, provider, and visits. The investigator then examined the rates of adherence to the American Diabetic Association (ADA), American Psychiatric Association (APA), American Association of Clinical Endocrinologists (AACE), and North American Association for the Study of Obesity (NAASO) monitoring protocol for persons treated on an AA medication. Rates of screening individual measures within the monitoring protocol were also analyzed. Finally, simultaneous multiple linear regression was used to examine associations between the patient and visit characteristics with quality outcome measures. This chapter will discuss the findings of these analyses.

Results of the following research questions will be discussed:

- 1. What are the baseline patient, provider, and visit characteristics of SMI patients prescribed an atypical antipsychotic medication?
- 2 What percent of SMI patients prescribed an atypical antipsychotic medication received cardiometabolic screening at a) baseline, b) follow-up, and c) both baseline and follow-up?
- 3. What delivery system characteristics are associated with receiving cardiometabolic screening at a) baseline, b) follow-up, and c) both baseline and follow-up?

### **Care Team Patient Characteristics**

Nine hundred seventy seven patients were newly admitted to the clinic between January 1, 2010 - December 31, 2010. From the administrative data query, 385 patients were identified as meeting the study inclusion criteria. After manual review of the 385 patient records, 195 patient records were found not to meet the study inclusion criteria. Of the 195 excluded patient records, four were under age 18; 19 did not have a follow-up visit; 29 did not have a SMI diagnosis; 54 were not new to the clinic; and 89 were not on an AA medication. Therefore, the final sample consisted of 190 patients. **Figure 3.1** provides a summary of the study sample.

The mean patient age was 37.13 years with a SD  $\pm$  11.7 and a range of 19 - 70 years. The majority of patients were men (58.4%, n = 111) and most patients were single (90.5%, n = 172). More than one-half of the study (53.7%, n - 102) was minority race,

though most patients were not Hispanic (95.3, n = 181). The majority of the patients were not currently employed (88.9%, n = 169) and nearly one-half of the patients were below the federal poverty guidelines (47.4%, n = 90); most patients were enrolled in the Medicare or State Medical Assistance program (90.0%n = 171).

More patients in the study were diagnosed with a mood disorder (72.1%, n = 137) compared to a thought disorder (27.9%, n = 53) and were treated on an AA medication at highest risk for weight gain, elevated blood glucose, and dyslipidemia (76.8%, n = 146). Less than half of the patients were self-reported current smokers (45.8%, n = 87) and a smaller percentage were diagnosed with a secondary Axis I diagnosis of a substance use disorder (36.8%, n = 70). Nearly half of the patients had a primary care provider at the clinic (47.4%, n = 90); however, a small number of patients had a cardiometabolic illness (22.2, n = 47), and of those who had hypertension, obesity, diabetes, or hyperlipidemia, most were male gender (67.0%).

**Table 4.1** provides a summary of care team patient characteristics. For all continuous variables, measures of central tendency are reported as mean or median, depending on the distribution of data values, and standard deviation. Nominal and categorical variables are reported as the percent and frequency. Age did not meet the conditions of normality; therefore, the median, 25<sup>th</sup>-75<sup>th</sup> interquartile range and minimum and maximum are reported.

### **Care Team Provider Characteristics**

Data were obtained for eight of the nine providers The majority of the psychiatric mental health advanced practice nurses (PMH APNs) had a Master of Science in Nursing (MSN) (75.0%, n = 6) as the highest level of education and more were certified by the American Nurses Credentialing Center (ANCC) as an Adult Clinical Nurse Specialist (50.0%, n = 4). Fewer were ANCC certified as an Adult Psychiatric Mental Health Nurse Practitioner (PMHNP) (37.5%, n = 3) and only one (12.5%, n = 1) was certified as a Family PMHNP. More providers were in practice for five or more years (62.5%, n = 5); however, most were in practice at the clinic for five years or less (75.0%, n = 6). Table 4.2 provides a summary of the provider characteristics.

#### Visit Characteristics

Most patients (61.6%) did not receive their baseline or follow-up care during a scheduled visit, but rather "walked" into the clinic without prior notice. Patients who presented as a walk-in at baseline or follow-up were more likely to be a white, male diagnosed with a mood disorder and co-morbid Axis I substance use disorder, and received primary care services in the clinic. Patients who had the same provider at baseline and follow-up (36.3%) were more often a not white female, diagnosed with a thought disorder but without a co-morbid Axis I substance use disorder, and received primary care services outside of the clinic. Nearly one-half (45.3%) of the patients failed

| Characteristic                       | All Patients* (N = 190) |
|--------------------------------------|-------------------------|
| Age (Median, IQR25-75, Min, Max)†    | 35.0, 27.0-45.0, 19, 70 |
| Gender                               |                         |
| Male                                 | 58.4 (111)              |
| Female                               | 41.6 (79)               |
| Race                                 |                         |
| Not White                            | 53.7 (102)              |
| African American                     | 26.1 (51)               |
| Somali                               | 15.3 (29)               |
| Asian                                | 4.7 (9)                 |
| Native American                      | 4.7 (9)                 |
| Mexican                              | 1.6 (3)                 |
| White                                | 46.3 (88)               |
| Ethnicity                            |                         |
| Not Hispanic/Latino                  | 95.3 (181)              |
| Hispanic/Latino                      | 4.7 (9)                 |
| Language Best Served                 |                         |
| English                              | 82.1 (156)              |
| Non English                          | 17.9 (34)               |
| Somali                               | 11.1 (21)               |
| Marital Status                       |                         |
| Single/Widowed/Divorced              | 90.5 (172)              |
| Married/Partnered                    | 9.5 (18)                |
| Employment Status                    |                         |
| None                                 | 88.9 (169)              |
| Part or Full-Time                    | 11.1 (21)               |
| Insurance Coverage                   |                         |
| Medicaid/Medicare/Medical Assistance | 90.0 (171)              |
| Private                              | 5.3 (10)                |
| None                                 | 4.7 (9)                 |
| Federal Poverty Level                |                         |
| Not Reported                         | 51.1 (97)               |
| Below Poverty Guidelines             | 47.4 (90)               |
| Over Poverty Guidelines              | 1.5 (3)                 |
| Current Smoker (self-reported)       |                         |
| Former/Never/Not Reported            | 54.2 (103)              |
| Current                              | 45.8 (87)               |
| Primary Care Provider at Clinic      |                         |
| No                                   | 52.6 (100)              |
| Yes                                  | 47.4 (90)               |

Table 4.1.Care Team – Baseline Patient Characteristics (N = 190)

| Table 4.1. | (Continued) |
|------------|-------------|
|------------|-------------|

| Characteristic                          | All Patients* (N = 190) |  |
|---|-------------------------|--|
| Axis I Diagnosis (Primary)              |                         |  |
| Mood Disorder                           | 72.1 (137)              |  |
| Major Depressive Disorder               | 38.9 (74)               |  |
| Bipolar I Disorder                      | 24.2 (46)               |  |
| Bipolar II Disorder                     | 8.9 (17)                |  |
| Thought Disorder                        | 27.9 (53)               |  |
| Schizophrenia                           | 11.1 (21)               |  |
| Schizoaffective Disorder                | 9.5 (18)                |  |
| Psychotic Disorder NOS                  | 7.4 (14)                |  |
| Axis I Secondary Substance Use Disorder | 36.8 (70)               |  |
| Axis III Cardiometabolic Illness        | 22.2 (47)               |  |
| AA Medication                           |                         |  |
| Highest Risk                            | 76.8 (146)              |  |
| Quetiapine Fumarate (Seroquel)          | 40.5 (77)               |  |
| Olanzapine (Zyprexa)                    | 17.9 (34)               |  |
| Risperidone (Risperdal)                 | 16.8 (32)               |  |
| Clozapine (Clozaril)                    | 1.6 (3)                 |  |
| High Risk                               | 23.2 (44)               |  |
| Aripiprazole (Abilify)                  | 18.9 (36)               |  |
| Ziprasidone (Geodon)                    | 3.2 (6)                 |  |
| Paliperidone (Invega)                   | 1.1 (2)                 |  |

\*Other than age, values in this column are percent (frequency). † Median, IQR25-75, Min, Max – data not meeting conditions of normality.

| Characteristic  | % (n)*   |
|---|----------|
| Education   |          |
| Master Science in Nursing                                 | 75.0 (6) |
| Doctor of Nursing Practice                                | 25.0 (2) |
| American Nurses Credentialing Center Certification        |          |
| Psychiatric Mental Health Nurse Practitioner - Family     | 12.5 (1) |
| Psychiatric Mental Health Nurse Practitioner - Adult      | 37.5 (3) |
| Clinical Nurse Specialist - Adult                         | 50.0 (4) |
| Years in Practice as an Advanced Practice Nurse           |          |
| 1-3 years   | 12.5 (1) |
| Greater than 3 years but less than 5 years                | 25.0 (2) |
| Greater than 5 years but less than 10 years               | 37.5 (3) |
| Greater than 10 years                                     | 25.0 (2) |
| Novice in practice (1 - 5 years)                          | 37.5 (3) |
| Years in Practice at Clinic as an Advanced Practice Nurse |          |
| Less than 1 year  | 25.0 (2) |
| 1-3 years   | 12.5 (1) |
| Greater than 3 years but less than 5 years                | 37.5 (3) |
| Greater than 10 years                                     | 25.0 (2) |
| Novice in practice at clinic (1 - 5 years)                | 75.0 (6) |

Table 4.2.Care Team - Provider Characteristics (N = 8)

to show up for one or more visits during the initial treatment period. Of those who had one or more no show visits, the patient was most likely to be male, with a mood disorder but without a co-morbid substance use disorder and a primary care provider outside of the clinic. The median number of visits, during the initial treatment phase was  $3.7 \pm 1.4$ visits. A summary of visit characteristics is provided in **Table 4.3**.

