TOOLKIT TO IMPROVE PROVIDER ADHERENCE TO METABOLIC MONITORING OF ATYPICAL ANTIPSYCHOTICS FOR YOUTHS

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ABSTRACT

Lindsey M. Carpenter: Toolkit to Improve Provider Adherence to Metabolic Monitoring of Atypical Antipsychotics for Youths
(Under the direction of Grace Hubbard)

Problem: The use of atypical antipsychotic medications (AAPs) to treat bipolar and other mood disorders has increased in pediatric populations. The potential metabolic side effects of these medications increase the risk of negative health outcomes. Providers are aware of practice guidelines regarding these medications but fail to adhere to them. Practice toolkits are quality-improvement interventions aimed at improving guideline compliance.

Purpose: The purpose of this project was to implement a toolkit to increase adherence to guidelines for metabolic measures in patients aged 5-18 with a bipolar disorder taking an atypical antipsychotic.

Methods: A toolkit containing necessary order, assessment, and documentation forms was deployed in an outpatient mental health office in North Carolina. Plan-Do-Study-Act cycles were conducted to guide implementation. Providers included a Doctor of Osteopathic Medicine, Psychiatric-Mental Health Nurse Practitioners, and a Physician Assistant. Chart audits were conducted and compliance data was displayed as run charts compared to baseline data. Outcome measures included: completion of metabolic assessment, appropriate laboratory ordering, and completion of vital sign measurements.

Results: Outcome measures showed improved adherence rates to monitoring vital signs, ordering appropriate labs, and performing a metabolic assessment. These improvements varied among providers.

Implications: While improvements occurred, there were still barriers to implementation such as lack of time. Ongoing assessment of barriers is necessary to sustain the changes and to ensure consistent application of the guideline recommendations by all providers.

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LIST OF ABBREVIATIONS

AAP	Atypical Antipsychotic
AACAP	American Academy of Child and Adolescent Psychiatry
AACE	American Association of Clinical Endocrinologists
ADA	American Diabetes Association
APA	American Psychiatric Association
BSD	Bipolar Spectrum Disorders
BMI	Body Mass Index
DMDD	Disruptive Mood Dysregulation Disorder
DNP	Doctor of Nursing Practice
DO	Doctor of Osteopathic Medicine
DSM	*Diagnostic and Statistical Manual of Mental Disorders*
ECT	Electroconvulsive Therapy
ECG	Electrocardiogram
FDA	Food and Drug Administration
IRB	Institutional Review Board
NAASO	North American Association for the Study of Obesity
PA	Physician Assistant
PCP	Primary Care Provider
PDSA	Plan-Do-Study-Act
PMHNP	Psychiatric-Mental Health Nurse Practitioner
RCT	Randomized Controlled Trial
SGA	Second Generation Antipsychotic

CHAPTER 1: PROBLEM

The diagnosis of bipolar spectrum disorders, Disruptive Mood Dysregulation Disorder (DMDD), and use of atypical antipsychotic medications (AAPs) or second-generation antipsychotics (SGAs) to treat these disorders have increased in the pediatric population in recent years. A common and potentially serious side effect of these medications is a condition called metabolic syndrome (De Hert, Dobbelaere, Sheridan, Cohen, & Correll, 2011; Haddad & Sharma, 2007; Koch & Scott, 2012; G. M. Reeves et al., 2013; Walter et al., 2008). To combat this growing epidemic of iatrogenic side effects, resources and treatment suggestions have been developed for providers who treat this population.

Professional organizations have developed practice guidelines that promote evidence-based practice to deliver the best care for these patients, however, these guidelines are severely underused in practice. The guideline formulated by a collaboration of the American Diabetes Association (ADA), the American Psychiatric Association (APA), the American Association of Clinical Endocrinologists (AACE), and the North American Association for the Study of Obesity (NAASO) (2004) provides recommendations for the monitoring of metabolic parameters for patients started on AAPs (Appendix A). Guidelines developed by the American Academy of Child and Adolescent Psychiatry (AACAP) outline the assessment and treatment of children and adolescents with a bipolar disorder and those treated with AAPs (Findling et al., 2011; McClellan, et al., 2007). These guidelines have been widely distributed electronically and in print, presented in symposiums across the nation, cited in quality improvement studies, and are readily available for access by providers (Velligan et al., 2013). While the rates of

compliance with these practice guidelines vary widely, the general consensus supports that these evidence-based recommendations are often not utilized in clinical practice as evidenced in studies of managed care and commercial insurance databases (Koch & Scott, 2012; Velligan et al., 2013). The findings of several studies reveal that most providers are familiar with these guidelines; however, awareness of these guidelines does not translate into performance of the recommended assessment, treatment, and monitoring (Jeffrey, 2015; Khan, Shaikh, & Ablah, 2010; Laugharne, Waterreus, Castle, & Dragovic, 2016; Sugawara et al., 2014; Walter et al., 2008; Wiechers et al., 2012). Researchers have also found that providers may be compliant with some of the recommendations, but not all of them, or do not adhere to the recommended schedule for monitoring (Khan et al., 2010; Walter et al., 2008). Suppes, McElroy, and Hirschfield (2007) found that providers believe metabolic syndrome is a significant health risk that requires monitoring and treatment yet, few diagnosed it in their patients and even fewer could identify the correct components for diagnosis of metabolic syndrome, even though they had diagnosed it in their patients. The findings of these studies support the pervasiveness of this gap in evidence-based care delivery using AAPs that can have serious physical and psychiatric implications.

Mental health providers at an outpatient mental health practice in Western North Carolina prescribes AAPs for children and adolescents without the benefit of consistent use of practice guidelines. This practice treats approximately fifty children ages 5-18 per year who are diagnosed with bipolar spectrum disorders or DMDD.

The purpose of this Doctor of Nursing Practice (DNP) project was to synthesize evidence-based guidelines and develop and implement a toolkit customized for this practice. Providers in this office implemented the toolkit to treat children and adolescents ages 5-18 years

diagnosed with a bipolar spectrum disorder or DMDD who are treated with an AAP. Emphasis was given to guideline recommendations for the prevention of weight gain and monitoring of metabolic side effects. The DMDD diagnosis was included in the project because of the possibility of the use of AAPs in the treatment of symptoms. Expected outcomes in respect to use of the toolkit were increased rates of provider compliance with guideline recommendations for metabolic assessment. Other outcome measures included were: completion of metabolic assessment, completion/recording of vital sign measurements, and appropriate laboratory ordering based on guidelines recommendations.

CHAPTER 2: LITERATURE SEARCH PROCESS

Searches for relevant articles were conducted across three electronic databases, CINAHL, PsychInfo, and PubMed. (Appendix B). The sampling frame of the study included research articles that focused on AAP use, the metabolic side effects of AAPs in children and adolescents, toolkit use in quality improvement, evidence-based guidelines, and barriers to the use of practice guidelines. Inclusion criteria included full-text articles published in English between 2007-2017.

The keyword searches included two or more of the following terms: bipolar disorders, atypical antipsychotics, metabolic side effects, weight gain, practice guideline, children, and adolescents. The abstracts of the articles were reviewed and articles were included if they met the inclusion criteria. Duplicate publications of key articles were eliminated. A manual search of the reference lists of key studies and articles was also performed. After a detailed review of the articles, 40 articles met the inclusion criteria of the study.

CHAPTER 3: REVIEW OF LITERATURE

Bipolar Spectrum Disorder Diagnosis in Children and Adolescents

Due to increased awareness, assessment, and treatment options, there has been a surge in the diagnosis of bipolar spectrum disorders (BSD) in younger patients in the United States (Birmaher, 2013; Crowley et al., 2014). The diagnosis of bipolar disorders in youth in the outpatient setting has increased 40-fold in the past 10 years and inpatient hospitalizations for these patients have increased 4-fold (Singh, Ketter, & Chang, 2010). Specifically, approximately 2.7% of persons 12-21 years old have a bipolar disorder with the percentage increasing to 5-6.7% when including those with subsyndromal manic symptoms (Birmaher, 2013; Crowley et al., 2014).

The introduction of the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)* by the American Psychiatric Association (APA) in 2013 introduced significant changes to bipolar spectrum and depressive disorder diagnoses including the addition of the Disruptive Mood Dysregulation Disorder (DMDD) diagnosis for children and adolescents. The DMDD diagnosis was created in response to concerns about the potential over-diagnosis of bipolar disorders in the pediatric population (APA, 2013). This diagnosis can be used in children ages 6 to 18 years who exhibit "Persistent irritability and frequent episodes of extreme behavior dyscontrol (APA, 2013, p. 156)." The age of onset of DMDD symptoms should be before age 10 years. APA (2013, p. 156) diagnostic criteria include:

- Severe, recurrent verbal and/or behavioral outbursts that are out of proportion in intensity and duration to the trigger

- The outbursts are inconsistent with developmental level and occur an average of three or more times a week
- The mood between outbursts is persistently irritable or angry, most of the day, nearly every day, and is observable
- The symptoms are present for 12 or more months in at least two settings and symptoms are not absent for more than three consecutive months
- Symptoms should not be better explained by another disorder, substance abuse, medical, or neurological condition
- The person has never experienced a hypomanic or manic episode and the symptoms occur at other times besides a major depressive episode
- It cannot coexist with Oppositional Defiant Disorder, Intermittent Explosive Disorder, or a bipolar disorder.

In the *DSM-5 (2013)*, bipolar and related disorders include: Bipolar I Disorder, Bipolar II Disorder, Cyclothymic Disorder, Substance/Medication-Induced Bipolar and Related Disorders, Bipolar and Related Disorders Due to Another Medical Condition, Other Specified Bipolar and Related Disorders, and Unspecified Bipolar and Related Disorders. These disorders are based on diagnostic criteria using three episodes of symptoms – major depressive, hypomanic, and manic. Differences among the disorders are based on the presence of certain episodes, severity, length of the episode, and cause.

The diagnostic criteria for a major depressive episode includes five or more of the following symptoms that are a change from normal functioning for at least two weeks: depressed mood (or irritable mood in children and adolescents) or diminished interest or loss of pleasure for most of the day, nearly every day, and changes to appetite/weight, changes to sleep,

psychomotor retardation/agitation, fatigue, feelings of worthlessness or extreme guilt, problems with concentration or decision-making, or suicidal thoughts or actions (APA, 2013). A hypomanic episode is a period of abnormally and persistently elevated, expansive, or irritable mood and increased activity or energy, lasting at least four consecutive days for most of the day, nearly every day (APA, 2013). Three or more (four if the mood is irritable) of the symptoms that must be present in hypomania include: inflated self-esteem or grandiosity, decreased need for sleep, more talkative, flight of ideas or racing thoughts, distractibility, increase in goal-directed activity, and/or excessive involvement in risky behaviors. A manic episode is similar to a hypomanic episode in criteria but the symptoms are more severe and lasts for at least a week (or less if hospitalization is necessary due to the severity of symptoms) (APA, 2013).

To meet diagnostic criteria for bipolar I disorder, a manic episode is required where as a major depressive or hypomanic episode is not required. For bipolar II disorder, the person must have experienced at least one hypomanic and at least one major depressive episode, but cannot have experienced a manic episode. In cyclothymic disorder, hypomanic and depressive symptoms that do not meet criteria for full episodes must be present for at least two years for adults and one year for children and adolescents with persistent symptoms for more than two months at a time. For the diagnosis of substance/medication-induced bipolar and related disorders, mood disturbances (elevation or depression) must occur during or soon after substance intoxication, withdrawal, or medication exposure. The diagnosis of bipolar and related Disorders due to another medical condition is specified when it is caused by a known medical condition evident in history, physical examination, or lab findings. The diagnosis of Specified Bipolar and Related Disorders refers to episodes that do not meet criteria for the number of symptoms for an episode or length of episode, a hypomanic episode without a prior major depressive episode, and

short-duration cyclothymia. Unspecified Bipolar and Related Disorders is diagnosed when symptoms that are characteristic of a bipolar disorder that cause significant distress or impairment that do not meet full criteria for any other bipolar and related disorder. As with DMDD, symptoms of these disorders cannot be explained by another psychiatric disorder, substance abuse, medical or neurological condition (unless otherwise specified) (APA, 2013).

