Prevalence of Baseline Serum Glucose and Lipid Testing in Users of Second-Generation Antipsychotic Drugs: A Retrospective, Population-Based Study of Medicaid Claims Data

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Objective: Increased risk of diabetes and dyslipidemia is associated with major mental illness and antipsychotic drug use. This study aimed to determine the prevalence of serum glucose and lipid monitoring in public mental health clients initiating second-generation antipsychotic (SGA) drugs.

Method: This retrospective cohort study using Medicaid claims data from California, Oregon, Tennessee, and Utah evaluated 55,436 enrollees with a prescription claim for an SGA drug between January 1, 1998, and December 31, 2003. Serum glucose and lipid testing were identified using Current Procedural Terminology (CPT) procedure codes. Baseline was defined as 14 days before through 28 days after the date of the first SGA prescription. Multivariate logistic regression identified patient characteristics associated with testing. Generalized estimating equations evaluated changes associated with SGA drug initiation compared to background rates of testing.

Results: On average, < 20% of individuals initiating SGA drug therapy received baseline glucose testing, and < 10% received baseline lipid testing. Baseline glucose and lipid testing increased modestly with SGA initiation (glucose: 7%-11% increase; lipids: 2%-3% increase; p < .001). Preexisting diabetes and dyslipidemia were associated with a 2- to 3-fold greater likelihood of baseline glucose and lipid testing. The likelihood of glucose testing increased 2-fold between 1998 and 2003 and was 46% more likely in patients with schizophrenia. Enrollees from Oregon, Tennessee, and Utah were 50% to 90% less likely to receive baseline glucose or lipid testing than enrollees from California.

Conclusions: Glucose and lipid screening is underutilized in patients initiating SGA drug therapy. Psychiatrists can play an important role to ensure metabolic risk is adequately assessed. (*J Clin Psychiatry 2008;69:316–322*) Received Feb. 27, 2007; accepted June 7, 2007. From the Department of Pediatrics and the Department of Preventive Medicine and Biometrics, School of Medicine (Dr. Morrato), and the Department of Clinical Pharmacy, School of Pharmacy (Drs. Morrato and Valuck), University of Colorado at Denver; the Departments of Psychiatry, Psychology, and Medicine, Washington University School of Medicine, St. Louis, Mo. (Dr. Newcomer); and Peak Statistical Services, Evergreen, Colo. (Mr. Allen).

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he U.S. Surgeon General concluded almost a dec-ade ago that mental health is "inextricably intertwined" with physical health and a high-quality mental health system must integrate primary medical care with psychiatric treatment.¹ As the Centers for Disease Control recently reported, persons with serious mental illness have a higher risk of death compared to the general population, primarily due to cardiovascular disease,² with an average of more than 20 years of potential life lost.^{2,3} Excess mortality has been attributed to poorer quality of medical care and lower socioeconomic status^{4,5} and to patient lifestyle, which can include poor dietary habits,⁶ obesity,⁷ physical inactivity,⁸ and high rates of smoking.⁹ Metabolic syndrome and diabetes, both associated with elevated cardiovascular risk, are also particularly prevalent among individuals with serious mental illness. Four of 10 patients with schizophrenia meet the criteria for having metabolic syndrome,¹⁰ and about 1 in 6 schizophrenia patients has diabetes^{11,12}; both rates are about double the rate found in the general population.¹³ Moreover, schizophrenia is a recognized risk factor for developing type 2 diabetes.¹⁴

Further complicating the clinical challenge in managing psychiatric patients with these complex chronic medical conditions is the fact that second-generation antipsychotic (SGA) drug therapy is itself associated with weight gain, insulin resistance, and dyslipidemia.^{15–17} Because of this safety risk, the U.S. Food and Drug Administration required a warning about increased risk for hyperglycemia and diabetes to be added to the product labeling for all SGA drugs.¹⁸ Recommendations from the American Diabetes Association (ADA) and American Psychiatric Association (APA) Consensus Development Conference specified that metabolic monitoring, including baseline assessment of serum glucose and lipid profiles, should be done for all patients initiating SGA drugs.¹⁹ Because mental health care providers have the most direct contact with schizophrenia patients, Marder et al.²⁰ have recommended that they be responsible for basic health screening, including metabolic testing. Fenton and Chavez²¹ acknowledge that screening responsibilities may need to reflect individual practice circumstances, although the provider responsible for ongoing monitoring of metabolic risk should be explicitly identified.