#### **Provision of Quality Care**

The second research study question addressed the provision of quality of care by asking: What percent of severe mental illness patients treated on an AA medication received cardiometabolic screening at a) baseline, b) follow-up, and c) both baseline and follow-up? **Table 4.4**. presents the research findings to answer this question.

Following the full American Diabetic Association (ADA), American Psychiatric Association (APA), American Association of Clinical Endocrinologists (AACE), and North American Association for the Study of Obesity (NAASO) monitoring protocol for persons treated on a second generation antipsychotic (SGA) medication no patient met the provision of quality care. Evaluation of the biological measures of the monitoring protocol (not assessing family and personal history of cardiovascular disease) at baseline 5.3% of the patients had full biological screening and 1.6% had full biological screening at follow-up. Individual evaluation of the quality outcome screening measures found the following mean and standard deviation number of measures at baseline ( $2.0 \pm 1.35$ ), follow-up ( $1.82 \pm 1.21$ ), and at both baseline and follow-up ( $1.21 \pm 1.02$ ). At baseline and follow-up the same number of patients (n = 2) had five screening measures. Patients were more likely to have two screening measures at baseline (25%) and follow-up (33.7%) as compared to three measures at baseline (27.9%) and follow-up (24.7%). At both baseline and follow-up two screening measures (27.9%) was slightly more common than three screening measures (21.0%).

One patient met the provision of quality care at baseline and follow-up (< 1%). The characteristics of this patient included: English speaking female diagnosed with a mood disorder and co-morbid substance use disorder, non-smoker, without any cardiometabolic illnesses who had a clinic primary care provider. The visit characteristics of this patient included: no walk-in visits, no no-show visits, with a total of 4 visits during the initial treatment phase. This patient had an increase of her body mass index at baseline of 24 kg/m<sup>2</sup> (normal weight) to 29 kg/m<sup>2</sup> (overweight) at follow-up. Her hemoglobin A1c remained the same at baseline and follow-up, 6 mg/dl but her cholesterol, Low-density lipoprotein, and Triglycerides were elevated at baseline and follow-up.

At baseline more patients had a blood pressure measure (n = 119), compared with body mass index (n = 65), cholesterol (n = 21), or a lipid profile (n = 16). Of the patients that had a body mass index at baseline, 46% were obese with a body mass index of 30 kg/m<sup>2</sup> or greater. The maximum body max index was 45 kg/m<sup>2</sup>. At follow-up, of the patients that had a body mass index, 48% were obese and the maximum body mass index

| Characteristic                                | % (n)*        |
|---|---------------|
| Walk-in Visit at Baseline                     |               |
| Yes   | 39.5 (75)     |
| Walk-in Visit at Follow-Up                    |               |
| Yes   | 35.3 (67)     |
| Walk-in Visit at Baseline & Follow-Up         |               |
| Yes   | 13.2 (25)     |
| Same Provider at Baseline & Follow-Up         |               |
| Yes   | 36.3 (69)     |
| One or More No Show Appointments <sup>†</sup> |               |
| Yes   | 45.3 (86)     |
| Total Number of Visits <sup>†</sup>           | $3.7 \pm 1.4$ |

#### Visit Characteristics (N = 190) Table 4.3.

\*Mean ±SD or Percent (frequency). <sup>†</sup>During the initial treatment phase.

| ADA and APA Guideline                         | Baseline<br>% (n) | Follow-Up<br>% (n) | Baseline & Follow-Up<br>% (n) |
|---|-------------------|--------------------|-------------------------------|
| Quality Outcomes - Biologic                   | 5.3 (10)          | 1.6 (3)            | > 1.0 (1)                     |
| Weight (BMI)                                  | 64.2 (122)        | 63.2 (120)         | 43.2 (82)                     |
| Waist Circumference*                          |                   |                    |                               |
| Blood Pressure                                | 62.1 (118)        | 61.6 (117)         | 38.9 (74)                     |
| Fasting Plasma Glucose (A1c)                  | 27.9 (53)         | 13.2 (25)          | 2.1(4)                        |
| Fasting Lipid Profile                         | 8.4 (16)          | 9.5 (18)           | 1.1 (2)                       |
| Quality Outcome - History of CVD <sup>†</sup> | 34.7 (66)         | -                  | -                             |

Table 4.4. Quality Outcomes at Baseline, Follow-Up, and Both Baseline and Follow-Up (N = 190)

Note: Data values in the columns are percent (frequency). \*Not measured.

†Baseline only measure.

was 45 kg/m<sup>2</sup>. At baseline and follow-up, of the 119 and 117 patients that had a blood pressure measurement, only 12% had an elevated reading. Rates of glycemic measurement were lower at baseline (n = 75) and follow-up (n = 39), as were rates of elevated measurements at baseline (16%) and follow-up (13.6%). Cholesterol measurements at baseline (n = 21) and follow-up (n = 20) were even lower; however, elevated readings were high at baseline (61.9%) and follow-up (65.0%). Lipid profile measurements were also low at baseline (n = 20) and follow-up (n = 18); however, of the measurements, high low-density lipoprotein and triglycerides at baseline (62.5% and 37.5%) and follow-up (33.3% and 55.6%) were also found to be elevated.

#### **Characteristics Associated with Provision of Quality**

The final research question asked: What delivery system characteristics are associated with receiving cardiometabolic screening at a) baseline, b) follow-up, c) both baseline and follow-up?

Simultaneous multiple linear regressions were used to address each of the three subcomponents of this research question. The following patient characteristics were not included in the correlation matrix or multiple linear regression models due to a lack of variation: ethnicity, language best served, marital status, employment status, insurance coverage, and federal poverty level. Prior to conducting parametric measures of association (Pearson correlations, multiple linear regression) for the remaining candidate variables, the skewed continuous age variable was transformed via the square root. This new distribution met assumptions. Bivariate correlations among all of the candidate variables did not reveal any problems with collinearity, nor did multicollinearity diagnostic statistics within each of the simultaneous regression analyses.

Associations among the patient characteristics are summarized in **Table 4.5**. Of the eight statistically significant correlations, associations were observed of race with language spoken (r = .26) and with presence of a mood disorder (r = .18). The interpretations suggest that non-white patients were more likely to speak English and more likely to have a mood disorder. Male patients were more likely than females to be a current smoker (r = .15) and less likely to have a mood disorder (r = ..19). In addition, having a clinic PCP was associated with lower likelihood of having a secondary SUD (r = ..17) and an increased likelihood of having a CMI (r = .17).

Associations among the provider characteristics are summarized in **Table 4.6**. Of the three statistically significant correlations, associations were observed of being a novice in practice (r = .75) and novice at the clinic (r = 1.0) and MSN education. Being a novice in practice and novice at the clinic were also associated (r = .75).

Associations among the visit characteristics are summarized in **Table 4.7**. Of the four statistically significant correlations, associations were observed of being a walk-in at baseline and follow-up with walk-in at baseline (r = .48.) and walk-in at follow-up

| Patient             | Age | Male | White | English | Smoker | РСР   | Mood | SUD  | CMI   | AA   |
|---------------------|-----|------|-------|---------|--------|-------|------|------|-------|------|
| Characteristic      | 0   |      |       | 0       |        |       |      |      |       |      |
| Age                 |     |      |       |         |        |       |      |      |       |      |
| Pearson Correlation | -   | 024  | .024  | 002     | 003    | .084  | .095 | .107 | .144* | 089  |
| Sig.                |     | .741 | .746  | .982    | .964   | .250  | .190 | .143 | .048  | .220 |
| Male Gender         |     |      |       |         |        |       |      |      |       |      |
| Pearson Correlation | -   | -    | .013  | .024    | .154*  | 012   | 191* | 042  | .093  | 058  |
| Sig.                |     |      | .863  | .742    | .034   | .865  | .008 | .566 | .566  | .426 |
| White Race          | -   | -    |       |         |        |       |      |      |       |      |
| Pearson Correlation |     |      |       | 25*     | .142   | .049  | 175* | 031  | 071   | .135 |
| Sig.                |     |      |       | <.001   | .051   | .502  | .015 | .670 | .333  | .064 |
| English Speaking    |     |      |       |         |        |       |      |      |       |      |
| Pearson Correlation | -   | -    | -     | -       | .016   | 107   | 015  | 015  | .066  | 094  |
| Sig.                |     |      |       |         | .830   | .141  | .839 | .168 | .363  | .199 |
| Current Smoker      |     |      |       |         |        |       |      |      |       |      |
| Pearson Correlation | -   | -    | -     | -       | -      | .144* | .077 | .065 | .010  | .004 |
| Sig.                |     |      |       |         |        | .048  | .291 | .376 | .893  | .960 |
| Clinic PCP          |     |      |       |         |        |       |      |      |       |      |
| Pearson Correlation | -   | -    | -     | -       | -      | -     | .096 | 171* | .166* | .071 |
| Sig.                |     |      |       |         |        |       | .185 | .018 | .022  | .330 |
| Mood Disorder       |     |      |       |         |        |       |      |      |       |      |
| Pearson Correlation | -   | -    | -     | -       | -      | -     | -    | .134 | .098  | 035  |
| Sig.                |     |      |       |         |        |       |      | .064 | .178  | .627 |
| Secondary SUD       |     |      |       |         |        |       |      |      |       |      |
| Pearson Correlation | -   | -    | -     | -       | -      | -     | -    | -    | .113  | .057 |
| Sig.                |     |      |       |         |        |       |      |      | .119  | .433 |

Table 4.5.Associations among Patient Characteristics (N = 190)

Table 4.5.(Continued)

| Patient<br>Characteristic                      | Age | Male | White | English | Smoker | РСР | Mood | SUD | CMI | AA          |
|--|-----|------|-------|---------|--------|-----|------|-----|-----|-------------|
| Cardiometabolic<br>Illness                     |     |      |       |         |        |     |      |     |     |             |
| Pearson Correlation Sig.                       | -   | -    | -     | -       | -      | -   | -    | -   | -   | 134<br>.065 |
| Highest Risk AA<br>Pearson Correlation<br>Sig. | -   | -    | -     | -       | -      | -   | -    | -   | -   | -           |

