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## Implementing a Protocol to Monitor Cardiometabolic Syndrome in Patients Prescribed Atypical Antipsychotics

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PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

IMPLEMENTING A PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME IN  
PATIENTS PRESCRIBED ATYPICAL ANTIPSYCHOTICS

A Quality Improvement Project

by

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# PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

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# PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

## **Abstract**

Atypical or second-generation antipsychotics (SGAs) are a vital part of the management of many psychotic disorders, as well as behavioral and psychological symptoms. However, these medications have serious cardiometabolic complications, such as an increase in obesity, glucose intolerance, dyslipidemia, and hypertension, and can place the patient at serious risk for cardiovascular disease. The American Diabetes Association (ADA) and the American Psychiatric Association (APA) recommend clinical guidelines for metabolic screening, which requires the regular monitoring of patients treated with SGAs (ADA, 2004). The goal of this quality improvement project was to 1) implement a metabolic screening protocol based on ADA and APA guidelines for patients admitted to an acute psychiatric hospital who were treated with second-generation antipsychotics and 2) increase healthcare personnel awareness of metabolic monitoring guidelines and metabolic syndrome. This quality improvement project was implemented at an inpatient behavioral hospital in New England. A protocol for the monitoring of metabolic disturbances was placed in thirty patients' medical charts, who were age eighteen and over, had been prescribed SGAs, and had been taking the medication daily since the admission to the hospital. Twenty-one psychiatric mental health staff members attended the educational interventions that were conducted by the author of the project

A retrospective chart review was performed post-intervention to assess guideline adherence by comparing the percentage of tests ordered pre-intervention versus the during the post-intervention period. Data were collected over a three-month period starting from November 2018 until January 2019. The healthcare personnel awareness of metabolic monitoring guidelines and metabolic syndrome have been evaluated by a survey. After the intervention period, there were slight increases in the numbers of orders for hemoglobin A1c and lipid panel, but rates of

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other baseline monitoring parameters (such as weight and blood pressure) remained the same or did not improve. The waist circumference was one of the indicators that had not been measured, even after the implementation of the screening protocol.

**Keyword:** *atypical antipsychotics, metabolic syndrome, guidelines, monitoring, diabetes, dyslipidemia, cardiovascular disease*

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## IMPLEMENTING A PROTOCOL TO MONITOR CARDIOMETABOLIC RISK IN PATIENTS PRESCRIBED ATYPICAL ANTIPSYCHOTICS

### **Introduction**

Second-generation antipsychotics (SGAs) medications brought new hope in the field of psychiatry, as they offered important benefits for people with mental health illness. Furthermore, they are associated with fewer complications of the extrapyramidal syndrome, tardive dyskinesia, and elevated prolactin, when compared with “typical antipsychotics” (Gill, Teong, Gee, Wen & Jawan, 2012; Newcomer & Haupt, 2006). However, soon after their introduction, several undesirable side effects, such as significant weight gain, insulin resistance, impaired glucose tolerance, and dyslipidemia, surfaced. All of these symptoms are associated with the development of metabolic syndrome, which is a key risk factor for cardiovascular disease (Ba, Su, Chen, Chen & Chang, 2013).

### **Background**

**Atypical Antipsychotics.** In 1950, the introduction of the first typical antipsychotic, chlorpromazine (Thorazine) into clinical practice revolutionized the treatment of schizophrenia (De Hert, Vancampfort, Correll, Mersken, van Winkel & Mitchell, 2012). After a historic study completed by Elkes and Elkes in 1954, which was randomized and placebo-controlled, chlorpromazine started being accepted by psychiatrists all over the world. By the end of 1975, there were fifteen antipsychotic drugs available in the United States, and about forty worldwide (Ramachandraiah, Subramaniam, & Tancer, 2009). The arrival of clozapine, the first atypical antipsychotics, turned a new page for the treatment of schizophrenia. This medication was not associated with extrapyramidal symptoms seen with typical antipsychotics. Clozapine became the model for a new class of atypical antipsychotic drugs, and thirty years later, risperidone was

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created, which became the most commonly prescribed antipsychotic medication in the United States (Perese, 2012).

Atypical antipsychotics are a vital part of medical management for a wide range of psychiatric disorders and behavioral disturbances. In addition to schizophrenia, atypical antipsychotics are often prescribed for the treatment of aggressive and disruptive behavior, bipolar mania and depression, unipolar severe depression that does not respond to standard antidepressant treatment, and Tourette's syndrome. Nowadays, atypical antipsychotics are widely used, especially among children and adolescents (De Hert et al., 2012) and their off-label usage is also seen in many older patients suffering from dementia.

Antipsychotics are divided into first-generation "typical" drugs that treat the positive, but not the negative, symptoms associated with psychosis (schizophrenia), and second-generation agents, called atypical antipsychotics, which have fewer extrapyramidal symptoms (EPS) and tardive dyskinesia (TD) symptoms, when compared with the typical antipsychotics. Although atypical antipsychotics do not exhibit the side effects of the typical antipsychotics to the same degree, some of them have a tendency to cause weight gain, as well as cardiovascular and metabolic changes, and insulin resistance (De Hert et al., 2012). Patients with the first episode of schizophrenia, those who are antipsychotic drug-naïve, children, and adolescents are especially at risk for developing metabolic disturbances and obesity (De Hert et al., 2012).

Atypical or second-generation antipsychotics (SGAs) contribute significantly to cardiometabolic and endocrine adverse symptoms constituting metabolic syndrome (MetS) (Newcomer & Haupt 2005). Metabolic syndrome is a group of risk factors, including dysglycemia, hypertension, dyslipidemia, and central obesity, that is associated with the development of cardiovascular disease (Alberti, Zimmet, & Shaw, 2005). Metabolic syndrome is



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a leading cause of increased morbidity and mortality in patients who also suffer from schizophrenia (Riordan, Antonini, & Murphy, 2011). Metabolic syndrome has substantial cost implications for society; however, ongoing patient monitoring of simple laboratory and clinical measures can help decrease adverse effects, improve patients' quality of life, and reduce healthcare costs.

With the development and introduction of the atypical antipsychotic medications, a new era in the treatment of psychiatric disorders began. The first in this class, clozapine (Clozaril), fell quickly out of favor in the beginning due to drug-induced agranulocytosis. During the 1990s, olanzapine (Zyprexa), risperidone (Risperdal), and quetiapine (Seroquel) were introduced, and ziprasidone (Geodon) and aripiprazole (Abilify) were introduced ten years later, during the 2000s. Paliperidone (Invega) was FDA -approved in 2006. Atypical antipsychotics soon constituted the first-line treatment for schizophrenia, due to the decreased incidence of extrapyramidal side effects (EPS) (Farah, 2005), tardive dyskinesia (TD), and the absence of prolactin elevation (Seeman, 2002).

Since their introduction, atypical antipsychotics have been prone to both on-label and off-label usage due to their many notable benefits. Despite their important role in the treatment of many psychiatric disorders, it was noted that these agents have the potential to cause significant metabolic disturbances, such as an increase in obesity, glucose intolerance, dyslipidemia and hypertension (Correll, Frederickson, Kane, & Manu 2007).

It is still uncertain why some of the atypical antipsychotics carry higher risks for metabolic syndrome than others. Apparently, the cardiometabolic complications vary with respect to receptor pharmacology that suggests common pathophysiological mechanisms. For

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example, olanzapine and clozapine, two drugs that are known to cause the largest weight gain, have a high affinity for 5-HT<sub>2C</sub> and histamine H<sub>1</sub> receptors (Reynolds & Kirk, 2010).

In 2004, the American Diabetes Association (ADA), the American Psychiatric Association (APA), the American Association of Clinical Endocrinologists (AACE), and the North American Association of the Study of Obesity (NAASO) acknowledged the correlation between atypical antipsychotics and the development of metabolic syndrome, and also provided recommendations for the use and monitoring of these agents (ADA, 2004). The report emphasized that prescribers should evaluate the risks and benefits of prescribing specific atypical antipsychotics. ADA and APA statement recommended routine monitoring frequencies for the weight (BMI), waist circumference, blood pressure (BP), fasting plasma glucose, and fasting lipid profile (ADA, 2004).