Achieving recommended levels of metabolic screening is therefore important for clinicians treating patients with serious mental illness and for those prescribing SGA medications, especially because a substantial portion of these patients has undiagnosed diabetes.^{22,23} However, the frequency of serum glucose and lipid testing in patients with serious mental illness, specifically those receiving antipsychotic medication, is understudied.^{23–28} Data suggest that less than 10% of managed-care patients receiving SGA drugs are being monitored in a manner consistent with ADA/APA recommendations.²⁷ However, information on the rate of testing for public health clients, for whom serious mental illness and antipsychotic utilization is common,²⁹ is lacking.

The aim of this retrospective, population-based cohort study was to determine the prevalence of baseline serum glucose and lipid testing for public mental health clients enrolled in Medicaid who were initiating SGA drug therapy. A secondary objective was to identify factors associated with a greater likelihood of testing.

METHOD

Source Population

This retrospective cohort was selected from individuals enrolled in the California, Oregon, Utah, or Tennessee Medicaid programs between January 1, 1998, and December 31, 2003. Individuals from California, Oregon, and Utah were enrolled in fee-for-service plans, and individuals from Tennessee participated in TennCare, a network of managed care organizations. Study subjects were excluded if they were Medicare dual-eligible. Each enrollee had a unique encrypted identifier, which allowed us to identify all medical and pharmacy claim records for each patient during the study period. Given the anonymous nature of the data, the Colorado Multiple Institutional Review Board determined that the protocol was exempt from IRB review.

Study Population

Enrollees with a prescription claim for an SGA drug (aripiprazole, clozapine, olanzapine, quetiapine, risperidone, or ziprasidone) and a 180-day enrollment history before the index SGA pharmacy drug claim were selected (N = 55,436). The index drug claim was the first SGA prescription in the study period. A patient was classified as receiving multiple SGA drugs if he or she had prescription claims for 2 or more SGA drugs on the index day. The likelihood of baseline metabolic testing was compared between index drugs using risperidone as the referent because risperidone was the SGA drug most commonly prescribed.

Ascertainment of Metabolic Testing

Glucose testing was identified using Current Procedural Terminology, 4th Revision (CPT) codes for a comprehensive metabolic panel (CPT codes 80050, 80053, and 80054), glucose test (82947, 82948, 82950, 82951, 81000, 81002, 81005, 81099), glycolated hemoglobin (A1C) test (83036), or home glucose monitoring device (82962).³⁰ This definition was designed to maximize sensitivity to the range of testing a physician might use to assess glucose metabolism. Lipid testing was defined as the presence of a lipid panel (CPT code 80061) or individual tests (CPT codes 83721, 83715, 83716, or [83718 and 82465 and 84478]).³⁰

Prevalence of Baseline Testing

The APA recommends that glucose and lipid profiles be assessed when initiating SGA treatment.¹⁹ The prevalence of baseline testing was calculated as the proportion of individuals initiating SGA medication who had at least 1 medical claim for a glucose or lipid test during the baseline period of 14 days before to 28 days after the index SGA drug claim. The prevalence of glucose and lipid testing in 2003 (the most recent year in the study cohort) was also calculated for four 30-day time periods before and after the index atypical antipsychotic prescription claim date and stratified by diabetes status to compare baseline testing associated with SGA initiation to background rates of testing. Patients included in this analysis had at least 120 days of enrollment history after the index SGA prescription claim.

