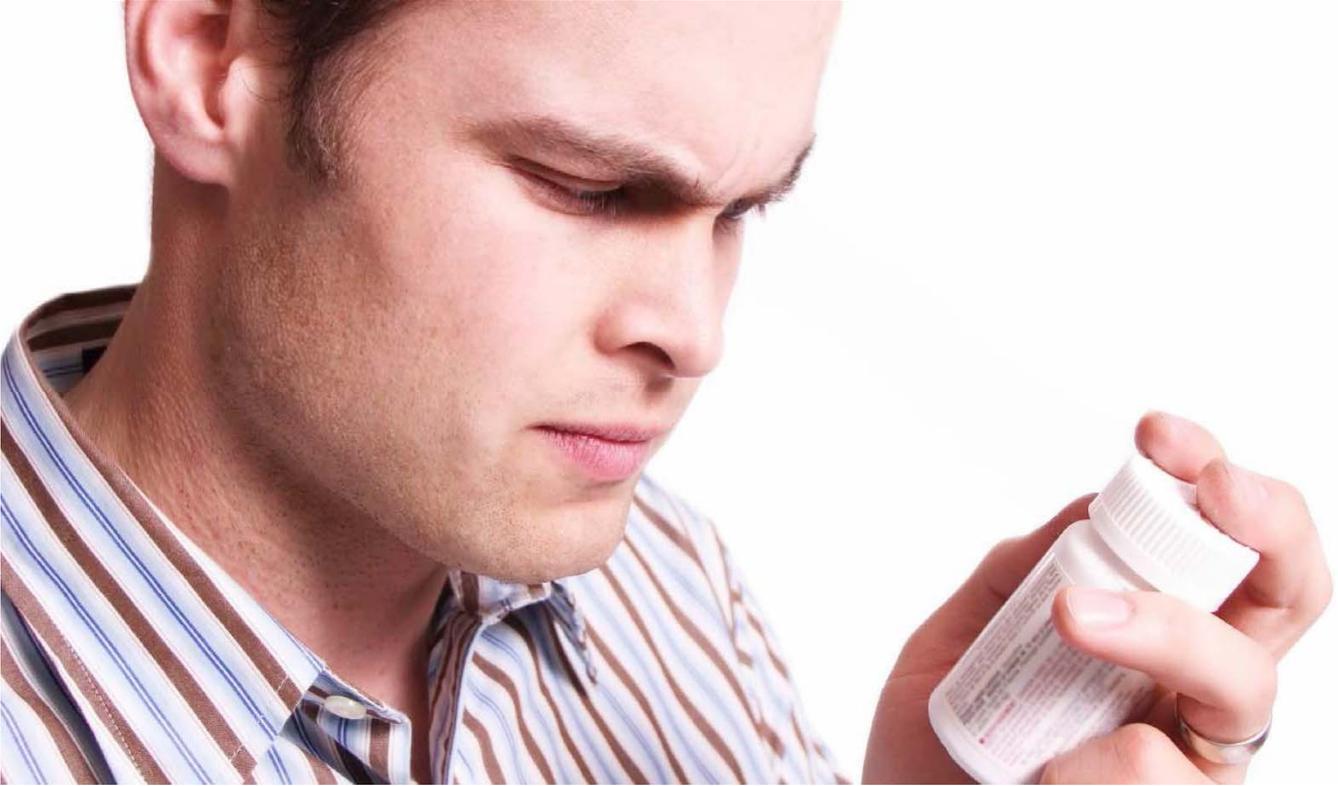


Medical Manual



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RAISE Connection Psychopharmacology Manual

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I. Medical Manual

This manual is designed to be a reference for psychiatrist and nurse prescribers and for nurses providing care through OnTrackNY. It summarizes our approach to the safe and effective use of antipsychotic medication and support of individuals' general health and wellbeing as they strive to achieve their goals. It includes guidelines for discussing and selecting antipsychotic medication, monitoring efficacy and side effects, managing related medical issues, and promoting overall wellness.

II. General Principles for Using Antipsychotic Medication in the Treatment of First Episode Psychoses

A. Antipsychotic Treatment of First Episode Psychosis

Antipsychotic agents are the mainstay of the pharmacological treatment of people diagnosed with schizophrenia. These medications are effective in reducing the positive symptoms of schizophrenia. Up to 80 percent of such individuals who take antipsychotic medications will have a clinically significant reduction of symptoms. For first episode psychosis, the efficacy of the different antipsychotic medications is similar but side effect profiles vary widely. People experiencing a first episode of schizophrenia are more likely to respond to lower doses and have an increased sensitivity to the adverse effects of antipsychotic medications.

Prescribers should select the antipsychotic medication with the side effects that are most benign and tolerable to the individual, at the lowest effective doses.

B. Shared Decision-Making

Shared decision-making is the central value shaping interactions between the clinician and the individual experiencing first episode psychosis. Clinicians provide detailed explanations of the risks and benefits of all appropriate and available medications, including detailed assessments of side effects and serious medical risks. Clinicians should help individuals identify and articulate their concerns about and goals for medication use. Educational materials should be made available to and reviewed with individuals and any involved caregivers. Clinicians should assess participants' interest in participating in medication decisions. While generally antipsychotic treatment decisions will be made jointly by the individual, the treating prescriber, and, if applicable, other caregivers, there may be situations where participants may prefer for the prescriber to make medication decisions. This should be reassessed over time. When participants do choose to participate in medication decisions, a decision-aid (such as the "Decisional Balance Worksheet") may help the individual clarify his/her values. Other handouts and modules that may be useful in discussing the use of antipsychotic medication with an individual are listed at the end of the manual.

C. Antipsychotic Polypharmacy and Use of Other Psychotropic Medication

A key principle is to keep medication regimens as simple as possible. Prescribe the smallest number of drugs with the fewest number of pills and simplest dosing to manage symptoms effectively.