**Metabolic Syndrome.** The criteria for metabolic syndrome, which is sometimes referred to as syndrome X, are diverse and a standard definition does not exist. The World Health Organization (WHO), the European Group for the Study of Insulin Resistance, and the National Cholesterol Education Program Adult Treatment Panel (NCEP ATP) III agree that the base components of metabolic syndrome are obesity, insulin resistance, dyslipidemia, and hypertension (Riordan et al., 2011). The International Diabetes Federation (IDF) proposed a set of metabolic syndrome criteria that include weight gain and hypertriglyceridemia, along with increased glucose and low-density lipoprotein cholesterol levels. Central obesity is a major component among the proposed sets of symptoms, with different waist circumferences for different ethnicity groups, along with triglyceride levels higher than 150 mg/dl; HDL cholesterol lower than 40 mg/dl in men or lower than 50 mg/dl in women; systolic blood pressure higher than 130 mmHg and diastolic blood

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pressure higher than 85 mmHg; and fasting plasma glucose higher than 100 mg/dl (Alberti Zimmet & Shaw 2005). The IDF metabolic syndrome criteria are shown in Table 1.

The National Institute of Health (NIH) (2001) defined metabolic syndrome as “a combination of risk factors that puts the individual at risk for cardiovascular disease” (NIH, 2001). Overwhelming evidence shows that metabolic syndrome can increase the risk of developing type 2 diabetes mellitus and can increase both the ten-year risk of coronary heart disease, three-to-six-fold (Bobes et al., 2007; De Hert et al., 2012), and the mortality rate from cardiovascular disease (Daumit, 2008). Prospective longitudinal studies reveal that the occurrence of metabolic adverse effects (such as weight gain, hyperglycemia, hypertension, and dyslipidemia) in patients increase significantly after the patient’s initial exposure to atypical antipsychotic medications (De Hert et al., 2012; Foley & Morley, 2011).

Patients with major mental illness have the same modifiable risk factors for cardiovascular disease and developing metabolic syndrome as the general population such as smoking, unhealthy lifestyles, diet, and a sedentary lifestyle or lack of physical activity (Hasnain et al., 2009). However, some researchers suggested that atypical antipsychotic drugs induce weight gain that is responsible for impaired glucose metabolism, which is independent of adiposity, and glucose and lipid metabolism abnormalities may occur without weight gain (Hasnain et al., 2009).

Impaired glucose metabolism and insulin resistance were the first abnormalities to be reported in patients with schizophrenia and bipolar disorders receiving atypical antipsychotic medications; however, weight gain is the most noticeable and distressing syndrome among patients. Different atypical antipsychotics are associated with varying effects on body weight, plasma glucose, and lipid levels. Overwhelming evidence shows that an increase in adipose

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tissue is associated with a decrease in insulin sensitivity, which contributes to increases in plasma glucose and lipids and a higher risk for diabetes and cardiovascular diseases.

In 2006, John Newcomer and Dan Haupt reviewed evidence showing that treatment with antipsychotic medications (particularly with atypical antipsychotics) can be associated with weight gain, insulin resistance, hyperglycemia, dyslipidemia, and diabetes (Newcomer & Haupt, 2006). The authors identified relevant publications through a search of MEDLINE from the years 1975 to 2006. They found that some of the atypical antipsychotics are associated with moderate increases in body weight (amisulpride, ziprasidone, and aripiprazole); however, others have a significant risk for weight gain and disordered glucose and lipid metabolism (olanzapine and clozapine) (Newcomer & Haupt, 2006). The SGAs side effects are shown in Table 2.

Differential metabolic profiles of atypical antipsychotics were also suggested by other researchers. The researchers involved in the Clinical Antipsychotic Trials in Intervention Effectiveness (CATIE) have shown a significant increase in the prevalence of metabolic syndrome for olanzapine and quetiapine over three months but a decrease for ziprasidone (Meyer et al., 2008). Olanzapine was associated with the largest mean increase in waist circumference, subsequent weight gain, and significant changes in fasting triglycerides (Meyer et al., 2008).

Saddichha and colleagues conducted an extensive prospective randomized, double-blind controlled study, including the measurement of waist circumference, blood pressure, triglyceride, high-density lipoproteins, and fasting blood sugar levels on patients with first-episode schizophrenia who received either first-generation haloperidol, or second-generation olanzapine or risperidone (Saddichha, Manjunath., Ameen & Akhtar, 2008). The analysis shows that the prevalence of MetS in a patient with schizophrenia was at least five times higher when compared to the matched healthy control group. The highest prevalence of MetS had olanzapine at twenty

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to twenty-five percent, followed by risperidone at nine to twenty-four percent, and haloperidol at zero to three percent (Saddichha et al., 2008).

The most noticeable sign of MetSyn is weight gain, and atypical antipsychotics have been frequently cited for causing it (Lieberman et al., 2004). Long-term treatment with these agents can cause weight gain from about one kilogram over one year with aripiprazole and ziprasidone; two to three kilograms with quetiapine and risperidone; and over six kilograms with olanzapine (Newcomer et al., 2006). Kahn and colleagues conducted a twelve-month open randomized clinical trial for patients with the first episode of schizophrenia treated with second-generation antipsychotic drugs (amisulpride, olanzapine, quetiapine, and ziprasidone) and found that there was notable weight gain, from 4.8 kg to 9.7 kg (Kahn et al., 2008).

**Insulin Resistance.** Another concern about treatment with atypical antipsychotics is an increased risk of insulin resistance, hyperglycemia, and diabetes. A population-based study associated with an increased risk of type 2 diabetes mellitus in patients treated with atypical antipsychotics versus control patients without schizophrenia was conducted by Liao and colleague (Liao et al., 2011). Authors reported that in the Cox models, significance adjusted hazard ratios (HR) associated with second-generation antipsychotics were 1.82 (95% confidence interval (CI) 1.30-2.55) for diabetes and 1.41 (95% CI 1.09-1.83) for hyperlipidemia. A ten-year nationwide population-based prospective cohort study using a nationwide database with a large sample size including patients with bipolar disorders (BD), major depressive disorder, and schizophrenia showed an increase in metabolic disturbances that required initiation of diabetic and hyperlipidemia medications, especially among patients with BD (HR of 1.506, 95% CI: 1.107-2.047) and schizophrenia (HR of 1.154, 95% CI: 1.002-1.329).

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### **Problem Statement**

Atypical, or second-generation antipsychotics, can lead to serious cardio-metabolic disturbances, such as weight gain, dyslipidemia, and glucose intolerance, and can increase the mortality from cardiovascular disease. Baseline and ongoing monitoring are recommended for patients prescribed atypical antipsychotic medications in order to reduce the risk and ensure the well-being of the patients.

### **Organizational “Gap” Analysis of Project Site**

The goal of this project was to help identify the existing gap between the current practice of tests ordered in patients treated with SGAs, according to guideline recommendations, and to propose corrective action, with the end goal of implementing a protocol for metabolic syndrome monitoring. Donabedian’s conceptual models align well with the gap analysis and can serve as a framework for this project (Davis-Ajami, Costa & Kulik, 2014). Donabedian’s structure, process, and outcomes framework incorporate clinical and patient factors as well as system and institutional factors and serves as a link between care intervention, outcomes and effectiveness evaluations (Davis-Ajami et al., 2014).

All atypical antipsychotics provide a warning about the risk of hyperglycemia and diabetes, as well as suggestions for regular monitoring of plasma glucose; however, very little data is available about adherence to these monitoring recommendations (US Food and Drug Administration, 2004). Inconsistencies with assessing the patient and the lack of adherence to monitoring for cardio-metabolic syndrome symptoms can also be problematic. The research suggests that in some clinics, less than one-third of the patients prescribed atypical antipsychotics undergo any blood glucose or lipid testing (Riordan et al., 2011). In addition to psychotic disorders, atypical antipsychotics are often prescribed off-label for the treatment of aggressive

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and disruptive behaviors in different age groups by primary care providers who have limited knowledge about guidelines and monitoring requirements (Mitchell, Delaffon, Vancampfort, Correll & De Hert, 2011).

Things are not any different at the project site. There is no available protocol for metabolic syndrome monitoring for patients who are being prescribed atypical antipsychotics; furthermore, prescribers do not adhere to guidelines for monitoring their patients as gap and SWOT analyses showed as you can see in Table 3.