Assessment of Mental and Physical Health

Because patients with schizophrenia are at higher risk for developing type 2 diabetes¹⁴ and the ADA recommends that adults with risk factors be screened more often,³¹ the likelihood of baseline testing was compared in patients with versus without schizophrenia. Individuals with diagnosed schizophrenia were identified by the

Table 1. Prevalence of Baseline Glucose and Lipid Serum	
Testing Among Patients Initiating Second-Generation	
Antipsychotic (SGA) Drug Therapy ^a	

Selected		Baseline Glucose	Baseline Lipid
Characteristic	N (%)	Serum Test, %	Serum Test, %
Total population	55,436 (100)	19.0	6.2
Sex			
Female	27,842 (50.2)	21.1	6.8
Male	27,594 (49.8)	16.8	5.6
Age group, y			
19 or younger	17,527 (31.6)	12.1	2.3
20–29	7,470 (13.5)	17.2	4.8
30-39	10,599 (19.1)	20.2	6.6
40-49	11,023 (19.9)	23.4	9.4
50-59	6,988 (12.6)	27.7	11.3
60–69	862 (1.6)	30.5	11.0
70 or older	967 (1.7)	20.5	4.3
Race/ethnicity	>07 (117)	2010	110
White	32,286 (58.2)	17.8	5.9
Nonwhite	23,150 (41.8)	20.7	6.6
State	25,150 (11.0)	20.7	0.0
California	46,471 (83.8)	21.1	7.2
Oregon	657 (1.2)	4.4	< 1.0
Tennessee	5,934 (10.7)	8.8	1.3
Utah	2,374 (4.3)	7.1	< 1.0
Schizophrenia	2,374 (4.3)	/.1	< 1.0
No	11,278 (20.3)	17.9	5.6
Yes	44,158 (79.7)	23.3	8.5
Preexisting diabetes		23.5	0.5
No	50,589 (91.3)	16.9	5.4
Yes	4,847 (8.7)	40.9	14.3
Preexisting	4,047 (0.7)	40.9	14.5
dyslipidemia			
No	50,144 (90.5)	17.4	4.7
Yes	5,292 (9.5)	34.3	19.9
Index SGA drug	5,292 (9.5)	54.5	19.9
Aripiprazole	104 (< 1.0)	25.3	4.8
Clozapine	130 (< 1.0)	18.5	13.8
Olanzapine	22,290 (40.2)	20.7	7.4
Quetiapine	7,933 (14.3)	19.3	5.6
Risperidone	22,494 (40.6)	19.3	5.1
1	/ / /		7.4
Ziprasidone Multiple	889 (1.6) 1,596 (2.9)	19.2 23.3	6.2
Year of index SGA	1,390 (2.9)	23.3	0.2
prescription	2,409(6,2)	10.7	7 4
1998	3,498 (6.3)	12.7	7.4 7.3
1999	7,896 (14.2)	13.0	
2000	9,213 (16.6)	13.9	5.6
2001	10,526 (19.0)	21.0	5.4
2002	12,658 (22.8)	22.4	6.3
^a Data are based on I	11,645 (21.0)	23.4	5.9

^aData are based on Medicaid enrollees from California, Oregon, Tennessee, and Utah (1998–2003). Baseline was defined as 14 days before, through 28 days after, the date of the initial SGA prescription claim.

presence of a medical claim during the study period with an *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) diagnosis code of 295.xx.

Patients with diabetes or dyslipidemia would also be expected to receive glucose and lipid testing more often. In order to maximize our sensitivity in classifying patients,³² individuals with preexisting diabetes were identified by the presence of a medical claim coded for diabetes

(ICD-9-CM code 250.xx) or a pharmacy claim for an antidiabetic drug (Generic Product Identifier [GPI; First DataBank, Inc., Indianapolis, Ind.] code 27) in the 180 days before the index SGA claim date. Similarly, individuals with preexisting dyslipidemia were identified by the presence of a medical claim coded for disorders of lipid metabolism (ICD-9-CM code 272.xx) or a pharmacy claim for an antihyperlipidemia drug (GPI code 39) in the 180 days before the index SGA claim date.

Assessment of Patient Demographic Characteristics

Sex, age at the time of the index SGA prescription claim, race/ethnicity, and state Medicaid program were also known for each patient. Race and ethnicity were classified as white, African American, Hispanic, or Asian. Because nonwhite race/ethnicity is a risk factor for developing type 2 diabetes,³³ the likelihood of baseline metabolic testing was compared in nonwhite versus white race/ethnicity.

