Metabolic Testing Rates in 3 State Medicaid Programs After FDA Warnings and ADA/APA Recommendations for Second-Generation Antipsychotic Drugs

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Context: In 2003, the Food and Drug Administration (FDA) required a warning on diabetes risk for second-generation antipsychotic (SGA) drugs. The American Diabetes Association (ADA) and American Psychiatric Association (APA) recommended glucose and lipid testing for all patients starting to receive SGA drugs.

Objective: To characterize associations between the combined warnings and recommendations and baseline metabolic testing and SGA drug selection.

Design: Interrupted time-series analysis.

Setting: California, Missouri, and Oregon.

Patients: A total of 109,451 individuals receiving Medicaid who began taking SGA medication and a control cohort of 203,527 patients who began taking albuterol but did not receive antipsychotic medication.

Interventions: Prewarning and postwarning trends in metabolic testing were compared using laboratory claims for the cohort collected January 1, 2002, through December 31, 2005. Changes in SGA prescribing practices were similarly evaluated.

Main Outcome Measures: Monthly rates of baseline serum glucose and lipid testing for SGA-treated and propensity-matched albuterol-treated patients and monthly share of new prescriptions for each SGA drug.

Results: Initial testing rates for SGA-treated patients were low (glucose, 27%; lipids, 10%). The warning was not associated with an increase in glucose testing among SGA-treated patients and was associated with only a marginal increase in lipid testing rates (1.7%; P = .02). Testing rates and trends in SGA-treated patients were not different from background rates observed in the albuterol control group. New prescriptions of olanzapine (higher metabolic risk) declined during the warning period (annual share decline, 19.9%; P < .001). New prescriptions of aripiprazole (lower metabolic risk) increased during the warning period (share increase, 12.1%; P < .001) but may be attributable to the elimination of prior authorization in California during the same time frame. Quetiapine, risperidone, and ziprasidone use were not associated with the warning.

Conclusions: In a Medicaid-receiving population, baseline glucose and lipid testing for SGA-treated patients was infrequent and showed little change following the diabetes warning and monitoring recommendations. A change in SGA drug selection consistent with intentions to reduce metabolic risk was observed.

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In late 2003, the Food and Drug Administration (FDA) announced that it was requiring that class warnings be added to the labeling of atypical or second-generation antipsychotic (SGA) drugs describing increased risk of hyperglycemia and diabetes, and it required that all drug manufacturers mail “Dear healthcare professional” letters to inform health care providers of the new warning. In some cases, the hyperglycemia was extreme and associated with ketoacidosis, hyperosmolar coma, or death. The first label changes were made in December 2003, and the letters were mailed, according to the FDA, to “neuropsychiatric healthcare professionals” through August 2004. The warning stated that glucose levels should be monitored in patients with an established diagnosis of diabetes, risk factors for diabetes, or symptoms of hyperglycemia. The goal was to increase awareness of the signs and symptoms of diabetes to promote earlier detection and appropriate treatment. Concurrent with the warning, the American Diabetes Association (ADA) published a consensus statement with the American Psychiatric Association (APA) that described the metabolic risks associated with SGA drugs, including the differential risks of metabolic dis-
turbances among individual SGA drugs. 3 The consensus statement also specified a monitoring protocol for all patients who were taking SGAs that included baseline assessment of personal/family history, weight (body mass index [calculated as weight in kilograms divided by height in meters squared]), waist circumference, blood pressure, fasting plasma glucose level, and fasting lipid profile. 5

Individuals with serious mental illness, commonly treated with SGA drug therapy, have higher risk of diabetes and cardiovascular disease and therefore represent a vulnerable population for whom more frequent metabolic monitoring is also indicated. 6-8 The population prevalence of dyslipidemia, hypertension, obesity, and type 2 diabetes mellitus is approximately 1.5 to 2 times higher in individuals with serious mental illness compared with the general population. 9,10; other modifiable risk factors for type 2 diabetes such as physical inactivity and poor dietary choices 11 are also more common. Unfortunately, diabetes and cardiovascular risk is often underrecognized 10 and undertreated 12 in patients with serious mental illness. 6