Individuals may enter care with OnTrackNY already taking one or more psychotropic medications. This is common, although there is no strong empirical basis for combining antipsychotics or the adjunctive use of antidepressants, anti-anxiety agents, anti-epileptics or lithium. At the first meeting, the clinician should evaluate the continued need for all medications and review with the individual their risks and benefits. The final decision to continue each medication should be a shared decision based on the individual's preference, any evidence of clinical benefit, and related side effects.

If an individual presents with symptoms of anxiety, depression or mania, then an effort should be made to optimize the antipsychotic treatment and psychosocial supports. If treatment has been optimized then adjunctive pharmacologic treatment with an antidepressant, anti-anxiety or anti-epileptic agent, or lithium should be discussed with the individual.

D. Decision To Take No Medication

Antipsychotic medication treatment is not required for individuals to receive care through OnTrackNY. However, the risks and benefits of antipsychotic treatment versus no treatment should be discussed. Team members including the prescriber and nurse should work with individuals who decide not to take antipsychotics to develop a plan to monitor signs and symptoms and to regularly revisit the decision.

III. Selection of an Antipsychotic Medication

Because antipsychotics are similarly efficacious for first episode psychosis, side effect profiles are important determinants of drug choice. Key factors include the individual's previous experience, including whether side effects compromised adherence to previous treatment recommendations, relevant medical history, including the presence of medical risk factors, and long-term treatment planning. The six side effect domains listed below must be discussed for every medication. Other side effects especially associated with specific agents (e.g., clozapine and agranulocytosis) should also be discussed when reviewing those medications. (See the section "Side Effects of Antipsychotic Medication and Their Management.")

A. Recommended Medications

Some antipsychotic agents are preferable to others for use in individuals experiencing first episode psychoses. These have relatively benign side effect profiles when appropriately prescribed.

Side effect domains to be considered for all antipsychotics:

- Weight gain
- Other metabolic side effects (e.g., lipid and glucose dysregulation)

- Prolactin elevation and associated effects (including amenorrhea, galactorrhea and sexual dysfunction)
- Motor side effects (i.e., extra-pyramidal side effects (EPS) and tardive dyskinesia (TD))
- Anticholinergic side effects (e.g., dry mouth and constipation)
- Sedation

First-line oral medications: risperidone, aripiprazole, ziprasidone, loxapine, perphenazine

The recommended first-line treatments were chosen on the basis of previous studies in people with first episode schizophrenia and/or due to the medications' side effect profile (see Table 1).

Risperidone, ziprasidone, and aripiprazole have been studied in this population and are effective. Although loxapine and perphenazine have not been studied extensively in first episode schizophrenia, they are first-line treatments because they are both effective antipsychotic medications with relatively benign metabolic and motor symptom side effect profiles. All of the recommended first-line medications are now available as generics. Olanzapine is a recommended medication but is not considered a good first choice due to its high liability for weight gain and other metabolic adverse effects.

When first-line treatments provide inadequate help: clozapine

If distressing psychopathology and/or intolerable extrapyramidal symptoms persist after two adequate antipsychotic medication trials, the individual should be offered a trial of clozapine. (See "Inadequate Response to Treatment" below for more details.)

B. Long-acting Injectable Medication

Some individuals may prefer to be treated with a long-acting injectable antipsychotic medication (LAI) and in that case should be offered any of the available LAIs, as there are currently no data to suggest differential efficacy among these agents in people with either first episode or multi-episode schizophrenia. Long-acting haloperidol and fluphenazine are available as generics while olanzapine, risperidone, paliperidone, and aripiprazole are still branded and relatively costly. Some recent data suggest that long-acting injectable medication may reduce the risk of relapse. A webinar on the use of long-acting injectable medications in early psychosis is available on the OnTrackNY Learning Management System (LMS).

C. Medication Dosing

Given reports of increased efficacy and fewer side effects when lower doses are used in persons experiencing a first episode of psychosis, prescribers should aim to stay within the lower half of the dose range recommended for the acute and maintenance treatment of people with schizophrenia.

D. Starting Antipsychotic Medication

Because individuals with a first episode may be particularly responsive to antipsychotic medication and sensitive to side effects, antipsychotic medications should be started at a low dose and titrated as

indicated, with the goal of using the lowest effective dose. Individuals may enter treatment with OnTrackNY already taking one or more antipsychotic medications as well as non-antipsychotic psychotropic medications. The prescriber should evaluate the continued need for such medications and review the associated risks and benefits with the individual for all medications initiated. If the individual is currently receiving an antipsychotic medication that is not a recommended medication, then response and side effects should be scrutinized to determine whether a change in either dose or agent is advisable. An individual who has had a good response with minimal side effects from a medication should not be switched.

IV. Inadequate Response to Antipsychotic Treatment

A major therapeutic challenge is what to do when someone has had an inadequate response to antipsychotic treatment. Substance use and medication non-adherence may complicate the response to treatment and should be ruled out before concluding that a treatment has failed. If after 4 weeks on an adequate dose of antipsychotic medication the individual continues to be distressed by symptoms or by associated side effects despite using strategies to alleviate them and/or the treating prescriber observes that an adequate symptom response has not been achieved, the prescriber should discuss a change in antipsychotic treatment with the individual (and caregivers, when appropriate). Although people with first episode psychosis are more likely to respond to antipsychotic medication than people with multi-episode schizophrenia, a significant number will have persistent positive symptoms, exhibit violent or suicidal behaviors, or have their response to treatment compromised by co-occurring alcohol and substance abuse/dependence.

