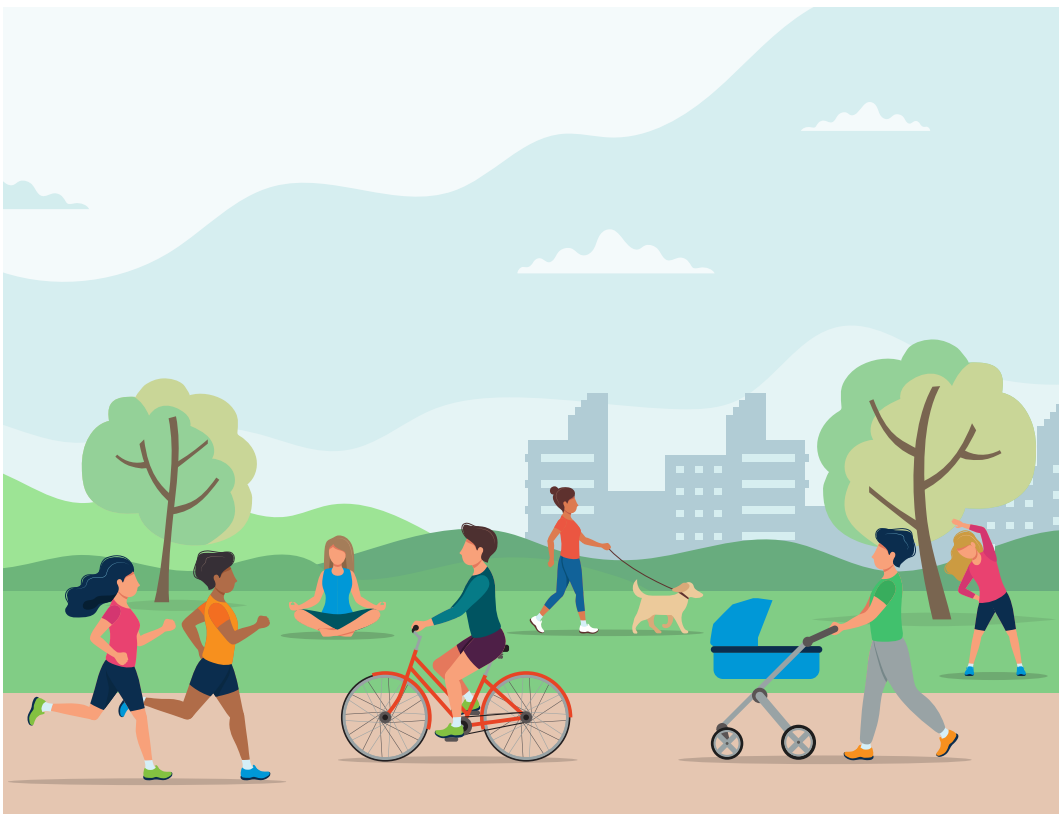
2020

Monitoring Physical Health and Side-Effects of Psychotherapeutic Medications in Adults and Children: An Integrated Approach



UNIVERSITY of SOUTH FLORIDA
College of Behavioral & Community Sciences
Florida Medicaid Drug Therapy
Management Program for Behavioral Health

AGENCY FOR HEALTH CARE ADMINISTRATION
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2020 Monitoring the Physical Health and Side-Effects of Psychotherapeutic Medications in Adults and Children: An Integrated Approach (2020). The University of South Florida, Florida Medicaid Drug Therapy Management Program sponsored by the Florida Agency for Health Care Administration.

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Introduction

Introduction

- Serious mental illness (SMI) is defined as adults ages 18 and older diagnosed with major depressive disorder, bipolar disorder, and schizophrenia spectrum disorders.
- Severe emotional disturbances (SED) are defined as children and adolescents with diagnoses of autism, conduct disorder, attention deficit-hyperactivity disorder, major depressive disorder, bipolar disorder, or schizophrenia spectrum disorders.
- Individuals SMI and SED face a higher burden of physical health problems compared to the general population.
- Many factors contribute to the poor physical health of individuals with SMI and SED, including disparities in health care access and utilization, as well as provision of health care services.
- Social determinants, defined by Healthy People 2020 as the environment in which people are born, live, learn, work, play, and age, are increasingly recognized for their contribution to individual-level risk and protective factors for behavioral health conditions.

Understanding the Scope of the Problem

- Studies have shown that individuals with serious mental illness have an excess mortality that is two to three times as high as that of the general population. This mortality gap translates to a 13 to 30 year shortened life expectancy.
- Maternal SMI has been independently associated with higher risk of adverse gestational, obstetric, and fetal outcomes, particularly among women with comorbid SMI and substance use disorders.
- Adverse childhood experiences are associated with lower self-rated health, functional limitations, diabetes, and myocardial infarction in adulthood.
- Barriers to care include geographic distance to access services, availability of qualified providers, social and cultural stigma associated with accessing behavioral health care, cost of care, and lack of integration across the health system.

Integrated Care

- Integrated care bridges the gap that often occurs between the medical and behavioral health care systems, and produces the best health outcomes for individuals with SMI and SED.
- There are different models and levels of integrated care that providers can adopt depending on their practice setting and its available resources.
- The most feasible for many providers treating individuals with SMI and SED is the clinical practice integration approach in which collaboration is built into service protocols and there are mechanisms to consult and collaborate with other providers.
- There is no one model of integration that works best for individuals with SMI and SED. Ultimately, integration efforts should incorporate the patient perspective and be matched to the patients' needs.

Use of technology

- Improvements in technology (e.g., increased bandwidth, better internet security) have allowed telepsychiatry to be increasingly used in the healthcare setting.
- Benefits of telepsychiatry include better access to care for rural and underserved communities, improved patient engagement, and increased care integration.

Introduction

Goal of this publication

- In creating this publication, the goal was to provide monitoring recommendations based on the most recent available evidence in order to administer better quality care and help minimize the potential adverse health effects of psychiatric medications, while ultimately improving patients' overall health and well-being.

Process for Creating the Guidelines

- Every two years, the Florida Medicaid Drug Therapy Management Program brings together a diverse array of stakeholders and experts to update the guidelines. This year's group of stakeholders known as the Florida Expert Panel was comprised of: local and nationally recognized experts, pediatricians, psychiatrists, APRNs, academicians, and pharmacists. The 2020 Florida Expert Panel met in Tampa, Florida on February 1, 2020 to review and update the previous version of the guidelines published in 2018.
- The guidelines are expanded in this most recent iteration to include information specific to children and adolescents.
- The panel listened to presentations on the latest evidence-based practices, discussed the guidelines, proposed revisions, and reached a consensus about whether to revise and adopt a particular set of guideline recommendations.
- The final guidelines are a product of an in-depth review of the literature with an emphasis on the highest level of clinical evidence (e.g., randomized controlled trials, systematic reviews) and expert panel consensus on the strength of the evidence.
- The names of the meeting attendees and meeting presentations are available on the Florida Medicaid Drug Therapy Management Program for Behavioral Health's website at ***floridamedicaidmentalhealth.org***. Financial disclosures are available upon request.

Organization

- This publication provides information regarding common physical health conditions that occur with greater frequency among individuals with SMI and SED, documents screening/monitoring recommendations for these physical health conditions, provides guidelines regarding management of pregnant/lactating women, and explores potential barriers that may adversely affect healthcare delivery, as well as treatment adherence in this population.

Disclaimer

- The *2020 Monitoring Physical Health and Side-Effects of Psychiatric Medications in Adults and Children: An Integrated Approach* guidelines reflect the current state of knowledge at the time of publication on effective and appropriate care.
- The inevitable changes in the state of scientific information and technology mandate that periodic review, updating, and revisions will be needed.
- These guidelines may not apply to all patients; therefore, each guideline must be adapted and tailored to the individual patient.
- Proper use, adaptation, modifications, or decisions to disregard these or other guidelines, in whole or in part, are entirely the responsibility of the clinician who uses these guidelines. The authors and expert panel members bear no responsibility for treatment decisions and outcomes based on the use of these guidelines.

***Note*: Strongly recommend coordination of care between all providers to facilitate optimal outcomes.**

Comprehensive Assessment

- A comprehensive health assessment includes:
  - A full medical history
  - An assessment of psychiatric co-occurring disorders and physical comorbidities
  - An assessment for trauma, suicide, violence, and substance use disorders
  - Assessment of pregnancy intentions in women of childbearing age
  - Assessment of a patient's social determinants of health (e.g., health literacy, transportation, food insecurity, housing stability)
  - Screening for adverse childhood experiences (ACEs) [e.g., child abuse/neglect, parental separation/divorce, substance use in the household, homelessness]
  - Relevant medical work-up including lab work, physical examination, and nutritional status evaluation
- Additional recommendations to promote ongoing comprehensive care include:
  - Medication reconciliation and assessment for medication adherence (labs for blood medication levels if needed)
  - Measurement-based care at baseline and regular intervals to assess symptoms, side-effects, and adherence.

    Note: Refer to Tables 3 and 4 for validated scales for children/adolescents and adults. Refer to the Florida Best Practice Psychotherapeutic Guidelines for Adults and the Florida Best Practice Psychotherapeutic Guidelines for Children and Adolescents.
  - Integration of all care team members including primary care and behavioral health
  - Obtaining release of information for coordination of care
  - Collaborative/shared decision-making with patients and family/caregivers
  - Psychosocial assessment
  - Assessment of social factors that may affect health (housing, family, other caregivers, coordination with community resources, etc.)
  - Evaluation of factors that pose a risk to the continuity of care (medication adherence, social determinants of health, etc.)
  - Assessment of legal system involvement and interaction with law enforcement as needed

General Recommendations: Baseline Monitoring of Physical Health in Adults with Serious Mental Illness (SMI) and Children/Adolescents with Serious Emotional Disturbance (SED)

Table 1a.

Recommended Assessments at Baseline and Subsequent Follow-up Monitoring – Adults		
Assessment	**Baseline**	**Follow-up Assessments**
Vital signs (blood pressure, pulse, weight, including calculation of body mass index)	✔	Each visit
Lifestyle behaviors (smoking, diet, exercise, substance use, sleep)	✔	Each visit
Personal/family history [hypertension, diabetes, cardiovascular disease, cerebrovascular disease (stroke), cancer, epilepsy, Parkinson's disease, thyroid disease]	✔	As clinically indicated
Dental history	✔	As clinically indicated
Sexual/reproductive function	✔	At 3 months and 6 months thereafter

Table 1b.

Recommended Laboratory Monitoring – Adults	
Parameter	**Recommendation**
Complete blood count with differential (CBC with diff)	As clinically indicated (e.g., treatment with clozapine)
Complete metabolic panel (CMP)	As clinically indicated
Fasting lipid profile	All patients over 40 years at baseline and annually thereafter, or sooner as indicated (e.g., cardiac history, obesity, diabetes, hypertension)
RBC Folate	As clinically indicated
Hemoglobin A1c (HbA1c)	All patients over 40 years at baseline and annually thereafter, or sooner as indicated
Prolactin	As clinically indicated (e.g., amenorrhea/oligomenorrhea, poor sexual function, osteopenia/osteoporosis)
Thyroid stimulating hormone (TSH)	As clinically indicated
Urine Drug Screen	As clinically indicated
Vitamin B12	As clinically indicated
Vitamin D	As clinically indicated

General Procedures for Monitoring Side-Effects of Antipsychotic Medications in Children and Adolescents

Table 2a.