According to the APA (2013), children and adolescents with a BSD are more likely to have increased familial rates of a BSD. Onset of symptoms during childhood or adolescence may be associated with a more severe lifetime course of the illness. In Cyclothymic Disorder, the mean age of onset is 6.5 years of age for children (APA, 2013).

Treatment Using Atypical Antipsychotic Medication

Options are limited for the treatment of bipolar disorders in children and adolescents. Currently, the only AAP medications that are approved by the Food and Drug Administration (FDA) for the treatment of Bipolar I Disorder Mixed/Manic in children and adolescents are: aripiprazole (Abilify) (ages 10-17), risperidone (Risperdal) (ages 10-17), olanzapine (Zyprexa) (ages 13-17), quetiapine (Seroquel) (ages 10-17), and lithium (ages 12+) (Stahl, 2014). Olanzapine in combination with fluoxetine (Symbyax) is approved for ages 10-17 years for the treatment of the depressive phase of Bipolar I disorder (Stahl, 2014). Off label use of AAPs is common practice by providers due to the limited numbers of medications with FDA approval for the symptoms of concern. This includes cases of subsymdromal symptoms, when a specific diagnosis cannot be made, or in cases where another bipolar spectrum disorder besides Bipolar I Disorder is suspected (Olfson, Blanco, Liu, Wang, & Correll, 2012). As the number of AAP medications and indications approved by the FDA increases, the use of AAPs is expected to increase (Olfson et al., 2012).

Another factor contributing to their use is that randomized controlled trials (RCTs) have been conducted in this age group and show they are superior to valproic acid and lithium in treating mania in this population (Crowley et al., 2014). RCTs on newer AAPs that have shown efficacy in adults are now being conducted in the pediatric population. AAPs also have a lower propensity for causing bothersome, acute and chronic extrapyramidal side effects than typical antipsychotics (Olfson et al., 2012). Other efforts have encouraged the use of AAPs including: greater acceptance of mental illness and treatment in general, greater public acceptance of psychiatric medications, and marketing by pharmaceutical companies (Olfson et al., 2012). Their use remains controversial due to the lack of population-specific data, ongoing debate about the prevalence of bipolar illness in children and adolescents, and the potential side effects (Crowley et al., 2014).

Metabolic Side Effects of Atypical Antipsychotic Medications

Atypical antipsychotics (AAPs) are widely used due to their overall efficacy and tolerability, especially when compared to their older counterparts. However, AAPs have a unique side effect profile. Due to their strong binding affinity to the 5-HT_2 serotonin receptor, they can cause metabolic side effects generally not seen in their predecessors (Ronsley, Raghuram, Davidson, & Panagiotopoulos, 2011). The metabolic side effects of AAPs include, but are not limited to: weight gain, increased blood sugar levels, increased triglycerides, and increased cholesterol (De Hert, Dobbelaere, Sheridan, Cohen, & Correll, 2011; Haddad & Sharma, 2007; Koch & Scott, 2012; G. M. Reeves et al., 2013; Walter et al., 2008). The side effects of increased appetite and sedation can increase caloric intake and decrease resting metabolic rate (Harvard Medical School, 2009). These metabolic side effects place patients at increased risk for long-term health implications including: obesity, insulin resistance,

dyslipidemia, hypertension, diabetes mellitus, stroke, coronary heart disease, and earlier mortality (Koch & Scott, 2012; G. M. Reeves et al., 2013; Walter et al., 2008). Weight gain is growing as one of the most troubling side effects and is a significant factor in treatment adherence (Kumra et al., 2008; R. Reeves, Kaldany, Lieberman, & Vyas, 2009). This iatrogenic weight gain can be rapid, profound and may not plateau even after one year on the medication (Kumra et al., 2008). Children and adolescents in the hospital setting who are receiving AAPs are three times more likely to be overweight than unaffected peers (Martinez-Ortega et al., 2013). Adolescents may be more vulnerable to metabolic side effects and are more likely to experience cardiovascular and metabolic disturbances as adults (De Hert, Dobbelaere, Sheridan, et al., 2011; Harvard Medical School, 2009; Jeffrey, 2015).

These metabolic side effects not only lead to physical comorbidities, but also psychosocial comorbidities. These sides effects decrease quality of life, proliferate the stigma associated with mental illness, exacerbate depression and anxiety, negatively influence self-esteem and body image, impact the therapeutic relationship with the prescriber, and lead to decreased treatment adherence despite symptom improvement (Haddad & Sharma, 2007; Harvard Medical School, 2009). Obesity increases the likelihood that the young person will experience bullying, discrimination, achieve lesser educational and employment goals, and have lower incomes as adults (The Joanna Briggs Institute, 2007). The failure to adhere to treatment with AAPs can result in destabilization of psychiatric symptoms and related sequelae of symptom reemergence including mood and behavioral instability, recurrence of suicidal thoughts, and/or psychosis (R. Reeves et al., 2009).

Monitoring of Metabolic Side Effects

The presence of potential metabolic side effects is still severely under-recognized by providers, despite the seriousness of the consequences (Velligan et al., 2013). Patients who suffer from mental illness are less likely to receive the appropriate health screenings in the primary care setting (Velligan et al., 2013). Furthermore, mental health providers may be the only healthcare provider the patient uses for care of any kind (Sernyak, 2007; Suppes, McElroy, & Hirschfeld, 2007; Velligan et al., 2013). These facts further underline the importance of adherence to metabolic monitoring recommendations by psychiatric healthcare providers.

Monitoring of metabolic side effects for patients on AAPs includes: assessment of height, weight, body-mass index (BMI), waist circumference, blood sugar, and cholesterol values. It is of particularly important to monitor these symptoms from day one of treatment as the side effects can be dramatic and may occur early, especially the onset of weight gain (R. Reeves et al., 2009). Failure to monitor for these side effects can lead to increased mortality caused by diabetic ketoacidosis and cardiovascular disease (Owen et al., 2013). Patients diagnosed with a bipolar spectrum disorder or schizophrenia are more likely to die of cardiovascular disease than of suicide (R. Reeves et al., 2009).

Recommendations for Management of Metabolic Side Effects

Numerous studies have been conducted to determine the most effective ways to handle metabolic side effects that may occur with AAP treatment. Both pharmacological and nonpharmacological interventions may be used to manage AAP metabolic side effects, such as, changing to a different AAP with a lower metabolic risk, adding medications such as metformin, topiramate, orlistat, amantadine, or sibutramine, and/or adding a diet and exercise plan (Kumra et al., 2008; G. M. Reeves et al., 2013). Most of the research to date has been conducted with

adults, thus, the efficacy of these approaches for managing AAP side effects in children is limited. (G. M. Reeves et al., 2013). Further, the addition of another medication to the regimen to decrease appetite or to promote weight loss also introduces the risk of destabilizing the child's psychiatric symptoms and introduces the possibility of even more side effects that will need to be managed (Kumra et al., 2008).

Early intervention to mitigate potential side effects is imperative as pediatric patients who have never taken atypical antipsychotic medications in the past are more prone to gain weight rapidly (Correll, Sheridan, & DelBello, 2010; De Hert, Dobbelaere, Sheridan, Cohen, & Correll, 2011). Early intervention programs to prevent weight gain that combine diet, physical activity, and behavioral therapy are shown to be more effective, but do decline in efficacy over time (The Joanna Briggs Institute, 2007; Lowe & Lubos, 2008). Evidence-based behavioral interventions that focus on diet and activity level have been developed for obese children without a mental health disorder, but these have not been tested in children and adolescents taking AAPs (Kumra et al., 2007). Psychoeducational interventions alone to do not seem to impact weight loss (Lowe & Lubos, 2008).

The Stoplight or Traffic Light diet that reduces total energy consumption while teaching smarter food choices has been shown to be successful with improving healthy eating habits in families with children and adolescents (The Joanna Briggs Institute, 2007). Specific interventions, such as providing examples of healthy meals and providing guidance like choosing low-fat or skim milk over whole fat, are more effective than general advice to reduce fat intake in the general population (The Joanna Briggs Institute, 2007). Also, more frequent visits where diet, exercise, and sedentary behaviors are discussed can increase weight loss success (The Joanna Briggs Institute, 2007). One study with adolescents in a group-home setting successfully

demonstrated weight loss and increased physical activity by implementation of the following: reduction of intake of sugar-sweetened beverages, increased fruit and vegetable consumptions, limited screen time to two hours, reduction of trips to restaurants, appropriate portion sizes, limited intake of energy-dense foods, and encouragement of participation in moderate to vigorous exercise for sixty minutes a day (Gephart & Loman, 2013). Another successful study utilized group interventions that focused on: adherence to diet, improved food choices, meal planning, choice of healthier options while eating out, and healthy snack options (Centorrino et al., 2006). Group members made trips to the grocery store together, sampled healthy, easy-to-prepare meals, and participated in individualized fitness training (Centorrino et al., 2006). Mindful eating is another technique that has been studied in families and focuses on slowing the pace of eating, removal of distractions while eating, awareness of internal cues of hunger and satiety, removal of positive and negative judgements from food, and reduction of emotional eating (Knol et al., 2016).

Practice Guideline Recommendations

Evidence-based guidelines can assist psychiatric healthcare providers in the assessment, treatment, and monitoring of metabolic side effects in children and adolescents diagnosed with a BSD who are taking AAPs. Implementation of guidelines can increase the accuracy of assessment and diagnosis, guide treatment and planning, and prevent long-term complications of metabolic side effects of AAPs (Koch & Scott, 2012). Monitoring of side effects can also identify other complications or undiagnosed conditions such as diabetes, hypertension, and hyperlipidemia (Ronsley, Raghuram, Davidson, & Panagiotopoulos, 2011). However, most practice guidelines at this time do not offer specific medication recommendations for a patient by phase of the illness or at the severity level of symptoms (Kumra et al., 2008).

There are four practice guidelines in publication that relate to the population affected by this practice problem (Appendix C). These particular guidelines were selected due to their relevance to the assessment, treatment, and management of metabolic side effects. The guidelines were reviewed and critiqued based on their content, grounding in evidence-based research, and feasibility and applicability to this particular patient population. Though some guidelines have not been updated recently, the foundational information contained in these guidelines is still relevant and pertinent to the purpose of this project. Interventions based on these guidelines can improve practice and thereby improve outcomes for this vulnerable population.

The *Practice Parameter for the Assessment and Treatment of Children and Adolescents with Bipolar Disorder by the American Academy of Child and Adolescent Psychiatry* (McClellan, et al., 2007) outlines recommendations for the assessment and treatment of pediatric patients diagnosed with a bipolar disorder. This guideline includes a synthesis of the literature, epidemiological statistics, disease prevalence and a definition of key terms in regard to the DSM-IV-TR. Included in these guidelines are the risk factors for the development of a bipolar disorder, its clinical presentation, and the controversy surrounding use of this diagnostic label in the pediatric population. Treatment recommendations for pharmacological and nonpharmacological interventions, including Electroconvulsive Therapy (ECT) are outlined based on studies mostly conducted in adults. General guidelines for monitoring symptoms and side effects are included. While the evidence and specific recommendations of this guideline are dated, the key themes of proper diagnosis, appropriate treatment with both pharmacological and nonpharmacological interventions, and ongoing monitoring of symptoms and side effects are still applicable today.

