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Prescribing second-generation antipsychotic medications: Practice guidelines for general practitioners

Increased risk of metabolic complications with the use of second-generation antipsychotics means that physicians must monitor patients on these medications, especially children and adolescents, according to approved protocol.

ABSTRACT: Second-generation antipsychotic medications have been prescribed with increasing frequency since they first became available in Canada in the 1990s. This is due in part to a better side effect profile when these agents are compared with first-generation antipsychotics, particularly with respect to extrapyramidal symptoms. However, serious adverse metabolic side effects are now being reported. In addition, these medications are increasingly being used off-label without clear guidelines for indications, dosing, and monitoring. In British Columbia, one-third of antipsychotic prescriptions are provided by general practitioners. Consequently, there is an urgent need for primary care physicians to be aware of practice guidelines. When prescribing second-generation antipsychotics, physicians should: (1) Ensure the appropriate psychiatric diagnosis is made. (2) Consider target symptoms, approved indications, and degree of functional impairment before initiating treatment. (3) Monitor all patients on a second-generation antipsychotic according to approved protocol. (4) Encourage preventive lifestyle practices.

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Since becoming available in Canada in the 1990s, second-generation antipsychotic (SGA) medications (e.g., clozapine, risperidone, olanzapine, and quetiapine) have been prescribed with increasing frequency to an expanding patient population. A study conducted in Manitoba found that the number of prescriptions increased from 9694 in 1996 to 259 376 in 2006,[1] and a growing body of literature demonstrates that this increase is not limited to adult patients.[2-5] In British Columbia between 1996 and 2010, a 4.5-fold increase in SGA prescriptions was seen for boys aged 13 to 18 years of age, followed by a similar 3.5-fold increase both for males aged 6 to 12 years and for females aged 13 to 18 years.[6]

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A number of studies have found that general practitioners are increasingly prescribing antipsychotic medications, especially second-generation antipsychotics, to patients in all age groups. For instance, the number of US office-based physician visits for second-generation antipsychotics nearly tripled between 1998 and 2002, with the proportion of visits as a percentage of visits for all antipsychotic drugs rising from approximately 48% in 1998 to 84% in 2002. Meanwhile, the percentage of visits involving first-generation antipsychotics declined.[7] In British Columbia, approximately one-third of prescriptions for antipsychotics are being provided in a primary care setting by general practitioners.[6]

The increasing number of SGA prescriptions is due in part to a growing awareness of the side effects associated with first-generation antipsychotics. Controlled trials have shown that SGA medications are less likely to cause extrapyramidal symptoms and tardive dyskinesia.[1,8,9] While a decreased risk of these side effects has been found, serious adverse metabolic side effects, including weight gain, diabetes, hyperlipidemia and hypertension,[1] and metabolic syndrome[10] have been reported in adults taking SGA medications. In recent reports, some of these adverse metabolic effects have been found in children and adolescents.[5,11,12] Furthermore, some studies suggest that children and adolescents may be at a higher risk than adults for developing SGA-related metabolic side effects.[13,14]

Controlled trials have shown that SGA medications are less likely to cause extrapyramidal symptoms and tardive dyskinesia.

Given the relative risks and benefits associated with SGA medications, it is of the utmost importance that physicians carefully consider all factors when making prescription decisions. Physicians should also be aware that these medications are being used off-label without the benefit of clear guidelines for indications, dosing, or monitoring,[15-18] with some studies suggesting that up to 50% of all prescriptions for antipsychotics are for off-label use.[15] Such high off-label prescribing rates indicate that there is an urgent need for primary care physicians to be aware of appropriate practice guidelines. Physicians considering the use of an SGA should:

1. Ensure the appropriate psychiatric diagnosis is made.
2. Consider target symptoms, approved indications, and degree of functional impairment before initiating treatment.
3. Monitor all patients on an SGA according to approved protocol.
4. Encourage preventive lifestyle practices.