### **Review of the Literature**

The focus of this literature review was on metabolic complications that arise when atypical antipsychotics were administered, and guidelines for the monitoring of metabolic risk in people treated with these agents. Databases and websites that have been reviewed included PubMed, CINAHL, Cochrane Reports, Agency for Healthcare Research and Quality (AHRQ), and Web of Science. Search terms used included: atypical antipsychotics, psychiatric disorders, metabolic syndrome, cardiovascular risk, and guidelines. Inclusion criteria consisted of full-text articles published between 2000 and 2017 in the English language, concerning adults greater than eighteen years old. The initial search using just two keywords, SGAs, and MetSyn, yielded 14,013 articles and guidelines. The search was further narrowed down to 242 publications by adding more keywords: guidelines, monitoring, diabetes, dyslipidemia, and cardiovascular diseases. The final search yielded forty-three articles and was performed by applying filters for age (above eighteen years old), language (English), and articles that were published in the past fifteen years.

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### **Level 1 Evidence: Case Reports and Uncontrolled Observational Studies**

Evidence from case reports, prospective observational studies, retrospective database analyses, and controlled experimental studies suggest a strong link between atypical antipsychotics and adverse effects on glucose and lipid metabolism (Newcomer & Haupt, 2006). The majority of metabolic complications occur within the first six months after the initiation of treatment and include substantial weight gain, hyperglycemia, metabolic acidosis, ketosis, and diabetic ketoacidosis-related deaths. All these complications are more frequently associated with clozapine (Clozaril) (Koller & Doraiswamy, 2001), olanzapine (Koller, Schneider, Bennett & Dubitsky, 2002), and risperidone treatments (Koller, Cross, Doraiswamy & Schneider, 2003). There is little evidence that ziprasidone, amisulpride, and aripiprazole cause such adverse effects.

A case report for olanzapine, risperidone, and quetiapine, that included data from the Federal Drug Administration (FDA) and Med Watch Drug Surveillance System, from 1999 to 2001 and 2002, reported high rates and incidents of diabetic ketoacidosis, hyperglycemia, metabolic acidosis, pancreatitis, and new-onset diabetes associated with use of these atypical antipsychotic medications (Koller et al., 2001, 2002,2003).

### **Level 2 Evidence: Observational database Analyses**

Two-thirds of observational database analyses studies report a connection between some atypical antipsychotic medications and weight gain, as well as a consequential increased risk for diabetes mellitus (Newcomer & Haupt, 2006). Newcomer and colleagues conducted a metanalytic review of the relevant literature in an effort to determine the relationship between antipsychotic treatment and risk for diabetes (Newcomer & Haupt, 2006). They searched MEDLINE and Current Contents from January 1990 to September 2004 for all relevant publications on studies using atypical antipsychotics for the treatment of different psychiatric



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disorders. Their analysis consistently shows that clozapine and olanzapine are the two antipsychotics that cause an increased risk for diabetes most often.

### **Level 3 Evidence: Controlled Experimental Studies and Randomized Clinical Trials**

Long-term schizophrenia trials using different atypical antipsychotics demonstrated statistically significant increases in fasting glucose and insulin levels with olanzapine and clozapine therapy and no significant changes with ziprasidone and aripiprazole (Pigott, Carson, Saha, Torbeyns, Stock, & Ingenito, 2003; Reynolds & Kirk, 2002). In an eight-week randomized, double-blind trial of 157 patients with schizophrenia treated with clozapine, olanzapine, risperidone, or haloperidol conducted by Lindenmayer and colleagues, the authors found that at the end of week six, there was a significant increase in mean glucose and cholesterol levels in patients who received olanzapine, and at the end of the eight-week period, there were increases in glucose and cholesterol levels in patients who received clozapine (Lindenmayer et al., 2003).

### **Monitoring Guidelines**

The screening and monitoring of metabolic complications when atypical antipsychotics were administered became a focus for many researchers, and different national and international organizations have developed their own guidelines for monitoring and managing the risk of these complications. The guidelines, defined as “systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances” (Institute of Medicine, 1992), is considered a good option for translating research into clinical practice (De Hert et al., 2011).

In November 2003, the ADA, the APA, the AACE, and the NAASO reviewed all available data on the metabolic effects of atypical antipsychotic medications and established a strong link between their use and the risk of developing the metabolic syndrome during their

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conference (Riordan et al., 2011). The majority recommended a baseline screening and ongoing monitoring of metabolic status and cardiovascular risk factors in patients treated with second-generation antipsychotic medications. The baseline screening measures when the atypical antipsychotic medication is initiated and includes body mass index (BMI), waist circumference, blood pressure, fasting plasma glucose, fasting lipid profile, and a personal and family history of metabolic syndrome disturbances. If the patient has one or more of the following abnormalities, initiation of the treatment is recommended: overweight (BMI 25.0-29.9), obesity (BMI>30), prediabetes (fasting plasma glucose (FPG) 120-125 mg/dl), diabetes (fasting plasma glucose >126 mg/dl), hypertension (blood pressure (BP)>140/90 mmHg), or dyslipidemia (Rabia, 2007).

The consensus also recommended ongoing monitoring for factors such as personal history, weight (BMI), waist circumference, BP, FPG, and fasting lipid profile at baseline, four weeks, eight weeks, twelve weeks, quarterly, annually, and every five years (Riordan et al., 2011). The ongoing monitoring protocol is shown in Table 4. This guideline is based on lifestyle management and is very easy to use in primary care settings. The metabolic syndrome time monitoring tool that the guideline proposed is an important instrument for the management of metabolic disturbances, and the most valuable evidence-based resource for this DNP project.

From the review of the literature, it is obvious that there are significant research and many practice guidelines for managing metabolic syndrome and metabolic complications. In 2011, De Hert and colleagues published a systematic review and quality assessment of all guidelines and recommendations for monitoring a cardiovascular risk in patients with schizophrenia published between 2000 and 2010, using the Appraisal of Guidelines for research and evaluation (AGREE) (De Hert et al., 2011). From a total of fifty-four guidelines that the authors found, eighteen were identified for AGREE evaluation. All the guidelines covered

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diabetes and cardiovascular disease risk in patients treated with antipsychotics. All guidelines included monitoring weight, body mass index (BMI), and fasting glucose; some included measurements of waist circumference and assessment of fasting lipids; and the more recent guidelines were more detailed and included evaluations of personal and family history, and cardiovascular risk factors (De Hert et al., 2011). Based on their review of the guidelines, the authors concluded that all patients with schizophrenia treated with SGAs should be under the active care of a medical physician, and they proposed a monitoring protocol. The protocol is shown in Table 4.

Despite the recommendations, there is an inconsistency in the implementation of these guidelines, and adherence to them by healthcare providers (Riordan et al., 2011).

Sankaranarayanan, A. & Castle, D. (2012) found that diabetes and dyslipidemia screening among patients treated with atypical antipsychotic drugs was low and did not improve after the recommendations from the ADA and APA. They reported that the best rates are around sixty percent coverage for the routine monitoring of blood glucose and lipids, and fifty-four percent for weight management.

When left untreated, metabolic syndrome can lead to serious cardiovascular complications and death. The researchers found that the risk for coronary heart disease and stroke was tripled, and cardiovascular mortality rates increase significantly among individuals diagnosed with metabolic syndrome (Lieberman et al., 2004). Despite ADA, APA, AACE, and NAASO recommendations for screening and the ongoing monitoring of patients receiving atypical antipsychotics, many healthcare providers do not consistently adhere to these guidelines (Cohn & Sernyak, 2013).

### **Theoretical Framework/Evidence-Based Practice Model**

The project was based on the Donabedian conceptual framework for the examination of health services and the evaluation of the quality of health care (Fig.1). Avedis Donabedian was a professor and a healthcare researcher at the University of Michigan, and he proposed that an improvement in the structure of care should lead to an improvement in clinical processes that would improve patient outcomes. His article “Evaluating the Quality of Medical Care,” published 1966, became the foundation of his body of work on the theory and practice of the quality assurance of health services research. During his career, he developed methods to measure the quality of healthcare, and in his landmark 1966 article, Donabedian suggests a triad of structure, process, and outcome to evaluate the quality of healthcare (Ayanian, 2016). He defined the structure as all factors delivered to the patients that directly affect their care, including the facility, equipment, human resources, training and qualification of the providers. The processes are technical processes or interpersonal processes, and they comprise the sum of all actions in terms of the way in which care is delivered. Lastly, the outcome is the effects on patients, changes to health status or knowledge, and patient satisfaction (Donabedian, 1966).

The structure, according to Donabedian, includes all the factors that affect the context in which care is delivered. This includes the facility, equipment, and human resources (psychiatrists, mental health nurse practitioners, and nurses), as well as organizational characteristics such as staff training and Joint Commission accreditation of the hospital. Using Donabedian’s conceptualization of quality of care, the present quality improvement project operationalized structure as hospital assets of psychiatrists, mental health care nurse

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practitioners, and staff nurses' knowledge about metabolic syndrome monitoring guidelines and recommendations.