The second guideline reviewed was the *Practice Parameter for the Use of Atypical Antipsychotic Medications in Children and Adolescents by the American Academy of Child and Adolescent Psychiatry* (Findling et al., 2011). This practice guideline is specific to pediatric patients who have been prescribed AAPs and provides recommendations for treatment and monitoring. Each AAP medication is described and includes the findings of studies conducted on that medication, approved indications, target symptoms, and possible side effects (Findling et al., 2011). Although the consistency of information for each medication is lacking, specific side effects and safety concerns are delineated and defined. Other medication information provided includes: suggestions for baseline and continuous monitoring and assessments, dosing recommendations, steps to take if side effects occur, the use of multiple AAPs and other psychotropic medications simultaneously, treatment trajectory and discontinuation, and what to do in cases of treatment failure. This guideline gives special attention to the monitoring of body mass index (BMI), weight, blood glucose, lipids, movement disorders, prolactin levels, heart rate, blood pressure, and electrocardiogram (ECG) changes. While this guideline is more recent and specific than the first guideline above, it does not give specific recommendations for the timing of lab work and vital signs. Again, because of the age of the literature, recent studies and evidence for newer AAPs is not included. Drug-specific recommendations are given for clozapine, quetiapine, and ziprasidone (Findling et al., 2011).

The third guideline was developed by the *Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes* by the ADA, APA, AACE, and NAASO (2004). This guideline was developed due to the recognition of the relationship between AAPs and obesity, diabetes, dyslipidemia, and cardiovascular disease. It uses evidence from the findings of studies to hypothesize possible mechanisms for metabolic disturbances. Metabolic parameters in

this guideline include assessing personal and family history of cardiac and metabolic disorders, weight, BMI, waist circumference, blood pressure, fasting blood glucose, and a fasting lipid panel at baseline and at regular intervals. Providers are also encouraged to educate patients and family members on signs and symptoms of diabetes (ADA et al., 2004). Nutrition and physical activity counseling in general are recommended and possible alternative treatments are suggested (ADA et al., 2004). The limitations of the guidelines and future research needs are also described (ADA et al., 2004). This guideline does not include specific interventions for dealing with metabolic side effects other than referral to a specialist and/or switching to another antipsychotic. It is also does not provide recommendations specific to the pediatric population. The taskforce does recognize that more research is needed to show that early metabolic changes are precursors to long-term implications and whether or not the metabolic changes are due to the medications or the disease process itself (ADA et al., 2004). The age of this guideline and the arrival of new medications can be factors in the lack its implementation by providers.

The fourth practice parameter reviewed was the *Prevention and Management of Obesity for Children and Adolescents by the Institute for Clinical Systems Improvement* (Fitch et al., 2013). While this guideline does not directly address cases of pediatric bipolar disorders and weight gain related to the use of AAPs, it provides comprehensive and specific interventions for prevention, assessment, and management of obesity. Recommendations are grouped by intervention level and the quality and strength of the recommendation. Specific points of teaching are given that can be easily employed during the appointment including, but not limited to, eating dinner together as a family, limiting screen time to two hours or less a day, and eating breakfast daily. Recommendations are given for diet changes, physical activity, sleep, and pharmacological, nonpharmacological, and surgical interventions. Screening and assessment

techniques are broken down by age group and body system and identification of comorbidities is discussed with symptoms, potential consequences, and assessment findings (Fitch et al., 2013). Algorithms for laboratory monitoring provide clear instructions for assessment and follow-up of patients on AAPs (Fitch et al., 2013). A section on assessing the patient's readiness for change using the Transtheoretical Model of Change is included (Fitch et al., 2013). Strategies for implementation address patient, provider, and system barriers (Fitch et al., 2013). Links to high quality Web resources such as HealthPeople.gov and ChooseMyPlate.gov and growth charts are given as well (Fitch et al., 2013). The comprehensiveness of this guideline and its extensive length are both facilitators and barriers to its feasibility. While much information is included that could aid mental health providers in assisting patients with weight loss, the lack of perceived responsibility to provide this education could prevent its implementation. This guideline is quite lengthy, which could impact the feasibility of implementation.

Barriers to Use of Practice Guidelines

There are numerous individual and organizational factors that contribute to the gap between the actual care delivered and the recommended care in a practice guideline. Individual barriers for providers to implement a guideline includes time constraints, personal attitudes, and years of practice experience. Organizational factors that may limit the implementation of guidelines includes the lack of referral systems and appropriate equipment. Finally, patient characteristics may be a barrier to implementation due to embarrassment, co-pay requirements, and transportation needs (Fagiolini, 2008; Jeffrey, 2015; Ronsley et al., 2011; Suppes et al., 2007; Taba et al., 2012; Teeluckdharry et al., 2013).

Provider Barriers. Lack of time is identified by providers as the largest barrier in adhering to assessment, treatment, and monitoring guidelines. Providers report having

inadequate time to review guidelines, perform assessments, interpret lab values, and educate patients on possible metabolic side effects, monitoring guidelines, diet, exercise, and lifestyle changes (Fagiolini, 2008; Jeffrey, 2015; Ronsley et al., 2011; Suppes et al., 2007; Taba et al., 2012; Teeluckdharry et al., 2013). Provider comfort level with conducting assessments, particularly with measurement of waist circumference is another important factor (Fagiolini, 2008; Jeffrey, 2015; Sernyak, 2007; Sugawara et al., 2014; Walter et al., 2008).

The provider's opinion about the guidelines and experience level can impact adherence (Khan et al., 2010; Teeluckdharry et al., 2013). Some find the recommendations impractical, wasteful, expensive, not applicable to their patients, inconvenient and/or too involved or complex (Khan et al., 2010; Sernyak, 2007; Taba et al., 2012; Walter et al., 2008). Some mental health providers do not feel that it is their responsibility to monitor metabolic parameters or that the psychiatric symptom management take precedent over physical health problems (Khan et al., 2010; Ronsley et al., 2011; Teeluckdharry et al., 2013; Walter et al., 2008). Other providers are concerned that providing more education on potential metabolic side effects to their patients will have a negative effect on treatment adherence (Ronsley et al., 2011). Providers with less experience are more likely to adhere to practice guidelines, possibly due to the inclusion of practice guidelines in their education program (Suppes et al., 2007; Taba et al., 2012). Younger providers are also more likely to have a positive outlook regarding guidelines and find them easy to access and use (Taba et al., 2012)

Organizational Barriers. There are also barriers at the level of the organization. Limited accessibility of primary care providers (PCPs) and lack of developed referral systems contribute to inadequate follow-through by the patient, provider, and/or office staff with regards to lab work and other recommendations (Jeffrey, 2015; Sernyak, 2007; Velligan et al., 2013).

Limited access to appropriate anthropometric equipment can also be an issue, especially for smaller offices (Jeffrey, 2015; Ronsley et al., 2011). Others site lack of reimbursement, staff availability, and resistance to change as reasons for noncompliance (Jeffrey, 2015; Sernyak, 2007; Velligan et al., 2013).

Large facilities may have access to additional resources needed to implement practice guidelines, including staff members and technology, for intervention development, implementation, data collection, and compliance auditing (Khan et al., 2010). It is labor-intensive to follow metabolic monitoring guidelines and involves the completion of multiple steps (Velligan et al., 2013). It may be difficult for offices that are under-staffed with limited working capital to comply with the practice recommendations (Sernyak, 2007; Velligan et al., 2013).

The evidence is contradictory regarding the use of practice guidelines in hospital settings as compared with private practice settings. There is some support for greater use by providers in hospital settings who were more likely to measure metabolic parameters, prescribe medications for metabolic derangements, and discontinue medications if metabolic side effects occurred (Suppes et al., 2007). There is some evidence that outpatient offices are more likely to experience barriers related to lack of resources including time and lack of established protocols (Sernyak, 2007; Taba et al., 2012). Yet, in contrast, Perlis (2007) found that community mental health practices were more likely to use practice guidelines and that those in the hospital setting were more likely to cite lack of time as a barrier to their use.

Patient Barriers. Other studies identify patient fear of needles, co-pay requirements, and lack of system support as potential barriers to adherence (Fagiolini, 2008; Khan et al., 2010; Sernyak, 2007; Teeluckdharry et al., 2013). Patient embarrassment with having weight and

waist circumference measured can also be a barrier. Difficulties with access to transportation to appointments or to the lab can impact patient adherence to recommendations. The patient may also lack access to a PCP, specialist, nutritious food, and/or exercise facilities.

Practice Change Interventions

Metabolic monitoring recommendations have been developed and studied by several researchers to improve provider compliance with practice guidelines. While the recommendations vary in the extent of their development, content, and delivery, most focus on increased frequency of monitoring of vital signs and metabolic-related laboratory values. Velligan et al. (2013) argued that knowledge of guidelines and expectations of compliance with guidelines are not enough to change practice. Strategies to facilitate use of practice guidelines include: focusing on early intervention and wellness, accounting for possible barriers to their implementation, improving awareness of the symptoms of diabetes and cardiovascular disease, and increasing awareness of the guideline recommendations through the use of evidence-based standards (Sernyak, 2007).

Implementation of guidelines must be tailored to fit the clinical setting (Velligan et al., 2013). Key to implementation is the establishment of responsibility for who monitors and coordinates care. Successful implementation of practice guidelines requires buy-in from the providers that monitoring is of value, a plan for monitoring, dissemination of the results, and for follow-up treatment (Sernyak, 2007). User-friendly, standardized assessments and order forms and provision of in-house lab draws can reduce potential barriers to implementation (R. Reeves et al., 2009; Ronsley et al., 2011; Velligan et al., 2013). Development of referral networks and collaboration with family physicians, endocrinologists, dieticians, and pharmacists can improve care for and monitoring of patients on AAPs (Khan et al., 2010; Sernyak, 2007).

Researchers at the New Jersey Department of Corrections incorporated an evidence-based monitoring protocol for inmates receiving AAPs (R. Reeves et al., 2009). The protocol included a revised progress note with designated sections for documenting personal and family history of risk factors, frequency intervals for specific metabolic monitoring protocols, clickable boxes for easy ordering of tests, and a user-friendly flowsheet to show changes in values over time (R. Reeves et al., 2009). The program developers utilized key factors that proved to be essential to the success of the project which included support of facility leadership, program prioritization and management, clear roles and assignments, deliberate implementation of the program, collaboration with nursing staff, and individual and management-level follow-up (R. Reeves et al., 2009).

A study at Veteran Affairs facilities in the United States utilized computer-based reminders, a poster display of monitoring and management recommendations, an automated computer system to identify patients due for initial metabolic monitoring, and a psychoeducational weight management program for patients (Owen et al., 2013). Assessment of organizational climate and readiness to change, identification of key staff members and stakeholders to facilitate the implementation of the program, and provider feedback regarding performance were included in the program (Owen et al., 2013).

A program evaluation in Texas employed the development of a new position called the *Medical Assistant for Metabolic Monitoring* who was responsible for ensuring that lab work and vital signs were collected, reviewed by the physician, and placed on the chart (Velligan et al., 2013). The findings of Velligan and others (2013) emphasized the importance of educating employees about the guidelines, who was responsible for each task, normal and abnormal lab values, and how to respond to lab values that were out of range. The research team also used

their computer system to identify patients who were in need of metabolic monitoring who also had appointments within the next week (Velligan et al., 2013).

Practice Toolkits. Care bundles or practice toolkits are quality improvement interventions that focus on improved quality of care through utilization of evidence-based practices and improved compliance with the guidelines (Clarkson, 2013; Yamada, Shorkey, Barwick, Widger, & Stevens, 2015). Use of guidelines and practice bundles have been shown to improve quality of care in other areas of medicine such as ventilator care, care of central lines, and treatment of sepsis (Taba et al., 2012; Wiechers et al., 2012). There are very few studies that critique the effectiveness of the practice toolkit as a quality improvement intervention (Yamada et al., 2015).