1. Ensure the appropriate psychiatric diagnosis is made

Physicians should always re-examine the primary diagnosis, as a diagnostic error could result in a chain of wrong decisions with untoward consequences. Diagnostic decisions are among the most error-prone decisions made by physicians and can have a negative impact on the quality of medical care.[19,20] The Harvard Medical Practice Study reported that diagnostic errors resulted in more adverse events than medication errors (14% vs 9%), were more likely to be considered negligent (47% vs 14%), and more often resulted in serious disability (47% vs 14%).[21] It is thus imperative that physicians guard against confirmation bias (i.e., sticking to the wrong preliminary diagnosis) and become familiar with techniques to reduce it.[22]

The General Practice Services Committee (GPSC), a partnership between the Ministry of Health and the BC Medical Association, has developed a Practice Support Program for general practitioners that includes mental health modules for both adults and children and youth. These modules include diagnostic tools and resources for primary care physicians. For the adult mental health module, see www.gpscbc.ca/psp-learning/mental-health/tools-resources. For the child and youth mental health module (currently being prototyped), see www.gpscbc.ca/psp-learning/child-and-youth-mental-health/tools-resources.

2. Consider symptoms, indications, and functional impairment

Primary care physicians should identify specific target symptoms, approved indications, and the degree of functional impairment before initiating treatment with a second-generation antipsychotic, as this will enable them to better evaluate the effectiveness of the treatment. In some cases, the physician may be challenged by the need to differentiate between symptoms of an illness and an adverse reaction to a medication.[23] Furthermore, symptoms of an illness can often delay appropriate management. This can be the case with individuals who are not able to communicate effectively or who are cognitively impaired and may not be able to accurately report their symptoms. These individuals may also be at risk for adverse drug reactions since they may not fully understand how to properly take their medications or may not be able to adequately communicate symptoms of adverse reactions.

Quite often, patients with a psychiatric illness require the use of a sedating medication. There is growing concern about the increased use of SGA medications for unapproved indications such as sedation. Primary care physicians are strongly discouraged from using this class of medications solely for the purpose of sedation given the potential metabolic sequela associated with SGA use.

Adults

Health Canada has approved the use of second-generation antipsychotics for treatment of schizophrenia, bipolar and unipolar mood disorders, and other select conditions in adults. **Table 1** outlines approved indications for second-generation antipsychotic drugs currently available in Canada, and **Table 2** provides resources for prescribing SGA medications by indication.

Table 1: Second-generation antipsychotics and Health Canada–approved indications for their use in adults.

Generic name	Trade name in Canada and dosage form*	Indications†
Aripiprazole	Abilify (tablet)	• Schizophrenia and related psychotic disorders. • Acute manic or mixed episodes associated with bipolar I disorder (may also be used in combination with lithium or divalproex sodium when there is an insufficient response to these agents alone).
Clozapine	Clozaril (tablet)	• Treatment-resistant schizophrenia.
Olanzapine	Zyprexa (tablet)	• Schizophrenia and related psychotic disorders • Acute manic or mixed episodes associated with bipolar I disorder (may also be used in combination with lithium or divalproex sodium).
Paliperidone	Invega ER (tablet)	• Schizophrenia and related psychotic disorders.
	Invega Sustenna ER (IM)	• Schizophrenia
Quetiapine	Seroquel (tablet) Seroquel XR (tablet)	• Manifestations of schizophrenia. • Acute manic episodes associated with bipolar disorder. • Acute depressive episodes associated with bipolar I and bipolar II disorder. • Major depressive disorder; used when currently available approved antidepressant drugs have failed either due to lack of efficacy and/or lack of tolerability.
Risperidone	Risperdal (oral solution, tablet, ODT)	• Acute schizophrenia and related psychiatric disorders. • Inappropriate behavior associated with severe dementia, including verbal and physical aggression (see the Serious Warnings and Precautions box and the Special Populations section in the manufacturer's product monograph). • Acute manic episodes associated with bipolar I disorder.
	Risperdal Consta (IM; powder for injectable prolonged release suspension)	• Manifestations of schizophrenia and related psychotic disorders. • Bipolar I disorder; used in patients who have previously responded to oral antipsychotic or other antimanic treatment to delay occurrence of manic episode.
Ziprasidone	Zeldox (capsule)	• Schizophrenia and related psychiatric disorders. • Acute manic or mixed episodes associated with bipolar disorder.

