Improving Metabolic Monitoring for Children Prescribed Second-Generation Antipsychotics

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Abstract

The number of children taking second-generation antipsychotics (SGA) is increasing. While SGAs produce fewer neurological side effects, the metabolic side effects of SGAs increase the risk for future cardiometabolic disease. In 2011, the American Academy of Child and Adolescent Psychiatry endorsed following guidelines established in 2004 recommending that people taking SGAs receive regular metabolic screening including waist circumference measurement, fasting blood glucose, and fasting lipids. Despite recommendations, studies have shown that children do not receive routine metabolic monitoring. Provider attitudes toward following guidelines can influence the rates of monitoring. Research suggests that monitoring rates improve after psychiatric providers receive educational programs on SGA use and recommended guidelines. In response to these findings, an evidence-based educational intervention discussing SGA use in children and recommended metabolic monitoring was proposed to increase the rates of metabolic monitoring in a community-based psychiatric practice that treats children. While no results were statistically significant, the average attitude score of providers toward following guidelines was higher post-education and the proportion of providers who ordered screening tests post-education increased. To further improve metabolic monitoring, it is recommended that interventions designed to increase the subjective norms and perceived behavioral control of providers be implemented. The main limitations of this project were the small sample size and the use of self-reports to assess provider ordering of screening tests.

Keywords: second-generation antipsychotics, atypical antipsychotics, metabolic monitoring, waist circumference.
Metabolic Monitoring in Children and Adolescents Receiving Second-Generation Antipsychotics

The use of second-generation antipsychotics (SGA) to treat psychiatric illness in children and adolescents has been increasing. Between the years of 1992 and 2002 in the United States, there was a six-fold increase in the number of office-based visits in which a child or adolescent received an antipsychotic prescription (Panagiotopoulos, Ronsley, Elbe, Davidson, & Smith, 2010; Panagiotopoulos, Ronsley, Kuzeljevic, & Davidson, 2012). By 2009, SGAs were being prescribed to children and adolescents at the same frequency as they were being prescribed to adults (Connolly, Toomey, & Schneeweiss, 2015). Despite the increased use of SGAs, however, many providers are not following current recommendations for metabolic monitoring (Connolly et al., 2015; Morrato et al., 2010).

**Background and Significance**

Second-generation or atypical antipsychotic use in children has been rapidly increasing (De Hert et al., 2011; Olfson, Blanco, Liu, Moreno, & Laje, 2006; Panagiotopoulos et al., 2010). SGAs are prescribed for a variety of psychiatric illnesses in children and adolescents including bipolar disorder, schizophrenia and other psychotic disorders, mood disorders, pervasive developmental disorders, and disruptive behavior disorders (Connolly et al., 2015; De Hert et al., 2011; Olfson et al., 2006). While the Food and Drug Administration (FDA) has approved the use of certain SGAs for the treatment of select psychiatric disorders in children and adolescents, SGAs continue to be prescribed off-label for other disorders such as the aggressive and disruptive disorders (De Hert et al., 2011; Panagiotopoulos et al., 2010; Pringsheim et al., 2011).

Although the efficacy and benefits of SGAs have been demonstrated in randomized controlled trials (RCTs), there is little evidence regarding the long-term safety of using these medications in the pediatric population (De Hert et al., 2010; Panagiotopoulos et al., 2010;
Pringsheim et al., 2011; Rodday et al., 2015). A systematic review conducted by Pringsheim et al. (2011) found evidence confirming the increased risk for both neurological and metabolic side effects related to SGA use in children. It has been found that children who receive SGAs have a four-fold risk of acquiring diabetes as compared to children who do not receive SGAs (NCQA, 2014). Panagiotopoulos et al. (2012) conducted a study to determine the prevalence of metabolic syndrome (MetS) in children and adolescents taking SGAs. They found the overall prevalence of MetS in children treated with SGAs was 19%. This is a 30-fold higher odds ratio than was observed in children with mental health conditions who were never treated with an SGA.

In response to concerns about the side effects of SGAs, the American Diabetes Association (ADA), the American Psychiatric Association (APA), the American Association of Clinical Endocrinologists, and the North American Association for the Study of Obesity all gathered in 2003 to investigate the relationship between antipsychotic drugs and diabetes. A panel of eight experts heard evidence related to the association of antipsychotic use with the development of cardiovascular disease (ADA, APA, American Association of Clinical Endocrinologists, & North American Association for the Study of Obesity, 2004). In 2004, the panel developed a consensus position on how patients taking antipsychotics should be monitored and recommended that all patients taking SGAs should have metabolic screening (ADA, APA, American Association of Clinical Endocrinologists, & North American Association for the Study of Obesity, 2004; Connolly et al., 2015; Morrato et al., 2010; Panagiotopoulos et al., 2010; Ronsley et al., 2011). In 2011, the American Academy of Child and Adolescent Psychiatry (AACAP) recommended that the metabolic monitoring of children and adolescents taking SGAs should follow the recommendations put forth by the ADA and APA whenever feasible.
Therefore, due to the risk of weight gain and serious metabolic side effects associated with the use of SGAs, it is recommended that children using SGAs have metabolic screening that includes measurement of blood pressure (BP), weight, body mass index (BMI), waist circumference (WC), fasting plasma glucose, and fasting lipid profile (De Hert et al., 2011; Ghate et al., 2012; Panagiotopoulos et al., 2010; Panagiotopoulos, Ronsley, Kuzeljevic, & Davidson, 2012; Pringsheim et al., 2011).

Despite the importance of monitoring children who are at risk of developing metabolic side effects of SGA treatment, a study by Morrato et al. (2010) found that only 31.6% of children starting an SGA had a plasma glucose level checked and lipid levels were checked in only 13.4% of the children. A study by Connolly et al. (2015) found that between the years of 2003-2011 in a population of 52,407 children with a mean age of 13.14 ± 3.72 years who were new users of SGAs, around 16% of the population had blood glucose testing per recommended guidelines. The National Committee for Quality Assurance (2014) recognizes this failure to obtain recommended laboratory monitoring of children and adolescents receiving SGAs as a gap in care.

Several barriers to obtaining recommended metabolic monitoring for children and adolescents have been identified. Ronsley et al. (2011) surveyed both community-based and hospital-based mental health professionals and found that half of the community-based participants reported having low confidence in knowing what metabolic parameters needed to be monitored and at what time intervals. A survey completed by Rodday et al. (2015) found that psychiatrists who felt the risk of children acquiring metabolic syndrome was low were less likely to measure blood pressure and waist circumference. Another potential barrier to metabolic
monitoring may be provider lack of familiarity and agreement with metabolic monitoring guidelines (Connolly, Toomey, & Schneeweiss, 2015).

Evidence suggests that the education and the implementation of metabolic monitoring programs can increase rates of monitoring. Ronsley et al. (2012) found that the monitoring rates of anthropometric and bloodwork parameters improved after the implementation of a metabolic monitoring program that included an educational handbook and training workshops. Gibson et al., (2015) found that psychiatric resident knowledge of SGA use in children and adolescents and recommended monitoring improved after the implementation of an educational handbook.

Following recommendations for metabolic monitoring would improve the health and wellbeing of children and adolescents who require SGAs for the effective treatment of their psychiatric illnesses. Evidence suggests that early screening for metabolic side effects contributes to early treatment and the potential to decrease the long-term adverse outcomes from treatment with SGAs (Ronsley, Raghuram, Davidson, & Panagiotopoulos, 2011). There are pharmacological and non-pharmacological treatments for preventing and managing the weight gain experienced by children who use SGAs (Thompson et al., 2011). In addition to healthy eating and physical activity, adjunctive treatment with metformin has been found to mitigate the weight gain associated with SGA use in children and adolescents (Chovil & Panagiotopoulos, 2010; Cottingham, Barton, Morrison, Klein, & Sorter, 2006; Pramyothin & Khaodhiar, 2015).

**Problem Statement**

The increase in use of SGAs for the treatment of psychiatric illness in children and adolescents may be a result of the perception that SGAs have an improved side-effect panel (Panagiotopoulos et al., 2010). While the risk for extrapyramidal symptoms decreases with the use of SGAs, these medications can lead to an elevated risk for cardiometabolic disease due to
the adverse side effects of weight gain, hyperglycemia, dyslipidemia, hypertension, and type 2 diabetes (De Hert, Dobbelare, Sheridan, Cohen, & Correll, 2011; National Committee for Quality Assurance, (NCQA), 2014; Nichol et al., 2016; Panagiotopoulos et al., 2010; Pringsheim, Lam, Ching, & Patten, 2011; Rodday et al., 2015). Due to the increased use of SGAs for children and adolescents with psychiatric illness and the concomitant increase in risk for metabolic side effects that these medications can cause, it is imperative that children and adolescents using SGAs receive appropriate metabolic monitoring to aid in preventing the development of diabetes and future cardiovascular disease (De Hert et al., 2011; Panagiotopoulos et al., 2010; Pringsheim et al., 2011).