American Diabetes Association/American Psychiatric Association Guidelines for Metabolic Monitoring in Recipients of Antipsychotic Medications							
	Monitoring Frequency						
Parameter	**Baseline**	**Week 4**	**Week 8**	**Week 12**	**Quarterly**	**Annually**	**Every 5 years**
Medical history*	✔					✔	
Weight (BMI)	✔	✔	✔	✔	✔		
Waist circumference**	✔					✔	
Blood pressure	✔			✔		✔	
Fasting glucose or hemoglobin A1c	✔			✔		✔	
Fasting lipids (HDL, LDL, triglycerides, total cholesterol)	✔			✔			✔

Notes:

**Medical history includes personal and family history of obesity, diabetes, hypertension, and cardiovascular disease. More frequent assessments may be warranted based on clinical status.*

***In children and adolescents, waist circumference may be less informative than for adults due to changes in waist circumference with growth and development. Various studies have sought to develop waist circumference percentile norms based on age, sex, and ethnicity.*

Age and Gender-Specific Waist Circumference Cutoff Values (In Centimeters) by Percentile:

Table 2b.

Waist Circumference (cm) Cutoffs for Males and Females for > 50th and > 90th and for Age/Gender Specific High-Normal Values that Correlate to Adult Cut Offs						
	Males			Females		
Age (in years)	50th	90th	High-Normal 91st	50th	90th	High-Normal 91st
2	48 cm	53 cm	53 cm	48 cm	53 cm	50 cm
3	50 cm	55 cm	55 cm	50 cm	56 cm	53 cm
4	52 cm	58 cm	58 cm	52 cm	59 cm	55 cm
5	53 cm	61 cm	61 cm	53 cm	61 cm	57 cm
6	55 cm	64 cm	65 cm	55 cm	64 cm	59 cm
7	57 cm	69 cm	69 cm	57 cm	69 cm	62 cm
8	60 cm	73 cm	74 cm	60 cm	73 cm	66 cm
9	63 cm	78 cm	79 cm	63 cm	78 cm	69 cm
10	65 cm	83 cm	83 cm	66 cm	83 cm	73 cm
11	68 cm	87 cm	87 cm	70 cm	87 cm	78 cm
12	71 cm	91 cm	91 cm	73 cm	91 cm	81 cm
13	73 cm	94 cm	95 cm	75 cm	94 cm	83 cm
14	75 cm	96 cm	97 cm	76 cm	96 cm	85 cm
15	77 cm	98 cm	99 cm	77 cm	97 cm	86 cm
16	79 cm	100 cm	100 cm	78 cm	98 cm	87 cm
17	80 cm	101 cm	101 cm	79 cm	99 cm	87 cm
18	81 cm	101 cm	102 cm	79 cm	100 cm	88 cm
Adult			102 cm			88 cm
The cut-off for abdominal obesity for men is 102 cm and for women it is 88 cm according to the NCEP guidelines. The 91st percentile curve for boys and the 75th percentile curves line for girls represent a smooth growth curve line that transitions into the respective adult cut-off values for abdominal obesity.						

Source: Adapted from Table 1B from Cook et all.

Note. cm = centimeter

Reference for Table 2b: Cook S. Anticipatory Guidance. In: Tanski S, Garfunkel LC, Duncan PM, and Weitzman M. Performing Preventive Services: A Bright Futures Handbook [book on Internet]. American Academy of Pediatrics: 2010. Available at: ***https://brightfutures.aap.org/Bright%20Futures%20Documents/Anticipatory%20Guidance.pdf***

General Procedures for Monitoring Side-Effects of Stimulant Medication in Children and Adolescents

Table 2c.

General Procedures for Monitoring Side-Effects of Stimulant Medication in Children and Adolescents		
	Monitoring Frequency	
	Baseline	Each Visit
Pulse	✔	✔
Blood Pressure	✔	✔
Weight	✔	✔
Height	✔	✔
BMI	✔	✔

Recommended Monitoring as Needed Based on Clinical Presentation:

- BMI (adults) / BMI percentile (for children/adolescents)
- Parkinsonism Screen (e.g., SAS or ESRS; cogwheel rigidity or clonus on exam)
- Tardive dyskinesia (e.g., AIMS or DISCUS)
- Akathisia Screen (e.g., ESRS)
- Electrocardiogram (ECG)

Prior to considering medication management, clinicians should weigh the risks and benefits of treatment, including the risk for interactions with other medications (both prescribed and over-the-counter), herbal supplements, and foods (e.g., grapefruit) that may increase or decrease drug levels. To check drug-drug interactions, visit: ***https://reference.medscape.com/drug-interactionchecker***

Notes:

Abbreviations: SAS = Simpson-Angus Scale; ESRS = Extrapyramidal Symptom Rating Scale; AIMS= Abnormal Involuntary Movement Scale. These scales are available at ***floridamedicaidmentalhealth.org****.*

There are many reasons patients may require testing earlier or more often than the recommendations noted above. If monitoring has been obtained by primary care provider, obtain records.

Studies have shown that waist circumference is a better predictor of cardiovascular risk compared to Body Mass Index (BMI). Check blood pressure (BP) and pulse during titration with clozapine and quetiapine.

For more information about clozapine monitoring, visit the Clozapine REMS Program at ***www.clozapinerems.com****.*

Note on pharmacogenomics testing: Limited data exists examining whether patient care that integrates pharmacogenomic test information results in better or safer treatment.

Measurement-Based Care for Behavioral Health Conditions

- Questionnaires and rating scales are strongly recommended for the initial diagnostic assessment and evaluation of treatment outcomes. These instruments can be helpful in providing supplemental information to the provider's clinical judgment.
- Integration of rating scales into routine clinical practice and for all follow-up appointments is also strongly suggested.
- Clinicians should use rating scales to assess symptom severity during the initial evaluation and treatment, when medication changes are implemented, and/or when the patient reports a change in symptoms.

Notes:

- *Effort should be made to communicate between primary care providers, psychiatrists, caseworkers, and other team members to ensure integrated care.*
- *Prior to initiating any intervention (e.g., psychosocial, medication), assess and document the risks/benefits of treatment.*
- *Education should be age-appropriate and targeted to the condition.*

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Measurement Scales

Internet links to the following psychiatric assessment scales are available on the Program website at ***floridamedicaidmentalhealth.org***. These scales were selected because they are brief and can be completed in the primary care office.

Table 3.

Child and Adolescent Assessment Scales				
Condition/ Symptoms	**Name of Scale**	**Type of Assessment**	**Age range**	**# of Items**
Attention-Deficit/ Hyperactivity Disorder (ADHD)	ADHD Rating Scale IV – Home Version	Parent rating	5–17	18
ADHD	NICHQ Vanderbilt Assessment Scales	Parent rating Teacher rating	6–12	55 43
Anxiety	Severity Measure for Generalized Anxiety Disorder	Patient self-report	11–17	10
Cognitive, emotional & behaviorial problems	Pediatric Symptom Checklist (PSC)	Parent rating	4–16	35
Depression	PHQ-9 Modified for Adolescents (PHQ-A)	Patient self-report	11–17	9
Depression	Center for Epidemiological Studies Depression Scale for Children (CES-DC)	Patient self-report	6–17	20
Manic symptoms	Child Mania Rating Scale	Parent rating	5–17	21
Mental health domains across psychiatric diagnoses	DSM-5 Parent/Guardian-Rated Level 1 Cross-Cutting Symptom Measure-Child	Parent rating	6–17	25
Mental health domains across psychiatric diagnoses	DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure-Child	Patient self-report	11–17	25
Post-Traumatic Stress Disorder (PTSD)	Child PTSD Symptom Scale (CPSS)	Patient self-report or clinician administered	8–18	24
Substance use (Alcohol & drugs)	The CRAFFT Screening Interview	Patient self-report	13–18	9
Substance use (Drugs)	Drug Use Questionnaire (DAST-20)	Patient self-report	13–18	20
Symptom severity across mental health domains	Brief Psychiatric Rating Scale for Children (BPRS-C)	Clinician rating	3–18	21

Table 4.

Adult Assessment Scales			
Condition/ Symptoms	**Name of Scale**	**Type of Assessment**	**# of Items**
Anxiety/general	Generalized Anxiety Disorder 7-Item (GAD-7) Scale	Patient self-report	7
Anxiety/general	Severity Measure for Generalized Anxiety Disorder-Adult	Patient self-report	10
Anxiety/panic	Severity Measure for Panic Disorder	Patient self-report	10
Bipolar disorder/ manic symptoms	Young Mania Rating Scale (YMRS)	Clinician rating	11
Bipolar disorder	The Mood Disorder Questionnaire (MDQ)	Patient self-report	16
Childhood trauma	Adverse Childhood Experiences (ACE) Questionnaire	Patient self-report	10
Dementia	Saint Louis University Mental Status Examination (SLUMS)	Clinician rating	11
Depression	Patient Health Questionnaire (PHQ-9)	Patient self-report	9
Depression	Beck Depression Inventory (BDI)	Patient self-report	21
Depression	Hamilton Rating Scale for Depression (HAM-D)	Clinician rating	21
Difficulties/ disability due to mental health conditions	World Health Organization Disability Assessment Scale 2.0	Patient self-report	36
Global rating of illness severity and response to treatment	Clinical Global Impression Scale (CGI)	Clinician rating	3
Mental health domains across psychiatric diagnosis	DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measures-Adult	Patient self-report	23
Psychosis	Clinician-Rated Dimensions of Psychosis Symptom Severity	Clinician rating	8
Psychotic disorders	Brief Psychiatric Rating Scale (BPRS)	Clinician rating	18
PTSD	National Stressful Events Survey PTSD Short Scale (NSESS)	Patient self-report	9
PTSD	Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5)	Patient self-report	20

Table 4. ***(continued)***

Adult Assessment Scales *(continued)*			
Condition/ Symptoms	**Name of Scale**	**Type of Assessment**	**# of Items**
Substance use (Alcohol)	The Alcohol Use Disorders Identification Test (AUDIT-C, AUDIT)	Patient self-report	3, 10
Substance use (Alcohol)	Tolerance, Annoyed, Cut Down, Eye-Opener (T-ACE) Questionnaire	Patient self-report	4
Substance use (Alcohol use during pregnancy)	Tolerance, Worried, Eye-Opener, Amnesia, Cut Down (TWEAK) Questionnaire	Patient self-report	5
Substance use (Alcohol & drugs)	NIDA Drug Use Screening Tool: Quick Screen	Patient self-report	4
Substance use (Drugs)	Drug Abuse Screen Test (DAST-10)	Patient self-report	10
Substance use (Opioids)	Opioid Risk Tool	Patient self-report	10

Screening, Brief Intervention, and Referral to Treaatment (SBIRT):

Screening, Brief Intervention, and Referral to Treatment (SBIRT) is an evidence-based practice for providing early intervention and treatment to individuals at risk for developing substance use disorders. SBIRT can be implemented in the primary care setting. For more information regarding SBIRT, visit ***http://www.samhsa.gov/sbirt*** and see the Substance Use Disorders section in these guidelines.

Social Determinants of Health and Potential Barriers to Effective Treatment

Social Determinants of Health

Healthy People 2020 defines the social determinants of health as the social factors and physical health conditions of the environment in which people are born, live, learn, play, work, and age. Social determinants of health are increasingly recognized as contributing to disparities in physical health outcomes between different populations. Social determinants of health should be assessed and reported given their contribution to disparate health outcomes.

Social determinants of health are categorized into five main domains. These domains and examples are:

- Neighborhood and built environment: Access to foods that support healthy eating patterns; crime and violence; quality of housing; environmental conditions
- Health and healthcare: Access to primary care services; health literacy
- Social and community context: Discrimination, incarceration, civic participation
- Education: Early childhood education and development; high school graduation; enrollment in higher education; language and literacy
- Economic Stability: Employment status; food insecurity; housing instability; socioeconomic status (e.g., poverty)

Potential Barriers to Effective Treatment

There are many potential barriers to effective treatment for individuals with SMI. It may be helpful for clinicians to be aware of the most common barriers, assess for them, and ensure that they are addressed and addressed in treatment plans.