\*Correlation is statistically significant at the 0.05 level.

| Provider Characteristic  | MSN       | NP            | Novice in | Novice at |
|--------------------------|-----------|---------------|-----------|-----------|
|                          | Education | Certification | Practice  | Clinic    |
| MSN Education            |           |               |           |           |
| Spearman Rho Correlation | -         | .000          | .745*     | 1.000*    |
| Sig.                     |           | 1.000         | .034      | .000      |
| NP Certification         |           |               |           |           |
| Spearman Rho Correlation | -         | -             | .258      | .000      |
| Sig.                     |           |               | .537      | 1.000     |
| Novice in Practice       |           |               |           |           |
| Spearman Rho Correlation | -         | -             | -         | .745*     |
| Sig.                     |           |               |           | .034      |
| Novice at Clinic         |           |               |           |           |
| Spearman Rho Correlation | -         | -             | -         | -         |
| Sig.                     |           |               |           |           |

# Table 4.6.Associations among Provider Characteristics (N = 8)

\*Correlation is statistically significant at the 0.05 level.

| Visit Characteristic        | Walk in<br>Visit at<br>Baseline | Walk in<br>Visit at<br>Follow-Up | Walk in<br>Visit at<br>Baseline &<br>Follow- Up | Same<br>Provider at<br>Baseline &<br>Follow- Up | One or More<br>No Show<br>Appointment | Total<br>Number<br>of Visits |
|-----------------------------|---------------------------------|----------------------------------|---|---|---------------------------------------|------------------------------|
| Walk in Visit at Baseline   |                                 |                                  |   | -   |                                       |                              |
| Pearson Correlation         | -                               | 033                              | .482*   | .017  | .044                                  | 026                          |
| Sig.                        |                                 | .655                             | .000  | .815  | .543                                  | .719                         |
| Walk in Visit at Follow-Up  |                                 |                                  |   |   |                                       |                              |
| Pearson Correlation         | -                               | -                                | .527*   | 145*  | .037                                  | .033                         |
| Sig.                        |                                 |                                  | .000  | .046  | .612                                  | .647                         |
| Walk in Visit at Baseline & |                                 |                                  |   |   |                                       |                              |
| Follow-Up                   |                                 |                                  |   |   |                                       |                              |
| Pearson Correlation         | -                               | -                                | -   | 035   | 010                                   | 034                          |
| Sig.                        |                                 |                                  |   | .632  | .892                                  | .645                         |
| Same Provider at Baseline & |                                 |                                  |   |   |                                       |                              |
| Follow-Up                   |                                 |                                  |   |   |                                       |                              |
| Pearson Correlation         | -                               | -                                | -   | -   | 027                                   | 162*                         |
| Sig.                        |                                 |                                  |   |   | .711                                  | .025                         |
| One or More No Show         |                                 |                                  |   |   |                                       |                              |
| Appointments                |                                 |                                  |   |   |                                       |                              |
| Pearson Correlation         | -                               | -                                | -   | -   | -                                     | 008                          |
| Sig.                        |                                 |                                  |   |   |                                       | .916                         |
| Total Number of Visits      |                                 |                                  |   |   |                                       |                              |
| Pearson Correlation         | -                               | -                                | -   | -   | -                                     | -                            |
| Sig.                        |                                 |                                  |   |   |                                       |                              |

# Table 4.7.Associations among Visit Characteristics (N = 190)

\*Correlation is statistically significant at the 0.05 level.

(r = .53). Patients who had a walk-in at follow-up were less likely to have the same provider at baseline and follow up (r = -.15). In addition, having the same provider at baseline and follow-up is less likely to be associated with the total number of visits (r = -.16).

Summaries of the unadjusted (*r*) and adjusted (*beta*) associations of the patient candidate variables with each of the quality outcome variables are presented in **Table 4.8**. At baseline, statistically significant, unadjusted associations were observed between being a current smoker (r = .15, p = .041) and having a clinic primary care provider (r = .21, p = .003) and the number of quality indicators assessed. At follow-up no statistically significant associations were observed. Finally, unadjusted associations between having a mood disorder (r = .22; p = .003) were observed for baseline and follow-up. None of the three multivariate adjusted models for patient characteristics were statistically significant (Baseline: R = .297, p = .076, Adjusted  $R^2 = .038$ ; Follow-Up: R = .184, p = .792, Adjusted  $R^2 = -.020$ ; Baseline & Follow-Up: R = .260, p = .234, Adjusted  $R^2 = .016$ ).

Summaries of the unadjusted (*r*) and adjusted (*beta*) associations of the visit candidate variables with each of the quality outcome variables at follow-up and baseline and follow-up are presented in **Table 4.9**. No statistically significant associations were observed. The multivariate adjusted model for visit characteristics was not statistically significant (Follow-Up: R = .100, p = .760, Adjusted  $R^2 = .011$ ; Both Baseline and Follow-Up: R = .111, p = .312, Adjusted  $R^2 = .002$ ).

Summaries of the unadjusted (*r*) and adjusted (*beta*) associations of the combined delivery system design candidate variables with each of the quality outcome variables are presented in **Table 4.10**. At baseline, statistically significant unadjusted associations were observed between being a current smoker (r = .15, p = .041), having a clinic primary care provider (r = .21, p = .003) and a walk-in baseline visit (r = .14, p = .048) and the number of quality indicators assessed. At follow-up no statistically significant associations were observed. At both baseline and follow-up having a mood disorder (r = .22, p = .003) found statistically significant unadjusted associations with the number of quality indicators assessed. In terms of the adjusted models, the baseline model was statistically significant (R = .324, p = .043, Adjusted  $R^2 = .049$ ). The single most important and statistically significant variable after controlling for all of the other delivery system variables was having a clinic primary care provider (beta = .19, p = .011). The adjusted follow-up (R = .215, p = .860, Adjusted  $R^2 = .030$ ) and both baseline and follow-up (R = .310, p = .105, Adjusted  $R^2 = .035$ ) models were not statistically significant.

| Baseline        |       |         |      |         |     | Follow-Up |       |         |      | <b>Baseline &amp; Follow-Up</b> |      |         |  |
|-----------------|-------|---------|------|---------|-----|-----------|-------|---------|------|---------------------------------|------|---------|--|
| Characteristic  | r     | p-value | beta | p-value | r   | p-value   | beta  | p-value | r    | p-value                         | beta | p-value |  |
| Age             | 06    | .436    | 07   | .323    | .06 | .400      | .07   | .381    | .08  | .263                            | .08  | .278    |  |
| Male Gender     | .07   | .329    | .06  | .406    | .05 | .509      | .05   | .480    | 02   | .789                            | .03  | .701    |  |
| White Race      | .02   | .748    | .02  | .833    | .01 | .980      | < .01 | .997    | 01   | .880                            | .03  | .747    |  |
| English         | .03   | .676    | .06  | .400    | 01  | .844      | 02    | .850    | .04  | .582                            | .07  | .390    |  |
| Speaking        |       |         |      |         |     |           |       |         |      |                                 |      |         |  |
| Current Smoker  | .15*  | .041    | .11  | .158    | .09 | .185      | .09   | .223    | .05  | .465                            | .30  | .691    |  |
| Clinic PCP      | .21*  | .003    | .19* | .011    | 05  | .516      | 07    | .356    | .02  | .829                            | .01  | .952    |  |
| Mood Disorder   | .06   | .404    | .06  | .424    | .10 | .172      | .11   | .156    | .22* | .003                            | .23* | .003    |  |
| Secondary SUD   | <.001 | 1.00    | 06   | .435    | 05  | .527      | 06    | .424    | 02   | .841                            | 058  | .438    |  |
| Cardiometabolic | .09   | .208    | .08  | .318    | .01 | .856      | .03   | .687    | .05  | .499                            | .06  | .394    |  |
| Illness         |       |         |      |         |     |           |       |         |      |                                 |      |         |  |
| Highest Risk    | .10   | .163    | .14  | .159    | .01 | .899      | .01   | .890    | .05  | .499                            | .06  | .394    |  |
| Medication      |       |         |      |         |     |           |       |         |      |                                 |      |         |  |

Table 4.8. Patient Characteristics - Multiple Linear Regression

\*Correlation or *beta* is statistically significant at the 0.05 level. Baseline: R = .297, p = .076;  $R^2 = .088$  (Adjusted  $R^2 = .038$ ). Follow-Up: R = .184, p = .792;  $R^{2^{=}}.034$  (Adjusted  $R^2 = .020$ ). Baseline & Follow-Up: R = .260, p = .234;  $R^2 = .068$  (Adjusted  $R^2 = .016$ ).

|  |   | Bas     | eline |         |     | Follow-Up |      |         |     | <b>Baseline &amp; Follow-Up</b> |      |         |  |
|--|---|---------|-------|---------|-----|-----------|------|---------|-----|---------------------------------|------|---------|--|
| Characteristic                             | r | p-value | beta  | p-value | r   | p-value   | beta | p-value | r   | p-value                         | beta | p-value |  |
| WI Baseline                                |   |         |       |         |     |           |      |         |     |                                 |      |         |  |
| WI Follow-Up                               |   |         |       |         | .03 | .676      | .02  | .799    |     |                                 |      |         |  |
| WI Pollow-Op<br>WI Baseline &<br>Follow-Up |   |         |       |         |     |           |      |         | .09 | .218                            | .07  | .366    |  |
| Same Provider at Baseline &                |   |         |       |         | 07  | .365      | 06   | .404    | .06 | .390                            | .092 | .207    |  |
| Follow-Up<br>One or More No<br>Show        |   |         |       |         | .07 | .346      | .07  | .363    |     |                                 |      |         |  |
| Appointments<br>Total Number of<br>Visits  |   |         |       |         | .04 | .604      | .03  | .701    |     |                                 |      |         |  |