A community-based mental health clinic that provides psychiatric services to children and adolescents in the southwestern US has experienced difficulty with obtaining recommended metabolic monitoring. A review of records suggests that 80% of children using SGAs have received fasting plasma glucose and lipid levels as recommended by current guidelines. Children have height, weight, and blood pressure measured at each visit, but, waist circumference is usually not measured. Factors cited by staff as possible barriers to obtaining recommended metabolic monitoring are patient non-compliance with obtaining labs, no formal procedure to alert providers that monitoring is due, and time constraints during medication review appointments.

The internal and external evidence surrounding this health care issue led to the relevant clinical inquiry: In providers who prescribe SGAs to children and adolescents (P) how does education on the use of SGAs, the risks of SGAs, and the importance of metabolic monitoring for children and adolescents using SGAs (I) compared to no education (C) affect the rates of
measuring BP, weight, BMI, waist circumference, fasting plasma glucose, and fasting lipids in children and adolescents prescribed SGAs (O) over three months (T)?

**Search Strategy**

An extensive literature review was performed to address the question of how providing education to providers on the risks of weight gain and the adverse metabolic side effects associated with SGA use in children and adolescents affects the rates of metabolic monitoring. The search strategy included reviews of the Cumulative Index of Nursing and Allied Health Literature (CINAHL) (Appendix A), PubMed (Appendix B), PsycINFO (Appendix C), and the National Guideline Clearing House (Appendix D). Keywords used to search the databases included: *second-generation antipsychotic*, *atypical antipsychotic*, *metabolic monitoring*, and *waist circumference*. Keywords were searched with Boolean connectors: *second-generation antipsychotic* (or) *atypical antipsychotic* (and) *metabolic monitoring* (and) *waist circumference*. In addition to database searching, hand-searching of reference lists was used to extract articles.

**Initial Search**

All databases were searched using the same combination of keywords and Boolean connectors: *second-generation antipsychotic* (or) *atypical antipsychotic* (and) *metabolic monitoring* (and) *waist circumference*. The initial search yielded 726 results in CINHAL, 25 results in PubMed, and 2434 results in PsycINFO. Database searches were then limited by year of publication, 2005-2017; the English language; and age, child 0-18 years of age. The decision to expand the limit for years of publication from 2005 to 2017 reflects the decision to include all evidence found after the initiation of metabolic monitoring guidelines in 2004. After the application of limits to the search, CINHAL yielded 139 studies, PubMed produced six studies, and PsycINFO yielded 229 results. Hand-searching resulted in one additional article.
The National Guideline Clearinghouse was searched using the keywords: Metabolic monitoring and second-generation antipsychotics and children. Initial results produced eight guidelines. The search was further limited by age: children 2-12 and adolescents 13-18 to capture guidelines specific to the pediatric population. After the application of limits, the National Guideline Clearinghouse produced a final yield of two guidelines.

**Search Strategy Results**

Studies were selected for further review based on the following inclusion criteria: primary research, systematic reviews, or meta-analyses; study population of children less than 18 years of age; and studies that addressed the metabolic side effects of SGAs in children, barriers to metabolic monitoring, recommended guidelines for metabolic monitoring, or proposed recommendations for improving metabolic monitoring in children taking SGAs.

Two studies were selected that did not meet the inclusion criterion for age. One study with a population of subjects greater than 18 years of age was selected as it addressed the cost-effectiveness of measuring abdominal obesity and fasting blood glucose. Another study, with a population age range of 15-25 years of age, was also selected since a portion of the population consisted of subjects that met the criterion for age. All articles were published after the year 2011 except for one article that was published in 2005. This article addressed the sensitivity and specificity of waist circumference as a predictor for metabolic syndrome and was considered relevant for this review. After critical appraisal of the 27 articles retrieved using these criteria, ten were chosen for inclusion in this literature review (Appendix E).

**Critical Appraisal and Synthesis of Evidence**

Ten studies were retained for this review including: two systematic reviews, level one evidence; three quasi-experimental studies (QES), level IV evidence; two surveys, a qualitative
study, and a correlational study, all level V evidence; and a cross-sectional retrospective study, level III evidence (Appendix E). Level of evidence for each study was determined by using the Hierarchy of Evidence presented by Melnyk and Fineout-Overholt (2015). Studies were retained if they addressed the following subjects: (a) possible metabolic side effects of SGAs that occur in children and adolescents, (b) recommended guidelines for metabolic monitoring, (c) barriers and challenges to obtaining recommended metabolic monitoring, (d) or interventions designed to improve the rates of metabolic monitoring; thus, the conceptual frameworks, study designs, variables, and interventions were heterogeneous and varied according to the purpose of each study.

The systematic reviews (SR) evaluated RCTs conducted with a population of children aged 18 years or younger. One SR, in addition to evaluating RCTs, included open-label and prospective cohort studies longer than 12 weeks in duration to assess for the longer-term effects of the SGAs. Clinical trials for both studies were evaluated for methodological quality using US Preventative Services Task Force criteria.

Seven studies were conducted in Canada and received funding from similar sources. The seven studies also shared many of the same researchers, some of whom received salary support from the Child & Family Research Institute and the Canadian Diabetes Association (Appendix E). These studies had heterogenous designs and variables as they addressed various issues of SGA use such as identification of adverse effects, recommendation of monitoring guidelines, barriers to metabolic monitoring, and interventions to improve metabolic monitoring. The sample populations in these studies differed as some study samples were comprised of children aged 18 years or younger and other samples were comprised of psychiatric providers who cared for children 18 years or younger.
Four studies identified obesity, increases in weight, body mass index (BMI), and waist circumference (WC) as adverse effects of SGA use and predictors of MetS (Appendix F). The sample populations of these studies were mostly homogenous; three of the study samples included children aged 18 and younger while one study sample included adults 18 years of age and older (Appendix E). Two of these studies calculated the sensitivity, specificity, positive predictive value, and positive likelihood ratio of abdominal obesity and WC as predictors of MetS and found that abdominal obesity and WC have the highest sensitivity in predicting MetS with WC having a higher sensitivity than BMI in predicting MetS in children.

Three studies evaluated interventions designed to improve the rates of metabolic monitoring for children and adolescents receiving SGAs. The various interventions included educational handbooks focused on SGA use and metabolic monitoring in children and adolescents, development of guidelines, didactic and interactive seminars, structural changes such as the provision of prompts for required monitoring, and provision of the equipment necessary to perform required monitoring (Appendix E). The settings in which the interventions were implemented were heterogeneous and included hospital-based inpatient units and community-based outpatient units. Interventions were provided to psychiatrists, psychiatric residents, and mental health professionals who worked with a pediatric population. All three studies used a pre-/post-test design. Data were compared using paired $t$-tests (Appendix E). Results in all three studies showed significant improvement in metabolic monitoring rates and significant improvement in provider knowledge of SGA use in children after implementation of a metabolic monitoring training program or educational handbook.

Two surveys explored provider attitudes toward metabolic monitoring and the perceived barriers to obtaining recommended monitoring. Descriptive statistics, univariate analysis, and
independent t-tests were used to analyze the data (Appendix E). The providers who were surveyed cared for pediatric populations in private practice, community, inpatient, and outpatient settings. Practice settings and provider attitudes were found to influence patterns of monitoring. Outpatient providers had lower confidence with monitoring physical health issues, availability of time to complete necessary monitoring, and equipment for performing physical examinations (Appendix F). One qualitative study explored the health literacy needs of families with children receiving SGAs and found that families felt that they had many questions about SGAs but found few resources available to help them.

Measurement instruments used across the studies included various types of medical equipment, questionnaires, surveys, and audit tools created for chart reviews (Appendix E). One study gave detailed information on the type of medical equipment that was used. There was no information available on the validity or reliability of the other instruments as they were created for the studies by the researchers.

Although the studies in this body of work are heterogeneous, when evaluated together, they suggest that SGAs increase the risk for metabolic side effects in children and they provide evidence that routine metabolic monitoring is required in order to provide quality care to this population. The body of work also suggests that barriers to obtaining metabolic monitoring exist and that these can be addressed with metabolic monitoring programs and education (Appendix E).

**Conclusions from the Evidence**

High level evidence suggests that SGA use in children and adolescents can lead to increased risk for metabolic syndrome and future cardiometabolic disease. Common predictors of MetS across studies included, increases in weight, BMI, WC, and abdominal adiposity.
Although guidelines and recommendations for metabolic monitoring have been developed that include measuring these parameters, routine monitoring of these parameters remains poor for children receiving these medications.

Studies have also shown that the attitudes and beliefs of providers regarding the use of SGAs in children can influence the prescribing and monitoring of these medications. Providers who believe that the risk for development of MetS in children is low, are less likely to monitor for adverse effects. One commonly held belief among providers is that metabolic monitoring is not completed due to family non-compliance, however, evidence suggests that families do not feel that they have adequate education on these medications, a fact which may contribute to non-compliance. Education on the use of SGAs and their possible adverse effects for both providers and families could increase routine metabolic monitoring.

In addition, common barriers to obtaining metabolic monitoring have been identified. The setting in which treatment occurs can influence which barriers are most likely to impact routine metabolic monitoring for children. Metabolic monitoring programs that provide targeted interventions specific to the identified barriers in a treatment setting can be successful in increasing the rates of metabolic monitoring in children receiving SGAs.