Box 1.

Potential Barriers to Effective Treatment

Patient and illness-related factors

- Not seeking adequate physical care due to psychiatric symptoms (e.g., cognitive impairment, social isolation, and suspicion)
- Difficulty comprehending health care advice and/or carrying out required changes in lifestyle due to psychiatric symptoms and adverse consequences related to mental illness (e.g., low educational attainment, reduced social networks, lack of employment and family support, poverty, poor housing)
- Severity of mental illness (SMI patients have fewer medical visits, with the most severely ill patients making the fewest visits)
- Health risk factors and lifestyle factors (e.g., substance abuse, poor diet, smoking, lack of exercise and unsafe sexual practices)
- Less compliant with treatment
- Unawareness of physical problems due to cognitive deficits or to a reduced pain sensitivity associated with antipsychotic medication
- Migrant status and/or cultural and ethnic diversity
- Lack of social skills and difficulties communicating physical needs

Treatment-related factors

- Deleterious impact of psychiatric medication on physical health (e.g., obesity, type 2 diabetes mellitus, cardiovascular disease, hyperprolactinemia, and xerostomia)

Psychiatrist-related factors

- Tendency to focus on mental rather than physical health with infrequent baseline and subsequent physical examination of patients
- Poor communication with patient or primary care health workers
- Physical complaints regarded as psychosomatic symptoms
- Suboptimal and worse quality of care offered by clinicians to patients with SMI. Lack of assessment, monitoring and continuity of care of the physical health status of people with SMI.
- Guidelines perceived as a threat to autonomy, not well known or clinically accepted
- Lack of knowledge regarding medical issues
- Erroneous beliefs (SMI patients are not able to adopt healthy lifestyles, weight gain is mainly adverse effect of medications, lower cardiac risk medications are less effective)
- Unequipped or underfunded teams to handle behavioral and emotional problems of patients with SMI

Box 1. ***(continued)***

Potential Barriers to Effective Treatment *(continued)*

Other physician-related factors

- Stigmatization of people with mental disorders
- Physical complaints regarded as psychosomatic symptoms
- Suboptimal and worse quality of care offered by clinicians to patients with SMI
- Lack of assessment, monitoring, and continuity of care of the physical health status of people with SMI
- Unequipped or underfunded teams to handle behavioral and emotional problems of patients with SMI
- Complexity and time intensity of coordinating both medical and psychiatric medications

Service-related factors

- Financial barriers, especially in developing countries; paucity of funding in some countries of general somatic care for patients with SMI
- High cost of (integrated) care
- Lack of access to health care
- Lack of clarity and consensus about who should be responsible for detecting and managing physical problems in patients with SMI
- Fragmentation or separation of the medical and mental health systems of care; lack of integrated services
- Under-resourcing of mental health care that provides little opportunity for specialists to focus on issues outside their core specialty
- Lack of health insurance coverage

Adapted from Hert, et al., 2011.

Prevention Strategies

The scope of chronic disease in persons with serious mental illness requires primary prevention strategies to reduce morbidity and mortality in this population. Modifiable risk factors for chronic disease should be discussed with clients such as the importance of a healthy diet and regular exercise. In fact, a whole health treatment and recovery plan is particularly important for this population because of the stress and unpredictability of living with mental illness, coupled with the side-effects of certain psychotherapeutic medications that can lead to chronic disease (e.g., weight gain, metabolic syndrome).

We can help clients develop healthier behavior and habits through education. However, educational efforts should be sensitive to the cognitive challenges and impairment common among people with mental illness. Remember that your clients can become easily overwhelmed with too much information and thus give up on developing healthier habits. Thus, it is recommended that health education should: 1) be simple; 2) focus on one health issue at a time; and 3) be repetitive (reviewed at each appointment as needed to reinforce learning).

Table 5.

Prevention Strategies to Reduce Morbidity and Mortality	
Area of concern	**Suggested Educational Tools and Strategies**
Diet*	**Healthy eating behavior** ✦ Decrease drinking soft drinks with sugar and artificial sweeteners ✦ Limit intake of food dyes ✦ Increase healthy food items (fruits, vegetables, fish) ✦ Make healthy snack choices ✦ Control portion size ✦ Consider time-restricted eating (limiting intake to a set number of hours) ✦ Eat more slowly ✦ Drink 6–8 glasses of water per day ✦ Mindful eating **Educational** ✦ Learn the types of foods that are healthy to eat. ✦ Learn the difference between physical hunger and emotional eating.
Exercise	**Physical activity** ✦ Increase physical activity such as moderate intensity walking or stretching. Target goal of 150 minutes/week. ✦ Reduce sedentary behaviors (TV watching, video/computer games, etc.). ✦ Treat/reduce sedation and extrapyramidal effects of medications. *Note: Refer to the Florida Best Practice Psychotherapeutic Medication Guidelines for Children/Adolescents and Adults for medication recommendations for specific behavioral health diagnoses.*

Table 5. ***(continued)***

Prevention Strategies to Reduce Morbidity and Mortality *(continued)*	
Area of concern	**Suggested Educational Tools and Strategies**
Tobacco Cessation	**Add tobacco use disorder to problem list and treatment plan** ✦ Assess level of use and motivation to quit ✦ Set short-term goals ✧ Increase motivation to quit ✧ Bring awareness to the consequences of tobacco use ✧ Attend a smoking cessation group ✦ Set long-term goals ✧ Move client toward preparation to quit ✧ Make a 24-hour quit attempt ✧ Quit smoking (abstinence) ✦ Use nicotine replacement (e.g., patch, gum, lozenge), medication (bupropion, varenicline) ✦ Longer treatment is often needed in this population than the standard 12 weeks
Stress Management	**Develop a personalized approach to stress management** ✦ Identify stressors and triggers ✦ Meditation and relaxation exercises ✦ Learn ways to constructively express emotions (e.g., journaling, drawing) ✦ Develop hobbies/do things that are enjoyable ✦ Daily exercise ✦ Eat well (See "Healthly eating behavior" above) ✦ Avoid alcohol and drugs ✦ Reach out to others and build a support network
Sleep Hygiene	**Promote good sleep habits** ✦ Establish a relaxing bedtime routine ✦ Maintain a regular sleep schedule (go to bed and wake up at the same time each day) ✦ Avoid alcohol, nicotine, and other substances that interfere with sleep ✦ Have a quiet, cool, dark, and comfortable bedroom ✦ Exercise each day. Avoid rigorous exercise before bed. ✦ Avoid naps during the day ✦ Avoid screen time 30-60 minutes before bed

Note: For more information on healthy recipes and resources, visit the USDA MyPlate Program at* ***https://www.choosemyplate.gov/**.*

Physical Disease and Mental Illness

Among individuals with serious mental illness, physical health problems including cardiovascular disease, metabolic disorders, infectious diseases, respiratory illnesses, and sexual dysfunction occur with greater frequency, especially when compared to the general population. Furthermore, individuals with serious mental illnesses such as schizophrenia and bipolar disorder have a greater relative risk of modifiable risk factors for cardiovascular disease. Relative risk is defined as the ratio of the probability of a particular event occurring in one group compared to the probability of that same event occurring in a comparison group.

In this section, the guidelines provide an overview of the physical ailments that occur with greater frequency among individuals with serious mental illness, review psychiatric medication side-effects that may contribute to or exacerbate these physical conditions, and provide monitoring recommendations in order to better evaluate and treat these physical health issues with the goal of better health outcomes.

Note: Strongly recommend coordination of care between all providers to facilitate optimal outcomes.

Table 6.

Modifiable Risk Factors for Cardiovascular Disease				
Modifiable Risk Factors	**Schizophrenia**		**Bipolar Disorder**	
	Prevalence rate	**Relative risk**	**Prevalence rate**	**Relative risk**
Smoking	50–80%	2–3 times the risk	54–68%	2–3 times the risk
Obesity	45–55%	1.5–2 times the risk	21–49%	1–2 times the risk
Metabolic Syndrome	37–63%	2–3 times the risk	30–49%	2–3 times the risk
Dyslipidemia	25–69%	≤ 5 times the risk	23–38%	≤ 3 time the risk
Hypertension	19–58%	2–3 times the risk	35–61%	2–3 times the risk
Diabetes Mellitus	10–15%	2–3 times the risk	8–17%	1.5–3 times the risk

Adapted from Hert, et al., 2011a. Physical Illness in patients with severe mental disorders: I. Prevalence, impact of medications and disparities in health care. World Psychiatry, 10(1): 52–77.

Note. The relative risk is compared to the general population.

Box 2.

Physical Diseases with Increased Frequency in Individuals with Serious Mental Illness

Cardiovascular diseases – stroke, myocardial infarction, hypertension, other cardiac and vascular diseases

Nutritional and metabolic diseases – obesity, hyperlipidemia, metabolic syndrome, diabetes mellitus

Bacterial infections and mycoses – tuberculosis

Viral diseases – HIV, Hepatitis B, Hepatitis C

Neoplasms – obesity-related cancers (e.g., breast, stomach)* and smoking-related cancers (e.g., lung)

Dental problems – gingivitis, dental caries, dry mouth

Respiratory tract diseases – COPD, impaired lung function

Urological conditions and male reproductive issues – sexual dysfunction

Female reproductive issues and pregnancy complications – obstetric complications, sexual dysfunction

Adapted from Hert, et al., 2011a.

**Note: Evidence regarding obesity-related cancers is conflicting; some studies indicate similar incidence of these cancers to the general population but with increased mortality among individuals with SMI, while other reports indicate increased rates of obesity-related cancers among individuals with SMI.*

Weight Change and Metabolic Side-Effects of Psychotherapeutic Medications

***Note*: Strongly recommend coordination of care between all providers to facilitate optimal outcomes.**

Weight changes are the most difficult issues patients and clinicians contend with and can have an effect on patient compliance with a particular regimen. Individual psychiatric medications, including those in the antidepressant, mood stabilizer, and antipsychotic classes, have been shown to have differential effects on weight gain.

Management of medication-induced weight gain and other metabolic problems depends on multiple factors, including response to different antipsychotics, severity of the metabolic disturbance, and patient willingness to implement lifestyle changes. Individuals with new-onset diabetes should receive an evaluation by a primary care provider.

Potential options to manage medication-induced metabolic side-effects include:

- Diet and exercise, including referral to a certified nutritionist if clinically indicated
- Switching to an antipsychotic with lower potential for weight gain or dyslipidemia (e.g., switch from olanzapine or risperidone to ziprasidone)
- Medication management if more conservative measures are ineffective (e.g., antihypertensives for hypertension and statins for dyslipidemia)

Initial randomized trials have also shown evidence that metformin may be effective in helping patients with schizophrenia lose weight. These trials found that twelve to sixteen weeks of metformin given at 750 mg/day or higher led to loss of approximately 50 percent of weight gain induced by antipsychotic treatment, and metformin combined with lifestyle changes had more effect than metformin alone in two of the trials. Metformin is indicated as an adjunct to diet and exercise to improve glycemic control in adults and children with Type 2 diabetes mellitus. Metformin is not yet FDA-indicated for psychotropic medication-induced weight gain and is contraindicated in individuals with known hypersensitivity or metabolic acidosis. Metformin has traditionally been contraindicated in chronic kidney disease; however, based on recent evidence and recommendations, metformin may be used with caution and close clinical supervision in individuals with a GFR >30 mL/min. The primary concern is the risk for lactic acidosis in this population.

Table 7.

