A Physician Handbook for

Metabolic Monitoring for Youth with Mental Illness treated with Second-Generation Antipsychotics

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Preamble

The Why Weight Program is a collaborative program between the Vancouver Community Child and Youth Mental Health Services (BC Ministry for Child and Family Development (MCFD)) and two clinical departments at BC Children's Hospital (Child and Adolescent Psychiatry; Endocrinology and Diabetes) to evaluate the effects of second-generation antipsychotics (SGAs) on weight gain, insulin resistance, metabolic syndrome, and glucose intolerance/type 2 diabetes in youth with mental illness. One of the main goals of this study is to promote appropriate clinical monitoring practices through the creation of an education resource for physicians and mental health workers. This handbook is meant to provide this framework for metabolic monitoring.

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Handbook for Psychiatry Residents

Second-Generation Antipsychotics

What Confers Atypicality of Second-Generation Antipsychotics?

Second-generation antipsychotics (SGAs) are defined by the following characteristics:

1. $5HT_2/D_2$ receptor blockade activity
2. Significantly reduced extrapyramidal side effects (EPS)
3. Observed improvement in both negative and positive symptoms of psychosis

The following is a list of SGAs available in Canada:

1. Clozapine (Clozaril®)
2. Olanzapine (Zyprexa®)
3. Paliperidone (Invega®)
4. Quetiapine (Seroquel®)
5. Risperidone (Risperdal®)
6. Ziprasidone (Zeldox®)

What are their uses in the pediatric population?

There are currently no "on-label" indications for the use of SGAs. All current usage is therefore considered to be "off-label" for children and adolescents.

The following target symptoms are off-label indications for the use of SGAs in youth[1]:

1. Aggression
2. Low frustration tolerance
3. Affect dysregulation
4. Impulsivity

The following diagnoses are off-label indications for the use of SGAs in youth[1]:

1. Psychosis
2. Mood disorders
3. Anxiety
4. Externalizing disorders
5. Pervasive Developmental Disorder (PDD)

Many of the 15% of BC youth who suffer from a mental illness will be treated with an SGA. The rate of prescription of these drugs in BC increased by 22%[2] between 2002 and 2006 despite limited evidence demonstrating their efficacy and with little evaluation of the potential metabolic side effects in growing children[3].

What are the potential side effects of SGAs in Youth?

In adults, there is growing evidence[4-6] that SGAs cause significant weight gain[7,8] and adverse metabolic disturbances, such as hyperlipidemia[9], and insulin resistance[10,11].

SGA use is therefore associated with the emergence of both metabolic syndrome and type 2 diabetes (T2D). The long-term micro- and macro-vascular complications associated with T2D contribute significantly to its related morbidity and mortality[12].

In youth, similar metabolic disturbances have been observed[13-19], but are based on fewer studies and individual case reports.

Table 1: Side-effects of Second-Generation Antipsychotics[17]

Common Side Effects	Rare Side Effects
Body Weight Gain	Hepatotoxicity or pancreatitis
Sedation/Somnolence	Agranulocytosis
Dyslipidemia (low HDL-C, high LDL-C, high TG, high total cholesterol)	Cardiovascular effects (e.g. QTc prolongation)
Prediabetes or T2D or impaired glucose metabolism	Seizures
Hyperprolactinemia	Sialorrhoea
	EPS/Tardive dyskinesia
	Decreased thyroxine (T_4) levels

Key: HDL-C = High Density Lipoprotein – Cholesterol ("good cholesterol"), LDL-C = Low Density Lipoprotein – Cholesterol ("bad cholesterol"), TG = Triglycerides

Data suggests that SGAs double the risk of weight gain and triple the risk for glucose intolerance in youth[21]. Most of the weight gain occurs within the first 6-months after starting an atypical antipsychotic medication, and a significant amount occurs within the first few weeks of starting treatment[16].

Implementing a metabolic monitoring program is a means of developing consistent practice amongst physicians to identify and prevent the progression of metabolic dysfunction in youth taking SGAs, and thereby reduce the associated long-term morbidities. **Appendix A** has more detailed information regarding specific side-effects found in the available SGAs in Canada.

Metabolic Monitoring

What is involved in metabolic monitoring?

At the time of prescription of these drugs, a baseline metabolic status must be established. Follow-up metabolic status assessments should then be done to evaluate for the potential onset of metabolic syndrome and type 2 diabetes, as well as other metabolic disturbances.

Metabolic Syndrome in Youth

The following table summarizes the guidelines provided by the International Diabetes Federation (IDF) and the National Cholesterol Education Program (NCEP) for the diagnosis of metabolic syndrome.