For these reasons, diabetes and dyslipidemia screening in patients who are starting to take SGA drugs is important; however, information on screening rates for SGA-treated patients is limited. 13-16 For commercially insured patients, the warnings have not been associated with a clinically meaningful increase in glucose and lipid monitoring. 17-19 However, the effect of the warnings on glucose and lipid testing has not been described in patients receiving Medicaid, for whom antipsychotic use is very common. 20 The aim of this retrospective, population-based cohort study was to evaluate whether glucose and lipid testing increased for patients initiating SGA medication following the FDA warnings and ADA/APA recommendations based on 4-year testing trends observed in the California, Missouri, and Oregon state Medicaid programs. Our secondary aim was to determine whether prescribing patterns changed following the warnings as an alternative to reduce metabolic risk. We hypothesized that the use of drugs with higher metabolic risk declined and that use of drugs with lower metabolic risk increased as a result of the warning.

METHODS

STUDY POPULATION

The study cohort was selected retrospectively from fee-for-service clients enrolled in the California, Missouri, and Oregon Medicaid programs between January 1, 2002, and December 31, 2005. Subjects were excluded if they were Medicare dual eligible or enrolled in a managed care plan because complete laboratory and medical claims were not available. Subjects had a unique encrypted identifier that allowed us to identify their medical, pharmacy, and laboratory claim records during the study period. The study received approval from the Colorado Multiple Institutional Review Board and the California Committee for the Protection of Human Subjects.

A cohort of 109,451 individuals with a new prescription claim for an SGA drug (aripiprazole, olanzapine, olanzapine/fluoxetine, quetiapine, risperidone, or ziprasidone) was selected. Individuals were excluded if they did not have continuous enrollment history 180 days before and after the first (index) SGA pharmacy claim in the study period. Given its unique neuropenia-related testing requirements, clozapine users were excluded.

A second control cohort of 203,527 patients initiating albuterol therapy, but not receiving antipsychotic medication, was identified. The asthma medication albuterol has been used as a control for other longitudinal claims-based research in psychiatry. 21 The control group was used to compare testing rates in SGA-treated patients with background rates of metabolic screening in the general Medicaid population from the same states. We hypothesized that glucose and lipid testing rates in individuals taking albuterol would not be affected by the antipsychotic warnings and therefore could provide a control for temporal trends.

ASSESSMENT OF METABOLIC TESTING

Glucose testing was identified if a medical claim with an American Medical Association Current Procedural Terminology (CPT) code for a metabolic or general health panel (80048, 80050, 80053) or glucose-specific serum test (82947, 82948, 82950, 82951) was present. Lipid testing was identified if a CPT code for a lipid panel (80061) or lipid-specific serum test (82465, 84478, 83721, 83713, 83700, 83716, 83701) was present. Baseline was operationalized as testing occurring 30 days before through 30 days after the index date. Sensitivity analyses were performed to evaluate testing rates in expanded windows of testing surrounding the index date.

ASSESSMENT OF BASELINE PATIENT CHARACTERISTICS

Disparities in diabetes care have been associated with the number of mental health conditions. 12 Mental health conditions were identified using diagnosis codes ascertained from medical claims in the 180 days before the index date and classified into 8 categories using Clinical Classifications Software coding developed by the Agency for Health Care Research and Quality. 22 The categories were affective disorders, alcohol and substance-related mental disorders, anxiety, somatoform, and personality disorders, preadult disorders, senility and organic mental disorders, schizophrenia and related disorders, other psychoses, and other mental conditions. The number of mental health conditions was categorized as none recorded, 1, or 2 or more.

Preexisting diabetes was defined as a recorded diagnosis code of 250 in the medical claims using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) coding scheme or a prescription claim for an antidiabetic drug (Generic Product Identifier 27) occurring in the 180 days before the index date. Dyslipidemia, hypertension, and heart disease are type 2 diabetes risk factors 23 and presumably should increase a clinician’s vigilance and trigger more frequent screening. Individuals with preexisting dyslipidemia, hypertension, and recent evidence of heart disease were identified using medical and pharmacy records for the 180 days before the index date. Dyslipidemia was defined as a diagnosis of dyslipidemia (Clinical Classifications Software 53) or a prescription claim for a cholesterol-lowering drug (Generic Product Identifier 37). Hypertension was defined as a diagnosis of hypertension (Clinical Classifications Software 98 or 99) or a prescription claim for an antihypertensive drug: Generic Product Identifier code 33 (β-blockers), 34 (calcium channel blockers), 36 (ace inhibitors), or 37 (diuretics). Heart disease was defined based on Clinical Classifications Software classification for acute myocardial infarction (100), coronary atherosclerosis (101), pulmonary heart disease (103), or other heart diseases (104). These vari-
variables were used to control for differences in diabetes risk factors when comparing metabolic testing rates and trends between SGA users and albuterol control subjects.