The process is the sum of all actions that make up healthcare. These include diagnosis, treatment, patient educations, and how care is delivered. The protocol for monitoring metabolic syndrome abnormalities that this quality improvement project proposes is a part of the process that will improve patients' outcome. Early recognition and the reduction of metabolic syndrome abnormality in patients treated with SGAs by screening and testing will improve their quality of life.

### **Goals, Objectives and Expected Outcomes**

The purpose of this quality improvement project was to provide information on metabolic screening and to implement a protocol for the metabolic screening and monitoring of patients who are prescribed second-generation antipsychotics, as well as to assess whether this protocol is followed up by the prescribers, which was evidenced by increased rates of relevant testing.

The objectives:

1. Increased awareness of metabolic screening guidelines among mental health care staff.
2. Increase psychiatric prescribers' readiness to implement a metabolic screening protocol based on guidelines as evidenced by the increased number of testing for HgA1c, fasting lipids, blood pressure, and waist circumference.

The quality improvement project followed Donabedian quality improvement conceptual model as a framework (Fig.1). The DNP student utilized the hospital base and organization, and mental health staff (structure) to implement a screening metabolic protocol (process) in order to improve the patient's health and clinical outcomes.

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### **Methods**

This quality improvement practice project aimed to increase the awareness by the psychiatric mental health providers and staff about metabolic complications with SGAs and their adherence to guidelines for metabolic monitoring of patients on atypical antipsychotics. During the project the following took place:

An informational session was provided to twenty-one mental health care prescribers and nursing staff who were involved in the monitoring and management of selected patients treated with SGA, as an educational component to introduce the APA and the ADA guideline of metabolic syndrome testing, and to identify the project objective (Appendix A).

Each psychiatrist, PMHNP and staff nurse was encouraged to take a survey to determine their knowledge of existing guidelines for metabolic syndrome monitoring, self-efficacy, and possible barriers to following up the guideline (Appendix B).

The protocol (Appendix C) was then placed in charts (the hospital uses paper charts) of the patients admitted to the institution between September 30, 2018, and December 31, 2018 with a goal of including up to thirty psychiatric patients who were adults (age eighteen and greater) and were treated with atypical antipsychotic medications.

### **Project Site and Population**

This project was conducted at a behavioral health hospital in New England, a 120-bed inpatient hospital with three adult units, one geriatric unit, and one adolescent unit that mandates twenty-four-hour coverage by board-certified psychiatrists. The hospital serves eighty-four towns and cities. These are the only counties in the nation where Portuguese Americans make up the plurality of the population including the Portuguese Americans, the Brazilians Americans, and the Portuguese Cape Verdean population. The region is home to approximately one million

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people residing in over 1,300 square miles. The area is ethnically and linguistically diverse with Portuguese speakers well represented. Most mental health services are provided through health insurance, such as Medicaid or private insurance. Despite the fact that more than sixty-two percent of the population is employed, many of the patients of Portuguese and Brazilians descent served by this hospital are poor or homeless (US Census). Many of them have mental health issues ranging from schizophrenia and bipolar disorders to PTSD, alcohol and substance abuse.

### **Implementation Plan**

At the pre-implementation phase, the DNP student offered a 45-minute educational session to nine psychiatric providers and twelve staff nurses working with the selected patients, to review the ADA/APA guideline recommendations for metabolic screening in patients treated with SGAs. Information was provided about the metabolic complications, the importance of screening, and the proposed screening protocol. By the end of the session, health care personnel were invited to take a survey with three closed-ended questions and two open-ended questions to test participants' knowledge about guidelines for the monitoring of metabolic syndrome in a patient treated with SGAs and anticipated barriers.

The author of the project created a metabolic monitoring protocol based on the recommendations made by the American Diabetic Association (ADA), American Psychiatric Association (APA), American Association of Clinical Endocrinologists (AACE), and North American Association of the Study of Obesity (NAASO). This protocol was placed during the implementation phase in the thirty paper charts of patients aged eighteen years old and above, who had been on at least one scheduled atypical antipsychotic.

The protocol was placed in the thirty selected patients' charts during the time period from October 25, 2018, until December 30, 2018. The review of the medical records of those patients

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who have had the protocol was carried out on a weekly basis between December 15, 2018, and January 31, 2019, by the DNP student. Based on national and international guidelines, the DNP student used the following standards for a monitor for metabolic disturbances in the selected patients' charts:

1. All patients on atypical antipsychotics should have their BMI, waist circumference, blood pressure, lipid level, and fasting or random glucose level tested at baseline and at three, six, and twelve months.

2. Results are abnormal and should be acted on if the following is noted in a patient:

- BMI  $\geq 30$  kg/m<sup>2</sup>
- waist circumference  $\geq 94$  cm for male and  $\geq 80$  cm for female
- total cholesterol  $\geq 240$  mg/dl (4.6 mmol/l)
- triglycerides  $\geq 150$  mg/dl (1.7 mmol/l)
- high-density lipoprotein cholesterol  $< 40$  mg/dl (1.03 mmol/l) for males and  $< 50$ mg/dl (1.29 mmol/l) for females
- systolic blood pressure  $\geq 130$  mmHg
- diastolic blood pressure  $\geq 85$  mmHg
- fasting plasma glucose  $\geq 100$  mg/dl (5.6 mmol/l)
- random plasma glucose  $\geq 110$  mg/dl (6.6 mmol/l).

3. All patients with abnormal results should be referred to the medical clinical specialist.

Charts of the patient who were prescribed SGAs were identified from the three adult inpatient units between September 1, 2018, and November 30, 2018. A chart review was performed by the DNP student (who is employed as a nurse at the facility), starting in September



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2018, to identify all patients over the age of eighteen receiving atypical antipsychotics, in order to identify patients for monitoring.

A list of all patients' charts (who were eighteen years and older) admitted to the three adult units at the Behavioral Hospital and prescribed atypical antipsychotics was created at the beginning of the implementation phase. Every eligible patient's chart was assigned a number and this number was used for identification during the implementation of the screening protocol. The list of the charts and their assigned numbers were kept in a secure location, in a locked drawer, that only the author of the project had access to, in order to protect patients' information in accordance with HIPAA (US Department of Health and Human Services, 2003). Table 5 shows a working data sheet that was created by the DNP nurse student for the collection of the information.

During the implementation phase, the screening metabolic monitoring protocol was placed in the medical record of the thirty eligible patients' charts, in the physician orders section. The number of parameters completed at baseline (weight, BMP, waist circumference, blood pressure, fasting glucose level, and fasting lipid levels) was recorded. During the post-implementation phase, after the screening protocol was placed in the patient's chart, the number of ordered tests (H<sub>g</sub>A<sub>1c</sub>, lipids) was recorded along with weight, BMI, blood pressure, and waist circumference.

### **Ethical Considerations**

All participants were protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which, among other guarantees, protects the privacy of patients' health information (Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 2013). Additionally, the DNP student carefully conducted this project

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following the Standards of Care for practice. All information collected as part of evaluating the impact of this project did not include any potential patient identifiers. The risk to patients participating in this project as reviewing their charts was no different from the risks of patients receiving standard psychiatric care.

Participant confidentiality was assured by coding the participants using individual identification numbers and keeping this list of participants with identifying numbers in locked filing cabinets in the hospital, only accessible to the DNP student. All electronic files containing identifiable information were password protected to prevent access by unauthorized users, and only the DNP student had access to the passwords.

This project consisted of implementing a protocol for metabolic syndrome monitoring of patients receiving SGAs and their charts review, and there were no risks to the participant; patients, and mental health prescribers, and nursing staff. The health care providers had a choice to participate in the explanatory meeting about the purpose of this quality improvement project. The patients' charts review was performed by the DNP student and the identity of patients was not shared with administration.

The project was reviewed and approved by The New England Behavioral Health administration and management, and by Human Research Protection Office at the University of Massachusetts Amherst. (Appendix D).

### **Data Analysis**

Planning activities for this practice quality improvement project began in September 2018. The main objectives were:

(1) To utilize a screening protocol for metabolic syndrome abnormalities in patients treated with atypical antipsychotics in an inpatient psychiatric hospital.

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(2) To increase the monitoring for metabolic syndrome by participants as evidenced by the increased number of laboratory testing (HgA1c and Lipids).