Year of the Index SGA Prescription Claim

Increasing clinical reports of the association between SGA drug use and glucose metabolism abnormalities began appearing in the medical literature in 1999.³⁴ To evaluate whether the prevalence of metabolic testing increased over time with increasing medical reports, the likelihood of baseline testing was compared by year of the index SGA prescription using 1998 as the referent.

Statistical Analysis

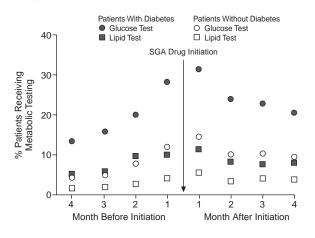
Multiple logistic regression was performed to estimate the adjusted odds of baseline glucose and lipid testing after controlling for sex, age, race/ethnicity, state Medicaid program, diabetes, dyslipidemia, schizophrenia, index SGA drug (excluding aripiprazole due to insufficient sample), and year of the index SGA prescription claim. Generalized estimating equations were used to test for changes in the proportion of patients initiating atypical antipsychotic drug therapy who received metabolic testing in the months before and after initiation. Statistical analyses were conducted using SAS version 9.1.3 (SAS Institute, Inc., Cary, N.C.).

RESULTS

Patient Characteristics

Table 1 summarizes characteristics of patients in the study cohort who initiated SGA drug therapy in California, Oregon, Tennessee, and Utah between 1998 and 2003. One half of the study population was female and slightly more than one half was white. In this sample, 80% of patients had a recorded diagnosis of schizophrenia. Based on recorded diagnoses and antidiabetic and antihyperlipidemia drug prescribing, 9% of patients were identified as having diabetes, and 10%, dyslipidemia.

Figure 1. Prevalence of Metabolic Testing Relative to Initiation of Second-Generation Antipsychotic (SGA) Drug Therapy in Patients With and Without Identified Diabetes^a



^aData are based on Medicaid enrollees from California, Oregon, Tennessee, and Utah in 2003.

Risperidone (41%) and olanzapine (40%) were the most common index SGA drugs. The majority of the study cohort was from California.

Prevalence of Metabolic Testing

Overall, 19% of patients received a baseline glucose test; 6% received a lipid test; and 5% received both tests. Expanding the baseline period to include 4 months before and 4 months after the index SGA drug claim, there was a 7% to 11% increase in glucose testing (p < .001) and a 2% to 3% increase in lipid testing (p < .001) in the month before and after SGA drug initiation compared to the average background rate of testing 2 to 4 months before drug initiation (Figure 1). The absolute increase in testing in the month before and after drug initiation compared to background rates was greatest in glucose testing for patients with preexisting diabetes.

Predictors of Metabolic Testing

Table 2 summarizes factors associated with the adjusted likelihood of baseline metabolic testing. Male and nonwhite patients were less likely to receive baseline glucose testing compared to female and white patients, but there was no association between gender or race and baseline lipid testing. Individuals were significantly (p < .05) more likely to receive glucose and lipid screening if they were enrolled in the California Medicaid program. Baseline glucose testing increased significantly between 1998 and 2003 (OR = 2.51, 95% CI = 2.24 to 2.81); however, there was no change in rates of baseline lipid testing. Individuals with a recorded diagnosis of schizophrenia were more likely to receive baseline glucose screening but were no more likely to receive lipid screening. Preexisting diabetes and dyslipidemia were associated with a 2- to