A. Clozapine

If an individual has had two adequate trials of antipsychotic medication and continues to suffer from the symptoms and behaviors above, the prescriber should offer clozapine. In addition, after two such trials, any individual suffering from intolerable side effects that might be relieved by changing to clozapine (e.g., EPS/TD) should be offered a trial of clozapine. To avoid an unnecessarily lengthy period of symptomatic and poor functioning, clozapine should be considered by no later than 1 YEAR into treatment for individuals with inadequate response, and likely earlier. The New York State Office of Mental Health has developed a number of resources to support the appropriate use of clozapine including a clinical manual and educational module for individuals about clozapine entitled "Considering Clozapine" which is readily accessible online. (See "Additional Resources" for more information.)

B. Co-morbid Substance Use

Clinicians should ask about substance use at every visit and consider its possible role in cases of medication inconsistency or poor response to treatment with antipsychotic medication. The OnTrackNY team should address the need to incorporate ongoing substance use as an issue during treatment planning.

C. Medication Inconsistency

In cases of inadequate response to antipsychotic treatment, clinicians should identify whether medication inconsistency may be contributing to poor response. Anywhere from 30 - 60% of individuals will be inconsistent with medication or stop medication altogether. Side effects, incomplete understanding of the illness, substance use/abuse, and actual or perceived lack of efficacy are among the factors that can contribute to medication inconsistency. Medication inconsistency can lead to inadequate symptom control, which then may compromise the ability of the person to adequately engage in treatment. If an individual is ambivalent about using antipsychotic medication, the handout "Finding Personal Motivation to Use Medication" may allow them to identify how antipsychotic medication can help them to realize their own goals.

Clinicians should seek to uncover and address the possible causes of problems with medication consistency. Cognitive-behavioral and motivational techniques can address beliefs and attitudes about illness and the role of medication and the risks and benefits of antipsychotic treatment. Clinicians should engage individuals in identifying concrete and contextually tailored strategies to support adherence (e.g., pillboxes or family support).

Long-acting injectable antipsychotics (LAIs) are a potential pharmacological approach that may enhance adherence and provide support for the continued involvement of the person with OnTrackNY.

V. Maintenance Treatment and Discontinuation

Even in individuals with good symptomatic response to antipsychotic treatment, the rate of relapse is high. Many research trials have demonstrated that relapse is much more likely for people who discontinue antipsychotic medications than for those who continue them. Continued treatment has been associated with better functioning and less hospitalization. Discontinuation of antipsychotic medication is therefore not recommended. Although some people who recover from a first episode of psychosis will not have a recurrence, we are unable to identify these individuals in advance. Efforts to support continued antipsychotic treatment, including understanding how medications may facilitate the accomplishment of recovery goals, should be a major focus of our interventions. For individuals who have had good symptomatic response and avoided recurrent hospitalization, prescribers may consider lowering the dose to minimize any potential negative effects of long-term antipsychotic exposure.

The prospect of lifelong medication treatment may be overwhelming to someone with a new diagnosis of schizophrenia or a related disorder. It is therefore essential to present the need for ongoing medication treatment in a manner that does not promote an idea of chronicity or end up impeding recovery, but is instead integrated with and phrased in terms of the overall recovery goals of the individual.

For individuals who are considering whether to continue on antipsychotic medication, change medication, or discontinue antipsychotic medication, the Option Grid decision aide may be helpful in outlining these options. This grid, from The Dartmouth Institute for Health Policy and Clinical Practice, can be accessed at: <http://optiongrid.org/option-grids/grid-landing/64>.

VI. Side Effects of Antipsychotic Medication and Their Management

A. Summary

One of the main obstacles to long-term antipsychotic treatment is the adverse effects associated with their use. These side effects may include: 1) weight gain; 2) other metabolic side effects (e.g., lipid and glucose dysregulation); 3) prolactin elevation and associated effects, including amenorrhea, galactorrhea and sexual dysfunction; 4) motor side effects (i.e., extra-pyramidal symptoms (EPS) and tardive dyskinesia (TD)); and 5) sedation. Table 1 provides a comparison of all of the currently marketed antipsychotic medications in each of these side effect domains.

The goal should be prevention of side effects where possible by using the lowest effective dose, prophylaxis for side effects where indicated, and early treatment of side effects where not.

B. Weight Gain and Metabolic Side Effects

Antipsychotic medications vary in their propensities to produce weight gain, insulin resistance, and dyslipidemias. Weight gain is a significant side effect of antipsychotic treatment that should be addressed early, if possible even before it has occurred, and tracked carefully at each visit. Graphic means of tracking such as a weight chart easily allow clinicians and individuals to keep focused on incremental weight gain. It is preferable to prevent weight gain rather than to attempt weight reduction later on.

The second-line agent olanzapine and third-line agent clozapine both produce substantially more weight gain and metabolic abnormalities than do the first-line agents.

In individuals who do not respond adequately to first line agents and who must be treated with olanzapine or clozapine to reduce psychopathology, or for individuals taking first-line agents for whom weight gain is a significant concern (e.g., those who are already overweight, have diabetes, or report increased appetite and initial weight gain after beginning treatment), attempts should be made to prevent weight gain. Psychosocial and pharmacological interventions are available.

Psychosocial approaches for preventing weight gain or achieving weight loss (education and support for a sensible diet and exercise) have produced modest benefits in research settings, but organized programs are not commonly available in routine clinical settings. Clinicians should carefully chart weight at each visit, provide basic dietary information (e.g., weight is more related to total caloric intake than to the type of food eaten) and reasonable suggestions such as the avoidance of fried food, and sugared sodas or teas. Aerobic exercise reduces cardiovascular risk irrespective of weight change; it burns calories, affects lipids, and reduces insulin resistance and inflammation. Even walking several miles daily has substantial beneficial effects. Useful clinical resources for working with individuals struggling with weight gain and other metabolic problems are listed in the Resources section of this manual under "Management of Metabolic Problems."