**Purpose and Rationale**

The purpose of this project was to present an educational intervention that discussed the use of SGAs in children, the risks of SGA use, and the current metabolic monitoring recommendations for children and adolescents taking SGAs to providers caring for children in a community-based mental health clinic with the aim of increasing provider adherence to following recommended metabolic monitoring guidelines. Improving metabolic monitoring for
children and adolescents who are taking SGAs is an important aspect of care that can increase the wellness of children and help to prevent future cardiometabolic disease.

**EBP Model to Guide Implementation of Evidence**

The Iowa Model of Evidence-Based Practice was chosen as the framework for designing this DNP project (Appendix G). The model provides a detailed algorithm that begins with identifying practice questions or triggers and then guides the practitioner through a decision-making process for planning a practice change (Dang et al., 2015; Reavy, 2016). There are three main decision points: (a) Is this a priority topic? (b) Is there sufficient evidence? and (c) Is this change appropriate for adoption into practice? The model then provides feedback and guidance on the next step for planning the project based on either a yes or no response to these questions (Dang et al., 2015; Reavy, 2016). The Iowa Model of Evidence-Based Practice was chosen for this DNP project and guided the process from identification of a practice question to the implementation of an evidence-based educational intervention.

**Contribution of Theory to Utility of Evidence**

The Theory of Planned Behavior (Appendix H) was the chosen conceptual model for this project. Evidence suggests that provider beliefs and attitudes towards following recommended metabolic monitoring guidelines can influence the rates of metabolic screening in children taking SGAs. The Theory of Planned Behavior suggests that to predict a person’s intention to do something, one needs to know whether the person is (a) in favor of the behavior, his/her attitude; (b) how much the person feels social pressure to perform the behavior, the subjective norm; and (c) whether the person feels he/she has control over performing the behavior (Francis et al., 2004). Implementing an educational intervention that affects any of these three variables has the potential to change the providers’ attitudes, subjective norms, and perceived behavioral control.
towards metabolic monitoring and could influence the providers’ intentions to perform metabolic monitoring and increase the behavior of metabolic monitoring for children taking SGAs (Francis et al., 2004).

**Application of Evidence to Practice**

Guidelines developed in 2004 recommend routine metabolic monitoring of all people taking SGAs. Routine metabolic monitoring includes the measurement of weight, BMI, WC, blood pressure (BP), fasting blood glucose, and fasting lipids at baseline, three months, and 12 months. Although the NCQA (2014) states that ongoing metabolic monitoring for children and adolescents taking SGAs is a standard of care, studies suggest that routine metabolic monitoring of children taking SGAs does not occur. Evidence suggests, however, that the rates of metabolic monitoring increase after providers receive education on SGA use and metabolic monitoring. Therefore, an evidence-based project was proposed to provide education on SGA use, risks of SGA use, and recommended metabolic monitoring for children to providers in an outpatient psychiatric clinic. The stakeholders include the physicians, nurse practitioners (NP), nursing staff, NP student, office management staff, children and adolescent patients, and their families.

**Proposed Implications of the Project on Outcomes**

Implementation of an evidence-based educational program that provides information on SGA use in children and adolescents, the risks of SGA use, and the recommended routine metabolic monitoring for children has the potential to improve quality outcomes in the outpatient psychiatric clinic. By adhering to recommendations for metabolic monitoring, psychiatric providers can improve the quality of care for children and adolescents who are treated with SGAs. Routine metabolic monitoring provides a means of identifying metabolic side effects in a timely manner making early treatment possible. The early treatment and management of
metabolic side effects reduces the long-term costs of treating cardiometabolic disorders by reducing the risk that children taking SGAs will develop diabetes or that they will grow into adults who have an increased risk for cardiovascular disease (Ghate et al., 2012; NCQA, 2014).

**Project Methods**

This evidence-based project was approved by the Arizona State University Institutional Review Board (Appendix I). A recruitment letter describing the project and details of participation was presented to all providers of an urban community-based clinic that provides psychiatric services for children prior to the pretest questionnaire and the educational intervention (Appendix J). A pretest-posttest design was used. An educational intervention specifying recommended metabolic monitoring guidelines was presented to providers (Appendix K). Providers were asked to complete a pre- and post-education questionnaire that was developed using the Francis et al. (2004) manual for constructing a questionnaire based on the theory of planned behavior. The questionnaire included a Likert-type scale with 12 items. Responses were on a 5-point scale ranging from strongly disagree to strongly agree including a neutral response. In addition, the questionnaire included a 14-item self-report of the screening tests ordered by providers prior to starting an SGA and at 12 weeks after starting an SGA (Appendix L). This instrument does not have established psychometric estimates, however, content validity was established by a panel of three experts (Appendix M). The IBM SPSS® Version 24 statistical package was used to store, manage, and analyze the data. Descriptive statistics were used to describe the sample and outcome variables. Nonparametric statistics were used to analyze the outcome variables. A two-tailed test was performed, and the critical value was set at $p < 0.05$.

**Outcomes/Project Results**
The sample ($N = 6$) were healthcare providers of an urban community-based clinic. The sample consisted of one (17%) male and five (83%) females. Most of the participants were four (67%) nurse practitioners. The remaining participants were medical doctors ($n = 2$, 33%). The average age of the participants was 47.5 ($SD = 10.25$) years and the ages ranged from 35-63 years in age. The average number of years in practice for the participants was 11.17 ($SD = 15.08$) with the range of years in practice from 1-41 years in practice.

Descriptive statistics were used to describe the pre-education and post-education means of the four variables of the theory of planned behavior (Table 1). A Wilcoxon test examined the results of the pre-education and post-education mean scores for each of the four variables of the theory of planned behavior (Table 1). No significant differences were found in the results for any variable.

Table 1

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-intervention</th>
<th>Post-intervention</th>
<th>Z</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intention</td>
<td>13.33 (1.21)</td>
<td>13 (1.55)</td>
<td>-.55</td>
<td>.581</td>
</tr>
<tr>
<td>Attitude</td>
<td>16.67 (3.08)</td>
<td>17.25 (1.50)</td>
<td>.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Subjective Norm</td>
<td>15.60 (4.72)</td>
<td>13.8 (3.77)</td>
<td>.37</td>
<td>.713</td>
</tr>
<tr>
<td>Perceived Behavioral</td>
<td>12.67 (1.97)</td>
<td>12.67 (2.58)</td>
<td>-.27</td>
<td>.785</td>
</tr>
</tbody>
</table>

Note ($N=6$)
A McNemar test determined that there was no significant difference in provider ordering of metabolic screening pre- and post-intervention (Table 2). The McNemar test was not performed on the variables of pre- and post-intervention BP, weight, height, and BMI as the variables for both pre- and post- education had the same value and were not dichotomous.

Table 2

Percentage of Providers Who Ordered Screening Tests Pre- and Post-Intervention (N = 6)

<table>
<thead>
<tr>
<th>Screening Test</th>
<th>Pre-education</th>
<th>Post-education</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline WC</td>
<td>0%</td>
<td>40%</td>
</tr>
<tr>
<td>Baseline FPG</td>
<td>100%</td>
<td>83%</td>
</tr>
<tr>
<td>Baseline FL</td>
<td>100%</td>
<td>83%</td>
</tr>
<tr>
<td>12-week WC</td>
<td>0%</td>
<td>20%</td>
</tr>
<tr>
<td>12-week FPG</td>
<td>20%</td>
<td>67%</td>
</tr>
<tr>
<td>12-week FL</td>
<td>20%</td>
<td>67%</td>
</tr>
</tbody>
</table>

Note. (N=6); WC = waist circumference; FPG = fasting plasma glucose; FL = fasting lipids.

Discussion

Project results found no significant differences in the average scores of the four variables of the theory of planned behavior from pre- to post-intervention; however, there was an increase in the average score for provider attitude toward following guidelines. The average scores for provider subjective norms and perceived behavioral control toward following guidelines were lower than the average provider attitude score. There was no difference in the proportion of providers ordering recommended screening tests from pre- to post-intervention, but, after the intervention, there was (a) an increase in the proportion of providers who measured waist circumference before starting an SGA and at 12 weeks after starting an SGA and (b) an increase in the proportion of providers who ordered lab tests at 12 weeks after starting an SGA.
Relation of Findings to Other Studies

These results are consistent with findings from Gibson et al. (2015) who found that psychiatric resident knowledge of SGA use in children and adolescents and knowledge of recommended monitoring improved after the implementation of an educational handbook. Thompson et al. (2011) and Ronsley et al. (2012) also reported finding that metabolic monitoring rates improved significantly with the implementation of metabolic monitoring programs that included education. Rodday et al. (2015) found that providers who believed that the risk for MetS was low did not measure WC and providers with more years in practice did not order FPG and FL due to beliefs that patients are noncompliant. Educating providers with evidence that SGAs increase the risk for elevated FPG, MetS, and future cardiometabolic disease may serve to change the attitudes and beliefs of these providers toward the value of routine monitoring. The increase in attitude toward following guidelines and the resulting increase in metabolic monitoring behaviors seen in this project is consistent with the theory of planned behavior that states that if there is a change in attitude, subjective norms, or perceived behavioral control, intention to perform a behavior and the actual performance of the behavior will change as well.

