Implementation of Monitoring and Management Guidelines for Second-Generation Antipsychotics

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It has long been known that psychiatric patients experience increased morbidity and mortality associated with a range of physical disorders. Lifestyle, inadequate health care, and a variety of other factors all contribute to the poor physical health of people with severe mental illness. Second-generation antipsychotics have gained widespread acceptance for the management of patients with schizophrenia and other forms of severe mental illness. While demonstrating several advantages over first-generation antipsychotics, second-generation antipsychotics have been found to cause or exacerbate several metabolic disorders, including diabetes, obesity, dyslipidemia, and metabolic syndrome. These disorders are closely linked and consistently associated with the development of cardiovascular disease, with varying prevalence rates depending on the second-generation antipsychotic used. As a result, several authoritative guidelines have been developed for the monitoring and management of metabolic disturbances in schizophrenia and other forms of severe mental illness. Specifically, the guidelines and recommendations generated from the Mount Sinai Conference on Medical Monitoring and the American Diabetes Association/American Psychiatric Association Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes call for a more integrated and cooperative approach between primary care physicians and mental health care providers to improve the quality of health care for people with severe mental illness. By routinely performing physical health monitoring, referrals, and/or treatment for patients with schizophrenia and other forms of severe mental illness, mental health care providers can take a lead role in transforming the current system of fragmented mental and physical health services into a system focused on early intervention, wellness, and recovery.
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Decades of research in the United States and other countries have consistently demonstrated that people with severe mental illness often have serious medical health problems.[1] Nowhere is this more evident than in the finding that the life expectancy of patients with schizophrenia is approximately 2 to 3 decades shorter than that of the general population, with the chief cause of this excess premature mortality attributed to cardiovascular disease (CVD).[2] Other causes of poor physical health in patients with severe mental illness include lifestyle risk factors and the metabolic side effects (i.e., weight gain and obesity, diabetes, dyslipidemia, and metabolic syndrome) associated with the use of second-generation antipsychotics (SGAs).[3–5] Although it is difficult to separate the contributions of illness, lifestyle, and medication side effects to the risk of CVD, there is a definite clinical need to monitor patients treated with SGAs for metabolic risk factors that increase the risk of death and severe disability.

The increased need to monitor the metabolic side effects in patients treated with SGAs is supported by the monitoring and management guidelines issued by 2 separate consensus development conferences. Both conferences, which are detailed later in this report, reviewed the clinical literature examining the metabolic changes associated with the use of SGAs and listened to presentations from experts in the management of patients with schizophrenia and other forms of severe mental illness, as well as from representatives from the U.S. Food and Drug Administration (FDA) and the pharmaceutical industry. Both conferences arrived at very similar conclusions that called for psychiatrists and other mental health care professionals to pay more attention to patients' physical health and monitor for the metabolic effects of SGAs. For the field of psychiatry, enacting the guidelines and recommendations from these conferences will amount to a significant change in usual practice.

For patients with severe mental illness, specialty mental health clinics are typically the first and often the only points of contact with the medical health care system. Because studies have shown that the integration of medical and mental health care services can improve the care and health status of patients with severe mental illness,[6] psychiatrists must assume an active role in facilitating this change for their patients with schizophrenia and other forms of severe mental illness who are treated with SGAs.

It is the intent of this report to address the utility of monitoring and management guidelines in helping mental health care providers who prescribe SGAs to facilitate appropriate medical care in patients with severe mental illness. First, background information is presented on the metabolic abnormalities and medical comorbidity risk factors that occur in patients treated with SGAs. Guidelines that provide a variety of strategies for monitoring and managing both the mental and physical health needs of mentally ill patients receiving SGAs are summarized. The benefits of and barriers to the implementation of such guidelines are also examined. Lastly, strategies that psychiatrists can use to reduce the medical morbidity associated with mental illness and its treatment are considered.