Metformin has been shown to reduce weight gain and to reduce insulin resistance. In young, otherwise healthy individuals with normal renal function, metformin has minimal risk. It is administered twice daily with breakfast and dinner, starting at 250 mg BID and gradually increased as tolerated to 1000 mg BID. The most common reason individuals stop metformin is gastrointestinal distress; this can be minimized by starting at a low dose, titrating slowly, and taking the medication with food. Rare complications from metformin include hypoglycemia and lactic acidosis.

C. EPS

All medications that have dopamine D2- receptor antagonist properties carry the risk of extrapyramidal side effects (EPS). Among our recommended first-line treatments, loxapine, perphenazine, and risperidone have the highest risk of EPS. The treating prescriber should keep in mind the following broad guidelines:

The risk of acute dystonia is greatest in young males taking high potency FGAs. Dystonic reactions typically occur hours or days after initiation of treatment or a marked dose increase. Prophylactic administration of anticholinergic agents (e.g., benztropine, trihexyphenidyl) can be considered for individuals at high risk or who have had prior dystonic reactions. Clinicians should educate individuals about the recognition and need for immediate treatment of acute dystonias.

Akathisia is also common with high potency FGAs and is a major cause of treatment non-adherence. Benzodiazepines, benztropine, and propranolol may be effective treatments for akathisia. Propranolol is often effective, at starting doses of 10-20 mg/day and transitioning to long-acting once daily versions (starting at 80 mg/day).

Pseudo-parkinsonism may be managed by lowering the dose of antipsychotic medication. The syndrome includes bradykinesia, tremors, and muscle rigidity. It can also include a flat or constricted affect, and pseudo-parkinsonism is a common cause of secondary negative symptoms. If these side effects cannot be controlled by lowering the dose or switching to a different antipsychotic medication, supplemental use of anticholinergic or dopamine agonist agents (e.g., amantadine) should be considered.

Prevention of tardive dyskinesia (TD) is a priority. TD includes involuntary choreoathetotic movements typically involving the lips, tongue, jaw, face, or extremities. Although TD may be reversible in many cases, TD is permanent in up to 50% of individuals. Incidence rates of TD vary, with one study finding a yearly risk of 5.5% with FGAs and 3.9% with SGAs. The risk of TD increases with cumulative lifetime exposure to antipsychotic medications and is a major reason to always use the lowest effective antipsychotic dose. All individuals taking antipsychotic medications should be monitored at least every 3 months for TD using the Abnormal Involuntary Movement Scale (AIMS) and the Simpson-Angus Extrapyramidal Side Effects Scale (or another standardized scale, such as the Extrapyramidal Symptom Rating Scale or Barnes Akathisia Rating scale).

D. Other Side Effects

1. Prolactin Elevation and Secondary Sexual Side Effects

Antipsychotic drugs may elevate prolactin levels and cause secondary sexual side effects. There are two major approaches for the treatment of prolactin elevation: 1) switching from a prolactin-raising antipsychotic to a prolactin-sparing antipsychotic (See Table 1, “Side Effects of Antipsychotic Medications” for comparisons); and 2) using an adjunctive pharmacological treatment to mitigate these side effects.

Antipsychotic medications with less potent D2 antagonism are less likely to cause prolactin elevation than those that are potent D2 antagonists. The major concern associated with switching is the possibility of clinical destabilization and symptom exacerbation. People who change medications should be monitored closely during the cross-titration period and for up to four weeks after the completion of the medication switch.

The other approach for the treatment of prolactin elevation is adjunctive medication treatment. A number of adjunctive agents have been used, including dopamine agonists (e.g., amantadine). An alternative approach is the use of adjunctive aripiprazole for the treatment of prolactin elevation. This approach takes advantage of the partial agonist properties of aripiprazole and minimizes the risk of symptom exacerbation, which may occur with switching.

2. Clozapine-Associated Side Effects

Raja (2011) (see “Selected Sources”) is a comprehensive review of the estimated prevalence of the side effects of clozapine, including several that are relatively unique to this agent (e.g., hypersalivation, myocarditis, seizures) and recommendations for monitoring and managing these side effects. In addition, the New York State Office of Mental Health has developed a clinical manual for the use of clozapine which is readily available on the OnTrackNY Learning Management System (LMS).

3. Other Side Effects

Patients may also report other side effects, including sedation, cognitive side effects, anticholinergic effects, and sexual side effects. These are important to ask about as they can affect patients’ quality of life and can be a major factor in patients’ decisions regarding whether to take medication. Sedation can be minimized with nighttime dosing and medication choice. Cognitive side effects due to medication may be difficult to distinguish from cognitive effects due to illness. It is important to educate patients that psychotic illnesses themselves can cause cognitive symptoms. Though little is known regarding how to minimize cognitive side effects due to medication, options to consider may be dose adjustments or considering a medication switch if cognitive side effects are significant.

Anticholinergic effects can be managed by adjusting the dose, selecting a medication with less anticholinergic effect, encouraging hydration, using sugar free sucking candies for dry mouth,

recommending diet changes or prescribing stool softeners or laxatives if needed for constipation. Sexual side effects may be managed by dose adjustment, medication choice, consideration of 1-day drug holidays if appropriate (although this may increase the risk of symptom recurrence), or consideration of use of adjunctive medication (e.g. sildenafil for erectile dysfunction).

VII. Monitoring Side Effects, Response to Treatment, and Adherence

A. Summary

Close monitoring of therapeutic response, occurrence of side effects, and adherence is especially crucial during the early course of treatment. First, there is now increased recognition that if an individual is going to respond to a particular antipsychotic medication, then she/he will exhibit signs of response within the first two weeks. A lack of response within the first two weeks may indicate that the person is not responsive to the current antipsychotic medication, the current dose is not effective, and/or there are problems with adherence to the prescribed medication. Second, although the recommended antipsychotic medications have relatively favorable side effect profiles, there is individual variability in sensitivity to medications. The early detection and management of side effects increases the likelihood that the side effect will not progress in severity and that an effective, trusting relationship will develop between the individual and the treatment team. This may, in turn, facilitate communication around medication issues and adherence with prescribed medications. Third, partial or complete non-adherence to antipsychotic treatment may stem from lack of treatment response or side effects, and can increase the risk of symptom relapse, seriously undermining an individual's likelihood of achieving recovery.