Impact of the Project

This evidence-based project presented providers with education on the current recommended metabolic monitoring guidelines and the importance of measuring WC in children younger than 18. The impact of this education on provider knowledge can be seen in the resulting increase in the proportion of providers who started (a) to measure WC when starting an SGAs and at 12 weeks after starting an SGA and (b) to order FPG and FL at 12 weeks after starting an SGA. While these results were not statistically significant, clinically, any improvement in metabolic monitoring serves to improve the safety and quality of care for
children who are taking these medications. Early identification of metabolic side effects and treatment of side effects through coordination with primary care providers mitigates the risk for future cardiometabolic disease.

**Sustaining the Improvement**

Fleiszer, Semenic, Ritchie, Richer, and Denis (2016) who studied the long-term sustainability of nursing best practice guidelines suggest that sustaining guideline adherence depends on three elements; benefits, routinization, and development. The study also found that one of the factors that sustains implementation is accountability (Fleiszer, 2016). To sustain the improvement in following metabolic monitoring guidelines that resulted from this evidence-based project, it will be important to (a) continue to reinforce the benefits of following guidelines for both providers and patients, (b) develop a culture of accountability toward following metabolic monitoring guidelines to increase provider subjective norms, (c) develop workflows to establish a metabolic monitoring routine in the clinic and increase the perceived behavioral control of providers, and (d) continue to monitor research for updates on guideline recommendations (Fleiszer, 2016). Strong leadership that supports the goal of improving metabolic monitoring for children taking SGAs, project champions, and alignment of the goal of improving metabolic monitoring with organizational values will also help to sustain this evidence-based project (Douglas, Button, & Casey, 2014).

**Limitations**

The main limitations of this project were the small sample size and the use of self-reports to measure the percentage of providers who ordered specific screening tests.

**Conclusion**
Using SGAs to treat children and adolescents with behavioral health diagnoses is becoming more common. These medications increase a child’s risk for future cardiometabolic disease. It is important to routinely monitor children for the cardiometabolic side effects of SGAs so that early identification and treatment can occur. The purpose of this evidence-based project was to improve metabolic monitoring for children taking SGAs by implementing an educational intervention that discussed the use and risks of SGAs with children and the attendant recommended metabolic monitoring guidelines. The theory of planning behavior was used as the conceptual framework for his project. While the results of the project were not statistically significant, there was some improvement in following recommended guidelines. Based on the theory of planned behavior and evidence on sustaining guidelines, it is recommended that future interventions aimed at improving and sustaining metabolic monitoring focus on improving provider subjective norms and perceived behavioral control.
References

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Clinical Endocrinologists, & North American Association for the Study of Obesity. (2004). Consensus development conference on antipsychotic drugs and obesity and
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of atypical antipsychotic medications in children and adolescents*. Retrieved from

Chovil, N., & Panagiotopoulos, C. (2010). Engaging families in research to determine health
literacy needs related to the use of second-generation antipsychotics in children and


Cardiometabolic risk of second-generation antipsychotic medications during first-time

randomized, double-blind, placebo-controlled trial of metformin treatment of weight gain
associated with initiation of atypical antipsychotic therapy in children and adolescents.


Appendix A

Database Search Strategy 1

CINAHL

<table>
<thead>
<tr>
<th>Search ID</th>
<th>Search Terms</th>
<th>Search Options</th>
<th>Actions</th>
</tr>
</thead>
</table>
| S1        | second-generation antipsychotic OR atypical antipsychotic AND metabolic monitoring AND waist circumference | Limiters - Published Date: 2005/10/1-2017/12/31
Narrow by Subject - all child
Narrow by Language - english
Search modes - Boolean/Phrase | View Results (738) [View Details] [Edit] |
| S2        | second-generation antipsychotic OR atypical antipsychotic AND metabolic monitoring AND waist circumference | Limiters - Published Date: 2005/10/1-2017/12/31
Search modes - Boolean/Phrase | View Results (989) [View Details] [Edit] |
| S3        | second-generation antipsychotic OR atypical antipsychotic AND metabolic monitoring AND waist circumference | Limiters - Published Date: 2005/10/1-2017/12/31
Narrow by Language - english
Search modes - Boolean/Phrase | View Results (637) [View Details] [Edit] |
| S4        | second-generation antipsychotic OR atypical antipsychotic AND metabolic monitoring AND waist circumference | Limiters - Published Date: 2005/10/1-2017/12/31
Narrow by Subject - all child
Narrow by Language - english
Search modes - Boolean/Phrase | View Results (135) [View Details] [Edit] |
Appendix B

Database Search Strategy 2

PubMed

<table>
<thead>
<tr>
<th>Search</th>
<th>Add to builder</th>
<th>Query</th>
<th>Items found</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Add</td>
<td>Search (((second-generation antipsychotics) OR atypical antipsychotic) AND metabolic monitoring) AND waist circumference Ffilters: Publication date from 2005/01/01 to 2017/12/31; English; Child: birth-18 years</td>
<td>6</td>
<td>12:17:01</td>
</tr>
<tr>
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<td>Add</td>
<td>Search (((second-generation antipsychotics) OR atypical antipsychotic) AND metabolic monitoring) AND waist circumference Ffilters: Publication date from 2005/01/01 to 2017/12/31; English</td>
<td>17</td>
<td>12:16:22</td>
</tr>
<tr>
<td>#2</td>
<td>Add</td>
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<td>12:15:56</td>
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</tbody>
</table>
Appendix C

Database Search Strategy 3

PsycINFO

<table>
<thead>
<tr>
<th>Set</th>
<th>Search</th>
<th>Databases</th>
<th>Results</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>S4</td>
<td>(second-generation antipsychotics) OR (atypical antipsychotics) AND (metabolic monitoring) AND (waist circumference)</td>
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<td>2188</td>
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<td>S3</td>
<td>(second-generation antipsychotics) OR (atypical antipsychotics) AND (metabolic monitoring) AND (waist circumference)</td>
<td>PsychINFO</td>
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<tr>
<td>S2</td>
<td>(second-generation antipsychotics) OR (atypical antipsychotics) AND (metabolic monitoring) AND (waist circumference)</td>
<td>PsychINFO</td>
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<tr>
<td>S1</td>
<td>(second-generation antipsychotics) OR (atypical antipsychotics) AND (metabolic monitoring) AND (waist circumference)</td>
<td>PsychINFO</td>
<td>2434</td>
<td>Actions</td>
</tr>
</tbody>
</table>
Appendix D