METABOLIC RISKS AND PHYSICAL HEALTH CARE DURING ANTIPSYCHOTIC TREATMENT

When SGAs first became available, they were considered to be safer and better tolerated than the traditional first-generation

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Table 1. Mount Sinai Conference on Medical Monitoring: Frequency of Monitoring for Patients Treated With Second-Generation Antipsychotics[a]

Parameter	Monitoring Frequency
Body weight/body mass index	At every visit for the first 6 months after starting or switching treatment, and quarterly when the antipsychotic dose is stable
Fasting plasma glucose or HbA_{1C}	Before starting new treatment Those with significant risk factors for diabetes and those who are gaining weight monitored 4 months after starting therapy and then annually
Lipids (total cholesterol, LDL-C, HDL-C, triglycerides)	At least once every 2 years Every 6 months if LDL-C > 130 mg/dL

[a]Based on Marder et al.[9]
Abbreviations: HbA_{1C} = glycosylated hemoglobin, HDL-C = high-density lipoprotein cholesterol, LDL-C = low-density lipoprotein cholesterol.

antipsychotics (FGAs), such as haloperidol and fluphenazine, due to their significantly lower propensity to cause extrapyramidal side effects. As a result, with the exception of clozapine, SGAs rapidly became first-line therapy for their indicated use, as well as for a number of off-label indications (i.e., the management of schizophrenia-spectrum disorders, bipolar disorder, dementia, psychotic depression, autism, and developmental disorders and, to a lesser degree, the management of delirium, aggressive behavior, personality disorders, and posttraumatic stress disorder).[7]

Although SGAs clearly have fewer motor side effects than FGAs, certain SGAs have been associated with their own set of unique problems, including weight gain and obesity, type 2 diabetes, dyslipidemia, and metabolic syndrome. As a result, several authoritative guidelines have been developed for the monitoring and management of schizophrenia and other forms of severe mental illness.[8] One of the first of these expert guidelines resulted from the Mount Sinai Conference on Medical Monitoring, held in October 2002 at the Mount Sinai School of Medicine in New York City.[9] A more focused set of recommendations on monitoring and managing metabolic concerns in patients with severe mental illness was established at the Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes, held in November 2003 by the American Diabetes Association (ADA), American Psychiatric Association (APA), American Association of Clinical Endocrinologists, and North American Association for the Study of Obesity (referred to as the ADA/APA Consensus Statement throughout this article).[7] The document reviews the content and implementation issues of the pivotal guidelines and evaluates the evidence showing that the SGAs are not all equally associated with adverse metabolic effects.[7] Both sets of guidelines offer clear recommendations on what parameters to monitor and the frequency with which they need to be monitored (Tables 1 and 2).[7,9]

Weight Gain and Obesity

As in the general population, obesity is an urgent and growing health problem in psychiatric patients. Data suggest that obesity is approximately 1.5 to 2.0 times more common in patients with schizophrenia than in the population at large.[7] Whether this is a function of the psychiatric illness itself or its treatment with SGAs is unknown. However, some SGAs (e.g., olanzapine and clozapine) are associated with a higher incidence of weight gain than others (e.g., aripiprazole and ziprasidone),[7,9] as discussed by Newcomer[10] elsewhere in this supplement.

In a sample described by Allison et al.,[11] over 40% of patients with schizophrenia were found to be significantly overweight. Obesity places these individuals at a much higher risk for a number of related medical conditions, such as type 2 diabetes and CVD.[12–15] In addition, obesity has been shown to correlate with a poor outcome in patients with bipolar I disorder.[16]

Type 2 Diabetes

Overall, epidemiologic data suggest an increased prevalence of impaired glucose tolerance, insulin resistance, and type 2 diabetes in people with severe mental illness compared to the general population.[7,17] Type 2 diabetes has been observed to be up to 2 to 4 times more common in those with schizophrenia compared to the general population.[18] Lifestyle factors (e.g., poor diet, sedentary behavior) have been shown to exacerbate this problem.[3]

Although a direct link between glycemic control and atherosclerotic disease has not been definitively established, diabetes has long been associated with a marked increase in the risk of coronary heart disease, and 75% of the morbidity caused by diabetes is attributed to the presence of CVD.[19] The Third Report of the National Cholesterol Education Program (NCEP) Expert Panel[20] considers diabetes to be a major independent risk factor for coronary heart disease and other forms of CVD, thereby elevating it to the highest risk category. This classification is based in part upon the observation that patients with type 2 diabetes (mean age 58 years) without a prior myocardial infarction (MI) were found to have the same level of risk for MI (20% vs. 19%, respectively) and coronary mortality (15% vs. 16%, respectively) as patients without diabetes (mean age 56 years) who had a prior MI.[21] As a result, in 2003, the FDA requested that all SGA manufacturers modify their product labeling to include a warning and additional information about the link between SGAs and diabetes, and recommended regular monitoring of blood glucose levels in patients treated with these agents. However, the FDA acknowledged that the relationship between SGAs and glucose abnormalities is complicated by an increased background risk of diabetes in people with schizophrenia and the growing incidence of diabetes in the general population.[22]