B. Monitoring Side Effects

Laboratory and vital sign measures must be used to monitor weight gain and the development of metabolic abnormalities. Prior to the start of antipsychotic treatment, baseline vital signs (i.e., weight and blood pressure) as well as laboratory values of glycosylated hemoglobin (HgA1c) and fasting lipid panel should be obtained. Thereafter, vital signs should be collected monthly. The laboratory tests should be performed 2 months after the initiation of antipsychotic treatment and then annually, with the assessment schedule repeated each time a new antipsychotic is started. If medically indicated, vital signs and laboratory measures may be collected more frequently. Other measures, including a CBC with differential or EKG, should only be obtained if clinically indicated (e.g., if the client is being considered for a trial of clozapine). All individuals taking antipsychotic medications should be monitored at least every 3 months for EPS/TD using the Abnormal Involuntary Movement Scale (AIMS) and Simpson-Angus Extrapyramidal Side Effects Scale (or other standardized rating scale). In addition, all individuals should be asked about changes in sexual functioning.

The medical staff (nurse and prescriber) should work together to ensure that all monitoring is occurring on schedule and that vital signs and lab results are reviewed in a timely fashion. This will be of particular importance in the case of clozapine, especially during initial titration, where coordination requires that nursing ensure the pharmacy in use is registered with the Clozapine Registry and able to dispense clozapine.

The prescriber should evaluate the individual's subjective medication side effects at each visit. In particular, the individual should be asked if she/he has any concerns that the medication has interfered with her/his ability to function and/or achieve goals: e.g., has he/she noticed any emotional dulling, clouded thinking, or problems with daytime sedation. If applicable, individuals' family members should also be asked to report any additional side effects that they have noticed.

The "Medication Side Effects Checklist" can be completed monthly during the first three months on any antipsychotic and quarterly thereafter. Individuals can complete the checklist prior to the visit or together with the clinicians.

C. Monitoring Response to Antipsychotic Treatment

Individuals receiving care through OnTrackNY should be seen on a regular basis by the prescriber for medication management.

Clinicians should monitor the individual's response to antipsychotic medication intensively and continuously during the first month of treatment. The response of the individual to antipsychotic medication should be intensively and continuously monitored by all team members, but especially the medical team, during the first month of treatment—at minimum twice a month but preferably weekly—to monitor symptom response and the occurrence of bothersome side effects. If the individual is responsive to the medication and experiencing minimal side effects, then the frequency of contact with the prescriber can be decreased to every two weeks through the first six months. Thereafter, the prescriber should evaluate the individual on a monthly basis. This recommended frequency of contact should be considered a guideline to be modified on a case-by-case basis to reflect each individual's clinical need or other life circumstances. Individuals can review the handout "Preparing to Talk about Symptoms" before their visits with the team to help them articulate how their treatment is affecting their symptoms and functioning.

If after 4 weeks on an adequate dose of antipsychotic medication an individual continues to be distressed by symptoms or by associated side effects despite using strategies to alleviate them and/or the prescriber observes that an adequate symptom response has not been achieved, clinicians should initiate a discussion with the individual (and caregivers, when appropriate) regarding a change in antipsychotic treatment. If there are any changes to medications, then the prescriber should continue to see the individual on a weekly basis until she/he has stabilized on the new medication regimen.

D. Other Health Issues

1. Initial Work-up

Clinicians must ensure that individuals entering treatment with OnTrackNY have had a complete medical work-up to exclude medical causes of psychosis and establish a medical baseline.

Freudenreich and colleagues (2009) (see "Selected Sources") suggest the elements of such a screening for first episode psychosis. An atypical presentation of psychosis, presence of neurologic signs or

symptoms, or a co-occurring medical illness that can be associated with psychosis should prompt a more extensive medical workup.

2. Pregnancy

Clinicians should ask women considering medication about sexual activity, birth control use and last menstrual period. Clinicians should help facilitate access to birth control for women who do not wish to become pregnant (e.g. referral to OB/Gyn or family planning clinic for discussion of contraceptive options and/or provision of condoms). If it is possible that a woman may be pregnant, clinicians should order a pregnancy test. For individuals entering treatment who are pregnant, become pregnant, or are considering pregnancy, clinicians should discuss the risks and benefits of specific medications in pregnancy, as well as the risks and benefits of coming off or staying off of medications in pregnancy. Recommendations regarding medication treatment should be made based on the individual's symptoms, individual circumstances, and needs and preferences.

3. Coordination of Medical Care

Given clinicians' close tracking of individuals' physical health through side effect monitoring, the medical team is well placed to attend to individuals' general health issues, whether or not they are related to the use of antipsychotic medication. Nurses should make referrals to and liaise with primary or other specialty health care providers including general medicine, pediatrics, and OB/GYN as needed. The nurse will often play a key role in coordinating care, including assisting with referrals and appointment scheduling, facilitating communication, and sharing or requesting relevant records and lab results. While we recommend that all individuals receiving care through OnTrackNY have a primary health care provider, this is essential for individuals on clozapine, and care should ideally be established with a primary medical doctor prior to initiating clozapine.

4. Smoking

Smoking is extremely common in individuals with schizophrenia (70-80% by some estimates). It is unclear whether individuals experiencing first episode psychoses are as likely to smoke. However, the morbidity and mortality associated with smoking has been amply established. The OnTrackNY medical team should **ASK** about smoking, **ASSESS** all individuals' smoking habits and desire to quit, **ADVISE** quitting, **ASSIST** in developing a cessation plan (e.g., referrals to a quit line or primary medical provider, prescriptions for nicotine replacement therapy and/or bupropion, encouraging the setting of a quit date) and **ARRANGE** to follow-up about smoking at subsequent visits.