Existing evidence supports practice toolkits can increase provider adherence to practice guidelines, but certain measures should be taken during the planning, implementation, and analysis phases to ensure high validity success (Yamada et al., 2015). Toolkits that contain superfluous steps, and/or include components that are not evidence-based can be difficult to implement (Clarkson, 2013). Introduction of too much information at one time, attempting to measure multiple outcomes with one project, and having a quality improvement project that is too complex are pitfalls to avoid with the introduction of toolkits. The interventions should have clear goals identified, should be based on evidence, and tailored to the environment (Yamada et al., 2015). Each piece of the toolkit should be based on high level evidence and its rationale for inclusion should be clear (Yamada et al., 2015). To avoid the common mistake in previous studies using toolkits, the outcome measures should demonstrate that the intervention is responsible for the changes (Yamada et al., 2015).

The findings of two recently published systematic reviews recognized that many of the individual studies failed to attribute the success of the intervention to the toolkit itself (Barac, Stein, Bruce, & Barwick, 2014; Yamada et al., 2015). In some of the studies, the toolkits were a part of a larger intervention and the impact of the toolkit alone may not have been reflected in the outcome measures. Additionally, the individual pieces of the toolkit were not consistently analyzed so the success or failure of that part of the toolkit could have affected the overall outcome (Barac et al., 2014; Yamada et al., 2015).

Strengths and Weaknesses of Existing Research and Utility of Research

There are several strengths in the existing research. Multiple studies have rendered similar results when comparing the level of knowledge of monitoring recommendations to actual practice. There have been studies across different settings and with providers who treat various age groups. Study participants are diverse in training and years of experience, giving a more comprehensive sample. Existing research can be used to tailor interventions to increase use of monitoring guidelines to fit the local setting. Barriers discussed in existing studies can be used preemptively to identify possible solutions.

Weaknesses in the existing literature include reliance on self-reporting of behaviors, conflicting data, and high variability of interventions, which makes comparison difficult. Some studies show conflicting data when in comparison of providers in certain practice settings, and comparison of providers based on years of practice. There is also a lack of consensus on the definition of metabolic syndrome. Most sources agree that metabolic syndrome includes abdominal obesity, elevated triglycerides, low high-density lipoprotein levels, and elevated fasting glucose. There is less agreement on the exact laboratory measurement ranges, the number of required symptoms, and if other measures such as microalbuminuria, coagulation

abnormalities, and/or presence of polycystic ovarian syndrome should be included or excluded (R. Reeves et al., 2009). Some question whether these symptoms are as or more significant collectively than the individual measures.

The results of studies about provider adherence to metabolic monitoring recommendations vary widely. There is also inconsistency in the variables studied. Some look at baseline monitoring at the time of treatment initiation and at regular intervals during treatment. These intervals differ in their frequency across studies. Other studies also look at other factors such as if the labs ordered by the physician were completed, documented in the chart, and viewed by the physician at completion. Inclusion of all these steps is important because it is not enough to order the labs, but to also follow through and take the necessary steps to ensure proper intervention. (Velligan et al., 2013). Many of the studies use self-report of monitoring practices by the providers which data suggests may be an overestimation when compared to actual practices (Suppes et al., 2007).

While the research findings can be useful, there are also concerns related to the feasibility of interventions to increase use of guidelines. High variability in practice sites can make implementation of these programs difficult. In a study conducted in the outpatient setting in Texas, staff members of the intervention clinic could not keep up with the demands of the metabolic monitoring program and also continue to complete other duties (Velligan et al., 2013). For a program to be successful it should be financially feasible and expectations of staff members should be reasonable.

CHAPTER 4: CONCEPTUAL MODEL

Ronald Havelock's (1970) Theory of Planned Change Model guides the design and implementation of this project. Havelock's model involves change agents to facilitate change. This model identifies four roles of a change agent – catalyst, solution giver, process helper, resource linker (Havelock, 1970). Identification of change agents who can fulfill these roles fosters the success of the project. These change agents will encourage the intervention, offer solutions to problems that arise, aid in the flow of the implementation, and who have access to the necessary resources provide critical support. This may take the form of one or more people within the setting. Additionally, the presence of these change agents at different levels of the organization further increases the potential for success of the project.

This model is comprised of six steps: build relationships, diagnose the problem, acquire resources, choose a solution, gain acceptance, and stabilize the change (Havelock, 1970). These steps are addressed in this project's setting. It was anticipated that the existing relationship between the author who is a practicing provider at one of the sites of implementation would facilitate building relationships around a new initiative. The recruitment of an additional DNP-prepared practitioner to serve on the project committee also assisted with the building of the relationship. The problem identification was achieved through recognition of the lack of practice guideline use to address a common practice problem. Resources are acquired through stakeholder involvement and analysis of the population and practice sites. Involvement of management assisted in acquiring resources necessary to carry out the plan. A solution was chosen based on evidence-based research. Involving stakeholders in the planning and

implementation of the project and soliciting their recommendations during the assessment of the project were used to increase acceptance. The change can be stabilized through consistent implementation, data analysis, and modifications as needed.

CHAPTER 5: METHODOLOGY

This project was a practice change initiative that implemented a toolkit developed from the evidence and customized for this setting. The toolkit provided direction for practice change to improve metabolic outcomes in child patients receiving AAPs. The practice change initiative required several phases and its full implementation was beyond the scope of the DNP project. All Phases of the practice change are identified in Appendix R. This project focused on implementation of Phase I. The steps for Phase I included: provider and staff education, implementation of the toolkit focusing on vital sign and BMI measurement and ordering of metabolic labs, and data collection and analysis.

Setting

The setting consisted of a private, outpatient mental health office located in a small city in Western North Carolina. The system is comprised of insurance providers, referring offices, pharmacies, hospitals, and laboratory collection centers. The characteristics of these components influenced the design, implementation, and effectiveness of the project. Due to the overall deficit of mental health settings in the region, this office serves patients from five counties, as well as patients who travel from a neighboring state. The office is accessible by limited public transportation and private vehicle. New patient appointments are allotted 45 minutes and established patient appointments are allotted 15 minutes. Due to a high number of patient no-shows, patients are frequently double-booked for the same time slot. Documentation is completed using written assessments or dictation services; not all assessments are performed

using standardized templates or forms. Electronic medical management software is used only for billing and scheduling purposes.

Referrals come from local primary care offices, inpatient units, crisis stabilization units, hospital emergency departments, mobile crisis community teams, case managers, and other community organizations and facilities. Laboratory offices and outpatient laboratory services through local hospitals are located near the office, some within reasonable walking distance. Urine drug screening is the only laboratory service available at the office.

Practice Change Participants

Providers at this practice include: a Doctor of Osteopathic Medicine (DO), two Psychiatric-Mental Health Nurse Practitioners (PMHNP), and a Physician Assistants (PA). These providers vary in their experience and years of practice ranging from a new-graduate PMHNP in his first year of practice to more than 40 years of experience for the DO. Other staff members include substance abuse therapists, office assistants, laboratory staff members, an office manager, and the directors of the clinic.

Stakeholders

Employees with greater receptivity to change were used as key stakeholders and role-models for those who were more resistant. Relationship-building to support this practice change was key for success. The participants in this project included people of diverse educational backgrounds and roles within the organization; therefore, it was imperative to have key stakeholders for each level of employee. To build relationships and gain acceptance, it was important to understand current job roles, clarify each member's role in the practice change initiative, identify interaction between roles, and understand how roles would be impacted by the practice change. Providers who were more open to quality improvement projects were used as

early adopters in hopes of encouraging other providers to participate. Those in management positions were key to the success of the project through demonstration of their support for the initiative. Managerial support occurred by ensuring providers had the proper equipment necessary for the completion of the assessments, verbalizing support of quality improvement efforts, and following up with providers regarding their participation. This project highlighted the need for evidence-based practice and quality improvement initiatives for those in all positions. There is not a person in the office designated to oversee quality improvement; therefore, discussion with management of the importance of quality improvement projects was important. Collegial discussion promoted relationship-building and created an opportunity to recognize the need for improvement. Stakeholders expressed interested in implementation of the project to raise the quality and safety of care.

Ethics and Human Subjects Permissions

This practice change project was submitted to the Office of Human Research Ethics at the University of North Carolina at Chapel Hill. It determined by this office that this submission did not constitute human subjects research as defined under federal regulations and did not require Institutional Review Board (IRB) approval.

Recruitment

All providers and involved staff members were encouraged to participate in the project implementation. Ideally, the project would be implemented with all patients who met the criteria. The providers had the ability to implement these assessments and interventions without the use of the toolkit contents; therefore, there was not an ethical dilemma if the provider failed to adapt to the practice of toolkit use.

Toolkit Development

The evidence supports toolkits can be effective in improving provider adherence to guidelines while addressing some of the barriers discussed previously (Clarkson, 2013; Yamada et al., 2015). A toolkit was developed and implemented as a guideline and to provide structure and reminders for best practice. This site relies on paper records. Without the standardization of electronic documentation with associated alerts, limited treatment time, and range of provider experience, consistent evidence-based practice often presented a challenge. Due to the scope of the toolkit and the culture of the practice change setting, it was planned to introduce the toolkit in three phases. Phase I was introduced and included recommendations based on the Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes by the ADA, APA, AACE, and NAASO (Appendix A) (2004). Phase I toolkit contents included the following resources:

- practice guideline recommendations (Appendix A)
- standardized personal and family metabolic history assessment (Appendix D)
- laboratory documentation form based on recommended schedule (Appendix E)
- vital sign documentation form (Appendix F)
- standardized laboratory ordering forms (Appendix G)
- normal laboratory ranges (Appendix H)
- preprinted referral forms for primary care providers and specialists (Appendix I)
- release of information form
- patient/caregiver education handout (Appendix J)
- list of tasks and the staff responsible (Appendix K)
- audit tool (Appendix L)

- communication checklist (Appendix M)
- interventions documentation form (Appendix N)
- tips for using the measuring equipment properly (Appendix P)

The information was organized in a file folder and assembled by office support staff. Each provider had a supply of pre-made folders in his or her office. From a workflow perspective, toolkit availability would eliminate time and effort required to locate the necessary resources. Other resource forms provided in Phase I of the project were included for the provider's convenience for reference and were not measured for compliance during the initial phase. For example, information regarding location of laboratory testing was also included in the toolkit so providers would know where to direct the patient for those ancillary services (Appendix G). The extra resources were included to streamline the process of information seeking. The goal was to facilitate the incorporation of best practices through use of the toolkit to complete the desired tasks.

Provider and Staff Education

The toolkit was introduced to providers and other staff members during a staff meeting outside of business hours to allow for adequate time to review the contents and to ask questions if necessary. The staff meeting allowed providers and other staff members involved in the project's implementation the opportunity to provide input into the toolkit design and implementation before project initiation. This inclusive meeting encouraged shared decision-making and was important to gain buy-in of the project. An explanation of the necessity for this intervention and a plan for its implementation was discussed. During this education phase, it was emphasized that the providers have the responsibility to monitor for potential side effects of the medications they prescribe (Sernyak, 2007). The project process and flow were explained.

All participants were given a handout that contained a summary of the literature review, the proposed project, the proposed methodology, data collection methods, outcome measures, timeline of implementation, and a sample toolkit.

Due to constraints of allotted time for appointments, providers were encouraged to consider review of the contents of the toolkit with the patient and caregivers during a separately scheduled appointment. Education was provided about documentation and billing tips for this type of appointment. For example, the appointment could be billed as a follow-up with a therapy add-on code due to the amount of time spent discussing interventions and engaging in psychoeducation. Providers were reminded to review the chart at each visit to ensure that proper follow-up had taken place. Roles and responsibilities of staff members were delineated and distributed so each staff member and provider understood who was responsible for the execution and follow-up tasks within the organization (Appendix K).

Providers and staff members had the opportunity to practice vital sign measurement with the new equipment to ensure knowledge of proper techniques as the staff members and providers may be unfamiliar with the equipment.