Note: Table is not intended to guide clinicians in treating patients. All information is derived from product monographs. Refer to the individual product monographs for information on dosage and administration.

*Abbreviations: ER—extended release; IM—intramuscular; XR—extended release; ODT—orally disintegrating tablet.

†According to Health Canada, 2010. Drug Product Database Online Query. http://webprod3.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp

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Table 2. Commonly approved indications for second-generation antipsychotics in adults and resources to help with prescribing decisions.

Indication	Resource	Website
Bipolar disorder	The Canadian Network for Mood and Anxiety Treatments provides detailed information on prescribing and monitoring for bipolar disorder, including a treatment algorithm.	www.canmat.org
Cognitive impairment and dementia in the elderly	The Guidelines and Protocols Advisory Committee, a joint committee of the BCMA and BC Ministry of Health, provides clinical practice guidelines for the use of antipsychotic medications for psychosis, aggression, or agitation in elderly patients with cognitive impairment or dementia.	www.bcguidelines.ca/guideline_cognitive.html
Major depression	The Canadian Network for Mood and Anxiety Treatments provides detailed information on prescribing and monitoring, and a treatment algorithm for when SGA medications should be prescribed for major depression.	www.canmat.org
	The Guidelines and Protocols Advisory Committee provides clinical practice guidelines for the management of major depression.	www.bcguidelines.ca/guideline_mdd.html
	The General Practice Services Committee, a joint committee of the BCMA and BC Ministry of Health, provides practice support modules that include a treatment algorithm for initiating antidepressant therapy and information on when to prescribe antipsychotic medications.	www.gpscbc.ca/psp-learning/mental-health/tools-resources
Schizophrenia and related disorders	The BC Ministry of Health provides specific prescribing and monitoring information for schizophrenia and related disorders.	www.health.gov.bc.ca/mhd/publications.html#Psychosis

Children and adolescents

With the exception of aripiprazole, which was authorized in December 2011 for the treatment of schizophrenia in adolescents 15 to 17 years old,[24] there are no Health Canada approved indications for SGA medication use in children and adolescents. However, there is evidence to support using specific medications for a limited number of indications and target symptoms within certain age groups, as shown in **Table 3**. A full list of sources for this evidence can be found in the referenced article by Panagiotopoulos and colleagues.[4]

There is no evidence to support the use of SGA medications for major depression, anxiety, or insomnia in children and adolescents. Additionally, based on recent FDA warnings[25] and the literature review conducted by Panagiotopoulos and colleagues,[4] it is clear that olanzapine should not be used as a first-line treatment in adolescents.

3. Monitor according to protocol

Primary care physicians are in a unique position to identify early signs of cardiometabolic dysfunction related to SGA medications, and are likely to encounter such patients in their practice.[26] Due to the significant metabolic effects associated with SGA treatment, monitoring protocols and tools have been developed both nationally and internationally to support metabolic monitoring in both adults and children and adolescents.[27,28] Despite the development of such protocols and tools, attention to these monitoring recommendations has been low in both adults and children,[5,26,27,29] with some evidence suggesting that children are less likely than adults to receive metabolic screening and monitoring.[5]

Adults

The American Diabetes Association (ADA) and the American Psychiatric Association (APA) have published a consensus position on appropriate monitoring of patients on SGA medications.[30] This position notes that the currently available medications vary in the contribution they make to weight gain, risk for the development of type 2 diabetes, and worsening lipid profiles. Because of this variability the ADA/APA guidelines recommend:

- Scheduled monitoring of metabolic risk factors.
- Switching to an SGA medication with a lower weight gain liability if the patient gains more than 5% of initial weight.