5. Obesity

Whether or not obesity results from treatment with antipsychotic medication, the OnTrackNY medical team should address this condition, as it raises the individual's risk for a number of serious medical conditions, as well as premature death. (See the recommendations above for "Weight gain and metabolic

side effects” in the section entitled “Side Effects of Antipsychotic Medication and Their Management” and resources under “Management of Metabolic Problems” at the end of this manual.)

VIII. Health Education

The nurse (or other personnel) will deliver one Core Session on physical health, “Maintaining/improving my physical health.” The material in the Core Session should be reviewed on a regular basis (e.g., when meeting with the nurse for vital signs or lab draws, during scheduled sessions with the nurse as needed, or by other members of the team). See appendix D for an outline of the core session. Ongoing education on health and wellness issues may be provided individually and/or in a group format and may cover such topics as exercise, nutrition, smoking cessation, sexual health, or other relevant topics. Nurses are encouraged to provide health information, elicit client’s goals and preferences, and to support individuals in making concrete changes to improve their physical health and wellness. Appendix E has some additional resources from the Wellness Self-Management Workbook that may be helpful. Education on physical health and wellness may be provided in individual and/or group formats and may include an experiential component (e.g. visit to a grocery store to discuss healthy food choices, visit to a local gym to sign up, cooking demonstration, etc.). Nurses or other team members may also provide health and wellness information through putting written materials (e.g. brochures, posters) on these issues in the waiting area and/or team office.

IX. Appendix

Table 1: Comparison of Side Effects of Antipsychotic Medications

Side Effect						
Antipsychotic Medication	Weight Gain	Metabolic Risk	Extra-pyramidal Side Effects and Tardive Dyskinesia	Hyper-prolactinemia	Anticholinergic Effects	Sedation
First-generation Antipsychotic (FGA) Medications						
High Potency						
Haloperidol (oral)	+	+	+++	+++	+	+
Haloperidol (LAI)	+	+	+++	+++	+	+
Fluphenazine (oral)	+	+	+++	+++	+	++
Fluphenazine (LAI)	+	+	+++	+++	+	++
Pimozide	-/+	+	+++	+++	+	++
Thiothixene	++	++	+++	++	+	++
Trifluoperazine	++	++	+++	++	+	+
Medium Potency						
Loxapine	++	++	++	++	+	+++
Perphenazine	++	++	++	++	+	++
Low Potency						
Chlorpromazine	+++	+++	+	++	++	+++
Thioridazine	+++	+++	+	++	+++	+++
Second-Generation Antipsychotic (SGA) Medications						
Asenapine	++	++	+	+	-	++
Aripiprazole	-	-	+	-	-/+	-/+
Clozapine	+++	+++	-	-	+++	+++
Iloperidone	++	++	+	+	-	++
Lurasidone	+	+	+	+	+	+
Olanzapine	+++	+++	+	+	++	+++
Paliperidone (oral)	++	++	++	++++	-/+	+
Paliperidone (LAI)	++	++	++	++++	-/+	+
Quetiapine	++	++	-	-	+	+++
Risperidone (oral)	++	++	++	++++	-/+	+

Risperidone (LAI)	++	++	++	+++++	-/+	+
Ziprasidone	-	-	+	+	+	+

Table 2: Sample Monitoring and Visit Schedule after Starting Antipsychotic Medication

	Start	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	7	8	9	10	11	12
Vital Signs	X				X				X				X				X				X				X					X	
Labs	X							X					X																	X	
EPS scale (e.g. AIMS)	X ²	X			X			X				X					X				X				X				X		
Side effect monitoring					X			X				X					X				X				X				X		
Medication Management Visit	X	X	X	X	X		X		X		X		X		X		X		X		X		X		X		X		X		

6 Months



A. Suggested OnTrackNY Handouts (CPI Learning Management System (LMS]):

- Medication Side Effect Checklist
- Finding Personal Motivation to Use Medication
- Psychiatric Medicine and Me
- Preparing to Talk About Symptoms
- Surviving Stress
- Improving Concentration
- Decisional Balance Worksheet

1. Selected Sources (CPI LMS):

American Diabetes Association. (2004). "Consensus development conference on antipsychotic drugs and obesity and diabetes." *Diabetes Care* 27(2): 596-601.

Buchanan, R. W., et al. (2010). "The 2009 schizophrenia PORT psychopharmacological treatment recommendations and summary statements." *Schizophr Bull* 36(1): 71-93.

Freudenreich, O., et al. (2009). "Initial medical work-up of first-episode psychosis: a conceptual review." *Early Interv Psychiatry* 3(1): 10-18.

Marder, S. R., et al. (2004). "Physical health monitoring of patients with schizophrenia." *Am J Psychiatry* 161(8): 1334-1349.

2. Other Required Reading (CPI LMS):

Team Manual

3. Other Prescribing Resources:

Lieberman, J. A., et al. (2012). *Essentials of schizophrenia*. Washington, DC, American Psychiatric Pub.
Raja, M. (2011). "Clozapine safety, 35 years later." *Curr Drug Saf* 6(3): 164-184.

New York State Office of Mental Health, Office of the Medical Director. *Clozapine: A Manual for Clinicians*, May 2012

4. Management of Metabolic Problems (CPI LMS):

"Individual Behavioral Treatment for the Management of Metabolic Problems in Patients with Schizophrenia" (Handbook & Clinician's Manual), adapted from *A Behavioral Group-based Treatment for Weight Reduction in Schizophrenia and Other Severe Mental Illnesses*, Rohan Ganguli, Jaspreet Singh Brar, University of Pittsburgh School of Medicine.

“Wellness Self-Management,” Center for Practice Innovations: workbook, available in English, Spanish, Chinese, and Korean. (Lessons from the curriculum that are particularly relevant to the integration of physical and mental health—50 & 51-- are included at the end of this manual).