Search Strategy 4

National Guideline Clearinghouse

"metabolic monitoring and Second-generation antipsychotics and children"
Table 1

**Evaluation Table**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Conceptual Framework</th>
<th>Design/ Method</th>
<th>Sample/ Setting</th>
<th>Major Variables &amp; Definitions</th>
<th>Measurement</th>
<th>Analysis</th>
<th>Findings</th>
<th>Decision for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chovil et al. (2010). Engaging families in research to determine health literacy needs related to the use of second-generation antipsychotics in children and adolescents. Funding: Lawson Foundation, CFRI, and CDA. No COI or biases recognized. Canada.</td>
<td>Inferred Health Belief Model</td>
<td>Design: EQS Purpose: To engage parents and caregivers in research that explores their health literacy needs regarding the use of SGAs in children and youths.</td>
<td>N= 14 Convenience sample Data collected from two focus groups, n=7 parents/caregivers. Setting: Community center Inclusion criteria: Parent/caregiver of a child or adolescent with a MH dx and</td>
<td>Health literacy needs of families with children taking SGAs</td>
<td>Focus groups Transcripts of focus groups were reviewed until no further themes were derived. Participants were asked to review the document for accuracy and completeness.</td>
<td>Themes: 1. Families’ experience in accessing information about medicines. 2. Parents/caregiver recommendations on provision of information to families. 3. Healthy eating: barriers and strategies. 4. Physical activity: barriers and strategies. 5. Recommendation s for resources on</td>
<td>Level V Strengths: validation of data by informants, transferability and confirmability. Weaknesses: little information on data collection and analysis. Conclusions: there is value in including the “family” voice when</td>
<td></td>
</tr>
<tr>
<td>Citation</td>
<td>Conceptual Framework</td>
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<td>Sample/ Setting</td>
<td>Major Variables &amp; Definitions</td>
<td>Measurement</td>
<td>Analysis</td>
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<tr>
<td>Gibson et al. (2015). Effectiveness of an educational handbook in improving psychiatry resident knowledge of second-generation antipsychotics.</td>
<td>Inferred Bandura’s Self-Efficacy.</td>
<td>Design: QED Prospective pre-/post-analysis study</td>
<td>N= 56 residents who completed baseline questionnaire n= 32 psychiatry residents who completed both baseline and post-intervention questionnaires. n= 20 female n=29 post graduate year 3 n= 3 post graduate year 4 and 5</td>
<td>IV- educational handbook DV1: knowledge of properties that distinguish SGAs from typical antipsychotic DV2: knowledge of on-label indications for SGA use in pediatrics in Canada. DV3: Knowledge of off-label indications for SGA use in pediatrics in Canada.</td>
<td>Questionnaire</td>
<td>Paired t-tests</td>
<td>Significant improvement in mean scores from 18.4 ± 4.23 at pre-test to 21.2 ± 3.28 at post-test. ( P = 0.001 ). Effect size 0.74</td>
<td>Level: III</td>
</tr>
<tr>
<td>Funding: One author has received funding support from the CFRI and CDA. No COI declared by authors. Bias: Lack of a control group. One author receives salary support from Canucks for Kids Fund, CIHR, and the CFRI Clinical Research Capacity Building Award.</td>
<td></td>
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<tbody>
<tr>
<td>AE- adverse effect, AMA- American Medical Association, BCCH- British Columbia Children’s Hospital, BMI- body mass index, BP- blood pressure, BS- blood sugar, CDA- Canadian Diabetes Association, CFRI- Child &amp; Family Research Institute, CHOL- cholesterol, CIHR- Canadian Institute of Health Research, CMHT- community mental health team, COI- conflict of interest, CSRS- cross-sectional retrospective study, CTSI- Clinical and Translational Service Institute, CYMHT- Child and Youth Mental Health Team, DB- double blind, DV- dependent variable, dx- diagnosis, ECG- electrocardiogram, EPS- extrapyramidal symptoms, EQS- exploratory qualitative study, FBG- fasting blood glucose, f/u- follow-up, H- height, HDL-C- high-density lipoprotein cholesterol, HR- heart rate, IV- independent variable, IP- inpatient, LDL-C- low-density lipoprotein cholesterol, LFT- liver function tests, MA- meta-analysis, MetS- metabolic syndrome, MH- mental health, MM- metabolic monitoring, MMP- metabolic monitoring program, MMTP- metabolic monitoring training program, OP- outpatient, PC- primary care, PCS- prospective cohort study, PE- physical exam, PPV- positive predictive value, QED- quasi-experimental design, QES- quasi-experimental study, RCR- retrospective chart review, RCS- retrospective cohort study, RCT- randomized controlled trial, SE- side effect, SGA- second-generation antipsychotic, SR- systematic review, T1D- type 1 diabetes, T2D- type 2 diabetes, TG- triglycerides, WC- waist circumference, W- weight</td>
<td>Canada. DV4: Knowledge of potential SEs of SGAs in children and adolescents. DV5: knowledge of pertinent information from patient history prior to starting an SGA. DV6: knowledge of specific aspects of PE that are required prior to starting and SGA and at f/u visits. DV7: knowledge of baseline and f/u labs to order.</td>
<td>Conclusions: results suggest that the implementation of a handbook can improve resident knowledge of related to SGA use in children over the short-term.</td>
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</table>
Physiologic Theory

**Design:** CSRS

**Purpose:** To compare the prevalence of MetS and its components in SGA-treated and SGA-naïve children. To explore the utility of clinical markers such as WC and BMI for as screening tools for MetS.

**Inclusions:** Children < than age 18 admitted to Child and Adolescent Psychiatric Emergency unit between 1/1/2008 and 2/5/2010.

**Exclusions:**
- eating disorder, pre-existing T1D or T2D, pre-existing endocrine disorder, receiving concomitant glucocorticoid medication, receiving intermittent treatment with an SGA.

**Setting:** IP

**N= 334**
- n= 117 SGA-treated
- n= 217 SGA-naïve

**IV1: SGA**

- prevalence of MetS.

**DV1:** utility of clinical markers such as WC.

**DV2:**

- Tronix Scale, Seca 240 stadiometer, non-elastic flexible measuring tape, Dinamap, lab results.

**Conclusions:**

- WC ≥ 90\(^{th}\) percentile had the highest sensitivity, 92.9%, of correctly identifying 13 of 14 patients with MetS.

**Strengths:**

- Prospective study with comparison of SGA treated children to an untreated group.

**Weaknesses:**

- Cross-sectional design, groups were not evenly matched for age or sex.

Limited number of subjects identified with MetS.

**Level III**

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</tr>
</thead>
<tbody>
<tr>
<td>Pringsheim et al. (2011). Metabolic and neurological complications of second-generation antipsychotic use in children.</td>
<td>Physiologic Theory</td>
<td><strong>Design:</strong> SR and MA</td>
<td>N= 35 RCTs n=19 RCTs for risperidone section n= 7 RCTs for olanzapine section n= 4 RCTs for quetiapine section n= 5 RCTs for aripiprazole section n= 3 RCTs for clozapine section n=1 RCT for ziprasidone section</td>
<td>IV1: risperidone IV2: olanzapine IV3: quetiapine IV4: aripiprazole IV5: clozapine IV6: ziprasidone DV1: W DV2: weight gain &gt;7% of baseline bodyweight</td>
<td>Physical examination, rating scales, and lab tests.</td>
<td>ORs with 95% CI, I² index, meta-analysis for each medication individually.</td>
<td>Separate results for each medication. Risk of metabolic adverse effects greatest with olanzapine followed by clozapine and quetiapine. Metabolic risks appear lower for risperidone and aripiprazole. Data on ziprasidone is scarce.</td>
<td>Level 1</td>
</tr>
</tbody>
</table>

**Strengths:** overall trial quality high with 32 of 35 studies receiving a rating of good or fair by USPSTF criteria

**Weaknesses:** short duration of the RCTs, some

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### Inclusions:
- DB RCT of SGA medications vs placebo or an active comparator in a pediatric population (children up to age 18) with a MH dx, or an RCT that included a separate analysis for pediatric participants if the study included adults.
- DV3: WC
- DV4: BMI
- DV5: BP
- DV6: HR
- DV7: EPS
- DV8: ECG
- DV9: Fasting total chol, LDL-C, HDL-C, TG
- DV10: BS
- DV11: prolactin
- DV12: LFT
- DV13: TSH, T4

### Conclusions:
There is good evidence to support the existence of both metabolic and neurological adverse effects in children treated with SGAs therefore proper attention and vigilance to potential metabolic and neurologic adverse effects is necessary.

<table>
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### Pringsheim et al. (2011)

**Evidence-based recommendations for monitoring safety of second-generation antipsychotics in children and youth.**

**Funding:** CIHR.

No COI declared by authors

Bias: One author receives salary support from the CFRI and CDA.

---

| Pringsheim et al. (2011). Evidence-based recommendations for monitoring safety of second-generation antipsychotics in children and youth. | **Physiologic Theory** | **Design:** SR  
**Purpose:** To synthesize the evidence for specific metabolic and neurological SEs associated with the use of SGAs in children and provide recommendations for monitoring SEs  

**Inclusions:** DB RCT of SGA medications performed specifically in a pediatric population with MH dx. Open-label and PCSs longer than 12 weeks. When data was not available from the above, RCSs, case series, case reports, and drug surveillance programs were searched.  

**IVs:**  
IV1: risperidone  
IV2: olanzapine  
IV3: quetiapine  
IV4: aripiprazole  
IV5: clozapine  
IV6: ziprasidone  

**DVs:**  
DV1: weight gain  
DV2: prolactin levels  
DV3: EPS  
DV4: BMI  
DV5: BS  
DV6: TG  
DV7: Total chol  
DV8: LFT  
DV9: WC  
DV10: Insulin  
DV11: TSH, T4  
DV12: LDL-C, HDL-C  

**USPSTF criteria to eval. methodological Quality. Trials rated using GRADE**  

**Meta-analysis**  
**Evidence-based guidelines for monitoring SGA safety developed.** | **Level I**  
**Strengths:** guidelines were based on current evidence that examined the metabolic and neurological adverse effects of SGA medications.  
**Limitations:** unable to develop guidelines for monitoring beyond one year due to lack of long-term studies.  
**Conclusions:** appropriate monitoring procedures for adverse effects will improve the quality of care for children treated with SGAs. |
### Citation
Rodday et al. (2015). Child and adolescent psychiatrists’ reported monitoring behaviors for second-generation antipsychotics.

### Conceptual Framework
Inferred Bandura’s Self-Efficacy.

### Design/ Method
**Design:** Survey Research

**Purpose:** To explore monitoring practices and factors that may be associated with monitoring for children prescribed SGAs.

### Sample/ Setting
N= 6156 child and adolescent psychiatrists identified from an AMA mailing list in 2012

n= 1600 randomly selected

n= 362 respondents

n= 334 final sample who met eligibility criteria.

### Major Variables & Definitions
**IV1:** psychiatrist characteristics

**IV2:** psychiatrist attitudes and use of SGAs

**IV3:** practice characteristics

**DV:** routine monitoring of the following at least once per year: patient history, H, W, BP, WC, lipid & glucose levels, ECG

### Measurement
Survey developed by the study investigators

### Analysis
Descriptive statistics, $\chi^2$ or Fisher exact test, Anova.

### Findings
66% of respondents reported routinely monitoring history, 92% routinely monitored H & W, 76% routinely monitored BP, 23% routinely monitored WC, 81% routinely monitored lipid and FPG, 12% routinely monitored ECG.

### Decision for use
Level V

**Strengths:** use of a national sample with random selection

**Weaknesses:** low response rate with inability to compare respondents with non-respondents. Inability to compare reported behaviors with actual performance.