The providers and staff members expressed much enthusiasm for the project. Discussion focused on the use of the toolkit with patients other than children taking AAPs, the logistics of implementation of the toolkit, and which resource forms might be optional. One provider voiced concerns about how time-consuming implementation of the toolkit would be. It was emphasized for each provider to review the toolkit and attempt implementation so that further concerns could be addressed before the project went live.

Outcomes and Outcome Measures

Four outcome measures were identified for Phase I of the project:

1. The toolkit was employed during the care of patients ages 5-18 years diagnosed with a BSD or DMDD who were taking an atypical antipsychotic (new start or continuation)
    a. presence of toolkit contents in the chart
    b. color sticker affixed to outside of chart
2. Personal and family history assessment of metabolic problems were completed by the provider.
    a. completed assessment form in the chart or within the progress note (Appendix D)
3. Metabolic laboratory studies were ordered at chronological increments recommended by the guidelines
    a. documentation of the order by the provider in the visit note or by presence of a copy of the order form in the chart (Appendix G)
4. Vital signs (specifically blood pressure, height, weight, BMI, and waist circumference) were taken at chronological increments recommended by the guidelines
    a. documentation of each of the vital signs on the documentation form (Appendix F)

Implementation Process

After the completion of the education session, the preliminary testing of the toolkit began. The implementation timeline can be found in Appendix O. A toolkit was to be utilized upon identification by the provider of a patient within the project population. A colored sticker was included in the toolkit for the provider to affix to the chart. This allowed for identification of the chart during data collection. The contents of the toolkit were to be added to the patient's chart or given to the patient if applicable. The providers were to use the practice guideline recommendations to order necessary labs, assess vital signs, and perform assessments based on recommendations for the specific patient.

Plan-Do-Study-Act (PDSA) cycles were used to refine the toolkit contents and implementation process. Cycle 1 consisted of implementation of the toolkit by two providers, who utilized the toolkit with two child patients. Following Cycle 1 minor revisions were made based on recommendations from the providers and office staff. This included reformatting of the vital sign documentation form to ensure that there was a designated place to document waist circumference. Other feedback included lack of clarity about which forms were mandatory and differences in preference among providers about whether or not to keep in the toolkit reference forms that were not mandatory. These requests were reviewed with the office staff member tasked with making the toolkits for the providers and the solution was that toolkits would be customized for individual providers.

After integration of the feedback from Cycle 1, Cycle 2 began with the addition of a third provider. Each of these three providers used the toolkit with three patients. No revisions were recommended after completion of Cycle 2. A fourth provider was added for Cycle 3. The fourth provider did not employ the toolkit with any patients. This provider reported there was insufficient time to do so. Despite efforts to streamline the process to address individual concerns, the provider chose not use the toolkit. These quick PDSA cycles allowed for fast turnaround and were effective in identifying weaknesses. The first three cycles were solely for the purposes of toolkit content and process refinement. The solutions identified from feedback after Cycle 1 proved effective for three of the providers and for office staff members. These were presented to all office staff and providers at the conclusion of Cycle 3.

PDSA Cycles 1-3 prepared the staff and providers for the official cycle - Cycle 4. This final cycle included all office staff and providers. The toolkit was to be utilized with all patients within the project population. Data for adherence rates was collected in Cycle 4.

CHAPTER 6: DATA COLLECTION AND DATA ANALYSIS

A pre-implementation collection of data using chart audits took place to obtain a numerical baseline for the outcome measurements. An audit tool was used to assist in the chart audit (Appendix L).

Table 1: Summary of Chart Audit Data

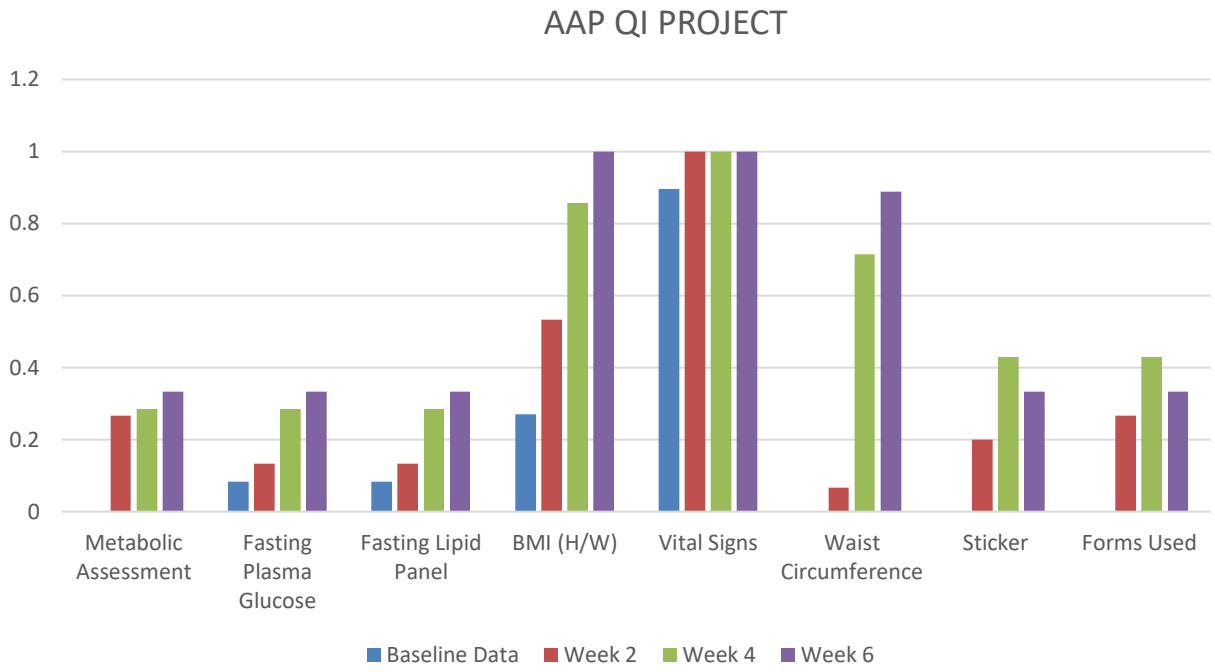
	Week 0 %	**Week 2 %**	**Week 4 %**	**Week 6 %**
Date of Audit		**10/22/17**	**11/5/17**	**11/19/17**
Dates Audited		**10/9-10/20**	**10/23-11/3**	**11/6-11/17**
Outcome Measure				
Fasting Plasma Glucose	8.3	13.3	28.6	33.3
Fasting Lipid Panel	8.3	13.3	28.6	33.3
Height/Weight	27.1	53.3	85.7	100
Vital Signs	89.6	100	100	100
Waist Circumference	0	6.7	71.4	88.9
Metabolic Assessment	0	26.7	28.6	33.3
Sticker on Chart	0	20	42.9	33.3
Forms on Chart	0	26.7	42.9	33.3
Number of Charts Reviewed	48	15	7	9

A total of 48 charts met the inclusion criteria and were reviewed for the existence or absence of the specific outcome measures prior to project initiation. Data from the baseline chart audit showed low rates of compliance (Appendix Q). Fasting plasma glucose and fasting lipid profile labs were current on only 8.3% of patients. BMI measurements were completed on 27.1% of patients. Vital signs (blood pressure, pulse) were completed on 89.6% of patients, the highest rate of compliance. None of the charts audited during the collection of baseline data showed evidence of a metabolic assessment or waist circumference measurement.

This baseline data was shared with stakeholders (office staff and providers) during staff/provider meetings prior to project implementation. Goals for improvement change were established by the respective staff or provider. The office staff identified a goal of 100% compliance for documentation of vital signs, height and weight, and waist circumference. Providers identified a goal of 100% compliance with ordering lab work, metabolic assessment, and 100% compliance of use of toolkit within the project population; and, to also use the toolkit with other applicable patients.

Measurement of these outcomes were accomplished with the final PDSA cycle (Cycle 4). Start and end dates for the final six-week-long PDSA cycle were scheduled after the completion of the first three cycles. Three chart audits were conducted at two-week intervals during this final cycle. The electronic schedule was used to identify patients who fell into the age category targeted during this practice improvement project who were seen for an appointment during the previous two weeks. These charts were then reviewed to determine they met the inclusion criteria of diagnosis and treatment. The charts of patients 18 years of age and younger, with a diagnosis of a bipolar mood disorder or DMDD, being treated with an atypical antipsychotic, were then reviewed for provider compliance with the outcome measures.

Graph 1: Compliance Data



It was important that each individual intervention was measured independently in order to identify potential barriers and points of failure. Provider compliance rates were calculated for each outcome for individual providers and the practice as a whole. Outcome measurement data was documented using run charts and results were displayed at the completion of each of the three chart audits in a central location visible to all staff members (Appendix Q).

Providers were given their individual rates after each audit to show their individual progress and areas for improvement. Each measure was scored independently and if applicable, the results were reviewed to see if components were more likely to completed independently or clustered with other outcomes.

CHAPTER 7: DISCUSSION AND IMPLICATIONS FOR PRACTICE

Upon completion of PDSA Cycles, evidence of successful implementation included increases in the incidences of compliance with the practice guideline recommendations of metabolic history-taking and assessment, laboratory and vital sign monitoring, and appropriate follow up. By the end of the implementation time period, the outcome measures of BMI and vital signs reached 100% compliance. The outcome measure of waist circumference improved from 0% to 88.9%. The completion of a metabolic assessment increased from 0% to 33.3%.

The use of the standardized metabolic assessment form in the toolkit and the use of the sticker for identification was a new practice, therefore there was no baseline data. Outcome data for these two measures increased from baseline to Week 2 and to Week 4 chart audits, then decreased during Week 6 audit, for a final rate of 33.3% for both measures.

The outcome measures for BMI, vital sign, and waist circumference measure were clustered together because these measurements were conducted by the same two office members. Both outcome measures pertaining to labs appeared to be clustered together possibly because they were ordered on the same form. While possible, it was unlikely that the provider would order one lab and not the other at the same time. In all instances, both laboratory markers were ordered together, as indicated by their identical rates of compliance. While the vital signs, height, weight, and waist circumference were listed on the same form, this was not a guarantee that they would all be performed. Along the same line, having the assessment forms, sticker, and other toolkit forms in one folder did not translate into the use of the individual parts. This is evident by the variations in rates of compliance for these outcome measures.

While the qualitative feedback from the providers and office staff members supported the use of the toolkit, the variations in compliance with each piece of the toolkit did not demonstrate that having these items packaged together made any significant impact on their use. The increased rates of compliance could be attributed to the increased awareness created by multiple discussions and visual reminders of the project goals. Having a standardized metabolic assessment and the lab order form included in the toolkit improved compliance rates with each of these measures. While a standardized metabolic assessment is not necessary to be in compliance with the practice guideline recommendations, this form served as a visual reminder and allowed for quick documentation of the patient's metabolic and family history. The inclusion of the lab order form also served as a visual reminder and increased compliance rates. The main differences in the compliance rates were with who was assigned the task(s). The office support staff members had the highest rates of compliance and the greatest improvement in compliance rates for the tasks for which they were responsible (vital signs, height, weight, and waist circumference). Provider experience level did not appear to play a role as both the providers with the least and the most years of experience had the lowest rates of compliance.

During Cycle 3 of the project it was revealed that two providers had requested that an office staff member complete the metabolic assessment form. The office staff member had agreed to complete the forms. The metabolic assessment is a function of a clinically trained provider, not of administrative staff. The purpose of the metabolic assessment and the intent of the toolkit were reviewed with the staff member and the two providers. It was emphasized that assessments completed by someone other than the designated person would not be counted as compliant during the chart audits. The providers complied with filling out the assessments after the discussion. These providers reported a lack of time to implement the toolkit as the reason for

outsourcing this task. This incident highlighted the work-arounds that providers may employ. The value of relationship-building in the Theory of Planned Change Model was exemplified during this exchange: open discussion by staff and providers, honest feedback about perceived/actual barriers, and resulting behavior change that supported the practice change. This type of interaction is important to stabilize change. The use of this particular model was not successful with all of the individual providers. This speaks to the other internal and external factors that prevent providers from utilizing clinical practice guidelines, much like those found in the literature.