5. Modules (CPI LMS):

“Considering Clozapine”: consumer educational module, freely accessible online at the website of the Center for Practice Innovations, <http://practiceinnovations.org/>

“Motivating Clozapine Use”: module for prescribers on engaging people in conversations about clozapine.

Suicide Prevention: Assessment of Suicidal Risk Using C-SSRS and Safety Planning Intervention for Suicide Prevention

Focus on Integrated Treatment: Substance Abuse Treatment

Wellness Self-Management

6. Recovery Videos on Themes Particularly Relevant to Prescribers (CPI LMS):

1. Corey: Tools for Getting Better (dealing with side effects, how medication helps me, how my family/friends support recovery)
2. Raquea: Finding What Works (handling stigma, dealing with side effects, how medication helps me)
3. Sherri: Learning What Helps (working with my psychiatrist, side effects, how medication helps)
4. Tina: Living my Everyday Life (how medication works with me)
5. Tina: Making Yourself Heard (shared decision-making)
6. Patrick: Getting Active (dealing with side effects)
7. William: Managing my Recovery (medication treatment)
8. Barbara: When my Son Became Ill (son’s illness, medication treatment)

7. Webinars

1. OnTrackNY Webinar on Long Acting Injectable Medications
2. Medication Treatments for Substance Use Disorders: An Overview

8. Other Videos (CPI LMS):

1. Shared Decision Making Series
2. Spirit of OnTrack Series
3. Pat Deegan’s Introduction to First Episode Psychosis

B. Simpson-Angus Extrapyramidal Symptom Rating

1. Gait

Instructions for rating gait: The patient is examined as he walks in to the examining room, his gait, the swing of his arms, his general posture. All form the basis for an overall score for this item. This is rated using the scale below.

- 1 Normal
- 2 Diminution in swing while the patient is walking
- 3 Marked diminution in swing with obvious rigidity in the arm
- 4 Stiff gait with arms held rigidly before the abdomen
- 5 Stopped shuffling gait with propulsion and retropulsion
- 9 Not ratable

2. Tremor

Instructions for rating tremor: The patient is observed walking into the room and is then reexamined for this item.

- 1 Normal
- 2 Mild finger tremor, obvious to sight and touch
- 3 Tremor of hand or arm occurring spasmodically
- 4 Persistent tremor of one or more limbs
- 5 Whole body tremor
- 9 Not ratable

3. Akathisia

Instructions for rating akathisia: Patient is observed for restlessness. If restlessness is noted, ask: "Do you feel restless or jittery inside? Is it difficult to sit still?" Subjective response is not necessary for scoring but patient report can help make the assessment.

- 1 No restlessness reported or observed
- 2 Mild restlessness observed (e.g., occasional jiggling of the foot occurs when patient is seated)
- 3 Moderate restlessness observed (e.g., on several occasions, jiggles foot, crosses or uncrosses legs or twists a part of the body)
- 4 Restlessness is frequently observed (e.g., the foot or legs moving most of the time)
- 5 Restlessness persistently observed (e.g., patient cannot sit still, may get up and walk)

C. OnTrackNY Medication Side Effect Checklist

Name/ID _____

Date form completed _____

Below is a list of common medication side effects. If you are experiencing any of these side effects, it's important to let your doctor know. Often your doctor will be able to help minimize or eliminate the side effect. It's okay to speak up about side effects! In the list below, put a check next to any side effects you may be experiencing. Add any questions you may have for the doctor.

Problem	Are you experiencing this problem?		Questions for your psychiatrist
	Yes	No	
Daytime sedation/drowsiness/sleeping too much			
Problems with memory or concentration			
Changes in appetite or weight			
Muscles being too tense or stiff, or muscles trembling or shaking			
Feeling restless, jittery, or the need to move around and pace			
Blurry vision, dry mouth, constipation, or urinary retention or hesitancy			
Changes in sexual functioning			
[In women only], menstrual or breast problems			
Feeling unlike my usual self			
Other concerns			
	Yes	No	Questions for your psychiatrist
I think the pros of using medication outweigh the cons of using medication			

D. Core Session with Nurse: Maintaining/Improving My Physical Health

1. Introduction to Meeting and Rationale

The purpose of this meeting is to talk about the importance of physical health and how it is connected to a person's mental health and recovery. The material in this session can be reviewed on a regular basis.

2. What is a Healthy Lifestyle and Why is it Important?

Nurse asks consumer her/his thoughts about what healthy lifestyle means and why it would be important.

Nurse notes that a healthy lifestyle refers to making choices and taking actions that keep you physically and mentally fit. A healthy lifestyle can prevent or improve serious health problems. It includes:

- Getting regular medical check ups
- Managing current physical health problems
- Finding ways to relax and have fun
- Maintaining good personal hygiene
- Exercising regularly
- Eating healthy foods
- Getting a good night's sleep
- Avoiding unhealthy activities such as drinking, smoking, using street drugs, and unsafe sex

Nurse notes that there are benefits to a healthy lifestyle. They include:

- People can improve their physical health in ways that support their mental health recovery
- Poor physical health takes energy away from activities that support recovery
- Good physical health helps you to better manage stress and other life problems

Nurse asks consumer about his/her lifestyle and how healthy he/she feels that it is. Nurse asks consumer whether he/she would be interested in making changes to make it healthier.

3. The Issue of Tobacco Smoking

Nurse asks the consumer if he/she smokes tobacco or uses tobacco in another way. If yes, Nurse asks consumer whether he/she is aware of the medical consequences. Nurse provides brief overview of these consequences and asks consumer about desire to cut back or stop tobacco use as a possible goal.

4. The Importance of Exercise

Nurse asks the consumer if he/she exercises on a regular basis and if so, how. Nurse asks consumer if he/she is aware of the medical and mental health benefits of exercise. Nurse provides brief overview of these consequences and asks consumer about desire to increase physical exercise as a possible goal.