The initiation and monitoring guidelines summarized in **Table 4** are based on the recommendations of the ADA/APA, as well as recent guidelines published by the Canadian Network for Mood and Anxiety Treatments.[31]

Children and adolescents

In 2011, evidence-based recommendations for monitoring the safety of second-generation antipsychotics in children and adolescents were endorsed by both the Canadian Academy of Child and Adolescent Psychiatry and the Canadian Pediatrics Society.[28] These recommendations include the use of the Metabolic Assessment, Screening and Monitoring Tool developed by clinical researchers at BC Children's Hospital and BC Mental Health and Addiction Services. Monitoring begins with family and personal history taking. The family history should include questions about diabetes (type 1, type 2, gestational), hyperlipidemia, cardiovascular disease, schizophrenia, schizoaffective disorder, psychosis not otherwise specified, and bipolar disorder. The personal history should include questions

Table 3. Second-generation antipsychotics and the specific indications for their use in children and adolescents that are supported by evidence.

Antipsychotic	Indications	Target symptoms	Age range
Aripiprazole	Autism*	Irritability	6–17
	Bipolar I disorder*	Manic or mixed episodes	8–17 (10–17)*
	Schizophrenia*	Positive and negative symptoms	13–17
Clozapine	Schizophrenia	Psychosis	8–18
Olanzapine	Bipolar I disorder*	Manic or mixed episodes (acute and maintenance treatment)	13–17
	Pervasive developmental disorder	Aggression	6–14
	Schizophrenia*	Positive and negative symptoms	13–17
Quetiapine	Schizophrenia*	Positive and negative symptoms	13–17
	Bipolar I disorder*	Manic episodes	12–18 (10–17)*
	Conduct disorder	Aggression	12–17
Risperidone	Autism*	Irritability, aggression, communication, hyperactivity, affect regulation	2–18 (5–16)*
	Bipolar I disorder*	Manic or mixed episodes	10–17
	Developmental disabilities Subaverage IQ	Aggression, self-injurious behavior	6–18
	Disruptive behavior disorders (including ADHD)	Conduct problems, irritability, hyperactivity, aggression	4–14
	Schizophrenia*	Positive and negative symptoms	13–17
	Tourette syndrome	Tics	7–17
Ziprasidone	Bipolar I disorder	Mania	10–17
	Tourette syndrome	Tics	7–17

Adapted and used with permission of the *Journal of the Canadian Academy of Child and Adolescent Psychiatry*.[4]
*FDA-approved indication or age range

Table 4. Metabolic monitoring protocol for adults on second-generation antipsychotic medications.

	Baseline	1 month	2 months	3 months	6 months	Reassess
Weight (BMI)	x	x	x	x	x	Q 3 months
Waist circumference	x	x	x	x	x	Q 3 months
Blood pressure	x			x	x	Q 3 months for 1 year then annually
Fasting glucose	x			x	x	Q 3 months for 1 year then annually
Fasting lipid profile	x			x		Annually

Table 5. Metabolic monitoring protocol for children and adolescents on second-generation antipsychotic medications.

Clinical evaluations								
	Tools	**Baseline**	**1 month**	**2 months**	**3 months**	**6 months**	**9 months**	**12 months**
Family and personal history*		x						
Height, weight, BMI, and age- and sex-specific percentiles	www.cdc.gov/growthcharts/	x	x	x	x	x	x	x
Waist circumference (at the level of the umbilicus) and percentiles	www.idf.org/webdata/docs/Mets_definition_children.pdf (pages 18-19); use adult cut-off (page 10) if lower	x	x	x	x	x	x	x
Blood pressure and percentiles	http://keltymentalhealth.ca/sites/default/files/HighBPGuidelines.pdf	x	x	x	x	x	x	x
Neurological examination for monitoring extrapyramidal symptoms	• AIMS (Abnormal Involuntary Movement Scale) www.mhsip.org/library/pdfFiles/abnormalinvoluntarymovementscale.pdf • SAS (Simpson-Angus Scale) www.outcometracker.org/library/SAS.pdf • ESRS (Barnes Akathisia Rating Scale) http://keltymentalhealth.ca/sites/default/files/BARS.pdf	x			x	x		x
Laboratory evaluations								
		Baseline	**1 month**	**2 months**	**3 months**	**6 months**	**9 months**	**12 months**
Fasting plasma glucose		x			x	x		x
Fasting insulin†		x			x	x		x
Fasting lipids (total cholesterol, LDL-C, HDL-C, triglycerides)		x			x	x		x
AST and ALT		x				x		x
TSH (quetiapine only)		x						x
Prolactin‡		x						x