There is no standardized definition of metabolic syndrome in children and adolescents; therefore, this document provides both ongoing definitions of metabolic syndrome in the pediatric population used in clinical practice today. One recommendation is to use the NCEP APTIII definition with the modified fasting glucose (FG) value of 5.6mmol/L. Controversy exists as to whether the diagnosis of metabolic syndrome is more important than the individual assessment of risk factors in children.

Table 2: Metabolic Syndrome Diagnosis Criteria[20]

	NCEP ATPIII	**IDF**
Waist circumference	≥ 90th percentile for age and sex or adult cut-off if lower	≥ 90th percentile for age, sex or adult cutoff if lower
Triglycerides	≥ 1.24 mmol/L	≥ 1.7 mmol/L
HDL	≤ 1.03mmol/L	≤ 1.03mmol/L
Fasting glucose (FG)	≥ 6.1 mmol/L	≥ 5.6 mmol/L or known T2D
Modified FG	≥ 5.6 mmol/L	
Blood pressure	Systolic or diastolic ≥ 90th percentile for age, height, sex	Systolic ≥ 130 mmHg or Diastolic ≥ 85mmHg
Metabolic syndrome	Any 3/5 criteria	Waist circumference AND any 2/4 criteria

= Suggested clinical definition because hypertension is defined using pediatric percentile norms

Appendix B contains the various charts required to determine percentiles to diagnose metabolic syndrome in the pediatric population, including waist circumference cut-offs

based on age, sex, and ethnicity and blood pressure charts corrected for age, sex, height, and weight.

Screening for type 2 diabetes and prediabetes in Youth[20]

Children should be screened for type 2 diabetes using a fasting plasma glucose test if they have $\geq$ 2 of the following risk factors:

- Obesity (BMI $\geq 95^{th}$ percentile for age and sex)
- Member of high-risk ethnic group and/or family history of type 2 diabetes and/or exposure to diabetes in utero
- Signs or symptoms of insulin resistance (including acanthosis nigricans, hypertension, dyslipidemia, non-alcoholic fatty liver disease)
- Impaired glucose tolerance
- Use of antipsychotic medications/atypical neuroleptics

*very obese children (BMI$\geq 99^{th}$ percentile for age and gender) who meet the criteria in above guidelines should have an OGTT performed annually
*OGTT also recommended for youth with fasting glucose $\geq$5.6 mmol/L

Appendix C contains the growth charts to determine height, weight and BMI percentiles for the pediatric population for boys and girls. This consists of two sets of charts: one for ages 0-3 and one for ages 2-20.

Appendix D has the CDA guidelines for the care of children and adults with the potential to develop or who have developed Type 2 diabetes.

Baseline Information for Metabolic Monitoring

History (Hx)

The purpose of the history specific for metabolic monitoring is to identify risk factors for type 2 diabetes, metabolic syndrome and other metabolic consequences.

In addition to the regular history, the following information is important to obtain from the child or adolescent and his or her parents/legal guardians upon prescription of an atypical or second-generation antipsychotic:

1. Family history of diabetes and related risk factors (e.g. gestational diabetes, cardiovascular disease such as heart attacks or strokes (particularly before age 50), obesity, high cholesterol, hypertension or metabolic syndrome)
2. Family history of psychiatric illness (treated/untreated), particularly schizophrenia or bipolar disorder
3. Any concurrent endocrine problems. (e.g. thyroid, puberty-related such as menstrual history or onset of puberty)
4. Current medications, alcohol, allergies, drugs, smoking
5. Physical activity and diet
    a. How many minutes of exercise per day?
    b. How much screen-time (i.e. TV, computer, and X-box or Gameboy use) per day?
    c. Are there sugar-sweetened drinks in the routine diet? How many sugar-sweetened drinks consumed/day and the quantity (e.g. juice, pop, Gatorade etc.)?
    d. Is candy/junk food part of the routine diet? How many junk items/candy does he/she consume in one day?

Physical Exam (PEx)

The following anthropometric measurements and metabolic parameters should be done before starting treatment with an SGA:

1. Height (m)
2. Weight (kg)
3. BMI
   BMI is calculated using weight (kg) and height (m) in the following formula:

   $$BMI = weight\ (kg)/(height(m))^2$$

   This is then interpreted in the context of age and sex as percentiles (BMI z-score) using the online BMI calculator at http://apps.nccd.cdc.gov/dnpabmi (See Appendix C for BMI charts)
4. Waist Circumference (cm) (see Appendix B for waist circumference cut-offs and Table 2 for Metabolic Syndrome diagnosis criteria)
   The standard practice is to measure waist circumference at the top of the iliac crest. Practically, however, this can be estimated at the level of the umbilicus.