5. Summary of Today's Meeting

Nurse asks the consumer to identify some important points from today's meeting. Nurse adds his/her perspective to this summary.

E. Resources for Health Education

The following 2 resources on exercise and healthy eating are taken from the Wellness Self-Management Workbook. The full workbook can be found on the LMS.

1. Exercise and Mental Health Recovery

EXERCISE AND MENTAL HEALTH RECOVERY	
<p>Exercise and mental health Exercise is good for your physical health. Exercise may help prevent or improve a number of physical health problems, such as diabetes, high blood pressure, and heart disease. Recently it has been found that exercise is also good for improving mental health. Physical activity can ease symptoms or anxiety and depression along with improving mood.</p> <p>How can exercise make you feel better?</p> <ul style="list-style-type: none"> • After exercising, mood is elevated • Exercising is a healthy distraction from life stressors • Exercising gives you more energy <p>Benefits of exercising</p> <ul style="list-style-type: none"> • Anxiety symptoms decreased • Stress decreased • Depression symptoms decreased • Elevated mood • Self-esteem improved • Increased feelings of physical and psychological well-being • Restful sleep <p>Inexpensive ways to exercise Gyms can sometimes be costly and time consuming. There are other methods of exercising that do not involve going to a gym:</p> <ul style="list-style-type: none"> • Lifting heavy household products, such as bottles or cans • Doing housework 	<ul style="list-style-type: none"> • Taking a walk in your neighborhood • Taking stairs instead of elevators • Getting off the bus or subway one stop early and walking the rest of the way • Dancing • Swimming • Playing sports • Yoga • Aerobics • Running • Riding a bike • Participating in an exercise program on TV • A job that involves physical labor <p>Getting Started Before you start exercising, it is important to get your doctor's ok. Sometimes getting started is the hardest step. It is important not to think of exercise as a chore. Here are a couple tips if you are having trouble getting started:</p> <ul style="list-style-type: none"> • Start slowly • Do something that is enjoyable for you; make exercising fun • Join a team • Exercise with a friend • Exercise by doing various activities - don't always do the same activity • Give yourself credit for every step in the right direction no matter how small • Don't give up if you get off hand

Discussion Points:

Honestly how do you feel about exercising?

What makes it hard for people to make exercise part of their day-to-day routine?

Personalized Worksheet Thinking more about ways to exercise		
Simple and practical ways to exercise. <i>Please read the following worksheet and check those that apply to you:</i>		
Ways to exercise	I already do this	I would like to do more of this
Lift household products, such as bottles and cans		
Do housework		
Take a walk in your neighborhood		
Take stairs instead of elevators		
Get off the bus or subway one stop early and walk the rest of the way		
Dance		
Swim		
Play sports		
Do yoga		
Aerobics		
Run		
Ride a bike		
Participate in an exercise program on TV		
Do a job that involves physical labor		

Other:		
Other:		

Action Step
<i>Choose one exercise you would like to try:</i>
Exercise:
When will you do it?
Where will you do it?
How will you remind yourself to do it?
Who could help you complete your action step?
What might get in the way of completing your action step?

1. Summary of main points of this lesson
2. Leader provides specific positive feedback
3. Invite participants to share feedback

2. Learning Healthier Eating Habits and Mental Health

Learning Healthier Eating Habits and Mental Health	
Important Information	
<p>What are healthy eating habits?</p> <p>Eating habits refer to what you eat and drink; how much, how often, and how the food is prepared. Healthy eating habits include eating a balance of foods that are nutritious and satisfying. Healthy eating habits also include avoiding foods that are low in nutrition and high in calories. A person's eating habits are affected by family culture, religion, income and community:</p> <p>Here are some tips for healthy eating:</p> <ul style="list-style-type: none">• Eat vegetables in a rainbow of colors• Don't skip meals• Eat balanced meals• Avoid fried foods• Eat baked, broiled, or steamed foods• Cut down on fast food• Snack on fruits and vegetables instead of sweets and salty foods• Read food labels• Become familiar with recommended portion sizes• Learn about good nutrition (some insurance companies will pay for a nutritionist, so talk to your doctor)	<p>Why is it important to eat healthy?</p> <ul style="list-style-type: none">• What you eat and how much you eat can affect how you feel, both emotionally and physically• Poor nutrition can lead to weight gain. Being overweight increases a person's chance of developing diabetes and heart disease• Some medications for mental health problems increase weight gain. Good eating habits are one way to manage this side effect• For some people, eating or drinking a lot of sugar or caffeine can affect mood• Good eating habits are associated with reducing or preventing disease• Overeating or undereating can be a sign of a mental health problem• Good eating habits include staying away from foods that you are allergic to• Good eating habits include knowing whether there are foods that may not work well with your medication
<p>Discussion Point: What gets in the way of healthy eating?</p>	

Personalized Worksheet
Thinking more about healthy eating

Please read the following worksheet and check those that apply to you:

Healthy eating habits	I already do this	I would like to do more of this
Eat vegetables every day		
Eat fruits every day		
Don't skip meals		
Eat balanced meals		
Avoid fried foods		
Eat baked, broiled, or steamed foods		
Cut down on fast food		
Snack on fruits and vegetables instead of sweets and salty foods		
Read food labels		
Become familiar with recommended portion sizes		
Learn about good nutrition		
Other:		

Action Step
Choose a healthy eating habit and try it out
<i>Write down one healthy eating habit you would like to do more of:</i>
Healthy Habit:
What will be your first step to try it?
When will you do it?
Where will you do it?
How will you remind yourself to do it?
Who could help you complete your Action Step?
What might get in the way of completing your Action Step?

1. Summary of main points of this lesson
2. Leader provides specific positive feedback
3. Invite participants to share feedback