One of the providers involved had initially been very enthusiastic for the project and voiced support for the project and the need for providers to be more accountable for the monitoring of metabolic side effects. Yet, as the implementation ensued, this provider was increasingly challenged by timely completion of documentation. As a result, this provider did not employ the toolkit with any patients during the period of data collection. Discussion with this provider (relationship building) revealed the PMHNP role was new and the quantity of new patients being seen was overwhelming. This highlighted an important consideration in the implementation of practice change. Administrative and clinical staff are seldom at the same experience level and will likely require different amounts of training and support to effectively engage with the change process. Awareness of the differing levels of support was also important to ensure stabilization of change.

Another provider voiced concerns regarding the toolkit at the initial staff/provider meeting. This provider did not provide input during the initial testing and did not complete any of the assessments independently. When challenges with participation in the project by these two providers were initially identified, individual changes were made to the contents of the

toolkits supplied to these providers. Only the absolutely necessary forms (metabolic assessment form, lab ordering forms, patient education handout, and sticker) were included in their toolkits in an effort to secure their buy-in, experience the project as less overwhelming and time consuming. This attempt was unsuccessful, as neither provider implemented the trimmed toolkit.

When office management realized a provider did not value the outcomes of toolkit use and was not going to cooperate or participate in the project, the decision was made to transition patients who met the criteria for the project off of this provider's caseload. This lack of willingness to use the established practice guidelines with the project population was considered a quality and safety issue for patient care. Discussion with office management resulted in a solution that maintained high quality and safety for patients and for the office. This exemplifies a management-level decision that promotes effective stabilization of change.

Despite improvements in compliance rates after the implementation of this practice change project, there is still significant room for improvement. There were changes in practice in this setting, but not with every provider, not consistently over time, and not with every patient. These outcomes are supported in the literature (Wiechers et al., 2012). Even though the compliance rate in many of the studies improved, the rates were not notably higher. The design of the intervention seemed to account for more patient and organization barriers. While many attempts were made to account for barriers at the provider level, it was impossible to mitigate all of them.

A debriefing with office staff and providers was conducted to review the data results, elicit feedback, and determine if more PDSA cycles are needed for Phase I, or if Phase II could commence. The biggest barrier to implementation of Phase I of the toolkit was the lack of time

to complete the forms. Providers felt it was too time consuming to fill out the metabolic assessment and order labs, yet no one utilized the suggestion of scheduling a separate appointment to focus solely on the toolkit contents. There was not a particular reason identified by providers for not using this strategy. This feedback from providers was congruent with previous studies. None of the providers verbalized that they did not feel like monitoring metabolic parameters was their responsibility nor did they voice concern that monitoring metabolic changes would impact treatment but it is certainly possible that they did feel this way but did not verbalize it.

Despite the perceived barriers, all staff and providers believed it was a good idea to have this type of project because it kept evidence-based practice in the spotlight and provided reminders for safe practice. This recognition of the value and necessity for practice guidelines did not translate into the consistent use of those guidelines. The disconnect between knowledge and behavior is well supported in the literature. Although use of the Phase I of the toolkit contents was not yet sustained, positive feedback included having an actual toolkit with all of the necessary information in one accessible folder. The consensus of the staff and providers was that more time was needed to further cement this new process before moving on to Phase II of toolkit implementation.

Future phases of the project will incorporate: a nutrition and activity assessment, side-effect assessment scales, risk assessments, medication indications, side effect management suggestions, educational material describing the illness, treatment options, side effects, and ways to manage side effects.

CHAPTER 8: STRENGTHS AND LIMITATIONS OF THE PROJECT

There were several strengths of this project. This project was based on high levels of research evidence. It was tailored according to the current resources available at the practice location and composition of the setting. The large quality improvement project was divided into smaller phases to avoid overwhelming participants, encourage buy-in, simplify a larger project, to avoid measuring too many outcomes at once, and to monitor progress with incremental changes before moving on to the next phase. There was sufficient evidence to demonstrate the immediate need for action. Many of the actions involved in the project required little effort to complete. The contents of the toolkit were evidenced-based and tailored to each provider to avoid superfluous steps. The rationale for the inclusion of each part of the toolkit was explained. A reasonable amount of information was introduced at one time and reiterated throughout the study. The outcomes, tasks, and roles, were clearly defined. The outcome measures were measured objectively and not based on self-reported data like some previous studies on provider adherence. The necessary tools and equipment to complete the tasks were readily available and in working condition.

One major weakness of this project was the insufficient mitigation of the productivity-focused culture. It was not enough to encourage the providers to schedule an additional appointment. More could have been done to plan for longer appointment time slots for patients meeting the criteria for toolkit use to reduce the impact of time as a barrier. Other weaknesses of the project were related to factors not immediately changeable. The office had not transitioned to electronic charting which affected the implementation and evaluation of the project. The

requirement of a paper-based toolkit lowered its transferability to a similar setting. There was not a way to obtain blood work on site, which may impact patient compliance with fulfillment of the provider order and thereby impact compliance with filing and reviewing results. As this portion of the project did not focus on interventions for metabolic side effects, the providers may not have seen the benefit of the assessments.

CHAPTER 9: SUSTAINABILITY

The cost of this project to the offices was minimal. One office staff member was assigned the task of ensuring that the toolkits were always readily available for providers. The initial cost of purchasing additional measuring equipment was minimal as the office already had most of the necessary equipment. Practice change initiatives can decrease productivity initially. This would impact the revenue during the implementation phase. However, if providers utilized the technique of scheduling more frequent appointments to monitor side effects and implement interventions, more revenue could be produced for the practice. Continuous assessment of barriers after implementation is imperative to adjust the process as needed. Feedback from office staff members and providers is required for continuous process improvement. Identification of issues (diagnosis of the problem) and problem-solving (solutions) of these issues leads to improved quality and safety of care and improved health outcomes for these patients. PDSA cycles as additional phases of implementation occur are necessary to assist with identification of barriers to implementation and further evaluate the components of the toolkit, tailoring the toolkit to the needs of the office.

CHAPTER 10: RECOMMENDATIONS FOR THE FUTURE

For this project, streamlining the process may assist in decreasing the feeling that time is a barrier. Implementation of an electronic medical record could greatly assist in this process. Strategic scheduling could also assist with the time barrier. If patients could be identified in the scheduling system, scheduled for a longer appointment that was designated to discuss the toolkit, there would not be as much pressure to rush through the appointment. Strategic interaction with office management to provide education about quality and safety as it relates to established practice guidelines would improve understanding of potential liability and promote discussion about solutions for system change.

This project highlights several other areas for future study. Because of the seriousness of the potential side effects and long-term consequences, there are ethical concerns regarding standards of care and safe practice by providers. Those in management roles need guidance in addressing these issues with their employees to maintain high quality and safe care delivery. Other studies could look at cost-models like those used in the treatment of asthma to explore the creation of protocols that would include the addition of a nurse to the practice who could execute standing orders and assist with following practice guidelines.

Future studies will be necessary to conclude if process improvements translate to patient outcome improvements. Providers often have concerns with time requirements for the use of guidelines as well as the amount of time they take to develop and the frequency with which they are updated (Taba et al., 2012).

This is of particular concern regarding the currency of guidelines that include recommendations for newer AAPs that come to market. Given this evidence, there are ample opportunities for future research in the problem itself, and in the practice changes to solve the problem.

APPENDIX A: MONITORING PROTOCOL FOR PATIENTS ON SGAS

*Monitoring Protocol for Patients on SGAs**

	Baseline	4 Weeks	8 Weeks	12 Weeks	Quarterly	Annually	Every 5 Years
Personal/Family History	X					X	
Weight (BMI)	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

Note. SGA = Second-Generation Antipsychotics; BMI = Body Mass Index.

*More frequent assessments may be warranted based on clinical status.

Adapted from American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, & North American Association for the Study of Obesity. (2004). Consensus development conference on antipsychotic drugs and obesity and diabetes. *Diabetes Care* 2004; 27: 596-601.

APPENDIX B: DATABASE SEARCH STRATEGY

Date	Search Engine	Search Terms	Search Limits	Results
9/18/16	CINAHL	Atypical antipsychotic* OR second generation antipsychotic* AND discontinua*AND (child* OR adolescen*)	Sept 2006 – Sept 2016, English	1,150
9/18/16	PubMed	(Atypical antipsyhotic* OR second generation antipsychotic*) AND discontinua* AND (child* OR adolescen*)		36
9/18/16	PsycINFO	Atypical antipsychotic* OR second generation antipsychotic* AND discontinua*AND child* OR adolescen*	2006-2016, English	210,398
9/18/16	CINAHL	weigh* AND gain* AND child* OR adolescen* AND consequenc* OR effec*	Sept 2006 – Sept 2016, English, all child (age)	101,449
9/18/16	CINAHL	weigh* AND gain* AND child* OR adolescen* AND consequenc* OR effec* AND iatrogen*	Sept 2006 – Sept 2016, English, all child (age)	5,438
9/18/16	CINAHL	iatrogen* ANDweigh* AND gain*	Sept 2006 – Sept 2016, English	12
9/18/16	CINAHL	weigh* AND gain* AND child* OR adolescen* AND consequenc* OR effec* AND iatrogen* OR adverse	Sept 2006 – Sept 2016, English, all child (age)	45,794
9/18/16	CINAHL	weigh* AND gain* AND child* OR adolescen* AND atypical antisphyschotic* OR second generation antipsychotic*	Sept 2006 – Sept 2016, English, all child (age)	1,909
9/18/16	CINAHL	side effect* OR adverse AND effect* OR consequence* AND treatment* OR relationship	Sept 2006 – Sept 2016, English	361,696
9/18/16	CINAHL	patient AND attitude OR percep* AND treatment AND compliance OR adherence	Sept 2006 – Sept 2016, English	75,874
10/1/16	Clinical Key	Weight atypical antipsychotic		2,980
10/1/16	Clinical Key	Weight atypical antipsychotic	Guidelines, full text articles	1690
10/1/16	Clinical Key	diet exercise weight child* adolescent	Guidelines, full text articles	1947
10/1/16	Clinical Key	diet exercise weight child* adolescent parent	Guidelines, full text articles	1330
10/1/16	Clinical Key	diet exercise weight child* adolescent atypical antipsychotic	Guidelines, full text articles	90
10/1/16	Joanna Briggs	“weight management” OR diet OR exercise AND child* OR adolsce*		113
10/1/16	PubMed	diet OR exercise OR "weight management" AND child* OR adolescen* AND parent* AND theor*		4394
10/15/16	National Guideline Clearinghouse	Atypical antipsychotic		27
10/15/16	National Guideline Clearinghouse	Second generation antipsychotic		53
10/15/16	National Guideline Clearinghouse	Bipolar AND children		28
10/15/16	TRIP	Bipolar disorder children adolescents	Guidelines	210
10/15/16	PubMed	bipolar disorder* children adolescent*	Guidelines, practice guidelines	17
10/15/16	CINAHL	Bipolar AND children OR adolescen*	Practice guidelines, 2006-2016	1
10/25/16	PubMed	((((((((((provider*) OR prescribe*) OR clinician) OR physician) OR practitioner) AND complian*) OR use) OR utiliz*) AND lab*) OR monitor*) AND atypical antipsychot*) OR second generation antipsych		631