For accurate measurement of waist circumference, the patient should be standing with their feet together and the measurement should be taken upon expiration and release of the abdomen.

5. Blood Pressure: should be corrected for age and height (see Appendix B)
6. Acanthosis Nigricans
   Acanthosis nigricans is a skin disorder characterized by dark, thick, velvety skin in body folds and creases, particularly in areas such as the back of the neck and the armpits. It often indicates insulin resistance, especially in obese patients.

Lab Tests

Typical baseline screening lab work includes:

1. Liver enzymes (AST, ALT, GGT) and Amylase
   A few cases of pancreatitis have been found with the use of Quetiapine.
2. TSH
   The SGA Quetiapine has been shown to produce reduced levels of T_4 in the blood as well.
3. CBC and Differential (Hbg, WBC, Platelets)
   Neutropenia has been observed in children treated with Clozapine. As with adults, children prescribed Clozapine require regular monitoring of CBC and Differential.
4. Electrolytes
5. BUN, Creatinine
6. Urine Toxicology

Additional lab work to screen for metabolic disturbances includes:

7. Fasting Glucose
8. Fasting Insulin (a fasting insulin $\geq$100 is suggestive of hyperinsulinemia/insulin resistance)
9. Fasting Lipid Profile (Total Cholesterol, TG, HDL-C, LDL-C)
10. Prolactin
    Hyperprolactinemia has been consistently found with the use of Risperidone, and at times with other SGAs, such as Ziprasidone, Clozapine, and Olanzapine, resulting in menstrual disturbances, sexual dysfunction, and galactorrhea, which has been found to be particularly distressing to adolescents.
11. 2hPG OGTT (if necessary – see Table 3 for reference values)

Other tests

1. ECG – if indicated

Appendix E has a lab order form example to be used as a checklist for the various tests to order.

Follow-up Metabolic Monitoring

The following items are to be completed on follow-up visits for children treated with SGAs.

History (Hx)

1. Has there been any recent weight change (gain or loss)?
2. Have there been changes in appetite and/or energy levels during the day?
3. Is there polyuria, polydypsia, nocturia, or fatigue evident?
4. Has there been any evidence of prolactin-related phenomena, such as galactorrhea or amenorrhea?
5. Other questions regarding known side-effects, such as other endocrine changes and cardiac changes for example, can be asked at follow-up. Examples include:
    e. Thyroid – heat/cold intolerance, skin/hair changes, changes in bowel habits
    f. Puberty-related – changes in menstrual cycle

Physical Exam (PEx) and Lab and Other Tests

There are currently no established clinical practice guidelines for metabolic monitoring. **Appendix F** is a proposed metabolic monitoring protocol being piloted by Vancouver Coastal Health. This may be used to guide required follow-up tests and their frequencies.

On follow-up, values for all lab tests should be compared to the normal range. If values fall outside the normal range, please refer to Tables 2 and 3 given above for metabolic syndrome and type 2 diabetes to determine if the diagnostic criteria are met.

A referral to a pediatric endocrinologist is warranted if any of the following occur:

1. Evidence of insulin resistance (eg. fasting insulin ≥100 pmol/L; acanthosis nigricans)
2. Metabolic syndrome
3. Polycystic ovarian syndrome (clinical diagnosis: evidence of irregular menstruation or amenorrhea with clinical or biochemical evidence of hyperandrogenism (i.e. hirsutism, acne, or increased testosterone) following exclusion of other pathological causes
4. Dyslipidemia
5. Glucose intolerance/type 2 diabetes
6. Nonalcoholic steatohepatitis (increased transaminases - 3x upper limit of normal; or evidence of fatty liver on ultrasound)
7. Persistent hypertension on three occasions with appropriate BP cuff
8. Clinical evidence of hyperprolactinemia, such as galactorrhea, menstrual irregularities or amenorrhea

NB. With Risperidone use, hyperprolactinemia is expected secondary to the D_2 blockade. In adults with significant D_2 blockade, prolactin levels greater than 2X normal levels are likely related to causes other than antipsychotic use. Please refer to the list above to determine if referral to a pediatric endocrinologist is warranted.