Age (at the index date), race/ethnicity, and sex have also been associated with the likelihood of diabetes screening and were included in the analysis.31

STATISTICAL ANALYSIS

Comparison of select baseline characteristics in SGA vs albuterol users was performed using χ² tests. The SGA- and albuterol-treated patients were dichotomously classified as either having or not having received a baseline glucose or lipid test. Metabolic testing rates for each month were expressed as the number of patients receiving a baseline test divided by the number of patients initiating drug therapy during that month. The study period was segmented into 3 time periods: prewarning (January 1, 2002–November 30, 2003), warning (December 1, 2003–August 31, 2004); and postwarning (September 1, 2004–December 31, 2005). The time span for the warning period starts when labeling changes were first instituted3 and ends in the December 31, 2005). The time span for the warning period starts when labeling changes were first instituted3 and ends in the December 31, 2005).

Regressions were performed for 3 cohorts: all SGA users (n=109,451); persistent SGA users (n=34,274), and propensity-matched pairs of persistent SGA users (n=33,213 pairs). Persistent SGA users had a maximum gap in SGA drug therapy of no more than 30 days during the initial 180 days of treatment. The study period was segmented into 3 time periods: prewarning (January 1, 2002–November 30, 2003), warning (December 1, 2003–August 31, 2004); and postwarning (September 1, 2004–December 31, 2005). The time span for the warning period starts when labeling changes were first instituted3 and ends in the December 31, 2005).

RESULTS

Table 1 summarizes patient characteristics of the cohort who started taking SGA medication during the study period as well as control subjects. One-fourth of the sample of SGA users were children, while the largest...
Table 2. Rates and Trends of Baseline Glucose and Lipid Testing by Perioda

<table>
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<tr>
<th>Group</th>
<th>Serum Glucose Testing</th>
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<th>Serum Lipid Testing</th>
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<td>First Month, % (95% CI)</td>
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<tr>
<td>All SGA users</td>
<td>26.9 (25.3-28.4)</td>
<td>0.2 .68</td>
<td>28.0 (26.0-29.9)</td>
<td>0.9 .20</td>
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<td>Persistent SGA users</td>
<td>30.1 (27.2-33.0)</td>
<td>-0.9 .09</td>
<td>26.7 (23.2-30.2)</td>
<td>1.2 .19</td>
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<td>Propensity-matched pairs</td>
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<td>Persistent SGA users</td>
<td>30.2 (27.3-33.2)</td>
<td>-1.1 .07</td>
<td>26.9 (23.4-30.5)</td>
<td>1.4 .16</td>
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<td>Albuterol users (control)</td>
<td>26.1 (23.6-28.6)</td>
<td>1.2 .28</td>
<td>23.5 (20.9-28.1)</td>
<td>0.1 .95</td>
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<tr>
<td>All SGA users</td>
<td>10.0 (8.9-11.0)</td>
<td>-0.5 .23</td>
<td>9.2 (8.0-10.4)</td>
<td>1.7 .02</td>
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<td>Persistent SGA users</td>
<td>11.3 (9.3-13.3)</td>
<td>-0.5 .29</td>
<td>11.4 (8.9-13.9)</td>
<td>1.9 .03</td>
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<td>Propensity-matched pairs</td>
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<tr>
<td>Persistent SGA users</td>
<td>11.4 (9.4-13.4)</td>
<td>-0.6 .28</td>
<td>11.2 (8.7-13.8)</td>
<td>1.9 .03</td>
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<tr>
<td>Albuterol users (control)</td>
<td>11.2 (9.4-13.0)</td>
<td>-0.7 .36</td>
<td>9.1 (7.4-10.9)</td>
<td>-0.5 .65</td>
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Abbreviations: CI, confidence interval; SGA, second-generation antipsychotic.