APPENDIX C: SUMMARY OF FOUR PRACTICE GUIDELINES SUMMARY FOR CHILDREN AND ADOLESCENTS WITH BIPOLAR DISORDER

Guideline	Target Population	Focus	Contents	Limitations
Practice Parameter for the Assessment & Treatment of Children & Adolescents with Bipolar Disorder (McClellan, et al., 2007)	Children and adolescents with a bipolar disorder	Assessment and treatment	Historical context, epidemiological statistics, prevalence; risk factors; clinical presentation; screening, diagnosis, and treatment recommendations; monitoring symptoms and side effects	Based on DSM-IV-TR criteria, vague and generic recommendations, based on studies conducted in adults, the age of the guideline, lengthy, dense guideline
Practice Parameter for the Use of Atypical Antipsychotic Medications in Children & Adolescents (Findling, et al., 2011)	Children and adolescents	Prescribed atypical antipsychotic medication	Recommendations for treatment and monitoring; breakdown of AAPs (study results, indications, target symptoms, side effects); recommendations for interventions in the case of side effects	Age of the guideline, vague and generic recommendations, based on studies conducted in adults, lacking information on newer medications
Consensus Development Conference on Antipsychotic Drugs & Obesity & Diabetes (ADA, et al., 2004)	Adults	AAPs and metabolic side effects	Discussion of the relationship between AAPs and physical conditions; recommendations for assessment and monitoring of metabolic side effects; nutrition and physical activity counseling recommendations	Age of the guideline, vague and generic recommendations, based on studies conducted in adults
Prevention & Management of Obesity for Children & Adolescents (Fitch, et al., 2013)	Children and adolescents	Obesity	Teaching recommendations; diet, activity, sleep, interventions, screening, and assessment recommendations; links to outside resources; implementation strategies	Extensive length, age of guideline

APPENDIX D: METABOLIC ASSESSMENT FORM

Patient Name: _____ DOB: _____

Assessment Date: _____

It is recommended that this assessment be completed at **baseline and **yearly** thereafter when initiating treatment with an atypical antipsychotic medication.*

Psychiatric Diagnosis(es):
_____

Medical Diagnosis(es): _____

Personal and Family History:

	No	Yes	Unknown	1st Degree Relative	2nd Degree Relative
Diabetes		__ Type 1 __ Type 2 __ Gestational			
Hyperlipidemia					
Cardiovascular Disease					
Obesity					

Risk Factors:

	No	Yes	
Smoking			___ cigarettes/day
Physical Activity			___ mins/day
Screen Time			___ mins/day
Sugar-Sweetened Beverages			___ cans of soda/day ___ juice boxes/day
Fast/Fried Foods			___ meals/week

Adapted from: BC Mental Health & Substance Use Services (2014). Metabolic assessment, screening, & monitoring tool. Accessed from http://www.bcchildrens.ca/health-professionals/clinical-resources/endocrinology-diabetes/atypical-antipsychotics.

APPENDIX E: PROVIDER DOCUMENTATION FORM

Use this form to document pertinent lab and vital sign values under the date of collection.

Patient Name: _____ DOB:_____

Date Completed → / Result Documented ↓									
Hx Completed									
Weight									
BMI									
Waist Circumference									
Blood Pressure									
Fasting Blood Sugar									
Fasting Total Cholesterol									
Fasting LDL-C									
Fasting HDL-C									
Fasting Triglycerides									
AST									
ALT									
TSH									
Free T4									
Prolactin									

Adapted from: BC Mental Health & Substance Use Services (2014). Metabolic assessment, screening, & monitoring tool. Accessed from http://www.bcchildrens.ca/health-professionals/clinical-resources/endocrinology-diabetes/atypical-antipsychotics

APPENDIX F: VITAL SIGN DOCUMENTATION FORM

Patient Name: _____ DOB:_____

Date	Height	Weight	BMI	Blood Pressure	Pulse	Respirations	Staff Signature	Provider Signature

Date	Waist Circumference	Staff Signature	Provider Signature

APPENDIX G: LAB ORDER FORM

You are due for LABWORK!

LABCORP

809 N. Lafayette St.
Shelby, NC 28150
Hours: M-F 7:30AM-1:00PM 2:00PM-4:30PM

640 Summit Crossing Pl Ste 206
Gastonia, NC 28054
Hours: M-F 7:30AM-5:00PM

CaroMont Outpatient Lab

2555 Court Drive, Ste 120
Gastonia, NC 28054
Phone: 704-834-4335
Hours: M-F 6:30AM-5:00PM

Carolinas Healthcare System – Kings Mountain
706 West Kings Street
Kings Mountain, NC 28086
Phone: 980-487-5000

Carolinas HealthCare System – Cleveland

201 E Grover St.
Shelby, NC 28150
Phone: 980-487-3000

Rutherford Regional Health System
288 S. Ridgecrest St.
Rutherfordton, NC 28139
Phone: 828-286-5123

INSTRUCTIONS:

Take this form with you to have the labs completed.

Labs can be drawn at any Lab Corp or Outpatient Lab at your nearest hospital.

Please do NOT eat or drink anything after midnight the night before your blood work is drawn. After your visit, you may eat and drink normally.

Please note that failure to have blood work drawn may result in a delay in your medications being filled. Lab work is an important tool in treating you safely and effectively.

Thank you!

Patient Name: _____ DOB: _____

Date of Order: _____

*Monitoring Protocol for Patients on AAPs**

	Baseline (0-3weeks)	4 Weeks	8 Weeks	12 Weeks	Quarterly (4-11 months)	Annually	Every 5 Years
Fasting Plasma Glucose	X			X		X	
Fasting Lipid Profile	X			X			X

Atypical Antipsychotic Lab Protocol

(Please circle the lab(s) you wish to order)

Fasting Glucose

Fasting Lipid Panel

Other labs:

Prolactin level

Fasting Insulin level

CBC w/ diff

CBC w/o diff

Other(s): _____

Diagnosis Code(s): _____

Provider Signature: _____ Date: _____

APPENDIX H: METABOLIC LAB VALUE REFERENCES TABLE

Metabolic Lab Value References

Test	Specimen	Conventional Units	SI Units
Cholesterol			
High-density lipoprotein (HDL-C)	Plasma	≥ 40 mg/dL	≥ 1.04 mmol/L
Low-density lipoprotein (LDL-C)	Plasma	≤ 130 mg/dL	≤ 3.36 mmol/L
Total (TC)	Plasma	150–199 mg/dL	3.88–5.15 mmol/L
Triglycerides (desirable level)	Serum	< 250 mg/dL	< 2.82 mmol/L
Fasting Glucose	Plasma	70–105 mg/dL	3.9–5.8 mmol/L

Wians, Jr, F. (2017). Blood tests: Normal values. Accessed from http://www.merckmanuals.com/professional/appendixes/normal-laboratory-values/blood-tests-normal-values#v8508814.

APPENDIX I: REFERAL FORM

Date: _____

Patient's Name: _____ DOB: _____

From: Referring Provider: _____

To: Provider Name: _____ Fax Number: _____

Reason for Referral: _____

_____

_____

Attachments:
□ Lab work
□ Note(s)

Date Referral Sent: _____ Staff Signature: _____

Appointment Made: _____

Additional Notes: _____

_____

_____

APPENDIX J: PATIENT EDUCATION HANDOUT

Atypical Antipsychotics & Metabolic Monitoring

What are they?

- Atypical antipsychotics (AAPs) are a class of medication used to treat certain mental health symptoms and disorders
- The most common ones used in children and teens are:
    - Seroquel (quetiapine)
    - Risperdal (risperidone)
    - Zyprexa (olanzapine)
    - Abilify (aripiprazole)
    - Geodon (ziprasidone)

Why are they used?

- In children and teens, these medications are commonly used to treat symptoms such as:
    - Aggression
    - Mood swings
    - Behavioral difficulties
    - Hallucinations

What are the side effects?

- Treatment with an atypical antipsychotic may result in side effects
- Not everyone will experience side effects
- Side effects may resolve quickly or may persist
- Potential side effects include, but are not limited to:
    - Changes to blood pressure
    - Weight gain
    - High cholesterol
    - High blood sugar
    - High triglycerides
    - Increased appetite
    - Drowsiness

What is the best way to monitor for side effects?

- Physical examination
    - Height
    - Weight
    - Body Mass Index (BMI)
    - Waist circumference
    - Blood pressure
- Blood tests
    - Cholesterol, triglycerides, and blood sugar
    - Before starting and at certain times while taking the medication

How can I help?

- Watch your child for the following symptoms:
    - Frequent urination
    - Feeling more thirsty than normal
    - Feeling much hungrier than normal
    - Feeling tired all of the time for no reason
- Be sure to tell your provider if a family member has a history of diabetes, stroke, heart attack, high blood pressure, or high cholesterol

What is the best way to treat and prevent side effects?

- Removing or switching AAP medications as advised by your provider
- Additional medications for managing high blood pressure, sugar, and/or cholesterol levels
- Lifestyle changes
    - Healthy eating
    - Exercise
    - Quitting smoking

Adapted from Endocrinology & Diabetes Unit and Child & Adolescent Psychiatry Department, Department of Learning & Development, & Vancouver Coastal Health. (n.d.). Atypical antipsychotics & metabolic monitoring. Accessed from http://www.bcchildrens.ca/health-professionals/clinical-resources/endocrinology-diabetes/atypical-antipsychotics

APPENDIX K: STAFF ROLES AND RESPONSIBILITIES

Children and Adolescents Diagnosed with a Bipolar Spectrum Disorder
Taking an Atypical Antipsychotic

Staff Member	Task	Task Description
Office assistant	Printing and compiling toolkit	Toolkits will need to be printed and put into a folder for providers to keep in their office
Provider	Using toolkit with appropriate patients	Toolkits should be used in patients ages 5-18 who are diagnosed with a bipolar spectrum disorder and who are taking an atypical antipsychotic
Provider	Placing toolkit contents on the chart or giving information to patient/caregiver	Documentation forms should be filed in the chart and educational handouts should be given to the patient and/or caregiver
Office assistant or Provider	Measuring/documenting vital signs	Blood pressure, pulse, height, weight, BMI, and waist circumference (if applicable) should be completed and staff completing should sign his/her name
Provider	Reviewing vital signs	Sign vital sign documentation form, include vital signs in the progress note, and/or document on the provider documentation form
Provider	Ordering lab work	Complete and sign lab form and document the intervention in the progress note and/or on the intervention documentation form
Office assistant	Placing a copy of the lab order on the chart	File a copy of the completed lab for to show documentation that lab work was ordered
Provider	Following up with patient regarding completion of lab work	Ask during appointment if lab work was completed
Office assistant	Filing lab results in chart	File results on the chart correctly and flag them for review, document this on the communication tool
Provider	Reviewing lab results	Sign and date lab results, include lab values in the progress note, and/or document on the provider documentation form
Provider	Ordering referral to PCP/specialist	Complete and sign referral form
Office assistant	Having patient complete release of information form	Have patient/caregiver sign release of information form for the PCP/specialist of the referral
Office assistant	Faxing referral form and attachments	Fax referral forms, lab results, and other pertinent notes to PCP/specialist, document this on the communication tool

APPENDIX L: AUDIT TOOL

Practice Guideline for Metabolic Monitoring Audit Tool

Directions: Calculate the amount of time the patient has been on an atypical antipsychotic medication (AAP) by using the first documented use of an AAP. Mark on the chart below where the patient falls. Anything falling under that column should be documented in order to satisfy the outcome measure. Only the items that are due at the time of the visit should be audited.

Examples are listed below.

*Monitoring Protocol for Patients on AAPs**

Months Since Initiation							
Example 1: 3 months				X			
Example 2: 8 months					X		
	Baseline (0-3weeks)	4 Weeks	8 Weeks	12 Weeks	Quarterly (4-11 months)	Annually	Every 5 Years
Personal/Family History	X					X	
Weight (BMI)	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

Example 1: At the time of the patient's last visit, it had been 3 months since the patient was started on an AAP. Height and weight (BMI), blood pressure, a fasting plasma glucose, and a fasting lipid profile are due and should be documented in the chart.