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Appendix A – Second-Generation Antipsychotics

Table A1: Adverse Effects of Atypical Antipsychotic Medications[17]

	TD	EPS	Sed	BWG	P	CV	Seiz	HT	Sial	A	Other	Recommendations
Clozapine	-	+	+++	+++	-	+	+	+	+++	+++	OCD (+), pancreatitis/ eosinophilia associated with pancreatitis (+), DKA/diabetes mellitus induction	Monitor fasting glucose every 6mo. (esp. w/ FHx DM); baseline EEG and EEG at optimal dose for seizure monitoring
Risperidone	+	+	+	+	+	+	+	+	-	+	Dysthymia/ major depressive disorder (+), mania in adults (+), nocturnal enuresis (++)	Liver enzymes for possible HT
Olanzapine	+	+	+++	+++	+	+	+	+	-	-	Glucose intolerance induction (++), mania development (+)	Liver enzyme monitoring recommended, body weight (BMI) and fasting glucose monitoring (esp. w/ FHx DM)
Quetiapine	+	+	+	+	-	+	+	-	-	-	Cataract formation (-)	Baseline slit-lamp and subsequent slit-lamp recommended in U.S.

Symbol	*Description*	*Symbol*	*Description*
TD	Tardive dyskinesia	HT	Hepatotoxicity
EPS	Extrapyramidal Symptoms	Sial	Sialorrhoea
Sed	Sedation	A	Agranulocytosis
BWG	Body Weight Gain	+	Minimal Risk
P	Prolactin	++	Moderate Risk
CV	Cardiovascular Effects	+++	Significant Risk
Seiz	Seizures	-	No Apparent Risk

Appendices

Appendix B Age and Sex-Specific Waist Circumference Guidelines (Pages 18-19)
Adapted from http://www.idf.org/webdata/docs/Mets_definition_children.pdf
Source: International Diabetes Federation

Appendix C Age and Sex-Specific Blood Pressure Guidelines
http://pediatrics.aappublications.org/cgi/content/full/114/2/S2/555
Source: *Pediatrics*

Appendix D Growth Charts for the Pediatric Population
http://www.cdc.gov/growthcharts/clinical_charts.htm#Set1
Source: Centers for Disease Control and Prevention

Appendix E Canadian Diabetes Association Guidelines for Type 1 and Type 2 Diabetes (Pages S10-13; S162-S167)
http://www.diabetes.ca/files/cpg2008/cpg-2008.pdf
Source: Canadian Diabetes Association

Appendix F Sample Pre-Printed Orders for Inpatient Unit Use
http://www.bcchildrens.ca/Services/SpecializedPediatrics/EndocrinologyDiabetesUnit/ForProfessionals/AtypicalAntipsychotics.htm
Source: BC Children's Hospital

Appendix G Proposed Metabolic Monitoring Protocol
http://www.bcchildrens.ca/NR/rdonlyres/766EFE02-8E31-4E9E-8DC1-A8EA98A5CC60/44241/metmonitor.pdf
Source: BC Children's Hospital

Metabolic Assessment, Screening & Monitoring Tool

Client Name (last, first)	PHN:	DOB: (dd/mm/yyyy)

PARIS ID:	Gender: Male / Female	Female Pts: Menstrual / Pre-menstrual	Assessment Date: (dd/mm/yyyy)

Target symptoms (check all that apply with respect to starting Second Generation Antipsychotic (SGA))

☐ Mania
☐ Mood/affect lability
☐ Mood stabilization (Bipolar Disorder)
☐ Oppositionality
☐ Psychosis
☐ Self-injurious behaviour
☐ Motor/vocal tic
☐ Aggression
☐ Augmentation of * _____(eg. Antidepressant, anti-anxiety, mood stabilizer, psychostimulant)
☐ Sedation/ Sleep
☐ Other (list) _____

Diagnoses

Axis I Diagnosis (Primary): 1._____

Axis I Diagnosis (Comorbid): 2._____ 3._____ 4._____

Axis II Diagnosis:_____ _____

Axis III Diagnosis (other medical conditions): _____ _____ _____

Axis V GAF Score:_____

Ethnicity

Is the patient's heritage defined by any of the following high-risk ethnicities?

☐ Aboriginal ☐ South Asian (i.e. Indian/Pakistani/Bangladesh) ☐ Asian (i.e. Japanese/Chinese)
☐ Mexican/Hispanic ☐ African/ Caribbean

Is the patient's heritage defined by the any of the following low risk ethnicities?