aData from California, Missouri, and Oregon state Medicaid programs, 2002-2005 (n = 109,451 SGA users; n = 34,274 persistent SGA users; n = 33,213 propensity-matched pairs of albuterol and persistent SGA users).

bThe prewarning period was defined as January 1, 2002, through November 30, 2003; warning, December 1, 2003, through August 31, 2004; postwarning, September 1, 2004, through December 31, 2005.

 subgroup of adults was aged 40 to 49 years. Two-thirds of the SGA sample were from California (n=73,544), 25.0% from Missouri (n=27,345), and 7.8% from Oregon (n=8,562). Half of the SGA users had 2 or more mental health conditions recorded. Of SGA users, 10.6% had identified diabetes; 29.4%, hypertension; 13.0%, dyslipidemia; and 6.0%, recent evidence of heart disease. Thirty-one percent of SGA users initiating SGA medication were therapy persistent for 180 days after starting to take medication.

BASELINE SERUM GLUCOSE AND LIPID TESTING TRENDS

Rates and trends of baseline glucose and lipid testing in patients who began taking SGA medication and the cohort of propensity-matched albuterol users are presented in Table 2 for the prewarning, warning, and postwarning study periods. In January 2002, 26.9% of patients starting to receive SGA medication had baseline serum glucose testing and 10.0% had baseline lipid testing. During the prewarning period, baseline testing rates remained constant (glucose trend change, 0.2%/y; lipid trend change, −0.5%/y). Glucose testing rates did not increase during (0.9%/y absolute change) or after the FDA warning (trend change, 0.2%/y). A clinically small but statistically significant step change of 1.7% in baseline lipid testing rates occurred during the warning period but testing rates did not increase significantly after the warning (trend change, 0.9%/y).

Persistent SGA users did not have clinically higher rates of baseline glucose or lipid testing than patients initiating SGA medication. Rates and trends of baseline glucose and lipid testing were comparable between propensity-matched pairs of SGA and albuterol users, with the exception of a slight increase observed in lipid testing during the warning period.

TESTING RATES IN PATIENTS WITH AND WITHOUT RECOGNIZED DIABETES

Figure 1 shows the relationship between testing window definitions and serum glucose and lipid testing rates by diabetes status in propensity-matched pairs of albuterol and persistent SGA users during the postwarning study period. In SGA-treated patients with and without diabetes, glucose and lipid testing rates increased 2- to 3-fold as the defined window of testing expanded from the primary baseline definition (30 days before or after drug initiation) to 180 days before or after drug initiation (P < .001; Figure 1 and Figure 2). Glucose and lipid testing rates were approximately 2-fold higher among SGA-treated individuals with preexisting diabetes compared with those without diabetes for each of the 4 testing windows evaluated (P < .001; Figures 1 and 2). Although glucose and lipid testing rates for SGA-treated individuals were statistically different from matched control subjects at several testing windows, the absolute clinical differences were small and, in most cases, the albuterol cohort outperformed the SGA cohort.

INDEX SGA MEDICATION TRENDS

Figure 2A shows trends in the index SGA medication prescribed during the prewarning, warning, and postwarning study periods for patients beginning to take a single SGA drug, regardless of indication. Changes in share of prescribing for olanzapine and aripiprazole were significantly

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Figure 1. Serum glucose (A) and lipid (B) testing rates by diabetes status. Data are from California, Missouri, and Oregon state Medicaid programs, September 2004 through December 2005. Propensity-matched groups of albuterol and second-generation antipsychotic (SGA) persistent users are shown (n=33,213).