Table 4.9. Visit Characteristics - Multiple Linear Regression

\*Correlation is significant at the 0.05 level. Follow-Up: R= .100, p = .760; R<sup>2</sup> = .010 (Adjusted R<sup>2</sup> = -.011). Baseline & Follow-Up: R = .111, p = .312; R<sup>2</sup> = .012 (Adjusted R<sup>2</sup> = .002).

|                  |     | Bas     | eline |         |     | Follow-Up |      |         |     | aseline & | Follow | -Up     |
|------------------|-----|---------|-------|---------|-----|-----------|------|---------|-----|-----------|--------|---------|
| Characteristic   | r   | p-value | beta  | p-value | r   | p-value   | beta | p-value | r   | p-value   | beta   | p-value |
| Age              | 06  | .436    | 07    | .382    | .06 | .400      | .08  | .316    | .08 | .263      | .05    | .511    |
| Male Gender      | .07 | .329    | .08   | .264    | .05 | .509      | .05  | .540    | 02  | .798      | 02     | .802    |
| White Race       | .02 | .748    | .05   | .949    | .00 | .980      | 01   | .947    | 01  | .880      | .12    | .121    |
| English Speaking | .03 | .676    | .04   | .584    | 01  | .844      | 03   | .697    | .04 | .582      | .11    | .440    |
| Current Smoker   | .15 | .041    | .09   | .242    | .10 | .185      | .10  | .229    | .05 | .465      | 14     | .072    |
| Clinic PCP       | .21 | .003    | .19   | .011    | 05  | .516      | 11   | .332    | .02 | .829      | .04    | .584    |
| Mood Disorder    | .06 | .404    | .06   | .442    | .10 | .172      | .11  | .163    | .22 | .003      | .15    | .052    |
| Secondary SUD    | .00 | 1.00    | 05    | .498    | 05  | .527      | 11   | .385    | 02  | .841      | .05    | .479    |
| CMI              | .09 | .208    | .08   | .265    | .01 | .856      | .02  | .788    | 04  | .590      | 18     | .016    |
| Highest Risk     | .10 | .163    | .10   | .198    | .01 | .899      | .04  | .603    | .05 | .499      | .11    | .219    |
| Medication       |     |         |       |         |     |           |      |         |     |           |        |         |
| Walk In Baseline | .14 | .048    | .13   | .073    |     |           |      |         |     |           |        |         |
| Walk In Follow-  |     |         |       |         | .03 | .676      | .01  | .917    |     |           |        |         |
| Up               |     |         |       |         |     |           |      |         |     |           |        |         |
| Walk In Baseline |     |         |       |         |     |           |      |         | .09 | .218      | 01     | .900    |
| & Follow-Up      |     |         |       |         |     |           |      |         |     |           |        |         |
| Same Provider    |     |         |       |         | 07  | .365      | 10   | .346    | .06 | .390      | .10    | .307    |
| Baseline &       |     |         |       |         |     |           |      |         |     |           |        |         |
| Follow-Up        |     |         |       |         |     |           |      |         |     |           |        |         |
| More Than One    |     |         |       |         | .07 | .346      | .11  | .305    |     |           |        |         |
| No Show Appt     |     |         |       |         |     |           |      |         |     |           |        |         |
| Total Visits     |     |         |       |         | .04 | .604      | .02  | .272    |     |           |        |         |

 Table 4.10.
 Delivery System Design - Multiple Linear Regression Models with Candidate Patient and Visit Characteristics

\*Correlation is significant at the 0.05 level. Baseline: R = .324, p = .043;  $R^2 = .105$  (Adjusted  $R^2 = .049$ ). Follow-Up: R = .215, p = .860;  $R^{2} = .046$  (Adjusted  $R^{2} = .030$ ). Baseline & Follow-Up: R = .310, p = .105;  $R^{2} = .096$  (Adjusted  $R^{2} = .035$ ).

## **CHAPTER 5. DISCUSSION AND RECOMMENDATIONS**

This study was undertaken to describe the impact of the delivery system design of a community mental health center and the effect on the provision of quality care provided to persons with a severe mental illness. The provision of quality of care was defined as adherence to American Diabetic Association (ADA), American Psychiatric Association (APA), American Association of Clinical Endocrinologists (AACE), and North American Association for the Study of Obesity (NAASO) monitoring protocol for persons treated on a second or third generation antipsychotic medication, referred to as Atypical Antipsychotic (AA) medication.

Firstly, this study investigated the demographic characteristics of the care team, which include the patient and provider, and the visits. The second investigation examined rates of adherence to the ADA and APA monitoring protocol for persons with a severe mental illness, treated on an AA medication. Finally, the study examined associations between the patient and visit characteristics with the provision of quality care.

This chapter includes a discussion of study findings and a comparison and contrast of the findings with other published studies. First, the elements of the care team and visits and provision of quality care for persons with a severe mental illness will be discussed. The uniqueness of using the delivery system design element of the Care Model, an adapted version of the Chronic Care Model, to evaluate the implementation of an evidence based practice monitoring protocol for persons with a severe mental illness treated on an AA medication will be discussed. Second, the strengths and limitations of this study will be provided, followed by implications for education and practice. Finally, this chapter will conclude with a summary and implications for future research.

#### **Demographic Characteristics**

#### **Care Team Patient**

The demographic characteristics of the patients in this study are consistent with published research, with few exceptions. The study sample included more males (58.4%) than females (41.6%), who are younger in age (mean age of 37.1 years), which is consistent with the literature. The National Comorbidity Survey found the lifetime risk of mental illness, which includes a severe mental illness diagnosis of Major Depression, Mania, or Psychosis to be higher in males (48.7%) compared to females (47.3%) (Kessler, McGonagle, Zhao, Nelson, Hughes, et al., 1994). The mean age of patients in this study is similar to the findings of the National Comorbidity Survey which found higher prevalence of mental illness to be in the age range of 30-44 years (Kessler, Berglund, Demler, Jin, Merikangas, et al., 2005).

Most patients were not white (53.7%), with African American being the most common (26.1%), followed by Somali (15.3%), and Asian (4.7%), as compared to White, which comprised a smaller portion of the study (46.3%). These findings are unique when compared to the U.S. Census data indicating that 74% of the population is white (U.S. Census, 2010). However, the city in the MidWest region, were this study was conducted, contains the largest population of Somali outside of Africa (Kroll, Yusuf & Fujiwara, 2010). While most of the sample spoke English (82.1%), expectedly Somali was the most common Non-English language (17.9%).

In this study, more males had mood disorders (38%), compared to females (34%); however, males had a thought disorder at a much higher rate (24%) as compared to females (7%). National survey data indicate that life time rates of major depressive disorders to be highest in the 35-44 age group, with females having higher rates (23.8%) compared to males (14.7%) (Kessler, McGongle, Swartz, Blazer & Nelson, 1993). The study findings are inconsistent with national survey data that identified rates of Schizophrenia to be non-significantly higher in females than males (Kendle, Gallageher, Abelson & Kessler, 1996).

In this study, more blacks had a secondary substance disorder (17%) compared to whites (16%). However, more whites (25%) were current smokers compared to blacks (16%). Of the nine Asians in this study, only one had a secondary substance use disorder and none were current smokers, and most (n = 7) were treated for a mood disorder. Studies have noted that few Asians seek mental health treatment (Lee, Martins, Keyes & Lee, 2011). While in Asian countries smoke at high rates, however many who come to the United States have more education and smoke at lower rates (Fong & Tsuang, 2007).

Consistent with the literature, patients in this study were single, widowed, or divorced (90.5%) as compared to those who are married or in a partnership (9.5%). The early age of onset of a SMI is a contributing factor to poor psychosocial development and which also may lead to low marriage rates. Persons with a mental disorder who receive mental health treatment have higher rates of marital disruption or were previously married or are single (Kendler, Gallagher, Abelson & Kessler, 1996; Kessler, Berglund, Delmer, Jin, Merikangas, et al., 2005; Wang, Lang, Olfson, Pincus, Wells, et al., 2005). Additionally, persons who are unemployed, uninsured, or have low income are at higher risk for developing a mental disorder or receiving mental health treatment (Kendler, Gallagher, Abelson & Kessler, 1996; Kessler, Berglund, Delmer, Jin, Merikangas, et al., 2005; Wang, Lang, Olfson, Pincus, Wells, et al., 2005). The findings of this study are similar, the majority of patients did not work (88.9%), received public insurance benefits (90.0%) and those that reported an income level, most were below the federal poverty guidelines (47.4%).

Expectedly, self-reported rates of being a current smoker were high (45.8%). While patients self-reported being a current smoker at high rates (45.8%), less than five patients have a documented diagnosis of Nicotine Dependence. Findings from this study are supported in the literature that report persons with a SMI smoke at very high rates, as compared to the general population, and several studies have cited smoking rates in this population to be as high as two to three times the general population (Dixon, Medoff, Wohlheiter, DiClemente, Goldberg, et al., 2007). The finding that few mental health providers diagnosis Nicotine Dependence is not uncommon. One study found Nicotine Use to be documented in the record up to 88% of the time; however, Nicotine Dependence was only documented in 2% of the records (Peterson, Hryshko-Mullen & Cortez, 2003). This finding is an example of the discrepancy between self-report data and data documented and / or diagnosed by a mental health provider.

The findings in this study are consistent with other published studies that found Mood Disorders, such as Major Depressive Disorder, are more common than Psychotic Illness, such as Schizophrenia (Bourdon, Rae, Locke, Narrow & Regier, 1992). In this study, Major Depressive Disorder was the most common SMI (38.9%), followed by Bipolar I Disorder (24.2%). Fewer patients had Schizophrenia (11.1%) or Schizoaffective Disorder (9.5%).