Studies Examining Weight Change Associated with Psychotherapeutic Medications used in the Treatment of Serious Mental Illness	
Antidepressants	
Selective Serotonin Reuptake Inhibitors (SSRIs)	**Weight loss** ✦ **Sertraline (Zoloft)** – Patients in controlled trials had minimal (1-2 pound) weight loss compared to smaller changes with placebo. **No weight change** ✦ **Citalopram (Celexa)** – Short-term placebo-controlled trial showed average weight loss of 0.5 kg with citalopram versus 0.2 kg weight gain with placebo in post-marketing studies; No significant changes in body mass in post-marketing studies. ✦ **Escitalopram (Lexapro)** – No difference from placebo-treated patients in premarketing trials. ✦ **Fluoxetine (Prozac)** – No overall associated weight changes; weight loss of 0.35 kg reported in acute-phase treatment, at 38 weeks, 2.0 kg weight gain with fluoxetine versus 2.5 kg weight gain with placebo. **Weight gain** ✦ **Paroxetine (Paxil)** – Of the SSRIs, paroxetine is most likely to cause weight gain. Fava, et al. showed >7% increase in weight from baseline compared with patients taking sertraline or fluoxetine.
Selective Serotonin Reuptake Inhibitors (SSRIs)/ Serotonin Receptor Modulator	**Weight gain (long term studies)** ✦ **Vortioxetine (Trintellix)** – No significant weight change in short-term studies; One long-term study showed a mean weight gain of 0.67 kg from baseline. ✦ **Vilazodone (Vibryd)** – Minimal weight gain in short-term studies; Average change from baseline was 1.0 kg weight gain in a one-year study of 599 adults treated with vilazodone 40 mg/day.
Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)	**Weight loss** ✦ **Duloxetine (Cymbalta)** – In acute placebo-controlled studies, duloxetine treated patients had average change of -0.5 kg compared with 0.2 kg for placebo treated patients. No consistent relationship between duloxetine dose and weight change. Similar acute mean weight changes seen in duloxetine versus fluoxetine treated patients (-0.7 kg versus -0.6 kg respectively). ✦ **Venlafaxine (Effexor)** – Weight loss of up to 7% of body weight compared to placebo during up to 12 weeks of treatment in studies of patients with MDD, GAD, SAD, and panic disorders. **Weight loss (short-term)/No weight change (long term)** ✦ **Desvenlafaxine (Pristiq)** – Post-hoc analysis of data from 8 short-term and 1 longer-term study of adults treated with 50 mg/day or 100 mg/day of desvenlafaxine versus placebo found statistically significant mean weight loss (<1 kg) during acute treatment for MDD and no significant weight change after longer-term treatment in normal (BMI ≤ 25 kg/m^2), overweight (BMI 25 kg/m^2 to ≤ 30 kg/m^2), and obese (BMI > 30 kg/m^2) adults.

Table 7. ***(continued)***

Studies Examining Weight Change Associated with Psychotherapeutic Medications used in the Treatment of Serious Mental Illness *(continued)*	
Antidepressants ***(continued)***	
Tricyclic Antidepressants (TCAs)	**No weight change** ✦ **Nortriptyline (Pamelor)** – Meta-analysis of 257 RCTs found non-significant weight change with nortriptyline. **Weight gain** ✦ **Amitriptyline (Elavil)** – Meta-analysis of 257 RCTs found average of 1.8 kg weight gain. ✦ **Imipramine (Tofranil)** – Average of 4.5 kg weight gain over one year in patients treated for panic disorder.
Other antidepressants	**Weight loss** ✦ **Bupropion (Wellbutrin)** – Meta-analysis of 257 RCTs found average of 1.3 kg weight loss. **Weight gain** ✦ **Mirtazapine (Remeron)** – Meta-analysis of 257 RCTs found average of 1.5 kg weight gain.
Anticonvulsants/Mood Stabilizers	
	Weight loss ✦ **Lamotrigine (Lamictal)** – Mean weight loss of 4.2 kg at week 52 of therapy in obese patients; mean weight loss of 0.5 kg in non-obese patients at week 52. ✦ **Topiramate (Topamax)** – Meta-analysis of 257 RCTs found average of 3.8 kg weight loss. **Weight gain** ✦ **Carbamazepine (Tegretol)** – Meta-analysis of 257 RCTs found average of 1.0 kg weight gain. ✦ **Gabapentin (Neurontin)** – Meta-analysis of 257 RCTs found average of 2.2 kg weight gain. ✦ **Lithium (Eskalith, Lithobid)** – Mean weight gain of 6.1 kg at week 52 of lithium therapy in obese patients; mean weight gain of 1.1 kg in non-obese patients at week 52. ✦ **Valproic Acid (Valproate, Valpro, Depakene)** – Weight gain of 0.49 kg after 3 weeks of treatment with up to 1,500 mg/day versus placebo in healthy volunteers.
Antipsychotics	
Typical Antipsychotics	**Weight gain** ✦ **Chlorpromazine (Thorazine)** – Meta-analysis estimated mean weight gain of 2.10 kg at 10-weeks of treatment. ✦ **Fluphenazine (Prolixn)** – Meta-analysis estimated mean weight gain of 0.43 kg at 10-weeks of treatment. ✦ **Haloperidol (Haldol)** – Meta-analysis estimated mean weight gain of 0.48 kg at 10-weeks of treatment.

Table 7. ***(continued)***

Studies Examining Weight Change Associated with Psychotherapeutic Medications used in the Treatment of Serious Mental Illness *(continued)*	
Antipsychotics ***(continued)***	
Atypical Antipsychotics	**Weight gain** ✦ **Aripiprazole (Abilify)** – 3-month cohort study of first-time use of atypical antipsychotics in children and adolescents reported mean weight gain of 4.4 kg. 6-month RCT reported mean weight gain of 0.40 kg with aripiprazole. A meta-analysis of metabolic effects associated with atypical antipsychotic treatment in children and adolescents found olanzapine, risperidone and aripiprazole were all associated with statistically significant weight gain. Olanzapine was associated with the most weight gain and aripiprazole was the least. ✦ **Asenapine (Saphris)** – A double-blind placebo-controlled study found mean weight gain of 0.9 kg compared to placebo. ✦ **Brexpiprazole (Rexulti)** – Weight gain with brexpiprazole was moderate (1.45 and 1.28 kg for 2 and 4 mg, respectively, versus 0.42 kg for placebo at week 6). ✦ **Cariprazine (Vraylar)** – Mean weight gain at endpoint of 6-week in patients with schizophrenia: 0.8 kg with 1.5-3 mg/day, 1.0 kg with ≥4.5 mg/day versus 0.3 kg with placebo. ✦ **Clozapine (Clozaril)**–6-week open-label study reported average weight gain of 2.5 kg. ✦ **Iloperidone (Fanapt)** – Mean change from baseline of 2.1 kg increase at endpoint. ✦ **Lurasidone (Latuda)** – The mean weight gain observed across 6-week trial in patients with schizophrenia was 0.43 kg for lurasidone versus mean weight loss of 0.02 kg for placebo. ✦ **Olanzapine (Zyprexa)** – Meta-analysis of 257 RCTs found average of 2.4 kg weight gain. A 3-month cohort study of first-time use of atypical antipsychotics in children and adolescents reported mean weight gain of 8.5 kg. CATIE trial found an average weight gain of 2.0 lbs (0.9 kg) per month, more than any other treatment group (quetiapine, risperidone, ziprasidone, or perphenazine). A meta-analysis of metabolic effects associated with atypical antipsychotic treatment in children and adolescents found olanzapine, risperidone and aripiprazole were all associated with statistically significant weight gain. Olanzapine was associated with the most weight gain and aripiprazole was the least. ✦ **Paliperidone (Invega)** – 6-month RCT reported mean weight gain of 2.3 kg for paliperidone ER. ✦ **Quetiapine (Seroquel)** – Meta-analysis of 257 RCTs found average of 1.1 kg weight gain. ✦ **Risperidone (Risperdal)** – Meta-analysis of 257 RCTs found average of 0.8 kg weight gain. A meta-analysis of metabolic effects associated with atypical antipsychotic treatment in children and adolescents found olanzapine, risperidone and aripiprazole were all associated with statistically significant weight gain. Olanzapine was associated with the most weight gain and aripiprazole was the least. ✦ **Ziprasidone (Geodon)** – Meta-analysis found mean weight gain of 0.04 kg.

Note. 1 kilogram = 2.2 pounds. Medications under each category (weight loss, no weight change, weight gain) are listed alphabeticaly.

Note: Strongly recommend coordination of care between all providers to facilitate optimal outcomes.

Prediabetes

Prediabetes identifies individuals who are at increased risk for type 2 diabetes and cardiovascular disease but do not yet meet the criteria for type 2 diabetes.

The American Diabetes Association (ADA) defines prediabetes as individuals who:

- Have an impaired fasting glucose of 100–125 mg/dL (which is lower than the World Health Organization's criteria of 110–125 mg/dL), and/or
- Have an impaired glucose tolerance defined by a 2-hour plasma glucose of between 100–199 mg/dL after a 75g oral glucose load, and/or
- Have a hemoglobin A1c between 5.7% and 6.4%

Note: Refer for further care and/or initiate treatment as clinically indicated if impaired fasting glucose, impaired glucose tolerance, or elevated HgA1c (>5.7%).

Metabolic Syndrome

According to the American Heart Association and the National Heart, Lung, and Blood Institute, there are five factors that make up metabolic syndrome:

- Large waist size (40 inches or larger for men, 35 inches or larger for women)*
- High triglycerides (either 150 mg/dL or higher or using a cholesterol medication)
- Low levels of high-density lipoprotein or HDL (HDL less than 40 mg/dL for men, less than 50 mg/dL for women, or any patient using a cholesterol medication)
- High blood pressure (blood pressure of 135/85 mmHg or greater or using a blood pressure medication)
- High fasting glucose level (100 mg/dL or higher)

**Note: Waist circumference may not be as informative for children as for adults.*

The following tables review antipsychotic medication effects on development of metabolic syndrome, review cutoff waist circumference values in different ethnic populations, and provide recommended guidelines for management of these risk factors when they are present.

Table 8.

Antipsychotic Medications and Metabolic Syndrome Risk				
Medication	**Low**	**Mild**	**Moderate**	**High**
Typical Antipsychotics				
Chlorpromazine (Thorazine)	—	—	—	✔
Haloperidol (Haldol)	✔	—	—	—
Perphenazine (Trilafon)	✔	—	—	—
Atypical Antipsychotics				
Aripiprazole (Abilify)	✔	—	—	—
Asenapine (Saphris)*	✔	—	—	—
Brexpiprazole (Rexulti)	—	✔	—	—
Cariprazine (Vraylar)	—	✔	—	—
Clozapine (Clozaril)	—	—	—	✔
Iloperidone (Fanapt)*	—	✔	—	—
Lurasidone (Latuda)*	✔	—	—	—
Olanzapine (Zyprexa)	—	—	—	✔
Quetiapine (Seroquel)	—	—	✔	—
Risperidone (Risperdal)	—	✔	—	—
Ziprasidone (Geodon)	✔	—	—	—

Adapted from Hert, et al., 2011a.

Note. mg/dL=milligrams per deciliter; mmHg=millimeters of mercury; mg/dL= milligrams per deciliter.

**Limited data with these medications. Some of the second-generation antipsychotics above have not been extensively studied with regard to metabolic syndrome.*

Ethnicity-Specific Cutoff Values of Waist Circumference Indicating Abdominal Obesity

Annual monitoring is recommended in a primary care setting.

Table 9.

Waist Circumference and Race Ethnicity		
	Females	**Males**
North Americans	≥88 cm (≥ 35 in)	≥102 cm (≥ 40 in)
European, Mediterranean, Middle Eastern, Sub-Saharan Africans	≥80 cm (≥ 32 in)	≥94 cm (≥ 37 in)
South Asians, Chinese, Ethnic South and Central Americans	≥80 cm (≥ 32 in)	≥90 cm (≥ 35 in)
Japanese	≥82-85 cm (≥ 32–34 in)	≥90 cm (≥ 35 in)

Adapted from Hert, et al., 2011a.