Adapted from the Metabolic Assessment, Screening and Monitoring Tool and used with permission of Drs C. Panagiotopoulos and J. Davidson.
*Family history of diabetes (type 1, type 2, gestational), hyperlipidemia, cardiovascular disease, schizophrenia, schizoaffective disorder, psychosis not otherwise specified, bipolar disorder; personal history of smoking, physical activity, screen time, and sugar-sweetened beverages.
†Note that this assessment is *not* recommended for aripiprazole or ziprasidone, but *is* appropriate for all other second-generation antipsychotic medications.
‡Assessment of prolactin levels should be completed according to protocol *except* when the patient is displaying clinical symptoms of hyperprolactinemia (i.e., menstrual irregularity, gynecomastia, or galactorrhea), in which case more frequent monitoring may be warranted. Please also note that risperidone is the SGA with the greatest effect on prolactin.

about smoking, physical activity, screen time (e.g., computers, TV), and use of sugar-sweetened beverages. Monitoring then proceeds with both clinical and laboratory evaluations.

These monitoring recommendations are summarized in **Table 5**, and the complete Metabolic Assessment, Screening and Monitoring Tool can be found online at http://keltymentalhealth.ca/sites/default/files/MMT.pdf.

Additional metabolic monitoring tools and resources for children and adolescents that are available at http://keltymentalhealth.ca/partner/provincial-mental-health-metabolic-program include:

- A brochure on metabolic monitoring for patients.
- A monitoring handbook for physicians.
- Information on BC Children's Hospital's Provincial Child and Youth Mental Health Metabolic Program.

4. Encourage preventive lifestyle practices

Physicians should inform patients taking second-generation antipsychotics of the need for preventive lifestyle practices (e.g., healthy eating, physical activity).[32] A number of resources are available for adults and children,

as well as for practitioners wishing to help patients develop healthy living habits (Table 6).

Conclusions

Second-generation antipsychotics are increasingly being prescribed by general practitioners in British Columbia. Although these medications are less likely than first-generation antipsychotics to cause extrapyramidal side effects, they are associated with an increased risk of metabolic complications. Of increasing concern, SGA medications are being used off-label without the benefit of clear guidelines for indications, dosing, or monitoring. It is thus very important that primary care physicians make themselves aware of the appropriate guidelines for both prescribing and monitoring the use of second-generation antipsychotics in their clinical practice.

Table 6. Preventive lifestyle resources for adults and children prescribed second-generation antipsychotic medications.

	Resources	Website
Adults	• The Public Health Agency of Canada provides a number of healthy living resources for Canadians.	www.phac-aspc.gc.ca/hp-ps/hl-mvs/index-eng.php
	• Here to Help, BC's information source for individuals managing mental health or substance use problems, provides a wellness module for managing mental well-being, including information on physical activity, healthy eating, stress management, and sleep.	www.heretohelp.bc.ca/skills/managing-well-being
	• The General Practice Services Committee provides a number of healthy living resources for individuals with mental health conditions.	www.gpscbc.ca/psp-learning/mental-health/tools-resources
Children and adolescents	• The Kelty Mental Health Resource Centre provides a number of healthy living resources for children and youth, including healthy living toolkits, that contain specific strategies for children and youth on second-generation antipsychotic medications.	http://keltymentalhealth.ca/toolkits

Competing interests

None declared.

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