In this study, only 22.2% (n = 47) patients had a documented diagnosis of a cardiometabolic illness. This finding is inconsistent with the literature which reports persons with a SMI have two or more chronic health conditions, which include: hypertension, hyperlipidemia, obesity, or diabetes (Jones, Macias, Barreira, Fisher, Hargreaves, et al., 2004; Kilbourne, Post, Nossek, Drill, Cooley, et al., 2008). Furthermore, persons with a SMI are diagnosed with diabetes at a younger age, have a higher body mass index, and are smokers, compared to those who do not have a SMI (Vinogradova, Coupland, Hippisley-Cox, Whyte & Penny, 2010). Of the patients in the study who had a body mass index (n = 65), 48% were considered obese with a body mass index of 30 kg /  $m^2$  or greater. Additionally, of the patients that had baseline (n = 21) and follow-up (n = 20) cholesterol screening, at baseline 61.9% had an elevated level and at follow-up 65% had an elevated level. These findings support difference between finding of objective measurement data in the record and actual diagnosis documented. A possible rational for this finding is that while psychiatric mental health advanced practice nurses are prepared to screen and identify abnormal health findings, some may not document physical health findings as the focus of their treatment is on the psychiatric disorder. However, holistic client centered care would support screening, documentation and referral for abnormal physical health findings.

This study sample is unique in that almost half (47.4%) of the patients did see a primary care provider, within the clinic, during the first 16 weeks of treatment. The location of the clinic and availability of psychiatric, primary care, and dental services might explain the rational for the large number of patients in this study having a primary care provider within the clinic. This patient population has both modifiable and unmodifiable risk factors for developing obesity and diabetes but few seek primary care services and when they do see a primary care provider, more time is used and less screening and preventive health care is provided (Daumit, Pratt, Crum, Powe & Ford, 2002). Unique to this study, patients who had a clinic primary care provider were more likely to receive cardiometabolic screening measures at baseline.

While high rates of cardiometabolic illnesses, such as obesity, diabetes, dyslipidemia, and hypertension have been reported among persons with a SMI (Jones, Macias, Barreira, Fisher, Hargreaves et al., 2004; Kilbourne, Post, Nossek, Drill, Cooley, et al., 2008), the study findings are not consistent with reported rates of these illnesses. Only a small number of patients had a documented diagnosis of hypertension (11.1%); however, in the study, of those 118 patients who had a blood pressure taken at baseline, 19.4% had an elevated blood pressure. And of those 117 patients who had a blood pressure at the follow- up visit, 20.5% had an elevated blood pressure. Similarly, in this study a small number of patients have a diagnosis of obesity (5.3%); however, 13.2% of patients had a body mass index of 30 or above, which meets the criteria for obesity. Documented rates of diabetes in this study were low (4.3%), as was hyperlipidemia (1.6%); however, rates of elevated glucose at baseline and follow -up were higher at 20% and 13.6% respectively. Similarly, at baseline, of the 16 patients who had a lipid profile completed, 61.9% had elevated cholesterol, 62.5% had an elevated low density lipoprotein and 31.2% had an elevated triglyceride level.

There are severe potential reasons for the differences in diagnosis of obesity, hypertension, diabetes, and hyperlimidemia and actual measurement findings that support a cardiometabolic illness. First, psychiatric providers are not treating these illness; they therefore, may not document the diagnosis. Second, during the initial treatment phase, psychiatric acuity is high and therefore, patients are poor self-reporters of co-morbid physical health conditions. Finally, a mental health provider may not perceive it within their scope of practice to diagnosis or document physical health co-morbidities, based on education, training, and experience.

All patients in this study were treated on an atypical antipsychotic medication. This study is consistent with three other large claims data base studies that report the three most common AA medications prescribed are Quetiapine, Olanzapine, and Risperidone (Barnett, VonMuenster, Wehring, Popish, McDonald, et al., 2010; Haupt, Rosenblatt, Kim, Baker, Whitehead, et al., 2009; Morrato, Newcomer, Allen & Valuck, 2008). Clozapine is not considered a first line AA medication due to the need for weekly blood draws during the first six months of treatment and monthly thereafter, because of a risk for developing agranulocytosis. In this study, a small number of patients were treated on this medication (1.6%). Additionally, Paliperidone, was prescribed at low rates (1.1%), which might be related to this medication being newest to the market during the study period as it was approved in 2006; however, it is found to have lower metabolic risks, and therefore may be used more often in the future (Hasnain, Vieweg, Fredrickson, Beatty-Brook & Fernandez, et al., 2008).

As a member of the care team, the patient characteristics are an important element of the Care Model. Understanding the characteristics of patients with a severe mental illness and the interaction with other members of the care team is critical to evaluation of quality care outcomes.

## **Care Team Provider**

The care team provider characteristics in this study are unique related to years in practice and type of American Nurses Credentialing Center certification, when compared to the published literature. Published data on the workforce of advanced practice nurses, credentialed as psychiatric mental health nurse practitioners (PMHNP) or clinical nurse specialists (CNS) note most providers have been in practice for 30 years or more (23.6%) followed by 21-25 years (20.6%), with the fewest being in practice 0-5 years (4.1%)(Hanrahan, Delanev & Stuart, 2011). In this study of eight providers, three have been in practice for five or less years (37.5%) and of those in practice more than five years; two have been in practice more than 10 years (25.0%). One would hypothesize that having a younger workforce would increase the likelihood that the advanced practice providers have a high level of knowledge related to evidence based practices incorporated in everyday practice. The majority of this study (75.0%) have worked at the clinic less than five years, suggesting they may not be as embedded and knowledgeable about the system in which they are providing care, compared to the two who have been in practice at the clinic over 10 years (25.0%). Alternatively, the system may not support the implementation of evidence based practices.

A recent workforce study indicated that there are 10,001 PMH APRNs who are certificated by the American Nurses Credentialing Center (ANCC), most as Adult CNS (70.2%) followed by Adult PMHNP (15.0%), very few as Family PMHNP (4.9%) (Drew & Delaney, 2009). The same survey found that most PMH APRNs work in public community mental health agencies (20.4%). Of the eight providers, half were credentialed as a CNS (50.0%), and only one was credentialed as a Family PMHNP (12.5%).

Workforce data on the highest level of education for psychiatric mental health advanced practice registered nurses (PMH APRNs) are not currently published. However, it can be postulated that most PMH APRNs' highest level of education is the Master's Degree, given the first clinical doctorate, Doctor of Nursing Practice (DNP) degrees were awarded in 2006. Consistent with the hypothesis, the highest level of education in this study six providers (75%) highest level of education was at the Master of Nursing Science level.

Given the recommendation of the American Academy of Colleges of Nurses (AACN) that the entry level of advanced practice nursing be a the doctoral level by 2015, one would expect an increase in the number of doctorally prepared providers (AACN, 2004). This study included two providers (25%) who had a Doctor of Nursing Practice (DNP) degree. Advance practice nurses with a DNP are educationally and clinically prepared guided by the AACN's eight essentials for doctorate education (ANCC, 2006). The eight DNP essentials identify that nurses prepared with a clinical doctorate practice at the highest level using evidence based practices in complex organizational systems to transform health care through quality improvement efforts and evaluate health outcomes and develop new approaches to practice. As expert leaders, DNP PMH APRN's have the

knowledge and skill to translate evidence into practice and have an impact on the morbidity and mortality of persons with a severe mental illness.

The characteristics of the provider are an important consideration when using the Care Model to guide changes within the delivery system of a community mental health center. Using the Care Model to develop an integrated care system, the care team can be expanded to include nurses who room patients, a primary care provider and case manager or care coordinator. Evaluation of the care team and understanding the role of each care team member will inform the workforce and guide the evaluation of quality outcomes, with the goal of providing client-centered, evidenced based and safe, timely and efficient, and coordinated care.

#### Visit Characteristics

Persons with a SMI have no-show rates twice that of other medical specialties; about 50% who miss an appointment fall out of treatment (Mitchell & Selmes, 2007). Failing an initial psychiatric appointment occurs at rates of about 36%, and follow- up fail rates are about 40% (Killaspy, Banerjee, King & Lloyd, 2000). Walk in psychiatric appointments are less common; however, they are a way to provide a service when the patient is in need. Consistent with the literature, many patients (45.3%) in this study had one or more no shows during the first 16 weeks of treatment. Walk in rates among this study sample for the initial appointment, baseline appointment were 38.9%.

In contrast, guidelines have been developed on visit frequencies and monitoring parameters for chronic physical health conditions, such as congestive heart failure and diabetes. Patients who present for few visits related to the treatment of diabetes or present for more frequent lower-priority physical health conditions have been found to receive care below the diabetes standard (Fenton, VonKorff, Lin, Ciechanowski, & Young, 2006). Similar findings relate to persons with congestive heart failure. Congestive heart failure patients who are followed as an outpatient per the guidelines, followed by family practice and specialty care, have improved outcomes (Ezekowitz, vanWalraven, McAlister, Armstrong, & Kaul, 2005).

Of interest is the lack of recommended standards of visit frequency for persons with a severe mental illness. Revisit intervals have been shown to be understudied and impacted by the following patient characteristics: physiological measures, provider perception of disease, patient compliance, and co-morbidities (Desalvo, Block, Muntner, & Merrill, 2003). However, these authors note the importance of revisit intervals as they impact both patient access to care, when patients are scheduled too frequently and other patients cannot schedule, and if patients are scheduled infrequently, quality suffers.

Persons with a SMI are treated for a chronic mental illness and the frequency of visits is dependent on the severity of the illness and those who miss appointments have higher functional impairments and are in greater need (Centorrio, Hernan, Drago-Ferrante, Rendall, & Apicella, et al., 2001; Killaspy, Banerjee, King & Lloyd, 2000;

Zivin, Pfeiffer, McCammon, Kavanagh, Walter, et al., 2009). In this study, during the first 16 weeks of treatment, the mean number of visits was 3.7, with the range being 2-12 visits and about one third (36.3%) of the patients were treated by the same provider, during the first 16 weeks of treatment. Development of guidelines on visit frequencies, including RVI could help prevent delayed treatment or prolonged treatment, both of which can impact quality outcomes. As part of the Care Model, the visit frequency is an important characteristic to consider and a better understanding of visit pattern can guide development of innovative care delivery models within an integrated care system.