Figure 2. Trends in new second-generation antipsychotic (SGA) prescriptions during the prewarning, warning, and postwarning study periods for all SGA users (A) and SGA users with schizophrenia (B). Data are from California, Missouri, and Oregon state Medicaid programs, 2002-2005. For an explanation of the study periods see the “Statistical Analysis” subsection of the “Methods” section.
associated with the FDA warnings. During the prewarning period, olanzapine share declined 5.4%/y ($P < .001$) but began to decline at a faster rate during the warning period (−19.9%/y; $P < .001$) resulting in a 14% step reduction during the warning period. The rate of decline after the warning was not significantly different from the prewarning trend. Aripiprazole market share increased at 2.1%/y before the warning period ($P < .001$), grew significantly during the warning period (12.1%/y; $P < .001$), and returned to prewarning growth rates after the warning period. The step change during the warning period was 7.4% ($P < .001$). The increase in aripiprazole prescribing during the FDA warning period was observed in California (10.0%/y; $P < .001$) and Missouri (3.0%/y; $P = .02$) but not in Oregon. Prewarning share trends for quetiapine (growth, 4.3%/y; $P < .001$), risperidone (decline, 1.7%/y; $P = .005$), and ziprasidone (growth, 0.6%/y; $P = .002$) continued unchanged after the FDA warning.

Changes in prescribing trends among SGA users with schizophrenia (Figure 2B) were qualitatively similar to the overall prescribing trends; however, changes in prescribing share were less pronounced and the association of the warning period with prescribing was attenuated.

**COMMENT**

The FDA warnings and related risk communication concerning SGA drugs and risk of diabetes and dyslipidemia appear to have had no detectable effect on average baseline serum glucose or lipid testing rates for SGA-treated adults in the 3 state Medicaid populations studied. Absolute rates of baseline testing were low; on average, less than 30% of SGA-treated patients received baseline serum glucose and less than 15% received lipid testing. Rates of baseline testing did not increase following the warning. Moreover, rates of testing among SGA-treated patients appeared to be no different from general background rates of screening in this Medicaid population, as evidenced by similar rates of testing in the albuterol-treated control group, despite well-characterized increased risk of diabetes and cardiovascular disease in the SGA-treated population.

Lack of awareness may be one cause behind the low rates of testing, although surveys of psychiatrists after the warning indicate high levels of knowledge concerning the need for metabolic monitoring. Lack of resources in Medicaid-receiving mental health settings for ordering blood tests may also explain low rates of screening. For comparison, the baseline testing rates in our SGA-treated Medicaid population are comparable with SGA-treated patients in 2 commercially insured populations, and the 6-month testing rates (data not shown) in older adults are similar to rates reported in a Veterans Affairs–based population (glucose, 57%; lipid, 39%). Thus, it appears that average screening rates may be more similar between health care settings than dissimilar.

The FDA warnings were associated with changes in SGA prescribing practices. The most notable was the use of olanzapine, a drug associated with greater metabolic risk, which declined significantly. The increase in aripiprazole prescribing is also noteworthy because it might signal an increase in the use of SGA drugs with low metabolic risk. However, much of the spike in aripiprazole use may be owing to a concurrent California formulary change that had been under way before the warning in which the California Medicaid program added aripiprazole to its List of Contract Drugs and eliminated prior authorization. Prescribing trends for quetiapine, risperidone, and ziprasidone were not associated with the warning. Thus, the findings suggest that the main effect of the FDA warning was to accelerate a decline in olanzapine prescribing, consistent with intentions to reduce metabolic risk, rather than to increase metabolic laboratory monitoring.

Although this retrospective study was not able to identify or quantify reasons why laboratory screening did not increase after the FDA warnings, whereas prescribing practices did change, we might speculate on some possible explanations. Diffusion and behavior change theory would predict that it is easier to adopt behaviors for which the relative advantage is clear and compatible with existing experience and practices than to adopt behaviors with greater perceived complexity or that are designed to lower the probability of some unwanted future event. Translating this to drug warnings, one would expect faster adoption of drug prescribing changes (eg, switching to lower-risk drugs or not treating) than the adoption of new screening or monitoring practices. This phenomenon was observed following the pediatric antidepressant suicide warning regarding an immediate decline in the pharmacological treatment of pediatric depression but a lack of change in the frequency of follow-up office visits.

On the other hand, the low rates of baseline blood testing observed in this study population are surprising given high awareness among psychiatrists of the metabolic risks associated with SGA medication and generally strong agreement regarding the need to screen and monitor patients. For example, in the year following the FDA warnings, 60% to 80% of psychiatrists reported monitoring glucose and lipid levels at regular intervals. A national survey of community mental health centers also indicated that two-thirds of the community mental health centers reported having protocols or procedures to screen for common medical problems such as diabetes and dyslipidemia. Therefore, more research is needed to better understand this gap between reported monitoring behavior and observed monitoring rates before improvements can be made in diabetes and dyslipidemia screening for this at-risk population.