Example 2: At the time of the patient's last visit, it had been 8 months since the patient was started on an AAP. Height and weight (BMI) should be documented

Patient Name: _____ DOB:_____

1st Atypical Antipsychotic Start Date: _____ Date: _____

*Monitoring Protocol for Patients on AAPs**

Months Since Initiation							
	Baseline (0-3weeks)	4 Weeks	8 Weeks	12 Weeks	Quarterly (4-11 months)	Annually	Every 5 Years
Personal/Family History	X					X	
Weight (BMI)	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

Phase I Outcome Measures Audit Checklist

Outcome Measure	√ / X	Measure Components Required		
		Acceptable Evidence that Measure was Satisfied		
Toolkit employed for patient aged 5-18 with bipolar spectrum disorder taking an atypical antipsychotic		Forms of toolkit present on chart		
		Color sticker on outside of chart		
Personal and family history assessment completed by the provider		Completed assessment form at baseline and annually		
Metabolic labs ordered at recommended intervals		Fasting Plasma Glucose ordered at baseline, 12 weeks, and annually		
		Copy of lab form on chart	OR	Order documented in assessment note
		Fasting lipid profile ordered at baseline, 12 weeks, and every 5 years		
		Copy of lab form on chart	OR	Order documented in assessment note
Vital signs taken and documented on chart		Height/Weight (BMI) taken at baseline, 4 weeks, 8 weeks, 12 weeks, and quarterly thereafter		
		Measurement documented on vital sign documentation form		
		Blood pressure taken at baseline, 12 weeks, and annually		
		Measurement documented on vital sign documentation form		
		Waist circumference measured at baseline and annually		
		Measurement documented on vital sign documentation form		

APPENDIX M: COMMUNICATION DOCUMENTATION FORM

Date	Message/Action Taken	Staff Signature	Provider Signature
1/2/34	Lab results filed on chart and flagged for Dr. C to review	D. Smith, Office Asnt	
2/3/45	Faxed lab results and referral form to patient's PCP	D. Smith, Office Asnt	

APPENDIX N: ATYPICAL ANTIPSYCHOTIC TREATMENT CHECKLIST AND INTERVENTION DOCUMENTATION FORM

Patient Name: _____ DOB: _____

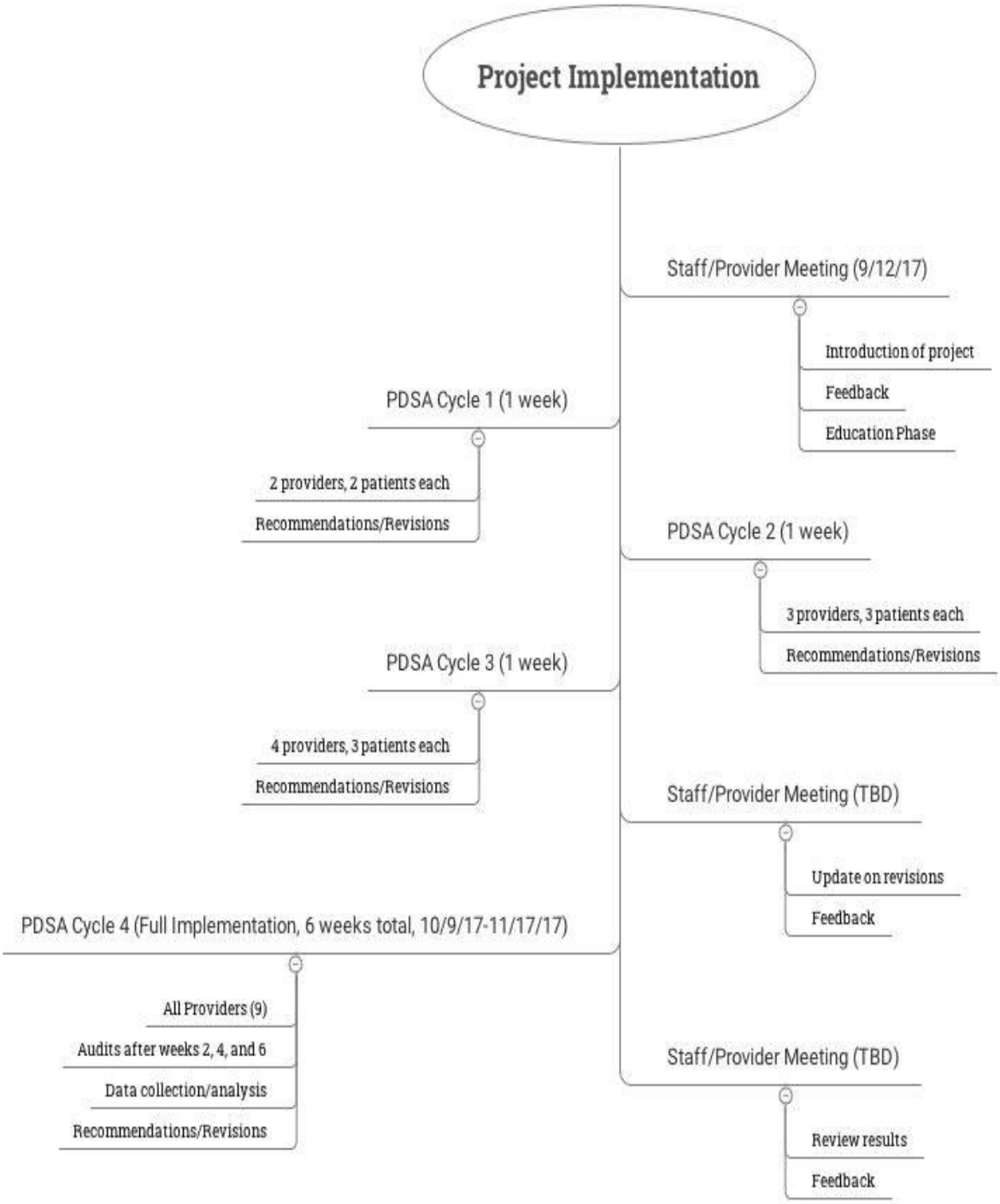
Psychiatric Diagnosis(es): _____

Medical Diagnosis(es): _____

Atypical Antipsychotic Medication/Dose: _____

Intervention	Date	Notes	Date	Notes
Pretreatment				
Discuss metabolic risks				
Discuss diet				
Discuss physical activity				
Risk/benefit assessment				
Discuss smoking cessation				
Lab work ordered				
During Treatment				
Discuss metabolic risks				
Discuss diet				
Discuss physical activity				
Risk/benefit assessment				
Discuss smoking cessation				
Lab work ordered				
Refer to dietician				
Refer to specialist				
Refer to PCP				
Consult with another provider				
Lab work forwarded to PCP/other provider				
Discuss signs/symptoms of diabetes/DKA				
Switch antipsychotic medication				
Change medication dose				
Addition of medication to counter metabolic side effects				
Other:				
Other:				

APPENDIX O: PROJECT IMPLEMENTATION TIMELINE



APPENDIX P: MEASUREMENT GUIDE FOR VITAL SIGNS

Children and Adolescents Diagnosed with a Bipolar Spectrum Disorder
Taking an Atypical Antipsychotic

Measurement	Technique
Height	- Shoes off - Patient standing with heels, back, and shoulders in contact with the stadiometer - Feet together - Gently straighten - Hold head aligned with lower portion of eye orbit in line with the middle portion of the ear
Weight	- Anything heavy off (shoes, jacket, etc.)
BMI Calculation	- Divide weight in pounds by height in inches - Divide that number by the height in inches again - Multiple that number by 703 - [W (lbs) / (H (in) x H (in))] x 703
Waist Circumference	- Use a flexible tape of adequate length - Have the patient stand erect with abdomen relaxed, feet shoulder-width apart, weight evenly distributed, arms loosely by their side - Make the measurement horizontally at the line of the umbilicus/belly button - Ask the patient to breathe normally - Alternately – ask the patient to hold one end of the tape over their belly button and spin around to decrease amount of physical touch
Blood Pressure	- Choose the right cuff size for the patient's arm: the dotted line on the cuff should rest between the solid lines - Have the patient sit down and relax - Heavy clothing should be removed or the sleeve rolled up - The Artery ↓ sign should be placed on the inside of the arm - Do not talk to the patient while measuring and ask that they wait until it is finished to talk

Adapted from: Provincial Mental Health Metabolic Program (2010). Measurement guide for metabolic assessment, screening, & monitoring tool. Accessed from http://www.bcchildrens.ca/health-professionals/clinical-resources/endocrinology-diabetes/atypical-antipsychotics.

APPENDIX Q: SUMMARY TABLES OF CHART AUDIT DATA

Table 1: Summary of Chart Audit Data

	Week 0 %	Week 2 %	Week 4 %	Week 6 %
Date of Audit		**10/22/17**	**11/5/17**	**11/19/17**
Dates Audited		**10/9-10/20**	**10/23-11/3**	**11/6-11/17**
Outcome Measure				
Fasting Plasma Glucose	8.3	13.3	28.6	33.3
Fasting Lipid Panel	8.3	13.3	28.6	33.3
Height/Weight	27.1	53.3	85.7	100
Vital Signs	89.6	100	100	100
Waist Circumference	0	6.7	71.4	88.9
Metabolic Assessment	0	26.7	28.6	33.3
Sticker on Chart	0	20	42.9	33.3
Forms on Chart	0	26.7	42.9	33.3
Number of Charts Reviewed	48	15	7	9

Table 2: Chart Audit Data with Provider Data

	Wk 0 %	Wk 2 %	P1%PP1	P2%	P3%	Wk 4 %	P1%PP1	P2%	P3%	Wk 6 %	P1%PP1	P2%	P3%
Date of Audit		**10/22/17**				**11/5/17**				**11/19/17**			
Dates Audited		**10/9-10/20**				**10/23-11/3**				**11/6-11/17**			
Outcome Measure													
FPG	8.3	13.3	0	7.1	100	28.6	25	0	100	33.3	0	66.7	100
FLP	8.3	13.3	0	7.1	100	28.6	25	0	100	33.3	0	66.7	100
H/W	27.1	53.3	66.7	64.2	100	85.7	50	100	100	100	100	100	100
VS	89.6	100	100	100	100	100	100	100	100	100	100	100	100
WC	0	6.7	0	7.1	100	71.4	75	100	100	88.9	80	100	100
Met Asmt	0	26.7	0	21.4	100	28.6	0	50	100	33.3	0	66.7	100
Sticker	0	20	0	14.3	100	42.9	0	100	100	33.3	0	66.7	100
Forms	0	26.7	0	21.4	100	42.9	0	100	100	33.3	0	66.7	100
Charts Reviewed	48	15	6	8	1	7	4	2	1	9	5	3	1

P1 – provider 1; P2 – provider 2, P3, provider 3

APPENDIX R: PHASE II AND PHASE III OUTCOME MEASURES

Phase II:

5. Metabolic laboratory study results were properly filed for review by office staff
    a. Evidenced by the presence of the laboratory results in the chart
    b. Evidenced by the documentation of receipt of and filing of results by office staff on communication tool in the chart (Appendix M)
6. Metabolic laboratory study results were reviewed by the provider
    a. Evidenced by provider signature on laboratory results
    b. Evidenced by the documentation of results in visit note or on lab documentation form (Appendix E)
7. Vital signs (specifically blood pressure, height, weight, BMI, and waist circumference) were reviewed by the provider at chronological increments suggested by the guidelines
    a. Evidenced by documentation of each of the vital signs on the visit note or acknowledgement of the values on the documentation sheet with provider signature

Phase III:

8. Abnormal metabolic laboratory study and/or vital sign results resulted in an action by the provider
    a. Evidenced by the documentation in the visit note or on the intervention form (Appendix N) of one or more of the following:
        i. Medication change
        ii. Medication dosage change
        iii. Referral to PCP or specialist

iv. Evidenced by copy of completed referral form in chart (Appendix I), documentation of referral completion by office staff, or documented communication between provider and PCP or specialist

v. Patient/caregiver education on interventions to improve values

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