Note. cm = centimeter; in = inch.

Type 2 Diabetes Mellitus and Cardiovascular Health Issues

Any of the following:

- Fasting plasma glucose ≥126 mg/dL

  **Note: Fasting is defined as no caloric intake for ≥8 hours. In absence of unequivocal hyperglycemia, result to be confirmed by repeat testing.*

- 2-hour plasma glucose ≥200 mg/dL during oral glucose tolerance test with glucose load containing equivalent of 75 g anhydrous glucose dissolved in water

  **Note: In absence of unequivocal hyperglycemia, result to be confirmed by repeat testing.*

- Hemoglobin A1c ≥6.5%
- Random plasma glucose ≥200 mg/dL in individuals with symptomatic hyperglycemia or hyperglycemic crisis

Diagnostic Criteria for Hypertension

- Normal blood pressure: <120/<80 mmHg
- Stage 1: 130–139 mmHg systolic or 80–89 mmHg diastolic
- Stage 2: ≥140 mmHg systolic or ≥90 mmHg diastolic

**Note: Prior to diagnosing hypertension, use an average based on two or more readings obtained on two or more occasions to estimate the individual's blood pressure. Out-of-office and self-monitoring of blood pressure measurements are recommended to confirm the diagnosis of hypertension.*

ADA Target Goals and Atherosclerotic Cardiovascular Disease (ASCVD) Risk Calculator

Note: Strongly recommend coordination of care between all providers to facilitate optimal outcomes.

The following recommendations were adapted from the American Diabetes Association (ADA).

Box 3.

ADA Target Goals for Blood Pressure, Lipid, and Glycemic Control

Blood pressure: Systolic <140 mmHg*; Diastolic <90 mmHg

Lipids: LDL-C <100 mg/dL**

After age 10 years old, the addition of a statin is suggested in patients who, despite medical nutrition therapy and lifestyle changes, continue to have LDL cholesterol >160 mg/dL with no cardiovascular risk factors or LDL cholesterol >130 mg/dL with one or more cardiovascular disease risk factors.***

Hemoglobin A1c: <7%‡ (treatment goal)

**Lower systolic blood pressure (SBP) goals may be appropriate based on individual patient characteristics and therapeutic response.*

***A lower LDL-C goal of <70 mg/dL using a high dose of a statin may be appropriate in persons with overt cardiovascular disease (CVD). See table below for further recommendations regarding lipid screening and management.*

****Be cautious of contraindications to statin therapy (e.g. pregnancy) and drug-drug interactions with psychiatric medications.*

‡More or less stringent glycemic goals may be appropriate for individual patients. Individualize goals based on diabetes duration, age/life expectancy, comorbidities, known CVD or advanced microvascular complications, hypoglycemia unawareness, and individual patient characteristics.

Note: mmHg= millimeters of mercury; mg/dL= milligrams per deciliter; LDL-C= low density lipoprotein.

Note: If statin therapy is initiated, monitor for side effects including, but not limited to statin-induced myopathy and impaired liver function.

Atherosclerotic Cardivascular Disease (ASCVD) Risk Calculator

The ASCVD risk calculator calculates the 10-year risk of heart disease or stroke using the ASCVD algorithm published in the 2013 American College of Cardiology (ACC)/American Heart Association (AHA) Guideline on the Assessment of Cardiovascular Risk for individuals between 40-79 years old. The calculator assumes no prior history of a heart attack or stroke. Currently, there is insufficient data to reliably predict risk for individuals under 40 years or older than 79 years of age, or those with a total cholesterol greater than 320 mg/dL.

The 2018 American College of Cardiology/American Heart Association Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults redefines high blood pressure as >130/80 mmHg and recommends starting anti-hypertensives based on an ASCVD risk score of >10%.

Link to ASCVD Risk Calculator: ***http://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/calculate/estimate/***

QT Prolongation Associated with Psychotherapeutic Medications

QT Interval Prolongation

The QT interval represents electrical depolarization and repolarization of the ventricles, and the QTc is this value corrected for the patient's heart rate. In clinical trials, a prolonged QTc interval of greater than 500 milliseconds during therapy has been a threshold for concern. Clinically, a QTc interval above 470 milliseconds in females and above 450 milliseconds in males is considered prolonged, and individual changes in QTc intervals of 30 to 60 milliseconds from baseline should heighten suspicion of increased risk of arrhythmias. Though data are limited, a prolonged QTc interval appears to be more common with tricyclic antidepressants than selective-serotonin reuptake inhibitors (SSRIs). Antipsychotic medications have also been reported to be associated with QTc interval prolongation, particularly with ziprasidone and thioridazine, and to a lesser extent with haloperidol and quetiapine.

ECG monitoring is recommended when administering antipsychotic medications in the presence of co-existing risk factors for QT interval prolongation such as older age, electrolyte disturbances (e.g., hypokalemia, hypomagnesemia), family history of sudden death, personal history of cardiac murmur, and/or use of concomitant medications known to prolong the QT interval. See table below for risk factors to evaluate for during initial assessment when considering use of antipsychotics or other medications with QT prolongation.

Cardiovascular Risk Associated with Antipsychotic Use in Youth Under 24 Years

- More frequent ECG monitoring may be warranted in youth under 24 years old prescribed antipsychotic medications compared to adult populations.
- A retrospective cohort study by Ray, et al. (2019) reported that antipsychotic medication use at doses greater than 50 mg chlorpromazine equivalents in youth ages 5 to 24 years was associated with increased risk of unexpected death compared to the control group of youth prescribed ADHD medications, antidepressants, or mood stabilizers. The adjusted and unadjusted incidence of death in youth prescribed lower-dose antipsychotics (50 mg or lower chlorpromazine equivalents) did not differ significantly from the control group.

Note: Strongly recommend coordination of care between all providers to facilitate optimal outcomes.

Box 4.

Risk Factors Associated with QT Prolongation*

Evaluate for:

- Older age (>65 years)
- Electrolyte disturbances (e.g., hypokalemia, hypomagnesemia)
- Congenital long QT syndrome
- Family history of sudden death
- Personal history of heart murmur, shortness of breath with exertion, episodes of tachycardia at rest, irregular heartbeats
- Personal history of syncope
- Known cardiac disease (myocardial ischemia, congestive heart failure, cardiac arrhythmias, bradycardia)
- Concomitant use of other medications known to prolong QT interval
- Concomitant medications known to inhibit metabolism of antipsychotic medications (i.e., cause increased serum concentrations of antipsychotic medications)
- History of liver disease
- Endocrine and metabolic disorders
- Central nervous system injury (e.g., stroke, infection, trauma)

**Adapted from Shah AA, el al (2014).*

Florida Medicaid Drug Therapy Management Program for Behavioral Health

Working with Medicaid health plans and providers to:

- Improve behavioral health prescribing practices
- Improve patient adherence to medication
- Reduce clinical risks and medication side effects
- Improve behavioral and physical health outcomes

The following treatment guidelines are available on our website at *floridamedicaidmentalhealth.org.*

- Best Practice Psychotherapeutic Medication Guidelines for Children and Adolescents
- Autism Spectrum Disorder & Intellectual Developmental Disorder: Best Practice Psychotherapeutic Medication Recommendations for Target Symptoms in Children and Adolescents
- Best Practice Recommendations for Women of Reproductive Age with Severe Mental Illness and Substance Use Disorders
- Best Practice Psychotherapeutic Medication Guidelines for Adults
- Monitoring Physical Health and Side-Effects of Psychotherapeutic Medications in Adults and Children: An Integrated Approach

The Florida Pediatric Psychiatry Hotline is a free service that provides consultation about medication management for behavioral health.

Florida Pediatric Psychiatry Hotline

1-866-487-9507

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College of Behavioral & Community Sciences

Florida Medicaid Drug Therapy
Management Program for Behavioral Health

For hard copies of the guidelines, email ***sabrinasingh@usf.edu***

For more information, visit us at ***floridamedicaidmentalhealth.org***

Hyperprolactinemia Associated with Psychotherapeutic Medications

***Note*: Strongly recommend coordination of care between all providers to facilitate optimal outcomes.**

Antipsychotics such as risperidone are associated with hyperprolactinemia. Hyperprolactinemia may be asymptomatic or may be associated with a wide range of clinical effects, including decreased sexual and reproductive function (e.g., oligomenorrhea, amenorrhea), weight gain, decreased bone density, gynecomastia, and galactorrhea. If symptomatic, other medical causes of hyperprolactinemia (e.g., pituitary adenoma) should be ruled out. Patients taking antipsychotic medications should be assessed and monitored for signs and symptoms of hyperprolactinemia, with appropriate referrals when clinically indicated. Prolactin levels should particularly be monitored in male patients prescribed antipsychotic medications due to the concern for gynecomastia, which is potentially irreversible. Management of symptomatic medication-induced hyperprolactinemia includes referral to a specialist, reduction in the medication dose, discontinuation of the offending agent, or switch to a prolactin-sparing agent such as aripiprazole.

Infectious Disease: Risk Factors and Screen Recommendations

***Note*: Strongly recommend coordination of care between all providers to facilitate optimal outcomes.**

Individuals with serious mental illness are often at increased risk for acquiring infectious diseases such as Hepatitis B, Hepatitis C, HIV, and tuberculosis due to a greater likelihood of engaging in high-risk behaviors such as using illicit substances and having multiple sexual partners. When planning to screen patients for infectious diseases, patients should be informed orally and in writing that testing will be performed. Unless they decline, they should receive explanation of the infection, how it can and cannot be acquired, the meaning of positive and negative test results, and the benefits and risks associated with treatment. They should also be offered the opportunity to ask questions and decline testing. This section reviews risk factors and screening recommendations for Hepatitis C (HCV), Hepatitis B (HBV), human immunodeficiency virus (HIV), and tuberculosis (TB).

Table 10.

Risk Factors and Screening Recommendations for Selected Infectious Diseases

Disease	Risk Factors	Screening/Treatment Recommendations
Hepatitis C (HCV)	Past/present drug use Sex with injection drug user Blood transfusion before 1992 Other: Long-term dialysis, incarceration, intranasal drug use, getting an unregulated tattoo, infant of HCV positive mother	1-time screening in all adults born between 1945 and 1965 High-risk patients FDA approved treatment
Hepatitis B (HBV)	Sexual contact with infected person Exposure to infectious bodily fluids Prolonged, close personal contact with infected person Perinatal exposure to infected mother	Hepatitis B surface antigen (HBsAg) Either Hepatitis B core antibody (anti-HBc) or hepatitis B surface antibody (anti-HBs)
Human Immunodeficiency Virus (HIV)	Injection drug use/sharing needles Sexual contact - anal, vaginal or oral sex; men who have sex with men; multiple partners; anonymous partners without using condom; sexual contact with infected person; exchange sex for drugs/money; unprotected sex with at-risk individuals. History of STI (syphilis, genital herpes, chlamydia, gonorrhea, bacterial vaginosis, trichomoniasis) Diagnosed with hepatitis, TB, or malaria Blood transfusion or clotting factor recipient in US between 1978 and 1985	All persons who seek evaluation and treatment for sexually transmitted infections (STIs) should be tested; consider rapid HIV test in this population as high proportion of patients may not return for HIV test results. Individuals suspected of recently acquired HIV infection - refer for immediate consultation with infectious disease specialist for evaluation (history, physical including gynecology exam in women, chest radiography, and lab tests - CBC, CMP, lipid profile, urinalysis toxoplasma antibodies, testing for STIs and hepatitis, HIV genotype, CD4 count and viral load, and TB test).