#### **Provision of Quality Care and Quality Outcomes**

The study findings indicate that screening rates, following the American Diabetic Association (ADA), American Psychiatric Association (APA), American Association of Clinical Endocrinologists (AACE), and North American Association for the Study of Obesity (NAASO) monitoring protocol for persons treated on a second generation antipsychotic (SGA) medication are dismal. Of the 190 in this study no patient had the full provision of care, per the ADA and APA monitoring protocol. Excluding history of personal and family history of cardiovascular disease, only one patient had the full provision of care at baseline and follow- up. Full provision of care is defined as all biological screening measures, which include weight or body mass index, blood pressure, fasting glucose or hemoglobin A1c, and fasting lipid profile. Following the biological measures of the protocol, 5.3% of the study had full provision of quality at baseline and 1.6% had full provision at follow-up.

In this study the abysmal rates of adherence to the provision of quality, defined as rates of full screening per the ADA and APA monitoring protocol may have a multifaceted rational. Firstly, the psychiatric acuity of the patient population can shift the clinical priorities to stabilization of the mental illness and then screen for cardiometabolic symptoms. Many patients are complex and have a hard time verbalizing needs and symptoms which can take away time within a clinical encounter to focus the measurements required, per the monitoring protocol. Secondly, electronic alerts are not in place to prompt providers to screen, per the protocol. Again, lack of built in supportive reminders can limit the provision of quality care defined by providing evidenced based care. Finally, one can postulate that the 12 week interval seems brief and therefore, providers are screening at baseline but the follow- up screening occurs more than three months from the baseline screening measures.

Evaluation of individual measures within the monitoring protocol were improved at baseline, follow- up, and both baseline and follow- up. However, rates of screening remain low. For example, having a weight or body mass index measure at baseline or follow-up occurred in 62.1% and 61.6% of patients at baseline and follow -up, respectively. However, only 43.2% of patients had weight or body mass index at baseline and follow-up. The one patient that had the full provision of biological screening measures at both baseline and follow-up had a baseline body mass index of 24 kg/m<sup>2</sup> and follow-up body mass index of 29 kg/m<sup>2</sup>. These findings highlight the importance of screening for secondary and tertiary preventions in a consistent systematic manner. Given that weight and body mass index are inexpensive measures, screening rates should be much higher. Additionally, body mass index has been found to be an indicator of cardiovascular disease event risk, and is recommended to be included in a cardiovascular risk assessment (deKoning, Merchant, Pogue, & Anand, 2007).

Similarly, 62.1% of patients had blood pressure measure at baseline and 61.6% had the measure at follow-up, but only 38.9% had the measure at baseline and follow-up. Similar to the results of this study, a study conducted looking at screening rates across inpatient, outpatient, and in a metabolic clinic found that waist circumference was never measured and blood pressure and weight were most commonly measured in the outpatient setting, while blood glucose and lipids were rarely measured (Batscha, Schneiderhan, Kataria, Rosen & Marvin, 2010).

Evaluation of glycemic measures at baseline were 27.9%, 13.2% at follow-up and only 2.1% at baseline and follow-up. Rates of lipid monitoring were even lower, 8.4% at baseline, 9.5% at follow-up, and 1.1% at baseline and follow-up. Similar to these findings, a large claims data study found that post guideline rates of monitoring lipids and glucose at baseline were 23% and 11% and at 12 weeks were 18% and 9% respectively (Haupt, Rosenblatt, Kim, Baker, Whitehead, et al., 2009). Consistently claims studies have found low rates of glucose and lipid monitoring and adherence to ADA and APA guidelines, and recommend interventions to increase screening rates (Barnett, VonMuenster, Wehring, Popish & McDonald, et al., 2010; Haupt, Rosenblatt, Kim, Baker, Whitehead, et al., 2009; Morrato, Newcomer, Kamat, Baser, Harnett, et al., 2009; Morrato, Newcomer, Kamat, Baser, Lombardo, Karmat, et al., 2007; Motsinger, Slack, Weaver & Reed, 2006; Shi, Ascher-Svanum, Chiang, Zhao, Fonseca, et al., 2009).

The findings of this study are consistent with a meta-analysis that found preguideline screening and monitoring of blood pressure, glycemic measures, and lipid measures are suboptimal, weight monitoring is inadequate, and post-guideline studies have insufficient data to make an assessment (Mitchell, Vancamfort, Correll & DeHert, 2012). Another challenge relates to the types of studies conducted and data collected. Of the 18 studies on metabolic monitoring, which were conducted in the United States, 10 are from claims data, six are from the Veterans Administration system, and only two are chart of case note review, one of which was with a Hispanic population (Mitchell et al., 2012). It is difficult to compare full provision of quality care, defined as adherence to the ADA and APA monitoring protocol, because most studies on metabolic monitoring used claims data. Claims and administrative data were created for billing purposes (Roth, Lim, Pevnick, Asch & McGlynn, 2009); therefore, assessment of non-billable measures, such as weight, body mass index, blood pressure, or waist circumference cannot be assessed.

The need to assess the validity of claims data is warranted, if data will drive care, because clinical data has the ability to evaluate quality outcomes and generate new knowledge (Tang, Ralston, Arrigotti, Qureshi & Graham, 2007). Electronic medical records were created to capture clinical data, not intended for research, claims data and

administrative data were created for billing purposes and lack the quality of clinical information, therefore, when extracted is less precise when compared to manual extraction (Roth, Lim, Pevnick, Asch & McGlynn, 2009). Quality performance rates are known to differ when looking at administrative data, clinical data, or a combined approach to data collection. Claims data only and combined collection methods have been found to differ by about 10% on specific quality measures (Kmetik, Chung & Sims, 2007).

In comparison, studies within the Veterans Administration (VA) system have higher screening rates. While the study inclusion period is longer in several VA studies, the VA is known to have transformed care in the 1990's by shifting the focus of care from outcomes to process and evaluation of measures of quality (Jha, Perlin, Kizer, & Dudley, 2003). In addition, the VA system, the largest integrated delivery system in the United States, has an electronic health record that allows for automatic queries about quality and has registry data, which has the ability to influence provider behavior and has improved diabetes care for veterans (Kupersmith, Francis, Kerr, Krein, Pogach, et al., 2007). The use of electronic medical record data to evaluate performance measures is also a rational for the VA systems higher screening rates.

One study in the VA population evaluated rates of screening over 180 days (Shi, Ascher-Svanum, Chiang, Zhao, Fonseca, et al., 2009) and the other over one year (Khatana, Kane, Taveria, Bauer & Wu, 2011). Both studies did not look at full adherence to ADA and APA guidelines, rather at the number of metabolic monitoring measures that were completed, which include the same measurements in the ADA and APA guideline. Of the Veterans who had one mental health visit in a year, and had complete metabolic monitoring (body mass index, blood pressure, blood glucose and lipids), rates were as high as 58% for persons with Bipolar Disorder or as low as 15.4% for persons with Schizophrenia (Khatana, Kane, Taveria, Bauer & Wu, 2011). In comparison, other authors found baseline rates of metabolic screening to be as high as 76% for persons with Schizophrenia (Shi, Ascher-Svanum, Chiang, Zhao, Fonseca, et al., 2009). These authors note that VA populations tend to be older than Medicaid patients and older patients tend to be screened at higher rates. In contrast, this study was younger with a median age of 35.0 years, but did have more men (n = 111, 58.4%), similar to the VA system; however, biological screening rates within the first 16 weeks of treatment were completed on only 14 patients. A study of patients with schizophrenia in the VA system age 50 old older, found rates of screening to be no more than 40%, noting "it would take 40 years to achieve 100% monitoring" (pg. 893), following the ADA and APA guidelines (Copeland, Parchman, Zeber, Lawrence, Downs, et al., 2010). Overall, screening rates in the VA are higher but not optimal; however, health systems can learn from the VA system, a leader in using an electronic medical record to evaluate quality performance measures and process outcomes to transform care.

In this study evaluations of associations between Patient, Visits, and Quality Outcomes did not identify many statistically significant results. However, the adjusted model at baseline was statistically significant (R = .324, p = .043, Adjusted R2 = .049). The single most important and statistically significant variable for all the other delivery

system variables was having a clinic primary care provider (beta = .10, p = .011). At baseline, being a current smoker, having a clinic primary care provider, and having a same provider at baseline and follow-up were associated with the number of quality outcomes. In this study, 47.4% of patients had a clinic primary care provider, and supported in the literature, patients with a primary care provider had higher screening rates (Haupt, Rosenblatt, Kim, Baker, Whitehead, Newcomer, 2009; Shi, Ascher-Svanum, Chiang, Zhao, Fonseca, et al., 2009). At follow-up no associations were found and at both baseline and follow-up an association was found with having a mood disorder; however, this is not cited in the literature.

The low rates of full provision of quality, ADA and APA monitoring protocol in addition to low rates of individual screening measures is multifocal. Within the Care Model, the care team and visits have an important interaction which can lead to improved quality care. For example, lack of continuity between a patient and provider can prevent implementation of a treatment plan as each new provider is "reacting" to the patient's need, rather than proactively planning care. In addition, how the patient "visits" the clinic has an impact on the provision of quality. A lack of defined roles among the care team can also lead to poor quality care due to possible assumptions about who is responsible for completing each screening measure and when. The Care Model element, the delivery system design allows for re-design of care delivery to develop innovative ways the care team and visits impact the provision of quality. Adding additional elements of the Care Model, such as self-management support, decision support, and clinical information systems can guide improved systems that provide quality care.

#### **Strengths and Limitations**

#### Strengths

A fundamental strength of the study was the use of an adapted version of the Chronic Care Model, the Care Model. The retrospective cross sectional design was also a key strength to the study. This study provides a description of the delivery system design of the Care Model, care team, and provider characteristics of persons with a serious mental illness, treated in a community mental health center.