(3) To increase healthcare providers' awareness about MetSyn and adverse effects of SGAs

In the initial planning process, a meeting with the clinical director and chief medical officer at the behavioral health hospital was held to discuss and determine the need of developing and implementing a protocol for metabolic syndrome monitoring for a patient treated with atypical antipsychotic medications.

The project proposal was reviewed and approved in September 2018 by the management of the behavioral hospital. After thorough research of the evidence-based literature, a protocol for metabolic syndrome monitoring was developed by the author of the project based on ADA and APA guidelines (ADA, 2004).

The data collected after the project was implemented was organized into a Microsoft Excel spreadsheet and then entered into IBM-SPSS (Statistic Package for the Social Science) statistics software. Qualitative data was used to assess the effectiveness of the implementation of the protocol in the hospital. During the information session with prescribers, a survey was offered with three closed-ended questions and two open-ended questions to assess their awareness about screening for metabolic complication in patients treated with SGAs.

The descriptive variables and demographic data were analyzed by calculating summary means and standard deviations for continuous variables. For this project, Microsoft Word and Microsoft Office Excel were used for the tables and spreadsheets. Intention-to-treat analysis was used to evaluate by comparing the percentage of baseline parameters recorded in the chart prior to the intervention and during the intervention. Categorical variables were analyzed by

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calculating frequencies and percentages, using the *t*-test. Statistical analysis to compare data in both audits (at the beginning and end of the monitoring period) were performed using paired-samples *t*-test.

The cost of planning, piloting, and implementation of this project was minimal until the final incorporation of the metabolic syndrome monitoring protocol into the patients' medical charts. This author developed a metabolic monitoring protocol based on ADA and APA recommendation guidelines in collaboration with the management of the hospital using practicum hours.

For the protocol to be created and implemented, estimated resources include a part-time employee equivalent (PTEE) for project coordinator position for four months. Additional cost included \$2,200 for materials, supplies, travel, food, etc. The budget for the project is shown in Table 6. There was no funding for this project. Following the time analysis (Appendix E), a chart was developed (Fig. 2) to identify major milestones and when these were achieved. The project started with an assessment of the project site during September of 2018 and was completed in April 2019.

### **Results**

Informational sessions were held by the DNP student for nurses and mental health care prescribers to describe the screening protocol. Participants included in the informational sessions were eight psychiatrists, twelve nurses, one psychiatric mental health nurse practitioner, and the chief nursing officer. A copy of the APA guidelines for metabolic screening, along with the modified protocol for monitoring for MetS was provided regarding the metabolic syndrome intervention. The informational sessions were held at various times and days over a three-week period in the effort to capture all involved health care professionals.

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At the beginning of the intervention phase, an educational session was held for psychiatric providers and nurses based on the literature search and best evidence-based practices, and they were familiarized with a screening protocol based on ADA and APA guidelines (Appendix C). After this information session, a survey was offered to the prescribers and staff nurses to obtain qualitative data about their experience working with SGAs and testing for metabolic complications. The survey that was offered to the health care providers after the educational session was used to assess individual knowledge of metabolic complications in a patient treated with SGAs and ADA/APA guideline's recommendations.

The short survey included three closed-ended questions with two open-ended questions where the participants could answer with their personal response. The response rate from psychiatrists was very low. Only three of all nine (33.3 percent) agreed to complete the survey. The three psychiatrists that agreed to complete the survey after taking part in the informational sessions answered that they were familiar with the guidelines and are following ADA guideline's recommendations for monitoring for metabolic complications in patients treated with SGAs. Those were the first two questions from the survey. Question three asked, "Who has the responsibility to screen for metabolic abnormalities?" Two of the psychiatrists answered that this is the responsibility of the psychiatrist because he or she prescribes the medications, but mostly in outpatient settings. One psychiatrist answered that the responsibility is in conjunction with the primary care provider (PCP). The fourth question asked what they think "are some barriers for screening...". The answers for this question were: "Patients are seeing a mental health provider and PCP separately", "Separate payment and billing the insurance twice for the same lab's tests", "Frequent exacerbation of symptoms that require inpatient hospitalizations", and "Unavailable documentation of the test results". Question five asked for participants opinion "If a screening

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protocol for metabolic syndrome.” placed in the patient record would improve the rate of testing. All three psychiatrists agreed that this will be “helpful”.

For the remaining six psychiatrists that did not complete the survey, the DNP student does not have information about their refusal. The response from the nursing staff was better. Ten RNs completed the survey with an average score of eighty-three percent with an SD of 24.9. Seven nurses that completed the survey voiced the opinion that ADA guidelines mainly concerned the psychiatrists and they are willing to monitor patients’ blood pressure, weight, BMI, and waist circumference if these parameters were part of the patients’ paperwork.

The patients’ medical charts from the three adult units were reviewed by the DNP student and the first thirty eligible patient’s charts that met the criteria were selected. The criteria were: age eighteen years and above, and treated with at least one SGAs that had been started in the past thirty days.

The chart audit and review were conducted weekly for ten weeks to track the percentage of baseline monitoring tests ordered before and after the protocol had been implemented. Nurses were involved in collecting these measurements (weight, BMI, and blood pressure). A cumulative summary statistic, the average number of screening measures completed at pre- and post-screening protocol placement, was used.

The family and personal history were recorded for all thirty of the selected patients (100 percent), blood pressure was recorded for twenty-seven patients (90 percent), and weight was recorded for twenty-nine patients (96.7 percent). BMI was one of the three parameters that had been regularly monitored and documented on admission. These three assessments are part of the admission paperwork and are performed for every patient admitted to the hospital, no matter what medications he or she was treated with.

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Six of the patients (20 percent) treated with SGAs had HgA1C and eight of them (26.7 percent) had fasting lipid profile obtained prior to starting SGAs. Surprisingly, not one of the patient's measurements of waist circumference was done. Seventeen of the patients (56.7 percent) had a BMI of twenty-seven and greater on admission and only four of them (23.5 percent) had glucose and lipid levels ordered for them prior to starting treatment with SGAs. Only three of the seven attending psychiatrists that had been treating these patients ordered the blood test prior the interventions, and from these three psychiatrists, one ordered 66.7 percent of HgA1C and 62.5 percent of the lipid tests.

After the screening protocol had been placed in patients' charts, the final analysis with a paired sample *t*-test demonstrated that the HgA1c tests that had been ordered after implementing the protocol ( $M = .33$ ,  $SD = .48$ ),  $t = 3.808$ ,  $p < .0$ ) increased slightly compared to the pre-intervention HgA1c tests that had been ordered ( $M = .20$ ,  $SD = .40$ ),  $t = 2.693$ ,  $p < .01$ ). The results are shown in Table 7.1 and Table 7.2. Prior to the intervention, only three psychiatrists (37.5%) ordered 20% of HgA1c tests. After the screening protocol was placed the number of psychiatrists that order the test increase to five (62.5%), and the percentage of HgA1c test that has been ordered increase to 33%. The same tendency was observed in ordered lipid tests also. The post-intervention lipid tests were slightly higher ( $M = .30$ ,  $SD = .47$ ), when compared with the pre-intervention lipid tests ( $M = .26$ ,  $SD = .44$ ),  $t = 3.525$ ,  $p < .01$ ). The results are shown in Tables 8.1 and 8.2. Three of the psychiatrists (37.5%) ordered 26 % of fasting lipid tests prior to the interventions; after the interventions, five psychiatrists (62.5%) ordered 30% of lipids tests. More than 50% (16) of the patients have been ordered HgA1c test and fasting lipids test.

### **Interpretation/Discussion**

Assessing patients for antipsychotic-associated metabolic disturbances and existing metabolic pathology or elevated risk factors can influence medications' choice and follow-up treatment plans. The data analysis shows that fasting blood glucose (FBG), Hg1AC and lipids testing remain low even post interventions. The ADA and APA guidelines recommended the FBG, weight, waist circumference, blood pressure, and fasting lipids to be performed for every patient who is treated with SGAs before the treatment with SGAs is initiated, at six weeks, at six months, at twelve months, and at least annually thereafter. However, the data from the project showed that if these tests are not incorporated in the existing hospital documentation, they are not performed regularly.

Blood pressure, weight, and BMI were recorded in higher percentages due to the fact that they were part of the admission assessment. Measuring waist circumference was not part of the admission assessment and was not recorded at all. This indicator was not measured after the implementation of the screening protocol. Slightly increased rates for Hg1AC and lipids testing after the screening protocol was implemented show that efficient metabolic monitoring requires an approach focused on educating psychiatrists and medical staff, and developing a system for recording the data and defining responsibility for these tasks.