Table 10. ***(continued)***

Risk Factors and Screening Recommendations for Selected Infectious Diseases *(continued)*		
Disease	**Risk Factors**	**Screening/Treatment**
Tuberculosis (TB)	Individuals in contact with patient who has TB Individuals from a country where TB is common Patients with HIV infection or problems that weaken the immune system Symptomatic patients (e.g., fever, productive cough, weight loss, night sweats, fatigue, and loss of appetite) Live/work in area where TB is common (e.g., homeless shelter, and/or prison/jail) Illicit drug users	TB testing generally is not recommended in patients with low risk of TB infection. High risk patients should have medical evaluation- history/ physical, TB test, chest radiograph at minimum and other laboratory tests as appropriate.

Adults aged 19 years or older should also receive immunizations recommended by the Centers for Disease Control (CDC):

- Influenza – 1 dose annually
- Tetanus, diphtheria, pertussis (Td/Tdap) – Substitute Tdap for Td once, then Td booster every 10 years
- Varicella – 2 doses
- Human papillomavirus (HPV) – 3 doses between 19 and 26 years old
- Herpes zoster – 1 does 60 years old or older
- Measles, mumps, rubella (MMR) – 1 or 2 doses depending on indication

Note. Other immunizations may be recommended for persons with a risk factor (medical, occupational, lifestyle, or other indication). See CDC website ***http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule-bw.pdf*** *and* ***https://www.cdc.gov/vaccines/vpd/shingles/hcp/shingrix/recommendations.html*****.**

USF/Aunt Bertha Comprehensive Web-Based Florida Resource Guide

https://floridamedicaidmentalhealth.auntbertha.com/

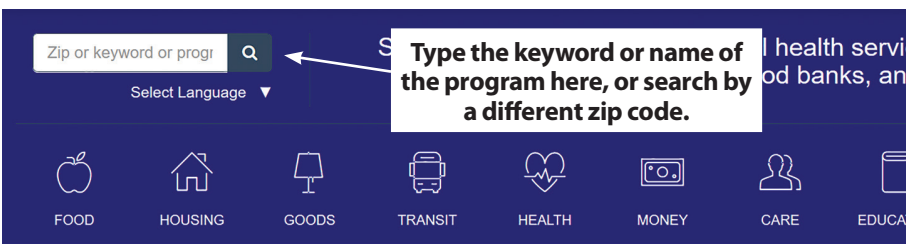
About

- The USF Florida Medicaid Drug Therapy Management Program for Behavioral Health has collaborated with Aunt Bertha to create a free, web-based search tool for behavioral and physical health services and community resources.
- Resources include health, housing, food banks, transportation, and other services.

How to Search for Local Resources

- After entering a local zip code, providers can search by category or keyword.

- Click the specific category of interest (e.g., food, housing, transit, health) to view available resources, or enter a keyword to narrow the search.



- Click on the program of interest to view information such as services provided, location, hours, and contact information about that program.

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Florida Medicaid Drug Therapy Management Program for Behavioral Health

AGENCY FOR HEALTH CARE ADMINISTRATION STATE OF FLORIDA

For any questions, email **sabrinasingh@usf.edu**.

Visit ***floridamedicaidmentalhealth.org*** for more information.

One in five individuals with a serious mental illness has a co-occurring substance use disorder. Similar to persons with SMI, individuals with substance use disorders are at risk for physical health problems such as cardiovascular disease, lung disease, hepatitis, HIV/AIDS, and cancer. The management of chronic disease is often complicated and more challenging in individuals with co-occurring disorders. For example, individuals who have depression, a substance use disorder, and medical comorbities are less likely to adhere to their treatment plan and medications for type 2 diabetes. Improvement of the health and functioning of these individuals requires the integration of care across primary care, mental health care, and substance use services. Many of the FDA-approved medications to help patients reduce alcohol or drug use, avoid relapse, and support abstinence (e.g., buprenorphine, naltrexone, and acamprosate) can be used in primary care settings which increases patient choice in being treated in the setting they are most comfortable.

Conduct a comprehensive assessment. Refer to Principles of Practice.

Note: Strongly recommend coordination of care between all providers to facilitate optimal outcomes.

Check E-FORCSE as required by law (the Electronic-Florida Online Reporting of Controlled Substance Evaluation Program, Florida's state prescription monitoring program), ideally prior to prescribing any medications, but at a minimum when prescribing any controlled substance. Checking E-FORCSE is also recommended for all new patients, with follow-up E-FORCSE monitoring at least once per year for each patient.

Concurrent Prescribing of Opioids and Benzodiazepines

Epidemiologic studies suggest that concurrent use of benzodiazepines and opioids increase the risk for potentially fatal overdose, as both classes of medications cause central nervous system depression, decrease respiratory drive, and will act synergistically. In the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, published in 2016, the CDC emphasized evidence in which a case-cohort study found concurrent benzodiazepine prescription with opioid prescription to be associated with a near quadrupling of risk for overdose death compared with opioid prescription alone. Among the CDC recommendations is: **"Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible."** When presented with a patient currently prescribed both benzodiazepines and opioids, in many instances it may be safer and more practical to taper the opioids first. Opioid withdrawal is often associated with an increase in anxiety, and benzodiazepine withdrawal can be relatively medically more complicated. Consultation with a pharmacist and a pain management specialist may be needed for optimal outcome.

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: ***http://dx.doi.org/10.15585/mmwr.rr6501e1external icon****.*

Older Adults

The 2019 American Geriatrics Society Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults identified benzodiazepines as medications to "avoid" in the older adult population. Benzodiazepines can increase the risk of cognitive impairment, delirium, falls and fractures, and motor vehicle accidents. A similar recommendation to avoid was made for the non-benzodiazepine, benzodiazepine receptor agonist hypnotics (the "z-drugs") eszopiclone, zaleplon, and zolpidem.

Highly anticholinergic antidepressants (typically tricyclic and tetracyclic antidepressants) are recommended to be avoided in the older adult population.

As a rule, clinicians should be especially aware of drug-drug interactions and increased risk of adverse side-effects in the older adult population.

American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc, 67: 674-694. doi:10.1111/jgs.15767

Screening, Brief Intervention, and Referral to Treatment (SBIRT)

SBIRT is a model to assess and deliver early intervention and treatment to individuals with substance use disorders and those that are at risk of developing substance use disorders.

- Screening quickly assesses the severity of substance use and identifies the appropriate level of treatment
- Brief intervention focuses on increasing insight and awareness of substance use and motivation towards behavioral change
- Referral provides those needing treatment access to specialty care services

Recommend screening for substance use disorders using validated questionnaires (see table in Principles of Practice) prior to patient visits. Obtain history of prescription, over-the-counter, and herbal medication use.

Pre-Screening for Substance Use Disorders

NIAAA/NIDA Pre-Screening Questions:

- "How many times in the past year have you had 4 or more drinks in a day?" (NIAAA)
- "How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons?" (NIDA)

Alcohol Use Disorders Identification Test (AUDIT): The Alcohol Use Disorders Identification Test (AUDIT) is a 10-item screening tool developed by the World Health Organization (WHO) to assess alcohol consumption, drinking behaviors, and alcohol-related problems. The AUDIT is available at: ***https://www.drugabuse.gov/sites/default/files/files/AUDIT.pdf***.

Box 5.

Behaviors that Increase Suspicion for Drug Misuse and Substance Use Disorders

- Taking a controlled substance for a long time period
- Refusing to grant permission to obtain old records or communicate with previous providers
- Reluctance to undergo a comprehensive history, physical examination, or diagnostic testing (especially urine drug screens)
- Requesting a specific drug
- Professing multiple allergies to recommended medications
- Resisting other treatment options

Other behaviors suggesting further screening for substance use:

- Issuing threats or displaying anger
- Targeting appointments at the end of the day or during off hours (nights or weekends)
- Excessive flattery
- Calling and visiting a physician's associates
- Repeatedly losing a prescription
- Requesting dose escalation
- Demonstrating noncompliance with prescription instructions
- Demonstrating other evidence of alcohol or illicit drug misuse

**Adapted from Standridge JB, et al (2010). Urine Drug Screening: A valuable office procedure*

For a list of screening tools for substance use disorders, refer to Principles of Practice.

Laboratory Drug Screening and Confirmatory Testing

Laboratory drug testing typically involves a two-step process: the initial drug screen for potentially positive specimens, followed by confirmatory testing of screened positive assays.

Screen Tests

Screening tests can be done in the laboratory or onsite and usually use an immunoassay of urine or saliva. Screening tests indicate the presence or absence of a substance or its metabolite, but can also indicate the presence of a cross-reacting, chemically similar substance. Screening tests are either positive or negative and generally do not measure the specific levels of drugs, alcohol, or metabolites present.

Box 6.

When Urine Drug Screening Should be Obtained

Drug testing may be useful for:

- New patients as part of regular care to identify use of illicit or non-prescribed drugs
- Patients being prescribed a controlled substance
- Aberrant patient behavior or high-risk patterns:
  - Patients who present with a condition that warrants prescription for a controlled substance but who resist full evaluation or who request a specific medication with addictive potential
  - Patients who consistently want appointments toward the end of office hours, arrive after office hours, insist on being seen immediately, repeatedly report losing prescriptions or medications, are reluctant to change medication, or do not adhere to the treatment plan
- Patients who are suspected of diversion
- Patients in recovery from substance use disorders
- Patients who need advocacy to verify their abstinence
- Pain management patients
- Patients who need a change in treatment
- Monitoring of adherence with treatment
- Patients who present with atypical or unusual clinical history of symptoms

Adapted from Standridge JB, et al (2010). Urine drug screening: A valuable office procedure; and SAMHSA (2012). Clinical Drug Testing in Primary Care.

Table 11.

Drugs that May Cause False-Positive Results in Screening (Immunoassay) Testing		
Drug Category Being Tested	**Duration of Detection**	**Medications that May Cause False-Positive Results**
Amphetamines	2–3 days	Amantadine; bupropion; chlorpromazine; desipramine; fluoxetine; L-methamphetamine (in nasal decongestants), labetalol, methylphenidate, phenteramine, phenylephrine, pseudoephedrine, ranitidine, thioridazine, trazodone
Benzodiazepines	Short-acting benzodiazepines (e.g., lorazepam): 3 days Long-acting benzodiazepines (e.g., diazepam): Up to 30 days	Sertraline, oxaprozin
Cocaine	2–3 days with occasional use; Up to 8 days with heavy use	Topical anesthetics containing cocaine
Opiates	1–3 days	Dextromethorphan, diphenhydramine, poppy seeds, quinine, rifampin, verapamil
Phencyclidine	7–14 days	Dextromethorphan, diphenhydramine, ibuprofen, imipramine, ketamine, meperidine, thioridazine, tramadol, venlafaxine
Tetrohydrocannabinol (Marijuana)	3 days (with single use) up to 30 days (with long-term, heavy use)	Dronabinol, nonsteroidal anti-inflammatory drugs (ibuprofen, naproxen, suldinac), proton pump inhibitor (e.g., protonix)

Adapted from Standridge JB, et al (2010). Urine drug screening: A valuable office procedure.

Confirmatory Testing

Confirmatory tests include gas chromatography-mass spectrometry or high-performance liquid chromatography to confirm or refute the results of screening assays. These tests provide quantitative concentrations of specific substances or their metabolites present in the specimen, have a high specificity and sensitivity, and can identify specific drugs within the drug class.

In individuals with a positive urine drug screen, obtain confirmatory drug testing if clinically warranted.

Behavioral Therapies for Substance Use Disorders

Behavioral therapies for substance use disorders include brief interventions, motivational enhancement therapy (MET)/motivational interviewing (MI), cognitive-behavioral therapy (CBT), contingency management, community reinforcement, coping skills training, couples therapy, individual and group counseling, brief family therapy, multi-dimensional family therapy, psychodynamic (supportive-expressive) therapy, and mutual help groups such as 12-step facilitation.