One hypothesis could be that psychiatrists, who frequently prescribe SGA drugs and who were the primary target audience for risk communication, may be aware of the warnings but primary care providers, who would generally order the necessary laboratory tests and provide general medical care, may have lower awareness. Diffusion theory predicts that it is difficult to make a change that is partly dependent on someone else to execute (eg, a psychiatrist ordering monitoring that is best accomplished in the primary care setting). In a commercially insured private practice population, patients who were prescribed SGA medication by a psychiatrist were less likely to receive testing than if the drug was prescribed by a primary care provider. We could not directly as-
evidence that Medicaid-receiving patients who are tak-
ing clinician) or disincentives (eg, sharing individual cli-
using incentives (eg, financial compensation to the order-
successful in increasing rates of glucose and lipid testing
that some local mental health treatment centers have been
grams or other care settings. Anecdotal evidence suggests
generalizing our findings to other state Medicaid pro-
tween the 3 state programs, caution should be applied in
environment and patients with Medicaid who receive care
sions other than the recommended evaluation of SGA
effects on blood glucose or lipid levels, and that the re-
results were not available to psychiatric treatment deci-
sion makers within these health systems. The fact that
screening rates for SGA-treated patients were not differ-
et from general screening in a group of patients start-
ing albuterol treatment supports this interpretation. There-
fore, the absolute rates of glucose and lipid testing we
observed for SGA-treated patients are likely overesti-
mates of actual metabolic monitoring performed specifi-
cally in relation to SGA treatment. However, the data also
suggest that more patients receive some glucose and lipid
testing at some point in time, even if not in close tem-
poral relation to the SGA prescription event. Because the
results of these tests reside somewhere in the patient health
records, optimizing the availability and sharing of that
information between mental and medical care provid-
could contribute to improvements in medical deci-
sion making.

The results of this research are subject to limitations.
One limitation of using outpatient administrative claims
records is that we could not evaluate the effect of the FDA
warnings on unbilled metabolic screening occurring dur-
ing the visit (eg, family history of diabetes, height and
body weight, finger-stick glucometer-based glucose test-
ing, waist circumference) or testing occurring during a
hospital admission. We also could not determine com-
pliance with fasting requirements. We were not able to
determine where the tests were ordered, the results of
the tests, or whether these results were effectively com-
municated between SGA prescribers and primary care pro-
viders. There are also limitations to using claims data to
define medical comorbidities. We identified comorbid-
ities based on pharmaceutical claims and diagnoses, and
this does not capture patients with unrecognized or un-
treated disease. In addition, some antidiabetic and cho-
sterol-lowering drugs are prescribed for people with-
out diabetes or hyperlipidemia.

Our results reflect care in a Medicaid fee-for-service
environment and patients with Medicaid who receive care
within a capitated plan may have more integrated and com-
prehensive care. Although we observed similar results be-
tween the 3 state programs, caution should be applied in
generalizing our findings to other state Medicaid pro-
grams or other care settings. Anecdotal evidence suggests
that some local mental health treatment centers have been
successful in increasing rates of glucose and lipid testing
using incentives (eg, financial compensation to the order-
ing clinician) or disincentives (eg, sharing individual cli-
nician performance rates among a peer group).

In summary, our study of laboratory claims offers little
evidence that Medicaid-receiving patients who are tak-
ing SGA medication typically receive baseline serum glu-
cose and lipid testing. Moreover, the FDA warning and
ADA/APA consensus statement recommendations were
not associated with an increase in baseline testing rates.
Instead, clinicians were more likely to reduce their use
of olanzapine, an SGA drug with higher metabolic risk.
More effort is needed to ensure that patients who re-
cieve SGA drugs are screened for diabetes and dyslipid-
emia and monitored for potential adverse drug effects,
beginning with baseline testing of serum glucose and lip-
ids, so that patients can receive appropriate preventive
care and treatment.

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