The Care Model was used to guide the development of the study framework. Many studies designed to evaluate and improve the provision of quality care, guided by the Chronic Care Model, for persons with other chronic physical health conditions, such as diabetes have been effective (Nutting, Dickinson, Dickinson, Nelson & King et al., 2007; Piatt, Orchard, Emerson, Simmons, & Songer et al; 2006). Additionally, the Chronic Care Model has been effective in increasing the adherence to evidence based standards, specifically monitoring lipid and glycosylated A1c levels (Siminerio, Piatt & Zgibor, 2005). The novel conceptualization of the Care Model and the application to persons with a serious mental illness, which is a chronic condition, who have mulimorbid physical health conditions, such as diabetes is strength to this study. Additionally, the care team and visit variables are present in many community mental health centers; therefore, this increases the generalizability of the study framework.

The study used a retrospective cross sectional design. Retrospective cross sectional designs are useful in providing a description of variables, patterns of distributions and explaining associations to define the clinical characteristics using an inexpensive method (Newman, Browner, Cummings, & Hulley, 2001). All candidate variables were carefully evaluated for statistical rigor and clinical significance. The statistical methods used to describe the study sample and test for associations between the candidate variables and quality outcome measures were completed to allow for reliability in future studies. Overall, there was a fit between the study design, theoretical framework, and research questions.

## Limitations

Study limitations relate to the methodological issues related to using retrospective, clinical data that combined manual extraction and extraction from data queries. First, study limitations are related to the use of clinical data that are not intended for research. Second, the data used for this study already existed; therefore, the design could not control for the completeness, accuracy, and documentation of study data values. Third, the use of raw data required that many study variables be transformed and re-coded into dummy dichotomous variables, limiting the statistical power when compared to studies that use continuous variables. Also, some predictor values could not be included in the study because they were not available in the electronic health record or from administrative data.

Additionally, treating all persons new to the system as newly prescribed AA medications is a limitation. The inclusion criteria did not identify patients who were AA naïve from patients who were continuing treatment. Finally, dismal rate of provision of quality defined by screening rates, following the American Diabetic Association (ADA), American Psychiatric Association (APA), American Association of Clinical Endocrinologists (AACE), and North American Association for the Study of Obesity (NAASO) monitoring protocol limited the analysis to associations between candidate variables and quality outcomes rather than the development of a prediction model.

#### Implications

#### **Nursing Education**

Psychiatric services provided to persons with serious mental illness (SMI), in rural areas or in urban areas with high ethnically diverse populations, who have lower educational levels and have lower socioeconomic status, are often delivered by Advanced Practice Nurses (APNs) who are certified as a Psychiatric Mental Health Nurse Practitioner (PMHNP) or Clinical Nurse Specialist (CNS). The findings from this study highlight the importance of educating APNs about evidence based practice and guidelines for specific patient populations. The data on the alarming premature morbidity and mortality of this patient population, due to preventable and treatable co-morbid physical health conditions, underscores the need for psychiatric APNs to be skilled in screening, detecting, and referring patients with a SMI for treatment and having ongoing dialog with primary care providers.

Education of psychiatric APNs should include care team clinical teaching and management of complex patients. Without instilling the importance of care teams and collaborative care, among health care disciplines, care will remain fragmented. Educational programs need to include clinical experiences for psychiatric APNs that allow for the interaction of multidisciplinary care teams with a focus on how patients and providers interact within health systems.

In addition to care teams, psychiatric APN programs should include the importance of documentation of accurate health data and assisting students to think about clinical data as a rich source of information to inform care and evaluate the provision of quality and to be used for research purposes. The American Association of College of Nursing Position Statement recommends entry into advanced practice nursing be at the doctorate level by 2015, with the rational being the need to prepare providers to work in complex health systems treating sicker patient populations (AACN, 2004). The push to prepare APNs at the doctorate level highlights that the discipline of nursing has a proactive vision to prepare APNs with knowledge and skill to provide quality care within complex, fragmented systems and have the knowledge and skills to transform care. Nursing educational programs have psychiatric APN students in programs that include an increase in clinical hours, which will enables students to learn about and evaluate clinical experiences and clinical outcomes with the goal of improving the provision of quality care.

Finally, nursing educational programs must educate students about pre-existing large data sets that can be accessed to learn about specific patient populations and diseases and current national research projects. For example, the Behavioral Risk Factor Surveillance System (BRFSS) managed by the Centers for Disease Control (CDC). The BRFSS is the largest telephone survey that collects data on health risks, behaviors, and practices (CDC, 2012). Understanding how to access large health databases, the data collected will help psychiatric APN practice leaders match clinical data to current data to compare outcomes and track quality improvement initiatives. Another initiative by the Substance Abuse and Mental Health Services Administration (SAMHSA) national wellness campaign identified eight domains of wellness, with the goal of addressing the morbidity and mortality for persons with a serious mental illness. For example in the state of Minnesota, the 10X10 initiative was developed to raise awareness in the state that persons with a serious mental illness. Soft example in the state that SMI patients in getting physical health care, with the goal of reducing mortality by

10 or more years in 10 years. Educating providers about national and state funded initiatives raises awareness of health priorities and provides access to resources.

#### Practice

The current study findings highlight the critical need to increase the provision of evidence based practices into everyday clinical practice. Dismal screening rates identify an opportunity to educate providers about current standards of care and the need for collaborative efforts to move toward the integration of physical and mental health care, especially for those patients with a SMI.

Psychiatric providers can re-examine the importance of assessing not only the mental health status but also the physical health status, at the first visit, of all patients with a SMI. Because psychiatric providers are prescribing high risk medications, which help the psychiatric disorder but may create new physical health co-morbidities or worsen pre-existing physical health co-morbidities, it is the responsibility of that prescriber to screen and monitor this high risk population and collaborate with primary care when a referral is indicated. The need to monitor for medication side effects, in the case of AA and the risk of metabolic side effects is the responsibility of the prescribing provider (Hasnain, Vieweg, Fredrickson, Beatty-Brooks & Fernandez, et al., 2008). However, taking a collaborative approach and educating primary care providers about monitoring and screening guidelines can create a synergistic opportunity to improve the provision of quality care.

This study highlights the uniqueness of how persons with a SMI interact with health systems and provides an opportunity for providers to re-think how best to deliver care to patients who present when a problem exists, rather than proactively to prevent an acute problem from developing. Incorporation of evidence based practices into each visit, which might not be a planned interaction, is a challenge for all providers. However, everyday practice should include the identification of the physical health status of the patient with a SMI, at the first visit, and comprehensively evaluate health promotion and risk reduction screening and interventions including smoking cessation, preventative health interventions such as flu shot / TB test, etc. Collaborative efforts with primary care and communication about patient health needs are the first steps in combining practice based evidence with evidence based practice with the goal of improving health of this high risk population.

The next step could be to more aggressively look at successful pay for performance programs in general medical services. While pay for performance programs exist in behavioral health, few providers opt into these programs (Pelonero & Johnson, 2007). The development of Accountable Care Organizations (ACOs) and identification of core measures for diabetes care is a model that could be used to develop core measures for SMI care. The ability to develop transparent and collaborative processes as core measurements is critical (Pelonero & Johnson). It is important to be consistent with the Institute of Medicine's aims, and address core quality measures. Systems that embrace and support the development and monitoring of core measures that adopt prospective longitudinal quality initiatives (Bremer, Scholle, Keyser, & Houtsinger, 2008) will add to available data to set benchmarks for SMI care. An example is the MN DIAMOND project which evaluates depression treatment in primary care. Key to pay for performance models is the evaluation of measure and outcome (Bremer et al, 2008.).

#### **Conclusion and Recommendations for Further Research**

The Care Model, an adapted version of the Chronic Care Model, is a useful theoretical framework to guide improving provision of quality care provided to patients with a SMI. The need to match evidence based practices with real world clinical practice is critical. The evidence is clear, persons with a SMI have both modifiable and un-modifiable risk factors for the development of cardiometabolic illnesses; however, rates of screening have not improved. SMI patients are unique in how they interact with the health care system. Therefore, as a first step, the system needs to be a planned and prepared "responsive" system that supports the provision of quality care, when the patient presents to receive care.

A mixed methods study would be useful to understand more about provider behavior, who is doing what, when and why along with understanding more about how patients with a severe mental illness interact with the health system. A qualitative study could increase the understanding about the lived experience of a person with a severe mental illness and how this population interacts with the health system. Findings could provide date about behaviors between visits, and both facilitators and barriers to seeking mental and physical health care. High walk in rates suggest that health systems need to provide care when the patient presents for a service and the care needs to respond to the need and provide preventive screening and care. The high walk in rate found in this study also suggests that provider behavior might be influenced by how patients with a severe mental illness interact with the health system. Qualitative study findings about provider responses to working with a population with a high no show and walk in rate can help design a care model to guide providers in providing quality care in a prepared "responsive" system when patients present for care.

Based on the current evidence and present findings, the next step is to design an intervention study. Developing an intervention study that uses the Care Model and includes the delivery system design, and adds additional elements such as the health system organization, decision support, self-management support, and clinical information systems has the ability to improve the provision of quality care. For example, providing patients with tools to make health decisions between visits by adding the element of self-management support will lead to more informed and empowered patients. The element of clinical information system can address increasing accessibility to evidence based standards at the point of care, when the provider is making clinical decisions. Prior to the clinical decision making, the clinical information system element can aid in pre-visit decision making through the development of patient a registry to guide outcome evaluation at the individual provider level and as a cohort.

Integrated care teams who work with SMI patients at high risk for developing cardiometabolic illnesses, or who already have a cardiometabolic illness guided by the Care Model is an innovative design to generate new evidence on an integrated care model. In addition, a future prospective intervention study would assist in understanding who is ordering the test and why the test is ordered (Morrato, Newcomer, Allen & Valuck, 2008), what is done with the result, and whether outcomes improve with increase ordering of screening tests (Kilbourne, Post, Bauer, Zeber, Copeland, et al., 2007).