### **Barriers to Screening and Monitoring**

Understanding causes for suboptimal metabolic screening in patients receiving atypical antipsychotic medications could provide valuable clues on how best to solve this problem. Overcoming the barriers to metabolic monitoring is an important aspect of process improvement and is directly related to the patient's outcome as it is shown in Fig. 3.



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**Patient Barriers.** Patient-related issues are persistent psychotic symptoms such as paranoia and mania, and an alteration in cognition, which can make the patient less compliant with testing no matter if he or she is in-patient or outpatient. The access and affordability to medical care are also barriers along with non-compliance with medical treatment (Gill, 2012). The impaired judgment that most of the patients with a chronic mental disorder have do not allow them to recognize and acknowledge the metabolic symptoms and to seek medical help.

**Providers' Barriers.** Cohn and Sernyak (2006) suggest that insufficient medical knowledge about the additive burden of cardiometabolic complications and not enough emphasis on the patient's medical needs from mental health providers are some of the reasons monitoring guidelines are not implemented in mental health settings. However, this does not seem to be supported by evidence. A survey conducted in 2007 by Suppes et al. on five hundred US psychiatrists found that 97% of them were familiar with the metabolic syndrome abnormalities, but only 78% monitored the weight of the patients, only 69% monitored glucose levels, 61% monitored lipid levels, 52% monitored blood pressures and 16% monitored HgA1c (Mitchell, 2011).

The lowest percentage of monitoring among metabolic syndrome parameters was waist circumference. Alberti et al. (2005) suggest that prescribers may not be aware of the importance of waist circumference as a strong independent predictor of cardiovascular disease. Limited medical resources for patients with severe mental illness have been blamed, as well as a lack of time and a shortage of staff to perform these procedures (Gill, 2012). Many psychiatric care providers do not assess patients for medical issues and do not order tests because of a lack of time, resources, or a lack of consideration regarding the importance of waist circumference (Mitchell, 2011).

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There is an ongoing debate in regards to where the responsibility lies for monitoring metabolic abnormality in psychiatric patients receiving SGAs. Does this obligation fall on the primary care physician or on the practitioner who actually prescribes the medications (i.e., the psychiatrist)? Additionally, who should follow up on abnormal cardiometabolic screening results? Some authors claim that this is not strictly the psychiatrist's responsibility, as long as they delegate the task and the tests were performed (Cohn, 2006).

In general, guidelines are very difficult to implement, not only due to a lack of resources and/or time but also because of low organizational support, clinicians' resistance to change, concerns over the quality of the guidelines, and lack of ownership (Mitchell, 2011).

**System Barriers.** Overwhelming evidence exists that patients with psychiatric diagnoses receive an inferior quality of medical care, including follow-ups for metabolic syndrome and diabetes care (Mitchell, 2011). The fact that these patients have to see a primary care provider and a mental health provider separately complicates the issue. Insurance coverage could also be a serious barrier, in terms of not covering some tests, the newest antipsychotic medications with the fewest metabolic complications, or limiting the number of health care providers and consultants.

As the SGAs that mental health providers prescribe increase vulnerability to metabolic syndrome, these providers need to be able to diagnose, refer for a medical consult or treat metabolic syndrome complications associated with these medications (Parks, 2011). The largest controlled study, the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE), found that 88% of the patients with dyslipidemia were untreated, as were 62% with hypertension and 38% with diabetes (Meyer et al. 2005; Correll et al. 2007). Obviously, it is imperative that the

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mental health provider assumes responsibility for ensuring appropriate medical management and collaborates with the primary care provider in regards to these issues.

### **Conclusion**

Cardiometabolic syndrome remains a serious concern among patients who are treated with atypical antipsychotic medications. There is overwhelming evidence-based data that the majority of these medications cause significant weight gain, dyslipidemia, hyperglycemia, and increased glucose levels that can lead to diabetes. Despite metabolic monitoring guidelines, there is still a gap in the monitoring of metabolic syndrome of all individuals on SGAs (Velligan et al., 2011). Implementation of screening protocols for monitoring and early detection of metabolic syndrome abnormalities could decrease the risk of developing those abnormalities and decrease morbidity and mortality of the patients receiving atypical antipsychotics.

This quality improvement project and the implementation of the monitoring protocol for cardiometabolic monitoring was successful in increasing the number of baseline relevant testing orders for a lipid panel and hemoglobin A1c in the selected patients treated with SGAs. Despite the improvement, however, the rates of monitoring for some metabolic parameters remained low (i.e., waist circumference). Staff nurse participants demonstrated improved knowledge about the metabolic disturbances in patients treated with SGAs and willingness to collaborate with psychiatric prescribers regarding metabolic screening. Some of the psychiatrists found the metabolic screening protocol somewhat helpful for their practices. The basic screening protocol incorporated into the patient medical record and brief staff education has potential to increase knowledge of the staff of metabolic disturbances in patients treated with SGAs and improve medical staff adherence to guideline recommendations, as well as improve overall patient outcomes.

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**Appendix A**

**Informational Session**

The author of the quality improvement project provided mental health care providers with the following information:

1. The significance of metabolic screening for patients treated with atypical antipsychotic medications; statistics.
2. The ADA and APA monitoring guidelines recommendation for metabolic monitoring of patients who are treated with SGAs.
3. A handout with risk factors and metabolic syndrome parameters that need to be considered.
4. A handout with the proposed monitoring protocol base on ADA and APA's guidelines (2004).
5. Overview of the quality improvement project.
6. Survey for psychiatric providers about their experience with SGA's and screening for metabolic syndrome.

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**Appendix B**

**Psychiatric Care Providers Survey**

This questionnaire is part of the student quality improvement project: IMPLEMENTING A PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME IN PATIENTS PRESCRIBED ATYPICAL ANTIPSYCHOTICS and all questions related to your care approach in the management of patients on second-generation antipsychotic medications (SGAs). The information provided by you is strictly confidential and will be seen by the DNP student and Project Committee. You and your practice will not be identified in any reports or publications that may result from this project.

1. Are you aware of the specific National Cholesterol Education Program metabolic syndrome diagnostic criteria?  
Yes.....  
No.....
2. Do you consider monitoring for metabolic abnormalities (weight, BP, Lipid profile, Fasting glucose or Hgb A1C, and waist circumference) when prescribing atypical antipsychotics (SGAs) and how often?  
Yes.....  
No.....  
How often.....
3. Who has the responsibility to screen for metabolic abnormalities in a patient treated with SGAs?.....  
.....  
.....
4. What do you think are some barriers for screening for metabolic syndrome in patients on SGAs?.....  
.....  
.....
5. Do you think placing a screening protocol for metabolic syndrome in the patient’s chart would improve the rate of monitoring for patients on SGAs therapy?  
Yes.....  
No.....

**Appendix C**

**Metabolic Monitoring Protocol**

- ✚ **Your patient is on the following atypical antipsychotic:**
  - \_\_\_ aripiprazole (Abilify)                      \_\_\_ olanzapine (Zyprexa)
  - \_\_\_ asenapine (Saphris)                      \_\_\_ paliperidone (Invega)
  - \_\_\_ clozapine (Clozaril)                      \_\_\_ quetiapine (Seroquel)
  - \_\_\_ iloperidone (Fanapt)                      \_\_\_ risperidone (Risperdal)
  - \_\_\_ Lurasidone (Latuda)                      \_\_\_ ziprasidone (Geodon)
- ✚ **Per ADA/APA guidelines, the following monitoring parameters/labs are recommended when a new atypical antipsychotic is started:**
  - ❖ Personal and Family History of obesity, diabetes, dyslipidemia, hypertension, cardiovascular disease
  - ❖ Weight
  - ❖ Fasting Plasma Glucose
  - ❖ Waist circumference
  - ❖ Hemoglobin A1c
  - ❖ Blood Pressure
  - ❖ Fasting Lipid Profile
- ✚ **For patients continuing previous atypical antipsychotics, please refer to following monitoring parameters/labs (Based on the APA/ADA Guidelines).**

	Baseline	4 Weeks	8 Weeks	12 Weeks	Quarterly	Annually
Personal/Family History	x					x
Weight (BMI)	x	x	x	x	x	x
Waist Circumference	x					x
Blood Pressure	x			x		x
Fasting Plasma Glucose	x			x		x
Fasting Lipid profile	x			x		x*

American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, North American Association for the Study of Obesity, Consensus Development Conference on antipsychotics drugs and obesity and diabetes. Diabetes Care 2004; 598-601

\*Fasting Lipid Profile should be monitored every five years unless significant abnormalities are present. If present, monitor annually.