In addition to baseline screening and ongoing monitoring recommendations, both sets of guidelines[7,9] recommend that mental health care professionals, patients, family members, and caregivers should be educated about the symptoms of diabetes. They advise clinicians to document the risk factors for diabetes and screen patients with severe mental illness for possible undiagnosed type 2 diabetes during the initial evaluation. Immediate care or referral for treatment is recommended in patients found to be prediabetic or diabetic.

Dyslipidemia

Although few published trials have examined the effect of SGAs on fasting blood lipids, a patient's lipid profile (especially low-density lipoprotein cholesterol level) is an important metabolic parameter that helps to predict the risk of CVD.

The Mount Sinai guidelines recommend that psychiatrists ensure that either the NCEP III or U.S. Preventive Services Task Force guidelines are followed for monitoring and treating

Table 2. Screening and Monitoring for Patients With Schizophrenia[a,b]

Parameter	Baseline	Every 4 Weeks	Every 8 Weeks	Every 12 Weeks	Quarterly	Annually	Every 5 Years
Personal/family history	✓					✓	
Weight (body mass index)	✓	✓	✓	✓	✓		
Waist circumference	✓					✓	
Blood pressure	✓			✓		✓	
Fasting plasma glucose	✓			✓		✓	
Fasting lipid profile	✓			✓			✓

[a]Reprinted with permission from the American Diabetes Association.[7]
[b]More frequent assessments may be warranted based on clinical status.

abnormal lipid levels in patients with schizophrenia. The ADA/APA Consensus Statement recommends that all patients with severe mental illness should undergo baseline screening for a family and personal history of dyslipidemia, provide a fasting lipid profile, and receive immediate care or referral for treatment if they are found to be hyperlipidemic. A fasting lipid profile should also be obtained at baseline and 3 months after starting any antipsychotic, at 5-year intervals if findings are normal, and more often if clinically indicated. It should be noted that several experts believe that the repeat lipid screen at 5 years is insufficient and that lipids should be monitored more frequently.[23] The 5-year monitoring recommendation, particularly in terms of CVD risk, is based on the fact that the schizophrenic population includes a substantial number of young people in whom lipids may be checked less frequently. However, patients with severe mental illness are frequently at increased risk for CVD independent of their use of SGAs, and there are a number of people who start SGA treatment at 45 or 50 years of age for indications other than schizophrenia in whom monitoring lipid levels every 5 years is probably not optimal. Given the fact that SGAs have intrinsic activity that goes beyond the effect of weight gain on lipids, this recommended frequency may result in inadequate monitoring.

Metabolic Syndrome

Because this syndrome is associated with a significant increase in CVD-related morbidity and mortality, mental health providers need to be able to identify patients who fulfill the diagnostic criteria. To be diagnosed with metabolic syndrome, patients must exhibit at least 3 of the following 5 criteria[24]:

- Obesity as measured by a waistline > 40 inches for males or > 35 inches for females
- Fasting serum triglyceride levels > 150 mg/dL
- Serum high-density lipoprotein cholesterol (HDL-C) levels < 40 mg/dL for males or < 50 mg/dL for females
- Hypertension, defined by an increase in systolic blood pressure, diastolic blood pressure, or both, to > 130/85 mm Hg
- Hyperglycemia, defined by elevated fasting serum glucose levels of > 110 mg/dL (some use glucose values of > 100 mg/dL)

The prevalence of metabolic syndrome in the general population is high, but in patients with severe mental illness, prevalence rates from 30% to 60% have been observed.[4] SGAs that are known to significantly increase the associated risk factors for metabolic syndrome should be avoided as first-line treatment. If clinically feasible, individuals with a personal or family history of obesity, hypertension, diabetes, or hyperlipidemia should be administered SGAs that do not worsen these disorders.