**Conclusion:** metabolic monitoring patterns are inconsistent for children prescribed SGAs.
<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Ronsley et al. (2011).</td>
<td>Inferred Bandura’s Self-Efficacy</td>
<td><strong>Design</strong>: Survey research, online questionnaire</td>
<td><strong>Sample</strong>: N= 161 MH professionals working at either CMHT or BCCH n= 26 CMHT respondents n= 44 BCCH respondents</td>
<td><strong>Themes</strong>: 1. Physical health care 2. Confidence with monitoring physical health 3. Interface with PC. 4. Practical issues faced by team. 5. Strategies for implementation</td>
<td><strong>Measurement</strong>: Questionnaire, 5-point Likert Scale</td>
<td><strong>Analysis</strong>: Descriptive analysis, independent t-test</td>
<td>1. Monitoring physical health is responsibility of MH professionals- CMHT, 83.3%, BCCH, 90.9% 2. Knowing what should be monitored - CMHT, 3.1±1.36 BCCH, 3.9±0.98 confidence with interpreting results- CMHT, 2.0±1.34, BCCH, 3.6±1.19 based on Likert scale</td>
<td><strong>Level V</strong></td>
</tr>
<tr>
<td><strong>Strengths</strong>:</td>
<td>Response rate is consistent with previous surveys in similar populations.</td>
<td><strong>Weaknesses</strong>: Larger number of BCCH than CMHT. Reflect the opinions of urban professionals only.</td>
<td><strong>Conclusion</strong>:</td>
<td></td>
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There are more barriers to implementing a MMP in the community vs a hospital-based setting. There is lower confidence in performing MM in the community and more practical issues such as lack of time and access to exam rooms.

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<tr>
<td>Ronsley et al. (2012). Metabolic monitoring training program implementation in the community setting was associated with improved monitoring in second-generation antipsychotic-treated children.</td>
<td>Inferred Cognitive Learning Theory</td>
<td>Design: QED, pre-/post-test/ RCS</td>
<td>N= 2376 children (mean age 11.8 years, SD= 4.81, range= 1.86-18.34) seen at CYMHTs</td>
<td>IV- MMTP DV1: percentage of SGA- treated children with MM completed before and after MMTP DV2: prescription changes pre-</td>
<td>review of paper charts and electronic records.</td>
<td>Descriptive Statistics, Chi-square</td>
<td>Differences between all pre- and post-MMTP were significant for all anthropometric measurements and blood work parameters, (p &lt; 0.01).</td>
<td>Level IV</td>
</tr>
<tr>
<td>Funding: Lawson Foundation and Provincial Health Services Authority.</td>
<td>Purpose: To determine if implementation of a MMTP improves monitoring and prescription rates of SGAs in children</td>
<td>n= 1114 children seen at CYMHTs 9/1/2007-12/31/2008 (pre-MMTP)</td>
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#### AE- adverse effect, AMA- American Medical Association, BCCH- British Columbia Children’s Hospital, BMI- body mass index, BP- blood pressure, BS- blood sugar, CDA- Canadian Diabetes Association, CFRI- Child & Family Research Institute, CHOL- cholesterol, CIHR- Canadian Institute of Health Research, CMHT- community mental health team, COI- conflict of interest, CSRS- cross-sectional retrospective study, CTSI- Clinical and Translational Service Institute, CYMHT- Child and Youth Mental Health Team, DB- double blind, DV- dependent variable, dx- diagnosis, ECG- electrocardiogram, EPS- extrapyramidal symptoms, EQS- exploratory qualitative study, FBG- fasting blood glucose, f/u- follow-up, H- height, HDL-C- high-density lipoprotein cholesterol, HR- heart rate, IV- independent variable, IP- inpatient, LDL-C- low-density lipoprotein cholesterol, LFT- liver function tests, MA- meta-analysis, MetS- metabolic syndrome, MH- mental health, MM- metabolic monitoring, MMP- metabolic monitoring program, MMTP- metabolic monitoring training program, OP- outpatient, PC- primary care, PCS- prospective cohort study, PE- physical exam, PPV- positive predictive value, QED- quasi-experimental design, QES- quasi-experimental study, RCR- retrospective chart review, RCS- retrospective cohort study, RCT- randomized controlled trial, SE- side effect, SGA- second-generation antipsychotic, SR- systematic review, T1D- type 1 diabetes, T2D- type 2 diabetes, TG- triglycerides, WC- waist circumference, W- weight |
No conflict of interest disclosed by authors.

Bias: No control group. Information bias. One author supported by CDA and CFRI.

Canada

Citation


Funding: Zucker Hillside Hospital Intervention research.

<table>
<thead>
<tr>
<th>Conceptual Framework</th>
<th>Design/ Method</th>
<th>Sample/ Setting</th>
<th>Major Variables &amp; Definitions</th>
<th>Measurement</th>
<th>Analysis</th>
<th>Findings</th>
<th>Decision for use</th>
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<tr>
<td>Physiological Theory</td>
<td>Design: Cross-sectional, descriptive correlational prevalence study</td>
<td>Purpose: To assess the</td>
<td>IV1 - SGA IV2 - elevated FBG or history T1D, T2D IV3 - high BP IV4 - fasting TG IV5 - LDL-C</td>
<td>BP, WC, FBG, and Lipid levels.</td>
<td>Chi-square tests, ANOVA, sensitivity &amp; specificity, PPV, and positive likelihood</td>
<td>Twenty-six participants (29.2%) met criteria for MetS. MetS was significantly associated with older age</td>
<td>Level V</td>
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</table>

Strengths: largest study to date assessing the relationship between

**Conclusion:** implementation of an MMTP was associated with improved MM
Center for schizophrenia; National Institute of Mental Health grant; and Stanley Research Fellowship Grant.

No COI noted by authors

Bias: Lack of a control without SGA use. Two authors have disclosed association to multiple pharmaceutical companies.

USA

<table>
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<td>Thompson et al. (2011). Targeted intervention to improve monitoring of antipsychotic-induced weight gain and metabolic disturbance in first episode psychosis.</td>
<td>Inferred Cognitive Learning Theory, Bandura’s Self-Efficacy.</td>
<td>Design: QES, Pre-/Post-intervention analysis</td>
<td>n= 106 pre-intervention (mean age 21.1 years, SD= 2.7). n= 86 post-intervention (mean age 20.2 years, SD= 2.5).</td>
<td>IV: targeted intervention including; provision of monitoring equipment, interactive education, reminders and prompts within</td>
<td>Predesigned audit form.</td>
<td>t-test, Pearson’s and Mantel-Haenszel chi.</td>
<td>Minimum metabolic screening was completed within 6 months of starting an antipsychotic on 22% (n= 24) of patients pre-intervention.</td>
<td>Level IV</td>
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**Strengths:**
- Detailed description of the intervention

**Weaknesses:**
- Non-

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Foundation.

No COI noted by authors

Bias: Information bias.
Selection bias. Sampling bias.
Three authors have disclosed funding/grants/awards/honoraria from fellowships and multiple pharmaceutical companies.

Australia

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<th>levels of monitoring in a first episode psychosis clinic. For admission into program, pts must have psychotic D/O and have not previously received more than 6 months of treatment. Pre-intervention audit: files of all patients admitted consecutively for the first time between 1/1/2006 and 6/30/2006. Post-intervention audit: files of all patients admitted consecutively between 9/1/2008 and 2/28/2009. Must be prescribed antipsychotics.</th>
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<td>team structure to entire cohort of clinicians working at the clinic DV1: guideline concordant monitoring DV2: minimum MM DV3: Minimum metabolic screening.</td>
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<td>significant improvement was found post-intervention, 81.4% (n=70) (Mantel-Haenszel chi = 8.171, p &lt; 0.001. The rate of minimum MM improved significantly from 1.7% (n=2) to 39.5% (n=34) post-intervention (Mantel-Haenszel chi = 6.897, p &lt; 0.001.</td>
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<td>randomized, acknowledged turnover of staff, the clinicians audited were not the same for each audit, tests may have been ordered by physicians from another service, and the post-intervention sample was statistically younger than the follow-up sample.</td>
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<td>Conclusion: using a targeted implementation strategy substantially improved routine screening and monitoring</td>
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**Barriers to MM**

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Appendix G

EBP Implementation Model

Iowa Model of Evidence-Based Practice to Promote Quality Care Iowa

Model begins with identifying problem focused or knowledge focused triggers

**Is this a priority topic?**
- If yes- form team, assemble research, and critique and synthesize.
- If no; consider other triggers

**Is there sufficient evidence?**
- If yes- pilot change
- If no-conduct research

**Is change appropriate for adoption onto practice?**
- If yes-institute change. Monitor and analyze structure, process, and outcomes.
- Disseminate results
- If no- continue to evaluate quality of care and new knowledge

(Melnyk & Fineout-Overholt, 2015).
Conceptual Framework

Theory of Planned Behavior

Theory of Planned Behavior suggests that the intention to perform a behavior is based on:

- a person’s attitude,
- the subjective norm - social pressure experienced by the person to perform a behavior,
- and perceived behavioral control- the person’s perceived amount of control to act.