	Likelihood of Baseline Serum		
	Laboratory Testing, OR (95% CI) ^b		
Selected Characteristic	Glucose	Lipid	
Sex (ref = female)	0.83 (0.79 to 0.87)	0.99 (0.92 to 1.06)	
Age group, y (ref = $20-29$)			
19 or younger	0.78 (0.72 to 0.84)	0.57 (0.49 to 0.66)	
30–39	1.12 (1.03 to 1.21)	1.21 (1.06 to 1.38)	
40-49	1.20 (1.11 to 1.30)	1.49 (1.31 to 1.69)	
50-59	1.34 (1.23 to 1.46)	1.49 (1.30 to 1.71)	
60–69	1.56 (1.32 to 1.84)	1.57 (1.23 to 2.01)	
70 or older	1.35 (1.12 to 1.62)	1.01 (0.72 to 1.42)	
Race/ethnicity (ref = white)	0.93 (0.89 to 0.98)	1.04 (0.97 to 1.12)	
State (ref = California)			
Oregon	0.23 (0.16 to 0.34)	0.10 (0.03 to 0.31)	
Tennessee	0.46 (0.42 to 0.51)	0.24 (0.19 to 0.30)	
Utah	0.27 (0.23 to 0.32)	0.12 (0.07 to 0.18)	
Schizophrenia (ref = no)	1.46 (1.38 to 1.54)	1.40 (1.29 to 1.53)	
Preexisting metabolic			
disorder			
Diabetes (ref = no)	2.49 (2.32 to 2.66)	1.51 (1.37 to 1.66)	
Dyslipidemia (ref = no)	1.49 (1.39 to 1.59)	3.35 (3.07 to 3.66)	
Index SGA drug			
(ref = risperidone)			
Aripiprazole	1.18 (0.71 to 1.96)	1.28 (0.50 to 3.26)	
Clozapine	1.04 (0.66 to 1.63)	2.35 (1.39 to 3.95)	
Olanzapine	1.13 (1.08 to 1.19)	1.21 (1.18 to 1.31)	
Quetiapine	0.94 (0.88 to 1.01)	0.97 (0.75 to 1.15)	
Ziprasidone	0.84 (0.71 to 1.01)	1.42 (1.09 to 1.86)	
Multiple	1.24 (1.09 to 1.40)	0.93 (0.75 to 1.15)	
Year of index SGA			
prescription (ref = 1998)			
1999	1.13 (1.00 to 1.28)	1.12 (0.96 to 1.32)	
2000	1.30 (1.15 to 1.46)	0.89 (0.76 to 1.05)	
2001	2.30 (2.06 to 2.58)	0.88 (0.75 to 1.03)	
2002	2.39 (2.14 to 2.67)	0.95 (0.82 to 1.11)	
2003	2.51 (2.24 to 2.81)	0.86 (0.74 to 1.00)	

^aData are based on Medicaid enrollees from California, Oregon, Tennessee, and Utah (N = 55,436). Baseline was defined as 14 days before, through 28 days after, the date of the initial SGA prescription claim.

^bOdds ratios were obtained from logistic regression models adjusting for sex, age, race/ethnicity, state Medicaid program, year of the index SGA prescription, the SGA drug prescribed, and the presence of schizophrenia and preexisting diabetes and dyslipidemia. Abbreviation: ref = reference.

3-fold greater likelihood of baseline glucose and lipid testing. Patients initiating olanzapine were more likely to receive baseline glucose and lipid testing than patients initiating risperidone. Baseline lipid testing was also more likely for patients initiating clozapine or ziprasidone.

DISCUSSION

In this Medicaid population, the rates of baseline metabolic screening were low. On average, less than 20% of individuals initiating SGA drug therapy received baseline serum glucose testing and less than 10% received lipid testing. These findings are even more discouraging given the fact that metabolic screening was lower in patients without preexisting diabetes or dyslipidemia. However,

Table 2. Factors Associated With Baseline Metabolic Testing Among Individuals Initiating Second-Generation Antipsychotic (SGA) Drug Therapy^a

results from our study are consistent with previous reports of low metabolic monitoring in the community for psychiatric patients taking antipsychotic medication,^{23,27} and our results now extend this observation into the public Medicaid sector, where many patients with serious mental illness receive health care. Findings from this study suggest a large gap existed between clinical practice and the ADA's and APA's goal of fasting serum glucose and lipid profiles for all patients initiating SGA drug therapy.

Some might argue, though, that the rates of baseline glucose and lipid screening have increased since these data were collected and after the FDA's warning on hyperglycemia risk and the ADA/APA's consensus recommendations. For example, surveys of psychiatrists indicate that their overall awareness of the risk for diabetes with SGA drug therapy increased after the warnings.^{35,36} However, results from a population-based study examining glucose and lipid testing trends in a commercially insured population suggest monitoring did not change following the warning.²⁷ This finding is consistent with postwarning survey results showing that less than 20% of psychiatrists reported assessing fasting serum glucose and lipid profiles before initiating treatment with SGA drug therapy.³⁵ Screening for metabolic side effects has also remained low in the United Kingdom, where only one quarter of community patients receiving antipsychotic medication in 2005 received a blood glucose or plasma lipid test in the past year.²⁸ While we are currently evaluating the effect of the warnings and ADA/APA recommendations on metabolic testing patterns in Medicaid patients, we suspect that a gap between clinical practice and medical and public health goals will remain.