✚ **ATP III Criteria for Clinical Identification of Metabolic Syndrome**

Risk Factors	Defining Level
Abdominal Obesity <ul style="list-style-type: none"> <li>• Men</li> <li>• Women</li> </ul>	Waist Circumference <ul style="list-style-type: none"> <li>• &gt;102 cm (&gt;40 inches)</li> <li>• &gt;88 cm (&gt;35 inches)</li> </ul>
Triglycerides	≥150 mg/dl
HDL Cholesterol <ul style="list-style-type: none"> <li>• Men</li> <li>• Women</li> </ul>	<ul style="list-style-type: none"> <li>• &lt;40 mg/dl</li> <li>• &lt;50 mg/dl</li> </ul>
Blood Pressure	≥ 130/85 mmHg
Fasting Glucose	≥ 110 mg/dl

If you have any questions, please contact:

Name: \_\_\_\_\_ Extension: \_\_\_\_\_

Appendix D



University of Massachusetts Amherst  
Human Research Protection Office  
Mass Venture Center  
100 Venture Way, Suite 116  
Hadley, MA 01035

Office of Research Compliance  
voice: (413) 545-3428  
fax: (413) 577-1728

**Memorandum – Not Human Subjects Research Determination**

**Date:** August 28, 2018

**To:** Svetlana Valkovska, College of Nursing

**Project Title:** Implementing a Protocol to Monitor Cardiometabolic Syndrome in Patients Prescribed Atypical Antipsychotics

**IRB Determination Number:** 18-164

The Human Research Protection Office (HRPO) has evaluated the above named project and has made the following determination based on the information provided to our office:

- The proposed project does not involve research that obtains information about living individuals [45 CFR 46.102(f)].
- The proposed project does not involve intervention or interaction with individuals OR does not use identifiable private information [45 CFR 46.102(f)(1),(2)].
- The proposed project does not meet the definition of human subject research under federal regulations [45 CFR 46.102(d)].

**Submission of an Application to UMass Amherst IRB is not required.**

Note: This determination applies only to the activities described in the submission. If there are changes to the activities described in this submission, please submit a new determination form to the HRPO prior to initiating any changes.

A project determined as “Not Human Subjects Research”, must still be conducted in accordance with the ethical principles outlined in the Belmont Report: respect for persons, beneficence, and justice. Researchers must also comply with all applicable federal, state and local regulations as well as UMass Amherst Policies and procedures which may include obtaining approval of your activities from other institutions or entities.

Please do not hesitate to call us at 413-545-3428 or email [humansubjects@ora.umass.edu](mailto:humansubjects@ora.umass.edu) if you have any questions.

Handwritten signature of Iris L. Jenkins in black ink.

Iris L. Jenkins, Assistant Director  
Human Research Protection Office

# PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

## Appendix E

### Time Analysis:

1. Assessment of the needs: September 2018
2. DNP Project approvals: October 2018
3. Meeting with clinical director and staff mental health prescribers to familiarize them with the project: September/October 2018
4. Data collection; first patient charts' audit; implementing of the protocol for monitoring of metabolic abnormalities: October 2018
5. Weekly char audit; final data collection: November 2018 through January 2019
6. Analysis of the data: February 2019
7. Project competition: March 2019
8. Final report and presentation: May 2019

PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

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## PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

Table 1

*Core Criteria for Diagnosing Metabolic Syndrome<sup>1</sup>*

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Central obesity	Waist circumference <sup>a</sup> - ethnicity-specific plus, any two of the following:
Raised triglycerides	≥ 1.7 mmol/l (150 mg/dl) or specific treatment for this lipid abnormality
Reduces HDL-Cholesterol	<1.03 mmol/l (40 mg/dl) in male <1.29 mmol/l (50 mg/dl) in female or specific treatment for this lipid abnormality
Raised Blood Pressure	Systolic: ≥130 mmHg or Diastolic: ≥ 85 mmHg or treatment of previously diagnosed hypertension
Raised Fasting Plasma Glucose <sup>b</sup>	Fasting plasma glucose ≥ 5.6 mmol/l (100 mg/dl) or previously diagnosed with Type 2 diabetes if >5.6 mmol/l or 100 mg/dl, oral glucose tolerance test strongly recommended but is not necessary to define presence of the syndrome

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1. Adopted from International Diabetes Federation- metabolic syndrome worldwide definition

<sup>a</sup> If body mass index is > 30 kg/m<sup>2</sup> then central obesity can be assumed, and waist circumference does not need to be measured.

<sup>b</sup> In clinical practice, impaired glucose intolerance is also acceptable, but all reports of the prevalence of the metabolic syndrome should use only the fasting plasma glucose and presence of previously diagnosed diabetes to assess this criterion.



## PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

Table 2

*Atypical Antipsychotics side effects<sup>1</sup>*

	<b>Weight gain</b>	<b>Dyslipidemia</b>	<b>DM</b>	<b>EPS increase</b>	<b>Prolactin</b>	<b>Sedation</b>	<b>QT-interval prolongation</b>
Amisulpride	+	-	+	+	+++	-	-
Aripiprazole	-	-	-	+/-	-	+	-
Asenapine	+/-	+/-	-	-	-	++	-
Clozapine	+++	++	+++	-	-	+++	+
Olanzapine	+++	++	++	-	-	+++	-
Quetiapine	++	+	++	-	-	++	-
Risperidone	++	+/-	++	+	+++	+	++
Ziprasidone	+/-	-	-	-	+	-	++

+++ high incidence; ++ moderate incidence; + low incidence; - very low incidence.

1. Adapted from American Diabetes Association/American Psychiatric Association, 2004; De Nayer et al., 2005; Cohn and Sernyak, 2006; De Hert et al., 2006; Tschoner et al., 2007; Leucht et al., 2009).

EPS = extra-pyramidal symptoms.

PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

Table 3

*SWOT Analysis*

	STRENGTHS	WEAKNESSES
INTERNAL	<ul style="list-style-type: none"> <li>-Hardworking and dedicated staff</li> <li>-Families involved with patient care</li> <li>-The staff welcomes new projects</li> <li>-Hospital management welcome nursing and advanced practice nursing students</li> </ul>	<ul style="list-style-type: none"> <li>-No current metabolic syndrome monitoring protocol</li> <li>-Inconsistencies following ADA/APA guidelines for metabolic screening in patients on SGAs</li> <li>-Short hospital stays</li> </ul>
	OPPORTUNITIES	THREATS
EXTERNAL	<ul style="list-style-type: none"> <li>-Hospital welcome and provide projects for practice improvement</li> <li>-Administration and management keep communication lines open</li> <li>-Administration and management supportive of the project</li> <li>-Metabolic monitoring protocol can be used as a part of the screening process</li> </ul>	<ul style="list-style-type: none"> <li>-Psychiatrists resistant to changes</li> <li>-Psychiatrists' mistrust of advanced practice nursing role</li> <li>-Needs for corporate management approval</li> </ul>

ADA- American Diabetes Association  
 APA-American Psychiatric Association

## PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

Table 4

*Monitoring Protocol for Managing Individuals with Normal Baseline Values at the Start of an Episode of Care<sup>1</sup>*

	Baseline	6 weeks (if starting drug treatment)	12 weeks (if starting drug treatment)	At least annually thereafter
Medical history	X			
Weight/waist/BMI	X	X	X	X
Blood pressure	X	X	X	X
Fasting glucose	X	X	X	X
Fasting lipids	X	X	X	X
Lifestyle advice	X	X	X	X

1. Adopted from De Hert, 2011.

PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

Table 5

*Patients Data Analyses*

Population Descriptors	Pre-intervention N = 30	Post-intervention N = 30
Sex: -male	20 (66.7%)	
-female	10 (33.3%)	
Age (years)	37.53	
Length of stay (days)	20.73	
Race: -White	21 (70%)	
-Africal American	8 (26.6%)	
-Other	1 (3.3%)	
Comorbidities:		
-Diabetes	6 (20%)	
-Hypertension	8 (26.7%)	
-Hyperlipidemia	4 (13.3%)	
-Obesity	17 (56.7%)	
-ADHD	7 (23.3%)	
Weight	29 (96.7%)	29 (96.7%)
Body mass index	28 (93.3%)	28 (93.3%)
Waist Circumference	0	0
Blood pressure	27 (90%)	27 (90%)
Fasting Blood Glucose (HgA1c)	6 (20%)	10 (33.3%)
Lipid Panel	8 (26.7%)	9 (30%)

ADHD-Attention Deficit Hyperactive Disorder

## PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

Table 6

*Budget*

	Annual Cost to implement the Project	
	2018	2019
Gas	\$ 100	\$50
Paper	\$50	\$50
Pens, pencils, markers	\$60	\$40
Making copies	\$500	\$100
Meetings/materials	\$100	\$50
Miscellaneous	\$100	\$500
Total	\$ 910	\$790

PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

Table 7.1.