☐ Caucasian ☐ Arab (i.e. Saudi Arabian/Egyptian/Iraqi)

Risk Factor Evaluation

FMHx:

Diabetes: ☐ Type 1 ☐ Type 2 ☐ Gestational ☐ No ☐ Unk Relationship*: ☐ 1st degree relative ☐ 2nd degree relative

Hyperlipidemia: ☐ Yes ☐ No ☐ Unk Relationship*: ☐ 1st degree relative ☐ 2nd degree relative

Cardiovascular Disease: ☐ Yes ☐ No ☐ Unk Relationship*: ☐ 1st degree relative ☐ 2nd degree relative

FΨHx:

Schizophrenia: ☐ Yes ☐ No ☐ Unk Relationship*: ☐ 1st degree relative ☐ 2nd degree relative

Schizoaffective Disorder: ☐ Yes ☐ No ☐ Unk Relationship*: ☐ 1st degree relative ☐ 2nd degree relative

Psychosis? Not otherwise specified: ☐ Yes ☐ No ☐ Unk Relationship*: ☐ 1st degree relative ☐ 2nd degree relative

Bipolar Disorder: ☐ Yes ☐ No ☐ Unk Relationship*: ☐ 1st degree relative ☐ 2nd degree relative

* **1st degree** relative (mother/father/sibling), Second degree relative (Grandmother/ Grandfather/ Cousin/Aunt/Uncle)

Individual Risk Factors:

Smoking ☐ No ☐ Yes (If yes, cigarettes/day: _____)
Physical Activity eg. Exercise (walking) ☐ No ☐ Yes (If yes, _____min/day)
Screen Time eg. computers, tv, video games ☐ No ☐ Yes (If yes, _____min/day)
Sugar sweetened beverages ☐ No ☐ Yes (If yes, _____cans of pop/day)
(If yes, _____juice boxes/day)

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Medications	Drug Initiation	1 month	2 month	3 month	6 month	9 month	12 month
SGAs Assessment Date (dd/mm/yyyy): →							
Risperidone (Risperdal)	Dose_______ Freq _______	Dose______ Freq ______	Dose______ Freq ______	Dose______ Freq ______	Dose______ Freq ______	Dose______ Freq ______	Dose_______ Freq _______
Quetiapine (Seroquel)	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______
Olanzapine (Zyprexa)	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq_______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______
Paliperidone (Invega)	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq_______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______
Clozapine (Clozaril)	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______
Ziprasidone (Zeldox)	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______
Aripiprazole (Abilify)	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______
Other Medications Assessment Date (dd/mm/yyyy): →							
	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______
	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______
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	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______	Dose_______ Freq _______
Physician Initials: →							

Comments and description of changes made to medication dose at other time interval:

Additional Comments:

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Metabolic Parameters: for patients *treated* with Second Generation Anti-psychotics (SGAs)

Parameter		Pre-treatment Baseline	1 month	2 month	3 month	6 month	9 month	12 month
Test Date (dd/mm/yyyy): →								
Height (cm): (maybe plotted on growth chart)	---							
Weight (kg): (maybe plotted on growth chart)	---							
BMI: (not required during project pilot) (Wt (kg) / Ht (cm^2) x 10,000)	---							
Waist Circumference: (At the level of the umbilicus)	*(See guidelines for ethnic specific values)*							
Blood Pressure:	Systolic ≤ 130 mm HG or Diastolic ≤ 85 mm HG							
Laboratory Evaluations:	(Normal Values)							
Fasting Plasma Glucose:	≤ 5.6 mmol/L (100 mg/dl)							
Fasting Insulin:								
Fasting Total Cholesterol:								
Fasting LDL-C:								
Fasting HDL-C:	> 1.03 mmol/l (>40 mg/dL)							
Fasting Triglycerides:	≤ 1.7 mmol/l (≤ 150 mg/dl)							
AST:								
ALT:								
GGT:								
Amylase:								
TSH								
Prolactin								
Hbg ($x10^9$)								
WBC ($x10^9$)								
Plts ($x10^9$)								
Other_____: (eg. HgbA1C, OGTT etc.)								
Physician Initials: →								

Interventions:

(continue checking as conducted throughout the year)

- ☐ Discuss metabolic risks
- ☐ Discuss signs and symptoms of diabetes
- ☐ Discuss signs and symptoms of DKA
- ☐ Discuss smoking cessation
- ☐ Other_____
- ☐ Discuss diet
- ☐ Refer to dietician
- ☐ Discuss physical activity
- ☐ Refer to rehab/groups for lifestyle management
- ☐ Risk/benefit assessment
- ☐ Switch antipsychotic medication
- ☐ Liaise with GP re: abnormal lab.
- ☐ Refer to specialized services (via GP) e.g. lipid clinic, diabetes clinic

Comments

Frequency of follow up after 12 month assessment recommended as yearly or sooner if clinically indicated

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