Changing attitudes, subjective norms, and perceived behavioral control can influence intention and the performance of behaviors (Francis et al., 2004).
Appendix I

Institutional Review Board

Exemption Letter

EXEMPTION GRANTED

Annmarie Lyles
CONHI - Research Faculty and Staff

Annmarie.Lyles@asu.edu

Dear Annmarie Lyles:

On 7/27/2017 the ASU IRB reviewed the following protocol:

<table>
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<th>Type of Review:</th>
<th>Initial Study</th>
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<tr>
<td>Title:</td>
<td>Improving Metabolic Monitoring for Children who are Prescribed Second-Generation Antipsychotics</td>
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<tr>
<td>Investigator:</td>
<td>Annmarie Lyles</td>
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<tr>
<td>IRB ID:</td>
<td>STUDY00006598</td>
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<tr>
<td>Funding:</td>
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Documents Reviewed:
- Pre-education Survey, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);
- IRB Recruitment Letter, Category: Recruitment Materials;
- Letter of Support, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc.);
- IRB Protocol, Category: IRB Protocol;
- Post-education Survey, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);
- Tinyke CTTI Training Certificate, Category: Other (to reflect anything not captured above);
- Educational Outline, Category: Other (to reflect anything not captured above);
Appendix J

Recruitment of Participants

Recruitment Letter

Improving Metabolic Monitoring for Children and Adolescents Receiving Second-Generation Antipsychotics

Date: 11/1/17

Dear Participant,

I am a graduate student under the direction of Dr. Annmarie Lyles and Dr. Ann Guthery in the College of Nursing and Health Innovation at Arizona State University.

I am inviting you to participate in an evidence-based educational program that will address the recommended metabolic monitoring for children who are prescribed second-generation antipsychotics and determine if education can improve adherence to metabolic monitoring guidelines. This will involve participating in an educational class and completing pre- and post-education questionnaires. The pre-education questionnaire will be administered prior to the educational program and will take approximately 10 minutes to complete. The total time required to complete the educational program will be approximately 15 minutes. There will be additional time allowed after the educational program to answer any questions you may have. The post-education questionnaire will be administered three months after the educational program and takes approximately 10 minutes to complete.

Your participation in the evidence-based educational program and completion of the questionnaires is voluntary. You must be 18 years of age or older to participate in this program. Responses to the questionnaires will be used to evaluate the effectiveness of the educational program. You can skip questions in the questionnaires if you wish. If you choose not to participate or to withdraw from the program at any time, there will be no penalty. There is no known risk greater than those associated with everyday types of activity associated with participation in this evidence-based educational program.

Your responses on the questionnaires will be anonymous and will not be connected to your name or other personal identifying information. You will be asked to create an ID using your favorite color, the date of your birth, and the first initial of the place of your birth; my ID for example would be Yellow23M. The results of this study may be used in reports, presentations, or publications, but your name will not be known or used.

If you have any questions concerning this program, please contact the following team members:

The Office of Research Integrity and Assurance at ASU can be reached at (480) 965-6788.
Dr. Annmarie Lyles- email: annmarie.lyles@asu.edu  Cell Phone: 608-219-7331
Dr. Ann Guthery- email: ann.guthery@asu.edu  ASU Phone: 602-496-0794
Janet Tinkey, RN- email: jmtinkey@gmail.com  Cell Phone:724-875-2661

Your attendance at the educational session and finishing the pre-education and post-education surveys will be considered your consent to participate.

Sincerely,

Appendix K
METABOLIC MONITORING IN CHILDREN

Project Educational Intervention

Educational Intervention Outline

Improving Metabolic Monitoring for Children who are Prescribed Second-Generation Antipsychotics

1. Background and Significance
   a. Increase in use of second-generation antipsychotics (SGAs) to treat psychiatric disorders in children
   b. Side effects of SGAs
      i. Weight changes significantly assoc. with adverse changes in body composition- fat mass and waist circumference (WC).
      ii. Increased levels of fasting glucose
      iii. Dyslipidemia
      iv. Hyperprolactemia
   c. SGA use and increased risk for Metabolic syndrome (MetS)
   d. Increase in risk for cardiometabolic disease in adulthood
   e. Need for routine metabolic monitoring
   f. Poor rates of adherence to metabolic monitoring guidelines are a gap in care for children prescribed SGAs

2. Metabolic Syndrome (MetS)
   a. Definition of MetS: International Diabetes Federation (Nolt et al., 2017)
   b. Abdominal adiposity is a hallmark of MetS and confers reliable degree of sensitivity in detecting metabolic changes in children over time (Nolt et al., 2017).
   c. Criteria for diagnosing MetS in
i. Children ages 6-10- can only diagnose obesity-- WC ≥ 90th percentile

ii. Children ages 10-16-- WC ≥ 90th Percentile and two or more of the following:
   triglycerides ≥150 mg/dl, HDL chol <40 mg/dl, systolic BP ≥130 mmHg/
   diastolic BP ≥85 mmHg or known Type II diabetes or FBG ≥100 mg/dl

iii. Children ages 16-18 – IDF criteria for diagnosing MetS in adults

3. Recommended metabolic monitoring
   a. 2004 ADA guidelines
   b. AACAP recommend following ADA guidelines in 2011
   c. CDC chart for WC in cm for children ages 2-19

   a. Determine risk-benefit of psychotropic medication.
   b. Is there a med with fewer SE?
   c. What is the child’s BMI, WC, and overall health?
   d. What are baseline labs and anthropomorphic values?
   e. Consultation with primary care provider

References

antipsychotic utilization and metabolic parameter monitoring in an inpatient pediatric
population: A retrospective analysis. Paediatric Drugs, 19(2), 139-146.
doi:10.1007/s40272-016-0209-x

Pearson, G. S. (2012). Psychopharmacology notes: Managing the metabolic side effects of
Appendix L

Project Instrument

Pre-intervention Questionnaire
Improving Metabolic Monitoring for Children Who Are Prescribed Second-Generation Antipsychotics (SGAs)

Pre-Test

This questionnaire will ask you to consider how you feel about using metabolic monitoring guidelines when caring for pediatric patients who are prescribed SGAs. Your participation in completing this questionnaire is voluntary and all your answers will be anonymous and confidential.

Please create an ID for your questionnaire using your favorite color, your date of birth, and the first initial of the place of your birth. For example, my ID would be: Yellow23M.

ID ____________

First, I would like to ask a few questions about you.

How old are you? ____________

How many years have you been in practice? ________________

What is your gender? 1 Male 2 Female

What is your professional title? 1 MD 2 DO 3 NP

For the following questions, please circle the number that most closely matches your response.

1. Using metabolic monitoring guidelines during the next three months for my pediatric patients who are prescribed SGAs is:
2. During the next three months, I expect to use guidelines for metabolic monitoring for my pediatric patients who are prescribed SGAs.

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Disagree or Agree</th>
<th>Agree</th>
<th>Strongly Agree</th>
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3. Most people who are important to me where I work think that I should

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<th>Should</th>
<th>Should Not</th>
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use metabolic monitoring guidelines for my pediatric patients who are prescribed SGAs.

4. It is expected of me that I will use metabolic monitoring guidelines for my pediatric patients who are prescribed SGAs.

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<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
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5. I feel under social pressure to use metabolic monitoring guidelines for my pediatric patients who are prescribed SGAs.

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<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
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<th>Strongly Disagree</th>
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METABOLIC MONITORING IN CHILDREN

6. People who are important to me where I work want me to use metabolic monitoring
guidelines for my pediatric patients who are prescribed SGAs.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
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</table>

7. During the next three months, I want to use guidelines for metabolic monitoring for my pediatric patients who are prescribed SGAs.

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<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Disagree or Agree</th>
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8. I am confident that I could use metabolic monitoring guidelines for my pediatric patients who are prescribed SGAs if I wanted to.

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<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Disagree or Agree</th>
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</table>

9. For me to use metabolic monitoring guidelines for my pediatric patients who are prescribed SGAs it is:

| Easy | 1 | 2 | 3 | 4 | 5 | Difficult |

10. The decision to use metabolic monitoring guidelines for pediatric patients who are prescribed SGAs is beyond my control.
11. Whether I use metabolic monitoring guidelines for my pediatric prescribed who are prescribed SGAs or not is entirely up to me.

12. During the next three months, I intend to use metabolic monitoring guidelines for my pediatric patients who are prescribed SGAs.

I would like to ask you a few more questions. In answering the following questions please consider the children and adolescents that you have prescribed second-generation antipsychotics for during the past month and circle the answer that describes your usual practice.

13. When you initiate a new prescription for a second-generation antipsychotic do you usually measure a baseline:
   a. Blood pressure  No  Yes
   b. Weight  No  Yes
   c. Height  No  Yes
   d. BMI  No  Yes
METABOLIC MONITORING IN CHILDREN

e. Waist circumference  No  Yes
f. Fasting plasma glucose,  No  Yes
g. Fasting Lipid Profile  No  Yes

14. Do you usually measure the following values 12 weeks after starting a new prescription for second-generation antipsychotics?

a. Blood pressure  No  Yes
b. Weight  No  Yes
c. Height  No  Yes
d. BMI  No  Yes
e. Waist circumference  No  Yes
f. Fasting plasma glucose,  No  Yes
g. Fasting Lipid Profile  No  Yes

I want to thank you for taking the time to complete this survey.