Brief Interventions

The goal of providing brief interventions is to reduce the risk of harm from continued use of substances providing clients with tools to change basic attitudes leading to substance use and addressing underlying problems. Brief interventions differ from long-term therapy by focusing on the present, emphasizing effect use of therapeutic tools over the short-term, and focusing on specific behavioral changes.

When to Use Brief Intervention

Criteria to consider when selecting individuals to participate in brief intervention include: dual diagnosis issues; range and severity of presenting problems; duration of substance dependence; availability of family and community support; influence from peers, family and community; previous treatment or attempts at recovery; level of client motivation; and short and long-term treatment goals.

Brief intervention is recommended for:

- Clients with less severe substance dependence, as measured by instruments such as the Addiction Severity Index (ASI)
- Level of past trauma affecting current substance use
- Insufficient time or resources available for more prolonged therapy/treatment
- Presence of coexisting medical or mental health diagnoses
- Inaccessibility of specialized treatment services due to logistical concerns (e.g., long waiting lists)

Brief interventions are most effective for clients with short-term problems with strong family and community support. It is essential to assess the patients' perceived obstacles to treatment engagement and identify beliefs that may hinder engagement in treatment.

Selected Brief Intervention Models

- **The FLO Model:** Includes providing feedback, listening and understanding, and exploring options.
- **The FRAMES Model:** Involves feedback, responsibility, advice, menu of strategies, empathy, and self-efficacy.

Selected Behavioral Therapies for Substance Use Disorders

- **Motivational Enhancement Therapy (MET)/Motivational Interviewing (MI)**

  Time-limited, evidence-based intervention that involves examining ambivalence to change, begins the process of change, enhances confidence in taking action, and strengthens individuals' commitment to change.

- **Contingency Management**

  Contingency management involves reinforcing abstinence through a voucher system, where vouchers are exchanged for goods or services compatible with a drug-free lifestyle.

- **Cognitive Behavioral Therapy (CBT)**

  CBT focuses on developing skills to cope with problematic substance use by exploring positive and negative consequences of continued substance use, self-monitoring to recognize cravings, identifying situations that put one at risk for substance use, developing strategies to cope with cravings, and avoiding high-risk situations.

- **Mutual Help Groups (e.g., 12-Step Facilitation)**

  Mutual help groups include 12-step facilitation through organizations such as Alcoholics Anonymous. Through mutual help groups, individuals who share a common experience or problem come together to share their experiences and provide help/support to one another.

Adolescents

Multiple approaches exist for treating adolescent substance use disorders (SUDs). Strong evidence exists for the efficacy of psychosocial or behavioral interventions in the treatment of adolescent SUDs. These interventions should be considered the primary treatment modality for youth with substance use problems. Working with parents and families typically improves treatment outcomes. Pharmacotherapy should be reserved for patients who have not been able to achieve abstinence or improvements in functioning with primary behavioral interventions. Examples of evidence-based behavioral interventions for adolescent substance use disorders include:

- Motivational Interviewing (MI) and Motivational Enhancement Therapy (MET)
- Multisystemic Therapy (MST)
- CBT
- Adolescent-Community Reinforcement (A-CRA)
- Contingency Management

Table 12.

Medications for Maintenance of Abstinence in Alcohol Use Disorders			
Medication	**Mechanism of Action**	**Dosing Recommendations**	**Notes**
Acamprosate (Campral®)	Exact mechanism not completely understood; possible blockage of glutaminergic N-methyl-D-aspartate (NMDA) receptors and activation of glamma-aminobutyric acid type A (GABA) receptors	Two 333 mg tablets by mouth three times per day. Dose adjustment recommended to one 333 mg tablet by mouth three times per day in patients with moderate renal impairment (CrCl 30–50 mL/min).	Contraindicated in individuals with severe renal impairment. Contraindicated if history of hypersensitivity reactions.
Disulfiram (Antabuse®)	Aldehyde dehydrogenase inhibition	500 mg by mouth every morning for 1–2 weeks, then reduce to 250 mg by mouth daily. Maintenance doses range from 125 mg to 500 mg once daily and should not exceed 500 mg/day.	After initiation, monitor every 2 weeks for first two months, then monthly for four months, and every 6 months thereafter. Contraindicated in patients with severe cardiovascular (heart failure, coronary artery disease, history of stroke, hypertension), suicidal risk, psychosis, active alcohol consumption, pregnant and breastfeeding patients. Contraindicated with concomitant use of metronidazole, paraldehyde, or alcohol-containing products. Contraindicated if hypersensitivity reactions, or with allergies to thiuram (found in pesticides and rubber).

Table 12. ***(continued)***

Medications for Maintenance of Abstinence in Alcohol Use Disorders *(continued)*			
Medication	**Mechanism of Action**	**Dosing Recommendations**	**Notes**
Naltrexone (Revia®)	Mu opioid receptor antagonist	50 mg/day orally starting 4–7 days after last drink; may begin at 25 mg po daily for first 3–5 day to minimize adverse effects	Contraindicated in patients receiving long-term opioid therapy Contraindicated in acute hepatitis or liver failure Monitor liver dysfunction. Contraindicated if history of hypersensitivity reactions.
Naltrexone, extended-release (Vivitrol®)	Mu opioid receptor antagonist	380 mg intramuscularly (IM) one time per month	Contraindicated in patients receiving long-term opioid therapy Contraindicated in acute hepatitis or liver failure Monitor liver dysfunction. Contraindicated if history of hypersensitivity reactions.

Note: Studies on the use of medications for maintenance of abstinence from alcohol use disorders are lacking in women who are pregnant; therefore, no definitive evidence-based recommendations can be provided. Disulfiram is contraindicated during pregnancy for maintenance of abstinence in alcohol use disorders.

Table 13.

Medication Assisted Therapy for Opioid Use Disorders: Methadone versus Buprenorphine		
	Methadone	**Buprenorphine**
Mechanism	Full mu receptor agonist	Partial mu receptor agonist
Use	More effective for severe dependence	Used for mild to moderate dependence
Half life	24–36 hours	36–48 hours
Route	Oral	Sublingual
Dosing	Daily dose	Daily to 3 times per week
Accessibility	Opioid treatment program	Physician's office or opioid treatment program
Abuse potential	More abuse potential Less risk of injection misuse with oral liquid	Less abuse potential Risk of injection misuse with sublingual tablet preparation
Overdose risk	No protective overdose factors	Ceiling effect limits risk of overdose
Withdrawal	Moderate to severe, prolonged withdrawal	Mild withdrawal symptoms
Common side-effects	Cardiac dysrhythmia, hypotension, diaphoresis, constipation, nausea, vomiting, dizziness, sedation	Headache, nausea, sweating, rhinitis, constipation
Use in pregnancy	Current standard of care in pregnancy	Combination buprenorphine/naloxone not recommended in pregnancy; use methadone or buprenorphine alone

Notes: For individuals receiving opioid medications requesting benzodiazepines from another provider, carefully assess benefits and risks of concomitant use of opioids and benzodiazepines. Ensure clear communication between providers, for example, through use of standardized letters. For a sample agreement on controlled substance therapy for chronic pain treatment by the American Academy of Pain Medicine, visit ***http://www.painmed.org/files/agreement-on-controlled-substances-therapy pdf****. Frequently monitor older adults prescribed benzodiazepine medications. Assess indications for which benzodiazepines are prescribed, potential drug-drug interactions, and presence of side-effects such as somnolence.*

Nicotine Dependence and Tobacco Use Disorder

According to the Centers for Disease Control (CDC), tobacco use alone accounts for 1 in 5 deaths each year. Individuals with mental illness have a higher risk of co-occurring tobacco use disorders.

Tobacco Cessation: 5 A's to Assess and Manage Tobacco/Nicotine Use

Ask: Quantify tobacco use

Advise: Recommend against initiation, or if smoking, recommend quitting

Assess: Determine state of change (precontemplative, contemplative, preparation, active)

Assist: Counsel, set quit date, offer support

Arrange: Arrange follow-up, offer additional encouragement, monitor for relapse

Table 14.

Nicotine Replacement Therapies and Other Medication-Assisted Treatment for Tobacco Use Disorders			
Nicotine Replacement Therapy (First-Line)			
Medication	**Mechanism of Action**	**Dosing Recommendations**	**Notes**
Patch	7, 14, or 21 mg/day	Skin reactions, vivid dreams, insomnia	Patch placed on skin; dose reduced over time
Gum	2 mg or 4 mg every 1–2 hours	Hiccups, nausea, jaw pain	Chew gum until it produces tingling feeling, then keep gum between cheek and gum and chew with cravings
Lozenges	2 or 4 mg lozenges as needed with cravings	Hiccups, nausea	Allow lozenge to dissolve slowly
Inhaler	4 mg/cartridge, up to 6–16 cartridges/day	Throat irritation, mouth irritation, nasal congestion, cough	Inhale through mouthpiece to deliver nicotine
Nasal spray	0.5 mg/spray; Use one spray per nostril as needed with cravings	Nasal irritation, nasal congestion, changes in taste and smell	Insert and spray into each nostril

Table 14. ***(continued)***

Nicotine Replacement Therapies and Other Medication-Assisted Treatment for Tobacco Use Disorders *(continued)*			
Nicotine Replacement Therapy (First-Line)			
Medication	**Mechanism of Action**	**Dosing Recommendations**	**Notes**
Bupropion (Zyban®)	150 mg/day for 3 days, then increase to 150 mg q12 hours; continue for 7–12 weeks. For moderate to severe hepatic impairment, max dose recommended is 150 mg every other day.	Dry mouth, insomnia, agitation, headache, nausea/vomiting, constipation, tremor, dizziness, tachycardia, confusion, blurred vision, rash, auditory disturbances lowers seizure threshold. Boxed warning that antidepressants increase the risk compared to placebo of suicidal thinking in children/adolescents <24 years. Patients should stop bupropion and seek care immediately if they notice any changes in mood, behavior, or thinking.	Mechanism: dopamine/norepinephrine reuptake inhibitor Begin 1 week before target quit date. May be used in combination with nicotine patch. Consider maintenance therapy if successfully quit after 7–12 weeks. Use caution with mild hepatic impairment.
Varenicline (Chantix®)	Days 1–3: 0.5 mg once daily Days 4–7: 0.5 mg twice per day Day 8–end of treatment: 1 mg twice per day In patients who may not be able to quit smoking abruptly, consider gradual approach: reduce tobacco use by 50% from baseline within first four weeks, additional 50% in next four weeks, and continue reduction with goal of complete abstinence by 12 weeks. For severe renal impairment, max dose recommended is 0.5 mg daily.	Nausea/vomiting, dry mouth, indigestion, constipation, unusual dreams, insomnia, headache, unpleasant taste in mouth. Rare but serious adverse effects include chest pain, difficulty breathing, depression/suicidal thoughts, paranoia, and seizures. Boxed warning regarding serious neuropsychiatric effects was removed by the FDA based on EAGLES trial; however, patients should stop taking varenicline and seek care immediately if they notice any changes in mood, behavior, or thinking.	Mechanism: Nicotine partial agonist. No dosage adjustment necessary for patients with mild to moderate renal impairment. No dose adjustment for hepatic impairment.

For more information on treatment considerations in women of reproductive age with severe mental illness and substance use disorders, view the online *Florida Medicaid Best Practice Psychotherapeutic Medications Guidelines* at ***floridamedicaidmentalhealth.org***.

Treatment decisions during pregnancy should be as collaborative as possible between health care providers and patients, and take into account the individualized risks and benefits of treatment options. In addition to the reproductive safety of psychopharmacologic treatments, the past course of illness and treatment responses should be strongly considered. Specifically, the potential risks of medications must be assessed along with the risks of untreated psychiatric disorders across pregnancy and the postpartum. Decision making around treatments for psychiatric disorders in pregnancy requires consideration of what is known about the medications in pregnancy, the course and severity of the woman's disorder being treated, and exposures to the baby of both untreated maternal illness and medication. Psychiatric mood and anxiety symptom burden during pregnancy is a major risk factor for serious postpartum illness.