GUIDELINE IMPLEMENTATION: BARRIERS AND BENEFITS

Despite the general acceptance of and easy accessibility to the Mount Sinai guidelines and the ADA/APA Consensus Statement recommendations, they do not appear to be routinely followed. During the 2006 APA annual meeting, a study by Cuffel et al.[25] analyzed a nationwide database containing health care claims from 85 health plans to determine whether psychiatrists began performing more lipid and glucose monitoring in schizophrenic patients taking SGAs after the release of the ADA/APA Consensus Statement. The results were surprising in that while 7.8% of 21,848 patients in the study had their lipids tested at baseline during the 6 months before the consensus statement was issued, only 8.5% of 8166 patients had baseline lipid testing 6 months after the consensus statement was issued. Among the same patients, 20.6% and 22.5%, respectively, underwent glucose testing 6 months before and 6 months after the release of the consensus statement.

As seen in Table 3, the implementation of monitoring and management guidelines to integrate physical health care into mental health is made more difficult by a variety of factors.[1,4,11,26–29] This was clearly demonstrated by the low rates of monitoring for metabolic risks (i.e., blood pressure, weight, waist circumference, lipid changes, blood glucose) reported in the Atypical Antipsychotic Therapy and Metabolic Issues National Survey in 2004.[30] Psychiatrists were found to be particularly averse to monitoring waist circumference.

Alternatively, when guidelines were viewed as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances,"[31] they promoted best practice for specific populations of patients. Guidelines have variable applicability for individual patients and, therefore, should not be interpreted as establishing inflexible protocols for patient care. They also do not replace the professional judgment of physicians. The effectiveness of guidelines, however, is dependent on many factors outside of their content. In particular, specific attention must be focused on utilizing appropriate implementation strategies if the full potential of a set of guidelines is to be realized.

Implementation of the Mount Sinai guidelines on medical monitoring could substantially improve the health of patients with schizophrenia. The conference participants acknowledged that psychiatrists and other mental health care providers may have to assume a role in physical health monitoring which, in the

Table 3. Potential Barriers to Implementation of Monitoring and Management Guidelines by Mental Health Providers[a]

Competing demands in mental health care
Demedicalization of psychiatry
Natural resistance to change
Lack of clinician familiarity or agreement with the guidelines
Guidelines seen as a threat to clinician autonomy
Lack of systems support (eg, computerized clinical information tracking abilities)
Patient issues, such as cognitive deficits that interfere with long-term management of medical comorbidity and lack of access to medical care
Unclear division of the roles and responsibilities between primary and secondary care
Poor coordination and communication between medical and mental health care providers
Reimbursement issues (ie, weight management programs are not always covered by Medicaid or insurance, and reimbursement rates must be made to reflect the cost of providing services and the time spent on care)
No profit incentive for mental health providers to provide or prescribe psychosocial treatment
Lack of start-up funds for establishment of embedded or unified programs to cover clinical and administrative needs
Failure to establish the requirements that mental health agencies furnishing on-site primary care must meet

[a]Based on references 1, 4, 11, and 26–29.

care of patients without schizophrenia, would be the responsibility of primary care providers. However, many schizophrenic patients who are treated in public mental health settings have no health insurance or a primary care provider. Furthermore, primary care providers may not be aware of the health risks associated with the different SGAs and the need for health monitoring in patients with schizophrenia. As a result, mentally ill patients seek care from hospital emergency departments 6 times more often than the general population.[32] An integrated care approach could help curb costly emergency room visits and shorten the length of time patients remain in the hospital,[32] shifting the focus of care from a crisis-driven one to one that emphasizes health promotion.

The ADA/APA Consensus Statement recommends that mental health care providers routinely perform a brief work-up for patients with severe mental illness before or as soon as clinically feasible.[7] Although many psychiatrists are not used to ordering tests, it is appropriate and in the best interest of patients that psychiatrists and other mental health care providers learn to be aware of fasting blood glucose measures, lipid levels, and body mass index (BMI) before starting the patient on a particular SGA.

Another important benefit of having psychiatrists and other mental health care providers become more focused on the medical health of patients with severe mental illness is that it should result in the earlier detection and management of potentially serious risk factors that could contribute to the impaired health of these individuals. It is hoped that the ADA/APA Consensus Statement will provide mental health care providers with a thoughtful summary of the use of SGAs in patients with medical comorbidities, as well as practical recommendations that could help avoid or minimize metabolic complications that can arise from SGA use.