*One-Sample Statistics of HgA1c Testing prior to and after Interventions*

	N	Mean	Std.Deviation	St. Error Mean
HgA1c <sup>a</sup>	30	.2000	.40684	.07428
postHgA1c <sup>b</sup>	30	.3333	.47946	.08754

<sup>a</sup> HgA1c prior interventions

<sup>b</sup> postHgA1c – HgA1c after the interventions

Table 7.2.

*One -sample Test of HgA1c Testing prior to and after Interventions*

	t	df	Sig. (2-tailed)	Test Value = 0 95% Confidence Interval of the Difference		
				Mean Difference	Lower	Upper
HgA1c <sup>a</sup>	2.693	29	.012	.20000	.0481	.3519
postHgA1c <sup>b</sup>	3.808	29	.001	.33333	.1543	.5124

<sup>a</sup> HgA1c prior interventions

<sup>b</sup> postHgA1c – HgA1c after the interventions

PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

Table 8.1.

*One-Sample Statistics of Lipids Testing Prior and after Interventions*

	N	Mean	Std. Deviation	Std. Error Mean
Lipids <sup>a</sup>	30	.2667	.44978	.08212
postLipids <sup>b</sup>	30	.3000	.46609	.08510

<sup>a</sup> Lipids prior interventions

<sup>b</sup> postLipids – Lipids after the interventions

Table 8.2.

*One-Sample Test of Lipids Testing Prior and after Interventions*

	t	df	Sig. (2-tailed)	Test Value = 0		
				Mean Difference	95% Confidence Interval of the Difference	
				Mean	Lower	Upper
Lipids <sup>a</sup>	3.247	29	.003	.26667	.0987	.4346
postLipids <sup>b</sup>	3.525	29	.001	.30000	.1260	.4740

<sup>a</sup> Lipids prior interventions

<sup>b</sup> postLipids – Lipids after the interventions

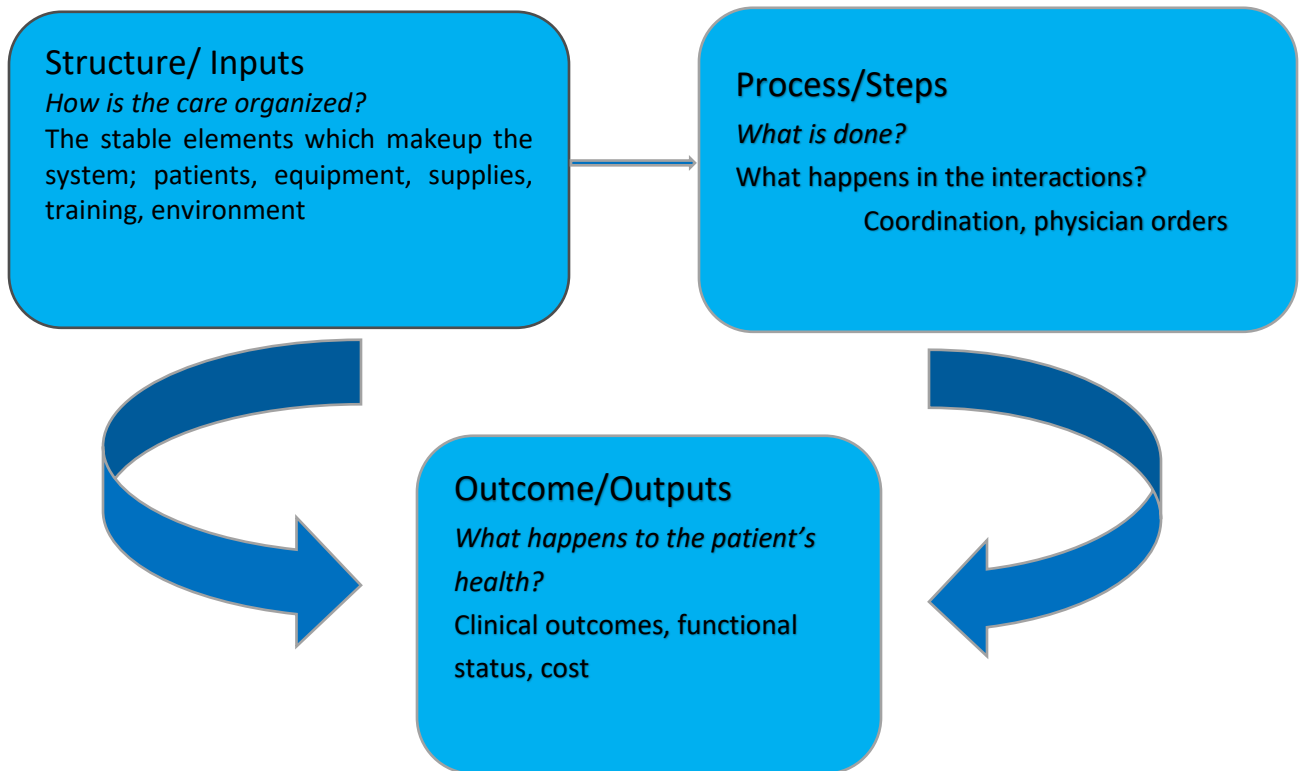
# PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

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# PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME



**Fig.1.** The Donabedian Model: Structure- Process-Outcome

PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

Task	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
	2018							2019				
The topic finalized												
Researched information and review the literature	<b>X</b>											
Gained permission to conduct the project; wrote the project prospectus; wrote the protocol		<b>X</b>	<b>X</b>	<b>X</b>								
Secure the necessary supplies; gained final approval from Southcoast Behavioral Health			<b>X</b>	<b>X</b>								
Final meeting with a medical director ; meeting with prescribers (psychiatrists, NPs) Chart Review of eligible patients				<b>X</b>	<b>X</b>							
Intervention: Implementing the protocol begin					<b>X</b>	<b>X</b>	<b>X</b>					
Weekly chart audit after the protocol was implemented and information collection starts; continuous implementation of metabolic protocol monitoring								<b>X</b>	<b>X</b>	<b>X</b>		
Analyze data and write a project report										<b>X</b>	<b>X</b>	
Presenting the final report to the clinical director and staff of the hospital												<b>X</b>

Fig.2. Timeline

PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME

<u>Family Barriers</u>	<u>Clinical Team Barriers</u>	<u>Structural/Process-of-care Barriers</u>
<ul style="list-style-type: none"> <li>-Emotional distress</li> <li>-Uncertainty about patient's preferences</li> <li>-Personal desires about goals for the patient</li> <li>-Intrafamily conflict</li> <li>-Distrust of clinicians</li> </ul>	<ul style="list-style-type: none"> <li>-Inadequate communication skills</li> <li>-Lack of interest</li> <li>-Inadequate attention to emotional and moral considerations</li> </ul>	<ul style="list-style-type: none"> <li>-Clinician turnover</li> <li>-Time constraints</li> <li>-Lack of timely/regular communication</li> <li>-Failure to include key members of the family or of the team</li> </ul>
<p><u>Ideal Clinical Team</u></p> <ul style="list-style-type: none"> <li>-Accept diverse goals of care</li> <li>-Effectively communicate prognostic information</li> <li>-Present treatment options without undue bias</li> <li>-Provide emotional and moral support</li> </ul>		<p><u>Ideal Structure/Process of Care</u></p> <ul style="list-style-type: none"> <li>-Early and timely communication</li> <li>-Clinician continuity</li> <li>-Convenient space for meetings</li> <li>-Multidisciplinary involvement</li> </ul>
<p><u>Good outcomes</u></p> <ul style="list-style-type: none"> <li>-Patient-centered decisions</li> <li>-Appropriate resource use</li> </ul>		<p><u>Bad outcomes</u></p> <ul style="list-style-type: none"> <li>-Non-patient centered decisions</li> <li>-Adverse psychiatric sequelae for surrogates</li> <li>-Inappropriate resource use</li> </ul>

**Fig.3.** The Donabedian Model: Barriers; outcomes

# PROTOCOL TO MONITOR CARDIOMETABOLIC SYNDROME