Women who do not desire a pregnancy should be counseled about their family planning options; highly effective methods such as the intrauterine device and contraceptive implant may be of particular benefit to women on teratogenic medications who are not trying to get pregnant. However, unplanned pregnancies are common, and the reproductive safety of treatments should be kept in consideration when treating women of reproductive potential. General recommendations for healthy pregnancies should be included in the treatment plan, as some elements are particularly relevant for individuals with mood disorders. These include getting regular exercise, abstaining from tobacco, alcohol, and illicit substances, and maintaining a healthy diet and weight.

For specific recommendations on the treatment of mood disorders in pregnancy, visit ***floridamedicaidmentalhealth.org***.

Treatment Goals and Management

- Optimal functioning of the mother, aiming for remission of illness, with a goal of achieving or maintaining euthymia, and relapse prevention and associated risks of morbidity and mortality, including risk of suicide.
- Managing risk of medication exposure to the infant.
- Individualized consideration of risk/benefit ratio for treatment options, realizing that untreated illness itself poses risks to the mother and baby.
- Wherever possible, multidisciplinary management involving the patient's obstetrician, mental health clinician, primary health care provider, and pediatrician is recommended to facilitate care.
- Prioritize medications that have worked for the mother in the past.
- Minimize polypharmacy, if possible, as multiple exposures may increase risk to the fetus.
- Maximize non-pharmacologic therapies if effective, either without pharmacotherapy or to augment pharmacotherapy (Psychotherapy is the most important effective non-medication treatment for mood disorders during pregnancy and the postpartum)

Table 15.

The Safety of Psychotherapeutic Medication in Pregnancy and Lactation			
Safety and Management Issues*			
Medication Class	**Pregnancy**	**Birth Defects and Other Neonatal Outcomes**	**Lactation****
Benzodiazepines	Ultrasonography for facial morphology	Possible increased incidence of cleft lip or palate Floppy infant syndrome Withdrawal syndrome	Infant sedation reported
SSRIs, SNRIs***, and tricyclic antidepressants	Decreased serum concentrations across pregnancy	No conclusive evidence of birth defects, with the exception of paroxetine Potential increased risk of congenital and cardiac defects in first trimester exposure to paroxetine[†] Prenatal antidepressant exposure syndrome	No conclusive evidence of adverse outcomes
Lithium	Ultrasonography, fetal echocardiography, or both for heart development Decreased serum concentrations across pregnancy Delivery - intravenous fluids; increased risk for lithium toxicity in mother	Increased incidence of cardiac malformations Increased risk for lithium toxicity in infant	Is incompatible with breastfeeding due to relatively high levels found in neonates, and multiple adverse event reports

Table 15. ***(continued)***

The Safety of Psychotherapeutic Medication in Pregnancy and Lactation *(continued)*			
Safety and Management Issues*			
Medication Class	**Pregnancy**	**Birth Defects and Other Neonatal Outcomes**	**Lactation****
Antiepileptic drugs	Decreased serum concentrations across pregnancy Folate supplementation and Vitamin K for some drugs	Valproic acid in the first trimester is associated with numerous neural tube defects and congenital malformations. Carbamazepine in the first trimester is associated with fetal carbamazepine syndrome – dysmorphic features and major malformations Neonatal symptoms Long-term adverse neurobehavioral outcomes	Carbamazepine has relatively higher levels in breast milk, with measurable levels in the infant
First and second generation antipsychotics	Avoid anticholinergic medications for side-effects	No conclusive evidence of birth defects Potential higher risk of preterm birth, low birthweight, and postnatal symptoms (e.g., jitteriness, somnolence)	Breastfeeding is not recommended for mothers on clozapine due to relatively high levels in breast milk that may affect the infant's complete blood count (CBC)

Note: SSRIs = Selective serotonin reuptake inhibitors; SNRIs = Serotonin–norepinephrine reuptake inhibitors.

**Many challenges exist in interpreting and evaluating evidence regarding adverse effects of psychotropic medication use during pregnancy. Key limitations include lack of well-conducted robust studies in pregnant women. Use of registry data and cohort designs has inherent flaws of lack of control for confounding variables such as psychiatric diagnoses, comorbid health conditions, obesity, tobacco use and use of alcohol and illicit substances.*

***Most medications can cross into breast milk but their levels vary. Formula feeding is an alternative that can allow the mother to use whichever medication works best for her.*

****Little is currently known about the safety of SNRIs, compared to SSRIs.*

†*Data also suggest that the risks of malformations associated with paroxetine use are inconsistent.*

Psychotherapeutic Medications Associated with Risks in Pregnancy

- Avoid benzodiazepines if possible, although the decision should be made on a case by case basis. There is inconsistent data suggesting that in the first trimester, there may be a small increased risk of oral clefts, and high doses in late pregnancy may be associated with a floppy infant syndrome at birth and withdrawal afterwards.
- Valproate exposure in pregnancy is associated with an increased risk of fetal anomalies, including neural tube defects, fetal valproate syndrome, and long-term adverse neurocognitive effects. It should be avoided in pregnancy, especially during the first trimester.
- Carbamazepine exposure in pregnancy is associated with fetal carbamazepine syndrome.
- It should be avoided during pregnancy, if possible, especially during the first trimester.
- Lithium exposure in pregnancy is associated with a small increase in a congenital cardiac malformation known as Epstein's anomaly. Risk of Ebstein's anomaly is estimated at 1/20,000 (0.005%) in the general population. The relative risk of developing Ebstein's anomaly has been estimated at 7.7 in patients exposed to lithium in utero compared to those not exposed to lithium in utero.
- Paroxetine use in pregnant women and women planning pregnancy should be avoided, if possible. Fetal echocardiography should be considered for women who are exposed to paroxetine in early pregnancy.

Note. The U.S. Food and Drug Administration's (FDA) new labeling is detailed in the Pregnancy and Lactation Labeling Rule (PLLR) or "final rule" at ***https://www.fda.gov/vaccines-blood-biologics/biologics-rules/pregnancy-and-lactation-labeling-final-rule****. The use of letter labeling (i.e., A, B, C, D, X) for pregnancy categories has been phased out by the FDA. This change was based on the major limitations of the letter category system.*

Psychotherapeutic Medications Use and Breastfeeding

The concentration of medication in breast milk depends on maternal drug plasma concentration, maternal pharmacogenomics, maternal plasma protein binding, size of the drug molecule, the degree of drug ionization, and the drug's lipid solubility. Risk of adverse effects on the baby during breastfeeding depends on the timing of the maternal dose, toxicity, oral bioavailability, volume of breast milk ingested, relative infant dose, and age of the infant. Breastfeeding an infant before the mother takes a medication dose results in the infant receiving the lowest possible drug concentration, but this principle does not apply to medications with a long half-life. Furthermore, premature babies and neonates have a lower ability to metabolize and excrete drugs. In infants who have been exposed to drugs in utero, exposure to drugs through breastmilk can augment these serum drug concentrations.

Most medications can cross into breast milk, but breast milk levels vary by medication. Recommendations regarding breastfeeding depend on the specific medications, known adverse effects, and assessment of benefits versus risks to both the mother and child. Generally, breastfeed babies should be monitored for unusual signs and symptoms (e.g., sleepiness, irritability, jaundice) if the mother is taking medications while breastfeeding.

Special Populations: Women of Childbearing Age *(continued)*

Psychotherapeutic medications found in relatively high concentrations in breastfed infants include lithium, carbamazepine, and clozapine. Although some sources state that lithium is contraindicated during pregnancy, other studies do not consider lithium an absolute contraindication to breastfeeding, particularly in babies over two months old with mothers on lithium monotherapy. In studies, most breastfed infants exposed to carbamazepine through breastmilk had no adverse reactions, but sedation, poor sucking, withdrawal, and three cases of hepatic dysfunction have been reported. Published reports have indicated sedation and adverse hematological effects in breastfeed infants of mothers taking clozapine. Because there is limited published experience with clozapine during breastfeeding, other medications are preferred.

For more information on treatment considerations in women of reproductive age, view the online Florida Medicaid Best Practice Psychotherapeutic Medications Guidelines at ***floridamedicaidmentalhealth.org***.

For updated data on medications during lactation and breastfeeding, visit the U.S. National Library of Medicine LactMed Database at: ***https://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm***.

Treatment guidelines are available on our Program website: floridamedicaidmentalhealth.org

- Monitoring Physical Health and Side-Effects of Psychotherapeutic Medications in Adults and Children: An Integrated Approach
- Best Practice Psychotherapeutic Medication Guidelines for Adults
- Autism Spectrum Disorder & Intellectual Developmental Disorder: Psychotherapeutic Medication Recommendations for Target Symptoms in Children and Adolescents
- Best Practice Recommendations for Women of Reproductive Age with Severe Mental Illness and Comorbid Substance Use Disorders
- Best Practice Psychotherapeutic Medication Guidelines for Children and Adolescents

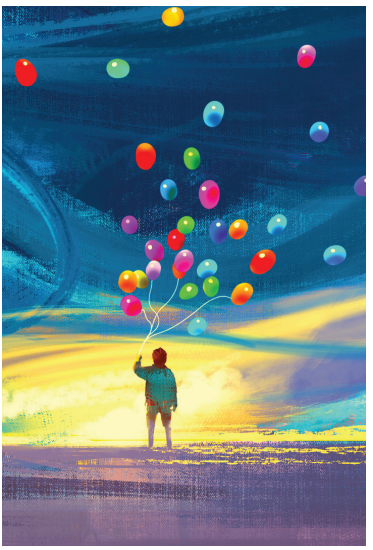
If you would like hard copies of the guidelines, please email sabrinasingh@usf.edu

Florida Pediatric Psychiatry Hotline

1-866-487-9507

No registration required.

The Florida Pediatric Psychiatry Hotline provides timely telephonic psychiatric and clinical guidance to primary care clinicians treating children with behavioral health conditions. The hotline enables primary care clinicians to get assistance for any child under their care and is highly rated by those using the service.



The Florida Pediatric Psychiatry Hotline is operated by the University of South Florida Division of Child and Adolescent Psychiatry and the Rothman Center for Neuropsychiatry in St. Petersburg, Florida. A team of board certified child psychiatrists from the University of South Florida oversee the hotline and provide many of the consultations.

The goals of the Pediatric Psychiatry Hotline are to:

- Provide consultation about psychotherapeutic medications for children with behavioral health conditions.
- Facilitate a referral to a child psychiatrist or psychiatric adanced practice registered nurse (APRN) when possible.
- Promote a collaborative relationship between primary care clinicians and child psychiatrists.

About the service:

- The hotline is free and related to consultation about medication management.
- Calls will be answered on non-holiday weekdays between 8:30 am and 4:30 pm.
- Most calls will be scheduled with a child psychiatrist within 1 to 4 hours.
- Telephone consultations are limited to 20 minutes per call.
- Only information relevant to medication management will be discussed. No patient names or other unique identifying information needs to be provided.

UNIVERSITY of SOUTH FLORIDA
College of Behavioral & Community Sciences
Florida Medicaid Drug Therapy
Management Program for Behavioral Health

AGENCY FOR HEALTH CARE ADMINISTRATION
STATE OF FLORIDA

floridamedicaidmentalhealth.org

The Florida Pediatric Psychiatry Hotline is funded by the Florida Medicaid Drug Therapy Management Program for Behavioral Health through a contract with the Florida Agency for Healthcare Administration.

Notes:

floridamedicaidmentalhealth.org

Please Visit Our Website to View:

Electronic versions of our guidelines can be downloaded in full or in part

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