WHAT DO WE DO NOW?

The separation of physical health care and mental health services has led to a fragmented system of care for people with mental illness. With the creation of The President's New Freedom Commission on Mental Health, the nation is now in the process of transforming our fragmented public mental health services into a system focused on early intervention, wellness, and recovery.[26]

Monitoring and management guidelines to integrate physical health care into mental health should be viewed as part of the process of change during this transformation. While all clinicians should try to follow the NCEP Adult Treatment Panel III guidelines,[20] immediate implementation of its recommendations in their entirety is not a realistic goal. Rather, mental health care providers should routinely begin to use as many of the Mount Sinai guidelines and ADA/APA Consensus Statement recommendations as possible. In light of the identification of numerous barriers to the implementation of these guidelines and recommendations, the transformation to a mental health system of early intervention, wellness, and recovery should be undertaken in stages that are both practical and simple. During the first stage, increased screening for obesity and abnormal glucose and lipid metabolism in patients receiving SGAs would illustrate the unmet medical needs in this population and clarify the need for action. These measures should not be viewed as an unreasonable change in emphasis in psychiatric treatment—psychiatrists should have the option of either directly addressing these issues or arranging for others to do so.

Other strategies to assist mental health care providers in transforming the current mental health system into a system focused on early intervention, wellness, and recovery include the following:

- Increasing their awareness of the symptoms of diabetes and CVD in patients treated with SGAs; this is particularly important when medications are started
- Providing them with more direction pertaining to the guidelines (e.g., in monitoring for diabetes, not all psychiatrists know that lipid screening should be performed more frequently after patients reach 60 years of age or a certain BMI)
- Establishing evidence-based standards to help ensure that they would know when and why specific metabolic risk factors should be monitored
- Encouraging better and more frequent communication with primary care providers
- Establishing who is going to be responsible for actually monitoring patients versus coordinating their care (e.g., psychiatrists, primary care practitioners, diabetologists, nurses)
- Directing them on what to do with the monitoring results (e.g., effectively communicating the results to patients and caregivers, recording them electronically, integrating them in problem lists and treatment plans)
- Ensuring who will pay for the extra efforts involved in implementing monitoring and management guidelines (e.g., public sector, private patients, Veterans Administration)
- Demonstrating the value of monitoring (e.g., screening yields new cases, prevention vs. tight monitoring, learning how value is calculated)
- Utilizing electronic record-keeping and automated systems to provide prompts or reminders

CONCLUSION

For many people with serious psychiatric disorders, SGAs provide great benefit. As with all drugs, however, SGAs are associated with adverse side effects. In recent years, there has been a growing concern over the fact that patients who take SGAs for the treatment of schizophrenia and other forms of severe mental illness are known to be at increased risk of weight gain and obesity, type 2 diabetes, dyslipidemia, and metabolic syndrome. These undesirable side effects are closely linked and consistently associated with the development of CVD, with varying prevalence rates depending on the SGA used.

Poor lifestyle habits, such as smoking, inadequate diet, lack of exercise, and alcohol and substance abuse, are also frequently associated with severe mental illness. Moreover, those suffering from mental disorders obtain fewer needed physical health care services and often receive substandard care for their physical illnesses. For these reasons, individuals with severe mental illness require an integrated approach to their health care that addresses both their mental and physical health needs.

Routine screening of all patients with schizophrenia and other forms of severe mental illness by mental health care providers is poised to become the standard of care. Preserving gains made in the management of patients with severe mental illness requires that psychiatrists increase their adherence to evidence-based monitoring and management guidelines and become more vigilant for the metabolic complications associated with the use of SGAs. Progress will, however, depend on psychiatrists and primary care physicians being aware of the problems inherent in the current health care system and willing to develop and integrate imaginative solutions for system-wide improvements that are both acceptable and useful for patients with severe mental illness.

Drug names: aripiprazole (Abilify), clozapine (FazaClo, Clozaril, and others), fluphenazine (Prolixin and others), haloperidol (Haldol and others), olanzapine (Zyprexa), ziprasidone (Geodon).

Disclosure of off-label usage: The author has determined that, to the best of his knowledge, no investigational information about pharmaceutical agents that is outside U.S. Food and Drug Administration–approved labeling has been presented in this article.

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