Appendix M

Instrument Validity

Content Validity Tool

Tool for Assessing the Content Validity of the Theory of Planned Behavior Questionnaire for Metabolic Monitoring Guidelines

Please highlight the response that best matches your answer.
METABOLIC MONITORING IN CHILDREN

For Q1.

1. Using metabolic monitoring guidelines during the next three months for my pediatric patients who are prescribed SGAs is:

<table>
<thead>
<tr>
<th>Harmful</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>Beneficial</th>
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</thead>
<tbody>
<tr>
<td>Good Practice</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>Bad Practice</td>
</tr>
<tr>
<td>Pleasant for Me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>Unpleasant for me</td>
</tr>
<tr>
<td>Worthless</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>Useful</td>
</tr>
</tbody>
</table>

Q1 is understandable.

Strongly Agree  Agree  Disagree  Strongly Disagree

Q1 is appropriate to assess the provider’s attitudes towards using metabolic monitoring guidelines

Strongly Agree  Agree  Disagree  Strongly Disagree

Q1 is relevant to assess the provider’s attitudes toward using metabolic monitoring guidelines.

Strongly Agree  Agree  Disagree  Strongly Disagree

If you chose Disagree or Strongly Disagree, please indicate why.

__________________________________________________________________

Any Suggestions for Q1?

__________________________________________________________________
For Q2.

2. During the next three months, I expect to use guidelines for metabolic monitoring for my pediatric patients who are prescribed SGAs.

<table>
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<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Disagree or Agree</th>
<th>Agree</th>
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</table>

Q2 is understandable.

Strongly Agree   Agree   Disagree   Strongly Disagree

Q2 is appropriate to assess the provider’s intention to use guidelines for metabolic monitoring.

Strongly Agree   Agree   Disagree   Strongly Disagree

Q2 is relevant to assess the provider’s intention to use guidelines for metabolic monitoring.

Strongly Agree   Agree   Disagree   Strongly Disagree

If you chose Disagree or Strongly Disagree, please indicate why.

__________________________________________________________________
Any Suggestions for Q2?

For Q3

3. Most people who are important to me think that I should
   use metabolic monitoring guidelines for my pediatric patients who are prescribed SGAs

Q3 is understandable.

Strongly Agree Agree Disagree Strongly Disagree

Q3 is appropriate to assess the provider’s subjective norms regarding the use of guidelines for metabolic monitoring.

Strongly Agree Agree Disagree Strongly Disagree

Q3 is relevant to assess the provider’s subjective norms regarding the use of guidelines for metabolic monitoring.

Strongly Agree Agree Disagree Strongly Disagree

If you chose Disagree or Strongly Disagree, please indicate why.
METABOLIC MONITORING IN CHILDREN

Any Suggestions for Q3?

For Q4

4. It is expected of me that I will use metabolic monitoring guidelines for my pediatric patients who are prescribed SGAs.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
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Q4 is understandable.

Strongly Agree      Agree      Disagree      Strongly Disagree

Q4 is appropriate to assess the provider’s subjective norms regarding the use of guidelines for metabolic monitoring.

Strongly Agree      Agree      Disagree      Strongly Disagree

Q4 is relevant to assess the provider’s subjective norms regarding the use of guidelines for metabolic monitoring.

Strongly Agree      Agree      Disagree      Strongly Disagree

If you chose Disagree or Strongly Disagree, please indicate why.
Any Suggestions for Q4?

For Q5

5. I feel under social pressure to use metabolic monitoring guidelines for my pediatric patients who are prescribed SGAs.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
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Q5 is understandable.

Strongly Agree    Agree    Disagree    Strongly Disagree

Q5 is appropriate to assess the provider’s subjective norms regarding the use of guidelines for metabolic monitoring.

Strongly Agree    Agree    Disagree    Strongly Disagree

Q5 is relevant to assess the provider’s subjective norms regarding the use of guidelines for metabolic monitoring.

Strongly Agree    Agree    Disagree    Strongly Disagree

If you chose Disagree or Strongly Disagree, please indicate why.
Any Suggestions for Q5?

For Q6

6. People who are important to me want me to use metabolic monitoring guidelines for my pediatric patients who are prescribed SGAs.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
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Q6 is understandable.

Strongly Agree       Agree       Disagree       Strongly Disagree

Q6 is appropriate to assess the provider’s subjective norms regarding the use of guidelines for metabolic monitoring.

Strongly Agree       Agree       Disagree       Strongly Disagree

Q6 is relevant to assess the provider’s subjective norms regarding the use of guidelines for metabolic monitoring.
For Q7

7. During the next three months, I want to use guidelines for metabolic monitoring for my pediatric patients who are prescribed SGAs.

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<th>Strongly Disagree</th>
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Q7 is understandable.

Strongly Agree  Agree  Disagree  Strongly Disagree

Q7 is appropriate to assess the provider’s intention to use guidelines for metabolic monitoring.

Strongly Agree  Agree  Disagree  Strongly Disagree
METABOLIC MONITORING IN CHILDREN

Q7 is relevant to assess the provider’s intention to use guidelines for metabolic monitoring.

Strongly Agree  Agree  Disagree  Strongly Disagree

If you chose Disagree or Strongly Disagree, please indicate why.

__________________________________________________________________

Any Suggestions for Q7?

__________________________________________________________________

For Q8

8. I am confident that I could use metabolic monitoring guidelines for my pediatric patients who are prescribed SGAs if I wanted to.

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Q8 is understandable.

Strongly Agree  Agree  Disagree  Strongly Disagree

Q8 is appropriate to assess the provider’s perceived behavioral control regarding the use of guidelines for metabolic monitoring.

Strongly Agree  Agree  Disagree  Strongly Disagree
Q8 is relevant to assess the provider’s perceived behavioral control regarding the use of guidelines for metabolic monitoring.

Strongly Agree      Agree      Disagree      Strongly Disagree

If you chose Disagree or Strongly Disagree, please indicate why.

__________________________________________________________________

Any Suggestions for Q8?

__________________________________________________________________

For Q9

9. For me to use metabolic monitoring guidelines for my pediatric patients who are prescribed SGAs it is:

Easy 1 2 3 4 5 Difficult

Q9 is understandable.

Strongly Agree      Agree      Disagree      Strongly Disagree
METABOLIC MONITORING IN CHILDREN

Q9 is appropriate to assess the provider’s perceived behavioral control regarding the use of guidelines for metabolic monitoring.

Strongly Agree  Agree  Disagree  Strongly Disagree

Q9 is relevant to assess the provider’s perceived behavioral control regarding the use of guidelines for metabolic monitoring.

Strongly Agree  Agree  Disagree  Strongly Disagree

If you chose Disagree or Strongly Disagree, please indicate why.

__________________________________________________________________

Any Suggestions for Q9?

__________________________________________________________________

For Q10

10. The decision to use metabolic monitoring guidelines for pediatric patients who are prescribed SGAs is beyond my control.

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<th>Strongly Disagree</th>
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Q10 is understandable.

Strongly Agree  Agree  Disagree  Strongly Disagree
Q10 is appropriate to assess the provider’s perceived behavioral control regarding the use of guidelines for metabolic monitoring.

Strongly Agree       Agree       Disagree       Strongly Disagree

Q10 is relevant to assess the provider’s perceived behavioral control regarding the use of guidelines for metabolic monitoring.

Strongly Agree       Agree       Disagree       Strongly Disagree

If you chose Disagree or Strongly Disagree, please indicate why.

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Any Suggestions for Q10?

__________________________________________________________________

For Q11

11. Whether I use metabolic monitoring guidelines for my pediatric prescribed who are prescribed SGAs or not is entirely up to me.

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<th>Strongly Disagree</th>
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Q11 is understandable.

Strongly Agree       Agree       Disagree       Strongly Disagree
Q11 is appropriate to assess the provider’s perceived behavioral control regarding the use of guidelines for metabolic monitoring.

Strongly Agree    Agree    Disagree    Strongly Disagree

Q11 is relevant to assess the provider’s perceived behavioral control regarding the use of guidelines for metabolic monitoring.

Strongly Agree    Agree    Disagree    Strongly Disagree

If you chose Disagree or Strongly Disagree, please indicate why.

__________________________________________________________________

Any Suggestions for Q11?

__________________________________________________________________

For Q12

12. During the next three months, I intend to use metabolic monitoring guidelines for my pediatric patients who are prescribed SGAs.

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Q12 is understandable.
METABOLIC MONITORING IN CHILDREN

Q12 is appropriate to assess the provider’s intention to use guidelines for metabolic monitoring.

Q12 is relevant to assess the provider’s intention to use guidelines for metabolic monitoring.

If you chose Disagree or Strongly Disagree, please indicate why.

__________________________________________________________________

Any Suggestions for Q12?

__________________________________________________________________
METABOLIC MONITORING IN CHILDREN