On a positive note, though, rates of glucose testing improved over time during the study period, and there was an increase in glucose testing associated with SGA drug initiation. These facts suggest that diabetes screening was increasing; however, the question that this retrospective study could not answer, and one that should be addressed by future research, is, who ordered the testing? and why? That is, did the prescriber of the antipsychotic medication order the testing, or, if not, was he or she aware of and able to easily obtain the results? We know the U.S. mental health system is complex and fragmented¹ and that only 1 in 7 Medicaid psychiatric visits provides preventive health services.³⁷ However, we have observed in this same Medicaid study population that one half of SGA patients without diabetes and more than three quarters with diabetes had an annual glucose test.³⁸ Perhaps one opportunity for improved coordination of metabolic monitoring may be to ensure, at minimum, that existing laboratory results from other health care settings are available to the SGAprescribing clinician.

Interestingly, there was significant (p < .05) variability in metabolic testing rates across the 4 states studied. Medicaid enrollees from Oregon, Tennessee, and Utah were 50% to 90% less likely to receive metabolic testing than those in California. Because data from California represented the majority of our study sample, mean rates of glucose and lipid testing thus largely reflect practices in California. The need for improved integration of primary medical care with psychiatric treatment across all states has been noted.^{39,40} Understanding the California model of care may provide insight for other states endeavoring to increase metabolic screening for patients with serious mental illness.

We also observed variability in the likelihood of baseline testing across SGA drugs. For example, glucose testing was more likely if the patient was initiating quetiapine or ziprasidone rather than risperidone. It is unclear why this variation occurred, especially since it appears to counter the understanding that quetiapine has a similar metabolic risk profile to risperidone, and ziprasidone is associated with a lower metabolic risk.¹⁵ Perhaps this variability reflects a differential in monitoring practices among physicians who were adopters of quetiapine and ziprasidone-or a differential in metabolic risk profile for the patients typically prescribed these 2 drugs; these possibilities could not be assessed using the available administrative claims data. More research is needed to investigate this finding and to evaluate whether a disparity in monitoring across drugs exists today. Until corroboration has occurred, these results should be treated with caution.

The results of this research are subject to limitations. The prevalence of baseline metabolic risk assessment relied on laboratory testing alone and clinician adoption of other recommended risk assessment measures, e.g., family history, waist circumference, and body mass index, could not be evaluated. For example, about 80% of psychiatrists have reported assessing patient and family history and 60% have reported measuring height and body weight more than one half the time when initiating SGA drug therapy.35 In addition, this study examined only whether or not a glucose or lipid test was done, not what the laboratory results were and how the clinician may have adjusted his or her treatment plan accordingly. Data from the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) indicate that 30% of patients with schizophrenia and diabetes and nearly 90% with dyslipidemia do not receive treatment for these metabolic disorders.⁴¹ Although the states included in this study represented one quarter of Medicaid enrollees,⁴² caution should also be applied in generalizing study findings nationally or to other reimbursement settings. Moreover, major budget cuts in state Medicaid funding occurred after the study time period,³⁹ so our findings may not reflect current testing practices.

People with serious mental illness are at increased risk for cardiovascular disease and diabetes. Secondgeneration antipsychotic drug therapy further contributes to patients' risk for developing diabetes and dyslipidemia. Results from this study suggest that serum glucose and lipid testing, as a tool for metabolic risk assessment, is greatly underutilized in Medicaid patients initiating SGA drug therapy. The adoption of metabolic monitoring into clinical practice should continue to be emphasized and supported. Psychiatrists are in an important position to ensure that metabolic risk is monitored before and during the course of SGA drug therapy so patients get the best quality of care.

Drug names: aripiprazole (Abilify), clozapine (Clozaril, FazaClo, and others), olanzapine (Zyprexa), quetiapine (Seroquel), risperidone (Risperdal), ziprasidone (Geodon).

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