The ability to communicate with the primary care provider is imperative for screening and early detection of metabolic side effects, as patients have a limited capacity to advocate and care for themselves (Hasnain, Vieweg, Fredrickson, Beatty-Brooks & Fernandez, et al., 2008). Furthermore, if a patient is prescribed a high risk medication, AA and the prescriber is not effectively monitoring the patient, the primary care provider should talk with the psychiatric prescriber. The integrated model would allow for identification of abnormalities, and a collaborative handover to the primary care provider for further monitoring and management.

Conceptualizing the chronic illnesses unique to this population and developing targeted collaborative initiatives can assist in providing integrative care. Several studies have indicated that integrated care models would increase screening rates (DeHert, Cohen, Bobes, Cetkovich-Bakmas, Leucht, et al, 2011; Khatana, Kane, Taveria, Bauer & Wu, 2011; Mithcell, Delaffon, Vancampfort, Correll & DeHert, 2012; Motsinger, Slack, Weaver & Reed, 2006). An example of an integrated care model is the four quadrant model (Collins, Hewson, Munger, & Wade, 2010). The four quadrant model is useful to identify patients from low behavioral health and low physical health needs to those with both high behavioral health and physical health needs. Using registries within an integrated clinic can help target the highest risk population and develop targeted mental and physical health interventions provided by interdisciplinary care teams.

Findings from additional studies can help identify what data needs to be matched with which provider, with the goal of delivering high quality care. Future studies can address challenges of using real clinical data to study outcomes and identify the infrastructure needed to support this type of research involving clinical data, given the discrepancies between clinical and administrative data (Kmetik, Chung & Sims, 2007; Roth, Lim, Pevnick, Asch & McGlynn, 2009). The importance of matching the evidence with care, in a model that allows a seamless flow, is imperative to the provision of quality care. While it is true that psychiatric care develops out of the relationship (Williams & Garner, 2002), and many psychiatric patients are seen in the community, which excludes this patient population from randomized clinical trials (Hannes, Pieters, Goedhuys & Aergeerts, 2010), mental health providers cannot ignore the need for treatment of multimorbid physical health conditions. Data has the ability to drive care and lead to highly efficient, effective systems that deliver quality care consistent with the Institute of Medicine's quality underpinnings: patient centered, timely and efficient, evidence based and safe, and coordinated (IOM, 2001). Translational research has the ability to bridge the quality chasm gap and decrease morbidity and mortality for persons with a SMI.

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#### APPENDIX A. INSTITUTIONAL REVIEW BOARD APPROVAL

THE UNIVERSITY OF TENNESSEE Health Science Center

Institutional Review Board 910 Madison Avenue, Suite 600 Memphis, TN 38163 Tel: (901) 448-4824

October 10, 2011

Dawn Marie Vanderhoef College of Nursing Department of Nursing

#### Re: 11-01536-XM

Study Title: The Impact of the Care Delivery Design on Quality Outcomes for Patients with Severe Mental Illness in a Community Mental Health Center

Dear Ms. Vanderhoef,

The Administrative Section of the UTHSC Institutional Review Board (IRB) has received your written acceptance of and/or response dated October 7, 2011, October 6, 2011 and September 30, 2011 to the provisos outlined in our correspondence of October 7, 2011, October 6, 2011 and September 29, 2011 concerning the application for the above referenced project. The IRB determined that your application is eligible for **exempt** review under 45CFR46.101 (b) (4) in that it involves the study/project of existing data or other materials that are publicly available or the information will be recorded in a way that subjects cannot be individually identified and under 45CFR46.101 (b) (2) in that the study/project involves eligible research using educational tests, surveys, interview procedures, or observation of public behavior. Informed consent may be altered in accord with 45CFR46.116 (d), with a consent cover statement used in lieu of a consent interview. The requirement to secure a signed consent form is waived under 45CFR46.117(c) (2). Your application has been determined to comply with proper consideration for the rights and welfare of human subjects. Therefore, this letter constitutes full approval of your application (version 1.1), consent cover statement and survey [stamped IRB approved on October 10, 2011] for the above referenced study.

# This study may not be initiated until you receive approval from the institution(s) where the research is being conducted.

In the event that volunteers are to be recruited using solicitation materials, such as brochures, posters, web-based advertisements, etc., these materials must receive prior approval of the IRB.

Any alterations (revisions) in the protocol, consent cover statement, or survey must be promptly submitted to and approved by the UTHSC Institutional Review Board prior to implementation of these revisions. You have individual responsibility for reporting to the Board in the event of unanticipated or serious adverse events and subject deaths.

Sincerely,

Signature applied by Donna L Stallings on 10/10/2011 07:01:08 AM CDT

Signature applied by Terrence F Ackerman on 10/10/2011 07:08:26 AM CDT

Donna Stallings, CIM Terrence F. Ackerman, Ph.D. IRB Administrator Chairman UTHSC IRB UTHSC IRB

## APPENDIX B. PROVIDER CONSENT FORM



## **The impact of the delivery system design on quality outcomes for patients with severe mental illness in a community mental health center: Advanced Practice Registered Nurse Provider Survey Consent Form**

This brief survey is part of a research study to examine the impact of the delivery system design at a community mental health center on quality outcomes for persons with a severe mental illness who are at high risk for developing cardiometabolic illness. The study period is January 1, 2010 to April 22, 2011. Prior to beginning this study, institutional review board (IRB) approval from the University of Tennessee Health Science Center (UTHSC) and the XXXXX was obtained.

Dawn Marie Vanderhoef is the primary investigator of this retrospective cross-sectional study. The identified study variables related to patient, visits and quality outcomes will be extracted from the XXXXX electronic health record by the data team. The advanced practice registered nurse provider variables are self-reported by you through a brief five-item multiple choice survey appended to this consent form. Survey questions address:

- Highest Level of Education
- Active Psychiatric Nursing Certifications Held
- Non-Psychiatric Nurse Practitioner Certification
- Years of APRN practice
- Years of APRN Employment at XXXXX

This brief survey should take no more than 10 minutes of your time to complete.

There are no foreseeable risks related to your participation in this brief survey. Your data will remain confidential, as there are no required identifiers. All paper research records will be stored in locked file cabinets and will be accessible only to me, the principle investigator. All electronic research records will be computer password protected and accessible only to me, the principle investigator. You will not be identified in any presentations or publications based on the results of this research study.

The benefits to participation in this study are to help develop a better understanding of the attributes of the community mental health centers delivery design that can lead to improved outcomes and impact the morbidity and mortality of persons with a severe mental illness. Participation in this brief survey is voluntary and there are no adverse affects if you choose not to participate. You may refuse to answer any of the questions, though completed surveys are preferred.

If you have any questions about this research study you may contact Dawn Marie Vanderhoef at XXXXX. You may contact Terrence F. Ackerman, Ph.D., UTHSC IRB Chairman at XXXXX or visit the IRB website at

http://www.uthsc.edu/research/research\_compliance/IRB/

<u>participant\_complaint.php</u> if you have any questions about your rights as a participant in this study or your rights as a research subject.

## **CONSENT OF SUBJECT:**

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

| Signature of Research Subject            | Date | Time |
|--|------|------|
| Printed Name of Research Subject         |      |      |
| Signature of Person Obtaining Consent    | Date | Time |
| Printed Name of Person Obtaining Consent |      |      |

## APPENDIX C. PROVIDER SURVEY



## **The impact of the delivery system design on** quality outcomes for patients with severe mental illness in a community mental health center: Advance Practice Registered Nurse Provider Survey Form

**SURVEY QUESTIONS:** Please answer the questions based on your work at XXXXX during the study period of January 1, 2010 to April 22, 2011.

- 1. What is your highest level of education (degree earned)?
  - a. Master of Science
  - b. Doctor of Nursing Practice
  - c. Educational Doctorate
  - d. Doctor of Nursing Science
  - e. Nursing Doctorate
  - f. Doctor of Philosophy
  - g. Other (please list)
- 2. What type(s) of American Nurses Credentialing Center (ANCC) certification do you hold? Circle all that apply.
  - a. Family Psychiatric Mental Health Nurse Practitioner
  - b. Adult Psychiatric Mental Health Nurse Practitioner
  - c. Child and Adolescent Clinical Nurse Specialist
  - d. Adult Clinical Nurse Specialist
- 3. Are you certified by a National Credentialing Body as a Family Nurse Practitioner, Pediatric Nurse Practitioner, Adult Nurse Practitioner or Geriatric Nurse Practitioner?
  - a. Yes
  - b. No
- 4. How many years have you practiced as an Advanced Practice Registered Nurse?
  - a. Less than 1 year
  - b. One to three years
  - c. Greater than three years but less than five years
  - d. Greater than five years but less than 10 years
  - e. Greater than 10 years
- 5. How many years have you been employed by XXXXX as an Advanced Practice Registered Nurse during the study period of January 1, 2010 to April 22, 2011?
  - a. Less than 1 year
  - b. One to three years
  - c. Greater than three years but less than five years
  - d. Greater than five years but less than 10 years
  - e. Greater than 10 years

### VITA

Dawn Marie Vanderhoef was born in 1971. She received an Associate Degree in Nursing from Western Wisconsin Technical College, a Bachelor of Science in Nursing from the University of Wisconsin, Milwaukee, a Master of Science in Nursing from Vanderbilt University School of Nursing, and a Doctor of Nursing Practice from The University of Tennessee Health Science Center. She has over 18 years of experience working as a nurse. She is board certified by the American Nurses Credentialing Center as an Adult Psychiatric Mental Health Nurse Practitioner and Clinical Nurse Specialist. She currently holds a full-time faculty appointment and enjoys teaching undergraduate and graduate students in clinical and didactic courses related to psychiatric and mental health nursing. In addition to her teaching responsibilities, she has an active faculty practice as a Psychiatric Mental Health Nurse Practitioner. In May 2012 she received her Doctor of Philosophy in Nursing from the University of Tennessee Health Science Center.